



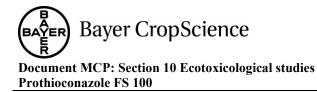
Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100

Bayer CropScience

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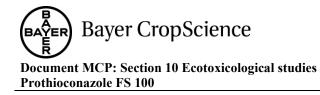
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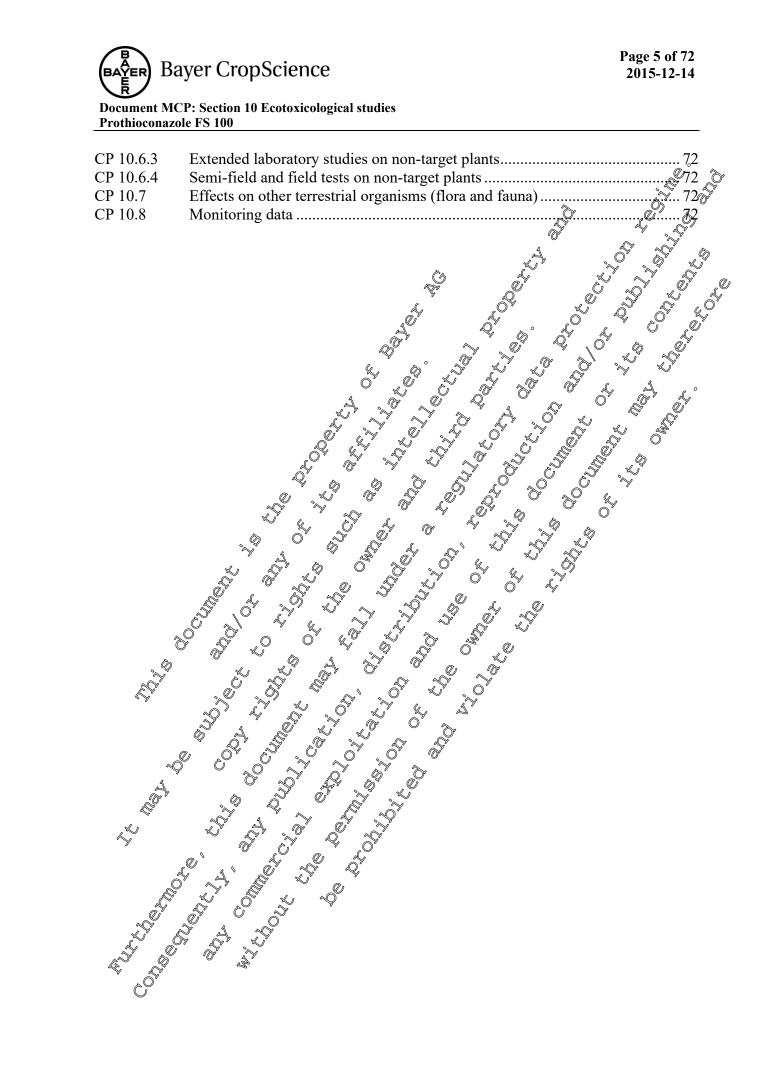
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# **Table of Contents**

	Table of Contents	0
		Ų ð
	Ĩ.	age
CP 10	ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION	Ô
	PRODUCT	<u>Ş.</u> 6
Use pattern c	onsidered in this risk assessment	7Ŋ
Definition of	the residue for risk assessment for prothioconazole.	
CP 10.1	Effects on birds and other terrestrial writebrates	<u>%</u> 8
CP 10.1.1	Effects on birds	
CP 10.1.1.1	Acute oral toxicity	. 20
CP 10.1.1.2	Higher tier data on birds	Ž0
CP 10.1.2	Effects on birds	. 28
CP 10.1.2.1	Acute oral toxicity to mammals	. 32
CP 10.1.2.2	Higher tier data on mammals	\$ <b>9</b> 2
CP 10.1.3	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)	. 32
CP 10.2	Effects on aquatic organisms	. 33
CP 10.2.1	Acute toxicity to fish, aquatic invertebrates, or effects on aquatical gae and	
	macrophytes	. 44
CP 10.2.2	Additional long-term and chronic toxicity studies on fish, aquatic invertebra	tes
	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians), Effects on aquatic organisms	. 50
CP 10.2.3	Further testing of aquatic organisms of	. 50
CP 10.3	Effects on arthropods	. 50
CP 10.3.1	Effects on bees	. 50
CP 10.3.1.1	Acute toxicity to bees	. 55
CP 10.3.1.1.1	Acore oral toxicoty to bees	. 55
CP 10.3.1.1.2	2 Acute contact toxicity to bees	. 57
CP 10.3.1.2 🎓	Chronic toxicity to bees	. 57
CP 10.3.1.3	Effects on honey bee development and other honey bee life stages	. 57
CP 10.3.14	Sub-lethal effects	. 57
CP 10 3, 1.5	Effects on honey bee development and other honey bee life stages Sub-lethal effects	. 57
CP 10.3.1.6	Field tests with honeybees	. 58
CP 10.3.2	Effects on non farget arthropods other than bees	. 58
CP 10.3.2.1	Standard laboratory testing for fon-target arthropods	. 59
CP 10.3.2.2	Extended aboratory testing, aged residue studies with non-target arthropods	59
CP 10.3.2\$	Semi-field studies with nongargetarthropods	. 59
CP 10.3 2.4	Semi-field studies with non-target arthropods Field studies with non-target arthropods	. 59
CP 10.3.2.5	Other routes of exposure for non-target arthropods	. 59
CP 10.4	Effects ap non-target Soil meso- and macrofauna	. 59
CP 10.4.1	Earthworms fQ.	. 60
CP 10.4.1.1	Earthworms sub-dethal effects	. 62
CP 10.4.1		. 62
CP 10.4.	Ffects on non target soil meso- and macrofauna (other than earthworms)	. 62
CP 10 2.1	Species lever testing	
CP 10.4.2.2	"Higher tier testing	. 69
CP\$10.5	Effects on soil nitrogen transformation	
CP 1060°	Effects on terrestrial non-target higher plants	
CP 10.6.1	Summary of screening data	
CP 10.6.2	Testing on non-target plants	



**BAYER** Bayer CropScience Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100

# CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

### Introduction

A dossier on prothioconazole (CAS No. 178928-70-6) was submitted February 2002 by Bayer CropScience to the EU RMS United Kingdom for agricultural use as a fungicide. Prothioconazole was included into Annex I of the Council Directive 91/414/EEC by the Commission Directive 2008 44/EC published 4 April 2008, with an entry into force by 1 August 2008.

This Supplemental Dossier contains only detailed summaries of studies, which were not part of the dossier during the first Annex I inclusion of prothic onazole and were, therefore, not evaluated during the first EU review of this compound. In order to facilitate discrimination between new and old information, the new information is written in black letters whereas go letters describe the old information.

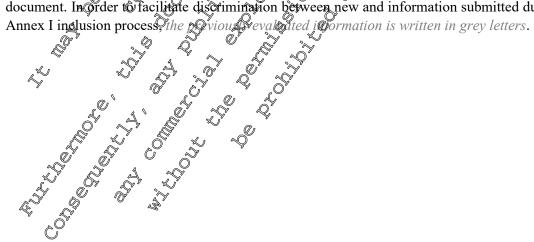
All studies, which have been already submitted by Bayer CropScience for the first Annex Finclusion, are contained in the Monograph and its Addenda and are included in the Baseline Dossier provided by Bayer CropScience. The summaries on the different endpoints were taken from the Monograph and its Addenda and supplemented with new information new studies, references, further comments).

A synonymous name for prothisconazole used at several locations on this Supplemental Dossier is JAU 6476.

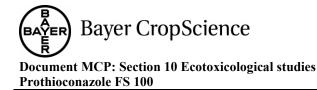
One of the representative formulations used for the submission for the repewal of approval of prothioconazole is the seed preatment formulation Prothioconazole FS 100. The summaries of those formulation studies which had not been presented in the dossier during the first Annex I inclusion of prothioconazole as well as the risk assessment are presented in the dossier.

Ecotoxicological enopoints used in the following risk assessment were derived from studies with the formulated product Proteioconszole FS 100, the active substance prothioconazole and the metabolites listed in the residue domition for risk assessment.

In this dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for prothioophazole 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 first Annex I inclusion process, the provious prevalitated information is written in grey letters.



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### Use pattern considered in this risk assessment

Table CP 10- 1:Intend	ed application pattern		
Сгор	Timing of application	Number of applications	Max application rate individual treatment [g a.s./ha] A Prothiocongrole*
Wheat (spring, winter), Barley (spring, winter), Oat, Spelt, Triticale	Seed treatment BBCH 00		

* Maximum label rate: 0.180 L prod./ha; seeding rate: 180 kg seeds/ha; 0.100 L product/100 kg seeds (i.e. 10 g a G/100 kg/seeds)

# Definition of the residue for risk assessment for prothioconazole

Due to changes in triggers for metabolites to be further assessed as well as due to new studies on the route of degradation in various environmental compartments, additional metabolites are proposed to be included in the residue definition for the risk assessment. Accordingly, studies have been prepared to describe the ecotoxicological profile of these metabolites in the relevant environmental compartment.

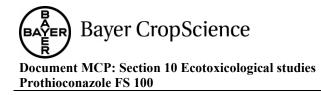
Т	able CP 10- 2:	Definition of the residue for risk assessment
	Compartment	Residue definition for risk assessment
	Soil	Prothiognazolo 2 2 JAU 6476-S-methyl (201) as 2 5 JAU 6476-Sthio 6(04)
	Groundwater	JAU 6476-S-methyl (M01) as JAU 6476-Asthio 6404) Prohioco@izole AU 6476-S-mothyl (A01) and JAU 076-destnio (M04)
	Surface water	JAU 6476-Asthio 6(04) Pretinioco@izole AU 6476-S-methyl (AQ1) and JAU 6476-destnio (M64) Presiloconazole, JAU 6476-S-methyl (M64), JAU 6476-destnio (M64), JAU 6476-destnio (M64), JAU 6476-thazocine (M12), JAU 6476-senethyle (M13) and JAU 6476-senethyle (M13) and JAU 6476-senethyle (M12) and JAU 6476-senethyle (M13) and JAU 6476-senethyle (
		JAU 6470S-methyl ( $M$ %4), JAU 6470-destaio ( $M$ %4), JAU 6476-destaio ( $M$ %4), JAU 6476-thazocine ( $M$ 12), 1.29-triazos ( $M$ 13) and JAU 6476*triazedy lketon ( $M$ 42) ,
	Sediment	1. 29-triazof (M13) and JAU 6476 triazetylketone (M42) Prothjoconazof, JAU 6476-Senethyl (M01) JAO 6476 testhic (M04) JAU 6476-thiazocine (AM2), JAU 6476 thiazocine (AM2),
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	JAU 6476-Senethy (M01) JAU 6476-Besthid (M04) JAU 6476-thiazocine (M2), JAU 6476-thiazocine (M2), JAU 6476-thiazol (M13) and JAU 6476-thiazol (M13) and JAU 6478-destfillo (M) Produce nazole and JAU 6478-destfillo (M) Produce nazole and JAU 6478-destfillo (M) Produce nazole and JAU 6478-destfillo (M) JAU
	Air	Prothioconazole and AU 6479-destflob (M)

*Justification for the residue definition for risk assessment is provided in MCA Sec.7, Point 7.4.1

Plant metabolites

In addition to the active obstance, its metabolite JAU 6476-desthio is assessed in the dietary exposure and risk assessment of terrestroal vertebrates (birds and mammals).

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



CP 10.1 Effects on birds and other terrestrial vertebrates

Endpoints used in risk assessment

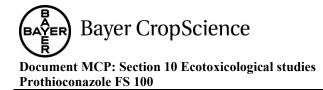
The risk assessment has been performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009) 7(12):1438), referred to in the following as "EFSA GD 2009".

Table CP 10.1.1-1:

Test substance	Test species	Ecotoxicologic	al endpoint	Reference
Prothioconazole	acute, oral <i>Colinus virginianus</i> (Bobwhite quail)			M-043030-0421 KCA78.1.1.1.701
	Reprod. 21 w dietary Anas platyrhynchos (Mallard duck)		Qug a.s./kg diet mg a.s./kg bvor	M-03523-01 KCA 8.1.1 \$02
JAU 6476- desthio	acute, oral Colinus virginian (Bobwhite quo)		Omg por./kg by	(1990) M-013305-01-1 KCA .1.1.1/02
	Reprod. 22 volietary Colinus vilginianus (Bobwhite qual)	NOE 7173 NOEL 14.8	ngp.m./kg diet (ng p.m./kg bw/d	(2002), Q-090509-01-1 KCA 8.1.1.3/03

		\sim α	
Type of Seeds, O	Generic/focal	species	FIR/bw
Large seeds (maize, deans of peas), O	Large granivot	ous bind,	0.1
'Small seeds'	Small granvor	ous bird	0.3
		Y XY O	

(1) n



Acute dietary risk assessment

Table CP 10	.1.1-3: Tier 1 acute	TER calculat	tion for bir	ds feeding on seed tro	eatment	
		LD50		Exposure	ð	
Compound	Indicator species	[mg/kg bw]	FIR/bw	NAR [mg a.s./kg seeds]	TERA	Yrigger
Prothio- conazole	Small granivorous bird	> 2000	0.3		> 67	
JAU 6476- desthio	Small granivorous bird	> 2000	0.3		×67 4	

 $^{1)}$ Assuming a thousand grain weight of the seeds of 50 g 1

²⁾ The Tier 1 TER calculation for the metabolite JAU 6476-desthio was conducted with the application rate of the parent compound prothioconazole – representing a worst case sefering approach

The TER values of relevant scenarios, e.g., birds feeding of treated seeds meet the required togger of 10 for acute exposure.

Risk assessment for birds drinking contaminated water

EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and manimals on the dietary route of exposure. An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed treatment is not required since this route seems unlikely to be a critical one or to lead to FER greater than direct dietary consumption.

Short-term dietary risk assessment?

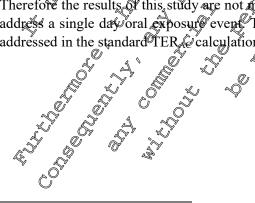
In the short-term dictory study with JAU 6476-desthic, mortalities occurred at the two top test levels after several days of reduced food consumption leading to sovere body weight loss. The seven chicks dying around day 5 at 5000 ppm had a mean bodyweight of 16.3 g/bird; Le less than 50% of the control bird weight of 35.2 g/at day 5. All birds found dead were extremely emaciated. Since no other severe clinical symptoms were observed it has to be assumed that they died on starvation.

During the post-exposure period the food consumption and body wight of the surviving birds started to recover.

The LC₅₀ was determined at 4000 mg/kg feed. Based on the measured concentrations the 5-d lethal dietary dose (5-d LDD) of 603 mg/kg bw/day was calculated by (2006; M-268832-02-1, KCA 8.1.1.2/04).

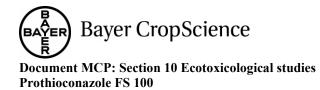
Effect profile and time course suggest that mortality secured only after multiple dosing over several days, and is associated with increasing weight loss and starvation over the treatment duration.

Therefore the results of this study are not meaningful in the acute risk assessment which is intended to address a single day oral exposure event. The effects after a single day of exposure are appropriately addressed in the standard TER calculation with the single exposure LD₅₀.



¹ Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

(M)



Long-term reproductive risk assessment

Table CP 10.1.1-	4: Tier 1 reproducti	ve risk asse	ssment for	birds feeding o	n seed tr	eatment	
		NOEL		Exposure	ð		
Compound	Indicator species	[mg/kg	EID /I	NAR	Q,	TERLT	
		bw/d]	FIR/bw	[mg a.s./kg seeds] ¹⁾ ്ష	Itwa)
Prothioconazole	Small granivorous bird	78	0.3	100	0.53	A.9 5 0	,©
JAU 6476- desthio	Small granivorous bird	14.8	<i>o</i> <i>s</i>		0.53		Ŝ

¹⁾ Assuming a thousand grain weight of the seeds of 50 g 2

²⁾ This value is taken from the parent compound and represents an uncealistic worst-pase scenario $\sqrt{3}$ Bold values do not meet the trigger

The TER values for birds feeding on treated seeds do not meet the trigger of for long-term exposure. Accordingly, a refined risk assessment is needed.

Refinement parameters for long-term risk assessment for small granivorous birds exposed to treated seeds

Refinement of focal bird species: skylark, chaffine and fellow bammer

PT and PD (, 2006; M-279616-01-1, KCP 10.(.1.2/14)

Measured time-weighted average concentration for a 21-day window and formation fraction of JAU 6476-desthio (**1997**) 2001; M-088988-01-1; KCP 49.1.1.2/02, **1997**) 2014a,b, M-486407-02-1, M-488935-01-3; KCP 10.1.1.2/18 & 19), resulting inva free of 0.085 for prothioconazole and an adjustment factor of 0.11 for JAV 6476 desthio after kinetic evaluation (**1997**) 2015a, b, c, M-535724-0.51, M-534804-01-1, M-534805-01-2, KCP 10.1.1.2/15, 16 & 17).

Focal bird species and measured surface densities of cereal seeds on freshly drilled cereal fields The relevant indicator species for the risk assessment is a 15 g granivorous bird, e.g. the linnet (*Carduelty cannabina*) Considering the linnet's feeding behaviour and habitat selection, it becomes obvious that linnets rely very much on small weed seeds throughout the year. To some extent, also crop seeds may be consumed during their milk ripe stages in summer or on stubble fields in autumn and winter. However, linnets are not considered to be the focal species for freshly drilled cereal fields, as cereal seeds tend to be slightly too big in size to fully match the linnets preference for smaller seeds (like weed seeds, see Cramp (1998)³ and Eybert & Constant (1998)⁴. Moreover, the feeding activity of linnets is reported to be low on freshly drilled fields in cases where the number of seeds remaining on the soil surface is not very high. According to a study of Moorcroft *et al.* (2002)⁵ linnets were rarely found on fields where densities of seeds in portant for their diets were lower than 250 seeds/m².

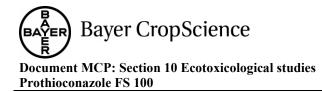
J D. (2002): The selection of stubble fields by wintering

granivorous birds reflects vegetation cover and food abundance. Journal of Applied Ecology 39, 535-547. M-107939-01-1.

² Faustzahlen für die Laudwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 199 edition, ISBN 3-7843-2194-1

³ (1998): The complete birds of the western palearctic. Oxford University Press, UK. Database on CD-ROM (Printon Can be provided on request).

⁴ (1998): Diet of nestling linnets (*Acanthis cannabina* L.); Journal of Ornithology 139, 277-286. M-266848-01-1.



This conclusion was confirmed by the avian observations of Crocker & Irving (1999)⁶. Based on their observations and observations made by **Example 1** (2006, M-279616-01-1, KCP 10.1.1.2/14) the **skylark** (*Alauda arvensis*), the **yellowhammer** (*Emberiza citrinella*) and the **chaffinch** (*Fingilla*) coelebs) are considered to be the relevant focal bird species for the refined risk assessment due to their abundance and frequency of occurrence in freshly drilled cereal fields in combination with their diefary demands.

Portion of time (PT) birds

To obtain quantifiable information about the potential foraging time of the focal bird species in freshly, drilled cereal fields, individuals of the three focal species (skylark vellowhammer and chaffinch) were captured, radio-tagged and their presence in the field was followed for 24 hours (**1999**, 2006; KCP 10.1.1.2/14).

Based upon the field observations made, worst-case PT values were determined to bolloo%035% and 22% (mean values) for skylark, yellowhammer and chaffinch respectively. It should be mentioned that for the long-term risk, the 90th-% tile would overestimate the exposure situation, which is also underlined by the limited availability of cereal-seeds for a maximum of approx. 2-3 weeks funtil seed emergence). Therefore, the use of mean PT-values measured in the field study could be considered in a further refinement if that should be necessary.

 Table CP 10.1.1- 5:
 Compilation of measured PT values of focal bird species (portion of time birds spent potential for sping in reshly drilled cereal fields), determined via radio-tracking (

 2006; KCP 10.1.1.2/140
 4

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c)

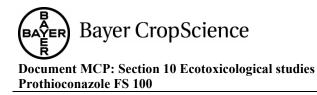
Portion of Diet (PD)

In the field study of (2008, M-2961601-1, KCP 10.1.1.2/14), ingested food items of focal species have been determined by the analysis of stomach contents and faeces. The results are shown in the following table.

In all tocal species (vellownammer, chattinch and skylark), food items from various sources have been identified, including cereal seeds. However, it must be taken into consideration that in and around the freshly drilled vereal fields under investigation, significant amounts of cereal and oil-seed rape (OSR) harvest remoants (comprising lots of un-freated seeds) were available from the previous crop.

These high levels of seed-remnants (from the previous crop), easily accessible for birds on the soil surface, mostly result from the minimum soil cultivation practices followed in the study region (i.e. the abdication of mechanical soil-turning operations like ploughing between the harvest of the preceding crop and the drilling of (new) cereals, in combination with only a limited harrowing, see also above). That these un-treated cereal-seed-remnants (from the previous crop) posed at least for the skylark an

⁶ Crocker, DR and Irving, PV (1999): Project PN0915, Improving estimates of wildlife exposure to pesticides in arable crops: milestone report 02/01, Variation of bird numbers on arable crops. M-290894-01-1.



important/easily exploitable food source, becomes obvious, when scrutinizing those skylarks in closer detail, which were captured on freshly drilled cereal fields and which were found to had cereal seeds in their gastro-intestinal tracts (GIT).

Table CP 10.1.1- 6:Content-list of the faeces and stomach flushes of scrutinged skylarks (n=10) and
identification of the previous crop (from raw-data),Content (2006, M) 279616 01-1,
(2006, M) 2006, M) 279616 01-1,
(2006, M) 279616 01-1,
(20

KC1 10,1,1,2/	(4)			Ĉa		L.			, °N	õ
Food item				T.	Samp	J €∕ĨD		Õ	~0~	
rood item	010	011	016	019	026	∛028	030	061	0 62 4	063 <u>/</u> 0
Animal matter			"©"		Š	0	ِ 0			
Acari	1		Ĩ				k Q	Ž		
Coleoptera		4	ð	l a	× *	<u>1</u>	× ~	\backslash .		
Diptera Tipulidae		s s s s s s s s s s s s s s s s s s s	Ô	1,2	l 🔊	Ś) ^r	¥ *	\mathcal{V}
Diptera		O`		Ö	à	A)	Ĩ	d,	A	0
Hymenoptera Formicidae		A	° .	©1	Ą,	a 🔍		0″	Ĩ	<u> </u>
Rhynchota Cicadellidae	×	1 ~	* ~	1 2	× £	\rightarrow . (D" «	1		Ç
Plant matter	<u> </u>	_ in		<u> </u>	<u> </u>	X	<u> </u>			C ^a
grass seed Poaceae	R	¢,	R.	$\sim Q^{1}$	2	<u> </u>	L.C.	Ũ	Å	
plant fibre	<u> </u>	<i>b</i> ″```	×			8	ž,	Ş	S.	
scale remains Brassicaceae	\$ <u>6</u>	Ô	Ó	ŝ	r _c c			۲ °	¥ 1	
Seed Poaceae [5mm]	, K'	Ø	- S	Ű	6	10	_ 1 \$	K		
Other seed		¢		4	_© [∞]	Ô	<u> </u>	Q		
unknown plant material		<u>ľ 1</u>		ð -		Ş 🔹		ĥ		
wheat grain [7mm]	<u>Ś</u>	<u>S</u>	k	1~~	1√3	Ş		ř 1	1	1
Previous crop on the site on which	ØSR	ŐSR	2 WW	Ŵ	WW	Peas	-WW	ww	WW	ww
the particular bird was captured	×1)		₩W.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0° W	Peas	NY W	** **	** **	** **
OSR = oil-seed rape, WW = Winter &	heat 🚕			r a	7	9	**			

Only those skylarks had cereals seeds in their GIT, which were contally captured on fields that carried winter wheat as the previous crop. Thus, especially the kylark as a bird species of the open landscape that avoids bush-and tree like structures at the field margins, can be expected to exploit the reservoir of un-incorporated and un treated cereal seed-remnants from the previous crop in the mid-field area. When calculating the portion of cereal seeds in the diet of skylarks for the refined risk assessment, the calculated PD-value can therefore be considered to be conservative estimate for this particular species. Moreover, unlike to yelfowhardmers and chaffinches, skylarks where never observed during the entire course of the study to feed on treated cereal seeds in the set of skylark set. (2006, M-279616-01-1, KCP 10.1.1.2/14).

To account for EU agreed input parameters the equations for the energy requirements as well as the values for energy and moisture content of the different feed items were calculated to comply with EFSA Guidance (2009). Appendix G, bull details of the mixed diets of each species are given in the following tables.

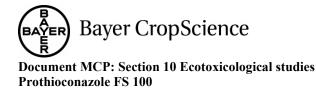


Table CP 10.1.1-7:Daily Consumption and Energy Expenditure for 37.2 g Skylark

Species: Body Weight (g): Proportion of diet based on			Passer	ine		£
	1		37.2	2	<u> </u>	
			Dry		ŷ, '	,Ø
				Wt (g) 🕅	Wt (g)	
	% in diet	kJ/g Dry	Assimilation	dry fogd	wet food	↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓
Food	DRY wt	weight	efficiency	constaned	consumed	∘_F¶ R/I
Dicot leaves	2	11.19	76	6 ,15	1.396	∀0.03
Grasses and cereal shoots		17.60	0.76			- AC
non-grass herbs		17.80	0.76	<u> </u>	Õ 🖓	
Browse		20.70	> 0.76			
Orchard topfruit		14.80	0.67 2 0.80			, ç
Cereal seeds	42	18,49	Ø 0.86°	_∾່ 3.2ສ	3.81	0.10
Weed seeds	23	2 P.70 🔬	080	} } } } 8	° 1.97	0.05ھ
Small mammals		¥1.66	~ Ø.76	A S		
Bird and mammal carrion		<u> 23,23</u>			0 [°] 8.18°	
Arthropods	33	<u>2</u> 2,70 ×	U 0.76	<u> </u>	0 8.1 8 7	Q.22
Caterpillars	L. C. Y	A.65	<u></u> 0.76			þ
Soil invertebrates	Q´	19.40	0.76	-0		
Fish		<u> </u>	076 076 0.76 0.76 0.76 0.76		Ş ^o ky	
Aquatic invertebrates		~2 <u>9</u> 0.90	<u> </u>		0 0	
Aquatic vegetation		<u>15.00</u>	©0.76 ×		0	
Sum 🏻 🔊	100		Å Ø	*0° 7.7 4 5*	15.32	
Daily Energy Expenditure	A24.080	kJ/@nimal			<u>p)</u>	
Bird and mammal carrion Arthropods Caterpillars Soil invertebrates Fish Aquatic invertebrates Aquatic vegetation Sum Sum Daily Energy Expenditure Control of the second						

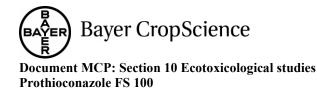
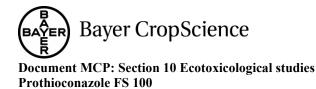


Table CP 10.1.1- 8:	Daily Consun	nption and Ener	gy Expenditure	for 26.5 g Yellowhammer
---------------------	--------------	-----------------	----------------	-------------------------

	•	and Energy	1	8			
Species:		Passerine					
Body Weight (g):		26.5					
Proportion of diet based on			Dry	,	ř	U D	
				Wt (g)	Wt (g)		
	% in diet	kJ/g Dry	Assimilation	dry food	· COV1	\$\$ ⁶ .0	
Food	DRY wt	weight	efficiency	consumed	consumed *	FIR/bw	
Dicot leaves	2	11.19	% 0.76	0.13	Q.11~	0.042	
Grasses and cereal shoots		17.60	ر 0.76	Ô¥		\$~ v ⁰	
non-grass herbs		17.80	0.76 🖉			Č, Č	
Browse		20.70	0.76			<u>Ó</u> Y	
Orchard topfruit		14.80	。0.670 [°]	N O		, Ç	
Cereal seeds	58	1-8:40	, 6 , 8 0 (3,66	4.29	0.162	
Weed seeds	12		9.80	Q .76	6 ?84 着	0.0 8 2°	
Small mammals	ŝ	21.70 × 21.70 × 21.66	× 0.76	A			
Bird and mammal carrion	Ô	23,23	2 ⁷ 0.46				
Arthropods		¢ 22.70	~0.76	Q.77	26/	0.214	
Caterpillars	4	© [×] 21.65× [×]	0.76				
Soil invertebrates	~~ 6	19640	0.76		Õ 'Y		
Fish		29.00	, 0.76 Q				
Aquatic invertebrates	\mathcal{S} .	\$\$20.9 0	0.76		0		
Aquatic vegetation 👸	Â	5 15.00	0.76				
Sum 🌱	A 100			632	11.91		
Daily Energy Expenditure	\$ 98.65 ²	kJ/anima			1		

sum <u>v 100 v sv v 632</u> Daily Energy Expenditure <u>v 98.65</u> k/anim<u>sv</u> <u>v 632</u> b <u>v 60 v 100 v 1</u>



Species:		Passerine				
Body Weight (g):		20.9				
Proportion of diet based on			Dry) A	ν, _φ
				Wt (g)	Wt (g)	
	% in diet	kJ/g Dry	Assimilation	dry food	wet fod	
Food	DRY wt	weight	efficiency	consumed		FIR/bw
Dicot leaves	3	11.19	% 0.76	Ø0.16	Q.37 ~	0.065
Grasses and cereal shoots		17.60	L 0.76	Č,		S 4
non-grass herbs		17.80 _	0.76 🔊	/ _ ^ _ A		e e
Browse		20.70	0.76			a, y
Orchard topfruit		14.80	_∘ 0.6.10°′	N. O		
Cereal seeds	32	18:40	, 6830 4	1,66	§ 1,95	0.093
Weed seeds	4	21.70 [√] √	Ø.80 LO	Ø.21	A .23 着	0.011
Small mammals	2	21.66	× 0.76	A		
Bird and mammal carrion		23,23	v 0.46 (A A A A A A A A A A A A A A A A A A A
Arthropods	61	& 22.70 ×	~@.76	\$17 £	10,15	0.486
Caterpillars		© 21.65	[∞] 0.76	<i>گر:</i> گرک		
Soil invertebrates		19040	0.76		Č N	
Fish		29.00 💮	0.76 Q			
Aquatic invertebrates	K ^Y G	\$20.90	0.76			
Aquatic vegetation		7 15 00	0.76			
Sum	<u>⊿</u> 100			5419	S 13.69	
Daily Energy Expenditure	\$ 84.03	k)/anim@			P	

Table CP 10.1.1-9: Daily Consumption and Energy Expenditure for 20.9 g Chaffinch

Time-weighted average (21-d frwa) and formation fraction

The dissipation of province and JAU 6476 desthior reaction 3 and the soil surface after drilling was determined in several studies (2001; M-088988-01-1, KCP 10.1.1.2/02, 2014a,b, MA86407-02-1, QI-488935-01-3, KGP 10.1.1 2/18 & 19).

DT₅₀ values and formation fractions of these Studies were re-evaluated using kinetic methods -01, M-594804-01-1, M-534805-01-1, KCP 10.1.1.2/15, & 5ấ⊁b. c M. (16 & 17).

Combined evaluation of both parent and metabolite allows to better address the metabolite kinetics (the metaboliters at the same time formed and degraded).

In this kinetic evaluation, the formation of AU 6476-desthio and its dissipation were investigated based on measured residue values from samples taken at different time intervals after sowing of prothioconazole treated cereal seres. All eleven trials provided acceptable fits for kinetics of prothioconazoe and eight of them provided acceptable fits for kinetics of JAU 6476-desthio.

Trial		PTZ DT ₅₀ (d)	PTZ f _{TWA} (21d)
EnSa-15-0606 LaacherHof early		1.47	⊘ 0.101
EnSa-15-0606 LaacherHof late		0.45	§ 0.031 § §
EnSa-15-0606 Hoefchen early		0.21	
EnSa-15-0607west		2.09	<u>0</u> .143 ×
EnSa-15-0607 south		T 2.13	<u>(0</u> .146, <u>,</u> <u>,</u>
EnSa-15-0607 north		£y 1.34 0 [♥]	
EnSa-15-0607 east	1	0.76 Q	0:052 C C
EnSa-15-0608 west	- Cor	2.30%	9.158 Q Q
EnSa-15-0608 south	K,	6)° ,2090 ,50	~ 0.198 ~ V
EnSa-15-0608 north	, °, _v	Č 1.72 Č	0 0 0 0 18 Å °
EnSa-15-0608 east		1.40 2	\$ 0.096 V
	geomean	Q 423 N	× × 0.085

 Table CP 10.1.1- 10:
 SFO-DT₅₀s and time-weighted average factor for prothioconazole (cereal seeds)

Based on these residue measurements of parent and metabolite in the same samples, both the maximum formation fraction "ff", and the SPO-D Φ_{s0} for dissipation of the metabolite were determined for each trial and the 21-d f_{TWA} was calculated for each SFO- Φ T₅₀.

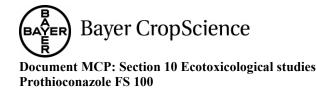
The resulting 21-d f_{TWA} for YAU 6476-desthio per trial was then multiplied with the corresponding formation fraction (ff) determined in the respective trial resulting in one "adjustment factor" per trial (see Table CP 10.1.1-1). This adjustment factor takes into account formation as well as dissipation of JAU 6476-desthio.

Table CP 10.1.1- DE: SFO-DE and time-weighted average factor for afjustment factor calculation for AU 6476-destrino (certral seeds)

	<u> </u>		
Trial	DT50 21-OFTWA	Ôff	adjustment factor: 21-d f _{TWA} × ff
EnSa-159606 LaacherHof earl	5.45 Q.333	0.359	_∞ O [♥] 0.119
EnSa-15-0606 Hoefchen early	¥2.1 0 0.582	@.032	۵.019 O.019
EnSa-15-0607west	2.62 0.1079	P.000	0.179
EnSa-15-0607 south	234 39.160	0.950	0.152
EnSa-15-060Qwest O	¥.81 × 0.314	0.540	0.170
EnSa-15-0608 south		9.660	0.096
EnSa-159608 north	3.68	0.540	0.134
EnSax15-0608 east 🏷 🙏	7.81 0.455	0.370	0.168
		eomean	0.110

In the refined exposure assessment for JAU 6476-desthio, the adjustment factor is multiplied with the amount of parent applied WAR nominal application rate).

A total of 11 data points for prothioconazole were extracted, resulting in overall geometric mean f_{TWA} values of 0.085 for prothioconazole. For JAU 6476-desthio, a total of 8 DT₅₀ values and 8 formation fraction for the swere obtained with an acceptable fit, resulting in a overall geometric mean adjustment factor of 0.11.



Refined long-term risk assessment

The refined long-term risk assessment for prothioconazole, and JAU 6476-desthio using the parameters described above is presented below.

Table CP 10.1.1-12: Refined long-term TER calculation for birds feeding on cereal seeds treated with prothioconazole

Species	Skylark	🖉 Yellowhammer	Chaffinch S
•	e e e e e e e e e e e e e e e e e e e		
Treatment	(14)	© Wereal seed to atment 0 mg prothiogonazole/kg so	
Body weight (g)	37.2	26.5	20.90
f_{TWA}	0.085	0.085	0.085
FIR related to bw for cereal	0.102		
seeds [g bw/d]	0.102		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
PT (90 th percentile)	1.0 ×	0°.35 ~	
DDD (mg a.s./kg bw /day)	<u>0</u> , 8, 67 , 0°	0.482	0,154
Lowest long-term NOEL			
(mg a.s. /kg bw /day)			
Long-term TER	<u> </u>	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	2 [°] 2 [°] 0 [°] 2 [°] 449
Long-term TER		<u>5</u> 762 5	

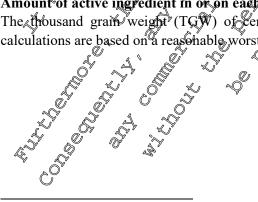
Table CP 10.1.1-13: Refined long-term TER calculation for AU 64%-desthio for Girds feeding on cereal seeds treated with JAU 6476-desthio

Species		Sky lark	Vellowhammer ~	🖉 Chaffinch
Treatment	× 1		Ceseal seed treatment (100 mg of parent/kg seed	<u>A</u>
~		K O 🚿	(100 mg of parent/kg seed	
Body weight (g)		ž 37.2 ž	26.5 [°] ₂	20.9
Adjustment factor	~ . K	y ~0.11 ~		0.11
Body weight (g) Adjustment factor FIR related to by for ce	rça 🏹	6 0.102 Å	× ~ ~ ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0.093
seeds [g bw/d]				0.093
PT (90 th perceptile)		0 ¥.0 Ø	0.35	0.22
DDD (mg æs./kg bw 7da	iy) 🧔	A 1.122	0.624	0.225
Lowest long-term NOL		E S	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
(mg p n) /kg bw /day) @			≪ ^y _0 ^{14.8}	
Long-term TER	~~~ L	/ <u>O</u> 13 x	لار <u>م</u> 24	347
			O' A	

Conclusion: The TER values meet the required trigger of 5 for long-term exposure. Hence, an acceptable risk can be concluded

Amount of active ingredient in or on each item

The thousand grain weight (TGW) of cereals ranges from 30 to 55 g⁷. Therefore, the following calculations are based on a reasonable worst case assumption of a TGW of 50 g.



⁷ Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

Table CP 10.1.1- 14: Calculation of the maximum amount of active substance on one dressed seed

Сгор	Max. dressing rate of the seed treatment product ^A [L/dt ^B seeds]	Content of active substances within the dressing product [g a.s./L product]		Maximum amount of a.s. on one individual dressed seed [µg a.s./seed]
		Prothioconazo	le	
Cereals	0.1	100	100	<u>, 5, 6, 4, 4</u>
A assuming a	thousand grain weight (TGW	/) of 50 g		

^B dt = deciton; 1 dt = 100 kg

Proportion of active ingredient LD50 per 100 items and per gram of items

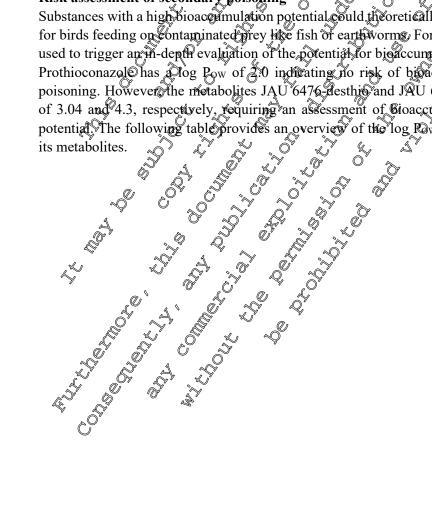
Calculation of the proportion of the LD5 for the a.s. in 100 particles / gram particles Table CP 10.1.1-15:

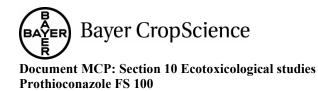
Сгор	Maximum amount of a.s. on one individual dressed seed ^A [µg a.s./seed]	substance on 100 soods and a substance on 33 soods = 4 g and a substance on 33 soods = 4 g and a soods = 4 g and a soods = 4 g a sood sood sood sood sood sood sood soo	int of bstance b ls/LD ₅₀
		Prothioconazole N O O N	
Cereals	5	2.5×10^{-4} 3×10^{-4} 3×10^{-4}	10-5
A Assuming	a thousand grain weight	PGW) 8450 g 0 4 6 0 0	
	» ي		

Risk assessment of secondary poisoning

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

Prothioconazole has along Pow of 2.0 indicating no risk of bioaccumulation and, hence, secondary poisoning. However the metabolites JAU 6476-desthip and JAU 6476-S-methyl have log Pow values of 3.04 and 4.3, respectively, requiring an assessment of Gioaccumulation and secondary poisoning potential The following table provides an overview of the log Row values of the active substance and





Compounds	Log Pow	Reference	
Prothioconazole	2.0	&, (2014) M-492539-01-1 KCA 2.7/02	
JAU 6476-desthio	3.04	M-010358-01-1 K 2.7/05	
JAU 6476-S-methyl	4.3	₩ 1997647-01-1 ₩ KCA 2.7/03	
1,2,4-Triazole	-0.71	KCA 2.7/03 6 (1933) Mo04557301-1 5 KCP k52.2/0k7 6	
JAU 6476-triazolylketone	0.33	& (2015)	
JAU 6476-thiazocine	4.9 Q9	KCA 2 %/06 0 4 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	

Table CP 10.1.1-16: Log Pow values of prothioconazole and metabolites

Long-term DDD and TER calculation for earthworm-eating birds Tier I long-term DDD and TER calculation for carthweirm-eating birds Table CP 10.1.1- 17:

Compound 😤	JAU 6476-desthio	JAI06476-Symethyl	& Origin of values				
BCE BCE aleviation							
P _{ow}	j ĵ ^y 3¥j096 ≪j ^y .		See Table CP 10.1.1-16				
K _{OC} [mL/gÛ	√ ∜575 🦕 🏠	L 2556.3	See MCA 7.1.3.1				
f _{oc} of a	0.0 0 🗐		Default				
BCFworm	1216	A7/00 - ·	S S				
	PER worm	calculation: 🔍 🔍)				
PEC 21 d-twa) ¹⁾ (mg/kg)		· · · · · · · · · · · · · · · · · · ·	See MCP 9.1.3				
PEC _{worm} [mg/kg]	6,913	© 0.014					
Q	🗇 🖉 👰DD 🤬	Culation:					
FIR/by	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>	<u></u> 0 [°] 1.09 [°]	Default				
DDD [mg/kg bw/d]	0.014	6 0015					
A		aculation:					
NO(A)EL [mg/kg bw/d]	🖗 Q, 14.8 🖉 🔊	7.8 ²⁾	See Table CP 10.1.1-1				
TER _{LT}	A 1957 04	520					
Trigger		5					
Refined risk assessment required?	No ^y No ^y	No					

¹⁾ Worst case of d TW soil value based on 1 x 1 g/ha prothioconazole, 0% interception ²⁾ NOEL of the parent compound profinoconazole was divided by a factor of 10 (worst-case assumption) All TER values are above the trigger of 5. Accordingly the risk to earthworm-eating birds from the use of the product on cereals is acceptable.

e P

Long-term DDD and TER calculation for fish-eating birds

Table CP 10.1.1-18: Tier 1 long-term DDD and TER calculation for fish-eating birds

	0		0	
Compound	JAU 6476-desthio	JAU 6476-S-methyl	Origin ovalues	
	PEC _{fish} c	alculation	ð	
BCF_{fish}	65	319.31)	See MCA 8.2	
PEC _{sw} (21d-twa) ²⁾ [mg/L]	0.000723	0.000082	See MCP 9.2.5	
PEC _{fish} [mg/kg]	0.047	0.026		9. 2 4
	DDD ca	lculation		
FIR/bw	0.159	A.0.159	° Default	
DDD [mg/kg bw/d]	0.007	0.004		in the second
	TER ca	lculation:		Y S
NO(A)EL [mg/kg bw/d]	14.8	0	See Gible CP 10.1.1-1	4
TER _{LT}	2 114	~~~ 1,950 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
Trigger	5			
Refined risk assessment required?	No			

¹⁾ New BCF value resulting from a statement from 2013 QI-459105-01-1, KCA & Q2.3/04

²⁾ Worst-case 21d-TWA_{sw} (winter cerears, 1×18 g a.s./ha, N-EG Single \mathcal{O} \mathcal{O}

All TER values are well above the required trigger accordingly, the risk to fish eating birds from the use of the product in coreals is considered acceptable.

CP 10.1.1.1 & Acute oral toxicity

Toxicity of the formulated product

For animal welfare reasons, no acute oral to write study with the preparation was performed. Such a study is not deemed necessary given the fact that the active substance is not acutely toxic to birds.

j

CP 10.1.1.2 Higher tief data on birds

The following studies are used for refining the ris Dasses ment for birds.

Report: A KCP 10, 1.2/14 ; 2006; M-279616-01-1

Title: General field monitoring of birds in freshly drilled winter cereal fields in Autumn in Germany BAR/FSA95

Report No.: BGR/FSQ35Document No.: M-279G6-01-1

Guideline(s): \mathcal{O} The test was designed especially for the purpose of this study. Guideline deviation(s), none \mathcal{O}

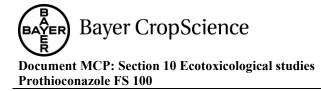
Material and methods:

GLP/GEP:

This generic study was performed to evaluate to which extent birds utilise freshly drilled treated cereal seeds as a cood source.

Test locality: The study has been conducted in the area of the agrarian co-operative located in the district of in the natural preserve region "

, which is



(federal state of Sachsen-Anhalt, Germany). This region is a typical area for cereal cultivation in Europe and known to hold an essential population of the three pre-selected focal species Skylarks (Alada 20 arvensis). Chaffinch (Fringilla coelobs) and Yellowhammer (Emberiza citrinella) are also common.

. 2005, Crocker & Irving 1999) theothree main focal species Methods: From the literature (were deduced: the Skylark, the Chaffinch and the Yellowhammer. In order to obtain a reliable in trate of for exposure of these species to treated seeds, the portion of time spent 'potentially foraging' on freshts drilled fields was acquired by radio tracking.

In total 13 Skylarks were trapped in winter cereal and adjacen habitats and tagger with radia transmitters; eight Skylarks were tracked for one (n = 5) or two (n = 3) daylight periods each. The respective number of trapped and radio tagged Chaffinches was 12. Totemetry sessions comprehended one (n = 6) or two (n = 1) daylight periods each. Eleven Yellow hammers were trapped and radio tagged. Eight individuals were tracked for one and the individuals for two daylight periods.

In order to assess the general relevance of winter coreal fields and other habitats as feeding locations for birds, 7 census counts each were carried out along five different transects, representing all main agrarian habitat types within the study area. These transects were walked once a week to coquire offull overview of bird life. °~ L)

Additionally on six defined subareas of freshly drilled winter cereal fields 2 winter barley, 4 winter wheat) - including a small adjagent 'outside-area' - a scan sompling procedure was conducted. Here all bird activities were observed from dawn till dusk. This procedure was conducted once before drilling and two times after drilling to quantify any changes of bird activities possibly caused by the availability of treated cereal seeds. For each session the portion of scaps a given species could be observed was calculated (frequency of occurrence FO).

In order to gain information aborc food tems selected by the focal species, 48 samples of faeces or stomach flushings were malysed quantitatively for their composition: taxonomic orders of plants, in particular components of winter cereals and arthropods or other identifiable items were recorded. Faeces and stomach forshing samples were taken buring the handling of individual birds after mist netting and as well if defecating was observed during the permetry session of tagged individuals.

To quantify the availability of winter cereal seeds to small and medium sized granivorous bird species, the initial exposure of the seeds was measured. Within 24 hours after the termination of drilling visible

the initial exposure of the speak was measured. Within 24 hours after the termination of drilling v seeds were counted on the six different study plots when there was no scan sampling conducted.

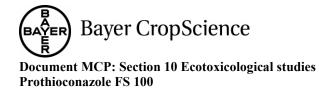
Findings:

PORTION OF TIME potentially for	oraging (PT) in cereal fie	lds by radi	in tracke	ed specie	
contrary of them potentially h			nuori		tracking
Potential foraging time ¹ radio	species	mean	[%]	90 th percentile	sessions
tracked birds spent in freshly	species	mean	[/0]	[%]	(individuals)
drilled winter cereal fields	Yellowhammer	هم 6.4	1	23.63	14 (1)
		16.9		<u>23.03</u> ک 95.73	
(wheat + barley)	Skylark	N/P	<u> </u>		
	Chaffinch	8.5	4_01	22.05	
HABITAT PREFERENCE of spec		icking	- <u>0</u> ,		· * 6 _0
Preference of winter cereals as a	species				
feeding habitat (D: Jacobs' Index,	Yellowhammer	a m		-0.79	
Range: -1 to +1; MCP [100%])	Skylark 🌾 🧞	- A	`	<u>~</u> 0.29 O*	NY W
	Chaffinch O [*]	L _e ,	<u>s</u>	-0.8	
DIET of species in cereal fields	<u> </u>	, OŠ – Á	Qĩ,		
	food items	Yellowh	ammel	Skylark	Chaffinch
		(n) = 8		n = 6.6	(n = 5 10)
	wheat seeds	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0 COV	c 🖉	80.00
	other cereal seeds	≪v" 4,	9 🔊	<u>z s s</u>	<u>_</u> Q -
Portion of samples [%]	Other seeds	, <u>1</u> Ŷ.	<u>50 </u>	50 8	\$\$ 53.33
containing each food item after @	other plant material 🖓	<i>3</i> 3.3	33	° 300 ₀	53.33
the analysis of faeces (19) and	Coleoptera	s 29.	Ŵ	a 10 C	53.33
samples of stomach flushing (29)	Diptera O A	25.	00 🔊	20	73.33
gathered in cereal fields 🔪 🖗	Hymenoptera .	8.3	3	~~ 10 K	13.33
(n: no. of faeces/flushings) 🕺 🔬	Dermaptera	<i>√</i> 4.1		K) _S	20.00
Č Š	Rhynchota	N 12	.		26.67
	Araneac S	12.		×-	26.67
	other animal material	<u>~</u> 4.1		<i>©</i> 10	20.00
	unidentified objects	≫ 16.0			20.00
BIRD ABUNDANCE on winter ce				n population) spe	
	N (//) (> 0		Ind./ha	
	species Skylart			1.321	
		~~~~	<u>-</u>		
Abundance of focal species and	Statening		0	1.266	
four other abundant species after	Chaffing y		/	1.260	
seven transect county covering	Linnet O	~~ <u>~</u> ,		0.319	
310.35 hectare 🖗 🖂	Yellowhamkoer	~~~		0.313	
	Wood pigeon	ď		0.213	
	Mistle Trush	<u>~</u>		0.113	
BIRD FREQUENCY OF OCCUR		in samplin	g		
	spe@es			[%]	
	Xellowhammer Q			5.83	
Frequency of occurrence 🖉 ,	Black Redstart			5.54	
(mean of the results for each	Chaffinch O			5.35	
session; $n = 12$ of focal species	Jay			3.56	
and five other prevalent species	Blackbird			2.92	
on six field	Brambing			2.90	
on six fields	Greenfinch			2.39	
	Skylark			0.16	

*^o* N.

# Conclusion:

Radio tracking Yellowhammers, Skylarks and Chaffinches in an agrarian landscape with a high number of freshly drilled winter cereal fields (wheat and barley) in the western part of Saxony-Anhalt showed that this field type was used as only a minor feeding habitat.



Eleven Yellowhammers (n = 14 sessions) were radio-tracked, of which three individuals did not use freshly drilled winter cereal fields as feeding habitat at all. Bird census and scan sampling data confirm that Yellowhammers evidently prefer non-crop habitats over freshly drilled winter cereal fields. However, when Yellowhammers visited freshly drilled cereal fields they could regularly be observed feeding on seeds. Additionally 75% of all diet samples contained wheat seeds. Whether these seeds were treated could not be ascertained in most instances. Four of 16 samples contained treated seeds deduced from the colour of the seed coating.

The radio tracking of 8 individual Skylarks (n = 11 sessions) showed that the majority of tagged Skylarks used plain fields and oilseed rape as feeding habitats. Only three individuals used treshly drilled sereat fields as a feeding habitat quite intensively. The results of the scaro sampling approach seem to support the minor significance of freshly drilled cereal fields for Skylarks. However, the scar plots were situated close to the field edge so that the actual number of Skylarks in the Whole Field was possibly underestimated. According to the transect counts Skylarks reached their taghest abundance on freshly drilled winter cereal fields (1.32 individuals per hectare). Additionally 55.6% of all die samples contained wheat seeds, which proves the usage of this food source by Skylarks. Fteshly drilled cereal fields offer a significant habitat for Skylarks, but individual Skylarks differ regarding their habitat choice and a variety of alternative habitats are also used extensively.

Radio tracking of 7 individual Chaffinches ( $n^2 = 8$  sessions) showed that freshly drilled winter cereal fields were used as a minor freeding habitat. Only four from these seven individuals were observed 'potentially foraging' in freshly drilled cereal fields. On average cereal fields were avoided (Jacobs' index [D]: -0.89). Bird census and scan sampling data confirm that Chaffinches evidently prefer noncrop habitats over freshly drilled winter cereal fields. However, direct observations demonstrate that Chaffinches feed on reated cereal seeds. Additionally 80% of all diet samples contained wheat seeds of unknown origin. Seed coafing could not be found within the samples, which fits to the observation that Chaffinches mostly de busk the seeds before swallowing.

The exposure assessment data show that cereat seeds were readily available for birds after drilling; the average number of seeds per me was 14.8 on midfield areas and 36.7 on headlands. Yellowhammers and Chaffinches could be observed repeatedly feeding on coated seeds on freshly drilled winter cereal fields.

For risk assessment purposes (value for portion of diet obtained in treated area (PT – estimated from the time spent potentially foraging) can be derived for Yellowhammer, Skylark and Chaffinch from the study results: Yellowhammers spent on perage 6.41% of their potentially foraging time in winter cereal fields (90th percentile = 23.63%); Skylarks's pent 16.97% of their potentially foraging time in winter cereal fields (90th percentile = 95.73%) and Chatfinches spent 8.54% of their potentially foraging time in winter cereals (90th percentile = 22.05%).

Report:KCP 104/1.2/12Title:ProthioconazoleReport No.:ProthioconazoleReport No.:ProthioconazoleDocument No.:ProthioconazoleGuideline(s):not applicableGLP/GEP:not

CP 10 4/1.2/13 Prothioconazole (PTZ) residue DT50 kinetics EUR - Residue dissipation of profisioconazole and its metabolite in or on wheat seeds: Kinetic evaluation En Sa-15-0606 A-535724-01-1 not applicable This statement provides a kinetic evaluation of the residues of prothioconazole and its metabolite JAU 6476-desthio in wheat seeds in the field that may represent food items for seed-eating herbiverous birds or mammals. The residue decline data are available from a specifically performed residue study (1990), 2001; M-088988-01-1, KCP 10.1.1.2/02).

The reliable single-first-order (SFO) half-lives of prothioconazole and JAU 6476-desthio derived in this evaluation are summarised in Table CP 10.1.1.2-1 below, along with the formation fraction of prothioconazole to desthio.

Table CP 10.1.1.2-2:	Summary of DT50 value	s for prothioco	onazole and JA	d 6476-desthio p	arent-to-
	metabolite kinetics	RO -	Ø	, v v	Ô,

Trial code	Compound	Model OT 50 BT 50 Formation [d] O [d] Fraction JAU-6476 Destrino
early drilling	JAU 6476	$\begin{array}{c c c c c c c c c c c c c c c c c c c $
early drilling	desthio JAU 6476	$\mathcal{S}$ FO $\mathcal{O}$ $\mathcal{A}$ 47 $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$
late drilling	desthio JAU 6476	$\begin{array}{c c} SF0 \\ \hline \\ $
-	desthio	SFO     0.45       SFO     0       SFO </td
ć	Grand Keep 10.1,	
Report:	К 🖓 К 🕮 10.1.	1.2/16 2015 @M-534804-01-1
Title:	Protniocor	azole (PTZ) Besidue DT50 Kinetics EUR - Statement on residue n of prothioconazole and its metabolite on wheat seeds in Germany: kinetic
Report No.:	© evaluation En§a-15-0	
Document No.: Guideline(s):	EnSa-15-0 M-53480 Onot applica	$\frac{1}{2} \frac{1}{2} \frac{1}$
Guideline devised	ion(s) not applica	
		n of prothioconazola and its metabolite on wheat seeds in Germany: kinetic

This statement provides a kinetic evaluation of the residues of prothioconazole and its metabolite JAU 6476-desthio in wheat seeds in the field that may represent food items for seed-eating herbivorous birds or mammals. The residue decline date are available from a specifically performed residue study (1990); 2014; M-486407-02-1, KCP 10.1.1.2/18).

The reliable single-first-order (SFO) half-lives of prothioconazole and JAU 6476-desthio derived in this evaluation are summarised in Table CP 10.1.1.2-3 below, along with the formation fraction of prothoconazole to desthic

**Bayer CropScience Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100** 

**Report:** 

Title:

#### Table CP 10.1.1.2-3: Summary of DT₅₀ values for prothioconazole and JAU 6476-desthio parent-tometabolite kinetics *a*r

	metabolite r	aneucs				N Or
Trial code	Compound	Model	DT ₅₀ [d]	DT ₅₀ [d]	Formation fraction	
			JAU 6476	Desthio		
site west	JAU 6476	SFO	2.09	4		
	desthio	SFO		2.62 🔊	1 🗞	
site south	JAU 6476	SFO	2.13		N.	
	desthio	SFO	. ¥r	2.34Q	0.95	19° × 4
site north	JAU 6476	SFO	1,54			
	desthio	SFO	1	KQ A ¹ ∘	ENA ¹	
site east	JAU 6476	SFO	0.76		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	lo di
	desthio	SFO "	× °	© NB [™]	⊘ NR ,	K ^a S
¹ Fit not acceptable ² Not reliable						

Prothiocongzole (P1Z) residue D150 kinetičs EUR- Statement opresidue dissipation of profhiocongzole and its metabolitic on wheat seeds in Germany: kinetic evaluation EnSa 15-0608 Meta 34805-01-1 not applicable no Report No.: EnS& 75-0608 Document No.: Me534805-01-1 Guideline (s): not applicable GLP/GEP: no This statement provides a kinetic evaluation of the residues of prothioconazole and its metabolite JAU Report No.:

Prothioconazole (PTZ) residue DT50 kinetics EUR - Statement on residue

2015; M-534 5-01

KCP 10.1.1.207

# Table CP 10.1.1.2-4: DT₅₀ values for prothioconazole and JAU 6476-desthio and results of the statistical analysis - scaled error (ε) and significance of the dissipation rate (t-test) for SFO model

	model					
Trial code	Compound	Model	DT50 [d]	DT50 [d]	formation fraction	
			JAU 6476	Desthio 🧹	, Č	
west	JAU 6476	SFO	2.30 🖏	, S	L.Y	
	desthio	SFO	- T	4.81	0.54 ^C	
south	JAU 6476	SFO	2.20	, O'Y		
	desthio	SFO	1 ⁰	<u>ک</u> ۲۱ .	9.66	
north	JAU 6476	SFO	<b>∂</b> \$₹.72			
	desthio	SFO	KØ _	3.68 3.68 5 5 5 5 5 5 5 5 5 5 5 5 5	<u>َ</u> 10,54	
east	JAU 6476	SFO 🖇		N N K		
	desthio	SFO O	x, ô	\$.81 S	00.37 L	A co
		A.		R ₄ °	N O	

**Report:** KCP 10.1.1.20 Dissipation of triadimenol, prothjocona Title: and and seedlings in Germany Report No.: B130124 Document No .: M-486407 Guideline(s): The study was For the present study type od official test guideline is available. conducted was under consideration of the recommendations in the current gostance document on risk of ssmen≰ Guideline deviation **GLP/GEP:** 

# Objective:

The purpose of the study was to quantify residue amounts of triadimenol, prothioconazole, JAU 6476desthio and fluopyran residues after seed treatment with the Baytan 3 (fluopyram + prothioconazole + triadimenol FS 2175) on spring wheat under field conditions:

1) on wheat seeds remaining on the soft surface if not buried after drilling,

2) in seedlings merging from drilled when seeds

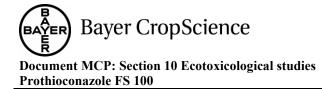
following the recommendations of the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. (EFSA Journal 2009; £(12):1438)

# Study Materials and Sites.

Study sites: The study was conducted on prinn field stripes (headland) at four different locations distributed over Germany, (1) hear **Stripes**, Rhineland (west), (2) near **Stripes**, Saxony (east), (3) near **Hesse** alatine (south) and (4) **Stripes**, Lower Saxony (north). An area of approximately 150 m2 of fallow and was demarcated per study site. Three plots, serving as replicates, were installed at each location

<u>Test item and application</u>: Dopyram + prothioconazole + triadimenol FS 217.5 (Baytan 3) was applied with rominal 200 mL product/100 kg seeds on spring wheat.

<u>Sampling</u> Treated seeds scattered on the soil surface were collected on DAT +1, +2, +3, +5, +7, +10, +15, +21 and +28. On the day of sowing (DAT 0), seed samples were taken directly from the package. Seedlings emerging from drilled seeds were sampled starting at BBCH 10/11 every two days until day



21 after first sampling. Seedlings were cut with scissors close to the soil surface with a targeted minimum seedling biomass per sampling day and replicate of approximately 10 - 12 g wet weight. <u>Residue analysis:</u> All samples (seeds and seedlings) were analysed for their content of triadinenoly (analytical method 01072/M001), fluopyram (analytical method 00984/M002) prothioconazole and JAU 6476-desthio (analytical method 01013) via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg or pure metabolite (mg a.s.(p.m.)/kg). The Limit of Quantification (LOO) value was 0.01 mg/kg.

<u>Calculations:</u> Mean and time-weighted-average concentrations were calculated with MS office Excel 2010. The residue decline (DT50) of fluopyram, triadimenol and prohioconazole on wheat seeds and seedlings was determined, assuming a first-order kinetic using King UI2, 1:

# **Results:**

For the purpose of refining the risk assessment for the product presented in this dossier only the results pertaining to prothioconazole and its desthic-metabolite are presented in this summar Mean measured initial concentrations on seeds, 21d TWA concentrations and resulting  $f_{twa}$  values relevant for risk assessments for terrestrial vertebrates summarised in the report are only used after a kinetic evaluation. Therefore they are not presented here in detail to avoid compsion.

Neither prothioconazole nor its metabolite JAF 6476 desthio were detected in seedlings in significant quantities (<LOQ and 0.014 mg p.m./kg f.w., respectively). Therefore, prothioconazole can be considered as "not systemic" when used as a seed treatment.

Report:	KCP 10, 10, 2/19
Title:	
	Oseedlings in Oerman 7
Report No.: Of	
Document No.:	M-488939201-3 A O O O
Guideline (3):	For the present study type no official lest guideline is available. The study was
	. Conducted under consideration of the recommendations in the current guidance
~	document on risk @sessment for birds & mammals (EFSA 2009)
Guideline deviation	
GLP/GEP: 🦃	$\tilde{\mathbf{y}}$ es $\tilde{\mathbf{y}}$ $\tilde{\mathbf{y}}$ $\tilde{\mathbf{y}}$ $\tilde{\mathbf{y}}$ $\tilde{\mathbf{y}}$

# **Objective:**

The purpose of the study was o quantify residue amounts of fludioxonil, penflufen, prothioconazole, and metabolite JAU 6476-desthio after seed treatment with the product (fludioxonil + penfluten + prothioconazofe FS 130) on spring wheat under field conditions:

1) on wheat seeds remaining or the soil surface if not buried after drilling,

2) in seedlings emerging from drilled wheatseeds,

following the recommendations of the Gaidance Document on Risk Assessment for Birds & Mammals on request from FFSA. (FFSA Journal 2009; 7(12):1438)

# Study Materials and Sites

Study sites The study was conducted on plain field stripes (headland) at four different locations distributed over Germany, (1) **Example**, Rhineland (west), (2) **Example**, Saxony (east), (3) near **Example**, Hesse-Palatine (south) and (4) **Example**, Lower Saxony (north). An area of approximately 150 m² of fallow land was demarcated per study site. Three plots, serving as replicates, were installed at each location.

Test item and application: fludioxonil + penflufen + prothioconazole FS 150 was applied with normal 100 mL product/100 kg seeds on spring wheat.

<u>Sampling</u>: Treated seeds scattered on the soil surface were collected on DAT $\cancel{2}$ 1, +2, +3, + $\cancel{5}$ , +7,  $\cancel{2}$ 10, +15, +21 and +28. On the day of sowing (DAT 0), seed samples were taken directly from the package. Seedlings emerging from drilled seeds were sampled starting at BBCH 10-11 every two days until day 21 after first sampling. Seedlings were cut with scissors close to the soil surface with a target of minimum seedling biomass per sampling day and replicate of approximately 10-12 wet weight.

<u>Residue analysis:</u> All samples (seeds and seedlings) were analysed for their control of fludiox mil, penflufen, prothioconazole and JAU 6476-desthio (analytical method 0/013) via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg (mg a s./kg) The Lamit of Quantification (LOQ) value was 0.01 mg/kg.

<u>Calculations</u>: Mean and time-weighted average concentrations were calculated with MS Office Excel 2010. The residue decline ( $DT_{50}$ ) officie concentrations and prothesion and prothesion of the seeds and seedlings was determined, assuming a first-order kinetic using KinGU2.

# Results

For the purpose of refining the risk assessment for the product presented in this dossier only the results pertaining to prothioconazole and its desthio-metabolite are presented in this summary.

Mean measured initial concentrations on solds, 2 d-TWR concentrations and resulting  $f_{TWA}$  values relevant for risk assessments for torrestrial vertebrates summarised in the report are only used after a kinetic evaluation. Therefore they are not presented here in detail to avoid confusion.

None of the compounds was detected in seedlings in Ognificant quantities. Prothioconazole can be considered as "not systemic" when used as a seed treatment

# CP 10.1.2 Effects on terrestrial vertebrates other than birds Table CP 10.1.2- 12 Endpoints used in risk assessment

- 6	$n \cap Y \land C$			1
Test 🧄 substance	Test species	<b>E</b> cotoxic	ological endpoint	Reference
Prothio	Relatives		>6200 mg a.s./kg bw	(1998) M-012312-01-1 KCA 5.2.1/01
	Long-tern (2-gen-reprodudy) R	NQA)EL	95.6 mg a.s./kg bw/d	(2001) M-036206-01-1 KCA 5.6.1/02
JAU 6474 desthio	A Mouse	LD50 (male) LD50 (female)	<b>2235 mg p.m./kg bw</b> 3459 mg p.m./kg bw	(1991) M-008521-01-1 KCA 5.8.1/34
	Low-term (2-genrepro study) Rat	NOEL	10 mg p.m./kg bw/d	& (2001) <b>M-036130-01-1</b> KCA 5.8.1/23

a.s.: active substance; p.m.: pure metabolite; bw = body weight

## Table CP 10.1.2- 2: Relevant generic focal species feeding on seeds for Tier 1 risk assessment

8	1 8		
Type of seeds	Generic focal species	> FIR/bw	
'Large seeds' (maize, beans or peas)	Small omnivorous mammal		
'Small seeds' (not maize, beans or peas)	Small omnivorous frammal		V V

Since prothioconazole and JAU 6476-desthio are non-systemic (2014a, b, M-486407-01, K M-488935-01-3, KCP 10.1.1.2/18 & 19), no risk assessment for bird@feeding on cop secolings was performed.

# Acute dietary risk assessment

# Table CP 10.1.2-3: Tier 1 acute TER executation for mammals feeding on seed treatment

Compound	Generic focal species	Qmg/kg bw]		Exposing NAR Ing a.s.4kg seeds ⁽¹⁾	TERA	© Trigger
Prothio- conazole	Small omnivorous mammal	× 262000	0.24		258	10
JAU 6476- desthio	Small omniverous mammal	2235		5° ( ¹ 00 ²⁾ 25°	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	10

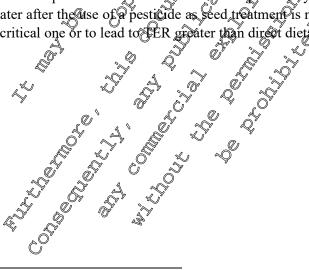
¹⁾ Assuming a thousand grow weight of the seeds of 50 g  8 

²⁾ This value is taken from the parent compound and represents an uprealistic worst-case scenario

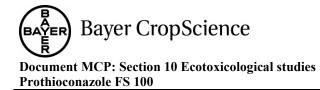
The TER values for mammals feeding on treated seeds of crop seedlings meet the required trigger of 10 for acute exposure, indicating no macceptable risk to mammals for the use of the product.

# Tier 1 risk assessment for mammals drinking contaminated water

EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and mammals on the dietary route of exposure An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed treatment is not required since this route seems unlikely to be a critical one or to lead to FER greater than direct dietary consumption.



⁸ Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1



### Long-term reproductive risk assessment

Table CP 10.1.2- 4:	Tier 1 long-term TER calculation for mammals feeding on seed treatment	4
1 abit C1 10.1.2- T.	The Thomester in The calculation for mainmais recuring on seed treatment	~ ~

	Generic focal	NOEL		Exposure	ð	
Compound	species	[mg/kg bw/d]	FIR/bw	NAR [mg a.s./kg seeds] ¹⁾	fTWA	
Prothioconazole	Small omnivorous mammal	95.6	0.24	<u>ک</u> 100 کې	0.53	
JAU 6476- desthio	Small omnivorous mammal	10	0.24	¥ 100 ²⁾	0.53 °C	

 $^{1)}$  Assuming a thousand grain weight of the seeds of 50 g  9 

²⁾ The application rate is taken from the parent compound and represent unrealistic worst **Bold** values do not meet the trigger

The TER values for mammals feeding on treated seeds to not required trigger of term exposure to JAU 6476-desthio. Accordingly, a refined ris

#### mammals feeding on seeds Refined risk assessment for long termexposure for mall mnivorou treated with JAU 6476-desthip

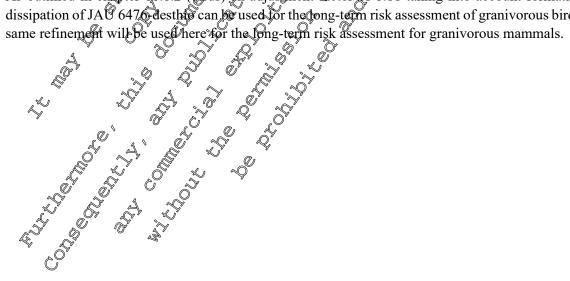
## **Focal species**

Freshly drilled cereal fields are best represented by the bare field scenarios, numbers 1-3 in the "Mammal Tier 1 tables of the EFSA Guidance (2009). In the ase of seed treatments, the meated seeds are the only feed items containing residues of the plant protection product. Accordingly only the granivorous mammal with a single die of seeds has to be considered in the risk assessment.

Scenario #2 lists the Wood mouse (Apodemus sylvaticus) as the generic focal species for Tier 1 risk assessment. Relevant ecological parameters are @PD of I (single die of seeds) and a FIR/bw of 0.17. These figures will be used in the refined risk assessment for granivorous mammals.

# Residue on feed

As outlined in chapter 10.1.2 (birds) an adjustment factor of 0.11 taking into account formation and Ô dissipation of JAC 6476 desthip can be used for the ong-term risk assessment of granivorous birds. The



Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

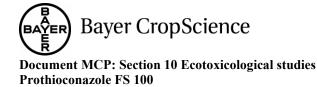


Table CP 10.1.2- 5:TER calculation based on long-term toxicity and exposure to JAU 6476-desthio
-------------------------------------------------------------------------------------------------

Application		Seed dressing (JAU 6476-desthio)	) )
Nominal seed treatment rate of the p	arent compound [mg a.s./kg seeds]		
Generic focal species		Wood mouse	
Feed		Treated seconds	
FIR/bw (Wood mouse)			Ş
Adjustment factor	Š.		¥
DDD [mg p.m./kg bw]			
NOEL [mg p.m./kg bw]			
TERLT	& Q° A		

The refined long-term risk assessment for the exposure of birds to residues of the metabolite AU 6476desthio after the application of the product indicates that no unacceptable adverse effects on marginals are to be expected.

# Long-term risk assessment for mammals drinking contaminated water

EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and manimals on the dietary route of exposure. An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed to atment is not required since this route seems unlikely to be a critical one or to lead to RER greater than direct dietary consumption.

# Risk assessment of secondary poisoning

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

Prothioconazole, however, has a log Pow of 2-9, indicating a very low risk of bioaccumulation and, hence, secondary poisoning.

Prothioconazole metabolites JAU6476 desthio (log Pow 3.04) and JAU 6476-S-methyl (log Pow 4.19) will be evaluated for potential effects of secondary poisoning of mammals.

Long-term DOD and TER calculation for earthworm-eating mammals

¥			
Table CP 10.1.2- 6:	Tievi long-term DD	) and TER <i>calculation</i> fo	r earthworm-eating mammals
	and the second sec		

		, <u> </u>	8
Compound	JAU 6476-desthig	JAU 6476-S-methyl	Origin of values
PECworm [mg/kg]	¢.013 ×	0.014	see Table CP 10.1.1-17
	DDD ca	lculation:	
FIR/by		1.28	Default
DDD [m&kg bw/d]	<b>∂</b> ^{\$\$} <b>40</b> .017 <b>√</b>	0.018	
	TER ca	lculation:	
NO(A)EL [mg kg bwd	<b>10</b>	9.56 ¹	See Table CP 10.1.2-1
$\sim$ TER $U_{\rm T}$	588	531	
C Trygger	S 5	5	
Refined Fisk assessment required?	No	No	

¹⁾ NOEL of the parent compound prothioconazole was divided by a factor of 10 (worst-case assumption)

# **Bayer CropScience Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100**

Both TER values are above the trigger of 5. Accordingly, the risk to earthworm-eating mammals following the use of the product in cereals is acceptable.

# Long-term DDD and TER calculation for fish-eating mammals

following the use of the product in cereals is acceptable.							
following the use of the product in cereals is acceptable.							
Table CP 10.1.2- 7: Tier 1 long-term DDD and TER calculation for fish-eating mammals         Compound       JAU 6476-desthio       JAU 6476-Smethyl       Prigin of values         PEC _{fish} [mg/kg]       0.047       0.026       see Table CP 100.1-18         DDD calculation       Output       Output       Output         FIR/bw       0.142       0.142       0.142							
Compound	JAU 6476-desthio	JAU 6476-Semethyl	Prigin of values				
PEC _{fish} [mg/kg]	0.047	0.026	See Table CP 1021.1-18				
DDD calculation by							
FIR/bw	0.142	0.142	by Betault of a				
DDD [mg/kg bw/d]	0.007	0.004					
TER calculation of the terms of terms o							
NO(A)EL [mg/kg bw/d]	10	0 [°] 0 ⁹ .56 ¹	$\checkmark$ See Table CR 10.1.2-1 4				
TER _{LT}	1 429	. [™] 2,3 <b>%</b> ~					
Trigger	5 🎝	$\sim \sim$					
Refined risk assessment required?	No	Nog of					

¹⁾NOEL of the parent compound prothiocorazole was divided by a factor of 10 (worst case assumption)

Accordingly the risk to fish-eating mammals from the use Both TER values are above the trigger of of the product in cereals is acceptable.

#### cute or al toxicity to manimal **CP 10.1.2.1**

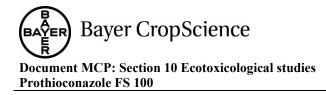
resold corresponds with LD₅₀ >2000 mg with Prothiocox F; 2001; M-137432-01-An acute study on Noted the r 1, KCP 7.1.1 grodeling prod./kg bw.

#### Högher Öjer data on mam Dåls CP 10.4.2.2

Additional data is presented to support the short half-file of prothioconazole and JAU 6476-desthio on seeds. This data is provided in chapter 10.1.1.2 and employed in the refined risk assessment for omnivorous manmals

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

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



#### **CP 10.2** Effects on aquatic organisms

The risk assessment has been performed according to the Regulation (EC) No 1,07/2009 and 1010 ming the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013; cited in the following paragraphs as "EESA AGD").

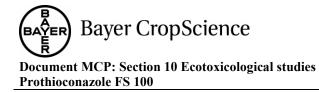
from the EU Regulation 283/2013 and the EFSA AGD (2013), and based on recommendations from the relevant standard test guideline e.g. Growth rate (r) is the most suitable endpoint from algae inhibition tests for use in risk assessment, as stated by OBCD Guideline 201 and the BFSA GD (2013). TER and RAC calculations presented in this dossien are thors based on the ErC 50 values. Indeed, processes in ecosystems are dominantly rate driven and therefore the wort development personal (growth rate) appears more suitable to measure effects in algae. Also, growth rates and their indibition can casily be compared between species, test durations and test conditions which is not the case for biomass. Moreover, the current test guidelines OECD TG 291, the FU-Mothod C3, the EC regulation for Classification and Labelling (E@regulation 1202/2008) and the PPR Opinion (EFSA Journal 461, 1-44; 2007) list growth rate as the most suitable endpoint of the algae inhibition test.

In accordance with Regulation (EC) No1107 2009 and with the EFSA AOD (2013), studies resulting in lower endpoints were used for the risk assessment. Although Regulation (EC) No 1107/2009 place no data requirement on marine species amarine studies resulting in lower endpoints compared to freshwater studies were considered for tisk assessment as a conservative approach.

For the aquation risk assessment an envelope approach was performed. Therebye, the highest FOCUS Step 2 PEC@alues were used to calculate the risk to aquatic organisms. This clearly represents the worstcase situation covering all other FOCUS STEP 2 scenarios

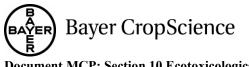
If the trigger was not met using this calculation, worst case FQCUS STEP 3 PEC values were used as

If the thigger was normet using this calculation, worst-case FQCUS STEP refinement until a spre use of each intered application can be considered.



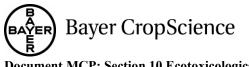
# Risk assessment for aquatic organisms

Test	Test species		Endpoint	ð	Reference A
ubstance	Fish soute		-		(1000)
	Fish, acute Oncorhynchus mykiss	LC ₅₀	1.83 mg a.s./L	•	M-015315-01
	(Rainbow trout)	$LC_{50}$		9	KÇA 8.2.1491
	Fish, early life stage	NOEC	0.49 mg a.s.		& (2007)
	Oncorhynchus mykiss (Rainbow trout)	NOEC	, 0.49 mg a.s.nz	~	KCA \$2.2.1
	· · · · · · · · · · · · · · · · · · ·				KCA 82.2.1.05
	Invertebrate, acute	U V	1.3 m a.s.	Q	(1999)
	Daphnia magna (Cladoceran)	<b>I</b> SQ 50		~ ·	M-013696201-1
	Invertebrate, acute		2.4 mga.s./L		et al. (2002)
	Americamysis bahia		24 mg , 1 0	10	M (983057 (91-1 4)
	(Mysid shrimp)			Q.	KCA 8.2.4.2/02
Prothio-	Invertebrate, chroni				& (2001)
conazole	Daphnia magnaQ	NOE	AX6 models /L &		M-055997-01-1
	(Cladoceran)				K&A 8.2, \$21/01
	Sediment dwelleQchronic			Õ	2000)
	Chironomurriparius	NOECC	900 mg ak /L		M-047356-01-1
	(ChiroSmid)	Ø		ð	KCA 8.2.5.4/01
		L.		Ô	&
	Skeletõgema costatum			y` r	J (2004)
	(Marine diatom)	$E_rC_{50}$	0.046 mg a.s./L ⁵ )	Ś	[*] M-000954-01-1
				s s	KCA 8.2.6.2/01
	Lamna gibya			Ż.	et al. (2004)
	Lemna gibba	ErC ₅₀	) > 0,404 mg(a.s./L @		M-000532-01-1
					KCA 8.2.7/01
2	Fish acute				(1990)
Ča.	Bncorhynchuz mykiss	×4°50	6.63 mg p.m./L		M-013303-01-1
	(Rainbow frout)	O'			KCA 8.2.1/04
Ê.	Ein, ear Mife stage	Ô	v, o'		(2002)
* %	Free, early life stage	NEEC	0.00334 mg p.m./L		M-038386-01-1
	(Italiioow (cout)		× · · · ·		KCA 8.2.2.1/02
	In Artebrate, acute,				(1990)
	Baphund magto	EQ	710 mg p.m./L		M-013308-01-1
AU 6476	U (Codoceran) y		<u>}</u>		KCA 8.2.4.1/02
A	Invertebrate acute		. 1 000 /7		et al. (2003)
	Americanosis baha	LG50	> 1.009 mg p.m./L		M-104620-01-1
↓U_6476-	(Mysid Shrimp)				KCA 8.2.5.2/02
		S,			&
	Daphnig magna,	NOEC	0.10 mg p.m./L		(2001)
Å	(Cla@ceran) Q	^o			M-073861-01-1 KCA 8.2.5.1/02
Q	Laura Granta - abaani				
Š	Inversebrate chronic S Americano Sis bahia	NOEC	0.064 mg n m /I		et al. (2003)
~~~	(Mysicshrimp)	NOEC	0.064 mg p.m./L		M-104620-01-1 KCA 8.2.5.2/02
desthio	Scriment Weller, chronic			1	(2000)
SY R	Chigonomus riparius	NOEC	2.0 mg p.m. /L ¹⁾		M-023234-01-1
	(Chironomid)	1.510	P		KCA 8.2.5.4/02
Ċ ^{O'}					(1990)
Ŭ		E_rC_{50}	0.55 mg p.m./L		M-013305-01-1
	(Green alga)	1.00	8 F		KCA 8.2.6.1/02



Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100

Test substance	Test species Endpoint		Reference 🖉 °	
	<i>Lemna gibba</i> (Duckweed)	$E_r C_{50}$	0.0809 mg p.m./L	et al. (2003) M-104599-004 KCA 8.2,702
	Fish, acute Oncorhynchus mykiss (Rainbow trout)	LC ₅₀	1.79 mg p.m./L	(201) M-074388-01-1 R& A 8, 105, 27
JAU 6476-S- methyl	Invertebrate, acute <i>Daphnia magna</i> (Cladoceran)	EC ₅	2.8 mg ô ^m ./L .	→ (2%01) → (2\%01) →
metnyr	Peudokirchneriella subcapitata ((Green alga)	ErCan		(2001) Mo61047@1-1 KCA 8.58.1/03
	Sediment dweller, chronic Chironomus ripartas (Chironomid	NOE		(2006) M-256605-01-1 KCA 8.2.624/04
	Fish, acuQ Oncorhynchor mykto (Rainbood trout)	OLC 50 OF	4 mg pm./L o	M-046022-01-1 KGX 8.2.1/06
1,2,4-Triazole	Fish, ju onile growth to Oncomynchus mykiss Rainbor trouto	TO CO	₩ 3\$\$Pmg.p.m./L 2	& (2002) M-030491-01-1 KCA 8.2.2/01
~	Invertebrate ocute Pophnia magna Cladoceran 4	YEC 50	> 149 mg p.n./L.20	(1995) M-088901-01-1 KCA 8.2.4.1/06
	Peudularchneriella sybcapica (GregQalga)	ČErC50	> 33 mg p. // 3)	et al. (2001) M-077067-01-1 KCA 8.2.6.1/04
2 Y	Fish, acute Soncornynchus mykiss Rainbox trout		→ > 100 mg p.m./L	(2006) M-266572-01-1 KCA 8.2.1/11
JAU 6476 - (triazolyl-) ketone	Daphnia magna (Cladoceran)		‴⊘″ ≫ > 100 mg p.m./L	(2006) M-266597-01-1 KCA 8.2.4.1/07
Ketona K	ReudokirChneriella A S subcapitata (Green ålga) Q	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	> 100 mg p.m./L	(2006) M-266567-01-1 KCA 8.2.6.1/05
	Fish ocute C Dicorth Schus Dikiss (Refibow trout)	LC ₅₀	1.83 mg a.s./L $^{4)}$	(1999) M-015215-01-1 KCA 8.2.1/01
JAU 6496 -	Fist, early fife stage	NOEC	0.49 mg a.s./L ⁴⁾	& (2007) M-291414-01-1 KCA 8.2.2.1/03
thiazocine 6	In virtebrate, acute Daphnia magna (Cladoceran)	EC ₅₀	1.3 mg a.s./L $^{4)}$	(1999) M-013690-01-1 KCA 8.2.4.1/01



Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100

Test substance	Test species	Endpoint	Reference of a
	Invertebrate, chronic <i>Daphnia magna</i> (Cladoceran)	NOEC 0.56 mg a.s./L ⁴⁾	M-055997-02 → M -055997-021 → KCA 8.2.3 /01
	<i>Pseudokirchneriella</i> <i>subcapitata</i> (Green alga)	E _r C ₅₀ 2.18 mg a.s./L ⁴⁾	(200 M-027625-0101 K Q 8.2 K 101
	Fish, acute Oncorhynchus mykiss (Rainbow trout)	LC ₅₀ 16.4 mg prod ./L	M-525350-01 K KCP 10.2.1001
PTZ FS 100	Invertebrate, acute Daphnia magna (cladoceran)	EC ₅₀ 9.8 mg prod./L	Q 2015 W-52534 -01-1 KCP 10.2.1/02
	Pseudokirchneriella subcapitata (Green alga)	E.G.0 18.6 mg prod /L	[™] 2013 [™] M-525314-01-1 [™] [™] KCP 10.2.1/03

a.s.: active substance; p.m.: pure metabolit \mathcal{P} prode formulated product Bold values: Endpoints considered relevant for kisk assessment

- ¹⁾ NOEC according to the list of endpoints given in the EFSA conclusion on orthogonazol 2007, the original study endpoint is the EC₁₅ = 4.4 mg/L; the cited OEC cas non-tatistically deoved, a was explained in the DAR by the RMS but proposed of a conservative endpoint.
 ²⁾ EU agreed endpoint for 1,223 triazole derod from the PRAPer experimenting on triazole metabolites (PRAPeR 13, 2007).
- (PRAPeR 13, 2007). Ì O
- ³⁾ EU agreed endpoint is derived from the @FSA Scientific Report (2014) 12(1) \$485, Conclusion on the peer ⁴⁾ JAU <u>6476-th</u>iazocine has lost the toxophore and shows no pesticidal activity as explained in detail in a statement
- 2015, (N 536612-01-1 CA 201). For metabolites with such properties, the 'EFSA Guidance on by tiered risk assessment for ant protection products for a quatic organisms in edge of field surface waters (2013)' prescribes to assume that the acute and chronic toxicity of the metabolite is equal to the toxicity of the a.s. (parent compound) for all first tie Caxonanic groups". Therefore, the endpoints of the parent compound prothioconazole from studies on first tier species were used for the acute and chronic risk assessment of JAU Ø Ø) 6476-thiazocine.
- 5) Although Regulation (FC) No F07/2009 place no data requirement or marine species, the endpoint from a study Although Regulation (FC) No $\frac{1}{100}$ No $\frac{1}{100}$ place no data requirement on marine species, the endpoint from a study on the marine diaton *Skelenonema costation* is used for algae tisk assessment for prothiconazole as a conservative approach. Indeed this endpoint is lower than the one from the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 2.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 2.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 2.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 2.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 2.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg a structure of the standard species (green algae, *P. subcapitata*, E_rCa⁻ = 1.18 mg

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Predicted environmental concentrations used in risk assessment

Full details of the predicted environmental concentrations are given in MCP 9 (KCP 9.2.5/08).

Table CP 10.2- 2:Initial max. PECsw values for prothioconazole and its metabolites – Use in winter and
spring cereals (FOCUS Step 1 & 2)

C	ompound	Prothio-	JAU	J 6476-		₫6476-	2 ,2,4-	Thiazocine	Triazoly	, O
		conazole	desthio		Semethyl		triazole		ketone	S
Ileo mottore	C	PEC _{sw}	PEC _{sw}	21d-TWA	PECsw	21d-TWA	⁹ PEC _{sw}	XPEC _{sw}	PEC _{sw}	o`
Use pattern	Scenario	[µg/L]	[µg/L]	[µg/L]	[seg/L]	[µg/L	[µg/L]	[©] [µg/L] ا	hug/L]	,×
	Step 1	1.789	3.441	3.028	0.385	0,352	0 .453 Q	0.668	0.294	
Winter cereals	Step 2				, ,				a võ	
1×18 g a.s./ha	N-EU Si	0.124	0.937	0.723*	0.4210		0.031	.046 ~	0.020	
_	S-EU Si	0.099	0.749	0.598	£0.088 (0.066	Q.Q25	0.037	ي 0.016_	
	Step 1	1.789	3.441	3,028	~0.385C	0.3 Ş Ž	0.453	0.668	Ø0.29 4 , V	
Spring cereals	Step 2					ð í	À, Ö [×]	*		
1×18 g a.s./ha	N-EU Si	0.049	0.375@	× 0.289	0 Ø 44	<u>,</u> ≪0.033Ô [°]	0,073		0,008	
	S-EU Si	0.099	0.74	0,578	ð.088 (0.066	0025	0.037	0.016	

Bold values were considered in risk assessment

* Values used for secondary poisoning (see 10.1.1, Table CB10.1.1, P8

Table CP 10.2- 3:	nitial anax. PECsw alues for the prothioconazole metabolite JAU 6476-desthio -	
	initial Anax. PECsw Salues for the prothioconazole metabolite JAU 6476-desthio – Use in winter and spring careals (FOCUS Step 3)	

	Use pattern	, 18 4	ga.s./har 🌾
	2 C	«Winter cereaks	Spring Cereals
Compound	FOCUS Scenario	REC sw, max	S PEC sw, max
		Ŵμg/Ŀ, "	
(℃D1 (dittch, 1st)	` ج <u>ک</u> (0,001 کې	~~<0.00¥ «
ð	D1_(stream,Qst)	O` ≪0,001 ~~	O <0.4901
Č0	D2 (ditch, 1st)	2 .1<0.001	- ×
	D2 (stream, 1st)	€0.00₽	-~~
Ê, ^Ş	D3 (dutch, 15)	<0.001	%_ [%] <0.001
~ ¥	D4 (pond, 1st)	× <0.001 ×	<u>k</u> < <u>0</u> .001
JAU 6476-	Da (stream, 1st)	× ×0.001	0.001
desthio	D5 (pand, 1st)	~0.00H	<0.001
_C	D5 (Stream Ast)	, Û <0 0 01 , O	® ^y <0.001
~Q`	D6 (ditch,Ost) \land	Ø.001	~ -
2	R1 (pond, 1st) 🍣	₩0.Q0¢	Ŭ -
	R1 (stream, 15)	<u> </u>	-
~~~	R3 (stream, 1st)	∽ < <b>6,0</b> 01 ,	-
~~~	R4 (stream, 1st)	0.004	< 0.001
//			

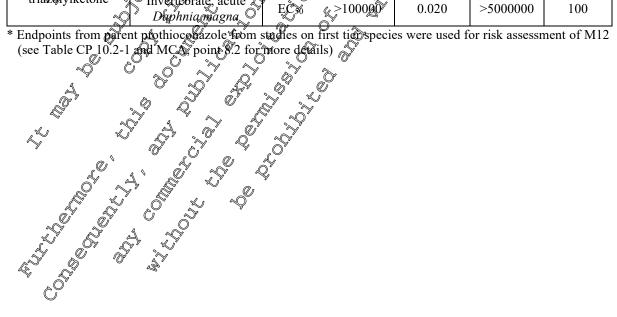
Acute Risk Assessment For Aquatic Organisms Based on the risk music and the risk music

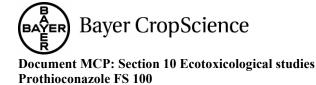
Based on the risk envelope approach, the highest PEC values were used to calculate the acute risk to aquatic organises. This clearly represents the worst-case situation covering all other intended uses of the product.

If the trigger was not measuring this calculation, worst-case FOCUS STEP 3 PEC values were used as refinement until a safe use of each intended application could be assumed.

Table CP 10.2-4: TERA calculations based on FOCUS Step 2

Compound	Test species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger	
Cereals (winter/sprin	lg)			á	Ô.		
	Fish, acute Oncorhynchus mykiss	LC ₅₀	1830	0.124	14758	100°)
Prothioconazole	Invertebrate, acute Daphnia magna	EC ₅₀	(3 00	0.424	10484		
	Invertebrate, acute Americamysis bahia	EC ₅₀	2400	0.124	^م لا9355 م		Ĵ,
	Fish, acute Oncorhynchus mykiss	L	6630	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	7096		
JAU 6476- desthio	Invertebrate, acute Daphnia magna	OEC ₅₀	>10900	0.9 3 0	€10672	<u> </u>	
	Invertebrate, acute		×1000	\$0.937 O	₹1077		
JAU 6476-	Fish, acute Oncorhynchus mykiss	LC ₅₀	A790		§ 162\$3	ل م ا	
S-methyl	Invertebrate, acute, Daphn@magne	EC 50	2800	~~0.1 kg	25455 [°]	100	
1,2,4-Triazole	Fish, acute		498000 [€]	0,031. 0	16064516	100	
1,2,4-111a201e	Invertebrate, acute	EC 50	>100000 (K	((k. °r	3225806	100	
JAU 6476- 🍠	Fish, acute Onéorhymeturs mytriss		1830	0.046	39783	100	
thiazocine Ö	Dinvertebrate, scute		1300* \$	0.046	28261	100	
JAU 6476-	Fish, agute A Oncorhynchus mykiss		>10 0 000	کر ۲ ۲	>5000000	100	
triazofylketone	[©] Invertebrate, acute Duphnia, magna	EČ% (2100000	0.020	>5000000	100	





Compound	Test species	Endp [μg/		RACsw; ac (LC50/100)	PECsw,max _ [µg/L]	PECARAC
Cereals (winter/sprin	ng)	[#5/		(100)		
	Fish, acute Oncorhynchus mykiss	LC ₅₀	1830	18.3	0.124	
Prothioconazole	Invertebrate, acute Daphnia magna	EC ₅₀	13490	13.	0.124	0.01
	Invertebrate, acute Americamysis bahia	EC ₅₀	<i>2</i> 400	24.0	& 124 Q	en i
	Fish, acute Oncorhynchus mykiss	LQ	6630 ~	6 623	Q 0.939	\$ 0.010°
JAU 6476- desthio	Invertebrate, acute Daphnia magna	CEC ₅₀	>10000	~>100°	9 .937	, <u></u> €0.01
	Invertebrate, acute		¥1009	₹ 10 .09 Č) 02937 Q: ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
JAU 6476-	Fish, acute Oncorhynchus mykiss	LC50	1390	× 17.9	0.110	0.01
S-methyl	Invertebrate, acute Daphn@magne	EC 50	2800	28.0 %	0 ¹¹⁰	0.004
1,2,4-Triazole	Fish, acute Oncorhynchers mykiss	LC	A9 8000 ^A		0.031	0.00001
1,2, 4- 111a2010	Invertebrate, acute	- -	>100000	>1000	\$0.031	< 0.00003
JAU 6476- 🔊	Fish, acute Onéorhymeturs mykirs	¥	Ĵ1830₩	18.3	0.046	0.003
thiazocine	nvertebrate, scute	br EC _{sto} r	4300* <u>*</u>		0.046	0.004
JAL 6476-	Fish, adute A Oncorhynchus mykiss	DC ₅₀	>100000	×1000	0.020	< 0.00002
triazofylketone	[©] Invertebrate, acute Duphniamagna	ĔĊ% ¢	>10000@	>1000	0.020	< 0.00002

Table CP 10.2-5: RAC_{sw; ac} calculations based on FOCUS Step 2 (acceptability of risk: PEC/RAC < 1)</th>

* Endpoints from parent prothioconazole from structies on first ticospecies were used for risk assessment of M12 (see Table CP 10.2-1 and MCA) point 8.2 for more details)

The TER trigger was exceeded for all organisms for prothioconazole and all its metabolites.

Chronic risk assessment for aquatic organisms

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For all metabolites where a complete chronic data package is available (e.g. JAU 6476-desthio), TER_{LT} and RAC_{sw,ch} calculations are presented below. For those metabolites where chronic data are not available for every first tier taxonomic group relevant to fungicide risk assessment (as defined in EFSA AGD (2013), TER_{LT} and RAC_{sw,ch} calculations are presented with the available studies. In addition, a complementary chronic risk assessment following the stepwise approach as recommended by EFSA AGD (see point 10.2.4 'Risk assessment scheme for metabolites', page 143) is performed in a stand-alone document (**Definition**); 2015; M-536697-01-1, KCP 10.2/02). This EFSA stepwise

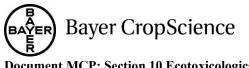
¹⁰ First the taxonomic groups relevant to fungicide risk assessment as defined in EFSA AGD (2013) are fish, invertebrates and algae. Sediment dwellers should also be considered, when metabolites accumulate in sediment (> 10% of the metabolite found in sediment at the end of the water/sediment study) and when toxicity to daphnids is expected (daphnid endpoint < 0.1 mg/L).

approach was placed in a stand-alone document because, as this approach is new, there is currently no agreed template how to formally include it in the Section 10 of the MCP Document. Further information about this approach and its results is presented after the TER / RAC tables below.

Based on the risk envelope approach, the highest PEC values were used to calculate the chronic risk to aquatic organisms. This clearly represents the worst-case situation covering all other intended uses of the product. If the trigger was not met using this calculation, worst-case FOCUS STEP 3 PEC values were used as refinement until a safe use of each intended application could be assumed.

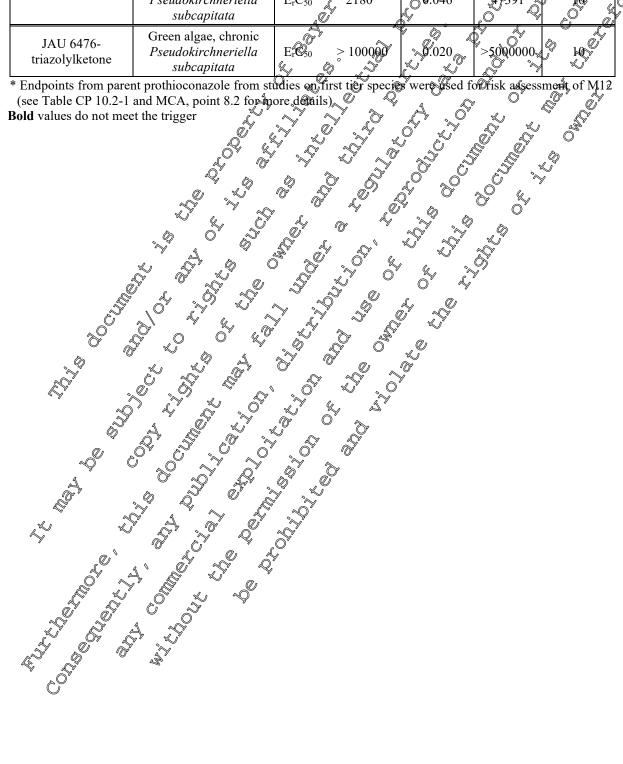
Table CP 10.2- 6:	TERLT calculations base	u on Pac US Step 2		2. 6.	
Compound	Test species	Endpoint of	PECsw, may	TERLT	Trigger
			[µg/K]	G 'Y	~
Cereals (winter/sprin	g)		<u>), 9, 1</u>		<u>à k</u> °
	Fish, early life stage	NOEC ~ 4900	£0.124	\$952	
	Invertebrate, chronic & Daphnia magna 🛷	NOEC 560	00F24	4546	6 10
Prothioconazole	Sediment dweller chronics Chironomus riparius	ROEG 2140	0.124	ک ^ت 7371 %	10
	Marine diatom, chronic Skeletonema costanum	ErC ₅₀ 46	£0.124	\$371	10
Ő	Aquaticplant, Aronic Lemna gibba	Er Q 404 0	8 M 24	Ø) ≠ > 3258	10
	Fish, early hife stage	NOEC 334	0.937	3.6	10
	Inveftebrate, Chronik Daphnia magna	NGEC S 100	0.937	107	10
JAU 6476-	Invertebrate, chronic <i>Americanysis bahia</i>	NOES 264	0.937	68	10
desthio	Sediment dweller Cheonic Chironomus raparius	NOEC 2000	0.937	2134	10
~~~ ( 	Green alga, throme Sceredesmo subspicatus	EC 50 550	0.937	587	10
	Aquatic Plant, chronic Lemna gibba	E _r Ç 80.9	0.937	86	10
JAU 6476	Sediment dwellen chronic Chironomus Charius Q	ROEC 100	0.110	909	10
S-method	Green algae, chronie Reudolfrechneriella succapitata	E _r C ₅₀ 47400	0.110	430909	10
	Fish, juvenile growth Orcorhynchus mykiss	NOEC 3200	0.031	103226	10
*1,2,4 Přiazole	Green alga, chronic Pseudokirchneriella subcapitata	$E_r C_{50} > 31000$	0.031	>1000000	10

	Å,
	"Q"
Table CP 10.2- 6:	TERLT calculations based on FOCUS Step 2



### **Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100**

Compound	Test species	Endpoint [μg/L]	PECsw, max [µg/L]	TERLT	Trigger。
Cereals (winter/spri	ing)				
	Fish, early life stage Oncorhynchus mykiss	NOEC 490*	0.046	× 10652	
JAU 6476- thiazocine	Invertebrate, chronic Daphnia magna	NOEC 560*	0.045	12174	
	Green alga, chronic Pseudokirchneriella subcapitata	ErC ₅₀ 2180*	69.046	4 ³⁹¹	
JAU 6476- triazolylketone	Green algae, chronic Pseudokirchneriella subcapitata	ErC50 > 100000	\$.020 \$.020	>5000000*	



# Table CP 10.2-7: RAC_{sw, ch} calculations based on FOCUS Step 2 (acceptability of risk: PEC/RAC < 1)</th>

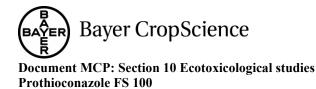
Compound	Test species	Test species Endpoint [µg/L]		RAC _{sw, ch} PEC _{sw,max} (NOEC/10)         [μg/L]           (ErC50/10)         Ο		PECARAC
ereals (winter/sprin	lg)			<u> </u>	y y	
	Fish, early life stage Oncorhynchus mykiss	NOEC	490	49.0	0.124	¢2003
	Invertebrate, chronic Daphnia magna	NOEC	₹560	\$6.0	0,24	
Prothioconazole	Sediment dweller, chronic Chironomus riparius	NOE	9140		0.134 0.134	0.0001 •
	Marine diatom, chronic Skeletonema costatum	€rC ₅₀		4.60°	€ ^{0.124}	0.03
	Aquatic plant, chronic	Er 250 ~	× 402	40.40	Q,124	<0.003
	Fish, early life Gage	NQEC	3 ³⁴	0,934	0.9 <b>2</b>	2.81
	Invertebrate chronic Daphna magka	SOEC S	× 1005	10.80°	0.937	0.09
JAU 6476-	Invertebrate, chronic Americamy & bahia	NOEC	[∞] 64 √	6.4	0.937	0.15
desthio	Sediment dweller, , chronic <i>Chirotiomus opparius</i> ,	NOF		200 200	0.937	0.005
	Green alga, chronic Scenedeswy's subspicatus		550	55 Q	0.937	0.02
	Aquativ plant chronic <i>Uemną</i> gibba		80.9 80.9	Ø8.09	0.937	0.12
JAU 6476-	Sediment dwelter, Chironic Chironomus riparin	NOES		∛ 10.0	0.110	0.01
S-methyl	Green alea, chronic Pseudalirchneriella O gibcapilgia O		47400	4740	0.110	0.00002
1,2,4 Triazole	Fish, juvenile growth Qncorhynchus mykiss >>	BOEC C	3200	320	0.031	0.0001
	Green algae, chronic Subcavitata	E So	> 31000	> 3100	0.031	< 0.00001
	f4sh, early life stage Oncorfynchur mykiss	NOEC	490*	49.0	0.046	0.001
JAU 6476-	Invertebrate, chronic Daphra magne	NOEC	560*	56.0	0.046	0.001
	Greenalga, chronic Sendokirchneriella Subcapitata	ErC ₅₀	2180*	218	0.046	0.0002
JAB 6476- triazolylketone	Green alga, chronic Pseudokirchneriella subcapitata	ErC ₅₀	> 100000	> 10000	0.020	< 0.000002

* Endpoints from parent prothioconazole from studies on first tier species were used for risk assessment of M12 (see Table CP 10.2-1 and MCA, point 8.2 for more details)

For JAU 6476-desthio the chronic trigger was not met for fish. Therefore, a refined risk assessment is required. The consideration of the more realistic FOCUS STEP 3 surface water concentrations is presented below.

Table CP 10.2- 8:	TERLT calculations for winter and spring cereals based on FOCUS Stor 3

Test species	Endpoint [µg/L]	PECsw.mrx [µg/L]	FOCUS secnario		Å.
JAU 6476-desthio, winter	& spring cereals, 1 x 1	8 g az /ha	Å		J
Fish, early life stage Oncorhynchus mykiss	NOEC 3.34	0.001	All (D100 R4)		
Table CP 10.2- 9:   RAC     acce	Csw; ch calculations for w ptability of risk: #EC/I	<b>RACC &lt; 1</b> )	ng coreals based on	POCUS Step 3	
Test species	[µg/ <b>L</b> 0(1	RAC 50 ch R NOEO/10) 7 Ec (550/10) 7	ECsw, max [µg4U]	Secenario PECRAC	
JAU 6476-desthio, winter	& spring cereals, 1 x J	8 g a.seha			
Fish, early life stage Oncorhynchus mykiss	NOCC 3.34	0.334			
The TER trigger is exceed	ed based on FOCUS	D' STEPS value	s for both winter a	nd spring cereals.	
The TER trigger is exceed					



### Stepwise approach (EFSA AGD 2013)

Siepwise approach (Ef	<u>SA AOD 2013 j</u>				aî 🛸
Report:	KCP 10.2/02	Q; ; 201	5; M-536697-01-1		
Title:	Stepwise approach f prothioconazole (for	mulated as prothiod	conazole FS 100 g/	LS following the	
	guidance on tiered ri organisms in edge-o			ducts for aquatic	
Report No.:	M-536697-01-1	Ĉa		, <u> </u>	
Document No.:	M-536697-01-1		Ŭ	Ő "Ő	Y O C
Guideline(s):	none	× 1.	Re l	U S	
Guideline deviation(s):	none	Ĵ	S.	.0 %	
GLP/GEP:	no			Q, or e	
		1 . 1 %		/1 🔊 🔊	

The EFSA AGD (2013) stepwise approach was used for an metabolites where chronic data is not available for each first tier taxonomic group@elevant to fungicide risk sessment (i.e. JAU16476-Smethyl (M01), JAU 6476-thiazocine (MA2), 1.2,4-Triazole (M13), and JAU 6476-triazolylketone (M42)). The EFSA AGD (2013) "risk assessment scheme for metabolites" (point ¥0.2.4, page 143 of the EFSA AGD) was followed, and the rationale for decision at each step of the cheme was explained in detail.

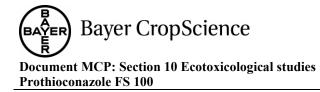
### **Overall conclusion**

In conclusion, a chronic risk assessment of all major aquatic metabolites of prothioconazole was provided addressing risks togall first tier axonomic groups fincluding sedment dwellers, where relevant). The 'classical' approach base on TPR- and RAC calculations as presented above was combined with the new stepwise approach from the OFSA & GD (2013) (see and , 2015). Based on the results from this combined approach, a low chronic risk is concluded for all aquatic metabolites oprothioconazoe. For each of the assessed metabolites the chronic trigger is met for all evaluated scenarios. Consequently, a safe use san be assumed according to the proposed GAP.

	A Y
CP 10.2.1 Acute toxicity to fish aquatic invo	ortebrates, or effects on aquatic algae
and macrophytes of or or	
<b>Report:</b> A KCP 10, 21/01 2015, 41-52	
Title: Acute Acute Toxicity of protheoconazole FS 1	100 G to fish (Oncorhynchus mykiss) under
static conditions	
Report/No.: 🗸 E 203 4790-1	
Document No.: $M^{2}-525350-01-1$	
Guideline(s): US EPA OCSPP 850 075; EPA-FIFR	RA § 72-1/SEP-EPA-540/9-85-006
(1982/1985) OCSPP 850.1075 (Public	c Draft, 1996); Council Regulation (EC) No
کې کې 4407/2008, C.1 (2008); OECD No. 203	(rev.1992); JMAFF, 12 Nousan No. 8147
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
Guideline deviation(s): none	
GLP/GÉP: 5 5 yes	
Obviortive	

Objective

The aim of the study was to determine the acute toxicity of Prothioconazole FS 100 to the Rainbow trout (Oncorhynchus mykiss), expressed as 96 hours LC₅₀.



Material and methods:

Test item: Prothioconazole FS 100 G, analyzed content a.s. content: 97.86 g/L (8.47 % w/w); Batch No 2015-001031, Specification No. 102000006421, TOX10850-00.

Rainbow trout (Oncorhynchus mykiss), mean body length 5.6 cm, mean body weight 2.6 g fish batch (Lot F 4/15) was delivered on February 12, 2015. The biomass loading for this rest was 0.650 g fish / L test medium.

The test was conducted according to FIFRA Guideline 2-1, OCSPP \$50.1075, QCD TO 203 and JMAFF, 12 Nousan No. 8147. Ten fish in each test level were provided for 96 hours under static conditions to nominal concentrations of 1.28, 2.82, 6.20, 13.6 and 30,0 mg ptod./L A control with further 10 fish was tested in parallel. Dissolved xygen conceptrations ranged from 70 % to 100% oxygen saturation, the pH values ranged from 6.6 to 7.3 and the water temperature anged from 128 °C to 13.6 °C in all aquaria over the whole testing period. Prothioconazole was analyzed in all test levels after 0 hours, on day 2 and on day 4 of the exposure period to confirm nominal concentrations. In fase 100% mortality occurred in a concentration prior to test terponation, the analytical determinations in this concentration were conducted at the respective assessment date Endings: Validity criteria: All validity criteria were met as presented below:

Table CP 10.2.1- 1	Validity cri	iteria 🏅 🗳	Č	§* «	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
Validity criteria	<u> </u>		Recomin	nended		Obtained
Mortality within the period	he 48-hour settlin	n S	$\sum_{n=1}^{n} \sum_{n=1}^{n} \sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i$			< 5 %
Mortality in the	ontrolo				Ø [™]	0 %
Dissolved oxygen test	same ation throug				7	0 % 104 %
pH variation			S S	.0 0		0.7
		× . 6 ⁴	J 4	AN A		

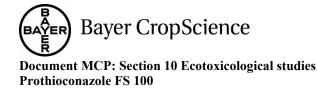
Analytical results

The chemical analysis of prothocon fole (m water by HPCC - UV) revealed that measured recoveries at experimental start ranged from 109 to 4,5% of nominal values, confirming the correct application of the test item. On day 2 the recoveries were between 70 and 94% and were between 47 and 90% at test termination. The mean accovery over the whole testing period of 96 hours was 47% to 115% of nominal. Due to the dissipation of prothioconazole in aqueous solution (mean measured concentration were below 80% of nominal values), the biological results are based on geometric mean measured concentrations of prothioconazole, The geometric mean measured concentrations of prothioconazole were recalculated to the following formulation concentrations: 0 (control), 0.926, 2.23, 5.08, 10.6 and 29.2 mg prod./L.

In the controls no portalities or sub-lethal findings were observed.

In all test levels ≥ 5.08 mg prod./L behavioral changes were observed during the entire exposure period. After % hours of exposure to the nominal concentration of 5.08 mg prod./L ten fish showed the following behavioural symptoms:

• remaining for unusually long periods on the bottom of the aquarium



- showed labored respiration
- strongly extended gills
- reduced activity; apathy

 showed lab 	ored respiration	on				_ 0	
• strongly ex	tended gills),
• reduced act	ivity; apathy					N N	,
Table CP 10.2	2.1-2: Effe	ct of Pro	othiocon	azole FS 100 G o	on <i>Oncorhvnchu</i>	s mykiss	
Test iter					onazole FS 100		
Test spec					Spheric mykiss		0
Exposur					rs static design		,Ø
	ire time	4 ho	ours	24 hours	48 hours	72 hours 96 hours	V
Test conc.	Geometric	no.	%	no.	no. 🦓	no. W & no. W	
nominal	mean	of	dead	of dead	of 🔷 dead	of dead of dead	
[mg prod.	[mg prod. /	dead		deard or	dead dead	defid 🖉 vierad 🖉	
/ Ĺ]	L]						
control	control	0	0		$\emptyset 0 $ $\emptyset 0$		
1.28	0.926	0	0				
2.82	2.23	0	0,©'		~0´		
6.20	5.08	0	,Ô ^v	\$0,\$0,			
13.6	10.6	0 ,	$\hat{0}^{\vee}0$				
30.0	29.2	0 🥡	× 0,,		\$ 0		
LC ₅₀ 96 ł	10urs (95% C	C.I.),	°~	<u>~</u> [16.4	mg prod/L (C		
	LOEC:	~	\$~ .		y 5.08 mg m	d./L. Q	
	NOEC: 🗞			<u> </u>	2\\$23 mg/pro		
	(no mortality		Ø		0 ⁹ 10.6 mg pro		
LC ₁₀₀ (1	00 % mortali	ty)	Š	<u>a 5 ×</u>	∫ 29.Ŷmg pro	ď./L ()	

Effect of Prothiocopagala ES 100 (Table CP 10 2 1- 2.

C.I.: Confidence interval

6) n.d. not determined due to mathematical reasons or inappropriate data

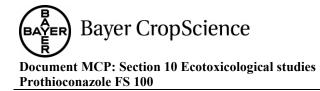
Ċ

~ Conclusion: Based on recalculated geometric mean concentrations, the LC₅ after 96 h of static exposure to Ś Prothiocoraole FS 100 @ was 6.4 mg prod. (L.

Å

Report: @ KCP/0.2.1/@
Title: \bigcirc Active toxicity of prothioconazole FS 100 G to the waterflea Daphnia magna in a
static laboratory test system _
Report No. $\mathcal{O}E 202\mathcal{A}719-5 $
Document No.: M-525311-01-1
Guideline(s): USEPA OCSPP \$0.1010 OECD guideline 202,(2004); EC Council Regulation No
[*] 4 0/2008, Method C.2 (2008); U.S. EPA P.A.G., Subdivision E, § 72-2 (1982);
OPPT Guide and 850 1010 public draft 1996 (modified); JMAFF 12 Nousan No.
× <u></u> <u></u> <u>814</u> (2000)
Guideline deviation (s): note
Objective: & A v

Objective: Or Solution of the study was performed to detect possible effects of Prothioconazole FS 100 on mobility of *Daphnia* magna soused by 48 hours of exposure in a static laboratory test system, expressed as EC₅₀ for immobilisation.



Material and methods:

Test item: Prothioconazole FS 100 G, analyzed a.s. content: 8.47 % w/w, Batch No. 2015-001031 TOX10850-00, Specification No. 102000006421 (V.5).

The test was conducted according to OECD Guideline 202, FIFRA Guideline 72-2, OPPTS Guideline 850.1010 and JMAFF 12 Nousan No. 8147. Daphnia magna (1st instars <24 h old, 6 × 3 animals per@ concentration) were exposed in a static test system for 48 hours to nominal concentrations of 0, 0.5, 2.0, 4.0, 8.0 and 16 mg prod./L without feeding.

The content of prothioconazole in exposure media was measured for verification of the test item concentrations.

The test vessels consisted of 100 mL glass beakers, individually labelled and filed with 50mL of the test solution (10 mL test solution per daphnid). Groups of the animals were randomly assigned to individual test vessels (replicates). The test solutions were not artificially berated during exposure. After 24 and 48 hours, behaviour of the water fleas was visually evaluated by counting mobile daphnies, defined as animals with swimming movements (slight provenuents of antennae were not interpreted as swimming movement) within approximately 3 seconds after gentle agitation of the test vessel Water temperatures within the test system were recorded at startand and of exposure from one vessel of the untreated control group and of the highest treatment group, using a hand-held measuring device. PH-value and of dissolved oxygen were determined for all freshly prepared solutions (batch sample) and again in the aged solutions (composite coplicates) at the end of exposure periode. \bigcirc

Findings:

Findings:			
Validity criteria:			
All validity criteri	a were met as presented	Below of the offer	4 Y
•	a were met as presented		D,
Table CP 10.2.1	Salidity criteria		
Validity criteria		Recommended	Obtained
Control mortality		$ \begin{array}{c} & & \\ & & $	0.0%
Analytical results		S 47 K A	

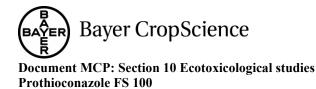
Analytical results:

The chemical analysis of prothice on azole in the freshly prepared test solutions at test initiation revealed measured conceptrations between 110% and Y20% mean Y16%) of the aspired nominal concentrations. Concentrations in the aged ost solutions at the end of the 48 hours exposure period ranged between 37% and 71% (mean: 49%) of nominal. No contaminations of prothioconazole were detected in samples from untreated water control. Due to the dissipation of prothioconazole in aqueous solution (mean measured concentration were below \$0% of pominal values), EC₅₀ calculations were performed for recalculated test concentrations, based on the geometric mean values of the measured a.s. concentrations.

Biological results:

No immobilities of other effects on behaviour occurred in untreated control within 48 hours of exposure. Effects of the mobility of dapphids in treated vessels are presented below. Observations on sublethal effects revealed no abnormal behaviour of the exposed daphnids over the entire exposure period of 48 hours

EC% alues for immobilization after 24h and 48h of exposure were calculating using probit analysis.



able CP 10.2.	I-T. Ellett	1110tinoconaz	ole FS 100 G on	Duphhia magn	u	@ °
Test	t item		Proth	nioconazole FS	100 G	
Test species				Daphnia magna	ı	N C
	osure			ite, static laborat	tory 🔊	
Test con	centration	Exposed	24	h		8 h 🦘 🔍 🖓 🍆
[mg p	rod./L]	daphnids			.1	
Nominally	Recalculated	(=100%)	n	%	N 🦻	V . %
control	0	30	0			
0.5	0.3	30	0	0.0	0_0	
1.0	0.8	30	0	0.0	90	
2.0	1.3	30	Ø	0.0	° A A	0.0
4.0	2.8	30				
8.0	7.1	30	& 0 ذ		× 9,0°	°∼y 30.°€y
16.0	12.1	30	° Z (2303 ?		63 .3 °
		1				
Probit	EC		lower !	95% Ctl 🗸	s tipper	95% cl
analysis for					¶l ⊚Vmati	nam / (
data	Nominally	K© [∞] ×	nomunally	^v recalizulated	Adminately	recalculated
obtained		calculated by			Aminat	»by measured
after		measured		as. content	Johnmany	a.s. content
		S. content	r fr			
24 hours	30.0 🖋	23.1 ×	n.d.	n.d. 🤇	n.d. O	n.d.
48 h	12.2	<u>9.8</u>	<u>9.1</u>	7.7	<u>مَحْ 18.3</u>	13.7

Table CP 10.2.1- 4:	Effect of Prothioconazole FS 100 G on Daphnia magna
	Effect of Fromocondente For For G of Duplinum mugnu

Conclusion: The EC₅₀ value for immobilization after 48 h of static exposure to prothioconazole FS 100 G was 9.8 mg prod. (b) based on mean measured concentrations.

Report:
Title:KČP 10.221/03x = 2015x =

Document No.: M-525317+01-1 Guideline(s): DECD Guideline 201: Freshwater Algo and Cyanobacteria, Growth Inhibition Test

Guideline devotion(s

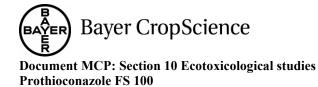
Objective:

The arm of the study was to determine the influence of Prothioconazole FS 100 on exponentially growing populations of *Pseudokirchneriella* subcapitata expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).

Material and methods

Test item? Prothioconazole FS 100 G analysed content: 8.47 % w/w prothioconazole, Batch No. 2015-001031, TOX 10850500, Specification No. 102000006421.

The test was conducted according to OECD Guideline 201. *Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multigeneration test for 72 hours under static exposure conditions to nominal concentrations of 0.954, 3.05, 9.77, 31.3



treatment groups and in the controls at test	
The pH values were 8.0 in the control replic	cates and the incubation temperature ranged from 22,3 °C to
23.5 °C (measured in an additional incub continuous illumination of 4.67 klux (mean	value).
Findings:	
Validity criteria:	
All validity criteria were met as presented b	pelow: L O ^A L O ^A Q
Table CP 10.2.1- 5: Validity criteria	
Validity criteria	Recommended S Obtained
	Recommended Obtained Obtained Stactor of ≥1 (Within 22 h
Validity criteria Control biomass increase Mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2, and 2-3) in the control cultures	
Validity criteria Control biomass increase Mean coefficient of variation for section-by- section specific growth rates (days 0-1, 1-2)	Factor of ≥ 16 within 12 h \sim 57.6

Analytical results:

 \bigcirc The analytical findings showed that prothioconfizole concentrations on day 0 in the treated vessels ranged between 86.1% and 103 % of nominal (average 93.4%). After 72 hours, concentrations ranged between 55.3% and 91,3% of forminal (average 65%). Due to the dissipation of the prothioconazole in aqueous solution (recan measured concentration) were below 80% of nominal values), endpoint values were based on geometric mean measured test concentrations of the formulation. Geometric mean measured concentrations were 6,659, 2.24, 7.36, 25.7 and 974 mg grod./ Respectively.

Biological results:

0 The static argae growth inhibition test provided the following tabulated effects after 72 hours. No effect occurred in untreated control within 72 hours of exposure.

0

		Y N	•
Test item		Prothioconazole FS 10	0 G
«Test species		Reudokirchneriella subco	apitata
Exposure	J G Y	🖉 Growth inhibtion test, '	72 h
geo mean meas.	🧳 cell number	(0-72h)-average specific	inhibition of average
_w concentration	A ster 720h N	growth rates	specific growth rate
[mg form./L]	(means) per ml	[days-1]	[%]
contro	578/000	1.351	0.0
0.659	\$ \$10 000 ×	1.304	3.5
284 2	526,000	1.320	2.3
7.36 5	స్ 254 000	1.077	20.3•
	55 000	0.547	59.5•
97.47	K 6 000	-0.173	112.8•

Effect of Prothioconazofe FS 100 G on Pseudokirchneriella subcapitata Table CP 10.2.1- 62

test initiation with 10,000 cells/mL

• significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure Ĉì

Based on these results, the ErC₅₀ were estimated to be 18.6 mg prod./L and the NOErC was 2.24 mg prod./L.

Conclusion:

After 72 hours of exposure, the ErC50 for Prothioconazole FS 100 G for the green Pseudokirchneriella subcapitata was 18.6 mg prod./L (95% CI: 16.2 – 21.3 mg corm./L).

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms. No further testing of the Prothioconazole FS 100 formulation has been performed nor is is required. Additional long-term and chronic toxicity studies on fish, aquatic

Further testing on aquatic organism

 CP 10.2.3
 Further testing on aquatic organisms

 No further testing of the Prothioconazole FS to0 formulation has been performed nor is it required.

 CP 10.3
 Effects on arthropods

 CP 10.3.1
 Effects on bets

 The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namedy the FU devidence.

 preparation and submission of this dossier namely the EU Buidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev2) and EPPO Standard PP 3/1093 Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees

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

- Acute oral and connect toxicity of prothioconazole and the representative formulation Prothioconazole FS 100, 🖉
- Acute orgenind contact toxicity of JAUG476-desthic (metabolite of prothioconazole),
- Acute contact exicits of proffiocon zole to adult bumble bees under laboratory conditions,
- Chronic 10 day toxicity test with of Prothioconazole SC 480 on adult bees under laboratory conditions,
- Colony feeding study with Prothio conazole SC 480 according to Oomen et al. 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood
- (eggs, young and old larvae) and heir development, nurse bee on-going behaviour in brood care and colony strength),
- Semi-field brood feeding study with Prothioconazole EC 250 following OECD guidance document 15 (using a more realistic spray scenario onto flowering *Phacelia tanacetifolia* at the maximum application rate for the approval renewal of prothioconazole and covering exposure For effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with prothioconazole and its metabolite JAU 6476-desthio are presented together with the ecotoxicological endpoints in MCA, Section 8, Point 8.3.1, as well as within the existing Review Report for prothioconazole (SANCO/3923/07 - 10.December 2007, for Annex I inclusion under Directive 94/414/EEC). Furthermore, contact laboratory toxicity data for bumble bees indicated that non-*Apis* bees are not more sensitive than honey bees and consequently the risk assessment for honey bees is considered to protective to other bees.

The acute toxicity test conducted with the formulation Prothioconazole FS 100 jcpresented in this MGP document.

A summary of the critical endpoints of prothioconazole, its metabolite JAU 6476 desthio and the formulated product Prothioconazole FS 100 are provided in the following tables. Endpoints show in bold are considered relevant for risk assessment.

Table CP 10.3.1- 1:	Critical endpoints for prothing	nazole.	JAÛ 647	76-desth	io and	Protin	ocon <i>á</i> zo	le FS400
	– acute toxicity to adult bees	(h)	, de la	5.	Ø	ð'	\sim	J.

			8
Test substance	Test species	C Endpoint of	Reference 2°
	Honey bee (controt 48 h)		M-505379-01-1
	Honey bee (or 148 b)	ED ₅₀ ≥105.1%µg a.s./bee	KCA 8.3.19.1/02 KCA 8.201.1.2/02
Prothioconazole	Honey bee (contact 48 kg		M-023105-01-1
	Hop & bee (Stal48 b)	9D50 \$71 µgas./ba	KGA 8.3.1.1.1/01
	Bumble bee (contact 48 by (Bombus tempestris)	^μ ^μ ^μ ^μ ^μ ^μ ^μ ^μ	(2015) M-521802-01-1
	Honey, bee (oral 48 h)	LD5 >196.5 µg p.m./bee	KCA 8.3.1.1.2/04 (2015) M-528139-01-1
JAU 6476-destatio		LD ₅₀ >100 ag p.m./bee	KCA 8.3.1.1.1/03 KCA 8.3.1.1.2/03
Prothio onazole	Honey bee (or 148 h)	LD ₅₀ ~106.1 fig a.s./bee	(2015) M-521546-01-1
A 100	Horrey bee (contact 48 h)	⁰ LD ₂₀ >1000 μg a.s./bee	KCP 10.3.1.1.1/01 KCP 10.3.1.1.2/01
Bold values used in risk	assessmen assessmen	Ŭ ô	

a.s.: active substance; p.no.: pure netabolic

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

Test substance 🔍	Test species		Endpoint	Reference
Prothioconazole SC 480	Broney bee Laboratory chronic (10 d) (adults)	LC ₅₀ LDD ₅₀ NOEC NOEDD	> 100 mg a.s./kg >3.8 μg a.s./bee/day 100 mg a.s./kg 3.8 μg a.s./bee/day	(2015) M-528888-01-1 KCA 8.3.1.2./01
a.s. = active substance				

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

Prothioconazole SC 480Bee brood feeding test (Oomen et al.)No adverse effects on brood development, mortality and behaviour after feeding honey bee colonies sugar syrup at 0.47 g a.s./L.M-478670-0121 KCA 8.3.120/01Prothioconazole EC 250Semi-field brood study, OECD 75No adverse effects on brood development, mortality, foraging condition and strength after application of \$87.5 g @s./ha onto flowering Ph@celia.agnacetifolia.M-478670-0121 KCA 8.3.120/01	Test substance	Test species	Endpoint	Reference
Prothioconazole EC 250 Semi-field brood study, OECD 75 development, mortality, foraging Condition and strength after Sepilication of \$7.5 g @s./ha onto		Ŭ	development, mortality and behaviour after feeding honey bee colonies sugar syrup at	M-478670-0121
			development, mortality, foraging activity, behaviour, colony Condition and Grength after	

Risk assessment for bees

The risk assessment for bees is based on the maximum single oplication rate of prothioconazole 18 g a.s./ha and 180 mL Prothioconazole F\$ 100/hc in cereals.

Hazard Quotients

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

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

According to the use pattern of Prothioconazole FS 500 as a seed treatment, direct oral or contact exposure of bees to the product in becrelevant matrices like nectar and pollen is not to be anticipated. Since howevees are not exposed to be relevant matrices like nectar or pollen, no unacceptable risk is to be expected and therefore the calculation of hazard quotients (Q_{HO} and Q_{HC}) is considered to be an unrealistic worst case assumption.

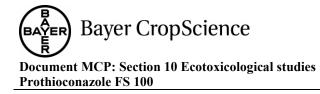
Hazard Quotient, oral: $Q_{\mu\nu}$ $max. appl. rate = \frac{g_{\mu\nu}}{\mu\nu} a.s./ha or g total substance/ha]}$

Hazard Quotient, contact: $P_{\text{He}} = \frac{p_{\text{He}}}{p_{\text{He}}} = \frac{p_$

Test substance	Crop	LD50 [µg/bee]	Application rate [g/ha]	Hazard quotient Qho	Trigger
Ptothioconazole F\$2100	Cereals	>106.1	18	<0.2	50
Prothjoconazole	Cereals	>105.1	18	< 0.2	50
JAU6476-desthio	Cereals	>106.5	18 ^A	< 0.2	50

Table CP 10.51-4: Hazard quotients for bees – oral exposure

^A The hazard quotient for the metabolite JAU-6476-desthio was calculated with the application rate of the parent



compound prothioconazole - representing a worst-case

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

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

	-		- 4		
Test substance	Crop	LD ₅₀ [µg/bee]	Application rate	Hazard quotient	Ø
Prothioconazole FS 100	Cereals	>100			
Prothioconazole	Cereals	>200		$Q^{\vee} < 0.1$	
JAU 6476-desthio	Cereals	>100			

A The hazard quotient for the metabolite JAU-6476 desthip was calculated with the application rate of the parent compound prothioconazole – representing a worst-case 🔬

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

Further considerations for the risk assessment

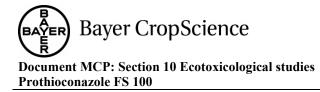
In addition to acute laboratory studies with addit honey bees, protheconacole was further subjected to S.; 2015; M-52180201-1, KCA 8.3.1.1.004). The study topical acute bumble bee testing (resulted in an LD50 of > 100 µg a.s. bumble bee and did not reveal sensitivity differences between honey bee and bumble bee foragers.

Moreover, prothiocomazole was further subjected to chronic laboratory testing with adult honey bees , S.; 2015, M-528, 88-01, P, KQX 8.3.1, 2/01)

This chronic study was designed as a limit test by exposing adult honey bees for 10 consecutive days to a nominal concentration of 190 mg prothioconazo e/kg feeding solution. The actual test was conducted by using the formulated product Prothioconazoic SC 480. After exposing honey bees for ten consecutive days exclusively to sugar solution containing prothoconatole, the 10 day LC₅₀ (Lethal Concentration) was determined to be 100 mg prothioconazole kg, which corresponds to a LDD₅₀ (Lethal Dietary Dose) of > 3.8 µg \$ /bee/day. The respective DEC No Observed Effect Concentration) for mortality was determined to be 100 mg prothio conazole/kg, which corresponds to the NOEDD (No Observed Effect Dietary (Dose), $G^{2} > 3.8 \mu g$ as (bee/dQ)

In order to reveal whether protoconarole poses a tisk to immature honey bee life stages, a bee brood , A.; 2014; M478670-01-1, KCA 8.3.1.3/01) has been conducted feeding Study (by following the provisions method of (OEPP/EPPO Bulletin 22:613-616 (1992)), which require, monogst other parameters to "...use formulated products only... products are fed at a concentration recommended for high-volume use...". The honey bee brood feeding test ioa worst² 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 which at very high concentration) and by investigating the development of eggs, young and old larvag by employing digital photo imaging technology.

This particular study was conducted with Prothioconazole SC 480. The administration of prothiocolazole at a concentration of 0.47 g a.s to honeybee colonies via feeding of 1 litre spiked sucrose solution has neither resulted in adverse effects on brood development, worker or pupal mortality, nor in behavioural abnormalities as compared to the control. Regarding brood development, the brood termination rates of the test item treatment were overall on a low level with 16.0, 12.4 and 3.6% for



eggs, young larvae and old larvae, respectively, which were not statistically significant different to the control with brood termination rates of 17.8, 10.2 and 6.47% for eggs, young larvae and old larvae, respectively at the end of the brood observation period.

In order to clarify whether prothioconazole 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 tig semifield honey bee brood study (according to the provisions of the OECD Guidance Document \$\[15]) was conducted under forced/confined exposure conditions using the formulation Prothigeonazoe EC 250, by application of 187.5 g a.s./ha under tunnel conditions to the full flowering and bighly bee attractive , R.; 2015, M-532419-00-1, KCA 8.3(1.3/02). surrogate crop Phacelia tanacetifolia (The study included three treatment groups: Control (tap water), Test item (187.5 g a.s. Dia and Reference item (300 g fenoxycarb/ha) with all applications being carried out with a sprag volume of 400 L water/ha. For all treatment groups, four replicates (turnels) were setup. The application of all treatments was conducted during daily bee flight activity at the time of full lowering of the crop. The fafter 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 26 after treatment). Daily, throughout the confined exposure phase, mortality of worker bees, larvae and pupae was assessed 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 800 day 26 after treatment). Colony assessments (food stores, brood areas, colony strength) were made before confinement, after confinement and at the end of the study. Detailed brood assessments (brood termination rate, brood index and brood compensation index) by employing digital photo imaging technology, jovestigating the fate of more than 200 individually marked cells was performed on Speccasions throughout the study, covering an entire brood cycle of honey bees. Ô

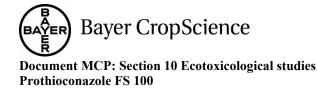
The application of prothioconazole at the rate of 487.5 g a.s./ha under tunnel conditions to the full flowering anchighly bee arractive surrogate crop Phycelia chacetefolia did not cause any adverse effects on mortality, flight intensity, brood development (brood termination rate: 46.6%, brood index: 2.7, compensation index. 3.8 is test item compared to the control with brood termination rate: 30.6%, brood index: 3.5, compensation index: 4.0% as well as on colony strength and condition. Neither brood termination rate nor brood or compensation index overe significantly different in the test item as compared to the control, indicating that these indices performed comparable to the control, including compensations of previous brood losses.

All in all at can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study (Oonen et a) and OECD Guidance Document 75) investigating side effects on immature honey bee life tages, that prothioconazole is of low general intrinsic toxicity to honey bees.

Synopsis

<u>Synopsis</u> Prothiocompose of low acute toxicity to honey bees, with LD₅₀ (oral and contact) above the highest tested dose levels.

The calculated Hazad Quotients for prothioconazole are below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be expected at the maximum envisaged application rate. This conclusion is confirmed by the results of the bee brood feeding study as well as by the results of the bee brood semi-field study, which covered the maximum application rate of 187.5 g a.s./ha.



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

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

Regarding potential side effects of prothioconazole on immature honey bee life stages, the conducted bee brood feeding study (., 1992) found no statistically significant differences between test item and control in brood termination rates of eggs, young and old farvae at 0.47 g a.s./ Over all the study revealed no adverse effects on the survival of adult bees and Qupa and bee behaviour. Thus, when considering the severity of the exposure situation if this worst case score ing test in Combination with the absence of effects on the overall development of bee brood, it can be concluded oven on the basis of this worst-case screening study that the use of protheconazole does not pose an unacceptable risk for adult honey bees, immature honey bee life stages and honey bee colonies.

In order to clarify whether the conclusions on the basis of lower tiered honey bes studies are correct, prothioconazole was subjected to confined semi-field testing (according to the provisions of OECD Guidance Document No. 75), by applying the rate of 1873 g a 97 ha to Full-flowering Phace ia during honey bees actively foraging on the crop, This study design is from an apidological and apicultural point of view more realistic than an in hive weding of the sest compound via a weated Sugar solution, which contains the test substance at a concentration typically present in the spipay tank (and as such at a very high concentration). The results of this higher for semi-field study confirmed the conclusions made above on the basis of the outcome of the lower need studies as no adverse director delayed effects on mortality of worker bessor pupae, for aging activity Dehaviour, colony strength and colony development as well as the development of bee brood were observed, even under aggravated, forced exposure conditions and by fitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.«

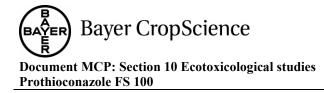
Conclusion

Š Overall, it can be concluded that pretrioconazole when spplied as a seed treatment in cereals at the maximum application rate of 8 g a.s./ha for Prothjoconazole FS/100 does not pose an unacceptable risk to honey bees and honey bee colonies.

, L

CP 10.3.1.1	Acute toxicity to bees
CP 10.3.1.1.1	Acute oraptoxicity to bees 2
Report:	K CP 10.3. 0.1.1/0 =; 2015; M-521546-01-1
Title.	Bothiogonazole PS 1000G: Effects (Acute contact and oral) on honey bees (Apis
. O	mellifera L.) is the laboratory
Report No.:	A 100651035
	M\$21546-01-1
Guideline(s):	CLP compliant study based on OECD 213 and 214 (1998))
Guideline deviate	n(s): not specified
GLP/GEP:	yes yes
Objectives	

The purpose of this study was to determine the acute contact and oral toxicity of prothioconazole FS 100 G to the honey bee (A. mellifera L.). Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.



Material and methods:

Tetst item: Prothioconazole FS 100 G, analysed a.s. content: 97.86 g/L (8.47% w/w); Batch Ng 001031, TOX10850-00; Specification No.: 102000006421.

Under laboratory conditions Apis mellifera 50 worker bees per dose were exposed for a house to aò single dose of 100.0 µg a.s. per bee by topical application (contact limit test) and 50 worker bees per dose were exposed for 48 hours for feeding (oral limit test, value based on the actual intak of the fest item) to a single dose of 106.1 µg a.s. per bee. During the test, the week were kept in an incubactor in complet darkness (except during observation). The temperature was 25°C and the relative humidity was between 38 and 70%. Findings: Validity criteria: All validity criteria were met as presented below; Table CP 10.3.1.1.1-1: Validity criteria between 38 and 70%.

	Ó [¥]	<u> </u>	<u> </u>	
Validity criteria	~~ . Q		Recommended 30	O Obtained
Control mortality			$\geq 10^{-70}$	Oral test: 0.0%
LD ₅₀ of Reference item			ontaet test (24h): \$0.30 µg a.s./bee Øral te® (24h): 0-0.25 µg a.Øbee	Contact test: 0.23 μg a.s./bee Oral test: 0.12 μg a.s./bee
	1. × ×		Nº 0	· W

Biological results:

Contact Test: Anthe end of the contact toxic by test (48 hours after application), 2.0% mortality occurred at 100.0 µg a.s./beenTherewas 6.0 % mortality in the control group (water + 0.5% Adhäsit). No test item induced behavioural effects were poserved at any time on the contact toxicity test.

2

Oral Test: In the oral toxicity test the maximum nominal test level of prothioconazole FS 100 G (i.e. 100 µg a.s./bee) corresponded to an actual infake of 06. µg a.s./bee. This dose level led to 16.0% mortality after 48 hours in the control group (50 % w/v sperose solution = 500 g sucrose/L tap water), no mortality ocurred During the 4/24 and 48-hrs assessments 1 - 3 bees were behaving abnormal (e.g. moribund), respectively.

Effect of Profiliocom vole F 100 G on Honey bees (Apis mellifera) -Table CP 10.3.1.1.1-2 contract & or al test

Test j@m	Prothi	oconazole FS 100 G
Test pecies		Apis mellifera
Desaure	Contact (Solution Adhäsit (0.5%/water)	Oral (sucrose solution)
Application of [µg, ¹ , ¹ , ¹] a.g. ² bee]	100	106.1
LD ₅₀ [µg a.s./bee]	>100	>106.1

Conclusion:

The toxicity of prothioconazole FS 100 G was tested in both, an acute contact and an acute oral toxicity test on honey bees. The contact LD₅₀ (48 h) was $> 100.0 \ \mu g$ a.s./bee. The oral LD₅₀ (48 h) was $> 100.0 \ \mu g$ a.s./bee. μg a.s./bee.

2015; M-521546-0

CP 10.3.1.1.2 Acute contact toxicity to bees

KCP 10.3.1.1.2/01

Report: Title:

Report No.: Document No.: Guideline(s): Guideline deviation(s): **GLP/GEP:**

Prothioconazole FS 100 G: Effects (Acute contact and oral) on heavy mellifera L.) in the laboratory 100051035 M-521546-01-1 (GLP compliant study base not specified ves

Same study as mentioned above. Pleas

Additionally, an acute contact texicity study was constructed on buomble bees with proteconazole; the corresponding summary is provided in Document MCA, Section 8.301.1 , S.; 2015; M-521802-01-1, KCA 8.3.1.1/2/04).

CP 10.3.1.2 Chronic toxicity to bees

A 10 day chronic fal toxicity study was conducted with ProthioconazoleSC 480; the corresponding summary is provided in Document MCA. Section(8.3.1 S. 2015; M-528888-01-1, KCA 8.3.1.2/01).

Effects on honey bee development and other honey bee life stages CP 10.301.3

A honey bee brood freeding study according to the method of Oomen et al. 1998 (. S.: , A.; 2014; MA78670-01-1 KCA S3.1.3(01) has been conducted with Prothioconazole SC 480 and is included in Document MCA, Section 8.3 P.3.

A semi-field boney bee broad study (according to OECD 75) (M. R.; 2015; M-532419-01-1, KCA 8.3.1.3/02) has been conducted with the Protheoconarole EC 250 and is included in Document MCA, Section \$3.1.3.

SubMethal effects **CP 10.3.1.4**

There is no particular study design first guideline to assess "sub-lethal effects" in honey bees. However, in each laboratory study a well as in any higher-tier study, sub-lethal effects, if occurring, are described and in the eports under other points of chapter CP10.3.1.

Cage and tunnel tests

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

CP 10.3.1.6 Field tests with honeybees

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

Effects on non-target arthropods other than bees **CP 10.3.2**

Prothioconazole FS 100 is a seed dressing product that is applied on cereals. The maximum? recommended rate is 0.18 L product/ha which corresponds to 18 g protheconazole/ha/In the case of a seed treatment the Guidance Document on Terrestrial Ecotoxicology (SANCO2103292002-final) recommends that the risk assessment for non-target arthropods should be covered with studies and the corresponding risk assessment for soil macro-invertebrates Hypoaspis' acuteifer and/or Folsonija candida. Data for H. aculeifer and F. candida and the corresponding risk assessment are presented in chapter CP 10.4.2. ÷

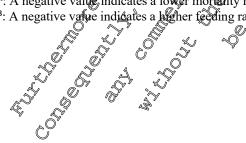
The study results for soil dwelling non-target arthropods for the spray formulation Prothoconazole EC 250 are presented below (see Table CP. 10.3.2-2) as additional information to the date from formulation Prothioconazole FS 100 (See Table CP 10.3.2 7). Alt these studies were saluated during the last EU evaluation and summaries of these studies are available in the original DAR for the first Annex I inclusion.

Table CP 10.3.2- 1:	Prothioconazole	FS 100	g/L:Æc	otoxicol	ogicał	endpoi	nts fotos	oil dwelling non-targ	et
	artheopods 🔿 🎽	Ň		°U r	<u>ر</u>	, Ş			

	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		ý _Q `	V _V Y		
Test organisms,	Tested for anulation	n, stu <b>Ø</b> type		Ecotoxicolo	gical endpoint	
Reference	<b>Oxposur</b> O	0.5	N O	o ^N 4	, ^У ,	
	▼DT7 ≴ፍ 100 ON	~(~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~ 0	6		
M-03837 <u>6-03-1</u>	Extended htb., dress	sed winter	Y 57 Q	, , , , , , , , , , , , , , , , , , ,		
Poecilus cupreus M-038376-03-1 Rep.No: Rep.009	voeat seeds in stand	dard 🞯 il 🧳	Corr. Kor	tality [%]	Effect on Feed	ing Rate [%]
, 2002	LUFAZ.1)	, × , Ø	G Corr. stor	, O	(day 1-7)	(day 8-14)
KCP 10.3.2.3.01	L 2 ^{32.47}	Sed winter dard onl Ag a.s. A		K) F	5.6	8.6
Aleochard						
	PUZ FS PW	wheat Wheat	K Å			
M-058111-01-1	Extended laberaress	sed wheat				
Rep. No: 12342071	seeds in stardard se	il (LUF @ 2.1)	Effect on Re	eproduction	[%]	
, 2002	Q \$19.340	′gas,∕ha .⊖	© Effect on Re	11.2		
KCP 10.3.2.2/04		g as ha d wheat il (LAFA 2)				
Pardosa spec.	PTZ 55 100	Q' Q'	Ô			
M-030622-0	Extended S., dre	ed wheat 🔍				
Rep. No: IK 72501	seeds in standard so	il (LSFA 2 💙	Corrected Mort	tality [%]	Effect on Feed	ing Rate [%]
¢2000	S A 273	@a.s./hay	-3.1 ^A		-18	В
KCP 10/3.2.2/02						

^A: A negative value indicates a lower mortality rate in the treatment than in the control.

^B: A negative value indicates a higher feeding rate in the treatment than in the control.



# Table CP 10.3.2- 2: Prothioconazole EC 250 g/L: Ecotoxicological endpoints for soil dwelling non-target arthropods

Test species, Dossier-file-No., reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aleochara bilineata M-066029-03-1 Rep.No.: 10191070 , 2001 KCA 8.3.2/02	PTZ EC 250 Laboratory, spray deposits on quartz sand, exposure: 28 d 42 g a.s./ha 200 g a.s./ha 400 g a.s./ha	ER ₅₀ : >400 g a.s./ha Effect to Reproduction $[\%]$ 2.5 9.9 24.6
Poecilus cupreus M-032402-01-1 Rep.No.: /PC001 , 2000 KCA 8.3.2/01	PTZ EC 250 Laboratory, spray deposits of quartz sand, exposure: 1 & d control 0 400.5 g a /ha 600.7 g & s./ha	Conf. Kood Consumption

The available data on ground dwelling arthropods indicate that no unacceptable adverse effects on soil dwelling non-target arthropods are to be expected from exposure rates even exceeding the maximum intended application rate of 18 g.a.s./ha for Prothioconazole (5) 100.

# CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Additional laboratory studies are not required for non-targed arthropods.

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

Additional extended aboratory studies are not required for non target arthropods.

# CP 10.3.2.3 Semi-field studies with non-target arthropods

Semi-field studies are not required

# CP 10.3.2.4 Field studies with non-target arthropods Field studies are not required for non-target arthropods

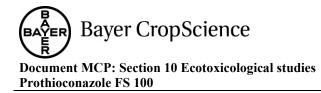
# CP 10.3.2.5 Other routes of exposure for non-target arthropods

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

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

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

Predicted environmental concentrations in soil (PEC_{soil}) values were calculated for the formulation, based on the standard assumptions of distribution in a soil layer of 5 cm with a bulk density of  $1.5 \text{ g/cm}^3$ ; a crop interception of 0% was taken into account.



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

### Table CP 10.4-1: Initial max PEC_{soil} values

Table CP 10.4- 1:	sk assessments. Initial max PEC _{soil} va	مايتوه		
		L'ereals		
Compound	PECsoil, max [mg/kg]	PECsoil acces		
Prothioconazole	0.024	0.024		
JAU 6476-desthio	0.012	0.012		
JAU 6476-S-methyl	0.004	0:004		
Table CP 10.4.1- 1:	Earthworms Endpoints used in p			
Test ash store as	Tastanain	(IT as to to all a start	and a set	

### **CP 10.4.1 Earthworms**

	Enupointo useu in		
Test substance	Test species 🧳	Ecotoxicological endroint	<b><i>W</i></b> Reference
Prothioconazole	Eisenia fetida	DER XI.0 kg. rod./kg	(20@2)
EC 250	reproductio	NOER $> 1.0$ g a.s./	M-033501-02-1
	56 d, sprayed 📈		QCA 8.4.1/04
Prothioconazole	Eiseniĝ Jetida 🔭	NOEC 21006 mg prod /kg dws	(2007)
FS 300	reproduction	257  mg frs./kg dws	🖗 M-287144-01-1
	56@, mixe@		KCA 8.4.1/09
JAU 6476-desthio	Eisenia <u>fe</u> tida	NORC 00.5 mcp.m/kg dws*	(2000)
	Seproduction ?		м-026193-01-2 м_м_м_м_м_м_м_м_м_м_м_м_м_м_м_м_м_м_м_
	56 d, mixed		KCA 8.4.1/05
JAU 6476-S-	🗧 Eischia fetidu 🖌	NOEC O mgg.m./kg.dws*_@	(2000)
methyl 🖉	reproduction		M-021370-01-1
<u> </u>	56 d mixed		KCA 8.4.1/06
Prothioconazole	🔗 Eisena fetida	NOER \$1150 Pg prod. na	&
FS 100	reproduction	→ → → → → → → → → → → → → → → → → → →	(2001)
<u>s</u> Q ¹	560, treated seed		M-088126-01-1
			KCP 10.4.1.1/01
Prothioconazole	Natura earth form	NOEAER $\ge 3 \times 200$ g a.s./ha	
EC 250	populations, 📈	Ý VÝ _A Ž	(2005)
<i></i>	Field Sudy		M-040814-03-1
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Cup to 1 months,		KCA 8.4.1/08
4	Graying		

* Adjusted by a factor of 2 to address the by Pow 2 and the high peat content of 10% in the artificial soil Bold values: Endpoints considered relevant for risk assessment

Risk assessment for earthworkins

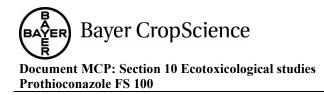
Based on the adopting in the table above the TER values are calculated using the following equations:

$$TER_{LT} = \bigotimes_{i=1}^{\infty} OEC_{i} OEC_{$$

Ň

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

For lipophilic substances (log $P_{OW} > 2$) the Terrestrial Guidance Document recommends to apply an additional assessment factor of 2 for the ecotoxicological endpoints (LC50, NOEC), if the study was



conducted in artificial soil with a high content of organic matter (i.e. 10 % peat), to consider the possible sorption of these compounds to the organic matter.

The log Pow trigger was exceeded by the prothioconazole metabolites JAU 6476-desthio (10 Powor 3.04) and JAU 6476-S-methyl (log $P_{OW} = 4.3$). Additionally, the chronic earthworm studies with these metabolites were performed with 10 % peat within the artificial soil. Therefore, in the risk assessment for those two metabolites an additional adjustment factor of 2 is applied on the respective endpoint.

Table CP 10.4.1- 2:	TER calculat	ions for earthwor	ms y	Å.	, o A	
Compound test design	Endpoint	[mg a.s./kg soil	PEC _{max} [mg/kg soil]	TEBLT	Trigger	Refined risk assessment ?
Prothioconazole chronic, mixed ¹⁾	NOEC	≥ 257 0	\$ 0.02	2 10708	\$ ⁷⁵	No
JAU 6476-desthio chronic	NOEC	0.5 *	~ <u>0</u> ?012 ~			Nor Nor
JAU 6476-S-methyl chronic	NOEC	50%	× 0.904	12500	5 0	No

¹⁾ The endpoint from the earthworm reproduction study with PTZ FS 300 better reflects the overall low toxicity of prothioconazole to earthworms than the EU-agreed endpoint given in the EFSA conclusion (2007). The EUagreed endpoint for prothiocomazole was derived from a study where PTZ EC 250 was sprayed onto the soil surface and the NOEC represents the highest application rate tested The study where PTZ FS 300 was mixed into is considered to better describethe low intrinste toxicity of prothiocond zole to E. fetida.

* Adjusted by a factor of 2 to address the log Pow 2 and the high peat content of 10% in the artificial soil

All TER values calculated with the worst case PEC some values exceed the grigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

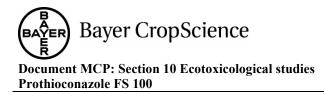
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Additional higher tiered evidence supporting the conclusion of an accecptable risk to earthworms A laboratory study on offects of seeds treated with Prothin conazole FS 100 on reproduction of Eisenia fetida was performed in order to assess the taxicity of prothioconazole to earthworms under more realistic exposure conditions. No effects on survival, biomass, and reproduction of E. fetida were observed up to 122 Sprotheconagole/ha the highest rate tested. This exceeds the recommended application rate by a factor of ≥ 6.8 (see table below) confirming the acceptable risk to earthworms.

Table CR 10.4.1-3: JER calculations for carthworms (higher tiered evidence)

Compound test design	Andpoint [mg a.s./kg soil]	PEC _{max} [mg/kg soil]	TER _{LT}	Trigger	Refined risk assessment ?
PTZ FS 100 chronic, treated seeds	NOEC 2122 g a.s./ha	18 g a.s. /ha	≥ 6.8	5	No

An earthworro field study with Prothioconazole EC 250 (, C.; 2005; M-040814-03-1, KCAP8.4.1908) is available. This study was evaluated during the last EU review and considered acceptable. Prothioconazole EC 250 did not reveal ecologically adverse effects up to an application rate of 3 × 200 g a.s./ha (NOEAER) on a grassland site. The total soil loading in this field study at the NOEAER of 3×200 g a.s./ha is 33 times higher than the proposed application rate for the use of



prothioconazole as a seed treatment in cereals $(1 \times 18 \text{ g a.s./ha})$. Thus, a low risk for earthworms is concluded if prothioconazole is applied as treated cereal seeds at a rate of 18 g a.s./ha in cereals.

CP 10.4.1.1 Earthworms sub-lethal effects

An earthworm reproduction study with Prothioconazole FS300 (test substance mixed into soil; T.; 2007; M-287144-01-1, KCA 8.4.1/09 is presented in the active substance dossier which better reflects the overall low intrinsic toxicity of Prothioconazere to Eisenia fenda than the chronic PU agreed endpoint for Eisenia fetida. The EU-agreed endpoint was derived from a study where Prothiocomzole O EC 250 was sprayed onto soil surface and the NOER in this study represents the highest tested rate of 1000 g a.s./ha. The NOEC of ≥257 mg a.s./kg from the Prothiogonazole FS 360 study clearly - and macrofauna (other than demonstrates a low toxicity of prothioconazole to Eis

CP 10.4.1.2 Earthworms field studies

Not required as the risk to earthworm Qs acceptable

Effects on non-target soil meso **CP 10.4.2** earthworms)

Table CP 10.4.2-1:	Endpoints used	in gis k	assessment	
--------------------	----------------	-----------------	------------	--

			, ,
Test substance	Test species	Kotoxie dogica Cendpoint	Reference
Prothioconazole	Fo lsomi@candida	$NOE \subseteq \mathbb{Y} \ge 1000 \text{ mg a.s./kg dws} \qquad \mathbb{A}^{1}$	(2011)
Ê			M-405273-01-1
	28 d, mixed		KCA 8.4.2.1/06
~O~	Hopoaspis aculetter	$OEC_{1} > 100 \text{ mg}$ a sykg dws	
	Reproduction		(2000)
	34 d mixed 0	3 3 3 3 3 3 3 3 3 3	M-037786-02-1
	Lug 2.1		KCA 8.4.2.1/02
JAU 6476-desthio	Peproduction Reproduction 28 d mixed	NOEC 31.3 mg p.m./kg dws*	&
~	Reproduction	OEC 31.3 mg p.or./kg dws*	(2002)
	28 d mixed		M-035070-03-1
			KCA 8.4.2.1/03
Ą	Peproduction 28 d mixed Bypoassis acutefer Reproduction 14 d, mixed	NOEC ≥100 mg p.m./kg dws	(2014)
*	Reproduction		M-491764-01-1
	14 d, mixed		KCA 8.4.2.1/07
JAU 6456-S-	Fofsomia Qandida,	$\otimes OEC \gg \geq 15.8 \text{ mg p.m./kg dws}^*$	&
methyl	Preproduction 28 d Sixed Q		(2001)
	28 d Sixed ~		M-087207-01-1
		1 A	KCA 8.4.2.1/04
Ś	Hypoasple aculeyer	S OEC ≥ 100 mg p.m./kg dws	(2014)
	Reproduction 7		M-491804-01-1
<u> </u>	14 dOnixed 🔍 🔍		KCA 8.4.2.1/08
	14 domixed ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
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\checkmark			



Prothioconazole FS 100

Test substance	Test species	Ecotoxicological endpoint	Reference
Prothioconazole	Folsomia candida	NOER \geq 1150 kg prod./ha	&
FS 100	Reproduction	\geq 112.4 g a.s./ha ¹⁾	(2002)
	28 d, treated seeds	×	M-033780-091
			KCP 10.40702
	Folsomia candida	NOER ≥ 230 kg prod./ha	(2001)
	Reproduction	\geq 24 g a.s./ha	M-076191-04 .
	28 d, treated seeds	Ča di	KGP10.4.2%1
	Hypoaspis aculeifer	NOEC ≥ 1000 mg prod./kg@ws	
	Reproduction	\geq 84.7 mg a.s./kg bws	2015) 2 .
	14 d, mixed		M-532652-001
			K€₽ 10.4.2.1/01 &
Prothioconazole	Folsomia candida	NOE $\geq 30 \text{ mg prod./kg} d\text{ ws}^{2}$	(2007)
FS 300	Reproduction	≥7:7 mg s.s./kg dws √	ØM-287951-014J
	28 d, mixed		KCP 10.4.2 1/02

* Adjusted by a factor of 2 to address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and the high peat content of 10% in the address the log $P_{\Delta x} > 2$ and $P_{\Delta x} = 10$. ¹⁾ The NOEC of \geq 24 g a.s./ha resulting from the Folsomia candidate production study with Prothioconazote FS The NOEC of ≥ 24 g a.s./ha resulting from the *Poisemiar analasce* production study with *Poisemiar and the Poisemiar analasce* production study with *Poisemia candide* and *Prothioconazole* FS 100 a NOEC of ≥ 12.4 g cs./ha was gained, which is more suitable to describe the realistic toxic potential of Prothioconazole FS 100 to *Poisomia fandida*. ²⁾ A collembola reproduction study where the test item was mixed into soil (5) not available with Prothioconazole FS 100. However, a study with Prothioconazole FS 300 (5) presented which can be used in the risk assessment instead as the formulation is (apart from the active substance content) slightly different to Prothio conazole FS 100.

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

Ecotoxicological endpoints and PEC pil values used for TOR calculations for Soil non-target macro-TER values were calculated using the equation: organisms are summarised bolow,

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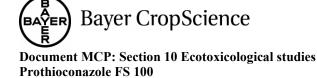
TER = NOEC / PEC

The risk is considered acceptable if the TER is

For lipophilic substances ($\log P_{ow} > 2$) the Terrestrial Guidance Document recommends to apply an additional assessment factor of 2 for the ecotoxicological enepoints (LC₅₀, NOEC), if the study was conducted in artificial soil with chigh content of organic matter (i.e. 10 % peat), to consider the possible sorption of these compounds to the organic matter ñ

The log Pow trigger was exceeded by the prothioconazole metabolites JAU 6476-desthio (log Pow = 3.04) and JAU 6476 method (log Pow & 4.3) Additionally, the collembolan studies with these metabolites were performed with 10 % pert within the artificial soil. Therefore, in the risk assessment for those two metabolites in additional adjustment factor of 2 is applied on the respective endpoint.

additional adjust, additional adjust,



Compound Test design	Endpoint	[mg a.s./kg soil]	PEC _{max,} PEC _{acc} [mg/kg soil]	TER _{LT}	Trigger	Refined risk assessment?
Folsomia candida					- OF	
Prothioconazole chronic	NOEC	≥ 1000	0.024	≥41667	5	
Prothioconazole FS 300 chronic, mixed ^{A)}	NOEC	≥7.7	0.024		5	S Now
JAU 6476-desthio chronic	NOEC	31.3*	Å 0.012	\$2608°		No 2
JAU 6476-S-methyl chronic	NOEC	≥ 15.8 *	Ø.004 5	≥3950 ×		NO NO
Hypoaspis aculeifer		.1	X Û			à s'
Prothioconazole chronic, mixed	NOEC	≥ 100 × ×	0,024	≥ 4 167 ~		NG
Prothioconazole FS 100 chronic, mixed	NOEC	≥89.7 00 €	~~~ 0.02¥	©≥ 3,529+		õ No
JAU 6476-desthio chronic	NOEC	$\sum_{n=1}^{\infty} 100^{n}$	\$0.012	×8333 C		No
JAU 6476-S-methyl chronic	NOEC	\$100 D	§ 0.004		\$ 5 g	No

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

* Adjusted by a factor of 2 to address the log P_{ow} 2 and the high reat content of 10% in the artificial soil ^{A)} A collembola reproduction study where the test item cas mixed into soil is not available with Prothioconazole FS 100. However, a study with Prothioconazole FS 500 is presented which can be used in the risk assessment instead as the formulation is (aparOfrom the active substance content) slightly different to Prothioconazole FS 100.

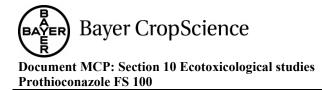
Ó II All TER values calculated with the worst case PEC values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product S K,

Further high tiere Devidence on the conclusion of low risk to Collembola

The conclusion of a low risk of Prothioconazolo FS 100 used as a seed treatment in cereals is further supported by a laboratory reproduction study with Folsomia candida considering a more realistic exposure, i.e. application of treated cereal seeds. No effectes on reproduction and survival of F. candida was observed up to the highest rat@tested@NOER 2112.4 g a.s./ha). The TER value in this extended tier 1 risk assessment reache@the value of ≥ 6.2 , see table below.

Table CP 10.42	- 3: 🔊	TER calculations for further higher tier evidence on the conclusion of low risk to Contembola
<u>C</u>	\sim	Celember V
@. [¥]	~~~~	California

Componend A Test design	Endpoint	[g a.s./ha]	PEC _{max} , [g a.s./ha]	TER _{LT}	Trigger	Refined risk assessment?
Folsomia candida	a a a a a a a a a a a a a a a a a a a					
Prothios Mazole FS 100 chronic, treated seeds	NOER	≥112.4	18	≥ 6.2	5	No



Please note that the NOER in this study represents the highest application rate tested and that the intrinsic toxicity of prothioconazole and the product to Collembola is considered very low (NOEC \geq 100 fmg \approx a.s./kg in the reproduction study with the active substance and NOEC \geq 7.7 mg a.s./kg for the product \approx Prothioconazole FS 300).

Thus, an overall low risk to Collembola and soil mites is concluded if prothioconazele is applied as treated cereal seeds at an application rate of 18 g a.s./ha.

CP 10.4.2.1 Species level testing

A new reproduction study with *Hypoaspis acutelfer* is available with Prothioconazole FS 100; a summary is presented below. A *Folsomia candida* reproduction study with Prothioconazole FS 100 (application of treated seeds) was evaluated during the EU teview (2007) with a NOER of 112.4 g a.s./ha, however, a study where the test item was mixed into the soil is not available with Prothioconazole FS 100. However, a *F. candida* reproduction study is available with Prothioconazole FS 300 which is a slightly different formulation compared to Prothoconazole FS 100. This study can be taken into account to describe the intrinsic toxicity of the product to *F. candida* A summary is presented below.

Report:	KCP40.4.2,1/01
Title:	Prophiocordizate FS 100 (PInfluence on mortality and reproduction of the soil mite
	species Hypoaspis aculater tested in artificial soil
Report No.: 3	LE 428@711-7Q O C
Document No.:	M-532652-61-1 (S L C C C C C C C C C C C C C C C C C C
Guideline(s):	US, EPA @SPP, Not Applicable OECI226 from October 03, 2008: OECD
, D	Relideline for the Testing of Chemicals, Predary mite (Hypoaspis (Geolaelaps)
Guideline deviation(s)	vaculeifer) reproductions test in soil
GLP/GEP:	yes y A A A A

Objective:

The purpose of this study was to assess the effect of prothoconazole FS 100 G on mortality and reproduction of the soil mite species *Hyposspis aculeife* tested during an exposure of 14 days in artificial soil comparing control and treatment.

Material and methods:

Test item: Prothioconazole F\$100 G, analysed a 5 content: 8.47 % w/w (97.86 g/L), Batch No. 2015-001031, TOX10850-90, Specification Nov102009006421, Density: 1.155 g/mL (20°C).

Ten adult, fertilized, female *Expossils acheifer* per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control and treatments. Concentrations of 100, 178, 316, 562, and 1000 mg test item Rg dry weight artificial soil were tested. During the test, the *Hypoaspiraculater* were fed with nematodes bred on watered oat flakes. During the study a temperature of 20 ± 2 °C and light regime of 400 - 800 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75 % fine quartz sand, 5 % Sphagnum peat, air dried and finely ground, 20 % Kaolin clay.

After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution

(20% ethylene glycol, 80% deionised water; 2 g detergent/L fixing solution were added). All Hypoaspis aculeifer were counted under a binocular.

Findings:

Validity criteria:

All validity criteria were met as presented below:

Table CP 10.4.2.1-1: Validity criteria

	¥ "O"	
Validity criteria	Recommended	With the work of the second
Mean adult mortality	$\leq 20\%$ \sim	· ~ 6,3% C ~
Mean number of juveniles per replicate (with 10 mites introduced)		291.32
Coefficient of variation calculated for the number of juveniles per replicate		

, LAR/HR-9-16/14, January 05-2015) The most recent non-GLP-test (Maria Long with the reference item dimethoate was performed at test concentrations 0.0, 1, 8, 3.2, 6, 6 and 10.0 mg m dimethoate/kg dry weight artificial soil.

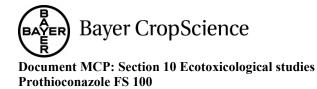
Dimethoate showed a LC50 of 2.51 mg a@./kg (95 % confidence limits from 9.85 pg a. s./kg to 3.30 mg a. s./kg) for mortality of the admit mites according Probit analysis using maximum likelihood regression. The reproduction of the soil mites was not significantly reduced in somparison to the control up to 3.2 mg a.s./kg dry weight artificial soil. Therefore the NOEC is calculated to be 3.2 mg a.s./kg and accordingly the LOEC is 5.6 mg a.s./kg. Since variables of the data were homogenous Williams-t test $\alpha = 0.05$, one-sided smaller was used. Dimethoate EC 400E G showed an EC 57 of 5.47 mg a. s./kg (95) % confidence limits from 4.09 mga s./kg to 7.30 mg a s./kg) for reproduction according Probit analysis using maximum likelihood regression.

This is in the Componded range of the guideline, indicating that an EC50 based on the number of juveniles of 3.0 - 7.0 mg a. s./ weight artificial soil shows that the test organisms are sufficiently sensitive.»

Biological results: 6.3 % of the adult Hyporspis acute ifer died which is below the allowed maximum *S*

of ≤ 20 % mortality. 3° 3° 3° 3° 3° 3° 3° 3° Concerning the adult mortality of the test organism statistical analysis (Fisher's exact Binomial Test with Bonferroni Correction, one-sided greater, $\alpha = 0.005$) revealed no significant difference between control and any treatment group.

Concerning the number δ_{ij} inverties statistical analysis (William's-t test, one-sided smaller, $\alpha = 0.05$) and solution of the solution o revealed no significant difference between control and any treatment group.



Test item		1	Prothioconazole FS	100 G	
Test species			Hypoaspis acule		
Exposure			Artificial soi		
*	A .]14	Start Carrie	Mean number		Significance
mg test	Adult	Significance		Reproduction	Significance
item/kg dry	mortality	(*)	of juveniles	(% of control)	
weight artificial soil	(%)		per test vessel		
artificial soli			± standard Ødev.	Ŭ (
Control	6.3		\$91.3 ± 10.3	0 ⁷ K	
100			325.0 ± 23.7	111.6	
	0.0	-		Ø 111 6 ⁸	
178	0.0		326.0 ± 8.8		
316	5.0	- *	320.5 ± 26.8		
562	2.5	- 0*	319.5€7.2 €	109.7	- -
1000	7.5		€ <u>318</u> €± 23.5°	\$109.2 ^{°0°}	
		<u>\$</u> \$		<u>A</u> Mortality	Reproduction
		dry weight artificia		√″ <u>≫</u> √000	≪J≥1000°
LOEC	C (mg test item/kg	dry weight actificia	Ksoil) Y K	<u>گې1000 کې</u>	$3^{\circ} > 10^{\circ}$
		1/kgdry weight arti		17 19 19 10 10 10 10 10 10 10 10 10 10 10 10 10	QU O Ø
		dig dry weight arti	ficial soil) 🔊		000
Calculations were	done with un-roun	ded values. 🖉			6
(*) = Fisher's exac	ct Binomial Test v	vith Bonferroni Co	rection, one-sided	-greater, α=0.05, "	- non-significant;
"+": significant	*	& 0° 4	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
(**) = William's-t	-test, one soded sm	@ler; α=0.05; "	on-significant; "+*	Significant	
	Y A	aller; α=0.05; " ^Q . r		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
conclusion.		di a	, . Y O'		
Overall NOEC: >	1000 mg test ite	ha/kg diy weight	artificial soil	oʻ 🖓	
Overall LOEC >	1000 mg test ite	m/kg dry weight	arthricial Coil 🤞		
<u></u>				~	
Û	ð v		Ş O	Ŵ	
	w		; 2007; M-287	ř	
Report:	KCP 40.4.	2.1/02	,; 2 00 7; M-287	951-01-1	
Title:	Prothiocor	nazole FS300 G: In	fluence on the repi	oduction of the col	llembola species
Folsomia candida Osted in artificial soil with 5 % peat					
Report No.: FRM-C@LL-51.07					
Guideline(s): Guideline deviation(s): With respect to the properties of the test item (Log pow i Ý 2) 5 % peat instead of 10					
Guideline devratio	on(s): With respe	set to the properties	ot the test item (L	$\log pow (Y 2) 5\%$	peat instead of 10
	% peat wa	s used considering	the influence on bi	oavaılabılity (EPPO	J 2002).
GLP/GEP:	yes Q		¥		
GLP/GEP:					
The purpose of a	he study was to	provide data for	the registration of	f plant protection	n products on the
					<i>ia candida</i> as a
	the soil faina.			r 1 015011	

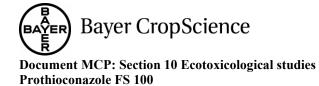
L ES 100 C Table CP 10 4 2 1 2. Effect of Prothic ... 1.:. .

Material and methods:

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Test frem: Prothioconazole FS 300 G, analysed a.s. content: 296.8 g/L, Batch No. 2006-006218, TOX07688-00, Specification No. 102000014331, Density: 1.155 g/mL (20°C). Ĉ

Ten Collembola (10-12 days old) per replicate (5 replicates per treatment group) were exposed to control (water treated), 1.0, 2.3, 5.5, 12.8 and 30.0 mg test item/kg artificial soil dry weight at 18 – 22°C, 400 –



800 Lux, 16h light : 8h dark, 5 % peat in the artificial soil. During the study, they were fed with granulated dry yeast. The study was conducted in artificial soil according to OECD 207 (1984) 5% sphagnum peat, 20% kaolin clay, 74.8% industrial quartz sand and 0.2% CaCO₃). Mortality and reproduction were determined after 28 days. To demonstrate the sensitivity of the test system Betosip (Phenmedipham 15.4%) as a toxic standard is

regularly tested (once a year) at concentrations of 89, 133, 200, and 300 mg test item/kg artifical soil dry weight.

Findings:

Validity criteria:

All validity criteria were met as presented below;

Table CP 10.4.2.1- 3: Validity criteria	
Validity criteria	A @Reconfermended @ Obtained ?
Average mortality of the adults in the control after 28 days	
Average reproduction rate in the control after 28 days	V>100 Suveniles/control vessel
Coefficient of variation of reproduction in the control after 28 days	
L'a a	

In the most recent reference test with Betosip (Phenmedipham 15.4%) , 2006, Non-GLP) the mortality rate of adulty collembola was 8 5, 14 %, 22 % and 32 % 37 89, 53, 200 and 300 mg Betosip/kg artificial soil dry weight. In all reatmont groups the number of juveniles was statistically significant reduced (William's-T Fest, on Sided Smaller, $\alpha = 0.05$) in Comparison to the control.

NOEC reproduction < 89 mg Betosip (13.7 mg a.s)/kg artificial son dry weight @

LOEC reproduction 89 mg Betosip (Y3.7 mg a.s) kg artificial soil dry weight × ×

The study proces the sensibility of the test system

Biological results:

In the control group 4% of the adult Cottembol died which is within the tolerated range of $\leq 20\%$ mortality recommended by the guideline. The highest mortality rate of 30 % was found in the test item concentration of \$23 mg test item kg soil dry weight. In all other treatment groups the mortality rate was lower than in the control group.

Concerning the number of Juvenile's statistical analysis (Dunnett's Test, one significant differences between the control and any treatment group.

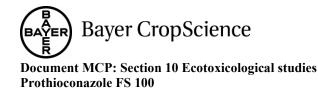


Table CP 10.4.2.1-4: Effect of Prothioconazole FS 300 G on Folsomia candida

Test item		Prothioconazole FS 300 G			
Test species		Folsomia candida			
Exposure		Artif	icial soil		
mg test item/kg dry	Adult	Mean number of	Byproduction		
weight artificial soil	mortality	juveniles per test	(% of controls		
	(%)	vessel			
		± standard dev.			
Control	14	$590\pm54\%$			
1.0	6	692 ±∳∕27	↓ 0° ¥¥7 Q 6° \$		
2.3	30	6524 164			
5.5	8	∂04 ± 62 ∧			
12.8	10	627±137			
30.0	8	763	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$		
			Reproduction 💭 🏑		
NOEC (mg test	item/kg dry weigł	ntartificial soil)	\searrow \bigtriangleup ≥ 30 \bigotimes \bigotimes		
LOEC (mg test	item/kg dry weigf	trartificial soil	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
	<u> </u>				

Conclusion:

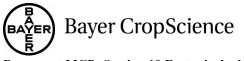
CP 10.4.2.2 Higher tier testing

CP 10.5

			4			
NOE	C (mg test item	/kg dry weigł	ntartificial soil)		A	≥ 30
LOE	C (mg test item	/kg dry weigf	trartificial soil	,X ,Q		$\frac{2}{2}30$
Conclusion: NOEC _{reproduction} Overall LOEC						
NOECreproduction	$a \ge 30 \text{ mg test}$	t item/kg dry	weightartific	mal soik		Č v
Overall LOEC	reproduction: > 30) mg test iten	n/kg dry weig	nt artificial	Qil ^O	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	-	L'	2 2			0
CP 10.4.2.2 No higher tier	Higher	tier Pestin				
No higher tier	testing was pe	erformed or 1	required.	× ×	4 4 2)) V
8			required.		0 ⁴ 4	, ,
CP 10.5	Effects	s on soil nit	rogen trans	formation		
ĉ		0 0 [×]	LO L'	ð s	i an	
CP 10.5 Effects of soil nitrogen transformation						
Test species	Test item	Of Test	Eco	otoxicoloĝiça	l endpoint	Reference
N-cycle	Prohioconaz	ole 28 d	no forfluence) ≥2,0	kg a.s./ha	(1999)
-				2.71	mg a.s./kg dv	
(¢ _s ov	$\delta \sim 0$	<u>, 0' , 0'</u>	<u></u>		KCA 8.5/01
N-cycle	JAU 6476) \$8 d	no influence	~	kg p.m/ha	(1999)
	methyl	J A		\geq 2.69	mg p.m./kg o	
		-Q-				KCA 8.5/03
N-cycle	JAU \$476- 1	28 d	no influence		kg p.m/ha	(2001)
4	desthio	í jy 🤇	Ş 29 [°]	\geq 1.37	mg p.m./kg d	
						KCA 8.5/06
	Ŵ <i>1</i>					
N-cycle	Prothipconaz	gle 28 a	Ro influence		L prod./ha	(2013)
N-cycle	Prothioconaz FS/300 ^{a)}	Ste 28 a	میں influence ا	≥ 0.15	L prod./ha mg prod./kg o mg a.s./kg d y	dws M-451627-01-1

^{a)} A N-cycle stud with Prothioconazole FS 100 is not available. However, a study with Prothioconazole FS 300 is presented which can be used in the risk assessment instead as the formulation is (apart from the active substance content) stightly different to Prothioconazole FS 100. Ŀ,

No nitrogen transformation study with Prothioconazole FS 100 is available, however, a study is available with Prothioconazole FS 300 which is a slightly different formulation compared to Prothioconazole FS 100. This study can be taken into account to describe the toxicity of the product to soil nitrogen transformation. A summary is presented below.



Document MCP: Section 10 Ecotoxicological studies Prothioconazole FS 100

Report:	KCP 10.5/01 E; 2013; M-451	.627-01-1	0
Title:	Prothioconazole FS 300 G: Effects on the	ne activity of soil microflor	ra (nitrogen
	transformation test)		
Report No.:	13 10 48 010 N	~	S
Document No.:	M-451627-01-1		
Guideline(s):	OECD 216 (2000)	Ĩ	
Guideline deviation(s):	none	2	
GLP/GEP:	yes	×»	
		<u>a</u>	
Objective:	۲ م ام		
The nurnose of this stu	dy was to determine the effect of Pro	thiocoparole FS 3000m	the Setivit Of soil

The purpose of this study was to determine the effect of Prothioconazole FS 3000n the activity of solve microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turpover.

Material and methods:

Test item: Prothioconazole FS 300 G, analysed a.s. content: 26,1% www (293/1 g/L), Batch No. 2011-004670, TOX09507-00, Specification 36. 102000021339-01, Density: 1.123 g/mC (20°C).

A loamy sand soil (DIN 4220) was exposed for 28 days to 0.03 and 0.15 mg prod./5g soil dry weight. Application rates were equivalent to 0.02 and 0.49 L prod./ha. Determination of the nitrogen transformation (NO₃-nitrogen production) in soil chriched with accerne meal (concentration in soil 0.5%). NH₄-nitrogen, NO₃- and NO₂-nitrogen were determined using the Autoanalyzer (BRAN+LUEBBE) at different sampling intervals (0,7, 14 and 28 days after treatment).

Findings:

<u>validity criteria:</u> The coefficients of variation in the control (NO₂-N) were maximum 7.4% and thus fulfilled the demanded range (≤ 15 %).

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

Biological results

No adverse effects of Prothioconazote FS 300 G on nitrogen transformation in soil could be observed at both test concentrations (0.03 mg/kg dry soil and 0.15 mg prod./kg dry soil) after 28 days. Differences from the control of +5.4 % (test concentration 0.03 mg/prod./kg dry soil) and +5.4 % (test concentration 0.15 mg/prod./kg dry soil) were measured at the entrol of the 28-day incubation period (time interval 14-

28).

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Table CP 10.5-2:	Effect of Prothioconazole FS 300 G on Nitrogen transformation in soil					
Time Interval (days)	Control		g soil dry weight)2 L test item/ha	0.15 mg prod./kg soil dry weight equivalent to 0.10 L test item/ha		
	Nitrate –N ¹⁾	Nitrate –N ¹⁾	% difference	Nitrate N ¹⁾	% difference	
			to control	O'	to control	
0-7	3.31 ± 0.33	3.47 ± 0.02	+4.6 ^{n.w.}	3.14 ± 0.18	0 ⁹ -5.5 ^h	
7-14	1.11 ± 0.39	1.18 ± 0.17	+6.0 ^{n.s.}	1.27 ± 0.09	+14. 1 ^{n.s.}	
14-28	0.80 ± 0.08	0.84 ± 0.14	₹5.4 ^{n.s.}	Ø.84 ± 0.04	6.4 ^{n.s.} 0	
T1 1 1 1	C 1'-1	1 1 1	•	\mathcal{Q}		

The calculations were performed with unrounded values

¹⁾ Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation n.s. = No statistically significant difference to the control (Student-t-test for pomogeneous variances, 2-sided $p \le 0.05$) est for inhomogeneous variances, 2-sided, n.w. = No statistically significant difference to the control

Conclusion:

 $p \le 0.05$)

Prothioconazole FS 300 G caused no adverse effects difference to control 25 % OECP 216 on the soil nitrogen transformation (measured as NQ3-N production) at the end of the 28 day indubation period. The study was performed in a field soil al concentrations up to 0.1 mg test item bg soil which are equivalent to application rates up to 0.16 L prof./ha

Risk assessment for Soil Nitrogen Transformation

Risk assessment for soil micro-organisms Table CP 10.5- 3:

Compound Species Fing/kg	PEC _{soil,max,} PEC _{soil,acc} [mg/kg]	Refinement required
Prothjoconazof Soil paicro-organisms ≥ 371 mg a.s./kg ws	0.024	No
JAU 6476-S-methyl Soft micro organisms 2.69 mg p.m. kg dws	0.012	No
JAU 6476-desthio $\sqrt{30}$ Soil micro-organisms $2 \ge 1.37$ mg $\sqrt{30}$./kg dws	0.004	No
Prothioconazole \mathbb{R}^{∞} 300 ³ Soil price or ganism ≥ 0.0392 mg a.s./kg dws	0.024	No

^{a)} A N-cycle study with Prothioconazole PS 100 is not available However, a study with prothioconazole FS 300 is presented which can be used in the risk assessment instead as the formulation is (apart from the active substance content) slightly different to Prothiocond ole FS100 ő,

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

Ŵ, In no case diddeviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentration by far exceeded the maximum predicted environmental concentrations in soil of the respective components This indicates acceptable risk to soil micro-organisms for the intended uses.