Document Title

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

Date Requirements

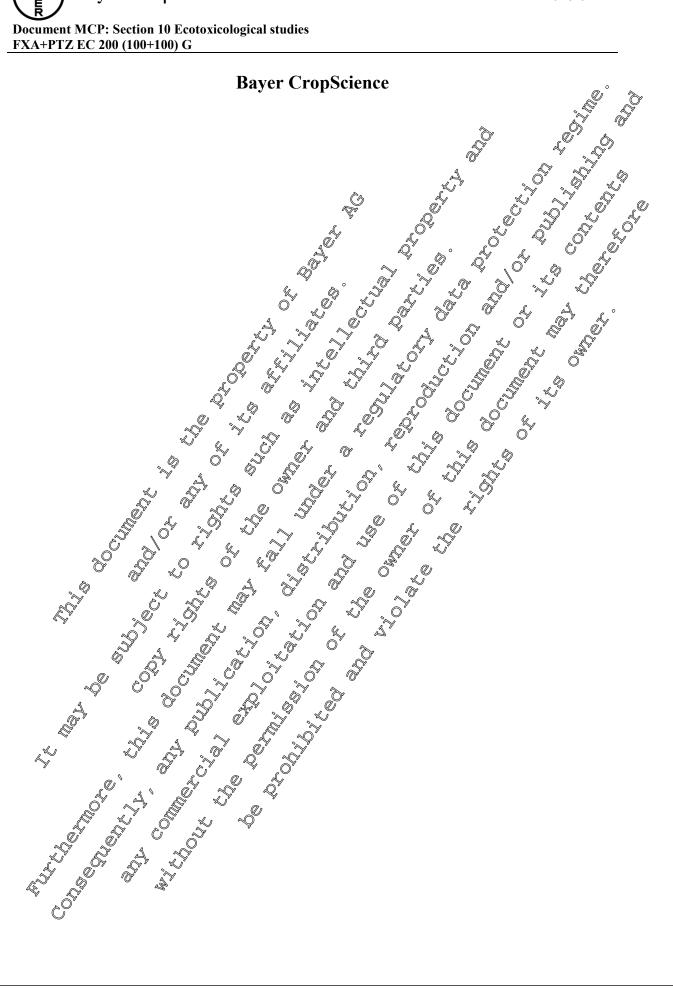
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Section-10: Ecotoxicological studies

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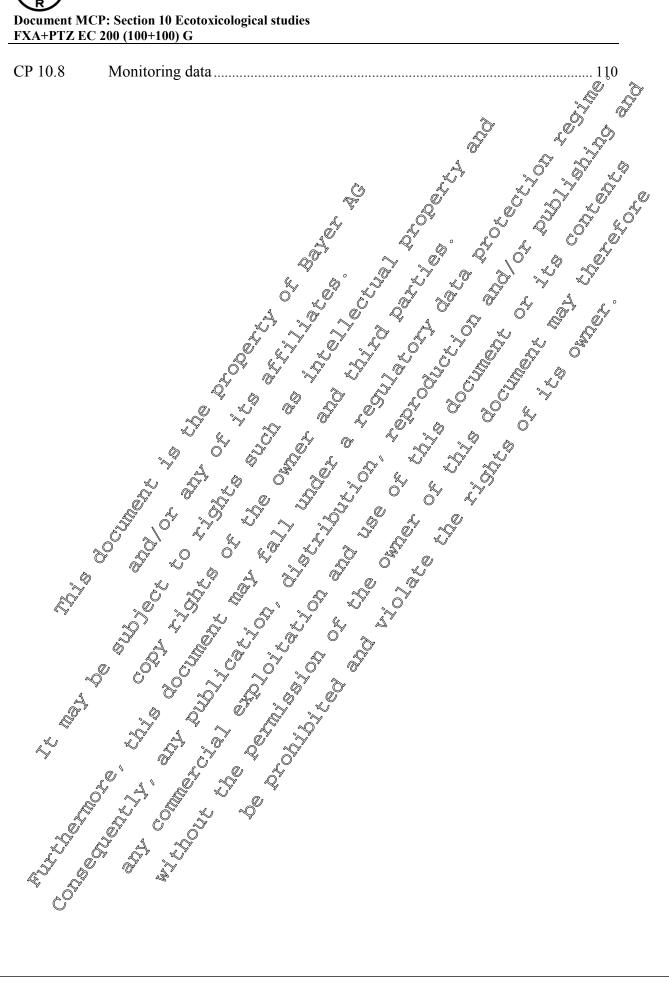
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## **Table of Contents**

			age
CP	10	ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION	-
CD	10.1	PRODUCT	
	10.1	Effects on birds and other terrestrial vertebrates	<u>%</u> 9
	10.1.1	Effects on birds.	9@
	10.1.1.1	Acute oral toxicity.  Higher tier data on birds.	JY
	10.1.1.2	Higher tier data on birds	<u>.</u> ¶1
	10.1.2	Effects on terrestrial vertebrates other than birds	1 🎉
	10.1.2.1	Acute oral toxicity to mammals	14
	10.1.2.2	Higher tier data on mammals	<b>V</b> 14
CP	10.1.3	Effects on other terrestrial vertebrate wild (repriles and amphibians)	ž. 14
CP	10.2	Effects on aquatic organisms.	14
CP	10.2.1	Effects on other terrestrial vertebrate wildlife (repriles and amphibians)  Effects on aquatic organisms.  Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes.  Additional long-term and chronic exicity studies on fish, aquatic invertebrate and sediment dwelling organisms.  Further testing on aquatic organisms.  Effects on arthropods	a Y
		macrophytes  Additional long-termand chronic exicity studies on fish, agratic invertebra and sediment dwelling organisms  Further testing on aquatic organisms  Effects on arthropods	ž. 60
CP	10.2.2	Additional long-termand chronic vicity studies on tish, agratic invertebra	ites
		and sediment dwelling organisms	64
CP	10.2.3	Further testing on aquatic organisms.	65
CP	10.3	Effects on arthropods?	66
CP	10.3.1	Additional long-termand chronic rexicity studies on this, agriatic invertebra and sediment dwelling organisms.  Further testing on aquatic organisms.  Effects on arthropods.  Acute toxicity to bees.  Acute oral toxicity to bees.  Acute contact toxicity to bees.	66
CP	10.3.1.1	Acute toxicity to bees	71
CP	10.3.1.1.1	Acute oral toxicity to bees	71
CP	10.3.1.1.2	Acute contact toxicity to bees	73
CP	10.3.1.2		
CP	10.3.1.3	Effects on hone bee development and other honey bee life stages	74
CP	10.3.1.4	Effects on bees  Acute toxicity to bees  Acute oral toxicity to bees  Acute contact toxicity to bees  Chronic toxicity to bees  Effects on hone bee development and other honey bee life stages  Sib-lethal effects  Cago and tunnel tests  Field tests with honeybees	74
CP	10.3.1.5	Cage and tunnel tests 40	75
CP	10.3.1.6	Field tests with honeybees	75
СP	10.3.2	Effects on non-targe arthropods other than bees	. 75
	10.3.2.1	Standard laboratory testing for con-target ar Propods	78
	10.3.2.2	Standard laboratory testing for con-target arthropods	s 78
	10.3.2.3	Semi-field studies with non-farget arthropods	88
		Field Rudies with non-target art proposition	
	10.3.2.50	Other routes of exposure for mon-target arthropods	88
_	10.4 🔏	Effects of non-parget soil moso- and macrofauna	89
	10.4	Other routes of exposure for non-target arthropods  Effects on non-target soil meso- and macrofauna  Earthworms  Earthworms sub-lethal effects	90
	10.4.1.1	Fartoworms sub-lethal effects	91
	19.4.1.2	Earthworms field studies.	94
		Effects on non-targer soil meso- and macrofauna (other than earthworms)	94
		Species level testing	
	10.4.2.2	Higher tier testing	100
CP	10.5	Exfects on soil nitrogen transformation	
CP	10.5	Effects on terrestrial non-target higher plants	
	10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0° 10.0°	Summary of screening data	
CI	10.6.2	Testing on non-target plants	
	10.6.3	Extended laboratory studies on non-target plants	
	10.6.4		
	10.6.4	Semi-field and field tests on non-target plants	110
$\cdot$	IU /	CALCAD OF OTHER FERENCIAL OLYMINSHIS CHOLA AUG TAUUAT	110



## 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 (200+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 fluorestrobin 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 presons of valuated in matical is written in grey and.

### 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 truscale at a maximum rate of 2 x 1.25 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	Piming of	Number of	Application 4	Maxonum, Q	Application ra	te per treatment
	application	appucations=\	interval O	label rate per	[g	/ha]
	(range)		్ద <sup>ు</sup> [days)్తో	Creatment [L/ha]	Fluoxastrobin	Prothioconazole
Wheat, rye, triticale*	BB(CH) 30-69			1.5	150	150
Barley, oats*	BBCH-Q, ** 30-64-	1-2	0 14-20	F 1.25	125	125
Onions**	* BBCH (*) 15-47			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 EBCH 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 -Z-isomer,
	HEC 5725-carboxylic acid (M40)
	HEC 5725-carboxylic acid (M40)// HEC 5725-E-des-chlorophenyl (M48-E), 2-chlorophenol (M82)
	HEC 5725 - Z-isomer, HEC 5725-carboxylic acid (M40%) HEC 5725-E-des-chlorophenyl (M48-E), 2-chlorophenol (M82)
Groundwater	fluoxastrobin (E-isomer), $\Delta$
	HEC 5725-Z-isomer, 2007 2007 2007 2007 2007 2007 2007 200
	HEC 5725-carboxylic acid (MAD), OF FOR THE STATE OF THE S
	HEC 5725-E-des-chtorophenyl (M48-E),
Surface water	
	HEC 5725-Z-isomer, J. Of St. O
	$  HEC 5/25$ -garboxyliv acid $(M40)$ , $  \sim   \sim   \sim   \sim   \sim   \sim   \sim   \sim   \sim   $
	HEC 5725-E-desschlorophenyl (M48-E)
Sediment	fluoxastrobin (EOsomer), HEC 5725-Z-isomer
	HEC 5725-Z-isomer
Air	none Sy C S S S S

A list of metabolities, which contains the structures, the synonyms and code numbers attributed to the compound fluorestrobin is presented in Document 3 of this document.

#### 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 tisk 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 Quilibrium 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; Guidence" 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", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA" GD 2009", 7(12):1438. doi:10.2903/

Test substance	Exposure	species/origin	, T	Endpoint		Referenço
	Acute risk assessment	Colinus virginianus (Bobwhite quasi)	LD <sub>50</sub> LD <sub>50</sub>	2000 Grig a.s	g bw O	2003 M- \$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Fluoxastrobin	Reproductive risk assessment	Lowest NOEL from thus platyrity nchos (Mal Grid duck)	NOE	2461 n kg	\$	2003; M2 087968-00-1

Relevant generic avianciocal species for risk assessment on the 1 level according to **Table CP 10.1.1-2:** EFSAGD 2099

Crop scenario	Scenario	Generic focal species	Representative species	Short cu for RA l	
				RUD90	RUDm
2 ^ 0.130	BOSCH 300- 39 0	Small omnivorous bird Salark"	Woodlark (Lullula Larborea)	12.0	5.4
kg/ha 💪 BBCH 30-69 14 d interval	BBCH ≥40	Small omnivorous blod "Fark"	Woodlark (Lullula arborea)	7.2	3.3
	BBCH Y0 - 39	Small granivo cous bire	Linnet (Carduelis cannabina	24.7	11.4
Oniona of	BBCiO10 - 30	Small grantvorous Fird  Small grantvorous Fird	Linnet (Carduelis cannabina	14.8	6.9
Onions Q 2 × 0.125 kg/ha		Small@mnivo@us bird	Woodlark ( <i>Lullula</i> arborea)	24.0	10.9
BBCH 5-47	BBCH > 40	Small omnivorous bird	Woodlark ( <i>Lullula</i> arborea)	14.4	6.5
To definite i var	BBCh 10 - 19	Small Osectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	26.8	11.3
	ABBCH 20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	25.2	9.7
Bold: Species co	onsidered in isk assossmer	Only worst case for each s	pecies)		
		Conly worst case for each s			

Bold values used for the risk assessment by the strain of the risk assessment by the Section 2.1.2, Tab. 1)

#### ACUTE DIETARY RISK ASSESSMENT

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

								$\sim$
			DDD			%LD50	Č	<b>b</b> . '01
Crop scenario	Generic focal species	Appl. rate [kg a.s./ha]	SV90	MAF90	DDD	[ang a.s./kg bw]	TERA	Trieger
Fluoxastrobin					J.	%		
Cereals BBCH 30 - 39	Small omnivorous bird "lark"	0.150	12.0	1.2	© Q2.2	3776	1348 Q	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Onions BBCH 10 - 39	Small granivorous bird "finch"	200	24.7	Q,	<b>4</b> 00°	Q, O	941	
Onions BBCH 10 - 39	Small omnivorous bird "lark"	0.125	\$4.0 \$4.0	\$\tag{1.3}	3.9L)	3796	*968 <sub>4</sub>	<b>3</b> 10
Onions BBCH 10 - 19	Small insectivorous bird "wagtail"		26 <b>%</b>		4.4		860	

The TERA values calculated in the acute risk assessment on Tier & level except the aprioriacceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to birds can be considered as low and acceptable without need to 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 15 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mampals:

<u>Leaf scenario:</u> Birds taking water that is collected in leaf whork after application of a pesticide to a crop and subsequent sainfall or irrigation.

<u>Puddle scenario</u>: Bords and mampals taking water from puddles formed on the soil surface of a field when a (heavy) ramfall event follows the application of a posticide of a crop or bare soil.

For the crops ander 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 ASSOSSMENT

Table CP 10.1.1- 45 Tier 1 reproductive risk assessment for birds

	, O V		- ₽DD	) <i>©</i>			NOEL		
Crop	Generie focal species	Tkg a.s./hat	SV	<b>₽</b>	f <sub>TWA</sub>	DDD	[mg a.s./ kg bw/d]	TER <sub>LT</sub>	Trigger
Fluoxastrobin	\$ A 0	y Ö							
Cereals BBCH 30 - 20	Small omniverous		5.4	1.4	0.53	0.6	51	84.9	5
Omors BBCH 10 - 39	Small granivorous bird "fireh"		11.4			1.1		45.0	
BBCH 16 39	Small opprivorous bird "lark"	0.125	10.9	1.5	0.53	1.1	51	47.1	5
Ortions BBCH 10 - 19	Small insectivorous bird "wagtail"		11.3			1.1		45.4	

The TER<sub>LT</sub> values calculated in the reproductive risk assessment on Tier 1 level exceed the a-prioriacceptability 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 chase)

Crop	Koc [L/kg]	Application rate * 2 a) [g as/ha]	NO(A)EL [mg as/ kg bw/di	Ratio Q (Application rate * MAF) / NQ(A)EL	"Escape clanse" No concern	Concrusion
Fluoxastrobin			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
Cereals	848.2	150 * 2	\$\\$1 \ \&		<b>₽</b> ≥ <b>,⊘\$</b> 000 .	No concern
Onions	848.2	125 * 2	0″ <sub>51</sub> Ø	\$ 4. <b>\$</b>	<b>₽</b> 3000∡	No concern

a): annual application rate (without interception) used a theoretical work 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  $P_{\rm OW} > 3$  is used to trigger an indepth evaluation of the potential to bioaccumulation.

As the log Pow of the active substance duoxastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed see MCA 2.70.

#### CP 10.1.1.1 Agate or al toxicity

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

## CP 10,197.2 Higher tier data on birds

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

## CP 10.1.2 Effects on terrestrial vertebrates other than birds

Table CP 19.1.2-1: Endpoints used in risk assessment

Test substance	Exposure	species/origin		Endpoint	Reference
A A	Acute Frisk assessment	Rat	LD <sub>50</sub>	> 2000 mg a.s./kg bw	1996; M-012717- 01-1
Fluoxastrobio	Long-term Grisk D Gssessment	Rat Rat	NOAEC NOAEL	2000 mg a.s./kg diet (F) 163 mg a.s./kg bw/d	; 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

				Shorte	ut vatue
Crop	Scenario	Generic focal species	Representative species	Long- term RA based on RUD	acute RA
Cereals 2 × 0.150	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew Sorex  araness		5.4
kg/ha BBCH 30-	BBCH ≥ 40	Small herbivorous mammal \( \) "vole"	TCommon vole (Microtus qodlis) &	21.75	<b>40</b> .9
69 14 d	BBCH 30 - 39	Small omnivorous mampal "mouse"	Wood prouse (Apodemus) sylvaticus)	3.9	8.6
interval	BBCH ≥ 40	Small omnivorous manmal "mouse" 📞	Wood mouse (Apodemus S sylvetticus)	2.3	\$.2
Onions	BBCH 10 - 19	Small insectivorous manufal "shrew"	Common shrew (Sorew)  Qaraneus)	<b>4.2</b>	7.60
$2 \times 0.125$ kg/ha	BBCH ≥ 20	Small insective rous mammal brings of the small was a small with the small sma	Common threw (Orex &	1.2	\$.4
BBCH 15-	BBCH ≥ 40	Small herbivorous manifial "vote"	Common vole Microns	3.4	81.9
10 d interval	BBCH 10 - 39	Smark omniyorous gamma	Wood mouse (Aposemus & special	7.8	17.2
interval	BBCH ≥ 40	Small omnivorous mammal w "mouse" & To	Wood rouse Apodemus  sylvaticus)	94.7	10.3

Bold: Species considered in Ger 1 risk assessment conly worst case for each species

#### ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2- 3: Fier lacute DDD and TER calculation for mammals

Crop 🖔	Organic wear species	Appl. rate [kg/ha]	DDD Sym	MAF90	<b>D</b> DD	LD <sub>50</sub> [mg/kg bw]	TERA	Trigger
Cereals BBCA ≥ 20	Small insection or support of the su		§ 5.4Z		1.0		> 2058	10
Cereals BBCH ≥ 40	Small herbivorous manamal "v@e"	0.150	<b>40</b> .9	1.2	7.4	> 2000	> 272	10
Cereals BBCH 30 - 39	Small omnisorous of manimal omnisorous of		8.6%	y Y	1.5		> 1292	10
Onions BBCH 10 19	Small insectivorous mammal "sinew"	\$\tag{\text{0.125}}	Ø.6		1.2		> 1619	10
Onions BBCH ≥ 40	ynannia von	Ø.125 ©	81.9	1.3	13.3	> 2000	> 150	10
Onions BBCH 10 - 39	Small Smniverous & mammal "mouse" @		17.2		2.8		> 716	10

The TERA values calculated in the cute risk assessment on Tier 1 level exceed the a-priori acceptability trigger of 90 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

		1						1	<del>ix Y m</del> í
			DDD				NO(A)EL	0	
Crop	Generic focal species	Appl. rate [kg/ha	SV <sub>m</sub>	MAFm	ftwa	DDD	Jmg Kg/bw/d]	TERL	Trigger
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"		1.9	Č		0.2		\$15 <sub>~</sub>	\$\frac{1}{2} 5 \display \frac{1}{2}
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	0.150	21.7	₹1.4	0.53	<b>4</b> .4	163		
Cereals BBCH 30 - 39	Small omnivorous mammal "mouse"		3.5		Ź,	0.4 .		, 408 (	) 5 W
Onions BBCH 10 - 19	Small insectivorous mammal "shrew"		\$\text{9}{4.2}	K. U.S.	A 4	©3 >0.4		.408 ~	\$5 \$5
Onions BBCH ≥ 40	Small herbivorous mammal "vole"	0.125	43,4 ~	(L)5	0.53	48	<b>16</b> 3 6	Ç 38 €	5, 0
Onions BBCH 10 - 39	Small omnivorous mammal "mouse"		7.8°		, , ,	0.8		204	\$\frac{1}{2}5

The TER<sub>LT</sub> values calculated in the reproductive risk assessment on Tier 1 level exceed the a-prioriacceptability trigger of 5 for all evaluated scenarios. Flus, the risk to manufals can be considered as low and acceptable without need for further, more realistic task 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 manimals drinking water

Cran	Koc V		Ratio O	"Escape clause"	Conclusion
Crop		reate * 2.2   Ling as/ (Appli g as/har)   kg bw/dl   M-sf	cation vate * / NO(A)EL	No concern if ratio	Conclusion
Fluoxastrobin					
Cereals	\$\$48.2 <sup>™</sup>	150 * 2 163 P	1.84	≤ 3000	No concern
onions	8482	125 🞾 🗸 163	1.53	≤ 3000	No concern

<sup>(</sup>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 manifolds in feeding on contaminated prey like fish or earthworms. For organic chemicals, a  $log P_{OW} > 3$  justed to trigger an in depth evaluation of the potential for bioaccumulation.

As the log Powof the active substance fluorastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary posoning 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 ; 2002; M-088922-02-1, the study is sugamarised in document MCP 7 (toxicology). According to OECD guideline 423 the results of this study correspond to LOSo > 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 the

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

No additional studies are available or required under the data requirements of EC 107/2009

The risk assessment was performed according to the Regulation (SC) No.1107,8009 and following the EFSA Guidance on tiered risk assessment for plant protection products for actuatic organisms in edge-of-field surface waters (2013).

#### Ecotoxicological endpoints used in risk assessment

Table CP 10.2-1: Endpoints relevant for risk assessment

<b>Table CP 10.2-1:</b>	Endpoints relevant for ris	sk assessment		, j
Test substance	Test species	E	Endpoint 😞	Reference
	Fish, acute		<u> </u>	: 4999;
	Oncorhynchus mykiss	$LC_{50}$	0.435 mg a.s./\(\infty\)	M-006770-01-1
	(rainbow trout)			W 0,077,001 1
	Fish, chronic	NOTE O	0.0286 n@ a.s./L	
	Oncorhynchus mykiss	NOEC	0.0286 nwg a.s./L	2001; M984463501-1
	(rainbow trout) Invertebrate, acute	\$		
	Daphnia magna	TANGO	0.9 mg 8./L	
	(cladoceran)		0.9 mg 8./L	1999; M-011257-01-1
	Invertebrate, acute	Co Co		
	Gammarus pulex	EGG &	0.15 mg a L	
	(amphipod)			
	Acanthocyclops venustus	*YEC	0.9 ma.s./10	
	Cloeon dipterup	F 50	Y Managara	
	(mayfly) O Daphnia gr. Meata	EC <sub>5</sub>	7 1.3 og a.s.6	₹2003; M-
	(cladocerán) Q  Asellus quaticas			,2003; M- 109491-01-2
	(ikanod)	EC 50	W mg s./L	
	Chaologrus ologuripes (diptera)	ECTO	> 3.2 mg a=02	
	Simocepladus velolus C C (claoceral)		3.2 mg/a.s./L	
	Clarine invertebote, actie		0,204 mg X.s./L	
Fluoxastrobin	Andricannysis bahid (Moridopsis bahid mysido		0.0004 mg/x.s./L	2002; M-
	Sarimp)		O Q	082793-01-1
Ş	Invertebrate, acute	ST CO	0.488 mg a.s./L <sup>1)</sup>	G MCA 9.2.4.2
	geometric mead "  U using species "	F650	7 0.488 mg a.s./L'7	See. MCA 8.2.4.2
,	2 Invertebrate Thronis		<b>S</b> "	
Ó	Aphnic magnit	NOEC	0.18 mg a.s./L	; 2000; M-042059-01-1
	(classicerary			WI 042037 01 1
4	Invo corate hronio	S SEC		
			0.0216 *** * 7	; 2003; M-
	(amQnipod) (anQnipod) (anQnipod)	NA EC	0.0316 mg a.s./L	110286-01-1
4 W	mulation)			
<b>"</b>	Invertebrate, chronic	,O <sup>V</sup>		; 2012;
	Habrophlebia touta Q	NOEC	0.0422 mg a.s./L	M-444119-01-1
Ő	Mayfly) 0,			KCA 8.2.5.2
				; 2012; M-
	Neocariding heteropoda	NOEC	0.060  mg a.s./L	442121-01-1
	(Freshwater shrimp)			KCA 8.2.5.2
	Macine invertebrate,			
	chronic	NOECsurvival	0.00061 mg a.s./L	
S S	Americamysis bahia	NOEC <sub>survival</sub> NOEC <sub>repro</sub>	0.0047 mg a.s./L	
		1.02 Crepto	3.00.7 2118 4.0.7 2	2002; M-082820-01-1
	shrimp)			

Test substance	Test species	E	ndpoint	Reference
	Sediment dweller, chronic Chironomus riparius (chironomid)	EC <sub>15</sub>	2.13 mg a.s./L	2000; M- 042042-07-1
	Pseudokirchneriella subcapitata (green algae)	E <sub>b</sub> C <sub>50</sub> E <sub>r</sub> C <sub>50</sub>	0.35 mg a.s./L 2.10 mg a.s./L	; 2000; M-033313-07-1
	<i>Lemna gibba</i> (Duck weed)	E <sub>b</sub> C <sub>50</sub> E <sub>r</sub> C <sub>50</sub>	> 6.0 mg a.s./L > 6.0 mg a.s./L	2001; M, 037727@1-1
	Lemna gibba (Duck weed)	E <sub>b</sub> C <sub>50</sub>	1.45 mg a.s./L (3.88 mg a.s./L (	2002; M-083023 01-1 KCA 8.2.7
HEC 5725-E-	Fish, acute  Oncorhynchus mykiss  (rainbow trout)  Invertebrate, acute		> 1/2 mg (m./L &	; 2000; M-033495-01-1°
des- chlorophenyl	Daphnia magna (cladoceran) Q	ECO	> 100 ng p, n//L	; 2600; M- 203822201-1
	Pseudokirchng fella & subcapitQa (green ) gae) &	ErCo	100 no p.m./ 100 mg p.mO/L	; 2000; M-025012-01-1
	Fish Sacute  Oncorhynchus Aykiss  (12 Abow tout)	ALC <sub>50</sub>	95.7 mg p.m. 2	; 2001; M- 052093-01-1
	Invertebede, acute  Daploda magna  (cladoceid)		7 000 mg/p.m./j.	; 2001; M-030332- 01-1
HEC 5725- carboxylic acid	SedinOnt dwelver, chronic Spironomis ripurius G (chOonomiO 4		mg Am./L	2001; M- 078605-01-1
	Pseudokircheriella Subcapitata (b (Selojastrum Taprigovnutur green) algas	FQZ 50 FrC 50	mg p.m./L	.; 2001; M- 073836-01-1
	Fish acute of Orcorhy ichus hekiss ( (1200 bow trout)	©C50	2.6 mg p.m./L	; 2006; M- 277036-01-1 KCA 8.2.1
	Fish Fronic Fish Fish Front (father ad mingrow)	DCso of the control o	4 mg p.m./L	EFSA Scientific Report 102 (2007)) ; 2006; M- 277036-01-1
2-chlorophe	Invertebrate, acute  Daphiva magna  (Qadoceran)	EC50	7.4 mg p.m./L	; 2006; M- 277036-01-1 KCA 8.2.1
2-chlorophenox	InvOtebrat, chronic Daphon magna (chaoceran)	NOEC	0.3 mg p.m./L <sup>2)</sup>	EFSA Scientific Report 102 (2007) ; 2006; M- 277036-01-1
	Psydokirchneriella subcapitata (Selenastrum capricornutum, green algae)	ErC50	70 mg p.m./L	EFSA Scientific Report 102 (2007) ; 2006; M- 277036-01-1

Test substance	Test species	Eı	ndpoint	Reference
	Fish, acute Oncorhynchus mykiss (Rainbow trout)	LC <sub>50</sub>	2.19 mg prod./L	; 2014/M- ( 491937-01) 1 S KCP 1002.1
FXA+PTZ EC 200 (100+100) G	Invertebrate, acute  Daphnia magna  (Cladoceran)	EC <sub>50</sub>	1.67 mg prod./10	2012; M-434883-01-1 KCP 102-1
	Pseudokirchneriella subcapitata (Green alga)	E <sub>r</sub> C <sub>50</sub> NOE <sub>r</sub> C	11.5 mg rhod./L 0.096 mg prod./L	L;2012; M 438495-01-10 C KS 10.23

**Bold letters** – values considered relevant for risk assessment

a.s.: active substance; p.m.: pure metabolite; prod.: formulated product.

When using the above acute invertebrate toxicity data (including Mysid excluding the two "greater than" values), with the geomean approach according to the most recentaquatic guidance document (SANTE 2015-00080, 15 January 2015) a geometric mean value of 0.458 mg.a.s./L can be calculated

<sup>©</sup>2006√M-27**7⊕**36-01-19 In the statement on the exposure of aquatic organisms to 2-chlorophonol ( a NOEC of 0.5 mg/L is presented as most sensitive chronic endpoint for Maphnia based on notional concentrations applied during testing. According to the EFSA Scientific Report (2007), the mighinum measured concentration of 0.3 mg/l must be considered as relevant endpoint.

#### Selection of endpoints for risk assessment

The relevant endpoint from each aguatic study was defined according to the current data requirements from the EU Regulation 283/2013 and the ESA Guidance on the red risk assessment for plant protection products for aquatic organisms of edge of-field surface waters (2013), and based on recommendations from the relevant standard test guideline e.g. Growth rate is is the most suitable endpoint from algaeanhibition 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<sub>r</sub>C<sub>50</sub> 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 biograss. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method 3, the EC regulation for Classification and Labelling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461), 1-44, 2007 Inst growth rate as the most suitable endpoint of the algae inhibition test

In accordance with Regulation (EC) No 1105/2009 and with the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013), studies esulting 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 (



Table CP 10.2-2: Initial max PECsw 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 as Tha
		PECsw, max	PECsw, max	PECsw, max
		[µg/L]	[μg/L] 🐧	[Qg/L]
Fluoxastrobin	STEP 1	52.69	43.91	43.91 Ø V
(E+Z)	STEP 2 - North	8.05	6.71	<i>\$</i> √ 7.39, <i>\$</i> √
(E+Z)	STEP 2 - South	14.66	12022	@/ 13960 V
HEC 5725-E-des-	STEP 1	35.93	<b>29</b> .94	🗸 🔊 .94 🖇 🖇
chlorophenyl	STEP 2 - North	5.19	4.33	ي 4.84°° ر
Ciliorophenyi	STEP 2 - South	10.10	~, *8.4 <del>,</del> ? ?	9.44
HEC 5725	STEP 1	19.46		¥6.22 ×
HEC 5725- carboxylic acid	STEP 2 - North	<b>2</b> .30 <b>2</b>	, "Y.91 🗳 ,	2.14
carboxyric acid	STEP 2 - South	4.48	v v 3.73€ °	√ 4.19 <sup>4</sup> , °
	STEP 1	23.56	19463	1263
2-chlorophenol	STEP 2 - North	291 ~	2,43 ° °	2.84
	STEP 2 - South	© (3.63 × )	94.69 V	5.51

Bold values considered in risk assessment

Table CP 10.2-3: Initial max PECsw and TWACsw values at day 7 following application to cereals FOCUS Sten 3 FOCUS Step 3

<del></del>
5
,
WACsw-7
VACsw-7 [μg/L]
1.204
0.320
0.155
0.044
0.024
0.043
0.009
-
-
-
-
-
0.489

Table CP 10.2-	4: Initial max PEG	Csw and TWAC	lsw values at day	7 following app	lication to cereal	ls
	FOCUS Step 3					Q S
			Cer	eals		
			2 × 125	g a.s./ha	<b>*</b>	
Compound	FOCUS Scenario	Win	nter	Spr	ring 🏈	
Compound		PECsw, max	TWAC <sub>sw</sub> -7	PECsw, max	WAC <sub>sw</sub> -7	
		[µg/L]	[µg/L]	[µg/L]	[μg/L]	
	D1 (ditch)	0.869	0.724	1.166	0.999 🏂	
	D1 (stream)	0.718	0.206	0.701© <sup>*</sup>	0.248	
	D2 (ditch)	0.936	0.676	-84	-0	
	D2 (stream)	0.700	0.3.13	4	, O *	
	D3 (ditch)	0.793	± <b>3</b> √166	<b>0</b> ₹792 ⊘°	#129 Ly	
	D4 (pond)	0.035	0.033	<b>→ 0.039</b> ©	0.036	
Fluoxastrobin	D4 (stream)	0.609 🐇	0.017	0.647	0.000° °	
(E+Z)	D5 (pond)	0.040 🔘	00038 📯	0.938	<b>9</b> 336	<u>.</u>
	D5 (stream)	0.631	30.008	Ø.665 <sup>©</sup>	0.007 Ö	
	D6 (ditch)	0.790	~ 0.29#/	> '-A	\(\sigma^{-1}\).	
	R1 (pond)	0 <b>,1</b> 87 _%	, 0. <b>05</b> 8		y Ey z	
	R1 (stream)	_Q355 <sub>6</sub> ~	D.169	\\ \Lambda \\ \tilde{\tilde{U}} \\ \tilde{U}	<u> </u>	
	R3 (stream)	1.090	~0.149G	~ ~	- 5 5 - 5	S. S
	R4 (stream)	Q 1.410	0.387	7 1.786	0.40)	

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

Initial max PECsw and T **Table CP 10.2-5:** FOCUS Step 3

Table CP 10.2-	5: Initial max PECsw and TWACsw values at day 7 following application to onions FOCUS Step 3  Onions  FOCUS Scenario
1 abit C1 10.2-	EOCUS Stop 2 & Son 2 & Son 3 &
	FOCUS Step 3 O Onioùs Onioùs VOCUS Scenarfo  Procus de la companya
	TO COLUMN TO THE STATE OF THE S
	FOCUS Scenario
Compound *	
	DEC, Works TWAC 7 [µg/L] [µg/L]
(m)	ν μg/L] γ [μg(L] ν
	D3 (dttch) 0.116 0
	D4 (pond) 0.045 \ 0.043 \ 0.043 \ 0
~ ~ ~	D3 (dttch)   D4 pond   D4 stream)   D604   D604   D604   D604   D705
	1968 (ditch, 1st) 65 0.7885 6 0.6000 6
Fluoxastrobin	\$\tilde{\Omega} 6 \text{ (ditch, 2nd)} \tag{783} \tag{242}
(E+Z)	$\mathbb{Z}_{l}$ R $\mathbb{Q}_{l}$ and $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$ $\mathbb{Z}_{l}$
~Ç	R (stream) 1.622 9 0.197
4	
	R2 (stream)
	R4 (stream) > 3.05% 0.414

Bold values considered in risk assessment

Bold values considered in risk assessment Italic values considered in formed tisk assessment

Table CP 10.2- 6: TWAC<sub>sw</sub> values at day 7 for fluoxastrobin – use in winter cereals FOCUS Step 4

				F	luoxastro	obin (E+	<b>Z</b> )		
		Cereals	(winter)	, 2 × 150	g a.s./ha	Cereals	(winter)	2 × 125 g	a.s./ha
			TWACsv	v-7 [μg/L]	]	TWAC 7 [µg/L]			
<b>Buffer Width</b>	Scenario			eduction	•		Drift Rec		300/2
& Type#		0%	50%	75%	90%	0%	50%	75%	90%
	D1 (ditch)	0.435	0.435	0.435	0,435	0.329	0.329	0.329	0.329 0.329 0.206 0.330 0.181 0.004 0.0016 0.0016
	D1 (stream)		0.433	0.433	272		0.206	0.206	0.52
	D2 (ditch)	0.419	0.419	0.419	0.419	0.330	0.330	0.200 02/30	30 5
	D2 (stream)		0.233	0.233	0.233	0.18,1	0.181	0.181	0 181
	D3 (ditch)	0.054 *		0.013 *	0.005 *	0.945	* 0.022	0.014	
	D4 (pond)	0.034	0.027	0.021	0.020	0.028	0.018	0.007	0.004
5m	D4 (pond) D4 (stream)		0.023	0.021	0.020	0.016	0.016	2016	\$016
SD	D5 (pond)	0.021	0.021	0.021	0.021	0.010		00.009	0.004
SD	D5 (pond) D5 (stream)		0.020	0.002	0.002	0.2003	0.001	\$0.005    V	J.00 ( )
	D6 (ditch)	0.004	0.002		0.009	0.075 <sub>4</sub>	0.038		0.007
	R1 (pond)	0.091	Q 178	9.172	0.1690	0.075	0.035		0.138
	R1 (stream)		Ø.207	0.207	0.207	0.130	0169	0.169	0.136 S
	R3 (stream)	L//	0.182	0.20	0.282	149	\$0.149	0.149	0.149
	R4 (stream)		0.18	0.1 <b>82</b> 0.483	0.483	0.397		0.133	3.397
	D1 (ditch)	0.43/5		©.483	0.435	0.329	Q.@29		¥397 ¥329
	D1 (dltcll)	0.433 Øv272 ¥		¥0.433 €	0.272	0.329	9.206 p		0.206
	D1 (stream) D2 (ditch)	0.272			0.419	Q 200	0.200		
	D2 (altery)	0.419	0.419	0.419	0.419 0.233	6.33U	0.330		0.330
	D2 (stream)	0.238				0.181 0.024	0.187	. %	0.181
	D3 (ditch) D4 (pond)	0.028	00.014	0.007 *	0.003	0.029	* 0.012   * 0.017   5	189	0.002
4.0	D4 (pond)	0.021	0.022	0.020	0.020	0.020	0.017	0.016	0.015
10m	DA (stream)	0.024	0.021	0.021	0.921	0.016	0.018	0.016	0.016
SD &RO	(popu)	U.W&8	U 914	00008	0.004 0.002	0.023			0.003
Ĩ,	D5 (stream)	10.002	0.002	0.002	0.000	0.002	02001		0.001
	D6 (ditch)		0.023	0.012	0.005	0939	9.019		0.004
	R (pond)	0.083	0.073	0.071		©.068	0.061		0.056
Č0	9 ()		0.093		0.093 C	0.076	0.076		0.076
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	R3 (stream)		081		0.084	0.067	0.066		0.066
	R4 Gream	0.220	~ 0	0.220	0,220	<b>Q</b> 781	0.181	0.181	0.181
6 A	D) (ditch)		0,4375	0.435	0.435	0.329	0.329	0.329	0.329
~	101 (stream)	0,272	272 6	JM 272	0.272	0.206	0.206	0.206	0.206
Ď	D2 (ditch)	0.419	0.419	0.419	0.40	0.330	0.330	0.330	0.330
<i>a</i> .	D2 (ditch) D2 (stream) D3 (ditch)	0.23	0.233	0.233	0.233	0.181	0.181		0.181
	103 (ditch)	0.018 *	0.007 *	0.004	0.001 *	0.012	* 0.006		0.001
4	D4 (n@id)	10H173	<i>18</i> 9¥0021 L≥	©.020	0.019	0.018	0.016		0.015
2010	D4 (stream)	Ø.021 6	0.021	0.419 0.253 0.004 0.024	0.021	0.016	0.016		0.016
SD & RO	D5 (pond)	0.019	0.010	Q <del>0</del> 05	0.003	0.015	0.008		0.002
	(ctraem)	റ മഹ്	$\Omega$	<b>0</b> 2002	0.002	0.001	0.001		0.001
•	D6 (disch) R1 (pond)				0.004	0.020	0.010		0.003
	R1 (pond) &	0.044	0.035	0.036	0.034	0.036	0.032		0.028
L. W	R1 (stream)	0.049	0.049	0.049	0.049	0.040	0.040		0.040
	R3 (stream)	0.042	0.042	0.042	0.042	0.035	0.035		0.035
	R4 (stream)	Ø415 °	9.115	0.115	0.115	0.095	0.095		0.095
jy S	TT Carrie	S.113	0.113	0.113	0.113	0.073	0.073	0.075	0.075

Forcies marked with \* result from single applications
SD and O denote spray frift and runoff buffer
Bold salues considered in refined risk assessment

Table CP 10.2-7: TWAC<sub>sw</sub> values at day 7 for fluoxastrobin – use in spring cereals FOCUS Step 4

		Fluoxastrobin (E+Z)							
		Caroola	Cereals (spring), 2 × 150 g a.s./ha Cereals (spring), 2 × 125 g a.s./ha  TWACsw-7 [μg/L]  TWACsw-7 [μg/L]						
					; a.s./11a	Cereals	(spring)	74 ^ 143	g a.y//na
D 60 ****			TWACsw-				TWACSw	-/ [μg/L]	Q .
Buffer Width	Scenario		Drift Re		0001	201	n 57	duction	O" <i>(2)</i>
& Type#		0%	50%	75%	90%	0%	<b>30%</b>	75%	_ ^ v
	D1 (ditch)	0.512	0.512		512	0.398	0.398	0.3	0.398
	D1 (stream)		0.320	0.320	0.320	0.248	0.248	0.248	<b>2</b> 248
	D3 (ditch)	0.042 *		0.01	0.004	0.03%	* 0.017  *	<b>6.009</b> *	90.003 C
5m	D4 (pond)	0.037	0.026	0.024	0.023	0.031	0°.021	0.019	0.018
SD	D4 (stream)			<b>Q</b> 024	0.024		0.019	0.019	0.019
	D5 (pond)	0.037	0.019	0.010		0.031	0.006		0.004
	D5 (stream)		0.002	0.00	0.001	0.003	0001	0.001	0.001
	R4 (stream)		0.476	0.474	<b>9</b> 473	8393	<b>390</b>	0.389	0.388
	D1 (ditch)	0.512		0,512	0.512	0.398	0.39	0.398	0\$98
	D1 (stream)		\$320. ************************************	0.320	0.320	0.248	0:248	<b>£</b> 248	0.248
	D3 (ditch)	0.022	0.014	0.006*	0.092	0.018	* 0.009	Ø.005	, 0.002 0.002
10m	D4 (pond)	0.0280	0.025		0,022	<b>©</b> 022	0.019		0.018
SD &RO	D4 (stream)		0.024	0.024	0.024	0.0190	0.019	0,009	0.019
	D5 (pond)	0.026		0.007	0.000	0.022	001	Ø06	0.003
	D5 (stream)	9.002	0.001	0.00	0.001	0.001	0.001	0.001	
	R4 (stream)	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.293	0.215	0.214	0.178	0.001	0.176	0.176
	D1 (ditch)	0.512		Ø.512	0.512	0.398	0.398	0.398	0.398
	D1 (stream)	0.320	0.320		0.320	0.248	0.248	<b>©</b> .248	0.248
	D3((ditch)	<b>*</b> 0.01 <b>19*</b>	0.00© *		·Q, <del>0</del> 01	<b>%</b> 010	0.005	0.002	0.001
20m	DA (pond)		0@24	Ø23 ×	Ø.022	0.020 C	0.010	0.018	0.017
SD & RO	54 (stream)	0024	0.024	0.024	0.02	0.019	0.019	0.019	0.019
	D5 (pend)	0.018	0.009	0.005	0,003	0.075	0,008	0.004	0.002
~0	D stream)	0.001	0.001	0,001	0.001	0.001	0.001	0.001	0.001
0*	RG (stream)	0.113	0.43	Ø 112	€0.112 <sub>©</sub>	0.093	0.092	0.092	0.092
Entrie marked	with * resu	lt from sig	n le appli	cations	<i>Q</i> 1	- O			
# So and RO de	note pray di	and ratio	ff buffer	Ş	~G				
Bold values co	nstdered in i	efined ris	sk assessn	nent		Y			
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Table CP 10.2-8: TWACsw values at day 7 for fluoxastrobin – use in onions FOCUS Step 4

		Fluoxastrobin (E+Z)							
		Onions, 2 × 125 g a.s./ha							
			Single ap	plication			Multiple a	pplications	
Buffer				-7 [μg/L]				-7 [μg/L]	
Width	Scenario			eduction				eduction	
& Type <sup>#</sup>		0%	50%	75%	90%	0%	50%	75%	×90%
от турс	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	e0.014	0.043	0.040	©0.039	0.039
	D4 (stream)	0.016	0.016	0.016	0.016	0.045	0.045	0.04	0.045
	D6 (ditch)	0.017	0.009	0.007	0.007	0.941	° 0.021√	0010	0.007
5m	D6 (ditch)	0.014	0.012	0.012	0.012	<b>√</b> 0.063 <i>®</i>	0.031	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.0
SD	R1 (pond)	0.070	0.063	0.060	0.058		Ø147 °	0.141	Q.J38
	R1 (stream)	0.081	0.081	0.081	@ 0.08¥	0.497	1076	0.197	a 0.197
	R2 (stream)	0.047	0.047	0.047 %	້າດທີ່	Ø.117 Ĉ	0.197	Ø¥17	0.11 <b>%</b>
	R3 (stream)	0.078	0.078 🏑	0.047	0.078	Ø.192	0.492	0.192	0.192
	R4 (stream)	0.175	0.175	Q <u>.</u> Î%5	Ø.175	0.444	20,414 å		Q\$\text{14}
	D3 (ditch)	0.017	0.00	<b>90.004</b> ×	0.002	Q.015	<b>₹</b> 0.008®	0.004	<b>@</b> .002
	D4 (pond)	0.015	0.014	0.014	0.094	Ør.041	0.040	Ø39 Ø	0.039
	D4 (stream)	0.016	0.016	0.016	0.016	0.0450	0045	\$0.045€	0.045
10m	D6 (ditch)	0.009	0.007	0,607	Ø.007 Ó	0.022	<b>9</b> .011	0.007	0.007
SD	D6 (ditch)	0.012	0.012	0.012	0.0	<b>99</b> 33	0.019	0.019	0.019
&RO	R1 (pond)	0.032)	0.028	\$0.02 <b>5</b>	0.024	(0.071)	0.063	0.058	0.056
ano	R1 (stream)	0.036	0.036		0.036	0.088	0.088	<b>№</b> 0.088	0.088
	R2 (stream)	0,021	0.021	0.021	√0.021 <sub>0</sub> °	0.653	<b>9</b> .053	0.053	0.053
	R3 (stream)	0.036	0.036	<b>6.036</b>	0.036	<b>20,</b> 088	0.088	0.088	0.088
	R4 (stream)	× 0.079×	<b>6.079</b>	0.079	0,079	00.186	0.186	0.186	0.186
	D3 (ditch) D4 (pond) D4 (stream)	0,009	0.004	0.002	<b>0</b> :001	0.008	0.004	0.002	0.001
	D4 (pond)	0014	0.014	0.014	0.013	0.040	Ø.039	0.039	0.038
			00016	Ø.016 &	0.016	0.045 <	¥ 0.0.E	0.045	0.045
20m	D6 (ditch)	0.007	©007 %	0.00	0007	0.011	0.007	0.007	0.007
SD &	D6 (ditch) ORL (pond)	0.012 <0.018 ×	0.012	0.012	0.012 0.012	0.049 0. <b>03</b> 8	0.019 0.032	0.019 0.030	0.019
RO	Ri (stream)	0.019	0.079	0.019	0.012	0.046	0.032	0.030	0.028 0.046
K	R2 (stream)	0.018	0.019	\$\\ 0.019\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0. <b>01</b>	♥.040 №0.028	0.048	0.048	0.048
	R3 (stream)	0.013	©0.011 ©0.019	0.0149	0.011	0.028	0.028	0.028	0.028
	D4 ( 4 🔊	90 044	11 0 00/10	041		0.040	0.040	0.040	0.040
# SD and					7 0.040	0.077	0.077	0.077	0.077
Bold val	ues considered	in refined r	isk°a⁄ssessana	ent 💸	* 10°				
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	RO denote spray, ues considered		off buffer isk assessm	ent of					
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## ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2-9: TERA 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)

case GAP 2 × 150 g a.s./ha and for onions on GAP 2 × 125 g a.s./ha)							
Compound	Species		lpoint g/L]	PECsw,max [µg/L]	TERA	Trigger	
Cereals (Winter/sprin	ng)			_1	Ş	, 23, 0	
	Fish, acute Oncorhynchus mykiss	LC <sub>50</sub>	<b>43</b> 5	14.66	29.	100	
Fluoxastrobin	Invertebrate, acute Daphnia magna	EC <sub>50</sub>	480	014.66	32.7		
(E+Z)	Invertebrate, acute Gammarus pulex	EC	150	14,66	\$\tag{\tag{\tag{2}}{\tag{2}}}\tag{\tag{2}}	100	
	Invertebrate, acute Americamysis bahia	\$C <sub>50</sub>	§ 6044	14.66	\$\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\f	100	
HEC 5725-E-des-	Fish, acute Oncorhynchus mykiss	LC3	\$102 000	40.10	> 10 099		
chlorophenyl	Invertebrate, acoe Daphnia magna	& EC <sub>50</sub>	/ > 100 000 T	10,40	\$\frac{1}{2} > 99\hat{0}\$	100	
HEC 5725-carboxylic	Fish, acute Oncorhyn@nus my&iss	<b>L</b> C 50	95 7000	4.48	21 362	100	
acid	Invertebrate, acute Daphnia magna	EC	>J00 000€	4,48	> 22 321	100	
2-chlorophenol	Fish sacute  Quecorhymchus mokiss	EC 50	2600	5.63	\$461.8	100	
2-emorophenor	Invertebrate acute   Daphnia magna	EC50	\$7400g	5.63 %	1314	100	
Onions	~ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \						
	Fish, acute Oncorhynchas mykiss	EC.	\$\frac{1}{2}435	¥3.60	32.0	100	
Fluoxastrobin	Invertebrate, acuse Daphina magna	EC <sub>50</sub>	480	13.60	35.3	100	
(E+Z)	Invertebrate, acute Gammards pules	W"	0 150	13.60	11.0	100	
	Invertebrate, wute Americamysis bahia	ECSO	80.4	13.60	4.4	100	
HEC 5 5-E-des-	Fish Scute Fish South Fish South Fish South	EC50, 4	> 102 000	9.44	> 10 805	100	
chlorophenyl	Investebrate acute Isaphnia magnaQ	EC%	> 100 000	9.44	> 10 593	100	
( ) -	Fish, acute@ 2Oncorkynchus mykiss	LC <sub>50</sub>	> 95 700	4.19	> 22 840	100	
acid	Insertebrate, acute Daphnto magna	EC <sub>50</sub>	> 100 000	4.19	> 23 866	100	
25 hlorophenol	S Firsh, acute  ▼Oncorhynchus mykiss	LC <sub>50</sub>	2600	5.51	471.9	100	
Simologicilor so	havertebrate, acute Daphnia magna	EC <sub>50</sub>	7400	5.51	1343	100	

Bold values do not meet the trigger

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

Compound	Species	End	point	RAC <sub>sw; ac</sub>	PEC <sub>sw,max</sub>	PEC/RAC
Cereals (Winter/sprin	-	Įμ	g/L]	(LC <sub>50</sub> /100)	<b>μg/L</b> ]	
Cereais (Winter/sprii	Fish, acute	T.C.	12.5	400	14.66	
	Oncorhynchus mykiss	LC <sub>50</sub>	435 💍	4.330	14.66	3.37
Fluoxastrobin	Invertebrate, acute Daphnia magna	EC <sub>50</sub>	480	4.8	1 <b>4</b> .66	3595
(E+Z)	Invertebrate, acute Gammarus pulex	EC <sub>50</sub>	150		14.66	9.77
	Invertebrate, acute Americamysis bahia	<b>E</b> C <sub>50</sub>	§ 60.45°	\$\int 0.604\$\int 0	94.66	<b>24.27</b>
HEC 5725-E-des-	Fish, acute Oncorhynchus mykis	LC560	≥ <b>1</b> 000 000 000 000 000 000 000 000 000 00		10.90	
chlorophenyl	Invertebrate, acute Daphnia magne	ÆC50 &	7 100,000 s	> 1000	\$10.10\$	Q 0.01
HEC 5725-carboxylic	Fish, acate Oncorhynchus myklas	L. 550	95 700	957	<b>3</b> .48 ×	< 0.005
acid	Invertebrate, acete Daphhia magna	C EC <sub>50</sub>	> 100 000	\$ <b>10</b> 000	4.48	< 0.004
2-chlorophenol	Fish, acute Oncorhynogus mykiss	\$\tilde{\text{C}}_{50} \tilde{\text{Q}}	2600° «	26	5.63	0.22
2 emorophenor	Invertoorate suute Daphnia jagna	EÇ	\$7400 \$7400	074 ×	5.63	0.08
Onions						
	Fish, acuto Oncochrynchus mykiss	LC	<b>3</b> 435	₩ <b>4</b> .35	13.60	3.13
Flugerastrobin	hovertebrate, acute Daphara magra	EC <sub>50</sub>	480 ^	4.8	13.60	2.83
(É+Z)	Invertebrate acute of Gammarity pulex	EC50	\$\frac{150^{2}}{2}	1.5	13.60	9.07
	Invertebrate, acote Americamysis bahiq	EC <sub>5</sub>	<b>6</b> 0.4	0.604	13.60	22.52
HEC 5725 E-des-	Fish acute Q Oncorhyndhus makiss	\$\$\times_{50}\$\$	> 102 000	> 1020	9.44	< 0.01
chlowphenyl	Vinvertebrate, acute ( Daphnia magna	ECS	> 100 000	> 1000	9.44	< 0.01
HEC 5725-carboxylic	Fish Cacute  Que Corhy Wichus Physics 2	$\mathcal{L}_{C_{50}}$	> 95 700	> 957	4.19	< 0.004
acid of	Investebrate, acute baphnist magna	EC <sub>50</sub>	> 100 000	> 1000	4.19	< 0.004
2-chloroph vol	Fist acute Oncorns nchus mykiss	LC <sub>50</sub>	2600	26	5.51	0.21
2-Agrioropaction	Invertebrate, acute Daphnia magna	EC <sub>50</sub>	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 FQCUS 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 of Aquatic Ecotoxicology (EFSA Journal 2013;11(7):3290), the geomean of the available acute toxicity data on aquatic invertebrates (EU

provided in the nev	v EFSA Guidance Document on Aquatic Ecotoxicology (EFSA Journal
2013;11(7):3290), the	geomean of the available acute toxicity date on aquatic invertebrates (EU alculated and used in the refined risk assessment in combination with the prigger
agreed endpoints) is ca	alculated and used in the refined risk assessment in combination with the prigger
value of 100:	
	Species ECm/LCs@mg a.v1)
	Species EC 50/LC 5@mg a, 5/L)
	Americanmysis bahia 0 00604 4 4 6 6
	Gammarus pulex 1 70.15  Q Q Q Q Q Q
	Daphnia magna V V 0.48 D D D
	Acanthocyclop Denustry 19 27 0 27 5
	Daphnia magna  Acanthocyclop Evenus (us)  Cloeon diptem   Daphnia go galeata  Asellus aquaticus  Cha Charles of Charles and Charles of Charles
	Cloeon diptemin 4 1.0 4 6 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5
	Asellus aquaticus & A C C C C C C C C C C C C C C C C C C
	Chagopirus obscurigis 73.2 7
	Simocephanis venues     >3.20       Simocephanis venues

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. It has to be noted that the greater than," endpoints for Chaoborus obscuripes and Simocephalus

Table CP 10.2-11: TER<sub>A</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

3 a		<u>ivertebrates en</u>	apoint (geometric	mean)	
Species	Endpoint [ug/L]	PECsw,max	FOCUS scenario	TERA	Trigger V
Fluoxastrobin (E+Z), win	•	<u> </u>		Ž, I Os	
( ),		1	D1 (ditch)	415.1 🔊	2100 B
				( )	
					100
Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin (E+Z), winter cereals, 2 × 150 g a.s./har   Illozastrobin	\$13.6	<b>100</b> 0 6			
			A		©100,©
		78 V	V . (2) .		2 100
Fish acute	<u> </u>	0331 2		\$95.1 %	400
· ·	$LC_{50}$ 435	√ 0.048 €		A(_)/	∠ 100 <sub>e</sub> ∘
		0.758	D5 (stream)	7 573.9 &	100
		0,948 1		<b>₹</b> 58.9≪	<b>2</b> 00
		0.203	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	2146	100
		1,663		2,6 ₹.6 . ≼	<i>§</i> 100
		1937 C	R3Cstream	325.4	100
		%.724%	(stream)	© 2523V	100
		/// 1.0 (O)		_	100
%		6 <u>4</u> 864	D1 (stream)	×555.6	100
		\$1.137,°	D2 (ditch)	Ŷ 422.2	100
Ø.		0.847	D2 (stream)	566.7	100
J.		-209952 Ø	D\$∕(ditch\$∕	504.2	100
		V0.042	D4 (pond)	11 429	100
Invertebrate, acuto	C. C. A. A. A. S.	0.751	D4 (Stream)	656.6	100
Daphfla magna 🦼	EC\$0 7480	0.048	Do (pond)	10 000	100
		0.758	(stream)	633.2	100
		0.948 /	D6 (ditch)	506.3	100
		0.203	R1 (pond)	2365	100
		5 1.66 <b>2</b>	R1 (stream)	288.6	100
. O .		1337	R3 (stream)	359.0	100
		√J.724	R4 (stream)	278.4	100
		1.048	D1 (ditch)	465.6	100
		0.864	D1 (stream)	564.8	100
		1.137	D2 (ditch)	429.2	100
4.4		0.847	D2 (stream)	576.2	100
		0.952	D3 (ditch)		100
Invertebrate Soute	LCO/EC50 488	0.042	D4 (pond)		100
Georgean, 7 species		0.731	D4 (stream)		100
		0.048	D5 (pond)		100
, O	<b>3</b>	0.758	D5 (stream)		100
O		0.948	D6 (ditch)		100
		0.203	R1 (pond)		100
		1.663	R1 (stream)	293.4	100



Species	Endpoint [μg/L]	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	TERA	Trigger
		1.337	R3 (stream)	365.0	100
		1.724	R4 (stream)	<b>283.1</b>	© 100g
Fluoxastrobin (E+Z), spri	ng cereals, 2 × 150 g a.	s./ha	C	<i>y</i>	
		1.403	D1 (ditch)	310.00	\$ <b>7</b> 00 \$
		0.8413	D1 (stream)	5172	~~~ 100°S
		0.950	D3 (Qitch)	<b>48</b> 7.9 S	11949
Fish, acute	LC <sub>50</sub> 435	<b>6</b> 047	D4 (pond)	9255 🗣	000
Oncorhynchus mykiss	LC50 433	6.777	Ď4 (stream)	2 558 <b>8</b>	100
	Co.	0.046	7 D5 (wond)	* <b>9</b> 457	100
	Ö	998 3	Da (stream)	\$545.1	100
	EC <sub>50</sub> 9480	2.17%	A4 (stream)	1968	Ø 100 √
	Ç".~	1.403	D1 (ditch) O	342.1	¥ 1000
		0.841	DP(streako)	\$70.7°	<b>0100</b>
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	OD3 (difteh)	\$ 50 <b>5</b> \$	ي 100 م
Invertebrate, acute	FC 50 0480	02947	D4 (pond)	213	100
Fish, acute Oncorhynchus mykiss		D.777 @	Da (stream)	°617. <b>€</b>	100
		0.046	(D5 (pond)	10 435	100
%		0.798	D5 (stream)	<b>6</b> 01.5	100
		<b>2</b> .177 5	R4 (stream)	220.5	100
		1.403	OD1 (ditch)	₹° 347.8	100
	4 .	0.841	D1 (stream)	580.3	100
		<b>39.950</b>	Ø3 (ditch)	513.7	100
Invertebrate, acute	ALC 50/EC 50 488 .	0.045	D4 (pond)	10 383	100
Geomean, 7 species		0377	D44stream)	628.1	100
		0.046	(pond)	10 609	100
		0.798	D5 (stream)	611.5	100
<u> </u>		2577	R4 (stream)	224.2	100
, 1					
, Q		<b>V</b>			
	\$	7			
<b>@</b> \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \					
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Table CP 10.2-12: TERA calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

and t	he refined aquatic inver		int (geometric me	an)	
Species	Endpoint [µg/L]	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	TERA	Trigger o
Fluoxastrobin (E+Z), win	ter cereals, 2 × 125 g a.s	s./ha	, 0	Ş.	4 , 4
		0.869	D1 (ditch)	500.6	<b>190</b>
		0.718	D1 (stream)	605,87	100
		0.930	D2 (dach)	464.7	100
Fluoxastrobin (E+Z), winter cereals, 2 × 125 g a.s./ha $ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	D2 (Stream)	<b>6</b> 21.4	<b>4.9</b> 00 6.9		
		△0.793	Q3 (ditch)	L 548,5	© 100,©
		0.035	>> D4 (p@nd)	₹ 13 <b>©</b> 29	2 100
Fish, acute	1.0 425		D4 (stream)	<b>9</b> 14.3 🔊	400
Oncorhynchus mykiss		Ø.040 Č	Drs (pond)	© 10 8 <b>7</b> 5	<u></u> 100, ∘
		0.63	D5 (stream) \$	§ 689.4 &	1000
		<b>%</b> 790 4	D6 (ditch)	\$50.6₺	<b>2</b> 000
		Ø.167	R/1 (pond)	260 <b>5</b>	100
		1,355	R1 (stoeam)	325.0	<b>7</b> 100
		<b>1,9</b> 90 ¢	R3(stream)	399.1	100
		Ø.410∜	(stream)	© 3085	100
		l≪√ 0.8 <b>6</b> 69	D1 (ditch)	5552.4	100
%		Ø4718 🔊	DF (stream)	668.5	100
*		©0.936 °	D2 (ditch) %	S 512.8	100
T. C.		0.7 <b>0</b> 6	D2 (stream)	685.7	100
, Š		√ <b>3</b> 99993 €	D\$/(ditch\$/	605.3	100
		0.035	©04 (pŏnd)	13 714	100
Invertebrate, acuto	EC22 480 %	0.609	D4 (Stream)	788.2	100
Daph 🛱 magna 🦼	EC5000 4800 0	0.040 @	Do (pond)	12 000	100
		Ô 0.63₽	(stream)	760.7	100
	\$ \$ . \$ . \$	) 0 <b>9</b> 90 /	D6 (ditch)	607.6	100
<b>3</b> 4		0.167	R1 (pond)	2874	100
		5 1.355	R1 (stream)	354.2	100
		12990	R3 (stream)	440.4	100
		.410	R4 (stream)	340.4	100
		<b>ॐ</b> 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
Invertebrate, Fute	LC50EC 188	0.035	D4 (pond)	13 943	100
Geomean, 7 species	400	0.609	D4 (stream)	801.3	100
	, and the second	0.040	D5 (pond)	12 200	100
	<b></b>	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 <sub>sw,max</sub> [μg/L]	FOCUS scenario	TERA	Trigge
		1.090	R3 (stream)	447.7	~ <b>1</b> 00
		1.410	R4 (stream)	<b>346</b> .1	© 100g
Fluoxastrobin (E+Z), spr	ing cereals, 2 × 125 g a.s	s./ha	0	<i>y</i>	
		1.166	D1 (ditch)	373.1 🔘	Ø100
		0.7010	D1 (stream)	6205	100%
		0.792	D3 (Qitch)	<b>54</b> 9.2 S	1890
Fish, acute	LC <sub>50</sub> 435	6039	D4 (pond)	J1 154®	Q 00
Oncorhynchus mykiss	2030	0.647	Ď4 (stream)	5 <sup>9</sup> 672 <sup>3</sup>	100
	Q.	0.038	D5 (pond)	41,447, 4	100
		<b>665</b>	Ds (stream)	\$654.1	100
		1.78	4 (stream)	24368	100%
		1/166	D1 (ditch)	411.7	¥ 1000
		0.701	D (stream)	684.7	<b>○100</b>
		· 50.7925	OD3 (ditteh)	6069	<b>5</b> 100
Invertebrate, acute	EC <sub>50</sub> Q Q80	02039	D4(pond)	308	100
Daphnia magna	EC 50 480 &	₩647 W	De (stream)	741.9	100
		0.038	D5 (pond)	12 632	100
Invertebrate acute LC Geomean 7 species		0,665	D5 (stream)	<b>J</b> 21.8	100
		<b>%</b> .786 \$	R4 (stream)	268.8	100
J.		0.701	OD1 (check)	¥ 418.5	100
Š,		0.701	D1 (stream)	696.1	100
		₹ 792 ₹ 0.0 <b>3</b> %	Ø3 (ditch) D4 (pond)	616.2 12 513	100
Geomean 7 spector	LO <sub>0</sub> /EC 0 488 .	0.00	D4 (golid)	754.3	100
Scomeda, 7 species		0.038	D4 (pond)	12 842	100
		0.665	D5 (stream)	733.8	100
	4 2 2	1.786	R4 (stream)	273.2	100
			K4 (sucam)	213.2	100
, Q O .					
		., <b>V</b>			
		The state of the s			
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Table CP 10.2-13: TER<sub>A</sub> calculations for onions calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)

	atic invertebrates endpoi	int (geometrie i	nean)		
Species	Endpoint [µg/L]	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	TERA	Trigger
luoxastrobin (E+Z), oni	•		, L	Ş	4 2
	_	0.791	D3 (ditch) <sub>√</sub>	549.9 🔊	<b>190</b>
		0.045	D4 (popd)	9667	× 100 ×
		0.604	D4 (steam)	720.2	100
		0.7.85	D6 (Dich, 1st)	\$54.1	<b>A</b>
Fish, acute	10.	<u>~0.783</u>	DeQditch, 2nd)	L 555,6	© 100, ©
Oncorhynchus mykiss	LC <sub>50</sub> 435	0.173	∕> R1 (p@nd)	25P5 /	D 100
	<b>&amp;</b>	, 10622	R 1 (stream)	\$68.2 °×\$	400
		Ø.684	KO (stream)	© 636AQ	A 100
		1.48	R3 (stream)	<sup>2</sup> 293.7 &	100
	\$\times_{\text{2}} \times_{\text{3}} \times_{\te	3 <del>6</del> 957 4	R4 stream)	42.3 📞	<b>20</b> 00
		0.791	93 (ditch)	606	100
		0.045	D4 (pond)	1 <b>05</b> 67 , 4	§ 100
		<b>9 6</b> 04 6	D4(stream)	794.7	100
		©.785√y	Do (ditch, 1st)	© 61 15	100
Invertebrate, acute		0.783	D6 (ditch, 2nd)	643.0	100
Daphnia magna 🦠	A CO	0(173	R*(pond)	2775	100
		\$1.622 <sup>0</sup>	RAI (stream) 💃	© 295.9	100
		0.684	R2 (stream)	701.8	100
ŢĘ,		\$19481 Ø	R3 (stream)	324.1	100
		3.057	R4 (stream)	157.0	100
		0.791	D3 (Witch)	616.9	100
		0.045	D@ (pond)	10 844	100
Ę		(\$\int 0.604) \int	©4 (stream)	807.9	100
		0.985	åĎ6 (ditch, 1st)	621.7	100
Invertebrate, white	LC504C 488	0.783	D6 (ditch, 2nd)	623.2	100
Geomean, 7 species		0.172	R1 (pond)	2821	100
<b>*</b>		13622	R1 (stream)	300.9	100
		£9.684	R2 (stream)	713.5	100
Invertebrate, white Geomean, 7 species		1.481	R3 (stream)	329.5	100
		3.057	R4 (stream)	159.6	100

Table CP 10.2- 14: RAC<sub>sw; ac</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Step	3 (acceptability of risk:	PEC/RAC < 1)			
Species	Endpoint [µg/L]	RAC <sub>sw; ac</sub> (LC <sub>50</sub> /100)	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	PEC/RACO
Fluoxastrobin (E+Z), win	•		<u>  17-8-1</u>	Ş <sup>7</sup>	4 8
			1.048	D1 (ditch)	0,24
		₽ <sub>A</sub>	0.864	D1 (stream)	0.20
			1.197	D2 (dirtch)	0.28
		4	Ø847	D1 (ditch) D1 (stream) D2 (ditch) D2 (stream) D3 (ditch) D4 (stream) D5 (pond) D5 (stream) D5 (stream) R1 (stream) R3 (stream) R4 (stream) R4 (stream) D1 (ditch) D2 (ditch) D2 (stream) D2 (ditch) D2 (stream)	Ø19 6
			Q0.952 ∘	D3 (ditch)	0.22
		Ø"	~ 0.0 <b>3</b> 2	D4 (pend)	Q.QV
Fish, acute	1.0	\$25 L	<b>10</b> 731 <b>3</b>	D4@stream	10/17
Oncorhynchus mykiss	LC50 433 0°	(#).33 (W)	0.04	D5 (pobd)	<b>△</b> 0.01, ∘
			0,358	D5 (stream) (	P .((\>\gamma\)
			948	De (ditch)	22.22
			0.200		0.05
			) 1. <b>66</b> 3	R1 (stream)	J 0.38
			<b>4</b> .337		0.31
	LC50 435 5	0 4	€ 1.72 <u>4</u>	R4 (stream)	0.40
			1048	2/	0.22
%			9.864 S	A >>	0.18
			1.137	D2 (ditch)	0.24
Ž <sup>*</sup>			0.\$47		0.18
ĮĮ (			<b>\$9.952</b>	D3 (ditch)	0.20
			0.042		0.01
Invertebrate, acuto	EC50 480 \$	480	O 9. <b>4</b> 31		0.15
Daphrila magna			<b>39</b> .048	· · ·	0.01
., O			© 0.758	` '	0.16
\$	4 5 2 2		0.948	` ′	0.20
			0.203	ů,	0.04
		Ŏ Õ	1.663		0.35
4			1.337		0.28
			1.724	` '	0.36
		Ó,	1.048	` ′	0.21
		<b>Y</b>	0.864	` '	0.18
~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~			1.137	` ′	0.23
			0.847	`	0.17
			0.952		0.20
Invertebrate de ute	LC <sub>5</sub> CC 488	4.88	0.042		0.01
Georgean, Species			0.731	` '	0.15
			0.048		0.01
			0.758	` '	0.16
Ũ			0.948	` ′	0.19
			0.203	<u> </u>	0.04
			1.663	R1 (stream)	0.34



Species	Endpoint [μg/L]	RAC <sub>sw; ac</sub> (LC <sub>50</sub> /100)	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	PEC/BA
			1.337	R3 (stream)	<b>20</b> .27
			1.724	R4 (stream)	© 0.35
Fluoxastrobin (E+Z), spri	ing cereals, 2 × 150 g a	.s./ha	C	7	
			1.403	D1 (ditclo	Ø.32
		Ö	0.844	D1 (stream)	0.19
			0,050	D3 (witch)	0.22
Fish, acute	LC <sub>50</sub> 435	4	9.047	D) (pond)	0.01
Oncorhynchus mykiss		4.33	0.77 <b>©</b>	D4 (stream)	0.18
				D& (pond)<	
	Š		<b>40</b> .798	DS (stream)	0.18
			2.17	R4 (stoam)	® 0.50
			1,493 0	Dk (ditch)	029
			9.841	D) (stream)	<b>©</b> 0.18
			© 0.950 ×	D3 (chich)	ۇي   0.20
Invertebrate, acute	FC : 2 2080		0047 C	D4 (pond)	0.01
Daphnia magna	FC. 2400 (		Ø.777 O	Da (stream)	0.16
			Z 0.040	D5 (pond)	0.01
Invertebrate, acute Daphnia magna  Invertebrate, acute Geomean, 7 species  LOGomean, 7 species			0998	D5 (stream)	0.17
√			2.177	(stream)	0.45
Ş			O 1.403	<sup>y</sup> Ď1 (ditch)	0.29
			0.841	D1 (stream)	0.17
			Ø0.95 <b>9</b> \$	D3 (ditch)	0.19
Invertebrate, acute	LO <sub>0</sub> /EC O 488	4.88	0.047	D4 (pond)	0.01
Geomean, / species	50 0 4		<b>9</b> ,777	D4 (stream)	0.16
		8 3	0.046	D5 (pond)	0.01
			0.798	D5 (stream)	0.16
			2.177	R4 (stream)	0.45
		*			
F D A					
	<b>)</b>				
Ö					

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

Step	3 (acceptability of risk:	PEC/RAC < 1)		T	
Species	Endpoint [µg/L]	RAC <sub>sw; ac</sub> (LC <sub>50</sub> /100)	PEC <sub>sw,max</sub> [μg/L]	FOCUS «scenario	PEC/RACO
Fluoxastrobin (E+Z), win	•		[µg/2]	S.	
	, 3		0.869	D1 (ditch)	2020 <sub>©</sub>
		<i>≿</i> ∧	0.718	D1 (stream)	0.17
			0.286	D2 (Ortch)	0.2
		4	<b>JO</b> 700	D1 (ditch) D1 (stream) D2 (crtch) D2 (stream) D3 (ditch) D4 (pond) D4 (stream) D5 (pond) D5 (stream) D5 (stream)	<b>1</b> 6 6
		4	Q0.793 °	D3 (ditch)	00.18
		Ø"	~ 0.035 °	D4 (pend)	Q.QV
Fish, acute	LC <sub>50</sub> 435	925 A	<b>10</b> 609 J	D4@stream	14
Oncorhynchus mykiss	LC50 433 0°	(A):33 (C)	0.040	D5 (pobd)	<b>△</b> 0.01, ∘
			0,631	D5 (stream)	· .(V)
			790	De (ditch)	18
			0.1670	W,	0.04
			1.855 E	R1 (stream)	§ 0.31
			J.090		0.25
		o L	€ 1.41 <u>0</u>	R4 (stream)	0.32
			<sup>2</sup> 0 8 69 - 3	. ~	0.18
%			9.718	A W	0.15
			0.936	D2 (ditch)	0.20
Ţ,			0.400	(***********************************	0.15
			9.793	` ′	0.17
			0.035		0.01
Invertebrate, acuto	EC50 480 &	() () 4280	O 0. <b>6</b> 09	`	0.13
Daphrila magna			<b>39</b> .040	<b>u</b> /	0.01
.,0			0.631	`	0.13
\$			0.790	` ′	0.16
S A			0.167	· · · ·	0.03
		Ŏ Ô	1.355		0.28
			1.090		0.23
	J G		1.410	`	0.29
		Q <sup>y</sup>	0.869	` ′	0.18
		7	0.718	`	0.15
(C)			0.936	` ´	0.19
			0.700	` ´	0.14
			0.793	` ′	0.16
Inverte Brate, de ute	LC TEC 488	4.88	0.035	* '	0.01
Georgean, Species	\$\tag{\pi_80}		0.609	`	0.12
			0.040	* '	0.01
			0.631	` ´	0.13
Invertebrate, acute Daphwa magna  Invertebrate Seute Geomean, Topecies			0.790	` ′	0.16
			0.16/	• •	0.03
			1.355	R1 (stream)	0.28



	[µg/L]		$(LC_{50}/100)$	[µg/L]	scenario	PEC/BAC
				1.090	R3 (stream)	0.22
				1.410	R4 (stream)	© 0.29
Fluoxastrobin (E+Z), spri	ing cereals, $2 \times 1$	25 g a.s./	'ha	C	ř	
				1.166	D1 (ditclo	Ø9.27
			Ö	0.704	D1 (stream)	$\sqrt{90.16}$
				0.492	D3@itch)	0.48
Fish, acute	LC <sub>50</sub> 4	35	49 35	Ø.039	(pond)	0.01
Oncorhynchus mykiss			Q-1.55	0.64%	D4 (stream)	0.15
				0.038	D5 (pond)	
		Ö		Ø.665	D\$ (stream)	0.15
		4	<del>~</del> ~~	2, 1.786	R4 (st@am)	0.41
	Į –			]:T66 , O	Dk (ditch)	0024
	Q,			9.701	D) (stream)	0.15
				0.793	* ************************************	© 0.17
Invertebrate, acute	EC <sub>50</sub>	80	Æ80 _6	0.039	D4 (pond)	0.01
Daphnia magna		10°		0.647	10 (stream)	0.13
			y ~ '	0.038	D5 (pond)	0.01
Invertebrate, acute Daphnia magna  Invertebrate, acute Geomean, 7 species  LO Geomean, 7 species				0.865	D5 (stream)	0.14
				1.786	(stream)	0.37
		o £	Ş L	0 1.166	D1 (ditch)	0.24
		,,	, \$\tag{\tag{\tag{\tag{\tag{\tag{\tag{	0.701	D1 (stream)	0.14
	4 4			<b>20.792</b>	D3 (ditch)	0.16
Invertebrate acute	$L_{\infty}^{\text{Co/EC}}$ 4	88 2	4.88	0.039	D4 (pond)	0.01
Geomean, 7 species		8	<i>"</i>	<b>%</b> 647	D4 (stream)	0.13
		. 0		0.038	D5 (pond)	0.01
			Y Ly 1	0.665	D5 (stream)	0.14
			<u> </u>	1.786	R4 (stream)	0.37
			S S			
		Y &	7 8			
			. V			
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¥ (						
4 4		Q"				
	* T					
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**Table CP 10.2-16:** RACsw; ac calculations for onions calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)

Csw; ac 50/100)	PECsw,max [μg/L]  0.791  0.045  0.604  0.795  0.170  1.622  0.684  1.484  3.087  9.791  0.005	D3 (ditch) D4 (pond) D4 (stream) D6 (ditch, 1st) D6 (ditch, 2nd) R1 (pond) R1 (stream) R2 (stream) R3 (stream) R4 (stream) D4 (pond)  R4 (pond)	PEC/RAC 8 0.01 0.18 0.18 0.16 0.70 0.16 0.16 0.01
.35	0.791 0.045 0.604 0.783 0.783 0.1,780 1.4822 0.684 1.484 3.87 9.791 0.045	D3 (ditch) D4 (pond) D4 (stream) D6 (ditch, 1st) D6 (ditch, 2nd) R1 (pond) R1 (stream) R2 (stream) R3 (stream) R4 (stream) R4 (stream)	0.01 0.18 0.18 0.02 0.24 0.16
.35	0.045 0.604 0.783 0.783 0.178 1.622 0.684 1.481 3.087 9.791 0.045	D4 (pond)  D4 (stream)  D6 (ditch, 1st)  D6 (ditch, 2nd)  R1 (pond)  R1 (stream)  R2 (stream)  R3 (stream)  R4 (stream)  R4 (stream)	0.01 0.18 0.18 0.02 0.24 0.16
.35	0.045 0.604 0.783 0.783 0.178 1.622 0.684 1.481 3.087 9.791 0.045	D4 (pond)  D4 (stream)  D6 (ditch, 1st)  D6 (ditch, 2nd)  R1 (pond)  R1 (stream)  R2 (stream)  R3 (stream)  R4 (stream)  R4 (stream)	0.01 0.18 0.18 0.02 0.24 0.16
.35	0.604 0.785 0.783 0.178 1.622 0.684 1.484 3.67 0.791 0.045	D4 (stream) D6 (ditch, 1st) D6 (ditch, 2nd) R1 (pord) R1 (stream) R2 (stream) R3 (stream) R4 (stream)	0.18 0.037 0.16 0.70 0.16
.35	0,783 ° 0,783 ° 0.1,7\$ 1,622	D6 (ditch, 1st) D6 (ditch, 2nd) R1 (pond) R1 (stream) R2 (stream) R3 (stream) R4 (stream) (ditch)	0.18 0.037 0.16 0.70 0.16
.35	0.783 0.172 1.622 0.684 1.484 3.67 0.791 0.045	D6 (ditch, 2nd)  R1 (pond)  R1 (stream)  R2 (stream)  R3 (stream)  R4 (stream)	0.18 0.037 0.16 0.70 0.16
	1,622 0.684 1.484 3,67 6.791 0.045	R1 (stream)  R2 (stream)  R3 (stream)  R4 (stream)  (ditum)	0.37 0.16 0.24 0.70 0.16
	1,622 0.684 1.484 3,67 6.791 0.045	R1 (stream)  R2 (stream)  R3 (stream)  R4 (stream)  (ditum)	0.16
	3.087 9.791 0.045	R3 (stream) & R4 (stream) & (diton)	0.20
	3.057 29.791 30.045	R4 (stream) (ditch)	0.16
		(ditch)	0.16
			<del>Cn</del>
		D4 (pond) «	0.01
		♥	0.01
4	0.604	D4 stream)	0.13
	Ø9:785	D6 ditch st)	0.16
(Const	0.783	Loc (ditch, 2nd)	0.16
.00	<sup>N</sup> 05.¥73 €	R1 (pond)	0.04
, O'	1.622	RP (stream)	0.34
	0.684	R2 (stream)	0.14
	1 <b>.4</b> 81	R3 (stream)	0.31
// N/	45/100	R4 (stream)	0.64
	0.7 <b>%</b>	D3 (ditch)	0.16
	00045	D4 (pond)	0.01
40	<u></u> ©0.604	D4 (stream)	0.12
	<b>5</b> 0.785	, , ,	0.16
88	-		0.16
T.	0.173	R1 (pond)	0.04
	1.622	R1 (stream)	0.33
/			0.14
	1.481	R3 (stream)	0.30
	3.057	R4 (stream)	0.63
	5	1.622 0.684 2.0.684 2.0.684 0.785 0.785 0.785 0.783 0.173 1.622 0.684 1.481	

## CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2-17: TER<sub>LT</sub> 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	Endj	point ;/L]	PECsw,max [µg/L]		Trigger
Cereals (Winter/sprir	ng)	, 13 <sub>1</sub>	<u>μ</u> β/ <b>L</b> ) / <sub>0</sub>			
Fluoxastrobin (E+Z)	Fish, chronic Oncorhynchus mykiss	NOEC	<b>3</b> 8.6	<b>1</b> 2.66	250	10,5
	Invertebrate, chronic Daphnia magna	NOEC	180	14.66	12.3 Q	
	Invertebrate, chronic Gammarus pulex	NOQC	31.6*	4.66	2.2	
	-	NOEC O	Ø561 &	14.66	0.04	<u>10</u> .
	Sediment dweller Chronic  Chironomus riporius	£C <sub>15</sub>	2130	14.66	\$145.3\(\sqrt{\frac{1}{2}}\)	<b>2</b> 10
	Green alga, dironic 🔗 Pseudokirchheriella subcapitata	F <sub>2</sub> C <sub>50</sub>	2100	© 14.66 ×	343.2 ×	10
	Aquatic plant chronic Lemna gibba	Er <b>Q</b> 50	3880	\$4.66 \$	264.7	10
HEC 5725-E-des- chlorophenyl	Cheen alga, chrome Pseudowirchneviella ( S subcapitata	E <sub>r</sub> C <sub>5</sub>	> 100 000K	10.10	> 9901	10
HEC 5725-carboylic	Sediment weller chronic Chironomus rparius O	EC <sub>15</sub>	98500 É	4.48	21 987	10
acid d	Green alga chronic  Pseudokirchnerietla  Sutscapitation	$\mathcal{D}_{r}^{\mathcal{C}_{50}}$	> 160,000 (	\$\times 4.48	35 714	10
2-chlorophe@ol	Pimephales promelas	NOEC &	400	5.63	710.5	10
	favertelerate, chronic Daplinia magna	NOE	\$00	5.63	53.3	10
	🧠 su <b>b</b> çapitată 🙈	ErC50	70 000	5.63	12 433	10
Onious						
Onions  Fluosastrobin (E+Z)	Fish Thronic Oncorporation Officers	NOEC	28.6	13.60	2.1	10
	Investebrate, chronic Saphnia magna	NOEC	180	13.60	13.2	10
	Invertebrate, chronic  A Gammarus pulex	NOEC	31.6	13.60	2.3	10
	Invertebrate, chronic Ämericamysis bahia	NOEC	0.61	13.60	0.04	10
	Sediment dweller, chronic Chironomus riparius	EC <sub>15</sub>	2130	13.60	156.6	10

Compound	Species		lpoint g/L]	PECsw,max [µg/L]	TER <sub>LT</sub>	Trigger
	Green alga, chronic Pseudokirchneriella subcapitata	E <sub>r</sub> C <sub>50</sub>	2100	13.60	154.4	
	Aquatic plant, chronic Lemna gibba	E <sub>r</sub> C <sub>50</sub>	3880	13.60	285,30	
HEC 5725-E-des- chlorophenyl	Green alga, chronic Pseudokirchneriella subcapitata	E <sub>r</sub> C <sub>50</sub>	\$\frac{\infty}{100 000}	©9.44	>00 593	**************************************
HEC 5725-carboxylic	Sediment dweller, chronic Chironomus riparius	EQ	98 500	<b>4</b> .19	23908	
acid	Green alga, chronic Pseudokirchneriella subcapitata	E <sub>r</sub> C	>#60 00@	4.19 A.5	> 385186	105
	Fish, chronic Pimephales promelas	NOEC	4000	554	© 726€	0 10
2-chlorophenol	Invertebrate Thronic Daphnia magnaty	NOEC 2	300	5.51	34.4	10
	Green alga, chronic Pseudokirchneriella Subcaptiata	E <sub>r</sub> C <sub>50</sub>	70 000	9.51	12 704	10
	Fish, chronic Pimephales promelas Invertebrate Phronic Daphnia magna Green alga, chronic Pseudokirchneriella Subcapitata Conducted with EC 100 for etathe trigger					

Table CP 10.2-18: RAC<sub>sw, ch</sub> 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 Species	End	point g/L]	RAC <sub>sw, ch</sub> (NOEC/10) (ErC <sub>50</sub> /10)	PEC <sub>sw,max</sub> [μg/L]	PEC/RAC
Cereals (Winter/sprin	ng)					
	Fish, chronic Oncorhynchus mykiss	NOEC	<b>\$</b> 8.6	<b>&amp;</b> .86	1 <b>4</b> .66	5.18
	Invertebrate, chronic Daphnia magna	NOEC	180	18.0	14.66 <sup>Q</sup>	0.81
		NO EC	31.6	3.16	M.66	464
Fluoxastrobin	Invertebrate, chronic Americamysis bahia	NOEQ"	<b>O</b> 61	0861	14.66	240 0
(E+Z)	Sediment dweller chronic & Chironomus ripacius &	FC <sub>15</sub>	2139	213.0	\$14.66 \$	.07
	Green alga, Garonic O' Pseudokircimerielig subcapitata	EC <sub>50</sub>	2106	210.0	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.07
	Aquatik plant, chronic S Lemna Sbba	E.C.	©3880 ×	₹\$88.Q \$\$\$8.Q	14.66	0.04
HEC 5725-E-des- chlorophenyl	Green alga, chronic LP seudottirchne Della S subcapitula	E <sub>r</sub> C <sub>5</sub>	~100 000 ~100 000 ~100 000	×10 000 ×	10.10	< 0.001
HEC 5725-carboxylic	Sediment Aweller ckyonic Chironomus rifarius O	EC <sub>154</sub>	98300 ( 3	7 9850 V	4.48	0.0005
acid @	Green alga, chronic Rseudokkechneriella subgapitato	TrC50	> 1600000	\$\infty \ 16 000	4.48	< 0.0003
	Fish, chronic Pimephales prometas	NOEC &	4000	400.0	5.63	0.01
2-chlorophe dol	nvertebrate, choonic Daphnia magna O	NOE	<b>3</b> 00	30.0	5.63	0.19
	Gren alga chronic Pseudold chnerfella Subcapitata	ÆrC <sub>50</sub> Z	70 000	7000	5.63	0.001
Onions &						
\$ Q \	Fish Chronic  Oncorh Inchus mykiss	NOEC	28.6	2.86	13.60	4.76
Onions  Fluorastrokum  (E+Z)	Investebrate, chronic Daphn a magna	NOEC	180	18.0	13.60	0.76
Fluovastrokûn	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
Č	Sediment dweller, chronic Chironomus riparius	EC <sub>15</sub>	2130	213.0	13.60	0.06

Compound	Species	Endpoint [µg/L]	RAC <sub>sw, ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	PEC <sub>sw,max</sub> [μg/L]	PEC/®AC
	Green alga, chronic Pseudokirchneriella subcapitata	E <sub>r</sub> C <sub>50</sub> 2100	210.0	13.60	0.06
	Aquatic plant, chronic Lemna gibba	E <sub>r</sub> C <sub>50</sub> 3880	388.0	13.60	0.04
HEC 5725-E-des- chlorophenyl	Green alga, chronic Pseudokirchneriella subcapitata	$E_rC_{50} > 100\ 000$	10 000	© 3 © 9.44 Q	\$\frac{1}{2}\text{.001}
HEC 5725-carboxylic	Sediment dweller, chronic Chironomus riparius	EC <sub>15</sub> . 98 500	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	1.19 ×	0.0904
acid	Green alga, chronic  Pseudokirchneriella  subcapitata	E & C W U U V V A	16 000	4.19	< 0.0003
	Fish, chroniQ  Pimephales promelas	NOEC 2000	490.0	0' 5 <b>0</b> 4	0.01
2-chlorophenol	Invertebrate chronic  Daphra magra	300 300 300 300 300 300 300 300 300 300	3000	5.51	0.18
	Green Alga, chrónic S Pseudokirchverielle Subcapitata S	E&50 070 000	7000	Ø5.51	0.001
	Fish, chronic Pimephales promelas.  Invertebrate chronic Daphra magna  Green alga, chronic Pseudokirchiveriella subcapitata  Fold letter need further water concentrations				

Table CP 10.2-19: TER<sub>LT</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3

$\frac{\text{Table CP 10.2-19: TER}_{\text{L}}}{\text{Species}}$	Endpoint [µg/L]	PEC <sub>sw,max</sub> [µg/L]	FOCUS scenario	TER <sub>LT</sub>	Trigger ,
Fluoxastrobin (E+Z), wir	ı		scenario	<u> </u>	
riuoxasti obili (E+Z), wii	1101 Cereais, 2 ^ 130 g a.:	1.048	D1 (ditch)	♠ ₹	10
		0.864	D1 (stream)	33.1	2970 Ø
		1.137	D1 (stream) D2 (ditch)	25,2,7	10
		0.84	D2 (diven)		10
		0.84¥ 0.84¥	Da (ditch)	35.8 × 30.0 × 30.0	FO &
		0.042	B4 (popd)	\$ 681. <b>Q</b>	
T' 1 1 '		0.731	D4 (pteam)	39.1	10
Fish, chronic <i>Oncorhynchus mykiss</i>	NOEC 28.6		Do (pond)	\$95.8 ×	10
oneonynenus mymss		I ((//n % )	(stream)	37.5	
		0.738	D6 (ditch)	× •	10 °
		©203 \	Ro (pond)	30.2	10
		21.663°		17 8	10
		1,337	R3 (stream)	2) 1/2 2) 1/2	10
		1237	R4 (stream)	©16.6 <sub>6</sub>	10
		1 048	ODI (ditoh)	30.0	10
		0.801	D1 (ctream)	<b>26</b> .6	10
<		19137 Q	D2 (ditck)	27.8	10
≪		© 84%	32 (stream) %	37.3	10
F		0.952	D3 (ditch)	33.2	10
Š,		\$0.042 Q	DA (pond)	752.4	10
Invertebrate Obranic		2 0 731	304 (stream)	43.2	10
Gammarus puler	100EC ○ 31.6	0.648	D5 (bond)	658.3	10
		0.758	(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) (1) (1) (1) (1) (1) (1) (1) (1) (1)		0 1.33%	R3 (stream)	23.6	10
		1.024	R4 (stream)	18.3	10
		₹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
Invertebrate, chronic	NQEC 0.61	0.731	D4 (stream)	0.8	10
Americamysicounid		0.048	D5 (pond)	12.7	10
		0.758	D5 (stream)	0.8	10
		0.948	D6 (ditch)	0.6	10
Ö		0.203	R1 (pond)	3.0	10
Invertebrate, chronic Americanysis bahia		1.663	R1 (stream)	0.4	10
		1.337	R3 (stream)	0.5	10

Species	Endpoint [μg/L]	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	TER <sub>LT</sub>	Trigger
		1.724	R4 (stream)	0.4	
Fluoxastrobin (E+Z), spri	ng cereals, 2 × 150 g a.s	s./ha	d	<u> </u>	
		1.403	D1 (ditch)	20.4	10,
Fish, chronic		0.841	D1 (stream)	34.0	\$10 C
		0.950	D3 (ditch)	30,4	10,5
	NOEC 28.6	0.047	D4 (pond)	6 <b>0</b> 8.5 Ŝ	
Oncorhynchus mykiss	100EC 20.0	<b>20</b> 777	D4 (stream)	36.8	
		0.046	D5 (polod)	£ 6215 ₹	10
	C <sub>1</sub>	0.798	D5 (stream)	≥3 <b>\</b> 5.8	
	Õ	~ <b>2</b> ,177 £	RA (stream)	\$13.1	10
	4	@1.40 <b>%</b>	OD1 (diteh)	225	0 10 V
	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.841	D1 (stream)	<b>3</b> 7.6	
		9.950 ×	DP (ditck)	33.3	<b>1</b> 0
Invertebrate, chronic	NOEC 4 31 6	0.047	OD4 (pond)	6723	Ø 10
Gammarus pulex		0377	D4 Stream	<b>3</b> 0.7 %	10
		<b>3</b> .046 ©	Do (pond)	°€687. <b>Q</b>	10
	NOEC 31.6	0.798	D5 (stream)	39.8	10
· · · · · · · · · · · · · · · · · · ·		2,177	R4 (stream)	J4.5	10
<b></b>	NOEC 4 0.61	.403	D1 (ditch)	<b>3</b> 0.4	10
		0.841	OD1 (stream)	<b>∀</b> 0.7	10
		0.330	D3 (ditch)	0.6	10
Invertebrate, chronic	NOFC & 0.61	<b>2</b> 7.047	DA (pond)	13.0	10
Americamy Pbahia		0.7 <b>%</b>	D4 (stream)	0.8	10
, Q		ž 0 <sub>0</sub> 946	D <b>5</b> (pond)	13.3	10
		0.798	(stream)	0.8	10
Endpoint from study cond		2.177	R4 (stream)	0.3	10
Endpoint from study cond sold values do not neet the	uted with EC 100 form	Mation of the state of the stat			

Table CP 10.2-20: TER<sub>LT</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3

Species	Endpoint [µg/L]	PECsw,max [µg/L]	FOCUS scenario	TERLT	Ţ <b>ŗigg</b> er
Fluoxastrobin (E+Z), win				ð	
( ),,		0.869	D1 (ditch)		100
		0.718	D1 (stream)	39.8	
		0.936	D2 (ditch)	30.6	× 10 ×
		0.700	D2 (stream)	45.9	10 0
		0,793	D3 (ditch)	36.1 Q	NO K
		0.035	B4 (popd)	\$ 817.A	U 10.6
Fish, chronic	NODG 20 (	0.609	D4 (stream)	47.0 «	7
Oncorhynchus mykiss	NOEC 28.6	0940	Do (pond)	\$15.0 ×	¥0
	O	<b>№</b> 0.631	(stream)	<sup>10</sup> 45 <b>.3</b> √	→ 10 °
		0,790	D6 (ditch)	36.2	
		Ø2167 . A	R(pond)	\$171.3\times	<b>1</b> 0
		\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	&I (stream)	21	<u>a</u> 10
		1,090	R3 (Seream)	26.2	J 10
		4,410 °C	R4 (stream)	20.3	10
		0.869	©D1 (dittoh)	36.4	10
		O.7P8	D1 (stream)	<b>44.</b> 0	10
0		936	D2 (ditck)	33.8	10
		0.700	32 (stream)	¥ 45.1	10
		0.793	D3 (ditch)	39.8	10
		20.035	DA (pond)	902.9	10
Invertebrate Phronic	MODEC 0 2144	£ 0.600,	504 (stream)	51.9	10
Gammarus pulen	\$ 31:4V	0,040	D5(pond)	790.0	10
		0.631	D\$ (stream)	50.1	10
		0.796	D6 (ditch)	40.0	10
<b>9</b>	4 & 0' 4	0,167	R1 (pond)	189.2	10
		1.355	R1 (stream)	23.3	10
		1.090	R3 (stream)	29.0	10
		1,010	R4 (stream)	22.4	10
		, <b>40</b> .869	D1 (ditch)	0.7	10
		© <sup>y</sup> 0.718	D1 (stream)	0.8	10
		0.936	D2 (ditch)	0.7	10
		0.700	D2 (stream)	0.9	10
A A		0.793	D3 (ditch)	0.8	10
Invertable alemin		0.035	D4 (pond)	17.4	10
Amegicamysichahia	NOEC 0.61	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
Invertebrate, chronic Americanysis bahia		1.355	R1 (stream)	0.5	10
		1.090	R3 (stream)	0.6	10

Species	Endpoint [µg/L]	PEC <sub>sw,max</sub> [μg/L]	FOCUS scenario	TER <sub>LT</sub>	Trigger
		1.410	R4 (stream)	0.4	<b>10</b>
Fluoxastrobin (E+Z), spri	ng cereals, 2 × 125 g a.s	s./ha	d	<u> </u>	
		1.166	D1 (ditch)	24.5	10
		0.701	D1 (stream)	40.8	\$10 K
Fish, chronic		0.7925	D3 (dirch)	36,4	10,5
	NOEC 28.6	0.039	D4 (pond)	<b>78</b> 3.3 S	
Oncorhynchus mykiss	100EC 20.0	647	D4 (stream)	644.2 Q	
		0.038	D5 (polod)	5 <sup>™</sup> 7526	10%
	Q.	0.665	D5 (stream)	<b>₹</b> 3.0 , ×	
	o v	7 <b>3</b> 786 X	RA (stream)	\$16.0	10
		1.16	OD1 (diteh)	276	10%
		0.701	D1 (stream)	45.1	
	NOEC 31.0	09.792 °~ "	D9 (ditck)	\$\frac{39.9}{39.9}	010
Invertebrate, chronic	NOEC 🖇 31.6	0.039	OD4 (pond)	81.03	© 10
Gammarus pulex		07647	D4 (stream)	\$8.8 °√	10
		0.665	(pond) (b5 (stream)	831. <b>6</b> 47.9	10
	NOEC 31.69	1,786	R4 (stream)	\$\frac{47.3}{\lambda}\frac{97.7}{\tau}	10
•		0.166	D1 (ditch)	\$\text{0.5}	10
Z.	NOEC 4 0.61	0.7019	Odl (stream)	9 0.9	10
Ž		0.7972	D3 (ditch)	0.8	10
Invertebrate, chronic		(V.039 S	DA (pons)	15.6	10
Americamys Phahig	NOEC % 0.61	× 0.647	D4 (stream)	0.9	10
		0,038	D5(pond)	16.1	10
		0.665	(stream)	0.9	10
		1.786	R4 (stream)	0.3	10
Endpoint from study cond sold values do not neet the	uted with EC 100 form	Mation of the state of the stat			

Table CP 10.2-21: TERLT calculations for onions calculation based on FOCUS Step 3

Species	Endp [µg/		PECsw,max [µg/L]	FOCUS scenario	TER <sub>LT</sub>	Ţ <b>rigg</b> er
Fluoxastrobin (E+Z), onic	ons, 2 × 125 g	a.s./ha			Ď	
			0.791	D3 (ditch)	36.2	100
			0.045	D4 (pond)	635.6	<b>370</b> . C
			0.604	D4 (stream)	47.A	~ 10 ~ T
			0.78	D6 (diton, 1st)	3€4 ≈	100
Fish, chronic	NOEC	28.6	0.783	D6 (ditch, 2nd)	36.5 Q	å¥0
Oncorhynchus mykiss	NOEC	28.0	<b>2</b> 9.173	Ri (popd)	√ 165&	
			1.622	R1 (stream)	√ N.6 «	
			0,084	R2 (stream)	41.8	<b>4</b> 0
		.4	≈1.481°	(stream)	193	→ 10 <u>~</u> °
			3.057	R4 (stream)	9.4	) H
			<b>JØ</b> 791 🎺	D3 (ditch)	§39.9 😂	ÖÎ0
	Ć		\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	7024 (popd) 2	~ 702 <b>©</b>	10
	Q,	"O"	0,604	D4 (Fream)	<b>5</b> 2.3 %	J 10
	_		<b>10,</b> 785 0	D6 (ditch, tot)	Q 40.3 <sub>6</sub>	10
Invertebrate, chronic	NOEC 4,	31.67	0.783	De (ditclo 2nd)	40.40	10
Gammarus pulex		31.0g	V 0.1 <b>%</b>	R L (pond)	J <b>P3</b> 2.7	10
%	Y A.		<b>1</b> /622 <	R1 (stream)	<b>19.5</b>	10
			0.684	2 (stream) 3	¥ 46.2	10
	L . 5		1.481	R3 (stream)	21.3	10
			23×057 5	Ra (stream)	10.3	10
		/	√√0.79 <b>↓</b>	D3 (ditch)	0.8	10
	W B	1	0,645	D4 (pond)	13.6	10
		T O	0.604	Q4 (stream)	1.0	10
			. O <sup>y</sup> 0.78≸ <sup>y</sup>	(ditch, 1st)	0.8	10
Invertebrate, chronc	NOFE	0′ « 70/61 «×	0 83	D6 (ditch, 2nd)	0.8	10
Invertebrate, chronic Americamysis bania	NOE &		0.173	R1 (pond)	3.5	10
			0 1.62 <b>D</b>	R1 (stream)	0.4	10
*\P\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \			0,684	R2 (stream)	0.9	10
			<u>\$</u> ≪1.481	R3 (stream)	0.4	10
	4 ~	Ç.	© 3.057	R4 (stream)	0.2	10

<sup>\*</sup> 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)

Step	3 (acceptability of risk:	)	T		
Species	Endpoint [μg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	PECsw,max [μg/L]	FOCUS Oscenario	PÉO/RAC
Fluoxastrobin (E+Z), win	ter cereals, 2 × 150 g a.s	./ha	. **	<del>/</del>	
, , ,	, ,		1.048	D1 (ditch)	\$ <b>90</b> .37 <b>\$</b>
		Ö	0.864	D1 (stream)	0.30
			15 <sup>8</sup> 7	D2 ditch	0.40
		, Ü	0.847 .	p2 (stream)	20.30 g
			*0.05%	D3 (Otch)	0.30
	NOEC 28.6	2.86 2.86 2.7 2.7	Ø <u>0</u> .042 0	D2 1) ×	( ) ( ) ( ) ( )
Fish, chronic	None of O		0.7310	DA (stream)	0.26 0.025
Oncorhynchus mykiss	NOEC 28.6	2.86	Q 0.048	D5 (pend)	0.02
	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		0.758	D5 (stream)	<b>2</b> 27
			<b>40.948</b>	D6 (ditch)	00.33
			0.203	R1 (gond)	0.07
	Q' & Q	D &	1.663	R1 (stream)	0.58
			Q1.337	B3 (stream)	0.47
		Ly m	√ 1.7¥4 , ¢	R4 (stream)	0.60
%			\$ 048 × \$	DA (ditch)	0.33
<b>≪</b> n			% 0.864 °	(stream)	0.27
			0 1.67	D2 (ditch)	0.36
			Ø.847 Ø	D2 (stream)	0.27
			0.952	D3 (ditch)	0.30
			0.042	D4 (pond)	0.01
Invertebrate, chronic &	NOTE OF THE PROPERTY OF		<b>0</b> .731	D4 (stream)	0.23
Ganararus pulex 💍	NOTE TO 1.6.	3.16	0.048	D5 (pond)	0.02
			0.758	D5 (stream)	0.24
l j			0.948	D6 (ditch)	0.30
		S S	0.203	R1 (pond)	0.06
			1.663	R1 (stream)	0.53
		4 V	1.337	R3 (stream)	0.42
			1.724	R4 (stream)	0.55
, L J		Y	1.048	D1 (ditch)	17.18
			0.864	D1 (stream)	14.16
Q ` 4 \			1.137	D2 (ditch)	18.64
			0.847	D2 (stream)	13.89
			0.952	D3 (ditch)	15.61
Inverteerate, Wronic	NOEC 0.61	0.061	0.042	D4 (pond)	0.69
A O A			0.731	D4 (stream)	11.98
	<b>L</b> °		0.048	D5 (pond)	0.79
Ö			0.758	D5 (stream)	12.43
Invertebrate, chronic  Gangarus pulex  Invertebrate, chronic  Americanyo, bahia			0.948	D6 (ditch)	15.54
			0.203	R1 (pond)	3.33

Species	Endpoint [µg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	PECsw,max [µg/L]	FOCUS scenario	PECKAC
			1.663	(stream)	@27.26
			1.337	R3 (stream)	21.92
			1.724	R4 (stream)	<b>28</b> .26 Ø
Fluoxastrobin (E+Z), spri	ing cereals, 2 × 150 g a.s	./ha 👸	Ž,		
		₩.	1.453	D1 (Htch)	0.49
		a s	0.841	DI (stream)	<b>6</b> .29 &
			\$0.95 <b>@</b> °	D3 (difch)	0.33
Fish, chronic	NOEC 20.6	200	0.047	D4 (pond)	
Oncorhynchus mykiss	NOEC 28.6		Ø.777 😓	Da stream	0.27
	4		0.046	D5 (pord)	€ 0.02€°
			0,498	D5 (stream)	0,28
		/ _Q" ~\\	<b>2</b> .177	R4 (stream)	<b>6</b> .76
		, \$ . \$	1.40	D1 (dileh)	© 0.44
			5 0 <b>9</b> 1 0	D1 (stream)	J 0.27
			<b>9</b> .950	(ditch)	0.30
Invertebrate, chronic	NOEC 4 31.67	2 16	√0.04 <b>%</b>	D4 (p@nd)	0.01
Gammarus pulex		3.16	9377	D4 (stream)	0.25
\ \ 			0.046	Do (pond)	0.01
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\			0.798	D5 (stream)	0.25
Į į			2.177	R4 (stream)	0.69
			£1.403	D1 (ditch)	23.00
			0.841	D1 (stream)	13.79
			Q.\$\\ 50	D3 (ditch)	15.57
Invertebrate, chronic Americamysis bahia	NOOC COLL	© 06 10°	<b>%</b> 0.047	D4 (pond)	0.77
Americamysis bahia	INCREC & U.01	O O O O O O O O O O O O O O O O O O O	0.777	D4 (stream)	12.74
Į Š			0.046	D5 (pond)	0.75
			0.798	D5 (stream)	13.08
	NOCC CO.61		2.177	R4 (stream)	35.69

<sup>\*</sup> Endpoint from study conducted with EC 100 formulation

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

Step	3 (acceptability of risk:	)	ī		
Species	Endpoint [μg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	PECsw,max [µg/L]	FOCUS Oscenario	PÉÇ/RAC
Fluoxastrobin (E+Z), win	ter cereals, 2 × 125 g a.s	./ha	· ·	<del>/</del>	, 2
, , ,	, ,		0.869	D1 (ditch)	\$ <b>30</b> .30 <b>3</b>
		Ö	0.768	D1 (stream)	0.25
			<b>6986</b>	D2 ditch	0.33
		, Ü	Ø.700 。	p2 (stream)	©0.24 @
			7030	D3 (Otch)	0.26
	NOEC 28.6	2.86 2.86 2.7 2.7	Ø Q.035 _ Ø	D2 1) ×	<b>(2)</b>
Fish, chronic	None 2006		0.609	DA (stream)	0.21
Oncorhynchus mykiss	NOEC 28.6	2.86	Q 0.Q40 Q	D5 (pend)	0.06
	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		0.631	D5 (stream)	<u>x</u> <b>Q</b> 22
			<b>40.790</b>	D6 (ditch)	00.28
			0.467	R1 (gond)	0.06
	Q' & Q		9.355	R1 (stream)	0.47
			Q1.090	B3 (stream)	0.38
		4 6	~ 1.24¥0 , Q	R4 (stream)	0.49
%			\$ 40,869 °C	DV (ditch)	0.28
<b>≪</b> n			& 0.718 s	(stream)	0.23
		Ş J	0.06	D2 (ditch)	0.30
			Ø.700 @	D2 (stream)	0.22
			0.792	D3 (ditch)	0.25
			0.035	D4 (pond)	0.01
Invertebrate, chronic &	NOTE A 6*	2 16 W	<b>3</b> .609	D4 (stream)	0.19
Ganguarus pulex	11026 101.0	3.10	0.040	D5 (pond)	0.01
			0.631	D5 (stream)	0.20
J 3			0.790	D6 (ditch)	0.25
			0.167	R1 (pond)	0.05
			1.355	R1 (stream)	0.43
		(	1.090	R3 (stream)	0.34
	Q S		1.410	R4 (stream)	0.45
		, Y	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
Inverteerate, coronic	NOEC 0.61	0.061	0.035	D4 (pond)	0.57
	<b>*</b>		0.609	D4 (stream)	9.98
	<b>L</b> °		0.040	D5 (pond)	0.66
Ö			0.631	D5 (stream)	10.34
Invertebrate, chronic  Gangarus pulex  Invertebrate, chronic  Americanyo, bahia			0.790	D6 (ditch)	12.95
			0.167	R1 (pond)	2.74

Species	Endpoint [µg/L]	RACsw; ch (NOEC/10) (ErC50/10)	PECsw,max [µg/L]	FOCUS scenario	PECÆAC
			1.355	(stream)	22.21
			1.090	R3 (stream)	17.87
			1.410	R4 (stream)	<b>23</b> :11 💍
Fluoxastrobin (E+Z), spr	ing cereals, 2 × 125 g a.s	s./ha 💍		47	
		N.	1,56	D1 (Htch)	0.4
			0.701	Di (stream)	<b>6</b> .25 &
			₹0.79 <b>2</b> ,°	D3 (ditch)	0.28
Fish, chronic	NOTE 20 6		0,099	D4 (pond)	
Oncorhynchus mykiss	NOEC 28.6	, 2,86	0.647	Da stream	0.23
	( )		0.03	D5 (pond)	€ 0.01€°
			0,665	D5 (stream)	1011
			Ø.786 V	R4 (stream)	62.62
	NOEC 28.6  NOEC 31.6	.9 .9	7 1.166	D1 (dileh)	0.37
			J 0,901 Û	D1 (stream)	0.22
			<b>%</b> .792 &	(ditch)	0.25
Invertebrate, chronic			(° 0.033)	D4 (p@nd)	0.01
Gammarus pulex	NOEC (, 31.6)	3.16	9647	D4 (stream)	0.20
2	NOEC ( 31.6)		0.038	D (pond)	0.01
			0.665	D5 (stream)	0.21
Į į			1.786	R4 (stream)	0.57
Inverte prate chronic &			€1.166€	D1 (ditch)	19.11
			0.701	D1 (stream)	11.49
			O Q.\$92	D3 (ditch)	12.98
Invertebrate, chronic			0.039	D4 (pond)	0.64
Invertebrate, chronic & Americanysis bahia	NONEC STUDIES	0.001	0.647	D4 (stream)	10.61
			0.038	D5 (pond)	0.62
	NOTE (2 0.61)		0.665	D5 (stream)	10.90
e jöy			1.786	R4 (stream)	29.28

\* Endpoint from study conducted with EC 100 formulation

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

115K.	PEC/RAC < 1)		1		
Species	Endpoint [µg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	PEC <sub>sw,max</sub> [μg/L]	FOCUS Cenario	PEC/RAC
Fluoxastrobin (E+Z), onic	ons, 2 × 125 g a.s./ha		4	10°	, ,
			0.791 🖔	D3 (ditch)	. 90.28 V
			0.045	D4 (pond)	0.02
		L *	0.664	D4 (stream)	Q.\$1
		40'	<b>6</b> .785 .	D6 (Pitch, 1st)	్రి.27 భ
Fish, chronic	NOEC 28.6	2.86	0.782	De (ditch 2nd)	© 0.2€
Oncorhynchus mykiss	NOLC 28.0	, 2.80 , &	0,173	© R1 (bond)	, <b>2</b> 06
	O		622	RA (stream)	<u></u> ∆ 0.57 。
			Q0.684	R2 (stream)	0.2 <b>6</b>
			1.487 %	R3 (stream)	6.52
			3.057 E	R44(stream)	© <sub>1.07</sub>
	NOEC 31.6* 2		<b>√</b> 0.79 <b>√</b>	D3 (diffeh)	© 0.25
			0.095	D4 (Pond) 📉	0.01
			604	DD (stream)	0.19
				<b>2</b> 6 (ditch, 1st)	0.25
Invertebrate, chronic %	©	\$\display 16	0.783	D6 (ditch, 2nd)	0.25
Gammarus pulex	YNOEC 31.6* \$		\$0.173	(pond)	0.05
Õ			1.623	R1 (stream)	0.51
		Y.16 5	0.684	R2 (stream)	0.22
			4.481	R3 (stream)	0.47
			3.057	R4 (stream)	0.97
			0,791	D3 (ditch)	12.97
			0.045	D4 (pond)	0.74
			<b>6</b> 0.604	D4 (stream)	9.90
<b>3</b> 4			0.785	D6 (ditch, 1st)	12.87
Invertebrate chronic	MOEC O 0.60	0.06	0.783	D6 (ditch, 2nd)	12.84
Invertebrate, chronic Americany s bahta	NOEC O OO		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

<sup>\*</sup> Endpoint from Grudy conducted with EC 100 formulation

Most of the TERs neet the required troger 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 TERLT/RACLT calculations of fluoxastrobin based on FOCUS Step 3 following application to cereals\* and onions

	Fluoxastrobin (E+Z)						
		Fish, ch	ronic: Oncorhynch				
	2 x 150 g	g a.s. /ha	2 x 125 g	g a.s. /ha	2 x Y25 g 4.s.		
Scenario	****		****	1 . 4.	/ha		
D1 (414-1)	Winter cereals	Spring cereals	Winter cereals	Spring cereals	Qnions &		
D1 (ditch) D1 (stream)				<del>Ů</del>	<u> </u>		
D1 (siteani) D2 (ditch)							
D2 (stream)		_					
D3 (ditch)		-	<del>\</del>				
D4 (pond)							
D4 (polid) D4 (stream)		<b>&amp;</b>	6 2 4		**************************************		
D5 (pond)		<b>─</b>			L A . o		
D5 (pond) D5 (stream)		A. O					
D6 (ditch, 1st)		\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \					
D6 (ditch, 2nd)	_			<i>V</i> - <i>N</i>			
R1 (pond)		6 <u>-</u> 4 -					
R1 (stream)		\$ <del>\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \</del>			, V		
R2 (stream)	-	<u> </u>			<b>*</b>		
R3 (stream)		*/ - <u></u>		_ ~ ~			
R4 (stream)	₩ Ç		~ ~		×		
(======)	C	Anvertebrat	e, chronic: Americ	amvsiSbahia 🗸			
D1 (ditch)	×	×		׊	_		
D1 (stream)	XXX	W x	XXX O		_		
D2 (ditch)		7 7	<b>*</b>	0 -	_		
D2 (stream)		-~		~	_		
D3 (ditch)	X		* * * * * * * * * * * * * * * * * * *	×	×		
D4 (pond)				<i>Q</i>	**		
D4 (stream)	XX V	× O		×	×		
D5 (pond)					_		
D5 (stream)	X		& ×A	×	-		
D6 (ditch, 1st)	J AX O	47 - 10°	0" ~	_	×		
D6 (ditch, 2nd)	<del>7</del> <del>-</del> 5		7 8 -	_	×		
R1 (pond)			×	-	×		
R1 (stream)	<b>\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\overline{\over</b>	A - 69	×	-	×		
R2 (stream)	~ Q - Q,		<del>-</del>	-	×		
R3 (stream)			×	-	×		
	1 XX // 🙈 - X/ - 4/(.	\ \ \					

<sup>\*</sup> Refinement for provertebrate chronic (Commarks pulex) passes the risk assessment based on FOCUS Step 3 with all scenarios and all intended applications.

× Scenario not passed

Results indicated with a need further refinement.

For fluoxastrobin and aquatic invertebrates, a refinement option based on the FOCUS Step 3 -TWAsw (7 day values is presented below. Justification for the use of the 7d PEC<sub>sw;twa</sub> is provided in MCA 8, Point 8.2.5.1 (M-535147-01-1).

<sup>-</sup> Scenario por relexant for the crop

**Table CP 10.2-26:** TER<sub>LT</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)

Species   Endpoint	0.874 0.273 0.825 0.386 0.200 0.021 0.010 0.35\$ 0.207	R L (prond)  R (stream)	61.0 1.9 3.2 3.0 3.0	10 10 10 10 10 10 10 10 10 10 10
Fluoxastrobin (E+Z), winter cereals, 2 × 150 g a.  Invertebrate, chronic  Americamysis bahia  NOEC 0.61	[μg/L]  ss./ha  0.874  0.272  0.825  0/386  0.200  0.021  0/010  0.35  0.35  0.207  0.180	D1 (ditch)  D1 (stream)  D2 (stream)  D3 (ditch)  D4 (stream)  D6 (ditch)  R1 (pond)  R3 (stream)	0.7 2.3 9.7 1.6 3.0 4.8 8.8 61.0 1.9 3.2 3.0 3.0 3.0	10 10 10 10 10 10 10 10 10 10
Invertebrate, chronic Americamysis bahia  NOEC 0.61	0.874 0.273 0.825 0.386 0.200 0.021 0.035 0.35 0.207 0.35 0.207	D1 (stream) D2 (stream) D3 (stream) D4 (stream) D5 (stream) D6 (ditch) R1 (pond) R3 (stream)	2.3 0.7 0.1.6 0.8.8 0.61.0 1.9 0.3.2 0.3.0 0.3.2	10 10 10 10 10 10 10 10 10 10
Americamysis bahia	0.27 0.825 0.386 0.200 0.021 0.010 0.35 0.207 0.207	D1 (stream) D2 (stream) D3 (stream) D4 (stream) D5 (stream) D6 (ditch) R1 (pond) R3 (stream)	2.3 0.7 0.1.6 0.8.8 0.61.0 1.9 0.3.2 0.3.0 0.3.2	10 10 10 10 10 10 10 10 10
Americamysis bahia	0.825 0.386 0.200 0.021 0.035 0.35 0.207 0.207	D2 (stream) D3 (ditch) D4 (stream) D5 (stream) D6 (ditch) R1 (pond) R3 (stream)	2.3 0.7 0.1.6 0.8.8 0.61.0 1.9 0.3.2 0.3.0 0.3.2	10 10 10 10 10 10 10 10 10
Americamysis bahia	©/386 0.200 0.021 0.035 0.35 0.35 0.207 0.180	D3 (stream)  D4 (stream)  D5 (stream)  D6 (ditch)  R1 (pond)  R3 (stream)	9.7 0 1.6 2 3.0 61.0 3.2 3.0 3.0 3.0	10 10 10 10 10 10 10 10 10
Americamysis bahia	0.200 0.021 0.010 0.35 0.35 0.207 0.207	D3 (ditch) D4 (stream) D5 (stream) D6 (ditch) R1 (pond) R3 (stream)	3.0 3.0 61.0 1.9 3.2 3.0 3.0	10 10 10 10 10 10 10 10
Americamysis bahia	0.021 © 010 © 0.35 0.35 0.207 0.180	D4 (stream) D5 (stream) D6 (ditch) R1 (pond) R3 (stream)	8.8 61.0 1.9 3.2 3.0 3.0	10 10 10 10 10 10 10 10
Americamysis bahia	©.010 © 0.35© 0.35© 0.207 © 0.180	DS (stream)  D6 (ditch)  R1 (pond)  R3 (stream)	61.0 1.9 3.2 3.0 3.0	10 10 10 10 10 10 10 10
Americamysis bania	0.35%	R L (prond)  R (stream)	1.9° 3.2° 3.0° 3.0°	10 10 10 10 10 10 10 10
Fluoxastrobin (E+Z), spring cereals, 2 150 g a.  Invertebrate, chronic Americamysis bahia.  Bold values do on meet the trigger	0.207	Rl (pond) Rl (stream)	3.0	10 10 10 10 10 10 10 10
Invertebrate, chronic Americanysis bahia.  Bold values do not meet the trigger	©.207 ×	RJ (stream)	3.0	10 10 10 10 10 10 10 10
Fluoxastrobin (E+Z), spring cereals, 2 150 g a.  Invertebrate, chronic Americamysis bahia.  Bold values do not meet the trigger	0.207 0.182 0.383 0.320 0.155 0.024 0.099 0.489	R3 (ottoam)	A\$* 3€\$*	10 10 10 10 10 10 10
Invertebrate, chronic Americamysis bahic.  Bold values do out meet the trigger	0.182 0.083 s./hav 1.204 0.320 0.155 0.024 0.489	R3 (stream) R4 (stream) D1 (dytch) D3 (ditch) D4 (stream) D5 (stream) D5 (stream)	0.5 0.5 1.9 25.0 70.9 1.2	10 10 10 10 10 10
Fluoxastrobin (E+Z), spring cereals, 2 150 g a.  Invertebrate, chronic Americamysis bahia.  Bold values do not meet the trigger	S./ha/ S./ha/ 1.204 0.320 0.155 0.024 0.489	D1 (ditch) D1 (ditch) D3 (ditch) D4 (stream) D5 ((stream)	0.5 1.9 25.0 70.9 1.2	10 10 10 10 10
Invertebrate, chronic Americamysis bahia.  Bold values do out meet the trigger	0.320 0.155 0.024 0.489	D1 (ditch) D1 (ditch) D3 (ditch) D4 (stream) D5 (stream) D5 (stream)	0.5 1.9 25.0 70.9 1.2	10 10 10
Invertebrate, chronic Americamysis bahia.  Bold values do not meet the trigger	0.320 0.155 0.024 0.489	DL(stream)  D3 (ditch)  D4 (socam)  D5((stream)	25.0 70.9 1.2	10 10 10
Invertebrate, chronic Americamysis bahia.  Bold values do rot meet the trigger	0.155 0.024 0.489	Date (stream)  D4 (stream)  D5 (stream)	3.9 25.0 70.9 1.2	10 10 10
Americamysis bahia.  Bold values do not meet the trigger	0.13,0	D4 (speam)  D5 (stream)  A (stream)	25.0 70.9 1.2	10 10
Bold values do not meet the trigger	\$0009 \$0.489	D5((stream)	70.9 1.2	10
Bold values do out meet the trigger	0.489	(stream)	1.2	
Bold values do not meet the trigger			<u> </u>	1
Invertebrate, chronic Americamysis bahid.  Bold values do not meet the trigger				

Table CP 10.2- 27: TER<sub>LT</sub> calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)

3-1	WAsw (7 days)				
Species	Endpoint [µg/L]	7-day TWA <sub>sw</sub> [μg/L]	FOCUS scenario	TERLT	<b>D</b> oigger
Fluoxastrobin (E+Z), win	ter cereals, 2 × 125 g a.s	./ha	4	, Q	
		0.724	D1 (ditck)	0.8	, \$10 J
		0.206	D1 (stream)	3.00	100
		0,676	D2 (strtch)	<b>9.9</b>	
		<b>9</b> .313	D3 (stream)	2.0 ×	2 10 2 10 2 10 2 10 2 10 2 10 2 10 2 10
		0.166	D3 (ditteh)	Q 30°	b 100
Invertebrate, chronic	NOEC 0.61 🖔	0,017	D4 (stream)	<b>3</b> 7.0 ⋅ √	i .Jø
Americamysis bahia	0.	Ø.008 ×	D\$ (stream)	72.6	<u>10</u> .
	, A.	© 0.2940	QD6 (ditch)	2.9"	10
		0)158	R Marond)	<b>3.9</b>	
		<b>20</b> .169	RJ (stream)	3.6	010
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	R3 (stream)	\$\tag{4}\tag{5}^{\tag{7}}  \lambda	<b>9</b> 10
	Q Q	) 0 <b>3</b> 97 <u>8</u>	R4 Stream	_ ŽI.5 °>	10
Fluoxastrobin (E+Z), spri	ing coreals, 2 125 g a.s	./har			
		<i></i> √ 0.9%	√D1 (dytch) Q	0.6	10
%		0r.248	Dl/streamQ	2.5	10
Invertebrate, chronic	NOFC Q 061	\$6.129 O	D3 (ditch)	<b>6</b> 4.7	10
Americamysis bahia	NGEC 9 0.61	\$ 0.019	D4 (s@eam) 🗸	31.9	10
		<b>. 400</b> 007	D5((stream)	84.7	10
		, \$\int 0.401 \infty	RA (stream)	1.5	10

Bold values do not meet the trigger

Table CP-0.2-28: TER calculations for onions calculation based on FOCUS Step 3 -TWAsw (7 days)

peeces y a mg/L1y σ	7-day TWA <sub>sw</sub> [µg/L]	FOCUS scenario	$TER_{LT}$	Trigger
FluoxastrobingE+Z), onions, 2×125 g a.s./ha	, O' O'			
Fish, chronic Oncorhynchus mykiss	<b>A</b> 14	R4 (stream)	69.0	10
	0.116	D3 (ditch)	5.3	10
	y 0.046	D4 (stream)	13.4	10
. 4 () .	0.160	D6 (ditch, 1st)	3.8	10
Invertebrate chronic NOEC (61)	0.242	D6 (ditch, 2nd)	2.5	10
Invertebrate chronic NOEC (61	0.163	R1 (pond)	3.8	10
Americanysis band 0 2	0.197	R1 (stream)	3.1	10
Invertebrate chronic ROEC  Americanissis bahia	0.117	R2 (stream)	5.2	10
	0.192	R3 (stream)	3.2	10
Americanysis bahia NOEC (61	0.414	R4 (stream)	1.5	10

Bold values do not meet the trigger

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

Step	3 -TWAsw (7 days) (acc		ISK: PEC/RAC < I	)	
Species	Endpoint [μg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10	7-day TWAsw [μg/L]	FOCUS Scenario	PEC/RAC
Fluoxastrobin (E+Z), win	ter cereals, 2 × 150 g a.s	s./ha	·		, %
			0.874	D1 (ditch)	\$\\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
		Č)	0.272	D1 (stream)	4.46
			0.525	D2 (ditch)	13.52
		, O	0.386	p2 (stream)	6.33
	NOEC 0.61 4 and the second sec		200	D3 (ditch)	3.28
Institute of the state of		99061 5	0.200 0 Q.021	D4 stream	3.2 <b>6</b> 1
Invertebrate, chronic Americamysis bahia	NOEC 0.61 🖔	, 0 <b>9</b> 061	0.010	(stream)	₹ 0.16
11mer teamy sis canta	4		Q 0.353	D6 (duch)	<i>⊆</i> \
			(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)		5.78 3.76
			0 0 193	Ri (pond)	
			0.20	(stream)	©3.39
			0.482	R3 (stream)	
			0.483	R4 (stream)	7.92
Fluoxastrobin, (E+Z) spri	ng coreals, 2 × 150 g a.s	s./ha⁄oʻ 🎺	<del>Š</del>	8	Г
			1.204	D1 (ditch)	19.74
9/			0,320 °C	DK (stream)	5.25
Invertebrate, chronic	NOFC 2 0.61	0.067	0.155	© 3 (ditch)	2.54
Americamysis bahid			0.034	D4 (stream)	0.39
		, Ş	Q.009 @	D5 (stream)	0.15
	4 4		0.482	R4 (stream)	8.02
TO A			O W		
\$ Q * X		7			
		F F			
			<u> </u>		
		Ş Ş			
		? 			
		~Q ~J			
		<b>A</b> .			
	5				
	~				
$\bigcirc$					
Invertebrate, chronic Americamysis bahia					

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

Биф	3 - 1 WASW ( / days) (acc	cptability of II	sk. i EC/KAC \ i	.,	
Species	Endpoint [µg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	7-day TWAsw [μg/L]	FOCUS Oscenario	PEC/RAC
Fluoxastrobin (E+Z), win	ter cereals, 2 × 125 g a.s	./ha	4	j L	
		۵.	0.724	D1 (ditch)	. \$P1.87√
			0.206	D1 (stream)	3.38
		L, *	Q <del>5</del> 76	D2 (ditch)	1,1,08
			Ø.313 °	P2 (stream)	S.13 0
			0.166	D3 (dich)	<b>2.72</b>
Invertebrate, chronic	NOEC 0.61	° 00061 ≈ 0	Ø .0.017 Ø	D4\stream	° .6.28
Americamysis bahia	NOLC 0.01 V		©0.008©	(stream)	<b>▲</b> 0.13 。
			© 0.294	D6 (duch)	© 4.82 ×
			D 0(158 · C)	R*(pond)	2.59
			£0.169	(stream)	©2.77
	NOEC 0.61	9961 5	0.19	R3 (stream)	<b>2.44</b>
	Q Q	D D	Ø9397 O	R4 (stream)	6.51
Fluoxastrobin (E+Z), spr	ing cereals, 2×125 g a.s	./har			
		laf.	~ 0.9 <b>9</b> 9 , @	D1 (ditch)	16.38
8			0,248	D\(\ell\)stream)	4.07
Invertebrate, chronic	NOEC 9 0.61	0.061	% 0.129 °	3 (ditch)	2.11
Americamysis bahi		\$ 2.001	O.009 4	D4 (stream)	0.31
			<b>Q</b> .007 <b>Q</b>	D5 (stream)	0.11
			0.404	R4 (stream)	6.57

Table CP 10.2-31: RAC<sub>sw; cr</sub> Calculations for onions calculation based on FOCUS Step 3 -TWAsw days) facceptability of risk; PEC/RAC < 1)

Species & Indpoint (Ing.)	· - · × · ·	7-day TWAsw [μg/L]	FOCUS scenario	PEC/RAC
Fluoxastrobin (E+Z) onions, 2 × 125 g a.s. ha				
Fish chronic Oncorporation with the second s	2.86	0.414	R4 (stream)	0.14
	Y.	0.116	D3 (ditch)	1.90
		0.046	D4 (stream)	0.75
		0.160	D6 (ditch, 1st)	2.62
T	0.061	0.242	D6 (ditch, 2nd)	3.97
Americanys bahia		0.163	R1 (pond)	2.67
Americany so bahig		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 TERLT/RACL@alculations of fluoxastrobin based FOCUS Step 3 -TWAsw (7 days) following application to cereals and onions

Fluorastrobin (E+Z)				Fluox <b>as</b> trobin (E-	<u> </u>	
D1 (ditch)   X	Scenario	2 x 150 g		7	Soa.s. /ha	125.g a.s.
D1 (ditch)   X		Winter cereals	Spring cereals	Winter cereals	Spring cereals	Onions
D1 (dtch)				te, chronic: <i>Amer</i>	icamysis bahia 🛝	
D2 (ditch)	D1 (ditch)	×	× &			~~ <u>~</u> ~
D2 (ditch)	D1 (stream)	×			, S. × Q.	A A
D2 (stream)  D3 (ditch)  X  X  X  X  X  X  X  X  X  X  X  X  X	D2 (ditch)	×			1 \$	9 & - &
D5 (stream)  D6 (ditch, 1st)  X  D6 (ditch, 2nd)  R1 (pond)  X  X  X  X  X  X  X  X  X  X  X  X  X	D2 (stream)	×	\$ - \Y		A	
D5 (stream)  D6 (ditch, 1st)  X  D6 (ditch, 2nd)  R1 (pond)  X  X  X  X  X  X  X  X  X  X  X  X  X	D3 (ditch)	×	Q * * *		Z X	
D6 (ditch, 1st)			~ ~ ~			Ş 29
D6 (ditch, 1st)		4				<u>~~~</u>
KI (pond)		× Q	~~		7 0 - 20	
KI (pond)	D6 (ditch, 2nd)	- V				
R1 (stream)  R2 (stream)  R3 (stream)  X  R4 (stream)  X  X  X  X  X  X  X  X  X  X  X  X  X	R1 (pond)	*50		<b>×</b>		<b>*</b>
R2 (stream)  R3 (stream)  X  R4 (stream)  X  Scenario not passed - Scenario not relevant for the rop  Results indicated with priced duther definement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.	R1 (stream)	* 4	- 3		V - S	×
R4 (stream)  Scenario not passed - Scenario not relevant for the crop  Results indicated with scheed surface refinement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.	R2 (stream)	\$ - \$ <sup>1</sup>		<u> </u>	\(\frac{1}{2}\)	×
Results indicated with a need durther refinement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.	R3 (stream)		Y <u>Q-</u> 3'	S ×		×
× Scenario not passed - Scenario not revent for the Fop  Results indicated with scheed further refinement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.	R4 (stream)		<b>"</b> " × ~>		× ×	×
	TWAswith days	calcations pr	esented below.			

Table CP 10.2- 33: TERLT calculations for invertebrates (long-term) based on FOCUS Step 4 -TWAsw (7 days) including mitigation measures

(7	days) including mitigat		Γ	1	, W			
Species	Endpoint [μg/L]	7-day TWA <sub>sw</sub> [µg/L]	FOCUS scenario	TERLT	Tengger			
Fluoxastrobin (E+Z), win	<u>l</u> ter cereals. 2 × 150 σ a.s			<u> </u>				
20 m buffer zone, 90% drij				<u> </u>				
		0.43	D1 (ditch)	1.4	<b>10</b>			
		0,272	D1 (stream)	<u> </u>	9 16			
		<b>42</b> 419	2 (ditch)	, O 1.5 Q	P0 0			
		0.233	D2 (stream)	.23	6 10 m			
Invertebrates, chronic	NOEC 0.61 &	0,001	D3 (ditch)	<b>3</b> 8.1 %	10			
Americamysis bahia	NOEC 0.61	Ø.004 ×	196 (dit@)	\$145,9	<u>4</u> 10			
		© 0.03₽	R1 (pond)	1197	100			
		0,049	RL (stream)	\$\frac{1}{2.5}				
		©.042 \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	R3 (stream)	Ŵ 14. <b>4</b> \$	$\bigcirc_{0}$			
		~~~ 0.1 M	R4 (stream)	<b>5</b> 3	<i>§</i> 10			
Fluoxastrobin (E+Z), spri	@ \/\ <sup>1</sup> \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	)/ha 💸 💍			1			
20 m buffer zone, 90% drij	ft reduction				T			
	NOEC 0.61	\$\tag{0.5}\$	D1 (witch)	1.2	10			
Invertebrates, chronic %	NOEC 0.61	Ø\$320 🔊	D'Mstrean)	1.9	10			
Americamysis bahia		\$0.001, <sup>©</sup>	D3 (ditch)	535.1	10			
		D 0.112	R4 (Stream)	5.4	10			
Fluoxastrobin (E+2), win	der cereals, 2 ×125 g a,s	s./ha 🌣 🐧						
20 m buffer zone, 90% drij	ft reduction 🗸 🧳			T				
		0.339	D1 Cditch)	1.9	10			
		0.206	D@ (stream)	3.0	10			
		0.330	©D2 (ditch)	1.8	10			
\$		0.91.81	D2 (stream)	3.4	10			
Invertebrates, chronic	NQ\$C . 0.61	0.001	D3 (ditch)	502.1	10			
Americamysis bahia		0.002	D6 (ditch)	195.4	10			
		02028	R1 (pond)	21.6	10			
		Ø.040	R1 (stream)	15.3	10			
	NOSC & 0.61	0.035	R3 (stream)	17.6	10			
Elucyactuchia (E   7)	Face Colors 2 × 125 color	0.095	R4 (stream)	6.4	10			
Fluoxastrobin (E+Z), spring celeals, 2×125 g a.s./ha  20 m buffer zone, 90% drift reduction								
20 in bujjer zone, 90% arij	Treductions &	0.398	D1 (ditch)	1.5	10			
Inverteble to a district in		0.398	D1 (atten)	2.5	10			
Invertebrates, spronic & Amgricamysts bahig	NØEC 0.61	0.248	D3 (ditch)	642.8	10			
		0.001	R4 (stream)	6.6	10			
Fluoxastyobin (E+Z), onic	ns. 2 × 125 g a s /ha	0.072	it (sircuiii)	0.0	10			
20 m buffer zone, 90% drij								
Invertebrates, chronic		0.001	D3 (ditch)	715.1	10			
Americamysis bahia	NOEC 0.61	0.007	D6 (ditch, 1st)	87.6	10			
		0.007	20 (411011, 151)	07.0	10			

Species	Endpoint	7-day TWAsw	FOCUS scenario	TERLT	Triada	<b>%</b> .
Species	[µg/L]	I W A <sub>sw</sub> [μg/L]	FOCUS scenario		Trigger	
		0.019	D6 (ditch, 2nd)	≫ 31.6		
		0.028	R1 (pond)	21.7	× 10 ×	
		0.046	R1 (stream)	13.3		Ža.
		0.028	R2 (strgam)	22,07		ř
		0.046	R3 (stream)	1\$12	710 710 710	.0
		0.01	R4 (stream)	₩6.3 Ø		Ő
Fluoxastrobin (E+Z), onic	   ns. 1 × 125 σ a.s./ha			(		<b>Y</b>
20 m buffer zone, 0% drift	reduction	Q Y		, 0		
20 m ougger cone, 070 urige		00009 <u>*</u>	D'S (ditck)	67.8	S S	
	(A)	<b>3</b> 0 007 ©	Po (ditco 1st)	874	_410 e°	
		m C	D6 (ditch, 2nd)	50.8	100	
Incontabuatas almania	NOEC 0.61	00018 . 4	Po (pond)	33.0 %		
Invertebrates, chronic Americamysis bahia	NOEC 0.61	©0.019©	K1 (stream)	33.9 \$\infty 32.0 \infty	10 Po	
11mer teumysis sumu		0.011	R2 (Stream)	52.5 °	V 10	
	NOEC (0.61 %)	0.011	R\$/(stream)	© 32.1,	10	
		0.041 S	(Stream)	140	10	
Rold values do not meet the	trigger V	0.041	OR4 (stream)	149	10	J
bold values do not meet the				L)		
A n						
Ÿ						
			~\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\			
<b>9</b>	4 3 2 4		<b>3</b> "			
		, K				
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				
		7				
· * Y						
Bold values do not meet the						

Table CP 10.2- 34:

RAC<sub>sw; ch</sub> calculations for invertebrates (long-term) based on FOCUS Step 4 TWAsw (7 days) including mitigation measures (acceptability of risk: PEC/RAC<sup>\*</sup><
1)

<u></u>	<u> </u>				
Species	Endpoint	RACsw; ch (NOEC/10)	7-day TWA <sub>sw</sub>	<b>E</b> OCUS	PEC/RA©
•	[µg/L]	$(E_rC_{50}/10)$	[µg/L]	Scenario	
Fluoxastrobin (E+Z), win	ter cereals, 2 × 150 g a.s	s./ha	£	<b>,</b> , , , ,	
20 m buffer zone, 90% drij	ft reduction	Ö		Z.	N S
			0.423	D1 (datch)	7.13
		a C	<b>0</b> ©72	D1 Otream)	
			0.419	D2 (ditch)	6.87
			0.233	D2 (stream) *	3.82
Invertebrates, chronic	NOEC 0.61	, Q ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	<b>6</b> 001	D3 (ditch)	<sub>3</sub> 0.02
Americamysis bahia	NOEC 0.61	\$ 0.001 C	Q0.004 O	D6 (ditch)	@0.07 & °
	<b>₩</b>		> 0.0 <del>3</del> → 、	R1 (gond)	0.50
			0 <del>,</del> 0049 ×	R1 stream	<b>©</b> .80
		- F J	0.0425	K (stream)	Ø 0.69
			0.105	R4 (stream) %	1.89
Fluoxastrobin (E+Z), spri	ing cer@als, 2 ×150 g æs	s./ha 🌣 🎺 💆		7 8 <u>4</u>	
20 m buffer zone, 90% drij	ft reduction 🤝	A a		<u> </u>	
<b>\</b>			0.392	D1 (ditch)	8.39
Invertebrates, chronic	NOTEC \$ 0.61	0.064	<b>%</b> 0.320 <b>★</b>	DD stream)	5.25
Americamysis bahi	NOTE 0.61	\$ 50.061	0.00	LD3 (ditch)	0.02
			0.012	R4 (stream)	1.84
Fluoxastrobin (FZ), win	ter céreals, 2 × 125 g/a.s	s./hal			l
Fluoxastrobin (\$\frac{1}{2}\), where the state of the sta	ft_reduction V		Ö W		
, Q /				D1 (ditch)	5.39
			0.206	D1 (stream)	3.38
			0.330	D2 (ditch)	5.41
			0.181	D2 (stream)	2.97
Invertebrates chronic		\$ 0.00	0.001	D3 (ditch)	0.02
Americamysis bahig	INDEC 9 0.00	0.06	0.003	D6 (ditch)	0.05
			0.028	R1 (pond)	0.46
			0.040	R1 (stream)	0.66
		Ž	0.035	R3 (stream)	0.57
		1	0.095	R4 (stream)	1.56
Fluoxastrobin (P+Z), spri	ing cereals × 1250 a.s	s./ha			
20 m buffer zone, 90% dri	ft Eduction 0				
			0.398	D1 (ditch)	6.52
Invertobrates Schronic	© 0.61	0.061	0.248	D1 (stream)	4.07
Americam sis balda		0.001	0.001	D3 (ditch)	0.02
	<b>L</b> *		0.092	R4 (stream)	1.51
Fluoxastrobin (E+Z), onic	ons, $2 \times 125 \overline{g}$ a.s./ha				
20 m buffer zone, 90% dri	ft reduction				
Invertebrates, chronic	NOEC 0.61	0.061	0.001	D3 (ditch)	0.02

Species	Endpoint [µg/L]	RAC <sub>sw; ch</sub> (NOEC/10) (E <sub>r</sub> C <sub>50</sub> /10)	7-day TWA <sub>sw</sub> [µg/L]	FOCUS scenario	PEC/RAC
Americamysis bahia			0.007	D6 ditch, 1st)	Ø211
			0.019	D6 (ditch, 2nd)	0.34
		r i	0.028	R1 (pond)	∘ <b>0</b> .46 ≾
		Ö	0.046	R1 (stream)	0.75
		4	0.008	R2 (stream)	0.46
			0.046	R3 (stream)	Ø.75 @
			~ 0.09 <b>%</b>	R# (stream)	© 1.590°
Fluoxastrobin (E+Z), oni	ons, 2 × 125 g a.s./ha 🐒	, <u>O</u>			
20 m buffer zone, 0% drift	t reduction O			6 4	<u> </u>
			0.009	©D3 (ditch)	0.150
			0.007	D6 (ditch, 1st)	037
	ons, 2 × 125 g a.s./ha & reduction		©0.012	De (ditch	0.20
Invertebrates, chronic Americamysis bahia	NOEC 661	<b>0.06</b> 1 6	0,008	R1 (Cond) 🖔	0.30
Americamysis banta			<b>Q</b> 019	R stream)	0.31
		Ly or	\$\tilde{0.01}	32 (stream)	0.18
			0.079	R3 (stream)	0.31
& n			& 0.041	R∰stream)	0.67

**Bold** values do not meanthe trigger

Concerning two applications in winter and spring cereals at rates of 2 × 50 g a.s./ha and 2 × 125 g a.s./ha, safe us without any refinement was identified for the scenarios D4 (pond), D4 (stream), D5 (pond) and DS (stream).

Concerning two applications in winter cereal at rate of 2 150 g a.s./ha and 2 × 125 g a.s./ha, safe use was identified for the scenarios 13 (ditch), D6 (ditch), R1 (pond), R1 (stream) and R3 (stream) when mitigation measures of 20 meters buffer zon + 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. The 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 (pand) and D4 (gream). A safe use for all other scenarios can be predicted Considering 20 m drift buffer without drift reduction.

Conchision

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

; 2014; M-491937-01-1 KCP 10.2.1/01 Report:

Acute toxicity of fluoxastrobin + prothioconazole EC 200 (00+100) G to fish Title:

(Oncorhynchus mykiss) under static conditions

Report No.: EBHEX243 M-491937-01-1 Document No.:

OECD Guideline 203, Fish, Acute Foxicity Test Quly, 1992); USEPA Redicides Guideline(s):

> Assessment Guidelines Subdivision E, FIFRA 729, Acute toxicity test for freshwater fish, October, 1982; USEPA QCSPP 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 dem Fruoxastrobin + Prothioconazole EC 200 to Rainbow trong (Oncorhynchus my liss). 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 pedian cethal concentration PC50 k

# Material and methods:

Test item: Fluoxastrobin Prothioconazole & 200 (100+00), G; Batch ID.: 2012-001071; Sample description: TOX09674-00; Specification No.: 10200005822-01; Master recipe ID: 0117103-001; Analysed content of active substance: 9,20% www (1013 g/L) fluoxastrobin, 9.13% w/w (100.4 g/L) prothioconazole; Density Y.100 mL 20°C)

Rainbow troug Oncomynchos mykos) were exposed for 96 hears under static conditions to nominal concentrations of 0.025, 1.25, 2.50, 5.00 and 100 mg/st item/L against a control. At the beginning of the test the mean body tength 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 ash / L test medium.

One replicate (one aquarium) of ten fish cach was used for each test concentration. The aquaria used were made of glass with a capacity of Av-litres and a dimension of 38 cm height, 32 cm width and 36 cm length. Within the study the plovalue, the coygen saturation level and the temperature were measured with compercial measurement devices, daily. The water temperature during the 96-hour exposure ranged from 100 to 10.7°C on 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 works. February 15, 2013 to December 09, 2013

# **Findings:**

# Validity criteria:

Validity criteria	Recommended	Obtained O
Mortality within the 48-hour settling-in period	≤ 5%	< 5% 💍
mortality in the control (or one fish if less than ten are used)	≤ 10%	
dissolved oxygen saturation throughout the test	$\gtrsim 60\%$	£88 - 10√% £
pH variation (units)	≤ 1.0	Q 20.4 V

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 HPLCUV) evealed recoveries of 58 % 92 % of nominal over the whole testing period of 90 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-letoal findings were observed

In all test levels  $\geq 1.25$  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 swiface
- showed labored respondition

Table CP 10.2.1- Cumulative mortality of the rainbow trout exposed to Fluorastrobin + Prothioconazole

		<del></del>		ν <u>Ψ</u>		<u> </u>				
Exposure 6	% h	1	, © 2 <u>4</u>	h 👸	® 48 ]	h	<b>🎺</b> 72 1	h	96	h
time '\'		<i>~</i> .~		0	~ ~	~	<b>Ö</b> '			
Test conc.	no. of @	% dead	no. of	<b>∞</b> % .	Õĥo. of€	′ ‰©′	no. of	%	no. of	%
form.	dead		geneau (	dead	∀ de@ad	‰° dead	dead	dead	dead	dead
[mg / L]		,		. ~	0, 1	<u>.</u>				
control	9	$\Rightarrow 0$		~ W	@ 0 C	0	0	0	0	0
0.625	@ 0 ©	° 0 €	, Ø	00 .	O 0 0°	0	0	0	0	0
1.25	$\bigcirc 0$	<b></b>	~~0 ~~	y 0 6	<b>6</b>	0	0	0	0	0
2.50	0	96 3	9 0	, 0°0		20	7	70	9	90
5.00	0 🔩	0 Q	1000	£00	× 10	100	10	100	10	100
10.0	10~	100	<b>1</b> 0	\$100°	P 10	100	10	100	10	100

# **Conclusion:**

Based on nonfrial concentrations the following endpoints were determined:

LC<sub>50</sub> 96 h (95% confidence interval): 3.19 mg test item/L (convidence interval 95 %: Not

determined due to mathematical reasons.)

1.25 mg test item /L

NOEC:

NOEC:

0.625 mg test item /L

1.25 mg test item /L



KCP 10.2.1/02 L; 2012; M-434883-01-1 Report:

Acute toxicity of fluoxastrobin + prothioconazole EC 200 (100+100)A G to the Title:

waterflea Daphnia magna in a static laboratory test system

Report No.: EBHEX242 Document No.: M-434883-01-1

OECD Guideline 202, Daphnia sp. Acute Immobilisation Tost (April, 2004), USEP Guideline(s):

Pesticide Assessment Guidelines Subdivision E, FIFRA 72-2, Acute tox for freshwater aquatic invertebrates, October, 1982.; OPPTS Guideline 850.1010 Aquatic Invertebrat

not applicable Guideline deviation(s):

**GLP/GEP:** yes

# **Objective:**

The study was performed, to detect possible effects of the test item Fluckastroom + Prothioconazole EC 200 on mobility of Daphnia magna during 48 mours of exposure in a static laboratory test system, expressed as EC<sub>50</sub> for immobilisation.

### **Material and methods:**

Test item: Fluoxastrobin + Prothicionazole EC 200 (100+100) A G. Batch D.: 2012-001071; Sample description: TOX09674-00; Specification No.: 102000025822-05, Analysed Content: 9.21% w/w fluoxastrobin, 9.13% w/w profinoconazole: Density: 1.100 g/mL 20 °C

Daphnia magna (1st instar 24 hours and), each study group comprising 30 daphnids (6 replicates per test concentration, 5 daphnids per replicate) were exposed in a static exposure vistem for 48 hours to Fluoxastrobin + Protocongole EC 200 at the concentration of 0 contreated control), 0.53, 0.95, 1.71, 3.09, 5.56 and 10.0 mg form./L (cominally) 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 contnept of fluoxastroom in exposure media was measured for verification of the test concnetrations.

Water quality parameters viz Gemperature of and dissolved oxygen were measured at 0 and 48 h after the commencement of the exposure. Dissolved exygen concentrations ranged from 8.5 to 9.1 mg O<sub>2</sub>/L, the pH values ranged from 7.9 ±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 wor

# Findings:

Validity criteria:

variatty criteria;	'n		
Validity criteria	1	Recommended	Obtained
Control mortality		© 0.0%	0.0%

The study neets 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 flu As the toxicity has to be report are related to nom	exastrobin were detected attributed to the tested that test concentrations of	in samples from untreated water control. Cormulation as a whole, all results submitted by this the formulated product.  In at 24 and 48 h exposure period  Illised daphnids  A8 h.  O O O O.O.  O O
Biological results:		
Table CP 10.2.1- 2: Immo	oility data of <i>Daphnia mag</i>	na at 24 and 48 h exposure period
nominal test concentration (mg form. / L)	exposed immobility dappened appendix (=100%) n %	ilised daphnids  7 48 h.
control	30 0 0.0	
0.53	30 0 0	
0.95	30 U U.3	1 0 3.54 0 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
3 09	30 25 83	$\frac{3}{2} \stackrel{\text{TV}}{=} 1 \text{TV$
5.56	30 29 96	**   **   **   **   **   **   **   **
10.0	30 30 0	0 1 30 ° 100 ° × × × × × × × × × × × × × × × × × ×
Observations:		
No immobility or other	effects on behaviour	occurred in untreated control within 48 hours of
exposure.		F O S. F S &
Caralysian.	7 "	
Conclusion.		
Based on nominal conce	ntrations of Francismon	n Prothoconazole EC 200 EC o values atter 24
and 48 h hours of statics	cposárě wero determinec	mathe 2 45 mosterm / I (95 s/2000 tidence limits L.85
· · · · · · · · · · · · · · · · · · ·	1 0 1 - 1 1 1	
-2.46 mg form./L) and 1	67095 Confidence light	its 1.24 – 2.25 mg form./L), respectively.
- 2.46 mg form./L) and 1	67095 % confidence light	As 1.24 – 2.25 mg form./LX, respectively.
- 2.46 mg form./L) and 1	67095 % confidence light	its 1.24 – 2.25 mg form./LA, respectively.
		its 1.24 – 2.25 mg form./L), respectively.
		its 1.24 – 2.25 mg form./LX, respectively.
		its 1.24 – 2.25 mg form./Ly, respectively.
		its 1.24 – 2.25 mg form./L.), respectively.
		ints 1.24 – 2.25 mg form./L), respectively.
		its 1.24 – 2.25 mg form./Ly, respectively.
		ats 1.24 – 2.25 mg form./Ly, respectively.
		ints 1.24 – 2.25 mg form./L), respectively.
		ats 1.24 – 2.25 mg form./Ly, respectively.
		ats 1.24 – 2.25 mg form./L), respectively.
		ints 1.24 — 2.25 mg form./L), respectively.
		ats 1.24 – 2.25 mg form./L. respectively.
		ats 1.24 – 2.25 mg form./L), respectively.
		ints 1.24 – 2.25 mg form./L), respectively.
		ints 1.24 – 2.25 mg form./L), respectively.
		ats 1.24 – 2.25 mg form./L), respectively.
		ints 1.24 — 2.25 mg form./L), respectively.
		ints 1.24 – 2.25 mg form./L), respectively.
		ats 1.24 – 2.25 mg form./L), respectively.
		its 1.24 – 2.25 mg form./L), respectively.
		Prothioconazole EC 200 EC 50 values after 24 be 2 95 mg form/L (95 % confidence limits 1.89 its 1.24 – 2.25 mg form./L), respectively.
	67(95 % confidence line	ats 1.24 – 2.25 mg form./L), respectively.
		ins 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

T; 2012; M-438495-01-1 Report: KCP 10.2.2/01

Title:

Report No.: Document No.:

Guideline(s):

Guideline deviation(s): **GLP/GEP:** 

# **Objective:**

M-438495-01-1
OECD Guideline 201: Freshwater Alga and Cyambacteria, Growth Inhibition Test (March 23, 2006) none
yes The aim of the study was to determine the influence of the test irem Fluoxastrobin + Prothoconazole EC 200 on exponentially growing Pseudokirchneriella subcapitata expressed as NOEC, LOEC and  $EC_x$  for growth rate of algal biomass (sells per volume).

# Material and methods:

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

Pseudokirchneriella subcapitata Greshwater microalgae, formerly known as Selenastrum capricornutum) with an initial cell density of 10,000 cells/mL in the est medium were exposed in a chronic multigeneration test for Odays under static posure conditions to nominal concentrations of 0.0960, 0.307, 0.980, 3.43 and 10.0 mg formulation/L in comparison to a control. Three replicate vessels per tes Oevel and 6 replicate vessels per control with 150 mL test medium per replicate were

The pH values ranged from 7.9 to 8.1 in the controls and the water remperature 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 \$658 lux,

Morphological examinations of gotts using a microscope were made over the exposure period on each study day. Quantitative amounts of thoxastrobin were measured in all treatment groups and in the control on day and day 3 of the exposure period

Dates of experimental work:

# 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 \$3%. 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.

Table CP 10.2.2-1: Eff	e growth inhibition	n test provided the f	following effects:	, S F
	cell number	(0-72h)-average	inhibition of average	Ąř
Ima form /I.]	after 72 h	specific growth	specific growth rate	
[IIIg IOIIII./ L.]	(means) per mL	rates [days-1]		
control	704 000	1.418		'j' L
0.0960	671 000	1.402		& O'
0.307	638 000	1.390	1.6 O	, Ü
0.980 3 13	331 000	1,35%	+ 2.00 18/7 & O O	<b>Y</b>
3.13	100 000	/. 0.767æ°	19.1 19.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
test initiation with 10,000 co	ells/mL			<b>,</b> °
Observations: No morphological char	nge in algae was	bserved in any test of	concentration of the second	
Conclusion:				
No further data of the factor	er testing our aque formulation is avail	uatic organisms Table or required.	following effects:  hibition test  inhibition of average specific growth rate  [%]  1.6  2.6  1.7  2.7  2.7  2.7  2.7  2.7  2.7  2.7	

# **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, fincluding subJethal 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 Ex 200.
- Acute contact toxicity of fluoxastrobin to adult bumble bees furder laboratory conditions.
- Chronic 10 day toxicity test with of Fluoxastrobin FS 480 on adult bees under laboratory conditions.
- Colony feeding study with Fluorastrobin FS 480 according to al. 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood (eggs, young and old farvae) and their development, nurse becon-going behaviour in brood care and colony strength)
- Semi-field broot feeding study with Fluorastrobin EC 100 Tollowing OECD guidance document 75 tursing Chiore feelistic spray scenario onto flowering Phacelia tanacetifolia at the maximum application rate for the approval renewal of fluorastrobin and covering exposure for effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with flux astrobin and ecotosicological 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 ensitive 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 fluorastrobin, the formulated products Fluorastrobin EC 100, Fluorastrobin FS 480 and Fluorastrobin Production Fluorastrobin FS 200 are provided in the following tables. Endpoints shown in bold are considered relevant for risk assessment.

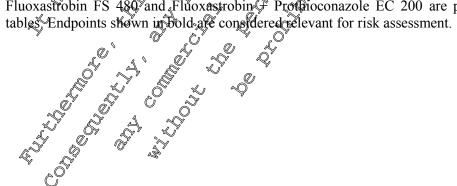


Table CP 10.3.1-1: Critical endpoints for fluoxastrobin – acute toxicity to adult bees

Test substance	Test species		Endpoint	Reference
	Honey Bee (oral 48 h)	LD <sub>50</sub>	> 129.1 μg a.s./bee	2014; M=50327\$
Fluoxastrobin	Honey Bee (contact 48 h)	LD <sub>50</sub>	> 100 μg a.s.Δpee	01-1 KA 8.3 71.1 KA 8.3 1.1.2
	Bumble bee (contact 48 h) (Bombus terrestris)	LD <sub>50</sub>	> 100 μg as bumble bee	20 <b>°4</b> ; M-5 <b>°</b> 2437, 67-1 K A 8.3 0.1.2
Fluoxastrobin +	Honey Bee (oral 48 h)	<b>12D</b> 50	> 160.3 µggrod./bec	2012; M-434652-
Prothioconazole EC 200	Honey Bee (contact 48 h)		> 200 hg proft./bee	XCP 103.1.1.1 KCP 103.1.1.1

a.s. = active substance; prod. = product

Critical endpoints for thioxastrobin - chronic loxicity to adult bees **Table CP 10.3.1-2:** 

Test substance	Test species Reference
Fluoxastrobin FS 480	Honey bee Laborator LC $_{50}$ $_{2}$ $_{3333}$ mg a.s./kg $_{2}$ $_{3333}$ mg a.s./kg $_{2}$ $_{2015}$ ; M-534974- $_{392}$ $_{4}$ $_{4}$ $_{2015}$ $_{392}$ $_{4}$ $_{4}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_{501}$ $_$

a.s. = active substance

(Ditical endpoints for flooxastrobin -toxicity to bee brood

Test substance	Test species 4	Endpoint	Reference
Fluoxastrobin FS 480	Bee brood feeding test (	No adverse effects on brood development and mortality after feeding honey bee colonies sugar syrup at 0.375 g a.s./L.	; 2013; M-476181-01-1 KCA 8.3.1.3
Fluoxassisobin EC 00  a.s. = active substan	Semi-field broods tudy (OFCD 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 <i>Phacelia tanacetifolia</i> .	.; 2015; M-515147-01-1 KCA 8.3.1.3
a.s. = active substan			

### Risk assessment for bees

The risk assessment for bees is based on the maximum application rates of  $2 \times 150$  g fluoxastroton/ha in cereals and for the maximum application rates of  $2 \times 125$  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  $\mu g$  a.s./bee or in  $\mu g$  total substance/bes.

 $Q_H$  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 hiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral:
$$Q_{HO} = \frac{\text{max. appl. rate}}{\text{LD. raral}} = \frac{\text{g a.s. bas or gotal substance/bas}}{\text{fug a.s. bee or ug total substance/bee}}$$

Hazard Quotient, contact:

$$Q_{HC} = \frac{m_{A}Q_{appl, rate}}{LD_{50} contact} - \frac{lg \ a.s. Aba \ or \ gratal \ substance/beel}{lg \ a.s. Aba \ or \ gratal \ substance/beel}$$

The maximum label rate of Fluorastrobin + Prothioconazole EC 200 (100 + 100) per application are 1.5 L (1500 mL) product/havin cereals (BBCH 30 - 69) and 1.25 L (250 mL) product/ha in onions (BBCH 15 - 47). With the content of fluorastrobin and prothioconazole within the formulation being 100 g fluorastrobin/L and 100 g prothioconazole/L, respectively, this accounts to a maximum application rate of 150 g fluorastrobin/ha in cereals and 125 g fluorastrobin/ha in onions. Considering a density of 1.100 g/m of Fluorastrobin + Prothioconazole EC 200, 1500 mL product/ha corresponds to 1650 g product/ha and 1230 mL product/ha corresponds to 275 g product/ha.

Table CP 10.3.0 4: Hazard quotients for bees - orabexposure

Crop LDs Application rat	Hazard quotient QHO	Trigger
Fluoxastrobin+Prothiceonazon EC 200   Cercuis   >1650*	< 10.3	50
Fluoxastrobin Cereals 129.17 150	< 1.2	50
Fluoxastrobin+Prophiocomazole R 200 Pnions > 160.3   1375*	< 8.6	50
Flygxastrofin Onions > 139.1 7 125	< 1.0	50

<sup>\*</sup> based on a product density of 1.100 g/mL

The hazaft quotients for oral posure 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

	Sop	LD <sub>50</sub> [µg/bee]	Application rate [g/ha]	Hazard quotient Qно	Trigger
Fluoxastr@in+Prothiocondzole & 200	Cereals	> 200	1650*	< 8.3	50
Flood xastrobin	Cereals	> 100	150	< 1.5	50
Fluorestrobio-Prothesconazole EC 200	Onions	> 200	1375*	< 6.9	50
Fluoxastrobin	Onions	> 100	125	< 1.3	50

<sup>\*</sup> 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 (2014; M-512437-01-1; in CA 8.3.1.2). The study resulted in an LD<sub>50</sub> of  $> 100 \mu g$  a.s./bumble bee and did not reveal sensitivity differences between honey are and bumble bee foragers.

Moreover, fluoxastrobin was further subjected to chronic laboratory testing with adult honey beging 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, 2667 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@ (Lethal Concentration) was determined to be > 3333 mg fluoxastrobin/kg, which corresponds to a LDD50 Lethal Dietary Dose) of 73.3 \u03c4g a.s./bee/day. The respective NOEC (No Observed Effect Concentration) for nortality was determined to be 1667 mg fluoxastrobin/kg, which corresponds to the NOEDD (No Observed Effect Dietary Dose) of 39.2 \u03c4g a.s./bee/day.

In order to reveal whether fluoxastrobin poses a risk to impature honey be life stages, a bee brood feeding study (2013; M-476 81-001, in A 8.3.1.3) has been conducted by following the provisions/method of (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 vorst-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 lary as by employing digital photo imaging technology.

This particular study was conducted with Flioxastrobin FS 480. The administration of fluoxastrobin at a concentration of \$\particle{0.0000}375\$ gas to honeybee colories via feeding of 1 fitre 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, 2.1 and \$1.3\% 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 fluorastrobin 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 Fluorastrobin EC 100, by application of 150 g a.s./ha under tonnel conditions to the full flowering and highly bee attractive surrogate crop hacelia tandetifolia (\$\frac{1}{2}\$\$) \$\frac{1}{2}\$\$ (\$\fra

surrogate crop thacetia tancetifold (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 fenovycarbyla) 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, where confinement and at the end of the study. Detailed brood assessments (brood termination rate) rood 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 turnel conditions to the full? flowering and highly bee attractive surrogate crop Phacelia tanacetifelia did not cause any adverse effects on mortality, flight intensity (except for a short ferm 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: 300%, brood index: 3.52 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 testoitem 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 vet al and OECD Gwidance Document 75 investigating as from the bee brood feeding study & side-effects on immature honey begine stages, that fluorastrobil is of low general in insignosticity to honey bees.

# **Synopsis**

Fluorastrobin 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 gluoxactrobin are below the validated trigger value which would indicate the need for refined risk assessment; so 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 seror-field study, which covered the maximum application rate of 150 g a.s. Ma.

The acute laboratory study conducted with burnele bees revealed no sensitivity differences between honey bee and bumble bee foragers.

It can be concluded from the scute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study and bee brood semi-field study (OECD 75), investigating side-effects on impature honey bee life stages that fluoxastrobin is of low general intrinsic toxicity to honey bees.

Regarding potential side effects of fluoxastrobin on immedire honey bee life stages, the conducted bee brood feeding study et al., 1922) found no statistically significant differences between test item and control in brood termination rates of oggs. 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 exposore situation in this worst-case screening test in combination with the absence of effects on the overall development of the brood, it can be concluded even on the basis of this worstcase 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 carify 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 Oby 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 apicoltural 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 a 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 manne@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 in unacceptable risk to hopey becand honey bee colonies.

CP 10.3.1.1.1 Acute oral toxicity to bees 200 formulation, was mistakenly added to list of studies to be subnutted in the supplemental dessier. Meanwhile, the respective formulation was replaced by a new EXA+PTZ EC 2000 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:

Title: Effects of fluoxastrobin prothic conazore EC 200 (100+100) C (Acute contact and

Coral) of honey bees (Apis medifera L) in the Vaboratory

73299035 🚕 Report No.: M43400201-1 Document No.:

OECD Guideline 213/214 for the Testing of Chemicals on Honeybee, Acute Guideline deviation(s) none CLP/CEP

GLP/GEP: 🔊

# **Objective:**

was to determine the acute contact and oral toxicity of Fluoxastrobin Prothoconazole E 200 to the hopey be 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: Flooxastrobin + Prothiconazole EC 200 (100+100) G; Short code: FXA + PTZ EC 200 (100+100) G; Batch 1D: 2012-001071; Sample description: TOX09674-00; Material No. 30485482; Specification No. 102000025822-01; active ingredients (analysed content): 9.21 % w/w (101.2 g/L) Duoxastrobin OHEC 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 staintess steel cages of 10 cm x 8.5 cm x 5.5 cm (length x height x width). 10 bees were used per test anit. 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 so used was used at the same ratio 50% (w/w) tap water, 50% (w/w) reacts-to-use sugar-syrup. The treated food was offered in syringes, which were weighed before and after introduction into the cage. After a maximum of 6 hours, the uptake was complete (duration of uptake was between 35 minutes and & hours) and the syringes containing the treated food were removed, weighed and replaced by one containing fresh, untreated food.

The number of dead bees was determined after  $4(\pm 0.5 \text{ h})$  hours (first day) 24 and 48 ( $\pm 2 \text{ h}$ ) 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; Plative Tumidity was 50 - 75%. Bees were kept in darkness (except during observation)

was 50 - 75%. Bees were	kept in darkness (except during observation)
Dates of work: April 17,	kept in darkness (except during observation).  2012 to Max 09, 2012  Recommended Obtained
Findings:	
Validity Criteria:	
Validity Criteria	
<b>%</b>	Contact Test
	CO2/water control 010% 000%
Control Mortanty	Of Test
Ž	
	0 10 - 6 30 ug a s /hee   0 26 ug a s /hee
LD <sub>50</sub> of Reference 10m (2-	(4 a) O O O O O O O O O O O O O O O O O O
	Ogal Test  Oμα ο ο ο ο ο ο ο ο ο ο ο ο ο ο ο ο ο ο ο

The contact and oral test is considered valid as the control mortality in each case was < 10% and the LD<sub>50</sub> values obtained with the reference from (diffrethoate) 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/beg. There was no mortality in the control group (water + 0.5 % Adhäsit).

One bee was Dound apathetic during the 4 and 24-hours assessment, respectively. This was the only occurrence of test Hem retailed behavioural impairments in the contact 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 behavi@ral abnormalities occurred.

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

abnormalities occurred.	
Table CP 10.3.1.1.1- 1: Toxicity	y to honey bees; laboratory tests
Test Item	Fluoxastrobin + Prothioconago le EC 200
Test Object	Apis melliferal & S
Exposure	contact & Gral F & Gral
	(solution in Adhäsit (00%)/water) (sugar solution)
Application rate µg product/bee	200 00 \$\tag{60.3}, 78.0, 39 \tag{19.8 and 9.9}
LD <sub>50</sub> μg product/bee	24 hours: > 200.0
LD <sub>20</sub> μg product /bee	24 hours: 200.0 24 hours: 160.3 48 hours: > 160.3 48 hours: > 200.0 24 hours: > 200.0 25 hours: > 200.0 26 hours: > 200.
LD <sub>10</sub> μg product /bee	24 hours: > 200.0
NOED μg product /bee*	24 hours: > 200.0

<sup>\*</sup> The NOED was estimated using Fisher Exact Cest (pairwise comparison, one sided greater, 0=0.05).

The contact and oral LD (24 h) value of the reference item (dimethoate) alculated to be 0.26 and 0.12 µg a.s./bee, respective

## **Conclusions:**

The toxicity of Euoxastrobin Prothjoconazole EC 200 was tested in both an acute contact limit test and an acute oral toxicity dose response test on horrey bees.

μg product/bee. The oral LD<sub>50</sub>(48) was > 160.3 μg product/bee, The contact LD<sub>50</sub> (48 h) was respectively.

## CP 10.3.1.1.2 Accute contact toxicity to bees

The acute confact toxicity studies of hone bees with the product are summarised in Point 10.3.1.1.1, therefore only the results are summarise below?

In the course of the application the study M5080740-01-1, 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 of 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-.. not rélevant. 080740-01- Cis not relevant.

KCP 10.3.1.1.2/01 ;; 2012; M-434002-01-1 Report:

# Table CP 10.3.1.1.2-1: Toxicity to honey bees; laborato

Report:	;; 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 73291035 M-434002-01-1
Report No.:	73291035
Document No.:	M-434002-01-1
Guideline(s):	OECD Guideline 213/214 for the Testing of Chemicals on Broneybee, Acute
	Oral/Contact Toxicity Test, adopted on 21st September 1998.
Guideline deviation(s):	none some
GLP/GEP:	73291035 M-434002-01-1 OECD Guideline 213/214 for the Testing of Chemicals on Froncybee, Acute Oral/Contact Toxicity Test, adopted on 21st September 1998. none yes  Toxicity to honey bees; laboratory tests
T. I.I. CD 10 2 1 1 2 1	
Table CP 10.3.1.1.2- 1:	Toxicity to honey bees; laboratory tests
Test Item	Formastrobin + Prothiocenazole EC 200 Q
Test Object	L & Apis melfifera L &
Exposure	C contract of the second
1	Solution in Adhasit (0.5 %)/water)
Application rate µg prod	unot/bee
1 //	2 / 2 / hours > 2000 / 7
LD <sub>50</sub> μg product/bee	2000 48 hours: > 2000
I.D. 1 . //	~ Ø Ø Ø 24 <b>6</b> 00urs; ₹200.0 Ø ~
LD <sub>20</sub> μg product /bee	2 24 July 13 2 200.0 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
ID 1 4 //	24 horses > 2000 @
LD <sub>10</sub> μg product /bee	6 0 48 hours: \$500.0 \$7
NOED 1 // *	
NOED µg product /bee*	48 hours: > 200.0

<sup>\*</sup> 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 8.3.4.1.2 ( ; 2014; M-512437-01-1; in GA 8.3.1.1.2).

### Cheonic toxicity to bees **CP 10.3.1.2**

A 10 day chronic oral toxicity study was conflucted with flooxastrobin; the corresponding summary is provided in Documen MCA: Section 8.3.102 ; 2015; M-534974-01-1).

# Effects on honey bee development and other honey bee life stages

A honey bee brood freeding study according to the method of et al. 1998 ( (2013; M-476181-02-1) has been condicted with Fluoxastrobin FS 480 and is included in Document MC Section 8.3 § 3.

A semi-field honey bee broad study (according to OECD 75) ( ; 2015; M-515147-01-1) has been conducted with the Fluorastrobin EC 100 and is included in Document MCA, Section 8.3.1.3.

## CP 19.3.1.4 Sub Tethal effects

There is particular study design / test guideline to assess "sub-lethal effects" in honey bees. Howeve 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 Fluorastrobin + Prohioconazole C 200 on the sensitive standard species *Typhlodromus pyri*, *Aphidius rhopalosigni*, *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,	Tested Formulation	Ecotoxicological En	dp@int ≼	
Dossier-File-No.,	Study Type Duration,			
Reference	Exposure &			<i>⊗</i>
Aphidius rhopalosiphi	FXA+PACZ EC 2000	$LR_{50} > 6750 \text{ mL}$ proc	luct Pia 💲 🧋	, 2
M-438699-01-1	Extended lab exposers on	$\mathbb{E}R_{50} \gg 750 \mathrm{m}$ prog	lvogt/ha _Ö 🌣	,
Rep. no: CW12/028	potted barley seedlings	Corr@Mortalify [%]	Effecton Repro	duction [%]
, 2012a	3 mL product/ha		© 09.8	
KCP 10.3.2.2	750 mk/product/ha		12.5	
	1500 mL product/ha	10.0	-12.8 <sup>A</sup>	
. **	3000 mL product/ha	<b>6</b> ¥3.3 <sub>€</sub> . ×	32.4	
	650 mL product/ha	∑√ 16.7 <sub>0</sub>	1.1	
Typhlodromus pyri	FXA+PCYZ EC©00	LR <sub>50</sub> 4537.8 ml pro	duct∕ha	
M-437028-01-1	Extended lab, exposure on	ER50 3000 mL proc	tooct∕ha	
Rep. no: CW12/009	detached maize leaves	Cord Mortality [%]	-	duction [%]
, 2012b KCP 10.3.2.2	375 ml product tra	-3.65	10.9	
KCP 10.3.2.2	750 mL product/ha	\$ 60 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	14.2	
	1500 mL product/har	©2.4 <sup>B</sup>	29.6	
	3000 mL product/ha	28.9	34.6	
		72%	n.a.	
Coccinella septempuncata	FXA+PTZ ECO200 &	4R <sub>50</sub> 47 4.4 mL proc		1
M-440859-01-1	Extended lab., exposure on	no effect on reproduc		
Rep. no: CW12/029	detached maize leaves	Coor. Mortality [%]		•
, 2012c	Ontrol 375 ml product/ha	-	10.7	96.2
KCP 10.3.2.2	3/5 mt product/na Q	-6.3	8.5	91.7
	750 mL product/ha	-3.1 -12.5	8.0 9.1	87.7 89.6
	1000 mL productha 3000 mL productha	3.1	19.5	89.0 87.1
	6750 mL product/ha	84.4	19.3 n.a.	67.1 n.a.
Chrysoperla carnea	FXQ+PTZ EČ 200	LR <sub>50</sub> 703.4 mL prod		11.a.
M-437029-01-1	Extended ab., exposure on	no effect on reproduc		roduct/ba
Rep. no: CW12.010	detached maize, leaves	Corr. Mortality [%]		
20124 V	Costrol ©	Con. Mortanty [70]	24.8	87.3
KCP 10.3.20	375 mL product/ha	7.9	33.7	86.5
	30 mL product/ha	60.5	33.8	85.3
	500 mL product/ha	92.1	n.a.	n.a.
	3000 mL product/ha	97.4	n.a.	n.a.
M-437029-01-1 Rep. no: CW12/010  , 2012  KCP 10.3.22	6750 mL product/ha	100.0	n.a.	n.a.
	p	1		

Test species,	Tested Formulation,	Ecotoxicological Endpoint
Dossier-File-No.,	Study Type, Duration,	
Reference	Exposure	
Chrysoperla carnea	FXA + PTZ EC 200	
M-449297-01-1	Aged residues, spray	
Rep.Nr: CW12/045	deposits on maize plants,	
, 2013	2 appl. of 1.5 L prod/ha,	
KCP 10.3.2.2	14 d spray interval	Eggs/ Sy Sy
	Residues aged for 0 d:	Cort. Mortality [%] Female/Day Hatching [%]
	Control	- Q n.av y n.av
	2 x 1.5 L prod./ha	f 64.9
	Residues aged for 14 d:	
	Control	\$24.10 \( \text{81.30} \)
	2 x 1.5 L prod./ha	0. 0.2 7 0 26 785 7 785
	Residues aged for 28 d:	The state of the s
	Control	1 0 -0 0 0 4.0 5 5.8 ° 1
	2 x 1.5 L prod./ha	7.7 4 2 24.7 2 79.40
	Residues aged for 42 dr.	
	Control	7 - 9 2 B.a. 9 D.a.
	2 x 15 L prod/ha . \$	-8.6 <sup>8</sup> \$ \$ n.a. \$ n.a.
A. A negative value indicat	tes a higher reproduction rate in the	treatment than in the control

A: A negative value indicates a higher reproduction rate in the treatment than in the control.

The tier 2 extended laboratory data indicate whigher sensitivity of C, carned C  $R_{50} = 703.4$  mL product/ha) whereas the twicity to A. Thoratesiphi T. pyre and C septempure at A was significantly lower. Therefore, an aged residue study was conducted with the species C. carned for the refinement of the in-field risk assessment.

## Tier 2 risk assessment

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

## Potential exposure

The exposure scepario is based on the intended uses in cereals with an application rate of 2 x 1500 mL prod./ha, at a minimum interval of 4 days, and or onigos with an application rate of 2 x 1250 mL prod./ha, at a minimum interval of 10 days.

According to ESCORT and the Terrestrial anidance Document the exposure is calculated as:

In-field. Application rate \*MAF

Off-field: Application rate \*MAF\_ (drift Factor / VDF) \*correction factor

Application rates: 2 x 1500 ml/ha (cereals) 2 x 1250 mL/ha (onions)

<u>Drift factor</u> = 2.38% (Tield grops, 1 m distance, 2 applications, 82<sup>nd</sup> percentile; ESCORT2)

MAF (multiple application factor) = \$\infty 7\$ for cereals and onions (default value for 2 applications; ESCORT)

<u>VDF</u> (regetation 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)

B: A negative value indicates a lower mortality on the treatment than in the control.

n.a.: Not assessed

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

Crop / no. of applications	Appl. rate [mL/ha]	MAF	in-field PEC <sub>max</sub> . [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 / no. of applications		in-field PEC <sub>max</sub> . [mL/ha]			
	Cereals /	2		1500	1.7	2550	
	Onions /	2		1250	1.7	2125	
				osure for off-fiel		Č.	
Crop	Appl.	MAF		Veg. distr.	Correctio		Remark &
	rate		[%]	factor	factor	I La Bomax.	
	[mL/ha]				1	[mL/ha]	
Cereals	1500	1.7	2.38	=	<b>7</b> 5	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	in case of 3-D study
							design
Cereals	1500	1.7	2.38	10		30,34	in case of 2-D study
							design, °
Onions	1250	1.7	2.38	- , 🗬	, O' -5 <sup>0</sup>	253	in case of D study
							U design S
	1050	1.7	2 20	an N	(1)	V 10" 250"	V. CO 100
Onions	1250	1.7	2.38		/ / 3 %		in case of 2-D study

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	<b>Test Species</b>	in-field FECmax, [mL/ha]	LR&, ER50	Trigger	Refinement required?
	*	mL/ha] Q			
	A. rhopalosiphi	√ <sup>3</sup> 255,0€2	©> 67 <b>5</b> 0°	Effects are < 50%	no no
Camaala	T. pyri	© 2550 @		Effects are < 50%	√y no
Cereals	C. septempunctata	<b>25</b> )50 , <b>3</b>	>3000	Effects are \( \frac{50\%}{}	no no
	C. carnea	2550	703°4	Effects are 50%	yes
	A. rhopalosiph	2125	) > 67 <b>5</b> 0	Effects are < 50%	no
Onions	T. pyrt	لال <u>2</u> 125 م	≥ <b>39</b> 00 ≤	Effect©are \\$9%	no
Onions	C. Geptempunctata,	<b>₹125</b>	<b>∂</b> 3000 <i>°</i> 0″	Effects are \$50%	no
	Ç <sup>i</sup> carnea 💍	2125	703,4	Effects are < 50%	yes

The tier 2 in-field risk assessment for 2. rhopdosiphi, T. pyri, and C. septempunctata indicates an acceptable risk for non-target anthropods 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 inafield risk assessment

The results of the tier 2 risk assessment indicate that initial effects on non-target arthropod species with sensitivity similar to Chrysoperla 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 *Chrysopetja cartiea* (1997); 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 <sub>max</sub> [mL/ha]		LR50; ER50 [mL/ha]	Trigger	Refinement require
	A. rhopalosiphi	303*	> 6750	Effects are < 50%	no s
C 1	T. pyri	30.3	>3000	Effects are < 50%	no O
Cereals	C. septempunctata	30.3	>3000	Effects are < 50%	no N
	C. carnea	30.3	703.4 #	Effects are < 50%	Ġo "Š
	A. rhopalosiphi	253*	> 6750 🛴	Effects are 50%	no S
Onions	T. pyri	25.3	>3000	Effects are 50%	
	C. septempunctata	25.3	>3000	Effects are < 50%	
	C. carnea	25.3	<b>₹</b> 03.4	Effects are <50%	no d

<sup>\*</sup> Off-field PEC for 3D-Study design. Potted barley seedlings

For T. pyri, A. rhopalosiphi, C. septempunctata and C. Carnea Ro effects > 50% neither of 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 10.3.201). 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.

## Standard laboratory testing for non-target arthropod **CP 10.3.2.1**

Since extended laboratory studies are available for front get arthropod species no tier 1 laboratory studies were conducted.

### residue studies with non-target Extended laboratory **CP 10.3.2.2** Carthropods.

2012; M-438699-01-1 Report:

Toxico to the parasitoid was Aphidius rhopalosiphi (DESTEPHANI-PEREZ) Title:

(Hymenoptera: Braconidae) vising an extended laboratory test on barley -

fluoxastratin + prothiocopazole & 200 (100 + 100 g/L)

Report No.:

Document No.: Л-4**38**899-01СЛ

Guideline(s):

To irective 91/414/EEC Regulation (EC) No. 1107/2009, ET & (2000), ET A ET AL. (2009),

ET &L. (20@/),

Guideline deviation(s)

GLP/GEP:

## Material and methods:

The emulation Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch ID: 2012-00107 [analysed content of active ingredients: Fluoxastrobin 101.3 g/L, Prohioconazole 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 was 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 of the separate observations were made at 30 - minute intervals starting 15,030 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 Righes test item rate of 6750 mL product/ha.

From the water control and all application sates, 15 impartially hosen females per treatment were each transferred to a cylinder containing untreated barley@seedlings infested with Rhabalosi@hum padi for a period of 24 h. The number of muminies was assessed 12 days later. ©

The climatic test conditions during the study were 49.0 - 22.0 °C temperature and 69\$ 90% Pelative humidity. The light / dark cycle was 16.8 h with a light intensity range of 438 — 189 Cux in the mortality phase, 836 - 2540 Lux of the parasitation phase and 5290 19050 Lux of the reproduction 4 May 29, 20120 phase of the study.

Dates of experimental work:

## **Findings:**

Validity criteria:

		T Q7-1:120	// E'- 1'
		y v and vy criteria	Finding
Mortality in water control	<u> </u>	<u> </u>	0 %
Corrected mortality reference the	m V 📡 a	$\mathbb{C}^2 \geq 50\%$	93.3 %
Mean reproduction per female in	wager control	<u> </u>	23.5
Number of wasps in the water co	itrol producing		0
The results of this study can be	e considered as well	id. O	
Biological findings: D		$\mathbb{O}_{\chi}$ $\mathbb{O}_{\chi}$	
Mortality reproduction and re-	neDency imeach &	the toatments are summa	rized below:
Mortality in water control  Corrected mortality reference the Mean reproduction per female in Number of wasps in the water concern values for reproduction.  The results of this study can be Biological findings:  Mortality, reproduction and reconstruction and reconstruction.			



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

Test i	tem:	Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)						
			1100	Austroom · 1		`	Troo g/L)	
Test org					Aphidius rh		Ž	
Exposu	re on:	Barley seedlings						
		Morta	lity after 4	18 h [%]	Rep	roduction	Repellenc	cy (first 3 h)
Treatment	mL prod ./ha	Uncorr.	Corr.	P- Value(*)	Rate Wummies per female)	Red Sel. to Control [%] P-Value(#)	%Wasps on plant	Red. rel to Control [%] & PValue##)
Control	0	0.0		(V)	©23.5		¥8.2	y *\times
Test item	375	0.0	0.0	1.000 0	2102	9.8	54.8	©-13.8
			Ű.			0.938 M.Sign.		noign.
Test item	750	0.0	0.00	J.:000 🤝	293	12.39	49.	<b>\$</b> -2.4
				n.sign.		0.813n.sign		0.749 n.sign.
Test item	1500	10.0 %	10.0	₹356 <sub>€</sub>	26.5	L -12,8 0	52.7	-9.3
			o <sup>v</sup>	Sn.sign		0.42\( \text{n.sign} \)	Ž	0.368 n.sign.
Test item	3000	\$13.3 ®	13/3	0.225	15,9	0 324	¥ 45.8	5.0
				n.sign.		0.095 n.sign.		0.577 n.sign.
Test item	<b>6</b> 930	016.7 <sub>0</sub>	16	& Ø.130 ×	252	1.1	18.8	60.9
٥,	Q (	%		n.sign		0.8 <b>27</b> n.sign.		< 0.001 sign.
Reference item	7.3	©93.3 ©93.3	93.3		n.ä.	n.a.	49.0	-1.7

LR50: > 6750 mL@roduct ha

ER50: > 6750 m product/hac

- \* Fisher's Exact test (one-speed), p-values are adjusted according to Bonferroni-Holm
- # Wilcoxoff test (one-sided), p-values are adjusted according to Bonferroni-Holm

## one-way ANOVA, Dunnett fest (one-sided)

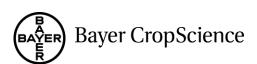
n.a. not assessed n.sign. not significant sign. significant

## 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 $_{00}^{\infty}$  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).



KCP 10.3.2.2/02 s; 2012; M-437028-01-1 Report:

Title: Toxicity to the predatory mite Typhlodromus pyri

laboratory test on maize - fluoxastrobin + prothioconazole EC 200 (100 + 100 gc)

Final report CW12/009

Report No.: Document No.: M-437028-01-1

Guideline(s): EU Directive 91/414/EEC, Regulation (EC) No. 1107/2009,

ET AL. (2000) modified

US EPA OCSPP Not Applicable

Use of natural substrate Guideline deviation(s):

(detached bean leaves) instead of glass plate

**GLP/GEP:** 

## Material and methods:

specified by sample description: TOX09674-00; specification on: 102000025822 OI; batch ID: 2012-001071 [analysed content of active ingredient. Fluorastrobyn 101. Pg/L Prothioconazole 100 g/L]; density: 1.1 g/mL.

The test item was applied onto detached maize Jeaves (Zea mors) at Cates of 375, 650, 1500, 3000 and 6750 mL product/ha and the effects of the predatory mite Typhlod omus 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 miles, protonymphs at Study start (5 replicates with 20 individuals per test group), was assessed 1, 4, 7, 10, 12 and 4 days after exposure by counting the number of living and dead mites. The number of escaped in test was calculated as the difference from the total number exposed.

The reproduction rate of surviving mites was the evaluated for the 4 dowest 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 our ing the study were 24.0 25.5 © temperature and 60 - 71% relative humidity. The light dark give was 16:84 with a light intensity range of 846 - 1415 Lux.

Dates of experimental work

## **Findings:**

Validity conteria:

	Validity criteria	Finding
Mortescrate in the control group of day 7	≤ 20 %	17 %
Average corrected mortality in the reference item	≥ 50 %	100 %
Average number of eggs female (calculated as sim of 4 assessment dates from day 7 or of in the control group	≥ 4	4.6

The results of this study can be considered as valid.

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 or	ganism:	Typhlodromus pyri					
Expos	ure on:	Detached maize leaves					
		Mo	rtality after 7	days [%]	2	Reproduction	
Treatment	mL product/h	Uncorr.	Corr.	PcValue(*)	Rate Eggs per female)	Red Sel. to Sontrol	Palue 49
Control	0	17.0	- C		<b>Q</b> .6		
Test item	375	14.0	-3.6🎉	1.0000 n.sign.	4.1	\$10.9 °×	0.338 n.sign.
Test item	750	22.0	6.0	0.713 Sign.	39	143	623 ft sign.
Test item	1500	15.0	2.4	1.000 n.sign	\$.2,0	29.6	0.1 <b>69</b> n.sign.
Test item	3000	41.0	2800	©0.001 sign.	3.0	34.6	Ol42 n.sign.
Test item	6750	77.0	72.3°	<0.001 sign.	n.a.	J. 16gr.	
Reference item	36.4	100.0	\$100.0\$		n.a.o	n.a.	

LR<sub>50</sub>: 4537.8 mL product/ha; 95% Confidence Interval; 35179-

## ER50: >3000 mL product/ha

- \* Fisher's Exact test (one-sided), p-values are adjusted according to Bonferroni-Holin # Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni Holin

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

## Conclusions:

The LR  $_{50}$  was calculated to be 4537.8 mL product ba. The LR  $_{5}$  was estimated to be >3000 mL product/hay The figure validity criteria of the Jaboratory method for exposure on glass plates.

**3**012; **№**440859-01-1 Report:

Title: Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera,

Coccinellinae) in an extended laboratory test on maize Fluoxastrobin +

Prothice nazole EC 200 (100 4 00 g/L)

Report No. W127029

Document No.: M-440859491-1

Guideline(s): ETAL. (2000) modified: Use of natural substrate (apple leaves) instead

> of glassplate; ET AL. (2001)

Guideline deviati

GLP/GEP

The emulsinable concentrate formulation Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L) was tested, specified by sample description: TOX 09674-00; specification no.: 102000025822-01; batch 1D: 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 morality of 40 larvae, 4 days old at study start (per test group), was assessed till the hatch of the imaging (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% collatives 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, 2042

## **Findings:**

## Validity criteria:

	<b>1</b>	Validity criteria	Finding V
Mortality in water control			20%
Corrected mortality reference item		<b>40 %</b>	/ <u>@</u>
Mean number of fertile eggs per female	eand day∕in ∘		\$ \$10.7.9
water control	Y "U"		

The results of this study can be

## **Biological findings**:

Mortality and reproduction in each of the treatments of

Table CP 10.3.2.2- 3 Effects of Fluorastroom + Prothiocorazole & C 200 on mortality and reproduction of Cocenella septempunctata

Tes	Test tiem Fluorastropin + Prothioconazolo EC 200 (100 + 100 g/L)					
Tes©o	rganism		Coccinella se	prempunctata	!	
Expos	sure on;		Detachedor	naize leaves		
			Mortality			
Treatment	[mL oproduct/ha]	Uncorrected margality	Sorrected mortality	P-Value (*)	Fertile eggs per female and day	Fertility (hatching rate)
4		~ [%] ~	[%]			[%]
Control		Z0.0 Z	-	-	10.7	96.2
Test item	7 375	15.0	-6.3	1.000 n. sign.	8.5	91.7
	750	<b>17.5</b>	-3.1	1.000 n. sign.	8.0	87.7
Test items	Ø 500 £	10.0	-12.5	1.000 n. sign.	9.1	89.6
Test Hem	3000	22.5	3.1	1.000 n. sign.	19.5	87.1

t item	Fluoxastrobin + Prothioconazole EC 200 (100 + 100 g/L)			/L) °	
rganism		Coccinella se	eptempunctata	!	
sure on:	Detached maize leaves				
			Ô	· ·	
		Mortality			
[mL product/ha]	Uncorrected mortality	Corrected wortality	Povalue (*)	Fertile eggs per female and day	Fertikty (hatching & Pate)
6750	87.5	84.87		$\bigcirc^{\nu}$	n.a.
24.3	100,00	100.0		χ1,α.	
	[mL product/ha]  6750  24.3	[mL product/ha] Uncorrected mortality  [%]  6750 87.5	marganism  Coccinella service on:  Detached resource on:  Mortality  [mL product/ha]  [%]  [%]  6750  87.5  84.8  24.3	rganism  Coccinella septempunctata  Bure on:  Detached maize leaves  Mortality  [mL product/ha]  [%]  [%]  [%]  [%]  6750  87.5  84.8  -0.00  sign.  24.3	Toccinella septempunctata  Detached maize leaves  Mortality  ImL product/ha  Uncorrected mortality  Image: Septempunctata product/ha  Image: S

LR<sub>50</sub>: 4774.4 mL product/ha; 95 % Confidence/Interval: 35% – 5606.1 (calculated with Parobit analysis)

## **Conclusions:**

The LR<sub>50</sub> was calculated to be \$1774.42mL product/bit.

Reproduction was not affected up to and including the test rate of 3000 mL product/ha. The figures obtained fulfil the additiverites of the aboratory method for exposure on glass plates.

**Report:** ,; 2012; M-437029-07-1

Title: Toxicity to the green lacewing Chrysoperla carnea using an extended

laboratory test on muze - fluoxastrobin + prothioconazole EC 200 (100 + 100 g/L)

Document No.: M-437029-01-1

Guideline(s): QEU Dipective QU/414/EEC, Regulation (EC) No. 1107/2009,

ET AL. (2000) magnified ET AL. (2001),

SPP Of Approable

Guideline Eviation(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 FOX 69674-00; 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 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 the 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.

<sup>\*</sup> Fisher's Exact test (one sided), p-values are adjusted according to bonferoni-Holm.a. not assessed; n. sign. not sign. cant; sign. sign. sign. sign.

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 1500 - 2996 Lux during the mortality phase and of 2560 - 2692 Lux during the reproduction phase of the study. of the study.

**Dates of experimental work:** March 28 – May 02, 201

## **Findings:**

## Validity criteria:

	Validity@riteria
Mortality in water control	\$\tag{20\%\tag{0\}}\$\tag{5.0\%}\$
Corrected mortality reference item	© 50 %0° 0° 44.7 %
Mean number of eggs per female and day in water	24.8° A
control	
Mean hatching rate of the eggs (fertility) water	\$\frac{1}{2}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\text{0.0}\tex
control	

The results of this study can be considered as

## Biological findings:

Mortality and reproduction in each of the treatments are summarized below

Table CP 10.3.2.2-4: Effects of Fluoxastrobin + Protinoconazole E 200 on mortality and reproduction of Chrysoperla carnea «

Test item: Fluoxastropin + Prothioconazole DC 200 (100 + 100 g/L)					
Test organisms Chrosoperl@carnea					
Exposure on:	De	Rached Maize lea	ives		
	Mortality [%]		Repro	duction	
Treatment mL product/ha Uniorr.  Control 0 5.0	Forr.	P-Value(*)	Eggs per female and day	Fertility [hatching rate in %]	
Control 0 5.0			24.8	87.3	
Test item 375 125	7.7.9	0.216 n.sign.	33.7	86.5	
Test item \$2.5	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 3,000 7.5	97.4	<0.001 sign.	n.a.	n.a.	
Test item 3000 75.5 C	100.0	<0.001 sign.	n.a.	n.a.	
Reference 38.9 95.0 item 95.0	94.7		n.a.	n.a.	

LRs 703.4 nL product/ha; 95 % Confidence Interval: 579.9 - 830.8 (calculated with Probit analysis)

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

<sup>\*</sup> Fisher` Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm

## **Conclusions:**

The LR<sub>50</sub> 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 plates.

Report: KCP 10.3.2.2/05 ,; 2013; M∰49297-01-1

Toxicity to the green lacewing Chrysoperla carnon using an extended laboratory ces Title:

with aged residues on maize - Floroxastrobin + prothioconazole CC 200 100 + 900

g/L)

CW12/045 Report No.: Document No.: M-449297-01-1

EU Directive 91/414/EEC; Regulation (EC) N Guideline(s):

**Applicable** 

During the reproduction phase of the second bioascay (14BAT2) and the mortality Guideline deviation(s):

phase of the third bioassay (28DA, 12), the relative humidity drecreased to 57% for 2.5 h. This had no negative impact on the outcome of the gudy as all validity criteria were

**GLP/GEP:** 

## **Materials and methods:**

The emusifiable concentrate Fluorastrobin + 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: Flanxastrobin 101.3 g/L, Prothoconazole 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 0.038 L product/b (16 g a.s./ha) diluted in 400 L deionised. water/ha on the day of the second application of the test teem 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 Lacionised 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 ratio 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 22DA 22).

Larvae of the green lacewing Chrysberla 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 feetundity of the surviving hatched adults were evaluated as well.

- October 02, 2012

Validitx criteria

			Fine	ding	
	Validity criteria		Start of	bioassay	
, S		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 %

		Finding			
	Validity criteria		Start of	bioassay	
		0DAT2*	14DAT2*	28DAT2*	42DAT2*%
Mean number of eggs per female and day in water control	≥ 15	n.a.	24.1	240°	n.a.
Mean hatching rate of the eggs (fertility) in water control	≥ 70 %	n.a.	81.3 %	75.8 %	IÇa.

<sup>\*</sup> 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 Fluosastrobin + Prothioconazole EC 200 (100 + 100 g/L) applied onto potted maize plants and Chrysoperla egrnea

	1		- <del> </del>	
Test item:	Fluoxastr	dbin + Prothioeona		+ 100 (L)
Application:	<b>Q</b> 2	2 x 1/5 L product/ha	(interval of 14 days	
Test organism:		Chrysoper	rla carnea 🖇 🚬	
Exposure on:	Dried spray	deposits on parize le	res (from treated)	maizeplants)
Start bioassay:	ODAT2	14DAT2ª	<b>28DAT</b> 2	7 42 <b>10 X</b> T2 <sup>a</sup>
		Preimaginal r	nortality®%) 🖇	
Control:	Ø 27.5 D	Z 7.5 Q	©2.5 L	© 12.5
Test item:	67.5 %	7.7	2 100 ×	5.0
Reference item:	\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	100,0	Ø0.0 <u></u>	100.0
		Orrected preimag	inal mortality (%)	)
Test item:	64,9	0.2		-8.6
	p-value p	(p-value O	(p-value	(p-value
Q) Q)	Q < 0.001.	0,650,	\$0.179, not	0.946, not
~Q~	significantb)	significant)	significant <sup>b</sup> )	significant <sup>b</sup> )
Reference tem:	64.9	1000.0	100.0	100.0
. L		Reprod		
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Eggs per fen	nale and day	1
Control:	n.a.Ç	ک <b>24.</b> 1	24.0	n.a.
Test item:	A Ca.	26.4	24.7	n.a.
		Fertily (hatchi	ing rate in %)	
Test item:	A na	81.3	75.8	n.a.
	n.a.	78.2	79.4	n.a.
W/		, hr: 1 / r	1 1	

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 wider 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. L product/havith on 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 applications and showed a corrected preimaginal mortality of only 0.2% in the test itom 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 mymores ... get arthropods
... and studies with non-target arthropods
... and studies with non-target arthropods
... and studies are not required for non-target arthropods
... and studies are not required for non-target arthropods
The exposure of soiledwelling non-target arthropods as assessed in chapter CP 10.3.2 is considered the main route of expedience for non-target arthropods. Reproduction was assessed in the second and third bioassay. In both bioassay 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 of glass plates

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

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

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 values were calculated and reported in MCP 9.1.3.

The relevant PEC values considered for TER capculations are summarised in the value Delow Maximum values are used for risk assessments.

Table CP 10.4- 1: Maximum PEC<sub>soil</sub> values

Compound

Cereals 2 × 150

Compound	Cereals, 2 150 g Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q
	Cereals, 2 %150 g Qnions O × 1250g Qnion
ها أ	mg/kg v v v v v v v v v v v v v v v v v v v
Fluoxastrobin + Prothioconazole E 00	0 880A 3 300B
Fluoxastrobin (E+Z) 🕡 💃	9.380° 0 0 0.386°
HEC 5725-E-des-chlorophenyl	0.019 V O 0.071
HEC 5725-carboxylic acid	0.01g ~ Q.041
2-chloropheno	0,009 000000000000000000000000000000000

Bold values: worst case considered in risk assessment

Id values: worst case considered in risk assessment 
Based on formulation density of 1.100 g/mL and 2 applications at 13 d interval (no pegradation between the 2 applications and my interception wors wase).

<sup>2</sup> applications and 80% intercepting worst (asse).

Based on formulation depixty of \$\text{P100 g/mL}\$ and 2 applications at 14 dinterval (no degradation between the 2 applications and 10% interception; worst case).

Including consideration of accumulation for fluoxastrobin after long term use considering a soil mixing depth of 20 cm Based on formulation density of 100 g/mL and 2 applications at 14 dinterval no degradation between the

### **CP 10.4.1 Earthworms**

Table CP 10.4.1-1: Endpoints used in risk assessment

Test substance	Test species	Endpoint	Ref@ence
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction	NOEC 562 mg prod. kg dws NOEC <sub>corr</sub> 281 <sup>A</sup> mg prod. kg dws	2010; M-402366- 010 KCP 10.4.1
Fluoxastrobin EC 100	Earthworm, reproduction	NOEC > 1000 g a.s./ha  NOEC ≥ 4.321 ng a.s./kg dw  NOEC ≥ 2.10 ng a.s./kg dws	2001; M-65/7395% 00-1
HEC 5725-E-des chlorophenyl	Earthworm, reproduction	ONOEC > 1000 mg/p.m./kg dws\	; 2 <b>6</b> 92; M* <b>0</b> 5853 <b>2</b> -91-1
HEC 5725- carboxylic acid	Earthworm, reproduction	NOEC 90 mg p.m. kg dws	; 2015; M-536000-01-1° K&A 8.40
2-chlorophenol	Earthworm, reproduction	NO 0.216 mg a 37 kg d 0	EFSA Scientific Report 102 (2007)

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

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

Endpoint corrected by a factor of 2 due to high organic matter content of est soil and log pow of 2

Be a 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 cm² and lost substrate of 500 g dws per test vessel.

Conversion is calculated based on the actually applied test rate of 1090 g a.s./ha, test vessel surface of 198 cm² and lost substrate of 500 g dws per test vessel.

Conversion is calculated based on the actually applied test rate of 1090 g a.s./ha, test vessel surface of 198 cm² and lost substrate of 500 g dws per test vessel.

Conversion is a conversion in the actual test vessel actually applied test rate of 1090 g a.s./ha, test vessel surface of 198 cm² and lost substrate of 500 g dws per test vessel.

102 (2007))

**Bold values:** endpoints

# Risk assessment for earthworms

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

The risk is considered acceptable if the TER is a solution of the TER i For lipophilic substances (log Pow > 2) and results from the laboratory studies are corrected by a fact 2 even when the organic matter is less than 10%.

This was applied to the wastrobin (logPow 2.86) before to Section 2 of the MCA document, CA 2.7). For lipophilic substances (log Par > 2) all results from the laboratory studies are corrected by a factor

Table CP 10.4.1-2: TER calculations for earthworms

Compound	Species	Endpoint [mg/kg]	PEC <sub>soil,max</sub> [mg/kg]	TER <sub>LT</sub>	Trigger
	C	ereals	Q	) <sup>y</sup>	
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction	NOEC 281	0.880	319	
Fluoxastrobin (E+Z) <sup>A</sup>	Earthworm, reproduction	NOEC 2.16	0080	$\geq 2 \widetilde{\mathcal{J}}^{\mathscr{V}}$	× 5
HEC 5725-E-des- chlorophenyl	Earthworm, reproduction	NOEC ≥ 1000	©0.019	2 632 S	
HEC 5725-carboxylic acid	Earthworm, reproduction	MOEC 90	<b>( ( 2 0 1</b> 1 <b>( 1</b>	8152	5 J
2-chlorophenol	Earthworm, reproduction	$NOEC^{\circ} \geq 0.316^{B}$	√ <sup>™</sup> 0.0 <b>0</b>	<b>⊘≥</b> 24 🔊	5
	O,C	Onions & &	7 70 1		4
Fluoxastrobin + Prothioconazole EC 200	Earthworm, reproduction		3.300	85	5 5 7
Fluoxastrobin (E+Z) <sup>A</sup>	Earthworm, reproduction	N@EC \$2.16	0.366	$\widetilde{\mathbb{Z}}^{i} \geq 7 \widetilde{\mathbb{Z}}^{i}$	$\mathbb{O}_{5}$
HEC 5725-E-des- chlorophenyl	Earthworn reproduction	NOEC > 1000	0.071	≥ <b>1</b> \$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	<i>§</i> 5
HEC 5725-carboxylic acid	Earthworm, reproduction	NODEC L 90	0.041	2195/	5
2-chlorophenol	Earthworm reproduction	$NOEC^{\circ} \ge 0.216^{\mathrm{B}}$	0.036	_ <b>©</b> ≥ 6	5

A conducted with the formation Fluoxastrobin 100 \$\infty\$

All TER values calculated with the worst case PEC soil wax values exceed the trigger value of 5 indicating that so unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

# CP 1041.1 Earthworms sub-lethal effects

## Terrestrial Risk Assessment

No study on the chronic toxicity of archlorophenot 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 00 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<sub>50</sub>. Assuming that 2 chlorophenol is formed and reaches its maximum between about 15 to 23 days (see Document MCA7, Point 7.12), the effects of this metabolite on mortality and weight of adult earthworms can be considered to be overed 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) is 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)).

be for the metabolite 2-chlorophonol, in the absence of corthworm reproduction data the conservative assumption has been made that the metabolite is 0 times more exic than the parent as (EFSA conclusion 102 (2007))



KCP 10.4.1.1/01 ; 2012; M-442366-01-1 Report:

Fluoxastrobin + prothioconazole EC 200A (100+100) G: Effects on survival, groven Title:

and reproduction on the earthworm Eisenia fetida tested in artificial soil

Report No.: kra-Rg-R-135/12 M-442366-01-1 Document No.:

OECD Guideline 222:, Earthworm Reproduction Test (Eisenia fetida / Eisenia andrei) Guideline(s):

earthworms (Eisenia fetida) – Part 2: Determination of effects on reproduction, Jul 1998.

not specified Guideline deviation(s):

**GLP/GEP:** ves

## **Objective:**

The purpose of this study was to assess the effect of Flyoxastrobin rothic conazole EC 200 on survival, growth and reproduction on the earthworm Eisenia fetila 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 11208-2: 1098 (E) and DECD 22: April 13, 2004).

## **Material and methods:**

Test item: Fluoxastrobin + Promioconazole FC 200 (100+100) ACG; Batch ID.: 2012-001071; Sample description: TOX09674-00; Material No \$0485\82; Specification No.: 102\000025822-01; Content: 101.3 g fluoxastrobin/L (921% w/w), 100.4 g prothioconazole/L (913% w/w); Derisity: 1.100 g/mL.

Adult Eisenia fetida (approx 5 montas old, x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) west exposed in an artificial sold (with 5 % peat content) to the nominal test concentrations of 100, 178, 316, 562 and 5000 mg test gem/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 (Carbendazing EC 360 G): 1.25 – 5.50 – 5.00 mg a.s./kg soil d.w.; control: untreated artificial soil moistered with deionised water, solvent control: ione.

Dates of experimental work: May 25, Findings:

Validity conteria:

Validity criteria	Recommended	Obtained
Mortality of the adults in the control of	≤ 10 %	0 %
Rate of reproduction of juveniles (carthworms 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. 7/12; 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<sub>50</sub> 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 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				a fetida <sub>v</sub>		
Test item	Control		FXA+PTZ	EC 200A (1	1 <b>00</b> +100) G	,
mg test item/kg dry weight artificial soil		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	178	316	502	\$\frac{1}{2}\text{000}
Mortality of adult earthworms [%] after 28 days						
Mean change of body weight of the adults from day 0 to day 28 [%] *	31.62	\$2.63 ×	2 <b>6</b> .60	Ž4.94Š	24592	\$20.61 *
Standard Deviation	₹.42 m	5.28	@.62 K	536	5.13	8.55
Mean number of offspring per test vessel after 56 days **	3525	348.5	322.	\$42.8°	$\sim$	262.5 **
Standard Deviation	<b>∂\$</b> 9.1 ,∢	§ 68 <sub>P</sub>	27.1	* 1 <b>808</b> *	<b>√</b> 47.1	19.7
Coefficient of variance (%)	16.8	<u>_1@/8</u>	8.4	<b>3</b> 45	15.3	7.5
% of control	?	<b>98</b> .9 \^	913	&97.3 ×	87.1	74.5

<sup>\*</sup> statistical significance compared to the control Williams Multiple Sequential t-test, two-sided,  $\alpha = 0.05$ 

## Mortality

After 28 days of exposure to 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 stimated to be 562 mg test tem/kg/dry weight artificial soil. The LOEC related to growth was 1000 mg test tem/kg/dry weight artificial soil.

## Effects of 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<sub>50</sub> 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.

<sup>\*\*</sup> statistical significance compared to the corneral (Williams Multiple Sequential t-154, one-sided smaller),  $\alpha = 0.05$ 

## **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 earthworks)

Table CP 10.4.2-1: Endpoints used in risk assessment

Test substance	Test species	Endpoint O	Reference
Fluoxastrobin + Prothioconazole EC	Folsomia candida	NOE 56 mg prod./kg 28 mg prod./kg (	1ws 019 01 KCP 10.4.20
200	Hypoaspis aculeifer	NOEC 16 mg prod.kg	M-441491-01-1 KCP 04.2.1
Fluoxastrobin	Folsomia candida	NOEC 10 mg 24/kg d	2001; M-081095- vs <sup>1)</sup> 01 P
	Hypoaspis acyleifer <sup>2</sup>	NOEC 11 ng a. kg d	2002; M- 039(55-01-1
HEC 5725-E-des-	Folsomed candida	7 NOTE 100.0g p.m. Rg	○ MI-033040-01-1
chlorophenyl	Hymaspis Oculeife	NOEÇ ≥ 100 mg p.m. de	; 2013; M-475673-01-1 KCA 8.4.2.1
HEG 5725	Folsomia andida V	NOEC > ≥ 100 mg pcm.//kg	
HEC 5725- carboxylic acid	Hypoaspis activeifer O	NOEC ≥ 100 mg p.m./kg	KCA 8.4.2.1 ; 2014; M-484792-01-1
	\$ 101 0 3 ¢		KCA 8.4.2.1
	Folsomia candida	NOEC 0 10 mg/p.m./kg of 5 mg/p.m./kg d	M-472327-01-1
2-chlorophenol	Hypoasp@aculeifer	NOEC 56 mg p.m./kg o	2012
Q		NOFC 28 mg p.m./kg d	WS <sup>1)</sup> KCA 8.4.2.1

dws = dry weight soil; a.g. = active substance; om. = pre metabolite

Bold values: endpoints used for risk assessment

2) Endpoint derived from EC 100 formulation

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

Ecotoxicological indpoints and PEC<sub>soil</sub> values used for TER calculations for soil non-target macroorganisms are summarised below. TER values were calculated using the equation:

TER NOTE / PEC soil

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

<sup>1)</sup> Corrected endpoint due to lipopolitic syntance (log P<sub>vv</sub> 2)

<sup>3)</sup> not corrected due to own organic matter content in test substrate LUFA 2.1

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

Compound	Species		point /kg]	PEC <sub>soil,max</sub> [mg/kg]	TERLT	Trigger
		Cer	eals	6	C.	
Fluoxastrobin +	Folsomia candida	NOEC	28	0.880	31.8	25/
Prothioconazole EC 200	Hypoaspis aculeifer	NOEC	≥ 158	0.880	≥ 179.5°	
Fluoxastrobin	Folsomia candida	NOEC	550	<b>9</b> 680	625	Ş <i>5</i>
(E+Z)	Hypoaspis aculeifer	NOEC	<b>√</b> 10	Q0.080	₹¥25.0 Q	
HEC 5725-E-des-	Folsomia candida	NOEC =	§ ≥ 100	Q" 0.019	&y ≥ 52, <b>6</b> 3	Ŭ 5 L
chlorophenyl	Hypoaspis aculeifer	NOEC	≥ 100	, 0 <b>.</b> 019	<sup>3</sup> ≥ √263 <sub>4</sub>	
HEC 5725-	Folsomia candida	NOEC	<b>\$</b> 100,\$	€0.01 kg	\$9091	<b>%</b> 5
carboxylic acid	Hypoaspis aculeifer	NOEC «	J ≥ 100	Ø 0. <b>%</b>	©≥ 90€¥	5 %°
2-chlorophenol	Folsomia candida	NOTEC S	~ \$ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	<b>A</b> .009 S	, 5 <u>56</u>	
2-cinorophenor	Hypoaspis aculeifer	NOEC	_@ <sup>2</sup> 28 _ &	0.009	\$ 111\$\times	25
	.0	Š ŠŽ ÓV	ons S			<u> </u>
Fluoxastrobin +	Folsomia candida	NOEC	28	© 300 ©	<b>8</b> 5 . 4	J 5
Prothioconazole EC 200	Hypoaspis ac@eifer	NOEC	\$≥ 158©	3.300	\$≥ 47. <b>Q</b>	5
Fluoxastrobin	Folsomia candida	NØEC &	50° &	<b>10,3</b> 06 &	16.3	5
(E+Z)	Hypoaspis aculeifer	Ø OEC	10	0.306	<b>₹</b> 32.7	5
HEC 5725-E-des-	Folsomia cándida 💍	NOE	$\sqrt[n]{2} \geq 100$	0.071	ỗ≥ 1408	5
chlorophenyl	Hypoaspis aculeifer	NOEC S	≥ <b>4</b> 000 °C	<b>6</b> 071 L	<sup>₩</sup> ≥ 1408	5
HEC 5725-		NOEC .	√2100 € √2100 €	£ 0.041	≥ 2439	5
carboxylic acid	Hypoaspis aculeifer	NOE® (	<sup>7</sup> >≥ 100°°	0.031	≥ 2439	5
2-chlorophenol	FotsomiaQandidQ"	NOEC &		<b>2</b> ,036	138.9	5
z-emorophenor	Hypoaspis acul@fer	NOEC	© 28 <sub>@,</sub>	0.036	777.8	5
ndicating that no	alculated with the wo	se effects on	soll/macro-oi	s clearly excerganisms are	ed the trigger to be expecte	value of 5 ed from the

### **CP 10.4.2.1 Species level testing**

KCP 10.4.2.1/01 ダ; 2012; M-439959-01-1 Report:

KCP 10.4.2.1/01 7; 2012; M-439959-01-1 Fluoxastrobin + prothioconazole EC 200 (100+100) G: Influence on the reproduction Title:

of the collembolan species Folsomia candida tested in artificial soil

Report No.: FRM-COLL-149/12 Document No.: M-439959-01-1

M-439959-01-1
OECD 232 adopted, September 07, 2009: OECD Godelines for Testing Guideline(s):

Guideline deviation(s): not specified

**GLP/GEP:** yes

## **Objective:**

The purpose of this study was to assess the effect of Puoxagrobin Prothoconagole EQ200 on survival and reproduction of the collemboling 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:

Fluoxastrobin # Prothiconazor EC 200 substance: FXA + PTZ EC 200 (100+100) G; Batch No.: 2012-001071; Castomer order No.: POX 09674-00; Master recipe ID: 0117103-001; Specification No.: 102000025822-01; active ingredients (analysed content): 0.21% www. (100-2-7) content): 9.21 % w/w (101.3 g/L) fluo@astropin (HEC 5725 E-ISO (BCS-AH45292)), 9.13 % w/w (100.4 g/L) prothioconazole (LAU 64% (BCS-AB\$0325)); Density: 1.100 g/ml 20°C).

Ten collembolans (10-12 days old) per replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), \$2, 56,000, 178 and 316 mg test item/kg artificial soil dry weight at 20 ± 2°C 400 –800 lux, 16h light: 817 dark. During the study, they were fed with granulated dry Oyeast. Mortality and reproduction were determined after 28 days.

25 mg Boric acid kg soil dry weight; control: quartz sand, Toxic standard: 44 solvent control: none

12 to October 09, 2012 Dates of experimental

## Findings: «

Validity criteria:

Validity criteria	Recommended by the guideline	Obtained in this study
Mean adult mortality	$Q \leq 20\%$	9.0 %
ioroduced &	∑	1184
Coefficient of variation coculated for the dumber of juveniles per period of the control of the	≤ 30%	11.9 %

In this study all valletity criteria have been fulfilled.

## Reference test:

In the most recent non-GLP-test (FRM-Coll-Ref-19/12, May 25, 2012) Boric Scid 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 are 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  $\leq 20$  % mortality. The LC<sub>10, 20, 50</sub> values could not be determined.

## Reproduction

Concerning the number of juveniles statistical analysis (William's Nest, one-side) smaller,  $\alpha = 0.05$ ) revealed a significant difference between control and the treatment groups with 100, \$78 and 316 mg test item/kg artificial soil dry weight.

Therefore the No-Observed-EffeQ-Concentration (NOEC) for reproduction is 66 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 100 mg test item/kg artificial soil bry weight. The EC<sub>10</sub> and EC<sub>20</sub> values determined by Probit analysis are 52.11 and 139.99 mg test item//s artificial soft dry weight, respectively. The &C<sub>50</sub> could not be calculated due to mathematical reasons.

Table CP 10.4.2.1- 1: Summary of the effects of Ebroxastrobin + Prothioconazofe EC 200 on Folsomia caudida

	(4)		a i		
Test item  Test object  Exposure	Fluoxá	strobin + P	rothio	conazole l	EC 200
Test object		Polson	ria car	ndida	
		Arti	ficial	foil	
mg test item/kg soil dry	Adult Cortality	Mean	numb	er of	D 1 //
weight	Adult mortality		ye Diles		Reproduction
nominal concentration		<b>≢</b> stand <b>a</b>			(% of control)
Control 3	Ø 10,0 Ø	1084.0€	±	140.4	-
32	15.0 × 0	1202.0	±	200.7	101.5 n.s.
56 W O	\$\tag{\P}0.0\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	1056®	±	126.9	89.2 n.s.
100	0 ~ 22.50 × 6	802.0	±	154.4	75.3 *
478	15.0	<b>43.8</b>	±	61.7	79.7 *
316	Q 20.0 S	√ 823.5	±	117.9	69.6 *
		Adult	morta	lity	Reproduction
LC <sub>10</sub> EC <sub>10</sub> (mg test item/kg so	MI dryweight) S	1	ı.d. <sup>2)</sup>		52.11 <sup>1)</sup>
LC <sub>20</sub> /EC <sub>20</sub> (mg test item/kg go	oil droweight)	1	1.d. <sup>2)</sup>		$139.99^{1)}$
LC <sub>50</sub> /EC <sub>50</sub> (mg test item/kg so	ongary weagan) Q	ı	1.d. <sup>2)</sup>		n.d. <sup>2)</sup>
NOEC reproduction mg test item/	ka soil dry weight)				56
LOEC reproduction (mg test item)	kg soik dry we@ht)				100

The calculations were performed with un-rounded values

SD = Standard deviation

<sup>1)</sup> Probit malysis 2) not determined due to maly rematical reasons

<sup>\* =</sup> 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<sub>reproduction</sub>: 56 mg test item/kg artificial soil dry weight. LOEC<sub>reproduction</sub>: 100 mg test item/kg artificial soil dry weight.

EC<sub>10</sub> (reproduction): 52.11 mg test item/kg artificial soil dry weight.

(95 % confidence limit could not be calculated due to mathematical reasons)

EC<sub>20</sub> (reproduction): 139.99 mg test item/kg artificial soil dry weight.

(95 % confidence limit could not be calculated due to mathematical reasons)

EC<sub>50</sub> (reproduction): could not be calculated due to mathematical reasons.

Report:

Title:

Report No.: Document No.:

Guideline(s):

Guideline deviation(s):

**GLP/GEP:** 

## **Objective:**

KCP 10.4.2.1/02

| C. 20,f2; Me41491-01-1
| Fluoxastrobin + prothioconazole EC 209 (100 = 100) C/2 influence on mortality and reproduction on the soil mite preciex trypoaspis acule fer tested in artificial soil kra-HR-81/12
| M-441491-01-1 | DECD 226 from October 03, 2008: OECD guideline for the Testing of Chredatory mite (Hypoaspis (Geolaelaps) acule ffer), reproduction tests applicable
| Vas to assess the in the soil | par The purpose of the study was to assess the effects of Duoxastrobin + Prothoconazole EC 200 on mortality and reproduction of 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 \$\frac{1}{2}6 (2008). OECD guideline 226 (2008).

## Material and methods:

Test substance: Francastrobin + Prothioconazole EC 200 (100+100) G; Short name: FXA + PTZ EC 200 (100+100) G; Batch No.: 2012-000071; Oustomer order No.: TOX09674-00; Material No.: 80485182; Specification No.: 102000025822-04, active ingredients (analysed content): 9.21 % w/w (101, 3g/L) fluoxa drobin (MEC, 5725 EQSO (BCS-AH45292)), 9.13 % w/w (100.4 g/L) prothioconazole (JAU 6476 (BCS-AP80325)), Denoity: 1400 g/mL.

Ten adult, fer lized, Temale Hypoaspis acaleifer 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 206 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 ofter start of egg laying). During the test, they were fed with cheese mites bred on brewer's yeast. During the study a temperature of  $20 \pm 2$  °C and light regime of 400 - 800Lux, 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, an driedand firely ground, 20 % Kaolin clay.

After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient sing 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 Hypoaspic 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	Dbtained in this stud
Mean adult female mortality	≤ 20%	2.5
Mean number of juveniles per replicate (with 10 adult females introduced)	≥ 50	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Coefficient of variation calculated for the number of juvenile mites per replicate		

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

## Reference test:

In the most recent non-GLP-test ( dimethoate showed a LC50 of 3.894 mg a.3./kg for mortality of the adult partes according Probit analysis using maximum likelihood regression. Confidence finits could not be determined due to mathematical reasons.

The reproduction of the soil miles 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 as /kg. Since variances of the data were even after ansformation not homogenous Welch-t test for Inhomogeneous Variances with Bonfertoni-Holm Adjustment procedure,  $\alpha = 0.05$ , one-sided smaller was used Dimethoate SC 400° G showed a EC<sub>50</sub> 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 result 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 25 % of the adult Hypoaspir acule if er died which is below the allowed maximum of  $\leq 20$  % mortality. The  $10^{\circ}C_{50}$  could not be calculated and is considered to be > 316 mg test item/kg dry weight artificial soil. dry weight artifical soil

## Reproduction

Concerning the number of juveroles startstical 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  $\geq 316$  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 EC50-values could not be calculated and is considered to be >316 mg test item/kg dry weight artificial coil. Lian Coil.

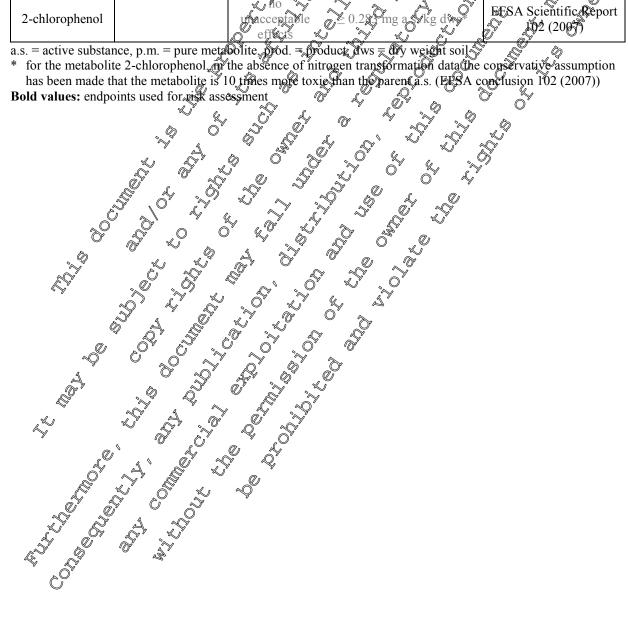
**Table CP 10.4.2.1-2:** Summary of the effects of Fluoxastrobin + Prothioconazole EC 200 on Hypoaspis 

Test item Test object Exposure			strobin + Prothioc <i>Hypoaspis acu</i> Artificial	l <b>èi</b> fer 🐠
mg test item/kg dry weight artificial soil	% mortality (adults)	Mean number of ju vesse ± standand d	veniles per test I eviation	Reproduction
Control	2.5	319.9 ± 😿	31.3	O - O 4
32	7.5	309.8 ±€	34.8	× 96.8 ×
56	5.0	310.8	<b>25</b> 2.7 ° °	97.1
100	12.5	304.3 0 ±	34.3	97.1
178	0.0	329.3 ± °	© 10,8% ©	1029
316	0.0	3528	27,4	110.1
mg test item/kg dry weight artificial soil  Control  32  56  100  178  316  NOEC (mg pure metabolite LOEC (mg pure metabolite no statistically significant difference  Conclusion:  NOEC: ≥ 316 mg test item LOEC: > 316 mg test item LOEC: > 316 mg test item  CP 10.4.2.2 Higher t No higher tier testing was	n/kg day weight n/kg dry weight performed or is	artificial soil.  artificial soil.  artificial soil.		Reproduction  2 345  2 316

### **CP 10.5** Effects on soil nitrogen transformation

Table CP 10.5-1: Endpoints used in risk assessment

Test substance	Test design		Endpoint	Reference	. "0"
Fluoxastrobin + Prothioconazole EC 200	Nitrogen transformation, 98 d	no unacceptable effects	≥ 22.00 mg prod./kg d (= 15 L prod./ha)		^ 
Fluoxastrobin		no unacceptable effects	\$2.83 mg a.s./\@dw	7S 1999; M2024686401-	.) -1
HEC 5725-E- des- chlorophenyl	Nitrogen transformation,	no unacceptable effects	Ø ≥ 2.73 mg Rm./kædw	VS Q 2000, M-026016-03	<b>1</b> €/21
HEC 5725- carboxylic acid	28 d	nog unacceoable ( effects	y ≥ 1,20 mg ym./kg ym	ys 2001; M-033474-01-	-1
2-chlorophenol		Tho y yacceptable effects &	0.289 mg a √kg d	EESA Scientific Repo	ort



## 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	Refinement required
	(	Cereals	<i>&gt;</i>	
Fluoxastrobin + Prothioconazole EC 200	Soil micro- organisms	≥ 22.00 mg prod./kg dy	0.880	No
Fluoxastrobin (E+Z)	Soil micro- organisms	2.83 mg a.s./kg/dws	. 0,080	
HEC 5725-E-des-chlorophenyl	Soil micro- organisms	≥ 2.73 mg p fax/kg d ws	0.019	NOS
HEC 5725-carboxylic acid	Soil micro- organisms	21.27 pg p.m. dg dws	0.011	Mo S
2-chlorophenol	Soil micro- organisms	/≥ 0.283 mg f.m./kg fws*	0.0 <b>0</b>	
	Ø 7 4(1)	Options & S	Ţ,	
Fluoxastrobin + Prothioconazole EC 200	Soil micro-	≥ 22.90 mg prod./kg dws	3.30	No No
Fluoxastrobin (E+Z)	Soil micro	√ ≥ 2.83 mg a.s kg dws	© 306	No
HEC 5725-E-des-chlorophenyl	Soil mero-	2.73 mg p.m./kg dws		No
HEC 5725-carboxy acid	Soul micro- Organisms	S ≥ 1.25 mg p.m./kg dws	0.041	No
2-chlorophenol	Soil micro	20.283 mg p.m æg dws	0.036	No

a.s. = active substanceOp.m. = pure metabolite, prod = prodoct, dws dry weight soil

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

For the metabolite 2 chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the userabolite 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<sub>soil</sub>.

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 microorganisms for the intended ses.

<sup>\*</sup> for the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the hetabolite is 10 times more to act than the parent a.s. (EFSA conclusion 102 (2007))



KCP 10.5/01 ; 2014; M-473548-01-1 Report:

Fluoxastrobin + prothioconazole EC 200 (100+100) G: Effects on the activity of sold Title:

microflora (nitrogen transformation test)

Report No.: 13 10 48 117 N Document No.: M-473548-01-1

OECD 216 (2000); adopted January 21, 2000, OECD Guidenne for the Testing Guideline(s):

Chemicals, Soil Microorganisms: Nitrogen Transformation

Guideline deviation(s): **GLP/GEP:** yes

## **Objective:**

The purpose of this study was to determine the effects of Flux astrobin + Prothioconazole EC 200 on the activity of soil microflora with regard to mtrogen transformation in a kaboratory test. The test was performed in accordance with OECD guideline 216 2000 by measuring the nittogen turnover

## Material and methods:

Test substance: Fluoxastrobin Prothroconazofe EC 200 (100+000) G; Short name: FXA + PTZ EC 200 (100+100) G; Batch ID: 2012-001071 Sample description TQX09674-00; Material No.: 80485182; Specification No.: 102000025822-01, active ingredients analysed content): 9.21 % w/w (101.3 g/L) fluoxa@robin\*(HEC \$725 FSO (BCS-A-45292)), 9 \$ % \( \sqrt{w} \) (100.4 g/L) prothioconazole (JAU 6476 (BCS-AB80325)); Density: 1.100 g/ML (200C).

A loamy sand soil (DIN 4220) was exposed to 98 days to 2.20 and 22.00 mg test item/kg soil dry weight. Application rates were equivalent to \$.5 and 15 Lifest item/ha. The nthrogen transformation was determined in soil enriched with lucerne mea Concentration in soil 0.5%). NH<sub>4</sub>-nitrogen, NO<sub>3</sub>and NO<sub>2</sub>-nitrogen were determined by a Automalyzer at different Sampling intervals (0, 7, 14, 28, 42, 56, 70, 84 and 88 days after treatment)

Dates of work September 100, 2013 to Dece

variation in the control (\$103-N) were maximum 8.7 % and thus fulfilled the The coefficients of demanded range 215

## Reference test

In a separate study the reference item Dinoterb caused a stimulation of nitrogen transformation of +33.7 % and +42.6 % at 1600 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, determined 28 days, after application.

## Biological findings:

The test item Fluoxastrobin Profisocona le EC 200 caused temporary stimulations and temporary inhibitions of the daily nitrate rate at 2,200 mg/kg and 22.00 mg/kg soil dry weight up to time interval 28-42 and \$4-98 days after application, respectively.

However no asverse effects of Fluoxastrobin + Prothioconazole EC 200 (100+100) G on nitrogen transformation in soft 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 drysoil, 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)	Co	nt	rol		2.20 mg test item/kg soil dry weight equivalent to 1.5 L test item/ha				/kg soil dry weight 5 5 Lest item/ha 4 % difference	Ţ		
	Nitr	ate	e-N <sup>1)</sup>	Nit	rate	-N <sup>1)</sup>	% difference to control	Nitı	rate-	$N^{1)}$	to constrol 🎺 🗸 🗸	)
0-7	3.72	±	0.57	3.75	±	0.24	+0.8 n.s.	4.39	±	<b>©</b> .20	+181 n.s. 249.9° Q 49.9° Q 49.	4
7-14	1.85	±	0.26	1.30	±	0.26	-30.1 n.s.	0.93	<b>*</b>	0.25	-49.9**Q 5	)` ,
14-28	0.83	±	0.03	1.08	±	0.04	+29.80	0.91	±	<b>\$</b>	Q +95 xs.	
28-42	0.87	±	0.17	0.94	±	0.06	47,4 n.s. &	1512	£	0.06	28.7 n.š	
42-56	0.37	±	0.29	-2)	±	_2)	_2)	0.23	D' ±	0.93	-376 dw.	
56-70	0.31	±	0.39	-2)	±	_2)		0.03	±\(\)	0.10	-37 6 W.W. 0 43.8 n.s.	
70-84	0.32	±	0.22	-2)	±	- <sup>2</sup> )	(L) -2) (L) (L) (L) (L) (L) (L) (L) (L) (L) (L	\$\frac{1}{2}\text{0.01}	y±	Q\$5	-103 Ois.	
84-98	0.88	±	0.41	-2)	±	Q <sup>3</sup> / <sub>2</sub> )		0.89	±(	0.16	0.8 n.s.	

The calculations were performed with unrounded values

- Rate: Nitrate-N in mg/kg soif day weight/time interval/day, mean of 3 replicate and standard deviation  $\bigcirc$  Since in this treatment group the deviation from the control was below 25 % on day 42 no further evaluations were performed. = No statistically significant difference to the control (Suddent-t-test for homogeneous variances, 2-side  $p \le 0.05$ ) 2)
- = No statistically significant difference to the control Welch-tyest for inhomogeneous variances, 2-sided,  $p \le 0.05$ ) = statistically significantly different to control (Stagent-t-type homogeneous variances, 2-sided  $p \le 0.05$ )

## **Conclusion:**

Fluoxastrobin + Prothioconazole EC 200 caused no adverse effects (difference to control < 25 %, OECD 216) of the soil nitrogen transformation (measured as NO<sub>3</sub>-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 the 98-day incubation period. The study was performed in a field soil at concentrations test item/kg dry soil, which are equivalent to application rates up to 45 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 "Suidance Documents of 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 argus.

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

Table CP 10.6-1: Endpoints used in risk assessment

Test organism	Study type, tested rate Man effects Post sensitive species References
Terrestrial non- target plants; 10 species	Seedling emergence Tier 1 single dose 1500 mL prod. All Solver reduction of the lianthys Shoot day weight annuals  All 39413-01-1
Terrestrial non- target plants; 10 species	Vegetative vigour, Tier 1 single dose, 1500 mL prod./ha  38.9% reduction of Suapis of a M442112-01-1

In the case of Fluoxastrolon + Prothioconazole C 200, neither the pier 1 seedling emergence study, nor the tier 1 vegetative vigour study showed phytotoxic effects ×30% at the tested rate of 1.5 L prod./ha, respectively.

In order to demonstrate the low risk of the formulation to derrestrial non-target plants, TER calculations have been performed for the representative uses in careals and onions. The test rates given in Table CP 1996-1 were used as most conservative endpoint estimates (i.e., ER<sub>50</sub> > 1.5 L prod./ha).

Table CP 16.6-2: Deterministic isk assessment based on the CR50 > 1500 mL prod./ha (vegetative vigour)

	<u> </u>	· · · · · · · · · · · · · · · · · · ·	<u> </u>		ı
Crop	Use pattern 🗸	Distance from	Drift	PER*	TER
	Use pattern  2 1500 mL prod./ha	Distance from Field edge	Dyrift [%]	[mL prod./ha]	(Trigger = 5)
				t r	( 88)
	-4 O 1 S		Q		
C 1	20x 1500 9mL prod./ha ⋅		2.38 <sup>1)</sup>	50 O 2)	> 20
Cereals	(14 d interval)		2.38 1)	50.0 <sup>2)</sup>	> 30
29					
Onions	2 × 1250 mL prod 25a		2.38 1)	44.6 <sup>3)</sup>	> 34
	(10 dinterval)		2.50	11.0	7 31
* Predicted en	vironmental rate value for two applications				
1) Basic drift	value for two and lications	in field crops			
2) 🕜 : - 1 :	MAD 1 4 C DECA	CDs D:1 - 6 N/ 1 - //	2000)		
Considering	g WIAF ~ 1.4 HOIII EFSA (	Olybiius & Iviaililliais (2	2009)		
Considering	$gMAF = M5^{\circ} from (CFSA)$	Birds Mammals (2	2009)		
لے		w w			
L.		<b>~</b> Q			
_Q <sup>v</sup>					
<b>1</b> .					
Ũ	MAF = 1.4 from Ers A (s) MAF = 1.5 from Ers A (s)				

<sup>\*</sup> Predicted environmental rate

<sup>1)</sup> Basic drift value for two applications in field crops

<sup>&</sup>lt;sup>2)</sup> Considering MAF = 1.4 from EFSA GlyBirds & Mammals (2009)

<sup>3)</sup> Considering MAF =

Table CP 10.6-3: Deterministic risk assessment based on the ER<sub>50</sub> > 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 <sup>2)4)</sup>	> 60
Onions	2 × 1250 mL prod./ha (10 d interval)	1	© 2.38 <sup>1)</sup>	22.3 3)4	\$ 67 F

<sup>\*</sup> Predicted environmental rate

From the calculations above, it is concluded that terrestrial plants in off-crop areas.

### **CP 10.6.1** Summary of screening

As full GLP studies are available (se

### Testing on non-target plants **CP 10.6.2**

Report:

FXA+PTZ-C 100-100A C: Effects on togrestrial (non target) plants - Seedling Title:

emergence and growth test

Report No .: Document No.?

OECD Gwideline 208: Terrestrial Plant Test: Sectling Emergence and Seedling Growth Fest adopted July 19, 2006 of applicable yes. Guideline(s)

Guideline deviation(s

GLP/GEP:

## **Objective:**

The effects of Fluoxastrosin + Prothigonazofe EC 290 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 C 200; Other name: FXA + PTZ EC 100 + 100A G; Sample description: TOX09674-00 Batch No.: 2012-001071; Specification No.: 102000025822-01; Analysed confent of active ingredients; 201.3 g/L fluoxastrobin, 100.4 g/L prothioconazole; Density (at 20°C): \$\tilde{1}00 \text{gmL}. \$\tilde{1}\text{C}\$

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

<sup>1)</sup> Basic drift value for two applications in field crops

<sup>&</sup>lt;sup>2)</sup> Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)

<sup>&</sup>lt;sup>3)</sup> Considering MAF = 1.5 from EFSA GD Birds & Manimals (2009)

<sup>4)</sup> Considering 50% interception by off-crop vegetation

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 woil immediately after sowing. The inhibition of plant emergence and early growth in relation the control plants was determined over a study period of 21 days, after 50% emergence in the control.

## **Findings:**

Table CP 10.6.2-1: Summary of effects on ten plant species after treatments Fluoxastrobin + Prothioconazole &C 200.

control plants was determined over a study period of 21 days, after 30% emergence in the control.										
The following rate was tested: 1500 mL product/ha.									ð	
Findings: The biological results are summarised in the following table:										
The biological results are summarised in the following table:								0		
Fluoxastrobin + Prothioconazole EC 200								,		
Emerged plants (%)  Ory weight (g)  Plant Surviva (%)										
Species	control	1500 mL prod./ha	Inhibition emergence reduction	Sontrol.	#500 mLx prod/ha	Inhibition =  wooght  reduction  (%)	control	15 <b>5</b> 44 47 47 47 47	Inhobition = survival reduction (%)	
Onion	88.0	100	n.ď	0.015	<b>®</b> .016 <u>~</u>	n P	100	1964	n.d.	
Oat	84.0	92.0		0.179	0.1480*	77.2	100	<b>©</b> 100	n.d.	
Wheat	96.0	100	1 n.d.	0.189	<b>6</b> 771	9.6	<b>100</b>	7 100	n.d.	
Corn	84.0	₹76.0 @	7 95	1.1174	0.611	Ø5.3 0	100	100	n.d.	
Sugar beet	80.0\$	88.0	And.	0,057	<b>,00</b> 89	n.d.C	<b>%</b> 1.1	90.0	1.2	
Cucumber	100	<b>3</b> 00	n.ď.	<b>6</b> 80 §		<b>18</b> .0 *	ى 100	100	n.d.	
Soybean	84.0	68.0	Ø9.0	0.607	0,684	n.d.	100	100	n.d.	
Sunflower	92.0	<b>200</b> 0	Ç n.dÇ	0.447	<b>Q</b> :230 <b>*</b>	7 48 ½5	100	100	n.d.	
Tomato	80.0	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Myd.	0.025	0.063	å n.d.	100	100	n.d.	
White mustard	88.00	840	\$\frac{4.5}{5}\frac{4.5}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}\frac{1}{5}	0.419	0.084 *	29.5	100	100	n.d.	

<sup>\*)</sup> There is significant difference between the control and treatment (t-test,  $\alpha = 0.05$ )

1500 mL product/ha of Fluox strobin + Promioconazole 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 Fluorestrobin Prothioconazole EC 200 at the treatment rate of 1500 mL product/ha aused/no adverse effects enemgence, survival and growth of emerged seedlings, shoot dry weight and with all phytotoxicity exceeding the 50% effect level.

n.d. = no inhibition was determined

KCP 10.6.2/02 B; 2012; M-442112-01-1 Report:

FXA+PTZ EC 100+100A G: Effects on terrestrial (non target) plants - Vegetative@ Title:

vigour

Report No.: 20120053 Document No.:

OECD Guideline 227 Terrestrial Plant Test: Vegetative Vigour Test, adopted July 19, 2006 not applicable Guideline(s):

Guideline deviation(s):

**GLP/GEP:** yes

## **Objective:**

Objective:

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

## Material and methods

Test item: Fluoxastrobin + Prothiocona Tole EC 200; Wither hame: XA Sample description: TOX09674-00; Patch No.: 2012-001071; Specification No.: 102000025822-01; Analysed content of active ingredients: 10 3 g/L fluoxastrobio, 100 g/L prothic onazofe, Density (at 20°C): 1.100 g/mL.

The plant species tested were corn (Zea mays), wheat (Trificum Gestivum var. Spelta) onion (Allium cepa) and oat (Avena sativa) as monocotyledonae, and sugar best (Beta vulgasis var. conditiva), white mustard (Sinapis alba), cacumber (Credumis Sativus), tomato (Salanum Aycopersicon), sunflower (Helianthus annuus) and soybean (Glycine max) as dicaryledonae. The study was conducted in compliance with of the OECD Guide me No. 227 (2006)

Plants of ten different species in growth tages 12 to 14 (BB@H) were treated with the test item at one application rate. The test item Fluoxastrobin+ Prothioconazole & 200 was dispersed in deionised water and applied to the plant surface by spray application. Fant 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

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

<b>Table CP 10.6.2-</b>	r treatment with				
	Dry weight (g)				Test item Inhibition 1500 (% reduction)
Species	Control	Test item 1500 mL/ha	Inhibition (% reduction)	Control	Test item 1500 Inhibition 1500 (% reduction)  100 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Corn**	1.086	1.098	-1.1	Ø100	
Wheat	0.353	0.390	-10.5	<sup>)</sup> 100	
Onion	0.028	0.022	19.2	<i>⊗</i> <sup>100</sup> .	
Oat	0.466	0.567	-2199	1000	
Sugar beet**	0.124	0.146	\$\frac{1}{8}.0\frac{1}{9}	100	
White mustard***	0.458	0.280	38.97	100	
Cucumber**	0.612	0.500	P8.4*	100 \$100	
Tomato**	0.435	0.391	\$\times 10.16^2		
Sunflower**	0.421	6513 (L)	ري 7.1 <b>ج</b> ي آ	100	
Soybean**	0.944	0.902 <sup>0</sup>		√100 √	

<sup>\*</sup> Significant difference between the control and test item treatment

The application of Fluorastrobin + Prothiocorazole EC 200 at a rate of \$500 mL/ha caused no adverse effects on the surviver 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 invistard and creumber planton the treated plants was statistically significantly reduced by 38.9% and 18.4%, respectively. At the end of the study period (Pe., 21 days after application), treated plants of wheat, onton, and oat did not how any playtotoxic 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. \$450% of leaf area

## Conclusion

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

# Extended laboratory studies on non-target plants

the Esults presented above under CP 10.6.2, extended laboratory studies are not deemed

## 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.

<sup>\*\*</sup> Symptoms of chlorosisms treated plants &

<sup>\*\*\*</sup> Symptoms of necros in treated plants

