Bayer CropScience

Document Title

Summary of the ecotoxicological studies fluoxastrobin + prothioconazole EC 200 (100+100 g/L)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013
Document MCP
Section 10: Ecotoxicological studies

According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[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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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Introduction

The representative formulation submitted in the first Annex I listing process is no longer considered as a representative formulation for the renewal of fluoxastrobin. One of the two representative formulations used for the submission of the renewal of the approval of fluoxastrobin is the spray formulation Fluoxastrobin + Prothioconazole EC 200 (100+100 g/L; 'FXA + PTZ EC200'). The summaries of formulation studies and the risk assessment will be presented in this dossier.

Ecotoxicological endpoints used in the following risk assessment were derived from studies with the formulated product, the active substance fluoxastrobin and the metabolites listed in the residue definition for risk assessment.

In this dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for fluoxastrobin and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, the previously evaluated information is written in grey font.

Use pattern considered in this risk assessment

There are two key use pattern for the formulation, FXA+PTZ EC 200. The first consists of two applications in wheat, rye and triticale at a maximum rate of 2 x 1.5 L per hectare at growth stage BBCH 30-69. The second consists of two applications of 2 x 1.25 L per hectare in onions at growth stage BBCH 15 to 47. In addition, a less critical use of two applications in barley and oats at a maximum rate of 1.25 L per hectare at growth stage 30-61 is addressed.

Table CP 10- 1: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate per treatment [L/ha]	Application rate per treatment [g/ha]	
					Fluoxastrobin	Prothioconazole
Wheat, rye, triticale*	BBCH 30-69	1-2	14-21	1.5	150	150
Barley, oats*	BBCH 30-61	1-2	14-21	1.25	125	125
Onions**	BBCH 15-47	1-2	10	1.0-1.25	100-125	100-125

* Use in Central Europe; ** Use in Southern Europe

Risk envelope

For envelope type risk assessment, the critical application pattern in cereals is defined as multiple application of 2 × 1.5 L product/ha at BBCH 30−69 with an application interval of 14 days. The other application pattern in cereals is considered as less critical. To enable a possible differentiation in mitigation measures adapted to the use rate, TER calculations for the less critical application pattern will also be provided in domains where exposure mitigation via use restriction is needed to pass risk assessment for the critical GAP (envelope rate).

Definition of the residue for risk assessment

Due to changes in the requirements under EU Regulation 1107/2009, additional degradation products were proposed to be included in the residue definition. All studies necessary to describe the ecotoxicological profile of these metabolites in the relevant environmental compartments are summarized in this document. The residue definition is presented in Table CP 10- 2.

Table CP 10- 2: Definition of the residue for risk assessment

Compartment	Residue Definition for Risk Assessment
Soil	fluoxastrobin (*E*- isomer), HEC 5725 -*Z*-isomer, HEC 5725-carboxylic acid (*M40*), HEC 5725-*E*-des-chlorophenyl (*M48-E*), 2-chlorophenol (*M82*)
Groundwater	fluoxastrobin (*E*-isomer), HEC 5725-*Z*-isomer, HEC 5725-carboxylic acid (*M40*), HEC 5725-*E*-des-chlorophenyl (M48-*E*), 2-chlorophenol (M82)
Surface water	fluoxastrobin (*E*- isomer), HEC 5725-*Z*-isomer, HEC 5725-carboxylic acid (*M40*), HEC 5725-*E*-des-chlorophenyl (*M48-E*)
Sediment	fluoxastrobin (*E*- isomer), HEC 5725-*Z*-isomer
Air	none

A list of metabolites, which contains the structures, the synonyms and code numbers attributed to the compound fluoxastrobin, is presented in Document N3 of this dossier.

Compounds addressed in this document

In addition to the active substance fluoxastrobin, the degradation products summarised in the Table CP 10- 2 were addressed in this document.
In this paragraph the approach to the risk assessment of the Z-isomer of fluoxastrobin is specifically considered. The chemical structure of fluoxastrobin contains an oxime ether moiety. Due to the substitution pattern of that double bond E- and Z-isomers exist. The common name fluoxastrobin denotes the *E*-isomer. The Z-isomer is known to be an impurity in technical fluoxastrobin (specification limit 2 mg/kg). The Z-isomer can be formed from the E-isomer by photolytic processes exclusively. The transformation will lead to an equilibrium state in which the E-isomer is the more stable and energetically preferred isomer (ratio in aqueous solution about 10:1 = E / Z). In the environment the Z-isomer shows very similar degradation behaviour and a better soil sorption than the E-isomer. Further, the Z-isomer shows a very similar toxicological profile. A study with *Daphnia magna* performed with an increased amount of Z-Isomer (isomer ratio (E/Z) = 65/35 demonstrated an at least comparable, potentially lower ecotoxicological profile than the parent E-isomer, demonstrating that there is no further risk for the aquatic compartment (please refer to CA 8.2.4.1 M-030533-01-1). Taking this information into account, both isomers can be evaluated as sum of E+Z-isomers, providing a conservative environmental risk assessment.

CP 10.1 Effects on birds and other terrestrial vertebrates

The risk assessment was performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA GD 2009".

CP 10.1.1 Effects on birds

Table CP 10.1.1- 1: Endpoints used in Tier 1 risk assessment

Test substance	Exposure	species/origin	Endpoint		Reference
Fluoxastrobin	Acute risk assessment	*Colinus virginianus* (Bobwhite quail)	LD_{50} $LD_{50\ extrapol}$	> 2000 mg a.s./kg bw **≡ 3776 mg/kg bw**[1]	[redacted]; 2003; M-024735-02-1
	Reproductive risk assessment	Lowest NOEL from *Anas platyrhynchos* (Mallard duck)	NOEC **NOEL**	461 mg/kg diet **51 mg as/kg bw/d**	[redacted] 2003; M-087968-01-1

Bold values used for the risk assessment

[1] LD_{50} extrapolated with EFSA GD factor 1.888 (10 birds, no mortality; EFSA GD Birds & Mammals (2009), Section 2.1.2, Tab. 1)

Table CP 10.1.1- 2: Relevant generic avian focal species for risk assessment on Tier 1 level according to EFSA GD 2009

Crop scenario	Scenario	Generic focal species	Representative species	Short cut values for RA based on	
				RUD_{90}	RUD_m
Cereals 2 × 0.150 kg/ha BBCH 30-69 14 d interval	BBCH 30 - 39	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	**12.0**	**5.4**
	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	7.2	3.3
Onions 2 × 0.125 kg/ha BBCH 15-47 10 d interval	BBCH 10 - 39	Small granivorous bird "finch"	Linnet (*Carduelis cannabina*)	**24.7**	**11.4**
	BBCH ≥ 40	Small granivorous bird "finch"	Linnet (*Carduelis cannabina*)	14.8	6.9
	BBCH 10 - 39	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	**24.0**	**10.9**
	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	14.4	6.5
	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (*Motacilla flava*)	**26.8**	**11.3**
	BBCH ≥ 20	Small insectivorous bird "wagtail"	Yellow wagtail (*Motacilla flava*)	25.2	9.7

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.1- 3: Tier 1 acute risk assessment for birds

Crop scenario	Generic focal species	DDD			DDD	LD_{50} [mg a.s./kg bw]	TER_A	Trigger
		Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}				
Fluoxastrobin								
Cereals BBCH 30 - 39	Small omnivorous bird "lark"	0.150	12.0	1.2	2.2	3776	1748	10
Onions BBCH 10 - 39	Small granivorous bird "finch"	0.125	24.7	1.3	4.0	3776	941	10
Onions BBCH 10 - 39	Small omnivorous bird "lark"		24.0		3.9		968	
Onions BBCH 10 - 19	Small insectivorous bird "wagtail"		26.8		4.4		867	

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Acute risk assessment for birds drinking contaminated water from pools in leaf whorls

In the EFSA GD 2009, section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:
Leaf scenario: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.
Puddle scenario: Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.
For the crops under assessment in this evaluation (cereals and onions) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table CP 10.1.1-5.

LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.1- 4: Tier 1 reproductive risk assessment for birds

Crop	Generic focal species	DDD				DDD	NOEL [mg a.s./ kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Fluoxastrobin									
Cereals BBCH 30 - 39	Small omnivorous bird "lark"	0.150	5.4	1.4	0.53	0.6	51	84.9	5
Onions BBCH 10 - 39	Small granivorous bird "finch"	0.125	11.4	1.5	0.53	1.1	51	45.0	5
Onions BBCH 10 - 39	Small omnivorous bird "lark"		10.9			1.1		47.1	
Onions BBCH 10 - 19	Small insectivorous bird "wagtail"		11.3			1.1		45.4	

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, the risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for birds drinking contaminated water in puddles

Table CP 10.1.1- 5: Evaluation of potential concern for exposure of birds drinking water (escape clause)

Crop	Koc [L/kg]	Application rate * 2 a) [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Fluoxastrobin						
Cereals	848.2	150 * 2	51	5.9	≤ 3000	No concern
Onions	848.2	125 * 2	51	4.9	≤ 3000	No concern

a): annual application rate (without interception) used as theoretical worst case

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the log P_{OW} of the active substance fluoxastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see MCA 2.7)).

CP 10.1.1.1 Acute oral toxicity

No additional studies are available or required as the toxicity can be derived from the studies on the active substance.

CP 10.1.1.2 Higher tier data on birds

Since fluoxastrobin is of low toxicity to birds, no higher tier data are needed.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Table CP 10.1.2- 1: Endpoints used in risk assessment

Test substance	Exposure	species/origin	Endpoint		Reference
Fluoxastrobin	Acute risk assessment	Rat	**LD_{50}**	**> 2000 mg a.s./kg bw**	[redacted] 1996; M-012717-01-1
	Long-term risk assessment	Rat	NOAEC NOAEL	2000 mg a.s./kg diet (F) **163 mg a.s./kg bw/d**	[redacted]; 1998; M-012710-01-1

Bold values used for the risk assessment

Table CP 10.1.2- 2: Relevant generic focal species for Tier 1 risk assessment

Crop	Scenario	Generic focal species	Representative species	Shortcut value: Long-term RA based on RUD_m	Shortcut value: acute RA based on RUD_{90}
Cereals 2 × 0.150 kg/ha BBCH 30-69 14 d interval	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	**1.9**	**5.4**
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**21.7**	**40.9**
	BBCH 30 - 39	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	**3.9**	**8.6**
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	2.3	5.2
Onions 2 × 0.125 kg/ha BBCH 15-47 10 d interval	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	**4.2**	**7.6**
	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	1.9	5.4
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**43.4**	**81.9**
	BBCH 10 - 39	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	**7.8**	**17.2**
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	4.7	10.3

Bold: Species considered in Tier 1 risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2- 3: Tier 1 acute DDD and TER calculation for mammals

Crop	Generic focal species	DDD: Appl. rate [kg/ha]	DDD: SV_{90}	DDD: MAF_{90}	DDD	LD_{50} [mg/kg bw]	TER_A	Trigger
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	0.150	5.4	1.2	1.0	> 2000	> 2058	10
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"		40.9		7.4		> 272	10
Cereals BBCH 30 - 39	Small omnivorous mammal "mouse"		8.6		1.5		> 1292	10
Onions BBCH 10 - 19	Small insectivorous mammal "shrew"	0.125	7.6	1.3	1.2	> 2000	> 1619	10
Onions BBCH ≥ 40	Small herbivorous mammal "vole"		81.9		13.3		> 150	10
Onions BBCH 10 - 39	Small omnivorous mammal "mouse"		17.2		2.8		> 716	10

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the a-priori acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.2- 4: Tier 1 long-term DDD and TER calculation for mammals

Crop	Generic focal species	DDD				DDD	NO(A)EL [mg kg/bw/d]	TER_{LT}	Trigger
		Appl. rate [kg/ha	SV_m	MAF_m	f_{twa}				
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"		1.9			0.2		815	5
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	0.150	21.7	1.4	0.53	2.4	163	68	5
Cereals BBCH 30 - 39	Small omnivorous mammal "mouse"		3.9			0.4		408	5
Onions BBCH 10 - 19	Small insectivorous mammal "shrew"		4.2			0.4		408	5
Onions BBCH ≥ 40	Small herbivorous mammal "vole"	0.125	43.4	1.5	0.53	4.3	163	38	5
Onions BBCH 10 - 39	Small omnivorous mammal "mouse"		7.8			0.8		204	5

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 5 for all evaluated scenarios. Thus, the risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for mammals drinking contaminated water

The puddle scenario is relevant for the long-term risk assessment.

Table CP 10.1.2- 5: Evaluation of potential concern for exposure of mammals drinking water

Crop	Koc [L/kg]	Application rate * 2 [a] [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Fluoxastrobin						
Cereals	848.2	150 * 2	163	1.84	**≤ 3000**	No concern
onions	848.2	125 * 2	163	1.53	**≤ 3000**	No concern

([a]: annual application rate (without interception) used as theoretical worst case

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a $\log P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the $\log P_{OW}$ of the active substance fluoxastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see MCA 2.7).

CP 10.1.2.1 Acute oral toxicity to mammals

The acute oral toxicity of the product Fluoxastrobin + Prothioconazole EC 200 in rat was studied by [redacted]S;[redacted]; 2002; M-088922-02-1, the study is summarised in document MCP 7 (toxicology). According to OECD guideline 423 the results of this study correspond to LD_{50} > 2000 mg/kg body weight.

CP 10.1.2.2 Higher tier data on mammals

No additional studies are required; the risk assessment indicates acceptable risk at Tier 1.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies are available or required under the data requirements of EC 1107/2009.

CP 10.2 Effects on aquatic organisms

The risk assessment was performed according to the Regulation (EC) No 1107/2009 and following the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013).

Ecotoxicological endpoints used in risk assessment

Table CP 10.2- 1: Endpoints relevant for risk assessment

Test substance	Test species	Endpoint		Reference
Fluoxastrobin	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	**LC_{50}**	**0.435 mg a.s./L**	[redacted]; 1999; M-016770-01-1
	Fish, chronic *Oncorhynchus mykiss* (rainbow trout)	**NOEC**	**0.0286 mg a.s./L**	[redacted] 2001; M-084463-01-1
	Invertebrate, acute *Daphnia magna* (cladoceran)	**EC_{50}**	**0.48 mg a.s./L**	[redacted] 1999; M-011257-01-1
	Invertebrate, acute *Gammarus pulex* (amphipod)	**EC_{50}**	**0.15 mg a.s./L**	[redacted]; 2003; M-109491-01-2
	Acanthocyclops venustus (copepod)	EC_{50}	0.9 mg a.s./L	
	Cloeon dipterum (mayfly)	EC_{50}	1.0 mg a.s./L	
	Daphnia gr. galeata (cladoceran)	EC_{50}	1.3 mg a.s./L	
	Asellus aquaticus (isopod)	EC_{50}	1.3 mg a.s./L	
	Chaoborus obscuripes (diptera)	EC_{50}	> 3.2 mg a.s./L	
	Simocephalus vetulus (cladoceran)	EC_{50}	> 3.2 mg a.s./L	
	Marine invertebrate, acute *Americamysis bahia* (*Mysidopsis bahia*, mysid shrimp)	**LC_{50}**	**0.0604 mg a.s./L**	[redacted] 2002; M-082793-01-1
	Invertebrate, acute geometric mean using 7 species	**EC_{50}**	**0.488 mg a.s./L[1)]**	See. MCA 8.2.4.2
	Invertebrate, chronic *Daphnia magna* (cladoceran)	**NOEC**	**0.18 mg a.s./L**	[redacted]; 2000; M-042059-01-1
	Invertebrate, chronic *Gammarus pulex* (amphipod) (conducted with EC 100 formulation)	NOEC	0.0316 mg a.s./L	[redacted]; 2003; M-110286-01-1
	Invertebrate, chronic *Habrophlebia lauta* (Mayfly)	NOEC	0.0422 mg a.s./L	[redacted]; 2012; M-444119-01-1 KCA 8.2.5.2
	Invertebrate, chronic *Neocaridina heteropoda* (Freshwater shrimp)	NOEC	0.060 mg a.s./L	[redacted]; 2012; M-442121-01-1 KCA 8.2.5.2
	Marine invertebrate, chronic *Americamysis bahia* (*Mysidopsis bahia*, mysid shrimp)	$NOEC_{survival}$ $NOEC_{repro}$	**0.00061 mg a.s./L** 0.0047 mg a.s./L	[redacted] 2002; M-082820-01-1

Test substance	Test species	Endpoint		Reference
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	EC_{15}	**2.13 mg a.s./L**	[redacted] 2000; M-042042-01-1
	Pseudokirchneriella subcapitata (green algae)	E_bC_{50} E_rC_{50}	0.35 mg a.s./L **2.10 mg a.s./L**	[redacted]; 2000; M-033313-01-1
	Lemna gibba (Duck weed)	E_bC_{50} E_rC_{50}	> 6.0 mg a.s./L > 6.0 mg a.s./L	[redacted] 2001; M-037727-01-1
	Lemna gibba (Duck weed)	E_bC_{50} E_rC_{50}	1.45 mg a.s./L **3.88 mg a.s./L**	[redacted] 2002; M-083021-01-1 KCA 8.2.7
HEC 5725-E-des-chlorophenyl	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	**LC_{50}**	**> 102 mg p.m./L**	[redacted]; 2000; M-033495-01-1
	Invertebrate, acute *Daphnia magna* (cladoceran)	**EC_{50}**	**> 100 mg p.m.//L**	[redacted]; 2000; M-038222-01-1
	Pseudokirchneriella subcapitata (green algae)	E_bC_{50} **E_rC_{50}**	> 100 mg p.m./L **> 100 mg p.m.//L**	[redacted]; 2000; M-025012-01-1
HEC 5725-carboxylic acid	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	**LC_{50}**	**> 95.7 mg p.m./L**	[redacted]; 2001; M-052093-01-1
	Invertebrate, acute *Daphnia magna* (cladoceran)	**EC_{50}**	**> 100 mg p.m./L**	[redacted]; 2001; M-030332-01-1
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	**EC_{15}**	**98.5 mg p.m./L**	[redacted] 2001; M-078605-01-1
	Pseudokirchneriella subcapitata (*Selenastrum capricornutum*, green algae)	E_bC_{50} **E_rC_{50}**	115 mg p.m./L **> 160 mg p.m./L**	[redacted].; 2001; M-073836-01-1
2-chlorophenol	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	**LC_{50}**	**2.6 mg p.m./L**	[redacted]; 2006; M-277036-01-1 KCA 8.2.1
	Fish, chronic *Pimephales promelas* (fathead minnow)	**NOEC**	**4 mg p.m./L**	EFSA Scientific Report 102 (2007)) [redacted]; 2006; M-277036-01-1
	Invertebrate, acute *Daphnia magna* (cladoceran)	**EC_{50}**	**7.4 mg p.m./L**	[redacted]; 2006; M-277036-01-1 KCA 8.2.1
	Invertebrate, chronic *Daphnia magna* (cladoceran)	**NOEC**	**0.3 mg p.m./L[2)]**	EFSA Scientific Report 102 (2007) [redacted]; 2006; M-277036-01-1
	Pseudokirchneriella subcapitata (*Selenastrum capricornutum*, green algae)	**E_rC_{50}**	**70 mg p.m./L**	EFSA Scientific Report 102 (2007) [redacted]; 2006; M-277036-01-1

Test substance	Test species	Endpoint		Reference
FXA+PTZ EC 200 (100+100) G	Fish, acute *Oncorhynchus mykiss* (Rainbow trout)	LC_{50}	2.19 mg prod./L	[redacted],; 2014; M-491937-01-1 KCP 10.2.1
	Invertebrate, acute *Daphnia magna* (Cladoceran)	EC_{50}	1.67 mg prod./L	[redacted]; 2012; M-434883-01-1 KCP 10.2.1
	Pseudokirchneriella subcapitata (Green alga)	E_rC_{50} NOE_rC	11.5 mg prod./L 0.096 mg prod./L	[redacted]; 2012; M-438495-01-1 KCP 10.2.2

Bold letters – values considered relevant for risk assessment
a.s.: active substance; p.m.: pure metabolite; prod.: formulated product.

1) When using the above acute invertebrate toxicity data (including Mysid, excluding the two "greater than" values), with the geomean approach according to the most recent aquatic guidance document (SANTE-2015-00080, 15 January 2015) a geometric mean value of 0.488 mg a.s./L can be calculated

2) In the statement on the exposure of aquatic organisms to 2-chlorophenol ([redacted]; 2006; M-277036-01-1) a NOEC of 0.5 mg/L is presented as most sensitive chronic endpoint for Daphnia based on nominal concentrations applied during testing. According to the EFSA Scientific Report (2007), the minimum measured concentration of 0.3 mg/l must be considered as relevant endpoint.

Selection of endpoints for risk assessment

The relevant endpoint from each aquatic study was defined according to the current data requirements from the EU Regulation 283/2013 and the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013), and based on recommendations from the relevant standard test guideline e.g. Growth rate (r) is the most suitable endpoint from algae inhibition tests for use in risk assessment, as stated by OECD Guideline 201 and the EFSA guidance document. TER and RAC calculations presented in this dossier are thus based on the E_rC_{50} values. Indeed, processes in ecosystems are dominantly rate driven and therefore, the unit development per time (growth rate) appears more suitable to measure effects in algae. Also, growth rates and their inhibition can easily be compared between species, test durations and test conditions, which is not the case for biomass. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method C3, the EC regulation for Classification and Labelling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461, 1-44, 2007) list growth rate as the most suitable endpoint of the algae inhibition test.

In accordance with Regulation (EC) No 1107/2009 and with the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013), studies resulting in lower endpoints were used for the risk assessment, including endpoints from estuarine or marine species.

Predicted environmental concentrations used in risk assessment

Full details of the predicted environmental concentrations are given in MCP 9.2.5 ([redacted],; [redacted]; 2015; M-537907-01-1).

Table CP 10.2- 2: Initial max PEC_{sw} values – FOCUS Step 1, 2

Compound	FOCUS Scenario	Cereals (spring, winter) 2 × 150 g a.s./ha	Cereals (spring, winter) 2 × 125 g a.s./ha	Onions 2 × 125 g a.s./ha
		$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]
Fluoxastrobin (E+Z)	STEP 1	52.69	43.91	43.91
	STEP 2 - North	8.05	6.71	7.39
	STEP 2 - South	**14.66**	12.22	**13.60**
HEC 5725-E-des-chlorophenyl	STEP 1	35.93	29.94	29.94
	STEP 2 - North	5.19	4.33	4.84
	STEP 2 - South	**10.10**	8.41	**9.44**
HEC 5725-carboxylic acid	STEP 1	19.46	16.22	16.22
	STEP 2 - North	2.30	1.91	2.14
	STEP 2 - South	**4.48**	3.73	**4.19**
2-chlorophenol	STEP 1	23.56	19.63	19.63
	STEP 2 - North	2.91	2.43	2.84
	STEP 2 - South	**5.63**	4.69	**5.51**

Bold values considered in risk assessment

Table CP 10.2- 3: Initial max PEC_{sw} and $TWAC_{sw}$ values at day 7 following application to cereals FOCUS Step 3

Compound	FOCUS Scenario	Cereals 2 × 150 g a.s./ha			
		Winter		Spring	
		$PEC_{sw, max}$ [µg/L]	$TWAC_{sw}$-7 [µg/L]	$PEC_{sw, max}$ [µg/L]	$TWAC_{sw}$-7 [µg/L]
Fluoxastrobin (E+Z)	D1 (ditch)	**1.048**	*0.874*	**1.403**	*1.204*
	D1 (stream)	**0.864**	*0.272*	**0.841**	*0.320*
	D2 (ditch)	**1.137**	*0.825*	-	
	D2 (stream)	**0.847**	*0.386*	-	
	D3 (ditch)	**0.952**	*0.200*	**0.950**	*0.155*
	D4 (pond)	**0.042**	0.040	**0.047**	0.044
	D4 (stream)	**0.731**	*0.021*	**0.777**	*0.024*
	D5 (pond)	**0.048**	0.046	**0.046**	0.043
	D5 (stream)	**0.758**	*0.010*	**0.798**	*0.009*
	D6 (ditch)	**0.948**	*0.353*	-	-
	R1 (pond)	**0.203**	*0.193*	-	-
	R1 (stream)	**1.663**	*0.207*	-	-
	R2 (stream)	-	-	-	-
	R3 (stream)	**1.337**	*0.182*	-	-
	R4 (stream)	**1.724**	*0.483*	**2.177**	*0.489*

Bold values considered in risk assessment
Italic values considered in refined risk assessment

Table CP 10.2- 4: Initial max PEC_{sw} and $TWAC_{sw}$ values at day 7 following application to cereals FOCUS Step 3

Compound	FOCUS Scenario	Cereals 2 × 125 g a.s./ha			
		Winter		Spring	
		$PEC_{sw, max}$ [µg/L]	$TWAC_{sw}$-7 [µg/L]	$PEC_{sw, max}$ [µg/L]	$TWAC_{sw}$-7 [µg/L]
Fluoxastrobin (E+Z)	D1 (ditch)	**0.869**	*0.724*	**1.166**	*0.999*
	D1 (stream)	**0.718**	*0.206*	**0.701**	*0.248*
	D2 (ditch)	**0.936**	*0.676*	-	-
	D2 (stream)	**0.700**	*0.313*	-	-
	D3 (ditch)	**0.793**	*0.166*	**0.792**	*0.129*
	D4 (pond)	**0.035**	0.033	**0.039**	0.036
	D4 (stream)	**0.609**	*0.017*	**0.647**	*0.019*
	D5 (pond)	**0.040**	0.038	**0.038**	0.036
	D5 (stream)	**0.631**	*0.008*	**0.665**	*0.007*
	D6 (ditch)	**0.790**	*0.294*	-	-
	R1 (pond)	**0.167**	*0.158*	-	-
	R1 (stream)	**1.355**	*0.169*	-	-
	R3 (stream)	**1.090**	*0.149*	-	-
	R4 (stream)	**1.410**	*0.397*	**1.786**	*0.401*

Bold values considered in risk assessment
Italic values considered in refined risk assessment

Table CP 10.2- 5: Initial max PEC_{sw} and $TWAC_{sw}$ values at day 7 following application to onions FOCUS Step 3

Compound	FOCUS Scenario	Onions 2 × 125 g a.s./ha	
		$PEC_{sw, max}$ [µg/L]	$TWAC_{sw}$-7 [µg/L]
Fluoxastrobin (E+Z)	D3 (ditch)	**0.791**	*0.116*
	D4 (pond)	**0.045**	0.043
	D4 (stream)	**0.604**	*0.046*
	D6 (ditch, 1st)	**0.785**	*0.160*
	D6 (ditch, 2nd)	**0.783**	*0.242*
	R1 (pond)	**0.173**	*0.163*
	R1 (stream)	**1.622**	*0.197*
	R2 (stream)	**0.684**	*0.117*
	R3 (stream)	**1.481**	*0.192*
	R4 (stream)	**3.057**	*0.414*

Bold values considered in risk assessment
Italic values considered in refined risk assessment

Table CP 10.2- 6: TWAC$_{sw}$ values at day 7 for fluoxastrobin – use in winter cereals FOCUS Step 4

		Fluoxastrobin (E+Z)							
		Cereals (winter), 2 × 150 g a.s./ha				Cereals (winter), 2 × 125 g a.s./ha			
Buffer Width & Type[#]	Scenario	TWAC$_{sw}$-7 [µg/L] Drift Reduction				TWAC$_{sw}$-7 [µg/L] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch)	0.435	0.435	0.435	0.435	0.329	0.329	0.329	0.329
	D1 (stream)	0.272	0.272	0.272	0.272	0.206	0.206	0.206	0.206
	D2 (ditch)	0.419	0.419	0.419	0.419	0.330	0.330	0.330	0.330
	D2 (stream)	0.233	0.233	0.233	0.233	0.181	0.181	0.181	0.181
	D3 (ditch)	0.054 *	0.027 *	0.013 *	0.005 *	0.045 *	0.022 *	0.011	0.004
	D4 (pond)	0.034	0.023	0.021	0.020	0.028	0.018	0.017	0.016
	D4 (stream)	0.021	0.021	0.021	0.021	0.016	0.016	0.016	0.016
	D5 (pond)	0.039	0.020	0.010	0.005	0.033	0.017	0.009	0.004
	D5 (stream)	0.004	0.002	0.002	0.002	0.003	0.001	0.001	0.001
	D6 (ditch)	0.091	0.045	0.022	0.009	0.075	0.038	0.019	0.007
	R1 (pond)	0.189	0.178	0.172	0.169	0.155	0.146	0.141	0.138
	R1 (stream)	0.207	0.207	0.207	0.207	0.169	0.169	0.169	0.169
	R3 (stream)	0.182	0.182	0.182	0.182	0.149	0.149	0.149	0.149
	R4 (stream)	0.483	0.483	0.483	0.483	0.397	0.397	0.397	0.397
10m SD &RO	D1 (ditch)	0.435	0.435	0.435	0.435	0.329	0.329	0.329	0.329
	D1 (stream)	0.272	0.272	0.272	0.272	0.206	0.206	0.206	0.206
	D2 (ditch)	0.419	0.419	0.419	0.419	0.330	0.330	0.330	0.330
	D2 (stream)	0.233	0.233	0.233	0.233	0.181	0.181	0.181	0.181
	D3 (ditch)	0.028 *	0.014 *	0.007 *	0.003 *	0.024 *	0.012 *	0.006	0.002
	D4 (pond)	0.025	0.022	0.021	0.020	0.020	0.017	0.016	0.015
	D4 (stream)	0.021	0.021	0.021	0.021	0.016	0.016	0.016	0.016
	D5 (pond)	0.028	0.014	0.008	0.004	0.023	0.012	0.006	0.003
	D5 (stream)	0.002	0.002	0.002	0.002	0.002	0.001	0.001	0.001
	D6 (ditch)	0.047	0.023	0.012	0.005	0.039	0.019	0.010	0.004
	R1 (pond)	0.083	0.075	0.071	0.068	0.068	0.061	0.058	0.056
	R1 (stream)	0.093	0.093	0.093	0.093	0.076	0.076	0.076	0.076
	R3 (stream)	0.081	0.081	0.081	0.081	0.067	0.066	0.066	0.066
	R4 (stream)	0.220	0.220	0.220	0.220	0.181	0.181	0.181	0.181
20m SD & RO	D1 (ditch)	0.435	0.435	0.435	**0.435**	0.329	0.329	0.329	**0.329**
	D1 (stream)	0.272	0.272	0.272	**0.272**	0.206	0.206	0.206	**0.206**
	D2 (ditch)	0.419	0.419	0.419	**0.419**	0.330	0.330	0.330	**0.330**
	D2 (stream)	0.233	0.233	0.233	**0.233**	0.181	0.181	0.181	**0.181**
	D3 (ditch)	0.015 *	0.007 *	0.004 *	**0.001** *	0.012 *	0.006	0.003	**0.001**
	D4 (pond)	0.023	0.021	0.020	0.019	0.018	0.016	0.016	0.015
	D4 (stream)	0.021	0.021	0.021	0.021	0.016	0.016	0.016	0.016
	D5 (pond)	0.019	0.010	0.005	0.003	0.015	0.008	0.004	0.002
	D5 (stream)	0.002	0.002	0.002	0.002	0.001	0.001	0.001	0.001
	D6 (ditch)	0.024	0.012	0.006	**0.004**	0.020	0.010	0.005	**0.003**
	R1 (pond)	0.044	0.039	0.036	**0.034**	0.036	0.032	0.030	**0.028**
	R1 (stream)	0.049	0.049	0.049	**0.049**	0.040	0.040	0.040	**0.040**
	R3 (stream)	0.042	0.042	0.042	**0.042**	0.035	0.035	0.035	**0.035**
	R4 (stream)	0.115	0.115	0.115	**0.115**	0.095	0.095	0.095	0.095

Entries marked with * result from single applications
[#] SD and RO denote spray drift and runoff buffer
Bold values considered in refined risk assessment

Table CP 10.2- 7: TWAC$_{sw}$ values at day 7 for fluoxastrobin – use in spring cereals FOCUS Step 4

		Fluoxastrobin (E+Z)							
		Cereals (spring), 2 × 150 g a.s./ha				Cereals (spring), 2 × 125 g a.s./ha			
Buffer Width & Type#	Scenario	TWAC$_{sw}$-7 [µg/L] Drift Reduction				TWAC$_{sw}$-7 [µg/L] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D1 (ditch)	0.512	0.512	0.512	0.512	0.398	0.398	0.398	0.398
	D1 (stream)	0.320	0.320	0.320	0.320	0.248	0.248	0.248	0.248
	D3 (ditch)	0.042 *	0.021 *	0.010 *	0.004	0.035 *	0.017 *	0.009 *	0.003
	D4 (pond)	0.037	0.026	0.024	0.023	0.031	0.021	0.019	0.018
	D4 (stream)	0.024	0.024	0.024	0.024	0.019	0.019	0.019	0.019
	D5 (pond)	0.037	0.019	0.010	0.004	0.031	0.016	0.008	0.004
	D5 (stream)	0.003	0.002	0.001	0.001	0.003	0.001	0.001	0.001
	R4 (stream)	0.479	0.476	0.474	0.473	0.393	0.390	0.389	0.388
10m SD &RO	D1 (ditch)	0.512	0.512	0.512	0.512	0.398	0.398	0.398	0.398
	D1 (stream)	0.320	0.320	0.320	0.320	0.248	0.248	0.248	0.248
	D3 (ditch)	0.022 *	0.011 *	0.006 *	0.002	0.018 *	0.009 *	0.005 *	0.002
	D4 (pond)	0.028	0.025	0.023	0.022	0.022	0.019	0.018	0.018
	D4 (stream)	0.024	0.024	0.024	0.024	0.019	0.019	0.019	0.019
	D5 (pond)	0.026	0.014	0.007	0.003	0.022	0.011	0.006	0.003
	D5 (stream)	0.002	0.001	0.001	0.001	0.001	0.001	0.001	0.001
	R4 (stream)	0.217	0.215	0.215	0.214	0.178	0.177	0.176	0.176
20m SD & RO	D1 (ditch)	0.512	0.512	0.512	**0.512**	0.398	0.398	0.398	**0.398**
	D1 (stream)	0.320	0.320	0.320	**0.320**	0.248	0.248	0.248	**0.248**
	D3 (ditch)	0.011 *	0.006 *	0.003 *	**0.001**	0.010 *	0.005 *	0.002	**0.001**
	D4 (pond)	0.026	0.024	0.023	0.022	0.020	0.019	0.018	0.017
	D4 (stream)	0.024	0.024	0.024	0.024	0.019	0.019	0.019	0.019
	D5 (pond)	0.018	0.009	0.005	0.003	0.015	0.008	0.004	0.002
	D5 (stream)	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
	R4 (stream)	0.113	0.113	0.112	**0.112**	0.093	0.092	0.092	**0.092**

Entries marked with * result from single applications
SD and RO denote spray drift and runoff buffer
Bold values considered in refined risk assessment

Table CP 10.2- 8: $TWAC_{sw}$ values at day 7 for fluoxastrobin – use in onions FOCUS Step 4

		Fluoxastrobin (E+Z)							
		Onions, 2 × 125 g a.s./ha							
		Single application				Multiple applications			
Buffer Width & Type#	Scenario	$TWAC_{sw}$-7 [µg/L] Drift Reduction				$TWAC_{sw}$-7 [µg/L] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m SD	D3 (ditch)	0.031	0.016	0.008	0.003	0.029	0.015	0.007	0.003
	D4 (pond)	0.021	0.015	0.014	0.014	0.042	0.040	0.039	0.039
	D4 (stream)	0.016	0.016	0.016	0.016	0.045	0.045	0.045	0.045
	D6 (ditch)	0.017	0.009	0.007	0.007	0.041	0.021	0.010	0.007
	D6 (ditch)	0.014	0.012	0.012	0.012	0.063	0.031	0.019	0.019
	R1 (pond)	0.070	0.063	0.060	0.058	0.159	0.147	0.141	0.138
	R1 (stream)	0.081	0.081	0.081	0.081	0.197	0.197	0.197	0.197
	R2 (stream)	0.047	0.047	0.047	0.047	0.117	0.117	0.117	0.117
	R3 (stream)	0.078	0.078	0.078	0.078	0.192	0.192	0.192	0.192
	R4 (stream)	0.175	0.175	0.175	0.175	0.414	0.414	0.414	0.414
10m SD &RO	D3 (ditch)	0.017	0.008	0.004	0.002	0.015	0.008	0.004	0.002
	D4 (pond)	0.015	0.014	0.014	0.014	0.041	0.040	0.039	0.039
	D4 (stream)	0.016	0.016	0.016	0.016	0.045	0.045	0.045	0.045
	D6 (ditch)	0.009	0.007	0.007	0.007	0.022	0.011	0.007	0.007
	D6 (ditch)	0.012	0.012	0.012	0.012	0.033	0.019	0.019	0.019
	R1 (pond)	0.032	0.028	0.025	0.024	0.071	0.063	0.058	0.056
	R1 (stream)	0.036	0.036	0.036	0.036	0.088	0.088	0.088	0.088
	R2 (stream)	0.021	0.021	0.021	0.021	0.053	0.053	0.053	0.053
	R3 (stream)	0.036	0.036	0.036	0.036	0.088	0.088	0.088	0.088
	R4 (stream)	0.079	0.079	0.079	0.079	0.186	0.186	0.186	0.186
20m SD & RO	D3 (ditch)	**0.009**	0.004	0.002	0.001	0.008	0.004	0.002	**0.001**
	D4 (pond)	0.014	0.014	0.014	0.013	0.040	0.039	0.039	0.038
	D4 (stream)	0.016	0.016	0.016	0.016	0.045	0.045	0.045	0.045
	D6 (ditch)	**0.007**	0.007	0.007	0.007	0.011	0.007	0.007	**0.007**
	D6 (ditch)	**0.012**	0.012	0.012	0.012	0.019	0.019	0.019	**0.019**
	R1 (pond)	**0.018**	0.015	0.013	0.012	0.038	0.032	0.030	**0.028**
	R1 (stream)	**0.019**	0.019	0.019	0.019	0.046	0.046	0.046	**0.046**
	R2 (stream)	**0.011**	0.011	0.011	0.011	0.028	0.028	0.028	**0.028**
	R3 (stream)	**0.019**	0.019	0.019	0.019	0.046	0.046	0.046	**0.046**
	R4 (stream)	**0.041**	0.041	0.041	0.041	0.097	0.097	0.097	**0.097**

SD and RO denote spray drift and runoff buffer
Bold values considered in refined risk assessment

ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 9: TER$_A$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 150 g a.s./ha and for onions on GAP 2 × 125 g a.s./ha)

Compound	Species	Endpoint [µg/L]	PEC$_{sw,max}$ [µg/L]	TER$_A$	Trigger
Cereals (Winter/spring)					
Fluoxastrobin (E+Z)	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 435	14.66	**29.7**	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ 480	14.66	**32.7**	100
	Invertebrate, acute *Gammarus pulex*	EC$_{50}$ 150	14.66	**10.2**	100
	Invertebrate, acute *Americamysis bahia*	EC$_{50}$ 60.4	14.66	**4.1**	100
HEC 5725-E-des-chlorophenyl	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ > 102 000	10.10	> 10 099	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ > 100 000	10.10	> 9901	100
HEC 5725-carboxylic acid	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ > 95 700	4.48	> 21 362	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ > 100 000	4.48	> 22 321	100
2-chlorophenol	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 2600	5.63	461.8	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ 7400	5.63	1314	100
Onions					
Fluoxastrobin (E+Z)	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 435	13.60	**32.0**	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ 480	13.60	**35.3**	100
	Invertebrate, acute *Gammarus pulex*	EC$_{50}$ 150	13.60	**11.0**	100
	Invertebrate, acute *Americamysis bahia*	EC$_{50}$ 60.4	13.60	**4.4**	100
HEC 5725-E-des-chlorophenyl	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ > 102 000	9.44	> 10 805	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ > 100 000	9.44	> 10 593	100
HEC 5725-carboxylic acid	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ > 95 700	4.19	> 22 840	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ > 100 000	4.19	> 23 866	100
2-chlorophenol	Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 2600	5.51	471.9	100
	Invertebrate, acute *Daphnia magna*	EC$_{50}$ 7400	5.51	1343	100

Bold values do not meet the trigger

Table CP 10.2- 10: $RAC_{sw; ac}$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 150 g a.s./ha and for onions on GAP 2 × 125 g a.s./ha) (acceptability of risk: PEC/RAC < 1)

Compound	Species	Endpoint [µg/L]		$RAC_{sw; ac}$ (LC_{50}/100)	$PEC_{sw,max}$ [µg/L]	PEC/RAC
Cereals (Winter/spring)						
Fluoxastrobin (E+Z)	Fish, acute *Oncorhynchus mykiss*	LC_{50}	435	4.35	14.66	**3.37**
	Invertebrate, acute *Daphnia magna*	EC_{50}	480	4.8	14.66	**3.05**
	Invertebrate, acute *Gammarus pulex*	EC_{50}	150	1.5	14.66	**9.77**
	Invertebrate, acute *Americamysis bahia*	EC_{50}	60.4	0.604	14.66	**24.27**
HEC 5725-E-des-chlorophenyl	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 102 000	> 1020	10.10	< 0.01
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 000	> 1000	10.10	< 0.01
HEC 5725-carboxylic acid	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 95 700	> 957	4.48	< 0.005
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 000	> 1000	4.48	< 0.004
2-chlorophenol	Fish, acute *Oncorhynchus mykiss*	LC_{50}	2600	26	5.63	0.22
	Invertebrate, acute *Daphnia magna*	EC_{50}	7400	74	5.63	0.08
Onions						
Fluoxastrobin (E+Z)	Fish, acute *Oncorhynchus mykiss*	LC_{50}	435	4.35	13.60	**3.13**
	Invertebrate, acute *Daphnia magna*	EC_{50}	480	4.8	13.60	**2.83**
	Invertebrate, acute *Gammarus pulex*	EC_{50}	150	1.5	13.60	**9.07**
	Invertebrate, acute *Americamysis bahia*	EC_{50}	60.4	0.604	13.60	**22.52**
HEC 5725-E-des-chlorophenyl	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 102 000	> 1020	9.44	< 0.01
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 000	> 1000	9.44	< 0.01
HEC 5725-carboxylic acid	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 95 700	> 957	4.19	< 0.004
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 000	> 1000	4.19	< 0.004
2-chlorophenol	Fish, acute *Oncorhynchus mykiss*	LC_{50}	2600	26	5.51	0.21
	Invertebrate, acute *Daphnia magna*	EC_{50}	7400	74	5.51	0.07

All TER values for the metabolites of fluoxastrobin meet the trigger for acute exposure. For fluoxastrobin the acute triggers were not met for fish and the invertebrates *D. magna*, *G. pulex* and *A. bahia*. Therefore, a refined risk assessment is required. The consideration of the more realistic FOCUS Step 3 surface water concentrations is presented below.

In accordance with the EFSA PPR Panel opinion on lowering the uncertainty factor when data on additional species are available (EFSA Journal (2005) 301, 1-45), as well as the recommendations provided in the new EFSA Guidance Document on Aquatic Ecotoxicology (EFSA Journal 2013;11(7):3290), the geomean of the available acute toxicity data on aquatic invertebrates (EU agreed endpoints) is calculated and used in the refined risk assessment in combination with the trigger value of 100:

Species	**EC_{50}/LC_{50} (mg a.s./L)**
Americanmysis bahia	0.0604
Gammarus pulex	0.15
Daphnia magna	0.48
Acanthocyclops venustus	0.9
Cloeon dipterum	1.0
Daphnia gr. galeata	1.3
Asellus aquaticus	1.3
Chaoborus obscuripes	>3.2
Simocephalus vetulus	>3.2
Geometric mean	**0.488**

It has to be noted that the "greater than" endpoints for *Chaoborus obscuripes* and *Simocephalus vetulus* were not considered suitable for use in the calculation of the geometric mean, since they do not represent true effect values.

The geomean value of 0.488 mg a.s./L can be used for further refinement of the acute risk of Fluoxastrobin to aquatic organisms.

Table CP 10.2- 11: TER_A calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC_{50} 435	1.048	D1 (ditch)	415.1	100
		0.864	D1 (stream)	503.5	100
		1.137	D2 (ditch)	382.6	100
		0.847	D2 (stream)	513.6	100
		0.952	D3 (ditch)	456.9	100
		0.042	D4 (pond)	10 357	100
		0.731	D4 (stream)	595.1	100
		0.048	D5 (pond)	9063	100
		0.758	D5 (stream)	573.9	100
		0.948	D6 (ditch)	458.9	100
		0.203	R1 (pond)	2143	100
		1.663	R1 (stream)	261.6	100
		1.337	R3 (stream)	325.4	100
		1.724	R4 (stream)	252.3	100
Invertebrate, acute *Daphnia magna*	EC_{50} 480	1.048	D1 (ditch)	458.0	100
		0.864	D1 (stream)	555.6	100
		1.137	D2 (ditch)	422.2	100
		0.847	D2 (stream)	566.7	100
		0.952	D3 (ditch)	504.2	100
		0.042	D4 (pond)	11 429	100
		0.731	D4 (stream)	656.6	100
		0.048	D5 (pond)	10 000	100
		0.758	D5 (stream)	633.2	100
		0.948	D6 (ditch)	506.3	100
		0.203	R1 (pond)	2365	100
		1.663	R1 (stream)	288.6	100
		1.337	R3 (stream)	359.0	100
		1.724	R4 (stream)	278.4	100
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50} 488	1.048	D1 (ditch)	465.6	100
		0.864	D1 (stream)	564.8	100
		1.137	D2 (ditch)	429.2	100
		0.847	D2 (stream)	576.2	100
		0.952	D3 (ditch)	512.6	100
		0.042	D4 (pond)	11 619	100
		0.731	D4 (stream)	667.6	100
		0.048	D5 (pond)	10 167	100
		0.758	D5 (stream)	643.8	100
		0.948	D6 (ditch)	514.8	100
		0.203	R1 (pond)	2404	100
		1.663	R1 (stream)	293.4	100

Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
			1.337	R3 (stream)	365.0	100
			1.724	R4 (stream)	283.1	100
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha						
Fish, acute *Oncorhynchus mykiss*	LC_{50}	435	1.403	D1 (ditch)	310.0	100
			0.841	D1 (stream)	517.2	100
			0.950	D3 (ditch)	457.9	100
			0.047	D4 (pond)	9255	100
			0.777	D4 (stream)	559.8	100
			0.046	D5 (pond)	9457	100
			0.798	D5 (stream)	545.1	100
			2.177	R4 (stream)	199.8	100
Invertebrate, acute *Daphnia magna*	EC_{50}	480	1.403	D1 (ditch)	342.1	100
			0.841	D1 (stream)	570.7	100
			0.950	D3 (ditch)	505.3	100
			0.047	D4 (pond)	10 213	100
			0.777	D4 (stream)	617.8	100
			0.046	D5 (pond)	10 435	100
			0.798	D5 (stream)	601.5	100
			2.177	R4 (stream)	220.5	100
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50}	488	1.403	D1 (ditch)	347.8	100
			0.841	D1 (stream)	580.3	100
			0.950	D3 (ditch)	513.7	100
			0.047	D4 (pond)	10 383	100
			0.777	D4 (stream)	628.1	100
			0.046	D5 (pond)	10 609	100
			0.798	D5 (stream)	611.5	100
			2.177	R4 (stream)	224.2	100

Table CP 10.2- 12: TER$_A$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

Species	Endpoint [µg/L]	PEC$_{sw,max}$ [µg/L]	FOCUS scenario	TER$_A$	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 435	0.869	D1 (ditch)	500.6	100
		0.718	D1 (stream)	605.8	100
		0.936	D2 (ditch)	464.7	100
		0.700	D2 (stream)	621.4	100
		0.793	D3 (ditch)	548.5	100
		0.035	D4 (pond)	12 429	100
		0.609	D4 (stream)	714.3	100
		0.040	D5 (pond)	10 875	100
		0.631	D5 (stream)	689.4	100
		0.790	D6 (ditch)	550.6	100
		0.167	R1 (pond)	2605	100
		1.355	R1 (stream)	321.0	100
		1.090	R3 (stream)	399.1	100
		1.410	R4 (stream)	308.5	100
Invertebrate, acute *Daphnia magna*	EC$_{50}$ 480	0.869	D1 (ditch)	552.4	100
		0.718	D1 (stream)	668.5	100
		0.936	D2 (ditch)	512.8	100
		0.700	D2 (stream)	685.7	100
		0.793	D3 (ditch)	605.3	100
		0.035	D4 (pond)	13 714	100
		0.609	D4 (stream)	788.2	100
		0.040	D5 (pond)	12 000	100
		0.631	D5 (stream)	760.7	100
		0.790	D6 (ditch)	607.6	100
		0.167	R1 (pond)	2874	100
		1.355	R1 (stream)	354.2	100
		1.090	R3 (stream)	440.4	100
		1.410	R4 (stream)	340.4	100
Invertebrate, acute Geomean, 7 species	LC$_{50}$/EC$_{50}$ 488	0.869	D1 (ditch)	561.6	100
		0.718	D1 (stream)	679.7	100
		0.936	D2 (ditch)	521.4	100
		0.700	D2 (stream)	697.1	100
		0.793	D3 (ditch)	615.4	100
		0.035	D4 (pond)	13 943	100
		0.609	D4 (stream)	801.3	100
		0.040	D5 (pond)	12 200	100
		0.631	D5 (stream)	773.4	100
		0.790	D6 (ditch)	617.7	100
		0.167	R1 (pond)	2922	100
		1.355	R1 (stream)	360.1	100

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
		1.090	R3 (stream)	447.7	100
		1.410	R4 (stream)	346.1	100
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC_{50} 435	1.166	D1 (ditch)	373.1	100
		0.701	D1 (stream)	620.5	100
		0.792	D3 (ditch)	549.2	100
		0.039	D4 (pond)	11 154	100
		0.647	D4 (stream)	672.3	100
		0.038	D5 (pond)	11 447	100
		0.665	D5 (stream)	654.1	100
		1.786	R4 (stream)	243.6	100
Invertebrate, acute *Daphnia magna*	EC_{50} 480	1.166	D1 (ditch)	411.7	100
		0.701	D1 (stream)	684.7	100
		0.792	D3 (ditch)	606.1	100
		0.039	D4 (pond)	12 308	100
		0.647	D4 (stream)	741.9	100
		0.038	D5 (pond)	12 632	100
		0.665	D5 (stream)	721.8	100
		1.786	R4 (stream)	268.8	100
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50} 488	1.166	D1 (ditch)	418.5	100
		0.701	D1 (stream)	696.1	100
		0.792	D3 (ditch)	616.2	100
		0.039	D4 (pond)	12 513	100
		0.647	D4 (stream)	754.3	100
		0.038	D5 (pond)	12 842	100
		0.665	D5 (stream)	733.8	100
		1.786	R4 (stream)	273.2	100

Table CP 10.2- 13: TER_A calculations for onions calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC_{50} 435	0.791	D3 (ditch)	549.9	100
		0.045	D4 (pond)	9667	100
		0.604	D4 (stream)	720.2	100
		0.785	D6 (ditch, 1st)	554.1	100
		0.783	D6 (ditch, 2nd)	555.6	100
		0.173	R1 (pond)	2515	100
		1.622	R1 (stream)	268.2	100
		0.684	R2 (stream)	636.0	100
		1.481	R3 (stream)	293.7	100
		3.057	R4 (stream)	142.3	100
Invertebrate, acute *Daphnia magna*	EC_{50} 480	0.791	D3 (ditch)	606.8	100
		0.045	D4 (pond)	10 667	100
		0.604	D4 (stream)	794.7	100
		0.785	D6 (ditch, 1st)	611.5	100
		0.783	D6 (ditch, 2nd)	613.0	100
		0.173	R1 (pond)	2775	100
		1.622	R1 (stream)	295.9	100
		0.684	R2 (stream)	701.8	100
		1.481	R3 (stream)	324.1	100
		3.057	R4 (stream)	157.0	100
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50} 488	0.791	D3 (ditch)	616.9	100
		0.045	D4 (pond)	10 844	100
		0.604	D4 (stream)	807.9	100
		0.785	D6 (ditch, 1st)	621.7	100
		0.783	D6 (ditch, 2nd)	623.2	100
		0.173	R1 (pond)	2821	100
		1.622	R1 (stream)	300.9	100
		0.684	R2 (stream)	713.5	100
		1.481	R3 (stream)	329.5	100
		3.057	R4 (stream)	159.6	100

Table CP 10.2- 14: $RAC_{sw;\,ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]	$RAC_{sw;\,ac}$ (LC_{50}/100)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC_{50} 435	4.35	1.048	D1 (ditch)	0.24
			0.864	D1 (stream)	0.20
			1.137	D2 (ditch)	0.26
			0.847	D2 (stream)	0.19
			0.952	D3 (ditch)	0.22
			0.042	D4 (pond)	0.01
			0.731	D4 (stream)	0.17
			0.048	D5 (pond)	0.01
			0.758	D5 (stream)	0.17
			0.948	D6 (ditch)	0.22
			0.203	R1 (pond)	0.05
			1.663	R1 (stream)	0.38
			1.337	R3 (stream)	0.31
			1.724	R4 (stream)	0.40
Invertebrate, acute *Daphnia magna*	EC_{50} 480	4.80	1.048	D1 (ditch)	0.22
			0.864	D1 (stream)	0.18
			1.137	D2 (ditch)	0.24
			0.847	D2 (stream)	0.18
			0.952	D3 (ditch)	0.20
			0.042	D4 (pond)	0.01
			0.731	D4 (stream)	0.15
			0.048	D5 (pond)	0.01
			0.758	D5 (stream)	0.16
			0.948	D6 (ditch)	0.20
			0.203	R1 (pond)	0.04
			1.663	R1 (stream)	0.35
			1.337	R3 (stream)	0.28
			1.724	R4 (stream)	0.36
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50} 488	4.88	1.048	D1 (ditch)	0.21
			0.864	D1 (stream)	0.18
			1.137	D2 (ditch)	0.23
			0.847	D2 (stream)	0.17
			0.952	D3 (ditch)	0.20
			0.042	D4 (pond)	0.01
			0.731	D4 (stream)	0.15
			0.048	D5 (pond)	0.01
			0.758	D5 (stream)	0.16
			0.948	D6 (ditch)	0.19
			0.203	R1 (pond)	0.04
			1.663	R1 (stream)	0.34

Species	Endpoint [µg/L]	RAC$_{sw; ac}$ (LC$_{50}$/100)	PEC$_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
			1.337	R3 (stream)	0.27
			1.724	R4 (stream)	0.35
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC$_{50}$ 435	4.35	1.403	D1 (ditch)	0.32
			0.841	D1 (stream)	0.19
			0.950	D3 (ditch)	0.22
			0.047	D4 (pond)	0.01
			0.777	D4 (stream)	0.18
			0.046	D5 (pond)	0.01
			0.798	D5 (stream)	0.18
			2.177	R4 (stream)	0.50
Invertebrate, acute *Daphnia magna*	EC$_{50}$ 480	4.80	1.403	D1 (ditch)	0.29
			0.841	D1 (stream)	0.18
			0.950	D3 (ditch)	0.20
			0.047	D4 (pond)	0.01
			0.777	D4 (stream)	0.16
			0.046	D5 (pond)	0.01
			0.798	D5 (stream)	0.17
			2.177	R4 (stream)	0.45
Invertebrate, acute Geomean, 7 species	LC$_{50}$/EC$_{50}$ 488	4.88	1.403	D1 (ditch)	0.29
			0.841	D1 (stream)	0.17
			0.950	D3 (ditch)	0.19
			0.047	D4 (pond)	0.01
			0.777	D4 (stream)	0.16
			0.046	D5 (pond)	0.01
			0.798	D5 (stream)	0.16
			2.177	R4 (stream)	0.45

Table CP 10.2- 15: $RAC_{sw; ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]		$RAC_{sw; ac}$ (LC_{50}/100)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha						
Fish, acute *Oncorhynchus mykiss*	LC_{50}	435	4.35	0.869	D1 (ditch)	0.20
				0.718	D1 (stream)	0.17
				0.936	D2 (ditch)	0.22
				0.700	D2 (stream)	0.16
				0.793	D3 (ditch)	0.18
				0.035	D4 (pond)	0.01
				0.609	D4 (stream)	0.14
				0.040	D5 (pond)	0.01
				0.631	D5 (stream)	0.15
				0.790	D6 (ditch)	0.18
				0.167	R1 (pond)	0.04
				1.355	R1 (stream)	0.31
				1.090	R3 (stream)	0.25
				1.410	R4 (stream)	0.32
Invertebrate, acute *Daphnia magna*	EC_{50}	480	4.80	0.869	D1 (ditch)	0.18
				0.718	D1 (stream)	0.15
				0.936	D2 (ditch)	0.20
				0.700	D2 (stream)	0.15
				0.793	D3 (ditch)	0.17
				0.035	D4 (pond)	0.01
				0.609	D4 (stream)	0.13
				0.040	D5 (pond)	0.01
				0.631	D5 (stream)	0.13
				0.790	D6 (ditch)	0.16
				0.167	R1 (pond)	0.03
				1.355	R1 (stream)	0.28
				1.090	R3 (stream)	0.23
				1.410	R4 (stream)	0.29
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50}	488	4.88	0.869	D1 (ditch)	0.18
				0.718	D1 (stream)	0.15
				0.936	D2 (ditch)	0.19
				0.700	D2 (stream)	0.14
				0.793	D3 (ditch)	0.16
				0.035	D4 (pond)	0.01
				0.609	D4 (stream)	0.12
				0.040	D5 (pond)	0.01
				0.631	D5 (stream)	0.13
				0.790	D6 (ditch)	0.16
				0.167	R1 (pond)	0.03
				1.355	R1 (stream)	0.28

Species	Endpoint [µg/L]		RAC$_{sw; ac}$ (LC_{50}/100)	PEC$_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
				1.090	R3 (stream)	0.22
				1.410	R4 (stream)	0.29
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha						
Fish, acute *Oncorhynchus mykiss*	LC_{50}	435	4.35	1.166	D1 (ditch)	0.27
				0.701	D1 (stream)	0.16
				0.792	D3 (ditch)	0.18
				0.039	D4 (pond)	0.01
				0.647	D4 (stream)	0.15
				0.038	D5 (pond)	0.01
				0.665	D5 (stream)	0.15
				1.786	R4 (stream)	0.41
Invertebrate, acute *Daphnia magna*	EC_{50}	480	4.80	1.166	D1 (ditch)	0.24
				0.701	D1 (stream)	0.15
				0.792	D3 (ditch)	0.17
				0.039	D4 (pond)	0.01
				0.647	D4 (stream)	0.13
				0.038	D5 (pond)	0.01
				0.665	D5 (stream)	0.14
				1.786	R4 (stream)	0.37
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50}	488	4.88	1.166	D1 (ditch)	0.24
				0.701	D1 (stream)	0.14
				0.792	D3 (ditch)	0.16
				0.039	D4 (pond)	0.01
				0.647	D4 (stream)	0.13
				0.038	D5 (pond)	0.01
				0.665	D5 (stream)	0.14
				1.786	R4 (stream)	0.37

Table CP 10.2- 16: $RAC_{sw;\,ac}$ calculations for onions calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]	$RAC_{sw;\,ac}$ (LC_{50}/100)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
Fish, acute *Oncorhynchus mykiss*	LC_{50} 435	4.35	0.791	D3 (ditch)	0.18
			0.045	D4 (pond)	0.01
			0.604	D4 (stream)	0.14
			0.785	D6 (ditch, 1st)	0.18
			0.783	D6 (ditch, 2nd)	0.18
			0.173	R1 (pond)	0.04
			1.622	R1 (stream)	0.37
			0.684	R2 (stream)	0.16
			1.481	R3 (stream)	0.34
			3.057	R4 (stream)	0.70
Invertebrate, acute *Daphnia magna*	EC_{50} 480	4.80	0.791	D3 (ditch)	0.16
			0.045	D4 (pond)	0.01
			0.604	D4 (stream)	0.13
			0.785	D6 (ditch, 1st)	0.16
			0.783	D6 (ditch, 2nd)	0.16
			0.173	R1 (pond)	0.04
			1.622	R1 (stream)	0.34
			0.684	R2 (stream)	0.14
			1.481	R3 (stream)	0.31
			3.057	R4 (stream)	0.64
Invertebrate, acute Geomean, 7 species	LC_{50}/EC_{50} 488	4.88	0.791	D3 (ditch)	0.16
			0.045	D4 (pond)	0.01
			0.604	D4 (stream)	0.12
			0.785	D6 (ditch, 1st)	0.16
			0.783	D6 (ditch, 2nd)	0.16
			0.173	R1 (pond)	0.04
			1.622	R1 (stream)	0.33
			0.684	R2 (stream)	0.14
			1.481	R3 (stream)	0.30
			3.057	R4 (stream)	0.63

The trigger is met for all evaluated scenarios. Consequently, a safe use can be assumed according to the proposed GAP.

CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 17: TER_{LT} calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 150 g a.s./ha and for onions on GAP 2 × 125 g a.s./ha)

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
Cereals (Winter/spring)						
Fluoxastrobin (E+Z)	Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	14.66	**2.0**	10
	Invertebrate, chronic *Daphnia magna*	NOEC	180	14.66	12.3	10
	Invertebrate, chronic *Gammarus pulex*	NOEC	31.6*	14.66	**2.2**	10
	Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	14.66	**0.04**	10
	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	2130	14.66	145.3	10
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	2100	14.66	143.2	10
	Aquatic plant, chronic *Lemna gibba*	E_rC_{50}	3880	14.66	264.7	10
HEC 5725-E-des-chlorophenyl	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 100 000	10.10	> 9901	10
HEC 5725-carboxylic acid	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	98 500	4.48	21 987	10
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 160 000	4.48	35 714	10
2-chlorophenol	Fish, chronic *Pimephales promelas*	NOEC	4000	5.63	710.5	10
	Invertebrate, chronic *Daphnia magna*	NOEC	300	5.63	53.3	10
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	70 000	5.63	12 433	10
Onions						
Fluoxastrobin (E+Z)	Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	13.60	**2.1**	10
	Invertebrate, chronic *Daphnia magna*	NOEC	180	13.60	13.2	10
	Invertebrate, chronic *Gammarus pulex*	NOEC	31.6	13.60	**2.3**	10
	Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	13.60	**0.04**	10
	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	2130	13.60	156.6	10

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	2100	13.60	154.4	10
	Aquatic plant, chronic *Lemna gibba*	E_rC_{50}	3880	13.60	285.3	10
HEC 5725-E-des-chlorophenyl	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	>100 000	9.44	>10 593	10
HEC 5725-carboxylic acid	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	98 500	4.19	23 508	10
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 160 000	4.19	> 38 186	10
2-chlorophenol	Fish, chronic *Pimephales promelas*	NOEC	4000	5.51	726.0	10
	Invertebrate, chronic *Daphnia magna*	NOEC	300	5.51	54.4	10
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	70 000	5.51	12 704	10

* Endpoint from study conducted with EC 100 formulation
Bold values do not meet the trigger

Table CP 10.2- 18: $RAC_{sw, ch}$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 150 g a.s./ha and for onions on GAP 2 × 125 g a.s./ha) (acceptability of risk: PEC/RAC < 1)

Compound	Species	Endpoint [µg/L]		$RAC_{sw, ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	PEC/RAC
Cereals (Winter/spring)						
Fluoxastrobin (E+Z)	Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	2.86	14.66	**5.13**
	Invertebrate, chronic *Daphnia magna*	NOEC	180	18.0	14.66	0.81
	Invertebrate, chronic *Gammarus pulex*	NOEC	31.6	3.16	14.66	**4.64**
	Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	14.66	**240**
	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	2130	213.0	14.66	0.07
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	2100	210.0	14.66	0.07
	Aquatic plant, chronic *Lemna gibba*	E_rC_{50}	3880	388.0	14.66	0.04
HEC 5725-E-des-chlorophenyl	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 100 000	> 10 000	10.10	< 0.001
HEC 5725-carboxylic acid	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	98 500	9850	4.48	0.0005
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 160 000	> 16 000	4.48	< 0.0003
2-chlorophenol	Fish, chronic *Pimephales promelas*	NOEC	4000	400.0	5.63	0.01
	Invertebrate, chronic *Daphnia magna*	NOEC	300	30.0	5.63	0.19
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	70 000	7000	5.63	0.001
Onions						
Fluoxastrobin (E+Z)	Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	2.86	13.60	**4.76**
	Invertebrate, chronic *Daphnia magna*	NOEC	180	18.0	13.60	0.76
	Invertebrate, chronic *Gammarus pulex*	NOEC	31.6	3.16	13.60	**4.30**
	Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	13.60	**223**
	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	2130	213.0	13.60	0.06

Compound	Species	Endpoint [µg/L]		$RAC_{sw, ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	PEC/RAC
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	2100	210.0	13.60	0.06
	Aquatic plant, chronic *Lemna gibba*	E_rC_{50}	3880	388.0	13.60	0.04
HEC 5725-E-des-chlorophenyl	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	> 100 000	> 10 000	9.44	< 0.001
HEC 5725-carboxylic acid	Sediment dweller, chronic *Chironomus riparius*	EC_{15}	98 500	9850	4.19	0.0004
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	>160 000	> 16 000	4.19	< 0.0003
2-chlorophenol	Fish, chronic *Pimephales promelas*	NOEC	4000	400.0	5.51	0.01
	Invertebrate, chronic *Daphnia magna*	NOEC	300	30.0	5.51	0.18
	Green alga, chronic *Pseudokirchneriella subcapitata*	E_rC_{50}	70 000	7000	5.51	0.001

Results indicated in bold letter need further refinement. The consideration of the more realistic FOCUS Step 3 surface water concentrations is presented below.

Table CP 10.2- 19: TER_{LT} calculations for cereals (winter and spring) calculation based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	1.048	D1 (ditch)	27.3	10
		0.864	D1 (stream)	33.1	10
		1.137	D2 (ditch)	25.2	10
		0.847	D2 (stream)	33.8	10
		0.952	D3 (ditch)	30.0	10
		0.042	D4 (pond)	681.0	10
		0.731	D4 (stream)	39.1	10
		0.048	D5 (pond)	595.8	10
		0.758	D5 (stream)	37.7	10
		0.948	D6 (ditch)	30.2	10
		0.203	R1 (pond)	140.9	10
		1.663	R1 (stream)	17.2	10
		1.337	R3 (stream)	21.4	10
		1.724	R4 (stream)	16.6	10
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	1.048	D1 (ditch)	30.2	10
		0.864	D1 (stream)	36.6	10
		1.137	D2 (ditch)	27.8	10
		0.847	D2 (stream)	37.3	10
		0.952	D3 (ditch)	33.2	10
		0.042	D4 (pond)	752.4	10
		0.731	D4 (stream)	43.2	10
		0.048	D5 (pond)	658.3	10
		0.758	D5 (stream)	41.7	10
		0.948	D6 (ditch)	33.3	10
		0.203	R1 (pond)	155.7	10
		1.663	R1 (stream)	19.0	10
		1.337	R3 (stream)	23.6	10
		1.724	R4 (stream)	18.3	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	1.048	D1 (ditch)	**0.6**	10
		0.864	D1 (stream)	**0.7**	10
		1.137	D2 (ditch)	**0.5**	10
		0.847	D2 (stream)	**0.7**	10
		0.952	D3 (ditch)	**0.6**	10
		0.042	D4 (pond)	14.5	10
		0.731	D4 (stream)	**0.8**	10
		0.048	D5 (pond)	12.7	10
		0.758	D5 (stream)	**0.8**	10
		0.948	D6 (ditch)	**0.6**	10
		0.203	R1 (pond)	**3.0**	10
		1.663	R1 (stream)	**0.4**	10
		1.337	R3 (stream)	**0.5**	10

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
		1.724	R4 (stream)	**0.4**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	1.403	D1 (ditch)	20.4	10
		0.841	D1 (stream)	34.0	10
		0.950	D3 (ditch)	30.1	10
		0.047	D4 (pond)	608.5	10
		0.777	D4 (stream)	36.8	10
		0.046	D5 (pond)	621.7	10
		0.798	D5 (stream)	35.8	10
		2.177	R4 (stream)	13.1	10
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	1.403	D1 (ditch)	22.5	10
		0.841	D1 (stream)	37.6	10
		0.950	D3 (ditch)	33.3	10
		0.047	D4 (pond)	672.3	10
		0.777	D4 (stream)	40.7	10
		0.046	D5 (pond)	687.0	10
		0.798	D5 (stream)	39.6	10
		2.177	R4 (stream)	14.5	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	1.403	D1 (ditch)	**0.4**	10
		0.841	D1 (stream)	**0.7**	10
		0.950	D3 (ditch)	**0.6**	10
		0.047	D4 (pond)	13.0	10
		0.777	D4 (stream)	**0.8**	10
		0.046	D5 (pond)	13.3	10
		0.798	D5 (stream)	**0.8**	10
		2.177	R4 (stream)	**0.3**	10

* Endpoint from study conducted with EC 100 formulation
Bold values do not meet the trigger

Table CP 10.2- 20: TER_{LT} calculations for cereals (winter and spring) calculation based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	0.869	D1 (ditch)	32.9	10
		0.718	D1 (stream)	39.8	10
		0.936	D2 (ditch)	30.6	10
		0.700	D2 (stream)	40.9	10
		0.793	D3 (ditch)	36.1	10
		0.035	D4 (pond)	817.1	10
		0.609	D4 (stream)	47.0	10
		0.040	D5 (pond)	715.0	10
		0.631	D5 (stream)	45.3	10
		0.790	D6 (ditch)	36.2	10
		0.167	R1 (pond)	171.3	10
		1.355	R1 (stream)	21.1	10
		1.090	R3 (stream)	26.2	10
		1.410	R4 (stream)	20.3	10
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	0.869	D1 (ditch)	36.4	10
		0.718	D1 (stream)	44.0	10
		0.936	D2 (ditch)	33.8	10
		0.700	D2 (stream)	45.1	10
		0.793	D3 (ditch)	39.8	10
		0.035	D4 (pond)	902.9	10
		0.609	D4 (stream)	51.9	10
		0.040	D5 (pond)	790.0	10
		0.631	D5 (stream)	50.1	10
		0.790	D6 (ditch)	40.0	10
		0.167	R1 (pond)	189.2	10
		1.355	R1 (stream)	23.3	10
		1.090	R3 (stream)	29.0	10
		1.410	R4 (stream)	22.4	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.869	D1 (ditch)	**0.7**	10
		0.718	D1 (stream)	**0.8**	10
		0.936	D2 (ditch)	**0.7**	10
		0.700	D2 (stream)	**0.9**	10
		0.793	D3 (ditch)	**0.8**	10
		0.035	D4 (pond)	17.4	10
		0.609	D4 (stream)	**1.0**	10
		0.040	D5 (pond)	15.3	10
		0.631	D5 (stream)	**1.0**	10
		0.790	D6 (ditch)	**0.8**	10
		0.167	R1 (pond)	**3.7**	10
		1.355	R1 (stream)	**0.5**	10
		1.090	R3 (stream)	**0.6**	10

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
		1.410	R4 (stream)	**0.4**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	1.166	D1 (ditch)	24.5	10
		0.701	D1 (stream)	40.8	10
		0.792	D3 (ditch)	36.1	10
		0.039	D4 (pond)	733.3	10
		0.647	D4 (stream)	44.2	10
		0.038	D5 (pond)	752.6	10
		0.665	D5 (stream)	43.0	10
		1.786	R4 (stream)	16.0	10
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	1.166	D1 (ditch)	27.1	10
		0.701	D1 (stream)	45.1	10
		0.792	D3 (ditch)	39.9	10
		0.039	D4 (pond)	810.3	10
		0.647	D4 (stream)	48.8	10
		0.038	D5 (pond)	831.6	10
		0.665	D5 (stream)	47.5	10
		1.786	R4 (stream)	17.7	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	1.166	D1 (ditch)	**0.5**	10
		0.701	D1 (stream)	**0.9**	10
		0.792	D3 (ditch)	**0.8**	10
		0.039	D4 (pond)	15.6	10
		0.647	D4 (stream)	**0.9**	10
		0.038	D5 (pond)	16.1	10
		0.665	D5 (stream)	**0.9**	10
		1.786	R4 (stream)	**0.3**	10

* Endpoint from study conducted with EC 100 formulation
Bold values do not meet the trigger

Table CP 10.2- 21: TER_{LT} calculations for onions calculation based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	0.791	D3 (ditch)	36.2	10
		0.045	D4 (pond)	635.6	10
		0.604	D4 (stream)	47.4	10
		0.785	D6 (ditch, 1st)	36.4	10
		0.783	D6 (ditch, 2nd)	36.5	10
		0.173	R1 (pond)	165.3	10
		1.622	R1 (stream)	17.6	10
		0.684	R2 (stream)	41.8	10
		1.481	R3 (stream)	19.3	10
		3.057	R4 (stream)	**9.4**	10
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	0.791	D3 (ditch)	39.9	10
		0.045	D4 (pond)	702.2	10
		0.604	D4 (stream)	52.3	10
		0.785	D6 (ditch, 1st)	40.3	10
		0.783	D6 (ditch, 2nd)	40.4	10
		0.173	R1 (pond)	182.7	10
		1.622	R1 (stream)	19.5	10
		0.684	R2 (stream)	46.2	10
		1.481	R3 (stream)	21.3	10
		3.057	R4 (stream)	10.3	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.791	D3 (ditch)	**0.8**	10
		0.045	D4 (pond)	13.6	10
		0.604	D4 (stream)	**1.0**	10
		0.785	D6 (ditch, 1st)	**0.8**	10
		0.783	D6 (ditch, 2nd)	**0.8**	10
		0.173	R1 (pond)	**3.5**	10
		1.622	R1 (stream)	**0.4**	10
		0.684	R2 (stream)	**0.9**	10
		1.481	R3 (stream)	**0.4**	10
		3.057	R4 (stream)	**0.2**	10

* Endpoint from study conducted with EC 100 formulation
Bold values do not meet the trigger

Table CP 10.2- 22: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]		$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha						
Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	2.86	1.048	D1 (ditch)	0.37
				0.864	D1 (stream)	0.30
				1.137	D2 (ditch)	0.40
				0.847	D2 (stream)	0.30
				0.952	D3 (ditch)	0.33
				0.042	D4 (pond)	0.01
				0.731	D4 (stream)	0.26
				0.048	D5 (pond)	0.02
				0.758	D5 (stream)	0.27
				0.948	D6 (ditch)	0.33
				0.203	R1 (pond)	0.07
				1.663	R1 (stream)	0.58
				1.337	R3 (stream)	0.47
				1.724	R4 (stream)	0.60
Invertebrate, chronic *Gammarus pulex*	NOEC	31.6*	3.16	1.048	D1 (ditch)	0.33
				0.864	D1 (stream)	0.27
				1.137	D2 (ditch)	0.36
				0.847	D2 (stream)	0.27
				0.952	D3 (ditch)	0.30
				0.042	D4 (pond)	0.01
				0.731	D4 (stream)	0.23
				0.048	D5 (pond)	0.02
				0.758	D5 (stream)	0.24
				0.948	D6 (ditch)	0.30
				0.203	R1 (pond)	0.06
				1.663	R1 (stream)	0.53
				1.337	R3 (stream)	0.42
				1.724	R4 (stream)	0.55
Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	1.048	D1 (ditch)	**17.18**
				0.864	D1 (stream)	**14.16**
				1.137	D2 (ditch)	**18.64**
				0.847	D2 (stream)	**13.89**
				0.952	D3 (ditch)	**15.61**
				0.042	D4 (pond)	0.69
				0.731	D4 (stream)	**11.98**
				0.048	D5 (pond)	0.79
				0.758	D5 (stream)	**12.43**
				0.948	D6 (ditch)	**15.54**
				0.203	R1 (pond)	**3.33**

Species	Endpoint [µg/L]	$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
			1.663	R1 (stream)	**27.26**
			1.337	R3 (stream)	**21.92**
			1.724	R4 (stream)	**28.26**
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	2.86	1.403	D1 (ditch)	0.49
			0.841	D1 (stream)	0.29
			0.950	D3 (ditch)	0.33
			0.047	D4 (pond)	0.02
			0.777	D4 (stream)	0.27
			0.046	D5 (pond)	0.02
			0.798	D5 (stream)	0.28
			2.177	R4 (stream)	0.76
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	3.16	1.403	D1 (ditch)	0.44
			0.841	D1 (stream)	0.27
			0.950	D3 (ditch)	0.30
			0.047	D4 (pond)	0.01
			0.777	D4 (stream)	0.25
			0.046	D5 (pond)	0.01
			0.798	D5 (stream)	0.25
			2.177	R4 (stream)	0.69
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	1.403	D1 (ditch)	**23.00**
			0.841	D1 (stream)	**13.79**
			0.950	D3 (ditch)	**15.57**
			0.047	D4 (pond)	0.77
			0.777	D4 (stream)	**12.74**
			0.046	D5 (pond)	0.75
			0.798	D5 (stream)	**13.08**
			2.177	R4 (stream)	**35.69**

* Endpoint from study conducted with EC 100 formulation

Table CP 10.2- 23: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]	$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	2.86	0.869	D1 (ditch)	0.30
			0.718	D1 (stream)	0.25
			0.936	D2 (ditch)	0.33
			0.700	D2 (stream)	0.24
			0.793	D3 (ditch)	0.28
			0.035	D4 (pond)	0.01
			0.609	D4 (stream)	0.21
			0.040	D5 (pond)	0.01
			0.631	D5 (stream)	0.22
			0.790	D6 (ditch)	0.28
			0.167	R1 (pond)	0.06
			1.355	R1 (stream)	0.47
			1.090	R3 (stream)	0.38
			1.410	R4 (stream)	0.49
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	3.16	0.869	D1 (ditch)	0.28
			0.718	D1 (stream)	0.23
			0.936	D2 (ditch)	0.30
			0.700	D2 (stream)	0.22
			0.793	D3 (ditch)	0.25
			0.035	D4 (pond)	0.01
			0.609	D4 (stream)	0.19
			0.040	D5 (pond)	0.01
			0.631	D5 (stream)	0.20
			0.790	D6 (ditch)	0.25
			0.167	R1 (pond)	0.05
			1.355	R1 (stream)	0.43
			1.090	R3 (stream)	0.34
			1.410	R4 (stream)	0.45
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	0.869	D1 (ditch)	**14.25**
			0.718	D1 (stream)	**11.77**
			0.936	D2 (ditch)	**15.34**
			0.700	D2 (stream)	**11.48**
			0.793	D3 (ditch)	**13.00**
			0.035	D4 (pond)	0.57
			0.609	D4 (stream)	**9.98**
			0.040	D5 (pond)	0.66
			0.631	D5 (stream)	**10.34**
			0.790	D6 (ditch)	**12.95**
			0.167	R1 (pond)	**2.74**

Species	Endpoint [µg/L]	$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
			1.355	R1 (stream)	**22.21**
			1.090	R3 (stream)	**17.87**
			1.410	R4 (stream)	**23.11**
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	2.86	1.166	D1 (ditch)	0.41
			0.701	D1 (stream)	0.25
			0.792	D3 (ditch)	0.28
			0.039	D4 (pond)	0.01
			0.647	D4 (stream)	0.23
			0.038	D5 (pond)	0.01
			0.665	D5 (stream)	0.23
			1.786	R4 (stream)	0.62
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	3.16	1.166	D1 (ditch)	0.37
			0.701	D1 (stream)	0.22
			0.792	D3 (ditch)	0.25
			0.039	D4 (pond)	0.01
			0.647	D4 (stream)	0.20
			0.038	D5 (pond)	0.01
			0.665	D5 (stream)	0.21
			1.786	R4 (stream)	0.57
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	1.166	D1 (ditch)	**19.11**
			0.701	D1 (stream)	**11.49**
			0.792	D3 (ditch)	**12.98**
			0.039	D4 (pond)	0.64
			0.647	D4 (stream)	**10.61**
			0.038	D5 (pond)	0.62
			0.665	D5 (stream)	**10.90**
			1.786	R4 (stream)	**29.28**

* Endpoint from study conducted with EC 100 formulation

Table CP 10.2- 24: $RAC_{sw; ch}$ calculations for onions calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]	$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	2.86	0.791	D3 (ditch)	0.28
			0.045	D4 (pond)	0.02
			0.604	D4 (stream)	0.21
			0.785	D6 (ditch, 1st)	0.27
			0.783	D6 (ditch, 2nd)	0.27
			0.173	R1 (pond)	0.06
			1.622	R1 (stream)	0.57
			0.684	R2 (stream)	0.24
			1.481	R3 (stream)	0.52
			3.057	R4 (stream)	**1.07**
Invertebrate, chronic *Gammarus pulex*	NOEC 31.6*	3.16	0.791	D3 (ditch)	0.25
			0.045	D4 (pond)	0.01
			0.604	D4 (stream)	0.19
			0.785	D6 (ditch, 1st)	0.25
			0.783	D6 (ditch, 2nd)	0.25
			0.173	R1 (pond)	0.05
			1.622	R1 (stream)	0.51
			0.684	R2 (stream)	0.22
			1.481	R3 (stream)	0.47
			3.057	R4 (stream)	0.97
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	0.791	D3 (ditch)	**12.97**
			0.045	D4 (pond)	0.74
			0.604	D4 (stream)	**9.90**
			0.785	D6 (ditch, 1st)	**12.87**
			0.783	D6 (ditch, 2nd)	**12.84**
			0.173	R1 (pond)	**2.84**
			1.622	R1 (stream)	**26.59**
			0.684	R2 (stream)	**11.21**
			1.481	R3 (stream)	**24.28**
			3.057	R4 (stream)	**50.11**

* Endpoint from study conducted with EC 100 formulation

Most of the TERs meet the required trigger of 10, indicating a safe use of the product. However, the risk assessment for *Gammarus pulex* and *Americamysis bahia* need further refinement for some scenarios. Table CP 10.2- 25 summarizes the assessments which need further consideration. .

Table CP 10.2- 25: Summary of the scenarios that did not pass the TER_{LT}/RAC_{LT} calculations of fluoxastrobin based on FOCUS Step 3 following application to cereals* and onions*

	Fluoxastrobin (E+Z)				
	Fish, chronic: *Oncorhynchus mykiss*				
Scenario	**2 x 150 g a.s. /ha**		**2 x 125 g a.s. /ha**		**2 x 125 g a.s. /ha**
	Winter cereals	**Spring cereals**	**Winter cereals**	**Spring cereals**	**Onions**
D1 (ditch)					-
D1 (stream)					-
D2 (ditch)				-	-
D2 (stream)		-		-	-
D3 (ditch)					
D4 (pond)					
D4 (stream)					
D5 (pond)					-
D5 (stream)					-
D6 (ditch, 1st)		-		-	
D6 (ditch, 2nd)	-	-	-	-	
R1 (pond)		-		-	
R1 (stream)		-		-	
R2 (stream)	-	-	-	-	
R3 (stream)		-		-	
R4 (stream)					×
	Invertebrate, chronic: *Americamysis bahia*				
D1 (ditch)	×	×	×	×	-
D1 (stream)	×	×	×	×	-
D2 (ditch)	×	-	×	-	-
D2 (stream)	×	-	×	-	-
D3 (ditch)	×	×	×	×	×
D4 (pond)					
D4 (stream)	×	×	×	×	×
D5 (pond)					-
D5 (stream)	×	×	×	×	-
D6 (ditch, 1st)	×	-	×	-	×
D6 (ditch, 2nd)	-	-	-	-	×
R1 (pond)	×	-	×	-	×
R1 (stream)	×	-	×	-	×
R2 (stream)	-	-	-	-	×
R3 (stream)	×	-	×	-	×
R4 (stream)	×	×	×	×	×

* Refinement for Invertebrate chronic (*Gammarus pulex*) passes the risk assessment based on FOCUS Step 3 with all scenarios and all intended applications.
× Scenario not passed
- Scenario not relevant for the crop

Results indicated with x need further refinement.

For fluoxastrobin and aquatic invertebrates, a refinement option based on the FOCUS Step 3 -TWA_{sw} (7 days) values is presented below. Justification for the use of the 7d $PEC_{sw;twa}$ is provided in MCA 8, Point 8.2.5.1 (M-535147-01-1).

Table CP 10.2- 26: TER_{LT} calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)

Species	Endpoint [µg/L]	7-day TWA_{sw} [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.874	D1 (ditch)	**0.7**	10
		0.272	D1 (stream)	**2.2**	10
		0.825	D2 (ditch)	**0.7**	10
		0.386	D2 (stream)	**1.6**	10
		0.200	D3 (ditch)	**3.1**	10
		0.021	D4 (stream)	28.8	10
		0.010	D5 (stream)	61.0	10
		0.353	D6 (ditch)	**1.7**	10
		0.193	R1 (pond)	**3.2**	10
		0.207	R1 (stream)	**3.0**	10
		0.182	R3 (stream)	**3.3**	10
		0.483	R4 (stream)	**1.3**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	1.204	D1 (ditch)	**0.5**	10
		0.320	D1 (stream)	**1.9**	10
		0.155	D3 (ditch)	**3.9**	10
		0.024	D4 (stream)	25.0	10
		0.009	D5 (stream)	70.9	10
		0.489	R4 (stream)	**1.2**	10

Bold values do not meet the trigger

Table CP 10.2- 27: TER_{LT} calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)

Species	Endpoint [µg/L]	7-day TWA_{sw} [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.724	D1 (ditch)	**0.8**	10
		0.206	D1 (stream)	**3.0**	10
		0.676	D2 (ditch)	**0.9**	10
		0.313	D2 (stream)	**2.0**	10
		0.166	D3 (ditch)	**3.7**	10
		0.017	D4 (stream)	37.0	10
		0.008	D5 (stream)	72.6	10
		0.294	D6 (ditch)	**2.1**	10
		0.158	R1 (pond)	**3.9**	10
		0.169	R1 (stream)	**3.6**	10
		0.149	R3 (stream)	**4.1**	10
		0.397	R4 (stream)	**1.5**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.999	D1 (ditch)	**0.6**	10
		0.248	D1 (stream)	**2.5**	10
		0.129	D3 (ditch)	**4.7**	10
		0.019	D4 (stream)	31.9	10
		0.007	D5 (stream)	84.7	10
		0.401	R4 (stream)	**1.5**	10

Bold values do not meet the trigger

Table CP 10.2- 28: TER_{LT} calculations for onions calculation based on FOCUS Step 3 -TWAsw (7 days)

Species	Endpoint [µg/L]	7-day TWA_{sw} [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
Fish, chronic *Oncorhynchus mykiss*	NOEC 28.6	0.414	R4 (stream)	69.0	10
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.116	D3 (ditch)	**5.3**	10
		0.046	D4 (stream)	13.4	10
		0.160	D6 (ditch, 1st)	**3.8**	10
		0.242	D6 (ditch, 2nd)	**2.5**	10
		0.163	R1 (pond)	**3.8**	10
		0.197	R1 (stream)	**3.1**	10
		0.117	R2 (stream)	**5.2**	10
		0.192	R3 (stream)	**3.2**	10
		0.414	R4 (stream)	**1.5**	10

Bold values do not meet the trigger

Table CP 10.2- 29: RAC$_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]	RAC$_{sw; ch}$ (NOEC/10) (E_rC_{50}/10	7-day TWA$_{sw}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	0.874	D1 (ditch)	**14.33**
			0.272	D1 (stream)	**4.46**
			0.825	D2 (ditch)	**13.52**
			0.386	D2 (stream)	**6.33**
			0.200	D3 (ditch)	**3.28**
			0.021	D4 (stream)	0.34
			0.010	D5 (stream)	0.16
			0.353	D6 (ditch)	**5.79**
			0.193	R1 (pond)	**3.16**
			0.207	R1 (stream)	**3.39**
			0.182	R3 (stream)	**2.98**
			0.483	R4 (stream)	**7.92**
Fluoxastrobin, (E+Z) spring cereals, 2 × 150 g a.s./ha					
Invertebrate, chronic *Americamysis bahia*	NOEC 0.61	0.061	1.204	D1 (ditch)	**19.74**
			0.320	D1 (stream)	**5.25**
			0.155	D3 (ditch)	**2.54**
			0.024	D4 (stream)	0.39
			0.009	D5 (stream)	0.15
			0.489	R4 (stream)	**8.02**

Table CP 10.2- 30: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]		$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	7-day TWA_{sw} [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha						
Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.724	D1 (ditch)	**11.87**
				0.206	D1 (stream)	**3.38**
				0.676	D2 (ditch)	**11.08**
				0.313	D2 (stream)	**5.13**
				0.166	D3 (ditch)	**2.72**
				0.017	D4 (stream)	0.28
				0.008	D5 (stream)	0.13
				0.294	D6 (ditch)	**4.82**
				0.158	R1 (pond)	**2.59**
				0.169	R1 (stream)	**2.77**
				0.149	R3 (stream)	**2.44**
				0.397	R4 (stream)	**6.51**
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha						
Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.999	D1 (ditch)	**16.38**
				0.248	D1 (stream)	**4.07**
				0.129	D3 (ditch)	**2.11**
				0.019	D4 (stream)	0.31
				0.007	D5 (stream)	0.11
				0.401	R4 (stream)	**6.57**

Table CP 10.2- 31: $RAC_{sw; ch}$ calculations for onions calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]		$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	7-day TWA_{sw} [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha						
Fish, chronic *Oncorhynchus mykiss*	NOEC	28.6	2.86	0.414	R4 (stream)	0.14
Invertebrate, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.116	D3 (ditch)	**1.90**
				0.046	D4 (stream)	0.75
				0.160	D6 (ditch, 1st)	**2.62**
				0.242	D6 (ditch, 2nd)	**3.97**
				0.163	R1 (pond)	**2.67**
				0.197	R1 (stream)	**3.23**
				0.117	R2 (stream)	**1.92**
				0.192	R3 (stream)	**3.15**
				0.414	R4 (stream)	**6.79**

Table CP 10.2- 32 summarizes the scenarios which did not meet the required trigger of 10 when based on FOCUS Step 3 -TWAsw (7 days) risk assessment. Consequently, further refinement is needed.

Table CP 10.2- 32: Summary of the scenarios that did not pass the TER_{LT}/RAC_{LT} calculations of fluoxastrobin based FOCUS Step 3 -TWAsw (7 days) following application to cereals and onions

	Fluoxastrobin (E+Z)				
Scenario	**2 x 150 g a.s. /ha**		**2 x 125 g a.s. /ha**		**2 x 125 g a.s. /ha**
	Winter cereals	**Spring cereals**	**Winter cereals**	**Spring cereals**	**Onions**
	Invertebrate, chronic: *Americamysis bahia*				
D1 (ditch)	×	×	×	×	-
D1 (stream)	×	×	×	×	-
D2 (ditch)	×	-	×	-	-
D2 (stream)	×	-	×	-	-
D3 (ditch)	×	×	×	×	×
D4 (stream)					
D5 (stream)					-
D6 (ditch, 1st)	×	-	×	-	×
D6 (ditch, 2nd)	-	-	-	-	×
R1 (pond)	×	-	×	-	×
R1 (stream)	×	-	×	-	×
R2 (stream)	-	-	-	-	×
R3 (stream)	×	-	×	-	×
R4 (stream)	×	×	×	×	×

× Scenario not passed
- Scenario not relevant for the crop

Results indicated with x need further refinement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.

Table CP 10.2- 33: TER_{LT} calculations for invertebrates (long-term) based on FOCUS Step 4 -TWA_{SW} (7 days) including mitigation measures

Species	Endpoint [µg/L]		7-day TWA_{sw} [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.435	D1 (ditch)	**1.4**	10
			0.272	D1 (stream)	**2.2**	10
			0.419	D2 (ditch)	**1.5**	10
			0.233	D2 (stream)	**2.6**	10
			0.001	D3 (ditch)	418.1	10
			0.004	D6 (ditch)	145.9	10
			0.034	R1 (pond)	17.7	10
			0.049	R1 (stream)	12.5	10
			0.042	R3 (stream)	14.4	10
			0.115	R4 (stream)	**5.3**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.512	D1 (ditch)	**1.2**	10
			0.320	D1 (stream)	**1.9**	10
			0.001	D3 (ditch)	535.1	10
			0.112	R4 (stream)	**5.4**	10
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.329	D1 (ditch)	**1.9**	10
			0.206	D1 (stream)	**3.0**	10
			0.330	D2 (ditch)	**1.8**	10
			0.181	D2 (stream)	**3.4**	10
			0.001	D3 (ditch)	502.1	10
			0.003	D6 (ditch)	195.4	10
			0.028	R1 (pond)	21.6	10
			0.040	R1 (stream)	15.3	10
			0.035	R3 (stream)	17.6	10
			0.095	R4 (stream)	**6.4**	10
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.398	D1 (ditch)	**1.5**	10
			0.248	D1 (stream)	**2.5**	10
			0.001	D3 (ditch)	642.8	10
			0.092	R4 (stream)	**6.6**	10
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.001	D3 (ditch)	715.1	10
			0.007	D6 (ditch, 1st)	87.6	10

Species	Endpoint [µg/L]		7-day TWA_{sw} [µg/L]	FOCUS scenario	TER_{LT}	Trigger
			0.019	D6 (ditch, 2nd)	31.6	10
			0.028	R1 (pond)	21.7	10
			0.046	R1 (stream)	13.3	10
			0.028	R2 (stream)	22.0	10
			0.046	R3 (stream)	13.2	10
			0.097	R4 (stream)	**6.3**	10
Fluoxastrobin (E+Z), onions, 1 × 125 g a.s./ha						
20 m buffer zone, 0% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.009	D3 (ditch)	67.8	10
			0.007	D6 (ditch, 1st)	87.1	10
			0.012	D6 (ditch, 2nd)	50.8	10
			0.018	R1 (pond)	33.9	10
			0.019	R1 (stream)	32.1	10
			0.011	R2 (stream)	55.5	10
			0.019	R3 (stream)	32.1	10
			0.041	R4 (stream)	14.9	10

Bold values do not meet the trigger

Table CP 10.2- 34: RAC$_{sw; ch}$ calculations for invertebrates (long-term) based on FOCUS Step 4 - TWAsw (7 days) including mitigation measures (acceptability of risk: PEC/RAC < 1)

Species	Endpoint [µg/L]		RAC$_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	7-day TWA$_{sw}$ [µg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.435	D1 (ditch)	**7.13**
				0.272	D1 (stream)	**4.46**
				0.419	D2 (ditch)	**6.87**
				0.233	D2 (stream)	**3.82**
				0.001	D3 (ditch)	0.02
				0.004	D6 (ditch)	0.07
				0.034	R1 (pond)	0.56
				0.049	R1 (stream)	0.80
				0.042	R3 (stream)	0.69
				0.115	R4 (stream)	**1.89**
Fluoxastrobin (E+Z), spring cereals, 2 × 150 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.512	D1 (ditch)	**8.39**
				0.320	D1 (stream)	**5.25**
				0.001	D3 (ditch)	0.02
				0.112	R4 (stream)	**1.84**
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.329	D1 (ditch)	**5.39**
				0.206	D1 (stream)	**3.38**
				0.330	D2 (ditch)	**5.41**
				0.181	D2 (stream)	**2.97**
				0.001	D3 (ditch)	0.02
				0.003	D6 (ditch)	0.05
				0.028	R1 (pond)	0.46
				0.040	R1 (stream)	0.66
				0.035	R3 (stream)	0.57
				0.095	R4 (stream)	**1.56**
Fluoxastrobin (E+Z), spring cereals, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic *Americamysis bahia*	NOEC	0.61	0.061	0.398	D1 (ditch)	**6.52**
				0.248	D1 (stream)	**4.07**
				0.001	D3 (ditch)	0.02
				0.092	R4 (stream)	**1.51**
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha						
20 m buffer zone, 90% drift reduction						
Invertebrates, chronic	NOEC	0.61	0.061	0.001	D3 (ditch)	0.02

Species	Endpoint [µg/L]	$RAC_{sw; ch}$ (NOEC/10) (E_rC_{50}/10)	7-day TWA_{sw} [µg/L]	FOCUS scenario	PEC/RAC
Americamysis bahia			0.007	D6 (ditch, 1st)	0.11
			0.019	D6 (ditch, 2nd)	0.31
			0.028	R1 (pond)	0.46
			0.046	R1 (stream)	0.75
			0.028	R2 (stream)	0.46
			0.046	R3 (stream)	0.75
			0.097	R4 (stream)	**1.59**
Fluoxastrobin (E+Z), onions, 2 × 125 g a.s./ha					
20 m buffer zone, 0% drift reduction					
Invertebrates, chronic *Americamysis bahia*	NOEC 0.61	0.061	0.009	D3 (ditch)	0.15
			0.007	D6 (ditch, 1st)	0.11
			0.012	D6 (ditch, 2nd)	0.20
			0.018	R1 (pond)	0.30
			0.019	R1 (stream)	0.31
			0.011	R2 (stream)	0.18
			0.019	R3 (stream)	0.31
			0.041	R4 (stream)	0.67

Bold values do not meet the trigger

Concerning two applications in winter and spring cereals at rates of 2 × 150 g a.s./ha and 2 × 125 g a.s./ha, safe use without any refinement was identified for the scenarios D4 (pond), D4 (stream), D5 (pond) and D5 (stream).
Concerning two applications in winter cereals at rates of 2 × 150 g a.s./ha and 2 × 125 g a.s./ha, safe use was identified for the scenarios D3 (ditch), D6 (ditch), R1 (pond), R1 (stream) and R3 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used.
Concerning two applications in spring cereals at rates of 2 × 150 g a.s./ha and 2 × 125 g a.s./ha, safe use was identified for the scenario D3 (ditch) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used.
Concerning two applications in onions at rates of 2 × 125 g a.s./ha, safe use without any refinement was identified for the scenarios D4 (pond) and D4 (stream). A safe use for all other scenarios can be predicted considering 20 m drift buffer without drift reduction.

Conclusion
For the representative uses considered for renewal of approval of Fluoxastrobin, acceptable risk can be considered for most scenarios, taking varying mitigation measures into account.

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Report:	KCP 10.2.1/01 [redacted].; 2014; M-491937-01-1
Title:	Acute toxicity of fluoxastrobin + prothioconazole EC 200 (100+100) G to fish (Oncorhynchus mykiss) under static conditions
Report No.:	EBHEX243
Document No.:	M-491937-01-1
Guideline(s):	OECD Guideline 203, Fish, Acute Toxicity Test (July, 1992); USEPA Pesticide Assessment Guidelines Subdivision E, FIFRA 72-1, Acute toxicity test for freshwater fish, October, 1982; USEPA OCSPP 850.1075 Fish Acute Toxicity Test, Freshwater and Marine, A
Guideline deviation(s):	none
GLP/GEP:	**yes**

Objective:

The aim of this study was to determine the acute toxicity of the test item Fluoxastrobin + Prothioconazole EC 200 to Rainbow trout (*Oncorhynchus mykiss*). The primary measure for acute toxicity was mortality. Sublethal and behavioral observations were made during the course of the study. Results of the test are expressed as a 96-hour median lethal concentration (LC_{50}).

Material and methods:

Test item: Fluoxastrobin + Prothioconazole EC 200 (100+100) G; Batch ID.: 2012-001071; Sample description: TOX09674-00; Specification No.: 102000025822-01; Master recipe ID: 0117103-001; Analysed content of active substance: 9.21% w/w (101.3 g/L) fluoxastrobin, 9.13% w/w (100.4 g/L) prothioconazole; Density: 1.100 g/mL (20 °C).

Rainbow trout (*Oncorhynchus mykiss*) were exposed for 96 hours under static conditions to nominal concentrations of 0.625, 1.25, 2.50, 5.00 and 10.0 mg test item/L against a control. At the beginning of the test the mean body length and the mean body weight of the tested rainbow trout were 4.1 cm and 0.6 g, respectively. The biomass loading for this test was 0.15 g fish / L test medium.
One replicate (one aquarium) of ten fish each was used for each test concentration. The aquaria used were made of glass with a capacity of 40-litres and a dimension of 38 cm height, 32 cm width and 36 cm length. Within the study the pH-value, the oxygen saturation level and the temperature were measured with commercial measurement devices, daily. The water temperature during the 96-hour exposure ranged from 10.5 to 11.7°C in all aquaria over the whole test period. Dissolved oxygen concentrations ranged from 88 to 101% oxygen saturation. The pH values ranged from 6.9 to 7.3.
During the test, fish were observed for mortalities and signs of intoxication four hours after application and then once daily.

Dates of experimental work: February 11, 2013 to December 09, 2013

Findings:

Validity criteria:

Validity criteria	Recommended	Obtained
Mortality within the 48-hour settling-in period	≤ 5%	< 5 %
mortality in the control (or one fish if less than ten are used)	≤ 10%	0 %
dissolved oxygen saturation throughout the test	≥ 60%	88 - 101 %
pH variation (units)	≤ 1.0	0.4

The study meets the proposed validity criteria, thus the test is valid.

Analytical findings:
Fluoxastrobin was analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations.
The chemical analysis of fluoxastrobin (in water by HPLC-UV) revealed recoveries of 58 % - 92 % of nominal over the whole testing period of 96 hours.
As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report were related to nominal test concentrations of the formulated product.

Biological results:
In the controls no mortalities or sub-lethal findings were observed.
In all test levels ≥ 1.25 mg form./L behavioral changes were observed during the entire exposure period. After 96 h of exposure towards the nominal concentration of 1.25 mg test item/L eight fish showed the following behavioural symptoms:
- remained for unusually long periods at the water surface
- showed labored respiration

Table CP 10.2.1- 1: Cumulative mortality of the rainbow trout exposed to Fluoxastrobin + Prothioconazole EC 200

Exposure time	4 h		24 h		48 h		72 h		**96 h**	
Test conc. form. [mg / L]	no. of dead	% dead	no. of dead	% dead	no. of dead	% dead	no. of dead	% dead	**no. of dead**	**% dead**
control	0	0	0	0	0	0	0	0	**0**	**0**
0.625	0	0	0	0	0	0	0	0	**0**	**0**
1.25	0	0	0	0	0	0	0	0	**0**	**0**
2.50	0	0	0	0	2	20	7	70	**9**	**90**
5.00	0	0	10	100	10	100	10	100	**10**	**100**
10.0	10	100	10	100	10	100	10	100	**10**	**100**

Conclusion:

Based on nominal concentrations the following endpoints were determined:

LC_{50} 96 h (95 % confidence interval):	2.19 mg test item/L (convidence interval 95 %: Not determined due to mathematical reasons.)
LOEC:	1.25 mg test item /L
NOEC:	0.625 mg test item /L
NOLEC:	1.25 mg test item /L
100 % mortality (96 h):	5.00 mg test item/L

Report:	KCP 10.2.1/02 [redacted]L; 2012; M-434883-01-1
Title:	Acute toxicity of fluoxastrobin + prothioconazole EC 200 (100+100)A G to the waterflea Daphnia magna in a static laboratory test system
Report No.:	EBHEX242
Document No.:	M-434883-01-1
Guideline(s):	OECD Guideline 202, Daphnia sp. Acute Immobilisation Test (April, 2004);USEPA Pesticide Assessment Guidelines Subdivision E, FIFRA 72-2, Acute toxicity test for freshwater aquatic invertebrates, October, 1982.; OPPTS Guideline 850.1010 Aquatic Invertebrat
Guideline deviation(s):	not applicable
GLP/GEP:	**yes**

Objective:

The study was performed, to detect possible effects of the test item Fluoxastrobin + Prothioconazole EC 200 on mobility of *Daphnia magna* during 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Material and methods:

Test item: Fluoxastrobin + Prothioconazole EC 200 (100+100) A G; Batch ID.: 2012-001071; Sample description: TOX09674-00; Specification No.: 102000025822-01; Analysed content: 9.21% w/w fluoxastrobin, 9.13% w/w prothioconazole; Density: 1.100 g/mL (20 °C).

Daphnia magna (1st instar, < 24 hours old), each study group comprising 30 daphnids (6 replicates per test concentration, 5 daphnids per replicate), were exposed in a static exposure system for 48 hours to Fluoxastrobin + Prothioconazole EC 200 at the concentrations of 0 (untreated control), 0.53, 0.95, 1.71, 3.09, 5.56 and 10.0 mg form./L (nominally) without feeding. Each vessel (glass beakers; 100 mL) served as one replicate was filled with 50 mL of the test solution (10 mL test solution per daphnid). A static toxicity test procedure was followed.
Visual comparison of untreated control animals and treated animals was performed after 24 and 48 hours of exposure. The contnent of fluoxastrobin in exposure media was measured for verification of the test concnetrations.
Water quality parameters *viz.* temperature, pH and dissolved oxygen were measured at 0 and 48 h after the commencement of the exposure. Dissolved oxygen concentrations ranged from 8.5 to 9.1 mg O_2/L, the pH values ranged from 7.9 to 8.0 and the water temperature ranged from 21.1°C to 21.7°C over the whole testing period. The photoperiod was 16 hours of light and 8 hours dark with a maximum intensity of 1200 lux.

Dates of experimental work: May 22, 2012 to June 05, 2012

Findings:

Validity criteria:

Validity criteria	Recommended	Obtained
Control mortality	0.0%	0.0%

The study meets the proposed validity criteria, thus the test is valid.

Analytical results:
The actually dissolved and analytically determined amounts of fluoxastrobin in the freshly prepared test solutions at test initiation ranged at test initiation revealed recoveries between 87% and 95% (mean: 91%) of the aspired nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 89% and 93% (mean: 91%) of nominal.

No contaminations of fluoxastrobin were detected in samples from untreated water control.
As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Biological results:

Table CP 10.2.1- 2: Immobility data of *Daphnia magna* at 24 and 48 h exposure period

nominal test concentration (mg form. / L)	exposed daphnids (=100%)	immobilised daphnids			
		24 h.		48 h.	
		n	%	n	%
control	30	0	0.0	0	0.0
0.53	30	0	0.0	0	0.0
0.95	30	0	0.0	1	3.3
1.71	30	10	33.3	15	50.0
3.09	30	25	83.3	30	100
5.56	30	29	96.7	30	100
10.0	30	30	100	30	100

Observations:
No immobility or other effects on behaviour occurred in untreated control within 48 hours of exposure.

Conclusion:

Based on nominal concentrations of Fluoxastrobin + Prothioconazole EC 200, EC_{50} values after 24 and 48 h hours of static exposure were determined to be 2.15 mg form./L (95 % confidence limits 1.89 – 2.46 mg form./L) and 1.67 (95 % confidence limits 1.24 – 2.25 mg form./L), respectively.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Report:	KCP 10.2.2/01 [redacted]T; 2012; M-438495-01-1
Title:	Pseudokirchneriella subcapitata growth inhibition test with fluoxastrobin + prothioconazole EC 200 (100+100) G
Report No.:	EBHEX241
Document No.:	M-438495-01-1
Guideline(s):	OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006)
Guideline deviation(s):	none
GLP/GEP:	**yes**

Objective:

The aim of the study was to determine the influence of the test item Fluoxastrobin + Prothioconazole EC 200 on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).

Material and methods:

Test item: Fluoxastrobin + Prothioconazole EC 200 (100+100) A G; Batch ID.: 2012-001071; Sample description: TOX09674-00; Specification No.: 102000025822-01; Anaylsed content: 9.21% w/w fluoxastrobin, 9.13% w/w prothioconazole; Density: 1.100 g/mL (20 °C).

Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) with an initial cell density of 10 000 cells/mL in the test medium were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.0960, 0.307, 0.980, 3.13 and 10.0 mg formulation/L in comparison to a control. Three replicate vessels per test level and 6 replicate vessels per control with 150 mL test medium per replicate were used.
The pH values ranged from 7.9 to 8.1 in the controls and the water temperature ranged from 21.3 °C to 22.3 °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8658 lux.
Morphological examinations of cells using a microscope were made over the exposure period on each study day. Quantitative amounts of fluoxastrobin were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Dates of experimental work: May 25, 2012 to June 20, 2012

Findings:

Validity criteria:
Biomass increased in the control by more than 16-fold within the evaluation period. Mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35%. Percent coefficient of variation of the average growth rate in each control replicate did not exceed 7%. Test conditions met all validity criteria, given by the mentioned guideline(s).

Analytical results:
The analytical findings of fluoxastrobin in the treatment levels found on day 0 were 88.2 % to 104 % of nominal (average 94.2 %). On day 3 analytical findings of 91.3 % to 105 % of nominal (average 96.9 %) were found. Given that the toxicity cannot be attributed to any of the a.s. compounds but to the formulation as a whole and based on the high recoveries, all results are based on nominal test concentrations of the formulation.

Biological results:
The static 72 hour algae growth inhibition test provided the following effects:

Table CP 10.2.2- 1: Effects of the static 72 hour algae growth inhibition test

nominal concentration [mg form./L]	cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	inhibition of average specific growth rate [%]
control	704 000	1.418	–
0.0960	671 000	1.402	1.1
0.307	658 000	1.395	1.6
0.980	630 000	1.381	2.6
3.13	331 000	1.167	17.7
10.0	100 000	0.767	45.9

test initiation with 10,000 cells/mL

Observations:
No morphological change in algae was observed in any test concentration.

Conclusion:

The (0 - 72h)-E_rC_{50} for Fluoxastrobin + Prothioconazole EC 200 (100+100) A G is 11.5 mg form./L (95 % CI: 10.8 – 12.3 mg form./L), the (0 - 72h)-E_rC_{10} is 1.97 mg form./L (95 % CI: 1.75 – 2.18 mg form./L) and the (0 - 72h) - NOE_rC is 0.0960 mg form./L.

CP 10.2.3 Further testing on aquatic organisms

No further data of the formulation is available or required.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namely the EU Guidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev 2) and EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided:

- Acute oral and contact toxicity of fluoxastrobin and the representative formulation Fluoxastrobin + Prothioconazole EC 200,
- Acute contact toxicity of fluoxastrobin to adult bumble bees under laboratory conditions,
- Chronic 10 day toxicity test with of Fluoxastrobin FS 480 on adult bees under laboratory conditions,
- Colony feeding study with Fluoxastrobin FS 480 according to [redacted] *et al.* 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood (eggs, young and old larvae) and their development, nurse bee on-going behaviour in brood care and colony strength),
- Semi-field brood feeding study with Fluoxastrobin EC 100 following OECD guidance document 75 (using a more realistic spray scenario onto flowering *Phacelia tanacetifolia* at the maximum application rate for the approval renewal of fluoxastrobin and covering exposure for effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with fluoxastrobin and ecotoxicological are presented together with the ecotoxicological endpoints in Document MCA 8, point 8.3.1, as well as within the EFSA Scientific Report (2007) 102. Furthermore, contact laboratory toxicity data for bumble bees indicated that non-*Apis* bees are not more sensitive than honey bees and consequently the risk assessment for honey bees is considered to protective to other bees.

The acute toxicity test conducted with the formulation Fluoxastrobin + Prothioconazole EC 200 is presented in this document.

A summary of the critical endpoints for fluoxastrobin, the formulated products Fluoxastrobin EC 100, Fluoxastrobin FS 480 and Fluoxastrobin + Prothioconazole EC 200 are provided in the following tables. Endpoints shown in bold are considered relevant for risk assessment.

Table CP 10.3.1- 1: Critical endpoints for fluoxastrobin – acute toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Fluoxastrobin	Honey Bee (oral 48 h)	**LD_{50}**	**> 129.1 µg a.s./bee**	[redacted] 2014; M-503275-01-1 KCA 8.3.1.1.1 KCA 8.3.1.1.2
	Honey Bee (contact 48 h)	**LD_{50}**	**> 100 µg a.s./bee**	
	Bumble bee (contact 48 h) (*Bombus terrestris*)	LD_{50}	> 100 µg a.s./bumble bee	[redacted] 2014; M-512437-01-1 KCA 8.3.1.1.2
Fluoxastrobin + Prothioconazole EC 200	Honey Bee (oral 48 h)	**LD_{50}**	**> 160.3 µg prod./bee**	[redacted] F. 2012; M-434002-01-1 KCP 10.3.1.1.1 KCP 10.3.1.1.2
	Honey Bee (contact 48 h)	**LD_{50}**	**> 200 µg prod./bee**	

a.s. = active substance; prod. = product **Bold: values used in risk assessment**

Table CP 10.3.1- 2: Critical endpoints for fluoxastrobin – chronic toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Fluoxastrobin FS 480	Honey bee Laboratory chronic oral (10 d) (adults)	LC_{50} LDD_{50} NOEC NOEDD	> 3333 mg a.s./kg > 73.3 µg a.s./bee/day 1667 mg a.s./kg 39.2 µg a.s./bee/day	[redacted]; 2015; M-534974-01-1 KCA 8.3.1.2

a.s. = active substance

Table CP 10.3.1- 3: Critical endpoints for fluoxastrobin – toxicity to bee brood

Test substance	Test species	Endpoint	Reference
Fluoxastrobin FS 480	Bee brood feeding test ([redacted] *et al.*)	No adverse effects on brood development and mortality after feeding honey bee colonies sugar syrup at 0.375 g a.s./L.	[redacted]; 2013; M-476181-01-1 KCA 8.3.1.3
Fluoxastrobin EC 100	Semi-field brood study (OECD 75)	No adverse effects on brood development, mortality, foraging activity, behaviour, colony condition and strength after application of 150 g a.s./ha onto flowering *Phacelia tanacetifolia*.	[redacted].; 2015; M-515147-01-1 KCA 8.3.1.3

a.s. = active substance

Risk assessment for bees

The risk assessment for bees is based on the maximum application rates of 2 × 150 g fluoxastrobin/ha in cereals and for the maximum application rates of 2 × 125 g fluoxastrobin/ha in onions.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral LD_{50} (expressed in µg a.s./bee or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation. Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral:
$$Q_{HO} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Hazard Quotient, contact:
$$Q_{HC} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

The maximum label rate of Fluoxastrobin + Prothioconazole EC 200 (100 + 100) per application are 1.5 L (1500 mL) product/ha in cereals (BBCH 30 - 69) and 1.25 L (1250 mL) product/ha in onions (BBCH 15 – 47). With the content of fluoxastrobin and prothioconazole within the formulation being 100 g fluoxastrobin/L and 100 g prothioconazole/L, respectively, this accounts to a maximum application rate of 150 g fluoxastrobin/ha in cereals and 125 g fluoxastastrobin/ha in onions. Considering a density of 1.100 g/mL of Fluoxastrobin + Prothioconazole EC 200, 1500 mL product/ha corresponds to 1650 g product/ha and 1250 mL product/ha corresponds to 1375 g product/ha.

Table CP 10.3.1- 4: Hazard quotients for bees – oral exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Fluoxastrobin+Prothioconazole EC 200	Cereals	> 160.3	1650*	< 10.3	50
Fluoxastrobin	Cereals	> 129.1	150	< 1.2	50
Fluoxastrobin+Prothioconazole EC 200	Onions	> 160.3	1375*	< 8.6	50
Fluoxastrobin	Onions	> 129.1	125	< 1.0	50

* based on a product density of 1.100 g/mL

The hazard quotients for oral exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$).

Table CP 10.3.1- 5: Hazard quotients for bees – contact exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Fluoxastrobin+Prothioconazole EC 200	Cereals	> 200	1650*	< 8.3	50
Fluoxastrobin	Cereals	> 100	150	< 1.5	50
Fluoxastrobin+Prothioconazole EC 200	Onions	> 200	1375*	< 6.9	50
Fluoxastrobin	Onions	> 100	125	< 1.3	50

* based on a product density of 1.100 g/mL

The hazard quotients for contact exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$).

Further considerations for the risk assessment

In addition to acute laboratory studies with adult honey bees, fluoxastrobin was further subjected to topical acute bumble bee testing ([redacted]; 2014; M-512437-01-1; in CA 8.3.1.1.2). The study resulted in an LD_{50} of > 100 µg a.s./bumble bee and did not reveal sensitivity differences between honey bee and bumble bee foragers.

Moreover, fluoxastrobin was further subjected to chronic laboratory testing with adult honey bees ([redacted]; 2015; M-534974-01-1; in CA 8.3.1.2).
This chronic study was designed as a dose-response test by exposing adult honey bees for 10 consecutive days to nominal concentration of 208, 417, 833, 1667 and 3333 mg fluoxastrobin/kg feeding solution, respectively. The actual test was conducted by using the formulated product Fluoxastrobin FS 480. After exposing honey bees for ten consecutive days exclusively to sugar solution containing fluoxastrobin, the 10 day LC_{50} (Lethal Concentration) was determined to be > 3333 mg fluoxastrobin/kg, which corresponds to a LDD_{50} (Lethal Dietary Dose) of >73.3 µg a.s./bee/day. The respective NOEC (No Observed Effect Concentration) for mortality was determined to be 1667 mg fluoxastrobin/kg, which corresponds to the NOEDD (No Observed Effect Dietary Dose) of 39.2 µg a.s./bee/day.

In order to reveal whether fluoxastrobin poses a risk to immature honey bee life stages, a bee brood feeding study ([redacted]; 2013; M-476181-01-1, in CA 8.3.1.3) has been conducted by following the provisions/method of [redacted]. (OEPP/EPPO Bulletin 22:613-616 (1992)), which require, amongst other parameters to *"...use formulated products only... products are fed at a concentration recommended for high-volume use..."*. The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology.
This particular study was conducted with Fluoxastrobin FS 480. The administration of fluoxastrobin at a concentration of 0.375 g a.s to honeybee colonies via feeding of 1 litre spiked sucrose solution has neither resulted in adverse effects on brood development, worker or pupal mortality compared to the control. Regarding brood development, the brood termination rates of the test item treatment were overall on a low level with 7.1, 9.1 and 11.3% for eggs, young larvae and old larvae, respectively, which were not statistically significant different to the control with brood termination rates of 9.6, 24.4 and 3.3% for eggs, young larvae and old larvae, respectively at the end of the brood observation period.

In order to clarify whether fluoxastrobin poses a risk to honey bee brood and colony development in particular as well as on honey bees in general under realistic worst-case conditions, a higher tier semi-field honey bee brood study (according to the provisions of the OECD Guidance Document 75) was conducted under forced/confined exposure conditions using the formulation Fluoxastrobin EC 100, by application of 150 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* ([redacted]; 2015; M-515147-01-1; in CA 8.3.1.3).
The study included three treatment groups: Control (tap water), Test item (150 g a.s./ha and Reference item (300 g fenoxycarb/ha) with all applications being carried out with a spray volume of 400 L water/ha. For all treatment groups, four replicates (tunnels) were set up. The application of all treatments was conducted during daily bee flight activity at the time of full flowering of the crop. Thereafter, the bees were kept for 7 days within the tunnels (confined exposure phase) and were then relocated out of the tunnels and transferred to a monitoring site without flowering crops and intensive agricultural area for further monitoring (day 8 to day 28 after treatment). Throughout the confined exposure phase, mortality of worker bees, larvae and pupae was assessed daily along with assessments of foraging activity and behaviour. Daily mortality assessments were continued along with behaviour

around the hive during the post-exposure observation period (day 8 to day 28 after treatment). Colony assessments (food stores, brood areas, colony strength) were made before confinement, after confinement and at the end of the study. Detailed brood assessments (brood termination rate, brood index and brood compensation index) by employing digital photo imaging technology, investigating the fate of more than 200 individually marked cells was performed on 5 occasions throughout the study, covering an entire brood cycle of honey bees.
The application of fluoxastrobin at the rate of 150 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* did not cause any adverse effects on mortality, flight intensity (except for a short term reduction in flight activity on the day of application), brood development (brood termination rate: 35.5%, brood index: 3.2, compensation index: 3.9 in test item compared to the control with brood termination rate: 30.0%, brood index: 3.5, compensation index: 4.0), as well as on colony strength and condition. Neither brood termination rate nor brood or compensation index were significantly different in the test item as compared to the control, indicating that these indices performed comparable to the control, including compensations of previous brood losses.

All in all, it can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.* and OECD Guidance Document 75) investigating side-effects on immature honey bee life stages, that fluoxastrobin is of low general intrinsic toxicity to honey bees.

Synopsis
Fluoxastrobin is of low acute toxicity to honey bees, with LD_{50} (oral and contact) above the highest tested dose levels.
The calculated Hazard Quotients for fluoxastrobin are below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be expected at the maximum envisaged application rate. This conclusion is confirmed by the results of the bee brood feeding study as well as by the results of the bee brood semi-field study, which covered the maximum application rate of 150 g a.s./ha.
The acute laboratory study conducted with bumble bees revealed no sensitivity differences between honey bee and bumble bee foragers.
It can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.*) and bee brood semi-field study (OECD 75), investigating side-effects on immature honey bee life stages that fluoxastrobin is of low general intrinsic toxicity to honey bees.
Regarding potential side effects of fluoxastrobin on immature honey bee life stages, the conducted bee brood feeding study ([redacted] *et al.*, 1992) found no statistically significant differences between test item and control in brood termination rates of eggs, young and old larvae at 0.375 g a.s./L. Overall the study revealed no adverse effects on the survival of adult bees and pupae. Thus, when considering the severity of the exposure situation in this worst-case screening test in combination with the absence of effects on the overall development of bee brood, it can be concluded even on the basis of this worst-case screening study that the use of fluoxastrobin does not pose an unacceptable risk for adult honey bees, immature honey bee life stages and honey bee colonies.
In order to clarify whether the conclusions on the basis of lower tiered honey bee studies are correct, fluoxastrobin was subjected to confined semi-field testing (according to the provisions of OECD Guidance Document No. 75) by applying the two rates of 150 g a.s./ha to full-flowering *Phacelia* during honey bees actively foraging on the crop. This study design is from an apidological and apicultural point of view more realistic than an in-hive feeding of the test compound via a treated sugar solution, which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration). The results of this higher tier semi-field study confirmed the conclusions made above on the basis of the outcome of the lower-tiered studies, as no adverse direct or delayed effects on mortality of worker bees or pupae, foraging activity, behaviour, colony

strength and colony development as well as the development of bee brood were observed, even under aggravated, forced exposure conditions and by digitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.

Conclusions

Overall, it can be concluded that fluoxastrobin, when applied in cereals at the maximum application rate of 150g a.s./ha and in onions at the maximum rate of 125 g a.s./ha, as foreseen for the use of Fluoxastrobin + Prothioconazole EC 200, does not pose an unacceptable risk to honey bees and honey bee colonies.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

In the course of the application the study M-080740-01-1, performed with the previous FXA+PTZ EC 200 formulation, was mistakenly added to list of studies to be submitted in the supplemental dossier. Meanwhile, the respective formulation was replaced by a new FXA+PTZ EC 200 recipe and which was finally tested for acute oral toxicity in bees to provide a valid endpoint within this supplemental dossier and resulting in document M-434002-01-1 and summarised hereunder. Thus, the study M-080740-01-1 is not relevant.

Report:	KCP 10.3.1.1.1/01 [redacted].; 2012; M-434002-01-1
Title:	Effects of fluoxastrobin + prothioconazole EC 200 (100+100) G (Acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.:	73291035
Document No.:	M-434002-01-1
Guideline(s):	OECD Guideline 213/214 for the Testing of Chemicals on Honeybee, Acute Oral/Contact Toxicity Test, adopted on 21st September 1998.
Guideline deviation(s):	none
GLP/GEP:	**yes**

Objective:

The purpose of this study was to determine the acute contact and oral toxicity of Fluoxastrobin + Prothioconazole EC 200 to the honey bee (*Apis mellifera* L.).
Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

Materials and Methods:

Test substance: Fluoxastrobin + Prothioconazole EC 200 (100+100) G; Short code: FXA + PTZ EC 200 (100+100) G; Batch ID: 2012-001071; Sample description: TOX09674-00; Material No.: 80485182; Specification No.: 102000025822-01; active ingredients (analysed content): 9.21 % w/w (101.3 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.13 % w/w (100.4 g/L) prothioconazole (JAU 6476); Certificate of analysis code (workorder): 12002722; Density: 1.100 g/mL (20°C).

Test units were stainless steel cages of 10 cm x 8.5 cm x 5.5 cm (length x height x width). 10 bees were used per test unit. For the contact toxicity test, 5 test units were used per test item dose level, control and reference item dose level, respectively (limit test). For the oral toxicity test, 3 test units were used per test item dose level, control and reference item dose level, respectively (dose response test). 50 female worker bees (*Apis mellifera*) were exposed for 48 hours to a single dose of 200.0 µg product/bee by topical application (contact limit test) and 30 female worker bees (*Apis mellifera*) were

exposed for 48 hours to doses of 160.3, 78.0, 39.4, 19.8 and 9.9 µg product per bee by feeding (oral dose response test, value based on the actual intake of the test item).
For the contact test a single 5 µL droplet of Fluoxastrobin + Prothioconazole EC 200, dissolved in tap water with 0.5 % Adhäsit, was placed on the dorsal bee thorax, likewise for the toxic reference (dimethoate) and the control (tap water). For the oral test aqueous stock solutions of the test item and reference item were prepared and mixed with ready-to-use sugar syrup (30 % sucrose, 31 % glucose, 39 % fructose) at a concentration of 50 % (w/w). For the control, tap water and sugar syrup was used at the same ratio 50% (w/w) tap water, 50% (w/w) ready-to-use sugar syrup. The treated food was offered in syringes, which were weighed before and after introduction into the cages. After a maximum of 6 hours, the uptake was complete (duration of uptake was between 35 minutes and 6 hours) and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.
The number of dead bees was determined after 4 (± 0.5 h) hours (first day), 24 and 48 (± 2 h) hours. Behavioural abnormalities (e.g. vomiting, apathy, intensive cleaning) were assessed after 4 (± 0.5 h) hours (first day), 24 and 48 (± 2 h) hours. Temperature during the test was 25 °C; relative humidity was 50 - 75%. Bees were kept in darkness (except during observation).

Dates of work: April 17, 2012 to May 09, 2012

Findings:

Validity Criteria:

Validity Criteria		**Recommended**	**Obtained**
Control Mortality	Contact Test		
	CO_2/water control	< 10%	0.0 %
	Oral Test		
	Tap water/ syrup control	< 10%	0.0 %
LD_{50} of Reference Item (24 h)	Contact Test		
		0.10 - 0.30 µg a.s./bee	0.26 µg a.s./bee
	Oral Test		
		0.10 - 0.35 µg a.s./bee	0.12 µg a.s./bee

The contact and oral test is considered valid as the control mortality in each case was < 10% and the LD_{50} values obtained with the reference item (dimethoate) were within the required ranges.

Biological results:

Contact test:

At the end of the contact toxicity test (48 hours after application), 2.0 % mortality occurred at 200.0 µg product/bee. There was no mortality in the control group (water + 0.5 % Adhäsit).
One bee was found apathetic during the 4 and 24-hours assessment, respectively. This was the only occurrence of test item related behavioural impairments in the contact test.

Oral test:

The test item was offered to the bees at oral doses of 160.3, 78.0, 39.4, 19.8 and 9.9 µg product/bee. Mortality occurred only at the highest dose level of 160.3 µg product/bee, where 16.7 % of the bees were found dead at the end of the test (after 48 hours). No mortality occurred at the other dose levels (78.0, 39.4, 19.8 and 9.9 µg product/bee), as well as in the control group, respectively.

During the 24-hours assessment one bee showed movement coordination problems in the highest dose groups (i.e. at the actual dose of 160.3 µg product/bee). No further test item related behavioural abnormalities occurred.

Table CP 10.3.1.1.1- 1: Toxicity to honey bees; laboratory tests

Test Item	Fluoxastrobin + Prothioconazole EC 200	
Test Object	*Apis mellifera*	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (sugar solution)
Application rate µg product/bee	200.0	160.3, 78.0, 39.4, 19.8 and 9.9
LD_{50} µg product/bee	24 hours: > 200.0 48 hours: > 200.0	24 hours: > 160.3 48 hours: > 160.3
LD_{20} µg product /bee	24 hours: > 200.0 48 hours: > 200.0	24 hours: > 160.3 48 hours: > 160.3
LD_{10} µg product /bee	24 hours: > 200.0 48 hours: > 200.0	24 hours: > 160.3 48 hours: > 160.3
NOED µg product /bee*	24 hours: > 200.0 48 hours: > 200.0	24 hours: > 160.3 48 hours: > 160.3

* The NOED was estimated using Fisher Exact Test (pairwise comparison, one-sided greater, α = 0.05).

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.26 and 0.12 µg a.s./bee, respectively.

Conclusions:

The toxicity of Fluoxastrobin + Prothioconazole EC 200 was tested in both an acute contact limit test and an acute oral toxicity dose response test on honey bees.
The contact LD_{50} (48 h) was > 200 µg product/bee. The oral LD_{50} (48) was > 160.3 µg product/bee, respectively.

CP 10.3.1.1.2 Acute contact toxicity to bees

The acute contact toxicity studies on honey bees with the product are summarised in Point 10.3.1.1.1, therefore only the results are summarised below.

In the course of the application the study M-080740-01-1, performed with the previous FXA+PTZ EC 200 formulation, was mistakenly added to list of studies to be submitted in the supplemental dossier. Meanwhile, the respective formulation was replaced by a new FXA+PTZ EC 200 recipe and which was finally tested for acute oral toxicity in bees to provide a valid endpoint within this supplemental dossier and resulting in document M-434002-01-1 and summarised hereunder. Thus, the study M-080740-01-1 is not relevant.

Report:	KCP 10.3.1.1.2/01 [redacted],; 2012; M-434002-01-1
Title:	Effects of fluoxastrobin + prothioconazole EC 200 (100+100) G (Acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.:	73291035
Document No.:	M-434002-01-1
Guideline(s):	OECD Guideline 213/214 for the Testing of Chemicals on Honeybee, Acute Oral/Contact Toxicity Test, adopted on 21st September 1998.
Guideline deviation(s):	none
GLP/GEP:	**yes**

Table CP 10.3.1.1.2- 1: Toxicity to honey bees; laboratory tests

Test Item	Fluoxastrobin + Prothioconazole EC 200
Test Object	*Apis mellifera*
Exposure	contact (solution in Adhäsit (0.5 %)/water)
Application rate µg product/bee	200.0
LD_{50} µg product/bee	24 hours: > 200.0 48 hours: > 200.0
LD_{20} µg product /bee	24 hours: > 200.0 48 hours: > 200.0
LD_{10} µg product /bee	24 hours: > 200.0 48 hours: > 200.0
NOED µg product /bee*	24 hours: > 200.0 48 hours: > 200.0

* The NOED was estimated using Fisher Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).

Additionally, an acute contact toxicity study was conducted on bumble bees with fluoxastrobin; the corresponding summary is provided in Document MCA, Section 8.3.1.1.2 ([redacted]; 2014; M-512437-01-1; in CA 8.3.1.1.2).

CP 10.3.1.2 Chronic toxicity to bees

A 10 day chronic oral toxicity study was conducted with fluoxastrobin; the corresponding summary is provided in Document MCA, Section 8.3.1.2 ([redacted]; 2015; M-534974-01-1).

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A honey bee brood feeding study according to the method of [redacted] *et al.* 1998 ([redacted]; 2013; M-476181-01-1) has been conducted with Fluoxastrobin FS 480 and is included in Document MCA, Section 8.3.1.3.
A semi-field honey bee brood study (according to OECD 75) ([redacted]; 2015; M-515147-01-1) has been conducted with the Fluoxastrobin EC 100 and is included in Document MCA, Section 8.3.1.3.

CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess “sub-lethal effects” in honey bees. However, in each laboratory study as well as in any higher-tier study, sub-lethal effects, if occurring, are described and reported.

CP 10.3.1.5 Cage and tunnel tests

Based on the findings presented above, a study with the formulated product is not required.

CP 10.3.1.6 Field tests with honeybees

Based on the findings presented above, a study with the formulated product is not required.

CP 10.3.2 Effects on non-target arthropods other than bees

Toxicity tests on non-target arthropods were conducted with Fluoxastrobin + Prothioconazole EC 200 on the sensitive standard species *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata* and *Chrysoperla carnea*. A summary of the results is provided in the table below.

Table CP 10.3.2- 1: FXA + PTZ EC 200: Ecotoxicological endpoints for arthropods other than bees

Test species, Dossier-File-No., Reference	Tested Formulation, Study Type, Duration, Exposure	Ecotoxicological Endpoint		
Aphidius rhopalosiphi	FXA+PTZ EC 200	LR_{50} > 6750 mL product/ha		
M-438699-01-1	Extended lab., exposure on	ER_{50} > 6750 mL product/ha		
Rep. no: CW12/028	potted barley seedlings	Corr. Mortality [%]	Effect on Reproduction [%]	
[redacted], 2012a	375 mL product/ha	0	9.8	
KCP 10.3.2.2	750 mL product/ha	0	12.5	
	1500 mL product/ha	10.0	-12.8[A]	
	3000 mL product/ha	13.3	32.4	
	6750 mL product/ha	16.7	1.1	
Typhlodromus pyri	FXA+PTZ EC 200	LR_{50} 4537.8 mL product/ha		
M-437028-01-1	Extended lab., exposure on	ER_{50} < 3000 mL product/ha		
Rep. no: CW12/009	detached maize leaves	Corr. Mortality [%]	Effect on Reproduction [%]	
[redacted], 2012b	375 mL product/ha	-3.6[B]	10.9	
KCP 10.3.2.2	750 mL product/ha	6.0	14.2	
	1500 mL product/ha	-2.4[B]	29.6	
	3000 mL product/ha	28.9	34.6	
	6750 mL product/ha	72.3	n.a.	
Coccinella septempunctata	FXA+PTZ EC 200	LR_{50} 4774.4 mL product/ha		
M-440859-01-1	Extended lab., exposure on	no effect on reproduction at 3000 mL product/ha		
Rep. no: CW12/029	detached maize leaves	Corr. Mortality [%]	Eggs/Female/Day	Hatching [%]
[redacted], 2012c	Control	-	10.7	96.2
KCP 10.3.2.2	375 mL product/ha	-6.3	8.5	91.7
	750 mL product/ha	-3.1	8.0	87.7
	1500 mL product/ha	-12.5	9.1	89.6
	3000 mL product/ha	3.1	19.5	87.1
	6750 mL product/ha	84.4	n.a.	n.a.
Chrysoperla carnea	FXA+PTZ EC 200	LR_{50} 703.4 mL product/ha		
M-437029-01-1	Extended lab., exposure on	no effect on reproduction at 1500 mL product/ha		
Rep. no: CW12/010	detached maize leaves	Corr. Mortality [%]	Eggs/Female/Day	Hatching [%]
[redacted], 2012d	Control	-	24.8	87.3
KCP 10.3.2.2	375 mL product/ha	7.9	33.7	86.5
	750 mL product/ha	60.5	33.8	85.3
	1500 mL product/ha	92.1	n.a.	n.a.
	3000 mL product/ha	97.4	n.a.	n.a.
	6750 mL product/ha	100.0	n.a.	n.a.

Test species, Dossier-File-No., Reference	Tested Formulation, Study Type, Duration, Exposure	Ecotoxicological Endpoint		
Chrysoperla carnea M-449297-01-1 Rep.Nr: CW12/045 [redacted], 2013 KCP 10.3.2.2	FXA + PTZ EC 200 Aged residues, spray deposits on maize plants, 2 appl. of 1.5 L prod/ha, 14 d spray interval			
	Residues aged for 0 d:	Corr. Mortality [%]	Eggs/ Female/Day	Hatching [%]
	Control	-	n.a.	n.a.
	2 x 1.5 L prod./ha	64.9	n.a.	n.a.
	Residues aged for 14 d:			
	Control	-	24.1	81.3
	2 x 1.5 L prod./ha	0.2	26.4	78.2
	Residues aged for 28 d:			
	Control	-	24.0	75.8
	2 x 1.5 L prod./ha	7.7	24.7	79.4
	Residues aged for 42 d:			
	Control	-	n.a.	n.a.
	2 x 1.5 L prod./ha	-8.6^{B}	n.a.	n.a.

^{A}: A negative value indicates a higher reproduction rate in the treatment than in the control.
^{B}: A negative value indicates a lower mortality in the treatment than in the control.
n.a.: Not assessed

The tier 2 extended laboratory data indicate a higher sensitivity of *C. carnea* (LR_{50} = 703.4 mL product/ha) whereas the toxicity to *A. rhopalosiphi*, *T. pyri* and *C. septempunctata* was significantly lower. Therefore, an aged residue study was conducted with the species *C. carnea* for the refinement of the in-field risk assessment.

Tier 2 risk assessment

Since extended laboratory studies are available for 4 non-target arthropod species no tier 1 laboratory studies were conducted. Therefore, the tier 1 risk assessment has been skipped and a tier 2 risk assessment based on the extended lab data is provided below.

Potential exposure

The exposure scenario is based on the intended uses in cereals with an application rate of 2 x 1500 mL prod./ha, at a minimum interval of 14 days, and in onions with an application rate of 2 x 1250 mL prod./ha, at a minimum interval of 10 days.

According to ESCORT2 and the Terrestrial Guidance Document the exposure is calculated as:
In-field: Application rate * MAF
Off-field: Application rate * MAF * (drift factor / VDF) *correction factor

<u>Application rates</u>: 2 x 1500 mL/ha (cereals), 2 x 1250 mL/ha (onions)
<u>Drift factor</u> = 2.38% (field crops, 1 m distance, 2 applications, 82nd percentile; ESCORT2)
<u>MAF</u> (multiple application factor) = 1.7 for cereals and onions (default value for 2 applications; ESCORT2)
<u>VDF</u> (vegetation distribution factor) = 10 (default value as recommended by the Terrestrial Guidance Document, to take into account the 3-dimensional structure of the off-field vegetation; in can only be applied in the context of 2D test systems)
<u>Correction factor</u> = 5 (default value for tier 2 risk assessment according to the Terrestrial Guidance Document)

Table CP 10.3.2- 2: Exposure calculation for in-field assessment

Crop / no. of applications	Appl. rate [mL/ha]	MAF	in-field $PEC_{max.}$ [mL/ha]
Cereals / 2	1500	1.7	2550
Onions / 2	1250	1.7	2125

Table CP 10.3.2- 3: Corrected exposure for off-field risk assessment

Crop	Appl. rate [mL/ha]	MAF	Drift [%]	Veg. distr. factor	Correction factor	off-field $PEC_{max.}$ [mL/ha]	Remark
Cereals	1500	1.7	2.38	-	5	303	in case of 3-D study design
Cereals	1500	1.7	2.38	10	5	30.3	in case of 2-D study design
Onions	1250	1.7	2.38	-	5	253	in case of 3-D study design
Onions	1250	1.7	2.38	10	5	25.3	in case of 2-D study design

Tier 2 in-field risk assessment

Table CP 10.3.2- 4: In-field risk assessment based on study results from extended laboratory studies

Crop	Test Species	in-field $PEC_{max.}$ [mL/ha]	LR_{50}; ER_{50} [mL/ha]	Trigger	Refinement required?
Cereals	*A. rhopalosiphi*	2550	> 6750	Effects are < 50%	no
	T. pyri	2550	>3000	Effects are < 50%	no
	C. septempunctata	2550	>3000	Effects are < 50%	no
	C. carnea	2550	703.4	Effects are < 50%	**yes**
Onions	*A. rhopalosiphi*	2125	> 6750	Effects are < 50%	no
	T. pyri	2125	>3000	Effects are < 50%	no
	C. septempunctata	2125	>3000	Effects are < 50%	no
	C. carnea	2125	703.4	Effects are < 50%	**yes**

The tier 2 in-field risk assessment for *A. rhopalosiphi*, *T. pyri*, and *C. septempunctata* indicates an acceptable risk for non-target arthropods but the risk assessment for *C. carnea* indicates that a further refinement is needed for both scenarios (2 x 1500 mL product/ha and 2 x 1250 mL product/ha).

Refined in-field risk assessment

The results of the tier 2 risk assessment indicate that initial effects on non-target arthropod species with sensitivity similar to *Chrysoperla carnea* cannot be excluded. According to the Terrestrial Guidance Document the potential for recovery needs to be demonstrated. For this purpose an aged residue study with *Chrysoperla carnea* ([redacted],; 2013; M-449297-01-1). The results of the aged residue study (application of 2 x 1500 ml a.s./ha with a 14-day interval) indicated effects of 64.9% on mortality after the second application. However, after an aging period of 14 days the mortality effects declined to values of 0.2%. The results of the reproduction assessment indicated that there were also no adverse effects on reproduction after day 14. These findings were confirmed by the assessment after 28 days. The data indicate that the potential for recovery is given after the intended 2 applications in cereals and onions.

Therefore, it can be concluded that no unacceptable adverse effects on non-target arthropods are expected in the in-field area from the applications of FXA + PTZ EC 200 according to the proposed use pattern.

Tier 2 off-field risk assessment

Table CP 10.3.2- 5: Off-field risk assessment based on study results from extended laboratory studies

Crop	Test Species	off-field $PEC_{max.}$, [mL/ha]	LR_{50}; ER_{50} [mL/ha]	Trigger	Refinement required?
Cereals	*A. rhopalosiphi*	303*	> 6750	Effects are < 50%	no
	T. pyri	30.3	>3000	Effects are < 50%	no
	C. septempunctata	30.3	>3000	Effects are < 50%	no
	C. carnea	30.3	703.4	Effects are < 50%	no
Onions	*A. rhopalosiphi*	253*	> 6750	Effects are < 50%	no
	T. pyri	25.3	>3000	Effects are < 50%	no
	C. septempunctata	25.3	>3000	Effects are < 50%	no
	C. carnea	25.3	703.4	Effects are < 50%	no

* Off-field PEC for 3D-Study design. Potted barley seedlings

For *T. pyri*, *A. rhopalosiphi*, *C. septempunctata* and *C. carnea* no effects > 50% neither on mortality nor on reproduction were observed in extended laboratory studies on natural substrate at exposure rates relevant for the off-crop risk assessment (see Table CP 10.3.2- 1). Therefore, it can be concluded that no unacceptable risks for non-target arthropods in the off-field area is to be expected from the use of the product according to the proposed use patterns.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Since extended laboratory studies are available for 4 non-target arthropod species no tier 1 laboratory studies were conducted.

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Report:	KCP 10.3.2.2/01 [redacted],; 2012; M-438699-01-1
Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using an extended laboratory test on barley - fluoxastrobin + prothioconazole EC 200 (100 + 100 g/L)
Report No.:	CW12/028
Document No.:	M-438699-01-1
Guideline(s):	EU Directive 91/414/EEC, Regulation (EC) No. 1107/2009, [redacted] ET AL. (2000), [redacted] ET AL. (2009), [redacted] ET AL. (2001), US EPA OCSPP Not Applicable
Guideline deviation(s):	not specified
GLP/GEP:	**yes**

Material and methods:

The emulsifiable concentrate formulation Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch ID: 2012-001071 [analysed content of active ingredients: Fluoxastrobin 101.3 g/L, Prothioconazole 100.4 g/L]; density: 1.100 g/mL.

The test item was applied on barley seedlings (*Hordeum vulgare*) at rates of 375, 750, 1500, 3000 and 6750 mL product/ha and the effects on the parasitoid wasp *Aphidius rhopalosiphi* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 7.3 mL product/ha (3 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.

Mortality of 30 female wasps, not older than 48 h at study start (6 replicates with 5 wasps per test group), was assessed 2, 24 and 48 h after exposure.

Repellency of the test item was assessed during the initial 3 hours after the release of the females. Five separate observations were made at 30 - minute intervals starting 15 - 30 minutes after the introduction of all wasps. An additional repellency assessment was conducted 24 hours after the release of the wasps into the exposure units for the control group and the test group of the highest test item rate of 6750 mL product/ha.

From the water control and all application rates, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley seedlings infested with *Rhopalosiphum padi* for a period of 24 h. The number of mummies was assessed 12 days later.

The climatic test conditions during the study were: 19.0 - 22.0 °C temperature and 60 - 90% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 438 - 1189 Lux in the mortality phase, 836 - 2540 Lux in the parasitation phase and 5290 - 19050 Lux in the reproduction phase of the study.

Dates of experimental work: May 14 – May 29, 2012

Findings:

Validity criteria:

	Validity criteria	Finding
Mortality in water control	≤ 10 %	0 %
Corrected mortality reference item	≥ 50 %	93.3 %
Mean reproduction per female in water control	≥ 5	23.5
Number of wasps in the water control producing zero values for reproduction	≤ 2	0

The results of this study can be considered as valid.

Biological findings:
Mortality, reproduction and repellency in each of the treatments are summarized below:

Table CP 10.3.2.2- 1: Effects of Fluoxastrobin + Prothioconazole EC 200 on mortality and reproduction of *Aphidius rhopalosiphi*

Test item:		Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)						
Test organism:		*Aphidius rhopalosiphi*						
Exposure on:		Barley seedlings						
		Mortality after 48 h [%]			Reproduction		Repellency (first 3 h)	
Treatment	mL prod ./ha	Uncorr.	Corr.	P-Value(*)	Rate (mummies per female)	Red. rel. to Control [%] P-Value(#)	% Wasps on plant	Red. rel. to Control [%] P-Value(##)
Control	0	0.0			23.5	0	48.2	
Test item	375	0.0	0.0	1.000 n.sign.	21.2	9.8 0.938 n.sign.	54.8	-13.8 0.187 n.sign.
Test item	750	0.0	0.0	1.000 n.sign.	20.5	12.5 0.813 n.sign.	49.3	-2.4 0.749 n.sign.
Test item	1500	10.0	10.0	0.356 n.sign.	26.5	-12.8 0.427 n.sign.	52.7	-9.3 0.368 n.sign.
Test item	3000	13.3	13.3	0.225 n.sign.	15.9	32.4 0.095 n.sign.	45.8	5.0 0.577 n.sign.
Test item	6750	16.7	16.7	0.130 n.sign.	23.2	1.1 0.827 n.sign.	18.8	60.9 < 0.001 sign.
Reference item	7.3	93.3	93.3		n.a.	n.a.	49.0	-1.7

LR_{50}: > 6750 mL product/ha
ER_{50}: > 6750 mL product/ha
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
one-way ANOVA, Dunnett test (one-sided)
n.a. not assessed n.sign. not significant sign. significant

Observations:

Repellent effects of the test item were observed for the highest rate of 6750 mL product/ha in the first 3 hours after the introduction of the wasps into the exposure units. At the assessment 24 hours after the introduction of the wasps, a mean of 36.7% of the wasps were found on the plants in the group treated with 6750 mL product/ha compared to 50.0% in the control group.

Conclusion:

The LR_{50} was estimated to be > 6750 mL product/ha. The ER_{50} was estimated to be > 6750 mL product/ha. The figures obtained fulfil the validity criteria of the extended laboratory method (Mead-Briggs *et al.*, 2009).

Report:	KCP 10.3.2.2/02 [redacted]s; 2012; M-437028-01-1
Title:	Toxicity to the predatory mite Typhlodromus pyri [redacted] using an extended laboratory test on maize - fluoxastrobin + prothioconazole EC 200 (100 + 100 g/L) - Final report
Report No.:	CW12/009
Document No.:	M-437028-01-1
Guideline(s):	EU Directive 91/414/EEC, Regulation (EC) No. 1107/2009, [redacted] ET AL. (2000) modified, [redacted] ET AL. (2001), US EPA OCSPP Not Applicable
Guideline deviation(s):	Use of natural substrate (detached bean leaves) instead of glass plate;
GLP/GEP:	**yes**

Material and methods:

The emulsifiable concentrate Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX09674-00; specification no.: 102000025822-01; batch ID: 2012-001071 [analysed content of active ingredient: Fluoxastrobin 101.3 g/L, Prothioconazole 100.4 g/L]; density: 1.1 g/mL.

The test item was applied onto detached maize leaves (*Zea mays*) at rates of 375, 750, 1500, 3000 and 6750 mL product/ha and the effects on the predatory mite *Typhlodromus pyri* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 36.4 mL product/ha (15 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.

Mortality of 100 predatory mites, protonymphs at study start (5 replicates with 20 individuals per test group), was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed.

The reproduction rate of surviving mites was then evaluated for the 4 lowest test rates from day 7 until day 14 after treatment by counting the total number of offspring (eggs and larvae) produced.

The climatic test conditions during the study were 24.0 - 25.5 °C temperature and 60 - 71% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 846 - 1415 Lux.

Dates of experimental work: March 22 – April 05, 2012

Findings:

Validity criteria:

	Validity criteria	Finding
MortEsc.-rate in the control group on day 7	≤ 20 %	17 %
Average corrected mortality in the reference item	≥ 50 %	100 %
Average number of eggs/female (calculated as sum of 4 assessment dates – from day 7 on) in the control group	≥ 4	4.6

The results of this study can be considered as valid.

Biological findings:

The mortality / escaping rate in the control exposure units up to day 7 after treatment was 17%. The mean corrected mortality of the mites and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

Table CP 10.3.2.2- 2: Effects of Fluoxastrobin + Prothioconazole EC 200 on mortality and reproduction of *Typhlodromus pyri*

Test item:		Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)					
Test organism:		*Typhlodromus pyri*					
Exposure on:		Detached maize leaves					
		Mortality after 7 days [%]			Reproduction		
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Rate (eggs per female)	Red. rel. to Control [%]	P-Value (#)
Control	0	17.0			4.6		
Test item	375	14.0	-3.6	1.000 n.sign.	4.1	10.9	0.338 n.sign.
Test item	750	22.0	6.0	0.713 n.sign.	3.9	14.2	0.623 n.sign.
Test item	1500	15.0	-2.4	1.000 n.sign.	3.2	29.6	0.150 n.sign.
Test item	3000	41.0	28.9	<0.001 sign.	3.0	34.6	0.142 n.sign.
Test item	6750	77.0	72.3	<0.001 sign.	n.a.	n.a.	
Reference item	36.4	100.0	100.0		n.a.	n.a.	

LR_{50}: 4537.8 mL product/ha; 95 % Confidence Interval: 3517.9 - 5730.7 (calculated with Probit analysis)
ER_{50}: >3000 mL product/ha
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed; n.sign. not significant; sign. significant

Conclusions:

The LR_{50} was calculated to be 4537.8 mL product/ha. The LR_{50} was estimated to be >3000 mL product/ha. The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates.

Report: KCP 10.3.2.2/03 [redacted]., 2012; M-440859-01-1
Title: Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) in an extended laboratory test on maize Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)
Report No.: CW12/029
Document No.: M-440859-01-1
Guideline(s): [redacted] ET AL. (2000) modified: Use of natural substrate (apple leaves) instead of glass plate; [redacted] ET AL. (2001)
Guideline deviation(s): not specified
GLP/GEP: **yes**

Material and methods:

The emulsifiable concentrate formulation Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch ID: 2012-001071 [analysed content of active ingredients: Fluoxastrobin 101.3 g/L, Prothioconazole 100.4 g/L]; density: 1.100 g/mL. The test item was applied to detached maize leaves (*Zea mays*) at rates of 375, 750, 1500, 3000 and 6750 mL product/ha and the effects on the ladybird

beetle *Coccinella septempunctata* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 24.3 mL product/ha (10 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system. The preimaginal mortality of 40 larvae, 4 days old at study start (per test group), was assessed till the hatch of the imagines (up to 15 days). The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 17 days.
The climatic test conditions during the study were 23.5 - 27.0 °C temperature and 66 - 79% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1211 - 5254 Lux during the study.

Dates of experimental work: May 30 – July 10, 2012

Findings:

Validity criteria:

	Validity criteria	Finding
Mortality in water control	≤ 30 %	20 %
Corrected mortality reference item	≥ 40 %	100 %
Mean number of fertile eggs per female and day in water control	≥ 2	10.7

The results of this study can be considered as valid.

Biological findings:
Mortality and reproduction in each of the treatments are summarized below.

Table CP 10.3.2.2- 3: Effects of Fluoxastrobin + Prothioconazole EC 200 on mortality and reproduction of *Coccinella septempunctata*

Test item	Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)
Test organism	*Coccinella septempunctata*
Exposure on:	Detached maize leaves

Treatment	[mL product/ha]	Mortality: Uncorrected mortality [%]	Mortality: Corrected mortality [%]	P-Value (*)	Fertile eggs per female and day	Fertility (hatching rate) [%]
Control	0	20.0	-	-	10.7	96.2
Test item	375	15.0	-6.3	1.000 n. sign.	8.5	91.7
Test item	750	17.5	-3.1	1.000 n. sign.	8.0	87.7
Test item	1500	10.0	-12.5	1.000 n. sign.	9.1	89.6
Test item	3000	22.5	3.1	1.000 n. sign.	19.5	87.1

Test item	Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)
Test organism	*Coccinella septempunctata*
Exposure on:	Detached maize leaves

Treatment	[mL product/ha]	Mortality			Fertile eggs per female and day	Fertility (hatching rate)
		Uncorrected mortality [%]	Corrected mortality [%]	P-Value (*)		[%]
Test item	6750	87.5	84.8	<0.001 sign.	n.a.	n.a.
Reference item	24.3	100.0	100.0	-	n.a.	n.a.

LR_{50}: 4774.4 mL product/ha; 95 % Confidence Interval: 3594.3 – 5606.1 (calculated with Probit analysis)

* Fisher`s Exact test (one sided), p-values are adjusted according to Bonferroni-Holm

n.a. not assessed; n. sign. not significant; sign. significant

Conclusions:

The LR_{50} was calculated to be 4774.4 mL product/ha.
Reproduction was not affected up to and including the test rate of 3000 mL product/ha. The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates.

Report: KCP 10.3.2.2/04 [redacted].; 2012; M-437029-01-1
Title: Toxicity to the green lacewing Chrysoperla carnea [redacted]. using an extended laboratory test on maize - fluoxastrobin + prothioconazole EC 200 (100 + 100 g/L)
Report No.: CW12/010
Document No.: M-437029-01-1
Guideline(s): EU Directive 91/414/EEC, Regulation (EC) No. 1107/2009, [redacted] ET AL. (2000) modified, [redacted] ET AL. (2001), US EPA OCSPP Not Applicable
Guideline deviation(s): none
GLP/GEP: yes

Material and methods:

The emusifiable concentrate Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch ID: 2012-001071 [analysed content of active ingredient: Fluoxastrobin 101.3 g/L, Prothioconazole 100.4 g/L]; density: 1.100 g/mL.

The test item was applied to detached maize leaves (*Zea mays*) at rates of 375, 750, 1500, 3000 and 6750 mL product/ha and the effects on the green lacewing *Chrysoperla carnea* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 38.9 mL product/ha (16 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.

The preimaginal mortality of 40 larvae (per test group), 2 days old at study start, was assessed till the hatch of the imagines (up to 24 days). The fertility and fecundity of the surviving hatched adults were then evaluated over the period of one week.

The climatic test conditions during the study were 23.5 - 27.0 °C temperature and 60 - 82% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1510 - 2996 Lux during the mortality phase and of 2560 - 2692 Lux during the reproduction phase of the study.

Dates of experimental work: March 28 – May 02, 2012

Findings:

Validity criteria:

	Validity criteria	Finding
Mortality in water control	≤ 20 %	5.0 %
Corrected mortality reference item	≥ 50 %	94.7 %
Mean number of eggs per female and day in water control	≥15	24.8
Mean hatching rate of the eggs (fertility) in water control	≥ 70 %	87.3 %

The results of this study can be considered as valid.

Biological findings:
Mortality and reproduction in each of the treatments are summarized below.

Table CP 10.3.2.2- 4: Effects of Fluoxastrobin + Prothioconazole EC 200 on mortality and reproduction of *Chrysoperla carnea*

Test item:		Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)				
Test organism:		*Chrysoperla carnea*				
Exposure on:		Detached maize leaves				
		Mortality [%]			Reproduction	
Treatment	mL product/ha	Uncorr.	Corr.	P-Value(*)	Eggs per female and day	Fertility [hatching rate in %]
Control	0	5.0			24.8	87.3
Test item	375	12.5	7.9	0.216 n.sign.	33.7	86.5
Test item	750	62.5	60.5	<0.001 sign.	33.8	85.3
Test item	1500	92.5	92.1	<0.001 sign.	n.a.	n.a.
Test item	3000	97.5	97.4	<0.001 sign.	n.a.	n.a.
Test item	6750	100.0	100.0	<0.001 sign.	n.a.	n.a.
Reference item	38.9	95.0	94.7		n.a.	n.a.
LR_{50}: 703.4 mL product/ha, 95 % Confidence Interval: 579.9 - 830.8 (calculated with Probit analysis)						
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm n.a. not assessed; n.sign. not significant; sign. significant						

Conclusions:

The LR_{50} was calculated to be 703.4 mL product/ha.

Reproduction was not affected up to and including the test rate of 750 mL product/ha.

The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

Report:	KCP 10.3.2.2/05 [redacted],; 2013; M-449297-01-1
Title:	Toxicity to the green lacewing Chrysoperla carnea using an extended laboratory test with aged residues on maize - Fluoxastrobin + prothioconazole EC 200 (100 + 100 g/L)
Report No.:	CW12/045
Document No.:	M-449297-01-1
Guideline(s):	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP Not Applicable
Guideline deviation(s):	During the reproduction phase of the second bioassay (14DAT2) and the mortality phase of the third bioassay (28DAT2), the relative humidity drecreased to 57% for 2.5 h. This had no negative impact on the outcome of the study as all validity criteria were met
GLP/GEP:	**yes**

Materials and methods:

The emusifiable concentrate Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch ID: 2012-001071 [analysed content of active ingredients: Fluoxastrobin 101.3 g/L, Prothioconazole 100.4 g/L]; density: 1.100 g/mL.

The test item was applied two times with 1.5 L product/ha diluted in 400 L deionised water/ha on potted maize plants (Zea mays). The interval between the applications was 14 days. The control was treated with deionised water in the same way as the test item.

The toxic reference Dimethoate was applied at 0.0389 L product/ha (16 g a.s./ha) diluted in 400 L deionised water/ha on the day of the second application of the test item on potted maize plants as well. For the further exposure dates it was applied directly on detached maize leaves (with 0.0389 L product/ha diluted in 200 L deionised water). It was included to indicate the relative susceptibility of the test organisms and the test system.

Aging of the spray deposits of the test item on the potted maize plants took place under semi-field conditions with UV permeable rain protection during the first four weeks. Four bioassays were performed, the first started on the day of the second application (0DAT2 = 0 days after treatment 2) and the last one six weeks later (42DAT2).

Larvae of the green lacewing (Chrysoperla carnea) were exposed to these residues on the treated leaf surfaces and the preimaginal mortality was assessed. In the second (14DAT2) and the third (28DAT2) bioassay the fertility and fecundity of the surviving hatched adults were evaluated as well.

Dates of experimental work: July 17 – October 02, 2012

Findings:

Validity criteria:

	Validity criteria	Finding			
		Start of bioassay			
		0DAT2*	**14DAT2***	**28DAT2***	**42DAT2***
Mortality in water control	≤ 20 %	7.5 %	7.5 %	2.5 %	12.5 %
Corrected mortality reference item	≥ 50 %	64.9 %	100.0 %	100.0 %	100.0 %

	Validity criteria	Finding			
		Start of bioassay			
		0DAT2*	14DAT2*	28DAT2*	42DAT2*
Mean number of eggs per female and day in water control	≥ 15	n.a.	24.1	24.0	n.a.
Mean hatching rate of the eggs (fertility) in water control	≥ 70 %	n.a.	81.3 %	75.8 %	n.a.

* Days after treatment
n.a.: not assessed

The results of this study can be considered as valid.

Biological findings:
Mortality and reproduction in each of the treatments are summarized below.

Table CP 10.3.2.2- 5: Summary of findings of Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) applied onto potted maize plants and *Chrysoperla carnea*

Test item:	**Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)**			
Application:	2 x 1.5 L product/ha (interval of 14 days)			
Test organism:	Chrysoperla carnea			
Exposure on:	Dried spray deposits on maize leaves (from treated maize plants)			
Start bioassay:	**0DAT2[a]**	**14DAT2[a]**	**28DAT2[a]**	**42DAT2[a]**
	Preimaginal mortality (%)			
Control:	7.5	7.5	2.5	12.5
Test item:	67.5	7.7	10.0	5.0
Reference item:	67.5	100.0	100.0	100.0
	Corrected preimaginal mortality (%)			
Test item:	**64.9** (p-value < 0.001, significant[b])	**0.2** (p-value 0.650, significant[b])	**7.7** (p-value 0.179, not significant[b])	**-8.6** (p-value 0.946, not significant[b])
Reference item:	64.9	100.0	100.0	100.0
	Reproduction			
	Eggs per female and day			
Control:	n.a.	**24.1**	**24.0**	n.a.
Test item:	n.a.	**26.4**	**24.7**	n.a.
	Fertily (hatching rate in %)			
Test item:	n.a.	**81.3**	**75.8**	n.a.
	n.a.	**78.2**	**79.4**	n.a.

n.a. = not assessed; [a] DAT = days after treatment; [b] Fisher´s Exact test (one-sided); p-values adjusted according to Bonferroni-Holm;

Conclusion:

In this extended laboratory test the effects of Fluoxastrobin + Prothioconazole EC 200 (aged under semi-field conditions, with rain protection during the first four weeks) on the survival of the green lacewing *Chrysoperla carnea* were determined after application of 2 times 1.5 L product/ha with an application interval of 14 days onto maize plants (*Zea mays*).
In the first bioassay started at the day of the second application, a corrected preimaginal mortality of 64.9% was found for the test item. A second bioassay was started 14 days after the second application and showed a corrected preimaginal mortality of only 0.2% in the test item group. In the third bioassay (after 28 days) 7.7% corrected preimaginal mortality was found and in the fourth bioassay (after 42 days) no corrected preimaginal mortality (-8.6%) in the test item group occurred anymore.
Reproduction was assessed in the second and third bioassay. In both bioassays no adverse effects of the test item on the reproductive performance of the test organisms were found.
The figures obtained fulfil the validity criteria of the laboratory method for the exposure on glass plates.

CP 10.3.2.3 Semi-field studies with non-target arthropods

Semi-field studies are not required for non-target arthropods.

CP 10.3.2.4 Field studies with non-target arthropods

Field studies are not required for non-target arthropods.

CP 10.3.2.5 Other routes of exposure for non-target arthropods

The exposure of soil-dwelling non-target arthropod as assessed in chapter CP 10.3.2 is considered the main route of exposure for non-target arthropods.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestrial Ecotoxicology.

Predicted environmental concentrations used in risk assessment

Predicted environmental concentrations of the active substance and the metabolites in soil (PEC_{soil}) values were calculated and reported in MCP 9.1.3.

The relevant PEC values considered for TER calculations are summarised in the table below. Maximum values are used for risk assessments.

Table CP 10.4- 1: Maximum PEC_{soil} values

Compound	Cereals, 2 × 150 g fluoxastrobin/ha (80% interception) PEC_{soil} [mg/kg]	Onions, 2 × 125 g fluoxastrobin/ha (10% interception) PEC_{soil} [mg/kg]
Fluoxastrobin + Prothioconazole EC 200	**0.880**[A]	**3.300**[B]
Fluoxastrobin (E+Z)	**0.080**[C]	**0.306**[C]
HEC 5725-E-des-chlorophenyl	**0.019**	**0.071**
HEC 5725-carboxylic acid	**0.011**	**0.041**
2-chlorophenol	**0.009**	**0.036**

Bold values: worst case considered in risk assessment

[A] Based on formulation density of 1.100 g/mL and 2 applications at 14 d interval (no degradation between the 2 applications and 80% interception: worst case).

[B] Based on formulation density of 1.100 g/mL and 2 applications at 14 d interval (no degradation between the 2 applications and 10% interception: worst case).

[C] Including consideration of accumulation for fluoxastrobin after long-term use considering a soil mixing depth of 20 cm

CP 10.4.1 Earthworms

Table CP 10.4.1- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction	NOEC $NOEC_{corr}$	**562 mg prod./kg dws** **281[A] mg prod./kg dws**	[redacted]; 2012; M-442366-01-1 KCP 10.4.1.1
Fluoxastrobin EC 100	Earthworm, reproduction	NOEC NOEC $NOEC_{corr}$	> 1000 g a.s./ha ≥ 4.32[B] mg a.s./kg dws **≥ 2.16[A,B] mg a.s./kg dws**	[redacted] 2001; M-057395-01-1
HEC 5725-E-des chlorophenyl	Earthworm, reproduction	NOEC	**≥ 1000 mg p.m. /kg dws**	[redacted]; 2002; M-058532-01-1
HEC 5725-carboxylic acid	Earthworm, reproduction	NOEC	**90 mg p.m. /kg dws**	[redacted]; 2015; M-536000-01-1 KCA 8.4.1
2-chlorophenol	Earthworm, reproduction	NOEC	**≥ 0.216[C] mg a.s./kg dws**	EFSA Scientific Report 102 (2007)

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite

[A] Endpoint corrected by a factor of 2 due to high organic matter content of test soil and log Pow of > 2

[B] The endpoint of 1.33 mg as/kg dws listed in the EFSA Scientific Report 102 (2007) is based on the standard conversion. In the actual study the test material had been sprayed onto the soil, the recalculated endpoint according to the actual test conditions is calculated based on the actually applied test rate of 1090 g a.s./ha, test vessel surface of 198 cm^2 and test substrate of 500 g dws per test vessel

[C] for the metabolite 2-chlorophenol, in the absence of earthworm reproduction data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

Bold values: endpoints used for risk assessment

Risk assessment for earthworms

Based on the endpoints in the table above the TER values are calculated using the following equations:

$TER_{LT} = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER_{LT} is >5.

For lipophilic substances (log P_{OW} > 2) all results from the laboratory studies are corrected by a factor 2 even when the organic matter is less than 10%.
This was applied to fluoxastrobin ($logP_{ow}$ = 2.86, refer to Section 2 of the MCA document, CA 2.7).

Table CP 10.4.1- 2: TER calculations for earthworms

Compound	Species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Cereals					
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction	NOEC 281	0.880	319	5
Fluoxastrobin (E+Z)[A]	Earthworm, reproduction	NOEC ≥ 2.16	0.080	≥ 27	5
HEC 5725-E-des-chlorophenyl	Earthworm, reproduction	NOEC ≥ 1000	0.019	≥ 52 632	5
HEC 5725-carboxylic acid	Earthworm, reproduction	NOEC 90	0.011	8182	5
2-chlorophenol	Earthworm, reproduction	NOEC ≥ 0.216 [B]	0.009	≥ 24	5
Onions					
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction	NOEC 281	3.300	85	5
Fluoxastrobin (E+Z)[A]	Earthworm, reproduction	NOEC ≥ 2.16	0.306	≥ 7.1	5
HEC 5725-E-des-chlorophenyl	Earthworm, reproduction	NOEC ≥ 1000	0.071	≥ 14 085	5
HEC 5725-carboxylic acid	Earthworm, reproduction	NOEC 90	0.041	2195	5
2-chlorophenol	Earthworm, reproduction	NOEC ≥ 0.216 [B]	0.036	≥ 6	5

[A] conducted with the formulation Fluoxastrobin EC 100

[B] for the metabolite 2-chlorophenol, in the absence of earthworm reproduction data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

All TER values calculated with the worst case $PEC_{soil,max}$ values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

CP 10.4.1.1 Earthworms sub-lethal effects

Terrestrial Risk Assessment

No study on the chronic toxicity of 2-chlorophenol to earthworms is available, but some information can be taken from the chronic earthworm study with the Fluoxastrobin EC 100 formulation presented in Document MCA 8. In this study the application of 1.0 kg a.s./ha fluoxastrobin had no influence on mortality, weight development, and reproduction of earthworms after 56 days. The NOEC (28 days) based on mortality and weight of adult earthworms is 1.0 kg a.s/ha. Additionally it is a NOEC and not an LC_{50}. Assuming that 2-chlorophenol is formed and reaches its maximum between about 15 to 23 days (see Document MCA7, Point 7.1.2), the effects of this metabolite on mortality and weight of adult earthworms can be considered to be covered up to an application of 1.0 kg fluoxastrobin/ha. Since this application rate is more than 4 times higher than the actual highest use rate (onions (10% interception): 225 g fluoxastrobin/ha) it can be assumed that higher amounts of the metabolite were present in the study than would occur under practical field conditions.

Additionally, for the purpose of the earthworm risk assessment the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007)).

Report:	KCP 10.4.1.1/01 [redacted],; 2012; M-442366-01-1
Title:	Fluoxastrobin + prothioconazole EC 200A (100+100) G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil
Report No.:	kra-Rg-R-135/12
Document No.:	M-442366-01-1
Guideline(s):	OECD Guideline 222:, Earthworm Reproduction Test (Eisenia fetida / Eisenia andrei) (April 2004); ISO 11268-2: 1998(E): „Soil quality - Effects of pollutants on earthworms (Eisenia fetida) – Part 2: Determination of effects on reproduction", July 1998.
Guideline deviation(s):	not specified
GLP/GEP:	**yes**

Objective:

The purpose of this study was to assess the effect of Fluoxastrobin + Prothioconazole EC 200 on survival, growth and reproduction on the earthworm *Eisenia fetida* during an exposure in an artificial soil with 5 different test concentrations. The method of application and the test species are recommended by the international test guidelines (ISO 11268-2: 1998 (E) and OECD 222: April 13, 2004).

Material and methods:

Test item: Fluoxastrobin + Prothioconazole EC 200 (100+100) A G; Batch ID.: 2012-001071; Sample description: TOX09674-00; Material No. 80485182; Specification No.: 102000025822-01; Content: 101.3 g fluoxastrobin/L (9.21% w/w), 100.4 g prothioconazole/L (9.13% w/w); Density: 1.100 g/mL.

Adult *Eisenia fetida* (approx. 5 months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in an artificial soil (with 5 % peat content) to the nominal test concentrations of 100, 178, 316, 562 and 1000 mg test item/kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Toxic standard (Carbendazim EC 360 G): 1.25 – 2.50 – 5.00 mg a.s./kg soil d.w.; control: untreated artificial soil moistened with deionised water, solvent control: none.

Dates of experimental work: May 25, 2012 to July 27, 2012

Findings:

Validity criteria:

Validity criteria	**Recommended**	**Obtained**
Mortality of the adults in the control	≤ 10 %	0 %
Rate of reproduction of juveniles (earthworms per control vessel)	≥ 30	352.3
Coefficient of variance of reproduction in the control	≤ 30 %	16.8 %

The validity criteria of the test according to the guideline were fulfilled.

In the most recent toxic standard reference test with the reference item Carbendazim EC 360 G (Study No.: Rg 07/12; Report No. kra-Rg-R-Ref 16/12; NON-GLP, performed from February 24, 2012 to May 02, 2012), no mortality of the adult earthworms was observed 28 days after application. The change of body weight of the adult earthworms of the test concentration of 2.5 and 5.0 mg a.s./kg dry weight soil was statistically significant reduced in comparison to the control. The number of juveniles per test vessel of all test concentrations were statistically significant reduced in comparison to the control. The EC_{50} for reproduction was calculated to be 1.66 mg a.s./kg dry weight artificial soil. The confidence could not be calculated. The results of the reference test item indicated that the test system was sensitive to the reference test item,

Biological results:
Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days are shown in the following table (values in this table are rounded values).

Table CP 10.4.1.1- 1: Effects of FXA+PTZ EC 200 on *Eisenia fetida*

Test object	*Eisenia fetida*					
Test item	Control	FXA+PTZ EC 200A (100+100) G				
mg test item/kg dry weight artificial soil	---	100	178	316	562	1000
Mortality of adult earthworms [%] after 28 days	0	0	0	0	0	0
Mean change of body weight of the adults from day 0 to day 28 [%] *	31.62	32.63	26.60	24.94	24.92	20.61 *
Standard Deviation	4.42	5.28	6.62	5.36	5.13	8.55
Mean number of offspring per test vessel after 56 days **	352.3	348.5	322.0	342.8	306.8	262.5 **
Standard Deviation	59.1	68.9	27.1	18.8	47.1	19.7
Coefficient of variance (%)	16.8	19.8	8.4	5.5	15.3	7.5
% of control	---	98.9	91.4	97.3	87.1	74.5

* statistical significance compared to the control (Williams Multiple Sequential t-test, two-sided, $\alpha = 0.05$)
** statistical significance compared to the control (Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$)

Mortality
After 28 days of exposure no worms died in the control group and no mortality was observed at any test item concentration.

Effects on growth
Statistically significant different values for the growth relative to the control were observed at the highest test concentration. Therefore, based on biological and statistical significance, the NOEC related to growth was estimated to be 562 mg test item/kg dry weight artificial soil. The LOEC related to growth was 1000 mg test item/kg dry weight artificial soil.

Effects on reproduction
Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the highest test concentration of 1000 mg test item/kg dry weight artificial soil. An EC_{50} could not be calculated. Therefore, based on biological and statistical significance the NOEC related to reproduction was calculated to be 562 mg test item/kg dry weight artificial soil. LOEC related to reproduction was 1000 mg test item/kg dry weight artificial soil.

Conclusion:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is 562 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 1000 mg test item/kg dry weight artificial soil.

CP 10.4.1.2 Earthworms field studies

Not required as the risk to earthworms is acceptable.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Table CP 10.4.2- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Fluoxastrobin + Prothioconazole EC 200	*Folsomia candida*	NOEC $NOEC_{corr}$	56 mg prod./kg dws **28 mg prod./kg dws[1]**	[redacted]N; 2012; M-439959-01-1 KCP 10.4.2.1
	Hypoaspis aculeifer	NOEC $NOEC_{corr}$	≥ 316 mg prod./kg dws **≥ 158 mg prod./kg dws[1]**	[redacted]., 2012; M-441491-01-1 KCP 10.4.2.1
Fluoxastrobin	*Folsomia candida*	NOEC $NOEC_{corr}$	10 mg a.s./kg dws **5 mg a.s./kg dws[1]**	[redacted] 2001; M-081095-01-1
	Hypoaspis aculeifer[2]	NOEC	**10 mg a.s./kg dws[3]**	[redacted] 2002; M-039155-01-1
HEC 5725-E-des-chlorophenyl	*Folsomia candida*	NOEC	**≥ 100 mg p.m./kg dws**	[redacted]; 2001; M-033640-01-1
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted]; 2013; M-475673-01-1 KCA 8.4.2.1
HEC 5725-carboxylic acid	*Folsomia candida*	NOEC	**≥ 100 mg p.m.//kg dws**	[redacted].; 2014; M-479456-01-1 KCA 8.4.2.1
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted].; 2014; M-484792-01-1 KCA 8.4.2.1
2-chlorophenol	*Folsomia candida*	NOEC $NOEC_{corr}$	10 mg p.m./kg dws **5 mg p.m./kg dws[1]**	[redacted] 2013; M-472327-01-1 KCA 8.4.2.1
	Hypoaspis aculeifer	NOEC $NOEC_{corr}$	56 mg p.m./kg dws **28 mg p.m./kg dws[1]**	[redacted].; 2013; M-475688-01-1 KCA 8.4.2.1

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment
1) Corrected endpoint due to lipophilic substance (log P_{ow} > 2)
2) Endpoint derived from EC 100 formulation
3) not corrected due to low organic matter content in test substrate LUFA 2.1

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints and PEC_{soil} values used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$$TER = NOEC / PEC_{soil}$$

The risk is considered acceptable if the TER is >5.

Table CP 10.4.2- 2: TER calculations for other non-target soil meso- and macrofauna

Compound	Species	Endpoint [mg/kg]		$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Cereals						
Fluoxastrobin + Prothioconazole EC 200	*Folsomia candida*	NOEC	28	0.880	31.8	5
	Hypoaspis aculeifer	NOEC	≥ 158	0.880	≥ 179.5	5
Fluoxastrobin (E+Z)	*Folsomia candida*	NOEC	5.0	0.080	62.5	5
	Hypoaspis aculeifer	NOEC	10	0.080	125.0	5
HEC 5725-E-des-chlorophenyl	*Folsomia candida*	NOEC	≥ 100	0.019	≥ 5263	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.019	≥ 5263	5
HEC 5725-carboxylic acid	*Folsomia candida*	NOEC	≥ 100	0.011	≥ 9091	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.011	≥ 9091	5
2-chlorophenol	*Folsomia candida*	NOEC	5	0.009	556	5
	Hypoaspis aculeifer	NOEC	28	0.009	3 111	5
Onions						
Fluoxastrobin + Prothioconazole EC 200	*Folsomia candida*	NOEC	28	3.300	8.5	5
	Hypoaspis aculeifer	NOEC	≥ 158	3.300	≥ 47.9	5
Fluoxastrobin (E+Z)	*Folsomia candida*	NOEC	5.0	0.306	16.3	5
	Hypoaspis aculeifer	NOEC	10	0.306	32.7	5
HEC 5725-E-des-chlorophenyl	*Folsomia candida*	NOEC	≥ 100	0.071	≥ 1408	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.071	≥ 1408	5
HEC 5725-carboxylic acid	*Folsomia candida*	NOEC	≥ 100	0.041	≥ 2439	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.041	≥ 2439	5
2-chlorophenol	*Folsomia candida*	NOEC	5	0.036	138.9	5
	Hypoaspis aculeifer	NOEC	28	0.036	777.8	5

All TER values calculated with the worst case $PEC_{soil, max}$ values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

CP 10.4.2.1 Species level testing

Report:	KCP 10.4.2.1/01 [redacted]; 2012; M-439959-01-1
Title:	Fluoxastrobin + prothioconazole EC 200 (100+100) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil
Report No.:	FRM-COLL-149/12
Document No.:	M-439959-01-1
Guideline(s):	OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing of Chemicals - Collembolan Reproduction Test in Soil
Guideline deviation(s):	not specified
GLP/GEP:	**yes**

Objective:

The purpose of this study was to assess the effect of Fluoxastrobin + Prothioconazole EC 200 on survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil comparing control and treatment. The test was performed in accordance with the OECD Guideline 232 (2009).

Material and methods:

Test substance: Fluoxastrobin + Prothioconazole EC 200 (100+100) G; Short name: FXA + PTZ EC 200 (100+100) G; Batch No.: 2012-001071; Customer order No.: TOX 09674-00; Master recipe ID: 0117103-001; Specification No.: 102000025822-01; active ingredients (analysed content): 9.21 % w/w (101.3 g/L) fluoxastrobin (HEC 5725 E-ISO (BCS-AH45292)), 9.13 % w/w (100.4 g/L) prothioconazole (JAU 6476 (BCS-AB80325)); Density: 1.100 g/mL (20°C).

Ten collembolans (10-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 32, 56, 100, 178 and 316 mg test item/kg artificial soil dry weight at 20 ± 2°C, 400 – 800 lux, 16h light : 8h dark. During the study, they were fed with granulated dry yeast. Mortality and reproduction were determined after 28 days.

Toxic standard: 44 – 67 – 100 - 150 - 225 mg Boric acid/kg soil dry weight; control: quartz sand, solvent control: none.

Dates of experimental work: September 07, 2012 to October 09, 2012

Findings:

Validity criteria:

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	≤ 20%	9.0 %
Mean number of juveniles per replicate (with 10 colembolan introduced)	≥ 100	1184
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30%	11.9 %

In this study, all validity criteria have been fulfilled.

Reference test:
In the most recent non-GLP-test (FRM-Coll-Ref-19/12, [redacted] May 25, 2012) Boric acid showed an EC_{50} of 116 mg test item/kg artificial soil dry weight (95 % confidence limits from 98 mg to 137 mg boric acid/kg artificial soil dry weight) for reproduction according Probit analysis using maximum likelihood regression. The result is in the recommended range of the guideline (about 100 mg Boric acid/kg artificial soil dry weight).
The $NOEC_{reproduction}$ was calculated to be 67 mg Boric acid/kg artificial soil dry weight and accordingly the $LOEC_{reproduction}$ is 100 mg Boric acid/kg artificial soil dry weight according Williams-Test multiple t-test procedure, $\alpha = 0.05$, one-sided smaller.

Biological findings:
Mortality
In the control group 10.0 % of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20 % mortality. The $LC_{10, 20, 50}$ values could not be determined.

Reproduction
Concerning the number of juveniles statistical analysis (William's-t test, one-sided smaller, $\alpha = 0.05$) revealed a significant difference between control and the treatment groups with 100, 178 and 316 mg test item/kg artificial soil dry weight.
Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 56 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 100 mg test item/kg artificial soil dry weight. The EC_{10} and EC_{20} values determined by Probit analysis are 52.11 and 139.99 mg test item/kg artificial soil dry weight, respectively. The LC_{50} could not be calculated due to mathematical reasons.

Table CP 10.4.2.1- 1: Summary of the effects of Fluoxastrobin + Prothioconazole EC 200 on *Folsomia candida*

Test item Test object Exposure	Fluoxastrobin + Prothioconazole EC 200 *Folsomia candida* Artificial soil				
mg test item/kg soil dry weight nominal concentration	**Adult mortality (%)**	**Mean number of juveniles ± standard deviation**			**Reproduction (% of control)**
Control	10.0	1184.0	±	140.4	-
32	15.0	1202.0	±	200.7	101.5 n.s.
56	10.0	1056.0	±	126.9	89.2 n.s.
100	22.5	892.0	±	154.4	75.3 *
178	15.0	943.8	±	61.7	79.7 *
316	20.0	823.5	±	117.9	69.6 *
		Adult mortality			**Reproduction**
LC_{10}/EC_{10} (mg test item/kg soil dry weight)		n.d.[2)]			52.11[1)]
LC_{20}/EC_{20} (mg test item/kg soil dry weight)		n.d.[2)]			139.99[1)]
LC_{50}/EC_{50} (mg test item/kg soil dry weight)		n.d.[2)]			n.d.[2)]
$NOEC_{reproduction}$ (mg test item/kg soil dry weight)					56
$LOEC_{reproduction}$ (mg test item/kg soil dry weight)					100

The calculations were performed with un-rounded values
SD = Standard deviation
1) Probit analysis
2) not determined due to mathematical reasons
* = statistically significant (William's-t test one-sided-smaller, $\alpha = 0.05$)
n.s. = statistically not significant (William's-t test one-sided-smaller, $\alpha = 0.05$)

Conclusion:

$NOEC_{reproduction}$: 56 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$: 100 mg test item/kg artificial soil dry weight.

EC_{10} (reproduction): 52.11 mg test item/kg artificial soil dry weight.
(95 % confidence limit could not be calculated due to mathematical reasons)
EC_{20} (reproduction): 139.99 mg test item/kg artificial soil dry weight.
(95 % confidence limit could not be calculated due to mathematical reasons)
EC_{50} (reproduction): could not be calculated due to mathematical reasons.

Report:	KCP 10.4.2.1/02 [redacted]; 2012; M-441491-01-1
Title:	Fluoxastrobin + prothioconazole EC 200 (100+100) G: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil
Report No.:	kra-HR-81/12
Document No.:	M-441491-01-1
Guideline(s):	OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals - Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil
Guideline deviation(s):	not applicable
GLP/GEP:	**yes**

Objective:

The purpose of the study was to assess the effects of Fluoxastrobin + Prothioconazole EC 200 on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested during an exposure of 14 days in artificial soil comparing control and treatment. The test was performed according to the OECD guideline 226 (2008).

Material and methods:

Test substance: Fluoxastrobin + Prothioconazole EC 200 (100+100) G; Short name: FXA + PTZ EC 200 (100+100) G; Batch No.: 2012-001071; Customer order No.: TOX09674-00; Material No.: 80485182; Specification No.: 102000025822-01; active ingredients (analysed content): 9.21 % w/w (101.3 g/L) fluoxastrobin (HEC 5725 E-ISO (BCS-AH45292)), 9.13 % w/w (100.4 g/L) prothioconazole (JAU 6476 (BCS-AB80325)); Density: 1.100 g/mL.

Ten adult, fertilized, female *Hypoaspis aculeifer* per replicate (8 control replicates and 4 replicates for each test item concentration) were exposed to control and treatments. Concentrations of 32, 56, 100, 178 and 316 mg test item/kg dry weight artificial soil were tested. In each test vessel 20 g dry weight artificial soil were weighed in. The *Hypoaspis aculeifer* were of an uniform age not differing more than three days (28 days after start of egg laying). During the test, they were fed with cheese mites bred on brewer's yeast. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75 % fine quartz sand, 5 % Sphagnum peat, air dried and finely ground, 20 % Kaolin clay.
After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20 % ethylene glycol, 80 % deionised water; 2 g detergent/L fixing solution were added). All *Hypoaspis aculeifer* were counted under a binocular.

Toxic standard (Dimethoate EC 400): 1.0 – 1.8 – 3.2 – 5.6 - 10.0 mg a.s./kg dry weight artificial soil; control: artificial soil mixed with deioised water only, solvent control: none.

Dates of work: September 07, 2012 to September 26, 2012

Findings:

Validity criteria:

Validity criteria (control values)	Recommended by the guideline	Obtained in this study
Mean adult female mortality	≤ 20%	2.5 %
Mean number of juveniles per replicate (with 10 adult females introduced)	≥ 50	319.9
Coefficient of variation calculated for the number of juvenile mites per replicate	≤ 30%	9.8 %

All validity criteria were met. Therefore this study is valid.

Reference test:

In the most recent non-GLP-test ([redacted], kra/HR-O-11/12, February 29, 2012), dimethoate showed a LC_{50} of 3.894 mg a.s./kg for mortality of the adult mites according Probit analysis using maximum likelihood regression. Confidence limits could not be determined due to mathematical reasons.

The reproduction of the soil mites was not significantly reduced in comparison to the control up to 3.2 mg a.s./kg dry weight artificial soil. Therefore the NOEC is calculated to be 3.2 mg a.s./kg and accordingly the LOEC is 5.6 mg a.s./kg. Since variances of the data were even after transformation not homogenous Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment procedure, $\alpha = 0.05$, one-sided smaller was used. Dimethoate EC 400E G showed a EC_{50} of 6.62 mg a. s./kg (95 % confidence limits from 6.02 mg a. s./kg to 2469.54 mg a.s./kg) for reproduction according Probit analysis using maximum likelihood regression. The results are in the recommended range of the guideline of 3.0 – 7.0 mg a.s./kg dry weight artificial soil and show, that the test organisms are sufficiently sensitive This shows that the test organisms are sufficiently sensitive.

Biological findings:

Mortality

In the control group 2.5 % of the adult *Hypoaspis aculeifer* died which is below the allowed maximum of ≤ 20 % mortality. The LC_{50} could not be calculated and is considered to be > 316 mg test item/kg dry weight artificial soil.

Reproduction

Concerning the number of juveniles statistical analysis (William`s t-test, one-sided smaller, $\alpha = 0.05$) revealed no significant difference between control and any treatment group. Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is ≥ 316 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is > 316 mg test item/kg dry weight artificial soil. The EC_{50}-values could not be calculated and is considered to be >316 mg test item/kg dry weight artificial soil.

Table CP 10.4.2.1- 2: Summary of the effects of Fluoxastrobin + Prothioconazole EC 200 on *Hypoaspis aculeifer*

Test item Test object Exposure	Fluoxastrobin + Prothioconazole EC 200 *Hypoaspis aculeifer* Artificial Soil		
mg test item/kg dry weight artificial soil	**% mortality (adults)**	**Mean number of juveniles per test vessel ± standard deviation**	**Reproduction (% of control)**
Control	2.5	319.9 ± 31.3	---
32	7.5	309.8 ± 34.8	96.8
56	5.0	310.8 ± 32.7	97.1
100	12.5	304.3 ± 34.3	95.1
178	0.0	329.3 ± 10.8	102.9
316	0.0	352.3 ± 27.4	110.1
			Reproduction
NOEC (mg pure metabolite/kg dry weight artificial soil)			≥ 316
LOEC (mg pure metabolite/kg dry weight artificial soil)			> 316

no statistically significant differences (Williams-t.-test one sided smaller; α=0.05)

Conclusion:

NOEC: ≥ 316 mg test item/kg dry weight artificial soil.
LOEC: > 316 mg test item/kg dry weight artificial soil.

CP 10.4.2.2 Higher tier testing

No higher tier testing was performed or is required.

CP 10.5 Effects on soil nitrogen transformation

Table CP 10.5- 1: Endpoints used in risk assessment

Test substance	Test design	Endpoint		Reference
Fluoxastrobin + Prothioconazole EC 200	Nitrogen transformation, 98 d	no unacceptable effects	≥ 22.00 mg prod./kg dws (= 15 L prod./ha)	[redacted]; 2014; M-473548-01-1 KCP 10.5
Fluoxastrobin	Nitrogen transformation, 28 d	no unacceptable effects	≥ 2.83 mg a.s./kg dws	[redacted]; 1999; M-024686-01-1
HEC 5725-E-des-chlorophenyl		no unacceptable effects	≥ 2.73 mg p.m./kg dws	[redacted] 2000; M-026016-01-1
HEC 5725-carboxylic acid		no unacceptable effects	≥ 1.27 mg p.m./kg dws	[redacted]; 2001; M-033474-01-1
2-chlorophenol		no unacceptable effects	≥ 0.283 mg a.s./kg dws*	EFSA Scientific Report 102 (2007)

a.s. = active substance, p.m. = pure metabolite, prod. = product, dws = dry weight soil
* for the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))
Bold values: endpoints used for risk assessment

Risk assessment for Soil Nitrogen Transformation

Table CP 10.5- 2: Risk Assessment for soil micro-organisms

Compound	Species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	Refinement required
Cereals				
Fluoxastrobin + Prothioconazole EC 200	Soil micro-organisms	≥ 22.00 mg prod./kg dws	0.880	No
Fluoxastrobin (E+Z)	Soil micro-organisms	≥ 2.83 mg a.s./kg dws	0.080	No
HEC 5725-E-des-chlorophenyl	Soil micro-organisms	≥ 2.73 mg p.m./kg dws	0.019	No
HEC 5725-carboxylic acid	Soil micro-organisms	≥ 1.27 mg p.m./kg dws	0.011	No
2-chlorophenol	Soil micro-organisms	≥ 0.283 mg p.m./kg dws*	0.009	No
Onions				
Fluoxastrobin + Prothioconazole EC 200	Soil micro-organisms	≥ 22.00 mg prod./kg dws	3.300	No
Fluoxastrobin (E+Z)	Soil micro-organisms	≥ 2.83 mg a.s./kg dws	0.306	No
HEC 5725-E-des-chlorophenyl	Soil micro-organisms	≥ 2.73 mg p.m./kg dws	0.071	No
HEC 5725-carboxylic acid	Soil micro-organisms	≥ 1.27 mg p.m./kg dws	0.041	No
2-chlorophenol	Soil micro-organisms	≥ 0.283 mg p.m./kg dws*	0.036	No

a.s. = active substance, p.m. = pure metabolite, prod. = product, dws = dry weight soil
* for the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is ≤ 25% after 100 days.

For the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007)). It is assumed that no influence occurs up to a concentration of 0.283 mg 2-chlorophenol/kg soil. This is conspicuously higher than the worst case PEC_{soil}.
In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil micro-organisms for the intended uses.

Report:	KCP 10.5/01 [redacted].; 2014; M-473548-01-1
Title:	Fluoxastrobin + prothioconazole EC 200 (100+100) G: Effects on the activity of soil microflora (nitrogen transformation test)
Report No.:	13 10 48 117 N
Document No.:	M-473548-01-1
Guideline(s):	OECD 216 (2000); adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation
Guideline deviation(s):	none
GLP/GEP:	**yes**

Objective:

The purpose of this study was to determine the effects of Fluoxastrobin + Prothioconazole EC 200 on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

Material and methods:

Test substance: Fluoxastrobin + Prothioconazole EC 200 (100+100) G; Short name: FXA + PTZ EC 200 (100+100) G; Batch ID: 2012-001071; Sample description: TOX09674-00; Material No.: 80485182; Specification No.: 102000025822-01; active ingredients (analysed content): 9.21 % w/w (101.3 g/L) fluoxastrobin (HEC 5725 E-ISO (BCS-AH45292)), 9.13 % w/w (100.4 g/L) prothioconazole (JAU 6476 (BCS-AB80325)); Density: 1.100 g/mL (20°C).

A loamy sand soil (DIN 4220) was exposed for 98 days to 2.20 and 22.00 mg test item/kg soil dry weight. Application rates were equivalent to 1.5 and 15 L test item/ha. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5 %). NH_4-nitrogen, NO_3- and NO_2-nitrogen were determined by an Autoanalyzer at different sampling intervals (0, 7, 14, 28, 42, 56, 70, 84 and 98 days after treatment).

Dates of work: September 02, 2013 to December 09, 2013

Findings:

Validity criteria:
The coefficients of variation in the control (NO_3-N) were maximum 8.7 % and thus fulfilled the demanded range (≤15 %).

Reference test:
In a separate study the reference item Dinoterb caused a stimulation of nitrogen transformation of +33.7 % and +42.6 % at 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, determined 28 days after application.

Biological findings:
The test item Fluoxastrobin + Prothioconazole EC 200 caused temporary stimulations and temporary inhibitions of the daily nitrate rate at 2.20 mg/kg and 22.00 mg/kg soil dry weight up to time interval 28-42 and 84-98 days after application, respectively.
However, no adverse effects of Fluoxastrobin + Prothioconazole EC 200 (100+100) G on nitrogen transformation in soil could be observed at 2.20 mg/kg and 22.00 mg/kg soil dry weight 42 days and 98 days after application, respectively. Differences from the control of +7.4 % (test concentration 2.20 mg/kg dry soil, time interval 28-42) and +0.8 % (test concentration 22.00 mg/kg dry soil, time interval 84-98) were measured at the end of the 42-day incubation period and at the end of the 98-day incubation period, respectively.

Table CP 10.5- 3: Effects on nitrogen transformation in soil after treatment with Fluoxastrobin + Prothioconazole EC 200

Time Interval (days)	Control			2.20 mg test item/kg soil dry weight equivalent to 1.5 L test item/ha				22.00 mg test item/kg soil dry weight equivalent to 15 L test item/ha			
	Nitrate-N 1)			Nitrate-N 1)			% difference to control	Nitrate-N 1)			% difference to control
0-7	3.72	±	0.57	3.75	±	0.24	**+0.8 n.s.**	4.39	±	0.20	**+18.1 n.s.**
7-14	1.85	±	0.26	1.30	±	0.26	**-30.1 n.s.**	0.93	±	0.25	**-49.9 *s**
14-28	0.83	±	0.03	1.08	±	0.04	**+29.8 *s**	0.91	±	0.08	**+9.5 n.s.**
28-42	0.87	±	0.17	0.94	±	0.06	**+7.4 n.s.**	1.12	±	0.06	**+28.7 n.s.**
42-56	0.37	±	0.29	-2)	±	-2)	**-2)**	0.23	±	0.03	**-37.6 n.w.**
56-70	0.31	±	0.39	-2)	±	-2)	**-2)**	0.45	±	0.10	**+43.8 n.s.**
70-84	0.32	±	0.22	-2)	±	-2)	**-2)**	-0.01	±	0.15	**-103.7 n.s.**
84-98	0.88	±	0.41	-2)	±	-2)	**-2)**	0.89	±	0.16	**+0.8 n.s.**

The calculations were performed with unrounded values

1) Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation

2) Since in this treatment group the deviation from the control was below 25 % on day 42, no further evaluations were performed.

n.s. = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

n.w. = No statistically significant difference to the control (Welch-t-test for inhomogeneous variances, 2-sided, $p \leq 0.05$)

*s = statistically significantly different *t*o control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

Conclusion:

Fluoxastrobin + Prothioconazole EC 200 caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO_3-N-production) at the end of the 98-day incubation period. The study was performed in a field soil at concentrations up to 22.00 mg test item/kg dry soil, which are equivalent to application rates up to 15 L test item/ha.

CP 10.6 Effects on terrestrial non-target higher plants

Risk assessment for Terrestrial Non-Target Higher Plants

The risk assessment for non-target terrestrial plants is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are defined as non-crop plants located outside the treated area. Spray drift from the treated areas may produce residues of a product in adjacent off-crop areas.

Tier 1 seedling emergence and vegetative vigour studies have been conducted with the formulation Fluoxastrobin + Prothioconazole EC 200. The results of the studies are presented in the tables below.

Table CP 10.6- 1: Endpoints used in risk assessment

Test organism	Study type, tested rate	Max. effects	Most sensitive species	References
Terrestrial non-target plants; 10 species	Seedling emergence, Tier 1 single dose, 1500 mL prod./ha	48.5% reduction of shoot dry weight	*Helianthus annuus*	[redacted], 2012; M-439413-01-1
Terrestrial non-target plants; 10 species	Vegetative vigour, Tier 1 single dose, 1500 mL prod./ha	38.9% reduction of shoot dry weight	*Sinapis alba*	[redacted]B; 2012; M-442112-01-1

In the case of Fluoxastrobin + Prothioconazole EC 200, neither the tier 1 seedling emergence study, nor the tier 1 vegetative vigour study showed phytotoxic effects > 50% at the tested rate of 1.5 L prod./ha, respectively.

In order to demonstrate the low risk of the formulation to terrestrial non-target plants, TER calculations have been performed for the representative uses in cereals and onions. The test rates given in Table CP 10.6-1 were used as most conservative endpoint estimates (i.e., ER_{50} > 1.5 L prod./ha).

Table CP 10.6- 2: Deterministic risk assessment based on the ER_{50} > 1500 mL prod./ha (vegetative vigour)

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER* [mL prod./ha]	TER (Trigger = 5)
Cereals	2 × 1500 mL prod./ha (14 d interval)	1	2.38 [1)]	50.0 [2)]	> 30
Onions	2 × 1250 mL prod./ha (10 d interval)	1	2.38 [1)]	44.6 [3)]	> 34

* Predicted environmental rate
1) Basic drift value for two applications in field crops
2) Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)
3) Considering MAF = 1.5 from EFSA GD Birds & Mammals (2009)

Table CP 10.6- 3: Deterministic risk assessment based on the ER_{50} > 1500 mL prod./ha (seedling emergence)

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER* [mL prod./ha]	TER (Trigger = 5)
Cereals	2 × 1500 mL prod./ha (14 d interval)	1	2.38 [1)]	25.0 [2)4)]	> 60
Onions	2 × 1250 mL prod./ha (10 d interval)	1	2.38 [1)]	22.3 [3)4)]	> 67

[*] Predicted environmental rate
[1)] Basic drift value for two applications in field crops
[2)] Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)
[3)] Considering MAF = 1.5 from EFSA GD Birds & Mammals (2009)
[4)] Considering 50% interception by off-crop vegetation

From the calculations above, it is concluded that the product poses no unacceptable risk to non-target terrestrial plants in off-crop areas.

CP 10.6.1 Summary of screening data

As full GLP studies are available (see CP 10.6.2 below), screening data were not generated.

CP 10.6.2 Testing on non-target plants

Report: KCP 10.6.2/01 [redacted]; 2012; M-439413-01-1
Title: FXA+PTZ EC 100+100A G: Effects on terrestrial (non target) plants - Seedling emergence and growth test
Report No.: 20120052
Document No.: M-439413-01-1
Guideline(s): OECD Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test adopted July 19, 2006
Guideline deviation(s): not applicable
GLP/GEP: **yes**

Objective:

The effects of Fluoxastrobin + Prothioconazole EC 200 on seedling emergence of ten higher plant species were assessed following exposure to the test item under greenhouse conditions.

Material and methods:

Test item: Fluoxastrobin + Prothioconazole EC 200; Other name: FXA + PTZ EC 100 + 100A G; Sample description: TOX09674-00; Batch No.: 2012-001071; Specification No.: 102000025822-01; Analysed content of active ingredients: 101.3 g/L fluoxastrobin, 100.4 g/L prothioconazole; Density (at 20°C): 1.100 g/mL.

The plant species tested were corn (*Zea mays*), wheat (*Triticum aestivum* var. *spelta*), onion (*Allium cepa*) and oat (*Avena sativa*) as monocotyledonae, sugar beet (*Beta vulgaris* var. *conditiva*), white mustard (*Sinapis alba*), cucumber (*Cucumis sativus*), tomato (*Lycopersicon esculentum*), sunflower (*Helianthus annuus*) and soybean (*Glycine max*) as dicotyledonae. The study was conducted in compliance with OECD Guideline No. 208 (2006).

Seeds of the ten species were exposed to soil treated with the test item at one rate. The test item Fluoxastrobin + Prothioconazole EC 200 was dispersed in deionised water and applied to the soil immediately after sowing. The inhibition of plant emergence and early growth in relation to the control plants was determined over a study period of 21 days, after 50% emergence in the control.

The following rate was tested: 1500 mL product/ha.

Findings:

The biological results are summarised in the following table:

Table CP 10.6.2- 1: Summary of effects on ten plant species after treatment with Fluoxastrobin + Prothioconazole EC 200

	Emerged plants (%)			Dry weight (g)			Plant survival (%)		
Species	control	1500 mL prod./ha	Inhibition = emergence reduction (%)	control	1500 mL prod./ha	Inhibition = weight reduction (%)	control	1500 mL prod./ha	Inhibition = survival reduction (%)
Onion	88.0	100	n.d.	0.015	0.016	n.d.	100	100	n.d.
Oat	84.0	92.0	n.d.	0.179	0.148 *	17.2	100	100	n.d.
Wheat	96.0	100	n.d.	0.189	0.171	9.6	100	100	n.d.
Corn	84.0	76.0	9.5	1.117	0.611 *	45.3	100	100	n.d.
Sugar beet	80.0	88.0	n.d.	0.057	0.089	n.d.	91.1	90.0	1.2
Cucumber	100	100	n.d.	0.680	0.558 *	18.0	100	100	n.d.
Soybean	84.0	68.0 *	19.0	0.607	0.684	n.d.	100	100	n.d.
Sunflower	92.0	100	n.d.	0.447	0.230 *	48.5	100	100	n.d.
Tomato	80.0	88.0	n.d.	0.025	0.063	n.d.	100	100	n.d.
White mustard	88.0	84.0	4.5	0.119	0.084 *	29.5	100	100	n.d.

*) There is significant difference between the control and treatment (t-test, $\alpha = 0.05$)
n.d. = no inhibition was determined

1500 mL product/ha of Fluoxastrobin + Prothioconazole EC 200 caused phytotoxicity (slight necrosis = 1-10% of leaf area) on two of the tested species, namely corn and sunflower.

Conclusion:

The application of Fluoxastrobin + Prothioconazole EC 200 at the treatment rate of 1500 mL product/ha caused no adverse effects on emergence, survival and growth of emerged seedlings, shoot dry weight and visual phytotoxicity exceeding the 50% effect level.

Report:	KCP 10.6.2/02 [redacted] B; 2012; M-442112-01-1
Title:	FXA+PTZ EC 100+100A G: Effects on terrestrial (non target) plants - Vegetative vigour
Report No.:	20120053
Document No.:	M-442112-01-1
Guideline(s):	OECD Guideline 227 Terrestrial Plant Test: Vegetative Vigour Test, adopted July 19, 2006
Guideline deviation(s):	not applicable
GLP/GEP:	**yes**

Objective:

The effects of Fluoxastrobin + Prothioconazole EC 200 on vegetative vigour of ten higher plant species were assessed following exposure to the test item under greenhouse conditions.

Material and methods

Test item: Fluoxastrobin + Prothioconazole EC 200; Other name: FXA + PTZ EC 100 + 100A G; Sample description: TOX09674-00; Batch No.: 2012-001071; Specification No.: 102000025822-01; Analysed content of active ingredients: 101.3 g/L fluoxastrobin, 100.4 g/L prothioconazole; Density (at 20°C): 1.100 g/mL.

The plant species tested were corn (*Zea mays*), wheat (*Triticum aestivum* var. *spelta*), onion (*Allium cepa*) and oat (*Avena sativa*) as monocotyledonae, and sugar beet (*Beta vulgaris* var. *conditiva*), white mustard (*Sinapis alba*), cucumber (*Cucumis sativus*), tomato (*Solanum lycopersicon*), sunflower (*Helianthus annuus*) and soybean (*Glycine max*) as dicotyledonae. The study was conducted in compliance with of the OECD Guideline No. 227 (2006).

Plants of ten different species in growth stages 12 to 14 (BBCH) were treated with the test item at one application rate. The test item Fluoxastrobin + Prothioconazole EC 200 was dispersed in deionised water and applied to the plant surface by spray application. Plant survival and visible detrimental effects were determined in relation to the control plants over a study period of 21 days. At test termination, shoot dry weight was determined.

The following rate was tested: 1500 mL product/ha.

Findings

The biological results are summarised in the following table:

Table CP 10.6.2- 2: Summary of effects on ten plant species after treatment with Fluoxastrobin + Prothioconazole EC 200

	Dry weight (g)			**Plant survival (%)**		
Species	Control	Test item 1500 mL/ha	Inhibition (% reduction)	Control	Test item 1500 mL/ha	Inhibition (% reduction)
Corn**	1.086	1.098	-1.1	100	100	0
Wheat	0.353	0.390	-10.5	100	100	0
Onion	0.028	0.022	19.2	100	100	0
Oat	0.466	0.567	-21.5	100	100	0
Sugar beet**	0.124	0.146	-18.0	100	100	0
White mustard***	0.458	0.280	38.9*	100	100	0
Cucumber**	0.612	0.500	18.4*	100	100	0
Tomato**	0.435	0.391	10.1	100	100	0
Sunflower**	0.421	0.513	-21.7	100	100	0
Soybean**	0.944	0.902	4.4	100	100	0

* Significant difference between the control and test item treatment (t-test, $\alpha = 0.05$)
** Symptoms of chlorosis in treated plants
*** Symptoms of necrosis in treated plants

The application of Fluoxastrobin + Prothioconazole EC 200 at a rate of 1500 mL/ha caused no adverse effects on the survival of all plant species tested. No statistically significant reductions of shoot dry weight were found for corn, wheat, onion, oat, sugar beet, tomato, sunflower and soybean. Dry weight of white mustard and cucumber plants in the treated plants was statistically significantly reduced by 38.9% and 18.4%, respectively. At the end of the study period (i.e., 21 days after application), treated plants of wheat, onion, and oat did not show any phytotoxic effects. In contrast, corn, sugar beet, cucumber, tomato, sunflower, and soybean treated plants showed mainly slight symptoms of chlorosis (i.e., 1-10% of leaf area), whereas white mustard plants showed slight to moderate symptoms of necrosis (i.e., 1-50% of leaf area).

Conclusion

The application of Fluoxastrobin + Prothioconazole EC 200 at the treatment rate of 1500 mL product/ha caused no adverse effects on survival and shoot dry weight reaching or exceeding the 50% effect level.

CP 10.6.3 Extended laboratory studies on non-target plants

In view of the results presented above under CP 10.6.2, extended laboratory studies are not deemed necessary.

CP 10.6.4 Semi-field and field tests on non-target plants

In view of the results presented above under CP 10.6.2, semi-field laboratory studies are not deemed necessary.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies are required.

CP 10.8 Monitoring data

No monitoring data are available or required.