



Document Title

**Summary of the residues in or on treated products, food and feed for
fosetyl**

Data Requirements

EU Regulation 1107/2009 & EU Regulation 283/2013

Document MCA

Section 6: Residues in or on treated products, food and feed

According to the Guidance Document SANCO/10181/2013 for
preparing dossiers for the approval of a chemical active substance

Date

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Version history

Date (yyyy-mm-dd)	Data points containing amendments or additions ¹ and brief description	Document identifier and version number
2015-09-21	Original Document MCA – Section 6 of Supplementary Dossier	M-534278-02-0
2016-05-02	<p>Dossier update according to “Request for additional information on the supplementary dossier submitted by Bayer CropScience for the approval renewal of the active substance Fosetyl (2015-5866) by RMS France on 2016-04-04:</p> <ul style="list-style-type: none"> - The study report KCA 6.1/04, [REDACTED], N.; 2015; M-529397-01-1, has been amended ([REDACTED]; 2016; M-529397-02-1) to demonstrate that the total fosetyl-Al derived residues (sum of the remaining fosetyl-Al and of the produced phosphonic acid calculated as fosetyl-Al) are stable over 2 years in one representative commodity of each of the five crop categories (please refer to chapter CA 6.1). - Change of application interval for cGAP of pome fruits from 7 to 10 days to 10 days only in chapter CA 6.3.4 and Table 6.3.4. 	M-534278-03-1

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 “How to revise an Assessment Report”

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CA 6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

Fosetyl was included in Annex I to Directive 91/414/EEC in 2006 (Directive 2006/64/CE of 18 July 2006, Entry into Force on 1 May 2007). This Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of fosetyl under Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer CropScience (BCS) for the Annex I inclusion under Directive 91/414/EEC are contained in the DAR, its Addenda and are included in the Baseline Dossier provided by BCS. These data are only mentioned in the Supplementary Dossier for the sake of completeness and only general information (e.g. author, reference etc.) is available for these data. In order to facilitate discrimination between new data and data submitted during the Annex I inclusion process under Directive 91/414/EEC, the old data are written in grey typeface. For all new studies, detailed summaries are provided within the Supplementary Dossier. However, for a better understanding of the residues of fosetyl in or on treated products, food and feed, short summaries including the results of all studies are given at the beginning of the relevant sections. Additional information requested by the RMS France on 2016-04-04 during the evaluation of the Supplementary Dossier is highlighted in yellow.

Fosetyl is the ISO common name for ethyl hydrogen phosphonate (HUPAC). Due to the fact that the aluminium salt, a variant of fosetyl, is used in the formulated product, it should be noted that the data in this section belong to the variant fosetyl-aluminium (fosetyl-Al), unless otherwise specified.

In original reports study authors may have used different names or codes for metabolites of fosetyl-Al. In this summary, a single name or a single code is used for each metabolite. A full list containing structural formula, various names, short forms, codes and occurrences of metabolites is provided as Document N3.

As some pragmatic approach "phosphonic acid" formed as a major metabolite is reported in this Supplementary Dossier as the free acid for the sake of clarity and unequivocal handling. After application, aluminium tris-O-ethyl phosphonate (i.e. fosetyl-Al) dissociates into the O-ethyl phosphonate and aluminium ions. Any phosphonate formed from O-ethyl phosphonate in the following would never be present in the form of the free acid (i.e. phosphonic acid) under the conditions of the environment (pH 4 to 9). This conclusion is supported by the molecular structure and by the dissociation constant observed (dissociation constant for the first step of deprotonation: $pK_a = 2.0$). Consequently phosphonates in their fully protonated form are strong acids that spontaneously form salts in contact with soil or natural water with any suitable counter ion present (i.e. sodium, potassium, magnesium, calcium). With the ability to readily form salts in the environment phosphonates are, in terms of their acidic or alkaline character, similar to the salts of phosphoric acid (i.e. phosphates) in their environmental behavior.

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Fosetyl

CA 6.1 Storage stability of residues

Former Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC

In the original Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC the storage stability of residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the study report) was investigated in vegetables (cucumber, potato and lettuce) and in fruit (grapes) with up to 12 months storage period.

Table 6.1- 1: Summary of storage stability of fosetyl-Al and its metabolite phosphonic acid in plant matrices submitted in the Annex II dossier

Compound	Category	Commodity	Stability up to	Study No.	Document N°	Dossier Reference
Fosetyl-Al	High water	Cucumber	< 3.5 months	00-2002-002 (1994-M-157971-01)	M-204268-01-1 (C010256)	KCA 6.1/01
		Lettuce	< 5 months			
	High starch	Potato	< 4 months			
	High acid	Grape	12 months			
Phosphonic acid	High water	Cucumber	12 months			
		Lettuce	12 months			
	High starch	Potato	12 months			
	High acid	Grape	12 months			

An additional study (CA 6.1-02, [redacted] 1994-M-157971-01) was provided in the DAR for grapes. As it was only analysed for fosetyl-Al it is therefore not considered in this table and the following summary. The study shows that fosetyl-Al was stable in grapes for 12 months.

The samples were fortified separately with fosetyl-aluminium (fosetyl-Al) and phosphonic acid at 2.0 mg/kg and they were kept at temperatures below -20 °C for up to 1 year.

The samples fortified with fosetyl-Al were analysed as fosetyl-Al and phosphonic acid in order to follow and quantify the degradation of fosetyl-Al into phosphonic acid.

Residues of fosetyl-Al and phosphonic acid in/on plant material were determined by derivatization with trimethylsilyldiazomethane and gas chromatography-using a flame photometric detector (phosphorous mode) according to the method AR 54-97. The validation of the method and the concurrent recoveries were performed at 2.0 mg/kg for fosetyl-Al and phosphonic acid.

The detailed results are presented in Table 6.1-2 to Table 6.1-4.

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Table 6.1- 2: Storage stability recoveries of fosetyl-Al fortified at 2.0 mg/kg

Commodity	Storage Period (months)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Fresh Concurrent Recoveries %	Average Corrected % Recovery ^b	
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery				
Cucumber	0	1.5	75	75	100	84*	99	
		1.5	75					
	3.5	1.1	55	50	67	85	44	
		0.9	45					
	6	1.0	50	50	63	91	59	
		1.0	50					
	9	0.9	45	48	43	100	30	
		1.0	50					
	12	0.6	30	33	3	-	-	
		0.7	35					
	Lettuce	0	1.5	75	75	100	79*	95
			1.5	75				
3.5		0.9	45	45	30	-	47	
		0.9	45					
6		0.6	20	20	3	-	24	
		0.6	20					
9		n.a.	n.a.	-	-	-	-	
		n.a.	n.a.					
12		n.a.	n.a.	-	-	-	-	
		n.a.	n.a.					
Potato		0	1.5	85	103	100	81*	105
			1.7	85				
	3.5	0.5	25	28	32	77	36	
		0.6	30					
	6	0.5	15	15	21	105	17	
		0.4	20					
	9	n.a.	n.a.	-	-	-	-	
		n.a.	n.a.					
	12	n.a.	n.a.	-	-	-	-	
		n.a.	n.a.					
	Grape	0	2.0	100	103	100	84*	122
			1.9	95				
3.5		1.5	75	73	71	123	59	
		1.1	70					
6		1.4	70	70	68	118	59	
		1.4	70					
9		1.1	70	75	73	100	75	
		0.6	80					
12		1.5	75	70	68	106	66	
		1.3	65					

*: Day 0, mean of 2 concurrent recovery values

n.a.: Not analysed as degradation of fosetyl-Al exceeds 70% after 6 months of storage.

^a: normalised by dividing with the mean recovery value obtained at Day 0

^b: corrected by dividing with the corresponding concurrent recovery value or mean of concurrent recovery values for Day 0

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Table 6.1- 3: Storage stability data for fosetyl-Al including produced phosphonic acid during storage

Commodity	Storage Period (months)	Residue Level in Stored Spiked Samples									
		Residue Level of fosetyl-Al			Residue Level of phosphonic acid* appeared as fosetyl-Al			Total Residue Level as fosetyl-Al			
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	
Cucumber	0	1.5	75	75	0.5	25	25	2.0	100	100	
		1.5	75		0.5	25		2.0	100		
	3.5	1.1	55	55	0.5	25	20	1.6	80	78	
		0.9	45		0.7	35		1.2	60		
	6	1.0	50	50	0.7	35	28	1.7	85	78	
		1.0	50		0.7	35		1.7	85		
	9	0.9	45	48	0.7	35	35	1.6	85	83	
		1.0	50		0.7	35		1.6	85		
	12	0.6	30	30	0.8	40	40	1.6	80	78	
		0.7	35		0.8	40		1.5	75		
	Lettuce	0	1.5	75	75	0.5	25	25	2.0	100	100
			1.5	75		0.5	25		2.0	100	
3.5		0.9	45	45	0.8	40	40	1.7	85	85	
		0.8	40		0.8	40		1.7	85		
6		0.4	20	20	1.1	55	60	1.6	80	83	
		0.6	30		1.1	55		1.7	85		
9		n.a.	n.a.	-	n.a.	n.a.	-	n.a.	n.a.	-	
		n.a.	n.a.		n.a.	n.a.		n.a.	n.a.		
12		n.a.	n.a.	-	n.a.	n.a.	-	n.a.	n.a.	-	
		n.a.	n.a.		n.a.	n.a.		n.a.	n.a.		
Potato		0	1.7	85	85	0.5	25	28	2.2	110	113
			1.7	85		0.6	30		2.3	115	
	4	0.5	25	28	0.9	45	55	1.4	70	83	
		0.6	30		1.0	50		1.9	95		
	6	0.3	15	20	0.8	40	83	2.1	105	100	
		0.4	20		1.5	75		1.9	95		
	9	n.a.	n.a.	-	n.a.	n.a.	-	n.a.	n.a.	-	
		n.a.	n.a.		n.a.	n.a.		n.a.	n.a.		
	12	n.a.	n.a.	-	n.a.	n.a.	-	n.a.	n.a.	-	
		n.a.	n.a.		n.a.	n.a.		n.a.	n.a.		

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Commodity	Storage Period (months)	Residue Level in Stored Spiked Samples								
		Residue Level of fosetyl-Al			Residue Level of phosphonic acid* appeared as fosetyl-Al			Total Residue level as fosetyl-Al		
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery
Grape	0	2.2	110	103	2.8	30	28	2.8	140	13
		1.9	95		2.5	25		2.4	120	
	3.5	1.5	75	73	0.4	20	20	1.1	90	93
		1.4	70		0.4	20		1.8	90	
	6	1.4	70	73	0.4	20	20	1.8	90	93
		1.4	70		0.4	20		1.8	90	
	9	1.4	70	73	0.4	20	20	1.1	90	95
		1.6	80		0.4	20		1.0	100	
	12	1.5	75	70	0.4	20	20	1.9	100	90
		1.3	65		0.4	20		1.1	85	

n.a.: not analysed as degradation of fosetyl-Al exceeds 70% after 6 months of storage.

* Metabolite named phosphorous acid in the study, expressed as % of fosetyl-Al.

Table 6.1- 4: Storage stability recoveries of phosphonic acid fortified at 2.0 mg/kg

Commodity	Storage Period (months)	Residue level in Stored Spiked Samples			Day 0 Normalized Recovery ^a	Fresh Concurrent Recoveries %	Average Corrected % Recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Cucumber	0	2.1	105	95	100	114*	83
		1.6	85				
	6	1.8	90	80	84	93	86
		1.6	80				
		2.1	105				
		2.0	100				
12	2.0	100	98	103	105	93	
	1.9	95					
Lettuce	0	1.8	90	93	100	101*	92
		1.7	85				
		1.8	90				
	6	1.7	85	88	95	78	112
		1.5	75				
	9	1.6	80	83	89	107	77
1.7		85					
12	2.2	110	108	116	103	104	
	2.1	105					

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Commodity	Storage Period (months)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Fresh Concurrent Recoveries %	Average Corrected % Recovery ^b	
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery				
Potato	0	2.0	100	100	100	90*	112	
		2.0	100					
	4	1.7	85	98	98	88	111	
		2.2	110					
	6	2.5	125	85	18	10	94	
		1.7	85					
	9	1.7	85	88	88	93	94	
		1.8	90					
	12	2.0	100	100	70	10	117	
		2.0	100					
	Grape	0	2.3	105	105	105	104	103
			2.0	100				
3.5		1.8	90	90	84	7	117	
		1.8	90					
6		1.9	95	98	95	100	99	
		2.1	100					
9		2.1	100	100	95	100	103	
		2.0	100					
12		2.1	105	105	88	100	146	
		2.1	105					

*: at day 0, mean of 2 concurrent recovery values
 a: normalised by dividing with the mean recovery value obtained at Day 0
 b: corrected by dividing with the corresponding concurrent recovery value or mean of concurrent recovery values for Day 0

The storage stability recoveries of fosetyl-Al indicate a rapid hydrolysis of fosetyl-Al to phosphonic acid. Day 0 samples were extracted about 2 hours after fortification and analysed. After analysis of the day 0 samples, 36 to 60% of the fosetyl-Al were converted to phosphonic acid. Also after freezing, hydrolysis of fosetyl-Al to phosphonic acid continued, in potato and lettuce fosetyl-Al declined after 6 months storage, 18 and 15%, respectively, whereas the amount of phosphonic acid increased accordingly.

In cucumber, less hydrolysis to phosphonic acid could be observed. After 12 months storage, 65% of the fortified fosetyl-Al were detected as phosphonic acid (expressed as fosetyl-Al) and 33% were quantified as fosetyl-Al.

Only in grape, hydrolysis of fosetyl-Al did not further increase after freezing the samples. After 12 months storage, 70% was quantified as fosetyl-Al and 29% as phosphonic acid.

The storage stability recoveries of phosphonic acid, remained stable for at least 12 months under these conditions in all matrices: grape, cucumber, potato and lettuce

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Conclusion

These data demonstrated a degradation of fosetyl-AI into phosphonic acid after several months in commodities with high water content and high starch content and low degradation of fosetyl-AI in commodity with high acid content. No degradation of phosphonic acid was observed in all commodities.

These data were evaluated during the EU review of the active substance. They demonstrated that the sum of fosetyl, phosphonic acid and their salts are stable under storage conditions at $\leq 20^{\circ}\text{C}$ for at least 12 months which was considered as acceptable regarding the consumer risk assessment and MRL proposals (EFSA Scientific Report (2005) 54, 1-79).

New studies submitted in Supplementary Dossier

A second storage stability study (study number 05-09, [REDACTED] A; [REDACTED], 2007, M-296649-01-1) was conducted on cucumber, cabbage, potato and grape to cover a storage period of two years. This study was submitted as an Addendum to Annex II in 2008 and was also evaluated in the modification of the existing MRLs (EFSA Journal 2012; 10(12):3019) and the review of the existing MRLs (EFSA Journal 2012; 10(11):2961).

An additional study (study number 13-02, [REDACTED] M, 2016, M-529397-02-1) was performed to cover at least one representative commodity of each crop category and to demonstrate the time period in several representative commodities of the main commodity categories (high water and high acid content).

All the available results are compiled in Table 6.1- 5.

Table 6.1- 5: Summary of storage stability of fosetyl-AI and its metabolite phosphonic acid in plant matrices

Compound	Category	Commodity	Stability up to		Study No	Document No	Dossier Reference
			Months	Days			
Fosetyl-AI	High water	Cucumber	< 3	na	00-22	M-204268-01-1	KCA 6.1/01
			8	244	05-09	M-296649-01-1	KCA 6.1/03
		Cabbage	6	202	05-09	M-296649-01-1	KCA 6.1/03
			1.5	na	00-22	M-204268-01-1	KCA 6.1/01
		Lettuce	< 2	70	13-02	M-529397-02-1	KCA 6.1/04
			78	13-02	M-529397-02-1	KCA 6.1/04	
	High oil	Avocado	< 2	< 67	13-02	M-529397-02-1	KCA 6.1/04
		Bean	4	748	13-02	M-529397-02-1	KCA 6.1/04
	High starch	Potato	< 4	na	00-22	M-204268-01-1	KCA 6.1/01
			5	164	05-09	M-296649-01-1	KCA 6.1/03
	High acid	Grape	12	na	00-22	M-204268-01-1	KCA 6.1/01
			25	761	05-09	M-296649-01-1	KCA 6.1/03
Orange		5	175	13-02	M-529397-02-1	KCA 6.1/04	

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Compound	Category	Commodity	Stability up to		Study No	Document No	Dossier Reference
			Months	Days			
Phosphonic acid	High water	Cucumber	12	na	00-22	M-204268-01-1	KCA 6.1/01
			25	761	05-09	M-296649-01-1	KCA 6.1/03
		Cabbage	24	734	05-09	M-296649-01-1	KCA 6.1/03
		Lettuce	12	na	00-22	M-204268-01-1	KCA 6.1/01
			24	729	13-02	M-529397-02-1	KCA 6.1/04
		Tomato	24	741	13-02	M-529397-02-1	KCA 6.1/04
	High oil	Avocado	24	732	13-02	M-529397-02-1	KCA 6.1/04
	High protein	Bean	24	748	13-02	M-529397-02-1	KCA 6.1/04
	High starch	Potato	12	na	00-22	M-204268-01-1	KCA 6.1/01
			25	758	05-09	M-296649-01-1	KCA 6.1/03
	High acid	Grape	12	na	00-22	M-204268-01-1	KCA 6.1/01
			25	751	05-09	M-296649-01-1	KCA 6.1/03
Orange	24	745	13-02	M-529397-02-1	KCA 6.1/04		

na: not available

Report: KCA 6.1/03 [redacted], [redacted] 2007; M-296649-01-1
Title: Storage stability of residues of fosetyl-Al (AE E053616) and its metabolite (Phosphorous Acid : AE 0540099) in grape, potato, cucumber and cabbage during deep freeze storage for at least 24 months
Report No.: MR 07/364
Document No.: M-296649-01-1
Guidelines: EU Council Directive 91/414/EEC amended by the Commission directive 96/68/EC; US EPA Residue Chemistry Pest Guideline OPPTS 860.1380: Storage Stability Data
Guideline deviation(s): Deviation n° 1: for the control point done at 19.5 months for grape, fresh phosphorous acid recoveries were performed at 2LOQ and 40LOQ, instead of LOQ and 20LOQ. There was no impact on the study.

GLP/GEP: yes

Material and Methods

This study was conducted in order to investigate the stability of residues of fosetyl-aluminium (fosetyl-Al) and its metabolite phosphonic acid in fortified control samples of plant origin (cucumber (whole fruit), cabbage (head), potato (tuber) and grape (whole fruit)) during freezer storage for 24 months.

The control material used for the storage stability experiments originated from a local grocery store (cucumber, cabbage and potato) or a private vine (grape). The control samples were shredded in a cutter with dry ice, 20 g aliquots of the homogenized control material were weighed into polypropylene bottles. The samples were fortified individually and separately with 400 µL of the spiking solution at 100 mg/L resulting in a fortification level of 2.0 mg/kg of fosetyl-Al or phosphonic acid. In addition untreated samples were prepared for control and recovery experiments.

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Immediately after fortification, a sample was taken to determine the initial residues. The remaining fortified samples were stored deep frozen at -18°C or below until analysis after nominal storage intervals of 2, 5, 8, 12, 19.5 and 25 months for cucumber, potato and grape and of 1, 4, 7, 11, 18 and 24 months for cabbage.

Residues of fosetyl-Al and phosphonic acid in/on plant material were determined by HPLC-MS/MS according to the method 00861/M001. The limit of quantification (LOQ) was 0.01 mg/kg for fosetyl-Al and 0.10 mg/kg for phosphonic acid.

Before day 0 (zero time analyses) to demonstrate the accuracy of the method one control and eight spiked samples were prepared as follows:

- 2 recoveries fortified at LOQ (0.01 mg/kg) for fosetyl-Al and at LOQ (0.10 mg/kg) for phosphonic acid with a mixture containing the two compounds,
- 2 recoveries fortified at 200xLOQ (2.0 mg/kg) for fosetyl-Al and at 20xLOQ (2.0 mg/kg) for phosphonic acid with a mixture containing the two compounds,
- 2 recoveries fortified at 200xLOQ for fosetyl-Al, only with this compound,
- 2 recoveries fortified at 20xLOQ for phosphonic acid, only with this compound.

On day 0 and at later sampling intervals three spiked samples were analysed for each sample material. One recovery was performed at the respective LOQ level and two recoveries at 2.0 mg/kg with a mixture of fosetyl-Al and phosphonic acid (except for cabbage at storage interval of 18 months: phosphonic acid was fortified at 0.20 mg/kg and 4.0 mg/kg). The freshly fortified samples were then extracted and analysed concurrently with the control and stored spiked storage samples.

The level of fortification is fixed at 2.0 mg/kg (200 and 20 times the LOQ method respectively for fosetyl-Al and phosphonic acid).

The level of 2.0 mg/kg for fosetyl-Al has been chosen to be able to follow up a degradation of 10% of this compound into phosphonic acid, equivalent to 0.14 mg/kg which is more than the phosphonic acid LOQ method and therefore calculate the total.

Findings

The results are presented following the order of the crops in the report.

In the control samples used for fortification, the residues were always below the LOQ (0.01 mg/kg for fosetyl-Al and 0.10 mg/kg for phosphonic acid).

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Table 6.1- 6: Results obtained for stored control samples

Sample material	Nominal Storage Interval (months)	Residue [mg/kg]	
		Fosetyl-Al	Phosphonic acid
Cucumber (whole fruit)	0	< 0.01	< 0.10
	2	< 0.01	< 0.10
	5	< 0.01	< 0.10
	8	< 0.01	< 0.10
	12	< 0.01	< 0.10
	19.5	< 0.01	< 0.10
	25	< 0.01	< 0.10
Cabbage (head)	0	< 0.01	< 0.10
	1	< 0.01	< 0.10
	4	< 0.01	< 0.10
	7	< 0.01	< 0.10
	11	< 0.01	< 0.10
	16	< 0.01	< 0.10
	24	< 0.01	< 0.10
Potato (tuber)	0	< 0.01	< 0.10
	5	< 0.01	< 0.10
	12	< 0.01	< 0.10
	19	< 0.01	< 0.10
	25	< 0.01	< 0.10
	31	< 0.01	< 0.10
	35	< 0.01	< 0.10
Grape (whole fruit)	0	< 0.01	< 0.10
	5	< 0.01	< 0.10
	12	< 0.01	< 0.10
	19	< 0.01	< 0.10
	25	< 0.01	< 0.10
	31	< 0.01	< 0.10
	35	< 0.01	< 0.10

As shown in Table 6.1- 5 to Table 6.1- 10, the validation recoveries and the concurrent recoveries determined from freshly fortified samples were in the 70 to 110% range except one mean value during validation at 114% (LOQ level for phosphonic acid in cucumber), four concurrent recoveries for fosetyl-Al at 112% (LOQ level in cucumber), 111% and 112% (200xLOQ level in potato) and 118% (LOQ level in grape) and six concurrent recoveries for phosphonic acid at 128% (LOQ level in cucumber), 112% and 112% (20xLOQ level in cucumber), 121% and 119% (20xLOQ level in potato) and 121% (LOQ level in grape).

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Table 6.1- 7: Recovery data for method validation for fosetyl-AI

Sample Material	Fortification level [mg/kg]	Single Values [%]		Mean Value [%]	RSD [%]
Cucumber (whole fruit)	0.01	89	88	89	-
	2.0 (a)	112	103	103	6.7
	2.0 (b)	97	98		
	Overall Recovery (n = 6)				98
Cabbage (head)	0.01	105	91	103	-
	2.0 (a)	97	97	95	5.0
	2.0 (b)	91	95		
	Overall Recovery (n = 6)				98
Potato (tuber)	0.01	89	90	90	-
	2.0 (a)	105	100	96	3.8
	2.0 (b)	96	96		
	Overall Recovery (n = 6)				96
Grape (whole fruit)	0.01	89	93	91	-
	2.0 (a)	108	111	106	4.7
	2.0 (b)	103	100		
	Overall Recovery (n = 6)				101

RSD: relative standard deviation

(a) recoveries fortified with a mixture containing the two compounds

(b) recoveries fortified only with fosetyl-AI

Table 6.1- 8: Recovery data for method validation for phosphonic acid

Sample Material	Fortification level [mg/kg]	Single Values [%]		Mean Value [%]	RSD [%]
Cucumber (whole fruit)	0.10	120	108	114	-
	2.0 (a)	107	107	109	1.8
	2.0 (b)	111	109		
	Overall Recovery (n = 6)				110
Cabbage (head)	0.10	105	83	97	-
	2.0 (a)	104	96	98	4.2
	2.0 (b)	95	97		
	Overall Recovery (n = 6)				98
Potato (tuber)	0.10	80	96	88	-
	2.0 (a)	102	100	102	1.5
	2.0 (b)	103	103		
	Overall Recovery (n = 6)				98
Grape (whole fruit)	0.10	106	99	103	-
	2.0 (a)	100	99	102	3.6
	2.0 (b)	100	107		
	Overall Recovery (n = 6)				102

RSD: relative standard deviation

(a) recoveries fortified with a mixture containing the two compounds

(b) recoveries fortified only with phosphonic acid

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Table 6.1- 9: Procedural (or “concurrent”) recovery data for fosetyl-AI

Plant material	Fortification Level [mg/kg]	Date of Extraction	Nominal Storage Interval (months)	Fosetyl-AI Single Recoveries [%]		Mean [%]	RSD [%]
Cucumber (whole fruit)	0.01	2005-10-06	0	99	-	99	-
		2005-12-09	2	112	-	112	-
		2006-03-17	5	86	-	86	-
		2006-06-07	8	99	-	99	-
		2006-10-12	12	96	-	96	-
		2007-05-16	19	93	-	93	-
		2007-11-06	25	90	-	90	-
	2.0	2005-10-06	0	106	106	106	-
		2005-12-09	2	95	94	95	-
		2006-03-17	5	98	99	99	-
		2006-06-07	8	94	93	93	-
		2006-10-12	12	90	88	90	-
		2007-05-16	19.5	89	95	92	-
		2007-11-06	26	92	94	93	-
Overall Mean and RSD [%]						96	6.6
Cabbage (head)	0.2	2005-11-17	0	100	-	100	-
		2005-12-12	1	91	-	91	-
		2006-03-22	4	92	-	92	-
		2006-06-07	7	101	-	101	-
		2006-10-13	11	95	-	95	-
		2007-05-21	17	92	-	92	-
		2007-11-21	24	89	-	89	-
	2.0	2005-11-17	0	101	104	102	-
		2005-12-12	1	90	91	91	-
		2006-03-22	4	101	101	101	-
		2006-06-07	7	98	97	97	-
		2006-10-13	11	86	89	87	-
		2007-05-21	18	83	83	83	-
		2007-11-21	24	92	91	91	-
		Overall Mean and RSD [%]					

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Nominal Storage Interval (months)	Fosetyl-Al Single Recoveries [%]		Mean [%]	RSD [%]
Potato (tuber)	0.01	2005-10-10	0	83	-	83	-
		2005-12-14	2	106	-	106	-
		2006-03-23	5	102	-	102	-
		2006-06-08	8	107	-	107	-
		2006-10-16	12	97	-	97	-
		2007-05-22	19.5	98	-	98	-
		2007-11-07	25	94	-	94	-
	2.0	2005-10-10	0	111	112	111	-
		2005-12-14	2	92	92	92	-
		2006-03-23	5	108	108	108	-
		2006-06-08	8	110	107	108	-
		2006-10-16	12	89	90	89	-
		2007-05-22	19.5	98	99	98	-
		2007-11-07	25	101	95	98	-
Overall Mean and RSD [%]						100	8.2
Grape (whole fruit)	0.01	2005-10-05	0	79	-	79	-
		2005-12-07	2	99	-	99	-
		2006-03-16	5	118	-	118	-
		2006-06-06	8	109	-	100	-
		2006-10-11	12	99	-	99	-
		2007-05-15	19.5	89	-	89	-
		2007-11-05	25	92	-	92	-
	2.0	2005-10-05	0	99	103	101	-
		2005-12-07	2	95	98	96	-
		2006-03-16	5	103	102	103	-
		2006-06-06	8	101	100	100	-
		2006-10-11	12	92	93	93	-
		2007-05-15	19.5	99	98	99	-
		2007-11-05	25	93	94	93	-
Overall Mean and RSD [%]						97	7.5

RSD: relative standard deviation

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Table 6.1- 10: Procedural (or “concurrent”) recovery data for phosphonic acid

Plant material	Fortification Level [mg/kg]	Date of Extraction	Nominal Storage Interval (months)	Phosphonic acid Single Recoveries [%]		Mean [%]	RSD [%]
Cucumber (whole fruit)	0.10	2005-10-06	0	109	-	109	-
		2005-12-09	2	128	-	128	-
		2006-03-17	5	91	-	91	-
		2006-06-07	8	102	-	102	-
		2006-10-12	12	82	-	82	-
		2007-05-16	19	97	-	97	-
		2007-11-06	25	87	-	87	-
	2.0	2005-10-06	0	103	103	104	-
		2005-12-09	2	112	111	112	-
		2006-03-17	5	106	110	108	-
		2006-06-07	8	101	101	101	-
		2006-10-12	12	92	-	94	-
		2007-05-16	19	99	102	100	-
		2007-11-06	25	104	100	102	-
Overall Mean and RSD [%]						102	9.6
Cabbage (head)	0.10	2005-11-17	0	88	-	88	-
		2005-12-12	1	110	-	110	--
		2006-03-22	7	84	-	84	-
		2006-06-07	10	76	-	76	-
		2006-10-13	11	89	-	89	-
		2007-11-21	14	94	-	94	-
	2.0	2006-05-21	18	93	-	93	-
		2007-05-21	18	100	99	100	-
	4.0	2005-11-17	0	99	101	100	-
		2005-12-12	1	112	109	110	-
		2006-03-22	7	80	86	83	-
		2006-06-07	10	104	103	103	-
		2006-10-13	11	90	89	89	-
		2007-11-21	14	94	90	92	-
2007-05-21	18	100	99	100	-		
Overall Mean and RSD [%]						95	10.3

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Nominal Storage Interval (months)	Phosphonic acid Single Recoveries [%]		Mean [%]	RSD [%]
Potato (tuber)	0.10	2005-10-10	0	106	-	106	-
		2005-12-14	2	106	-	106	-
		2006-03-23	5	108	-	108	-
		2006-06-08	8	98	-	99	-
		2006-10-16	12	97	-	97	-
		2007-05-22	19.5	99	-	99	-
		2007-11-07		100	-	100	-
	2.0	2005-10-10	0	109	102	105	-
		2005-12-14	2	95	98	96	-
		2006-03-23	5	121	119	120	-
		2006-06-08	8	105	103	104	-
		2006-10-16	12	88	91	89	-
		2007-05-22	19.5	100	99	99	-
		2007-11-07	25	104	101	102	-
Overall Mean and RSD [%]						102	7.7
Grape (whole fruit)	0.10	2005-10-05	0	99	-	99	-
		2005-12-07		90	-	90	-
		2006-03-16	5	121	-	121	-
		2006-06-06	8	104	-	104	-
		2006-10-11	12	103	-	103	-
		2007-05-15	19.5	95	-	95	-
		2007-11-05	5	86	-	86	-
	2.0	2005-10-05	0	99	107	103	-
		2005-12-07		105	103	104	-
		2006-03-16	5	104	106	105	-
		2006-06-06	8	104	105	105	-
		2006-10-11	12	91	93	92	-
		2007-05-15	19.5	102	100	101	-
		2007-11-05	25	100	98	99	-
Overall Mean and RSD [%]						101	7.3

RSD: relative standard deviation

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The concentrations of fosetyl-Al and phosphonic acid in cucumber, cabbage, potato and grape in stored spiked samples are presented in Table 6.1- 11 to Table 6.1- 13.

Table 6.1- 11: Storage stability data for fosetyl-Al

Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries ^c	Average Corrected % Recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Cucumber	0	2.04	102	102	100	106	96
		2.03	102				
	64	1.68	84	86	84	99	98
		1.74	87				
	162	1.65	83	82	81	99	84
		1.64	82				
	244	1.50	75	74	73	97	84
		1.46	73				
	371	1.26	63	69	67	90	77
		1.48	74				
	587	1.46	74	72	70	92	78
		1.59	79				
	761	1.18	59	62	61	91	67
		1.31	66				
Cabbage	0	2.70	105	106	100	103	103
		2.12	106				
	25	1.78	85	85	80	91	94
		1.69	85				
	126	1.33	67	66	63	101	66
		1.32	66				
	202	1.27	71	69	66	98	71
		1.35	69				
	330	1.40	70	51	48	88	58
		1.00	51				
	550	0.85	43	40	39	83	50
		0.82	40				
	737	0.67	33	32	31	92	35
		0.63	32				

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Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Average Corrected % Recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Potato	0	2.06	103	103	100	112	82
		2.06	103				
	65	1.45	73	75	73	92	82
		1.54	77				
	164	1.48	74	76	73	108	80
		1.54	77				
	241	1.50	75	69	66	100	63
		1.24	62				
	371	1.35	68	69	67	90	77
		1.40	70				
	589	0.90	45	46	50	88	50
		1.05	53				
		1.03	52				
	758	1.03	52	48	47	98	49
0.91		45					
Grapes	0	2.04	102	103	100	101	102
		2.08	103				
	63	1.93	96	96	93	97	100
		1.92	96				
	162	1.89	95	95	92	103	93
		1.92	96				
	244	1.89	95	95	92	101	95
		1.92	96				
	371	0.83	95	92	89	93	99
		1.83	92				
	587	1.84	97	95	92	99	97
		1.87	94				
	581	1.91	96	95	92	94	102
		1.90	95				

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Table 6.1- 12: Storage stability data for fosetyl-Al including produced phosphonic acid during storage

Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples									
		Residue Level of fosetyl-Al			Residue Level of phosphonic acid appeared as fosetyl-Al			Total Residue Level as fosetyl-Al			
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	
Cucumber	0	2.04	102	102	0.18	9	16	2.22	111	110	
		2.03	102		0.16	9		2.19	110		
	64	1.68	84	86	0.35	17	16	2.04	102	102	
		1.74	87		0.30	15		2.04	102		
	162	1.65	83	82	0.38	19	19	2.03	102	102	
		1.64	82		0.39	20		2.00	102		
	244	1.50	75	69	0.43	22	32	1.93	97	97	
		1.46	73		0.47	24		1.93	97		
	371	1.26	63	69	0.75	38	32	2.00	101	101	
		1.48	74		0.74	37		2.02	101		
	587	1.47	74	71	0.62	31	31	2.09	104	102	
		1.39	70		0.62	31		2.01	101		
	761	1.18	59	62	0.53	27	44	2.01	101	106	
		1.31	66		0.82	41		2.13	107		
Cabbage	0	2.10	105	106	0.06	3	4	2.16	108	109	
		2.09	106		0.09	4		2.21	110		
	125	1.70	85	66	0.17	8	34	1.87	93	94	
		1.69	85		0.21	10		1.90	95		
	202	1.33	67	69	0.66	33	33	1.99	100	102	
		1.52	76		0.69	35		2.01	101		
	330	1.41	71	51	0.58	29	50	1.99	100	101	
		1.35	68		0.73	36		2.08	104		
	550	1.40	70	32	0.65	32	56	2.05	102	98	
		1.02	51		1.02	51		2.04	102		
	734	0.85	43	31	0.90	45	66	1.96	98	98	
		0.81	40		1.14	57		1.95	97		
			0.67	34	32	1.29	65	66	1.96	98	98
			0.83	41		1.34	67		1.97	98	

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Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples								
		Residue Level of fosetyl-Al			Residue Level of phosphonic acid appeared as fosetyl-Al			Total Residue Level as fosetyl-Al		
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery	mg/kg (mg/kg)	% of nominal spiking level	Average % recovery
Potato	0	2.06	103	103	0.14	7	7	2.20	110	110
		2.06	103		0.14	7		2.09	110	
	65	1.45	73	75	0.58	29	26	2.03	102	101
		1.54	77		0.47	23		2.01	100	
	164	1.48	74	76	0.55	28	29	2.00	102	104
		1.54	77		0.60	30		2.14	107	
	241	1.50	75	69	0.66	33	34	2.16	104	103
		1.24	62		0.71	36		1.96	98	
	371	1.35	68	70	0.74	37	36	2.09	105	108
		1.40	70		0.81	41		2.21	111	
	589	0.90	45	49	1.19	60	56	2.09	105	105
		1.05	53		1.06	53		2.01	105	
	758	1.03	52	48	1.07	54	56	2.10	105	104
		0.91	46		1.16	58		2.07	103	
Grapes	0	2.04	102	103	0.76	38	8	2.20	110	111
		2.08	104		0.15	8		2.23	112	
	63	1.93	96	96	0.19	9	9	2.12	106	105
		1.82	96		0.70	35		2.08	104	
	108	1.89	95	95	0.28	14	13	2.17	109	108
		1.92	96		0.22	11		2.14	107	
	244	1.89	95	95	0.20	10	12	2.12	106	107
		1.92	96		0.25	12		2.17	108	
	371	1.83	92	92	0.24	12	12	2.07	104	104
		1.83	92		0.24	12		2.07	104	
	587	1.94	97	97	0.24	12	12	2.18	109	107
		1.87	94		0.25	12		2.12	106	
	761	1.91	96	95	0.20	10	13	2.17	109	109
		1.90	95		0.27	14		2.17	109	

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Table 6.1- 13: Storage stability data for phosphonic acid

Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Average Corrected % Recovery
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Cucumber	0	1.89	95	96	100	104	92
		1.93	97				
	64	2.10	105	95	98	102	88
		1.68	84				
	162	2.10	105	109	113	108	100
		2.24	112				
	244	2.00	100	101	105	101	100
		2.04	102				
	371	2.07	104	103	107	95	100
		2.04	102				
	587	1.94	97	98	103	101	98
		1.99	100				
	761	2.13	107	107	112	102	105
		2.15	108				
Cabbage	0	1.94	97	96	100	100	96
		1.90	95				
	25	1.99	99	99	103	111	90
		1.98	99				
	121	2.07	104	104	109	83	126
		2.10	105				
	202	1.92	96	97	101	104	93
		1.94	97				
	330	2.00	100	99	103	90	111
		1.95	98				
	550	2.01	104	99	104	100	100
		1.96	98				
	734	1.95	99	98	102	92	107
		1.93	97				
Potato	0	1.99	100	102	100	106	97
		2.02	104				
	65	2.05	103	102	100	97	106
		2.03	102				
	164	2.01	101	99	98	120	83
		1.95	98				
	241	2.14	107	105	103	104	101
		2.07	104				
	371	2.00	101	101	99	90	113
		2.01	101				
	589	2.06	103	103	101	100	104
		2.05	103				
	758	2.03	102	102	100	103	100
		2.06	103				
Grapes	0	1.95	98	95	100	103	93

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Commodity	Storage Period (days)	Residue Level in Stored Spiked Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Average Corrected % Recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
63	63	1.85	93	105	109	104	100
		2.08	104				
162	162	2.10	105	105	110	105	100
		2.19	110				
244	244	2.19	110	105	110	105	100
		2.09	105				
371	371	2.10	105	106	111	102	115
		2.13	107				
587	587	2.09	105	100	105	101*	100
		2.03	102				
761	761	1.97	99	101	106	99	103
		2.00	100				
		2.05	103				

*: fortification level at 4 mg/kg

Conclusion

Residues of phosphonic acid in cabbage were shown to be stable during deep-frozen storage for at least 24 months and up to 25 months in grapes, cucumber and potato sample materials. Residues of fosetyl-AI were shown to be stable during deep-frozen storage for at least 25 months in grapes. For potato, fosetyl-AI was stable in an acceptable range for 5 months and was partially converted into phosphonic acid with a correct balance, nearly 100% of the nominal fortification level. At all storage periods the total residue level was found in an acceptable range (between 101 and 110%). For cucumber it was stable in an acceptable range for 8 months and was partially converted into phosphonic acid with a correct balance, nearly 100% of the nominal fortification level. At all storage periods the total residue level was found in an acceptable range (between 97 and 110%). For cabbage it was stable in an acceptable range for 6 months, and then degraded into phosphonic acid largely. At all storage periods the total residue level was found in an acceptable range (between 94 and 109%).

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Report: KCA 6.1/04 [REDACTED]; 2016; M-529397-02-1
Title: Amendment no. 1 to report no: 13-02 - Storage stability of residues of fosetyl-Al (AE F053616) and its metabolite (Phosphorous acid: AE 0540099) in tomato, lettuce, avocado, orange and bean during deep freeze storage for at least 24 months

Report No.: 13-02
 Document No.: M-529397-02-1
 Guideline(s): EU Directive 91/414/EEC amended by the Commission directive 7032/VI/95 rev.5 (1997)
 US EPA Residue Chemistry Test Guideline OPPTS 860.1380: Storage Stability Data
 OECD Test Guideline 506, adopted 16 October 2007
 PMRA Ref.: DACO 7.3, Storage Stability

Guideline deviation(s): none
GLP/GEP: yes

Material and Methods

This study was conducted in order to investigate the stability of residues of fosetyl-aluminium (fosetyl-Al) and its metabolite phosphonic acid in fortified control samples of plant origin (in lettuce (head), cherry tomato (fruit), avocado (fruit), white dry bean (seed) and orange (fruit), during freezer storage for 24 months. The aim was to have storage data for two or three representative commodities for the main crop categories, compiling the data of both studies conducted over 2 years.

The control material used for the storage stability experiments originated from a local grocery store (lettuce, cherry tomato, avocado and dry bean) or from a residue study (orange). The control samples were shredded in a cutter with dry ice. 5 g aliquots of the homogenized control material were weighed into 60 mL HDPE Nalgene bottles with plastic caps. The samples were fortified individually and separately with 100 µL of the spiking solution at 100 mg/L resulting in a fortification level of 2.0 mg/kg of fosetyl-Al or phosphonic acid.

In addition untreated samples were prepared for control and recovery experiments.

Immediately after fortification, a sample was taken to determine the initial residues. The remaining fortified samples were stored deep frozen at -18 °C or below until analysis after nominal storage intervals of 2, 4, 5, 8-9, 10-11, 14, 18-19, 24 and 29 months for fosetyl-Al and after nominal storage intervals of 2, 4, 5, 8-9, 10-11, 14, 18-19 and 24 months for phosphonic acid.

Residues of fosetyl-Al and phosphonic acid in/on plant material were determined by HPLC-MS/MS according to the method 0086/M004. The limit of quantification (LOQ) was 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid.

Before day 0 (zero time analyses) to demonstrate the accuracy of the method one control and twelve spiked samples were prepared as follows for lettuce, cherry tomato, avocado and orange:

- 1 control sample,
- 3 recoveries fortified at LOQ (0.01 mg/kg) for fosetyl-Al and at LOQ (0.20 mg/kg) for phosphonic acid with a mixture containing the two compounds,
- 3 recoveries fortified at 200xLOQ (2.0 mg/kg) for fosetyl-Al and at 10xLOQ (2.0 mg/kg) for phosphonic acid with a mixture containing the two compounds,
- 3 recoveries fortified at 200xLOQ for fosetyl-Al, only with this compound,
- 3 recoveries fortified at 10xLOQ for phosphonic acid, only with this compound.

For dry bean a full validation of the method was performed as follows:

- 3 control samples,
- 5 recoveries fortified at LOQ (0.01 mg/kg) and 10xLOQ (0.10 mg/kg) for fosetyl-Al,
- 5 recoveries fortified at LOQ (0.20 mg/kg) and 10xLOQ (2.0 mg/kg) for phosphonic acid.

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On day 0 and at later sampling intervals four spiked samples were analysed for each sample material. One recovery was performed at the respective LOQ level and three recoveries at 2.0 mg/kg with a mixture of fosetyl-AI and phosphonic acid. The freshly fortified samples were then extracted and analysed concurrently with the control and stored spiked storage samples.

Findings

In the control samples used for method validation and fortification, the residues were always below 30% of the LOQ as shown in Table 6.1- 14 and Table 6.1- 15.

Table 6.1- 14: Results of the control samples for method validation

Matrix	Residue [mg/kg]	
	Fosetyl-AI	Phosphonic acid
Lettuce (head)	< 0.003	< 0.06
Cherry tomato (fruit)	0.003	< 0.06
Avocado (fruit)	< 0.003	< 0.06
dry bean (seed)	< 0.003	< 0.06
	0.003	< 0.06
	< 0.003	< 0.06
Orange (fruit)	< 0.003	< 0.06

Table 6.1- 15: Results of the stored control samples at each storage interval

Matrix	Actual Storage Interval (days)	Residue [mg/kg]	
		Fosetyl-AI	Phosphonic acid
Lettuce (head)	0	< 0.003	< 0.06
	70	< 0.003	< 0.06
	148	< 0.003	< 0.06
	256	-	< 0.06
	326	-	< 0.06
	421	-	< 0.06
	567	-	< 0.06
	729	-	< 0.06
Cherry tomato (fruit)	0	< 0.003	< 0.06
	78	< 0.003	< 0.06
	162	0.003	< 0.06
	261	0.003	< 0.06
	342	-	< 0.06
	435	-	< 0.06
	576	-	< 0.06
	741	-	< 0.06
Avocado (fruit)	0	< 0.003	< 0.06
	67	0.003	< 0.06
	151	0.003	< 0.06
	257	< 0.003	< 0.06
	328	-	< 0.06
	421	-	< 0.06
	567	-	< 0.06
	729	-	< 0.06
	576	< 0.003	< 0.06

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Matrix	Actual Storage Interval (days)	Residue [mg/kg]	
		Fosetyl-Al	Phosphonic acid
White dry bean (seed)	0	< 0.003	< 0.06
	81	< 0.003	< 0.06
	169	< 0.003	< 0.06
	271	< 0.003	< 0.06
	343	< 0.003	< 0.06
	447	< 0.003	< 0.06
	587	< 0.003	< 0.06
	748	< 0.003	< 0.06
Orange (fruit)	0	< 0.003	< 0.06
	78	< 0.003	< 0.06
	175	< 0.003	< 0.06
	266	< 0.003	< 0.06
	343	< 0.003	< 0.06
	442	< 0.003	< 0.06
	582	< 0.003	< 0.06
	745	< 0.003	< 0.06

As shown in Table 6.1- 16 to Table 6.1- 19, the validation recoveries and the concurrent recoveries determined from freshly fortified samples were in the 70 to 110% range except one mean concurrent recovery validation at 115% (20xLOQ level for fosetyl in orange at 582 days) and one mean concurrent recovery for phosphonic acid at 112% (10xLOQ level in orange at 582 days).

Table 6.1- 16: Recovery data for method validation for fosetyl-Al

Matrix	Fortification Level (FL) [mg/kg]	Recoveries % (Single Values)				per FL		Overall	
		1	2	3	4	Mean [%]	RSD [%]	Mean [%]	RSD [%]
Lettuce (head)	0.01 ^(a)	96	97	-	-	91	4.9	92	3.1
	2.0 ^(a)	93	94	94	-	94	0.6		
	2.0 ^(b)	90	92	89	-	90	1.7		
Cherry tomato (fruit)	0.01 ^(a)	104	99	98	-	100	3.2	94	5.4
	2.0 ^(a)	91	94	90	-	92	2.3		
	2.0 ^(b)	91	90	90	-	90	0.6		
Avocado (fruit)	0.01 ^(a)	83	82	83	-	83	0.7	87	4.8
	2.0 ^(a)	92	92	92	-	92	0.0		
	2.0 ^(b)	85	85	85	-	86	1.3		
White dry Bean (seed)	0.01 ^(a)	91	89	87	92	91	3.3	87	6.5
	2.0 ^(a)	77	78	88	88	84	6.9		
	2.0 ^(b)	80	81	86	-	84	3.3		
Orange (fruit)	0.01 ^(a)	80	80	80	-	80	0.7	87	6.1
	2.0 ^(a)	91	90	91	-	91	0.6		
	2.0 ^(b)	90	93	90	-	91	1.9		

RSD: relative standard deviation

^(a) recoveries fortified with a mixture containing the two compounds

^(b) recoveries fortified only with Fosetyl-Al

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Table 6.1- 17: Recovery data for method validation for phosphonic acid

Matrix	Fortification Level (FL) [mg/kg]	Recoveries % (Single Values)					per FL		Overall	
							Mean [%]	RSD [%]	Mean [%]	RSD [%]
Lettuce (head)	0.20 ^(a)	92	86	91	-	-	90	3.6	89	5.5
	2.0 ^(a)	97	89	91	-	-	92	2.8		
	2.0 ^(b)	87	84	83	-	-	85	2.5		
Cherry tomato (fruit)	0.20 ^(a)	87	91	95	-	-	91	4.4	95	4.5
	2.0 ^(a)	97	102	96	-	-	98	3.3		
	2.0 ^(b)	97	93	97	-	-	96	2.4		
Avocado (fruit)	0.20 ^(a)	88	101	88	-	-	92	8.1	94	4.7
	2.0 ^(a)	90	89	89	-	-	89	0.6		
	2.0 ^(b)	89	91	87	-	-	89	0.6		
White dry Bean (seed)	0.20 ^(a)	75	85	80	83	85	82	5.2	86	5.6
	2.0 ^(a)	76	72	83	83	82	79	6.3		
Orange (fruit)	0.20 ^(a)	75	68	70	-	-	71	5.2	82	10.2
	2.0 ^(a)	88	89	89	-	-	89	0.7		
	2.0 ^(b)	87	88	88	-	-	88	0.7		

RSD: relative standard deviation

^(a) recoveries fortified with a mixture containing the two compounds

^(b) recoveries fortified only with phosphonic acid

Table 6.1- 18: Procedural (or “concurrent”) recovery data for fosetyl-Al

Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Fosetyl-Al Single Recoveries [%]			Mean [%]	RSD [%]
				1	2	3		
Lettuce (head)	0.1	2013-04-29	0	98	-	-	-	-
		2013-07-08	70	98	-	-	-	-
		2013-09-24	148	105	-	-	-	-
	2.0	2013-04-29	0	101	101	103	102	1.1
		2013-07-08	70	89	96	92	90	1.7
		2013-09-24	148	97	96	91	95	3.4
	Overall Mean and RSD [%]							97
Cherry tomato (fruit)	0.01	2013-04-17	0	94	-	-	-	-
		2013-07-04	78	95	-	-	-	-
		2013-09-26	162	93	-	-	-	-
		2014-01-03	261	83	-	-	-	-
	2.0	2013-04-17	0	94	96	95	95	1.1
		2013-07-04	78	91	88	92	90	2.3
		2013-09-26	162	101	103	96	100	3.6
		2014-01-03	261	98	98	99	98	0.6
Overall Mean and RSD [%]							95	5.2

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Fosetyl-AI Single Recoveries [%]			Mean [%]	RSD [%]	
Avocado (fruit)	0.01	2013-05-02	0	84	-	-	-	-	
		2013-07-08	67	94	-	-	-	-	
		2013-09-30	151	102	-	-	-	-	
		2014-01-08	251	75	-	-	-	-	
		2015-09-25	876	96	100	100	99	100	
	2.0	2013-05-02	0	93	94	94	94	0.0	
		2013-07-08	67	86	87	89	87	0.7	
		2013-09-30	151	92	93	94	93	1.1	
		2014-01-08	251	93	92	93	93	0.6	
		2015-09-25	876	100	102	99	100	1.5	
Overall Mean and RSD [%]							93	4.7	
White dry bean (seed)	0.01	2013-04-13	0	81	80	82	81	1.2	
		2013-07-01	81	83	-	-	82	0.0	
		2013-09-27	169	101	-	-	94	3.4	
		2014-01-07	271	86	93	93	93	0.0	
		2014-03-20	343	84	-	-	95	2.2	
		2014-07-02	447	97	-	-	86	2.7	
		2014-11-19	587	71	-	-	106	1.9	
		2015-04-29	748	97	-	-	95	1.6	
		2.0	2013-04-13	0	81	80	82	81	1.2
	2013-07-01		81	82	82	82	82	0.0	
	2013-09-27		169	96	95	90	94	3.4	
	2014-01-07		271	93	93	93	93	0.0	
	2014-03-20		343	90	96	93	95	2.2	
	2014-07-02		447	82	86	86	85	2.7	
	2014-11-19		587	108	106	104	106	1.9	
	2015-04-29		748	93	92	95	93	1.6	
	Overall Mean and RSD [%]							91	9.2

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Fosetyl-AI Single Recoveries [%]			Mean [%]	RSD [%]
Orange (fruit)	0.01	2013-04-15	0	91	-	-	-	-
		2013-07-02	78	105	-	-	-	-
		2013-10-07	175	90	-	-	-	-
		2014-01-06	266	75	-	-	-	-
		2014-03-24	343	87	-	-	-	-
		2014-07-01	442	98	-	-	-	-
		2014-11-18	582	101	-	-	-	-
	2015-04-30	745	98	-	-	-	-	
	2.0	2013-04-15	0	93	86	92	90	4.4
		2013-07-02	78	95	92	98	95	3.2
		2013-10-07	175	93	95	94	94	1.1
		2014-01-06	266	98	99	100	99	1.0
		2014-03-24	343	96	95	94	95	0.1
		2014-07-01	442	106	88	91	92	10.2
		2014-11-18	582	114	111	113	115	1.0
2015-04-30	745	93	95	95	94	1.2		
Overall Mean and RSD [%]							96	8.6

RSD: relative standard deviation

Table 6.1- 19: Procedural for “concurrent”) recovery data for phosphonic acid

Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Phosphonic acid Single Recoveries [%]			Mean [%]	RSD [%]
Lettuce (head)	0.01	2013-04-29	0	99	-	-	-	-
		2013-07-08	70	100	-	-	-	-
		2013-09-24	148	102	-	-	-	-
		2014-01-10	256	107	-	-	-	-
		2014-03-21	326	97	-	-	-	-
		2014-06-27	424	101	-	-	-	-
		2014-11-17	567	103	-	-	-	-
	2015-04-28	729	98	-	-	-	-	
	2.0	2013-04-29	0	99	100	102	100	1.5
		2013-07-08	70	93	98	99	97	3.3
		2013-09-24	148	104	103	100	102	2.0
		2014-01-10	256	99	98	98	98	0.6
		2014-03-21	326	104	104	101	103	1.7
		2014-06-27	424	97	96	95	96	1.0
		2014-11-17	567	113	107	108	109	2.9
2015-04-28	729	99	93	95	96	3.2		
Overall Mean and RSD [%]							100	4.4

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Phosphonic acid Single Recoveries [%]			Mean [%]	RSD [%]
Cherry tomato (fruit)	0.20	2013-04-17	0	93	-	-	-	-
		2013-07-04	78	107	-	-	-	-
		2013-09-26	162	100	-	-	-	-
		2014-01-03	261	113	-	-	-	-
		2014-03-25	342	94	-	-	-	-
		2014-06-26	435	100	-	-	-	-
		2014-11-14	576	103	-	-	-	-
	2015-04-28	741	94	-	-	-	-	
	2.0	2013-04-17	0	99	101	102	101	1.5
		2013-07-04	78	101	99	103	101	2.7
		2013-09-26	162	104	100	96	100	4.0
		2014-01-03	261	97	104	100	100	3.5
		2014-03-25	342	96	100	98	98	2.9
		2014-06-26	435	107	108	106	107	0.9
		2014-11-14	576	101	112	106	106	5.2
2015-04-28	741	93	98	98	94	1.1		
Overall Mean and RSD [%]							101	5.2
Avocado (fruit)	0.6	2013-05-02	0	87	-	-	-	-
		2013-07-08	67	87	-	-	-	-
		2013-09-30	151	92	-	-	-	-
		2014-01-08	251	96	-	-	-	-
		2014-03-28	328	95	-	-	-	-
		2014-06-27	421	85	-	-	-	-
		2014-11-20	567	97	-	-	-	-
		2015-05-04	732	94	-	-	-	-
		2015-09-25	876	96	-	-	-	-
	2.0	2013-05-02	0	97	96	98	97	1.0
		2013-07-08	67	95	93	94	94	1.1
		2013-09-30	151	93	96	97	95	2.2
		2014-01-08	251	96	91	97	95	3.4
		2014-03-28	328	97	97	97	97	0.0
		2014-06-27	421	92	102	99	98	5.3
2014-11-20	567	111	97	102	103	6.9		
2015-05-04	732	90	94	93	92	2.3		
2015-09-25	876	97	98	98	98	0.6		
Overall Mean and RSD [%]							97	4.2

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Plant material	Fortification Level [mg/kg]	Date of Extraction	Storage Interval (days)	Phosphonic acid Single Recoveries [%]			Mean [%]	RSD [%]
White dry bean (seed)	0.20	2013-04-11	0	93	-	-	-	-
		2013-07-01	81	83	-	-	-	-
		2013-09-27	169	76	-	-	-	-
		2014-01-07	271	101	-	-	-	-
		2014-03-20	343	85	-	-	-	-
		2014-07-02	447	81	-	-	-	-
		2014-11-19	587	80	-	-	-	-
	2015-04-29	748	87	-	-	-	-	
	2.0	2013-04-11	0	78	74	77	78	2.7
		2013-07-01	81	80	85	84	84	3.1
		2013-09-27	169	88	84	83	85	1.9
		2014-01-07	271	94	91	91	92	1.0
		2014-03-20	343	89	87	86	87	0.7
		2014-07-02	447	82	81	81	81	3.0
2014-11-19		587	86	87	91	88	0.0	
2015-04-29	748	88	88	88	82	6.6		
Overall Mean and RSD [%]							85	6.6
Orange (fruit)	0.2	2013-04-15	0	81	-	-	-	-
		2013-07-02	78	102	-	-	-	-
		2013-10-07	166	90	-	-	-	-
		2014-01-06	266	102	-	-	-	-
		2014-03-24	343	92	-	-	-	-
		2014-07-01	442	111	-	-	-	-
		2014-11-18	582	108	-	-	-	-
	2015-04-30	745	98	-	-	-	-	
	2.0	2013-04-15	0	97	90	97	95	4.3
		2013-07-02	78	96	90	100	95	5.3
		2013-10-07	175	97	98	99	98	1.0
		2014-01-06	266	92	94	97	94	2.7
		2014-03-24	343	96	96	94	95	1.2
		2014-07-01	442	102	88	87	92	9.1
2014-11-18		582	113	115	111	113	1.8	
2015-04-30	745	95	95	97	96	1.2		
Overall Mean and RSD [%]							97	8.0

RSD: relative standard deviation

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The concentrations of fosetyl-Al and phosphonic acid in cucumber, cabbage, potato and grape in stored spiked samples are presented in Table 6.1- 20 to Table 6.1- 22.

Table 6.1- 20: Storage stability data for fosetyl-Al

Commodity	Storage Period (days)	Residue Level in Stored Samples			Day-0 Normalized Recovery	Average % of Fresh Concurrent Recoveries	Mean Corrected Recovery
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery			
Lettuce (head)	0	1.81	91	88	100	92	92
		1.75	88				
		1.71	86				
	70	0.04	2	2	0	95	0
		0.05	3				
		0.03	2				
	148	0	0	0	0	95	0
		0	0				
		0	0				
Cherry tomato (fruit)	0	1.79	90	91	100	95	96
		1.88	94				
		1.79	90				
	78	1.24	62	61	68	90	68
		1.23	62				
		1.19	60				
	162	0.98	49	50	56	100	50
		1.07	54				
		0.96	48				
	251	0.25	12	15	19	98	16
		0.3	16				
		0.35	18				
		1.70	88				
		1.70	85				
		1.71	86				
Avocado (fruit)	67	0.58	29	38	38	87	37
		0.80	40				
		0.56	28				
	151	0	32	27	32	93	29
		0.58	29				
		0.42	21				
	251	0.23	11	14	16	93	15
		0.3	12				
		0.36	12				
876	0.078	4	4	5	100	4	
	0.12	6					
	0.058	3					

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Commodity	Storage Period (days)	Residue Level in Stored Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Mean Corrected % Recovery ^b
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery			
White dry bean (seed)	0	1.56	78	81	100	81	100
		1.63	82				
		1.63	82				
	81	1.38	69	68	84	82	83
		1.33	66				
		1.38	69				
	169	1.47	73	73	90	94	78
		1.47	74				
		1.45	72				
	271	1.50	75	75	93	93	80
		1.49	75				
		1.47	74				
	343	1.36	68	69	86	86	86
		1.39	70				
		1.39	69				
	447	1.34	65	66	87	87	78
		1.33	67				
		1.28	64				
	587	1.44	77	76	94	106	71
		1.47	74				
1.52		76					
748	1.26	63	63	78	93	68	
	1.24	61					
	1.28	64					
Orange (fruit)	0	1.73	89	88	100	90	97
		1.75	88				
		1.74	87				
	78	1.70	85	77	88	95	81
		1.49	74				
		1.46	73				
	146	1.35	67	68	77	94	72
		1.28	64				
		1.24	72				
	266	1.06	53	56	64	99	57
		1.15	58				
		1.15	57				
	343	0.75	38	46	52	95	48
		0.97	49				
		1.02	51				
	442	0.85	43	38	43	95	40
		0.83	41				
		0.60	30				
	582	0.67	34	34	38	115	29
		0.73	36				
0.61		31					
745	0.48	24	19	22	94	20	
	0.30	15					
		0.38	19				

^aDay-0 Normalized Recovery = (Average recovery / average recovery at day 0) X 100%

^bMean Corrected percent recovery = (Mean % recovery (stored) / Average of fresh concurrent recoveries) X 100%

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Table 6.1- 21: Storage stability data for fosetyl-Al including produced phosphonic acid during storage

Residue Level in Stored Spiked Samples											
Commodity	Storage Period (days)	Residue Level of fosetyl-Al			Residue Level of phosphonic acid appeared as fosetyl-Al			Total Residue Level as fosetyl-Al			
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery	mg/kg (ppm)	% of nominal spiking level	Mean % recovery	mg/kg (ppm)	% of nominal spiking level	Mean % recovery	
Lettuce (head)	0	1.81	91	88	0.15	11	11	1.96	101	99	
		1.75	88		0.15	11		1.90	99		
		1.71	86		0.15	11		1.86	96		
	70	0.04	2	2	1.46	105	98	1.50	107	100	
		0.05	3		1.31	97		1.36	97		
		0.03	2		1.32	95		1.36	97		
	148	0.00	0	0	1.36	98	101	1.96	98	101	
		0.00	0		1.41	101		2.03	101		
		0.00	0		1.38	104		2.09	104		
Cherry tomato (fruit)	0	1.79	90	91	0.11	6	8	1.90	95	98	
		1.88	94		0.17	8		2.05	102		
		1.79	90		0.17	8		1.92	96		
	78	1.24	62	62	0.53	33	38	1.96	99	99	
		1.23	62		0.79	40		2.02	101		
		1.19	60		0.75	37		1.94	97		
	162	0.98	49	50	1.02	51	50	2.06	100	100	
		1.07	54		0.99	49		2.06	103		
		0.96	48		0.97	49		1.93	97		
	261	0.25	12	15	1.77	89	87	2.02	101	102	
		0.21	10		1.70	88		2.08	104		
		0.35	18		1.67	83		2.02	101		
	Avocado (fruit)	0	1.70	85	85	0.24	12	12	1.94	97	97
			1.70	85		0.24	12		1.95	97	
			1.71	86		0.24	12		1.95	97	
67		0.58	29	32	1.25	62	60	1.83	91	92	
		0.80	40		1.06	53		1.86	93		
		0.56	28		1.30	65		1.86	93		
151		0.53	32	31	1.27	63	67	1.90	95	95	
		0.58	29		1.39	69		1.97	98		
		0.42	21		1.39	69		1.81	90		
251		0.23	11	1	1.09	83	80	1.91	95	93	
		0.23	12		1.61	81		1.85	92		
		0.36	18		1.51	76		1.88	93		
876		0.078	4	4	1.76	88	89	1.84	92	93	
		0.02	1		1.81	91		1.93	96		
		0.058	3		1.77	89		1.83	91		

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Residue Level in Stored Spiked Samples										
Commodity	Storage Period (days)	Residue Level of fosetyl-Al			Residue Level of phosphonic acid appeared as fosetyl-Al			Total Residue Level as fosetyl-Al		
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery	mg/kg (ppm)	% of nominal spiking level	Mean % recovery	mg/kg (ppm)	% of nominal spiking level	Mean % recovery
White dry bean (seed)	0	1.56	78	81	0.17	8	19	1.73	86	89
		1.63	82		0.17	9		1.80	90	
		1.63	82		0.17	9		1.80	90	
	81	1.38	69	68	0.40	20	19	1.77	88	87
		1.33	66		0.42	16		1.85	82	
		1.38	69		0.40	20		1.78	89	
	169	1.47	73	73	0.37	18	19	1.84	91	92
		1.47	74		0.39	19		1.85	93	
		1.45	72		0.40	20		1.85	92	
	271	1.50	75	75	0.48	24	24	1.98	99	99
		1.49	75		0.47	23		1.95	97	
		1.47	74		0.51	25		1.99	99	
	343	1.36	68	69	0.47	24	22	1.83	92	91
		1.39	70		0.43	22		1.82	91	
		1.39	69		0.44	22		1.83	91	
	447	1.34	67	68	0.40	20	21	1.84	87	86
		1.33	67		0.41	21		1.74	87	
		1.28	64		0.42	21		1.70	85	
	587	1.54	77	77	0.47	24	19	1.97	95	94
		1.47	74		0.42	21		1.99	95	
		1.52	76		0.33	17		1.85	93	
	744	1.24	62	63	0.44	22	23	1.72	86	86
		1.28	64		0.45	22		1.69	84	
		1.28	64		0.45	23		1.73	87	
Orange (fruit)	0	1.77	89	88	0.10	5	5	1.87	93	93
		1.75	88		0.12	6		1.87	94	
		1.74	87		0.10	5		1.84	92	
	78	1.70	85	77	0.33	16	16	2.03	101	93
		1.49	74		0.37	18		1.82	89	
		1.46	73		0.32	16		1.78	89	
	175	1.35	67	68	0.64	32	31	1.99	99	99
		1.28	64		0.70	35		1.98	99	
		1.47	73		0.52	27		1.97	99	
	266	1.06	53	54	0.90	45	44	1.96	98	99
		1.15	58		0.85	43		2.00	100	
		1.15	57		0.86	43		2.01	100	
	343	0.78	39	44	1.08	54	48	1.83	92	94
		0.97	49		0.97	49		1.94	97	
		1.02	51		0.83	41		1.85	92	
	444	0.83	41	38	0.95	48	53	1.80	90	91
		0.93	47		0.99	49		1.82	91	
		0.60	30		1.22	61		1.82	91	
	582	0.67	34	34	1.51	76	70	2.18	109	104
		0.71	36		1.30	65		2.03	101	
		0.61	31		1.39	69		2.00	100	
	745	0.48	24	19	1.43	71	76	1.91	96	95
		0.30	15		1.63	81		1.93	96	
		0.38	19		1.51	76		1.89	95	

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Table 6.1- 22: Storage stability data for phosphonic acid

Commodity	Storage Period (days)	Residue Level in Stored Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Mean Corrected ^a % Recovery ^b
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery			
Lettuce (head)	0	1.85	93	94	100	100	93
		1.90	95				
		1.89	95				
	70	1.87	93	97	94	100	97
		2.03	101				
		1.96	98				
	148	1.97	98	98	100	100	95
		1.95	97				
		1.96	98				
	256	1.87	93	91	98	98	93
		1.82	91				
		1.81	90				
	326	1.89	95	96	102	103	93
		1.89	95				
		1.94	97				
	424	1.73	87	88	94	96	92
		1.68	84				
		1.86	93				
	567	1.89	95	93	99	99	85
		1.84	92				
		1.84	92				
720	1.79	89	88	94	96	92	
	1.72	86					
	1.76	88					
Cherry tomato (fruit)	0	1.93	97	97	100	101	97
		1.93	97				
		1.96	98				
	78	1.92	96	98	101	101	97
		1.91	100				
		1.95	98				
	162	1.87	93	93	96	100	93
		1.92	97				
		1.92	96				
	261	1.86	93	94	97	100	94
		1.88	94				
		1.90	95				
	342	1.85	92	91	94	98	93
		1.84	91				
		1.84	91				
	435	1.84	95	98	100	107	91
		1.96	98				
		2.06	103				
	576	1.78	89	98	101	106	92
		1.98	99				
		2.13	107				
741	1.80	90	90	93	94	96	
	1.84	92					
	1.78	89					

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Commodity	Storage Period (days)	Residue Level in Stored Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Mean Corrected % Recovery ^b
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery			
Avocado (fruit)	0	2.05	103	94	100	97	97
		1.82	91				
		1.76	88				
	67	1.80	90	96	103	94	102
		1.99	100				
		1.98	99				
	151	1.87	94	93	99	95	97
		1.85	93				
		1.82	91				
	251	1.81	91	90	96	95	95
		1.81	90				
		1.81	90				
	328	1.79	90	89	93	95	93
		1.72	86				
		1.82	91				
	421	1.52	86	80	88	103	82
		1.78	89				
		1.52	76				
	567	1.79	89	90	96	103	87
		1.83	92				
1.81		90					
732	1.78	89	90	96	92	97	
	1.85	91					
	1.76	88					
White dry bean (seed)	0	1.42	74	75	100	76	99
		1.51	76				
		1.52	76				
	81	1.60	80	79	105	84	94
		1.62	81				
		1.55	77				
	166	1.67	84	80	106	85	94
		1.56	78				
		1.75	77				
	271	1.73	87	86	115	92	94
		1.71	86				
		1.72	86				
	343	1.56	77	77	102	87	88
		1.54	77				
		1.53	76				
	447	1.58	79	81	107	81	99
		1.60	80				
		1.67	83				
	587	1.79	90	84	111	88	95
		1.60	80				
1.62		81					
748	1.56	78	77	102	82	93	
	1.50	75					
	1.53	77					

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Commodity	Storage Period (days)	Residue Level in Stored Samples			Day-0 Normalized Recovery ^a	Average % of Fresh Concurrent Recoveries	Mean Corrected % Recovery ^b
		mg/kg (ppm)	% of nominal spiking level	Mean % recovery			
Orange (fruit)	0	1.79	90	90	100	95	95
		1.81	91				
		1.79	90				
	78	1.76	88	88	98	95	92
		1.78	89				
		1.75	87				
	175	1.87	93	94	105	98	96
		1.91	96				
		1.88	94				
	266	1.80	90	90	100	94	95
		1.80	90				
		1.78	89				
	343	1.70	85	85	94	95	89
		1.68	84				
		1.70	85				
	442	1.89	95	90	100	97	97
		1.83	91				
		1.67	84				
	582	1.94	87	84	104	113	83
		1.86	93				
		1.84	92				
	745	1.79	90	93	103	96	97
		1.90	95				
		1.88	94				

^aDay-0 Normalized Recovery = (Average recovery / average recovery at day 0) X 100%

^bMean Corrected percent recovery = (Mean % recovery / stored / Average of fresh concurrent recoveries) X 100%

Conclusion

These data demonstrated a quick degradation of fosetyl-Al into phosphonic acid in high water content commodities (lettuce and tomato) and high oil content commodity (avocado) whereas no degradation was observed in dry bean (high protein content commodity). The degradation happened in orange (high acid content commodity) while no degradation was observed in grape. No degradation of phosphonic acid was observed in all commodities.

Overall conclusion

Three storage stability studies were conducted to evaluate the stability of residues of fosetyl-Al and phosphonic acid in samples during deep freeze storage conditions. The storage stability was investigated on many crops which belong to the five commodity categories. According to the Regulation (EU) No 283/2013, degradation is significant when more than 30%. Significant degradation of fosetyl-Al into phosphonic acid was observed in high water content and high oil content commodities. Fosetyl-Al was rapidly converted into phosphonic acid in these commodities. However it was demonstrated that the total residue (expressed as fosetyl-Al) was always found in an acceptable range (86 to 111%) in both recent studies **over 2 years in one representative commodity of each of the five crop categories.** Fosetyl-Al residues are found stable in other commodities for a period of 5 to 25 months when stored deep frozen at ≤ -18 °C. No degradation of phosphonic acid was observed in all commodities.

**Document MCA – Section 6: Residues in or on treated products, food and feed
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The stability of the residues of fosetyl-Al and phosphonic acid in the sample extracts was checked during the validation of the recent analytical methods referenced 00861/M001 and 01501 (please refer to Document MCA, Section 4). The stability in the extract A (which is the extract after centrifugation and before dilution for the final extract) has been investigated in recovery samples let in the fridge at about 4 °C after a storage period of about few days. In addition, the stability of final extract of recovery samples was also examined. Final extracts were let in the auto sampler at about 10 °C after initial analysis and re-analysed by LC-MS/MS after a storage period of about few days.

Moreover, control samples fortified with the test substance were always extracted and analysed concurrently with the untreated and treated samples of the studies. The satisfactory recovery rates obtained from the fortified samples demonstrate the stability of the residues in the sample extracts throughout the analytical procedure, from extraction until chromatographic determination.

CA 6.2 Metabolism, distribution and expression of residues**CA 6.2.1 Plants**

Plant metabolism studies have been conducted in fruits (citrus, apples, pineapple and grapes) and fruiting vegetables (tomatoes), which represent the major uses of Fosetyl-aluminium (Fosetyl-Al). These metabolism studies have already been evaluated for the Annex inclusion of fosetyl under Directive 91/414/EEC by the RMS France in DAR Volume 3, Annex B, B.7 (February 2005). They are briefly compiled in the following list to provide an overview on the plant metabolism.

Annex point / reference number	Test substance and test plant	Scope of study	Reference
KCA 6.2.1/01	¹⁴ C-fosetyl-Al Citrus metabolism study	Painbrush treatment, cultivation, sampling and fractionation of oranges and organ Mon of radioactivity remained in the peel	[REDACTED]; 1982; M-161888-01-1
KCA 6.2.1/02	¹⁴ C-fosetyl-Al Determination of fosetyl and its metabolites in citrus fruit Analysis of citrus treated by [REDACTED] (1992)	Carbon group of fosetyl-Al is largely integrated in the natural glycolytic cycle resulting in ¹⁴ C-glucose as main product and other ¹⁴ C-sugars and -lipids	[REDACTED]; [REDACTED]; 1982; M-159448-01-1
KCA 6.2.1/03	Fosetyl-Al: Supplemental: Publication in Pest Sci. (1993), 3, 319-323: The metabolism of fosetyl-Al and the evolution of residue levels in oranges and tangerines	Confirmation of rapid metabolism of fosetyl-Al in oranges and tangerines. Detection of phosphonic acid in the two citrus fruits	[REDACTED]; [REDACTED]; 1993; M-200275-01-1
KCA 6.2.1/04	¹⁴ C-fosetyl-Al Determination of the nature of residue in apples after treatment with ¹⁴ C radiolabelled fosetyl-Al	Large portion of fosetyl-Al remained on the surface of the fruit and can be washed off. The major metabolite in the fruit is ¹⁴ C-ethanol. Additionally, integration of ¹⁴ C in glucose	[REDACTED]; 1988; M-202680-01-1

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Annex point / reference number	Test substance and test plant	Scope of study	Reference
KCA 6.2.1/05 KCA 6.2.1/06	¹⁴ C-fosetyl-Al Metabolism in pineapples	Metabolic formation of ¹⁴ C-ethanol, subsequently incorporated in natural products (i.e. oleic and palmitic acid, 1-docosanol, and bound residues)	[Redacted]; 1982; M-159340-01-1 [Redacted]; 1983; M-229587-01-1
KCA 6.2.1/07	¹⁴ C-fosetyl-Al Metabolism in vines/grapes	Translocation and metabolism study on vine leaves: Absorption by the leaves is limited; translocation product was phosphonic acid	[Redacted]; 1977; M-161435-01-1
KCA 6.2.1/08	¹⁴ C-fosetyl-Al Metabolism in tomatoes	Metabolism to ethanol and phosphonic acid. Ethanol is integrated in the glycolate cycle forming ¹⁴ C-glucose. ¹⁴ C also incorporated in cellulose, lignin and starch	[Redacted]; 1991; M-15772-01-1
KCA 6.2.1/09	Fosetyl-Al; Supplemental: Publication in Agronomie (5) 423, 1980 and Acad. Sci. Paris t.307, Serie III, 1981, 221-227: Absorption, metabolism and translocation of fosetyl-Al in tomatoes	Fosetyl-Al is absorbed and translocated acropetal and basipetal. It is metabolized to phosphonic acid tending to migrate towards the apex of the plants. Uptake by roots is rather dissociated. Fosetyl and phosphonic acid are distributed over the roots and foliage with favour to the growing organs	[Redacted]; 1984; M-165506-01-1 [Redacted] S; [Redacted]; 1988; M-159938-01-1

The following summary on the plant metabolism of fosetyl-Al is paraphrased from the EFSA conclusion on the peer review of fosetyl (EFSA Scientific Report (2005) 54, 1-79, revised publication dated 12th June 2013).

“Plant metabolism studies have been conducted in fruit (strawberries, apples and pineapples) and fruiting vegetables (tomatoes) covering the scope of representative uses proposed by the applicant. A translocation study on grapes was also submitted. In addition the metabolism of ¹⁴C-fosetyl-Al has been investigated in apple and vine leaves. Penetration and translocation through the plant of parent fosetyl-Al is limited.

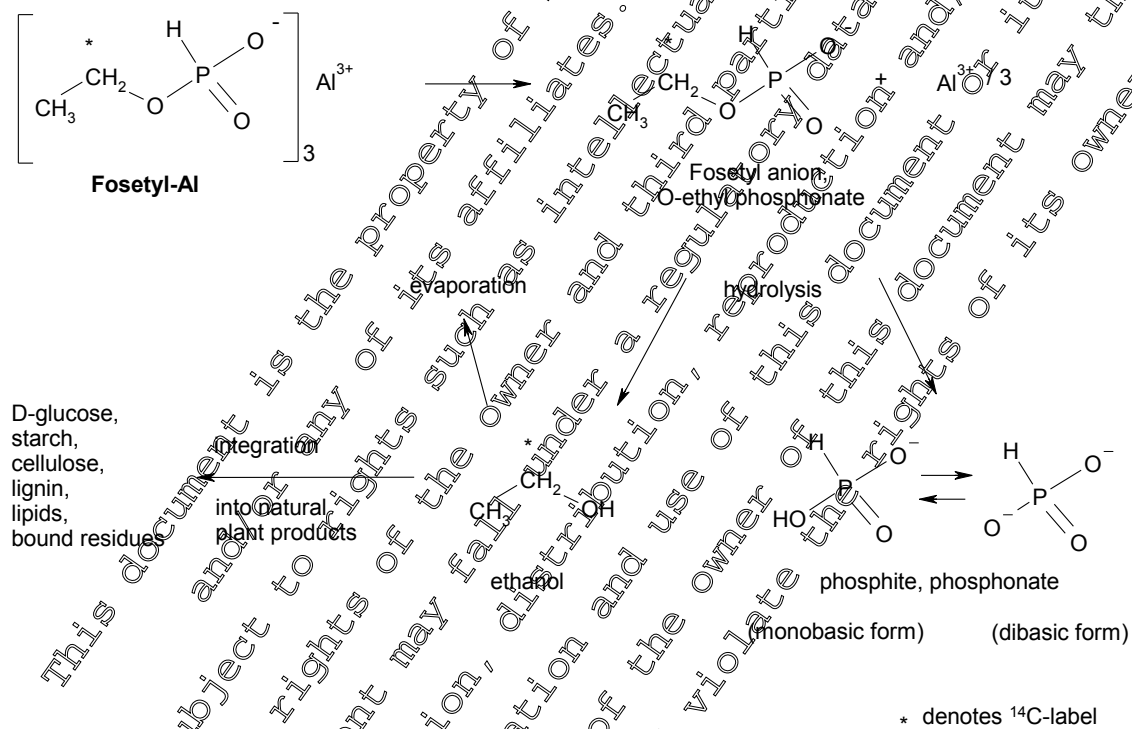
The initial step of fosetyl-Al metabolism proceeds through the hydrolytic cleavage of the ethyl ester bond with phosphonic acid and ethanol as the major plant metabolites. The metabolism of ethanol, when not lost by volatilisation, further consists in incorporation into natural products such as D-glucose, starch, lignin, cellulose or fatty acids. Due to the elementary nature of fosetyl-Al, and given the similar results obtained on fruits and leafy parts of plant, it can be expected that the metabolite pattern should be similar in all crops.

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Phosphonic acid is considered to be toxicologically relevant and its level is generally higher than that of parent (since cleavage of one molecule of fosetyl-Al results in three molecules of phosphonates), therefore the residue definition should include both compounds and is proposed by the Expert meeting (EPCO 19) to be the sum of fosetyl, its salts and phosphonic acid expressed as fosetyl. However, as the method of analysis extracts not only phosphonic acid but also its salts, EFSA is proposing a slightly different wording of the residue definition: sum of fosetyl, phosphonic acid and their salts expressed as fosetyl. This residue definition is valid for monitoring and risk assessment purposes and is acceptable in terms of consumer safety.”

A proposed common metabolic pathway of fosetyl-Al in plants is shown in the following figure.

Figure 6.2.1- 1: Proposed common metabolic pathway of fosetyl-Al in plants



CA 6.2.2 Poultry

No metabolism study was conducted on poultry as none of the crops supported as representative use is fed to poultry.

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CA 6.2.3 Lactating ruminants

Four ruminant metabolism studies have been conducted with lactating goats. These metabolism studies have already been evaluated for the Annex I inclusion of fosetyl under Directive 91/414/EEC by the RMS France in DAR Volume 3, Annex B, B.7 (February 2005). They are briefly compiled in the following list.

Annex point / reference number	Test substance and objective	Scope of study	Reference
KCA 6.2.3/01	¹⁴ C-fosetyl-Al Metabolism in lactating dairy goats	Intensive metabolism after oral dosing of 10 mg/kg diet for 7 consecutive days	[Redacted]; 1987; M-160470-01-1
KCA 6.2.3/02	¹⁴ C-fosetyl-Al Metabolism in lactating dairy goats (Supplement)	Intensive metabolism after oral dosing of 10 mg/kg diet for 7 consecutive days with 17% of the dose in milk, 17.5% ¹⁴ C (with in 3 days), and 1-2.2% in tissues. ¹⁴ C plateau in milk reached after 2 days.	[Redacted]; 1987; M-165777-01-1
KCA 6.2.3/03	¹⁴ C-fosetyl-Al Characterization of metabolites in goat milk (Milk originated from the Stumper, [Redacted] 1987 study)	¹⁴ C-plateau in milk reached after 2 days amounting to ca. 0.05 mg eq/kg. ¹⁴ C in milk was fosetyl and could not be distinguished from naturally occurring fats in milk	[Redacted]; 1987; M-160774-01-1
KCA 6.2.3/04	¹⁴ C-fosetyl-Al Metabolism in lactating goats	Following oral dosing of ca. 3 mg/kg diet for 7 consecutive days the max. ¹⁴ C residue was detected in the liver (ca. 38 mg eq/kg). ¹⁴ C in milk reached a max of 1.23-1.52 mg eq/kg. ¹⁴ C-residues in edible tissues were isolated in natural products (glucose, glycogen, saponifiable fatty acids and lipids, amino acids and peptides)	[Redacted]; 1992; M-202696-01-1

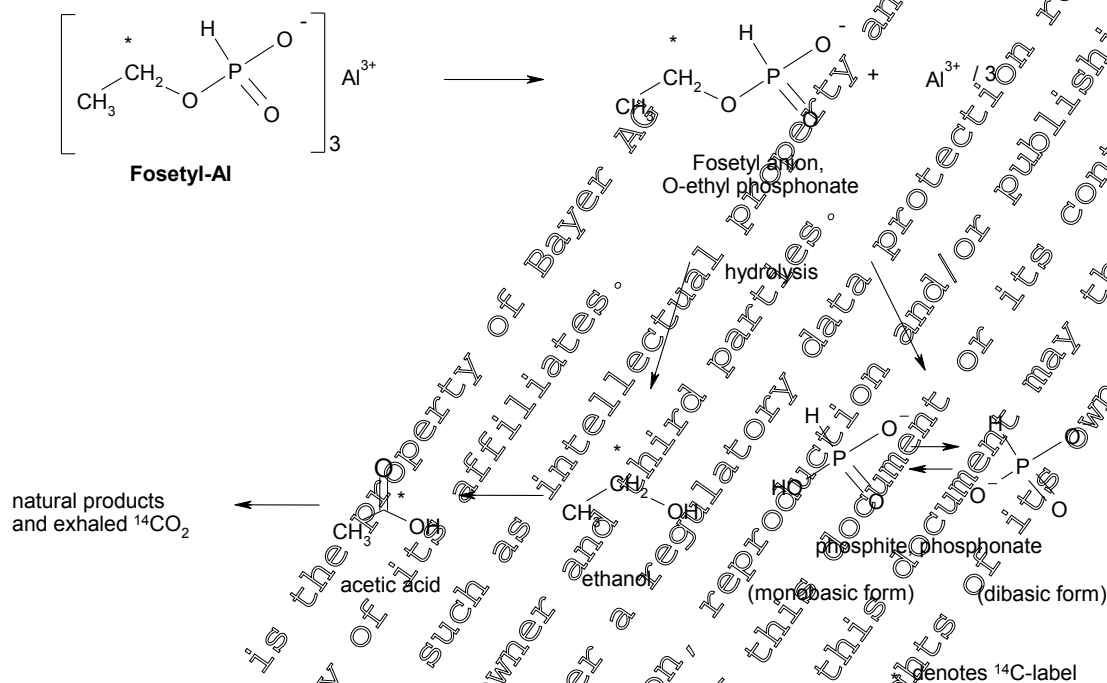
The following summary on the nature of residues in livestock is paraphrased from the EFSA conclusion on the peer review of fosetyl (EFSA Scientific Report (2005) 54, 1-79, revised publication dated 12th June 2013):

“The metabolism of fosetyl-Al was investigated in lactating goats. As in plants, fosetyl is cleaved in ethanol and phosphonic acid. Ethanol is then degraded, excreted as CO₂ in the expired air or reincorporated into natural products, such as glucose, glycogen, lactose, saponifiable lipids and amino acids. In milk and tissues no parent compound or related metabolite is present as residue. Only phosphonic acid is a possible metabolite of toxicological relevance in animal matrices, resulting from the use of fosetyl-Al.”

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From the fosetyl-Al residues in urine and stomach contents the following metabolic pathway in goats can be constructed (██████████, ██████████, ██████████; 1992; M-202696-01-1):

Figure 6.2.3- 1: Proposed metabolic pathway of fosetyl-Al in goats



CA 6.2.4 Pigs

The following summary on the necessity of fosetyl-aluminium study in pigs is taken from the EFSA conclusion on the peer review of fosetyl (EFSA Scientific Report (2005) 54, 1-79, revised publication dated 12th June 2013):

“It is not considered necessary to conduct a metabolism study in porcine animals due to the very simple nature of the molecule and the information gained from the metabolism study in ruminants.”

CA 6.2.5 Fish

Fosetyl-aluminium (fosetyl-Al) is a very polar compound with a log Kow of -2.11 at pH 6, 21 to 13 °C (██████████ Y; 1997; M-18417-01-1). The main metabolite phosphonic acid has an even lower log Kow of -3.44 to -4.69 (██████████; 1999; M-166324-01-1). Therefore, bioaccumulation of fosetyl-Al or phosphonic acid in fish is very unlikely and no bioaccumulation study has been conducted.

From the metabolism of fosetyl-Al in rat (see Document MCA, Section 5.1) and goat (see Section CA 6.2.3) it is concluded that fosetyl-Al is rapidly and intensively metabolized via hydrolysis of fosetyl to ethanol and phosphonic acid. In animals the ethanol is oxidized to acetic acid. The acetic acid is widely incorporated in natural animal constituents (e.g. sugars, lipids and fatty acids and peptides) or further oxidized and exhaled as CO₂ from land animals. No fosetyl residue was detected in any milk, muscle, fat and offal.

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As already been stated by EFSA for plant metabolism in the conclusion on the peer review of fosetyl (see above) an analogous statement can be made for animals:

“Due to the elementary nature of fosetyl-Al, and given the similar results obtained in rat and pig, it can be expected that the metabolic pattern should be similar in other animals.”

Therefore, no metabolism study of fosetyl-Al in fish seemed to be necessary and no fish metabolism study has been conducted.

In addition, waiving of a particular data requirement is considered acceptable according to the “Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and the renewal of approval of the chemical active substance according to regulation (EU) No 283/2013 and regulation (EU) No 284/2013” (SANCO/10181/2013-rev. 2 of 2 May-2013) if no official test guideline or guidance exists. For fish metabolism neither an official test guideline or guidance nor a feeding table for fish is available.

CA 6.3 Magnitude of residue trials in plants

In the original Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC, the uses of fosetyl-aluminium (fosetyl-Al) were supported on citrus, grapes and cucumber.

In corresponding residue reports, the residues were determined and expressed as fosetyl-Al for the parent and determined and expressed as phosphonic acid (named phosphorous acid in the reports) for the plant metabolite. The total residue was calculated and expressed as the sum of residues of fosetyl-Al and phosphonic acid expressed as fosetyl-Al.

Total residue as fosetyl-Al [mg/kg]	$\text{fosetyl-Al [mg/kg]} + \frac{\text{phosphonic acid [mg/kg]} \times M_{\text{fosetyl-Al}}}{M_{\text{phosphonic acid}}}$
-------------------------------------	--

M_{fosetyl-Al}: Molecular weight of fosetyl-Al: 254.1 g/mol
 M_{phosphonic acid}: Molecular weight of phosphonic acid: 82 g/mol

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In the approval renewal of fosetyl, the representative uses are proposed on grapes and pome fruit as recorded in Table 6.3- 1.

Table 6.3- 1: Representative uses for the approval renewal of fosetyl

Crop	Zone	F, G or I**	Formulation	Application				Application rate per treatment		
				method kind	growth stage BBCH	number min max	interval between applications (days)	water L/ha min max	kg as/ha	PHI (days)
Grapes	N-EU	F	WG 71.11	Foliar spray	15-81	3	10-14	100-1000	2.0	21
Grapes	S-EU	F	WG 71.11	Foliar spray	15-81		10-14	100-1000	2.0	21
Pome fruit	N-EU	F	WG 80	Foliar spray	35-85		7-10	300-1500	3.0	28
Pome fruit	S-EU	F	WG 80	Foliar spray	35-85	3	7-10	300-1500	3.6	28

* N-EU: northern Europe S-EU: southern Europe
 ** F: Field; G: Greenhouse; I: Indoor
 WG 71.11: water dispersible granule formulation containing 66.7 g/kg of fosetyl-Al and 44.4 g/kg of flupropidate (e.g. Profiler)
 WG 80: water dispersible granule formulation containing 800 g/kg of fosetyl-Al (e.g. Ahoite)

For the metabolite, the term of phosphorous acid was used in the residue studies but the IUPAC name phosphonic acid is used for all sections of this dossier.

In the new residue reports, the residues are determined and expressed as fosetyl-Al for the parent and determined and expressed as phosphonic acid (named phosphorous acid in the reports) for the metabolite.

When the total residue is expressed as fosetyl-Al in the residue report, it will be calculated in this dossier as total residue expressed as fosetyl and as total residue expressed as phosphonic acid according to the following formula.

When the total residue is expressed as fosetyl in the residue report, it will be reported in this dossier without correction and the total residue expressed as phosphonic acid will be calculated according to the following formula.

Formula for total residue expressed as fosetyl (mg/kg):

$$\text{Total residue calculated as fosetyl [mg/kg]} = \frac{\text{fosetyl-Al [mg/kg]} \times M_{\text{fosetyl}} \times 3}{M_{\text{fosetyl}}} + \frac{\text{phosphonic acid [mg/kg]} \times M_{\text{fosetyl}}}{M_{\text{phosphonic acid}}}$$

M_{fosetyl-Al}: Molecular weight of fosetyl-Al = 354.1 g/mol
 M_{phosphonic acid}: Molecular weight of phosphonic acid = 82 g/mol
 M_{fosetyl}: Molecular weight of fosetyl = 110 g/mol

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Formula for total residue expressed as phosphonic acid (mg/kg):

$$\begin{matrix} \text{Total residue} \\ \text{calculated} \\ \text{as phosphonic acid} \\ \text{[mg/kg]} \end{matrix} = \frac{\text{fosetyl-Al [mg/kg]} \times M_{\text{phosphonic acid}} \times 3}{M_{\text{fosetyl-Al}}} + \text{phosphonic acid [mg/kg]}$$

M_{fosetyl-Al}: Molecular weight of fosetyl-Al = 354.1 g/mol

M_{phosphonic acid}: Molecular weight of phosphonic acid = 82 g/mol

M_{fosetyl}: Molecular weight of fosetyl = 110 g/mol

CA 6.3.1 Citrus

Not applicable, see GAP in Section CA 6.3.

CA 6.3.2 Grapes

Former Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC

The critical Good Agricultural Practice (GAP) supported at the European level in the Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC consisted of 6 foliar spray applications at 2.0 kg/ha of fosetyl-aluminium (fosetyl-Al) with an interval between applications of 10 to 14 days and a PHI of 28 days.

Table 6.3.2- 1: Summary of the critical GAP supported in the former Annex II dossier

Crop	Zone or I**	Formulation	Application				Application rate per treatment		PHI (days)
			method and stage	BBCH	number min max	interval between applications (days)	water L/ha min max	kg as/ha	
Grapes	N-EU	F WG 71.14	Foliar spray	56-81	6	10	150-1000	2.0	28
Grapes	S-EU	WG 71.14	Foliar spray	56-81	6	10	150-1000	2.0	28

* N-EU: northern Europe; S-EU: southern Europe; F: Field; G: Greenhouse; I: Indoor

Before flowering to 28 days before harvest, from spring to autumn; BBCH 53 – 81

WG 71.14: water dispersible granule formulation containing 60 g/kg of fosetyl-Al and 44.4 g/kg of fenamidone (e.g. Verita)

A total of 21 supervised residue trials were conducted in Europe over two growing seasons (9 in Northern Europe and 12 in Southern Europe) with 7 applications of the WG formulation containing fosetyl-Al and fenamidone. These residue trials were submitted in the Annex II dossier for setting the EU MRL and were evaluated during the EU Evaluation Process of fosetyl. They were re-described in the EU MRL compilation dossier for fosetyl which was submitted to the Rapporteur France in 2008.

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Table 6.3.2- 2: Residue trials conducted per geographical region and formulation

Region	Crop	Formulation	Number of Trials		Report-No.	Document No.	Dossier-Ref.
			Vegetation period				
			1997	1998			
<i>Annex II data</i>							
N-EU	Grape	WG 71.14	1	-	97-579	M-165834-01-1	KCA 6.3.2/01
	Grape	WG 71.14	1	-	97-580	M-165259-01-1	KCA 6.3.2/09
	Grape	WG 71.14	1	-	97-581	M-165494-01-1	KCA 6.3.2/10
	Grape	WG 71.14	1	-	97-582	M-165735-01-2	KCA 6.3.2/11
	Grape	WG 71.14	-	2	98-551	M-166547-01-1	KCA 6.3.2/12
	Grape	WG 71.14	-	1	98-562	M-170328-01-1	KCA 6.3.2/04
	Grape	WG 71.14	-	2	98-563	M-166535-01-1	KCA 6.3.2/05
S-EU	Grape	WG 71.14	2	-	97-579	M-165834-01-1	KCA 6.3.2/01
	Grape	WG 71.14	-	1	97-76	M-165270-01-1	KCA 6.3.2/02
	Grape	WG 71.14	1	-	97-74	M-165477-01-1	KCA 6.3.2/03
	Grape	WG 71.14	-	2	98-562	M-165479-01-1	KCA 6.3.2/04
	Grape	WG 71.14	-	2	98-562	M-170328-01-1	KCA 6.3.2/05
	Grape	WG 71.14	-	1	98-563	M-166535-01-1	KCA 6.3.2/06
	Grape	WG 71.14	-	2	98-590	M-166463-01-1	KCA 6.3.2/07
Grape	WG 71.14	-	1	98-73	M-170375-01-1	KCA 6.3.2/08	

N-EU: northern Europe S-EU: southern Europe
WG 71.14: water dispersible granule formulation containing 44.4 g/kg of fenamidone and 667 g/kg of fosetyl-Al (e.g. Verita)

The formulation Fosetyl-Al/Fenamidon WG 71.14 (667 + 44.4 g/kg, e.g. Verita) was applied by seven foliar applications at the dose rate of 2.0 kg/ha which is equivalent to 1.8 kg/ha of fosetyl-Al (180 to 1200 L water) between growth stages 35 and 89 with a spray interval of approximately 14 days and the last application 28 days prior to the expected date of harvest (desired waiting period). The total residues were expressed as fosetyl-Al in the studies and were recorded without correction.

At the proposed harvest date of 28 days, total residues expressed as fosetyl-Al were between 9.2 and 38 mg/kg in Northern Europe (n=7) and between 14 and 49 mg/kg in Southern Europe (n=12).

These data have been used in the calculation of the proposed European MRL of **60 mg/kg** for fosetyl in grapes as indicated in [Table 6.3.2.5](#).

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Table 6.3.2- 3: Summary of the residue data in the peer review (EFSA Scientific Report (2005) 54, 1-79)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP	Recommendation/ comments	MRL	STMR
Grapes	N and S	S 12 trials 25-34-32-8.6-22-25-41-30-9.9-7.4-32-49	Data are acceptable	60	26
		N 9 trials 21-9.2-27-35-18-21-36-17-26			

Considering the new rule where the highest residue level at the proposed harvest date or after should be retained and the expression of the total residues as fosetyl, total residues were recalculated in this dossier. Total residue as fosetyl are between 8.6 and 56 mg/kg in Northern Europe (n=9) and between 7.0 and 46 mg/kg in Southern Europe (n=12). The overall summary is presented in Table 6.3.2- 4 and the detailed results in Table 6.3.2- 5.

Table 6.3.2- 4: Overall summary of residue data on grape evaluated in the Annex II dossier with the current rule of result presentation

Application	Sample material	n	Total residue calculated and expressed as	Residue level (mg/kg)		
				Min.	Max.	STMR
Northern Europe						
7 applications 2.0 kg a.s./ha, interval of 14 days, PHI of 28 days	fruit		fosetyl*	8.6	56	26
Southern Europe						
7 applications 2.0 kg a.s./ha, interval of 14 days, PHI of 28 days	fruit		fosetyl*	7.0	46	30

*: Sum of fosetyl phosphonic acid and the salts expressed as fosetyl
EFSA Scientific report (2005) 54, 1-79: Conclusion on the peer review of fosetyl

Table 6.3.2- 5: Compilation of the residue data in/on grapes supporting the EU GAP in the peer review

Region	No of trials	Commodity	Range of residues		STMR	HR
			Residue component	mg/kg		
Northern Europe		Bunch of grapes	Fosetyl-Al	0.30-0.33-0.47(DALT41)-0.65*(DALT46)-0.68(DALT39)-0.83-0.92-1.0-1.4	0.68	1.4
			Phosphonic acid	6.2*-12*-14* -18*-19(DALT39)-20*(DALT41)-23-25*-41*(DALT46)	19	41
			Total residue as fosetyl ⁽¹⁾	8.6*-17*-20*-25*-26(DALT39)-27*(DALT41)-32-34*-56*(DALT46)	26	56

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Region	No of trials	Commodity	Range of residues		STMR	HR
			Residue component	mg/kg	mg/kg	mg/kg°
Southern Europe	12	Bunch of grapes	Fosetyl-Al	0.22-0.38- 0.38 (DALT42)- 0.39-0.59-0.64(DALT41)- 0.70-0.85-0.85(DALT42)- 2x0.92-1.3	0.67	1.3
			Phosphonic acid	4.6-5.8-6.2-15*-19*- 2x22*-22*(DALT41)- 27*(DALT42)-33- 33*(DALT42)-34*	22	4
			Total residue as fosetyl ⁽¹⁾	7.0-8.0-9.2-20*23*- 2x30*-30*(DALT41)- 37(DALT42)- 45*(DALT42)-46-46*	9	46

Notes: When the residue result is higher after the PHI=28 days, this result is retained and the corresponding DALT (DALT = Days after last treatment in days) is indicated in brackets. The residue value of fosetyl-Al marked in bold corresponds to the result of fosetyl-Al when the highest total residue as fosetyl is calculated.

⁽¹⁾: Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54, 1-79. Conclusion of the peer review of fosetyl

*: apparent residue found in the corresponding control sample. Residue level at 0.20 mg/kg for fosetyl-Al from 0.22 to 4.8 mg/kg for phosphonic acid and from 0.48 to 6.6 mg/kg for total residue as fosetyl

New studies submitted in Supplementary Dossier

The critical Good Agricultural Practice (eGAP) supported at the European level for the approval renewal process of fosetyl consists of foliar spray applications at 2.0 kg/ha of fosetyl-aluminium (fosetyl-Al) with an interval between applications of 10 to 14 days and a PHI of 21 days.

Table 6.3.2- 6: Summary of the critical GAP proposed in the Supplementary Dossier

Crop	Zone	F, G, I**	Formulation	Application				Application rate per treatment		PHI (days)
				method kind	growth stage BBCH	number min max	interval between applications (days)	water L/ha min max	kg as/ha	
Grapes	N-EU	F	WG 71.11	Foliar spray	15-81	3	10-14	100-1000	2.0	21
Grapes	S-EU	F	WG 71.11	Foliar spray	15-81	3	10-14	100-1000	2.0	21

* N-EU: northern Europe S-EU: southern Europe ** F Field; G Greenhouse; I Indoor

WG 71.11: water dispersible granule formulation containing 666.7 g/kg of fosetyl-Al and 44.4 g/kg of fluopicolide

New residue trials were conducted under GLP conditions between 2001 and 2008 to support the European GAP relevant for approval renewal of fosetyl. They were performed in northern Europe (Germany (6), France (7)) and in southern Europe (Spain (3), Italy (3), France (5) and Greece (1)). They were conducted with the formulation Fosetyl-Al + Fluopicolide WG 71.11 (666.7 + 44.4 g/kg, e.g. ProFlor). The residue trials are listed in Table 6.3.2- 7 and the overall summary of the residue data is provided in Table 6.3.2- 8.

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Table 6.3.2- 7: Residue trials conducted per geographical region and formulation

Region	Crop	Formulation	Number of Trials				Report-No.	Document No.	Dossier-Ref.
			Vegetation period						
			2001	2002	2007	2008			
Supplementary data									
N-EU	Grape	WG 71.11	5	-	-	-	01R284	M-214899-01-1	KCA 6.3.2/14
	Grape	WG 71.11	-	4	-	-	02R288	M-230759-01-1	KCA 6.3.2/14
	Grape	WG 71.11	-	-	-	4	08-2040	M-356927-01-1	KCA 6.3.2/15
S-EU	Grape	WG 71.11	5	-	-	-	01R285	M-214901-02-1	KCA 6.3.2/16
	Grape	WG 71.11	-	4	-	-	02R289	M-230761-01-1	KCA 6.3.2/16
	Grape	WG 71.11	-	-	3	-	RA-2671/07	M-366645-01-1	KCA 6.3.2/18

N-EU: northern Europe S-EU: southern Europe
WG 71.11: water dispersible granule formulation containing 666.7 g/kg of fosetyl-Al and 44.4 g/kg of fluopicolide

Table 6.3.2- 8: Overall summary of residue data on grape covering the critical GAP for approval renewal

Application	Sample material	n	Total residue calculated and expressed as	Residue level (mg/kg)		
				Min.	Max.	STMR
Northern Europe						
3 applications 2.0 kg a.s./ha, interval of 7-14 days, PHI of 21 days	fruit	13	fosetyl*	14	54	26
			phosphonic acid**	10	40	19
Southern Europe						
3 applications 2.0 kg a.s./ha, interval of 7-14 days, PHI of 21 days	fruit	12	fosetyl*	6.4	51	18
			phosphonic acid**	4.7	37	13

*: Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54, 1-79: Conclusion on the peer review of fosetyl
**: Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid
EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2013: Conclusion on the peer review of fosetyl

The detailed results are provided in Table 6.3.2- 9, presented as fosetyl-Al and phosphonic acid and also as total residue expressed as fosetyl or as phosphonic acid.

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Table 6.3.2- 9: Compilation of the residue data in/on grapes supporting the critical EU GAP

Region	No of trials	Commodity	Range of residues		STMR	HR
			Residue component	mg/kg	mg/kg	mg/kg
Northern Europe	13	Bunch of grapes	Fosetyl-Al	3.1*(DAL T29) - 2.2(DAL T29) - 0.39(DAL T28) - 0.62(DAL T28) - 0.25 - 1.9 - 4.3 - 1.2 - <0.5 - 1.4 - 1.9 - 3.2 - 2.2(DAL T28)	1.9	
			Phosphonic acid	23*(DAL T29) - 22(DAL T29) - 16*(DAL T28) - 16(DAL T28) - 11* - 13* - 21 - 14* - 19* - 9.2 - 26 - 24 - 21*(DAL T28)	7	
			Total residue as fosetyl ⁽¹⁾	34*(DAL T29) - 32(DAL T29) - 22*(DAL T28) - 23(DAL T28) - 15* - 19* - 54 - 20* - 26* - 4 - 36 - 37 - 31*(DAL T28)	26	54
			Total residue as phosphonic acid ⁽²⁾	25*(DAL T29) - 24(DAL T29) - 16*(DAL T28) - 16(DAL T28) - 11* - 14* - 40 - 15* - 19* - 0 - 27 - 8 - 23*(DAL T28)	19	40
Southern Europe	12	Bunch of grapes	Fosetyl-Al	1.0(DAL T28) - 0.94(DAL T28) - 0.42 - 0.28(DAL T28) - 0.2 - 8.1 - 0.97 - 1.4 - 0.5 - 0.4(DAL T28) - 0.34 - 1.6(DAL T28)	0.96	8.1
			Phosphonic acid	31*(DAL T28) - 11*(DAL T28) - 7.7 - 43*(DAL T28) - 4.6(DAL T28) - 26* - 23 - 11* - 12 - 33*(DAL T28) - 13 - 12(DAL T28)	12	33
			Total residue as fosetyl ⁽¹⁾	43*(DAL T28) - 16*(DAL T28) - 11* - 16*(DAL T28) - 6.4(DAL T28) - 42* - 32 - 16* - 17 - 51*(DAL T28) - 18 - 18(DAL T28)	18	51
			Total residue as phosphonic acid ⁽²⁾	32*(DAL T28) - 12*(DAL T28) - 8.0* - 12*(DAL T28) - 4.7(DAL T28) - 32* - 24 - 12* - 12 - 37*(DAL T28) - 14 - 13(DAL T28)	13	37

Note: When the residue result is higher after the PHI=21 days, this result is retained and the corresponding DAL T (DAL T = Days after last treatment in days) is indicated in brackets.

(1): Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54-79: Conclusion on the peer review of fosetyl

(2): Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid
EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2013: Conclusion on the peer review of fosetyl

*: apparent residue found in the corresponding control sample. Residue level at 0.32 mg/kg for fosetyl-Al, from 0.40 to 11 mg/kg for phosphonic acid, from 0.72 to 15 mg/kg for total residue as fosetyl and from 0.54 to 11 mg/kg for total residue as phosphonic acid

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****Field trials – northern Europe:**

Report: KCA 6.3.2/13 [REDACTED]; 2003; M-214899-01-1
Title: Residue behaviour in grapevine European Union (Northern zone) 2001 AE C638206 + fosetyl-aluminium water dispersible granule (WG) 4.44 percent + 66.7 percent w/w
 Code: AE F053616 06 WG71 A101 (EXP11074B)
Report No.: 01R284
Document No.: M-214899-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.2/14 [REDACTED]; 2003; M-230759-01-1
Title: Residue behaviour in grapevine European Union (Northern zone) 2002 AE C638206 + fosetyl-aluminium water dispersible granule (WG) 4.44 percent + 66.7 percent w/w
 Code: AE F053616 06 WG71 A102
Report No.: 02R288
Document No.: M-230759-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.2/15 [REDACTED]; 2009; M-356927-01-1
Title: Determination of the residues of fluopicolide and fosetyl-Al in/on grape after spraying of fluopicolide & fosetyl-Al WG 71 in the field in France (North) and Germany
 Code: 08-2040
Report No.: 08-2040
Document No.: M-356927-01-1
Guideline(s): EU-Ref: Council Directive 90/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8
 Residues in or on Treated Products, Food and Feed ; EU guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Guideline deviation(s): none
GLP/GEP: yes

Material and Methods:

In 2001 a total of five supervised field trials were performed in Germany (2) and Northern France (3), in 2002 a total of four supervised field trials were performed in Northern France (2) and Germany (2) and in 2008 a total of four supervised field trials were performed in Germany (2) and Northern France (2) on grapevines. Profiler (AE F053616 06 WG71 A1, WG 71), a co-formulation of fosetyl-Al (666.7 g/kg) and fluopicolide (44.4 g/kg) was sprayed three times on grapevines with a product rate of 2.815 to 3 kg product/ha and a water rate of 200 to 1000 L/ha, corresponding to a fosetyl-Al use rate of 1.878 to 2.086 kg a.s./ha and a fluopicolide use rate of 0.125 to 0.139 kg a.s./ha per application. The applications were carried out with a spray interval of 13 to 14 days (7 to 8 days for the study performed in 2008) with the last application 20 days prior to the expected date of harvest.

The first treatment was conducted at growth stages between BBCH 77 and 81, whilst the last application was carried out at BBCH 79 to 85, 21 days (+/- 1 day) before the anticipated commercial harvest.

In all trials, bunch of grapes samples were taken at day 0 and at day 21 (the intended PHI) after the last application at BBCH 81 to 89. In addition, samples were taken on the day before the last application in study 08-2040, at day 7 and 14 in study 01R284 and at day 28 in studies 01R284 and 08-2040.

In the study 01R284, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method AR 155-97 (derivatization with diazomethane and GC-FPD) with a LOQ of 0.20 mg/kg for fosetyl-Al and its metabolite.

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In the study 02R288, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method AR 154-97 (derivatization with trimethylsilyldiazomethane and GC-FPD) with a LOQ of 0.50 mg/kg for fosetyl-Al and its metabolite.

In the study 08-2040, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method 00861/M001 by LC-MS/MS with a LOQ of 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid.

When the total residue is expressed as fosetyl-Al in the residue report (studies 01R284 and 02R288), it will be calculated in this dossier as total residue expressed as fosetyl and as total residue expressed as phosphonic acid (see Section CA 6.3 for calculation).

When the total residue is expressed as fosetyl in the residue report (study 08-2040), it will be reported in this dossier without correction and the total residue expressed as phosphonic acid will be calculated (see Section CA 6.3 for calculation).

Findings

- **Method performance:** In the case of recovery experiments for methods validation, recovery means (n≥2) were within the range of 74 to 108% with RSD <20%, as shown in Table 6.3.2- 10. All results of the methods validation are in accordance with the general requirements for residue analytical methods. For the study 08-2040, full validation of the method on grape is documented with the method 00861/M001 itself, recovery means ranged between 99 and 102% with RSD <20%. No additional validation was performed in this study.

For concurrent recoveries, recovery means (n≥2) at fortification levels between 0.01 and 10 mg/kg for fosetyl-Al and between 0.20 and 40 mg/kg for phosphonic acid were within the range of 73 to 104% with RSD <20%, as shown in Table 6.3.2-11.

Table 6.3.2- 10: Method validation data for fosetyl-Al and phosphonic acid during studies 01R284 and 02R288

Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
01R284	AR 154-97	Fosetyl-Al	bunch of grapes	0.20	108; 104; 101	104	3.4	0.20
				2.0	74; 74	74	-	
				Overall Recovery (n = 5)		92	18.3	
		Phosphonic acid	bunch of grapes	0.20	104; 110; 109	108	3.0	0.20
				2.0	90; 86	88	-	
Overall Recovery (n = 5)		100	11.1					
02R288	AR 154-97	Fosetyl-Al	bunch of grapes	0.50	94; 119; 93; 89	99	13.8	0.50
				5.0	97; 109; 122	109	11.4	
				Overall Recovery (n = 7)		103	12.9	
		Phosphonic acid	bunch of grapes	0.50	104; 76; 73; 70	81	19.4	0.50
				5.0	82; 95; 97	91	8.9	
Overall Recovery (n = 7)		85	16					

RSD: Relative Standard Deviation

LOQ = Practical Limit of Quantification

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Fosetyl

Table 6.3.2- 11: Concurrent recoveries for fosetyl-Al and phosphonic acid

Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
01R284	Fosetyl-Al	bunch of grapes	0.20	72; 97; 90	86	14.9	0.20
			0.50	71; 75	73	-	
			1.0	72	-	-	
			2.0	85	-	-	
			5.0	71	-	-	
			Overall Recovery (n = 8)	79	52.8		
	Phosphonic acid	bunch of grapes	0.20	88; 109; 95	97	11.0	0.20
			10	80; 80	84	-	
			15	49	-	-	
			20	98	-	-	
30			90	-	-		
Overall Recovery (n = 8)			91	41.1			
02R288	Fosetyl-Al	bunch of grapes	0.50	102; 74*; 100; 81	92	17.0	0.50
			10	113; 94	104	-	
			Overall Recovery (n = 6)	96	15.3		
	Phosphonic acid	bunch of grapes	0.50	107; 86*; 96; 92	95	9.3	0.50
			4.0	104	-	-	
			Overall Recovery (n = 6)	96	8.6		
08-2040	Fosetyl-Al	bunch of grapes	0.01	95; 107	101	-	0.01
			0.10	99; 106	103	-	
			1.0	98; 108	103	-	
			Overall Recovery (n = 6)	102	5.4		
	Phosphonic acid	bunch of grapes	0.20	99; 110	104	-	0.20
			2.0	98; 109	104	-	
			Overall Recovery (n = 6)	103	6.2		

RSD: Relative Standard Deviation LOQ = Practical Limit of Quantification

* Mean value of two analyses

- Storage stability:

The storage periods of deep frozen untreated and treated samples for grape samples are summarised in Table 6.3.2- 12. For fosetyl-Al and its metabolite, before analysis, the maximum storage period of deep-frozen samples did not exceed 391 days (13 months) which is covered by the respective storage stability studies (see Section 6.A.6.4).

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Table 6.3.2- 12: Storage periods of deep frozen samples in/on grape after use of Fosetyl-Al + Fluopicolide WG 71.11

Study	Crop	Analyte	Storage period of deep frozen samples	
			Min [days]	Max [days]
01R284	grape	fosetyl-Al phosphonic acid	342	390
02R288	grape	fosetyl-Al phosphonic acid	60	119
08-2040	grape	fosetyl-Al phosphonic acid	265	310

- Residue results: In the northern European field trials, the residues in grape at a PHI of 21 days (6 - 1 day) or at longer PHI if a higher residue value was obtained, ranged from 0.35 to 5.2 mg/kg for fosetyl-Al and from 9.2 to 37 mg/kg for phosphonic acid. The total residues expressed as fosetyl were between 14 and 54 mg/kg. The total residues expressed as phosphonic acid were between 10 and 40 mg/kg.

- For fosetyl-Al no apparent residues were found in any of the untreated samples, i.e. residues were < LOQ, except in the trial 01R284, where apparent residues of fosetyl-Al were found in all untreated samples between 0.29 and 0.48 mg/kg and in the trial 02R288, where apparent residues of fosetyl-Al were found at 0.57 mg/kg at day 0.

For phosphonic acid, apparent residue samples were found in many trials between 0.29 and 12 mg/kg. In spite of no information was reported in the study reports, a contamination with phosphonic acid via fertilizers or another source could be suspected. However this level of contamination can be considered as acceptable.

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Table 6.3.2- 13: Application data, residues for fosetyl-Al and phosphonic acid and total residues calculated and expressed as fosetyl and as phosphonic acid in/on grape treated with Fosetyl-Al + Fluopicolide WG 71.11 in the field in northern Europe

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DAIT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R284 01R284-1 01R284-1 GLP yes 2001	Grape Riesling, white variety	Germany [REDACTED] Europe, North	71.11 WG	3	1.878	0.576	85	bunch of grapes	0 7 14 21 29	5.2/<0.48 3.2/0.39 2.2/0.29 1.5/0.29 0.31/0.32	13/10 11/9 10/12 15/12 23/11	22/14 18/13 28/16 22/16 34/15	17/10 13/10 21/12 16/12 25/11
01R284 01R284-2 01R284-2 GLP yes 2001	Grape Silvaner, white variety	Germany [REDACTED] Europe, North	71.11 WG	3	1.878	0.576	85	bunch of grapes	0 7 14 21 29	4.3/<0.20 5.2/<0.20 3.4/<0.20 1.3/<0.20 2.2/<0.20	13/<0.20 18/<0.20 21/<0.20 21/<0.20 22/<0.20	21/<0.45 29 /<0.45 31/<0.45 29/<0.45 32/<0.45	16/<0.34 22/<0.34 23/<0.34 22/<0.34 24/<0.34
01R284 01R284-3 01R284-3 GLP yes 2001	Grape Cabernet Franc, red variety	France [REDACTED] Europe, North	71.11 WG	3	1.878	0.754	85	bunch of grapes	0 7 14 21 28	2.1/<0.20 1.5/<0.20 1.3/<0.20 <0.2/0.7 0.39/<0.20	9.4/2.1 12/2.3 11/2.4 3.3/13 16/3.4	15/3.0 17/3.3 16/3.4 4.6/18 22/4.7	11/2.2 13/2.4 12/2.5 3.4/14 16/3.5
01R284 01R284-4 01R284-4 GLP yes 2001	Grape Chenin white variety	France [REDACTED] Europe, North	71.11 WG	3	1.878	0.854	85	bunch of grapes	0 7 14 21 28	1.5/<0.20 1.3/<0.20 0.93/<0.20 0.85/<0.20 0.62/<0.20	7.7/<0.20 12/<0.20 9.7/<0.20 14/<0.20 16/<0.20	12/<0.45 17/<0.45 14/<0.45 20/<0.45 22/<0.45	8.7/<0.34 13/<0.34 10/<0.34 15/<0.34 16/<0.34

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Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R284 01R284-5 01R284-5 GLP yes 2001	Grape Pinot Meunier, red variety	France [REDACTED] Europe, North	71.11 WG	3	1.878	0.1878	85	bunch of grapes	0 7 14 21 28	0.07/<0.20 0.62/<0.20 0.47/<0.20 0.25/<0.20 0.20/<0.20	7.1/0.29 9.6/0.29 12/0.36 11/0.46 11/0.49	11/0.58 13/0.58 17/0.67 15/0.72 15/0.84	8.5/0.43 10/0.43 12/0.50 11/0.54 11/0.63
02R288 02R288-1 02R288-1 GLP yes 2002	Grape Müller - Thurgau white variety	Germany [REDACTED] Europe North	71.11 WG	3	1.878	0.376	83	bunch of grapes	0 21	2.2/<0.50 1.9/<0.50	8.4/0.93 13/1.1	10/1.7 19/2.9	9.9/1.3 14/2.1
02R288 02R288-2 02R288-2 GLP yes 2002	Grape Spätburgunder red variety	Germany [REDACTED] Europe, North	71.11 WG	3	1.878	0.376	85	bunch of grapes	0 21	9.7/<0.50 4.3/<0.50	24/<0.50 37/<0.50	41/<1.1 54/<1.1	31/<0.85 40/<0.85
02R288 02R288-3 02R288-3 GLP yes 2002	Grape Pinot Meunier red variety	France [REDACTED] Europe, North	71.11 WG	3	1.878 2.086	0.376	83	bunch of grapes	0 21	3.8/<0.50 1.2/<0.50	13/0.79 14/0.61	21/1.5 20/1.3	16/1.1 15/0.96
02R288 02R288-4 02R288-4 GLP yes 2002	Grape Chardonnay white variety	France [REDACTED] Europe, North	71.11 WG	3	1.878	0.376	83	bunch of grapes	0 21	4.3/0.57 <0.5/<0.50	14/5.0 19/2.3	23/7.2 26/3.6	17/5.4 19/2.7

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Document MCA – Section 6: Residues in or on treated products, food and feed

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DAIT (days)	fosetyl-AI (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
08-2040 08-2040-01 08-2040-01 GLP yes 2008	Grape Cot	France [REDACTED] Europe, North	71.11 WG	3	2.0	1.0	85	bunch of grapes 0* 0 21 28	0.8/ 6.6/n.a 1.4/n.a 0.7/<0.01	4.1/1.7 4.6/n.a 9.2/n.a 8.5/2.0	7.2/2.3 12 14 13/2.7	5.4/1.7 9.2 10 9.5/2.0	
08-2040 08-2040-02 08-2040-02 GLP yes 2008	Grape Cabernet franc	France [REDACTED] Europe, North	71.11 WG	3	2.0	1.0	85	bunch of grapes 0* 0 21 28	0.8/ 7.7/n.a 1.9/n.a 1.8/<0.01	10/2.6 9.9/n.a 26/n.a 24/2.5	13/3.5 21 36 34/3.4	13/2.6 15 27 25/2.5	
08-2040 08-2040-03 08-2040-03 GLP yes 2008	Grape Dornfelder	Germany [REDACTED] Europe, North	71.11 WG	3	2.0	1.0	83	bunch of grapes 0* 0 21 28	4.9/<0.01 12/n.a 5.2/n.a 4.5/<0.01	12/0.35 13/n.a 24/n.a 24/0.36	21/0.48 28 37 36/0.49	15/0.36 21 28 27/0.37	

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[REDACTED]

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	DALT (days)	fosetyl-Al (mg/kg)	Residues ⁽¹⁾			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS				phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)
08-2040 08-2040-04 08-2040-04 GLP yes 2008	Grape Mueller-Thurgau	Germany [REDACTED] Europe, North	71.11 WG	3	2.0	1.0	28	bunch of grapes	0.8 0 2.2 2.8	<0.01 5.2/n.a 1.8/n.a 2.2<0.01	13/7.4 1/n.a 19/n.a 21/7.5	19/10 20 20 31/10	14/7.4 15 20 23/7.5	

FL: Formulation No: number of applications GS = growth stage (BBCH code) at last application DALT = days after last treatment
/value: Residue found in the corresponding control sample 0* prior to last treatment
n.a: not available, control sample not collected

- ⁽¹⁾: The residue values of fosetyl-Al and phosphonic acid marked in boldface are those retained for the calculation of the highest total residues expressed as fosetyl and as phosphonic found at the PHI of 21 days or after. The total residue expressed as fosetyl is calculated as the sum of fosetyl-Al expressed as fosetyl and phosphonic acid expressed as fosetyl. The total residue expressed as phosphonic acid is calculated as the sum of fosetyl-Al expressed as phosphonic acid and phosphonic acid.
- ⁽²⁾: A potential inversion of the results between untreated sample and treated sample at 21 days seems being happened. So the highest values are proposed for the treated samples as worst case.

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**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****Field trials – southern Europe:**

Report: KCA 6.3.2/16 [REDACTED]; 2003; M-214901-02-1
Title: Residue behaviour in table grapes and wine grapes European Union (Southern zone)
 2001 Fosetyl-aluminium + AE C638206 water dispersible granule (WG) 66.7% +
 4.44 % w/w Code: AE F053616 06 WG71 A101
Report No.: 01R285
Document No.: M-214901-02-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.2/17 [REDACTED]; 2003; M-230761-01-1
Title: Residue behaviour in grapevine European Union (Southern zone), 2002 AE C638206
 + fosetyl-aluminium water dispersible granule (WG) 4.44% + 66.7% w/w Code: AE
 F053616 06 WG71 A101
Report No.: 02R289
Document No.: M-230761-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.2/18 [REDACTED]; [REDACTED] 2010; M-366645-01-1
Title: Determination of the residues of AE C638206 and fosetyl-Al on grape after low-
 volume spraying and spraying of AE F053616 06 WG71 A1 (71 WG) in the field in
 Southern France, Spain and Italy
Report No.: RA-2671/07
Document No.: M-366645-01-1
Guideline(s): EU-Reg: Council Directive 90/414/EEC of July 15, 1991,
 Annex II, part A, section 6 and Annex III, part A, section 8
 Residues in or on Treated Products, Food and Feed
 EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Guideline deviation(s): none
GLP/GEP: yes

Material and Methods:

In 2001 a total of five supervised field trials were performed Southern France (2), Italy (1), Greece (1) and Spain (1), in 2002 a total of four supervised field trials were performed in Southern France (2) Spain (1) and Italy (1) and in 2007 a total of three supervised field trials were performed in Southern France, Spain and Italy on grapevines. Profiler (AE F053616 06 WG71 A1, WG 71), a co-formulation of fosetyl-Al (666.7 g/kg) and fluopicolide (44.4 g/kg) was sprayed three times on grapevines with a product rate of 2.815 to 3 kg product/ha and a water rate of 150 to 1000 L/ha, corresponding to a fosetyl-Al use rate of 1.878 to 2.078 kg a.s./ha and a fluopicolide use rate of 0.125 to 0.138 kg a.s./ha per application. The applications were carried out with a spray interval of 13 to 15 days (6 to 7 days for the study performed in 2007), with the last application 21 days prior to the expected date of harvest. The first treatment was conducted at growth stages between BBCH 75 and 83, whilst the last application was carried out at BBCH 79 to 85, 21 days (+/- 1 day) before the anticipated commercial harvest.

In all trials, bunches of grapes samples were taken at day 0 and at day 20 (the intended PHI) after the last application at BBCH 85 to 89. In addition, samples were taken on the day before the last application in study RA-2671/07 at day 1 and 14 (+/- 2 days) in study 01R285 and at day 28 in studies 01R285 and RA-2671/07.

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In the study 01R285, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method AR 155-97 (derivatization with diazomethane and GC-FPD) with a LOQ of 0.20 mg/kg for fosetyl-Al and its metabolite.

In the study 02R289, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method AR 154-97 (derivatization with trimethylsilyldiazomethane and GC-FPD) with a LOQ of 0.50 mg/kg for fosetyl-Al and its metabolite.

In the study RA-2671/07, bunch of grapes were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the report) according to the method 00861/M001 by GC-MS/MS with a LOQ of 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid.

When the total residue is expressed as fosetyl-Al in the residue report (studies 01R285 and 02R289), it will be calculated in this dossier as total residue expressed as fosetyl and as total residue expressed as phosphonic acid (see Section CA 6.3 for calculation).

When the total residue is expressed as fosetyl in the residue report (study RA-2671/07), it will be reported in this dossier without correction and the total residue expressed as phosphonic acid will be calculated (see Section CA 6.3 for calculation).

Findings

- **Method performance:** For studies 01R285 and 02R289, the confirmation of the method validity in bunch of grapes was already performed in the study 01R284 or 02R288 respectively. For results, see Table 6.3.2- 10.

For the study RA-2671/07, full validation of the method on grape is documented with the method 00861/M001 itself, recovery means ranged between 99 and 102% with RSD < 20%. No additional validation was performed in this study.

For concurrent recoveries, recovery means (n ≥ 2) at fortification levels between 0.01 and 10 mg/kg for fosetyl-Al and between 0.20 and 40 mg/kg for phosphonic acid were within the range of 77 to 113% with RSD < 20%, as shown in Table 6.3.2- 14.

Table 6.3.2- 14 Concurrent recoveries for fosetyl-Al and phosphonic acid

Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]		
01R285	Fosetyl-Al	bunch of grapes	0.20	90; 81; 73	81	10.5	0.20		
			0.50	78	-	-			
			1.0	75	-	-			
			2.0	74	-	-			
			3.0	81	-	-			
			10	76	-	-			
			Overall Recovery (n = 8)			79		7.0	
			Phosphonic acid	bunch of grapes	0.20	92; 108; 99		100	8.0
	5.0	87			-	-			
	10	79			-	-			
	15	107			-	-			
	20	72			-	-			
	30	78			-	-			
	Overall Recovery (n = 8)			90	15.1				

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Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
02R289	Fosetyl-Al	bunch of grapes	0.50	87; 87; 72; 67 ⁽¹⁾ ; 87; 64	77	14.1	0.50
			10	75	-	-	
			Overall Recovery (n = 7)		77	13.0	
	Phosphonic acid	bunch of grapes	0.50	99; 85; 78 ⁽¹⁾ ; 82 ⁽¹⁾ ; 85; 60	82	16.6	0.50
			40	72	-	-	
			Overall Recovery (n = 7)		86	15.1	
RA-2671/07	Fosetyl-Al	grape, fruit	0.01	101 ⁽²⁾ ; 96 ⁽³⁾	99	-	0.01
			0.10	99 ⁽³⁾	-	-	
			1.0	98 ⁽³⁾	-	-	
			Overall Recovery (n = 4)		99	2.1	
	Phosphonic acid	grape, fruit	0.2	115 ⁽²⁾ ; 110 ⁽⁴⁾	113	-	0.20
			2.0	100 ⁽³⁾	-	-	
			20	102 ⁽⁴⁾	-	-	
			Overall Recovery (n = 4)		107	6.2	

RSD: Relative Standard Deviation

LOQ = Practical Limit of Quantification

(1): Mean value of two analyses

(2): recovery prepared with organic grape; value obtained not corrected

(3): Residues of fosetyl-Al were found in the control sample at the LOQ level. The recoveries presented in this table have been corrected accordingly.

(4): Residues of phosphonic acid were found in the control sample at 1 mg/kg. The recoveries presented in this table have been corrected accordingly.

- Storage stability

The storage periods of deep frozen untreated and treated samples for grape samples are summarised in Table 6.3.2- 15. For fosetyl-Al and its metabolite, before analysis, the maximum storage period of deep-frozen samples did not exceed 679 days (23 months) which is covered by the respective storage stability studies (see Section 6.1).

Table 6.3.2- 15: Storage periods of deep frozen samples in/on grape after use of Fosetyl-Al + Fluopicolide WG 71.11

Study	Crop	Analyte	Storage period of deep frozen samples	
			Min [days]	Max [days]
01R285	grape	fosetyl-Al phosphonic acid	353	434
02R289	grape	fosetyl-Al phosphonic acid	60	197
RA-2671/07	grape	fosetyl-Al phosphonic acid	637	679

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- Residue results: In the southern European field trials, the residues in grape at a PHI of 21 days (+/- 1 day) or at longer PHI if a higher residue value was obtained, ranged from <0.2 to 8.1 mg/kg for fosetyl-Al and from 4.6 to 33 mg/kg for phosphonic acid.

The total residues expressed as fosetyl were between 6.4 and 51 mg/kg. The total residues expressed as phosphonic acid were between 4.7 and 37 mg/kg.

- For fosetyl-Al no apparent residues were found in any of the untreated samples, i.e. residues were < LOQ, except in the trial R 2007 0816 5 where apparent residues of fosetyl-Al were found at 0.01 mg/kg (LOQ) on the day before last treatment.

For phosphonic acid, apparent residue samples were found in many trials between 0.27 and 6.8 mg/kg. In spite of no information was reported in the study reports, a contamination with phosphonic acid via fertilizers or another source could be suspected.

However this level of contamination can be considered as acceptable.

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Table 6.3.2- 16: Application data, residues for fosetyl-Al and phosphonic acid and total residues calculated and expressed as fosetyl and as phosphonic acid in/on grape treated with Fosetyl-Al + Fluopicolide in the field in southern Europe

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DLT (days)	fosetyl-Al (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R285 01R285-1 01R285-1 GLP yes 2001	Grape Cabernet Sauvignon, red variety	France [REDACTED] Europe, South	71.11 WG	3	1.878	0.25	85	bunch of grapes	0 7 12 14 28	<0.20 3.8/<0.20 3.8/<0.20 1.1/<0.20	20/68 28/5.1 27/5.8 21/5.3 20/6.1	30/9.3 41/7.0 40/8.0 30/7.3 43/8.4	23/6.9 31/5.2 30/5.9 22/5.4 32/6.2
01R285 01R285-2 01R285-2 GLP yes 2001	Grape Chardonnay, white variety	France [REDACTED] Europe, South	71.11 WG	3	1.878 2.078	0.94 0.94	79	bunch of grapes	0 7 14 21 28	1.0/<0.20 1.0/<0.20 0.93/<0.20 0.97/<0.20 0.94/<0.20	6.6/1.1 8.6/1.2 8.6/1.3 8.6/1.1 11/1.3	10/1.7 12/1.8 12/1.9 12/1.7 16/1.9	7.8/1.2 9.3/1.3 9.2/1.4 9.3/1.2 12/1.4
01R285 01R285-3 01R285-3 GLP yes 2001	Grape Lambrusco Di Sorbara, red variety	Italy [REDACTED] Europe, South	71.11 WG	3	1.878	0.1878	83	bunch of grapes	0 7 14 20 28	5.2/<0.20 2.7/<0.20 0.81/<0.20 0.42/<0.20 0.23/<0.20	7.0/0.38 6.4/0.27 11/0.37 7.7/0.39 7.7/0.40	14/0.70 11/0.55 16/0.68 11/0.71 11/0.72	11/0.52 8.3/0.41 12/0.51 8.0/0.53 7.9/0.54
01R285 01R285-4 01R285-4 GLP yes 2001	Table grape Moscatel, white variety	Spain [REDACTED] Europe, South	71.11 WG	3	1.878	0.1878	83	bunch of grapes berry	0 7 14 22 28	1.6/<0.20 1.3/<0.20 1.2/<0.20 0.20/<0.20 0.28/<0.20	11/0.63 11/0.85 13/0.88 12/0.94 12/0.58	16/1.0 16/1.3 19/1.4 16/1.4 16/1.0	12/0.77 12/0.99 14/1.0 12/1.1 12/0.72

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R285 01R285-5 01R285-5 GLP yes 2001	Grape Xinomavro, red variety	Greece [REDACTED] Europe, South	71.11 WG	3	1.878	0.235	85	bunch of grapes	0	23/<0.20	2.2/<0.20	5.1/<0.45	3.8/<0.34
									7	2.8/<0.20	4.7/<0.20	8.9/<0.45	6.7/<0.34
									14	1.4/<0.20	4.2/<0.20	6.9/<0.45	5.2/<0.34
									22	0.2/<0.20	3.1/<0.20	4.3/<0.45	3.2/<0.34
28	<0.2/<0.20	4.6/<0.20	6.4/<0.45	4.7/<0.34									
02R289 02R289-1 02R289-1 GLP yes 2002	Grape Gamay, red variety	France [REDACTED] Europe, South	71.11 WG	3	1.878	0.626	85	bunch of grapes	0	7/<0.50	36/1.8	50/2.9	38/2.2
									21	8.1/<0.50	26/1.0	42/1.8	32/1.4
02R289 02R289-2 02R289-2 GLP yes 2002	Grape Carignan, red variety	France [REDACTED] Europe, South	71.11 WG	3	1.878	0.626	85	bunch of grapes	0	5/<0.50	22/0.86	32/1.6	24/1.2
									21	0.97/<0.50	23/<0.50	32/<1.1	24/<0.85
02R289 02R289-3 02R289-3 GLP yes 2002	Grape Malvasia Leccese, white variety	Italy [REDACTED] Europe, South	71.11 WG	3	1.878	0.1878	85	bunch of grapes	0	10/<0.50	11/<0.50	24/<1.1	18/<0.85
									21 ⁽²⁾	1.4/1.5	11/5.5	16/8.8	12/6.5

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
02R289 02R289-4 02R289-4 GLP yes 2002	Grape Macabeo, white variety	Spain [REDACTED] Europe, South	71.11 WG	3	1.878	0.250	85	bunch of grapes	0 21	1.1/<0.50 <0.5/<0.50	12/<0.50 12/<0.50	17/<1.1 17/<1.1	13/<0.85 12/<0.85
RA-2671/07 R 2007 0816 5 0816-07 GLP yes 2007	Grape Carignan, Red variety	France [REDACTED] Europe, South	71.11 WG	3	2.00	1.00	85	fruit	0* 0 21 28	6.0/0.01 9.8/n.a 7.1/n.a 6.4/<0.01	17/1.8 10/n.a 29/n.a 33/2.5	20/2.4 23 46 51/3.3	15/1.8 17 34 37/2.5
RA-2671/07 R 2007 0817 3 0817-07 GLP yes 2007	Grape Macabeo	Spain E[REDACTED] Europe, South	71.11 WG	3	2.00	0.20	79	fruit	0* 0 21 28	6.3/<0.01 12/n.a 0.84/n.a 0.56/<0.01	8.6/<0.2 6.5/n.a 13/n.a 10/<0.2	18/<0.28 20 18 14/<0.28	13/<0.21 15 14 10/<0.21

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
RA-2671/07 R 2007 0818 1 0818-07 GLP yes 2007	Grape Sangiovese, Red variety	Italy [REDACTED] Europe, South	71.11 WG	3	2.00	0.20	85	fruit	0	0.4/<0.01	7.7/<0.2	15/<0.28	12/<0.21
									0	8.7/n.a	13/n.a	20	15
									21	1.8/n.a	11/n.a	12	12
								28	1.6/<0.01	12/<0.2	18/<0.28	13/<0.21	

FL: Formulation No: number of applications GS = growth stage (BCH code) at last application DALT = days after last treatment
/value: Residue found in the corresponding control sample 0: prior to last treatment
n.a: not available, control sample not collected

- ⁽¹⁾: The residue values of fosetyl-AL and phosphonic acid marked in bold are those retained for the calculation of the highest total residues expressed as fosetyl and as phosphonic found at the PHI of 21 days or after. The total residue expressed as fosetyl is calculated as the sum of fosetyl-AL expressed as fosetyl and phosphonic acid expressed as fosetyl. The total residue expressed as phosphonic acid is calculated as the sum of fosetyl-AL expressed as phosphonic acid and phosphonic acid.
- ⁽²⁾: Due to this anomalous results in the untreated sample the spare sample was analysed and confirmed that the no residue situation in the untreated samples of this trial.

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Overall conclusions – Grape

Table 6.3.2- 17: Overview of the available residues data for total residue calculated as fosetyl

Commodity/ study	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Total residue calculated as fosetyl									
Grapes 3x2.0 kg /ha, PHI of 21 days	EU-N	Outdoor	14, 15, 19, 20, 2x22, 26, 31, 32, 34, 36, 37, 54	14, 15, 19, 20, 2x22, 26, 31, 32, 34, 36, 37, 54	26	54	90	1.0	New data generated to support the current critical GAP in Europe. Modification of MRL within the MR process
	EU-S	Outdoor	6.4, 11, 3x16, 17, 2x18, 32, 42, 43, 51	6.4, 11, 3x16, 17, 2x18, 32, 42, 43, 51	18	51	90	1.0	

The total residue expressed as fosetyl is calculated as the sum of fosetyl-AI expressed as fosetyl and phosphonic acid expressed as fosetyl.

(a): EU-N, EU-S, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between EU-N and EU-S.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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Table 6.3.2- 18: Overview of the available residues data for total residue calculated as phosphonic acid

Commodity/ study	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Total residue calculated as phosphonic acid									
Grapes 3x2.0 kg /ha, PHI of 21 days	EU-N	Outdoor	10, 11, 14, 15, 2x16, 19, 23, 24, 25, 27, 28, 40	10, 11, 14, 15, 2x16, 19, 23, 24, 25, 27, 28, 40	19	40	70	1.0	New data generated to support the current critical GAP in Europe.
	EU-S	Outdoor	4.7, 8.0, 4x12, 13, 14, 24, 2x32, 37	4.7, 8.0, 4x12, 13, 14, 24, 2x32, 37	13	37	60	1.0	

The total residue expressed as phosphonic acid is calculated as the sum of fosetyl-Al expressed as phosphonic acid and phosphonic acid.

(a): EU-N, EU-S, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between EU-N and EU-S.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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CA 6.3.3 Cucumber

Not applicable, see GAP in Section CA 6.3.

CA 6.3.4 Pome fruit

Former Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC

In the original Annex II dossier for the Annex I inclusion of fosetyl under Directive 91/414/EEC the use of fosetyl-aluminium (fosetyl-Al) was supported in citrus, grapes and cucumbers. Further information on the expected residues of fosetyl-Al in pome fruit may be found in the EFSA reasoned opinion on the review of the existing maximum residue levels (MRLs) for fosetyl according to Article 12 of Regulation (EC) No 396/2005 [EFSA Journal 2012; 10(11):2961].

MRL compilation dossier

In the MRL compilation dossier submitted in 2008 to the Rapporteur France, the critical Good Agricultural Practice (cGAP) supported in Europe on pome fruit consisted of a foliar spray treatment with a maximum of 3 treatments at a maximum rate of 3.6 kg/ha of fosetyl-Al with a PHI of 28 days. The first two applications were performed between growth stages BBCH 60 and 70 with an interval of 20 to 30 days (+/- 3 days) (except in two trials where the first application was carried out earliest) and the third application 28 days before harvest (growth stage BBCH 75 to 85). The information is summarized in the Table 6.3.4- 1.

Table 6.3.4- 1: Critical Good Agricultural Practice (cGAP) supported in the MRL compilation dossier

Crop	Zone	F, G or I**	Formulation	Application			Application rate per treatment		PHI (days)	
				method kind	growth stage BBCH	number min max	interval between applications (days)	water L/ha min max		kg as/ha
Pome fruit	N-EU		WG 80	Foliar spray	55-85	3	nr	300-1500	3.6	28
Pome fruit	S-EU	F	WG 80	Foliar spray	55-85	3	nr	300-1500	3.6	28

* N-EU: northern Europe ; S-EU: southern Europe ** F: Field; G: Greenhouse; I: Indoor
WG 80: water dispersible granule formulation containing 800 g/kg of fosetyl-Al (e.g. Aliette)
nr: not relevant

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Table 6.3.4- 2: Residue trials conducted per geographical region and formulation

Region	Crop	Formulation	Number of Trials			Total	Report-No.	Document No.	Dossier-Ref.
			Vegetation period						
			2000	2001	2003				
Supplementary data									
N-EU	Apple	WG 80	2	-	-	10	00-537	M-208895-01-1	KCA 6.3.4/01
	Apple	WG 80	2	-	-		DR00EUN155	M-203992-01-1	KCA 6.3.4/02
	Apple	WG 80	-	5	-		01R105	M-216729-01-1	KCA 6.3.4/03
	Pear	WG 80	1	-	-		DR00EUN155	M-203992-01-1	KCA 6.3.4/02
S-EU	Apple	WG 80	5	-	-	10	DR00EUS156	M-200577-01-1	KCA 6.3.4/04
	Pear	WG 80	4	-	-		DR00EUS157	M-20036301-1	KCA 6.3.4/05
	Pear	WG 80	-	4	-		01R107	M-215861-01-1	KCA 6.3.4/06
	Pear	WG 80	-	-	3		R-2720/05	M-21608-01-1	KCA 6.3.4/07

N-EU: northern Europe S-EU: southern Europe
WG 80: water dispersible granule formulation containing 800 g/kg of fosetyl-A (e.g. Allette)

Table 6.3.4- 3: Overall summary of residue data on pome fruit supported in the MRL compilation dossier

Application	Sample material	n	Total residue calculated and expressed as	Residue level (mg/kg)		
				Min	Max.	STMR
Northern Europe						
3 applications 3.6 kg a.s./ha PHI of 28 days	fruit	10	fosetyl*	2.2	15	5.1
			phosphonic acid**	1.6	11	3.8
Southern Europe						
- 3 applications 0.6 kg a.s./ha (+ 25%), PHI of 28 days - 5 applications 0.6 kg a.s./ha plus 2 applications 3.6 kg a.s./ha PHI of 28 days	fruit	16	fosetyl*	1.3	32	15
			phosphonic acid**	0.94	24	11

*: Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54, 1-9: Conclusion on the peer review of fosetyl

** : Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid
EFSA Scientific report (2005) 54, 1-79 updated on 31 May 2013: Conclusion on the peer review of fosetyl

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Table 6.3.4- 4: Compilation of the residue data in/on pome fruit supported in the MRL compilation dossier

Region	No of trials	Commodity	Range of residues		STMR	MR
			Residue component	mg/kg	mg/kg	mg/kg
Northern Europe	10	Bunch of grapes	Fosetyl-Al	5x<0.2-0.23*-0.24-0.27-0.33-0.47	0.22	0.47
			Phosphonic acid	1.5-1.8-2.4-2.5-3.5-3.8-5.5-5.3-11		11
			Total residue as fosetyl ⁽¹⁾	2.2-2.9-3.4-3.6-4.9-5.3-6.9*-7.0-7.3-15	5.1	15
			Total residue as phosphonic acid ⁽²⁾	0.6-2.1-2.5-2.7-3.6-3.9-5.2-5.2*-5.4-11	5.1	11
Southern Europe	16	Bunch of grapes	Fosetyl-Al	12x<0.2-0.23-2x0.32-0.36	<0.36	0.36
			Phosphonic acid	0.8-1.7-1.7*-2.3-2.6-7.7-19-2x11-12-12*-15-19-19*-20-24*	11	24
			Total residue as fosetyl ⁽¹⁾	1.3-2.5-2.5-3.3-3.7-11-14-2x15-16-16*-21-26-26*-20-32*	15	22
			Total residue as phosphonic acid ⁽²⁾	0.94-1.8-1.8*-2.4-2.8-5.8-10-2x11-12-12*-16-19-19*-20-24*	11	24

(1): Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54, 71-79: Conclusion on the peer review of fosetyl

(2): Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid
EFSA Scientific report (2007) 54, 1-79, updated on 31 May 2013: Conclusion on the peer review of fosetyl

*: apparent residue found in the corresponding control sample. Residue level at 0.20 mg/kg for fosetyl-Al, from 0.23 to 1.9 mg/kg for phosphonic acid, from 0.49 to 2.7 mg/kg for total residue as fosetyl and from 0.37 to 2.0 mg/kg for total residue as phosphonic acid

New studies submitted in Supplementary Dossier

The critical Good Agricultural Practice (cGAP) supported at the European level in the approval renewal process of fosetyl consists of 3 foliar spray applications at 3.6 kg/ha of fosetyl-Al with an interval between applications of 10 days and a PHI of 28 days.

Table 6.3.4- 5: Summary of the critical GAP for the proposed uses of Fosetyl-Al WG 80

Crop	Zone	F, G or I**	Formulation	Application			Application rate per treatment		PHI (days)	
				method kind	growth stage BBCH	number min max	interval between applications (days)	water L/ha min max		kg as/ha
Pome fruit	N-EU	F	WG 80	Foliar spray	55-85	3	10	300-1500	3.6	28
Pome fruit	S-EU	F	WG 80	Foliar spray	55-85	3	10	300-1500	3.6	28

* N-EU: northern Europe; S-EU: southern Europe; ** F: Field; G: Greenhouse; I: Indoor
WG 80: water dispersible granule formulation containing 800 g/kg of fosetyl-Al (e.g. Aliette)

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New residue trials were conducted under GLP conditions in 2009 and 2010 to support the European GAP relevant for approval renewal of fosetyl. They were performed in northern Europe (Germany (2), France (2), Belgium (2), United Kingdom (1) and Netherlands (1)) and in southern Europe (Spain (3), Italy (2), France (3) and Portugal (1)). They are recorded in Table 6.3.4- 6 and the overall summary of the residue data in Table 6.3.4- 7.

Table 6.3.4- 6: Residue trials conducted per geographical region and formulation

Region	Crop	Formulation	Number of Trials		Report-No.	Document No.	Dossier-Ref.
			Vegetation period				
			2009	2010			
Supplementary data							
N-EU	Apple	WG 80	-	4	10-2058	M-434868-01-1	KCA 6.3.4/08
	Pear	WG 80	4	-	09-2039	M-402916-01-1	KCA 6.3.4/09
S-EU	Apple	WG 80	-	4	10-2064	M-434869-01-1	KCA 6.3.4/10
	Pear	WG 80	5*	-	09-2252	M-402919-01-1	KCA 6.3.4/09

N-EU: northern Europe S-EU: southern Europe
WG 80: water dispersible granule formulation containing 800 g/kg of Fosetyl-AI (e.g. Abette)
*: in one trial, the samples were harvested 14 days after the last application instead of 28 days (desired waiting period).

Table 6.3.4- 7: Overall summary of residue data on some fruit covering the critical GAP for approval renewal

Application	Sample material	n	Total residue calculated and expressed as	Residue level (mg/kg)		
				Min.	Max.	STMR
Northern Europe						
3 applications 3.6 kg a.s./ha, interval of 10 days, PHI of 28 days	fruit	8	fosetyl	10	23	17
			phosphonic acid**	7.6	17	13
Southern Europe						
3 applications 3.6 kg a.s./ha, interval of 10 days, PHI of 28 days ⁽¹⁾	fruit	9	fosetyl*	15	29	20
			phosphonic acid**	12	22	15

*: Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl; EFSA Scientific report (2005) 54, 1-79: Conclusion on the peer review of fosetyl (see formula on page 30)
**: Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid; see formula on page 30
⁽¹⁾: in one trial the samples were harvested 14 days after the last application (worst case) instead of 28 days (desired waiting period).

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Table 6.3.4- 8: Compilation of the residue data in/on pome fruit covering the critical GAP for approval renewal

Region	No of trials	Commodity	Range of residues		STMR	MR
			Residue component	mg/kg	mg/kg	mg/kg
Northern Europe	8	Bunch of grapes	Fosetyl-Al	2x<0.01-2x0.01-0.01*-0.03-2x0.06	0.01	0.06
			Phosphonic acid	7.6-8.2-11-12-14-15-16-17*		17
			Total residue as fosetyl ⁽¹⁾	10-11-15-16-18-19-21-23*	17	23
			Total residue as phosphonic acid ⁽²⁾	7.6-8.2-11-12-14-15-16-17*	17	17
Southern Europe	9	Bunch of grapes	Fosetyl-Al	4x<0.01-0.01-2x0.03-0.33-0.89	0.02	0.89
			Phosphonic acid	22-13-2x0.5-15*-2x17-18-22*	15	22
			Total residue as fosetyl ⁽¹⁾	15-17-2x20-26*-23-2x24-29*	20	29
			Total residue as phosphonic acid ⁽²⁾	22-13-15-15*-16-17-2x18-22*	16	22

(1): Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl
EFSA Scientific report (2005) 54, 1-79: Conclusion on the peer review of fosetyl

(2): Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid
EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2016: Conclusion on the peer review of fosetyl

*: apparent residue found in the corresponding control sample. Residue level from 0.88 to 2.1 mg/kg for phosphonic acid, 1.2 to 5.5 mg/kg for total residue as fosetyl and 0.89 to 4.4 mg/kg for total residue as phosphonic acid

Field trials – northern Europe

Report: KCA 6.3.4/02 [redacted]; 2001; M-208095-01-1
Title: Residues in apple (fruit) North / France / 2000 - trials - decline study Fosetyl-Al and Phosphorous acid (metabolite) Formulation EX010369F (WG)
Report No.: 00-537
Document No.: M-208095-01-1
Guideline(s): Directive 91/414/EEC as amended by Directive 96/68/EC
 Residues in or on treated products, food or feed (Annex HA, Point 6)
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/02 [redacted]; 2002; M-203992-01-1
Title: Residues at harvest in apple and pear European Union (Northern zone) 2000 Fosetyl-aluminium water dispersible granule (WG) 80 % w/w Code: AE F053616 00 WG80
 201
Report No.: DR004UN152
Document No.: M-203992-01-1
Guideline(s): EC Commission Working Document
 029/V1/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

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Report: KCA 6.3.4/03 [REDACTED]; 2002; M-216729-01-1
Title: Residue behaviour in apple European Union (northern zone) 2001 Fosetyl-aluminium, AE F053616 water dispersible granule (WG) 80% w/w Code: AE F053616 00 WG80 A102
Report No.: 01R105
Document No.: M-216729-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/08 [REDACTED]; [REDACTED]; 2012; M-434868-01-1
Title: Determination of the residues of fosetyl-AL in/on apple after spraying of fosetyl-AL WG 80 in the field in Germany, France (North), Belgium and United Kingdom
Report No.: 10-2058
Document No.: M-434868-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EU guidance working document 7029/VI/95 rev. 5 (1997-07-22); US EPA OCSPP Guideline No. 8601500, SUPP
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/09 [REDACTED]; [REDACTED]; 2011; M-402916-01-1
Title: Determination of the residues of fosetyl-AL in/on pear after spraying of fosetyl-AL WG 80 in the field in Belgium, France (North), Germany and Netherlands
Report No.: 09-2039
Document No.: M-402916-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Guideline deviation(s): none
GLP/GEP: yes

Material and methods

In 2000 to 2010, a total of 18 residue trials in/on apple and pear were conducted in northern Europe. They were located in Germany (5), France (7), Belgium (2), United Kingdom (3) and Netherlands (1). The formulation Fosetyl-aluminium WG 80 (Fosetyl-Al WG 80), a water dispersible formulation containing 80% (w/w) fosetyl-aluminium (fosetyl-Al), was applied three times at application rate of 4.5 kg/ha and 500 to 1000 L water per hectare corresponding to 3.6 kg a.s./ha.

During the 2000 and 2001 growing seasons, the applications were carried out at growth stages BBCH 60 to 81 with an interval period of 30 days (+/- 2 days) between the two first treatments (between BBCH 60 and 77), except for both trials of the study 00-537 where interval periods were 69 and 77 days. The third treatment was carried out between BBCH 75 and 81, 28 days before harvest with an interval period of 30 days (+/- 2 days) between the two last treatments, except for the three trials of the study DR00EUN155 where the interval periods ranged from 71 to 87 days.

During the 2009 and 2010 growing seasons, the applications were carried out at growth stages between BBCH 74 and 79 with an interval period of 10 days (+/- 1 day).

In all trials, fruit samples were taken for analysis on the day of last application (0 day) and at harvest (PHI = 20 days +/- 1 day, growth stages 81 to 89). For some trials, additional samples were taken on the day before the last application, at day 7 (+/- 2 days), 14 (+/- 1 day) and 21 (+/- 1 day) after the last application in order to determine residue decline.

For 2000 and 2001 trials, fruit samples were analysed following the principle of the method AR 155-97 (derivatization with diazomethane) by Gas Chromatography (GC) using a Flame Photometric Detector (FPD). The Limits of Quantification (LOQs) were 0.20 mg/kg for each compound.

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For 2009 and 2010 trials, fruit samples were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the reports) according to method 00861/M001 by LC-MS/MS with a LOQ of 0.01 and 0.20 mg/kg, respectively.

When the total residue is expressed as fosetyl-Al in the residue report (studies 00-357, DR00EUN155 and 01R105), it will be calculated in this dossier as total residue expressed as fosetyl and as total residue expressed as phosphonic acid (see Section CA 6.3 for calculation).

When the total residue is expressed as fosetyl in the residue report (studies 09-2039 and 10-2058), it will be reported in this dossier without correction and the total residue expressed as phosphonic acid will be calculated (see Section CA 6.3 for calculation).

Findings

- Method performance: In the case of recovery experiments for method validation, recovery means (n≥2) ranged between 93 and 109% with RSD <20%, as shown in Table 6.3.4-9.

For the study 00-537, validation of the method was performed during the study DR00EUN156 and for the study DR00EUN155 during studies DR00EUN156 and DR00EUN157, recovery means ranged between 71 and 91% with RSD <20%. For details, see Table 6.3.4-13. For the study 01R105, validation of the method was performed during the study 01_90, recovery means in apple fruit ranged between 80 and 92% with RSD <20%. For details, see Table 6.5.3-18. All results of the methods validation are in accordance with the general requirements for residue analytical methods.

For concurrent recoveries, recovery means (n≥2) at fortification levels between 0.01 and 20 mg/kg for fosetyl-Al and between 0.20 and 100 mg/kg for phosphonic acid were within the range of 78 to 127% with RSD <20%, except for phosphonic acid in apple fruit (23 and 34% at LOQ level and 10xLOQ level, respectively) as shown in Table 6.3.4-10.

Table 6.3.4- 9: Method validation data for fosetyl-Al and phosphonic acid during studies 09-2039 and 10-2058

Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
09-2039	00861/M001	Fosetyl-Al	apple fruit	0.01	99; 105; 108	104	4.4	0.01
				0.10	96; 90; 92	93	3.3	
				1.0	92	-	-	
				Overall Recovery (n = 7)		97	7.1	
		Phosphonic acid	apple fruit	0.20	97; 94; 121	104	14.2	0.20
				2.0	100; 93; 96	96	3.6	
				20	96	-	-	
Overall Recovery (n = 7)		100	9.8					
10-2058	00861/M001	Fosetyl-Al	apple fruit	0.01	107; 109; 111	109	1.8	0.01
				0.10	98; 106; 112	105	6.7	
				Overall Recovery (n = 6)		107	4.7	
		Phosphonic acid	apple fruit	0.20	104; 106; 109	106	2.4	0.20
				2.0	98; 106; 116	107	8.5	
				Overall Recovery (n = 6)		107	5.6	

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Table 6.3.4- 10: Concurrent recoveries for fosetyl-Al and phosphonic acid

Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]		
00-537	Fosetyl-Al	apple fruit	0.20	80; 103; 81	88	14.8	0.20		
			2.0	78 ⁽¹⁾ ; 75; 80	78	3.2			
			Overall Recovery (n = 6)		83	12.2			
	Phosphonic acid	apple fruit	0.20	160 ⁽²⁾ ; 104; 118	127	22.9			
			2.0	125; 74; 70	90	34.0			
			Overall Recovery (n = 6)		109	21.1			
DR00EUN155	Fosetyl-Al	apple fruit	0.20	91	-	-	0.20		
			2.0	82	-	-			
			Overall Recovery (n = 2)		86	-			
	Phosphonic acid	apple fruit	0.20	71	-	-			
			2.0	88	-	-			
			Overall Recovery (n = 2)		80	-			
	Fosetyl-Al	pear fruit	0.20	101	-	-		0.20	
			2.0	87	-	-			
			Overall Recovery (n = 2)		93	-			
	Phosphonic acid	pear fruit	0.20	80	-	-			0.20
			2.0	90	-	-			
			Overall Recovery (n = 2)		85	-			
01R105	Fosetyl-Al	apple fruit	0.20	76; 90; 82; 97	86	10.6	0.20		
			0.50	88	-	-			
			2.0	76; 97; 80; 94; 88	86	9.8			
			5.0	99	-	-			
			20	87	-	-			
			Overall Recovery (n = 12)		87	9.1			
	Phosphonic acid	apple fruit	0.20	73; 73; 104; 92	86	17.8			
			0.50	79	-	-			
			2.0	74; 72; 86; 109; 94	87	17.5			
			5.0	76	-	-			
			20	74	-	-			
			Overall Recovery (n = 12)		84	15.5			

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Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
10-2058	Fosetyl-Al	apple fruit	0.01	87; 91; 93	90	3.4	0.01
			0.10	86; 95	91	-	
			2.0	78	-	-	
			Overall Recovery (n = 6)			92	
	Phosphonic acid	apple fruit	0.20	84; 87; 87	86	2.0	0.20
			2.0	96; 100	99	-	
21							
Overall Recovery (n = 6)			90	8.4			
09-2039	Fosetyl-Al	pear fruit	0.10	90	90	-	0.10
			5.0	99	99	-	
			Overall Recovery (n = 2)			94	
	Phosphonic acid	pear fruit	2.0	98	98	-	2.0
			100	100	100	-	
Overall Recovery (n = 2)			99	-			

RSD: Relative Standard Deviation

LOQ = Practical Limit of Quantification

(1): contaminated control or co-eluted peak; residue in control sample found at 0.20 mg/kg. The recovery performed for fosetyl-Al using this control sample was not corrected for interference.

(2): contaminated control or co-eluted peak; residue in control sample found at 0.47 mg/kg. The recovery performed for phosphonic acid using this control sample was not corrected for interference.

*: the respective LOQs of 0.01 mg/kg for fosetyl-Al and 0.2 mg/kg for phosphonic acid were set and validated during the method validation as recorded in Table 6.3.4.9.

- Storage stability:

The storage periods of deep frozen untreated and treated samples for apple and pear samples are summarised in Table 6.3.4.11. For fosetyl-Al and its metabolite, before analysis, the maximum storage period of deep-frozen samples did not exceed 608 days (20 months) which is covered by the different storage stability studies (see Section CA 6.1).

With the calculation of the total residue as fosetyl or as phosphonic acid, the potential degradation of fosetyl-Al is taken into account in the total residue.

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Table 6.3.4- 11: Storage periods of deep frozen samples in/on pome fruit after use of Fosetyl-Al WG 80

Study	Crop	Analyte	Storage period of deep frozen samples	
			Min [days]	Max [days]
00-537	apple	fosetyl-Al phosphonic acid	230	262
DR00EUN155	apple	fosetyl-Al phosphonic acid	218	259
	pear		234	262
01R105	apple	fosetyl-Al phosphonic acid	205	262
10-2058	apple	fosetyl-Al phosphonic acid	283	308
09-2039	pear	fosetyl-Al phosphonic acid	300	383

- Residue results: In the northern European field trials, the residues in apple and pear fruits at a PHI of 28 days (+/- 1 day) ranged from 0.2 to 0.4 mg/kg for fosetyl-Al and from 0.5 to 17 mg/kg for phosphonic acid.

The total residues expressed as fosetyl were between 2.2 and 23 mg/kg. The total residues expressed as phosphonic acid were between 0.6 and 17 mg/kg.

- No residues of fosetyl-Al were detected in any of the untreated samples (below the limit of quantification of 0.02 or 0.20 mg/kg depending on the method) except for one control sample found at 0.20 mg/kg (equal to the limit of quantification) at 28 days.

No residues of phosphonic acid were detected in any of the untreated samples (below 0.20 mg/kg) except for the control samples of three trials. The apparent residues of phosphonic acid were detected between 0.45 mg/kg and 0.47 mg/kg (in Table 6.3.4- 9 the mean of two values is reported) in apple in the study 00-537 (trial 00537RS1 in France), between 3.8 and 4.9 mg/kg in apple in the study 10-2058 (trial 10-2058-02 in France) and between 0.88 and 1.1 mg/kg in pear in the study 09-2039 (trial 09-2039-03 in Belgium).

In spite of no information was reported in the study reports, a contamination with phosphonic acid via fertilizers or another source could be suspected. However this level of contamination can be considered as acceptable.

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Table 6.3.4- 12: Application data, residues for fosetyl-Al and phosphonic acid and total residues calculated and expressed as fosetyl and as phosphonic acid in/on apple and pear treated with Fosetyl-Al WG 80 in the field in northern Europe

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	DLT (days)	Residues ⁽¹⁾			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS			fosetyl-Al (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
00-537 ⁽²⁾ 00537AM1 GLP: Yes 2000	Apple Idared	France [redacted] Europe, North	80 WG	3	3.58	0.24	79	fruit	0.08	0.76/<0.2	5.8/<0.2	8.5/<0.45	6.3/<0.34
					0.25/<0.2	7.3/<0.2	10/<0.45	7.5/<0.34					
					0.22/<0.2	7.8/<0.2	11/<0.45	8.0/<0.34					
					0.2/<0.2	5.3/<0.2	7.2/<0.45	5.4/<0.34					
00-537 ⁽²⁾ 00537RS1 GLP: yes 2000	Apple Douce coët	France [redacted] Europe, North	80 WG	3	3.58	0.24	81	fruit	0.08	0.6/<0.2	3.9/<0.2	5.9/<0.45	4.4/<0.34
					0.25/<0.2	4.0/<0.2	5.6/0.63	4.1/0.47					
					<0.2/<0.2	4.3/<0.2	6.0/<0.45	4.4/<0.34					
					0.25/0.20	5.0/0.34	6.9/0.64	5.2/0.48					
DR00EUN155 DR00EUN155D EU0201 GLP: yes 2000	Apple Jonagold	Germany [redacted] Europe, North	80 WG	3	3.6	0.47	79	fruit	0	<0.2/<0.2	2.6/<0.2	3.7/<0.45	2.7/<0.34
					0.24/<0.2	2.5/<0.2	3.6/<0.45	2.7/<0.34					
DR00EUN155 DR00EUN155D EU0501 GLP: yes 2000	Apple Elstar	Germany [redacted] Europe, North	80 WG	3	3.6	0.24	81	fruit	0	<0.2/<0.2	3.3/<0.2	4.6/<0.45	3.4/<0.34
					0.25/<0.2	1.5/<0.2	2.2/<0.45	1.6/<0.34					
DR00EUN155 DR00EUN155D EU0601 GLP: yes 2000	Pear Conference	Germany [redacted] Europe, North	80 WG	3	3.6	0.46	81	fruit	0	0.30/<0.2	3.4/<0.2	4.8/<0.45	3.6/<0.34
					0.54	1.8/<0.2	2.9/<0.45	2.1/<0.34					

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Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R105 01R105-1 GLP: yes 2001	Apple Bramley	United Kingdom [REDACTED] Europe, North	80 WG	3	3.6	0.72	80	fruit	0	0.95/<0.2	2.0/<0.2	3.6/<0.45	2.7/<0.34
									5	0.30/<0.2	4.6/<0.2	4.8/<0.34	
									13	0.21/<0.2	5.5/<0.2	5.7/<0.34	
									20	0.31/<0.2	5.8/<0.2	6.0/<0.34	
									27	<0.2/<0.2	2.4/<0.2	3.4/<0.45	2.5/<0.34
01R105 01R105-2 GLP: yes 2001	Apple Cox	United Kingdom [REDACTED] Europe, North	80 WG	3	3.6	0.72	75	fruit	0	1.8/<0.2	6.7/<0.2	11/<0.45	8.0/<0.34
									7	0.44/<0.2	8.7/<0.2	7.0/<0.34	
									14	0.41/<0.2	12/<0.2	12/<0.34	
									21	0.39/<0.2	14/<0.2	14/<0.34	
									27	0.33/<0.2	11/<0.2	15/<0.45	11/<0.34
01R105 01R105-3 GLP: yes 2001	Apple Jonagored	France [REDACTED] Europe, North	80 WG	3	3.6	0.36	77	fruit	0	2.2/<0.2	2.1/<0.2	4.9/<0.45	3.6/<0.34
									7	0.92/<0.2	3.8/<0.2	6.0/<0.45	4.4/<0.34
									14	0.23/<0.2	3.4/<0.2	4.8/<0.45	3.6/<0.34
									21	<0.2/<0.2	2.6/<0.2	3.7/<0.45	2.7/<0.34
									28	<0.2/<0.2	3.8/<0.2	5.3/<0.45	3.9/<0.34
01R105 01R105-4 GLP: yes 2001	Apple Golden Delicious	France [REDACTED] Europe, North	80 WG	3	3.0896	0.72- -3.6	81	fruit	0	0.97/<0.2	6.5/<0.2	9.6/<0.45	7.2/<0.34
									7	<0.2/<0.2	4.9/<0.2	6.8/<0.45	5.0/<0.34
									14	0.49/<0.2	8.3/<0.2	12/<0.45	8.6/<0.34
									21	<0.2/<0.2	5.4/<0.2	7.4/<0.45	5.5/<0.34
									27	0.27/<0.2	5.0/<0.2	7.0/<0.45	5.2/<0.34
01R105 01R105-5 GLP: yes 2001	Apple Royal Gala	France [REDACTED] Europe, North	80 WG	3	3.6	0.2	81	fruit	0	2.2/<0.2	2.5/<0.2	5.4/<0.45	4.0/<0.34
									7	1.1/<0.2	3.1/<0.2	5.2/<0.45	3.9/<0.34
									14	0.32/<0.2	5.1/<0.2	7.1/<0.45	5.3/<0.34
									21	0.22/<0.2	4.3/<0.2	6.0/<0.45	4.5/<0.34
									28	<0.2/<0.2	3.5/<0.2	4.9/<0.45	3.6/<0.34

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Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
10-2058 10-2058-01 GLP: yes 2010	Apple Jonagold	Germany [REDACTED] Europe, North	80 WG	3	3.6	0.72	85	fruit	0* 0 7 14 28	0.68/<0.01 0.12/n.a 0.14/n.a 0.11/n.a 0.03/<0.01	6.8/<0.2 6.5/n.a 8.8/n.a 9.5/n.a 7.6/<0.2	9.7/<0.28 8.8 13 10/<0.28	7.3/<0.21 6.6 8.9 9.6 7.6/<0.21
10-2058 10-2058-02 GLP: yes 2010	Apple Golden	France [REDACTED] Europe, North	80 WG	3	3.6	0.72	79	fruit	0* 0 7 14 28	0.10/<0.01 0.61/n.a 0.28/n.a 0.04/n.a 0.06/<0.01	14/4.9 14/n.a 5/n.a 14/n.a 16/3.8	16.5 20 20 19 21/5.1	14/4.9 14 15 14 16/3.8
10-2058 10-2058-03 GLP: yes 2010	Apple Reinettes de Flandres ⁽¹⁾	Belgium [REDACTED] Europe, North	80 WG	3	0.6	0.29	85	fruit	0* 0 7 14 28	0.02/<0.01 0.52/n.a 0.05/n.a 0.02/n.a <0.01/<0.01	6.3/<0.2 10/n.a 9.7/n.a 12/n.a 11/<0.2	8.5/<0.28 14 13 15 15/<0.28	6.3/<0.21 10 9.7 12 11/<0.21
10-2058 10-2058-04 GLP: yes 2010	Apple Jonathan	United Kingdom [REDACTED] Europe, North	80 WG	3	1.6	0.36	76	fruit	0* 0 8 15 28	<0.01/<0.01 0.15/n.a 0.03/n.a 0.03/n.a <0.01/<0.01	3.6/<0.2 5.9/n.a 11/n.a 8.8/n.a 8.2/<0.2	4.8/<0.28 8.1 14 12 11/<0.28	3.6/<0.21 6.0 11 8.8 8.2/<0.21
09-2039 09-2039-01 GLP: yes 2009	Pear Beurré hardy	France [REDACTED] Europe, North	80 WG	3	0.6	0.24	79	fruit	0* 0 7 14 28	0.03/<0.01 1.4/n.a 0.24/n.a 0.21/n.a 0.06/<0.01	9.5/<0.2 13/n.a 13/n.a 12/n.a 12/<0.2	13/<0.28 18 18 16 16/<0.28	9.5/<0.21 14 13 12 12/<0.21

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Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					GS	Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)				DAIT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
09-2039 09-2039-02 GLP: yes 2009	Pear Williams Christ	Germany [REDACTED] Europe, North	80 WG	3	3.6	0.72	79	fruit	9*	0.01/<0.01	21/<0.2	28/<0.28	21/<0.21	
									0	0.62/n.a	18/n.a	25	18	
									7	0.04/n.a	17/n.a	27	17	
									14	0.02/n.a	17/n.a	22	17	
									28	0.01/<0.01	15/<0.2	19/<0.28	15/<0.21	
09-2039 09-2039-03 GLP: yes 2009	Pear Conference	Belgium [REDACTED] Europe, North	80 WG	3	3.6	0.36	79	fruit	9*	0.01/<0.01	11/1.1	15/1.5	11/1.1	
									0	1.1/n.a	16/n.a	22	17	
									7	0.25/n.a	20/n.a	27	20	
									14	0.05/n.a	19/n.a	25	19	
									28	0.01/<0.01	17/0.88	23/1.2	17/0.89	

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Fosetyl

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DALT (days)	fosetyl-AI (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
09-2039 09-2039-04 GLP: yes 2009	Pear Conference	Netherlands	80 WG	3	3.6	0.36	60	fruit	0*	0.10/<0.01	15/<0.2	20/<0.28	15/<0.21
		0						1.7/n.a	7/n.a	24	18		
		7						0.08/n.a	20/n.a	20	20		
		14						0.01/n.a	14/n.a	19	14		
		28						0.01/<0.01	14/<0.2	18/<0.28	14/<0.21		

FL: Formulation No: number of applications GS = growth stage (BBCH code) at last application DALT = days after last treatment

/value: Residue found in the corresponding control sample

0*: prior to last treatment

n.a: control sample not harvested therefore no corresponding result available

⁽¹⁾: The residue values of fosetyl-AI and phosphonic acid marked in bold are those retained for the calculation of the highest total residues expressed as fosetyl and as phosphonic found at the PHI of 21 days or after. The total residue expressed as fosetyl is calculated as the sum of fosetyl-AI expressed as fosetyl and phosphonic acid expressed as fosetyl. The total residue expressed as phosphonic acid is calculated as the sum of fosetyl-AI expressed as phosphonic acid and phosphonic acid.

⁽²⁾: Two independent samplings were performed for each untreated and treated plot. The mean values of residues results are reported in this table.

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**Document MCA – Section 6: Residues in or on treated products, food and feed
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Report: KCA 6.3.4/04 [REDACTED]; 2002; M-200577-01-1
Title: Decline of residues in apple European Union southern zone (2000) Fosetyl-aluminium water dispersible granule (WG), 80 % w/w Code: AE F053616 00 WG80 A101 (EXP10369F)
Report No.: DR00EUS156
Document No.: M-200577-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/05 [REDACTED]; 2002; M-203630-01-1
Title: Decline of residues in pear European Union southern zone (2000) Fosetyl-aluminium water dispersible granule (WG) 80 % w/w Code: AE F053616 00 WG80 A101
Report No.: DR00EUS157
Document No.: M-203630-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/06 [REDACTED]; 2002; M-245861-01-1
Title: Decline of residues in pear European Union southern zone 2001 Fosetyl-aluminium, AE F053616 water dispersible granule (WG) 80% w/w Code: AE F053616 00 WG80 A102 (EXP10369F)
Report No.: 01R107
Document No.: M-245861-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/07 [REDACTED]; 2005; M-251608-01-1
Title: Determination of the Residues of Fosetyl-Al in/on Pear after Spraying of AE F053616 00 WG80 A1 (80 WG) in the Field in Italy, Spain and Southern France
Report No.: RA-2720/03
Document No.: M-251608-01-1
Guideline(s): EU-Ref. Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.3.4/10 [REDACTED]; 2012; M-434869-01-1
Title: Determination of the residues of fosetyl-AL in/on apple after spraying of fosetyl-AL WG 80 in the field in Spain, Italy, France (South) and Portugal
Report No.: 10-0064
Document No.: M-434869-01-1
Guideline(s): EU-Ref. Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EU guidance working document 7029/VI/95 rev.5 (1997-07-22); US EPA OCSPP Guideline No. 860.1500.SUPP
Guideline deviation(s): none
GLP/GEP: yes

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Report: KCA 6.3.4/11 [REDACTED]; [REDACTED]; 2011; M-402919-01-1
Title: Determination of the residues of fosetyl-AL in/on pear after spraying of fosetyl-AL WG 80 in the field in France (South), Italy and Spain
Report No.: 09-2252
Document No.: M-402919-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed, EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Guideline deviation(s): none
GLP/GEP: yes

Material and methods

In 2000 to 2010, a total of 25 residue trials in/on apple and pear were conducted in southern Europe. They were located in Italy (9), Spain (8), Greece (0), France (6) and Portugal (4). During the 2000 (study on apple DR00EUS156), 2009 and 2010 growing seasons, the formulation Fosetyl-aluminium WG 80 (Fosetyl-Al WG 80), a water dispersible formulation containing 80% (w/w) fosetyl-aluminium (fosetyl-Al), was applied three times at an application rate of 4.5 kg/ha and 800 to 1500 L water per hectare corresponding to 3.6 kg a.s./ha. In 2000, the applications were carried out at growth stages BBCH 63 to 85 with an interval period of 30 days (+/- 3 days) between the two first treatments (BBCH 63 to 73). The third treatment was carried out between BBCH 79 and 85, 28 days before harvest with an interval period from 99 to 111 days between the two last treatments. In 2009 and 2010, the applications were carried out at growth stages between BBCH 74 and 85 with an interval period of 10 days (+/- 2 days). During the 2003 growing season, the formulation Fosetyl-Al WG 80 was applied three times at an application rate of 3.75 kg/ha and 1000 to 1500 L water per hectare corresponding to 3.0 kg a.s./ha. The applications were carried out at growth stages between BBCH 74 and 79 with an interval period of 21 days (+/- 2 days). During the 2000 (study on pear DR00EUS157) and 2001 growing seasons, there were 7 applications, the first one starting at growth stage BBCH 65 and 69. The following 4 applications were done in a 3 days (+/- 1 day) spray interval with the last treatment between BBCH 69 and 71. Additionally two applications were carried out at 30 days (+/- 2 days) before harvest and the day of harvest between BBCH 71 and 77. The spray interval between applications no. 5 and 6 ranged from 18 to 82 days. For the first 5 applications, the application rates of Fosetyl-Al WG 80 were 0.75 kg/ha, which is equivalent to 600 g ai/ha per application. For the applications no. 6 and 7, the application rates of Fosetyl-Al WG 80 were 4.5 kg/ha and 400 to 1000 L water per ha, which is equivalent to 3.6 kg ai/ha per application.

Fruit samples were taken for analysis on the day of last application (0 day) and at harvest (PHI = 28 days +/- 1 day, growth stages 79 to 89). For some trials, additional samples were taken on the day before the last application, on day 7 (+/- 1 day), 14 (+/- 1 day), 21 (+/- 1 day) and 38 (+/- 2 days) after the last application in order to determine residue decline.

For trials from 2000 to 2003, fruit samples were analysed following the principle of the method AR 155-97 (derivatization with diazomethane) by Gas Chromatography (GC) using a Flame Photometric Detector (FPD) or a Nitrogen-Phosphorous Detector (NPD). The Limits of Quantification (LOQs) were 0.20 mg/kg for each compound.

For 2009 and 2010 trials, fruit samples were analysed for residues of fosetyl-Al and its metabolite phosphonic acid (named phosphorous acid in the reports) according to method 00861/M001 by LC-MS/MS with a LOQ of 0.01 mg/kg and 0.20 mg/kg respectively.

When the total residue is expressed as fosetyl-Al in the residue report (studies DR00EUS156, DR00EUS157, 01R107 and RA-2720/03), it will be calculated in this dossier as total residue expressed as fosetyl and as total residue expressed as phosphonic acid (see Section CA 6.3 for calculation).

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When the total residue is expressed as fosetyl in the residue report (studies 09-2252 and 10-2064), it will be reported in this dossier without correction and the total residue expressed as phosphonic acid will be calculated (see Section CA 6.3 for calculation).

Findings

- **Method performance:** In the case of recovery experiments for methods validation, recovery means ($n \geq 2$) were within the range of 71 to 98% with RSD <20%, as shown in Table 6.3.4- 13.

For study 09-2252, validation of the method on pear is documented with the study 09-2039, recovery means ranged between 93 and 104 % with RSD <20%. No additional validation was performed in this study. For details, see Table 6.3.4- 9. For study 10-2064, the confirmation of the method validity in apple fruit was already performed in the study 10-2058, recovery means ranged between 105 and 109% with RSD <20%. For details, see Table 6.3.4- 9. All results of the methods validation are in accordance with the general requirements for residue analytical methods.

For concurrent recoveries, recovery means ($n \geq 2$) at fortification levels between 0.01 and 5 mg/kg for fosetyl-Al and between 0.20 and 100 mg/kg for phosphonic acid were within the range of 76 to 103% with RSD <20%, except for fosetyl-Al (25%) and phosphonic acid (26%) in apple fruit at LOQ level as shown in Table 6.3.4- 14.

Table 6.3.4- 13: Method validation data for fosetyl-Al and phosphonic acid during studies DR00EUN156, DR00EUN157, 01R107 and RA-2720/03

Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
DR00EUN 156	AR 155-97	Fosetyl-Al	apple fruit	0.20	70; 71	71	-	0.20
				2.0	80; 86	83	-	
				Overall Recovery (n = 4)		77	9.6	
		Phosphonic acid	apple fruit	0.20	91; 90	91	-	0.20
				2.0	94; 81	86	-	
				Overall Recovery (n = 4)		88	5.5	
DR00EUN 157	AR 155-97	Fosetyl-Al	pear fruit	0.20	80; 88	84	-	0.20
				2.0	80; 80	80	-	
				Overall Recovery (n = 4)		82	4.9	
		Phosphonic acid	pear fruit	0.20	74; 73	74	-	0.20
				2.0	71; 79	75	-	
				Overall Recovery (n = 4)		74	4.6	
01R107	AR 155-97	Fosetyl-Al	pear fruit	0.20	82; 82; 103	89	13.6	0.20
				2.0	76; 86; 74	79	8.2	
				Overall Recovery (n = 6)		84	12.4	
		Phosphonic acid	pear fruit	0.20	107; 86; 95	96	11.0	0.20
				2.0	76*; 85**; 85	82	6.3	
				Overall Recovery (n = 6)		89	12.0	

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Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
RA-2720/03	AR 155-97	Fosetyl-Al	pear fruit	0.20	103; 92; 87	94	8.7	0.20
				2.0	84; 87; 74	82	8.0	
				Overall Recovery (n = 6)		88	10.9	
		Phosphonic acid	pear fruit	0.20	106; 97; 92	98	7.2	
				2.0	87; 89; 71	82	12.0	
				Overall Recovery (n = 6)		90	12.9	

RSD: Relative Standard Deviation LOQ = Practical Limit of Quantification

* corrected by residues found in control sample at 0.26 mg/kg

** corrected by residues found in control sample at 0.23 mg/kg

Table 6.3.4- 14: Concurrent recoveries for Fosetyl-Al and Phosphonic acid

Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
DR00EUN156	Fosetyl-Al	apple fruit	0.20	88; 75; 124; 6	91	25.3	0.20
			2.0	73; 85; 76; 79	78	6.5	
			Overall Recovery (n = 8)		85	19.9	
	Phosphonic acid	apple fruit	0.20	87; 80; 125* 71	91	26.2	
			2.0	80; 106; 87; 72	86	16.8	
			Overall Recovery (n = 8)		89	20.8	
DR00EUN157	Fosetyl-Al	pear fruit	0.20	102; 99; 62	98	5.3	0.20
			2.0	98; 105; 75	93	16.9	
			Overall Recovery (n = 6)		95	11.3	
	Phosphonic acid	pear fruit	0.20	83; 88; 81	83	4.8	
			2.0	93; 93; 103	96	6.0	
			Overall Recovery (n = 6)		90	9.4	
01R107	Fosetyl-Al	pear fruit	0.20	78; 73; 84	78	7.0	0.20
			0.40	92	-	-	
			0.50	87	-	-	
			1.0	73	-	-	
			Overall Recovery (n = 6)		81	9.6	
	Phosphonic acid	pear fruit	0.20	86**; 70; 86	81	11.5	
			10	93	-	-	
			1	81	-	-	
			20	75	-	-	
			Overall Recovery (n = 6)		82	10.2	

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Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
RA-2720/03	Fosetyl-Al	pear fruit	0.20	72; 79	76	-	0.20
			0.40	108; 98	103	-	
			1.0	88	-	-	
			Overall Recovery (n = 5)			89	
	Phosphonic acid	pear fruit	0.20	89; 86	88	2.4	0.20
			10	78; 86	82	6.8	
30			92	-	-		
Overall Recovery (n = 5)			86	6.1			
10-2064	Fosetyl-Al	apple fruit	0.01	114	-	-	0.01
			0.40	82; 83	88	-	
			10	88	-	-	
			Overall Recovery (n = 4)			92	
	Phosphonic acid	apple fruit	0.20	100	-	-	0.20
			10	96; 97	97	-	
10			93	-	-		
Overall Recovery (n = 4)			99	7.1			
09-2252	Fosetyl-Al	pear fruit	0.01	85	-	-	0.01
			0.10	87	-	-	
			1.0	92	-	-	
			10	84	-	-	
	Overall Recovery (n = 4)			87	4.6		
	Phosphonic acid	pear fruit	0.20	94	-	-	0.20
10			101	-	-		
20			103	-	-		
100			92	-	-		
Overall Recovery (n = 4)			98	5.1			

RSD: Relative Standard Deviation LOQ = Practical Limit of Quantification

* not corrected by residues found in control sample at 0.24 mg/kg

** corrected by residues found in control sample at 0.095 mg/kg

- Storage stability:

The storage periods of deep frozen untreated and treated samples for apple and pear samples are summarised in Table 6.3.4- 15. For fosetyl-Al and its metabolite, before analysis, the maximum storage period of deep-frozen samples did not exceed 475 days (16 months) which is covered by the different storage stability studies (see Section CA 6.1).

With the calculation of the total residues as fosetyl or as phosphonic acid, the potential degradation of fosetyl-Al is taken into account in the total residue.

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Table 6.3.4- 15: Storage periods of deep frozen samples in/on pome fruit after use of Fosetyl-Al WG 80

Study	Crop	Analyte	Storage period of deep frozen samples	
			Min [days]	Max [days]
DR00EUS156	apple	fosetyl-Al phosphonic acid	154	197
DR00EUS157	pear	fosetyl-Al phosphonic acid	149	239
01R107	pear	fosetyl-Al phosphonic acid	293	350
RA-2720/03	pear	fosetyl-Al phosphonic acid	281	350
10-2064	apple	fosetyl-Al phosphonic acid	309	475
09-2252	pear	fosetyl-Al phosphonic acid	367	413

- **Residue results:** In the southern European field trials, the residues in apple and pear fruits at a PHI of 28 days (+/- 1 day) ranged from <0.01 to 9.89 mg/kg for fosetyl-Al and from 0.8 to 24 mg/kg for phosphonic acid.

The total residues expressed as fosetyl were between 1.3 and 32 mg/kg. The total residues expressed as phosphonic acid were between 0.94 and 24 mg/kg.

- No residues of fosetyl-Al were detected in any of the untreated samples (below the limit of quantification of 0.01 or 0.20 mg/kg depending on the method) except for one control sample found at 0.03 mg/kg (LOQ at 0.01 mg/kg) the day before the last application.

No residues of phosphonic acid were detected in any of the untreated samples (below 0.20 mg/kg) except for the control samples of eight trials. The apparent residues of phosphonic acid were detected between 0.23 and 2.2 mg/kg in apple in trial DR00EUS156ESP0102 (Spain) and DR00EUS156ITA0101 (Italy), between 0.23 and 0.72 mg/kg in pear in trial 01R107-1 (Spain) and 01R107-3 (France), between 1.9 and 2.6 mg/kg in pear in trial R 2003 0526 5 (Italy, study RA-2720/03), between 1.4 and 3.1 mg/kg in pear in trial 09-2252-01 (France) and 09-2252-04 (Italy) and equal to 4.1 mg/kg in apple in trial 10-2064-02 (Italy).

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Table 6.3.4- 16: Application data, residues for fosetyl-Al and phosphonic acid and total residues calculated and expressed as fosetyl and as phosphonic acid in/on apple and pear treated with Fosetyl-Al WG 80 in the field in southern Europe

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALF (days)	fosetyl-Al (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
DR00EUS156 DR00EUS156E SP0101 GLP yes 2000	Apple Starking	Spain [REDACTED] Europe, South	80 WG	3	3.6	0.36	81	fruit	0 7 14 28	0.66/<0.2 0.36/<0.2 0.48/<0.2 0.22/<0.2	2.3/0.2 0.6/<0.2 0.69/<0.2 2.6/0.2	3.7 2.5 1.4 3.7	2.8 1.9 1.0 2.8
DR00EUS156 DR00EUS156E SP0102 GLP yes 2000	Apple Reineta	Spain [REDACTED] Europe, South	80 WG	3	3.6	0.36	79	fruit	0 28	<0.2/<0.2 <0.2/<0.2	0.33/0.24 1.7/0.23	0.64/0.51 2.5/0.49	0.48/0.38 1.8/0.37
DR00EUS156 DR00EUS156 GRC0101 GLP yes 2000	Apple Granny Smith	Greece [REDACTED] Europe, South	80 WG	3	3.6	0.36	81	fruit	0 28	0.34/<0.2 0.2/<0.2	1.6/<0.2 0.80/<0.2	2.5 1.3	1.8 0.94
DR00EUS156 DR00EUS156I TA0101 GLP yes 2000	Apple Golden Delicious	Italy [REDACTED] Europe, South	80 WG	3	3.6	0.36 0.45	85	fruit	0 7 14 28	0.66/<0.2 0.55/<0.2 0.34/<0.2 <0.2/<0.2	2.1/2.2 2.3/0.55 3.2/<0.2 2.3/<0.2	3.4/3.1 3.6/0.92 4.6 3.3	2.6/2.3 2.7/0.69 3.4 2.4

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAI (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
DR00EUS156 DR00EUS156I TA0102 GLP yes 2000	Apple Staymared	Italy [REDACTED] Europe, South	80 WG	3	3.6	0.36	79	fruit	0 28	0.21/<0.2 <0.2/<0.2	3.2/<0.2 1.7/<0.2	4.5 2.5	5.3 1.8
DR00EUS157 DR00EUS157E SP0101 GLP yes 2000	Pear Ercolina	Spain [REDACTED] Europe, South	80 WG	5+ 2	0.60- 3.6	0.060- 0.36	74	fruit	0 7 14 21 28	1.5/<0.2 1.1/<0.2 1.8/<0.2 0.52/<0.2 <0.2/<0.2	15/<0.2 18/<0.2 19/<0.2 24/<0.2 12/<0.2	26 28 33 16	19 18 21 24 12
DR00EUS157 DR00EUS157E SP0102 GLP yes 2000	Pear Ercolini	Spain [REDACTED] Europe, South	80 WG	5+ 2	0.60- 3.6	0.060- 0.36	74	fruit	0 27	1.8/<0.2 0.36/<0.2	22/<0.2 20/<0.2	31 27	23 20
DR00EUS157 DR00EUS157I TA0101 GLP yes 2000	Pear William	Italy [REDACTED] Europe, South	80 WG	5+ 2	0.60- 3.6	0.060- 0.36	77	fruit	0 14 21 28	1.2/<0.2 0.60/<0.2 0.27/<0.2 0.51/<0.2 <0.2/<0.2	5.6/<0.2 11/<0.2 13/<0.2 9.1/<0.2 15/<0.2	8.5 16 18 13 21	6.4 12 13 9.5 16
DR00EUS157 DR00EUS157I TA0102 GLP yes 2000	Pear Abate fetel	Italy [REDACTED] Europe, South	80 WG	5+ 2	0.60- 3.6	0.060- 0.36	77	fruit	0 28	3.1/<0.2 <0.2/<0.2	7.6/<0.2 11/<0.2	13 15	9.8 11

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAI (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
01R107 01R107-1 GLP yes 2001	Pear Ercolini	Spain [redacted] Europe, South	80 WG	5+2	0.60-3.6	0.080-0.48	77	fruit	0	1.1/<0.2	26/0.51	36/0.87	17/0.65
									7	<0.2/<0.2	23/<0.2	31	23
									4	0.79/<0.2	32/0.78	4	33/0.86
									21	0.2/<0.2	27/0.2	36	27
									28	0.32/<0.2	24/0.26	32/0.54	24/0.40
01R107 01R107-2 GLP yes 2001	Pear William Rouge	France [redacted] Europe, South	80 WG	5+2	0.60-3.6	0.15-0.88	76	fruit	0	<0.2/<0.2	16/<0.2	22	16
									7	<0.2/<0.2	0.2/17	<0.4/23	<0.34/17
									13	0.2/<0.2	13/<0.2	18	13
									20	0.49/<0.2	17/0.2	23	17
									27	<0.2/<0.2	11/<0.2	15	11
01R107 01R107-3 GLP yes 2001	Pear Guyot	France [redacted] Europe, South	80 WG	5+2	0.60-3.6	0.15-0.88	73	fruit	0	1.8/<0.2	34/0.34	47/0.64	35/0.48
									15	<0.2/<0.2	23/0.29	31/0.58	23/0.43
									21	0.41/<0.2	36/<0.2	49	36
									21	<0.2/<0.2	23/<0.2	31	23
									29	<0.2/<0.2	12/0.23	16/0.49	12/0.37
01R107 01R107-4 GLP yes 2001	Pear William	Italy [redacted] Europe, South	80 WG	5+2	0.60-3.6	0.060-0.36	75	fruit	0	0.69/<0.2	25/<0.2	34	25
									7	0.35/<0.2	37/<0.2	50	37
									4	<0.2/<0.2	37/<0.2	50	37
									21	<0.2/<0.2	31/<0.2	42	31
									28	<0.2/<0.2	19/<0.2	26	19
RA-2720/03 R 2003 0526 5 0526-03 GLP yes 2003	Pear Abate Fetel	Italy [redacted] Europe, South	80 WG	3	0.30000	0.0000	77	fruit	0	0.95/<0.2	20/2.4	28/3.4	21/2.5
									14	0.49/<0.2	26/2.4	35/3.4	26/2.5
									21	0.44/<0.2	23/2.4	31/3.4	23/2.5
									28	0.32/<0.2	19/1.9	26/2.7	19/2.0
									40	0.30/<0.2	16/2.6	22/3.7	16/2.7

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues ⁽¹⁾					
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DAI (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
RA-2720/03 R 2003 0914 7 0914-03 GLP yes 2003	Pear Flor de Invierno	Spain [redacted] Europe, South	80 WG	3	3	0.20000	78	fruit	0	0.29/<0.2	5.4/<0.2	7.5	5.6
									14	<0.2/<0.2	5.8/<0.2	8.0	5.9
									4	<0.2/<0.2	4.8/<0.2	6.6	4.9
									28	0.2/<0.2	7.7/<0.2	11	7.8
									40	<0.2/<0.2	9.1/<0.2	7.6	5.2
RA-2720/03 R 2003 0915 5 0915-03 GLP yes 2003	Pear Doyenne du comice	France [redacted] Europe, South	80 WG	3	3	0.24000	79	fruit	0	0.80/<0.2	7.9/<0.2	11	8.1
									14	<0.2/<0.2	5.4/<0.2	11	9.5
									21	0.2/<0.2	5.8/<0.2	8.0	5.9
									28	0.2/<0.2	9.9/<0.2	12	9.2
									38	<0.2/<0.2	10/<0.2	14	10
10-2064 10-2064-01 GLP: yes 2010	Apple Golden	Spain [redacted] Europe, South	80 WG	3	3.6	0.26	78	fruit	0*	0.77/<0.01	7.9/<0.2	11	8.0
									0	n.a	8.2/n.a	13	9.7
									6	1.3/n.a	13/n.a	19	14
									15	0.78/n.a	15/n.a	21	16
									28	0.33/<0.01	17/<0.2	24	18
10-2064 10-2064-02 GLP: yes 2010	Apple Golden Delicious	Italy [redacted] Europe, South	80 WG	3	3.6	0.36	81	fruit	0*	0.03/<0.01	13/<0.2	17	13
									0	1.4/n.a	14/n.a	21	15
									14	0.73/n.a	17/n.a	24	18
									14	0.72/n.a	19/n.a	26	20
									28	0.01/<0.01	22/4.1	29/5.5	22/4.1
10-2064 10-2064-03 GLP: yes 2010	Apple Gala	France [redacted] Europe, South	80 WG	3	3.6	0.36	85	fruit	0*	0.3/<0.01	9.6/<0.2	13	9.8
									0	2.1/n.a	9.9/n.a	15	11
									7	0.39/n.a	12/n.a	16	12
									14	0.28/n.a	12/n.a	17	12
									28	0.03/<0.01	12/<0.2	15	12

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	DALI (days)	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS			fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)	
10-2064 10-2064-04 GLP: yes 2010	Apple mondial Gala	Portugal [REDACTED] Europe, South	80 WG	3	3.6	0.36	81	fruit	0*	0.69/<0.01	9.2/<0.2	13	9.7	
									0	1.7/n.a	11/n.a	16	12	
									7	1.4/n.a	17/n.a	24	18	
									14	0.88/n.a	17/n.a	23	18	
									28	0.89/<0.01	15/<0.2	20	16	
09-2252 09-2252-01 GLP: yes 2009	Pear Williams	France [REDACTED] Europe, South	80 WG	3	3.6	0.24	85	fruit	0*	0.62/<0.01	17/<0.2	22	17	
									0	0.61/n.a	1/n.a	24	17	
									7	0.0/n.a	20/n.a	20	20	
									14	0.01/n.a	20/n.a	26	20	
									28	<0.01/<0.01	15/<0.2	20	15	
09-2252 09-2252-02 ⁽⁴⁾ GLP: yes 2009	Pear William	France [REDACTED] Europe, South	80 WG	3	3.6	0.24	76	fruit	0*	0.15/0.03 ⁽³⁾	12/3.1 ⁽³⁾	17/4.2 ⁽³⁾	12/3.1 ⁽³⁾	
									0	1.5/n.a	19/n.a	27	20	
									7	0.09/n.a	29/n.a	36	27	
									14	0.03/n.a	18/n.a	24	18	
									28	<0.01/<0.01	17/<0.2	23	17	
09-2252 09-2252-03 GLP: yes 2009	Pear Conference	Spain [REDACTED] Europe, South	80 WG	3	3.6	0.24	81	fruit	0*	0.01/<0.01	9.4/<0.2	13	9.4	
									0	0.5/n.a	10/n.a	15	11	
									6	0.91/n.a	17/n.a	23	18	
									14	0.78/n.a	16/n.a	22	17	
									28	<0.01/<0.01	17/<0.2	23	17	
09-2252 09-2252-04 GLP: yes 2009	Pear William	Italy [REDACTED] Europe, South	80 WG	3	3.6	0.24	76	fruit	0*	0.01/<0.01	19/1.8	25/2.4	19/1.8	
									0	1.4/n.a	20/n.a	28	21	
									7	<0.01/n.a	21/n.a	28	21	
									14	<0.01/n.a	21/n.a	28	21	
									28	<0.01/<0.01	15/1.4	20/1.8	15/1.4	

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Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Portion analysed	Residues ⁽¹⁾				
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		DALT (days)	fosetyl-AL (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
09-2252 09-2252-05 GLP: yes 2009	Pear Conference	Spain [REDACTED] Europe, South	80 WG	3	3.6	0.24- 0.28	81	fruit	0*	0.01/<0.01	9.7/<0.2	13	9.7
									0	1.5/n.a	12/n.a	17	13
									6	0.67/n.a	14/n.a	19	14
									14	0.42/n.a	13/n.a	18	13
									28	<0.01/<0.01	13/<0.2	17	13

FL: Formulation No: number of applications GS = growth stage (BBCH code) at last application DALT = days after last treatment
/value: Residue found in the corresponding control sample 0*: prior to last treatment
n.a: control sample not harvested therefore no corresponding result available

- (1): The residue values of fosetyl-AL and phosphonic acid marked in bold are those retained for the calculation of the highest total residues expressed as fosetyl and as phosphonic found at the PHI of 21 days or after. The total residue expressed as fosetyl is calculated as the sum of fosetyl-AL expressed as fosetyl and phosphonic acid expressed as fosetyl. The total residue expressed as phosphonic acid is calculated as the sum of fosetyl-AL expressed as phosphonic acid and phosphonic acid.
- (2): An inversion between the “untreated” and the “treated” specimen is suspected. Mean of 2 values found at 15 and 19 mg/kg from different samplings is reported for residues of phosphonic acid in control sample.
- (3): An inversion between the control sample and the treated sample was suspected. Values reported in this table correspond to the likely correct values.
- (4): The last sampling at PHI= 28 days has not been done because the complete trial was harvested at DALT 14.

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Overall conclusions – Pome fruit

Table 6.3.4- 17: Overview of the available residues data for total residue calculated as fosetyl

Commodity/ study	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Total residue calculated as fosetyl									
Apple/Pear 3x3.6 kg /ha, 28 days or 5x0.6 kg /ha + 2x3.6 kg/ha, PHI of 28 days	EU-N	Outdoor	2.2, 2.9, 3.4, 3.6, 4.9, 5.3, 6.9, 7.0, 7.3, 15	2.2, 2.9, 3.4, 3.6, 4.9, 5.3, 6.9, 7.0, 7.3, 15	5	15	60	1.0	Data evaluated by EFSA in the review of the existing MRLs. However no MRL proposed with this residue definition.
	EU-S	Outdoor	1.3, 2x2.5, 3, 3.7, 11, 14, 15, 2x16, 21, 2x26, 27, 32	1.5, 2x2.5, 3, 3.7, 11, 14, 2x15, 2x16, 21, 2x26, 27, 32	15	32	60	1.0	
Apple/Pear 3x3.6 kg /ha, spray interval of 10 days, PHI of 28 days	EU-N	Outdoor	10, 11, 15, 16, 18, 19, 21, 23	10, 11, 15, 16, 18, 19, 21, 23	17	23	50	1.0	New data generated to support the current critical GAP in Europe. Modification of MRL within the AIR process
	EU-S	Outdoor	15, 17, 3x20, 23, 24, 29	15, 17, 3x20, 23, 24, 29	20	29	70	1.0	

The total residue expressed as fosetyl is calculated as the sum of fosetyl-Al expressed as fosetyl and phosphonic acid expressed as fosetyl.

(a): EU-N, EU-S, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between EU-N and EU-S.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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Table 6.3.4- 18: Overview of the available residues data for total residue calculated as phosphonic acid

Commodity/ study	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Total residue calculated as phosphonic acid									
Apple/Pear 3x3.6 kg /ha, 28 days or 5x0.6 kg /ha + 2x3.6 kg/ha, PHI of 28 days	EU-N	Outdoor	1.6, 2.1, 2.5, 2.7, 3.6, 3.9, 2x5.2, 5.4, 11	1.6, 2.1, 2.5, 2.7, 3.6, 3.9, 2x5.2, 5.4, 11	1.6	5.4	15	1.0	Data evaluated by EFSA in the review of the existing MRLs.
	EU-S	Outdoor	0.94, 2x1.8, 2.4, 2.8, 7.8, 10, 2x11, 2x12, 16, 2x19, 20, 24	0.94, 2x1.8, 2.4, 2.8, 7.8, 10, 2x11, 2x12, 16, 2x19, 20, 24	1.0	24	40	1.0	
Apple/Pear 3x3.6 kg /ha, spray interval of 10 days, PHI of 28 days	EU-N	Outdoor	7.6, 8.2, 11, 12, 14, 15, 16, 17	7.6, 8.2, 11, 12, 14, 15, 16, 17	13	17	40	1.0	New data generated to support the current critical GAP in Europe.
	EU-S	Outdoor	12, 13, 2x15, 16, 17, 2x18, 22	12, 13, 2x15, 16, 17, 2x18, 22	16	22	50	1.0	

The total residue expressed as fosetyl is calculated as the sum of fosetyl-Al expressed as phosphonic acid and phosphonic acid

(a): EU-N, EU-S, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between EU-N and EU-S.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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CA 6.4 Feeding studies

Data/information on livestock feeding studies, were evaluated for the Annex I inclusion of fosetyl under Directive 91/414/EEC and were considered to be acceptable and no further data have been generated. A poultry feeding study and a ruminant feeding study were conducted in Europe whereas a dairy cow study was performed in the United States.

Currently, the MRLs for milk and eggs are 0.1 mg/kg and the MRLs for other products of animal origin are 0.5 mg/kg based on the residue definition “sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl”. They were published in Regulation (EC) No 839/2008 of 31 July 2008 as temporary MRLs corresponding to lower limit of analytical determination. Since no modification has been proposed.

The dietary burden calculations were performed by EFSA in 2012 in the context of the review of the existing MRLs (EFSA Journal 2012 10(11)2964). All the uses supported with formulations containing fosetyl were taken into account and dietary burden calculations were proposed as listed in Table 6.4-1 and Table 6.4-2 for phosphonic acid and fosetyl separately. It is noted that the high contribution in the dietary burden calculation is based on residue levels in kale or potato.

Table 6.4- 1: Dietary Burden calculation for phosphonic acid (EFSA Journal 2012)

Dietary burden	Dairy ruminants	Meat Ruminants	Poultry	Pigs
Median dietary burden (mg/kg bw/d):	0.9834	2.8770	0.6389	1.2139
Maximum dietary burden (mg/kg bw/d):	1.2076	3.3913	0.9257	1.7577
Highest contributing commodity:	Potatoes	Potatoes	Potatoes	Potatoes
Max dietary burden (mg/kg feed DM):	33.043	79.130	14.648	43.943
Trigger exceeded (Y/N)	Y	Y	Y	Y

Table 6.4- 2: Dietary Burden calculation for fosetyl (EFSA Journal 2012)

Dietary burden	Dairy ruminants	Meat Ruminants	Poultry	Pigs
Median dietary burden (mg/kg bw/d):	0.1345	0.1993	0.0516	0.0980
Maximum dietary burden (mg/kg bw/d):	0.2527	0.3236	0.0826	0.1569
Highest contributing commodity:	Kale	Kale	Kale	Kale
Max dietary burden (mg/kg feed DM):	6.950	7.550	1.307	3.921
Trigger exceeded (Y/N)	Y	Y	Y	Y

Following this EFSA evaluation, MRLs in animal commodities were recommended for phosphonic acid but not for fosetyl.

With regard to the supported uses of fosetyl in this Supplementary Dossier for approval renewal of fosetyl, the only feedstuff that can be fed to livestock is apple wet pomace.

The maximum dietary burdens were therefore calculated for different groups of livestock as described in the OECD Guidance Document on Residues in Livestock (ENV/JM/MONO (2013)8 dated of 04-Sep-2013).

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Based on the plant residue definition for risk assessment (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl), input values were derived from the residue data as summarized in Section CA 6.3.4. These values are summarised in Table 6.4- 3.

Table 6.4- 3: Feed items and residue levels (as measured) used to calculate the intake of fosetyl residues by livestock

Commodity	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl		
Apple, wet pomace	24	STM _R -P STM _R = 20 mg/kg (see Section CA 6.3.4, data from southern EU) P = 1.2 (see Section CA 6.5.3)

The results of the dietary burden calculations are reported on Table 6.4- 4.

Table 6.4- 4: Results of the dietary burden calculations OECD methodology

	Maximum dietary burden (mg/kg bw/day)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl				
Cattle - Beef	0.288	Apple wet pomace	6	Y
Cattle - Dairy	0.231	Apple wet pomace	6	Y
Sheep – Rams/Ewes	0.200	Apple wet pomace	6	Y
Sheep – Lambs	0.255	Apple wet pomace	6	Y
Swine - Breeding	0	-	0	N
Swine - Finishing	0	-	0	N
Poultry - Broiler	0	-	0	N
Poultry - Layer	0	-	0	N
Poultry - Turkey	0	-	0	N

According to current EU data requirements [Regulation (EU) 283/2013 of 1 March 2013] livestock feeding studies are only required if:

- i) Metabolism studies indicate that residues at levels of above 0.01 mg/kg may occur in edible animal tissue, milk, eggs or fish, taking into account the residue levels in potential feeding stuffs, obtained at the 1x dose rate, calculated on a dry weight basis
- ii) Dietary intake is above 0.004 mg/kg bw/day, except in cases where the residue (active substance, its metabolites or breakdown products, as defined in the residue definition for risk assessment), tends to accumulate.

The maximum expected dietary burden of fosetyl is above the EU trigger level of 0.004 mg/kg bw/day for cattle (beef and dairy) and sheep (rams, ewes and lambs). Therefore there is also a requirement to consider ruminant livestock feeding studies and the potential transfer of residues into food of animal origin for the supported uses of fosetyl. See the relevant section for each livestock species of relevance for EU evaluation.

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CA 6.4.1 Poultry

The uses of fosetyl-aluminium (fosetyl-Al) supported in this submission result in no significant residues in the feed of poultry using the OECD method of calculating dietary burden. Therefore no poultry feeding study is required to support these uses.

A poultry feeding study has been already evaluated during the peer review for the Annex I inclusion of fosetyl under Directive 91/414/EEC and then in the review of the existing MRLs for fosetyl according to Article 12 of regulation (EC) No 396/2005 (EFSA Journal 2012;10(11):2961). This study is referenced in Table 6.4.1- 1.

Table 6.4.1- 1: Fosetyl hen feeding study

Annex Point/ Reference number	Species	Dose and duration (fosetyl-Al equivalent)	Samples Taken	CLP	Reference (Doc. No.)
KCA 6.4.1/01	Laying hen	20 (X), 60 (3X) and 200 (10X) mg/kg wet (D) 28 days	Egg, liver, muscle, heart, fat	Yes	[REDACTED]; 2004; M-23827-1

The dose consisted of fosetyl-Al ($(C_2H_3O_3P)_2$) and sodium phosphite basic pentahydrate ($Na_2HPO_3 \cdot 5H_2O$) at a 1:9 ratio calculated as fosetyl-Al equivalent. 1 mole of the sodium salt contains 1/3 moles of fosetyl equivalents after correction for purities) with concentrations in dry matter of feed as follows:

Table 6.4.1- 2: Dose level calculation as fosetyl-Al equivalent

Dose level	Fosetyl-Al equivalent mg/kg DM	Fosetyl-Al mg/kg DM	Sodium phosphonate equivalent fosetyl-Al mg/kg DM
1x	20	20	18
3x	60	60	54
10x	200	200	180

The dosing of hens 20, 60 and 200 mg/kg in the diet results in calculated intakes of 1.53, 5.93 and 18.22 mg Fosetyl-Al equivalent/kg and day, respectively.

Residues of fosetyl-Al and phosphonic acid were determined with a limit of quantification of 0.5 mg/kg.

There were no residues of either fosetyl-Al or phosphonic acid found above the LOQ (0.5 mg/kg) in any of the egg or tissue samples analysed. Concentrations were detected in some samples as recorded in both following tables.

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Table 6.4.1- 3: Detected concentration range of fosetyl-Al

Sample	Group	Fosetyl-Al equivalent mg/kg DM	Fosetyl-Al mg/kg
Egg	control	0	ND to 0.024
	1x dose level	20	ND
	3x dose level	60	ND to 0.025
	10x dose level	200	0.036 to 0.06
Muscle	control	0	ND
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND
Liver	control	0	ND to 0.129
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND
Fat	control	0	ND to 0.15
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND

ND: not detected

Table 6.4.1- 4: Detected concentration range of phosphonic acid

Sample	Group	Fosetyl-Al equivalent mg/kg DM	Phosphonic acid mg/kg
Egg	control	0	0.01 to 0.93
	1x dose level	20	0.25 to 0.76
	3x dose level	60	0.010 to 0.196
	10x dose level	200	0.013 to 0.18
Muscle	control	0	ND
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND
Liver	control	0	ND to 0.111
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND
Fat	control	0	ND
	1x dose level	20	ND
	3x dose level	60	ND
	10x dose level	200	ND

ND: not detected

Conclusion

No significant amounts of fosetyl-Al or phosphonic acid were found in eggs, muscle liver and fat after 28 days repeated oral administration at all three dose levels.

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Fosetyl

CA 6.4.2 Ruminants

The uses of fosetyl-aluminium (fosetyl-Al) supported in this Supplementary Dossier result in significant residues in the feed of cattle (beef and dairy) and sheep (rams/ewes and lambs) (see Section CA 6.4). Therefore a lactating ruminant feeding study is required to support these uses with respect to potential residues in milk and meat products.

Two ruminant feeding studies have been already evaluated during the peer review under Directive 91/414/EEC and then in the review of the existing MRLs for fosetyl according to Article 12 of regulation (EC) No 396/2005 (EFSA Journal 2012;10(11):2961). This study is referenced in Table 6.4.2- 1.

Table 6.4.2- 1: Fosetyl ruminant feeding study

Annex Point/ Reference number	Species	Dose and duration (fosetyl-Al equivalent)	Samples taken	GLP	Reference (doc. No.)
KCA 6.4.2/01	Dairy cow	10 (X), 30 (3X) and 100 (10X) mg/kg dry DM; 28 days	Milk, muscle, liver, kidney, fat	Yes	[redacted]; 2000; M198684-01-1
KCA 6.4.2/02 KCA 6.4.2/03	Dairy cow	3 (X), 9 (3X) and 30 (10X) mg/kg dry DM; 28 days	Milk, liver, kidney, heart, muscle, fat, blood	No	[redacted]; 1984; M184515-01-1 [redacted]; 1984; M184519-01-1

Only the results of the GLP study are summarized here.

The dose consisted of fosetyl-Al ($Al(C_2H_4O_2)_2$) and sodium phosphite dibasic pentahydrate ($Na_2HPO_3 \cdot 5H_2O$) at a 1:9 ratio calculated as fosetyl-Al equivalents (1 mole of the sodium salt contains 1/3 moles of fosetyl equivalents after correction for parties) with concentrations in dry matter of feed as follows:

Table 6.4.2- 2: Dose level calculation of fosetyl-Al equivalent

Dose level	Fosetyl-Al equivalent mg/kg DM	Fosetyl-Al mg/kg DM	Sodium phosphonate equivalent fosetyl-Al mg/kg DM
1x	10	1	9
3x	30	3	27
10x	100	10	90

Assuming a daily consumption of 20 kg feed for a 550 kg cow, this corresponded to 0.36, 1.09 and 3.64 mg fosetyl-Al equivalent/kg and day, respectively.

Residues of fosetyl-Al and phosphonic acid were determined with a limit of quantification of 0.1 mg/L in milk and 0.5 mg/kg in the tissues/organs.

No residues of fosetyl-Al were found in the milk and in the tissue and organ samples at all three dose levels, except for an inconsequential residue (0.081 mg/kg) below the LOQ detected in the liver of one cow at the 3x dose level.

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Table 6.4.2- 3: Detected concentration range of fosetyl-Al

Sample	Group	Fosetyl-Al equivalent mg/kg DM	Fosetyl-Al mg/kg
Milk	control	0	ND
	1x dose level	10	ND
	3x dose level	30	ND
	10x dose level	100	ND
Kidney	control	0	ND
	1x dose level	10	ND
	3x dose level	30	ND
	10x dose level	100	ND
Muscle	control	0	ND
	1x dose level	10	ND
	3x dose level	30	ND to 0.081
	10x dose level	100	ND
Liver	control	0	ND
	1x dose level	10	ND
	3x dose level	30	ND
	10x dose level	100	ND
Fat	control	0	ND
	1x dose level	10	ND
	3x dose level	30	ND
	10x dose level	100	ND

ND: not detected

Concentrations of phosphoric acid detected at all three dose levels were always below the respective LOQ in milk, muscle, liver and fat and in kidney at 1x and 3x dose levels. At the 10x dose level, low residues of 0.495 to 0.598 mg phosphoric acid per kg were quantified.

Table 6.4.2- 4: Detected concentration range of phosphonic Acid

Sample	Group	Fosetyl-Al equivalent mg/kg DM	Phosphonic acid mg/kg
Milk	control	0	ND
	1x dose level	10	0.012 to 0.041
	3x dose level	30	0.008 to 0.051
	10x dose level	100	0.030 to 0.061
Kidney	control	0	ND to 0.145
	1x dose level	10	0.096 to 0.215
	3x dose level	30	0.278 to 0.302
	10x dose level	100	0.495 to 0.598
Muscle	control	0	0.058 to 0.155
	1x dose level	10	ND to 0.088
	3x dose level	30	0.051 to 0.086
	10x dose level	100	ND to 0.060
Liver	control	0	ND to 0.069
	1x dose level	10	ND
	3x dose level	30	ND to 0.327
	10x dose level	100	0.080 to 0.275
Fat	control	0	0.030 to 0.067
	1x dose level	10	0.070 to 0.166
	3x dose level	30	0.066 to 0.184
	10x dose level	100	0.182 to 0.221

ND: not detected

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Conclusion

No significant amounts of fosetyl-Al or phosphonic acid were found in milk, muscle liver and fat after 28 days repeated oral administration at all three dose levels, as well as in kidney at the 1x and 3x dose level.

Residues of phosphonic acid only slightly above the limit of quantification were found in kidney at the 10x dose level (corresponding to 100 mg/kg fosetyl equivalent in the diet)

For this feeding study conducted under GLP, the feeding doses of 10, 30 and 100 mg/kg DM in the diet are equivalent to 0.36, 1.09 and 3.64 mg/kg bw/day, expressed as fosetyl-Al. These dose levels are re-expressed in this Supplementary Dossier as fosetyl. The total residues as the sum of fosetyl and phosphonic acid, expressed as fosetyl are re-calculated for animal commodities and summarized in the table below. When residues of fosetyl-Al or phosphonic acid were not detected in the samples residues equal to 0 were considered for the calculation of the total residues.

Table 6.4.2- 5: Detected concentration range of total residue (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)

Sample	Feeding dose (in fosetyl equivalents)		Residues in food of animal origin		
	mg/kg DM	mg/kg bw/day	Fosetyl-Al mg/kg	Phosphonic acid mg/kg	Total residues expressed as fosetyl mg/kg
Milk	0	0	ND	ND	ND
	9.3	0.34	ND	0.012 to 0.041	0.02 to 0.06
	28	1.02	ND	0.008 to 0.031	0.01 to 0.07
	93	3.39	ND	0.030 to 0.061	0.04 to 0.08
Kidney	0	0	ND	ND to 0.145	ND to 0.19
	9.3	0.34	ND	0.096 to 0.215	0.13 to 0.29
	28	1.02	ND	0.278 to 0.302	0.37 to 0.41
	93	3.39	ND	0.495 to 0.598	0.66 to 0.80
Muscle	0	0	ND	0.058 to 0.155	0.08 to 0.21
	9.3	0.34	ND	ND to 0.088	ND to 0.12
	28	1.02	ND to 0.081	0.051 to 0.086	0.07 to 0.19
	93	3.39	ND	ND to 0.060	ND to 0.08
Liver	0	0	ND	ND to 0.069	ND to 0.09
	9.3	0.34	ND	ND	ND
	28	1.02	ND	ND to 0.327	ND to 0.44
	93	3.39	ND	0.080 to 0.275	0.11 to 0.37
Fat	0	0	ND	0.030 to 0.067	0.04 to 0.09
	9.3	0.34	ND	0.070 to 0.166	0.09 to 0.22
	28	1.02	ND	0.066 to 0.184	0.09 to 0.25
	93	3.39	ND	0.182 to 0.221	0.24 to 0.30

ND: not detected

The feeding dose of 0.34 mg/kg bw/day expressed as fosetyl (equivalent to 9.3 mg/kg DM in the diet) is considered the most appropriate dose to refer to when calculating the anticipated transfer of residues in commodities of animal origin. Transfer factors Tf are derived from this dose level and applied to the maximum anticipated intake of fosetyl for livestock.

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****Table 6.4.2- 6: Tf for the feeding dose of 0.34 mg/kg bw/day**

Sample	Highest total residues expressed as fosetyl mg/kg	Feeding dose mg/kg bw/day	Tf
Milk	0.06	0.34	0.18
Kidney	0.29	0.34	0.85
Muscle	0.12	0.34	0.35
Liver	ND	0.34	-
Fat	0.22	0.34	0.65

Tf = residues in animal commodity / feeding dose

The maximum residue levels in animal commodities are estimated considering the anticipated intake for livestock as calculated in Table 6.4- 4 as well as the Tf derived from the feeding study. Results of these calculations are indicated in the following table.

Table 6.4.2- 7: Estimated highest residues in animal commodities

Commodity	Maximum dietary burden (mg/kg bw/day)	Highest residues (mg/kg)
Bovine milk	0.231	0.04
Bovine kidney	0.288	0.25
Bovine muscle	0.288	0.10
Bovine liver	0.288	ND
Bovine fat	0.288	0.19
Sheep milk	0.260	0.04
Sheep kidney	0.255	0.22
Sheep muscle	0.255	0.09
Sheep liver	0.255	ND
Sheep fat	0.255	0.17

ND: not detected

No residues above the existing MRLs (0.1 mg/kg for milk, eggs and 0.5 mg/kg for other products of animal origin) are anticipated when applying fosetyl-Al following the representative uses supported in this dossier. Thus, existing MRLs in animal commodities do not need to be modified.

CA 6.4.3 Pigs

The uses of fosetyl-aluminum supported in the Supplementary Dossier result in no significant residues in the feed of pigs using the OECD method of calculating dietary burden. Therefore no pig feeding study is required to support these uses and no such study has been performed.

CA 6.4.4 Fish

Not required according to the crop uses of fosetyl-aluminum.

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CA 6.5 Effects of processing

CA 6.5.1 Nature of the residue

The effect of processing on the nature of fosetyl-aluminium (fosetyl-Al) was investigated in the framework of the peer review for the Annex I inclusion of fosetyl under Directive 91/414/EEC and was also reviewed by EFSA within the review of the maximum residue limits for fosetyl-Al (EFSA Journal 2012; 10(11):2961). No hydrolysis of fosetyl-Al or its metabolite phosphonic acid was observed under any of the processing conditions (██████████; 2001; M-203002-02-1). Fosetyl-Al and phosphonic acid are therefore considered to be hydrolytically stable under these conditions. No further studies were submitted or are required. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

Summary

The hydrolysis of fosetyl-Al and its metabolite phosphonic acid was investigated under the following conditions:

- pH 4 at 90 °C for 30 minutes to simulate pasteurisation
- pH 5 at 100 °C for 60 minutes to simulate baking, boiling and boiling
- pH 6 at 120 °C for 20 minutes to simulate sterilisation

Due to the nature of the compounds, the studies were not conducted with radiolabelled form of the substances investigated.

Portions (approximately 250 ml) of the test solutions containing either fosetyl-Al or phosphonic acid were incubated at the appropriate pH, temperature and during the appropriate time. Control solutions were incubated alongside the test solutions. The pH 4 and pH 5 test solutions were incubated in the dark in an oven. The pH 6 test solutions were incubated in the dark in an autoclave. The temperature was monitored during the incubation period. Since treated and control samples were analysed at T₀ and at the end of each incubation period. Portions of the solutions were analysed by ion chromatography with conductivity detection.

The concentrations obtained before and after incubation are summarised in [Table 6.5.1- 1](#) and [Table 6.5.1- 2](#) for fosetyl-Al and its metabolite phosphonic acid, respectively.

Table 6.5.1- 1: Concentration of fosetyl-Al in the buffer solutions treated with fosetyl-Al and incubated at each pH and incubation condition

Incubation condition	Fosetyl-Al detected (mg/L)	
	T ₀	Post incubation
pH 4, 90 °C for 30 minutes	98.6	97.4
pH 5, 100 °C for 60 minutes	98.6	99.9
pH 6, 120 °C for 20 minutes	96.7	96.2

No phosphonic acid or phosphonic acid was detected

Table 6.5.1- 2: Concentration of phosphonic acid in the buffer solutions treated with phosphonic acid and incubated at each pH and incubation condition

Incubation condition	Phosphonic acid detected (mg/L)	
	T ₀	Post incubation
pH 4, 90 °C for 30 minutes	95.9	97.6
pH 5, 100 °C for 60 minutes	95.9	98.4
pH 6, 120 °C for 20 minutes	98.0	99.9

No phosphonic acid was detected

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Conclusion

No hydrolysis of fosetyl-Al or its metabolite phosphonic acid was observed, nor any phosphoric acid detected, under any of the processing conditions. Fosetyl-Al and phosphonic acid are therefore considered to be hydrolytically stable under conditions representative of pasteurisation, heating, brewing, boiling and sterilisation.

CA 6.5.2 Distribution of the residue in peel and pulp

The distribution of the residue in peel and pulp is not relevant for the supported crops

CA 6.5.3 Magnitude of residues in processed commodities

Grape

The following studies were already submitted in the original Annex II dossier for the Annex I inclusion of fosetyl under Directive 91/414/EEC.

Table 6.5.3- 1: Processing trials submitted in the original Annex I dossier

Region	Crop	Formulation	Number of Trials				Report No.	Document No.	Dossier-Ref.
			Vegetation period			Total			
			1996	1997	1998-2006				
<i>Annex II data</i>									
N-EU	Grape	WG 80	1	-	-	1	96-50	M-164695-01-1	KCA 6.5.3/03
	Grape	WG 71.14	-	1	-	1	98-562	M-170328-01-1	KCA 6.5.3/01
	Grape	WG 71.14	-	-	1	1	99-629	M-189116-01-1	KCA 6.5.3/06
	Grape	WG 71.14	-	-	-	1	00-2531	M-189118-01-1	KCA 6.5.3/07
S-EU	Grape	WG 80	1	-	-	1	96-50	M-164695-01-1	KCA 6.5.3/03
	Grape	WG 71.14	-	1	-	1	98-562	M-170328-01-1	KCA 6.5.3/01
	Grape	WP 60	-	-	2	2	98-721	M-170375-01-1	KCA 6.5.3/02
	Grape	WP 60	-	-	1	1	98-736	M-166521-01-1	KCA 6.5.3/04
	Grape	WP 60	-	-	1	1	98-738	M-170371-01-1	KCA 6.5.3/05
	Grape	WG 71.14	-	-	-	1	99-629	M-189116-01-1	KCA 6.5.3/06
	Grape	WG 71.14	-	-	-	4**	00-2006	M-228263-01-1 M-228237-01-1 M-228225-01-1 M-228229-01-1	KCA 6.5.3/14 KCA 6.5.3/15 KCA 6.5.3/16 KCA 6.5.3/17

N-EU: northern Europe S-EU: southern Europe

WG 80: formulation containing 40% fosetyl-Al and 40% folpet

WG 71.14: formulation containing 60.7% fosetyl-Al and 4.44% fenamidone

WP 60: formulation containing 60% fosetyl-Al, 4.8% iprovalicarb and 4% fenamidone

*: 2 trials with 2 different plots

** : specific study for the evaluation of various numbers of treatments

A total of fifteen processing trials were conducted between 1996 and 1999. They were conducted to determine the transfer of the residues of fosetyl-Al and its metabolite phosphonic acid from grape fruit into processed fractions.

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A specific processing study was conducted in 2000 to evaluate the unintentional effect of the formulation containing fosetyl-aluminium (fosetyl-Al) and fenamidone on the production and quality of wines and to assess the influence of number of treatments.

A summary of the processing trials conducted in 1996 and 1998 is recorded below.

A full description of both studies conducted in 1999 is proposed in this dossier in order to illustrate the conditions of the processing trials on grapes.

For the study 00-2006 it seems that only the results of aluminium were evaluated in the Final Addendum to the Draft Assessment Report for the Annex I inclusion of fosetyl under Directive 91/414/EEC. It was concluded that the analysis of aluminium residues in different samples do not reveal any significant difference between specimens from crops untreated with fosetyl-Al containing formulations and specimens from treated crops. In the case of grapes, the highest aluminium levels are found in "solid" fractions such as pomace and lees with no significant difference between treated and untreated. The liquid fraction "wine" contains aluminium at < LOQ level only (< 1 µg/kg). The processing results of fosetyl-Al and phosphonic acid of the study 00-2006 are therefore summarized in this Supplementary Dossier.

Processing trials conducted in 1996 and 1998

Production of red or white wine was performed in each trial with collection of wine sample and of must in some trials. Additionally production of grape juice was done in some trials.

All the information concerning the field part, the processing and the analytical part were described in the Annex II dossier for Annex I inclusion of fosetyl under Directive 91/414/EEC and then in the MRL Compilation dossier.

The samples were analysed for the parent compound fosetyl-Al and the metabolite phosphonic acid (named phosphorous acid in the reports) following the analytical method based on the referenced method DFG 522.

Residues of fosetyl-Al and phosphonic acid were extracted with acidic water, methylated with diazomethane then quantified by GC/FID (Gas Chromatography / Flame Photometric Detector).

The limit of quantification (LOQ) was 0.20 µg/kg for each analyte in all matrices.

Residue values of fosetyl-Al, phosphonic acid in grape fruit and the processed by-products are summarised in [Table 6.5.3-2](#).

As the total residue was not calculated (study conducted in 1996) or calculated as fosetyl-Al (studies conducted in 1998), it will be calculated here as total residue expressed as fosetyl (see [Section CA 6.3](#) for calculation).

The transfer factor is proposed for the total residues expressed as fosetyl and are recorded in [Table 6.5.3-2](#) and [Table 6.5.3-2](#).

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.5.3- 2: Residues of fosetyl-Al, phosphonic acid and total residues of fosetyl in grapes and processed fractions

Country, Study No., Trial No.	Crop Portion analysed	Formulation	Number of applications	DALT (days)	Residues (mg/kg or mg/L)			Transfer factor
					Fosetyl-Al	Phosphonic acid	Total residues expressed as fosetyl	
Northern France 96-598 96598DJ1	Grape fruit (RAC)	WG 80	8	32	1.9	14	21	-
	Grape juice				1.4	15	21	1.5
	Red Wine				0.89	21	29	1.4
Northern France 98-562 98562RN1	Grape fruit (RAC)	WG 71.14	7	24	0.33	25	36	-
	Grape juice				0.35	24	35	1.1
	Must				0.68	29	29	5.8
	Red Wine				0.2	21	21	0.9
Southern France 96-598 96598TL1	Grape fruit (RAC)	WG 80	8	25	1.9	17	19	-
	Grape juice				0.51	7	21	1.2
	Red Wine				0.4	25	24	1.8
Southern France 98-562 98562AV1	Grape fruit (RAC)	WG 71.14	7	25	0.39	14	22	-
	Grape juice				0.4	14	18	1.0
	Must				0.7	12	18	0.8
	Red Wine				0.34	25	25	1.1
Southern France 98-562 98562TL1	Grape fruit (RAC)	WG 71.14	7	25	0.3	17	25	-
	Grape juice				1.0	19	28	1.1
	Must				1.1	24	35	1.4
	Red Wine				0.7	22	32	1.3
Italy 98-721 98721B01	Grape fruit (RAC)	WP 60.8	5	41	0.58	22	32	-
	White Wine				0.3	14	20	0.6
Italy 98-721 98721BO1	Grape fruit (RAC)	WP 60.8	5	41	0.53	14	21	-
	White Wine				0.38	16	24	1.1
Italy 98-736 98736BO1	Grape fruit (RAC)	WP 60.8	5	40	0.24	6.7	9.8	-
	White Wine				0.39	9.8	15	1.5
Italy 98-736 98738BO1	Grape fruit (RAC)	WP 60.8	5	40	0.68	17	25	-
	White Wine				1.1	6.8	11	0.4

RAC: Raw Agricultural Commodity; DALT: days after last application
 WG 80: formulation containing 40% fosetyl-Al and 40% folpet
 WG 71.14: formulation containing 66.7% fosetyl-Al and 4.44% fenamidone
 WP 60.8: formulation containing 52% fosetyl-Al, 4.8% iprovalicarb and 4% fenamidone

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.5.3- 3: Transfer factor for the total residues of fosetyl in wine and grape juice

Study Number	Trial Number Location	Transfer factor for wine	Transfer factor for juice	Remark
96-598	96598DJ1 Northern France	1.4	1.0	Production of red wine
	96598TL1 Southern France	1.8	1.2	
98-562	98562RN1 Northern France	0.9	1.0	Production of red wine
	98562AV1 Southern France	1.1	1.0	
	98562TL1 Southern France	1.3	1.1	
98-721	98721BO1 Italy	-	-	Production of white wine
	98721BO1 Italy	1.1	-	
98-736	98736BO1 Italy	-	-	Production of white wine
98-738	98738BO1 Italy	0.4	-	Production of white wine

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**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl**

Report: KCA 6.5.3/06 [redacted] B; 2001; M-189116-01-1
Title: Residues in grape (fruit) and processed products (juice, must, wine) Fenamidone (RPA407213) and metabolite (RPA405862) Fosetyl-Al and metabolite (phosphorous acid) Formulation EXP10745D (WG) North / France / 1999 - 1 harvest trial; South / France / 1999 - 1 harvest trial
Report No.: 99-629
Document No.: M-189116-01-1
Guideline(s): EU Council Directive 91/414/EEC as amended by Directive 96/68/EC Residues in or on treated products, food or feed
Guideline deviation(s): none
GLP/GEP: yes

Materials and Method

Studies on processing of grapes into grape juice and wine were conducted to determine the transfer of the residues of fosetyl-aluminium (fosetyl-Al) and its metabolite phosphonic acid from grape fruit into processed fractions.

Two supervised trials on vine were conducted in Northern France (trial 99629RS1/ vine variety: Chardonnay) and in Southern France (trial 99629AV1, vine variety: Grenache). The formulation used was EXP10745D (WG) containing fosetyl-Al and fenamidone.

A summary of the field part is presented in [Table 6.5.3- 4](#).

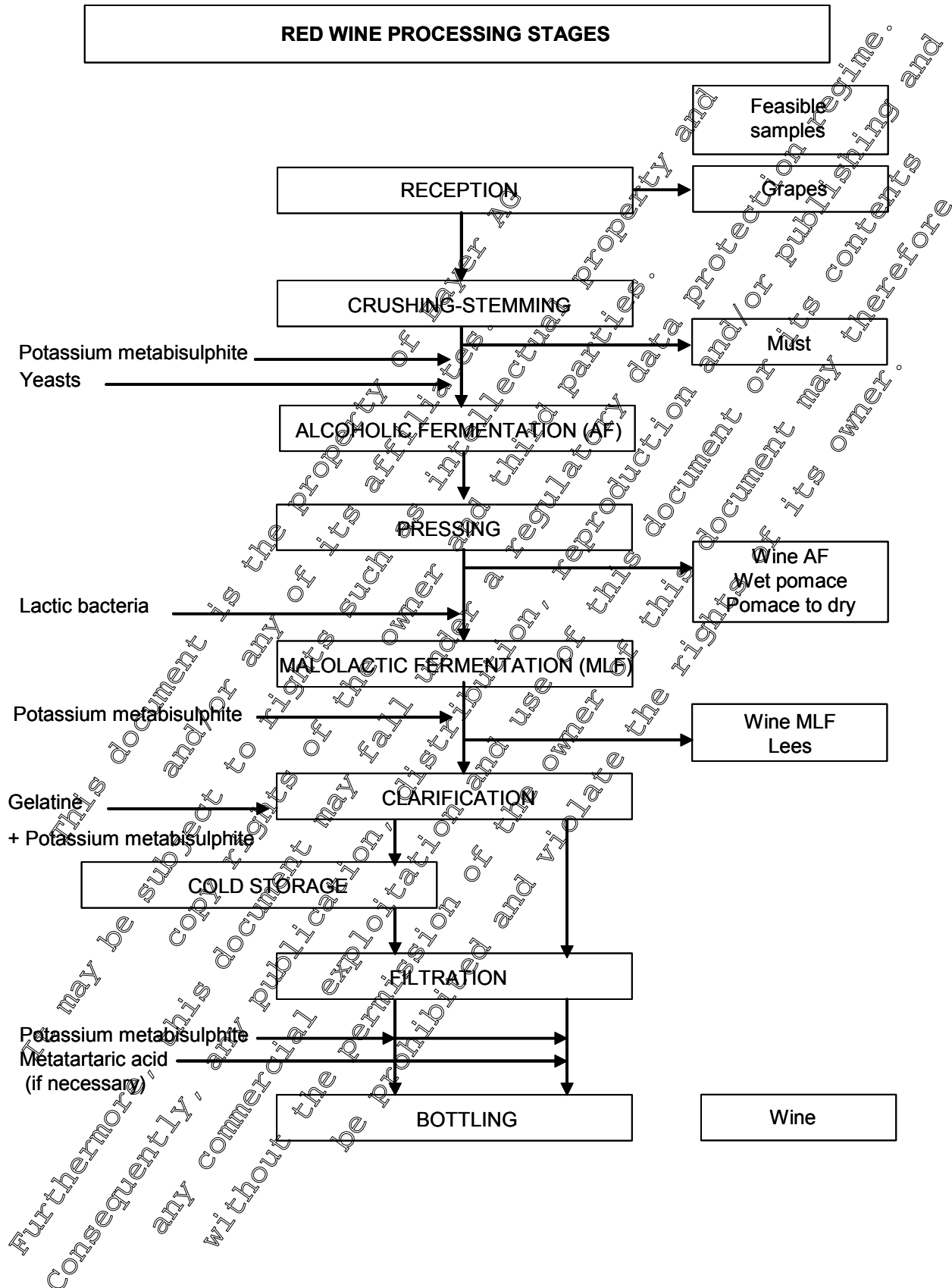
Table 6.5.3- 4: Field information

Trial No.	Application No.	Treatment dates (D/M/Y)	Dose rate fosetyl-Al per treatment (kg a.i./ha)	Water (l/ha)	Cumulated dose rate fosetyl-Al (kg a.i./ha)	PHI (days)
99629RS1 Northern France	4	05/07/1999	2.06	300	8.2	30
		21/07/1999	2.06	300		
		04/08/1999	2.06	300		
		07/08/1999	2.06	300		
99629AV1 Southern France	4	07/07/1999	2.06	273	8	28
		23/07/1999	2.06	273		
		08/08/1999	2.06	273		
		19/08/1999	2.06	273		

The processed fractions were produced from grape fruit samples (1 untreated and 1 treated per trial) obtained from 2 different trials. [redacted] wine was prepared from grape fruit coming from trial 99629RS1 and red wine was produced from grape fruit coming from trial 99629AV1. Grape juice was prepared from grape fruit coming from both trials. The processing procedures followed the VITI R&D methods No VINIF/01 (white wine processing), VINIF/002 (red wine processing) and VINIF/006 (grape juice processing). Flow charts to describe the production of red wine, white wine and grape juice are presented in [Figure 6.5.3- 1](#), [Figure 6.5.3- 2](#) and [Figure 6.5.3- 3](#).

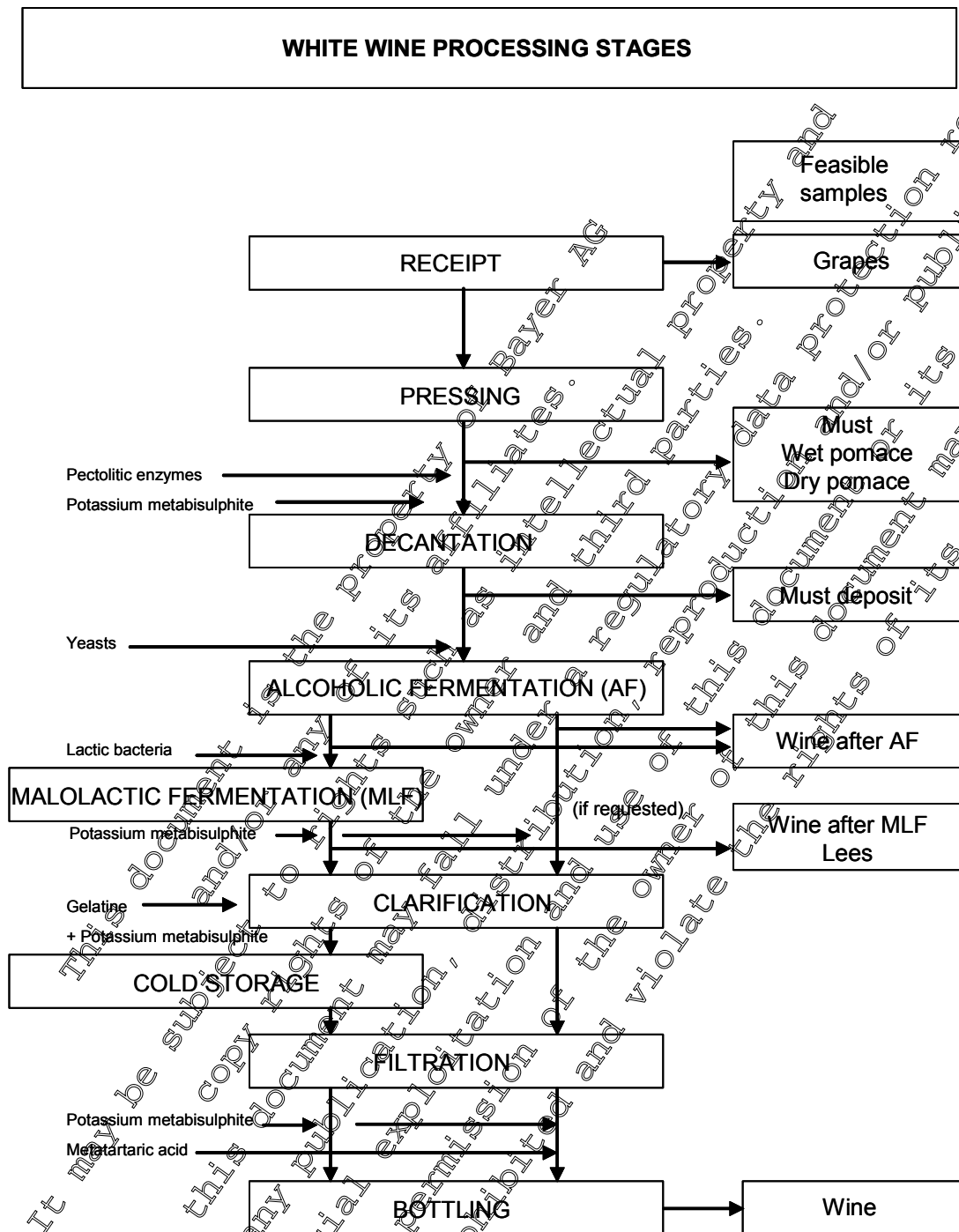
Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Figure 6.5.3- 1: Flow chart for the preparation of grapes into red wine



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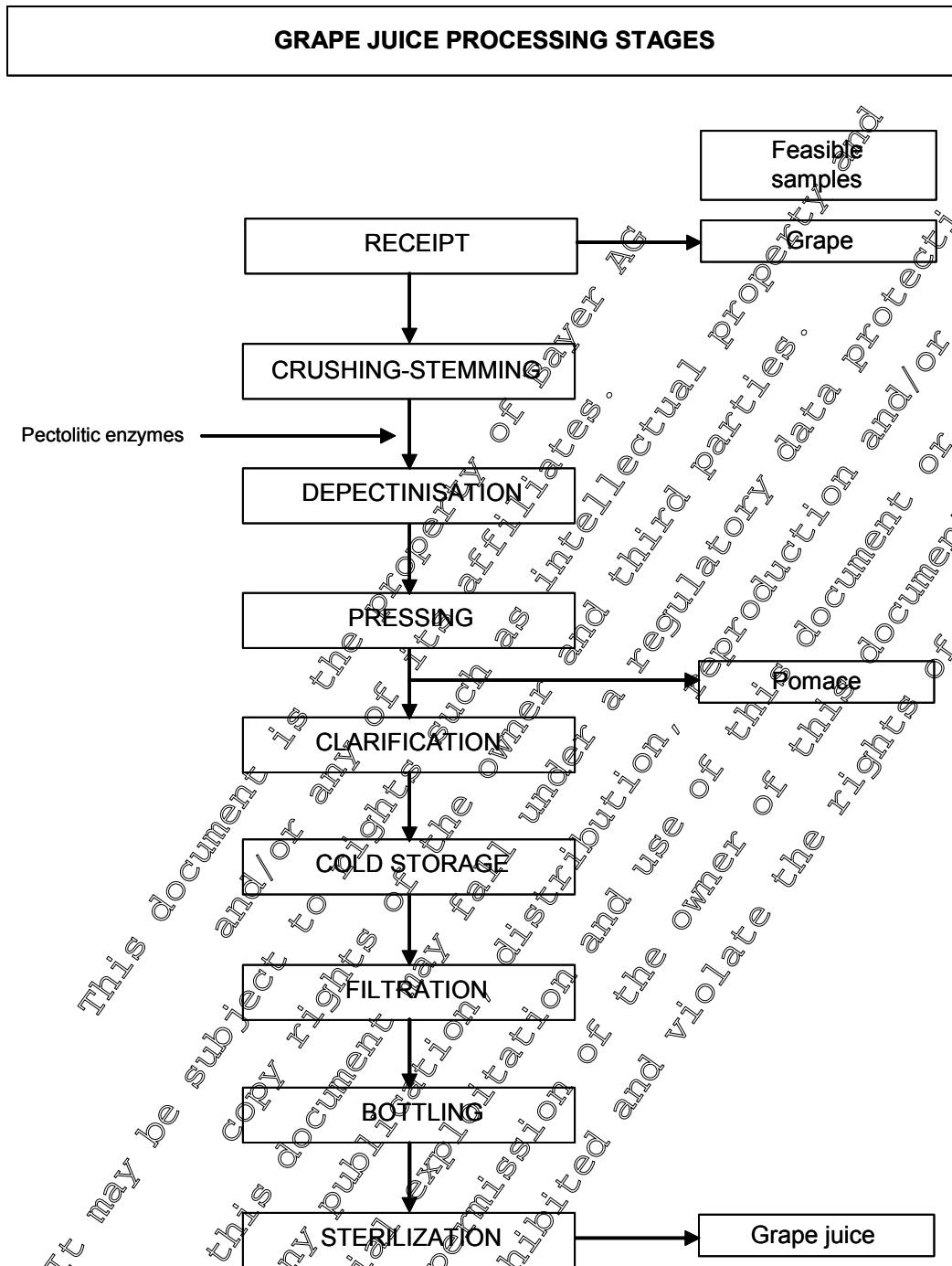
Figure 6.5.3- 2: Flow chart for the preparation of grapes into white wine



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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Figure 6.5.3- 3: Flow chart for the preparation of grapes into grape juice



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**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl**White wine production (trial 99629RS1)

After weighing the bunches, 10 kg grape samples were taken for grape juice processing. The remaining grapes were pressed with a water press and the must recovered in a stainless steel tank. The wet pomace was then weighed and discarded.

Two 0.65 L must samples were taken and placed in a freezer at approximately -20 °C. The must was decanted for at least 12 hours with the addition of pectolytic enzymes at 0.2 g/L and potassium metabisulphite at 0.14 g/L, according to the health status of the harvest. After decanting, the must deposit was discarded. Dry active yeast at 0.10 g/L was added to the must.

The progress of the alcoholic fermentation was followed each working day by measuring the density, temperature and pH of the must. The density and temperature were measured using a mustimeter, which was plunged into a 250 mL measuring-cylinder containing the must. The pH was measured with a pH-meter. The alcohol content estimated from the refractometric degree was judged insufficient to produce normal quality wine. Thus, white crystallized sugar was added to the must during alcoholic fermentation, in order to increase the probable alcohol content of all these samples to the same alcoholic content 11.5%.

The alcoholic fermentation was considered completed when the density of the must fell below the value 1000. Potassium metabisulphite (0.14 g/L) was then added. The wine was racked at least five days after the completion of alcoholic fermentation. To improve the clarification of the wine, 0.1 g/L of dry gelatine and 0.04 g/L of potassium metabisulphite were added to wine.

The wine was kept into demijohns and stored for 31 days in the cold room (temperature +5 to +10 °C) to be stabilized with regards to tartaric deposits and so that clarification could be achieved.

To remove impurities (solid material), the wine was filtered using a stainless steel filtration unit with a 10 litres capacity under pressure using nitrogen (maximum 3 bar). The filtration was carried out over cellulose filter plates of trimming 2.50 µm and 1.50 µm porosity at 90 mm diameter. During this operation, each sample received 10 g of potassium metabisulphite, which protects the wine from oxidation.

The new bottles were rinsed with water and then with wine to condition them. The wine was then bottled. For each sample, 2 x 0.65 L wine bottles were taken and immediately frozen (at approximately -20 °C).

Red wine production (trial 99629A01)

After weighing the bunches, 10 kg grape samples were taken for grape juice processing. The remaining grapes were pushed and tumbled with an electric crusher/stemmer. The crushed grapes were recovered in a stainless steel tank. Two 0.65 L must samples were sampled and placed in a freezer at approximately -20 °C. 0.08 g/L of potassium metabisulphite was added to the crushed grapes, according to the health status of the harvest. The must volume was estimated by division of the weight of the grapes with a coefficient depending on grape variety: 1.3. Dry active yeasts (0.10 g/L) were added to the must.

The progress of the alcoholic fermentation was followed each day by measuring the density, temperature and pH of the must. The density and temperature were measured using a mustimeter, which was plunged into a 250 mL measuring cylinder containing the must. The pH was measured with a pH-meter. The alcoholic fermentation was considered completed when the density of the must fell below the value 1000.

The wine was run off to the tank (free-run wine) and the solid part was pressed with a water press in such a manner as to recover the maximum quantity of wine. The pressed wine was added to the free-run wine in demijohns which were completely filled and the wet pomace was weighed and discarded.

The malolactic fermentation was carried out in absence of air, at ambient temperature with a direct inoculation of lactic bacteria: *Leuconostoc oenos*, after pressing to accelerate this process. The progress of the malolactic fermentation was monitored once a week by chromatography on paper.

When the malolactic fermentation was complete, 0.10 g/L of potassium metabisulphite was added to the samples and natural clarification occurred for 14 days. After racking, 0.10 g/L of dry gelatine and 0.04 g/L of potassium metabisulphite were added, to improve the clarification.

The wine was kept into demijohns and stored for 31 days, in the cold room (temperature +5 to +10 °C) to be stabilized with regards to tartaric deposits and so that clarification could be achieved.

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Fosetyl**

To remove impurities (solid material), the wine was filtered using a stainless steel filtration unit with a 10 litre capacity under pressure using nitrogen (maximum 3 bar).

The new bottles were rinsed with water and then with wine to condition them. The wine was then bottled. For each sample, 2 x 0.65 L wine bottles were taken and immediately frozen (at approximately -20 °C).

Grape juice production (trials 99629RS1 and 99629AV1)

After weighing the bunches, 10 kg grape samples were crushed and stemmed manually for the trial No 99629RS1 or with an electric crusher/stemmer for the trial No 99629AV1. The crushed grapes were recovered in a large sauce pan, weighed. After addition of pectolytic enzymes (0.05% per weight of grapes), the crushed grapes were transferred into glass jars which were placed in the steriliser containing warm water. The juice depectinisation lasted two hours with a temperature included in 40 and 60 °C.

After depectinisation, the crushed grapes were pressed with a water press. Degree Brix, pH and total Acidity were measured in juice obtained. The juice was transferred into glass jars which were placed in the steriliser containing warm water. The juice clarification lasted five minutes at a temperature bordering 85 °C.

The juice samples were stored for at least twelve hours in a cold room (+5, -10 °C) in order to obtain a deposit on the bottom of jars. After racking, the clear juice was filtered using a stainless steel filtration unit with a 10 litres capacity under pressure using nitrogen (maximum 3 bar). The filtration was carried out over cellulose filter plates of trimming porosity with 9 mm diameter.

The juice was pasteurized (1 minute at 85 °C) and bottled in glass jars closed with cap. For each sample, 4 x 0.45 L juice jars were taken and immediately frozen (approximately -20 °C).

The samples were analysed for the parent compound fosetyl-Al and the metabolite phosphonic acid following the analytical method based on the referenced method DFG 522. Residues of fosetyl-Al and phosphonic acid were extracted with acidic water, methylated with diazomethane then quantified by GC/FPD (Gas Chromatography / Flame Photometric Detector).

The limits of quantification (LOQ) were:

- 0.20 mg/kg for fosetyl-Al in all matrices
- 0.4 mg/kg for phosphonic acid in juice
- 0.0 mg/kg for phosphonic acid in fruit, meat and wine.

Findings

Validation of the method was performed during the study 98-563 for grape fruit and during the study 98-736 for wine. Recovery in grape fruit were at 73% (5xLOQ level) and 74% (10xLOQ level) for fosetyl-Al and 124% (5xLOQ level) and 111% (10xLOQ level) for phosphonic acid with LOQ at 0.20 mg/kg for both substances in fruit. Recoveries in wine were at 113 and 109% (5xLOQ level) for fosetyl-Al and 109 and 99% (5xLOQ level) for phosphonic acid with LOQ at 0.20 mg/kg for both substances in wine. Recovery findings in grape fruit and in processed commodities were considered as to be acceptable. Details of the concurrent recovery results are summarised in [Table 6.5.3- 5](#).

In most of the cases, the apparent residues in the control samples were below the LOQ. When the residue level of phosphonic acid was found to be above the LOQ, the contamination represented less than 12% of the amount of residues in the corresponding treated samples.

The maximum storage period of deep frozen processed samples was 294 days (from deep-freezing to last analysis).

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Fosetyl

Table 6.5.3- 5: Recovery results (concurrent recoveries) for fosetyl-Al and phosphonic acid in grapes and processed fractions

Sample Material	FL	n	Fosetyl-Al	Phosphonic acid	LOQ
	[mg/kg]		[%]	[%]	
Fruit	0.20	1	96	-	Fosetyl-Al : 0.20 Phosphonic acid : 0.40 in juice 0.50 in fruit, must and wine
	0.50	1	103	-	
	0.50	1	-	83	
	10.0	1	-	10	
Juice	0.20	1	87	-	
	0.50	1	-	-	
	0.40	1	-	-	
	6.0	1	-	98	
Must	0.20	1	101	-	
	0.50	2	76	-	
	0.50	1	-	80	
	2.0	1	-	-	
	10.0	1	-	105	
Wine	0.20	1	92	-	
	0.50	1	91	-	
	0.50	1	-	82	
	8.0	1	-	88	

FL = fortification level; n = number of tests

The total residue was calculated and expressed as fosetyl-Al in the report therefore it will be calculated in this dossier as total residue expressed as fosetyl (see Section CA 6.3 for calculation).

Residue values of fosetyl-Al, phosphonic acid and total residue expressed as fosetyl in grape and the processed by-products are summarised in Table 6.5.3- 6.

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.5.3- 6: Residues of fosetyl-Al, phosphonic acid and total residues of fosetyl in grape and processed fractions

Country	Crop	DALT (days)	Residues (mg/kg)			Transfer factor
			Fosetyl-Al	Phosphonic acid	Total residues expressed as fosetyl	
Northern France 99-629 99629RS1	Grape (RAC)	30	0.34	7.2	10.0	
	Grape juice	30	<0.20	3.6	5.0	0.5
	Must	30	0.34	4.1	5.0	0.8
	White Wine	30	0.34	2.4	2.5	0.4
Southern France 99-629 99629AV1	Grape (RAC)	28	0.94	12	17.0	
	Grape juice	28	0.20	8	11.8	
	Must	28	0.20	0.56	0.94	2.06
	Red Wine		0.48	9.4	13	0.8

RAC: Raw Agricultural Commodity DALT: days after last application
*: must sampling during the wine processing before the fermentation step

Conclusion

Two supervised trials on vine were conducted in Northern France (variety, Chardonnay) and in Southern France (variety Grenache). Each trial received four applications of the formulation EXP10745D (WG) containing fenamidone and fosetyl-Al. Grape samples were processed into wine and juice. Transfer factor calculated for the total residue ranged between 0.4 and 0.8 from grape fruit into wine and 0.5 to 0.7 from grape into juice.

Report:

Title: KCA 6.5.3/07 [redacted] 2000; M-189118-01-1
Residues in grape (fruit) and processed products (wine) Fenamidone and metabolite (RPA 5862) fosetyl-Al and metabolite (phosphorous acid) Formulations EXP10745D (WG) and EXP10936B (WG) North / France / 1999 - 2 harvest trials 99-531
Report No.: M-189118-01-1
Document No.: M-189118-01-1
Guideline(s): EU Council Directive 91/413/EEC as amended by Directive 96/68/EC Residues in or on treated products, food and feed
Guideline deviation(s): none
GLP/GEIP: yes

Materials and Method

Studies on processing of grape into wine were conducted to determine the transfer of the residues of fosetyl-Al and its metabolite phosphonic acid from grapes into processed fraction. Two supervised trials on vine were conducted in Northern France (trial 99531RS1, vine variety: Chardonnay and trial 99631D, vine variety: Pinot noir). The formulations used were EXP10745D (WG) containing fenamidone and fosetyl-Al and EXP10936B (WG) containing fenamidone and copper hydroxide. Several plots were defined where three, four or five foliar applications were performed. Both plots which received four applications of EXP10745D were dedicated to grape processing.

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A summary of the corresponding field part is presented in [Table 6.5.3- 7](#).

Table 6.5.3- 7: Field information

Trial No.	Repetition	Application No.	Treatment dates D/M/Y	Dose rate fosetyl-Al per treatment (kg a.i./ha)	Water (L/ha)	Cumulated dose rate fosetyl-Al (kg a.i./ha)	PH (days)
99531RS1 Northern France	1	4	02/06/1999	2.33	432	8	74
			16/06/1999	2.06	432		
			28/06/1999	2.06	432		
			09/07/1999	2.06	432		
	2	4	02/06/1999	2.06	432	8	74
			16/06/1999	2.06	418		
			28/06/1999	2.06	487		
			09/07/1999	2.06	432		
99531DJ1 Northern France	1	4	04/06/1999	2.06	300	8	81
			16/06/1999	2.06	300		
			25/06/1999	2.06	300		
			01/07/1999	2.06	300		
	2	4	04/06/1999	2.06	300	8	81
			11/06/1999	2.06	300		
			25/06/1999	2.06	300		
			01/07/1999	2.06	300		

The processed fractions were produced from grape samples (1 untreated and 1 treated per trial) obtained from 2 trials. White wine was prepared from grapes coming from trial 99531RS1 and red wine was produced from grapefruit coming from trial 99531DJ1. The non-treated samples were processed prior to the treated samples. Separating equipment was used for the non-treated and treated samples. The processing procedures followed VITI R&D methods No VINIF/001 (white wine processing) and VINIF/002 (red wine processing). Flow charts to describe the production of red wine and white wine are presented in [Figure 6.5.3- 1](#) and [Figure 6.5.3- 2](#), respectively.

White wine production (trial 99531RS1)

After weighing the bunches, the grapes were pressed with a water press and the must recovered in a stainless steel tank. The wet pomace was then weighed. The must was decanted for at least 12 hours with the addition of catalase enzymes at 0.02 g/L and potassium metabisulphite at 0.14 g/L, according to the health state of the harvest. After decanting, the must deposit was discarded. Dry active yeast at 0.10 g/L was added to the must.

The progress of the alcoholic fermentation was followed each working day by measuring the density, temperature and pH of the must. The density and temperature were measured using a mustimeter, which was plunged into a 200 mL measuring cylinder containing the must. The pH was measured with a pH meter.

The alcohol content estimated from the refractometric degree was judged insufficient to produce normal quality wine. Thus, white crystallised sugar was added to the must during alcoholic fermentation in order to increase a probable alcohol content of all these samples to 2.0%.

The alcoholic fermentation was considered completed when the density of the must fell below the value 1.000. Then, potassium metabisulphite (0.10 g/L) was added. The wine was racked seven days after the completion of alcoholic fermentation. To improve the clarification of the wine, 0.10 g/L of dry stabilising and 0.4 g/L of potassium metabisulphite were added to wine.

The wine was kept into demijohns and stored for 31 days in the cold room (temperature +5 to +10 °C) to be stabilized with regards to tartaric deposits and so that clarification could be achieved.

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl**

To remove impurities (solid material), the wine was filtered using a stainless steel filtration unit with a 10 litres capacity under pressure using nitrogen (maximum 3 bar). The filtration was carried out over cellulose filter plates of trimming, 2.50 µm and 1.50 µm porosity and 90 mm diameter. During this operation, each sample received 0.10 g/L of potassium metabisulphite, which protects the wine from oxidation.

The new bottles were rinsed with water and then with wine to condition them. The wine was then bottled. For each sample, 2 x 0.65 L wine bottles were taken and immediately frozen (at approximately -20 °C).

Red wine production (trial 99531DJ1)

The grape samples were weighed, then crushed and stemmed with an electric crusher/hammer. The crushed grapes were recovered in a stainless steel tank. 0.08 g/L of potassium metabisulphite was added to the crushed grapes, according to the health status of the harvest. The must volume was estimated by division of the weight of the grapes with a coefficient depending on grape variety: 1. Dry active yeasts (0.10 g/L) were added to the must. The progress of the alcoholic fermentation was followed each day by measuring the density, temperature and pH of the must. The density and temperature were measured using a mustimeter, which was plunged into a 250 mL measuring cylinder containing the must. The pH was measured with a pH meter.

The alcoholic fermentation was considered completed when the density of the must fell below the value 1000. The wine was run off the tank (free-run wine) and the solid part was pressed with a water press in such a manner as to recover the maximum quantity of wine. The pressed wine was added to the free-run wine in demijohns which were completely filled and the wet pomace was weighed and discarded.

The malolactic fermentation was carried out in the absence of air at ambient temperature with a direct inoculation of lactic bacteria: *Lactobacillus*, after pressing, to accelerate this process. The progress of the malolactic fermentation was monitored once a week by chromatography on paper. When the malolactic fermentation was complete, 0.10 g/L of potassium metabisulphite was added to the samples and natural clarification occurred for nine days. After racking, 0.10 g/L of dry gelatine and 0.04 g/L of potassium metabisulphite were added to improve the clarification.

The wine was kept into demijohns and stored for 22 days, in the cold room (temperature +5 to +10 °C) to be stabilized with regards to tartaric deposits and so that clarification could be achieved.

To remove impurities (solid material), the wine was filtered using a stainless steel filtration unit with a 10 litre capacity under pressure using nitrogen (maximum 3 bar).

The new bottles were rinsed with water and then with wine to condition them. The wine was then bottled. For each sample, 2 x 0.65 L wine bottles were taken and immediately frozen (at approximately -20 °C).

The samples were analysed for the parent compound fosetyl-Al and the metabolite phosphonic acid following the analytical method based on the referenced method DFG 522.

Residues of fosetyl-Al and phosphonic acid were extracted with acidic water, methylated with diazomethane then quantified by GC/FPD (Gas Chromatography / Flame Photometric Detector).

The limit of quantification (LOQ) was 0.10 mg/kg for each analyte in all matrices.

Findings

Validation of the method was performed during the study 98-563 for grape fruit and during the study 98-736 for wine. Recoveries in grape fruit were at 73% (5xLOQ level) and 74% (10xLOQ level) for fosetyl-Al and 24% (5xLOQ level) and 112% (10xLOQ level) for phosphonic acid with LOQ at 0.20 mg/kg for both substances in fruit. Recoveries in wine were at 113 and 109% (5xLOQ level) for fosetyl-Al and 109 and 109% (5xLOQ level) for phosphonic acid with LOQ at 0.20 mg/kg for both substances in wine.

Recovery findings in grape fruit and in processed commodities were considered as to be acceptable.

Details of the recovery results are summarised in [Table 6.5.3- 8](#).

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The apparent residues in the control samples were below the LOQ. The maximum storage period of deep frozen processed samples was 230 days (from deep-freezing to last analysis).

Table 6.5.3- 8: Recovery results (concurrent recoveries) for fosetyl-Al and phosphonic acid in grapes and processed fractions

Sample Material	FL [mg/kg]	n	Fosetyl-Al [%]	Phosphonic acid [%]	LOQ [mg/kg]
Fruit	0.20	2	86; 108	-	0.20
	0.20	1	-	76*	
	0.40	2	73; 76	-	
	0.50	1	72	-	
	4.0	1	-	89	
	5.0	1	-	91	
	8.0	1	-	94	
Wine	0.20	1	72; 100, 109	71**	0.20
	6.0	1	-	-	

FL = fortification level; n = number of tests

*: recovery corrected by the estimated residue level found in the control sample (0.19 mg/kg)

** : recovery corrected by the estimated residue level found in the control sample (0.5 mg/kg)

The total residues was calculated and expressed as fosetyl-Al in the report therefore it will be calculated here as total residue expressed as fosetyl (see Section CA 6.3 for calculation).

Residue values of fosetyl-Al, phosphonic acid and total residue expressed as fosetyl in grapes and the processed by-products are summarized in Table 6.5.3- 9

Table 6.5.3- 9: Residues of fosetyl-Al, phosphonic acid and total residues of fosetyl in grapes and processed fractions

Country	Crop	DALT (days)	Residues (mg/kg)			Transfer factor
			Fosetyl-Al	Phosphonic acid	Total residues expressed as fosetyl	
Northern France 99-531 99531RS1	Grape fruit (RA)	74	<0.20	9.0	12.3	-
	White Wine	74	<0.20	4.9	6.8	0.6
Northern France 99-531 99531RS1	Grape fruit (RA)	74	<0.20	6.8	9.3	-
	White Wine	74	<0.20	3.4	4.7	0.5
Northern France 99-531 99531DJ	Grape fruit (RA)	81	<0.20	9.7	13.2	-
	Red Wine	81	<0.20	6.7	9.2	0.7
Northern France 99-531 99531DJ	Grape fruit (RA)	81	<0.20	11	14.9	-
	Red Wine	81	0.24	6.8	9.3	0.6

RA: Raw Agricultural Commodity DALT = days after last application

**Document MCA – Section 6: Residues in or on treated products, food and feed
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Two supervised trials on vine were conducted in Northern France (varieties, Chardonnay and Pinot noir). In each trial, two plots received four applications of the formulation EXP10745D (WG) containing fenamidone and fosetyl-Al. Grape samples were processed into white wine or red wine. Transfer factor calculated for the total residue ranged between 0.5 and 0.7 from grape fruit into wine.

Report: KCA 6.5.3/14 [REDACTED]; 2003; M-228263-01-1

Title: Study 00-2006 Formulation EXP10745D Residues of Fosetyl-Al and phosphorous acid (metabolite), fenamidone and FSA405862 (metabolite) and aluminium in grapes, processed products and intermediate fractions

Report No.: 00-2006

Document No.: M-228263-01-1

Guideline(s): none

Guideline deviation(s): not applicable

GLP/GEP: yes

Report: KCA 6.5.3/15 [REDACTED]; 2003; M-228237-01-1

Title: Etude des effets non intentionnels de la préparation fondide expérimentale EXP10745D sur l'élaboration et la qualité des jus et des vins

Report No.: VCE0001AV

Document No.: M-228237-01-1

Guideline(s): none

Guideline deviation(s): not applicable

GLP/GEP: no

Report: KCA 6.5.3/16 [REDACTED]; 2002; M-228225-01-1

Title: Fosetyl-Al and phosphorous acid (metabolite) Formulation EXP10745D (Trial FRA01F47) Residues in grapes (fruit and processed fractions)

Report No.: AVE/01-01

Document No.: M-228225-01-1

Guideline(s): none

Guideline deviation(s): not applicable

GLP/GEP: yes

Report: KCA 6.5.3/17 [REDACTED]; 2003; M-228229-01-1

Title: Determination of the residues of aluminium in grapes and in processed products after application of fosetyl-aluminium

Report No.: AVA2901

Document No.: M-228229-01-1

Guideline(s): none

Guideline deviation(s): not applicable

GLP/GEP: yes

Materials and Method

Study on processing of grapes into wine was conducted to determine the transfer of the residues of fosetyl-aluminium (fosetyl-Al) and its metabolite phosphonic acid from grapes into processed fractions. The objective of this study was to evaluate the unintentional effects of various numbers of treatments with EXP10745D on production and quality of wines, in comparison with a commercial reference fungicide (Pacneos). A specific analytical study was conducted to determine the residues of aluminium in grapes and processed products (must and wine).

The study is summarised in the document M-228263-01-1. The processing phase of the study is reported under the document M-228237-01-1 and the analytical phases under documents M-228225-01-1 and M-228229-01-1.

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One supervised trial on vine was conducted in Southern France (trial FRA00F47, vine variety: Gamay). The formulations used were:

- Pantheos containing dimethomorph (113 g/kg) and folpet (600 g/kg)
- EXP10745D (WG) containing fosetyl-Al (667 g/kg) and fenamidone (44 g/kg).

Detailed descriptions on the performed treatments are presented in the following table:

Table 6.5.3- 10: Field information

Plot Ref.	1R	2R	3R	4R	5R
Program	Ref	P1	P2	P3	P6
Number of treatments	6	6	6	6	6
Treatments with fosetyl-Al	0			5	
Treatment 1	Pantheos	Pantheos	Pantheos		
Treatment 2					
Treatment 3		EXP10745D	EXP10745D	EXP10745D	
Treatment 4					
Treatment 5					
Treatment 6					

Dose rates: Pantheos: 2 kg/ha
EXP10745D: 3 kg/ha

The processed fractions were produced from grapes (samples: 1 untreated and 4 treated) obtained from 1 trial. The red wine processing procedure was performed by VIN & C. Flow chart to describe the production of red wine is presented in [Figure 6.5.3- 1](#).

From each trial plot, 4 batches (replicates) of 20 kg were received at the processing laboratory. On each batch, the percentage of damaged berries was estimated and a sampling of 100 berries was made for the refractometric index. After the mixing of the four batches of each plot, the grapes were crushed and stemmed using a crusher-stemmer, then separated at a level of 3 g/hL or more, depending on the health status. Each working day, the cap was manually punched or a pumping-over was carried out, and densities and temperature were recorded.

The start of the alcoholic fermentation was systematically induced, by adding yeast at a level of 10g/hL (*Saccharomyces Cerevisiae* « FV K1 Marqués », obtained from Institut Cooperatif du Vin). The alcoholic fermentation completed, the free run wine was run off and the pomace pressed ; free run wine and press wine were then mixed, stored in full, closed containers in order to wait the malolactic fermentation process without any further sulphuring.

The start of the malolactic fermentation was systematically induced by a sowing, after pressing, of lactic bacteria *Leuconostoc oenos* « Vinifera oenos » from Institut Cooperatif du Vin), at a level of 1 g/hL. Before this sowing a wine sample was put into a small bottle to research the natural malolactic fermentation. The progress of the malolactic fermentation was followed weekly using paper chromatography. Once it was finished, the wine was sulphited at a level of 5 g/hL, then racked, fined with dry gelatin (10 g/hL), clarified by cold storage (at least one month at + 5°C), filtered and bottled. At bottling the SO₂ level was readjusted in order to obtain a free SO₂ level between 25 and 30 mg/L.

The samples were analysed for the parent compound fosetyl-Al and the metabolite phosphonic acid following the analytical method based on the referenced method DFG 522.

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Residues of fosetyl-Al and phosphonic acid were extracted with acidic water, methylated with diazomethane then quantified by GC/FPD (Gas Chromatography / Flame Photometric Detector).

The limits of quantification (LOQ) were:

- 0.20 mg/kg for fosetyl-Al in all matrices,
- 0.20 mg/kg for phosphonic acid in fruit, must and wine,
- 0.50 mg/kg for phosphonic acid in wine after malolactic fermentation, wine after alcohol fermentation, wine before filtration, lees and pomace.

The samples were examined for aluminium by the method of G. [REDACTED] ("Eine Methode zur Bestimmung von Aluminium in Obst und Gemüsen mittels ICP-OES" VA Method 01-S.O.P./10002; 13. February 2001). The sample material was digested with a mixture of nitric acid, perchloric acid and sulfuric acid at a temperature of 180 °C after evaporating and dilution with aqueous nitric acid solution the aluminium content was determined by ICP-Emission Spectrometry (ICP-OES) at 396.149 nm.

The level of method and result validation was depending of the level of aluminium naturally present in the untreated samples. Therefore, at first the natural aluminium content in the untreated samples was determined and thereafter the fortification levels were established for definition of the limit of quantification 5 reagent blanks were fortified with 20 µg aluminium as fosetyl-Al and worked up according to the sample preparation procedure. The fortification level corresponds to a limit of quantification of 1 mg/kg aluminium.

For fruit, validation was performed at level of 10 mg/kg aluminium as fosetyl-Al. For must, marc and less of wine E_M, validation was performed at level of 50 mg/kg and 20 mg/kg at levels of 2 and 6 mg/kg aluminium as fosetyl-Al.

Findings

In the case of recovery experiments for DFG 322 method validation, recovery means were within the range of 72 to 109% with RSD 20% as shown in [Table 6.5.3- 11](#). All results of the methods validation are in accordance with the general requirements for residue analytical methods.

For concurrent recoveries, findings in grape fruit and in processed commodities were considered as to be acceptable. Details of the recovery results are summarized in [Table 6.5.3- 12](#).

In most of the cases, the apparent residues in the control samples were below the LOQ. When the residue level of phosphonic acid was found to be above the LOQ, the contamination represented less than 14% of the amount of residues in the corresponding treated samples.

The maximum storage period of deep frozen processed samples was 293 days (from deep-freezing to last analysis).

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Table 6.5.3- 11: Method validation data for fosetyl-Al and phosphonic acid in grape and processed fractions

Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LLO [µg/kg]
00-2006	DFG 522	Fosetyl-Al	fruit	0.20	90; 89	90	-	0.20
				2.0	91; 84	88	-	
				Overall Recovery (n = 2)		89	9.5	
		Phosphonic acid	fruit	0.20	97; 88	103	-	
				5.0	87; 93	89	-	
				Overall Recovery (n = 4)		90	10.4	
00-2006	DFG 522	Fosetyl-Al	must	0.20	98; 85	102	-	0.20
				2.0	96; 73	85	-	
				Overall Recovery (n = 2)		14.9	14.9	
		Phosphonic acid	must	0.20	110; 107	109	-	
				5.0	90; 89	90	-	
				Overall Recovery (n = 2)		11.2	11.2	
00-2006	DFG 522	Fosetyl-Al	wine	0.20	107; 92	98	-	0.20
				2.0	93; 98	84	-	
				Overall Recovery (n = 4)		91	6.0	
		Phosphonic acid	wine	0.20	97; 88	90	-	
				2.0	111; 89	100	-	
				Overall Recovery (n = 4)		95	11.4	
00-2006	DFG 522	Fosetyl-Al	Wine (after malolactic fermentation)	0.20	82; 87	85	-	0.20
				2.0	114; 85; 90	93	10.4	
				Overall Recovery (n = 5)		90	9.6	
		Phosphonic acid	Wine (after malolactic fermentation)	0.50	88; 92	91	-	
				2.0	81; 89	-	-	
				2.0	80; 84	82	-	
Overall Recovery (n = 5)		87	5.5					
00-2006	DFG 522	Fosetyl-Al	Wine (after alcoholic fermentation)	0.20	101; 96	99	-	0.20
				2.0	78; 88	83	-	
				Overall Recovery (n = 4)		91	11.1	
		Phosphonic acid	Wine (after alcoholic fermentation)	0.50	88; 93	91	3.9	
				5.0	80; 84	82	-	
				Overall Recovery (n = 4)		86	6.4	

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Report No.	Analytical method	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
00-2006	DFG 522	Fosetyl-Al	Lees	0.20	93; 104	99	-	0.20
				2.0	103; 78; 84	88	14.8	
				Overall Recovery (n = 5)		92	12.4	
		Phosphonic acid	Lees	0.50	72; 72	72	-	0.50
				2.0	96	-	-	
				Overall Recovery (n = 5)		81	13	
00-2006	DFG 522	Fosetyl-Al	Wine (before filtration)	0.20	81; 88	-	-	0.20
				2.0	93; 89	91	-	
				Overall Recovery (n = 4)		88	27	
		Phosphonic acid	Wine (before filtration)	0.20	99; 94	-	-	0.20
				2.0	96; 98	97	-	
				Overall Recovery (n = 4)		91	27	
00-2006	DFG 522	Fosetyl-Al	Pomac	0.20	81	-	-	0.20
				2.0	-	-	-	
				Overall Recovery (n = 2)		75	-	
		Phosphonic acid	Pomac	0.50	100	-	-	0.50
				5.0	-	-	-	
				Overall Recovery (n = 2)		50	-	

RSD: Relative Standard Deviation LOQ: Practical Limit of Quantification

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Table 6.5.3- 12: Recovery results (concurrent recoveries) for fosetyl-Al and phosphonic acid in grape and processed fractions

Sample Material	FL [mg/kg]	n	Fosetyl-Al [%]	Phosphonic acid [%]	LOQ [mg/kg]
Fruit	0.20	1	79	105	Fosetyl-Al : 0.20 in fruit, must and wine Phosphonic acid: 0.20 in wine after malolactic fermentation, wine before alcoholic fermentation, wine before filtration, lees and pomace
	0.50	1	74	-	
	1.0	1	94	-	
	5.0	1	-	85	
	10.0	1	-	89	
Must	0.20	1	82	-	
	0.50	1	74	-	
	1.0	1	72	-	
	5.0	1	-	70	
	10.0	1	-	70	
Wine	0.20	1	81	109	
	1.0	1	81	109	
	10.0	1	-	109	
Wine (after malolactic fermentation)	1.0	1	75	-	
Wine (after alcoholic fermentation)	0.50	1	105	-	
Lees	0.20	1	-	-	
	0.50	1	98	-	
	0.50	1	-	104	
	1.0	1	-	-	
	5.0	1	-	105	
	10.0	1	-	95	
Wine (before filtration)	0.20	1	87	-	
	0.50	1	83	-	
	0.50	1	-	90*	
	5.0	1	-	95	
Pomace	1.0	1	76	-	
	0.50	1	-	85	

FL = fortification level; n = number of tests; LOQ = Practical Limit of Quantification

*: taking into account the presence of interference in the control sample injected with the analysis sequence

Residue values of fosetyl-Al, phosphonic acid and total residue of fosetyl (expressed as fosetyl) in grape fruit and the processed by-products are summarised in [Table 6.5.3- 13](#).

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Table 6.5.3- 13: Residues of fosetyl-Al, phosphonic acid and total residues of fosetyl in grape and processed fractions

Country Study No. Trial No. Plot Ref.	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L)			Transf facto
			Fosetyl-Al	Phosphonic acid	Total residues calculated as fosetyl	
Southern France 00-2006 FRA00F47 2R	Grape (RAC)	78	<0.20*	4.0*	5.6	
	Must	78	<0.20*	0.58*	1.0	0.2
	Wine (after alcoholic fermentation)	78	<0.20	1.6	2.3	0.5
	Pomace	78	<0.20	5.3	5.3	0.6
	Wine (after malolactic fermentation)	78	<0.20	1.8	2.3	0.5
	Lees (1st clarification)	78	<0.20	4.1	4.1	0.7
	Wine (before filtration)	78	<0.20	1.6	2.6	0.5
	Lees (2nd clarification)	78	<0.20	2.7	2.7	0.4
Southern France 00-2006 FRA00F47 3R	Grape (RAC)	64	<0.20*	1.6*	-	-
	Must	64	<0.20*	3.2*	4.5	0.3
	Wine (after alcoholic fermentation)	64	<0.20	0.9	5.4	0.4
	Pomace	64	<0.20	16	16	1.2
	Wine (after malolactic fermentation)	64	<0.20	4.1	5.7	0.4
	Lees (1st clarification)	64	<0.20	6.8	9.3	0.7
	Wine (before filtration)	64	<0.20	4.2	5.8	0.4
	Lees (2nd clarification)	64	<0.20	4.9	6.8	0.5
Red Wine (after bottling)	64	<0.20	4.9	6.8	0.5	

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Country Study No. Trial No. Plot Ref.	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L)			Transfer factor
			Fosetyl-Al	Phosphonic acid	Total residues calculated as fosetyl	
Southern France 00-2006 FRA00F47 4R	Grape (RAC)	50	<0.20*	16*	-	-
	Must	50	0.35*	5.8*	8.1	0.6
	Wine (after alcoholic fermentation)	50	<0.20	8.6	12	0.9
	Pomace	50	<0.20	22	30	2.5
	Wine (after malolactic fermentation)	50	<0.20	7.2	9.8	0.8
	Lees (1st clarification)	50	<0.20	12	18	1.5
	Wine (before filtration)	50	<0.20	8	9.3	0.8
	Lees (2nd clarification)	50	<0.20	7.8	12	1.0
	Red Wine (after bottling)	50	<0.20	6	2.3	0.1
Southern France 00-2006 FRA00F47 5R	Grape (RAC)	35	<0.20*	8.9*	12	-
	Must	35	0.22*	5.5*	7.6	0.6
	Wine (after alcoholic fermentation)	35	<0.20	8.4	12	0.9
	Pomace	35	<0.20	22	30	2.5
	Wine (after malolactic fermentation)	35	<0.20	7.2	9.8	0.8
	Lees (1st clarification)	35	<0.20	13	18	1.5
	Wine (before filtration)	35	<0.20	8	9.3	0.8
	Lees (2nd clarification)	35	<0.20	9	12	1.0
	Red Wine (after bottling)	35	<0.20	11	15	1.3

RAC: Raw Agricultural Commodity DALT = days after last application

* Each result corresponds to the mean of two determinations.

Note: Must samples obtained after crushing step, pomace samples obtained after alcoholic fermentation and pressing step

For aluminium results, the results obtained by definition of the limit of quantification and the recovery rates obtained by method and results validation are recorded in [Table 6.5.3- 14](#).

Recovery mean (n ≥ 5) in grape fruit and in processed commodities were within the range of 85 to 100% with RSD < 20% and therefore were considered as to be acceptable.

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Table 6.5.3- 14: Recovery results (method and result validation) for aluminium in blank, grapes and processed fractions

Sample Material	FL		Single values [%]	Mean Value [%]	RSD [%]
	Level	Unit			
Reagent blank	0.20	µg	91; 95; 100; 101; 111	100	6.8
Fruit	10	mg/kg	87; 81; 95; 102; 91	91	11.8
Must, marc, less of wine	50	mg/kg	96; 93; 92; 95; 96	92	4.9
Wine	2.0	mg/kg	81; 82; 100; 78; 87; 83	85	14.4
	6.0	mg/kg	88	-	-
Overall Recovery (n=6)					
				88	9.9

FL = fortification level fosetyl-Al at levels of aluminium µg
n = number of tests RSD: Relative Standard Deviation

Residue values of aluminium in grapes and the processed by products are summarised in Table 6.5.3- 15.

Table 6.5.3- 15: Residues of aluminium in grapes and processed fractions

Stage	Fraction	Residue aluminium (mg/kg)		Variation [%]
		Unreated		
		Program Result	Mean Result	
Receipt	Fruit	1R	7.8	28
		3R	8.6	8
		4R	8.1	10
		5R	6.6	-20
Crushing	Must	1R	15.8	-64
		2R	15.7	-64
		3R	12.8	-102
		4R	14.4	-79
Alcoholic fermentation (AF)	Wine (W_alco_F)	2R	3.3	-12
		3R	4.3	14
		4R	3.2	-16
		5R	4.1	10
	Pomace	1R	2R	74.2
3R			61.7	-2
4R			52.4	-20
5R			83.8	25

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Stage	Fraction	Residues aluminium (mg/kg)				Variation %
		Untreated		Treated		
		Program	Mean Result	Program	Mean Result	
Malolactique fermentation (MLF)	Wine MLF (W_E_Malco_F)	1R	< 1.0	2R	< 1.0	-
				3R	< 1.0	-
				4R	< 1.0	-
				5R	< 1.0	-
	Lees of clarification 1 (Less on wine E_M)	1R	48.3	2R	70.5	31
				3R	110	55
				4R	10.5	1
				5R	48.0	-1
Clarification 2	No filtered wine	1R	< 1.0	2R	< 1.0	-
				3R	< 1.0	-
				4R	< 1.0	-
				5R	< 1.0	-
	Lees of clarification 2 (Less on wine E_A)	1R	1.0	2R	1.2	-
				3R	-	-
				4R	< 1.0	-
				5R	< 1.0	-
Filtration and bottling	Wine	1R	< 1.0	2R	< 1.0	-
				3R	< 1.0	-
				4R	< 1.0	-
				5R	< 1.0	-
				5R	1.0	-

Program 1R: 1 application EXP 11074A "reference" compound (folpet Dimethylmorph)
 Program 2R: 1 application EXP 10745D + 5 Reference
 Program 3R: 3 applications EXP 10745D, 3 Reference
 Program 4R: 5 applications EXP 10745D, 1 Reference
 Program 5R: 6 applications EXP 10745D, 1 Reference

Conclusion

Two supervised trials on vine were conducted in Northern France (variety Chardonnay) and in Southern France (variety Gamache). Each trial received four applications of the formulation EXP10745D (WG) containing fosetyl-Al and pyramidone. Grape samples were processed into wine and juice.

Transfer factor calculated for the total residue ranged between 0.4 and 0.8 from grape fruit into wine and 0.5 to 0.7 from grape into juice.

The analysis of aluminium residues in different samples do not reveal any significant difference between specimens from crop untreated with fosetyl-Al containing formulations and specimens from treated crops. The highest aluminium levels are found in "solid" fractions such as pomace and lees with no significant difference between treated and untreated. The liquid fraction "wine" contains aluminium in < LOQ level only.

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Average factors were calculated for the transfer of total residues of fosetyl from grapes into wine and juice, combining recent trials with those already evaluated during the EU evaluation process for the Annex I inclusion of fosetyl under Directive 91/414/EEC. They are summarised in [Table 6.5.3- 16](#).

Table 6.5.3- 16: Transfer factor for the total residues of fosetyl in wine and grape juice

Study Number	Trial Number Location	Transfer factors for wine	Transfer factors for juice	Remark
96-598	96598DJ1 Northern France	1.4	1.0	Production of red wine
	96598TL1 Northern France	1.8	1.2	
98-562	98562RN1 Northern France	0.9	1.0	Production of red wine
	98562AV1 Southern France	0.1	1.0	
	98562TL1 Southern France	1.3	1.1	
98-721	98721BO1 Italy	0.6	-	Production of white wine
	98721BO1 Italy	1.1	-	
98-736	98736BO1 Italy	1.5	-	Production of white wine
98-738	98738BO1 Italy	0.2	-	Production of white wine
99-629	99629RS1 Northern France	0.3	0.5	Production of white wine
	99629AV1 Southern France	0.8	0.7	Production of red wine
99-531	99531RS1 Northern France	0.6	-	Production of white wine
	99531RS1 Northern France	0.5	-	
	99531DJ1 Northern France	0.7	-	Production of red wine
	99531DJ1 Northern France	0.6	-	
00-266	FRA00F46 2R Southern France	2.5	-	Production of red wine
	FRA00F47 1R Southern France	0.5	-	
	FRA00F47 4R Southern France	0	-	
	FRA00F47 5R Southern France	1.3	-	
	Min	0.1	0.5	
	Max	2.5	1.2	
	Mean	0.9	0.9	
	Median	0.8	1.0	

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Pome fruit

Studies investigating the magnitude of residues in processed commodities of apples were submitted in the MRL compilation dossier.

In the Review of the existing maximum residue levels (MRLs) for fosetyl, EFSA did not state on these studies as EFSA considered that they are not expected to affect the outcome of the risk assessment. Therefore this study is presented in this dossier.

An overview of the available processing studies is provided in [Table 6.5.3-17](#).

Table 6.5.3- 17: Summary of processing studies with fosetyl-Al on apples

Processed commodity	Number of trials	Median PF*	Median CF**	Comments
<i>Enforcement residue definition: sum of fosetyl and phosphonic acid expressed as fosetyl</i>				
Apples: juice	4	1.9	1	
Apples: wet pomace	4	1	1	
Apples: puree	4	0.9	1	

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Report:

KEA 6.5.3/18 [redacted]; 2006, M-274866-01-1
 Title: Fosetyl-Al and phosphorous acid (metabilate) Formulation EOP10369F (WG) code AE F03616-00 WG80 A102 Residue Study on Washed Apples and Apple Processed Fractions (juice, pomace and puree)
 Report No.: Q-90
 Document No.: M-274866-01-1
 Guideline(s): Directive 91/414/EEC as amended by Directive 96/68/EC Residues in or on treated products, food or feed (Annex IIA, Point 6)
 Guideline deviation(s): none
 GLP/GEP: yes

Materials and Method

Balance studies on processing of apple fruit into juice and puree were conducted to determine the transfer of the residues of fosetyl-aluminum (fosetyl-Al) and its metabolite phosphonic acid from apple fruit into processed fractions.

Detailed descriptions of the field parts are presented in Section [CA 6.3.4](#) (study 01R105).

The processed fractions were produced from apple fruit samples (1 untreated and 1 treated per trial) obtained from 4 different trials located in the United Kingdom (0190GBR1 (01R105-1) and 0190GBR2 (01R105-2)) in Northern France (0190FR1 (01R105-3) and 0190FR2 (01R105-4)).

The processing procedures followed VITI R&D Standard Operating Procedures and methods no. APPLE/001 (pip fruit juice processing) and APPLE/002 (pip fruit puree processing). They corresponded to industry procedures adapted to residue studies in little volumes. Flow charts to describe the production of apple juice and apple puree are presented in [Figure 6.5.3- 4](#) and [Figure 6.5.3-5](#), respectively.

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After weighing, two 2 kg whole apple sub-specimens were taken in plastic bags and frozen at approximately -20 °C. For all trials, at least 12 apples were taken in each sub-specimen, except for the trial No 0190GBR1. All the apples were counted, weighed and washed thoroughly with water sprayed from constant gas pressure sprayer (about 500 mL of washing water per kg of apple) and strained. The washed apples were then divided in two parts. All washing waters were separated in two parts, taken into glass bottles, labelled and frozen (approximately -20 °C). 5 litres of tap water used for the washing, were sampled into glass bottles in order to constitute a blank for the analysis laboratory.

Apple juice preparation:

The washed apples were crushed with an electric crusher and then pressed. The apple juice was collected in a stainless steel tank and the wet pomace was weighed. Two 0.50 kg wet pomace sub-specimens were taken in plastic bags and frozen. The remaining pomace was stored in a cold room at +5 / +10 °C until the drying start. The pomace was dried into an oven regulated +60 °C during two or three days. The dry pomace was then weighed and discarded. Pectolytic enzymes (0.02 mL/L) were added to the apple juice for depectinisation. The juice was left to settle for at least 12 hours, after which a deposit had formed in the bottom of the tank.

For the trial No 0190FRA2, the juice of treated specimen was cooked (until +5 °C), by error, after the addition of pectolytic enzymes (0.12 mL). After juice cooling, a new addition of pectolytic enzymes (0.12 mL) was made.

The apple juice was decanted and the lees were separated in two parts, taken into glass bottles and frozen (approximately -20 °C). The clear juice was filtered using a stainless steel filtration unit with a 10 litres capacity under nitrogen pressure (maximum 3 bars). The filtration was carried out over trimming plates. The used filter plates were collected in plastic bags and frozen. The juice was pasteurized by heating to approximately 85 °C for at least one minute and subsequently placed in glass bottles with screw cap which were sterilized in boiling water for 20 minutes. After cooling, the glass bottles were frozen (at approximately -20 °C).

Apple puree preparation

The washed apples were blanched in boiling water for 2 minutes to avoid enzymatic browning. The blanching waters were separated into two parts, taken into glass bottles and frozen (approximately -20 °C). The blanched apples were crushed with an electric crusher and sieved to obtain puree. All wastes (seeds and peels) were divided in two parts, collected in plastic bags and frozen (approximately -20 °C). After addition of sugar, the puree was reduced by heating to obtain a degree Brix of approximately 24%. The puree sub-specimens were packaged in glass bottles with a screw cap and sterilized at +115 / +120 °C for 10 minutes. After cooling, the bottles were frozen (approximately -20 °C).

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Figure 6.5.3- 4: Flow chart for the preparation of apple fruit into apple juice

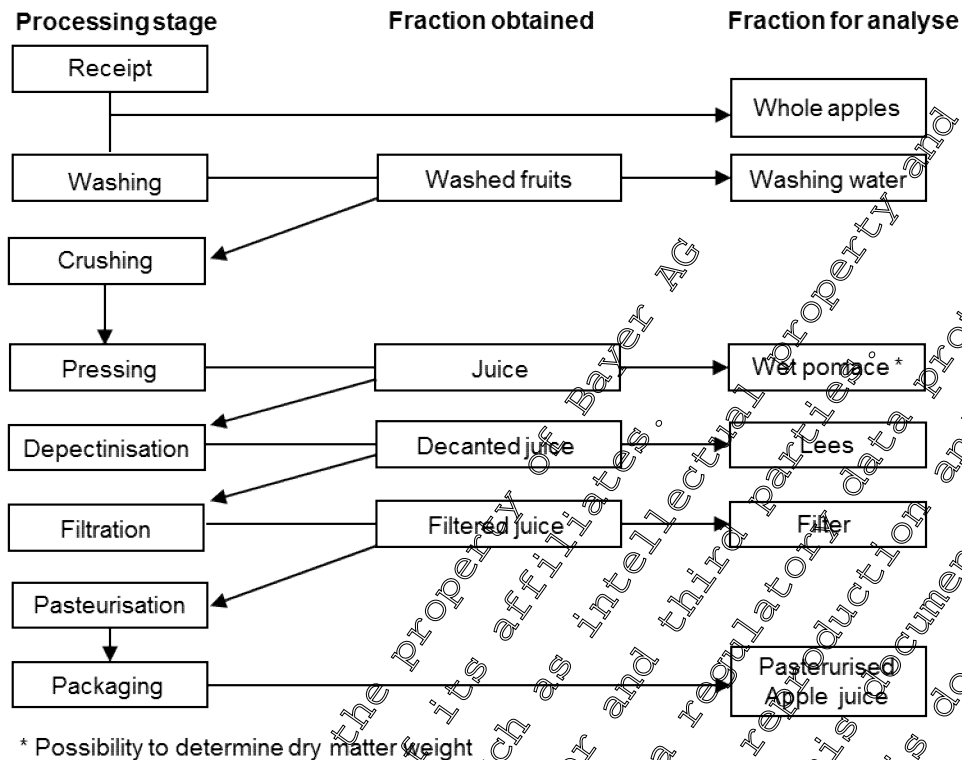
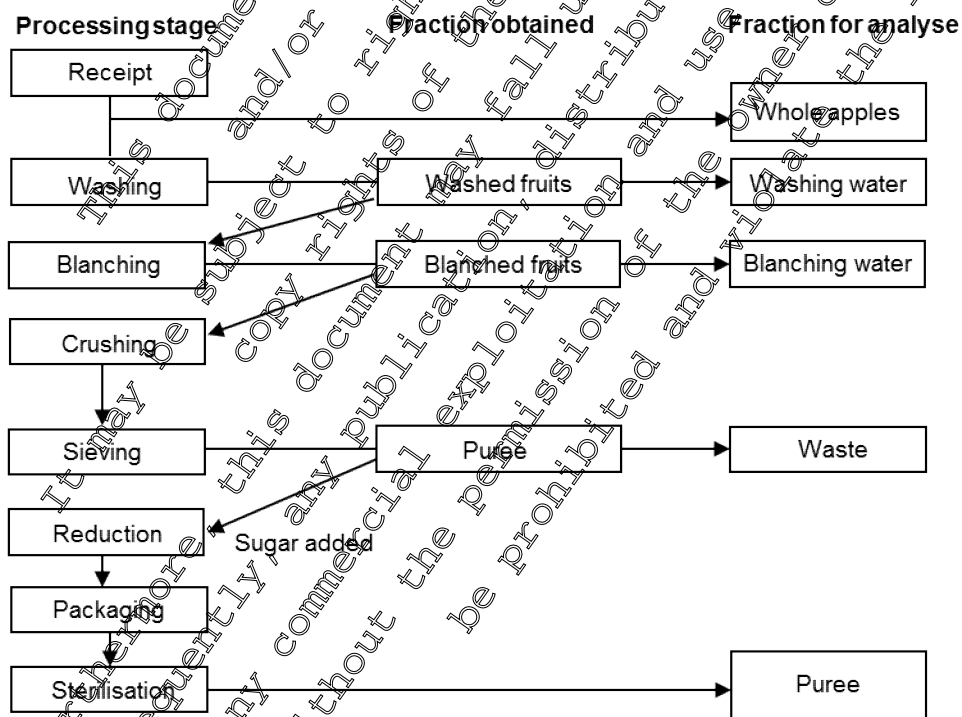


Figure 6.5.3- 5: Flow chart for the preparation of apple fruit into apple puree



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The samples were analysed for the parent compound fosetyl-Al and the metabolite phosphonic acid by the appropriate method:

- Method AR 155-97 for apples, processed fractions (pomace, puree) and intermediates samples (lees, waste puree),
- Method AR 171-98 for juice,
- Method AR 231-99 for washing water and blanching water.

For plant samples, residues of fosetyl-Al and phosphonic acid were extracted, methylated with diazomethane then quantified by GC/NPD (Gas Chromatography using a Nitrogen Phosphor Detector).

For water samples, the samples were concentrated, methylated with diazomethane then quantified by GC/NPD (Gas Chromatography using a Nitrogen Phosphor Detector)

The limits of quantification (LOQ) were as follows:

- 0.20 mg/kg for each analyte in apples, apple processed fractions (pomace, puree) and intermediates samples (lees, waste puree),
- 0.50 mg/kg for each analyte in apple juice,
- 1 µg/L for fosetyl-Al and 20 µg/L for phosphonic acid in washing and blanching water.

The total residue is expressed as fosetyl-Al in the report and is calculated in this dossier as total residue expressed as fosetyl according to the following formula.

Formula for total residue expressed as fosetyl (mg/kg):

Total residue calculated as fosetyl [mg/kg]	$\frac{\text{fosetyl-Al [mg/kg]} \times M_{\text{fosetyl}} \times 3 + \text{phosphonic acid [mg/kg]} \times M_{\text{fosetyl}}}{M_{\text{fosetyl-Al}} + M_{\text{phosphonic acid}}}$
---	--

*: multiplied by 3 because 1 fosetyl-Al mole gives 3 fosetyl moles.

M_{fosetyl-Al}: Molecular weight of fosetyl-Al = 354.1 g/mol

M_{phosphonic acid}: Molecular weight of phosphonic acid = 82 g/mol

M_{fosetyl}: Molecular weight of fosetyl = 110 g/mol

Findings:

- **Method performance** In the case of recovery experiments for methods validation, recovery means in apple fruit and in processed commodities were within the range of 80 to 102% with RSD <20%, as shown in [Table 6.5.3- 18](#). All results of the methods validation are in accordance with the general requirements for residue analytical methods. For concurrent recoveries, single values in apple fruit and in processed commodities were within the acceptable range of 72 to 105 % for fosetyl-Al and 72 to 106% for phosphonic acid. Details of the recovery results (concurrent recoveries) are summarised in [Table 6.5.3- 19](#).

The apparent residues in the control samples were below the respective LOQ. The maximum storage period of deep frozen processed samples was 229 days (from deep-freezing to last analysis).

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Table 6.5.3- 18: Method validation data for fosetyl-Al and phosphonic acid in apple fruit and processed fractions

Sample Material	Analytical method	Analyte	FL [mg/kg or mg/L]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg or mg/L]
Fruit	AR 155-97	Fosetyl-Al	0.20	98; 88; 91	92	5.6	0.20 mg/kg
			2.0	96; 90; 87	91	5.0	
			Overall Recovery (n = 6)	92	4.8		
		Phosphonic acid	0.20	94; 86; 87	89	4.9	
			2.0	82; 80; 78	80	2.5	
			Overall Recovery (n = 6)	85	6.8		
Juice	AR 171-98	Fosetyl-Al	0.50	86; 96	91	-	0.50 mg/kg
			5.0	82; 90	86	-	
			Overall Recovery (n = 4)	89	6.7		
		Phosphonic acid	0.50	81; 94	88	-	
			5.0	86; 96	91	-	
			Overall Recovery (n = 4)	89	7.8		
Washing water	AR 231-99	Fosetyl-Al	0.001	100; 104	102	-	0.001 mg/L
			0.010	81; 97	89	-	
			Overall Recovery (n = 5)	96	11		
		Phosphonic acid	0.020	86; 85	86	-	
			0.20	82; 83	83	-	
			Overall Recovery (n = 4)	84	2.2		

FL = fortification level; n = number of tests

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Table 6.5.3- 19: Recovery results (concurrent recoveries) for fosetyl-Al and phosphonic acid in apple fruit and processed fractions

Sample Material	FL [mg/kg or mg/L]	n	Fosetyl-Al [%]	Phosphonic acid [%]	LOQ [mg/kg or mg/L]
Fruit	0.20	1	86	89	0.20 mg/kg
	2.0	1	85	79	
	4.0	1	94	99	
Waste puree	0.20	1	78	87	
	2.0	1	91	106	
	20	1	73	72	
Pomace	0.20	1	94	73	
	2.0	1	73	79	
	20	1	72	76	
Puree	0.20	1	100	89	
	2.0	1	82	87	
	20	1	73	78	
Lees	0.20	1	10	10	
	2.0	1	94	86	
	20	1	74	79	
Juice	0.50	1	103	83	0.50 mg/kg
	5.0	1	76	74	
Washing water	0.001 * 0.020 **	1	75	85	0.001 mg/L for fosetyl-Al
	0.010 * 0.20 **	1	91	95	
Blanching water	0.001 * 0.020 **	1	97	85	0.020 mg/L for phosphonic acid
	0.010 * 0.20 **	1	99	76	

FL = fortification level; n = number of tests
 * Fortification level for fosetyl-Al
 ** Fortification level for phosphonic acid

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- Residue results: Residue values of fosetyl-Al, phosphonic acid and total residue as fosetyl in pome fruit and the processed by-products are summarised in [Table 6.5.3- 20](#) and [Table 6.5.3- 21](#).

Table 6.5.3- 20: Residues of fosetyl-Al, phosphonic acid and total residues as fosetyl in apple fruit and processed fractions of juice processing

Country, Study No., Trial No.	Processing	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L)			Transfer factor*
				Fosetyl-Al	Phosphonic acid	Total residue as fosetyl	
United Kingdom 01-90 0190GBR1	Washing and juice production	Apple fruit (RAC)	27	1.5	4.2	7.0	-
		Washing water	27	<0.001	<0.020	0.028	0.004
		Wet pomace	27	<0.20	4.5	5.0	0.8
		Lees	27	0.24	5.5	7.6	1.1
		Apple juice	27	<0.50	15	21	2.9
United Kingdom 01-90 0190GBR2	Washing and juice production	Apple fruit (RAC)	27	2.1	4.7	8.3	-
		Washing water	27	0.002	0.038	0.040	0.006
		Wet pomace	27	0.40	9.3	10.0	1.6
		Lees	27	0.24	6.6	9.2	1.1
		Apple juice	27	<0.50	11	13	1.2
Northern France 01-90 0190FRA1	Washing and juice production	Apple fruit (RAC)	28	0.50	9.3	13	-
		Washing water	28	0.001	0.029	0.040	0.003
		Wet pomace	28	<0.20	4.6	6.4	0.5
		Lees	28	0.26	4.1	5.7	0.4
		Apple juice	28	<0.50	5.7	8.1	0.6
Northern France 01-90 0190FRA2	Washing and juice production	Apple fruit (RAC)	27	0.71	3.0	4.7	-
		Washing water	27	<0.001	<0.020	<0.028	<0.006
		Wet pomace	27	0.20	5.4	7.4	1.6
		Lees	27	0.24	4.7	6.5	1.4
		Apple Juice	27	<0.50	8.3	12	2.5

RAC: Raw Agricultural Commodity, DALT = days after last application

* Transfer factor = Total residue as fosetyl in the processed fraction (mg/kg or mg/L)/Total residue as fosetyl in RAC (mg/kg or mg/L)

For the processing of apple juice production, the percentages of absolute residue recovered in apple juice were 87% (trial 0190GBR1), 65% (trial 0190GBR2), 36% (trial 0190FRA1) and 130% (0190FR02).

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Table 6.5.3- 21: Residues of fosetyl-Al, phosphonic acid and total residues as fosetyl in apple fruit and processed fractions of puree processing

Country, Study No., Trial No.	Processing	Crop Portion analysed	DALT (days)	Residues (mg/kg or mg/L)			Transfer factor*
				Fosetyl-Al	Phosphonic acid	Total residue as fosetyl	
United Kingdom 01-90 0190GBR1	Washing and juice production	Apple fruit (RAC)	27	1.5	4.2	7.0	-
		Washing water	27	<0.001	<0.020	<0.028	<0.004
		Blanching water	27	<0.001	<0.020	<0.028	<0.004
		Waste puree	27	0.47	2.7	4.1	0.6
		Apple puree	27	0.35	3.5	5.0	0.7
United Kingdom 01-90 0190GBR2	Washing and juice production	Apple fruit (RAC)	27	2.1	4.7	6.3	-
		Washing water	27	0.002	0.003	0.005	0.006
		Blanching water	27	<0.001	<0.020	<0.028	<0.003
		Waste puree	27	1.4	17	24	2.9
		Apple puree	27	0.39	9.5	10	1.6
Northern France 01-90 0190FRA1	Washing and juice production	Apple fruit (RAC)	28	0.5	9.3	13	-
		Washing water	28	0.001	0.039	0.040	0.003
		Blanching water	28	<0.001	<0.020	<0.028	<0.002
		Waste puree	28	0.52	7.1	10	0.8
		Apple puree	28	0.20	4.1	5.7	0.4
Northern France 01-90 0190FRA2	Washing and juice production	Apple fruit (RAC)	27	0.7	3.0	4.7	-
		Washing water	27	<0.001	<0.020	<0.028	<0.006
		Blanching water	27	<0.001	<0.020	<0.028	<0.006
		Waste puree	27	0.40	4.7	6.7	1.4
		Apple puree	27	1.1	3.0	5.0	1.1

RAC: Raw Agricultural Commodity, DALT = days after last application

* Transfer factor = Total residue as fosetyl in the processed fraction (mg/kg or mg/L)/Total residue as fosetyl in RAC (mg/kg or mg/L)

For the processing of apple puree production, the percentages of absolute residue recovered in apple puree were 29% (trial 0190GBR1), 69% (trial 0190GBR2), 18% (trial 0190FRA1) and 44% (trial 0190FRA2).

Average factors were calculated for the transfer of total residues as fosetyl from apple fruit into juice, wet pomace and puree respectively. They are summarised in the following table:

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Table 6.5.3- 22: Transfer factor for the total residue as fosetyl in processed commodities (apple juice, apple wet pomace and apple puree)

Sample material	Transfer factors for total residue as fosetyl					
	0190GBR1 United Kingdom	0190GBR2 United Kingdom	0190FRA1 Northern France	0190FRA2 Northern France	Mean	Median
Apple juice	2.9	1.2	0.6	1.5	1.8	1.9
Apple wet pomace	0.8	1.6	0.5	1.6	1.1	1.2
Apple puree	0.7	1.6	0.4	1.4	1.0	0.9

Conclusion

The present study allowed to evaluate the magnitude of residues of fosetyl-Al and its metabolite phosphonic acid and to calculate transfer factors corresponding to the transfer of residues from apple fruit to apple juice, wet pomace and apple puree.

CA 6.6 Residues in rotational crops

CA 6.6.1 Metabolism in rotational crops

Fosetyl-aluminium (fosetyl-Al) degrades very rapidly in soil with a half-life of ≤ 1 day (please refer to Document MCA, Section 9). The only relevant metabolite in soil is phosphonic acid (resp. its salts). Therefore, a rotational crop study (EFSA Scientific Report (2005) 54, 1-99; 2001; M-203498-01-1) has been conducted with phosphonic acid on radish (root crop), lettuce (leafy crop) and barley (cereals). Due to the difficulties in radio-labelling of this metabolite and the short half-life of labelled ^{32}P it was decided to conduct a study with unlabelled material.

This study has already been evaluated for the Annex I inclusion of fosetyl under Directive 91/414/EEC by the RMS France in DAR Volume 3/Annex B, B (February 2005) The following summary on the nature of residues in succeeding crops is paraphrased from the EFSA conclusion on the peer review of fosetyl (EFSA Scientific Report (2005) 54, 1-99, revised publication dated 12th June 2013):

“Fosetyl-Al degrades in soil very rapidly to its metabolite phosphonic acid. For that reason a study has been conducted to investigate the potential of phosphonic acid residues in succeeding crops. Cultivation of radishes, lettuce and barley 1 month after a soil treatment with phosphonic acid at 4.9 mg/kg soil, representing the concentration resulting from application of 15 kg/ha of fosetyl-Al (maximum dose applied during one growing season), results in levels of phosphonic acid higher than under natural conditions, but only slightly above the LOQ (Limit of Quantification) of 0.5 mg/kg for monitoring of products of plant origin.”

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The study is described in more detail in the following:

A root crop (radish), a leafy crop (lettuce) and a cereal/grain crop (barley) were grown in soil treated with phosphonic acid at a target concentration of 4.9 mg/kg. This would be the concentration in a 15-cm soil layer resulting from the application of 15 kg/ha of fosetyl-Al, i.e. total amount of active substance, which can be applied during a growing season (realistic worst case). The treated soil was aged for one month prior to sowing/planting of the representative succeeding crops. An additional experiment was made with radish sown 6 months after treatment of the soil. Phosphonic acid was determined in the plants at harvest, and in the soil at various stages of the study, with a limit of quantification of 0.5 mg/kg.

The results of the amounts of phosphonic acid in soil (not corrected for recovery) are summarized in [Table 6.6.1- 1](#).

Table 6.6.1- 1: Residue results in soil of phosphonic acid after application on bare soil

Timing	Phosphonic acid in soil (mg/kg)	
	bare soil	cropped soil
Day 0 (treatment of soil)	na	na
Day 32 (sowing/planting)	3.9	na
Day 69 (harvest of radish & lettuce)	1.2	<0.10 (0.08)-0
Day 182 (harvest of barley)	<0.10 (0.04)	<0.10 (0.04)

na: not analysed

In the soil, no appreciable decline of phosphonic acid is observed during the ageing period of one month following treatment. However, significant degradation (or irreversible binding) is observed afterwards. Of interest is the fact that the depletion of phosphonic acid is higher in cropped soil than in bare soil, and such differences are not due to the amount of phosphonic acid taken up by the plants, which remains minimal.

The results of the amounts in plants of phosphonic acid expressed as phosphonic acid and as fosetyl (not corrected for recovery) are summarised in [Table 6.6.1- 2](#).

Table 6.6.1: Residue results in radish, lettuce and barley after application on bare soil

Crop	Time between treatment & sowing/planting	Phosphonic acid (mg/kg)	Residue expressed as fosetyl (mg/kg)
Radish	32 days	Roots : 0.8 - Leaves : 0.35	Roots : 1.1 - Leaves : 0.47
Radish	182 days	Roots : <0.1 - Leaves : <0.1	Roots : <0.13 - Leaves : <0.13
Lettuce	32 days	Leaves : 0.76	Leaves : 1.0
Barley	32 days	Grain : 0.19 - Straw : 0.42	Grain : 0.19 - Straw : 0.56

From the data obtained on plants, although in some cases this is considered not to be very accurate because the values are below the validated limit of quantitation (LOQ of 0.5 mg/kg), the following conclusions can be drawn:

- for barley (grain and straw) sown one month after soil treatment, and for radish (roots and leaves) sown 6 months after treatment of the soil, differences between treated and untreated samples are not significant, residues clearly below 0.5 mg/kg).
- in radish (roots and leaves) and in lettuce (leaves) sown/planted one month after treatment, residues in treated samples are observed at levels higher than in untreated samples, however not exceeding 1 mg/kg.

**Document MCA – Section 6: Residues in or on treated products, food and feed
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To support the uses of Fosetyl + Propamocarb SL 840 (e.g. Previcur Energy) on vegetables, four rotational residue trials were conducted in 2008. They are presented here to demonstrate the level of residues of fosetyl and phosphonic acid in succeeding crops after a plant back interval of 30 days.

Report:	KCA 6.6.2/01 [REDACTED]; [REDACTED]; 2010; M-349882-02-
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands - Rotational crop study
Report No.:	08-2504
Document No.:	M-349882-02-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) EC guidance working document 7524/VI/95 rev. 2 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes
Report:	KCA 6.6.2/02 [REDACTED]; [REDACTED]; 2010; M-349137-02-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) - Rotational crop study
Report No.:	08-2505
Document No.:	M-349137-02-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) EC guidance working document 7524/VI/95 rev. 2 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes
Report:	KCA 6.6.2/03 [REDACTED]; [REDACTED]; 2010; M-361470-01-1
Title:	Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain
Report No.:	08-2506
Document No.:	M-361470-01-1
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) EC guidance working document 7524/VI/95 rev. 2 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan. 2007
Guideline deviation(s):	none
GLP/GEP:	yes

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Report: KCA 6.6.2/04 [REDACTED] ([REDACTED]); 2010; M-349147-02-1
Title: Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy
Report No.: 08-2507
Document No.: M-349147-02-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8
Residues in or on Treated Products, Food and Feed
EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan 2007
Guideline deviation(s): none
GLP/GEP: yes

Material and Methods:

The purpose of the presented studies was to perform field trials on rotational crops (carrots, lettuce and winter wheat or winter barley) in Northern Europe (France and the Netherlands) and in Southern Europe (Italy and Spain) following three spraying applications with 2.5 L Previcur Energy / ha on lettuce (primary crop).

The formulation Fosetyl + Propamocarb SL 840 (e.g. Previcur Energy), a water soluble concentrate containing 310 g/L fosetyl and 530 g/L propamocarb was sprayed three times on lettuce plants (primary crop) with a product rate of 2.5 L/ha and a water rate of 300 L/ha corresponding to a fosetyl use rate of 0.775 kg a.s./ha and a propamocarb use rate of 1.25 kg a.s./ha per application. All applications were made at the specified rates except for the Spanish trial 08-2506-01 where the product rate was at 2.3 L/ha with a water rate at 177 L/ha, corresponding to a fosetyl use rate of 0.710 kg a.s./ha and a propamocarb use rate of 1.21 kg a.s./ha per application. The applications were carried out with a spray interval of 7 to 13 days.

The first treatment on lettuce (primary crop) was conducted at BBCH 14 to 42, whilst the last application was carried out at BBCH 19 to 48, 5 to 7 days before the anticipated commercial harvest.

Lettuce (primary crop) was harvested at normal harvest stage, 32 to 69 days after planting. No lettuce samples were taken for analysis. Harvested primary crop lettuce was destructed and the remaining plant parts were incorporated by a mulling machine or a little rotary machine.

At the 27 to 38 day plant back interval for carrots, 26 to 46 day plant back interval for lettuce and 30 to 38 day plant back interval for cereals the plots were prepared for crop planting/sowing (secondary crops) following normal agronomic practices for each crop type in the regions. In study 08-2506, the proposed plant back interval of 30 days was not respected due to adverse meteorological conditions reported in deviations. Indeed it was impossible to do the sowing within the proposed timeline because there were freezing temperatures and rainy days. Nevertheless, if we consider all the four studies together the mean PBI is 31 days for carrots, 33 days for lettuce and 33 days for cereals.

The secondary crop carrot samples were harvested at growth stage BBCH 46 to 49, 103 to 212 days after the last treatment, the secondary crop lettuce samples were harvested at growth stage BBCH 45 to 49, 54 to 141 days after the last treatment, and the secondary crop cereal samples were harvested at growth stage BBCH 29 to 49, 106 to 309 days after the last treatment.

Lettuce, carrot and cereal samples were analysed for residues of fosetyl and its metabolite phosphonic acid according to method 00861/M001 by LC-MS/MS with a LOQ of 0.0093 mg/kg for carrot (root and leaf), lettuce (head), winter wheat and winter barley (grain) and with a LOQ of 0.047 mg/kg for winter wheat and winter barley (green material and straw) for fosetyl and with a LOQ of 0.10 mg/kg for carrot (root and leaf), lettuce (head), winter wheat and winter barley (grain) and with a LOQ of 0.50 mg/kg for winter wheat and winter barley (green material and straw) for phosphonic acid.
Residues of fosetyl were determined as fosetyl-Al and expressed as fosetyl with the formula below:

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Fosetyl [mg/kg]	=	$\frac{\text{fosetyl-Al [mg/kg]} \times 110 \times 3^*}{354.1}$
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110 g/mol: Molecular weight of fosetyl;
 *: multiplied by 3, because 1 fosetyl-Al mole gives 3 fosetyl moles;
 354.1 g/mol: Molecular weight of fosetyl-Al

Residues of phosphonic acid were determined and expressed as phosphonic acid. The total residue as fosetyl (mg/kg) expressed as fosetyl is the sum of fosetyl (mg/kg) calculated as fosetyl and phosphonic acid (mg/kg) calculated as fosetyl.
 The formula used for this calculation is as follows:

Total residue calculated as fosetyl [mg/kg]	=	fosetyl (mg/kg) + $\frac{\text{phosphonic acid [mg/kg]} \times 110}{354.1}$
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110 g/mol: Molecular weight of fosetyl
 82 g/mol: Molecular weight of phosphonic acid

Findings:

- Method performance: The means of the concurrent recoveries (n2) for fosetyl-Al were for all fortification levels, within the acceptable range of 70 to 110%, except in carrot leaf at 0.01 and 0.10 mg/kg: 178 and 160% (study 08-2507). Nevertheless, the results are considered acceptable because the residue values found in the treated samples were largely less than 30% of the LOQ value (analytical deviation).

The means of the concurrent recoveries (n2) for phosphonic acid were for all fortification levels, within the acceptable range of 70 to 110% with the exception:

- in carrot leaf at 1.0 mg/kg and overall: 50 and 57% (study 08-2504),
- in carrot leaf at 0.10 and 1.0 mg/kg and overall: 66, 63 and 64% (study 08-2505),
- in carrot leaf at 0.10 and 1.0 mg/kg and overall: 159, 194 and 157% (study 08-2507). See analytical deviation cited above.
- in straw of winter wheat at 5.0 mg/kg: 57% (study 08-2507).

Nevertheless, the results are considered valid.

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Table 6.6.2- 1: Recovery data for fosetyl and phosphonic acid in lettuce, carrots and cereals (secondary crops)

Study, Trial No., GLP, Year	Crop	Portion analysed	a.s./metabolite	Fortification level (mg/kg)	Recovery (%)				
					Single values	n	Mean	RSD	
08-2504 08-2504-01 08-2504-02 08-2504-03 GLP yes 2008	Carrot	leaf	fosetyl-Al	0.01	112	1	-	-	
				0.10	92	2	82	-	
			Overall Recovery			3	99	12	
		root	fosetyl-Al	0.01	82	1	-	-	
				0.10	92	1	-	-	
			Overall Recovery			3	91	9.4	
		leaf	phosphonic acid	0.10	72	1	-	-	
				1.0	42	2	50	-	
			Overall Recovery			3	57	26	
			phosphonic acid	0.10	131	1	-	-	
				1.0	97	1	-	-	
				5.0	104	1	-	-	
	Overall Recovery			3	111	16			
	Lettuce	head	fosetyl-Al	0.01	88	1	-	-	
				0.10	94	2	93	-	
			Overall Recovery			3	91	3.3	
		head	phosphonic acid	0.10	110	1	-	-	
				1.0	95	2	95	-	
			Overall Recovery			3	100	9.0	
	Wheat	grain	fosetyl-Al	0.01	93	1	-	-	
				0.10	94	2	95	-	
			Overall Recovery			3	94	1.6	
			green material	fosetyl-Al	0.05	94	3	96	1.8
					0.50	92	3	92	0
Overall Recovery						6	94	2.6	
straw		fosetyl-Al	0.05	97	3	94	2.7		
			0.50	91	3	92	0.6		
		Overall Recovery			6	93	2.4		
grain		phosphonic acid	0.10	92	1	-	-		
			1.0	85	2	88	-		
		Overall Recovery			3	89	4.2		
		green material	phosphonic acid	0.50	93	3	93	3.8	
5.0				95	3	93	1.6		
Overall Recovery					6	93	2.6		
straw	phosphonic acid	0.50	98	3	99	6.1			
		5.0	98	3	94	3.7			
	Overall Recovery			6	97	5.2			

RSD: relative standard deviation.

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Table 6.6.2- 1: Recovery data for fosetyl and phosphonic acid in lettuce, carrots and cereals (secondary crops) (continued)

Study, Trial No., GLP, Year	Crop	Portion analysed	a.s./metabolite	Fortification level (mg/kg)	Recovery (%)			n	Mean	RSD	
					Single values						
08-2505 08-2505-01 08-2505-02 08-2505-03 GLP yes 2008	Carrot	leaf	fosetyl-Al	0.01	95	90	94	3	93	2.2	
				0.10	87	84	80	3	84	4.2	
			Overall Recovery				6	88	6.6		
		root	fosetyl-Al	0.01	86	95	97	3	93	6.1	
				0.10	89	91	88	3	89	3.2	
			0.50	88	-	-	1	-	-		
		Overall Recovery				7	91	4.5			
		leaf	phosphonic acid	0.10	82	53	62	3	66	23.2	
				1.0	64	66	59	3	63	5.7	
			Overall Recovery				6	64	15		
			phosphonic acid	0.10	99	96	106	3	100	5.1	
				1.0	88	94	93	3	92	3.2	
	Overall Recovery					7	95	6.3			
	Lettuce	head	fosetyl-Al	0.01	118	-	-	2	-	-	
				0.10	100	95	-	2	98	-	
			Overall Recovery				3	104	12		
		head	phosphonic acid	0.10	116	-	-	2	-	-	
				1.0	97	98	-	2	98	-	
		Overall Recovery				3	104	10			
	Barley	grain	fosetyl-Al	0.01	107	110	100	3	106	4.9	
				0.10	90	90	88	3	89	1.3	
			Overall Recovery				6	98	9.8		
			green material	fosetyl-Al	0.05	95	95	89	3	89	1.7
					0.50	93	94	94	3	94	0.6
Overall Recovery						6	91	3.2			
straw		fosetyl-Al	0.05	76	79	76	3	77	2.2		
			0.50	75	76	80	3	77	3.4		
Overall Recovery					6	77	2.6				
grain		phosphonic acid	0.10	108	73	91	3	91	19		
			1.0	84	84	85	3	84	0.7		
Overall Recovery					6	88	13				
green material		phosphonic acid	0.50	92	98	98	3	96	3.6		
			5.0	94	97	95	3	95	1.6		
Overall Recovery					6	96	2.5				
straw		phosphonic acid	0.50	84	77	78	3	80	4.8		
			5.0	80	82	80	3	81	1.4		
Overall Recovery					6	80	3.2				

RSD: relative standard deviation

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Table 6.6.2- 1: Recovery data for fosetyl and phosphonic acid in lettuce, carrots and cereals (secondary crops) (continued)

Study, Trial No., GLP, Year	Crop	Portion analysed	a.s./metabolite	Fortification level (mg/kg)	Recovery (%)			
					Single values	n	Mean	RSD
08-2506 08-2506-01 08-2506-02 08-2506-03 GLP yes 2008	Carrot	leaf	fosetyl-Al	0.01	81	1	-	
				0.10	88	2	88	
				Overall Recovery		3	85	4.4
		root	fosetyl-Al	0.01	102	1	-	-
				0.10	90 84	2	88	-
				Overall Recovery		3	92	10
	leaf	phosphonic acid	0.10	91	1	-	-	
			1.0	72 71	2	72	-	
			Overall Recovery		3	78	14	
		phosphonic acid	0.10	64	1	-	-	
			1.0	87 81	2	84	-	
			Overall Recovery		3	77	15	
	Lettuce	head	fosetyl-Al	0.01	95	1	-	-
				0.10	89 93	2	91	-
				Overall Recovery		3	93	4.3
		head	phosphonic acid	0.10	83	1	-	-
				1.0	88 80	2	87	-
				Overall Recovery		3	85	2.4
	Winter wheat	grain	fosetyl-Al	0.01	86	1	-	-
				0.10	80 77	2	103	-
				Overall Recovery		3	97	18
		green material	fosetyl-Al	0.05	92	1	-	-
				0.50	91 94	2	93	-
				Overall Recovery		3	92	1.7
straw		fosetyl-Al	0.05	73	1	-	-	
			0.50	75 76	2	76	-	
			Overall Recovery		3	75	2.0	
grain		phosphonic acid	0.10	95	1	-	-	
			1.0	85 75	2	80	-	
			Overall Recovery		3	85	12	
green material	phosphonic acid	0.50	100	1	-	-		
		5.0	90 93	2	92	-		
		Overall Recovery		3	94	5.4		
straw	phosphonic acid	0.50	75	1	-	-		
		5.0	69 71	2	70	-		
		Overall Recovery		3	72	4.3		

RSD: relative standard deviation

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Table 6.6.2- 1: Recovery data for fosetyl and phosphonic acid in lettuce, carrots and cereals (secondary crops) (continued)

Study, Trial No., GLP, Year	Crop	Portion analysed	a.s./metabolite	Fortification level (mg/kg)	Recovery (%)					
					Single values	n	Mean RSD			
08-2507 08-2507-01 08-2507-02 08-2507-03 GLP yes 2008	Carrot	leaf	fosetyl-Al	0.01	177	178	2	178*	-	
				0.10	161	158	2	160*	-	
		Overall Recovery						4	169*	6.2
		root	fosetyl-Al	0.01	89	-	-	1	-	-
				0.10	95	94	2	95	-	
		Overall Recovery						3	93	3.5
	leaf	phosphonic acid	0.10	169	149	2	159*	-		
			1.0	156	152	2	154*	-		
		Overall Recovery						4	157*	5.6
		phosphonic acid	0.10	94	-	-	1	-	-	
			1.0	94	86	2	90	-		
		Overall Recovery						3	91	5.1
	Lettuce	head	fosetyl-Al	0.01	85	-	-	1	-	-
				0.10	98	99	2	99	-	
		Overall Recovery						3	93	9.6
		head	phosphonic acid	0.10	75	-	-	1	-	-
				1.0	83	89	2	91	-	
		Overall Recovery						3	86	11
	Winter wheat	grain	fosetyl-Al	0.01	109	-	-	1	-	-
				0.10	88	89	2	89	-	
Overall Recovery						3	95	12		
green material		fosetyl-Al	0.05	92	-	-	1	-	-	
			0.50	89	90	2	89	-		
Overall Recovery						3	90	1.7		
straw		fosetyl-Al	0.05	104	96	2	100	-		
			0.50	83	85	2	84	-		
Overall Recovery						2	92	11		
grain		phosphonic acid	0.10	100	-	-	1	-	-	
			1.0	76	81	2	79	-		
Overall Recovery						3	86	15		
green material	phosphonic acid	0.50	93	-	-	1	-	-		
		5.0	89	89	2	89	-			
Overall Recovery						3	90	2.6		
straw	phosphonic acid	0.50	86	79	2	83	-			
		5.0	57	57	2	57	-			
Overall Recovery						4	70	22		

RSD: relative standard deviation

* Analytical Deviation: These recovery results on carrot (leaf) are considered as being acceptable because the residue values found in the treated samples were largely less than 30% of the LOQ value.

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- Storage stability: The storage periods of deep frozen untreated and treated samples for lettuce, carrot and cereals samples are summarised in [Table 6.6.2- 2](#).

Table 6.6.2- 2: Storage periods of deep frozen rotational crops samples in lettuce, carrots and cereals (winter wheat and winter barley) after use of Fosetyl + Propamocarb SL 840

Study	Analytes	Storage period of deep frozen samples	
		Min [days]	Max [days]
08-2504	Fosetyl-Al and phosphonic acid	105	408
08-2505	Fosetyl-Al and phosphonic acid	119	444
08-2506	Fosetyl-Al and phosphonic acid	114	238
08-2507	Fosetyl-Al and phosphonic acid	135	407

- Residue results: Residues of fosetyl for the secondary crops lettuce (head), carrots (root and leaf) and winter wheat or winter barley (grain) were <0.093 mg/kg (LOQ) and <0.047 mg/kg (LOQ) in winter wheat or winter barley (straw) at 27 to 38 day plant back interval for carrots, 26 to 46 day plant back interval for lettuce and 30 to 38 day plant back interval for cereals.

Residues of phosphonic acid for the secondary crops lettuce (head), carrots (root and leaf) and winter wheat or winter barley (grain) were <0.10 mg/kg (LOQ) and <0.50 mg/kg (LOQ) in winter wheat or winter barley (straw) at 27 to 38 day plant back interval for carrots, 26 to 46 day plant back interval for lettuce and 30 to 38 day plant back interval for cereals except in the grain sample of the Spanish trial 08-2506-03 where apparent residues of phosphonic acid were found at 0.21 mg/kg (2 x LOQ).

- No apparent residues of fosetyl and phosphonic acid were found in any of the untreated samples, i.e. residues were <LOQ.

The results of these trials are summarised in [Table 6.6.2- 3](#).

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Table 6.6.2- 3: Application data, residues results in lettuce, carrots and cereals (secondary crops) after use of Fosetyl + Propamocarb SL 840
Residues of parent fosetyl, metabolite phosphonic acid and total residues calculated as fosetyl and as phosphonic acid

Study, Trial No., GLP Year	Crop Variety	Country	FL	No	Application			Portion analysed	DALT (days)	Residues			
					kg/ha (a.s.)	kg/hL (a.s.)	GS			fosetyl (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
08-2504 08-2504-01 GLP yes 2008	Lettuce Legenda Carrot Amsterdam	Netherlands [REDACTED] Europe, North	840 SL	3	0.775	0.258	19	Root	128	< 0.0093	< 0.10	< 0.14	< 0.11
								Leaf	128	< 0.0093	< 0.10	< 0.14	< 0.11
								Root	142	< 0.0093	< 0.10	< 0.14	< 0.11
								Leaf	142	< 0.0093	< 0.10	< 0.14	< 0.11
08-2504 08-2504-02 GLP yes 2008	Lettuce Legenda Lettuce Gisela	Netherlands [REDACTED] Europe, North	840 SL	3	0.775	0.258	Head	65	< 0.0093	< 0.10	< 0.14	< 0.11	
								79	< 0.0093	< 0.10	< 0.14	< 0.11	
08-2504 08-2504-03 GLP yes 2008	Lettuce Gisela Winter Wheat Tataros	Netherlands [REDACTED] Europe, North	840 SL	3	0.775	0.258	Green material	249	< 0.047	< 0.50	< 0.72	< 0.54	
							Grain	309	< 0.0093	< 0.10	< 0.14	< 0.11	
							Straw	309	< 0.047	< 0.50	< 0.72	< 0.54	
08-2505 08-2505-01 GLP yes 2008	Lettuce Noisette Carrot Nandrin F1	France [REDACTED] Europe, North	840 SL	3	0.775	0.258	Root	133	< 0.0093	< 0.10	< 0.14	< 0.11	
							Leaf	133	< 0.0093	< 0.10	< 0.14	< 0.11	
							Root	147	< 0.0093	< 0.10	< 0.14	< 0.11	
							Leaf	147	< 0.0093	< 0.10	< 0.14	< 0.11	

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Study, Trial No., GLP Year	Crop Variety	Country	Application					Portion analysed	DALT (days)	Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS			fosetyl (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
08-2505 08-2505-02 GLP yes 2008	Lettuce Noisette	France	840	3	0.775	0.258	48	Head	54	< 0.0093	< 0.10	< 0.14	< 0.11
	Lettuce Noisette	Europe, North	SL						68	< 0.0093	< 0.10	< 0.14	< 0.11
08-2505 08-2505-03 GLP yes 2008	Lettuce Eole	France	840	3	0.775	0.258	47	Green material	207	0.047	< 0.50	0.72	< 0.54
	Winter Barley Marado	Europe, North	SL					Grain	290	< 0.0093	< 0.10	< 0.14	< 0.11
								Straw	290	0.047	< 0.50	0.72	< 0.54
08-2506 08-2506-01 GLP yes 2009	Lettuce Filipo	Spain	840	3	0.71-0.77	0.256-0.258	46	Root	197	< 0.0093	< 0.10	< 0.14	< 0.11
		Andalucia	SL					Leaf	212	< 0.0093	< 0.10	< 0.14	< 0.11
	Carrot Coral	Europe, South						Root		< 0.0093	< 0.10	< 0.14	< 0.11
								Leaf		< 0.0093	< 0.10	< 0.14	< 0.11
08-2506 08-2506-02 GLP yes 2009	Lettuce Filipo	Spain	840	3	0.775	0.258	46	Head	127	< 0.0093	< 0.10	< 0.14	< 0.11
	Lettuce Isasa	Andalucia	SL						41	< 0.0093	< 0.10	< 0.14	< 0.11

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Fosetyl

Study, Trial No., GLP Year	Crop Variety	Country	Application					Portion analysed	DALT (days)	Residues			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS			fosetyl (mg/kg)	phosphonic acid (mg/kg)	total residue calculated as fosetyl (mg/kg)	total residue calculated as phosphonic acid (mg/kg)
08-2506 08-2506-03 GLP yes 2009	Lettuce Filipo	Spain [Redacted] Andalucia Europe, South	840	3	0.731	0.256-	46	Green material	106	< 0.047	< 0.50	< 0.72	< 0.54
	Winter Wheat Cajeme		SL		-	0.258		Grain	183	0.0093	0.21	0.29	0.22
						0.775			Straw	183	0.047	0.50	0.72
08-2507 08-2507-01 GLP yes 2008	Lettuce Gentile	Italy [Redacted] Europe, South	840	3	0.775	0.258	48	Root	103	< 0.0093	< 0.10	< 0.14	< 0.11
	Carrot Berlicum		SL					Leaf		< 0.0093	< 0.10	< 0.14	< 0.11
								Root	117	< 0.0093	< 0.10	< 0.14	< 0.11
								Leaf		< 0.0093	< 0.10	< 0.14	< 0.11
08-2507 08-2507-02 GLP yes 2008	Lettuce Gentile	Italy	840	3	0.775	0.258	48	Head	57	< 0.0093	< 0.10	< 0.11	
	Lettuce Lactuca Estony	[Redacted]	SL						71	< 0.0093	< 0.10	< 0.11	
08-2507 08-2507-03 GLP yes 2008	Lettuce Lactuca Estony	Italy [Redacted] Europe, South	840		0.775	0.258		Green material	175	< 0.047	< 0.50	< 0.72	< 0.54
	Winter Wheat Aubusson		SL					Grain	264	< 0.0093	< 0.10	< 0.14	< 0.11
									Straw	264	< 0.047	< 0.50	< 0.72

FL: Formulation No: number of applications
GS = growth stage (BBCH code) at last application DALT = days after last treatment

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**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****Conclusion**

Four residue trials were conducted in Europe in 2008 in/on lettuce as primary crop, followed with lettuce, carrots and winter wheat or winter barley as secondary crops with an intended plant back interval of 30 days. The formulation fosetyl + propamocarb SL 840 (310 + 530 g/L) was applied on the primary crop with three spray applications at 2.5 L product/ha corresponding to a fosetyl use rate of 0.775 kg a.s./ha per application.

The residues of fosetyl were < LOQ (LOQ = 0.0093 mg/kg in lettuce (head), carrots (root and leaf) and cereal (grain) and LOQ= 0.047 mg/kg in straw).

The residues of phosphonic acid were < LOQ (LOQ = 0.10 mg/kg in lettuce (head), carrots (root and leaf) and cereal (grain) and LOQ= 0.50 mg/kg in straw) except in the Spanish trial where apparent residue of phosphonic acid were found in the grain sample at 0.21 mg/kg. The total residues expressed as fosetyl were at 0.29 mg/kg and 0.22 mg/kg for the total residues expressed as phosphonic acid.

The proposed plant back interval (PBI) of 30 days was not respected in study 08-2506 due to adverse meteorological conditions (freezing temperature and rainy days) reported in deviations. Nevertheless, if we consider all the four studies together, the mean PBI is 31 days for carrots, 33 days for lettuce and 33 days for cereals.

CA 6.7 Proposed residue definitions and maximum residue levels**CA 6.7.1 Proposed residue definitions**

Plant metabolism studies (see Section CA 6.2) have shown a similar residue profile. Residues found in crops are fosetyl (the acid moiety of fosetyl-aluminum) and its metabolite phosphonic acid (H_3PO_3). Therefore residues of fosetyl and phosphonic acid were detected in all crops treated with plant protection products containing fosetyl-aluminum (fosetyl-Al) in the residue studies (see Section CA 6.3).

In the conclusion of the peer review of fosetyl (EFSA Scientific report (2005) 54, 1-79), “phosphonic acid is considered to be toxicologically relevant and its level found generally higher than that of the parent, therefore the residue definition should include both compounds and is proposed by the Expert meeting (EPCO19) to be the sum of fosetyl, its salts and phosphonic acid expressed as fosetyl. EFSA is proposing a slightly different wording of the residue definition, sum of fosetyl, phosphonic acid and their salts expressed as fosetyl”.

For animal products, the same residue definition has been proposed for monitoring and risk assessment, consistently with the residue definition for plants.

According to Commission Regulation (EU) 991/2014, this residue definition is still in force today: “The residue definition for monitoring applicable to fosetyl comprises the parent compound fosetyl, the degradation product phosphonic acid and their salts. Salts of phosphonic acid are named phosphonates.”

However, this residue definition was discussed extensively at the EU level in the last years; the different proposals are provided on the following pages and in [Table 6.7.1- 1](#).

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EFSA Scientific report (2005) 54, 1-79: conclusion on the peer review of fosetyl, updated on 31 May 2013

Because of the slightly lower ADI set for fosetyl compared to phosphonic acid, the peer review of 2005 had decided to express the total residue as fosetyl. However, in the light of the recent correction of the ADI for phosphonic acid towards a lower value, the total residues should be expressed as phosphonic acid. This residue definition is valid for monitoring and risk assessment purposes and is acceptable in terms of consumer safety.

This point should be re-evaluated in this Supplementary Dossier as it is demonstrated in Document MCA, Section 5.8.1, that the correction of the NOAEL for the water content in the revised ADI setting for phosphonic acid is not appropriate because the correction for the water content of the test material was applied twice.

Hence:

ADI_{phosphonic acid} = 2.74 mg/kg bw/day (not: 2.25 mg/kg bw/day)

The different ADI proposals are compiled in the [Table 6.7.1- 1](#) and expressed as fosetyl-Al, fosetyl and phosphonic acid for comparison.

Table 6.7.1- 1: Different ADI proposals

Analyte	ADI mg/kg bw per day	ADI mg/kg/bw per day expressed as		
		fosetyl-Al	fosetyl	phosphonic acid
Fosetyl-Al (2005)	3.0	3.0	2.8	1.9
Phosphonic acid (2005)	3.9	5.6	5.2	3.9
Phosphonic acid (2013)	2.25	3.2	3.0	2.3
Phosphonic acid – Supplementary Dossier	2.74	3.9	3.7	2.7

Molecular weight of fosetyl-Al = 354.4 g/mol

Molecular weight of phosphonic acid = 82 g/mol

Molecular weight of fosetyl = 110 g/mol

EFSA Journal (2012); 10(11): 296. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fosetyl according to Article 12 of Regulation (EC) No 396/2005

Phosphonic acid is considered to be toxicologically relevant and its level is generally expected to be higher than that of the parent compound. Phosphonic acid in plants results from the use of fosetyl-Al, but also the use of pesticides containing potassium phosphonate, foliar P fertilizers and some organic products used for foliar fertilization can be a source of phosphonic acid which could mimic a treatment with fosetyl-Al (Malusà et al. 2005). Other pesticide active substances generating phosphonic acid have not yet been peer reviewed under Regulation (EC) No 1107/2009. EFSA is therefore not yet in a position to include such active substances in the assessment at this stage. EFSA is also not in a position to assess the impact of phosphonic acid-generating fertilizers as they do not fall within the remit of EFSA and adequate data to estimate levels of phosphonic acid generated by fertilizers are not available to EFSA. Risk managers should therefore consider measures to avoid MRL exceedances resulting from the use of such fertilizers.

During the consultation of Member States, France (RMS) proposed that the current residue definition for risk assessment and monitoring (the *sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl*) should be amended to phosphonic acid only. This issue was further discussed in a meeting of experts where other member states raised the concern that based on the citrus metabolism study significant fosetyl residues may be expected. France clarified that there was a mistake in the DAR and that levels of fosetyl in metabolism studies and residue trials are very low compared to phosphonic acid. The meeting also discussed the instability of fosetyl residues during storage (see also Section 6.1) but France considers this

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instability not significant compared to the natural degradation of fosetyl in field conditions. Concerns were also raised that an enforcement residue definition based on phosphonic acid would not be specific to the use of fosetyl. However, the meeting agreed that the residue definition for both risk assessment and monitoring should be set as *phosphonic acid* and that risk managers should consider if a separate residue definition for *fosetyl* should be established to enforce residues that are specific to the use of fosetyl-AI.

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Regarding fosetyl, the Authority drafted its reasoned opinion considering the enforcement residue definitions proposed in the framework of the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005. Since other substances, for which the MRLs are currently under review, have a shared metabolite with fosetyl, it is appropriate to keep the existing residue definition unchanged until the review of these substances has been carried out. Therefore, the Commission requested the Authority to recommend MRLs according to the current enforcement residue definition, i.e. sum of fosetyl, phosphonic acid and their salts expressed as fosetyl.

The residue definition in force and the different proposals which were made are listed in [Table 6.7.1- 2](#).

Table 6.7.1- 2: Residue definition in force and proposed residue definitions of fosetyl

Matrices	EU Residue Definition		Reference
Food of plant origin	Risk assessment and monitoring	Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl	EFSA Scientific report (2005) 54, 1-79 ⁽¹⁾ Regulation (EU) No 991/2014 ⁽²⁾
		Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid	EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2013 ⁽³⁾
		Phosphonic acid and fosetyl separately	EFSA Journal 2012; 10(11):2961 ⁽⁴⁾
Food of animal origin	Risk assessment and monitoring	Sum of fosetyl, phosphonic acid and their salts expressed as fosetyl	EFSA Scientific report (2005) 54, 1-79 ⁽¹⁾ Regulation (EU) No 991/2014 ⁽²⁾
		Sum of fosetyl, phosphonic acid and their salts expressed as phosphonic acid	EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2013 ⁽³⁾
		Phosphonic acid	EFSA Journal 2012; 10(11):2961 ⁽⁴⁾

⁽¹⁾: EFSA Scientific report (2005) 54, 1-79: Conclusion on the peer review of fosetyl

⁽²⁾: Regulation (EU) No 991/2014

⁽³⁾: EFSA Scientific report (2005) 54, 1-79, updated on 31 May 2013: Conclusion on the peer review of fosetyl

⁽⁴⁾: EFSA Journal 2012; 10(11):2961: Reasoned opinion on the review of existing MRLs for fosetyl

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In conclusion, taking into consideration the re-evaluated ADI for phosphonic acid, the residue definition for risk assessment should be **the sum of fosetyl, phosphonic acid and their salts expressed as fosetyl**, since fosetyl has a lower ADI than phosphonic acid (see [Table 6.7.1- 1](#)).

Bayer CropScience is of the opinion that

- fosetyl should be included in the residue definition for monitoring since fosetyl residues can be determined in fresh food as tracer of plant protection products containing fosetyl due to new analytical methods with a very low limit of quantification (0.01 mg/kg for fosetyl-Al or 0.0093 mg/kg for fosetyl).
- the **total residue as the sum of fosetyl, phosphonic acid and their salts expressed as fosetyl** is the best way to obtain accurate residue data for setting MRLs due to the potential degradation of fosetyl residues into phosphonic acid during sample storage.
- the same residue definition for monitoring and risk assessment can be consistently proposed for plants and animal products.

CA 6.7.2 Proposed MRLs and justification of the acceptability of the levels proposed

The EU MRL for grape was established during the European Evaluation of fosetyl and published in the EFSA Scientific Report (2005) 54, 1-79 finalized on 04 December 2005. It was **60 mg/kg**, based on the following data sets which supported the critical European GAP of fosetyl. MRLs of animal products were also proposed based on the results of the feeding studies. The residue definition for enforcement was “the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl”. But at this date the total residues were calculated as the sum of fosetyl-aluminium (fosetyl-Al) and phosphonic acid expressed as fosetyl-Al and was not corrected as fosetyl.

Table 6.7.2- 1: Summary of the residue data published in the peer review (EFSA Scientific Report (2005) 54, 1-79)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP	Recommendation/ comments	MRL	STMR
Grapes	N and S	S 12 trials 25-34-32-8.6-22-25-41-30- 9.9-7.4-32-49 N 9 trials 21-9.2-27-5-18-1-36-38-26	Data are acceptable	60	26

Table 6.7.2- 2: Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6 (EFSA Scientific Report (2005) 54, 1-79)

Grapes	60 mg/kg
Milk	0.1* mg/kg
Meat, liver, kidney and fat of ruminants	0.5* mg/kg

* indicates that the MRL is set at the limit of quantification of the method of analysis

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The **temporary EU MRLs** which were based on the highest existing national MRLs were published in the Regulation (EC) No 839/2008 of 31 July 2008. The temporary EU MRL was set at 75 mg/kg for pome fruit, 100 mg/kg for table and wine grape and 0.1 or 0.5 mg/kg for animal products respectively.

Table 6.7.2- 3: Excerpt of Regulation (EC) No 839/2008 of 31 July 2008: Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fosetyl-AI (sum fosetyl + phosphonic acid and their salts, expressed as fosetyl)
0130010	(iii) Pome fruit	75
0151000	(a) Table and wine grapes	100
1010000	(i) Meat,	0.5(*)
1020000	(ii) Milk	0.1(*)
1030000	iii) Birds' eggs,	0.1(*)

(*): Limit of Quantification

The latest Regulation (EC) No 991/2014 was published on 19 September 2014 including additional **temporary EU MRLs** based on monitoring data. The residue definition for enforcement is still the sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl.

Since fosetyl is under the MRL review process at EU Level according to Regulation (EC) 396/2005, a dossier has been prepared summarizing the critical GAPs per crop and the residue data according to these GAPs. In this MRL compilation dossier submitted to the French Rapporteur, proposals of MRLs were done according to the residue definition in force. These MRLs are listed in [Table 6.7.2- 4](#).

Table 6.7.2- 4: Published EU MRLs and proposals done in the MRL compilation dossier for fosetyl

Crop / Animal Commodities	EU MRL EFSA Scientific Report (2005) 54, 1-79 (mg/kg)	Temporary EU MRL Regulation (EC) No. 839/2008 No. 991/2014 (mg/kg)	EU MRL Proposed in the MRL compilation dossier (mg/kg)
Residue definition: sum fosetyl + phosphonic acid and their salts expressed as fosetyl			
Pome fruit	Not supported	75	50
Table and wine grapes	50	100	60
Products of animal origin:			
▪ meat and other products	0.1*	0.5*	1.0*
▪ milk	0.1*	0.1*	0.2*
▪ egg	not recorded	0.1*	0.2*

* indicates lower limit of analytical determination

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In the review of the existing MRLs EFSA evaluated the residue data presented in the MRL Compilation dossier and proposed to set MRLs for phosphonic acid and fosetyl separately. These MRLs are recorded in Table 6.7.2- 5.

Table 6.7.2- 5: Proposed EU MRLs for fosetyl and phosphonic acid in the review of the existing MRLs

Crop / Animal Commodities	Temporary EU MRL fosetyl Regulation (EC) No. 991/2014 (mg/kg)	Proposed MRL	
		fosetyl EFSA 2012; 10(11):2961 (mg/kg)	phosphonic acid EFSA 2012; 10(11):2961 (mg/kg)
Pome fruit	75	0.6	40
Table and wine grapes	75	2	70
Products of animal origin:			
▪ meat and other products	0.5*		0.5*
▪ milk	0.1*		0.6 ⁽¹⁾ -0.7 ⁽²⁾
▪ eggs	Not recorded		0.1* 0.5*

*: indicates lower limit of analytical determination

(1): MRL for swine kidney

(2): MRL for bovine, sheep and goat kidney

The following tables summarise the residue endpoints (STMR and HR) for grapes and pome fruit as described in Sections CA 6.3.2 and CA 6.3.4 respectively, and the results of the MRL calculation using the OECD MRL calculator.

In this Supplementary Dossier the residue data for MRL calculation are presented according to the residue definition in force, i.e. the total residue expressed as fosetyl.

Table 6.7.2- 6: Summary of residue data for grapes

Commodity/ study	Region (a)	Outdoor / Indoor	Individual trial results (mg/kg)	n	STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)
New data set submitted in Supplementary Dossier: Total residue expressed as fosetyl							
Grapes 3x2.0 kg /ha, PHI of 21 days	EU-N	Outdoor	14, 15, 19, 20, 22, 26, 31, 32, 34, 36, 37, 54	13	26	54	90
	EU-S	Outdoor	7, 11, 13, 16, 17, 32, 42, 43, 51	12	18	51	90

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Table 6.7.2- 7: Summary of residue data for pome fruit

Commodity/ study	Region (a)	Outdoor / Indoor	Individual trial results (mg/kg)	n	STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)
New data set submitted in Supplementary Dossier: Total residue expressed as fosetyl							
Apple/Pear 3x3.6 kg /ha, spray interval of 10 days, PHI of 28 days	EU-N	Outdoor	10, 11, 15, 16, 18, 19, 21, 23	8	17	23	50
	EU-S	Outdoor	15, 17, 3x20, 23, 2x24, 29	9	20		70

Subsequently to the new results obtained in the residue trials submitted in this Supplementary Dossier, a request for EU MRL modification is going to be submitted to the Rapporteur in parallel to this Supplementary Dossier in order that the MRL for Fosetyl (total residue expressed as fosetyl) is set to **90 mg/kg for grapes** (table and wine grapes) and **70 mg/kg for pome fruit**.

For food of animal origin, no residues above the existing MRLs (0 mg/kg for milk, eggs and 0.5 mg/kg for other products of animal origin) are anticipated when applying fosetyl following the representatives uses supported in this Supplementary Dossier. Thus, existing MRLs in animal commodities do not need to be modified.

CA 6.7.3 Proposed MRLs and justification of the acceptability of the levels proposed for imported products (import tolerance)

MRL settings based on imported products are not proposed within this Supplementary Dossier for approval renewal of fosetyl.

CA 6.8 Proposed safety intervals

The minimum pre-harvest intervals (PHI) are proposed in [Table 6.8.1](#) below.

Table 6.8.1: Pre-harvest intervals for fosetyl

Crop	Region	F, G or I **	Applications	Maximum application rate (kg ai/ha)	Interval (days)	PHI (days)
Grapes	N-EU S-EU	F	foliar sprays	2.0	10-14	21
Pome fruit	N-EU S-EU	F	3 foliar sprays	3.6	7-10	28

* N-EU: northern Europe; S-EU: southern Europe; F: Field; G: Greenhouse; I: Indoor

Further safety intervals are not needed.

Document MCA – Section 6: Residues in or on treated products, food and feed
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According to the Review Report for the active substance fosetyl (EFSA Scientific Report (2005) 54, 1-79, Conclusion on the peer review of fosetyl) the Acceptable Daily Intake (ADI) of fosetyl-Al is 3.0 mg/kg bw/day and 3.9 mg/kg bw/day for phosphonic acid.

In the update of the peer review of fosetyl published on 31 May 2013, the ADI of phosphonic acid has been amended to include a correction for the water content of the material tested in the rat study and was set at 2.25 mg/kg bw/day.

Table 6.9- 1: Toxicological endpoints

Active substance	End-Point	Value (mg/kg bw/day)	Study	Safety factor	Reference
Fosetyl	Acceptable Daily Intake (ADI)	3.0 for fosetyl-Al 2.8 for fosetyl 2.25 for phosphonic acid (previously 3.9)	2 year dog and 2 year rat	100	EFSA Scientific Report (2005) 54, 1-79 + updated version on 31 May 2013
	Acute Reference Dose (ARfD)	Not allocated/not necessary			

However in the Document MCA, section 8.1 it is demonstrated that the correction for water content is inappropriate, since the study NOEL had already reported as a dose of anhydrous monosodium phosphonate. Therefore the corrected NOEL expressed as phosphonic acid is $348 \text{ mg/kg bw/day} \times (82/104) = 274 \text{ mg/kg bw/day}$, resulting in an ADI of $2.74 \text{ mg/kg bw/day}$ by applying an uncertainty factor of 100.

The calculation of the TMDI is performed in this Supplementary Dossier with the total residue expressed as fosetyl according to the residue definition in force and as phosphonic acid.

TMDI calculation

In order to evaluate the potential chronic exposure to fosetyl residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 2). For the evaluation of the chronic exposure the model uses 9 WHO diets relevant to the EU and 22 national diets from 13 different EU Member States.

The calculation of the TMDI was performed based on the existing EU MRLs for fosetyl laid down in Regulation (EU) No 991/2014.

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Table 6.9- 2: Existing EU MRLs for fosetyl

Pesticides - Web Version - EU MRLs		
Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) No 991/2014 (mg/kg)
110000	Citrus fruits	75
120010	Almonds	2.0* 75 (ft)
120030	Cashew nuts	2.0* 75 (ft)
120060	Hazelnuts/cobnuts	2.0* 75 (ft)
120070	Macadamias	2.0* 75 (ft)
120100	Pistachios	2.0* 75 (ft)
120110	Walnuts	2.0* 75 (ft)
130000	Pome fruits	75
140000	Stone fruits	2.0* 75 (ft)
151000	Grapes	100
152000	Strawberries	75
153000	cane fruits	2.0* 75 (ft)
154010	Blueberries	2.0* 75 (ft)
154030	Currants (black, red and white)	2.0* 75 (ft)
154040	Gooseberries (green, red and yellow)	2.0* 75 (ft)
161020	Figs	2.0* 75 (ft)
161040	Kumquats	2.0* 75 (ft)
161060	Kaki/Japanese persimmons	2.0* 75 (ft)
162010	Kiwi fruits (green, red, yellow)	150
162030	Passionfruits/maracujas	2.0* 75 (ft)
163010	Avocados	50
163040	Papayas	2.0* 75 (ft)
163050	Granate apples/pomegranates	2.0* 75 (ft)
163080	Pineapples	50
211000	Potatoes	30
213000	Radishes	25
220010	Garlic	2.0* 75 (ft)
220020	Onions	50
220040	Spring onions/green onions and Welsh onions	30
231010	Tomatoes	100
231020	Sweet peppers/bell peppers	130
231030	Aubergines/eggplants	100
232000	Cucurbits with edible peel	75
233000	Cucurbits with inedible peel	75
234000	Sweet corn	5
239000	Other fruiting vegetables	5
240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	10
251000	Lettuces and salad plants	75
252010	Spinaches	75
252030	Chards/beet leaves	15
255000	Witloofs/Belgian endives	75
256000	Herbs and edible flowers	75
260010	Beans (with pods)	2.0* 75 (ft)

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Pesticides - Web Version - EU MRLs		
Fosetyl-Al (sum fosetyl + phosphorous acid and their salts, expressed as fosetyl)		
260020	. Beans (without pods)	2.0* 75 (ft)
260030	. Peas (with pods)	2.0* 75 (ft)
260040	. Peas (without pods)	2.0* 75 (ft)
270010	. Asparagus	2.0* 75 (ft)
270050	. Globe artichokes	
270060	. Leeks	30
610000	. Teas	5.0*
620000	. Coffee beans	5*
630000	. Herbal infusions	500
700000	. Hops	1500
800000	. Spices	400
900030	. Chicory roots	75
	All other plant commodities	2*
1010000	(i) Tissue	0.5*
1020000	(ii) Milk	0.1*
1030000	(iii) Bird eggs	0.1*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0.5*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.5*
1060000	(vi) Snails	0.5*
1070000	(vii) Other terrestrial animal products (Wild game)	0.5*

* indicates lower limit of analytical determination.

† except of horseradish, the MRL for horseradish in the Spice group (code 0840040) is the one set for horseradish in the tuber vegetables group (code 0213040) taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Regulation (EC) No 396/2005.

(ft) MRL applicable until 30 December 2015, after that date 2*) will be applicable unless modified by a Regulation.

Calculations were made using the lowest aggregation level of food commodities meaning that in the spreadsheet the MRL were not entered at crop group levels but at individual crop levels.

The detailed result of the TMDI calculation is presented in Table 6.9- 4. The TMDI estimates for the various diets were found to range between 10.8 and 72.3% of ADI. The highest TMDI was calculated for the German child diet. For this diet apples and oranges were the highest contributors to the residue intake, representing 32.3 and 10.2% of ADI, respectively.

With EU MRLs of 90 and 70 mg/kg for grapes and pome fruit, respectively, as proposed in this Supplementary Dossier, the TMDI estimates for the various diets were found to range between 10.6 and 69.5% of ADI.

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Fosetyl

To calculate the TMDI with the total residue of fosetyl expressed as phosphonic acid, the temporary MRLs of fosetyl are re-calculated using the ratio of the molecular weight using the following formula. Then they are rounded as listed in Table 6.9- 3.

$$\text{Total residue as phosphonic acid [mg/kg]} = \frac{\text{total fosetyl [mg/kg]} \times M_{\text{phosphorous acid}}}{M_{\text{fosetyl}}}$$

M_{phosphorous acid}: Molecular weight of phosphorous acid: 82 g/mol
M_{fosetyl}: Molecular weight of fosetyl: 110 g/mol

Table 6.9- 3: Proposed temporary MRLs of fosetyl expressed as phosphonic acid (recalculated)

Total residue: sum fosetyl + phosphonic acid and their salts, expressed as phosphonic acid		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) No 991/2014 (recalculated)
110000	Citrus fruits	60
120010	Almonds	60 (ft)
120030	Cashew nuts	60 (ft)
120060	Hazelnuts/cobnut	60 (ft)
120070	Macadamias	60 (ft)
120100	Pistachios	60 (ft)
120110	Walnuts	60 (ft)
130000	Pome fruits	60
140000	Stone fruits	60 (ft)
151000	Grapes	75
152000	Strawberries	60
153000	Pine fruits	60 (ft)
154010	Blueberries	60 (ft)
154030	Currants (black, red and white)	60 (ft)
154040	Gooseberries (green, red and yellow)	60 (ft)
161020	Figs	60 (ft)
161040	Kumquats	60 (ft)
161060	Kaki/Japanese persimmons	60 (ft)
162010	Kiwi fruits (green, red, yellow)	120
162030	Passionfruits/maracujas	60 (ft)
163010	Avocados	40
163040	Papayas	60 (ft)
163050	Granate apples/pomegranates	60 (ft)
163080	Pineapples	40
211000	Potatoes	25
213080	Radishes	20
220010	Garlic	40 (ft)
220020	Onions	40
220040	Spring onions/green onions and Welsh onions	25
231010	Tomatoes	75
231020	Sweet peppers/bell peppers	100
231030	Aubergines/eggplants	75
232000	Cucurbits with edible peel	60
233000	Cucurbits with inedible peel	60

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Total residue: sum fosetyl + phosphonic acid and their salts, expressed as phosphonic acid		
234000	Sweet corn	5
239000	Other fruiting vegetables	5
240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	7
251000	Lettuces and salad plants	60
252010	Spinaches	60
252030	Chards/beet leaves	15
255000	Witloofs/Belgian endives	60
256000	Herbs and edible flowers	60
260010	Beans (with pods)	60 (ft)
260020	Beans (without pods)	60 (ft)
260030	Peas (with pods)	60 (ft)
260040	Peas (without pods)	60 (ft)
270010	Asparagus	40 (ft)
270050	Globe artichokes	40
270060	Leeks	25
610000	Teas	5.0*
620000	Coffee beans	5.0*
630000	Herbal infusions	400
700000	Hops	1200
800000	Spices	300†
900030	Chicory roots	60
	All other plant commodities	2*
1010000	(i) Tissue	0.5*
1020000	(ii) Milk	0.1*
1030000	(iii) Bird eggs	0.1*
1040000	(iv) Honey (Royal jelly, pollen, honeycomb with honey (comb honey))	0.5*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.5*
1060000	(vi) Snails	0.5*
1070000	(vii) Other terrestrial animal products (Wild game)	0.5*

* indicates lower limit of analytical determination.

† except of horseradish. The MRL for horseradish (*Armoracia rusticana*) in the spice group (code 0840040) is the one set for horseradish (*Armoracia rusticana*) in the Vegetables category, tuber vegetables group (code 0213040) taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Regulation (EC) No 396/2005.

(ft) MRL applicable until 31 December 2015, after that date (ft) will be applicable unless modified by a Regulation.

The detailed result of the TMDI calculation is presented in [Table 6.9- 5](#). The TMDI estimates for the various diets were found to range between **8.8** and **58.8% of ADI**. The highest TMDI was calculated for the German child diet. For this diet, apples and oranges were the highest contributors to the residue intake, representing **26.4** and **8.3% of ADI**, respectively.

Based on these results, chronic exposure to fosetyl residues, expressed as fosetyl or phosphonic acid is unlikely to cause any unacceptable risk to consumers.

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Fosetyl

Table 6.9- 4: TMDI calculation of fosetyl according to EFSA PRIMo (rev. 2.0) using the existing EU MRLs; total residue as fosetyl

		Fosetyl		Prepare workbook for refined calculations	
Status of the active substance:		Code no.			
LOQ (mg/kg bw):		proposed LOQ:			
Toxicological end points					
ADI (mg/kg bw/day):		2,8		ARfD (mg/kg bw): not applicable	
Source of ADI:		Dir 06/64		Source of ARfD: Dir 06/64	
Year of evaluation:				Year of evaluation:	
Explain choice of toxicological reference values. The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.					
Chronic risk assessment					
		TMDI (range) (% of ADI) minimum / maximum			
		11 / 7			
No of diets exceeding ADI: 11					
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	2nd contributor to MS diet (in % of ADI)	3rd contributor to MS diet (in % of ADI)	pTMRLs at LOQ (in % of ADI)
72,3	DE child	32,0 Apples	30,2 Oranges	4,5 Table grapes	
53,5	NL child	32,0 Apples	8,3 Oranges	6,3 Potatoes	
48,6	WHO Cluster diet B	11,0 Tomatoes	6,4 Wine grapes	6,0 Potatoes	
38,2	IE adult	4,5 Wine grapes	2,0 Oranges	2,5 Potatoes	
34,8	FR toddler	7,1 Apples	5,4 Potatoes	5,4 Oranges	
30,0	PT General population	6,9 Wine grapes	5,7 Potatoes	3,2 Tomatoes	
27,1	WHO cluster diet E	5,7 Wine grapes	4,1 Potatoes	3,0 Apples	
26,4	FR all population	14,3 Wine grapes	3,5 Tomatoes	1,3 Apples	
25,3	FR infant	6,0 Apples	4,4 Potatoes	2,4 Oranges	
24,7	UK Toddler	6,0 Oranges	4,6 Apples	3,7 Potatoes	
24,0	WHO regional European diet	4,3 Potatoes	3,9 Tomatoes	1,8 Apples	
23,7	DK child	6,2 Apples	1,1 Cucumbers	2,6 Potatoes	
23,6	SE general population 90th percentile	4,5 Potatoes	3,8 Apples	2,7 Tomatoes	
23,0	ES child	3,8 Oranges	3,5 Tomatoes	3,1 Apples	
22,5	NL general	4,0 Oranges	3,2 Apples	2,9 Potatoes	
22,0	WHO cluster diet D	4,4 Potatoes	3,6 Tomatoes	1,8 Apples	
19,6	ES adult	3,5 Oranges	2,8 Tomatoes	2,1 Apples	
19,4	WHO Cluster diet F	4,2 Potatoes	2,4 Tomatoes	2,3 Oranges	
19,1	UK Infant	4,2 Apples	3,5 Potatoes	3,5 Oranges	
18,7	IT kids/toddler	5,1 Tomatoes	2,4 Apples	1,3 Oranges	
17,6	PL general population	5,5 Apples	3,2 Potatoes	3,2 Tomatoes	
17,0	IT adult	4,1 Tomatoes	2,1 Apples	1,0 Lettuce	
15,9	UK vegetarian	2,9 Wine grapes	2,3 Oranges	2,2 Tomatoes	
14,9	DK adult	5,0 Wine grapes	2,1 Apples	1,6 Potatoes	
13,8	LT adult	5,0 Apples	3,4 Potatoes	2,2 Tomatoes	
13,6	UK Adult	3,0 Wine grapes	1,6 Tomatoes	1,5 Oranges	
10,8	FI adult	2,6 Oranges	1,5 Tomatoes	1,3 Potatoes	
Conclusion: The estimated Theoretical Maximum Daily Intake (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fosetyl is unlikely to present a public health concern.					

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Fosetyl

Table 6.9- 5: TMDI calculation of fosetyl according to EFSA PRIMo (rev. 2.0) using the existing EU MRLs; total residue as phosphonic acid.

		Phosphonic acid		Prepare workbook for refined calculations				
Status of the active substance:		Code no.						
LOQ (mg/kg bw):		proposed LOQ:						
Toxicological end points								
ADI (mg/kg bw/day):		2,74	ARfD (mg/kg bw):	not applicable				
Source of ADI:		Dir 06/64	Source of ARfD:	Dir 06/64				
Year of evaluation:			Year of evaluation:					
Explain choice of toxicological reference values. The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.								
Chronic risk assessment								
		TMDI (range) in % of ADI minimum / maximum						
		9 / 59						
		No of diets exceeding ADI:						
		0 / ---						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
58,8	DE child	26,1	Apples	3,5	Oranges	3,5	Potatoes	
43,8	NL child	2,2	Apples	6,8	Oranges	5,4	Potatoes	
39,1	WHO Cluster diet B	8,4	Potatoes	4,9	Wine grapes	2,1	Potatoes	
31,1	IE adult	3,4	Wine grapes	2,3	Oranges	2,1	Potatoes	
28,6	FR toddler	5,7	Apples	4,9	Potatoes	4,4	Oranges	
24,1	PT General population	4,4	Wine grapes	3,5	Potatoes	2,4	Potatoes	
22,0	WHO cluster diet E	4,4	Wine grapes	3,5	Potatoes	1,0	Apples	
20,9	FR infant	5,5	Apples	3,8	Potatoes	2,0	Oranges	
20,8	FR all population	10,9	Wine grapes	3,2	Tomatoes	1,0	Apples	
20,6	UK Toddler	3,7	Oranges	3,0	Apples	3,2	Potatoes	
19,6	WHO regional European diet	3,7	Potatoes	2,7	Tomatoes	1,5	Apples	
19,5	DK child	5,1	Apples	3,6	Cucumbers	2,2	Potatoes	
19,4	SE general population 90th percentile	3,8	Potatoes	2,3	Apples	2,1	Tomatoes	
18,8	ES child	4,7	Oranges	2,7	Tomatoes	2,5	Apples	
18,4	NL general	3,3	Oranges	2,6	Apples	2,5	Potatoes	
18,0	WHO cluster diet D	3,7	Potatoes	2,8	Tomatoes	1,5	Apples	
15,9	UK Infant	3,4	Apples	3,4	Potatoes	2,8	Oranges	
15,9	ES adult	3,3	Oranges	2,1	Tomatoes	1,7	Apples	
15,8	WHO Cluster diet F	3,1	Potatoes	1,9	Oranges	1,9	Tomatoes	
15,1	IT kids toddler	3,9	Tomatoes	1,9	Apples	1,1	Oranges	
14,3	PL general population	4,5	Apples	3,0	Potatoes	2,4	Tomatoes	
13,8	IT adult	3,1	Tomatoes	1,9	Apples	0,8	Lettuce	
12,9	UK vegetarian	2,2	Wine grapes	1,9	Oranges	1,7	Tomatoes	
11,9	DK adult	3,8	Wine grapes	1,7	Apples	1,3	Potatoes	
11,3	LT adult	4,1	Apples	2,9	Potatoes	1,7	Tomatoes	
10,9	UK Adult	3,0	Wine grapes	1,3	Potatoes	1,2	Oranges	
8,8	FI adult	1,2	Oranges	1,2	Tomatoes	1,1	Potatoes	
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of phosphonic acid is unlikely to present a public health concern.								

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****NEDI calculation**

Since the TMDI calculations for fosetyl-Al demonstrate a considerable margin of safety, it was not deemed necessary to perform National Estimated Daily Intake (NEDI) calculations in order to refine the dietary risk assessment.

NESTI calculation

Fosetyl-Al is characterized by low acute toxicity and it was not deemed necessary to set or propose an ARfD for this compound. It is, therefore, not relevant to perform the National Estimated Short Term Intakes (NESTI)/International Estimated Short Term Intakes (IESTI) calculations.

CA 6.10 Other studiesResidue studies with fertilizers

The aim of these studies is to compare the residue level in phosphonic acid quantified in several crops at harvest resulting from treatments with fertilizers or with plant protection products containing fosetyl.

Report:	KCA 6.10/01 [REDACTED], 2003; M-232740-01-1
Title:	Residues at harvest in pear European Union (Southern zone) 2002 Fosetyl-aluminium, AE F053616 Water dispersible granule (WG) 80% w/w Code: AE F053616 00 WG80 A103
Report No.:	02R107
Document No.:	M-232740-01-1
Guideline(s):	EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s):	none
GLP/GEP:	yes
Report:	KCA 6.10/02 [REDACTED], 2003; M-232744-01-1
Title:	Residues at harvest in grapes European Union (Southern zone) 2002 Mancozeb + cymoxanil + fosetyl-aluminium wettable powder (WP) 25% + 2.5% + 32.5% w/w and Copper oxychloride + fosetyl-aluminium wettable powder (WP) 25% + 25% w/w Code: AE F053616 08 WP60 A103 + AE F053616 07 WP50 A102
Report No.:	02R117
Document No.:	M-232744-01-1
Guideline(s):	EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s):	none
GLP/GEP:	yes
Report:	KCA 6.10/03 [REDACTED], 2003; M-228954-01-1
Title:	Residues at harvest in leaf lettuce European Union (Southern zone) 2002 Fosetyl-aluminium, AE F053616 water dispersible granule (WG) 80% w/w Code: AE F053616 00 WG80 A103
Report No.:	02R115
Document No.:	M-228954-01-1
Guideline(s):	EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s):	none
GLP/GEP:	yes

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Fosetyl**

Report: KCA 6.10/04 [REDACTED]; [REDACTED]; 2005; M-251608-01-1
Title: Determination of the Residues of Fosetyl-Al in/on Pear after Spraying of AE F053616 00 WG80 A1 (80 WG) in the Field in Italy, Spain and Southern France
Report No.: RA-2720/03
Document No.: M-251608-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15,1991, Annex II, part A, section 6 and Annex III, part A, section 6 Residues in or on Treated Products, Food and Feed
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/05 [REDACTED]; [REDACTED]; 2005; M-251488-01-1
Title: Determination of the residues of Fosetyl-Al in/on grape after spraying of AE F053616 07 WP50 A1 (50 WP) and AE F053616 08 WP60 A1 (60 WP) in the field in Spain, Portugal and Italy
Report No.: RA-2702/03
Document No.: M-251488-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/06 [REDACTED]; [REDACTED]; 2005; M-251606-01-1
Title: Determination of the Residues of Fosetyl-Al in/on Lettuce after Spraying of AE F053616 00 WG80 A1 (80 WG) in the Field in Italy, Spain and Southern France
Report No.: RA-2722/03
Document No.: M-251606-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/07 [REDACTED]; [REDACTED]; 2003; M-233646-01-1
Title: Residues at harvest in pear European Union (Southern zone) 2002 Test items (fertilizer) containing phosphorous acid, water miscible suspension concentrate (SC) water soluble powder (SP) 273 g/L; 603 g/kg; 258 g/kg Code AE 0540099 00 SC20 A101, AE 0540099 00 SP60 A101, AEF081256 00 SP26 A101
Report No.: 02R109
Document No.: M-233646-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/08 [REDACTED]; [REDACTED]; 2003; M-232746-01-1
Title: Residues at harvest in wine grapes European Union (Southern zone) 2002 Phosphorous acid SC (water miscible suspension concentrate) SP (water soluble powder) SP (water soluble powder) 273 g/L; 603 g/kg; 258 g/kg Codes: AE 0540099 00 SC20 A101, AE 0540099 00 SP60 A101, AEF081256 00 SP26A101
Report No.: 02R118
Document No.: M-232746-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97
Guideline deviation(s): none
GLP/GEP: yes

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Fosetyl

Report: KCA 6.10/09 [REDACTED]; 2003; M-233642-01-1
Title: Residues at harvest in leaf lettuce European Union (Southern zone) 2002 Test items (fertilizers) containing phosphorous acid water miscible suspension concentrate (SC) water soluble powder (SP) 273 g/L; 60.3%; 25.8% Codes: AE 0540099 00 SC20 A101, AE 0540099 00 SP60 A101, AEF081256 00 SP26 A101

Report No.: 02R114
Document No.: M-233642-01-1
Guideline(s): EU Commission Working Document 7029/VI/95 rev. 5 - 22/07/97

Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/10 [REDACTED]; [REDACTED]; 2005; M-251270-01-1
Title: Determination of the Residues of Phosphorous acid in/on Pear after Spraying of AE 0540099 00 SC20 A1 (273 SC), AE 0540099 00 SP60 A1 (60.3 SP) and AE F081256 00 SP26 A1 (25.8 SP) in the Field in Italy, Spain and Southern France

Report No.: RA-2721/03
Document No.: M-251270-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed

Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/11 [REDACTED]; [REDACTED]; 2005; M-251275-01-1
Title: Determination of the Residues of Phosphorous acid in/on Grape after Spraying of AE 0540099 00 SC20 A1 (273 SC), AE 0540099 00 SP60 A1 (60.3 SP) and AE F081256 00 SP26 A1 (25.8 SP) in the Field in Spain, Portugal and Italy

Report No.: RA-2703/03
Document No.: M-251275-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed

Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/12 [REDACTED]; [REDACTED]; 2005; M-249490-01-1
Title: Determination of the residues of phosphorous acid in / on lettuce after spraying of AE 0540099 00 SC20 A1 (273 SC), AE 0540099 00 SP60 A1 (60.3 SP) and AE F081256 00 SP26 A1 (25.8 SP) in the field in Italy, Spain and Southern France

Report No.: RA-2723/03
Document No.: M-249490-01-1
Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed

Guideline deviation(s): none
GLP/GEP: yes

Report: KCA 6.10/03 [REDACTED]; [REDACTED]; 2013; M-454027-01-1
Title: Comparison of the residue level in phosphorous acid after applications of fertilizers or plant protection products containing fosetyl-A1 - Residue trials on pear, grapes and lettuce

Report No.: M-454027-01-1
Document No.: M-454027-01-1
Guideline(s): not applicable
Guideline deviation(s): not applicable
GLP/GEP: no

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl**

Residue trials were conducted over two growing seasons in 2002 and 2003 on pear, grapes and lettuce which were selected as representative crops of the uses of fosetyl-aluminium (fosetyl-Al) in southern Europe (Italy, Spain, France and Portugal). These residue trials were conducted under GLP conditions (Good Laboratory Practices).

The residue trials performed with the fertilizers were conducted in the same residue study. Therefore a total of four residue studies were conducted over 2 years for each crop. The study references are compiled in [Table 6.10- 1](#).

Table 6.10- 1: Study references by crop, year and product

Crop	Fosetyl-Al product		Fertilizers	
	Study number		Study number	
	2002	2003	2002	2003
Pear	02R107	RA-2720/03	02R109	RA-2721/03
Grapes	02R117	RA-2702/03	02R118	RA-2703/03
Lettuce	02R115	RA-2722/03	02R114	RA-2723/03

Three commercialised fertilizers (“Kendal”, “Alexin 95P” and “Fruttaflor”) were selected to conduct these trials. The plant protection products containing fosetyl-Al were the formulated product Fosetyl-Al WG 80 (“Aliette WG”) for the trials carried out on pear and lettuce and both products “Fosetyl-Al + Mancozeb + Cymoxanil” (WP 60) and “Fosetyl-Al + Copper oxychloride” (WP 50) for the trials carried out on grapes.

The concentration of fertilizers in phosphite ion (for “Kendal” and “Alexin 95P”) or in phosphate ion (for “Fruttaflor”) was determined by ion chromatography. The applied quantities were calculated for each crop according to the available use recommendations of each fertilizer. The number of applications and the recommended pre-harvest interval (PHI) were defined according to the intended uses of fosetyl-Al products.

According to the crop and the year control and treated samples were taken at different sampling days after the last application (decline or harvest trials).

Residues of phosphonic acid (named phosphorous acid in the study reports) were determined in all harvested samples with a limit of quantification of 0.2 or 0.5 mg/kg according to the used method. Residues of fosetyl-Al were only determined in samples from trials with applications of plant protection product containing fosetyl-Al with a limit of quantification of 0.2 or 0.5 mg/kg according to the used method.

These residue trials demonstrate that applications of Kendal or Alexin 95P lead to comparable residue levels of phosphonic acid with the residue level of phosphonic acid resulting from applications of fosetyl-Al formulations. On the other hand there is no significant residue level of phosphonic acid after applications of Fruttaflor.

**Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl****Composition of the three fertilizers used in the residue trials**

- **Kendal** marketed by Valagro

Fertilizer containing NK 3.5-15.5 in suspension: liquid formulation.

Composition: Nitrogen (N) total 3.5 %
Nitrogen (N) organic 0.3 %
Nitrogen (N) ureic 3.2%
Potassium oxide (K₂O) water soluble 15.5%

Rate recommended on the label: 1.5-2.0 L/ha.

Remark: despite this is not declared on the label, KENDAL also contains phosphorus as phosphonic acid.

Content determined by Ion Chromatography*:

Phosphites (as phosphite ion (PO₃)³⁻): 273 g/L (in 2002) and 316 g/L (in 2003).

- **Alexin 95 PS** marketed by Masso - Chimasso Italia SpA

Fertilizer containing PK, formulated as soluble powder.

Composition: Phosphor as phosphor dioxide (P₂O₅) : 52 %
Potassium as potassium oxide (K₂O) : 42%

Rate recommended on the label: foliar spray 250 g/hl (25 kg/ha) with 2-4 applications.

Remark: The product is a potassium phosphate, 60% phosphorous acid.

Content determined by Ion Chromatography*:

Phosphites (as phosphite ion (PO₃)³⁻): 603 g/kg (in 2002) and 514 g/kg (in 2003).

- **Fruttaflor 20-20-20** marketed by SGAM

Fertilizer as soluble powder for foliar application and fertirrigation

Composition: Nitrogen (N): 20.0 % (of which ammonium-N 4%, nitric-N 5,5%, ureic-N 10,5%)
Phosphor dioxide (P₂O₅) : 20.0 %
Potassium oxide (K₂O) : 20.0%

Rate recommended on the label: foliar spray 200 g/hl with 2-4 applications

Content determined by Ion Chromatography*:

Phosphates (as phosphate ion (PO₄)³⁻): 258 g/kg (in 2002) and 251 g/kg (in 2003).

*: The certificates of GLP analysis are recorded in the corresponding residue report.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

For each crop and year, the trials were performed in three different locations. In each location different plots were selected in the same area in order to perform the trials in comparable conditions. These plots were clearly identified according to each product (fosetyl-Al product, Kendal SC20, Alexin SP 60 and Fruttaflor SP26). As an example the grape trials are presented in the following table.

Table 6.10- 2: List of the grape residue trials (24 residue trials)

Year	Country	Location	Product	Study No	Trial No	Plot
2002	Italy	44020 Masi Torello	Fosetyl-Al	02R117	02R117-1	-
			Kendal SC20	02R118	02R118-1	02
			Alexin SP60	02R118	02R118-1	03
			Fruttaflor SP26	02R118	02R118-1	04
	Italy	41030 San Prospero	Fosetyl-Al	02R117	02R117-2	-
			Kendal SC20	02R118	02R118-2	02
			Alexin SP60	02R118	02R118-2	03
			Fruttaflor SP26	02R118	02R118-2	04
	Italy	40026 Casola Canina	Fosetyl-Al	02R117	02R117-3	-
			Kendal SC20	02R118	02R118-3	02
			Alexin SP60	02R118	02R118-3	03
			Fruttaflor SP26	02R118	02R118-3	04
2003	Spain	46340 Campo Arcis	Fosetyl-Al	RA-2702/03	R 2003 0528/1	-
			Kendal SC20	RA-2703/03	R 2003 0535/4	-
			Alexin SP60	RA-2703/03	R 2003 0537/0	-
			Fruttaflor SP26	RA-2703/03	R 2003 0539/7	-
	Portugal	25804 Alenquer	Fosetyl-Al	RA-2702/03	R 2003 0906/6	-
			Kendal SC20	RA-2703/03	R 2003 0908/2	-
			Alexin SP60	RA-2703/03	R 2003 0910/4	-
			Fruttaflor SP26	RA-2703/03	R 2003 0912/0	-
	Italy	40158 Vignola	Fosetyl-Al	RA-2702/03	R 2003 0907/4	-
			Kendal SC20	RA-2703/03	R 2003 0909/0	-
			Alexin SP60	RA-2703/03	R 2003 0911/2	-
			Fruttaflor SP26	RA-2703/03	R 2003 0913/9	-

-: not relevant

The main information about the applications (product content and GAP) and the obtained results are compared in the following tables and are presented in greater detail in the Tier 1 summary forms in Appendix 1.

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.10- 3: Comparison of the residue trials conducted on pear

	Aliette WG80	Kendal SC20	Alexin SP60	Fruttaflor SP26
Application	3.75 kg product/ha	3 L or 4 L product/ha	2.5 kg product/ha	3.75 kg product/ha
Product content in 2002	819 g/kg of fosetyl-Al	273 g/L as (PO ₃) ³⁻	603 g/kg as (PO ₃) ³⁻	258 g/kg as (PO ₄) ³⁻
Product content in 2003	819 g/kg of fosetyl-Al	316 g/L as (PO ₃) ³⁻	514 g/kg as (PO ₃) ³⁻	251 g/kg as (PO ₄) ³⁻
Active ingredient kg/ha in 2002	3.0 g/kg of fosetyl-Al/ha	0.819 kg as (PO ₃) ³⁻ /ha	1.507 kg as (PO ₃) ³⁻ /ha	0.968 kg as (PO ₄) ³⁻ /ha
Active ingredient kg/ha in 2003	3.0 g/kg of fosetyl-Al/ha	1.092 kg as (PO ₃) ³⁻ /ha	1.508 kg as (PO ₃) ³⁻ /ha	0.968 kg as (PO ₄) ³⁻ /ha
Mean active ingredient kg/ha	3.0 kg/ha of fosetyl-Al x 3T PHI = 40 d	0.8-1.1 kg as (PO ₃) ³⁻ /ha x 3T PHI = 40 d	1.5 kg as as (PO ₃) ³⁻ /ha x 3T PHI = 40 d	0.97 kg as as (PO ₄) ³⁻ /ha x 3T PHI = 40 d
Active ingredient kg/ha expressed as fosetyl-Al**	3.0 kg fosetyl-Al/ha	1.4 kg/ha equivalent fosetyl- Al	2.3 kg/ha equivalent fosetyl- Al	1.3 kg/ha equivalent fosetyl-Al

Residues of phosphonic acid (mg/kg)

Year 2002	Study 02R107	Study 02R109		
Italy	6.6 (0.32)	4.0 (0.44)	0.7 (0.44)	0.3 (0.44)
Italy	11	6.4 (3.3)*	4.7 (3.3)*	0.53 (3.3)*
Italy	11	3.7 (0.8)	3.7 (0.5)	0.65 (0.81)

Year 2003	Study RA-2720/03	Study RA-2721/03		
Italy	2.6 (2.6)	1 (1.0)	9.0 (2.5)	3.4 (3.3)
Spain	5.1	4.4	4.2	< 0.5
France	10	4.7	4	< 0.5

Mean (2002 and 2003)	4.0	5.5	4.5	1.0
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- (): residue level of phosphonic acid found in the corresponding control sample
 *: contamination or co-eluted chromatographic peak not elucidated during the study
 **: example of calculation is given below
 T: treatment

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.10- 4: Comparison of the residue trials conducted on grapes

	Fosetyl-Al WP 50 and WP 60	Kendal SC20	Alexin SP60	Fruttaflor SP26
Application	4.0 kg then 2.5 kg product/ha	3 L product/ha	2.5 kg product/ha	2.5 kg product/ha
Product content in 2002	314 g/kg then 249 g/kg of fosetyl-Al	273 g/L as (PO ₃) ³⁻	603 g/kg as (PO ₃) ³⁻	258 g/kg as (PO ₄) ³⁻
Product content in 2003	319 g/kg then 244 g/kg of fosetyl-Al	316 g/L as (PO ₃) ³⁻	514 g/kg as (PO ₃) ³⁻	251 g/kg as (PO ₄) ³⁻
Active ingredient kg/ha in 2002	1.3 kg/kg then 0.6 kg/kg of fosetyl-Al/ha	0.819 kg as (PO ₃) ³⁻ /ha	1.507 kg as (PO ₃) ³⁻ /ha	0.645 kg as (PO ₄) ³⁻ /ha
Active ingredient kg/ha in 2003	1.3 g/kg then 0.6 g/kg of fosetyl-Al/ha	0.950 kg as (PO ₃) ³⁻ /ha	1.285 kg as (PO ₃) ³⁻ /ha	0.628 kg as (PO ₄) ³⁻ /ha
Mean active ingredient kg/ha	1.3 kg a.i./ha of fosetyl-Al x 3T + 0.6 kg a.i./ha x 2T PHI = 40 d	0.82-0.95 kg as (PO ₃) ³⁻ /ha x 5 PHI = 40 d	1.3-1.3 kg as (PO ₃) ³⁻ /ha x 5 PHI = 40 d	0.65-0.6 kg as (PO ₄) ³⁻ /ha x 5 PHI = 40 d
Active ingredient kg/ha expressed as fosetyl-Al**	1.0 kg fosetyl-Al/ha	1.3 kg/ha equivalent fosetyl-Al	1.1 kg/ha equivalent fosetyl-Al	0.8 kg/ha equivalent fosetyl-Al

Residues of phosphonic acid (mg/kg)

Year 2002	Study 02P17	Study 02P18		
Italy	16	14		<0.5
Italy	17	19	13	3.0
Italy *	25	21 ^(3.6)	31	10 ^(3.6)

Year 2003	Study RA-2702/03	Study RA-2703/03		
Spain	23	28	28	< 0.5
Portugal	5.7	18	32	< 0.5
Italy	3	3	3	< 0.5

Mean (2002 and 2003)	14	19	23	2.5
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*: contamination in H₃PO₃ in the control samples

** : example of calculation is given below

T: treatment

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Table 6.10- 5: Comparison of the residue trials conducted on lettuce

	Aliette WG80	Kendal SC20	Alexin SP60	Fruttaflor SP26
Application	2.5 kg	1.5 L or 2.0 L product/ha	2.5 kg product/ha	2.5 kg product/ha
Product content in 2002	819 g/kg of fosetyl-Al	273 g/L as (PO ₃) ³⁻	603 g/kg as (PO ₃) ³⁻	258 g/kg as (PO ₄) ³⁻
Product content in 2003	819 g/kg of fosetyl-Al	316 g/L as (PO ₃) ³⁻	514 g/kg as (PO ₃) ³⁻	251 g/kg as (PO ₄) ³⁻
Active ingredient kg/ha in 2002	2.0 g/kg of fosetyl-Al/ha	0.410 kg as (PO ₃) ³⁻ /ha	1.507 kg as (PO ₃) ³⁻ /ha	0.645 kg as (PO ₄) ³⁻ /ha
Active ingredient kg/ha in 2003	2.0 g/kg of fosetyl-Al/ha	0.546 kg as (PO ₃) ³⁻ /ha	1.508 kg as (PO ₃) ³⁻ /ha	0.645 kg as (PO ₄) ³⁻ /ha
Mean active ingredient kg/ha	2.0 kg fosetyl-Al/ha x 2T PHI = 14 d	0.41-0.55 kg as (PO ₃) ³⁻ /ha x 2T PHI = 14 d	1.5 kg as (PO ₃) ³⁻ /ha x 2T PHI = 14 d	0.65 kg as (PO ₄) ³⁻ /ha x 2T PHI = 14 d
Active ingredient kg/ha expressed as fosetyl-Al*	2.0 kg fosetyl-Al/ha	0.7 kg/ha equivalent fosetyl- Al	2.3 kg/ha equivalent fosetyl- Al	0.8 kg/ha equivalent fosetyl-Al

Residues of phosphonic acid (mg/kg)

Year 2002	Study 02R115	Study 02R143		
Italy	1.6	0.50	1.6	<0.2
Italy	1.6	0.78	3.1	<0.2
Italy	3.0	1.7	4.9	<0.2

Year 2003	Study RA 2722/03	Study RA 2723/03		
Italy	2.5	0.9	13	<0.5
Spain	4.9	1.2	4.6	<0.5
France	1.9	<0.1	2.3	<0.5

Mean (2002 and 2003)	3.4	1.4	4.9	<0.5
---------------------------------	------------	------------	------------	----------------

*: example of calculation is given below

T: treatment

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Example of calculation for application rate of fertilizer expressed as fosetyl-Al

Example of calculation for application rate: residue trial on pear with Alexin 95 PS

Application rate: 2.5 kg product/ha

Active ingredient as ion phosphite (PO₃)³⁻: 603 g/L in 2002

514 g/L in 2003

Mean: 559 g/L

Theoretical amount of fosetyl-Al kg/ha corresponding to the phosphite ion content:

$$\text{Equivalent fosetyl-Al [kg/ha]} = \frac{2.5 \times 0.559 \times 354.1}{3 \times 79} = \mathbf{2.1 \text{ kg/ha}}$$

79 = molecular weight of (PO₃)³⁻

354.1 = molecular weight of fosetyl-Al

3 moles of ion phosphite are necessary to build fosetyl-Al

Example of calculation for application rate: residue trial on pear with Frutaflo

Application rate: 3.75 kg product/ha

Active ingredient as ion phosphate (PO₄)³⁻: 258 g/L in 2002

251 g/L in 2003

Mean: 255 g/L

Theoretical amount of fosetyl-Al kg/ha corresponding to the phosphate ion content:

$$\text{Equivalent fosetyl-Al [kg/ha]} = \frac{3.75 \times 0.255 \times 354.1}{3 \times 95} = \mathbf{1.2 \text{ kg/ha}}$$

95 = molecular weight of (PO₄)³⁻

354.1 = molecular weight of fosetyl-Al

3 moles of ion phosphate are necessary to build fosetyl-Al

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Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Summary of the results

The mean results of the residue trials conducted over 2 years are compiled in the following tables.

Table 6.10- 6: Comparison of the application rate in kg fosetyl-Al equivalent/ha

Crop	Fosetyl-Al kg fosetyl-Al /ha	Fertilizer		
		Kendal kg /ha equivalent fosetyl-Al	Alexin 95 PS kg /ha equivalent fosetyl-Al	Fruttolor 20-20-20 kg /ha equivalent fosetyl-Al
Pear	3.0	1.6	2.1	1.2
Grapes	1.0	1.3	2.1	0.8
Lettuce	2.0	0.8	2.1	0.8

Table 6.10- 7: Residue levels at harvest time expressed as mg/kg of phosphonic acid

Crop	Fosetyl-Al mg/kg H ₃ PO ₃	Fertilizer		
		Kendal mg/kg H ₃ PO ₃	Alexin 95 PS mg/kg H ₃ PO ₃	Fruttolor 20-20-20 mg/kg H ₃ PO ₃
Pear	10*	5.5*	4.5*	1.0*
Grapes	14*	1.9*	2.3*	2.5*
Lettuce	3.4	1.4	1.9	< 0.5

H₃PO₃: phosphonic acid (named phosphorous acid in the study reports)

*: in some residue trials, residues of phosphonic acid were detected in control and treated samples, however these contamination were not explained.

Conclusion

When fertilizers containing salts of phosphonic acid (phosphonates), e.g. Alexin 95 PS or Kendal, residues of phosphonic acid were measured at harvest at levels comparable to applications with products containing fosetyl-Al.

Therefore there is no way to conclude that the residue of phosphonic acid observed in a commodity results from the use of a pesticide or a fertilizer or both.

When plant production products containing fosetyl-Al as the active substance are used, any additional use of fertilizers containing phosphonates will result in an increase of the residue found as phosphonic acid.

CA 6.10.1 Effect on the residue level in pollen and bee products

No suitable test method for the determination of residues in pollen and bee products is listed in Commission Communication 2013/C 95/01, about the implementation of Regulation (EU) No 283/2013. Therefore, this point does not need to be addressed.

Honey and bee products are included in the dietary risk assessment by its default MRL of 0.5 mg/kg with the residue expressed as fosetyl (see Table 6.9- 2) or expressed as phosphonic acid (see Table 6.9- 3). When expressed as fosetyl the total residue intake was calculated as 10.8 to 72.3% of the ADI. When expressed as phosphonic acid the total residue intake accounted for 8.8 to 58.8% of the ADI. The highest TMDI contributed from residues in apple and orange for a diet of the most vulnerable subgroup "German child". In the PRIMO rev.2-calculations (see Table 6.9- 4 and Table 6.9- 5) honey was not listed among the 2nd highest contributors.

Appendix 1 Tier 1 summaries

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Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Grape treated with Profiler in the field in northern Europe

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED] Crop/Crop Group : Vines
 Country : Germany Page : 1

Content of active substance (g/kg or g/L) : 666.7 g/kg
 Formulation (e.g. WP) : 71.11 WG

Active substance : Fosetyl-Al

Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1
 Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s) Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days)	Remarks
				kg a.s./ha	Water (l/ha)	kg a.s./hl				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R284 01R284-1 [REDACTED] 2001	Grape Riesling, white variety	1) 1989 2) 10.06.2001 - 20.06.2001 3) 05.10.2001	SPI SPI SPI	1.878 1.878 1.878	500 500 500	0.376 0.376 0.376	85	Softening of berries	bunch of grapes	5.2 3.2 2.2 1.6 3.1	13 11 19 15 23	22 18 28 22 34	17 13 21 16 25	0 7 14 21<< 29	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
										0.48 0.39 0.43 0.29 0.32	10 9.2 12 12 11	14 13 16 16 15	10 10 12 12 11	0 7 14 21<< 29	Residue in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 2

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	11	
				Kg a.s./ha	Water (L/ha)	kg (i) aL			Application rate per treatment	Dates of treatment(s)/ Application interval or no. of treatments and last date	Growth stage at last treatment	Portion analysed (a)			Analyte 1
01R284 01R284-2 Germany [redacted] 2001	Grape Silvaner, white variety	1) 1985 2) 09.06.2001 - 19.06.2001 3) 05.10.2001	SPI SPI SPI	1.978 1.878 1.878	500 300 300	0.376 0.376 0.376	85	Softening of berries	bunch of grapes	4.3 3.2 3.4 1.3 2.2	13 18 21 21 22	21 29 31 29 32	16 22 23 22 24	0 7 14 21<< 29	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 3

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11			
				kg a.s./ha	Water (L/ha)	kg a.s./L									
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or post-treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				Analyte 1	Analyte 2	Analyte 3				Analyte 4					
01R284 01R284-3 France [REDACTED] 2001	Grape Cabernet Franc, red variety	1) 1992 2) 10.06.2001 - 25.06.2001 3) 04.10.2001	SPI SPI SPI	1.878 1.878 1.878	250 250 250	0.754 0.754 0.754	85	Berries brightening in color	bunch of grapes	2.1 1.3 <0.20* 0.39	9.4 12 11 3.3* 16	15 17 16 4.6* 22	11 13 12 3.4* 16	0 7 14 21<< 28	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples *Day 21: A potential inversion of the results between untreated sample and treated sample at 21 days seems being happened.
										<0.20 <0.20 <0.20 0.7* <0.20	2.1 2.3 2.4 13* 3.4	3.0 3.3 3.4 18* 4.7	2.2 2.4 2.5 14* 3.5	0 7 14 21<< 28	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 4

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7				8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R284 01R284-4 France [REDACTED] 2001	Grape Chenin, white variety	1) 1986 2) 10.06.2001 - 25.06.2001 3) 27.09.2001	SPI SPI SPI	1.878 1.878 1.878	220 220 220	0.854 0.854 0.854	85	Softening of bunches of grapes	1.5 4 0.93 0.85 0.62	7.7 12 9.7 14 16	12 17 14 20 22	8.7 13 10 15 16	0 7 14 21<< 28	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

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Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE 0638206 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT (PHI) (days) (i)	Remarks
01R284 01R284-5 [REDACTED] 2001	Grape Pinot Meunier, red variety	1) 1987 2) 15.06.2001 - 20.06.2001 3) 26.09.2001	SPI SPI SPI	0.878 1.878 1.878	1000 1000 1000	0.1878 0.1878 0.1878	09.08.2001/0 22.08.2001/13 05.09.2001/14	bunch of grapes	2.0 0.62 0.47 0.25 <0.20	7.1 9.6 12 11 11	11 13 17 15 15	8.5 10 12 11 11	0 7 14 21<< 28	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples	
									<0.20 <0.20 <0.20 <0.20 <0.20	0.29 0.29 0.36 0.40 0.49	0.58 0.58 0.67 0.72 0.84	0.43 0.43 0.50 0.54 0.63	0 7 14 21<< 28		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 6

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT / PHI (days) (i)	Remarks
02R288 02R288-1 Germany [REDACTED] 2002	Grape Müller - Thurgau white variety	1) 15.05.1985 2) 15.06.2002 - 29.06.2002 3) 16.09.2002	SPI SPI SPI	1.878 1.878 1.878	500 500 500	0.376 0.376 0.376	29.07.2002/0 12.08.2002/14 26.08.2002/14	bunch of grapes	2 19	8.4 13	13 19	9.9 14	0 21<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples	
									<0.50 <0.50	0.93 1.8	1.7 2.9	1.3 2.1	0 21<<		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 7

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			6	7	8				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT / PHI (days) (f)	Remarks
02R288 02R288-2 Germany [REDACTED] 2002	Grape Spätburgunder red variety	1) 15.05.1985 2) 08.06.2002 - 22.06.2002 3) 07.10.2002	SPI SPI SPI	1.878 1.878 1.878	500 500 500	0.376 0.376 0.376	19.08.2002/0 02.09.2002/14 06.09.2002/14	bunch of grapes	4.3	24 37	41 54	31 40	0 21<<	(c) SPI: Spraying (g) AR 154-97 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 8

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
02R288 02R288-3 France [REDACTED] 2002	Grape Pinot Meunier red variety	1) 01.04.1987 2) 05.06.2002 - 15.06.2002 3) 23.09.2002	SPI SPI SPI	1.08 2.086 1.878	500 300 300	0.376 0.376 0.376	05.08.2002/05.08.2002/14 19.08.2002/14 03.09.2002/14	80 bunches of grapes	3.8 13 14	21 20 15	16 15	0 21<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples		
									<0.50 <0.50	0.79 0.61	1.5 1.3	1.1 0.96	0 21<<		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 9

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE F638206 4.44%

Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate of treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				Date of PHI (days) (f)	Remarks
02R288 02R288-4 France [REDACTED] 2002	Grape Chardonnay white variety	1) 15.03.1977 2) 10.06.2002 - 25.06.2002 3) 18.09.2002	SPI SPI SPI	1.878 1.878 1.878	500 500 500	0.376 0.376 0.376	31.07.2002/0 08.2002/14 28.08.2002/14	83	Bunch of grapes	4.3 <0.50	14 19	23 26	17 19	0 21<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples
										0.57 <0.50	5.0 2.3	7.2 3.6	5.4 2.7	0 21<<	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 10

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : fluopicolide 4.44 %

Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s) / Application interval or of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (a)	Residues (mg/kg) (f)				Residues /PHI (days)	Remarks
08-2040 08-2040-01 France, north [REDACTED] 2008	Grape Cot	1) 01.01.2002 2) 02.06.2008 - 09.06.2008 3) 17.09.2008 - 07.10.2008	SPI SPI SPI	2.0 2.0 2.0	200 200 200	1.0 1.0 1.0	14.08.2008/0 21.08.2008/7 28.08.2008/7	8 8 8	bunch of grapes	1.8 6.6 1.4 1.5	4.1 4.6 9.2 8.5	7.2 12 14 13	5.4 9.2 10 9.5	0** 0 21<< 28	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples ** days before last treatment
									<0.01 <0.01	1.7 2.0	2.3 2.7	1.7 2.0	0** 28		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 11

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : fluopicolide 4.44 %

Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				Kg a.s./ha	Water (L/ha)	kg (i) a.i.L				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date	Growth stage at last treatment	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days)	Remarks
08-2040 08-2040-02 France, north [REDACTED] 2008	Grape Cabernet franc	1) 01.01.1975 2) 09.06.2008 - 16.06.2008 3) 17.09.2008 - 07.10.2008	SPI SPI SPI	2.0 2.0 2.0	200 200 200	1.0 1.0 1.0	11.08.2008/6 18.08.2008/7 20.08.2008/7	bunch of grapes	3.9 1.9 1.8	10 9.9 26 24	17 21 36 34	13 15 27 25	0** 0 21<< 28	(c) SPI:Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc.	
									<0.01 <0.01	2.6 2.5	3.5 3.4	2.6 2.5	0** 28	Residue in untreated control samples ** days before last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 12

Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : fluopicolide 4.44 %

Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				Kg a.s./ha	Water (L/ha)	kg a.s./ha			(a)	Analyte 1	Analyte 2	Analyte 3			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment	Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	(f)	Remarks	
08-2040 08-2040-03 Germany 2008	Grape Dornfelder	1) 01.04.1992 2) 04.06.2008 - 19.06.2008 3) 12.09.2008 - 12.10.2008	SPI SPI SPI	2.0 2.0 2.0	800 800 800	0.25 0.25 0.25	04.08.2008/6 11.08.2008/7 08.08.2008/7	bunch of grapes	4.8 4.2 5.2 4.5	12 13 24 24	21 28 37 36	15 21 28 27	0** 0 21<< 28	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples ** days before last treatment	
								<0.01 <0.01	0.35 0.36	0.48 0.49	0.36 0.37	0** 28<<			

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg

Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : Fluopicolide & Fosetyl-AI WG 71

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AI

Crop/Crop Group : Vines

Page : 13

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : Fluopicolide 44.4%

Analyte 1 Residues determined as : Fosetyl-AI

Analyte 2 Residues determined as : Phosphonic acid

Analyte 3 Residues determined as : Total residue fosetyl calc.

Analyte 4 Residues determined as : Total residue phosphonic acid calc.

Residues calculated as : Fosetyl-AI

Residues calculated as : Phosphonic acid

Residues calculated as : Fosetyl

Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate of treatment (d)			Date of treatment(s)/ Application interval (e)	BBCH stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALP/PHI (days) (f)	Remarks
08-2040 08-2040-04 [REDACTED] 2008	Grape Mueller-Thurgau	1) 25.04.1983 2) 25.05.2008 - 09.06.2008 3) 20.09.2008 - 10.10.2008	SPI SPI SPI	2.0 2.0 2.0	750 750 750	0.22 0.27 0.27	11.08.2008/0 18.08.2008/7 26.08.2008/9	79	branch of grapes	F.8 5.2 1.8 2.2	13 11 19 21	19 20 28 31	14 15 20 23	0** 0 22<< 28	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-AI and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc.
										<0.01 <0.01	7.4 7.5	10 10	7.4 7.5	0** 28	Residue in untreated control samples ** days before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALP, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Grape treated with Profiler in the field in southern Europe

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg

Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 1

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C638206 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	Application rate per treatment		Dates of treatments) Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (l/ha)				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R285 01R285-1 France [REDACTED] 2001	Grape Cabernet Sauvignon, red variety	1) 1992 2) 15.05.2001 - 15.06.2001 3) 26.09.2001	SPI SPI SPI	1.878 1.878 1.878	150 150 150	1.25 1.25 1.25	08.08.2001/ 22.08.2001/14 05.09.2001/14	bundle of grapes	3.9 3.8 3.8 1.4 1.1	20 28 27 21 31	31 41 40 30 43	23 31 30 22 32	0 7 12 21<< 28	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
									<0.20 <0.20 <0.20 <0.20 <0.20	6.8 5.1 5.8 5.3 6.1	9.3 7.0 8.0 7.3 8.4	6.9 5.2 5.9 5.4 6.2	0 7 12 21<< 28	Residue in untreated control samples

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page :
 Content of active substance (g/kg or g/L) : 666.7 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.11 WG Other a.s. in formulation (common name and content) : AE C638206 4.4 %
 Commercial product (name) : AE F053616 06 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha) g a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R285 01R285-2 France [redacted] 2001	Grape Chardonnay , white variety	1) 1983	SPI	2.078	200	26.07.2001/0	79	bunch of grapes	1.7	6.6	10	7.8	0	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
		2) 30.05.2001	SPI	1.878	200	10.08.2001/15			1.9	8.6	12	9.3	7	
		- 30.06.2001	SPI	1.0	200	23.08.2001/13			0.97	8.6	12	9.2	14	
		3) 13.09.2001							0.94	11	16	9.3	21<<	
									<0.20	1.1	1.7	1.2	0	
									<0.20	1.2	1.8	1.3	7	
									<0.20	1.3	1.9	1.4	14	
					<0.20	1.1	1.7	1.2	21<<					
					<0.20	1.3	1.9	1.4	28					
													Residue in untreated control samples	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED] Crop/Crop Group : Vines

Country : Germany Page : 3

Content of active substance (g/kg or g/L) : 666.7 g/kg Indoor/outdoor : Outdoor

Formulation (e.g. WP) : 71.11 WG Other a.s. in formulation (Common name and content) : AE 638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 3

Indoor/outdoor : Outdoor

Other a.s. in formulation (Common name and content) : AE 638206 4.44 %

Analyte 1	Residues determined as	Methyl ethyl phosphonate	Residues calculated as	Fosetyl-Al
Analyte 2	Residues determined as	Dimethyl phosphonate	Residues calculated as	Phosphonic acid
Analyte 3	Residues determined as	total residue fosetyl calc.	Residues calculated as	Fosetyl
Analyte 4	Residues determined as	total residue phosphonic acid calc.	Residues calculated as	Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				g a.s./ha	Water (l/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application Interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg)				DALT/ PHI (days) (g)	Remarks
01R285 01R285-3 Italy [REDACTED] 2001	Grape Lambrusco Di Sorbara, red variety	1) 1995 2) 01.06.2001 - 20.06.2001 3) 12.09.2001	SPI SPI SPI	1.878 1.878 1.878	1000 1000 1000	0.1878 0.1878 0.1878	26.07.2001/14 09.08.2001/14 23.09.2001/14	82 bunch of grapes	5.2 0.81 0.42 0.23	7.0 6.4 11 7.7 7.7	14 11 16 11 11	11 8.3 12 8.0 7.9	0 7 14 20<< 28	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples	
									<0.20 <0.20 <0.20 <0.20 <0.20	0.38 0.27 0.37 0.39 0.40	0.70 0.55 0.68 0.71 0.72	0.52 0.41 0.51 0.53 0.54	0 7 14 20<< 28		

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████ Crop/Crop Group : Vines

Country : Germany Page : 4

Content of active substance (g/kg or g/L) : 666.7 g/kg Indoor/outdoor : Outdoor

Formulation (e.g. WP) : 71.11 WG Other a.s. in formulation (Common name and content) : AE 638206 4.44 %

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				g a.s./ha	Water (l/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s) Application Interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT/ PHI (days) (i)	Remarks
01R285 01R285-4 ██████████ 2001	Table grape Moscatel, white variety	1) 1990 2) 10.05.2001 - 25.05.2001 3) 21.08.2001	SPI SPI SPI	1.878 1.878 1.878	1000 1000 1000	0.1878 0.1878 0.1878	02.07.2001/14 16.07.2001/14 30.07.2001/14	82 bunch of grapes	1.6 1.1 1.2	11 11 13	16 16 19	12 12 14	0 7 14	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples	
								berry	<0.20 <0.20 <0.20	0.63 0.85 0.88	1.0 1.3 1.4	0.77 0.99 1.0	0 7 14		
									0.20 0.28	12 12	16 16	12 12	22<< 28	Residue in untreated control samples	
									<0.20 <0.20	0.94 0.58	1.4 1.0	1.1 0.72	22<< 28		

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
 Country : Germany
 Content of active substance (g/kg or g/L) : 666.7 g/kg
 Formulation (e.g. WP) : 71.11 WG
 Commercial product (name) : AE F053616 06 WG71 A1
 Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 5

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C038206 4.44%

Analyte 1 Residues determined as Methyl ethyl phosphonate Residues calculated as Fosetyl-Al
 Analyte 2 Residues determined as Dimethyl phosphonate Residues calculated as Phosphonic acid
 Analyte 3 Residues determined as total residue fosetyl calc. Residues calculated as Fosetyl
 Analyte 4 Residues determined as total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment	Portion analysed (a)	Residues (mg/kg)				DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	g a.s./mL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R285 01R285-5 Greece ██████████ 2001	Grape Xinomavro, red variety	1) 1976 2) 05.06.2001 - 20.06.2001 3) 12.09.2001	SPI SPI SPI	1.878	800	0.235	24.07.2001/08.08.2001/15.08.2001/13	grapes	bunches	2.3	2.2	5.1	3.8	0	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
				1.878	800	0.235			grapes	1.4	4.7	8.9	6.7	7	
				1.878	800	0.235				<0.2	3.1	4.3	3.2	14	
										<0.2	4.6	6.4	4.7	28	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg

Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 6

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C638206 4.44%

Analyte 1	Residues determined as	Fosetyl-Al	Residues calculated as	Fosetyl-Al
Analyte 2	Residues determined as	Phosphonic acid	Residues calculated as	Phosphonic acid
Analyte 3	Residues determined as	total residue fosetyl calc.	Residues calculated as	Fosetyl
Analyte 4	Residues determined as	total residue phosphonic acid calc.	Residues calculated as	Phosphonic acid

1	2	3	4	5			7	8	9				10	11	
				Kg a.s./ha	Water (L/ha)	kg a.s./ML			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) (f)				DALT PHI (days)	Remarks
02R289 02R289-1 France [REDACTED] 2002	Grape Gamay, red variety	1) 15.04.1992 2) 01.06.2002 - 20.06.2002 3) 11.09.2002	SPI SPI SPI	1.78 1.878 1.878	300 300 300	0.626 0.626 0.626	24.07.2002 07.08.2002/14 20.08.2002/14	83 bunch of grapes	8.1	36 26	50 42	38 32	0 21<<	(c) SPI: Spraying (g) AR 154-97 (h) 0.50 mg/kg fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples	
									<0.50 <0.50	1.8 1.0	2.9 1.8	2.2 1.4	0 21<<		

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg

Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 7

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C638206 4.43%

Analyte 1	Residues determined as	Fosetyl-Al	Residues calculated as	Fosetyl-Al
Analyte 2	Residues determined as	Phosphonic acid	Residues calculated as	Phosphonic acid
Analyte 3	Residues determined as	total residue fosetyl calc.	Residues calculated as	Fosetyl
Analyte 4	Residues determined as	total residue phosphonic acid calc.	Residues calculated as	Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./L				Residues (mg/kg)					
Study Trial No.; Trial SUBID	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date	Growth stage at last treatment	Portion analysed	Analyte 1	Analyte 2	Analyte 3	Analyte 4	DALT/PHI (days)	Remarks
Location incl. postal code	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)
02R289 02R289-2 France [REDACTED] 2002	Grape Carignan, red variety	1) 11.04.1996 2) 20.05.2002 - 03.06.2002 3) 12.09.2002	SPI SPI SPI	1.878 1.878 1.878	300 300 300	0.626 0.626 0.626	26.07.2002 08.08.2002/13 23.08.2002/14	85	bunch of grapes	0.97	22 23	32 32	24 24	0 21<<	(c) SPI: Spraying (g) AR 154-97 (h) 0.50 mg/kg fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc.
										<0.50	0.86	1.6	1.2	0	Residue in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 666.7 g/kg

Formulation (e.g. WP) : 71.11 WG

Commercial product (name) : AE F053616 06 WG71 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 8

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : AE C638206 44 %

Analyte 1	Residues determined as	Fosetyl-Al	Residues calculated as	Fosetyl-Al
Analyte 2	Residues determined as	Phosphonic acid	Residues calculated as	Phosphonic acid
Analyte 3	Residues determined as	total residue fosetyl calc.	Residues calculated as	Fosetyl
Analyte 4	Residues determined as	total residue phosphonic acid calc.	Residues calculated as	Phosphonic acid

1	2	3	4	5			6	7	9				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Date of treatment(s) Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
02R289 02R289-3 Italy [REDACTED] 2002	Grape Malvasia Leccese, white variety	1) 12.03.1982 2) 15.05.2002 - 31.05.2002 3) 01.10.2002	SPI SPI SPI	1.878 1.878 1.878	1000 1000 1000	0.1878 0.1878 0.1878	13.08.2002/0 23.08.2002/15 10.09.2002/2	85	bunch of grapes	10 1.4 1.5	11 11 5.5	24 16 8.8	18 12 6.5	0 21<< 21<<	(c) SPI: Spraying (g) AR 154-97 (h) 0.50 mg/kg fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
Country : Germany
Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG
Commercial product (name) : AE F053616 06 WG71 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
Crop/Crop Group : Vines
Page : 9
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : AE C638206 1.44 %
Analyte 1 Residues determined as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid
Analyte 3 Residues determined as : total residue fosetyl calc.
Analyte 4 Residues determined as : total residue phosphonic acid calc.

Residues calculated as : Fosetyl-Al
Residues calculated as : Phosphonic acid
Residues calculated as : Fosetyl
Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	9				10	11	
				kg a.s./ha	Water (L/ha)	g a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Date of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
02R289 02R289-4 Spain ██████████ 2002	Grape Macabeo, white variety	1) 1993 2) 15.06.2002 - 30.06.2002 3) 03.09.2002	SPI SPI SPI	1.878 1.878 1.878	750 750 750	0.250 0.250 0.250	16.07.2002/0 13.08.2002/14	85	bunch of grapes	11 <0.5	12 12	17 17	13 12	0 21<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc., 0.85 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany
Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG
Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
Crop/Crop Group : Vines
Page : 10
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : flupicolide 4.44 %
Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	9				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Date of treatment(s) / Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
RA-2671/07 R 2007 0816/5 0816-07 [REDACTED] 2007	Grape Carignan; Red variety	1) 15.03.2002 2) 25.05.2007 - 05.06.2007 3) 05.09.2007 - 15.09.2007	SRU SRU SRU	2.0010 2.0010 2.0010	200 200 200	1.0005 1.0005 1.0005	30.07.2007/0 08.2007/7 13.08.2007/7	85	fruit	6.0 9.8 7.1 6.4	11 10 29 33	20 23 46 51	15 17 34 37	0** 0 21<< 28 0** 28	(c) SRU: Spraying, low-volume (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residue in untreated control samples ** days before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany
Content of active substance (g/kg or g/L) : 666.7 g/kg
Formulation (e.g. WP) : 71.11 WG
Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
Crop/Crop Group : Vines
Page : 11
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : Flupicolide 4.44 %
Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	9				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Date of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DLT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
RA-2671/07 R 2007 0817/3 0817-07 Spain [REDACTED] 2007	Grape Macabeo	1) 15.01.2000 2) 20.05.2007 - 10.06.2007 3) 20.08.2007 - 30.09.2007	SPI SPI SPI	2.0010 2.0010 2.0010	1000 1000 1000	0.20010 0.20010 0.20010	24.07.2007/0 20.07.2007/6 06.08.2007/7	79	fruit	6.5 12 0.84 0.56	8.6 6.5 13 10	18 20 18 14	13 15 14 10	0** 0 21<< 28	(c) SPI:Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** days before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DLT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany
 Content of active substance (g/kg or g/L) : 666.7 g/kg
 Formulation (e.g. WP) : 71.11 WG
 Commercial product (name) : Fluopicolide & Fosetyl-Al WG 71
 Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
 Crop/Crop Group : Vines
 Page : 12
 Indoor/outdoor : Outdoor
 Other a.s. in formulation (common name and content) : fluopicolide 1.44 %

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate of treatment			Dates of treatment(s), Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg)				DALT /PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
RA-2671/07 R 2007 0818/1 0818-07 [REDACTED] 2007	Grape Sangiovese; Red variety	1) 15.03.2001 2) 20.05.2007 - 30.05.2007 3) 01.09.2007 - 25.09.2007	SPI SPI SPI	2.0010 2.0010 2.0010	5000 1000 1000	0.20010 0.0010 0.20010	06.08.2007/0 08.2007/7 20.08.2007/7	85	fruit	5.4 8.7 1.8 1.6	7.7 8.8 11 12	15 20 16 18	12 15 12 13	0** 0 21<< 28	(c) SPI:Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** days before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Pome fruit treated with Fosetyl-AI WG 80 in the field in northern Europe

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AI

Crop/Crop Group : Pomaceous fruit

Page : 1

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-AI
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	9				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) / application interval or no. of treatments and last date	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
00-537 00537AM1 France, north [REDACTED] 2000	Apple Idared	1) 1987 SPI 3) 29.07.2000 SPI	SPI SPI SPI	1.58 3.58 3.58	962 962 962	0.37 0.37 0.37	25.05.2000/0 02.08.2000/69 08.2000/29	fruit	0.76 0.25 0.23 <0.20	5.8 7.3 7.8 5.3	8.5 10 11 7.3	6.3 7.5 8.0 5.4	0.08 7 15 29<<	(c) SPI: Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-AI and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate
Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate
Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc.
Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc.
Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/° PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
00-537 00537RS1 France, north [redacted] 2000	Apple Douce coët	1) 1989 2) [redacted] 3) 26.09.2000	SPI SPI SPI	0.58 3.71 3.58	100 555 1503	0.24 0.24 0.24	16.05.2000/0 01.08.2000/77 29.08.2000/28	fruit	0.6	3.9	5.9	4.4	0.08	(c) SPI: Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples	
									<0.20 0.23 0.20	4.0 4.3 5.0	5.6 6.0 6.9	4.1 4.4 5.2	7 14 28<<<		
									<0.20 0.34	0.33 0.64	0.63 0.64	0.47 0.48	7 28<<<		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s) Application interval or no. of treatments and last date/	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/ PHI (days) (f)	Remarks	
				kg/ha	Water (L/ha)				kg a.s./hl	Analyte 1	Analyte 2	Analyte 3			Analyte 4
DR00EUN155 DR00EUN155 DEU0201 [REDACTED] 2000	Apple Jonagold	1) 15.11.1987 2) 20.04.2000 - 04.05.2000 3) 14.09.2000	SPI SPI SPI	3.6 3.6 3.6	764 764 764	0.47 0.47 0.47	20.04.2000/0 22.05.2000/0 17.08.2000/87	79	Fruit	<0.20 0.24	2.6 2.5	3.7 3.6	2.7 2.7	0 28<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 4

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7				8	11	
				kg a.s./ha	Water (L/ha)	kg a.s./ha		Analyte 1	Analyte 3	Analyte 4	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment	Dates of treatment(s)/ Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)				DALT/ PHI (days) (f)	Remarks	
DR00EUN155 DR00EUN155 DEU0501 Germany [REDACTED] 2000	Apple Elstar	1) 01.01.1986 2) 23.04.2000 - 10.05.2000 3) 04.09.2000	SPI SPI SPI	3.6 3.6 3.6	610 497 497	0.59 0.59 0.59	25.04.2000/0 25.05.2000/30 07.08.2000/74	fruit	<0.20 0.20	3.3 1.5	4.6 2.2	3.4 1.6	0 28<<	(c) SPI: Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 5

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	11	
				kg a.s./ha	Water (L/ha)	kg a.s./L			Application rate per treatment	Dates of treatment(s)/ Application interval or of treatments and last date	Growth stage at last treatment	Portion analysed (a)			Analyte 1
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	kg a.s./ha	Water (L/ha)	kg a.s./L	Application rate per treatment	Dates of treatment(s)/ Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Analyte 1	Analyte 3	Analyte 4	DALT/ PHI (days) (f)	Remarks
DR00EUN155 DR00EUN155 DEU0601 Germany [REDACTED] 2000	Pear Conference	1) 1983 2) 25.04.2000 - 01.05.2000 3) 01.09.2000	SPI SPI SPI	3.6 3.6 3.6	663 794 794	0.54 0.47 0.46	25.04.2000/0 25.05.2000/30 01.08.2000/7	79	fruit	0.30 0.47	3.4 1.8	4.8 2.9	3.6 2.1	0 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.2 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
01R105 01R105-1 United Kingdom [REDACTED] 2001	Apple Bramley	1) 1991 2) 01.05.2001 - 31.05.2001 3) 09.10.2001	SPI SPI SPI	3.6 3.6 3.6	500 500 500	0.72 0.72 0.72	16.07.2001/0 14.08.2001/29 12.09.2001/29	79	fruit	0.95 0.30 0.23 0.31 <0.20	2.0 4.6 5.5 5.8 2.4	3.6 6.5 7.6 8.1 3.4	2.7 4.8 5.7 6.0 2.5	0 5 13 20 27<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 6

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/° PHI (days) (f)	Remarks
01R105 01R105-2 United Kingdom [REDACTED] 2001	Apple Cox	1) 1991 2) 01.04.2001 - 01.06.2001 3) 20.09.2001	SPI SPI SPI	3.6 3.6 3.6	200 500 500	0.72 0.72 0.72	26.06.2001/0 26.07.2001/30 26.08.2001/29	fruit	1.2 0.44 0.41 0.39 0.33	6.7 6.7 12 14 11	11 9.4 16 19 15	8.0 7.0 12 14 11	0 7 14 21 27<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.2 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	
01R105 01R105-3 France, north [REDACTED] 2001	Apple Jonagored	1) 1991 2) 03.04.2001 - 10.04.2001 3) 1.09.2001	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	21.06.2001/0 20.07.2001/29 20.08.2001/31	77 fruit	2.2 0.92 0.23 <0.20 <0.20	2.1 3.8 3.4 2.6 3.8	4.9 6.0 4.8 3.7 5.3	3.6 4.4 3.6 2.7 3.9	0 7 14 21 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantification
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 7

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7				8	9	10	11
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or Date of first treatment and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)				DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R105 01R105-4 France, north [REDACTED] 2001	Apple Golden Delicious	1) 1972 2) 20.04.2001 - 05.05.2001 3) 10.09.2001	SPI SPI SPI	3.00 3.60 3.60	429 500 500	0.720 0.72 0.72	15.06.2001/9 16.07.2001/31 14.08.2001/28	fruit	0.97 0.20 0.49 <0.20 0.27	6.5 4.9 8.3 5.4 5.0	9.6 6.8 12 7.4 7.0	7.2 5.0 8.6 5.5 5.2	0 7 14 21 27<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 8

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				Kg a.s./ha	Water (L/ha)	kg a.s./ha			Application interval	Growth stage at last treatment	Portion analysed (a)	Analyte 1			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date	Growth stage at last treatment	Portion analysed (a)	Residues (mg/kg) Analyte 1 Analyte 2 Analyte 3 Analyte 4				DALT/ PHI (days) (f)	Remarks
01R105 01R105-5 France, north 49400 Saint [REDACTED] 2001	Apple Royal Gala	1) 1985 2) 12.04.2001 - 30.04.2001 3) 07.09.2001	SPI SPI SPI	3.6 3.6 3.6	500 500 500	0.72 0.72 0.72	11.06.2001 11.07.2001/30 08.2001/30	fruit	2.1 1.1 0.32 0.22 <0.20	2.5 3.1 5.1 4.3 3.5	5.4 5.2 7.1 6.0 4.9	4.0 3.9 5.3 4.5 3.6	0 7 14 21 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 9

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT/PHI (days) (i)	Remarks
10-2058 10-2058-01 10-2058-01 Germany [REDACTED] 2010	Apple Jonagold	1) 01.02.1996 2) 22.04.2010 - 14.05.2010 3) 13.09.2010 - 22.10.2010	SPI SPI SPI	33.6 3.6	500 500	0.72 0.72	05.08.2010/0 16.08.2010/11 23.08.2010/9	fruit	0.68 0.12 0.14 0.11 0.03	6.8 6.5 8.8 9.5 7.6	9.7 8.8 12 13 10	7.3 6.6 8.9 9.6 7.6	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 10

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT, PHI (days) (i)	Remarks
10-2058 10-2058-02 10-2058-02 France, north [REDACTED] 2010	Apple Golden	1) 01.01.1993 2) 15.04.2010 - 27.04.2010 3) 15.09.2010 - 25.09.2010	SPI SPI SPI	33.6 3.6	1500 1500	0.24 0.24 0.24	03.08.2010/0 13.08.2010/10 23.08.2010/14	fruit	0.09 0.61 0.28 0.14 0.06	14 14 15 14 16	19 20 20 19 21	14 14 15 14 16	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc.	
									<0.01 <0.01	4.9 3.8	6.5 5.1	4.9 3.8	0** 28<<	Residues in untreated control samples **prior to last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 11

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (a)	Residues (mg/kg) Analyte 1 Analyte 2 Analyte 3 Analyte 4				DALT/PHI (days) (f)	Remarks
10-2058 10-2058-03 10-2058-03 Belgium [REDACTED] 2010	Apple Reinettes de Flandres; Old variety with small fruit very hardly	1) 15.11.1999 2) 01.05.2010 - 20.05.2010 3) 08.10.2010 - 14.10.2010	SPI SPI SPI	33.6 3.6	1250 1250	0.29 0.28 0.29	20.08.2010/0 31.08.2010/11 09.2010/10	fruit	0.02 0.52 0.02 0.02 <0.01	6.3 10 9.7 12 11	8.5 14 13 15 15	6.3 10 9.7 12 11	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 12

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (a)	Residues (mg/kg)				DALT/PHI (days) (f)	Remarks
10-2058 10-2058-04 10-2058-04 United Kingdom [REDACTED] 2010	Apple Jonathan	1) 01.12.1994 2) 28.03.2010 - 15.04.2010 3) 01.10.2010 - 15.10.2010	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	18.08.2010/0 27.08.2010/9 07.09.2010/14	fruit	0.01 0.15 0.03 0.03 <0.01	3.6 5.9 11 8.8 8.2	4.8 8.1 14 12 11	3.6 6.0 11 8.8 8.2	0** 0 8 15 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 13

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7				8	9	10	11
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)				DALT/ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
09-2039 09-2039-01 France, north [REDACTED] 2009	Pear Beurré hardy	2) 14.04.2009 - 30.04.2009 3) 25.08.2009 - 31.08.2009	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.24 0.36	10.07.2009/10 20.07.2009/10 30.07.2009/10	fruit	0.08 0.14 0.24 0.21 0.06	9.5 13 13 12 12	13 18 18 16 16	9.5 14 13 12 12	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 14

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate of treatment			Date(s) of treatment(s)/ Application interval or no. of treatments and last date/	BBCH stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/ PHI (days) (f)	Remarks
09-2039 09-2039-02 Germany [REDACTED] 2009	Pear Williams Christ	1) 05.11.2005 2) 15.03.2009 - 15.04.2009 3) 20.08.2009 - 15.09.2009	SPI SPI SPI	3.6 3.6 3.6	500 500 500	0.72 0.72 0.72	13.07.2009/0 13.07.2009/16 02.08.2009/40	78	Fruit	0.01 0.62 0.04 0.02 0.01	21 18 17 22 15	28 25 22 17 19	21 18 17 14 15	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 15

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
09-2039 09-2039-03 Belgium [REDACTED] 2009	Pear Conference	1) 15.10.2002 2) 07.04.2009 - 22.04.2009 3) 26.08.2009 - 11.10.2009	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	20.07.2009/0 31.07.2009/0 10.08.2009/10	79	fruit	0.03 1.1 0.25 0.05 0.01	11 16 20 19 17	15 22 27 25 23	11 17 20 19 17	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc.
										<0.01 <0.01	1.1 0.88	1.5 1.2	1.1 0.89	0** 28<<	Residues in untreated control samples ** day before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 16

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				Kg a.s./ha	Water (L/ha)	kg a.s./L			Residue (mg/kg)	Analyte 1	Analyte 2	Analyte 3			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment	Portion analysed (a)	Residues (b)				DALT/ PHI (days) (f)	Remarks
09-2039 09-2039-04 Netherlands 2009	Pear Conference	1) 01.04.2001 2) 10.04.2009 - 25.04.2009 3) 15.09.2009 - 20.09.2009	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	31.07.2009 10.08.2009/10 20.08.2009/10	fruit	0.1 1 0.08 0.01 0.01	15 17 20 14 14	20 24 27 19 18	15 18 20 14 14	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Pome fruit treated with Fosetyl-Al WG 80 in the field in southern Europe

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
 Country : Germany
 Content of active substance (g/kg or g/L) : 800 g/kg
 Formulation (e.g. WP) : 80 WG
 Commercial product (name) : Fosetyl-AL WG 80
 Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 1

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
 Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				Application rate per treatment	Water (l/ha)	kg a.s./ha			Residue (mg/kg)	Analyte 1	Analyte 2	Analyte 3			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment	Water (l/ha)	kg a.s./ha	Dates of treatments Application interval or no. of treatments and last date/	Growth stage at last treatment	Portion analysed (a)	Residue (mg/kg)	DALT/ PHI (days)	Remarks			
DR00EUS156 DR00EUS156E SP0101 Spain [REDACTED] 2000	Apple Starking	1) 1975 2) 19.03.2000 - 30.03.2000 3) 06.09.2000	SPI SPI SPI	3.6 1.6 3.6	1000 1000 1000	0.36 0.36 0.36	31.03.2000/0 27.04.2000/27 09.08.2000/104	fruit		0.66 0.36 0.48 0.22	2.3 1.6 0.69 2.6	3.7 2.5 1.4 3.7	2.8 1.9 1.0 2.8	0 7 14 28<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./HL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment	Water	kg a.s./HL	Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
DR00EUS156 DR00EUS156E SP0102 Spain [REDACTED] 2000	Apple Reineta	1) 1986 2) 01.04.2000 - 30.04.2000 3) 14.09.2000	SPI SPI SPI	33.6 1000 3.6	1000 1000 1000	0.36 0.36 0.36	29.03.2000/0 28.04.2000/30 17.08.2000/11	fruit	<0.20 <0.20	0.34 1.7	0.64 2.5	0.48 1.8	0 28<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples	
									<0.20 <0.20	0.24 0.23	0.51 0.49	0.38 0.37	0 28<<		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
DR00EUS156 DR00EUS156 GRC0101 [REDACTED] 2000	Apple Granny Smith	1) 1993 2) 10.04.2000 - 20.04.2000 3) 28.09.2000	SPI SPI SPI	2.6 3.6 3.6	1500 1500 1500	0.24 0.24 0.24	14.04.2000/0 15.08.2000/31 31.08.2000/108	fruit	0.34 0.20	1.6 0.80	2.5 1.3	1.8 0.94	0 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 4

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8				9	10	11
				Application rate per treatment	Doses of treatment (Application interval or no. of treatments and last date/	Growth stage at last treatment			Portion analysed	Residues (mg/kg)					
Study Trial No.; Trial SubID	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Method of treatment	kg a.s./ha	Water (l/ha)	kg a.s./l	Application interval	Stage	Portion	Analyte 1	Analyte 2	Analyte 3	Analyte 4	DALT/ PHI (days)	Remarks
DR00EUS156 DR00EUS156I TA0101 Italy [REDACTED] 2000	Apple Golden Delicious	1) 1993 2) 10.04.2000 - 20.04.2000 3) 15.08.2000	SPI SPI SPI	3.6 3.6 3.6	800 800 800	0.45 0.45 0.45	11.04.2000/0 11.05.2000/28 18.08.2000/99	85	fruit	0.66 0.55 0.34 <0.20	2.1 2.3 3.2 2.3	3.4 3.6 4.6 3.3	2.6 2.7 3.4 2.4	0 7 14 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
										<0.20 <0.20	2.2 0.55	3.1 0.92	2.3 0.69	0 7	Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 5

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				Application rate per treatment	Doses of treatment (Application interval or no. of treatments and last date/	Growth stage at last treatment				Portion analysed	Residues (µg/kg)	Residues	Residues		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	g a.s./ha	Water (l/ha)	kg a.s./l	(d)	(e)	(f)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	(f)	Remarks
DR00EUS156 DR00EUS156I TA0102 Italy [REDACTED] 2000	Apple Staymared	1) 1986 2) 05.04.2000 - 20.04.2000 3) 21.09.2000	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	11.04.2000/0 12.05.2000/39 24.08.2000/104	79	fruit	0.21 <0.20	3.2 1.7	4.5 2.5	3.3 1.8	0 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 6

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL			Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment	Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/ PHI (days) (f)	Remarks	
DR00EUS157 DR00EUS157E SP0101 Spain [REDACTED] 2000	Pear Ercolina	1) 1980 2) 01.03.2000 - 30.03.2000 3) 28.06.2000	SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	1000 1000 1000 1000 1000 1000	0.060 0.060 0.60 0.060 0.36 0.36	24.03.2000/0 27.03.2000/3 30.03.2000/3 03.04.2000/4 07.04.2000/4 02.05.2000/25 14.05.2000/29	fruit	1.1 2.8 0.52 <0.20	18 18 19 24 12	26 25 28 33 16	19 18 21 24 12	0 7 14 21 28<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 7

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha				Analyte 1	Analyte 3	Analyte 4	(f)		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT/ PHI (days)	Remarks
DR00EUS157 DR00EUS157E SP0102 Spain [REDACTED] 2000	Pear Ercolini	1) 1965 2) 01.03.2000 - 30.03.2000 3) 26.06.2000	SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	1000 1000 1000 1000 1000 1000	0.060 0.060 0.060 0.060 0.36 0.36	28.03.2000/0 31.03.2000/3 03.04.2000/3 07.04.2000/4 10.04.2000/3 28.04.2000/18 30.05.2000/32	fruit	1.8 0.36	22 20	31 27	23 20	0 27<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	
DR00EUS157 DR00EUS157I TA0101 Italy [REDACTED] 2000	Pear William	1) 01.11.1986 2) 01.04.2000 - 20.04.2000 3) 16.08.2000	SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	798 798 798 798 1000 1000	0.075 0.075 0.075 0.075 0.36 0.36	07.04.2000/0 11.04.2000/4 13.04.2000/4 17.04.2000/4 20.04.2000/3 19.06.2000/60 19.07.2000/30	77 fruit	1.2 0.60 0.27 0.51 <0.20	5.6 11 13 9.1 15	8.5 16 18 13 21	6.4 12 13 9.5 16	0 7 14 21 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report
 Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 8

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
DR00EUS157 DR00EUS17I TA0102 Italy [REDACTED] 2000	Pear Abate fetel	1) 10.01.1978 2) 01.04.2000 - 16.04.2000 3) 07.09.2000	SPI SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	1005 1005 1005 1005 1005 1005	0.060 0.060 0.060 0.060 0.36 0.36	08.04.2000/0 11.04.2000/3 14.04.2000/3 17.04.2000/3 20.04.2000/3 14.07.2000/82 10.08.2000/30	fruit	0.20	7.6 11	13 15	9.8 11	0 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 9

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (a)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
01R107 01R107-1 Spain [REDACTED] 2001	Pear Ercolini	1) 21.01.1980 2) 15.03.2001 - 30.03.2001 3) 04.07.2001	SPI SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	750 750 750 750 750 750	0.080 0.080 0.080 0.080 0.48 0.48	30.03.2001/0 02.04.2001/3 05.04.2001/3 09.04.2001/4 11.04.2001/2 07.05.2001/26 06.06.2001/30	fruit		<0.2 0.79 <0.2 0.32	26 23 32 27 24	36 31 44 36 32	27 23 33 27 24	0 7 14 21 28<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples
										<0.20 <0.20 <0.20	0.51 0.72 0.26	0.87 1.2 0.54	0.65 0.86 0.40	0 14 28<<	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 10

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as Methyl ethyl phosphonate Residues calculated as Fosetyl-Al
Analyte 2 Residues determined as Dimethyl phosphonate Residues calculated as Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT [†] PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
01R107 01R107-2 France, south [redacted] 2001	Pear William Rouge	1) 01.01.1968 2) 04.04.2001 - 14.04.2001 3) 02.08.2001	SPI SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 0.60 3.6 3.6	400 400 400 400 400 400 400	0.15 0.15 0.15 0.15 0.15 0.88 0.88	11.04.2001/0 14.04.2001/3 19.04.2001/3 20.04.2001/3 24.04.2001/4 07.06.2001/44 06.07.2001/29	76 fruit	<0.20 <0.20 <0.20 0.49 <0.20 <0.20	16 <0.2* 13 17 11	22 <0.45* 18 23 15	16 <0.34* 13 17 11	0 7 13 20 27<< 7	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples *day 7 an inversion between the "untreated" and the "treated" specimen is suspected.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 11

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (a)	Portion analysed (a)	Residues (mg/kg) (f)				DAIT/ PHI (days)	Remarks
01R107 01R107-3 France, south [REDACTED] 2001	Pear Guyot	1) 30.01.1958 2) 01.04.2001 - 13.04.2001 3) 17.07.2001	SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 3.6 3.6	400 400 400 400 400 400	0.15 0.15 0.15 0.15 0.34 0.88	11.04.2001/0 14.04.2001/3 17.04.2001/3 20.04.2001/3 23.04.2001/3 17.05.2001/24 18.06.2001/32	fruit		<0.20 0.41 <0.20 <0.20	34 23 36 23 12	47 31 49 31 16	35 23 36 23 12	0 7 15 21 29<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples
										<0.20 <0.20 <0.20	0.34 0.29 0.23	0.64 0.58 0.49	0.48 0.43 0.37	0 7 29<<	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 12

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT _{0.01} (days) (f)	Remarks
01R107 01R107-4 Italy [redacted] 2001	Pear William	1) 10.10.1991 2) 05.04.2001 - 20.04.2001 3) 25.07.2001	SPI SPI SPI SPI SPI SPI SPI	0.60 0.60 0.60 0.60 0.60 3.6 3	1000 1000 1000 1000 1000 1000 1000	0.060 0.060 0.060 0.060 0.060 0.36 0.36	17.04.2001/0 20.04.2001/3 20.04.2001/3 26.04.2001/3 30.04.2001/4 28.05.2001/28 27.06.2001/30	fruit	0.39 0.35 <0.20 <0.20 <0.20	25 37 37 31 19	34 50 50 42 26	25 37 37 31 19	0 7 14 21 28<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 13

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (a)	Portion analysed (a)	Residues (mg/kg) (f)				DAIT/ PHI (days)	Remarks
RA-2720/03 R 2003 0526/5 0526-03 Italy [REDACTED] 2003	Pear Abate Fétel	1) 1980 2) 15.04.2003 - 30.04.2003 3) 25.08.2003	SPI SPI SPI	3 3 3	1000 1000 1000	0.30000 0.30000 0.30000	11.06.2003/1 02.07.2003/21 26.07.2003/21	fruit		0.35 0.49 0.44 0.32 0.30	20 26 23 19 16	28 35 31 26 22	21 26 23 19 16	0 14 21 28<< 40	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.
										<0.20 <0.20 <0.20 <0.20 <0.20	2.4 2.4 2.4 1.9 2.6	3.4 3.4 3.4 2.7 3.7	2.5 2.5 2.5 2.0 2.7	0 14 21 28<< 40	Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 14

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
RA-2720/03 R 2003 0914/7 0914-03 [REDACTED] 2003	Pear Flor de Invierno	1) 1965 2) 01.04.2003 - 30.04.2003 3) 20.09.2003 - 10.10.2003	SPI SPI SPI	3 3 3	500 500 1500	0.20000 0.20000 0.20000	10.07.2003/8 31.07.2003/21 20.08.2003/21	8	fruit	<0.20 <0.20 <0.20 <0.20	5.4 5.8 4.8 7.7 5.1	7.5 8.0 6.6 11 7.0	5.6 5.9 4.9 7.8 5.2	0 14 21 28<< 40	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 15

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11	
				Application rate per treatment	Dates of treatment(s) Application interval or no. of treatments and last date.				Residues (mg/kg)	Analyte 1	Analyte 2	Analyte 3			Analyte 4
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	a.s./ha	Water (L/ha) kg a.s./L	(d)	Growth stage at last treatment	Portion analysed	Analyte 1	Analyte 2	Analyte 3	Analyte 4	(f)	Remarks	
RA-2720/03 R 2003 0915/5 0915-03 France, south [REDACTED] 2003	Pear Doyenne du comice	1) 01.01.1981 2) 08.04.2003 - 20.04.2003 3) 25.08.2003 - 1 Nov. 2003	SPI SPI SPI	3 3 1	1250 1230 1230	0.24000 0.24000 0.24000	2006.2003/0 15.07.2003/0 04.08.2003/20	79 a	fruit	0.80 <0.20 <0.20 <0.20	7.5 9.4 5.8 9.1 10	11 13 8.0 12 14	8.1 9.5 5.9 9.2 10	0 14 21 28<< 38	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc., 0.34 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 16

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11
				Application rate per treatment	Water (l/ha)				Dates of treatment(s) Application interval or no. of treatments and last date.	Residues (mg/kg)	Analyte 1	Analyte 2		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	a.s./ha	kg a.s./ha	(d)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
10-2064 10-2064-01 10-2064-01 Spain [REDACTED] 2010	Apple Golden	1) 1991 2) 13.04.2010 3) 01.08.2010 - 30.09.2010	SPI SPI SPI	3.6 3.6 3.6	1400 1400 1400	22.07.2010/0 03.08.2010/2 12.08.2010/9	78	fruit	0.77 2.1 1.3 0.78 0.33	7.5 8.2 13 15 17	11 13 19 21 24	8.0 9.7 14 16 18	0** 0 6 15 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 17

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as Fosetyl-Al Residues calculated as Fosetyl-Al
Analyte 2 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAET/ PHI (days) (f)	Remarks
10-2064 10-2064-02 10-2064-02 Italy [REDACTED] 2010	Apple Golden Delicious; early medium variety	1) 20.01.2004 2) 20.04.2010 - 05.05.2010 3) 01.09.2010 - 24.09.2010	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	30.07.2010 09.08.2010/10 10.08.2010/10	81 fruit	0.03 1.4 0.73 0.72 0.01 0.01	13 14 17 19 22	17 21 24 26 29	13 15 18 20 22	0** 0 7 14 28<< 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples **prior to last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAET, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 18

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
10-2064 10-2064-03 10-2064-03 France, south [REDACTED] 2010	Apple Gala	1) 2008 2) 08.04.2010 - 18.04.2010 3) 05.09.2010 - 01.10.2010	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	13.08.2010/0 23.08.2010/10 02.09.2010/10	85	fruit	0.21 2.1 0.39 0.28 0.03	9.6 9.9 12 12 12	13 15 16 17 15	9.8 11 12 12 12	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment
10-2064 10-2064-04 10-2064-04 [REDACTED] 2010	Apple momdial Gala; Red	1) 30.10.1997 2) 07.04.2010 - 30.04.2010 3) 10.08.2010 - 10.08.2010	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	07.07.2010/0 13.07.2010/10 23.07.2010/10	81	fruit	0.69 1.7 1.4 0.88 0.89	9.2 11 17 17 15	13 16 24 23 20	9.7 12 18 18 16	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. **prior to last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 19

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as Fosetyl-Al Residues calculated as Fosetyl-Al
Analyte 2 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DALT ¹ PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
09-2252 09-2252-01 France, south [redacted] 2009	Pear Williams	1) 01.01.1992 2) 25.03.2009 - 15.04.2009 3) 07.08.2009 - 20.08.2009	SPI SPI SPI	3.6 3.6 3.6	1500 1500 1500	0.24 0.24 0.24	30.06.2009/0 14.07.2009/10 29.07.2009/10	85	fruit	0.02 0.61 0.01 <0.01 <0.01	17 17 20 20 15	22 24 27 26 20	17 17 20 20 15	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 20

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) (f)				DAIT/ PHI (days)	Remarks
09-2252 09-2252-02 France, south [REDACTED] 2009	Pear William	1) 01.03.1962 2) 06.04.2009 - 25.04.2009 3) 10.08.2009 - 15.08.2009	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	24.06.2009/0 03.07.2009/9 10.07.2009/10	0.36	fruit	0.03 1.5 0.09 0.03 0.03*	12* 19 27 18	17* 27 36 24	12* 20 27 18	0** 0 7 14 0**	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples *Day 0**: probably exchange of control and treated samples. Values given correspond to the likely correct values. The complete trial was harvested at DAIT 14. ** day before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 21

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (a)	Portion analysed (a)	Residues (mg/kg) (f)				DAIT/ PHI (days)	Remarks
09-2252 09-2252-03 Spain [REDACTED] 2009	Pear Conference	1) 01.01.2000 2) 20.03.2009 - 10.04.2009 3) 10.08.2009 - 15.08.2009	SPI SPI SPI	3.6 3.6 3.6	500 500 1500	0.24 0.24 0.24	25.06.2009/07 06.07.2009/11 16.07.2009/10	fruit		0.04 1.5 0.91 0.78 <0.01	9.4 10 17 16 17	13 15 23 22 23	9.4 11 18 17 17	0** 0 6 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 22

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3	Analyte 4			
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ application interval or no. of treatments and last date (e)	Growth stage at last treatment (a)	Portion analysed	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks
09-2252 09-2252-04 Italy [REDACTED] 2009	Pear William	1) 01.02.2003 3) 25.07.2009 - 10.08.2009	SPI SPI SPI	3.6 3.6 3.6	500 500 1500	0.24 0.24 0.24	12.06.2009/07 22.06.2009/10 02.07.2009/10	7 7 7	fruit	<0.01 1.4 <0.01 <0.01	19 20 21 21 15	25 28 28 28 20	19 21 21 21 15	0** 0 7 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. Residues in untreated control samples ** day before last treatment
										<0.01 <0.01	1.8 1.4	2.4 1.8	1.8 1.4	0** 28<<	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 23

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				Application rate per treatment						Residues (mg/kg)					
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Dates of treatment(s)/ application interval or no. of treatments and last date (d)			Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)				DAIT/ PHI (days) (f)	Remarks	
09-2252 09-2252-05 Spain ██████████ 2009	Pear Conference	1) 01.01.1995 2) 10.03.2009 - 30.03.2009 3) 15.08.2009 - 30.08.2009	SPI SPI SPI	3.6 3.6 3.6	1500 400 1500	0.28 0.28 0.24	26.06.2009/08.07.2009/10.07.2009/10.07.2009/10	fruit	0.01 1.5 0.67 0.42 <0.01	9.7 12 14 13 13	13 17 19 18 17	9.7 13 14 13 13	0** 0 6 14 28<<	(c) SPI: Spraying (g) 00861/M001 (h) 0.01 mg/kg for fosetyl-Al and 0.20 mg/kg for phosphonic acid, 0.28 mg/kg for total residue fosetyl calc., 0.21 mg/kg for total residue phosphonic acid calc. ** day before last treatment	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Processing studies with fosetyl-Al on grape

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 667 g/kg
Formulation (e.g. WP) : 71.14 WG

Commercial product (name) : AE F053616 03 WG71 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
Crop/Crop Group : Vines
Page : 1

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : Fenamidone 4.44 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11	
				kg a.s./ha	Water (l/ha)				Residues (mg/kg)	Analyte 1	Analyte 2			Analyte 3
99-629 99629RS1 France, north [REDACTED]	Grape Chardonnay	1) 01.04.1979 2) 16.09.1999 3) 16.09.1999	SPI SBI SPI SPI	2.064 2.064 2.064 2.064	300 300 300 300	0.687 0.687 0.687 0.687	05.07.1999/0 21.07.1999/16 04.08.1999/14 04.08.1999/14	BBCH 83 85	fruit juice must wine	0.34 <0.20 <0.20 0.37 0.34	7.2 3.6 0.44 4.1 2.4	10.0 5.0 0.78 5.8 3.5	30 30 30 30 30	(c) SPI: Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al, 0.50 mg/kg for phosphonic acid and 0.86 mg/kg for total residue fosetyl calc. (h) 0.20 mg/kg for fosetyl-Al, 0.40 mg/kg for phosphonic acid and 0.72 mg/kg for total residue fosetyl calc. (h) 0.20 mg/kg for fosetyl-Al, 0.50 mg/kg for phosphonic acid and 0.86 mg/kg for total residue fosetyl calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 2

Content of active substance (g/kg or g/L) : 667 g/kg
Formulation (e.g. WP) : 71.14 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : fenarimolone 4.44 %

Commercial product (name) : AE F053616 03 WG71 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting	Method of treatment	Application rate per treatment			Date of treatment(s) / application interval	Growth stage at last treatment	Portion analysed	Residues (mg/kg)			DALT/ PHI (days)	Remarks
Location incl. postal code	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	
Year of Trial	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	
99-629 99629AV1 France, south [REDACTED]	Grape Grenache	1) 01.04.1993 2) [REDACTED] 3) 16.09.1999	SPI SPI SPI SPI	2.064 2.064 2.064 2.064	273 273 273 273	0.754 0.754 0.754 0.754	07.07.1999/0 28.07.1999/16 06.08.1999/04 19.08.1999/13	BBCH 81 firm juice must wine	firm juice must wine	0.94 1.1 <0.20 0.48	12 8.0 0.56 9.4	17 11.8 0.94 13.1	28 28 28 28	(c) SPI:Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al, 0.50 mg/kg for phosphonic acid and 0.86 mg/kg for total residue fosetyl calc. (h) 0.20 mg/kg for fosetyl-Al, 0.40 mg/kg for phosphonic acid and 0.72 mg/kg for total residue fosetyl calc. (h) 0.20 mg/kg for fosetyl-Al, 0.50 mg/kg for phosphonic acid and 0.86 mg/kg for total residue fosetyl calc.

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 3
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8			9	10	11	
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)		Dates of treatment(s)/ Application interval or no. of treatment and last date/ (d)	Growth stage at last treatment (e)	Residues (mg/kg) (a)			DALT/ PHI (days) (f)	Remarks		
				kg a.s./ha	Water (L/ha) kg a.s./L			Analyte 1	Analyte 2	Analyte 3				
99-531 99531RS1 99531RS1 France, north [redacted] 1999	Grape Chardonnay	1) 1990 3) 21.09.1999	SPI	1.85	432	0.428	02.06.1999/0	BBCH 73	fruit	<0.20	9.9	13.5	74	(c) SPI:Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	1.79	418	0.428	16.06.1999/13			<0.20	8.1	11.1	74	
			SPI	1.79	487	0.428	28.06.1999/12			Mean: <0.20	Mean: 9.0	Mean: 12.3		
			SPI	1.85	432	0.428	09.07.1999/11							
99-531 99531RS1 99531RS1 France, north [redacted] 1999	Grape Chardonnay	1) 1990 3) 21.09.1999	SPI	1.85	432	0.428	02.06.1999/0	BBCH 73	fruit	<0.20	8.1	11.1	74	(c) SPI:Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	1.79	418	0.428	16.06.1999/13			<0.20	5.4	7.4	74	
			SPI	1.79	487	0.428	28.06.1999/12			Mean: <0.20	Mean: 6.8	Mean: 9.3		
			SPI	1.85	432	0.428	09.07.1999/11							
								wine	<0.20	4.9	6.8	74		
								wine	<0.20	3.4	4.7	74		

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Country : Germany Page : 4
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8			9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha			Residue (µg/kg)	Analyte 1	Analyte 2			
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (g)	Residues (µg/kg)			DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./ha				Analyte 1	Analyte 2	Analyte 3		
99-531 99531DJ1 99531DJ1 France, north 1999	Grape Pinot noir	1) 1985 3) 20.09.1999	SPI	1.85	300	0.616	04.06.1999/7	BBCH 73	fruit	<0.20	11	14.9	81	(c) SPI:Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	1.85	300	0.616	11.06.1999/7			<0.20	8.3	11.3	81	
			SPI	1.85	300	0.616	25.06.1999/14			Mean: <0.20	Mean: 9.7	Mean: 13.1	81	
			SPI	1.85	300	0.616	01.07.1999/6		wine	<0.20	6.7	9.2	81	
99-531 99531DJ1 99531DJ1 France, north 1999	Grape Pinot noir	1) 1985 3) 20.09.1999	SPI	1.85	300	0.616	04.06.1999/7	BBCH 73	fruit	<0.20	13	17.6	81	(c) SPI:Spraying (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	1.85	300	0.616	11.06.1999/7			<0.20	9.5	12.9	81	
			SPI	1.85	300	0.616	25.06.1999/14			Mean: <0.20	Mean: 11.3	Mean: 15.3	81	
			SPI	1.85	300	0.616	01.07.1999/6		wine	0.24	6.8	9.3	81	

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, Crop/Crop Group : Vines

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Country : Germany Page : 5
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11
				a.s./ha	Water (l/ha)				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)		Dates of treatment(s) Application interval or no. of treatments and last date/	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)	DAIT PHI (days)	Remarks		
00-2006 002006FR1 002006FR1-2R France, south 2000	Grape Gamay (red variety)		#	2.0	#	21.05.2000/0	fruit		<0.20 <0.20 Mean: <0.20	2.6 6.0 Mean: 4.0	2.9 8.2 Mean: 5.6	78 78 78	(c) #:no information (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Residue in untreated control samples
							must		<0.20 <0.20 <0.20 Mean: <0.20	0.27 <0.20 0.52 0.64 Mean: 0.58	0.55 <0.45 0.9 1.0 Mean: 1.0	78 78 78 78	
							Wine (after alcoholic fermentation)		<0.20	1.6	2.3	78	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.
							Pomace		<0.20	2.3	3.3	78	
							Wine (after malolactic fermentation)		<0.20	1.8	2.6	78	

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY) Active substance : Fosetyl-Al
 (Application on agricultural and horticultural crops)

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report
 Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 5 (continued)
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8			10	11	
				kg a.s./ha	Water (L/ha)			Residues (mg/kg)	Analyte 1	Analyte 2			Analyte 3
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment kg a.s./ha	Water (L/ha)	Dates of treatment(s)/ Application interval no. of treatments and last date (d)	Growth stage at last treatment (e)	Partion analysed (a)	Analyte 1	Analyte 2	Analyte 3	(f)	Remarks
00-2006 002006FR1 002006FR1-2R France, south [redacted] 2000 (continued)								Lees (1st clarification)	<0.20	2.9	4.1	78	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.
								Wine (before filtration)	<0.20	1.8	2.6	78	
								Lees (2nd clarification)	<0.20	1.7	2.5	78	
								Red Wine (after bottling)	<0.20	10	14	78	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
									<0.20	0.23	0.49	78	Residue in untreated control samples
									<0.20	<0.20	0.45	78	
									Mean: <0.20	Mean: 0.22	Mean: 0.47	78	

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Country : Germany Page : 6
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11
				kg a.s./ha	Water (L/ha) kg a.s./L				Residues (mg/kg)				
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment		Date of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Analyte 1	Analyte 2	Analyte 3	DALT/ PHI (days) (f)	Remarks
00-2006 002006FR1 002006FR1-3R France, south [Redacted] 2000	Grape Gamay (red variety)	#	#	2.0	#	07.06.2000/0	fruit		<0.20	6.1	8.4	64	(c) #:no information (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Residue in untreated control samples
				2.0	#	06.06.2000/14	fruit		0.20	9.3	17.6	64	
				2.0	#	05.07.2000/14	fruit		Mean: <0.20	Mean: 9.6	Mean: 13	64	
							must		<0.20	0.27	0.55	64	
							must		<0.20	<0.20	<0.45	64	
							must		<0.20	3.2	4.5	64	
							must		<0.20	3.2	4.5	64	
							must		Mean: <0.20	Mean: 3.2	Mean: 4.5	64	
							Wine (after alcoholic fermentation)		<0.20	3.9	5.4	64	
							Pomace		0.21	12	16	64	
			Wine (after malolactic fermentation)		<0.20	4.1	5.7	64					

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY) Active substance : Fosetyl-Al
 (Application on agricultural and horticultural crops)

- (a) According to Codex (or other e.g. EU) Classification/Guide
 - (b) Only if relevant
 - (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 - (d) Year must be indicated
 - (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 - (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 - (g) Reference to analytical method
 - (h) Limit of determination/quantitation
 - (i) Dosage of a.s. or water given as...
 - (-) Missing data in the above columns occurs where the information is not available in the original report
- Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 6 (continued)
 Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.24 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue Fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)				Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)	Dates of treatment(s)/ Application interval no. of treatments and last date (e)	Growth stage at last treatment (f)	Partion analysed (a)	Residues (mg/kg)	Analyte 1	Analyte 2	Analyte 3	(f)	Remarks
00-2006 002006FR1 002006FR1-3R France, south [redacted] 2000 (continued)							Lees (1st clarification)	<0.20	6.8	9.3	64	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.	
							Wine (before filtration)	<0.20	4.2	5.8	64		
							Lees (2nd clarification)	<0.20	4.9	6.8	64		
							Red Wine (after bottling)	<0.20	4.9	6.8	64	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.	
								<0.20	0.23	0.49	64	Residue in untreated control samples	
								<0.20	<0.20	0.45	64		
							Mean: <0.20	Mean: 0.22	Mean: 0.47	64			

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 7
 Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Country : Germany Page : 7 (continued)

Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor

Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %

Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al

Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid

Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11	
				a.s./ha	Water (l/ha)				kg a.s./ha	Analyte 1	Analyte 2			Analyte 3
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment		Date of treatment(s) Application interval or no. of treatments and last date/	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DAIT/PHI (days)	Remarks	
00-2006 002006FR1 002006FR1-4R France, south 2000 (continued)							Lees (1st clarification)	<0.20	12	16	50	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.		
								Wine (before filtration)	<0.20	6.8	9.3		50	
								Lees (2nd clarification)	<0.20	7.8	11		50	
								Red Wine (after bottling)	<0.20	1.6	2.3		50	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
									<0.20	0.23	0.49		50	Residue in untreated control samples
									<0.20	<0.20	0.45		50	
								Mean: <0.20	Mean: 0.22	Mean: 0.47	50			

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines

Country : Germany Page : 8

Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatment. (DAIT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)			DALP (days) (f)	Remarks
00-2006 002006FR1 002006FR1-5R France, south [redacted] 2000	Grape Gamay (red variety)		# # # # # #	2.0 2.0 2.0 2.0 2.0 2.0	# # # # # #	24.05.2000/0 07.06.2000/14 21.06.2000/14 05.07.2000/14 19.07.2000/14 03.08.2000/15	fruit must Wine (after alcoholic fermentation) Pomace Wine (after malolactic fermentation)		<0.20 0.20 0.23 Mean: 0.22	9.7 8.5 0.27 <0.20 5.5 5.4 Mean: 5.5	13 13 0.55 <0.45 7.6 7.5 Mean: 7.6	35 35 35 35 35 35 35 35	(c) #:no information (g) DFG 522 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Residue in untreated control samples (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.	

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)
 (Application on agricultural and horticultural crops)
 Active substance : Fosetyl-Al
 Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 8 (continued)

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALP, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report
 Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Content of active substance (g/kg or g/L) : 667 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 71.14 WG Other a.s. in formulation (common name and content) : fenamidone 4.44 %
 Commercial product (name) : AE F053616 03 WG71 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot	Commodity / Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting	Method of treatment	Application rate per treatment			Dates of treatment (Application interval or no. of treatments and last date)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)			DALT/PHI (days)	Remarks
Location incl. postal code														
Year of Trial	(a)	(b)	(c)				(d)	(e)						
00-2006 002006FR1 002006FR1-5R France, south [redacted] 2000 (continued)									Lees (1st clarification)	<0.20	13	18	35	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.86 mg/kg for total residue fosetyl calc.
									Wine (before filtration)	<0.20	6.8	9.3	35	
									Lees (2nd clarification)	<0.20	9	12	35	
									Red Wine (after bottling)	<0.20	11	15	35	(h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
										<0.20	0.23	0.49	35	Residue in untreated control samples
										<0.20	<0.20	0.45	35	
										Mean: <0.20	Mean: 0.22	Mean : 0.47	35	

Processing study with fosetyl-Al on apple

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer Crop Science AG, [redacted] Crop/Crop Group

Country : Germany Page : 1

Content of active substance (g/kg or g/L) : 800 g/kg Indoor/outdoor : Outdoor

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Formulation (e.g. WP) : 80 WG Other a.s. in formulation (common name and content) :
 Commercial product (name) : Fosetyl-AL WG 80 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)	kg of a.s./L				Residue (mg/kg)	Analyte 1	Analyte 2		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)			DALT/ PHI (days) (f)	Remarks
01-90 0190FRA1 France, north ██████████ 2001	Apple Jonagored	1) 1991 2) 03.04.2001 - 10.04.2001 3) 17.09.2001	SPI SPI SPI	3.6 3.6 3.6	1000 1000 1000	0.36 0.36 0.36	21.06.2001/0 20.07.2001/29 20.08.2001/31	Fruit about 70% of final size	fruit juice pasteurised pomace, wet	0.5 5.7 4.6	2.5 8.1 6.4	13 28 28	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Field Information from Study 01R105 (g) AR 171-98 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc. (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.	

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)
 Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████ Crop Group
 Country : Germany Page : 1 (continued)
 Content of active substance (g/kg or g/L) : 800 g/kg Indoor/outdoor : Outdoor

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Formulation (e.g. WP) : 80 WG Other a.s. in formulation (common name and content) :
 Commercial product (name) : Fosetyl-AL WG 80 Analyte 1 Residues determined as : Methyl ethyl phosphonate
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl-Al
 Residues calculated as : Phosphonic acid
 Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water L/ha	kg P ₂ O ₅ /ha				Residue (mg/kg)	Analyte 1	Analyte 2		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s), Application interval or of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)			DALT/ PHI (days) (f)	Remarks
01-90 0190FRA1 France, north ██████████ 2001 (continued)	Apple Jonagored	1) 1991 2) 03.04.2001 - 10.04.2001 3) 17.09.2001	SPI SPI SPI	3	1000	0.36	1.06.2001/0	Fruit about 70% of final size	puree	0.26	4	5.7	28	(g) AR 231-99 (h) 0.001 mg/L for fosetyl-Al and 0.02 mg/L for phosphonic acid, 0.03 mg/kg for total residue fosetyl calc.
				3.6	1000	0.36	20.07.2001/29			0.001	0.029	0.040	28	
				3.6	1000	0.36	20.08.2001/31			0.001	<0.020	<0.028	28	
				3.6	1000	0.36				0.26	4.1	5.7	28	
								washings	0.32	7.1	10	28		
								blanching water leech						
								waste, sieving						

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg

Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AL

Crop/Crop Group : Pomaceous fruit

Page : 2

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment	Date of treatment(s)/ Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	DALT/ PHI (days) (f)	Remarks				
01-90 0190FRA2 France, north [REDACTED] 2001	Apple Golden Delicious	1) 1972 2) 20.04.2001 - 05.05.2001 3) 10.09.2001	SPI SPI SPI	3.090 3.6 3.6	500 500 500	0.72 0.72 0.72	15.06.2001/0 15.07.2001/31 14.08.2001/9	beginning of ripening fruit juice, pasteurised pomace, wet	0.71 <0.50 0.20	3.0 8.3 5.4	4.7 12 7.4	27 27 27	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Field Information from Study 01R105 (g) AR 171-98 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc. (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg

Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2 (continued)

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate

Analyte 2 Residues determined as : Dimethyl phosphonate

Analyte 3 Residues determined as : Total residue fosetyl calc.

Residues calculated as : Fosetyl-Al

Residues calculated as : Phosphonic acid

Residues calculated as : Fosetyl

1	2	3	4	5		6	7	8	9			10	11	
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date/	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DALT/° PHI (days) (f)	Remarks	
				kg a.s./ha	Water (L/ha)				kg a.s./ha	Analyte 1	Analyte 2			Analyte 3
								puree	1.1	3.0	5.0	27		
01-90 0190FRA2 France, north [REDACTED] 2001 (continued)	Apple Golden Delicious	1) 1972 2) 20.04.2001 - 05.05.2001 3) 10.09.2001	SPI SPI SPI	3.090 3.6 3.6	429 500 500	0.720 0.72 0.72	15.06.2001/0 16.07.2001/31 14.08.2001/26	beginning of ripening	washings	<0.001	<0.020	<0.028	27	(g) AR 231-99 (h) 0.001 mg/L for fosetyl-Al and 0.02 mg/L for phosphonic acid, 0.03 mg/kg for total residue fosetyl calc.
								blanching water lees	<0.001	<0.020	<0.028	27		
								lees	0.24	4.7	6.5	27	(g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.	
								waste, sieving	0.40	4.7	6.7	27		

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)

1	2	3	4	5			6	7	8	9			10	11
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval No. of treatments up to last date (d)	Growth stage at last treatment (e)	Position analysed (a)	Residues (mg/kg)			DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	g a.s./hL				Analyte 1	Analyte 2	Analyte 3		
01-90 0190GBR1 United Kingdom [REDACTED] 2001	Apple Bramley	1) 1991 2) 01.05.2001 - 31.05.2001 3) 09.10.2001	SPI SPI SPI	3.6 3.6 3.6	500 500 500	0.72 0.72 0.72	16.07.2001/0 14.08.2001/29 12.09.2001/29	Fruit about 10% of final size	fruit	1.5	4.2	7.0	27	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Field Information from Study 01R105 (g) AR 171-98 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc. juice, pasteurised waste, sieving washings
										<0.50	15	21	27	
										0.47	2.7	4.1	27	
										<0.001	<0.020	<0.028	27	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3 (continued)

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)

1	2	3	4	5			6	7	8	9			10	11
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval no. of treatments and last date	Growth stage at last treatment (e)	Position analysed (a)	Residues (mg/kg)			DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	g a.s./hL				Analyte 1	Analyte 2	Analyte 3		
01-90 0190GBR1 United Kingdom [redacted] 2001 (continued)	Apple Bramley	1) 1991 2) 01.05.2001 - 31.05.2001 3) 09.10.2001	SPI	3.6	500	0.72	16.07.2001/0	Fruit about 90% of final size	purch	0.35	3.5	5.0	27	(g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	3.6	500	0.72	14.08.2001/29			0.20	4.3	5.9	27	(g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
			SPI	3.6	500	0.72	2.09.2001/29			<0.20	4.3	5.9	27	(g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.
										blanching water	<0.001	<0.020	<0.028	27
								lees	0.28	5.5	7.6	27	(g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 4

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)

1	2	3	4	5			6	7	8	9			10	11
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ application interval no. of treatments at last date	Growth stage at last treatment (e)	Position analysed (a)	Residues (mg/kg)			DALT/ PHI (days)	Remarks
				kg a.s./ha	Water (L/ha)	g a.s./hL				Analyte 1	Analyte 2	Analyte 3		
01-90 0190GBR2 United Kingdom [REDACTED] 2001	Apple Cox	1) 1991 2) 01.04.2001 - 01.06.2001 3) 20.09.2001	SPI SPI SPI	3.6 3.6 3.6	500 500 500	0.72 0.72 0.72	26.06.2001/0 20.07.2001/30 19.08.2001/29	Fruit about half final size	fruit juice, pasteurised pomace, wet	2.1 <0.50 0.40	4.7 7.1 9.3	8.3 10 13	27 27 27	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc. Field Information from Study 01R105 (g) AR 171-98 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid, 1.1 mg/kg for total residue fosetyl calc. (g) AR 155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid, 0.45 mg/kg for total residue fosetyl calc.

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<-')>
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Pomaceous fruit
 Country : Germany Page : 4 (continued)
 Content of active substance (g/kg or g/L) : 800 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 80 WG Other a.s. in formulation (common name and content) :
 Commercial product (name) : Fosetyl-AL WG 80 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl

1	2	3	4	5			7	8	9			10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./ha			Residues (mg/kg)	Analyte 1	Analyte 2			Analyte 3
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (i)	Dates of treatment(s)/ Application interval or no. of treatments and date/ (d)	Growth stage at last treatment (e)	Portion analysed (g)	Residues (mg/kg)			Days PHI (days) (f)	Remarks		
01-90 0190GBR2 United Kingdom [redacted] 2001 (continued)	Apple Cox	1) 1991 2) 01.04.2001 - 01.06.2001 3) 20.09.2001	SPI	3.6	500	0.72	26.06.2001/0	Fruit about	puree	0.39	9.5	13	27	(g) AR 231-99 (h) 0.001 mg/L for fosetyl-Al and 0.02 mg/L for phosphonic acid, 0.03 mg/kg for total residue fosetyl calc.
			SPI	3.6	500	0.72	26.07.2001/0	half final	washings	0.002	0.038	0.053	27	
			SPI	3.6	500	0.72	24.08.2001/29	size	blanching water	<0.001	<0.020	<0.028	27	
									lees	0.32	6.6	9.2	27	
							waste, sieving		1.4	17	24	27		

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Rotational studies with Fosetyl & Propamocarb SL 840

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
Country : Germany

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al
Crop/Crop Group : Leaf and stem vegetables
Page : 1
Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./hL				Residues (mg/kg)		DALT/PHI (days)			
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	(f)	Remarks
08-2504 08-2504-01 Netherlands ██████████ 2008	Lettuce Legenda Carrot Amsterdam	1) 05.06.2008 2) 07.07.2008 3) 07.07.2008 1) 30.07.2008 3) 09.11.2008	SPI SPI SPI	0.775 0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	10.06.2008/0 20.06.2008/10 30.06.2008/10	BBCH 19	root leaf	<0.0093 <0.0093 <0.0093 <0.0093	<0.10 <0.10 <0.10 <0.10	<0.14 <0.14 <0.14 <0.14	<0.11 <0.11 <0.11 <0.11	128 142 128 142	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 30 days

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 2

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as Fosetyl-Al Residues calculated as Fosetyl
Analyte 2 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date/ last date	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg)				DALT/° PHI (days)	Remarks
08-2504 08-2504-02 Netherlands [redacted] 2008	Lettuce Legenda Lettuce Gisela	1) 05.06.2008 3) 07.07.2008 1) 30.07.2008 3) 17.09.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	10.06.2008/10 20.06.2008/10 30.06.2008/10	BBCH 45 heart	<0.0093 <0.0093	<0.10 <0.10	<0.14 <0.14	<0.11 <0.11	65 79	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 30 days	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY) Active substance : Fosetyl-LAI
(Application on agricultural and horticultural crops)
Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████ Crop/Crop Group : Leaf and stem vegetables
Country : Germany Page : 3
Content of active substance (g/kg or g/L) : 310 g/L Indoor/outdoor : Outdoor
Formulation (e.g. WP) : 840 SL Other a.s. in formulation (common name and content) : propanoic acid 530 g/L
Commercial product (name) : Fosetyl & Propamocarb SL 840 Analyte 1 Residues determined as : Fosetyl-LAI Residues calculated as : Fosetyl
Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8				10	11		
				kg a.s./ha	Water (L/ha)			kg a.s./ha	Residues (mg/kg)	Analyte 1	Analyte 2			Analyte 3	Analyte 4
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)	Water (L/ha)	kg a.s./ha	Dates of treatments/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	Residues (mg/kg) (h)	Remarks (i)
08-2504 08-2504-03 Netherlands ██████████ 2008	Lettuce Gisela Wheat, winter Tataros	1) 30.07.2008 2) 22.09.2008 3) 22.09.2008 1) 15.10.2008 2) 05.06.2009 - 20.06.2009 3) 21.07.2009	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	26.08.2008/0 05.09.2008/10 15.09.2008/10	BBCH 4 green material straw grain	<0.047 <0.047 <0.0093	<0.50 <0.50 <0.10	<0.72 <0.72 <0.14	<0.54 <0.54 <0.11	219 309 309	(c) SPI: Spraying (g) 00861/M001 (h) 0.047 mg/kg for fosetyl, 0.50 mg/kg for phosphonic acid, 0.72 mg/kg for total residue fosetyl calc. and 0.54 mg/kg for total residue phosphonic acid calc. (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 30 days	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 4

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as Fosetyl-Al Residues calculated as Fosetyl
Analyte 2 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid
Analyte 3 Residues determined as Total residue fosetyl calc. Residues calculated as Fosetyl
Analyte 4 Residues determined as Total residue phosphonic acid calc. Residues calculated as Phosphonic acid

1	2	3	4	5		7	8	9				10	11	
				kg a.s./ha	Water (L/ha)			Analyte 1	Analyte 2	Analyte 3	Analyte 4			DALT/PHI (days)
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)		Dates of treatment(s)/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residue (mg/kg) (h)				DALT/PHI (days) (i)	Remarks
08-2505 08-2505-01 France, north [redacted] 2008	Lettuce Noisette Carrot Nandrin F1	1) 16.04.2008 2) [redacted] 3) 09.06.2008 1) 01.07.2008 2) [redacted] 3) 29.09.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	15.05.2008/09 22.05.2008/09 04.06.2008/13							(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 27 days
							root	<0.0093	<0.10	<0.14	<0.11	133		
							leaf	<0.0093	<0.10	<0.14	<0.11	147		
								<0.0093	<0.10	<0.14	<0.11	133		
								<0.0093	<0.10	<0.14	<0.11	147		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 5

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./L			Analyte 1	Analyte 2	Analyte 3	Analyte 4			(f)
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatments/ Application interval or no. of treatments and last date	Growth stage at last treatment (e)	Portion analysed	Residues (mg/kg)				DALT/ PHI (days)	Remarks
08-2505 08-2505-02 France, north [redacted] 2008	Lettuce Noisette Lettuce Noisette	1) 16.04.2008 2) 09.06.2008 3) 09.06.2008 1) 30.06.2008 2) 08.08.2008 3) 11.08.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	22.05.2008/04.06.2008/13	BBCH 49	head	<0.0093 <0.0093	<0.10 <0.10	<0.14 <0.14	<0.11 <0.11	54 68	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 26 days

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY) Active substance : Fosetyl-Al
(Application on agricultural and horticultural crops)
Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Leaf and stem vegetables
Country : Germany Page : 6
Content of active substance (g/kg or g/L) : 310 g/L Indoor/outdoor : Outdoor
Formulation (e.g. WP) : 840 SL Other a.s. in formulation (common name and content) : propamocarb 530 g/L
Commercial product (name) : Fosetyl & Propamocarb SL 840 Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		7	9	10				11		
				kg a.s./ha	Water (L/ha)			kg a.s./L	Residues (mg/kg)	Analyte 1	Analyte 2		Analyte 3	Analyte 4
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	(f)	Remarks
08-2505 08-2505-03 France, north [redacted]	Lettuce Eole	1) 06.08.2008 3) 22.09.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	26.08.2008/04.09.2008/15.09.2008/11	BBCH 4						(c) SPI:Spraying
2008	Barley, winter Marado	1) 17.10.2008 2) 30.04.2009 - 12.05.2009 3) 02.07.2009						green material straw grain	<0.047 <0.047 <0.0093	<0.50 <0.50 <0.10	<0.72 <0.72 <0.14	<0.54 <0.54 <0.11	207 290 290	(g) 00861/M001 (h) 0.047 mg/kg for fosetyl, 0.50 mg/kg for phosphonic acid, 0.72 mg/kg for total residue fosetyl calc. and 0.54 mg/kg for total residue phosphonic acid calc. (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 7

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8				9	10	11
				kg a.s./ha	Water (l/ha)			kg a.s./L	Residues (mg/kg)	Analyte 1	Analyte 2			
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment	Water	Dates of treatment (Application interval or no. of treatments and last date/last treatment) (d)	Growth stage at last treatment (e)	Portion analysed (a)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	DALT/ PHI (days) (f)	Remarks
08-2506 08-2506-01 Spain [REDACTED] 2008	Lettuce Filipo Carrot Coral	1) 30.09.2008 2) 08.11.2008 3) 08.12.2008 1) 08.01.2009 3) 01.07.2009	SPI SPI SPI	0.775 0.775 0.775	277.4 400 300	0.256 0.258 0.258	11.11.2008/0 21.11.2008/10 01.12.2008/10	BBCH 46						(c) SPI: Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 38 days
								root	<0.0093 <0.0093	<-0.10 <-0.10	<-0.14 <-0.14	<-0.11 <-0.11	197 212	
								leaf	<0.0093 <0.0093	<-0.10 <-0.10	<-0.14 <-0.14	<-0.11 <-0.11	197 212	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 8

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propanoic acid 530 g

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al (Residues calculated as : Fosetyl)
Analyte 2 Residues determined as : Phosphonic acid (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl calc. (Residues calculated as : Fosetyl)
Analyte 4 Residues determined as : Total residue phosphonic acid calc. (Residues calculated as : Phosphonic acid)

1	2	3	4	5			7	8	9				10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./L			Analyte 1	Analyte 2	Analyte 3	Analyte 4			(f)
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatments/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (g)	Portion analysed (h)	Residues (mg/kg) (i)				DALT/ PHI (days) (f)	Remarks
08-2506 08-2506-02 Spain [REDACTED] 2008	Lettuce Filipo Lettuce Isasa	1) 30.09.2008 2) [REDACTED] 3) 08.12.2008 1) 16.01.2009 2) [REDACTED] 3) 25.04.2009	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	11.2008/10 21.11.2008/10 01.12.2008/10	BBCH 40 head		<0.0093 <0.0093	<0.10 <0.10	<0.14 <0.14	<0.11 <0.11	127 141	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 46 days

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 9

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propamocarb 530 g/L

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)				kg a.s./ha	Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)		Dates of treatments/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (f)	Portion analysed (g)	Residues (mg/kg) (h)				DALT/ PHI (days) (i)	Remarks
08-2506 08-2506-03 Spain [REDACTED] 2008	Lettuce Filipo Wheat, winter Cajeme	1) 30.09.2008 2) 08.12.2008 1) 08.01.2009 2) 30.03.2009 - 15.04.2009 3) 02.06.2009	SPI SPI SPI	0.775 0.775 0.775	300 300 285.6	0.258 0.258 0.258	11.2008/0 11.2008/13 11.2008/7	BBCH 40 green material straw grain	<0.047 <0.047 <0.0093	<0.50 <0.50 0.21	<0.72 <0.72 0.29	<0.54 <0.54 0.22	106 183 183	(c) SPI: Spraying (g) 00861/M001 (h) 0.047 mg/kg for fosetyl, 0.50 mg/kg for phosphonic acid, 0.72 mg/kg for total residue fosetyl calc. and 0.54 mg/kg for total residue phosphonic acid calc. (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 38 days

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 10

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propanoic acid 530 g

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		7	8	9				10	11	
				kg a.s./ha	Water (L/ha)			kg a.s./ha	(d)	(e)	Analyte 1			Analyte 2
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments/ Application interval or no. of treatments and last date	Growth stage at last treatment (g)	Portion analysed (h)	Residues (mg/kg)				DALT/ PHI (days)	Remarks
08-2507 08-2507-01 Italy ██████████ 2008	Lettuce Gentile Carrot Berlicum 2	1) 09.05.2008 1) 30.05.2008 3) 16.07.2008 1) 07.08.2008 3) 03.11.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	06.2008/0 30.06.2008/11 09.07.2008/9	BBCH 40 root leaf	<0.0093 <0.0093 <0.0093 <0.0093	<-0.10 <-0.10 <-0.10 <-0.10	<-0.14 <-0.14 <-0.14 <-0.14	<-0.11 <-0.11 <-0.11 <-0.11	103 117 103 117	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 29 days

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 11

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propanoic acid 530 g

Commercial product (name) : Fosetyl & Propamocarb SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9				10	11
				kg a.s./ha	Water (L/ha)	kg a.s./ha				Analyte 1	Analyte 2	Analyte 3	Analyte 4		
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatments/ Application interval or no. of treatments and last date (e)	Growth stage at last treatment (g)	Portion analysed (h)	Residues (mg/kg) (i)				DALT/PHI (days) (f)	Remarks
08-2507 08-2507-02 Italy [REDACTED] 2008	Lettuce Gentile Lettuce Lactuca Estony	1) 09.05.2008 1) 30.05.2008 3) 16.07.2008 1) 17.07.2008 1) 07.08.2008 3) 09.09.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	09.06.2008/11 30.06.2008/11 09.07.2008/9	BBCH 45	head	<0.0093 <0.0093	<0.10 <0.10	<0.14 <0.14	<0.11 <0.11	57 71	(c) SPI:Spraying (g) 00861/M001 (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 29 days

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 12

Content of active substance (g/kg or g/L) : 310 g/L
Formulation (e.g. WP) : 840 SL

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) : propanoic acid 530 g/l

Commercial product (name) : Fosetyl & Propanoic acid SL 840
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl
Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl calc. Residues calculated as : Fosetyl
Analyte 4 Residues determined as : Total residue phosphonic acid calc. Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9				10	11	
				kg a.s./ha	Water (L/ha)				Residue (mg/kg)	Analyte 1	Analyte 2	Analyte 3			Analyte 4
Study Trial No.; Plot Location incl. postal code Year of Trial	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest 4) Transplanting (b)	Method of treatment (c)	Application rate per treatment kg a.s./ha	Water (L/ha)	Dates of treatments/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residue (mg/kg)	Analyte 1	Analyte 2	Analyte 3	Analyte 4	DALT/PHI (days)	Remarks
08-2507 08-2507-03 Italy [REDACTED] 2008	Lettuce Lactuca Estony	1) 27.08.2008 3) 09.10.2008	SPI SPI SPI	0.775 0.775 0.775	300 300 300	0.258 0.258 0.258	09.2008/11 22.09.2008/11 02.10.2008/10	BBCH 40							(c) SPI: Spraying
	Wheat, winter Aubusson	1) 03.11.2008 2) 15.05.2009 3) 23.06.2009						green material straw grain	<0.047 <0.047 <0.0093	<0.50 <0.50 <0.10	<0.72 <0.72 <0.14	<0.54 <0.54 <0.11	175 264 264	(g) 00861/M001 (h) 0.047 mg/kg for fosetyl, 0.50 mg/kg for phosphonic acid, 0.72 mg/kg for total residue fosetyl calc. and 0.54 mg/kg for total residue phosphonic acid calc. (h) 0.0093 mg/kg for fosetyl, 0.10 mg/kg for phosphonic acid, 0.14 mg/kg for total residue fosetyl calc. and 0.11 mg/kg for total residue phosphonic acid calc. PBI 32 days	

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Residue studies with fertilizers

Pear treated with Fosetyl-AI WG 80

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-AI

Crop/Crop Group : Pomaceous fruit

Page : 1

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate
Residues calculated as : Fosetyl-AI
Analyte 2 Residues determined as : Dimethyl phosphonate
Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl-AI calc.
Residues calculated as : Fosetyl-AI

1	2	3	4	Application rate per treatment			Dates of treatment(s) Application interval or no. of treatments and last date	Growth stage at last treatment	Portion analysed	Residues (mg/kg)			10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	kg a.s./ha	Water (l/ha)	kg a.s./ha	(d)	(e)	(a)	Analyte 1	Analyte 2	Analyte 3	(f)	Remarks
				02R107 02R107-1 [REDACTED] 2002	Pear Abate Fetel	1) 10.01.1970 2) 30.03.2002 - 15.04.2002 3) 02.09.2002				SPI SPI SPI	3.00 3.00 3.00	1500 1500 1500		

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl-Al calc. Residues calculated as : Fosetyl-Al

1	2	3	4	5			6	7	9			10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DALI/ PHI (days) (f)	Remarks
				g a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3		
02R107 02R107-2 Italy [REDACTED] 2002	Pear Conference	1) 10.01.1996 2) 25.03.2002 - 10.04.2002 3) 19.08.2002	SPI SPI SPI	3.00 3.00 3.00	1500 1500 1500	0.20 0.20 0.20	30.05.2002/0 19.06.2002/20 09.07.2002/20	78	fruit	0.68 0.29	16 11	24 16	0 41<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.
02R107 02R107-3 Italy [REDACTED] 2002	Pear Packam'S Triumph	1) 15.11.1980 2) 25.03.2002 - 10.04.2002 3) 22.08.2002	SPI SPI SPI	3.00 3.00 3.00	1500 1500 1500	0.20 0.20 0.20	04.06.2002/0 24.06.2002/20 19.07.2002/21	75	fruit	0.25 <0.20 <0.20	7.6 11 0.61	11 16 1.1	0 38<< 0	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc. Residues in untreated control samples

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALI, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Pomaceous fruit
 Country : Germany Page : 3
 Content of active substance (g/kg or g/L) : 800 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 80 WG Other a.s. in formulation (common name and content) :
 Commercial product (name) : Fosetyl-AL WG 80 Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl-Al calc. Residues calculated as : Fosetyl-Al

1	2	3	4	5		7	8	9			10	11	
				kg a.s./ha	Water (L/ha)			Residues (mg/kg)	Analyste 1	Analyste 2			Analyste 3
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval No. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Analyste 1	Analyste 2	Analyste 3	DALT/ PHI (days) (f)	Remarks
RA-2720/03 R 2003 0526/5 0526-03 [redacted] 2003	Pear Abate Felcel	1) 1980 2) 15.04.2003 - 30.04.2003 3) 25.08.2003	SPI SPI SPI	1000 1000 1000	0.30000 0.30000 0.30000	11.06.2003/0 02.07.2003/21 23.07.2003/21	fruit	fruit	0.49 0.44 0.30 0.30	20 26 23 16	30 38 34 28 23	0 14 21 28 40<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc. Residues in untreated control samples
RA-2720/03 R 2003 0914/7 0914-03 Spain [redacted] 2003	Pear Flor de Invierno	1) 1965 2) 01.04.2003 - 30.04.2003 3) 20.09.2003 - 10.10.2003	SPI SPI SPI	1500 1500 1500	0.20000 0.20000 0.20000	10.07.2003/0 31.07.2003/21 01.08.2003/21	fruit	fruit	0.29 <0.20 <0.20 <0.20 <0.20	5.4 5.8 4.8 7.7 5.1	8.1 8.6 7.1 11 7.5	0 14 21 28 40<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Pomaceous fruit
 Country : Germany Page : 4
 Content of active substance (g/kg or g/L) : 800 g/kg Indoor/outdoor : Outdoor
 Formulation (e.g. WP) : 80 WG Other a.s. in formulation (common name and content) :
 Commercial product (name) : Fosetyl-AL WG 80 Analyte 1 Residues determined as : Fosetyl-Al Residues calculated as : Fosetyl-Al
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl-Al calc. Residues calculated as : Fosetyl-Al

1	2	3	4	5		7	8	9			10	11	
				kg a.s./ha	Water (L/ha)			Residues (mg/kg)	Analyte 1	Analyte 2			Analyte 3
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval No. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DALT/ PHI (days) (f)	Remarks
RA-2720/03 R 2003 0915/5 0915-03 France, south [redacted] 2003	Pear Doyenne du comice	1) 01.01.1988 2) 08.04.2003 - 20.04.2003 3) 25.08.2003 - 11.09.2003	SPI SPI SPI	1250 1250 1250	0.24000 0.24000 0.24000	26.06.2003/0 15.07.2003/19 04.08.2003/20	fruit	79	7.5 0.20 0.20 0.20	7.5 0.4 5.8 9.1 10	12 14 8.6 13 15	0 14 21 28 38<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Pear treated with Fertilizers

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 1- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte / Residues determined as : Phosphonic acid / Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment / Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water l/ha	kg a.s./l						
02R109 02R109-1 02R109-1-P2 Italy [REDACTED] 2002	Pear Abate Fetel	1) 10.01.1970 2) 30.03.2002 - 14.04.2002 3) 02.09.2002	SPI SPI SPI	0.8193 0.8193 0.8193	1500 1500 1500	0.05462 0.05462 0.05462	13.06.2002/0 03.07.2002/20 23.07.2002/20	77	fruit	4.2 4.0 0.45 0.44	0 41<< 0 41<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
02R109 02R109-2 02R109-2-P2 Italy [REDACTED] 2002	Pear Conference	1) 10.01.1996 2) 25.03.2002 - 04.04.2002 3) 19.08.2002	SPI SPI SPI	0.8193 0.8193 0.8193	1500 1500 1500	0.05462 0.05462 0.05462	30.05.2002/0 19.06.2002/20 09.07.2002/20	78	fruit	8.0 5.4 32 3.3	0 41<< 0 41<<	(c) SPI: Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)	DALI/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)				kg a.s./hL		
02R109 02R109-3 02R109-3-P2 Italy [REDACTED] 2002	Pear Packam's Triumph	1) 15.11.1980 2) 25.03.2002 - 10.04.2002 3) 22.08.2002	SPI SPI SPK	0.8193 0.8193 0.8193	500 1500 1500	0.05462 0.05462 0.05462	04.06.2002/07 23.06.2002/20 15.07.2002/21	fruit	8.1 3.7 1.6 0.81	0 38<< 0 38<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
RA-2721/03 R 2003 0655/5A 0655-03 Italy [REDACTED] 2003	Pear Abate Fefel	1) 1980 2) 15.04.2003 - 30.04.2003 3) 25.08.2003	SPI SPK SPI	1.1 1.1 1.1	1000 1000 1000	0.11 0.11 0.11	11.06.2003/07 02.07.2003/21 23.08.2003/21	fruit	7.6 8.5 17 18 11 4.1 4.2 2.3 2.7 1.0	0 14 21 28 40<< 0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALI, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte / Residues determined as : Phosphonic acid / Residues calculated as Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment / Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water l/ha	kg a.s./l						
RA-2721/03 R 2003 0916/3A 0916-03 Spain [REDACTED] 2003	Pear Flor de Invierno	1) 1965 2) 01.04.2003 - 30.04.2003 3) 20.09.2003 - 01.10.2003	SPI SPI SPI	1.1 1.1 1.1	1500 1500 500	0.0729 0.0729 0.0729	10.07.2003/20 31.07.2003/21 21.08.2003/21	78	fruit	2.9 1.6 3.7 6.2 4.4	0 14 21 28 40<<	(c) SPI: Spraying (g) 00861 (h) 0.50 mg/kg
RA-2721/03 R 2003 0917/1A 0917-03 France, south [REDACTED] 2003	Pear Doyenne du comice	1) 01.01.1981 2) 08.04.2003 - 20.04.2003 3) 25.08.2003 - 11.09.2003	SPI SPI SPI	1.1 1.1 1.1	1250 1250 1250	0.087 0.087 0.087	26.06.2003/0 15.07.2003/19 04.08.2003/20	79	fruit	4.0 3.9 3.7 2.5 4.4	0 14 21 28 38<<	(c) SPI: Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 1- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte	DALI/PHI (days) (g)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
02R109 02R109-1 02R109-1-P3 Italy [REDACTED] 2002	Pear Abate Fetel	1) 10.01.1970 2) 30.03.2002 - 14.04.2002 3) 02.09.2002	SPI SPI SPI	1.5075 1.5075 1.5075	1500 1500 1500	0.1005 0.1005 0.1005	13.06.2002/0 03.07.2002/20 23.07.2002/20	77	fruit	2.8 0.71 0.45 0.44	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
02R109 02R109-2 02R109-2-P3 Italy [REDACTED] 2002	Pear Conferenza	1) 10.01.1996 2) 25.03.2002 - 10.04.2002 3) 19.08.2002	SPI SPI SPI	1.5075 1.5075 1.5075	1500 1500 1500	0.1005 0.1005 0.1005	30.05.2002/0 19.06.2002/20 09.07.2002/20		fruit	11 4.7 32 3.3	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALI, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid

Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments) Application interval or no. of treatments and last date	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) Analyte	DALT/PHI (days) (f)	Remarks
02R109 02R109-3 02R109-3-P3 Italy [REDACTED] 2002	Pear Packam's Triumph	1) 15.11.1980 2) 25.03.2002 - 10.04.2002 3) 22.08.2002	SPI SPI SPI	1.5075 1.5075 1.5075	1500 1500 1500	0.1005 0.1005 0.1005	04.06.2002/0 24.06.2002/20 15.07.2002/21	75	fruit	4.5 3.7 1.6 0.81	0 38<< 0 38<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
RA-2721/03 R 2003 0656/3A 0656-03 Italy [REDACTED] 2003	Pear Abate Fetel	1) 1980 2) 15.04.2003 - 30.04.2003 3) 25.08.2003	SPI SPI SPI	1.5 1.5 1	1000 1000 1000	0.15 0.15 0.15	11.06.2003/0 03.07.2003/21 25.07.2003/21	77	fruit	13 12 14 12 9.0 3.6 2.6 2.3 1.9 2.5	0 14 21 28 40<< 0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg Residues in untreated control samples

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3-B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte	DALI/PHI (days) (f)	Remarks	
				kg a.s./ha	Water (L/ha)							kg a.s./HL
RA-2721/03 R 2003 0922/8A 0922-03 Spain [REDACTED] 2003	Pear Flor de Invierno	1) 1965 2) 01.04.2003 - 30.04.2003 3) 20.09.2003 - 10.10.2003	SPI SPI SPI	1.5 1.5 1.5	1500 500 1500	0.101 0.101 0.101	10.07.2003/30 31.07.2003/21 21.08.2003/21	78	fruit	5.9 5.0 4.7 4.6 4.2	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2721/03 R 2003 0923/6A 0923-03 France, south [REDACTED] 2003	Pear Doyenné du comice	1) 01.01.1981 2) 08.04.2003 - 20.04.2003 3) 25.08.2003 - 11.09.2003	SPI SPI SPI	1.5 1.5 1.5	1250 1250 1250	0.12 0.12 0.12	26.06.2003/0 15.07.2003/19 04.08.2003/20	79	fruit	3.1 7.6 5.3 4.2 4.7	0 14 21 28 38<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALI, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg
Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 1- C

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments) Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
02R109 02R109-1 02R109-1-P4 Italy [REDACTED] 2002	Pear Abate Fetel	1) 10.01.1970 2) 30.03.2002 - 14.04.2002 3) 02.09.2002	SPI SPI SPI	0.9675 0.9675 0.9675	1500 1500 1500	0.06450 0.06450 0.06450	13.06.2002/0 03.07.2002/20 23.07.2002/20	77	fruit	<0.20 0.31 0.45 0.44	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
02R109 02R109-2 02R109-2-P4 Italy [REDACTED] 2002	Pear Conferenc	1) 10.01.1996 2) 25.03.2002 - 10.04.2002 3) 19.08.2002	SPI SPI SPI	0.9675 0.9675 0.9675	1500 1500 1500	0.06450 0.06450 0.06450	30.08.2002/0 19.06.2002/20 09.07.2002/20	78	fruit	0.34 0.53 32 3.3	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 2- C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)						
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments) Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
02R109 02R109-3 02R109-3-P4 Italy [REDACTED] 2002	Pear Packam's Triumph	1) 15.11.1980 2) 25.03.2002 - 10.04.2002 3) 22.08.2002	SPI SPI SPI	0.9675 0.9675 0.9675	1500 1500 1500	0.06450 0.06450 0.06450	04.06.2002/0 24.06.2002/20 15.07.2002/21	75 fruit	1.2 0.65 1.6 0.81	0 38<< 0 38<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg Residues in untreated control samples
RA-2721/03 R 2003 0657/1 0657-03 Italy [REDACTED] 2003	Pear Abate Fetel	1) 1980 2) 15.04.2003 - 30.04.2003 3) 25.08.2003	SPI SPI SPI	0.9675 0.9675 0.9675	1000 1000 1000	0.09675 0.09675 0.09675	11.06.2003/0 02.07.2003/21 25.07.2003/21	77 fruit	4.1 5.1 4.2 4.0 3.4 3.2 1.6 3.6 4.1 3.3	0 14 21 28 40<< 0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg Residues in untreated control samples

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Pomaceous fruit

Page : 3-C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
RA-2721/03 R 2003 0919/8 0919-03 Spain [REDACTED] 2003	Pear Flor de Invierno	1) 1965 2) 01.04.2003 - 30.04.2003 3) 20.09.2003 - 10.10.2003	SPI SPI SPI	0.9675 0.9675 0.9675	1500 500 1500	0.06450 0.06450 0.06450	10.07.2003/0 31.07.2003/21 21.09.2003/52	78 fruit	<-0.50 <-0.50 <-0.50 <-0.50 <-0.50	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2721/03 R 2003 0920/1 0920-03 France, south [REDACTED] 2003	Pear Doyenne du comice	1) 01.01.1981 2) 08.04.2003 - 20.04.2003 3) 25.08.2003 - 11.09.2003	SPI SPI SPI	0.9675 0.9675 0.9675	1250 1250 1250	0.07740 0.07740 0.07740	26.06.2003/0 19.07.2003/19 04.08.2003/20	79 fruit	<-0.50 <-0.50 <-0.50 <-0.50 <-0.50	0 14 21 28 38<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Grapes treated with Fosetyl-AI WP 50 and WP 60

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 325 g/kg
250 g/kg

Formulation (e.g. WP) : 60 WP
50 WP

Commercial product (name) : AE F053616 08 WP60 A1
AE F053616 07 WP50 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AI

Crop/Crop Group : Vines

Page : 1

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) : cymoxanil 25 %
Mancozeb 25 %
Copper oxychloride 25 %

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-AI

Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid

Analyte 3 Residues determined as : Total residue Fosetyl-AI calc. Residues calculated as : Fosetyl-AI

1	2	3	4	5			6	7	8	9			10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3			(f)
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of Treatment (c)	Application rate per treatment	Water	kg a.s./L	Dates of treatment(s) or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)	Analyte 1	Analyte 2	Analyte 3	DALT/ PHI (days) (f)	Remarks
02R117 02R117-1 Italy [REDACTED] 2002	Grape Trebbiano	1) 10.01.1975 2) 25.05.2002 3) 10.06.2002 - 30.09.2002	SPI SPL SPL SPL	1.3 1.3 1.3 0.63	1000 1000 1000 1000	0.13 0.13 0.13 0.063	12.06.2002/0 (WP) 27.06.2002/13 (WP) 24.07.2002/14 (WP) 07.08.2002/12 (WP)	83	fruit	0.80 0.69	13 8.8	20 13	0 41<<	(c) SPI:Spraying (g) AR154-97 (h) 0.50 mg/kg for fosetyl-AI and phosphonic acid and 1.2 mg/kg for total residue fosetyl-AI calc.	
02R117 02R117-2 Italy [REDACTED] 2002	Grape Lambrusco Di Sorbara	1) 10.01.1975 2) 25.05.2002 3) 10.06.2002 - 30.09.2002	SPI SPL SPL SPL	1.3 1.3 1.3 0.63	1000 1000 1000 1000	0.13 0.13 0.13 0.063	12.06.2002/0 (WP) 26.06.2002/14 (WP) 10.07.2002/14 (WP) 24.07.2002/14 (WP) 05.08.2002/12 (WP)	83	fruit	2 <0.50 <0.50	17 17 0.75	27 25 1.6	0 42<< 0	(c) SPI:Spraying (g) AR154-97 (h) 0.50 mg/kg for fosetyl-AI and phosphonic acid and 1.2 mg/kg for total residue fosetyl-AI calc. Residues in untreated control samples	

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 2

Content of active substance (g/kg or g/L) : 325 g/kg
250 g/kg

Indoor/outdoor : Outdoor

Formulation (e.g. WP) : 60 WP
50 WP

Other a.s. in formulation (common name and content) : Pyrimoxanil 25%
Mancozeb 25%
Copper oxychloride 25%

Commercial product (name) : AE F053616 08 WP60 A1
AE F053616 07 WP50 A1

Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al

Producer of commercial product : Bayer CropScience AG

Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
Analyte 3 Residues determined as : Total residue fosetyl-Al calc. Residues calculated as : Fosetyl-Al

1	2	3	4	5		6	7	8	9			10	11
				kg a.s./ha	Water (L/ha)				kg a./HL	Analyte 1	Analyte 2		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Date of treatment(s)/ Application interval Number of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DAIT/ PHI (days) (f)	Remarks
02R117 02R117-3 Italy [REDACTED] 2002	Grape Trebbiano	1) 01.11.1982 2) 01.06.2002 - 10.06.2002 3) 05.09.2002 - 20.09.2002	SPI SPL SPL SPI	1.3 1.3 1.3 0.63	1000 1000 1000 1000	0.13 0.13 0.13 0.063 0.063	06.06.2002/0 (WP) 20.06.2002/14 (WP) 04.07.2002/14 (WP) 04.07.2002/14 (WP) 31.07.2002/13 (WP)	fruit	1.6 1.4 1.2 1.4	28 25 14 14	42 37 22 22	0 41<< 0 41<<	(c) SPI:Spraying (g) AR154-97 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid and 1.2 mg/kg for total residue fosetyl-Al calc. Residues in untreated control samples
RA-2702/03 R 2003 0528/1 0528-03 Spain [REDACTED] 2003	Grape Tempranillo; Red variety	1) 1999 2) 01.06.2003 - 15.06.2003 3) 01.09.2003 - 30.09.2003	SPI SPL SPL SPL SPL	1.3 1.3 1.3 0.625 0.625	600 600 700 700 700	0.217 0.17 0.186 0.089 0.089	06.06.2003/0 (WP) 20.06.2003/14 (WP) 04.07.2003/14 (WP) 16.07.2003/12 (WP) 28.07.2003/12 (WP)	79 bunch of grapes	7.3 3.0 0.97 <0.50 <0.50	22 18 38 35 23	39 29 55 51 33	0 14 21 28 39<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid and 1.2 mg/kg for total residue fosetyl-Al calc.

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active substance : Fosetyl-Al

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DAIT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted] Crop/Crop Group : Vines
 Country : Germany Page : 3
 Content of active substance (g/kg or g/L) : 325 g/kg Indoor/outdoor : Outdoor
 250 g/kg
 Formulation (e.g. WP) : 60 WP Other a.s. in formulation (common name and content) : cymoxanil 25 %
 50 WP Mancozeb 25 %
 Commercial product (name) : AE F053616 08 WP60 A1 Analyte 1 Residues determined as : Methyl ethyl phosphonate Residues calculated as : Fosetyl-Al
 AE F053616 07 WP50 A1
 Producer of commercial product : Bayer CropScience AG Analyte 2 Residues determined as : Dimethyl phosphonate Residues calculated as : Phosphonic acid
 Analyte 3 Residues determined as : Total residue fosetyl-Al calc. Residues calculated as : Fosetyl-Al

1	2	3	4	5			6	7	8	9			10	11
				kg a.o.a	Water (L/ha)	a.s./hL				Analyte 1	Analyte 2	Analyte 3		
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (d)			Dates of treatment(s) Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) (f)			DALT/PHI (days) (f)	Remarks
RA-2702/03 R 2003 0906/6 0906-03 Portugal [redacted] 2003	Grape Arinto	1) 1995 2) 25.05.2003 - 07.06.2003 3) 07.09.2003 - 30.09.2003	SPI SPI SPI SPI	1.3000 1.3000 1.3000 0.6250	1000 1000 1000 700	0.1300 0.1300 0.1300 0.0893	13.06.2003/0 (WP) 27.06.2003/14 (WP) 07.2003/14 (WP) 23.07.2003/2 (WP) 04.08.2003/12 (WP)	79 79 79 79	bunch of grapes	1.8 1.5 0.52 <0.50 <0.50	6.9 12 10 4.6 5.7	12 19 15 7.0 8.6	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid and 1.2 mg/kg for total residue fosetyl-Al calc.
RA-2702/03 R 2003 0907/4 0907-03 Italy [redacted] 2003	Grape Trebbiano White variety	1) 10.11.1982 2) 20.05.2003 - 30.05.2003 3) 10.09.2003 - 20.09.2003	SPI SPI SPI SPI SPI	1.3000 1.3000 1.3000 0.6250 0.6250	1000 1000 1000 1000 1000	0.1300 0.1300 0.1300 0.0893 0.0625	16.06.2003/0 (WP) 30.06.2003/14 (WP) 14.07.2003/14 (WP) 25.07.2003/11 (WP) 07.08.2003/13 (WP)	83 83 83 83 83	bunch of grapes	0.89 0.98 <0.50 <0.50 <0.50	9.9 9.2 10 8.2 7.3	15 14 15 12 11	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg for fosetyl-Al and phosphonic acid and 1.2 mg/kg for total residue fosetyl-Al calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
 (f) Minimum no. of days after last treatment. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Grapes treated with Fertilizers

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 273 g/L

Formulation (e.g. WP) : 273 SC

Commercial product (name) : AE 0540099 00 SC20 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AI

Crop/Crop Group : Vines

Page : 1- A

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
				Application rate per treatment	Water (L/ha)							kg a.s./ha
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	kg a.s./ha	Water (L/ha)	kg a.s./ha	Dates of treatment(s)/ Application interval or no. of treatments and last date/	BBCH stage at last treatment (e)	Portion analysed (mg/kg) (a)	Residues (mg/kg) Analyte 1	DALT, PHI (days) (f)	Remarks
02R118 02R118-1 02R118-1-P2 Italy [REDACTED] 2002	Grape Trebiano	1) 10.01.1975 2) 25.05.2002 - 10.06.2002 3) 17.09.2002	SPI SPK SPI SPI SPI	0.8193 0.8193 0.8193 0.8193 0.8193	1000 1000 1000 1000 1000	0.08193 0.08193 0.08193 0.08193 0.08193	12.06.2002/0 27.06.2002/0 12.07.2002/15 26.07.2002/14 07.08.2002/12	83	bunch of grapes	10 16	0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg
02R118 02R118-2 02R118-2-P2 Italy [REDACTED] 2002	Grape Lambrusco Di Sorbara	1) 10.01.1996 2) 25.05.2002 - 05.06.2002 3) 16.09.2002	SPI SPI SPI SPI SPI	0.8193 0.8193 0.8193 0.8193 0.8193	1000 1000 1000 1000 1000	0.08193 0.08193 0.08193 0.08193 0.08193	12.06.2002/0 26.06.2002/14 10.07.2002/14 24.07.2002/14 05.08.2002/12	83	bunch of grapes	14 19	0 42<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-AI

Crop/Crop Group : Vines

Page : 2- A

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) Analyte 1	DALT, PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
02R118 02R118-3 02R118-3-P2 Italy [REDACTED] 2002	Grape Trebiano	1) 01.11.1982 2) 01.06.2002 - 10.06.2002 3) 10.09.2002	SPI SPE SPE SPE SPE	0.8193 0.8193 0.8193 0.8193 0.8193	1000 1000 1000 1000 1000	0.08193 0.08193 0.08193 0.08193 0.08193	06.06.2002/04 20.06.2002/04 04.07.2002/14 18.07.2002/14 01.07.2002/14	81 bunch of grapes	39 21 16 3.6	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg Residues in untreated control samples
RA-2703/03 R 2003 0535/4A 0535-03 Spain [REDACTED] 2003	Grape Tempranillo ; red variety	1) 1999 2) 01.06.2003 05.06.2003 3) 01.09.2003 - 30.09.2003	SPI SPE SPE SPE SPE	1.1 1.1 1.1 1.1 1.1	500 600 700 700 700	0.156 0.182 0.156 0.156 0.156	06.06.2003/04 20.06.2003/14 04.07.2003/14 16.07.2003/12 28.07.2003/12	79 bunch of grapes	58 49 36 21 28	0 14 21 28 39<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 3- A

Indoor/outdoor : Outdoor
Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date/last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
RA-2703/03 R 2003 0908/2A [REDACTED] 2003	Grape Arinto; white variety	1) 1995 2) 25.05.2003 - 07.06.2003 3) 07.09.2003 - 30.09.2003	SPI SPR SPI SPI SPI	1.1 1.1 1.1 1.1 1.1	1000 1000 1000 1000 1000	0.11 0.11 0.11 0.11 0.11	16.06.2003/09 27.06.2003/14 11.07.2003/14 22.07.2003/12 04.08.2003/11	99 83	bunch of grapes 20 20 19 14 18	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2703/03 R 2003 0909/0A [REDACTED] 2003	Grape Trebbiano	1) 10.11.1982 2) 20.05.2003 - 30.05.2003 3) 10.09.2003 - 09.09.2003	SPI SPR SPI SPI SPI	1.1 1.1 1.1 1.1 1.1	1000 1000 1000 1000 1000	0.11 0.11 0.11 0.11 0.11	16.06.2003/09 30.06.2003/14 14.07.2003/14 25.07.2003/11 07.08.2003/13	83	bunch of grapes 12 11 13 12 13	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 1- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
				kg a.s./ha	Water (L/ha)							
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment kg a.s./ha	Water (L/ha)	Dates of treatments (Application interval or gap of treatments and last date) (d)	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
02R118 02R118-1 02R118-1-P3 Italy [REDACTED] 2002	Grape Trebiano	1) 10.01.1975 2) 25.05.2002 - 10.06.2002 3) 17.09.2002	SPI SPI SPI SPI SPI	1.5075 1.5075 1.5075 1.5075 1.5075	1000 1000 1000 1000 1000	0.1508 0.1508 0.1508 0.1508 0.1508	14.06.2002/0 27.06.2002/13 13.07.2002/15 26.07.2002/14 07.08.2002/12	83	bunch of grapes	8.2 14	0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg
02R118 02R118-2 02R118-2-P3 Italy [REDACTED] 2002	Grape Lambrusco Di Sorbara	1) 10.01.1996 2) 25.05.2002 - 05.06.2002 3) 16.09.2002	SPI SPI SPI SPI SPI	1.5075 1.5075 1.5075 1.5075 1.5075	1000 1000 1000 1000 1000	0.1508 0.1508 0.1508 0.1508 0.1508	12.06.2002/0 26.06.2002/14 10.07.2002/14 24.07.2002/14 05.08.2002/12		bunch of grapes	16 13	0 42<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 2- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
02R118 02R118-3 02R118-3-P3 Italy [REDACTED] 2002	Grape Trebiano	1) 01.11.1982 2) 01.06.2002 - 10.06.2002 3) 10.09.2002	SPI SPI SPI SPK SPI	1.5075 1.5075 1.5075 1.5075 1.5075	1000 1000 1000 1000 1000	0.1508 0.1508 0.1508 0.1508 0.1508	06.06.2002/0 20.06.2002/14 04.07.2002/14 18.07.2002/14 31.07.2002/13	81	bunch of grapes	36 31 16 3.6	0 41<< 0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg Residues in untreated control samples
RA-2703/03 R 2003 0537/0A 0537-03 Spain [REDACTED] 2003	Grape Tempranillo ; Red variety	1) 1999 2) 01.06.2003 - 15.06.2003 3) 01.09.2003 - 09.2003	SPI SP SPI SPI SP	1.5 1.5 1.5 1.5 1.5	600 600 600 700 700	0.251 0.251 0.213 0.215 0.215	06.06.2003/0 20.06.2003/14 04.07.2003/14 16.07.2003/12 28.07.2003/12	79	bunch of grapes	45 48 34 31 28	0 14 21 28 39<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 3-B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
				kg a.s./ha	Water (L/ha)							kg a.s./HL
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
RA-2703/03 R 2003 0910/4A [REDACTED] 2003	Grape Arinto; white variety	1) 1995 2) 25.05.2003 - 07.06.2003 3) 07.09.2003 - 30.09.2003	SPI SPI SPI SPK SPI	1.5 1.5 1.5 1.5 1.5	1000 1000 1000 1000 1000	0.15 0.15 0.15 0.15 0.15	13.06.2003/0 27.06.2003/14 14.07.2003/14 23.07.2003/02 04.08.2003/12	79	bunch of grapes	25 28 29 -0.50 32	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2703/03 R 2003 0911/2A 0911-03 Italy [REDACTED] 2003	Grape Trebbiano; green variety	1) 10.11.1982 2) 20.05.2003 - 30.05.2003 3) 10.09.2003 - 20.09.2003	SPI SPK SPI SPI SPI	1.5 1.5 1.5 1.5 1.5	1000 1000 1000 1000 1000	0.15 0.15 0.15 0.15 0.15	08.06.2003/0 30.06.2003/14 14.07.2003/14 23.07.2003/14 07.08.2003/13	83	bunch of grapes	38 28 27 15 22	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 1- C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
				kg a.s./ha	Water (L/ha)							kg a.s./HL
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or gap of treatments and last date)	Growth stage at last treatment	Portion analysed (g)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
02R118 02R118-1 02R118-1-P4 Italy [REDACTED] 2002	Grape Trebiano	1) 10.01.1975 2) 25.05.2002 - 10.06.2002 3) 17.09.2002	SPI SPI SPI SPI	0.645 0.645 0.645 0.645	1000 1000 1000 1000	0.0645 0.0645 0.0645 0.0645	14.06.2002/0 27.06.2002/13 13.07.2002/15 26.07.2002/14 07.08.2002/12	83	bunch of grapes	<0.50 <0.50	0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg
02R118 02R118-2 02R118-2-P4 Italy 41030 San Prospero [REDACTED] 2002	Grape Lambrusco Di Sorbara	1) 10.01.1996 2) 25.05.2002 - 05.06.2002 3) 16.09.2002	SPI SPI SPI SPI	0.645 0.645 0.645 0.645	1000 1000 1000 1000	0.0645 0.0645 0.0645 0.0645	12.06.2002/0 26.06.2002/14 10.07.2002/14 24.07.2002/14 05.08.2002/12		bunch of grapes	0.60 3.0	0 42<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 2- C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
				kg a.s./ha	Water (L/ha)						
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment kg a.s./ha	Water (L/ha)	Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
02R118 02R118-3 02R118-3-P4 Italy [REDACTED] 2002	Grape Trebiano	1) 11.01.1982 2) 01.06.2002 - 10.06.2002 3) 10.09.2002	SPI SPI SPI SPI SPI	0.645 0.645 0.645 0.645 0.645	1000 600 1000 1000 1000	0.0645 0.0645 0.0645 0.0645 0.0645	06.06.2002/0 20.06.2002/14 04.07.2002/14 18.07.2002/14 31.07.2002/13	81 bunch of grapes	16 10 16 3.6	0 41<<	(c) SPI:Spraying (g) AR 154-97 (h) 0.50 mg/kg Residues in untreated control samples
RA-2703/03 R 2003 0539/7 0539-03 Spain [REDACTED] 2003	Grape Tempranillo ; Red variety	1) 1999 2) 01.06.2003 - 15.06.2003 3) 01.09.2003 - 30.09.2003	SPI SPI SPI SPI SPI	0.6450 0.6450 0.6450 0.6450 0.6450	600 600 700 700 700	0.10759 0.10759 0.09211 0.09211 0.09211	06.06.2003/0 20.06.2003/14 04.07.2003/14 16.07.2003/12 28.07.2003/12	bunch of grapes	0.97 1.3 1.5 <0.50 <0.50	0 14 21 28 39<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Vines

Page : 3-C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment	Portion analysed (e)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
				kg a.s./ha	Water (L/ha)							
RA-2703/03 R 2003 0912/0 0912-03 [REDACTED] 2003	Grape Arinto; white variety	1) 1995 2) 25.05.2003 - 07.06.2003 3) 07.09.2003 - 30.09.2003	SPI SPI SPI SPK SPI	0.6450 0.6450 0.6450 0.6450 0.6450	1000 1000 1000 1000 1000	0.06450 0.06450 0.06450 0.06450 0.06450	13.06.2003/14 27.06.2003/14 14.07.2003/14 23.07.2003/14 04.08.2003/12	79	bunch of grapes	<-0.50 0.70 <-0.50 26 <-0.50	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2703/03 R 2003 0913/9 0913-03 Italy [REDACTED] 2003	Grape Trebbiano	1) 10.11.1982 2) 20.05.2003 - 30.05.2003 3) 10.09.2003 - 20.09.2003	SPI SPI SPI SPI SPI	0.6450 0.6450 0.6450 0.6450 0.6450	1000 1000 1000 1000 1000	0.06450 0.06450 0.06450 0.06450 0.06450	08.06.2003/14 30.06.2003/14 14.07.2003/14 23.07.2003/14 07.08.2003/13	83	bunch of grapes	<-0.50 <-0.50 <-0.50 <-0.50 <-0.50	0 14 21 28 40<<	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

(a) According to Codex (or other e.g. EU) Classification/Guide
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc. overall broadcast
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
 (g) Reference to analytical method
 (h) Limit of determination/quantitation
 (i) Dosage of a.s. or water given as...
 (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed
Fosetyl

Lettuce treated with Fosetyl-Al WG 80

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 800 g/kg

Formulation (e.g. WP) : 80 WG

Commercial product (name) : Fosetyl-AL WG 80

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 1

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Methyl ethyl phosphonate

Analyte 2 Residues determined as : Dimethyl phosphonate

Analyte 3 Residues determined as : Total residue fosetyl-Al calc.

Residues calculated as : Fosetyl-Al

Residues calculated as : Phosphonic acid

Residues calculated as : Fosetyl-Al

1	2	3	4	5			7	8	9			10	11	
				kg a.s./ha	Water (L/ha)	kg a.s./hL			Analyte 1	Analyte 2	Analyte 3			
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residue (mg/kg)			PHI (days) (f)	Remarks
02R115 02R115-1 Italy [REDACTED] 2002	Lettuce Gentile Fanly	1) 29.04.2002 1) 23.05.2002 3) 20.06.2002 - 10.07.2002	SPI SPI	2.0 2.0	800 800	0.25 0.25	05.06.2002/0 20.06.2002/15	43	whole plant with root	2.0 1.5	13 1.6	39 3.8	0 14<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.
02R115 02R115-2 Italy [REDACTED] 2002	Lettuce Justine	1) 20.05.2002 1) 07.06.2002 3) 08.07.2002 - 20.07.2002	SPI SPI	2.0 2.0	800 800	0.25 0.25	11.06.2002/0 20.06.2002/15	43	whole plant with root	19 <0.20	14 1.6	39 2.5	0 15<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.

(a) According to Codex (or other e.g. EU) Classification/Guide

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc. overall broadcast

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')

(g) Reference to analytical method

(h) Limit of determination/quantitation

(i) Dosage of a.s. or water given as...

(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 2

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl-Al calc. (Residues calculated as : Fosetyl-Al)

1	2	3	4	5			6	7	9			10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DALT/ PHI (days) (f)	Remarks
				g a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3		
02R115 02R115-3 Italy [REDACTED] 2002	Lettuce Regina Di Maggio	1) 15.03.2002 3) 01.06.2002 - 20.06.2002	SPI SPI	2.0 2.0	1000 1000	0.20 0.20	20.05.2002/04.06.2002/15	47	whole plant with root	10 0.6	17 3.0	34 4.9	0 14<<	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.
RA-2722/03 R 2003 0128/6 0128-03 Italy [REDACTED] 2003	Lettuce Dinamo; Butter head variety	1) 25.09.2003 3) 25.12.2003	SPI SPI	600 600	0.33360 0.33360	0.20 0.20	26.11.2003/0 13.12.2003/17	48	head	1.7 <0.20 <0.20 <0.20	20 7.1 7.5 4.3	30 10 11 6.4	0 7 14<< 21	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, ██████████
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 3

Content of active substance (g/kg or g/L) : 800 g/kg
Formulation (e.g. WP) : 80 WG

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : Fosetyl-AL WG 80
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Methyl ethyl phosphonate (Residues calculated as : Fosetyl-Al)
Analyte 2 Residues determined as : Dimethyl phosphonate (Residues calculated as : Phosphonic acid)
Analyte 3 Residues determined as : Total residue fosetyl-Al calc. (Residues calculated as : Fosetyl-Al)

1	2	3	4	5			6	7	9			10	11	
Study Trial No.; Trial SUBID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatment(s) Application interval or no. of treatments and last date/ (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg)			DALT/PHI (days) (f)	Remarks
				g a.s./ha	Water (L/ha)	kg a.s./L				Analyte 1	Analyte 2	Analyte 3		
RA-2722/03 R 2003 0924/4 0924-03 Spain E-46230 ██████████ 2003	Lettuce Felipo; COS variety	1) 04.07.2003	SPI SPI	2 300	0.66640 0.66640	0.66640	26.07.2003/0 30.07.2003/14	45	head	0.38 <0.20 <0.20	18 6.6 4.9 1.6	26 9.7 7.3 2.5	0 7 14<< 21	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.
RA-2722/03 R 2003 0925/2 0925-03 France, south ██████████ 2003	Lettuce Sagesse; Loose leaf variety	1) 19.05.2003	SPI SPI	2 450	0.44480 0.44480	0.44480	13.06.2003/0 27.06.2003/14	49	head	0.21 <0.20 <0.20 <0.20	18 3.6 1.9 0.38	26 5.4 2.9 0.75	0 7 14<< 21	(c) SPI:Spraying (g) AR155-97 (h) 0.20 mg/kg for fosetyl-Al and phosphonic acid and 0.49 mg/kg for total residue fosetyl-Al calc.

(a) According to Codex (or other e.g. EU) Classification/Guide
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc. overall broadcast
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
(g) Reference to analytical method
(h) Limit of determination/quantitation
(i) Dosage of a.s. or water given as...
(-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

Lettuce treated with Fertilizers

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 1- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content)

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte / Residues determined as : Phosphonic acid / Residues calculated as Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
				Application rate per treatment	Water							
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	kg a.s./ha	kg a.s./ha	Dates of treatment / Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
02R114 02R114-1 02R114-1-P2 Italy [REDACTED] 2002	Lettuce, leaf Gentile Fanly	1) 29.04.2002 3) 04.07.2002	SPI SPI	0.4095 0.4095	800 800	0.0512 0.0512	05.06.2002/0 20.06.2002/15	43	leaf	0.25 0.50	0 14<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
02R114 02R114-2 02R114-2-P2 Italy [REDACTED] 2002	Lettuce, leaf Justine	1) 20.05.2002 3) 11.07.2002	SPI SPI	0.4095 0.4095	800 800	0.0512 0.0512	11.06.2002/0 26.06.2002/15	44	leaf	4.2 0.78	0 15<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 2- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
02R114 02R114-3 02R114-3-P2 Italy [REDACTED] 2002	Lettuce, leaf Regina Di Maggio	1) 15.03.2002 3) 18.06.2002	SPI SPI	0.4095 0.4095	600 1000	0.04095 0.04095	20.05.2002/0 04.06.2002/15	42 10	11 1.7	0 14<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
RA-2723/03 R 2003 0659/8A 0659-03 Italy [REDACTED] 2003	Lettuce Dinamo Butter head variety	1) 25.09.2003	SPI SPI	0.55 0.55	600 600	0.0909 0.0909	26.12.2003/0 15.12.2003/14	head	6.2 5.4 3.9 3.2	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [redacted]
Country : Germany

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 3- A

Content of active substance (g/kg or g/L) : 273 g/L
Formulation (e.g. WP) : 273 SC

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Commercial product (name) : AE 0540099 00 SC20 A1
Producer of commercial product : Bayer CropScience AG

Analyte 1 Residues determined as Phosphonic acid Residues calculated as Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	Growth stage at last treatment (e)	Portion analysed (a)	Residues (mg/kg) Analyte 1	DALT/PHI (d/s) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
RA-2723/03 R 2003 0926/0A 0926-03 Spain [redacted] 2003	Lettuce Felipo; COS-variety	1) 04.07.2003	SPI SPI	0.55 0.55	300 300	0.182 0.182	16.07.2003/0 20.07.2003/14	49 49	head 5.9 3.0 1.2 1.1	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2723/03 R 2003 0927/9A 0927-03 France, south [redacted] 2003	Lettuce Sagesse	1) 19.05.2003 2) 20.06.2003 3) 20.07.2003	SPI SPI	0.55 0.55	450 450	0.121 0.121	13.06.2003/0 27.06.2003/14	49 49	head 6.5 0.71 <0.50 0.63	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 1- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
02R114 02R114-1 02R114-1-P3 Italy [REDACTED] 2002	Lettuce, leaf Gentile Fanly	1) 29.04.2002 2) 04.07.2002 3) 04.07.2002	SPI SPI	1.5075 1.5075	800 800	0.188 0.188	05.06.2002/0 20.06.2002/15	43	leaf	8.0 1.6	0 14<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
02R114 02R114-2 02R114-2-P3 Italy [REDACTED] 2002	Lettuce, leaf Justine	1) 20.05.2002 2) 04.07.2002 3) 11.07.2002	SPI SPI	1.5075 1.5075	800 800	0.188 0.188	11.06.2002/0 26.06.2002/15	43	leaf	20 3.1	0 15<<	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 2- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
02R114 02R114-3 02R114-3-P3 Italy [REDACTED] 2002	Lettuce, leaf Regina Di Maggio	1) 15.03.2002 3) 18.06.2002	SPI SPI	1.5075 1.5075	1000 600	0.1508 0.1508	20.05.2002/04.06.2002/15	47	leaf	22 4.9	0 14	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
RA-2723/03 R 2003 0660/1A 0660-03 Italy [REDACTED] 2003	Lettuce Dinamo; Butter head variety	25.09.2003	SPI SPI	1.5 1.5	600 600	0.251 0.25	26.11.2003/013.12.2003/17	48	head	21 13 13 12	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 603 g/kg

Formulation (e.g. WP) : 60.3 SP

Commercial product (name) : AE 0540099 00 SP60 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 3- B

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11	
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks	
				kg a.s./ha	Water (L/ha)							
RA-2723/03 R 2003 0928/7A 0928-03 Spain [REDACTED] 2003	Lettuce Felipo; COS-variety	1) 04.07.2003	SPI SPI	1.5 1.5	300 300	0.502 0.502	16.07.2003/30 30.07.2003/14	45	head	26 8.6 4.6 3.9	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2723/03 R 2003 0929/5A 0929-03 France, south [REDACTED] 2003	Lettuce Sagesse	1) 19.05.2003 2) 20.06.2003 3) 20.06.2003 - 30.07.2003	SPI SPI	1.5 1.5	400 450	0.335 0.335	13.06.2003/0 27.06.2003/14	49	head	18 4.2 2.3 1.7	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 1- C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5		6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment		Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (f)	Remarks
				kg a.s./ha	Water (L/ha)						
02R114 02R114-1 02R114-1-P4 Italy [REDACTED] 2002	Lettuce, leaf Gentile Fanly	1) 29.04.2002 3) 04.07.2002	SPI SPI	0.645 0.645	800 800	0.0806 0.0806	05.06.2002/0 20.06.2002/15	43 leaf	<0.20 <0.20	0 14	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
02R114 02R114-2 02R114-2-P4 Italy [REDACTED] 2002	Lettuce, leaf Justine	1) 20.05.2002 3) 11.07.2002	SPI SPI	0.645 0.645	800 800	0.0806 0.0806	11.06.2002/0 26.06.2002/15	43 leaf	<0.20 <0.20	0 15	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 2- C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1 Study Trial No.; Trial SubID Location incl. postal code Year of study	2 Commodity / Variety (a)	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment			6 Dates of treatment(s)/ Application interval or no. of treatments and last date (d)	7 Growth stage at last treatment (e)	8 Portion analysed (f)	9 Residues (mg/kg) Analyte 1	10 DALT/PHI (days) (f)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./hL						
02R114 02R114-3 02R114-3-P4 Italy [REDACTED] 2002	Lettuce, leaf Regina Di Maggio	1) 15.03.2002 3) 18.06.2002	SPI SPI	0.645 0.645	1000 1000	0.0645 0.0645	20.05.2002/0 04.06.2002/15	47	leaf	<0.20 <0.20	0 14	(c) SPI:Spraying (g) AR 155-97 (h) 0.20 mg/kg
RA-2723/03 R 2003 0662/8 0662-03 Italy [REDACTED] 2003	Lettuce Dinamo; Butter head variety	1) 25.09.2003	SPI SPI	0.6450 0.6450	600 600	0.1075 0.1075	26.11.2003/0 12.12.2003/17	48	head	<0.50 <0.50 <0.50 <0.50	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.

Document MCA – Section 6: Residues in or on treated products, food and feed

Fosetyl

RESIDUE DATA FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Responsible body for reporting (name and address) : Bayer CropScience AG, [REDACTED]

Country : Germany

Content of active substance (g/kg or g/L) : 258 g/kg

Formulation (e.g. WP) : 25.8 SP

Commercial product (name) : AE F081256 00 SP26 A1

Producer of commercial product : Bayer CropScience AG

Active substance : Fosetyl-Al

Crop/Crop Group : Leaf and stem vegetables

Page : 3-C

Indoor/outdoor : Outdoor

Other a.s. in formulation (common name and content) :

Analyte 1 Residues determined as : Phosphonic acid Residues calculated as : Phosphonic acid

1	2	3	4	5			6	7	8	9	10	11
Study Trial No.; Trial SubID Location incl. postal code Year of study	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment			Dates of treatments (Application interval or no. of treatments and last date) (d)	Growth stage at last treatment (e)	Portion analysed (f)	Residues (mg/kg) Analyte 1	DALT/PHI (days) (g)	Remarks
				kg a.s./ha	Water (L/ha)	kg a.s./HL						
RA-2723/03 R 2003 0930/9 0930-03 Spain [REDACTED] 2003	Lettuce Felipo; COS-variety	1) 04.07.2003	SPI SPI	0.6450 0.6450	300 300	0.21491 0.21491	16.07.2003/30 30.07.2003/14	45	head	<0.50 <0.50 <0.50 <0.50	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg
RA-2723/03 R 2003 0931/7 0931-03 France, south [REDACTED] 2003	Lettuce Sagesse	1) 19.05.2003 2) 20.06.2003 3) 20.06.2003 - 20.07.2003	SPI SPI	0.6450 0.6450	450 450	0.1434 0.1435	13.06.2003/0 27.06.2003/14	49	head	<0.50 <0.50 <0.50 <0.50	0 7 14<< 21	(c) SPI:Spraying (g) 00861 (h) 0.50 mg/kg

- (a) According to Codex (or other e.g. EU) Classification/Guide
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc. overall broadcast
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

- (f) Minimum no. of days after last treatm. (DALT, Label pre-harvest interval, PHI = '<<')
- (g) Reference to analytical method
- (h) Limit of determination/quantitation
- (i) Dosage of a.s. or water given as...
- (-) Missing data in the above columns occurs where the information is not available in the original report

Note: All entries to be filled in as appropriate. Date format dd.mm.yy.