

Document Title

**Tier 2 Summary of the Metabolism and Residues Data for
Flupyradifurone (BYI 02960)
- Part 2 of 3 -**

Date Requirements

**Regulation (EC) No 1107/2009
Regulatory Directive 2003-01/Canada/PMRA
OPPTS guidelines/US/EPA**

**Annex IA
Section 4, Point 6.3 to Point 6.3.2.19
Document M**

According to OECD format guidance for industry data submissions
on plant protection products and their active substances

Date

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(updated EU version for GJK countries)

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TABLE OF CONTENTS

		Page
IIA 6.3	Residue trials (supervised field trials)	4
IIA 6.3.1	Residue trials in the EU	4
IIA 6.3.1.1	Lettuce	4
IIA 6.3.1.2	Hops	26
IIA 6.3.1.3	Pome fruit - apple	39
IIA 6.3.1.4	Berries and small fruit - grapes	60
IIA 6.3.1.5	Fruiting vegetables – tomato, incl. eggplant (solanacea)	81
IIA 6.3.1.6	Fruiting vegetables – sweet (bell) pepper (solanacea)	97
IIA 6.3.1.7	Fruiting vegetables - cucumber (incl. zucchini and gherkin) (cucurbits - edible peel)	113
IIA 6.3.1.8	Fruiting vegetables - watermelon (cucurbits – inedible peel)	129
IIA 6.3.2	Residue trials from the Global Joint Review partner countries Australia, Brazil, Canada, and the USA to support import tolerances	154
IIA 6.3.2.1	Citrus Fruits	154
IIA 6.3.2.2	Tree nuts	257
IIA 6.3.2.3	Pome fruit	272
IIA 6.3.2.4	Berries and small fruit - grapes	297
IIA 6.3.2.5	Berries and small fruit - blueberries	316
IIA 6.3.2.6	Miscellaneous fruit - prickly pear cactus (fruit)	334
IIA 6.3.2.7	Root and tuber vegetables - potatoes and sweet potatoes	341
IIA 6.3.2.8	Fruiting vegetables - solanacea	369
IIA 6.3.2.9	Stem vegetables - celery	427
IIA 6.3.2.10	Pulses, dry - beans and peas	441
IIA 6.3.2.11	Oilseeds – peanuts	460
IIA 6.3.2.12	Oilseeds - soybean	472
IIA 6.3.2.13	Oilseeds - cotton seed	487
IIA 6.3.2.14	Cereals - barley	499
IIA 6.3.2.15	Cereals - corn	514
IIA 6.3.2.16	Cereals - sorghum	546
IIA 6.3.2.17	Cereals - wheat	557
IIA 6.3.2.18	Coffee	577
IIA 6.3.2.19	Hops	599

IIA 6.3 Residue trials (supervised field trials)

Numerous residue trials have been conducted to support the use of BYI 02960 in/on various crops. In the Annex II dossier, submitted in May 2012, only the so-called "safe uses" (lettuce and hops) have been described. In this Annex II dossier further data on additional crops are submitted besides the "safe uses".

General remark:

In this summary section (KIIA 6.3), the name DFEAF will be used for the metabolite BYI 02960-difluoroethyl-amino-furanone, which is relevant to the tested residue definitions.

<u>Name</u>	<u>Metab. No.</u>	<u>Standard "dossier" name</u>
DFEAF	M34	BYI 02960-difluoroethyl-amino-furanone

IIA 6.3.1 Residue trials in the EU

➤ "SAFE USES" (Lettuce and Hops)

IIA 6.3.1.1 Lettuce

BYI 02960 (common name: flupyradifurone) is to be registered in Europe for use in lettuce. European residue data in lettuce crops are therefore presented below to support the intended "safe use". Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.1-1.

Table 6.3.1.1-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulations in/on lettuce in European fields (northern and southern residue regions) and greenhouses

Description	F/G	No. of apps.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"agricultural" use*	F†	1	125	125	200-800	--	10
	G		125	250	200-800	10	3
"home & garden" **	F†	2	125	250	200-800	10	3

* agricultural use based on an SL 200 formulation

** "home & garden" uses with an L 50 formulation (available to the general public via retail sale)

† uses in both the northern and southern residue regions (EU-N and EU-S)

In order to support the EU "safe use" of BYI 02960, sets of GLP trials were conducted in northern and southern European fields and in greenhouses in 2010 and 2011. In northern and in southern European field-grown lettuce, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200, containing 200 g/L BYI 02960 a.s.), at 10-day intervals. For the envisaged agricultural use, samples were taken immediately prior to the second application, thus representing a 1-application, 10-day PHI



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

use pattern. Further samples were taken subsequent to the 2nd application, with an envisaged PHI of 3 days, reflecting the intended use of a retail-sale formulation for private home and garden use.

In the greenhouse trials, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200) at 10-day intervals, with an envisaged PHI of 3 days.

Residue levels of BYI 02960 and its metabolites DFA and DFEAF were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the greenhouse trials, in which a highest total residue value (HR) of 6.0 mg/kg was determined. The STMR in these trials was also the highest for any set, at 2.2 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.1-1.

Table 6.3.1.1-2: Overview of European residue trials conducted in lettuce, per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.1-1)	Region	No. of trials			Residue level (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.1/...
		Veget. period 2010	2011	Σ	HR	STMB		
<i>trials in EUROPE</i>								
"agricultural" use*	EU-N	5	4	18	0.86	0.23	10-2223, 11-2082	01, 02
	EU-S	5	4	18	0.83	0.32	10-2213, 11-2071	03, 04
	G	5	4	18	6.0	2.2	10-2212, 11-2070	05, 06
"home & garden"**	EU-N	5	4	18	3.0	0.71	10-2223, 11-2082	01, 02
	EU-S	5	4	18	3.2	1.2	10-2213, 11-2071	03, 04

EU-N = northern EU field, EU-S = southern EU field, G = greenhouse

* residue levels shown based on total residues in lettuce head samples taken at a PHI of 10 days (field uses) or 3 days (greenhouse)

** residue levels shown based on total residues in lettuce head samples taken at a PHI of 3 days.

Northern Europe (residue region)

Report:	KflA 6.3.1.1/01, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium, France (North) and Germany
Report No. & Document No.:	10-2223, dated February 23, 2012 M-424742-01-1

Report:	KflA 6.3.1.1/02, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Germany, northern France and Belgium
Report No. & Document No.:	11-2082, dated February 23, 2012 M-425941-02-1

Guidelines (applies to both studies):	Directive 91/414/EEC, residues in or on treated products, food and feed
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Nine field residue trials were conducted in the northern European residue region, as follows:

In 2010, 5 trials (Netherlands, Belgium, France, and Germany [2]) were conducted to support the use of BYI 02960 SL 200 in lettuce (█ & █, 2012, KIIA 6.3.1.1/01). The lettuce varieties used were either closed-head (3 trials) or leafy (2) varieties, as per the prevailing EU guidance at the time. Two applications were made at intervals of 10 days (9 in one trial) at a nominal rate of 0.625 L/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 300-600 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Four further trials were carried out in 2011, in France, Belgium and Germany (2), to complete the data package (█, 2012, KIIA 6.3.1.1/02). All lettuce varieties used were leafy (open-head) varieties, in order to comply with the upcoming revision of the EU guidance for this crop. The basic application parameters were as in 2010; water rates ranged from 500-750 L/ha. Again, all treatments were made at the scheduled rates.

Samples of lettuce heads were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 or 14 days after treatment in 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or 01210 (2011 trials; cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of lettuce heads. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.50, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (91-104%, RSDs of the larger validation sets [$n > 2$] 2.2-10.7%, $n=2-15$).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.50 mg/kg, as well as 0.20, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (90-98%, RSDs of the larger validation sets [$n > 2$] 4.3-10.2%, $n=2-12$).

Details of recovery data are shown in table 6.3.1.1-4. All trial data are summarised below in table 6.3.1.1-3a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)



Relevant residues of BYI 02960 were determined in lettuce head samples taken 10 days subsequent to the first application (immediately prior to the 2nd treatment) as well as at various intervals after the final application. Analyses showed that total residue levels declined with time.

"Agricultural" use

Lettuce heads were taken 9-10 days after the first treatment (before the final treatment) in order to represent a 1-application use with a 10-day PHI, as is envisaged for general agricultural use in northern European fields. Total residue levels ranged from 0.07-0.83 mg/kg (n=9, median 0.23 mg/kg).

"Home & garden" use

On day 0, immediately following the 2nd and final treatment, residue levels in lettuce heads were between 1.5 and 4.1 mg/kg (median 2.6 mg/kg). By day 3 — the PHI for home & garden use — the levels had declined to 0.14-3.0 mg/kg (n=9), with a median value of 0.71 mg/kg. Residues continued to decrease until day 14, the final sampling event, when levels ranged from 0.04-1.0 mg/kg (n=4, median 0.10 mg/kg).

III. Conclusions (lettuce, northern Europe)

In order to support the use in the EU of BYI 02960 in lettuce, 9 valid trials were conducted in the northern European residue region in the year 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha per treatment. The application intervals were 9-10 days. All applications were at the required rates, and all trials were conducted according to GLP.

The envisaged "agricultural use" nominally calls for 1 spray at 125 g/ha and a PHI of 10 days. To evaluate this use, samples were taken just prior to the 2nd application, i.e. 10 days after the first treatment. For the "home & garden use", samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days.

Samples were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 dissipated rapidly in lettuce heads, from levels of 1.5-4.1 mg/kg on day 0 after the final treatment to 0.14-3.0 mg/kg on day 3 (PHI for the "home & garden" use). The respective median values were 2.6 and 0.71 mg/kg.
- ten days after a single application of BYI 02960 SL 200 – representing the envisaged "agricultural" use total residue levels ranged from 0.11-0.83 mg/kg, with a median value of 0.23 mg/kg.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.1-3a: Application scenario in residue trials conducted in/on lettuce after spraying with BYI 02960 SL 200 in the field (northern EU residue region)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2223 (10-2223-01) Netherlands [redacted] EU-N 2010	lettuce Gisela, Butterhead variety	200 SL	2	0.125	0.0417	48	3
10-2223 (10-2223-02) Belgium [redacted] EU-N 2010	lettuce Lucan, Butterhead variety	200 SL	2	0.125	0.0250	48	3
10-2223 (10-2223-03) France [redacted] EU-N 2010	lettuce Abago, Butterhead variety	200 SL	2	0.125	0.0208	48	3
10-2223 (10-2223-04) Germany [redacted] EU-N 2010	lettuce Cavernet Lollo rosso, loose leaf variety	200 SL	2	0.125	0.0417	48	3
10-2223 (10-2223-05) Germany [redacted] EU-N 2010	lettuce Chloe Lollo rosso, loose leaf variety	200 SL	2	0.125	0.0313	48	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-3a (cont'd): Application scenario in residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in field (*northern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2082 (11-2082-01) Germany [redacted] EU-N 2011	lettuce Aleppo Lollo bionda, loose leaf variety	200 SL	2	0.125	0.0208	48	3
11-2082 (11-2082-02) Germany [redacted] EU-N 2011	lettuce Kitara Lollo bionda, loose leaf variety	200 SL	2	0.125	0.0250	48	3
11-2082 (11-2082-03) France [redacted] EU-N 2011	lettuce Quenty Feuille de chêne (oak leaf lettuce)	200 SL	2	0.125	0.0208	48	3
11-2082 (11-2082-04) Belgium [redacted] EU-N 2011	lettuce Furnas, leafy variety curly	200 SL	2	0.125	0.0167- 0.0167	48	3

FL = formulation GS = growth stage (BBC11-code) at last treatment

EU-N = northern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-3b: Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in the field (*northern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoro-ethylamino-furanone	total residue of BYI 02960 (a)
10-2223 (10-2223-01) Netherlands	head	0*	0.20	<0.02	<0.01	0.23
		0	1.9	<0.02	<0.01	2.0
		1	1.8	<0.02	<0.01	1.8
		3	0.58	<0.02	<0.01	0.6
		5	0.34	<0.02	<0.01	0.37
		7	0.22	<0.02	<0.01	0.25
		GLP: yes				
10-2223 (10-2223-02) Belgium	head	0*	0.08	<0.02	<0.01	0.11
		0	1.7	<0.02	<0.01	1.8
		1	0.43	<0.02	<0.01	0.46
		3	0.37	<0.02	<0.01	0.40
		5	0.34	<0.02	<0.01	0.37
		7	0.21	<0.02	<0.01	0.22
		GLP: yes				
10-2223 (10-2223-03) France	head	0*	0.13	<0.02	<0.01	0.16
		0	1.5	<0.02	<0.01	1.5
		1	1.1	<0.02	<0.01	1.3
		3	0.68	<0.02	<0.01	0.71
		5	0.52	<0.02	<0.01	0.55
		7	0.46	<0.02	<0.01	0.50
		GLP: yes				
10-2223 (10-2223-04) Germany	head	0*	0.8	<0.02	<0.01	0.40
		0	1.8	<0.02	<0.01	1.8
		1	1.1	<0.02	<0.01	1.1
		3	1.0	<0.02	<0.01	1.0
		5	0.8	<0.02	<0.01	0.90
		7	0.66	<0.02	<0.01	0.69
		GLP: yes				
10-2223 (10-2223-05) Germany	head	0*	0.80	<0.02	<0.01	0.83
		0	4.1	<0.02	<0.01	4.1
		1	1.0	<0.02	<0.01	1.1
		3	0.83	<0.02	<0.01	0.87
		5	0.83	<0.02	<0.01	0.86
		7	0.65	<0.02	<0.01	0.68
		GLP: yes				
11-2082 (11-2082-01) Germany	head	0*	0.19	<0.02	<0.01	0.22
		0	2.7	<0.02	<0.01	2.7
		3	1.5	0.023	0.017	1.6
		7	0.52	0.028	<0.01	0.56
		10	0.13	0.020	<0.01	0.16
		14	0.073	0.024	<0.01	0.11
		GLP: yes				
11-2082 (11-2082-02) Germany	head	0*	0.11	<0.02	<0.01	0.14
		0	2.6	<0.02	<0.01	2.6
		3	0.1	<0.02	<0.01	0.14
		7	0.033	0.022	<0.01	0.065
		10	0.023	0.027	<0.01	0.060
		14	0.01	0.027	<0.01	0.047
		GLP: yes				

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-3b (cont'd): Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in the field (*northern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960- difluoro- ethylamino- furanone	total residue of BYI 02960 cal
GLP:						
11-2082 (11-2082-04) Belgium	head	-10	5.6	<0.02	0.011	5.6
		-8	2.0	<0.02	0.015	2.0
		-5	0.63	0.028	<0.01	0.67
		-2	0.35	0.030	<0.01	0.38
GLP: yes		0*	0.25	0.026	<0.01	0.28
		0	2.8	0.022	<0.01	2.8
		3	0.43	0.028	<0.01	0.47
		7	0.22	0.030	0.01	0.25
		10	0.12	0.021	0.01	0.15
		14	0.058	0.025	<0.01	0.093

 DALT = days after last treatment
 * prior to last treatment

 Table 6.3.1.1-4: Recovery data for BYI 02960 in **lettuce**

Study No. Trial No.	Crop	Portion analysed	a.s. metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
11-2082	lettuce	head	BYI 02960	2	0.01	106;111	106	111	109	
11-2082-01 to 11-2082-04				1	0.10	104;105	104	105	105	
GLP: yes 2011				1	2.0	116;119	119	119	119	
				6	overall	114	114	114	114	
			difluoroacetic acid	2	0.02	89;109	89	109	99	
				1	0.20	98;106	98	106	102	
				1	4.0	102	102	102	102	
				16	overall	102	102	102	102	
				6	overall		89	109	101	6.9
			BYI 02960- difluoroethyl- aminofuranone	2	0.01	114;123	114	123	119	
				2	0.10	108;109	108	109	109	
				1	2.0	107	107	107	107	
				1	8.0	116	116	116	116	
				6	overall		107	123	113	5.4

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-4 (cont'd): Recovery data for BYI 02960 in lettuce

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				RSD					
						Individual recoveries	Min	Max	Mean						
10-2223 10-2223-01 to 10-2223-05 GLP: yes 2010	lettuce, head	head	BYI 02960	15	0.01	79;87;102;106; 107;109;110; 116;92;97;107; 108;114;116; 110;98;99	79	117	104	10.7					
				2	0.10	88;90;90;92;93	88	93	92	2.2					
				2	0.50	103;106	103	106	105						
				2	1.0	92;94	92	94	93						
				2	5.0	90;98	90	98	94						
				26	Overall	79	117	100	10.5						
			12	difluoroacetic acid	BYI 02960	12	0.02	90;93;94;95;97; 112;112;116; 86;89;93;95	86	116	98	10.2			
						3	0.05	90;94;98	90	98	94	4.3			
						2	0.20	92;94	92	94	93				
						2	0.50	93;101;90;91; 92	90	101	93	4.7			
						2	1.0	90;92	90	92	91				
						2	5.0	90;89	89	90	90				
						26	Overall	86	116	95	7.9				
						15	BYI 02960 difluoroethyl- aminofuranone	BYI 02960	15	0.01	87;93;95;100; 100;104;105; 107;83;83;86; 88;90;92;96	83	107	94	8.4
									5	0.10	83;98;97;97;99	85	99	95	6.1
2	0.50	97;109	97	109	103										
2	1.0	86;101	86	101	94										
2	5.0	97;96	96	97	97										
26	overall	83	109	95	7.7										



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Southern Europe

Report:	KIIA 6.3.1.1/03, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce, head after spray application of BYI 02960 SL 200 in the field in France (South), Spain and Italy - Amendment no. 0001 to report no. 10-2213
Report No. & Document No.:	10-2213, dated February 27, 2012 M-425913-02-1
Report:	KIIA 6.3.1.1/04, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Spain, Italy, southern France and Portugal
Report No. & Document No.:	11-2071, dated February 23, 2012 M-425784-02-1
Guidelines (applies to both studies):	Directive 91/414/EEC, residues in/on treated products, food and feed
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Nine field residue trials were conducted in southern Europe, as follows:

In 2010, 5 trials (France [2], Italy [2], and Spain [2]) were conducted to support the use of BYI 02960 SL 200 in lettuce ([REDACTED] & [REDACTED] 2012, KIIA 6.3.1.1/03). The lettuce varieties used were either closed-head (3 trials) or leafy (2) varieties, as per the prevailing EU guidance at the time. Two applications were made at intervals of 10 days (11 in one trial) at a nominal rate of 0.625 L/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 500-700 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Four further trials were carried out in 2011, in France, Spain, Portugal, and Italy, to complete the data package ([REDACTED] 2012, KIIA 6.3.1.1/04). All lettuce varieties used were leafy (open-head) varieties, in order to comply with the upcoming revision of the EU guidance for this crop. The basic application parameters were as in 2010 (interval in one trial: 9 days), water rates ranged from 500-800 L/ha. Again, all treatments were made at the scheduled rates.

Samples of lettuce heads were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 or 14 days after treatment in 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials, for method details, cf. KIIA 4.3/03) or 01212 (2011 trials; cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).



II. Findings

During the conduct of the complete set of lettuce studies in 2010-2011, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of lettuce heads. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.50, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (91-104%, RSDs of the larger validations sets [n > 2] 2.2-10.7%, n=2-12).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.50 mg/kg, as well as 0.20, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (90-98%, RSDs of the larger validations sets [n > 2] 3-10.2%, n=2-12).

Details of recovery data are shown in table 6.3.1.1-6. All trial data are summarised below in table 6.3.1.1-5a & b and in greater detail in the Tier 1 summary forms. Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.

Relevant residues of BYI 02960 were determined in lettuce head samples taken 10 days subsequent to the first application (immediately prior to the 2nd treatment) as well as at various intervals after the final application. Analyses showed that total residue levels declined with time.

"Agricultural" use

Lettuce heads were taken 9-11 days after the first treatment (before the final treatment) in order to represent a 1 application use with a 10-day PHI as is envisaged for general agricultural use in southern European fields. Total residue levels ranged from 0.07-0.83 mg/kg (n=9, median: 0.32 mg/kg).

"Home & garden" use

On day 0, immediately following the 2nd and final treatment, residue levels in lettuce heads were between 1.9 and 7.4 mg/kg (median 2.9 mg/kg). By day 3 — the PHI for home & garden use — the levels had declined to 0.39-3.2 mg/kg (n=9) with a median value of 1.2 mg/kg. Residues continued to decrease until day 14, the final sampling event, when levels ranged from 0.094-0.30 mg/kg (n=4, median 0.17 mg/kg).

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III. Conclusions (lettuce, southern Europe)

In order to support the use in the EU of BYI 02960 in lettuce, 9 valid trials were conducted in southern Europe in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha per treatment. The application intervals were 9-11 days. All applications were at the required rates, and all trials were conducted according to GLP.

The envisaged "agricultural use" nominally calls for 1 spray at 125 g/ha and a PHI of 10 days. To evaluate this use, samples were taken just prior to the 2nd application, i.e. 10 days after the first treatment. For the "home & garden use", samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days.

Samples were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 dissipated rapidly in lettuce heads, from levels of 1.9-4 mg/kg on day 0 after the final treatment to 0.39-3.2 mg/kg on day 3 (PHI for the "home & garden" use). The respective median values were 2.9 and 1.2 mg/kg.
- ten days after a single application of BYI 02960 SL 200 – representing the envisaged "agricultural" use – total residue levels ranged from 0.07-0.83 mg/kg, with a median value of 0.32 mg/kg.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-5a: Application scenario in residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2213 (10-2213-01) France [redacted] EU-S 2010	lettuce Madita Head	200 SL	2	0.125	0.0250	48	3
10-2213 (10-2213-02) Spain [redacted] EU-S 2010	lettuce Dauair Trocadero	200 SL	2	0.125	0.0208	49	3
10-2213 (10-2213-03) Italy [redacted] EU-S 2010	lettuce Ballerina butterhead	200 SL	2	0.125	0.0208	46	3
10-2213 (10-2213-04) Spain [redacted] EU-S 2010	lettuce Murai Lollo Rosso, loose leaf variety	200 SL	2	0.125	0.0208	49	4
10-2213 (10-2213-05) Spain [redacted] EU-S 2010	lettuce Becamo Blond lolo, loose leaf variety	200 SL	2	0.125	0.0179	49	3
11-2071 (11-2071-01) Spain [redacted] EU-S 2010	lettuce Livigna RZ loose leaf variety	200 SL	2	0.125	0.0250	49	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-5a (cont'd): Application scenario in residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2071 (11-2071-02) Italy [REDACTED] EU-S 2010	lettuce Lollo Rosso, loose leaf variety	200 SL	2	0.125	0.0179	46	3
11-2071 (11-2071-03) France [REDACTED] EU-S 2010	lettuce Pitice, loose leaf variety	200 SL	2	0.125	0.0156	48	3
11-2071 (11-2071-04) Portugal [REDACTED] EU-S 2010	lettuce Caypira, loose leaf variety	200 SL	2	0.125	0.0156	48	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-5b: Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoro-ethylamino-furanone	total residue of BYI 02960 (a)
10-2213 (10-2213-01) France GLP: yes	head	0*	0.04	<0.02	<0.01	0.07
		0	2.6	<0.02	<0.01	2.6
		1	0.57	<0.02	<0.01	0.60
		3	0.40	0.02	<0.01	0.42
		5	0.29	0.02	<0.01	0.32
		7	0.15	0.02	<0.01	0.19
		7	0.15	0.02	<0.01	0.19
10-2213 (10-2213-02) Spain GLP: yes	head	0*	0.80	0.02	<0.01	0.83
		0	3.8	0.02	<0.01	3.8
		1	3.5	0.03	0.02	3.5
		3	2.7	0.03	0.02	2.7
		4	2.3	0.03	0.02	2.4
		7	2.3	0.03	0.01	2.4
		7	2.3	0.03	0.01	2.4
10-2213 (10-2213-03) Italy GLP: yes	head	0*	0.05	0.03	0.01	0.09
		0	2.7	0.04	0.01	2.7
		1	2.2	0.04	0.01	2.2
		3	0.48	0.05	0.01	0.53
		5	0.21	0.05	0.01	0.27
		7	0.09	0.05	<0.01	0.15
		7	0.09	0.05	<0.01	0.15
10-2213 (10-2213-04) Spain GLP: yes	head	0*	0.03	0.03	<0.01	0.41
		0	3.8	0.03	<0.02	3.7
		1	2.6	0.04	0.02	3.1
		4	2.1	0.05	0.02	2.2
		5	2.0	0.05	0.02	2.1
		7	1.3	0.05	0.02	1.3
		7	1.3	0.05	0.02	1.3
10-2213 (10-2213-05) Spain GLP: yes	head	0*	0.04	<0.02	<0.01	0.07
		0	2.9	<0.02	<0.01	2.9
		1	1.9	<0.02	0.01	2.0
		5	1.1	<0.02	0.02	1.2
		7	0.21	<0.02	<0.01	0.24
		7	0.17	0.02	<0.01	0.20
		7	0.17	0.02	<0.01	0.20
11-2071 (11-2071-01) Spain GLP: yes	head	0*	0.43	0.046	0.021	0.49
		0	2.5	0.062	0.031	2.7
		3	1.5	0.077	0.046	1.6
		7	0.77	0.097	0.034	0.90
		10	0.5	0.11	0.024	0.71
		14	0.33	0.15	<0.01	0.19
		14	0.33	0.15	<0.01	0.19
11-2071 (11-2071-02) Italy GLP: yes	head	0*	0.55	0.051	0.011	0.61
		0	7.3	0.039	0.023	7.4
		3	3.1	0.083/0.032**	0.045	3.2/0.052**
		7	1.4	0.13	0.025	1.5
		10	0.24	0.11	<0.01	0.37
		14	0.17	0.12	<0.01	0.30
		14	0.17	0.12	<0.01	0.30
11-2071 (11-2071-03) France GLP: yes	head	-9	5.2	<0.02	0.015	5.4
		0	3.4	<0.02	0.024	3.5
		4	0.69	<0.02	0.014	0.72
		-1	0.39	<0.02	<0.01	0.42
		0	0.29	<0.02	<0.01	0.32
		3	3.5	0.020	0.022	3.6
		7	0.72	0.035	0.020	0.78
		7	0.25	0.032	0.011	0.29
		10	0.20	0.047	0.012	0.26
14	0.094	0.046	<0.01	0.15		

 DALT = days after last treatment
 * prior to last treatment

**residues in control

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-5b (cont'd): Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960- difluoro- ethylamino- furanone	total residue of BYI 02960 (cal)
BYI 02960 SL 200						
11-2071 (11-2071-04) Portugal	head	-10	<0.01	<0.02	<0.01	0.04
		-8	1.8	0.022	0.021	1.8
		-5	0.92	0.031	0.015	0.9
		-2	0.27	0.027	<0.01	0.27
GLP: yes		0*	0.11	0.029	<0.01	0.15
		0	1.9	0.026	<0.01	1.9
		3	0.35	0.030	<0.01	0.35
		7	0.16	0.034	<0.01	0.20
		10	0.067	0.034	<0.01	0.11
		14	0.046	0.038	<0.01	0.094

DALT = days after last treatment
* prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-6: Recovery data for BYI 02960 in lettuce

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)							
						Individual recoveries	Min	Max	Mean	RSD			
10-2213 10-2213-01 to 10-2213-05 GLP: yes 2010	Lettuce, head	head	BYI 02960	15	0.01	79;87;102;106; 107;109;110;116; 92;97;107;108; 114;116;117	79	117	94	10.7			
				5	0.10	88;90;96;92;93	88	93	91	2			
				2	0.50	103;106	103	106	105				
				2	1.0	92;94	92	94	93				
				2	5.0	90;98	90	98	94				
				26	overall		79	117	100	10.5			
			BYI 02960- difluoroacetic acid	12	0.02	90;93;94;95;97; 112;112;116;86; 89;93;95	86	116	98	10.2			
				3	0.05	90;92;98	90	98	94	4.3			
				2	0.20	92;94	92	94	93				
				5	0.50	93;101;90;91;92	90	101	93	4.7			
				2	1.0	90;92	90	92	91				
				2	5.0	90;89	89	90	90				
				26	overall		86	116	95	7.9			
				BYI 02960- difluoroethyl- aminofuranone	15	0.01	87; 93; 95; 100; 100; 104; 105; 107; 83; 83; 86; 88; 90; 92; 96	83	107	94	8.4		
					5	0.10	85; 98; 97; 97; 99	85	99	95	6.1		
					2	0.50	95; 109	97	109	103			
			2		1.0	86; 101	86	101	94				
			2		5.0	97; 96	96	97	97				
			26		overall		83	109	95	7.7			
			11-2071 11-2071-01 to 11-2072-04 GLP: yes 2011	Lettuce head	head	BYI 02960	1	0.01	88	88	88	88	
							3	0.10	98;111;95	95	111	101	8.4
							3	10	104	104	104	104	
						3	overall		88	111	99	8.8	
						difluoroacetic acid	1	0.02	87	87	87	87	
							4	0.20	113;95;95	95	113	101	10.3
							4	overall		87	113	98	11.3
BYI 02960- difluoroethyl- aminofuranone	1	0.01				105	105	105	105				
	3	0.10				98;105;99	98	105	101	3.8			
	4	overall					98	105	102	3.7			



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Greenhouse

Report:	KIIA 6.3.1.1/05, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the greenhouse in France (North), Germany, the Netherlands and Italy
Report No. & Document No.:	10-2212, dated February 22, 2012 M-425829-01-1
Report:	KIIA 6.3.1.1/06, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the greenhouse in northern France, Italy, Spain and Germany
Report No. & Document No.:	11-2070, dated February 23, 2012 M-425786-01-1
Guidelines (applies to both studies):	Directive 91/414/EEC, residues in or on treated products, food and feed
GLP (applies to both studies):	yes, (certified laboratory); Deviations: none

I. Materials and Methods

Nine residue trials were conducted in European greenhouses, as follows:

In 2010, 5 trials (France, Germany [2], the Netherlands, and Italy) were conducted to support the use of BYI 02960 SL 200 in lettuce ([REDACTED] 2012, KIIA 6.3.1.1/05). The lettuce varieties used were either closed-head (1 trial) or leafy (2) varieties, as per the prevailing EU guidance at the time. Two applications were made at intervals of 10 days (11 in one trial) at a nominal rate of 0.625 L/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 400-600 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Four further trials were carried out in 2011, in France, Spain, Germany, and Italy, to complete the data package ([REDACTED] 2012, KIIA 6.3.1.1/06). In 3 of the 4 trials, the lettuce varieties used were leafy (open-head) varieties. The basic application parameters were as in 2010 (interval in one trial: 9 day); water rates ranged from 400-600 L/ha. Again, all treatments were made at the scheduled rates.

Samples of lettuce heads were taken immediately prior and subsequent to the final application, and at several intervals thereafter, up to 7 or 14 days after treatment in 2010 and 2011 trials, respectively). The envisaged PHI was 34 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or 01212 (2011 trials; cf. KIIA 4.3/05). The respective LOQ for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).



II. Findings

During the conduct of the complete set of lettuce studies in 2010-2011, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of lettuce heads. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.50, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (91-104%, RSDs of the larger validations sets [n > 2] 2.2-10.7%, n=2-12).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.50 mg/kg, as well as 0.20, 1.0, and 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (90-98%, RSDs of the larger validations sets [n > 2] 3-10.2%, n=2-12).

Details of recovery data are shown in table 6.3.1.1-8. All trial data are summarised below in table 6.3.1.1-7a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

Relevant residues of BYI 02960 were determined in lettuce head samples taken 10 days subsequent to the first application (immediately prior to the end treatment) as well as at various intervals after the final application. Analyses showed that total residue levels declined with time.

On day 0, immediately following the final treatment, residue levels in lettuce heads were between 1.5 and 7.7 mg/kg (median 3.9 mg/kg). By day 3 — the envisaged PHI — the levels had declined to 0.80-6.0 mg/kg (n=9), with a median value of 2.2 mg/kg. Residues continued to decrease until day 14, the final sampling event, when levels ranged from 0.21-2.7 mg/kg (n=4, median 0.28 mg/kg).

III. Conclusions (lettuce, greenhouse)

In order to support the use in the EU of BYI 02960 in lettuce, 9 valid trials were conducted in European greenhouses in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha per treatment. The application intervals were 9-11 days. All applications were at the required rates, and all trials were conducted according to GLP.

The greenhouse use calls for 2 sprays at 125 g/ha and a PHI of 3 days. To evaluate this use, samples were taken at several intervals after the final application, including the envisaged PHI of 3 days.

Samples were analysed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

- total residues of BYI 02960 dissipated rapidly in lettuce heads, from levels of 1.5-7.7 mg/kg on day 0 after the final treatment to 0.80-6.0 mg/kg on day 3 (envisaged PHI). The respective median values were 3.9 and 2.2 mg/kg.
- based on a comparison of the residue values from field and greenhouse testing and using the same use pattern, it is evident that the greenhouse use yielded somewhat higher total residues in lettuce than did the field uses.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-7a: Application scenario in residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in European greenhouses

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2212 (10-2212-01) France [redacted] EU-N 2010	lettuce Kitonia, leafy variety	200 SL	2	0.125	0.0208	49	3
10-2212 (10-2212-02) Germany [redacted] EU-N 2010	lettuce Antoni, leafy variety	200 SL	2	0.125	0.0208	48	3
10-2212 (10-2212-03) Germany [redacted] EU-N 2010	lettuce Torpedo, butterhead variety	200 SL	2	0.125	0.0313	48	3
10-2212 (10-2212-04) Netherlands [redacted] EU-N 2010	lettuce Gardia, butterhead variety	200 SL	2	0.125	0.0208	45	3
10-2212 (10-2212-05) Italy [redacted] EU-S 2010	lettuce Cappuc cina, butterhead variety	200 SL	2	0.125	0.0250	45	3
11-2070 (11-2070-01) France [redacted] EU-N 2011	lettuce Quenty, open ear variety	200 SL	2	0.125	0.0208	48	3

 FL = formulation
 EU-N = northern Europe

 GS = growth stage (BBCH-code) at last treatment
 EU-S = southern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-7a (cont'd): Application scenario in residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in European greenhouses

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2070 (11-2070-02) Italy [REDACTED] EU-S 2011	lettuce Expedition RZ, Green incised-leaf variety	200 SL	2	0.125	0.0208	47	3
11-2070 (11-2070-03) Spain [REDACTED] EU-N 2011	lettuce Oak Leaf, leaf variety	200 SL	2	0.125	0.0250- 0.0228	47	3
11-2070 (11-2070-04) Germany [REDACTED] EU-N 2011	lettuce Judita, head lettuce	200 SL	2	0.125	0.0208	47	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern Europe

EU-S = southern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.1-7b: Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in European greenhouses

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoro-ethylamino-furanone	total residue of BYI 02960
10-2212 (10-2212-01) France GLP: yes	head	0*	0.23	<0.02	<0.01	0.26
		0	1.5	<0.02	<0.01	1.5
		1	1.3	<0.02	<0.01	1.4
		3	1.4	<0.02	<0.01	1.4
		5	1.2	0.02	<0.01	1.2
		7	1.4	0.02	<0.01	1.4
10-2212 (10-2212-02) Germany GLP: yes	head	0*	2.7	<0.02	0.01	2.7
		0	6.7	<0.02	0.02	6.7
		1	2.3	<0.02	<0.01	2.4
		3	2.0	<0.02	0.01	2.0
		5	1.7	<0.02	0.01	1.5
		7	2.3	<0.02	<0.01	1.7
10-2212 (10-2212-03) Germany GLP: yes	head	0*	0.13	<0.02	<0.01	0.16
		0	5.2	<0.02	0.01	5.3
		1	4.6	<0.02	0.01	4.7
		3	3.5	<0.02	0.01	3.5
		5	2.4	0.02	0.01	2.4
		7	1.7	0.02	0.01	1.8
10-2212 (10-2212-04) Netherlands GLP: yes	head	0*	0.29	0.02	0.01	0.32
		0	3.1	0.02	0.02	3.1
		1	2.5	0.02	0.02	2.5
		3	2.5	0.03	0.02	2.5
		5	2.0	0.02	0.03	2.0
		7	0.99	0.04	0.02	1.0
10-2212 (10-2212-05) Italy GLP: yes	head	0*	0.6	<0.02	0.01	0.68
		0	3.8	<0.02	0.02	3.9
		1	2.7	<0.02	0.02	2.7
		3	1.8	<0.02	0.02	1.8
		5	1.3	0.02	0.01	1.3
		7	0.4	0.03	0.01	0.78
11-2070 (11-2070-01) France GLP: yes	head	0	3.0	0.02	<0.01	3.0
		3	2.1	0.022	0.011	2.2
		7	0.5	0.026	<0.01	0.62
		14	0.18	0.028	<0.01	0.43
		14	0.18	0.026	<0.01	0.21
		14	0.18	0.026	<0.01	0.21
11-2070 (11-2070-02) Italy GLP: yes	head	0	4.1	0.040	<0.01	4.1
		3	0.2	0.059	<0.01	0.80
		10	0.43	0.073	<0.01	0.52
		10	0.32	0.098	<0.01	0.42
		14	0.13	0.13	<0.01	0.27
		14	0.13	0.13	<0.01	0.27
11-2070 (11-2070-03) Spain GLP: yes	head	0	7.6	0.029	0.024	7.7
		3	6.0	0.035	0.027	6.0
		7	4.6	0.055	0.037	4.7
		11	2.9	0.061	0.038	3.0
		11	2.9	0.061	0.038	3.0
		11	2.6	0.069	0.049	2.7

 DALT = days after last treatment
 * prior to last treatment

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-7b (cont'd): Results of residue trials conducted in/on **lettuce** after spraying with BYI 02960 SL 200 in European greenhouses

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960
GLP						
11-2070	head	0	3.7	0.027	0.015	
(11-2070-04)		3	2.6	0.036	0.014	2.7
Germany		7	0.87	0.043	0.010	0.93
		10	0.46	0.053	<0.01	0.52
GLP: yes		14	0.23	0.041	<0.01	0.28

DALT = days after last treatment

* prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.1-8: Recovery data for BYI 02960 in lettuce

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)							
						Individual recoveries	Min	Max	Mean	RSD			
10-2213 10-2213-01 to 10-2213-05 GLP: yes 2010	Lettuce, head	head	BYI 02960	15	0.01	79;87;102;106; 107;109;110;116; 92;97;107;108; 114;116;117	79	117	94	10.7			
				5	0.10	88;90;96;92;93	88	93	91	2.2			
				2	0.50	103;106	103	106	105				
				2	1.0	92;94	92	94	93				
				2	5.0	90;98	90	98	94				
				26	overall		79	117	100	10.5			
			BYI 02960- difluoroacetic acid	12	0.02	90;93;94;95;97; 112;112;116;86; 89;93;95	86	116	98	10.2			
				3	0.05	90;92;98	90	98	94	4.3			
				2	0.20	92;94	92	94	93				
				5	0.50	93;101;90;91;92	90	101	93	4.7			
				2	1.0	90;92	90	92	91				
				2	5.0	90;89	89	90	90				
				26	overall		86	116	95	7.9			
				BYI 02960- difluoroethyl- aminofuranone	15	0.01	87; 93; 95; 100; 100; 104; 105; 107; 83; 83; 86; 88; 90; 92; 96	83	107	94	8.4		
					5	0.10	85; 98; 97; 97; 99	85	99	95	6.1		
					2	0.50	95; 109	97	109	103			
			2		1.0	86; 101	86	101	94				
			2		5.0	97; 96	96	97	97				
			26		overall		83	109	95	7.7			
			11-2071 11-2071-01 to 11-2072-04 GLP: yes 2011	Lettuce head	head	BYI 02960	1	0.01	88	88	88	88	
							3	0.10	98;111;95	95	111	101	8.4
							10	overall	104	104	104		
						difluoroacetic acid	1	0.02	87	87	87	87	
							4	0.20	113;95;95	95	113	101	10.3
							4	overall		87	113	98	11.3
						BYI 02960- difluoroethyl- aminofuranone	1	0.01	105	105	105	105	
3	0.10	98;105;99					98	105	101	3.8			
4	overall						98	105	102	3.7			

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
IIA 6.3.1.2 Hops

BYI 02960 (common name: flupyradifurone) is to be registered in northern Europe for use in hops. Thus, European residue data in hops are presented below to support the intended "safe" use. Use pattern (GAP) information is summarized in Table 6.3.1.2-1.

Table 6.3.1.2-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulations in/on hops in European fields

Description	Reg.	No. of appls.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"safe use"*	EU-N	1	120	120	2000-3000	-	21

EU-N = northern EU residue region

* use based on an SL 200 formulation

In order to support the EU "safe use" of BYI 02960, sets of GLP trials were conducted in northern European fields in 2010 and 2011. BYI 02960 SL 200 (containing 200 g/L BYI 02960 a.s.) was applied once. Samples were taken at various intervals subsequent to the application. The envisaged PHI was 21 days.

Residue levels of BYI 02960 and its metabolites DFA and DFEAF were analyzed individually and summed to yield the calculated total residue of BYI 02960. Total residue levels determined in the trials reached a maximum of 2.4 mg/kg in dried cones, with an STMRO of 1.1 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.2-2.

Table 6.3.1.2-2: Overview of European residue trials conducted in hops per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.2-1)	Region	No. of trials		Residue levels* (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.2/...
		2010	2011	HR	STMRO		
<i>trials in EUROPE</i>							
"safe use"	EU-N	1	1	<i>green cone:</i> 0.87 0.47 <i>dried cone:</i> 2.4 1.1		10-2225, 11-2076	01, 02

EU-N = northern EU residue region

* residue results based on total residues in samples taken on day 21 (= envisaged PHI)



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Northern Europe (residue region)

Report:	KIIA 6.3.1.2/01, [REDACTED]; [REDACTED], A. 2012
Title:	Determination of the residues of BYI 02960 in/on hop after spraying of BYI 02960 SL 200 in the field in Germany
Report No. & Document No.:	10-2225, dated February 13, 2012 M-425351-01-1
Report:	KIIA 6.3.1.2/02, [REDACTED]; [REDACTED], A. 2012
Title:	Determination of the residues of BYI 02960 in/on hop after spray application of BYI 02960 SL 200 in Germany
Report No. & Document No.:	11-2076, dated February 13, 2012 M-425339-01-1
Guidelines (applies to both studies):	Directive 91/414/EEC residues in or on treated products, food and feed
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Eight residue trials were conducted in the northern European residue region, as follows:

In 2010 and 2011, 8 trials (4 trials per year, all in Germany) were conducted to support the use of BYI 02960 SL 200 in hops ([REDACTED] & [REDACTED], 2012, KIIA 6.3.1.2/01 and /02). A single application was made 21 days before the projected harvest at a nominal rate of 0.6 L/ha, corresponding to 120 g/ha BYI 02960 a.s. Water rates were 2000-3000 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Samples of green hop cones were taken immediately subsequent to the final application and at several intervals thereafter (up to 28 days after treatment). The envisaged PHI was 21 days. (In two trials, the PHI samples were taken on day 20; in one other, on day 22.) In addition to the green cone samples, additional cones were taken at the later sampling intervals (nominally days 14, 21, and 28) and dried according to standard practice, as dry cones are the primary traded commodity from the grower to the market.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (cf. KIIA 4.3/03). The respective LOQs for the 3 analytes were 0.10, 0.20, and 0.10 mg/kg (all in parent equivalents), yielding a calculated total-residue LOQ of 0.40 mg/kg.

II. Findings

During the conduct of the 2010 studies, both validation and concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of hop cones (green and dried). (The validation work was done due to the fact that hops are considered "difficult to analyze" but were not included in the original validation set for method 01304. Details of the validation recoveries are

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

presented in chapter 4.3 of this dossier with method 01304.) In 2011, samples were analyzed for concurrent recoveries.

Concurrent recovery samples for parent compound and DFEAF were spiked at levels of 0.10 mg/kg and 1.0 mg/kg, as well as 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries in green cones in 2010 were 80-94%, with RSDs of the larger validation sets ($n > 2$) of 6.0-13.9%; $n = 1-6$. In 2011, mean recoveries were 85-91%, with RSDs of the larger validation sets (1.0 mg/kg) of 0.7-3.3%; $n = 1-3$. All values were within acceptable ranges.

Mean recoveries in dried cones in 2010 were 103-112%, with RSDs (of the larger validation sets [$n > 2$]) of 1.4-7.2%; $n = 1-6$. All of these values were considered to be acceptable because, even in the case of values over 110%, they were only marginally higher and the RSD values were very low; also, in the cases of the exceptions, the overall means of all recovery analyses for the given matrices with each individual analyte were 107% and 108%, with overall RSDs of 6.2% and 4.2%. In 2011, recoveries were 79-91%; $n = 1$ for each concentration.

For DFA, concurrent recovery samples were spiked at levels of 0.20 mg/kg and 1.0 mg/kg, as well as 5.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries in green cones in 2010 were 83-99%, with RSDs (of the larger validation sets [$n > 2$]) of 8.2% and 8.9%; $n = 1-6$. In 2011, mean recoveries were 79% and 88%, with an RSD of the larger validation set (1.0 mg/kg) of 3.2%; $n = 1-3$. All values were within acceptable ranges.

In dried cones, mean DFA recoveries in 2010 were 98-106%, with RSDs of the larger validation sets ($n > 2$) of 3.1 and 8.3%; $n = 1-6$. In 2011, recoveries were 70% and 73%; $n = 1$ for each concentration. The values were all within acceptable ranges.

Details of recovery data are shown in table 6.3.1.2-4. All trial data are summarised below in table 6.3.1.2-3a & b and in greater detail in the Tier 1 summary forms. Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

Relevant residues of BYI 02960 were determined in hop cone samples taken at various intervals after application.

Analyses of green cones showed that total residue levels generally declined with time. On day 0, immediately following treatment, residue levels in green hop cones were between 0.79 and 2.7 mg/kg (median 1.3 mg/kg). By day 21 — the envisaged PHI (samples were taken on day 20 in two trials and day 22 in one further trial) — the levels had declined to <0.40-0.87 mg/kg ($n = 8$), with a median value of 0.47 mg/kg. Residues continued to decrease until day 26-28, the final sampling event, when levels ranged from 0.40-0.69 mg/kg ($n = 8$, median 0.41 mg/kg).

The residue behaviour was somewhat less predictable in dried cones. Whereas a decline was generally evident over time, in three of the trials, residue levels at the final sampling interval (28 days) were higher than at the PHI (day 21). Residue levels on day 21 (20 in two trials, 22 in one other) ranged



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

from 0.56-2.4 mg/kg, with a median value of 1.1 mg/kg. On day 28 (day 26 and 27 in one trial each), they were generally lower, at <0.40-2.3 mg/kg (median 0.71 mg/kg). Taking the highest residues at relevant sampling intervals into consideration (either day 21 or 28), residues ranged from 0.61-2.4 mg/kg; the median value was 1.2 mg/kg.

III. Conclusions (hops)

In order to support the use in the EU of BYI 02960 in hops, 8 valid trials were conducted in the northern European residue region in the years 2010-2011. BYI 02960 was applied once as an SD 200 formulation at an active substance rate of 120 g/ha. All applications were at the required rates, and all trials were conducted according to GLP.

To evaluate this use, samples of both green and dried hop cones were taken at several intervals after the final application, including the envisaged PHI of 21 days. Samples were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 dissipated rapidly in green hop cones, from levels of 0.79-2.7 mg/kg on day 0 after the treatment to 0.40-0.87 mg/kg on day 21, (envisaged PHI). The respective median values were 1.3 and 0.47 mg/kg.
- in dried cones, residue levels also tended to decline with time. When evaluating the highest residues at relevant sampling intervals (either day 21 or, in three trials, day 28), residues ranged from 0.61-2.4 mg/kg, with a median of 1.2 mg/kg.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.2-3a: Application scenario in residue trials conducted in/on hops after spraying with BYI 02960 SL 200 in the field

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (days)
				kg/ha (a.s.)	kg/hl (a.s.)		
10-2225 (10-2225-01) Germany [redacted]	hop Hallertauer Gold	200 SL	1	0.12	0.004	BBCH: 3-74	21
EU-N 2010							
10-2225 (10-2225-02) Germany [redacted]	hop Magnum	200 SL	1	0.12	0.0055	75	21
EU-N 2010							
10-2225 (10-2225-03) Germany [redacted]	hop Hallertauer Magnum	200 SL	1	0.12	0.0055	5	20
EU-N 2010							
10-2225 (10-2225-04) Germany [redacted]	hop Hallertauer Tradition	200 SL	1	0.12	0.0055	85	21
EU-N 2010							
11-2076 (11-2076-01) Germany [redacted]	hop Hallertauer mittelfrüh	200 SL	1	0.15	0.006	75	21
EU-N 2011							

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern Europe

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.2-3a (cont'd): Application scenario in residue trials conducted in/on hops after spraying with BYI 02960 SL 200 in the field

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (days)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2076 (11-2076-02) Germany [redacted] EU-N 2011	hop Magnum	200 SL	1	0.15	0.006	BBCH: 73	21
11-2076 (11-2076-03) Germany [redacted] EU-N 2011	hop Hallertauer Tradition	200 SL	1	0.15	0.006	86	20
11-2076 (11-2076-04) Germany [redacted] EU-N 2011	hop Tettnanger	200 SL	1	0.15	0.0075	BBCH: 78	22

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern Europe

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.2-3b: Results of residue trials conducted in/on hops after spraying with BYI 02960 SL 200 in the field

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoro-ethylamino-furanone	total residue of BYI 02960 cal
10-2225 (10-2225-01) Germany GLP: yes	cone, green	0	1.3	<0.2	<0.1	1.6
		7	0.62	<0.2	<0.1	0.92
		14	0.29	<0.2	<0.1	0.59
		21	0.52	<0.2	<0.1	0.82
	cone, kiln-dried	28	0.16	<0.2	<0.1	0.44
		14	1.5	0.27	<0.1	1.6
		21	0.81	0.28	<0.1	1.1
		28	1.1	0.4	<0.1	1.6
10-2225 (10-2225-02) Germany GLP: yes	cone, green	0	0.46	<0.2	<0.1	0.79
		8	0.27	<0.2	<0.1	0.57
		13	0.19	<0.2	<0.1	0.49
		20	0.1	<0.1	<0.1	0.4
	cone, kiln-dried	27	<0.1	<0.2	<0.1	<0.4
		13	0.54	0.2	<0.1	0.84
		20	0.48	<0.2	<0.1	0.78
		27	<0.1	<0.2	<0.1	<0.4
10-2225 (10-2225-03) Germany GLP: yes	cone, green	0	1.4	<0.2	<0.1	1.7
		7	0.54	<0.2	<0.1	0.84
		14	0.36	<0.2	<0.1	0.66
		21	0.20	<0.2	<0.1	0.50
	cone, kiln-dried	28	<0.1	<0.2	<0.1	<0.4
		14	1.4	0.25	<0.1	1.7
		21	0.77	0.28	<0.1	1.1
		28	0.32	<0.2	<0.1	0.62
10-2225 (10-2225-04) Germany GLP: yes	cone, green	0	0.5	<0.2	<0.1	0.86
		8	0.27	<0.2	<0.1	0.57
		14	0.17	<0.2	<0.1	0.47
		21	0.14	<0.2	<0.1	0.44
	cone, kiln-dried	28	<0.1	<0.2	<0.1	<0.4
		14	0.54	0.2	<0.1	0.84
		21	0.90	0.21	<0.1	1.2
		28	0.49	<0.2	<0.1	0.79

DALT = days after last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.2-3b (cont'd): Results of residue trials conducted in/on **hops** after spraying with BYI 02960 SL 200 in the field

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 cal
BYI 02960 SL 200						
11-2076 (11-2076-01) Germany	cone, green	0	2.4	<0.2	<0.1	2.7
		14	0.47	<0.2	<0.1	0.77
	cone, kiln-dried	21	0.51	<0.2	<0.1	0.81
		28	0.39	<0.2	<0.1	0.69
		GLP: yes	28	1.8	0.3	0.1
11-2076 (11-2076-02) Germany	cone, green	0	0.55	<0.2	<0.1	0.85
		14	0.21	<0.2	<0.1	0.51
	cone, kiln-dried	21	0.1	<0.2	<0.1	0.4
		28	0.10	<0.2	<0.1	0.40
		GLP: yes	28	0.26	<0.2	<0.1
11-2076 (11-2076-03) Germany	cone, green	0	2.1	<0.2	<0.1	2.4
		13	0.78	<0.2	<0.1	1.1
	cone, kiln-dried	20	0.57	<0.2	<0.1	0.87
		26	0.23	<0.2	<0.1	0.53
		GLP: yes	26	2.0	0.27	<0.1
11-2076 (11-2076-04) Germany	cone, green	0	0.61	<0.2	<0.1	0.91
		13	0.11	<0.2	<0.1	0.41
	cone, kiln-dried	22	0.1	<0.2	<0.1	<0.4
		28	0.11	<0.2	<0.1	0.41
		GLP: yes	28	0.43	<0.2	<0.1
						0.59

DALT = days after last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.2-4: Recovery data for BYI 02960 on hops

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./metabolite	n	Fortification level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean	RSD	
10-2225 10-2225-01 to 10-2225-04 GLP: yes 2010	hop	cone, green	BYI 02960	6	0.10	89;89;91;94;95;107	89	107	94	7.2	
				5	1.0	85;86;87;92;98	85	98	90	6.0	
				1	5.0	87	87	87	87	6.8	
			12	overall						92	6.8
			difluoroacetic acid	6	0.20	92;92;95;99;100;115	91	115	99	8.9	
				5	1.0	76;79;83;84;94	76	94	83	8.2	
				1	5.0	86	86	86	86	11.7	
			12	overall						91	11.7
			BYI 02960-difluoroethyl-aminofuranone	6	0.10	68;73;79;85;95;96	68	96	83	13.9	
		5		1.0	76;77;78;84;94	76	94	81	7.8		
		1		5.0	80	80	80	80	10.6		
		12	overall						82	10.6	
		cone, kiln-dried	BYI 02960	6	0.10	102;103;103;104;105;106	102	106	104	1.4	
				5	1.0	107;108;111;114;115	107	115	111	3.2	
				1	5.0	112	112	112	112	4.2	
			12	overall						108	4.2
			difluoroacetic acid	6	0.20	92;96;97;103;103;106	82	106	98	8.9	
				5	1.0	101;105;106;109;110	101	110	106	3.1	
1	5.0			98	98	98	98	7.3			
12	overall							101	7.3		
BYI 02960-difluoroethyl-aminofuranone	6		0.10	89;100;106;107;107;108	89	108	103	7.2			
	5	1.0	108;109;110;112;114	108	114	111	2.2				
	1	5.0	112	112	112	112	6.2				
12	overall						107	6.2			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.2-4 (cont'd): Recovery data for BYI 02960 on hops

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./metabolite	n	Fortification level (mg/kg)	Recovery (%)						
						Individual recoveries	Min	Max	Mean	RSD		
11-2076 11-2076-01 to 11-2076-04 GLP: yes 2011	hop	cone, green	BYI 02960	1	0.10	90	90	90	90			
				3	1.0	84;85;85	84	85	85	0.7		
				4	overall		84	90	86	3.1		
			difluoroacetic acid	1	0.20	88	88	88	88			
				3	1.0	77;79;82	77	82	79	3.2		
				4	overall		77	88	82	5.9		
		BYI 02960-difluoroethyl-aminofuranone	1	0.10	91	91	91	91				
			4	1.0	87;90;91	87	91	89	2.3			
			4	overall		87	91	90	2.1			
		11-2076 11-2076-01 to 11-2076-04 GLP: yes 2011	hop	cone, kiln-dried	BYI 02960	1	0.10	89	90	90	90	
						2	1.0	87	87	87	87	
						2	overall		87	90	89	
difluoroacetic acid	1				0.20	73	73	73	73			
	1				1.0	70	70	70	70			
	2				overall		70	73	72			
BYI 02960-difluoroethyl-aminofuranone	1			0.10	79	79	79	79				
	1			1.0	91	91	91	91				
	2			overall		79	91	85				

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➤ **"FURTHER USES"**

The following paragraphs describe all uses to be intended for registration in Europe besides the two "safe uses" lettuce and hops, which have been submitted in May 2012.

IIA 6.3.1.3 Pome fruit - apple

BYI 02960 is to be registered in Europe for use in pome fruit. European residue data in apple are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.3-1.

Table 6.3.1.3-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulations in/on apple in European fields

Description	Reg.	No. of appls.	Application rate per treatment (g a.s. [ha×m])	Application rate per season (g a.s./ha)	Water volume (L/[ha×m])	Interval (days)	PHI (days)
"home & garden"*	EU-N	2	60†	120-360	250-500	14	14
	EU-S	1	67.5	68-203	250-500	n/a	14
agricultural**	EU-N	2	60†	120-180	250-500	n/a	14
	EU-S	1	60†	60-180	250-500	n/a	14

EU-N = northern European residue region EU-S = southern European residue region
 * "home & garden" use with SL 50 formulation (available to the general public via retail sales)
 ** agricultural use based on SL 200 formulation
 † core rate per meter crown height (CH). Testing based on a max. CH of 3m, equating to max. 180 or 203 g a.s./ha, respectively.

In order to support the use of BYI 02960, sets of GLP trials were conducted in both the northern and southern European residue regions in 2010 and 2011. In northern and in southern European apple trees, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200, containing 200 g/L BYI 02960 a.s.), at 14-day intervals, except the residue trials conducted in southern Europe in 2011, where only a single application was made.

At the beginning of the program, the envisaged GAP specified two applications in both northern and southern Europe. However, this GAP was changed in southern Europe, and only one application became the current GAP for use in that region. The trials conducted in southern Europe in 2011 were performed according to the newer (current) GAP. In northern Europe, the 2-application scheme will be supported for home & garden use (SL 50), while the main agricultural use (SL 200) will also be limited to a single application.

In the 2010 trials and northern 2011 trials, samples were taken immediately prior to the second application, thus reflecting conditions representative of a 1-application, 14-day PHI use pattern. In all trials, samples were taken at various intervals subsequent to final application, with an envisaged PHI of 14 days, reflecting the intended worst-case PHI.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Residue levels of BYI 02960 and its metabolites DFA and DFEAF were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the northern European trials, in which a highest total residue value (HR) of 0.37 mg/kg was determined. The STMR in these trials was also the higher of the two sets, at 0.12 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.3-2.

Table 6.3.1.3-2: Overview of European residue trials conducted in apple per geographical region and vegetation period, including key results

Use description (cf. table 6.3.1.3-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dosier ref.: IIA 6.3.1.3-2...
		Veget. period 2010	2011	Σ	HR	STMR		
<i>trials in EUROPE</i>								
"home & garden"	EU-N	6	4	20	0.21	0.13	10-2171, 11-2777	01, 02
	EU-S	6	4		0.11	0.06	10-2172, 11-2078	03, 04

EU-N = northern EU residue region, EU-S = southern EU residue region

Northern European residue region

Report:	KIIA 6.3.1.3/01, [redacted] 2012
Title:	Determination of the residues of BYI 02960 in/on apple after spraying of BYI 02960 SL 200 in the field in Germany, France, northern the Netherlands and Belgium
Report No. & Document No.:	10-2171, dated July 5, 2012 M-434587-01-1

Report:	KIIA 6.3.1.3/02, [redacted]; [redacted] 2012
Title:	Determination of the residues of BYI 02960 in/on apple after spray application of BYI 02960 SL 200 in the field in Germany, northern France and the United Kingdom
Report No. & Document No.:	11-2077, dated September 17, 2012 M-438329-01-1

Guidelines (applies to both studies)	Directive 91/414/EEC, residues in or on treated products, food and feed EC Guidance working document 7029/VI/95 rev. 5 US EPA OPSP Guideline No. 860.1500.SUPP
GLP (applies to both studies)	yes (certified laboratory); Deviations: none

I. Materials and Methods

Ten field residue trials were conducted in the northern European residue region, as follows:

In 2010, trials (Germany [3], northern France, the Netherlands, and Belgium) were conducted to support the use of BYI 02960 SL 200 in apple ([redacted] & [redacted], 2012, KIIA 6.3.1.3/01). Two applications were made at intervals of 14 days (13 days in one trial) at a nominal rate of 0.205-



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

0.375 L/(ha×m), corresponding to 50-75 g/(ha×m) BYI 02960 a.s.; the water rate was 500 L/(ha×m), reflecting local practice in the trial regions. (In two trials each, the application rate was 50, 60, or 75 g/[ha×m CH]. The intended GAP now specifies 60 g/[ha×m CH]; all trials from the 2010 program can be considered representative, as the difference in rates is 25% or less, and thus within the EU's acceptance criteria for use pattern comparability.) All treatments were made at the scheduled rates.

Four further trials were carried out in 2011, in Germany [2], northern France and the United Kingdom to complete the data package ([redacted] & [redacted], 2012, KHA 6.3.1.3/02). The basic application parameters were as in 2010; application rates were 0.300 L/(ha×m) in all trials, corresponding to 60 g/(ha×m) BYI 02960 a.s. Water rates ranged from 250-450 L/(ha×m). The application intervals ranged from 13-15 days. Again, all treatments were made at the scheduled rates.

Samples of apple fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 21 days after treatment in 2010 and up to 35 days after treatment in 2011). The envisaged PHI was 14 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (for method details, cf. KHA 4/3/03). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

4. Findings

Validation and concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of apple fruit. This sample material is representative for all sample materials collected in these trials. Validation recoveries for apple fruit were conducted within study 10-2172 (cf. KHA 6.3.1.3/03), additional recoveries were conducted concurrently to the analysis of all samples (concurrent recoveries). Concurrent recoveries for studies 10-2171 and 10-2172, as well as concurrent recoveries for studies 11-2071 and 11-2072 were done in parallel. Thus the same recoveries are reported for the respective studies.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (85-101%, RSDs of the larger validation sets [n > 2] 4.4-13.0%, n=1-9).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.20 mg/kg, as well as 0.50 mg/kg, and 1.0 mg/kg (expressed in BYI 02960 equivalents) for trials conducted in 2010 and 0.02 mg/kg, 0.20 mg/kg and 1.0 mg/kg (expressed in BYI 02960 equivalents) for trials conducted in 2011. Mean recoveries were all within acceptable ranges (85-94%, RSDs of the larger validation sets [n > 2] 2.9-8.6%, n=1-9).

Details of recovery data are shown in Table 6.3.1.3-4. All trial data are summarised below in table 6.3.1.3-4a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in apple fruit were between 0.13 and 0.57 mg/kg (median 0.18 mg/kg). By day 14 — the envisaged PHI — the levels were 0.09-0.35 mg/kg, with a median value of 0.12 mg/kg.

The analytical results of the 2010 program revealed that total residue levels had reached a "plateau level" by the nominal PHI (14 days). In those trials, the peak residue levels were seen on day 14 (5 trials), or day 21, the final sampling interval (1 trial). However, in some crops residue levels had not yet reached their peaks at the nominal PHI. Therefore, steps were taken to ensure that highest residue levels were captured. Additional samplings were conducted 28-29 and 35-36 days after treatment in the 2011 program. In 2011 trials, the highest residue levels were seen on day 15 (1 trial), day 21 (1 trial), day 28 (1 trial), or day 36 (1 trial).

Peak residue levels at any relevant sampling interval (≤14 days post application) over the complete set of trials ranged from 0.09-0.37 mg/kg (median 0.15 mg/kg).

Evaluation of representativity

As highest residue levels were seen on the final sampling interval of two trials (10-2171-05, day 21; and 11-2077-03, day 28), the entire set of trials was re-evaluated for its representativity.

In the 2010 package, in trial 10-2171-01 and -06 residues showed "normal" decline behaviour. The PHI of 14 days is clearly within the range of declining residues. Trials 10-2171-01, -02, -04, and -05 essentially showed "plateau behaviour", with residues remaining fairly constant from the PHI to the final sampling date, often even prior to the PHI (day 5 to day 21). Residues in trial 10-2171-05 showed the highest variability over time. The increase in residue from 0.15 mg/kg on day 14 to 0.17 mg/kg on day 21 may be caused by sampling and, additionally, typical biological and analytical variability. Thus, taken in the context of all of the trials, this trial can also be seen as yielding representative results.

In 2011, "normal" decline behaviour or at least "plateau behaviour" was evident seen in the samples taken from day 14 onwards. Trial 11-2077-01, which showed peak residues on day 36, showed a very minor increase in residues over time, from 0.11 mg/kg on day 14 to 0.13 mg/kg on day 36. The same trend is true for trials 11-2077-03 and 11-2077-04, where peak residues were found on days 28 and 21, respectively, with very minor increases over time, from 0.35 mg/kg on day 14 to 0.37 mg/kg on day 28 and from 0.11 mg/kg on day 14 to 0.15 mg/kg on day 21, respectively.

These "increases" are very small, with the difference of only 0.01 mg/kg or 0.02 mg/kg; they are also within the scope of variability caused by sampling or biological or analytical variability. Thus, taken in the context of all of the trials, these trials can be seen as yielding representative results.

Thus the trials summarized here are considered to be valid and representative of the use described.

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III. Conclusions (apple, northern Europe)

In order to support the use in the EU of BYI 02960 in apple, 10 valid trials were conducted in the northern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 50-75 g/(ha×m) per treatment, supporting a GAP of 60 g/(ha×m). The application intervals were 13-15 days. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 14 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DPA and DFEAF. The residues of all three analyses were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 declined somewhat in apple fruit between the final application and the nominal PHI, from levels of 0.13-0.57 mg/kg on day 0 after the final treatment to 0.09-0.35 mg/kg on day 14. The respective median values were 0.18 mg/kg and 0.12 mg/kg.
- analytical results revealed that total residue levels generally had reached the plateau of residue level at the nominal PHI. In the few cases in which peak residues were reached later than at the nominal PHI, the residue levels were nevertheless similar to those at the PHI.
- peak residue levels at any relevant sampling interval (≥14 days post-application) ranged from 0.09 -0.37 mg/kg (median 0.13 mg/kg).
- the trials reported here are considered to yield representative results suitable for MRL evaluation, since residue levels had at least reached a plateau at the envisaged PHI of 14 days. Deviations are acceptable and may be explained by normal variability caused by sampling or biological and/or analytical aspects.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-3a: Application scenario in residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*northern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2171 (10-2171-01) Germany [redacted] EU-N 2010	apple Pinova	200 SL	2	0.085 (0.050 kg/[ha×m])	0.0100	87	14
10-2171 (10-2171-02) Germany [redacted] EU-N 2010	apple Gala	200 SL	2	0.15 (0.050 kg/[ha×m])	0.012	77	14
10-2171 (10-2171-03) Germany [redacted] EU-N 2010	apple Jonagold	200 SL	2	0.15 (0.075 kg/[ha×m])	0.01	74	14
10-2171 (10-2171-04) northern France [redacted] EU-N 2010	apple Galaxy	200 SL	2	0.125 (0.050 kg/[ha×m])	0.0100	79	14
10-2171 (10-2171-05) Netherlands [redacted] EU-N 2010	apple Elstar	200 SL	2	0.150 (0.075 kg/[ha×m])	0.0120	85	14
10-2171 (10-2171-06) Belgium [redacted] EU-N 2010	apple Elstar	200 SL	2	0.169 (0.075 kg/[ha×m])	0.0150	85	14

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern European residue region

Continued on next page...

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.3-3a (cont'd.): Application scenario in residue trials conducted in/on **apple after spraying with BYI 02960 SL 200 in field (northern EU residue region)**

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/h (a.s.)		
11-2077 (11-2077-01) Germany [redacted] EU-N 2011	apple Jonagold	200 SL	2	0.159 (0.060 kg/[ha×m])	0.0240	79	14
11-2077 (11-2077-02) northern France [redacted] EU-N 2011	apple Gala early variety	200 SL	2	0.168 (0.060 kg/[ha×m])	0.0133	71	14
11-2077 (11-2077-03) Germany [redacted] EU-N 2011	apple Delbarestiva le automn apple	200 SL	2	0.159 (0.060 kg/[ha×m])	0.0240		14
11-2077 (11-2077-04) United Kingdom [redacted] EU-N 2011	apple Jonathan MidOct Harvest	200 SL	2	0.168 (0.060 kg/[ha×m])	0.020	77	14

FL = formulation GS = growth stage (BBC II code) at last treatment
 EU-N = northern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-3b: Results of residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*northern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960 DFE	total residue of BYI 02960 ca
GLP						
10-2171 (10-2171-01) Germany	fruit	0*	0.02	<0.02	<0.01	0.05
		0	0.14	<0.02	<0.01	0.15
		5	0.05	<0.02	<0.01	0.08
		10	0.05	<0.02	<0.01	0.08
GLP: yes		14	0.07	<0.02	<0.01	0.10
		21	0.07	0.02	<0.01	0.09
10-2171 (10-2171-02) Germany	fruit	0*	0.07	<0.02	<0.01	0.10
		0	0.14	<0.02	<0.01	0.17
		5	0.12	<0.02	<0.01	0.15
		10	0.14	0.02	<0.01	0.17
GLP: yes		14	0.14	<0.02	<0.01	0.18
		21	0.16	0.03	<0.01	0.15
10-2171 (10-2171-03) Germany	fruit	0*	0.03	<0.02	<0.01	0.06
		0	0.15	<0.02	<0.01	0.18
		5	0.10	<0.02	<0.01	0.13
		10	0.08	<0.02	<0.01	0.11
GLP: yes		14	0.07	<0.02	<0.01	0.10
		21	0.05	<0.02	<0.01	0.08
10-2171 (10-2171-04) northern France	fruit	0*	0.02	<0.02	<0.01	0.05
		0	0.10	<0.02	<0.01	0.13
		5	0.06	<0.02	<0.01	0.10
		10	0.06	<0.02	<0.01	0.09
GLP: yes		14	0.06	<0.02	<0.01	0.09
		21	0.07	<0.02	<0.01	0.08
10-2171 (10-2171-05) Netherlands	fruit	0*	0.05	<0.02	<0.01	0.08
		0	0.20	<0.02	<0.01	0.23
		5	0.12	<0.02	<0.01	0.15
		10	0.12	<0.02	<0.01	0.20
GLP: yes		14	0.12	<0.02	<0.01	0.15
		21	0.14	0.03	<0.01	0.17
10-2171 (10-2171-06) Belgium	fruit	0*	0.03	<0.02	<0.01	0.06
		0	0.13	<0.02	<0.01	0.16
		5	0.14	<0.02	<0.01	0.17
		11	0.14	<0.02	<0.01	0.17
GLP: yes		14	0.09	<0.02	<0.01	0.12
		21	0.05	<0.02	<0.01	0.08

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-3b (cont'd): Results of residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*northern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960 DFE	total residue of BYI 02960 ca
GLP:						
11-2077 (11-2077-01) Germany	fruit	0 15 22 29 36	0.16 0.043 0.043 0.044 0.051	0.044 0.055 0.063 0.063 0.069	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.2 0.14 0.12 0.12 0.13
11-2077 (11-2077-02) France	fruit	0 14 21 28 35	0.11 0.064 0.063 0.062 0.057	< 0.02 < 0.02 < 0.02 0.02 0.02	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.14 0.094 0.09 0.092 0.089
11-2077 (11-2077-03) Germany	fruit	0 14 21 28 35	0.5 0.1 0.25 0.32 0.24	< 0.02 0.03 0.08 0.09 0.045	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.57 0.35 0.28 0.37 0.30
11-2077 (11-2077-04) United Kingdom	fruit	0 14 21 28 35	0.7 0.11 0.12 0.1 0.09	< 0.02 < 0.01 0.021 0.027 0.020	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.20 0.14 0.15 0.14 0.099
GLP: yes						

DALT = days after last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.3-4: Recovery data for BYI 02960 in apple

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean	RSD	
10-2072/ 10-2171 (10-2171-01), to (10-2171-06) GLP: yes 2010	apple	fruit	BYI 02960	9	0.01	89; 90; 94; 94; 96; 99; 99; 100; 107	89	107	95	5.8	
				5	0.10	88; 90; 94; 94; 99	88	99	93	4.4	
				6	1.0	76; 88; 90; 92; 94; 101	76	101	90	9.2	
				20	overall		76	107	92	7.1	
				DFA	3	0.05	87; 88; 88; 92; 96; 100	87	100	92	5.5
					3	0.05	83; 90; 93	83	93	89	5.0
					4	0.5	92; 92; 92	92	92	92	0.0
					4	1.50	93; 91; 93; 96	90	96	93	2.9
					6	1.0	73; 87; 83; 88; 91; 93	73	97	85	8.6
					10	overall		73	100	90	6.6
BYI 02960 DFEAF	9	0.01	75; 81; 85; 86; 87; 88; 89; 91; 95	75	95	86	6.7				
	5	0.10	89; 92; 94; 96; 97	69	97	90	13.0				
	6	1.0	70; 83; 90; 94; 95; 100	70	100	89	12.3				
	20	Overall		69	100	88	9.9				
	BYI 02960 DFEAF	3	0.010	95; 98; 109	95	109	101	7.3			
		1	0.10	88; 93; 96	88	96	92	4.4			
11-2078/ 11-2077 (11-2077-01), to (11-2077-04) GLP: yes 2011	apple	fruit	BYI 02960	2	0.01	89; 97; 103	89	103	96	7.3	
				5	0.10	89; 93; 99	80	97	90	9.9	
				1	1.0	93	93	93			
				7	overall		80	103	93	7.8	
				DFA	3	0.020	89; 95; 97	90	97	94	3.8
					3	0.20	89; 92; 99	89	99	93	5.5
					1	1.0	87	87	87		
7	overall		87		99	93	4.8				
BYI 02960 DFEAF	3	0.010	95; 98; 109	95	109	101	7.3				
	1	0.10	88; 93; 96	88	96	92	4.4				
	1	1.0	100	100	100						
	7	overall		88	109	97	6.7				

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Southern European residue region

Report:	KIIA 6.3.1.3/03, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on apple after spraying of BYI 02960 SL 200 in the field in France (south), Italy and Spain
Report No. & Document No.:	10-2172, dated July 5, 2012 M-434603-01-1

Report:	KIIA 6.3.1.3/04, [REDACTED]; [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on apple after spray application of BYI 02960 SL 200 in the field in southern France, Spain, Italy and Portugal
Report No. & Document No.:	11-2078, dated October 16, 2012 M-439845-01-1

Guidelines (applies to both studies):	Directive 2002/32/EC, residues in or on treated products, food and feed EU Guidance working document 7029/01/95 rev 5 US EPA OCSPP Guideline No 860.1000.SLUP
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Ten field residue trials were conducted in southern Europe, as follows:

In 2010, 6 trials (southern France, Italy [2], and Spain [2]) were conducted to support the use of BYI 02960 SL 200 in apple [REDACTED] & [REDACTED], 2012, KIIA 6.3.1.3/03). Two applications were made at intervals of 14 days at a nominal rate of 0.25-0.375 g/(ha×m), corresponding to 50-75 g/(ha×m) BYI 02960 a.s.; the water rate was 500-527 L/(ha×m), reflecting local practice in the trial regions.

(In two trials each, the application rate was 50, 60, or 75 g/[ha×m CH]. The worst-case intended GAP – for the "home and garden" use – now specifies 67.5 g/[ha×m CH], with a GAP of 60 g/[ha×m CH] for the agricultural use.

Within the scope of the home and garden use, the trials from the 2010 program conducted at 60 and 75 g/[ha×m CH] can be considered representative, as the difference in rates is 25% or less, and thus within the EU's acceptance criteria for use pattern comparability. As for the trials at 50 g/[ha×m CH], although they differ from the envisaged GAP by 26%, they were nevertheless evaluated below for their validity.

All treatments were made at the scheduled rates, except in one trial (Spanish trial 10-2172-05, 1st appl. underdosed by 10% and appl. by 15%), but this deviation was well within the EU's standard acceptance criteria.

Four further trials were carried out in 2011, in France, Spain, Italy, and Portugal, to complete the data package ([REDACTED], [REDACTED] & [REDACTED], 2012, KIIA 6.3.1.3/04). In 2011, only one application was made,



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

at a nominal rate of 0.34 L/(ha×m), corresponding to 68 g/(ha×m) BYI 02960 a.s; water rates ranged from 400-450 L/(ha×m). All treatments were made at the scheduled rates.

In 2010, samples of apple fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 21 days [20 days in one trial]); in 2011, samples were taken immediately subsequent to the application, and at several intervals thereafter (up to 35 days [34 days in one trial]). The envisaged PHI was 14 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (for method details, cf. KIIA 4.3/03). The respective LOQs for the 3 analytes were 0.01 mg/kg, 0.02 mg/kg, and 0.01 mg/kg (all in parent equivalents).

II. Findings

During the conduct of the complete set of apple studies in 2010-2011, validation and concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of apple fruit. This sample material is representative of all sample materials collected in these trials. Validation recoveries for apple fruit were conducted within study 10-2172 (cf. KIIA 6.3.1.3/03), additional recoveries were conducted concurrently to the analysis of all samples (concurrent recoveries). Concurrent recoveries for studies 10-2171 and 10-2172, as well as concurrent recoveries for studies 11-2077 and 11-2078 were done in parallel. The same recoveries are reported for the respective studies.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg, 0.10 mg/kg and 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (86-101%, RSDs of the larger validation sets [n > 2] 4-13.0%, n=9).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.20 mg/kg, as well as 0.50 mg/kg and 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (85-94%, RSDs of the larger validation sets [n > 2] 2.9-8.6%, n=1-6).

Details of recovery data are shown in table 6.3.1.3-6. All trial data are summarised below in table 6.3.1.3-5 & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalent.)

Relevant residues of BYI 02960 were determined in apple fruit samples taken 14 days subsequent to the first application (immediately prior to the 2nd treatment) in 2010 and 14 days – and at various other intervals – after the single application in 2011.

In the 2010 trials, residue levels declined somewhat between the day of the final application, on which they ranged from 0.11-0.24 mg/kg, and the nominal PHI (day 14), on which they were between 0.05-0.11 mg/kg; the median values were 0.16 and 0.09 mg/kg, respectively. However, these values reflect

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

two applications. To evaluate the intended one-application GAP, residues in samples taken immediately before the second treatment in 2010 (corresponding to 14 days after the first treatment) were found ranging from 0.04-0.12 (median 0.06 mg/kg); these were quite similar to those from samples taken 14 days after the single treatment in 2011 (0.051-0.11 mg/kg, median 0.09 mg/kg).

In the 2011 trials, on day 0 immediately following the application, residue levels in apple fruit were between 0.19 and 0.25 mg/kg (median 0.19 mg/kg). By day 10 (8-10 days), the levels were 0.06 mg/kg-0.12 mg/kg, with a median value of 0.09 mg/kg. On day 14 – the envisaged PHI – the levels were 0.051-0.11 mg/kg, again with a median value of 0.09 mg/kg. These results show a fairly constant residue level by 10 days after the application; they appear to have reached a "plateau" level. Median values of 0.08, 0.07, and 0.08 mg/kg at the 14-day, 28-day, and 56-day sampling intervals, respectively, further support that the residues had reached a plateau.

As residue levels have reached a plateau by day 14, residue values measured in day-14 samples taken "normally" in the 2011 trials can be evaluated together with those taken between applications in the 2010 study, i.e. 14 days subsequent to the first application. Residue values from the entire set of trials in samples taken 14 days after one application ranged from 0.04-0.12 mg/kg, with a median of 0.07 mg/kg.

In some of the trials, the highest relevant measured residue was seen at later sampling intervals that at the nominal PHI, even if the level remained very similar. When considering the peak residues at any sampling interval ≥ 14 days post 1-application over the complete set of trials, levels ranged from 0.04-0.12 mg/kg (median 0.07 mg/kg).

Evaluation of representativity:

In all trials, residues showed "normal" decline behaviour directly after the application, but seemed to reach a plateau level within the following days. This behaviour was independent of the number of applications (1 or 2).

In 2010, peak residues were determined on day 56 (the final day of sampling), in 3 of the 6 trials. However, closer examination reveals that the residue levels had reached a "plateau", starting on approx. day 10, in all trials. While the values themselves reflect a 2-application scheme, they are nevertheless of importance in understanding the general behaviour of BYI 02960 in apples.

Trials conducted in 2011 all showed plateau behaviour around day 14. Only in trial 11-2078-01 was an increase in residues evident, from 0.051 mg/kg at day 14 to 0.058 mg/kg at day 35. Additionally, in trial 11-2078-02, residues increased from 0.082 mg/kg at day 14 to 0.083 mg/kg at day 21. These minor increases may be due to sampling aspects and, additionally, biological and/or analytical variability. Thus, taken in the context of all of the trials, these trials can also be seen as yielding representative results.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

And, as it is evident that residues had reached a plateau level by approx. day 10 in general, values measured after a single application in 2010 can be evaluated together with those in the 2011 program, as a complete set of trial data.

In 2010, applications in two of the trials were at a rate of 50 g/(ha×m). This is 2% less than the rate to be registered for home & garden use, 68 g/(ha×m), and thus is nominally outside of the EU's criteria for comparability (±25%). The residue values from these two trials 14 days after the first application were each 0.06 mg/kg. Taking all 2010 and 2011 trials into account, residues at that sampling interval ranged from 0.04-0.12 mg/kg, with a median of 0.07 mg/kg; if the two trials in question are excluded, the values still range from 0.04-0.12 mg/kg, still with a median of 0.07 mg/kg. The results are firmly within this framework, not representing an extreme value in any way. Thus, those two trials can be included in the evaluation of this use.

III. Conclusions (apple, southern European residue region)

In order to support the use in the EU of BYI 02960 in apple, 10 valid trials were conducted in southern Europe in the years 2010-2011. BYI 02960 was applied as an GL 200 formulation twice in 2010 trials and once in 2011, at an active substance rate of 50-75 g/(ha×m) per treatment in 2010 and 68 g/(ha×m) per treatment in 2011. In 2010, the application interval was 14 days. All applications were at the required rates except for minor deviation in a single trial, which were less than 25% and, therefore, well within the EU's standard acceptance criteria. All trials were conducted according to GLP.

Samples were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DGA and DFEA. The residues of all three analytes were summed to yield a calculated "total residue" of BYI 02960. The results of the trials presented above demonstrate that:

- in the 2010 trials, total residue levels declined from the day of the final application, on which they ranged from 0.11-0.24 mg/kg, to the nominal PHI (day 14), on which they were 0.04-0.12 mg/kg. The respective median values were 0.16 and 0.06 mg/kg. At sampling intervals 10 and 21 days after the final application, median values of 0.10 and 0.09 mg/kg were determined.
- residues in samples taken immediately before the second treatment in 2010 (corresponding to 14 days after the first treatment) were found at similar levels (0.04-0.12; median 0.06 mg/kg) to those from samples taken 14 days after the single treatment in 2011 (0.05-0.11 mg/kg, median 0.09 mg/kg).
- in 2011, total residues of BYI 02960 declined somewhat in apple fruit sampled after the single application and at the nominal PHI, from levels of 0.19-0.25 mg/kg on day 0 after the final treatment to 0.051-0.11 mg/kg on day 14. The respective median values were 0.19 mg/kg and 0.09 mg/kg. At subsequent sampling intervals (days 21, 28, and 35), median values of 0.08, 0.07, and 0.06 mg/kg were determined.
- analytical results revealed that total residue levels often had reached a plateau by the nominal PHI.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

- as the residue levels reached a plateau after approx. 10 days, 2010 residue results from sampling intervals after the first application (but prior to the second one) can also be taken to support a 1-application use pattern on apple trees with 14-day PHI.
- peak residue levels at any relevant sampling interval (≥ 14 days post 1-application) ranged from 0.04-0.12 mg/kg (median 0.07 mg/kg).
- the trials reported here are considered to yield representative results suitable for MRL evaluation since residue levels at least reached a plateau by the envisaged PHI of 14 days. Slight variations in the data are acceptable and may be explained by normal variability caused by sampling aspects or biological and/or analytical variability.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-5a: Application scenario in residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2172 (10-2172-01) southern France [REDACTED] EU-S 2010	apple Gala	200 SL	2	0.25 (0.050 kg/[ha×m])	0.0100	85	14
10-2172 (10-2172-02) southern France [REDACTED] EU-S 2010	apple Canada	200 SL	2	0.12 (0.060 kg/[ha×m])	0.012	85	14
10-2172 (10-2172-03) Italy [REDACTED] EU-S 2010	apple Fuji	200 SL	2	0.14 (0.075 kg/[ha×m])	0.013	85	14
10-2172 (10-2172-04) Italy [REDACTED] EU-S 2010	apple Jonathan	200 SL	2	0.14 (0.050 kg/[ha×m])	0.010	76	14
10-2172 (10-2172-05) Spain [REDACTED] EU-S 2010	apple Golden	200 SL	2	0.162 (1st appl.), 0.15 (2nd appl.) (0.054 kg/(ha×m), 0.051 kg/(ha×m) (1st Appl.), (2nd Appl.)	0.0103	81	14
10-2172 (10-2172-06) Spain [REDACTED] EU-S 2010	apple Galaxia	200 SL	2	0.188 (0.075 kg/[ha×m])	0.0150	81	14

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.3-5a (cont'd.): Application scenario in residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2078 (11-2078-01) southern France [redacted] EU-S 2010	apple Granny smith; Cultivar	200 SL	1	0.204 (0.068 kg/[ha×m ²])	0.0170	85	14
11-2078 (11-2078-02) Spain [redacted] EU-S 2010	apple Golden Smoothy; yellow var. fresh consumption	200 SL	1	0.204 (0.068 kg/[ha×m ²])	0.0151	81	14
11-2078 (11-2078-03) Italy [redacted] EU-S 2010	apple gala variety precoce	200 SL	1	0.170 (0.068 kg/[ha×m ²])	0.0051	78	14
11-2078 (11-2078-04) Portugal [redacted] EU-S 2010	apple Fuji Red apple	200 SL	1	0.204 (0.068 kg/[ha×m ²])	0.0170	77	14

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-5b: Results of residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFEA	total residue of BYI 02960 cal
10-2172 (10-2172-01) southern France GLP: yes	fruit	0*	0.03	<0.02	<0.01	0.06
		0	0.12	<0.02	<0.01	0.11
		5	0.06	<0.02	<0.01	0.06
		10	0.04	<0.02	<0.01	0.07
		14	0.06	<0.02	<0.01	0.09
		21	0.04	0.03	<0.01	0.08
10-2172 (10-2172-02) southern France GLP: yes	fruit	0*	0.01	<0.02	<0.01	0.01
		0	0.13	<0.02	<0.01	0.16
		5	0.08	<0.02	<0.01	0.11
		9	0.07	<0.02	<0.01	0.10
		14	0.07	<0.02	<0.01	0.10
		21	0.03	0.03	<0.01	0.08
10-2172 (10-2172-03) Italy GLP: yes	fruit	0*	0.03	<0.02	<0.01	0.05
		0	0.09	<0.02	<0.01	0.12
		5	0.08	<0.02	<0.01	0.11
		10	0.04	<0.02	<0.01	0.07
		14	0.04	<0.02	<0.01	0.07
		21	0.04	0.03	<0.01	0.08
10-2172 (10-2172-04) Italy GLP: yes	fruit	0*	0.03	<0.02	<0.01	0.06
		0	0.08	<0.02	<0.01	0.11
		5	0.07	<0.02	<0.01	0.10
		10	0.07	<0.02	<0.01	0.10
		14	0.04	0.03	<0.01	0.07
		21	0.05	0.04	<0.01	0.10
10-2172 (10-2172-05) Spain GLP: yes	fruit	0*	0.09	<0.02	<0.01	0.12
		0	0.12	<0.02	<0.01	0.24
		4	0.14	<0.02	<0.01	0.17
		11	0.14	0.03	<0.01	0.18
		14	0.16	0.03	<0.01	0.13
		20	0.11	0.05	<0.01	0.17
10-2172 (10-2172-06) Spain GLP: yes	fruit	0*	<0.01/0.06**	<0.02	<0.01	<0.04/0.09**
		0	0.16	<0.02	<0.01	0.19
		7	0.16	<0.02	<0.01	0.13
		14	0.10	0.03	<0.01	0.15
		14	0.10	0.03	<0.01	0.15
		20	0.08	0.03	<0.01	0.13

DALT = days after last treatment

* prior to last treatment

** residues were <LOQ in the "treated" sample but 0.06 mg/kg in the "control". This may be due to a sample mix-up. Thus, 0.09 mg/kg will be considered to be correct for the "treated" sample in further evaluation in this chapter.

Continued on next page...

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.3-5b (cont'd): Results of residue trials conducted in/on **apple** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFEAF	total residue of BYI 02960 cal
BYI 02960 SL 200						
11-2078 (11-2078-01) southern France GLP: yes	fruit	0	0.16	<0.02	<0.01	0.19
		10	0.031	<0.02	<0.01	0.06
		14	0.021	<0.02	<0.01	0.051
		21	0.020	<0.02	<0.01	0.050
		28	0.020	<0.02	<0.01	0.050
		35	0.022	0.025	<0.01	0.03
11-2078 (11-2078-02) Spain GLP: yes	fruit	0	0.16	0.023/0.023**	<0.01	0.19/0.04**
		8	0.079	0.031/0.03**	<0.01	0.12/0.03**
		14	0.066	0.036/0.021**	<0.01	0.11/0.041**
		21	0.047	0.043	<0.01	0.1
		27	0.038	0.06	<0.01	0.05
		34	0.04	0.07	<0.01	0.11
11-2078 (11-2078-03) Italy GLP: yes	fruit	0	0.02	<0.02	<0.01	0.19
		10	0.058	<0.02	<0.01	0.088
		14	0.058	0.02	<0.01	0.088
		21	0.035	0.025	<0.01	0.070
		28	0.025	0.024	<0.01	0.060
		35	0.031	0.036	<0.01	0.078
11-2078 (11-2078-04) Portugal GLP: yes	fruit	0	0.22	<0.02	<0.01	0.25
		10	0.06	<0.02	<0.01	0.094
		14	0.05	<0.02	<0.01	0.082
		21	0.053	0.02	<0.01	0.083
		28	0.037	0.02	<0.01	0.069
		35	0.039	0.038	<0.01	0.078

DALT = days after last treatment
 * prior to last treatment
 ** residues in control

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.3-6: Recovery data for BYI 02960 in apple

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean RSD	
10-2171/ 10-2172 (10-2172-01), to (10-2172-06) GLP: yes 2010	apple	fruit	BYI 02960	9	0.01	89; 90; 94; 94; 96; 99; 99; 100; 107	89	107	96	7.8
				5	0.10	88; 90; 94; 96; 99	88	99	92	4.3
				6	1.0	76; 88; 90; 92; 94; 101	76	101	90	9.2
				20	overall		76	101	84	7.7
				6	0.02	87; 88; 89; 92; 98; 100	87	100	92	5.5
				3	0.05	83; 90; 93	83	93	88	5.8
				1	0.20	92	92	92		
				6	1.0	90; 91; 95; 96; 73; 82; 83; 88; 91; 99	90	96	93	2.9
				20	overall		73	100	90	6.6
				9	0.01	75; 81; 85; 86; 87; 88; 89; 91; 95	75	95	86	6.7
11-2077/ 11-2078 (11-2078-01), to (11-2078-04) GLP: yes 2011	apple	fruit	BYI 02960	3	0.01	65; 92; 94; 96; 97	69	97	90	13.0
				6	1.0	70; 83; 90; 94; 96; 100	70	100	89	12.3
				20	overall		69	100	88	9.9
				3	0.01	103; 99; 97	89	103	96	7.3
				1	0.10	93; 80; 97	80	97	90	9.9
				7	overall		80	103	93	7.8
				3	0.01	97; 95; 90	90	97	94	3.8
				3	0.20	82; 99; 89	89	99	93	5.5
				1	1.0	87	87	87		
				7	overall		87	99	93	4.8
BYI 02960- DFEAF				3	0.01	98; 95; 109	95	109	101	7.3
				3	0.10	93; 88; 96	88	96	92	4.4
				1	1.0	100	100	100		
				7	overall		88	109	97	6.7

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IIA 6.3.1.4 Berries and small fruit - grapes

BYI 02960 is to be registered in Europe for use in grape. European residue data in grape are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.4-1.

Table 6.3.1.4-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulation in/on grape in European fields

Description	F/G	No. of appls.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"home & garden"*	F†	2	100	200	na	na	14
agricultural**	F†	1	100	100	100-1000	na	14

* "home & garden" uses with an SL 50 formulation (available to the general public via retail sale)

** agricultural use based on an SL 200 formulation

† uses in northern and southern residue region

na = not applicable

In order to support the use of BYI 02960, sets of GLP trials were conducted in northern and southern European fields in 2010 and 2011. In the northern and southern European residue regions, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200 containing 200 g/L BYI 02960 a.s.), at 14-day intervals. The envisaged PHI was 14 days, reflecting the intended worst-case GAP.

Residue levels of BYI 02960 and its metabolites DEFA and DEFAI were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the northern residue region, in which a highest total residue value (HR) of 0.50 mg/kg was determined. The STMR in these trials was also the higher of the two sets, at 0.26 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.4-2.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.4-2: Overview of European residue trials conducted in grape per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.4-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.4-2
		Veget. period 2010	2011	Σ	HR	STMR		
<i>trials in EUROPE</i>								
"home & garden"	EU-N	5	4	9	0.50	0.26	10-2218, 11-2089	01, 02
	EU-S	4	4	8	0.35	0.18	10-2219, 11-2090	03, 04

EU-N = northern EU residue region, EU-S = southern EU residue region

Northern Europe residue region

Report:	KIIA 6.3.1.4/01, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on grape after spraying and spraying low-volume of BYI 02960 SL 200 in the field in Germany, France (North) and Belgium
Report No. & Document No.:	10-2218, dated August 22, 2012 M-437138-01-1
Report:	KIIA 6.3.1.4/02, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on grape after high or low-volume spray application of BYI 02960 SL 200 in Germany and northern France
Report No. & Document No.:	11-2089, dated August 17, 2012 M-436857-01-1
Guidelines (applies to both studies):	Directive 91/414/EEC, residue in or on treated products, food and feed EC guidance working document 7029/VI/95 rev.5 US EPA OPSP guideline No. 800.1500.SUPP
GLP (applies to both studies):	Yes (certified laboratory), Deviations: none

Materials and Methods

Nine field residue trials were conducted in the northern European residue region, as follows:

In 2010, 5 trials (Germany [2], northern France [2] and Belgium) were conducted to support the use of BYI 02960 SL 200 in grape ([REDACTED] and [REDACTED], 2012, KIIA 6.3.1.4/01). Two applications were made at intervals of 14 days (12 days in one trial) at a nominal rate of 0.50 L/ha, corresponding to 100 g/ha BYI 02960 a.s. the water rate was 200-949 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates, except for the first application in one trial (10-2218-05, overdosed by 5%), this deviation was within the EU's standard acceptance criteria.

For further trials were carried out in 2011, in Germany (2) and northern France (2), to complete the data package ([REDACTED], 2012, KIIA 6.3.1.4/02). The basic application parameters were similar as in 2010; the water rate was 200-800 L/ha. All treatments were made at the scheduled rates.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Samples of bunches of grapes were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 21-28 days after treatment in 2010 and up to 42 days in 2011 trials); samples of the grapes themselves (destemmed berries) were also taken at day 14 in 2010 and on days 21 and 28 in 2011. The envisaged PHI was 14 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01212 (cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of bunches of grape was done with method 01212 (cf. KIIA 4.3/05). Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of "bunch of grape" and "berry". These sample materials are representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF in bunches were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.80 mg/kg (expressed in BYI 02960 equivalents) in study 10-218 and at levels of 0.01 mg/kg, 0.10 mg/kg, and 2.0 mg/kg (expressed in BYI 02960 equivalents) in study 11-2089. The recovery samples for parent and DFEAF in "berry" were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.50 mg/kg (expressed in BYI 02960 equivalents) in both studies. Overall mean recoveries were all within acceptable ranges (87-103%, overall RSDs 0.8-12.2%, n=3-6).

Fortification levels in for DFA were 0.02 mg/kg, 0.20 mg/kg, and 1.6 mg/kg (study 10-2218) or 4.0 mg/kg (study 11-2089) (expressed in BYI 02960 equivalents) for the sample material "bunch", and 0.02 mg/kg, 0.20 mg/kg, and 2.0 mg/kg (expressed in BYI 02960 equivalents) for "berry". Overall mean recoveries were all within acceptable ranges (81-97%, overall RSDs 5.1-16.5%, n=3-6).

Details of recovery data are shown in table 6.3.1.4-4. All trial data are summarised below in table 6.3.1.4-3a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in grape bunches were between 0.22 and 0.53 mg/kg (median 0.36 mg/kg). By day 14 — the envisaged PHI — the levels had declined to 0.03-0.44 mg/kg with a median value of 0.24 mg/kg. The analysis of samples of the destemmed fruit ("berry") taken at day 14 showed that there are no obvious differences in residues between bunches and in the grapes themselves. The residue levels in berries ranged from 0.11-0.52 mg/kg (median 0.26 mg/kg; n=5) on day 14, with values of 0.13-0.44 mg/kg in the corresponding bunch samples (median 0.22 mg/kg). The same behavior was evident in bunches and in destemmed berries taken on day 21, with residues of 0.17-0.50 mg/kg (median 0.26 mg/kg) and 0.16-0.40 mg/kg (median 0.25 mg/kg), respectively; and on day 28, with residues of 0.21-0.34 mg/kg (median 0.26 mg/kg) and 0.18-0.44 mg/kg (median 0.28 mg/kg), respectively (n=4 in both cases).



The analytical results revealed that total residues often had not yet reached their highest levels at the nominal PHI (14 days). This was already evident in the 2010 trials, in which peak residue values were seen on day 21 (1 trial) or day 28 (2 trials), the final day of sampling. In order to capture the maximum relevant residue levels, additional sampling was conducted 35 and 42 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 14 (1 trial), day 21 (2 trials), or day 42 (1 trial).

Peak residue levels at any relevant sampling interval (≥ 14 days post-application) over the complete set of trials ranged from 0.18-0.50 mg/kg (median 0.26 mg/kg).

Evaluation of representativity:

As highest residue levels were seen on the final sampling interval of four trials (10-2218-01, day 21; 10-2218-02 and -03, day 28; and 11-2089-01, day 42), the entire set of trials was re-evaluated for its representativity.

In the 2010 package, trials 10-2218-03 to -05 essentially showed "plateau behaviour", with residues remaining fairly constant from the PHI to the final sampling date (day 14 to day 28). In trial 10-2218-01, there was an apparent "jump" in the residues on the final day, with the day 21 value of 0.49 mg/kg nevertheless being only approx. 10% more than that at the PHI. Trial 10-2218-01 showed a constant increase in residue levels from day 7 on, but again only about 10% between the final two intervals, reaching 0.45 mg/kg on day 28.

In 2011, "plateau" behaviour was again evident, essentially in all of the trials. Only in trial 11-2089-01 were the peak residues found at the final sampling interval, 0.38 mg/kg on day 42. However, again, this value is only about 15% more than that at day 14, and the course of the residues over time was quite variable, with small rises and falls between sampling dates. These changes are generally quite small, and may in part be attributable to sampling, biological, and/or analytical variability. Thus, taken in the context of all of the trials, this trial can also be seen as yielding representative results.

Trials 10-2189-01 and -02 (cf. above) can also be viewed in a larger context. Although the peak values in these two trials are among the highest values in the set presented here, there is reason to believe that they would not continue to increase appreciably, as most trials showed "plateau" behaviour with peak residues measured at non-terminal sampling events (day 14, 1 trial; day 21, 3 trials; day 35, 1 trial). Due to additional statistical factors applied in MRL-setting, even slightly higher residue values would not likely have any effect on the MRL proposals.

Thus the trials are considered to be sufficient to evaluate the use described.

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III. Conclusions (grape, northern European residue region)

In order to support the use in the EU of BYI 02960 in grape, 9 trials were conducted in the northern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 100 g/ha. The application intervals were approx. 14 days. All applications were at the required rates, except for minor deviations in a single trial, which were less than 25% and, therefore, well within the EUs standard acceptance criteria. All trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter including the envisaged PHI of 14 days. They were analyzed for the relevant residues of BYI 02960 comprising the parent compound and its metabolites DPA and DFPAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 declined in bunch of grape between the final application and the nominal PHI, from levels of 0.29-0.53 mg/kg on day 0 after the final treatment to 0.13-0.44 mg/kg on day 14. The respective median values were 0.26 mg/kg and 0.24 mg/kg, respectively.
- analytical results revealed that total residue levels generally had not yet reached their peak levels at the nominal PHI, but that plateau behaviour was evident.
- peak residue levels at any relevant sampling intervals (≥ 14 days post-application) ranged from 0.18-0.50 mg/kg (median 0.26 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.
- there was no evident difference between residues in bunches and in the grapes themselves (destemmed berries).

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.4-3a: Application scenario in residue trials conducted in/on **grape after spraying with BYI 02960 SL 200 (northern European residue region)**

Study No. Plot No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (days)
				kg/ha (a.s.)	kg/h (a.s.)		
10-2218 10-2218-01 Germany [redacted] EU-N 2010	grape Müller Thurgau; white variety	200 SL	2	0.100	0.0125	89	14
10-2218 10-2218-02 Germany [redacted] EU-N 2010	grape Spätbur- gunder; red variety	200 SL	2	0.100	0.0125	85	14
10-2218 10-2218-03 northern France [redacted] EU-N 2010	grape Gardon- nay; white variety	200 SL	2	0.100	0.0500	85	14
10-2218 10-2218-04 northern France [redacted] EU-N 2010	grape Cabernet Franc; red variety	200 SL	2	0.100	0.0500	85	14
10-2218 10-2218-05 Belgium [redacted] EU-N 2010	grape Regent; red variety	200 SL	2	0.100- 0.105*	0.0111	85	14

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-N = northern European residue region

* the first application was over-dosed by 5%.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.4-3a (cont'd.): Application scenario in residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200 (northern European residue region)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2089 11-2089-01 Germany [redacted] EU-N 2011	grape Müller Thurgau; white variety	200 SL	2	0.100	0.0125	85	14
11-2089 11-2089-02 Germany [redacted] EU-N 2011	grape Spätbur- gunder; red variety	200 SL	2	0.100	0.0125	85	14
11-2089 11-2089-03 northern France [redacted] EU-N 2011	grape Chardon- nay; white variety	200 SL	2	0.100	0.0500	83	14
11-2089 11-2089-04 northern France [redacted] EU-N 2011	grape Cabernet Franc; red variety	200 SL	2	0.100	0.0500	83	14

FL = formulation GS = growth stage (BBCH-code) at last treatment
EU-N = northern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.4-3b: Results of residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200
 (northern European residue region)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960 DFEA	total residue of BYI 02960 cal
GLP						
10-2218 (10-2218-01-T) Germany	bunch of grapes	0*	0.18	<0.02	<0.01	0.21
		0	0.36	<0.02	<0.01	0.33
		7	0.43	0.02	<0.01	0.43
		14	0.38	0.05	<0.01	0.44
	21	0.42	0.06	<0.01	0.49	
GLP: yes	berry	14	0.46	0.05	<0.01	0.51
10-2218 (10-2218-02-T) Germany	bunch of grapes	0*	0.05	<0.02	<0.01	0.08
		0	0.33	<0.02	<0.01	0.36
		7	0.23	0.02	<0.01	0.26
		14	0.23	0.04	<0.01	0.28
	21	0.34	0.07	<0.01	0.41	
GLP: yes	28	0.38	0.07	<0.01	0.45	
	berry	14	0.30	0.04	<0.01	0.35
10-2218 (10-2218-03-T) France	bunch of grapes	0*	0.08	0.02	<0.01	0.12
		0	0.22	0.03	<0.01	0.27
		7	0.24	0.05	<0.01	0.20
		14	0.14	0.06	<0.01	0.22
	21	0.13	0.07	<0.01	0.21	
GLP: yes	28	0.15	0.11	<0.01	0.26	
	berry	14	0.20	0.07	<0.01	0.26
10-2218 (10-2218-04-T) France	bunch of grapes	0*	0.04	<0.02	<0.01	0.07
		0	0.19	<0.02	<0.01	0.22
		7	0.09	0.02	<0.01	0.13
		14	0.08	0.04	<0.01	0.13
	21	0.11	0.06	<0.01	0.18	
GLP: yes	28	0.06	0.06	<0.01	0.13	
	berry	14	0.06	0.04	<0.01	0.11
10-2218 (10-2218-05-T) Belgium	bunch of grapes	0*	0.09	<0.02	<0.01	0.12
		0	0.42	<0.02	<0.01	0.45
		7	0.20	<0.02	<0.01	0.23
		14	0.10	<0.02	<0.01	0.17
	21	0.09	0.03	<0.01	0.23	
GLP: yes	28	0.16	0.03	<0.01	0.20	
	berry	14	0.20	<0.02	<0.01	0.23

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.4-3b (cont'd): Results of residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200 (northern European residue region)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960 DFEA	total residue of BYI 02960 ca
GLP						
11-2089 (11-2089-01) Germany GLP: yes	bunch of grapes	0*	0.079	<0.02	<0.01	0.11
		0	0.33	<0.02	<0.01	0.33
		14	0.26	0.078	<0.01	0.33
		21	0.21	0.078	<0.01	0.29
		28	0.20	0.089	0.01	0.30
		35	0.21	0.12	<0.01	0.33
		42	0.22	0.15	<0.01	0.38
	berry	21	0.22	0.069	<0.01	0.30
		28	0.21	0.088	<0.01	0.31
11-2089 (11-2089-02) Germany GLP: yes	bunch of grapes	0*	0.23	<0.02	<0.01	0.23
		0	0.50	<0.02	<0.01	0.53
		14	0.36	0.047/0.031**	<0.01	0.42/0.41**
		21	0.22	0.075	<0.01	0.50
		28	0.25	0.081	<0.01	0.34
		35	0.29	0.075	<0.01	0.39
		42	0.35	0.12	<0.01	0.48
	berry	21	0.21	0.077	<0.01	0.40
		28	0.34	0.088	<0.01	0.44
11-2089 (11-2089-03) France GLP: yes	bunch of grapes	0*	0.09	<0.02	<0.01	0.12
		0	0.3	<0.02	<0.01	0.42
		14	0.24	0.038	<0.01	0.18
		21	0.18	0.045	<0.01	0.23
		28	0.14	0.05	<0.01	0.21
		35	0.14	0.064	<0.01	0.23
		42	0.5	0.075	<0.01	0.21
	berry	21	0.12	0.05	<0.01	0.19
		28	0.15	0.092	<0.01	0.25
11-2089 (11-2089-04) France GLP: yes	bunch of grapes	0*	0.070	<0.02	<0.01	0.10
		0	0.26	<0.02	<0.01	0.29
		14	0.21	0.07	<0.01	0.24
		21	0.13	0.055	<0.01	0.17
		28	0.13	0.038	<0.01	0.21
		35	0.93	0.054	<0.01	0.16
		42	0.092	0.052	<0.01	0.15
	berry	21	0.12	0.05	<0.01	0.16
		28	0.1	0.060	<0.01	0.18

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.4-4: Recovery data for BYI 02960 in grape

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
10-2218 (10-2218-01), to (10-2218-04) GLP: yes 2010	grape	bunch of grape	BYI 02960	3	0.01	102; 106; 116	102	116	108	4.7
				1	0.10	102	102	102		
				2	0.80	105; 107	105	107	106	
				6	overall		102	107	105	4.9
				3	0.02	65; 84; 91	65	101	83	21.6
				1	0.20	101	101	101		
	2	1.6	98; 105	98	105	102				
	6	overall		65	105	92	16.5			
	3	0.01	102; 103; 107	102	107	104	2.7			
	1	0.1	100	100	100					
	1	0.80	99; 100	99	100	100				
	6	overall		99	107	103	3.3			
grape	berry	BYI 02960	2	0.01	107; 108	107	108	108		
			1	0.10	107	107	107			
			1	0.50	109	109	109			
			4	overall		107	109	108	0.8	
			2	0.02	88; 86	78	86	82		
			1	0.20	97	97	97			
	1	1.6	97	97	97					
	4	overall		78	97	90	10.3			
	2	0.01	103; 107	103	107	105				
	1	0.1	106	106	106					
	1	0.50	101	101	101					
	4	overall		101	107	104	2.6			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.4-4 (cont'd): Recovery data for BYI 02960 in grape

Study No. Trial No.	Crop	Portion analysed	a.s./metabolite	n	Fortification level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean	RSD	
11-2089 (11-2089-01), to (11-2089-04) GLP: yes 2011	grape	bunch of grape	BYI 02960	2	0.01	98; 93	93	98	96	7.5	
				1	0.10	111	111	111			
				1	2.0	101	101	101			
				4	overall		93	101	101		
			DFA	2	0.02	70; 83	70	83	77		
				1	0.20	79	79	79			
		berry	BYI 02960	DFA	2	0.01	96; 107	96	110	104	7.5
					1	0.10	96	96	96		
				1	0.50	107	107	107			
				4	overall		95	110	103		
			DFA	1	0.02	83	83	83			
				1	0.20	82	82	82			
BYI 02960 DFA	DFA	1	0.01	75	75	75	5.1				
		1	0.10	94	94	94					
	1	0.50	93	93	93						
	3	overall		75	94	87					

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Southern Europe

Report:	KIIA 6.3.1.4/03, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on Grape after Spraying and Spraying, low-volume of BYI 02960 SL 200 in the Field in France (South), Spain and Italy
Report No. & Document No.:	10-2219, dated August 22, 2012 M-437131-01-1

Report:	KIIA 6.3.1.4/04, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on grape after high or low volume spray application of BYI 02960 SL 200 in the field in south of France, Spain and Italy
Report No. & Document No.:	11-2090, dated September 18, 2012 M-438482-01-1

Guidelines (<i>applies to both studies</i>):	Directive 91/414/EEC, Residues in or on treated products, food and feed EC guidance working document 7029/VI/95 rev.5 US EPA QCPPP Guideline No. 8601500 QPP GLP (certified laboratory); Deviations: none
GLP (<i>applies to both studies</i>):	yes (certified laboratory); Deviations: none

Materials and Methods

Eight field residue trials were conducted in the southern European residue region, as follows:

In 2010, 4 trials (France [2], Spain [2], and Italy) were conducted to support the use of BYI 02960 SL 200 in grape ([REDACTED] & [REDACTED], 2012, KIIA 6.3.1.4/03). Two applications were made at intervals of 14 days at a nominal rate of 0.50 L/ha, corresponding to 100 g/ha BYI 02960 a.s.; the water rate was 200-1000 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates, except in one trial (10-2219-04, applications undosed by 10.22%); this deviation was within the EU's standard acceptance criteria.

Four further trials were carried out in 2011, in southern France, Spain (2), and Italy, to complete the data package ([REDACTED], 2012, KIIA 6.3.1.4/04). The basic application parameters were similar as in 2010. All treatments were made at the scheduled rates.

Samples of bunches of grapes were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 27-28 days after treatment in 2010 and up to 42 days in 2011 trials), samples of the grapes themselves (deshinned berries) were also taken at day 14 in 2010, and on days 21 and 28 in 2011. The envisaged PHI was 14 days.

The samples were analysed for the parent compound and its metabolites DFA and DFEAF using method 01212 (cf. KIIA 4/05). The respective LOQs for the 3 analytes were 0.01 mg/kg, 0.02 mg/kg, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of bunches of grape was done within method 01212 (cf. KIIA 4.3/05). Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of bunches and of "berry". These sample materials are representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.1 mg/kg, as well as, 1.0 mg/kg (study 10-2219) or 2.0 mg/kg (study 11-2090) (expressed in BYI 02960 equivalents). Overall mean recoveries were all within acceptable ranges (92-104% overall RSDs 1.5-7.7%, n=3-5).

Fortification levels for DFA were 0.01 mg/kg, 0.20 mg/kg, and 2.0 mg/kg (study 10-2219) or 4.0 mg/kg (study 11-2090) (expressed in BYI 02960 equivalents) for the sample materials "berry" and "bunch of grapes". Overall mean recoveries were all within acceptable ranges (88-95%, overall RSDs 2.2-17.1%, n=3-5).

Details of recovery data are shown in table 6.3.1.4-6. All trial data are summarised below in table 6.3.1.4-5a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents). From these individual values, the total residue of BYI 02960 was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in grape bunches were between 0.18 and 0.50 mg/kg (median 0.31 mg/kg). By day 14 — the envisaged PHI — the levels had declined to 0.08-0.26 mg/kg, with a median value of 0.14 mg/kg.

The analysis of samples of the stemmed fruit "berry" taken at day 14 showed that there are no differences in residues between bunches and of the grapes themselves. The residue levels in berries ranged from 0.08-0.20 mg/kg (median 0.16 mg/kg, n=4) on day 14, with values of 0.08-0.23 mg/kg in the corresponding bunch samples (median 0.16 mg/kg). The same behavior was evident in bunches and in berries taken at day 21 where residues were 0.11-0.27 mg/kg (median 0.16 mg/kg) and 0.11-0.28 mg/kg (median 0.17 mg/kg), respectively; and on day 28, with residues of 0.10-0.31 mg/kg and 0.12-0.32 mg/kg, respectively (median 0.28 mg/kg in both cases); n=4 in all cases.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (14 days). This was already evident in the 2010 trials, in which peak residue values were seen on day 21 (2 trials) or on day 28 (1 trial), the final day of sampling. In order to capture the maximum relevant residue levels, additional sampling was conducted 34-35 and 42 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 14 (1 trial), 21 (2 trials), or day 42 (1 trial).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Peak residue levels at any relevant sampling interval (≥ 14 days post-application) over the complete set of trials ranged from 0.08-0.33 mg/kg (median 0.18 mg/kg).

Evaluation of representativity:

As highest residue levels were seen on the final sampling interval of three trials (10-2219-01, and -02, day 21 and 28, respectively; and 11-2090-01, day 42), the entire set of trials was re-evaluated for its representativity.

In the 2010 package, the trials generally showed "plateau behaviour" with residues remaining fairly constant from the PHI to the final sampling date (day 14 to day 28).

Trials 10-2219-03 and -04 showed residues reaching a plateau level by day 14, with peak values on day 14 or 21. In trial 10-2219-02, residues showed "normal" decline behaviour early, followed by a slow increase in residues up to day 28. However, the increase in residues between day 21 and 28 was very small, only 0.01 mg/kg, indicating that a plateau level had been reached. The increase was also within the scope of variability caused by sampling, biological, and/or analytical aspects.

In trial 10-2219-01, residues showed normal decline behaviour at first, then reaching a plateau level by day 7 to day 14, followed by an apparent "jump" in the residues on the final day from 0.23 mg/kg on day 14 to 0.28 mg/kg on day 28.

In 2011, "normal" decline behaviour was evident in trials 11-2090-02 and -04, both reaching a plateau level by at least day 21. In trials 11-2090-01 and -03, residues remained fairly constant over the entire sampling period. In trial 11-2090-01, the highest residue of 0.33 mg/kg was found on day 42, i.e. the last day of sampling. However, this "increase" is very small, with the difference per sampling interval of just 0.01 mg/kg, and may be considered within context of variability due to sampling or analytical error. Thus, taken in the context of all of the trials, this trial can also be seen as yielding representative results.

Trial 10-2219-01 (see above) can also be viewed in the larger context. Even given the "jump" from 0.23 mg/kg on day 14 to 0.28 mg/kg on the final sampling day of this trial, there is reason to believe that residues would not continue to climb appreciably. In none of the trials did the residues climb higher over time than residues directly after the application. Thus, it can be assumed that even if values in this trial were to increase, they would still be in the same range as the highest residue seen in the rest of the trials (0.33 mg/kg), and would therefore have no effect on the critical data used to evaluate and establish MRLs.

Thus the trials are considered to be valid and representative of the use described.

2. Conclusions (grape, southern European residue region)

In order to support the use in the EU of BYI 02960 in grape, 8 valid trials were conducted in the southern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 100 g/ha. The application intervals were 14 days. All

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

applications were at the required rates, except for minor deviations in a single trial, which were less than 25% and, therefore, well within the EUs standard acceptance criteria. All trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 14 days. They were analyzed for the relevant residues of BYI 02960 comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 declined in bunches of grapes between the final application and the nominal PHI, from levels of 0.18-0.50 mg/kg on day 0 after the final treatment to 0.08-0.26 mg/kg on day 14. The respective median values were 0.21 mg/kg and 0.14 mg/kg, respectively.
- analytical results revealed that total residue levels often had not yet reached their peak levels at the nominal PHI.
- peak residue levels at any relevant sampling interval (≥ 14 days post-application) ranged from 0.08-0.33 mg/kg (median 0.18 mg/kg).
- despite the delayed attainment of the peak residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.
- there was no evident difference between residues in bunches and in the grapes themselves (destemmed berries).

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.4-5a: Application scenario in residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200 (southern European residue region)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2219 10-2219-01 southern France [redacted] EU-S 2010	grape Chardon- nay; white variety	200 SL	2	0.100	0.0500	85	14
10-2219 10-2219-02 [redacted] EU-S 2010	grape Bobal; red variety	200 SL	2	0.100	0.0500	85	14
10-2219 10-2219-03 Italy [redacted] EU-S 2010	grape Trabiano white variety	200 SL	2	0.100	0.0100	81	14
10-2219 10-2219-04 Spain [redacted] EU-S 2010	grape Marlet; red variety	200 SL	2	0.0875- 0.0850	0.0110- 0.0112	81	14

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.4-5a (cont'd.): Application scenario in residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200 (southern European residue region)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2090 11-2090-01 southern France [redacted]	grape Ugni blanc; white variety	200 SL	2	0.10	0.050	83	14
EU-S 2011							
11-2090 11-2090-02 Spain [redacted]	grape Bobal; red variety	200 SL	2	0.10	0.010	81	14
EU-S 2011							
11-2090 11-2090-03 Spain [redacted]	grape Xarello; white variety	200 SL	2	0.10	0.010	79	14
EU-S 2011							
11-2090 11-2090-04 Italy [redacted]	grape Lambrusco; red variety	200 SL	2	0.10	0.010	81	14
EU-S 2011							

FL = formulation GS = growth stage (BBCH code) at last treatment
EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.4-5b: Results of residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200
 (southern European residue region)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFE	total residue of BYI 02960 ca
GLP						
10-2219 (10-2219-01) France GLP: yes	bunch of grapes	0*	0.09	<0.02	<0.01	0.10
		0	0.32	<0.02	<0.01	0.33
		7	0.19	0.03	<0.01	0.23
		14	0.17	0.05	<0.01	0.23
		21	0.22	0.05	<0.01	0.23
	berry	14	0.15	0.04	<0.01	0.20
10-2219 (10-2219-02) Spain GLP: yes	bunch of grapes	0*	0.07	<0.02	<0.01	0.10
		0	0.29	<0.02	<0.01	0.33
		7	0.11	0.03	<0.01	0.15
		14	0.06	0.05	<0.01	0.12
		21	0.12	0.06	<0.01	0.19
	28	0.14	0.08	<0.01	0.20	
berry	14	0.10	0.05	<0.01	0.16	
10-2219 (10-2219-03) Italy GLP: yes	bunch of grapes	0*	0.11	0.03	<0.01	0.14
		0	0.47	0.02	<0.01	0.50
		7	0.08	0.04	<0.01	0.14
		14	0.07	0.03	<0.01	0.12
		21	0.09	0.06	<0.01	0.16
	28	0.06	0.06	<0.01	0.13	
berry	14	0.11	0.04	<0.01	0.16	
10-2219 (10-2219-04) Spain GLP: yes	bunch of grapes	0*	0.03	<0.02	<0.01	0.06
		0	0.15	<0.02	<0.01	0.18
		6	0.06	0.02	<0.01	0.11
		14	0.05	<0.02	<0.01	0.08
		21	0.05	<0.02	<0.01	0.08
	28	0.04	0.02	<0.01	0.07	
berry	14	0.05	<0.02	<0.01	0.08	

DALT = days after last treatment

* prior to last treatment

Residues calculated and expressed as BYI 02960

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.4-5b (cont'd.): Results of residue trials conducted in/on **grape** after spraying with BYI 02960 SL 200 (southern European residue region)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960				
			BYI 02960	DFA	BYI 02960- DFE	total residue of BYI 02960 ca	
GLP							
BYI 02960 SL 200							
11-2090 (11-2090-01-T) France GLP: yes	bunch of grapes	0*	0.072	0.041	<0.01	0.11	
		0	0.24	0.056	<0.01	0.30	
		14	0.10	0.14	<0.01	0.26	
		21	0.081	0.17	<0.01	0.22	
		28	0.073	0.22	<0.01	0.31	
		35	0.055	0.26	<0.01	0.32	
	berry	21	0.086	0.18	<0.01	0.28	
		28	0.091	0.17	<0.01	0.27	
		11-2090 (11-2090-02-T) Spain GLP: yes					
		bunch of grapes	0*	0.047	0.02	<0.01	0.077
			0	0.17	0.024	<0.01	0.20
			14	0.052	0.020	<0.01	0.08
21	0.048		0.02	<0.01	0.11		
28	0.033		0.051	<0.01	0.10		
35	0.043		0.036	<0.01	0.089		
berry	21	0.050	0.047	<0.01	0.11		
	28	0.067	0.054	<0.01	0.12		
	11-2090 (11-2090-03-T) Spain GLP: yes						
	bunch of grapes	0*	0.25	0.023	<0.01	0.058	
		0	0.12	0.01	<0.01	0.18	
		14	0.064	0.055	<0.01	0.15	
21		0.065	0.11	<0.01	0.18		
28		0.076	0.090	<0.01	0.15		
34		0.050	0.09	<0.01	0.15		
berry	21	0.036	0.10	<0.01	0.14		
	28	0.038	0.079	<0.01	0.14		
	11-2090 (11-2090-04-T) Italy GLP: yes						
	bunch of grapes	0*	0.046	0.033	<0.01	0.076	
		0	0.39	0.25	<0.01	0.42	
		14	0.16	0.064	<0.01	0.17	
21		0.053	0.070	<0.01	0.13		
28		0.053	0.074	<0.01	0.13		
35		0.049	0.055	<0.01	0.15		
berry	21	0.056	0.092	<0.01	0.15		
	28	0.039	0.098	<0.01	0.19		
	28	0.071	0.077	<0.01	0.15		

DALT = days after last treatment

* prior to last treatment

Residues calculated and expressed as BYI 02960

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.4-6: Recovery data for BYI 02960 in grape

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean RSD		
10-2219 (10-2219-01), to (10-2219-04) GLP: yes 2010	grape	bunch of grapes	BYI 02960	2	0.01	110; 98	98	110	104	5.8	
				2	0.10	108; 97	97	108	103		
				1	1.0	95	95	95	95		
				5	overall		95	105	102		
				5	overall		95	105	102		
			DFA	2	0.02	97; 95	95	97	96		2.2
				2	0.20	92; 96	92	96	94		
				1	2.0	97	97	97	97		
				5	overall		92	97	95		
	BYI 02960- DFEAF	2	0.01	93; 91	91	93	92	6.0			
		2	0.10	104; 97	98	104	101				
		1	1.0	103	103	103	103				
		5	overall		91	104	98				
		5	overall		91	104	98				
grape	berry	BYI 02960	1	0.01	102	102	102	2.5			
			1	0.10	101	107	107				
			1	1.0	103	103	103				
			3	overall		100	107		104		
		DFA	1	0.02	83	83	83	10.8			
			1	0.20	102	102	102				
			1	2.0	99	99	99				
		3	overall		83	102	95				
		BYI 02960- DFEAF	1	0.01	102	102	102	3.5			
1	0.10		100	100	100						
1	1.0		107	107	107						
3	overall			100	107	103					

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.4-6 (cont'd.): Recovery data for BYI 02960 in grape

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean RSD	
11-2090 (11-2090-01), to (11-20-90-04) GLP: yes 2011	grape	bunch of grapes	BYI 02960	2	0.01	104; 95	95	104	100	
				2	0.10	89; 103	89	103	96	
				1	2.0	108	108	108		
				5	overall		89	108	97	
			DFA	2	0.02	62; 100	62	100	81	
				2	0.20	92; 96	92	96	94	
				1	4.0	89	89	89		
				5	overall		62	100	88	17.1
	BYI 02960- DFAEF	2	0.01	100; 107	100	107	103			
		2	0.10	97; 106	97	106	102			
		1	2.0	103	103	103				
		5	overall		97	107	102	4.1		
grape	berry	BYI 02960	1	0.01	104	104	104			
			1	0.10	104	104	104			
			1	2.0	103	103	103			
			3	overall		104	104	103	1.5	
		DFA	1	0.02	90	100	100			
			1	0.20	91	91	91			
			1	4.0	85	85	85			
			3	overall		85	100	92	8.2	
BYI 02960- DFAEF	1	0.01	97	97	97					
	1	0.10	102	102	102					
	1	2.0	107	107	107					
	3	overall		97	107	102	4.9			

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IIA 6.3.1.5 Fruiting vegetables – tomato, incl. eggplant (solanacea)

BYI 02960 is to be registered in Europe for use in tomato. European residue data in tomato are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported is summarized in Table 6.3.1.5-1.

Table 6.3.1.5-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulation in/on tomato in European fields (southern residue region) and greenhouses

Description	F/G	No. of appls.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"agricultural" use*	G	2	112.5 g/ha×m [†]	450	750 L/(ha×m)	10	3
	F†	1	112.5	112.5	500-750	n/‡	3
"home & garden"***		2	112.5	225	500-750	4	3

* agricultural use based on an SL 200 formulation

** "home & garden" uses with an SL 50 formulation (available to the general public via retail sale)

† uses in southern residue region (EU-S)

‡ core rate per meter plant foliage height. Testing in greenhouse based on a max. height of 2 m, equating to max. 225 g a.s./ha.

In order to support the use of BYI 02960, sets of GLP trials were conducted in southern European fields and in greenhouses in 2010 and 2011. In southern European field-grown tomato, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200, containing 200 g/L BYI 02960 a.s.), at 14-day intervals. For the use in greenhouses, BYI 02960 was applied as in the field, but at 10-day intervals. In both cases, the envisaged PHI was 3 days, reflecting the planned agricultural use in the greenhouse, as well as the intended worst-case field use.

Residue levels of BYI 02960 and its metabolites DEA and DEAT were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the greenhouse trials, in which a highest total residue value (HR) of 0.50 mg/kg was determined. The STMR in these trials was also the highest, for both sets, at 0.14 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.5-2.

Table 6.3.1.5-2: Overview of European residue trials conducted in tomato per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.5-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.5/...
		2010	2011	Σ	HR	STMR		
<i>trials in EUROPE</i>								
"agricultural" use	G	4	4	8	0.50	0.14	10-2190, 11-2085	03, 04
"home & garden"	EU-S	4	4	8	0.11	0.08	10-2186, 11-2087	01, 02

EU-S = southern EU field residue region, G = greenhouse

Southern European residue region (field)

Report:	KIIA 6.3.1.5/01, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on tomato after spraying of BYI 02960 SL 200 in the field in France (south), Italy, Spain and Portugal
Report No. & Document No.:	10-2186, dated September 6, 2012 M-438184-01-1
Report:	KIIA 6.3.1.5/02, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on tomato after spray application of BYI 02960 SL 200 in the field in Spain, Italy, Portugal and Greece
Report No. & Document No.:	11-2087 dated September 17, 2012 M-438275-01-1
Guidelines (applies to both studies):	Directive 2002/31/EC, residues in/on treated products, food and feed EU Guidance working document, 7029/04/95 rev. 5 US EPA OCSPP Guideline No. 860.1000.SL-PP
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Eight field residue trials were conducted in southern Europe, as follows:

In 2010, 4 trials (Southern France, Italy, Spain and Portugal) were conducted to support the use of BYI 02960 SL 200 in tomato ([REDACTED] & [REDACTED], 2012, KIIA 6.3.1.5/01). Two applications were made at intervals of 14 days at a nominal rate of 0.625 L/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 600-1000 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates. (The higher application rate used in 2010 was 11% higher than the rate to be registered, thus well within the EPA's acceptance criteria for use pattern comparability.)

Four further trials were carried out in 2011 in Spain, Italy, Portugal, and Greece, to complete the data package ([REDACTED], 2012, KIIA 6.3.1.5/02). The basic application parameters were similar to those in 2010, except that applications were made at a nominal rate of 0.563 L/ha, corresponding to 112.5 g/ha BYI 02960 a.s.; the water rate was 600-1000 L/ha, reflecting local practice in the trial regions. Again, all treatments were made at the scheduled rates.

Samples of tomato fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 or 14 days after treatment in the 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.

The samples were analysed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or 01212 (2011 trials; cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).



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II. Findings

Validation of tomato fruit was done within method 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or within method 01212 (2011 trials; cf. KIIA 4.3/05). During the conduct of the complete set of tomato studies in 2010-2011, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of tomato fruit. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg as well as 0.50 mg/kg for trials conducted in 2010, and 0.01 mg/kg for trials conducted in 2011 (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (86-100%, RSDs of the larger validation sets [$n > 2$] 4.2-10.9%, $n = 140$).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.50 mg/kg (expressed in BYI 02960 equivalents) for trials conducted in 2010 and 0.02 mg/kg, 0.20 mg/kg, and 4.0 mg/kg (expressed in BYI 02960 equivalents) for trials conducted in 2011. Mean recoveries were all within acceptable ranges (88-96%, RSDs of the larger validation sets [$n > 2$] 1.5-6.2%, $n = 140$).

Details of recovery data are shown in table 6.3.1.5-4. All trial data are summarized below in table 6.3.1.5-3a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in tomato fruit were between 0.07 mg/kg and 0.17 mg/kg (median 0.13 mg/kg). By day 3 — the envisaged PHI — the levels were <0.04-0.11 mg/kg, with a median value of 0.08 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). This was evident in the 2010 trial packages for other crops, although peak residue values for tomatoes were seen on day 5 in one trial as well. In order to ensure that the maximum relevant residue levels are captured, additional sampling was conducted 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 7 (1 trial), or day 10 (2 trials).

Maximum residue levels at any relevant sampling interval (≥ 3 days post-application) over the complete set of trials ranged from <0.04-0.11 mg/kg (median 0.08 mg/kg).

Evaluation of representativity

As highest residue levels were also seen in samples taken after the envisaged PHI of 3 days – on day 5 (trial 10-2087-04), day 7 (11-2087-02), and on day 10 (11-2087-03 and -04) – the entire set of trials was re-evaluated for its representativity.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

In the 2010 package, "plateau behaviour" was evident in all four of the trials at PHI 3. Only in trial 10-2186-04 were residues on day 5 (0.08 mg/kg) higher than on day 3 (0.07 mg/kg). However, this increase is very small, and even within the scope of sampling or analytical variability; also, as mentioned, a plateau level appears to have been reached. Thus, taken in the context of all of the trials, this trial can also be seen as yielding representative results.

In 2011, "plateau" behaviour was evident in all four of the trials, as seen in the samples taken from day 3 onwards. In trials 11-2087-01, -02, and -04, a very minor increase in residues was seen over time, from 0.083 mg/kg on day 3 to 0.096 mg/kg on day 10, from 0.089 mg/kg on day 3 to 0.095 mg/kg on day 7, and from 0.064 mg/kg on day 3 to 0.067 mg/kg on day 10, respectively. These "increases" are very small; they are also within the scope of analytical error or variability caused by sampling. Thus, taken in the context of all of the trials, these trials can also be seen as yielding representative results.

Thus the trials are considered to be valid and representative of the use described.

III. Conclusions (tomato, southern European residue region)

In order to support the use in the EU of BYI 02960 in tomato, 8 valid trials were conducted in the southern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha per treatment in 2010 and at an active substance rate of 112.5 g/ha in 2011, both of which support the intended use rate (112.5 g/ha). The application intervals were 14 days. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the final application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analysed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and FEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 in tomato fruit declined somewhat between the final application and the nominal PHI, from levels of 0.03 to 0.17 mg/kg on day 0 after the final treatment to <0.04-0.11 mg/kg on day 3. The respective mean values were 0.13 mg/kg and 0.08 mg/kg, respectively.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI. However, these "increases" are very small; they are also within the scope of variability caused by sampling, biological, and/or analytical aspects.
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from <0.04-0.11 mg/kg (median 0.08 mg/kg).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.5-3a: Application scenario in residue trials conducted in/on **tomato** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2186 (10-2186-01) southern France [redacted] EU-S 2010	tomato Perfect Peel (Hybrid variety)	200 SL	2	0.125	0.0208	87	3
10-2186 (10-2186-02) Italy [redacted] EU-S 2010	tomato Missouri (Multiple use variety)	200 SL	2	0.125	0.0208	88	3
10-2186 (10-2186-03) Spain [redacted] EU-S 2010	tomato Malpica (Tomate de industria)	200 SL	2	0.125	0.0125	83	3
10-2186 (10-2186-04) Portugal [redacted] EU-S 2010	tomato H9144 Industry	200 SL	2	0.125	0.0179	88	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

Continued on next page...

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Table 6.3.1.5-3a (cont'd.): Application scenario in residue trials conducted in/on **tomato after spraying with BYI 02960 SL 200 in field (*southern EU residue region*)**

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2087 (11-2087-01) Spain [REDACTED] EU-S 2011	tomato Malpica; Tomate de industria	200 SL	2	0.113	0.0161	72	3
11-2087 (11-2087-02) Italy [REDACTED] EU-S 2011	tomato Discovery F1; Processing tomato	200 SL	2	0.113	0.0161	86	3
11-2087 (11-2087-03) Portugal [REDACTED] EU-S 2011	tomato H-9144- Industrial	200 SL	2	0.113	0.0055	85	3
11-2087 (11-2087-04) Greece [REDACTED] EU-S 2011	tomato 902 Heintz, flat growing var. Hybrid	200 SL	2	0.113	0.0188	87	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.5-3b: Results of residue trials conducted in/on **tomato** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFEA	total residue of BYI 02960 cap
10-2186 (10-2186-01) southern France GLP: yes	fruit	0*	<0.01	<0.02	<0.01	<0.04
		0	0.04	<0.02	<0.01	0.03
		1	<0.01	<0.02	0.01	<0.04
		3	<0.01	<0.02	<0.01	0.04
		5	<0.01	<0.02	<0.01	0.04
		7	<0.01	<0.02	<0.01	0.04
		7	<0.01	<0.02	<0.01	0.04
10-2186 (10-2186-02) Italy GLP: yes	fruit	0*	0.03	<0.02	<0.01	0.06
		0	0.06	<0.02	<0.01	0.09
		1	0.03	<0.02	<0.01	0.06
		3	0.05	<0.02	<0.01	0.08
		5	0.03	<0.02	<0.01	0.06
		7	0.03	<0.02	<0.01	0.06
		7	0.03	<0.02	<0.01	0.06
10-2186 (10-2186-03) Spain GLP: yes	fruit	0*	0.04	<0.02	<0.01	0.07
		0	0.11	<0.02	<0.01	0.13
		1	0.10	<0.02	<0.01	0.13
		3	0.08	<0.02	<0.01	0.11
		4	0.05	0.02	<0.01	0.08
		7	0.07	0.03	<0.01	0.11
		7	0.07	0.03	<0.01	0.11
10-2186 (10-2186-04) Portugal GLP: yes	fruit	0*	0.04	<0.02	<0.01	0.07
		0	0.06	<0.02	<0.01	0.11
		1	0.04	<0.02	<0.01	0.10
		3	0.04	<0.02	<0.01	0.07
		5	0.05	<0.02	<0.01	0.08
		7	0.05	<0.02	<0.01	0.08
		7	0.05	<0.02	<0.01	0.08
11-2087 (1-2087-01) Spain GLP: yes	fruit	0*	0.03	<0.024	<0.01	0.13
		0	0.073	<0.024	<0.01	0.10
		3	0.053	<0.024	<0.01	0.083
		7	0.053	<0.024	<0.01	0.084
		7	0.057	<0.029	<0.01	0.096
		14	0.041	0.035	<0.01	0.086
		14	0.041	0.035	<0.01	0.086
11-2087 (11-2087-02) Italy GLP: yes	fruit	0*	0.036	<0.02	<0.01	0.066
		0	0.14	<0.02	<0.01	0.17
		3	0.039	<0.02	<0.01	0.089
		7	0.062	0.023	<0.01	0.095
		10	0.048	0.035	<0.01	0.083
		14	0.043	0.038	<0.01	0.091
		14	0.043	0.038	<0.01	0.091
11-2087 (11-2087-03) Portugal GLP: yes	fruit	0*	0.077	<0.02	<0.01	0.047
		0	0.24	<0.02	<0.01	0.17
		3	0.033	<0.02	<0.01	0.063
		7	0.023	<0.02	<0.01	0.057
		10	0.035	<0.02	<0.01	0.055
		14	0.024	<0.02	<0.01	0.054
		14	0.024	<0.02	<0.01	0.054
11-2087 (11-2087-04) Greece GLP: yes	fruit	0*	0.026	<0.02	<0.01	0.056
		0	0.12	<0.02	<0.01	0.15
		3	0.034	<0.02	<0.01	0.064
		7	0.023	<0.02	<0.01	0.053
		10	0.032	0.025	<0.01	0.067
		14	0.021	0.026	<0.01	0.057
		14	0.021	0.026	<0.01	0.057

 DALT: days after last treatment
 * prior to last treatment

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.5-4: Recovery data for BYI 02960 in tomato

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
10-2186 (10-2186-01), to (10-2186-04) GLP: yes 2010	tomato	fruit	BYI 02960	10	0.01	93; 94; 94; 95; 97; 98; 98; 102; 104; 104	93	104	98	5.2
				3	0.00	83; 91; 91	83	98	88	5.8
				3	0.50	90; 98; 98	90	98	95	4.8
				16	overall		83	104	96	5.7
			DFA	4	0.02	87; 88; 90; 94; 96; 101; 101	87	101	94	6.0
				3	0.05	94; 95; 97	94	97	95	1.6
				6	0.5	83; 85; 89; 90; 91; 92	83	95	88	4.0
				16	overall		83	101	92	5.7
			DFEAF	4	0.01	73; 81; 82; 84; 86; 89; 89; 90; 91; 95	73	95	86	7.3
				3	0.10	83; 91; 93	83	93	89	6.2
4	0.5	87; 92; 107		87	107	95	10.9			
16	overall			73	107	88	8.4			
11-2087 (11-2087-01), to (11-2087-04) GLP: yes 2011	tomato	fruit	BYI 02960	2	0.01	98; 102	98	102	100	
				1	0.05	106	106	106		
				1	0.0	105	105	105		
				4	overall		98	106	103	3.5
			DFA	2	0.02	100; 91	91	100	96	
				1	0.20	84	84	84		
				1	4.0	97	97	97		
				4	overall		84	100	93	7.6
			DFEAF	2	0.01	96; 99	96	99	98	
				1	0.10	101	101	101		
2	0.5	114		114	114					
4	overall			96	114	103	7.7			

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Greenhouse

Report:	KIIA 6.3.1.5/03, [REDACTED]; [REDACTED], [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on tomato after spray application of BYI 02960 SL 200 in the greenhouse in Germany, the Netherlands, France (North) and Belgium
Report No. & Document No.:	10-2190, dated March 1, 2012 M-426300-01-1
Report:	KIIA 6.3.1.5/04, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on tomato and cherry tomato after spray application of BYI 02960 SL 200 in the greenhouse in Germany, the Netherlands, Italy and Spain
Report No. & Document No.:	11-2085, dated March 3, 2012 M-427056-01-1
Guidelines (applies to both studies):	Directive 91/414/EEC, residues in or on treated product, food and feed EC guidance working document 7029 CI/95 rev.5
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Eight residue trials were conducted in the greenhouse, as follows:

In 2010, 4 trials (Germany, the Netherlands, northern France, and Belgium) were conducted to support the use of BYI 02960 SL 200 in tomato ([REDACTED] & [REDACTED] 2012, KIIA 6.3.1.5/03). Two applications were made at intervals of 10 days (1st in one trial) at a nominal rate of 0.625 L/(ha×m), corresponding to 125 g/(ha×m) BYI 02960 a.s., the water rate was 650 L/(ha×m), reflecting local practices in the trial regions. All treatments were made at the scheduled rates. (The higher application rate used in 2010 was 11% higher than the rate to be registered, thus well within the EU's acceptance criteria for use pattern comparability.)

Four further trials were carried out in 2011, in Germany, the Netherlands, Italy, and Spain, to complete the data package ([REDACTED] 2012, KIIA 6.3.1.5/04). The basic application parameters were similar to those in 2010, except that applications were made at a nominal rate of 0.563 L/(ha×m), corresponding to 112.5 g/(ha×m) BYI 02960 a.s. Again, all treatments were made at the scheduled rates.

Samples of tomato fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 days after treatment in 2010 trials and up to 14 days in 2011 trials). The end usage PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or 01212 (2011 trials; cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of tomato fruit was done within method 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or within method 01212 (2011 trials; cf. KIIA 4.3/05). Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of tomato fruit. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.50 mg/kg or 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (86-95%, RSDs of the larger validation sets [$n > 2$] 4.2-10.9%, $n=1-7$).

Fortification levels for DFA were 0.02 mg/kg, 0.05 mg/kg, and 0.50 mg/kg (2010 study) as well as 0.02 mg/kg, 0.20 mg/kg, and 1.0 mg/kg (2011 study) (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (88-95%, RSDs of the larger validation sets [$n > 2$] 1-6.2%, $n=1-7$).

Details of recovery data are shown in table 6.3.1.5-3. All trial data are summarised below in table 6.3.1.5-5a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in tomato fruit were between 0.07 and 0.17 mg/kg (median 0.17 mg/kg). On day 3 — the envisaged PHI — the levels were 0.08-0.37 mg/kg, with a median value of 0.13 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). This was already evident in the 2010 trials, in which peak residue values were seen on day 5 (3 trials) or day 7 (1 trial), the final day of sampling. In order to capture the maximum relevant residue levels, additional sampling was conducted up to 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 3-4 (3 trials), or day 14 (1 trial).

Maximum residue levels at any relevant sampling interval (≥ 3 days post-application) over the complete set of trials ranged from 0.09-0.60 mg/kg (median 0.14 mg/kg).

Evaluation of Representativity:

As highest residue levels were seen on the final sampling interval of two trials (10-2190-02, day 7; and 11-2085-04, day 14), the entire set of trials was re-evaluated for its representativity.

In the 2010 package, residues essentially showed "plateau behaviour", with residues remaining fairly constant from the PHI to the final sampling date (day 3 to day 7). Even in trial 10-2190-02, in which residues peaked on the final day of sampling (day 7), there was only a very minor increase in residues over time, from 0.13 mg/kg on day 3 to 0.15 mg/kg on day 7. These "increases" are very small, with



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

the difference per sampling interval of only 0.01 mg/kg, and also within the scope of analytical error or variability caused by sampling.

In 2011, trials 11-2085-01 to -03 showed slightly decreasing behaviour or at least "plateau" levels starting at the PHI. In trial 11-2085-04, there was an continuous increase in residues over time, from 0.24 mg/kg on day 3 to 0.35 mg/kg on day 6 to 0.45 mg/kg on day 10 and to 0.50 mg/kg on day 14. Between day 3 and day 6 as well as days 6 and 10, there was an increase over time of 0.10 mg/kg and 0.10 mg/kg, respectively, while between days 10 and 14 there was only an increase of residues of 0.05 mg/kg. However, 0.50 mg/kg found at the last sampling day is the highest residue value found in any of these trials. It will "drive" the MRL (see KIIA 6.7.2), and this must be considered carefully during MRL-setting.

III. Conclusions (tomato, greenhouse)

In order to support the use in the EU of BYI 02960 in tomato, 8 valid trials were conducted in the greenhouse in the years 2010-2011. BYI 02960 was applied twice, as an GL 200 formulation at an active substance rate of 125 g/(ha x m) per treatment in 2010 and 112.5 g/(ha x m) per treatment in 2011, both of which support the intended use rate (12.5 g/(ha x m)). The application intervals were approx. 10 days. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites IFA and DFHAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 remained fairly constant in tomato fruit between the final application and the nominal PHI, from levels of 0.07-0.37 mg/kg on day 0 after the final treatment to 0.08-0.37 mg/kg on day 3. The respective median values were 0.17 and 0.13 mg/kg, respectively.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.09-0.50 mg/kg (median 0.44 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation. (Care must be taken during MRL calculation to evaluate the effect of the HR of 0.50 mg/kg on the MRL proposal.)

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.5-5a: Application scenario in residue trials conducted in/on **tomato** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/m ² (a.s.)		
10-2190 (10-2190-01) Germany [redacted] Greenhouse 2010	tomato Albis	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	82	3
10-2190 (10-2190-02) Netherlands [redacted] Greenhouse 2010	tomato Doloress	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	74	3
10-2190 (10-2190-03) France [redacted] Greenhouse 2010	tomato Crista tomato gripe	200 SL	2	0.188 (0.125 kg/[ha×m])	0.0167	83	3
10-2190 (10-2190-04) Belgium [redacted] Greenhouse 2010	tomato Madison	200 SL	2	0.188 (0.125 kg/[ha×m])	0.0167	86	3

FL = formulation

GS = growth stage (BBCH code) at last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.5-5a (cont'd.): Application scenario in residue trials conducted in/on tomato after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/m ² (a.s.)		
11-2085 (11-2085-01) Germany [REDACTED]	tomato Mikano	200 SL	2	0.225 (0.113 kg/[ha×m])	0.0150	88	4
Greenhouse 2011							
11-2085 (11-2085-02) Netherlands [REDACTED]	tomato Komeet Tomato	200 SL	2	0.225 (0.113 kg/[ha×m])	0.0150	85	3
Greenhouse 2011							
11-2085 (11-2085-03) Italy [REDACTED]	tomato, cherry Corbus Tomato cherry	200 SL	2	0.225 (0.113 kg/[ha×m])	0.0150	81	3
Greenhouse 2011							
11-2085 (11-2085-04) Spain [REDACTED]	tomato, cherry Quindo Tomato cherry	200 SL	2	0.225 (0.113 kg/[ha×m])	0.0150	83	3
Greenhouse 2011							

FL = formulation GS = growth stage (BBCH code) of last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.5-5b: Results of residue trials conducted in/on **tomato** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFE	total residue of BYI 02960 ca
GLP						
10-2190 (10-2190-01) Germany	fruit	0* 0 1 3 5 7	0.03 0.11 0.06 0.06 0.06 0.06	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.0 0.4 0.09 0.09 0.09 0.09
10-2190 (10-2190-02) Netherlands	fruit	0* 0 1 3 5 7	0.04 0.14 0.11 0.10 0.11 0.12	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.07 0.17 0.14 0.13 0.14 0.15
10-2190 (10-2190-03) northern France	fruit	0* 0 1 3 5 7	0.03 0.08 0.08 0.05 0.08 0.08	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.06 0.1 0.11 0.08 0.11 0.11
10-2190 (10-2190-04) Belgium	fruit	0* 0 1 3 5 7	0.02 0.04 0.04 0.05 0.07 0.08	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.05 0.07 0.07 0.08 0.10 0.07
11-2085 (11-2085-01) Germany	fruit	0* 0 4 10 14	0.15 0.29 0.23 0.23 0.22 0.15	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.18 0.32 0.30 0.28 0.25 0.18
11-2085 (11-2085-02) Netherlands	fruit	0* 0 3 7 10 14	0.04 0.04 0.097 0.078 0.08 0.25	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.075 0.17 0.13 0.11 0.11 0.086
11-2085 (11-2085-03) Italy	fruit	0* 0 3 7 10 14	0.03 0.34 0.34 0.27 0.07 0.25	<0.02 <0.02 <0.02 0.027 0.034 0.054	<0.01 <0.01 <0.01 <0.01 <0.01 0.010	0.16 0.37 0.37 0.27 0.32 0.32
11-2085 (11-2085-04) Spain	fruit	0* 0 3 6 10 14	0.06 0.24 0.09 0.27 0.32 0.36	0.022 0.026 0.037 0.063 0.10 0.11	<0.01 <0.01 0.015 0.021 0.026 0.029	0.099 0.27 0.24 0.35 0.45 0.50

 DALT = days after last treatment
 * prior to last treatment

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.5-6: Recovery data for BYI 02960 in tomato

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
10-2190 (10-2190-01), to (10-2190-04) GLP: yes 2010	tomato	fruit	BYI 02960	10	0.01	93; 94; 94; 95; 97; 98; 98; 102; 104; 104	93	104	98	4.2
				3	0.10	83; 91; 91	83	91	88	2.2
				3	0.50	90; 98; 98	90	98	95	4.8
				16	Overall		83	100	96	5.5
				7	0.02	87; 88; 90; 92; 96; 101; 101	87	101	94	5.2
				3	0.05	94; 95; 97	94	97	96	1.8
				6	0.20	87; 85; 88; 89; 91; 92	83	92	88	4.0
				16	Overall		82	100	90	5.7
				16	0.01	77; 81; 82; 83; 86; 88; 89; 90; 94; 95	73	95	86	7.3
				3	0.10	83; 92; 93	83	93	89	6.2
3	0.50	87; 92; 100	87	107	95	10.9				
16	Overall		73	107	88	8.4				
11-2085 (11-2085-01), to (11-2085-04) GLP: yes 2011	tomato	fruit	BYI 02960	1	0.01	100	100	100		
				1	0.10	100	100	100		
				1	0.50	94	94	94		
				3	Overall		94	100	98	3.5
				9	0.02	93	93	93		
				1	0.20	98	98	98		
				1	1.0	92	92	92		
				9	Overall		92	98	94	3.4
				1	0.01	98	98	98		
				1	0.10	100	100	100		
3	1.0	87	87	87						
3	Overall		87	100	95	7.4				

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IIA 6.3.1.6 Fruiting vegetables – sweet (bell) pepper (solanacea)

BYI 02960 is to be registered in Europe for use in sweet peppers. European residue data in peppers are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.6-1.

Table 6.3.1.6-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulations in/on peppers in European fields (southern residue regions) and greenhouses

Description	F/G	No. of appls.	Application rate		Water volume (l/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"agricultural" use*	G	2	112.5 <small>g/(ha×m)</small>	450	750 <small>L/(ha×m)</small>	10	
"home & garden"**	F†	1	112.5	112.5	500-750	n/a	3
		2	112.5	225	500-750	14	3

* agricultural use based on an SL 200 formulation

** "home & garden" uses with an SL 50 formulation (available to the general public via retail sale)

† uses in the southern residue region (EU-S)

‡ core rate per meter plant foliage height. Testing in greenhouse based on a max. height of 2 m, equating to max. 225 g a.s./ha.

In order to support the EU "safe use" of BYI 02960, sets of GLP trials were conducted in southern European fields in 2010 and 2011 and in the greenhouses in 2011. In southern European field-grown peppers, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200, containing 200 g/L BYI 02960 a.s.), at 10-day intervals. For the use in greenhouses, BYI 02960 was applied as in the field, but at 10-day intervals. In both cases, the envisaged PHI was 3 days, reflecting the planned agricultural use in the greenhouse, as well as the intended worst-case field use.

Residue levels of BYI 02960 and its metabolites DEA and DEAF were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the greenhouse trials in which a highest total residue value (HR) of 0.63 mg/kg was determined. The DTMP in these trials was also the higher of the two sets, at 0.27 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.6-2.

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Table 6.3.1.6-2: Overview of European residue trials conducted in peppers per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.6-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.6/...
		Veget. period 2010	2011	Σ	HR	STMR		
<i>trials in EUROPE</i>								
"agricultural" use	G	-	8	8	0.23	0.27	11-2081	03
"home & garden"	EU-S	4	4	8	0.25	0	10-2187 11-2080	01 02

EU-S = southern EU field residue region, G = greenhouse

Southern European residue region (field)

Report:	KIIA 6.3.1.6/01, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on sweet pepper after spraying of BYI 02960 SL 200 in the field in France (south), Italy, Spain and Portugal
Report No. & Document No.:	10-2187, dated September 27, 2012 M-439089-01

Report:	KIIA 6.3.1.6/02, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on sweet pepper after spray application of BYI 02960 SL 200 in the field in southern France, Spain and Italy
Report No. & Document No.:	10-2083, dated September 25, 2012 M-439083-01

Guidelines (applies to both studies):	Directive 91/416/EEC, residues in or on treated products, food and feed EC Guidance Working document 7029/VI/95 rev. 5 US EPA OCSPP Guideline No. 860.1500.SUPP (applies only to 11-2075)
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

Materials and Methods

Eight field residue trials were conducted in the Southern European residue region, as follows:

In 2010, 4 trials (France, Italy, Spain, and Portugal) were conducted to support the use of BYI 02960 SL 200 in sweet peppers ([REDACTED], 2012, KIIA 6.3.1.6/01). Two applications were made at intervals of 14 days at a nominal rate of 0.625 g/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 500-800 l/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates, except for a single treatment in one trial (10-2187-01, first application overdosed by 6%). (The higher application rate used in 2010 was 11% higher than the rate to be registered, thus well within the EU's acceptance criteria for use pattern comparability.)

Four further trials were carried out in 2011, in France, Spain, and Italy (2), to complete the data package ([REDACTED], 2012, KIIA 6.3.1.6/02). The basic application parameters were as in 2010, except



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

that applications were made at a nominal rate of 0.563 L/ha, corresponding to 112.5 g/ha BYI 02960 a.s.; water rates ranged from 600-750 L/ha. All treatments were made at the scheduled rates.

Samples of pepper fruit were taken immediately prior and subsequent to the final application and at several intervals thereafter (up to 7 or 14 days after treatment in 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (2010 trials; for method details, cf. KIIA 4.3/03). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of pepper fruit was done within study 10-2187 (cf. KIIA 6.3.1.6/01). Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained concurrently to the analysis of the field samples of sweet pepper fruit of all studies. This sample material is representative for all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg (expressed in BYI 02960 equivalents), as well as 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (88-102%, RSDs of the larger validation sets [n>2] 2.6-6.6%, n=2-6).

Fortification levels for DFA were 0.02 mg/kg and 0.20 mg/kg, as well as 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (90-98%, RSDs of the larger validation sets [n>2] 1.9-4.3%, n=2-6).

Details of recovery data are shown in table 6.3.1.6-4. All trial data are summarised below in table 6.3.1.6-3a & b and in greater detail in the Tier 1 summary form (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0 immediately following the 2nd and final treatment, residue levels in pepper fruit were between 0.069 mg/kg and 0.32 mg/kg (median 0.12 mg/kg). On day 3 — the envisaged PHI — the levels were 0.05-0.25 mg/kg, with a median value of 0.13 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). This was already indicated in the 2010 trial packages for other crops, although peak residue values for peppers were seen on day 6 in one trial as well. In order to ensure that the maximum relevant residue levels are captured, additional sampling was conducted 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 14 in 3 trials.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Maximum residue levels at any relevant sampling interval (≥ 3 days post-application) over the complete set of trials ranged from 0.05-0.25 mg/kg (median 0.17 mg/kg).

Evaluation of representativity:

As highest residue levels were also seen in samples taken after the envisaged PHI of 3 days – on day 6 (trial 10-2187-04) or on day 14 (11-2083-01, -02, and -04) – the entire set of trials was re-evaluated for its representativity.

In the 2010 package, either "normal" or "plateau" residue behaviour was evident in all four of the trials at PHI 3. Only in trial 10-2186-04 were residues on day 5/6 (0.12 mg/kg higher than on day 3 (0.11 mg/kg). However, this increase is very small, and even within the scope of sampling or analytical variability; also, as mentioned, a plateau level appears to have been reached.

In 2011, peak residues were determined at the scheduled PHI 3 days in trial 11-2083-03, although similarly high levels at the day-10 sampling suggest more of a "plateau". In trials 11-2083-01, -02, and -04, residue levels increased slowly and somewhat erratically from the PHI to the final sampling event (day 14). Although it is theoretically possible that these values might continue to increase slightly, the slow and generally irregular nature of their "ascension", the fact that peak residues were, in fact, seen at earlier sampling intervals in 5 of 8 the trials in the package; and the fact that none of these trials represents a "remarkable" value, e.g. the HR, in this data set would seem to indicate that the values are indeed part of one population and representative of the whole. However, as they are close to the HR, which itself is an important "driver" of the MRL (see IIA 6.1.2), these trials must be considered carefully during MRL setting.

III. Conclusions (sweet peppers, southern European residue region)

In order to support the use in the EU of BYI 02960 in peppers, 8 valid trials were conducted in the southern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha per treatment in 2010 and at an active substance rate of 112.5 g/ha per treatment in 2011, both of which support the intended use rate (112.5 g/ha). The application intervals were approx. 7 days. All applications were at the required rates except for a very minor deviation in one trial, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that

- Total residues of BYI 02960 remained fairly constant in bell pepper fruit between the final application and the nominal PHI, from levels of 0.069-0.32 mg/kg on day 0 after the final treatment to 0.05-0.25 mg/kg on day 3. The respective median values were 0.12 and 0.13 mg/kg.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.05-0.25 mg/kg (median 0.17 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield suitable results for MRL evaluation, though care must be taken to evaluate the effects of peak residue levels determined at the final sampling interval.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-3a: Application scenario in residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2187 (10-2187-01) France [REDACTED] EU-S 2010	pepper, sweet Albi	200 SL	2	0.125-0.133	0.0250- 0.0250	82	3
10-2187 (10-2187-02) Italy [REDACTED] EU-S 2010	pepper, sweet Ividor	200 SL	2	0.125	0.0179	85	3
10-2187 (10-2187-03) Spain [REDACTED] EU-S 2010	pepper, sweet Carboni - Tubo Italiano	200 SL	2	0.125	0.0156	85	3
10-2187 (10-2187-04) Portugal [REDACTED] EU-S 2010	pepper, sweet Pompeu - Industry	200 SL	2	0.125	0.0179	79	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-3a (cont'd.): Application scenario in residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2083 (11-2083-01) France [REDACTED] EU-S 2011	pepper, sweet Albi Hybride	200 SL	2	0.113	0.0188	81	3
11-2083 (11-2083-02) Spain [REDACTED] EU-S 2011	pepper, sweet Lloret	200 SL	2	0.113	0.0161- 0.0188	82	3
11-2083 (11-2083-03) Italy [REDACTED] EU-S 2011	pepper, sweet Adina	200 SL	2	0.113	0.0188	82	3
11-2083 (11-2083-04) Italy [REDACTED] EU-S 2011	pepper, sweet Cleur	200 SL	2	0.113	0.0150	82	3

FL = formulation GS = growth stage (BBCH-code) at first treatment
 EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-3b: Results of residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca
10-2187 (10-2187-01) France GLP: yes	fruit	0*	0.05	0.03	<0.01	0.08
		0	0.09	0.03	<0.01	0.12
		1	0.06	0.03	<0.01	0.09
		3	0.08	0.03	<0.01	0.12
		5	0.04	0.03	<0.01	0.08
		7	0.05	0.03	<0.01	0.08
		7	0.05	0.03	<0.01	0.08
10-2187 (10-2187-02) Italy GLP: yes	fruit	0*	0.01	<0.02	<0.01	0.04
		0	0.05	<0.02	<0.01	0.08
		1	0.03	<0.02	<0.01	0.06
		3	0.02	<0.02	<0.01	0.05
		5	0.02	<0.02	<0.01	0.05
		7	0.02	<0.02	<0.01	0.04
		7	0.02	<0.02	<0.01	0.04
10-2187 (10-2187-03) Spain GLP: yes	fruit	0*	0.04	<0.02	<0.01	0.07
		0	0.25	0.03	<0.01	0.28
		1	0.20	<0.02	<0.01	0.23
		3	0.21	0.03	<0.01	0.24
		4	0.02	0.03	<0.01	0.16
		7	0.02	0.03	<0.01	0.16
		7	0.02	0.03	<0.01	0.17
10-2187 (10-2187-04) Portugal GLP: yes	fruit	0*	0.04	<0.02	<0.01	0.07
		0	0.05	<0.02	<0.01	0.11
		1	0.08	<0.02	<0.01	0.11
		3	0.08	<0.02	<0.01	0.11
		6	0.08	0.03	<0.01	0.12
		7	0.08	0.03	<0.01	0.12
		7	0.08	0.03	<0.01	0.09
11-2083 (11-2083-01) France GLP: yes	fruit	0*	0.00	0.03	<0.010	0.077
		0	0.15	0.03	<0.010	0.20
		3	0.12	0.045	<0.010	0.17
		10	0.11	0.065	0.010	0.19
		14	0.093	0.087	0.011	0.19
		14	0.098	0.10	0.015	0.22
		14	0.098	0.10	0.015	0.22
11-2083 (11-2083-02) Spain GLP: yes	fruit	0*	0.095	0.038	<0.010	0.15
		0	0.09	0.038	<0.010	0.069
		3	0.087	0.046	<0.010	0.14
		7	0.076	0.046	<0.010	0.17
		9	0.063	0.067	<0.010	0.14
		14	0.071	0.12	<0.010	0.20
		14	0.071	0.12	<0.010	0.20
11-2083 (11-2083-03) Italy GLP: yes	fruit	0*	0.044	<0.020	<0.010	0.074
		0	0.29	<0.020	<0.010	0.32
		3	0.22	<0.020	<0.010	0.25
		14	0.15	<0.020	<0.010	0.17
		14	0.08	0.026	<0.010	0.22
		14	0.11	0.020	<0.010	0.14
		14	0.11	0.020	<0.010	0.14
11-2083 (11-2083-04) Italy GLP: yes	fruit	0*	0.013	0.025	<0.010	0.049
		0	0.04	0.021	<0.010	0.075
		3	0.033	0.034	<0.010	0.077
		7	0.022	0.032	<0.010	0.065
		10	0.030	0.074	<0.010	0.11
		14	0.029	0.098	<0.010	0.14
		14	0.029	0.098	<0.010	0.14

 DALT = days after last treatment
 * prior to 1st treatment



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.6-4: Recovery data for BYI 02960 in peppers

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean RSD	
10-2187 10-2187-01 to 10-2187-04 GLP: yes 2010	pepper, sweet	fruit	BYI 02960	6	0.01	94;97; 98; 101; 101; 103	94	103	99	1.3
				4	0.10	89; 91; 93; 95	89	95	92	2.8
				10	overall		89	103	92	2.8
				6	0.02	89; 91; 91; 92; 93; 94	89	94	92	1.9
				4	0.20	86; 87; 92; 93	86	94	90	4.3
				10	overall		86	94	91	5.0
11-2083 11-2083-01 to 11-2083-04 GLP: yes 2011	pepper, sweet	fruit	BYI 02960	6	0.01	89; 88; 93; 93; 94; 94	79	94	90	6.6
				4	0.10	88; 91; 93; 93	88	93	91	2.6
				10	overall		79	94	91	5.1
				2	0.01	93; 101	93	102	98	
				2	0.10	88; 101	88	101	95	
				6	overall		88	102	97	6.1
11-2083 11-2083-01 to 11-2083-04 GLP: yes 2011	pepper, sweet	fruit	BYI 02960	2	0.02	94; 101	94	101	98	
				2	0.20	94; 95	87	95	91	
				2	1.0	95; 99	95	97	96	
				6	overall		87	101	95	4.8
				2	0.01	87; 88	87	88	88	
				2	0.10	96; 101	96	102	99	
11-2083 11-2083-01 to 11-2083-04 GLP: yes 2011	pepper, sweet	fruit	BYI 02960- DFEAF	2	1.0	99; 105	99	105	102	
				6	overall		87	105	96	7.7

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Greenhouse

Report:	KHIA 6.3.1.6/03, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on sweet pepper after spraying of BYI 02960 SL 200 in the Greenhouse in France, Spain, Italy, Greece and the Netherlands
Report No. & Document No.:	11-2081, dated August 17, 2012 M-436855-01-1
Guidelines:	Directive 91/414/EEC, residues in or on treated products, food and feed EC Guidance working document 7029/2005 rev. 5 US EPA OCSPP Guideline No. 860.1500.SUPP
GLP:	yes (certified laboratory); Deviation none

I. Materials and Methods

Eight residue trials were conducted in the greenhouse as follows:

In 2011, 8 trials (France [2], Spain [2], Italy [2], and Greece [2]) were conducted to support the use of BYI 02960 SL 200 in sweet pepper [REDACTED] 2012, KHIA 6.3.1.6/03. Two applications were made at intervals of 10 days (13 in one trial) at a nominal rate of 1.563 L/(ha×m), corresponding to 112.5 g/(ha×m) BYI 02960 a.s.; the water rate was 500-750 L/(ha×m) reflecting local practice in the trial regions. All treatments were made at the scheduled rates with the exception of one trial (11-2081-01) in which both applications were overdosed by 1.42% (159 g/(ha×m)), which is outside of the EU's nominal acceptance criteria (1.25%). Thus, this trial must be considered carefully in the evaluation of the data package.

Samples of pepper fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 14 days after treatment). The engaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01212 (cf. KHIA 4.3/05). The respective LOQs for the 3 analytes were 0.01 mg/kg, 0.02 mg/kg, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of pepper fruit was done within studies 10-2226 (soil drench study; available on request) and within study 11-2081 (cf. KHIA 6.3.1.6/03). Concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained during the conduct of all studies in sweet pepper. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg and 0.10 mg/kg, as well as 0.25 and 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (96-105%, RSDs of the larger validations sets [n > 2] 3.1-8.1%, n=1-7).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Fortification levels for DFA were 0.02 mg/kg, 0.20 mg/kg, and 0.40 mg/kg, as well as 2.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (96-97%, RSDs of the larger validations sets [n > 2] 4.0-13.4%, n=1-7).

Details of recovery data are shown in table 6.3.1.6-6. All trial data are summarized below in table 6.3.1.6-5a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in pepper fruit were between 0.11 mg/kg and 0.93 mg/kg (median 0.22 mg/kg). On day 3 – the envisaged PHI – the levels were 0.12-0.56 mg/kg, with a median value of 0.19 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). In these trials, the highest residue levels were seen on day 10 in one trial, and on day 14 in 5 trials.

Maximum residue levels at any relevant sampling interval (3 days post-application) over the complete set of trials ranged from 0.12-0.63 mg/kg (median 0.27 mg/kg).

Evaluation of representativity:

Trial 11-2081-01 was covered by approx. 41% of a considerably larger deviation than those nominally deemed "acceptable" in the EU (25%) or this reason, results of the trial at various sampling intervals were evaluated in the context of the entire peppers greenhouse program presented here. Residue levels at critical sampling events were close to the median over the entire set of trials. On day 0, immediately after the final application, 0.25 mg/kg was determined in this trial (median of all trials: 0.22 mg/kg). Similarly the values from e.g. day 3 (0.23 mg/kg) and from the maximum at any relevant interval (0.27 mg/kg) were very similar to the respective median values over all trials, 0.19 and 0.27 mg/kg. Thus, despite the nominal over dosage, this trial can be considered to be valid and its data representative.

In addition as highest residue levels were also seen in samples taken after the envisaged PHI of 3 days – on day 10 (trial 11-2081-01) or on day 14 (11-2081-02 and -05 through -08) – the entire set of trials was re-evaluated for its representativity.

Either "normal" or "plateau" residue behaviour was evident in three of the trials, 11-2081-01, -03, and -04, in which peak residues were measured on day 3 or 10. Similar behaviour was observed in 11-2081-06 and -08 as well, in which peak residues were seen at the final sampling interval (day 14); residue levels in these two tests were erratic from interval to interval, but fairly steady over time, and only minimally higher at day 14 (by 0.02 mg/kg) than at other earlier but non-consecutive intervals.

In the remaining three trials, residue levels increased steadily from approx. day 5 or 7 on, reaching their peak levels on day 14, the final sampling interval. Peak total residue levels here were 0.20, 0.40, and 0.18 mg/kg, meaning that none of these results is particularly close to the HR (0.63 mg/kg); even

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

if residues were to continue to increase, there is little indication that they would "arrive" at a level even close to the HR. This would seem to indicate that the values are indeed representative, and can be used in MRL evaluation.

The HR, 0.63 mg/kg, is itself derived from a day-14 sample (trial 11-2081-06). But as stated previously, the trial in question seems to exhibit "plateau" behaviour. As the HR is an important "driving factor" of the MRL (see KIIA 6.7.2), this situation must be considered carefully during MRL setting.

III. Conclusions (sweet peppers, greenhouse)

In order to support the use in the EU of BYI 02960 in sweet peppers, 8 valid trials were conducted in European greenhouses in the 2011 season. BYI 02960 was applied twice as an SL 20% formulation at an active substance rate of 112.5 g/(ha×m) per treatment. The application intervals were 10-13 days. All applications were at the required rates with the exception of one trial, in which the applications were overdosed by approx. 42% (150 g/(ha×m)); the trial in question was evaluated based on its residue results and is considered also to be valid. All trials were conducted according to G.P.

Samples were taken immediately after the final application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DEAF. The residues of all three analytes were summed to yield a calculated total residue of BYI 02960. The results of the trials presented above demonstrate that:

- total residue of BYI 02960 remained fairly constant in bell pepper fruit between the final application and the nominal PHI, from levels of 0.14-0.93 mg/kg on day 0 after the final treatment to 0.12-0.56 mg/kg on day 3. The respective median values were 0.22 and 0.19 mg/kg, respectively.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.12-0.63 mg/kg (median 0.27 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield suitable results for MRL evaluation, though care must be taken to evaluate the effects of peak residue levels determined at the final sampling interval.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-5a: Application scenario in residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2081 (11-2081-01) France [redacted] Greenhouse 2011	pepper, sweet Galileo type Lamayo/ 1/2 length	200 SL	2	0.15 (0.159 kg/[ha×m]) *	0.0150	81	3
11-2081 (11-2081-02) France [redacted] Greenhouse 2011	pepper, sweet Almuden; Pepper sweet	200 SL	2	0.191-0.203 (0.15 kg/[ha×m])	0.0150- 0.0160	89	3
11-2081 (11-2081-03) Spain [redacted] Greenhouse 2011	pepper, sweet Araan; greenhouse pepper	200 SL	2	0.214-0.225 (0.113 kg/[ha×m])	0.0150	89	3
11-2081 (11-2081-04) Spain [redacted] Greenhouse 2011	pepper, sweet Elvis California type	200 SL	2	0.214-0.225 (0.113 kg/[ha×m])	0.0150	89	3
11-2081 (11-2081-05) Italy [redacted] Greenhouse 2011	pepper, sweet clear: Yellow	200 SL	2	0.135 (0.113 kg/[ha×m])	0.0150	83	3
11-2081 (11-2081-06) Italy [redacted] Greenhouse 2011	pepper, sweet Corso di torre rossa	200 SL	2	0.135 (0.113 kg/[ha×m])	0.0150	83	3

FL = formulation GS = growth stage (BBCH-code) at last treatment

* In the first trial, the applications were overdosed by 40.6-41.8% due to the wrong height of crops used as a basis for the calculations for the application rate.

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Table 6.3.1.6-5a (cont'd): Application scenario in residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PH ₅₀ (Days)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2081 (11-2081-07) Greece GR [REDACTED] Greenhouse 2011	pepper, sweet Rico	200 SL	2	0.169-0.175 (0.113 kg/[ha×d])	0.0150- 0.0225	86	3
11-2081 (11-2081-08) Netherlands [REDACTED] Greenhouse 2011	pepper, sweet Stayer; Yellow	200 SL		0.225 (0.113 kg/[ha×d])	0.0150	84	3

FL = formulation GS = growth stage (BBCH-code) at last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-5b: Results of residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca
11-2081 (11-2081-01) France GLP: yes	fruit	0*	0.11	<0.02	<0.01	0.11
		0	0.22	<0.02	<0.01	0.22
		1	0.19	<0.02	<0.01	0.22
		3	0.19	0.031	<0.01	0.23
		5	0.17	0.031	<0.01	0.21
		7	0.17	0.040	<0.01	0.21
		10	0.20	0.063	<0.01	0.27
		14	0.16	0.087	0.013	0.26
11-2081 (11-2081-02) France GLP: yes	fruit	0*	0.053	0.026	<0.01	0.083
		0	0.15	0.035	<0.01	0.19
		1	0.13	0.022	<0.01	0.16
		3	0.13	0.026	<0.01	0.15
		5	0.9	0.035	<0.01	0.15
		7	0.088	0.026	<0.01	0.10
		10	0.066	0.044	<0.01	0.14
		14	0.08	0.10	<0.01	0.20
11-2081 (11-2081-03) Spain GLP: yes	fruit	0*	0.24	<0.02	<0.01	0.17
		0	0.23	<0.02	<0.01	0.26
		1	0.25	<0.02	<0.01	0.28
		3	0.24	<0.02	<0.01	0.28
		5	0.23	<0.02	<0.01	0.23
		7	0.35	0.021	<0.01	0.18
		10	0.14	0.00	0.015	0.19
		14	0.13	0.037	0.014	0.18
11-2081 (11-2081-04) Spain GLP: yes	fruit	0*	0.21	<0.02	<0.01	0.051
		0	0.084	<0.02	<0.01	0.11
		1	0.076	<0.02	<0.01	0.11
		3	0.088	<0.02	<0.01	0.12
		5	0.054	<0.02	<0.01	0.084
		7	0.056	0.021	<0.01	0.087
		10	0.029	0.035	<0.01	0.062
		14	0.051	0.038	<0.01	0.099
11-2081 (11-2081-05) Italy GLP: yes	fruit	0*	0.10	<0.02	<0.01	0.18
		0	0.29	<0.02	<0.01	0.32
		1	0.25	0.020	<0.01	0.28
		3	0.31	0.021	<0.01	0.34
		5	0.27	0.042	<0.01	0.25
		7	0.25	0.053	<0.01	0.24
		10	0.22	0.098	<0.01	0.33
		14	0.25	0.14	0.012	0.40
11-2081 (11-2081-06) Italy GLP: yes	fruit	0*	0.30	0.024	<0.01	0.43
		0	0.09	0.029	<0.01	0.93
		1	0.78	0.022	<0.01	0.81
		3	0.53	<0.02	<0.01	0.56
		5	0.57	0.022	0.011	0.61
		7	0.38	0.032	0.014	0.51
		10	0.36	0.030	0.012	0.40
		14	0.55	0.054	0.022	0.63

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.6-5b (cont'd): Results of residue trials conducted in/on **peppers** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca
GLP						
11-2081 (11-2081-07) Greece	fruit	0*	0.041	0.032	<0.01	0.073
		0	0.26	0.033	<0.01	0.303
		1	0.15	0.033	<0.01	0.193
		3	0.15	0.062	<0.01	0.222
		5	0.099	0.053	<0.01	0.166
GLP: yes		7	0.090	0.086	<0.01	0.176
		10	0.10	0.13	<0.01	0.24
		14	0.089	0.16	<0.01	0.26
11-2081 (11-2081-08) Netherlands	fruit	0*	0.061	<0.02	<0.01	0.091
		0	0.12	<0.02	<0.01	0.15
		1	0.12	<0.02	<0.01	0.15
		3	0.07	<0.02	<0.01	0.11
		5	0.02	<0.02	<0.01	0.15
GLP: yes		7	0.13	<0.02	<0.01	0.16
		10	0.12	0.022	<0.01	0.15
		14	0.14	0.033	<0.01	0.18

 DALT = days after last treatment
 * prior to last treatment

 Table 6.3.1.6-6: Recovery data for BYI 02960 in **peppers**

Study No. Trial No.	Crop	Portion analyzed	a.s. metakolite	n	Certification level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
11-2081 (11-2081-07) to (11-2081-08)	pepper and/or sweet	fruit	BYI 02960	7	0.01	94; 98; 88; 99; 98; 109; 98; 99	88	109	98	6.4
				5	0.10	108; 113; 101; 110; 94	94	110	103	6.1
				1	0.20	98	98	98		
				1	1.0	103	103	103		
GLP: yes 2011				14	overall		88	110	100	6.2
			DFA	7	0.01	91; 89; 90; 93; 90; 102; 125	89	125	97	13.4
				5	0.20	89; 98; 97; 96; 98	89	98	96	4.0
				1	0.40	95	95	95		
				1	2.0	94	94	94		
				14	overall		89	125	96	9.5
			BYI 02960-DFAF	7	0.01	90; 97; 85; 106; 102; 102; 105	85	106	98	8.1
				5	0.10	107; 100; 105; 103; 108	100	108	105	3.1
				1	0.20	96	96	96		
				1	1.0	106	106	106		
				14	overall		85	108	101	6.7

IIA 6.3.1.7 Fruiting vegetables – cucumber, incl. zucchini and gherkin (cucurbits – edible peel)

BYI 02960 is to be registered in Europe for use in cucumber and related crops (zucchini, gherkin). European residue data in cucumber crops are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.7-1.

Table 6.3.1.7-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulations in/on cucumber and related crops in European fields (southern residue regions) and greenhouses

Description	F/G	No. of appls.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"agricultural" use*	G	2	112.5 (g/ha×m) [†]	450	750 (ha×m)	14	3
"home & garden"***	F†	1	112.5	112.5	500-750	n/a	3
		2	112.5	450	500-750	14	3

- * agricultural use based on an SL 200 formulation
- ** "home & garden" uses with an SL 20 formulation (available to the general public via retail sales)
- † uses in southern residue region (EU-S)
- ‡ core rate per meter plant foliage height. Testing in greenhouse based on a max. height of 2 m, equating to max. 225 g a.s./ha.

In order to support the use of BYI 02960, sets of GAP trials were conducted in southern European fields and in greenhouses in 2010 and 2011. In southern European field-grown cucumber and gherkin, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200 containing 200 g/L BYI 02960 a.s.) at 14 day intervals. For the use in greenhouses, BYI 02960 was applied as in the field but at 10-day intervals. In both cases, the envisaged PHI was 3 days, reflecting the planned agricultural use in the greenhouse, as well as the intended worst-case field use.

Residue levels of BYI 02960 and its metabolites DFA and DF EAF were analyzed individually and summed to yield the calculated total residue of BYI 02960. The final residue levels of BYI 02960 in all cucumber fruit samples taken at or after the envisaged PHI for this crop of 3 days after the final application were 0.09-0.70 mg/kg in the southern field trials (median 0.21 mg/kg) and 0.18-0.52 mg/kg in the greenhouse (median 0.31 mg/kg).

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.7-2.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-2: Overview of European residue trials conducted in cucumber per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.7-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.7-2
		Veget. period 2010	2011	Σ	HR	STMR		
<i>trials in EUROPE</i>								
"agricultural" use	G	4	4	8	0.52	0.31	10-2189, 11-2067	03, 04
"home & garden"	EU-S	4	4	8	0.74	0.21	10-2184, 11-2066	01, 02

EU-S = southern EU field residue region, G = greenhouse

Southern European residue region (field)

Report:	KIIA 6.3.1.7/01, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on cucumber after spraying of BYI 02960 SL 200 in the field in France (south), Spain and Italy
Report No. & Document No.:	10-2184, dated September 10, 2012 M-438188-01-1

Report:	KIIA 6.3.1.7/02, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on gherkin after spray application of BYI 02960 SL 200 in the field in southern France, Spain and Italy
Report No. & Document No.:	11-2066, dated September 10, 2012 M-438326-01-1

Guidelines (<i>applies to both studies</i>):	Directive 91/414/EEC, residues in or on treated products, food and feed EC Guidance working document 629/VI/95 rev. 5 US EPA OCSPP Guideline No. 660.1500.SUPP
GLP (<i>applies to both studies</i>):	yes (certified laboratory); Deviations: none

I. Material and Methods

Eight field residue trials were conducted in the southern European residue region, as follows:

In 2010, 4 trials (southern France, Italy and Spain [2]) were conducted to support the use of BYI 02960 SL 200 in cucumber ([REDACTED] & [REDACTED], 2012, KIIA 6.3.1.7/01). Two applications were made at intervals of 14 days at a nominal rate of 0.625 L/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 500-800 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates. (The higher application rate used in 2010 was 11% higher than the rate to be registered as well with the EU's acceptance criteria for use pattern comparability.)

Four further trials were carried out in 2011, in France, Spain (2), and Italy, to complete the data package ([REDACTED] & [REDACTED], 2012, KIIA 6.3.1.7/02). All 2011 trials were conducted with gherkin varieties, in order to properly represent a typical array of sizes of this crop over the two-year span of



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

the trials. The basic application parameters were similar to those in 2010, except that applications were made at a nominal rate of 0.563 L/ha, corresponding to 112.5 g/ha BYI 02960 a.s.; the water rate was 500-600 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Samples of cucumber fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 or 14 days after treatment in the 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (for method details, cf. KIIA 4.3/03). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of cucumber fruit was done within study 19-2189 (cf. KIIA 6.3.1.7/03). During the conduct of the complete set of cucumber studies in 2010-2011, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of cucumber fruit. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg, 0.02 mg/kg, 0.10 mg/kg, and 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (90-102%, RSDs of the larger validation sets [n > 2] 0.6-7.7%, n=1-6).

Fortification levels for DFA were 0.02 mg/kg, 0.04 mg/kg, and 0.10 mg/kg, as well as 0.20 and 1.0 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (87-100%, RSDs of the larger validation sets [n > 2] 0.6-11.9%, n=6).

Details of recovery data are shown in table 6.3.1.7-4. All trial data are summarised below in table 6.3.1.7-3a & b and in greater detail in the Tier 2 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the total residue of BYI 02960 was calculated as the sum of these three analytes, expressed in parent equivalents).

On day 0, immediately following the 2nd and final treatment, residue levels in cucumbers/gherkins were between 0.12 and 1.0 mg/kg (median 0.15 mg/kg). On day 3 — the envisaged PHI — the levels were 0.07-0.67 mg/kg, again with a median value of 0.15 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). This was already evident in the 2010 trials, in which peak residue values were seen on day 4 (2 trials), or on day 7 (2 trials), the final day of sampling. In order to capture the maximum relevant residue levels, additional sampling was conducted 9-10 and 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 3 (1 trial), 9 (2 trials), or day 14 (1 trial).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Maximum residue levels at any relevant sampling interval (≥ 3 days post-application) over the complete set of trials ranged from 0.09-0.74 mg/kg (median 0.21 mg/kg).

There was no evidence of a difference in residue behaviour between gherkin and "normal" cucumber varieties.

Evaluation of representativity:

As highest residue levels were seen on the final sampling interval of three trials (10-2184-03 and -04 day 7; and 11-2066-01, day 14), the entire set of trials was re-evaluated for its representativity. In the 2010 package, trials 10-2184-01 to 03 essentially showed "plateau behaviour", with residues remaining fairly constant from the PHI to the final sampling date (day 3 to day 7). Only in trial 10-2184-04 was there an apparent "jump" in the residues on the final day, with the day-7 value of 0.22 mg/kg representing approx. twice the residue levels seen on days 2-4.

In 2011, "normal" decline behaviour was evident in trial 11-1066-02. In the remaining trials, a plateau was again seen in the samples taken from day 3 onwards. Trial 11-2066-01, which showed highest residues on day 14, showed a very minor increase in residues over time, from 0.12 mg/kg on day 3 to 0.16 mg/kg on day 14. These "increases" are very small, with the difference per sample interval of only 0.01-0.02 mg/kg; they are also within the scope of variability caused by sampling and analytical error. Thus, taken in the context of all of the trials, this trial can also be seen as yielding representative results.

Trial 10-2184-04 (cf. above) can also be viewed in the larger context. All of the general evidence from the remaining trials indicates that residue levels tend to "flatten" in the phase between days 3 and 14. Even given the "jump" to 0.22 mg/kg on the final sampling day of this trial, there is reason to believe that residues would not continue to climb appreciably. In addition, even if they were to reach double their day-7 levels, they would still not be higher than the highest residue seen in the rest of the studies (0.74 mg/kg), and thus would have no particular effect on the critical data used to evaluate and establish MRLs.

Thus the trials are considered to be valid and representative of the use described.

III. Conclusions (cucumber, southern European residue region)

In order to support the use in the EU of BYI 02960 in cucumber, 8 valid trials were conducted in the southern European residue region in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/ha and 112.5 g/ha per treatment in 2010 and 2011, respectively, both of which support the intended use rate (112.5 g/ha). The application intervals were approx. 4 days. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 remained fairly constant in cucumber/gherkin fruit between the final application and the nominal PHI, from levels of 0.12-1.0 mg/kg on day 0 after the final treatment to 0.09-0.67 mg/kg on day 3. The respective median values were 0.15 mg/kg at both dates.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.09 to 0.74 mg/kg (median 0.21 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.
- the residue behaviour in gherkin and "normal" cucumber varieties is similar.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-3a: Application scenario in residue trials conducted in/on **cucumber/gherkin** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/h (a.s.)		
10-2184 (10-2184-01) southern France [redacted] EU-S 2010	cucumber Marinda; Gherkin	200 SL	2	0.125	0.0250	88	3
10-2184 (10-2184-02) Spain [redacted] EU-S 2010	cucumber Llanoverde	200 SL	2	0.125	0.0156	73	3
10-2184 (10-2184-03) Italy [redacted] EU-S 2010	cucumber Mezzo lungo di Pognano	200 SL	2	0.125	0.0156	82	3
10-2184 (10-2184-04) France [redacted] EU-S 2010	cucumber Vert petit de Paris	200 SL	2	0.125	0.0227	79	3

FL = formulation

GS = growth stage (BBCO code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-3a (cont.): Application scenario in residue trials conducted in/on **cucumber/gherkin** after spraying with BYI 02960 SL 200 in field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2066 (11-2066-01) southern France [redacted] EU-S 2011	gherkin Raider F1; Cucumber	200 SL	2	0.113	0.0188	85	3
11-2066 (11-2066-02) Spain [redacted] EU-S 2011	gherkin Potomac; short cucumber	200 SL	2	0.113	0.0188	73	3
11-2066 (11-2066-03) Spain [redacted] EU-S 2011	gherkin Suso; field gherkin	200 SL	2	0.113	0.0188	79	3
11-2066 (11-2066-04) Italy [redacted] EU-S 2011	gherkin cetriolino di parisi; small fruit	200 SL	2	0.113	0.0226	87	3

FL = formulation

GS = growth stage (BBCO code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.7-3b: Results of residue trials conducted in/on **cucumber/gherkin** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFEA	total residue of BYI 02960 cal
10-2184 (10-2184-01) southern France GLP: yes	fruit	0*	<0.01	0.07	<0.01	0.09
		0	0.05	0.09	<0.01	0.14
		1	0.05	0.06	<0.01	0.11
		3	0.06	0.09	<0.01	0.17
		5	0.05	0.12	<0.01	0.19
		7	0.03	0.14	<0.01	0.17
		7	0.03	0.14	<0.01	0.17
10-2184 (10-2184-02) Spain GLP: yes	fruit	0*	0.05	0.20	<0.01	0.25
		0	0.04	0.18	<0.01	0.23
		1	0.05	0.17	<0.01	0.24
		3	0.04	0.17	<0.01	0.21
		4	0.06	0.20	<0.01	0.27
		7	0.03	0.19	<0.01	0.23
		7	0.03	0.19	<0.01	0.23
10-2184 (10-2184-03) Italy GLP: yes	fruit	0*	<0.01	0.03	<0.01	0.05
		0	0.04	0.03	<0.01	0.11
		1	0.04	0.03	<0.01	0.08
		3	0.02	0.04	<0.01	0.07
		5	0.02	0.04	<0.01	0.07
		7	<0.01	0.07	<0.01	0.09
		7	<0.01	0.07	<0.01	0.09
10-2184 (10-2184-04) southern France GLP: yes	fruit	0*	0.01	0.20	<0.01	0.09
		0	0.07	0.06	<0.01	0.13
		1	0.06	0.07	<0.01	0.15
		2	0.03	0.06	<0.01	0.10
		4	0.02	0.06	<0.01	0.12
		7	0.01	0.20	<0.01	0.22
		7	0.01	0.20	<0.01	0.22
11-2066 (11-2066-01) southern France GLP: yes	fruit	0*	<0.01	0.054	<0.01	0.074
		0	0.055	0.04	<0.01	0.12
		3	0.042	0.064	<0.01	0.12
		5	0.04	0.085	<0.01	0.13
		7	0.031	0.11	<0.01	0.15
		14	0.23	0.13	<0.01	0.16
		14	0.23	0.13	<0.01	0.16
11-2066 (11-2066-02) Spain GLP: yes	fruit	0*	0.06	0.20	<0.01	0.17
		0	0.2	0.096	<0.01	0.31
		3	0.27	0.088	<0.01	0.37
		7	0.082	0.2	<0.01	0.31
		10	0.064	0.20	<0.01	0.27
		14	0.15	0.19	<0.01	0.24
		14	0.15	0.19	<0.01	0.24
11-2066 (11-2066-03) Spain GLP: yes	fruit	0*	0.79	0.31	<0.01	0.40
		0	0.64	0.36	<0.01	1.0
		3	0.31	0.35	<0.01	0.67
		7	0.03	0.56	<0.01	0.64
		14	0.36	0.67	<0.01	0.74
		14	0.15	0.66	<0.01	0.69
		14	0.15	0.66	<0.01	0.69
11-2066 (11-2066-04) Italy GLP: yes	fruit	0*	0.01	0.036	<0.01	0.056
		0	0.10	0.026	<0.01	0.14
		3	0.46	0.045	<0.01	0.10
		7	0.028	0.066	<0.01	0.10
		9	<0.01	0.10	<0.01	0.12
		14	<0.01	0.090	<0.01	0.11
		14	<0.01	0.090	<0.01	0.11

 DALT = days after last treatment
 * prior to last treatment

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-4: Recovery data for BYI 02960 in cucumber/gherkin

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./metabolite	n	Fortification level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean RSD		
10-2184 (10-2184-01), to (10-2184-04) GLP: yes 2010	cucumber	fruit	BYI 02960	6	0.01	98; 103; 102; 97; 97; 88	98	103	98	5.9	
				1	0.02	96	96	96	96		
				4	0.1	105; 91; 101; 90	90	105	97	7.3	
				2	1.0	92; 96	90	92	91	5.6	
				13	overall		89	101	96	5.6	
			DFA	6	0.02	81; 110; 103; 103; 104; 88	88	110	100	11.5	
				1	0.04	92	92	92	92		
				3	0.1	98; 97; 98	97	98	98	6.6	
				1	0.20	95	95	95	95		
				2	1.0	86; 91	86	91	89	7.3	
				13	overall		86	100	97	7.3	
				BYI 02960-DFEAF	6	0.01	90; 89; 96; 100; 91; 84	84	100	92	6.1
					4	0.02	97	97	97	97	
4	0.10	97; 87; 92; 100	87		100	94	6.1				
2	1.0	95; 103	95		103	99	6.0				
13	overall		84		103	94	6.0				
11-2066 (11-2066-01) to (11-2066-04) GLP: yes 2011	cucumber/gherkin	fruit	BYI 02960	5	0.01	97; 104; 111; 98; 98	97	112	102	6.2	
				4	0.10	93; 93; 94; 94	93	94	94	0.6	
				2	1.0	89; 90	89	90	90	6.8	
				11	overall		89	112	97	6.8	
				DFA	5	0.02	77; 101; 106; 95; 102	77	106	96	11.9
			4		0.20	81; 91; 95; 89	81	95	89	6.6	
			2		1.0	87; 86	86	87	87	9.8	
			11		overall		77	106	92	9.8	
			BYI 02960-DFEAF		5	0.01	95; 99; 101; 94; 96	94	101	97	3.0
					4	0.10	90; 94; 97; 97	90	97	95	3.5
				2	1.0	90; 101	90	101	100	3.9	
				11	overall		90	101	96	3.9	

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Greenhouse

Report:	KIIA 6.3.1.7/03, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on cucumber after spray application of BYI 02960 SL 200 in the greenhouse in France (South), the Netherlands, Germany and Italy
Report No. & Document No.:	10-2189, dated July 23, 2012 M-435235-01-1

Report:	KIIA 6.3.1.7/04, [REDACTED]; [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on cucumber after spray application of BYI 02960 SL 200 in the greenhouse in Greece, Italy, Spain and Portugal
Report No. & Document No.:	11-2067, dated September 24, 2011 M-439079-01-1

Guidelines (applies to both studies):	Directive 2002/414/EC, residues in/on treated products, food and feed EC Guidance working document 7029/04/95 rev. 5 US EPA OCSPP Guidance No. 860.100.SL.P
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

1. Materials and Methods

Eight residue trials were conducted in the greenhouse, as follows:

In 2010, 4 trials (France, the Netherlands, Germany and Italy) were conducted to support the use of BYI 02960 SL 200 in cucumber. [REDACTED] & [REDACTED] 2012, KIIA 6.3.1.7/03. Two applications were made at intervals of 10 days (11 days in one trial) at a nominal rate of 0.625 L/(ha×m), corresponding to 125 g/(ha×m) BYI 02960 a.s.; the water rate was 750 L/(ha×m), reflecting local practice in the trial regions. All treatments were made at the scheduled rates. (The higher application rate used in 2010 was 11% higher than the rate to be registered, thus well within the EU's acceptance criteria for use pattern comparability.)

Four further trials were carried out in 2011 in Greece, Italy, and Portugal (2), to complete the data package ([REDACTED] & [REDACTED] 2012, KIIA 6.3.1.7/04). The basic application parameters were similar to those in 2010, except that applications were made at a nominal rate of 0.563 L/(ha×m), corresponding to 112.5 g/(ha×m) BYI 02960 a.s.. All treatments were made at the scheduled rates, except in one trial where the first application was over-dosed by 10% (corresponding to 124 g/[ha×m] BYI 02960 a.s.; water rate 788 L/[ha×m]) however, deviations were less than 25% and, therefore, well within the EU's standard acceptance criteria.

Samples of cucumber fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 or 14 days after treatment in the 2010 and 2011 trials, respectively). The envisaged PHI was 3 days.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using method 01304 (for method details, cf. KIIA 4.3/03). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of cucumber fruit was done within study 10-2189 (cf. KIIA 6.3.1.7/03). During the conduct of the complete set of cucumber studies in 2010-2011, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of cucumber fruit. This sample material is representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF were spiked at levels of 0.01 mg/kg, 0.02 mg/kg, 0.10 mg/kg, and 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2010 samples, and at levels of 0.01 mg/kg, 0.10 mg/kg, and 1.0 mg/kg in 2011. Mean recoveries were all within acceptable ranges (90-102%, RSDs of the larger validation sets $n > 2$ 0.6-7.7%, $n = 6$).

Fortification levels for DFA were 0.02 mg/kg, 0.04 mg/kg, and 0.10 mg/kg as well as 0.20 mg/kg and 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2010 samples and at levels of 0.02 mg/kg, 0.20 mg/kg, and 1.0 mg/kg in 2011. Mean recoveries were all within acceptable ranges (87-100%, RSDs of the larger validation sets $n > 2$ 0.6-1.9%, $n = 1-6$).

Details of recovery data are shown in table 6.3.1.7-5b. All trial data are summarised below in table 6.3.1.7-5a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the total residue of BYI 02960 was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in cucumbers were between 0.15 and 0.56 mg/kg (median 0.26 mg/kg). On day 3 — the envisaged PHI — the levels were 0.17-0.47 mg/kg with a median value of 0.29 mg/kg.

The analytical results revealed that total residue level often had not yet reached their highest levels at the nominal PHI (3 days). This was already evident in the 2010 trials for various crops, including cucumber, in which peak residue values were seen on day 7 in one trial, the final day of sampling. In order to ensure that the maximum relevant residue levels are captured, additional sampling was conducted 10 and 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 3 (3 trials), or day 10 (2 trials).

Maximum residue levels at any relevant sampling interval (≥ 3 days post-application) over the complete set of trials ranged from 0.18-0.52 mg/kg (median 0.31 mg/kg).

Evaluation of representativity:

As highest residue levels were seen on the final sampling interval of one of the trials (10-2189-03, day

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

7) and at intervals later than the PHI in others, the entire set of trials was re-evaluated for its representativity.

In the 2010 package, trials 10-2189-01, -02, and -04 essentially showed "plateau behaviour", with residues remaining fairly constant from the PHI to the final sampling date (day 0 to day 7). Only in trial 10-2189-03 was there an apparent "jump" in the residues on the final day, with the day-7 value of 0.52 mg/kg. However, this value represents only a small increase over the residue levels seen on days 1-5 (0.41-0.47 mg/kg).

In 2011, a plateau was again seen in three trials (11-2067-01, -02, -03) in the samples taken from day 3 onwards. Trial 11-2067-04, which showed highest residues on day 10, showed an increase in residues over time, from 0.25 mg/kg on day 3 to a peak value of 0.43 mg/kg on day 10; this was followed by a decrease, at least to the previous "plateau" level of residues on day 14 (0.40 mg/kg).

Trial 10-2189-03 (cf. above) can also be seen in this context. Its residues peaked at day 10, and essentially reached a "plateau" earlier. There is little reason to expect that the residues in this trial would continue to climb appreciably.

Thus the trials are considered to be valid and representative of the use described.

IIA Conclusions (cucumber greenhouse)

In order to support the use in the EU of BYI 02960 in cucumber, 8 valid trials were conducted in greenhouses in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/(ha×m) and 12.5 g/(ha×m) per treatment in 2010 and 2011, respectively, both of which support the intended use rate (112.5 g/[ha×m]). The application intervals were approx. 10 days. All applications were conducted as scheduled except for a minor deviation in a single trial, which was well within the EU acceptance criteria for use pattern comparability. All trials were conducted according to GLP.

Samples were taken immediately after the final application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analysed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DF and FEAF. The residues of all three analytes were summed to yield a calculated "total residue" of BYI 02960. The results of the trials presented above demonstrate that:

- total residues of BYI 02960 remained fairly constant, or even increased slightly, in cucumber fruit between the final application and the nominal PHI, from levels of 0.15-0.36 mg/kg on day 0 after the final treatment to 0.17-0.47 mg/kg on day 3. The median values were 0.26 mg/kg and 0.29 mg/kg on day 0 and 3, respectively.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.18-0.52 mg/kg (median 0.31 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.

Table 6.3.1.7-5a: Application scenario in residue trials conducted in/on cucumber after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application kg/ha (a.s.)	kg/hl (a.s.)	GS	PHI (days)
10-2189 (10-2189-01) southern France [redacted] Greenhouse 2010	cucumber Columbia	200 SL	2	0.213-0.231 (0.125 kg/[ha×m])	0.0167	81	3
10-2189 (10-2189-02) Netherlands [redacted] Greenhouse 2010	cucumber Roxanna	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	81	3
10-2189 (10-2189-03) Germany [redacted] Greenhouse 2010	cucumber Farmer	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	89	3
10-2189 (10-2189-04) Italy [redacted] Greenhouse 2010	cucumber Marina F1	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	73	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-5a (cont'd.): Application scenario in residue trials conducted in/on **cucumber** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/hl (a.s.)		
11-2067 (11-2067-01) Greece [redacted] Greenhouse 2011	cucumber Palmera long variety	200 SL	2	0.251-0.226 (0.113 kg/[ha×m])	0.0150	75	3
11-2067 (11-2067-02) Italy [redacted] Greenhouse 2011	cucumber Edona	200 SL	2	0.150-0.226 (0.113 kg/[ha×m])	0.0150 0.0151	77	3
11-2067 (11-2067-03) Portugal [redacted] Greenhouse 2011	cucumber Desoverde Small fruits	200 SL	2	0.223-0.226 (0.113 kg/[ha×m])- (0.124 kg/[ha×m])*	0.0150- 0.0157	83	3
11-2067 (11-2067-04) Portugal [redacted] Greenhouse 2011	cucumber Kanton ; Small fruits variety	200 SL	2	0.225 (0.113 kg/[ha×m])	0.0150	77	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

* The first application was overtopped by 18%

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.7-5b: Results of residue trials conducted in/on **cucumber** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country GLP	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	DFA	BYI 02960- DFEA	total residue of BYI 02960 cal
10-2189 (10-2189-01) southern France	fruit	0* 0 1 3 5 7	0.03 0.21 0.17 0.12 0.11 0.06	0.05 0.05 0.05 0.11 0.12 0.15	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.09 0.22 0.24 0.24 0.24 0.22
10-2189 (10-2189-02) Netherlands	fruit	0* 0 1 3 5 7	0.05 0.12 0.13 0.10 0.15 0.10	0.08 0.10 0.09 0.21 0.21 0.13	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.14 0.22 0.23 0.32 0.32 0.24
10-2189 (10-2189-03) Germany	fruit	0* 0 1 3 5 7	0.03 0.20 0.22 0.19 0.10 0.04	0.15 0.15 0.25 0.30 0.30 0.47	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.19 0.31 0.44 0.47 0.41 0.52
10-2189 (10-2189-04) Italy	fruit	0* 0 1 3 5 7	0.04 0.21 0.20 0.19 0.14 0.08	0.05 0.07 0.06 0.08 0.08 0.10	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.10 0.34 0.26 0.28 0.22 0.19
11-2067 (11-2067-01) Greece	fruit	0* 0 3 7 14	0.02 0.14 0.10 0.06 0.05 0.016	0.057 0.08 0.03 0.088 0.098 0.15	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.089 0.21 0.17 0.17 0.18 0.18
11-2067 (11-2067-02) Italy	fruit	0* 0 3 7 10 14	0.01 0.091 0.14 0.075 0.049 0.020	0.071 0.045 0.14 0.19 0.16 0.06	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.071 0.15 0.33 0.28 0.32 0.29
11-2067 (11-2067-03) Portugal	fruit	0* 0 3 7 10	0.06 0.05 0.13 0.04 0.04	0.11 0.12 0.15 0.22 0.20	<0.01 <0.01 <0.01 <0.01 <0.01	0.15 0.28 0.29 0.28 0.25
11-2067 (11-2067-04) Portugal	fruit	0* 0 3 10 14	0.084 0.19 0.16 0.09 0.058 0.13	0.062 0.057 0.078 0.12 0.37 0.16	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.16 0.25 0.25 0.32 0.43 0.30

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.7-6: Recovery data for BYI 02960 in cucumber

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level (mg/kg)	Recovery (%)						
						Individual recoveries	Min	Max	Mean	RSD		
10-2189 (10-2189-01), to (10-2189-04) GLP: yes 2010	cucumber	fruit	BYI 02960	6	0.01	98; 103; 102; 97; 97; 88	88	103	98	5.9		
				1	0.02	96	96	96				
				4	0.05	105; 91; 101; 90	90	105	95	2.1		
				2	1.0	92; 90	90	92	91			
				13	overall		88	105	96	5.8		
				DFA	6	0.02	91; 110; 105; 95; 103; 88	88	110	100	5.3	
					1	0.04	92	92	92			
					1	0.10	98; 97; 98	97	98	98	0.5	
					2	1.0	86; 91	86	91	89		
					7	overall		88	105	97	7.3	
					BYI 02960-DFAF	6	0.01	93; 89; 93; 100; 91; 84	84	100	92	6.1
						1	0.02	97	97	97		
				4		0.10	97; 87; 97; 100	87	100	94	6.1	
2	1.0	95; 102	95	103		99						
7	overall		87	103		94	6.0					
11-2067 (11-2067-01), to (11-2067-04) GLP: yes 2011	cucumber/ gherkin	fruit	BYI 02960	5	0.010	97; 112; 104; 98; 98	97	112	102	6.2		
				4	0.10	94; 99; 93; 88	93	94	94	0.6		
				1	1.0	89; 90	89	90	90			
				11	overall		89	112	97	6.8		
				DFA	5	0.02	101; 106; 95; 100; 77	77	106	96	11.9	
					4	0.20	95; 91; 89; 81	81	95	89	6.6	
					2	1.0	87; 86	86	87	87		
					7	overall		77	106	92	9.8	
					BYI 02960-DFAF	5	0.010	95; 101; 99; 94; 96	94	101	97	3.0
				2		0.10	97; 90; 94; 97	90	97	95	3.5	
				2		1.0	90; 101	90	101	96		
				11		overall		90	101	96	3.9	

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IIA 6.3.1.8 Fruiting vegetables – watermelon (cucurbits – inedible peel)

BYI 02960 is to be registered in Europe for use in watermelons. European residue data in melon crops are therefore presented below to support the intended use. Use pattern (GAP) information, including the European "agricultural use" as well as the "home & garden use" to be supported, is summarized in Table 6.3.1.8-1.

Table 6.3.1.8-1: Use patterns (GAPs) for the spray application of BYI 02960-containing formulation in/on watermelon in European fields (southern residue regions) and greenhouses

Description	F/G	No. of appls.	Application rate		Water volume (L/ha)	Interval (days)	PHI (days)
			per treatment (g a.s./ha)	per season (g a.s./ha)			
"agricultural" use*	G	2	112.5	225	500	14	3
"home & garden"***	F†	1	112.5	112.5	500-750	n/a	3
		2	112.5	225	500-750	14	3

* agricultural use based on an SL 200 formulation

** "home & garden" uses with an SL 50 formulation (available to the general public via retail sale)

† uses in the southern residue region (EU-S)

In order to support the EU "agricultural use" of BYI 02960, sets of GLP trials were conducted in southern European fields and in greenhouses in 2010 and 2011. In southern European field-grown melons or watermelons, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200, containing 200 g/L BYI 02960 a.s.), at 14-day intervals. In the greenhouse trials, BYI 02960 was applied twice as an SL formulation (BYI 02960 SL 200), at 10-day intervals. In both cases, the envisaged PHI was 3 days, reflecting the planned agricultural use in the greenhouse, as well as the intended worst-case field use.

Residue levels of BYI 02960 and its metabolites DFA and DEAF were analyzed individually and summed to yield the calculated "total residue of BYI 02960". The most critical residue levels were observed in the greenhouse trials, in which a highest total residue value (HR) of 0.30 mg/kg was determined. The STMR in these trials was also the highest for any set, at 0.17 mg/kg.

The number of trials conducted for each use described above (incl. information on geographical region and vegetation period) is summarized below in table 6.3.1.7-2.

Table 6.3.1.7-2: Overview of European residue trials conducted in melons/watermelons per geographical "residue region" and vegetation period, including key results

Use description (cf. table 6.3.1.8-1)	Region	No. of trials			Residue levels (mg/kg)		Report No.	Dossier ref.: IIA 6.3.1.8/...
		Veget. period 2010	2011	Σ	HR	STMR		
trials in Europe								
"home & garden"	EU-S	4	5	18	0.25	0.13	10-2185, 11-2074	01, 02
"agricultural" use	G	3	6		0.30	0.17		

EU-S = southern EU field residue region, G = greenhouse

Southern European residue region (field)

Report:	KIIA 6.3.1.8/01, [REDACTED], [REDACTED], [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on melon after spray application of BYI 02960 SL 200 in the field in Spain, Italy, France (South) and Portugal
Report No. & Document No.:	10-2185, dated October 1, 2012 M-439328-01-1
Report:	KIIA 6.3.1.8/02, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on water melon after spray application of BYI 02960 SL 200 in the field in Portugal, Italy and Spain
Report No. & Document No.:	11-2074, dated September 10, 2012 M-438099-01-1
Guidelines (applies to both studies):	Directive 2002/414/EC, residues in/on treated products, food and feed EU Guidance working document 02960/95 rev 5 US EPA OCSPP Guideline No. 860.1500.SUP
GLP (applies to both studies):	yes (certified laboratory); Deviations: none

I. Materials and Methods

Nine field residue trials were conducted in the southern European residue region, as follows:

In 2010, 4 trials (Spain, Italy, southern France and Portugal) were conducted in melons to support the use of BYI 02960 SL 200 ([REDACTED] & [REDACTED] 2010, KIIA 6.3.1.8/01). Two applications were made at intervals of 14 days at a nominal rate of 0.625 g/ha, corresponding to 125 g/ha BYI 02960 a.s.; the water rate was 800-900 L/ha reflecting local practice in the trial regions. All treatments were made at the scheduled rates. The higher application rate used in 2010 was 11% higher than the rate to be registered, thus well within the EU's acceptance criteria for use pattern comparability.)

Five further trials were carried out on watermelon in 2011, in Portugal, Italy (2) and Spain (2), to complete the data package ([REDACTED], 2012, KIIA 6.3.1.8/02). The basic application parameters were similar to those in 2010 but applications were made at a nominal rate of 0.563 L/ha, corresponding to 112.5 g/ha BYI 02960 a.s.; the water rate was 500-750 L/ha. Again, all treatments were made at the scheduled rates.

In 2010, samples of melon fruit were taken immediately prior and subsequent to the final application, and at several intervals thereafter (up to 7 days after treatment). In addition, samples of peel and pulp were taken on day 3. In 2011, samples of watermelon fruit were taken subsequent to the final application, and at several intervals thereafter (up to 14 days after treatment), and samples of peel and pulp were taken up to 10 days after the treatment. The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01304 (2010 trials; for method details, cf. KIIA 4.3/03) or 01212 (2011 trials; cf. KIIA

4.3/05). The respective LOQs for the 3 analytes were 0.01, 0.02, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of melon fruit was done within study 10-2185 (cf. KIIA 6.3.1.8/01) using method 01399 and within study 10-2074 (cf. KIIA 6.3.1.8/02) using method 01212. During the conduct of the complete set of melon studies, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of melon fruit, melon peel and melon pulp for samples originating from 2011. Samples of melon pulp are covered by the sample material of fruit in the 2010 study. The chosen sample materials are representative of all sample materials collected in these trials.

The recovery samples for parent and DFEAF in melon fruit were spiked at levels of 0.01 mg/kg and 0.50 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials and at levels of 0.01 mg/kg, 0.10 mg/kg and 2.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (93-104%, RSDs of the larger validation sets [$n > 2$] 4-8.1%, $n = 1-7$).

The recovery samples for parent and DFEAF in melon peel were spiked at levels of 0.01 mg/kg and 0.50 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials and at levels of 0.01 mg/kg, 0.10 mg/kg and 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (91-106%, RSDs of the larger validation sets [$n > 2$] 3-7.0%, $n = 1-5$).

The recovery samples for parent and DFEAF in melon pulp were spiked at levels of 0.01, 0.10, 0.50 and 1.0 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials. Mean recoveries were all within acceptable ranges (100-112%, RSDs of the larger validation sets [$n > 2$] 3.0-9.3%, $n = 1-3$).

Fortification levels for DFA in melon fruit were 0.02 mg/kg, and 0.50 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials and were 0.02 mg/kg, 0.20 mg/kg and 4.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (93-102%, RSDs of the larger validation sets [$n > 2$] 2.1-7%, $n = 1-7$).

Fortification levels for DFA in melon peel were 0.02 mg/kg, and 0.50 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials and were 0.02 mg/kg, 0.20 mg/kg and 2.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (92-101%, RSDs of the larger validation sets [$n > 2$] 2.6-8.0%, $n = 1-5$).

The recovery samples for DFA in melon pulp were spiked at levels of 0.02 mg/kg, 0.20 mg/kg, 1.0 mg/kg and 2.0 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Mean recoveries were all within acceptable ranges (96-102%, RSDs of the larger validation sets [$n > 2$] 2.6-4.7%, $n = 1-3$).

Details of recovery data are shown in table 6.3.1.8-4. All trial data are summarised below in table 6.3.1.8-3a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)



On day 0, immediately following the 2nd and final treatment, residue levels in melon/watermelon fruit were between 0.05 and 0.21 mg/kg (median 0.10 mg/kg). On day 3 — the envisaged PHI — the levels were 0.04-0.22 mg/kg, with a median value of 0.09 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI (3 days). This was already indicated by the 2010 trial packages for other crops, although peak residue values for melons were seen on day 4-5 in 3 trials as well. In order to ensure that the maximum relevant residue levels are captured, additional sampling was conducted 10 and 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 10 (2 trials), or day 14 (3 trials).

Maximum residue levels at any relevant sampling interval (3-14 days post-application) over the complete set of trials ranged from 0.05-0.25 mg/kg (median 0.13 mg/kg).

Residues were also determined in the edible portion of the fruit. In 2010, residue in pulp were either the same or slightly lower than those in the whole fruit; in pulp, they ranged from 0.04-0.12 mg/kg (median 0.06 mg/kg, mean peeling factor 0.89, n=4), as opposed to 0.04-0.15 mg/kg (median 0.07 mg/kg) in the corresponding fruit samples. Again in 2011, residues in the pulp were somewhat lower than in the fruit. Appropriate samples were analysed on days 3, 7 and 10; the mean peeling factors in the range of 0.71-0.74 at each interval (n=5 per interval). Across all samples measured, the mean peeling factor was determined to be 0.73.

Evaluation of representativity

As highest residue levels were seen at the final sampling interval of three trials (11-2074-02, -03, and -04, day 14), the entire set of trials was re-evaluated for its representativity.

In the 2010 package, the residue maximum (at least a "plateau level") was reached by day 3-5 in all trials.

In 2011, a plateau level of residues was again seen in the samples taken from at least day 10 onwards in trials 11-2074-01 and -05. The same trend is evident in the other three trials: Trials 11-2074-03 and -04, which yielded peak residues on day 14, showed minor increases in residues over time, 0.13 and 0.12 mg/kg on day 10 to 0.16 mg/kg and 0.16 mg/kg on day 14, respectively, the difference per sample interval being only 0.03-0.04 mg/kg. They are also within the scope of variability caused by sampling, biological, and/or analytical aspects. The peak residue value in trial 11-2074-02, 0.25 mg/kg, was also determined on day 14, the final day of sampling; this sample also reflects the highest relevant residue in any trial. However, from day 7 on, this trial also seems to exhibit plateau behaviour, evident in residue levels of 0.24, 0.24, and 0.25 mg/kg on days 7, 10, and 14, respectively. The residue value from this trial is the HR for this program and is thus significant for MRL calculation; yet, in light of the plateau behaviour, there is little reason to believe that the residues in this trial would increase appreciably at any further interval.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

When re-examining the previously mentioned trial nos. 11-2074-03 and -04 within a larger context, even if residues were to continue to increase after day 14, there is little indication that they would likely reach levels higher than the current HR value, and thus they will have little effect on the critical data used to evaluate and establish MRLs. Therefore, taken in the context of all of the trials, these trials can also be seen as yielding representative results.

Thus the trials as presented are considered to be valid and representative of the use described.

III. Conclusions (watermelon, southern European residue region)

In order to support the use in the EU of BYI 02960 in watermelon, 9 valid trials were conducted in the southern European residue region in the years 2010-2011 (4 on melon and 5 on watermelon). BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 25 g/ha per treatment in 2010 and at an a.s. rate of 112.5 g/ha in 2011, both of which support the intended use rate (112.5 g/ha). The application intervals were 4 days. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites, DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 remained fairly constant in melon/watermelon fruit between the final application and the nominal PHI from levels of 0.05-0.21 mg/kg on day 0 after the final treatment to 0.04-0.22 mg/kg on day 3, the respective median values were 0.10 mg/kg and 0.09 mg/kg.
- analytical results revealed that total residue levels often had not yet reached their highest levels at the nominal PHI.
- peak residue level at any relevant sampling interval (≥ 3 days post-application) ranged from 0.05-0.25 mg/kg (median 0.13 mg/kg).
- despite the delayed attainment of the maximum residue levels, the trials reported here are considered to yield representative results suitable for MRL evaluation.
- residue levels in the edible portion of this commodity (pulp) were slightly lower than those in the whole fruit; over 19 relevant samples, an average "peeling factor" of 0.76 was elucidated.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.8-3a: Application scenario in residue trials conducted in/on **melon/watermelon**, after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2185 (10-2185-01) Spain [redacted] EU-S 2010	melon, Seda	200 SL	2	0.125	0.0139	87	3
10-2185 (10-2185-02) Italy [redacted] EU-S 2010	melon, Mambo	200 SL	2	0.125	0.0208	88	3
10-2185 (10-2185-03) France [redacted] EU-S 2010	melon, Felino (typical of region)	200 SL	2	0.125	0.0208	87	3
10-2185 (10-2185-04) Portugal [redacted] EU-S 2010	melon, Lusitan (white melon)	200 SL	2	0.125	0.0208	85	3

FL = formulation

GS = growth stage (BBCO code) at last treatment

EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-3a (cont'd.): Application scenario in residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in field (*southern EU residue region*)

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2074 (11-2074-01) Portugal [REDACTED] EU-S 2011	watermelon Crimson- sweet; Striped	200 SL	2	0.113	0.0225	85	3
11-2074 (11-2074-02) Italy [REDACTED] EU-S 2011	watermelon Caravan; Typical Variety of Region	200 SL	2	0.113	0.0225	88	3
11-2074 (11-2074-03) Spain [REDACTED] EU-S 2011	watermelon Azabache hybrid, dark bark with seeds	200 SL	2	0.113	0.0161- 0.0188	82	3
11-2074 (11-2074-04) Italy [REDACTED] EU-S 2011	watermelon Vanity; Red	200 SL	2	0.113	0.0150	81	3
11-2074 (11-2074-05) Spain [REDACTED] EU-S 2011	watermelon Huelva	200 SL	2	0.113	0.0150	85	3

FL = formulation GS = growth stage (BBCH code) at last treatment
 EU-S = southern European residue region

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-3b: Results of residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca.
10-2185 (10-2185-01) Spain GLP: yes	fruit	0*	<0.01	0.02	<0.01	0.05
		0	0.02	0.02	<0.01	0.05
		1	<0.01	<0.02	<0.01	0.04
		3	0.01	<0.02	<0.01	0.04
		4	<0.01	0.03	<0.01	0.04
	7	0.01	0.03	<0.01	0.05	
	peel	3	0.02	<0.02	<0.01	0.05
	pulp	3	0.01	0.01	<0.01	0.04
10-2185 (10-2185-02) Italy GLP: yes	fruit	0*	0.01	0.06	<0.01	0.08
		0	0.07	0.05	<0.01	0.12
		1	0.07	0.05	<0.01	0.12
		3	0.05	0.09	<0.01	0.15
		5	0.05	0.13	<0.01	0.18
	7	0.02	0.13	<0.01	0.17	
	peel	3	0.07	0.01	<0.01	0.15
	pulp	3	<0.01	0.10	<0.01	0.12
10-2185 (10-2185-03) France GLP: yes	fruit	0*	0.02	0.05	<0.01	0.07
		0	0.05	0.05	<0.01	0.11
		1	0.06	0.05	<0.01	0.12
		3	0.03	0.06	<0.01	0.09
		5	0.04	0.06	<0.01	0.12
	7	0.02	0.08	<0.01	0.12	
	peel	3	0.01	0.06	<0.01	0.13
	pulp	3	<0.01	0.01	<0.01	0.07
10-2185 (10-2185-04) Portugal GLP: yes	fruit	0*	<0.01	0.02	<0.01	0.04
		0	<0.01	0.02	<0.01	0.06
		1	<0.01	0.03	<0.01	0.05
		3	0.02	0.03	<0.01	0.05
		6	0.01	0.03	<0.01	0.05
	7	<0.01	0.03	<0.01	0.05	
	peel	3	<0.01	0.02	<0.01	0.06
	pulp	3	<0.01	0.03	<0.01	0.05

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-3b (cont'd): Results of residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca.
11-2074 (11-2074-01) Portugal GLP: yes	fruit	0	0.030	0.057	<0.01	0.077
		3	0.022	0.068	<0.01	0.10
		7	0.010	0.073	<0.01	0.093
		10	0.010	0.10	<0.01	0.13
	peel	3	0.040	0.095	<0.01	0.15
		7	0.017	0.095	<0.01	0.12
		10	0.027	0.12	<0.01	0.15
	pulp	3	<0.01	0.50	<0.01	0.070
		7	<0.01	0.50	<0.01	0.070
10		<0.01	0.069	<0.01	0.089	
11-2074 (11-2074-02) Italy GLP: yes	fruit	0	0.067	0.12	<0.01	0.2
		3	0.069	0.14	<0.01	0.22
		7	0.044	0.18	<0.01	0.24
		10	0.06	0.18	<0.01	0.24
	peel	3	0.16	0.21	<0.01	0.34
		7	0.095	0.22	<0.01	0.33
		10	0.06	0.21	<0.01	0.29
	pulp	3	0.18	0.10	<0.01	0.13
		7	0.016	0.3	<0.01	0.16
10		0.019	0.15	<0.01	0.18	
11-2074 (11-2074-03) Spain GLP: yes	fruit	0	0.027	0.039	<0.01	0.076
		3	0.022	0.038	<0.01	0.090
		6	0.027	0.089	<0.01	0.13
		10	0.01	0.10	<0.01	0.13
	peel	3	0.049	0.069	<0.01	0.13
		6	0.053	0.11	<0.01	0.18
		10	0.021	0.11	<0.01	0.14
	pulp	3	0.10	0.04	<0.01	0.063
		6	0.01	0.061	<0.01	0.081
10		0.01	0.093	<0.01	0.11	

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-3b (cont'd): Results of residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in the field (*southern EU residue region*)

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960			
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylammonofuranone	total residue of BYI 02960 ca.
11-2074 (11-2074-04) Italy GLP: yes	fruit	0	0.031	0.062	<0.01	0.10
		3	0.021	0.071	<0.01	0.10
		7	0.011	0.086	<0.01	0.11
		10	0.010	0.096	<0.01	0.12
		14	<0.01	0.13	<0.01	0.13
	peel	3	0.042	0.080	<0.01	0.13
		7	0.015	0.092	<0.01	0.12
		10	0.022	0.11	<0.01	0.13
	pulp	3	<0.01	0.046	<0.01	0.069
		7	<0.01	0.05	<0.01	0.085
		10	<0.01	0.057	<0.01	0.077
	11-2074 (11-2074-05) Spain GLP: yes	fruit	0	0.011	0.058	<0.01
3			<0.01	0.046	<0.01	0.066
7			<0.01	0.059	<0.01	0.079
10			<0.01	0.081	<0.01	0.11
14			<0.01	0.074	<0.01	0.094
peel		3	<0.01	0.075	<0.01	0.075
		7	<0.01	0.083	<0.01	0.10
		10	<0.01	0.099	<0.01	0.12
pulp		3	<0.01	0.057	<0.01	0.057
		7	<0.01	0.049	<0.01	0.069
		10	<0.01	0.063	<0.01	0.083

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.8-4 (cont'd.): Recovery data for BYI 02960 in melon/watermelon

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
11-2074 11-2074-01- to 11-2074-05 GLP: yes 2011	water- melon	fruit	BYI 02960	3	0.01	91; 99; 107	91	107	99	8.1
				7	0.10	105; 94; 105; 108; 102; 95; 117	94	117	104	7.7
				1	1.0	105	105	105	105	0.0
			11	overall		91	117	103	7.7	
			DFA	3	0.02	91; 102; 104	97	104	101	3.6
				7	0.20	104; 103; 101; 104; 102; 98; 101	98	104	102	2.1
	11	overall			97	104	102	2.3		
	BYI 02960- DFAEAF	3	0.01	91; 91; 99	91	99	94	4.9		
		7	0.10	104; 103; 113; 101; 102; 104	93	113	103	5.7		
		11	overall		91	113	100	6.5		
	water- melon	peel	BYI 02960	3	0.01	100; 101; 109	100	109	103	4.8
				7	0.10	94; 106; 107; 108; 94	94	108	102	7.0
1				1.0	103	103	103	0.0		
9			overall		94	109	102	5.5		
DFA			3	0.02	102; 104; 98	98	104	101	3.0	
			5	0.20	96; 100; 101; 98; 95	95	101	98	2.6	
	9	overall		92	104	98	3.8			
BYI 02960- DFAEAF	3	0.01	100; 102; 93	93	102	98	4.8			
	7	0.10	101; 106; 105; 111; 109	101	111	106	3.6			
	1	1.0	95	95	95	0.0				
9	overall		93	111	102	5.9				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-4 (cont'd.): Recovery data for BYI 02960 in **melon/watermelon**

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean RSD	
11-2074 11-2074-01- to 11-2074-05 GLP: yes 2011	water- melon	pulp	BYI 02960	3	0.01	96; 111; 94	94	111	100	6.3
				3	0.10	101; 104; 98	98	104	101	3.0
				1	0.50	99	99	99		
				1	1.0	95	95	99		
				8	overall		94	111	100	5.6
				3	0.02	91; 100; 96	91	100	96	4.0
			DFA	3	0.20	100; 100; 101	100	100	100	2.6
				1	0.50	94	94	94		
				1	2.0	93	93	93		
				8	overall		93	100	98	2.9
				3	0.01	116; 108; 111	108	116	112	3.6
				3	0.10	111; 106; 100	104	111	107	3.4
BYI 02960- DFA	1	0.50	105	105	105					
	8	overall		97	116	107	5.3			

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Greenhouse

Report:	KIIA 6.3.1.8/03, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on melon after spray application of BYI 02960 SL 200 in the greenhouse in the Netherlands, Italy and Spain
Report No. & Document No.:	10-2188, dated February 23, 2012 M-425792-01-1
Guidelines:	Directive 91/414/EEC, residues in or on treated products, food and feed EC Guidance working document 7029/VI/95 rev. 5
GLP:	yes (certified laboratory); Deviations: none

Report:	KIIA 6.3.1.8/04, [REDACTED] 2012
Title:	Determination of the residues of BYI 02960 in/on water melon after spraying application of BYI 02960 SL 200 in the greenhouse in Spain and Italy
Report No. & Document No.:	11-2075, dated September 4, 2012 M-437681-01-1
Guidelines:	Directive 91/414/EEC, residues in or on treated products, food and feed EC Guidance working document 7029/VI/95 rev. 5 US EPA OCSPP Guideline No. 960.1500.SUPP applies only to 11-2075
GLP:	yes (certified laboratory); Deviations: none

Materials and Methods

Nine residue trials were conducted in the greenhouse as follows:

In 2010, 3 trials were conducted in melons in the greenhouse (in the Netherlands, Italy, Spain) to support the use of BYI 02960 SL 200 ([REDACTED] 2012, KIIA 6.3.1.8/03). Two applications were made at intervals of 10 days at a nominal rate of 0.625 L/(ha×m), corresponding to 125 g/(ha×m) BYI 02960 a.s.; the water rate was 750 L/(ha×m), reflecting local practice in the trial regions. All treatments were made at the scheduled rates with the exception of the second application in one trial, which was underdosed by 7.7% (nominal rate: 115 L/ha (0.57 L/[ha×m]), corresponding to 115 g/[ha×m] BYI 02960 a.s.), but well within the EU's standard acceptance criteria allowing a deviation of 25%. In addition the higher application rate used in 2010 was 41% higher than the rate to be registered, thus well within the EU's acceptance criteria for use pattern comparability.

Six further trials were carried out in 2011 in the greenhouse in watermelons (in Italy [4] and Spain [2]), to complete the data package ([REDACTED] 2012, KIIA 6.3.1.8/04). The basic application parameters were similar to those in 2010: two applications were made at intervals of 13-14 days at a nominal rate of 0.63 L/ha, corresponding to 112.5 g/ha BYI 02960 a.s. (watermelon plants are not commonly cultivated into high plants in greenhouses, thus height adjustment was not considered to be necessary); the water rate was 500-900 L/ha, reflecting local practice in the trial regions. All treatments were made at the scheduled rates.

Samples of melon/watermelon fruit were taken immediately prior and subsequent to the second application, and at several intervals thereafter (up to 7 days after treatment in 2010 and up to 14 days



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

in 2011 trials). In addition, samples of pulp and peel were taken 3 days after the second application in 2010, and up to 9-10 days after the second application in 2011.

The envisaged PHI was 3 days.

The samples were analyzed for the parent compound and its metabolites DFA and DFEAF using methods 01212 (cf. KIIA 4.3/05). The respective LOQs for the 3 analytes were 0.01 mg/kg, 0.02 mg/kg, and 0.01 mg/kg (all in parent equivalents).

II. Findings

Validation of melon fruit was done within study 10-2785 (cf. KIIA 6.3.1.8/01) using method 01304 and within study 10-2074 (cf. KIIA 6.3.1.8/02) using method 01212. During the conduct of the complete set of melon studies, concurrent recoveries of BYI 02960 and its metabolites DFA and DFEAF were obtained from samples of melon fruit, peel and pulp. The chosen sample materials are representative of all sample material collected in these trials.

The recovery samples for parent and DFEAF in melon fruit were spiked at levels of 0.01 mg/kg, 0.1 mg/kg and 1 mg/kg (expressed in BYI 02960 equivalents). Mean recoveries were all within acceptable ranges (85-100%, RSDs of the large validation sets [$n \geq 10$]: 8.1%, $n=1-5$).

The recovery samples for parent and DFEAF in melon peel were spiked at levels of 0.01 mg/kg, 0.1 mg/kg and 1 mg/kg (expressed in BYI 02960 equivalents) for 2010 trials and at levels of 0.01 mg/kg, 0.1 mg/kg and 2 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Overall mean recoveries were all within acceptable ranges (87-103%, overall RSDs 4.9-8.7%, $n=3-2$).

The recovery samples for parent and DFEAF in melon pulp were spiked at levels of 0.01 mg/kg, 0.10 mg/kg, 1.0 mg/kg (expressed in BYI 02960 equivalents). Overall mean recoveries were all within acceptable ranges (89-99%, overall RSDs 3.0-8.6%, $n=4-6$).

Fortification levels for DFA in melon fruit were 0.02 mg/kg, and 0.20 mg/kg and 2.0 mg/kg (expressed in BYI 02960 equivalents). Overall mean recoveries were all within acceptable ranges (89-94%, overall RSDs 7.9-12.9%, $n=3-8$).

Fortification levels for DFA in melon peel were 0.02 mg/kg, 0.20 mg/kg and 2.0 mg/kg (2010 trial), and were 0.02 mg/kg, 0.2 mg/kg and 4 mg/kg (expressed in BYI 02960 equivalents) for 2011 trials. Overall mean recoveries were all within acceptable ranges (89-95%, overall RSDs 8.9-10.0%, $n=3-5$).

The recovery samples for DFA in melon pulp were spiked at levels of 0.02 mg/kg, 0.20 mg/kg, and 2.0 mg/kg (expressed in BYI 02960 equivalents). Overall mean recoveries were all within acceptable ranges (90-97%, overall RSDs 7.1-15.5%, $n=4-6$).

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Details of recovery data are shown in table 6.3.1.8-6. All trial data are summarised below in table 6.3.1.8-5a & b and in greater detail in the Tier 1 summary forms. (Residues of parent BYI 02960 as well as its metabolites DFA and DFEAF are expressed in BYI 02960 equivalents. From these individual values, the "total residue of BYI 02960" was calculated as the sum of these three analytes, expressed in parent equivalents.)

On day 0, immediately following the 2nd and final treatment, residue levels in melon/watermelon fruit were between 0.085 and 0.23 mg/kg (median 0.10 mg/kg). On day 3 — the envisaged PHI — the levels were 0.069-0.21 mg/kg, with a median value of 0.16 mg/kg.

The analytical results revealed that total residue levels often had not yet reached their peak levels at the nominal PHI (3 days). This was already evident in the 2010 trials, in which peak residue values were seen on the final day of sampling, day 7 in 2 trials. In order to capture the maximum relevant residue levels, additional sampling was conducted 9-10 and 14 days after treatment in the 2011 program; in those trials, the highest residue levels were seen on day 14 in all six of the trials.

Maximum residue levels at any relevant sampling interval (≥ 3 days post application) over the complete set of trials ranged from 0.10-0.30 mg/kg (median 0.17 mg/kg).

Residues were also determined in the edible portion of the fruit. In 2010, residues in pulp were somewhat lower than those in the whole fruit; in pulp, they ranged from 0.05-0.15 mg/kg (median 0.11 mg/kg, mean peeling factor 0.64, n=3) as opposed to 0.16-0.17 mg/kg (median 0.17 mg/kg) in the corresponding fruit samples. Again in 2011, residues in the pulp were lower than in the fruit. Appropriate samples were analysed on days 3, 7, and 14; the mean peeling factors ranged from 0.75-0.82 at each interval (n=6 per interval). Across all samples measured, the mean peeling factor was determined to be 0.77.

Evaluation of representativity

As highest residue levels were seen at the final sampling interval of eight trials (10-2188- 02 and -03, day 7; and 11-2075, all trials, day 14) the entire set of trials was re-evaluated for its representativity.

In the 2010 package, peak residues were determined at the scheduled PHI (3 days) in trial 10-2188-01. In trials 10-2188-02 and -03, residue levels increased slowly from the PHI to the final sampling event (day 7). In 2011, this trend was also evident, with fairly "flat" yet slowly increasing levels up to the final sampling interval (day 14) in all trials.

Given these conditions, the highest measured residues – generally the final sampling interval – will be chosen from each trial for MRL calculation. Further evaluation of the effects of the increasing residues on the validity of the calculations will be made in the appropriate chapter (KIIA 6.7.2).

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III. Conclusions (watermelon, greenhouses)

In order to support the use in the EU of BYI 02960 in watermelon/melon, 9 trials were conducted in the greenhouse in the years 2010-2011. BYI 02960 was applied twice as an SL 200 formulation at an active substance rate of 125 g/(ha×m) and 112.5 g/ha per treatment in 2010 and 2011, respectively, both of which support the intended use rate (112.5 g/ha). The application intervals were 10 days in 2010 and 13-14 days in 2011. All applications were at the required rates, and all trials were conducted according to GLP.

Samples were taken immediately after the 2nd application and at several intervals thereafter, including the envisaged PHI of 3 days. They were analyzed for the relevant residues of BYI 02960, comprising the parent compound and its metabolites DFA and DFEAF. The residues of all three analytes were summed to yield a calculated "total residue of BYI 02960". The results of the trials presented above demonstrate that:

- total residues of BYI 02960 remains quite constant, even increasing slightly in watermelon/melon fruit between the final application and the nominal PHI, from levels of 0.08-0.23 mg/kg on day 0 after the final treatment to 0.06-0.21 mg/kg on day 3. The respective median values were 0.10 and 0.16 mg/kg, respectively
- analytical results revealed that total residue levels generally had not yet reached their highest levels at the nominal PHI. In most trials, total residues continued to increase over the sampling period, with the final sampling interval yielding the highest residues.
- peak residue levels at any relevant sampling interval (≥ 3 days post-application) ranged from 0.10-0.30 mg/kg, median 0.17 mg/kg.
- residue levels in the edible portion of this commodity (pulp) were slightly lower than those in the whole fruit; over 7 relevant samples, an average "peeling factor" of 0.77 was elucidated.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-5a: Application scenario in residue trials conducted in/on **melon/watermelon**, after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (days)
				kg/ha (a.s.)	kg/ha (a.s.)		
10-2188 (10-2188-01) Netherlands [REDACTED] Greenhouse 2010	melon, Haon	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	81	3
10-2188 (10-2188-02) Italy [REDACTED] Greenhouse 2010	melon, Talento (Clause)	200 SL	2	0.250 (0.125 kg/[ha×m])	0.0167	81	3
10-2188 (10-2188-03) Spain [REDACTED] Greenhouse 2010	melon, Jucar	200 SL	2	0.250 - 0.250 (0.115 - 0.125 kg/[ha×m])	0.0167	89	3

FL = formulation

GS = growth stage (BBCH-code) at last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-5a (cont'd.): Application scenario in residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country Location Region Year	Crop Variety	FL	No.	Application		GS	PHI (day)
				kg/ha (a.s.)	kg/ha (a.s.)		
11-2075 (11-2075-01) Spain [redacted] Greenhouse 2011	watermelon Fashion; Black	200 SL	2	0.113	0.0125	88	3
11-2075 (11-2075-02) Italy [redacted] Greenhouse 2011	watermelon Melania; Typical of the region	200 SL	2	0.113	0.0141	82	3
11-2075 (11-2075-03) Spain [redacted] Greenhouse 2011	watermelon Motril; White	200 SL	2	0.113	0.0125	81	3
11-2075 (11-2075-04) Italy [redacted] Greenhouse 2011	watermelon Sentinel; Typical of the region	200 SL	2	0.113	0.0141	72	3
11-2075 (11-2075-05) Italy [redacted] Greenhouse 2011	watermelon top gun late variety	200 SL	2	0.113	0.0226	87	3
11-2075 (11-2075-06) Italy [redacted] Greenhouse 2011	watermelon Gimson Sweet Red	200 SL	2	0.113	0.0161	83	3

FL = formulation GS = growth stage (BBCH-code) at last treatment

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-5b (cont'd): Results of residue trials conducted in/on **melon/watermelon** after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960				
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca.	
11-2075 (11-2075-01) Spain GLP: yes	fruit	0*	<0.01	0.044	△0.01	0.00	
		0	0.052	0.042	△0.01	0.10	
		3	0.012	0.047	△0.01	0.069	
		5	0.014	0.047	△0.01	0.072	
		7	0.012	0.087	△0.01	0.11	
		9	<0.01	0.082	△0.01	0.08	
	peel	14	<0.01	0.11	△0.01	0.13	
		3	0.033	0.072	△0.01	0.12	
		7	0.028	0.13	△0.01	0.17	
		9	0.020	0.12	△0.01	0.15	
		pulp	3	<0.01	0.026	△0.01	0.046
			7	<0.01	0.058	△0.01	0.078
9	<0.01		0.068	△0.01	0.08		
11-2075 (11-2075-02) Italy GLP: yes	fruit	0*	0.028	0.049	△0.01	0.087	
		0	0.04	0.038	△0.01	0.094	
		3	0.033	0.051	△0.01	0.094	
		5	0.029	0.058	△0.01	0.097	
		7	0.025	0.06	△0.01	0.11	
		10	0.027	0.081	△0.01	0.12	
	peel	14	0.027	0.11	△0.01	0.14	
		3	0.087	0.056	△0.01	0.15	
		7	0.049	0.09	△0.01	0.15	
		10	0.061	0.1	△0.01	0.18	
		pulp	3	<0.01	0.040	△0.01	0.060
			7	<0.01	0.07	△0.01	0.091
10	<0.01	0.056	△0.01	0.076			
11-2075 (11-2075-03) Spain GLP: yes	fruit	0*	<0.01	0.024	△0.01	0.044	
		0	0.050	0.030	△0.01	0.089	
		3	0.027	0.03	△0.01	0.071	
		5	0.014	0.04	△0.01	0.068	
		7	0.015	0.057	△0.01	0.078	
		10	<0.01	0.045	△0.01	0.065	
	peel	14	<0.01	0.081	△0.01	0.10	
		3	0.061	0.07	△0.01	0.12	
		7	0.026	0.074	△0.01	0.11	
		10	0.028	0.065	△0.01	0.10	
		pulp	3	<0.01	0.035	△0.01	0.055
			7	<0.01	0.049	△0.01	0.069
9	<0.01		0.054	△0.01	0.074		

 DALT = days after last treatment
 * prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.8-5b (cont'd.): Results of residue trials conducted in/on melon/watermelon after spraying with BYI 02960 SL 200 in the greenhouse

Study No. (Trial No.) Country	Portion analyzed	DALT (days)	Residues (mg/kg) expressed as BYI 02960				
			BYI 02960	difluoroacetic acid	BYI 02960-difluoroethylamino-furanone	total residue of BYI 02960 ca	
11-2075 (11-2075-04) Italy GLP: yes	fruit	0*	0.019	0.12	△0.01	0.18	
		0	0.073	0.11	△0.01	0.19	
		3	0.044	0.12	△0.01	0.18	
		5	0.049	0.11	△0.01	0.17	
	GLP: yes		7	0.034	0.16	△0.01	0.20
			10	0.024	0.21	△0.01	0.23
			14	0.022	0.24	△0.01	0.27
			14	0.022	0.24	△0.01	0.27
	peel	3	0.076	0.13	△0.01	0.22	
		7	0.066	0.22	△0.01	0.29	
		10	0.042	0.23	△0.01	0.31	
		10	0.042	0.23	△0.01	0.31	
pulp	3	0.014	0.12	△0.01	0.14		
	7	0.014	0.14	△0.01	0.16		
	7	0.014	0.14	△0.01	0.16		
	10	0.012	0.15	△0.01	0.17		
11-2075 (11-2075-05) Italy GLP: yes	fruit	0*	0.012	0.18	△0.01	0.18	
		0	0.046	0.18	△0.01	0.23	
		3	0.033	0.16	△0.01	0.21	
		5	0.032	0.19	△0.01	0.23	
	GLP: yes		7	0.024	0.21	△0.01	0.24
			10	0.027	0.24	△0.01	0.26
			14	0.017	0.28	△0.01	0.30
			14	0.017	0.28	△0.01	0.30
	peel	3	0.038	0.18	△0.01	0.27	
		7	0.044	0.19	△0.01	0.30	
		10	0.029	0.29	△0.01	0.33	
		10	0.029	0.29	△0.01	0.33	
pulp	3	0.011	0.16	△0.01	0.19		
	7	0.013	0.19	△0.01	0.21		
	7	0.013	0.19	△0.01	0.21		
	10	0.012	0.20	△0.01	0.22		
11-2075 (11-2075-06) Italy GLP: yes	fruit	0*	0.019	0.031	△0.01	0.059	
		0	0.041	0.034	△0.01	0.085	
		3	0.011	0.06	△0.01	0.098	
		5	0.037	0.17	△0.01	0.12	
	GLP: yes		7	0.028	0.11	△0.01	0.15
			10	0.020	0.096	△0.01	0.14
			14	0.025	0.12	△0.01	0.16
			14	0.025	0.12	△0.01	0.16
	peel	3	0.029	0.16	△0.01	0.095	
		7	0.035	0.093	△0.01	0.14	
		10	0.021	0.11	△0.01	0.16	
		10	0.021	0.11	△0.01	0.16	
pulp	3	△0.01	0.055	△0.01	0.075		
	7	△0.01	0.093	△0.01	0.11		
	7	△0.01	0.093	△0.01	0.11		
	10	△0.01	0.084	△0.01	0.10		

DALT = days after last treatment
* prior to last treatment

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-6: Recovery data for BYI 02960 in **melon/watermelon**

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean RSD	
10-2188 (10-2188-01- to 10-2188-03) GLP: yes 2010	Melon	fruit	BYI 02960	1	0.01	81	81	81	78.1	
				1	0.1	110	110			
				1	1	82	82			
				3	overall	81	110			
				1	0.02	78	78			
				3	overall	78	101			
		1	0.20	101	101	12.9				
		1	2.0	89	89					
		3	overall	78	101					
		1	0.01	72	72					
		3	overall	72	102					
		3	overall	72	102					
	1	0.5	102	102	85	17.9				
	1	1.0	82	82						
	3	overall	72	102						
	1	0.01	94	94			100	5.5		
	1	0.1	94	94						
	1	1	103	103						
	3	overall	94	104						
	1	0.02	84	84						
	3	overall	84	101						
	1	0.20	100	100	95	10.0				
	1	2.0	102	102						
	3	overall	84	101						
1	0.05	102	102	103			4.9			
1	0.5	108	108							
1	1.0	98	98							
3	overall	98	108							
1	0.05	104; 98; 99; 91	98		104	2.6				
1	0.1	96	96							
1	1	97	97							
3	overall	96	104							
4	0.02	76; 89; 119; 90	76	94			19.4			
1	0.20	105	105							
1	2.0	101	101							
6	overall	76	119							
4	0.01	88; 96; 90; 74	74		87	10.7				
1	0.10	92	92							
1	1.0	91	91							
6	overall	74	96							
4	0.01	88; 96; 90; 74	74	89			8.6			
1	0.10	92	92							
1	1.0	91	91							
6	overall	74	96							

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Table 6.3.1.8-6 (cont'd.): Recovery data for BYI 02960 in **melon/watermelon**

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)					
						Individual recoveries	Min	Max	Mean RSD		
11-2075 (11-2075-01 to 11-2075-06) GLP: yes 2011	water-melon	fruit	BYI 02960	2	0.01	104; 93	93	104	98	13	
				5	0.1	101; 105; 109; 106; 77	77	109	100		
				1	1	98	98	98	10.3		
				8	overall		77	109			
				2	0.02	104; 94	94	104			99
				5	0.2	95; 95; 93; 95; 78	78	99			92
	1	1	96	96	96	7.7					
	8	overall		78	104		94				
	2	0.01	97; 105	97	105		101				
	5	0.1	108; 104; 96; 113; 88	78	113		100	13.7			
	1	1	100	100	100	10.6					
	8	overall		78	113		100				
2	0.01	94; 93	80	94	87						
5	0.1	80; 91	80	91	86						
1	1	89	89	89	7.4						
5	overall		80	94		87					
2	0.01	76; 94	76	94		85					
2	0.2	95; 86	86	95		91					
1	1	92	92	92	8.9						
4	overall		76	95		89					
2	0.01	101; 97	97	101		99					
2	0.1	109; 92	92	109		101					
2	1	114	114	114	8.7						
5	overall		92	114		103					

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.1.8-6 (cont'd.): Recovery data for BYI 02960 in melon/watermelon

Study No. Trial No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level (mg/kg)	Recovery (%)			
						Individual recoveries	Min	Max	Mean RSD
11-2075 (11-2075-01- to 11-2075-06) GLP: yes 2011	water-melon	pulp	BYI 02960	1	0.01	90	90	90	
				2	0.1	95; 92	92	95	94
				1	1	103	103	103	
				4	overall		90	103	95
			DFA	1	0.02	80	80	80	
				2	0.2	93; 92	92	93	93
				1	2	92	92	92	
				4	overall		80	93	90
			BYI 02960- DFEAF	1	0.01	91	91	91	
				2	0.1	92; 96	92	96	94
				1	1	103	103	103	
				4	overall		91	103	96

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IIA 6.3.2 Residue trials from the Global Joint Review partner countries Australia, Brazil, Canada, and the USA to support import tolerances

IIA 6.3.2.1 Citrus Fruits

Residue data from NORTH AMERICA (Crop Group 10)

BYI 02960 is to be registered in USA and Canada for use as a soil or foliar treatment in/on citrus. The use pattern in North America is summarized in Table 6.3.2.1-1.

A total of thirty-four trials were conducted in citrus crops for each of the intended GAPs (12 trials in orange, 6 trials in grapefruit, 8 trials in lemon and 8 trials in mandarin). In addition 4 comparative trials in oranges (with foliar spray) were conducted to support the import tolerance trials in Brazil. The use patterns - corresponding to the intended GAPs - are described below.

Table 6.3.2.1-1: Target Use Patterns for the Application of BYI 02960 on Citrus

Application Type	Test Substance	No. of Apps	Target Rate/Application (±5%)						Target PHI (Days)	Adjuvant Additive (% v/v)	Spray Volume	
			Formulated Product (fp)		Active Substance (a.s.)		Target App. Interval (Days)	GPA			LPHA	
			mL/A	fl oz/A	Name of Product	lb a.s./A						g a.s./ha
Foliar, Dilute Spray	BYI 02960 200 SL	1	414.8	14.0	BYI 02960	0.18	205	10	1	0.25	200–300	1870–2805
Foliar, Ultra-Low Volume Spray	BYI 02960 200 SL	1	414.8	14.0	BYI 02960	0.18	205	10	1	0.25 + 33.33	2.5–3	23–28
Soil	BYI 02960 200 SL	1	829.6	28.1	BYI 02960	0.366	410	NA ¹	30	0.25	1 qt/tree	0.95 L/tree

¹ NA = Not applicable

Report:	IIA 6.3.2.1/01; [REDACTED], E. and L. [REDACTED]; 2012
Title:	BYI 02960 200 SL Magnitude of the Residue in/on Citrus (Crop Group 10)
Report No. & Document No	RARVY012, dated June 27, 2012 M-333259-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.2, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, adopted Sept 7, 2009.
GLP	Yes

Twenty-six field trials were conducted to measure the magnitude of BYI 02960 residues in/on grapefruit (six trials), lemon (eight trials), and orange (12 trials) (representative test systems for NAFTA Crop Group 10; Citrus Fruits) following either two airblast applications (diluted or concentrated spray) or one soil drench application of BYI 02960 200 SL. BYI 02960 200 SL is a



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.1-2).

Table 6.3.2.1-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Citrus Fruits

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2		
3	3	12
4		
5		
5A		
5B		
6		2
7		
7A		
8		
9		
10	11	9
11		
12		
13		
14		
Total	26	23

^a Ten of the 26 trials were decline trials (five in Region 9 and five in Region 10). The additional decline trials were performed to meet EU import tolerance requirements.

Material and Methods

Three use patterns/application forms were tested: either 2 dilute or 2 concentrated foliar airblast applications, or a single soil drench. Individual application rates ranged from 0.179 to 0.193 lb BYI 02960/A/application (0.200 to 0.216 kg BYI 02960/ha/application) for plots with dilute airblast applications. For plots with ultra-low volume (concentrated) applications, individual application rates ranged from 0.187 to 0.200 lb BYI 02960/A/application (0.175 to 0.224 kg BYI 02960/ha/application). The application rate ranged from 0.355 to 0.381 lb BYI 02960/A/application (0.398 to 0.427 kg BYI 02960/ha/ application) for plots with a soil drench application. Seasonal application rates for all plots ranged from 0.344 to 0.381 lb BYI 02960/A (0.386 to 0.427 kg BYI 02960/ha).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

All applications were made at growth stages ranging from BBCH 79 to 89 (BBCH 79: fruits about 90% of final size; BBCH 89: fruit ripe for consumption; fruit has typical taste and firmness; beginning of senescence and fruit abscission). The interval between the airblast applications was 7 to 12 days. For plots with dilute airblast applications, spray volumes ranged from 199 to 301 GPA (1867 to 2821 L/ha). For plots with ultra-low volume applications, spray volumes ranged from 2.2 to 3.1 GPA (21 to 29 L/ha). For plots with soil drench applications, the applications were made in a volume of 1 qt (950 mL) per tree or in spray volumes ranging from 29 to 38 GPA (273 to 354 L/ha).

All applications were made using ground-based equipment. The adjuvant Dyne-Amec, a typical non-ionic surfactant, was used in all of the applications. Applications to the "TRTDU plots (low volume applications) also included the adjuvant 435 Citrus Oil.

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.1-3. Study use patterns are summarized in Table 6.3.2.1-4.

Table 6.3.2.1-3: Trial Site Conditions for BYI 02960 on Citrus

Trial Identification; Crop	Trial Location (City, Country/State Year)	Soil Characteristics				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV152-10DA Orange	██████, FL 2010	Yavres	1.7	7.1	1.8	2.26	27-91
RV153-10DA Orange	██████, FL 2011	Candler Sand	1.5	7.9	6.3	10.36	30-90
RV154-10DA Orange	██████, FL 2010	Sand	1.1	7.4	4.4	2.74	40-78
RV155-10HA Orange	██████, FL 2010	Sand	1.6	6.9	6.7	2.62	40-78
RV156-10HA Orange	██████, FL 2010	Sand	2	6.8	6.6	2.62	40-78
RV157-10HA Orange	██████, FL 2010	Sand	2	7.5	10.2	3.22	41-77
RV158-10HA Orange	██████, FL 2011	Sand	2	7.1	4.4	10.36	30-90
RV159-10HA Orange	██████, FL 2010	St. Lucie Sand	1	5.5	0.1-1.8	12.90	71-95
RV160-10HA Orange	██████, TX 2010	Clay	0.7	8.2	24.4	0.00	52-80
RV161-10DA Orange	██████, CA 2011	Loam	1.5	8.1	17	1.38	45-72
RV162-10HA Orange	██████, CA 2010	Loam	0.9	6.9	16.7	4.35	50-74
RV163-10HA Orange	██████, CA 2010	Clay Loam	2.7	8.2	33.6	0.06	53-80

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-3 (cont'd): Trial Site Conditions for BYI 02960 on Citrus

Trial Identification; Crop	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV164-10DA Lemon	██████, FL 2010	Candler fine sand	1.5	5	0.1-1.8	0.77	61-104
RV165-10HA Lemon	██████, FL 2010	Candler sand	1.4	7.6	4	0.04	56-87
RV166-10DA Lemon	██████, CA 2011	Loam	1.5	7.7	11.6	5.89	43-64
RV167-10DA Lemon	██████, CA 2011	Hesperia Fine Sandy Loam	0.55	7.5	7.5	3.78	46-73
RV168-10DA Lemon	██████, CA 2011	Sandy Loam	0.64	7.4	1.1	3.28	36-69
RV169-10HA Lemon	██████, CA 2010	Loam	1.5	7.7	20	2.17	53-78
RV170-10HA Lemon	██████, CA 2011	Hesperia Fine Sandy Loam	0.55	7.5	7.5	3.78	46-73
RV171-10HA Lemon	██████, CA 2010	Clay Loam	2.7	8.2	33.6	0.05	50-72
RV172-10DA Grapefruit	██████, FL 2011	Candler sand	1.2	6.8	4.5	10.36	30-90
RV173-10HA Grapefruit	██████, FL 2010	Sand	0.1	6.2	4.8	2.38	40-78
RV174-10HA Grapefruit	██████, FL 2010	Candler sand	0.9	6.2	3.8	1.88	41-79
RV175-10HA Grapefruit	██████, TX 2010	Clay	0.7	8.4	26.5	0.00	52-80
RV176-10DA Grapefruit	██████, CA 2011	Fine Sandy Loam	0.75	7	7.5	3.78	46-73
RV177-10HA Grapefruit	██████, CA 2010	Sandy Loam	0.55	7.7	3.7	7.75	40-64

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling.
 Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4: Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
Orange										
RV152-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	83	21 (197)	0.187 (0.209)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
					83	206 (1929)	0.184 (0.206)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
RV152-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (concentrated appl.)	83	2.8 (26)	0.187 (0.209)	NA	0.373 (0.418)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.9 (27)	0.186 (0.209)	8	0.373 (0.418)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV152-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	79	29 (273)	0.373 (0.418)	NA	0.373 (0.418)	Dyne-Amic, 0.25% v/v
RV152-10DA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	89	243 (2269)	0.181 (0.202)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
					89	247 (2307)	0.184 (0.206)	9	0.365 (0.409)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV153-10DA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	89	2.5 (23)	0.184 (0.206)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.5 (23)	0.186 (0.208)	9		Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV153-10DA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDS	Soil drench	81	36 (337)	0.360 (0.404)	NA	0.360 (0.404)	Dyne-Amic, 0.25% v/v
RV154-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	219 (2035)	0.180 (0.202)	NA	0.361 (0.405)	Dyne-Amic, 0.25% v/v
					81	219 (2051)	0.181 (0.203)	10		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV154-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	81	2.8 (2632)	0.187 (0.209)	NA	0.368 (0.413)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.7 (2487)	0.187 (0.209)	10	0.368 (0.413)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV154-10DA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^c	0.366 (0.400)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
RV155-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	81	287 (2632)	0.186 (0.209)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
					83	266 (2487)	0.184 (0.206)	10	0.370 (0.415)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV155-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	89	2.9 (27)	0.185 (0.207)	NA	0.367 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.8 (27)	0.185 (0.207)	10	0.367 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV155-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^c	0.365 (0.409)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
RV156-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (date appl.)	89	272 (2612)	0.185 (0.207)	NA	0.369 (0.413)	Dyne-Amic, 0.25% v/v
					266 (2489)	0.184 (0.206)	10		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV156-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	89	2.9 (2067)	0.184 (0.206)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.8 (2067)	0.184 (0.206)	10	0.369 (0.414)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV156-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^c	0.381 (0.427)	NA	0.381 (0.427)	Dyne-Amic, 0.25% v/v
RV157-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	81	220 (2065)	0.180 (0.202)	NA	0.361 (0.404)	Dyne-Amic, 0.25% v/v
					81	221 (2067)	0.181 (0.203)	10	0.361 (0.404)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV157-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	81	2.7 (2338)	0.186 (0.208)	NA	0.362 (0.405)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.7 (2338)	0.186 (0.208)	10	0.362 (0.405)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV157-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^b	0.366 (0.400)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
RV158-10HA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	89	248 (221)	0.185 (0.208)	NA	0.372 (0.417)	Dyne-Amic, 0.25% v/v
					250 (2338)	0.187 (0.209)	9		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV159-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	83	3.1 (29)	0.187 (0.208)	NA	0.377 (0.416)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	3.1 (29)	0.187 (0.208)	10	0.377 (0.416)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV159-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	79	38 (354)	0.371 (0.406)	NA	0.371 (0.416)	Dyne-Amic, 0.25% v/v
RV160-10HA	██████, TX, Region 6, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	83	252 (2364)	0.186 (0.208)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
					83	251 (2345)	0.184 (0.207)	9	0.370 (0.415)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV160-10HA	[REDACTED], TX, Region 6, 2010	BYI 02960 200 SL	TRTDU	Airblast (concentrated appl.)	83	2.6 (24)	0.184 (0.206)	NA	0.375 (0.420)	Dyne-Amic, 0.25% v/v + 435 Dormant Oil, 33% v/v
RV160-10HA	[REDACTED], TX, Region 6, 2010	BYI 02960 200 SL	TRTDS	Soil trench	83	2.6 (24)	0.21 (0.214)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v
RV161-10DA	[REDACTED], TX, Region 10, 2011	BYI 02960 200 SL	TRFDD	Airblast (dilute appl.)	81	276 (2580)	0.187 (0.209)	NA	0.373 (0.418)	Dyne-Amic, 0.56% v/v
				83	276 (2580)	0.187 (0.209)	11		Dyne-Amic, 0.56% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV162-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	81	2.5 (24)	0.179 (0.220)	NA	0.362 (0.406)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.6 (24)	0.183 (0.225)	7		
RV162-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDS	Soil drench	79	1.0 ^c	0.366 (0.400)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
RV163-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	85	30 (17)	0.193 (0.216)	NA	0.376 (0.421)	Dyne-Amic, 0.25% v/v
					88	288 (2694)	0.183 (0.205)	10		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV163-10HA	[REDACTED] CA, Region 10, 2010	BYI 02960 200 SL	TRTDU	Airblast (concentrated appl.)	85	2.6 (26)	0.157 (0.175)	NA	0.344 (0.386)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.2 (22)	0.188 (0.21)	10	0.366 (0.41)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV163-10HA	[REDACTED] CA, Region 10, 2010	BYI 02960 200 SL	TRTDS	Soil drench	83	1.0 ^c	0.366 (0.41)	NA	0.366 (0.41)	Dyne-Amic, 0.25% v/v
Lemon										
RV164-10DA	[REDACTED] FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	79	210 (1968)	0.184 (0.207)	NA	0.368 (0.413)	Dyne-Amic, 0.25% v/v
					83	208 (1943)	0.184 (0.206)	12		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV164-10DA	[REDACTED], FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	79	2.7 (2309)	0.184 (0.200)	NA	0.369 (0.413)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.7 (2309)	0.184 (0.200)	12		Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV164-10DA	[REDACTED], FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	79	1.0 ^c	0.355 (0.398)	NA	0.355 (0.398)	Dyne-Amic, 0.25% v/v
RV165-10HA	[REDACTED], FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	83	247 (2309)	0.179 (0.200)	NA	0.358 (0.402)	Dyne-Amic, 0.25% v/v
					83	247 (2309)	0.180 (0.202)	9		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV165-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	83	2.5 (23)	0.184 (0.206)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	2.5 (23)	0.184 (0.206)	9	0.369 (0.414)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV165-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	83	1.0 ^c	0.364 (0.408)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
RV166-10DA	██████, CA, Region 10, 2011	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	84	282 (632)	0.183 (0.205)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
					84	289 (2701)	0.183 (0.205)	10	0.366 (0.410)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV166-10DA	CA, Region 10, 2011	BYI 02960 200 SL	TRTDU	Airblast (concentrated appl.)	81	3.0 (28)	0.191 (0.224)	NA	0.375 (0.420)	Dyne-Amic, 0.25% v/v + Omni Oil 6E (435 Oil), 33% v/v
RV166-10DA	CA, Region 10, 2011	BYI 02960 200 SL	TRTDS	Soil trench	81	2.2 (20)	0.266 (0.410)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
RV167-10DA	CA, Region 10, 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	89	248 (2316)	0.181 (0.203)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
					89	250 (2335)	0.183 (0.205)	11		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV167-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	89	2.7 (2337)	0.183 (0.205)	NA	0.365 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.7 (2337)	0.183 (0.205)	11	0.365 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV167-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDS	Soil drench	85	1.0 ^c	0.365 (0.409)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
RV168-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	227 (226)	0.183 (0.205)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
					250 (2337)	0.183 (0.205)	10		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV168-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	85	2.6 (24)	0.185 (0.21)	NA	0.367 (0.41)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.6 (24)	0.185 (0.21)	10	0.367 (0.41)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV168-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDS	Soil drench	83	1.0 ^c	0.366 (0.40)	NA	0.366 (0.41)	Dyne-Amic, 0.25% v/v
RV169-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	85	259 (241)	0.189 (0.21)	NA	0.380 (0.42)	Dyne-Amic, 0.25% v/v
					88	262 (245)	0.191 (0.21)	10	0.380 (0.42)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV170-10HA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	89	2.7 (2763)	0.184 (0.204)	NA	0.364 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.7 (2763)	0.184 (0.204)	11	0.364 (0.409)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV170-10HA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDS	Soil drench	85	1.0 ^c	0.364 (0.409)	NA	0.364 (0.409)	Dyne-Amic, 0.25% v/v
RV171-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	84	286 (274)	0.182 (0.204)	NA	0.365 (0.410)	Dyne-Amic, 0.25% v/v
					295 (2763)	0.184 (0.206)	10		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (E/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV171-10HA	Region 10, 2010	BYI 02960 200 SL	TRTDU	Airblast (concentrated appl.)	83	3.0 (28)	0.184 (0.22)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					83	3.0 (28)	0.184 (0.22)	10	0.366 (0.410)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV171-10HA	Region 10, 2010	BYI 02960 200 SL	TRTDS	Soil drench	79	1.0 ^c	0.366 (0.40)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
Grapefruit										
RV172-10DA	Region 3, 2012	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	89	243 (2270)	0.181 (0.202)	NA	0.367 (0.411)	Dyne-Amic, 0.25% v/v
					89	250 (2334)	0.186 (0.209)	9	0.367 (0.411)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV172-10DA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	89	2.5 (23)	0.184 (0.206)	NA	0.369 (0.413)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.5 (23)	0.184 (0.206)	9	0.369 (0.413)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV172-10DA	██████, FL, Region 3, 2011	BYI 02960 200 SL	TRTDS	Soil drench	83	36 (335)	0.360 (0.403)	NA	0.360 (0.403)	Dyne-Amic, 0.25% v/v
RV173-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	21 (202)	0.182 (0.204)	NA	0.367 (0.411)	Dyne-Amic, 0.25% v/v
					85	212 (1982)	0.185 (0.207)	9	0.367 (0.411)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV173-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	85	2.6 (24)	0.186 (0.205)	NA	0.363 (0.407)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.6 (24)	0.182 (0.205)	9	0.364 (0.408)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV173-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^c	0.369 (0.404)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v
RV174-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	27 (2569)	0.182 (0.204)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
					268 (2509)	0.183 (0.205)	9		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV174-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDU	Airblast (con. appl.)	85	2.8 (2339)	0.184 (0.209)	NA	0.381 (0.427)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	3.1 (2339)	0.200 (0.224)	9	0.368 (0.412)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV174-10HA	██████, FL, Region 3, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^c	0.368 (0.412)	NA	0.368 (0.412)	Dyne-Amic, 0.25% v/v
RV175-10HA	██████, TX, Region 6, 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	83	250 (2368)	0.186 (0.209)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
					86	250 (2339)	0.184 (0.206)	9	0.368 (0.412)	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV176-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDU	Airblast (complete appl.)	89	2.7 (2068)	0.186 (0.208)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
					89	2.7 (2068)	0.186 (0.204)	11		Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV176-10DA	[REDACTED], CA, Region 10, 2011	BYI 02960 200 SL	TRTDS	Soil drench	85	1.0 ^c	0.364 (0.408)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
RV177-10HA	[REDACTED], CA, Region 10, 2010	BYI 02960 200 SL	TRTDD	Airblast (complete appl.)	84	25 (2068)	0.186 (0.208)	NA	0.368 (0.412)	Dyne-Amic, 0.25% v/v
						221 (2068)	0.182 (0.204)	11		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Citrus

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank-Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (E/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV177-10HA	██████, CA, Region 10, 2010	BYI 02960 200 SL	TRTDD	Airblast (concentrated appl.)	81	2.9 (2.7)	0.187 (0.274)	NA	0.363 (0.407)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
			TRTDD	Airblast (dilute spray)	85	2.6 (2.3)	0.187 (0.273)	11	0.363 (0.407)	Dyne-Amic, 0.25% v/v + 435 Citrus Oil, 33% v/v
RV177-10HA	██████, CA, Region 10, 2010	BYI 02960 200 SL	TRTDS	Soil drench	81	1.0 ^a	0.366 (0.400)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v

a NA = Not Applicable

b Value represents volume applied per tree/ft [equivalent to 0.95 L/ha]

Single composite samples of grapefruits, lemons, or oranges were collected at a 1-day pre-harvest interval (PHI) from each of the TRTDD (dilute spray volume) and TRTDD (concentrated spray volume) plots, except for lemon Trial RV168-10HA, which did not collect a sample from the TRTDD plot. Duplicate composite samples of grapefruits, lemons, or oranges were collected at a PHI of 30 days from the TRTDS plots. In ten decline trials, single composite grapefruit, lemon, and orange samples were collected from both the TRTDD and the TRTDD plots at 0, 1, 3, 10, and 21 days after the last treatment. Single composite samples of grapefruits, lemons, and oranges were collected from the control plots on the same day the target 0-day samples were collected from the treated plots.

From four trials, additional grapefruit, lemon, or orange samples were collected at a 1-day PHI and were processed to evaluate potential residue reduction resulting from the common practice of peeling citrus.

In addition, single composite samples of grapefruits, lemons, or oranges were collected from plots TRTDD and TRTDD immediately before the second application (after only one application of BYI 02960); however, as these do not reflect the proposed use rate, the residue data from these samples were collected for informational purposes only.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.1-5)

Table 6.3.2.1-5: Summary of Recoveries of BYI 02960 from Citrus

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)	
Fruit	BYI 02960 ^b	0.010	16	95, 104, 80, 93, 97, 104, 128, 115, 116, 116, 100, 119, 95, 107, 107, 112	105	11	
		0.020	4	108, 85, 102, 70	91	17	
		0.100	8	95, 117, 83, 108, 77, 103, 96, 76, 97, 107, 119, 100, 113, 109, 94, 115, 94, 85, 110, 108, 104, 78, 86, 103, 95, 93, 85, 102, 102, 93	99	12	
		1.500	3	86, 97, 91	92	5	
	DFA ^b	0.020	9	71, 74, 88, 73, 98, 86, 70, 74, 88	80	10	
		0.050	15	88, 95, 64, 96, 78, 85, 84, 78, 88, 80, 75, 93, 92	84	10	
		0.100	30	71, 82, 97, 82, 79, 78, 106, 90, 107, 83, 85, 74, 75, 86, 104, 106, 103, 98, 95, 92, 75, 89, 84, 85, 87, 84, 101, 86, 101, 92	89	10	
		1.500	3	91, 94, 95	93	2	
		DFEAF ^b	0.010	6	95, 114, 93, 120, 109, 73, 110, 95, 71, 118, 71, 73, 78, 118	96	19
			0.020	6	101, 83, 108, 89, 118, 118	103	15
			0.100	30	79, 89, 115, 97, 84, 105, 112, 94, 107, 87, 118, 115, 102, 95, 105, 108, 118, 95, 108, 93, 105, 97, 103, 89, 99, 104, 98, 95, 108, 103	101	10
			1.500	3	86, 85, 86	86	1

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-5 (cont'd): Summary of Recoveries of BYI 02960 from Citrus

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)	
Peel	BYI 02960	0.030	3	96, 108, 89	98	9	
		0.100	1	81	81	NA	
		1.000	3	92, 83, 88	87	5	
	DFA	0.020	2	84, 86	85	1	
		0.030	3	85, 83, 92	87	1	
		0.100	1	71	71	NA	
	DFA	1.000	3	94, 82, 92	89	7	
		DFEAF	0.010	3	74, 71, 89	77	11
			0.030	3	105, 119, 108	110	8
			0.100	1	99	99	NA
	Pulp	BYI 02960	0.010	3	100, 88, 89	92	6
			0.030	3	117, 103, 88	103	15
0.100			1	82	82	NA	
DFA		0.020	3	72, 92, 102	88	15	
		0.030	3	96, 100, 103	99	3	
		0.100	1	83	83	NA	
DFA		0.010	3	118, 118, 83	106	20	
		DFA	0.030	3	99, 94, 103	98	5
			0.100	1	88	88	NA

^a Mean Recovery = mathematical average of all recoveries.

^b Recoveries of BYI 02960, DFA, and DFEAF from orange fruit were conducted at 2.20 ppm for each analyte in Bayer CropScience Study PARVY035 (IIA 6.5.4.6). Recoveries ranged from 88 to 112%.

Freezer storage stability data for BYI 02960, DFA, and DFEAF in orange fruit (high acid content representative), spinach leaves and tomato fruit (high water content representatives), wheat grain (high starch content representative), navy bean seed (high protein content representative), coffee and soybean seed (high oil content representatives), and sugar cane are being generated through 24 months and will be reported separately. Preliminary data (18-month storage interval) from the freezer storage

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

stability study suggest BYI 02960 residues were stable (<30% decomposition) in all matrices during the storage period.

As described above, the freezer storage stability study indicates that BYI 02960 residues were stable in orange during frozen storage for at least 18 months (556 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 352 days. A summary of the storage conditions are shown in Table 6.3.2.1-6.

Table 6.3.2.1-6: Summary of Storage Conditions for Citrus

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration Months (days) ^b	Interval of Demonstrated Storage Stability months (days)
BYI 02960	Fruit	< -2	12 (35)	18 (556)
	Peel	< -17	12 (351)	18 (556)
	Pulp	< -17	12 (352)	18 (556)
DFA	Fruit	< -2	12 (351)	18 (556)
	Peel	< -17	12 (351)	18 (556)
	Pulp	< -17	12 (352)	18 (556)
DFEAD	Fruit	< -2	12 (351)	18 (556)
	Peel	< -17	12 (351)	18 (556)
	Pulp	< -17	12 (352)	18 (556)

^a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

^b The storage duration is the time from field sampling through the last sample extraction.

^c [REDACTED] and A. [REDACTED], 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data. (KIIA 01.1/01)

The total BYI 02960 residue data for citrus following a single soil drench, or two foliar applications (diluted or a concentrated) of BYI 02960 200 SL are shown in Tables 6.3.2.1-7. The results from samples taken just prior to the final foliar application are shown in Table and 6.3.2.1-8. These latter results do not reflect the proposed use pattern, and the residue data from these samples were collected for informational purposes only.

The effect of common food preparation practices (peeling) on the total BYI 02960 residue in/on citrus is summarized in Table 6.3.2.1-9.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7: Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Orange fruit										
RV152-10DA	██████, FL, Region 3, 2010	Hamilins	Orange fruit	TRDD	0.370 (0.415)	0	0.175	<0.020	<0.010	0.21
					1	0.191	<0.020	<0.010	0.22	
					3	0.154	<0.020	<0.010	0.19	
					21	0.072	<0.020	<0.010	0.14	
				TRIDU	0.373 (0.418)	0	0.799	<0.020	<0.010	0.83
					1	0.780	<0.020	<0.010	0.81	
					3	1.21	0.034	<0.010	1.3	
					10	0.528	0.032	<0.010	0.57	
				TRDS	0.373 (0.418)	30	<0.010	<0.020	<0.010	<0.040
							<0.010	<0.020	<0.010	<0.040
										Avg: <0.040
RV153-10DA	██████, FL, Region 3, 2011	Valencia	Orange fruit	TRDD	0.365 (0.409)	0	0.203	<0.020	<0.010	0.23
					1	0.274	<0.020	<0.010	0.30	
					3	0.264	<0.020	<0.010	0.29	
					10	0.240	<0.020	<0.010	0.27	
				TRTD	0.369 (0.414)	0	0.673	<0.020	<0.010	0.70
					1	0.310	<0.020	<0.010	0.34	
					3	0.322	<0.020	<0.010	0.35	
					10	0.339	0.024	<0.010	0.37	
				TRDS	0.360 (0.404)	30	0.021	<0.020	<0.010	0.051
							0.041	<0.020	<0.010	0.071
										Avg: 0.061 ^e

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)		
RV154-10DA	██████ FL, Region 3, 2010	Navel	Orange fruit	TRTDD	0.361 (0.405)	0	0.258	<0.020	<0.010	0.258		
						1	0.258	<0.020	<0.010	0.30		
						3	0.258	<0.020	<0.010	0.25		
						10	0.202	<0.020	<0.010	0.23		
				TRTDS	0.366 (0.413)	21	0.205	0.024	<0.010	0.25		
						30	0.292	0.020	<0.010	0.32		
						1	0.607	0.025	<0.010	0.64		
						3	0.884	0.028	<0.010	0.92		
				TRTDS	0.366 (0.413)	7	0.766	0.041	<0.010	0.22		
						21	0.080	0.05	<0.010	0.15		
						30	<0.010	<0.020	<0.010	<0.040		
						Avg:	<0.010	<0.020	<0.010	<0.040		
RV155-10HA	██████ FL, Region 3, 2010	Navel	Orange fruit	TRTDD	0.370 (0.415)	1	0.09	<0.020	<0.010	0.13		
						TRTDU	0.367 (0.412)	1	0.207	<0.020	<0.010	0.24
						TRTDS	0.365 (0.409)	30	0.020	<0.020	<0.010	0.050
						Avg:	0.026	<0.020	<0.010	0.056		
RV156-10HA	██████ FL, Region 3, 2010	Hamlin	Orange fruit	TRTDD	0.369 (0.413)	1	0.286	<0.020	<0.010	0.32		
						TRTDU	0.369 (0.414)	1	0.232	<0.020	<0.010	0.26
						TRTDS	0.381 (0.427)	30	<0.010	<0.020	<0.010	<0.040
						Avg:	<0.010	<0.020	<0.010	<0.040		
RV157-10HA	██████ FL, Region 3, 2010	Hamlin	Orange fruit	TRTDD	0.361 (0.404)	1	0.251	<0.020	<0.010	0.28		
						TRTDU	0.362 (0.405)	1	0.230	<0.020	<0.010	0.26
						TRTDS	0.366 (0.410)	30	<0.010	<0.020	<0.010	<0.040
Avg:	<0.010	<0.020	<0.010	<0.040								

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

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Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV158-10HA	██████, FL, Region 3, 2011	Early Gold	Orange fruit	TRTDD	0.372 (0.417)	1	0.179	<0.020	<0.010	0.21
				TRTDU	0.365 (0.412)	1	0.634	<0.020	<0.010	0.6
				TRTDS	0.369 (0.413)	30	<0.010 <0.010	<0.020 <0.010	<0.010 <0.010	0.040 <0.040 Avg: <0.040
RV159-10HA	██████, FL, Region 3, 2010	Valencia	Orange fruit	TRTDD	0.377 (0.423)	1	0.697	<0.020	<0.010	0.73
				TRTDU	0.372 (0.416)	1	0.228	<0.020	<0.010	0.26
				TRTDS	0.374 (0.416)	30	0.014 <0.010	<0.020 <0.020	<0.010 <0.010	0.044 <0.040 Avg: 0.042
RV160-10HA	██████, FL, Region 6, 2010	Early Gold	Orange fruit	TRTDD	0.370 (0.415)	1	0.155	<0.020	<0.010	0.17
				TRTDU	0.375 (0.420)	1	0.194	<0.020	<0.010	0.22
				TRTDS	0.369 (0.414)	30	0.029 0.013	<0.020 <0.020	<0.010 <0.010	0.059 0.043 Avg: 0.051
RV161-10DA	██████, CA, Region 10, 2011	Valencia	Orange fruit	TRTDD	0.377 (0.418)	0	0.426	0.016	<0.010	0.45
						1	0.753	<0.020	<0.010	0.78
						3	1.46	0.053	<0.010	1.5
						10	0.410	0.041	<0.010	0.46
						21	0.488	0.079	<0.010	0.58
				TRTDU	0.365 (0.409)	0	0.490	0.015	<0.010	0.52
						1	0.577	<0.020	<0.010	0.61
						3	0.225	<0.020	<0.010	0.26
						10	2.08	0.097	<0.010	2.2
						21	0.310	0.080	<0.010	0.40
TRTDS	0.365 (0.409)	30	<0.010 0.015	<0.020 <0.020	<0.010 <0.010	<0.040 0.045 Avg: 0.043				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s./equiv./kg)	DFEAF Residue (mg a.s./equiv./kg)	Total BYI 02960 Residue (mg a.s./equiv./kg) ^b		
RV162-10HA	██████, CA, Region 10, 2010	Mandarin-Satsuma	Orange fruit	TRTDD	0.365 (0.410)	1	0.119 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.15		
				TRTDD	0.362 (0.406)	1	0.069 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.08		
				TRTDS	0.366 (0.410)	30	<0.010 ⁱ 0.072 ⁱ	<0.020 ⁱ 0.027 ⁱ	<0.010 ⁱ 0.010 ⁱ	0.040 0.049 Avg: 0.045		
RV163-10HA	██████, CA, Region 10, 2010	Olinda Valencia	Orange fruit	TRTDD	0.376 (0.421)	1	0.067 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.097		
				TRTDD	0.344 (0.386)	1	0.020 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.050		
				TRTDS	0.366 (0.410)	30	<0.010 ⁱ 0.010 ⁱ	<0.020 ⁱ 0.020 ⁱ	<0.010 ⁱ 0.010 ⁱ	<0.040 <0.040 Avg: <0.040		
Lemon, fruit												
RV164-10DA	██████, FL, Region 3, 2010	NA	Lemon fruit	TRTDD	0.258 (0.413)	0	0.366 ⁱ	0.056 ⁱ	<0.010 ⁱ	0.43		
							3	0.349 ⁱ	0.073 ⁱ	<0.010 ⁱ	0.43	
							5	0.440 ⁱ	0.098 ⁱ	<0.010 ⁱ	0.55	
							10	0.192 ⁱ	0.103 ⁱ	<0.010 ⁱ	0.31	
							21	0.073 ⁱ	0.128 ⁱ	<0.010 ⁱ	0.21	
							TRTDD	0	0.171 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.20
								1	0.214 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.24
								3	0.100 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.13
								10	0.042 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.072
								21	0.018 ⁱ	<0.020 ⁱ	<0.010 ⁱ	0.048
TRTDS	0.355 (0.398)	30	<0.010 ⁱ <0.010 ⁱ	<0.020 ⁱ <0.020 ⁱ	<0.010 ⁱ <0.010 ⁱ	<0.040 <0.040 Avg: <0.040						
	Lemon fruit											
RV165-10HA	██████, FL, Region 2010	Myer	Lemon fruit	TRTDD	0.358 (0.402)	1	0.230 ^j	<0.020 ^j	<0.010 ^j	0.26		
				TRTDD	0.369 (0.414)	1	0.052 ^j	<0.020 ^j	<0.010 ^j	0.082		
				TRTDS	0.364 (0.408)	30	<0.010 ^j <0.010 ^j	<0.020 ^j <0.020 ^j	<0.010 ^j <0.010 ^j	<0.040 <0.040 Avg: <0.040		



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

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Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV166-10DA	[REDACTED] CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.366 (0.410)	0	0.124	<0.020	<0.010	0.155
						1	0.123	<0.020	<0.010	0.15
						3	0.118	<0.020	<0.010	0.15
						10	0.102	<0.020	<0.010	0.12
						15	0.089	<0.020	<0.010	0.12
RV166-10DA	[REDACTED] CA, Region 10, 2011	Lisbon	Lemon fruit	TRTBU	0.375 (0.420)	0	0.038	<0.020	<0.010	0.068
						1	0.054	<0.020	<0.010	0.084
						3	0.025	<0.020	<0.010	0.055
						10	0.011	<0.020	<0.010	0.041
				TRTDS	0.366 (0.410)	30	<0.010	<0.020	<0.010	<0.040
							<0.010	<0.020	<0.010	<0.040
										Avg: <0.040
RV167-10DA	[REDACTED] CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.364 (0.408)	0	0.785	<0.020	<0.010	0.82
						1	0.255	<0.020	<0.010	0.29
						3	0.325	<0.020	<0.010	0.36
						10	0.183	<0.020	<0.010	0.21
						21	0.194	0.021	<0.010	0.23
				TRTBU	0.367 (0.412)	0	0.290	<0.020	<0.010	0.32
						1	0.713	<0.020	<0.010	0.74
						3	0.437	<0.020	<0.010	0.47
						10	0.541	<0.020	<0.010	0.57
						21	0.320	0.033	<0.010	0.36
TRTDS	0.365 (0.409)	30	<0.010	<0.020	<0.010	<0.040				
			<0.010	<0.020	<0.010	<0.040				
						Avg: <0.040				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)		
RV168-10DA	[redacted] CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.365 (0.409)	0	0.264	<0.020	<0.010	0.264		
						1	0.278	<0.020	<0.010	0.31		
						3	0.278	<0.020	<0.010	0.31		
						10	0.296	<0.020	<0.010	0.33		
						21	0.285	<0.020	<0.010	0.32		
						Avg:	0.278	<0.020	<0.010	0.17		
				TRTDS	0.366 (0.411)	30	<0.010	<0.020	<0.010	<0.040		
						Avg:	<0.010	<0.020	<0.010	<0.040		
						1	0.088	<0.020	<0.010	0.12		
						3	0.091	<0.020	<0.010	0.12		
						7	0.099	<0.020	<0.010	0.13		
						21	0.050	<0.020	<0.010	0.080		
RV169-10HA	[redacted] CA, Region 10, 2010	Eureka	Lemon fruit	TRTDD	0.380 (0.426)	1	0.285	<0.020	<0.010	0.31		
						TRTDU	0.368 (0.412)	1	0.352	<0.020	<0.010	0.38
						TRTDS	0.366 (0.410)	30	<0.010	<0.020	<0.010	<0.040
RV170-10HA	[redacted] CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.365 (0.409)	1	0.233	<0.020	<0.010	0.26		
						TRTDU	0.367 (0.412)	1	0.669	<0.020	<0.010	0.70
						TRTDS	0.365 (0.409)	30	<0.010	<0.020	<0.010	<0.040
						Avg:	<0.010	<0.020	<0.010	<0.040		
RV171-10HA	[redacted] CA, Region 10, 2010	Eureka	Lemon fruit	TRTDD	0.365 (0.410)	1	0.183	<0.020	<0.010	0.21		
						TRTDU	0.366 (0.410)	1	0.037	<0.020	<0.010	0.067
						TRTDS	0.366 (0.410)	30	<0.010	<0.020	<0.010	<0.040
Avg:	<0.010	<0.020	<0.010	<0.040								

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b	
Grapefruit fruit											
RV172-10DA	██████, FL, Region 3, 2011	Flame	Grapefruit fruit	TRTDD	0.367 (0.411)	1	0.109	<0.020	<0.010	0.119	
						7	0.126	<0.020	<0.010	0.136	
						3	0.151	<0.020	<0.010	0.161	
						10	0.123	<0.020	<0.010	0.133	
				TRTDU	0.369 (0.413)	0	0.481	<0.020	<0.010	0.511	
						1	0.02	<0.020	<0.010	0.22	
						3	0.146	<0.020	<0.010	0.18	
						10	0.053	<0.020	<0.010	0.08	
				TRTDS	0.360 (0.403)	30	0.010	<0.020	<0.010	<0.040	
							0.010	<0.020	<0.010	<0.040	
							Avg:			<0.040	
							<0.040				
RV173-10HA	██████, FL, Region 3, 2010	White	Grapefruit fruit	TRTDD	0.367 (0.411)	1	0.185	<0.020	<0.010	0.22	
						TRTDU	1	0.165	<0.020	<0.010	0.20
				TRTDS	0.369 (0.414)	30	0.047	<0.020	<0.010	0.077	
							0.029	<0.020	<0.010	0.059	
Avg:					0.068						
RV174-10HA	██████, FL, Region 3, 2010	White	Grapefruit fruit	TRTDD	0.364 (0.408)	1	0.160	<0.020	<0.010	0.19	
						TRTDU	1	0.287	<0.020	<0.010	0.32
						TRTDS	30	<0.010	<0.020	<0.010	<0.040
Avg:					0.045						
									0.043		
RV175-10HA	██████, TX, Region 3, 2010	Rio Red	Grapefruit fruit	TRTDD	0.370 (0.415)	1	0.116	<0.020	<0.010	0.15	
						TRTDU	1	0.158	<0.020	<0.010	0.19
						TRTDS	30	0.014	<0.020	<0.010	0.044
Avg:					0.044						
									0.044		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)				
RV176-10DA	██████, CA, Region 10, 2011	Oro Blanco	Grapefruit fruit	TRTDD	0.364 (0.408)	0	0.053	<0.020	<0.010	0.10				
						1	0.203	<0.020	<0.010	0.23				
						5	0.100	<0.020	<0.010	0.10				
						10	0.129	<0.020	<0.010	0.16				
						15	0.084	<0.020	<0.010	0.11				
						21	0.084	<0.020	<0.010	0.11				
				TRTDU	0.366 (0.410)	0	0.208	<0.020	<0.010	0.24				
						1	0.129	<0.020	<0.010	0.16				
						3	0.272	<0.020	<0.010	0.30				
						5	0.126	<0.020	<0.010	0.16				
						15	0.151	<0.020	<0.010	0.18				
						21	0.151	<0.020	<0.010	0.18				
TRTDS	0.364 (0.408)	30	0.056	<0.020	<0.010	0.086								
			0.041	<0.020	<0.010	0.071								
			Avg:			0.079								
			Fruit (additional samples for residue reduction determination) ^c											
			RV159-10HA			0.372 (0.416)	1	0.076	<0.020	<0.010	0.11			
			██████, FL, Region 3, 2010	Valencia	Orange fruit	TRTDD	0.102	<0.020	<0.010	0.13				
0.076	<0.020	<0.010					0.11							
Avg:							0.11							
RV163-10HA	██████, CA, Region 10, 2010	Olimpia Valencia	Orange fruit	TRTDU	0.344 (0.386)	1	0.055	<0.020	<0.010	0.085				
						0.045	<0.020	<0.010	0.075					
						0.045	<0.020	<0.010	0.075					
						Avg:			0.078					
						RV159-10HA			0.372 (0.416)	1	0.076	<0.020	<0.010	0.11
						██████, FL, Region 3, 2010	Valencia	Orange fruit	TRTDD	0.102	<0.020	<0.010	0.13	
0.076	<0.020	<0.010	0.11											
Avg:			0.11											

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV166-10DA	██████ CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDH	0.375 (0.420)	1	0.077 0.017 0.012 0.012	<0.020 <0.020 <0.020 <0.020	<0.010 <0.010 <0.010 <0.010	0.000 0.027 0.042 Avg: 0.000
RV174-10HA	██████ FL, Region 3, 2010	White	Grapefruit fruit	TRTDH	0.381 (0.427)	1	0.320 0.360 0.360	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	0.339 0.39 0.39 Avg: 0.38
Fruit Peel (for residue reduction determination)										
RV159-10HA	██████ FL, Region 3, 2010	Valencia	Orange peel	TRTDU	0.372 (0.416)	1	0.450 0.310 0.279	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	0.48 0.34 0.31 Avg: 0.38
RV163-10HA	██████ CA, Region 10, 2010	Olinda Valencia	Orange peel	TRTDU	0.344 (0.386)	1	0.121 0.109 0.115	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	0.15 0.14 0.15 Avg: 0.15
RV166-10DA	██████ CA, Region 10, 2011	Lisbon	Lemon peel	TRTDU	0.375 (0.420)	1	0.043 0.043 0.041	<0.020 <0.020 <0.020	<0.010 0.014 <0.010	0.073 0.077 0.071 Avg: 0.074
RV174-10HA	██████ FL, Region 3, 2010	White	Grapefruit peel	TRTDU	0.381 (0.427)	1	0.607 0.540 0.642	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	0.64 0.57 0.67 Avg: 0.63
Fruit Pulp (for residue reduction determination)										
RV159-10HA	██████ FL, Region 3, 2010	Valencia	Orange pulp	TRTDU	0.372 (0.416)	1	<0.010 <0.010 <0.010	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	<0.040 <0.040 <0.040 Avg: <0.040
RV163-10HA	██████ CA, Region 10, 2010	Olinda Valencia	Orange pulp	TRTDU	0.344 (0.386)	1	<0.010 <0.010 <0.010	<0.020 <0.020 <0.020	<0.010 <0.010 <0.010	<0.040 <0.040 <0.040 Avg: <0.040

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-7 (cont'd): Total BYI 02960 Residue Data from Citrus after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, NAFTA Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.i./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAEF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV166-10DA	[REDACTED] CA, Region 10, 2011	Lisbon	Lemon pulp	TRTDH	0.375 (0.420)	7	<0.010 0.010 0.010	<0.020 0.020 0.020	<0.010 0.010 0.010	<0.040 0.040 0.040 Avg: <0.040
RV174-10HA	[REDACTED] FL, Region 3, 2010	White	Grapefruit pulp	TRTDS	0.381 (0.427)	7	<0.010 0.010 0.010	<0.020 0.020 0.020	<0.010 0.010 0.010	<0.040 0.040 0.040 Avg: <0.040

- ^a days after last treatment = interval between last application and sampling
- ^b Total BYI 02960 residue is the sum of BYI 02960, DFA and DFAEF residues in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- ^c Each trial conducting a residue reduction determination created a single sample each of whole fruit, pulp, and peel, and each sample was analyzed in triplicate for residues of BYI 02960, DFA, and DFAEF.

TRTDU = treated plot receiving two concentrate (ultra-low volume) airblast applications
 TRTDD = treated plot receiving two dilute airblast applications
 TRTDS = treated plot receiving one soil drench application
 Maximum residue values for the different application scenarios and crops are printed in **bold**.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-8 (cont'd): Total BYI 02960 Residue Data on Citrus Collected Immediately Prior to the Final Foliar Application of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Rate ^a lb a.i./A (kg a.s./ha)	Sampling Interval (days after first treatment) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV160-10HA	██████, TX, Region 6, 2010	N-33	Orange fruit	TRTDD	0.186 (0.208)	9 DAA1	0.096	0.020	<0.010	0.116
				TRTDU	0.184 (0.206)	9 DAA1	0.083	0.020	<0.010	0.103
RV161-10DA	██████, CA, Region 10, 2011	Valencia	Orange fruit	TRTDD	0.187 (0.209)	11 DAA1	0.937	0.094	0.010	0.98
				TRTDU	0.182 (0.204)	11 DAA1	0.301	<0.020	<0.010	0.33
RV162-10HA	██████, CA, Region 10, 2010	Mandarin Satsuma	Orange fruit	TRTDD	0.183 (0.205)	7 DAA1	0.041	<0.020	<0.010	0.071
				TRTDU	0.179 (0.200)	7 DAA1	<0.010	<0.020	<0.010	0.040
RV163-10HA	██████, CA, Region 10, 2010	Olinda Valencia	Orange fruit	TRTDD	0.193 (0.216)	10 DAA1	0.089	0.020	<0.010	0.12
				TRTDU	0.175 (0.195)	10 DAA1	0.042	<0.020	<0.010	0.072
RV164-10DA	██████, FL, Region 3, 2010	WA ^d	Lemon fruit	TRTDD	0.184 (0.207)	12 DAA1	0.274	0.063	<0.010	0.35
				TRTDU	0.184 (0.207)	12 DAA1	<0.010	<0.020	<0.010	0.040
RV165-10HA	██████, FL, Region 3, 2010	Mys	Lemon fruit	TRTDD	0.179 (0.200)	9 DAA1	0.190 ^e	0.024 ^e	<0.010 ^e	0.22
				TRTDU	0.184 (0.206)	9 DAA1	0.056 ^e	<0.020 ^e	<0.010 ^e	0.086
RV166-10DA	██████, CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.183 (0.205)	10 DAA1	0.030	<0.020	<0.010	0.060
				TRTDU	0.191 (0.214)	10 DAA1	<0.010	<0.020	<0.010	0.040
RV167-10DA	██████, CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.181 (0.203)	11 DAA1	0.093	<0.020	<0.010	0.12
				TRTDU	0.185 (0.207)	11 DAA1	0.138	<0.020	<0.010	0.17

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-8 (cont'd): Total BYI 02960 Residue Data on Citrus Collected Immediately Prior to the Final Foliar Application of BYI BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Rate ^a lb a.i./A (kg a.s./ha)	Sampling Interval (days after first treatment) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV168-10DA	██████, CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.183 (0.205)	10 DAA1	0.352	<0.020	<0.010	0.362
RV169-10HA	██████, CA, Region 10, 2010	Eureka	Lemon fruit	TRTDD	0.189 (0.212)	10 DAA1	0.205	<0.020	<0.010	0.215
				TRTDD	0.184 (0.206)	10 DAA1	0.188	<0.020	<0.010	0.222
RV170-10HA	██████, CA, Region 10, 2011	Lisbon	Lemon fruit	TRTDD	0.182 (0.204)	10 DAA1	0.167	<0.020	<0.010	0.200
				TRTDD	0.184 (0.207)	11 DAA1	0.349	<0.020	<0.010	0.388
RV171-10HA	██████, CA, Region 10, 2010	Eureka	Lemon fruit	TRTDD	0.182 (0.204)	10 DAA1	0.072	<0.020	<0.010	0.110
				TRTDD	0.184 (0.207)	10 DAA1	0.018	<0.020	<0.010	0.048
RV172-10DA	██████, FL, Region 3, 2011	Flame	Grapefruit fruit	TRTDD	0.181 (0.202)	9 DAA1	0.070	<0.020	<0.010	0.110
				TRTDD	0.184 (0.206)	9 DAA1	0.069	<0.020	<0.010	0.099
RV173-10HA	██████, FL, Region 2010	White	Grapefruit fruit	TRTDD	0.182 (0.204)	9 DAA1	0.127	<0.020	<0.010	0.166
				TRTDD	0.180 (0.202)	9 DAA1	0.085	<0.020	<0.010	0.122
RV174-10HA	██████, FL, Region 3, 2010	White	Grapefruit fruit	TRTDD	0.182 (0.204)	9 DAA1	0.108	<0.020	<0.010	0.144
				TRTDD	0.181 (0.203)	9 DAA1	0.187	<0.020	<0.010	0.222
RV175-10HA	██████, TX, Region 2010	Rio Red	Grapefruit fruit	TRTDD	0.186 (0.209)	9 DAA1	0.065	<0.020	<0.010	0.095
				TRTDD	0.185 (0.207)	9 DAA1	0.106	<0.020	<0.010	0.144
RV176-10DA	██████, CA, Region 10, 2011	Oro Blanco	Grapefruit fruit	TRTDD	0.182 (0.204)	11 DAA1	0.116	<0.020	<0.010	0.156
				TRTDD	0.183 (0.205)	11 DAA1	0.074	<0.020	<0.010	0.110

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

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Table 6.3.2.1-8 (cont'd): Total BYI 02960 Residue Data on Citrus Collected Immediately Prior to the Final Foliar Application of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Rate lb a.i./A (kg a.s./ha)	Sampling Interval (days after first treatment) ^b	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DPEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV177-10HA	██████, CA, Region 10, 2010	White	Grapefruit fruit	TRTDD	0.186 (0.208)	11 DAA1	0.079	<0.020	<0.010	0.11
				TRTDU	0.186 (0.204)	11 DAA1	0.056	0.020	<0.010	0.086

- ^a The residue data in this table are after a single application of BYI 02960 at a target rate of 0.183 lb a.s./A (205 g a.s./ha). A single application does not represent the proposed use pattern of two applications of BYI 02960 (total rate of 0.183 lb a.s./A/application (205 g a.s./ha/application)). Therefore, the data in this table are provided for information only and should not be used for the setting of tolerance or risk assessment.
- ^b Sampling Interval: DAA1 = days after first treatment (application)
- ^c Total BYI 02960 residue is the sum of BYI 02960, DEA, and DPEAF residues in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be after only one application of BYI 02960.
- ^d NA = Not available.
- ^e Sample analyzed twice; average value reported here.

TRTDU = treated plot receiving two concentrate (ultra-low volume) airblast applications
 TRTDD = treated plot receiving two dilute airblast applications
 DAA1 = days after first application (= application 1)

Table 6.3.2.1-9: Effect of Processing on Total BYI 02960 Residue

Plot Name	Commodity	PHI (Pre-Harvest Interval)	Processing Factor	Average Processing Factor
TRTDU	Grapefruit RAC	1	NA	Peel = 2.1X Pulp = 0.46X
	Peel		1.7	
	Pulp		0.10	
TRTDU	Lemon RAC	1	NA	
	Peel		1.6	
	Pulp		0.89	
TRTDU (2 trials)	Orange RAC	1	NA	
	Peel		3.3, 1.9 (average 2.6)	
	Pulp		0.33, 0.51 (average 0.42)	

TRTDU = Treated plot receiving two concentrate (ultra-low volume) airblast applications

Results in this table are based on "additional samples" as shown above in Table 6.3.2.1-7



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Conclusion

Twenty-six field trials were conducted to measure the magnitude of total BYI 02960 residues in/on the fruit of grapefruit (six trials), lemon (eight trials), and orange (12 trials) (representative commodities for NAFTA Crop Group 10; Citrus Fruits) following either two airblast applications (diluted or concentrated spray) or one soil drench application of BYI 02960 200 SL. Ten decline trials were conducted after foliar application; 4 in orange, 4 in lemon and 2 in grapefruit.

The total BYI 02960 residue data for citrus following soil drench or foliar application(s) are summarized in Table 6.3.2.1-10.

Table 6.3.2.1-10: Summary of Residue Data for Total BYI 02960 from Citrus

Commodity	Use Pattern description	Total Appl. Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm) ¹							
				Min at PHI	Max at PHI	Max after PHI	HAF ²	Median	Mean ³	Standard Deviation	
Grapefruit	2 foliar (dil.)	0.364 to 0.370 (0.408 to 0.405)	1	6	0.15	0.2	---	NA	0.21	0.20	0.034
	2 foliar (con)	0.363 to 0.381 (0.407 to 0.427)	1	6	0.092	0.32	---	NA	0.20	0.20	0.075
	soil drench	0.360 to 0.369 (0.403 to 0.414)	30	18	<0.040	0.086	---	0.079	0.044	0.052	0.017
Lemon	2 foliar (dil.)	0.358 to 0.380 (0.402 to 0.420)	1	8	0.15	0.43	0.55 (3) ⁵	NA	0.28	0.28	0.082
	2 foliar (con)	0.366 to 0.375 (0.410 to 0.420)	1	8	0.067	0.74	---	NA	0.18	0.30	0.28
	soil drench	0.355 to 0.366 (0.398 to 0.410)	30	18	<0.040	<0.040	---	<0.040	<0.040	<0.040	0.0
Orange	2 foliar (dil.)	0.361 to 0.377 (0.404 to 0.423)	1	12	0.097	0.78	1.5 (3) ⁵	NA	0.25	0.31	0.22
	2 foliar (con)	0.344 to 0.355 (0.386 to 0.420)	1	12	0.050	0.81	2.2 (10) ⁵	NA	0.26	0.37	0.25
	soil drench	0.360 to 0.381 (0.404 to 0.420)	30	24	<0.040	0.071	---	0.061	<0.040	0.045	0.008

1 Data from the decline trial samples collected at intervals other than a 1- or 30-day PHI are not included in this table.

2 HAF = Highest Average Field Trial

3 calculated on the basis of the residue values at the PHI

4 NA = Not Applicable. Only one sample was collected from each plot with dilute airblast applications and one sample from each plot with low volume applications. See the maximum residue for the highest residue observed from a given plot.

5 sampling day after PHI which showed the highest residue

6 no decline samples were collected

The change in the total BYI 02960 residue with time in the grapefruit, lemon, and orange samples was variable depending on the trial. In general, the total BYI 02960 residue either declined or leveled off

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

by the end of the sampling interval. The highest residue was always detected before the last sampling event (21 days after the last treatment).

The effect of the common food preparation practice of peeling citrus on the total BYI 02960 residue is as follows: peeling the fruit reduced the total BYI 02960 residue in citrus pulp by an average processing factor of 0.46X. The total BYI 02960 residue in citrus peel increased when compared to the whole fruit by an average processing factor of 2.1X.

The total BYI 02960 residues in the representative commodities for NAFTA Crop Group 10 (Citrus Fruits; grapefruit, lemon, and orange) were within a factor of 5 of each other and therefore, within the EPA guidelines for the establishment of a group tolerance for Crop Group 10.

To address EU requirements for residue trials on small citrus fruits, eight additional field trials were conducted to measure the magnitude of BYI 02960 residues in/on mandarin oranges.

Report:	KIIA 6.3.2.1/02: [REDACTED] 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in/on Mandarin Orange (CG 19)
Report No & Document No	RARVP064, dated June 5, 2012 M-432184-01-2
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1 Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009
GLP	Yes

Following either two airblast spray applications of BYI 02960 200 SL (diluted spray), two ultra-low volume applications of BYI 02960 200 SL (concentrated spray) or one soil drench application of BYI 02960 200 SL, relevant residues were determined in mandarin oranges. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.1-11).



Table 6.3.2.1-11: Trial Numbers and Geographical Locations for BYI 02960 on Mandarin Orange

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2		
3	3	
4		
5		
5A		
5B		
6	1	
7		
7A		
8		
9		
10	4	
11		
12		
13		
14		
Total	8	8

a Eight mandarin orange trials were conducted in citrus growing regions in the United States to address citrus crop residue requirements from Europe.

Material and Methods

Three use patterns/application forms were tested: either 2 dilute or 2 concentrated foliar airblast applications, or a single soil drench. For plots receiving two airblast applications – either dilute or concentrated – , individual application rates ranged from 0.173 to 0.190 lb BYI 02960/A/application (0.194 to 0.214 kg BYI 02960/ha/application) and total seasonal application rates ranged from 0.357 to 0.380 lb BYI 02960/A (0.400 to 0.426 kg BYI 02960/ha). The interval between the applications was 8 to 10 days.

For plots receiving a single soil drench application, application rates ranged from 0.364 to 0.366 lb BYI 02960/A (0.408 to 0.410 kg BYI 02960/ha), except for 2 plots, RV224 and RV228. These plots each inadvertently received too high applications of 0.904 lb BYI 02960/A/application (1.013 kg BYI 02960/ha).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

All applications were made at growth stages ranging from BBCH 72 to 89 (BBCH 72: Green fruit surrounded by sepal crown; BBCH 89: Fruit ripe for consumption; fruit has typical taste and firmness; beginning of senescence and fruit abscission).

All applications were made using ground-based equipment. An adjuvant (Dyne-Amic, or other NIS) was used in all of the applications. In plots receiving a concentrated spray, Citrus Oil was used as an additional adjuvant.

Table 6.3.2.1-12: Trial Site Conditions for BYI 02960 on Mandarin Orange

Trial Identification	Trial Location (City, State/Country, Year)	Soil Characteristics ^a			Meteorological Data ^b		
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV221-11DA	██████, FL USA 2011	Sand	1.1	7.4	4.4	9.64	55-82
RV222-11DA	██████, FL USA 2011	Sand	0.5	7.3	6.4	7.85	62-82
RV223-11DA	██████, CA USA 2011	Loam	2.4	7.9	3.9	4.1	32-77
RV224-11DA	██████, CA USA 2011	Sandy Clay Loam	2.09	7	13.3	1.41	33-61
RV225-11DA	██████, FL USA 2011	Sand	0.6	6.6	3.7	0.87	54-80
RV226-11DA	██████, TX USA 2011	Sandy Clay Loam	0.6	6.9	7.8	0.25	66-100
RV227-11DA	██████, CA USA 2011	Loam	1.1	8.2	17.0	4.51	32-77
RV228-11DA	██████, CA USA 2011	Sandy Clay Loam	2.93	7.4	21.8	0.83	33-60

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

Trial site conditions, including soil characteristics are summarized in Table 6.3.2.1-12. Study use patterns are summarized in Table 6.3.2.1-10.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-13: Study Use Pattern for BYI 02960 200 SL on Mandarin Orange

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV221-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 81	225 (210)	0.182 (0.204)	NA ^a	0.364 (0.408)	NIS
					BBCH 83	225 (210)	0.182 (0.204)	10	0.364 (0.408)	NIS
RV221-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 80	225 (26)	0.182 (0.204)	NA	0.365 (0.410)	Citrus Oil + NIS
					BBCH 83	225 (26)	0.184 (0.206)	10	0.365 (0.410)	Citrus Oil + NIS
RV221-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 79	NA	0.364 (0.408)	NA	0.364 (0.408)	NIS
RV222-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 81	225 (2100)	0.181 (0.203)	NA	0.363 (0.406)	NIS
					BBCH 83	225 (2100)	0.181 (0.203)	10	0.363 (0.406)	NIS
RV222-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 81	2.8 (26)	0.184 (0.207)	NA	0.357 (0.400)	Citrus Oil + NIS
					BBCH 83	2.6 (24)	0.173 (0.194)	10	0.357 (0.400)	Citrus Oil + NIS
RV222-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 79	NA	0.365 (0.409)	NA	0.365 (0.409)	NIS

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-13 (cont'd): Study Use Pattern for BYI 02960 200 SL on Mandarin Orange

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l./ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV223-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 79	24 (330)	0.183 (0.205)	NA	0.366 (0.411)	NIS
					BBCH 85	23 (330)	0.183 (0.205)	10		NIS
RV223-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 79	3 (28)	0.183 (0.205)	NA	0.365 (0.410)	Citrus Oil + NIS
					BBCH 83	3 (28)	0.183 (0.205)	10		Citrus Oil + NIS
RV223-11DA	Region 10 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH NA	NA	0.366 (0.410)	NA	0.366 (0.410)	NIS
RV224-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 79	19 (1860)	0.175 (0.196)	NA	0.358 (0.401)	NIS
					BBCH 85	212 (1980)	0.183 (0.205)	8		NIS
RV224-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 83	3.0 (28)	0.191 (0.214)	NA	0.375 (0.420)	Citrus Oil + NIS
					BBCH 85	2.7 (26)	0.184 (0.206)	8		Citrus Oil + NIS
RV224-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 81	NA	0.904 (1.013)	NA	0.904 (1.013)	NIS

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-13 (cont'd): Study Use Pattern for BYI 02960 200 SL on Mandarin Orange

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV224-11DA	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 83	199 (1860)	0.175 (0.198)	NA	0.358 (0.401)	NIS
					BBCH 85	212 (1980)	0.183 (0.205)		NIS	
RV224-11DA	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 83	3.0 (28)	0.191 (0.214)	NA	0.375 (0.420)	Citrus Oil + NIS
					BBCH 85	2.2 (26)	0.184 (0.206)	8	Citrus Oil + NIS	
RV224-11DA	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTDS	Oil drench	BBCH 81	NA	0.904 (1.013)	NA	0.904 (1.013)	NIS
RV225-11DA	[REDACTED] FL Region 3 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 89	259 (2420)	0.184 (0.206)	NA	0.367 (0.411)	NIS
					BBCH 89	259 (2420)	0.183 (0.205)	10	NIS	
RV225-11DA	[REDACTED] FL Region 3 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 89	2.7 (26)	0.182 (0.204)	NA	0.365 (0.409)	Citrus Oil + NIS
					BBCH 89	2.8 (26)	0.183 (0.205)	10	Citrus Oil + NIS	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-13 (cont'd): Study Use Pattern for BYI 02960 200 SL on Mandarin Orange

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV225-11DA	FL Region 3 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 81	NA	0.366 (0.410)	NA	0.366 (0.410)	NIS
RV226-11DA	TX Region 6 2011	BYI 02960 SL 200	TRTDD	Airblast (dilute appl.)	BBCH 81	251 (2350)	0.190 (0.213)	NA	0.366 (0.426)	NIS
					BBCH 83	251 (2340)	0.189 (0.213)		NIS	
RV226-11DA	TX Region 6 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 81	2.5 (24)	0.188 (0.205)	NA	0.376 (0.422)	Citrus Oil + NIS
					BBCH 83	2.6 (25)	0.189 (0.211)	8	Citrus Oil + NIS	
RV226-11DA	TX Region 6 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 81	NA	0.366 (0.410)	NA	0.366 (0.410)	NIS
RV227-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Airblast dilute appl.)	BBCH 79	249 (2330)	0.183 (0.205)	NA	0.366 (0.411)	NIS
					BBCH 83	250 (2330)	0.183 (0.205)	10	NIS	
RV227-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDD	Ultra Low Volume	BBCH 79	3.0 (28)	0.183 (0.205)	NA	0.366 (0.410)	Citrus Oil + NIS
					BBCH 83	3.0 (28)	0.183 (0.205)	10	Citrus Oil + NIS	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-13 (cont'd): Study Use Pattern for BYI 02960 200 SL on Mandarin Orange

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV227-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 75	NA	0.366 (0.410)	NA	0.366 (0.410)	NIS
RV228-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDS	Airblast dilute app ^a	BBCH 85	2.08 (1940)	0.183 (0.205)	NA	0.366 (0.411)	NIS
				BBCH 85	2.13 (1990)	0.184 (0.206)		NIS		
RV228-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDS	Ultra Low Volume	BBCH 83	3.0 (28)	0.189 (0.213)	NA	0.374 (0.419)	Citrus Oil + NIS
				BBCH 85	2.7 (26)	0.184 (0.207)	8	Citrus Oil + NIS		
RV228-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDS	Soil drench	BBCH 81	NA	0.904 (1.013)	NA	0.904 (1.013)	NIS

a NA = Not applicable.

Composite samples of mandarin oranges were collected from the plot receiving two airblast applications, at sampling intervals of 0, 1, 3, 40, 20 to 21, and for some trials 29 to 30 days after the second application. The intended pre-harvest interval (PHI) after foliar application is 1 day. Composite samples were collected from the plot receiving one soil drench application at a 28 to 30-day PHI. Single composite samples of mandarin oranges were collected from the control plots on the same day the target day samples were collected from the treated plots.

Samples were also collected immediately before the second foliar application of BYI 02960 200 SL. Residue data from these samples are provided for information only, and should not be used for risk assessment, or for the setting of tolerance levels.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries at each fortification level was within the acceptable range of 70 to 110%, and the standard deviation (SD) values were below 20% (Table 6.3.2.1-14).

Table 6.3.2.1-14: Summary of Recoveries of BYI 02960 from Mandarin Oranges

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean % Recovery ^a	Stan. % Dev.
Mandarin fruit	BYI 02960	0.010	15	95, 88, 97, 103, 98, 96, 92, 100, 95, 117, 113, 94, 105, 113	100%	8.6%
		1.000	3	96, 99, 98	98%	1.7%
	DFA	0.750	15	93, 94, 94, 104, 95, 96, 102, 92, 89, 94, 90, 91, 106, 106, 118	96%	9.8%
		1.000	3	93, 93, 92	93%	0.9%
	DFEAF	0.010	15	97, 84, 95, 97, 87, 111, 90, 96, 90, 88, 106, 98, 87, 94, 111	95%	8.4%
		1.000	3	97, 97, 98	98%	0.6%

^a Mean Recovery = mathematical average of all recoveries.

The freezer storage stability study indicates that BYI 02960 residues were stable in orange fruits as representative crops of the respective commodity (high acid content) during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 199 days. A summary of the storage conditions are shown in the Table 6.3.2.1-15.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-15: Summary of Storage Conditions for Mandarin Oranges

Residue Component(s)	Matrix (RAC)	Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^{b,c}
BYI 02960	Mandarin oranges	-22.4	6.5 months (199 days)
DFEAF	Mandarin oranges	-22.4	6.5 months (199 days)
DFA	Mandarin oranges	-22.4	6.5 months (199 days)

- a The average storage temperature is from the time of sample receipt at BPP until the final sample analysis and is the maximum of all three freezers that the samples were stored in. Actual temperature values can be found in raw data notebook RARVP064.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED], [REDACTED] and A. [REDACTED], 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for citrus following a single soil drench, or two foliar application(s) of BYI 02960 200 SL are shown in Tables 6.3.2.1-16. The results from samples taken just prior to the final application are shown in Table 6.3.2.1-17. The samples collected after a single foliar application do not reflect the proposed use rate, and the residue data from these samples were collected for informational purposes only.

Table 6.3.2.1-16: Total BYI 02960 Residue Data from Mandarin Oranges after a Single Soil Drench Two Foliar Application(s) of BYI 02960 SL

Trial Number	Location (City, State, and NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A a.s. (kg a.s./ha)	PHI (Preharvest Interval)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV221-11DA	[REDACTED], FL Region 3, 2011	TRTDD	W Murcotts	Fruit	0.364 (0.408)	0	0.144	<0.050	<0.010	0.204
						1	0.160	<0.050	<0.010	0.220
						3	0.053	<0.050	<0.010	0.113
						10	0.070	<0.050	<0.010	0.130
						21	0.071	0.054	<0.010	0.135
						30	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-16 (cont'd): Total BYI 02960 Residue Data from Mandarin Oranges after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg ai/ha)	PHI (Preharvest ^a Interval)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue ^b (mg a.s. equiv./kg)
RV221-11DA	██████, FL, Region 3, 2011	TRTDU	W. Murcotts	Fruit	0.365 (0.410)	0	0.025	<0.050	<0.010	0.086
						1	0.025	<0.050	<0.010	0.085
						10	0.015	<0.050	<0.010	0.075
						21	0.015	<0.050	<0.010	0.077
RV221-11DA	██████, FL, Region 3, 2011	TRTDS	W. Murcotts	Fruit	0.364 (0.408)	0	0.010	<0.050	<0.010	<0.070
						30	0.010	<0.050	<0.010	<0.070
Avg: <0.070										
RV222-11DA	██████, FL, Region 3, 2011	TRTDD	Sunburst	Fruit	0.363 (0.406)	0	0.289	<0.050	<0.010	0.349
						1	0.353	<0.050	<0.010	0.413
						3	0.240	<0.050	<0.010	0.300
						10	0.23	<0.050	<0.010	0.294
						21	0.197	0.069	<0.010	0.276
						30	0.012	<0.050	<0.010	0.072
Avg: 0.071										
RV222-11DA	██████, FL, Region 3, 2011	TRTDU	Sunburst	Fruit	0.357 (0.403)	0	0.056	<0.050	<0.010	0.116
						1	0.056	<0.050	<0.010	0.116
						3	0.044	<0.050	<0.010	0.104
						10	0.052	<0.050	<0.010	0.112
						21	0.053	<0.050	<0.010	0.113
RV222-11DA	██████, FL, Region 3, 2011	TRTDS	Sunburst	Fruit	0.365 (0.409)	30	0.012 <0.010	<0.050 <0.050	<0.010 <0.010	0.072 <0.070
Avg: 0.071										

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-16 (cont'd): Total BYI 02960 Residue Data from Mandarin Oranges after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg a.s./ha)	PHI (Preharvest ^a Interval)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV223-11DA	[REDACTED], CA, Region 10, 2011	TRTDD	Satsuma	Fruit	0.366 (0.411)	0	0.129	<0.050	<0.010	0.189
						1	0.108	<0.050	<0.010	0.168
						3	0.104	<0.050	<0.010	0.164
						10	0.156	<0.050	<0.010	0.216
						21	0.132	<0.050	<0.010	0.192
RV223-11DA	[REDACTED], CA, Region 10, 2011	TRTDU	Satsuma	Fruit	0.366 (0.410)	0	0.065	<0.050	<0.010	0.125
						1	0.165	<0.050	<0.010	0.225
						3	0.162	<0.050	<0.010	0.222
						10	0.197	<0.050	<0.010	0.257
						21	0.210	<0.050	<0.010	0.270
RV223-11DA	[REDACTED], CA, Region 10, 2011	TRTDS	Satsuma	Fruit	0.366 (0.410)	0	<0.010	<0.050	<0.010	<0.070
						3	<0.010	<0.050	<0.010	<0.070
Avg: <0.070										
RV224-11DA	[REDACTED], CA, Region 10, 2011	TRTDD	Tango	Fruit	0.358 (0.401)	0	0.268	<0.050	<0.010	0.328
						1	0.328	<0.050	<0.010	0.388
						3	0.277	<0.050	<0.010	0.337
						10	0.361	<0.050	<0.010	0.421
						21	0.175	<0.050	<0.010	0.235
RV224-11DA	[REDACTED], CA, Region 10, 2011	TRTDU	Tango	Fruit	0.375 (0.420)	0	0.287	<0.050	<0.010	0.347
						1	0.398	<0.050	<0.010	0.458
						3	0.546	<0.050	<0.010	0.606
						10	0.357	<0.050	<0.010	0.417
						21	0.249	<0.050	<0.010	0.309
RV224-11DA	[REDACTED], CA, Region 10, 2011	TRTDS	Tango	Fruit	0.904 (1.013)	0	<0.010	<0.050	<0.010	<0.070
						3	<0.010	<0.050	<0.010	<0.070
Avg: <0.070										

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-16 (cont'd): Total BYI 02960 Residue Data from Mandarin Oranges after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg a.s./ha)	PHI (Preharvest ^a Interval)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV225-11DA	██████, FL, Region 3, 2011	TRTDD	Sunburst	Fruit	0.367 (0.411)	0	0.242	<0.050	0.010	0.272
						1	0.151	<0.050	<0.010	0.211
						3	0.233	<0.050	0.010	0.193
						10	0.137	<0.050	<0.010	0.16
						21	0.069	<0.050	<0.010	0.29
RV225-11DA	██████, FL, Region 3, 2011	TRTDU	Sunburst	Fruit	0.365 (0.409)	0	0.510	0.050	0.010	0.570
						1	0.365	0.0	0.010	0.446
						10	0.492	<0.050	<0.010	0.552
						21	0.375	<0.050	<0.010	0.435
RV225-11DA	██████, FL, Region 3, 2011	TRTDS	Sunburst	Fruit	0.366 (0.410)	29	<0.010	<0.050	<0.010	<0.070
							0.010	<0.050	<0.010	<0.070
										Avg: <0.070
RV226-11DA	██████, TX, Region 6, 2011	TRTDD	Dancy	Fruit	0.480 (0.426)	0	0.233	<0.050	<0.010	0.293
						1	0.236	<0.050	0.047	0.333
						3	0.329	<0.050	0.045	0.424
						10	0.177	0.053	<0.010	0.240
						21	0.148	0.063	<0.010	0.221
RV226-11DA	██████, TX, Region 6, 2011	TRTDD	Dancy	Fruit	0.376 (0.422)	0	0.858	<0.050	<0.010	0.918
						1	0.486	<0.050	<0.010	0.546
						3	0.228	<0.050	<0.010	0.288
						10	0.898	0.094	<0.010	1.002
						21	0.414	0.092	<0.010	0.516 ^s
RV226-11DA	██████, TX, Region 6, 2011	TRTDS	Dancy	Fruit	0.366 (0.410)	29	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-16 (cont'd): Total BYI 02960 Residue Data from Mandarin Oranges after a Single Soil Drench or Two Foliar Application(s) of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg a.s./ha)	PHI (Preharvest ^a Interval)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV227-11DA	█, CA, Region 10, 2011	TRTDD	Satsuma	Fruit	0.366 (0.411)	0	0.252	<0.050	<0.010	0.312
						1	0.142	<0.050	<0.010	0.202
						3	0.280	<0.050	<0.010	0.340
						10	0.177	<0.050	<0.010	0.257
						21	0.249	<0.050	<0.010	0.309
RV227-11DA	█, CA, Region 10, 2011	TRTDU	Satsuma	Fruit	0.366 (0.410)	0	0.148	<0.050	<0.010	0.208
						1	0.152	<0.050	<0.010	0.212
						3	0.189	<0.050	<0.010	0.249
						10	0.274	<0.050	<0.010	0.331
						21	0.393	<0.050	<0.010	0.453
RV227-11DA	█, CA, Region 10, 2011	TRPDS	Satsuma	Fruit	0.366 (0.410)	30	<0.010	<0.050	<0.010	<0.070
						30	<0.010	<0.050	<0.010	<0.070
										Avg: <0.070
RV228-11DA	█, CA, Region 10, 2011	TRTDD	Owari Satsuma	Fruit	0.366 (0.411)	0	0.192	<0.050	<0.010	0.252
						1	0.186	<0.050	<0.010	0.246
						3	0.159	<0.050	<0.010	0.219
						10	0.144	<0.050	<0.010	0.204
						21	0.124	<0.050	<0.010	0.184
RV228-11DA	█, CA, Region 10, 2011	TRTDU	Owari Satsuma	Fruit	0.374 (0.419)	0	0.331	<0.050	<0.010	0.391
						1	0.091	<0.050	<0.010	0.151
						3	0.610	<0.050	<0.010	0.670
						10	0.080	<0.050	<0.010	0.140
						21	0.035	<0.050	<0.010	0.095
RV228-11DA	█, CA, Region 10, 2011	TRTDS	Owari Satsuma	Fruit	0.904 (1.013)	29	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070

a Pre-Harvest Interval (PHI) is the interval between last application and Sample Date.

b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

 Maximum residue values for the different application scenarios and crops are printed in **bold**.

Table 6.3.2.1-17: Total BYI 02960 Residue Data from Mandarin Oranges taken immediately prior to the second foliar application of BYI 02960

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Days Before Application ^a	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV221-11DA	██████, FL, Region 3, 2011	TRTDD	W. Murcotts	Fruit	0.364 (0.488)	0	0.119	<0.050	<0.010	0.179
RV221-11DA	██████, FL, Region 3, 2011	TRTDU	W. Murcotts	Fruit	0.365 (0.410)	0	0.011	0.050	<0.010	0.071
RV222-11DA	██████, FL, Region 3, 2011	TRTDD	Sunburst	Fruit	0.363 (0.406)	0	0.129	0.050	<0.010	0.189
RV222-11DA	██████, FL, Region 3, 2011	TRTDU	Sunburst	Fruit	0.357 (0.400)	0	0.048	0.050	<0.010	0.108
RV223-11DA	██████, CA, Region 10, 2011	TRTDD	Satsuma	Fruit	0.366 (0.411)	0	0.102	0.050	<0.010	0.162
RV223-11DA	██████, CA, Region 10, 2011	TRTDU	Satsuma	Fruit	0.365 (0.410)	0	0.145	<0.050	<0.010	0.205
RV224-11DA	██████, CA, Region 10, 2011	TRTDD	Tango	Fruit	0.368 (0.401)	0	0.106	<0.050	<0.010	0.166
RV224-11DA	██████, CA, Region 10, 2011	TRTDU	Tango	Fruit	0.371 (0.420)	0	0.460	<0.050	<0.010	0.520
RV225-11DA	██████, FL, Region 3, 2011	TRTDD	Sunburst	Fruit	0.367 (0.411)	0	0.131	<0.050	<0.010	0.191
RV225-11DA	██████, FL, Region 3, 2011	TRTDU	Sunburst	Fruit	0.365 (0.409)	0	0.471	<0.050	<0.010	0.531
RV226-11DA	██████, TX, Region 6, 2011	TRTDD	Dancy	Fruit	0.380 (0.426)	0	0.178	<0.050	<0.010	0.238
RV226-11DA	██████, TX, Region 6, 2011	TRTDU	Dancy	Fruit	0.376 (0.422)	0	0.484	<0.050	<0.010	0.544 ^{c,d}
RV227-11DA	██████, CA, Region 10, 2011	TRTDD	Satsuma	Fruit	0.366 (0.411)	0	0.176	<0.050	<0.010	0.236



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Table 6.3.2.1-17 (cont'd): Total BYI 02960 Residue Data from Mandarin Oranges taken immediately prior to the second foliar application of BYI 02960

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Days Before Application ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV227-11DA	██████, CA, Region 10, 2011	TRTDU	Satsuma	Fruit	0.366 (0.410)	0	0.404	0.050	0.010	0.464
RV228-11DA	██████, CA, Region 10, 2011	TRTDD	Owari Satsuma	Fruit	0.366 (0.411)	0	0.084	0.050	0.010	0.144
RV228-11DA	██████, CA, Region 10, 2011	TRTDU	Owari Satsuma	Fruit	0.324 (0.419)	0	0.064	0.050	0.010	0.124

a Samples were collected immediately prior to the second foliar application and do not reflect the proposed use rate. Therefore, the residue data from these samples were collected for informational purposes only, are provided for information only, and should not be used for risk assessment, or for the setting of tolerance levels.

b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

c Maximum residue found in mandarin orange at IBA2 (immediately before application).

d Highest average field trial (HAFT) residue found in mandarin orange at IBA2.

Conclusion

Eight field trials were conducted to measure the magnitude of total BYI 02960 residue in/on mandarin oranges following either two spray applications of BYI 02960 200 SL (diluted or concentrated spray) or one soil drench application of BYI 02960 200 SL. All trials with foliar spray application were designed as decline trials.

The total BYI 02960 residue data for mandarin oranges following a soil drench or foliar application(s) are summarized in Table 6.3.2.1-18.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-18.: Summary of Residue Data for Total BYI 02960 from Mandarin Oranges

Commodity	Plot Name ²	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm) ¹							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ³	Median ⁴	Mean	Standard Deviation
Mandarin oranges	TRTDD	0.358 to 0.380 (0.406 to 0.426)	1	8	0.118	0.363	0.424	0.3630	0.1951	0.2295	0.0922
Mandarin oranges	TRTDU	0.357 to 0.376 (0.400 to 0.422)	1	8	0.035	0.496	1.002	0.4955	0.1685	0.2350	0.1829
Mandarin oranges	TRTDS	0.364 to 0.366 (0.408 to 0.410) & 0.904 (1.013)*	30	8	0.070	0.072	---	0.070	0.070	0.070	0.0004

- * Plot TRTDS for trials RV224 and RV228 had soil drench applications made at higher rates.
- 1 Data from the decline trial samples collected at intervals other than the 1 or 30 day PHI are not included in this table.
- 2 TRTDD = Treated plot receiving two airblast applications;
TRTDU = Treated plot receiving two ultra-low volume applications;
TRTDS = Treated plot receiving one soil drench application.
- 3 HAFT = Highest Average Field Trial.
- 4 calculated on the basis of the residue values at the PHI
- 5 sampling day after PHI which showed the highest residue
- 6 no decline samples were collected

Spray application uses were clearly more critical in respect to possible residues in mandarin oranges compared to the soil drench use. Samples collected from decline trials after spray application indicated that the total BYI 02960 residue in edible mandarin oranges declined initially with a subsequent increase in total residue with either a leveling or a continued increase in total BYI 02960 residue until approximately 10 days after the last application. The highest residue value detected in all trials was in a sample collected 10 days after the last application. Only one trial showed the highest residue value at the last sampling event (21 days after the last application), in all other trials the peak residue was detected prior to that. Therefore it can be assumed that the peak maximum is reached and the residue data provided in this report are suitable for regulatory purposes.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

An additional study was conducted to compare residues from citrus trials following the use patterns for BYI 02960 200 SL from Brazil and North America.

Report:	KIIA 6.3.2.1/03; [REDACTED] 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in/on Citrus (including Bridging Trials to Brazil Import Tolerance).
Report No & Document No	RARVP076, dated June 15, 2012 M-432687-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 866.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, adopted Sept. 7, 2009.
GLP	Yes

Four field trials were conducted to measure the magnitude of BYI 02960 residues in/on orange following either one soil drench application followed by two broadcast foliar spray applications of BYI 02960 200 SL (simulating the potential use pattern for Brazil), or two foliar broadcast foliar spray applications of BYI 0296 200 SL (simulating the worst-case use pattern from North America) (Table 6.3.2.1-19).

Table 6.3.2.1-19: Target Use Patterns for the Application of BYI 02960 on Orange (comparative trials)

Plot ID ¹	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI ² (Days)	Adjuvant/Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
UTC	NA ³	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
TRTSE	BYI 02960 200 SL	1 soil	398.7	102.6	BYI 02960	1.339	1.5	90	106	0.25	NA	500 ⁴
		2 foliar	414.8	14.03	BYI 02960	0.1829	0.205	15	10	0.25	200	1877
TRTDF	BYI 02960 200 SL	2 foliar	414.8	14.03	BYI 02960	0.1829	0.205	30	10	0.25	200	1877

1 UTC = Untreated control plot; TRTSE = Treated plot receiving one soil drench application followed by two foliar applications; TRTDF = Treated plot receiving two foliar applications.

2 Samples were to be collected at target PHIs of 0, 3, 10, 21, and 28 days.

3 NA = Not applicable.

4 Soil drench applications were to be made at approximately 500 mL spray solution per plant.

The number and location of field trials are shown in Table 6.3.2.1-20.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-20: Trial Numbers and Geographical Locations for BYI 02960 on Orange (comparative trials)

NAFTA Growing Region	Submitted
10	4
Total	4

Material and Methods

For plots receiving a single soil drench application followed by two foliar applications, soil drench application rates ranged from 0.921 to 1.339 lb BYI 02960/A (1.033 to 1.501 kg BYI 02960/ha); foliar application rates ranged from 0.178 to 0.184 lb BYI 02960/A/application (0.199 to 0.206 kg BYI 02960/ha/application) and total seasonal application rates ranged from 1.281 to 1.706 lb BYI 02960/A (1.438 to 1.912 kg BYI 02960/ha). Soil drench applications were made 90-91 days before the first foliar application.

For plots receiving two foliar applications, individual application rates ranged from 0.179 to 0.184 lb BYI 02960/A/application (0.200 to 0.207 kg BYI 02960/ha/application) and total seasonal application rates ranged from 0.362 to 0.369 lb BYI 02960/A (0.406 to 0.413 kg BYI 02960/ha).

The interval between the foliar applications was 9 to 13 days. Soil drench applications were made at growth stages ranging from BBCH 73 to 79 (BBCH 73: some fruits slightly yellow, beginning of physiological fruit drop; BBCH 79: Fruits about 90% of final size). Foliar applications were made at growth stages ranging from BBCH 81 to 89 (BBCH 81: Beginning of fruit colouring; BBCH 89: Fruit ripe for consumption).

All applications were made using ground-based equipment. An adjuvant (non-ionic surfactant [for the plot receiving two foliar applications] or methylated seed oil [for the plot receiving one soil drench followed by two foliar applications]) was used in all of the applications at 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.1-21. Study use patterns are summarized in Table 6.3.2.1-20.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-21: Trial Site Conditions for BYI 02960 on Oranges (comparative trials)

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (F)
RV239-11DA	██████, CA, 2011	Loam	1.5	8.1	17	10.20	32 - 82
RV240-11DB	██████, CA, 2011	Sandy Loam	0.95	7.1	10	3.92	29 - 92
RV241-11DA	██████, CA, 2011	Clay Loam	2.2	8.2	33	7.79	51 - 77
RV242-11DA	██████, CA, 2011	Sandy Loam	0.82	7.6	10	5.35	29 - 82

- a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity
- b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.
- c NA = Not Available.

Table 6.3.2.1-22: Study Use Pattern for BYI 02960 200 SL on Oranges (comparative trials)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV239-11DA	██████ Region 10 2012	BYI 02960 SL 200	TRTSF	Soil Drench	81	201 (1875)	0.183 (0.205)	90	1.71 (1.91)	MSO, 0.25% v/v
				Airblast	81	201 (1875)	0.183 (0.205)	90		MSO, 0.25% v/v
				Airblast	85	201 (1876)	0.183 (0.205)	18		MSO, 0.25% v/v
RV239-11DA	██████ CA Region 10 2012	BYI 02960 SL 200	TRTDF	Airblast	81	200 (1872)	0.182 (0.204)	NA	0.365 (0.409)	NIS, 0.25% v/v
				Airblast	85	200 (1874)	0.183 (0.205)	13		NIS, 0.25% v/v



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-22 (cont'd): Study Use Pattern for BYI 02960 200 SL on Oranges (comparative trials)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate (kg a.s./A) (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV240-11DB	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTSF	Soil Drench	74	NA	1.34 (1.50)	NA	1.70 (1.91)	MSO, 0.25% v/v	
				Airblast	85	212 (1978)	0.182 (0.204)	90	MSO, 0.25% v/v		
				Airblast	85	214 (2000)	0.182 (0.204)	15	MSO, 0.25% v/v		
RV240-11DB	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTDF	Airblast	85	215 (2014)	0.183 (0.205)	NA	0.364 (0.408)	NIS, 0.25% v/v	
				Airblast	85	213 (1992)	0.181 (0.203)	9	NIS, 0.25% v/v		
RV241-11DA	[REDACTED] CA Region 10 2011	BYI 02960 SL 200	TRTSF	Soil Drench	81	NA	1.34 (1.50)	NA	1.71 (1.91)	MSO, 0.25% v/v	
				Airblast	83	285 (2664)	0.184 (0.206)	89	MSO, 0.25% v/v		
				Airblast	85	274 (2565)	0.183 (0.205)	14	MSO, 0.25% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-22 (cont'd): Study Use Pattern for BYI 02960 200 SL on Oranges (comparative trials)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate (kg a.s./A) (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing (Growth Stage) (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV241-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDF	Airblast	83	283 (2646)	0.184 (0.206)	NA	0.362 (0.406)	NIS, 0.25% v/v	
				Airblast	89	278 (2558)	0.184 (0.206)	NA			
RV242-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTSF	Soil Drench	NA	NA	0.21 (1.03)	NA	0.28 (1.44)	MSO, 0.25% v/v	
				Airblast	89	201 (1881)	0.184 (0.206)	91			MSO, 0.25% v/v
				Airblast	89	244 (2279)	0.178 (0.199)	14			
RV242-11DA	CA Region 10 2011	BYI 02960 SL 200	TRTDF	Airblast	89	251 (2347)	0.183 (0.205)	NA	0.362 (0.406)	NIS, 0.25% v/v	
				Airblast	89	245 (2289)	0.179 (0.200)	9			NIS, 0.25% v/v

a NA = Not applicable

TRTSF = Treated plot receiving one soil drench application followed by two foliar applications

TRTDF = Treated plot receiving two foliar applications

Duplicate composite samples of oranges were collected from the all plots, at intervals of 0, 1, 3, 8 to 10 and 21 days after the second foliar application. An additional duplicate sample was collected from the plot receiving an additional soil drench application at 28 days after the final treatment. Single composite samples of oranges were collected from the control plots on the same day the target-PHI 1-day samples were collected from the treated plots.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries at each fortification level was within the acceptable range of 70 to 110%, and the standard deviation (SD) values were below 20% (Table 6.3.2.1-23).

Table 6.3.2.1-23: Summary of Recoveries of BYI 02960 from Orange (comparative trials)

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Oranges	BYI 02960	0.01	15	75, 77, 72, 68, 77, 67, 64, 65, 62, 78, 78, 70, 64, 64, 61	71	6.2
		1.0	3	76, 76, 76	76	0.93
	DFA	0.05	12	86, 82, 74, 78, 73, 73, 69, 78, 68, 77, 72, 72	76	6.9
		1.0	3	79, 79, 76	78	1.9
	DFEAF	0.01	15	93, 75, 86, 68, 55, 73, 56, 84, 104, 71, 71, 67, 69, 72, 66	74	13
		1.0	3	83, 89, 79	84	5.1

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in orange during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 210 days. A summary of the storage conditions is shown in the Table 6.3.2.1-24.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-24: Summary of Storage Conditions for Orange

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^{b,c}
BYI 02960	Oranges	< -20	7 (210)
DFEAF	Oranges	< -20	7 (210)
DFA	Oranges	< -20	7 (210)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Bxant. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A. [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for oranges following either two foliar applications, or alternatively a single soil drench and two foliar applications, of BYI 02960 200 SL are shown on Table 6.3.2.1-25.

Table 6.3.2.1-25: Total BYI 02960 Residue Data from Citrus after Two Foliar Applications of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb/a.s./A (kg a.s./ha)	Sampling Interval (days) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total Residue (mg a.s. equiv./kg) ^b
RV239 -11DA	[REDACTED] CA Region 10, 2012	TRTDF	Valencia	Fruit	0.365 (0.409)	0	0.016 0.010	<0.050 <0.050	<0.010 <0.010	0.076 <0.070 Avg: <0.070
						1	0.018 0.023	<0.050 <0.050	<0.010 <0.010	0.078 0.083 Avg: 0.08
						3	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
						10	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
						21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-25 (cont'd): Total BYI 02960 Residue Data from Citrus after Two Foliar Applications of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb(a.s.)/A (kg a.s./ha)	Sampling Interval (days) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAD Residue (mg a.s. equiv./kg)	Total Residue (mg a.s. equiv./kg) ^b
RV239 -11DA	[REDACTED] CA, Region 10, 2012	TRTSF	Valencia	Fruit	1.71 (1.91)	0	0.075 0.067	<0.050 <0.050	<0.010 <0.010	0.135 0.127 Avg: 0.13
						1	0.071 0.054	<0.050 <0.050	<0.010 <0.010	0.132 0.085 Avg: 0.11
						3	0.074 0.064	<0.050 <0.050	<0.010 <0.010	0.097 <0.070 Avg: 0.07
						10	0.019 0.025	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
						21	0.017 0.013	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
						28	0.015 0.011	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
						28	0.015 0.011	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV240 -11DB	[REDACTED] CA, Region 10, 2011	TRTDE	Washington Navel	Fruit	0.364 (0.405)	0	0.108 0.109	<0.050 <0.050	<0.010 <0.010	0.168 0.169 Avg: 0.17
						1	0.108 0.207	<0.050 <0.050	<0.010 <0.010	0.168 0.267^c Avg: 0.22^d
						3	0.141 0.155	0.383 0.383	<0.010 <0.010	0.534 0.548 Avg: 0.54
						8	0.136 0.103	<0.050 <0.050	<0.010 <0.010	0.196 0.163 Avg: 0.18
						21	0.034 0.060	<0.050 <0.050	<0.010 <0.010	0.094 0.120 Avg: 0.11
						21	0.034 0.060	<0.050 <0.050	<0.010 <0.010	0.094 0.120 Avg: 0.11

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-25 (cont'd): Total BYI 02960 Residue Data from Citrus after Two Foliar Applications of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb(a.s./A (kg a.s./ha)	Sampling Interval (days) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAO Residue (mg a.s. equiv./kg)	Total Residue (mg a.s. equiv./kg) ^b
RV240 -11DB	[REDACTED] CA, Region 10, 2011	TRTSF	Washing on Navel	Fruit	1.70 (1.91)	0	0.136 0.147	0.327 0.411	<.010 <.010	0.494 0.578
						1	0.155 0.188	0.271 0.431	<.010 <.010	0.433 0.579 ^e
						3	0.136 0.152	0.050 0.050	<.010 <.010	0.166 0.182
						7	0.147 0.152	0.223 0.434	<.010 <.010	0.48 0.596
						14	0.09 0.067	0.329 0.364	<.010 <.010	0.429 0.441
						21	0.078 0.106	0.388 0.409	<.010 <.010	0.476 0.525 ^g
						Avg:				0.54
						Avg:				0.43
						Avg:				0.43
						Avg:				0.43
RV241 -11DA	[REDACTED] CA, Region 10, 2011	TRTDF	Olinda Valencia	Fruit	0.369 (0.413)	0	0.102 0.083	<.050 <.050	<.010 <.010	0.162 0.143
						1	0.054 0.061	<.050 <.050	<.010 <.010	0.114 0.121
						3	0.034 0.041	<.050 <.050	<.010 <.010	0.094 0.101
						10	0.068 0.0916	<.050 <.050	<.010 <.010	0.128 0.152
						21	0.094 0.081	<.050 <.050	<.010 <.010	0.154 0.141
						Avg:				0.15

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-25 (cont'd): Total BYI 02960 Residue Data from Citrus after Two Foliar Applications of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb(a.s./A (kg a.s./ha)	Sampling Interval (days) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAO Residue (mg a.s. equiv./kg)	Total Residue (mg a.s. equiv./kg) ^b
RV241 -11DA	[REDACTED] CA, Region 10, 2011	TRTSF	Olinda Valencia	Fruit	1.71 (1.91)	0	0.208 0.128	<0.050 <0.050	<0.010 <0.010	0.268 0.188 Avg: 0.233
						1	0.050 0.050	<0.050 <0.050	<0.010 <0.010	0.118 0.190 Avg: 0.16
						3	0.067 0.14	<0.050 <0.050	<0.010 <0.010	0.121 0.174 Avg: 0.15
						10	0.039 0.069	<0.050 <0.013	<0.010 <0.010	0.099 0.092 Avg: 0.10
						15	0.121 0.092	<0.050 <0.050	<0.010 <0.010	0.198 0.136 Avg: 0.17
						21	0.068 0.038	<0.050 <0.050	<0.010 <0.010	0.128 0.098 Avg: 0.11
						Avg:				
RV242 -11DA	[REDACTED] CA, Region 10, 2011	TRTDF	Naval	Fruit	0.362 (0.406)	0	0.1 0.107	<0.050 <0.050	<0.010 <0.010	0.16 0.167 Avg: 0.16
						1	0.091 0.089	<0.050 <0.050	<0.010 <0.010	0.151 0.149 Avg: 0.15
						3	0.090 0.076	<0.050 <0.050	<0.010 <0.010	0.150 0.136 Avg: 0.14
						10	0.12 0.113	<0.050 <0.050	<0.010 <0.010	0.18 0.173 Avg: 0.18
						21	0.035 0.035	<0.050 <0.050	<0.010 <0.010	0.095 0.095 Avg: 0.10
						Avg:				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-25 (cont'd): Total BYI 02960 Residue Data from Citrus after Two Foliar Applications of BYI 02960 SL

Trial Number	Location (City, State, NAFTA Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	PHI (Preharvest Interval) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAE Residue (mg a.s. equiv./kg)	Total Residue (mg a.s. equiv./kg) ^b
RV242-11DA	[REDACTED], CA, Region 10, 2011	TRTSF	Naval	Fruit	1.25 (1.41)	0	0.172 0.188	<0.050 0.050	<0.010 0.010	0.232 0.248
						1	0.125 0.162	<0.050 0.050	<0.010 0.010	0.187 0.210
						3	0.125 0.171	<0.050 0.050	<0.010 0.010	0.184 0.17
						10	0.141 0.162	<0.050 0.050	<0.010 0.010	0.201 0.222
							0.11 0.072	<0.050 0.050	<0.010 0.010	0.17 0.132
							0.058 0.053	<0.050 0.050	<0.010 0.010	0.118 0.113
										Avg: 0.18
										Avg: 0.21

- a Sampling interval is the interval between last application and sampling date at harvest.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFAE residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Maximum residue found in oranges, sampled at 1 day.
- d Highest average field trial (HAFT) residue found in oranges, sampled at 1 day.
- e Maximum residue found in oranges, sampled at 1 day.
- f Highest average field trial (HAFT) residue found in oranges, sampled at 1 day.
- g Maximum residue found in oranges, sampled at 28 days.
- h Highest average field trial (HAFT) residue found in oranges, sampled at 28 days.

TRTSF = Treated plot receiving two airblast applications subsequent to a soil drench application

TRTDF = Treated plot receiving two foliar (ditch airblast) applications

Conclusion

Four decline field trials were conducted to measure the magnitude of total BYI 02960 residue in/on oranges following one soil drench application of BYI 02960 200 SL followed by two foliar applications, as well as the magnitude of total BYI 02960 residue following two foliar applications, thus comparing the planned NAFTA use pattern with the worst-case GAP for Brazil.

The total BYI 02960 residue data for oranges following foliar applications are summarized in Table 6.3.2.1-26.

Table 6.3.2.1-26: Summary of Residue Data for Total BYI 02960 from Orange (comparative trials)

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days) ³	n	Total BYI 02960 Residue Levels (ppm)						
					Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean ³	Standard Deviation
Orange	TRTDF	0.362-0.369 (0.406-0.413)	1	8	0.072	0.230	0.248 (3) ⁴	0.181	0.122	0.132	0.049
Orange	TRTSF	1.281-1.706 (1.438-1.912)	1	8	0.085	0.579	---	0.506	0.470	0.236	0.175
Orange	TRTSF	1.281-1.706 (1.438-1.912)	1	8	<0.070	0.525	---	0.504	0.091	0.185	0.196

- 1 TRTDF = Treated plot receiving two dilute airblast applications; TRTSF = Treated plot receiving one soil drench application followed by two foliar applications.
- 2 HAFT = Highest Average Field Trial.
- 3 calculated on the basis of residue values at the PHI.
- 4 Sampling day showing highest residue

The decline trials showed that the total BYI 02960 residues remained generally flat, or decreased slightly by the end of the study. In general, the plot receiving a soil drench application followed by two foliar applications (based upon the proposed Brazilian GAP) had slightly higher residues than the plot receiving only two foliar applications. However, the highest residue found in the plot using the proposed Brazilian GAP is significantly lower than the proposed MRL for the citrus crop group (which is calculated from the residue data from the definitive residue study (RARVY012; KIIA 6.3.2.1/01) and from the foliar-treated plots from this bridging study. In all trials, the highest residue was always detected before the last sampling event (28 days after the last application).

Residue Data from BRAZIL

BYI 02960 is to be registered in Brazil for soil and/or foliar treatment use in/on citrus. The use pattern in Brazil is summarized in Table 6.3.2.1-27.

A total of ten trials (5 trials covering the worst case use of a soil treatment followed by two foliar-spray applications and 5 trials covering the two foliar spray applications, only) were conducted in orange. The studies are described below.

Table 6.3.2.1-27: Target Use Patterns for the Application of BYI 02960 on Citrus in Brazil

Test Substance	Appl. No.	Mode of Appl.	Target Application Rate		Target App. Interval (Days) ^a	Target PHI (Days)	Adjuvant Additive (% v/v) ^b	Spray Volume
			Form. Product (fp)	Active Substance (a.s.) g a.s./ha				
BYI 02960 200 SL	1	Soil Drench (Directed Jet at the base of the plants)	5 mL /meter tree height	Var ^c	NA ^d	105	None	50 mL/plant
	2	Foliar	1.0 L/Ha	200	90	15	0.25	2000 L/Ha
	3	Foliar	1.0 L/Ha	200	15	0	0.25	2000 L/Ha
BYI 02960 200 SL	1	Foliar	1.0 L/Ha	200	NA	15	0.25	2000 L/Ha
			1.0 L/Ha	200	15	0	0.25	2000 L/Ha

a A single soil drench application applied at 90 days before the first foliar application.

b Adjuvant: Methylated Soybean Oil

c Var = Variable. Application rate for formulated product is 5 ml/meter tree height. Active substance rate per hectare depends on tree density and height.

d NA = Not Applicable

Report:	KIA 6.3.2.1/04; [REDACTED]; 2012
Title:	Determination of residues of BYI 02960 and its metabolites, in citrus after drench application at the base of the plants, followed by foliar spray application of BYI 02960 200 SL in field trials in Brazil
Report No. & Document No.:	I11-029, dated March 06, 2012 M-427041-02-3
Guidelines:	Resolution of Collegiate Board of Directors RDC No. 216 of December 2006, 15 th RDC No. 4 of January 2012, 18 th National Health Surveillance Agency – ANVISA, from the Ministry of Health
GLP:	Yes

Five trials were conducted to measure the magnitude of BYI 02960 residues in/on citrus, following a single soil drench application followed by two broadcast foliar spray applications of BYI 02960



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-29: Trial Site Conditions for BYI 02960 on Citrus

Identification of Field Trials	I11-022-01	I11-022-02	I11-022-03	I11-022-04	I11-022-05
Principal Investigator	[Redacted] Junior	[Redacted] Junior	[Redacted]	[Redacted]	[Redacted]
Size of the Plots Control / Treated (m ²)	200 / 120	180 / 144	226 / 126	144 / 144	143 / 34
Number of Plots	2	2	2	2	2
Spacing between the lines (m)	5	6	6	6	7
Type of Soil	Clayey	Clayey	Red Yellow Clayey	Clayey	Clayey
pH value of Soil in CaCl ₂	5.4	6.0	7.7	6.1	6.1
pH value of Soil in Water	-	-	-	-	4.7
Content of organic (%)	3.5	2.1	1.8	2.1	2.8
Soil Topography	Declivity < 5%	Declivity < 5%	Declivity < 5%	Declivity < 5%	Declivity < 5%
Test System	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)
Variety	Pera Rio	Pera Rio	Valencia	Valência	Valência
Date of planting/seeding or age of the plant	11/2006	02/2002	11/2004	11 years	09/1998
Date of commercial harvest	May to August	May to August	June to October	July to August	May to August

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-30: Study Use Pattern for BYI 02960 200 SL on Citrus

Identification of the Field trial	Type of Application	Dates of application (mm/dd/yy)	Culture stage (BBCH)	Effective spray volume (L)	Effective applied dose (L/ha)	Height of Plant (m)
111-022-01	Directed jet	03/30/2011	75	4.0	5 mL / meter of height of the plant	1.8
	Foliar Pulverization	06/29/2011	85	25.0	1.004	1.8
	Foliar Pulverization	07/14/2011	86	25.0	1.005	1.8
111-022-02	Directed jet	04/01/2011	77	4.0	5 mL / meter of height of the plant	3.0
	Foliar Pulverization	06/30/2011	86	30.0	1.014	3.0
	Foliar Pulverization	07/15/2011	86	30.0	1.007	3.0
111-022-03	Directed jet	03/22/2011	73	4.0	5 mL / meter of height of the plant	3.0
	Foliar Pulverization	06/20/2011	83	30.0	0.952	3.7
	Foliar Pulverization	07/05/2011	87	30.0	1.051	3.7
111-022-04	Directed jet	03/24/2011	71	4.0	mL / meter of height of the plant	3.5
	Foliar Pulverization	06/22/2011	88	39.0	0.904	3.5
	Foliar Pulverization	07/07/2011	89	39.0	0.975	3.5
111-022-05	Directed jet	03/25/2011	75	4.0	5 mL / meter of height of the plant	3.0
	Foliar Pulverization	06/23/2011	88	75.0	0.962	3.0
	Foliar Pulverization	07/08/2011	89	75.0	1.022	3.5

Duplicate composite samples of citrus were collected from the treated plot at sampling intervals of 0, 7, 14, 21, and 28 days. The intended pre-harvest interval is 0 days. A single control sample was collected at each sampling event.

The residue(s) of BYI 02960 DFA and DFCAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. For the purpose of this summary document and to provide residue data for calculation of MRLs, residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.



Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 80 to 110%, and the standard deviation values were ≤ 20% (Table 6.3.2.1-31).

Table 6.3.2.1-31: Summary of Recoveries of BYI 02960 from Citrus

Crop Matrix	Analyte	Fortification Level (mg/kg) ^a	Sample Size (n)	Recoveries (%)	Mean % Recovery	CV (%)	LOQ (mg/kg)
Citrus/Fruits	BYI 02960	0.01	7	102; 112; 97; 104; 99; 80; 79	93	15	0.01
		0.1	7	107; 111; 72; 79; 93; 105; 86	93	16	
		1	7	95; 92	94	16	
	DFA	0.1505	7	83; 79; 101; 92; 104; 98; 97	93	16	0.05
		1.505	7	77; 83; 90; 98; 97; 100; 88	90	9.4	
	DFEAF	0.0177	6	87; 83; 91; 82; 85; 83	86	3.7	0.01
		0.177	6	91; 86; 85; 87; 90; 86	86	6.6	

a Expressed as parent BYI 02960 equivalents

The freezer storage stability study indicates that BYI 02960 residues were stable in orange fruits during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 110 days. A summary of the storage conditions are shown in Table 6.3.2.1-32.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-32: Summary of Storage Conditions for Citrus Fruits

Identification of the Field trial	Scheduled DAT (days) ^a	Crop date (mm/dd/yy)	Date of last extraction (mm/dd/yy)	Storage Temperature ^b (°C)	Storage Period (days) ^c	Period covered by the evaluation of Stability (days) ^d
I11-022-01	0	07/14/2011	10/05/2011	<-20	83	556
	7	07/21/2011		<-20	76	
	14	07/27/2011		<-20	70	
	21	08/03/2011		<-20	63	
	28	08/11/2011		<-20	55	
I11-022-02	0	07/15/2011	10/05/2011	<-20	82	556
	7	07/22/2011	10/26/2011	<-20	96	
	14	07/30/2011	10/05/2011	<-20	87	
	21	08/06/2011	10/26/2011	<-20	81	
	28	08/12/2011	10/11/2011	<-20	60	
I11-022-03	0	07/05/2011	10/11/2011	<-20	93	556
	7	07/12/2011	10/11/2011	<-20	91	
	14	07/19/2011	10/26/2011	<-20	99	
	21	07/26/2011	10/11/2011	<-20	80	
	28	08/02/2011	10/11/2011	<-20	70	
I11-022-04	0	07/07/2011	10/09/2011	<-20	104	556
	7	07/14/2011		<-20	97	
	14	07/21/2011		<-20	90	
	21	07/28/2011		<-20	83	
	28	08/04/2011		<-20	76	
I11-022-05	0	07/08/2011	10/26/2011	<-20	110	556
	7	07/15/2011	10/21/2011	<-20	98	
	14	07/22/2011	10/21/2011	<-20	91	
	21	07/29/2011	10/21/2011	<-20	84	
	28	08/05/2011	10/21/2011	<-20	77	

- a DAT – Days after Last Treatment. Data for each sampling is equivalent to control and treated sample of corresponding scheduled DAT.
- b Samples were stored with dry ice during transportation to UPA and from UPA to the Laboratory and at <-20 °C during storage at UPA and the Laboratory.
- c Period between processing and sample extraction of corresponding sampling (DAT). For samples extracted more than once, the date of the last extraction of treated sample was taken into consideration for the calculation of storage period.
- d [REDACTED], [REDACTED], [REDACTED] and A. [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for citrus fruits following a single soil drench and two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.1-33.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-33: Total BYI 02960 Residue Data from Citrus Fruits after a Single Soil drench and Two Foliar Applications of BYI 02960 SL

Field trial / Location	Identification of Sample	Type	Rate (L/ha) (directed jet-drench) ^a	Rate (g a.s./ha) per appl. (foliar)	DAI (days) ^b	Residues (mg/kg)				
						BYI 02960				
						BYI 02960	DFEAF	DFEAF	Total of call BYI 02960 ^c	Total Average of call BYI 02960
I11-022-01	I11-022-01-001C-01L	C	--	--	0	<0.01	<0.01	<0.05	<0.07	-
	I11-022-01-004C-01L	C	--	--	7	<0.01	<0.01	<0.05	<0.07	-
	I11-022-01-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-022-01-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-022-01-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-022-01-002C-01L	T	5	200	0	0.25	<0.01	<0.05	0.31	0.30
	I11-022-01-003C-01L	T	15	200	0	0.25	<0.01	<0.05	0.29	0.30
	I11-022-01-005C-01L	T	15	200	7	0.31	<0.01	0.24	0.56	0.49
	I11-022-01-006C-01L	T	15	200	7	0.25	<0.01	0.16	0.41	0.49
	I11-022-01-008C-01L	T	15	200	14	0.32	<0.01	0.06	0.39	0.34
	I11-022-01-009C-01L	T	15	200	14	0.23	<0.01	0.05	0.29	0.34
	I11-022-01-011C-01L	T	15	200	21	0.23	<0.01	0.22	0.46	0.47
	I11-022-01-012C-01L	T	15	200	21	0.22	<0.01	0.23	0.47	0.47
	I11-022-01-014C-01L	T	15	200	28	0.13	<0.01	0.13	0.27	0.37
I11-022-01-015C-01L	T	15	200	28	0.22	<0.01	0.24	0.47	0.37	
I11-022-02	I11-022-02-001C-01L	C	--	--	0	<0.01	<0.01	<0.05	<0.07	-
	I11-022-02-004C-01L	C	---	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-022-02-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-022-02-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-022-02-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-022-02-002C-01L	T	15	200	0	0.33	<0.01	0.21	0.55	0.53
	I11-022-02-003C-01L	T	15	200	0	0.34	<0.01	0.16	0.51	0.53
	I11-022-02-005C-01L	T	15	200	7	0.18	<0.01	0.10	0.29	0.35
	I11-022-02-006C-01L	T	15	200	7	0.25	<0.01	0.14	0.40	0.35
	I11-022-02-008C-01L	T	15	200	7	0.24	<0.01	0.16	0.41	0.41
	I11-022-02-009C-01L	T	15	200	14	0.23	<0.01	0.16	0.40	0.41
	I11-022-02-011C-01L	T	15	200	21	0.19	<0.01	0.20	0.40	0.35
	I11-022-02-012C-01L	T	15	200	21	0.13	<0.01	0.16	0.30	0.35
	I11-022-02-014C-01L	T	15	200	28	0.27	<0.01	0.38	0.66	0.53
I11-022-02-015C-01L	T	15	200	28	0.17	<0.01	0.21	0.39	0.53	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-33 (cont'd): Total BYI 02960 Residue Data from Citrus Fruits after a Single Soil drench and Two Foliar Applications of BYI 02960 SL

Field trial / Location	Identification of Sample	Type	Rate (L/ha) (directed jet-drench) ^a	Rate (g a.i./ha) (foliar)	DAT (days) ^b	Residues (mg/kg)				
						BYI 02960				
						BYI 02960	DFEAF	DFA	Total of call BYI 02960 ^c	Total Average of call BYI 02960
I11-022-03	I11-022-03-001C-01L	C	--	--	0	<0.01	<0.01	<0.05	<0.07	-
	I11-022-03-004C-01L	C	--	--	7	<0.01	<0.01	<0.05	<0.07	-
	I11-022-03-007C-01L	C	--	--	14	<0.01	<0.01	<0.05	<0.07	-
	I11-022-03-010C-01L	C	--	--	21	<0.01	<0.01	<0.05	<0.07	-
	I11-022-03-013C-01L	C	--	--	28	<0.01	<0.01	<0.05	<0.07	-
	I11-022-03-002C-01L	T	15	200	0	0.20	<0.01	0.09	0.3	0.33
	I11-022-03-003C-01L	T	15	200	0	0.23	<0.01	0.11	0.35	0.31
	I11-022-03-005C-01L	T	15	200	7	0.20	<0.01	0.08	0.29	0.31
	I11-022-03-006C-01L	T	15	200	7	0.20	<0.01	0.07	0.32	0.36
	I11-022-03-008C-01L	T	15	200	14	0.15	<0.01	0.15	0.35	0.36
	I11-022-03-009C-01L	T	15	200	14	0.24	<0.01	0.12	0.37	0.31
	I11-022-03-011C-01L	T	15	200	21	0.13	<0.01	0.12	0.26	0.31
	I11-022-03-012C-01L	T	15	200	21	0.18	<0.01	0.17	0.36	0.32
	I11-022-03-014C-01L	T	15	200	28	0.17	<0.01	0.19	0.37	0.32
I11-022-03-015C-01L	T	15	200	28	0.13	<0.01	0.12	0.26	0.32	
I11-022-04	I11-022-04-001C-01L	C	--	--	0	<0.01	<0.01	<0.05	<0.07	-
	I11-022-04-004C-01L	C	--	--	7	<0.01	<0.01	<0.05	<0.07	-
	I11-022-04-007C-01L	C	--	--	14	<0.01	<0.01	<0.05	<0.07	-
	I11-022-04-010C-01L	C	--	--	21	<0.01	<0.01	<0.05	<0.07	-
	I11-022-04-013C-01L	C	--	--	28	<0.01	<0.01	<0.05	<0.07	-
	I11-022-04-002C-01L	T	15	200	0	0.16	<0.01	<0.05	0.22	0.21
	I11-022-04-003C-01L	T	15	200	0	0.13	<0.01	<0.05	0.19	0.19
	I11-022-04-005C-01L	T	15	200	7	0.13	<0.01	<0.05	0.19	0.19
	I11-022-04-006C-01L	T	15	200	7	0.12	<0.01	<0.05	0.18	0.12
	I11-022-04-008C-01L	T	15	200	14	0.05	<0.01	<0.05	0.11	0.12
	I11-022-04-009C-01L	T	15	200	14	0.07	<0.01	<0.05	0.13	0.12
	I11-022-04-011C-01L	T	15	200	21	0.06	<0.01	<0.05	0.12	0.12
	I11-022-04-012C-01L	T	15	200	21	0.06	<0.01	<0.05	0.12	0.12
	I11-022-04-014C-01L	T	15	200	28	0.04	<0.01	<0.05	0.1	0.11
I11-022-04-015C-01L	T	15	200	28	0.05	<0.01	<0.05	0.11	0.11	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-33 (cont'd): Total BYI 02960 Residue Data from Citrus Fruits after a Single Soil drench and Two Foliar Applications of BYI 02960 SL

Field trial / Location	Identification of Sample	Type	Rate (L/ha) (directed jet-drench) ^a	Rate (g ai./ha) (foliar)	DAT (days) ^b	Residues (mg/kg)				
						BYI 02960				
						BYI 02960	DFEAF	DFA	Total of cal- BYI 02960 ^c	
I11-022-05	I11-022-05-001C-01L	C	---	---	0	<0.01	<0.01	0.05	<0.07	-
	I11-022-05-004C-01L	C	---	---	7	<0.01	<0.01	0.05	<0.07	-
	I11-022-05-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-022-05-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-022-05-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-022-05-002C-01L	T	15	200	0	0.33	<0.01	<0.05	0.39	0.34
	I11-022-05-003C-01L	T	15	200	0	0.22	<0.01	<0.05	0.28	0.34
	I11-022-05-005C-01L	T	15	200	7	0.33	<0.01	0.05	0.42	0.41
	I11-022-05-006C-01L	T	15	200	7	0.33	<0.01	0.05	0.39	0.41
	I11-022-05-008C-01L	T	15	200	14	0.29	<0.01	0.08	0.38	0.40
	I11-022-05-009C-01L	T	15	200	14	0.33	<0.01	0.08	0.42	0.40
	I11-022-05-011C-01L	T	15	200	21	0.21	<0.01	0.09	0.31	0.32
	I11-022-05-012C-01L	T	15	200	21	0.23	<0.01	0.08	0.32	0.32
	I11-022-05-014C-01L	T	15	200	28	0.20	<0.01	0.09	0.28	0.34
I11-022-05-015C-01L	T	15	200	28	0.33	<0.01	0.09	0.39	0.34	

a Drench Application: 70 mL/meter of height of the plant. Height of the plants of the Study = 3 meters

b DAT: Days after Last Treatment

c All residues found below the Limit of Quantitation (LOQ) of the method (but higher than the respective LOD values) are reported as <0.01 mg/kg for BYI 02960 and DFEAF, and <0.05 mg/kg for DFA. Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

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Conclusion

Five field trials were conducted to measure the magnitude of total BYI 02960 residues in/on citrus fruits (orange) following a single soil drench and two foliar spray applications of BYI 02960 200 SL. The residues found in the fruits are summarized in Table 6.3.2.1-34.

Table 6.3.2.1-34a: Summary of Residue Data for Total BYI 02960 from Citrus after a Single Soil Drench followed by Two Foliar Spray Applications of BYI 02960 200 SL

Identification of the Field trial/Place	Crop	Scheduled DAT (days) ^a	Residues (mg/kg) Expressed in BYI 02960 Equivalents			
			BYI 02960	BYI 02960, difluoroethyl-aminofuranone (DFEAF)	difluoroacetic acid (DFA)	Total of BYI 02960 ^b
I11-022-01 Ribeirão Preto-SP	Citrus fruits	0	0.24	<0.01	<0.05	0.30
		7	0.28	<0.01	0.20	0.49
		14	0.24	<0.01	0.00	0.24
		21	0.24	<0.01	0.21	0.47
		28	0.18	<0.01	0.19	0.37
I11-022-02 [REDACTED]-SP	Citrus fruits	0	0.33	<0.01	0.19	0.53
		7	0.22	<0.01	0.12	0.35
		14	0.24	<0.01	0.16	0.41
		21	0.16	<0.01	0.18	0.35
		28	0.22	<0.01	0.30	0.53
I11-022-03 [REDACTED]-SP	Citrus fruits	0	0.22	<0.01	0.10	0.33
		7	0.20	<0.01	0.10	0.31
		14	0.22	<0.01	0.14	0.36
		21	0.16	<0.01	0.15	0.31
		28	0.15	<0.01	0.16	0.32
I11-022-04 [REDACTED]-PR	Citrus fruits	0	0.15	<0.01	0.05	0.21
		7	0.13	<0.01	0.05	0.19
		14	0.06	<0.01	0.05	0.12
		21	0.05	<0.01	0.05	0.12
		28	0.05	<0.01	0.05	0.11
I11-022-05 Paulínia-SP	Citrus fruits	0	0.28	<0.01	0.05	0.34
		7	0.33	<0.01	0.05	0.41
		14	0.31	<0.01	0.08	0.40
		21	0.22	<0.01	0.09	0.32
		28	0.27	<0.01	0.08	0.34

a DAT: Days after last Treatment

b The results were reported as the average of 2 (two) results obtained in each sampling. All residues found below the Limit of Quantitation (LOQ) of the method (but higher than the respective LOD values) are reported as < 0.01 mg/kg for BYI 02960 and DFEAF, and < 0.05 mg/kg for DFA. Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents.

Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-34b: Summary of Residue Data for Total BYI 02960 from Citrus after a Single Soil Drench followed by Two Foliar Spray Applications of BYI 02960 200 SL (considering single values from a sampling event)

Commodity	Plot Name ¹	Total Application Rate	PHI (days) ³	n	Total BYI 02960 Residue Levels (ppm)						
					Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean ³	Standard Deviation
Orange	TRTSF	1 g a.s. / m plant height plus 0.376-0.404 kg a.s. /ha	0	5	0.19	0.55	0.66 (28) ⁴	0.53	0.33	0.34	0.116

1 TRTSF = Treated plot receiving one soil drench application followed by two foliar applications.

2 HAFT = Highest Average Field Trial.

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

Table 6.3.2.1-34c: Summary of Residue Data for Total BYI 02960 from Citrus after a Single Soil Drench followed by Two Foliar Spray Applications of BYI 02960 200 SL (considering average values from 2 sampling event)

Commodity	Plot Name ¹	Total Application Rate	PHI (days) ³	n	Total BYI 02960 Residue Levels (ppm)					
					Min at PHI	Max at PHI	Max after PHI	Median ²	Mean ²	Standard Deviation
Orange	TRTSF	1 g a.s. / m plant height plus 0.376-0.404 kg a.s. /ha	0	5	0.21	0.53	-	0.33	0.34	0.117

1 TRTSF = Treated plot receiving one soil drench application followed by two foliar applications.

2 calculated on the basis of residue values at the PHI

The change in the total BYI 02960 residue with time in the citrus samples was variable depending on the trial. In general, the total BYI 02960 residue either declined or leveled off by the end of the sampling interval. The peak residue was reached at day 14 at latest, when considering the average values of two samplings per sampling event. The overall highest residue detected was detected at the PHI of 6 days and accounted for 0.53 mg/kg when considering the average residue values.

Considering the single values, the highest residue (0.66 mg/kg) was detected in one trial at the last sampling event, 28 days after the last application.



Report:	KIIA 6.3.2.1/02; [REDACTED]; 2012
Title:	Determination of residues of BYI 02960 and its metabolites, in citrus after foliar spray application of BYI 02960 (200 SL) in field trials in Brazil.
Report No. & Document No.:	I11-006, dated March 09, 2012 M-427468-02-3
Guidelines:	Resolution of Collegiate Board of Directors RDC No. 216 of December 2006, 15 th RDC No. 4 of January 2012, 18 th National Health Surveillance Agency, ANVISA, from the Ministry of Health
GLP:	Yes

Five trials were conducted to measure the magnitude of BYI 02960 residues in/on citrus (orange) following two broadcast foliar spray applications of BYI 02960 200 SL. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The location of field trials are presented in Table 6.3.2.1-35.

Table 6.3.2.1-35: Trial Number and Geographical Locations for BYI 02960 Foliar Application Trials in/on Citrus in Brazil

Identification of Field trial	Test Unit (municipality / state, country)	Name and address of the property
I11-006-03	[REDACTED] SP, Brazil	[REDACTED]
I11-006-04	[REDACTED] PR, Brazil	[REDACTED]
I11-006-05	[REDACTED] SP, Brazil	[REDACTED]
I11-006-06	[REDACTED] SP, Brazil	[REDACTED]
I11-006-07	[REDACTED] / SP, Brazil	[REDACTED]

Material and Methods

Two foliar applications were made to citrus trees at rates ranging from 0.194 to 0.204 kg BYI 02960/ha per application. Total seasonal rates ranged from 0.388 to 0.408 kg a.s./ha. The interval between the application was 15 days.

A typical non-ionic adjuvant, Dash HC (mix of methyl esters, aromatic hydrocarbons, unsaturated fatty acids and surfactants) was used in all of the foliar applications at 0.25% (v/v).

Trial site conditions, including soil characteristics are summarized in Table 6.3.2.1-36.

Table Table 6.3.2.1-36: Trial Site Conditions for Foliar Application Trials of BYI 02960 on Citrus

Identification of Field Trials	I11-006-03	I11-006-04	I11-006-05	I11-006-06	I11-006-07
Principal Investigator	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED] Junior	[REDACTED] Junior
Plots Size (m ²) Untreated/Treated	343 / 343	144 / 144	126 / 126	200 / 120	180 / 144
Number of Plots	2	2	2	2	2
Spacing between the lines (m)	7	6	7	6	6
Type of Soil	Clayey	Clayey	Red Yellow clayey	Clayey	Clayey
pH-value of soil (in CaCl ₂)	-	6.1	5.7	5.4	6.2
pH-value of soil (in H ₂ O)	4.7	-	-	-	-
Content of organic (%)	2.8	2.1	1.8	3.5	3.1
Soil Topography	Declivity < 5%	Declivity < 5%	Declivity < 5%	Declivity < 5%	Declivity < 5%
Test System	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)	Citrus (fruits)
Variety	Valencia	Valencia	Valencia	Pêra Rio	Pêra Rio
Date of the planting	09/1998	11 years	11/2004	11/2006	02/2002
Date of commercial harvest	May to August	July to August	June to October	May to August	May to August

Duplicate composite samples of citrus were collected from the treated plot at sampling intervals of 0, 7, 14, 21, and 28 days. The intended pre-harvest interval is 0 days. A single control sample was collected at each sampling event.

The residue(s) of BYI 02960, DFA, and DF EAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. For the purpose of this summary document and to provide residue data for calculation of MRLs, residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DF EAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.1-37).

Table 6.3.2.1-37: Summary of Recoveries of BYI 02960 from Citrus

Crop Matrix	Analyte	Fortification Level (mg/kg) ^a	Sample Size (n)	Recoveries (%)	Mean % Recovery	CV (%)	LOQ (mg/kg) ^b
Citrus/Fruits	BYI 02960	0.01	5	90; 97; 79; 90; 87	89	7.3	0.01
		0.1	5	100; 84; 87; 99; 82	90	7.4	
		1	5	96; 95; 96; 92; 99	98	5.7	
	DFA	0.05	5	99; 103; 115; 99; 89	101	9.3	0.01
		0.5	5	103; 102; 105; 94; 89	99	6.9	
	DFEAF	0.01	5	85; 93; 85; 87; 90	88	5.9	0.05
		0.1	5	86; 93; 93; 91; 87	90	7.1	

a Expressed as parent BYI 02960 equivalents

The freezer storage stability study indicates that BYI 02960 residues were stable in citrus fruits commodities during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 127 days. A summary of the storage conditions are shown in Table 6.3.2.1-38.

Table 6.3.2.1-38: Summary of Storage Conditions for Citrus Fruits

Identification of the Field trial	Scheduled DAT sampling (days) ^a	Harvest date (mm/dd/yy)	Date of last extraction (mm/dd/yy)	Storage Temperature (°C) ^b	Storage Period (days) ^c	Period covered by Evaluation of Stability (days) ^d
I11-006-03	0	07/08/11	11/07/11	<-20	122	556
	7	07/15/11		<-20	115	
	14	07/22/11		<-20	108	
	21	07/29/11		<-20	101	
	28	08/05/11		<-20	94	
I11-006-04	0	07/14/11	11/09/11	<-20	118	556
	7	07/21/11		<-20	111	
	14	07/28/11		<-20	104	
	21	08/04/11		<-20	97	
	28	08/11/11		<-20	90	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-38 (cont'd): Summary of Storage Conditions for Citrus Fruits

Identification of the Field trial	Scheduled DAT sampling (days) ^a	Harvest date (mm/dd/yy)	Date of last extraction (mm/dd/yy)	Storage Temperature (°C) ^b	Storage Period (days) ^c	Period covered by the evaluation of Stability (days) ^d
111-006-05	0	07/05/11	11/09/11	<-20	127	556
	7	07/12/11		<-20	120	
	14	07/19/11		<-20	113	
	21	07/26/11		<-20	106	
	28	08/02/11		<-20	99	
111-006-06	0	07/15/11	11/17/11	<-20	129	556
	7	07/22/11		<-20	122	
	14	07/30/11		<-20	104	
	21	08/06/11		<-20	97	
	28	08/12/11		<-20	91	
111-006-07	0	07/15/11	11/17/11	<-20	125	556
	7	07/22/11		<-20	118	
	14	07/30/11		<-20	110	
	21	08/06/11		<-20	103	
	28	08/12/11		<-20	97	

- a DAT – Days after last Treatment; Data for each sampling is equivalent to control and treated sample of corresponding scheduled DAT.
- b Samples were stored with dry ice during transportation to UPA and from UPA to the Laboratory and at <-20 °C during storage at UPA and the Laboratory.
- c Period between processing and sample extraction of corresponding sampling (DAT). For samples extracted more than once, the date of the last extraction of treated sample was taken into consideration for the calculation of storage period.
- d [Redacted] and A. [Redacted]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KHA 6.1/01).

The total BYI 02960 residue data for citrus fruits following two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.1-39.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-39: Total BYI 02960 Residue Data from Citrus Fruits after Two Foliar Applications of BYI 02960 SL

Field trial / Site	Identification of Sample	Type	Dose (g a.s./ha) (foliar)	Scheduled DAT (days) ^a	Residues (mg/kg)				
					BYI 02960				
					BYI 02960	DFA	DFA	Calculated Total of BYI 02960 ^b	Calculated Total Average of BYI 02960
I11-006-03 / [redacted] SP	I11-006-03-001C-01L	C	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-006-03-004C-01L	C	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-006-03-007C-01L	C	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-006-03-010C-01L	C	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-006-03-013C-01L	C	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-006-03-002C-01L	T	200	0	0.18	<0.01	<0.05	0.23	0.24
	I11-006-03-003C-01L	T	200	7	0.17	<0.01	<0.05	0.23	-
	I11-006-03-005C-01L	T	200	7	0.22	<0.01	<0.05	0.28	0.29
	I11-006-03-006C-01L	T	200	7	0.24	<0.01	<0.05	0.30	-
	I11-006-03-008C-01L	T	200	14	0.16	<0.01	<0.05	0.22	0.24
	I11-006-03-009C-01L	T	200	14	0.19	<0.01	<0.05	0.25	-
	I11-006-03-011C-01L	T	200	21	0.14	<0.01	<0.05	0.20	0.21
	I11-006-03-012C-01L	T	200	28	0.16	<0.01	<0.05	0.22	-
	I11-006-03-013C-01L	T	200	28	0.17	<0.01	<0.05	0.23	0.25
I11-006-03-015C-01L	T	200	28	0.19	<0.01	<0.07	0.27	-	
I11-006-04 / [redacted] PR	I11-006-04-001C-01L	C	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-006-04-004C-01L	C	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-006-04-007C-01L	C	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-006-04-010C-01L	C	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-006-04-013C-01L	C	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-006-04-002C-01L	T	200	0	0.08	<0.01	<0.05	0.14	0.16
	I11-006-04-003C-01L	T	200	0	0.11	<0.01	<0.05	0.17	-
	I11-006-04-005C-01L	T	200	7	0.04	<0.01	<0.05	0.10	0.09
	I11-006-04-006C-01L	T	200	7	0.01	<0.01	<0.05	0.07	-
	I11-006-04-008C-01L	T	200	14	0.02	<0.01	<0.05	0.08	0.09
	I11-006-04-009C-01L	T	200	14	0.03	<0.01	<0.05	0.09	-
	I11-006-04-011C-01L	T	200	21	0.03	<0.01	<0.05	0.09	0.09
	I11-006-04-012C-01L	T	200	28	0.02	<0.01	<0.05	0.08	-
	I11-006-04-014C-01L	T	200	28	0.02	<0.01	<0.05	0.08	0.08
I11-006-04-015C-01L	T	200	28	0.02	<0.01	<0.05	0.08	-	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-39 (cont'd): Total BYI 02960 Residue Data from Citrus Fruits after Two Foliar Applications of BYI 02960 SL

Field trial / Site	Identification of Sample	Type	Dose (g a.s./ha) (foliar)	Scheduled DAT (days) ^a	Residues (mg/kg)				
					BYI 02960				
					BYI 02960	DFEAF	DEA	Calculated Total of BYI 02960 ^b	Calculated Total Average of BYI 02960
I11-006-05 - SP	I11-006-05-001C-01L	C	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-006-05-004C-01L	C	---	7	0.01	<0.01	<0.05	<0.07	-
	I11-006-05-007C-01L	C	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-006-05-010C-01L	C	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-006-05-013C-01L	C	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-006-05-002C-01L	T	200	0	0.2	<0.01	<0.05	0.2	0.27
	I11-006-05-003C-01L	T	200	0	0.22	<0.01	<0.05	0.28	-
	I11-006-05-005C-01L	T	200	7	0.2	<0.01	<0.05	0.27	0.28
	I11-006-05-006C-01L	T	200	7	0.22	<0.01	<0.05	0.28	-
	I11-006-05-008C-01L	T	200	14	0.18	<0.01	<0.05	0.24	0.24
	I11-006-05-009C-01L	T	200	14	0.18	<0.01	<0.05	0.24	-
	I11-006-05-011C-01L	T	200	21	0.2	<0.01	<0.05	0.26	0.25
	I11-006-05-012C-01L	T	200	21	0.18	<0.01	<0.05	0.24	-
	I11-006-05-014C-01L	T	200	28	0.18	<0.01	<0.05	0.24	0.21
I11-006-05-015C-01L	T	200	28	0.12	<0.01	<0.05	0.18	-	
I11-006-06 - SP	I11-006-06-000C-01L	C	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-006-06-004C-01L	C	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-006-06-007C-01L	C	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-006-06-010C-01L	C	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-006-06-013C-01L	C	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-006-06-002C-01L	T	200	0	0.14	<0.01	<0.05	0.20	0.23
	I11-006-06-003C-01L	T	200	0	0.19	<0.01	<0.05	0.25	-
	I11-006-06-005C-01L	T	200	7	0.13	<0.01	0.07	0.21	0.19
	I11-006-06-006C-01L	T	200	7	0.11	<0.01	<0.05	0.17	-
	I11-006-06-008C-01L	T	200	14	0.07	<0.01	0.06	0.14	0.16
	I11-006-06-009C-01L	T	200	14	0.1	<0.01	0.06	0.17	-
	I11-006-06-011C-01L	T	200	21	0.04	<0.01	0.07	0.12	0.12
	I11-006-06-012C-01L	T	200	21	0.06	<0.01	<0.05	0.12	-
	I11-006-06-014C-01L	T	200	28	0.06	<0.01	0.06	0.13	0.13
I11-006-06-015C-01L	T	200	28	0.06	<0.01	<0.05	0.12	-	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-39 (cont'd): Total BYI 02960 Residue Data from Citrus Fruits after Two Foliar Applications of BYI 02960 SL

Field trial / Site	Identification of Sample	Type	Dose (g a.s./ha) (foliar)	Scheduled DAT (days) ^a	Residues (mg/kg)				
					BYI 02960				
					BYI 02960	DFA	DFA	DFEAF	Calculated Total of BYI 02960 ^b
I11-006-07 - SP	I11-006-07-001C-01L	C	---	0	<0.01	<0.01	<0.05	<0.07	
	I11-006-07-004C-01L	C	---	7	<0.01	<0.01	<0.05	<0.07	
	I11-006-07-007C-01L	C	---	14	<0.01	<0.01	<0.05	<0.07	
	I11-006-07-010C-01L	C	---	21	<0.01	<0.01	<0.05	<0.07	
	I11-006-07-013C-01L	C	---	28	<0.01	<0.01	<0.05	<0.07	
	I11-006-07-002C-01L	T	200	0	0.24	<0.01	0.2	0.44	0.40
	I11-006-07-003C-01L	T	200	7	0.2	<0.01	0.4	0.6	0.40
	I11-006-07-005C-01L	T	200	14	0.14	<0.01	0.05	0.24	0.21
	I11-006-07-006C-01L	T	200	21	0.09	<0.01	0.06	0.15	0.17
	I11-006-07-008C-01L	T	200	28	0.09	<0.01	0.06	0.15	0.17
	I11-006-07-009C-01L	T	200	14	0.12	<0.01	0.05	0.18	0.14
	I11-006-07-011C-01L	T	200	21	0.07	<0.01	0.07	0.15	0.14
	I11-006-07-012C-01L	T	200	28	0.06	<0.01	0.06	0.13	0.14
	I11-006-07-014C-01L	T	200	28	0.07	<0.01	0.07	0.15	0.13
I11-006-07-015C-01L	T	200	28	0.05	<0.01	0.05	0.11	0.13	

a DAT: Days after last Treatment

b All residues found below the Limit of Quantitation (LOQ) of the method (but higher than the respective LOD values) are reported as < 0.01 mg/kg for BYI 02960 and DFEAF, and < 0.05 mg/kg for DFA. Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents.

Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

Conclusion

Five field trials were conducted to measure the magnitude of total BYI 02960 residues in/on citrus fruits following two foliar spray applications of BYI 02960 200 SL. The residues found in the fruits are summarized in Table 6.3.2.1-40.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-40a: Summary of Residue Data for Total BYI 02960 from Citrus after Two Foliar Spray Applications of BYI 02960 200 SL

Identification of the Field trial/Place	Crop	Scheduled DAT (days) ^a	Residues (mg/kg) Expressed in BYI 02960 Equivalents			
			BYI 02960	BYI 02960-difluoroethyl-aminofuranone (DFEAF)	difluoroacetic acid (DFA)	Calculated Total BYI 02960
I11-006-03	Citrus fruits	0	0.18	<0.01	< 0.05	0.24
		7	0.23	<0.01	< 0.05	0.29
		14	0.18	<0.01	< 0.05	0.24
		21	0.15	<0.01	< 0.05	0.21
		28	0.18	<0.01	0.06	0.25
I11-006-04	Citrus fruits	0	0.10	<0.01	< 0.05	0.16
		7	0.03	<0.01	< 0.05	0.09
		14	0.03	<0.01	< 0.05	0.09
		21	0.03	<0.01	< 0.05	0.09
		28	0.02	<0.01	< 0.05	0.08
I11-006-05	Citrus fruits	0	0.21	<0.01	< 0.05	0.27
		7	0.22	<0.01	< 0.05	0.28
		14	0.18	<0.01	< 0.05	0.24
		21	0.16	<0.01	< 0.05	0.25
		28	0.15	<0.01	< 0.05	0.21
I11-006-06	Citrus fruits	0	0.17	<0.01	< 0.05	0.23
		7	0.12	<0.01	0.06	0.19
		14	0.09	<0.01	0.06	0.16
		21	0.05	<0.01	0.06	0.12
		28	0.06	<0.01	0.06	0.13
I11-006-07	Citrus fruits	0	0.2	<0.01	0.17	0.40
		7	0.15	<0.01	< 0.05	0.21
		14	0.11	<0.01	0.06	0.17
		21	0.07	<0.01	0.07	0.14
		28	0.06	<0.01	0.06	0.13

a DAT: Days after last treatment.

b The results were reported as the average of two results obtained in each sampling. All residues found below the Limit of Quantitation (LOQ) of the method (but higher than the respective LOD values) are reported as < 0.01 mg/kg for BYI 02960 and DFEAF, and < 0.05 mg/kg for DFA. Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were rounded into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.1-40b: Summary of Residue Data for Total BYI 02960 from Citrus after Two Foliar Spray Applications of BYI 02960 200 SL (considering single values from a sampling event)

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days) ³	n	Total BYI 02960 Residue Levels (ppm)						
					Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean ³	Standard Deviation
Orange	TRTDF	0.388-0.408	0	5	0.14 ³	0.45	0.30 (7) ⁴	0.40	0.25	0.26	0.08

1 TRTDF = Treated plot receiving two foliar applications (dilute spray).

2 HAFT = Highest Average Field Trial.

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

Table 6.3.2.1-40c: Summary of Residue Data for Total BYI 02960 from Citrus after Two Foliar Spray Applications of BYI 02960 200 SL (considering average values from a sampling event)

Commodity	Plot Name ¹	Total Application Rate kg a.s./ha	PHI (days)	n	Total BYI 02960 Residue Levels (ppm)					
					Min at PHI	Max at PHI	Max after PHI	Median	Mean ²	Standard Deviation
Orange	TRTSF	0.388-0.408	0	5	0.16	0.40	0.20 (7) ³	0.40 ⁴	0.26	0.088

1 TRTDF = Treated plot receiving two foliar applications (dilute spray).

2 calculated on the basis of residue values at the PHI

3 Sampling day showing highest residue

In general, the total BYI 02960 residue either declined or leveled off by the end of the sampling interval.

Overall Conclusion – Citrus

Supervised residue trials were conducted in citrus in the US and in Brazil to achieve a national registration in the NAFTA countries and in Brazil.

The NAFTA countries support two different GAPs: Either two foliar spray applications or one soil drench application of BYI 02960 200 SL. Twenty-six to thirty field trials were conducted according to each GAP to measure the magnitude of BYI 02960 residues in/on grapefruit (six trials), lemon (eight trials), and orange (12 trials plus 4 comparative foliar spray trials to support the import tolerance of citrus fruits in Brazil) as representative test systems for NAFTA Crop Group 10; Citrus Fruits. In addition eight field trials in mandarins were conducted to support the import tolerance of small citrus fruits in Europe.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Brazil supports two different GAPs, as well – either a soil drench application followed by two foliar spray applications or two foliar spray applications. Five supervised residue trials were conducted each according to the different GAPs.

A summary of the use patterns tested and the corresponding residue levels are shown in Table 6.3.2.1-41.

Table 6.3.2.1-41: Summary of Residue Data for Total BYI 02960 from Citrus

Crop	Formulation	Use pattern	Method	PHI	No. Application	No. Trials	Total Residue of BYI 02960 (mg a.s./kg) at PHI	Peak residue (mg/kg)	Day of peak residue
NAFTA									
Orange	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (diluted)	1	2	2+4	0.072-0.78	1.5	3
	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (concentrated)	1	2	12	0.050-0.81	2.2	10
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	30	1	1	<0.04-0.071	0.07	30
Grapefruit	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (diluted)	1	2	6	0.15-0.23	0.23	1
	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (concentrated)	1	2	6	0.09-0.32	0.32	1
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	30	1	1	<0.04-0.086	0.09	30
Lemon	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (diluted)	1	2	8	0.15-0.43	0.55	3
	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (concentrated)	1	2	8	0.07-0.74	0.74	1
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	30	1	8	<0.04	---	30
Mandarin	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (diluted)	1	2	8	0.118-0.363	0.42	3
	SL 200	2 x 0.205 kg a.s./ha	Foliar spray (concentrated)	1	2	8	0.035-0.496	1.0	10
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	30	1	8	0.018 -0.043	0.04	30
Brazil									
Orange	SL 200	2 x 1 g a.s. x m CH/plant	Soil drench followed by Foliar spray	0	3	5	0.19-0.55	0.66	28
	SL 200	2 x 0.200 kg a.s./ha	Foliar spray	0	2	5	0.14-0.45	0.45	0

Highest residue levels were observed in the NAFTA trials after two foliar spray application of BYI 02960 SL 200. In general, low volume spraying resulted in slightly higher residues. However, the residue values corresponding to low volume spray and normal spray were from similar populations (Whitney-Mann-Wilcoxon test), as well as the residues from the different crops of the crop group.

The total residue levels of BYI 02960 did not always peak at the intended PHI, however the total residue either declined or leveled off by the end of the sampling period, which covered in maximum 21 days in the NAFTA trials or 28 days in the Brazilian trials.

The residue data provided for citrus are suitable for regulatory purposes.

IIA 6.3.2.2 Tree nuts
Residue data from NORTH AMERICA (Crop Group 14)

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on tree nuts. The use pattern in North America is summarized in Table 6.3.2.2-1.

Report:	KIIA 6.3.2.2/01; [REDACTED] and I, [REDACTED]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in Tree Nuts (Crop Group 14)
Report No & Document No	RARVY016, dated June 27, 2012 M-433350-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 800.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals 209, Crop Field Trial, Adopted Sept. 7, 2009
GLP	Yes

A total of ten trials were conducted in tree nuts for the intended GAPs (5 trials in almond and 5 trials in pecan). The use pattern - corresponding to the intended GAP - is described below.

Table 6.3.2.2-1: Target Use Patterns for the Application of BYI 02960 on Tree Nuts

Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
		mg/A	fl oz/A	Name of a.s.	lb a.s./A	g a.s./fl oz					
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	205	14	7	0.25	10-50	93-467
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	205	14	7	0.25	200-300	1870-2805

Ten field trials were conducted to measure the magnitude of BYI 02960 residues in/on almond hulls and almond and pecan nutmeat (representative test systems for NAFTA crop group 14; Tree nuts) following two airblast applications of BYI 02960 200 SL. Since almond hulls (as feed item) are not imported into Europe, this dossier will focus on the food items almond and pecan nutmeat. Complete information on the study, including the data on almond hulls has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.2-2).



Table 6.3.2.2-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Tree Nuts

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2	2	
3		
4	1	1
5		
5A		
5B		
6		1
7		
7A		
8	1	1
9		
10		5
11		
12		
13		
14		
Total	10	10

a Four of the ten trials were decline trials (two in Region 2 and two in Region 10). The additional decline trials were performed to meet EU requirements.

Material and Methods

Two application forms were tested: two dilute or two concentrated foliar airblast applications. Individual application rates ranged from 0.179 to 0.188 lb BYI 02960/A/application (0.201 to 0.211 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.360 to 0.375 lb BYI 02960/A (0.403 to 0.421 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 78 to 97 (BBCH 78: 80% of fruits have reached final size; BBCH 97: plant resting or dormant). The interval between the applications was 13 to 15 days. For sites with concentrated spray applications, spray volumes ranged from 10 to 52 GPA (94 to 489 L/ha). For sites with dilute spray applications, spray volumes ranged from 195 to 256 GPA (1791 to 2391 L/ha).

All applications were made using ground-based equipment. The adjuvant Dyne-Amic, a typical non-ionic surfactant, was used in all of the applications at 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.2-3. Study use patterns are summarized in Table 6.3.2.2-4.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-3: Trial Site Conditions for BYI 02960 on Tree Nuts

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV204-10DA Almond	██████, CA, 2010	Sandy Loam	1.01	5.9	7.3	0	53-96
RV205-10DA Almond	██████, CA, 2010	Loam	2.4	7.9	3.9	0	57-90
RV206-10HA Almond	██████, CA, 2010	Sandy Loam	0.9	6.8	0	0	59-88
RV207-10HA Almond	██████, CA, 2010	Sandy Loam	6.6	8.3	31.3	0	57-93
RV208-10HA Almond	██████, CA, 2010	Sandy Loam	0.7	6.5	7.5	0	55-81
RV209-10DA Pecan	██████, GA, 2010	Sandy loam	2.4	6.2	1.8	3.1	31-70
RV210-10DA Pecan	██████, GA, 2010	Sandy Loam	3.27	6.2	6.4	3.52	31-70
RV211-10HA Pecan	██████, LA, 2010	Loam	2.2	5.9	8.4	2.30	47-85
RV212-10HA Pecan	██████, TX, 2010	Clay Loam	2.2	8.2	38.7	0.07	57-84
RV213-10HA Pecan	██████, OK, 2010	Sandy loam	1	7	7.9	2.73	38-77

a Abbreviations used: OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-4: Study Use Pattern for BYI 02960 200 SL on Tree Nuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing (Growth Stage) (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
Almond										
RV204-10DA	█ CA, Region 10, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	78	45 (423)	0.182 (0.204)	NA	0.365 (0.409)	Dyne-Amic 0.25% v/v
					79	45 (423)	0.182 (0.205)	NA		Dyne-Amic 0.25% v/v
RV204-10DA	█ CA, Region 10, 2010		TRTD	Dilute Airblast	78	228 (211)	0.187 (0.210)	NA	0.365 (0.421)	Dyne-Amic 0.25% v/v
					79	230 (217)	0.188 (0.211)	14		Dyne-Amic 0.25% v/v
RV205-10DA	█ CA, Region 10, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	78	10 (94)	0.182 (0.204)	NA	0.366 (0.410)	Dyne-Amic 0.25% v/v
					79	10 (94)	0.184 (0.206)	14		Dyne-Amic 0.25% v/v
RV205-10DA	█ CA, Region 10, 2010		TRTD	Dilute Airblast	88	200 (1869)	0.182 (0.204)	NA	0.365 (0.409)	Dyne-Amic 0.25% v/v
					89	200 (1871)	0.182 (0.204)	14		Dyne-Amic 0.25% v/v
RV206-10HA	█ CA, Region 10, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	85	41 (379)	0.181 (0.203)	NA	0.364 (0.408)	Dyne-Amic 0.25% v/v
					89	41 (382)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Tree Nuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate, lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing (Growth Stage) (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV206-10HA	[REDACTED] CA, Region 10, 2010		TRTD	Dilute Airblast	85	237 (2217)	0.180 (0.204)	NA	0.362 (0.406)	Dyne-Amic 0.25% v/v
					89	234 (2185)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV207-10HA	[REDACTED] CA, Region 10, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	85	38 (358)	0.183 (0.205)	NA	0.366 (0.411)	Dyne-Amic 0.25% v/v
					85	38 (353)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV207-10HA	[REDACTED] Region 10, 2010		TRTD	Dilute Airblast	85	246 (2296)	0.184 (0.206)	NA	0.367 (0.411)	Dyne-Amic 0.25% v/v
					85	237 (2216)	0.184 (0.206)	14		Dyne-Amic 0.25% v/v
Pecan										
RV208-10HA	[REDACTED] CA, Region 10, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	79	45 (417)	0.179 (0.201)	NA	0.360 (0.403)	Dyne-Amic 0.25% v/v
					85	45 (420)	0.181 (0.202)	14		Dyne-Amic 0.25% v/v
RV208-10HA	[REDACTED] CA, Region 10, 2010		TRTD	Dilute Airblast	79	253 (2364)	0.184 (0.206)	NA	0.371 (0.415)	Dyne-Amic 0.25% v/v
					85	256 (2391)	0.186 (0.209)	14		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Tree Nuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing (Growth Stage) (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV209-10DA	█, GA, Region 2, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	79	22 (202)	0.183 (0.205)	NA	0.366 (0.411)	Dyne-Amic 0.25% v/v
					89	21 (197)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV209-10DA	█, GA, Region 2, 2010	BYI 02960 200 SL	TRTD	Dilute Airblast	79	248 (2322)	0.186 (0.208)	NA	0.369 (0.413)	Dyne-Amic 0.25% v/v
					89	247 (2311)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV210-10DA	█, GA, Region 2, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	79	22 (202)	0.183 (0.205)	NA	0.366 (0.410)	Dyne-Amic 0.25% v/v
					89	21 (197)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV210-10DA	█, GA, Region 3, 2010	BYI 02960 200 SL	TRTD	Dilute Airblast	79	249 (2324)	0.186 (0.208)	NA	0.369 (0.413)	Dyne-Amic 0.25% v/v
					89	247 (2308)	0.183 (0.205)	14		Dyne-Amic 0.25% v/v
RV211-10HA	█, LA, Region 4, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	95	27 (248)	0.187 (0.210)	NA	0.372 (0.417)	Dyne-Amic 0.25% v/v
					97	32 (301)	0.185 (0.207)	14		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Tree Nuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing (Growth Stage) (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV211-10HA	[REDACTED], LA, Region 4, 2010		TRTD	Dilute Airblast	95	219 (2048)	0.186 (0.209)	NA	0.374 (0.419)	Dyne-Amic 0.25% v/v
					77	192 (1791)	0.187 (0.210)	14		Dyne-Amic 0.25% v/v
RV212-10HA	[REDACTED], TX, Region 6, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	87	4 (81)	0.186 (0.208)	2A	0.367 (0.412)	Dyne-Amic 0.25% v/v
					87	2 (419)	0.182 (0.204)	13		Dyne-Amic 0.25% v/v
RV212-10HA	[REDACTED], TX, Region 6, 2010		TRTD	Dilute Airblast	87	18 (1851)	0.179 (0.201)	NA	0.362 (0.406)	Dyne-Amic 0.25% v/v
					87	2 (41)	0.183 (0.205)	13		Dyne-Amic 0.25% v/v
RV213-10HA	[REDACTED], OK, Region 8, 2010	BYI 02960 200 SL	TRTC	Concentrate Airblast	87	5 (78)	0.188 (0.211)	NA	0.375 (0.421)	Dyne-Amic 0.25% v/v
					89	52 (489)	0.187 (0.209)	15		Dyne-Amic 0.25% v/v
RV213-10HA	[REDACTED], OK, Region 8, 2010		TRTD	Dilute Airblast	85	228 (2133)	0.183 (0.205)	NA	0.366 (0.410)	Dyne-Amic 0.25% v/v
					89	238 (2225)	0.183 (0.205)	15		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

In the harvest trials, duplicate composite samples of almonds and pecans were collected from the treated plots at a pre-harvest interval (PHI) of 7 days. In the four decline trials, duplicate composite samples of almonds and pecans were collected from the treated plots at 0, 3, 7, 14, and 21 days after the last treatment. Single composite samples of almonds and pecans were also collected from the control plots on the same day the target 7-day samples were collected from the treated plots. The almonds and pecans were shelled to produce the commodity of nutmeat (without shells).

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\le 20\%$ (Table 6.3.2.2-5).

Table 6.3.2.2-5: Summary of Recoveries of BYI 02960 from Tree Nuts

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Nutmeat without shell	BYI 02960	0.010	11	67, 89, 86, 105, 88, 72, 73, 113, 80, 81, 81, 71	86	15
		0.100	12	78, 7, 81, 79, 93, 84, 85, 84, 91, 87, 99, 96	88	7
	DFA	0.050	12	70, 72, 67, 82, 71, 77, 81, 76, 71, 84, 71, 73	75	5
		0.100	11	76, 96, 73, 74, 74, 78, 76, 72, 80, 71, 79, 81	77	7
	DFEAF	0.010	12	90, 76, 88, 111, 104, 83, 107, 86, 85, 83, 92, 85	94	12
		0.100	12	90, 111, 82, 101, 94, 103, 93, 79, 99, 97, 94, 100	95	9

^a Mean Recovery = mathematical average of all recoveries.

The freezer storage stability study indicates that BYI 02960 residues were stable in coffee beans and soybean seeds, as representative crops of the commodity group (high oil content), during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 491 days. A summary of the storage conditions are shown in Table 6.3.2.2-6.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-6: Summary of Storage Conditions for Tree Nuts

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration Months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Almond Nutmeat	< -17	16 (491)	18 (558)
	Pecan Nutmeat	< -17	12 (364)	18 (558)
DFA	Almond Nutmeat	< -17	16 (491)	18 (558)
	Pecan Nutmeat	< -17	12 (364)	18 (558)
DFEAF	Almond Nutmeat	< -17	16 (491)	18 (558)
	Pecan Nutmeat	< -17	12 (364)	18 (558)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARYR046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for tree nuts following two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.2-7.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-7: Total BYI 02960 Residue Data from Tree Nuts after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Almond Nutmeat										
RV204-10DA	[REDACTED], CA, Region 10, 2010	Non-Pareil	Almond Nutmeat w/out Shell	TRTC	0.365 (0.409)	0	<0.010 0.010	<0.050 0.050	<0.010 0.010	0.070 0.070
					Avg:	0.070	<0.070	<0.070	<0.070	
					3	<0.010 <0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070	
					Avg:	<0.070	<0.070	<0.070	<0.070	
					7	<0.010 <0.010	0.073 0.055	<0.010 0.010	0.093^d 0.075	
					Avg:	0.084^e				
					14	<0.010 <0.010	0.104 0.092	<0.010 <0.010	0.12 0.11	
					Avg:	0.12				
					21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070	
					Avg:	<0.070				
TRTD	0.375 (0.421)	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070	<0.070 <0.070	<0.070 <0.070		
Avg:	<0.070									

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-7 (cont'd) Total BYI 02960 Residue Data from Tree Nuts after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DCAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
RV205-10DA	[REDACTED], CA, Region 10, 2010	Non-Pareil	Almond Nutmeat w/out Shell	TRTD	0.366 (0.410)	6	<0.010	<0.050	<0.010	<0.070	
						7	<0.010	<0.050	<0.010	<0.070	
						14	<0.010	<0.050	<0.010	<0.070	
						21	<0.010	<0.050	<0.010	<0.070	
						Avg:				<0.070	
						7TD	7	<0.010	<0.050	<0.010	<0.070
						Avg:				<0.070	
RV206-10HA	[REDACTED], CA, Region 10, 2010	Sonora	Almond Nutmeat w/out Shell	TRTD	0.364 (0.406)	7	<0.010	<0.050	<0.010	<0.070	
						Avg:				0.075	
						Avg:				0.072	
RV207-10HA	[REDACTED], CA, Region 10, 2010	Monterey	Almond Nutmeat w/out Shell	TRTD	0.362 (0.406)	7	0.015	<0.050	<0.010	0.075^f	
						Avg:				0.074	
						Avg:				0.075^g	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-7 (cont'd) Total BYI 02960 Residue Data from Tree Nuts after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV207-10HA (cont'd)	█, CA, Region 10, 2010	Monterey	Almond Nutmeat w/out Shell	TR7	0.367 (0.411)	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
				TRTD	0.367 (0.411)	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV208-10HA	█, CA, Region 10, 2010	Padre	Almond Nutmeat w/out Shell	TR7C	0.360 (0.403)	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
				TRTD	0.371 (0.415)	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
Pecan Nutmeat										
RV209-10DA	█, GA, Region 2, 2010	Summer	Pecan Nutmeat w/out Shell	TR7	0.366 (0.411)	7	0.011 <0.010	<0.050 <0.050	<0.010 <0.010	0.071 <0.070 Avg: 0.071
				3		<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
				7		<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
				14		<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
				21		<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
				TRTD	0.369 (0.413)	7	0.013 <0.010	<0.050 <0.050	<0.010 <0.010	0.073^h <0.070 Avg: 0.071ⁱ

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-7 (cont'd) Total BYI 02960 Residue Data from Tree Nuts after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)		
RV210-10DA	█ GA, Region 2, 2010	Sumner	Pecan Nutmeat w/out Shell	TRTD	0.366 (0.410)	6	0.048 0.015	<0.050 <0.050	<0.010 0.010	0.011 0.075 Avg: 0.091		
						7	0.010 0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
						14	0.010 0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
						21	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
						TRTD	0.369 (0.413)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070
						TRTD	0.372 (0.417)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070
						TRTD	0.374 (0.419)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070
RV211-10HA	█ LA, Region 4, 2010	Creek	Pecan Nutmeat w/out Shell	TRTD	0.372 (0.417)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
				TRTD	0.374 (0.419)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
RV212-10HA	█ TX, Region 6, 2010	Cheyenne	Pecan Nutmeat w/out Shell	TRTD	0.367 (0.412)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		
				TRTD	0.362 (0.406)	7	<0.010 <0.010	<0.050 <0.050	<0.010 0.010	<0.070 0.070 Avg: <0.070		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-7 (cont'd) Total BYI 02960 Residue Data from Tree Nuts after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV213-10HA	██████, OK, Region 8, 2010	Kiowa and Washita	Pecan Nutmeat w/out Shell	TRTC	0.375 (0.421)	7	<0.010° <0.010°	<0.050° <0.050°	<0.010° <0.010°	<0.070° <0.070° Avg: <0.070°
				TRTD	0.366 (0.410)	>	<0.010° <0.010°	<0.050° <0.050°	<0.010° <0.010°	<0.070° <0.070° Avg: <0.070°

- a Sampling interval is the interval between last application and the sampling date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFAF residues in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Sample analyzed twice; average value reported here.
- d Maximum residue found in almond nutmeat from the TRTC plot.
- e HAF residue found in almond nutmeat from the TRTC plot.
- f Maximum residue found in almond nutmeat from the TRTD plot.
- g HAF residue found in almond nutmeat from the TRTD plot.
- h Maximum residue found in pecan nutmeat from the TRTD plot.
- i HAF residue found in pecan nutmeat from the TRTD plot.

TRTC = treated plot receiving a concentrate airblast application
 TRTD = treated plot receiving a dilute airblast application

Conclusion

Ten field trials were conducted to measure the magnitude of total BYI 02960 residues in/on almond and pecan nutmeat (representative commodities for Crop Group 14; Tree Nuts) following two airblast applications (diluted or concentrated spray) of BYI 02960 200 SL.

The total BYI 02960 residue data for tree nuts following foliar applications are summarized in Table 6.3.2.2-8.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-8: Summary of Residue Data for Total BYI 02960 from Tree Nuts

Commodity	Plot Name	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm) ¹							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean	Standard Deviation
Almond Nutmeat	TRTC	0.360 to 0.366 (0.403 to 0.411)	7	5	<0.070	0.093	0.12 (14) ⁴	0.084	<0.070	0.073	0.0072
Almond Nutmeat	TRTD	0.362 to 0.375 (0.406 to 0.421)	7	5	<0.070	0.075	NA ⁵	0.075	<0.070	0.071	0.0019
Pecan Nutmeat	TRTC	0.366 to 0.375 (0.410 to 0.421)	7	5	<0.070	<0.070	<0.070	<0.070	<0.070	<0.070	0
Pecan Nutmeat	TRTD	0.362 to 0.374 (0.406 to 0.419)	7	5	<0.070	0.073	NA ⁵	0.071	<0.070	<0.070	0.00095

1 Data from the decline trial samples collected at intervals other than a 7-day PHI are not included in this table.

2 HAFT = Highest Average Field Trial.

3 calculated on the basis of residue values at the PHI.

4 Sampling day showing highest residue

5 Not applicable, no decline trials were conducted.

TRTC = treated plot receiving a concentrate airblast application

TRTD = treated plot receiving a dilute airblast application

Total BYI 02960 residues in almond and pecan nutmeat were generally below the LOQ. Samples collected from the four decline trials indicated an incline of residues in nutmeat in only one trial in almonds where the highest residue was detected 14 days after the last application. However, the residues declined to < 0.07 mg/kg within the next seven days.

The total BYI 02960 residues in the representative commodities for Crop Group 14 (Tree Nuts; almond and pecan) were within a factor of 5 of each other and therefore, within the EPA guidelines for the establishment of a group tolerance for Crop Group 14.

The residue data provided for tree nuts are suitable for regulatory purposes.

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IIA 6.3.2.3 Pome fruit
Residue data from NORTH AMERICA (Crop Group 11)

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on pome fruits. The use patterns in North America are summarized in Table 6.3.2.3-1.

A total of twenty-three trials were conducted in apple for each of the intended GAPs. The studies are described below.

Table 6.3.2.3-1: Target Use Patterns for the Application of BYI 02960 on Pome Fruits

Test Substance	No. of Apps	Target Rate/Application					Target App Interval (Days)	Target PHI (Days)	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s)					GPA	LPHA
		mL/ha	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha				
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	0.205	10	14	40-50	94-69
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	0.205	10	14	150-200	1408-2816

GPA = gallons per acre

LPHA = liter per hectar

Report	IIA 6.3.2.3/01; [REDACTED] V.; 2012
Title	BYI 02960 200 SL, Magnitude of the Residue in/on Pome Fruits (Crop Group 11)
Report No & Document No	RARVY013, dated June 18, 2012 M-432703-01
Guidelines	US: EPA Residue Chemistry Test Guidelines OPP 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009
GLP	Yes

Twenty-three field trials were conducted to measure the magnitude of BYI 02960 residues in/on apple (14 trials) and pear (9 trials) following two broadcast foliar spray applications (either diluted or concentrated spray) of BYI 02960 200 SL. Apple and pear were chosen as the representative test systems for NAFTA Crop Group 11, Pome fruits. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.3-2).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Pome Fruits

NAFTA Growing Region	Apple		Pear	
	Submitted	Requested	Submitted	Requested
1	3	3	1	1
2	1	1		
3				
4				
5	4		3	
5A				
5B				
6				
7				
7A				
8				
9		1		
10	1	1	2	2
11	4	4	3	3
12				
13				
14				
Total	14	14	9	9

Material and Methods

Two application forms were tested, 2 diluted or 2 concentrated foliar airblast applications. Individual application rates ranged from 0.078 to 0.193 lb BYI 02960/A/application (0.199 to 0.216 kg BYI 02960/ha/application) and total seasonal application rates ranged from 0.359 to 0.383 lb BYI 02960/A (0.403 to 0.430 kg BYI 02960/ha). The interval between the applications was 10 to 11 days. All applications were made at growth stages ranging from BBCH 75 to 87 (BBCH 75: Fruit about half final size; BBCH 87: Fruit ripe for harvest).

All applications were made using ground-based equipment. A typical non-ionic adjuvant (MSO, NIS, COC) was used in all of the applications at 0.2 to 1% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.3-3. Study use patterns are summarized in Table 6.3.2.3-4.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-3: Trial Site Conditions for BYI 02960 on Pome Fruits

Trial Identification; Crop	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV050-11HA Apple	██████, NY	Sandy Loam	5.5	6.6	11.3	3.56	55-72
RV051-11DA Apple	██████, PA	Loam	2.0	5.9	10.5	21.5	38-70
RV052-11HA Apple	██████, GA	Loam	2.4	6.9	5.5	4.95	63-89
RV053-11HA Apple	██████, MI	Fine Sand	1.25	6.0	6.0	5.1	53-84
RV054-11DA Apple	██████, IL	Silt Loam	2.2	6.8	11.5	6.70	45-89
RV055-11HA Apple	██████, UT	Sandy Loam	1.4	5.2	30.9	2.19	61-91
RV056-11HA Apple	██████, CA	Clay Loam	3.8	7.4	26.1	0.00	59-95
RV057-11HA Apple	██████, ID	Silt Loam	2.04	6.5	19.0	1.56	39-88
RV058-11HA Apple	██████, OR	Loam	1.8	5.6	11.8	0.50	53-81
RV059-11DA Apple	██████, ID	Sandy Loam	1.7	7.5	12.7	0.36	50-94
RV060-11HA Apple	██████, NY	Silt Loam	4.6	5.4	3.9	10.97	55-78
RV061-11HA Apple	██████, MI	Loam	2.5	6.6	9.4	6.84	52-78
RV062-11DA Apple	██████, MI	Sand	0.9	5.5	6.3	6.12	41-70
RV063-11HA Apple	██████, OR	Loam	7.4	6.0	7.8	1.97	46-78
RV064-11DA Pear	██████, NY	Sandy Loam	1.1	6.3	8.4	12.46	56-82
RV065-11HA Pear	██████, MI	Loam	2.1	6.8	8.2	4.44	61-78
RV066-11HA Pear	██████, CA	Sandy Loam	3.5	7.0	16.9	0.79	56-90
RV067-11DA Pear	██████, CA	Sandy Loam	1.0	6.5	7.2	1.79	40-79
RV068-11HA Pear	██████, WA	Sandy Loam	1.1	7.2	12.6	0.05	48-87
RV069-11DA Pear	██████, ID	Fine Sandy Loam	0.75	7.9	7.0	0.36	50-94

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-3 (cont'd): Trial Site Conditions for BYI 02960 on Pome Fruits

Trial Identification; Crop	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV070-11HA Pear	██████, MI	Sand	2.3	5.6	7.1	12.99	45-83
RV071-11DA Pear	██████████, MI	Loam	2.5	6.8	8.2	16.49	49-82
RV072-11HA Pear	██████████, BC, Canada	Sandy Loam	2.6	7.3	9.1	17.10	40-85

- a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.
- b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4: Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s.A (kg a.s./ha)			
Apple												
RV050-11HA	[REDACTED] NY Region 1 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	76	40.09 (375)	0.184 (0.206)	NA	0.369 (0.414)	Induce @0.2%v/v		
					78	40.39 (379)	0.185 (0.208)	10	Induce @0.2%v/v			
RV050-11HA	[REDACTED] NY Region 1 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	76	160 (1496)	0.185 (0.205)	NA	0.365 (0.411)	Induce @0.2%v/v		
					78	160 (1496)	0.184 (0.205)	10	Induce @0.2%v/v			
RV051-11DA	[REDACTED] PA Region 1 2010	BYI 02960 200 SL	TRTDD	Airblast (concentr. appl.)	85	46.91 (439)	0.182 (0.204)	NA	0.363 (0.407)	MSO@0.25 %v/v		
					87	46.84 (438)	0.182 (0.203)	11	MSO@0.25 %v/v			
RV051-11DA	[REDACTED] PA Region 1 2010	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	165 (1543)	0.190 (0.213)	NA	0.379 (0.425)	MSO@0.25 %v/v		
					87	164 (1533)	0.189 (0.212)	11	MSO@0.25 %v/v			
RV052-11HA	[REDACTED] GA Region 2 2011	BYI 02960 200 SL	TRTDD	Airblast (concentr. appl.)	87	39.28 (367)	0.183 (0.205)	NA	0.366 (0.411)	COC@ 1% v/v		
					87	45.67 (427)	0.183 (0.205)	10	COC@ 1% v/v			
RV052-11HA	[REDACTED] GA Region 2 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	174 (1627)	0.183 (0.205)	NA	0.365 (0.410)	COC@ 1% v/v		
					87	171 (1599)	0.183 (0.205)	10	COC@ 1% v/v			
RV053-11HA	[REDACTED] MI Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	81	47.09 (440)	0.183 (0.205)	NA	0.364 (0.407)	NIS@ 0.2% v/v		
					85	46.67 (436)	0.181 (0.203)	10	NIS@ 0.2% v/v			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV053-11HA	[REDACTED], MI Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	187 (178)	0.182 (0.204)	NA	0.363 (0.406)	NIS@ 0.2% v/v
					85	189 (176)	0.189 (0.203)	10		NIS@ 0.2% v/v
RV054-11DA	[REDACTED], IL Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	85	25.31 (237)	0.184 (0.206)	NA	0.368 (0.411)	COC@ 1% v/v
					87	27.12 (254)	0.183 (0.205)	10		COC@ 1% v/v
RV054-11DA	[REDACTED], IL Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	475 (636)	0.183 (0.205)	NA	0.366 (0.410)	COC@ 1% v/v
					87	189 (167)	0.183 (0.205)	10		COC@ 1% v/v
RV055-11HA	[REDACTED], UT Region 9 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	78	51.4 (41)	0.181 (0.202)	NA	0.363 (0.406)	Pierce MSO@0.25 %v/v
					81	46.42 (434)	0.182 (0.204)	10		Pierce MSO@0.25 %v/v
RV055-11HA	[REDACTED], UT Region 9 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	78	206 (1926)	0.179 (0.201)	NA	0.359 (0.403)	Pierce MSO@0.25 %v/v
					81	207 (1935)	0.180 (0.202)	10		Pierce MSO@0.25 %v/v
RV056-11HA	[REDACTED], MI Region 10 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	77	50.01 (468)	0.181 (0.203)	NA	0.364 (0.408)	R-11 NIS@ 0.2% v/v
					79	49.37 (462)	0.183 (0.205)	10		R-11 NIS@ 0.2% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s.A (kg a.s./ha)			
RV056-11HA	Region 10 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	77	224 (2094)	0.178 (0.200)	NA	0.363 (0.409)	R-10 NIS@ 0.2% v/v		
					81	223 (2085)	0.187 (0.210)	10	R-11 NIS@ 0.2% v/v			
RV057-11HA	Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	79	47.78 (428)	0.188 (0.210)	NA	0.374 (0.419)	Pierce MSO@0.25 %v/v		
					81	47.55 (424)	0.186 (0.209)	10	Pierce MSO@0.25 %v/v			
RV057-11HA	Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	77	167 (1561)	0.184 (0.207)	NA	0.369 (0.414)	Pierce MSO@0.25 %v/v		
					81	168 (1571)	0.185 (0.207)	10	Pierce MSO@0.25 %v/v			
RV058-11HA	Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	78	31.00 (290)	0.180 (0.202)	NA	0.364 (0.407)	Mor-Act COC@ 0.25% v/v		
					81	30.15 (291)	0.182 (0.204)	10	Mor-Act COC@ 0.25% v/v			
RV058-11HA	Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	78	175 (1636)	0.182 (0.204)	NA	0.365 (0.409)	Mor-Act COC@ 0.25% v/v		
					81	169 (1580)	0.183 (0.205)	10	Mor-Act COC@ 0.25% v/v			
RV059-11HA	Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	79	41.47 (388)	0.181 (0.203)	NA	0.363 (0.407)	Dyne-Amic@ 0.2% v/v		
					81	41.48 (388)	0.181 (0.203)	10	Dyne-Amic@ 0.2% v/v			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s.A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)			
RV059-11DA	Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	79	201 (1879)	0.182 (0.203)	NA	0.366 (0.410)	Dex-Amic@ 0.2% v/v	
					81	197 (1842)	0.184 (0.206)	10	Dex-Amic@ 0.2% v/v		
RV060-11HA	NY Region 1 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	80	50.23 (470)	0.185 (0.207)	NA	0.371 (0.415)	MSO@ 0.25% v/v	
					85	50.66 (474)	0.186 (0.209)	10	MSO@ 0.25% v/v		
RV060-11HA	NY Region 1 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	228 (2113)	0.184 (0.207)	NA	0.368 (0.413)	MSO@ 0.25% v/v	
					85	228 (2104)	0.184 (0.206)	10	MSO@ 0.25% v/v		
RV061-11HA	MI Region 20 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	78	45.03 (421)	0.183 (0.205)	NA	0.367 (0.412)	Agri-Dex@ 1% v/v	
					81	45.68 (427)	0.184 (0.206)	10	Agri-Dex@ 1% v/v		
RV061-11HA	MI Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	78	179 (1673)	0.181 (0.203)	NA	0.364 (0.408)	Agri-Dex@ 1% v/v	
					81	183 (1711)	0.182 (0.204)	10	Agri-Dex@ 1% v/v		
RV062-11DA	MI Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	77	34.56 (323)	0.183 (0.206)	NA	0.367 (0.411)	Induce @0.2%v/v	
					81	36.50 (341)	0.183 (0.206)	10	Induce @0.2%v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.a. (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s.a. (kg a.s./ha)	
RV062-11DA	MI Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	77	198 (1851)	0.184 (0.205)	NA	0.368 (0.412)	Induce @ 0.2%v/v
					81	202 (1888)	0.184 (0.205)	10	0.368 (0.412)	Induce @ 0.2%v/v
RV063-11HA	OR Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	81	33.0 (14)	0.183 (0.205)	NA	0.368 (0.412)	Aero Dyne-Amic@0.25 %v/v
					88	39.1 (69)	0.185 (0.207)	10	0.368 (0.412)	Aero Dyne-Amic@0.25 %v/v
RV063-11HA	OR Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	169 (1580)	0.185 (0.207)	NA	0.367 (0.411)	Aero Dyne-Amic@0.25 %v/v
					82	171 (1589)	0.182 (0.204)	10	0.367 (0.411)	Aero Dyne-Amic@0.25 %v/v
Pear										
RV064-11DA	MI Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	75	40.00 (374)	0.183 (0.206)	NA	0.366 (0.411)	Induce NIS@ 0.2% v/v
					76	39.88 (373)	0.183 (0.205)	10	0.366 (0.411)	Induce NIS@ 0.2% v/v
RV064-11HA	NE Region 1 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	75	160 (1496)	0.183 (0.205)	NA	0.372 (0.417)	Induce NIS@ 0.2% v/v
					76	165 (1543)	0.189 (0.212)	10	0.372 (0.417)	Induce NIS@ 0.2% v/v
RV065-11HA	MO Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	77	46.56 (435)	0.183 (0.205)	NA	0.366 (0.410)	Hasten@ 0.25% v/v
					78	45.84 (429)	0.183 (0.205)	10	0.366 (0.410)	Hasten@ 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s.A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)		
RV065-11HA	MI Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	77	186 (1739)	0.183 (0.205)	NA	0.367 (0.41)	Hasten@ 0.25% v/v
					88	186 (1739)	0.184 (0.206)	10	0.367 (0.41)	Hasten@ 0.25% v/v
RV066-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDD	Airblast (concentr. appl.)	77	40.04 (449)	0.183 (0.205)	NA	0.367 (0.41)	COC-Moract@ 1% v/v
					88	40.39 (452)	0.184 (0.206)	11	0.367 (0.41)	COC-Moract@ 1% v/v
RV066-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	77	235 (197)	0.182 (0.204)	NA	0.364 (0.408)	COC-Moract@ 1% v/v
					88	237 (216)	0.183 (0.205)	11	0.364 (0.408)	COC-Moract@ 1% v/v
RV067-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	77	47.58 (389)	0.182 (0.204)	NA	0.364 (0.408)	Dyne-Amic NIS@0.2 %v/v
					88	40.57 (379)	0.183 (0.205)	10	0.364 (0.408)	Dyne-Amic NIS@0.2 %v/v
RV067-11DA	CA Region 10 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	85	162 (1515)	0.189 (0.212)	NA	0.371 (0.416)	Dyne-Amic NIS@0.2 %v/v
					85	161 (1505)	0.182 (0.204)	10	0.371 (0.416)	Dyne-Amic NIS@0.2 %v/v
RV068-11HA	CA Region 14 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	81	40.27 (376)	0.185 (0.207)	NA	0.368 (0.413)	Super Spread MSO@ 0.25%v/v
					85	39.99 (374)	0.183 (0.206)	10	0.368 (0.413)	Super Spread MSO@ 0.25%v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s.A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)		
RV068-11HA	Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	81	201 (1879)	0.186 (0.205)	NA	0.372 (0.417)	Super Spread ISO@ 0.25%v/v
					85	200 (1870)	0.186 (0.205)	10		Super Spread ISO@ 0.25%v/v
RV069-11DA	Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	78	48.55 (45)	0.183 (0.205)	NA	0.370 (0.415)	Herbimax@ 1%v/v
					79	45.2 (41)	0.187 (0.210)	10		Herbimax@ 1%v/v
RV069-11DA	Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	78	207 (1888)	0.178 (0.199)	NA	0.360 (0.403)	Herbimax@ 1%v/v
					79	193 (1804)	0.182 (0.204)	10		Herbimax@ 1%v/v
RV070-11HA	Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	78	38.84 (362)	0.183 (0.205)	NA	0.366 (0.411)	Induce@ 0.2% v/v
					81	37.60 (352)	0.183 (0.205)	10		Induce@ 0.2% v/v
RV070-11HA	Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	78	216 (2019)	0.184 (0.206)	NA	0.367 (0.412)	Induce@ 0.2% v/v
					81	190 (1776)	0.183 (0.206)	10		Induce@ 0.2% v/v
RV071-11DA	Region 5 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	75	46.62 (436)	0.183 (0.205)	NA	0.366 (0.410)	Hasten@ 0.25% v/v
					77	47.37 (443)	0.183 (0.205)	10		Hasten@ 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Pome Fruits

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s.A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (l/ha)	Rate lb a.s.A (kg a.s./ha)	Retreatment Interval (days)	Rate lb a.s.A (kg a.s./ha)		
RV071-11DA	MI Region 5 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	75	186 (1739)	0.183 (0.209)	NA	0.366 (0.419)	Harsten@ 25% v/v	
					77	190 (1776)	0.182 (0.209)	10	0.364 (0.419)	Harsten@ 25% v/v	
RV072-11HA	BC, Canada Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast (concentr. appl.)	75	414 (415)	0.191 (0.214)	NA	0.383 (0.430)	Merge@ 1% v/v	
					85	43.16 (404)	0.193 (0.216)	10	0.386 (0.430)	Merge@ 1% v/v	
RV072-11HA	Falls, BC, Canada Region 11 2011	BYI 02960 200 SL	TRTDD	Airblast (dilute appl.)	75	162 (1515)	0.186 (0.209)	NA	0.376 (0.421)	Merge@ 1% v/v	
					85	164 (1533)	0.190 (0.213)	10	0.376 (0.421)	Merge@ 1% v/v	

TRTDD = Treated plot receiving two diluted airblast applications
TRTDC = Treated plot receiving two concentrated airblast applications

In the harvest trials, single composite samples of apples and pears were collected at a pre-harvest interval (PHI) of 14 days from all treated plots; in the decime trials (TRTDD plots), samples were collected 0, 7, 14, 21, 28, and 35 days after the second application.

In addition, apple samples were collected immediately before the second application (IBA2), 10 to 11 days after the first application. All these samplings do not reflect the proposed use rate, the residue data from these samples were collected for informational purposes only.

The residues of BYI 02960, DFA, and DFCAF were quantitated by HPLC-MS/MS using stable isotopically labeled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.



Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. With the exception of one recovery sample, the overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.3-5).

Table 6.3.2.3-5: Summary of Recoveries of BYI 02960 from Apples and Pears

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean % Recovery ^a	Std % Dev.
Apple	BYI 02960	0.010	8	82, 69, 87, 86, 95, 86, 93, 118	89%	14%
		0.100	1	105	105%	NA
		0.500	1	92	92%	NA
Pear	BYI 02960	0.010	1	70, 103, 87, 96, 105	93%	13%
		0.800	1	103	103%	3%
Apple	DFEAF	0.010	8	70, 90, 94, 130, 106, 90, 114, 98	96%	18%
		0.100	1	84	84%	NA
Pear	DFEAF	0.010	4	92, 86, 96, 79	88%	7%
		0.500	1	101	101%	NA
		0.800	1	95	95%	NA
Apple	DFA	0.050	8	68, 70 ^b , 80, 103, 92 ^b , 87 ^b , 89, 97	86%	12%
		0.500	1	87	87%	NA
		2.500	1	77	77%	NA
Pear	DFA	0.050	5	75, 84 ^b , 97 ^b , 106, 106	93%	14%
		0.500	1	124	124% ^a	NA

a Mean Recovery = mathematical average of all recoveries

b Outside of criteria range (70-120%)

The freezer storage stability study indicates that BYI 02960 residues were stable in spinach leaves and tomato fruits as representative crops of the respective commodity groups (high water content and high acid content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 211 days. A summary of the storage conditions are shown in Table 6.3.2.3-6.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-6: Summary of Storage Conditions for Pome Fruits

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^{b,c}
BYI 02960	Apples and Pears	< -20	6 (211)
DFEAF	Apples and Pears	< -20	6 (211)
DFA	Apples and Pears	< -20	6 (211)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and ABC Laboratories. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED], [REDACTED] and A. [REDACTED]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. PARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for pome fruits following two foliar application(s) of BYI 02960 200 SL are shown in Table 6.3.2.3-7 (apple) and Table 6.3.2.3-8 (pear). Results from samples taken just prior to the final foliar application are shown for apple in Table 6.3.2.3-9. These latter results do not reflect the proposed use rate, and the residue data from these samples were collected for informational purposes only.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-7: Total BYI 02960 Residue Data from Apple Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV050-11HA	Region 1, NY, 2011	TRTDC	Jonagold	Fresh Fruit	0.369 (0.414)	14	0.256	<0.050	<0.010	0.31
RV050-11HA	Region 1, NY, 2011	TRTDD	Jonagold	Fresh Fruit	0.369 (0.414)	7	0.111	<0.050	<0.010	0.17
RV051-11DA	Region 1, PA, 2011	TRTDC	Rome	Fresh Fruit	0.363 (0.407)	0	0.338	<0.050	<0.010	0.40
						7	0.213	<0.050	<0.010	0.27
						14	0.112	<0.050	<0.010	0.17
						21	0.127	<0.050	<0.010	0.19
						35	0.110	<0.050	<0.010	0.17
RV051-11DA	Region 1, PA, 2011	TRTDD	Rome	Fresh Fruit	0.379 (0.425)	0	0.289	<0.050	<0.010	0.35
						7	0.171	<0.050	<0.010	0.23
						14	0.107	<0.050	<0.010	0.17
						21	0.108	<0.050	<0.010	0.17
						35	0.081	<0.050	<0.010	0.14
RV052-11HA	Region 2, GA, 2011	TRTDC	Rome Beauty	Fresh Fruit	0.366 (0.414)	14	0.050	<0.050	<0.010	0.11
RV052-11HA	Region 2, GA, 2011	TRTDD	Rome Beauty	Fresh Fruit	0.365 (0.410)	14	0.084	<0.050	<0.010	0.14
RV053-11HA	Region 3, MI, 2011	TRTDC	Red Delicious	Fresh Fruit	0.364 (0.407)	14	0.016	<0.050	<0.010	0.08
RV053-11HA	Region 5, MI, 2011	TRTDD	Red Delicious	Fresh Fruit	0.363 (0.406)	14	0.060	0.050	<0.010	0.12
RV054-11DA	Region 5, IL, 2011	TRTDC	Golden Delicious	Fresh Fruit	0.367 (0.411)	0	0.447	<0.050	<0.010	0.51
						7	0.322	<0.050	<0.010	0.38
						14	0.296	0.088	<0.010	0.39 ^c
						21	0.245	0.164	<0.010	0.42
						35	0.194	0.160	<0.010	0.36
RV054-11DA	Region 5, IL, 2011	TRTDD	Golden Delicious	Fresh Fruit	0.366 (0.410)	0	0.396	<0.050	<0.010	0.46
						7	0.372	0.090	<0.010	0.47
						14	0.209	0.146	<0.010	0.37
						21	0.181	0.193	<0.010	0.38
						35	0.260	0.362	<0.010	0.63 ^d
						35	0.195	0.297	<0.010	0.50

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-7 (cont'd): Total BYI 02960 Residue Data from Apple Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV055-11HA	[REDACTED], UT Region 9, 2011	TRTDC	Gala	Fresh Fruit	0.363 (0.406)	14	0.077	<0.050	<0.010	0.14
RV055-11HA	[REDACTED], UT Region 9, 2011	TRTDD	Gala	Fresh Fruit	0.358 (0.403)	7	0.118	<0.050	<0.010	0.18
RV056-11HA	[REDACTED] CA Region 10, 2011	TRTDC	Summerfield	Fresh Fruit	0.364 (0.408)	14	0.068	<0.050	<0.010	0.13
RV056-11HA	[REDACTED] CA Region 10, 2011	TRTDD	Summerfield	Fresh Fruit	0.365 (0.409)	14	0.055	0.079	<0.010	0.29
RV057-11HA	[REDACTED], ID, Region 11, 2011	TRTDC	Early Spur Rome	Fresh Fruit	0.374 (0.419)	14	0.188	<0.050	<0.010	0.25
RV057-11HA	[REDACTED], ID, Region 11, 2011	TRTDD	Early Spur Rome	Fresh Fruit	0.369 (0.414)	14	0.224	<0.050	<0.010	0.28
RV058-11HA	[REDACTED], OR Region 11, 2011	TRTDC	Honey Crisp	Fresh Fruit	0.362 (0.405)	14	0.060	<0.050	<0.010	0.12
RV058-11HA	[REDACTED], OR Region 11, 2011	TRTDD	Honey Crisp	Fresh Fruit	0.365 (0.409)	14	0.094	<0.050	<0.010	0.15
RV059-11DA	[REDACTED], ID, Region 11, 2011	TRTDC	Jonathan	Fresh Fruit	0.363 (0.407)	0	0.198	<0.050	<0.010	0.26
						7	0.153	<0.050	<0.010	0.21
						14	0.175	<0.050	<0.010	0.23
						21	0.082	<0.050	<0.010	0.14
						28	0.132	0.057	<0.010	0.20
						35	0.070	0.069	<0.010	0.15
RV059-11DA	[REDACTED], ID, Region 11, 2011	TRTDD	Jonathan	Fresh Fruit	0.366 (0.410)	0	0.092	<0.050	<0.010	0.15
						7	0.108	<0.050	<0.010	0.17
						14	0.118	<0.050	<0.010	0.18
						21	0.087	0.050	<0.010	0.15
						28	0.069	0.052	<0.010	0.13
						35	0.063	0.056	<0.010	0.13

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-7 (cont'd): Total BYI 02960 Residue Data from Apple Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV060-11HA	█ NY Region 1, 2011	TRTDC	Greening Perennial	Fresh Fruit	0.371 (0.415)	14	0.059	<0.050	0.010	0.12
RV060-11HA	█ NY Region 1, 2011	TRTDD	Greening Perennial	Fresh Fruit	0.368 (0.413)	14	0.097	<0.050	0.010	0.16
RV061-11HA	█ MI Region 5, 2011	TRTDC	Golden Delicious	Fresh Fruit	0.367 (0.412)	14	0.219	0.066	<0.010	0.29
RV061-11HA	█ MI Region 5, 2011	TRTDD	Golden Delicious	Fresh Fruit	0.364 (0.408)	14	0.153	0.066	<0.010	0.22
RV062-11DA	█ MI Region 5, 2011	TRTDC	Yellow Delicious	Fresh Fruit	0.367 (0.412)	0	0.338	<0.050	<0.010	0.40
						7	0.153	<0.050	<0.010	0.21
						14	0.148	<0.050	<0.010	0.21
						21	0.111	<0.050	<0.010	0.17
						28	0.151	0.097	<0.010	0.26
						35	0.132	0.100	<0.010	0.24
RV062-11DA	█ MI Region 5, 2011	TRTDD	Yellow Delicious	Fresh Fruit	0.367 (0.412)	0	0.248	<0.050	<0.010	0.31
						7	0.133	<0.050	<0.010	0.19
						14	0.109	<0.050	<0.010	0.17
						21	0.128	<0.050	<0.010	0.19
						28	0.090	0.056	<0.010	0.16
						35	0.077	0.064	<0.010	0.15

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-7 (cont'd): Total BYI 02960 Residue Data from Apple Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV063-11HA	██████████ OR Region 11, 2011	TRTDC	Jonagold	Fresh Fruit	0.368 (0.412)	14	0.104	0.060	0.010	0.16
RV063-11HA	██████████ OR Region 11, 2011	TRTDD	Jonagold	Fresh Fruit	0.367 (0.411)	14	0.142	0.050	0.010	0.20

- a Sampling interval is the interval between last application and sampling date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFAE residue on parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c The maximum total BYI 02960 residue found at the proposed 14-day PHI.
- d The maximum total BYI 02960 residue found at or later than the proposed 14-day PHI.

TRTDD = Treated plots receiving two diluted airblast applications
 TRTDC = Treated plots receiving two concentrated airblast applications

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-8: Total BYI 02960 Residue Data from Pear Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b																
RV064-11DA	[redacted], NY Region 1, 2011	TRTDC	Bartlett	Fresh Fruit	0.366 (0.411)	0	0.396	0.161	<0.010	0.50																
						7	0.338	0.164	<0.010	0.51																
						14	0.216	0.151	<0.010	0.38																
						21	0.174	0.196	<0.010	0.34																
						28	0.186	0.200	<0.010	0.38																
RV064-11DA	[redacted], NY Region 1, 2011	TRTDD	Bartlett	Fresh Fruit	0.372 (0.417)	0	0.446	0.178	<0.010	0.63																
						7	0.337	0.236	<0.010	0.58																
						14	0.203	0.288	<0.010	0.50																
						21	0.174	0.252	<0.010	0.44																
						28	0.161	0.231	<0.010	0.40																
RV065-11HA	[redacted], MI Region 5, 2011	TRTDC	Bartlett	Fresh Fruit	0.366 (0.410)	14	0.213	0.225	<0.010	0.45																
						RV065-11HA	[redacted], MI Region 5, 2011	TRTDD	Bartlett	Fresh Fruit	0.366 (0.411)	7	0.136	0.154	<0.010	0.30										
						RV066-11HA						[redacted], CA Region 10, 2011	TRTDC	Bartlett	Fresh Fruit	0.367 (0.411)	14	0.059	<0.050	<0.010	0.12					
						RV066-11HA											[redacted], CA Region 10, 2011	TRTDD	Bartlett	Fresh Fruit	0.364 (0.408)	14	0.197	0.097	<0.010	0.30
						RV067-11DA																[redacted], CA Region 10, 2011	TRTDC	Chinko	Fresh Fruit	0.364 (0.408)
7	0.209	<0.050	<0.010	0.27																						
14	0.166	<0.050	<0.010	0.23																						
21	0.144	0.070	<0.010	0.22																						
28	0.069	0.081	<0.010	0.16																						
RV067-11DA	[redacted], CA Region 10, 2011	TRTDD	Chinko	Fresh Fruit	0.371 (0.416)	0	0.275	<0.050	<0.010	0.34																
						7	0.239	<0.050	<0.010	0.30																
						14	0.180	<0.050	<0.010	0.24																
						21	0.174	<0.050	<0.010	0.23																
						28	0.131	0.066	<0.010	0.21																
35	0.118	0.087	<0.010	0.21																						

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-8 (cont'd): Total BYI 02960 Residue Data from Pear Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV068-11HA	Region 11, 2011	TRTDC	Concorde	Fresh Fruit	0.368 (0.413)	14	0.255	0.161	<0.010	0.43
RV068-11HA	Region 11, 2011	TRTDD	Concorde	Fresh Fruit	0.372 (0.417)	14	0.225	0.210	<0.010	0.44
RV069-11DA	Region 11, 2011	TRTDC	Bartlett	Fresh Fruit	0.370 (0.415)	7	0.254	<0.050	<0.010	0.31
						14	0.190	<0.050	<0.010	0.26
						21	0.192	0.088	<0.010	0.29
						28	0.175	0.107	<0.010	0.29
						35	0.184	0.138	<0.010	0.33
						0	0.295	<0.050	<0.010	0.20
RV069-11DA	Region 11, 2011	TRTDD	Bartlett	Fresh Fruit	0.366 (0.403)	7	0.165	<0.050	<0.010	0.23
						14	0.158	0.056	<0.010	0.22
						21	0.125	0.072	<0.010	0.21
						28	0.106	0.081	<0.010	0.20
						35	0.125	0.083	<0.010	0.22
						0	0.295	<0.050	<0.010	0.35
RV070-11HA	Region 11, 2011	TRTDC	Bartlett	Fresh Fruit	0.365 (0.411)	14	0.319	0.261	<0.010	0.59
RV070-11HA	Region 11, 2011	TRTDD	Bartlett	Fresh Fruit	0.367 (0.412)	14	0.155	0.194	<0.010	0.36
RV071-11DA	Region 11, 2011	TRTDC	Bartlett	Fresh Fruit	0.366 (0.410)	0	0.648	0.068	<0.010	0.73
						7	0.508	0.105	<0.010	0.62
						14	0.467	0.167	<0.010	0.64
						21	0.386	0.206	<0.010	0.60
						28	0.264	0.270	<0.010	0.54
						35	0.275	0.326	<0.010	0.61
RV071-11DA	Region 11, 2011	TRTDD	Bartlett	Fresh Fruit	0.366 (0.410)	0	0.361	<0.050	<0.010	0.42
						7	0.314	0.086	<0.010	0.41
						14	0.208	0.102	<0.010	0.32
						21	0.169	0.161	<0.010	0.34
						28	0.138	0.149	<0.010	0.30
						35	0.107	0.144	<0.010	0.26

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-8 (cont'd): Total BYI 02960 Residue Data from Pear Fruits after Two Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFEAL Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV072-11HA	[REDACTED], BC, Canada Region 11, 2011	TRTDC	Anju	Fresh Fruit	0.383 (0.430)	14	0.393	0.297	0.010	0.70
RV072-11HA	[REDACTED], BC, Canada Region 11, 2011	TRTDD	Anju	Fresh Fruit	0.376 (0.421)	14	0.172	0.138	0.010	0.32

- a sampling interval is the interval between last application and sampling date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFEA, and DFEAL residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

TRTDD = Treated plot receiving two diluted airblast applications
 TRTDC = Treated plot receiving two concentrated airblast applications

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-9: Total BYI 02960 Residue Data on Apple Fruits Collected Immediately Prior to the Final Foliar Application of BYI BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV050-11HA	██████, NY, Region 1, 2011	TRTDC	Jonagold	Fresh Fruit	0.369 (0.414)	-0(IBA2)	0.094	<0.050	<0.010	0.15
RV050-11HA	██████, NY, Region 1, 2011	TRTDD	Jonagold	Fresh Fruit	0.367 (0.411)	-0(IBA2)	0.062	<0.050	<0.010	0.12
RV051-11DA	██████, PA, Region 1, 2011	TRTDC	Rome	Fresh Fruit	0.363 (0.407)	-0(IBA2)	0.072	<0.050	<0.010	0.13
RV051-11DA	██████, PA, Region 1, 2011	TRTDD	Rome	Fresh Fruit	0.369 (0.425)	-0(IBA2)	0.081	<0.050	<0.010	0.14
RV052-11HA	██████, GA Region 2, 2011	TRTDC	Rome Beauty	Fresh Fruit	0.366 (0.411)	-0(IBA2)	0.041	<0.050	<0.010	0.10
RV052-11HA	██████, GA Region 2, 2011	TRTDD	Rome Beauty	Fresh Fruit	0.366 (0.411)	-0(IBA2)	0.050	<0.050	<0.010	0.11
RV053-11HA	██████, MI, Region 5, 2011	TRTDC	Red Delicious	Fresh Fruit	0.364 (0.407)	-0(IBA2)	0.018	<0.050	<0.010	0.08
RV053-11HA	██████, MI, Region 5, 2011	TRTDD	Red Delicious	Fresh Fruit	0.363 (0.406)	-0(IBA2)	0.056	<0.050	<0.010	0.12
RV054-11DA	██████, IL, Region 5, 2011	TRTDC	Golden Delicious	Fresh Fruit	0.367 (0.411)	-0(IBA2)	0.382	<0.050	<0.010	0.44
RV054-11DA	██████, IL, Region 5, 2011	TRTDD	Golden Delicious	Fresh Fruit	0.366 (0.410)	-0(IBA2)	0.176	<0.050	<0.010	0.24
RV055-11HA	██████, UT, Region 9, 2011	TRTDC	Gala	Fresh Fruit	0.363 (0.406)	-0(IBA2)	0.088	<0.050	<0.010	0.15
RV055-11HA	██████, UT, Region 9, 2011	TRTDD	Gala	Fresh Fruit	0.359 (0.403)	-0(IBA2)	0.079	<0.050	<0.010	0.14

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-9 (cont'd): Total BYI 02960 Residue Data on Apple Fruits Collected Immediately Prior to the Final Foliar Application of BYI BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFE Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV056-11HA	[REDACTED], CA Region 10, 2011	TRTDC	Summerfeld	Fresh Fruit	0.364 (0.408)	-0(IBA2)	0.204	0.055	0.010	0.27
RV056-11HA	[REDACTED], CA Region 10, 2011	TRTDD	Summerfeld	Fresh Fruit	0.365 (0.409)	-0(IBA2)	0.185	0.050	0.010	0.24
RV057-11HA	[REDACTED], ID, Region 11, 2011	TRTDC	Early Spur Rome	Fresh Fruit	0.374 (0.419)	-0(IBA2)	0.072	0.050	0.010	0.13
RV057-11HA	[REDACTED], ID, Region 11, 2011	TRTDD	Early Spur Rome	Fresh Fruit	0.369 (0.414)	-0(IBA2)	0.133	<0.050	<0.010	0.19
RV058-11HA	[REDACTED], OR Region 11, 2011	TRTDC	Honey Crisp	Fresh Fruit	0.362 (0.405)	-0(IBA2)	0.042	<0.050	<0.010	0.10
RV058-11HA	[REDACTED], OR Region 11, 2011	TRTDD	Honey Crisp	Fresh Fruit	0.365 (0.409)	-0(IBA2)	0.049	<0.050	<0.010	0.11
RV059-11DA	[REDACTED], ID Region 11, 2011	TRTDC	Jonathan	Fresh Fruit	0.363 (0.407)	-0(IBA2)	0.072	<0.050	<0.010	0.13
RV059-11DA	[REDACTED], ID Region 11, 2011	TRTDD	Jonathan	Fresh Fruit	0.366 (0.410)	-0(IBA2)	0.085	<0.050	0.010	0.14
RV060-11HA	[REDACTED], NY Region 1, 2011	TRTDC	Greening Perennial	Fresh Fruit	0.371 (0.415)	-0(IBA2)	0.066	<0.050	<0.010	0.13
RV060-11HA	[REDACTED], NY Region 1, 2011	TRTDD	Greening Perennial	Fresh Fruit	0.368 (0.413)	-0(IBA2)	0.067	<0.050	<0.010	0.13

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-9 (cont'd): Total BYI 02960 Residue Data on Apple Fruits Collected Immediately Prior to the Final Foliar Application of BYI BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling interval (days after last treatment) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV061-11HA	Region 5, MI 2011	TRTDC	Golden Delicious	Fresh Fruit	0.367 (0.412)	-0 (IBA2)	0.144	<0.050	0.010	0.20
RV061-11HA	Region 5, MI 2011	TRTDD	Golden Delicious	Fresh Fruit	0.364 (0.408)	-0 (IBA2)	0.107	<0.050	<0.010	0.17
RV062-11DA	Region 5, MI 2011	TRTDC	Yellow Delicious	Fresh Fruit	0.367 (0.411)	-0 (IBA2)	0.086	0.050	<0.010	0.15
RV062-11DA	Region 5, MI 2011	TRTDD	Yellow Delicious	Fresh Fruit	0.368 (0.412)	-0 (IBA2)	0.012	0.050	0.010	0.17
RV063-11HA	Region 11, OR 2011	TRTDC	Jonagold	Fresh Fruit	0.368 (0.412)	-0 (IBA2)	0.072	0.050	<0.010	0.13
RV063-11HA	Region 11, OR 2011	TRTDD	Jonagold	Fresh Fruit	0.367 (0.411)	-0 (IBA2)	0.050	<0.050	<0.010	0.11

a Pre-Harvest Interval (PHI) is the interval between last application and sampling date.

b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

TRTDD = Treated plot receiving two diluted airblast applications
TRTDC = Treated plot receiving two concentrated airblast applications
IBA2 = Immediately before the second application (= application 2)

Conclusion

Twenty-three field trials were conducted to measure the magnitude of total BYI 02960 residue in/on apples and pears following two foliar spray applications of BYI 02960 200 SL following two airblast applications, either with a concentrated or a diluted spray solution. In total eight decline trials were conducted, four in apple and four in pear.

The total BYI 02960 residue data for pome fruits are summarized in Table 6.3.2.3-10.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.3-10: Summary of Residue Data for Total BYI 02960 from Pome Fruits

Commodity	Plot Name ²	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days) ³	n	Total BYI 02960 Residue Levels (ppm) ¹						
					Min at PHI	Max at PHI	Max after PHI	HAFT ³	Median ⁴	Mean	Standard Deviation
Apples	TRTDC	0.362 to 0.374 (0.405 to 0.419)	14	14	0.076	0.395	0.52 (35)	NA ⁶	0.166	0.194	0.092
Apples	TRTDD	0.359 to 0.379 (0.403 to 0.425)	14	14	0.120	0.366	0.63 (18) ⁵	NA	0.177	0.200	0.069
Pears	TRTDC	0.364 to 0.383 (0.408 to 0.430)	14	9	0.119	0.701	---	NA	0.426	0.414	0.205
Pears	TRTDD	0.360 to 0.376 (0.403 to 0.421)	14	9	0.224	0.502	---	NA	0.320	0.335	0.090

1 Data from the decline trial samples collected at intervals other than the 14-day PHI are not included in this table.

2 TRTDC = Treated plot receiving two concentrate airblast applications;

TRTDD = Treated plot receiving two dilute airblast applications.

3 HAFT = Highest Average Field Trial.

4 calculated on the basis of residue values at the PHI

5 Sampling day showing highest residue

6 NA = Not applicable. A single sample was collected from each treated plot.

Most trials showed a general slow decline in total BYI 02960 residues throughout the sampling intervals. Other trials showed a decrease in total BYI 02960 residue with either a leveling of the total residue or a slight increase in total residue at the end of the decline intervals. One trial in apple showed the highest residue at day 35, the last sampling day of the decline trials. However the overall highest residue level (0.70 mg/kg) was detected at the PHI of 14 days.

The total BYI 02960 residues in the representative commodities for Crop Group 11 (Pome Fruits; apples and pears) were within a factor of 5 of each other and, therefore, within the EPA guidelines for the establishment of a group tolerance for Crop Group 11.

The residue data provided for pome fruits are suitable for regulatory purposes.

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IIA 6.3.2.4 Berries and small fruit - grapes
Residue data from NORTH AMERICA (Crop Subgroup 13-07F)

BYI 02960 is to be registered in USA and Canada for use as a foliar or soil treatment in/on small fruit vine climbing subgroup, except fuzzy kiwifruit (crop subgroup 13-07F). The use patterns in North America are summarized in Table 6.3.2.4-1.

A total of sixteen trials were conducted in grapes as representative test system. The studies are described below.

Table 6.3.2.4-1: Target Use Patterns for the Application of BYI 02960 in/on Small Fruit Vine Climbing Subgroup (Crop Subgroup 13-07F) in North America

App- lication Type	Test Substance	No. of Apps	Target Rate/Application						Target App- Interval (Days)	Target PHI (Days)	Adjuvant/ Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)		lb a.s./A	kg a.s./ha				GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	a.s./A							
TRTDF	BYI 02960 200 SL	2	415	14.0	BYI 02960	0.193	0.205	10	0	0.25	200- 300	1870- 2806	
TRTDS	BYI 02960 200 SL	1	831	28.1	BYI 02960	0.366	0.410	NA	30	0.25	NA ¹	NA ¹	

1 NA = Not applicable

TRTDF = Treated plot receiving two broadcast foliar spray applications

TRTDS = Treated plot receiving a single soil application

Report	IIA 6.3.2.4/01; [REDACTED] 2012
Title:	BYI 02960: Magnitude of the Residue in/on Small Fruit Vine Climbing Subgroup (except Fuzzy Kiwifruit), Crop Subgroup 13-07F
Report No & Document No	R-RVY007, dated June 4, 2012 M-432181-01-2
Guidelines	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	

Sixteen field trials were conducted to measure the magnitude of BYI 02960 residues in/on grapes as a representative crop for NAEFA small fruit vine climbing subgroup following two broadcast foliar spray applications or a single soil application of BYI 02960 200 SL. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.4-2).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Grapes

NAFTA Growing Region	Submitted ^a	Requested
1	2	2
5A	4	4
10	8	8
11	2	2
Total	16	16

Material and Methods

Two use patterns/application forms were tested: either two two broadcast foliar spray applications or a single soil application of BYI 02960 200 SL. For plots receiving two airblast applications, individual application rates ranged from 0.168 to 0.189 lb BYI 02960/A/application (0.188 to 0.211 kg BYI 02960/ha/application) and total seasonal application rates ranged from 0.346 to 0.372 lb BYI 02960/A (0.388 to 0.417 kg BYI 02960/ha). The interval between the applications was 9 to 11 days. For plots receiving a single soil drench application, application rates ranged from 0.369 to 0.380 lb BYI 02960/A (0.408 to 0.426 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 75 to 89 (BBCH 75: berries pea-sized, bunches hanging; BBCH 89: berries ripe for harvest). All applications were made using ground-based equipment. A typical non-ionic surfactant (Dyne-Amic or Agral 90) was used as adjuvant in all of the applications at 0.25% (v/v).

Trial Site conditions including soil characteristics are summarized in Table 6.3.2.4-3. Study use patterns are summarized in Table 6.3.2.4-4.

Table 6.3.2.4-3 Trial Site Conditions for BYI 02960 on Grapes

Trial Identification Crop	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV092-10DA Grape	██████, NY	Loam	1.4	4.3	7.8	13.29	42-80
RV093-10HA Grape	██████, PA	Loam	2.8	5.9	10.7	10.19	63-95
RV094-10HA Grape	██████, ON	Loam	1.8	7.2	11.4	6.58	49-80
RV095-10DA Grape	██████, ON	Loam	1.8	7.2	11.4	10.86	39-80
RV096-10HA Grape	██████, ON	Loam	1.8	7.2	11.4	6.58	49-80
RV097-10HA Grape	██████, ON	Loam	1.8	7.2	11.4	6.58	49-80
RV098-10DA Grape	██████, CA	Loam	1.5	8.1	17	0.01	52-93
RV099-10DA Grape	██████, CA	Loamy sand	0.5	8.2	6.9	0.00	51-96
RV100-10HA Grape	██████, CA	Loamy Sand	0.5	8.2	6.9	0.00	55-96

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-3 (cont'd): Trial Site Conditions for BYI 02960 on Grapes

Trial Identification Crop	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°C)
RV101-10HA Grape	██████, CA	Sandy Loam	0.7	7.6	9.3	0.00	59-92
RV102-10HA Grape	██████, CA	Clay Loam	2.3	3.7	36.4	1.15	45-83
RV103-10HA Grape	██████, CA	Clay loam	1.8	7.8	19.1	0.00	52-93
RV104-10HA Grape	██████, CA	Loamy Sand	0.4	6.5	5	0.00	55-93
RV105-10HA Grape	██████, CA	Sandy Loam	1.1	6.9	5.7	0.00	60-96
RV106-10HA Grape	██████, WA	Sandy Loam	3.2	7.6	13.9	1.35	40-84
RV107-10HA Grape	██████, OR	Loam	2.6	6	9.8	0.05	41-73

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

c NA = Not Available.

Table 6.3.2.4-4: Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End Use Product (Formulation)	Plot Name	Method	Application					Tank Mix Adjuvants
					Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV092-10DA	██████ NY Region 1 2010	BYI 02960 200 SL	TRVDF	Airblast	85	51 (476)	0.186 (0.209)	NA	0.371 (0.416)	Dyne-Amic @0.25%v/v
					89	50 (472)	0.185 (0.207)	10		Dyne-Amic @0.25%v/v
RV092-10DA	██████ NY Region 1 2010	BYI 02960 200 SL	TRTDS	Chemigation	83	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV093-10HA	Region 1 2010	BYI 02960 200 SL	TRTDS	Airblast	87	270	0.285	NA	0.369	Dyne-Amic @0.25%v/v
						(367)	(0.207)			
RV093-10HA	Region 1 2010	BYI 02960 200 SL	TRTDS	Airblast	89	209	0.184	NA	0.366	Dyne-Amic @0.25%v/v
						(153)	(0.206)			
RV093-10HA	Region 1 2010	BYI 02960 200 SL	TRTDS	Drip Irrigation	81	NA	0.369	NA	0.366	Dyne-Amic @0.25%v/v
RV094-10HA	Region 5 2010	BYI 02960 200 SL	TRTDS	Airblast	87	201	0.168	NA	0.346	Agral 90 @ 0.25 %
						(382)	(0.188)			
RV094-10HA	Region 5 2010	BYI 02960 200 SL	TRTDS	Airblast	89	222	0.178	9	0.346	Agral 90 @ 0.25 %
						(314)	(0.199)			
RV094-10HA	Region 5 2010	BYI 02960 200 SL	TRTDS	Dripline Irrigation	89	NA	0.364	NA	0.364	Agral 90 @ 0.25 %
RV095-10DA	Region 2010	BYI 02960 200 SL	TRTDS	Airblast	83	42	0.175	NA	0.361	Agral 90 @ 0.25 %
						(392)	(0.197)			
RV095-10DA	Region 2010	BYI 02960 200 SL	TRTDS	Airblast	89	38	0.185	9	0.361	Agral 90 @ 0.25 %
						(353)	(0.207)			
RV095-10DA	Region 2010	BYI 02960 200 SL	TRTDS	Dripline irrigation	75	NA	0.364	NA	0.364	Agral 90 @ 0.25 %

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Agral 90 @ Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)			
RV096-10HA	Region 5 2010	BYI 02960 200 SL	TRTDF	Airblast	82	140 (191)	0.183 (0.205)	NA	0.371 (0.416)	9	Agral 90 @ 0.25 % Agral 90 @ 0.25 %	
RV096-10HA	Region 5 2010	BYI 02960 200 SL	TRTDS	Drip/line irrigation	86	NA	0.364 (0.408)	NA	0.364 (0.408)	9	Agral 90 @ 0.25 %	
RV097-10HA	Region 5 2010	BYI 02960 200 SL	TRTDF	Airblast	83	41 (34)	0.189 (0.211)	NA	0.372 (0.417)	9	Agral 90 @ 0.25 % Agral 90 @ 0.25 %	
RV097-10HA	Region 5 2010	BYI 02960 200 SL	TRTDS	Drip/line irrigation	86	NA	0.364 (0.408)	NA	0.364 (0.408)	9	Agral 90 @ 0.25 %	
RV098-10DA	Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	83	246 (2296)	0.184 (0.206)	NA	0.369 (0.413)	11	Dyne-Amic @0.25%v/v Dyne-Amic @0.25%v/v	
RV098-10DA	Region 10 2010	BYI 02960 200 SL	TRTDS	Drench	77	NA	0.366 (0.410)	NA	0.366 (0.410)	11	Dyne-Amic @0.25%v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate, lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV099-10DA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	87	22 (2062)	0.184 (0.207)	NA	0.368 (0.413)	Dyne-Amic @0.25%v/v	
					88	22 (2076)	0.184 (0.206)	NA	0.368 (0.413)	Dyne-Amic @0.25%v/v	
RV099-10DA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDS	Drench	77	NA	0.366 (0.410)	NA	0.366 (0.410)	EXP8089- 2A 0.25% v/v	
RV100-10HA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	91	23 (2083)	0.186 (0.209)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v	
					89	23 (2085)	0.180 (0.202)	10	0.366 (0.410)	Dyne-Amic @0.25%v/v	
RV100-10HA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDS	Drench	75	NA	0.366 (0.410)	NA	0.366 (0.410)	EXP8089- 2A 0.25% v/v	
RV101-10HA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	87	240 (2244)	0.188 (0.211)	NA	0.372 (0.417)	Dyne-Amic @0.25%v/v	
					89	235 (2196)	0.184 (0.206)	10	0.372 (0.417)	Dyne-Amic @0.25%v/v	
RV101-10HA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDS	Chemigation	77	NA	0.367 (0.411)	NA	0.367 (0.411)	Dyne-Amic @0.25%v/v	
RV102-10HA	[REDACTED], CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	85	45 (418)	0.184 (0.206)	NA	0.369 (0.414)	Dyne-Amic @0.25%v/v	
					89	46 (430)	0.185 (0.208)	10	0.369 (0.414)	Dyne-Amic @0.25%v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV102-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDS	Soil Drench	85	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v
RV103-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	85	245 (2294)	0.184 (0.205)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v
					89	246 (2300)	0.183 (0.205)	10		Dyne-Amic @0.25%v/v
RV103-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDS	Drench	83	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v
RV104-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	85	250 (2337)	0.183 (0.205)	NA	0.367 (0.411)	Dyne-Amic @0.25%v/v
					85	253 (2361)	0.184 (0.207)	11		Dyne-Amic @0.25%v/v
RV104-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDS	Drip Irrigation	85	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v
RV105-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDF	Airblast	85	201 (1881)	0.173 (0.194)	NA	0.360 (0.403)	Dyne-Amic @0.25%v/v
					89	212 (1980)	0.187 (0.209)	10		Dyne-Amic @0.25%v/v
RV106-10HA	CA Region 10 2010	BYI 02960 200 SL	TRTDS	Chemigation	81	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Grapes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV106-10HA	WA Region 11 2010	BYI 02960 200 SL	TRTDF	Airblast	89	50 (465)	0.182 (0.20)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v
RV106-10HA	WA Region 11 2010	BYI 02960 200 SL	TRTDS	Chemigation	85	NA	0.380 (0.426)	NA	0.380 (0.426)	Dyne-Amic @0.25%v/v
RV107-10HA	OR Region 11 2010	BYI 02960 200 SL	TRTDF	Airblast	89	67 (628)	0.177 (0.198)	NA	0.356 (0.399)	Dyne-Amic @0.25%v/v
RV107-10HA	OR Region 11 2010	BYI 02960 200 SL	TRTDS	Drip emitters	83	NA	0.366 (0.410)	NA	0.366 (0.410)	Dyne-Amic @0.25%v/v

a Values for spray volume and total rate have been rounded.

b NA = Not applicable.

TRTDF = Treated plot receiving two broadcast foliar spray applications

TRTDS = Treated plot receiving a single soil application

Duplicate composite samples of grapes were collected from the plot receiving two airblast applications, at sampling intervals of 0, 3 and 5 to 7 days after the second application. The intended pre-harvest interval was 0 days. In four decline trials, duplicate composite grape samples were collected from the treated plots at day 0, 3, 5 to 7, 14, and 20 to 21 days after the second application. In addition, samples were collected just prior to the final foliar application. These samples were collected for informational purposes, only.

Duplicate composite samples were also collected from the plot receiving one soil drench application at a 28 to 30-day PHI. Single composite samples of grapes were collected from the control plots on the same day the target 0-day samples were collected from the treated plots.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residues of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20% (Table 6.3.2.4-5).

Table 6.3.2.4-5: Summary of Recoveries of BYI 02960 from Grapes

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%)	Std Dev (%)
Grapes	BYI 02960	0.010	31	88, 105, 89, 99, 105, 96, 103, 99, 75, 99, 93, 100, 97, 116, 102, 115, 117, 145, 105, 104, 107, 94, 112, 99, 81, 100, 99, 103, 107, 123, 107	103	13
		0.100	3	97, 91, 97	95	4
		0.200	7	86, 87, 103, 95, 98, 94, 103	95	7
		0.400	7	94, 109, 95, 78, 103, 93, 117	98	13
		2.50	3	92, 92, 99	94	4
	DFA	0.050	51	99, 95, 102, 90, 96, 110, 102, 103, 110, 105, 90, 110, 105, 112, 104, 96, 103, 103, 107, 105, 104, 97, 102, 105, 88, 91, 87, 111, 84, 100, 78	100	9
		0.500	3	112, 107, 108	109	3
		1.00	7	102, 111, 108, 109, 104, 101, 105	106	4
		2.00	3	106, 106, 100, 101, 103, 102, 105	103	2
		DFEAF	0.010	31	88, 84, 92, 106, 108, 94, 97, 87, 95, 90, 99, 98, 106, 105, 100, 89, 101, 97, 100, 103, 104, 95, 96, 106, 92, 92, 93, 102, 107, 113, 99	98
	0.100		3	95, 88, 90	91	4
	0.200		7	89, 97, 91, 92, 89, 92, 86	91	3
	0.400		7	89, 89, 80, 88, 88, 92, 98	89	5



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The freezer storage stability study indicates that BYI 02960 residues were stable in spinach leaves, tomato fruits and orange fruits as representative crops for the respective crop commodities (high water and high acid content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 271 days.

A summary of the storage conditions are shown in the Table 6.3.2.4-6 below.

Table 6.3.2.4-6: Summary of Storage Conditions for Grapes

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration (days) ^{b,c,d}
BYI 02960	Grapes	< -20	9 (271)
DFEAF	Grapes	< -20	9 (271)
DFA	Grapes	< -20	9 (271)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and ALS. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RABVP046, amended version including 18-month data (KIIA 6.1.1/01)

Residue of BYI 02960 and metabolites in grapes harvested after two foliar applications or a single soil application are shown in Table 6.3.2.4-7.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7: Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./X (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV092-10DA	[REDACTED] NY, Region 1, 2010	TRTDF	Concord	Fresh Fruit	0.371 (0.416)	0	0.346 0.364	<0.050 <0.050	<0.010 <0.010	0.50 0.42 Avg: 0.51
						14	0.388 0.343	<0.050 <0.050	<0.010 <0.010	0.45 0.40 Avg: 0.42
						28	0.177 0.247	<0.050 <0.050	<0.010 <0.010	0.23 0.29 Avg: 0.26
						14	0.222 0.240	<0.050 0.0525	0.011 0.014	0.28 0.31 Avg: 0.30
						20	0.206 0.160	<0.050 <0.050	0.013 0.011	0.29 0.22 Avg: 0.25
						30	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV093-10HA	[REDACTED] PA, Region 3, 2010	TRTDF	Concord	Fresh Fruit	0.369 (0.416)	0	0.394 0.382	<0.050 <0.050	<0.010 <0.010	0.45 0.44 Avg: 0.44
						3	0.332 0.375	<0.050 <0.050	<0.010 <0.010	0.39 0.43 Avg: 0.41
						7	0.233 0.221	<0.050 <0.050	<0.010 <0.010	0.29 0.28 Avg: 0.28
RV093-10HA	[REDACTED] PA, Region 1, 2010	TRTDS	Concord	Fresh Fruit	0.366 (0.410)	28	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV094-10HA	Region 5, 2010	TRTDF	Sebrevois	Fresh Fruit	0.346 (0.388)	0	0.365 0.486	<0.050 <0.050	<0.010 <0.010	0.44 0.54 Avg: 0.48
						1	0.160 0.170	<0.050 <0.050	<0.010 <0.010	0.22 0.22 Avg: 0.22
						3	0.190 0.166	<0.050 <0.050	<0.010 <0.010	0.25 0.22 Avg: 0.23
						7	0.193 0.175	<0.050 <0.050	<0.010 <0.010	0.25 0.23 Avg: 0.24
						14	0.169 0.167	<0.050 <0.050	<0.010 <0.010	0.23 0.22 Avg: 0.22
						21	0.121 0.162	<0.050 <0.050	<0.010 <0.010	0.18 0.20 Avg: 0.18
RV094-10HA	Region 5, 2010	TRTDS	Sebrevois	Fresh Fruit	0.364 (0.408)	30	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV095-10DA	Region 5, 2010	TRTDF	Concord	Fresh Fruit	0.361 (0.404)	0	0.326 0.300	<0.050 <0.050	<0.010 <0.010	0.39 0.37 Avg: 0.38
						3	0.289 0.263	<0.050 <0.050	<0.010 <0.010	0.34 0.32 Avg: 0.33
						7	0.193 0.175	<0.050 <0.050	<0.010 <0.010	0.25 0.23 Avg: 0.24
						14	0.169 0.167	<0.050 <0.050	<0.010 <0.010	0.23 0.22 Avg: 0.22
						21	0.121 0.162	<0.050 <0.050	<0.010 <0.010	0.18 0.20 Avg: 0.18
						30	0.121 0.162	<0.050 <0.050	<0.010 <0.010	0.18 0.20 Avg: 0.18
RV095-10DA	Region 5, 2010	GRTDS	Concord	Fresh Fruit	0.364 (0.408)	30	<0.010 <0.010	0.058 0.053	<0.010 <0.010	<0.07 0.07 Avg: 0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./X (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV096-10HA	Region 5, 2010	TRTDF	Frontenac	Fresh Fruit	0.371 (0.416)	0	0.581 0.465	<0.050 <0.050	<0.010 <0.010	0.62 0.52 Avg: 0.58
						30	0.114 0.152	<0.050 <0.050	<0.010 <0.010	0.07 0.20 Avg: 0.19
						60	0.133 0.101	<0.050 <0.050	<0.010 <0.010	0.19 0.15 Avg: 0.17
						90	0.016 0.020	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV096-10HA	Region 5, 2010	TRTDS	Montenac	Fresh Fruit	0.364 (0.408)	30	0.016 0.020	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV097-10HA	Region 5, 2010	TRTDF	Marchal Foch	Fresh Fruit	0.372 (0.416)	0	0.311 0.311	<0.050 <0.050	<0.010 <0.010	0.37 0.38 Avg: 0.37
						3	0.244 0.194	<0.050 <0.050	<0.010 <0.010	0.30 0.25 Avg: 0.27
						7	0.196 0.206	<0.050 <0.050	<0.010 <0.010	0.25 0.26 Avg: 0.25
						30	<0.010 <0.010	0.072 <0.050	<0.010 <0.010	0.09 <0.07 Avg: 0.08
RV097-10HA	Region 5, 2010	TRTDS	Marchal Foch	Fresh Fruit	0.364 (0.408)	30	<0.010 <0.010	0.072 <0.050	<0.010 <0.010	0.09 <0.07 Avg: 0.08

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV098-10DA	[REDACTED], CA, Region 10, 2010	TRTDF	Rubired	Fresh Fruit	0.369 (0.413)	5	2.28 1.52	<0.050	0.013	2.36 1.60
						7	2.50 0.777	<0.050	0.013	2.28 0.83
						14	1.07 1.38	<0.050	0.011	1.1 1.4 ^g
						21	0.886 0.407	<0.050	<0.010	0.74 0.46
						Avg:				1.5 ^f
						Avg:				1.3 ^h
RV098-10DA	[REDACTED], CA, Region 10, 2010	TRTDS	Rubired	Fresh Fruit	0.366 (0.410)	30	0.049 0.031	0.067 <0.050	<0.010 <0.010	0.13 ⁱ 0.07
						Avg:				0.10 ^j
RV099-10DA	[REDACTED], CA, Region 10, 2010	TRTDF	Thompson Seedless	Fresh Fruit	0.368 (0.412)	0	0.621 0.512	<0.050 <0.050	<0.010 <0.010	0.68 0.55
						3	0.499 0.626	<0.050 <0.050	<0.010 <0.010	0.54 0.67
						7	0.480 0.431	0.091 0.084	<0.010 <0.010	0.58 0.52
						14	0.513 0.412	0.121 0.147	<0.010 <0.010	0.64 0.56
						21	0.375 0.505	0.202 0.177	<0.010 <0.010	0.58 0.69
						Avg:				0.63

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DF A Residue (mg a.s. equiv./kg)	DFE A Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV099-10DA	[REDACTED] CA, Region 10, 2010	TRTDS	Thompson Seedless	Fresh Fruit	0.366 (0.410)	30	0.005 <0.010	0.073 <0.050	<0.010 <0.010	0.09 0.07
						Avg:	<0.07			
RV100-10HA	[REDACTED] CA, Region 10, 2010	TRTDF	Thompson Seedless	Fresh Fruit	0.366 (0.410)	0	0.586 0.392	<0.050 <0.050	<0.010 <0.010	0.65 0.45
						3	0.317 0.398	<0.050 <0.050	<0.010 <0.010	0.37 0.42
						7	0.27 0.274	<0.050 <0.050	<0.010 <0.010	0.30 0.33
						Avg:				0.55
						Avg:				0.39
RV100-10HA	[REDACTED] CA, Region 10, 2010	TRTDS	Thompson Seedless	Fresh Fruit	0.366 (0.410)	30	<0.010 <0.010	<0.050 0.094	<0.010 <0.010	<0.07 0.11
						Avg:				0.09
RV101-10HA	[REDACTED] CA, Region 10, 2010	TRTDF	Thompson Seedless	Fresh Fruit	0.37 (0.417)	0	0.896 0.706	<0.050 <0.050	<0.010 <0.010	0.93 0.75
						3	0.569 0.637	0.063 0.068	<0.010 <0.010	0.64 0.71
						7	0.606 0.544	0.093 0.091	0.010 <0.010	0.71 0.64
						Avg:				0.84
						Avg:				0.68
RV101-10HA	[REDACTED] CA, Region 10, 2010	TRTDS	Thompson Seedless	Fresh Fruit	0.367 (0.411)	29	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 0.07
Avg:					<0.07					

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV102-10HA	[REDACTED], CA, Region 10, 2010	TRTDF	Syrah Noir	Fresh Fruit	0.369 (0.414)	0	0.242 0.382	<0.050 0.050	<0.010 0.010	0.396 0.44
						3	0.053 0.295	<0.050 0.050	<0.010 0.010	0.17 0.05
						7	0.088 0.052	<0.050 0.050	<0.010 0.010	0.15 0.11
						Avg:				0.26
RV102-10HA	[REDACTED], CA, Region 10, 2010	TRTDS	Syrah Noir	Fresh Fruit	0.366 (0.410)	0	0.010 0.010	<0.050 0.050	<0.010 0.010	<0.07 0.07
						Avg:				<0.07
RV103-10HA	[REDACTED], CA, Region 10, 2010	TRTDF	Syrah	Fresh Fruit	0.367 (0.412)	0	0.207 0.477	<0.050 0.050	<0.010 0.010	0.27 0.53
						3	0.365 0.504	<0.050 0.050	<0.010 0.010	0.42 0.56
						7	0.215 0.177	<0.050 0.050	<0.010 0.010	0.27 0.24
						Avg:				0.25
						30	0.015 0.032	<0.050 0.050	<0.010 0.010	0.07 0.07
RV104-10HA	[REDACTED], CA, Region 10, 2010	TRTDF	Thompson Seedless	Fresh Fruit	0.367 (0.411)	0	0.654 0.543	<0.050 0.050	<0.010 0.010	0.71 0.60
						3	0.826 0.552	<0.050 0.050	0.010 0.010	0.89 0.61
						7	0.392 0.332	<0.050 0.050	<0.010 0.010	0.45 0.39
Avg:				0.42						

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV104-10HA	[REDACTED], CA, Region 10, 2010	TRTDS	Thompson Seedless	Fresh Fruit	0.366 (0.410)	30	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07
						Avg:	<0.07	<0.07	<0.07	
RV105-10HA	[REDACTED], CA, Region 10, 2010	TRTDF	Thompson Seedless	Fresh Fruit	0.360 (0.403)	0	1.06 0.927	<0.050 <0.050	<0.010 <0.010	1.0 1.0
						3	0.875 0.879	0.07 0.07	<0.010 <0.010	0.95 0.96
						7	0.789 1.24	0.10 0.10	<0.010 0.013	0.90 1.4
						Avg:	0.96	0.96	1.2	
RV105-10HA	[REDACTED], CA, Region 10, 2010	TRTDS	Thompson Seedless	Fresh Fruit	0.366 (0.410)	30	<0.010 <0.010	0.083 0.079	<0.010 <0.010	0.10 0.10
						Avg:	0.10	0.10	0.10	
RV106-10HA	[REDACTED], WA, Region 11, 2010	TRTDF	White Riesling	Fresh Fruit	0.366 (0.410)	0	1.31 0.951	<0.050 <0.050	<0.010 <0.010	1.4 1.0
						3	1.07 1.04	<0.050 <0.050	<0.010 <0.010	1.1 1.1
						7	0.830 0.957	0.088 0.090	<0.010 <0.010	0.92 1.1
Avg:	1.0	1.0	1.0							
RV106-10HA	[REDACTED], WA, Region 11, 2010	TRTDS	White Riesling	Fresh Fruit	0.380 (0.426)	30	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07
Avg:	<0.07	<0.07	<0.07							

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-7 (cont'd): Total BYI 02960 Residue Data from Grapes after Two Foliar or a Single Soil, Application(s) of BYI 02960

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total BYI 02960 Residue (mg a.s./X) (kg a.s./ha)	Sampling interval (days after last application) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV107-10HA	OR, Region 11, 2010	TRTDF	Chardonnay	Fresh Fruit	0.356 (0.399)	0	0.459	<0.050	<0.010	0.459
						7	0.555	<0.050	<0.010	0.562
						14	0.680	<0.050	<0.010	0.644
						21	0.484	<0.050	<0.010	0.534
									Avg: 0.57	
RV107-10HA	OR, Region 11, 2010	TRTDS	Chardonnay	Fresh Fruit	0.366 (0.410)	28	0.016	<0.050	<0.010	<0.07
						35	0.012	<0.050	<0.010	<0.07
						42	0.016	<0.050	<0.010	<0.07
						49	0.016	<0.050	<0.010	<0.07
									Avg: <0.07	

- a Pre-Harvest Interval (PHI) is the interval between the last application and sample date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFAE residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Maximum residue found in grapes, sampled at 0 days.
- d Highest average field trial (HAFT) residue found in grapes, sampled at 0 days.
- e Maximum residue found in grapes, sampled at 7 days.
- f Highest average field trial (HAFT) residue found in grapes, sampled at 3 days.
- g Maximum residue found in grapes, sampled at 7 days.
- h Highest average field trial (HAFT) residue found in grapes, sampled at 7 days.
- i Maximum residue found in grapes, sampled at 30 days.
- j Highest average field trial (HAFT) residue found in grapes, sampled at 30 days.

Conclusion

Sixteen field trials were conducted to measure the magnitude of total BYI 02960 residue in/on grapes following two foliar spray applications or a single soil application of BYI 02960 200 SL.

The residue data provided in this report are suitable for regulatory purposes and are summarized in Table 6.3.2.4-8.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.4-8: Summary of Residue Data for Total BYI 02960

Commodity	Plot Name ²	Total Application Rate lb ai/A (kg ai/ha)	PHI (days) ³	Total BYI 02960 Residue Levels (ppm) ¹							
				n	Min at PHI	Max at PHI	Max after PHI	HAF T ³	Median ⁴	Mean ⁴	Standard Deviation
Grapes	TRTDF	0.346 to 0.372 (0.388 to 0.417)	0*	16	0.267	2.342	1.4 (9) ⁵	1.961	0.544	0.684	0.427
Grapes	TRTDF	0.346 to 0.372 (0.388 to 0.417)	3	16	0.173	2.167	1.4 (9) ⁵	1.499	0.439	0.575	0.395
Grapes	TRTDF	0.346 to 0.372 (0.388 to 0.417)	7-9	16	0.112	1.239	---	1.267	0.289	0.473	0.365
Grapes	TRTDS	0.364 to 0.380 (0.408 to 0.426)	30	16	<0.0	0.125	---	0.100	0.070	0.076	0.014

1 Data from the decline trial samples collected at intervals other than the 14-day PHI are not included in this table.

2 TRTDF = Treated plot receiving two concentrate airblast applications;

TRTDD = Treated plot receiving two dilute airblast applications.

3 HAF T = Highest Average Field Trial.

4 calculated on the basis of residue values at the PHI.

5 Sampling day showing highest residue.

* The intended pre-harvest interval (PHI) is 0 days.

Comparing the different use patterns tested, it is obvious that the total BYI 02960 residues are generally higher when applying the GAP with the two Goliard spray applications.

Total BYI 02960 residues in samples collected from the grape decline trials generally decreased with time. With an intended PHI of 0 days, the highest residue level is always at the PHI, with the exception of only one trial where the highest residue level (1.4 mg/kg) was detected at the last sampling day (day 9). However the overall highest residue level (2.3 mg/kg) was detected at the PHI of 0 days.

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IIA 6.3.2.5 Berries and small fruit - blueberries
Residue data from NORTH AMERICA and other regions with significant blueberry production (SOUTH AMERICA, AUSTRALIA, NEW ZEALAND AND EUROPE)

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment on/on bushberry subgroup (Crop Subgroup 10-07B). The use pattern in North America is summarized in Table 6.3.2.5-1.

Table 6.3.2.15-1 Target Use Patterns for the Application of BYI 02960 on Bushberry Subgroup (Crop Subgroup 13-07B)

Test Substance	No. of Apps	Target Rate/Application				Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s.)					GPA	LPHA
		mL/A	fl oz/A	Name of a.s.	lb. a.s./A					
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	205	7	25	50	93-467

GPA = gallons per acre
 LPHA = liter per hectare

Since blueberries are heavily traded, an IR-4 program (Inter-Regional Research Project Number 4) was initiated to establish a globally harmonized tolerance (maximum residue level). Therefore 26 trials in 5 different regions were conducted, all according to the NAFPA use pattern.

Report:	KHA 6.3.2.5/01; [REDACTED] W.: 2012
Title:	BYI 02960: Magnitude of the Residue on Blueberry
Report No & Document No	IR-4 PR No. 10637; Bayer CropScience Report No. FARVY024, dated M-465476-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1 Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

To establish the U.S. tolerance and provide for international maximum residue levels (MRLs) in all countries with significant blueberry production, 26 filed trials were conducted on low bush, high bush, and rabbit eye blueberries in North America, South America, Australia, New Zealand, and Europe during the 2011 growing season. The North American trials were conducted in Maine (ME01), New Jersey (NJ01 and NJ02), Michigan (MI01, MI02, and MI03), North Carolina (NC01 and NC02), Oregon (OR01), Nova Scotia (NS01, NS02, and NS03), and Quebec (QC16). The South American trials were conducted in Chile (CL01, CL02, and CL03). The Australian trials were conducted in Victoria (AU01 and AU02) and New South Wales (AU04) and the New Zealand trials were conducted on the North Island (NZ01) and the South Island (NZ02). The European trials were conducted in the United Kingdom (UK01 and UK02), Italy (IT01), Spain (SP01), and Denmark (DK01)



Material and Methods

Low bush blueberries were grown in ME01, NS01, NS02, and NS03; rabbit eye blueberries in AZ04; and high bush blueberries in the 21 remaining trials. The high bush blueberries in UK01 and SP01 were grown in the field under plastic-covered tunnels to protect the plants from environmental extremes. Blueberries in all other trials were grown under standard field conditions.

In each trial, the test substance was applied in two foliar applications of approximately 205 g a.s./ha (0.183 lb a.s./A) each, for a total of approximately 0.410 g a.s./ha (0.366 lb a.s./A). A non-ionic surfactant, crop oil concentrate, or another adjuvant was included in each tank mix, except in NZ02 and SP01. The two applications were made 6 to 8 days apart.

The location of the field trials as well as the trial site conditions, including soil characteristics are summarized in Table 6.3.2.5-2. Study use patterns are summarized in Table 6.3.2.5-3.

Samples of marketable blueberries were collected 2.5 to 3 days after each application. Additional samples for decline determination were collected from one low bush trial (NS01) and six high bush trials (MI01, CL01, UK01, UK02, F001, and SP01) at 0, 1, 7 or 8, and 14 or 15 days after the second application.

Table 6.3.2.5-2: Location of Field Trials and Trial Site Conditions for BYI02960 on Blueberry

Trial ID (City, State, Country)	Trial Start Year	Soil Characteristics			
		Type	%OM	pH	CEC (meq/100 g)
Low Bush Blueberry					
ME01 (██████, ME, United States)	2011	Sandy loam	5.0	4.8	2.8
NS01 (██████, NS, Canada)	2011	Sandy glacioluvial	2.9	4.9	6.6
NS02 (██████, NS, Canada)	2011	Gravelly sandy loam	7.4	4.6	6.8
NS03 (██████, NS, Canada)	2011	Sandy loam	9.1	4.5	8.6

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-2 (cont'd): Location of Field Trials and Trial Site Conditions for BYI 02960 on Blueberry

Trial ID (City, State, Country)	Trial Start Year	Soil Characteristics			
		Type	%OM	pH	CEC (meq/100g)
High Bush Blueberry					
NJ01 (██████████, NJ, United States)	2011	Sandy clay loam	2.3	4.5	16.5
NJ02 (██████████, NJ, United States)	2011	Sandy clay loam	2.3	4.4	11.6
MI01 (██████████, MI, United States)	2011	Sandy loam	5.3	5.3	9.3
MI02 (██████████, MI, United States)	2011	Sandy loam	7.5	5.3	11.1
MI03 (██████████, MI, United States)	2011	Sandy loam	2.2	4.5	7.5
NC01 (██████████, NC, United States)	2011	Loamy sand	4.1	4.5	13.6
NC02 (██████████, NC, United States)	2011	Loamy sand	4.0	4.0	12.4
OR01 (██████████, OR, United States)	2011	Loam	1.0-2.0	5.6-6.0	10-15
QC16 (██████████, QC, Canada)	2011	Loam	6.1	7.10	12
AU01 (██████████, VIC, Australia)	2011	Red volcanic soil	~ 1	Acidic	Not available
AU02 (██████████, VIC, Australia)	2011	Red volcanic soil	~ 1	Acidic	Not available
NZ01 (██████████, New Zealand)	2011	Sandy loam	15	5.5	20
NZ02 (██████████, New Zealand)	2011	Sandy loam/clay loam	Not reported	Not reported	Not reported

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Table 6.3.2.5-2 (cont'd): Location of Field Trials and Trial Site Conditions for BYI 02960 on Blueberry

Trial ID (City, State, Country)	Trial Start Year	Soil Characteristics			
		Type	%OM	pH	CEC (meq/100 g)
High Bush Blueberry					
CL01 (██████████, Chile)	2011	Silt loam	13	5.11	Not reported
CL02 (██████████, Chile)	2011	Silt loam	13	5.11	Not reported
CL03 (██████████, Chile)	2011	Silt loam	13	5.11	Not reported
UK01 ^a (██████████, United Kingdom)	2011	Sandy clay loam	Not reported	Not reported	Not reported
UK02 (██████████, United Kingdom)	2011	Sandy clay loam	Not reported	Not reported	Not reported
IT01 (██████████, Italy)	2011	Loam	10.9	5.7	10.67
SP01 ^a (██████████, Spain)	2011	Sand	7	7	Not reported
DK01 (██████████, Denmark)	2011	Sand	Not reported	5.1	Not reported
Rabbit Eye Blueberry					
AU04 (██████████, NSW, Australia)	2011	Clay loam	2	4.9	4

a Blueberries were grown under protective tunnel

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-3: Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Application					Tank Mix Adjuvants
			Method/Timing	L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	
Low Bush Blueberry								
ME01 (, ME, United States)	2011	BYI 02960 200SL	Foliar broadcast/Fruiting/ 3 days prior to harvest	230.62 [24.65]	201.7 [0.1799]	—	400.2 [0.3570]	Dyne- Amic
			Foliar broadcast/Fruiting 2.5 days prior to harvest	226.99 [24.27]	198.5 [0.1771]	—		Dyne- Amic
NS01 (NS, Canada)	2011	BYI 02960 200SL	Foliar broadcast/Berries 75% Blue/3 days prior to harvest	350.42 [37.46]	207 [0.1846]	—	415 [0.3703]	Agral 90
			Foliar broadcast/Fruiting/ 0 days prior to harvest	352.28 [37.60]	208.7 [0.1856]	7		Agral 90
NS02 (, NS, Canada)	2011	BYI 02960 200SL	Foliar broadcast/Fruiting 3 days prior to harvest	354.03 [37.85]	209.7 [0.1868]	—	419.1 [0.3738]	Agral 90
			Foliar broadcast/Fruiting 3 days prior to harvest	354.65 [37.91]	209.7 [0.1871]	7		Agral 90
NS03 (, NS, Canada)	2011	BYI 02960 200SL	Foliar broadcast/Fruiting 3 days prior to harvest	354.74 [36.96]	204.5 [0.1824]	—	410.8 [0.3665]	Agral 90
			Foliar broadcast/Fruiting 3 days prior to harvest	349.09 [37.31]	206.4 [0.1841]	7		Agral 90

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-3 (cont'd): Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Method/Timing	Application				Tank Mix Adjuvants
				L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	
High Bush Blueberry								
NJ01 (██████, NJ, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	319.88 [34.20]	210.2 [0.1875]	—	—	Attach
			Foliar directed/Fruiting/ 3 days prior to harvest	224.13 [24.65]	211.8 [0.1889]	—	422 [0.3764]	Attach
NJ02 (██████, NJ, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	294.57 [31.17]	210.7 [0.1879]	—	—	Attach
			Foliar directed/Fruiting/ 3 days prior to harvest	313.65 [33.53]	242.5 [0.1895]	—	423.1 [0.3774]	Attach
MI01 (██████, MI, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	748.57 [80.02]	207.7 [0.1852]	—	—	Prime Oil
			Foliar directed/Fruiting/ 0 days prior to harvest	34.28 [78.49]	206 [0.1838]	7	413.7 [0.3690]	Prime Oil
MI02 (██████, MI, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	310.02 [33.14]	205.1 [0.1830]	—	—	Super Spread 7000
			Foliar directed/Fruiting/ 3 days prior to harvest	292.55 [31.27]	206.2 [0.1839]	7	411.3 [0.3669]	Super Spread 7000

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-3 (cont'd): Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Application					
			Method/Timing	L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	Tank Mix Adjuvants
High Bush Blueberry								
MI03 (MI, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	524.35 [56.05]	206.7 [0.1844]	—	414	Prime Oil
					Foliar directed/Fruiting/ 3 days prior to harvest	523.07 [55.92]	207.3 [0.1849]	—
NC01 (NC, United States)	2011	BYI 02960 200SL	Foliar directed/Green and blue fruit/3 days prior to harvest	290.59 [32.03]	202.1 [0.1805]	—	—	Induce
					Foliar directed/Mature fruit/3 days prior to harvest	207.86 [31.84]	201.0 [0.1795]	6
NC02 (NC, United States)	2011	BYI 02960 200SL	Foliar directed/Green and blue fruit/3 days prior to harvest	449.04 [48.00]	201.3 [0.1796]	—	—	Silicone
					Foliar directed/Mature fruit/3 days prior to harvest	450.91 [48.20]	202.1 [0.1803]	6

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-3 (cont'd): Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Application					Tank Mix Adjuvant s
			Method/Timing	L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	
High Bush Blueberry								
OR01 (██████████, OR, United States)	2011	BYI 02960 200SL	Foliar directed/Fruiting/ 3 days prior to harvest	467.39 [49.96]	205 [0.1829]	7	420.1 [0.3747]	Prime Oil
			Foliar directed/Ripe fruit/3 days prior to harvest	490.26 [52.41]	215 [0.1918]			Prime Oil
QC16 (██████████, QC, Canada)	2011	BYI 02960 200SL	Foliar directed/Fruiting, 70% mature/3 days prior to harvest	516.45 [55.21]	211.7 [0.1889]	7	420.5 [0.3760]	Agral 90
			Foliar directed/Fruiting, 85% mature/3 days prior to harvest	514.61 [54.69]	209 [0.1871]			Agral 90
AU01 (██████████, VIC, Australia)	2011	BYI 02960 200SL	Foliar directed/Fruits 3 days prior to harvest	306.43 [32.76]	208.6 [0.1861]	8	415.8 [0.3709]	Du-Wett
			Foliar directed/Fruits/ 3 days prior to harvest	304.29 [32.53]	207.1 [0.1848]			Du-Wett
AU02 (██████████, VIC, Australia)	2011	BYI 02960 200SL	Foliar directed/Fruiting, fruit ripening 3 days prior to harvest	456.57 [48.81]	207.1 [0.1847]	7	405 [0.3613]	Du-Wett
			Foliar directed/Fruiting, fruit ripening 3 days prior to harvest	436.38 [46.65]	197.9 [0.1766]			Du-Wett
NZ01 (██████████, New Zealand)	2011	BYI 02960 200SL	Foliar directed/Early fruit ripening (20% ripe)/3 days prior to harvest	694 [74.19]	202.3 [0.1805]	7	406.2 [0.3624]	Actiwett
			Foliar directed/Early, late fruiting (80% ready for harvest)/3 days prior to harvest	699.5 [74.78]	203.9 [0.1819]			Actiwett


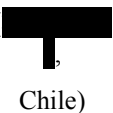

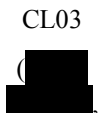
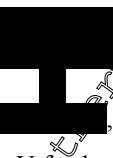
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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)






Table 6.3.2.5-3 (cont'd): Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Application					Tank Mix Adjuvant s
			Method/Timing	L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	
High Bush Blueberry								
NZ02 ( New Zealand)	2011	BYI 02960 200SL	Foliar directed/Early fruit ripening/3 days prior to harvest	732.51 [78.31]	241.2 [0.1811]			None
			Foliar directed/Fruit fully ripened/3 days prior to harvest	730.98 [78.15]	213.0 [0.1907]		408 [0.3818]	None
CL01 ( Chile)	2011	BYI 02960 200SL	Foliar directed/Fruiting/3 days prior to harvest	351.85 [37.61]	207.9 [0.1854]			Bond
			Foliar directed/Fruiting/0 days prior to harvest	351.08 [37.55]	208.4 [0.1859]		416.3 [0.3714]	Bond
CL02 ( Chile)	2011	BYI 02960 200SL	Foliar directed/Fruiting/3 days prior to harvest	494.48 [52.86]	209.7 [0.1826]			Bond
			Foliar directed/Fruiting/3 days prior to harvest	504.14 [53.90]	208.7 [0.1861]	7	413.3 [0.3687]	Bond
CL03 ( Chile)	2011	BYI 02960 200SL	Foliar directed/Fruiting/3 days prior to harvest	601.8 [64.30]	204.4 [0.1824]	—		Bond
			Foliar directed/Fruiting/3 days prior to harvest	594.7 [63.58]	202 [0.1802]	7	406.4 [0.3626]	Bond
UK01 ^c ( United Kingdom)	2012	BYI 02960 200SL	Foliar directed/75-81 BBCH/ 0 days prior to harvest	700.07 [74.84]	204.5 [0.1824]	—		Activator 90
			Foliar directed/85-87 BBCH/ 0 days prior to harvest	702.24 [75.07]	205.1 [0.1830]	7	409.7 [0.3654]	Activator 90

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-3 (cont'd): Study Use Pattern for BYI 02960 200 SL on Blueberry

Trial ID (Location)	Trial Start Year	EP ^a	Application					
			Method/Timing	L/ha [GPA]	Rate (g a.s./ha) [lb a.s./A]	RTI ^b (Days)	Total Rate (g a.s./ha) [lb a.s./A]	Tank Mix Adjuvant s
High Bush Blueberry								
UK02  United Kingdom)	2011	BYI 02960 200SL	Foliar directed/79- 81 BBCH/ 3 days prior to harvest	697.49 [74.57]	203.8 [0.1848]	—	409	Activator 90
			Foliar directed/ BBCH 87/ 0 days prior to harvest	702.5 [75.10]	205.2 [0.1831]	—	409	Activator 90
IT01  Italy)	2011	BYI 02960 200SL	Foliar directed/ BBCH 85/ 3 days prior to harvest	513.71 [54.92]	210.6 [0.1879]	—	415.6	Silwet Fastex
			Foliar directed/ BBCH 87-89/ 0 days prior to harvest	499.95 [53.45]	205 [0.1829]	7	415.6	Silwet Fastex
SP01 ^c  Spain)	2011	BYI 02960 200SL	Foliar directed/Fruiting days prior to harvest	806.47 [85.22]	206.3 [0.1840]	—	—	None
			Foliar directed/Fruiting BBCH 81-83/ 0 days prior to harvest	787.66 [84.22]	201.5 [0.1797]	8	407.7	None
DK01  Denmark)	2011	BYI 02960 200SL	Foliar directed/ BBCH 86/ 3 days prior to harvest	302.18 [21.61]	137.5 [0.1227]	—	—	Agropol
			Foliar directed/ BBCH 87/ 3 days prior to harvest	481.54 [30.10]	191.5 [0.1709]	7	329.1	Agropol
Rabbit Eye Blueberry								
AU04  NSW Australia)	2011	BYI 02960 200SL	Foliar directed/Fruiting/3 da ys prior to harvest	884.56 [94.57]	201.4 [0.1797]	—	—	Agral
			Foliar directed/Fruiting/3 da ys prior to harvest	892.17 [95.38]	203.2 [0.1812]	8	404.6	Agral

a EP = End Use Product

b RTI = Retreatment Interval

c Blueberries were grown under a protective tunnel



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were ≤ 20% (Table 6.3.2.5-4).

Table 6.3.2.5-4: Summary of Recoveries of BYI 02960 from Blueberry.

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%)	Std. Dev (%)
Blueberry fruit	BYI 02960	0.010	7	83, 104, 90, 111, 80, 76, 81	89	13
		1	20	82, 72, 8, 93, 99, 87, 7, 99, 95, 80, 95, 115, 98, 97, 93, 96, 115, 102, 97, 90	93	12
		2	3	95, 99, 104	99	5
		5	3	89, 81, 94	88	7
		0.05	7	91, 93, 99, 91, 90, 96, 85	92	4
	DFA	1	20	82, 98, 93, 91, 95, 101, 97, 93, 97, 95, 88, 92, 90, 95, 92, 88, 92, 89	93	4
		5	3	89, 93, 92	91	2
		5	3	88, 88, 87	88	1
		0.01	7	94, 110, 85, 77, 95, 84, 81	89	11
	DFEAF	1	20	80, 95, 89, 93, 91, 100, 87, 101, 91, 86, 101, 105, 93, 89, 105, 96, 95, 94, 96, 94	94	6
		2	3	92, 96, 96	95	2
		5	3	95, 103, 89	96	7
		0.01	7	94, 110, 85, 77, 95, 84, 81	89	11

The freezer storage stability study indicates that BYI 02960 residues were stable in representative crops of the respective commodities (high water content and high acid content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 271 days. A summary of the storage conditions are shown in Table 6.3.2.5-5.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-5: Summary of Storage Conditions for Blueberries

Matrix	Analyte	Storage Temp. (°C)	Actual Maximum Storage Duration (days)	Interval of Demonstrated Storage Stability (Months) ^a
Fruit	BYI 02960 plus metabolites	-20	271	12 (558 days)

a [REDACTED] and A. [REDACTED]. 2012. Storage Stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. PARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for blueberries following two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.5-6. All trials were conducted according to the NAFTA GAP, with exception of the Danish trial (DK01) which was under-applied by approx. 33% at the first application and by approx. 7% at the second application.

Table 6.3.2.5-6 Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha) (lb a.s./A)	PHI (Days)	Residues from Treated Samples (mg/kg a.s. equiv.)						
									BYI 02960	DFA	DFAEF	Total	Mean		
ME01	[REDACTED]	United States	2011	Blueberry	Cow bush	Fruit	201.7 [0.179]	3	0.7564	<0.050	<0.010	0.8164	1.01		
									1.1358	<0.050	<0.010	1.1958			
									400.2 [0.3570]	2.5	2.4806	0.1055	<0.010	2.5961	2.59
									2.4765		0.1065	<0.010	2.5930		
NS01	[REDACTED] NS	Canada	2011	Blueberry	Wild clones low bush	Fruit	207.0 [0.846]	3	0.1365	<0.050	<0.010	0.1965	0.21		
									0.1623	<0.050	<0.010	0.2223			
									415.1 [0.3703]	0	0.3238	<0.050	<0.010	0.3838	0.65
											0.8631	<0.050	<0.010	0.9231	
									1	0.6093	<0.050	<0.010	0.6693	0.49	
										0.2516	<0.050	<0.010	0.3116		
									3	0.3093	<0.050	<0.010	0.3693	0.41	
										0.3851	<0.050	<0.010	0.4451		
									7	0.2918	<0.050	<0.010	0.3518	0.36	
										0.2985	<0.050	<0.010	0.3585		
14	0.2519	<0.050	<0.010	0.3119	0.34										
	0.3156	<0.050	<0.010	0.3756											

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-6 (cont'd): Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha) [lb a.s./A]	PHI (days) ^a	Residues from Treated Samples (mg/kg a.s. equiv.)				Mean
									BYI 02960	DFA	PFE/AF	Total ^b	
NS02	NS	Canada	2011	Blueberry	Wild clones low bush	Fruit	209.4 [0.1868]	3	0.3641	<0.050	<0.010	0.4241	0.47
							419.1 [0.3738]	3	0.4546	<0.050	<0.010	0.5146	0.89
NS03	NS	Canada	2011	Blueberry	Wild clones low bush	Fruit	207.5 [0.1824]	3	0.4157	<0.050	<0.010	0.5757	0.57
							410.8 [0.3665]	3	0.5040	<0.050	<0.010	0.6640	1.64
NJ01	NJ	United States	2011	Blueberry	Duke high bush	Fruit	210.2 [0.1875]	3	1.1208	<0.050	<0.010	1.1808	1.14
							422.0 [0.3764]	3	1.0350	<0.050	<0.010	1.0950	1.08
NJ02	NJ	United States	2011	Blueberry	Bluecrop high bush	Fruit	210.7 [0.1879]	3	0.7148	<0.050	<0.010	0.7748	0.79
							423.1 [0.3774]	3	0.7417	<0.050	<0.010	0.8017	1.21
MI01	MI	United States	2011	Blueberry	Jersey high bush	Fruit	207.7 [0.1852]	3	0.1704	<0.050	<0.010	0.2304	0.25
							413.7 [0.3690]	3	0.2169	<0.050	<0.010	0.2769	0.80
								1	0.9404	<0.050	<0.010	1.0004	0.58
								1	0.5305	<0.050	<0.010	0.5905	0.58
								1	0.4697	<0.050	<0.010	0.5297	0.58
								1	0.5616	<0.050	<0.010	0.6216	0.58
								3	0.4137	<0.050	<0.010	0.4737	0.45
								3	0.3730	<0.050	<0.010	0.4330	0.45
MI02	MI	United States	2011	Blueberry	Jersey high bush	Fruit	205.1 [0.1830]	3	0.0950	<0.050	<0.010	0.1550	0.14
							411.3 [0.3669]	3	0.0604	<0.050	<0.010	0.1204	0.48
								3	0.4691	<0.050	<0.010	0.5291	0.48
								3	0.3693	<0.050	<0.010	0.4293	0.48

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-6 (cont'd): Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha [lb a.s./A])	PHI (days) ^a	Residues from Treated Samples (mg/kg a.s. equiv.)				Mean
									BYI 02960	DFA	DFAAF	Total ^b	
MI03	MI	United States	2011	Blueberry	Jersey high bush	Fruit	206.7 [0.1844]	3	0.1684	<0.050	<0.010	0.2284	0.22
							414.0 [0.3693]	3	0.1607	<0.050	<0.010	0.2267	0.29
NC01	NC	United States	2011	Blueberry	Crown high bush	Fruit	202.4 [0.1805]	3	0.3836	<0.050	<0.010	0.4436	0.43
							403.6 [0.3600]	3	0.3581	<0.050	<0.010	0.4181	0.84
NC02	NC	United States	2011	Blueberry	Duplin high bush	Fruit	201.2 [0.1796]	3	0.5723	<0.050	<0.010	0.6352	0.61
							403.5 [0.3599]	3	0.512	<0.050	<0.010	0.5812	0.83
OR01	OR	United States	2011	Blueberry	Bluecrop high bush	Fruit	205.0 [0.1829]	3	0.2630	<0.050	<0.010	0.3230	0.35
							420.1 [0.3447]	3	0.3079	<0.050	<0.010	0.3679	0.63
QC16	Canada	2011	Blueberry	Bluecrop high bush	Fruit	211.7 [0.1889]	3	0.4686	<0.050	<0.010	0.5286	0.51	
						421.5 [0.3760]	3	0.4319	<0.050	<0.010	0.4919	0.51	
AU01	VIC	Australia	2011	Blueberry	Reka high bush	Fruit	208.6 [0.1861]	3	<0.010	<0.050	<0.010	0.0700	0.78
							415.8 [0.3709]	3	1.4322	<0.050	<0.010	1.4922	2.39
AU02	VIC	Australia	2011	Blueberry	Dea high bush	Fruit	207.1 [0.1847]	3	0.4526	<0.050	<0.010	0.5126	0.48
							405.0 [0.3613]	3	0.3921	<0.050	<0.010	0.4521	1.01
NZ01	New Zealand	2011	Blueberry	Maru high bush	Fruit	202.3 [0.1805]	3	0.1244	<0.050	<0.010	0.1844	0.17	
						406.2 [0.3624]	3	0.1045	<0.050	<0.010	0.1645	0.19	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-6 (cont'd): Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha) [lb a.s./A]	PHI (days) ^a	Residues from Treated Samples (mg/kg a.s. equiv.)				
									BYI 02960	DFA	DFEAF	Total ^b	Mean
NZ02	[REDACTED]	New Zealand	2011	Blueberry	Darrow high bush	Fruit	241.2 [0.1911]	3	0.5798	<0.050	<0.010	0.6398	0.65
							428.0 [0.3818]	3	0.5975	<0.050	<0.010	0.6575	0.96
CL01	[REDACTED]	Chile	2011	Blueberry	Elliot high bush	Fruit	207.9 [0.1854]	3	0.8928	<0.050	<0.010	0.9528	1.07
							416.3 [0.4714]	3	0.9064	<0.050	<0.010	0.9664	2.03
							1	1.5400	<0.050	<0.010	1.6007	1.87	
							3	2.0754	<0.050	<0.010	2.1354	1.22	
							3	1.0800	<0.050	<0.010	1.1680	1.22	
							3	1.2202	<0.050	<0.010	1.2802	1.60	
							3	1.5078	0.3506	<0.010	1.6684	1.23	
							14	1.4536	0.0634	<0.010	1.5270	1.23	
							14	1.0916	0.1446	<0.010	1.2462	1.23	
							14	1.1080	0.0979	<0.010	1.2159	1.23	
CL02	[REDACTED]	Chile	2011	Blueberry	Elliot high bush	Fruit	204.7 [0.1824]	3	0.6941	<0.050	<0.010	0.7541	0.74
							413.3 [0.3687]	3	0.6565	<0.050	<0.010	0.7165	1.30
CL03	[REDACTED]	Chile	2011	Blueberry	Elliot high bush	Fruit	204.7 [0.1824]	3	1.1413	<0.050	<0.010	1.2013	1.30
							406.4 [0.3626]	3	1.3481	<0.050	<0.010	1.4081	1.30
UK01	[REDACTED]	United Kingdom	2011	Blueberry	Duke high bush (protective tunnel)	Fruit	204.5 [0.1824]	3	0.8384	<0.050	<0.010	0.8984	0.85
							406.4 [0.3626]	3	0.7456	<0.050	<0.010	0.8056	1.78
UK01	[REDACTED]	United Kingdom	2011	Blueberry	Duke high bush (protective tunnel)	Fruit	204.5 [0.1824]	3	1.3376	<0.050	<0.010	1.3976	1.78
							409.7 [0.3654]	0	2.1085	<0.050	<0.010	2.1685	1.78
							1	0.4739	<0.050	<0.010	0.5339	0.54	
							1	0.4956	<0.050	<0.010	0.5556	0.54	
							1	0.9888	<0.050	<0.010	1.0488	1.10	
							1	1.0812	<0.050	<0.010	1.1412	1.10	
							1	0.8422	<0.050	<0.010	0.9022	0.83	
							1	0.6912	<0.050	<0.010	0.7512	0.83	
							3	0.5760	<0.050	<0.010	0.6360	0.62	
							3	0.5451	<0.050	<0.010	0.6051	0.62	
UK01	[REDACTED]	United Kingdom	2011	Blueberry	Duke high bush (protective tunnel)	Fruit	204.5 [0.1824]	8	0.4757	<0.050	<0.010	0.5357	0.54
							409.7 [0.3654]	8	0.4865	<0.050	<0.010	0.5465	0.54
UK01	[REDACTED]	United Kingdom	2011	Blueberry	Duke high bush (protective tunnel)	Fruit	204.5 [0.1824]	15	0.3522	<0.050	<0.010	0.4122	0.44
							409.7 [0.3654]	15	0.4001	<0.050	<0.010	0.4601	0.44

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-6 (cont'd): Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha) [lb a.s./A]	PHI (days) ^a	Residues from Treated Samples (mg/kg a.s. equiv.)				
									BYI 02960	DFA	PFEAF	Total ^b	Mean
UK02	[REDACTED]	United Kingdom	2011	Blueberry	Blue-crop high bush	Fruit	203.8 [0.1818]	3	0.4442	<0.050	<0.010	0.5042	0.48
									0.3946	<0.050	<0.010	0.4546	
							409.0 [0.3648]	0	0.6577	<0.050	<0.010	0.7177	0.68
									0.5795	<0.050	<0.010	0.6395	
									1.4326	<0.050	<0.010	1.4926	1.47
									1.3900	<0.050	<0.010	1.4500	
									0.6491	<0.050	<0.010	0.7001	0.73
									0.7013	<0.050	<0.010	0.7613	
								8	0.4211	<0.050	<0.010	0.4817	0.51
									0.4793	<0.050	<0.010	0.5373	
15	0.3225	<0.050	<0.010	0.3825	0.37								
	0.3032	<0.050	<0.010	0.3632									
IT01	[REDACTED]	Italy	2011	Blueberry	Duke high bush	Fruit	210.6 [0.1879]	0	0.7777	<0.050	<0.010	0.8577	0.84
									0.7660	<0.050	<0.010	0.8260	
							415.6 [0.3807]	0	3.5805	<0.050	<0.010	3.6405	3.82
									3.9453	<0.050	<0.010	4.0053	
								1	3.4471	<0.050	<0.010	3.5071	3.54
									3.5037	<0.050	<0.010	3.5637	
									1.5630	<0.050	<0.010	1.6230	1.68
									1.6851	<0.050	<0.010	1.7451	
								7	1.6811	<0.050	<0.010	1.7411	1.65
									1.4951	<0.050	0.0113	1.5564	
14	1.8590	0.0751	<0.010	1.9441	1.80								
	1.5702	0.0744	<0.010	1.6546									
SP01	[REDACTED]	Spain	2011	Blueberry	Jewel high bush (protected by tunnel)	Fruit	206.3 [0.1840]	3	0.3082	<0.050	<0.010	0.3682	0.37
									0.3125	<0.050	<0.010	0.3725	
							407.7 [0.3637]	0	0.4778	<0.050	<0.010	0.5378	0.60
									0.5935	<0.050	<0.010	0.6535	
								1	0.2366	<0.050	<0.010	0.2966	0.31
									0.2596	<0.050	<0.010	0.3196	
								3	0.1403	<0.050	<0.010	0.2003	0.19
									0.1277	<0.050	<0.010	0.1877	
								7	0.1514	0.0944	<0.010	0.2558	0.28
									0.2442	<0.050	<0.010	0.3042	
14	0.1535	0.0747	<0.010	0.2382	0.25								
	0.1667	0.0945	<0.010	0.2712									

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-6 (cont'd): Total BYI 02960 Residue Data from Blueberries after Foliar Applications of BYI 02960 200 SL

Trial ID	Trial Location	Country	Trial Start Year	Crop	Variety	Commodity	Total Rate (g a.s./ha [lb a.s./A])	PHI (days) ^a	Residues from Treated Samples (mg/kg a.s. equiv.)				
									BYI 02960	DFA	DFEAF	Total ^b	Mean
DK01	[REDACTED]	Denmark	2011	Blueberry	Herbert high bush	Fruit	137.5 [0.1227]	3	0.5431	<0.050	0.010	0.6031	0.66
									0.6545	<0.050	<0.010	0.7145	
							329.1 [0.2935]	3	0.9986	<0.050	<0.010	1.0586	1.04
									0.9595	<0.050	0.010	0.0195	
AU04	[REDACTED] NSW	Australia	2011	Blueberry	Rabb rabbit eye	Fruit	207.4 [0.1797]	3	0.0890	<0.050	<0.010	0.1490	0.15
									0.0875	<0.050	<0.010	0.1475	
							404.6 [0.3699]	3	0.2549	<0.050	<0.010	0.3149	0.33
									0.2789	<0.050	<0.010	0.3389	

a Samples were collected after the first and second applications at target rate of 205 g a.s./ha.

b Total BYI 02960 = Sum of BYI 02960 + DFA + DFEAF residues.

Conclusion

Twenty-six residue field trials were conducted on low bush, high bush, and rabbiteye blueberries in North America, South America, Australia, New Zealand, and Europe. High bush blueberries were grown under a protective tunnel in two trials; all other blueberries were grown under standard field conditions. A total of approximately 0.410 g a.s./ha (0.366 lb a.s./A) was applied to the treated plots in two foliar applications of BYI 02960 200SL at a rate of approximately 205 g a.s./ha (0.183 lb a.s./A) each.

The total BYI 02960 residue data for blueberries following foliar applications are summarized in Table 6.3.2.15-7.

Maximum total BYI 02960 residues (BYI 02960 + DFA + DFEAF) were 1.49 ppm (1.50 ppm when considering the mean of the two samplings) in day-3 samples collected after the first application and 2.61 ppm (2.39 ppm when considering the mean of the two samplings) in day-3 samples collected after the second application. Total residues of BYI 02960 declined over time as shown in seven decline trials. However the residue peak was not always at the intended PHI of 3 days. Peak residues detected after the PHI were always lower as the overall maximum total BYI 02960 residue in blueberries.

The residue data from these globally conducted trials can be used to establish a US tolerance and provide for international MRLs for BYI 02960 on blueberry.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.5-7: Summary of Residue Data for Total BYI 02960 from Blueberries

Commodity	Plot Name ¹	Total Appl. Rate lb a.s./A (kg a.s./ha)	PHI (days) ³	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean	Standard Deviation
Blueberry fruit	TRTD	0.123 to 0.191 (0.138 to 0.241)	3	26	0.070	1.492	NA	1.1379	0.522	0.557	0.321
Blueberry fruit	TRTDF	0.294 to 0.381 (0.329 to 0.428)	3	26	0.188	2.606	1.944 (14) ⁵	2.5946	0.511	0.574	0.639

- 1 TRTD = treated plot receiving one dilute spray application
TRTDF = treated plot receiving two dilute spray applications
- 2 HAFT = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 NA = not applicable; no decline trials were conducted after one application
- 5 Sampling day showing highest residue

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IIA 6.3.2.6 Miscellaneous fruit - prickly pear cactus (fruit)

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment on prickly pear cactus. The use pattern in North America is summarized in Table 6.3.2.6-1.

An IR-4 program (Inter-Regional Research Project Number 4) was initiated to establish an MRL (maximum residue level) for prickly pear cactus. A total of 8 trials were conducted to support this minor use initiative.

Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant Additive (%)	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
		mL/A	fl oz/A	Name of a.s.	lb a.s./A	g a.s./ha					
BYI 02960 200 SL	2	1025	14.0	BYI 02960	0.183	205	1	9.25	10-50	93-467	

GPA = gallons per acre
LPHA = liter per hectare

Report:	KIIA 6.3.2.6/01; [REDACTED] W.; 2012
Title:	BYI 02960 Magnitude of the Residue on Prickly Pear Cactus
Report No & Document No	IR-4 RR No. 10722; dated June 14, 2012 Bayer CropScience Report No. RARVP078 M432542-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

A total of eight trials were conducted in prickly pear cactus according to the intended GAP during the 2011 growing season. The use pattern - corresponding to the intended GAP - is described below. Four trials generated fruit samples and four trials generated pad samples. The number of trials and their locations are adequate for a regional registration in the US. The number and location of field trials are shown in Table 6.3.2.6-2.



Table 6.3.2.6-2: Trial Numbers and Geographical Locations for BYI 02960 on Prickly Pear Cactus

NAFTA Growing Region	Prickly Pear Cactus (Fruit and Pads)		
	Submitted	Requested	
		Canada	U.S.
1			
1A			
2			
3			
4			
5			
5A			
5B			
6			
7			
7A			
8			
9			
10			
11			
12			
13			
14			
Total	8		8

a OPPTS 860.1500 does not specify growing regions for prickly pear cactus. However, prickly pear cactus are primarily grown in California (region 10) and Texas (regions 6 and 8).

Material and Methods

One use pattern/application form was tested. In each trial, the test substance was applied in two foliar directed applications of approximately 0.183 lb a.s./A each for a total of approximately 0.366 lb a.s./A. A non-ionic surfactant was included in each tank mix. The applications were made at 7- to 8-day intervals and timed so that mature fruit and pads could be collected approximately 21 days after the final application.

In each trial, duplicate samples of fruit (CA*01, CA*02, CA*143, and CA*144) or duplicate samples of pads (CA*160, CA*161, CA*162, and CA*163) were collected from each plot 20 to 21 days following the final application.

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.6-3. Study use patterns are summarized in Table 6.3.2.6-4.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.6-3. Trial Site Conditions for BYI 02960 on Prickly Pear Cactus

Trial ID (City, State)	Trial Start Year	Soil Characteristics			
		Type	%OM	pH	CEC (meq/100 g)
Fruit					
CA*01 (██████, CA)	2011	Sandy loam	2.1	7.3	13
CA*02 (██████, CA)	2011	Sandy loam	2.1	7.3	13
CA*143 (██████, CA)	2011	Sandy loam	2.1	7.5	24
CA*144 (██████, CA)	2011	Sandy loam	2.1	7.5	24
Pads					
CA*160 (██████, CA)	2011	Sandy loam	2.1	7.3	13
CA*161 (██████, CA)	2011	Sandy loam	2.1	7.3	13
CA*162 (██████, CA)	2011	Sandy loam	2.1	7.5	24
CA*163 (██████, CA)	2011	Sandy loam	2.1	7.3	24

Table 6.3.2.6-4. Study Use Pattern for BYI 02960 200 SL on Prickly Pear Cactus

Trial ID (City, State)	Trial Start Year	EP ^a	Application					
			Method/Timing	CPA	Rate (lb a.s./A)	RTI ^b (days)	Total Rate (lb a.s./A)	Tank Mix Adjuvants
CA*01 (██████, CA)	2011	BYI 02960 200 SL	Foliar directed/All stages of fruits and flowers/28 days prior to harvest	100.07	0.1854	—		R-11 Spreader
			Foliar directed/All stages of fruits and flowers/21 days prior to harvest	99.46	0.1843	7	0.3696	R-11 Spreader
CA*02 (██████, CA)	2011	BYI 02960 200 SL	Foliar directed/All stages of fruits and flowers/28 days prior to harvest	72.43	0.1862	—		R-11 Spreader
			Foliar directed/All stages of fruits and flowers/20 days prior to harvest	72.90	0.1875	8	0.3737	R-11 Spreader

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.6-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Prickly Pear Cactus

Trial ID (City, State)	Trial Start Year	EP ^a	Application					
			Method/ Timing	GPA	Rate (lb a.s./A)	RTI ^b (days)	Total Rate (lb a.s./A)	Tank Mix Adju- vants
CA*143 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/All stages of fruits and flowers/27 days prior to harvest	45.83	0.1832	—		R-11 Spreader
			Foliar directed/All stages of fruits and flowers/20 days prior to harvest	45.80	0.1830	—	0.3662	R-11 Spreader
CA*144 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/All stages of fruits and flowers/28 days prior to harvest	19.91	0.1796	—		R-11 Spreader
			Foliar directed/All stages of fruits and flowers/21 days prior to harvest	19.97	0.1795	7	0.3591	R-11 Spreader
CA*160 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/Various sizes of pads/28 days prior to harvest	97.78	0.1834	—		R-11 Spreader
			Foliar directed/Various sizes of pads/21 days prior to harvest	98.81	0.1853	7	0.3688	R-11 Spreader
CA*161 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/Various sizes of pads/28 days prior to harvest	72.55	0.1833	—		R-11 Spreader
			Foliar directed/All sizes of pads/20 days prior to harvest	73.81	0.1866	8	0.3699	R-11 Spreader
CA*162 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/Various sizes of pads/27 days prior to harvest	47.13	0.1871	—		R-11 Spreader
			Foliar directed/All sizes of pads/20 days prior to harvest	46.85	0.1872	7	0.3743	R-11 Spreader
CA*163 (██████, CA)	2011	BYI 02960 200SL	Foliar directed/All stages and sizes of pads/28 days prior to harvest	21.34	0.1843	—		R-11 Spreader
			Foliar directed/All stages of pads/21 days prior to harvest	21.13	0.1920	7	0.3763	R-11 Spreader

a EP = End-use Product

b RTI = Retreatment Interval

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.6-5)

Table 6.3.2.6-5: Summary of Recoveries of BYI 02960 from Prickly Pear Cactus

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%)	Std Dev (%)
Blueberry fruit	BYI 02960	0.01	7	89, 94, 108, 96, 105, 98, 94	97	8
		0.2	7	94, 94, 103	97	5
	DFA	0.05	7	83, 86, 108, 89, 88, 101, 79	91	10
		0.2	7	94, 95, 93	94	1
	DFEAF	0.01	7	95, 103, 96, 97, 95, 101, 89	95	7
		0.2	7	97, 103, 96	99	4

The freezer storage stability study indicates that BYI 02960 residues were stable in a representative crop of the respective crop commodity (high water content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 101 days. A summary of the storage conditions are shown in Table 6.3.2.6-6.

Table 6.3.2.6-6: Summary of Storage Conditions for Prickly Pear Cactus

Matrix	Analyte	Storage Temp. (C)	Actual Maximum Storage Duration (days)	Interval of Demonstrated Storage Stability (Months) ^a
Fruit	BYI 02960 + metabolites	-20	99	18 (558 days)
Pads	BYI 02960 + metabolites	-20	101	18 (558 days)

a [redacted] and A. [redacted]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The total BYI 02960 residue data for prickly pear cactus following two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.6-7.

Table 6.3.2.6-7: Total BYI 02960 Residue Data from Prickly Pear Cactus after Foliar Application(s) of BYI 02960 SL

Trial ID	Trial Location (City, State)	NAFTA Growing Region	Trial Start Year	Crop	Variety	Commodity	Total Rate (lb a.s./A)	PHI (days)	Residues from Treated Samples (mg a.s. equiv./kg)				Mean
									BYI 02960	DFA	DFAAF	Total ^a	
CA* 01	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Fruit	0.3668	20	0.1527	<0.050	<0.010	0.2117	0.18
									0.0834	<0.050	<0.010	0.1434	
CA* 02	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Fruit	0.3733	20	0.1293	<0.050	<0.010	0.1813	0.18
									0.2555	<0.050	<0.010	0.1855	
CA* 143	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Fruit	0.3662	20	0.1069	<0.050	<0.010	0.1669	0.16
									0.0954	<0.050	<0.010	0.1554	
CA* 144	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Fruit	0.3591	21	0.0469	<0.050	<0.010	0.1069	0.13
									0.0886	<0.050	<0.010	0.1486	
CA* 160	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Pads	0.3688	21	0.2132	<0.050	0.0119	0.2751	0.27
									0.1054	<0.050	<0.010	0.2554	
CA* 161	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Pads	0.3699	20	0.2546	<0.050	0.0133	0.3179	0.27
									0.1540	<0.050	<0.010	0.2140	
CA* 162	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Pads	0.3743	20	0.2183	<0.050	0.0186	0.2869	0.29
									0.2339	<0.050	0.0161	0.3000	
CA* 163	CA	10	2011	Prickly Pear Cactus	Andy Boy "Red"	Pads	0.3763	21	0.2380	<0.050	0.0232	0.3112	0.33
									0.2706	<0.050	0.0254	0.3460	

a Total BYI 02960 = Sum of BYI 02960 + DFA + DFAAF Residues.

Conclusion

Eight residue field trials in prickly pear cactus (four for fruit and four for pads) were conducted in California. A total of approximately 0.400 kg a.s./ha (0.366 lb a.s./A) was applied to the treated plots in two foliar directed applications of BYI 02960 200SL at a rate of approximately 0.200 (0.183 lb a.s./A) each.

The total BYI 02960 residue data for prickly pear cactus following two foliar applications are summarized in Table 6.3.2.6-8.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Maximum total BYI 02960 residues were 0.212 ppm (0.18 ppm when considering the mean of the two samplings) in fruit and 0.346 ppm (0.33 ppm when considering the mean of the two samplings) in pads at a PHI of 20 to 21 days when applying BYI 02960 200 SL according to the proposed use pattern.

Data from this study can be used to support a US tolerance proposal and to provide for international MRLs for BYI 02960 on prickly pear cactus.

Table 6.3.2.6-8: Summary of Residue Data for Total BYI 02960 from Prickly Pear Cactus

Commodity	Plot Name ¹	Total Appl. Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (mg a.s. equiv./kg)							Standard Deviation
				n	Min at PHI	Max at PHI	Max after PHI	HAFT	Median ³	Mean ³	
Cactus Fruit	TRTDF	0.359 to 0.374 (0.402 to 0.419)	20-21	4	0.1069	0.2117	NA ⁴	0.1834	0.1612	0.1625	0.0317
Cactus pads	TRTDF	0.369 to 0.376 (0.413 to 0.421)	20-21	4	0.214	0.346	NA ⁴	0.3286	0.2935	0.2883	0.0408

- 1 TRTDF = treated plot receiving two dilute spray applications
- 2 HAFT = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 NA = not applicable, no decline trials were conducted

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IIA 6.3.2.7 Root and tuber vegetables - potatoes and sweet potatoes

Residue data from NORTH AMERICA (Crop Subgroup 1C)

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on tuberous and corm vegetables (Crop Subgroup 1C). The use pattern in North America is summarized in Table 6.3.2.7-1.

A total of twenty-six trials were conducted in potatoes. The studies are described below.

Table 6.3.2.7-1 Target Use Patterns for the Application of BYI 02960 on Tuberous and Corm Vegetables (Crop Subgroup 1C) in North America

Test Substance	No. of Apps	Target Rate/Application						Spray Volume			
		Formulated Product (FP)		Active Substance (a.s.)			Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	GPA	LPHA
		mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
BYI 02960 200 SL	2	415	14.0	BYI 02960	0.183	0.205	7	7	0.35	10-50	93-467

GPA = gallons per acre
LPHA = liter per hectare

Report:	IIA 6.3.2.7-1; [redacted] and ACM. [redacted]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in Potato (Tuberous and Corm Vegetables (Crop Subgroup 1C))
Report No & Document No	BARVY015, dated May 4, 2012 M-430532-042
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPS 860.1500, Crop Field Trials Canada: PMRA/DACO 7.4.1, Supervised Residue Trial Study PMR/DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009
GLP	Yes

Twenty-six field trials were conducted to measure the magnitude of BYI 02960 residues in/on potato tubers following two broadcast foliar spray applications of BYI 02960 200 SL. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.7-2).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Potato

NAFTA Growing Region	Submitted	Requested ^a	
		EPA	PMRA
1	7	2	7
2	1	1	
3	1	1	
4			
5	5	4	
6			
7			
7A	1		1
8			
9	1	1	
10	1		
11		6	
12	1		1
13			
14	2		2
Total	26	16	16

^a Decline trials were conducted in Regions 1, 3, 11, and 14. The additional decline trials were performed to meet EU requirements.

Material and Methods

Individual application rates ranged from 0.178 to 0.197 lb BYI 02960/A/application (0.200 to 0.221 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.359 to 0.385 lb BYI 02960/A (0.402 to 0.432 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 42 to 95 (BBCH 42: 20% of total final tuber mass reached; BBCH 95: 50% of the leaves brownish). The interval between the applications was 6 to 8 days.

All applications were made using ground-based equipment. All applications included a non-ionic surfactant (NIS) adjuvant at a rate of 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.7-3. Study use patterns are summarized in Table 6.3.2.7-4.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-3: Trial Site Conditions for BYI 02960 on Potatoes

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV178-10DA	██████, NY, 2010	Loam	4	6.5	9.7	8.82	54-78
RV179-10HA	██████ NY, 2010	Sand	3.4	6.7	8.8	9.06	52-82
RV180-10HA	██████, PA, 2010	Loam	4	6.2	9.2	9.25	61-95
RV181-10HA	██████, NJ, 2010	Loam	2.8	7.0	9.9	5.2	70-91
RV182-10HA	██████ NY, 2010	Silt Loam	2.8	6.6	5.6	11.06	41-72
RV183-10HA	██████ NY, 2010	Silt Loam	2.8	6.6	5.6	11.06	41-72
RV184-10HA	██████, NC, 2010	Loamy sand	1	5.9	3.5	7.64	63-94
RV185-10HA	██████, FL, 2010	Sand	0.9	7.0	2.4	8.34	69-94
RV186-10HA	██████, IA, 2010	Silt loam	3.9	6.2	16.5	5.11	66-86
RV187-10HA	██████, MO, 2010	Silt Loam	1.8	5.5	10.9	0.68	43-72
RV188-10HA	██████, IL, 2010	Silt Loam	2.3	5.9	11.9	5.32	69-90
RV189-10HA	██████, 2010	Sandy Loam	2.1	6.6	14.1	5.31	49-66
RV190-10HA	██████, Alberta, 2010	Loam	1	8	19	2.3	35-63
RV191-10HA	██████, ID, 2010	Fine Sandy Loam	2.8	7.3	20.1	0.44	47-80
RV192-10HA	██████, CA, 2010	Sandy Loam	0.4	5.7	0.2	0	64-96
RV193-10HA	██████, ID, 2010	Silt Loam	1.31	7.2	11.7	0.16	53-90
RV194-10HA	██████, ID, 2010	Loam	1.2	8.1	24.3	0.16	40-84
RV195-10HA	██████, MD, 2010	Sandy Loam	2.5	7.4	18.8	0.16	53-90
RV196-10HA	██████, WA, 2010	Loamy Sand	1.1	6.9	10.2	0.56	48-84
RV197-10HA	██████, WA, 2010	Loamy Sand	1.1	6.9	10.2	0.02	54-84

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-3 (cont'd): Trial Site Conditions for BYI 02960 on Potatoes

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV198-10HA	British Columbia, 2010	Sandy Loam	2.47	6.3	11.5	7.58	57-69
RV199-10HA	Manitoba, 2010	Loam	3.8	8.3	2.3	5.9	42-71
RV200-10HA	NY, 2010	Sandy Loam	0.3	7.2	25.5	8.82	54-78
RV201-10DA	KS, 2010	Silt Loam	1.8	7.8	16.8	7.72	68-92
RV202-10DA	ID, 2010	Sandy Loam	0.7	7.1	10.8	0.16	40-81
RV203-10DA	Alberta, 2010	Silt/Clay Loam	11.3	5.6	45.1	1.65	37-59

- a Abbreviations used: %OM = percent organic matter, CEC = cation exchange capacity.
- b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.
- c NA = Not Available

Table 6.3.2.7-4: Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region) and Year	End Use Product (Formulation)	Plot Name	Method	Application					Tank Mix Adjuvants
					Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV178-10DA	Region, 2010	BYI 02960 200 SL	TR10	Broadcast foliar	BBCH 91	30 (280)	0.185 (0.208)	NA ^a	0.369 (0.413)	Dyne-Amic, 0.25%v/v
					BBCH 93	30 (280)	0.183 (0.206)	8		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./ha (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Rate lb a.s./A (kg a.s./ha)		
RV179-10HA	NY Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 81	28 (300)	0.179 (0.201)	NA ^a	0.359 (0.402)	Dyne-Amic, 0.25%v/v	
					BBCH 91	28 (280)	0.179 (0.201)				
RV180-10HA	PA Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 81	20 (190)	0.189 (0.212)	NA ^a	0.372 (0.417)	Dyne-Amic, 0.25%v/v	
					BBCH 89	20 (190)	0.183 (0.205)				
RV181-10HA	NJ Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 85	22 (300)	0.197 (0.221)	NA ^a	0.385 (0.432)	Dyne-Amic, 0.25%v/v	
					BBCH 91	28 (260)	0.189 (0.211)				
RV182-10HA	NY Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 89	37 (340)	0.185 (0.207)	NA ^a	0.370 (0.414)	Dyne-Amic, 0.25%v/v	
					BBCH 91	37 (350)	0.185 (0.208)				
RV183-10HA	NY Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 89	36 (340)	0.183 (0.205)	NA ^a	0.369 (0.414)	Dyne-Amic, 0.25%v/v	
					BBCH 91	37 (350)	0.186 (0.209)				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./ha (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV184-10HA	Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 1	28 (260)	0.178 (0.200)	NA	0.363 (0.406)	Dyne-Amic, 0.25%v/v
					BBCH 74	28 (280)	0.184 (0.206)	NA		Dyne-Amic, 0.25% v/v
RV185-10HA	Region 3 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	30 (280)	0.183 (0.205)	NA ^a	0.367 (0.411)	Dyne-Amic, 0.25%v/v
					BBCH 93	30 (280)	0.184 (0.206)	7		Dyne-Amic, 0.25% v/v
RV186-10HA	Region 4 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 93	29 (180)	0.184 (0.206)	NAa	0.366 (0.410)	Dyne-Amic, 0.25%v/v
					BBCH 93	20 (190)	0.182 (0.204)	7		Dyne-Amic, 0.25% v/v
RV187-10HA	MO Region 5 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 45	20 (190)	0.182 (0.204)	NAa	0.363 (0.407)	Dyne-Amic, 0.25%v/v
					BBCH 45	20 (190)	0.182 (0.204)	7		Dyne-Amic, 0.25% v/v
RV188-10HA	Region 5 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 93	22 (210)	0.178 (0.200)	NAa	0.364 (0.408)	Dyne-Amic, 0.25%v/v
					BBCH 95	25 (240)	0.186 (0.209)	8		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./ha (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV189-10HA	Region 5 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 11	15 (20)	0.184 (0.206)	NA	0.368 (0.413)	Dyne-Amic, 0.25% v/v	
					BBCH 93	14 (30)	0.184 (0.207)			Dyne-Amic, 0.25% v/v	
V190-10HA	Region 7 2010, Alberta	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 49	14 (40)	0.189 (0.211)	NAa	0.369 (0.414)	Agsurf, 0.25% v/v	
					BBCH 49	14 (40)	0.181 (0.203)			Agsurf, 0.25% v/v	
RV191-10HA	Region 11 2010, ID	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	22 (21)	0.184 (0.206)	NAa	0.364 (0.408)	Dyne-Amic, 0.25% v/v	
					BBCH 93	22 (20)	0.180 (0.201)	7		Dyne-Amic, 0.25% v/v	
RV192-10HA	Region 10 2010, CA	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 85	39 (37)	0.180 (0.202)	NAa	0.360 (0.403)	Dyne-Amic, 0.25% v/v	
					BBCH 91	39 (37)	0.180 (0.201)	7		Dyne-Amic, 0.25% v/v	
RV193-10HA	Region 11 2010, ID	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	30 (28)	0.184 (0.206)	NAa	0.372 (0.417)	Dyne-Amic, 0.25% v/v	
					BBCH 91	31 (29)	0.189 (0.211)	6		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./ha (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV194-10HA	██████ ID Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 35	17 (160)	0.186 (0.209)	7	0.375 (0.421)	Dyne-Amic, 0.25%v/v
					BBCH 95	17 (160)	0.189 (0.212)			Dyne-Amic, 0.25% v/v
RV195-10HA	██████ ID Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	20 (280)	0.184 (0.206)	7	0.369 (0.414)	Dyne-Amic, 0.25%v/v
					BBCH 95	20 (280)	0.185 (0.207)			Dyne-Amic, 0.25% v/v
RV196-10HA	██████ WA Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 48	15 (230)	0.182 (0.204)	7	0.368 (0.412)	Dyne-Amic, 0.25%v/v
					BBCH 48	25 (240)	0.186 (0.209)			Dyne-Amic, 0.25% v/v
RV197-10HA	██████ WA Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 47	20 (190)	0.185 (0.208)	7	0.367 (0.412)	Dyne-Amic, 0.25%v/v
					BBCH 48	20 (190)	0.182 (0.204)			Dyne-Amic, 0.25% v/v
RV194-10HA	██████ ID Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 93	17 (160)	0.186 (0.209)	8	0.375 (0.421)	Dyne-Amic, 0.25%v/v
					BBCH 95	17 (160)	0.189 (0.212)			Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate (lb a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate (lb a.s./ha)	Retreatment Interval (days)		
RV195-10HA	██████, ID Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 31	35 (280)	0.184 (0.206)	7	0.369 (0.414)	Dyne-Amic, 0.25% v/v
					BBCH 95	8 (280)	0.185 (0.207)			Dyne-Amic, 0.25% v/v
RV196-10HA	██████, WA Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 48	30 (230)	0.182 (0.204)	7	0.368 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 48	25 (240)	0.186 (0.209)			Dyne-Amic, 0.25% v/v
RV197-10HA	██████, WA Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 47	30 (190)	0.185 (0.208)	7	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 48	20 (190)	0.182 (0.204)			Dyne-Amic, 0.25% v/v
RV198-10HA	██████, British Columbia Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 42	22 (200)	0.190 (0.213)	7	0.374 (0.419)	Agral 90, 0.25% v/v
					BBCH 43	21 (200)	0.184 (0.206)			Agral 90, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Potatoes

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Active Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV199-10HA	Manitoba Region 14 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 95	17	0.186 (0.209)	7	0.375 (0.421)	Agsurf, 0.25% v/v
					BBCH 91	16	0.189 (0.212)	7		Agsurf, 0.25% v/v
RV200-10HA	NY Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	21	0.183 (0.205)	NA ^a	0.366 (0.410)	Dyne-Amic, 0.25%v/v
					BBCH 93	30	0.183 (0.205)	8		Dyne-Amic, 0.25% v/v
RV201-10DA	KS Region 1 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 91	16	0.187 (0.209)	NA ^a	0.375 (0.420)	Dyne-Amic, 0.25%v/v
					BBCH 93	16	0.188 (0.211)	7		Dyne-Amic, 0.25% v/v
RV202-10DA	ND Region 11 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 47	12	0.183 (0.205)	NA ^a	0.366 (0.411)	Dyne-Amic, 0.25%v/v
					BBCH 91	12	0.184 (0.206)	7		Dyne-Amic, 0.25% v/v
RV203-10DA	Alberta Region 14 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 49	11	0.186 (0.209)	NA ^a	0.371 (0.416)	Agral 90, 0.25% v/v
					BBCH 49	11	0.184 (0.207)	7		Agral 90, 0.25% v/v

a NA = Not applicable.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Duplicate composite samples of potato tubers were collected at the intended pre-harvest interval (PHI) of 7 days. The actual samplings ranged from 6 to 8-days. In four decline trials, duplicate composite potato tuber samples were collected from the treated plots 0, 3, 7, 13 to 14, and 19 to 21 days after the last treatment. Single composite samples of potato tuber were collected from the control plots on the same day the target 7-day samples were collected from the treated plots.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20%. (Table 6.3.2.7-5)

Table 6.3.2.7-5: Summary of Recoveries of BYI 02960 from Potato

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Potato Tuber	BYI 02960	0.01	14	112, 97, 72, 97, 76, 78, 83, 85, 78, 103, 78, 120, 72, 97	88	15
		0.2	3	102, 89, 86	92	9
	DFA	0.05	14	82, 80, 72, 94, 69, 73, 66, 90, 110, 95, 109, 107, 102, 96	89	15
		0.2	3	90, 81, 87	86	5
	DFEAF	0.01	14	92, 95, 101, 109, 110, 100, 100, 92, 103, 77, 113, 112, 96, 100	100	10
		0.2	3	81, 95, 103	93	11

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in a representative crop of the respective crop commodity (high starch content) during frozen storage for at least 18 months (557 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 378 days. A summary of the storage conditions are shown in the Table 6.3.2.7-6.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.2-6. Summary of Storage Conditions for Potatoes

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Potato Tuber	< -20	9 (318)	18 (557)
DFEAF	Potato Tuber	< -20	9 (318)	18 (557)
DFA	Potato Tuber	< -20	9 (318)	18 (557)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Pyxent. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A. [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARXP046, amended version including 18-month data (KIIA 6.1.1/01)

The total BYI 02960 residue data for potato tubers following foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.7-7

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-7: Total BYI 02960 Residue Data from Potato Tubers after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% DM Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAER Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV178-10DA	[REDACTED] NY, Region 1, 2010	TRTD	Superior	Tuber	0.369 (0.413)	18	0	<0.010 0.011	<0.050 0.050	<0.010 0.012	<0.070 0.073
							3	<0.010 0.015	<0.050 0.050	<0.010 0.010	<0.070 0.073
							18	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
							19	<0.010 0.011	<0.050 0.050	<0.010 0.010	<0.070 0.071
							20	0.011 0.012	<0.050 0.050	<0.010 0.010	0.072 0.072
RV179-10HA	[REDACTED] NY, Region 1, 2010	TRTD	Carola	Tuber	0.369 (0.402)	28	6	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
RV180-10HA	[REDACTED] PA, Region 1, 2010	TRTD	Dark Red M [REDACTED]	Tuber	0.372 (0.417)	22	8	<0.010 0.010	0.087 0.085	<0.010 0.010	0.11 0.10
RV181-10HA	[REDACTED] NJ, Region 1, 2010	TRTD	Dark Red M [REDACTED]	Tuber	0.385 (0.432)	14	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
RV182-10HA	[REDACTED] NY, Region 1, 2010	TRTD	NorDonna	Tuber	0.370 (0.414)	23	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-7 (cont'd): Total BYI 02960 Residue Data from Potato Tubers after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% DM Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAER Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV183-10HA	NY, Region 1, 2010	TRTD	NY-129	Tuber	0.369 (0.414)	17	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV184-10HA	NC, Region 2, 2010	TRTD	Snowden	Tuber	0.363 (0.406)	20	7	<0.010 <0.010	0.083 0.057	<0.010 <0.010	0.10 0.07 Avg: 0.090
RV185-10HA	FL, Region 3, 2010	TRTD	Kennebec	Tuber	0.367 (0.411)	13	7	0.021 0.018	0.050 0.050	<0.010 <0.010	0.081 0.078 Avg: 0.079
RV186-10HA	IA, Region 5, 2010	TRTD	Kennebec	Tuber	0.366 (0.410)	13	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV187-10HA	MO, Region 5, 2010	TRTD	Kennebec	Tuber	0.363 (0.407)	25	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV188-10HA	IL, Region 5, 2010	TRTD	Kennebec	Tuber	0.364 (0.408)	16	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV189-10HA	Region 5, 2010	TRTD	Russett burbank	Tuber	0.368 (0.413)	23	7	<0.010 0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: 0.070
RV190-10HA	Region 7, 2010	TRTD	Russett burbank	Tuber	0.369 (0.414)	23	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV191-10HA	Region 11, 2010	TRTD	Ranger Russet	Tuber	0.364 (0.408)	29	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-7 (cont'd): Total BYI 02960 Residue Data from Potato Tubers after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% DM Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAER Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV192-10HA	██████, CA, Region 10, 2010	TRTD	Red La Soda	Tuber	0.360 (0.403)	18	7	<0.010 0.034	<0.050 <0.050	<0.010 0.010	<0.070 0.094 Avg: 0.082
RV193-10HA	██████, ID, Region 11, 2010	TRTD	Dark Red N██████	Tuber	0.332 (0.417)	19	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070 Avg: 0.070
RV194-10HA	██████, ID, Region 11, 2010	TRTD	Russet Burbank	Tuber	0.375 (0.421)	19	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070 Avg: 0.070
RV195-10HA	██████, ID, Region 11, 2010	TRTD	Russet Norkotah	Tuber	0.369 (0.414)	19	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070 Avg: 0.070
RV196-10HA	██████, CA, Region 11, 2010	TRTD	██████	Tuber	0.368 (0.412)	31	7	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070 Avg: 0.070
RV197-10HA	██████, WA, Region 11, 2010	TRTD	Norkotah	Tuber	0.367 (0.412)	34	7	0.057 0.016	<0.050 0.016	<0.010 0.010	0.12 ° 0.076 Avg: 0.097
RV198-10HA	██████, British Columbia, Region 12, 2010	TRTD	Russet Burbank	Tuber	0.374 (0.419)	23	7	0.046 0.027	<0.050 0.027	<0.010 0.010	0.11 0.087 Avg: 0.097
RV199-10HA	██████, Manitoba, Region 14, 2010	TRTD	N██████	Tuber	0.375 (0.421)	29	7	<0.010 0.010	<0.050 0.010	<0.010 0.010	<0.070 0.070 Avg: 0.070
RV200-10HA	██████, NY, Region 1, 2010	TRTD	Reba	Tuber	0.366 (0.410)	21	7	<0.010 0.014	<0.050 0.014	<0.010 0.010	<0.070 0.074 Avg: 0.072

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-7 (cont'd): Total BYI 02960 Residue Data from Potato Tubers after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% DM Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAER Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV201-10DA	██████, KS, Region 5, 2010	TRTD	N██████ Red	Tuber	0.375 (0.520)	28	0	0.046 0.021	<0.050 <0.050	<0.010 0.010	0.10 0.081
							Avg: 0.091				
							15	0.012 0.016	<0.050 0.050	<0.010 0.010	0.072 0.070
							Avg: 0.074				
							18	0.008 0.019	<0.050 0.050	<0.010 0.010	0.078 0.079
							Avg: 0.079				
5	0.029 0.010	<0.050 0.050	<0.010 0.010	0.089 <0.070							
Avg: 0.079											
4	0.016 0.010	<0.050 0.050	<0.010 0.010	0.076 <0.070							
Avg: 0.073											
RV202-10DA	██████, ID, Region 11, 2010	TRTD	Ranger Russet	Tuber	0.366 (0.412)	23	0	0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
							Avg: 0.070				
							28	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
							Avg: 0.070				
							24	<0.010 0.010	<0.050 0.050	<0.010 0.010	<0.070 0.070
							Avg: 0.070				
23	<0.010 0.010	0.073 0.102	<0.010 0.010	0.093 0.12							
Avg: 0.11											
25	<0.010 0.010	<0.050 0.105	<0.010 0.010	<0.070 0.13							
Avg: 0.098											

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-7 (cont'd): Total BYI 02960 Residue Data from Potato Tubers after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% DM Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV203-10DA	Region 14, 2010	TRTD	Russet Nacota	Tuber	0.374 (0.916)	30	0	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070
							3	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	Avg: <0.070
							23	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	Avg: <0.070
							24	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	Avg: <0.070
							21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	Avg: <0.070

a Total BYI 02960 residue is the sum of BYI 02960, DFA and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

b Highest average field trial (HAFT) residue found in potato tubers.

c Maximum residue found in potato tubers.

TRTD = treated plot receiving two foliar spray applications

Conclusion

Twenty-six field trials were conducted to measure the magnitude of total BYI 02960 residues in/on potato tubers following two foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data are shown in Table 6.3.2.7-7.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-8: Summary of Residue Data for Total BYI 02960 from Potato Tubers

Commodity	Plot Name ¹	Total Appl. Rate lb a.s./A (kg a.s./ha)	PHI (days) ³	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean	Standard Deviation
Potato Tuber	TRTD	0.359 to 0.385 (0.402 to 0.432)	7	26	<0.070	0.12	0.13	0.11	0.070	0.075	0.012

1 TRTD = treated plot receiving two foliar spray application

2 HAFT = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

Total BYI 02960 residues were generally low in potatoes; the maximum residue detected at the PHI of 7 days was 0.12 mg/kg. The four decline trials indicated that the residues plateaued in three trials at a time interval of approximately 7 to 14 days. The overall highest total BYI 02960 residue was detected in a sample collected 21 days after the last application. The residue was slightly higher than the highest residue detected at the PHI however it was in the same range as the sample collected at the PHI. Therefore it was concluded that the residue data provided in this report are suitable for regulatory purposes.

Residue data from AUSTRALIA

BYI 02960 is to be registered in Australia for use as a foliar treatment in/on potato and sweet potato. The use pattern in Australia is summarized in Table 6.3.2.7-9.

A total of eight trials was conducted in potatoes/sweet potatoes. The studies are described below.

Table 6.3.2.7-9: Critical aspects of the use pattern for application of BYI 02960 200 SL to potatoes and sweet potatoes

Situation	Maximum no. of applications	Maximum application rate		Minimum Spray interval	WHP
		Per treatment	Per season		
Field	2	150 g a.s./ha	450 g a.s./ha	7 days	7 days

Residues trials supporting this use pattern are presented in 2 study reports.

Report	KIHA 6.3.2.7/02; [REDACTED]; 2011
Title	Amendment No. 1 - Determination of residues of BYI 02960 in potatoes and sweet potatoes following two or three applications of BYI 02960 200 SL at rates of 100, 150 or 200 g a.s./ha seven days apart
Report No & Document No	BCS-0352.02 including sites C516, C517, C518 and C519, dated September 23, 2011 M-415292-02-1
Guidelines	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes



Report	KHIA 6.3.2.7/03; [REDACTED]; 2012
Title	Amendment no. 1 - Determination of residues of BYI 02960 in potatoes and sweet potatoes following two or three applications of BYI 02960 200 SL at rates of 100, 150 or 200 g a.i./ha seven days apart
Report No & Document No	BCS-0358.02 including sites C538, C539, C632 and C541, dated February 27, 2012 M-426841-02-1
Guidelines	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes

Material and methods

Eight trials were conducted in Australia to measure the magnitude of residues of BYI 02960 and its metabolites following application of BYI 02960 200 SL to potato and sweet potato crops. These included 6 trials in potatoes and 2 trials in sweet potato. Trials were conducted over two seasons with 4 trials in 2010, and 4 trials in 2011.

Trials were conducted in the field for both potatoes and sweet potatoes. Treatments were applied by hand held boom sprayer applying spray volumes of 413-644 L/ha (potatoes) and 592-669 L/ha (sweet potatoes).

For potatoes and sweet potatoes, BYI 02960 200 SL was applied at target rates equivalent to 100 g a.s./ha (i.e. 0.67 x maximum proposed rate), 150 g a.s./ha (1.0 x proposed rate) and 200 g a.s./ha (1.34 x proposed rate) in all trials.

In the first year of trials (2010) for both potatoes and sweet potatoes application of each treatment was made either 2 or 3 times, at approximately 7 day intervals. Samples were collected at approximately 7, 10, 14 and 21 days after the second application, and at approximately 0, 1, 3, 7, 10, 14 days after the third application.

For the second year of trials (2011) for both potatoes and sweet potatoes application of each treatment was again made either 2 or 3 times, at approximately 7 day intervals, however it was necessary to extend the sampling times. For both potatoes and sweet potatoes samples were collected at approximately 7, 14, 21, 28 and 35 days after the second application and at 0, 7, 14, 21, 28 and 35 days after the third application. Trial details including location, year, application rate, application timing, application no. and sampling times are summarised in Table 6.3.2.7-10 for potatoes and 6.3.2.7-11 for sweet potatoes.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-10: Trial details for residue trials with BYI 02960 200 SL in potatoes

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing	
		Rate		Application Timing		No. of Applications (Timing of applications)
		Product (mL/ha)	Active Substance (g a.s./ha)			
BCS-0352 C516 [redacted] 2010 KIIA 6.3.2.7/01	Potatoes	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	7 DAAB
	Russet	750	150			10 DAAB
	Burbank	1000	200			14 DAAB
	Field					21 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 14 DAAC
BCS-0352 C517 [redacted] WA 2010 KIIA 6.3.2.7/01	Potatoes	500	100	A=14 DBFH B=6 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	6 DAAB
	Nadine	750	150			9 DAAB
		1000	200			13 DAAB
	Field					22 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 11 DAAC 16 DAAC
BCS-0352 C518 [redacted] 2010 KIIA 6.3.2.7/01	Potatoes	500	100	A=14 DBFH B=8 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	8 DAAB
	Sebago	750	150			11 DAAB
		1000	200			15 DAAB
	Field					22 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 11 DAAC 14 DAAC
BCS-0358 C539 [redacted] WA 2011 KIIA 6.3.2.7/02	Potatoes	500	100	A=15 DBFH B=6 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	6 DAAB
	Nadine	750	150			13 DAAB
		1000	200			20 DAAB
	Field					27 DAAB 34 DAAB 0 DAAC 7 DAAC 14 DAAC 21 DAAC 28 DAAC 35 DAAC

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-10 (cont'd): Trial details for residue trials with BYI 02960 200 SL in potatoes

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application				Sampling Timing
		Rate		Application Timing	No. of Applications (Timing of applications)	
		Product (mL/ha)	Active Substance (g a.s./ha)			
BCS-0358 C632 [REDACTED] 2011 KIIA 6.3.2.7/02	Potatoes	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	7 DAAB
	Nicola	750	150			14 DAAB
	Field	1000	200			21 DAAB 28 DAAB 35 DAAB 0 DAAC 7 DAAC 14 DAAC 21 DAAC 28 DAAC 35 DAAC
BCS-0358 C541 [REDACTED] 2011 KIIA 6.3.2.7/02	Potatoes	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	7 DAAB
	Sebago	750	150			14 DAAB
	Field	1000	200			21 DAAB 6 DAAC 14 DAAC 23 DAAC

DBFH = days before first harvest
 DAAB = Days after application B of A and B
 DAAC = Days after application C of A, B, C

Table 6.3.2.7-11: Trial details for residue trials with BYI 02960 200 SL in sweet potatoes

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application				Sampling Timing
		Rate		Application Timing	No. of Applications (Timing of applications)	
		Product (mL/ha)	Active Substance (g a.s./ha)			
BCS-0352 C519 [REDACTED] 2010 KIIA 6.3.2.7/01	Sweet potatoes	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	2 (A and B) 3 (A, B and C)	7 DAAB
	Beaufort	750	150			10 DAAB
	Field	1000	200			14 DAAB 21 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 11 DAAC 14 DAAC

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Table 6.3.2.7-11 (cont'd): Trial details for residue trials with BYI 02960 200 SL in sweet potatoes

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing
		Rate		Application Timing	
		Product (mL/ha)	Active Substance (g a.s/ha)		
BCS-0358 C538 2011 KIIA 6.3.2.7/02	Sweet potatoes Beauregard Field	500	100	A=14 DBFH	2 (A and B)
		750	150	B=7 DBFH	3 (A, B and C)
		1000	200	C=0 DBFH	
					7 DAAB
					14 DAAB
					21 DAAB
					28 DAAB
			35 DAAB		
			0 DAAC		
			7 DAAC		
			14 DAAC		
			21 DAAC		
			28 DAAC		
			35 DAAC		

DBFH = days before first harvest

DAAB = Days after application B of A and B

DAAC = Days after application C of A, B and C

The analytical test method ATM-0048 "Determination of residues of BYI 02960 and its metabolites 6-chloronicotinic acid, difluoroethyl-amino-furone and difluoroacetic acid in or on plant material by LC MS/MS" was used to analyse the test samples.

Residues of BYI 02960 and the metabolites 6-CNA, DFEAF and DFA in test samples were extracted with 20:80 water:acetonitrile with 0.2 mL/L formic acid. The extract was filtered using a 0.45 µm syringe filter. For the analysis of DFA an aliquot was taken at this point and diluted with acetonitrile. For the analysis of BYI 02960, 6-CNA and DFEAF an aliquot of the extract was reduced to its aqueous remainder and then partitioned against ethyl acetate on a Chem Elut column. The ethyl acetate was then reduced to dryness and the sample was reconstituted in acetonitrile.

Chromatography was performed by high performance liquid chromatography coupled to a triple quadrupole mass spectrometer using MRM for analyte detection. Quantitation was achieved with matrix matched analytical standards for all analytes and stable labelled internal standards for 6-CNA and DFEAF.

By this method the single analytes (BYI 02960 and its metabolites 6-CNA, DFEAF and DFA) were determined. The limit of quantitation (LOQ) of BYI 02960, DFEAF and 6-CNA was 0.01 mg/kg for each component and 0.02 mg/kg for DFA. The total residue of BYI 02960 was calculated by summing up the values determined for parent compound BYI 02960, DFEAF and DFA, expressed as parent equivalent. Metabolite 6-CNA is not included in the proposed residue definition for risk assessment and was measured for additional information, only. The total LOQ for the three analytes of interest was 0.088 mg/kg (rounded to 0.09 mg/kg) when expressed as BYI 02960. Considerin all four analytes, the total LOQ expressed as BYI 02960 was 0.1061 mg/kg (rounded to 0.11 mg/kg).

A full description of the method can be found as an appendix to each of the study reports cited above.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The analytical test method was validated by analysing fortified samples concurrently with the analysis of the test samples. Mean concurrent recoveries for BYI02960 and its metabolites at fortification levels of 0.01 (0.02 DFA) and 1.0 mg/kg of each analyte are shown in Table 6.3.2.7-12 and 6.3.2.7-13 below.

Table 6.3.2.7-12: Recovery results for BYI02960 and its metabolites in study BCS-0350

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (Percent)	Recovery Means and RSD (Percent)
BYI 02960	Potatoes	0.01	81, 81	81 ± 0
		1.0	81, 87, 88	85 ± 5
6-CNA		0.01	108, 89, 83	93 ± 14
		1.0	78, 79	78 ± 0
DFEAF		0.01	76, 89	84 ± 9
		1.0	72, 82, 86	80 ± 4
DFA		0.02	88, 91, 104	94 ± 9
		1.0	111, 111, 112	112 ± 0
BYI 02960	Sweet potatoes	0.01	78, 83, 75	75 ± 3
		1.0	79, 83	81 ± 3
6-CNA		0.01	86, 86, 110	94 ± 15
		1.0	84, 82, 71	79 ± 9
DFEAF		0.01	92, 91, 90	92 ± 0
		1.0	81, 88, 70	80 ± 11
DFA		0.02	85, 82, 94	87 ± 7
		1.0	105, 105, 111	107 ± 3

Table 6.3.2.7-13: Recovery results for BYI02960 and its metabolites in study BCS-0358

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (Percent)	Recovery Means and RSD (Percent)
BYI 02960	Potatoes	0.01	71, 78, 78, 90, 74	78 ± 9
		1.0	78, 79, 82, 85, 92	83 ± 7
6-CNA		0.01	75, 89, 80, 107, 96	89 ± 14
		1.0	81, 74, 73, 98, 115	88 ± 20
DFEAF		0.01	82, 83, 93, 83, 71, 76	81 ± 9
		1.0	81, 84, 84, 81, 96, 92	87 ± 7
DFA		0.02	77, 84, 114, 118, 115	101 ± 19
		1.0	105, 105, 98, 100, 97, 97	100 ± 3

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-13 (cont'd): Recovery results for BYI02960 and its metabolites in study BCS-0358

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (Percent)	Recovery Means and RSD (Percent)
BYI 02960	Sweet potatoes	0.01	92, 91, 100	94 ± 5
		1.0	88, 95, 93	92 ± 4
6-CNA		0.01	98, 117, 103	106 ± 9
		1.0	78, 74, 70	74 ± 5
DFEAF		0.01	89, 93, 96	93 ± 4
		1.0	89, 93, 89	90 ± 3
DFA	0.02	93, 85	89 ± 6	
	1.0	85, 90, 103	93 ± 10	

Findings

Residues determined for BYI02960 and its metabolites in potatoes and sweet potatoes are given in Table 6.3.2.7-14 and Table 6.3.2.7-15 respectively.

Only data relating to the target rate of 150 g a.s./ha, and one result (6 or 8 DAAB) from the treatments receiving just two applications is presented here. Complete data, including results following applications at 100 and 200 g a.i./ha can be found in the study report.

Results for BYI02960 and the three metabolites, 6-CNA, DFEAF and DFA, along with the total residue expressed as total BYI02960 parent equivalent are shown in the tables below. Since the proposed residue definition excludes 6-CNA, the total residue excluding 6-CNA is also shown.

Table 6.3.2.7-14: Results of residue trials conducted in potatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Study no. Trial no. Location Year Situation	DAAT (days)	Concentrations (mg/kg)					
		Detected as BYI 02960	Detected as 6-CNA	Detected as DFEAF	Detected as DFA	Total expressed as BYI 02960 Equivalent	Total expressed as BYI 02960 Equivalent (excluding 6-CNA)
BCS-0352 C516 [redacted] Tas 2010 Field	7 DAAB	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	0 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	1 DAAC	0.01	0.01	<0.01	<0.02	<0.11	<0.09
	3 DAAC	<0.01	0.01	<0.01	<0.02	<0.11	<0.09
	7 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	14 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
BCS-0352 C517 [redacted] WA 2010 Field	6 DAAB	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	0 DAAC	0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	1 DAAC	0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	3 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	7 DAAC	<0.01	<0.01	<0.01	0.03	<0.11	<0.09
	11 DAAC	<0.01	<0.01	<0.01	0.02	<0.11	<0.09
	16 DAAC	<0.01	<0.01	<0.01	0.05	0.20	0.16

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7- 14 (cont'd): Results of residue trials conducted in potatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					
		Detected as BYI 02960	Detected as 6-CNA	Detected as DFEAF	Detected as DFA	Total expressed as BYI 02960 Equivalent	Total expressed as BYI 02960 Equivalent (excluding 6-CNA)
BCS-0352 C518 Vic 2010 Field	8 DAAB	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	0 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	1 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	3 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	7 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	11 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	14 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
BCS-0358 C539 2011 Field	6 DAAB	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	0 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	7 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	14 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	21 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	28 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
BCS-0358 C632 Tas 2011 Field	7 DAAB	<0.01	0.01	<0.01	0.02	0.11	<0.09
	0 DAAC	<0.01	0.01	<0.01	0.03	0.11	0.09
	7 DAAC	<0.01	0.02	<0.01	0.04	0.15	0.11
	9 DAAC	<0.01	0.03	<0.01	0.05	0.20	0.15
	21 DAAC	<0.01	0.02	<0.01	0.04	0.20	0.16
	28 DAAC	<0.01	0.02	<0.01	0.04	0.16	0.12
	35 DAAC	<0.01	0.01	<0.01	0.04	0.15	0.13
BCS-0358 C541 2011 Field	0 DAAC	<0.01	0.01	<0.01	<0.02	<0.11	<0.09
	6 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	7 DAAC	<0.01	<0.01	<0.01	<0.02	<0.11	<0.09
	23 DAAC	<0.01	0.01	<0.01	<0.02	<0.11	<0.09

DALT = days after last treatment

DAAB = Days After Application B of applications A and B

DAAC = Days After Application C of applications A, B and C

Note:

The above results might not match the raw data because of rounding adjustments.

All values for BYI 02960, 6-CNA and DFEAF below the LOQ of 0.01 mg/kg are expressed as <0.01 mg/kg.

All values for DFA below the LOQ of 0.02 mg/kg are expressed as <0.02 mg/kg.

All values for the BYI 02960 parent equivalent below the LOQ of 0.1061 mg/kg are expressed as <0.11 mg/kg.

All values for the BYI 02960 parent equivalent excluding 6-CNA below the LOQ of 0.088 mg/kg are expressed as <0.09 mg/kg.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-15: Results of residue trials conducted in sweet potatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					
		Detected as BYI 02960	Detected as 6-CNA	Detected as DFEAF	Detected as DFA	Total expressed as BYI 02960 Equivalent	Total expressed as BYI 02960 Equivalent (excluding 6-CNA)
BCS-0352 C519 [redacted] 2010 Field	7 DAAB	<0.01	0.09	<0.01	0.03	0.25	0.09
	0 DAAC	<0.01	0.05	<0.01	0.02	0.15	0.05
	1 DAAC	<0.01	0.07	<0.01	0.03	0.21	0.08
	3 DAAC	<0.01	0.05	<0.01	0.03	0.17	0.08
	7 DAAC	<0.01	0.07	<0.01	0.03	0.23	0.11
	9 DAAC	<0.01	0.07	<0.01	0.05	0.28	0.15
	14 DAAC	<0.01	0.07	<0.01	0.05	0.32	0.19
BCS-0358 C538 [redacted] 2011 Field	7 DAAB	0.09	0.01	<0.01	0.03	0.15	0.09
	0 DAAC	<0.01	0.07	<0.01	0.08	0.43	0.23
	7 DAAC	<0.01	0.11	<0.01	0.05	0.40	0.20
	14 DAAC	0.09	0.08	<0.01	0.05	0.31	0.16
	21 DAAC	0.01	0.06	<0.01	0.07	0.33	0.22
	28 DAAC	<0.01	0.09	<0.01	0.11	0.54	0.38
	35 DAAC	<0.01	0.08	<0.01	0.20	0.36	0.61

DALT = days after last treatment

DAAB = Days After Application B of applications A and B

DAAC = Days After Application C of applications A, B and C

Note:

The above results might not match the raw data because of rounding adjustments.

All values for BYI 02960, 6-CNA and DFEAF below the LOQ of 0.01 mg/kg are expressed as <0.01 mg/kg.

All values for DFA below the LOQ of 0.02 mg/kg are expressed as <0.02 mg/kg.

All values for the BYI 02960 parent equivalent below the LOQ of 0.1061 mg/kg are expressed as <0.11 mg/kg.

All values for the BYI 02960 parent equivalent excluding 6-CNA below the LOQ of 0.088 mg/kg are expressed as <0.09 mg/kg.

Results from all trials in potato and sweet potato are summarised in Table 6.3.2.7-16. This shows the highest residue (expressed as total BYI 02960 parent equivalent for the sum of BYI02960, DFEAF and DFA, i.e. excluding 6-CNA) from each site, and indicates the sampling time (days after last application) when this occurred.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.7-16: Summary of results of residue trials conducted in potatoes and sweet potatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Crop (proposed WHP)	Situation	Trial no.	Final sampling timing DALT	Sampling timing where highest residue recorded DALT	Maximum residue at or beyond proposed WHP* (mg/kg)
Potato (7 days)	Field	C516	14	7	<0.09
	Field	C517	14	14	0.16**
	Field	C518	14	7	<0.09
	Field	C539	35	7	<0.09
	Field	C632	35	7	0.16
	Field	C541	23	6	<0.09
Sweet potato (7 days)	Field	C519	14	14	0.19
	Field	C538	35	35	0.61

DALT = Days after last treatment

* Maximum residue concentration expressed as total BYI 02960 parent equivalent (BYI02960, DFEAF and DPA i.e. excluding 6-CNA)

** Site C517 had product applied at late senescence rather than during tuber formation, as was the case for all other sites.

Conclusion

Six field trials were conducted to measure the magnitude of total BYI 02960 residues in/on potato tubers following three foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data are shown in Table 6.3.2.7-17.

Table 6.3.2.7-17: Summary of Residue Data for Total BYI 02960 from Potato Tubers

Commodity	Plot Name ¹	Total Appl. Rate kg a.s./ha	PHI (days) ³	Total BYI 02960 Residue Levels (ppm)						
				n	Min at PHI	Max at PHI	Max after PHI	Median ³	Mean ³	Standard Deviation
Potato Tuber	TRTD	0.447 to 0.457	7	6	<0.09	0.11	0.16 (21) ⁴	<0.09	0.093	0.008
Sweet Potato Tuber	TRTD	0.452 to 0.454	7	2	0.11	0.20	0.61 (35) ⁴	---	---	---

1 TRTD = treated plot receiving three foliar spray application

2 HAFI = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

In five of the six decline trials BYI 02960 residues were below the LOQ in potato tubers at the PHI of 7 days, only one trial showed residues at the PHI (0.11 mg/kg). However, two trials showed maximum total residues after the PHI, both accounting for 0.16 mg/kg, either at day 14 or day 21. Additional sampling intervals in one trial (days 28 and 35) indicated that the residues plateaued after 21 days, both levels were lower than the one detected at day 21. Therefore it can be concluded that the total residue levels will not further increase with the time.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Total BYI 02960 residues in sweet potatoes were significantly higher and did not reach the maximum slightly after the PHI. Residues up to 0.61 mg/kg were detected at the last sampling event (35 days after the last application) indicating that the residue plateau was still not reached.

On the basis of the available residue data, it was concluded that the residue behaviour of BYI 02960 is different for potatoes and sweet potatoes. Whereas the potato results indicated that the residues plateaued at a maximum of approx. 0.16 mg/kg within 7 to 14 days, no plateau could be established for sweet potatoes.

Overall Conclusion – Potatoes

Supervised residue trials in potatoes were conducted in the US and in Australia to achieve a national registration in the NAFTA countries and in Australia.

The NAFTA countries support a use with two foliar spray applications of BYI 02960 200 SL with a total application rate of 410 g a.s./ha. Twenty-six trials were conducted according to the GAP to measure the magnitude of BYI 02960 residues in/on potato tubers (Representative test system for NAFTA Crop Group 1C; Tuberous and Corn Vegetables). The intended pre-harvest interval is 7 days.

Australia supports a use with three foliar spray applications of BYI 02960 200 SL with a total application rate of 450 g a.s./ha and a pre-harvest interval (withholding period) of also 7 days. Six trials were conducted in potatoes and two in sweet potatoes.

A summary of the use patterns tested and the corresponding residue levels is shown in Table 6.3.2.7-18.

Table 6.3.2.7-18: Summary of Residue Data for Total BYI 02960 from Potatoes

Crop	Formulation	Use pattern	Method	PHI	No. Application	No. Trials	Total Residue of BYI 02960 (mg a.s./kg) at PHI	Peak residue (mg a.s./kg)	Day of peak residue
NAFTA									
Potato	SL 200	2 x 0.205 kg a.s./ha	Foliar spray	7	2	26	<0.07-0.12	0.13	21
Australia									
Potato	SL 200	3 x 0.150 kg a.s./ha	Foliar spray	7	3	4	<0.09-0.11	0.16	21
Sweet potato						2	0.11-0.20	0.61	35

Total BYI 02960 residues in potato tubers were comparable in the NAFTA and the Australian trials with slightly higher residues in potato tubers harvested in Australia after applying the slightly higher

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

total application rate of 450 g a.s./ha. NAFTA and Australian decline trials suggest that the residues leveled off by the end of the sampling interval for potatoes.

Sweet potatoes showed generally higher residues than potatoes and did not reach a residue plateau around the PHI. Residues up to 0.61 mg/kg were detected at the last sampling event, i.e. 35 days after the last application. The limited number of residue trials does not allow further conclusions.

Thus the data clearly shows that the residue behaviour in potatoes and sweet potatoes is different. Potatoes show a conclusive residue behaviour which allows the calculation of a maximum residue value on the basis of the NAFTA and Australian results, whereas this is not the case for sweet potatoes.

IIA 6.3.2.8 Fruiting vegetables - solanacea
Residue data from NORTH AMERICA (Crop Group 8)

BYI 02960 is to be registered in USA and Canada for use as a foliar or soil treatment in/on fruiting vegetables (Crop Group 8). The use patterns in North America are summarized in Table 6.3.2.8-1.

A total of thirty-three trials were conducted in fruiting vegetables. The studies are described below.

Table 6.3.2.8-1 Target Use Patterns for the Application of BYI 02960 on Fruiting Vegetables (Crop Group 8) in North America

Application Type	Test Substance	No. of Apps	Target Rate/Application				Target App. Interval (Days)	Target PHI (Days)	Spray Volume		
			Formulated Product (FP)		Active Substance (a.s.)				GPA	LPHA	
			mL/A	fl oz/A	Name of a.s.	lb a.s./A					kg a.s./ha
Foliar	BYI 02960 200 SL	1	1025	14.0	BYI 02960	0.183	0.205	NA ¹	NA ¹	10-30	94-282
		2	1025	14.0	BYI 02960	0.183	0.205	7	1	10-30	94-282
Soil	BYI 02960 200 SL	1	2050	28.0	BYI 02960	0.366	0.410	NA ¹	45	NA ¹	NA ¹

1 NA = Not applicable

GPA = gallons per acre

LPHA = liter per hectare

Report:	KIIA 6.3.2.8/01: [REDACTED] and K. [REDACTED]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in/on Fruiting Vegetables (Crop Group 8)
Report No. / Document No	RARC Y022 - dated June 22, 2012 M433126-01-1
Guidelines:	USA: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Thirty-three field trials were conducted to measure the magnitude of BYI 02960 residues in/on tomato (19 trials), bell pepper (10 trials) and chili pepper (4 trials) as representative test system for the NAFTA Crop Group 8; Fruiting Vegetables. The GAPs comprise either two broadcast foliar spray applications or one soil drench application of BYI 02960 200 SL. The number and location of field trials conform to the guidance given by the EPA with exceptions as noted in Tables 6.3.2.8-2, 6.3.2.8-3, and 6.3.2.8-4. BYI 02960 200 SL is a soluble concentrate formulation containing 200g BYI 02960/L.

Table 6.3.2.8-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Tomato

NAFTA Growing Region	Submitted ^a	Requested
1		1
1A		
2		
3		2
4		
5		8
5A		
5B		
6		
7A		
9		
10	7	7
11		
12		
13		
14		
Total	19	19

a Eight of the 19 trials were decline trials



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-3: Trial Numbers and Geographical Locations for BYI 02960 in/on Bell Pepper

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2	1	
3	1	1
4		
5		
5A		
5B		
6	1	1
7		
7A		
8		
9		
10		2
11		
12		
13		
14		
Total	10	10

a Eight of the ten trials were decline trials

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-4: Trial Numbers and Geographical Locations for BYI 02960 in/on Non-Bell (Chili) Pepper

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2		
3		
4		
5		
5A		
5B		
6		
7		
7A		
8		
9		
10		
11		
12		
13		
14		
Total	4	3

a Two of the four trials were declined.

Material and Methods

Two different use patterns using the same total application rate of BYI 02960 were tested: either two foliar applications (TRTD plots) or a single soil drench (TRTDS plots).

For the TRTDF plots, individual application rates ranged from 0.176 to 0.189 lb BYI 02960/A/application (0.197 to 0.212 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.356 to 0.376 lb BYI 02960/A (0.399 to 0.422 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 72 to 89 (BBCH 72: 2nd fruit cluster: first fruit has reached typical size; BBCH 89: fully ripe: fruits have typical fully ripe color) and the interval between the applications ranged from 5 to 7 days.

For the TRTDS plots, application rates ranged from 0.351 to 0.374 lb BYI 02960/A/application (0.394 to 0.419 kg BYI 02960/ha/application). All applications were made at growth stages ranging from BBCH 29 to 86 (BBCH 29: 9 or more apical primary side shoots visible; BBCH 86: 60% of fruits show typical fully ripe color).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

All applications were made using ground-based equipment. Each trial used NIS (0.2%), MSO (0.25%), or COC (1.0%) as an adjuvant for the application of the test substance.

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.8-5. Study use patterns are summarized in Table 6.3.2.8-6.

Table 6.3.2.8-5: Trial Site Conditions for BYI 02960 in/on Fruiting Vegetables

Study Location (City, State)	Trial Number	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
[REDACTED] NY	RV098-11HA	Silt Loam	2.8	6.6	5.6	2.00	55-85
[REDACTED] GA	RV099-11HA	Sandy Clay	1.2	6.5	8	5.07	70-93
[REDACTED] FL	RV100-11HA	Sand	1.5	5.1	<1%	5.92	49-91
[REDACTED] FL	RV101-11HA	Sand	0.8	6.2	3	0.00	63-92
[REDACTED] IA	RV102-11HA	Silty Clay Loam	2.8	6.6	10.8	5.66	58-92
[REDACTED]	RV103-11HA	Loam	2.4	7.1	10.3	7.99	52-86
[REDACTED] Manitoba	RV104-11HA	Sand	3.5	8.4	22.3	4.23	45-81
[REDACTED] IL	RV105-11DA	Silt Loam	2.3	5.8	10.7	12.00	64-92
[REDACTED] KS	RV106-11HA	Silty Clay Loam	3	6.6	18.4	4.49	68-96
[REDACTED] WI	RV107-11HA	Silt Loam	2.7	5.3	6	9.06	61-88
[REDACTED] IL	RV108-11DA	Clay Silty Loam	3.1	7.3	12.6	13.20	45-93
[REDACTED]	RV109-11DA	Loam	3	7.3	11	12.34	51-82
[REDACTED] CA	RV110-11DA	Loam	3	6.8	19.4	0.00	59-95
[REDACTED] CA	RV111-11DA	Loamy Sand	0.55	6.3	4.9	0.03	59-96
[REDACTED] CA	RV112-11HA	Sandy Loam	1	6.3	34.5	0.05	52-94
[REDACTED] CA	RV113-11HA	Sandy Loam	0.8	7.6	6.8	0.28	49-92
[REDACTED] CA	RV114-11DA	Sandy Loam	0.73	5.7	8.9	2.07	58-96
[REDACTED] CA	RV115-11DA	Loamy Sand	0.83	7.3	7.3	1.05	54-94
[REDACTED] CA	RV116-11DA	Clay	2.6	6.3	25.2	1.21	57-95
[REDACTED] GA	RV117-11DA	Sand	0.93	5.9	4.1	7.86	47-85
[REDACTED] FL	RV118-11HA	Sand	1	5.1	<1%	5.92	49-91
[REDACTED] NE	RV119-11DA	Silt Loam	2.3	6.9	11	5.89	53-90
[REDACTED] IL	RV120-11DA	Silt Loam	2.3	5.8	10.7	12.00	64-92
[REDACTED]	RV121-11HA	Loam	3.3	7.3	11	5.54	57-82
[REDACTED] WI	RV122-11DA	Silt Loam	2.7	5.3	6	8.90	51-88
[REDACTED] Manitoba	RV123-11DA	Sand	3.5	8.4	22.3	4.43	54-81
[REDACTED] TX	RV124-11DA	Clay	2	8	40.4	4.63	58-104
[REDACTED] CA	RV125-11DA	Loamy Sand	0.83	7.3	7.3	1.05	54-94
[REDACTED] CA	RV126-11DA	Loamy Sand	0.55	6.3	4.9	0.03	59-96
[REDACTED] CA	RV127-11DA	Silty Clay Loam	2.8	6.6	17.8	5.66	50-92
[REDACTED] TX	RV128-11HA	Sandy Loam	0.5	8.1	16.3	3.08	48-99
[REDACTED] ID	RV129-11HA	Sandy loam	2.8	7.3	20.1	0.31	51-91
[REDACTED] CA	RV130-11DA	Loamy Sand	0.8	7.6	6.8	0.28	49-92

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6: Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV098-11HA	Region 1 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 82	234	0.283 (0.205)	NA ^a	0.266 (0.410)	Dyne-Amic @ 0.2% v/v
					BBCH 84	234	0.283 (0.205)	NA ^a	0.266 (0.410)	Dyne-Amic @ 0.2% v/v
RV098-11HA	Region 1 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 81	NA ^a	0.364 (0.416)	NA ^a	0.371 (0.416)	Dyne-Amic @ 0.2% v/v
RV099-11HA	Region 2 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 79	20	0.184 (0.206)	NA ^a	0.368 (0.413)	MSO @ 0.25% v/v
					BBCH 81	200	0.184 (0.206)	7	0.368 (0.413)	MSO @ 0.25% v/v
RV099-11HA	Region 2 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 81	NA ^a	0.364 (0.408)	NA ^a	0.364 (0.408)	MSO @ 0.25% v/v
RV100-11HA	Region 3 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 28	(259)	0.185 (0.207)	NA ^a	0.366 (0.410)	COC @ 1% v/v
BBCH 79					(272)	0.181 (0.203)	7	0.366 (0.410)	COC @ 1% v/v	
RV100-11HA	Region 3 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 56	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	COC 30ml to total mixture
RV101-11HA	Region 3 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 77	(280)	0.181 (0.203)	NA ^a	0.361 (0.404)	DyneAmic 0.2% v/v
					BBCH 81	(277)	0.179 (0.201)	7	0.361 (0.404)	DyneAmic 0.2% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)			
RV101-11HA	██████, FL Region 3 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 63	NA ^a	0.359 (0.403)	NA ^a	0.359 (0.403)	Destiny HC (MSO), 0.2%		
RV102-11HA	██████, IA Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 73	15 (141)	0.184 (0.206)	NA ^a	0.184 (0.413)	Destiny HC (MSO), 0.25% (v/v)		
					BBCH 84	20 (188)	0.184 (0.207)	6		Destiny HC (MSO), 0.25% (v/v)		
RV102-11HA	██████, IA Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 55	NA ^a	0.364 (0.408)	NA ^a	0.364 (0.408)	Destiny HC (MSO), 0.25% (v/v)		
RV103-11HA	██████, IA Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 84	21 (196)	0.179 (0.200)	NA ^a	0.365 (0.409)	Hastens COC, 1% v/v		
					BBCH 85	22 (205)	0.186 (0.209)	5		Hastens COC, 1% v/v		
RV103-11HA	██████, IA Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 69	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	Hastens COC, 1% v/v		
RV104-11HA	██████, Manitoba Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 81	11 (980)	0.180 (0.202)	NA ^a	0.363 (0.407)	Agral 90 at 0.2% v/v		
					BBCH 82	11 (100)	0.183 (0.205)	6		Agral 90 at 0.2% v/v		
RV104-11HA	██████, Manitoba Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 51-60	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	Agral 90 at 0.2% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)			
RV105-11DA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 79	255	0.286 (0.209)	NA ^a	0.273 (0.418)	MSO		
					BBCH 81	240	0.287 (0.209)	NA ^a	0.273 (0.418)	MSO		
RV105-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 83	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	MSO		
RV106-11HA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 72	15 (43)	0.181 (0.202)	NA ^a	0.367 (0.411)	COC (1.0% v/v)		
					BBCH 89	147	0.186 (0.209)	6	0.367 (0.411)	COC (1.0% v/v)		
RV106-11HA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 86	NA ^a	0.365 (0.409)	NA ^a	0.365 (0.409)	COC (1.0% v/v)		
RV107-11HA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 85	20 (191)	0.183 (0.205)	NA ^a	0.366 (0.410)	NIS @ 0.2% v/v		
					BBCH 89	21 (196)	0.183 (0.205)	7	0.366 (0.410)	NIS @ 0.2% v/v		
RV107-11HA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 61	NA ^a	0.367 (0.411)	NA ^a	0.367 (0.411)	NIS @ 0.2% v/v		
RV108-11D	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 82	26 (244)	0.182 (0.204)	NA ^a	0.367 (0.411)	MSO 0.25 % v/v		
					BBCH 83	27 (249)	0.185 (0.207)	7	0.367 (0.411)	MSO 0.25 % v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV108-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 65	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	MSO @ 0.25% v/v	
RV109-11DA	Region 5 2011	BYI 02960 200 SL	FRTDS	Foliar spray	BBCH 79	16 (146)	0.189 (0.212)	NA ^a	0.365 (0.409)	Assist (COC) @ 1% v/v	
					BBCH 79	15 (144)	0.176 (0.197)	6		Assist (COC) @ 1% v/v	
RV109-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 29	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	Assist (COC) @ 1% v/v	
RV110-11DA	Region 10 2011	BYI 02960 200 SL	FRTDS	Foliar spray	BBCH 88	20 (187)	0.183 (0.205)	NA ^a	0.369 (0.413)	R-11 / 0.2 % v/v	
					BBCH 89	20 (187)	0.185 (0.208)	7		R-11 / 0.2 % v/v	
RV110-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 63	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	R-11 / 0.2 % v/v	
RV111-11DA	Region 10 2011	BYI 02960 200 SL	FRTDS	Foliar spray	BBCH 87	20 (187)	0.183 (0.205)	NA ^a	0.365 (0.410)	Monterey MSO @ 0.25% v/v	
					BBCH 85	20 (186)	0.182 (0.204)	7		Monterey MSO	
RV111-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 71	NA ^a	0.357 (0.400)	NA ^a	0.357 (0.400)	Monterey MSO @ 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV112-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 89	285 (235)	0.285 (0.207)	NA ^a	0.368 (0.413)	COC @ 1.0%	
					BBCH 89	283 (233)	0.283 (0.205)	NA ^a			COC @ 1.0% v/v
RV112-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 84	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	COC @ 1.0% v/v	
RV113-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 88	28 (257)	0.187 (0.210)	NA ^a	0.368 (0.413)	NIS (Pro 90) @ 0.20% v/v	
					BBCH 89	281 (250)	0.281 (0.202)	6		NIS (Pro 90) @ 0.20% v/v	
RV113-11HA	CA Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 86	NA ^a	0.367 (0.411)	NA ^a	0.367 (0.411)	NIS (Pro 90) @ 0.20% v/v	
RV114-11DA	CA Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 81	20 (192)	0.180 (0.202)	NA ^a	0.365 (0.409)	MSO at 0.25% v/v	
					BBCH 82	21 (193)	0.185 (0.207)	7		MSO at 0.25% v/v	
RV114-11DA	CA Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 54	NA ^a	0.367 (0.411)	NA ^a	0.367 (0.411)	MSO at 0.25% v/v	
RV115-11DA	CA Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 82	26 (239)	0.188 (0.210)	NA ^a	0.371 (0.416)	COC 1.0% v/v	
					BBCH 89	26 (239)	0.183 (0.206)	7		COC 1.0% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV115-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 69	NA ^a	0.351 (0.394)	NA ^a	0.351 (0.394)	COC 1.0% v/v
RV116-11DA	Region 10 2011	BYI 02960 200 SL	FRTDF	Foliar spray	BBCH 83	20 (187)	0.183 (0.205)	NA ^a	0.183 (0.205)	R-11 / 0.2% v/v
					BBCH 89	20 (187)	0.184 (0.206)	7	0.184 (0.206)	R-11 / 0.2% v/v
RV116-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 83	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	R-11 / 0.2% v/v
RV117-11DA	Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 84	20 (186)	0.183 (0.205)	NA ^a	0.365 (0.409)	MSO @ 0.25% v/v
					BBCH 89	21 (197)	0.182 (0.204)	6	0.182 (0.204)	MSO @ 0.25% v/v
RV117-11DA	Region 20 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 83	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	MSO @ 0.25% v/v
RV118-11DA	Region 3 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 74	20 (185)	0.181 (0.203)	NA ^a	0.362 (0.405)	NIS @ 0.2% v/v
					BBCH 89	20 (183)	0.180 (0.202)	7	0.180 (0.202)	NIS @ 0.2% v/v
RV118-11DA	Region 3 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 51	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	NIS at 6 ml based on 3000 ml

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV119-11DA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 87	234	0.283 (0.205)	NA ^a	0.365 (0.409)	COC	
					BBCH 89	137	0.282 (0.204)	NA ^a			
RV119-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 87	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	COC	
RV120-11DA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 72	239	0.188 (0.211)	NA ^a	0.371 (0.416)	NIS	
					BBCH 74	250	0.283 (0.205)	5			
RV120-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 87	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	NIS	
RV121-11HA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 15	144	0.186 (0.209)	NA ^a	0.366 (0.410)	Hasten (MSO) @0.25% v/v	
					BBCH 87	148	0.180 (0.202)	6			
RV121-11HA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 51	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	Hasten (MSO) @0.25% v/v	
RV122-11DA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 89	192	0.184 (0.206)	NA ^a	0.367 (0.411)	COC 26.38 mL	
					BBCH 89	207	0.183 (0.205)	7			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)			
RV122-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 65	NA ^a	0.367 (0.411)	NA ^a	0.367 (0.411)	COC 431 ml		
RV123-11DA	Manitoba Region 5 2011	BYI 02960 200 SL	FRTDF	Foliar spray	BBCH 87	20	0.179 (0.200)	NA ^a	0.366 (0.399)	Agral 90 at 0.2% v/v		
					BBCH 89	10	0.177 (0.198)	7		Agral 90 at 0.2% v/v		
RV123-11DA	Manitoba Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 51-60	NA ^a	0.366 (0.410)	NA ^a	0.366 (0.410)	Agral 90 at 0.2% v/v		
RV124-11DA	Region 6 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 85	28	0.183 (0.205)	NA ^a	0.364 (0.408)	MSO @ 0.25% v/v		
					BBCH 84	16	0.182 (0.204)	5		MSO @ 0.25% v/v		
RV124-11DA	Region 6 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 51-60	NA ^a	0.365 (0.409)	NA ^a	0.365 (0.409)	MSO @ 0.25% v/v		
RV125-11DA	Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 83	26	0.188 (0.211)	NA ^a	0.373 (0.418)	COC 1% v/v		
					BBCH 89	25	0.185 (0.207)	7		COC 1% v/v		
RV125-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 68	NA ^a	0.351 (0.394)	NA ^a	0.351 (0.394)	COC 1% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV126-11DA	Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 87	284 (287)	0.284 (0.206)	NA ^a	0.267 (0.412)	Dyne-Amic @ 0.2% v/v
					BBCH 87	20 (187)	0.283 (0.206)	NA ^a	0.267 (0.412)	Dyne-Amic @ 0.2% v/v
RV126-11DA	Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 71	NA ^a	0.338 (0.402)	NA ^a	0.358 (0.402)	Dyne-Amic @ 0.2%
RV127-11DA	Region 5 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 76	15 (241)	0.185 (0.207)	NA ^a	0.371 (0.416)	Destiny HC 0.25% (v/v)
					BBCH 89	20 (204)	0.186 (0.209)	7	0.371 (0.416)	Destiny HC 0.25% (v/v)
RV127-11DA	Region 5 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 6	NA ^a	0.364 (0.408)	NA ^a	0.364 (0.408)	Destiny HC 0.25% (v/v)
RV128-11HA	Region 8 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 89	20 (191)	0.189 (0.211)	NA ^a	0.373 (0.418)	Rigo Oil COC
					BBCH 89	20 (187)	0.185 (0.207)	7	0.373 (0.418)	Rigo Oil COC
RV128-11HA	Region 8 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 59	NA ^a	0.371 (0.415)	NA ^a	0.371 (0.415)	Rigo Oil COC
RV129-11HA	Region 11 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 78	23 (213)	0.187 (0.210)	NA ^a	0.376 (0.422)	Pierce MSO 0.25% V/V
					BBCH 89	23 (211)	0.189 (0.212)	7	0.376 (0.422)	Pierce MSO 0.25% V/V

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-6 (cont'd): Study Use Pattern for BYI 02960 200 SL in/on Fruiting Vegetables

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)			
RV129-11HA	█ ID Region 11 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 64	NA ^a	0.374 (0.419)	NA ^a	0.374 (0.419)	Pro 90 @ 0.25% v/v		
RV130-11DA	█ CA Region 10 2011	BYI 02960 200 SL	TRTDF	Foliar spray	BBCH 87	27 (255)	0.188 (0.211)	NA ^a	0.170 (0.415)	Pro 90 @ 0.2% v/v		
					BBCH 89	32 (298)	0.182 (0.204)	7		Pro 90 @ 0.2% v/v		
RV130-11DA	█ CA Region 10 2011	BYI 02960 200 SL	TRTDS	Soil drench	BBCH 64	NA ^a	0.365 (0.409)	NA ^a	0.365 (0.409)	Pro 90 @ 0.2% v/v		

a NA = Not applicable

TRTDF = treated plot receiving two foliar spray applications

TRTDS = treated plot receiving one soil drench application

In the harvest trials, duplicate composite samples (two separate runs through the plot) of tomato, bell pepper, and non-bell (chili) pepper were harvested from the TRTDF plots (foliar application) at a 1-day pre-harvest interval (PHI) and from the TRTDS plots (soil application) at a 45-day PHI. In the decline trials (eight for tomato, eight for bell pepper and two for non-bell (chili) pepper), duplicate composite samples of tomato, bell pepper, and non-bell (chili) pepper were harvested from the TRTDF plots at 0, 1, 7, 14, 21, and 28 days after the last treatment, while samples were harvested from the TRTDS plots at 40, 45, 50, 50, and 70 days after the last treatment. In addition, duplicate composite samples were collected from all tomato trials 1 day after the first application (1DAA1). As these samples do not reflect the proposed use rate, the residue data from these samples were collected for informational purposes only. Single composite samples of tomato, bell pepper, and non-bell (chili) pepper from the control plots were harvested on the same day as the 1 day-PHI or the 45 day-PHI samples from the treated plots.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.



Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20%. (Table 6.3.2.8-7).

Table 6.3.2.8-7: Summary of Recoveries of BYI 02960 from Fruiting Vegetables

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Tomato	BYI 02960	0.01	21	76, 75, 79, 72, 78, 78, 70, 79, 84, 89, 70, 83, 73, 71, 75, 68, 79, 89, 92, 79, 70	77	6.9
		2	3	79, 91, 66	79	
	DFA	0.05	21	84, 84, 90, 82, 82, 82, 78, 93, 76, 77, 105, 83, 79, 81, 78, 79, 77, 97, 86, 79, 101	88	8.6
		2	3	88, 89, 86	88	1.4
	DFEAF	0.01	21	81, 88, 92, 83, 78, 83, 86, 93, 109, 100, 119, 69, 72, 97, 75, 75, 82, 98, 84, 98, 95	89	13
		2	3	86, 87, 82	85	2.5
Bell Pepper	BYI 02960	0.01	17	76, 66, 50, 74, 76, 74, 77, 77, 71, 84, 76, 76, 100, 76, 84, 78, 77	76	10
		3	3	83, 92, 76	84	8.0
	DFA	0.05	17	78, 76, 77, 76, 75, 71, 77, 74, 79, 111, 79, 115, 97, 78, 75, 80, 80	82	13
		2	3	79, 77, 78	77	1.6
	DFEAF	0.01	17	87, 85, 81, 92, 80, 81, 81, 83, 82, 86, 87, 79, 76, 94, 73, 77, 88	83	5.5
		2	3	71, 79, 69	73	4.9
Non-Bell (Chili) Pepper	BYI 02960	0.01	10	74, 91, 95, 66, 83, 96, 80, 83, 77, 78	82	9.4
		1.0	3	90, 87, 83	87	3.4
	DFA	0.05	10	80, 73, 82, 79, 82, 81, 81, 77, 85, 91	81	4.2
		1.0	3	93, 89, 92	91	2.3
	DFEAF	0.01	10	81, 79, 79, 72, 83, 80, 75, 91, 75, 95	81	7.2
		1.0	3	87, 83, 89	86	3.2
Non-Bell (Chili) Pepper Dried	BYI 02960	0.01	8	74, 70, 72, 70, 70, 69, 68, 79	71	3.5
		1.5	3	85, 83, 83	83	1.1
	DFA	0.05	8	81, 80, 81, 80, 94, 88, 59, 106	84	13
		1.5	3	73, 74, 58	69	8.8
	DFEAF	0.01	8	63, 77, 79, 71, 74, 77, 73, 79	74	5.4
		1.5	3	77, 85, 75	79	5.3

a Mean recovery = mathematical average of all recovery values



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The freezer storage stability study indicates that BYI 02960 residues were stable in spinach leaves and tomato fruits as representative crops of the respective crop commodity (high water content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 266 days. A summary of the storage conditions are shown in the Table 6.3.2.8-8.

Table 6.3.2.8-8: Summary of Storage Conditions for Tomato, Bell Pepper, and Non-Bell (Chili) Pepper

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (Days) ^b	Interval of Demonstrated Storage Stability months ^c
BYI 02960	Tomato Fruit Bell Pepper Fruit Non-Bell (Chili) Pepper (Fruit and Dried Fruit)	<0	266	18 (558 days)
DFAEF	Tomato Fruit Bell Pepper Fruit Non-Bell (Chili) Pepper (Fruit and Dried Fruit)	<0	266	18 (558 days)
DFA	Tomato Fruit Bell Pepper Fruit Non-Bell (Chili) Pepper (Fruit and Dried Fruit)	<0	266	18 (558 days)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and [REDACTED], 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethylamino-fenarone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIL/06.1.1/04)

The total BYI 02960 residue data for fruiting vegetables following foliar or soil application(s) of BYI 02960 200 SI are shown in Tables 6.3.2.8-9, 6.3.2.8-10, and 6.3.2.8-11.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9: Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV098-11HA	NY, Region 1, 2011	TRTDF	Early Girl	Fruit	0.183 (0.205)	1DAA1	0.093 0.091	<LOQ <LOQ	<LOQ <LOQ	0.15 0.15 Av: 0.15
					0.366 (0.410)	1	0.132 0.135	<LOQ <LOQ	<LOQ <LOQ	0.19 0.20 Av: 0.19
RV098-11HA	NY, Region 1, 2011	TRTDS	Early Girl	Fruit	0.371 (0.416)	45	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.07 0.07 Av: 0.07
RV099-11HA	GA, Region 2, 2011	TRTDE	Celebrity	Fruit	0.184 (0.205)	1DAA1	0.069 0.065	<LOQ <LOQ	<LOQ <LOQ	0.13 0.13 Av: 0.13
					0.368 (0.415)	1	0.090 0.085	<LOQ <LOQ	<LOQ <LOQ	0.15 0.15 Av: 0.15
RV099-11HA	GA, Region 2, 2011	TRTDS	Celebrity	Fruit	0.364 (0.408)	45	<LOQ <LOQ	0.293 0.333	<LOQ <LOQ	0.31 0.35 Av: 0.33
RV100-11HA	FL, Region 3, 2011	TRTDF	6 02	fruit	0.085 (0.207)	1DAA1	0.147 0.148	<LOQ <LOQ	<LOQ <LOQ	0.21 0.21 Av: 0.21
					0.366 (0.410)	1	0.202 0.249	<LOQ <LOQ	<LOQ <LOQ	0.26 0.31 Av: 0.29
RV100-11HA	FL, Region 3, 2011	TRTDS	6 02	fruit	0.366 (0.410)	44	0.030 0.028	0.162 0.154	<LOQ <LOQ	0.20 0.19 Av: 0.20

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV101-11HA	██████, FL, Region 3, 2011	TRTDF	Beefmaster	fruit	0.181 (0.203)	1DAA1	0.043 0.029	<LOQ <LOQ	<LOQ <LOQ	0.10 0.09 Av: 0.10
					0.367 (0.404)	1	0.050 0.064	<LOQ <LOQ	<LOQ <LOQ	0.11 0.12 Av: 0.12
RV101-11HA	██████, FL, Region 3, 2011	TRTDS	Beefmaster	fruit	0.359 (0.403)	43	0.012 0.011	0.017 0.0147	<LOQ <LOQ	0.15 0.17 Av: 0.16
RV102-11HA	██████, IA, Region 5, 2011	TRTDF	Keepsake	Fruit	0.184 (0.206)	1DAA1	0.057 <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.12 0.07 Av: 0.09
					0.368 (0.413)	1	0.098 0.172	<LOQ <LOQ	<LOQ <LOQ	0.16 0.23 Av: 0.20
RV102-11HA	██████, IA, Region 5, 2011	TRTDS	Keepsake	Fruit	0.364 (0.408)	43	<LOQ <LOQ	0.065 0.072	<LOQ <LOQ	0.09 0.09 Av: 0.09
RV103-11HA	██████, Region 5, 2011	TRTDF	TSH 29	Fruit	0.179 (0.200)	1DAA1	0.161 0.171	<LOQ <LOQ	<LOQ <LOQ	0.22 0.23 Av: 0.23
					0.365 (0.409)	1	0.320 0.223	<LOQ <LOQ	<LOQ <LOQ	0.38 0.28 Av: 0.33
RV103-11HA	██████, Region 5, 2011	TRTDS	TSH 29	Fruit	0.366 (0.410)	43	0.017 0.012	0.061 <LOQ	<LOQ <LOQ	0.09 0.07 Av: 0.08
RV104-11HA	Manitoba, Region 5, 2011	TRTDF	Bush Beefsteak	Fruit	0.180 (0.202)	1DAA1	0.082 0.071	<LOQ <LOQ	<LOQ <LOQ	0.14 0.13 Av: 0.14

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV104-11HA	Manitoba, Region 5, 2011	TRTDF	Bush Beefsteak	Fruit	0.363 (0.407)	1	0.063 0.056	<LOQ <LOQ	<LOQ <LOQ	0.12 0.12 Av: 0.12
RV104-11HA	Manitoba, Region 5, 2011	TRTDS	Bush Beefsteak	Fruit	0.366 (0.410)	45	0.039 0.022	0.845 0.36	<LOQ <LOQ	0.89 0.77 Av: 0.83
RV105-11DA	IL, Region 5, 2011	TRTDF	Early Girl	Fruit	0.186 (0.209)	1D/1A	0.030 0.054	<LOQ <LOQ	<LOQ <LOQ	0.15 0.11 Av: 0.13
					0.333 (0.418)		0.083 0.082	<LOQ <LOQ	<LOQ <LOQ	0.14 0.14 Av: 0.14
							0.057 0.114	<LOQ <LOQ	<LOQ <LOQ	0.12 0.17 Av: 0.15
							0.046 0.052	<LOQ <LOQ	<LOQ <LOQ	0.11 0.11 Av: 0.11
						14	0.026 0.021	0.063 0.091	<LOQ <LOQ	0.10 0.12 Av: 0.11
						21	0.020 0.024	0.139 0.110	<LOQ <LOQ	0.17 0.14 Av: 0.16
						27	0.022 0.027	0.109 0.137	<LOQ <LOQ	0.14 0.17 Av: 0.16
RV105-11DA	IL, Region 5, 2011	TRTDS	Early Girl	Fruit	0.366 (0.410)	41	0.017 0.013	1.07 0.995	<LOQ <LOQ	1.1 1.0 Av: 1.1

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
RV105-11DA	IL, Region 5, 2011	TRTDS	Early Girl	Fruit	0.366 (0.410)	45	0.013 0.011	0.73 0.752	<LOQ <LOQ	0.74 0.77 Av: 0.75	
						56	0.013 0.013	0.651 0.594	<LOQ <LOQ	0.67 0.82 Av: 0.75	
						72	<LOQ <LOQ	0.33 0.657	<LOQ <LOQ	0.75 0.68 Av: 0.72	
						70	<LOQ <LOQ	0.14 0.783	<LOQ <LOQ	0.83 0.80 Av: 0.82	
RV106-11HA	KS, Region 5, 2011	TRTDF	Celebrity	Fruit	0.171 (0.202)	1DA A1	0.048 0.065	<LOQ <LOQ	<LOQ <LOQ	0.11 0.13 Av: 0.12	
							0.367 (0.411)	0.072 0.111	<LOQ <LOQ	<LOQ <LOQ	0.23 0.17 Av: 0.20
RV106-11HA	KS, Region 5, 2011	TRTDS	Celebrity	Fruit	0.365 (0.409)	44	<LOQ <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.07 0.07 Av: 0.07	
RV107-11HA	WI, Region 5, 2011	TRTDF	Red Defender	Fruit	0.383 (0.205)	1DA A1	0.021 <LOQ	<LOQ <LOQ	<LOQ <LOQ	0.08 0.07 Av: 0.08	
RV107-11HA	WI, Region 5, 2011	TRTDS	Red Defender	Fruit	0.366 (0.410)	1	0.05 0.06	<LOQ <LOQ	<LOQ <LOQ	0.11 0.12 Av: 0.12	
RV107-11HA	WI, Region 5, 2011	TRTDS	Red Defender	Fruit	0.367 (0.411)	45	0.011 0.016	<LOQ <LOQ	<LOQ <LOQ	0.07 0.08 Av: 0.07	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV108-11DA	[REDACTED] IL, Region 5, 2011	TRTDF	Jet Star	Fruit	0.182 (0.204)	1	0.064 0.098	<LOQ <LOQ	<LOQ <LOQ	0.12 0.16 Av: 0.14
						0	0.119 0.085	<LOQ <LOQ	<LOQ <LOQ	0.18 0.16 Av: 0.17
						7	0.055 0.072	<LOQ <LOQ	<LOQ <LOQ	0.12 0.13 Av: 0.12
						14	0.054 0.082	0.070 0.088	<LOQ <LOQ	0.13 0.18 Av: 0.16
						21	0.042 0.049	0.104 0.114	<LOQ <LOQ	0.16 0.17 Av: 0.16
						28	0.039 0.034	0.088 0.090	<LOQ <LOQ	0.14 0.13 Av: 0.14
						35	0.023 0.029	0.080 0.085	<LOQ <LOQ	0.11 0.12 Av: 0.12
						42	0.013 <LOQ	0.754 1.11	<LOQ <LOQ	0.78 1.1 Av: 0.95
						49	0.010 <LOQ	0.930 0.809	<LOQ <LOQ	0.95 0.83 Av: 0.89
						56	<LOQ <LOQ	1.33 0.79	<LOQ <LOQ	1.3 0.81 Av: 1.1

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV108-11DA	IL, Region 5, 2011	TRTDS	Jet Star	Fruit	0.366 (0.410)	59	<LOQ	0.90	<LOQ	0.92
							<LOQ	0.638	<LOQ	0.66
						76	<LOQ	0.638	<LOQ	0.66
							<LOQ	0.346	<LOQ	0.37
										Av: 0.49
RV109-11DA	ON, Region 5, 2011	TRTDF	H2401	Fruit	0.186 (0.412)	1D, A1	0.04	<LOQ	<LOQ	0.15
							0.04	<LOQ	<LOQ	0.16
							0.366 (0.409)	0.161	<LOQ	0.29
							0.23	0.051	<LOQ	0.22
							0.097	<LOQ	<LOQ	0.16
							0.115	0.067	<LOQ	0.19
										Av: 0.17
							0.068	0.089	<LOQ	0.17
							0.099	0.138	<LOQ	0.25
										Av: 0.21
						14	0.070	0.122	<LOQ	0.20
							0.050	0.094	<LOQ	0.15
										Av: 0.18
						20	0.067	0.107	<LOQ	0.18
							0.046	0.071	<LOQ	0.13
										Av: 0.16
						28	0.054	0.122	<LOQ	0.19
							0.036	0.076	<LOQ	0.12
										Av: 0.15
RV109-11DA	ON, Region 5, 2011	TRTDS	H2401	Fruit	0.366 (0.410)	40	0.011	0.149	<LOQ	0.17
							0.011	0.134	<LOQ	0.16
										Av: 0.16

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV109-11DA	[REDACTED] ON, Region 5, 2011	TRTDS	H2401	Fruit	0.366 (0.410)	45	0.013	0.20	<LOQ	0.22
							0.015	0.217	<LOQ	0.24
							Av:			0.23
						49	<LOQ	0.158	<LOQ	0.18
							<LOQ	0.164	<LOQ	0.18
							Av:			0.18
						52	0.014	0.181	<LOQ	0.21
							0.016	0.214	<LOQ	0.24
							Av:			0.22
						56	0.013	0.111	<LOQ	0.24
							0.010	0.163	<LOQ	0.18
							Av:			0.21
RV110-11DA	[REDACTED] CA, Region 10, 2011	TRTDF	SUN 6366	Fruit	0.369 (0.413)	1DAA1	0.168	<LOQ	<LOQ	0.23
							0.271	<LOQ	<LOQ	0.33
							Av:			0.28
							0.405	<LOQ	<LOQ	0.47
							0.323	<LOQ	<LOQ	0.38
							Av:			0.42
							0.413	<LOQ	<LOQ	0.49
							0.492	<LOQ	<LOQ	0.55
							Av:			0.52
						7	0.351	0.147	0.010	0.51
							0.284	0.084	<LOQ	0.38
							Av:			0.44
						14	0.225	0.212	0.012	0.45
							0.399	0.179	0.020	0.60
							Av:			0.52
						21	0.238	0.182	0.012	0.43
							0.251	0.205	0.013	0.47
							Av:			0.45
RV110-11DA	[REDACTED] CA, Region 10, 2011	TRTDF	SUN 6366	Fruit	0.369 (0.413)	28	0.149	0.204	<LOQ	0.36
							0.294	0.348	0.017	0.66
							Av:			0.51

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV110-11DA	██████, CA, Region 10, 2011	TRTDS	SUN 6366	Fruit	0.366 (0.410)	40	0.048 0.087	0.008 0.066	<LOQ LOQ	0.15 0.26 Av: 0.20
						45	0.050 0.087	0.206 0.55	<LOQ LOQ	0.27 0.25 Av: 0.26
						47	0.041 0.043	0.008 0.190	<LOQ LOQ	0.23 0.24 Av: 0.24
						60	0.070 0.020	0.355 0.436	<LOQ LOQ	0.38 0.47 Av: 0.42
						70	0.016 0.021	0.349 1.01	<LOQ LOQ	0.58 1.0 Av: 0.81
RV111-11DA	██████, Region 10, 2011	TRDDF	AB3	Fruit	0.493 (0.205)	1DA1	0.457 0.148	<LOQ LOQ	<LOQ LOQ	0.22 0.21 Av: 0.21
						1	0.419 0.325	<LOQ LOQ	<LOQ LOQ	0.48 0.39 Av: 0.43
						1	0.330 0.261	<LOQ LOQ	<LOQ LOQ	0.39 0.32 Av: 0.36
						7	0.396 0.215	<LOQ LOQ	<LOQ LOQ	0.46 0.28 Av: 0.37

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV111-11DA	CA, Region 10, 2011	TRTDF	AB3	Fruit	0.365 (0.410)	14	0.293 0.218	<LOQ <LOQ	<LOQ <LOQ	0.36 0.28 Av: 0.32
						21	0.334 0.218	0.148 0.085	0.016 0.011	0.50 0.31 Av: 0.41
						27	0.335 0.32	0.086 0.167	0.012 0.010	0.38 0.31 Av: 0.35
RV111-11DA	CA, Region 10, 2011	TRTDS	AB3	Fruit	0.365 (0.400)	40	<LOQ <LOQ	<LOQ 0.058	<LOQ <LOQ	0.07 0.08 Av: 0.07
						45	<LOQ <LOQ	0.059 <LOQ	<LOQ <LOQ	0.08 0.07 Av: 0.07
						50	<LOQ <LOQ	<LOQ 0.077	<LOQ <LOQ	0.07 0.10 Av: 0.08
						60	<LOQ <LOQ	0.085 0.085	<LOQ <LOQ	0.11 0.11 Av: 0.11
						70	<LOQ <LOQ	0.122 0.113	<LOQ <LOQ	0.14 0.13 Av: 0.14
RV111-11HA	CA, Region 10, 2011	TRTDF	Washington Cherry	Fruit	0.185 (0.207)	1DAA1	0.366 0.295	<LOQ <LOQ	<LOQ <LOQ	0.43^d 0.36 Av: 0.39^e
					0.368 (0.413)	1	0.601 0.538	<LOQ <LOQ	<LOQ <LOQ	0.66^f 0.60 Av: 0.63^g

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV112-11HA	CA, Region 10, 2011	TRTDS	Washington Cherry	Fruit	0.366 (0.410)	44	0.013 1.00	0.14 0.174	<LOQ LOQ	0.20 0.19 Av: 0.20
RV113-11HA	CA, Region 10, 2011	TRTDF	Roma AB2	Fruit	0.18 (0.210)	14	0.126 0.122	<LOQ LOQ	<LOQ LOQ	0.19 0.18 Av: 0.18
					0.366 (0.413)		0.025 LOQ	<LOQ LOQ	<LOQ LOQ	0.30 0.39 Av: 0.34
RV113-11HA	CA, Region 10, 2011	TRTDS	Roma ABC	Fruit	0.36 (0.411)	44	<LOQ LOQ	0.134 0.132	LOQ LOQ	0.17 0.15 Av: 0.16
RV114-11DA	CA, Region 10, 2011	TRTDF	Galii T-2	Fruit	0.18 (0.202)	14	0.015 0.078	<LOQ LOQ	<LOQ LOQ	0.18 0.14 Av: 0.16
					0.365 (0.409)		0.231 0.217	<LOQ LOQ	<LOQ LOQ	0.29 0.28 Av: 0.28
							0.166 0.142	<LOQ LOQ	<LOQ LOQ	0.23 0.20 Av: 0.21
						7	0.099 0.070	0.072 0.064	<LOQ LOQ	0.18 0.14 Av: 0.16
						14	0.074 0.085	0.121 0.161	<LOQ LOQ	0.21 0.26 Av: 0.23
						21	0.106 0.062	0.322 0.262	<LOQ LOQ	0.44 0.33 Av: 0.39

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV114-11DA	Region 10, 2011	TRTDF	Quali T-27	Fruit	0.365 (0.409)	28	0.073 0.096	0.300 0.353	<LOQ	0.39 0.46 Av: 0.43
RV114-11DA	Region 10, 2011	TRTDS	Quali T-27	Fruit	0.365 (0.411)	40	0.029 0.047	0.595 0.553	<LOQ	0.63 0.38 Av: 0.51
						7	0.033 0.033	0.49 0.562	<LOQ	0.59 0.61 Av: 0.60
						49	0.038 0.029	0.60 0.583	<LOQ	0.61 0.62 Av: 0.61
						60	0.024 0.028	0.543 0.475	<LOQ	0.58 0.51 Av: 0.55
						60	0.027 0.025	0.594 0.593	<LOQ	0.63 0.63 Av: 0.63
RV115-11DA	Region 10, 2011	TRTDF	Quali T-27	Fruit	0.388 (0.210)	10	0.052 0.072	<LOQ	<LOQ	0.11 0.13 Av: 0.12
						0	0.122 0.080	<LOQ	<LOQ	0.18 0.14 Av: 0.16
						1	0.116 0.101	<LOQ	<LOQ	0.18 0.16 Av: 0.17
						7	0.187 0.088	<LOQ	<LOQ	0.25 0.16 Av: 0.21

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV115-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	Quality 27	Fruit	0.371 (0.416)	14	0.104	0.077	<LOQ	0.19
							0.100	0.077	<LOQ	0.19
							Av:	0.19		
						21	0.148	0.150	<LOQ	0.31
							0.127	0.26	<LOQ	0.26
							Av:	0.29		
						27	0.05	0.050	<LOQ	0.26
							0.064	0.160	<LOQ	0.23
							Av:	0.25		
RV115-11DA	[REDACTED], CA, Region 10, 2011	TRTDS	Quality 27	Fruit	0.357 (0.394)	40	<LOQ	0.077	<LOQ	0.10
							<LOQ	0.087	<LOQ	0.11
							Av:	0.10		
						45	<LOQ	0.059	<LOQ	0.08
							<LOQ	0.073	<LOQ	0.09
							Av:	0.09		
						50	<LOQ	0.085	<LOQ	0.11
							<LOQ	0.082	<LOQ	0.10
							Av:	0.10		
						60	<LOQ	0.078	<LOQ	0.10
							<LOQ	0.095	<LOQ	0.12
							Av:	0.11		
						70	<LOQ	<LOQ	<LOQ	0.07
							<LOQ	<LOQ	<LOQ	0.07
							Av:	0.07		
RV116-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	SUN 6366	Fruit	0.183 (0.205)	1DAA1	0.180	<LOQ	<LOQ	0.24
							0.205	<LOQ	<LOQ	0.27
							Av:	0.25		
						0	0.438	<LOQ	<LOQ	0.50
							0.683	0.055	<LOQ	0.75
							Av:	0.62		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV116-11DA	██████, CA, Region 10, 2011	TRTDF	SUN 6366	Fruit	0.367 (0.412)	1	0.276 0.437	<LOQ <LOQ	<LOQ 0.013	0.34 0.50 Av: 0.42
						7	0.882 0.75	0.157 0.38	0.020 0.020	1.1 0.73 Av: 0.90
						7	0.27 0.26	0.11 0.205	0.018 0.013	0.2 0.54 Av: 0.86
						21	0.483 0.301	0.55 0.227	0.018 0.013	0.78 0.54 Av: 0.66
						28	0.93 0.206	0.509 0.595	0.019 0.017	0.86 0.82 Av: 0.84

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-9 (cont'd): Total BYI 02960 Residue Data from Tomato after Two Foliar or a Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./ha (kg ai/ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV116-11DA	██████, CA, Region 10, 2011	TRTDS	SUN 6366	Fruit	0.366 (0.410)	40	0.176	0.409	0.011	0.69
							0.234	0.848	LOQ	1.1
						45	0.115	0.683	<LOQ	0.81
							0.357	0.15	0.010	1.1 ^h
										Av: 0.89
							0.26	0.23	LOQ	1.0
							0.275	0.53	0.016	1.8
										Av: 1.4
						60	0.284	1.3	0.017	2.0
							0.184	1.46	0.021	1.7
										Av: 1.9
						70	0.105	1.3	0.012	1.2
							0.123	1.48	0.011	1.6
										Av: 1.4

- a Total Rate for the 1DAA1 sample is the rate following the first application only. In plots with two applications, the Total Rate is the sum of the two application rates. Application rates were rounded to three significant figures following calculations.
- b Pre-Harvest Interval (PHI) is the interval between last application and sample harvest date. 1DAA1 is one day after the first application.
- c Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEA residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue level might be.
- d Maximum residue found in tomato at 1DAA1 PHI.
- e Highest average field trial (HAFT) residue found in tomato at 1DAA1 PHI.
- f Maximum residue found in tomato at 1 day PHI.
- g Highest average field trial (HAFT) residue found in tomato at 1 day PHI.
- h Maximum residue found in tomato at 45 day PHI following soil drench application.
- i Highest average field trial (HAFT) residue found in tomato at 45 day PHI following soil drench application.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10: Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	DTF AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV117-11DA	█, GA, Region 2, 2011	TRTDF	Aristotle	Fruit	0.365 (0.409)	0	0.091 0.123	<LOQ <LOQ	<LOQ <LOQ	0.091 0.123 Av: 0.17
						1	0.085 0.082	<LOQ <LOQ	<LOQ <LOQ	0.085 0.082 Av: 0.14
							0.082 0.066	<LOQ <LOQ	<LOQ <LOQ	0.082 0.066 Av: 0.13
						14	0.038 0.052	0.070 <LOQ	<LOQ <LOQ	0.038 0.052 Av: 0.13
						21	0.042 0.033	0.132 0.130	<LOQ <LOQ	0.042 0.033 Av: 0.18
						28	0.030 0.024	0.104 0.120	<LOQ <LOQ	0.030 0.024 Av: 0.15

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	DTAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV117-11DA	[REDACTED], GA, Region 2, 2011	TRTDS	Aristotle	Fruit	0.366 (0.410)	40	<LOQ <LOQ	0.063 0.101	<LOQ <LOQ	0.063 0.101 Av: 0.10
						45	<LOQ <LOQ	0.090 0.080	<LOQ <LOQ	0.090 0.080 Av: 0.11
						49	<LOQ <LOQ	<LOQ 0.033	<LOQ <LOQ	0.07 0.08 Av: 0.08
RV117-11DA	[REDACTED], GA, Region 2, 2011	TRTDS	Aristotle	Fruit	0.366 (0.410)	59	<LOQ <LOQ	0.067 0.085	<LOQ <LOQ	0.09 0.11 Av: 0.10
						70	<LOQ <LOQ	0.079 <LOQ	<LOQ <LOQ	0.10 0.07 Av: 0.09
RV118-11HA	[REDACTED], FL, Region 3, 2011	VRTDF	Aristotle	fruit	0.366 (0.405)	1	0.109 0.123	<LOQ <LOQ	<LOQ <LOQ	0.17 0.18 Av: 0.18
RV118-11HA	[REDACTED], FL, Region 3, 2011	TRTDS	Aristotle	fruit	0.366 (0.410)	44	0.033 0.020	0.146 0.067	<LOQ <LOQ	0.19 0.10 Av: 0.14

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	BPE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV119-11DA	██████, NE, Region 5, 2011	TRTDF	California Wonder	Fruit	0.365 (0.409)	0	0.044 0.061	<LOQ <LOQ	<LOQ <LOQ	0.12 0.11
						1	0.056 0.066	<LOQ <LOQ	<LOQ <LOQ	0.11 0.11
						6	0.021 0.021	<LOQ <LOQ	<LOQ <LOQ	0.08 0.08
						13	0.038 0.045	0.064 0.071	<LOQ <LOQ	0.10 0.10
						20	0.011 0.012	0.098 0.084	<LOQ <LOQ	0.13 0.11
						27	0.048 0.033	0.174 0.144	<LOQ <LOQ	0.23 0.19
						40	<LOQ 0.012	0.107 0.076	<LOQ <LOQ	0.13 0.10
RV119-11DA	██████, NE, Region 5, 2011	TRTDF	California Wonder	Fruit	0.366 (0.410)	40	<LOQ 0.012	0.107 0.076	<LOQ <LOQ	0.13 0.10
						44	<LOQ <LOQ	0.112 0.097	<LOQ <LOQ	0.13 0.12
						48	<LOQ 0.012	0.112 0.131	<LOQ <LOQ	0.13 0.15
						59	<LOQ 0.010	0.128 0.134	<LOQ <LOQ	0.15 0.15
						68	<LOQ <LOQ	0.153 0.148	<LOQ <LOQ	0.17 0.17
						Av:				0.11
						Av:				0.15

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	BPE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV120-11DA	[REDACTED] IL, Region 5, 2011	TRTDF	Better Bell	Fruit	0.371 (0.416)	0	0.111 0.089	<LOQ <LOQ	<LOQ <LOQ	0.15 0.16
						1	0.117 0.18	<LOQ <LOQ	<LOQ <LOQ	0.18 0.19
						7	0.09 0.08	<LOQ <LOQ	<LOQ <LOQ	0.19 0.19
						14	0.03 0.046	0.169 0.20	<LOQ <LOQ	0.21 0.28
						21	0.03 0.017	0.255 0.233	<LOQ <LOQ	0.26 0.28
						28	<LOQ 0.018	0.201 0.296	<LOQ <LOQ	0.22 0.33
						41	0.033 0.037	0.253 0.192	<LOQ <LOQ	0.30 0.24
						45	0.041 0.028	0.251 0.343	<LOQ <LOQ	0.30 0.38
RV120-11DA	[REDACTED] IL, Region 5, 2011	TRTDF	Better Bell	Fruit	0.366 (0.410)	50	0.029 0.025	0.546 0.440	<LOQ <LOQ	0.59 0.47
						59	0.012 0.017	0.328 0.294	<LOQ <LOQ	0.35 0.32
						70	0.016 <LOQ	0.205 0.292	<LOQ <LOQ	0.23 0.31
										0.27

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	DTAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV121-11HA	[REDACTED], Region 5, 2011	TRTDF	California Wonder	Fruit	0.366 (0.412)	1	0.088 0.085	<LOQ <LOQ	<LOQ <LOQ	0.088 0.15 Av: 0.15
RV121-11HA	[REDACTED], Region 5, 2011	TRTDS	California Wonder	Fruit	0.366 (0.412)	45	0.011 0.010	0.073 0.104	<LOQ <LOQ	0.084 0.13 Av: 0.11
RV122-11DA	[REDACTED], WI, Region 5, 2011	TRTDF	California Wonder	Fruit	0.366 (0.412)	0	0.021 0.021	<LOQ <LOQ	<LOQ <LOQ	0.09 0.08 Av: 0.08
						1	0.041 0.046	<LOQ <LOQ	<LOQ <LOQ	0.10 0.08 Av: 0.09
RV122-11DA	[REDACTED], WI, Region 5, 2011	TRTDF	California Wonder	Fruit	0.366 (0.412)	7	0.022 0.019	0.070 0.069	<LOQ <LOQ	0.10 0.10 Av: 0.10
						14	0.023 0.018	0.087 0.085	<LOQ <LOQ	0.12 0.11 Av: 0.12
						21	0.012 0.020	0.103 0.073	<LOQ <LOQ	0.13 0.10 Av: 0.11
						28	0.016 0.013	0.085 0.065	<LOQ <LOQ	0.11 0.09 Av: 0.10

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	BPE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
RV122-11DA	[Redacted], WI, Region 5, 2011	TRTDS	California Wonder	Fruit	0.367 (0.412)	40	<LOQ 0.013	0.084 0.099	<LOQ <LOQ	0.084 0.112	
						45	0.012 <LOQ	0.080 0.067	<LOQ <LOQ	0.080 0.099	
						50	<LOQ <LOQ	0.090 0.122	<LOQ <LOQ	0.090 0.144	
						60	<LOQ <LOQ	0.131 0.116	<LOQ <LOQ	0.131 0.144	
						70	<LOQ <LOQ	0.110 0.107	<LOQ <LOQ	0.110 0.133	
						Av:					0.11
						Av:					0.10
						Av:					0.12
						Av:					0.14
						Av:					0.13
RV123-11DA	Manitoba, Region 5, 2011	VRTDF	Unknown	Fruit	0.356 (0.399)	0	0.365 0.215	<LOQ <LOQ	<LOQ <LOQ	0.43 0.28	
						Av:				0.35	
						Av:				0.26	
RV123-11DA	Manitoba, Region 5, 2011	VRTDF	Unknown	Fruit	0.356 (0.399)	1	0.199 0.340	<LOQ <LOQ	<LOQ <LOQ	0.26 0.40	
						Av:				0.33	
						7	0.345 0.259	0.053 0.052	0.017 0.013	0.42 0.32	
						Av:				0.37	
						13	0.148 0.168	0.078 0.066	0.013 0.012	0.24 0.25	
						Av:				0.24	
						20	0.165 0.125	0.101 0.090	0.015 0.011	0.28 0.23	
						Av:				0.25	
						28	0.115 0.095	0.113 0.118	0.013 <LOQ	0.24 0.22	
						Av:				0.23	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	DTF AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV123-11DA	Manitoba, Region 5, 2011	TRTDS	Unknown	Fruit	0.366 (0.412)	42	0.245 0.251	1.26 1.27	0.045 0.040	1.7 1.9
						45	0.176 0.180	1.49 1.27	0.034 0.034	1.7 1.6
						50	0.066 0.100	0.6 1.0	0.01 0.021	0.76 1.6
						59	0.07 0.075	0.789 0.852	0.014 0.014	0.88 0.94
						69	0.057 0.046	0.711 0.610	<LOQ <LOQ	0.78 0.67
RV124-11DA	TX Region 6, 2011	VRTDF	Taurus	Fruit	0.366 (0.408)	0	0.149 0.107	<LOQ <LOQ	<LOQ <LOQ	0.21 0.17 0.19
						1	0.083 0.057	<LOQ <LOQ	<LOQ <LOQ	0.14 0.12
						7	0.061 0.057	<LOQ <LOQ	<LOQ <LOQ	0.12 0.12
						14	0.029 0.050	0.091 0.051	<LOQ <LOQ	0.13 0.11 0.12
						21	0.011 0.018	0.102 0.125	<LOQ <LOQ	0.12 0.15 0.14
						28	0.024 0.025	0.118 0.265	<LOQ <LOQ	0.15 0.30
										Av: 0.23
										Av: 1.6 ^c

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	BPE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV124-11DA	██████, TX, Region 6, 2011	TRTDS	Taurus	Fruit	0.365 (0.409)	40	<LOQ <LOQ	0.322 0.236	<LOQ <LOQ	0.322 0.36 Av: 0.35
						45	<LOQ <LOQ	0.120 0.134	<LOQ <LOQ	0.120 0.15 Av: 0.15
						49	<LOQ <LOQ	0.103 0.093	<LOQ <LOQ	0.12 0.15 Av: 0.14
						63	<LOQ <LOQ	0.115 0.069	<LOQ <LOQ	0.14 0.09 Av: 0.11
RV124-11DA	██████, TX, Region 6, 2011	TRTDS	Taurus	Fruit	0.365 (0.409)	70	<LOQ <LOQ	0.064 0.081	<LOQ <LOQ	0.08 0.10 Av: 0.09
RV125-11DA	██████, CA, Region 10, 2011	VRTDF	Cyprus	Fruit	0.375 (0.418)	0	0.206 0.242	0.083 0.088	<LOQ <LOQ	0.30 0.34 Av: 0.32
						1	0.180 0.243	<LOQ <LOQ	<LOQ <LOQ	0.24 0.30 Av: 0.27
						7	0.323 0.261	<LOQ <LOQ	0.021 0.015	0.39 0.33 Av: 0.36
						14	0.121 0.120	<LOQ <LOQ	0.010 <LOQ	0.18 0.18 Av: 0.18
						21	0.117 0.138	0.084 0.264	0.013 0.015	0.21 0.41 Av: 0.32
						28	0.096 0.112	0.332 0.344	0.010 0.013	0.44 0.47 Av: 0.45

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DTA Residue (mg a.s. equiv./kg)	BPE AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV125-11DA	██████, CA, Region 10, 2011	TRTDS	Cyprus	Fruit	0.351 (0.394)	40	0.011 <LOQ	0.122 0.136	<LOQ <LOQ	0.133 0.16
						45	<LOQ 0.010	0.108 0.135	<LOQ <LOQ	0.108 0.16
						50	<LOQ <LOQ	0.112 0.088	<LOQ <LOQ	0.112 0.09
										0.14 Av: 0.12
RV125-11DA	██████, CA, Region 10, 2011	TRTDS	Cyprus	Fruit	0.351 (0.394)	60	<LOQ <LOQ	0.065 0.079	<LOQ <LOQ	0.09 0.10
						70	<LOQ <LOQ	0.086 0.086	<LOQ <LOQ	0.10 0.10
										0.10 Av: 0.10
RV126-11DA	██████, CA, Region 10, 2011	VRTDF	Red	Fruit	0.367 (0.412)	0	0.553 0.481	<LOQ <LOQ	<LOQ <LOQ	0.61 0.54
										0.58
RV126-11DA	██████, CA, Region 10, 2011	TRTDF	Red	Fruit	0.367 (0.412)	1	0.546 0.402	<LOQ <LOQ	<LOQ <LOQ	0.61^f 0.46
										Av: 0.53^g
						7	0.291 0.333	<LOQ <LOQ	0.011 0.012	0.35 0.40
										Av: 0.37
						14	0.348 0.240	0.085 0.085	0.017 0.013	0.45 0.34
										Av: 0.39
						21	0.237 0.183	0.258 0.198	0.018 0.015	0.51 0.40
										Av: 0.46
						28	0.051 0.069	0.317 0.256	<LOQ <LOQ	0.38 0.34
										Av: 0.36

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-10 (cont'd): Total BYI 02960 Residue Data from Bell Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV126-11DA	[REDACTED], CA, Region 10, 2011	TRTDS	Red	Fruit	0.358 (0.402)	40	<LOQ	<LOQ	<LOQ	0.07
						45	<LOQ	<LOQ	<LOQ	0.07
RV126-11DA	[REDACTED], CA, Region 10, 2011	TRTDS	Red	Fruit	0.358 (0.402)	50	<LOQ	0.069	<LOQ	0.08
						60	<LOQ	<LOQ	<LOQ	0.07
						70	<LOQ	0.072	<LOQ	0.09
							<LOQ	<LOQ	<LOQ	0.07
									Av:	0.08

- a In plots with two applications, Total Rate is the sum of the two application rates. The Total Rate was rounded to three significant figures following calculations.
- b Pre-Harvest Interval (PHI) is the interval between last application and sample harvest date.
- c Total BYI 02960 residue is the sum of BYI 02960, DEA, and DEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- d Maximum residue found in bell pepper at 45 day PHI following soil drench application.
- e Highest average field trial (HAFT) residue found in bell pepper at 45 day PHI following soil drench application.
- f Maximum residue found in bell pepper at 1 day PHI.
- g Highest average field trial (HAFT) residue found in bell pepper at 1 day PHI.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-11: Total BYI 02960 Residue Data from Non-Bell (Chili) Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.i.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DSEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV127-11DA	IA, Region 5, 2011	TRTDF	Early Jalapeno	Fruit	0.371 (0.416)	0	0.084 0.187	<LOQ <LOQ	<LOQ <LOQ	0.14 0.20
						1	0.095 0.078	<LOQ <LOQ	<LOQ <LOQ	0.14 Av: 0.15
							0.05 0.078	0.053 0.057	<LOQ <LOQ	0.12 0.15 Av: 0.13
						14	0.124 0.118	0.250 0.093	<LOQ <LOQ	0.28 0.22 Av: 0.25
						1	0.05 0.085	0.246 0.255	<LOQ <LOQ	0.36 0.35 Av: 0.36
						8	0.059 0.071	0.343 0.305	<LOQ <LOQ	0.41 0.39 Av: 0.40
RV127-11DA	IA, Region 5, 2011	TRTDS	Early Jalapeno	Fruit	0.364 (0.408)	39	0.023 0.020	0.268 0.156	<LOQ <LOQ	0.30 0.19 Av: 0.24
						45	0.024 0.021	0.361 0.459	<LOQ <LOQ	0.40 0.49 ^d Av: 0.44 ^e

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-11 (cont'd): Total BYI 02960 Residue Data from Non-Bell (Chili) Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.i.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV127-11DA	IA, Region 5, 2011	TRTDS	Early Jalapeno	Fruit	0.364 (0.408)	50	0.019 0.020	0.445 0.462	<LOQ <LOQ	0.47 0.48 Av: 0.48
						60	0.023 <LOQ	0.661 0.300	<LOQ <LOQ	0.68 0.32 Av: 0.51
						70	0.021 0.020	0.800 0.920	<LOQ <LOQ	0.83 0.98 Av: 0.91
RV128-11HA	TX, Region 8, 2011	TRTDF	"M"	Dried Fruit	0.373 (0.418)	1	0.811 0.891	0.080 0.100	0.046 0.045	0.94 1.0 Av: 0.99
RV128-11HA	TX, Region 8, 2011	TRTDS	"M"	Dried Fruit	0.371 (0.415)	43	0.176 0.164	0.981 1.00	0.024 0.019	1.2 1.2 Av: 1.2
RV128-11HA	TX, Region 8, 2011	TRTDF	"M"	Fruit	0.373 (0.418)	1	0.361 0.381	<LOQ <LOQ	<LOQ <LOQ	0.42 0.44 Av: 0.43
RV128-11HA	TX, Region 8, 2011	TRTDS	"M"	Fruit	0.371 (0.415)	43	0.048 0.046	0.303 0.325	<LOQ <LOQ	0.36 0.38 Av: 0.37
RV129-11HA	ID, Region 11, 2011	TRTDS	Jalapenos	Dried Fruit	0.376 (0.422)	1	0.439 0.843	0.172 0.162	0.014 0.030	0.63 1.0 Av: 0.83
RV129-11HA	ID, Region 11, 2011	TRTDS	Jalapenos	Dried Fruit	0.374 (0.419)	44	<LOQ <LOQ	1.14 1.06	<LOQ <LOQ	1.2 1.1 Av: 1.1
RV129-11HA	ID, Region 11, 2011	TRTDF	Jalapenos	Fruit	0.376 (0.422)	1	0.083 0.063	<LOQ <LOQ	<LOQ <LOQ	0.14 0.12 Av: 0.13
RV129-11HA	ID, Region 11, 2011	TRTDS	Jalapenos	Fruit	0.374 (0.419)	44	<LOQ <LOQ	0.174 0.143	<LOQ <LOQ	0.19 0.16 Av: 0.18

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-11 (cont'd): Total BYI 02960 Residue Data from Non-Bell (Chili) Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.i.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV130-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	[REDACTED] Chili	Fruit	0.370 (0.415)	0	0.462	<LOQ	<LOQ	0.52
						1	0.369	<LOQ	<LOQ	0.33
						7	0.481	<LOQ	0.014	0.48
						14	0.576	<LOQ	0.014	0.59 ^f
						21	0.233	0.056	0.014	0.30
						28	0.176	<LOQ	0.014	0.23
						40	0.220	0.139	0.031	0.39
RV130-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	[REDACTED] Chili	Fruit	0.365 (0.409)	40	0.235	0.204	0.039	0.58
						44	0.139	0.674	0.040	0.85
						49	0.132	0.396	0.046	0.58
						49	0.138	0.297	0.036	0.47
						49	0.086	0.383	0.033	0.50
RV130-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	[REDACTED] Chili	Fruit	0.365 (0.409)	40	<LOQ	0.263	<LOQ	0.28
						44	<LOQ	0.366	<LOQ	0.39
						49	<LOQ	0.389	<LOQ	0.41
RV130-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	[REDACTED] Chili	Fruit	0.365 (0.409)	44	<LOQ	0.358	<LOQ	0.38
						49	<LOQ	0.437	<LOQ	0.46
RV130-11DA	[REDACTED], CA, Region 10, 2011	TRTDF	[REDACTED] Chili	Fruit	0.365 (0.409)	49	<LOQ	0.533	<LOQ	0.55
						49	<LOQ	0.533	<LOQ	0.51

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-11 (cont'd): Total BYI 02960 Residue Data from Non-Bell (Chili) Pepper after Two Foliar or a Single Soil Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.i.s./ha) ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DDEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV130-11DA	██████ CA, Region 10, 2011	TRTDS	██████ Chili	Frut	0.365 (0.409)	60	<LOQ <LOQ	0.856 0.565	<LOQ <LOQ	0.88 0.58 Av: 0.73
						70	<LOQ <LOQ	0.792 0.503	<LOQ <LOQ	0.8 0.32 Av: 0.67

- a Total rate is the sum of the two application rates in plots with two applications. The Total Rate was rounded to three significant figures following calculations.
- b Pre-Harvest Interval (PHI) is the interval between last application and sample harvest date.
- c Total BYI 02960 residue is the sum of BYI 02960, DFA and DDEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- d Maximum residue found in non-bell (chili) pepper at 45 day PHI following soil drench application.
- e Highest average field trial (HAFT) residue found in non-bell (chili) pepper at 45 day PHI following soil drench application.
- f Maximum residue found in non-bell (chili) pepper at 1 day PHI.
- g Highest average field trial (HAFT) residue found in non-bell (chili) pepper at 1 day PHI.

Conclusion

Thirty-three field trials were conducted to measure the magnitude of total BYI 02960 residue in/on fruiting vegetables (Crop Group 8) following two foliar spray applications or one soil drench application of BYI 02960 200 SL.

The total BYI 02960 residue data for the representative commodities of tomato, bell peppers and non-bell peppers following foliar applications are summarized in Table 6.3.2.8-12.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-12: Summary of Residue Data for Total BYI 02960 in Tomato, Bell Pepper, and Non-Bell Pepper

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFI	Median ³	Mean ³	Standard Deviation
Tomato fruit	TRTDF	0.404 to 0.418	1	18	0.11	0.66	1.22 (14) ⁴	0.63	0.19	0.25	0.15
	TRTDS	0.394 to 0.416	45	18	0.07	1.1	2.0 (60) ⁴	0.94	0.19	0.31	0.31
Bell Pepper fruit	TRTDF	0.399 to 0.418	1	10	0.08	0.61	0.47 (28) ⁴	0.53	0.16	0.21	0.14
	TRTDS	0.394 to 0.411	45	10	0.07	0.7	0.39 (50) ⁴	1.60	0.15	0.29	0.47
Non-bell Pepper fruit	TRTDF	0.415 to 0.422	1	4	0.12	0.64	0.85 (21) ⁴	0.58	0.29	0.33	0.21
	TRTDS	0.408 to 0.419	45	4	0.16	0.49	0.98 (70) ⁴	0.43	0.38	0.35	0.11
Non-bell Pepper fruit, dried	TRTDF	0.418 to 0.422	1	2	0.63	1.04	1.4	0.99	0.99	0.91	0.19
	TRTDS	0.415 to 0.419	45	2	0.8	1.19	NA ⁵	1.1	1.17	1.15	0.05

- 1 TRTDF = Treated plot receiving two foliar spray applications; TRTDS = Treated plot receiving one soil application.
- 2 HAFI = Highest Average Field Trial.
- 3 calculated on the basis of residue values at the PHI.
- 4 Sampling day showing highest residue.
- 5 NA = not applicable, no decline trials were conducted.

Comparing the different use patterns tested, slightly higher residue levels were observed in the NAFTA trials after one soil drench application of BYI 02960 SL 200. However, the residue values corresponding to foliar spray and soil drench application were from similar populations (Whitney-Mann-Wilcoxon test), as well as the residues from the different crops of the crop group.

The total residue levels of BYI 02960 did not always peak at the intended PHI. Nevertheless, after foliar application, the total residue either declined or leveled off by the end of the sampling interval, which covered in maximum 28 days. After soil application, a residue plateau was less distinct – in tomato, the highest total BYI 02960 residues occurred at the last sampling event (69 to 70 days after the application) in seven out of eight decline trials and in pepper in one of eight decline trials. However, the overall maximum residue for fruiting crops (2.0 mg/kg) was detected before the last sampling event (60 days after the application).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
Residue data from AUSTRALIA

BYI 02960 is to be registered in Australia for use as a foliar treatment in/on fruiting vegetables (excluding cucurbits). The critical aspects of the proposed use pattern are summarized in Table 6.3.2.8-13.

A total of twelve trials were conducted in fruiting vegetables. The studies are described below.

Table 6.3.2.8-13: Critical aspects of the use pattern for application of BYI 02960 200 SL to fruiting vegetables (tomatoes, peppers, eggplant)

Application type	Maximum no. of applications	Maximum application rate		Minimum spray interval	WHP
		Per treatment	Per season		
Foliar	3	150 g a.s./ha or 15 g a.s./100 L*	450 g a.s./ha	7 days	1 day

Residues trials supporting this use pattern are presented in 4 study reports.

Report:	KIA 6.3.2.8/02; [REDACTED]; 2011
Title:	Amendment no. 1 - Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to [REDACTED] and bush tomatoes at rates of 100, 150 or 200 g a.i./ha seven days apart, and in glass house tomatoes at rates of 10, 15 and 20 g a.i./100 L seven days apart
Report No & Document No	BCS-0348/02 including sites C504, C505 and C506, dated July 20, 2011 M-41173-02-1
Guidelines:	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes

Report:	KIA 6.3.2.8/03; [REDACTED]; 2011
Title:	Amendment no. 1 - Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to capsicums at rates of 100, 150 or 200 g a.i./ha seven days apart
Report No & Document No	BCS-0349/02 including sites C507, C629 and C509, dated August 11, 2011 M-43074-02-1
Guidelines:	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes

Report:	KIA 6.3.2.8/04; [REDACTED]; 2011
Title:	Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to [REDACTED] and bush tomatoes at rates of 100, 150 or 200 g a.i./ha seven days apart, and in glass house tomatoes at rates of 10, 15 and 20 g a.i./100 L seven days apart – Amendment no. 1 to the report BCS-0354
Report No & Document No	BCS-0354/02 including sites C683, C525 and C526, dated May 31, 2011 M-433790-02-1
Guidelines:	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes



Report:	KIIA 6.3.2.8/05; [REDACTED]; 2011
Title:	Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to capsicum at rates of 100, 150 or 200 g a.i./ha seven days apart - Amendment no. 1 to the report BCS-0355
Report No & Document No	BCS-0355.02 including sites C527, C528 and C529, dated May 14, 2011 M-432144-02-1
Guidelines:	Australian Pesticides and Veterinary Medicines Authority, Manual of Requirements and Guidelines, Edition 3
GLP	Yes

Materials and methods

12 trials were conducted in Australia to measure the level of residues of BYI 02960 and its metabolites following application of BYI 02960 200 SL to fruiting vegetables (excluding cucurbitid crops). These included 6 trials in tomatoes and 6 trials in capsicum (pepper). Trials were conducted over two seasons, with 6 trials in 2010, and 6 trials in 2011.

Trials were conducted in the field (tomatoes and capsicum), and in protected cropping environments (tomatoes). Treatments were applied by hand held boom sprayer applying spray volumes of 500 -700 L/ha (tomatoes), 496-729 L/ha (capsicum) and as a high volume application of 929-2851 L/ha in glasshouse tomatoes. Product was applied on a per ha basis for field trials, 500, 750 or 1000 mL/ha (100, 150 or 200 g a.i./ha). However for tomatoes in a protected cropping situation, which are grown "vertically" on a trellis or string, product was applied on a concentration or "dilute" basis; 50, 75 or 100 mL/100 L (10, 75 or 20 g as/100 L) with application volumes to the "point of run-off" but no more than 1000 L/ha. The target rates applied represented 0.67, 1.0 and 1.5 times the maximum proposed rate. (Note: In studies BCS-0348, site C555, and BCS-0354, site C683 application volumes substantially exceeded 1000 L/ha, with up to 2800 L/ha applied in some instances).

In the first year of trials (2010) for both tomatoes and capsicum, application of each treatment was made 3 times, at approximately 7 day intervals. Samples were collected 1 and 7 days after the second application, and at approximately 0, 3, 7, 10, 14 days after the third application.

For the second year of trials (2011) for both capsicum and tomatoes application of each treatment was again made 3 times, at approximately 7 day intervals, however it was necessary to extend the sampling times. Samples were collected at approximately 1, 7, 14, 21, 28 and 35 days after the third application. Trial details including location, year, application rate, application timing, application no. and sampling times are summarised in Table 6.3.2.8-14 for tomatoes and Table 6.3.2.8-15 for capsicum respectively.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-14: Trial details for residue trials with BYI 02960 200 SL in tomatoes (field and glasshouse)

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing	
		Rate		Application Timing (Spray volume)		
		Product (mL/ha or mL/100L)	Active Substance (g a.s./ha or g a.s./100 L)			
BCS-0348 C504 [redacted] Vic 2010 KIIA 6.3.2.8/02	Tomatoes Roma Field	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C)	1 DAAB 7 DAAB 9 DAAC 1 DAAC 3 DAAC 7 DAAC 10 DAAC 14 DAAC
		750	150			
		1000	200			
BCS-0348 C505 [redacted] Tas 2010 KIIA 6.3.2.8/02	Tomatoes Cheamy Glasshouse	50	10	A=14 DBFH (1050-1067 L/ha) B=7 DBFH (1850-2050 L/ha) C=0 DBFH (1567-2116 L/ha)	3 (A, B and C)	1 DAAB 7 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 10 DAAC 14 DAAC
		75	15			
		100	20			
BCS-0348 C506 [redacted] 2010 KIIA 6.3.2.8/02	Tomatoes Trifecta Field	500	100	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C)	1 DAAB 7 DAAB 0 DAAC 1 DAAC 3 DAAC 6 DAAC 9 DAAC 13 DAAC
		750	150			
		1000	200			
BCS-0354 C683 [redacted] Tas 2011 KIIA 6.3.2.8/04	Tomatoes Cherame Glasshouse	50	10	A=14 DBFH (929-1750 L/ha) B=5 DBFH (2107-2429 L/ha) C=0 DBFH (2679-2857 L/ha)	3 (A, B and C)	1 DAAC 8 DAAC 14 DAAC 21 DAAC 29 DAAC 37 DAAC
		75	15			
		100	20			
BCS-0354 C525 [redacted] WA 2011 KIIA 6.3.2.8/04	Tomatoes Roma Field	500	100	A=15 DBFH B=8 DBFH C=0 DBFH	3 (A, B and C)	1 DAAC 8 DAAC 15 DAAC 22 DAAC 29 DAAC 36 DAAC
		750	150			
		1000	200			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-14 (cont'd): Trial details for residue trials with BYI 02960 200 SL in tomatoes (field and glasshouse)

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing	
		Rate		Application Timing (Spray volume)		No. of Applications (Timing of applications)
		Product (mL/ha or mL/100L)	Active Substance (g a.s./ha or g a.s./100 L)			
BCS-0354 C526 [REDACTED] 2011 KIIA 6.3.2.8/04	Tomatoes Guardian Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 1 DAAC 7 DAAC 14 DAAC 21 DAAC 28 DAAC 35 DAAC	

DBFH = days before first harvest

DAAB = Days after application B of A and B

DAAC = Days after application C of A, B, C

Table 6.3.2.8-15: Trial details for residue trials with BYI 02960 200 SL in capsicum

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing	
		Rate		Application Timing (Spray volume)		No. of Applications (Timing of applications)
		Product (mL/ha or mL/100L)	Active Substance (g a.s./ha or g a.s./100 L)			
BCS-0349 C507 [REDACTED] 2010 KIIA 6.3.3.2/02	Capsicums Warlock Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 3 DAAB 7 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 10 DAAC 14 DAAC	
BCS-0349 C629 [REDACTED] 2010 KIIA 6.3.3.2/02	Capsicums Plato Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 3 DAAB 7 DAAB 0 DAAC 1 DAAC 3 DAAC 6 DAAC 11 DAAC 13 DAAC	
BCS-0349 C509 [REDACTED] Vic 2010 KIIA 6.3.3.2/02	Capsicums Not recorded Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 3 DAAB 7 DAAB 0 DAAC 1 DAAC 3 DAAC 7 DAAC 10 DAAC 14 DAAC	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-15 (cont'd): Trial details for residue trials with BYI 02960 200 SL in capsicum

Study No. Test Site Location Year Annex Pt	Crop Variety Situation	Application			Sampling Timing
		Rate		Application Timing (Spray volume)	
		Product (mL/ha or mL/100L)	Active Substance (g a.s./ha or g a.s./100 L)		
BCS-0355 C527 [REDACTED] Vic 2011 KIIA 6.3.3.2/04	Capsicums Aires Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 1 DAAC 7 DAAC 14 DAAC 21 DAAC 28 DAAC 34 DAAC
BCS-0355 C528 [REDACTED] 2011 KIIA 6.3.3.2/04	Capsicums Warlock Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 1 DAAC 7 DAAC 14 DAAC 21 DAAC 28 DAAC 33 DAAC
BCS-0355 C529 [REDACTED] 2011 KIIA 6.3.3.2/04	Capsicums Plato Field	500 750 1000	100 150 200	A=14 DBFH B=7 DBFH C=0 DBFH	3 (A, B and C) 1 DAAC 7 DAAC 14 DAAC 22 DAAC 28 DAAC 35 DAAC

DBFH = days before first harvest

DAAB = Days after application B of A and B

DAAC = Days after application C of A, B and C

The analytical test method ATM-0048 "Determination of residues of BYI 02960 and its metabolites 6-chloronicotinic acid, difluoroethylamino-uracil and difluoroacetic acid in or on plant material by HPLC-MS/MS" was used to analyse the test samples.

Residues of BYI 02960 and the metabolites 6-CNA, DFEAF and DFA in test samples were extracted with 20:80 water:acetonitrile with 0.22 mL/L formic acid. The extract was filtered using a 0.45 µm syringe filter. For the analysis of DFA an aliquot was taken at this point and diluted with acetonitrile. For the analysis of BYI 02960, 6-CNA and DFEAF an aliquot of the extract was reduced to its aqueous remainder and then partitioned against ethyl acetate on a Chem Elut column. The ethyl acetate was then reduced to dryness and the sample was reconstituted in acetonitrile.

Chromatography was performed by high performance liquid chromatography coupled to a triple quadrupole mass spectrometer using MRM for analyte detection. Quantitation was achieved with matrix matched analytical standards for all analytes and stable labelled internal standards for 6-CNA and DFEAF.

By this method the single analytes (BYI02960 and its metabolites 6-CNA, DFEAF and DFA) were determined. The limit of quantitation (LOQ) of BYI 02960, DFEAF and 6-CNA was 0.01 mg/kg for

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

each component and 0.02 mg/kg for DFA. The total residue of BYI02960 was calculated by summing up the values determined for the individual analytes expressed as parent equivalent. The total LOQ expressed as BYI 02960 was 0.1061 mg/kg (rounded to 0.11 mg/kg) considering all four analytes. However, the residue definition for risk assessment is proposed to comprise only the analytes BYI 02960, DFA and DFEAF. The total LOQ for these three compounds is 0.098 mg/kg (rounded to 0.09 mg/kg).

A full description of the method can be found as an appendix to each of the study reports cited above.

The analytical test method was validated by analysing fortified samples concurrently with the analysis of the test samples. Mean concurrent recoveries for BYI02960 and its metabolites at fortification levels of 0.01 mg/kg (0.02 mg/kg DFA) and 1.0 mg/kg of each analyte are shown in Table 6.3.2.8-16 to 6.3.2.8-19 below.

Table 6.3.2.8-16: Recovery results for BYI02960 and its metabolites in study BCS-0348

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (Percent)	Recovery Means and RSD (Percent)
BYI 02960	Tomatoes	0.01	89, 81, 96, 88, 91, 81	87 ± 6
		1.0	81, 86, 94, 82, 90, 76	85 ± 8
6-CNA		0.01	86, 82, 104, 90, 77, 71	85 ± 13
		1.0	73, 79, 77, 78, 84, 76	78 ± 5
DFEAF		0.01	90, 89, 73, 85, 78	83 ± 9
		1.0	77, 85, 87, 87, 85, 83	84 ± 4
DFA		0.02	99, 89, 93, 91, 96	93 ± 4
		1.0	110, 104, 109, 110, 110, 111	109 ± 2

Table 6.3.2.8-17: Recovery results for BYI02960 and its metabolites in study BCS-0349

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (Percent)	Recovery Means and RSD (Percent)
BYI 02960	Capsicum	0.01	118, 111, 85, 87, 96	99 ± 15
		1.0	94, 96, 96, 87, 81, 86	89 ± 7
6-CNA		0.01	81, 93, 87, 99, 93, 78	88 ± 9
		1.0	79, 106, 70, 77, 71, 79	80 ± 16
DFEAF		0.01	75, 83, 94, 81, 87, 87	85 ± 7
		1.0	77, 100, 74, 89, 73, 80	82 ± 13
DFA		0.02	73, 81, 74, 84, 86, 87	81 ± 7
		1.0	99, 95, 102, 111, 112, 114	105 ± 7

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-18: Recovery results for BYI02960 and its metabolites in study BCS-0354

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (%)	Recovery Means and RSD (%)
BYI 02960	Tomatoes	0.01	104, 90, 112, 83, 116	101 ± 14
		1.0	89, 88, 72, 85, 86, 71	82 ± 10
6-CNA		0.01	97, 81, 77, 73	82 ± 13
		1.0	78, 79, 70, 80	77 ± 6
DFEAF		0.01	93, 81, 74, 78	81 ± 10
		1.0	91, 91, 72, 79, 77, 82	82 ± 10
DFA		0.02	87, 97, 92, 103, 107, 99	97 ± 7
		1.0	98, 106, 102, 114, 112, 110	107 ± 6

Table 6.3.2.8-19: Recovery results for BYI02960 and its metabolites in study BCS-0354

Analyte	Test Samples	Fortification Levels (mg/kg)	Individual Recoveries (%)	Recovery Means and RSD (%)
BYI 02960	Capsicums	0.01	105, 96, 83, 89, 88, 84	91 ± 9
		1.0	84, 82, 85, 73, 72, 71	78 ± 8
6-CNA		0.01	84, 75, 81, 79, 94, 76	81 ± 9
		1.0	84, 75, 92, 82, 79, 79	82 ± 7
DFEAF		0.01	74, 73, 79, 78	76 ± 4
		1.0	89, 78, 90, 83, 72, 73	81 ± 10
DFA		0.02	85, 84, 85, 115, 103, 103	96 ± 13
		1.0	98, 95, 93, 100, 74, 77	89 ± 12

Findings

Residues determined for BYI02960 and its metabolites in tomatoes and capsicums are given in Table 6.3.2.8-20 and Table 6.3.2.8-21 respectively.

Only data relating to the target rate of 150 g a.s./ha (or 15 g a.i./100 L in glasshouse tomatoes) is presented here. Complete data, including results following applications at 100 and 200 g a.s./ha (and 10 or 20 g a.s./100 L in glasshouse tomatoes) can be found in the study report.

Results for BYI02960 and the three metabolites, 6-CNA, DFEAF and DFA, along with the total residue expressed as total BYI02960 parent equivalent are shown in the tables below. Since the proposed residue definition excludes 6-CNA, the total residue excluding 6-CNA is also shown.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-20: Results of residue trials conducted in tomatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.i./ha (field tomatoes) or 15 g a.s./100 L (glasshouse tomatoes)

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					
		Detected as BYI 02960	Detected and expressed as 6-CAN	Detected and expressed as DFEAF	Detected and expressed as DFA	Total Expressed as BYI 02960 Equivalent	Total Expressed as BYI 02960 Equivalent (excluding 6-CAN)
BCS-0348 C504 [redacted] Vic 2010 Field	1 DAAB	0.09	<0.01	<0.01	0.02	0.11	<0.09
	7 DAAB	0.06	<0.01	<0.01	<0.02	0.11	<0.09
	0 DAAC	0.06	<0.01	<0.01	<0.02	<0.10	<0.09
	1 DAAC	0.08	<0.01	<0.01	0.02	0.11	0.09
	3 DAAC	0.08	<0.01	<0.01	0.02	0.11	0.09
	7 DAAC	0.08	<0.01	<0.01	<0.02	0.11	<0.09
	10 DAAC	0.08	<0.01	<0.01	0.02	0.15	0.15
BCS-0348 C505 [redacted] Tas 2010 Glasshouse	1 DAAB	0.10	<0.01	<0.01	<0.02	0.11	<0.09
	7 DAAB	0.12	<0.01	<0.01	<0.02	0.11	0.12
	0 DAAC	0.21	<0.01	<0.01	<0.02	0.20	0.21
	1 DAAC	0.17	<0.01	<0.01	<0.02	0.17	0.17
	3 DAAC	0.2	0.01	<0.01	<0.02	0.24	0.22
	7 DAAC	0.18	<0.01	<0.01	<0.02	0.18	0.18
	10 DAAC	0.18	<0.01	<0.01	0.02	0.18	0.18
BCS-0348 C506 [redacted] 2010 Field	1 DAAB	0.06	<0.01	<0.01	<0.02	<0.11	<0.11
	7 DAAB	0.04	<0.01	<0.01	<0.02	<0.11	<0.11
	0 DAAC	0.06	<0.01	<0.01	<0.02	<0.11	<0.11
	1 DAAC	0.03	<0.01	<0.01	<0.02	<0.11	<0.11
	3 DAAC	0.09	<0.01	<0.01	<0.02	<0.11	<0.11
	8 DAAC	0.04	<0.01	<0.01	<0.02	<0.11	<0.11
	9 DAAC	0.04	<0.01	<0.01	0.03	0.13	0.13
BCS-0344 C683 [redacted] Tas 2011 Glasshouse	1 DAA	0.50	<0.01	<0.01	<0.02	0.50	0.50
	8 DAAC	0.39	<0.01	<0.01	<0.02	0.39	0.39
	14 DAAC	0.35	<0.01	<0.01	<0.02	0.35	0.35
	21 DAAC	0.22	<0.01	<0.01	<0.02	0.22	0.22
	29 DAAC	0.15	<0.01	<0.01	0.02	0.22	0.22
BCS-0354 C525 [redacted] WA 2011 Field - tr	37 DAAC	0.06	<0.01	<0.01	0.03	0.14	0.14
	1 DAAC	0.03	0.03	<0.01	<0.02	<0.11	<0.09
	8 DAAC	0.02	0.02	<0.01	0.03	0.14	0.10
	15 DAAC	0.01	<0.01	<0.01	0.03	<0.11	<0.09
	22 DAAC	0.04	<0.01	<0.01	0.03	0.11	0.11
29 DAAC	<0.01	<0.01	<0.01	0.03	<0.11	<0.09	
36 DAAC	0.01	0.01	<0.01	0.04	0.13	0.13	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-20 (cont'd): Results of residue trials conducted in tomatoes where BYI 02960 200 SL was applied three times at the target rate of 150 g a.i./ha (field tomatoes) or 15 g a.s./100 L (glasshouse tomatoes)

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					Total Expressed as BYI 02960 Equivalent	Total Expressed as BYI 02960 Equivalent (excluding 6-CNA)
		Detected as BYI 02960	Detected and expressed as 6-CAN	Detected and expressed as DFEAF	Detected and expressed as DFA	Detected and expressed as DFA		
BCS-0354 C526 [REDACTED] 2011 Field - Bush	1 DAAC	0.04	<0.01	<0.01	<0.02	<0.02	0.11	<0.09
	7 DAAC	0.02	<0.01	<0.01	<0.02	<0.02	0.11	<0.09
	14 DAAC	0.04	<0.01	<0.01	<0.02	<0.02	<0.11	<0.09
	21 DAAC	0.02	<0.01	<0.01	<0.02	<0.02	0.11	<0.09
	28 DAAC	0.01	<0.01	<0.01	<0.02	<0.02	0.11	<0.09
	33 DAAC	<0.01	<0.01	<0.01	<0.02	<0.02	0.11	<0.09

DALT = Days after last treatment

DAAB = Days After Application B of applications A and B

DAAC = Days After Application C of applications A, B, and C

Note:

The above results might not match the raw data because of rounding adjustments.

All values for BYI 02960, 6-CNA and DFEAF below the LOQ of 0.01 mg/kg are expressed as <0.01 mg/kg.

All values for DFA below the LOQ of 0.02 mg/kg are expressed as <0.02 mg/kg.

All values for the BYI 02960 parent equivalent below the LOQ of 0.1061 mg/kg are expressed as <0.11 mg/kg.

All values for the BYI 02960 parent equivalent excluding 6-CNA below the LOQ of 0.088 mg/kg are expressed as <0.09 mg/kg.

Table 6.3.2.8-21 Results of residue trials conducted in capsicum where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					Total Expressed as BYI 02960 Equivalent	Total Expressed as BYI 02960 Equivalent (excluding 6-CNA)
		Detected as BYI 02960	Detected and expressed as 6-CAN	Detected and expressed as DFEAF	Detected and expressed as DFA	Detected and expressed as DFA		
BCS-0349 C507 [REDACTED] 2010 Field	3 DAAB	0.11	<0.01	<0.01	<0.02	<0.02	0.11	0.11
	7 DAAB	0.15	<0.01	<0.01	<0.02	<0.02	0.15	0.15
	0 DAAC	0.09	<0.01	<0.01	<0.02	<0.02	<0.11	<0.09
	1 DAAC	0.20	<0.01	<0.01	<0.02	<0.02	0.20	0.20
	3 DAAC	0.18	<0.01	<0.01	<0.02	<0.02	0.18	0.18
	7 DAAC	0.42	<0.01	<0.01	<0.02	<0.02	0.42	0.42
	0 DAAC	0.30	<0.01	0.01	<0.02	<0.02	0.32	0.32
	14 DAAC	0.27	<0.01	<0.01	0.03	<0.02	0.35	0.35

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.8-21 (cont'd): Results of residue trials conducted in capsicum where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha

Study no. Trial no. Location Year Situation	DALT (days)	Concentrations (mg/kg)					
		Detected as BYI 02960	Detected and expressed as 6-CAN	Detected and expressed as DFEAF	Detected and expressed as DFA	Total Expressed as BYI 02960 Equivalent	Total Expressed as BYI 02960 Equivalent (excluding 6-CNA)
BCS-0349 C629 2010 Field	3 DAAB	0.09	<0.01	<0.01	0.03	0.17	0.17
	7 DAAB	0.12	<0.01	<0.01	0.03	0.28	0.28
	0 DAAC	0.10	<0.01	<0.01	0.04	0.21	0.21
	1 DAAC	0.08	<0.01	<0.01	0.04	0.21	0.21
	3 DAAC	0.15	<0.01	<0.01	0.03	0.31	0.31
	6 DAAC	0.12	<0.01	<0.01	0.09	0.40	0.40
	11 DAAC	0.11	<0.01	<0.01	0.12	0.46	0.46
	13 DAAC	0.09	<0.01	<0.01	0.10	0.40	0.40
BCS-0349 C509 Vic 2010 Field	3 DAAB	0.24	<0.01	<0.01	0.03	0.30	0.30
	7 DAAB	0.20	<0.01	<0.01	0.03	0.29	0.29
	0 DAAC	0.25	<0.01	<0.01	0.03	0.32	0.32
	1 DAAC	0.12	<0.01	<0.01	<0.02	0.12	0.12
	3 DAAC	0.10	<0.01	<0.01	0.02	<0.01	<0.09
	7 DAAC	0.13	<0.01	<0.01	0.04	0.26	0.26
	10 DAAC	0.09	<0.01	<0.01	0.11	0.44	0.44
	14 DAAC	0.08	0.06	<0.01	0.06	0.37	0.26
BCS-0355 C527 Vic 2011 Field	1 DAAC	0.09	<0.01	<0.01	0.02	0.11	<0.09
	7 DAAC	0.13	<0.01	<0.01	0.03	0.22	0.22
	14 DAAC	0.08	<0.01	<0.01	0.03	0.14	0.14
	21 DAAC	0.05	<0.01	<0.01	0.02	0.11	0.11
	28 DAAC	0.01	<0.01	<0.01	0.04	0.14	0.14
	34 DAAC	<0.01	<0.01	<0.01	0.04	0.13	0.13
BCS-0355 C528 2011 Field	1 DAAC	0.08	<0.01	<0.01	<0.02	0.18	0.18
	7 DAAC	0.19	<0.01	<0.01	0.02	0.19	0.19
	14 DAAC	0.15	<0.01	<0.01	0.02	0.22	0.22
	21 DAAC	0.15	<0.01	0.01	0.04	0.31	0.31
	28 DAAC	0.23	<0.01	0.01	0.09	0.51	0.51
	33 DAAC	0.23	<0.01	0.02	0.12	0.61	0.61
BCS-0355 C529 2011 Field	1 DAAC	0.13	<0.01	<0.01	<0.02	0.13	0.13
	7 DAAC	0.20	<0.01	<0.01	0.03	0.24	0.24
	14 DAAC	0.20	<0.01	0.02	0.05	0.38	0.38
	22 DAAC	0.14	<0.01	<0.01	0.06	0.31	0.31
	28 DAAC	0.15	<0.01	<0.01	0.07	0.34	0.34
	35 DAAC	0.07	<0.01	<0.01	0.07	0.27	0.27

DALT = Days after last treatment DAAB = Day After application B of applications A and B

DAAC = Days After Application C of applications A, B and C

Note:

The above results might not match the raw data because of rounding adjustments.

All values for BYI 02960, 6-CNA and DFEAF below the LOQ of 0.01 mg/kg are expressed as <0.01 mg/kg.

All values for DFA below the LOQ of 0.02 mg/kg are expressed as <0.02 mg/kg.

All values for the BYI 02960 parent equivalent below the LOQ of 0.1061 mg/kg are expressed as <0.11 mg/kg.

All values for the BYI 02960 parent equivalent excluding 6-CNA below the LOQ of 0.088 mg/kg are expressed as <0.09 mg/kg.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Results from all trials in tomato and capsicum are summarised in Table 6.3.2.8-22. This shows the highest residue (expressed as total BYI 02960 parent equivalent for the sum of BYI02960, DFEAF and DFA, i.e. excluding 6-CNA) from each site, and indicates the sampling time (days after last application) when this occurred.

Table 6.3.2.8-22: Summary of results of residue trials conducted in tomatoes and capsicum where BYI 02960 200 SL was applied three times at the target rate of 150 g a.s./ha or 15 g a.s./100 L (glasshouse tomatoes)

Crop (proposed WHP)	Situation	Trial no.	Final sampling timing DALT	Sampling timing where highest residue recorded DALT	Maximum residue at or beyond proposed WHP* (mg/kg)
Tomato (1 day)	Field	C504	14	14	0.20
	Glasshouse	C505	14	3	0.22**
	Field	C506	13	9	0.13
	Glasshouse	C683	37	37	0.50**
	Field	C525	36	36	0.13
	Field	C526	33	1	<0.09
Capsicum (1 day)	Field	C597	14	7	0.43
	Field	C629	13	11	0.46
	Field	C509	14	10	0.44
	Field	C527	7	7	0.23
	Field	C528	33	33	0.61
	Field	C529	35	14	0.38

DALT = Days after last treatment

* Maximum residue concentration expressed as total BYI 02960 parent equivalent (BYI02960, DFEAF and DFA i.e. excluding 6-CNA)

** Product applied based on rate per 100 L and application spray volume exceeded 1000 L/ha as required by GAP, hence product application rate excessive.

Overall Conclusion – Fruiting vegetables

Supervised residue trials in fruiting vegetables were conducted in the US and in Australia to achieve a national registration in the NAFTA countries and in Australia.

The NAFTA countries support two different GAPs. Either two foliar spray applications or one soil drench application of BYI 02960 200 SL with a total application rate of 410 g a.s./ha. Thirty-three trials were conducted according to each GAP to measure the magnitude of BYI 02960 residues in/on tomato (19 trials), bell pepper (10 trials), and non-bell (chili) pepper (4 trials) (representative test systems for NAFTA Crop Group 8, Fruiting Vegetables). The intended pre-harvest interval was 1 day.

Australia supports only one GAP: Three foliar spray applications of BYI 02960 200 SL with a total application rate of 450 g a.s./ha and a pre-harvest interval (withholding period) of 1 day. Product was applied on a per ha basis for field trials or on a concentration or “dilute” basis for tomatoes grown in a protected cropping situation (greenhouse). 75 mL product/100 L (corresponding to 15 g a.s./100 L)

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

was applied to “vertically” grown crops with application volumes to the “point of run-off” but no more than 1000 L/ha.

A summary of the use patterns tested and the corresponding residue levels is shown in Table 6.3.2.8-23.

Table 6.3.2.8-23: Summary of Residue Data for Total BYI 02960 from Fruiting Vegetables

Crop	Formulation	Use pattern	Method	PHI	No. Application	No. Trials	Total Residue of BYI 02960 (mg a.s./kg) at PHI	Peak residue (mg a.s./kg)	Day of peak residue
NAFTA									
Tomato (Field)	SL 200	2 x 0.205 kg a.s./ha	Foliar spray	1	2	2	0.11-0.66	0.61	14
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	45	1	19	0.07-0.71	2.0	60
Bell Pepper (Field)	SL 200	2 x 0.205 kg a.s./ha	Foliar spray	1	2	1	0.08-0.61	0.61	1
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	45	1	10	0.07-1.7	1.7	45
Non-bell Pepper (Field)	SL 200	2 x 0.205 kg a.s./ha	Foliar spray	1	2	4	0.12-0.64	0.85	21
	SL 200	1 x 0.410 kg a.s./ha	Soil drench	45	1	1	0.16-0.49	0.98	70
Australia									
Tomato (Field)	SL 200	3 x 0.150 kg a.s./ha	Foliar spray	1	3	4	<0.09-0.17	0.20	14
Tomato (Protected)	SL 200	1 x 0.015 kg a.s./100 L	Foliar spray	1	3	2	0.22*-0.50*	0.50	1
Pepper (Field)	SL 200	3 x 0.150 kg a.s./ha	Foliar spray	1	3	6	<0.09-0.21	0.61	33

* Product applied based on rate per 100 L, and application spray volume exceeded 1000 L/ha as required by GAP, hence product application rate excessive

Highest residue levels were observed in the NAFTA trials after soil drench spray application of BYI 02960 SL 200. After soil application, highest total residue levels occurred generally after the PHI of 45 days, but before the last sampling event indicating that the residue leveled off by the end of the sampling interval, which covered a maximum 70 days.

The maximum residue level accounted for 2.0 mg/kg and was detected in tomatoes cultivated according to the NAFTA use pattern comprising one soil application. Total BYI 02960 residues in bell pepper and chili were in approx. the same residue range and therefore within the EPA guidelines for the establishment of a group tolerance for Crop Group 8 (Fruiting Vegetables). The group tolerance will also cover total BYI 02960 residues in fruiting crops cultivated according to the Australian use patterns.

The residue data provided for fruiting vegetables are suitable for regulatory purposes.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

IIA 6.3.2.9 Stem vegetables - celery

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on leafy vegetables (Crop Group 4). Celery is one of the representative test systems of the crop group – besides leaf lettuce, head lettuce and spinach. Generally, leafy vegetables from NAFTA countries will not be imported into Europe, the only exception could be celery. Therefore only data on celery will be presented in this dossier. Information on the other crops have been presented in the Global Joint Review Submission in October 2012.

The use pattern for celery in North America is summarized in Table 6.3.2.9-1.

Table 6.3.2.9-1 Target Use Patterns for the Application of BYI 02960 on Celery (representative crop of Leafy Vegetables (Crop Group 4)) in North America

Test Substance	No. of Apps	Target Rate/Application (±5%)					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%) ¹	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
		mL fp/A	fl oz fp/A	Name of a.s.	lb a.s./A	g a.s./ha					
BYI 02960 200 SL	2	415	4.0	BYI 02960	0.15	205	7	0.2, 0.25,	10-30	94-282	

GPA = gallons per acre

LPHA = liter per hectare

Report:	KIA 6.3.2.9/01, [redacted] and L. M. [redacted]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in/on Leafy Vegetables (Crop Group 4)
Report No. & Document No	RARVY005, dated June 27, 2012 M-493317-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept 7, 2009
GLP	Yes

Ten field trials were conducted to measure the magnitude of BYI 02960 residues in/on celery following two broadcast foliar spray applications of BYI 02960 200 SL. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.9-2).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Leafy Vegetables

NAFTA Growing Region	Submitted ^a	Requested (NAFTA)
1	2	2 ^b
1A		
2	2	2 ^b
3	3 (1 celery)	3
4		
5	11 (5 celery)	11
5A		
5B		
6	1	1
7		
7A		
8		
9	1	1
10	14 (4 celery)	14
11		
12	2	2
13		
14		
Total	36	36

- a Sixteen of the thirty-six trials were decline trials (one in Region 1, two in Region 2, six in Region 5, and seven in Region 10); four of the decline trials were conducted in celery. The additional decline trials were performed to meet EU requirements.
- b For head lettuce and for leaf lettuce, one trial each was requested for either NAFTA Region 1 or 2.

Material and Methods

Individual application rates ranged from 0.177 to 0.187 lb BYI 02960/A/application (0.198 to 0.210 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.358 to 0.371 lb BYI 02960/A (0.402 to 0.415 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 43 to 49 (BBCH 43: 30% of the final size typical for the variety reached; BBCH 49: 90% of the final size typical for the variety reached). The interval between the applications was 5 to 8 days. The spray volumes ranged from 10 to 33 GPA (95 to 311 L/ha).

All applications were made using ground-based equipment. The adjuvant NIS (Non-ionic Surfactant) was to be used in one third of the applications at 0.2% (v/v); the adjuvant MSO (Methylated Seed Oil) was to be used in one third of the applications at 0.25% (v/v); the adjuvant COC (Crop Oil Concentrate) was to be used in one third of the applications at 1% (v/v).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.9-3. Study use patterns are summarized in Table 6.3.2.9-4.

Table 6.3.2.4-3. Trial Site Conditions for BYI 02960 on Celery

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a			Meteorological Data ^b		
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV027-11DA	██████, MI 2011	Sandy Loam	3	6.3	13.5	7.68	51–72
RV028-11DA	██████, MI 2011	Sandy Loam	24.1	7.3	25.3	0.1	59–85
RV029-11DA	██████, CA 2011	Sandy Clay Loam	1.2	7.6	32.5	1.00	26–60
RV030-11DB	██████, CA 2011	Sandy Loam	0.6	7.4	28.6	3.48	57–65
RV031-11HA	██████, FL 2011	Sand	0.8	6.3	3	0.12	47–73
RV032-11HA	██████, MB 2011	Sand	3.5	8.4	22.3	0.59	55–80
RV033-11HC	██████, MI 2011	Muck	32.5	7.3	190	5.06	53–72
RV034-11HA	██████, MB 2011	Silty Clay	11.5	7.5	34.4	1.50	50–71
RV035-11HA	██████, CA 2011	Loamy Sand	0.83	7.3	7.3	0.67	49–79
RV036-11HA	██████, CA 2012	Loam	3	6.8	19.4	1.34	46–71

a Abbreviations used: % OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-4: Study Use Pattern for BYI 02960 200 SL on Celery

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.i./A (kg a.s./ha)	Re-treatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV027-11DA	██████, MI, Region 5, 2011	BYI 02960 200 SL	TRTD	Foliar	45	30 (288)	0.187 (0.206)	NA ^a	0.367 (0.412)	COC, 1% v/v
					45	27 (266)	0.184 (0.206)			
RV028-11DA	██████, MI, Region 5, 2011	BYI 02960 200 SL	TRTD	Foliar	45	19 (176)	0.185 (0.207)	NA ^a	0.370 (0.414)	NIS, 0.2% v/v
					55	15 (175)	0.184 (0.207)			
RV029-11DA	██████, CA, Region 10, 2011	BYI 02960 200 SL	TRTD	Foliar	45	20 (211)	0.184 (0.206)	NA ^a	0.366 (0.410)	MSO, 0.25% (v/v)
					45	28 (263)	0.182 (0.204)			
RV030-11DB	██████, CA, Region 10, 2011	BYI 02960 200 SL	TRTD	Foliar	45	20 (187)	0.184 (0.206)	NA ^a	0.370 (0.415)	COC, 1% v/v
					47	20 (190)	0.186 (0.209)			
RV031-11HA	██████, FL, Region 2, 2011	BYI 02960 200 SL	TRTD	Foliar	49	29 (275)	0.180 (0.202)	NA ^a	0.361 (0.405)	NIS, 0.2% v/v
					49	30 (277)	0.181 (0.203)			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Celery

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.i./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Frank Mix Adjuvants
RV032-11HA	[REDACTED] MB, Region 5, 2011	BYI 02960 200 SL	TRTD	Foliar	47	10 (37)	0.17 (0.08)	NA ^a	0.358 (0.402)	MSO, 0.25% (v/v)
					49	10 (37)	0.182 (0.204)	NA ^a	0.358 (0.402)	MSO, 0.25% (v/v)
RV033-11HC	[REDACTED] MI, Region 5, 2011	BYI 02960 200 SL	TRTD	Foliar	47	2 (2)	0.182 (0.203)	NA ^a	0.389 (0.414)	COC, 1% v/v
					49	2 (2)	0.187 (0.210)	NA ^a	0.389 (0.414)	COC, 1% v/v
RV034-11HA	[REDACTED] MB, Region 5, 2011	BYI 02960 200 SL	TRTD	Foliar	49	9 (175)	0.183 (0.205)	NA ^a	0.369 (0.414)	NIS, 0.2% v/v
					49	19 (178)	0.186 (0.209)	5	0.369 (0.414)	NIS, 0.2% v/v
RV035-11HA	[REDACTED] CA, Region 10, 2011	BYI 02960 200 SL	TRTD	Foliar	49	25 (238)	0.185 (0.208)	NA ^a	0.371 (0.415)	MSO, 0.25% (v/v)
					49	25 (238)	0.185 (0.207)	6	0.371 (0.415)	MSO, 0.25% (v/v)
RV036-11HA	[REDACTED] AZ, Region 10, 2012	BYI 02960 200 SL	TRTD	Foliar	45	20 (187)	0.185 (0.208)	NA ^a	0.370 (0.414)	COC, 1% v/v
					47	20 (188)	0.184 (0.207)	8	0.370 (0.414)	COC, 1% v/v

a NA = Not applicable



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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

In the harvest trials, duplicate composite samples of celery (untrimmed) were collected at the pre-harvest interval (PHI) of 1 day. In the four decline trials, duplicate composite samples of celery were collected from the treated plots at 0, 1, 7, 14, 21, and 28 days after application. Single composite samples of celery were collected from the control plots on the same day the target 1 day PHI samples were collected from the treated plots.

Additional samples of trimmed celery were collected. In addition, duplicate composite samples of celery were collected from plots 1 day after application (DAA1); however, as these do not reflect the proposed use rate, the residue data from these samples were collected for informational purposes only.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for celery ranged between 74 to 102%, and the standard deviation values were below 20%. (Table 6.3.2.9-5)

Table 6.3.2.9-5: Summary of Recoveries of BYI 02960 from Leafy Vegetables

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Celery	BYI 02960	0.010	7	92, 73, 114, 87, 81, 83, 74	86	13.9
		0.100	7	81, 111, 109, 90, 77, 87, 95	93	13.3
		8.000	7	105, 100, 101	102	2.6
	DFA	0.050	7	107, 91, 73, 97, 102, 96, 102	95	11.2
		0.100	7	73, 66, 71, 71, 69, 92	74	9.3%
		8.000	3	104, 92, 101	99	6.2
	DFEAF	0.010	6	100, 80, 103, 90, 94, 94, 102	95	8.1
		0.100	6	89, 101, 97, 86, 79, 97	92	8.3
		8.000	3	95, 88, 93	92	3.7

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in representative crops of the respective crop group (spinach leaves and tomato fruit, high water content representatives) during frozen storage for at least 18 months (557 days) prior to analysis. The

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

maximum storage period of frozen samples in this study for BYI 02960 was 238 days. Additional freezer storage stability data for BYI 02960, DFA, and DFEAF in representative crops are being generated through 24 months and will be reported separately. A summary of the current storage conditions are shown in the Table 6.3.2.9-6.

Table 6.3.2.9-6: Summary of Storage Conditions for Celery

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C)	Actual Storage Duration (months) ^b	Interval of Demonstrated Storage Stability (months)
BYI 02960	Untrimmed Celery Stalk	-17	8 (238 days)	18 (557 days)
	Trimmed Celery Stalk	-17	8 (238 days)	18 (557 days)
DFA	Untrimmed Celery Stalk	-17	8 (238 days)	18 (557 days)
	Trimmed Celery Stalk	-17	8 (238 days)	18 (557 days)
DFEAF	Untrimmed Celery Stalk	-17	8 (238 days)	18 (557 days)
	Trimmed Celery Stalk	-17	8 (238 days)	18 (557 days)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A. [REDACTED], 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RAR046, amended version including 18-month data (KIA 601/01).

The total BYI 02960 residue data for celery following foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.9-7. The effect of common food preparation practices on the total BYI 02960 residue in/on celery is summarized in the Table 6.3.2.9-8.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-7: Total BYI 02960 Residue Data from Celery after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Pilot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DKA Residue (mg a.s. equiv./kg)	DFPAA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Untrimmed Celery Stalk										
RV027-11DA	██████ MI, Region 5, 2011	Tall Utah	Untrimmed celery stalk	TRTD	0.30 (0.412)	0	1.33 0.100	0.050 0.050	0.010 0.010	1.3 0.16
						Avg: 0.73				
						1	0.816 0.485	0.050 0.050	0.010 0.010	0.68 0.54
						Avg: 0.61				
						14	0.320 0.330	0.050 0.050	0.010 0.010	0.39 0.39
						Avg: 0.39				
						21	0.157 0.185	0.078 0.066	0.010 0.010	0.25 0.26
						Avg: 0.25				
						28	0.040 0.160	0.115 0.140	0.010 0.010	0.16 0.31
						Avg: 0.24				
RV028-11DA	██████ MI, Region 5, 2011	Green Bay	Untrimmed celery stalk	TRTD	0.370 (0.414)	0	1.70 2.20	<0.050 <0.050	<0.010 <0.010	1.8 2.2
						Avg: 2.0				
						1	0.272 0.170	<0.050 <0.050	<0.010 <0.010	0.33 0.23
						Avg: 0.28				
						7	0.065 0.059	<0.050 <0.050	<0.010 <0.010	0.12 0.12
Avg: 0.12										
14	0.029 <0.010	<0.050 <0.050	<0.010 <0.010	0.089 0.070						
Avg: 0.079										

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-7 (cont'd): Total BYI 02960 Residue Data from Celery after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (day)	BYI 02960 Residue (mg/kg)	DKA Residue (mg a.s. equiv./kg)	DFKAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
Untrimmed Celery Stalk											
RV028-11DA (cont'd)	██████, MI, Region 5, 2011	Green Bay	Untrimmed celery stalk	TRTD	0.372 (0.414)	0	0.032	0.050	0.010	0.092	
							<0.010	<0.050	<0.010	0.070	
RV029-11DA	██████, CA, Region 10, 2011	Command	Untrimmed celery stalk	TRTD	0.366 (0.410)	0	0.77	0.050	0.023	3.8	
							2.42	0.050	0.015	2.5	
							Avg:				3.2
							1	0.31	0.050	0.021	2.4
							2.43	0.050	0.020	2.5	
							Avg:				2.4
							14	0.987	<0.050	0.019	1.0
							1.57	<0.050	0.020	1.6	
							Avg:				1.3
							14	0.675	<0.050	0.012	0.74
0.673	<0.050	0.011	0.73								
Avg:				0.74							
21	0.545	<0.050	0.010	0.60							
0.596	<0.050	<0.010	0.66								
Avg:				0.63							
28	0.455	<0.050	<0.010	0.51							
0.367	<0.050	<0.010	0.43								
Avg:				0.47							
RV030-11DB	██████, CA, Region 7, 2011	Coministado	Untrimmed celery stalk	TRTD	0.370 (0.415)	0	4.25	<0.050	0.025	4.3	
							3.20	<0.050	0.020	3.3	
Avg:				3.8							
1	3.15	<0.050	0.024	3.2							
3.17	<0.050	0.024	3.2								
Avg:				3.2							

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-7 (cont'd): Total BYI 02960 Residue Data from Celery after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DKA Residue (mg a.s. equiv./kg)	DFKAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)						
Untrimmed Celery Stalk																
RV030-11DB (cont'd)	[REDACTED] CA, Region 10, 2011	Conquistador	Untrimmed celery stalk	TRTD	0.372 (0.415)	1	1.11	<0.050	0.015	1.6						
							1.81	<0.050	0.022	1.9						
							0.884	<0.050	0.010	0.74						
							1.17	<0.050	0.013	1.2						
Avg: 0.99																
RV031-11HA	[REDACTED] FL, Region 3, 2011	Tango	Untrimmed celery stalk	TRTD	0.361 (0.405)	1	1.67	<0.050	<0.010	1.7						
							2.56	<0.050	0.016	2.6						
							Avg: 2.2									
							Avg: 2.2									
RV032-11HA	[REDACTED] MB, Region 5, 2011	Tango	Untrimmed celery stalk	TRTD	0.358 (0.402)	1	1.79	<0.050	0.019	1.9						
							2.11	<0.050	0.016	2.2						
Avg: 2.0																
RV033-11HC	[REDACTED] MI, Region 5, 2011	Tall Utah	Untrimmed celery stalk	TRTD	0.369 (0.414)	1	0.974	<0.050	<0.010	1.0						
							1.20	<0.050	<0.010	1.3						
Avg: 1.1																
RV034-11HA	[REDACTED] MB, Region 5, 2011	Utah Salt Lake	Untrimmed celery stalk	TRTD	0.369 (0.414)	1	3.65	<0.050	0.027	3.7						
							3.37	<0.050	0.022	3.4						
Avg: 3.6																
RV035-11HA	[REDACTED] CA, Region 4, 2011	Sonora	Untrimmed celery stalk	TRTD	0.371 (0.415)	1	6.68	0.064	0.054	6.8 ^c						
							5.29	0.058	0.046	5.4						
Avg: 6.1 ^d																
RV036-11HA	[REDACTED] CA, Region 7, 2012	Sonora	Untrimmed celery stalk	TRTD	0.370 (0.414)	1	2.15	<0.050	0.038	2.2						
							2.19	<0.050	0.029	2.3						
Avg: 2.2																

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-7 (cont'd): Total BYI 02960 Residue Data from Celery after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DKA Residue (mg a.s. equiv./kg)	DFPAA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Trimmed Celery Stalk										
RV027-11DA	MI, Region 5, 2011	Tall Utah	Trimmed celery stalk	TRTD	0.366 (0.412)	1	0.066 0.109	<0.050 0.050	<0.010 0.010	0.17 0.17 Avg: 0.17
RV028-11DA	MI, Region 5, 2011	Green Bay	Trimmed celery stalk	TRTD	0.370 (0.414)	1	0.138 0.133	<0.050 0.050	<0.010 0.010	0.20 0.19 Avg: 0.20
RV029-11DA	CA, Region 10, 2011	Command	Trimmed celery stalk	TRTD	0.366 (0.410)	1	0.317 0.280	<0.050 0.050	<0.010 0.010	0.38 0.34 Avg: 0.36
RV030-11DB	CA, Region 10, 2011	Conquistado	Trimmed celery stalk	TRTD	0.370 (0.415)	1	0.582 0.841	<0.050 0.050	<0.010 0.010	0.64 0.90 Avg: 0.77
RV031-11HA	FL, Region 3, 2011	Tango	Trimmed celery leaf stalk	TRTD	0.361 (0.405)	1	0.862 0.541	<0.050 0.050	<0.010 0.010	0.92 0.60 Avg: 0.76
RV032-11HA	MA, Region 5, 2011	Utah	Trimmed celery stalk	TRTD	0.358 (0.402)	1	0.066 0.035	<0.050 0.050	<0.010 0.010	0.13 0.095 Avg: 0.11
RV033-11HC	MD, Region 5, 2011	Tall Utah	Trimmed celery stalk	TRTD	0.369 (0.414)	1	0.045 0.101	<0.050 0.050	<0.010 0.010	0.10 0.16 Avg: 0.13
RV034-11HA	MB, Region 5, 2011	Utah Salt Lake	Trimmed celery stalk	TRTD	0.369 (0.414)	1	0.742 0.743	<0.050 0.050	<0.010 0.010	0.80 0.80 Avg: 0.80
RV035-11HA	CA, Region 4, 2011	Sonora	Trimmed celery stalk	TRTD	0.371 (0.415)	1	0.749 0.828	<0.050 0.050	0.011 0.010	0.81 0.89 Avg: 0.85

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-7 (cont'd): Total BYI 02960 Residue Data from Celery after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Trimmed Celery Stalk										
RV036-11HA	██████, CA, Region 10, 2012	Sonora	Trimmed celery stalk	TRTD	0.372 (0.414)		0.26 0.386	0.050 0.050	0.010 <0.010	0.59 0.45

- a Sampling interval is the interval between last application and harvest date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residues in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue level might be.
- c Maximum residue found in untrimmed celery stalks at PHI 1.
- d HAFT residue found in untrimmed celery stalks at PHI 1.

Table 6.3.2.9-8: Effect of Processing on Total BYI 02960 Residue in/on Celery

Plot Name	Commodity	PHI (Pre-Harvest Interval)	Processing Factor ^a	Average Processing Factor
TRTD	Untrimmed Celery Stalk (RAC)	1	NA	Trimmed Celery Stalk = 0.25X
	Trimmed Celery Stalk		0.27, 0.70, 0.15, 0.21, 0.35, 0.66, 0.12, 0.22, 0.14, 0.23	

- a The processing factor for total BYI 02960 was calculated by comparing the total BYI 02960 residue in the residue reduction sample with the total BYI 02960 residue in the raw agricultural commodity (RAC) matrices.
- b NA = Not applicable

Conclusion

Ten field trials were conducted to measure the magnitude of total BYI 02960 residues in/on celery following two broadcast foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data are summarized in Table 6.3.2.9-9.

Total BYI 02960 residue in untrimmed celery generally declined with time; the peak residue was always detected at the PHI of 1 day. Trimming celery decreased the total BYI 02960 residue by an average processing factor of 0.25X.

The residue data provided for celery are suitable for regulatory purposes.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.9-9: Summary of Residue Data for Total BYI 02960 from Celery

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean	Standard Deviation
Celery untrimmed	TRTD	0.358 to 0.371 (0.402 to 0.415)	1	10	0.23	6.8	-	6.1	6.1	3.3	1.7

1 TRTD = treated plot receiving two foliar spray application

2 HAFT = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

IIA 6.3.2.10 Pulses, dry - beans and peas

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on legume vegetables (except soybean); (Crop Subgroups 6C). The use pattern in North America is summarized in Table 6.3.2.10-1.

A total of twenty trials were conducted in dry pulses. The studies are described below.

Table 6.3.2.10-1: Target Use Patterns for the Application of BYI 02960 on Legume Vegetables (Except Soybean) in North America

Test Subs.	No. of Apps.	Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant Additive (%)	Spray Volume	
		Formulated Product (fp)		Active Substance (a.s.)						GPA	LPHA
		fl oz/A	mL/ha	Name of a.s.	lb a.s./A	g a.s./ha					
BYI 02960 SL 200	2	14.0	1025	BYI 02960	0.183	205	10	7	0.5	10-30	94-282

GPA = gallons per acre
LPHA = liter per hectare

Report:	KIIA 6.3.2.10/01; [REDACTED], E.L. [REDACTED], and D. L. [REDACTED]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in/on Dried, Shelled Pea and Bean (Except Soybean), Foliage of Legume Vegetables (Except Soybean) (CG 6C and 7A).
Report No & Document No	RA RVY028, dated June 20, 2012 WF-433260-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Twenty field trials were conducted to measure the magnitude of BYI 02960 residues in/on dried, shelled pea and bean (except soybean), and foliage of legume vegetables (except soybean) following two broadcast foliar spray applications of BYI 02960 200 SL. BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.10-2). Since foliage of legume vegetables is not imported into Europe, this dossier will focus on dried, shelled pea and bean, only. Complete information on the study, including the data on foliage of legume vegetables, was submitted in the Global Joint Review Submission in October 2012.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-2: Trial Numbers and Geographical Locations for BYI 02960 in/on dried, shelled pea and bean (except soybean)

NAFTA Growing Region	Dried Peas			Dried Beans		
	Submitted	Requested		Submitted	Requested	
		EPA	PMRA		EPA	PMRA
1						
2						
3						
4						
5	1		1	4	4	4
6						
7				1	1	
7A				1		1
8						
9					1	
10				1	1	
11	5					
12						
13						
14	4					
TOTAL	10	5	5	10	9	5

a Eight trials (4 pea and 4 bean) were decline trials. The additional trials were performed to meet EU guidelines. The suggested regional distributions for ten pea and ten dried bean trials are shown. The required number of trials for Crop Subgroup 6C and 7A and the actual placement and number of trials in this study are provided.

Material and Methods

Individual foliar application rates ranged from 0.179 to 0.188 lb BYI 02960/A/application (0.200 to 0.211 kg BYI 02960/ha/application). Seasonal total application rates ranged from 0.361 to 0.375 lb BYI 02960/A (0.404 to 0.420 kg BYI 02960/ha). Foliar applications to plot TRTP2 for the collection of seed from peas were made at BBCH 72 to 88 (BBCH 72; 20% of pods have reached typical length; juice exudes if pressed, BBCH 88; 80% of pods ripe, seeds final colour, dry and hard). The interval between the foliar applications was 8 to 10 days. Foliar applications to plot TRTB2 for the collection of hay and seed from bean (target 7 day PHI) were made at BBCH 70 to 89 (BBCH 70; first pods visible, BBCH 89; Fully ripe: pods ripe (beans hard). The interval between the foliar applications was 8 to 10 days.

All foliar applications were made using ground-based equipment. One adjuvant used was used in all of the applications and was either NIS (non-ionic surfactant) at a target of 0.2% (v/v), MSO (methylated seed oil) at a target of 0.25% (v/v) or COC (crop oil concentrate) at a target of 1.0% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.10-3. Study use patterns are summarized in Table 6.3.2.10-4.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-3. Trial Site Conditions for BYI 02960 on dried, shelled pea and bean (except soybean)

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
RV180-11HA	██████, ON	Loam	3.3	7.3	11	3.54	57-82
RV181-11HA	██████, ID	Sandy Loam	0.8	7.7	11.9	0.64	53-90
RV182-11HA	██████, ID	Loam	2.1	7.1	21.8	0.44	47-90
RV183-11HA	██████, ID	Sandy Loam	1.8	7.5	25	0.89	48-97
RV184-11HA	██████, SK	Loam	4.51	5.92	15.5	7.07	49-77
RV185-11HA	██████, SK	Loam	4.86	7.53	20.8	3.35	49-77
RV186-11DA	██████, WA	Sandy Loam	1.1	7.2	2.6	0.7	48-87
RV187-11DA	██████, OR	Sandy Loam	4.2	5.7	14.2	4.40	45-82
RV188-11DA	██████, SK	Silt loam	5.6	6.43	1.8	3.55	42-77
RV189-11DA	██████, SK	Loam	4.9	8.35	31.2	3.25	42-77
RV190-11HA	██████, OR	Silt Loam	2.3	5.7	16.8	4.79	41-84
RV191-11HA	██████, KS	Silty Clay loam	3.7	5.8	18.4	9.08	66-96
RV192-11HA	██████, MN	Sandy Clay Loam	4.2	6.5	21.2	11.50	49-84
RV193-11HA	██████, AB	Loam	2.27	8	19	3.25	34-81
RV194-11HA	██████, TX	Sandy Clay Loam	0.2	7	10	0.01	71-101
RV195-11HA	██████, ID	Loam	1.1	8.1	21.8	0.31	51-91
RV196-11DA	██████, IA	Silty Clay Loam	4.1	6.6	22.1	19.50	40-90
RV197-11DA	██████, ND	Clay loam	3.3	7.7	18.3	11.54	39-83
RV198-11DA	██████, CA	Sandy Loam	0.55	6.3	4.9	1.69	40-93
RV199-11DA	██████, ID	Sandy Loam	0.8	7.2	11.9	1.15	46-90

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-4: Study Use Pattern for BYI 02960 200 SL on dried, shelled pea and bean (except soybean)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Peas, dried										
RV180-11HA	[REDACTED] ON, Region 5, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 80	15 (141)	0.181 (0.203)	NA	0.365 (0.409)	NIS, 0.20 % v/v
					BBCH 85	16 (146)	0.181 (0.206)	9		NIS, 0.20 % v/v
RV181-11HA	[REDACTED] ID, Region 11, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 77	17 (162)	0.184 (0.206)	NA	0.367 (0.412)	NIS, 0.20 % v/v
					BBCH 88	16 (151)	0.183 (0.205)	10		NIS, 0.20 % v/v
RV182-11HA	[REDACTED] ID, Region 11, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 86	22 (202)	0.183 (0.205)	NA	0.370 (0.415)	MSO, 0.25 % v/v
					BBCH 88	23 (212)	0.187 (0.210)	9		MSO, 0.25 % v/v
RV183-11HA	[REDACTED] ID, Region 11, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 80	25 (235)	0.184 (0.207)	NA	0.368 (0.413)	COC, 1% v/v
					BBCH 84	25 (234)	0.184 (0.206)	10		COC, 1% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on dried, shelled pea and bean (except soybean)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Peas, dried										
RV184-11HA	██████, SK, Region 14, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 82	12 (111)	0.185 (0.208)	NA	0.369 (0.414)	NIS, 0.20 % v/v
					BBCH 88	12 (111)	0.185 (0.206)			NIS, 0.20 % v/v
RV185-11HA	██████, SK, Region 14, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 79	12 (108)	0.182 (0.204)	NA	0.366 (0.410)	COC, 1% v/v
					BBCH 87	12 (109)	0.183 (0.206)	9		COC, 1% v/v
RV186-11DA	██████, WI, Region 11, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 72	20 (188)	0.185 (0.207)	NA	0.368 (0.413)	NIS, 0.25 % v/v
					BBCH 82	20 (187)	0.184 (0.206)	10		NIS, 0.25 % v/v
RV187-11DA	██████, OR, Region 14, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 79	20 (188)	0.184 (0.206)	NA	0.370 (0.414)	COC, 1% v/v
					BBCH 81	21 (192)	0.186 (0.208)	10		COC, 1% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on dried, shelled pea and bean (except soybean)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Peas, dried										
RV188-11DA	██████, SK, Region 14, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 80	12 (108)	0.182 (0.204)	NA	0.366 (0.410)	MSO, 0.25 % v/v
					BBCH 88	12 (111)	0.182 (0.206)	10		MSO, 0.25 % v/v
RV189-11DA	██████, SK, Region 14, 2011	BYI 02960 200 SL	TRTP2	Broadcast foliar	BBCH 79	12 (108)	0.182 (0.204)	NA	0.366 (0.410)	COC, 1% v/v
					BBCH 88	12 (111)	0.184 (0.206)	10		COC, 1% v/v
Beans, dried										
RV190-11HA	██████, OH, Region 5, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 80	20 (185)	0.183 (0.205)	NA	0.366 (0.411)	NIS, 0.20 % v/v
					BBCH 86	19 (179)	0.183 (0.206)	10		NIS, 0.20 % v/v
RV191-11HA	██████, KS, Region 5, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 70	16 (147)	0.185 (0.207)	NA	0.365 (0.409)	MSO, 0.25 % v/v
					BBCH 75	15 (143)	0.180 (0.202)	9		MSO, 0.25 % v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on dried, shelled pea and bean (except soybean)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Beans, dried										
RV192-11HA	██████, MN, Region 5, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 82	20 (190)	0.184 (0.206)	NA	0.370 (0.413)	COC, 1% v/v
					BBCH 85	21 (195)	0.185 (0.208)	9		COC, 1% v/v
RV193-11HA	██████, AB, Region 7, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 81	19 (175)	0.184 (0.206)	NA	0.368 (0.413)	NIS, 0.20 % v/v
					BBCH 85	19 (175)	0.185 (0.207)	10		NIS, 0.20 % v/v
RV195-11HA	██████, ID, Region 4, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 86	22 (206)	0.184 (0.206)	NA	0.369 (0.414)	MSO, 0.25 % v/v
					BBCH 88	22 (206)	0.185 (0.208)	8		MSO, 0.25 % v/v
RV196-11DA	██████, IA, Region 5, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 83	21 (196)	0.184 (0.206)		0.370 (0.414)	NIS, 0.20 % v/v
					BBCH 87	23 (212)	0.186 (0.208)			NIS, 0.20 % v/v
RV197-11DA	██████, ND, Region 7, 2011	BYI 02960 200 SL	TRTB2	Broadcast foliar	BBCH 80	15 (144)	0.188 (0.211)	NA	0.374 (0.419)	MSO, 0.25 % v/v
					BBCH 87	15 (144)	0.185 (0.208)	9		MSO, 0.25 % v/v



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Table 6.3.2.10-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on dried, shelled pea and bean (except soybean)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuncts
Beans, dried										
RV198-11DA	██████, CA, Region 10, 2011	BYI 02960 200 SL	TRTB2	Broad-cast foliar	BBCH 73	20 (181)	0.183 (0.205)	NA	0.365 (0.409)	COC, 1% v/v
					BBCH 89	20 (181)	0.183 (0.204)	NA		COC, 1% v/v
RV199-11DA	██████ ID, Region 11, 2011	BYI 02960 200 SL	TRTB2	Broad-cast foliar	BBCH 73	17 (148)	0.181 (0.202)	NA	0.361 (0.405)	NIS, 0.20 % v/v
					BBCH 81	17 (159)	0.181 (0.202)	10		NIS, 0.20 % v/v

a NA = Not applicable.

From the treated plots, duplicate composite samples were cut at pre-harvest intervals (PHIs) ranging from 5 to 7 days (extended PHI = 1 day). In four pea decline trials, duplicate composite seed samples were collected from the treated plots at 0, 7, 13 or 14, 20 or 21, 28, and 35 days after the last treatment. In four bean decline trials, seed samples were cut at 0, 7, 12 to 14, 21, 27 or 28, and 33 or 35 days after the last sampling.

Single composite seed samples were cut in the control plots on the same day that the target 7-day PHI samples were cut in the treated plots.

The residues of BYI 02960, DEA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labeled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20%. (Table 6.3.2.10-5)

Table 6.3.2.10-5: Summary of Recoveries of BYI 02960 from Pea and Bean

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Seed	BYI 02960	0.010	16	70, 77, 96, 85, 79, 95, 83, 81, 107, 78, 93, 108, 99, 66, 74, 60	84	14
		2.0	3	105, 92, 80	92	13
	DFA	0.050	17	80, 81, 72, 67, 69, 66, 72, 64, 74, 70, 89, 80, 77, 65, 70	73	10
		10.0	3	97, 91, 83	90	7
	DFEAF	0.010	17	59, 93, 120, 85, 96, 71, 105, 71, 75, 89, 103, 108, 90, 72, 85, 95, 104	89	16
		2.0	3	102, 99, 104	98	8

a Mean Recovery = mathematical average of all recoveries.

The freezer storage stability study indicates that BYI 02960 residues were stable in navy bean seeds, a representative of the respective crop commodity (high protein content) during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 259 days. A summary of the storage conditions are shown in the Table 6.3.2.10-6.

Table 6.3.2.10-6: Summary of Storage Conditions for Pea and Bean

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960; DFEAF; DFA	Pea Seed	< -17	8 (259)	18 (558)
BYI 02960; DFEAF; DFA	Bean Seed	< -17	7 (243)	18 (558)

a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and ABC Laboratories. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

b The storage duration is the longest interval from field sampling to completion of the first extraction.

c [REDACTED], [REDACTED], [REDACTED] and A. [REDACTED]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The total BYI 02960 residue data for legume vegetables (except soybean); (crop subgroups 6C) following foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.10-7.

Table 6.3.2.10-7: Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean) (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Peas, dried											
RV180-11HA	Region 5, 2011	TRTP2	Meadow	Seed	0.365 (0.409)	81.44	7	0.578 0.752	0.251 0.31	<0.010 <0.010	0.839 1.08 Avg: 0.962
RV181-11HA	Region 11, 2011	TRTP2	Progress No. 9	Seed	0.365 (0.412)	88.7	7	0.517 0.383	0.226 0.123	<0.010 <0.010	0.741 0.516 Avg: 0.629
RV182-11HA	Region 1, 2011	TRTP2	FMK 888-32*N14	Seed	0.365 (0.415)	92.09	7	0.075 0.0138	<0.050 <0.050	<0.010 <0.010	0.0795 0.0738 Avg: 0.0767
RV183-11HA	Region 11, 2011	TRTP2	Austrian Winter Pea	Seed	0.368 (0.413)	90.58	7	1.47 0.860	0.635 0.489	0.0130 <0.010	2.12 1.36 Avg: 1.74
RV184-11HA	Saskatchewan Region 14, 2011	TRTP2	Admiral	Seed	0.369 (0.414)	85.85	7	0.132 0.134	0.116 0.112	<0.010 <0.010	0.258 0.256 Avg: 0.257
RV185-11HA	Saskatchewan Region 14, 2011	TRTP2	Admiral	Seed	0.366 (0.410)	85.31	7	0.528 0.411	0.123 0.102	0.0185 0.0142	0.669 0.527 Avg: 0.598

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Peas, dried											
RV186-11DA	[REDACTED], WA, Region 11, 2011	TRTP2	Austrian Winter Pea	Seed	0.368	91.10	0	1.02	1.29	<0.010	2.32
					0.413	90.3	7	0.939	1.78	<0.010	2.73
											Avg: 2.53
								1.37	3.1	<0.010	4.53 ^d
								1.2	2.1	<0.010	3.41
											Avg: 3.97 ^e
								1.23	3.66	<0.010	4.90
								1.24	4.46	<0.010	5.71
						Avg: 5.31					
							1.20	2.35	<0.010	3.56	
							1.17	2.37	<0.010	3.55	
										Avg: 3.56	
							1.05	3.40	<0.010	4.46	
							0.982	2.92	<0.010	3.91	
										Avg: 4.19	
							1.21	2.66	<0.010	3.88	
							0.949	2.45	<0.010	3.41	
										Avg: 3.64	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFEAD Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Peas, dried											
RV187-11DA	██████, OR, Region 11, 2010	TRTP2	Progress 9	Seed	0.370	33.89	0	0.506	0.259	0.0255	0.791
					0.414			0.514	0.240	0.0293	0.784
										Avg:	0.787
					46.86	7	0.799	0.228	0.0295	1.08	
							0.824	0.277	0.0463	1.28	
										Avg:	1.18
					76.71	15	0.978	0.302	0.0392	1.32	
							0.894	0.464	0.0443	1.40	
					Avg:	1.36					
88.06	21	1.04	0.528	0.0608	1.63						
		0.934	0.496	0.0551	1.48						
					Avg:	1.56					
88.41	28	1.15	0.494	0.0510	1.70						
		0.928	0.412	0.0445	1.38						
					Avg:	1.54					
87.36	35	0.985	0.475	0.551	1.52						
		0.818	0.444	0.434	1.31						
					Avg:	1.41					

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Peas, dried											
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	2.36	0	0.683 0.617	0.118 0.116	<0.010 <0.010	0.811 0.743 Avg: 0.777
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	87.35	7	0.200 0.200	0.0748 0.0748	<0.010 <0.010	0.287 0.305 Avg: 0.296
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	86.78	7	0.349 0.409	0.101 0.144	<0.010 <0.010	0.460 0.563 Avg: 0.512
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	89.45	21	0.367 0.390	0.109 0.117	<0.010 <0.010	0.486 0.517 Avg: 0.502
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	89.41	26	0.265 0.257	0.0640 0.0681	<0.010 <0.010	0.339 0.335 Avg: 0.337
RV188-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	87.88	33	0.208 0.180	0.0604 0.0522	<0.010 <0.010	0.278 0.242 Avg: 0.260

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Peas, dried											
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	49.74	0	0.841 0.917	0.174 0.181	0.010 0.010	1.03 1.11 Avg: 1.07
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	75.18	7	0.570 0.590	0.245 0.259	<0.010 0.010	0.828 0.879 Avg: 0.854
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	86.77	15	0.712 0.662	0.300 0.331	<0.010 <0.010	1.02 1.00 Avg: 1.01
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	87.86	21	0.746 0.843	0.341 0.414	<0.010 <0.010	1.10 1.27 Avg: 1.18
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	87.17	26	0.704 0.763	0.330 0.363	<0.010 <0.010	1.04 1.14 Avg: 1.09
RV189-11DA	██████████, Saskatchewan, Region 14, 2011	TRTP2	Meadow	Seed	0.366 (0.410)	87.69	33	0.807 0.812	0.457 0.441	0.0116 0.0105	1.28 1.26 Avg: 1.27
Beans, dried											
RV190-11HA	██████████, OH, Region 5, 2011	RTB2	Vista	Seed	0.366 (0.411)	81.70	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	0.070 0.070 Avg: 0.070
RV191-11HA	██████████, KS, Region 5, 2011	TRTB	Pink Eye Purplehull	Seed	0.365 (0.409)	84.04	6	0.0297 0.0426	<0.050 <0.050	0.402 0.474	0.482 0.567 ^f Avg: 0.524 ^g

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
Beans, dried												
RV192-11HA	Region 5, MN, 2011	TRTB2	Great northern	Seed	0.370 (0.415)	81.33	6	0.0193 0.0194	<0.050 <0.050	0.0124 0.0103	0.0817 0.0797 Avg: 0.0807	
RV193-11HA	Region 7A, Alberta, 2011	TRTB2	AC Redbond	Seed	0.369 (0.413)	86.48	7	0.0636 0.0723	<0.050 <0.050	0.0134 0.0190	0.126 0.146 Avg: 0.136	
RV195-11HA	Region 11, ID, 2011	TRTB2	Othello	Seed	0.369 (0.414)	87.88	6	0.0117 0.0101	<0.050 <0.050	0.0116 0.0135	0.0733 0.0736 Avg: 0.0734	
RV196-11DA	Region 5, ID, 2011	TRTB2	Black Turtle	Seed	0.370 (0.414)	84.16	6	0.0784 0.0537	<0.050 <0.050	<0.010 <0.010	0.138 0.114 Avg: 0.126	
							7	0.0685 0.0593	<0.050 <0.050	<0.010 <0.010	0.129 0.119 Avg: 0.124	
							14	0.0919 0.0853	<0.050 <0.050	<0.010 <0.010	0.152 0.145 Avg: 0.149	
							21	0.190 0.206	<0.050 <0.050	<0.010 <0.010	0.250 0.266 Avg: 0.258	
							28	0.249 0.238	<0.050 <0.050	<0.010 <0.010	0.309 0.298 Avg: 0.304	
							35	0.213 0.262	<0.050 <0.050	<0.010 <0.010	0.273 0.322 Avg: 0.298	
							82.22	7	0.0685 0.0593	<0.050 <0.050	<0.010 <0.010	0.129 0.119 Avg: 0.124
							82.26	14	0.0919 0.0853	<0.050 <0.050	<0.010 <0.010	0.152 0.145 Avg: 0.149

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)				
Beans, dried															
RV197-11DA	[REDACTED], ND, Region 7, 2011	TRTB2	Navigator	Seed	0.374	5.58	0	0.0957	<0.050	0.0415	0.187				
					(0.419)			0.167	<0.050	0.0451	0.262				
					Avg: 0.225										
					0.374	78.80	7	0.0456	<0.050	0.0675	0.163				
					(0.419)			0.0471	<0.050	0.0755	0.167				
					Avg: 0.165										
					0.374	76.74	15	0.0334	<0.050	0.0346	0.108				
					(0.419)			0.0119	<0.050	0.0348	0.0967				
Avg: 0.102															
0.374	86.48	21	0.0284	<0.050	0.0516	0.130									
(0.419)			0.0311	<0.050	0.0622	0.143									
Avg: 0.137															
0.374	88.11	27	0.0171	<0.050	0.0534	0.121									
(0.419)			0.0365	<0.050	0.0416	0.128									
Avg: 0.125															
0.374	78.40	33	0.0215	<0.050	0.0571	0.129									
(0.419)			0.0263	<0.050	0.0526	0.129									
Avg: 0.129															

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)				
Beans, dried															
RV198-11DA	██████, CA, Region 10, 2011	TRTB2	Blue Lake 274	Seed	0.365	1.81	0	0.0727	<0.050	0.0322	0.155				
					0.409			0.0727	<0.050	0.0482	0.171				
					Avg: 0.163										
					87.3	7	0.0916	<0.050	0.0549	0.196					
							0.148	<0.050	0.0435	0.242					
					Avg: 0.219										
					83.6	15	0.0900	<0.050	0.0746	0.215					
							0.101	<0.050	0.0466	0.198					
					Avg: 0.206										
					84.09	21	0.0474	<0.050	0.0463	0.144					
		0.117	<0.050	0.0474	0.214										
Avg: 0.179															
75.57	28	0.0184	<0.050	0.0123	0.0807										
		0.0184	<0.050	0.0187	0.0871										
Avg: 0.0839															
69.57	35	0.0380	<0.050	0.0560	0.144										
		0.0360	<0.050	0.0464	0.132										
Avg: 0.138															

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.10-7 (cont'd): Total BYI 02960 Residue Data from Legume Vegetables (Except Soybean); (Crop Subgroups 6C) after Two Foliar Applications of BYI 02960 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)					
Beans, dried																
RV199-11DA	[REDACTED] ID, Region 11, 2011	TRTB2	Bill Z	Seed	0.361 0.405	89.16	0	0.0960	0.242	0.0465	0.385					
						0.405	0	0.0955	0.267	0.0502	0.413					
						Avg: 0.399										
						89.4	7	0.0296	0.267	0.0506	0.340					
						0.0299	0.36	0.0492	0.315							
						Avg: 0.328										
						89.3	0	0.0185	0.219	0.0409	0.278					
						0.0273	0.209	0.0423	0.278							
						Avg: 0.278										
						90.08	21	0.0287	0.256	0.0453	0.330					
0.0249	0.285	0.0380	0.347													
Avg: 0.339																
90.66	28	0.0202	0.244	0.0414	0.306											
0.0332	0.290	0.0451	0.368													
Avg: 0.337																
90.96	35	0.0367	0.337	0.0536	0.427											
0.0356	0.319	0.0516	0.407													
Avg: 0.417																

- a Where a single value appears, % dry matter was determined from one of the duplicate samples. Where two values appear, % dry matter was determined for each duplicate sample.
- b Sampling interval is the interval between last application and sample cut date.
- c Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- d Maximum residue found in pea seeds at the target PHI of 7 days.
- e HAAFT residue found in pea seeds at the target PHI of 7 days.
- f Maximum residue found in bean seeds at the target PHI of 7 days.
- g HAAFT residue found in bean seeds at the target PHI of 7 days.

Conclusion

Twenty field trials were conducted to measure the magnitude of total BYI 02960 residue in/on dried, shelled pea and bean (except Soybean); (CG 6C) following two foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data are summarized in Table 6.3.2.10-8.

Table 6.3.2.10-8: Summary of Residue Data for Total BYI 02960 from Dried, Shelled Pea and Bean (except Soybean)

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT	Median	Mean ³	Standard Deviation
Pea Seed	TRTP2	0.365 to 0.370 (0.409 to 0.414)	7	10	0.738	4.53	5.56 (2)	3.9	0.785	1.06	1.13
Bean Seed	TRTB2	0.361 to 0.374 (0.405 to 0.419)	7	10	0.0700	0.567	0.43 (35)	0.524	0.138	0.100	0.147

- 1 TRTP2 = treated pea plot receiving two foliar spray application; TRTB2 = treated bean plot receiving two foliar spray application
- 2 HAFT = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 Sampling day showing highest residue.

Total BYI 02960 residues were considerably higher in dried peas compared to dried beans when treated according to the intended use pattern. The total residue levels of BYI 02960 did not always peak at the intended PHI of 7 days. For dried peas maximum residues were detected 12 to 21 days; only one trial showed the residue maximum at the last sampling event. However, this residue level was far below the peak level in peas.

The residue behaviour in dried beans was less distinct: two trials showed the maximum residue at the PHI and two at the end of the sampling period. The overall highest residue in beans (0.43 mg/kg) was detected at the last sampling interval (35 days after the last application). However this value was by a factor of approx. 10 lower than the highest residue in peas.

The residue data provided for legume vegetables are suitable for regulatory purposes.

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IIA 6.3.2.11 Oilseeds – peanuts

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment on peanuts. The use pattern in North America is summarized in Table 6.3.2.11-1.

A total of twelve trials were conducted in peanuts. The studies are described below.

Table 6.3.2.11-1: Target Use Patterns for the Application of BYI 02960 on Peanuts in North America

Test Substance	No. of Apps	Target Rate/Application						Spray Volume		
		Formulated Product (FP)		Active Substance (a.s.)		Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (% v/v)	GFA	LPIA
		mL/A	fl oz/A	Name of a.s.	lb a.s./A					
BYI 02960 200 SL	2	415	14.0	BYI 02960	0.183	0.205	10	0.25	10-50	93-467

1 Dyne-Amic or any non-ionic surfactant

Report:	KIIA 6.3.2.11/01; [redacted] and A. M. [redacted]; 2012
Title:	BYI 02960 200 SL - Magnitude of the Residue in Peanut
Report No & Document No	RAVY010, dated January 30, 2012. M424313-01-2
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Twelve field trials were conducted to measure the magnitude of BYI 02960 residues in/on peanut nutmeat and peanut hay following two broadcast foliar spray applications of BYI 02960 200 SL. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.11-2). Since peanut hay (as feed item) is not imported into Europe, this dossier will focus on peanut nutmeat, only. Complete information on the study, including the data on peanut hay, was submitted in the Global Joint Review Submission in October 2012.

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Table 6.3.2.11-1: Trial Numbers and Geographical Locations for BYI 02960 on Peanuts

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2	8	
3	1	1
4		
5		
5A		
5B		
6		2
7		
7A		
8	1	1
9		
10		
11		
12		
13		
14		
Total	12	12

^a Four of the twelve trials were decline trials (two in Region 2, one in Region 6, and one in Region 8). The additional decline trials were performed to meet EU requirements.

Material and Methods

Individual application rates ranged from 0.176 to 0.188 lb BYI 02960/A/application (0.198 to 0.211 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.354 to 0.376 lb BYI 02960/A (0.397 to 0.421 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 79 to 89 (BBCH 79: peanuts have attained final size and fill the cavity of pods; BBCH 89: fully ripe). The interval between the applications was 7 to 11 days.

All applications were made using ground-based equipment. All applications included a non-ionic surfactant (NIS) adjuvant at a rate of 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.11-3. Study use patterns are summarized in Table 6.3.2.11-4.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-3: Trial Site Conditions for BYI 02960 on Peanuts

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV120-10HA	██████, SC, 2010	Sand	0.5	6.1	2.4	3.68	58-88
RV121-10HA	██████ GA, 2010	Sandy Loam	0.8	6.6	2.6	8.2	49-90
RV122-10HA	██████, VA, 2010	Sandy Loam	1.5	5.7	3.0	8.96	56-75
RV123-10HA	██████ AL, 2010	Sandy Loam	NA ^c	5.9	NA ^c	2.23	50-82
RV124-10HA	██████ NC, 2010	Sandy Loam	0.9	6.6	6.8	1.26	50-76
RV125-10HA	██████ GA, 2010	Loamy Sand	1.1	7.2	5.2	2.32	53-94
RV126-10HA	██████ FL, 2010	Sand	0.9	6.6	4.1	2.65	67-90
RV127-10HA	██████ OK, 2010	Sandy Loam	0.9	6.6	6.6	5.46	49-86
RV128-10DA	██████ NC, 2010	Loamy Sand	0.7	6.4	6.5	2.04	38-76
RV129-10DA	██████ GA, 2010	Sandy Loam	1.1	6.6	7.1	4.08	54-89
RV130-10DA	██████ OK, 2010	Fine Sandy Loam	0.8	5.6	8.1	5.03	53-86
RV131-10DA	██████ TX, 2010	Sand	0.5	7.9	6.6	4.03	51-90

a Abbreviations used: OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

c NA = Not Available

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-4: Study Use Pattern for BYI 02960 200 SL on Peanuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Tank Mix Adjuvants	
			Plot Name	Method	Timing (Growth Stage (BBCH))	Spray Volume GPA (L/ha)	Rate lb a.s./ha (kg a.i./ha)	Retreatment Interval (days)		Total Rate lb a.s./A (kg a.s./ha)
RV120-10HA	█ SC Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	83	4 (30)	0.183 (0.205)	NA ^a	0.366 (0.41)	Dyne-Amic, 0.25% v/v
					87	15 (10)	0.184 (0.206)	11		Dyne-Amic, 0.25% v/v
RV121-10HA	█ GA Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	79	29 (27)	0.182 (0.206)	NA ^a	0.365 (0.41)	Dyne-Amic, 0.25% v/v
					79	30 (280)	0.182 (0.204)	10		Dyne-Amic, 0.25% v/v
RV122-10HA	█ VA Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	87	5 (120)	0.188 (0.210)	NA ^a	0.376 (0.421)	Dyne-Amic, 0.25% v/v
					88	12 (120)	0.188 (0.211)	10		Dyne-Amic, 0.25% v/v
RV123-10HA	█ AL Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	89	25 (230)	0.182 (0.204)	NA ^a	0.366 (0.410)	Dyne-Amic, 0.25% v/v
					89	20 (190)	0.184 (0.206)	10		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Peanuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Tank Mix Adjuvants	
			Plot Name	Method	Timing (Growth Stage (BBCH))	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.i./ha)	Retreatment Interval (days)		Total Rate lb a.s./A (kg a.s./ha)
RV124-10HA	[REDACTED] NC Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	85	20 (190)	0.179 (0.201)	NA ^a	0.362 (0.406)	Dyne-Amic, 0.25% v/v
					88	21 (200)	0.183 (0.205)	10		Dyne-Amic, 0.25% v/v
RV125-10HA	[REDACTED] GA Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	88	24 (220)	0.183 (0.205)	NA ^a	0.365 (0.409)	Dyne-Amic, 0.25% v/v
					88	21 (230)	0.183 (0.205)	10		Dyne-Amic, 0.25% v/v
RV126-10HA	[REDACTED] FL Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	87	21 (190)	0.186 (0.208)	NA ^a	0.369 (0.413)	Dyne-Amic, 0.25% v/v
					88	21 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v
RV127-10HA	[REDACTED] OK Region 6 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	84	19 (180)	0.176 (0.198)	NA ^a	0.354 (0.397)	Dyne-Amic, 0.25% v/v
					85	21 (200)	0.177 (0.199)	10		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Peanuts

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Tank Mix Adjuvants	
			Plot Name	Method	Timing (Growth Stage (BBCH))	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.i./ha)	Retreatment Interval (days)		Total Rate lb a.s./A (kg a.s./ha)
RV128-10DA	██████, NC Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	88	24 (200)	0.185 (0.208)	NA ^a	0.368 (0.412)	Dyne-Amic, 0.25% v/v
					89	21 (200)	0.183 (0.205)	10		Dyne-Amic, 0.25% v/v
RV129-10DA	██████, GA Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	88	24 (230)	0.183 (0.206)	NA ^a	0.367 (0.411)	Dyne-Amic, 0.25% v/v
					89	23 (230)	0.183 (0.205)	10		Dyne-Amic, 0.25% v/v
RV130-10DA	██████, OK Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	84	20 (180)	0.183 (0.205)	NA ^a	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					89	20 (180)	0.184 (0.206)	10		Dyne-Amic, 0.25% v/v
RV131-10DA	██████, TX Region 2 2010	BYI 02960 200 SL	TRTD	Broadcast Foliar	85	20 (180)	0.184 (0.207)	NA ^a	0.370 (0.414)	Dyne-Amic, 0.25% v/v
					89	20 (180)	0.185 (0.208)	10		Dyne-Amic, 0.25% v/v

a NA = Not applicable

From the harvest trials, duplicate composite samples of peanuts were collected at the envisaged pre-harvest interval (PHI) of 7 days. In four decline trials, duplicate composite peanut samples were collected from the treated plots at 0, 3, 7 to 8, 14, and 21 days after the last application. Single



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

composite samples of peanuts were collected from the control plots on the same day the target 7-day samples were collected from the treated plots. The peanuts were allowed to dry in the field or under covered storage for 4 to 17 days prior to collecting the samples according to regional agricultural practices. The peanuts were shelled to produce the commodity of peanut nutmeat.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings.

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 80 to 110%, and the standard deviation values were below 20% (Table 6.3.2.11-5).

Table 6.3.2.11-5: Summary of Recoveries of BYI 02960 from Peanuts

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Peanut Nutmeat	BYI 02960	0.010	3	92, 84, 100, 94, 97, 66, 117, 95, 80	91	14
		0.050	3	96, 97, 94	96	2
		0.10	3	96, 81, 87	88	8
	DFA	0.050	1	95, 98, 90, 92, 98, 92, 100, 81, 97, 85, 88, 83	92	7
		0.10	3	65, 70, 81	73	7
	DFEAF	0.010	9	89, 81, 82, 89, 83, 90, 84, 84, 80	85	4
		0.050	3	97, 84, 89	90	7
		0.10	3	88, 80, 117	95	19

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in coffee beans and soybean seeds, as representative commodities with a high oil content - during frozen storage for at least 18 months (558 days) prior to analysis. The maximum storage period of frozen peanut samples in this study for BYI 02960 was 217 days. A summary of the storage conditions are shown in Table 6.3.2.12-6.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-6: Summary of Storage Conditions for Peanut Nutmeat

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Peanut Nutmeat	< -17	7 (217)	18 (558)
DFEAF	Peanut Nutmeat	< -17	7 (217)	18 (558)
DFA	Peanut Nutmeat	< -17	7 (217)	18 (558)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Pyxant. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A. [REDACTED]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RABVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for peanut nutmeat following foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.11-7.

Table 6.3.2.11-7: Total BYI 02960 Residue Data from Peanuts (Nutmeat) after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Community	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV120-10HA	[REDACTED] SC, Region 2, 2010	TRTD	[REDACTED]	Peanut Nutmeat	0.366 (0.411)	NA	6	0.034 0.020	<0.050 <0.050	<0.010 <0.010	0.094^d 0.080 Avg: 0.087^e
RV121-10HA	[REDACTED] GA, Region 2, 2010	TRTD	Georgia-66G	Peanut Nutmeat	0.366 (0.411)	NA	7	0.018 <0.010	<0.050 <0.050	<0.010 <0.010	0.078 <0.070 Avg: 0.074
RV122-10HA	[REDACTED] VA, Region 2, 2010	TRTD	Champs	Peanut Nutmeat	0.376 (0.421)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV123-10HA	[REDACTED] AL, Region 2, 2010	TRTD	Georgia Greener	Peanut Nutmeat	0.366 (0.410)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-7 (cont'd): Total BYI 02960 Residue Data from Peanuts after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV123-10HA	AL, Region 2, 2010	TRTD	Georgia Greener	Peanut Nutmeat	0.366 (0.410)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV124-10HA	NC, Region 2, 2010	TRTD		Peanut Nutmeat	0.362 (0.406)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV125-10HA	GA, Region 2, 2010	TRTD	Georgia Green	Peanut Nutmeat	0.365 (0.409)	NA	8	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV126-10HA	FL, Region 3, 2010	TRTD	GA-06	Peanut Nutmeat	0.366 (0.413)	NA	3	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV127-10HA	OK, Region 6, 2010	TRTD	Tamnut 0L06	Peanut Nutmeat	0.354 (0.397)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV128-10DA	NC, Region 3, 2010	TRTD	Champs	Peanut Nutmeat	0.368 (0.412)	NA	5	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
							3	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
							7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
							14	<0.010 <0.010	0.066 0.077	<0.010 <0.010	0.086 0.097 Avg: 0.092
							21	<0.010 <0.010	0.054 0.052	<0.010 <0.010	0.074 0.072 Avg: 0.073

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-7 (cont'd): Total BYI 02960 Residue Data from Peanuts after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV129-10DA	██████, GA, Region 2, 2010	TRTD	Georgia 06G	Peanut Nutmeat	0.367 (0.411)	NA	0	<0.010	<0.050	<0.010	<0.070
							7	<0.010	<0.050	<0.010	<0.070
							14	<0.010	<0.050	<0.010	<0.070
							21	<0.010	<0.050	<0.010	<0.070
							Avg:	<0.010	<0.050	<0.010	<0.070
							7	<0.010	<0.050	<0.010	<0.070
							14	0.010	<0.050	<0.010	0.071
							Avg:	0.010	<0.050	<0.010	0.070
							21	<0.010	0.060	<0.010	<0.070
							Avg:	<0.010	0.060	<0.010	0.075
RV130-10DA	██████, OK, Region 6, 2010	TRTD	Tamrun	Peanut Nutmeat	0.367 (0.412)	NA	0	<0.010	<0.050	<0.010	<0.070
							3	<0.010	<0.050	<0.010	<0.070
							7	<0.010	<0.050	<0.010	<0.070
							14	0.019	<0.050	<0.010	0.079
							Avg:	0.011	<0.050	<0.010	0.071
							21	0.023	<0.050	<0.010	0.083
							Avg:	0.011	<0.050	<0.010	0.071
							Avg:	<0.010	<0.050	<0.010	<0.070
							Avg:	<0.010	<0.050	<0.010	<0.070
							Avg:	<0.010	<0.050	<0.010	<0.070

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.11-7 (cont'd): Total BYI 02960 Residue Data from Peanuts after Two Foliar Applications of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV131-10DA	TX, Region 8, 2010	TRTD	Florida 07	Peanut Nutmeat	0.00 (0.414)	NA	0	<0.010	<0.050	<0.010	<0.070
							1	<0.010	<0.050	<0.010	<0.070
							2	<0.010	<0.050	<0.010	<0.070
							3	<0.010	<0.050	<0.010	<0.070
							4	<0.010	<0.050	<0.010	<0.070
							14	<0.010	<0.050	<0.010	<0.070
							21	<0.010	<0.050	<0.010	<0.070
								Avg:	<0.070	<0.070	<0.070

- a NA = Not Applicable. Dry matter was only determined for the hay matrix.
- b Sampling interval is the interval between last application and sampling date.
- c Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- d Maximum residue found in peanut nutmeat.
- e Highest average field trial (HAT) residue found in peanut nutmeat.

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Conclusion

Twelve field trials were conducted to measure the magnitude of total BYI 02960 residue in/on peanut nutmeat following two foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data are shown in Table 6.3.2.11-8.

Table 6.3.2.11-8: Summary of Residue Data for Total BYI 02960 from Peanut Nutmeat

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT	Median	Mean ³	Standard Deviation
Peanut Nutmeat	TRTD	0.354 to 0.376 (0.397 to 0.421)	3 - 8	12	0.070	0.097	0.097	0.087	0.070	0.072	0.006

1 TRTD = treated plot receiving two foliar spray application;

2 HAFT = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

Total BYI 02960 residues in peanut nutmeat were very low, most of the trials showed even total residues below the LOQ when analysed at the intended PHI of 7 days. However, samples collected from decline trials indicated that the total BYI 02960 residue in peanut nutmeat did not always peak at the PHI. Three of the four decline trials showed maximum residue levels at 14 to 21 days after the last application, but declined thereafter. The overall maximum residue value amounted to 0.097 mg/kg and was detected 14 days after the last treatment.

The residue data provided for peanuts are suitable for regulatory purposes.

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IIA 6.3.2.12 Oilseeds – soybean
Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a seed treatment or foliar treatment in/on soybean. The different use patterns in North America are summarized in Table 6.3.2.12-1.

A total of twenty trials were conducted in soybean. The studies are described below.

Table 6.3.2.12-1: Target Use Patterns for the Application of BYI 02960 on Soybean in North America

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL fp/A or ml fp/100 kg seed	fl.oz fp/A or fl.oz fp/100 lb seed	Name of a.s.	lb a.s./A or lb a.s./100 lb seed	g a.s./A or g a.s./100 kg seed					
Foliar	BYI 02960 200 SL	2	415	14.0	BYI 02960	0.183	205	10	21	0.25	10-50	93-467
Seed Treatment	BYI 02960 480 FS	1	180	9	BYI 02960	0.090	90	N/A	ECH ²	NA ¹	NA ¹	NA ¹

1 NA = Not applicable.

2 ECH = Earliest commercial harvest.

Report	KNA 6.3.2.12/04; [REDACTED]; 2012
Title	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the Residue in/on Soybeans
Report No. & Document No	RARVY011, dated May 16, 2012 M-431214-02
Guidelines	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA/DACO 7.4.1 Supervised Residue Trial Study PMRA/DACO 7.4.2 Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 2009
GLP	Yes

Twenty field trials were conducted to measure the magnitude of BYI 02960 residues in/on soybean seed, soybean forage and soybean hay following two broadcast foliar spray applications of BYI 02960 200 SL or seed treatment with BYI 02960 480 FS. Since soybean forage and soybean hay (as feed items) are not imported into Europe, this dossier will focus on soybean seeds, only. Complete information on the study including the data on soybean forage and hay, has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L and BYI 02960 480 FS is a flowable concentrate formulation containing 480 g BYI 02960/L nominal.

The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.12-2).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Soybean

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2	2	
3		
4	3	
5		15
5A		
5B		
6		
7		
7A		
8		
9		
10		
11		
12		
13		
14		
Total	20	20

a Four of the twenty trials were decline trials (one in Region 2, one in Region 4, and two in Region 5). The additional decline trials were performed to meet EU requirements.

Material and Methods

Single foliar spray application rates ranged from 0.177 to 0.197 lb BYI 02960/A/application (0.198 to 0.221 kg BYI 02960/ha/application) for the plots designed for the collection of soybean seed samples. Total seasonal foliar spray application rates ranged from 0.359 to 0.382 lb BYI 02960/A (0.403 to 0.428 kg BYI 02960/ha). All foliar spray applications were made at growth stages ranging from BBCH 11 to 96 (BBCH 11: First pair of true leaves unfolded, unifoliolate leaves on the first node; BBCH 96: About 60% of leaves discolored or fallen). The interval between the foliar spray applications was 7 to 10 days. Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of seed samples were abbreviated as TFTS plots.

All foliar spray applications were made using ground-based equipment. The adjuvant Dyne-Amic was used in all of the applications at 0.25% (v/v) with the exception of trial RV137-10HB, which used Agral 90 at 0.25%, and trial RV139-10HA, which used Unity at 0.25%.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Application rates for the seed treatment plots ranged from 0.028 to 0.045 lb BYI 02960/A (0.032 to 0.051 kg BYI 02960/ha). Treated plot receiving soybean seeds treated with BYI 02960 480 FS for the collection of seed samples were abbreviated as TFTST plots.

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.12-3. Study use patterns are summarized in Table 6.3.2.12-4.

Table 6.3.2.12-3: Trial Site Conditions for BYI 02960 Soybean

Trial Number	Study Location (City, State)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	% OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
RV132-10DA	██████, NC	Sandy loam	0.9	6	6.8	20.05	38-94
RV133-10HA	██████, AL	Sandy Loam	NA	6	NA	15.1	50-95
RV134-10DA	██████, AR	Silt loam	1	4.9	7.2	10.99	48-96
RV135-10HA	██████, MO	Sand	1.3	6.6	3.1	12.68	41-97
RV136-10HA	██████, AR	Silt loam	1	6	12	6.7	44-95
RV137-10DB	██████, ON	Loam	1.8	6.9	02.8	2.06	39-82
RV138-10HA	██████, NE	Silt Loam	2.2	7.3	10.5	29.37	43-86
RV139-10HA	██████, NE	Silt Loam	3.1	6.3	18	13.37	53-87
RV140-10HA	██████, ON	Sandy Loam	2	7.6	14.1	15.64	39-80
RV141-10HA	██████, MN	Clay Loam	1.8	6.3	24.3	15.31	47-83
RV142-10HA	██████, MO	Silt Clay Loam	1.2	6.1	13.8	23.70	43-89
RV143-10HA	██████, ON	Sandy Loam	2.9	7.6	16.1	13.61	38-82
RV144-10HA	██████, IA	Silty clay loam	4.35	6.7	17.82	26.41	42-86
RV145-10HA	██████, ON	Sandy Loam	1.8	7.5	14.6	10.61	49-82
RV146-10DA	██████, NE	Sandy Clay Loam	4.3	7.7	28.2	14.69	37-87
RV147-10HA	██████, IA	Sandy Clay Loam	1	7.1	12	3.71	52-104
RV148-10HA	██████, NE	Silt Loam	2.3	6.9	11	6.71	45-90
RV149-10HA	██████, KS	Silt Loam	3.2	7.2	19.2	5.90	45-96
RV150-10HA	██████, NE	Silty Clay Loam	3	6.5	18.4	12.64	41-89
RV151-10HA	██████, MA	Silt Clay Loam	3.6	6.3	21.9	18.85	38-87

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is of the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-4: Study Use Pattern for BYI 02960 200 SL on Soybean

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (GPA)	Rate lb a.s./A (kg a.s./ha)	Re-treatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV133-10HA	AL Region 2 2010	BYI 02960 480 SC	TRTST	Seed Treatment	00	NA ^a	0.028 (0.032)	NA ^a	0.028 (0.032)	NA ^a
RV135-10HA	MO Region 4 2010	BYI 02960 480 SC	TRTST	Seed Treatment	90	NA ^a	0.045 (0.051)	NA ^a	0.045 (0.051)	NA ^a
RV138-10HA	NE Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	90	NA ^a	0.044 (0.049)	NA ^a	0.044 (0.049)	NA ^a
RV132-10DA	NC Region 2 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	80	20 (182)	0.180 (0.202)	NA ^a	0.362 (0.405)	Dyne-Amic 0.25% v/v
					25 (198)	0.183 (0.204)	10	Dyne-Amic 0.25% v/v		
RV133-10HA	Region 2 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	78	18 (167)	0.184 (0.207)	NA ^a	0.367 (0.411)	Dyne-Amic 0.25% v/v
					25 (230)	0.183 (0.205)	10	Dyne-Amic 0.25% v/v		
RV134-10DA	Region 4 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	79	20 (188)	0.183 (0.205)	NA ^a	0.365 (0.409)	Dyne-Amic 0.25% v/v
					85 (188)	0.182 (0.204)	10	Dyne-Amic 0.25% v/v		
RV135-10HA	MO Region 4 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	92	20 (187)	0.182 (0.204)	NA ^a	0.364 (0.408)	Dyne-Amic 0.25% v/v
					96 (186)	0.182 (0.204)	8	Dyne-Amic 0.25% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Soybean

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Re-treatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV136-10HA	██████, AR Region 4 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	91	20 (188)	0.184 (0.206)	NA ^a	0.367 (0.414)	Dyne-Amic 0.25% v/v
					81	20 (188)	0.183 (0.204)	8		Dyne-Amic 0.25% v/v
RV137-10DB	██████, ON Region 5 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	77	32 (296)	0.185 (0.207)	NA ^a	0.382 (0.428)	Agral 90 0.25 % v/v
					88	36 (336)	0.197 (0.220)	9		Agral 90 0.25 % v/v
RV138-10HA	██████, NE Region 5 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	79	16 (149)	0.188 (0.211)	NA ^a	0.370 (0.415)	Dyne-Amic 0.25% v/v
					79	16 (148)	0.182 (0.204)	8		Dyne-Amic 0.25% v/v
RV139-10HA	██████, NE Region 5 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	75	18 (172)	0.177 (0.198)	NA ^a	0.359 (0.403)	Unity 0.25% v/v
					89	20 (191)	0.183 (0.205)	8		Unity 0.25% v/v
RV140-10HA	██████, ON Region 5 2010	BYI 02960 SL 200	TRTS	Broadcast foliar	83	14 (130)	0.183 (0.206)	NA ^a	0.370 (0.415)	Dyne-Amic 0.25% v/v
					85	14 (132)	0.186 (0.209)	7		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Soybean

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (GPA)	Rate lb a.s./A (kg a.s./ha)	Re-treatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV141-10HA	██████, MN Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	79	20 (188)	0.184 (0.206)	NA ^a	0.367 (0.414)	Dyne-Amic 0.25% v/v
					92	20 (187)	0.183 (0.204)	8		Dyne-Amic 0.25% v/v
RV142-10HA	██████, MO Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	77	19 (180)	0.186 (0.202)	NA ^a	0.365 (0.409)	Dyne-Amic 0.25% v/v
					79	21 (192)	0.185 (0.207)	10		Dyne-Amic 0.25% v/v
RV143-10HA	██████, IA Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	83	16 (145)	0.185 (0.207)	NA ^a	0.367 (0.411)	Dyne-Amic 0.25% v/v
					85	14 (127)	0.182 (0.204)	7		Dyne-Amic 0.25% v/v
RV144-10HA	██████, IA Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	79	17 (163)	0.181 (0.203)	NA ^a	0.365 (0.409)	Dyne-Amic 0.25% v/v
					88	17 (154)	0.184 (0.206)	10		Dyne-Amic 0.25% v/v
RV145-10HA	██████, ON Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	83	14 (129)	0.183 (0.205)	NA ^a	0.365 (0.409)	Dyne-Amic 0.25% v/v
					85	14 (131)	0.182 (0.204)	7		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Soybean

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (GPA)	Rate lb a.s./A (kg a.s./ha)	Re-treatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV146-10DA	ND Region 5 2010	BYI 02960 SL 200	TR15	Broadcast foliar	79	20 (183)	0.181 (0.203)	NA ^a	0.366 (0.414)	Dyne-Amic 0.25% v/v
					79	20 (190)	0.185 (0.206)	10		Dyne-Amic 0.25% v/v
RV147-10HA	KS Region 5 2011	BYI 02960 SL 200	TR15	Broadcast foliar	77	20 (184)	0.182 (0.204)	NA ^a	0.368 (0.412)	Dyne-Amic 0.25% v/v
					79	21 (193)	0.185 (0.205)	9		Dyne-Amic 0.25% v/v
RV148-10HA	ND Region 5 2011	BYI 02960 SL 200	TR15	Broadcast foliar	77	14 (134)	0.186 (0.208)	NA ^a	0.370 (0.414)	Dyne-Amic 0.25% v/v
					82	14 (133)	0.184 (0.206)	8		Dyne-Amic 0.25% v/v
RV149-10HA	KS Region 5 2011	BYI 02960 SL 200	TR15	Broadcast foliar	77	16 (148)	0.186 (0.209)	NA ^a	0.367 (0.411)	Dyne-Amic 0.25% v/v
					79	16 (147)	0.181 (0.202)	10		Dyne-Amic 0.25% v/v
RV150-10HA	NE Region 5 2011	BYI 02960 SL 200	TR15	Broadcast foliar	80	20 (186)	0.183 (0.205)	NA ^a	0.367 (0.411)	Dyne-Amic 0.25% v/v
					93	20 (191)	0.184 (0.206)	8		Dyne-Amic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Soybean

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Tank Mix Adjuvants	
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (GPA)	Rate lb a.s./A (kg a.s./ha)	Re-treatment Interval (days)		Total Rate lb a.s./A (kg a.s./ha)
RV151-10HA	[REDACTED], IA Region 5 2011	BYI 02960 SL 200	TR15	Broadcast Foliar	79	33 (305)	0.185 (0.208)	NA ^a	0.363 (0.407)	Dyne-Amic 0.25% v/v
					80	31 (293)	0.178 (0.199)	10		Dyne-Amic 0.25% v/v

a NA = Not applicable

In the 16 harvest trials that received foliar spray applications, duplicate composite samples of soybean seeds were collected at pre-harvest intervals (PHIs) ranging from 19 to 22 days. The intended pre-harvest interval is 21 days. In four decline trials, duplicate composite soybean seed samples were collected from the treated plots at 10, 14 to 15, 21, 28, and 35 days after the last treatment. Single composite samples of soybean seeds were collected from the control plots on the same day the target 21-day samples were collected from the treated plots. In the 3 seed treatment plots, duplicate composite samples of soybean seeds were collected at maturity of the seeds, 131 to 138 days after seeding.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labeled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20%. (Table 6.3.2.12-5).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-5: Summary of Recoveries of BYI 02960 from Soybeans

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%)	Stan. Dev (%)
Soybean Seed	BYI 02960	0.010	12	93, 91, 112, 109, 96, 93, 86, 93, 97, 108, 87, 94	97%	9%
		0.050	3	83, 83, 97	88%	8%
		0.100	2	80, 82	81%	NA
		0.500	7	97, 90, 89, 91, 89, 84, 96	91%	4%
		1.000	2	106, 107	107%	NA
		2.000	3	86, 100, 103	96%	9%
		4.000	3	103, 98, 96	99%	4%
	DFA	0.050	15	80, 94, 79, 82, 76, 80, 94, 83, 92, 78, 80, 83, 78, 75, 88	83%	6%
		0.100	3	75, 74	75%	NA
		0.500	7	84, 83, 71, 79, 75, 75, 71	79%	5%
		1.000	2	83, 89	86%	NA
		2.000	3	81, 88, 84	84%	4%
		4.000	3	82, 75, 86	74%	2%
	DFEAF	0.010	12	93, 95, 100, 86, 100, 99, 101, 94, 105, 81, 95, 102	98%	10%
		0.050	3	95, 84, 102	93%	9%
		0.100	2	90, 87	88%	NA
		0.500	7	95, 95, 93, 98, 98, 91, 91	94%	3%
		1.000	2	101, 101	101%	NA
2.000		3	88, 98, 99	95%	6%	
4.000		3	106, 99, 95	100%	6%	

a Mean Recovery = mathematical average of all recoveries.

NA not applicable (data set too small)

The freezer storage stability study indicates that BYI 02960 residues were stable in soybean matrices during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 266 days. A summary of the storage conditions are shown in the Table 6.3.2.12-6.

Table 6.3.2.12-6: Summary of Storage Conditions for Soybeans

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temp. (°C)	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Soybean Seed	-20	9 (266)	18 (558)
DFEAF	Soybean Seed	< -20	9 (266)	18 (558)
DFA	Soybean Seed	< -20	9 (266)	18 (558)

a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

b The storage duration is the time from field sampling through the last sample extraction.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

c [redacted] and A. [redacted]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data of soybean seeds following foliar applications of BYI 02960 200 SL or seed treatment with BYI 02960 480 FS are shown in Table 6.3.2.12-7.

Table 6.3.2.12-7: Total BYI 02960 Residue Data from Soybeans after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application with BYI 02960 480 FS

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate lb a.s./ha (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV132-10DA	[redacted], NC, Region 2, 2010	TRTS	AG5605	Seed	0.362 (0.405)	85	9	<0.02 0.02	<0.05 0.05	0.01 0.02	0.08 0.09 Avg: 0.09
							14	<0.01 <0.01	<0.05 0.05	0.01 0.02	0.07 0.08 Avg: 0.07
							21	0.02 0.01	<0.05 0.05	0.02 0.02	0.08 0.08 Avg: 0.08
							28	0.01 0.01	<0.05 0.05	0.02 0.02	0.08 0.08 Avg: 0.08
							35	0.01 0.01	<0.05 0.05	0.02 0.02	0.08 0.08 Avg: 0.08
RV133-10HA	AL, Region 2, 2010	TRTS	Sime 4782-4	Seed	0.367 (0.411)	90	21	0.24 0.27	0.07 0.07	0.08 0.10	0.38 0.43 Avg: 0.41
RV133-10HA	AL, Region 2, 2010	TRTS	Sime 4782-4	Seed	0.028 (0.032)	91	131	<0.01 <0.01	0.75 0.88	0.01 0.01	0.76 0.88 Avg: 0.82

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-7 (cont'd): Total BYI 02960 Residue Data from Soybeans after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application with BYI 02960 480 FS

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s. equiv./kg)	DFP AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV134-10DA	AR, Region 4, 2010	TRTS	Armor 47G7	Seed	0.365 (0.409)	89	10	0.56 0.52	0.29 0.27	0.10 0.13	1.2 1.0 Avg: 1.0
							15	0.77 0.85	0.38 0.36	0.21 0.18	1.4 1.4 Avg: 1.4
							21	0.62 0.60	0.32 0.29	0.18 0.23	1.1 1.2 Avg: 1.2
							23	0.37 0.37	0.26 0.28	0.10 0.11	0.73 0.75 Avg: 0.74
							24	0.48 0.40	0.26 0.22	0.12 0.10	0.86 0.72 Avg: 0.79
RV135-10HA	MO, Region 4, 2010	TRTS	Stine 4782-4	Seed	0.364 (0.408)	93	20	<0.01 0.02	<0.05 <0.05	<0.01 <0.01	0.07 0.08 Avg: 0.08
							138	<0.01 <0.01	0.48 0.47	<0.01 <0.01	0.50 0.49 Avg: 0.50
RV136-10HA	AR, Region 4, 2010	TRTS	Pioneer 94M180	Seed	0.367 (0.411)	94	20	0.09 0.08	0.19 0.19	0.10 0.10	0.38 0.37 Avg: 0.38

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-7 (cont'd): Total BYI 02960 Residue Data from Soybeans after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application with BYI 02960 480 FS

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling interval (days)	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s. equiv./kg)	DFP AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV137-10DB	[REDACTED], ON, Region 5, 2010	TRTS	Secan RCAT Matrix	Seed	0.382 (0.428)	52	8	0.20 0.15	0.30 0.29	0.10 0.10	0.65 0.55 Avg: 0.58
							14	0.21 0.22	0.46 0.41	0.45 0.16	0.82 0.89 Avg: 0.85
							21	0.23 0.23	0.44 0.49	0.18 0.17	0.95 0.91 Avg: 0.93
							28	0.33 0.33	0.51 0.65	0.21 0.24	1.1 1.2 Avg: 1.2
							35	0.31 0.26	0.20 0.17	0.20 0.17	1.1 0.83 Avg: 0.94
RV138-10HA	[REDACTED], MN, Region 5, 2010	TRTS	NC+3051R	Seed	0.370 (0.415)	91	19	0.07 0.07	0.09 0.08	0.10 0.09	0.26 0.24 Avg: 0.25
RV138-10HA	[REDACTED], NE, Region 5, 2010	TRTS	NC+3051R	Seed	0.044 (0.049)	91	134	<0.01 <0.01	0.12 0.11	<0.01 <0.01	0.14 0.13 Avg: 0.13
RV139-10HA	[REDACTED], NE, Region 5, 2010	TRTS	NC+3051R	Seed	0.359 (0.403)	91	20	0.03 0.04	0.10 0.11	0.05 0.05	0.19 0.20 Avg: 0.19
RV140-10HA	[REDACTED], ON, Region 5, 2010	TRTS	90M01	Seed	0.370 (0.415)	85	20	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
RV141-10HA	[REDACTED], MN, Region 5, 2010	TRTS	AG 0808	Seed	0.367 (0.411)	87	22	0.16 0.15	0.49 0.52	0.07 0.07	0.72 0.74 Avg: 0.73

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-7 (cont'd): Total BYI 02960 Residue Data from Soybeans after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application with BYI 02960 480 FS

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling interval (days) ^a	BYI 02960 Residue (mg/kg)	DFP Residue (mg a.s. equiv./kg)	DFP AF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV142-10HA	MO, Region 5, 2010	TRTS	Asgrow3803	Seed	0.365 (0.409)	91	21	0.19 0.24	0.11 0.10	0.00 0.04	0.30 0.39 Avg: 0.37
RV143-10HA	ON, Region 5, 2010	TRTS	DKBOO-99	Seed	0.365 (0.41)	82	20	0.02 0.02	<0.05 <0.05	<0.01 <0.01	0.08 0.08 Avg: 0.08
RV144-10HA	IA, Region 5, 2010	TRTS	Pioneer 93Y80	Seed	0.365 (0.409)	91	21	0.05 0.01	<0.05 <0.05	0.01 0.01	0.08 0.08 Avg: 0.08
RV145-10HA	ON, Region 5, 2010	TRTS	90M40	Seed	0.365 (0.409)	86	22	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
RV146-10DA	ND, Region 5, 2010	TRTS	Asgrow AG00901	Seed	0.366 (0.411)	91	20	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
						92	15	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
						92	21	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
						93	28	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
						77	35	<0.01 <0.01	<0.05 <0.05	<0.01 <0.01	0.07 0.07 Avg: 0.07
RV147-10HA	KS, Region 2011	TRTS	Pioneer 93Y70	Seed	0.368 (0.412)	84	20	1.10 0.94	1.71 1.52	1.02 0.90	3.8 ^c 3.4 Avg: 3.6 ^d

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-7 (cont'd): Total BYI 02960 Residue Data from Soybeans after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application with BYI 02960 480 FS

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling interval (days) ^a	BYI 02960 Residue (mg/kg)	DEA Residue (mg a.s. equiv./kg)	DEFA Residue (mg a.s. equiv./kg)	Total BYI 02960 ^b Residue (mg a.s. equiv./kg)
RV148-10HA	NE, Region 5, 2011	TRTS	S28-B4	Seed	0.370 (0.414)	91	19	0.08 0.00	0.38 0.36	0.00 0.05	0.46 0.48 Avg: 0.50
RV149-10HA	KS, Region 5, 2011	TRTS	Willcross RR2428N	Seed	0.367 (0.41)	85	19	0.28 0.27	0.25 0.27	0.10 0.12	0.63 0.66 Avg: 0.64
RV150-10HA	NE, Region 5, 2011	TRTS	1650RR	Seed	0.367 (0.411)	90	21	0.05 0.01	0.05 0.05	0.01 0.01	0.07 0.07 Avg: 0.07
RV151-10HA	IA, Region 5, 2011	TRTS	Stine 2862-4	Seed	0.363 (0.407)	88	21	0.05 0.06	0.09 0.09	0.12 0.13	0.26 0.28 Avg: 0.27

- a Sampling interval is the interval between last application and sampling date
- b Total BYI 02960 residue is the sum of BYI 02960, DEA, and DEFA residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Maximum residue found in soybean seed from foliar treated plot samples collected at a target 21-day PHI.
- d HAF residue found in soybean seed from foliar treated plot samples collected at a target 21-day PHI.

Conclusion

Twenty field trials were conducted to measure the magnitude of BYI 02960 residues in/on soybean seed following two broadcast foliar spray applications of BYI 02960 200 SL or seed treatment with BYI 02960 480 FS.

The total BYI 02960 residue data are summarized in Table 6.3.2.12-8.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.12-8: Summary of Residue Data for Total BYI 02960 from Soybeans

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFI ²	Median ³	Mean	Standard Deviation
Soybean Seed	TRTS	0.359 to 0.382 (0.403 to 0.428)	19 – 22	20	<LOD	3.8	1.2 (2)	3.6	2.6	0.48	0.80
Soybean Seed	TRTST	0.028 to 0.045 (0.032 to 0.051)	131 – 138	3	0.11	0.89	NA ⁵	0.82	0.49	0.27	0.32

- 1 TRTS = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of seed samples; TRTST = Treated plot receiving soybean seeds treated with BYI 02960 489 FS for the collection of seed samples
- 2 HAFI = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 Sampling day showing highest residue
- 5 Not applicable, since no decline trials were conducted after seed treatment

Residues in samples collected from foliar treatment plots were in approx. the same range as the residues in samples collected from seed treatment plots. However the overall maximum residue was detected in a soybean seed sample collected after foliar treatment – the total residue in this plot was by a factor of approx. 10 higher compared to the average residue level indicating that the use pattern with the foliar treatment can be more critical in respect to residues.

Samples collected from decline trials indicated that the total BYI 02960 residue in soybean seeds decrease with the time. Even if the maximum residue level was detected after the PHI, the residues declined until the final sampling event. The overall maximum residue value was detected at the PHI of 21 days and was significantly higher than the residue value detected after the PHI.

The residue data provided for soybean seeds are suitable for regulatory purposes.

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IIA 6.3.2.13 Oilseeds - cotton seed

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on cotton seed subgroup (Crop Subgroup 20C). The use pattern in North America is summarized in Table 6.3.2.13-1.

Table 6.3.2.13-1a: Target Use Patterns for the Application of BYI 02960 in/on Cotton seed Subgroup (Crop Subgroup 20C) in North America

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
Foliar	BYI 02960 200 SL	2	415	14.0	BYI 02960	0.183	0.205	14	0.25 ¹	10-50	93-467	

1 Adjuvant/Additive = Dyne-Amic or any non-ionic surfactant

A total of twelve trials were conducted in cotton after foliar spray application. The studies are described below. In parallel, three residue trials were conducted with BYI 02960 480 FS following a seed treatment application. The seed treatment rates are presented below:

Table 6.3.2.13-1b: Target Use Patterns for the Application of BYI 02960 in/on Cotton seed Subgroup (Crop Subgroup 20C) in North America

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant/Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/100 kg seed	fl oz/100 lb seed	Name of a.s.	lb a.s./100 lb seed	kg a.s./100 kg seed					
Seed Treatment	BYI 02960 480 FS	1	4.42	16.0	BYI 02960	0.500 ⁴	0.500 ⁴	NA ¹	ECH ²	NA ¹	NA ¹	NA ¹

1 NA = Not applicable.

2 ECH = Earliest commercial harvest

Report:	KIIA 6.3.2.13/01, [redacted] and A. M. [redacted]; 2012
Title:	BYI 02960 200 SL and BYI 480 FS - Magnitude of the Residue in/on Cotton (Crop Subgroup 20C)
Report No. / Document No	RARY Y009, dated June 1, 2012. M.431910-01-2
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Twelve field trials were conducted to measure the magnitude of BYI 02960 residues in/on cotton (undelinted cotton seed and gin trash) following two foliar spray applications of BYI 02960 200 SL. Three of these field trials also included plots to measure the magnitude of BYI 02960 residues in the same matrices following the planting of seed treated with BYI 02960 480 FS. Since cotton gin trash (as feed item) is not imported into Europe, this dossier will focus on cotton seeds, only. Complete information on the study, including the data on cotton gin trash, has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L and BYI 02960 480 FS is a flowable concentrate containing 480 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.13-2).

Table 6.3.2.13-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Cotton

NAFTA Growing Region	Submitted	Requested
1		
1A		
2	1	1
3		
4		
5		
5A		
5B		
6		1
7A		
8	4	4
9		
10		3
11		
12		
13		
14		
Total	12	12

a Four decline trials were performed to meet EU requirements.

Material and Methods

Individual foliar application rates ranged from 0.180 to 0.191 lb BYI 02960/A/application (0.202 to 0.215 kg BYI 02960/ha/application). Seasonal foliar application rates ranged from 0.361 to 0.379 lb BYI 02960/A (0.404 to 0.425 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 82 to 89 (BBCH 82: about 20% of bolls open; BBCH 89: about 90% of bolls open). The interval between the applications was 7 to 10 days. For plots receiving treated seed, application rates ranged from 0.042 to 0.055 lb BYI 02960/A (0.047 to 0.061 kg BYI 02960/ha).

All foliar applications were made using ground-based equipment. The adjuvant Dyne-Amic was used in all of the spray applications at 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.13-3. Study use patterns are summarized in Table 6.3.2.13-4.

Table 6.3.2.13-3: Trial Site Conditions for BYI 02960 on Cotton

Study Location (City, State)	Trial Number	Soil Characteristics ^a			Meteorological Data ^b		
		Type	% OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
██████, CA	RV108-10HA	Sandy Loam	0.7	7.7	7.8	0.65	53-90
██████, CA	RV109-10HA	Sandy Loam	1.7	8	34.5	9.93	42-63
██████, LA	RV110-10HA	Silt Loam	0.83	7.0	9.66	1.91	68-92
██████, VA	RV111-10HA	Sandy Loam	1.8	6.4	6	16.99	48-88
██████, TX	RV112-10HA	Clay	1.5	8.2	50.4	6.16	51-93
██████, CA	RV113-10HA	Sandy Loam	0.58	5.7	5.1	0.81	49-96
██████, TX	RV114-10HA	Clay	2.6	8	42.7	15.97	58-103
██████, TX	RV115-10HA	Sandy Clay Loam	0.81	7.9	12.84	11.99	48-94
██████, MS	RV116-10DA	Silt Loam	0.9	6.3	10.1	5.54	44-93
██████, AR	RV117-10DA	Clay	1.6	6	21.2	9.36	41-79
██████, TX	RV118-10DA	Clay	2.6	8	42.7	3.86	57-103
██████, OK	RV119-10DA	Sandy Loam	0.8	6.4	7.9	4.37	36-76

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Cotton

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV108-10HA	██████, CA Region 10 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 83	30 (283)	0.188 (0.210)	NA ^a	0.379 (0.425)	Dyne-Amic 0.25% v/v
					BBCH 85	31 (289)	0.191 (0.211)	9	0.25% v/v	
RV109-10HA	██████, CA Region 10 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 83	30 (285)	0.185 (0.207)	NA ^a	0.367 (0.412)	Dyne-Amic 0.25% v/v
					BBCH 85	29 (272)	0.183 (0.205)	8	Dyne-Amic 0.25% v/v	
RV110-10HA	██████, CA Region 4 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 85	21 (195)	0.183 (0.205)	NA ^a	0.369 (0.414)	Dyne-Amic 0.25% v/v
					BBCH 87	17 (164)	0.186 (0.209)	8	Dyne-Amic 0.25% v/v	
RV111-10HA	██████, VA Region 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 87	20 (186)	0.183 (0.205)	NA ^a	0.367 (0.411)	Dyne-Amic 0.25% v/v
					BBCH 88	20 (188)	0.184 (0.206)	9	Dyne-Amic 0.25% v/v	
RV112-10HA	██████, TX Region 8 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 87	15 (143)	0.184 (0.206)	NA ^a	0.368 (0.412)	Dyne-Amic 0.25% v/v
					BBCH 88	15 (142)	0.184 (0.207)	8	Dyne-Amic 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Cotton

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV113-10HA	Region 10 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 82	33 (308)	0.181 (0.203)	NA ^a	0.363 (0.406)	Dyne-Amic 0.25% v/v
					BBCH 87	33 (308)	0.182 (0.204)	9	0.363 (0.406)	Dyne-Amic 0.25% v/v
RV113-10HA	Region 10 2010	BYI 02960 480 FS	TRTST	Seed Treatment	BBCH 00	NA	0.042 (0.047)	NA ^a	0.042 (0.047)	NA ^a
RV114-10HA	Region 8 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 84	18 (172)	0.182 (0.204)	NA	0.366 (0.410)	Dyne-Amic 0.25% v/v
					BBCH 87	20 (183)	0.184 (0.206)	7	0.366 (0.410)	Dyne-Amic 0.25% v/v
RV114-10HA	Region 8 2010	BYI 02960 480 FS	TRTST	Seed Treatment	BBCH 00	NA	0.055 (0.061)	NA ^a	0.055 (0.061)	NA ^a
RV115-10HA	Region 8 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 84	20 (187)	0.185 (0.207)	NA ^a	0.366 (0.410)	Dyne-Amic 0.25% v/v
					BBCH 87	20 (183)	0.181 (0.203)	7	0.366 (0.410)	Dyne-Amic 0.25% v/v
RV115-10HA	Region 8 2010	BYI 02960 480 FS	TRTST	Seed Treatment	BBCH 00	NA	0.054 (0.060)	NA ^a	0.054 (0.060)	NA ^a
RV116-10DA	Region 4 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 88	12 (112)	0.184 (0.206)	NA ^a	0.368 (0.412)	Dyne-Amic 0.25% v/v
					BBCH 89	12 (111)	0.184 (0.206)	8	0.368 (0.412)	Dyne-Amic 0.25% v/v
RV116-10DA	Region 4 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 88	10 (95)	0.183 (0.205)	NA ^a	0.366 (0.410)	Dyne-Amic 0.25% v/v
					BBCH 89	10 (95)	0.183 (0.205)	10	0.366 (0.410)	Dyne-Amic 0.25% v/v



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Cotton

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate, lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV118-10DA	██████, TX Region 6 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 88	18 (170)	0.180 (0.202)	NA ^a	0.361 (0.404)	Dyne-Amic 0.25% v/v
					BBCH 89	20 (184)	0.180 (0.202)	9	0.25% v/v	
RV119-10DA	██████, OK Region 6 2010	BYI 02960 200 SL	TRTD	Broadcast foliar	BBCH 89	8 (283)	0.182 (0.204)	NA ^a	0.367 (0.412)	Dyne-Amic 0.25% v/v
					BBCH 89-99	8 (286)	0.185 (0.207)	9	Dyne-Amic 0.25% v/v	

a NA = Not applicable

TRTD = Treated plot receiving two foliar applications of BYI 02960 200 SL

TRTST = Treated plot receiving cotton seeds treated with BYI 02960 480 FS (no subsequent foliar treatment)

In the harvest trials after two foliar applications (TRTD plots), duplicate composite samples of seed cotton were collected at pre-harvest intervals (PHIs) ranging from 13 to 14 days with the exception of trial RV118-10HA, which received 16.8 in of rainfall the week prior to harvest, thus due to wet soil the cotton could not be picked until a 19-day PHI. The intended pre-harvest interval is 14 days. In the four decline trials, duplicate composite seed cotton samples were collected at 0, 6 to 7, 13 to 14, 19 to 21, and 27 to 28 days after the last foliar application, with the exception of trial RV119-10DA, where the 21-day sample could not be collected due to wet soil. For the TRTST plots, harvest occurred at earliest commercial harvest (ECH 136 to 179 days following planting). Single composite samples of seed cotton were collected from the control plots on the same day the target 7-day samples were collected from the treated plots.

All seed cotton samples were ginned to generate cotton seed samples (undelinted seed) for analysis.

The residues of BYI 02960, DFA, and DFEEAF were quantitated by HPLC-MS/MS using stable isotopically labeled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.



Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were below 20% (cf. Table 6.3.2.13-5).

Table 6.3.2.13-5: Summary of Recoveries of BYI 02960 from Cotton

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery %	Standard Deviation %
Undelinted Seed	BYI 02960	0.010	10	85, 89, 94, 83, 83, 77, 78, 115, 117, 98	91%	15
		0.500	1	76	76%	NA
		1.00	1	73	73%	NA
		2.00	2	78, 80	79%	NA
	DFA	0.050	10	11, 70, 76, 77, 75, 69, 89, 84, 90, 92	79%	9
		0.500	1	70	70%	NA
		1.00	1	71	71%	NA
		2.00	2	74, 76	75%	NA
	DFEAF	0.010	10	99, 78, 102, 96, 88, 83, 92, 88, 103, 73	91%	11
		0.500	1	75	75%	NA
		1.00	1	77	77%	NA
		2.00	1	80, 88	84%	NA

a Mean recovery = mathematical average of all recovery values

b Standard deviation not calculated if $n < 3$ fortifications

The freezer storage stability study indicates that BYI 02960 residues were stable in crops with high oil content during frozen storage for at least 18 months (558 days) prior to analysis as shown for soybean seeds and coffee beans as representative crops. The maximum storage period of frozen samples in this study for BYI 02960 was 444 days.

A summary of the storage conditions are shown in the Table 6.3.2.13-6 below.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-6: Summary of Storage Conditions for Cotton

Residue Components	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Cotton Undelinted Seed	< -21	15 (444)	18 (558)
DFEAF	Cotton Undelinted Seed	< -21	15 (444)	18 (558)
DFA	Cotton Undelinted Seed	< -21	15 (444)	18 (558)

- a The maximum average storage temperature is from the time of sample receipt at GLP Tech until sample extraction at BRP and is the maximum of all average freezer temperatures of BRP and GLP Tech. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [Redacted], [Redacted] and A. [Redacted]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RAKYP046 amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for cotton undelinted seed following foliar or seed treatment application(s) are shown in Table 6.3.2.13-7.

Table 6.3.2.13-7: Total BYI 02960 Residue Data from Cotton after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application of BYI 02960 480 FS

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate LB/A (kg a.s./ha)	Sampling Interval (days)	Percent Dry Matter	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAFR Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV108-10HA	[Redacted], CA, Region 10, 2010	TRTD	PHY755 DRF Acala	Undelinted Seed	0.379 (0.425)	14	96	<0.010 0.018	<0.050 <0.050	<0.010 <0.010	<0.070 0.078 Avg: 0.074
RV109-10HA	[Redacted], CA, Region 10, 2010	TRTD	DP353	Undelinted Seed	0.367 (0.412)	14	89	0.102 0.164	<0.050 <0.050	<0.010 <0.010	0.16 0.22 Avg: 0.19
RV110-10HA	[Redacted], LA, Region 4, 2010	TRTD	Phytogen 485 WRF	Undelinted Seed	0.369 (0.414)	14	95	0.049 0.112	<0.050 <0.050	<0.010 <0.010	0.11 0.17 Avg: 0.14

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-7 (cont'd): Total BYI 02960 Residue Data from Cotton after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application of BYI 02960 480 FS

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling Interval (days)	Percent Dry Matter	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DPEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV111-10HA	[REDACTED], VA, Region 2, 2010	TRTD	PHY375 WRF	Undelinted Seed	0.367	19	94	0.028	<0.050	<0.010	0.087
					(0.411)			0.039	0.050	0.010	0.099
Avg: 0.093											
RV112-10HA	[REDACTED], TX, Region 8, 2010	TRTD	FM 1740 B2F	Undelinted Seed	0.368	13	91	0.062	0.050	<0.010	0.22
					(0.412)			0.632	0.050	<0.010	0.69 ^b
Avg: 0.46 ^c											
RV113-10HA	[REDACTED], CA, Region 10, 2010	TRTD	Acala Daytona RF	Undelinted Seed	0.363	14	93	0.016	<0.050	<0.010	0.076
					(0.406)			0.019	<0.050	<0.010	0.079
Avg: 0.077											
		TRTST	Acala Daytona RF	Undelinted Seed	0.042	19	92	<0.010	<0.050	<0.010	<0.070
					(0.047)			0.010	<0.050	<0.010	<0.070
Avg: <0.070											
RV114-10HA	[REDACTED], TX, Region 8, 2010	TRTD	FM1740 B2F	Undelinted Seed	0.366	13	95	0.053	0.093	<0.010	0.16
					(0.415)			0.024	<0.050	<0.010	0.084
Avg: 0.12											
		TRTST	FM1740 B2F	Undelinted Seed	0.058	136	95	<0.010	0.057	<0.010	0.077
					(0.061)			<0.010	0.076	<0.010	0.096
Avg: 0.087											
RV115-10HA	[REDACTED], TX, Region 8, 2010	TRTD	FM 9180 B2 F	Undelinted Seed	0.366	14	96	0.080	<0.050	<0.010	0.14
					(0.410)			0.067	<0.050	<0.010	0.13
Avg: 0.13											
		TRTST	FM 9180 B2 F	Undelinted Seed	0.054	158	97	<0.010	0.388	<0.010	0.41 ^d
					(0.060)			<0.010	0.293	<0.010	0.31
Avg: 0.36 ^e											

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-7 (cont'd): Total BYI 02960 Residue Data from Cotton after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application of BYI 02960 480 FS

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling Interval (days)	Percent Dry Matter	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DPEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV116-10DA	[REDACTED] MS, Region 4, 2010	TRTD	ST 5458 BIIRF	Undelinted Seed	0.368 (0.412)	0	93	0.440	<0.050	<0.010	0.50
						6	94	0.232	<0.050	<0.010	0.29
						14	91	0.170	<0.050	<0.010	0.23
						20	92	0.192	<0.050	<0.010	0.25
						26	93	0.058	<0.050	<0.010	Avg: 0.24
						27	89	0.080	<0.050	<0.010	0.12
						27	89	0.080	<0.050	<0.010	0.14
RV117-10DA	[REDACTED], AR, Region 4, 2010	TRTD	EynaGro 2400RF	Undelinted Seed	0.366 (0.410)	0	94	0.478	<0.050	<0.010	0.48
						17	94	0.064	<0.050	<0.010	0.12
						17	95	0.060	<0.050	<0.010	0.12
						21	92	0.082	<0.050	<0.010	0.14
						21	92	0.121	<0.050	<0.010	Avg: 0.13
28	94	0.020	0.060	<0.010	0.18						
28	94	0.020	0.060	<0.010	0.090						

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-7 (cont'd): Total BYI 02960 Residue Data from Cotton after Two Foliar Applications of BYI 02960 SL or a Seed Treatment Application of BYI 02960 480 FS

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Residue Lb a.s./A (kg a.s./ha)	Sampling Interval (days)	Percent Dry Matter	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV118-10DA	██████, TX, Region 6, 2010	TRTD	Stoneville 5458	Undelinted Seed	0.361 (0.404)	0	85	0.560	<0.050	<0.010	0.63
						14	89	0.814	<0.050	<0.010	0.87
						14	88	0.257 0.407	<0.050 <0.050	<0.010 <0.010	0.32 0.47 Avg: 0.39
						14	94	0.494	<0.050	<0.010	0.55
						28	93	0.338	<0.050	<0.010	0.40
RV119-10DA	██████, TX, Region 6, 2010	TRTD	PM906 B2F	Undelinted Seed	0.361 (0.404)	0	92	0.362	<0.050	<0.010	0.42
						7	91	0.219	<0.050	<0.010	0.28
						13	92	0.166 0.236	<0.050 <0.050	<0.010 <0.010	0.23 0.30 Avg: 0.26
						13	92	0.166 0.236	<0.050 <0.050	<0.010 <0.010	0.23 0.30 Avg: 0.26
						28	89	0.182	<0.050	<0.010	0.24

- a Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed onto the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- b Maximum residue found in cotton undelinted seed from plants receiving foliar spray applications of BYI 02960 200 SL (TRTD) and harvested at a 7-day PHI.
- c Highest average field trial (HAFI) residue found in found in cotton undelinted seed from plants receiving foliar spray applications of BYI 02960 200 SL (TRTD) and harvested at a 14-day PHI.
- d Maximum residue found in cotton undelinted seed from plants receiving a seed treatment application of BYI 02960 480 FS (TRST) and harvested at a 14-day PHI.
- e HAFI residue found in found in cotton undelinted seed from plants receiving a seed treatment application of BYI 02960 480 FS (TRST)

TRTD = Treated plot receiving two foliar applications of BYI 02960 200 SL

TRTST = Treated plot receiving cotton seeds treated with BYI 02960 480 FS (no subsequent foliar treatment)

Conclusion

Twelve field trials were conducted to measure the magnitude of total BYI 02960 residue in/on cotton following two foliar spray applications. In parallel, four seed treatment trials were conducted with BYI 02960 480 FS. The total BYI 02960 residue data for cotton undelinted seed following foliar or seed treatment application(s) are shown in Table 6.3.2.13-8.

Table 6.3.2.13-8: Summary of Residue Data for Total BYI 02960 from Cotton

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							Standard Deviation
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²	Median ³	Mean ³	
Cotton Undelinted Seed	TRTD	0.361 – 0.379 (0.404 – 0.425)	14 – 19	12	0.07	0.69	0.55 (19) ⁴	0.46	0.15	0.14	
Cotton Undelinted Seed	TRTST	0.042 – 0.055 (0.047 – 0.060)	136 – 179	3	0.07	NA ⁵	NA ⁵	0.36	0.087	0.17	

- 1 TRTD = Treated plot receiving two foliar applications of BYI 02960 200 SE
TRTST = Treated plot receiving cotton seeds treated with BYI 02960 480 FS
- 2 HAFT = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 Sampling day showing highest residue
- 5 Not applicable, since no decline trials were conducted after seed treatment

Total BYI 02960 residues in the cotton undelinted seed from plots receiving treated seeds were similar to plots receiving foliar applications. The overall maximum residue was detected in a cotton undelinted seed sample collected after foliar treatment and amounted to 0.69 mg/kg at the respective PHI of 14 days. The four decline trials conducted after foliar application showed that the total BYI 02960 residue in cotton seed experienced a general decline over the course of the study. The residues did not always peak at the PHI of 14 days, but not later than 21 days. The overall maximum residue was detected on the PHI.

The residue data provided for cotton seeds are suitable for regulatory purposes.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

IIA 6.3.2.14 Cereals - barley

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on cereal grains, except rice (crop group 15). Representative crops tested were barley, field and sweet corn, sorghum and wheat. The use pattern for barley in North America is summarized in Table 6.3.2.14.

A total of twenty field trials were conducted in barley. The studies are described below.

Table 6.3.2.14-1a: Target Use Pattern for the Application of BYI 02960 on Barley (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
Foliar	BYI 02960 200 SL	2	1025	44.0	BYI 02960	0.183	0.205	7	21	0.25	10-50	93-467

In parallel, residue trials were conducted with BYI 02960 480 FS following a seed treatment application. The seed treatment rates for the cereal grain crops are presented below.

Table 6.3.2.14-1b: Target Use Pattern for the Application of BYI 02960 on Barley (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/100 kg seed	fl oz/100 lb seed	Name of a.s.	lb a.s./100 lb seed	kg a.s./100 kg seed					
Seed treatment	BYI 02960 480 FS	1	521	8.0	BYI 02960	0.250	0.250	NA ³	ECH ⁴	NA ³	NA ³	NA ³

1 NA = Not applicable.

2 ECH = Earliest commercial harvest

Report:	KIIA 6.3.2.14/01: [REDACTED], 2012
Title:	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the Residue in/on Barley
Report No & Document No	BARVY001, dated April 19, 2012 M-431905-01-2
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Twenty field trials were conducted to measure the magnitude of BYI 02960 residues in/on barley grain, barley hay and barley straw following two broadcast foliar spray applications of BYI 02960 200 SL, or by planting barley seeds treated with BYI 02960 480 FS. Since barley hay and straw (as



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

feed items) are not imported into Europe, this dossier will focus on barley grain, only. Complete information on the study, including the data on barley hay and straw, has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. BYI 02960 480 FS is a flowable concentrate containing 480 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.14-2).

Table 6.3.2.14-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Barley

NAFTA Growing Region	Submitted ^a	Requested
1	1	1
1A		
2		
3		
4		
5	3	3
5A		
5B		
6		
7		4
8		
9	1	1
10	1	1
11		2
12		
13		
14	8	8
Total	20	20

a Four of the twenty trials were decline trials (one in Region 5, one in Region 7, and two in Region 14). Four decline trials were performed to meet EU requirements.

Material and Methods

Individual foliar application rates ranged from 0.174 to 0.228 lb BYI 02960/A/application (0.195 to 0.256 kg BYI 02960/ha/application). Seasonal total application rates ranged from 0.355 to 0.412 lb BYI 02960/A (0.398 to 0.462 kg BYI 02960/ha). Foliar applications to plots for the collection of straw and grain were made at BBCH 58 to 87 (BBCH 58; 80% florescence emerged, BBCH 87; hard dough). The interval between the foliar applications was 5 to 8 days. All foliar applications were made using ground-based equipment. The adjuvants Dyne-Amic, Agral 90 or Ag Surf were used in all of the applications at a rate of 0.25% (v/v).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Soil loading/application rates for plots into which treated barley seed was planted (TRTST plots) ranged from 0.111 to 0.180 lb BYI 02960/A (0.124 to 0.202 kg BYI 02960/ha), depending upon planting density. Barley seed was treated by Bayer CropScience, RTP, North Carolina at a nominal rate of 0.250 kg BYI 02960/100 kg seed.

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.14-3. Study use patterns are summarized in Table 6.3.2.14-4.

Table 6.3.2.14-3: Trial Site Conditions for BYI 02960 on Barley

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics				Meteorological Data ^a	
		Type	OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
RV001-10HA	[REDACTED], PA, 2011	Loam	2.4	7.2	17.2	9.25	61-95
RV002-10HA	[REDACTED], NE, 2011	Silt Loam	2.2	7.3	10.5	24.92	46-84
RV003-10DA	[REDACTED], IL, 2011	Silt Loam	2.5	7.08	13.3	24.50	49-93
RV004-10HA	[REDACTED], 2011	Sandy Loam	2.7	7.6	14.1	6.59	58-80
RV005-10HA	[REDACTED], NE, 2011	Silt Loam	2.7	6.8	17.4	20.78	41-89
RV006-10DA	[REDACTED], ND, 2011	Loam	3.9	7.2	17.2	4.34	57-88
RV007-10HA	[REDACTED], ND, 2011	Loam	3.8	7.6	30.8	3.52	55-87
RV008-10HA	[REDACTED], ND, 2011	Clay Loam	3.6	6	19.9	6.11	57-81
RV009-10HA	[REDACTED], ID, 2011	Loam	2	7.1	21.8	1.09	49-88
RV010-10HA	[REDACTED], CA, 2011	Sandy Loam	2.54	5.7	7.3	4.21	43-76
RV011-10HA	[REDACTED], WA, 2011	Loam/Sand	1.1	6.9	10.2	1.22	49-86
RV012-10HA	[REDACTED], ID, 2011	Silt Loam	1.7	7.2	11.7	4.48	35-93
RV013-10DA	[REDACTED], Alberta, 2011	Silty Clay Loam	11.3	5.6	45	6.89	37-73
RV014-10DA	[REDACTED], Saskatchewan, 2011	Loam	4.3	6.8	17	4.80	66-100
RV015-10HA	[REDACTED], Saskatchewan, 2011	Loam	8	7.5	24.8	2.43	52-71
RV016-10HA	[REDACTED], Manitoba, 2011	Loam	4.4	7.5	25.8	5.51	53-76
RV017-10HA	[REDACTED], Manitoba, 2011	Loam	5.3	7.5	24.4	8.78	53-76
RV018-10HA	[REDACTED], Manitoba, 2011	Sand Loam	2.32	5.5	NA ^c	5.91	52-77
RV019-10HA	[REDACTED], Alberta, 2011	Loam	3.4	6.4	21	6.89	37-73
RV020-10HA	[REDACTED], Saskatchewan, 2011	Loam	NA ^c	7.1	NA ^c	5.18	41-72

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

c NA = Not Available.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Barley

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
RV001-10HA	PA Region 1 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 77	19 (75)	0.185 (0.207)	NA ^a	0.370 (0.414)	Dyne-Amic, 0.25% v/v	
					BBCH 85	19 (13)	0.185 (0.207)	6		Dyne-Amic, 0.25% v/v	
RV002-10HA	Region 5 NE 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 71	15 (13)	0.186 (0.208)	NA ^a	0.370 (0.414)	Dyne-Amic, 0.25% v/v	
					BBCH 83	14 (13)	0.184 (0.206)	5		Dyne-Amic, 0.25% v/v	
RV002-10HA	Region 5 NE 2010	BYI 02960 SL 200	TRTST	Seed Treatment	BBCH 00	NA	0.110 (0.123)	NA ^a	0.110 (0.123)	NA	
RV003-10DA	Region 5 IL 2011	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 75	17 (55)	0.186 (0.209)	NA ^a	0.372 (0.417)	Dyne-Amic 0.25% v/v	
					BBCH 78	17 (48)	0.186 (0.208)	7		Dyne-Amic 0.25% v/v	
RV004-10HA	Region 5 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 83	12 (109)	0.180 (0.202)	NA ^a	0.364 (0.408)	Dyne-Amic, 0.25% v/v	
					BBCH 85	12 (114)	0.184 (0.206)	7		Dyne-Amic, 0.25% v/v	
RV005-10HA	Region 7 NE 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 75	20 (190)	0.185 (0.207)	NA ^a	0.368 (0.413)	Dyne-Amic, 0.25% (v/v)	
					BBCH 85	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% (v/v)	
RV005-10HA	NE Region 7 2010	BYI 02960 480 FS	TRTST	Seed Treatment	BBCH 00	NA ^a	0.180 (0.202)	NA ^a	0.180 (0.202)	NA ^a	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Barley

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV006-10DA	██████, ND Region 7 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 77	20 (187)	0.182 (0.204)	NA ^a	0.364 (0.408)	Dyne-Amic, 0.25% v/v
					BBCH 83	20 (186)	0.182 (0.204)	5		Dyne-Amic, 0.25% v/v
RV007-10HA	██████, ND Region 7 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 83	20 (187)	0.182 (0.203)	NA ^a	0.364 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 85	20 (190)	0.186 (0.209)	5		Dyne-Amic, 0.25% v/v
RV008-10HA	██████, ND Region 7 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 83	20 (189)	0.186 (0.208)	NA ^a	0.372 (0.417)	Dyne-Amic 0.25% (v/v)
					BBCH 85	20 (191)	0.186 (0.208)	5		Dyne-Amic 0.25% (v/v)
RV009-10HA	██████, ID Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 83	20 (188)	0.185 (0.207)	NA ^a	0.372 (0.417)	Dyne-Amic, 0.25% v/v
					BBCH 87	21 (192)	0.187 (0.210)	7		Dyne-Amic, 0.25% v/v
RV010-10HA	██████, CA Region 10 2011	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	31 (289)	0.182 (0.204)	NA ^a	0.367 (0.411)	Dyne-Amic, 0.25% v/v
					BBCH 87	32 (300)	0.184 (0.207)	7		Dyne-Amic, 0.25% v/v
RV011-10HA	██████, W Region 4 2010	BYI 02960 SL 200	TRTSG	Broadcas foliar	BBCH 85	30 (280)	0.183 (0.205)	NA ^a	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 87	30 (282)	0.184 (0.207)	7		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Barley

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l/ha)	Rate lb a.s./A (kg s./ha)	Retreatment Interval (days)			
RV012-10HA	██████ ID Region 11 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 73	25 (233)	0.183 (0.205)	NA ^a	0.369 (0.414)	Dyne-Amic, 0.25% v/v	
					BBCH 78	27 (238)	0.187 (0.209)			Dyne-Amic, 0.25% v/v	
RV012-10HA	██████ ID Region 11 2010	BYI 02960 480 SC	TRTST	Seed treatment	BBCH 00	NA	0.174 (0.195)	NA	0.174 (0.195)	NA	
RV013-10DA	██████ Alberta Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 73	11 (107)	0.184 (0.206)	NA ^a	0.367 (0.412)	Agral 90, 0.25% v/v	
					BBCH 85	11 (99)	0.183 (0.206)	8		Agral 90, 0.25% v/v	
RV014-10DA	██████ Saskatchewan Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 65	22 (207)	0.188 (0.211)	NA ^a	0.362 (0.406)	Ag Surf, 0.25% v/v	
					BBCH 72	22 (192)	0.174 (0.195)	5		Ag Surf, 0.25% v/v	
RV015-10HA	██████ Saskatchewan Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 58	21 (198)	0.180 (0.201)	NA ^a	0.359 (0.402)	Ag Surf, 0.25% v/v	
					BBCH 64	21 (197)	0.179 (0.201)	6		Ag Surf, 0.25% v/v	
RV016-10HA	██████, Manitoba Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 83	17 (158)	0.182 (0.204)	NA ^a	0.364 (0.407)	Ag Surf, 0.25% v/v	
					BBCH 87	17 (158)	0.182 (0.204)	7		Ag Surf, 0.25% v/v	
RV017-10HA	██████ Manitoba Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 77	17 (159)	0.182 (0.204)	NA ^a	0.369 (0.413)	Ag Surf, 0.25% v/v	
					BBCH 83	17 (162)	0.186 (0.209)	7		Ag Surf, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Barley

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (l/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Rate lb a.s./A (kg a.s./ha)		
RV018-10HA	Manitoba Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 65	21 (198)	0.181 (0.203)	NA ^a	0.558 (0.401)	Ag surf, 0.25% v/v	
					BBCH 21	21 (5)	0.077 (0.198)			Ag surf, 0.25% v/v	
RV019-10HA	Alberta Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 77	11 (10)	0.18 (0.24)	NA	0.366 (0.493)	Ag surf, 0.25% v/v	
					BBCH 85	10 (98)	0.178 (0.199)	8		Ag surf, 0.25% v/v	
RV020-10HA	Saskatchewan Region 14 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 77	11 (201)	0.185 (0.207)	NA ^a	0.372 (0.417)	Ag Surf, 0.25% v/v	
					BBCH 77	22 (204)	0.187 (0.210)	7		Ag Surf, 0.25% v/v	

a NA = Not Available.

In the harvest trials after foliar applications, duplicate composite samples of barley grain were harvested at PHIs ranging from 16 to 22 days (intended PHI = 21 days). In the four decline trials, duplicate composite barley grain samples were collected from the treated plots at 10, 15, 21, 28 and 35 days after the last application. Single composite samples of barley grain were collected from the control plots on the same day the target 21 day PHI samples were collected from the treated plots.

Duplicate samples of required commodities were collected from plots into which BYI 02960 treated seed was planted.

The residue(s) of BYI 02960, DFA, and DEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.14-5).

Table 6.3.2.14-5: Summary of Recoveries of BYI 02960 from Barley

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Barley Grain	BYI 02960	0.01	9	111, 82, 129, 107, 87, 116, 112, 95, 100	104	5.5
		0.5	5	105, 96, 89, 85, 85	92	8.5
		50	3	79, 81, 75	78	8
	DFA	0.05	9	95, 96, 94, 95, 95, 89, 83, 84, 83	90	5.7
		0.5	3	79, 80, 70, 75	76	4.4
	DFEAF	50	3	75, 79, 73	76	3.2
		0.01	9	109, 97, 113, 99, 81, 100, 116, 98, 82	99	12
		0.5	4	92, 93, 87, 87	90	3.2

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in crops with high starch content during frozen storage for at least 18 months prior to analysis as shown for wheat grain as representative crop. The maximum storage period of frozen samples in this study for BYI 02960 was 401 days. A summary of the storage conditions are shown in Table 6.3.2.14-6.

Table 6.3.2.14-6: Summary of Storage Conditions for Barley

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration (days) ^b	Interval of Demonstrated Storage Stability (days) ^c
BYI 02960	Barley Grain	< -16	13 (401)	18 (557)
DFEAF	Barley Grain	< -16	13 (401)	18 (557)
DFA	Barley Grain	< -16	13 (401)	18 (557)

a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Pyxant. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

b The storage duration is the time from field sampling through the last sample extraction.

c [REDACTED], [REDACTED], and A. [REDACTED]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The total BYI 02960 residue data for barley following seed treatment application with BYI 02960 480 FS or two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.14-7.

Table 6.3.2.14-7: Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
RV001-10HA	PA Region 1 2010	TRTSG	AC Minoa	Grain	0.372 (0.414)	89	16	0.855 0.793	0.342 0.297	0.160	1.33 1.33 Avg: 1.33
RV002-10HA	NE Region 5 2010	TRTSG	Robust	Grain	0.370 (0.414)	87	19	0.0665 0.0606	1.20 1.19	0.0345 0.0341	1.21 1.28 Avg: 1.24
RV002-10HA	NE Region 5 2010	FRYST	Robust	Grain	0.111 (0.124)	82	9	0.010 0.010	0.472 0.524	0.010 0.010	0.492 0.544 Avg: 0.518
RV003-10DA	IL Region 5 2011	TRTSG	NA	Grain	0.372 (0.417)	90	10	0.72 4.62	0.137 0.127	0.0959 0.102	3.96 4.85 Avg: 4.40
							15	2.19 1.83	0.0747 0.0628	0.0277 0.0293	2.29 1.92 Avg: 2.11
							20	1.33 1.05	0.0837 0.0783	0.0249 0.0250	1.44 1.16 Avg: 1.30
							28	0.945 0.990	0.0569 0.0709	0.0107 0.0165	1.01 1.08 Avg: 1.04
							35	0.568 0.694	0.0669 0.0802	0.0156 0.0161	0.651 0.790 Avg: 0.721

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-7 (cont'd): Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV004-10HA	Region 5 2010	TRTSG	Dignity	Grain	0.364 (0.408)	74	21	0.236 0.36	0.0824 0.0893	0.0338 0.0431	2.27 2.49 ^c Avg: 2.38 ^d
RV005-10HA	NE Region 7 2010	TRTSG	Robust	Grain	0.368 (0.413)	80	20	0.418 0.471	0.275 0.238	0.0232 0.0254	0.716 0.734 Avg: 0.725
RV005-10HA	NE Region 7 2010	TRTSG	Robust	Grain	0.180 (0.202)	81	10	0.010 0.010	0.692 0.690	<0.010 <0.010	0.712 ^e 0.710 Avg: 0.711 ^f
RV006-10DA	ND Region 200	TRTSG	Binnacle	Grain	0.364 (0.408)	90	10	0.500 0.505	0.426 0.409	0.136 0.145	1.07 1.06 Avg: 1.06
						83		0.519 0.590	0.456 0.440	0.105 0.133	1.08 1.16 Avg: 1.12
						88	21	0.340 0.354	0.297 0.315	0.129 0.144	0.767 0.813 Avg: 0.790
						86	29	0.437 0.490	0.313 0.329	0.149 0.134	0.899 0.953 Avg: 0.926
						73	35	0.276 0.221	0.215 0.197	0.0830 0.0667	0.574 0.485 Avg: 0.529

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-7 (cont'd): Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV007-10HA	ND Region 7 2010	TRTSG	Pinneacle	Grain	0.368 (0.412)	88	21	0.482 0.470	0.068 0.187	0.101 0.113	0.750 0.771 Avg: 0.761
RV008-10HA	ND Region 7 2010	TRTSG	Tradition	Grain	0.372 (0.417)	80	21	0.588 0.764	0.0844 0.112	0.0378 0.0467	0.710 0.922 Avg: 0.816
RV009-10HA	ID Region 11 2010	TRTSG	Harrington	Grain	0.372 (0.48)	92	20	0.756 0.92	<0.050 <0.050	0.0351 0.0313	0.841 1.01 Avg: 0.925
RV010-10HA	CA Region 7 2010	TRTSG	AC937	Grain	0.369 (0.411)	90	21	1.87 1.9	0.0818 0.0734	0.0507 0.0430	2.00 1.61 Avg: 1.81
RV011-10HA	WA Region 11 2010	TRTSG	AC Metcalfe	Grain	0.367 (0.412)	91	21	0.798 0.627	<0.050 <0.050	0.0483 0.0547	0.896 0.732 Avg: 0.814
RV012-10HA	ID Region 11 2010	TRTSG	Champion	Grain	0.369 (0.419)	92	21	0.205 0.205	0.339 0.274	0.0684 0.0583	0.612 0.537 Avg: 0.575
RV012-10HA	ID Region 11 2010	TRTSG	Champion	Grain	0.174 (0.195)	92	101	<0.010 <0.010	0.230 0.224	<0.010 <0.010	0.250 0.244 Avg: 0.247

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-7 (cont'd): Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV013-10DA	Alberta Region 14 2010	TRTSG	Coalition	Grain	0.367 (0.412)	72	16	0.465 0.283	0.91 0.588	0.0727 0.0774	1.13 1.05 Avg: 1.09
					0.367 (0.412)	34	3	0.277 0.240	0.633 0.648	0.0713 0.0726	0.982 0.958 Avg: 0.970
					0.367 (0.412)	59	19	0.290 0.296	0.697 0.676	0.0637 0.0584	1.05 1.03 Avg: 1.04
					0.367 (0.412)	57	27	0.313 0.301	0.661 0.663	0.0616 0.0567	1.04 1.02 Avg: 1.03
					0.367 (0.412)	75	42	0.364 0.250	0.847 0.786	0.0681 0.0683	1.28 1.10 Avg: 1.19

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-7 (cont'd): Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV014-10DA	██████████, Saskatchewan Region 14 2010	TRTSG	Metcalf	Grain	0.362 (0.406)	63	9	0.349 0.349	0.334 0.407	0.0456 0.0446	0.829 0.801 0.815
					0.362 (0.406)	63	13	0.349 0.349	0.596 0.548	0.0477 0.0497	0.957 0.946 Avg: 0.952
					0.362 (0.406)	71	20	0.222 0.313	0.430 0.510	0.0374 0.0420	0.690 0.865 Avg: 0.778
					0.362 (0.406)	71	28	0.180 0.141	0.363 0.326	0.0309 0.0278	0.574 0.494 Avg: 0.534
					0.362 (0.406)	70	34	0.126 0.130	0.392 0.398	0.0346 0.0309	0.553 0.560 Avg: 0.556
					0.362 (0.406)	48	21	0.0425 0.0327	0.537 0.514	0.0170 <0.010	0.596 0.557 Avg: 0.576
RV016-10HA	██████████, Manitoba Region 14 2010	TRTSG	CDC Copeland	Grain	0.364 (0.407)	85	21	0.262 0.335	0.500 0.580	0.103 0.105	0.865 1.02 Avg: 0.942
RV017-10HA	██████████, Manitoba Region 14 2010	TRTSG	Metcalfe	Grain	0.369 (0.413)	76	21	0.0835 0.109	0.969 1.22	0.0411 0.0552	1.09 1.38 Avg: 1.24
RV018-10HA	██████████, Manitoba Region 14 2010	TRTSG	Tradition	Grain	0.358 (0.401)	81	21	0.254 0.231	0.425 0.372	0.0617 0.0625	0.741 0.665 Avg: 0.703

Continued on next page...



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-7 (cont'd): Total BYI 02960 Residue Data from Barley after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification ^a	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFR Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV019-10HA	Alberta Region 14 2010	TRTSG	Coalition	Grain	0.360 (1.403)	72	15	0.738 2.506	0.226 2.339	0.0921 0.0747	1.18 1.02 Avg: 1.10
RV020-10HA	Saskatchewan Region 14 2010	TRTSG	Metcalf	Grain	0.372 (0.417)	62	20	0.230 0.266	0.237 0.244	0.0282 0.0253	0.496 0.535 Avg: 0.515

- a sampling interval is the interval between last application and the date of sampling.
- b Total BYI 02960 residue is the sum of BYI 02960, DFR, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Maximum residue found in barley grain after foliar application at the target PHI of 21 days.
- d Highest average field trial (HAFT) residue found in barley grain after foliar application at the target PHI of 21 days.
- e Maximum residue found in mature barley grain after seed treatment.
- f Highest average field trial (HAFT) residue found in mature barley grain after seed treatment.

Conclusion

Twenty field trials were conducted to measure the magnitude of total BYI 02960 residue in/on barley grain following two foliar spray applications of BYI 02960 200 SL, or seed treatment application of BYI 02960 480 FS.

The total BYI 02960 residue data for barley foliar applications or seed treatment are summarized in Table 6.3.2.14-8.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.14-8: Summary of Residue Data for Total BYI 02960 from Barley

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFI ²	Median ³	Mean	Standard Deviation
Barley Grain	TRTSG	0.358 to 0.372 (0.401 to 0.417)	21 (16 – 22)	20	0.496	2.49	1.23 (2)	2.38	0.009	1.02	0.45
Barley Grain	TRTST	0.111 to 0.180 (0.124 to 0.202)	92 - 110	3	0.244	0.712	NA ⁵	0.712	0.538	0.92	0.21

- 1 TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for collection of straw and grain samples
TRTST = Treated plot receiving cotton seeds treated with BYI 02960 480 FS for collection of grain samples
- 2 HAFI = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 Sampling day showing highest residue
- 5 Not applicable, since no decline trials were conducted after seed treatment

Total BYI 02960 residues in the barley grain from plots receiving two foliar sprays were generally slightly higher compared to barley grain from plots after seed treatment. The overall maximum residue was detected in a barley grain sample collected after foliar treatment and amounted to 0.24 mg/kg at the respective PHI of 21 days. The four decline trials conducted after foliar application showed that the total BYI 02960 residue in barley grain experienced a general decline over the course of the study. The residues did not always peak at the PHI of 21 days; one trial showed the maximum total residue at the last sampling interval (34 days after the last application), however this residue value was by far lower than the overall maximum level detected in a sample collected at the PHI.

The residue data provided for barley are suitable for regulatory purposes.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
IIA 6.3.2.15 Cereals - corn
Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on cereal grains, except rice (crop group 15). Representative crops tested were barley, field and sweet corn, sorghum and wheat. The use pattern for field and sweet corn in North America is summarized in Table 6.3.2.15-1.

A total of thirty-three field trials were conducted in corn. The studies are described below.

Table 6.3.2.14-1a: Target Use Pattern for the Application of BYI 02960 on Corn (to gain grains and kernels plus cob with husks removed)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
Foliar	BYI 02960 200 SL	2	415	14.0	BYI 02960	0.182	0.205	21	0.25	10 - 50	93 - 467	

In parallel, six residue trials were conducted with BYI 02960 480 FS following a seed treatment application. The seed treatment rates for corn are presented below.

Table 6.3.2.14-1b: Target Use Pattern for the Application of BYI 02960 on Corn (to gain grains and kernels plus cob with husks removed)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/100 kg seed	fl oz/100 lb seed	Name of a.s.	lb a.s./100 lb seed	kg a.s./100 kg seed					
Seed treatment	BYI 02960 480 FS	1	3.1 X 10 ⁻⁰³	1.06 X 10 ⁻⁰⁴	BYI 02960	5.29 X 10 ⁻⁰⁵	1.5	NA ¹	ECH ²	NA ¹	NA ¹	NA ¹

1 NA = Not applicable.

2 ECH = Earliest commercial harvest

Report	KIIA 6.3.2.15/01; [REDACTED]; 2012
Title	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the Residue in/on Corn
Report No & Document No	RAVY002, dated June 18, 2012 M-43274-01-1
Guidelines	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Thirty-three field trials were conducted to measure the magnitude of BYI 02960 residues in/on field corn forage, field corn stover, field corn grain, sweet corn forage, sweet corn stover, and sweet corn kernels plus cob (= ear) with husks removed (K+CWHR) following two broadcast foliar spray applications of BYI 02960 200 SL. Six of these field trials also included plots to measure the magnitude of BYI 02960 residues in these same matrices following the planting of seed treated with BYI 02960 480 FS. Since corn forage and corn stover (as feed items) are not imported into Europe, this dossier will focus on field and sweet corn kernels, only. Complete information on the study including the data on the feed items, has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L and BYI 02960 480 FS is a flowable concentrate containing 480 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Tables 6.3.2.15-2 and 6.3.2.15-3).

Table 6.3.2.15-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Field Corn

NAFTA Growing Region	Submitted ^a	Requested
1	1	1
1A		
2		
3		
4		
5		17
5A		
5B		
6	1	1
7		
7A		
8		
9		
10		
11		
12		
14		
Total	20	20

a Four of the twenty field corn trials were decline trials (four trials in Region 5). The additional decline trials were performed to meet EU requirements.

Table 6.3.2.15-3: Trial Numbers and Geographical Locations for BYI 02960 in/on Sweet Corn

NAFTA Growing Region	Submitted ^a	Requested
1	2	2
1A		
2	1	1
3	1	1
4		
5	5	5
5A		
5B		
6		
7		
7A		
8		
9		
10		
11	1	1
12	1	1
13		
14		
Total	15	13

a Two of the thirteen sweet corn trials were decline trials (one trial each in Regions 1 and 5).

Material and Methods

For the plots receiving foliar applications, individual application rates ranged from 0.178 to 0.200 lb BYI 02960/A/application (0.199 to 0.224 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.361 to 0.380 lb BYI 02960/A (0.405 to 0.426 kg BYI 02960/ha) for the plots receiving foliar applications. Foliar applications were made to the TRTF plots (= treated plots receiving two foliar applications of BYI 02960 200 SL for the collection of forage samples from field corn trials and forage and kernel plus cob without husk samples from sweet corn trials at a target 7-day PHI) at growth stages ranging from BBCH 63 to 85 (BBCH 63: male: pollen shedding; female: tips of stigmata visible; BBCH 85: dough stage) and to the TRTSG plots (= treated plots receiving two foliar applications of BYI 02960 200 SL for the collection of grain and stover samples from field corn trials and stover samples from sweet corn trials at a target 21-day PHI) at growth stages ranging from BBCH 71 to 89 (BBCH 71: beginning of grain development; BBCH 89: fully ripe). The interval between the applications ranged from 5 to 8 days and the spray volumes ranged from 10 to 41 GPA (94 to 380 L/ha).

All foliar applications were made using ground-based equipment. An adjuvant (Dyne-Amic, Agral 90, Unity, or Ag Surf) was used in all of the foliar applications at a rate of 0.25% (v/v).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Corn seeds were treated at the Bayer CropScience Seed Technology Center with BYI 02960 480 FS at a target rate of 1.5 mg BYI 02960/seed using procedures typical of commercial seed treatment operations. Following treatment and shipment to the field sites, the treated seeds were planted into the TRTST plots (= seed treatment plots) at seeding rates ranging from 21,876 to 32,000 seeds/A (54,057 to 79,074 seeds/ha). The resulting soil application rates ranged from 0.048 to 0.006 lb BYI 02960/A (0.054 to 0.119 kg BYI 02960/ha).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.15-4. Study use patterns are summarized in Table 6.3.2.15-5.

Table 6.3.2.15-4: Trial Site Conditions for BYI 02960 on Corn

Study Location (City, State)	Trial Number	Soil Characteristics ^a				Meteorological Data ^b	
		Type	% OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
[REDACTED], NY	RV021-10HA	Sandy Loam	3.2	6.6	11	4.70	54-71
[REDACTED], SC	RV022-10HA	Loamy sand	1	6.8	11	3.68	65-91
[REDACTED], IA	RV023-10HA	Silt loam	2	6.8	14.8	44.68	52-86
[REDACTED], KS	RV024-10HA	Silt Loam	3.2	7.2	19.2	28.84	54-92
[REDACTED], ND	RV025-10HA	Silty Clay Loam	4.3	7.7	28.2	9.55	37-86
[REDACTED], ON	RV026-10HA	Silt Loam	3.19	7.5	26.6	11.20	36-82
[REDACTED], KS	RV027-10HA	Sand	0.5	6.2	15.5	16.58	51-93
[REDACTED], MO	RV028-10HA	Silt Loam	1.8	5.6	13.8	9.74	43-89
[REDACTED], ON	RV029-10HA	Loam	2.5	7	12.1	11.20	36-82
[REDACTED], NE	RV030-10HA	[REDACTED] Silt Loam	2.1	6.3	18	3.62	53-87
[REDACTED], IA	RV031-10HA	Clay loam	2	7.8	15.5	9.91	39-84
[REDACTED], ON	RV032-10HA	Sandy loam	2	7.6	14.1	5.31	39-66
[REDACTED], KS	RV033-10HA	Silt Loam	3.2	7.2	19.2	8.70	59-92
[REDACTED], ON	RV034-10HA	Sandy Loam	2.9	7.6	16.1	7.43	38-68
[REDACTED], KS	RV035-10HA	Sand	0.3	6.5	5.7	6.67	59-93
[REDACTED], IA	RV036-10DA	Silty clay loam	3.9	6.2	21	7.00	41-78
[REDACTED], ON	RV037-10DA	Silty clay loam	4.1	7.7	25.8	10.86	39-80
[REDACTED], NE	RV038-10DA	Silt loam	2.2	7.3	10.5	13.32	56-86
[REDACTED], MN	RV039-10DA	Clay loam	5.7	7.3	24.4	22.38	38-83
[REDACTED], TX	RV040-10HA	Sandy Clay Loam	1.1	8.1	30.2	15.35	77-97
[REDACTED], PA	RV041-10HA	Loam	2.4	6.2	9.2	22.57	53-95
[REDACTED], NY	RV042-10DA	Sand	2.5	6.9	6.6	14.44	41-82
[REDACTED], GA	RV043-10HA	Loamy Sand	0.75	5.3	3	4.95	33-82
[REDACTED], FL	RV044-10HA	sandy loam	1.5	5.9	8.7	9.32	69-94
[REDACTED], IA	RV045-10HA	Silt Loam	3.9	6.87	12.9	44.68	52-86
[REDACTED], IL	RV046-10HA	Silt Loam	2.3	5.9	11.9	11.46	56-90
[REDACTED], ON	RV047-10HA	Sandy Loam	2.1	7.6	14.1	15.64	39-80



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

NE	RV048-10HA	Loamy Sand	1.3	7.4	7.2	20.76	47-94
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Table 6.3.2.15-4 (cont'd): Trial Site Conditions for BYI 02960 on Corn

Study Location (City, State)	Trial Number	Soil Characteristics ^a				Meteorological Data ^b	
		Type	% OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
NE	RV049-10DA	Silty Clay Loam	3	6.1	18.4	8.76	53-88
SK	RV050-10HA	Loam	4	6.5	NA ^c	4.41	47-62
CA	RV051-10HA	Sandy Loam	0.58	5.7	5.1	0.64	53-92
ID	RV052-10HA	Fine sandy loam	2.8	6.3	20.1	0.69	41-68
OR	RV053-10HA	Clay Loam	3.4	5.5	15.3	7.75	43-73

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

c NA = Not Available.

Table 6.3.2.15-5: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, Region, and Year)	End-use Product (Formulation)	Plot Name	Method	Application					Tank Mix Adjuvants
					Timing/Growth Stage (BBCH)	Actual Spray Volume (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
Foliar Application/Field Corn										
RV021-10HA	NE Region 2 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 79	30 (280)	0.184 (0.206)	NA ^a	0.366 (0.411)	Dyne-Amic, 0.25% v/v
					BBCH 83	30 (280)	0.183 (0.205)	5	Dyne-Amic, 0.25% v/v	
RV021-10HA	NY Region 1 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 79	30 (280)	0.183 (0.205)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
					BBCH 83	30 (280)	0.182 (0.204)	6	Dyne-Amic, 0.25% v/v	
RV022-10HA	SC Region 2 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	15 (140)	0.183 (0.205)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
					BBCH 83	15 (140)	0.183 (0.205)	6	Dyne-Amic, 0.25% v/v	



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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV022-10HA	Region 2 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 89	16	0.181	NA	0.364	Dyne-Amic, 0.25% v/v
					BBCH 89	130	0.83		0.205	Dyne-Amic, 0.25% v/v
RV023-10HA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 85	16	0.183	NA	0.365	Dyne-Amic, 0.25% v/v
					BBCH 85	150	0.83	6	0.205	Dyne-Amic, 0.25% v/v
RV023-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	16	0.185	NA	0.368	Dyne-Amic, 0.25% v/v
					BBCH 87	170	0.183	7	0.205	Dyne-Amic, 0.25% v/v
RV024-10HA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	16	0.186	NA	0.368	Dyne-Amic, 0.25% v/v
					BBCH 83	150	0.182	7	0.204	Dyne-Amic, 0.25% v/v
RV024-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	16	0.182	NA	0.362	Dyne-Amic, 0.25% v/v
					BBCH 85	150	0.180	5	0.201	Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV025-10HA	[REDACTED], ND Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 79	20 (190)	0.186 (0.208)	NA	0.366 (0.413)	Dyne-Amic, 0.25% v/v
					BBCH 83	20 (190)	0.183 (0.205)			Dyne-Amic, 0.25% v/v
RV025-10HA	[REDACTED], ND Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (190)	0.183 (0.206)	NA	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 85	20 (190)	0.184 (0.206)	6		Dyne-Amic, 0.25% v/v
RV026-10HA	[REDACTED], ON Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	32 (300)	0.183 (0.205)	NA	0.366 (0.410)	Agral 90 @ 0.25 % v/v
					BBCH 83	32 (300)	0.183 (0.205)	5		Agral 90 @ 0.25 % v/v
RV026-10HA	[REDACTED], ON Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	33 (310)	0.185 (0.207)	NA	0.371 (0.416)	Agral 90 @ 0.25 % v/v
					BBCH 85	33 (310)	0.186 (0.209)	7		Agral 90 @ 0.25 % v/v
RV027-10HA	[REDACTED], KS Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 73	20 (190)	0.185 (0.207)	NA	0.365 (0.410)	Dyne-Amic, 0.25% v/v
					BBCH 75	20 (180)	0.181 (0.202)	7		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV027-10HA	Region 5, KS 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (190)	0.183 (0.205)	NA	0.367 (0.405)	Dyne-Amic, 0.25% v/v
					BBCH 87	20 (180)	0.188 (0.199)			Dyne-Amic, 0.25% v/v
RV028-10HA	Region 5, MO 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 79	19 (170)	0.18 (0.199)	NA	0.364 (0.409)	Dyne-Amic, 0.25% v/v
					BBCH 85	20 (190)	0.187 (0.210)	7		Dyne-Amic, 0.25% v/v
RV028-10HA	Region 5, MO 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (180)	0.180 (0.202)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v
					BBCH 87	20 (190)	0.186 (0.209)	7		Dyne-Amic, 0.25% v/v
RV029-10HA	Region 5, ON 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	32 (300)	0.187 (0.209)	NA	0.370 (0.414)	Agral 90, 0.25 % v/v
					BBCH 83	33 (300)	0.183 (0.205)	5		Agral 90, 0.25 % v/v
RV029-10HA	Region 5, ON 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	33 (310)	0.183 (0.205)	NA	0.367 (0.411)	Agral 90, 0.25 % v/v
					BBCH 87	32 (300)	0.184 (0.206)	7		Agral 90, 0.25 % v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate (lb a.s./A (kg a.s./ha))	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate (lb a.s./A (kg a.s./ha))			
Foliar Application/Field Corn												
RV030-10HA	Region 5, NE 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	20 (180)	0.181 (0.203)	NA	0.368 (0.412)	Unity, 0.25% v/v		
					BBCH 83	20 (180)	0.187 (0.210)			Unity, 0.25% v/v		
RV030-10HA	Region 5, NE 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	20 (190)	0.182 (0.204)	NA	0.365 (0.409)	Unity, 0.25% v/v		
					BBCH 78	20 (180)	0.182 (0.204)	7		Unity, 0.25% v/v		
RV031-10HA	Region 5, IA 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 71	19 (170)	0.184 (0.206)	NA	0.368 (0.412)	Dyne-Amic, 0.25% v/v		
					BBCH 79	19 (180)	0.184 (0.206)	8		Dyne-Amic, 0.25% v/v		
RV031-10HA	Region 5, IA 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 79	20 (190)	0.179 (0.201)	NA	0.362 (0.406)	Dyne-Amic, 0.25% v/v		
					BBCH 87	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v		
RV032-10HA	Region 5, ON 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	13 (120)	0.183 (0.205)	NA	0.366 (0.411)	Dyne-Amic, 0.25% v/v		
					BBCH 85	14 (130)	0.183 (0.205)	6		Dyne-Amic, 0.25% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV032-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	4	0.184 (0.206)	NA	0.368 (0.413)	Dyne-Amic, 0.25% v/v
					BBCH 87	5	0.185 (0.207)		Dyne-Amic, 0.25% v/v	
RV033-10HA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	16	0.185 (0.208)	NA	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 83	16	0.182 (0.204)	7	Dyne-Amic, 0.25% v/v	
RV033-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	16	0.184 (0.206)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v
					BBCH 85	16	0.185 (0.207)	5	Dyne-Amic, 0.25% v/v	
RV034-10HA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	16	0.189 (0.212)	NA	0.376 (0.421)	Dyne-Amic, 0.25% v/v
					BBCH 85	16	0.187 (0.210)	6	Dyne-Amic, 0.25% v/v	
RV034-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	21	0.180 (0.202)	NA	0.362 (0.405)	Dyne-Amic, 0.25% v/v
					BBCH 87	21	0.182 (0.204)	7	Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV035-10HA	Region 5, KS 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 73	20 (190)	0.188 (0.210)	NA	0.366 (0.411)	Dyne-Amic, 0.25% v/v
					BBCH 75	20 (180)	0.179 (0.200)			Dyne-Amic, 0.25% v/v
RV035-10HA	Region 5, KS 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (190)	0.185 (0.207)	NA	0.371 (0.416)	Dyne-Amic, 0.25% v/v
					BBCH 87	20 (190)	0.186 (0.209)	7		Dyne-Amic, 0.25% v/v
RV036-10DA	Region 5, IA 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 85	29 (290)	0.184 (0.206)	NA	0.370 (0.414)	Dyne-Amic, 0.25% v/v
					BBCH 85	32 (300)	0.186 (0.208)	7		Dyne-Amic, 0.25% v/v
RV036-10DA	Region 5, IA 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	32 (300)	0.189 (0.211)	NA	0.376 (0.421)	Dyne-Amic, 0.25% v/v
					BBCH 85	32 (300)	0.187 (0.210)	7		Dyne-Amic, 0.25% v/v
RV037-10DA	Region 5, ON 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	31 (290)	0.180 (0.202)	NA	0.380 (0.426)	Agral 90, 0.25 % v/v
					BBCH 83	34 (320)	0.200 (0.224)	6		Agral 90, 0.25 % v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application								
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants	
Foliar Application/Field Corn											
RV037-10DA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (280)	0.182 (0.203)	NA	0.355 (0.403)	Agral 90, 0.25 % v/v	
					BBCH 85	20 (300)	0.178 (0.199)			Agral 90, 0.25 % v/v	
RV038-10DA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	24 (220)	0.181 (0.203)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v	
					BBCH 85	20 (190)	0.184 (0.206)	6		Dyne-Amic, 0.25% v/v	
RV038-10DA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	25 (180)	0.182 (0.204)	NA	0.362 (0.406)	Dyne-Amic, 0.25% v/v	
					BBCH 87	18 (170)	0.180 (0.202)	6		Dyne-Amic, 0.25% v/v	
RV039-10DA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 83	20 (190)	0.184 (0.206)	NA	0.367 (0.411)	Dyne-Amic, 0.25% v/v	
					BBCH 85	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v	
RV039-10DA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (190)	0.183 (0.205)	NA	0.365 (0.410)	Dyne-Amic, 0.25% v/v	
					BBCH 85	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/Field Corn										
RV040-10HA	TX Region 6 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	28	0.184	NA	0.370	Dyne-Amic, 0.25% v/v
						(94)	(0.207)		(0.415)	
RV040-10HA	TX Region 6 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 79	40	0.186	NA	0.377	Dyne-Amic, 0.25% v/v
						(95)	(0.208)		(0.423)	
RV040-10HA	TX Region 6 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	40	0.188	NA	0.377	Dyne-Amic, 0.25% v/v
						(96)	(0.211)		(0.423)	
RV040-10HA	TX Region 6 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	40	0.189	7	0.377	Dyne-Amic, 0.25% v/v
						(96)	(0.212)		(0.423)	
Foliar Application/Sweet Corn										
RV041-10HA	PA Region 4 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 71	28	0.185	NA	0.371	Dyne-Amic, 0.25% v/v
						(260)	(0.208)		(0.416)	
RV041-10HA	PA Region 1 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 73	28	0.186	6	0.371	Dyne-Amic, 0.25% v/v
						(260)	(0.208)		(0.416)	
RV041-10HA	PA Region 1 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	33	0.184	NA	0.371	Dyne-Amic, 0.25% v/v
						(310)	(0.206)		(0.416)	
RV041-10HA	PA Region 1 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	33	0.188	6	0.371	Dyne-Amic, 0.25% v/v
						(310)	(0.210)		(0.416)	
RV042-10DA	NY Region 1 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 71	36	0.185	NA	0.370	Dyne-Amic, 0.25% v/v
						(330)	(0.207)		(0.414)	
RV042-10DA	NY Region 1 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 75	36	0.185	7	0.370	Dyne-Amic, 0.25% v/v
						(330)	(0.207)		(0.414)	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/ Sweet Corn										
RV042-10DA	NY Region 1 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 71	330	0.182 (0.204)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
					BBCH 75	330	0.182 (0.204)			Dyne-Amic, 0.25% v/v
RV043-10HA	GA Region 2 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 73	200	0.186 (0.208)	NA	0.370 (0.415)	Dyne-Amic, 0.25% v/v
					BBCH 75	190	0.184 (0.207)	7		Dyne-Amic, 0.25% v/v
RV043-10HA	GA Region 2 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	200	0.179 (0.201)	NA	0.366 (0.411)	Dyne-Amic, 0.25% v/v
					BBCH 85	25 (240)	0.187 (0.210)	7		Dyne-Amic, 0.25% v/v
RV044-10HA	FL Region 1 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 65	26 (240)	0.179 (0.201)	NA	0.361 (0.405)	Dyne-Amic, 0.25% v/v
					BBCH 73	25 (240)	0.182 (0.204)	7		Dyne-Amic, 0.25% v/v
RV044-10HA	FL Region 3 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 87	25 (240)	0.186 (0.208)	NA	0.365 (0.409)	Dyne-Amic, 0.25% v/v
					BBCH 89	24 (230)	0.179 (0.201)	7		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
Foliar Application/ Sweet Corn										
RV045-10HA	Region 5 2010, IA	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 71	17 (180)	0.184 (0.207)	NA	0.363 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 71	16 (160)	0.183 (0.205)			Dyne-Amic, 0.25% v/v
RV045-10HA	Region 5 2010, IA	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 75	17 (160)	0.185 (0.207)	NA	0.371 (0.415)	Dyne-Amic, 0.25% v/v
					BBCH 83	16 (150)	0.186 (0.208)	7		Dyne-Amic, 0.25% v/v
RV046-10HA	Region 5 2010, IL	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 67	33 (310)	0.184 (0.206)	NA	0.363 (0.407)	Dyne-Amic, 0.25% v/v
					BBCH 71	34 (320)	0.179 (0.201)	7		Dyne-Amic, 0.25% v/v
RV046-10HA	Region 5 2010, ML	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 75	36 (330)	0.188 (0.210)	NA	0.374 (0.419)	Dyne-Amic, 0.25% v/v
					BBCH 85	35 (330)	0.186 (0.209)	7		Dyne-Amic, 0.25% v/v
RV047-10HA	Region 5 2010, ON	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 79	12 (110)	0.180 (0.202)	NA	0.364 (0.408)	Dyne-Amic, 0.25% v/v
					BBCH 79	12 (110)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/ Sweet Corn										
RV047-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 83	20 (130)	0.184 (0.206)	NA	0.368 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 85	20 (130)	0.184 (0.207)			Dyne-Amic, 0.25% v/v
RV048-10HA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 63	20 (190)	0.185 (0.207)	NA	0.369 (0.414)	Dyne-Amic, 0.25% v/v
					BBCH 69	20 (190)	0.184 (0.206)	6		Dyne-Amic, 0.25% v/v
RV048-10HA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	20 (180)	0.180 (0.202)	NA	0.366 (0.411)	Dyne-Amic, 0.25% v/v
					BBCH 85	20 (190)	0.186 (0.209)	7		Dyne-Amic, 0.25% v/v
RV049-10DA	Region 5 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 63	20 (190)	0.184 (0.207)	NA	0.367 (0.412)	Dyne-Amic, 0.25% v/v
					BBCH 71	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v
RV049-10DA	Region 5 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 85	21 (190)	0.188 (0.210)	NA	0.371 (0.416)	Dyne-Amic, 0.25% v/v
					BBCH 87	20 (190)	0.184 (0.206)	7		Dyne-Amic, 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/ Sweet Corn										
RV050-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIF	Broadcast foliar	BBCH 71	39	0.182	NA	0.367	Ag Surf, 0.25% v/v
						(200)	(0.205)			
RV050-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIFSG	Broadcast foliar	BBCH 71	31	0.183	NA	0.368	Ag Surf, 0.25% v/v
						(200)	(0.205)			
RV051-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIF	Broadcast foliar	BBCH 71	39	0.184	NA	0.370	Dyne-Amic, 0.25% v/v
						(360)	(0.206)			
RV051-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIF	Broadcast foliar	BBCH 75	29	0.187	6		Dyne-Amic, 0.25% v/v
						(270)	(0.209)			
RV051-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIFSG	Broadcast foliar	BBCH 85	41	0.183	NA	0.367	Dyne-Amic, 0.25% v/v
						(380)	(0.205)			
RV051-10HA	██████, SK Region 7A 2010	BYI 2960 200 SL	TRIFSG	Broadcast foliar	BBCH 85	37	0.184	7		Dyne-Amic, 0.25% v/v
						(350)	(0.206)			
RV052-10HA	██████, ID Region 7A 2010	BYI 2960 200 SL	TRIF	Broadcast foliar	BBCH 71	20	0.186	NA	0.371	Dyne-Amic, 0.25% v/v
						(190)	(0.208)			
RV052-10HA	██████, ID Region 7A 2010	BYI 2960 200 SL	TRIF	Broadcast foliar	BBCH 75	20	0.185	7		Dyne-Amic, 0.25% v/v
						(180)	(0.207)			

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application/ Sweet Corn										
RV052-10HA	██████, ID Region 11 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 83	22 (200)	0.184 (0.206)	NA	0.367 (0.408)	Dyne-Amic, 0.25% v/v Dyne-Amic, 0.25% v/v
RV053-10HA	██████, OR Region 12 2010	BYI 2960 200 SL	TRTF	Broadcast foliar	BBCH 73 BBCH 75	22 (200) 20 (90)	0.188 (0.211) 0.186 (0.208)	NA 7	0.374 (0.419)	Dyne-Amic, 0.25% v/v Dyne-Amic, 0.25% v/v
RV053-10HA	██████, OR Region 12 2010	BYI 2960 200 SL	TRTSG	Broadcast foliar	BBCH 73 BBCH 75	22 (200) 20 (180)	0.183 (0.205) 0.183 (0.205)	NA 7	0.366 (0.410)	Dyne-Amic, 0.25% v/v Dyne-Amic, 0.25% v/v
Seed Treatment/Field Corn										
RV023-10HA	██████, IA Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.106 (0.119)	NA ^b	0.106 (0.119)	NA ^b
RV024-10HA	██████, KS Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.048 (0.054)	NA ^b	0.048 (0.054)	NA ^b
RV027-10HA	██████, KS Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.105 (0.118)	NA ^b	0.105 (0.118)	NA ^b

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-5 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Corn

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Seed Treatment/Sweet Corn										
RV041-10HA	PA Region 1 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.102 (0.115)	NA	0.102 (0.115)	NA ^b
RV045-10HA	IA Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.083 (0.093)	NA ^b	0.083 (0.093)	NA ^b
RV048-10HA	NE Region 5 2010	BYI 02960 480 SC	TRTST	Seed Treatment	BBCH 00	NA	0.076 (0.085)	NA ^b	0.076 (0.085)	NA ^b

a NA = Not applicable.

TRTF = Treated plot receiving two foliar applications of BYI 02960 200 SL for collection of K+CWHR samples from sweet corn trials at a target PHI of 7 days.

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from field corn trials at a target PHI of 21 days.

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain (field corn) and K+CWHR (sweet corn) samples.

Duplicate composite samples of kernels plus cobs with husks removed (K+CWHR; sweet corn) were collected from the TRTF plots of the harvest trials at pre-harvest intervals (PHIs) of 5 to 7 days. The intended PHI is 7 days. Duplicate composite samples of grain (field corn) were collected from the TRTSG plots of the harvest trials at PHIs of 19 to 22 days.

In the decline trials, duplicate composites of K+CWHR and grain were harvested at five intervals of 0, 3, 7, 14, and 21 days, or of 11, 13 to 15, 19 to 22, 26 to 28, and 33 to 35 days, respectively. Single composite samples of K+CWHR were collected from the control plots on the same day the target 7-day samples were collected from the treated plots. Single composite samples of grain were collected from the control plots on the same day the target 21-day samples were collected from the treated plots.

For K+CWHR and grain from the TRTST plots, sampling occurred at earliest commercial harvest (ECH).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 20\%$ (Table 6.3.2.15-6).

Table 6.3.2.15-6: Summary of Recoveries of BYI 02960 from Corn

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Standard Deviation (%)
Corn Grain	BYI 02960	0.01	13	95, 117, 94, 97, 95, 104, 115, 105, 103, 105, 107, 99, 94	102	10
	DFA	0.05	13	83, 79, 84, 83, 80, 80, 85, 88, 89, 88, 95, 84, 84	85	4
		0	3	84, 86, 79	83	4
	DFEAF	0.01	13	94, 89, 87, 80, 88, 90, 92, 88, 92, 96, 103, 91, 89	91	5
0		3	86, 88, 79	84	5	
Corn K+CWHR	BYI 02960	0.01	11	87, 88, 100, 97, 95, 100, 87, 96, 115, 95, 98	97	8
	DFA	0.05	3	76, 104, 99, 108, 86, 121, 91, 91, 104, 85, 95	96	12
		10	3	86, 80, 89	86	3
	DFEAF	0.01	1	84, 83, 98, 94, 72, 104, 100, 88, 91, 75, 97	90	10
10		3	89, 74, 86	83	8	

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in crops with high starch content during frozen storage for at least 18 months prior to analysis as shown for wheat grain as representative crop. The maximum storage period of frozen samples in this study for BYI 02960 was 325 days. A summary of the storage conditions are shown in Table 6.3.2.15-7.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.13-7: Summary of Storage Conditions for Corn

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration Months (Days) ^b	Interval of Demonstrated Storage Stability Months (Days) ^c
BYI 02960	Corn Grain	< -20	9 (269)	18 (557)
BYI 02960	Corn K+CWHR	< -20	11 (325)	18 (557)
DFEAF	Corn Grain	< -20	9 (269)	18 (557)
DFEAF	Corn K+CWHR	< -20	11 (325)	18 (557)
DFA	Corn Grain	< -20	9 (269)	18 (557)
DFA	Corn K+CWHR	< -20	11 (325)	18 (557)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Pyrant. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A. [REDACTED]. 2012. Storage stability of BYI 02960 difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RAKYP046 amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for field and sweet corn commodities following seed treatment application with BYI 02960 480 FS or two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.15-8.

Table 6.3.2.15-8: Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
Corn Grain/Foliar Application/Field Corn											
RV01-10HA	[REDACTED] NY, Region 1, 2010	RTSG	Hyland Seeds, HL 693	Grain	0.365 (0.409)	59	20	<0.010 <0.010	<0.050 0.195	<0.010 <0.010	<0.07 Avg: 0.14^e
RV02-10HA	[REDACTED] C, Region 2, 2010	RTSG	DKC6972	Grain	0.364 (0.408)	86	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV03-10HA	[REDACTED] IA, Region 5, 2010	RTSG	09HYBK11 0HOER	Grain	0.368 (0.412)	80	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFAFR Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
Corn Grain/Foliar Application/Field Corn											
RV024-10HA	Region 5, 2010	TRTSG	09HYBK11 0HOER	Grain	0.362 (0.405)	85	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV025-10HA	Region 5, 2010	TRTSG	Dekalb DKC35-19	Grain	0.367 (0.412)	85	20	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV026-10HA	Region 5, 2010	TRTSG	Dekalb 3832 Non BT	Grain	0.371 (0.416)	85	22	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV027-10HA	Region 5, 2010	TRTSG	A-09HYB1 0HOER	Grain	0.361 (0.405)	85	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV028-10HA	Region 5, 2010	TRTSG	MFA Trophy	Grain	0.366 (0.410)	85	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV029-10HA	Region 5, 2010	TRTSG	Dekalb 4660	Grain	0.367 (0.411)	85	22	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV030-10HA	Region 5, 2010	TRTSG	Channel 007-03VT	Grain	0.365 (0.409)	83	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV031-10HA	Region 5, 2010	TRTSG	P1162XR	Grain	0.362 (0.406)	87	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV032-10HA	Region 5, 2010	TRTSG	25T87	Grain	0.368 (0.413)	80	21	<0.010 0.011	<0.050 <0.050	<0.010 <0.010	<0.07 0.07 Avg: 0.07
RV033-10HA	Region 5, 2010	TRTSG	83R38- 3000GT	Grain	0.369 (0.414)	82	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
Corn Grain/Foliar Application/Field Corn											
RV034-10HA	██████, ON, Region 5, 2010	TRTSG	20T16	Grain	0.322 (0.405)	82	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV035-10HA	██████, KS, Region 5, 2010	TRTSG	Pioneer 2B34	Grain	0.371 (0.416)	82	21	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV040-10HA	██████, TX, Region 6, 2010	TRTSG	Dyna-Gro H628416	Grain	0.377 (0.423)	82	20	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV036-10DA	██████, IA, Region 5, 2010	TRTSG	Garst 5R08 300064	Grain	0.376 (0.421)	82	10	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
							14	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
							22	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
							84	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
							85	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg of equiv./kg) ^b
Corn Grain/Foliar Application/Field Corn											
RV037-10DA	██████, ON, Region 5, 2010	TRTSG	Maize	Grain	0.359 (0.403)	72	10	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.010	<0.050	<0.07	
							75	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.010	<0.050	<0.07	
							74	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.010	<0.050	<0.07	
77	<0.010	<0.050	<0.010	<0.07							
Avg:	<0.010	<0.050	<0.07								
80	<0.010	<0.050	<0.010	<0.07							
Avg:	<0.010	<0.050	<0.07								
RV038-10DA	██████, NE, Region 5, 2010	TRTSG	N38B4	Grain	0.362 (0.406)	80	10	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.010	<0.050	<0.07	
							84	<0.010	<0.050	<0.010	<0.07
							Avg:	0.010	<0.050	<0.07	
							85	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.010	<0.050	<0.07	
85	<0.010	<0.050	<0.010	<0.07							
Avg:	<0.010	<0.050	<0.07								
84	<0.010	<0.050	<0.010	<0.07							
Avg:	<0.010	<0.050	<0.07								

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg of equiv/kg) ^b
Corn Grain/Foliar Application/Field Corn											
RV039-10DA	██████, MN, Region 5, 2010	TRTSG	Dekalb 38-89	Grain	0.365 (0.410)	70	10	<0.010	<0.050	<0.010	<0.07
							Avg:	<0.07	<0.07	<0.07	
							74	0.012	0.056	0.011	0.07
							Avg:	0.07	0.07	0.07	
							76	0.010	0.050	0.010	0.07
							Avg:	<0.07	<0.07	<0.07	
							82	0.010	0.050	0.010	0.07
Avg:	<0.07	<0.07	<0.07								
87	0.010	0.050	0.010	0.07							
Avg:	<0.07	<0.07	<0.07								
Corn Grain/Seed Treatment/Field Corn											
RV023-10HA	██████, Region 5, 2010	TRTST	09HYBK01 0HOER	Grain	0.106 (0.118)	79	ECH	<0.010	0.118	<0.010	0.14
								<0.010	0.105	<0.010	0.13
											Avg: 0.13
RV024-10HA	██████, KS, Region 5, 2010	TRTST	09HYBK11 0HOER	Grain	0.048 (0.054)	78	ECH	<0.010	0.055	<0.010	0.08
								<0.010	0.089	<0.010	0.11
											Avg: 0.09
RV025-10HA	██████, KS, Region 5, 2010	TRTST	09HYBK11 05HOER	Grain	0.105 (0.118)	85	ECH	<0.010	0.174	<0.010	0.19 ^f
								<0.010	0.168	<0.010	0.19 ^f
											Avg: 0.19 ^g

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg of equiv./kg) ^b
Corn K+CWHR/Foliar Application/Sweet Corn											
RV041-10HA	PA, Region 1, 2010	TRTF	Extra-Tender	K+CWHR	0.371 (0.416)	NA	6	0.017 0.019	0.209 0.237	<0.010 <0.010	0.24 0.27 ^h Avg: 0.25 ⁱ
RV043-10HA	GA, Region 2, 2010	TRTF	Bi-color	K+CWHR	0.370 (0.415)	NA	7	0.010 0.010	0.143 0.08	<0.010 <0.010	0.16 0.11 Avg: 0.13
RV044-10HA	FL, Region 3, 2010	TRTF	Obsession	K+CWHR	0.364 (0.405)	NA	7	0.010 <0.010	0.109 0.114	<0.010 <0.010	0.13 0.13 Avg: 0.13
RV045-10HA	IA, Region 5, 2010	TRTF	Augusta	K+CWHR	0.368 (0.412)	NA	7	0.010 0.010	0.106 0.118	<0.010 <0.010	0.13 0.14 Avg: 0.13
RV046-10HA	IL, Region 5, 2010	TRTF	XTRA-tender 274A	K+CWHR	0.365 (0.407)	NA	7	0.010 <0.010	0.167 0.167	<0.010 <0.010	0.19 0.19 Avg: 0.19
RV047-10HA	ON, Region 2, 2010	TRTF	Brocade TSW	K+CWHR	0.364 (0.408)	NA	7	<0.010 <0.010	0.089 0.088	<0.010 <0.010	0.11 0.11 Avg: 0.11
RV048-10HA	NE, Region 5, 2010	TRTF	Augusta	K+CWHR	0.369 (0.414)	NA	7	0.047 0.028	0.138 0.083	<0.010 <0.010	0.20 0.12 Avg: 0.16
RV050-10HA	SK, Region 7, 2010	TRTF	Jackpot	K+CWHR	0.367 (0.412)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV051-10HA	CA, Region 10, 2010	TRTF	Golden Queen	K+CWHR	0.370 (0.415)	NA	5	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07
RV052-10HA	ID, Region 1, 2010	TRTF	Jackpot	K+CWHR	0.371 (0.415)	NA	7	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.07 <0.07 Avg: <0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg of equiv./kg) ^b	
Corn K+CWHR/Foliar Application/Sweet Corn												
RV053-10HA	██████, OR, Region 12, 2010	TRTF	Serendipity	K+CWHR	0.374 (0.419)	NA	0	0.010 0.010	0.051 0.064	<0.010 <0.010	0.07 0.08 Avg: 0.08	
RV042-10DA	██████ NY, Region 1, 2010	TRTF	Serendipity	K+CWHR	0.370 (0.414)	NA	0	0.014 0.017	0.091 0.089	<0.010 <0.010	0.11 0.11 Avg: 0.11	
							NA	3	0.016 0.017	0.128 0.119	<0.010 <0.010	0.15 0.16 Avg: 0.15
							NA	7	0.030 0.023	0.141 0.148	<0.010 <0.010	0.18 0.18 Avg: 0.18
							NA	14	0.017 0.020	0.187 0.168	<0.010 <0.010	0.21 0.20 Avg: 0.21
							NA	21	0.016 0.010	0.208 0.159	<0.010 <0.010	0.23 0.18 Avg: 0.21

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
Corn K+CWHR/Foliar Application/Sweet Corn											
RV049-10DA	█ NE, Region 5, 2010	TRTF	Xtra-Tender 278A	K+CWHR	0.367 (0.42)	NA	0	0.022	0.051	<0.010	0.08
								0.019	0.057	<0.010	0.09
											0.08
							3	0.014	0.101	<0.010	0.12
								0.019	0.095	<0.010	0.12
											0.12
						7	0.017	0.192	<0.010	0.22	
							0.014	0.167	<0.010	0.19	
										Avg:	0.21
							14	0.011	0.232	<0.010	0.25
								0.015	0.247	<0.010	0.27^h
										Avg:	0.26ⁱ
							21	0.010	0.228	<0.010	0.25
								0.010	0.248	<0.010	0.27
										Avg:	0.26

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.15-8 (cont'd): Total BYI 02960 Residue Data from Field and Sweet Corn after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg of equiv./kg) ^b
Corn K+CWHR/Seed Treatment/Sweet Corn											
RV041-10HA	PA, Region 1, 2010	TRTST	Extra-Tender	K+CWHR	0.102 (0.105)	NA	ECH	0.010 0.010	0.109 0.103	<0.010 <0.010	0.13 0.12 Avg: 0.13^k
RV045-10HA	IA, Region 5, 2010	TRTST	Augusta	K+CWHR	0.083 (0.093)	NA	ECH	0.010 0.010	0.060 0.060	<0.010 <0.010	0.08 0.09 Avg: 0.08
RV048-10HA	NE, Region 5, 2010	TRTST	Augusta	K+CWHR	0.076 (0.085)	NA	ECH	0.012 0.013	0.099 0.148	<0.010 <0.010	0.12 0.14 Avg: 0.13^k

- a Sampling interval is the interval between the last application and the sampling date.
 - b Total BYI 02960 residue is the sum of BYI 02960, DFA and DFAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
 - c NA = Not applicable. Dry matter was not determined for the K+CWHR matrix.
 - d Maximum residue found in field corn grain receiving a broadcast foliar spray application of BYI 02960 200 SL.
 - e HAF residue found in field corn grain receiving a broadcast foliar spray application of BYI 02960 200 SL.
 - f Maximum residue found in field corn grain following the planting of seed treated with BYI 02960 480 FS.
 - g HAF residue found in field corn grain following the planting of seed treated with BYI 02960 480 FS.
 - h Maximum residue found in sweet corn K+CWHR receiving a broadcast foliar spray application of BYI 02960 200 SL.
 - i HAF residue found in sweet corn K+CWHR receiving a broadcast foliar spray application of BYI 02960 200 SL.
 - j Maximum residue found in sweet corn K+CWHR following the planting of seed treated with BYI 02960 480 FS.
 - k HAF residue found in sweet corn K+CWHR following the planting of seed treated with BYI 02960 480 FS.
- ECH = Earliest commercial harvest

TRTF = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of K+CWHR samples from sweet corn trials at a target PHI of 7 days.

TRTS = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from field corn trials at a target PHI of 21 days.

TRTST = Seed treatment trials for the collection of grain samples from field corn trials and K+CWHR samples from sweet corn trials.

K+CWHR = kernels plus cob (ear) with husks removed

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Conclusion

Thirty-three field trials were conducted to measure the magnitude of total BYI 02960 residues in/on corn matrices following two foliar spray applications of BYI 02960 200 SL. Six of these field trials also included plots to measure the magnitude of BYI 02960 residues in these same matrices following the planting of seed treated with BYI 02960 480 FS.

The total BYI 02960 residue data for corn following seed treatment or foliar application are summarized in Table 6.3.2.15-9.

Table 6.3.2.15-9: Summary of Residue Data for Total BYI 02960 from Corn following Foliar Applications of BYI 02960 200 SL or Seed Treatment with BYI 02960 480 FS

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFI ²	Median ³	Mean ³	Standard Deviation
Foliar Application/Field Corn											
Grain	TRTSG	0.359 to 0.377 (0.403 to 0.423)	21 (19 – 22)	20	0.07	0.21	--	0.19	0.07	0.074	0.023
Foliar Application/Sweet Corn											
K+CWHR	TRTF	0.361 to 0.374 (0.405 to 0.419)	7 (5 – 7)	13	<0.07	0.27	0.25 (14)	0.13	0.13	0.14	0.058
Seed Treatment/Field Corn											
Grain	TRTST	0.048 to 0.106 (0.054 to 0.119)	ECH	3	0.07	0.16	NA ⁵	0.19	0.13	0.14	0.042
Seed Treatment/Sweet Corn											
K+CWHR	TRTST	0.076 to 0.102 (0.085 to 0.115)	ECH	3	0.07	0.14	NA ⁵	0.13	0.12	0.11	0.022

1 TRTF = Treated plot receiving two foliar applications of BYI 02960 200 SL for collection of K+CWHR samples from sweet corn trials at a target PHI of 7 days

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from field corn trials at a target PHI of 21 days

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain (field corn) and K+CWHR (sweet corn) samples

2 HAFI = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

5 Not applicable since no decline trials were conducted after seed treatment

ECH = Earliest commercial harvest

K+CWHR = kernels plus cob (– ear) with husks removed

Total BYI 02960 residues in grains from field corn plots receiving two foliar sprays were generally below the LOQ at the PHI of 21 days; only one of the twenty trials showed residues amounting to 0.21 mg/kg in maximum. The decline trials indicated that total residues do not increase at sampling intervals after the PHI of 21 days.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Total BYI 02960 residues in kernels plus cob with husk removed (K+CWHR samples) from sweet corn plots receiving two foliar sprays were generally higher; ten of thirteen trials showed residues at the intended PHI of 7 days. The maximum residue at the PHI amounted to 0.27 mg/kg. Decline trials indicated that the residues did not always peak at the PHI, however the residue levels suggest that a residue plateau was reached around the PHI. The highest residue detected after the PHI was also 0.27 mg/kg.

Total BYI 02960 residues in grains (field corn) and in K+CWHR (sweet corn) after seed treatment showed approx. the same residues at harvest. The highest residue was detected in grains of field corn, amounting to 0.19 mg/kg.

Considering the results of all trials it becomes obvious that the use pattern with the two foliar spray applications in sweet corn is most critical in respect to possible residues on food items.

The residue data provided for field and sweet corn are suitable for regulatory purposes.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

IIA 6.3.2.16 Cereals - sorghum

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on cereal grains, except rice (crop group 15). Representative crops tested were barley, field and sweet corn, sorghum and wheat. The use pattern for sorghum in North America is summarized in Table 6.3.2.16-1.

A total of nine field trials were conducted in sorghum. The studies are described below.

Table 6.3.2.16-1a: Target Use Pattern for the Application of BYI 02960 on Sorghum (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
Foliar	BYI 02960 200 SL	2	1025	44.0	BYI 02960	0.183	0.205	7	21	0.25	10-50	93-467

In parallel, three residue trials were conducted with BYI 02960 480 FS following a seed treatment application. The seed treatment rates for the cereal grain crops are presented below and in the respective summaries.

Table 6.3.2.16-1b: Target Use Pattern for the Application of BYI 02960 on Sorghum (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/100 kg seed	fl oz/100 lb seed	Name of a.s.	lb a.s./100 lb seed	kg a.s./100 kg seed					
Seed treatment	BYI 02960 200 SL	4	52	2.1	BYI 02960	0.250	250	NA ³	ECH ³	NA ³	NA ³	NA ³

- 1 NA = Not applicable
- 2 ECH = Earliest commercial harvest

Report:	IIA 6.3.2.16/01; [redacted] and K. A. [redacted]; 2012
Title:	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the Residue in/on Sorghum
Report No & Document No	RARVY004, dated March 14, 2012 M427048-01-2
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Nine field trials were conducted to measure the magnitude of BYI 02960 residues in/on sorghum forage, sorghum grain and sorghum stover following two broadcast foliar spray applications of

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

BYI 02960 200 SL. Three for these field trials also included plots to measure the magnitude of BYI 02960 residues in these same matrices following the planting of seed treated with BYI 02960 480 FS. Since sorghum forage and stover (as feed items) are not imported into Europe, this dossier will focus on sorghum grain, only. Complete information on the study, including the data on the feed items, has been submitted in the Global Joint Review Submission in October 2002.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L and BYI 02960 480 FS is a flowable concentrate containing 480 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.16-2).

Table 6.3.2.16-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Sorghum

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2		
3		
4	1	
5		
5A		
5B		
6		
7		
8	2	2
9		
10		
11		
12		
13		
14		
Total	9	9

a One of the nine trials was a decline trial (one in Region 5). The total number of trials meets the required number of trials needed as a representative crop for Crop Group 15.

Material and Methods

Individual foliar spray application rates ranged from 0.181 to 0.193 lb BYI 02960/A/application (0.202 to 0.216 kg BYI 02960/ha/application). Seasonal application rates ranged from 0.362 to 0.382 lb BYI 02960/A (0.406 to 0.428 kg BYI 02960/ha). All applications were made at growth stages ranging from BBCH 55 to 87 (BBCH 55: half of inflorescence emerged; BBCH 87: fruit begins



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

to soften). The interval between the applications was 5 to 7 days. All applications were made using ground-based equipment. An adjuvant (Dyne-Amic) was used in all of the foliar applications at 0.25% (v/v).

For plots receiving treated seed, application rates ranged from 0.012 to 0.024 lb BYI 02960/A to 0.014 to 0.026 kg BYI 02960/ha).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.16-3. Study use patterns are summarized in Table 6.3.2.16-4.

Table 6.3.2.16-3: Trial Site Conditions for BYI 02960 on Sorghum

Study Location (City, State)	Trial Number	Soil Characteristics				Meteorological Data ^b	
		Type	% OM	pH	CEC	Total Rainfall (in)	Temp. Range (°F)
██████, AR	RV083-10HA	Clay	4.1	6.3	17.4	8.4	62 - 96
██████, KS	RV084-10HA	Silt Loam	3.2	7.2	19.2	8.84	54 - 92
██████, MO	RV085-10HA	Silt Loam	1.8	7.4	29	2.6	57 - 100
██████, NE	RV086-10DA	Silt Loam	2.2	7.3	10.5	6.3	56 - 86
██████, TX	RV087-10HA	Clay loam	2.1	8.1	40.1	12.69	58 - 103
██████, TX	RV088-10HA	Clay Loam	1	7.8	18	1.28	77 - 93
██████, NE	RV089-10HA	Silt Loam	2.1	6.8	17.1	1.17	39 - 81
██████, TX	RV090-10HA	Sandy Clay Loam	0.81	7.9	12.84	10.14	48 - 94
██████, TX	RV091-10HA	Clay	2.6	8.1	50.4	6.33	73 - 102

a Abbreviations used: %OM = percent organic matter, CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

Table 6.3.2.16-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Sorghum

Trial Identification	Location (City, State, NATA Region, and Year)	End-use Product (Formulation)	Application								Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)		
RV083-10HA	██████, AR Region 4 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	10 (96)	0.185 (0.208)	NA	0.369 (0.414)	Dyne-Amic 0.25% v/v	
					BBCH 85	10 (95)	0.184 (0.206)	7			Dyne-Amic 0.25% v/v



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	

Continued on next page

Table 6.3.2.16-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Sorghum

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV084-10HA	[REDACTED] KS Region 5 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	16 (149)	0.186 (0.207)	NA	0.370 (0.415)	Dyne-Amic 0.25% v/v
					BBCH 85	16 (151)	0.186 (0.208)	5		Dyne-Amic 0.25% v/v
RV084-10HA	[REDACTED] KS Region 5 2010	BYI 02960 480 FS	TRPST	Seed Treatment	BBCH 00	NA	0.024 (0.026)	NA	0.024 (0.026)	NA
RV085-10HA	[REDACTED] MO Region 5 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 75	20 (188)	0.183 (0.205)	NA	0.364 (0.408)	Dyne-Amic 0.25% v/v
					BBCH 85	20 (184)	0.181 (0.202)	7		Dyne-Amic 0.25% v/v
RV086-10DA	[REDACTED] NE Region 5 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 87	20 (184)	0.182 (0.204)	NA	0.363 (0.407)	Dyne-Amic 0.25% v/v
					BBCH 87	19 (174)	0.181 (0.203)	6		Dyne-Amic



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV087-10HA	██████, TX Region 6 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	20 (188)	0.183 (0.204)	NA	0.364 (0.408)	Dyne-Amic 0.25% v/v
					BBCH 85	17 (160)	0.183 (0.205)	7		Dyne-Amic 0.25% v/v

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Table 6.3.2.16-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Sorghum

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	
RV087-10HA	██████, TX Region 6 2010	BYI 02960 480 FS	TRTSG	Seed Treatment	BBCH 00	NA	0.012 (0.014)	NA	0.012 (0.014)	NA
RV088-10HA	██████, TX Region 6 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	10 (96)	0.188 (0.211)	NA	0.375 (0.420)	Dyne-Amic 0.25% v/v
					BBCH 85	10 (95)	0.186 (0.209)	7		Dyne-Amic 0.25% v/v
RV089-10HA	██████, TX Region 6 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	20 (188)	0.183 (0.206)	NA	0.367 (0.412)	Dyne-Amic 0.25% v/v
					BBCH 85	20 (191)	0.184 (0.206)	7		Dyne-Amic 0.25% v/v



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume (L/ha)	Rate lb a.s./ha (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./ha (kg a.s./ha)	
RV090-10HA	██████, TX Region 8 2010	BYI 02960 SL 200	TRTSG	Broadcast foliar	BBCH 85	20 (190)	0.185 (0.211)	NA	0.170 (0.415)	Dyne-Amic 0.25% v/v
					BBCH 85	20 (184)	0.182 (0.204)			Dyne-Amic 0.25% v/v
RV090-10HA	██████, TX Region 8 2010	BYI 02960 400CS	TRTSG	Seed Treatment	BBCH 09	NA	0.018 (0.020)	NA	0.018 (0.020)	NA

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.16-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Sorghum

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate (lb a.s./A (kg a.s./ha))	
RV091-10HA	██████, TX Region 8 2010	BYI 02960 SL 200	TRTSG	Broadcast forlar	BBCH 85	19 (251)	0.081 (0.203)	NA	0.362 (0.465)	Dyne-Amic 0.25% v/v Dyne-Amic 0.25% v/v
					BBCH 8	15 (179)	0.181 (0.205)	7	0.405 (0.465)	

a NA = Not applicable

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from sorghum trials at a target PHI of 21 days

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain samples

Duplicate composite samples of grain were collected from the TRTSG plots at pre-harvest intervals (PHIs) ranging from 20 to 21-days (intended PHI = 21 days). In one decline trial, duplicate composite grain samples were collected from the TRTSG plot at 10, 13, 16, 26, and 33 days after the last application. Grain from the TRTST plots was sampled at the date of earliest commercial harvest (ECH).

Single composite samples of grain were collected from the control plots on the same day the target 21-day samples were collected from the treated plots.

The residues of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were ≤ 20% (Table 6.3.2.16-5).

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.16-5: Summary of Recoveries of BYI 02960 from Sorghum

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean % Recovery	Stan. % Dev.
Grain	BYI 02960	0.010	7	106, 95, 104, 113, 100, 117, 89	104%	9.7%
		0.100	3	104, 96, 119	106%	11.9%
		1.000	2	97, 101	99%	NA ^b
		2.000	3	95, 103, 88	95%	11.4%
	DFA	0.050	7	89, 81, 84, 88, 89, 85, 83	88%	3.4%
		0.100	3	99, 86, 99	95%	7.4%
		1.000	2	108, 94	101%	NA ^b
		2.000	3	97, 90, 88	92%	4.4%
	DFEAF	0.010	7	102, 87, 92, 130, 111, 103, 104	103%	11.1%
		0.100	3	103, 92, 111	102%	9.8%
		1.000	2	118, 103	110%	NA ^b
		2.000	3	104, 96, 97	98%	2.5%

a Mean Recovery = mathematical average of all recoveries

b NA = Not applicable, as a Standard Deviation is not calculated for less than three values

The freezer storage stability study indicates that BYI 02960 residues were stable in crops with high starch content during frozen storage for at least 18 months prior to analysis as shown for wheat grain as representative crop. The maximum storage period of frozen samples in this study for BYI 02960 was 196 days. A summary of the storage conditions are shown in Table 6.3.2.16-6.

Table 6.3.2.16-6: Summary of Storage Conditions for Sorghum

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Grain	-20°C	6.5 (196)	18 (557)
DFEAF	Grain	-20°C	6.5 (196)	18 (557)
DFA	Grain	-20°C	6.5 (196)	18 (557)

a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

b The storage duration is the time from field sampling through the last sample extraction.

c [REDACTED] and A. [REDACTED]. 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-4-imidazo-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/01)

The total BYI 02960 residue data for sorghum commodities following seed treatment application with BYI 02960 480 FS or two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.16-7.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.16-7: Total BYI 02960 Residue Data from Sorghum after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	% Dry Matter	Total Rate Lb a.s./A (kg a.s./ha)	Sampling Interval (days)	BYI 02960 Residue (mg/kg)	DFA Residue (µg a.s. equiv./kg)	DFEA Residue (µg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV083-10HA	Region 4, 2010	TRTSG	Pioneer 85Y40	Grain	86	0.369 (0.414)	21	1.23 1.46	<0.050 0.050	0.021 0.022	1.3 1.5 ^c Avg: 1.4 ^d
RV084-10HA	Region 5, 2010	TRTSG	B-7B47	Grain	86	0.376 (0.415)	21	0.971 0.749	<0.050 0.050	0.019 0.014	1.0 0.81 Avg: 0.93
		TRTST	B-7B47	Grain	86	0.376 (0.415)	21	0.010 0.010	0.050 0.050	0.010 0.010	<0.070 <0.070 Avg: <0.070
RV085-10HA	Region 5, 2010	TRTSG	DKS 400	Grain	81	0.364 (0.408)	21	0.386 0.530	0.137 0.124	0.062 0.065	0.58 0.72 Avg: 0.65
RV086-10DA	Region 5, 2010	TRTSG	NC 371	Grain	79	0.363 (0.407)	10	1.68 1.34	<0.050 <0.050	0.022 0.015	1.7 1.4 Avg: 1.6
							13	1.28 1.38	<0.050 <0.050	0.018 0.019	1.3 1.4 Avg: 1.4
							19	0.777 0.830	<0.050 <0.050	0.015 0.015	0.84 0.89 Avg: 0.87
							26	1.26 1.80	<0.050 0.052	0.014 0.016	1.3 1.9 Avg: 1.6
							33	0.825 0.811	<0.050 0.053	0.017 0.020	0.89 0.88 Avg: 0.89

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.16-7 (cont'd): Total BYI 02960 Residue Data from Sorghum after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Number	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	% Dry Matter	Total Rate Lb a.s./A (kg a.s./ha)	Sampling Interval (days) ^a	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV087-10HA	██████, TX, Region 6, 2010	TRTSG	Asgrow A571	Grain	87	0.364 (0.408)	12	0.559 0.457	0.138 0.119	0.051 0.051	0.75 0.63 Avg: 0.69
		TRTST	Asgrow A571	Grain	88	0.012 (0.014)	ECH	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV088-10HA	██████, TX, Region 6, 2010	TRTSG	Dekalb; DKS 3707	Grain	85	0.375 (0.420)	20	0.866 0.720	0.061 0.052	0.044 0.036	0.97 0.81 Avg: 0.89
RV089-10HA	██████, NE, Region 2010	TRTSG	7B47	Grain	83	0.367 (0.412)	21	0.320 0.322	0.053 0.055	0.039 0.034	0.41 0.44 Avg: 0.43
RV090-10HA	██████, TX, Region 8, 2010	TRTSG	F-270E	Grain	88	0.370 (0.415)	21	0.488 0.505	<0.050 <0.050	<0.010 <0.010	0.55 0.56 Avg: 0.56
		TRTST	F-270E	Grain	89	0.010 (0.020)	ECH	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070
RV091-10HA	██████, TX, Region 8, 2010	TRTSG	Garst 5574	Grain	89	0.362 (0.406)	21	0.391 0.525	<0.050 <0.050	<0.010 <0.010	0.45 0.58 Avg: 0.52

a Sampling interval is the interval between last application and sampling date.

b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFAF residue in parent equivalents. Residue measurements below the analytical LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

c Maximum residue found in sorghum grain after foliar application.

d DFAF residue found in sorghum grain after foliar application.

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from sorghum trials at a target PHI of 21 days

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain samples

ECH = Earliest Commercial Harvest.

Conclusion

Nine field trials were conducted to measure the magnitude of total BYI 02960 residues in/on sorghum grain following two foliar spray applications of BYI 02960 200 SL. Three of these field trials also included plots to measure the magnitude of BYI 02960 residues following the planting of seed treated with BYI 02960 480 FS.

The total BYI 02960 residue data for sorghum following seed treatment or foliar applications are summarized in Table 6.3.2.16-8.

Table 6.3.2.16-8: Summary of Residue Data for Total BYI 02960 from Sorghum following Foliar Applications of BYI 02960 200 SL or Seed Treatment with BYI 02960 480 FS

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)					Mean	Standard Deviation	
				n	Min at PHI	Max at PHI	Max after PHI	HAFT ²			Median ³
Sorghum Grain	TRTSG	0.362 – 0.379 (0.406 – 0.420)	21	18	0.404	1.523	1.9 (26)	1	0.687	0.758	0.307
Sorghum Grain	TRTST	0.012 – 0.024 (0.014 – 0.026)	ECH	6	<0.070	<0.070	NA ⁵	0	<0.070	<0.070	0

1 TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples at a target PHI of 21 days

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain samples

2 HAFT = Highest Average Field Trial

3 calculated on the basis of residue values at the PHI

4 Sampling day showing highest residue

5 Not applicable, since no decline trials were conducted after seed treatment

ECH = Earliest commercial harvest

Total BYI 02960 residues in sorghum grain samples from seed treatment plots were always below the LOQ of 0.07 mg/kg, whereas grain samples from plots receiving rather late spray applications showed considerable BYI 02960 residues. The maximum total BYI 02960 residue at the PHI of 21 days amounted to 1.5 mg/kg. The only decline trial available indicated that the residue peak might be some days after the PHI: a maximum residue of 1.9 mg/kg was detected 26 days after the last application in the decline trial. However a subsequent decrease of the residues suggested a further decline of the residues or at least a residue plateau at later time points.

Therefore it was concluded that the residue data provided for sorghum are suitable for regulatory purposes.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

IIA 6.3.2.17 Cereals - wheat

Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment in/on cereal grains, except rice (crop group 15). Representative crops tested were barley, field and sweet corn, sorghum and wheat. The use pattern for wheat in North America is summarized in Table 6.3.2.17.

A total of twenty-nine field trials were conducted in wheat. The studies are described below.

Table 6.3.2.17-1a: Target Use Pattern for the Application of BYI 02960 on Wheat (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/A	fl oz/A	Name of a.s.	lb a.s./A	kg a.s./ha					
Foliar	BYI 02960 200 SL	2	415	14.0	BYI 02960	0.183	205	7	21	0.25	10-50	93-467

In parallel, three residue trials were conducted with BYI 02960 480 FS following a seed treatment application. The seed treatment rates for wheat grain is presented below.

Table 6.3.2.17-1b: Target Use Pattern for the Application of BYI 02960 on Wheat (to gain Grains)

Application Type	Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
			Formulated Product (FP)		Active Substance (a.s.)						GPA	LPHA
			mL/100 kg seed	fl oz/100 lb seed	Name of a.s.	lb a.s./100 lb seed	kg a.s./100 kg seed					
Seed treatment	BYI 02960 200 SL	1	219	3.4	BYI 02960	0.105	105	NA ¹	ECH ²	NA ¹	NA ¹	NA ¹

1 NA = Not applicable.

2 ECH = Earliest commercial harvest

Report:	IIA 6.3.2.17/01; [redacted] and L. M. [redacted]; 2012
Title:	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the Residue in/on Wheat
Report No & Document No	RARVY003, dated June 27, 2012 M43325-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD, Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Twenty-nine field trials were conducted to measure the magnitude of BYI 02960 residues in/on wheat forage, grain, hay, and straw following two broadcast foliar spray applications of BYI 02960 200 SL. Three of these field trials also included plots to measure the magnitude of BYI 02960 residues in these same matrices following the planting of seed treated with BYI 02960 480 FS. Since wheat forage, hay, and straw (as feed items) are not imported into Europe, this dossier will focus on wheat grain only. Complete information on the study, including the data on the feed items, has been submitted in the Global Joint Review Submission in October 2012.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L and BYI 02960 480 FS is a flowable concentrate containing 480 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.17-2):

Table 6.3.2.17-2: Trial Numbers and Geographical Locations for BYI 02960 in/on Wheat

NAFTA Growing Region	Submitted ^a	Requested
1		
1A		
2		1
3		
4		
5	5	5
5A		
6	1	7
7		5
7A	1	1
8		6
10		
11		1
12		
13		
14	8	8
Total	29	29

a Four of the twenty-nine trials were decline trials (one in Region 5, one in Region 7, one in Region 8, and one in Region 14). The additional decline trials were performed to meet EU requirements.

Material and Methods

Individual foliar application rates ranged from 0.175 to 0.190 lb BYI 02960/A/application (0.196 to 0.213 kg BYI 02960/ha/application). Seasonal foliar application rates ranged from 0.353 to 0.378 lb BYI 02960/A (0.396 to 0.423 kg BYI 02960/ha).

All foliar applications were made at growth stages ranging from BBCH 12 to 99 (BBCH 12: two leaves unfolded; BBCH 99: harvested product). The interval between the applications was 4 to 8 days. For sites with two foliar applications, spray volumes ranged from 10 to 31 GPA (93 to 290 L/ha).

All foliar applications were made using ground-based equipment. The adjuvant Dync-Amic was used in all of the foliar applications at 0.25% (v/v).

Wheat seeds were treated at the Bayer CropScience Seed Technology Center with BYI 02960 480 ES at a target rate of 0.105 lb BYI 02960/100 lb seed (10.5 g BYI 02960/100 kg seed) using procedures typical of commercial seed treatment operations. Following treatment and shipment to the field sites, the treated seeds were planted into the TRIST plots at seeding rates ranging from 89.9 to 109 lb seed/A (97.3 to 122 kg seed/ha). The resulting soil application rates ranged from 0.091 to 0.114 lb BYI 02960/A (0.102 to 0.128 kg BYI 02960/ha).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.17-3. Study use patterns are summarized in Table 6.3.2.17-4.

Table 6.3.2.17-3 Trial Site Conditions for BYI 02960 on Wheat

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a	Meteorological Data ^b				
			Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)
RV054-10HA	[REDACTED], NC, 2010	Sandy Loam	0.9	6	6.8	4.55	50–93
RV055-10HA	[REDACTED], LA, 2011	Silt Loam	2	5.3	4.2	8.16	41–86
RV056-10HA	[REDACTED], KS, 2010	Sand	0.6	6.4	3.5	9.17	16–98
RV057-10HA	[REDACTED], KS, 2010	Silt Loam	1.8	5.8	16.8	17.83	47–87
RV058-10HA	[REDACTED], ON, Canada, 2010	Sandy Loam	2.1	7.6	14.1	15.99	55–80
RV059-10HA	[REDACTED], MN, 2010	Clay Loam	5.4	6	23.4	11.42	57–83
RV060-10DA	[REDACTED], MO, 2011	Silt Loam	1.7	5.7	8.7	29.68	40–95

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-3 (cont'd): Trial Site Conditions for BYI 02960 on Wheat

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV061-10HA	██████████, TX, 2011	Sandy Loam	0.9	6.6	10	1.37	55-87
RV062-10HA	██████████, NE, 2010	Silt Loam	2.7	6.8	17.1	20.8	41-85
RV063-10HA	██████████, ND, 2010	Loam	3.9	7	27.2	10.82	43-88
RV064-10HA	██████████, ND, 2010	Clay Loam	3.6	7.1	19.9	10.85	55-81
RV065-10HA	██████████, ND, 2010	Loam	3.8	7.6	30.8	10.48	42-87
RV066-10DA	██████████, NE, 2011	Silt Loam	2.7	6.8	17	15.53	38-91
RV067-10HA	██████████, AB, Canada, 2010	Loam	1.3	8	19	10.00	42-78
RV068-10HA	██████████, TX, 2011	Fine Sandy Loam	0.75	7.4	7.5	0.61	38-101
RV069-10HA	██████████, OK, 2010	Sandy Loam	1	5.9	7.7	5.06	50-93
RV070-10HA	██████████, TX, 2010	Sandy Loam	0	6	12.3	1.17	23-101
RV071-10HA	██████████, TX, 2011	Silty Clay	2.2	8.1	46.3	1.21	35-93
RV072-10HA	██████████, TX, 2011	Clay	2	8	40.4	2.88	41-94
RV073-10DA	██████████, TX, 2011	Clay	0	8.2	50.4	2.35	29-103
RV074-10HA	██████████, OR, 2010	Loam	7.2	6.3	15.5	4.46	40-81
RV075-10HA	██████████, SK, Canada, 2010	Loam	4.3	6.8	17	10.08	75-100
RV076-10HA	██████████, MB, Canada, 2010	Loam	4.4	7.5	25.8	9.57	51-76
RV077-10HA	██████████, MB, Canada, 2010	Loam	5.3	7.5	24.4	18.13	42-76
RV078-10HA	██████████, MB, Canada, 2010	Sand Loam	2.32	5.5	NA ^c	8.76	49-77
RV079-10HA	██████████, SK, Canada, 2010	Loam	8	7.5	24.75	12.92	50-74

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-3 (cont'd): Trial Site Conditions for BYI 02960 on Wheat

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV080-10HA	[REDACTED], SK, Canada, 2010	Loam	Not Reported	7.1	Not Reported	13.64	4-74
RV081-10HA	[REDACTED], AB, Canada, 2010	Loam	3.4	6.2	1	8.82	37-73
RV082-10DA	[REDACTED], AB, Canada, 2010	Silty Clay Loam	11.3	5.6	15	8.88	37-73

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

c NA = Not Available.

Table 6.3.2.17-4: Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 F on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (Days)	Total Rate lb a.s./A (kg a.s./ha)	
Foliar Application										
RV054-10HA	[REDACTED], Region 2, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	75	31 (290)	0.186 (0.209)	NA	0.370 (0.415)	DyneAmic 0.25% v/v
					83	31 (290)	0.184 (0.206)	6	DyneAmic 0.25% v/v	
RV055-10HA	[REDACTED], LA, Region 4, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	77	19 (180)	0.185 (0.207)	NA	0.369 (0.414)	DyneAmic 0.25% v/v
					85	19 (180)	0.184 (0.206)	7	DyneAmic 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
Foliar Application											
RV056-10HA	██████, KS, Region 5, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	69	20 (190)	0.183 (0.205)	NA	0.373 (0.418)	DyneAmic 0.25% v/v	
					77	20 (190)	0.183 (0.205)	7		DyneAmic 0.25% v/v	
RV057-10HA	██████, KS, Region 5, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	77	15 (140)	0.180 (0.201)	NA	0.364 (0.408)	DyneAmic 0.25% v/v	
					83	15 (150)	0.184 (0.206)	7		DyneAmic 0.25% v/v	
RV058-10HA	██████, ON, Region 5, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	11 (110)	0.176 (0.197)	NA	0.359 (0.402)	DyneAmic 0.25% v/v	
					83	11 (110)	0.183 (0.205)	7		DyneAmic 0.25% v/v	
RV059-10HA	██████, MA, Region 5, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar		20 (190)	0.183 (0.205)	NA	0.366 (0.410)	Dyne-Amic, 0.25% v/v	
					83	20 (190)	0.183 (0.205)	7		Dyne-Amic, 0.25% v/v	
RV060-10DA	██████, MO, Region 5, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	77	20 (190)	0.184 (0.206)	NA	0.367 (0.412)	DyneAmic 0.25% v/v	
					83	20 (190)	0.184 (0.206)	6		DyneAmic 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
Foliar Application											
RV061-10HA	██████ TX, Region 6, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	85	29 (270)	0.184 (0.207)	NA	0.366 (0.410)	DyneAmic 0.25% v/v	
RV062-10HA	██████ NE, Region 7, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	71	20 (190)	0.184 (0.206)	NA	0.368 (0.413)	DyneAmic 0.25% v/v	
RV063-10HA	██████ NE, Region 7, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	73	20 (190)	0.182 (0.204)	NA	0.365 (0.409)	DyneAmic 0.25% v/v	
RV064-10HA	██████ NE, Region 7, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	19 (180)	0.185 (0.207)	6	0.368 (0.412)	DyneAmic 0.25% v/v	
RV065-10HA	██████ NE, Region 7, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	73	19 (180)	0.176 (0.197)	NA	0.360 (0.403)	Dyne-Amic, 0.25% v/v	
					77	20 (190)	0.184 (0.206)	5		Dyne-Amic, 0.25% v/v	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Adjuvants
Foliar Application										
RV066-10DA	██████, NE, Region 7, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	20 (190)	0.183 (0.205)	NA	0.366 (0.410)	DyneAmic 0.25% v/v
					83	20 (180)	0.183 (0.205)	NA	0.366 (0.410)	DyneAmic 0.25% v/v
RV067-10HA	██████, AB, Region 7, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	14 (140)	0.181 (0.204)	NA	0.358 (0.401)	Agsurf, 0.25% v/v
					87	14 (130)	0.176 (0.197)	7	0.358 (0.401)	Agsurf, 0.25% v/v
RV068-10HA	██████, TX, Region 8, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	89	20 (190)	0.186 (0.208)	NA	0.371 (0.416)	Dyne Amic 0.25%
					77	20 (190)	0.186 (0.208)	6	0.371 (0.416)	Dyne Amic 0.25%
RV069-10HA	██████, OK, Region 8, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	19 (180)	0.179 (0.201)	NA	0.364 (0.408)	DyneAmic 0.25% v/v
					83	19 (180)	0.185 (0.207)	7	0.364 (0.408)	DyneAmic 0.25% v/v
RV070-10HA	██████, TX, Region 8, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	71	20 (190)	0.183 (0.205)	NA	0.366 (0.411)	DyneAmic 0.25% v/v
					83	20 (190)	0.184 (0.206)	8	0.366 (0.411)	DyneAmic 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)			
Foliar Application											
RV071-10HA	██████, TX, Region 8, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	85	19	0.18	NA	0.362 (0.406)	DyneAmic 0.25% v/v	
						(180)	(0.205)				DyneAmic 0.25% v/v
RV072-10HA	██████, TX, Region 8, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	77	21	0.179	NA	0.359 (0.402)	DyneAmic 0.25% v/v	
						(190)	(0.201)				DyneAmic 0.25% v/v
RV073-10DA	██████, TX, Region 8, 2011	BYI 02960 200 SL	TRTSG	Broadcast foliar	85	19	0.179	NA	0.359 (0.402)	DyneAmic 0.25% v/v	
						(180)	(0.201)			7	DyneAmic 0.25% v/v
RV074-10HA	██████, OR, Region 11, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	80	21	0.187	NA	0.369 (0.414)	DyneAmic 0.25% v/v	
						(200)	(0.209)			7	DyneAmic 0.25% v/v
RV075-10HA	██████, SK, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	51	21	0.182	NA	0.371 (0.416)	Agsurf, 0.25% v/v	
						(200)	(0.204)			5	Agsurf, 0.25% v/v
					59	22	0.189	5		Agsurf, 0.25% v/v	
						(210)	(0.212)				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							Total Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Retreatment Interval (days)			
Foliar Application												
RV076-10HA	██████, MB, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	17 (160)	0.185 (0.205)	NA	0.361 (0.405)	Ag-Surf, 0.25% v/v		
					88	15 (160)	0.185 (0.200)	NA		Ag-Surf, 0.25% v/v		
RV077-10HA	██████, MB, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	74	17 (160)	0.185 (0.208)	NA	0.369 (0.414)	Agsurf, 0.25% v/v		
					73	17 (160)	0.184 (0.206)	NA		Agsurf, 0.25% v/v		
RV078-10HA	██████, MB, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	71	21 (200)	0.177 (0.199)	NA	0.356 (0.399)	Agral 90, 0.25% v/v		
					73	21 (200)	0.179 (0.201)	5		Agral 90, 0.25% v/v		
RV079-10HA	██████, SK, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	64	22 (200)	0.184 (0.206)	NA	0.372 (0.417)	Agsurf, 0.25% v/v		
					64	22 (210)	0.188 (0.211)	5		Agsurf, 0.25% v/v		
RV080-10HA	██████, SK, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	65	21 (200)	0.184 (0.206)	NA	0.371 (0.415)	Agsurf, 0.25% v/v		
					73	22 (200)	0.187 (0.210)	7		Agsurf, 0.25% v/v		

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-4 (cont'd): Study Use Pattern for BYI 02960 200 SL and BYI 02960 480 FS on Wheat

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
Foliar Application										
RV081-10HA	██████████ AB, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	75	11 (99)	0.186 (0.201)	NA	0.366 (0.410)	Agral 90, 0.25% v/v
RV082-10DA	██████████ AB, Region 14, 2010	BYI 02960 200 SL	TRTSG	Broadcast foliar	83	11 (100)	0.186 (0.209)	NA	0.378 (0.423)	Agral 90, 0.25% v/v
Seed Treatment										
RV056-10HA	██████████ KS, Region 5, 2010	BYI 02960 480 SC	TRTST	Seed Treatment	00	NA	0.114 (0.128)	NA	0.114 (0.128)	None
RV062-10HA	██████████ NE, Region 7, 2010	BYI 02960 480 SC	TRTST	Seed Treatment	00	NA	0.101 (0.113)	NA	0.101 (0.113)	None
RV070-10HA	██████████ TX, Region 8, 2010	BYI 02960 480 SC	TRTST	Seed Treatment	00	NA	0.091 (0.102)	NA	0.091 (0.102)	None

a NA = Not applicable

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples from wheat trials at a target PHU of 21 days

TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain samples



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Duplicate composite samples of wheat grain were collected at the pre-harvest interval (PHI) of 21 days in the plots receiving two foliar spray applications (TRTSGplots). In the four decline trials, duplicate composite samples of grain were collected from the treated plots at 10, 15, 21, 28, and 35 days after the last application. For grain from the plots receiving treated seeds (TRTST), harvest occurred at earliest commercial harvest (ECH).

Single composite samples of grain were collected from the control plots on the same day. The target 21 day samples were collected from the treated plots.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were $\leq 29\%$ (Table 6.3.2.17-5).

Table 6.3.2.17-5: Summary of Recoveries of BYI 02960 from Wheat

Crop Matrix	Analyte	Spill Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)	
Grain	BYI 02960	0.010	8	105, 92, 91, 98, 85, 75, 112, 119	97	14	
		0.10	21	74, 92, 92, 112, 86, 97, 95, 70, 82, 75, 97, 81, 89, 90, 82, 97, 91, 72, 102, 88, 91	88	10	
		3.0	3	96, 100, 86	92	7	
	DFA	0.50	8	70, 71, 75, 80, 84, 116, 84, 70	81	15	
		0.10	21	72, 73, 76, 93, 76, 85, 80, 72, 82, 77, 83, 79, 96, 73, 75, 77, 76, 71, 80, 99, 83	80	8	
		1.00	3	80, 82, 71	78	5	
	DFEAF	0.010	8	72, 78, 85, 96, 90, 112, 95, 82	89	12	
		0.10	2	75, 105, 86, 115, 78, 93, 100, 76, 83, 89, 99, 96, 109, 87, 86, 94, 112, 88, 99, 82, 87	92	12	
			1.0	3	94, 91, 91	92	2

a Mean Recovery = mathematical average of all recoveries.

b NA = Not applicable as a Standard Deviation is not calculated for less than three values.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The freezer storage stability study indicates that BYI 02960 residues were stable in crops with high starch content during frozen storage for at least 18 months prior to analysis as shown for wheat grain as representative crop. The maximum storage period of frozen samples in this study for BYI 02960 was 390 days. Only one untreated wheat grain samples was held in frozen storage for up to 644 days (21 months) prior to extraction.

A summary of the storage conditions are shown in Table 6.3.2.17-6.

Table 6.3.2.17-6: Summary of Storage Conditions for Wheat

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months ^c
BYI 02960	Grain	-17	13 (390) ^d	18 (557)
DFA	Grain	-17	13 (390)	18 (557)
DFEAF	Grain	< -17	13 (390)	18 (557)

- a The maximum average storage temperature is from the time of sample receipt at BPP until sample extraction. While preparing for sample analysis the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and A [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-uranone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KSA 6.1.11).
- d One control grain sample was analyzed after 644 days of freezer storage. All samples from treated plots were analysed within 13 months.

The total BYI 02960 residue data for wheat grain following seed treatment application with BYI 02960 480 FS or two foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.17-7.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-7: Total BYI 02960 Residue Data from Wheat after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval, (days)	BYI 02960 Residue (mg/kg)	DKA Residue (mg a.s. equiv./kg)	DPFAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Grain/Foliar Application											
RV054-10HA	█, NC, Region 2, 2010	Pioneer 26R15	Grain	TRTSG	0.370 (0.415)	84.64	21	0.085 (0.226)	0.03 (0.161)	<0.010 (0.010)	0.70 (0.80) Avg: 0.75
RV055-10HA	█, LA, Region 4, 2011	Terral Brand LA821	Grain	TRTSG	0.369 (0.414)	84.63	21	0.067 (0.125)	0.15 (0.118)	<0.010 (0.010)	0.29 (0.25) Avg: 0.27
RV056-10HA	█, KS, Region 5, 2010	Found. Juniper	Grain	TRTSG	0.373 (0.418)	92.94	21	0.088 (0.118)	0.57 (0.282)	<0.010 (0.010)	0.35 (0.41) Avg: 0.38
RV057-10HA	█, KS, Region 5, 2010	Winter Hawk	Grain	TRTSG	0.364 (0.408)	87.98	21	0.331 (0.342)	0.58 (0.413)	<0.010 (<0.010)	0.78 (0.77) Avg: 0.77
RV058-10HA	█, Region 5, 2010	Glenn (Hard Red, spring)	Grain	TRTSG	0.354 (0.402)	76.64	21	0.586 (0.583)	0.278 (0.288)	<0.010 (<0.010)	0.87 (0.88) Avg: 0.88
RV059-10HA	█, MO, Region 5, 2010	RB07	Grain	TRTSG	0.368 (0.410)	88.02	21	0.078 (0.101)	0.943 (1.03)	<0.010 (<0.010)	1.0 (1.1) Avg: 1.1
RV060-10DA	█, MO, Region 5, 2011	Beretta	Grain	TRTSG	0.367 (0.412)	62.1	10	0.186 (0.196)	1.19 (1.13)	<0.010 (<0.010)	1.4 (1.3) Avg: 1.4
						90.56	15	0.119 (0.082)	1.56 (1.51)	<0.010 (<0.010)	1.7 (1.6) Avg: 1.6
						89.09	21	0.169 (0.153)	1.52 (1.35)	<0.010 (<0.010)	1.7 (1.5) Avg: 1.6
						89	28	0.136 (<0.010)	1.31 (1.11)	<0.010 (<0.010)	1.5 (1.1) Avg: 1.3
						86.72	35	0.157 (0.172)	1.60 (1.72)	<0.010 (<0.010)	1.8 (1.9) Avg: 1.8

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-7 (cont'd): Total BYI 02960 Residue Data from Wheat after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval, (days)	BYI 02960 Residue (mg/kg)	DFFA Residue (mg a.s. equiv./kg)	DFEF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
Grain/Foliar Application												
RV061-10HA	██████ TX, Region 6, 2011	Fannin	Grain	TR1SG	0.366 (0.410)	66.65	21	0.259 0.203	0.079 <0.050	<0.010 <0.010	0.35 0.26 Avg: 0.31	
RV062-10HA	██████ NE, Region 7, 2010	Traverse	Grain	TR1SG	0.368 (0.413)	67.27	21	0.038 0.030	1.37 1.47	<0.010 <0.010	1.4 1.5 Avg: 1.5	
RV063-10HA	██████ ND, Region 7, 2010	Faller	Grain	TR1SG	0.365 (0.409)	66.36	21	0.058 0.060	0.811 0.863	<0.010 <0.010	0.88 0.93 Avg: 0.91	
RV064-10HA	██████ ND, Region 7, 2010	Okleg	Grain	TR1SG	0.368 (0.412)	66.74	21	0.171 0.158	0.446 0.517	<0.010 <0.010	0.63 0.68 Avg: 0.66	
RV065-10HA	██████ ND, Region 7, 2010	Faller	Grain	TR1SG	0.360 (0.403)	65.73	21	0.074 0.074	0.596 0.604	<0.010 <0.010	0.68 0.69 Avg: 0.68	
RV066-10DA	██████ NE, Region 7, 2011	Overland HRW	Grain	TR1SG	0.366 (0.410)	66.83	10	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
							15	<0.010 <0.010	<0.050 <0.050	<0.010 <0.010	<0.070 <0.070 Avg: <0.070	
							88.2	21	0.118 0.174	0.330 0.332	<0.010 <0.010	0.46 0.52 Avg: 0.49
							87.73	28	0.138 0.152	0.485 0.522	<0.010 <0.010	0.63 0.68 Avg: 0.66
							87.33	35	0.099 0.089	0.375 0.397	<0.010 <0.010	0.48 0.50 Avg: 0.49

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-7 (cont'd): Total BYI 02960 Residue Data from Wheat after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval, (days)	BYI 02960 Residue (mg/kg)	DFFA Residue (mg a.s. equiv./kg)	DFEFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)	
Grain/Foliar Application												
RV067-10HA	██████, AB, Region 7, 2010	Supurb	Grain	TR18G	0.358 (0.401)	95.55	21	0.018 0.019	<0.050 <0.050	<0.010 <0.010	0.078 0.079 Avg: 0.078	
RV068-10HA	██████, TX, Region 8, 2011	Hatcher	Grain	TR18G	0.371 (0.416)	95.25	21	0.050 0.051	<0.050 <0.050	<0.010 <0.010	0.11 0.11 Avg: 0.11	
RV069-10HA	██████, OK, Region 8, 2010	Jagger	Grain	TR18G	0.364 (0.408)	91.02	21	0.232 0.288	0.314 0.345	<0.010 0.010	0.56 0.64 Avg: 0.60	
RV070-10HA	██████, TX, Region 8, 2010	TAM 111	Grain	TR18G	0.366 (0.411)	95.71	21	0.041 0.026	<0.050 <0.050	<0.010 <0.010	0.10 0.086 Avg: 0.093	
RV071-10HA	██████, TX, Region 8, 2011	Coronado	Grain	TR18G	0.362 (0.406)	95.64	21	0.048 0.033	<0.050 <0.050	<0.010 <0.010	0.11 0.093 Avg: 0.100	
RV072-10HA	██████, TX, Region 8, 2011	TAM 202	Grain	TR18G	0.359 (0.402)	89.35	21	0.163 0.205	0.051 0.053	<0.010 <0.010	0.22 0.27 Avg: 0.25	
RV073-10DA	██████, TX, Region 8, 2011	Doans	Grain	TR18G	0.359 (0.402)	93.47	10	0.105 0.102	<0.050 <0.050	<0.010 <0.010	0.16 0.16 Avg: 0.16	
							94.16	15	0.106 0.075	<0.050 <0.050	<0.010 <0.010	0.17 0.13 Avg: 0.15
							94.21	21	0.069 0.083	<0.050 <0.050	<0.010 <0.010	0.13 0.14 Avg: 0.14
							93.45	28	0.066 0.078	<0.050 <0.050	<0.010 <0.010	0.13 0.14 Avg: 0.13
							95.06	35	0.344 0.074	1.03 <0.050	<0.010 <0.010	1.4 0.13 Avg: 0.76

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-7 (cont'd): Total BYI 02960 Residue Data from Wheat after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval, (days)	BYI 02960 Residue (mg/kg)	DF A Residue (mg a.s. equiv./kg)	DFE Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Grain/Foliar Application											
RV074-10HA	██████, OR, Region 11, 2010	Penawawa	Grain	TR18G	0.369 (0.414)	8.88	21	0.012 (0.021)	0.541 (0.547)	<0.010 (<0.010)	0.56 (0.58) Avg: 0.57
RV075-10HA	██████, SK, Region 14, 2010	Infinity	Grain	TR18G	0.371 (0.416)	52.03	21	0.749 (0.708)	2.03 (1.88)	0.029 (0.026)	2.8 ^d (2.6) Avg: 2.7 ^e
RV076-10HA	██████, MB, Region 14, 2010	Infinity	Grain	TR18G	0.361 (0.405)	35.43	21	0.083 (0.255)	0.075 (0.894)	0.079 (<0.010)	0.24 (1.2) Avg: 0.70
RV077-10HA	██████, MB, Region 14, 2010	Glenn	Grain	TR18G	0.369 (0.414)	76.9	21	0.028 (0.020)	0.264 (0.264)	<0.010 (<0.010)	0.30 (0.29) Avg: 0.30
RV078-10HA	██████, MB, Region 14, 2010	Glenn	Grain	TR18G	0.356 (0.399)	8.89	21	0.032 (0.030)	0.179 (0.175)	<0.010 (<0.010)	0.22 (0.21) Avg: 0.22
RV079-10HA	██████, SK, Region 14, 2010	Harvest	Grain	TR18G	0.372 (0.417)	6.36	21	0.361 (0.375)	2.07 (2.27)	0.026 (0.029)	2.5 (2.7) Avg: 2.6
RV080-10HA	██████, SK, Region 14, 2010	Infinity	Grain	TR18G	0.371 (0.415)	5.44	21	0.251 (0.196)	1.00 (0.958)	0.019 (0.015)	1.3 (1.2) Avg: 1.2
RV081-10HA	██████, AB, Region 14, 2010	Supert	Grain	TR18G	0.366 (0.410)	59.17	21	0.102 (0.099)	0.695 (0.649)	<0.010 (0.011)	0.81 (0.76) Avg: 0.78

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.17-7 (cont'd): Total BYI 02960 Residue Data from Wheat after a Seed Treatment Application with BYI 02960 480 FS or Two Foliar Applications of BYI 02960 200 SL

Trial Identification	Location (City, State, Region, and Year)	Crop Variety	Commodity	Plot Name	Total Rate lb a.s./A (kg a.s./ha)	% Dry Matter	Sampling Interval, (days)	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg)
Grain/Foliar Application											
RV082-10DA	[REDACTED] AB, Region 14, 2010	Superb	Grain	TRTSG	0.378 (0.423)	9.15	10	0.400 ^c 0.376 ^c	0.536 ^c 0.471 ^c	0.017 ^c 0.016 ^c	0.95 0.86 Avg: 0.91
							15	0.425 ^c 0.285 ^c	0.792 ^c 0.535 ^c	0.014 ^c <0.010 ^c	1.2 0.83 Avg: 1.0
							21	0.082 ^c 0.097 ^c	0.675 ^c 0.759 ^c	<0.010 ^c <0.010 ^c	0.77 0.87 Avg: 0.82
							28	0.061 ^c 0.056 ^c	0.715 ^c 0.720 ^c	<0.010 ^c <0.010 ^c	0.78 0.79 Avg: 0.78
							35	0.071 ^c 0.067 ^c	0.644 ^c 0.686 ^c	<0.010 ^c <0.010 ^c	0.72 0.76 Avg: 0.74
							42	0.071 ^c 0.067 ^c	0.644 ^c 0.686 ^c	<0.010 ^c <0.010 ^c	0.72 0.76 Avg: 0.74
Grain/Seed Treatment											
RV056-10HA	[REDACTED] KS, Region 5, 2010	Found Juniper	Grain	TRTST	0.114 (0.128)	92.83	0	<0.010 <0.010	0.538 0.641	<0.010 <0.010	0.56 0.66^f Avg: 0.61^g
RV062-10HA	[REDACTED] KS, Region 7, 2010	Traverse	Grain	TRTST	0.101 (0.113)	71.14	0	<0.010 <0.010	0.276 0.266	<0.010 <0.010	0.30 0.29 Avg: 0.29
RV070-10HA	[REDACTED] TX, Region 8, 2010	TAM011	Grain	TRTST	0.091 (0.102)	95.15	0	<0.010 <0.010	0.069 0.069	<0.010 <0.010	0.089 0.089 Avg: 0.089

- a Sampling interval is the interval between last application and the sampling date.
- b Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residues in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- c Sample analyzed twice, average value reported here.
- d Maximum residue found in grain from the TRTSG plot.
- e HAF T residue found in grain from the TRTSG plot.
- f Maximum residue found in grain from the TRTST plot.
- g HAF T residue found in grain from the TRTST plot.

TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL
 TRTST = Seed treatment trials with BYI 02960 480 FS



Conclusion

Twenty-nine field trials were conducted to measure the magnitude of total BYI 02960 residues in/on wheat grain following two foliar spray applications of BYI 02960 200 SL. In parallel, three of the field trials also included plots to measure the magnitude of BYI 02960 residues in grains following the planting of seed treated with BYI 02960 480 FS.

The total BYI 02960 residue data for wheat grain following seed treatment or foliar applications are summarized in Table 6.3.2.17-8.

Table 6.3.2.17-8: Summary of Residue Data for Total BYI 02960 from Wheat

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)							
				n	Min at PHI	Max at PHI	Max after PHI	HAFT	Median ³	Mean ³	Standard Deviation
Wheat Grain	TRTSG	0.356 to 0.378 (0.399 to 0.423)	21	5	0.078	2.8	0.5	0.7	0.64	0.74	0.67
Wheat Grain	TRTST	0.091 to 0.114 (0.102 to 0.128)	ECH	6	0.089	0.66	NA	0.5	0.30	0.33	0.24

- 1 TRTSG = Treated plot receiving two foliar applications of BYI 02960 200 SL for the collection of grain samples at a target PHI of 21 days
TRTST = Seed treatment trials with BYI 02960 480 FS for collection of grain samples
- 2 HAFT = Highest Average Field Trial
- 3 calculated on the basis of residue values at the PHI
- 4 Sampling day showing highest residue
- 5 Not applicable since no decline trials were conducted after seed treatment

ECH = Earliest commercial harvest

Samples collected from plots following two foliar applications had generally higher total BYI 02960 residues than samples collected from seed treatment plots.

The maximum total BYI 02960 residue detected in grains amounted to 2.8 mg/kg at the PHI of 21 day. Samples collected from decline trials indicated that the total BYI 02960 residues did not always peak at the PHI. In three of four decline trials, maximum residues appeared after the PHI; in one trials at 28 days after the last treatment and in two trials at the last sampling event (35 days after the last treatment). However, the residue concentrations were in the same range as those at the PHI indicating that a residue plateau was reached at the end of the study. Moreover, the residue levels detected after the PHI were all below the overall highest residue concentration detected at the PHI.

The residue data provided for wheat are suitable for regulatory purposes.



IIA 6.3.2.18 Coffee

Residue data from CENTRAL AND SOUTH AMERICA

BYI 02960 is to be registered in North, Central, and South America for use as a soil drench application followed by three foliar spray applications on coffee. All countries support the same worst-case use pattern as summarized in Table 6.3.2.18-1, except for Brazil. Additional coffee trials conducted in Brazil are reported separately in this section, subsequent to the data presented for the trials in Mexico and Guatemala. The Brazilian use pattern is slightly different, but shows the same application rates.

A total of eleven trials were conducted in coffee. The studies are described below.

Table 6.3.2.18-1 Target Use Patterns for the Application of BYI 02960 on Coffee

Test Substance	App. No.	Target Rate / Application						Target App. Interval (Days)	Target PHI (Days)	Adjuvant Additive (%)	Application Solution Volume	
		Formulated Product (fp)		Active Substance (a.s.)			mL/plant				L/ha	
		fl oz /A	mL/ha	Name of a.s.	lb a.s./A	kg a.s./ha						
BYI 02960 SL 200	Drench Application											
	1	41.1	3 000	BYI 02960	0.535	0.600	NA ¹	18	None	45-55	75-500	
	Foliar Applications										GPA	L/ha
	2	13	1,000	BYI 02960	0.178	0.200	90	28	0.25%	32-53	300-500	
	3	13.7	1,000	BYI 02960	0.178	0.200	14	14	0.25%	32-53	300-500	
	13	1,000	BYI 02960	0.178	0.200	14	0	0.25%	32-53	300-500		

1 NA = Not applicable

Report:	IIA 6.3.2.18/01; [REDACTED] 2012
Title:	BYI 02960 200 SL, Magnitude of the Residue in/on Coffee; U.S., Canada and E.O. Import Tolerances
Report No & Document No	RARVP 074, dated June 27, 2012 M-433257-01-1
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPTS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guideline for the Testing of Chemicals, 509, Crop Field Trial, adopted Sept. 7, 2009.
GLP	Yes

Seven field trials located in Colombia, Guatemala and Mexico, are included in this study. Four trials performed in Guatemala and Mexico are reported in this interim report with three trials yet to be conducted in Colombia.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. Four additional coffee trials conducted in Brazil are reported separately (cf. KIIA 6.3.2.18/02).

The number and location of field trials conform to the guidance given by the EPA (Table 6.3.2.18-2).

Table 6.3.2.18-2: Trial Numbers and Geographical Locations for BYI 02960 on Coffee

Growing Region	Submitted ^a	Requested ^b
Colombia	0	0
Guatemala	0	0
Mexico	2	0
Total	2	0

- a All of the four trials are decline trials and were performed to meet EU requirements.
- b Based upon the NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada, December, 2005. The number and location of field trials was determined as a result of analyzing trade flow data as detailed in the Guidance Document.

Material and Methods

Soil drench applications ranged from 0.535 to 0.943 lb BYI 02960/A/application (0.600 to 0.609 kg BYI 02960/ha/application). Individual foliar application rates ranged from 0.174 to 0.181 lb BYI 02960/A/application (0.195 to 0.203 kg BYI 02960/ha/application). Seasonal total application rates ranged from 1.068 to 1.074 lb BYI 02960/A (1.197 to 1.204 kg BYI 02960/ha). The drench applications were made at 114 to 118 days before harvest at growth stages ranging from BBCH 72 to 78 (BBCH 72: 20% of fruit have reached final size, to BBCH 78: 80% of fruits have reached final size). Foliar applications were made at BBCH 77 to 88 (BBCH 77: 70% of fruit have reached final size, BBCH 88: nearly all fruit are fully ripe). The interval between the drench and foliar applications was 86 to 91 days and interval between the foliar applications was 12 to 14 days.

The volume of the soil drench applications ranged from 13.5 to 24.6 GPA (126 to 230 L/ha) and the foliar application spray volumes ranged from 39.2 to 44.3 GPA (367 to 414 L/ha).

All foliar applications were made using ground-based equipment. Methylated seed oil (MSO) or Dyne-Amic were used as adjunct in all of the foliar applications at a rate of 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.18-3. Study use patterns are summarized in Table 6.3.2.18-4.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-3: Trial Site Conditions for BYI 02960 on Coffee

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a			Meteorological Data		
		Type	OM	pH	CEC (meq/100g)	Total Rainfall in. (mm)	Temp. Range °F (°C)
RV232-11DA	[REDACTED], Guatemala, Guatemala	Sandy Clay	3.7	5.7	17	6.8 (1,728)	50-95 (10-35)
RV233-11DA	[REDACTED], Guatemala, Guatemala	Sandy Clay Loam	4.0	5.7	17	6.8 (1,730)	57-91 (14-33)
RV234-11DA	[REDACTED] De Mexico, Mexico	Clay	7.7	5.5	17	1.3 (33.1)	59-84 (15-29)
RV246-11DA	[REDACTED] De Mexico	Loamy Sand	8.1	5.6	14	2.2 (55.1)	57-88 (14-31)

- a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.
- b Data are for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

Table 6.3.2.18-4: Study Use Pattern for BYI 02960 209 SL on Coffee

Trial Identification	Location (City, State, Region, and Year)	End-use Product (Formulation)	Plot Name	Method	Application					Tank Mix Adjuvants
					Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha) ^a	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha) ^a	
RV232-11DA	[REDACTED] Guatemala 2011	BYI 02960 SL 200	E97D	Soil drench	BBCH 78	24 (227)	0.535 (0.600)	NA ^b	1.071 (1.201)	NA ^b
				Leaf spray	BBCH 79	42 (394)	0.178 (0.199)	91		MSO 0.25% v/v
				Leaf spray	BBCH 80	44 (412)	0.179 (0.201)	13		MSO 0.25% v/v
				Leaf spray	BBCH 88	39 (367)	0.179 (0.201)	12		MSO 0.25% v/v

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-4 (cont'd): Study Use Pattern for BYI 02960 200 SL on Coffee

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application						Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
			Plot Name	Method	Timing/Growth Stage (BBCH)	Actual Spray Volume GPA (L/ha) ^a	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)		
RV233-11DA	[REDACTED] Guatemala 2011	BYI 02960 SL 200	TRTD	Soil drench	BBCH 78	0.230 (0.600)	0.535 (0.600)	NA ^b	1.068 (1.197)	NA ^b
				Foliar broadcast	BBCH 81	0.178 (0.199)	0.178 (0.199)	8	MSO 0.25% v/v	
				Foliar broadcast	BBCH 47	0.178 (0.199)	0.178 (0.199)	14	MSO 0.25% v/v	
				Foliar broadcast	BBCH 88	0.178 (0.199)	0.178 (0.199)	14	MSO 0.25% v/v	
RV234-11DA	[REDACTED] Mexico 2011	BYI 02960 SL 200	TRTD	Soil drench	BBCH 73	0.126 (0.609)	0.540 (0.609)	NA ^b	1.070 (1.200)	NA ^b
				Foliar broadcast	BBCH 77	0.178 (0.199)	0.178 (0.199)	86	Dyne-Amic 0.25%	
				Foliar broadcast	BBCH 79	0.176 (0.197)	0.176 (0.197)	14	Dyne-Amic 0.25%	
				Foliar broadcast	BBCH 43	0.178 (0.199)	0.178 (0.199)	14	Dyne-Amic 0.25%	
RV246-11DA	[REDACTED] Mexico 2011	BYI 02960 SL 200	TRTD	Soil drench	BBCH 72	0.195 (0.609)	0.543 (0.609)	NA ^b	1.074 (1.204)	NA ^b
				Foliar broadcast	BBCH 81	0.176 (0.197)	0.176 (0.197)	89	Dyne-Amic 0.25%	
				Foliar broadcast	BBCH 81	0.174 (0.195)	0.174 (0.195)	12	Dyne-Amic 0.25%	
				Foliar broadcast	BBCH 85	0.181 (0.203)	0.181 (0.203)	13	Dyne-Amic 0.25%	

^a NA = Not applicable

TRTD = Treated plot receiving one soil drench application followed by three foliar applications of BYI 02960 200 SL

Duplicate composite samples of coffee cherries were collected from the treated plots at 0, 7, 14, 21 and 28 days after the last application. The target pre-harvest interval was 0 days.

Single composite samples of coffee cherries were collected on the same day that the target 0-day PHI samples were collected from the treated plots.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Immediately after harvest the coffee cherries were processed using the wet processing method typical for the region in which the trials were conducted. Using readily available hand operated equipment, the outer husk of the coffee cherries was removed and the remaining coffee beans were washed and allowed to ferment overnight in water to allow the mucilage (thin protective membrane surrounding the coffee beans) to loosen and be removed the next day by washing. For trial RV 234-11DA coffee cherries were not completely ripe and additional time was required to remove all of the husks, therefore not all husks were removed on the day of harvest. The coffee beans were spread out and allowed to air-dry in a protected area to avoid contamination. The coffee beans were turned regularly to promote drying. After the coffee beans, were allowed to dry to commercial dryness (8-12 days) the parchment (third layer of protective coating) was removed using hand operated equipment to yield the commodity, dried coffee bean, green. The dried coffee beans were placed into properly labelled residue sample bags for shipment to the laboratory.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries at each fortification level was within the acceptable range of 70 to 110%, and the standard deviation (SD) values were below 30% (Table 6.3.2.18-5).

Table 6.3.2.18-5: Summary of Recoveries of BYI 02960 from Coffee

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean Recovery (%) ^a	Std Dev (%)
Coffee, bean, green	BYI 02960	0.05	7	85, 81, 84, 109, 90, 93, 89	92	10
		0.5	2	92, 90	91	NA ^b
		1.000	3	86, 84, 86	85	1
	DFA	0.050	6	98, 85, 85, 92, 90, 96, 95	92	5
		0.500	2	83, 82	82	NA ^b
		1.000	3	81, 82, 84	82	1
		0.5	7	103, 89, 74, 97, 76, 77, 91	87	11
	DFEAF	0.5	2	89, 87	88	NA ^b
		1.000	3	89, 90, 89	89	1

a Mean Recovery = mathematical average of all recoveries.
b No standard deviation where n ≤ 2.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The freezer storage stability study indicates that BYI 02960 residues were stable in coffee bean during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 115 days. A summary of the storage conditions are shown in Table 6.3.2.18-6.

Table 6.3.2.18-6: Summary of Storage Conditions for Coffee

Residue Component(s)	Matrix (RAC)	Maximum Average Storage Temperature (°C) ^a	Actual Storage Duration months (days) ^b	Interval of Demonstrated Storage Stability months (days) ^c
BYI 02960	Coffee bean, green	< -17	4 (115)	18 (560)

- a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction and is the maximum of all average freezer temperatures at BRP and Pyxant. While preparing for sample analysis, the samples were maintained in a laboratory freezer.
- b The storage duration is the time from field sampling through the last sample extraction.
- c [REDACTED] and [REDACTED] 2012 Storage stability of BYI 02960 difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. KARVP046, amended version including 18-month data (KIIA 6.1.1/01).

The total BYI 02960 residue data for coffee beans following a single soil drench and three subsequent foliar application(s) of BYI 02960 200 SL are shown in Table 6.3.2.18-7.

Table 6.3.2.18-7: Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Crop Maturity	Total Rate LB a.s./A (kg ai/ha)	% Dry Matter ^a	Sampling Interval (days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg a.s. equiv./kg)	DFEAF Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV232-11DA	[REDACTED] Region Guatemala, 2011	PRTD	Catuai	Coffee bean, green	1.071 (1.201)	ND	0	0.0853 0.0787	0.132 0.230	<0.010 <0.010	0.228 0.318 Avg. 0.273
						ND	7	0.0976 0.109	0.140 0.0940	0.0128 0.0146	0.251 0.218 Avg. 0.234
						ND	14	0.114 0.131	0.0528 0.0627	0.0148 0.0152	0.181 0.209 Avg. 0.195

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-7 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (Days) ^b	BYI 02960 Residue (mg/kg)	FFA Residue (mg a.s. equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV232-11DA (cont'd)	Region Guatemala, 2011	TRTD	Catuai	Coffee bean, green	1.071 (1.201)	ND	21	0.118 0.109	0.100 0.0968	0.0144 0.0182	0.232 0.224 Avg. 0.228
						ND	28	0.145 0.12	0.121 0.0894	0.023 0.0200	0.286 0.238 Avg. 0.262
RV233-11DA	Region Guatemala, 2011	TRTD	Catuaí	Coffee bean, green	1.068 (1.197)	ND	0	0.0459 0.0552	0.011 0.120	<0.010 <0.010	0.158 0.185 Avg. 0.171
						ND	7	0.0451 0.0399	0.108 0.0974	<0.010 <0.010	0.163 0.147 Avg. 0.155
						ND	14	0.0607 0.0459	0.118 0.0803	<0.010 <0.010	0.189 0.136 Avg. 0.163
						ND	21	0.0628 0.0674	0.135 0.127	<0.010 <0.010	0.208 0.205 Avg. 0.206
						ND	28	0.0524 0.0502	0.119 0.104	<0.010 <0.010	0.181 0.164 Avg. 0.171
						ND	28	0.0524 0.0502	0.119 0.104	<0.010 <0.010	0.181 0.164 Avg. 0.171

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-7 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (Days) ^b	BYI 02960 Residue (mg/kg)	FFA Residue (mg equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV234-11DA	Region Mexico, 2011	TRTD	Costa Rica	Coffee bean, green	1.070 (1.200)	ND	0	0.207 0.188	0.350 0.665	0.0125 0.0070	0.569 0.870 Avg. 0.720
						ND	7	0.166 0.149	0.648 0.47	0.0231 0.0191	0.833 0.925 Avg. 0.879
						ND	14	0.102 0.131	0.224 0.397	0.015 <0.010	0.341 0.538 Avg. 0.400
						ND	21	0.144 0.138	0.503 0.332	<0.010 0.0185	0.662 0.575 Avg. 0.619
						ND	28	0.123 0.112	0.330 0.514	0.0151 0.0187	0.468 0.644 Avg. 0.556

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-7 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Application(s) of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate Lb a.s./A (kg a.s./ha)	% Dry Matter ^a	Sampling Interval (Days) ^b	BYI 02960 Residue (mg/kg)	DFA Residue (mg equiv./kg)	DFFA Residue (mg a.s. equiv./kg)	Total BYI 02960 Residue (mg a.s. equiv./kg) ^b
RV246-11DA	Region Mexico, 2011	TRTD	Caturra	Coffee bean, green		ND	0	0.123 0.117	0.126 0.114	0.0142 0.0135	0.257 0.245 Avg. 0.251
						ND	7	0.245 0.242	0.126 0.133	0.0284 0.0304	0.400 0.405 Avg. 0.403
						ND	15	0.409 0.362	0.113 0.100	0.0547 0.0432	0.607 0.506 Avg. 0.556
						ND	20	0.462 0.440	0.115 0.123	0.0644 0.0600	0.642 0.624 Avg. 0.633
						ND	26	0.588 0.516	0.306 0.284	0.0898 0.0948	0.984^d 0.895 Avg. 0.939^e

- a Dry Matter not determined (ND).
- b Sampling interval is the interval between last application and the sampling date.
- c Total BYI 02960 residue is the sum of BYI 02960 DFA and DFFA residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.
- d Maximum residue found in coffee bean, green occurred at a PHI of 26 days.
- e Highest average field trial (HAFT) residue found in coffee bean, green occurred at a PHI of 26 days.

Conclusion

Four field decline trials were conducted to measure the magnitude of total BYI 02960 residue in/on coffee bean, green, following a single soil drench and three subsequent foliar spray applications of BYI 02960 200 SL. The total BYI 02960 residue data for coffee beans are summarized in Table 6.3.2.18-8.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-8: Summary of Residue Data for Total BYI 02960 from Coffee

Commodity	Plot Name	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm) ¹						
				n	Min	Max	HAFT ²	Median	Mean	Standard Deviation
Coffee bean, green	TRTD	1.068 to 1.074 (1.197 to 1.204)	0	4	0.158	0.870	0.720	0.342	0.354	0.244
			7	4	0.147	0.925	0.879	0.326	0.418	0.302
			13-14	4	0.166	0.607	0.556	0.275	0.335	0.187
			20-21	4	0.205	0.662	0.633	0.360	0.411	0.213
			26-28	4	0.164	0.984	0.939	0.377	0.482	0.225

The data of the four decline trials showed rather similar total BYI 02960 residues independent from the sampling time. The overall maximum residue was detected in a sample collected 26 days after the last application which amounted to 0.98 mg/kg. However, the residue maximum was reached in each trials at a different day, no conclusive residue pattern was observed.

Residue data from BRAZIL

BYI 02960 is to be registered in Brazil for soil and foliar treatment use in/on coffee. The most critical use pattern for Brazil is summarized in Table 6.3.2.18-9. This use pattern is nearly identical with the worst-case use pattern in coffee tested in Mexico, Columbia and Guatemala (cf. KIIA 6.3.2.18/01).

Table 6.3.2.18-9 Most critical Use Patterns for the Application of BYI 02960 on Coffee in Brazil

Test Substance	App. No.	Target Rate Application					Target App. Interval (Days) ^a	Target PHI (Days)	Adjuvant /Additive (%) ^b	Application Solution Volume	
		Formulated Product (fp)		Active Substance (a.s.)						mL/plant	L/ha
		fl oz/A	ml/ha	Name of a.s.	lb a.s./A	kg a.s./ha					
BYI 02960 SL 200	Drench Application										
	1	41.4	3,000	BYI 02960	0.535	0.600	NA ^c	118	None	50	NA ^c
	Foliar Applications										
	2	13.7	1,000	BYI 02960	0.178	0.200	90	30	0.25%	43	400
		13.7	600	BYI 02960	0.178	0.200	15	15	0.25%	43	400
	4	13.7	1,000	BYI 02960	0.178	0.200	15	1	0.25%	43	400

a Single soil drench application (Application No. 1) made at 90 days before the first foliar application (Application No. 2).

b Adjuvant: Methylated Soybean Oil.

c NA = Not Applicable



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Report:	KIIA 6.3.2.18/02; [REDACTED]; 2012
Title:	Determination of residues of BYI 02960 and its metabolites, in coffee after drench application at the base of the plants, followed by foliar application of BYI 02960 (200 SL) in field trials in Brazil
Report No & Document No	I11-008, dated March 12, 2012 M-427469-03-2
Guidelines:	Resolution of Collegiate Board of Directors RDC No. 216 of December 2006,15 th RDC No. 4 of January 2012,18 th National Health Surveillance Agency – ANVISA, from the Ministry of Health
GLP	Yes

Four trials were conducted to measure the magnitude of BYI 02960 residues in/on coffee bean, following a single soil drench application followed by three broadcast foliar spray applications of BYI 02960 200 SL.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The location of field trials are presented in Table 6.3.2.18-10. Additional coffee trials conducted in Mexico, Colombia, and Guatemala are reported separately (Bayer CropScience Report No. BARVP074 (KIIA 6.3.2.18/01).

Table 6.3.2.18-10: Trial Numbers and Geographical Locations for BYI 02960 in/on Coffee

Identification of Field trial	Test Unit of the Field trial (municipality, State, Country)	Name and address of the location
I11-008-01	[REDACTED] Brazil	[REDACTED]
I11-008-02	[REDACTED] Brazil	[REDACTED]
I11-008-04	[REDACTED] Brazil	[REDACTED]
I11-008-05	[REDACTED] Brazil	[REDACTED]

Material and Methods

Drench application was carried out using a pulverization spear nozzle in Trials I11-008-01, I11-008-02, and I11-008-05. In Trial I11-008-04, the test substance was applied directly at the base of the plants, using a graduated beaker.

Soil drench applications ranged from 0.596 to 0.606 kg BYI 02960/ha/application. Individual foliar application rates ranged from 0.170 to 0.214 kg BYI 02960/ha/application. Seasonal total application rates ranged from 1.188 to 1.22 kg BYI 02960/ha. The interval between the drench and first foliar application was 90 days and the interval between the foliar applications was 13 to 15 days.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Methylated soybean oil was used as adjuvant in all of the foliar applications at 0.25% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.18-11. Study use patterns are summarized in Table 6.3.2.18-12.

Table 6.3.2.18-11: Trial Site Conditions for BYI 02960 on Coffee

Identification of the Field Trial	I11-008-01	I11-008-02	I11-008-04	I11-008-05
Principal Investigator	████████ Junior	████████	████████	████████ Junior
Plots Size (m ²) Untreated/Treated	140 / 140	226.8 / 236.8	30 / 30	90 / 90
Number of Plots	2	2	2	2
Spacing between the lines (m)	3.5	4	2	-
Type of Soil	Clayey	Clayey	Clayey	Average
pH-value of soil (in CaCl ₂)	5.1	-	6.1	5.8
pH-value of soil (in H ₂ O)	-	4.4	-	-
Content of organic (%)	3.0	1.8	4.1	2.2
Soil Topography	Declivity < 5%	Declivity < 5%	Declivity < 5%	Declivity < 5%
Test System	Coffee (grains)	Coffee (grains)	Coffee (grains)	Coffee (grains)
Variety	Catuaí	Catuaí-Vermelho	Catuaí	Mundo Novo
Date of the planting	8 years	6/2001	2001	9 years
Date of commercial harvest	May to October	May to August	August to September	May to October

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-12: Study Use Pattern for BYI 02960 200 SL on Coffee

Identification of the Field trial	Type of Application	Dates of application (mm/dd/yy)	Crop stage (BBCH)	Effective volume of spray (L)	Effective applied dose (L/ha)	Effective applied dose (g/a.s./ha)
I11-008-01	Drench	03/29/2011	81	2.80	3.00	600
	Foliar Pulverization	06/27/2011	85	5.62	1.01	202
	Foliar Pulverization	07/12/2011	88	5.80	1.04	208
	Foliar Pulverization	07/27/2011	89	5.22	0.93	186
I11-008-02	Drench	03/25/2011	75	3.67	2.98	598
	Foliar Pulverization	06/23/2011	88	10.0	1.06	212
	Foliar Pulverization	07/08/2011	88	9.48	1.00	200
	Foliar Pulverization	07/22/2011	89	9.11	0.96	192
I11-008-04	Drench	04/08/2011	73	0.996	2.99	598
	Foliar Pulverization	07/07/2011	85	1.23	1.03	206
	Foliar Pulverization	07/22/2011	88	1.02	0.85	170
	Foliar Pulverization	08/05/2011	89	1.28	1.07	214
I11-008-05	Drench	06/24/2011	85	1.90	3.03	606
	Foliar Pulverization	09/22/2011	87	3.80	1.06	212
	Foliar Pulverization	10/07/2011	88	3.60	1.00	200
	Foliar Pulverization	10/20/2011	89	3.65	1.01	202

Duplicate composite samples of coffee beans were collected from the treated plot at 0, 7, 14, 21, and 28 days after the last application. A single control sample was collected at each sampling event. The samples were processed in the field as shown in Table 6.3.2.18-13.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-13: Field processing

Identification of Field trial	Sample Identification	Start Date (mm/dd/yyyy)	Final Date (mm/dd/yyyy)	Processing Type
I11-008-01	I11-008-01-001C	07/27/2011	08/09/2011	Drying after pulping
	I11-008-01-002C			
	I11-008-01-003C			
	I11-008-01-004C	08/03/2011		
	I11-008-01-005C			
	I11-008-01-006C			
	I11-008-01-007C	08/10/2011		
	I11-008-01-008C			
	I11-008-01-009C			
	I11-008-01-010C	08/17/2011		
	I11-008-01-011C			
	I11-008-01-012C			
	I11-008-01-013C	08/24/2011	08/30/2011	
I11-008-01-014C				
I11-008-01-015C				
I11-008-02	I11-008-02-001C	07/22/2011	07/29/2011	Drying after pulping and removal of parchment
	I11-008-02-002C			
	I11-008-02-003C			
	I11-008-02-004C	07/29/2011	08/05/2011	
	I11-008-02-005C			
	I11-008-02-006C			
	I11-008-02-007C	08/05/2011	08/15/2011	
	I11-008-02-008C			
	I11-008-02-009C			
	I11-008-02-010C	08/12/2011	08/19/2011	
	I11-008-02-011C			
	I11-008-02-012C			
	I11-008-02-013C	08/19/2011	08/25/2011	
I11-008-02-014C				
I11-008-02-015C				
I11-008-04	I11-008-04-001C	08/05/2011	08/09/2011	Drying and manual pulping
	I11-008-04-002C			
	I11-008-04-003C			
	I11-008-04-004C	08/07/2011	08/16/2011	
	I11-008-04-005C			
	I11-008-04-006C			
	I11-008-04-007C	08/19/2011	08/23/2011	
	I11-008-04-008C			
	I11-008-04-009C			
	I11-008-04-010C	08/26/2011	08/31/2011	
I11-008-04-011C				
I11-008-04-012C				
I11-008-04-013C	09/02/2011	09/06/2011		
I11-008-04-014C				
I11-008-04-015C				

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-13 (cont'd): Field processing

Identification of Field trial	Sample Identification	Start Date (mm/dd/yyyy)	Final Date (mm/dd/yyyy)	Processing Type
111-008-05	I11-008-05-001C	10/20/2011	11/03/2011	Drying after pulping
	I11-008-05-002C			
	I11-008-05-003C			
	I11-008-05-004C	10/27/2011		
	I11-008-05-005C			
	I11-008-05-006C			
	I11-008-05-007C	11/03/2011		
	I11-008-05-008C			
	I11-008-05-009C			
	I11-008-05-010C	11/10/2011		
	I11-008-05-011C			
	I11-008-05-012C			
	I11-008-05-013C	11/17/2011		
	I11-008-05-014C			
I11-008-05-015C				

The residue(s) of BYI 02960, DFA and DPEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. For the purpose of this summary document and to provide residue data for calculation of MRLs, residue measurements below the analyte LOQ were summed to the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA and DPEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries for each matrix was within the acceptable range of 70 to 110%, and the standard deviation values were ≤ 20% (Table 6.3.2.18-14).

Table 6.3.2.18-14: Summary of Recoveries of BYI 02960 from Coffee

Crop Matrix	Analyte	Fortification Level (mg/kg)	Sample Size (n)	Recoveries (%)	Mean % Recovery	CV (%)	LOQ (mg/kg)
Coffee, Beans	BYI 02960	0.01	4	80; 84; 76; 87; 85	82	5.4	0.01
		0.1	4	84; 87; 85; 84	85	1.8	
	DFA	0.05	6	76; 72; 77; 77; 73; 71	74	3.6	0.01
		0.5	5	84; 70; 82; 83; 82	80	7.2	
	DPEAF	0.01	5	86; 90; 82; 81; 85	85	4.2	0.05
		0.1	4	89; 90; 80; 83	86	5.6	



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

The freezer storage stability study indicates that BYI 02960 residues were stable in coffee bean commodities during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 145 days. A summary of the storage conditions are shown in Table 6.3.2.18-15.

Table 6.3.2.18-15: Summary of Storage Conditions for Coffee

Identification of Field trial	Scheduled DAT (days) ^a	Date of the end of field processing (mm/dd/yy)	Date of last extraction (mm/dd/yy)	Storage Temperature ^b (°C)	Storage Period (days) ^c	Period covered by evaluation of Stability (Days) ^d
I11-008-01	0	08/09/11	12/21/11	<-20	134	560
	7	08/09/11	12/21/11		134	
	14	08/19/11	12/21/11		124	
	21	08/19/11	12/21/11		124	
	28	08/30/11	12/21/11		113	
I11-008-02	0	07/29/11	12/21/11	-20	145	560
	7	08/05/11	12/21/11		128	
	14	08/19/11	12/21/11		128	
	21	08/19/11	12/21/11		124	
	28	08/25/11	12/21/11		118	
I11-008-04	0	08/09/11	12/19/11	-20	132	560
	7	08/16/11	12/19/11		125	
	14	08/25/11	12/27/11		126	
	21	08/31/11	12/27/11		118	
	28	09/06/11	12/27/11		112	
I11-008-05	0	11/03/11	12/19/11	<-20	46	560
	7	11/03/11	12/19/11		46	
	14	11/22/11	12/19/11		27	
	21	11/22/11	12/19/11		27	
	28	11/22/11	12/19/11		27	

- a DAT – Days after last treatment.
- b Samples were stored with dry ice during transportation to UPA and from UPA to the Laboratory and at <-20 °C during storage at UPA and the Laboratory.
- c Period between processing and sample extraction of corresponding sampling (DAT). For samples extracted more than once, the date of the last extraction of treated sample was taken into consideration for the calculation of storage period.
- d [Redacted] and A. [Redacted] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 01.1/01).

The total BYI 02960 residue data for coffee beans following a single soil drench and three foliar applications of BYI 02960 200 SL are shown in Table 6.3.2.18-16.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-16: Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Applications of BYI 02960 SL

Field trial	Identification of Sample	Type	Rate (L/ha) (directed jet-drench)	Rate (g a.s./ha) (foliar)	DAT (days) ^a	Residues (mg a.s. equiv./kg)				
						BYI 02960	DFEAF	DEA	Average of Total cal BYI 02960 ^b	
I11-008-01	I11-008-01-001C-01L	C	---	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-008-01-004C-01L	C	---	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-008-01-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-008-01-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-008-01-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-008-01-002C-01L	T		200	0	0.03	<0.01	<0.05	0.09	0.1
	I11-008-01-003C-01L	T	3	200	0	0.04	<0.01	<0.05	0.1	0.1
	I11-008-01-005C-01L	T	3	200	7	0.03	<0.01	<0.05	0.09	0.08
	I11-008-01-006C-01L	T	3	200	7	<0.01	<0.01	<0.05	<0.07	0.08
	I11-008-01-008C-01L	T		200	14	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-01-009C-01L	T	3	200	14	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-01-011C-01L	T	3	200	1	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-01-012C-01L	T	3	200	21	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-01-014C-01L	T	3	200	28	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-01-015C-01L	T		200	28	<0.01	<0.01	<0.05	<0.07	<0.07

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-16 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Applications of BYI 02960 SL

Field trial	Identification of Sample	Type	Rate (L/ha) (directed jet-drench)	Rate (g a.s./ha) (foliar)	DAT (days) ^a	Residues (mg a.s. equiv./kg)				Average of Total cal BYI 02960
						BYI 02960	DFEAF	DEA	Cal Total of BYI 02960 ^b	
I11-008-02	I11-008-02-001C-01L	C	---	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-008-02-004C-01L	C	---	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-008-02-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-008-02-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-008-02-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-008-02-002C-01L	T		200	0	0.04	<0.01	<0.05	0.1	0.1
	I11-008-02-003C-01L	T	3	200	0	0.04	<0.01	<0.05	0.1	
	I11-008-02-005C-01L	T	3	200	7	0.04	<0.01	<0.05	0.1	0.1
	I11-008-02-006C-01L	T	3	200	7	0.03	<0.01	<0.05	0.09	
	I11-008-02-008C-01L	T		200	14	0.03	<0.01	<0.05	0.09	0.1
	I11-008-02-009C-01L	T	3	200	14	0.04	<0.01	<0.05	0.1	
	I11-008-02-011C-01L	T	3	200	21	0.02	<0.01	<0.05	0.08	0.08
	I11-008-02-012C-01L	T	3	200	21	0.02	<0.01	<0.05	0.08	
	I11-008-02-014C-01L	T	3	200	28	0.07	0.01	0.09	0.17	0.19
	I11-008-02-015C-01L	T		200	28	0.08	0.01	0.1	0.19	

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-16 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Applications of BYI 02960 SL

Field trial	Identification of Sample	Type	Rate (L/ha) (directed jet-drench)	Rate (g a.s./ha) (foliar)	DAT (days) ^a	Residues (mg a.s. equiv./kg)				
						BYI 02960	DFEAF	DEA	Cal Total of BYI 02960 ^b	Average of Total cal BYI 02960
I11-008-04	I11-008-04-001C-01L	C	---	---	0	<0.01	<0.01	<0.05	<0.07	-
	I11-008-04-004C-01L	C	---	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-008-04-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-008-04-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-008-04-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-008-04-002C-01L	T		200	0	0.02	<0.01	<0.05	0.08	0.08
	I11-008-04-003C-01L	T	3	200	0	0.02	<0.01	<0.05	0.08	0.08
	I11-008-04-005C-01L	T	3	200	7	0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-04-006C-01L	T	3	200	7	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-04-008C-01L	T		200	14	0.01	<0.01	<0.05	<0.07	0.07
	I11-008-04-009C-01L	T	3	200	14	0.01	<0.01	<0.05	0.07	0.07
	I11-008-04-011C-01L	T	3	200	21	0.05	<0.01	<0.05	0.11	0.11
	I11-008-04-012C-01L	T	3	200	21	0.05	<0.01	<0.05	0.11	0.11
	I11-008-04-014C-01L	T	3	200	28	0.03	<0.01	<0.05	0.09	0.09
	I11-008-04-015C-01L	T		200	28	0.03	<0.01	<0.05	0.09	0.09

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-16 (cont'd): Total BYI 02960 Residue Data from Coffee Beans after a Single Soil Drench and Three Foliar Applications of BYI 02960 SL

Field trial	Identification of Sample	Type	Rate (L/ha) (directed jet-drench)	Rate (g a.i./ha) (foliar)	DAT (days) ^a	Residues (mg a.s. equiv./kg)				
						BYI 2960	DFEAF	DFA	Total of BYI 02960 ^b	Average of Total cal BYI 02960
I11-008-05	I11-008-05-001C-01L	C	---	---	AG	<0.01	<0.01	<0.05	<0.07	-
	I11-008-05-004C-01L	C	---	---	7	<0.01	<0.01	<0.05	<0.07	-
	I11-008-05-007C-01L	C	---	---	14	<0.01	<0.01	<0.05	<0.07	-
	I11-008-05-010C-01L	C	---	---	21	<0.01	<0.01	<0.05	<0.07	-
	I11-008-05-013C-01L	C	---	---	28	<0.01	<0.01	<0.05	<0.07	-
	I11-008-05-002C-01L	T	3	200	0	0.05	<0.01	<0.05	0.08	0.08
	I11-008-05-003C-01L	T	3	200	0	0.02	<0.01	<0.05	0.08	
	I11-008-05-005C-01L	T	7	200	7	0.05	<0.01	<0.05	0.08	0.08
	I11-008-05-006C-01L	T	3	200	0	0.01	<0.01	<0.05	0.07	
	I11-008-05-008C-01L	T	14	200	14	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-05-009C-01L	T	3	200	14	<0.01	<0.01	<0.05	<0.07	
	I11-008-05-011C-01L	T	21	200	21	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-05-012C-01L	T	3	200	21	<0.01	<0.01	<0.05	<0.07	
	I11-008-05-014C-01L	T	28	200	28	<0.01	<0.01	<0.05	<0.07	<0.07
	I11-008-05-015C-01L	T	3	200	28	<0.01	<0.01	<0.05	<0.07	

a DAT: Days after last Treatment

b For the purpose of this summary document, all residues found below the Limit of Quantitation (LOQ) of the method are reported as < 0.01 mg/kg for BYI 02960 and DFEAF and < 0.05 mg/kg for DFA. Total BYI 02960 residue is the sum of BYI 02960, DFA, and DFEAF residue in parent equivalents. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value at the analyte LOQ value. These totals represent the upper limit of what the residue levels might be.

Conclusion

Four field trials were conducted to measure the magnitude of total BYI 02960 residues in/on coffee beans following a single soil drench and three foliar spray applications of BYI 02960 200 SL.

The total BYI 02960 residue data for coffee beans are summarized in Table 6.3.2.18-17.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.18-17: Summary of Residue Data for Total BYI 02960 from Coffee Trials in Brazil

Commodity	Plot Name	Total Application Rate (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)						
				n	Min	Max	HAFT ²	Median	Mean	Standard Deviation
Coffee bean, green	TRTD	1.19 to 1.22	0	4	0.08	0.10	0.10	0.09	0.08	0.01
			7	4	<0.07	0.10	0.09	0.08	0.08	0.01
			14	4	<0.07	0.10	0.10	0.07	0.08	0.02
			21	4	<0.07	0.11	0.10	0.08	0.08	0.02
			28	4	<0.07	0.19	0.19	0.08	0.11	0.06

TRTD = Treated plot receiving a soil drench application followed by three foliar applications of BYI 02960 200 SL

The data of the four decline trials showed rather similar total BYI 02960 residues independent from the sampling time. The overall maximum residue was detected in a sample collected 28 days after the last application which amounted to 0.19 mg/kg. The residue maximum was reached in two trials at the day of the last application, in one trial 21 days after the last application and in another trial at 28 days after the last application. Thus, no conclusive decline behaviour was detected in coffee beans, however a kind of residue plateau seemed to be reached after the third foliar application.

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Overall conclusion - Coffee

Supervised residue trials were conducted in coffee in the Guatemala, Mexico and in Brazil to achieve national registrations and global import tolerances.

Globally one worst-case GAP was supported and tested: one soil drench application followed by three foliar spray applications of BYI 02960 200 SL. Eight field trials were conducted according to the GAP to measure the magnitude of BYI 02960 residues in/on green coffee beans. In addition three field trials will be conducted in Columbia.

A summary of the use pattern tested and the corresponding residue levels detected in the field samples are shown in Table 6.3.2.18-18.

Table 6.3.2.18-18: Summary of Residue Data for Total BYI 02960 from Coffee

Crop	Formulation	Use pattern	Method	PHI	No. Application	No. Trials	Total Residue of BYI 02960 at PHI (ppm)	Peak residue (ppm)	Day of peak residue
Mexico, Guatemala									
Coffee	SL 200	1 x 600 kg a.s./ha 3 x 200 kg a.s./ha	Soil drench followed by foliar spray	0	4	4	0.16-0.87	0.98	26
Brazil									
Coffee	SL 200	1 x 600 kg a.s./ha 3 x 200 kg a.s./ha	Soil drench followed by foliar spray	0	4	4	0.08-0.10	0.19	28

Highest residue levels were observed in the coffee trials in Guatemala and Mexico although all trials were conducted according to very similar use patterns. Overall, total residue levels of BYI 02960 did not always peak at the intended PHI, two trials showed the maximum residue level at the last sampling event. However, the residues were in the same range than the residues at the intended PHI of 0 days and it can be concluded that generally the total residue leveled off after the third application.

The residue data provided for coffee are suitable for regulatory purposes.

Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)
IIA 6.3.2.19 Hops
Residue data from NORTH AMERICA

BYI 02960 is to be registered in USA and Canada for use as a foliar treatment on hops. The use pattern in North America is summarized in Table 6.3.2.19-1.

Three field trials were conducted in hops. The studies are described below.

Table 6.3.2.19-1: Target Use Patterns for the Application of BYI 02960 on Hops

Test Substance	No. of Apps	Target Rate/Application					Target App. Interval (Days)	Target PHI (Days)	Adjuvant /Additive (%)	Spray Volume	
		Formulated Product (FP)		Active Substance (a.s.)						GPA	LPIA
		mL/A	fl oz/A	Name of a.s.	lb a.s./A	Kg a.s./ha					
BYI 02960 SL 200	1	311.7	10.54	BYI 02960	0.1374	0.154	NA ¹	21	0.25-1.0	10-50	94-468
BYI 02960 SL 200	1	311.7	10.54	BYI 02960	0.1374	0.154	NA ¹	21	0.25 - 1.0	50-450	468-1410

1 NA = Not applicable.

Report:	KIIA 6.3.2.19/01; [REDACTED] 2012
Title:	BYI 02960 SL 200 - Magnitude of the Residue in/on Hops
Report No & Document No	PARVY008, dated June 2, 2012 M-432695-01
Guidelines:	US: EPA Residue Chemistry Test Guidelines OPPS 860.1500, Crop Field Trials Canada: PMRA DACO 7.4.1, Supervised Residue Trial Study PMRA DACO 7.4.2, Residue Decline OECD: Guidelines for the Testing of Chemicals, 509, Crop Field Trial, Adopted Sept. 7, 2009.
GLP	Yes

Three field trials were conducted to measure the magnitude of BYI 02960 residues in/on hops following a single broadcast foliar spray application (either as a diluted or a concentrated spray) of BYI 02960 200 SL.

BYI 02960 200 SL is a soluble concentrate formulation containing 200 g BYI 02960/L. The number and location of field trials conform to the guidance given by the EPA (Table Table 6.3.2.19-2).

Table 6.3.2.19-2: Trial Numbers and Geographical Locations for BYI 02960 on Hops

NAFTA Growing Region	Submitted ^a	Requested
4	2	
12	1	
Total	3	3^a

a There is no specified guidance on distribution of trials for hops, although virtually all of the production is in EPA region 11.

Material and Methods

Individual application rates ranged from 0.137 to 0.139 lb BYI 02960/A (0.154 to 0.156 kg BYI 02960/ha) for the concentrated plot and from 0.136 to 0.138 lb BYI 02960/A (0.152 to 0.155 kg BYI 02960/ha) for the dilute plot. Spray volumes ranged from 33.6 GPA to 45.1 GPA for the concentrated plot and from 63.6 GPA to 126 GPA for the dilute plot. All applications were made at BBCH growth stage 85 (advanced ripening).

All applications were made using ground-based equipment. Trial RV047-11HA used a non-ionic surfactant (NIS) in applications to both plots at 0.2% (v/v), trial RV048-11HA used a crop oil concentrate (COC) in applications to both plots at 1.0% (v/v), and trial RV049-11HA used methylated seed oil (MSO) in applications to both plots at 0.2% (v/v).

Trial Site conditions, including soil characteristics are summarized in Table 6.3.2.19-3. Study use patterns are summarized in Table 6.3.2.19-4.

Table 6.3.2.19-3: Trial Site Conditions for BYI 02960 on Hops

Trial Identification	Trial Location (City, Country/State, Year)	Soil Characteristics ^a				Meteorological Data ^b	
		Type	OM (%)	pH	CEC (meq/100g soil)	Total Rainfall (in)	Temp. Range (°F)
RV047-11HA	██████, ID 2011	Loam	1.2	8	33.7	0.10	50 - 92
RV048-11HA	██████, WA 2011	Loamy Sand	1.2	5.1	11.7	0.05	48-82
RV049-11HA	██████, OR	Silt Loam	3	5.7	16.1	0.27	50 - 81

a Abbreviations used: %OM = percent organic matter; CEC = cation exchange capacity.

b Data is for the interval of the month of first application through the month of last sampling. Meteorological data were obtained from nearby government weather stations.

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Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.19-4: Study Use Pattern for BYI 02960 200 SL on Hops

Trial Identification	Location (City, State, NAFTA Region, and Year)	End-use Product (Formulation)	Application							
			Plot Name	Method	Timing/Growth Stage (BBCH)	Spray Volume GPA (L/ha)	Rate lb a.s./A (kg a.s./ha)	Retreatment Interval (days)	Total Rate lb a.s./A (kg a.s./ha)	Tank Mix Adjuvants
RV047-11HA	[REDACTED] ID Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast	85	45 (422)	0.139 (0.156)	NA ^a	0.139 (0.156)	R11 NIS, 0.2% v/v
			TRTDD	Airblast	85	126 (1178)	0.138 (0.155)	NA ^a	0.138 (0.155)	R11 NIS, 0.2% v/v
RV048-11HA	[REDACTED] WA Region 11 2011	BYI 02960 200 SL	TRTDC	Airblast	85	45 (421)	0.138 (0.155)	NA ^a	0.138 (0.155)	MOR-ACT COC, 1% v/v
			TRTDD	Airblast	85	104 (974)	0.138 (0.154)	NA ^a	0.138 (0.154)	MOR-ACT COC, 1% v/v
RV049-11HA	[REDACTED] OR Region 12 2011	BYI 02960 200 SL	TRTDC	Airblast	85	64 (615)	0.137 (0.154)	NA ^a	0.137 (0.154)	MSO, 0.25% v/v
			TRTDD	Airblast	85	64 (595)	0.136 (0.152)	NA ^a	0.136 (0.152)	MSO, 0.25% v/v

a NA = Not applicable.

Single composite samples of fresh hop cones from both the concentrated and dilute spray plots, along with an untreated control sample, were collected at the pre-harvest interval (PHI) of 21 days. The fresh hops were kiln-dried on the day of harvest to generate the RAC of dried hop cones.

The residue(s) of BYI 02960, DFA, and DFEAF were quantitated by HPLC-MS/MS using stable isotopically labelled internal standards. The individual analyte residues were summed to give a total BYI 02960 residue. Residue measurements below the analyte LOQ were summed into the total BYI 02960 residue value as the analyte LOQ value.

Findings

Concurrent recoveries of BYI 02960, DFA, and DFEAF were measured with each set of samples to verify method performance. All recoveries were corrected for any interferences in corresponding controls. The overall mean of the recoveries at each fortification level was within the acceptable range of 70 to 116%, and the standard deviation (SD) values were below 20% (Table 6.3.2.19-5).



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.19-5: Summary of Recoveries of BYI 02960 from Hops

Crop Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean % Recovery	Stan. % Dev.
Hop Cone, kiln-dried	BYI 02960	0.010	7	88, 91, 93, 97, 101, 96, 85	93	5.3
		2.400	3	99, 97, 97	98	1.4
		4.800	3	89, 89, 87	88	1.3
	DFA	0.050	7	86, 88, 90, 89, 93, 95, 90	90	2.9
		2.400	3	87, 85, 82	85	2.3
		4.800	3	89, 91, 89	90	1.1
	DFEAF	0.010	7	107, 94, 94, 97, 92, 95, 79	93	8.2
		2.400	3	99, 101, 103	101	1.8
		4.800	3	94, 92, 90	92	1.9

a Mean Recovery = mathematical average of all recoveries

The freezer storage stability study indicates that BYI 02960 residues were stable in coffee beans and soybeans - as high oil content representatives - during frozen storage for at least 18 months prior to analysis. The maximum storage period of frozen samples in this study for BYI 02960 was 226 days. A summary of the storage conditions are shown in Table 6.3.2.19-6.

Table 6.3.2.19-6: Summary of Storage Conditions for Hops

Residue Component(s)	Matrix (RAE)	Maximum Average Storage Temperature (°C)	Actual Storage Duration months (days) ^{b,c,d}
BYI 02960	Hops Dried Cones	< -19	8 (226)
DFEAF	Hops Dried Cones	< -19	8 (226)
DFA	Hops Dried Cones	< -19	8 (226)

a The maximum average storage temperature is from the time of sample receipt at BRP until sample extraction. While preparing for sample analysis, the samples were maintained in a laboratory freezer.

b The storage duration is the time from field sampling through the last sample extraction.

c [REDACTED] and A. [REDACTED] 2012. Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices. Bayer CropScience Report No. RARVP046, amended version including 18-month data (KIIA 6.1.1/02)

The total BYI 02960 residue data for hops following one foliar application of BYI 02960 200 SL are shown in Table 6.3.2.19-



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.19-7: Total BYI 02960 Residue Data from Hops after One Foliar Application of BYI 02960 SL

Trial Identification	Location (City, State, Region, and Year)	Plot Name	Crop Variety	Commodity	Total Rate kg a.s./A (kg a.s./ha)	% Dry Matter	Pre-harvest interval (days)	BYI 02960 Residue (ppm)	DFA Residue (ppm)	DFEAF Residue (ppm)	Total BYI 02960 Residue (ppm) ^b
Dried Cones											
RV047-11HA	██████ ID, Region 11, 2011	TRTDC	Apollo	Hops, dried cones	0.138 (0.156)	70	21	2.44	0.90	0.011	3.32
		TRTDD	Apollo	Hops, dried cones	0.138 (0.155)	70	21	2.7	0.862	0.006	3.14
RV048-11HA	██████ WA, Region 11, 2011	TRTDC	Cascade	Hops, dried cones	0.138 (0.155)	70	21	4.63	2.32	0.037	7.98^c
		TRTDD	Cascade	Hops, dried cones	0.138 (0.149)	70	21	4.72	2.97	0.070	7.76^d
RV049-11HA	██████ OR, Region 12, 2011	TRTDC	Nugget	Hops, dried cones	0.137 (0.14)	70	21	2.26	0.804	0.004	3.07
		TRTDD	Nugget	Hops, dried cones	0.136 (0.152)	70	21	2.70	0.642	0.008	3.35

- a Pre-Harvest Interval (PHI) is the interval between last application and sampling date at harvest
- b Total BYI 02960 residue is the sum of BYI 02960, DFA and DFEAF residue in parent equivalents. These totals represent the upper limit of what the residue levels might be.
- c Maximum residue found in dried hops cones from a concentrated spray treatment.
- d Maximum residue found in dried hops cones from a dilute spray treatment.

Conclusion

Three field trials were conducted to measure the magnitude of total BYI 02960 residue in/on dried hops cones following one foliar spray application of BYI 02960 200 SL. The total BYI 02960 residue data for hops are summarized in Table 6.3.2.19-8.



Tier 2, IIA, Sec. 4, Point 6: Flupyradifurone (BYI 02960)

Table 6.3.2.19-8: Summary of Residue Data for Total BYI 02960 from Hops

Commodity	Plot Name ¹	Total Application Rate lb a.s./A (kg a.s./ha)	PHI (days)	Total BYI 02960 Residue Levels (ppm)						
				n	Min at PHI	Max at PHI	HAFT ²	Median	Mean	Standard Deviation
Dried Hops Cones	TRTDC	0.137 to 0.139 (0.154 to 0.156)	21	3	3.07	7.98	7.98	3.32	3.99	2.77
	TRTDD	0.135 to 0.138 (0.152 to 0.155)	21	3	3.14	7.76	7.76	3.35	4.27	2.77

1 TRTDC = Treated plot receiving one concentrated airblast application
 TRTDC = Treated plot receiving one diluted airblast application

2 HAFT = Highest Average Field Trial; As single samples were collected from each plot, the HAFT is set equal to the maximum residue measured.

Total BYI 02960 residues were in the same range independent from application of a diluted or a concentrated spray. The highest residue in kiln-dried hops cones amounted to 7.98 mg/kg and was significant higher than the residues detected in the European residue trials with an application rate of 0.12 kga.s./ha.

The residue data provided for hops are suitable for regulatory purposes.

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