





OWNERSHIP STATEMENT

Ŷ This document, the data contained in it and copyright therein are owned by Bayer AG and/or affiliated entities. No part of the document or any information contained the to any third party without the prior written authorisation of Bayer AG and or affiliated entities.

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority. Other a repartation on the basis of the importance of the i registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they of have received the data on which the summaries and evaluation are based as they



Version history

	version history	0
Date [yyyy-mm-dd]	Data points containing amendments or additions ¹ and brief description	Document identifier and version number
		version number
It is suggested th SANCO/10180/	at applicants adopt a similar approach to showing revisions a 2013 Chapter 4, 'How to revise an Assessment Report'.	ind version history as outlined in the second seco
	Date [yyyy-mm-dd]	



Table of Contents

		Pañe .
CP 10	ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUC	\$ 5.
CP 10.1	Effects on birds and other terrestrial vertebrates	190
CP 10.1.1	Effects on birds	æ9
CP 10.1.1.1	Acute oral toxicity	\$29
CP 10.1.1.2	Higher tier data on birds	290
CP 10.1.2	Effects on terrestrial vertebrates other than hirds $\mathcal{A}^{(1)}$	36
CP 10.1.2.1	Acute oral toxicity to mammals	
CP 10.1.2.2	Acute oral toxicity to mammals	52 0
CP 10.1.3	Effects on other terrestrial vertebrate@vildlife (reptiles and amphibians).	
CP 10.2	Effects on aquatic organisms	
CP 10.2.1	Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrop	hytes
	Effects on aquatic organisms.	
CP 10.2.2	Additional long-term and chronic toxicity studies on fish, aquatic invertebrate	s and
	sediment dwelling organisms	. 180
CP 10.2.3	Further testing on aquatic organisms	\$180
CP 10.3	Effects on arthropods	
CP 10.3.1	Effects on bees	
CP 10.3.1.1	Additional long-term and chronic texicity studies on fish, aquatic invertebrate sediment dwelling organisms.	
CP 10.3.1.1.1	Acute oral toxicity to bees 2 5 5	
CP 10.3.1.1.2	Acute oral toxicity to bees	198
CP 10.3.1.2	Chronic toxicity to bees	200
CP 10.3.1.3	Effects on poney bee development and other honey bee life stages	209
CP 10.3.1.4	Sub-lethal effects	215
CP 10.3.1.5	Cage and tunnel tests?	216
CP 10.3.1.6	Field tests with hope vheed and a second s	
CP 10.3.2	Acute contact exicity to bees	
CP 10 3 2 1	Standard laboratory testing for non-target arthropods	239
CP 10.3.2.2 🐐	Externed lakerator religion aged beid wetudie with non target arthropode	246
CP 10.3.2.3	Semi-field studies with non-target arthropods Field studies with non-target arthropods	256
CP 10.3.2.4	Field studies with non-varget arthropods	256
CP 10.3 2.5	Other routes of exposure for non-target atthropods.	256
CP 10.4	Effects on non-target soil meso- and macrotautoa	257
CP 10.4.1	Effects on non-target soil neso, and macrofauna Eauthworms	259
CP 10.4.1.1	Farthworms sop-lethereffects	263
CP 10.4.1.2	Tearth Parme Field styling O' O'	268
CP 10.4.2	Effects or pion-target southes and macrofauna (other than earthworms) Species level testing.	
CP 10.4.2	Species level testing.	273
CP 10.4 2.2	Higher testing	278
CP 10.5	Effects on soil nitrogen tansformation	279
CP 10.6	Effects op terrestrial non-targer higher plants	286
CP 10.6.1	Summary of screening data 5.	287
CP 10.6.2	Testing on ron-target plants	
CP 10.6.3	Extended aboratory studies on non-target plants	
CP 10.6.4	Semi-field and field tests on non-target plants	
CP 10 🗫	Effects on other terrestrial organisms (flora and fauna)	
CP 10.8	Montoring data	299
	O' ÉT	
CP 10.8	\sim	
Õ		



CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Fluopicolide (AE C638206) was included in Annex I to Council Directive 91/414/EEC in 2010 (Commission Directive 2010/15/EU, Entry into Force on June 1, 2010). The expiration of approval of fluopicolide is May 31, 2023 (Commission Implementing Regulation EU) 2017/1527). The Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of fluopicolide under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline Dossier provided by Bayer AG

The formulation Fluopicolide + Propamocarb-hydrochloride SC 687.5% (62.5625 g/k), abbreviation FLC+PCH SC 687.5, is a suspension concentrate formulation (SC) containing 62.5 g/L of fluopicolide. This formulation is registered throughout Excope under trade names such as plfinito and Volare. FLC+PCH SC 687.5 was already a representative formulation of Bayer AG for the Afnex Lanclusion of fluopicolide under Council Directive 91/414/EFC.

Fluopicolide is a fungicidal active substance developed by Bayer It is the only active substance in Europe representing a class of chemicity (pyridinylbrethyl-benzamides) with a unique mode of action via delocalization of a spectrin-like protein in the Comycetes fungi.

Fluopicolide has a long track record of safe use in a large number of largeted crops within horticulture, e.g. cucumbers, lettuce and in a label ecops (e.g. potago).

Fluopicolide is active against a write range of Opmyceto fungi, the causal agents of devastating plant diseases of economic importance in EU27 such as potato late blight (*Phytophthord infestans*) or downy mildew diseases in a broad range of crops.

It provides effective long lasting protection at low application rate against Oomycetes diseases at different stage of development of the fungi, giving flexibility of use to the termer.

Fluopicolide can be formulated with other active ingredients of different types of formulations to optimise and complete its activity.

The development of resistances of Comycetes against existing well-established fungicide groups represent a threat for European farmers by increasing the complexity of their plant protection programs leading to severe economic impacts. With Fluopicolide, farmers in EU-27 have access to a modern tool for their integrated crop protection programs, contribuing to effective and sustainable management of resistance development and preserving high level of protection against Oomycete diseases.

By reducing the Ootbycete damages, applications of Fluopicolide + Propamocarb SC 687.5 on target crops contribute to the achievement of optimum yield and quality, thus securing sufficient supply of high-quality potatoes and hopficultural produces for European consumer destinations and markets abroad, being it fresh of for the processing industo.

high-quality potatoes and hopficultural produces f abroad, being it fresh of for the processing industry.



Use pattern considered in this risk assessment

Сгор	BBCH range	Appl. number	Interval (days)	Product 🖉	Applicate rate active substances
Potato	21-89	4	7	1.6	
Potato	21-89	3	7 😵	Q.6	FLG. 100 5 FLG. 100 5 FCH: 1000 5
Potato	21-89	2	A 7 2007		FLC: 100 PCHD10006
Potato	21-89	1		۲ <u>(</u> 1.6 ۲	FOC: 109
Lettuce	41-49	2		2 1.6	FLCO100 7 7 PCH: 1000 7
Lettuce	13-49				FLC: 100 0 PCH 2000
Cucumber (Greenhouse use)	21-89				FLÓ? 100≪ PCH: 1000

Definition of the residue for risloassessment

The definition of the sidue for risk assessment has been derived in the environmental fate chapter (see MCA 7.4.1). For cotox cology only soil, surface water and sectiment are relevant environmental compartments. The residue definition for risk assessment is therefore given as:

-02/(AE C678188), M-03 (AE 0608000) Soil: Fluopicolide M 02 (AP C657188), M-03 (AE 0608000) Surface water: Fluopicolfe Sediment:

Issue Da Technical Report Outcome of the pesticides Peer Review Meeting on In June 2019 EFSA general reduring issues in ecotoricology. doi 90.2909/sp.efsa.2019.EN-1673

As part of this document suidance and otemplate were provided to complete the questionnaire for the use of residue data extracted from vol 3 B.7 to support the ecotoxicological assessment of pesticides.

The completed template of provided below.



Data Point:	KCP Section 10/01
Report Author:	
Report Year:	2020
Report Title:	Fluopicolide - Residue information supporting the ecotoxicological assessment of pesticides
Report No:	VC/19/038B
Document No:	M-687286-01-1
Guideline(s) followed in study:	
Deviations from current test guideline:	Not applicable
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	not applicable
Acceptability/Reliability:	Yes O C C C C

Metabolism in primary crops Reference material: Test No. 501: Netabolism in Props (DECU 2007a)

Question 1: Are the provided metabolism studies in primary props orbinities in the residue section sufficient to depict a metabolic pathway of residues. If yes which are the crop goups covered by the available metabolism studies?

Is a metabolism study available in a crop that belongs to the same metabolism crop group than the GAP(s) under assessment? Please provide an overview of the available information.¹

The following metabo		available for	Popicoside:		
Report reference	Author, O' Year	Category	Trop &	Application	Fluopicolide label
<u>M-241268-0240</u>	, 26 94	Fait cróp	Grapes	Foliar	[U- ¹⁴ C- phenyl]- and [2,6- ¹⁴ C- pyridyl]- Fluopicolide
<u>M-20267-03-1</u>		Root and tuber crop	Potato	Foliar	[U- ¹⁴ C- phenyl]- and [2,6- ¹⁴ C- pyridyl]- Fluopicolide

¹ The metabolism study should be conducted on a crop which belongs to the crop category representative of the GAP/intended use/representative use (e.g., a metabolism on fruit crops should be provided to support the GAP on pome fruit). It is also relevant to highlight that the metabolism study should be compliant with the GAP in terms of type of application (foliar, soil treatment, etc.), location, covering the dose rate of application, BBCH growth stage at application, PHI.



Page 8 of 299 2020-08-11 Document MCP - Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

_						nde - Margard		
	<u>M-241269-02-1</u>	2004	Leafy crop (L)	Lettuce	Foliar	[U- ¹⁴ C- phenyl]- and [2,6- ¹⁴ C- pyridyl]- Fluopicoble		
			Leafy crop (L)	Lettuce	Soil drench	[U-14C- phenyl]- Eltopicolate		
	<u>M-358357-01-1</u>	2009	Pulses and oilseed (P/O)	Oilseed Trape	Seed +	<pre> [U-4¢- % pheny]- and [2¢-¹⁴Co % pyridy]- % Pluoptcolide </pre>		
Metabolism studies have been conducted in three crop groups with folian applications, namely fruit								
L	Metabolism studies h	ave been condu	cted in three c	op groups w	an foliae applaca	tions, namely fruit		
L	(F), root (R) and leafy	(L), and since	the metabolism	n 15 scomilar Au	all three crop gro	oups thus on crops		
	are covered. Addition	al studies are av	vailable coveri	ng the drench	and seed theatme	nt uses. All of the		
	foliar applied metabo	olism studies ha	been prev	iously review	ved at the EU le	vel; the following		
	conclusion was made	for these studie	S. C. D			Û, k		
		Ś	$O_{n} \sim O_{n}$	\$\$`				
	foliar applied metabo conclusion was made	otatoes (foliar a	protication	ð S)		
	TT 1 1 1	1. 0.			SY OF AU	1. 10 0 1		

When fluopicolide was applied as a foliar treatment, the quantity of the metholites formed was extremely low. When fluopicolide reached the soil during application, it was degraded and there was an increased quantity of the metabolites M-01 (QE C653711) and MQ02 (AE C657988) taken up into the plant parts. This information is sufficient to cover the proposed representative uses on foliar treated potatoes, lettuce and cucumbers.

Lettuce (soil drengi)

Following soil drench application, with [1] 14C-plenyl] Huopicalide, the majority of the residue consisted of theopicolide, with significant amounts of M-01 (AEC653711) and minor amounts of M-06 (AE C643890)? No other single metabolite comprised more than 1% of the total residue in any matrix.

Oilseed rape (seed froatment) The only prominent metabolite observed was M-00 (BAM, AE C653711), when fluopicolide is applied as a seed treatment to pilseed rape seed. All other metabolites were detected in low amounts $(\leq 4.1\%$ of $\mathcal{D}RR$ and ≤ 0.002 mg/kg). The only observed metabolic reaction is the cleavage of fluopicolide to form M-QQ This information is sufficient to cover the proposed representative use on C. seed treated oilseed rape.

For the lettuce (soft@irench) and @iseed rape (seed treatment) metabolism, while these studies have been reviewed by EU Member States, they are only representative of their own respective commodity groupings ('leafy vegetable' and 'purses / gliseeds'), as there is only one study available for each of these application types, so it would not be possible to infer whether the metabolic pathway would be similar for other crop groups based on this information alone.



Question 2: Which are the plant metabolites recovered in the study(s) in relative amount and absolute amount (greater than 10 (TRR %) and/or 0.05 mg/kg)² addressing the metabolic pathway of the representative use(s) ³?

In the metabolism in primary crop studies and metabolism in rotational crop study conducted with [phenyl-U-¹⁴C]-fluopicolide or [2,6-pyridyl-¹⁴C]-fluopicolide, a number of plant metabolites were detected in matrices considered as relevant for leafy substrates above the criteria of > 10% of the rotal radioactive residue (TRR) or present at concentrations > 0.05 mg/kg thus triggering the need to be considered for ecotoxicological assessments.

The matrices available from radiolabelled studies were lettuce, potato foliage as a substitute for palatable leaves), radish tops, wheat forage and oilseed rape forage.

For lettuce and potato, foliage investigations with both radiofabelled test items were conducted in metabolism in primary crop studies after foliar application and for lettuce further investigations were conducted after soil application with [phenyl-U-4C]-fluopicolide. Additionally, for lettuce, radish tops and wheat forage, seed was sown 29 days; 133 days and 1 year after treating soil with [phenyl-U-¹⁴C]-fluopicolide in the metabolism in votational crop study.

Finally, for oilseed rape foliage (BBCH 17-19) investigations were conducted in a metabolism in primary crop study with both [phenyl- U^{14} C]-fluopicolide and [2, Cpyridy]- 1^{4} C]-fluopicolide after seed treatment. The dose rate in this study was 10 times (nominal 120 gRg seeff) the normal field application rate to aid investigation into the metabolism of fluopicolide in oilseed rape.

The metabolites M-01 (AE C657711), M-02 (AE C657188), M-04 (AE C657378), M-05 (AE 1344122), M-06 (AE C643890) and M09 (AE B102859) met the criteria of > 10% TRR or > 0.05 mg/kg. It should be noted the maximum overall concentration of each metabolite either as %TRR or as mg/kg did not typically come from the same matrix sample.

Ğ			
Metabolite) ∕Øvera∰Ma	ximum Concentration
	%TRR \$	A mg/kg (as metabolite)	Comment
M-01	§ 87.5 §	×~2.170	Maximum values from different matrices
M-02	A3.0 E	J 1, 1987	Maximum values from same matrix
M-04	590° ·~~	9.870 °	Maximum values from different matrices
M-05	€1.0 °	Q 0.108	Maximum values from different matrices
M206	<u></u>	Ø 0.068 ·	Maximum values from different matrices
M-09	29 1 <u>0</u> 5	0.052	Maximum values from different matrices

Residue data from supervised residue trials and rotational residue trials are available for each of the metabolites listed above for the metabolites M-01 and M-02 in oilseed rape (green material) and for

² These tregger values of 0.05 mg/kg or 10%TRR of total radioactive residues are only meant as guidance. In some circumstancer generably governed by toxicological concerns, it may be necessary to identify terminal metabolites, which are present at concentrations lower than 0.05 mg/kg or <10%TRR of total radioactive residues (European Commission, 1997).

³ For the ecotox section, a selection of the relevant metabolites should reflect only the representative uses. It is not necessary to cover the residue situation for consumer risk assessment but the expected residue situation in the field for the use(s) under assessment. It is recommend consulting whether metabolism studies were summarized following harmonized templates for further assessment (I.e. EFSA/OECD templates).



M-01, M-02, M-04, M-05, M-06 and M-09 in lettuce. The purpose of supervised residue trials is to determine the magnitude of the residues under realistic field conditions and data from these trials should be considered in the ecotoxicological assessments in preference to data from radiolabelled studies. In addition, a number of conjugated metabolites were detected and identified in samples of wheat forage sown 29 days after treating soil with [phenyl-U-¹⁴C]-fluopicolide or [2,6-pyridy, ¹⁴C]-fluopicolide in an addendum to the metabolism in rotational crop study. These metabolites are reported as %TRR only (and in some cases the %TRR is for a radio-peak subsequently separated into different metabolites). In all cases amounts do not exceed 10% TRR. The metabolite oncentration has been calculated from the reported data and exceeds 0.05 mg/kg for M-18, M-23, M-25, M-26, M-27, M-28 and M-32.

Metabolite		Overall	Maximum Concen	tration 💍 🧟 💭
	%TRR	mg/kg (as	mg/kg (as free >	Comment
M-18 (P11)	1.6	conjugatery 0.086	gnetabolite) (* 60071 (* 7) (*)	Onimal metabolite observed in her cow & rat. Solfate conjugate of M-06 or its
M-23 (P2a,b)	2.2 A		\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	2 malonyl glacoside conjugates of M-04 and its isomer
M-25 (P4a)	6.3 ^A 4			Major cat metabolite in bile. Conjugate which contains both phenyl and pyridyl grings
M-26 (P4b)	\$3.4 A			Conjugate which contains both phenyl and pyridyl
M-27 (P4c)				Conjugate which contains both phenyl and pyridyl rings
M-28 (P5)		0.2 9 3	0.180	Malonyl glucoside conjugate of M-06
M-32 (P10)			5 5	Conjugate which contains both phenyl and pyridyl rings

^A Individual %TRR for M-23 M-25 M-26 and M-27 (called P2a,b, P4a, P4b and P4c in the report have been revalculated from reported data.

M-18 and M-25 are known animal metabolites, and M-25 is the main metabolite observed in rat bile (ca. 50% dose). A

M-23 is a malonyl glucoside conjugate of M-04 (AE C657378) and its isomer, while M-18 and M-28 are sulfate and malonyl glucoside conjugates of M-06 (AE C643890). If ingested by a small mammal it is presumed malonyl glucoside plant conjugates will be cleaved to their aglycons via glucoside conjugates. When considered in combination with the levels of the free unconjugated metabolite the overall maximum concentrations are as follows.



	Ι		1	
Metabolite	Overall N Concer	Aaximum Itration		Appendix) of this of the plants?
	%TRR	mg/kg	-	Q° -
M-04	59.3 (59.3)	0.928 (0.870)	-	
M-06	56(2.8)	0.251 (0.068)	-	
Values for unco	niugated metaboli	te are in		
parentheses	njuguted metuoon		4	
Metabolites seen	in the confined ro	tational crop stud	y are presented within	Appendix of this
locument.			T D	
			ý _O v	
		4	° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° °	
Could it be drawn	n a general conclu	sion on trapslocat	fon of residues based	on the available data? I.e.
s there any partie	cular distribution	of the residues of	oserved in specific pla	nt tissues deaves, grains, °
oots, etc)? Is this	s occurring over ti	me? ⁴		
Franslocation of	radioactive residu	iestrom. file soil	was of served (for all	crops, at all pland back
	confined rotational		2003; N=24	0707-03-9. The relevant
				st residues were found at
he shortest interv	al, in this case 29	days after soil ap	plication.	
otal radioactive	residues (mg/kg f	luonicotide equiv	alents) in crops (no an	values):
	,		- 0 ,, 1 - F - 6 - 8 - 8	
Phenyl Labe	° 🛛 🛛 🔊			× ^L
Cro	in 🔬 🛝		Residue (mg/kg fluop	
		29 Day	133Day	365 Day
Lettuce Radish Tops		<u>6 40</u>		0.53
Radish R@ts		0.40	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0.03
Immature Wi		4.95	\$ 0.22 J	0.86
Wheat Grain	<u> </u>	9.16	© 0.020	0.05
Wheat Straw		\$ 13.56	0.84	2.37
Pyridyl Lab			& 5 ⁷	
CÌÑ		tal Radioactive	Residine (mg/kg fluopi	icolide equivalents)
		> 29 Day 5	5 133 Day	365 Day
Lettuce		<u>0,27 x</u>	0.03	0.05
Radish Tops		<u>4</u> 96 6 (0.23	0.40
Ractish Roots		$\frac{0.00}{4.00}$	0.02	0.02
Wheat Grain	IERE A	2.60	0.16	0.24 0.18
Wheat Straw	- à b	7.05	0.35	1.01
			0.00	1.01
The total radioac	tivity in soil was	found to declin	e steadily over the co	ourse of the study. Total
adioactive residu	es in Pant matric	es declined with l	longer soil ageing. The	mean residues in 29-day
Raw Agricultura	ll Commodoies) I	RACs ranged from	n 0.09 ppm (radish ro	oot) to 13.56 ppm (wheat
traw), but residu	les declined great	y in the 133-day	and 365-day ageing p	eriods. The 133-day crop
esidues ranged fi	nom 0.02 ppm (rad	dish root) to 0.84	(wheat straw). The 36	5-day crop residues were
× . Ô ^y *				

⁴ Special attention must be given to compare results at same BBCH/sampling time; particularly, for avoiding erroneous assessments due to crop growth and dissipation.



observed to increase slightly, ranging from 0.02 ppm (radish root) to 2.37 ppm (wheat straw). This was considered to be a result of seasonal variation. The 133-day plots were planted in October and developed through the winter when formation of soil metabolites from the degradation of parent would be slowest. In contrast, the 365-day plots were planted in March when the plant uptake would be less pronounced, due to the increased degradation.

Metabolism in rotational crops Reference material: Test No. 502: Metabolism in Rotational Crops (ODCD 2007b), Zest No. Residues in Rotational Crops (OECD, 2007d)

Question 4: Do results of the rotational crops show my translocation of residues (uptake from soil) from roots to the aerial parts of the plant⁵? If so, which metabolites might be observed at the source?

Is there any indication of accumulation of residues over time occurring in the rotational crop scenario? If so, in which crop categories (leafy, roots, creals) crop parts is the accumulation observed?

In the confined rotational crop studies (2003: MS240705-03-1) [14C] phenys and pyridinyl ring labelled fluopicolide was applied to soil at a rate of 0.4 kg a.s./hg. Lettuce, wheat and radish were planted after 29, 133 and 365 days of ageing. The highest total radioactive residue (TRR) levels were observed at a plant back interval (PBI) of 29 days in wheat straw (up to 13.6 mg eq./kg), radish tops (up to 6.71 mg eq./kg), wheat grain (up to 26 mg eq./kg) and lettuce (ap to 1.01 mg eq./kg). Although total radioactivity tends to decline over time in the succeeding crops, significant levels were also found at the PBI %365 days (up to 2 mg eq./kg in radiah tops; 1.0 mg eq./kg in wheat straw and 0.62 mg eq./kg in lettuce).

Based on this information, residues tend to accumulate within the leafy (aerial) potions of the crops and cereal grains (for the early PBIs), but lower levels tend accumulate within the roots (based on the data for radistics).

Question 5: If the GAP is for seed treatment or other presence (BBCHs<10) for the crop(s) under assessment?

The seed treatment ver for winter Bilseed rape (product – Scenic Gold®) is included among the representative uses ought for the fluopic lide renewal:

The residues field trials did not cover the magnitude of the residues for early post emergence (BBCH <10). The studies included an initial assessment of the residue adhered to the surface of the treated seed. The first assessment of the residues for the plant was made at BBCH 19 (green material) and for the seed and rest of the plant at commercial harvest (BBCH 89). The residues BBCH 19 and 89 were <LOQ (001 mg/kg) for metabolites M-01 and M-02. For the fluopicolide residues, two of the trials showed levels of 0.02 mg/kg at BBCH 19, with the remaining trials showing levels <LOQ (0.01

⁵ It must be noted that this information may not only refer specifically to the succeeding crops/crops growing in rotation; but also, it may be useful to give indications on a possible residue situation for the new emerging plants in the crop area after certain uses. For instance, the data can be used to disregard a possible residue situation to non-target organisms originated due to the consumption of contaminated seedlings /residues in weeds.

⁶ Consideration for the seedling scenario, relevant for bird & mammals and the guttation water scenario for bees might be necessary.



mg/kg). No residues above the LOQ were found in the seed / rest of the plant at BBCH 89 for fluopicolide.

Study references			
Test commodity	Report reference	Author, Year	Dossier reference
Oilseed rape	<u>M-390353-01-1</u>	2010a 🚽	M-CA@.3.5
Oilseed rape	<u>M-396237-02-1</u>	2010a	M-CA 6.35
Oilseed rape	<u>M-390357-01-1</u>	201	MCA 63.5

Magnitude of the residues in supervised residue of al Reference material: Test No. 509: Crop Field Triat (OEC9, 2005); Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MPLs (European Commission 2017)

Question 6: From the supervised residue trials, 1/2 there any indication of a sesidue decline over time?^{7,8} If so, please indicate the reference to the residue trial and the part of the plants, where the decline was observed.

Were the residue determinations performed at 0 days after the last application of at a given time close to the last application(s)?

Of the representative uses, only leftuce has any residue decline trials which contain meaningful information for the ecotoxicology risk assessment. While some decline trials are available for potatoes, the vast majority of the residue levels at all pre-havest intervals (PHIs) were <LOQ (<0.01 mg/kg), with only a few of the results being at of slightly above the LOQ. Decline trials were not conducted in the seed treated oilseed rape and (indoor) oncumber residue trial studies.

The supervised residue trials for lettice are summarised and referenced within Appendix 2 of this document. In the trials, fluopeolide residue level were repicall found to gradually decline in lettuce heads over a 14-day period.

For metabolite M-01 many of the trials showed LOO (0.01 m/kg) residue levels. In some cases, residues were observed and some of the trials showed decline from day 0, to day 7 and finally to day 14. In other cases, an upper in the residue content was observed from day 7 to day 14, which may be explained by an uptake of M-OF from the serie.

Residue levels or metabolity M-02 (which does not form part of the risk assessment residue definition for consumers) were practically <LOQ (<0.0) mg/kg) in all of the trials, with two exceptions (0.012 and 0.015 mg/kg).

⁷ Please report if the residue rials were fully validated in terms of storage stability, GAP compliance, etc.

⁸ It is mentioned in the EU data requirement that when planning residue trials, it shall be borne in mind that information on the residues in ripe or unripe crops may be of interest with respect of the risk assessment in other areas like ecotoxicology and worker safety. Please include this information if available.

⁹ Residue determinations close to the application(s) and/or the last application may provide relevant information for certain non-target taxa that can forage in the crop area at a time close to the application(s).



The residues field trials were conducted according to the guidance in place at the time when they were conducted. All of the trials were conducted at rates and timings comparable to the requested GAPs for the fluopicolide renewal. The residue data are supported by validated methods of analysis and procedural (concurrent) recovery data. The deep-frozen storage stability periods for the samples (from the time of sampling to residue extraction), were covered by separate storage stability studies

Question 7: On which crops were field residue trials performed? 10 Has an extrapolation b suggested and is it considered appropriate?¹¹

Residues trials have been conducted to support the representative uses of potatoes, lettuce uses indoor only) and oilseed rape (seed peatment only).

According to the EU 'Guidelines on comparability, extrapolation, group plerances and data requirements for setting MRLs' (SANCO 7525/V) 95Rev. 10.30 it is possible to extrapolate the data generated on the representative composities to support other similar cops (those specifically identified within the EU guidance document). However, for the purposes of the representation additional uses for extrapolated commodities have been sought.

Metabolism studies in animas (livertock, fish) Reference material: Test No. 503; Metabolism in Livestock (QECD, 2007c), Test No. 505: Residues in Livestock (QECD, 2007e), Pest No. 305; Bioaccumulation in Esh (QECD, 2012)

m

Question 8: Is a metabolism study in fish/boaccuanilation study part of the residue section? If the fish metabolism study is available, does it indicate an accumulation of residues in fish tissues? ¹²

A fish metabolism souly has not been undertaken for fluopicolide. According to the current EU guidance (SANCO/U187/2013 rev. 3) the metabolism in fish is only required where the partition coefficient (Log Pow) is ≥ 3 . Based on the partition coefficients available in the physical-chemical properties data package for fluopicolide, neither the parent (fluopicolide) nor the primary metabolite (BAM) are considered to be at soluble.

However, a fish broaccumulation study is available (2003; M-241273-01-1). The bioaccumulation of the fluopeolide residues in fish was determined using a continuous flow-through set-up over b days (which included a 24-day uptake period and a 21-day depuration period). The study was previously assessed thring the original EU inclusion for fluopicolide (DAR, 2006; RMS = UK). A brief summary of the study is described within the following paragraph:



¹⁰ The mininum number of supervised residue trials considers for MRL setting might not be applicable for the ecotox. We might build a residue decline curve with less than 4 residue data points. For this consideration, please do not divegard the residue data only based on the minimum number of residue trials. If the residue trials are compliant with the GAP table, cotox experts might use them for further refinements.

¹¹ Ecolox colleagues might need advice on questions such as e.g. can residue decline studies in tomato be used to refine the residues entering throughout diet of frugivorous birds when the representative use is on pome trees? And can we use residue data generated in the SEU for refinements in the NEU zone when the representative use is in whole EU?

¹² If we observe any accumulation in tissues, it might help in case that further assessment of bioaccumulation and/or biomagnification (accumulation throughout trophic chain) are necessary.



S)

The study showed that [2,6-14C-pyridinyl]-fluopicolide accumulates rapidly in fish tissues (bluegill sunfish), principally in the non-edible portions, regardless of the exposure concentration. The steadystate bioconcentration factors (BCFs) for the low treatment ($0.8 \ \mu g/L$) were 48x, 117x and 197x in edible, whole fish, and non-edible, respectively. For the high treatment ($8.0 \ \mu g/L$) were 40x, 164x, and 175x in edible, whole fish and non-edible, respectively. Fluopicolide cleared rapidly from fish tissues regardless of the exposure concentration. The depuration appeared to be biphasic with the "fast" phase as the major component. Based on a one-compartment model with whole fish, the calculated bioconcentration concentration factor's (BCFs) were 121x and 102x for the low and high treatment, respectively. The time to reach 90% of the steady-state was about 2, days for both treatments. The depuration half-life was much shorter at about 0.5 day for both treatments.

The major residue in all fish tissues was unchanged parent fluopic lide:

Treatment	Tissue type	Residue in 🖉			Largest single
		analysed extracts	🖉 residues 🔊	Identified	unidentified
		0 *		So Or	component
		mg/kg 🍌 % 🖉	mg/kg %		mg/kg %
Low	Edible	0.039 87.6	0,039 0.87.6	× 500 ×	
(0.8 µg/L)	Non-edible	0.158 21.4	×0.128 73.8	×73.8	00013 07.8
High	Edible	0.20 85.5	0.271 85.5	か 104	<u> </u>
(8.0 µg/L)	Non-edible	1228 91,8	0.908 A7.9	م <u>وب</u> ې	0.169 12.7

While the bioaccumulation study noted that fluopicolide rapidly accumulates within the tissues of fish, the study also shows that the fluopicolide residue levels rapidly crear from the fish tissues during the depuration phase. No metabolites of fluopicolide were identified and only fluopicolide was present within the edible portions of the analysed fish.

As low BCFs were obtained during the study for the low and high treatment rates, it can be concluded there is no indication of any significant accumulation of residues within fish tissues.

Question 9: Can² the metabolism in animals (manimals/fish/hens) bring any information on accumulation/exposure²³ to different metabolites in addition to those present in the plants? Is it possible to observe an accumulation of residues in fatty tissue other animal tissues considering all available metabolism studies?

The following tables	uma	rised the	resique	leves	found	within	animal	tissues	products from the	
metabolism studies:	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		R.		ð				1	

Fluopicolide poultry metabolism study close level of 10 mg/kg in the diet):												
<i>A</i>	Č,			V O Total C-residue identified/characterised (ppb)								
\sim	Residu	Extracte	FL [⊗]	Mô	M-	Metabolit	Unknow	Pola	Non-			
Tissue	e løyel	d 🎸		Ø 6	01	e 1	n	r	extracte			
	(ppb) 🛎	(ppb)		~~~					d			
			~0									
Egg	× 43	ర 42 స్	1 "	n.d	n.d	22	n.d.	n.d.	1			
white												
Ű,	v											

¹³ If there is information of new metabolites in the excreta, it might be relevant for the environment. Non-target organisms might be exposed to these new metabolites if there is a release in the environment after animal metabolization.



Page 16 of 299 2020-08-11 Document MCP - Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

Egg yolk	154	126	17	n.d	n.d	n.d.	20	69	35
Liver	976	762	n.d.	53	36 1	n.d.	212	n.d.	214
Skin	69	47	n.d.	10	n.d	7	n.d.	y 23	
Fat	61	46	4	n.d	n.d	23	n.d.	12	
Muscl e	39	22	n.d.	n.d	n.d	on.d.	n.d.		
n.d. = not	detected		•	•		C.	.0 [%]		

M-01 (BAM) poultry metabolism study (dose level of 2 mg/kg in the diet)

Limited metabolism of M-01 (BAM) in the hen was observed with M-01 (BAM) excreted essentally unchanged following 14 days repeated oral administration, Phere was indication of accumulation of M-01 (BAM) in eggs and in the high proportion of the cumulative dose detected in while tissues at sacrifice. Only minor metabolites of BAM were detected in the excreta mainly hydroxylation products.

			Q. 1.	× ~		/ %	Ĉ,		ay	•
	Li	iver	[₽] Ŏmøj	ital Fat	Egg	Yolka	Ègg \	Xhite ^a	W// .	scle
Metabolite	% TR	mg eg./k	%₀ ≂_TR	ûng eq./kő	°% ⊂ TR _C	Smg (ν TR	mg egy/k	%∕ ≶₹R	mg eq./k
	R	¢ g γ	″ R 🎘	g,	R	eq./R	Ĉ	φġ.	$\mathcal{O}_{\mathbf{R}}^{\mathbf{K}}$	g
Chromatographe d radioactivity	98ag	4	9 8 .3	£.90	,98.9	×5.20≪	93, 3 5	2,59	96.5	3.34
Identified metabolities										
M-01 (BAM)	96.4	10.00	26 2	1.86	3 7.9	©5.15	93.3	2.59	96.0	3.32
a) Pool of egg volks	and w	hites Day	κ 7 – Dâ	w/14	Y Q	, D	Z.			

Fluonicolide rummant metabolism study (dose lever of 10 mg/kg in the diet):

		[©] % Total [©] C-residue identified/characterised							
Tissue	Residue level X %	° %	Total ^E	C-resid	lue ider	ntified/ch	aracterised		
ja ka	(ppb) Extracted	FLÓ	M	MO″	М-	Polar§	Non-		
			%06	107	01		extracted		
Urine	NA V NA	<i>•</i> -	039 🔊	8.5	-	47	NA		
Faeces	2/06	14.00	1.70	0.92	-	1.7	78.4		
Milk	180° × \$5.9~	36,9	<u> </u>	-	3.9*	37.8	14.1		
Fat	4Ĭ 🕉 84.9Q	98 .4	Ŏ.	-	-	-	16.8		
Muscle		¥ 5.1 ≪	-	-	-	13.2	74.2		
Liver	644 . 89.9	0.0	1.6	1.2	-	79.7	10.9		
Kidney	302 5 592.40	Q.7	6.8	3.3	-	77.5	7.6		
NT X NT 1		[™] ×							

NA[™] Not Appliçable *©* Ů.

* The presence of this metabolite could not be confirmed in a second system or by HPLC/MS. § In most cases there were number of areas of radioactivity in the polar region, each of which could contain more than one metabolite. 1 ñ

M-01 (BAM) ruminant metabolism study:

There was andication of accumulation of M-01 (BAM) in milk and in the high proportion of the conulative dose detected in edible tissues at sacrifice. More extensive metabolism was found in the liver and kidneys.



Sample	Skimmed Milk Day 2- 4 Pool		Muscle Pool		Fat	Pool	Liver		Kidney	
TRR [mg/kg]	0	.104	0.	690		238	13.	977	6	.249
	% of TRR	mg/kg	% of TRR	mg/kg	% of TR R	mg/k g	TRR	ng/k g	% of TRE	mgdig
M-01 (BAM)	82.1	0.085	69.6	0.481	92.4	0.220	Q 16.3	2.278	0 9.4	0.586
L1, Glutathione conjugate				A.		, Â		2.007		
L2, USHD/9 relation				6	5	0	1 23.3	3.268		, <u>5</u>
L3/K4, USHD/6							38.8	5.015	\$2.8	1.423
L5/K13, FSHD/8 L6								0.188 0.188 0.188	ANONE .	
K1/K2 USHD/3	a.							23°°°°	19.2	ر 1.198
К3			Ģ*		Å,		, Q	1 Contractions	Q1.1	0.693
K7 USHD/10b									9.9	0.615
K13	S.		Ĩ,			<i>6</i>	× ·		9.7	0.607
Total identified	82.1	0:085	69.6	0.491	9204	0.239	2109	12.86 9	82.1	5.122
References of a), () ()					
compound)		erence		withor	Xear			ossier	referen	ice
Poultry (FLC)	23336	-02-1	, L	~ "	2003				A 6.2.2	
Poultry (FLC)	23397	7-03-1 ~~~~			2009				A 6.2.2	
Cow_(FLC) M-	23339	-02			2003			KARY COMPACTION	4 6.2.3	
	21862	7 Ó			2008	3			A 6.2.3	
Poultry (M-01)	ot awai	lable [™]	Ó		20	20		nary resort not		ovided – lised
Goat (NC01)	ot avai	table	V		2020)		nary resort not		ovided – lised
Poultry (M-01)										
No Co										

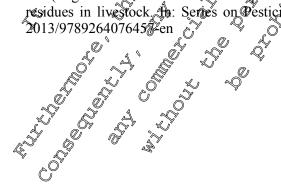


References

- EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438. doi:10.2903/j.efsa.2009;438
- EFSA (European Food Safety Authority), 2013. EFSA Guidance Document of the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp. doi:10.2903/j.efsa.2013.3295

European Commission, 1997. Appendix A. Metabolism and distribution in plants. 7928/IV/29-rev 3

- European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRES. 7525/VI/95 rev.10.3
- European Commission, 2018. Technical guide tones for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey. SANJE/11956/2016 rev. 9/14 September 2018.
- OECD (Organisation for Economic Co-operation and Development), 2007a. Test 300. 501. Metabolism in Crops, OECD Guidelines for the Testing of Chemoals, Section 5, OECD Publishing, Paris. doi:10.1787/9780264061835-64
- OECD (Organisation for Economic Co-operation and Development), 2007b. Fest 80. 502: Metabolism in Rotational Crops, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris. doi:10.1257/978926400859-01
- OECD (Organisation for Conomic Cooperation and Development), 2007c, Test No. 503: Metabolism in Livestock, OECD Condelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris. doi:10.1787/97892640(\$873-cm
- OECD (Organisation for Economic Co-operation and Development), 2007d, Vest No. 504: Residues in Rotational Gops (Limited Field Studies), OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris, https://doi.org/10.1787/9789264043384-en.
- OECD (Organisation for Economic Co-operation and Development), 2007e, Test No. 505: Residues in Livestock, OFCD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris. doi:10.9787/9789264061993 en
- OECD Organisation for Economic Co-operation and Development), 2009. Test No. 509: Crop Field Trial, OECD Guidelities for the Testing of Chemicals Section 5, OECD Publishing, Paris. https://doi.org/10.1787/20705796
- OECD (Organisation for Economic & operation and Development, 2012. Test No. 305: Bioaccumulation in Fish: Aqueous and Distary Exposure, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, https://doi.org/10.1787/9789264185296-en.
- OECD Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock the Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013/978926407645 en





CP 10.1 Effects on birds and other terrestrial vertebrates

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. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA GD 2009". 400 ×

Table 10.1.1- 1	l: Endpo	ints used in	risk assessment	4	
Test substance	Risk assessment	Test species	Endpoint 👸	Reference	
		Mallard duck	$LD_{50} > 2250 \text{ mg a.s./kg bw}$ $LD_{50} \neq 4248 \text{ fog a.s./kg bw}$	200 CA 8:4:1.1.00 Extrapolated ac 2009	<u>1c. M-2405/76-01</u> cc. to EFSA GD
	Acute	Bobwhite quail	LD ₅₀ $> 2250 \text{ mg H.s./kg-bw}$ $DD_{50} = 4248 \text{ mg A.s./kg-bw}$	CAT 8.1.1 (200 KCAT 8.1.1 (200 Katrapolated ac 2009	1: M-240577 91-1 2 2 5 To EFSA GD
		Zebra@ fingh	$DD_{50} = 1109 \text{ mg a s/kg by}$	201 2 KCA \$1.1.1693	<u>∞M-544294-01-</u> ©
	\$7 \$2	Bird acute geomean	LD ₅₀ 27117 mg a. kg bw ^{b)}	Geometric mea 2009	n acc. EFSA GD
	Short-term	Bobwhite	$LC_{50} > 5620 \text{ ppm}$ $LDD_{50} > 1747 \text{ mg a.spkg bw/da}$	110110.1.1.2/01	<u>2002; M-</u>
Fluopicolide		Mallard	2343 mg a s/kg bw/da		2; M-240714-01-
4			NOAEC \geq 1000 ppm NOAEL \geq 88.9 mg a.s./kg bw/day $E^{2}_{10} \rightarrow =$ 46.7.29.7 – 89.7) mg a.s./kg bw/d	M-225403-01-2 KCA 8.1.1.3/01	
				M-660212-01-1	2019;
TY State			$ \begin{array}{c} $	M-225404-01-2	2003:
47 47 47 47 47 47 47 47 47 47 47 47 47 4		Mallard duck	$\dot{NOEL} \ge 140.8 \text{ mg a.s./kg bw/da}$ $EC_{10} = 32.2 \text{ mg a.s./kg bw/da}$	EC ₁₀ calculation	n 2019;
M-01 (2,6-dichloro- benzamide)	Short-term	Bobwhite quail	LC ₅₀ = 3867 ppm LDD ₅₀ = 1171 mg a.s./kg bw/da	KCA 8.1.1.3/04 y <u>01-2</u>	4 2003; M-225551-



Test substance	Risk assessment	Test species	Endpoin	ıt	Reference
					KCA 8.1.1.2/03
Propamocarb-	Acute	Bobwhite quail/ Mallard duck	LD ₅₀	> 1842 mg a.s./kg bw	EFSA Scientific Report (2006) 78, 1-80
hydrochloride	Short term	Bobwhite quail	LC ₅₀ LDD ₅₀	> 5000 mg/kg feed > 962 mg a \$2kg bw/d	EKSA Scientific Report. (2006) 4 78, 1-80
	Long term	Bobwhite quail	NOEC NOEL	1139 mg a.s./kg feed/d 105 mg s./kg bw/d	T8, 1-80 Control EFSA Scientific Report (2006) Control 78, 1-80 Control
Fluopicolide+ Propamocarb- hydrochloride	Acute	Bobwhite quail	LD _{50 MIX}	> 1897 mg total a Sykg by	Crable 101.1.1.

Endpoints in **bold** considered relevant for risk assessment a) The study endpoint was extrapolated according to EFSA GD 2009. The extrapolation actor of 1.888 was derived from (EFSA GD 2009, section 2.1.2, table 1 for studies in which 10 animals were dosed and 65 mortality occurred.

b) In accordance with EFSA GD 2009, the geometric mean LD50 of the three species mallard nuck (ED50 = 4248 mg as kg

bw), bobwhite quail (LD₅₀ = 4248 mg a $\frac{2}{kg}$ bw) and zabra finch (LD₅₀ = $\frac{100}{2}$ mg a.s./kg bw) was used.

Metabolites of fluopicolide

As presented in the section "definition of the residues for fisk as sessment", the plant metabolites M-01 (AE C653711), M-02 (AE C657188), M-02 (AE 6657378), M-05 (AE 1344122), M-06 (AE C643890) and M-09 (AE B102859) met the criteria of 10% TRR or > 0.05 mg/rg. It should be noted the maximum overall concentration of each metabolite (ther as 70% TRR or as mg/kg/rd not typically come from the same matrix sample A worst-case screening level rise assessment for birds is presented in Table 10.1.1- 14 for M-01, M-02 M-04 and M 5, based on field residue and rotational crop studies evaluated in 10.1. 52/01. @ quantitative risk assessment for M-06 and M-09 is not conducted since their residues in the field residue and rotational crop studies were < LQQ.

An acute risk assessment is not conducted since this is considered to be covered by the worst-case screening-level long-term risk assessment.

	Shortcut value (SV)				
Crop of the Indicator species of the	Acute RA based on RUD ₉₀	Long-term RA based on RUD _m			
Potatoes deafy vegetables <u>lettuce</u>) Small omniverous kird A A A A A A A A A A A A A	158.8	64.8			



		Shortcut value (SV)			
Сгор	Generic focal species	Acute RA based on RUD ₉₀	Long-term RA based on RVDm		
	Small omnivorous bird "lark" BBCH 10–39	24.0	10,9		
Potatoes BBCH 21-89	Small omnivorous bird "lark" BBCH ≥ 40	7,23	\$ ⁹ 3,3,5 ⁹		
	Small insectivorous bird "wagtail"BBCH ≥ 20	Q 25.2			
	Small granivorous bird "finch" BBCH 10–49	27:4 Q			
T C (11	Small omnivorous bird "lark" BBCH 10–49		× × 10.9 v		
Leafy vegetables (lettuce) BBCH 13-49	Medium herbivorous/granivorous bitd "pigeon" BBCH 10–19	0.556^{a}	0 ⁴ 220 ⁴ 220 ⁴		
	Small insectivorous bird wagtait	268 268 25.2 25.2 27.4 27.5 27.5 27.5 27.5 27.5 27.5 27.5 27.5 27.5 27.5 27	11.20		
	Small insectivorous bird "wagtail" \sim \sim \sim BBCH ≥ 20 \sim \sim \sim \sim \sim	× 25.2 c	5 L9.7		
Leafy vegetables (lettuce)	Small granivor ous birds finch of a constant of the second	27.4	ل الم الم الم الم الم الم الم الم الم ال		
	Small omgivorous bird "lark" (7 (7 BBCH 19–49		10.9		
	Small insection fous bard "wagtail" \mathcal{F} \mathcal{F} BBCH $\geq 20^{\circ}$ \mathcal{F} \mathcal{F}	\$25.2 ×	9.7		
	Small insectivorous bird wagtail BBCH 10–19 Small insectivorous bird wagtail BBCH ≥ 20 Small granivorous bird finch BBCH 10–49 Small ongivorous bird wagtail BBCH 10–49 Small insectivorous bird wagtail BBCH 20 Small insectivorous bird wagtail BBCH ≥ 20 Small insectivorous bird wagtail bird for the first state of the first st				

Table 10.1.1- 3:	Relevant generic focal species for first-tier risk assessment



ACUTE DIETARY RISK ASSESSMENT

Screening step

Screening step									
Table 10.1.1- 4: Screening acute risk assessment for birds (fluopicolide)									
		DDD				OLD50	×		
Сгор	Indicator species	Appl. rate [kg a.s./ha]	SV90	MAF90	DDD	[mg a.s./ kg bw]	TÉŘA	Trigger	, , ,
Potatoes 4 × 1.6 L prod./ha	Small omnivorous bird	0.1	158.8	1.8	28 .6	2711	94.9°		Ó
Potatoes 3 × 1.6 L prod./ha	Small omnivorous bird	0.1	458.8	1.6	25 &)°	Į ⁿ i, ó	v 106.7		Ŷ
Potatoes 2 × 1.6 L prod./ha	Small omnivorous bird	0.1 &	15 8 8	104 12	×22.2 4	¢ 2710	1241.9	×ã0	
Potatoes 1 × 1.6 L prod./ha	Small omnivorous bird		0158.8		15.9	2711 Č	170		
Lettuce 2 × 1.6 L prod./ha	Small omnivorous bird		158.8	×1.4 ,	¢22.2¢	2761	g/21.9	Ö 10	
Lettuce 1 × 1.6 L prod./ha	Small omnivorous	0.1	158.8	1.9	§3.9	0 2711	1.70.7	10	
		Y ₂ g	- O	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				·	

	K, ^v			, V
	~ (Ch .
Table 10.1.1- 5:	Screening acute Msk	assessment for high	ls (fluonicolidě + 1	propamocarb-hydrochloride)
	Ser coming acare isin	approximent for birt	is (indepreditive .]	propullio injulocilio lituc)

		r o do	R	· · ·	17 Ā	\sim \sim	•	· · · · ·
Сгор		Appl. rate [kg] prod./hat	SV90	0 ⁵ 4 7 0 MA(590		(png a.s./ kg bw]	TERA	Trigger
Potatoes $4 \times 1.6 \text{ L prod.}$	Small omnivorous		₹ 158.8©	r 1.85	314.4	1897	6.0	10
Potatoes 2 3 × 1.6 Lprod./ha	Small omnivorous bird	\$ 1.1 °	158.8	©1.6	279.5	1897	6.8	10
Potatoes	Small omnivorous Fird		15868	134	244.6	1897	7.8	10
Potatoes 1 × 1.6 L prod./ba	Gird 4 Smathomnixorous bird 2		\$\$\$8.8	\$ ⁰ 1.0	174.7	1897	10.9	10
Lettuce $2 \times 1.6 \text{ L prod./ha}$	Small opinivorous bird	Q 1.1 Q	158,8	1.4	244.6	1897	7.8	10
Lettuce & 1 × 1.6 L prod./ha	Small ommeorous		ð 158.8	1.0	174.7	1897	10.9	10
~~~	The second se	Q 28						

For fluopicolide the  $\text{RER}_A$  is above the trigger of 10. Therefore, no further risk assessment at Tier 1 is required for huppicolide. For fluopicolide + propamocarb-hydrochloride the TER_A is below the trigger of 10. Therefore  $\alpha$  risk assessment at Tier 1 is required for fluopicolide + propamocarb-hydrochloride for the 4 1.6 L prod/ha, 3 (-6) L prod/ha and 2  $\times$  1.6 L prod/ha applications in potatoes and for the 2  $\times$  1.6 L prod/ha application in lettuce.



### Tier 1

	Generic focal	D	DDD			<b>159</b> 50	
Сгор	species	Appl. rate [kg/ha]	SV90	MAF ₉₀	DDD	[mg@.s./kg bw]	TERA Trigger
Potatoes BBCH 21-89 4 × 1.6 L prod./ha	Small insectivorous bird "wagtail" $(BBCH \ge 20)^{a}$	1.1	25.2	1.8	49.90	بر 1897 کې رو	
Potatoes BBCH 21-89 3 × 1.6 L prod./ha	Small insectivorous bird "wagtail" $(BBCH \ge 20)^{a}$	1.1	\$25.2	1.6	4.35 0	° 697 6	
Potatoes BBCH 21-89 2 × 1.6 L prod./ha	Small insectivorous bird "wagtail" $(BBCH \ge 20)^{a}$		¢5.2	₹¥.4	3 <b>8</b> .80,		
Leafy vegetables BBCH 41-49 2 × 1.6 L prod./ha	Small granivorous bird "finch" (BBCH 10–49) ^{a)}		20.4		4 <b>0</b> .20		45.0 310

First-tier acute risk assessment for birds (fluopicolide + pronamocarb-hydrochlowide) Table 10 1 1- 6.

L,

The TERA values calculated in the acute risk assessment exceed the a-priori-acceptability trigger of 10 6 for all evaluated scenarios. Thus, the acuterisk tobirds can be considered as how and acceptable without need for further, more realistic risk assessment

Ô

### Combined toxicity risk assessment

According to current requirements when a product contains more than one active substance, an additional assessment on combined Toxicity risk of the product has to be done.

For the assessment of acute effects (mortality) a surrogate LD₅₀ (mix) can be calculated for the mixture risk assessment. The EESA GO 2009 indicates that the following equation should be used for deriving a surrogate LD_{50mix} for a mixture of active substances with known toxicity assuming dose additivity:  $\sim$ 

$$LD_{50} \text{ (mix)} = \left(\sum_{i}^{\infty} \frac{X(q.s._i)}{LO_{50}(aO.i)}\right)^{1} \sqrt{2} \sqrt{2} \sqrt{2}$$

where:

Ò tion of active substance (i) to the formulation mixture

= acute toxicity LD50 (a.s.i) for the active substance (i)

The active substance control of the formulation FLC+PCH SC 687.5 addressed in this dossier is 62.5 g fluopicolide/L prod. and 925 g propamocarb-hydrochloride/L prod., making up a total of 687.5 g a.s./L product

The table below shows the calculation of the predicted LD₅₀ (mix) of fluopicolide and propamocarbhydrochlouide when mixed in these proportions (step 1 in Appendix B of EFSA GD 2009).



# Table 10.1.1-7:Avian LD50 (mix) for fluopicolide and propamocarb-hydrochloride when combined as<br/>FLC+PCH SC 687.5 (step 1 in Appendix B of EFSA GD 2009)

	Fluopicolide	Propamocarb- 🖉 🏷
Content of a.s. in product [g a.s./L prod.]	62.5	<u>ک</u> 625 ک
Fraction in the a.s. mixture	0.0909	0.9091
LD ₅₀ of a.s. [mg a.s./kg bw]	2711	₹ \$42, \$
Fraction / LD ₅₀	Ø.0000335	<0004935
Sum	0.00 × 0.00	005271
1/sum = predicted LD ₅₀ (mix) [mg total a.s./kg bw]		8974 A C Q
&		

It is obvious from the comparison of the (loss) acute oral toxicity of the active substances, and their relative proportions of the formulated product FLC+PCD SC 687.5, that propamocarb has a tox per fraction of > 90% and thus clearly drives the risk assessment.

# Table 10.1.1- 8: Avian "tox per fraction" for FLC+PCH-SC 687.5 (step 1 in Appends B of EFSA GD 2009)

Fluopicolide Spamocarb-	O [°] "mix"
Content of a.s. in product [g. s./L prod.]	
Fraction in the a.s. mixture $\sqrt{2}$	1
LD ₅₀ of a.s. [mg a.s./k@bw]	1897
Tox per fraction $\sqrt[3]{2026}$	31847
Contribution to predicted toxicity Or 6% & 94 %	100 %

Fluopiconde contributes to % % to the predicted acute mature toxicity, while propamocarbhydrochloride contributes 94% to the mixture toxicity. Consequently, according to EFSA GD (2009) the acute risk assessment, can be performed only for perparacerb-hydrochloride.

EFSA GD 2009 recommends as next step 2a and 2b in Appendix B) to check the predicted toxicity against measured toxicity from LD₀ studies conducted with the formulation. However, no study with the formulation was conducted. Therefore, steps 2a and 2 b cannot be conducted.

EFSA GO 2009 recommends not to conduct a combined reproductive risk assessment for compounds not sharing the same mode of action (step 3). Therefore, no combined reproductive risk assessment is required for the FLC+PCF SC §87.5 in this ACR-evaluation but will be conducted post-AIR according to the respective zonal guidance.

EFSA GD 2009 recommends calculation methods to generate MAF values for the exposure assessment appropriate for comparison to the LD₂ (mix). This is not necessary here since no combined risk assessment is required, only the assessment for the risk driver propamocarb-hydrochloride with 94 % tox per fraction. This is presented in Table 10.1.1-6.

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

The leaf scenario is relevant for leafy vegetables and is therefore considered for the use in lettuce.



# Table 10.1.1-9:Tier 1 acute TER calculation for exposure via drinking water from pools in leaf axils<br/>or on leaves

Сгор	Compound	DWR [L/kg bw/d]	PEC _{pool} ^{a)} [mg/L]	DWR × PEC _{pool} [mg/kg bw/d]	LD ₅₀ [mg/ kg bw]	TERA	Frigger	
Leafy vegetables	Fluopicolide	0.46	100	46	2711	58.9 🗳	10,0	
$1 \times 1.6$ L prod./ha	LD ₅₀ (mix)	0.46	1100	506	1897	3	160	ĝ

a) PEC_{pool} = C_{spray}/5 [mg/L] whereas C_{spray} is 500 mg FLC/L and 5500 mg FLC+PCH/L considering a spraysolution of 100 FLC/ha and 1000 PCH/ha dissolved in a minimum of 200 L water/ha as worst-case approach.

The acute TER value is above the trigger of 10 for fluopicolide but below the trigger of 10 with the LD₅₀ (mix) for fluopicolide + propamocarb-hydrochloride. As stated before, propamocarb-hydrochloride contributes 94 % to the mixture toxicity, so in order to fefine the acute TER for exposure via druking water from pools in leaf axils or on leaved for the mixture we will focus on the refinement for propamocarb-hydrochloride. The following refined assessment is provided in the AIR submission dossier for propamocarb-hydrochloride, where this scenario was also evaluated:

"The TER value for Propamocarb HCl forbirds drinking from pool on leaves is still below the trigger of 10 which would indicate an unacceptable sisk to birds

Indeed, according to the EFSA Guidance Document for Birds and Manufals (2009), 'incidents reported in the past confirm that infact a potential for adverse effects exists that may be realised when several conditions (applications of pesticides followed by rainfall and irrigation in a period of draught) are simultaneously met. In such cases, typical approaches for refining the risk assessment, e.g. the estimation of a PT factor, are not possible...' and 'as a consequence, a risk identified in a leaf scenario will typically have to be managed'.

However, in the EFSA Guidance Document for Birds and Maromals (2009), reference is made to a few cases of incidents reported in Germany in between 1980-1990. There are in total 12 incidents reported in Germany in between 1980-1990. There are in total 12 incidents reported in Germany from 1983 to 2003. They include acutely toxic substances like methomyl (LD₅₀ ca. 17 mg a.s./kg bw; application rates 150 and 228 ga.s./ha 7 incidents), methamidophos (LD₅₀ ca. 12 mg a.s./kg bw; application rates 360 g a.s./ha 2 incidents) dimethoate (LD₅₀ ca. 28 mg a.s./kg bw; application rate: 240 g a.s./ha; 1 incident), methopo (1 incident), parathen (1 incident), and oxydemeton-methyl (1 incident, in combination with methomyl). Phese compounds cannot be compared in their profile to low acutely toxic compounds with a Proparationary field with an LD₅₀ higher than 2637 a.s./kg bw.

According to the application rates (with a water volume of 200 L/ha used) and the acute toxicity of methonyl, methanidophos, and dimethoate to birds, the drinking water risk assessment approach envisaged for the leaf scenario in the EFSA Guidance (2009) would lead to TER values in between 0.01 and 0.05. These values are far below the FER value of (>) 5.7 for Propamocarb-HCl and the trigger value of 10, the Propamocarb-HCl being of very low toxicity to birds according to results of the toxicity studies presented in Tables CP 30.1.1-1 to CP 10.1.1-3. Actually, as mentioned in the EFSA Guidance Document for Birds and Mammals (2009), *as regards calculated TER values, the leaf scenario obviously constitutes in extreme worse-case scenario. It can be shown that even substances of moderate to 16w toxicity (LD₅₀ > 1600 mg/kg) will often fail this scenario. 'Consequently, the occurrence of a bird incident with Propamocarb-HCl is unlikely and the drinking water risk to birds for use on cabbage after BBCH 40 (i.e. Development of harvestable vegetative plant part) can be considered as fully acceptable."* 



### Acute risk assessment for birds drinking contaminated water from puddles

Because propamocarb-hydrochloride is the risk driver in the LD₅₀mix, and since propamocarbhydrochloride belongs to the group of more sorptive substances with a Koc of 516.7, it is appropriate to set the threshold for no concern at 3000 for the combined assessment.

### Table 10.1.1-10: Evaluation of potential concern for exposure of birds from drinking water, clause)

	lause)				s v	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
Сгор	Compound	K _{oc} [L/kg]	AR _{eff} (Appl. rate × MAF) [g a.s./ha	© ▼LD50 , [mg a.s./ kg bw]	Ratio OAReff / LD50)		Conclusion,
	Fluopicolide	267.7	400 ^a )	271	×0,15	<u> </u>	No concern
Potatoes (4 × 1.6 L prod./ha)	Fluopicolide + Propamocarb- hydrochloride	-	4400	00000000000000000000000000000000000000	2.32 2.32	3000 ×	No concern
Potatoes (3 × 1.6 L prod./ha)	Fluopicolide	267	300 a)	27,1	\$0.11 ×	\$50 x	No concern
	Fluopicolide + Propamocarb- hydrochloride		3300	×1897	274 274		No concern
	Fluopicolid	269.7	200 a)	2941	Q 0.07	⊗≤ 50 %	No concern
Potatoes and lettuce $(2 \times 1.6 \text{ L prod./ha})$	FluopicoHde +« Propagnocarb© hydrochloride			© 1897	29.16 V	2 2 2 3 000 2 3 3 000	No concern
	Fluopicoffe	267.7	0100	° <b>≫2</b> 711 Õ	0%0,4	°≫ ≤ 50	No concern
Potatoes and lettuce (1 × 1.6 L prod./ha)	fluopicolide Propâmocarb hydrochloride		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	1.597		≇ ≤ 3000	No concern

a) Instead of the QIAF, the number of applications was used as a worst-case multiplicator. Š

According to the EFSA Guidance document for fisk assessment for bird and mammals (2009) "no specific calculations of exposure and TEROare necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of the respective substances (Koc > 500 L/kg)." This is the case for fluopicolide and propamocarb-hydrochlorde. Therefore, the acute risk for birds from drinking water that may contain residues from fluggicolide and fluopicolide + propamocarb-hydrochloride is acceptable £

0

## LONG-TERM REPROPUCTIVE ASSESSMENT

EFSA GD 2009 recommende not to conduct a combined reproductive risk assessment for compounds not sharing the same mode of action (step 3). Therefore, no combined reproductive risk assessment is required for the FLC+PCO SC 687.5 in this AIR-evaluation but may be conducted post-AIR according to the respective zonal guidance.

E ST G



(1) n

### Screening step

Screening long-term reproductive risk assessment for birds (fluopicolide)							Ś		
Indicator		DDD	)			ÊC 10	Q		0*
species	Appl. rate [kg a.s./ha]	SVm	MAFm	ftwa	DDD	[mg-a.s./ kg bw/d]	TER ₁	Trigger	Ĉo
Small omnivorous bird	0.1	64.8	<i>L</i>	0.53	7.6	32.2	× 4.3 *		, C
Small omnivorous bird	0.1	ء 64.8 ©	2.0	0.53	56.9	32	Q.7	6 ⁵⁵	N N
Small omnivorous bird	0.1	<b>A</b> .8	1.6	0.53	[°]	\$2.2	5.9	Zer,	
Small omnivorous bird	0.1	64.8		0.53	3.4	32,2	9.4	5	
Small omnivorous bird		~ <b>6</b> 4.8	₹ 1.6	0.53	A5.5	€ ^{32.2}	5:9°		
Small omnivorous bird	Q 0.1	64.8		0,53	3.	Q.2	9.4	Õ ₅	
	Indicator speciesSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous birdSmall omnivorous bird	Indicator speciesAppl. rate [kg a.s./ha]Small omnivorous bird0.1Small 	Indicator speciesDDDAppl. rate [kg a.s./ha]SVmSmall omnivorous bird0.164.8Small omnivorous bird0.1	Indicator speciesDDDAppl. rate [kg a.s./ha]SVmMAFmSmall omnivorous bird0.164.82.2Small omnivorous bird0.164.82.0Small omnivorous bird0.164.82.0Small omnivorous bird0.164.82.0Small omnivorous bird0.164.81.6Small omnivorous bird0.164.81.0Small omnivorous bird0.164.81.0Small omnivorous bird0.164.81.0Small omnivorous bird0.164.81.0Small omnivorous bird0.164.81.0	Indicator speciesAppl. rate [kg a.s./ha]SVmMAFmfTWASmall omnivorous bird0.164.82.20.53Small omnivorous bird0.164.82.00.53Small omnivorous bird0.164.82.00.53Small omnivorous bird0.164.82.00.53Small omnivorous bird0.164.81.00.53Small omnivorous bird0.164.81.00.53Small omnivorous bird0.164.81.00.53Small omnivorous bird0.164.81.00.53Small omnivorous bird0.164.81.00.53	Indicator speciesAppl. rate [kg a.s./ha]DDDDDDSmall omnivorous bird0.164.8220.537.6Small omnivorous bird0.164.82.00.536.9Small omnivorous bird0.164.82.00.536.9Small omnivorous bird0.164.81.60.535.5Small omnivorous bird0.164.81.60.533.4Small omnivorous bird0.164.81.60.535.5Small omnivorous bird0.164.81.60.535.5Small omnivorous bird0.164.81.60.535.5Small omnivorous bird0.164.81.60.535.5Small omnivorous bird0.164.81.60.535.5	Indicator species         DDD         Image: Constraint of the species         Appl. rate [kg a.s./ha]         SVm         MAFm         frwa         DDD         Image: Constraint of the species           Small omnivorous bird         0.1         64.8         2.2         0.53         7.6         32.2         32.2           Small omnivorous bird         0.1         64.8         2.0         0.53         6.9         32.2         32.2           Small omnivorous bird         0.1         64.8         2.0         0.53         5.3         32.2         32.2           Small omnivorous bird         0.1         64.8         1.6         0.53         5.3         32.2         32.2           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2         32.2	Indicator species         DDD         DDD         Image: Constraint of the species         Appl. rate [kg a.s./ha]         SVm         MAFm         frwa         DDD         Image: Constraint of the species         TERut           Small omnivorous bird         0.1         64.8         2.2         0.53         7.6         32.2         4.3           Small omnivorous bird         0.1         64.8         2.0         0.53         6.9         32.2         4.3           Small omnivorous bird         0.1         64.8         2.0         0.53         6.9         32.2         4.3           Small omnivorous bird         0.1         64.8         1.6         0.53         5.3         2.2         5.9           Small omnivorous bird         0.1         64.8         1.0         0.53         5.5         32.2         9.4           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         32.2         9.4           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         32.2         9.4           Small omnivorous bird         0.1         64.8         1.6         0.53         4.2         9.4	Indicator species         Appl. rate [kg a.s./ha]         SVm         MAFm         fTWA         DDD         fty a.s./kg bw/d]         TERta         Trigger           Small omnivorous bird         0.1         64.8         2.2         0.53         7.6         32.2         4.3         5.5           Small omnivorous bird         0.1         64.8         2.0         0.53         6.9         32.2         4.3         5.5           Small omnivorous bird         0.1         64.8         2.0         0.53         6.9         32.2         5.9         5.5           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         5.2         5.9         5.5           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         5.2         5.9         5.5           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         5.2         5.9         5.5           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         5.2         5.9         5.5           Small omnivorous bird         0.1         64.8         1.6         0.53         5.5         5.2

For the 2 × 1.6 L prod./ha and the 1 × 4.6 L prod./ha applications in potatoes an effective the screening level TER_{LT} is above the trigger of 5. Therefore, no further risk assessment at Tier 1 is required. For the  $4 \times 1.6$  L prod./ha and  $3 \times 1.6$  L prod./ha applications in potatoes the TER₁₇ is below the trigger of 5. Therefore, a risk assessment at Tier 1 is required.

 $\bigcirc$ 

Tier 1

Enst-tier fong-term reproductive risk assessment for birds (fluopicolide) Table 10.1.1- 12

Crop	Generic forat species	Appl, rate [kg@s./hay		Drwa	DDD	EC10 [mg a.s./ kg bw/d]	TER _{LT}	Trigger
Potatoes BBCH 21-89 4 × 1.6 L prod Ha	(BBCH 10-39) *~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			0.53	1.27	32.2	25.3	5
Potatoes BBCH 21-89 $3 \times 1.6$ K prod./ha	(BBCH 10–39) a)		10% 10%	0.53	1.16	32.2	27.9	5

a) Covers all other relevant generity focal species with lowers hortcut values

Ø1

The TERLT values calculated in the long-term risk assessment exceed the a-priori-acceptability trigger of 5 for all evaluated scenarios. Thus, the fong-term risk to birds can be considered as low and acceptable without need for further more tralistic risk assessment.

0

(1)



ð

### Long-term risk assessment for birds drinking contaminated water from puddles

	Compound	K _{oc} [L/kg]	(Appl. rate × MAF)	NO(A)EL [mg a.s./ kg bw/d]	Ratio (AR _{eff} / NO(A)	Cause"	Conctasion
Potatoes 4 × 1.6 L prod./ha)	Fluopicolide	267.7	[g a.s./ha]	32.2	012.4	if ratio	No concern
Potatoes 3 × 1.6 L prod./ha)	Fluopicolide	267.7	366	° 32.2		O, se	No concern
Potatoes and lettuce $2 \times 1.6 \text{ L prod./ha}$	Fluopicolide	267.7		32.2 Q	6.2 A C	S = 500 ⁻¹	Nor concern
Potatoes and lettuce $1 \times 1.6 \text{ L prod./ha}$	Fluopicolide	201.7	×100 av	s s			No concern

 Table 10.1.1-13:
 Evaluation of potential concern for exposure of birds from drinking water (escape)

According to the EFSA Guidance Document for risk assessment for bird and mammals (2009) "no specific calculations of exposure and TEP are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed to so not exceed 30 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc > 500 L/kg)." This is the case for fluopicolide to acceptable

### RISK ASSESSMENT OF SECONDARY POLSONING

According to the EFSA GD 2009, substances with  $2 \log P_0 \sqrt{2} \ge 3$  have potential for bioaccumulation and should be assessed for the risk of biomagnetication in aquatic and terrestrial food chains.

The log  $P_{ow}$  value of fluopicolate is 2.9. Since the  $P_{og}$  Pow does not exceed the trigger value of 3, fluopicolide is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment for secondary poisoning is therefore required.

## RISK ASSESSMENT FOR PLANT METABOLATES

A worst case screening level risk assessment for herbivorous bird exposure to plant metabolites can be based on the maximum RUDs determined by 2020 (M-686445-01-1, 10.1.1.2/01) for M-01, M-02, M-04 and M-05 in feltage sampled during the course of field residue or rotational crop studies. For that screening evel risk assessment, the maximum MAF for the uses under assessment is set to be 4 (number of applications), and no deposition factor is applied. The FIR/bw represents a small omnivor dis bird eating foliage at a rate 0.5 times its own bodyweight each day. The toxicity endpoint is set at one teach of the reproductive risk assessment endpoint for the parent.

Thes this screening level assessment combines worst case elements in a risk-envelope. If needed, more realistic and crop-/use – specific input parameters can be included.



Compound	GFS	FIR/bw	PD	RUD _{max}	AR	MAF	<b>f</b> _{TWA}	<b>f</b> DEP	DDD	NOAEL	TEŖ	]
M-01	lark	0.5	25% foliage	1.714	0.1	4	0.53	1	0.18	3.22	<b>J</b> .7	ð
M-02	lark	0.5	25% foliage	0.498	0.1	4	0.53	1	0.05	3.22 &	61.0	6 ⁷
M-04	lark	0.5	25% foliage	0.090	0.1	4	0.53	1	0.01	3.22	33705	
M-05	lark	0.5	25% foliage	0.200	0.1	4	0.53	1 10	0.02	3,22	£\$1.9	æ.
				•				A			× .	Q

Table 10.1.1-14: Risk envelope assessment for plant metabolites (birds)

### **CP 10.1.1.1** Acute oral toxicity

For animal welfare reasons, no acute oral toxicity study with the preparation was performed Such study is not deemed necessary, given the fact that the formulated product was more toxic to gats that to on birds be expected based on its active substance content.

CP 10.1.1.2	Higher tier data	on birds
-------------	------------------	----------

	KCP 10.107.2/017
Data Point:	KCP 10.1012/01 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Report Author:	
Report Year:	
Report Title:	Flugpicolide. Plant metabolite residues for merbivarous bird and mammal risk
	assessment Of A or A Sy a
Report No:	PnSa-20-0482 M-626445-01-1
Document No:	M-626445-01-1
Guideline(s) followed in	EFSA 2009 Guidance document for bird and manual risk assessment and EFSA
study:	2019 General referring tissues in ecotoxicology $\sim$
Deviations from current	none of the second seco
test guideline:	
Previous evaluation:	No not previously Submitted
GLP/Officially	, not applicable & & & & & & & & & & & & & & & & & & &
recognized testing	not applicable
Acceptability/Reliability:	Yes a a a a a a a a a a a a a a a a a a a
	Yes to
() . O ^V	

### Executive summary

In this document residue results for the plant metabolites M-01 (AE C653711), M-02 (AE C657188), M04 (AE C657378) and M-09 (AE 1344129) of floopicolide were compiled.

The objective of this compilation was to establish realistic exposure concentrations for use in the risk assessment for herbivorous birds and mamma Therefore, only samples from leaves, shoots, or stalks were considered in order to match the diet categories in the generic focal species scenarios in the EFSA GD 2009¹⁴) for risk assessment on birds and mammals.

For this compilation, all wailable plant metabolism studies were evaluated in order to define the nature of the residue sensu EFSA 2019¹⁵). For these metabolites, all measured residue concentrations reported in the field residue of rotational crop studies were compiled to evaluate the level of the residue



¹⁴ EFSA 2009 Guidance document for bird and mammal risk assessment. doi:10.2903/sp.efsa.2019.EN-1673

¹⁵ EFSA 2019 General recurring issues in ecotoxicology. doi:10.2903/sp.efsa.2019.EN-1673



(sensu EFSA 2019). These measured residue concentrations were tabled in Excel spreadsheets, and the corresponding residue per unit doses (RUDs) were calculated to normalize the residue concentrations for the cumulative application rate applied prior to the measurement time point. Thus, the RUDs represent measured concentrations of the metabolite per kg applied of the parent.

With that approsphere.	bach, plai the equat	nt metabo	blite concentrations can be estimated also for other (untested)
C _{metabolite} [mg m	netabolite	/kg plant	] = RUD x cumulative parent application rate [kg a.s./ha
Table 10.1.1.2-1	: Natu mam	re and qu mal risk a	antity of the metabolite residues in plants for herbivorous bitd and assessment idue es)
		<b>of the resi</b> lism studie	idue Level of the residue (field residue and @itational crop studies)
Metabolite			Concentration Al RED & Maximum RUD found
	%TRR	mg/kg	Comment Contraction of the contr
M-01 AE C653711 BAM	87.5	2.170	Maximum values 479 1,714 (max) carrot leaves (r) from different 453 DAFA matrices (r) (00759 (90 th pere) 453 d DAFA (9076) (mean) 453 d DAFA
M-02 AE C657188 PCA	43.0	1.087	Maximum values 47.9 0.498 (max) 5 potate caves (cd) from same matrix 0.938 (90 perc.) 72d DAFA 0.938 (90 perc.) 25 DALA
M-04 AE C657378	59.3	0.87 <del>0</del>	Maximum values     165     0.090 max)     Spring wheat stalks (r)       grom different     0.023 (90% perc.)     376d DAFA       matrices     0.012 (mean)     318d DALA
M-05 AE 1344122 P1x	41.0	0.108	Maximum values (165 0.200 (max) from different 0.050 (90 th perc.) 312d DAFA ortatrice 32 0.020 (mean) 257d DALA
M-06 AE C643890		6068 <u>}</u>	from different for risk assessment
M-09 AE B102859	10.50	0.052	Maximum values Maximum values from different matrices

Table 10.1.1.2-1:	Nature and quantity of the n	netabolite Residues in	plants for	herbivorous	biçd	and
	mammal risk assessment	Å.	,0¥	×	õ	S

(d) direct overspray trial DAFA: days after first application

DALA days after last application (r) rotational crop 2

RUD: based on total application rate of the parent (e.g., 4 applications with 100 g a.s./ha each = 400 g/ha total rate). The RUD & expressed in metabolite equivalents.

No residue data are compiled for M-06 No experimental toxicity data are available for M-06. However, M-06 is structurally very similar to the parent fluop colide; being a hydroxylation product (at position 3 of the phenyl ring) which is generall considered as detoxification reaction. Therefore, M-06 is considered to be equally or less toxic compared to fluopicolide. This assumption is substantiated by the results of the Q&AR analysis Furthermore, the rotational crop studies (M-623459-02-1, M-679637-01-1 and M-67962-01-4 show that there is negligible exposure potential, given that the residue of M-06 are <LOQ (\$0.01 mg/kg within barley grain and maize fractions). M-06 is therefore not considered to be a relevant metabolite for the risk assessment.

No residue date are compiled here for M-09. M-09 is more acutely toxic than fluopicolide (the LD₅₀ for M-09/s 103/ mg/kg bw, while the corresponding value for fluopicolide is >2000 mg/kg bw). While this indicates apotential hazard, the actual exposure expected from M-09 is negligible, as all of the rotational crop staties presented within section MCA 6.6.2 (covering matrices of barley green material, carrot leaves, lettuce, maize green material) show that residues of M-09 do not exceed the LOQ (0.01 mg/kg in all of the tested crop fractions) for any of the tested plant-back scenarios. For this reason, metabolite M-09 is not considered to be relevant for inclusion within the risk assessment.



### I. MATERIAL AND METHODS:

For compilation of the measured residue levels in the field and rotational crop studies, the findings were tabled to document the input data for calculating the specific RUD for each data point. The collected information consisted of the trial ID, the application scenario, and the measured residues for each timepoint where foliage samples were taken for chemical analysis.

Where residues were < LOQ, a value of 0.5 x LOQ was included for use in the descriptive statistic

Afterwards the results were ranked in decreasing order of the RUDs, to facilitate the identification of the trial conditions that resulted in the highest measured RUDs, e.g. the specific plant in which the residues were determined, and the time span between application and residue measurement.

Descriptive statistics (number of data points, maximum RUD, 90th percentile RUD and mean RUD) were calculated for each of the four plant metabolities.

A plot was generated presenting each of the individual metabolite RUDs of the paxis versus the time since first application on the x-axis, visualising the temporal profile of the metabolite concentrations,

### II. RESULTS AND DISCUSSION:

### M-01 (AE C653711, BAM)

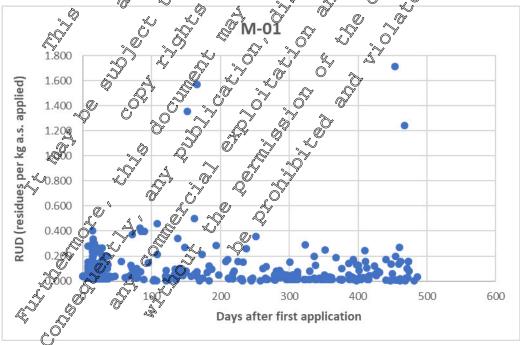
The maximum residues of M 01 were found in carrot leaves 453 days after a single pre-planting application, with a RUD_{max} of 1.714 mg metabolite per 1 kg of parent applied

The 90th percentile RUD was found at 0.159, and the mean RUD was 0.076 n = 479).

The data used for these calculations is preserved in Appendrx 1 of the report.

The distribution of the RUDs in all evaluated trials is presented in the figure below.

# RUD for M-01 AE C653711, BAM) in field to sidue of rotational crop studies





### M-02 (AE C657188, PCA)

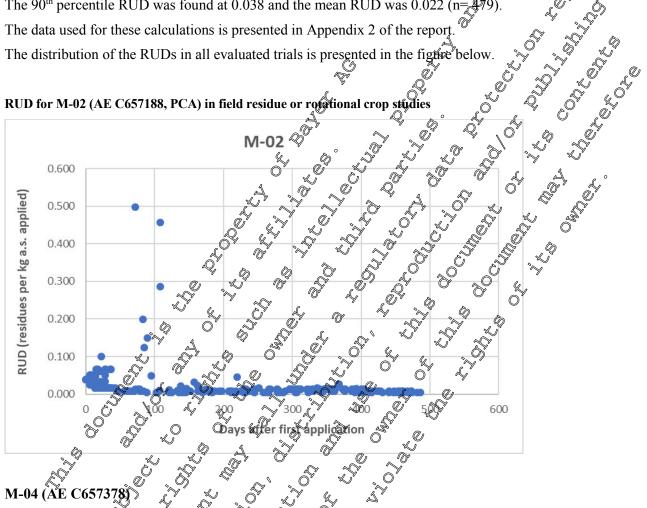
The maximum residues of M-02 were found in directly treated potato leaves 25 days after the last of 4 spray applications (72 days after the first of these applications), with a RUD_{max} of 0.498 mg metabolite per 1 kg of parent applied.

T.

The 90th percentile RUD was found at 0.038 and the mean RUD was 0.022 ( $n=\sqrt{9}$ ).

The data used for these calculations is presented in Appendix 2 of the report.

The distribution of the RUDs in all evaluated trials is presented in the figure below.



RUD for M-02 (AE C657188, PCA) in field residue or rotational crop studies

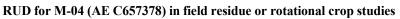
The maximum residues of M-QE were found in spring wheat stalks as succeeding crop in a rotational crop study 318 days after the best of Aspray applications ( $\sqrt[5]{6}$  days after the first of these applications), with a RUD of 0.000 mg metabolite per 1 kg of parent applied.

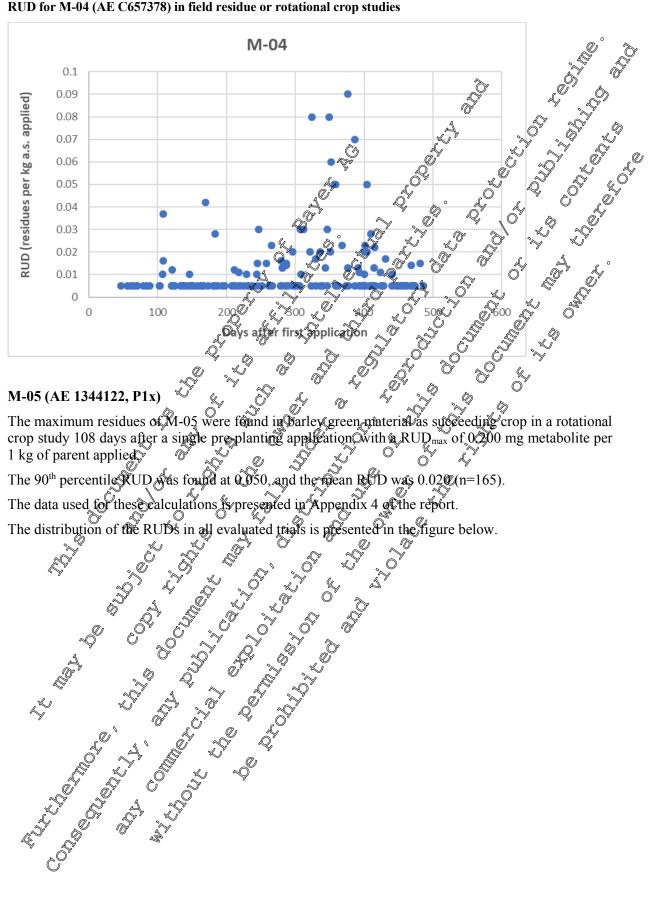
The 90th percentile RUD was found at 0.023, and the mean RUD was 0.012 (n= 169).

The data used for the so calculations is presented in Appendix 3 of the report.

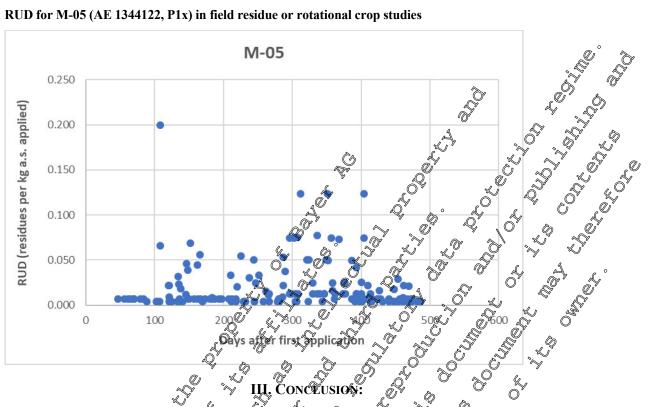
The distribution of the RIPDs in all evaluated thats is presented in the figure below.











RUD for M-05 (AE 1344122, P1x) in field residue or rotational crop studies

The samples evaluated in this document were from field studies and were taken after different time points following different application sequences of fluopicolide on different crops (e.g., potato, barley, lettuce, spinach and leek). Residues in the for age of succeeding stops were also included (e.g., carrots, winter wheat, spring wheat, faba beans and cabbase). These different plants are considered as surrogate for unspecified grasses and weeds that herbivorous birds and mammals may eat when foraging in agricultural fields that are treated with fluopicolide. 2

The residue concentrations were related to the time between the first application and the sampling time point, in order to account for the time span over which he metabolite could be formed prior to reaching the measured concentration. This is only one of the possible temporal relations between the application sequence and the sampling sequence, but considered suitable for the current purpose, i.e. to visualize the temporal profile of the metabolite concentrations. & 2

In order to account for the different application rates applied in different application sequences in the data set, the residues in each sample are normalised for the otal application rate applied in the respective field trial prior to taking this sample, resulting if the so-called RUD (residue-per-unit dose). This RUD is used in hird and mammal rise assessment to establish the expected residue concentration C of an active substance (in mg/as/kg) when multiplied with the application rate AR in [kg as/ha]: AR x RUD = C. Here this concept is applied for the metabolites of fluopicolide: the product of the RUD for the metabolite with the application rate of the parent is the expected residue concentration of that metabolite and can be used in the TER-calculation together with the toxicity endpoint of that metabolite.

Based on the available information, the maximum RUDs of M-01, M-04 and M-05 are found after uptake from soil by successing crops. The maximum measured RUD for M-02 was found in the foliage of the directly treated plants, which are therefore protective for metabolite concentrations in succeeding plants with residues from soil uptake.

With regard the main metabolites M-01 and M-02, the available data set contains nearly 500 data points at different time points after application, so that the information can be considered as appropriate to establish realistic worst case RUDs for these metabolites for use in bird and mammal risk assessments. Less data points are available for M-03 and M-05 but these confirm the level of residues to be considerably lower for these metabolites.



The maximum RUD for M-01 from 479 measurements is 1.714 (90th percentile 0.159).

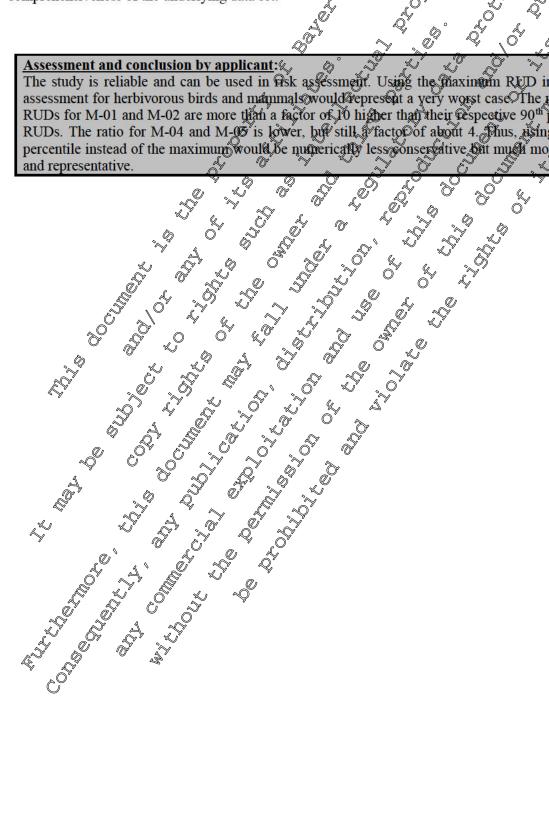
The maximum RUD for M-02 from 479 measurements is 0.498 (90th percentile 0.038).

The maximum RUD for M-04 from 165 measurements is 0.090 (90th percentile 0.023).

The maximum RUD for M-05 from 165 measurements is 0.200 (90th percentile 0.050).

The maximum RUDs for M-01 and M-02 are more than a factor of 10 higher than their respective 90 percentile RUDs. The ratio for M-04 and M-05 is lower, but still a factor of about 4. Using the maximum RUD in the risk assessment for herbivorous birds and mammals would represent a very worst case, and RUD in the risk assessment for herofvorous onds and manimals would represent a very constrainties overable should therefore be considered as conservative, and to account for any remaining uncertainties overable comprehensiveness of the underlying data set.

assessment for herbivorous birds and mammalsowould represent a very worst case. The maximum RUDs for M-01 and M-02 are more than a factor of 10 higher than their respective 90th percentile RUDs. The ratio for M-04 and M-06 is lower, but still a facto of about 4. Thus, using the 90th percentile instead of the maximum would be numerically less conservative but much more typical





### CP 10.1.2 Effects on terrestrial vertebrates other than birds

Test substance	Risk assessment	Species	Endpoint	Reference
Fluopicolide	Acute	Rat	LD ₅₀ > 5000 mg/kg bw	
	Long-term	Rabbit	NOAEL = \$0 mg/kg bw/day	2023 <u>¥3-02-0</u> KCA 5.6 ₂ /04
M-01 (AE C653711, BAM)	Acute	Rat	LD ₅₀ & 147°0 mgAg bw 2 2	<u>014</u> KCA 5.8₩/02 A
	Long-term	Rat	NOAED - 9.5 mg/kg bw@lay	<u>1995; M-</u> 302025-0451 ©
Propamocarb- hydrochloride	Acute	Q ^y Rat ^x	20 0 2 2 1330 mg /kg bw	(2006) 78 1-80
	Long-term	Rat G	NOAE	EFSA Scientific Report (2006) 78, 1-80
ing di o cimorita c	A Soute	Kat	EDSOATTY JBW JY C JY	Table 10.1.2- 7
Endpoints in bold c	onsigered relevant	ant for risk a	issessment a free free free free free free free fr	·]

As presented in the section "definition of the residue for risk assessment", the plant metabolites M-01 (AE C653711), M-02 (AE C657188) M-04 (AE C657378) M-05 (AE 1344122), M-06 (AE C643890) and M-09 (AF B102959) met the criteria of > 0% TRR or > 0.05 mg/kg. It should be noted the maximum overall concentration of each oretabolite either as %TRR or as mg/kg did not typically come from the same matrix sample. A worst case screening level long-term risk assessment for mammals is presented in Table 10 (2-18 for M-01, M-02, M-04 and M-05, based on field residue and rotational crop studies evaluated in 10.1.1/2/01. A quantitative risk assessment for M-06 and M-09 is not conducted since their residues in the field residue and rotational crop studies were < LOQ.

The screening level risk assessment for M-Q0 (AE C653711, BAM) is conducted with the NOAEL from the rat reproduction study conducted with this metabolite. For M-02, M-04 and M-05, the screening level risk assessment is conducted with the worst-case NOAEL = 2 mg/kg bw/d (parent NOAEL / 10), although there are toxicological studies with them confirming that they are not 10x more toxic than the parent please offer to Table \$.1.2.2-3 in MCA).

An acute task assessment is not conducted since this is considered to be covered by the worst-case screening level long-term risk assessment.



		Shortcut	value (SV)
Сгор	Indicator species	Acute RA based on RUD ₉₀	Long-term RA based on RVDm
Potatoes	Small herbivorous mammal	118.4	48.9 0
Leafy vegetables (lettuce)	Small herbivorous mammal	136.4	\$72.3 ×

### Table 10.1.2- 2: Relevant indicator species for screening risk assessment

### Relevant generic focal species for first-Her risk asses Table 10.1.2.3.

, , , , , , , , , , , , , , , , , , ,			
Fable 10.1.2- 3:	Relevant generic focal species for first-fier risl	x assessment	
Crop	Generic focal species	Agate RA Agate RA based on RJD 100 ?	value (SV)
	Small insectivorous mammal "bhrew" BBCH $\geq 20$ Small herbivorous mammal "vole" BBCH $\geq 20$	40.9 [°]	
Potatoes	Large herbivorous mammal&lagomoph"	0"	
3BCH 21-89	BBCH 10–40 $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ Large herbivorous mammaal "lagomorph" $\bigcirc$ BBCH $\geq$ 40 $\checkmark$ $\checkmark$ $\checkmark$		4.3
	Small omnivorous mammal "mouse" BBCH 10-39 Small omnivorous mammal "mouse"	¥ ¥17.2 ¥ 17.2	7.8
	$BBC \Psi \geq 40 \mathcal{S}^{*} \mathcal{S} $	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	2.3
â	Speall insectivorous manufal "show" 5 BBCH BH-19 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	L. 1.6	4.2
eafy vegetables	Small insective rous (mamma) shrew $3^{\circ}$ BBCH $\geq 20^{\circ}$ (mamma) shrew $3^{\circ}$ (mamma	\$ 5.4	1.9
ettuce) SBCH 13C49	BBCH 40-49	136.4	72.3
> ¥	Large herbivorous mammaty "lagomorph"	35.1	14.3
	Small Amnivorsus maternal "soluse"	17.2	7.8
A Y	Small insectivorous manipal "shrew"	5.4	1.9
eafy vegetables ettuce)	BBCH 40-49 Large hebivorous manual "lassmorph"	136.4	72.3
BBCM 41-49	All season Small omnivorous, mammal mouse"	35.1	14.3
	<b>B</b> BCH 40€ ³⁴ 9 ℃ Ø [©] [©] [©] [©] [©]	17.2	7.8
	Srsall insortivorous mammal "shfew" BBCH 20 Small herbivorous mammal vole" BBCH 40-49 L'arge herbivorous mammal "lasomorph" All season Small omnicorous mammal smouse" BBCH 40-49		
U			



### ACUTE DIETARY RISK ASSESSMENT

### Screening step

Screening step Table 10.1.2- 4:	Screening acute risl	k assessmen	t for ma	ummals	(fluopi	colide)	Ş		
		1	DDD					Q 1	Ì.
Сгор	Indicator species	Appl. rate [kg a.s./ha]		C MAF90		(mg a.s./kg bw]		Trigger	
Potatoes 4 × 1.6 L prod./ha	Small herbivorous mammal	0.1	A-18.4	1.8	21.31	© > 5000	^{234.6}		•
Potatoes 3 × 1.6 L prod./ha	Small herbivorous mammal	0.1	11894	1.9	18.04	\$5000	> 263.9	10	
Potatoes 2 × 1.6 L prod./ha	Small herbivorous mammal		9118. <b>4</b>	1.4	9 16.58	> 5000	3018		
Potatoes 1 × 1.6 L prod./ha	Small herbivorous mammal		148.4	120	140.84	5000	2 <b>4</b> 22.3	0 ¹⁰ 10	
Lettuce 2 × 1.6 L prod./ha	Small herbivorous mammal	0.1 0.1	136	1.4	19.10		> 264.8	10	
Lettuce 1 × 1.6 L prod./ha	Small herkivorous mammal		136.4	1.0	¥3.64	\$ > 5000 \$ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	© 366.6	10	
				S.	<i>S</i>				

### Screening acute risk assessment for manonals (Ruopicolide + popamocarb-hydrochlopide) Table 10.1.2- 5:

(			1 ~	× -	C	) ~~		
Crop	Indicator species	Appl, rate [kg./ha]		MAF99	ADD	UD50 mix [mg a.s./kg bw]	TERA	Trigger
Potatoes 4 × 1.6 L prod./ha	Small herbiyorous		118.4	108	234043	> 1425	> 6.1	10
Potatoes	Small herbivorous		0 [.] /1184	1.6	208.38	> 1425	> 6.8	10
Potatoes 2 × 1.6 L prod./ha	Small herbisorous		1948.4	Q1.4	182.34	> 1425	> 7.8	10
Potatoes $\sqrt[\infty]{1 \times 1.6 \text{ L prod./ha}}$	Small Gerbiverous mammal		1180	1.0	130.24	> 1425	> 10.9	10
Lettuce $2 \times 1.6$ L prod./ha	Small heroivorous		) 136.4	1.4	210.06	> 1425	> 6.8	10
Lettoge 1 × 1.6 L prod./ha	mammal 🖉 🖉		136.4	1.0	150.04	> 1425	> 9.5	10
	A & J	-Qi		•	•			

For fluopicolide the TER is above the origger of 10. Therefore, no further risk assessment at Tier 1 is required for fluopicolide. For the opicolide + propamocarb-hydrochloride the TER_A is below the trigger of 10. Therefore, a risk assessment at Tier 1 is required for fluopicolide + propamocarb-hydrochloride the TER_A is below the trigger of 10. Therefore, a risk assessment at Tier 1 is required for fluopicolide + propamocarb-hydrochloride the TER_A is below the trigger of 10. Therefore, a risk assessment at Tier 1 is required for fluopicolide + propamocarb-hydrochloride for the 4 × 16 L prof./ha 3 × 1.6 L prof./ha and 2 × 1.6 L prof./ha applications in potatoes and for the 2 × 1.6 L prof./ha and the 1 × 1.6 L prof./ha applications in lettuce.



Õ

Tier 1

Table 10.1.2- 6:	First-tier acute risk hydrochloride)	assessment	for ma	mmals (	fluopic	olide + propamo	carb-		F
	Generic focal	I	DDD			12050	4		]
Сгор	species	Appl. rate [kg a.s./ha]	SV90	MAF90	DDD	[mg]a.s./kg bw]		Trigger	Ê,
Potatoes BBCH 21-89 4 × 1.6 L prod./ha	Small herbivorous mammal "vole" BBCH $\ge 20^{a}$	1.1	40.9	1.8	81.00	) > 1425	> 1396 Q		, Ó ^y
Potatoes BBCH 21-89 3 × 1.6 L prod./ha	Small herbivorous mammal "vole" BBCH $\geq 20^{a}$	1.1 4	40.9	1.6 ~	~Q,* 72.0 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		> 1908		
Potatoes BBCH 21-89 2 × 1.6 L prod./ha	Small herbivorous mammal "vole" BBCH $\geq 20^{a}$		0.9 10.9	©1.4	<b>6</b> 3.0	€ 1425 C	> 22. Č		
Leafy vegetables	Small herbivorous mammal "vole" BBCH 40–49		1536.4	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	240.1		\$ \$> 6.8	0 ³ 10	
BBCH 41-49 2 × 1.6 L prod./ha	Large herbivorous mammal "lagomorph" All season ^{a)}		, 39∂.1 ∦	4J.4		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	°≫ ≫ 26.4	10	
Leafy vegetables	Small berbivorous mammal "vole" BBCH 40049		4 <b>5</b> 6.4		\$150.0 0	> 1405	> 9.5	10	
BBCH 13-49 1 × 1.6 L prod./ha	targe Herbivoroos mammal "lagemorph" All season a vant generic focal speci	v .	83.1 2	~P.0	\$8.6	ر چ > 1425	> 36.9	10	

Table 10.1.2- 6:	First-tier acute risk assessment for mammals (fluopicolide + propamocarb-		'n
	hydrochloride)	, S	P

The TERA values calculated in the acute risk assessment exceed the a-priori-acceptability trigger of 10 for all evaluated exposure scenarios, except for the generic focal species small herbivorous mammal "vole" in leafy vertables with the  $kD_{50}$  (m) of fluopicalide + propamocarb-hydrochloride. This failure to reach the TERA of  $\mathfrak{M}$  is due to the contribution of propamocarb-hydrochloride to the LD₅₀ (mix). A more detailed evaluation is provided in the next section on the combined toxicity assessment.

### Combined toxicity risk assessment

According to current requirements when a product contains more than one active substance, an additional assessment on combined foxicity sisk of the product has to be done.

For the assessment of acute effects (mortality), a surrogate LD50mix can be calculated for the mixture risk assessment. The FFSA GD 2009 indicates that the following equation should be used for deriving a surrogate LDson for a mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(\mathbf{ms}) = \left(\sum_{i} \frac{X(\mathbf{a}.s._{i})}{LD_{50}(a.s._{i})}\right)^{-1}$$

where:



 $X(a.s._i)$ = fraction of active substance (i) in the formulation mixture

= acute toxicity for the active substance (i)  $LD_{50}(a.s._{i})$ 

The active substance content of the formulation FLC+PCH SC 687.5 addressed in this dossier fluopicolide/L prod. and 625 g propunce-product. The table below shows the calculation of the predicted  $LD_{50}$  (mix) of fluopicolide and propunce and propunce hydrochloride when mixed in these proportions (step 1 in Appendix B of EFSA GD 2009).

Table 10.1.2- 7:	Mammalian LD50 (mix) for flu	10picolide and	propamocarb-l	verochloride when
	combined as FLC+PCH SC 68	step 1 in	Appendix B of I	EFSA GD 2009)

Firopicolité Propamocarb- hydrochloride	L°
Content of a.s. in product [g a.s./L prod.]	Ŋ,
Fraction in the a.s. mixture	
LD ₅₀ of a.s. [mg a.s./kg bw]	
Fraction / LD ₅₀	
Sum	
$1/\text{sum} = \text{predicted LD}_{50} \text{ (mix)} \text{ [mg total a.s./kg bw]} $	

It is obvious from the comparison of the dlow) source ot al toxicity of the active substances, and their relative proportions of the formulated product FLC+BCH S@ 687,5, that propamocarb has a tox per fraction of > 90% and thus clearly drives the risk assessment

Table 10.1.298:	Mammalian, fox per fraction, for FLC+P Appendix B	GH SC 87.5 (step 1 in	n EFSA GD 2009,
<u> </u>	Appêndix By		
~ 7	Flypicolide	Propamocarb- hydrochloride	"mix"
Content of a.s. in	produce a.s. Fprod for 57 625 fr	625	687.5
Fraction in thea.s	$\cdot \operatorname{mixture} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} O$	0.9091	1
LD ₅₀ of a.s img a	.s./kg bw]	>1330	>1425
Tox per fraction	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	1463	56463
Contribution to pr	edicted togetity	97 %	
0			

Fluopicolide contributes to % to mixture toxicity, while propamocarb-hydrochloride has 97 % impact on the mixture toxicity. Consequently, according to EFSA GD (2009) the acute risk assessment can be performed for propamocarb-hydrochloride only.

EFSA GD 2009 recommends as next step (2a and 2b in Appendix B) to check the predicted toxicity against measured toxicity from LD₅₀ studies conducted with the formulation.

According to EFSA GD 2009 the following equation should be used for the comparison:



$$\sum_{i} \frac{X(a. s._{i})}{LD_{50}(a. s._{i})} = \frac{1}{LD_{50}(mix)}$$

With:	
X(a.s.i)	= fraction of active substance [i] in the mixture
$LD_{50}(a.s.i)$	= acute toxicity value for active substance [i] = measured acute toxicity value for the mixture $\sum \frac{X(a.s.i)}{x(a.s.i)} = \frac{0.0909}{0.0909} + \frac{0.9691}{0.9691} = 0.09070$
$LD_{50}(mix)$	= measured acute toxicity value for the mixture
	X(a.si) = 0.090% = 0.96% = 0.96%
Left side of th	e equation: $\sum_{i} \frac{X(a.s{i})}{LD_{50}(a.s{i})} = \frac{0.090\%}{\frac{5000 \text{ mg a.s}}{\text{kg bw}}} + \frac{0.96\%1}{\frac{1463 \text{ mg a.s}}{\text{kg bw}}} = 0.09070\%$
	$\sum_{i} LD_{50}(a.s{i.}) = \frac{5000 \text{ mg a.s}}{1463 \text{ mg a.s}} + \frac{1463 \text{ mg a.s}}{1463 \text{ mg a.s}} = 0.000700 \text{ mg}$
	NA DW ARD W A
Right side of t	The equation: $= = = 0.00064$
0	$LD_{50}(mix) = \frac{1554}{1554} mgcotal a.s. = 00000070$
	A LEGOW OF Q O' O' O'
0.00070 < 0.00	

A greater value on the left side of the equation indicates that the measured oxicity of a formulation is lower than predicted from the togricity of the individual components in such as case, the use of LD₅₀ for formulation is recommended for the firscrier assessment. However as already Oscussed above, propamocarb-hydrochloride was clearly identified as the risk driver

1 m

The acute Tier 1 risk assessment with the Los mix of 1420 mg/kg bw is conducted in Table 10.1.2-6, triggering a refined assessment for the scenario of small berbivorous mammals (voles). Since propamocarbenydrochlorides the fisk driver here, it is appropriate to focus the refined assessment on this compound 2

A refined assessmen of the acute oral LD50 endpoint for propand carb, wydrochloride has been submitted in the AJR MCA and the stop-the-clock orbmission (EFSA requests 66/67) for propamocarbhydrochloride (see below for further of formation).

Based on that refinement, the LD is assessed at 2334 mg/kg bw instead of > 1330 mg/kg bw (the value used in Table 100.1-7 to calculate the LD₅₀/mix). With the D₅₀ of 2334 mg/kg bw for propamocarbhydrochloride an LD mix of 24530s calculated for fluopicolide + propamocarb-hydrochloride (Table 10.1.2-9).

### Refined mammalian LD (mix) for when combined as FLC+PCH SC 687.5 (step 1 in Table 103.2-9: Appendix B of FFSA (D) 2009) K 1

	Fluopicolide	Propamocarb- hydrochloride
Content of a Sn product [g.S./L prod.]	62.5	625
Fraction in the a.s. mixture	0.0909	0.9091
LD ₅₀ of a.s. [mg a.s./kg bw]	>5000	2334
Fraction / Loso	0.000018	0.0003895
Sum ov	0.00	0408
1/sum = predicted LD ₅₀ (mix) [mg total a.s./kg bw]	>2-	453



With the  $LD_{50 \text{ mix}}$  of > 2453 for fluopicolide + propamocarb-hydrochloride, the refined TER_A for the vole scenarios also exceed the trigger, indicating acceptable risk also for voles (Table 10.1.2-10).

Table 10.1.2- 10:	Refined acute risk assessment for mammals (fluopico	uopicolide + propamocarb-		
	hydrochloride)	~	e	

	<b>J</b>					<u>O</u> r		U'A
Crop	Generic focal	DDD				I Des 1	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	species	Appl. rate [kg a.s./ha]SV90MAF			DDD	LD50 mix [mg a.s./kg bw]	Ţ₿Ŕ _A	Trigger
Leafy vegetables BBCH 41-49 2 × 1.6 L prod./ha	Small herbivorous mammal "vole" BBCH 40–49	1.1	136.4	1.4	2100	> 2453	>4¥.7	
Leafy vegetables BBCH 13-49 1 × 1.6 L prod./ha	Small herbivorous mammal "vole" BBCH 40–49	1.1	07 136.4 0		×150.0		> <b>16</b> 4	
		0	*	õ	_O ^v		Ç d	1 00

### Refined assessment of the acute oral LD50 endpoint for propamoearb-hydrochloride

As mentioned above, a refined assessment of the acrite or LDS endpoint for propamocarbhydrochloride has been submitted in the EU renewal process AIR) in MCA8 and the stop-the-clock submission (EFSA requests 66/67) for propamocarb-hydrochloride

The table below was submitted with the AR MCA for propamocarb-hydrochloride and shows the acute oral toxicity data for mammals:

# Table 10.1.2-11: Acute oralitoxicity data for manimals Table CA 8.1 21-1 in the AIR MCA for propany carb-by droch or ide

		<u> </u>		<u> </u>	
Test species	Test design 🔗	Ecotoxicological endpoi	nt 👋 🖉		Reference
	Acute, or the second	LD50 male (EngA 2006 C)	9928.54 ⁵ 2900 ¹	mæ PCH/kg bw Ag PCH/kg bw	(1982) M-157621-01-1
		LD509emale (EESA 2006) LD200 femalo		mg PCH/kg bw mg PCH/kg bw	KCA 5.2.1/03 BCS
~Ç	Acute, Bi	LD C A C A C A C A C A C A C A C A C A C	>0444 ² 2032 ²	mg PCH/kg bw mg PCH/kg bw	(1995) <u>M-310337-01-1</u> KCA 5.2.1/01 AGR
	Acute dal		> 3400 ³	mg PCH/kg bw	(2001) <u>M-205214-01-1</u> KCA 5.2.1/02 BCS
Kat	Acute pral		> 5000 ⁴	mg PCH/kg bw	(2008) <u>M-480178-01-2</u> KCA 8.1.2.1/01
		LD50 male (EFSA 2006) LD50 male	1762.25 ⁵ 2650 ⁵	mg PCH/kg bw mg PCH/kg bw	(1982) A89469
Mouse G	Acung, ora	$LD_{50}$ female (EFSA 2006) $LD_{50}$ female	1862 ⁵ 2800 ⁵	mg PCH/kg bw mg PCH/kg bw	<u>M-164833-01-1</u> KCA 5.2.1/04 BCS
		LD ₅₀ (geometric mean)	2724	mg PCH/kg bw	



Test species	Test design	Ecotoxicologic	al endpoint		Reference
-	Acute, oral	LD ₅₀	2334	mg PCH/kg bw	Overall calculated "acute LD ₅₀ gettern" value <u>Christing</u> <u>underlined LD₅₀ values from rat and</u> <u>mice data</u> ) <u>See</u> justification below

### Bold letters: Values considered relevant for risk assessment

* Endpoint listed in EFSA Scientific Report 78 (2006)

- ¹ dose-response study where rats were used with 6 doses of Preview N covering a tange of 1300 26 mg/kg bw Dreview N contained 66.5% of Propamocarb-HCl (SN 66752); The LD₅₀ values in this oudy are 2900 mg/kg by in males and 2000 mg/kg bw in females. In the past, however, these values were erroneously corrected with a pure fact of 66.5%, resulting in LD₅₀ values of 1928.5 and 1330 mg/kg bw for males and females, respectively feading to determine an LB₅₀ value to the risk assessment. As stated in the Kojima, 1987 report, the rat LD₅₀ values represent dose levels as active ingredient, so that the LD₅₀ values to the used for ecotoricology are 2900 and 2000 mg/kg bw for males and females, respectively; a geometric mean cannot be used because there is a clear indication of a difference in sensitivity between sexes (refer EFSA Guidance Document 2009).
- between sexes (refer EFSA Guidance Document 2009). ² fixed dose method (OECD 420) study performed with Bronant (Propamorarb-HCK 22 g/LSL) at 2000 ppm with 10 animals; no mortality or clinical signs of toxicity during the study on extrapolation factor 60 1.407 was used to calculate an extrapolated calculated endpoint (ECPA Poster, Extrapolation factors for LDs values from marginal studies conducted at the limit dose, Foudoulakis et al. 2015, SETAC Conference 2018 in Barcelona, report under preparation which can be submitted under request).
- ³ the OECD 401 guideline was used; study performed with undiffied Previour N containing 68% of Propanocarb-HCl at one tested dose (5000 ppm); only two females died four hours after the treatment; this result confirms the low foxicity toxicity of Propamocarb to rats.
- ⁴ the endpoint extracted from the scientificarticle optian et a. 2008 (i.e. acute oral LES values measured with UDP and Horn's Procedures) confirms the low acute toxicity of Propange arb to fats.
- ⁵ dose-response study where rats were used with 6 doses of Previcur Neovering a range of 1309, 4826 mg/kg bw Previcur N contained 66.5% of Propamocarb-HCF (SN 66%2); The LD₅₀ values in this study are 2960 mg/kg bw in males and 2000 mg/kg bw in females on the past, however, they values were erroneously corrected with a purity factor of 66.5%, resulting in LD₅₀ values of 1702.25 and 1862 mg/kg bw for males and females, respectively. As stated in the Kojima, 1982 report, the rat LD₅₀ values represent use levels as active ingredient, so that the LD₅₀ values to be used for ecotoxicology are 2650 and 2800 mg/kg bw for males and females, respectively, a geometric mean can be calculated because there is no clear indication of a difference in sensitivity between sexes (refer EFSA-Guidance Document 2000).

During the stop-the-clock submission (EFSA represented by the not field by

Answer to EFSA request 66 (Baver) and 67 (Arysta) during stop the clock for propamocarb ("The applicant is given the opportunity to provide details of studies considered for calculation of the geometric mean  $LD_{50}$  for the acute oral toxicity to mammals (e.g. information regarding their equivalence of test design, test item and carrier used). With reference to Reporting table 5(27) - Vel. 3 CA, B 9 J.2.1 Acute oral toxicity to mammals")

As requested by EFSA, details of the studies considered for calculation of the geometric mean LD₅₀ for the acute oral toxicity to maximals are provided.

The LD₅₀ value listed by EFSA ( $\geq$ 1330 og Propamocarb-HCl/kg bw; EFSA Scientific Report 2006, 78, 1-80) is not used in the Kisk assessment. The LD₅₀ values in the Kojima et al. (1982) study performed on rat are 2000 mg/kg bw in mates and 2000 mg/kg bw in females, respectively. In the past, however, these values were proneously corrected with a purity factor of 66.5 %, resulting in LD₅₀ values of 1928.5 and 1330 mg/kg bw for males and females, respectively leading to determine an LD₅₀ value higher than 1330 mg/kg bw used in the risk assessment. The value of 1330 mg Propamocarb-HCl/kg bw should be replaced by the value 2000 mg Propamocarb-HCl/kg bw. As stated in the EFSA Guidance Document for birds and mammals (2009), *'it is proposed that the geometric mean be used unless there is a clear indication of a difference in sensitivity between the sexes (e.g. > 25 % in the LD₅₀; EPCO, 2005) - in* 



which case the data from the more sensitive sex should be taken'. Since results of the Kojima et al. (1982) study performed on mice did not show any higher sensitivity between the sexes, a geometric mean value of 2724 mg Propamocarb-HCl/kg bw was calculated with the two LD₅₀ values (2650 mg Propamocarb-HCl/kg bw and 2800 values mg Propamocarb-HCl/kg bw) from males and females, respectively. It gave a geometric mean LD₅₀ value (mice) of 2724 mg Propamocarb-HCl/kg bw

According to the EFSA Guidance Document for birds and mammals (2009) (paragraph 2.4.1.), LD₃₀ values of different species can be combined to give a multispecies geometric mean value when the studies were performed under an equivalent guideline and in particular with, an equivalent vehicle/solvent. This applies to the studies from (1982) of rats and mice. Both studies were done with the same active substance, i.e. propanocarb-HCl and with water as solvent. The guidelines used in the studies are the US EPA proposed guideline for pesticide registration (1978) and the Japanese Guideline (1972). Comparable methods were used in both tests and the same endpoints were assessed. A detailed comparison of both studies is presented in in the table below.

Consequently, the LD₅₀ value (mice) of 2724 mg Propanocarb-HCl/kg bw was combined with the LD₅₀ of 2000 mg/kg bw (rat, female) to give a multispecies geometric mean of 2334 mg Propanocarb-HCl/kg bw as LD₅₀ value which is used in the risk assessment. This value of 2334 mg Propanocarb-HCl/kg bw can be considered conservative enough if compared to the LD of the most recent acute toxicity studies performed on rat by (2001) and (2001) (2008), respectively. In the study by (2001) the OECD 401 guideline was used. The study was performed with undiluted Previous Mccontaining 68% of Propamocarb-HCl at one tested dose (5000 ppm). Only two fetnales died four hours after the treatment. The LD₅₀ was calculated to be 3400 mg PCH/kg bw, The endpoint extracted from the scientific article of Lian et al. 2008 (i.e. acute or LD₅₀ values measured with UDP and Horn's Procedures), LD₅₀ > 5000 mg PCH/kg bw confirms the low acute toxicity of Propamocarb to rats.

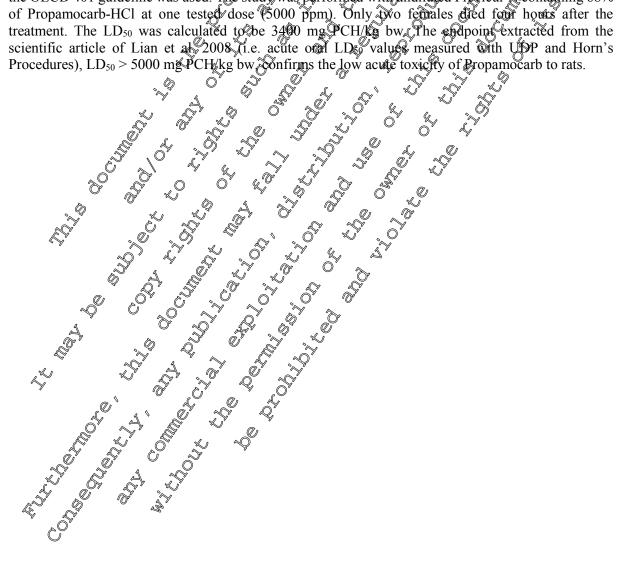




Table 10.1.2- 12:	Comparison of acute studies with mammals conducted with propamocarb-
	hydrochloride

-		
Parameter	Rat study of (1982)	Mice study of (1982)
Test substance	Previcur N (Propamocarb HCl);	Previcur N (Propamocarb HCl);
	Purity: 66.5 %	Purity: 66.5 %
Solvent	Water	Water S
Species	Rat	Mouse
Age	Approximately 7-week-old rats	7-week old mile O
	Male Co	7-week old mile <u>Male &amp; Female</u> 1300, 1690, 2197, 2856, 5713, 4826
Dose range (mg	2000, 2300, 2645, 3042, 3498, 4023	1300, 1690, 2197, 2856, 8713, 4826 , V
Propamocarb-	d a	
HCl (a.s.)/kg bw)	Female	
	1512, 1739, 2000, 2300, 2645, 3042, 3498	
Number of		
mammals tested		$\mathcal{S}^{\mathbf{H}0}$ $\mathcal{S}'$ $\mathcal{S}'$ $\mathcal{S}'$ $\mathcal{S}'$ $\mathcal{S}'$
per concentration		$\frac{1}{1} \frac{1}{64y} = \frac{1}{\sqrt{2}} $
Exposure	1 day A T	$1 \text{ flaw}$ $\sim$ $0^{\text{y}}$ $2^{\text{y}}$
duration	1 day	
Verification of		Not performed
test substance	Not performed	Notperformed
concentrations		
Photoperiod	12/12 light/dark (artificial lighting)	St2/12 light/darts (artificial lighting)
Temperature	22-24°C ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	22- <b>2</b> C
Relative humidity	40-60%	40,60% ~ 0
	Observations Oor mortality and clinical	Observations for mortality and clinical
	signs (frequently at day 1: wice for day	signs (frequently at Qay 1; twice per day
	thereafter, body weight (measured shortly	thereafter, body weight (measured shortly
Endpoints	before administration weekly there there	before administration, weekly thereafter
	and at death or end of the test), chrical	and at death or end of the test), clinical
, S	signs, gross post mortem examination of	signs gross post mortem examination of
<u>^</u>	abtest animals	all est animals
Dose responses	Findings. Mortality occurred in all	Ending Mortality occurred in all
, Ô	concentrations except in the two lowest	
	test concentrations done with female rates	
R. V.	Dead anomals occurred within 24 hours	response could be observed so that LD ₅₀
~	after dosing. A clear orse-response could	salues for female and male mice could be
$\sim$	be observed that LD 50 values for @male	derived. Body weights of surviving
Q	and male rats could be derived. Body	
	weights of surviving mimals were not	after dosing.
****	affect@at 1 or 2 weeks after dosing	Clinical signs including hypokinesia,
Å	Clinical stens including hypolunesia,	clonic convulsion, staggering gait, hearing
, and the second s	clénic convulsion, nasal & mouth Gaemorrhage, bleeding Q eyelid,	loss, touch response loss and prone followed.
×. ~	bleeding v eyelid, piloerection steek, drappearing hair and	ionowed.
N N	staggering gait were obser@d. Symptoms	
<i>n</i> . \	were seeff from thous to 3 days after	
L,	dosing surviving animals recovered to	
, O' ^	normal within 4 hours to 2 days after	
	dosing.	
	dosing.	I
J G	A ST	

Conclusion of the refined assessment of the acute oral  $LD_{50}$  endpoint for propamocarb-hydrochloride

According to the information provided above, the multispecies geometric mean of 2334 mg/kg bw is the refined  $LD_{50}$  value which is used in the acute mammal risk assessment of propamocarb-hydrochloride for the formulation Fluopicolide + Propamocarb-hydrochloride SC 687.5.



### Acute risk assessment for mammals drinking contaminated water from puddles

Because propamocarb-hydrochloride is the risk driver in the LD₅₀mix, and since propamocarbhydrochloride belongs to the group of more sorptive substances with a Koc of 516.7, it is appropriate to y water 5 set the threshold for no concern at 3000 for the combined assessment.

Table 10.1.2- 13:	Evaluation of potential concern	n for exposure of	mammats from	drinking	wate
	(escape clause)	G		s, s	$\searrow$

(	escape clause)			N.	<u> </u>	O i	
Сгор	Compound	K _{oc} [L/kg]	AR _{eff} (Appl. rate × MA(5m) [g a.s./ha]	LD50 [mg a.s./ kg bw	.7 @	"Escape Pause" So concern if ratio	Conclusion
	Fluopicolide	267.7	0400 ^{a)}	>5000	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	£ 50	Noconcern
Potatoes (4 × 1.6 L prod./ha)	Fluopicolide + Propamocarb- hydrochloride	- 4	4400 a) ~	×1425 ^{b)}	A3.1 C	³ ≤3000	No concern
	Fluopicolide	<b>E</b> 67.7	\$ ³⁰⁰	×3000 a	~ 	$\frac{1}{\sqrt{2}}$ $1$	No concern
Potatoes (3 × 1.6 L prod./ha)	Fluopicolide + Propamocarb- hydrochloride		300 a)	×>1499 ^{b)}	€,<2.3 €,<2.3 €,	500 53000 €	No concern
		√267.7		@>5000 [€]	\$9.1 	\$ ≤530	No concern
Potatoes and lettuce $(2 \times 1.6 \text{ L prod./ha})$	Fluopicolide + Propamocatio- hydrochloride		52200-0 ⁵	20125 b) &	<1.5	₹ 3000	No concern
l l	Fluopiçolide 🖒	267.9	100 a)	>5060	<0.1	$\leq 50$	No concern
Potatoes and lettue (1 × 1.6 L prod (ba)	Fluopicolide + Propam@arb- Prydrochloride	1.	2 1106 Å)	₹ 31425 €		≤ 3000	No concern

a) Instead of the MAF, the number of applications was used as a worst-case multiplicator.

\$1

b) endpoinces used prior to ferinemate during AIR PCH Ő

Š  $\langle \rangle$ K, According to the DFSA Guidance document for riso assessment for bird and mammals (2009) "no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevent endpoint (immg/kg bw) does not exceed does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc > 500 L/kg)." This is the case for fluopicolide and propamocarb hydrochloride. Therefore, the acute risk for mammals from drinking water that may contain residues from fluopicolide and fluopicolide + propamocarbhydrochloride is acceptable. K)

 $\bigcirc$ 

K)

### LONG-TERM REPRODUCTIVE ASSESSMENT

EFSA GD 2009 recommends not to cooduct a combined reproductive risk assessment for compounds not sharing the some mode of action (step 3). Therefore, no combined reproductive risk assessment is required for the FLC-PCH SC 687.5 in this AIR-evaluation but may be conducted post-AIR according to the respective zonal guidance.



### Screening step

			DDD				N@(A)EL	,¢	
Сгор	Indicator species	Appl. rate [kg a.s./ha]	SVm	MAF _m	<b>f</b> _{TWA}	DDD	[mg a.s./ kg bw/d]	TERM	Trigger
Potatoes 4 × 1.6 L prod./ha	Small herbivorous mammal	0.1	48.3	<u>3</u> .2	0.53	5,6 0	20	3.6	
Potatoes 3 × 1.6 L prod./ha	Small herbivorous mammal	0.1	48.J	2.0	0.50	5.1	20	3.9	6 ⁷⁵
Potatoes 2 × 1.6 L prod./ha	Small herbivorous mammal	0.1	<b>a</b> 8.3	1.6 🦱	0.53	Å.1	\$20,0°	4.9	
Potatoes 1 × 1.6 L prod./ha	Small herbivorous mammal	0.10	485	KO KO	0.53	2.5	20 A	7.8	5
Lettuce 2 × 1.6 L prod./ha	Small herbivorous mammal		72.3	× 1.6	0.53	6.1	⁵ 20	3:3	
Lettuce 1 × 1.6 L prod./ha	Small herbivorous		72.3	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ø.53	\$18 \$18	20 g	5.2	5

unnundunt. 

For the  $1 \times 1.6$  L prod./ha application in potatoes and lettuce the TER_{LT} is above the trigger of 5. Therefore, no further risk assessment at Tier 1 is required. For the  $4 \times 1.6$  L prod./ha,  $3 \times 1.6$  L prod./ha applications in potatoes and for the  $2 \times 1.6$  L prod./ha application in lettuce the TER_{LT} is below the trigger of 5. Therefore, a risk as essment at Tier 1 is required.

Tier 1 Table 10.1.2, 15: First-tier long@erm reproductive risk assessment for mammals (fluopicolide)

					107		1		
Crop	Generie focal			MASEm	ftwa	DDD	NO(A)EL [mg a.s./ kg bw/d]		Trigger
(4 × 1.6 L <u>prod</u> ./ha)			) 21.7 0	8 7 2.2	0.53	2.53	20	7.9	5
Potatoes BBCH 21-89 (3 ×4 6 L prod./ha)	Small heroivorous mammal "vole" BBCQ ≥ 20 a		21.7	2.0	0.53	2.30	20	8.7	5
Potatoes BBCH 21-89 (2 × 1.6 L prop/ha)	Small herbi√orous mamma@vole ²⁰ BBCHS 20 a)		21.7	1.6	0.53	1.84	20	10.9	5
J J J	Small herbivorous mammal Oole" BBCH 40–49	0.1	72.3	1.6	0.53	6.13	20	3.3	5
BBC\$741-49 (2 ⁴ , 1.6 L.prod./ha)	Large herbivorous mammal "lagomorph" All season ^{a)}	0.1	14.3	1.6	0.53	1.21	20	16.5	5

a) Covers all other relevant generic focal species with lower shortcut values



The TER_{LT} values calculated in the long-term risk assessment exceed the a-priori-acceptability trigger of 5 for all applications in potatoes and for the scenario of the large herbivorous mammal ("lagomorgh") in the  $2 \times 1.6$  L prod./ha application in lettuce. The TER_{LT} value is below the a-priori-acceptability 4 trigger of 5 for the scenario of small herbivorous mammals ("vole") for the 2 × 1.6 L prod./ha application in lettuce and a refined risk assessment is needed and is provided below.

### Refined risk assessment for long-term exposure of mammals

A refined risk assessment is triggered for exposure of small heteivorous macomals fluopicolide in leafy vegetables.

However, it might be pertinent to consider that the foint Working Group on the Guidance Document on Risk Assessment for Birds & Mammals (SANCO 10997/2009) raised the question on the weed for the vole scenario... given the resilience of the vole populations", ".e. well-known fact that voles are able to recover after large population breakdowns, or despite eradication programs with targeted redenticide use.

The most straightforward interpretation of the data would be that the failure to meet the priori acceptability trigger for small herbiverous mammals is not to consider as problematic as long as the TER trigger for the other wild mammal scorarios reach the TER trigger of 5.

This is the case for the exposure to fluopecolide where all other scenarios pass the TER trigger of 5.

### m Refined exposure assessment foesmall herbivorous mammals: generic field study

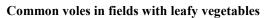
2013; M-449690-05-1) demonstrates that A field monitoring study in least vegetables such fields are not a preferre@habitar(systematically lower trapping success than in the surroundings). Colonisation was bot observed before BBCH 45, as can be seen when plotting the vole in-field abundance against the BBCH stage of the vegetable field (see figure below).

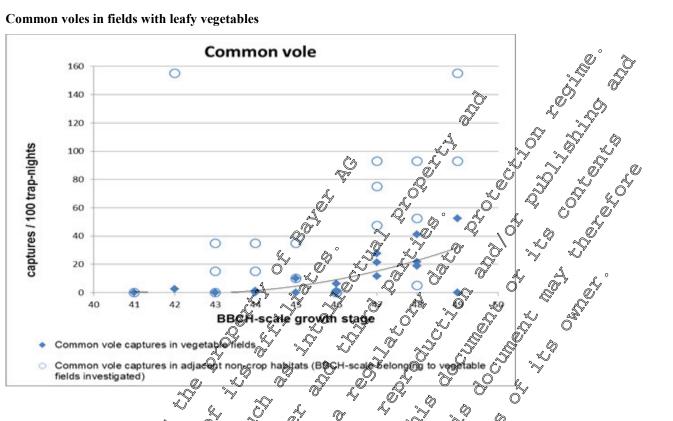
Leafy vegetables are typically harvested at BBCH stage 49. Vole populations cannot survive on postn

Thus, leafy vegetable fields sorve only for a very short time as habitat for voles (i.e. from BBCH 45 to 49) and thus a lower level of protection for voles during that short time before the harvest of the crop

BBCH stage after removal of the e only for a very short time or protection for voles during the acceptable the office of the office office of the office office office of the office offic





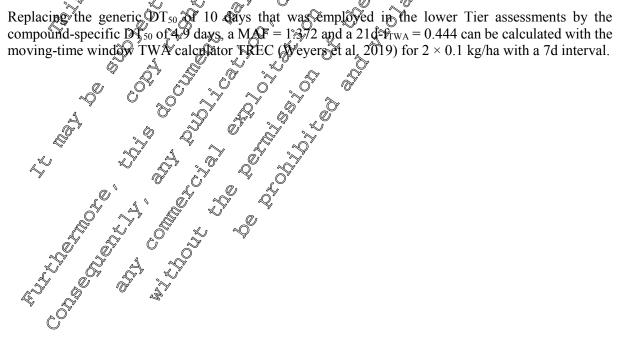


## Refined exposure assessment for small herbivorous mammals: residue decline

Finally, the DT50 of fluopicolide in plant foliage is morter fran the default DT50 of 10 days employed in Ô the Tier 1 risk assessment. L  $\bigcirc$ 

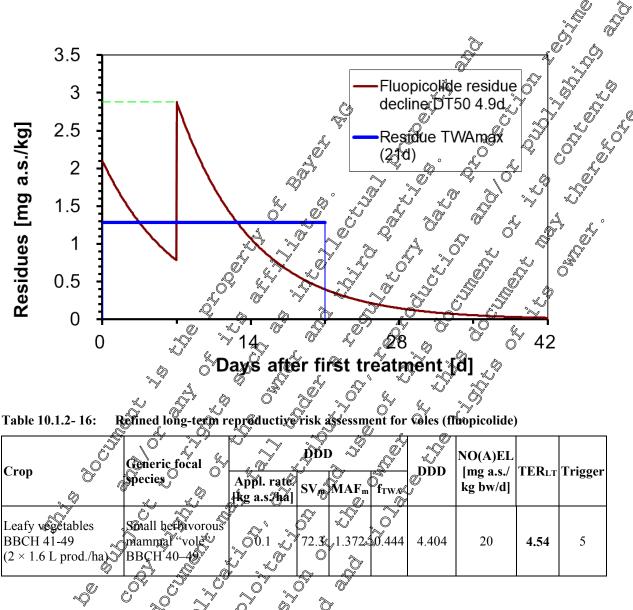
Based on residue decline of als conducted with fluopic lide in young cereal (as surrogate for the diet of voles; please refer to GP 10.1.22), a geometric mean DT₅₀ can be proposed for refined risk assessment on small herbovorous mammals as friggered for eafy vegetables (please refer to CP 10.1.2.2 for the derivation of the geometric mean  $DT_{50}$  value in v1-687/18-01-1). 1

Replacing the generic DT50 of 10 days that was employed in the lower Tier assessments by the





### Fluopicolide residue decline and residue TWA/max for 21 days



### Conclusions from the refined exposure assessment for small herbivorous mammals

Lettuce fields are of low relevance for the long-term sustainability of vole populations, because they are less attractive than the surroundings, and are only colonized during a very short time window between BBCH 45 and BBCH 49 Lates at BBCH 49 the lettuce is harvested and the vegetation cover is set back to the status of basically bare soft (where voles were found not to use the lettuce fields, due to the lack of cover)

The TER for that part of the vole population that is using lettuce fields, and for that time window between BBCH 45 and 49, is 4.54 when considering the decline of the fluopicolide residues.

Furthermore this TER is calculated with the NOAEL of 20 mg/kg bw/d from the rabbit developmental toxicity study. The evaluation of the toxicological profile of fluopicolide clearly shows that the susceptibility of rodents (i.e. the taxon comprising the voles as well as the tested species rat and mouse) is much lower than that of rabbits (i.e. the taxon which provided the NOAEL employed here). Therefore, the level of protection provided for voles is very high when using the endpoint from the rabbit.



Taking these factors together with the known resilience of vole populations it can be concluded that the TER of 4.54 for the small part of the vole population that may be exposed over a short period of time in lettuce fields is sufficiently high and acceptable at the local population level.

### Long-term risk assessment for mammals drinking contaminated water from puddles

Table 10.1.2- 17:	Evaluation of potential con	cern for exposure of	of mammats from	drinkin
	(escape clause)	G	a star	Į,

				· »	õ		
Сгор	Compound	K _{oc} [L/kg]	AR _{eff} (Appl. rate × MAF) [g a.s.ha]	NO(A)EL [mg a.s./ kg bw/ðł	(ARegge?	"Escape Pause" So concern if ratio	Conclusion
Potatoes (4 × 1.6 L prod./ha)	Fluopicolide	267.7			\$ 26°		No concernº
Potatoes (3 × 1.6 L prod./ha)	Fluopicolide	269.7	(~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				No Concern
Potatoes and lettuce $(2 \times 1.6 \text{ L prod./ha})$	Fluopicolide	26703	200 ^{a)}			P S.	No concern
Potatoes and lettuce (1 × 1.6 L prod./ha)	Fluopicolide	¥267.7	100 ^{/a)}				No concern
a) Instead of the MAF, t	the number of appli	cations w	as as abio	rst-@se mu	tiplicator.		

According to the FSA Guidance document for risk assessment for bird and mammals (2009) "no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw) does not exceed does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or \$000 in the case of more sorptive substances (Koc > 500 L/kg)." This is the case for fluopicolide. Therefore the acute risk for mammals from drinking water that may contain residues from fluopic@ide is acceptable.

### RISK ASSESSMENT OF SECONDARY POISONING

According to the EFSA (midance Document on Risk Assessment for Birds and Mammals (2009), substances with a log  $P_{ow} \ge 3$  have potential for bioaccumulation and should be assessed for the risk of biomagnification in aquatic and terrestrial ford chains.

The log Pow value of fluopicolide is 2 % Since the log Pow does not exceed the trigger value of 3, fluopicolide is deemed to have a regligible potential to bioaccumulate in animal tissues. No formal risk assessment for secondary poisoning is therefore required.

## RISK ASSESSMENT FOR PEANT METABOLITES

A worst case screening level risk assessment for herbivorous mammals exposure to plant metabolites can be based on the maximum RUDs determined by 2020 (M-686445-01-1, 10.4.1.2/00) for M-01, M-02, M-04 and M-05 in foliage sampled during the course of field residue or rotational crop studies. For that screening level risk assessment, the maximum MAF for the uses under assessment is set to be 4 (number of applications), and no deposition factor is applied. The FIR/bw represents a small herbivorous mammal eating only contaminated foliage at a rate of 1.33 times its own bodyweight each day. The toxicity endpoint is set at one tenth of the reproductive risk assessment



endpoint for the parent, except for M-01 where the NOAEL of the rat reproduction study with this

metabolite is used. Thus this screening level assessment combines all possible worst case elements in a risk-envelope. If

Compound	GFS	FIR/bw	PD	<b>RUD</b> _{max}	AR	MAF	<b>f</b> TWA	TOEP	DDD	NOAEL	TER
M-01	Vole	1.33	100% foliage	1.174	0.1	4	0.53C	1	0.330	7.50	3207
M-02	Vole	1.33	100% foliage	0.498	<b>Q</b> 1	4	0.63	1	044	3.00	Q14.2 C
<b>M-04</b>	Vole	1.33	100% foliage	0.090 🚄	0.1	4	Q.53	°1	Q.03	€ <b>2.00</b> Ĉ	78.80
M-05	Vole	1.33	100% foliage	0.200	0.1	4	0.53	1	0.06 ⁰	2,00	38.5
				4	Ô	Š	*	10			K.

Table 10.1.2- 18:	Risk envelope assessment for pla	ant metabolites (	(mammals)	"((
-------------------	----------------------------------	-------------------	-----------	-----

### CP 10.1.2.1 Acute oral toxicity to mammal

The result from the acute study with the formulated product F predicted toxicity of > 1425 mg total a.s./kg by calculated in Table 90

Table 10.1.2- 19:	Mamn	nalian foxicity data of the formulated product FLC+PCHOSC 6	
Test substance	Risk aşş	essment Species Encropoint Species	Reference
FLC+PCH SC 687.5	Agate	$\int_{0}^{\infty} Rat = \int_{0}^{\infty} LD_{30} = 2060 \text{ mg prod./kgOw} = 1000 \text{ mg prod./kgOw}$	<u>2004: M-</u> <u>220883-02-1</u> KCA 7.1.1/01
) Based on a total s.	Highe	er tier data on mammals	13 g/cm ³ )
Data Point: Ø	X A	KCPapil 2 Mai x	
Report Author:	Â,		
Report Year	Õ	2013	
Report Title:		Voles in fields with leafy vegetables	
Report N@	Ô		
Document No:		<u>M-449690-01-1</u>	
Guideline(s) follow	ved in	Commission Diffective 96/46EC of 16 July 1996 amending Counc	il Directive
study:		91/41 EEC Concerning the Placing of Plant Protection Compoun	ds on the Marke
Deviations from		Not applicable	
test guideline	A		
Previous evaluation	×××	No, not previously submitted	
A S	, O	for Propamocarb in RAR June 2017	
GLP/Officially recognised testing	.1	Ye Conducted under GLP/Officially recognised testing facilities	
recognised tering	der a	K) ^Y	
facilities:	Ø j	×	
Acceptability/Relia	bility:	Yes	
ĉ			

Mammalian foxicity Table 10.1.2-19: Aata

(Cr



### **Executive summary**

According to the EFSA GD on risk assessment for birds and wild mammals, exposure of small herbivorous mammals on fields cropped with leafy vegetables should be considered from growth fage BBCH 40 upwards.

This field study was conducted in order to generate information on the occurrence of Common voles (*Microtus arvalis*) on arable fields cropped with leafy vegetables (lettuce, cabbages) whick could be used in more realistic, refined risk assessments.

The findings of the study support the thesis that vegetable fields are no primary habitat for vo

### I. MATERIAL AND METHODS:

The study site selection for the main study was based on the results of pre-trappings (non-GLP) conducted during spring at 9 candidate sites in Germany and one site in the Metherlands. This ptetrapping was conducted in suitable vole prime habitats in the Metherlands of Vegetable fields. In order to ensure the presence of a source population with the potential for colonisation of the vegetable fields. Only sites where Common voles were identified during spring were selected for the main study. Based on the results of this pre-trapping, the main study was conducted in 5 different fegions of Germany: Gäuboden (Lower Bavaria): 5 sites; Rhineland (North Rhine-Westphalia): 6 sites; filder (Württemberg): 3 sites; Heilbronner Becken (Württemberg) 3 sites and Dithmarschen (Scheswig-

Holstein): 3 sites.

During the main study trapping was conducted during summer, at other when the vole population development in the source habitats could have reduced colonisation of adjacent secondary habitats like the vegetable fields.

In the second year of the study additional surveys were conducted in late spring in order to complement the information also for vegetable fields in earlier development stages

Altogether 20 fields with different types of leafy veretables and different growth stages (BBCH-scale) were studied.

As a standard, 40 Ugglan life traps were placed inside each field in order to confirm the presence of voles in the landscape and to estimate their density in potential source habitats, traps were also placed outside the fields in optimal vole habitats in the surrouteding up to 500 m distance ("control" traps).

It was originally intended to complement each study field (40 traps) with one "control" with 20 traps each. However, in some areas one set of control traps was able to cover more than one plot. The number of control traps was enlarged for Dithmarscher (32 traps to cover all three sites with one control); for Filder only 14 traps were available as a common control for all plots. In the Heilbronn area some traps were destroyed during the 2° trapping. This was considered when calculating the trapping rate.

The trapping was carried out on each field or control for two consecutive nights. Species, sex, weight and reproductive state of voles captured were recorded. The traps were equipped with oat flakes as bait.

### Dates

Experimental Starting Date: 2011-07-26 Experimental Completion Bate: 2012-06-04

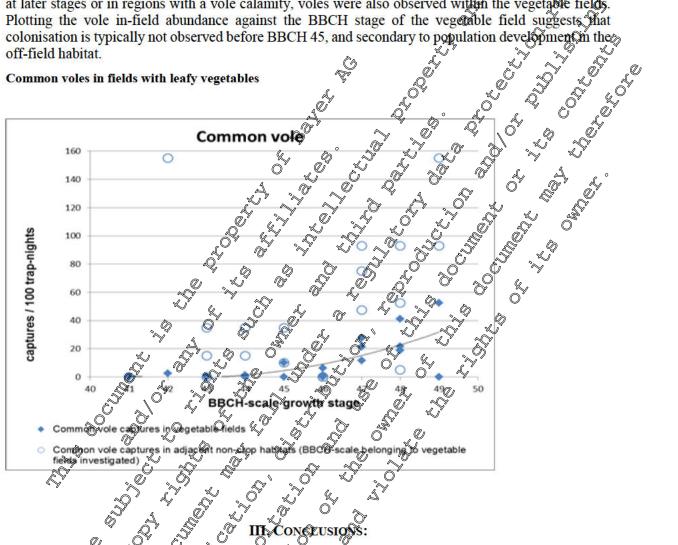
### II. RESULTS AND DISCUSSION:

In total, 345 Common votes (*Microtus arvalis*) trappings were recorded over 2045 trap nights. Overall the trapping success in the fields was 10.6 voles/100 trap nights compared to 36.8 voles/100 trap nights in the surroundings ("controls").



Additional to Common voles, other species were trapped on the fields (mainly Wood mice Apodemus sylvaticus) or the surroundings (mainly bank voles Myodes glareolus). Other species trapped included Yellow-necked mice (Apodemus flavicollis) and Field vole (Microtus agrestis).

Typically, voles were trapped early and more frequently in the surroundings than in the field. However? at later stages or in regions with a vole calamity, voles were also observed within the vegetable fields. Plotting the vole in-field abundance against the BBCH stage of the vegenable field suggests that colonisation is typically not observed before BBCH 45, and secondary to population development in the off-field habitat.



This finding remonstrates, that vegetable fields age no primary habitat for voles. The grassy surroundings serve as base habitat from which vole may migrate to the fields, if the population density increases. Ő

### Assessment and conclusion by applicant:

Q

The study is reliable, and the findings demonstrates that vegetable fields are no primary habitat for voles. Colonization of the Gelds, was not found until BBCH 45, shortly before the crop is harvested (BBCH 49). Vole populations cannot survive on post-harvest fields that lack cover and food after removal of the grop.

Solution States

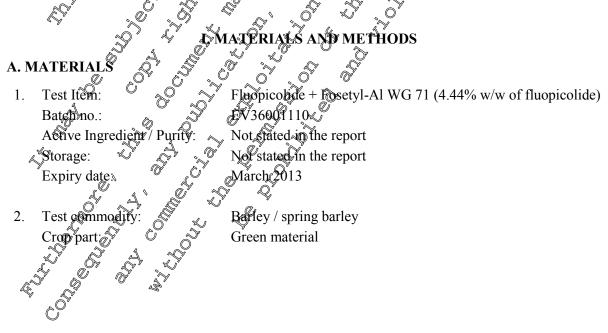


Data Point:	KCP 10.1.2.2/02
Report Author:	
Report Year:	2011
Report Title:	Determination of the residues of deltamethrin and fluopicolide in/on Barley and
	Barley, spring after spraying of fluopicolide & fosetyl-Al OG 71 and Degis EC
	025 in the field in Spain, Germany, Belgium and United Kingdom
Report No:	10-2120
Document No:	<u>M-408272-01-1</u>
Guideline(s) followed in	EU-Ref: Council Directive 91/41 🕼 EC of July 15/1991, 🔬 🔊 🖉
study:	Annex II, part A, section 6 and Annex III, part A, section 8
	Residues in or on Treated Products, Food and Deed
	EC guidance working document 7029/VI/95 Yev. 5 (1997-022)
Deviations from current	Not applicable
test guideline:	
Previous evaluation:	No, not previously submitted a star where the su
GLP/Officially	Yes, conducted under GLB Offic ally recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes Q X X X X X X X

### **Executive Summary**

An open field study with four residue trials was conducted in northern Europe (Germany, Belgium and United Kingdom) and southern Europe (Spain) on barley, during the 2010 season. One application of 'Fluopicolide + Fosety-Al WG 11' (a product containing 4 44 % of fluopicolide and 66.67% of fosetyl-Al) and Decis EC 025 (a product containing 25 g/C deltamethrin) was made at a target rate of 0.13 kg a.s. / ha (for fluopicolide). Only the parameters and results relevant to fluopicolide have been reported within this study sommary

The residues of Duopicolide after spray application of the "Fluopicolide  $\neq$  Fosetyl-Al WG 71" on barley barley green material declined markedly during the sampling period. No residues above 0.01 mg/kg for the metabolizes M-01 or M-02 were found in /on the green material samples.





### **B. STUDY DESIGN AND METHODS**

### **1. Test Procedure**

The purpose of the study 10-2120 was to determine the magnitude of the relevant residues of fluopicolide in/on barley / spring barley (green material) after one spray application with "Fluopicolide" + Fosetyl-Al WG 71", a WG formulation containing 4.44% w/w fluopicolide This summary focuses only on the residues of fluopicolide.

only on the residues o	f fluopicolide.		ч <i>О</i> г	
Field phase		Ó	a f	ermany Belgium and
		. K.	Q	
The study included fo	ur supervised residue	e trials conducted in	northern Europe (Ge	rmany Belgium and
The study included fo the United Kingdom)	and southern Europe	e (Spain) during the	201Qseason.	ormany Belguin and
Description of the tr	ial locations and cro	opping information	on treated plots	çi v di
Trial number	10-2120-01	10-2120-02	10-2120-03 0	10-2120-04
	E-08520 Llerona –		B-6224	,CB22 Elattle
Trial location	Les Franqueses del	D-5/13/99 Burscheid		Shelford
	Vallès			
Country	Spain O [*]	Germany 🗸	Belgium	United Kongdom
Area of application	Field Q	Field		Pield w
Plot size [m ² ]	80 0 5	1440 5	45 × ×	108
Type of soil	Loam	🔊 Sandy loam	Suty loan	Sandy loam
pH-value of soil		6.5 0 6 C	70 ~ ~	8.3
(in water)			7.9	J0.3
Content of organic C	47 0		of & in	1.3
[%]				1.5
Test system	Bachey 🔊 🔊	Spring bark	Spring barles	Spring barley
Variety O	Graphic	Quench X N	Henley	Tipple
Date of sowing	2010-01-03 0 🖇	2010-0≇406 ⊘	2010-03-14	2010-03-10
Date , Q of	2010-06-200	2010-08-01	2010407-15	2010-08-05
		to a a	to	to
commercial harvest	2010-0710	2010-0015 💞	2910-07-28	2010-08-15
			4 ·	

The actual application data are presented in the following table. This data reflects the intended application scheme, or, fiminer deviations occurred, these were within the acceptable range:

## Application summary of Quopreside Fosetyl-Al &G 71 on barley / spring barley

Trial Sio. Country	Appl. No. 🐇	, Ôj	r en V	Appl mode	Growth Otage (BBCH code)	DBH PHI (days)	Test item rate (kg/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
10-2120-01 Spain		Ĩ,	Fluepicolid + Fosetyl-Al WG	ŜPI	32	-	3.0	600	FLC Fosetyl- AL	0.13
10-2120-02 Germany 1022120-02 Belgium	Contraction of the second		Fluopicolide + Fosetyl-Al WG	SPI	30	-	3.0	300	FLC Fosetyl- AL	0.13 2
162120-02 Belgium	1	T	Fluopicolide + Fosetyl-Al WG 71	SPI	30	-	3.0	600	FLC Fosetyl- AL	0.13



Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (kg/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s.Jaa)
10-2120-04 UK	1	Т	Fluopicolide + Fosetyl-Al WG 71	SPI	30	-	3.0	200	FLC Fosetyl- AL	
Appl.: App	ive subs plication aying <b>ppling</b> s	L	I	DBH: PHI:	Pre-har	efore harvo est interv	al O ⁴		Fosetyl- AL	
Trial		Cr	op Sam	ple mat	eria		ontrol reated (1	р Г) Ф ²		ALT [
10-2120-01 10-2120-02 10-2120-03 10-2120-04		spr bai	ô OÍ s	S _ Q	eria ************************************					2 

DALT: Days after last treatment (0): before the last application

Samples were collected in a manner designed to obrain representative samples. They were taken, prepared in the field where necessary transported and stored according to EC guidance 7029/VI/95 rev.5 (1987-07-22).

Each sample consisted of at least 500 s of green material for samples up to 5 days after the last application and at least 1 kg of green material for samples taken more than 5 days after the last application.

### 2. Description of Analytical Brocedures

Residues of fluopicolide and its metabolites, M-OI and M-02 were, analysed within the residue trials samples according to the following method:

Method $\sqrt[3]{01209}$ $\sqrt[3]{01209}$
Extraction $\beta$ Acetone water, acidified with formic acid (75/25/1, v/v/v), with centrifugation.
Detection HPLC-MS/MS
LOQ 0.01 mg/kg (for fluopicolide, M-01 and M-02, in barley green material)

## Summary of the analytical method

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANCO/3029/99 rev 4.



In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study.

Recoveries were not corrected for apparent residues in the control samples used for these recoveries.

The average recoveries were generally within the acceptable range of 70 - 110%. For fluopicolide, high recoveries were noted for the 10 and 15 mg/kg fortification levels (139 and 144 %, respectively). These results are considered to be acceptable, as they maximise the residue levels, therefore the results from the treated samples would be potentially overestimated, rather than underestimated.

### Fortification Sample matrix Recovery values Meansecovers RŠĎ LOQ (mg⁄\$ğ) level value n (%) (mg/kg) Barley or spring 0.01 84 barley green 0.1 83 86 8Ã Ð material 39 10 129 144 15 ₩44 Overalk recovery (n= 94 =**†**0

### Procedural recoveries for Fluopicolide (AE C638206)

RSD = Relative standard deviation, LOQ Practical limit of quantification

Fortified with fluopicolide, determined as fluopicolide and calculated as fluopicolide

* Recovery was performed on barley. All the other recoveries were performed on spring barley. The results at the 10 and 15 mg/kg fortification levels are higher than the results for the other recovery levels. As they maximise the results at the 10 and 15 considered to be acceptable to support the data generation phase.

## Procedural recoveries for M-01 (AE C653711)

Sample matrix	Cortification lavel (fug/kg)		Mean recovery Value (%)	RSD (%)	LOQ (mg/kg)
Barley or spring	∂°0.0k	× 73, 7 <i>\$</i> 976 ~ √	∫_ <i>©</i> ¶5	2.0	
barley green	0,1 «	² 7, 79 80, 81, 82 ₀	80	2.4	
material	00 x	<u>93*</u> §	93	-	0.01
	×15 ×	~ 105 ⁰	105	-	
	\$° 4'	Overall recovery (n≠3) ²	82	11.9	

RSD = Relative standard deviation, LOQ = Practical Jimit of quantification

Fortified with AF@653719, determined as AE C653911 and Galculated as AE C653711

* Recovery was performed on Karley. At the other recoveries were performed on spring barley.

## Procedmal recoveries for M-02 (AE C65)188)

Sample matrix	level 🖒	<b>Recovery values</b>	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Barley or spring	~~0.01	⁶⁶ , 72, 74	71	5.9	
barley green	× 00 ×	<i>"</i> ~ <b>9</b> 6, 77, 79, 83, 87	80	5.7	
material 🖉	× 40 ~	81*	81	-	0.01
	A 15 ~	84	84	-	]
		Overall recovery (n=10)	78	8.0	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with AE C657188, determined as AE C657188 and calculated as AE C657188

* Recovery was performed on barley. All the other recoveries were performed on spring barley.



### 3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopicolide and its metabolites (M-01 and M-02) ranged between 213 and 311 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopicolide and its metabolites (M-01 and M-02) when stored in high water matrices (a)-18°C or below) for up to 30 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and ney were analysed as part of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopicolide and its metabolites (M-0) and M-02) were stable within the sample extract solutions.

## II. RESULTS AND DISCUSSION

No residues above the LOQ were found in the control samples Results were not corrected for consurrent recoveries. For fluopicolide and its metabolites (M-01 and M-02) the residues revels in / on Darley / spring barley green material are sumparised in the following table.

	·~ &	O″		<u>Y Y Q</u>	<i>to</i>
Trial No.	Sample	DALT		Residues [mg/kg]	
Country	material	DALT &	<b>F</b> hiopicotide 6:0 2 0 6.0 2 2	a.s. Fluopicolide	M-02
			enopiconde (		
	Greetomaterial		0:0° >>	< 0.01	< 0.01
	Green material		6.6	< 8 01	< 0.01
10-2120-01	Green material	¢	1600	<b>©</b> 0.01 [∞]	< 0.01
Spain ©	Green materia	3 **	2. <b>9</b>	< 0.0	< 0.01
	Green material	5 🔶 🐧	§.8 0°	< 0,01	< 0.01
je G	Green material	¢,	2.7 8 28	60.01	< 0.01
47	Green material	10 🚿	1.97 6 5	< 0.01	< 0.01
	Green material	0 📎 🛛	§.3 O [™] ∧.	< 0.01	< 0.01
	Green material 🔊	10° ×	7.8 2 2	< 0.01	< 0.01
10 2120 02 00	Green materiat	2 _0	7.8 × 5 7.00	< 0.01	< 0.01
10-2120-02 🔊 Germany 🔬	Green material	<b>x</b> ( ))		< 0.01	< 0.01
Germany A	Green material		3.9 , %	< 0.01	< 0.01
	Green naterial 🔨 👡	7	2. <i>A</i> Q	< 0.01	< 0.01
A CONTRACTOR	Green material	10	6,60	< 0.01	< 0.01
Ÿ		8. s	6.4	< 0.01	< 0.01
A	Breen material	N Q	6.8	< 0.01	< 0.01
	Green, material	2	5.2	< 0.01	< 0.01
10-2120-03	Green material	3^0	5.7	< 0.01	< 0.01
	Green material	5	3.6	< 0.01	< 0.01
	Greenmaterial	7	2.6	< 0.01	< 0.01
	Green material	10	0.88	< 0.01	< 0.01
	· ~ ~		•	•	•
Ũ					

### Residue summary of fluopie dide, M-01 and M-02 in/on barles green material

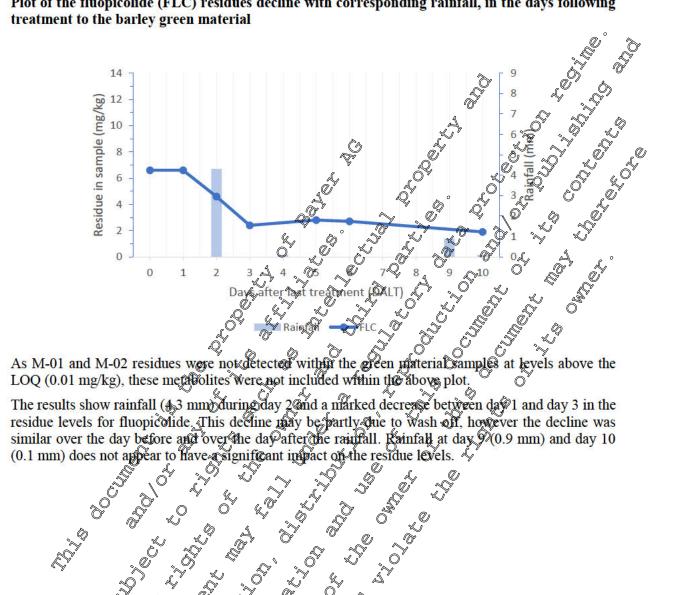


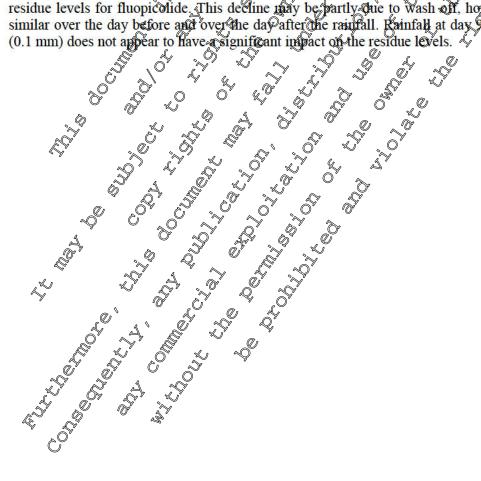
Trial No	Commle			Residues [mg/kg]	
Trial No.	Sample material	DALT		a.s. Fluopicolide	
Country	materiai		Fluopicolide	M-01	M-02
	Green material	0	13	< 0.01	M-02 < 0.01 ∞ 5 5
	Green material	1	11	< 0.01	< 0.01
10 2120 04	Green material	2	9.9	< 0.01	< 0.01 &
10-2120-04 UK	Green material	3	9.4	< 0.01	< 0.01 ~ ~
UK	Green material	5	7.1	< 0.01	< 0.09
	Green material	7	4.2	< 0.01	50.01 × 5
	Green material	9	3.5		<b>6</b> 0.01 <b>7 7</b>

Green ma	aterial	7 4	1.2	<u>ک</u> < 0.01 ک	$\leq$	€4.01 🔊 🔗	Ø
Green ma			0.0	$\sim 0.09$	, Ø	901 7 57 0.01 7 57 7 5 5 7 5 0 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	. (
DALT = Days after last tre	atmant a c	- Active sub	stance		.0	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	×
DALT – Days after last ut	catificiti a.s	- Active subs	stance			4 V 4	Û
				$\sim$ $\sim$			
Climatic conditions and	time cours	se of residue	concentrati	ons m/on barley	green note	rial V	
~		0'			r F	L A .	0
Climatic conditions and	was not co	nducted acco	ordung to G	onsth/on.barley	Rainfall	) Q' q	
		£`.^	$\sqrt[n]{}$	ð A	, O' 🔬		
Trial No.:	10-2120	-01 (* )				A O	
Origin of Data:	Weather	station, Pare	t del Valle	(10 km away)			
Trial Location:	E-08520	Elerona – Le	es Franque	ses del Valles	Û N	, se	
Climatic data recording Trial No.: Origin of Data: Trial Location: Date/Period of Time	<i>a</i> ,				° ∧	· *	
Date/Period of Time			<u> </u>		Rainfall	ÖŘesidue (FLC)	٦
(dd/mm/yyyy)	DALI	& Setivi	itx 🔗	Mean Tempo PCL		[mg/kg]	
10/04/2010		Treatment, St	mpling	<u> </u>		6.6	
11/04/2010	14	G 1: ()		6 ⁵ k4.9	<u> </u>	6.6	
12/04/2010		Sampling		SV (A	°¥.3	4.6	
13/04/2010	3	Sampling		<i>Q</i> 10.2 ^O	[∞] 0	2.4	
14/04/2010	0 [×] 4 ×	/- 🖏 💊	, [°]	\$ 10.8y	Ø 0.1	-	
15/04/2010	5 🗇	Sampling > Sampling	, S	~ L & ~~	0	2.8	
15/04/2010 16/04/2010 17/04/2010	<u>6</u>	Sampling		3.2	0	2.7	_
17/04/2010	~7 @			12.6	0	-	
18/04/2010		- 67 0 - 67 0	<u> </u>		0	-	_
20/04/2010		- N		<u>j' 0</u> 4.3	0.9	- 1.9	_
20/04/2010	L w d	sampleng		13.0	0.1	1.9	
rrigation during same	ting pario	d. No irriet	ion done	ð			
Ingation during sang				Ş ^v			
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		$\gamma \sim \gamma$	× ×				
4	° 29'						
Q [°]		U X	°∼				
	4		~9`				
	S in						
	10° 0'						
× .1 `	Ŭ.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~					
	je j						
Å å		~Q					
	, S						
in the second							
18/04/2010 20/04/2010 20/04/2010 rrigation during sam							



Plot of the fluopicolide (FLC) residues decline with corresponding rainfall, in the days following treatment to the barley green material





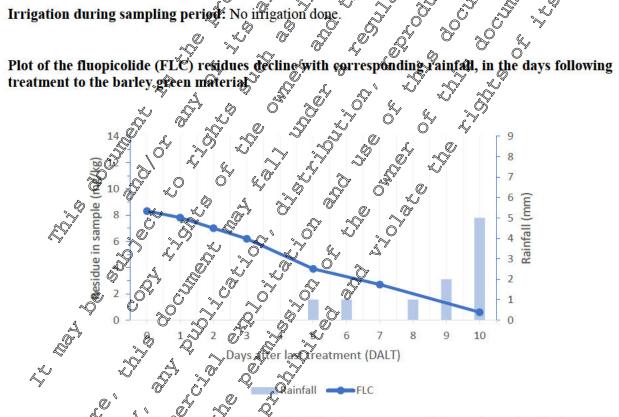


Trial No.: Origin of Data: Trial Location:

10-2120-02 Weather station, Versuchsgut Höfchen at the test plot D-51399 Burscheid

Date/Period of Time (dd/mm/yyyy)	DALT	Activity	Mean Temp. [°C]	Rainfall [mm]	Residue (FLC) (FLC)
01/06/2010	0	Treatment, Sampling	14	0	
02/06/2010	1	Sampling 💍	16	0 🔊	~7.8 ~7.0 ~7.0 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
03/06/2010	2	Sampling	16 180		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
04/06/2010	3	Sampling 4	9 [°]	40 0	D. 63 (
05/06/2010	4	- 4	Q21 °	2 ⁰ 0	° 0, -0 °
06/06/2010	5	Sampling	~ 21		6 3.9 QY
07/06/2010	6	-	N IN O		K - S
08/06/2010	7	Sampling V		Ĩ,	2.7
09/06/2010	8				à- s'
10/06/2010	9		204	2°	
11/06/2010	10	Sampling, Y			0.60

Irrigation during sampling period. No infigation done.

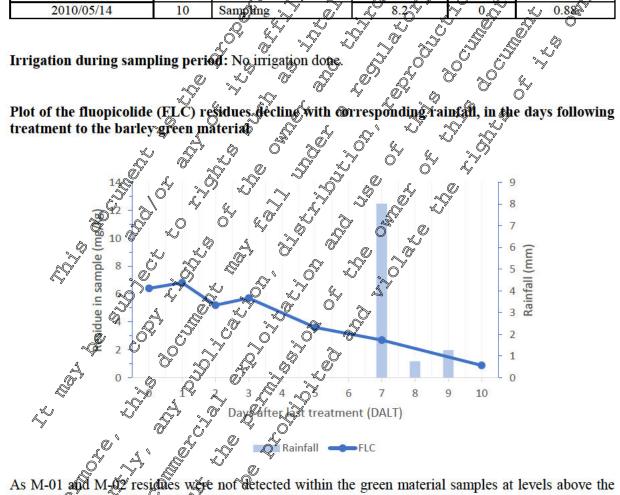


As M-01 and M-02 residues were not detected within the green material samples at levels above the LOQ (0.01(mg/kg), these metabolites were not included within the above plot.

The residue levels generally decline over the 10-day period. Rainfall begins at day 5 (1 mm). Rainfall does not appear to have a significant impact on the residue levels.



Trial No.: Origin of Data: Trial Location:		0-03 r station - Redebel (0.5 l Saint-Amand	km away)		
Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Ronnfall (mm]	Residue (FLC)
2010/05/04	0	Treatment, Sampling	7.3 🕺	¥ •	~ 6. P ×
2010/05/05	1	Sampling	6.9	0	V V.8 6 V
2010/05/06	2	Sampling	8.0 2	0 0	
2010/05/07	3	Sampling A	7.9	0	Q 5.75 ⁴ 4
2010/05/08	4	A	9.Q		
2010/05/09	5	Sampling	<u>~9.2</u> €	~~~ \(\$3.6 Q
2010/05/10	6	lu ko	9.2	<u>0</u>	· · · · ·
2010/05/11	7	Sampling O	\$ 5.5	8.03	2,7
2010/05/12	8		0 <u>6</u> 4 0	0.75	
2010/05/13	9		6.9 4	1.27	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
2010/05/14	10	Sampling N	\$ 8.2	Y ON	≪ 0.88



LOQ (0, 12 mg/22), these metholites were not included within the above plot.

The residue kyels generally decline over the 10-day period. Rainfall begins at day 7 (8.02 mm). Rainfall does not appear to have assignificant impact on the residue levels.



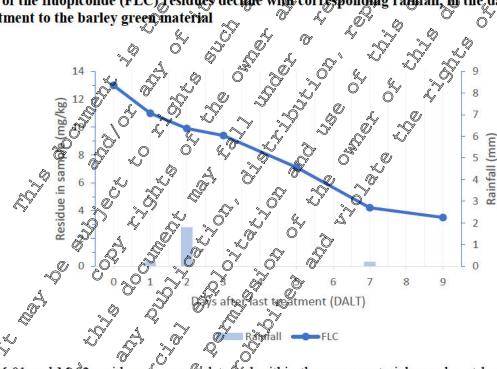
Trial No.: Origin of Data: Trial Location:

10-2120-04 Weather station, Little Shelford (0.5 km away) CB22 - Little Shelford

Trial Location:	CB22 -	Little Shelford			
Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Rainfall	Residue (FLC) [mg/kg]
17/06/2010	0	Treatment, Sampling	13.9	∢ 0.0	
18/06/2010	1	Sampling	11.0 🛒	0.2	
19/06/2010	2	Sampling	§ 9.2	1.8	
20/06/2010	3	Sampling	12.9	0.0	9.4 0
21/06/2010	4	- 4	15.90	0.0%	
22/06/2010	5	Sampling	1203	. 000	, 70 , 0 [×]
23/06/2010	6	-	19.0	-Q,0 , (<u> </u>
24/06/2010	7	Sampling	@18.0°	@ 0.2	≪ 4.2 ~ €
25/06/2010	8	- & ?	N 18	0.0	× - ×
26/06/2010	9	Sampling	0 100 0	0.0	S A C

Irrigation during sampling period: No irrigation do 2 and

Plot of the fluopicolide (FLC) residues decline with corresponding randall, in the days following treatment to the barley green material



As M-01 and Mc02 residues were not detected within the green material samples at levels above the LOQ (0.01 ms/kg), these metabolites were not included within the above plot.

The residue levels generally dechine over the 10-day period. Rainfall occurs at days 1 (0.2 mm), 2 (1.8 mm) and (0.2 mm). The raise all does not appear to significantly impact the residue decline.

Ser .



ð

III. CONCLUSION

The residues of fluopicolide after spray application of the "Fluopicolide + Fosetyl-Al WG 71" on barley / spring barley green material declined markedly during the sampling period. No residues above 9.01 mg/kg for the metabolites M-0 or M-02 were found in / on the green material samples.

Assessment and conclusion by applicant:

The study is acceptable. Positive residues were found for fluopicolide in barley green material, which markedly declined over the test period. No residues above the LOO(0.01 mg/kg) were found for BAM (M-01) and M-02.

	KCP 10.1.2.2/03
Data Point:	KCP 10.1.2.2/03
Report Author:	KCP 10.1.2.2/03
Report Year:	
Report Title:	Determination of the revidues of fluop colide and proprimocally hydrochloride in/on wheat/spring after spray application of Pluopicolide & Propanocarb hydrochloride SC 687.5 in Germany, the Setherlands and Belgium
Report No:	18-2950
Document No:	M-686559-01 2 2 5 6 6 5 5
Guideline(s) followed in	M-686559-0142 Regulation (EC) No P107/2009 of the European Parliament and of the Council of
study:	21 Actober 2009 Soncerning the placing of plant protection products on the
Deviations from Current	OECD Guideline for the Feying of then icals on Crop Field Trial (TG 509 provisied in September 2009)
	Not applicable
test guideline Previous evaluation:	No, not previously submitted of L
GLP/Officially	Yes conducted under GLP Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Relability-	Yes y y y
Acceptability/Relability	Yes Conducted under GLOOTHORMy recognised testing facilities

Executive Summary

An open field study with 4 residue trials was conducted in northern Europe (Germany, Belgium and The Netherlands) on spring wheat, during the 2018 season. One application of "SC 687.5" (a product containing 62.5 g/L fluopicolide and 62 g/L propamocarb hydrochloride) was made at a target rate of 0.10 kg a.s. / ha/(for fluopicolide). Only the parameters and results relevant to fluopicolide have been reported within this study summary.

The residues of fluppicolide, M204 and M-02 after spray application of the "SC 687.5" on spring wheat green material declined markedly during the sampling period.

C.



I. MATERIALS AND METHODS

A. MATERIALS

Test Item: 1. Batch no.: Active Ingredient / Purity: Storage: Expiry date:

SC 687.5 EM4L023437 Not stated in the report Not stated in the report March 2021

Test commodity: 2. Crop part:

Spring wheat Green materia

B. STUDY DESIGN AND METHODS

1. Test Procedure

des of the relevant r with SC (87.5 luss of fluopi The purpose of the study 18-2950 was to determine the magnitude of the relevant residues of fluopicolide in/on wheat (green material) after one spray application with SC 687.5" to product containing (2.5 c/l. fluori, with SC 687.5") to product containing 62.5 g/L fluopicolide). This summary focuses onl y on the residues of fluopicolide.

Field phase

The study included four supervised residue trials conducted in northern Europe (Germany Belgium and the Netherlands) during the 2018 season. Ô 0

\bigcirc Ø Description of the trial location and exopping information on treated plots

Trial number	18-2950-01	18-2950-02	18,2950-03	18-2950-04
Trial location	Burscheid	Vechta, VI) NDZwaagdijk	6211 Mellet
Countr	Germany 🛇	Germans S	The Netherlands	Belgium
Area of application	Field 🗸 🏑	Field	Pield	Field
Plot size $[m^2]$	144 5 3	125	180	65
Type of soil	Sandy Loam	Standy silt	Clay	Silty loam
pH-value of soil (in water)	Field Saudy Loam	Study silt	7.1	7.1
Content of organic C	1.05 5 5		3.43	2.15
Test system	Spring wheat	Springwheat	Spring wheat	Spring wheat
Variety 🗸	Typath of	Tyball A	Nobless	Mistral
Date of sowing (yyyy/mm/dd)	2018-04-09	N.	2018-04-13	2018-03-21
Date of commercial harvest	2018-04-09 2018-07-31 to 2018-07-31 2018-08-91	2018-08-10 to 2018-08-20	2018-07-18 to 2018-08-01	2018-08-07 to 2018-08-15

The sectual application data are presented in the following table. This data reflects the intended application scheme, or, iteminor deviations occurred, these were within the acceptable range:



10

Trial no. Country	Appl. No.	Plot	Formulation	Appl. mode	Growth stage (BBCH code)	DBH PHI (days)	Test item rate (L/ha)	Water rate (L/ha)	a.s.	Appl. rate (kg , s./ha)
18-2950-01 Germany	1	Т	SC 687.5	SPI	30	-	1.56	29 4	FLC	0.097
18-2950-02 Germany	1	Т	SC 687.5	SPI	30	-	1.60 Å	301	FLO	Q ¥00
18-2950-03 Netherlands	1	Т	SC 687.5	SPI	30 💎	-	167	261	CFLC ~	0.10
18-2950-04 Belgium	1	Т	SC 687.5	SPI	300 Days bet	- Q	1.6	2500 9 9 9	FLC ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	P.100
SPI: Sprayin	-	edule			Days bet Pre-flarv		ontrol reacted (T	Š 4,		
Trial	ing sen	Crop		k mate			ontrøl,		К К При	
11141		стор		•			reated (T			
10 00 00 01		*		r L P				ð	×	
18-2950-01 18-2950-02 18-2950-03		Spring wheat	Green	materia		Ŝ [™] €			0 1 2	
18-2950-04	Un					O [*] T	ő -	Š,	3	

Application summary of SC 687.5 on spring wheat

before the last application DALT: Days after last dreatment Ò

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary, transported and stored according to EC guidance 7029/VI/95 rev.5 (1997-07-22).

Each sample consisted of at least 500 g of green material for samples up to 5 days after the last greep material for samples taken more than 5 days after the last application, and at least Tkg application

2. Description of Analytical Procedures

Residues of thopicolide and its metabolites, M-01 and M-02 were, analysed within the residue trials samples according to the following method:



Summary of the analytical method

Method	01209/M001
Extraction	Acetone/water, acidified with formic acid $(75/25/1, v/v/v)$, with centrifugation.
Detection	HPLC-MS/MS
LOQ	0.01 mg/kg (for fluopicolide, M-01 and M-02, in cereal green material)

Full details and acceptable validation data to support this method are presented within document A, which comply with the EU regulatory requirements outfined within SANCO/3029/99 reg.

In order to check the performance of the method, recovery determinations were included in each set of analysis. Control samples from the study were for field and used as the recovery samples. All the recovery determinations were performed in parallely to the analyses of control and treated samples from the study.

Recoveries were not corrected for apparent residues in the control sample used for these recoveries, .

The average recoveries were within the acceptable range of 70 - 110

Procedural recoveries for Fluopicolide (AE/C638206)

Sample matrix	Fortification	Recovery values	Mean ecovery KSD	LOQ
	level 🚿			(mg/kg)
	(mg/kg)			
Spring wheat /	0.01	97; 100; 106; 112 ⁹		
green material	0.10	94; 96, 97; 97, 103; 107	× × × × × × × × × × ×	0.01
		\$2;86; \$ 7;90; 9 6	× 88 × 5.9	0.01
		Øyerall recovery (n=160)	<u>& 98</u> <u>5</u> 8.7	

RSD = Relative standard Deviation, LOQ Practice/limit of quantification

Fortified with fluopice determined as fluopic lide and calculated as floopicolide

Procedural recoveries for M-01 (AE C653711)

Sample matrix	Fortification leyel		Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Spring wheat /	~0.0K	, <u>9</u> Q95; 9Z; 98; 1 8 Q 4	96	3.6	
green material		ZŽ, 90; 92, 92; 99, 97 🏷	90	7.6	0.01
	Q.0 5	Ø 88; 93; 93; 94, 96 Ø	93	3.2	0.01
		Overall recovery (n=16)	93	5.7	

RSD = Relative standard deviation, LOO = Practical limit of quadrification Fortified with AE C653711, determined as AE C653207 and eaculated as AE C653711

Procedural recoveries for M-02 (AE (657188)

Sample matrix	Alevel (mg/kg)	Recovery values	Mean recovery value (%)	RSD (%)	LOQ (mg/kg)
Spring wheat /	S 9.9 S	94; 95; 96; 96; 102	97	3.2	
green material	4 0.10 O	92; 94; 98; 99; 101	97	3.8	0.01
	5.0	84; 85; 85; 89; 91	87	3.5	0.01
	O X	Overall recovery (n=15)	93	6.1	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with AE C657188, determined as AE C657188 and calculated as AE C657188



3. Storage stability:

The storage period of deep-frozen samples (at -18°C or below) for fluopicolide and its metabolites (M-01 and M-02) ranged between 245 and 338 days.

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopicolide and its metabolites (M-01 and M-02) when stored in high water matrices ($\mathbf{a}_{\mathcal{F}}$ 18°C or below) for up to 30 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed appart of the same analytical phase. Based on the acceptable procedural recoveries obtained, it can be concluded that the residues of fluopicolide and its metabolites (M-01 and M-02) were stable within the sample extract solutions.

II. RESULTS AND DISCUSSION

No residues above the LOQ were found in the control samples, Results, were not corrected for concorrent recoveries. For fluopicolide and its metabolities (Metal and M-02) the residues levels in / of spring wheat green material are summarise on the following table

ſ.

r	-			<u>~~~</u>		
Trial No.	Sample	Growth stage BBCH	DALT		Residues/mg/kg/	
Country	material A	stage	DALT	a s .	a.s. Faropicolide	
Country	material	BBCH	O Q	Fluepcolide	<u>س M-04 (۲) (۲) (۲) (۲) (۲) (۲) (۲) (۲) (۲) (۲)</u>	M-02
	Green material	30 @	0 5	2.4	\bigcirc $^{\vee}$ < 0.4 1	< 0.01
	Green material 🔬	30,5	<u>1</u>	~~ 1.6~ J	r< ⊘ 01	< 0.01
18-2950-01	Green material	30 30	≈ 2	~~ 0.67 <i>(</i> //	\$0.01	< 0.01
Germany	Geen material	ى ³ 0		× ~0.86	< 0.01	< 0.01
	Greenmaateriat	31	5 9	₹0.76 O	∠ < 0.01	< 0.01
Q	Green material 🔬	31- 2	ð	0.50	× < 0.01	< 0.01
	Green material	2			< 0.01	< 0.01
	Green material	<u>,</u> 30		3.4 ×	< 0.01	< 0.01
	GreenQnaterial	≥ 30 _°	1%	2.5	< 0.01	< 0.01
18-2950-02	Green material 🦉	300/	×7	2	< 0.01	< 0.01
Commence	Green material	Â	$\begin{array}{c} & & \\$	× 21 1.3	< 0.01	< 0.01
	Green material	°≫30 ~	6 📎	a 1.3	< 0.01	< 0.01
4	Green material	≥ 30 Q	<i>ZQ</i>		< 0.01	< 0.01
	Green material 🔊	30		le 0.78 🖉	< 0.01	< 0.01
	Green matérial 🏾 🖇	<u>∧</u> 30	$\approx 0 \approx$	¥ 4.2*	0.048*	0.024
<i>"</i> «	Green material	g 30 (1.	3.6	0.085	0.024
18-2980-03	Green material	30~	- 3 ⁵⁷	1.6	0.030	0.019
The	Green material	30	~3	1.4	0.022	0.012
Netherlands	Green material	31	₹ 5	0.69	0.015	0.013
	Green material	$\frac{31}{32}$	7	0.81	0.011	0.012
, S	Green material	32	10	0.53	0.019	0.011
	Green material Green material Green material Green material Green material					

Residue summary of fluopiconde, M-01 and M-02 in/on whear green materi »

an

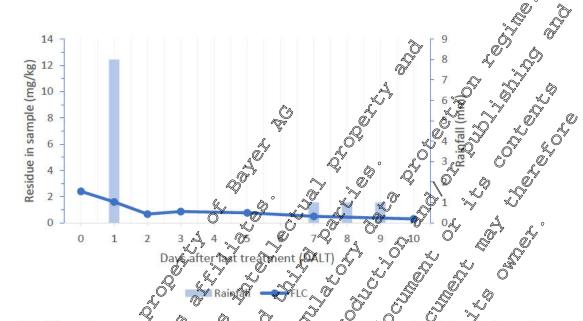


Trial No.	Samula	Growth		Residues [mg/kg]				
	Sample	stage	DALT	a.s. Fluopicolide				
Country	material	BBCH		Fluopicolide	M-01	M-02^		
18-2950-04 Belgium	Green material	30	0	5.7	< 0.01	< 0.01		
	Green material	30	1	4.5*	< 0.01	< 0.01		
	Green material	30	2	3.9*	< 0.01	< 0.001		
	Green material	31	3	3.5*	< 0.0	0.011		
	Green material	31	6	2.2	< 0.01	<u>~</u> 0.01		
	Green material	32	7	1.8	0.01			
	Green material	32	10	<u>(</u> (6)3	0.01	<>√ <>0,01 <>		
DALT = Days a * Mean value, t	after last treatment a. this sample has been e	s. = Active extracted a	e substanc nd analyse	ce edonultiple times		0:011		
Climatic cond	litions and time cour	rse of resi	idue conc	centrations in on	wheat green mate	rial & S		
Climatic data	recording was not c	onducted		to GEP.				
T ' 1 M		a .						
I rial No.:	18-2950	0-01 🔊		. V . 4 (
Origin of D	ata: Weathe	0-01 🖉 er station,			t trial@ocation)			
Origin of D Trial Locati	ata: Weathe	0-01 0 er station,	Germa	nv)	t trialQocation)			
Origin of D Trial Locati	ata: Weathe	0-01 ^{or} er stårton,	(Germa	ny)	t tria Docation)			
Origin of D Trial Locati	ata: Weathe	0-01 $\mathcal{O}^{\mathcal{P}}$	(Germa	ny)	t triatocation)			
Origin of D Trial Locat	ata: Weathe	0-01 ^(b) er stærion,	(German	ny)	t tria Docation)	Residue (FLC)		
Trial No.: Origin of D Trial Locat: Date/Period (yyyy/mr	ata: Weather ion: Contribution: Contribution	0-01 $\mathcal{O}^{\mathcal{P}}$	Germa Germa	ny) MeanOf PMeanOf	t tria Docation)	Residue (FLC) [mg/kg]		
Drigin of D Trial Locat Date/Period (yyyy/mr 2018-05	18-2950 vata: Weather ion: 0 of Time DAUT n/dd) \$200	0-01 r station,	Germa Germa Setivity ent, Sempl	ny) Mean M	t tria Docation emp: Rainfall mm] 0 2 0 2 0 2 0 2 0 2 0 2 0 2 0 2	OResidue (FLC) [mg/kg] 2.4		
Drigin of D Trial Locat: Date/Period (yyyy/mr 2018-05 2018-05	18-2950 pata: Weather ion: Image: Constraint of the second secon	0-01 r station, v 2 v 2 Treating Samplir	Germa Setivity nt, Sampl	ny) MeanOT MeanOT C ing S J 6 S J 6	t tria Docation)	A A A A A A A A A A A A		
Date/Period (yyyy/mr 2018-05 2018-05 2018-05	18-2950 pata: Weather ion: Image: Constraint of the second secon	0-01 r station, Treating Samplir Samplir	Germa Setivity ent, Sampl	ing 19. 0 19. 0 19. 0 10. 0 19. 0 16. 0 20. 0 20.	t tria Docation)	Kesidue (FLC) [mg/kg] 2.4 1.6 0.67		
	Green material Green material after last treatment a. this sample has been e litions and time cour recording was not c 18-2950 vata: Weathe ion: Image: Colored state of Time DAUT 5-15 Image: Colored state 5-16 1 5-17 Image: Colored state 5-18 Image: Colored state		Germa Setivity ent, sampl ig ig ig ig ig ig ig ig ig ig			Kesidue (FLC) [mg/kg] 2.4 1.6 0.67 0.86		
2018-05	5-19 5 6 4 3	, P- 🗸	\sim	ny) Meaver mg 19. 19. 19. 19. 19. 19. 19. 19.	Ç Ø 0	-		
2018-05 2018-05	5-19 5 4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	, - V Samplir	\sim			Kesidue (FLC) [mg/kg] 2.4 1.6 0.67 0.86 - 0.76		
2018-05 2018-05 2018-05	5-19 $5-20$ $5 - 5$ $5 - 5$ $5 - 5$ $5 - 5$ $5 - 5$, - x, Scamplir O &				- 0.76 -		
2018-05 2018-05 2018-05 2018-05	5-19 $5 -20$ $5 -20$ $5 -20$ $5 -20$ $5 -20$ $5 -20$ $5 -20$ $5 -22$ $7 -20$ -20	, - V Samplir		20 20 20 20 20 18		-		
2018-05 2018-05 2018-05 2018-05 2018-05 2018-05	5-19 5 -20 5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -	Samplir Samplir Samplir Samplir				- 0.76 -		
2018-05 2018-05 2018-05 2018-05	5-19 5 -20 5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -	- X Samplir O & Samplir		20 20 20 20 20 18		- 0.76 -		

Irrigation during sampling period. No integration done.



Plot of the fluopicolide (FLC) residues decline with corresponding rainfall, in the days following treatment to the wheat green material



As M-01 and M-02 residues were not detected within the green paterial samples at levels above the LOQ (0.01 mg/kg), these merabolites were not included within the above plot.

The results show rainfall (8 mm) during day (and a marked decline betyeen day 1 and day 3 in the residue levels for fluopicolide. This decline may be partly due to wash off, however the decline was similar over the day before the rainfall and over the day after the rainfall. The residue levels generally decline thereafter. Fainfall at day 7-9 () mm rainfall for each day) did not appear to have a significant impact on the residue levels.

Trial No .:	€ 18,2950-02 × × × × ×
Origin of Data:	Weather station Vechta Langförden (1.4 km away)
C	
Trial Location:	4937 Wechta, OT Deindrup (Germany)

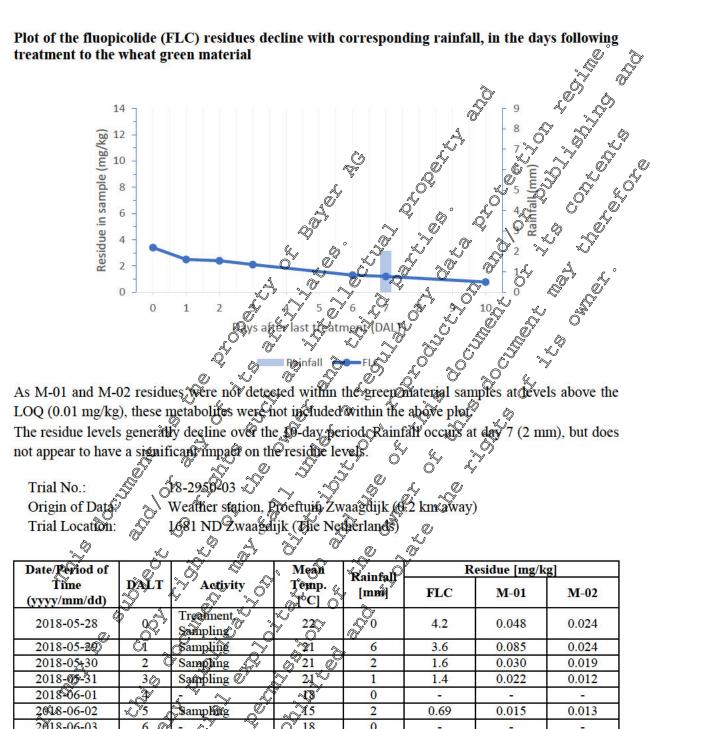
Date/Period of Time (yyy)mm/dd)	DAL	Activity	Mean Temp. [°C]	Rainfall [mm]	Residue (FLC) [mg/kg]
2018-05-16	4 0 A	Treatment, Sampling	17	0	3.4
لي≪2018-05-17 لل		Sampling	11	0	2.5
2018-05-18		Sampling	12	0	2.4
2018-05-09	A A	Sampling	13	0	2.1
2018-05-20	4 4	Į	18	0	10
2018 05-21	\$ 54,	- ~0	19	0	1
2008-05-25 C	Ô	Sampling	19	0	1.3
2018-05 23		Sampling	21	2	1.2
2018-5-24	\$ 8	1	21	0	201
2010-05-25 D	9		22	0	1
2018-05-26	10	Sampling	23	0	0.78

ã

 \bigcirc

Irrigation during sampling period: No irrigation done.





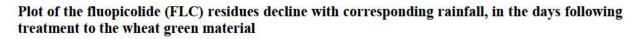
Plot of the fluopicolide (FLC) residues decline with corresponding rainfall, in the days following

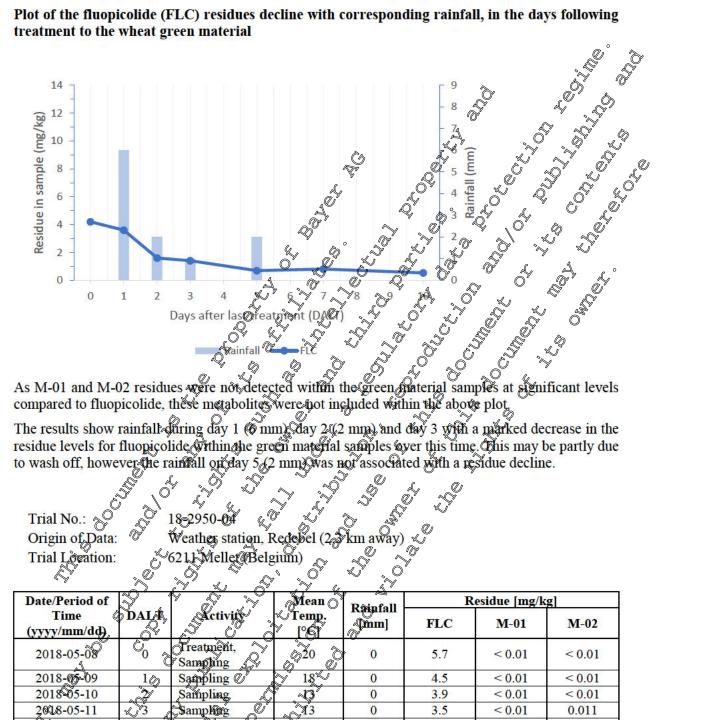
	_W		
Trial No.:	Ş.	18-2950-03	N A
Origin of Data		Weather sta	
Trial Location	Ś	1681 ND2	waagdijk
~	"0"		4

Date/Period of			Mean	Rainfall	Residue [mg/kg]		
Ťime (yyyy/mm/dd)	DALT	Activity	Temp.	[mm]	FLC	M-01	M-02
2018-05-28		Treament Sampling	226	00	4.2	0.048	0.024
2018-05-20	Ŭ,	Sampling N	21		3.6	0.085	0.024
2018-05-30	2 (Sampling (6 [°] 21 0	2	1.6	0.030	0.019
2018-05-31	30	Sampling @	× 21	1	1.4	0.022	0.012
2018 06-01		- × ~		0	-		- E
2018-06-02	\$ 5	Samphorg	15	2	0.69	0.015	0.013
2018-06-03	6 7	- 67 - 4	0 [×] 18	0	-		-
2018-06-04	°7,	Sampling	16	0	0.81	0.011	0.012
2018-06-05			16	0	-		
2018-06-06	2 9		17	0	-	-	
2018-06-07	100	Sampling	21	0	0.53	0.019	0.011

Irrigation ouring sampling period: No irrigation done.







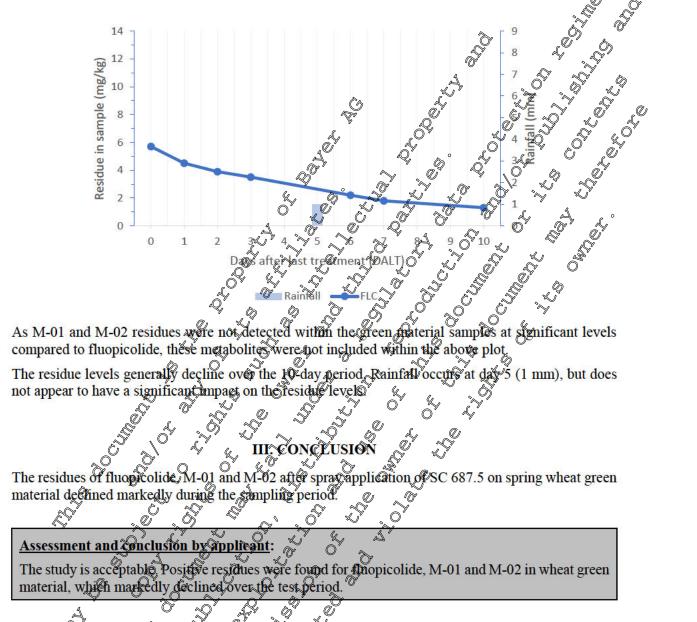
<u> </u>	´ _\ ^	Ý 4.	\searrow	Ĺ	s.	
Trial No.: 🔊		950-04	L.	L,	ð	AN IN
Origin of Data:	Weat	her statie	n, Redel	el (2,3	km aw	ay) 🛛
Trial Location:	621	Mellet	Belgium)			\sim

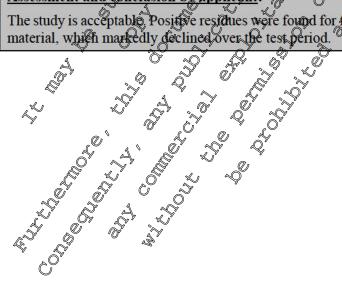
Date/Period of	/Period of Cartinity Team Rainfall Residu					esidue [mg/k	ie [mg/kg]	
Time (yyyy/mm/dd),	DALA	Activity	V lemp.	(mm]	FLC	M-01	M-02	
2018-05-08	5 ⁰	Sangoing		0	5.7	< 0.01	< 0.01	
2018-05-09	10	Sampling @	× 18	0	4.5	< 0.01	< 0.01	
2018 05-10		C 1'		0	3.9	< 0.01	< 0.01	
2048-05-11	13	Sampling C	13	0	3.5	< 0.01	0.011	
2018-05-12	4 0		0 [×] 17	0	-	1-1		
2018-05-13	<mark>۶</mark>	Sampling	× 12	1	-	141		
2018-05-14	A C		13	0	2.2	< 0.01	< 0.01	
2018-05-05	277	Sampling	16	0	1.8	< 0.01	0.012	
2018-05-16	80	- 5°	16	0	-	141	-	
2018-05-17	2		12	0	110 	340	-	
2018-05-107	A10 .	Sampling	11	0	1.3	< 0.01	< 0.01	

Irrigation during sampling period: No irrigation done.



Plot of the fluopicolide (FLC) residues decline with corresponding rainfall, in the days following treatment to the wheat green material





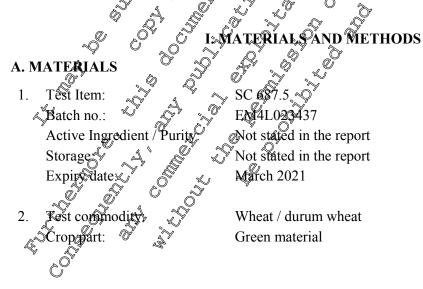


Data Point:	KCP 10.1.2.2/04
Report Author:	
Report Year:	2020
Report Title:	Determination of the residues of fluopicolide and propamocarb hydrochloride
	in/on wheat and durum wheat after spray application of fluopicolide &
	propamocarb-hydrochloride SC 687.5 in Southern France draly, Spain and
	Greece
Report No:	18-2955
Document No:	<u>M-686561-01-1</u>
Guideline(s) followed in	Regulation (EC) No 1107/2009 of the European Purliament and of the Council of
study:	21 October 2009 concerning the placing of plant protection products on the
	market \mathcal{L} \mathcal{O}^{\vee} \mathcal{L}^{\vee} \mathcal{O}^{\vee}
	OECD Guideline for the Testing of Chemicals on Grop Fred Triat (TG 509 published in September 2009)
	published in September 2009)
	US EPA OCSPP 8601500, Ctop Field Triaty of of A
Deviations from current	Not applicable A O O O O O O
test guideline:	
Previous evaluation:	No, not previously submitted
GLP/Officially	Yes, conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yest y y y y y

Executive Summary

An open-field study with four residue trials was conducted in Southern Europe (south France, Italy, Spain and Greece) on wheat and Ourum wheat, during the 2018 season. One application of "SC 687.5" (a product containing 62.5 g/L fluopicolide and 62.5 g/L propamorarb hydrochloride) was made at a target rate of 0, 00 kg a 2. / ha (for fluopicolide). Only the parameters and results relevant to fluopicolide and the second s have been reported within this study summary. . پي Õ

The residues of fluopicoted after spra application of the SC 687 on wheat and durum wheat green material declined markedly during the sampling period. No sign ficant residues for the metabolites M-01 or M-02 were found in 10n the green material samples (i.e. 0.02 mg/kg).





B. STUDY DESIGN AND METHODS

1. Test Procedure

The purpose of the study 18-2955 was to determine the magnitude of the relevant residues of fluopicolide in/on wheat (green material) after one spray application with "SC 687.5" (a product" containing 62.5 g/L fluopicolide). This summary focuses only on the residues of fluopicolide,

The study included four supervised residue trials conducted in southern Europe (south Exerce, study, span and Greece) during the 2018 season. Description of the trial locations and cropping information on treated plots

Trial number	18-2955-01	18- 2 955-02	18-2955-03	₽18-2955-04 🖑
Trial location	84840 Lapalud	20090 Settala	18028 Zadarraya	GR 50200. Apatoliko Kozafi
Country	France	litaly 🗡 🧳 🦄	Spain Spain	Greece X
Area of application	Field	Field C .	Field	Field
Plot size [m ²]	120	60%		270
Type of soil	Clayey loam	🔊 îlty lởa m 🕬	905 C C	Cay 🖉
pH-value of soil (in water)	8.3	7.2 0 0 0		€7.1 ×
Content of organic C [%]	2.04	£.45 J	AZ73	1.86
Test system	Wheat O	Wheat	Wheat A	JWheat, durum
Variety	Orégrain, winter	Illieo, worter soit wheat (aestivum)	Marius, soft wheat	Bronde, Triticum durum
Date of sowing	2017-12-07	2017.00-18	2017-19-15	2017-12-20
Date Of commercial harcest	2008-07-04 2018-07-07 0 2018-07-07 0			2018-06-30 to 2018-07-10

* Remark: Last sampling before flowering

The actual application data are presented in the following table. This data reflects the intended application scheme or, if minor deviations occurred, these were within the acceptable range: L 1

Trial no. Country	Appl. No.	Plet	4 ' 💙	Appl. prode	Growth stage (BBCH Qode)	DBH PHI (days)	Test item rate (kg/ha)	Water rate (L/ha)	a.s.	Appl. rate (g a.s./ha)
18-2955-01 Southern France		A N	SC (87.5	SPAC	30	-	1.62	204	FLC	0.101
Italy 🏑		T C	SC 687,5 ~	SPI	30	-	1.63	203	FLC	0.102
opum	D'	A C	\$687.5	SPI	30	-	1.61	227	FLC	0.101
18-2955-04 Greece		Т	SC 687.5	SPI	30	-	1.59	199	FLC	0.099
a.s.: Act	ive subs	stance	E	BH:	Days be	efore harve	est			

Ô Application summary of SC 887.50n wheat and durug wheat

DBH: Days before harvest Active substance PHI:

Appl.: Application SPI: Spraying

Pre-harvest interval



Planned sampling schedule

Trial	Сгор	Sample material	Control (C) Treated (T)	
18-2955-01 18-2955-02 18-2955-03 18-2955-04	Wheat and durum wheat	Green material		-0 -0 -0 -0 -0 -0 -0 -0

DALT: Days after last treatment "-0": before the last application

Samples were collected in a manner designed to obtain representative samples. They were taken, prepared in the field where necessary gransported and stored according to EC saidance 7029 VI/95 rev.5 (1997-07-22).

Each sample consisted of at least 500 g of green material for samples up to 5 days after the last application and at least 1 kg of green material for sample taken more than 6 days after the last

2. Description of Analytical Procedures

Residues of fluopic and its metabolites, M-D1 and M-02 were, analysed within the residue trials samples according to the following metabol:

Summary of the analytical method

Method	01209/Meon 2 0 0
Extraction	Acetone water, acidified with formic acid $(75/25/1, v/v/v)$, with centrifugation.
Detection	HPLC-MSMS ~ ~ ~
LOQ	gol merkg (for fluopicolide M-01 and M-02, in cereal green material)

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANCO/3029/99 rev 4.

In order to check the performance of the method, pecovery determinations were included in each set of analysis. Control samples from the study were fortified and used as the recovery samples. All the recovery determinations were performed in parallel to the analyses of control and treated samples from the study.

Recoveries were not corrected for apparent residues in the control samples used for these recoveries.

The average recoveries were within the acceptable range of 70 - 110 %.



Procedural recoveries for Fluopicolide (AE C638206)

Wheat / green material 0.01 $97; 115; 115$ 109 9.5 0.10 $83; 90; 91; 92; 95; 97$ 91 5.3 5.0 92 - $ 10$ 96 - $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ 0.04$ $ -$	Sample matrix	Fortification level (mg/kg)	Recovery values (%)	Mean recovery value (%)	RSD (%)	LOQ (mg/k@)
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Wheat / green	0.01	97; 115; 115	109	9.5	
	material	0.10	83; 90; 91; 92; 95; 97	91	5.3	
10 96 - <u> </u>		5.0	92	- ""	-	× 0.04
Overall recovery $(n=11)$ 97^{2} 10.3^{2}		10	96	- 1	- ô	
			Overall recovery (n=11)	97	10,37	

Procedural recoveries for M-01 (AE C653711)

RSD = Relative stan	dard deviation, LOO	Q = Practical limit of quantification			
Fortified with fluopi	colide, determined a	s fluopicolide and calculated as fluop	vicolide	Å Å	
Procedural reco	overies for M-01	(AE C653711)			
Sample matrix	Fortification	Recovery values 🔊	Mean recovery	∕ " _{\$} [®] RSD [°] ≫	LÔQ
	level		🖉 vahue	\$¥ (%)	(<u>mg</u> /kg)
	(mg/kg)	A	Q (%)	" O″	Q'A
Wheat / green	0.01	× 13; &2,985 ~ ~		7.8	
material	0.10	7 2 ,75; 82 ,87; 9,4 2 ,100 , 4	° 85 √ °	\$12.8	0 .01
	5.0	Q 4, 92 0 ~0	<u> </u>	8 <u>-</u> 0	Q .01
		≪Overatorecovery (n=10)	y 884 A	19.1	<u></u>

RSD = Relative standard deviation, LOQ = Practical limit of quantification Fortified with AE C653711, determined as AEXC653711 and calculated as AE (6)

Procedural recoveries for M-02 AE CO57188

		A (Y	
Sample matrix		🔊 RSD	LOQ
	$\begin{bmatrix} \text{Stevel } 0 \\ 0 \end{bmatrix} = \begin{bmatrix} 0 \\ 0 \end{bmatrix} \begin{bmatrix}$	(%)	(mg/kg)
	(mg/kg) $(%)$ $(%)$		
Wheat / green	S 0.01 97, 101; 109 S 102	6.0	
material	2 30 .10 7 30 ; 80 ; 80 ; 80 ; 81	1.4	0.01
8		-	0.01
à	Overall recovery (n=9) 88	13.2	

RSD = Relative standard decition, SOQ = Practical limit of quantification

Fortified with AE C657188, determined at AE C657188 and calculated as AE C657188

3. Storage stability:

The storage period of deep frozen samples (at -18 C or below) for fluopicolide and its metabolites (M-01 and M-02) ranged between 343 and 339 days

Acceptable storage stability data are available (presented under point M-CA 6.1) which demonstrate the stability of fluopicolde and its metabolites (M-Q) and M-02) when stored in high water matrices (at -18° (Sor below) for up to 90 months. These available data are sufficient to support the storage period between sampling and extraction.

Regarding the interval between extraction and analysis, the samples used for the procedural recovery determination were prepared at the same time as the field samples and they were analysed as part of the same analytical phase. Based of the acceptable procedural recoveries obtained, it can be concluded that the residues of Ruopicolide and its metabolites (M-01 and M-02) were stable within the sample extract solutions.

Ŀ,



II. RESULTS AND DISCUSSION

No residues above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries. For fluopicolide and its metabolites (M-01 and M-02), the residues levels in / on wheat barley green material are summarised in the following table.

Residue summary of fluopicolide, M-01 and M-02 in/on wheat green material

					« »	<u>~~`~~~~~~</u> *	3
Trial No.	Sample	Growth		Š	Residues [mg/kg]		a
Country	material	stage	DALT	- As	a. Fluopicolide		S
Country	material	BBCH		Auopicolide	ОУ M-01 🔊	<u> </u>	O /
	Green material	30	0	3.4 Q	≤0.01 C	V<0.01V	/
	Green material	30	$\frac{1}{2}$	y 3.4 🔊	Q<0.04Q	S ^Y ≤ 0.01	
18-2955-01	Green material	30		。2.7 °	`~y < 0 ₂ 01 ~	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	
Southern	Green material	30	31		₹9.01	≫< 0.01	
France	Green material	30	5 8		8 0.01 °	√ < 0.001 °	
	Green material	30	A, 7 🔊		a < 0.00	P.01	
	Green material	30 🛴	_9\		~ ~ <u>0</u> 0 1	< 0.01 (S) < 0.01 (S) < < 0.00	
	Green material	300°	¢0	k laty	° ≰0.01 🔊	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
	Green material	- E	\$1 . A	7 A5 0		Ø < <u>0</u> .01	
18-2955-02 Italy	Green material	Å30 ⁽	°°2 °≫	1.9	<u></u> < 0.01	v ≪0.01	
	Green material	[™] 31 Ø	3Q 4	Q 1.76	C ≤ 0 .01	∞ 0.01	
	Green material	31	4	or k. Q	< 0.01	<i>‱</i> < 0.01	
	Green material 📣	<u>32</u>	Ş7.	0.85	<0.01 ≤	◎ < 0.01	
	Green material	$\sqrt[32]{33}$	100	0.72	\$ < 0.91 \$	< 0.01	
	Green material	$\begin{array}{c} 32 \\ 33 \\ 30 \\ 20 \\ \end{array}$		≶ي 1.3 ا	<0.01 20.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0	< 0.01	
	Green material	<i>QQ</i>		\$.1 9 * \$	< 0.010	< 0.01	
18-2955-03	Green material 🔊	30	, 2 🔊	×2.8* 0	0.01	< 0.01	
Spain	Green material	∫x) 30 ≪ x		2.1 C	$\sim < 0.01$	< 0.01	
Spann	Green material	31	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	× 15	0.01	< 0.01	
	Green material	⁽³ 3) 031 (2	~ ⁸ 1	v <u>0.53</u>	∞€ 0.01	< 0.01	
	Oreen material			0.53 0.18	⊘ < 0.01	< 0.01	
	Green material	30 ▲	Â,	0 0.0	< 0.01	0.012	
	Green material	300° 30	Ϋ́,		< 0.01	0.010	
18-2955-04 Greece	Green marerial	50	⊳ [∿] 2	× 4.2 .0	< 0.01	0.012	
	Greenmaterial	[∞] 30. Õ		& 3.4 Å	< 0.01	< 0.01	
	Greed material	31	40	0 3 <u>4</u> 9	< 0.01	< 0.01	
	Green material	30° ~~32		> 3,0	< 0.01	0.017	
	Creen paterial		<u>0'9,0</u>	Ø.4	< 0.01	0.018	

DALT = Days after last treatment = Active substance

* Mean value, this sample has been stracted and analysed multiple times

Ò O Climatic conditions and time course of residue concentrations in/on wheat green material

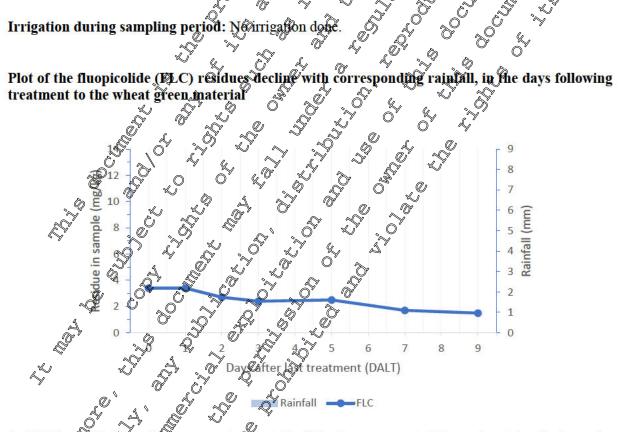
Climatic data recording was not conducted according to GLP.



Trial No.: Origin of Data: Trial Location:

18-2955-01 30760 Saint Julien de Peyrolas (9.3 km away) 84840 Lapalud (France)

Trial Location:	84840	Lapalud (Fr	ance)		
Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Rainfall 🕅 [mm] 🖉	Residue (FLC) [mg/kg] -
2018-04-17	0	treatment, sampling	17.5	0.0 (2018-04 18, 11:03)	5 ³ 3.45 ³
2018-04-18	1	sampling	18.0 🖒	(2018-04-18, 11:03)	
2018-04-19	2	sampling	17.5	0.0 (20]©04-19, 08:45	2.7 × 4
2018-04-20	3	sampling	48.5	0.0 (2018-0, 20, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0	
2018-04-21	4	-	19.0		x" - x
2018-04-22	5	sampling	× 1890 ~	(2018-04-22, 17:45)	₹ 2.5
2018-04-23	6	-	0 18.0 C	_0~ 19,00 °0	L A co
2018-04-24	7	sampling	019.5	(2018-04-24, 07:50)	O Q. 7 <i>G</i>
2018-04-25	8	- 2	~ 19:5	0.0 ° ×	
2018-04-26	9	sampung		(2000-04-20, 12:309	



As M-01 and M-02 resides were not detected within the green material samples at levels above the LOQ (0, 12 mg/22), these metholites were not included within the above plot.

No rainfall secures during the period of the test. Residues of fluopicolide within the green material sample declined over the 10-day test period.

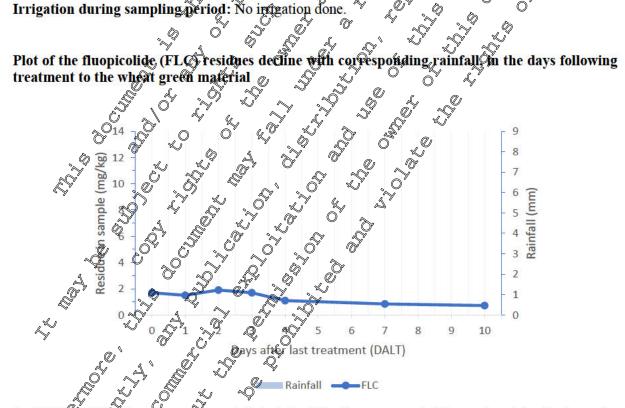


Trial No.: Origin of Data: Trial Location:

18-2955-02 20090 Rodano (5 km away) 20090 Settala (Italy)

Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Rainfall [mm] (FLC) [ms/kg]
2018-04-16	0	Treatment, sampling	18.2	
2018-04-17	1	sampling		(2018-04-17, ¥2:05) 1.5 S
2018-04-18	2	sampling	22.5	(2018-04-48 16:00)
2018-04-19	3	sampling	22.0	Q2018 Q4-19, (4:25)
2018-04-20	4	sampling	6° 25° 1	(3018-04-20, 11:39)
2018-04-21	5	- 0 4	624.4	0.0 L A
2018-04-22	6	- A.O	24.0	(2018-04-23, 04:15)
2018-04-23	7	sampling ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~ 206	
2018-04-24	8	- 0 0 0 0 - 0 0 0 0	× 23.3 0	× 8 -
2018-04-25	9	- 64 47 .0	~~23.5	(2018-04-26, 16/15) 0.72
2018-04-26	10	sampling O 💙	23,3	0.72

Irrigation during sampling period: No irogation done

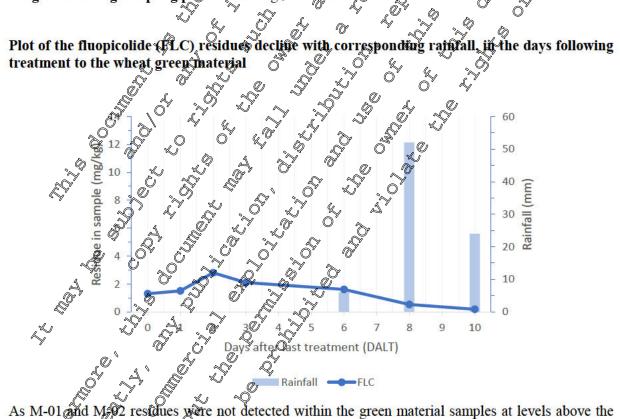


residues were not detected within the green material samples at levels above the M As Mthese motabolites were not included within the above plot. morkg) LOQ m and and Ò, Ŀ

No rainfall occurred during the period of the test. Residues of fluopicolide within the green material sample declined over the 10-day test period.



Trial No.: Origin of Data Trial Locatior	a: 18	-2955-03 128 Zafarraya (3.9 km aw 128 Zafarraya, Spain	vay)	
Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Rainfall [mm] (RtC) [mg/kg]
2018-04-03	0	Treatment, Sampling	_ [©] 11.0	
2018-04-04	1	Sampling	10.3	(2018-04-04,11:50) 1:5
2018-04-05	2	Sampling	لم 10.7 م	(2018-04-05, 12:00)
2018-04-06	3	Sampling	13.4	$\begin{array}{c} 0.00 \\ (2018-04-05, 12:00) \\ \hline 0.0 \\ (2048-04-96, 12:05) \\ \hline 0.0 \\ \hline 0.$
2018-04-07	4	- ~ ~	7.8	
2018-04-08	5		0 7.3 0	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
2018-04-09	6	Sampling	6.2	(2018-04-09, Q ² .31)
2018-04-10	7	-		52
2018-04-11	8	Sampling ()	\$5.5	(2018-04)(1, 11, 50) (0.53
2018-04-12	9	- 0 4 . 4	\$\$ 5.7 m	
2018-04-13	10	Sampling	4.2	(2016-04-13)12:20) 0.18
Irrigation duri	ng sampling	period: No irrigation de	ne.	



LOQ (0.01 mg0rg), these metabolites were not included within the above plot.

The residue levels and the fluopicolide residues generally decline over the rest of the 10-day period. Rainfall occurs at days 6 (6 mm), 7 (52 mm) and 10 (24 mm). The pronounced rainfall during the later timepoints does not appear to have a significant impact on the residue levels.

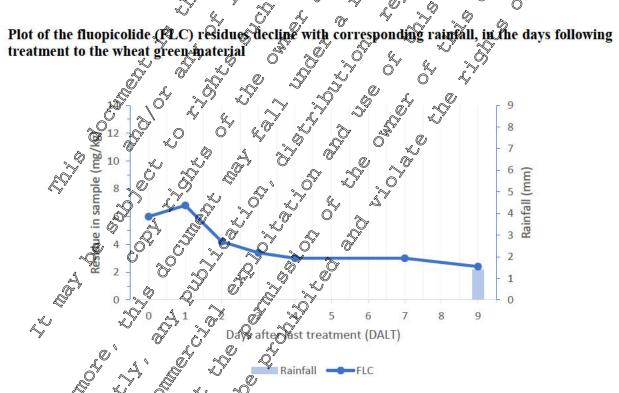


Trial No.: Origin of Data: Trial Location:

18-2955-04 Ptolemaida (8 km away) GR 50200 Anatoliko, Kozani (Greece)

Date/Period of Time (yyyy/mm/dd)	DALT	Activity	Mean Temp. [°C]	Rainfall [mm]		sidue [mg@g] M-01 M-02	
2018-04-11	0	Treatment, Sampling	12.6	0.0	6.0	20.01 0.012	K.
2018-04-12	1	Sampling	13.8	(201) 04-12, 12:36	6.8		Í
2018-04-13	2	Sampling	14.7	0.0 0 (2018-04-13, 6.45)	4.20	< 6.01	
2018-04-14	3	Sampling	16.1 Q	0.0 (2018-04-14, 09:24)	34		1
2018-04-15	4		15.6	2018 4-15, 39:45)			0
2018-04-16	5	Sampling	12.5		20	Q 0.01 < 0	r
2018-04-17	6	1.00	13.9	2018-04-18, 12,09)	0'- 🔬		
2018-04-18	7	Sampling	0 14.94		3.05	< 0.01 0.017	
2018-04-19	8	-	18.3	2018-04-29, 13:19 (2018-04-29, 13:19)		<u></u> -	
2018-04-20	9	Sampling	105.4	(2018-04-29, 13:10)	2.4	× 0.01 0.018	

Irrigation during sampling period: No urigation done.



As M-01 and M-02 resignes were not detected within the green material samples at significant levels compared to floopicolide, these metabolites were not included within the above plot.

The psidue fevels mental does not appear to have a orgnificant impact on the residue levels.



III. CONCLUSION

The residues of fluopicolide, M-01 and M-02 after spray application of SC 687.5 on wheat green material declined markedly during the sampling period.

Assessment and conclusion by applicant:

The study is acceptable. Positive residues were found for fluopicolide, M-01 and M-02 in wheat steen material, which markedly declined over the test period.

L,

	KCP 10.1.2.2/05
Data Point:	KCP 10.1.2.2/05
Report Author:	
Report Year:	
Report Title:	2020 Fluopicolide (FLQ): Kinetic evaluation of esidue dissipation after application in or on cereals
Report No:	VC/19/041M
Document No:	M-687818-00-1 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
Guideline(s) followed in study:	
Deviations from current test guideline:	Not applicable " of the
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	
Acceptability/Reliakanty:	$\frac{\mathbf{y}_{\text{res}}}{\sqrt{2}} \frac{\mathbf{y}_{\text{res}}}{\sqrt{2}} \frac{\mathbf{y}_{\text{res}}}{2$

Executive summary

This statement provides a kinetic evaluation of the residue decline of fluopicolide in young cereals that may represent food items for the residue herbivor the birds or manimals.

n

Fluopicolide has been analysed in 3 crop residue declare studies with 4 trials each (2011: 10-2120-01 to -04 (21-408-72-01); 2020: 18-2950-01 to -04 (M-686559-01-1; 2020: 18-2950-01 to -04 (M-686559-01-1; 2020: 18-2950-01 to -04 (M-686559-01-1)). Additional trials (8) conducted in studies E19RP087 and E10RP102 are also evaluated for sake of completeness, although final reports for these studies are not yet available. To that the kinetic analysis was conducted with pre-QA residue results.

The model fits as well as the statistical evaluation of the results were carried out with the software KinGUI, version 2.1. $\sqrt[3]{2}$

Acceptable fits were obtained for 1 Trials, with an overall geometric mean DT₅₀ of 4.9 days.

I. MATERIAL AND METHODS:

The residue decline that reported for fluopicolide in 20 field trials were submitted to kinetic evaluation. The model that were submitted to kinetic evaluation. The model that were submitted to kinetic evaluation of the results was carried out with KinGUI version 2.1 (Meyer and Witt 2014). In this software the fitting algorithms as well as the statistical evaluation of the results implemented on the basis of the statistical computing language R (<u>http://www.r-project.org/index.html</u>). For the optimisation the implemented algorithm Iteratively Reweighted Nonlinear Least Squares (IRLS) was used.

For all additional calculations a Microsoft EXCEL spreadsheet was used.



, K

The visual fit and distribution of residuals were the principal criteria for deciding if a particular kinetic fit is appropriate or not. However, even moderately good fits can have quite high χ^2 test values (*i.e.* > 15 %).

It should be remembered that data points beyond the DT_{90} point have much less weight than those before. Hence, the fit to a long, low tail is not as important as the fit to the first part of the curve to the DT_{90} point.

Parameter uncertainty should be tested but only becomes more relevant when model predictives are made beyond the conditions of the experiment from which the parameter was derived. This was not the case here because typically most of the residues had discipated within the experimental period of 10° days. If a parameter is not considered reliable, reasons for the uncertainty should be examined (1-test alone is not sufficient to judge acceptability or non-acceptability, it is more of a guide). The acceptability of a fit should then be decided case by case, taking into account the reason for the uncertainty, the effect of a parameter on the endpoint, and the use of the endpoint (*e.g.*, will it be used individually or pooled).

FOCUS kinetics gives some further proposals on how to separate between biphasic models: A Residues at study end < 10 %: FOMC might be more appropriate Residues at study end > 10 %: DFOP or HS might be more appropriate.

Nevertheless, this should be considered as a proposal only and the visual fit remains a principal decision criterion.

The evaluation workflow was always started with an SFO ffr.

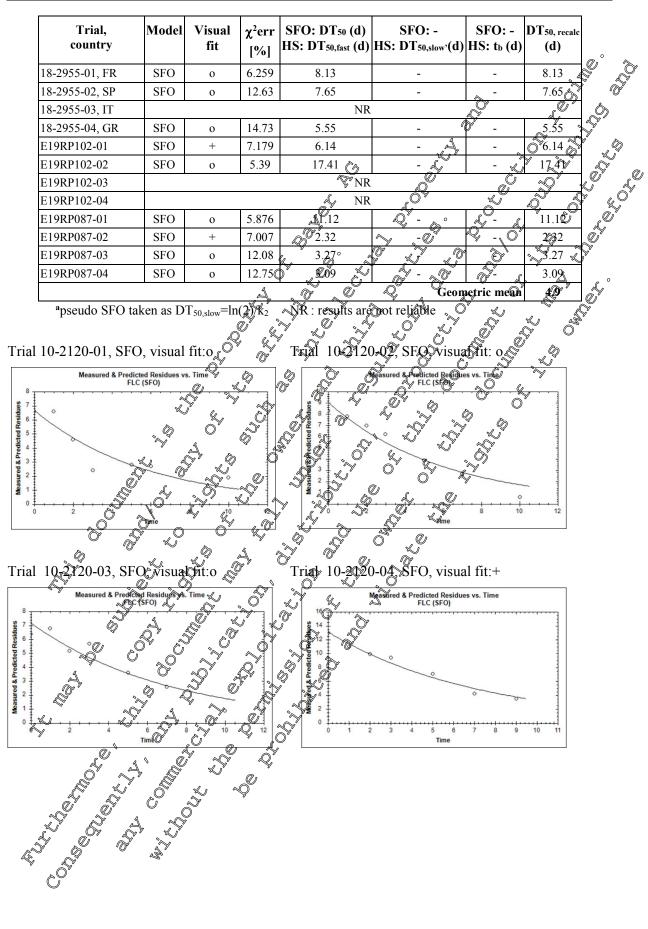
- 1. If $\chi^2 \text{err} < 15\%$ and all other conteria are acceptable (visual fit, restonal distribution), the SFO fit was considered acceptable and gelected.
- 2. If χ^2 err for the SFO fit was between 15 and 25%, and all other criteria are acceptable (visual fit, residual distribution) the SFO fit was not rejected, but biphasic models FOMC, DFOP, HS were also checked, by the FOMC, DFOP or HS fit were superior over the SFO fit, the biphasic fit was selected. If there was no significant improvement with the FOMC, DFOP or HS fit, the SFO fit was selected.
- selected. γ if $\chi^2 \text{err} > 15$ for the SFO fit and a clear faiture on any other criteria (visual fit, residual distribution), the SFO fit was rejected. Biphasic models (FOMC, DFOP, HS) were checked. If a biphasic fit was acceptable it was selected. If the biphasic fits were also not acceptable, a reliable fit cannot be obtained from the data set and the trial was rejected.

OF THE RESULTS AND DISCUSSION:

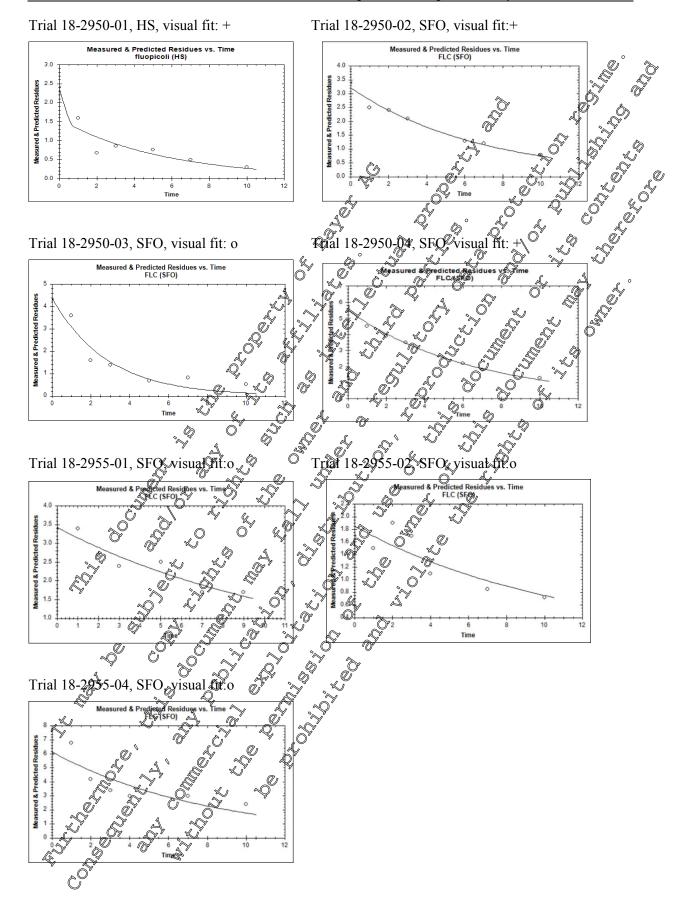
Acceptable fits were obtained for 17 tricks, with an overall geometric mean DT₅₀ of 4.9 days. SFO was considered acceptable for 16 trials, and for one trial the HS fit was selected. The remaining 3 trials did not allow for an acceptable fit and were rejected.

	*	a sur	× 4	Q, '	S.			
	Triat, S country	Model	Visual fit	χ ² ern⁄ [%]		SFO: - HS: DT50,slow'(d)		DT _{50, recalc} (d)
	vaille10-2120-09, SP	O O		915.41	3.95	-	-	3.95
	10-2420-02 ØE	SFO () O	9.284	4.13	-	-	4.13
	16-2120-65 ВЕ	SFQ	0	11.16	4.90	-	-	4.90
R	10-2126-05 BE	ST O	+	4.722	4.98	-	-	4.98
~~~	10 <b>20</b> 01, DL	HS	+	18.90	0.86	3.89	0.69	3.89 ^a
	1 <b>&amp;-2</b> 950-02, DE	SFO	+	5.244	4.72	-	-	4.72
	18-2950-03, BE	SFO	0	16.02	2.00	-	-	2.00
	18-2950-04, NL	SFO	+	3.258	4.46	-	-	4.46

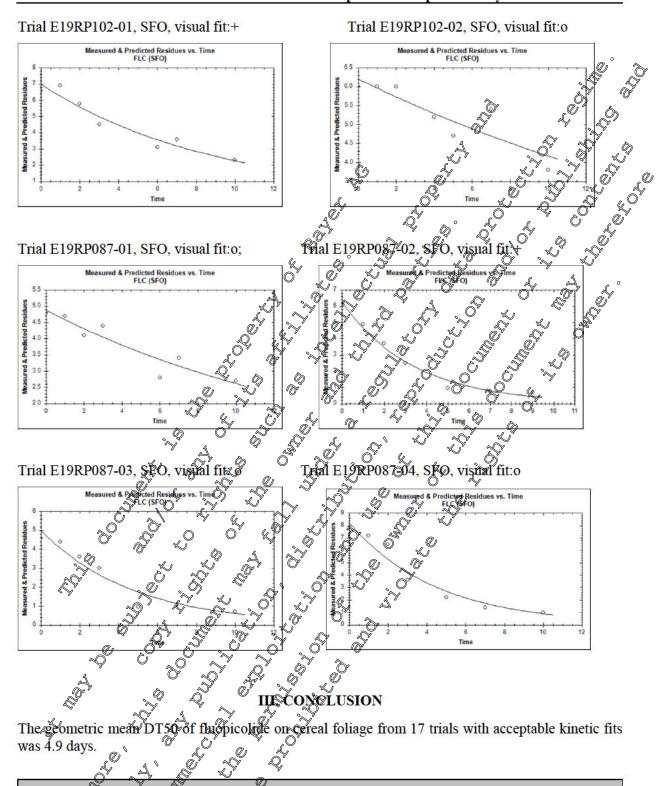












## Assessment and conclusion by applicant:

The sport is acceptable. The geometric mean DT50 of fluopicolide on foliage was 4.9 days.

Ĩ 



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

The available and relevant data covering potential effects of fluopicolide and propamorphylorkoholde on terrestrial vertebrate en presented under point P1 0.1 for bits and CP 10.1 generative and covering potential effects on reptiles and amphibians neither godanoc documents nor testing guidelines are available at present. Therefore, no additional data on terrestrial vertebrate wildlife is presented here. The available and relevant data covering potential effects of fluopicolide and propamocarbmammals. Regarding assessment of potential effects on reptiles and amphibians neither gindance documents nor testing guidelines are available at present. Therefore, no additional data hydrochloride on terrestrial vertebrates are presented under point CP 10.1.1 for birds and CP 10.1.4 for And in the second of the secon and the service of the owner owner



### CP 10.2 Effects on aquatic organisms

The risk assessment is based on the current guidance: EFSA PPR Panel (EFSA Panel on Plant Protection Table 10.2-1: Endpoints used in risk assessment

Table 10.2- 1: E	ndpoints used in risk ass	sessment	<u>_</u> 1	
Test substance	Test species	Endpoint		Reference
FLC + PCH SC 687.5	Oncorhynchus mykiss	96 h LC ₅₀	<b>%6.6 mg prod</b>	<u>9003: M</u>
		NOEC	2.5 mg proDL	CZ5109 01-1 KCP 10:2.1/0
	Cyprinus carpio	96 h LC 50	18 mg prod./I	2003; M
	cyprimus curpio	NOE		<u>227280-00-1</u>
				KCP 10.2.1/02
	Daphnia magna	48 h E©50 NOEC	the second second	2008; Mr °
	L.	NOFC		227283-061 CP 10.2.1/03
	Pseudokirchnerica	2 h E 60	100 mg prod. ( 13.8 mg prod. ( 4.3 mg prod. ( 0.69 mg prod. ( 0.40 mg prod. ( 0.10 mg prod. ( 0.35 mg	2009: M-
	subcapitata	72 h EtC50	VI3.8 mg prod D	22790-0102
	Q' è	72 h NOE	4.3 mg prod L	KCP 10,2,1/04
	Navicula melliculas	72 h ErC 50 72 h E _b C 50	0 89 mg arod./LO	2003; M- 227@4-01-1
		72 h NOEr	0.10 mg prod L	KCP 10.2.1/05
		72 ErC10	0.10 mg prod./L 0.35 mg prod./L	
		6° 5°	0.35 mg prost./L	2020; M- 679538-01-1
		S.		Endpoint
l S		$\land$		recalculation. KCP 10.2.1/06
Fluopicolide	Fish, agute of concording the concording of the	96 h C 50	<b>0.36 mg a.s./L (mm)</b>	RCT 10.2.1/00
	Oncorhynchus mykiss	NOEC	0.16 mg a.s. (mm)	2003; M-240806-
				01-1 KCA 8.2.1/01
	Fish 200	96 10 000	0.75 mg a.s./L (mm)	2003;
	Fish, agate Lepomis magroching	96 IN C 50 K	0.56 mg a.s./L (mm)	M-240805-01-1
le la				KCA 8.2.1/02
	Bish, agine	96 h DC 50	©1.3 mg a.s./L (mm)	
	Cyprous capto		) 0.25 mg a.s./L (mm)	2003;
				M-219743-01-1
			10 / / )	KCA 8.2.1/03
	Fish, acute	960 LC50	1.8 mg a.s./L (mm) 1.0 mg a.s./L (mm)	
^o		Y	110 IIIg (100 II (1111)	2003;
		8		<u>M-234508-01-2</u>
	Figh acuto	96 h LC50	0.7 mg a.s./L (mm)	KCA 8.2.1/04
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Oryzias latipes	NOEC	0.44 mg a.s./L (mm)	
	OryzieClatipes			2002
li g	L'AL			<u>2003;</u> M-234510-01-2
				KCA 8.2.1/05
	Fish, acute	96 h LC ₅₀	0.41 mg a.s./L (mm)	
	Cyprinodon variegatus	NOEC	0.20 mg a.s./L (mm)	2003; M-223359-01-2

Table 10.2-1:	Endpoints used in risk assessment



fest substance	Test species	Endpoint	Reference
			KCA 8.2.1/06
	Fish, acute	96 h LC ₅₀ 1.34 mg a.s./L (nom)	
	Pimephales promelas	NOEC 0.313 mg a.s./L (nom)	
	1 1	Č	2015; M-53792-01-1
		L S	KCA 8.2.1/20
	Fish, chronic (ELS)	33 d NOEC 0.155 mg a.s./L (mm)	
	Pimephales promelas	EC10 0.278 mg a.s./L (mm)	
			2065.
			$\frac{M}{24119} \frac{24119}{101}$
			GCA 0Q.2.11014
			2018; MY
			643769-01-1
			Calculation of EC10
			endpoint.
			KCQ 8.2.20/02
	Fish, BCF flow through Lepomis macrochi@is	Bet ss, lipter 65 lotg (whole fish)	.: 2003: M-2 1273-
			01-10
			KCA 8.2,2,3/01
	Invertebrate, acute &	BEEss, lipid 65 Okg (whole fish) normalised 49 a EC 20 > 138 mg g.S./L (ann)	
	Daphnia magna		2003; M-240807-
			<u>01-P</u>
		95 h EC (y > 5 o mg a.S./L (mm)	KQCA 8.2.4.1/01
	Invertebrate, acute	95 h EC > 2 co mg a.s./L (ann)	<u>2003; M-</u>
	Crassostrea virganica		
ĺ			KCA 8.2.4.2/01
Š	Investebrate, acute	96 h LC so 3.2 mg a.s. (L (mm)	2003; M-220513-01-2
. 0	Americantysis bahia		KCA 8.2.4.2/02
	Invertebrate, chronic	21 dNOEC 0.19 mg a s. (mm)	
	Dophnia magna	EC10 Counot becalculated	2003; M-241191-
			01-1
N° Y			KCA 8.2.5.1/01
Ş			2010.10
<i>ل</i> ې	A & A &	K a a	<u>2018; M-</u> 617757-01-1
. O			Endpoint
C			recalculation.
à la caracteria de la c	S S OF		KCA 8.2.5.1/02
	Invertebrate, chronic	28 (DOEC 0.34 mg a.s./L (mm)	2015; M-
	Americamysin bahia	28 d NOEC 0.34 mg a.s./L (mm) EC00 0.18 mg a.s./L (mm)	<u>544290-02-1</u>
Ϋ́Υ,	O O V	EC10 0.18 mg a.s./L (mm)	KCA 8.2.5.2/01
Ű.	Sediment dweller,	28 d NOEC 1.98 mg a.s./kg (nom)	<u>2020; M-</u>
jý 🔨	chrone 4		<u>671529-03-1</u> KCA 8 2 5 4/02
	Lungericulus variegatus		KCA 8.2.5.4/02
	Americannysin bahia Americannysin bahia Sediment dweller, chronic Lumbriculus variegenus		
	, C		
L'S' & O'	A		
· · · · · · · · · · · · · · · · · · ·	~		
. 07			



Test substance	Test species	Endpoint	Reference
	Algae	$72 h E_r C_{50} > 4.3 mg a.s./L (mm)$	
	Pseudokirchneriella	72 h E _b C ₅₀ 3.0 mg a.s./L (mm)	l d'
	subcapitata	72 h NOErC 2.4 mg a.s./L (mm)	2003;
	Green algae		
			KCA 8.2.6 1901
		72 h E_rC_{10} 2.6 mg a.s./L (mm)	
		4	<u>2010 M-</u>
			643768-01-1
			Endpoint ~
		× Q	recalculation.
			KCA 80.6.1/05
	Algae,	72 h Ereso 0.073 mga.s./L (hom)	
	Skeletonema costatum	96 http:// 0.0612 mg a. 2 (nom)	<u>2015: 15-5332@-</u>
	(Marine diatom)	72 h ErCos • 0.01 00 mg a. s./L (nom)	
	- 55 ^{- 6} - 63 - 54	7 h ErCo 0.0424 mg a.s./L nom)	KCA 8.2.6.2/07
	1		XCA 8.2.6.2/07
	Algae,	72 by $E_r C_{50}$ 0.129 mg as L (man)	
	Navicula pelliculo a	2 ² h EyQ30 0.067 mg a.s./L (num)	
	(Freshwater dia Om)	72 h.NOE.C. 9.043 nog a.s./5 (mm) 72 h E.C. 0.064 mg a.s./C (mm)	
		72 h E_rC_{10} 0.064 mg a.s C (mm)	<u>2020:</u> M-678011-01-1
			KCA 8.2.6.2/08
			KCA9.2.0.2/08
	Aquatic macrophytes,	7 d ErC50 > 3.2 kpg a.s. (mm) frond number & div	2003;
		frond number & dix	M-220201-01-2
		weight	KCA 8.2.7/01
		NOE 3.2 mg s./L (mm)	Ren 0.2.001
	Amphibian Arvae,		
		48 hLC ₅₀ \rightarrow > 1 mg a.s./L (nom) NOEC \rightarrow 0.25 mg a.s./L (nom)	2010; M-
Õ	Xenopus Thevis		393869-01-1
	A 0 0 4		KCA 8.2.8/01
M-01	Fish, acute (2)	96 M LC56 240 mg p.m.//L (nom)	
2,6-dichlorø-	One or hypernus motorss		2001;
enzamide (BAM;			M-234311-01-2
			KCA 8.2.1/07
BCS-AA65784))	Invertebrate acute	480h EC50 180 mg p.m./L (nom)	
Q	Imphnia magna or		2001;
Q			M-234306-01-2
~Q		O O	KCA 8.2.4.1/02
	Algae	2 h E ₁ 2 mg p.m./L (nom)	
	Pseudokachneriella	$72 \text{ h} \text{E}_{3}\text{C}_{50}$ 60 mg p.m./L (nom)	
	Ssubcapitata	72 h NOE _r C 40 mg p.m./L (nom)	2001; M-234304-
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		$72$ $E_rC_{10}$ 49 mg p.m./L (nom)	01-2
- ^			KCA 8.2.6.1/03
"Q .		*	
Ő ^v A	Algace of	72 h ErC ₅₀ 92 mg p.m./L (mm)	
A. X	Nargeula pelliculo	$72 h E_y C_{50}$ 46 mg p.m./L (mm)	
Ŭ A	(Freshwater diatom)	$72 h NOE_r C$ 30 mg p.m./L (mm)	
LA D	A X	$72 h E_r C_{10}$ 42 mg p.m./L (mm)	2020;
	ST N		<u>M-678377-01-1</u>
A A C			KCA 8.2.6.2/10
× 41¥			



Test substance	Test species	Endpoint		Reference
	Aquatic macrophytes,	7 d ErC50	97.6 mg p m./L (nom),	°
	Lemna gibba	= 1 D G	frond number	2003:
		7 d E _y C ₅₀	71.8 mg p m./L (nom)	
		NOErC	25.0 mg p m./L (nom)	<u>M-219725-0165</u>
		$E_rC_{10}$	51.0 mg p m./L (nom)	KCA 8.2.7/02
			(D'	
			4	<u>2008:</u>
			Ra S.	<u>M-664031-01-1</u>
				Endpoint Y
			¥ Q	recalculation.
			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	KCA 8Q.7/03
M-02	Fish, acute	96 h Les	> 102 mg/p m.J. (mm)	ٽي ٽ
3-chloro-5-	Oncorhynchus mykiss	96 h Leşo		
(trifluoromethyl)	C. Comprendo mynass	· ·		2003
oyridine-2-carboxylic				M-218631-01-2
acid; (BCS-AB43478))			$\tilde{\mathcal{O}}$ $\tilde{\mathcal{O}}$ $\tilde{\mathcal{O}}$ $\tilde{\mathcal{O}}$ $\tilde{\mathcal{O}}$	KCA 8.2.1/08
(DC5-AD45470))				RC 0.2.100
	Algae,	72 li ErC59	74 mg p.m. A. (mm)	
	Navicula pelliculos	72 HEyC	72 mg p.m L (mm)	
	(Freshwater diatoon)	^{₹2} h NOE _r C	Amg pan./L (min)	
	L 0	72 h E C 10	A8 mg p.m./L (mm)	2020;
	Q' m	6 8		MP <u>678012-01-1</u>
		Nº S	A mg pin /L (min)	KCA 8.2.6.2/09
Propamocarb-	Fish, active	LC ₅₀	≫/92 m@a.s./L	EFSA Scientific
nydrochloride	Lepomis mackochirus			Report (2006) 78, 1-
				180
	Fish, chronic	NOEC U	6.3 mg a.s./L	EFSA Scientific
	Pimepholes promelas1)	PICLOS	6.3 mg a.s./L	Report (2006) 78, 1-
Ô				80
, C				T
e e e e e e e e e e e e e e e e e e e	Invortebrate, acute	12450 °	> 200 mg a.s./L	EFSA Scientific
<u>م</u>	Bophnia Magner			Report (2006) 78, 1-
		l o c	<u> </u>	80
	Invertebrate chronic	NOEC O	12.3 mg a S./L	EFSA Scientific
	Daphnia magna			Report (2006) 78, 1-
i i i i i i i i i i i i i i i i i i i			×, O	80
	Alga	E-Ron &	> 85 mg a.s./L	EFSA Scientific
T	Pseudokir Oneriella	Er&so V	- 05 mg a.s./ L	Report (2006) 78, 1-
Q	sobcapita 0	K a		80
Ø.	6 C S C O		O ^Y	
~~~~~ (	Aquate plant ~		> 18 mg a.s./L	EFSA Scientific
•	Lenna gibba			Report (2006) 78, 1-
<u>A</u>	Lenou Stere	<u>0</u> .0		80

a.s.: active substance; p n. pure metabolite nom nominal concentrations, htm = mean measured concentration

## Selection of Agae and man ophytes endpoints for risk assessment

Q

Following current state of science, the test guidelines OECD TG 201 and 221, the EU-Method C3, the Regulation for Classification and Labelling (Regulation (EC) No 1272/2008), the PPR Opinion (EFSA Journal 461, 44; 2007), the EFSA supporting publication 2015 (EN-924 published 22 December 2015) and also the EFSA Aquatic Guidance Document (AGD, 2013, noted by SCFCAH on July 10-11th, 2014), list growth rate as the relevant endpoint of the algae and the *Lemma* growth inhibition test. Therefore, the risk assessment is based on the  $E_rC_{50}$ , when available.

Valid algae studies with green algae and freshwater and marine diatoms species are available for fluopicolide. In general, diatoms show a greater sensitivity to fungicides targeting oomycetes. That is



the reason why tests on *Navicula* were also performed with the metabolites in order to cover the most sensitive organism group, even though diatoms do not belong to tier 1 standard species. The endpoint selected for algae risk assessment is the lowest of the 72h- $E_rC_{50}$  (0.073 mg a.s./L), it was obtained with *Skeletonema costatum*.

### Selection of endpoints for chronic risk assessment

According to the AGD,  $EC_{10}$  values are preferred over NOEC and should be used for risk assessment, when robust values are available. In the fish ELS study, the NOEC is 0.455 mg/L based on wet weight and length, the lowest  $EC_{10}$  is 0.278 mg a.s./L based on wet weight. It is proposed to use the  $EC_{40}$  for risk assessment (refer to MCA for further explanations).

### Metabolites

A

Metabolites M-01, M-02 and M-03 are relevand for the aquate risk assessment. No metabolite is relevant for sediment risk assessment.

Some studies were performed with metabolites M-01 and M-02, however, M-03 cannot be tested due to its very fast degradation in water and consequently also in the test medium. When data are available, they are used in the metabolite risk assessment. The EFSA AGD (2013) stepwise approach is used for all metabolites when no data are available.

The decision scheme is followed step by step.

- Step 1: None of the studies with the active substance is adequate for assessing the potential effect of the metabolites: Step 3.
- Step 3: Is it clear that the tox ophore has been lost from the molecule?

M-01 and M-02 do bot show any pringicinal activity (see MCA 3.6 report by Management and M-02. On this basis, it is assumed that the toxophore has been lost. However, data on the most sensitive organism group are available so the comparison with parent of step 4 is performed anyway.

Regarding 1-03, the toxophore is considered as present because it molecular structure is very similar to the parent.  $\Rightarrow$  Step 4.

• Step 4: Identify the species or takonomic group determining the lowest tier 1 RAC_{sw,ac} for the active substance 1s the genter metabolic  $L(E)C_{50} > 0$  times the a.s.  $L(E)C_{50}$  (on a molar basis)?

Studies on *Navecula* are available for fluopoolide and its metabolites M-01 and M-02, they are used for the comparison (see table below)

Substance name N A & V	Fluopicolide	<b>M-01</b>	M-02
Endpoint (mg/L)	0.121	92	74
Molecular Worght (g/mol)	383.59	190	225.6
Molecular Weight (g/mol) $\sqrt{2}$ $\sqrt{2}$ Parent endpoint recalculated on a molecularis (mg/L) $10 \frac{M_{men}}{LC} \frac{1}{2}$			
	NA	0.60	0.71

The *Navicula* endpoints for both M-01 and M-02 are much greater than 10 times the parent endpoint recalculated on a molar basis  $\Rightarrow$  Step 6



This comparison cannot be performed for metabolite M-03. It is proposed, as a screening step, to use parent endpoints and an additional safety factor of 10, i.e. assuming that M-03 is 10 times more toxic than the parent.

Step 6: Assume that the acute and chronic toxicity of the metabolite is equal to the toxicity of • the a.s. for all first-tier taxonomic groups.

This approach will be followed for all missing endpoints for M-01 and M-02.

Summary of the metado		y s
Endpoints (mg/L)	M-01 M-02 M-02 M-03	
Acute fish	$LC_{50} = 240$ $C_{50} = 102$ $LC_{50} = 0.036^{**}$	Û ^Y
Acute invertebrates	$EC_{50} = 180 \ \bigcirc \ \bigcup \ \bigcup$	L,°
Algae	$E_rC_{50} = 92$ $E_rC_{50} = 74$ $E_rC_{50} = 0.0121$	Ø ?
Macrophyte	$E_rC_{50} \neq 97.6$ $E_rC_{50} \neq 3.2*$ $E_rC_{60} > 0.32**$	
Chronic fish	$EC_{10} = 0.278 * 0 EC_{10} = 0.278 * 0 EC_{10} = 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 * 0.0278 *$	
Chronic invertebrates	$\sim$ NOEC = 0.019* NOEC = 0.019*	:
* 1 st tier parent endpoint (S	keletonema and may side are not considered as tier species)	_

## Summary of the metabolite endpoints used in rick

1st tier parent endpoint divided by 10

Predicted environmental concentrations used in the risk assessment Predicted environmental concentrations of fluopicolide and its metabolites in surface water were calculated according to FOCUS Steps 1-3 for the use in potatoes, lettice and cucumber.



			Potatoes					
Compound	FOCUS	4 × 100 g/ha	3 × 100 g/ha	2 × 100 g/ha	1 × 100g/h			
Compound	Scenario	PEC _{sw, max} [µg/L]	PEC _{sw, max} [µg/L]	PEC _{sw, max}	PEOw, max			
	Ear	ly application	,	°0'				
	STEP 1	102	76.5	51.0	25.5			
Fluopicolide	STEP 2 North		8.69	6.08	3.00			
	STEP 2 South	20.6	15.8	10.9 0	<b>\$</b> ,58 0			
И-01	STEP 1	4400	33,4 0		11.0 			
(2,6-dichlorobenzamide (BAM))	(	4.34	9.32 🤉 🕺	2.27	1.16			
	STEP 2 South	8.44	6.440 °	4.39 0	2.24			
M-02 (3-chloro-5-(trifluoromethyl)	STEP 1	19.3	4.5 ×	9,66 ×	4.83			
pyridine-2-carboxylic acid)	STEP	0.78	0.610 0	0.44	0.258			
		<b>b</b> 44 >		<b>6.816</b>	0,471			
M-03 2,6-dichloro-N-{[3-chloro-5- 炎		3.22 ² 4		3.22 O	3.22			
(trifluoromethyl)-2-pyridinyl] (hydroxy)methyl} benzamide)	STEP 2 North	0.969	0.647	0:\$86	0.276			
()	STEP 2 South	1.54 V Ó	1.29	0.973	0.552			
Ĵ, O		te application		L'Y				
s a sub-	CARLED 1 V V	100 80		<i>a</i> .	-			
	STEP1√ ~	402 × ×	76.5	\$1.0	25.5			
Fluopicolide	STEP 2 North				25.5 2.19			
Fluopicolide	STEP 2 South		5.865	4.17				
	STEP North	7.57 19:4 5 44.15 5	5.867 7.98 33.67 33.67	4.17	2.19			
	STEP 2 South STEP 2 South STEP 4 STEP 2 North	7.52 19:4 44.15 2.70 5 7 5 7 5 7 5 7 5 7 5 7 5 7 5 7 5 7 5 7 7 7 7 7 7 7 7 7 7 7 7 7	5.865 7.98 x	4.17 <b>5.60</b> 22.0	2.19 <b>2.92</b>			
M-01 K Y K K	STEP 2 South STEP 2 South STEP 4 STEP 2 North	7.57 <b>19:4</b> 44.15 <b>2.70</b> <b>2.70</b> <b>3.9</b>	5.865 7.98 33.0 2.07	4.17 <b>5.60</b> 22.0 1.43	2.19 2.92 11.0			
M-01 (2,6-dichlorobenzamere (BAM)) M-02 (3-chloro-5-(trifluoromethy)	STEP 2 South STEP 2 South STEP 2 South STEP 2 North STEP 2 South STEP 2 South	7.52 <b>19.4</b> 44.15 <b>2.70</b> <b>3.93</b> <b>3.93</b> <b>5</b> <b>3.93</b> <b>5</b> <b>3</b>	5.865 7.98 33.15 2.07 3.01	4.17 <b>5.60</b> 22.0 1.43	2.19 2.92 11.0 - 0.734			
M-01 2,6-dichlorobenzambe (BAM)) M-02 3-chloro-5-(trifluoromethy) byridine-2, carboxylic acid)	STEP 2 South STEP 2 South STEP 2 North STEP 2 North STEP 2 South STEP 1 STEP 1	7.52 <b>19.4</b> <b>3.93</b> 0.516	5.865 7.98 33.15 2.07 3.01 14.5	4.17 <b>5.60</b> 22.0         1.43 <b>2.06</b> 9.66	2.19 2.92 11.0 - 0.734 1.06			
M-01 2,6-dichlorobenzanite (BAM)) M-02 3-chloro-5-(trifluoromethy)	STEP 2 South STEP 2 South STEP 2 North STEP 2 North STEP 2 South STEP 1 STEP 1	7.52 <b>19.4</b> <b>3.93</b> 0.516	5.865 7.98 33.0 2.07 3.01 14.5 0.407	4.17 <b>5.60</b> 22.0         1.43 <b>2.06</b> 9.66         0.299	2.19 2.92 11.0 - 0.734 1.06 4.83 -			
M-01 2,6-dichlorobenzanate (BAM)) M-02 3-chloro-5-(trffluoromethy) byridine-2, carboxylic acid) M-03 2,6-dichloro-N-{{3-chloro-5-	STEP 2 South STEP 2 South	7.52 <b>19.4</b> 44.15 <b>2.70</b> <b>3.93</b> <b>3.93</b> <b>0.516</b>	5.865 7.98 33.0 2.07 3.01 14.5 0.407	4.17 <b>5.60</b> 22.0         1.43 <b>2.06</b> 9.66         0.299 <b>0.410</b>	2.19 <b>2.92</b> 11.0 - 0.734 <b>1.06</b> 4.83 - 0.172			
M-01 2,6-dichlorobenzanate (BAM)) M-02 3-chloro-5-(trifluoromethy) byridine-2, carboxylic acid)	STEP 2 South STEP 2 South	7.52 10.4 2.70 2.70 3.93 0.516 0.516 0.795 5	5.867 <b>*</b> <b>7.98</b> <b>33.0</b> <b>2.07</b> <b>3.01</b> 14.5 0.407 <b>0.563</b> 3.22	4.17 <b>5.60</b> 22.0         1.43 <b>2.06</b> 9.66         0.299 <b>0.410</b> 3.22	2.19 2.92 11.0 - 0.734 1.06 4.83 - 0.172 0.236			

### Table 10.2- 2: Initial max PEC_{sw} values – FOCUS Steps 1 and 2 (potatoes)



		Potatoes					
Compound	FOCUS	4 × 100 g/ha	3 × 100 g/ha	2 × 100 g/ha	1 × 100g/ha		
<b>r</b>	Scenario	PEC _{sed, max} [µg/kg]	PEC _{sed, max} [µg/kg]	PEC sed, max mg/kg]	PEÔ _{ed, max}		
		rly application	,	ч <i>о</i> г А			
	STEP 1	270	203	135	67.5~		
Fluopicolide	STEP 2 North	270 29.7 <b>X</b>	22.9	16.0	8.28		
	STEP 2 South	54.6	41.8	28.7	67.5 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		
	La	te application		16.0 0 28.7 0 28.7 0 28.7 0 28.7 0 28.7 0 28.7 0 20 20 20 20 20 20 20 20 20 20 20 20 20	67.5 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		
	STEP 1	270 °	203 2	195 0	67.5 J		
Fluopicolide	STEP 2 North	19.8	15.3	10.9 🔗 🔬	5.69		
	STEP 2 South	27,2 ~	21.0	14.7	7.63		
Fluopicolide							

### Table 10.2- 3: Initial max PECsed values – FOCUS Steps 1 and 2 (potatoes)



		Lettuce	Lettuce
Compound	FOCUS	2 ×100 g/ha	1 ×100 g/ha
	Scenario	PECsw, max [µg/L]	PECsw, max [μg/L]
	Early	application	
	STEP 1	- _{ČA} –	25.5
Fluopicolide	STEP 2 North	- 🕅 🧕	4.37
	STEP 2 South		8.00 0 9 0
	STEP 1		
M-01 (2,6-dichlorobenzamide (BAM))	STEP 2 North		
	STEP 2 South		3.31 🖓 🔬 🔬
M-02 (3-chloro-5-(trifluoromethyl)	STEP 1		4.89
pyridine-2-carboxylic acid)	STEP & North		9.364 x x x
	STEP 2 South		0.68
M-03 (2,6-dichloro-N-{[3-chloro-5- 🖉	SQEP 1		82 8 3
(trifluoromethyl)-2-pyridinyl	STER North	- 67 4 69	0.414 %
(hydroxy)methyl} benzamide)	SEEP 2 South		0.828
× 4		application 🔊 🗸	Š. Š.
	STEP 1	59.0 y o ky	25,5%
Fluopicolide	SEP 2 North	4.17 2	2.19
	STEP 2 South	5.60 S	2.92
M-01	STEP 1 🐇 🔪	22.0 0 0 0 1.43 0 0	11.0
M-01 (2,6-dichlorobenzamide (BAM))	STEP 2 North	1.43 0 0	0.734
	STEP 2 South		1.06
M-02	STEP 1 0° 🔬	9.66 4 2	4.83
(3-chloro-5-(trifthoromethyl) pyridine-2-carboxylic@rd)	STER 2 North	0 299	0.172
	STEP 1 STEP 2 North STEP 2 South	<b>6.410</b> 3.22	0.236
	STEP &	3.22	3.22
(trifluoromethyl)-2-pyridinyl]	STEP 2 North	Ů 292	0.166
(hydroxy)methyl} (hydroxy)methyl	St EP 2 South	0.438	0.248
pyridine-2-carboxylic.co.rd)			

### Table 10.2-4: Initial max PEC_{sw} values – FOCUS Steps 1 and 2 (lettuce)



		Lettuce	Lettuce
Compound	FOCUS	2 ×100 g/ha	1 ×100 g/ha
	Scenario	PEC _{sed, max} [µg/kg]	μg/kg
	Early app	lication	
	STEP 1		67.5 11.5 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2 21.2
Fluopicolide	STEP 2 North	- ኛ 🧕 🦉	11.5
	STEP 2 South		
	Late appl		
	STEP 1		<b>6</b> 7.5 0 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Fluopicolide	STEP 2 North	410.9 2 6 6	5.69
	STEP South	14 4	7.63
le 10.2- 6: Initial m	ax PEC values FOC		erb ^G ^G ^G ^G

### Table 10.2- 5: Initial max PEC_{sed} values – FOCUS Steps 1 and 2 (lettuce)

Table 10.2- 6:	Initial max PEC, value	n≁ FOC€S S	teps 1 and 2	(cucumber)
	Č [∦]	÷ ,	· ~	`_O` Ci

	<i></i>			
		Early	Cucumber	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Compound	<b>FOCUS</b>	Early Early	Nia	^O [*] Late
	POCUS Scenario	PECsw, max [µg/L]	PKC sw, max	PECsw, max (µg/L)
Fluopicolide		3 × 100 g/ha		<del>0)</del> /
Fluopicolide	STERO	76 5 2 0	Ø6.5 L	76.5
Fluopicolide	STEP 2 North	76.5 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		12.2
ð Å ×	STEP 2 South		<b>598</b> O	10.1
M-01	STEP 1	301 0	33.10	33.1
M-01 (2,6-dichlorobenzami@e (BAM))	SODEP 2 North	2.07 O ^Y W	2.00	4.88
		3.94	3.01	3.94
M-02	STEP 1 0 STEP 2 North	14.5 S S	14.5	14.5
M-02 (3-chloro-5- (trifluoromethyl) pyrdine (		0.407	0.407	0.874
2-carbox (lic acid)	STEP 2 South	0@18	0.563	0.718
M-03		3 22	3.22	3.22
(2,6-dichloro-N-{[3 chloro-5-(trifluoromethy]) 2-pyridiny]	STEP 2 North	0.388	0.388	0.970
2-pyridinyl]		0.776	0.582	0.776
benzamide	©TEP 2 South	\$ 		
2-pyridinyl] (hydroxy)methyl} benzamide				L



					Cucumber		
Compound	FOCUS		Early	Mid		Late	
	Scenario		CCsed, max µg/kg]	PEC _{sed,} [µg/kg		PECsecomax [µg/kg]	
		3 × 100 g	g/ha	.4	0		
	STEP 1	203	Ĉa	203	203		
Fluopicolide	STEP 2 North	15.3	- T	15.3	\$2.3	S N	
	STEP 2 South	26.7	ŷ	21.0	26.7	Q Q	
Fable 10.2- 8: Initial ma	x PEC _{sw} values	- KOCUS	Steps 3 (pot	atoes)	tatoes		
Compound	FOC		4 ×166, g/har	3→100 ( ○ ⁹ g/ha, ) [×]	2 ×100 2 ×100	1 ×100 g/ha	
	20 × 0		PEC sw,max	PECsy,max	PECswalad [µg/I]	PECsw,max	
		Carly appl	ation 5	<u> </u>			
			0.524	0.5240	0.524 0	0.524	
. Q	O DADpo	ond O	3.70	2.66	1.72	0.823	
×	D4 str	ream 🖉	3.47	2.50 💞	1.62	0.777	
Ţ.	D6 di	tch S	1.5) C	1.12	0.742	0.564	
Fluopicolide	by Dordi	tch 2nd	Q.36	4,93	2.98	1.33	
	× & R1 pc	nd s'	0.260	D.217	0.152	0.111	
	R1 str	ream	<b>2,8</b> 6 Õ	~	1.42	1.42	
	Rez str	ream	1.82	1982	1.32	0.574	
		eam, O	4.00	2.58	2.58	0.864	
Fluopicolide	D3 di	tch 🖉	0.021	0.014	0.008	0.003	
	5 . O D4 pg	wid Sz	0.206	0.153	0.101	0.049	
	D4şti	ream	0,365	0.272	0.181	0.091	
			AL D			0.051	
M-03	59 <b>196</b> di	tch? v	0.191	0.144	0.098	0.031	
M-03 (2,6-dicharo-N-{[3-chloro-5- (trifluoromethyl)-2-pythinyl]	D6 di	tch ² tch 2nd	0.191 0.489	0.144 0.364	0.098 0.242	0.121	
M-03 (2,6-dichtoro-N-{[3-chloro-5- (trifluoromethyl)-2-pycdinyl] (hydtoxy)methyl} benzamide)	D6 di B0 pc	tch? v					
M-03 (2,6-dichtero-N-{[3-chloro-5- (trifluoromethyl)-2-pyterinyl] (hydroxy)methyl} benzamide)	D6 di D6 di B0 pc	tch 2nd whet S	0.489	0.364	0.242	0.121	
M-03 (2,6-dichtero-N-{[3-chloro-5- (trifluoromethyl)-2-pythinyl] (hydtoxy)methyl} benzamide)	D6 df D6 df B0 pc R1 st R2 st	tch 2nd ich 2nd ind cam cam	0.489 0.003	0.364 0.003	0.242 0.002	0.121 <0.001	



		Potatoes				
Compound	FOCUS Scenario	4 ×100 g/ha	3 ×100 g/ha	2 ×100 g/ha	) 1 ×100 g/ha	
	Scenario	PEC _{sw,max} [µg/L]	PEC _{sw,max} [µg/L]	PECsw,n Sug/L]		
	Late applic	cation	L	de la companya de la		
	D3 ditch	0.524	0.524	0.524		
	D4 pond	3.6	2.59	1.71 💉	0.754 5	
	D4 stream	3.54	2.49	1.63 @	£701 ×	
	D6 ditch	1.96	<b>1</b> 85	0.700	⁽¹ 0.555 ⁰	
Fluopicolide	D6 ditch 2pd	14.4 🔊	14.1	₽Ø0 (Č	3.00	
	R1 pond	9.125 S	0.072	0.05	° 0.026 x	
	R1 stream 🔊	2.770	ðr.54 💍	1.18	~ 0.4 <b>69</b>	
	R2 stream >	2.01 2	1.32	¥.16	0.\$89	
k	🕺 stream	4.05	3967 2	2.98	J.50 0	
Č,	D3 dựch	0.001	0.007	<b>6</b> 005 £	0,002	
Q″	Da pond	0.150	0,198	0.075	0.039	
	D4 stream	0.266	<b>9</b> /191	0.033	0.069	
NI-03	D6 Hitch	0.226	0.161 ~	0.100	0.051	
2,6-dichloro-N-{[3-chloro+5]	D6 ditch 2nd	0.360	0.326	0.243	0.114	
hydroxy)methyl} benzamide)	R1 pond	0,001 0	<0.001	<b>20</b> .001	< 0.001	
hydroxy)methyl} benzanide)	R Stream	0.085 Ø	0,054	0.041	0.019	
	R2 stream	0.092	9.064	0.043	0.020	
	R3 stream	Q. 918 Ö	0.109	0.083	0.046	
2,6-dichloro-N-{[3-chloross trifluoromethyl)-2-pyridinyl] hydroxy)methyl} benzamide)		O' (I) .	Ċ.			
	alues-FOCOS	Steps 3 (lette	≫ lce)			
				Lett	uce	
	FOCUS Scenario		2 ×100		1 ×100 g/ha	
	FUCHS Scenario	) <i>6</i> ″	PEC _{sw} , 1	J	PECsw, max	
× · · · · · · · · · · · · · · · · · · ·	,∩° ©°	() ²				
	<u> </u>	ÿ	[µg/L]		[µg/L]	
	Early appli	cation	[µg/L]		[µg/L]	
	<b>Early appli</b>	cation	[μg/L]		0.634	
	<b>Early appli</b> D3 ditch 7 D3 ditch 9nd	cation	[μg/L] - -			
	Early appli D3 ditch D3 ditch 2nd D4 pond	cation	[μg/L] - - - -		0.634	
	Barly appli D3 Ottch D3 Ottch 2nd D4 pond D4 pond D9 stream	<u>cation</u>	[μg/L] - - - - -		0.634 0.635	
Fluopicotide	Early appli D3 ditch D3 ditch 2nd D4 pord D9 stream D6 ditch	<u>cation</u>	[μg/L] - - - - - - -		0.634 0.635 0.714	
Fluopicolide	Early appli D3 ditch D3 ditch 2nd D4 pond D4 pond D6 ditch R1 pond	<u>cation</u>	[μg/L] - - - - - - - - -		0.634 0.635 0.714 0.675	
Fluopicoude	Early appli D3 ditch D3 ditch 2nd D4 pond D4 pond D6 ditch R1 pond R1 pond 2nd	<u>cation</u>	[μg/L] - - - - - - - - - -		0.634 0.635 0.714 0.675 1.67	
Compound     Initial mace EC	Karly appli         D3 ditch         D3 ditch         D3 ditch         D4 pond         D9 stream         D6 ditch         R1 pond         R1 pond 2nd         R1 stream	<u>cation</u>	[μg/L] - - - - - - - - - - - -		0.634 0.635 0.714 0.675 1.67 0.094	



		Let	tuce
Compound	FOCUS Scenario	2 ×100 g/ha	1 ×100 g/ha _ 。
Compound		PEC _{sw, max} [µg/L]	PECsw, max [µg/L]
	R2 stream	~	0.553
	R2 stream 2nd	- "	0.562
	R3 stream	-	
	R3 stream 2nd		2.00
	R4 stream		2.20 5
	R4 stream 2nd		<b>\$</b> 40
	D3 ditch		0.003
	D3 ditch nd 2 2 4 D4 pend 2 2 2	- ~ ~ ~ ~	0.003
	D4 pond . O Q Q	j S	0.046
	D4 stream		0.084
ſ	By6 ditter of the the		Ø130
Q	R1 pond		<0.004
M-03 (2,6-dichloro-N-{[3-chloro-5-x] (trifluoromethyl)-2-pyridiny]] (hydroxy)methyl} benzamide)	Ki pond Did S	- 0	Ø.002
(2,6-dichloro-N-{[3-chloro-S- $\sqrt{2}$ (trifluoromethyl)-2-pyridinyl]	R1 stream	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>	0.018
(hydroxy)methyl} benzamide)	Rt stream and		0.031
	R2 stream		0.018
	R2 stream 20d		0.056
	RY stream 2 5	- ~~	0.033
	R3 stream 2nd	- ``` Ø	0.062
	RA stream y o	<i>4</i> -	0.015
	AR4 stream 2nd S S	-	0.040
	Late application		
	D3 ditch	0.634	0.634
	D3 dich 2nd	0.631	0.631
A & S	Depond &	1.53	0.646
	D4 stueam	1.46	0.599
	Dewitch	13.1	4.67
	R1 pond	0.437	0.288
Fluopicolide of A C	R1 pond 2nd	0.222	0.084
	RØstream	2.39	1.11
	R1 stream 2nd	1.92	0.685
	R2 stream	0.963	0.562
	R2 stream 2nd	1.09	0.596
$Fluopicolide \int_{C}^{C} $	R3 stream	2.18	0.862
	R3 stream 2nd	2.65	1.50



		Lettuce		
Compound	FOCUS Scenario	2 ×100 g/ha	1 ×100 g/ha	
		PEC _{sw, max} [µg/L]	PECsw, max [µg/L]	
	R4 stream	3.17	2.01	
	R4 stream 2nd	3.29	1.90	
	D3 ditch	0.005	<u>0.982</u>	
	D3 ditch 2nd	02005	0.002	
	D4 pond	0.061	0.061 5	
	D4 stream	0.298	0,055	
	D6 ditch	9.184		
	R1 pondo 2 5 5	0.000	0.001	
M-03	R1 poind 2nd @ Q	0.003	0.001	
(2,6-dichloro-N-{[3-chloro-5- (trifluoromethyl)-2-pyridinyl]		0.047	0.015	
(hydroxy)methyl} benzamide)	RI stream 2nd	0.03	0015	
Q,	R2 stream	9.052 Č Š	0.022	
	K2 stream 2nd S	0.029	0.015	
		0.954	0.030	
	R2 stream and	0.064	0.064	
	R4 stream &	0,020	0.016	
	R4 stream 20d	<b>9</b> .032 ×	0.023	

Table 10.2- 10 Initial max PEC, wvalues - FOGUS Steps 3 (outumber)

				Cucumber	
Compound		FOCUS Sconario	Pt Carly	Mid	Late
•			$[\mu g 0 E]$	PECsw, max [µg/L]	PEC _{sw, max} [µg/L]
			0 g/ha		
J.		DG ditch 🤉	1.50	4.75	10.2
		R2 stream	2.10	1.14	2.39
Fluopiconde	S A P	R3 stream	5.37	3.06	6.01
	N OF ET	R4 stream	8.33	7.85	9.06
M-03	A A A A A A A A A A A A A A A A A A A	D6 chich	0.169	0.324	0.367
M-03 (2,6-dichloro N-{[]	34 hlorof	Re stream	0.047	0.124	0.045
(trifluoror@thyl)	pyridinyl]	R3 stream	0.067	0.093	0.047
(hydroxy)methyl	benzamide	R4 stream	0.069	0.241	0.099
	Schloro pyridinyl] benzamide) S				



PEC _{sw} (µg/L)	Scenario				Early aj	pplication				<i>L</i>
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 m	≫ 10 m	20 m 6	> >
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	10\m	15 m 💍	20 ga	Ŝ
None	D3 Ditch	0.524	0.172	0.091	0.06	0.047	0.091	0.062	<b>%</b> .047	
50 %		0.262	0.086	0.046	0.031	0.024	0.046	0,031	S 0.024	40 [×]
75 %		0.131	0.043	0.023	<b>4</b> Ø.016	0.062	0,023	O _{0.016}	00912	Ċ,
90 %		0.052	0.017	0.009	[©] 0.006	~Q_006	©"0.009°♀	0,000	¢0.006 ()	ĺ
None	D4 Pond	3.70	3.70	3.70	3,70	3.70	3,70	<b>3</b> .70 %	3.70	
50 %		3.70	3.70	3.69	J 3.69	3.69	<b>3</b> .69 ⁶	9 ⁷ 3.69	\$69	o
75 %		3.69	3.69	€3.69 °C	3:69	3.69	3.69	3.69	\$ 3.69 V	
90 %		3.69	3.69	3:69	<u></u> B.69	3.69	3.09	~~ <del>3</del> .69 ~	3 69	
None	D4 Stream	3.47	3.45%	\$3.47	≥ 3.4 <del>7</del> €	377	3.47 S	3.40 [°]	3.47	
50 %		3.47	Q.47	^{3.47}	3.47	3.47	3.40	30Å7 .,	[≪] 3.47	
75 %		3.47	3.475	3?@7	<b>3</b> .47	3.45	2047 a	03.47	3.47	
90 %		3.47	3.47	~\$3.47	3.47	<i>3</i> .4 ⁷	© 3.47	3.49	3.47	
None	D6 Ditch	<u>ุ</u> 1651	Õ.51	₹ 1.5 Ø	1.51	1.51°S		£.51	1.51	
50 %		1.51	1.51	LISI a	©1.51 ô	<i>I</i> &51	¥.51	\$ 1.51	1.51	
75 %	S.	× 1.51	<u></u> #.\$1	J.51	1.5]	Ø.51	× 1.51	1.51	1.51	
90 %		K\$1 .	Ó¥.51,S	1.51	<u>~</u> .51	© 1.51	151	1.51	1.51	
None	D6 Durch	7.36 🖇	7,36	~₹,36	⁷ .36		<b>A.36</b>	7.36	7.36	
50 %	and	r 7.30	<u>9</u> 36	7.36	7 <b>\$</b> 6	₹.36 Q	, 7.36	7.36	7.36	
75 %	, , , , , ,	7.36	9 7.36 A	738	Ø.36	, 7.36	7.36	7.36	7.36	
90 %	×″	[©] 7.36	7.\$\$	.36 Ć	¥ 7.36	7.36	7.36	7.36	7.36	
None	R1 Pond	0.260	Q.258 (	0.251×	042,48	<u>\$0</u> .246	0.113	0.109	0.059	
50 %		<u>9</u> .248	2°0.246	0,243	0.241	0.240	0.104	0.103	0.054	
75 %		\$\$0.24£	0.CA1	J.239	^{\$*} 0.23	0.238	0.100	0.099	0.051	
90 %	~Q U	0,98	~9.237 _Q	0.233	<b>3</b> 6	0.236	0.098	0.097	0.049	
None	Rt1 Stream	<u>2</u> .86 å	2.865	2,86	L 2.86	2.86	1.30	1.30	0.682	
50 % 🛇		2.86 🖤	~2,86	£ ² .86Q	2.86	2.86	1.30	1.30	0.682	
78	&″	286	~2.86 Q	2:30	2.86	2.86	1.30	1.30	0.682	
90 %		2.86	2.86	\$.86	2.86	2.86	1.30	1.30	0.682	
None	R2 Stream	, 1.2	×U.82	1.82	1.82	1.82	0.812	0.812	0.422	
50 %		£82 x	<i>پ 1.82</i>	1.82	1.82	1.82	0.812	0.812	0.422	
75 %		1.820	1.82	1.82	1.82	1.82	0.812	0.812	0.422	
90 %		1:82	1.82	1.82	1.82	1.82	0.812	0.812	0.422	
None	R3 Stream	Å.00	4.00	4.00	4.00	4.00	1.82	1.82	0.957	
50 %	) ^v	4.00	4.00	4.00	4.00	4.00	1.82	1.82	0.957	
75 %		4.00	4.00	4.00	4.00	4.00	1.82	1.82	0.957	
90 %		4.00	4.00	4.00	4.00	4.00	1.82	1.82	0.957	

### Table 10.2- 11: Initial max PEC_{sw} values – FOCUS Steps 4 in potatoes (4 × 100 g a.s./ha)



PEC _{sw} (µg/L)	Scenario	Late application								
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 m	10 m	20 m	
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	107		[~] 20 m [~]	
None	D3 Ditch	0.524	0.172	0.091	0.062	0.047	0.091	0.06	<u>0.0</u> 47	
50 %		0.262	0.086	0.046	<b>Q93</b> 1	0.024	♥ 0.046	0.031	<b>%</b> .024	
75 %		0.131	0.043	0.023	0.016	0.0	0.023	¢.016	0.012	
90 %		0.052	0.017	0.009	0.006	QQ005	0.009 ⁰	0.006	<b>CO</b> 05	
None	D4 Pond	3.65	3.65	3.55	3.64	⇒ 3.64 Ø	3.65	\$064	© 3.64 Ø	
50 %		3.64	3.64	\$3.64	°3.64	3,64	3.64	<b>3.64</b>	3.64	
75 %		3.64	3.64	^O 3.64	3.64	<b>B</b> .64 ^	[©] 3.64 °	3.64	A,64	
90 %		3.64	3.64	3.63	<u>₹.63</u> ~	[™] 3.6 <u>3</u>	3.55	3.63 <i>4</i>	3.63 [°]	
None	D4 Stream	3.54	354	م مجانعة 1.54 (	3.54	364	<b>3</b> .54	3.54	3494	
50 %		3.54	€ ³ .54 %	3.54	3.\$4	B.54	3.54	364	<u>کی</u> 3.54	
75 %		3.54 🖉	3.54	3.54	3.54	3.5	394	3.54°	J 3.54	
90 %		3.5¢	<b>35</b> 4	03.54	3.50	334	03.54 ×	3.54	3.54	
None	D6 Ditch	1)96 U	1.96	1.96	1.96	<i>€</i> 1.96	1.96	1.96	1.96	
50 %	۰.	© 1.96 0	1.90	£96	1.96	1.96	L96 ;	\$1.96	1.96	
75 %		1.94	1.96	₹ ³ 1.96 Û	1.6	<u></u> (1.96	×1.96	1.96	1.96	
90 %	-S	Q96 _	× 1.96	1.00	<u>~1</u> .96	01.96	1,96	1.96	1.96	
None	D6 Ditch	§ 14.4	12,4	14.4	€ [™] 14.4€	14.4	\$4.4	14.4	14.4	
50 %	2 nd	14.4	& ]4.4 <i>°</i>	∀ 14.4C	14.4	¥.4 &	\$ 14.4	14.4	14.4	
75 %	ð S	<i>¶</i> 4.4	0' _{14.} 4%	14,4	94.4 č	14.4	14.4	14.4	14.4	
90 % 🎾	·0 */	14.4 ⁹	14.4	A.4	0 [°] 14.¢	<i>la</i> 4	14.4	14.4	14.4	
None	R1 Pond	0325	Ø.123	0.118	0,175	0.114	0.055	0.053	0.030	
50 %		0.115	₽ 0.Į <b>1</b>	Q:112	& 0.110 Å	[♥] 0.110	0.049	0.048	0.026	
75 %	6 A	0.1	Ø.J10	0.109	0.108	0.107	0.047	0.046	0.024	
90 %	\$°, 6°	Q. 207 .	C0.107	0.16	07 <b>7</b> 06	0.106	0.045	0.045	0.023	
None	R1 Stream ?	Q2.77	2.75	<b>2</b> 77	2.77	2.77	1.24	1.24	0.643	
50 %	) à	2.55	Q.77 _	₹2.7 <u>7</u> ¢	2.77	2.77	1.24	1.24	0.643	
75 %		2.77 ~	¥ 2.77	2:0	2.77	2.77	1.24	1.24	0.643	
AQ0 %		\$ ⁹ 2.7¶	2.Q	<b>\$</b> .77	2.77	2.77	1.24	1.24	0.643	
None	R2 Stream	2.01	Q.01 _	\$ 2.01	2.01	2.01	0.916	0.916	0.480	
50 %	by A	£2.01 ×	2.01	2.01	2.01	2.01	0.916	0.916	0.480	
75 % 🖉		€ 2.0£	2:91	2.01	2.01	2.01	0.916	0.916	0.480	
90.20		2001	2.01	2.01	2.01	2.01	0.916	0.916	0.480	
None	R3 Steam	×4.05	4.05	4.05	4.05	4.05	1.85	1.85	0.968	
£30 % S		4.05	4.05	4.05	4.05	4.05	1.85	1.85	0.968	
758		4.05	4.05	4.05	4.05	4.05	1.85	1.85	0.968	
90 %		4.05	4.05	4.05	4.05	4.05	1.85	1.85	0.968	

* Maximum values coming from multiple applications are marked in italics



PEC _{sw} (µg/L)	Scenario				Early aj	oplication			, Line Starte	
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 0	10 m 🦼	20 m	0
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	10 m	15 8	20 [°] m	êj Î
None	D3 Ditch	0.524	0.172	0.091	0,062	0.047	0.091	0.062 ^	y 0.04	
50 %		0.262	0.086	0.046	0.031	0.02	0.046		0,024	Ó
75 %		0.131	0.043	0.023	© 0.016	6 <b>9</b> 12	。0.023	0.016	©0.012 ©	ľ
90 %		0.052	0.017	0.000	0.006	0.005	0.009	.006 č	0.005	
None	D4 Pond	2.66	2.66	2.66	©2.66	2:66	2.66 C	2.66	266	
50 %		2.66	2.66		2.66	<b>3</b> .66	⁹ 2.660 [°]	2,66	<i>⊉ 2.66</i> ∘	_
75 %		2.66	2.66		~2,06	2.66	<b>3</b> 866	2.66	2.00	
90 %		2.66	2.66	2,86	2.66 Å	266	<i>ڳ</i> 2.66 ج	2.60	<b>3</b> .66	
None	D4 Stream	2.50	<b>5</b> 50	2.50 Q	2:50	2.50 C	2.50	Q.50	2.50	
50 %		2.50	Q ⁴ 2.50	2.50	2.50	2.50°	Ø.50	S 2.50 (	2.50	
75 %		2.50	2.30	Ø:50	§ 2.50	530	<u>)</u> 2.500	2.50	2.50	
90 %		2.50	2.50	2.50	2.50	2.50	2,50	Q.50	2.50	
None	D6 Ditch	J.12	0 [°] 1.125°		<i>I.12</i>	1.10	¥.12	₽ 1.12	1.12	
50 %	~	1.12	1.12	A.12	× 1.15	<u> </u>	J 1.12	1.12	1.12	
75 %	Ĵ,	1.12	¥1.12	1.12	1.12	°″1.12℃	ŀ.M2	1.12	1.12	
90 %	J.	<i>√↓.12</i> , (	Ŋ 1.12Ş [×]	1.12	€ ^{1.12}		© 1.12	1.12	1.12	
None	D6Ditch	<u>4.93</u> √	4.93	~4.93 J	4.93	¥.93	4.93	4.93	4.93	
50 %	^{2nd}	4.93	Q4.93 &	4.95	<i>993</i>	4.92 	4.93	4.93	4.93	
75 %		4.93	4.93	<b>3</b> 93	© 4.93	4.93	4.93	4.93	4.93	
90 % S		4.95	4293	4.93	4.23	<u>4.93</u>	4.93	4.93	4.93	
None	R1 Pond	0.217	\$40.213 0	0.203	60,199 ž	⁹ 0.197	0.096	0.091	0.052	
50 %	Ŵ.	<u>4</u> 0.199©	0.498	_09195	0.195	0.192	0.084	0.081	0.044	
75 %		0.1993	0193	⁹ 0.196 ⁹	01,00	0.190	0.079	0.078	0.040	ŀ
90 %	The D 1 Ctore	~0190 ^	90.196 268	0.439	9.189	0.188	0.077	0.077	0.039	
None	R1 Stream رُ	2.86	2000	~2.86 ×	2.86	2.86	1.30	1.30	0.682	
50 %		2,86	~2.86 Ľ 2.80	2.8Q	2.86	2.86	1.30	1.30	0.682	
75%		2.80 ×	¥.	~\$\$6	2.86	2.86	1.30	1.30	0.682	
90 %	D [°] Ctroop	2.86	2086	√y2.86	2.86	2.86	1.30	1.30	0.682	
None	K Stream,		ي 1.82 آ	[♥] 1.82	1.82	1.82	0.812	0.812	0.422	
50 %	Ĩ,	ĎĨ.82 ≪.	1.82	1.82	1.82	1.82	0.812	0.812	0.422	
75 %	8 A	1.80	1.82	1.82	1.82	1.82	0.812	0.812	0.422	
90.0%	DD2 Star	<u>_</u> 4_82 2.58	1.82	1.82	1.82	1.82	0.812	0.812	0.422	-
A one	R3 Stream		2.58	2.58	2.58	2.58	1.17	1.17	0.612	
50 % ^{©*} 75 %		2.58 2.58	2.58 2.58	2.58 2.58	2.58 2.58	2.58 2.58	1.17 1.17	1.17	0.612 0.612	
								1.17		
90 %		2.58	2.58	2.58	2.58	2.58	1.17	1.17	0.612	]

### Table 10.2- 12: Initial max PEC_{sw} values – FOCUS Steps 4 in potatoes (3 × 100 g a.s./ha)



PECsw (µg/L)	Scenario	Late application								
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 m	10 m	20 m	<i>S</i>
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	1⁄0 m	15 m	20 m	Âa
None	D3 Ditch	0.525	0.172	0.091	0.062	0.047	Ĵ <b>0</b> .091	0,002	<b>\$\$</b> 00047 4	Ş
50 %		0.262	0.086	0.046	<b>0</b> 31	0.024	0.046	0:031	∀0.02¢	
75 %		0.131	0.043	0.023	0.016	0.002	0.023 🛒	0.01	0.012	, O ^Y
90 %		0.052	0.017	0.009	0.006	.005 .005	。0.000	0,006	0.005	,×
None	D4 Pond	2.59	2.59	239'	2.58 🔊	2.58	2:39	Q.58 Q	2.58	
50 %		2.58	2.58	& 2.58 Q	° 2.5&	258	£ 2.58	∑` 2.58y	<b>\$.</b> \$8	
75 %	-	2.58	2.58	2.58	2058	2.58	2.58	<b>2</b> ,58	2.58 °	
90 %		2.58	2.58	2,58	~2.58	2.58	358	2.58 🚭	2.5	
None	D4 Stream	2.49	279	~2.49 @	2,49	\$49	×2.49	2. <b>49</b>	£.49	
50 %		2.49	<u>6</u> 2.49 %	2,49	\$\$49	2.49 S	2.49	Q.49	2.49	
75 %	-	2.49	2.49	2.49	2.49	2.69	Q.49	2.49 ⁴	2.49	
90 %		2.40	<i>ي 20</i> ,49	𝔅 2.49 ♀	2.00	A.49	0° 2.490°	2,49	2.49	
None	D6 Ditch	×2,35	1.35	1.35	1.35	[©] 1.35 [©]	1,35	<i><b>P</b>.35</i>	1.35	
50 %		\$ 1.35 °	1,33	¥.35	1.35	<u>I</u> .S.S	J.35 🔬	2 1.35	1.35	
75 %		1.35	<i>⊾</i> 1.35	^{\$\$`} 1.350 [°]	ାର୍ଟ୍ର	× 1.35 °	1.35	1.35	1.35	
90 %	<u>Ś</u>	Ø.35	[©] [*] 1.35	1.35	£7.35 (	● 1.35	k.35	1.35	1.35	
None	D6Ditch	\$ 14.19	A	Ĩ4.1 ~Č	° 14.₽	£4.1	©14.1	14.1	14.1	
50 %	^{2nd}	141	& 14.1 [~]	14.4	<i>1¥.1</i>	€ ¹ 4.1√	14.1	14.1	14.1	
75 %	ð Í	94.1 ⁽	° 14.₩	£4.1	Q14.1 0	14d	14.1	14.1	14.1	
90 % 🍣	×.	14,1,2	H,I	∂ ⁷ 14.1 [©]	[°] 14d,	1 <del>4</del> .1	14.1	14.1	14.1	
None	R1 Pond	<u>6</u> 972	\$0.071 N	0.067	Q.965	0.064	0.033	0.031	0.018	
50 %		£0.065	0.00	<i>.0,062</i>	€ 0.06 <i>1</i> Š	0.061	0.028	0.028	0.015	
75 %	\$ A	0.001		°0.060	0.000	0.059	0.026	0.026	0.014	
90 %	<u>v</u> jõ ^v	Ø. Ø. 59 .	Ç 0.055	Q. 659	<b>\$</b> 059	0.058	0.025	0.025	0.013	
None	R1 Stream	₩ 1.54 ¥	1,54	ð.54 (	<b>)</b> r 1.54	1.54	0.690	0.690	0.359	ļ
50 %	, Q	1 DA	Ø.54 ×	y" 1.540	1.54	1.54	0.690	0.690	0.359	
75 %		1.54	1.54	<u>194</u>	1.54	1.54	0.690	0.690	0.359	
AQD %		1.54	IQ4	°\$Í.54	1.54	1.54	0.690	0.690	0.359	
None	B2 Stream	K33	@1.33	1.33	1.33	1.33	0.607	0.607	0.318	
50 %	ρ ^γ λ ^γ .	€1.33 ≪	1.33	1.33	1.33	1.33	0.607	0.607	0.318	
75 %		1.33	°¶\$33	1.33	1.33	1.33	0.607	0.607	0.318	
90.20	S A	033	1.33	1.33	1.33	1.33	0.607	0.607	0.318	
None	R3 Stream	[≪] 3.67	3.67	3.67	3.67	3.67	1.67	1.67	0.877	
\$\$0 % ^{\$}	ŝ	<i>3.67</i>	3.67	3.67	3.67	3.67	1.67	1.67	0.877	
75		3.67	3.67	3.67	3.67	3.67	1.67	1.67	0.877	
90 %		3.67	3.67	3.67	3.67	3.67	1.67	1.67	0.877	]

* Maximum values coming from multiple applications are marked in italics



PEC _{sw} (µg/L)	Scenario				Early ap	plication			
Nozzle	Vegetated strip (m)	None	None	None	None	None	to m	10 m@	20 m
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m 🕰	10 m	<b>€</b> §m	\$ 20 mb
None	D3 Ditch	0.524	0.172	0.091	<b>Q</b> 0.062	0.047	چ 0.091	0.062	<b>6</b> 947
50 %		0.262	0.086	0.046	0.031	6.024	0.04	0.031	0.024
75 %		0.131	0.043	0.029	0.016	0.012。	0,023	0.016	0.002
90 %		0.052	0.017	<b>\$</b> 009	0.006	0.005	~@:009 C	0.006	Ø.005
None	D4 Pond	1.72	<i>1.72 «</i>	1.72°°°	1,52	xJ.72	0° 1.700°	° 1,72 s	J 1.72
50 %		1.72	1.72 C	1.72	J.72	× 1.75	10 <b>7</b> 2	£, 1.72Å,	1.71
75 %		1.72	1.77	»"J.71 ~	/ I. <u>ZI</u>	A71	\$1.71	1.25	Q.71
90 %		1.71	ð:71 °,	¥ 1.71		0 ⁴ 1.71	1.70	<i>₩.71</i>	¥ 1.71
None	D4 Stream	1.62	Sv1.62		~J.62	1.6	£.62	Q 1.62	1.62
50 %		1.62	1.62	Ĩ.62	1.63	Q.62	0 1.62 Š	1.62	1.62
75 %		1.62	L.62 @	r 1.6 <b>2</b> ,7	<i>\$</i> 62	€¥ 1.62	4,62	<u>د</u> 1.62	1.62
90 %		J.62	1.65	1.62	[™] 1.62	Į.62	1.62	D [*] 1.62	1.62
None	D6 Ditch @	0.74D	0,242	Ø.742	0.742	~Q742	× 0.742	0.742	0.742
50 %		0,442	0.742	0,702	\$742 y	0.742	0,242	0.742	0.742
75 %		Ø.742 🐇	0.742	Q 42 4	~0.742 ⁰	0 42	<b>X0</b> .742	0.742	0.742
90 %		0.740	0.742	0.742	0, <b>54</b> 2	0.742 _{@/}	0.742	0.742	0.742
None	D6Ditch 2nd	<b>2</b> .98 ç	2.98	2,08	Å.98	2.98	2.98	2.98	2.98
50 %		02.98 C	2.98	67.98	2.98	<b>2</b> ,98	2.98	2.98	2.98
75 % ू 🖉		2,28	A.98 Q	2.98	2,98	÷2.98	2.98	2.98	2.98
90 🔊	Ď	2.98	S 2.98 💊	2,98	2.98	2.98	2.98	2.98	2.98
None	R1 Pond	0.152	0.650	J.146&	0.1 <b>4</b> 4	0.143	0.066	0.064	0.035
50 %		0.244	×0.143	0.14P	<b>6</b> 140	0.139	0.061	0.060	0.031
75 %		0.140 (	0.139	. Ē ³ 8	<del>o</del> 0.138	0.138	0.058	0.058	0.030
90 %	¢°°	0.138	037	60.137	0.137	0.137	0.057	0.056	0.029
None	R1 Stream	1,342	J1.42	1.40	1.42	1.42	0.648	0.648	0.339
50 %		_ 1.42 ~	1.40	<u></u>	1.42	1.42	0.648	0.648	0.339
A5%		1.42	42 ~	S 1.42	1.42	1.42	0.648	0.648	0.339
90 %		1,42	© 1.42 🗸	1.42	1.42	1.42	0.648	0.648	0.339
None	R2 Stream	£ 1.32	1.32	1.32	1.32	1.32	0.587	0.587	0.305
50 %	, s s	<u> </u>	~Q.32	1.32	1.32	1.32	0.587	0.587	0.305
75 2		1. <b>3.2</b> Ø.32	1.32	1.32	1.32	1.32	0.587	0.587	0.305
90%		© 1.32	1.32	1.32	1.32	1.32	0.587	0.587	0.305
&None &	R3 Streams	2.58	2.58	2.58	2.58	2.58	1.17	1.17	0.612
50 8 2	1	2.58	2.58	2.58	2.58	2.58	1.17	1.17	0.612
75 %	1	2.58	2.58	2.58	2.58	2.58	1.17	1.17	0.612
90 %	1	2.58	2.58	2.58	2.58	2.58	1.17	1.17	0.612

### Table 10.2- 13: Initial max PEC_{sw} values – FOCUS Steps 4 in potatoes (2 × 100 g a.s./ha)



PEC _{sw} (µg/L)	Scenario				Late ap	plication			<i>a</i> ,°
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 m	10 m	29 m
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	<i>l∕</i> ĝ∳m	15 m	20 19
None	D3 Ditch	0.525	0.172	0.091	0.062	0.047	<b>5</b> 0.091	0,002	<b>0</b> .047
50 %		0.263	0.086	0.046	<b>0</b> 931	0.024	0.046	ð.031 ^	0.02
75 %		0.131	0.043	0.023	ð.016	0.692	0.023 🔬	0.010	0012
90 %		0.053	0.017	0.002	0.006	Ø.005	。 0.000	0.006	©0.005 ©
None	D4 Pond	1.71	1.71	<i>l</i> ∭ [™]	1.71 🕿	1.700	1.9 <b>1</b>	01.71 Ø	1.70
50 %		1.71	1.71	& 1.70 g	° 1.70	K.70	√¶.70 Ç	1.7%	<b>4</b> )70
75 %		1.70	1.70	0 1.7Q	100	A.70 S	1.700	Ay70	∠, 1.70 <u>,</u> °
90 %		1.70	1.70	1.70	N.70	× 1.70	£\$70	1.70 &	1 <b>29</b>
None	D4 Stream	1.63	163	~√1.63 @	1,63	663	¢ً∕1.63 ¢	1,63	¥.63
50 %		1.63	€ [¶] .63 &	1,6\$	A63	~1.63 °C	1.65	Q.63	1.63
75 %		1.63	1.63	1.63	1.63	1.63	Q.63	) 1.63 ()	1.63
90 %		1.68	<b>₹</b> \$3	𝑘1.63 🖓	1.63	ð!:63	0° 1.630°	4.63	1.63
None	D6 Ditch	0¢796	0.796	0.796	0.796	0.79 <i>6</i> Q	0,796	Ø.796	0.796
50 %		<i>©</i> 0.796	0.798	Ø196	0.796	0,796	J.796	0.796	0.796
75 %		× 0.79	0.796	^{\$0.7960}	0.796	<u>د</u> 0.796 [×]	0.79	0.796	0.796
90 %	Ş	<i>9</i> 8796	Ç0.796,	0.796	<u>40.</u> 796	0.796	0.796	0.796	0.796
None	D6 Ditch	\$y 7.70 \$	Z DO	7.70	7.70	7.70	© 7.70	7.70	7.70
50 %	2 ^{2nd}	7.70	& <u>7</u> .70 [*]	7.70	7.90	7.70	7.70	7.70	7.70
75 %		× 9.70	°7.76√	7070	7.70	7.70	7.70	7.70	7.70
90 % 🖉	 	7.70	7.70	ð.70 °	7.70	670	7.70	7.70	7.70
None	R1 Pons	039	Ø.058	0.055	Q.953	0.052	0.027	0.026	0.015
50 %		£0.053 ×	/ 0.0 <b>.0</b>	Q.051	< 0.05 1≦ ²	0.050	0.024	0.023	0.013
75 %		0.05	Ø.Ø50	0.050	0.050	0.049	0.022	0.022	0.012
90 %	]e`^	0;949	Ç0.049	0.059	6049	0.049	0.021	0.021	0.011
None	R1 Stream	Q1.15	1.6	Ø.15	➢ 1.15	1.15	0.515	0.515	0.268
50 %	) b	1.13	Q.15	∀ 1. <b>15</b> 0	1.15	1.15	0.515	0.515	0.268
75 %		1.15 ∧	¥ 1.15€	_ <u>1:</u> \$5	1.15	1.15	0.515	0.515	0.268
490 %		\$1.1 <b>5</b> ~	1.Q5	~Q.15	1.15	1.15	0.515	0.515	0.268
None	R2 Stream	140	Q1.16	1.16	1.16	1.16	0.515	0.515	0.268
50 %	× ~ ^	S.16 ×	1.16	1.16	1.16	1.16	0.515	0.515	0.268
75 % 🖉		Ĩ.1¢	<i>1</i> .96	1.16	1.16	1.16	0.515	0.515	0.268
90.00		1,06	1.16	1.16	1.16	1.16	0.515	0.515	0.268
None	R3 Stream	×2.98	2.98	2.98	2.98	2.98	1.36	1.36	0.713
2,50 %		2.98	2.98	2.98	2.98	2.98	1.36	1.36	0.713
75	1	2.98	2.98	2.98	2.98	2.98	1.36	1.36	0.713
90 %	1	2.98	2.98	2.98	2.98	2.98	1.36	1.36	0.713



PEC _{sw} (µg/L)	Scenario				Early ap	plication			, ² ² ² ²	
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 00	10 m	© 20 m	0
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	10 m	15 m	go m	Ê,
None	D3 Ditch	0.524	0.172	0.091	0,062	0.047	0.091	0.062 ^	y 0.04	(Q
50 %		0.262	0.086	0.046	0.031	0.02		0.03	0,024	0×
75 %		0.131	0.043	0.023	© 0.016	Ø <b>0</b> 12	。0.023	0.016	CØ.012	Ĩ
90 %		0.052	0.017	0.000	0.006	0.005	0.009	@ ³ .006 @	0.005	
None	D4 Pond	0.823	0.823	0,822	©0.822	0.821	<b>9</b> .822 C	× 0.822	<b>6 8</b> 21	
50 %		0.822	0.821	9.821 _x	0.82)	\$21	0.820	0(821	0.821 •	
75 %		0.821	0.821	0.820	0,820	0.820	0\$20	0.820	0.820	_
90 %		0.820	0.820	0.820	@Ö.820\$	0820	¢%0.820	0.820	\$820	
None	D4 Stream	0.777	677	\$0.777.Ş	0.707	Ø.777 Č	0.757	Ø177	0.777	
50 %		0.777	Q0.777 ^{"(}	0.777	0.777	0.77	¢777	ॐ0.77 <b>7</b> √	0.777	
75 %		0.777	0.707	05177	\$0.77 <i>7</i>	6777	0.777 ⁰	0,777	0.777	
90 %		0.7	0.777	©0.777 °	0.777	£ 0.777 Q	0,777	Ø.777	0.777	
None	D6 Ditch	06564	0.3675	0.367	0.367	0.367	ð⁄.367	0.367	0.367	_
50 %		0.367	0.367	<b>6</b> .367	0.36	<u>0.367</u> *	⁹ 0.365	0.367	0.367	
75 %		0.36	Q.367	0.360	0.367	©0.367∜	0367	0.367	0.367	
90 %		Ø\$367 . (	≫0.367	0.367	ð.367 °	0.367	©0.367	0.367	0.367	_
None	D6 Dûtch	1.33	4.33	<b>≫</b> 1.33	1.33	¥.33 2	1.33	1.33	1.33	
50 %	Sind	1,9	Q.33 &	1.38	Q33	1.32	1.33	1.33	1.33	
75 %		× ^{1.33}	1.3 <del>3</del> 433	<b>A</b> 33	@1.33	1233	1.33	1.33	1.33	
90 %	×	1.35	4\$33	<u>1.33</u>	1,33	<u>1.33</u>	1.33	1.33	1.33	
None	R1 Pond	0,111	<b>‰0.109∂̂</b>	0,105	<u>¢0</u> .102 🛓	0.101	0.049	0.047	0.027	
50 %		0.102	0.401	<u>0</u> 9099	0.09	0.097	0.043	0.042	0.023	
75 %		[©] 0.09	<u>0</u> 097 (	³ 0.096 ³	0.095	0.095	0.040	0.040	0.021	
90 %	~Q U	AQ995 ^	0.09	0,094	<b>@</b> .094	0.094	0.039	0.038	0.020	
None	R1 Stream	لا 1.42	1012	°~J1.42  ≪	1.42	1.42	0.648	0.648	0.339	
50 % 🛇		¥ 1.42 [™]	~1.42 <i>š</i>	°1,420″	1.42	1.42	0.648	0.648	0.339	_
750	Ŵ	\$.42 ×	1.42	AQ#2	1.42	1.42	0.648	0.648	0.339	
90 %	, Ø`	1.42	<b>2%</b> 42	<i>∛</i> √1.42	1.42	1.42	0.648	0.648	0.339	
None	R2Stream	, 0.574	×0.574	[♥] 0.574	0.574	0.574	0.256	0.256	0.133	
50 %		ð	0.5%	0.574	0.574	0.574	0.256	0.256	0.133	
75 %		0.574 % 0.570	0.574	0.574	0.574	0.574	0.256	0.256	0.133	
90 %		0.4574	0.574	0.574	0.574	0.574	0.256	0.256	0.133	
Kone	R3 Stream	<u>گ</u> 0.864	0.864	0.864	0.864	0.864	0.390	0.390	0.204	
50 % ^C	)″	0.864	0.864	0.864	0.864	0.864	0.390	0.390	0.204	
75 %		0.864	0.864	0.864	0.864	0.864	0.390	0.390	0.204	
90 %		0.864	0.864	0.864	0.864	0.864	0.390	0.390	0.204	

## Table 10.2- 14: Initial max PEC_{sw} values – FOCUS Steps 4 in potatoes (1 × 100 g a.s./ha)



PEC _{sw} (µg/L)	Scenario				Late apj	plication			@L ^o
Nozzle	Vegetated strip (m)	None	None	None	None	None	10 m	10 m	20 m
reduction	No spray buffer (m)	0 m	5 m	10 m	15 m	20 m	100m	15 m 🗳	
None	D3 Ditch	0.524	0.172	0.091	0.062	0.047	€0.091	0.062	@.047 ²
50 %		0.262	0.086	0.046	0.031	0.024	0.046	×94031 ~	0.02
75 %		0.131	0.043	0.023	0.016	0.012	0.023	0.016	0.012
90 %		0.053	0.017	0.009	© ⁷ 0.006	05005	0.009	0.006	c)9.005
None	D4 Pond	0.754	0.753	0.7520	0.751	0.751	0.782	@.751 ©	0.75
50 %		0.751	0.751	0,750	©0.750	0.749	<b>0</b> .750 (	0.750	Q)49
75 %		0.749	0.749	@.749	0.749	\$749	0.74 <b>9</b>	00749	<u> </u>
90 %		0.749	0.748	1	<b>0</b> , 48	0.748	0.0748	0.748	0.748
None	D4 Stream	0.701	0.70	0,701	0.701	0.591	¢_0.701	0.701	<b>9</b> 701
50 %		0.701	0501	0.701	0.701	Ø.701 Č	0.70	Ø701	0.701
75 %		0.701	Ø.701	0.701	0.701	¥ 0.70	¢701	Ŝ°0.70₩	0.701
90 %		0.701	0.701	6701	Ç0.70	05%01	0.7010	0,701	0.701
None	D6 Ditch	0.555	0.393	¢0.393 ^{°C}	0.393	Ø.393 Ø	0.393	Q.393	0.393
50 %		06393	0.393	0.3093	0.393	0.303	°0/393	0.393	0.393
75 %		0.393	0.393	a9.393	0.393	<u>0.393</u> ×	J0.395	0.393	0.393
90 %		0.39	Qi 393	0.393	0,393	00.393	0,393	0.393	0.393
None	D6 Ditch	<b>3</b> ,00 (	§ 3.00	3.00	₹ <u>3.00</u> 3.00	3,00	<i>2</i> ,00	3.00	3.00
50 %	2nd	3.00 4	3.00	3.00		\$.00 Å	3.00	3.00	3.00
75 %	ð f	× 3,00	Q.00 &	3.00	<b>Q0</b> 0	3.00 ×	3.00	3.00	3.00
90 %	<u>, Q</u>	3.00	3.00	3,00	@3.00	3,00	3.00	3.00	3.00
None	R1 Pond	0.026	0.025	0.024	0,028	0.022	0.014	0.012	0.009
50 %		0,023	×0.023	0.022	<u>¢0</u> .022 <u>é</u>	[≫] 0.021	0.010	0.010	0.006
75 %		0.021			0 _{0.02}	0.021	0.010	0.009	0.005
90 %		\$ 0.02D	0021	¥0.025	0,620	0.020	0.009	0.009	0.005
None	RIStream	Q.@69 ^	0.469	0.469	<b>@</b> .469	0.469	0.210	0.210	0.109
50 %	à.	0.469	0.409	∘_0.469 ≪	0.469	0.469	0.210	0.210	0.109
75 % 🖏	ž °r ~(C)	\$ 0.469	~0.469 <i>"</i>	0.469 ⁹	0.469	0.469	0.210	0.210	0.109
90.**	s s s s s s s s s s s s s s s s s s s	Q,469	0.469	0(469	0.469	0.469	0.210	0.210	0.109
None	R2 Stream	0.589	0589	LO.589	0.589	0.589	0.263	0.263	0.137
50 %	de la	0.589	£.589	∛ 0.589	0.589	0.589	0.263	0.263	0.137
75 %		£.589 🔬	0.589	0.589	0.589	0.589	0.263	0.263	0.137
90 %	Ų Į ,	0.586	0.589	0.589	0.589	0.589	0.263	0.263	0.137
None	R OStream	× 1450	1.50	1.50	1.50	1.50	0.686	0.686	0.360
<i>5</i> 0%		ÂI.50	1.50	1.50	1.50	1.50	0.686	0.686	0.360
75 %	»°	1.50	1.50	1.50	1.50	1.50	0.686	0.686	0.360
90 %		1.50	1.50	1.50	1.50	1.50	0.686	0.686	0.360



PECsw (µg/L)	Scenario	Early application	Mid application	Late application
Nozzle	Vegetated strip (m)	None	None	None None
reduction	No spray buffer (m)	0 m	© 0 m	
None	D6 Ditch	1.54	4.79 ×	L B.2 St 4
90 %		1.54	₽75 °°	L 10.2 C
95 %		1.54	~ 4.75 °	V 10.9 ~~
99 %		1.54 4 23	2 4 7 5 L	10.2 ×
None	R2 Stream	2.10	P.14 0	0 2.39 × ~
90 %		<i>3.40 ~</i> ~	1.14 O	2.39
95 %		Q.10 2.10	~~ J.Q4 ~~	J.39 J
99 %		<u>2.10</u> ~ ~	Q _ QI.14 _ Z	2.3%
None	R3 Stream	Q ¹ 5,37 0 0	3.00	S 6.91
90 %		5.37 ° °	Q06 . O	° 46.01
95 %		× × 5.37 ×	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	6.01
99 %	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0° (3.37 (3° (	3.26	6.01
None	R4 Stream	\$ 8.330 S	0 47,85 v	9.06
90 %	<u> </u>	0 30 803 S	7.850 4	9.06
95 %		× × × × ×		9.06
99 %		8.33	\$7.85 W	9.06

Table 10.2-15: Initial max PEC_{sw} values – FOCUS Steps 4 in cucumber (3 × 100 g a.s./ha)

* Maximum values compose from multiple applications are warked in italics

## Risk assessment for aquatic organisms

According to the Aquarc Gundance Document (EFSA PPR Panel Guidance, 2013), the risk to aquatic organisms is evaluated based on the derivation of Regulatory Acceptable Concentrations (RACs) as follows: follows:

A.

The risk is considered acceptable, if the BA  $_{sw, ac} \ge PEC_{sw, max}$ . r, D

Chronic risk assessment:  
RAC
$$_{w, ch} = OOEC$$
 or  $EC_{w}$  10  
RAC $_{swee} = E_r C_{50} / 10$ 

The risk is considered acceptable, if the  $RAC_{sw, ch} \ge PEC_{sw, max}$ 



To summarise, these abbreviations are used in subscript following the term PEC or RAC: ac: acute, ch: chronic, sw: surface water, max: maximum.

## ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Oncorhynchus mykiss

Invertebrate, acute

Dapania magna Fish, acute

M-02

(3-chloro-5-

dichlerobenzenide

ac: acute, ch: chronic, sw: surface water, max: maximum.									
	ESSMENT FOR AQU.								
	Table 10.2- 16:       Acute risk assessment based on FOCUS Step 2 for the application in pool to so as a solution of the second se								
Compound	Species	Endpoint [µg/L]		RECsw,max [µg/L]	$\mathbf{R} \mathbf{A} \mathbf{C} \geq \mathbf{P} \mathbf{E} \mathbf{C}_{sw}$				
	Ea	arly application	, Q	Å Ô					
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC 50 6600		44,558					
	Invertebrate, acute Daphnia magna	EC ₅₀ 100000	> 1000		Yes O Y				
Fluopicolide	Fish, acute	12 0 3 0 · · ·	3.6 O						
	Invertebrate, acate	EC ₅₀ > 1800	28		No.S. L				
M-01 (2,6- dichlorobenzamide	Fish, acute	LC ₅₀ 240000	2400 ⁰	8,44 Ø	Yes y				
(BAM))	Invertebrate, acute	ES 180000	1800 🔬		Yes				
M-02 (3-chloro-5-	Fish, acute ( Oncorhylichus mykiss ()	LC ₅₀ 102000	> 1020	P.44					
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Dàphnia magna 🖉 🔺	BC 50 \$9800*	> 18 /	S.	Yes				
	Fish, acore O & O O O O O O O O O O O O O O O O O	LC 36*	656	Ø I	No				
chloro-5- (trifluoromethyl)-2- pyridinyl (hydroxy)methyl}ber zamide)	Baphrija magna	EC 30 > 180**		1.54	Yes				
		ate application	1						
	Fish acute 🕎 🖉	ate appreation	66		Yes				
FLC + PCDFSC 687.5	Oncorhynchus mykrss Invertebrate, acute Daphnia magna	$EC_{50} > 100000$	> 1000	44.558	Yes				
	Fish acute Oncorhynchus myteiss	PC ₅₀ 360	3.6	10.4	No				
Fluopicolide	havertebrate, asute Daphna magna	$EC_{50} > 1800$	> 18	10.4	Yes				
M-01	Fish, acute QncorhQachus mykiss	LC ₅₀ 240000	2400		Yes				

3.93

0.715

Yes

Yes

1800

 $EC_{50}$ 

180000

 $LC_{50} > 102000 > 1020$ 



				Parisonal	iyurocillorlue SC 087.5
Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$
(trifluoromethyl) pyridine-2-carboxylic acid)	Invertebrate, acute Daphnia magna	$EC_{50} > 1800*$	> 18	\$	Yes
M-03 (2,6-dichloro-N-{[3-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 36**	0.36	8	No A A
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben zamide)	Invertebrate, acute Daphnia magna	EC ₅₀ > 180	> 1.8	0.692	Yes No Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes
<ul> <li>* 1st tier parent endpoin</li> <li>** 1st tier parent endpoint</li> </ul>					
Table 10.2- 17: A	.cute risk assessment base a.s./ha)	ed on FOCUS Ste	p 2 for t	he applicati	on in gotatoes 3 × 100°
		Èridpoint	RAC O	PEQsy,max	
Compound	species S &	μg/L γ	[μg/]	[µg4L]	
	<u> </u>	arly application	Š.	<u>ð</u> <u>ð</u>	N. S.
FLC + PCH SC 687.5	Fish, acute	LC 50 6500		362309	Ses &
	Invertebrate, acute 💭 Daphna magna	ECC > 100000	> 1000~		Y &
Fluopicolide		LC 50 0360 50	3.6	\$ \$\vee\$.8	No
	Invertebrate, Sute 🔨 Dapania magna	EC50 20800 Q	\$ 18 L		Yes
M-01 (2,6-	Fush, acute	LC 240000	2400	© 6.44	Yes
dichlorobenzamide (BAM))	Duphnia magna &	EC ₅₀ 180000	1800	0.11	Yes
M-02 (3-chloro-5-	Fish, acute Oncorhynchus mykiss	LC30 > 102000	⇒1020		Yes
(trifluoromethyl) Ø pyridine-2-carboxylic acid)	Invertebrate, acuto	EC ₅₀ 0 > 1800	> 18	1.13	Yes
M-03 (2,6-dichlero-N-{[3-	Fish, acute	¥C ₅₀ , 36**	0.36		No
chloro-5- (triflutoromethyl)-2- pyridinyl] (hydroxy)methyl	Inversebrate acute Daphnia magna	PC ₅₀ > 180**	> 1.8	1.29	Yes

(hydroxy)methyl benzamide)		Ĭ				
	Í Í Á Á Í L	ate ap	plication			
FLC + PCH SC 687 5	Fish, acuo Oncorhynchus mykiss	LC ₅₀	6600	66	36.309	Yes
	Invertebrate, acute Daphnia magna	EC ₅₀	> 100000	> 1000	50.509	Yes
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀	360	3.6	7.98	No



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
	Invertebrate, acute Daphnia magna	EC ₅₀ > 1800	> 18		Yes
				Ĩ	
M-01 (2,6-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 240000	2400	3.01	Yes y
dichlorobenzamide (BAM))	Invertebrate, acute Daphnia magna	EC ₅₀ 18000	1800		Yes y y y
M-02 (3-chloro-5-	Fish, acute Oncorhynchus mykiss	$LC_{50} > 102000$	> 1020		Yes Q Q
(trifluoromethyl) pyridine-2-carboxylic acid)	Invertebrate, acute Daphnia magna	EC	>* <b>1</b> \$8 ©		Yes Q Q Q
M-03 (2,6-dichloro-N-{[3-	Fish, acute Oncorhynchus mykiss		0.360		No of of of
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl} benzamide)	Invertebrate, acute	PC ₅₀ 2180**	> 1.80 > 1.80	0.582 y	
* 1 st tier parent endpoin ** 1 st tier parent endpo	nt int divideed by 10 \$				

Table 10.2- 18:	Acute risk assessment	based on FOCUS	Step 2 for the app	lication in potatoes (2 × 100
	g ass/ha) 🖓 🖉	0 0 %		

5			v	× ×	·
Compound	Species Species	Endpoint	₿AC  µg/Lj [€] ∕	PECsw,max	$RAC \ge PEC_{sw}$
O		arly application		£'	
FLC + PCP SC 687.5	Fish, acute Ongorhynchu's mykfs	LCX0 6600		© 28.662	Yes
		$EC_{s_0} > 100000$	>1900	28.002	Yes
	Fish, acute	4 C 50 360 0	3.6	10.9	No
Fluopicolide	invertenzate, acute	EÇ 7 > 1800	> 18		Yes
l d	Daphya magna Q ¹				
	Sish, agute Oncochýnchu mykiss Invertebrate, acute	LC 240000	2400	4.39	Yes
(2,64) dichlorobenzamide (BAM))	Invertebrate, acute Daphniamagna	.© ÆC ₅₀ 180000	1800	4.39	Yes
M-02 (3-chloro-54 (trifluotonethyl)	Fish, acute Oncorhynchyds mykiss	$LC_{50} > 102000$			Yes
pyridine 2-carboxylic acid)		EC ₅₀ > 1800*	> 18	0.816	Yes
M-63	Fish acute	LC ₅₀ 36**	0.36	0.973	No



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben zamide)	Invertebrate, acute Daphnia magna	EC ₅₀ > 180**	> 1.8		Yes
	L	ate application			<u>67 87 8</u>
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC ₅₀ 6600	66	<b>28</b> .662	Yes y y y
	Invertebrate, acute Daphnia magna	EC ₅₀ 200000	> 1000		Bes Q O
	Fish, acute Oncorhynchus mykiss	LC 360	36		No V C C
Fluopicolide	Invertebrate, acute Daphnia magna	PC ₅₀ 91800	> 180	5.607	over the second
M-01	Fish, acute	××××××××××××××××××××××××××××××××××××××			
(2,6- dichlorobenzamide	Invertebrate 20th	EC 50 240000 50 EC 50 180900	2400 800		
(BAM)) M-02	<i>Daphnia magna</i>	<u>v</u> Ş			¥`
(3-chloro-5- (trifluoromethyl)	Oncorhynchus mykiss	$LC_{50} > 102000$	> 620	0.410	Yes U
pyridine-2-carboxylic acid)	Daphnia magna 🖉 🤇	EC 50 21800*	× 18		Yes
(2,6-dichloro-N-{[3\$	Fish, acute S Oncorhynchus mykits	LC ₅₀ 36	<b>Ø</b> .36		No
chloro-5-	Divertebrate, acute		9.8 ×	0.438	Yes
(hydroxy)methyl}ben zamide)		51° 10°			
* 1 st tier parent endpoi ** 1 st tier parent endpo	int divided by 70		Å		
چ Table 10.2- 145 A	ant divided by 70		en 2 for t	he annlicati	on in notatoes (1 × 100
A g	a.s./h@)		-p = 101 (	uppneati	
Composid		Endroint [µg2]	RAC [µg/L]	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
<u> </u>		ary application			
ELC + PCH SO 687	Fish, acute	LC ₅₀ 6600	66	16.679	Yes
FLC + PCH 6875	Daphnia magna	$EC_{50} > 100000$	> 1000	10.077	Yes
Fluessicolide	Fish, acute Oncochynchus mykiss	LC ₅₀ 360	3.6	-5.58	No
	Invertebrate, acute Daphnia magna	EC ₅₀ > 1800	> 18	2.20	Yes



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PEC _{sw,max} [µg/L]	$\mathbf{RAC} \ge \mathbf{PEC}_{sw}$
M-01 (2,6-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 240000	2400	2.24	Yes
dichlorobenzamide (BAM))	Invertebrate, acute Daphnia magna	EC ₅₀ 180000	1800		Yes y y
M-02 (3-chloro-5-	Fish, acute Oncorhynchus mykiss	$LC_{50} > 102000$	> 1020	er c	Yes 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
(trifluoromethyl) pyridine-2-carboxylic acid)	Invertebrate, acute Daphnia magna	EC ₅₀ > <b>1800</b> *	> 18	©471	Kes Q D D
M-03 (2,6-dichloro-N-{[3- chloro-5-	Fish, acute Oncorhynchus mykiss	LC50 36**	0,36		No v v v v
(trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben zamide)	Invertebrate, acute Daphnia magna				Yes to be a second seco
		ate application	~Ø	2° 3	
FLC + PCH SC 687.5	Fish, acute <i>Oncorhynchus myklss</i> Invertebrate, acute <i>Daphnia magna</i> Fish, acute	$L_{250} = 6690$ $EC_{56} > 109000$	200 200 21000	16,679	Yes
Fluopicolide	Oncorhynatius motoiss	$EC_{50} \xrightarrow{0} 0 \xrightarrow{0} 0$	3.6 3.6 18		Yes
M-01	Fish, achte	LC 38 240000	2400 ~	Ø 1.06	Yes
dichlorobenzamide (BAM)	Incertebrate, acute	EC ₅₀ 780000	1800		Yes
(3-chloro-5-	Fish, acute Oncorhynomias mykies	L@50 > @02000	> 1020	0.000	Yes
(trifluoromethyl) pyridine-2-carboxylic acid)	prvertebiate, acute Daphoja magna	EC37 > 1800*	> 18	0.236	Yes
M-03 (2,6-dichloro-N-{[3-	Fish, acute Quecorhynchus-mykiss	LC ₅₀ 36**	0.36		Yes
chlor 5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl, ben zamide)	Invertebrate, acute, Daphnicmagna	EC ₅₀ > 180**	> 1.8	0.248	Yes
* 1 st tier parent endpoin ** 1 st tier parent endpo	nt divided by 10				

For the  $4\times$  100 g/ha application in potatoes the acute trigger was not met for fish and *Daphnia* for fluopicolide and for fish with metabolite M-03. For the 3 x 100 g/ha, 2 x 100 g/ha and 1 x 100 g/ha applications in potatoes the acute trigger was not met for fish for fluopicolide and for metabolite M-03. The consideration of the more realistic FOCUS Step 3 water concentrations is presented below.



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PEC _{sw,max} [µg/L]	RAC≥ PEC _{sw}
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC ₅₀ 6600	66	-28.667	Yes
FLC + FCH SC 087.3	Invertebrate, acute Daphnia magna	$EC_{50} > 100000$	> 1000	28.002	Yes 2 2 2
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀ 36	3.6	5.69°	No Q D
ruopiconde	Invertebrate, acute Daphnia magna	EC 2 > 1800	>18		Yes y
M-01 (2,6-	Fish, acute Oncorhynchus mykiss	QC 50 240000	2400	2.06	Yes A A
dichlorobenzamide (BAM))	Invertebrate, acute	EC.57 180000	<b>10</b> 800		Yes S
M-02 (3-chloro-5-	Fish, acute	LC ₅₀ (\$ 102090	> 1020		Yes
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Invertebrate, acute Daphnia magna	FC 50 > 800*		0.410 C	joes y
M-03 (2,6-dichloro-N-{[3-	Fish, active	LC 5 36**	0.36		No
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben	Lavertebrare, acute Daphnia magna	EC 55 > 180 *	> <u>9</u> > <u>9</u> 8	0,438	Yes
zamide)	Paphnia magna Q				

Table 10.2- 20: Acute risk assessment based on FOCUS Step 2 for the application in lettuce (2  $\times$  100 g a.s./ha) Øĩ

 Table 10.2- 21:
 Acute risk assessment based on FOODS Step 2 for the application in lettuce (1 × 100 g a.s./ba)

	Speciels 2 5	Endpoint,	RAC	PEC _{sw,max}	
			[µg/L]	IECsw,max [μg/L]	$RAC \ge PEC_{sw}$
Q		rly application	2		
FLC + PCHASC 687.5	Fish, acute	LÇ 6600	66	16.679	Yes
	Invertebrate, acuto Daphnia magna	ÉC ₅₀ >> 100000	> 1000	10.079	Yes
	Fish, acate . O Oncorhynchils mykiss	B 360	3.6	8.00	No
	Invertebrate, acute Q Daphuga magna Q	$EC_{50} > 1800$	> 18	8.00	Yes
(2,6-	Oncornyngnus mykiss	LC ₅₀ 240000	2400	3.31	Yes
$(BAND)$ $\mathcal{O}$	Davertabrate, acute Daptinia magna	EC ₅₀ 180000	1800	5.51	Yes
M-02 (3-chloto-5-	Oncorhynchus mykiss	$LC_{50} > 102000$	> 1020	0.685	Yes
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Invertebrate, acute Daphnia magna	$EC_{50} > 1800*$	> 18	0.085	Yes



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
M-03 (2,6-dichloro-N-{[3-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 36**	0.36		No
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben zamide)	Invertebrate, acute Daphnia magna	EC ₅₀ > 180**	> 1.8	0.828	Yes
	L	ate application		<u></u>	
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC ₅₀ 6600	66	16,679 Å	Kes Q Q
	Invertebrate, acute Daphnia magna	EC 2 100000	>1,000 0		Yes Of S
Fluopicolide	Fish, acute Oncorhynchus mykiss	OC 50 360	3.6	2.92	Fes , A
	Invertebrate, acute	EC.57 > 1800			Yes
M-01 (2,6-	Fish, acute	LC ₅₀ 240000	2400		Yes
dichlorobenzamide (BAM))	Invertebrate, asute Daphnia magna .	FC 180000	90800 x		Kes «
M-02 (3-chloro-5-	Fish, acute	$LC_{50} > 102000$	> 1020	10 236 T	Yes
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Daphnia magna 🖗 🤇	EC 50 E 1800	> 18		Ses
(2,6-dichloro-N-{[3,6]	Fish, acute C Oncomynchus mykiss		<b>9</b> ,36		Yes
chloro-5- (trifluoromethyl)@2- pyridinyl] (hydroxy)methyl}ben zamide)	Daphnia magna	$\mathbf{E}_{\mathbf{x}}^{\mathbf{y}} \geq 1_{\mathbf{x}}^{\mathbf{y}} \geq 1_{\mathbf{x}}^{\mathbf{y}} = 1_{\mathbf$	× × ×	0.248	Yes
* 1 st tief parent endpoint ** 1 st tier parent endpoint	ant divided by 0		, , ,	1	<u> </u>

For the  $2 \times 100^{\circ}$  g/ha application and the  $100^{\circ}$  g/ha early application in lettuce the acute trigger was not met for fish for fluopæolide and for metabolite M-03. A risk assessment for fluopicolide and its metabolite M-03 under consideration of more realistic FOCUS Step 3 water concentrations is presented below. not met for fish for fluopteolide and for metabolite 39-03. A risk assessment for fluopicolide and its

# BAYER

Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw,max [µg/L]	RAC≥PEC _{sw}	Ø,
		Early		Ĉ		
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC ₅₀ 6600	66	36.30 <del>9</del>	Yes y	
	Invertebrate, acute Daphnia magna	$EC_{50} > 1000$	<u>00</u> > 1000	50.507y	Yes 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	¢ L
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀ 360	3.6	S≶ 10.1∘ ∡	No Q O	2
	Invertebrate, acute Daphnia magna	EC 200 > 1800			Yes	
M-01 (2,6-	Fish, acute Oncorhynchus mykiss	bC 50 2240000		3.94	Fes A A C	
dichlorobenzamide (BAM))	Invertebrate, acute				Yes	
M-02 (3-chloro-5-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 7 1020	00 > 1020		Yes	
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Daphnia magna 📣	EØ30 > Ø00				
M-03 (2,6-dichloro-N-{[3- chloro-5-	Fish, acute Oncorhynchus mykiss	LC 56 36**	0.36		No.	
(trifluoromethyl)-2- pyridinyl]	Invertebrate, acuto	EC ₅₆ > 180 [*]	× > 108	0.776 È	Yes	
(hydroxy)methyl}ben( zamide)	54 59 59 19					
		y Mid	<u> </u>	st v		
FLC + PCH SC 687.5	Fish, acute Oncorhynchtis mykiss	LE30 6600		© ) 36.309	Yes	
	Incertebrate, acute Baphnia magna	EC ₅₀ 1000	\$0 > 1000		Yes	
Fluopicolide		LC 50 360	3.6	7.98	No	
~\$	Devertebrate, acute O' Daphrua magna	ECsy > 1800			Yes	
M-01 (2,6- dichlorobenzamide	Fish, acute	¥C50, 240000	2400	3.01	Yes	
(BA1))	Invertebrate, and C Daphnia magna		) 1800		Yes	
M-02 (3-chloro-5- (trifluoromethyl)pyrid	Qncorhonchusznykiss	$LC_{50} > 1020$	00 > 1020	0.563	Yes	
ine-2-carboxylic acid)	Daphnia magna	$EC_{50} > 1800$	* > 18		Yes	
M-03 (2,6-dehloroon-{[3-5] chloro-5-	hish, apore Oncorpynchus mykiss	LC ₅₀ 36**	0.36		No	
(trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben zamide)	Invertebrate, acute Daphnia magna	EC ₅₀ > 180*	* > 1.8	0.582	Yes	
	1	l		I	1	

Table 10.2- 22:Acute risk assessment based on FOCUS Step 2 for the application in cucumber (3 ×<br/>100 g a.s./ha)



#### Page 121 of 299 2020-08-11 Document MCP - Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

		[µg/L]	[µg/L]	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
		Late	•		
FLC + PCH SC 687.5	Fish, acute Oncorhynchus mykiss	LC ₅₀ 6600	66	36.309	Yes
	Invertebrate, acute Daphnia magna	$EC_{50} > 100000$	> 1000	30.309	Yes
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀ 360	3.6	190	
	Invertebrate, acute Daphnia magna	$EC_{50} > 1800$	> 18	5	Yes Q Q
M-01 (2,6-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 240000	2400	2° Q 4×88 ~	Yes of g
dichlorobenzamide (BAM))	Invertebrate, acute Daphnia magna	ET 50 18000 x	J800 L	¥.88 00 0	Ses L A Co
M-02 (3-chloro-5-	Fish, acute Oncorhynchus mykisg	$LC_{50} > 102000$	≥1020		Yes
(trifluoromethyl)pyrid ine-2-carboxylic acid)	Invertebrate, acute	EC ₅₀ 1800	> 18		Yes of o
M-03 (2,6-dichloro-N-{[3-	Fish, acute Q Oncorhynchys mykiss	LC30 360	\$36		NG ^{SY}
chloro-5- (trifluoromethyl)-2- pyridinyl] (hydroxy)methyl}ben		EC 5 > 180**	₹ 1.8 ¢	<b>9.9</b> 70 g	vê Vê
zamide) ^{1 st} tier parent endpoint ^{1 st} tier parent endro	int divided by $50^{\circ}$				P

For the  $3 \times 100$  g/ha early, and and late application in encumber the scute trigger was not met for fish for fluopicolide and for metabolite M-03. A fisk assessment for fluopicolide and its metabolite M-03 under consideration of more realistic OCUS Step 3 water concentrations is presented below. L L 

**X** 

Acute risk assess	mant based	d on FOCL	18 Step 3	PEC _{sw} values

## Potatoes

Acute risk assessment based on FOCUS Step 3 for potatoes (4 × 100 g a.s./ha) Table 10 2-23:

Compound	Species of co	Endpoint µg/L}	RAC [µg/L]	FOCUS Scenario	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$
4	<u> </u>	Rarly applica	tion			
				D3 ditch	0.524	Yes
		, v		D4 pond	3.70	No
	FisheStute &			D4 stream	3.47	Yes
Fluopicolide	Fish acute y Oncorhynchus mykiss	LC ₅₀ 360	3.6	D6 ditch	1.51	Yes
Fluepicolide				D6 ditch 2nd	7.36	No
				R1 pond	0.260	Yes



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$
				R1 stream	2.86	Yes 🖉 ိ
				R2 stream	1.82	Yes
				R3 stream	4.00	No 🖉 💭
				D3 ditch	0.524	Yes
			<i>Č</i> a	D4 pond	3.70	Yes of a
			R.	D4 stream	3.47	Yes
				D6(ditch	1.51	Yes of a
	Invertebrate, acute Daphnia magna	$EC_{50} > 1800$	> 18	Do ditclô 2nd	3.47 (C) 1.51 (C) 7.36 (C)	Yes of O
		× 9		R1 pond ×	0.260	Yðs
			ê,	BI stream	2.86 0	Yes y
			× s	R2 streams	14.82 W	Yes
				RS stream	4.00	Yes O
		<u>o</u> v v		D3 ditch	0:021	Yes
			r h	D4 pond	0.2060	Yes
M-03 (2.6-dichloro-			- 	194 stream	0.365	No
N-{[3-chloro-				D6 durch 🔍		Yes
5- (trifluorometh	Fish, acute Oncorhurchus mykiss Fish, acute Oncorhurchus mykiss Fish, acute Oncorhurchus mykiss Fish, acute Oncorhynchus mykiss	LC ₅₀ 36*	0.98	D6 ditch [%] and %	0.489	No
pyridinyl]				R1 pond	0.003	Yes
(hydroxy)meth			S.	Rystream	0.097	Yes
y1;0enzannue)		4° & 4		R2 st@am	0.081	Yes
		A 87 8		R30stream	0.086	Yes
Ê,		Late applicat	tion ,	0		
				D3 ditch	0.524	Yes
				D4 pond	3.65	No
~			Ø	D4 stream	3.54	Yes
A			P	D6 ditch	1.96	Yes
Fluopiconde	Fish, acute Oncor winchus mykiss	LC. 3600	3.6	D6 ditch 2nd	14.4	No
<i>y</i>				R1 pond	0.125	Yes
	K A R A	-Q [×]		R1 stream	2.77	Yes
				R2 stream	2.01	Yes
		v		R3 stream	4.05	No
M-034				D3 ditch	0.011	Yes
2.6 dichlor	Fish, acute			D4 pond	0.150	Yes
N-{[3-ch]oro- 5-	Oncorhynchus mykiss	LC ₅₀ 36*	0.36	D4 stream	0.266	Yes
(trifluorometh				D6 ditch	0.226	Yes



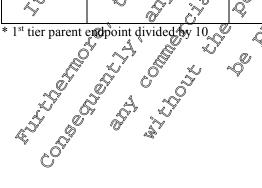
point divided by 10 Acute risk assessme ecies	Endpoint 🧔	S Step 3		0.360 0.004 0.085 0.092 0.118	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes
Acute risk assessme	Enders: 4	ັ» S Step∕3	R1 stream	0.685	Yes y
Acute risk assessme	Enders: 4	ັ» S Step∕3	R2 stream	<b>.</b>	
Acute risk assessme	Enders: 4	ັ» S Step∕3	R3 stream	0.092 0.118 ×	YOS CON A
Acute risk assessme	Enders: 4	ັ» S Step∕3	6 ⁴	0.118	Yes y g
Acute risk assessme	Enders: 4	ັ» S Step∕3	6 ⁴		
	Enders: 4		An botton	s (3🛠 100@)	a.s./ha)
	$   \sigma/   >   \sigma  $	RAC [©] [µg/L]	FOCUS ⊀	PEC sermax	RAC≥PEC _{sw}
		, Ø		<u>~ [⊊ 'an]</u>	
	and the of		D3ortch	0.524 C	Yes 2
Ő			N O	2.66	Yes o
Q.			D4 stream	2.50 A	Yes
			DQ ditch	1.12	∛yes
sh, acute	LC 360 (	<b>3</b> .6	D6 ditch 2ng S	4,93 Q	No
		. 6 ⁹ °	R1 pond	0.218	Yes
		j (	R1 stream	2\$86	Yes
\$ , o ; o	29° 29°		R2 stream	1.82	Yes
			R3 stream	2.58	Yes
NA N B		Ő	D3 duch	0.014	Yes
			D\$ pond	0.153	Yes
			D4 stream	0.272	Yes
		8	D6 ditch	0.144	Yes
sh, active Star C acorthynchus mykiss y		0.36	D6 ditch 2nd	0.364	No
			R1 pond	0.003	Yes
			R1 stream	0.067	Yes
			R2 stream	0.063	Yes
			R3 stream	0.069	Yes
	sh, acute hcorhynchus mykiss	sh, acute h, ac	sh, acute hcorhynchus mykisson LCS 360 + 3.6 hcorhynchus mykisson LCS 360 + 4.6 $hcorhynchus mykisson LCS 36* OF 0.36$	sh, acute <i>icorhynchus mykis</i> <i>LC</i> <i>a</i> <i>b</i> <i>b</i> <i>b</i> <i>corhynchus mykis</i> <i>b</i> <i>corhynchus mykis</i> <i>b</i> <i>corhynchus mykis</i> <i>c</i> <i>c</i> <i>c</i> <i>c</i> <i>c</i> <i>c</i> <i>c</i> <i>c</i>	sh, acute corhynchio mykist h, acute corhynchio mykist LCar 360 LCar 360 Car 493 R1 pond 0.216 R1 stream 2.86 R2 stream 1.82 R3 stream 0.153 D4 stream 0.272 D6 ditch 0.144 D9 pond 0.153 D4 stream 0.272 D6 ditch 0.144 D6 ditch 0.364 R1 pond 0.036 R1 stream 0.67 R2 stream 0.063 R3 stream 0.069



Compound	Species	Endpoint	RAC	FOCUS	PEC _{sw,max}	$RAC \ge PEC_{sw}$
compound	species	[µg/L]	[µg/L]	Scenario	[µg/L]	°
	1	Late applic	ation			
				D3 ditch	0.524	Yes
				D4 pond	2.50	Yes V O
				D4 stream	2.49	Yes
			Ĉa	D6 ditch 🖑	-11	Yes of the
Fluopicolide	Fish, acute	LC ₅₀ 360	<b>3</b> .6	D6 dit	14.1	No S
1	Oncorhynchus mykiss	Å	, Y	2nd	×	Yes O
		A A	~	Répond .	1.54 0	
				R1 stream		Yes
				R2 stream	1.33	Yèx 💞
		A	<u> </u>	B3 stream	3.67	No of so
			y ô	D3 ditch	Q007 🔬	Yes
M-03				B4 pond		¢es O
(2,6-dichloro-	A A			D4 stream	09991 S	Yes
N-{[3-chloro-				D6 ditch 💍	0.161	Yes
5- (trifluorometh yl)-2-	Fish, acute		0.36	Ø6 ditcb	0,3,26	Yes
pyridinyl]		\$ \$ X		R1 pond	×0.001	Yes
(hydroxy)meth yl}benzamide)				R1 stream	0.054	Yes
yi}benzannue)			Š.	R2 stream	0.064	Yes
				Restream	0.109	Yes
* 1 st tier parent				a y		11
, Q		AN	, F a,	N M		
Fable 10.27 25	: Acute riskassessm	nt based on FØC	US Step 3	for potatoe	s (2 × 100 g	a.s./ha)
×¥ C 1		Endpoint		FOCUS	PEC _{sw,max}	
Compound	species	ų ug/Lį C	) [µ@JL]	Scenario	[µg/L]	$RAC \ge PEC_{sw}$
		Farly applic	ation	1	1	
~			) ,	D3 ditch	0.524	Yes
, A	. 4	÷ 2 .2		D4 pond	1.72	Yes
				D4 stream	1.62	Yes
$\sim$		\$~_\$\$ [*]		D6 ditch	0.742	Yes
Fluopicolide (	Species Species	$LC_{50} 360$	3.6	D6 ditch 2nd	2.98	Yes
Å		Ą		R1 pond	0.152	Yes
.~~				R1 stream	1.42	Yes
Å .0				R2 stream	1.32	Yes
	L'É			R3 stream	2.58	Yes
<u> </u>			1			



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
				D3 ditch	0.008	Yes 🖉 °
				D4 pond	0.101	Yes
M-03 (2,6-dichloro-				D4 stream	0.18	Yes S
N-{[3-chloro-				D6 ditch	0.098	Yes
5- (trifluorometh yl)-2-	Fish, acute Oncorhynchus mykiss	LC ₅₀ 36*	0:36	D6 ditch 2nd	0.242	Yes y g
pyridinyl]		L	8	R1 pond	0.002	Yes C
(hydroxy)meth yl}benzamide)		A		R⊕ stream₀		
, , , , , , , , , , , , , , , , , , , ,					0.040	Yes
			<i>z</i>	R3 stream	0.040	Yes
		Late applicat	ion .	Q O		Y Q Y
				D3 ditch	0.524 🔬	Yes
				B4 pond	1.71	Yes O
				D4 stream	193 <u>5</u>	Yes
			, O	D6 ditch	0.796	Yes
Fluopicolide	Fish, acute	LC 3 360	3.6 A	Øð ditcb 2nd	7 <i>3</i> 0 °C	No
			S,	R1 ^{sp} ond	0.059	Yes
			$\sim$	R1 stream	1.15	Yes
				R2 stream	1.16	Yes
			Ň	Restream	2.98	Yes
â				D3 diach	0.005	Yes
M-03		A S' O		D4 pond	0.075	Yes
(2,6-dichloro-			di se	D4 stream	0.133	Yes
N-{[3-chloro- 5-				D6 ditch	0.100	Yes
(trifluorometh yl)-2-	Fish, acute Oncorhynchus mykiss Fish, acute Oncorhynchus mykiss Fish, acute Oncorhynchus mykiss Charles of the second seco	LC ₅₀ ~36*	0.36	D6 ditch 2nd	0.243	Yes
pyridinyl] 🔍 (hydroxy) 🔬				R1 pond	< 0.001	Yes
methyl}				R1 stream	0.041	Yes
benzamite)				R2 stream	0.043	Yes
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		R3 stream	0.083	Yes
^{1 st} tier parent	endpoint divided by 10	, Q,				





Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{o}^{\circ}$	
Early application							
				D3 ditch	0.524	Yes 0	
				D4 pond	0.823	Yes	
			<i>A</i>	D4 stream	0.777	Nes 2 X	
			Ö	D6 ditch	0.564	Yes	
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀ 360	\$ 3.6	D6 ortch 2 of stress	1.33	Yes of g	
		~		0.191 0	Yes Q		
		<u>کر</u> اچ	Rlestream	1.42	Ýðs 💞		
			82 stream	0.574	Yes A		
				R3 stream .	0.864	Yes y	
				B3 ditch	0.00	çes O	
				B1 -	0:049 \$	Yes	
M-03 (2,6-dichloro-				D4 atrace	0.091	Yes	
N-{[3-chloro-		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	4	196 ditch	0.051	Yes	
5- (trifluorometh yl)-2-	Fish, acute		0.36	D6 ethch 2nd	0.121	Yes	
	Oncorhynchus mykiss			R1 pond	<0.001	Yes	
(hydroxy)meth	Oncorhynchus mykiss		å .e	R1 stream	0.022	Yes	
yi, ochzannuc)			1 N	Restream	0.020	Yes	
			1	100 × 100	1		

Table 10.2- 26:	Acute risk assessment based on FOCUS Step 3 for potatoes (1 × 100 g a.s./ha)
	reduce risk assessment based on 1 0 0 0 5 5tep 0 101 potatoes (1 ~ 100 g als/ha)

For the 4 x 100 g/kg application in potatoes the acute trigger was not met for fish for fluopicolide for the scenarios D4 gond, D6 ditch 2^{nd} and R3 stream; for metabolite M-03 the acute trigger was not met for fish for the scenarios D4 stream and D6 ditch 2^{nd} .

For the 3 x 100 g/ha application in potatoes the acute origger was not met for fish for fluopicolide for the scenarios D6 ditch 2^{nd} and R9 stream, for metabolite M-03 the acute trigger was not met for fish for the scenario D6 ditch 2^{nd} .

For the 2 x 100 g/ha application in potatoes the acute trigger was not met for fish for fluopicolide for the scenario D6 ditch 2^{nd} for metabolite M-Q3 the acute trigger was met for fish for all scenarios.

For the 1 x 100 g/ha application in potatoes the acute trigger was met for fish for fluopicolide and for metabolite M_{003} for all scenarios.

A refined isk assessment for the use in potatoes for the acute risk to fish is presented below. Those scenarios are presented which do not pass the risk assessment at Tier 1.



Lettuce

Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	RAC≥ PEC _{sw}
				D3 ditch	0.604	Yes
				D3 ditch 2nd	0.631	YE
			Č) V	D4 nond	1 53 🕺	Yes y fr Yes y fr Yes y fr No fr
			,	D4 meam	1.46	Yes
				DQ ditch •		No C C
				RI pond	0.437	Yes
				Ripond *	0.222	Yes Yes Yes Yes
Juonicolide	Fish, acute	1650 369	36.0	R1 stream	2339 x	103
luopiconae	Oncorhynchus mykiss			R lotream	1.92 J D63 J	tes O
				R2 stream	4963 5	Yes
				R2 stream	1.09	& es
			~~ [′]	R3 stream	2.98	Yes
				R3 stream	2.65	Yes
				R4 stream	3 .∦7	Yes
				R4 stream	3.29	Yes
				D3 ditch	0.005	Yes
				D30ditch 2nd	0.005	Yes
K∖y'			Å	D4 pond	0.061	Yes
			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	D4 stream	0.108	Yes
			Ő,	D6 ditch	0.184	Yes
1-03			r	R1 pond	0.003	Yes
V-{[3-ch]@o-				R1 pond 2nd	0.003	Yes
trifluorometh	Oncorhynchus mykiss	L 30 36*	0.36	R1 stream	0.047	Yes
yridinyl] hydroxy)meth				R1 stream 2nd	0.033	Yes
1}benzamide				R2 stream	0.052	Yes
	Fish, acute Oncorhynchus mykiss	, w		R2 stream 2nd	0.029	Yes
ST R				R3 stream	0.054	Yes
				R3 stream 2nd	0.064	Yes
				R4 stream	0.020	Yes



Compound SI	pecies	Endpoint [µg/L]	RAC [μg/L]	FOCUS Scenario	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$	
				R4 stream 2nd	0.032	Yes 🖉	
* 1 st tier parent end	dpoint divided by	10					<b>"</b> 0"

## Acute risk assessment based on FOCUS Step 3 for lettuce (1 × 100 g a.s. (a) Table 10.2-28:

C I	<b>c</b>	Endpoint	RAC	FOCU	PEC _{sw,max}	
Compound	Species	[µg/L]	[µg/L]	FOCUS Scenatio	PEC _{sw,max} [µg/L]	RACZPEC
		Early applica	tion	`	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u>Q</u> Q
				D3 ditck D3 ditch 2nd		
				2nd ×	0.714	Yes a A
				D4 streams	0675	Yes
				R1 pond	0.094	Yes O
				04 pond D4 stream B6 ditch R1 p6 R1 p6 R1 stream	0,094 0.079 1(\$)2	Ves
Fluopicolide	Fish, acute	LC70 360	3.6	R1 střeám R1 střeám R1 střeam	1002 0.985	Yes
				Qnd R2 stream	0,553	Yes
				R2 stream @	0.562	Yes
í				R3 stream	1.31	Yes
	Species			R3 stream	2.00	Yes
		. 6 ⁹ , 7 4		R4 stream	2.27	Yes
				R4 stream 2nd	2.40	Yes
$\sim$			*	D3 ditch	0.003	Yes
A.				D3 ditch 2nd	0.003	Yes
M-03	S A . F			D4 pond	0.046	Yes
(2,6-Michloro- N-{[3-chloro-5	S S			D4 stream	0.084	Yes
(trifluorometh	Fish and the state	, Q ^y		D6 ditch	0.130	Yes
yl)-2-	Oncorhynchus mykiss	L@s0 36*	0.36	R1 pond	< 0.001	Yes
(hydroxy) methyl		2		R1 pond 2nd	0.002	Yes
benzahaide)				R1 stream	0.018	Yes
				R1 stream 2nd	0.031	Yes
				R2 stream	0.018	Yes



Compound	Species	Endpoint [μg/L]	RAC [μg/L]	FOCUS Scenario	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
				R2 stream 2nd	0.056	Yes 🖉
				R3 stream	0.033	Yes
				R3 stream 2nd	0,052	Yes
			Ĉ4	R4 stream	0.015	Yes a the
				R4 stream 2nd	0.040 Ĉ	Yes

1st tier parent endpoint divided by 10

For the 2 x 100 g/ha application in lettuce the soute trigger was not met for fish for fluopicolide for the scenario D6 ditch; for metabolite M-03 the acute trigger was met for fish for all scenarios. For the 1 x 100 g/ha application in letture the acute trigger was met for fish for fluopicofide and for ()

metabolite M-03 for all scenarios. Ø Ñ Ó °

1 C C C A refined risk assessment for the use in lettuce for the acute rock to fish is presented below. Those scenarios are presented which do not pass the risk assessment at Tier

## Cucumber

Acutearsk assessment based on FOCUS Step 3 for cucumper (3 2100 g a.s./ha) Table 10.2- 29:

Compound	Species 5	Endpoint [µg2L] 5	.∭µg/L]	FOCUS Scenapio	PEC sw, max [pg/L]	$RAC \ge PEC_{sw}$
	S O >	🖉 🖉 Eastly appli	eation		<u>þ</u>	
6			2	Q6 ditch	1.54	Yes
(				R2 stream	2.10	Yes
Fluopicolide	OncorhynAbus myki	2 HC 50 260	3.6 S	R3 stream	5.37	No
<i>K</i> y	Fish, acute	$\begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} $		$\sqrt{R4}$ stream	8.33	No
M-03				D6 ditch	0.169	Yes
(2,6-dichloro- N-{[3-chloro-]				R2 stream	0.047	Yes
5-	Fish acute		ð	R3 stream	0.067	Yes
(trifluorometh yl)-2-	Oncorhynchus mytor		0.36	R4 stream	0.069	
pyridinyl (hydróxy)meth yl}benzamide)						Yes
		🛷 🛷 Atid applic	ation			
		, Ģ		D6 ditch	4.75	No
	Figh, acute			R2 stream	1.14	Yes
	Oncorhynchus wykis	LC ₅₀ 360	3.6	R3 stream	3.06	Yes
FluopiceOrde	Figh, acute 5 Oncortixnchuş aykis			R4 stream	7.85	No
WI-U3				D6 ditch	0.324	Yes
(2,6-dichloro- N-{[3-chloro-	Fish, acute Oncorhynchus mykis	LC ₅₀ 36*	0.36	R2 stream	0.124	Yes
5-	Sheornynenus mykis	ى.		R3 stream	0.093	Yes



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw, max [µg/L]	$RAC \ge PEC_{sw}$
(trifluorometh yl)-2- pyridinyl] (hydroxy)meth yl}benzamide)				R4 stream	0.241	Yes
		Late applicat	tion	Æ	A.	
Fluopicolide	Fish, acute Oncorhynchus mykiss	LC ₅₀ 360	€ 3.6	R3 stream R4 stream	2.39	
M-03 (2,6-dichloro- N-{[3-chloro- 5- (trifluorometh yl)-2- pyridinyl] (hydroxy)meth yl}benzamide) * 1 st tier parent	Fish, acute Oncorhynchus mykiss endpoint divided by 10			D6 dirch Rá stream R4 stream R4 stream	97:367 0 0.049 0.0995 0.0995 0.0995	Ney V Yes A C Yes A Xes A Xes A Y

For the 3 x 100 g/ha early application in cucumber the acute trigger was not met for fish for fluopicolide for the scenarios R3 stream and R4 stream; for metabolite M-03 the acute trigger was met for fish for all scenarios.

For the 3 x 100 g/ba mid application in cucumber the acute frigger was not met for fish for fluopicolide for the scenarios D6 ditch and R4 stream; for metabolite M-03 the acute trigger was met for fish for all scenarios.

For the 3 × 100 g/ha late application in a cumber the acute tagger was not met for fish for fluopicolide for the scenarios D6 duch, R 25 tream and R4 stream, for metabolite M-03 the acute trigger was not met for fish for the scenario D6 duch.

A refined risk assessment for the use in cucumber for the coute risk to fish is presented below. Those scenarios are presented which do not pass the risk assessment at Tier 1.

## Refined risk assessment (Tier 2b) for aquatic vertebrates

Acute studies on 8 aquatic vertebrate specie were performed with fluopicolide (7 on fish and 1 on amphibian). According to the Aquatic Guidance document, it is thus, possible to refine the risk assessment with a species sensitivity distribution (SSD). Several options are proposed in the guidance (table 28 page 10) for acute risk assessment: When no latency of effects is expected,  $LC_{50}$  can be used to derive the median HC, the BAC is then based on a assessment factor of 9; or the median HC₅ can be derived from VOEC or LC₀ values from acute studies, the assessment factor in this case is 3. If latency of effects is expected, the SD should be based on chronic data.

Latency of effects for fluopicolide:

The relevant effect to be considered for acute risk assessment is mortality. In all acute vertebrate studies, mortality is observed within the first 24h of the test, and as early as 3-4 h of exposure in some studies. Sublethal effects are observed in all tests, at the 1st observation time (3 or 4 h). Therefore, no latency of



Ŵ

mortality onset is expected with fluopicolide and the acute SSD can be derived with endpoints of acute studies.

TT1 1	· · 1.	• • • •	
The endpoints from	n acute studies are s	summarised in th	e table below:

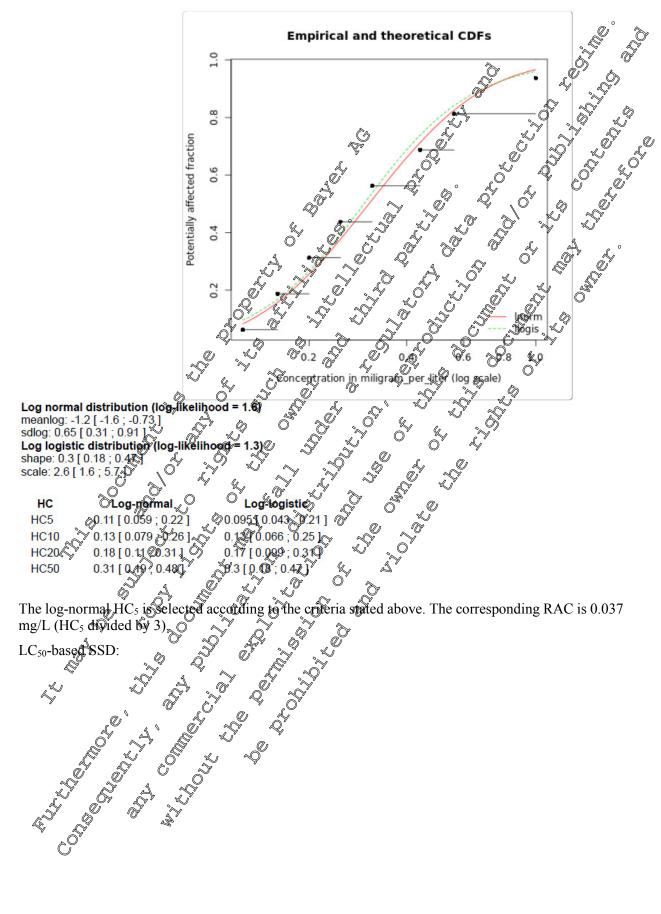
$LC_{50}$	NOEC based on both subsethal
(mg a.s./L)	
	(mg a.s./L)
0.36	A 0.16 × ×
0.75	0.56%
1.3	
1.8	
0.70″	
134	
0.41 °	× ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
$\langle \gamma \rangle = \frac{1}{2} \langle \gamma \rangle $	0.125
	(mg a.s./L) 0.36 0.75 1.3 1.8

The NOEC-based SSD is preferred because it ensures less uncertainty regarding the complement with the protection goals since no extrapolation is necessary from endpoints producing 50% of mortality to a safe concentration. Moreover, the dos response for Quopicelide Svery steep: the ratio between the NOEC and the LC₅₀ is below 2 for some species. To even allow a higher level of protection, the NOEC considered here are based on both mortality and sublethal effects.

However, for completeness reasons, SSD approaches based on both LCS and SOEC, are presented below. The SSD calculations were performed with Mosaic Modeling and StAtistical tools for ecotoxICology, developed by Lyon University), for both available models: log normal and log logistic. ecotoxICology, developed by Lyon University), for both available models: log norn The best fit is evaluated on the basis of the contractice interval width of the tO's and data in the lower part of the curve. NOEC-based SSD: The best fit is evaluated on the basis of the confidence interval width of the  $C_5$  and the visual fit to the data in the lower part of the curve

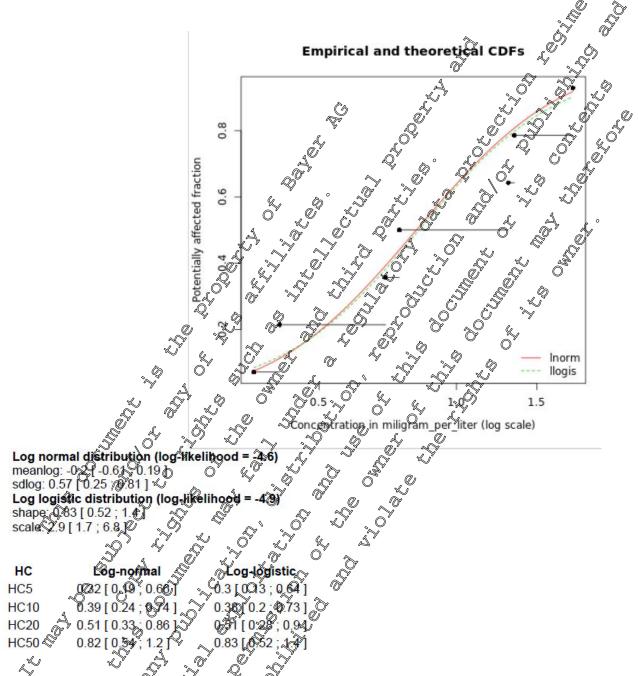


## Calculation of NOEC based on SSD





## Calculation of LC₅₀ based on SSD



The fit to the LC₅₀ data is worse than to the NOEC and less data can be included in the SSD since the LC₅₀ for *Xenopus* is an unbound value. Applying an assessment factor of 9 to these HC₅ would result in a RAC of 0.003 mg/C, which is very similar to the RAC derived from the NOEC-based SSD. Therefore, for these reasons and the casons given previously, the SSD-RAC of 0.037 mg/L should be used to refine the fluopfolide ask assessment for aquatic vertebrates.



## Potatoes

### Acute risk assessment based on FOCUS Step 3 for potatoes (4 × 100 g a.s./ha) considering a refined acute endpoint for aquatic vertebrates

Table 10.2- 30:Acute risk assessment based on FOCUS Step 3 for potatoes (4 × 100 g a.s./ha) considering a refined acute endpoint for aquatic vertebrates						
Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg@]	
		Early applica		1	<i>w</i>	
Fluopicolide	Aquatic vertebrates, acute Oncorhynchus mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis	HC5 110	37	D4 pond D6 ditch 2nd R3 stream	7.36 4.09 0 0 0 0 0 0 0 0 0 0	
	Aquatic vertebrates, acute Oncorhynchus mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Pimephales prometas Xenopus laevis	A		D4 stream D6 diach 2nd	0,365 C	Yes 7 Yes 7 Ye
<u> </u>		Late applica	tion 🔬			
	Aquatic yertebrates, acute Oncorhonchus mokiss Leportus macrochirus Cypenus copio Brachydanio rerio Gryziac fatipes Cyprhodon variegatus Pimephales prometas Xenopus devis			D6 diQh 2nd R3 stream	3.65) 14.4 4.05	Yes Yes Yes
*parent endpoir			Y Å	¥		



Table 10.2- 31:	Acute risk assessment based on FOCUS Step 3 for potatoes (3 × 100 g a.s./ha)
	considering a refined acute endpoint for aquatic vertebrates

Compound	Species	Endpoint	RAC	FOCUS	PEC _{sw,max}	RAC≥ PECsw
	~P****	[µg/L]	[µg/L]	Scenario	[µg/L]	
		Early applica	tion		<u> </u>	
Fluopicolide	Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis	HC5 110	37 37	D6 dite	4.93 ×	57 57 57 Yes9 29 Q ₄ 57 57 Q ₄ 57 Q ₅ 77 Q ₅ 7
yl)-2- pyridinyl] (hydroxy)meth	Aquatic vertebrates, acute Oncorhynchus mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis	<u> </u>		200 2 200 200		
		Cate applicat	tion 🦼			
	Aquatic vertebrates, Quite Oncorhynchus mykiss Lepomismacrochrus Cyprings carpio			Dő ditch 2 Zpd	14.15	Yes
Fluopicolide	Brachedanic verio Brachedanic verio Orszias latipes Prinophiles prometas Xenopus laevis			€ ¶3 stream	3.67	Yes
*parent endpoin	it divided by 10		Ç,	ð í		
Table 10.2- 32:	Considering a refined a	cute endpoint f	or aquat	∮ for potatoe ic vertebrat	s (2 × 100 g es	a.s./ha)
Compound	Species Species	Endpoint [µg/] 0	RAC [µg/L]	FOCUS Scenario	PECsw, max [µg/L]	$RAC \ge PEC_{sw}$
		Into any inot		I		L
Fluopicolide	Aquatic Vertebrates, acute Oncorhynchins mykis Lepomis macrochinis Oprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Emephales promelas Xenomia laevis	HC ₅ 110	37	D6 ditch 2nd	7.70	Yes
4						

For all application patterns in potatoes the risk assessment indicates acceptable acute risk for all aquatic organisms.



## Lettuce

#### Table 10.2-33: Acute risk assessment based on FOCUS Step 3 for lettuce (2 × 100 g a.s./ha) considering a refined acute endpoint for aquatic vertebrates

Table 10.2- 33	: Acute risk assessment considering a refined a					.s./ha)
Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw, max [µg@]	
Fluopicolide	Aquatic vertebrates, acute Oncorhynchus mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Pimephales promelas	HC5 110	8 37	D6 ditch		$\begin{array}{c} \mathbf{RAC} \geq \mathbf{PPC}_{sw} \\ \hline \\ & & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ & & \\ $
	Xenopus laevis					
For all applica organisms. <u>Cucumber</u> Table 10.2- 34	Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis ation patterns in lettuce the Acute risk assessment acute endpoint for aqu	tisk assessmen based on FØCU atig vertebrates	us step 3	tes acceptal	ble acute ris	k for all aquatic
Compound	Species Species	Endpoint	RAC [µg/L]		PECswinax	$RAC \ge PEC_{sw}$
		Early applica		O ^V &	<u>inesca</u>	<u> </u>
	Aquatic vertebrates, agute			R3 stream	5.37	Yes
Fluopicolide	Oneorhynchus mykiss Spomi macrochirus Cyprings carph Brachydanio rerio Oryzias lättpes Cyprinocon vanegatus Pimepholes promelas Xenopus laevis	HC 710 7 Nid applicat			8.33	Yes
		Mid applicat	tion,	-		
~	Aquatic vertebrates, acoute		* *	D6 ditch	4.75	Yes
Fluopicolide	Oncorhynchus mykis Lepomis macrochibus Cyprinits carpio Brach danio rerio Oryzias latipes Cyprinodon variegatus Eimephales prothelas Xenopus laevis	NJid applicat	37	R4 stream	7.85	Yes
<u> </u>		Late applicat	tion		1	
	Squatic vertebrates, acute			D6 ditch	10.2	Yes
Fluepicolide	Oncortynchils mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio	HC5 110	37	R3 stream	6.01	Yes



Compound	Species	Endpoint [μg/L]	RAC [µg/L]	FOCUS Scenario	PECsw, max [µg/L]	$\mathbf{RAC} \geq \mathbf{I}$	PECsw
	Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis			R4 stream	9.06	Yes	
1) hongomido)	Aquatic vertebrates, acut Oncorhynchus mykiss Lepomis macrochirus Cyprinus carpio Brachydanio rerio Oryzias latipes Cyprinodon variegatus Pimephales promelas Xenopus laevis t divided by 10	HC ₅ 11*	3.7 3.7	D6 ditten		Yes Yes Yes	
For the use in	t divided by 10 cucumber the risk asses	ssment indicates a	eceptable	e acute risk	for all aqu	atic organ	usins.
CHRONIC R Potatoes	ISK ASSESSMENQ F		JRGAD			°∼° ≪	
Table 10.2- 35:		smen Based on FO	GUS Ste	p/2 for the a	pplication	© in potatoe	es (4 ×
Compound		species		Effdpoint [ng/L]	RAC μg/L]	<b>PEC</b> sw.max	RAC≥ PEC _{sw}
		Early appłię		<u> </u>	) )		
FLC + PCH SC		Algae y 🧳 Navibula pelliculosa		EC 50 890	89	44.558	Yes
N.		Fish, chronit		EC160 278	27.8		Yes
				BC ₁₀ 180	18	• • •	No
Fluopicolide		Algae Keletőnéma costatu Aquatic macjöphyte		ErC ₅₀ 73	7.3	20.6	No
ې م		Aquatic macrophyte	» I	$E_r C_{50} > 3200$	) > 320		Yes
			ls	EC ₁₀ 278*	27.8		Yes
<i>S</i>		Invertebrate, chronic	2	NOEC 190*	19		Yes
M-01 (2,6-dichlorobe	izamide (BAM)	Algae Pseudokirchneriella subcapitata	]	ErC ₅₀ 92000	9200	8.44	Yes
		Aquatic macrophyte Lemna gibba	'S, ]	E _r C ₅₀ 97600	9760		Yes
M-62		Fish, chronic Pimephales promela	ls ]	EC ₁₀ 278*	27.8	1 4 4	Yes
(3-chloro-3-(tri 2-carboxylic ac	id)	Invertebrate, chronic Daphnia magna	· ]	NOEC 190*	19	1.44	Yes



Compound	Species	Endpoint [µg/L]		PEC _{sw.max} [µg/L]	RAC≥ PEC _{sw}
	Algae Navicula pelliculosa	E _r C ₅₀ 74000	7400		Y
	Aquatic macrophyte <i>Lemna gibba</i>	$E_r C_{50} > 3200*$	<b>3</b> 20		Yes
	Fish, chronic Pimephales promelas	EC ₁₀ 27.8**	2.78		NCP2S
M-03 2,6-dichloro-N-{[3-chloro-5-	Invertebrate, chronic 🔇 Daphnia magna 🚿	NOEC 100*	1.9		Yes
trifluoromethyl)-2-pyridinyl] hydroxy)methyl} benzamide)	Algae	Er <b>C</b> 12.1**	1.0	1.345°	Ño d
	Aquatic macrophyte Lemna gibba	FrC ₅₀ 320**	> 32		Yes
	Late application		ð	& A	, _c °
FLC + PCH SC 687.5	Algae Naviçula pelficulosa	ErC50 \$90 5	89	0 44.558	Yes
	Fish, cheonic & A	EC 278	9.8 7.8		) Yes
Fluopicolide	Invertebrate chrome, Americanosis bakta	EC ₁₀ , 180	18	55 55 156 an	Yes
-	Mgae Skeletonema zostatum	ELC 50 72 0	7.3	27.8 Y	No
	Aquatic maerophyte	$E_r C_{50} > 3200$	\$20		Yes
	Fish, chronic <i>Pintephales prometers</i>	EC ₁₀ 278*	∛ 27.8	3.93	Yes
M-01	Invertebrate, chronic 5 ⁴ Daphuna magna	NOEC 190	19		Yes
M-01 (2,6-dichlorobenzamide (BAM))	Algae [®] A PreudokirChneriella Gibcapitata A	Er <b>C</b> 50 92000	9200		Yes
	Aquatic mactophytes.	E _r C ₅₀ 97600	9760		Yes
	Tosh, chronic PimepDales pomelas	EC ₁₀ 278*	27.8		Yes
M-02	Invertebrate chron Dophnia magna	NOEC 190*	19	0.715	Yes
	Algae Naveula petviculosa	ErC ₅₀ 74000	0.715	Yes	
	Aquatic rocrophyte Gemna gibba	$E_r C_{50} > 3200*$	> 320		Yes
	Fish _g chronic Pincephales promelas	EC ₁₀ 27.8**	2.78		Yes
M-03 2,6-dictioro-15 [3-chtoro-5, 5]	Invertebrate, chronic Daphnia magna	NOEC 19**	1.9	0.692	Yes
trifluoromethyl)-2-pyridinyl	Algae	E _r C ₅₀ 12.1**	1.21	0.092	Yes
(hydroxy)paethyl} benzamide)	Navicula pelliculosa				

* 1st tier parent endpoint (*Skeletonema* and mysids are not considered as tier 1 species) ** 1st tier parent endpoint divided by 10



applicati Compound	Species		Endpoint			PECsed.max	
Compound	Species		[µg/kg]	[]	µg/k@j	[µg/kg]	PEC sed
		Early applicatio	n		°,		
Fluopicolide		nt dweller, chronic culus variegatus	NOEC 198		98	54.6°	X CS X
		Late application	n	Q			
Fluopicolide	Sedime Lumbri	nt dweller, chronic	NOEC 15	0 1	98 Č	10.6	Yes
Гаble 10.2- 37: Chronic 100 g a.s	risk asses	ssment based on COCU	Sestep 25	or the ap	oplicati	on in pota	toes (3 ×
100 g a.s	./IIA)		/ ~~ Ændpoin	.4			
Compound		Species 2	`≫[µg/L]			()	max <b>KA</b> C≥ <b>PEC</b> sw
	Å	Carly applicatio		2°	J.		<u>^</u>
FLC + PCH SC 687.5	, Qi	Algae & & Navicula pelliculora	eg D.	890 %	890	36.309	Yes
Ô		Fish, chronic Pimephales gromelas	EC%	278	\$27.8	3.Q	Yes
مې Eluonioolido		Invertebrate, chronic Americanysis bohia 🤸	ECity	180	, B	15.8	Yes
Fluopicolide		Alga 5 Skeletonema costatijim	€,C ₅₀	,73 [°] _©	7.3	13.8	No
		Aquatic macrophyte	Er <b>C</b>	> 3200	> 32	20	Yes
	N. Y	Fish, chrome of the prometer of the property of the prometer o	EC ₁₀	278*	27.8	3	Yes
M-01		Înverțebrate, coronic [%] Daponia magna %	NOTEC	190*	19		Yes
M-01 (2,6-dichlorobenzamide (BAN		Adgae Pšeudőkirchneftella subeapitata	ErC ₅₀	92000	920	0 6.44	Yes
		Aquatic macrophytes,	$E_rC_{50}$	97600	976	0	Yes
	Â, Â	Fish, chronic Q Pimephaler promelas	$EC_{10}$	278*	27.8	3	Yes
M-02 (3-chloro-5-(trifficromathyl)	Quiding?	Invertebrate, chronic Daphna magna	NOEC	190*	19		Yes
2-carboxylicaeid)		Alg <b>æ</b> Navicula pelliculosa	E _r C ₅₀	74000	740		Yes
	59°	Aquatic macrophyte Lemna gibba	E _r C ₅₀	> 3200*	* > 32	20	Yes
M-02 (3-chloro-5-(triffuoromethyl)) 2-carboxylicærid) M-03 (2,6-dichloro-N-{[3-chloro-5-(triffuoro-5-(triffuoro-1))]	2	Fish, chronic Pimephales promelas	EC10	27.8**	2.78	3 1.29	Yes
(trifluo@methyl)-2-pyridinyl] (hydroxy)methyl} benzamide)		Invertebrate, chronic Daphnia magna	NOEC	19**	1.9	1.27	Yes



Compound	Species	Endpoint [µg/L]		PECsw.max [µg/L]	RAC≥ PEC _{sw}
	Algae Navicula pelliculosa	E _r C ₅₀ 12.1**	1.21		No
	Aquatic macrophyte Lemna gibba	$E_r C_{50} > 320 **$	©82	, , , , , , , , , , , , , , , , , , ,	Yes 5
	Late application		<i>.</i>	S	
FLC + PCH SC 687.5	Algae Navicula pelliculosa	ErC ₅₀ 890	89	36:309	Yes ,
	Fish, chronic Pimephales promotas	EC ₁₀ 278	27.8		y des g
Fluopicolide	Invertebrate, chronic Americamystepahia	E.C. 180	<b>Q</b> 8	7 98 ⁴	Yes
	Algae & Skeletonema costatum	ErC 50 4 73	7,5,7		No No
	Aquatic macrophyte	5C50 \$3200	> 320		Yes
k	Fish, cheonic 2 ? Dimepholes promelas	EC 278	29.8		) Yes
А-01	Invertebrate chrome. Daphnia magna	\$0EC 990* 0			Yes
(2.6-dichlorobenzamide (BAM)	Algae Pseulokirchteriella subcapitata	ErĈ ₅₀ <b>ĝ</b> 2000 .	9200	ðð1	Yes
	Aquatic macrophytes, O	Er <b>C</b> 9 <b>7</b> 600	9760		Yes
M-02 (3-chloro-5-(grifluoromethyl) pyridiæ-	Pimephales prometas	C10 \$ 278*	27.8		Yes
M-02	Invertebrate, chronic	NOPEC 190*	19	0.563	Yes
2-carboxylis acid)	Afgae 🛇 🤅 🖓	E _r C 50 74000	7400	0.505	Yes
M-03 (2 6-dichleror N-/[3-chloror 5-	Aquatrc macrophyte	$E_{1}C_{50} > 3200*$	> 320		Yes
	Pish, chronic	EC ₁₀ 27.8**	2.78		Yes
	Invertebrate chron	NOEC 19**	1.9	0.582	Yes
(trifluore) (trifl	Algae	ErC ₅₀ 12.1**	1.21	0.002	Yes
	Aquatic macrophyte Gemna Stoba	$E_r C_{50} > 320 **$	> 32		Yes

* 1st tier parent endpoint (*Skeleonema* and mysids are not considered as tier 1 species) ** 1st tier parent endpoint divided by 10



Compound	Specie		Endpoint [µg/kg]	RAC	PECsed.max [µg/kg]	RÅ⊄≥ PECsed ∧
		Early application			[#6/ *6]	× sed
Fluopicolide		ent dweller, chronic	NOEC 1980	198	41.8	X CS
		Late applicatio	n o	7		
Fluopicolide		nt duvallar abrania	NOEC 1880	198	21.0	Yes
Гаble 10.2- 39: Chron	ic risk asse a.s./ha)	ssment based on EOCU	Setep 2 for the	applicat	ion in pota	toes (2 ×
Compound		Species , , , , , ,	Endpoint	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		.max RAC≥ PECsw
	k	Carly application		, <u>ne</u>		<u>+</u>
FLC + PCH SC 687.5	Q Q	Algae & & Navicula pelliculosa	ErC 56 890	89	28.662	Yes
		Fish, chronic Pimeshales promela	ÉC10 278	<u>گ</u> وي مح	0	Yes
Fluopicolide		Invertebrate, chronic			10.9	Yes
Fluopicolide		Alga 5	ErC50, 73	7.3		No
		Aquatic macrophyte	$E_{50} > 32$	200 > 3	20	Yes
	~~~~~	Fish, chronite Prorephales promelas	EC10 278*	* 27.	8	Yes
M-01		Invertebrate, chronic Dapônia magha	NOEC 190*	* 19	4.39	Yes
M-01 (2,6-dichlorobenzamide (B)	M))	Algae Pseudokirchnefiëlla subeapltata	$E_{r}C_{50}$ 9200	920		Yes
		Agnatic macrophytes,	ErC ₅₀ 9760	00 976	50	Yes
		Fish, chronic Q Pimephaler Promelas	EC10 278*	* 27.	8	Yes
M-02 (3-chloro-5-(trifftorom)thy) widing	Invertebrate, chronic Daphna magna	NOEC 190*	* 19	0.816	Yes
2-carboxylic arid)		Alg æ Navicula pelliculosa	ErC ₅₀ 7400	00 740		Yes
		Aquatic macrophyte <i>Lemna gibba</i>	$E_r C_{50} > 32$	00* > 3	20	Yes
M-02 (3-chloro-5-(triffuoromethy 2-carboxylic acid) M-09 (2,6-dichloro-N-{[3-chloro- criftuoromethy]	5-	Fish, chronic Pimephales promelas	EC ₁₀ 27.8	** 2.7	8 0.973	Yes
(trifluo@methyl)-2-pyridiny (hydroxy)methyl} benzamio	/1]	Invertebrate, chronic Daphnia magna	NOEC 19**	* 1.9		Yes



Compound	Species	Endpoint [µg/L]		PECsw.max [µg/L]	RAC≥ PEC _{sw}
	Algae Navicula pelliculosa	ErC ₅₀ 12.1**	1.21		Y¢¢°
	Aquatic macrophyte Lemna gibba	$E_r C_{50} > 320 **$	\$ 3 2	, , , , , , , , , , , , , , , , , , ,	Yes
	Late application	.1	<i>)</i>	Ş	
FLC + PCH SC 687.5	Algae Navicula pelliculosa	ErC ₅₀ 890	89	28.662	Yes ,
	Fish, chronic Pimephales prométas	EC ₁₀ 278	27.8		X es
Fluopicolide	Invertebrate, chronic Americamysts pahia	EC10 180	Q 8	5.60%	Yes
	Algae	ErC 73	7,5		Yes
	Aquatic macrophyte	ErČ ₅₀ 3200	> 320		Yes
Å	Fish, cheonic Dimephales promelas	EGT 278	2.8		Yes
-01 6-dichlorobenzamide (BAM)	Invertebrate chromic, Daphnia magna	NOE¢990*0		َمَنْ 2006	Yes
	Pseudokirchporiella	ErC ₅₀ 92000	9200	Øuo	Yes
	Aquatic macrophytes.	E650 97600 2	9760		Yes
	Fish chronic Pimephales promotas	EC10 278*@	27.8		Yes
M-02	Phyertebrate, chronic Daphnia magna	NOEC 190*	19	0.410	Yes
2-carboxyliv acid)	Afgae & @	Eres 74000	7400		Yes
M-02 (3-chloro-5-(trifluoromethyl) pyridia- 2-carboxyliv acid)	Aquatic macforphyte	$E_{\rm r}C_{50} > 3200*$	> 320		Yes
	Pinephales promelas	EC ₁₀ 27.8**	2.78		Yes
		NOEC 19**	1.9	0.438	Yes
(trifluoremethyl)-2-pyridinyl] (hydroxy)methyl} benzamideA	Algae	ErC ₅₀ 12.1**	1.21		Yes
	Aquatic pacrophyte Gemna Sibba	$E_rC_{50} > 320**$	> 32		Yes

* 1st tier parent endpoint (*Skeleonema* and mysids are not considered as tier 1 species) ** 1st tier parent endpoint divided by 10



Compound	Species	.	Endpoir [µg/kg]	nt	RAC [µg/k@]	PECsed.max [µg/kg]	RÅ⊄≥ PECsed
		Early applicat	ion		ð		
Fluopicolide		ent dweller, chronic culus variegatus	NOEC	1980 🐇	198	28.7	¥ CS
		Late applicati	on	Q			
Fluopicolide	Sedime Lumbri	nt dweller, chronic	NOEC 2	Q80	198	14.7	Yes
Cable 10.2- 41: Chronic	risk asse	ssment based on POC	US Step	Sfor the	applicat	ion in pota	toes (1 ×
100 g a.s	s./ha)			4	<u> </u>		<u> </u>
Compound	e	Species 4 2				× × /	$\begin{array}{c} \text{max} \\ \text{RAC} \geq \\ \text{PEC}_{\text{sw}} \end{array}$
	Ŵ	Early applicat	ion N	,0°	Ô	S X	, [°]
FLC + PCH SC 687.5	Ĵ,	Algae V S Navicuta pelliculosa	K Ere	\$ \$ 890		16.679	Yes
		Fish chroni	EC	10 278	27	Ş, Ş,	Yes
		avertebrate, claonic Americamysis Bahia	° °≻ ₽©		***	5.58	Yes
uopicolide		Algae Skeletonevia costatum	ErC		Ø 7.3		Yes
		Aquanc macrophyte) GrC	$\sum_{j=1}^{\infty} \sum_{j=1}^{\infty} \frac{j}{j}$	200 > 3	20	Yes
		Figh, chromc Fimephales pronelas	EÉ	278		8	Yes
M-01		Invertebrate, chronic	_ [▲] NO	EC 190	* 19		Yes
(2,6-dichlorobenzamide)	M) N	Algae ' Pseudokirchneriella subQipitata	ErC	5 ₅₀ 920	00 920	0 2.24	Yes
		Requatic macrophytes, Lemng gibba	ErC	c ₅₀ 976	00 976	0	Yes
		Fish chronic Pimephales promelas	EC	10 278	* 27.	8	Yes
M-02		nverteorate, chronic Daphnia magna	NC	EC 190	* 19	0 471	Yes
M-02 3-chloro-5-(trifluoromethyle 2-carboxyle acid)	pyridine-	Aîgae Navicula pelliculosa	ErC	c ₅₀ 740	00 740	0.471	Yes
	Ŝ	Aquatic macrophyte Lemna gibba	ErC	2 ₅₀ > 3	200* > 3	20	Yes



Compound	Species	Endpoint [µg/L]		PEC _{sw.max} [µg/L]	$RAC \ge PEC_{sy}$
	Fish, chronic Pimephales promelas	EC ₁₀ 27.8**	2.78		Wes of
M-03 (2,6-dichloro-N-{[3-chloro-5-	Invertebrate, chronic Daphnia magna	NOEC 19** 🖉	9.9	0.55 Q *	Yes
(trifluoromethyl)-2-pyridinyl] (hydroxy)methyl} benzamide)	Algae Navicula pelliculosa 💍	ErC50 12	1.21		Yes 🗸
	Aquatic macrophyte 🕅 Lemna gibba	ErC ₅₀ 320**	> 320		Yes
	Late application	Ŷ [¥] &	Ś.	s č	ĭ "Qʻ
FLC + PCH SC 687.5	Algae		89	16,6 79	Xez O
	Fish, chronic Pimephales prometas	EGR 208	27.8		Yes
Fluopicolide	Invertebrate chrome	EC100 180 7		a ser a c	ares -
	Algae Steletonema costatum	BC 50 33 5	7.3		Yes
	Aquatic macrophore	$E_r CQ > 3200$	≫ 20	ů,	Yes
	Fish Phronic Pinzphale prometas	EC ₁₀ 278* 7	27.8 [©]		Yes
M-01	hyvertebrate, chuchic O Daphnia magna	NOTEC 490* >	\$9 [°]	1.00	Yes
(2,6-dichlorobenzamede (BAMI))	Algae Pseudokironnerielja Ssubcapijata	E _r C ₆ 92090	9200	1.06	Yes
		E _r C ₅₀ 97600	9760		Yes
	Orsh, chronic	EO ₁₀ 278*	27.8		Yes
M-02 (3-chloro-5-(trifluoromethyl) pyptine-	Invertebrate, chrome Paphnia magna	» NOEC 190*	19	0.236	Yes
2-carboxylic action 2	AlgaeO ⁷ O ⁸ O ⁷ Nayicula pelliculoso	ErC ₅₀ 74000	7400	0.230	Yes
	Aquatic macrophyte Lemna bba	$E_r C_{50} > 3200*$	> 320		Yes
	Fish@chronic Pimephal promelas	EC ₁₀ 27.8**	2.78		Yes
M-03 (2,6-dichloro-8){[3-cmbro-5]	Givertebrate, chronic Daphnia magna	NOEC 19**	1.9	0.248	Yes
(trifluorometoyl)-2-pyridiny	Algae Navicula pelliculosa	E _r C ₅₀ 12.1**	1.21	0.240	Yes
	Aquatic macrophyte Lemna gibba	$E_r C_{50} > 320^{**}$	> 32		Yes

* Kier parent endpoint (*Skeletonema* and mysids are not considered as tier 1 species) ** 1st tier@arent endpoint divided by 10



Ø1

Table 10.2- 42:	Chronic risk assessment for sediment organisms based on FOCUS Step 2 for the
	application in potatoes (1 × 100 g a.s./ha)

	FF					, Or
Compound	Species	Endpoint [µg/kg]	RAC [µg/kg]	PECsed.max [µg/kg]	RÅC≥ ØFCsed	<u> </u>
	Early applic	ation	- O			
Fluopicolide	Sediment dweller, chronic Lumbriculus variegatus	NOEC 1980	×198	14.8	X	ò
	Late applic	ation Q	Ų [*]	.0 .2		Å
Fluopicolide	Sediment dweller, chronic Lumbriculus variegatus	NOLC DOU	198	7.63	Yes	1
			<u>,</u> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		

For the 4 x 100 g/ha application in potatoes the chronic trigger was not not for invertebrates and algae for fluopicolide and for algae for metabolite M-03. For the 3 Q100 g ha application in poratoes the chronic trigger was not met for algae for fluopicolide and for metabolite MO03. For the 2 x 100 g/ha application in potatoes the chronic trigger was not mer for afgae foo fluopicolide. For the 1 x 100 g/ha application in potatoes the risk assessment indicates acceptable chronic esk for all aquatic organisms. The consideration of the more realistic FOOUS Step 3 water concentrations is presented below.

Lettuce

ĉ

Lettuce Table 10.2- 43: Chronic risk assessment based on FOCUS Step 2 for the application in lettuce (2 × 100 g a.s./ha)

a.s./na)			K,		5		
Compound		Species 5 5	Endpo [µg/L]		RAC [µg/L]	PECsw.max [µg/L]	RAC≥ PECsw
FLC + PCH SC 6	\$7.5 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	Algae / / / S	ErC 80	890	89	28.662	Yes
Ū,	ÂV,	Fish, chronic <i>Pippephal& promelas</i>	EC10	@ 278	27.8		Yes
Fluopicolide		Privertebrate chronic 🖉 🎽	EC10	180	18	5.60	Yes
Thopfconde		Algae 7 0 Sweletonema costatum 7	E_rC_{50}	73	7.3	5.00	Yes
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Aquane macrophyte	ErC50	> 3200	> 320		Yes
A B		Pimentales prometes	$EC_{10}$	278*	27.8		Yes
м 01		Invertebrate, chronic Dáphnia Dágna	NOEC	190*	19		Yes
(2,6-dichlorobetza	Amide (BAM®	Algae A Pseudokirchneriella subgapitata	$E_rC_{50}$	92000	9200	2.06	Yes
	× ~ ~ ~	Aquatic macrophytes, Lemna gibba	$E_rC_{50}$	97600	9760		Yes
	J j						



Compound	Species	Endpoint [µg/L]		PECsw.max [µg/L]	RAC≥ PEC _{sw}
	Fish, chronic Pimephales promelas	EC ₁₀ 278*	27.8		Y
1-02	Invertebrate, chronic Daphnia magna	NOEC 190*	(D)	0.410	Yes
(3-chloro-5-(trifluoromethyl) pyridine- 2-carboxylic acid)	Algae Navicula pelliculosa	ErC50 74000	7400	0.410	NGES (
	Aquatic macrophyte 🔇 Lemna gibba 🕅	ErC50 > 200*	> 320 (		Yes
	Fish, chronic	EC 27.8**	2,08	2° c	Ŷes
M-03	Invertebrate offonic Daphnia magna	DOECAD**	1.9		Yes
(2,6-dichloro-N-{[3-chloro-5- (trifluoromethyl)-2-pyridinyl] (hydroxy)methyl} benzamide)	Algae O O C Algae Navicula pelliculosa	E.G. 123	1.21	0(438 A	Yes
Å	Aquatic macrophyte	Er <b>C</b> > 320**			N es

* 1st tier parent endpoint (*Skeletonem* and mysids are not considered as tier) species)

Table 10.2- 44:	Chronic risk assessment for sed		on FQCUS Step 2 for the
	application in lettuce (29 100 g	a.s./hay	

Compound	Species &		Endpoint ug/kg		PECsed.max	RAC≥ PEC _{sed}
Fluopicolide	Sediment dwe	fler, chronic S variegatus		198	14.7	Yes
	× (L)	2.4		K)		

Table 10.2- 45: Chronic risk assessment based on FOCKS Step 2 for the application in lettuce (1 × 100 g

Compound	2687.50° 0° 0°	Species 27 4 5	Endpoint [µg/L]	RAC [µg/L]	PEC _{sw.max} [µg/L]	RAC≥ PECsw
		Early application				
FLC + PCH SO	0687.50 × × ×	Algae	E _r C ₅₀ 890	89	16.679	Yes
L. C.		Pimephales prometas	EC ₁₀ 278	27.8		Yes
لمج Fluopicolide	No N	Invertebrate Chronic American Sis bahia	EC ₁₀ 180	18	8.00	Yes
		Algae O ^Y Skeletonema costatum	ErC ₅₀ 73	7.3		No
		Acpatic macrophyte Lemna gibba	$E_r C_{50} > 3200$	> 320		Yes
Fluopicolide						



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw.max [µg/L]	RAC≥ PEC _{sw}
	Fish, chronic Pimephales promelas	EC ₁₀ 278*	27.8		Y
M-01	Invertebrate, chronic Daphnia magna	NOEC 190*	ÍO,	, de la constante de la consta	Yes
(2,6-dichlorobenzamide (BAM))	Algae Pseudokirchneriella subcapitata	E _r C ₅₀ 92000	9200	3.31	ses of
	Aquatic macrophytes, K	ErC ₅₆ 97600	9760		Yes
	Fish, chronic A Pimephales promelas	EC10 258*	37.8	j č	Yes
M-02 3-chloro-5-(trifluoromethyl) pyridine-	Invertebrate, chronic ^o Daphnia magna	NOÉC 1900	19	، مين و(685 ج	¥es
2-carboxylic acid)	Algae Naviéula pelticulosa	BrC ₅₀ 74000 (	7400 %		Yeg
	Aquatic macrophyte	E4C 50 3200*	-@20		Yes
Q.	Fish, Aronic Pimephale&prometas	EC10 27.8*	2.78		Yes
J. K.	hwertebrate, chronic	BOEC 29**	1.9	Ő	Yes
M-03 (2,6-dichloro-N-{[3-chloro-5-	Algae Navicula Delliculosa	Ercs 12,19*	1.2	0.020	Yes
(trifluoromethyl)-2-pyrithyl]				0.828	
(hydroxy)methyl} benzimide)	Aquatic mecrophyre	EQ50 \$20**	> 32		Yes
	Late application		1	1	
FLC + PCH SC 687	Algo A A Navicula polliculo A	E _r C ₅₀ 890	89	16.679	Yes
	Arsh, chronic Ar an	EC ₁₀ 278	27.8		Yes
	Invertebrate, chrone Americanyssis balaia	EC ₁₀ 180	18	2.92	Yes
	Algae Skefelonemá, costatum	ErC ₅₀ 73	7.3	2.92	Yes
	Aquatic macrophyte	$E_r C_{50} > 3200$	> 320		Yes
	Fishychronic Pthephales promelas	EC10 278*	27.8		Yes
	Invertebrate, chronic Daphnia magna	NOEC 190*	19	]	Yes
Fluopicobale M-014 2 (c) dichlor@benzamide (B&M))	Algae Pseudokirchneriella subcapitata	ErC ₅₀ 92000	9200	1.06	Yes
	Aquatic macrophytes, Lemna gibba	ErC ₅₀ 97600	9760		Yes

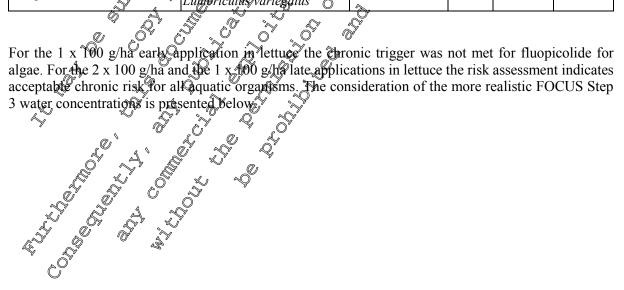


Compound	Species	Endpoint [µg/L]		PECsw.max [µg/L]	RAC≥ PEC _{sw}	
	Fish, chronic Pimephales promelas	EC ₁₀ 278*	27.8		Y	
M-02 (3-chloro-5-(trifluoromethyl) pyridine- 2-carboxylic acid)	Invertebrate, chronic Daphnia magna	NOEC 190*	(D)	0.226	Yes	0°
	Algae Navicula pelliculosa	ErC ₅₀ 74000	7400	0.236	Noes 4	Ŝ,
	Aquatic macrophyte 🖒 Lemna gibba 🔗	ErC ₅₀	> 320		Yes	, ,
	Fish, chronic	EG 27.8**	2,08		Ŷes 0	,O ¥
M-03	Invertebrate offonic Daphnia magna	NOEC 19**	1.9		Yes	
(2,6-dichloro-N-{[3-chloro-5- (trifluoromethyl)-2-pyridinyl]	Algae O O C	Fac 50 18:1 **	1921	0(248	Yes	
(hydroxy)methyl} benzamide)	Agatic macrophyle		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Yes	
* 1 st tier parent endpoint ( <i>Skeletonema</i>	Semna gibba					

** 1st tier parent endpoint divided **by** 10

point divided by 10 Chronic risk assessment for sediment organisms based on FOCUS Step 2 for the application in lettuce (1 × 100 g a c ha) Table 10.2-46:

	· 1			10	× 4.			
Compound		Species		En En	dpoint O [Kg] _(L)	R∱C ∱µg/kg]	PECsed.max [µg/kg]	RAC≥ PECsed
			Early appl	ication		y y		
Fluopicolide	<i>™</i> ~~~	Lumpricul	lwelter, chronic	NO NO	E 1980	198	21.2	Yes
	Ď	A A	Late appli	cation	ð			
Fluopicolide	×	Lumpriculi	lwéller, chironic	NO	ÉC 1980	198	7.63	Yes
		\$.0	/ / r	- A				





#### Cucumber

 Table 10.2- 47:
 Chronic risk assessment based on FOCUS Step 2 for the application in cucumber (3 × 100 g a.s./ha)

Compound	Species	Endpoint		PECsw.max	
Compound	-	[µg/L]	wg/L]	[µg/L]	PEC
	Early application	Ő	ř	^/	
FLC + PCH SC 687.5	Algae Navicula pelliculosa 🔊	ErC50 890	89	36,309	Yes 🐇
	Fish, chronic <i>Pimephales prometas</i>	EC10 278	27.8°		Yes
Fluopicolide	Invertebrate, chronic Americamysis Bahia	EC10 180°	\$8	ر 10.2 ر می	Yes &
laopteonae	Algae Skeletonema costantum	ErC50 73 4	7.3	c A	No
	Aquatic macrophyte C	$E_{r} E_{50} \ge 3200$	⊳ 320 ≪	or do'	Ye
	Fish, chuốn C Simephales promelas	EG40 278 278	2 <b>0</b> 8		Yes
M-01	Invertebrate, chronic Dappnia magna	NOEC 90*	19 లో		Yes
	Algae O L Pseudokirchneriella subcopitata	ExC 50 92000	ලි 9200 දේ දී	3%94 ©	Yes
	Aquatic macrophytes, S Gemna gibba S	E ₁ <b>C</b> ₅₀ 97600	\$ <b>6</b> 0		Yes
M-02	Fish Chronic T Pinephales prometias	EC ₁₀ 278*	27.8		Yes
M-02	Invertebrate, cl <del>ik</del> onic Daphina magga	NOEC 190*	19	0.718	Yes
2-carboxylic acid)	Algae	Er <b>C</b> 50° 74000	7400	0.710	Yes
	Aquatics macrophyte	$E_{\rm r}C_{50} > 3200**$	> 320		Yes
201 201 201 201 201 201 201 201 201 201	Fish, chronic	EC ₁₀ 27.8**	2.78		Yes
M-03 (2,6-dichloré-N-{[3-chloro-S-	Invertebrate, throme, Dáphnia maigna ©	NOEC 19**	1.9	0 776	Yes
M-02 (3-chloro-5-(trifluoromethyl)) pyridine- 2-carboxylic acid) M-03 (2,6-dichloro-N-{[3-chloro-5- (trifluoromethyl)-2-pyridiayl] (hydroxy)methyl} benzamide)	Algae A Navisma pelloulosa	E _r C ₅₀ 12.1**	1.21	0.776	Yes
	Aquatic maerophyte Egmna gubba	$E_r C_{50} > 320^{**}$	> 32		Yes
M-03 (2,6-dichloro-N-{[3-chloro-S- (trifluorontethyl)-2-pyridhayl] (hydroxy)methyl} benzamide)					



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	PECsw.max [µg/L]	RAC≥ PEC _{sw}
	Mid application	•		•	Q
FLC + PCH SC 687.5	Algae Navicula pelliculosa	ErC ₅₀ 890	89 89	36.309	yes (
	Fish, chronic Pimephales promelas	EC10 278	27.8		Yes
Fluopicolide	Invertebrate, chronic Americamysis bahia	$EC_{10}$ 180 $r$	18	7.98 ~O	Yes S
	Algae Skeletonema costantim	ErC ₅₀ 073	7.3%		
	Aquatic macrophyte		\$ 320		Yes
	Fish, chrottic Pimephales pronelas Invertebrates chronic	EC16 278	278	6 Å	Yes
M-01	Dartinia magna	NÓEC 490* 6	19 25		Yes
(2,6-dichlorobenzamide (BAM))	Deudovirchnervella	Er050 92900	9200		Yes
	Aquatic macrophytes,	ErCQ 97600	9560		Yes
	Fish Chronic Pingphale prometas	EC ₁₀ 778* 7	27.89		Yes
M-02 (3-chloro-5-(trifluoromethyl) pyridine 2-carboxylic acid)	Invertebrate, chronic O	NOEC 190* 2	<b>\$9</b> [°]	0.563	Yes
2-carboxylic acid)	Algae Navicula pelliculosa		7400		Yes
	Xquati@macrophyte Lemna gibba?	57C ₅₀ 3200*	> 320		Yes
	Fish, chronic Emephales provielas	EChy 27.8**	2.78		Yes
(2,6-dichloro-N-{[35hloro-5-	Dàphnia magna	NOEC 19**	1.9	0.582	Yes
M-03 (2,6-dichloro-N-{[3;0hloro-5- (trifluoromethyl)-2 pyridifyl] (hydroxy)methyl) benzamide)	NavicQa pellQulosa V AqQuic macrophy	E _r C ₅₀ 12.1**	1.21		Yes
		$E_r C_{50} > 320^{**}$	> 32		Yes
FLC PCH SC 687.5	Algae	E _r C ₅₀ 890	89	36.309	Yes
	Fish, chonic Pimophales promelas	EC ₁₀ 278	27.8		Yes
Fluonicatide of a score	Invertebrate, chronic Americamysis bahia	EC ₁₀ 180	18	12.2	Yes
	Algae Skeletonema costatum	ErC ₅₀ 73	7.3	12.2	No
× CO ^y	Aquatic macrophyte Lemna gibba	$E_r C_{50} > 3200$	> 320		Yes



Compound	Species	Endpoint [µg/L]		PEC _{sw.} .] [μg/L]	max RAC≥ PEC _{sw}
	Fish, chronic Pimephales promelas	EC10 278*	27.8		Y
M-01	Invertebrate, chronic Daphnia magna	NOEC 190*	io,		Ves o
(2,6-dichlorobenzamide (BAM))	Algae Pseudokirchneriella subcapitata	ErC ₅₀ 9200	9200	4.88	in the second
	Aquatic macrophytes, <i>Lemna gibba</i>	ErC ₅₀ 7600	9760		YES
	Fish, chronic A Pimephales pronelas	EC10 2785°	37.8		Yes
M-02 (3-chloro-5-(trifluoromethyl) pyridine-	Invertebrate, chronic ^o Daphnia magna	NOEC 190*		-0 <b>(</b> \$74	¥ es
2-carboxylic acid)	Algae Navićula pelticulosa	Ere 50 74000	, (7400 )		Yes
	Aquatic macrophyte	$E_r C_{59} > 3290^{\circ}$	* <u>&gt;@</u> 20		- Ves
Â,	Fish, Aronic V Pintophale&prometas	EC ₁₀ 7.8**	2.78		Yes
M-03 (2,6-dichloro-N-{[3-chloro-5-	nvertebrate, chronic	NØEC 195*	1.9	0 <del>7</del> 0.970	Yes
(trifluoromethyl)-2-pyridinyl O [*] (hydroxy)methyl} benzamide)	Algae Navicula pelliculosa	ErC56 12.1			Yes
	Aquatic macrophyte	$E_{r}C_{50} = 320*$	Ÿ		Yes
* 1 st tier parent endpoint ( <i>Skoletonend</i> a ** 1 st tier parent endpoint divided by 10			,		
	ssment for sediment organ omber (3 × 100 g a.s. hr)	Ň	OCUS	Step 2 for	r the
Compound Species			AC P 1g/kg] [į	ECsed.max 1g/kg]	RAC≥ PEC _{sed}
	garly application				Γ
Fluopicolide [*]	cuntes variegatus	EC 1980 19	98 2	6.7	Yes
	Mid application				[
	nt dweller, chronic culus variegatus	EC 1980 19	98 2	1.0	Yes
Fluopicolide	<b>Q</b> ate application				

For the early, mid and late 3 x 100 g/ha application in cucumber the chronic trigger was not met for fluopicolitie for algae. The consideration of the more realistic FOCUS Step 3 water concentrations is presented below.



## Chronic risk assessment based on FOCUS Step 3 PEC_{sw} values

#### Potatoes

Potatoes					$\sim$	s./ha)
Table 10.2- 49: C	hronic risk assessmen			á	4 × 100 g a.	s./ha) . ~~
Compound	Species	Endpoint [µg/L] 🔊	RAC [µg/L]	FOCUS Scenario	PEC _{sw,ma}	RAG≥ RÉCsw ⊘
		Farly application	[µg/1]			
			Å	D3 ditch	0524 2	Yes
				~	3.70	Yes y Yes y Yes y
			ø.	D4 stream	3.25	Yes
		Ö Ü ž		D6 alurch	D.51 L	Yés
	Invertebrate, chronic 🔬			D6 ditch		Yes Yes
	Americamysis bahia	EC 10 180		Qnd	7.36	r es
		4 . 4 . 9		R1 pond	9.260 5 2.865 ×	Yes
			S	Ro stream	2.86	X es
		o a s		R2 stream	1082	Yes
Eluonicolide	J ^r 4			R3 stream	4.00 ^O	Yes
luopiconde				193 ditch	0.524	Yes
	x x y		× ×	D4 pond	5.70	Yes
				DQ stream	3.47	Yes
Ĩ,				D6 ditch	1.51	Yes
	Augae Skeletonema costatum	FrC ₅₀ 73	7.3	D6 ditch 26rd	7.36	No
N. N				R1 pond	0.260	Yes
Ę,				R1 stream	2.86	Yes
Ĩ			A'	R2 stream	1.82	Yes
Ŵ.		N & &	2	R3 stream	4.00	Yes
				D3 ditch	0.021	Yes
Å				D4 pond	0.206	Yes
И-03				D4 stream	0.365	Yes
2,6 dichloro-N-{[3-				D6 ditch	0.191	Yes
chloro-5- trifluoromethy	Algae A Algae A Algae A Algae A Algae A A A A A A A A A A A A A A A A A A A	C 12.1*	1.21	D6 ditch 2nd	0.489	Yes
hydroxy)methyl}				R1 pond	0.003	Yes
penzamido S				R1 stream	0.097	Yes
				R2 stream	0.081	Yes
				R3 stream	0.086	Yes
CO*	1	1	1	<u> </u>	1	41



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	RAC≥ PEC _{sw}
		Late applicati	on			<u></u>
				D3 ditch	0.524	Yes
				D4 pond	9.65	Yes
				D4 stream	3.54	Yes
	luopicolide Algae Skeletonema costatum		~	D6 ditter	1.96	Yes
Fluopicolide		7111101	7.3	D©ditch 2nd	14.4	
			, Q	R1 pond	Q125	Yes V
		QO'	$\sim$	Restream	2.770	Øges
			R2 stream	2,01 ~		
				R3 Gream	4.05	Yes ~ °
[•] 1 st tier parent en	dpoint divided by 10 (S		vsidered as a	tier 1 speare	s) 🔬	

* 1 st tier parent en	dpoint divided by 10	(Skeletonema i	synot considered	as a tier 1 specie	s) ", Š
-					
					N Q O
Table 10.2- 50:	Chronic risk asse	and hand		- Con - States	
1 able 10.2- 50:	Chronic risk asse	ssment pased	BUT FUCUS SUR	p's lot paratoes	3 × Leg g a.s.(na)
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			C Pocul	

		A 🔍			
Species 🔬 🧎		BAC (µg/LQ	FOCUS	PEC _{sw,max}	RAC≥ PECsw
D' W	Early applicat	ion 🖑	2 Q	~~~ <u>0</u>	
			D3 ditch	0*524	Yes
~ ~ ~			D4 pond	2.66	Yes
			D4 stream	2.50	Yes
		S Q	D6 ditch	1.12	Yes
Algae Skeletonema costa) 7.5 ^{6,7}	D6 ditch 2nd	4.93	Yes
			R1 pond	0.217	Yes
			R1 stream	2.86	Yes
	N N O		R2 stream	1.82	Yes
		Â	R3 stream	2.58	Yes
		0	D3 ditch	0.014	Yes
6 2 0			D4 pond	0.153	Yes
			D4 stream	0.272	Yes
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		D6 ditch	0.144	Yes
Algae Navicuta pelliculo	sa	1.21	D6 ditch 2nd	0.364	Yes
	~\$		R1 pond	0.003	Yes
			R1 stream	0.067	Yes
			R2 stream	0.063	Yes
Ĵ.			R3 stream	0.069	Yes
	Algae Navicuto pellicuto	Algae Navicula pelliculosa	Algae Navicula pelliculosa	Image: Second role       Second role         Early application       D3 direction         D4 pond       D4 pond         D6 direch       D6 direch         D7 direction       R1 stream         R2 stream       D3 direch         D4 pond       D4 pond         D4 pond       D4 pond         D4 pond       D4 pond         D4 pond       D4 stream         D6 direch       D6 direch         D6 dire	Image         Image <th< td=""></th<>



Õ

Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	RAC≥ PEC _{sw}
		Late applicati	ion			<u></u>
				D3 ditch	0.524	Yes
				D4 pond	2.59	Yes
				D4 stream	2.49	Yes
				D6 diten	1.35	Yes
Fluopicolide	Algae Skeletonema costatui	n $1 = 50$ $1 = 10$	₹ 7.3	D@ditch Znd	14.1	
				R1 pond	00072	Yes
		AD T		Restream	1.54 0	øşes Ø
		s s		R2 stream	1,00 ~	
				R3 Gream	9.67	Yes ~
¹ 1 st tier parent en	dpoint divided by 10 (Skel	etonema is not con	vsidered as a	tier 1 specie	s)	

i tier purent ene	ipoliti divided by it	o (Sheren ienia		Og us u tree	i shours) «	1
			' 0,' L	ĩ N	N N	
			`~~`~~`		S 01	
				×9.	Û 🔊	
Table 10.2- 51:	Chronic risk as	sessment based	an FOCAS S	ten 3 for p	otatoes 2 × 1	(H) g a.s.(Da)
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				<b>B 1 1 1 1 1</b>

Compound	Species 2		ℳµ́g/L Q	FOCUS Scenario		RAC≥ PEC _{sw}
	st in the second	Early application	on 🖑		Ča –	
				D3 ditch	0*\$24	Yes
				D4 pond	0.72	Yes
ð				D4 stream	1.62	Yes
, S			S Ó	D6 ditch	0.742	Yes
Fluopicolide	Algae	Entry approximation of the second sec	, 3 ² , 0 7, 5 ⁵ ,	D6 ditch	2.98	Yes
				R1 pond	0.152	Yes
1 A A A A A A A A A A A A A A A A A A A				R1 stream	1.42	Yes
				R2 stream	1.32	Yes
			¹ S	R3 stream	2.58	Yes
~Ŷ		Y & A	ý ·			

For the 40x 100 g/ha and 3 x 100 g/ha applications in potatoes the chronic trigger was not met for fluopicolide for algae for the scenario D6 ditch 2% for metabolite M-03 the chronic trigger was met for algae for all scenarios. For the 2 x 100 g/ha application in poratoes the chronic trigger was met for algae for all scenarios.

A refined tisk assessment for the use in potatoes for the chronic algae is presented below. Those scenarios are presented which do not pass the risk assessment at Tier 1.



0

Lettuce

Table 10.2- 52: Chronic risk assessment based on FOCUS Step 3 for lettuce (1 × 100 g a.s./ha)

Compound	Species	Endpoint	RAC	FOCUS	PEC _{sw,max}	RAC≥ PEC _{sw}
1	•	[µg/L]	[µg/L]	Scenario	[µg/L]	
		Early applic	ation			
				D3 ditch	0.634	Yes
			Ì	D3 ditch &	0.635	Yes y a
			, ^(C)	D4 pond	0.714	Yes
		Ú.	Y	D∮ stream₀	0.675	Yes 2 2 Yes 2 2 Yes 2 2 Yes 2 2
		Q ^{0, y}	~	D6 diten	1.6%	Yes O O Yes O O Yes O O Yès V
				R1 pond	0.094	Ýð 🗸
	A		BI pond 2nd	0.079 Č	Yes y	
Chuoni a a li da	Algae			Rlotream	0.983	Yes S
Fluopicolide	Skeletonema costatum			Rel stream 2nd	0.983 0.553 0.562	Yes
				D Matura and	0.553	Yes
				1 stream	0.562 (Yes
				2nd R3 stream	1.31	Yes
			R3 stream	1.31 2.00 4	Yes	
		Å.	2nd O			
			R4 stream		Yes	
				R4 stream 2nd @	2.40	Yes

For the 1x 100 g/ha application in lettuce acceptable chronic risk to algae could be proven for all FOCUS Step 3 scenarios.

Compound	Species A	Endpoint O	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	$RAC \ge PEC_{sw}$
		Early applica	tion			
		Q.		D6 ditch	1.54	Yes
F1 · 1.	Algae 5 1		7.2	R2 stream	2.10	Yes
Fluopicolid	Algae 5 5 Steletonema costatum	Ĕ _r C ₅₀ 73	7.3	R3 stream	5.37	Yes
				R4 stream	8.33	No
			1	•	1	
°°						



Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$
		Mid appl	ication			<u>v</u> °
Fluopicolide Algae Skeletonema costatum			D6 ditch	4.75	Yes X	
	F.G. 72	7.0	R2 stream	1.1	Yes 0 5	
		$E_r C_{50}$ 73	7.3	R3 stream	3.06	Yes
			R4 stream		R4 stream	7.85
	•	Late appl	ication	Ű	Č	
Fluopicolide	Algae Skeletonema costatum	ErC50 73		D6 Grich R2 stream R3 stream R4 stream	10.2 × 2.39 × 2.	No A

For the early applications in cucumber the chronic trigger was not met for fluppicolide for algae for the scenario R4 stream.

For the mid applications in cucumber the chronic trigger was not met for fluoppeolide for algae for the n scenario R4 stream.

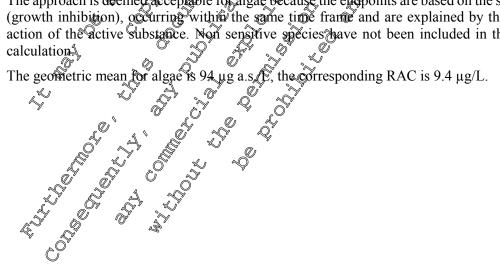
For the late applications in cucumber the chronic trigger scenarios D6 ditch and P4 at 2 not met for Duopic Quide for algae for the scenarios D6 ditch and R4 stream.

2007 A refined risk assessment for the use in cuclimber for the chronic algae is presented below. Those scenarios are presented which do not pass the risk assessment at the 3

Refinement of chromic risk assessment for algae

Two diatoms species Naviana periculosa and Skeletoneme Costatum) have been tested with fluopicoude and as expected for fungicides targeting on weeks diatoms are the most sensitive algae taxonomic group. Ageometric mean endpoint can be calculated for these 2 species (tier 2a of the AGD).

The approach is deemed acceptable for algae because the endpoints are based on the same type of effects (growth inhibition), occurring within the some time frame and are explained by the specific mode of action of the active substance. Non sensitive species have not been included in the geometric mean





Potatoes

Table 10.2- 54:	Refined chronic risk assessment based on FOCUS Step 3 for potatoes (4 × 100 g a.s./ha)
-----------------	--

Compound	Species	Endpoint [µg/L]	RAC [µg/L]	FOCUS Scenario	PECsw,max [µg/L]	RAC≥PEC	sw jog
		Early appli	cation		Å.	L.	Ś
Fluopicolide	Navicula pelliculosa Skeletonema costatum	94	9.4	D6 ditch 2nd	7.36	Yes	, A A
		Late applic	ation		\$ }		S.
Fluopicolide	Navicula pelliculosa Skeletonema costatum	94	9.4	D6 ditch 2nd	14.4	NO ST	
		A		Q' p		r. O	. V

Table 10.2- 55: Refined chronic risk assessment based on FOCLS Step 3 for potatoe 3 × 100 g a.s. (ba)

Compound	Species	Endpoint		OCUS scenario	PECW,max R	ACOPEC
		/ Late applica	tion 20°			
Fluopicolide	Navicula pelliculosa	944 0	7 94 1/4	90 ditch	144 N	
			r S			° M

No acceptable chronic risk to argae could be proven for the FOCL'S Step3 scenarios. Therefore, the risk assessment based on FOCUS Step 4 water conceptrations is presented below.

Cucumber

Table 10.2- 56: Refined chronic risk assessment based on FOGUS Step 3 for cucumber

Compound	Species (Endpoint hg/L]	RAC	FOCUS Scengrio	PEC _{sw,max} [µg/L]	$RAC \ge PEC_{sw}$		
2 L L Eady application								
Fluopicolide	Navicula pellicutosa Skeletonema costatum		9.4	\mathbf{R}^{*} R4 stream	8.33	Yes		
ک م ⁽								
Fluopicolide	Navicula velliculosa Skeletogema costatum		9 04	R4 stream	7.85	Yes		
A O D Late application								
Fluopicolide	Navicuta pellicutosa			D6 ditch	10.2	No		
	Skeletonema costatum		9.4	R4 stream	9.06	Yes		
Ĭ	O' E'	<u>~~</u> _0×						

No acceptable chronic risk to algae could be proven for the FOCUS Step 3 D6 ditch scenario of the late application. Therefore, the risk assessment based on FOCUS Step 4 water concentrations is presented below.

Chronic risk assessment based on FOCUS Step 4 PEC_{sw} values

The only scenario that does not pass the chronic risk assessment based on FOCUS Step 3 PEC_{sw} values is D6 ditch. Even though mitigation by the introduction of buffer zones or by the use of drift reduction



nozzles is not relevant for drainage scenarios, the chronic risk assessment based on FOCUS Step 4 water concentrations is presented below for the sake of completeness.

	FOCUS Scenario				PEC _{sw} ,	, max [µg/L]	<i>A</i>		ha)
				Late ap	plication		Č,	, N	
Nozzle	Vegetated strip (m)	None	None	None	Norpe	None	©10 m	100m	20 m
reduction	No spray buffer (m)	0 m	5 m	10 m	_4⊈15 m	20 m	10 m	^O 15 m [^]	20 m
None	D6 Ditch	14.4	14.4	14.4	14.4	©14.4	14.2	A.4 👡	V 14.9
50 %	2nd	14.4	14.4	10.4	,¢14.4 ×	14.3	204 .4	§ 14.4	<u>ال</u> 4.4
75 %		14.4	14.4	A14.4 0	14.4	19.4	14.4	1494	\$14.4°
90 %		14.4	14.4	14.4	J 4 .4	014.4	1%A	, ×4.4 ∢	144
	· · · ·		R	«ƘAC≥ٍ	PECsa		Č é	<u>, 6</u> 7	è.
None	RAC	No	No	[™] No [™]	No		NO	No .	🖉 No
50 %	= 9.4 μg/L	No	No	No	No d	Nor	ð,	O No ₆	No
75 %] [No	No	- NT	No		ار No	NO	No
90 %		Ng	No .	> No		No 🔊	Noy	N O	No

		0
Table 10 2- 57	Chronic risk assessment based on FOCUS Step 4 for notatoes $(4 \times 100 \text{ g a s})$	s.

 Table 10.2- 58:
 Chronic fisk assersment based on FOCOS Step 4 for potatoes (3 × 100 g a.s./ha)

	FOCUS Scenario					, mæstur fug/L]	¥)		
	Late application								
Nozzle [×] reduction	Vegetater strip (m)	None [®]	None	None C	O.	None	10 m	10 m	20 m
	No spray buffer (m)	70 m 4	5 m	100 m	15 m	20 m	10 m	15 m	20 m
None	D6 Ditch	4₽Ĩ	~14.1 Q	1405	₩ .1	14.1	14.1	14.1	14.1
50 %	2nd	© 14.1 ~	7 14 5 -	*#.1 .	L 14.1	14.1	14.1	14.1	14.1
75 %		14,1	~1.4.1	\$~14.] ~Q	14.1	14.1	14.1	14.1	14.1
9 0 /%	\$\$°	19.1	~14.1 Q	149	14.1	14.1	14.1	14.1	14.1
	$\mathbb{R}^{R} \to \mathbb{R}^{R} \to \mathbb{R}^{R}$								
None		NO	Ň0 (No	No	No	No	No	No
50 %	\$9.4 µgµL	No Å	ÿ No ^{≁Q™}	No	No	No	No	No	No
75 % \$ 90%	9.4 µter	No	No	No	No	No	No	No	No
90%		Ň	No	No	No	No	No	No	No
45 6 ⁵	900 - E 9	L.							



La	te application	<i>◎</i>
Nozzle reduction	PEC _{sw, max} [µg/L]	
FOCUS Scenario	D6 ditch	
None	10.2	
90 %	10.2	
95 %	10.2	
99 %	10.2	
$RAC = 9.4 \ \mu g/L$	A A	
None	No 20 27 27 27 27 27 27 27 27 27 27 27 27 27	
50 %		
75 %	No & C O	
90 %	No Y Y	A S & C

Combined toxicity risk assessment

According to the EFSA "Guidance on fiered task assessmen for plant projection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013,11(7):3290, chapter 10.3.11), for products containing more than one active substances, the mixture toxicity shall be addressed via the Concentration Addition (CA) Model. And, following the recommendations of the FFSA "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (EFSA Supporting publication 2019: ENX 673), it is necessary to consider whether the formulation is more or less toxic than the parents. When the endpoint of the PPP (expressed in terms of fluopicolide) is at least three times lower than the equivalent endpoint for the active substance. It should be considered to be more toxic.

The measured toxicity data (ECx) available for the given endpoint is shown in the table below for the formulated product (PPP) Fluopicolitie + Propamocarb bydrochloride SC 687.5 and the active substances fluopicolide and propamocarb-hydrochloride.

Is the formulation three times more toxic than furpicotide?

Table 10.2- 60: Table 10.2-

Test species	Endopoint and Test system	Measured toxicity of PPE [mg.prod./L	Éuopicolide	Formulation endpoint recalculated for fluopicolide* [mg a.s./L]	Fluopicolide endpoint / Recalculated formulation endpoint
O. myking	C ₅₀ , soute,		0.36	0.38	0.95
D. magnet	BC_{50} , as a term 48 h	> 100	> 1.8	not calculated	-
N. petiticulosa	E _r C ₅₀ , short- term, 72 h	0.89	0.121	0.05	2.4

* amount of fluopicolide in the test item used in formulation studies: 5.73%



Regarding fish, aquatic invertebrates and algae, endpoints are available for both, formulation (ECx_{PPP}) and a.s. (ECx as).

No meaningful comparison can be performed for *Daphnia* due to unbound values for both the formulation and the active substance.

The formulation is not more than 3 times more toxic than fluopicolide.

MDR calculation

Th calculation is performed only for fish and algae due to the unbound values for *Darphia*. As a conservative approach the lowest endpoints for fish and algae are used in the calculation, therefore different species are considered.

Table 10.2- 61:	Overview of endpoints available for the formulated product (PPP) Fluopicotie +	
	Propamocarb-hydrochloride SC 87.5 and the active substances fluopicolide and	
	propamocarb-hydrochloride	

I	oropamocarb-nyurocnieriue
Test species	Endpoint and test system prig prof./L]
O. mykiss/ L. macrochirus	LC ₅₀ , acute, 96, b \bigcirc
D. magna	EC_{50} , acute 48 h 3^{-3} 3^{+} 5^{-3}
N. pelliculosa / S. costatum	$E_{rC_{50}}$

 Table 10.2- 62:
 Summary of results Obtained in the studies with the formulated product (PPP)

 Fluopicolide + Propamocard-hydrochloride SC 687.5 and comparison of calculated and measured mixture toxicity

Test species	Endpoint and test	Measured oxicity oPPP (converted to be a.s. based) (EC 50 ppp or EC 50 ppp) (mg tofal a.s. J.)	Calculated mixture toxicity ^A (a.s. in product) LC _{50 mix-CA} or EC _{50 mix-CA} [mg total a.s./L]	Model deviation ratio (MDR = EC _{50 mix-CA} / EC _{50 PPP})
Fish	LC50, acute, 96 h	4.085	3.744	0.92
Algae	ErC50, stort-term, 72 h	0.551	0.782	1.42

^A The mixture oxicity of the formulation was re-calculated based on the measured contents of fluopicolide (64.7 g/L), and propamocate-hydrochloride 634 g/L) within the formulation and the product density (1.129 g/cm³).

The calculated MDR values are between 0.2 and 5 for fish, and algae, indicating that the formulation does not cause an (inexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants.

Therefore, the evaluation of the safety of the formulation can be based on the risk assessment of fluopicolide. Nevertheless, a formulation-based risk assessment has also been performed and was presented above.



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

Data Point:	KCP 10.2.1/01
Report Author:	
Report Year:	2003
Report Title:	AE B066752 04 SC61 A1: Acute toxicity test with rainbow trout (Oncorhynchits
	mykiss) under static conditions
Report No:	C038493
Document No:	<u>M-225109-01-1</u>
Guideline(s) followed in	OECD: 203, (1992)
study:	
Deviations from current	Method: Deviations from current guideline SANCO/302999 rev 4 Limited sets of validation recoveries were analysed. However, the average
test guideline:	
	recoveries were within the acceptable time of 70–110% and the RSD values were
	below 20%. The analytical nothod can be regarded as fit for purpose.
	Study: Current Guideline: DECD 203 (2009)
	The temperature slightly exceeded the nighest recommended value of 14°C (144°
	C for discrete measurements of 14.6° according to the min-max recording). This
	deviation is considered minor with no impact on the test results because the former
	version of the OECP guideline recommended a range of 3-17° Stor troat.
	The fish bading is 0.92 g/L which exceed the recommended value of 0.8 g/L but
	all validity criteria of the study are fulfilled and the former version of the guideline
Previous evaluation:	allowed a loading rate up to 0 g/L.
rievious evaluation.	yes, evaluated and accepted and FLC DAR 2005; in Repamocarb RAR June 2017
GLP/Officially	Yes, conducted under GLP/Officially recognised testing factities
recognised testing	of the second se
facilities:	
Acceptability/Reliability:	Ayes S S S S S S
S N	

Executive summary O

An acute toxicity test was performed with the rainbow frout (Oncorffynchus mykiss) in a static system. Juvenile rainbow trout were expressed to fluopicolide + proparnocarb-hydrochloride SC 687.5 at nominal concentrations of 0.628, 1.2507.5, 5.0 and 10 mg/D in well water for a 96- hour period. Additionally, a negative and a solvent coutrol was included. All treatments had 10 fish per test vessel (10 fish per treatment level). Dest solution were not reflewed. Mortality, toxicity values and behaviour were recorded at time points 0, 24, 48, 72, and 96 hours.

Recoveries were between 68.2 and 109%. Analysis of the test solution were only 68.2% recovery occurred at day 0 showed recovery of 22.2% at day PAs all other measured values were in the range of 80-120% recovery LC 50 values and biological data are based on nominal concentrations. There was no flucpicolide residue found in the control samples. All samples were analysed by Gas Chronoatography with ECP detector.

The study fulfils all validity criteria of the current version of OECD 203 guideline.

Ľ

Mortality occurred at 5 mg/L and above, with 100% mortality observed at 72 h at 10 mg/L. Sublethal effects were observed in one fish at 0.625 and 5.0 mg/L and in all living fish at 10 mg/L. The 96-hour LC_{50} of fluppicolide technical to rainbox trout is calculated as 6.6 mg/L (95% CL = 5 to 10 mg/L). The lowest observed soncentration with mortality is 5 mg/L. The highest concentration without mortality is 2.5 mg

E THE CHART ST



I. MATERIAL AND METHODS:

Test material	Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625)
i est materiai	Code (AE B066752 04 SC61 A1)
	Batch No: OP220159 Active ingredients: 64.7 g/L fluopicolide, 634 g/L propamocarb- hydrochloride Density: 1.129 g/mL None specified Rainbow trout (<i>Oncorhynchus mykiss</i>)
	Density: 1.129 g/mL
Guideline(s)	None specified
adaptation	
Test species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Acclimation	Health during acclimation: No mortality during 48 hours prior to testing, less than 10% during 7 days before test start
Organism age/size	Mean length: 51 cm (range: 44 – 60 cm) representative sample two days before exposure Mean body weight 1.34 g (range: 0.77 = 2.12 g) representative sample two days before exposure
Test solutions	Nominal concentrations: 0,625, 1, 25, 2.5, 5.0 and 10 mg/L. Corresponding mean recovery: 80.2, 98, 98, 5, 104.0 100 4% Controls: water Evidence of undissolved material: Not stated
Replication	No. of vessels per concentration beplicates): 1
Organisms per replicate	No. of organisms per vessel 10
Exposure	Static & & & & & & & & & & & & & & & & & & &
Test Vessel Loading	
Feeding during test	None & OF & S
Test conditions	Temperature: $13.6-14.4$ (single measurements in all test vessels) 13.9-14.6 (continuous measurements in the control wessels)
	Photoperiod: 6 hours light 8 hours dark; with 30 min transition periods Light 19 hours dark; with 30 min transition periods
	pH: $\sqrt{7.32} - 7.68$ Dissolved oxygen: 9 10 - 11.09 mg/L (91 - 113 % of saturation)
^	Water hardness: 552 - 156 mg CaCO ₃ /L
°	The test vessels were examined at start of exposure and after 24, 48, 72 and 66 hours for portality, sublethal effects and physical characteristics.
	The pH, dissolved oxygen concentration and temperature were measured in the control and the test concentrations daily. The temperature was monitored continuously by placing the probe of a min/max thermometer in the control aquarium.
Sampling for Chemical analysis	Samples of test solutions were taken at test initiation (0 hour) and at test termination (96 hours) for analysis of fluopicolide. Samples were analysed by using a gas-chromatography with ECD detector. Fluopicolide, one active



	ingredient of Fluopicolide + Propamocarb-hydrochloride SC 687.5 was measured to derive the concentration of Fluopicolide + Propamocarb- hydrochloride SC 687.5 in the samples.
Data analysis	The LC _{50 values} were calculated by a computer program. The 24 hour 155_{50} was calculated by probit analysis, a binomial test was selected for the calculation of the 24, 48, 72 and 96-hour LC ₅₀ values.

II. RESULTS AND DISCUSSION:	II.	RESULTS	AND	DISCUSSION:
-----------------------------	-----	---------	-----	-------------

П.	RESULTS AND DISCUSSION:	
Validity criteria (OECD 203, 2019)	Required	Officianed 2
Mortality in control during test	£10%	
Dissolved oxygen saturation		Q 91,-013% 0 0
Analytical measurement of test concentrations	Compulsory	Done w
	A W Q	~ 07 27

Analytical results:

Recoveries were between 68.2 and 10% (see table below). Analysis of the test solution where only 68.2% recovery occurred at day 0, showed precovery of 2.2% at day 4. As all other measured values were in the range of 80-120% recovery, and this low recovery was observed at a concentration which had no impact on the statistical analysis, I 450 values and biological data are based on nominal concentrations. No residues were found in the control samples above the limit of quantification (0.01 mg/L for fluopicolide + propamocarb-hydrochloride SC 687.5). Ś

Nominal concentration	S Day 0 (New) Day 4 (Aged)	Day 0 and Day 4
(mg/L)	Keeøvery K	% Mean recovery
0.625		80.2
1.25	96.8 × 1010 0	98.9
2:5,7		98.5
\$5.0		104.0
10.0		100.4
Ô		

Full details an Caccep able validation data of support this method are presented within document M-CA 4, which comply with the EU regulatory requirements outlined within SANCO/3029/99 rev 4 with minor acceptable exceptions only.

Biological results:

Observations

After 48-hours sub-lethal effects, i.e. dark colour was observed in one fish in the 0.625 mg/L treatment. In the treatment with 5 mg/L, sub-lether effects were observed int one fish, i.e. complete loss of equilibrium, swimming on bottom and lethargy. In the highest treatment, sublethal effects (complete loss of equilibrium, swimming on bottom, lethargy) were observed in all living fish.

and a start



Exposure time (hours)	0	24	48	72	96 °
Nominal conc. (mg/L)	No of dead (%)	No of dead (%)	No of dead (%)	No of dead (%	No of dead
Control	0 (0)	0 (0)	0 (0)	0,00)	*(0), *(
0.625	0 (0)	0 (0)	0 (0)	<u> (10)</u>	\$1(140)
1.25	0 (0)	0 (0)	0 (0)	× ^v 0 (0)	2 0 0 × 2
2.5	0 (0)	0 (0)	Q 0 (0)	<mark>ග් 0 (0)</mark> රී	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
5.0	0 (0)	0 (0)	0 (0)	1 (10)	×1 (100)
10.0	0 (0)	5 (50)	8 (80)	,10 (100)	10 (100)

Mortality

Ó III. CONCLUSION

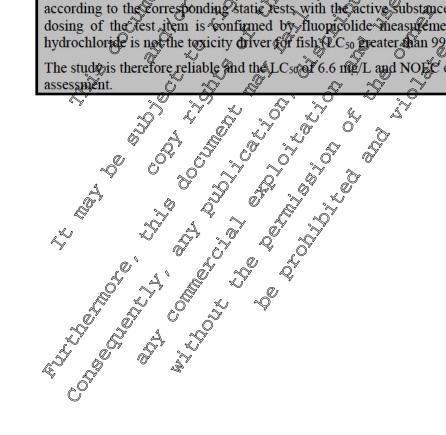
The study meets the validity criteria and the endpoints based on cominal concentrations are:

LC50 96 hours (95% @L):	6.6 mg/L 5 (5 – W mg/L) 0
LOEC: Of the second sec	T T T So mg D T
NOEC: A Solution NOEC: N	

Assessment and conclusion by applicant:

The concentrations of fluor colide only were an ovtically determined during the test. However, this study is still considered refiable because propariocare hydrochloride is stable in the test conditions according to the corresponding static rests with the active substance propamocarb and the correct dosing of the test item is confirmed by fluopicolide measurements. Moreover, propamocarbhydrochloride is no the toxicity oriver for fish (LC50 greater than 92 mg/L).

The stude is therefore reliable and the LC 50 of 6.6 mg/L and NOFC of 2.5 mg/L can be used in risk





Data Point:	KCP 10.2.1/02	
Report Author:		
Report Year:	2003	
Report Title:	AE B066752 04 SC61 A1: Acute toxicity test with common carp (Cyprinus carpio) under static conditions	F F
Report No:	C039853	
Document No:	M-227280-01-1	
Guideline(s) followed in study:	OECD: 203 (1992)	ļo,
Deviations from current test guideline:	Method: Deviations from current grideline SANCQ/3029/99 rev 4 Limited sets of validation recoveries were analysed. However, the average recoveries were within the acceptable range of 00–110% and the RSD values were below 20%. The analytical method can be regarded as fit for purpose. Study: Current Guideline: DECD 203 (2019)	
Previous evaluation:	yes, evaluated and accepted & A A Jupe 2017	
GLP/Officially	Yes, conducted under GLP Officially recognised testing facilitie	
recognised testing facilities:	Yes, conducted under GLB Officially recognised testing facilities	
Acceptability/Reliability:	Yes Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q	
Executive summary		

Executive summary

An acute toxicity test was performed with the common carp (Cyprinus carpio) in a static system. Juvenile common carp were exposed to fluppicolide + propamoearb-hydrochlogide SC 687.5 at nominal concentrations of 6.25, 126, 25, 50 and 500 mg/L in well water for 96-hour period. Additionally, a negative and a solvent control was included All treatments had 10 fish per test vessel (10 fish per treatment level). Test solutions were not renewed. Mortality toxicity values and behaviour were recorded at time points 0, 24, 48, 72 and 96 hours Recoveries were between 58.9 and 101% (see table between recoveries at 50 and 100 mg test

item/L were most likely due to precipitation Since all concentrations relevant for the interpretation of the biological data were within $\pm 20\%$ of the mean measured concentrations, the biological data were based on nominal concentrations. No residues were found in the control samples. All samples were analysed by Gas Chromatography with ECD detector. analysed by Gas Chromatography with ECD detector. The study fulfils all validity operia of the current persion of OEOD 203 guideline.

Mortality occurred at 12.5 mg/L and above with 100% mortality observed at 48 h at 50 mg/L. Sublethal effects were observed in one fish at 12.5 mg/L and above all over the study in surviving fish. The 96-hour LC_{50} of fluopicolice + propamorarb-hydrochloride SC 687.5 to common carp is calculated as 18 mg/L (95% Cle = 12 Dio 25 mg/L), The lowest observed Concentration with mortality is 25 mg/L. The highest concentration without mortality is 12.5 mg/L.

	I. MATERIAL AND METHODS:
Test material	Fluopicolide Propanocarb-hydrochloride SC 687.5 (62.5 + 625)
	Code (AE B066752 04 SC61 A1)
	Batch No. OP220159
	Active ingredients: 64.7 g/L fluopicolide, 634 g/L propamocarb-
	hydrochloride Donsity: 1.129 g/mL
Guideline(s)	None specified
Test species	Common carp (<i>Cyprinus carpio</i>)



Acclimation	At least 14 days Health during acclimation: 2.6% mortality during 72 hours prior to testing
Organism age/size	Mean length: 3.7 cm (range: $3.0 - 4.0 \text{ cm}$) at the end of the study Mean body weight: 0.48 g (range: $0.23 - 0.71 \text{ g}$) at the end of the study
Test solutions	Nominal concentrations: 6.25 – 12.5 – 25 – 50 – 100 mg/L. Corresponding mean recovery: 97.0, 98.6, 97.1, 870, 85.0% Controls: reconstituted water Evidence of undissolved material: At the 50 and 100 mg/L concentrations precipitated test material was observed on the bottom of the test vessels
Replication	No. of vessels per control deplicates): 1
Organisms per replicate	No. of organisms per vessel: 10
Exposure	Static Total exposure duration: 96 bours A A A A A A A A A A A A A A A A A A A
Test Vessel Loading	0.28 g fish/b test medium
Feeding during test	None of the state
Test conditions	Temperature: 21.7 22.8 C (single measurements in all test vessels) 21.8 – 23.6 °C (continuous measurements in the control vessels) Photoperiod: 16 hours light / 8 hours dark, with 30 min transition periods Light intensity: 362 - 467 tax pH 7.17 - 7.71. Water hardness, 160-164 mg CaCO/L Dissolved oxygen: 7.20 - 8.52 mg L (79 + 103 %) Conductivity: 480 × 500 ft S/cm Atkalinity: 30 × 40 mg C
Parameters Measured / Observations	after 24, 48 72 and 96 hours. The pH, dissolved oxygen concentration and temperature were measured in the control anothe test concentrations daily. The temperature was also monifored continuously by placing the probe of a min/max thermometer in the control aquarrum.
	Samples of test solutions were taken at test initiation (0 hour) and at test fermination (96 hours) for analysis of test substance. Samples were analysed by using a gas-chiomatography with ECD detector. Fluopicolide, one active ingredient of Fluopicolide + Propamocarb-hydrochloride SC 687.5 was measured to derive the concentration of Fluopicolide + Propamocarb- hydrochloride SC 687.5 in the samples.
Data analys	The LC v_{values} were calculated by a computer program. The 24-hour LC ₅₀ was calculated by probit analysis, a binomial test was selected for the calculation of the 48, 72 and 96-hour LC ₅₀ values.
Data analysts	



			^` ~
Validity criteria (OECD 203, 2019)	Required	Obtained	
Mortality in control during test	<u>≤</u> 10%	> 10 %	
Dissolved oxygen saturation	<u>≥</u> 60%	79 - 103%	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Analytical measurement of test concentrations	<u>Compulsory</u>		
		ja di si	<u>N IV</u> IV

II. RESULTS AND DISCUSSION:

Analytical results:

Recoveries were between 68.9 and 101% (see table below). The lower recoveries at 50 and 100 mg test item/L were most likely due to precipitation. Since all concentrations refevant for the interpretation of the biological data were within ± 20% of the mean measured concentrations, the biological data were based on nominal concentrations.

No residues were found in the control samples aboy whe light of quantification (0.76 mg fluopicolide + propamocarb-hydrochloride SC 687.5). Ő,

Nominal concentration	Day 0 (New) T Day 4 (Aged) T Day 9 and Day 4
(mg/L)	% Recovery % % Mean recovery
6.25	\$9.6 \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$ \$\$
12.5	98.8 5 0 0 98.4 5 98.6
25	$1 \qquad \qquad$
50	99.3 75.2* ° 75.2* ° 87.3
100	85.0 K 100 K K K K K K K K K K K K K K K K
*M	

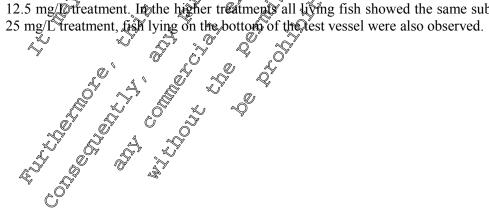
*Measured at 48h because all fish were dead

Full details and acceptable validation data to support this method are presented within document M-CA 4, which comply with the Et regulatory requirements offlined within SANCO/3029/99 rev 4 with minor acceptable exceptions only.

Õ

Biological results

12.5 mg/@treatment. In the higher treatments all living fish showed the same sublethal effects. In the





Exposure time (hours)	0	24	48	72	96°
Nominal conc. (mg/L)	No of dead (%)	No of dead (%)	No of dead (%)	No of dead	No of dead
Control	0 (0)	0 (0)	0 (0)	0.10)	1 (10)
6.25	0 (0)	0 (0)	0 (0)	₄ 0 (0)	S 0 (Q)
12.5	0 (0)	0 (0)	0 (0)	× ¹ 0 (0)	~ 0,0 ×
25	0 (0)	1 (10)	6 (60)	(90)	10(100)
50	0 (0)	2 (20)	10 (100)	10 (100)	310 (106)
100	0 (0)	1 (10)	10 (100)	10 (100)	×10 (190)

Mortality

III. CONCLASSIONS

The study meets the validity criteria and the endpoints based on nominal concentrations are

	/ . ¥ _¥		2 V
LC50 96 hours (95% .I.		√ 0 √ 18 mg/L ~ ∀ ~	Ő
LOEC: Jowest concentration with an effect	(mortadity)		N Y
highest concentration without m	nocality	12.9mg/by	

Assessment and conclusion by applicant

The concentrations of fluopicolide only were analytically determined during the test. However, this study is still considered reliable because propamocarb is stable in the test conditions according to the corresponding static tests with the active substance propanacarb and the correct dosing of the test item is confirmed by fluopicolide measurements. Moreover, propamocarb-hydrochloride is not

Ø

The study is reliable and the LC of 18 mg/L and NBEC of 12.5 mg/L can be used in risk assessment.

the second state of the se



Data Point:	KCP 10.2.1/03	
Report Author:		
Report Year:	2003	~
Report Title:	AE B066752 04 SC61 A1: Acute immobilisation test with daphnids (Daphnia) magna) under static conditions	J. D
Report No:	C039856	
Document No:	<u>M-227283-01-1</u>	
Guideline(s) followed in study:	OECD: 202-1 (1984)	Ĩ,
Deviations from current test guideline:	Method: Deviations from current goideline SANCO/3029/99 rev4. Limited sets of validation recoveries were analysed. However, the average recoveries were within the acceptable range of 0–110% and the RSB values were below 20%. The analyse all method can be regarded as at for purpose. Study: Current Guideline, DECD 202 (2004)	
Previous evaluation:	yes, evaluated and accepted 6 2 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	
GLP/Officially	Yes, conducted under GLP Officially recognised testing facilities	
recognised testing facilities:	Yes, conducted under GLAPOfficially recognised testing facilities	
Acceptability/Reliability:	Yes Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q	
Exacutiva summary		

Executive summary

An acute toxicity test was performed with water the (Daphnia pagna) in a Gatic System. Neonate daphnids (less than 24 hours old), were exposed to nominal concentrations of @(control), 6.25, 12.5, 25, 50 and 100 mg prod./ L of the test substance floopicolide + propanse carb-by droch or de SC 687.5 in modified Elendt M4 medium (19.4 - 21.2°C) for a 48 hour period. All treatments were conducted with 4 replicates with 5 daphnids per test vessel. Test solutions were got renewed. Observations for immobility and for approximal appearance and behaviour were performed at 0, 24, and 48 hours. Samples of the test solutions were taken at 9 hours and 48 hours (study termination) All samples were analysed using gas chromatography (GC) with ECD detector, The recoveries from the test solutions at hour 0 and hour 48 ranged from \$1.6 to 1200. Since all concentrations relevant for the interpretation of the biological data were within ± 20% of the nominal concentration, the biological data were based on nominal concentrations. The study fullis al validity criteria of the current version of OECD 202 guideline. No mortality or sofstance related subjethal effects overe observed in the control or any treatment during the study. The endpoints based on nominal concentrations are: EC_{50} 48 hours > 100 mg prod./L and NOEC = 100 mol.

~	
Test material	Fluopicolide Propanocaro-hydrochloride SC 687.5 (62.5 + 625)
	Code AE B066752 04 SC61 A
A.	Batch No. OP220159
	Activeingredients: 64.7 g/2 fluopicolide, 634 g/L propamocarb-hydrochloride
<u> </u>	Dunsity. 12/2/2011
Guideline(s)	None specified
adaptation	
adaptation Test species	Water flea (Daphnia magna)
Organish	First instar neonates, less than 24 hours old
age/sige at	
study	
initiation	



Culture conditions	Same conditions as in the test. Daphnids were fed green algae (Ankistrodesmus falcatus)
Test solutions	6.25, 12.5, 25, 50 and 100 mg product/L (nominal concentration) Controls: dilution water control (modified Elendt M4 medium) A stock solution with a nominal concentration of 1000 mg test item/L was prepared by diluting 501.0 mg test item in 500 mL medium. This speck was further diluted with medium to obtain the exposure concentrations. Flasks were carefully shaken in order to make the suspension as homogeneous as possible. Appearance of test solution: no information reported No. of vessels per concentration (replicates): 4 No. of organisms per vessel: 5
Replication	No. of vessels per control (replicates): 4
Organisms per replicate	No. of organisms per vessel: 5
Exposure	No. of vessels per control (replicates): 4 No. of organisms per vessel: 5 Static Total exposure duration: 48 hours None Temperature: 19 4 - 24 2°C (contingous recording), 20 - 25.0°C (discrete recording)
Feeding during test	None
Test conditions	Water hardness 160 ang CaCO ₃ /L Specific conductivity. 460 µS/cm Photoperiod: 16 hours light / 8 hours dark with a 30 minutes transition period Light intensity 399-400 lux pH: 7:36 - 8,16 Dissolved avgen(83 - 95% saturation (7.10 ±8.15 mg/L).
Parameters Measured / Observations	Observations for immobility (i.e. daphnids were not able to swim within approximately 15 seconds after gentle agitation of the test vessel) were performed at 0, 24 and 48 hours. Dissolved oxygen concentration and pH were measured at hour 0 in each test vessel and at hours 24 and 48 in one replicate of the control and of each test concentration level. The temperature of the water bath was commuously monitored throughout the exposure period. Daily temperature measurements were performed in each replicate of day 0. At 24 and 48 hours the temperature was measured in one replicate of the
Chemical	Sontrol and one replicate of each test concentration. The parent test solutions were sampled a start of exposure and at the end of exposure.
analysis of Data analysis	Fluopicolicite analysis vois performed dising gas chromatography (GC) with ECD detector Not applicable: no offects were observed during the study.
	IN tappincapie. not appincapie. Not appincapie
Validity criter	ria (OECD 202, 2004)

Validity criteria (OECD 202, 2004)	Required	Obtained
Immobilisation and subsethal effects of control during test	<u>≤</u> 10%	0 %
Dissolved ox gen concentration at the end of the test \sim	\geq 3 mg/L	\geq 7.1 mg/L



Analytical results:

Only fluopicolide was analysed in the test. The measured concentrations are in the range of 80-120% of nominal concentrations therefore the endpoints are based on nominal concentrations. Q ð

Nominal Concentration (mg/L)	Day 0 % of Nominal concentrations	Day 2 % of Nominal concent ortions
Control	<loq<sup>a</loq<sup>	
6.25	112	
12.5	97.4	
25.0	81.8	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$
50.0	82.7	
100	850 × ~	
OQ = 0.15 mg/L		

Full details and acceptable validation data to support this method are pre-4, which comply with the EU regulatory requirements outlined 4 with minor acceptable exceptions only.

Biological results:

No floating or sub-lethally affected daplinids were observed except the lowest treatment level where 4 out of 20 daphnids were lethagic. These effects were not dose desponse related and hence were not considered for the definition of the NOECO Ô Å Ø Ô

xposure time (hours) x x x x x x x x x x x x x x x x x x x	48
	8.4
mg product/ L)	No of immobilized (%)
Control $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$	0 (0)
	0 (0)
	0 (0)
5.0 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	0 (0)
0.0 5 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 (0)
	0 (0)

CONCLUSIONS:

The study meets the varidity criteria and the endpoints based on nominal concentrations are:

	Ä ^v
EC50 48 hou (95% C.I.)	> 100 mg prod. / L (not applicable)
NOEC:	
highest concentration without adverse	100 mg prod. / L
effects of other	



Assessment and conclusion by applicant:

The study is reliable and the relevant endpoint for risk assessment is the 48-hour $EC_{50} > 100 \text{ mg}$ prod./L.

The concentrations of fluopicolide only were analytically determined during the test. However, this study is still considered acceptable because propamocarb-hydrochloride is stable in the test conditions according to the corresponding static tests with the active substance and the correct dosing of the test item is confirmed by fluopicolide measurements. Moreover, propamocarb-hydrochloride is not the toxicity driver for daphnia (EC₅₀ greater than 196 mg/L).

Data Point:	KCP 10.2.1/04
Report Author:	KCP 10.2.1/04
Report Year:	
Report Title:	AE B066752 04 SCO A1: Alga, growth inhabition fest with Pseudokirchneriella
•	subcapitata (syn. Selenastorm cap@cornut@n)
Report No:	
Document No:	M-227290-010 OECD: 201 9984 Method: Deviations from current guidetine SADICO/3629/99 (ev.4:
Guideline(s) followed in	OECD: 201 984
study:	
Deviations from current	Method Deviations from current guidetine SAOCO/3629/99 (ev.4: ~
test guideline:	Limit@d sets at validation recoveries@veries@vere approved. Bloweyer, the average
	recoveries were within the acceptable range of 70,110% and the BSD values were
	below 20%. The analytical method can be regarded as ff for purpose.
·	Study: Current Guideline: OECD 201 (2011)
	The study does not meet the validity oriteria of the new version of the OECD guideline 201. Moreover, the pH in controls deviated by more than 1.5 unit at 72h.
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	guideline 201. Moreover, the pH in controls deviated by more than 1.5 unit at 72h.
Previous evaluation:	ves, evaluated and accepted
	n FLC DAR 2005; in Propanocarb BAR June 2017
Previous evaluation:	Yes conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities:	Supportive onthe Contraction of the Contraction of
Acceptabili /Reliability:	Supportive onthe Contraction of Cont
facilities:	
)	

The green alga, *Psiudokirchmendila subcapitua*, was exposed to a series of six test concentrations of fluopicolide + propanocarb-hydrochtoride SC 6855 and a negative (culture medium) control under static conditions for  $\frac{1}{2}$  hours. Three replicate test chambers were maintained in each treatment group and twelve replicates for the control group. The selected nominal test concentrations of the test item were 1.9, 453, 9.4, 20.7, 45.5 and 100 mg prod./L. Concentration of the test substance in the solution was determined by analysing the active substance thiopicolide by gas chromatography (GC) with ECD detector. Samples of the test solutions were concentrations for the test substance. Measured concentrations for the treatment levels  $\leq 45.5$  mg prod./L were in the range of 86.6-105% of the nominal concentrations and no residues above the limit of quantification (LOO) were measured in the controls. However, recoveries for the highest treatment group decreased from 82.5% at 0 hours of 62.8% after 72 hours. Given that the toxicity of the product cannot be aftributed to any one of the active ingredients but to the formulated product as a whole, EC₅₀ values and biological data are based on nominal concentrations.

The study does not meet the validity criteria of the guideline OECD 201. The 72-hour calculated  $E_rC_{50}$  and  $E_bC_{50}$  values were >100 and 13 mg prod./L, respectively. The 72-hour NOEC, based on biomass and growth rate is 4.3 mg prod./L.

Ũ



#### I. MATERIAL AND METHODS:

Test material	Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) Code (AE B066752 04 SC61 A1)
	Batch No: OP220159
	Active ingredients: 64.7 g/L fluopicolide, 634 g/L propamocarb-hydrochlogide
	Density: 1.129 g/mL
Guideline(s)	None specified
adaptation	
Test species	Green algae Pseudokirchneriella subcapitata (formerly Selenastrum
	capricornutum)
Culturing	Stock cultures were transferred to thesh medium approximately twice week. The
conditions	inoculum used to initiate the toxicity test with the test item was taken from a stock
	culture that had been set of five days prior of testing. Stock captures of
	Pseudokirchneriella subcapitata were maintained under similar conditions as during the test. The culture medium used was OFCD medium prepared with sterile
	deionized water and adjusted to $PH 8.0 \pm 0.1$
Test solutions	Nominal concentrations $19^{\circ}43$ $94220$ $7$ $455$ and $100$ mg prod /
i est solutions	Nominal concentrations: 1.9, 4.3, 9.4, 20.7, 45.5 and 100 mg prod./L Control: culture medium (OECD medium)
Replication	No of vessels personceptration treplicates): 3 0 0
i i i i i i i i i i i i i i i i i i i	Control: culture medium (OECD medium) No. of vessels per control (replicates): 3 No. of vessels per control (replicates). 12 Due to a bigh variability in the results of
	the growth of the constrol versels, the constrols of a second test which had run in
	parallel to this test in the same water bath were included.
Exposure	Static V C C C C
	Total exposure duration: 72 bours
Initial cells	$1 \times 10^{4}$ cells mL in each test group $3^{4}$
density	
Test	$\frac{1}{20}$ mperature: $\frac{25}{7} - \frac{25}{2}$ °C (continuous monitoring)
conditions	Photoperiod continuous light Light intensity: 7300 - 8790 lux (variation less than 15%)
Ċ	Light intensity: 7300 - 8700 lux (variation less than 15%)
ð	ple 7.67 to 7.83 (beginning of exposure), 8 18 to 10.09 (end of exposure)
, Q	Growth medium same as culture medium: Yes
Danava	Type of light Coop white fluorescent lapps Ateach 26 hour interval, cell counts were conducted on all replicate vessels of each
Parameters Measured /	test concentration and the controls using a haemocytometer and a microscope.
Observations	Seconcentration and the controls using a naemocytometer and a microscope. Semperature was monitore acontinuously in a control flask which ran in parallel in
	the same water both. Light intensity was measured at test initiation and every 24
Ø	hours, plt was measured at test initiation and termination.
Sampling for	Samples of the test solutions were collected at approximately 0 and 72 hours to
chemicat	measure concentrations of fluopicolide. Samples at test initiation were collected
analves	from the individual flasks in which the test solutions were prepared for each
	freatment and control group prior to addition of the algae. At the end of the
$\sim$	exposure, algae were removed by centrifugation. The supernatant was analysed by
, O	gas chromatography (GG) with ECD detector. QC (quality control) samples were
Ő	prepared at hour 72 at nominal concentrations of 0.277, 278, 3.03, 13.9 and 15.1
Ĺ,	ing test item/L and were stored and analysed together with the test solutions after
Ú,	approximately 1-month storage (deep frozen) to validate the storage stability.
Data analysis	The highest test concentration that caused no significant adverse effects (No-
	Observed-Effect-Concentration, NOEC) was determined using Dunnett's test and
G G	Bonformiet-Test. Before the analysis of variance was conducted, the data were
Č	examined for normality using Chi - Square Test, and for homogeneity of variance using Bartlett's Test. The E. C., and E. C., were calculated by Probit analysis using
	using Bartlett's Test. The $E_bC_{50}$ and $E_rC_{50}$ were calculated by Probit analysis using a special $EC_{50}$ program.



#### **II. RESULTS AND DISCUSSION:**

Validity criteria (OECD 201, 2011)	Required	<b>Obtained</b> 。
Increase of biomass in the control cultures	16	95.6
Mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3) in the control cultures	<u>&lt;</u> 35%	<b>99</b> .7
Coefficient of variation of average specific growth rates in replicate control cultures	<u>≤ 7%</u>	A 6.73 O A
		<u>v</u> č č

#### Analytical results:

Recovery of fluopicolide of the QC samples ranged from 102 to 07%. At the start of the exposure recoveries of fluopicolide from the test solutions ranged from 82.3 to 102 Rindicoling that the fest solutions were correctly dosed. After 72 hours of exposure recoveries panged from 89.1 to 105 % of the nominal concentrations for the treatment levels with 1.9 to 15.5 mg prod/L. For the 100 mg prod/L treatment level, 62.8 % recovery was found. Given that the toxicity of the product cannot be autibuted to any one of the active ingredients but to the formulated product as a whole, EC 50 values and biological data are based on nominal concentration Ø

Nominal Concentration (mg prod./L)	
Control	
1.9	0 ⁴ 5 ⁴ 0 ⁶ 0 ⁷
4.3	
9.4	2 10 Y O 4 Y 96.0
20.7 5 5 4 A	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$
45.5	2 ~ 90.4 ~ ~ ~ @ ~ ~ 89.1
$\frac{45.5}{100}$ $OQ = 0.13 \text{ mg prod/L}$	0     4     8     3     0     8     62.8       2     3     0     8     0     62.8

Ş Full details and acceptable variation data to support this method are presented within document M-CA Solution of the support was included are presented within document M-CA solution requirements outlined within SANCO/3029/99 rev 4 with 4, which comply with the EU minor acceptable@xceptions only

#### Biological tesults:

The variance between the control replicates was relatively high, whereas the variance between the replicates of within the treatment groups was sinall. Therefore, additional controls of a test which had run in parallel to this test in the same water bath were included.

The inhibition of biomass and growth rate compared to control after 72 hours of exposure are presented in the table boow in the table below.



Nominal Concentration (mg prod./L)	Biomass inhibition after 72 hours (%)	Growth rate inhibition after 72 hours (%)
(ing prod./L) 1.9	5.0	1.3 °
	28.7	5.3
4.3		
9.4	50.8*	11.2*
20.7	61.3*	0 13.6*
45.5	76.5*	27.2* × <u>5</u>
100	73.3*	27.0* 5
Exponential growth in the control:	yes III. Covolusions:	Line endpoint based on nominal
The study does not meet the val oncentrations are: ErC50 72 hours		
28	2 - 100 mg prod./I	
E _b C ₅₀ , 72 h	5.8 mg prod_10	
NOErC 72 hours highest concentration without advers NOEbC 72 hours highest concentration without advers	se effects 4.3 mg prod)L 4.3 mg prod)L 4.3 mg prod./L	
Assessment and conclusion by The study is not cliable and sho	applicant:	
Assessment and conclusion by The study is not eliable and sho	<b>spplicant:</b>	



Data Point:	KCP 10.2.1/05
Report Author:	
Report Year:	2003
Report Title:	Alga, growth inhibition test with Navicula pelliculosa AE B066752 04 SC61
Report No:	C039857
Document No:	<u>M-227284-01-1</u>
Guideline(s) followed in study:	OECD 201 (1984)
Deviations from current	Method: Deviations from current guideline SANCQ(3)29/99 rev.4;
test guideline:	Limited sets of validation recoveries were analysed. However, the average $\mathcal{I}$
C	recoveries were within the acceptable range of $70^{2}110\%$ and the RSD values were   $\mathcal{A}$
	below 20%. The analytical method can be regarded as fit for purpose $\mathcal{N}$ $\mathcal{N}$
	Study: OECD 201 (1984)
	Current Guideline: OECD 201 (2011)
	The OECD guideline recommends 2 growth media (OECD or AAP). In this story,
	the OECD medium was supplemented by 3% (v/v) of soil extract according to
	Schloesser (1994) to ensure good growth conditions Since alidity criteria were
	met in the study, this is not considered as a major guideline deviation.
Previous evaluation:	yes, evaluated and accepted a start of the second
	in the DAR (2005) in the DAR (2005) in the DAR (2005) in the DAR (2005) in the day of th
GLP/Officially	Yes, conduced under/GLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes a a a a a a a a a a a
Executive summary	

#### **Executive summary**

**Executive summary** The freshwater diatom, *Naviculta pelliculoso* was exposed to a series of five test concentrations of fluopicolide + propanocarb/bydrocoloride SC 689.5 and a negative culture medium) control under static conditions for 2 hours. Three replicate test chambers were maintained in each treatment group and control group. The selected nominal test concentrations of the test item were 10.1, 0.32, 1.0, 3.2 and 10 mg prod./L Concentration of the test substance in the solution was determined by analysing the active substance fluoncolide by gas chromatography (GC) with EGD detector. Samples of the test solutions were collected at approximately 0 and 12 hours to measure concentrations of the test substance. Measured concentrations ranged from 004 to 108% at start of the exposure and from 96.2 to 107% at the end of exposure and no residues above the lonit of quantification (LOQ) were measured in the controls. Therefore  $\mathcal{FC}_{50}$  values and biological data are based on nominal concentrations.

The study meets the validity criteria of the guideline OECD 201. The 72-hour calculated  $E_bC_{50}$  and  $E_rC_{50}$ values were 0.40 and 0.63 mg prod. IP, respectively. The 72 hour NOEC, based on biomass and growth rate were 0.1 and 0.32 mg prod./L, respectively.

,	2 I.ØIATEMAL AND METHODS:
Test material	Repropicolide + Propana Carb Bydrochloride SC 687.5 (62.5 + 625)
~~	Code (XE B066752-Q4 SC60 A1)
a,	Batch No: OP220459
	Active ingrediens: 64. Pg/L fluopicolide, 634 g/L propamocarb-hydrochloride
l	Ipensity 1.129 g/III.
Guideline(s)	Nonespecified
adaptation 🔊	
Test species	Peshwater diatom Navicula pelliculosa
Culturing	The sulture medium used was OECD medium with addition of soil extract and
conditions	Na ₂ SiO ₃ 9H ₂ O prepared with sterile deionized water and adjusted to pH $8.0 \pm 0.1$ .
	Stock cultures were transferred to fresh medium, approximately twice a week. The
	inoculum used to initiate the toxicity test with the test item was taken from a stock



	culture that had been set up four days prior to testing. Stock cultures of Navicula
	pelliculosa were maintained under similar conditions as during the test.
Test solutions	<i>pelliculosa</i> were maintained under similar conditions as during the test. Nominal concentrations: 0.1, 0.32, 1.0, 3.2 and 10 mg prod./L Control: culture medium No. of vessels per concentration (replicates): 3 No. of vessels per control (replicates): 3 Static Total exposure duration: 72 hours $1 \times 10^4$ cells/mL in each test group Temperature: 21.3 – 24.0°C (continuous monitoring) Photoperiod: continuous light Light intensity: 7700 - 8200 lug pH: 7.44 to 7.50 (beginning of exposure), 7/3 to 8/83 (ead of exposure) Growth medium same as culture medium. Yes Type of light: Cool white fluorescent lamps At each 24-hour interval, cell counts were conducted on all replicate vessels of each test concentration and the controls using a haemocytometer and a microscope. Temperature was monitored continuous in a control flask which ran in parallel in the
	Control: culture medium
Replication	No. of vessels per concentration (replicates): 3
	No. of vessels per control (replicates): 3
Exposure	Static
	Total exposure duration: 72 hours
Initial cells	$1 \times 10^4$ cells/mL in each test group $\circlearrowright$
density	
Test	Temperature: 21.3 – 24.0°C (continuous monitoring)
conditions	Photoperiod: continuous light $\mathcal{A}^{\vee}$ $\mathcal{A}^{\vee}$ $\mathcal{A}^{\vee}$ $\mathcal{A}^{\vee}$ $\mathcal{A}^{\vee}$ $\mathcal{A}^{\vee}$
	Light intensity: 7700 - 8200 lug pH: 7.44 to 7.50 (beginning of exposure), 76/3 to 883 (end of exposure) Growth medium same as conture medium? Yes
	pH: 7.44 to 7.50 (beginning of exposure), 2073 to \$83 (end of exposure)
	Growth medium same as culture medium? Yes Type of light: Cool white fluorescent lamps
	Type of light: Cool white fluorescent lamps of the second se
Parameters	At each 24-hour interval, cell counts were conducted on all replicate vessels of each
Measured /	test concentration and the controls using a haemocytometer and a microscope.
Observations	test concentration and the controls using a knewocytometer and a microscope. Temperature was ponitored continuous in a control flask which rap in parallel in the
	same water bath Light intensity was measured at test initiation and every 24 hours,
	pH was measured at test initiation and termination
Sampling for	Samples of the test solutions were collected at approximately 0 and 72 hours to
chemical	measure concentrations of the test substance Samples at test initiation were collected
analysis	from the individual flasks in which the test solutions were prepared for each treatment
	and control group. Ab the end of the exposure, algae were removed by centrifugation.
	The supernatiant was analysed for fluopicolide by gas chromatography (GC) with ECD
	detector. QC (quality control) samples were prepared at hour 72 at nominal
	concentrations of 0.09, 1.0 and 12 mg test dem/L and were analysed together with the test solutions to validate the procedures used.
	Ptest solutions to validate the procedures used.
Data analysig	The highest test concentration that caused no significant adverse effects (No-
, Or	(Deserved-Effect-Concentration, NOEC) was determined using Dunnett's test. Before
	the analysis of variance was conducted, the data were examined for normality using
<u>í</u> G ^v	Shapiro-Wilks Test, and for homogeneity of variance using Bartlett's Test. The $E_bC_{50}$
<u>«</u> »	and $E_rC_{50}$ were calculated by Probit analysis using a special EC ₅₀ program.

# 

Validity criteria (OECD 201, 2011)	Required	Obtained
Increase of biomass in the control cultures	16	89.2
Mean coefficient of variation for section by section specific growth rates (days 0-1, 1, 2 and 2-3) in the control cultures	<u>≤ 35%</u>	32.5%
Coefficient of variation of average specific growth rates in replicate control cultures	<u>≤</u> 7%	2.29%

Analytica result. Recovery of the picoticle of the QC (quality control) samples prepared on both sampling intervals ranged from 96.4 to 106% apart from one QC sample which showed a recovery of 28.6%. However, based on the results of the other QC samples and the recoveries found for the samples from the algae study it can be consided that the appropriate quality control was maintained. The recoveries of fluopicolide from the test solutions ranged from 104 to 108% at start of the exposure and from 96.2 to 107% at the end of exposure. The concentrations were reported as nominal concentrations.



Nominal Concentration (mg prod./L)	0-hour % of Nominal concentrations	72-hour % of Nominal concentrations
Control	<loq< th=""><th><loq< th=""></loq<></th></loq<>	<loq< th=""></loq<>
0.1	104	<u>ک</u> 107 گ
0.32	104	
1.0	104	99.5 0 5 4
3.2	108 🖉	6 989 × 6
10.0	104	989 <u>7</u> 9 9 96.2 7 7

LOQ = 0.010 mg prod. /L (0 hour) and 0.011 mg prod. /L (0 hour)

Full details and acceptable validation data to support this method are presented within document M&A 4, which comply with the EU regulatory requirements outlined within SANCOO029/99 rev 4 with minor acceptable exceptions only.

#### **Biological results:**

The inhibition of biomass and growth rate compared to control after 72 hours of exposible are presented in the table below.

v					
Nominal Concentration (mg prod./L)		Biomans inhibition	after 72	arowth rate inhibition at hours (%)	fter 72
0.1	Y A	Q 4 3.34		~~~ 0.5	
0.32		37,9*		10.9	
1.0	W.	@0.3* «		≶ 54.2*	
3.2	L Å .	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		107.3*	
10.0	) ⁽ ⁽ ) ⁽ ⁽ ) ⁽ ) ⁽ )			125.7*	

* Statistically significant difference (p<0.05 thom the control replicates using Romnett's test.

Exponential growth in the control; yes

K III. CONCLUSIONS:

The study meets the validity criteria of the guideline. The endpoints based on nominal concentrations are:

	1 &
ErC ₅₀ 72 hours (95% C)	<b>0.@mg prod./L</b> (0.28-1.45)
	0.40 mg prod./L (0.15-1.11)
NOErC 72 hourse highest concentration without adverse effects	0.32 mg prod. /L
NOE _b C 72 hours highest concentration without adverse effects	0.1 mg prod./L

## Assessment and conclusion by applicant:

The study os reliable and can used in risk assessment. However, the growth rate endpoints were not correctly calculated therefore the  $E_rC_{50}$  and NOE_rC for this study are presented in the next summary.

The concentrations of fluopicolide only were analytically determined during the test. However, this study is still considered acceptable because propamocarb-hydrochloride is stable in the test



Ø

ð

conditions according to the corresponding static tests with the active substance propamocarb and the correct dosing of the test item is confirmed by fluopicolide measurements.

Data Point:	KCP 10.2.1/06
Report Author:	
Report Year:	2020
Report Title:	2020 ECx calculation of Infinito study on Navicula pelliculosa (2003; M, 2003; M, 20
Report No:	M-679538-01-1
Document No:	M-679538-01-1
Guideline(s) followed in study:	
Deviations from current test guideline:	none y y y y y y
Previous evaluation:	
GLP/Officially recognised testing facilities:	
Acceptability/Reliability:	Yes y y y y y y y

 $EC_{10}$  and  $EC_{20}$  values are data requirements for chronic studies according to regulation EU 283/2013. Recalculations of  $EC_x$  for both growth rate and bomass variables were performed with ToxRat, version 3.2.1, using the same statistical method as in the initial report: probit analysis.

These recalculations privelled calculation errors for the growth rate values in the report. The raw data of the study were checked to identify the source of error, but to no avail. However, it was possible to reproduce the growth rate values of the report when an initial cell density of 11 000 cells/mL was used instead of 10 000. Since the initial density was 10 000 cell/mL, it is then concluded, that the growth rate endpoints (EC  $_{50}$  and NOEC) found in the report were not correct and should be ignored. The correct endpoints are provided within this statement and are:

Endpoints (95% confidence limits) in mg prod. L SEC ₅₀ C SEC ₅₀	Biomass (AUC)
(3) $(2)$ $(2)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$ $(3)$	0.40 (0.38 – 0.42)
$EC_{20} \xrightarrow{2} 0 \xrightarrow{2} 0$	0.21 (0.20 – 0.23)
$F_{0}$	0.15 (0.14 – 0.17)
	0.1**
NOTE         0.1           OBEC         0.32	0.32**

*The  $\mathbf{F}_{r}C_{50}$  calculate in the peport was 0.63 mg prod./L.

** not recalculated, taken from the report



#### Assessment and conclusion by applicant:

The study is acceptable (see summary of M-227284-01-1) and the endpoint relevant for risk

C12.2 Additional long-term and chronic toxicity studies on fish, additional incretebrates and sediment dwelfing organistics. The set of the Dopment of the Dopment of the Set of the Dopment of the Set of the Dopment of the Set of the Dopment of



### CP 10.3 Effects on arthropods

In June 2019 EFSA issued a Technical Report Outcome of the pesticides Peer Review Meeting on general recurring issues in ecotoxicology. doi:10.2903/sp.efsa.2019.EN-1673

As part of this document guidance and a template were provided to complete the questionnaire for the use of residue data extracted from vol. 3 B.7.to support the ecotoxicological assessment of pesticides.

The completed template is provided below.

Magnitude of residues in pollen and bee products

Reference material: Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels to hone? (EC, 2018); Guidance on the risk assessment to plant protection products on bees (*Apis melliferal bombus* spp) and softary bees (ECSA, 2413).

Question 10: Are data on the magnitude of residues on pollen and bee products part of the residue section? If so, please indicate which data are available and sampling times.¹⁶

No data are available in the residers section concerning residers of HopicOlde / M-01 within the pollen of treated plants.

A study investigating fluopicolide and Mori residues within honey is available (1996) 2020; M-681610-01-1). The study was conducted during the 2019 season in northern and southern Europe.

Four treatments of Suspension concentrate formulation, containing 0.1 kg fluopiolide / ha, were applied to *Phacetra tangetifolis* under semi-field conditions.

$ \begin{array}{c cccc}  & 50 \\  & 55 \\  & 63 \\  & 67 \\  & 50 \\  & 55 \\  & 61 \\ \end{array} $	0.098 0.099 0.100 0.100 0.101 0.101 0.100 0.098
63 67 50 55	0.100 0.100 0.101 0.100
63 67 50 55	0.100 0.101 0.100
50 55	0.101 0.100
55	0.100
61	0.098
	0.090
65	0.101
59 - 60	0.109
61	0.100
63	0.099
65	0.102
59 - 60	0.102
_	61 63 65

¹⁶ Residue section may contain information of residues in pollen, leaves and flowers. For residues assessment, data on nectar and pollen would be also useful for deriving a more realistic MRL/PF for nectar/honey and pollen/honey. Specific residue data can be used for refinement of higher tier studies in the risk assessment for bees if considered representative of the situation under assessment.



Spain	2	6	61	0.100
	3	7	63	0.107
	4	7	65	0.101

Even at the exaggerated application rates, only low levels of fluopicolide residues were found within the sampled honey (mature). Residues of M-01 were not observed above the LOQ for more (mature):

					A	
Trial No.	Growth stage	DALT	Honey:	Residues (i		Sugar content
Country	at sampling*		fresh or dried	Fluopicolid	M-01	of honey (%)
S19-01063-01	68	9	Fresh	< 0.01	< 0.01	Ø \$7.0 × 64
Germany	68	9	Dried**	<0.00	< 0.01	Q80.3
S19-01063-02	69	8	Fresh	<0.Q1	° <0.0∮	× 80.0°
Germany				🔷 . Ŭ	~~~	
S19-01063-03	65	1	Fresh o	×0.01	<b>\$0.01</b>	81.1
Spain				X 4	o S	
S19-01063-03	66	2	Fresh	C 0,0914 C	× <0.01	80,57 (1)
Spain		4			A la	
DALT = Days after		Å				
* Growth stage of	phacelia at samplir	ig 🖉				A O

** Drying period = 3 days

No plant matrices (i.e. leaves and flowers) were analysed as part of this study.

# CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing gudance in force at the time of the preparation and sobmission of this dossier namely the FU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and EPPO Standard PR 3/10 Environmental Risk Assessment Scheme for Plant Protection Products Chapter 10 Plant Protection Products

Comission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing of both acute (oral and contact) and chronic toxicity, including sub-lethal effects. Consequently, in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided (please refer to M&A, Section 8):

- Chronic 10-day Toxicity test with the solo formulation fluopicolide SC 486 on adult bees under laboratory conditions (2016; <u>0-55223-01-1</u>)
- Repeated exposure toxicity test with Buopicende tech. on honey bee larvae under laboratory conditions (QEOD guidance document 239), (2018; M-615695-01-1).

• Acute contact and oral toxicity of fluoricolide tech. to adult bumble bees under laboratory conditions, (2015; <u>M-51990)-01-1</u> and 2015; <u>M-511408-01-1</u>)

Broodteeding test according to Oorden *et al.* (1992) with the solo formulation fluopicolide SC 486 using a realistic worse case pray solution concentration and covering exposure for effects or brood eggs, Soung and old larvae) and their development, nurse bee on-going behaviour in brood care and colon strength), (2016; M-545732-01-1)

Two semi-field brood studies following OECD guidance document 75 (using a more realistic spray scenario onto flowering *Phacelia* covering effects on mortality, foraging activity as well as general colony development) with the solo formulation fluopicolide SC 486 (these semi-field studies are presented in KCA Section 8, Point 8.3.1.3/03 and Point 8.3.1.3/04), 2016; M-547124-01-1 and 2020; M-685049-01-1)



Two semi-field studies following EPPO 170 with the representative formulation fluopicolide,+ propamocarb-hydrochloride SC 687.5 using a more realistic spray scenario onto flowering *Phacelia* covering effects on brood development, adult and pupal mortality, foraging activity, behaviour and colony development and strength. These semi-field studies are presented in MCP Section 10, Point 10.3.1.5. One study was conducted in C-EU (2019: M-651103-01-1) and another study was conducted in S-EU (2019: M-651103-01-1) to cover two climatic zones within the EU.

The toxicity tests conducted with the representative formulation Fluopicolide + Propandearby C hydrochloride SC 687.5 are presented in this MCP document. The toxicity tests conducted with Fluopicolide tech., its bee relevant metabolites MOT (AE C652711) and M-02 (AE C657188) and the solo formulation Fluopicolide SC 486 are presented in MCA, Section 8, Point 8.3.

A summary of the critical endpoints of Fluopicolide tech ats metabolites M-01 (AE C6537) and M-02 (AE C657188), the solo formulation Fluopicolide SC 486 and the representative formulated product Fluopicolide + Propamocarb-hydrochloride SC 687, are provided in the following tables. Empoints shown in bold are considered relevant for risk assessment.

			(Å)
Test substance	Test species/ ©″ study type⊴	Endpoint 2 5	References
	study type		∀
	Hopeybee, adult, acute 72 h		<u>2012;</u> <u>M-200452-03-1</u> <u>KCA 8 2 1 1 1/01</u>
			KCA 8.3.1.1.1/01
	Hopeybee adult,		<u>2012;</u>
l ô	acute D2 h	$LD_{50}$ contact $>$ 100 µg $\beta$ ./bee	<u>M-200506-03-1</u>
	Gacule 202 II	A AT O A	KCA 8.3.1.1.2/01
Fluopeolide	Honeybee, mult,	ED50 - oral 5 > 1003 µg 6./bee	2015; M-
tech.	acute, 48 h	ED ₅₀ – oral ³ > 107.3 μg Ωs./bee LD ₅₀ contact > 100 μg a.s./bee	<u>539964-01-1</u> KCA 8.3.1.1.1/02
	Bumble bee, stult,	$ED_{50}$ or al $5^{\circ}$ > 875 µg a.s./bumble bee	<u>2015; M-</u> 519981-01-1
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	evite, 48 h		KCA 8.3.1.1.1/03
A B B B B B B B B B B B B B B B B B B B	Bumble bee, aduilt,	ED_{50} - contact > 100 µg a.s./bumble bee	<u>2015; M-</u> 511408-01-1
			KCA 8.3.1.1.2/02
Bold values used in	risk assessment .		
a.s.: active substanc			

Table 10.3.1- 1: Critical endponts for Pluopicolide tech. - acute to acity to adult honey and bumble bees

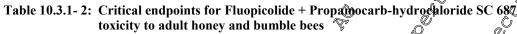
Acute toxicity to adult bumble bees ~

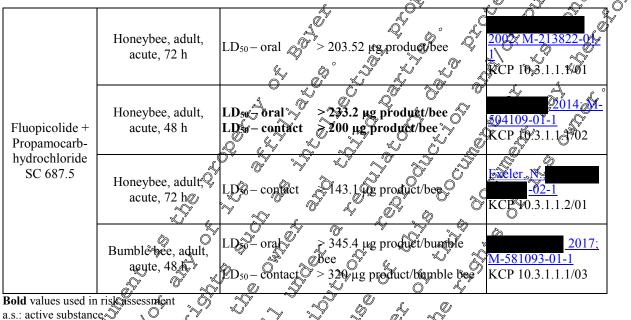
Currently there are no testing equirements for any bee other than for the honey bee within Regulation EU 1007/2009. Neverthetess, acute oral and contact bumble bee studies were conducted with Fluopicolide tech. and the representative formulation Fluopicolide + Propamocarb-hydrochloride SC 687.5 which is presented as additional information (Table 10.3.1-2).

At time of study conduct, both guidelines for testing bumble bees (OECD 246 and OECD 247) were still undergoing the OECD validation process. However, the bumble bee oral and contact toxicity studies



with Fluopicolide + Propamocarb-hydrochloride SC 687.5 were performed considering the latest version of the draft OECD guidelines at that point in time. The findings for the formulation indicate comparable or even higher endpoints compared to the acute oral and contact bumble bee study or even compared to the honey bee acute endpoints performed with the active ingredient fluopicolide tech. Hence, the findings indicate that the bumble bee is not more sensitive to Fluopicolide + Proparocarb-hydrochloride SC 687.5 or fluopicolide tech. compared to the honey bee.





Acute toxicity to achilt honey bees for bee relevant metabolites

According to Regulation EU 1007/2009 testing of metabolites should be driven by an examination of existing data on other organisms and biological screening. Moreover, the higher exposure level of the parent will compensate for any higher toxicity of the metabolite and therefore the risk will already be covered in the majority of cases. When referring to the EFSA Bee Guidance Document (2013), metabolites exceeding a total radioactive residue OTRR) of 10% or identified as > 0.01 mg/kg in plant metabolism studies should be assessed for risk assessment to bees. The same parameter was chosen to identify the relevant metabolites of Huopicolide in the present case. Moreover, the focus is on metabolites that may occur in pollen and neetar, as these are defined as the major route of exposure.

Several plant metabolism studies were performed with the active fluopicolide and its metabolites using seed, foliar or soil application methods conducted on three crop groups (fruit, leafy and root) (see MCA 6.2.1). In addition, confined rotational crop studies (CRC) performed with the active fluopicolide and its metabolites as soil application, were also conducted (see MCA 6.6.1). From these studies, the most relevant plant parts for exposure to bees were identified as oilseed rape seeds, grapes and wheat grain. In these erop parts six metabolites were found to be > 10% TRR or > 0.01 mg/kg as parent equivalents, two for the active formed in other plant parts and no metabolites were unique to the least relevant erop parts for bees (i.e. roots and tubers formed underground). The metabolites found were grouped according to their chemical structures into three groups: similar to parent (meaning covered by parent), M-01 (AE C653711) and M-02 (AE C657188). Hence, the metabolites M-01 (AE C653711)



and M-02 (AE C657188) were identified to be the focus for bees in relevant plant parts and were further investigated for toxicity and exposure to bees.

Both bee relevant metabolites (M-01 (AE C653711) and M-02 (AE C657188)) were tested for their acute oral and contact toxicity on honey bees (Table 10.3.1-3). The endpoints for both metabolites are of low toxicity to bees and comparable to the acute oral and contact honey bee study endpoints performed with the active ingredient fluopicolide. These findings indicate that the bee relevant metabolites M-01 (AE C653711) and M-02 (AE C657188) are not to be considered more oxic than the parent. Consequently, the risk for plant metabolites is considered to be covered by the risk as essent for the parent molecule.

Details of the honey bee testing with the fluopicolide relevant metabolites M-01 (DE C653711) and M 02 (AE C657188) are presented together with the ecotoxicological endpoints in MCA Section 8, Point 8.3.1.

Table 10.3.1- 3: Critical endpoints for metabolites Mell (AFC 653767) and 1-02 (AE C 657188) Acute o toxicity to adult honey

Metabolite M-01 (AE C653711)	Honeybee, adult, acute, 48 h D_{50} – contact $> 80.8 \ \mu g \ p. 0.7 \ bee M = 577897 - 01 - 1 \ K \propto 8.3 \ f = 1.1/04$	
Metabolite M-02 (AE C657188)	Honeybee, adapt, acute, 48 f LD ₅₀ – orage 110.9 µg p.m/bee 110.9 µg p.m/bee 100.9 µg p.m/bee 100	
p m.: pure metaboli		

Chronic toxicity to adult honey bees

In the year of study conduct (<u>1996, M-552253, 91-1</u>) of the chronic adult honey bee study with Fluopicolide SC 486 there was no finalized and adopted test guideline available. However, the study was conducted considering the latest version and recommendations according to

(2015). The final guideline OEOD 245 for testing chronic oral toxicity on adult honey bees was implemented and adopted in October 2017. The performed study by (2016) included analytical verification of the active ingredient fluopicolide in the final feeding solution which is also a requirement of the OECD 245. A simple SC formulation was chosen in place of technical material to enable chronic administration of fluopicolide is a 50% sugar solution and to overcome any solubility or palatability issues that may have occurred by using technical fluopicolide and organic solvents.

The endpoint for the solo formulation presented as a.s./bee/day is comparable to the acute oral toxicity endpoint for Fluopicolide tech., indicating that there are no signs of accumulated toxicity expected after chronic exposure to the active substance fluopicolide.

A chronic adult honey bee study was also conducted with the representative formulation Fluopicolide + Propamocarb hydrochloride SC 687.5

 Table 10.3.1-4
 Critical endpoints for Fluopicolide SC 486 and Fluopicolide + Propamocarb-hydrochloride

 SC 687.5
 chronic toxicity to adult bees

Test substance	Test species	Endpoint	Reference
Fluopicolide	Honeybee, adult,	$\begin{array}{llllllllllllllllllllllllllllllllllll$	<u>2016;</u>
SC 486	10 day feeding test		M-552253-01-1



Test substance	Test species		Endpoint	Reference	
				KCA 8.3.1.2/01	8
Fluopicolide + Propamocarb- hydrochloride SC 687.5	Honeybee, adult, 10 day feeding test	LDD ₅₀ NOEDD	> 119 μ g product/bee/day > 119 μ g product/bee/day	<u>M-682991</u> KCP 10.3 M.2/01	<u>S</u>
a.s. = active substant	nce		-		Ĉ

Effects on honeybee development and other honeybee life stages (

The chronic toxicity to larvae of honey bees under laboratory conditions considering emergence after 22 days was performed with fluopicolide tech. Applowing the OECD TG 239 (2016). The finding do not indicate a risk of fluopicolide tech. after repeated feeding of contaminated food to larvae and considering emergence after 22 days. Details of the study are presented together with the ecotoxicological endpoints in MCA, Section 8, Point 8.2 C.

A chronic study with first instar large of proney bee was also conducted with the representative formulation Fluopicolide + Propamoentb-hydrochloride SC 687.5

 Table 10.3.1- 5: Critical endpoints for Enopicolide tech and Fluopicolide + Propanocarb-hydrochloride

 SC 687.5 - repeated exposure to honey bee larvae

Test substance	Test species	Endpoint J	Reference
Fluopicolide tech.	Honeybee harvae, chronic (omergeney after 22 Onys follow repeated feeding)	NOED 60.1 gg a.s./Jarva	2018; M-615695- 01-1 KCA 8.3.1.3/01
Fluopicolide Propamocarb- hydrochloride SC 687.5	chronic (emergence after 22 days follow repeated feeding)	NOED OF S00 μαρroducolarva	<u>2020;</u> <u>M-682868-01-1</u> KCP 10.3.1.3/01
a.s. = active substar			

In order to reveal whether fluopicolide poses a tisk to immature honey bee life stages, a bee brood feeding study (2016, M-54,732,41-1) was conducted by following the provisions/method of OomeroP.A., de Ruijter, A. & van der Steep, J. (OEPP/EPPO Bulletin 22:613-616 (1992)). Moreover, and to clarify whether fluopicolide 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, two higher tier semi-field honey bee brood studies (according to the provisions of the OECD Guidance Document 75) were conducted under forced/confined exposure conditions. One study was conducted in C-EU 2010, M-54/124-01-1) and another study was conducted in S-EU (2020; M-685049-054) to cover two climatic zones within the EU. All three higher tier studies were conducted with the solo formulation fluopicolide SC 486 (Table 10.3.1-6).

In addition, wo higher tier semi-field honey bee studies (according to the provisions of the OEPP/EPPO guideline No. 170 (4) (2010)) with the representative formulation Fluopicolide + Propamocarbhydrochoride SC 687.5 were conducted under forced/confined exposure conditions. One study was conducted in C-EU (2019; M-651105-01-1) and another study was conducted in S-EU (2019; M-653952-01-1) to cover two climatic zones within the EU.



It can be concluded from all five higher tier studies (Oomen *et al.*, OECD Guidance Document 75 and OEPP/EPPO guideline No. 170 (4)) performed with Fluopicolide SC 486 and Fluopicolide + Propamocarb-hydrochloride SC 687.5, investigating side-effects on immature honey bee life stages that fluopicolide and the representative formulation Fluopicolide + Propamocarb-hydrochloride SC 687.5, are of low general intrinsic toxicity to honey bees.

Table 10.3.1- 6:	Critical endpoints for Fluopicolide SC 486 and Fluopicolid SC 687.5 – toxicity to bee brood and colony development	de + R ropamo	carb-hvd	lrochtoi	ride 🔊
	SC 687.5 – toxicity to bee brood and colony development	× T			de la companya de la

Test substance	Test species	Endpoint	Reference
Fluopicolide SC 486	Honeybee brood feeding test (Oomen <i>et al.</i> , 1992)	No adverse effects were observed on the development of brood (eggs, young and old larvae) and on pupal mortably. Adult bee mortality in the test item freatment group appeared higher compared to the compare group. However, since this observation was not consistent amongst replicates at is onsidered to be candom and no of biological relevance. Overall, fluopicolide fed at a concentration of 1.33 g a.s.d. sugar solution caused no adverse effects on honey bee colony performance including no indication for negative impacts on brood reating success. Overall, no adverse effects on brood development, adult and pupal mortality, foraging activity, behaviour colony	2016: M-545772 01-1 KC7 8.3.1.3/02
	Honeybee Brood – Semi-Field FOECD GD 75 Honeybee Brood – Semi-Field GECD GD 75	foraging activity, behaviour oolony development and strength after application of 337.6 g product/ha (corresponding to 133/g fluopicolide/ha) onto flowering <i>Phacelia</i> <i>tanacetifolia</i> Overall, no adverse effects on brood development, adult and pupal mortality, foraging activity, behaviour, colony development, and strength after application of 133 g fluopicolide/ha onto flowering <i>Phacelia</i> <i>tanacettolia</i> .	2016; M-547124- 01-1 KCA 8.3.1.3/03 2020; M- <u>685049-01-1</u> KCA 8.3.1.3/04
Fluopicolide + Propamocarb-	HoneybeOcolomy development Scini-Field (EPPO 170)	Overall, no adverse effects on brood development, adult and pupal mortality, for aging activity behaviour, colony development and strength when applied twice onto those in <i>Phacelia tanacetifolia</i> at a rate of 4.965 L product/ha and at 1.6 L product/ha.	<u>2019; M-651105-</u> <u>01-1</u> KCP 10.3.1.5/01
hydrochloride SC 687.5	developpent – * SemiField (EKPO 170)	Overall, no adverse effects on brood development, adult and pupal mortality, foraging activity, behaviour, colony development and strength when applied twice onto flowering <i>Phacelia tanacetifolia</i> at a rate of 1.965 L product/ha and at 1.6 L product/ha.	<u>2019:</u> <u>M-653952-01-1</u> KCP 10.3.1.5/02
a.s. = active substan			



Risk assessment for bees

The risk assessment for bees for fluopicolide is based on the application rates of 1.6 L prod./ha corresponding to the maximum single application rate of 100 g FLC/ha for applications in potatoes and lettuce using the endpoints (LD50 values) for the formulation FLC + PCH SC 687.5 and the active substance fluopicolide.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between application rate (expressed in g/ha) and the laboratory contact and ora LD50 (expressed in yg/bee)

QH values are calculated using data from the studies performed with the active substance and with the formulation. QH values higher than 50 indicate theneed of higher tiered activities to farify the actual risk to honeybees.

	mathemum application rate of [g.a.s./ha of 2 product/hal
Hazard Quotient, oral:	$Q_{HO} = \frac{\text{maximum application rate}}{50 \text{ or al}} = \frac{\text{[g.a.s./ha oCg product/ha]}}{\text{[µg.a.s./bee or µg product/bee]}}$
Hazard Quotient, contact:	$Q_{AC} = \frac{\text{maximum application rate}}{LD_{30}\text{context}} = \frac{[g_{AS}^{os}]/ha of g \text{ product/ha}]}{[\mu g_{AS}^{os}]/ha of g \text{ product/ha}]}$

Table 10.3.1-7:	Hazard quotients for bees for the application in potatoes and lettuce - oral exposu	re

Compound	Oral LD50	Max. appl. rate [g/ha]	Hazard quotient Qiro		<i>A-priori</i> acceptable risk for adult bees
FLC + PCH SC 687.5	2332	179 3	57.7	50	yes
Fluopicolide	> 1,09.3		< 0.25		yes

Based on an application rate of 1600 nd prod the and appoduce density of 1.123 g/mL a) O

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

Hazard quotients for bees for the application in potatoes and lettuce - contact Table 10.3.1-8 exposure ~

J.	[ug/bee]		Hazard quotient Qнc		<i>A-priori</i> acceptable risk for adult bees
FLC & PCH SC 687.5	≥ 200	179	< 9.0	50	yes
Fluopicolide	> 100 0	190° 20°	< 1.0	50	yes

Based on an application rate of 600 mC prod./Re and a product density of 1.123 g/mL a)

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



CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

Data Point:	KCP 10.3.1.1.1/01
Report Author:	
Report Year:	
Report Title:	Oral toxicity (LD50) to honey bees (Apis mellifera LA Propamocarb
-	hydrochloride + AE C638206 water miscible suspension concentrate 634 + 64.7
	hydrochloride + AE C638206 water miscible suspension concentrate 634 + 84.7 g/L Code: AE B066752 04 SC61 A02
Report No:	C027693
Document No:	M-213822-01-1
Guideline(s) followed in	EPPO 170 (1992); OECD: 243 (1998)
study:	
Deviations from current	Current Guideline: OECD 213 (1998) 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
test guideline:	Triazophos was used as reference item instead of dimethoate as recommended in
	the guideline. Only 3 test item doses were used with a spacing factor of 10 instead °
	of 5 with a maximum spacing factor of 2.2 as recommended in the guideline.
	Behavioural abtormalities were not checked during the study These deviations
	are not expected to have impacted the study results a start of the start o
Previous evaluation:	yes, evaluated and accepted for the second
	In the DAR (2005)
GLP/Officially	Yes, conducted under @LP/Of Deially & cognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Xes X X Q Q X X X Q

Executive Summary 🔬

Ľ

The purpose of this study was to determine the actie or toxicity of propamocarb hydrochloride + AE C638206 to the honeybes (A. meltifered L.) in the laboratory. Mortality of the bees was used as toxic endpoint.

Therefore, under laboratory conditions *Apis mellifera* worker bers were exposed by use of 50% sucrose solution to mean measured doses of 2.76, 29 19 and 203.52 µg product/bee during a 5-hour feeding period. Furthermore, each test consisted of a control and a reference item group. Each treatment group consisted of 5 replicates (test units) with 10 bees per replicate. The tests were conducted in darkness, temperature was 24, 26°C and relative homidity was between 53 and 63 %. The number of dead bees in each cage was assessed 24, 48 and 72 hours after application. The oral LD₅₀ values were calculated with the aid of SAS probit – analysis to mortality occurred during the test in the control and in the test with the different test evels in the test with the reference from the doses of 0.0928, 0.13325 and 0.60592 µg product/bee resulted in 5, 7 and 32 dead bees after 72 hours. The LD₅₀ of the reference item was calculated to be 0.168 µg/bee. All validity criteria of the test were met. The LD₅₀ (72 h) for honeybees was > 205.52 µg product/bee in the oral to validity test.

I. MATERIAL AND METHODS:

Test item: Propamocarb hydrochloride + AP C638206: 634 g/L propamocarb hydrochloride, 64.7 g/L AE C638206 g/L, density: 7.129 g/L, Identification code: AE B066752 04 SC61 A102, Certificate of Analysis: AGF2002-002 D01 (dated 19 Pebruary 2002).

Test organism: Temale Worker honeybees (*Apis mellifera*), obtained from a healthy and queen-right colony of the second s

Under laboratory conditions *Apis mellifera* worker bees were exposed by use of 50% sucrose solution to mean measured doses of 2.76, 29.19, and 203.52 µg product/bee during a 5-hour feeding period. Furthermore, each test consisted of a control and a reference item group. In the control untreated 50% sucrose solution was offered to the bees as food source. In the test AE F002960 00 EC40 C668 (active ingredient: 40.9 % w/w triazophos, Batch no.: AAEH00057) was used as reference item; the reference item was tested at three different doses (0.09298, 0.13325 and 0.60592 µg product/bee).



Each treatment group consisted of 5 replicates (test units) with 10 bees per replicate. Test units were 12-13 cm high cylindrical test cages with a diameter of 5 cm.

The tests were conducted in darkness, temperature was $24 - 26^{\circ}$ C and relative humidity was between 53 and 63 %. The number of dead bees in each cage was assessed 24, 48 and 72 hours after application. The oral LD₅₀ values were calculated with the aid of SAS probit – analysis.

II. RESULTS AND DISCUSSION:

Observations

No mortality occurred during the test in the control and in the test with the difference test keels. In the test with the reference item the doses of 0.0928, 0.13325 and 0.60592 μ g product bee resulted in 5, 7 and 32 dead bees after 72 hours.

	Total number of dead bees after 2 2 2 2 2
	24 h 0 48 h 72 h 2
Control	
Test item [µg product/bee]	
2.76448	
29.19202	
203.51760	
Reference item [µg product/bee]	
0.09298	
0.09298 Ø 0.13325	
0.60592	

Riolo	nical	finding	CTC'
DIOIO	gicai	mum	25

Test substance	S.	Ô S	\sim	J.	\sim	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ś	Endpoint	
Propamocarb hy	drochdo	ride + A	É C638	206	24-72	LD50	μg a.s	(bee]	> 203.52
Reference it on	C)		0	Ś	72		g produ	ct/beed	0.411
	-0		Ĉo	a	\sim			× 1	

<u>Validitý criteria:</u> All validity criteria of the test were met.

Validity crit@ia (OECD 213, 1998)	Obtained in this study
Control mortality should not exceed 10 % at test and	Control: 0 %
LD ₅₀ of the reference item should be in the spectfled range (oral test. $0.10 - 0.35$ ug a.s./Qe)	0.168 μg a.s./bee*

*0.411µg product/bee × 40.9 % w/w triazophos

^Φ^Δ^ν ^VIII₂ ^Q^ΔONCLUSIONS:

The LD₅₀ (72 10 was 203.5 µg product/bee in the oral toxicity test.

Assessment and conclusion by applicant:

This study is considered teliable for risk assessment and the endpoint is: LD_{50} or ab (72 h) 203 32 µg product/bee

Ô



Data Point:	KCP 10.3.1.1.1/02
Report Author:	
Report Year:	2014
Report Title:	Effects of fluopicolide + propamocarb-hydrochlorid SC 687.5 (62.5+625)
	(Acute contact and oral) on honey bees (Apis mellifera L.) The laboratory
Report No:	92591035
Document No:	<u>M-504109-01-1</u>
Guideline(s) followed in	OECD 213 and 214 (1998)
study:	
Deviations from current	Current Guidelines: OECD 213 (1998) and OEC 214 (1998)
test guideline:	A 5 μ L droplet was chosen in the contact toxic Φ test in deviation to the guideline $\int \Phi$
	recommendation of a 1 μ L deplet, since a higher volume ensured a more reliable Q^2
	dispersion of the test item and allows to test for a fagher application dose. The
	relative humidity was 399 68%, below the 50 × 70% recommended range as given
	in the guideline. These deviations are not expected to have impacted the study
	results.
Previous evaluation:	No, not previously submitted for Propamocarb RAR June 2007
	for Propamocarb RAR June 2017 A OV
GLP/Officially	Yes, conducted under GLP/Officially recognized testing facilities ~
recognised testing	
facilities:	
Acceptability/Reliability:	Yes Q & A A O O O A
Executive Summary	

Executive Summary

The purpose of this study was to determine the acute contact and oral toxicity of fluopicolide + propamocarb-HCl SC 687.5 (62.5+625) G to the honey bec (A. mellifera L.). Mortality of the bees was used as the toxic endpoint Subletial effects, such as changes in behaviour, were also assessed. Therefore, under laboratory conditions *this methifera* 50 worker bees were exposed for 48 hours to a single dose of 2000 µg product/bee by topical application and 50 worker bees were exposed for 48 hours to a single dose of 233.2 µg product/bee by freeding. At the end of the contact toxicity test, there was no mortality at 200.0 µg product/bee. Also, no mortality occurred in the control group. In the oral toxicity test an actual intake of 233.2 µg product/bee led to 2.0% mortality after 48 hours. No mortality occurred in the control group. The LD₅₀ of the reference item was calculated to be 0.19 and 0.14 µg/bee in the contact and oral test, respectively. Atl validity criteria of the test were met. The contact LD₅₀ (48 h) was > 200.0 µg product/bee. The oral 400.0 µg product/bee.

. . MATERIAL AND METHODS:

Test item: Fluopicolide + Propanocarb HCl Sc 687.5(62.5+625) G: Fluopicolide (AE C638206): 5.18 % w/w, 58.14 g/L; Propanocarb-HCl (AE 18066752): 55.8 % w/w, 627.0 g/L; (all values analytical); Batch ID.: EM4L01 180; Sample, Description FAR01771-00; Specification No.: 102000027553; density: 1.123 g/mk (20 °C):

Under laboratory conditions *Apris mellifera* 50 worker bees were exposed for 48 hours to a single dose of 200.0 μ g product/bee by torical application (contact limit test) and 50 worker bees were exposed for 48 hours to a single dose of 233.2 μ g product/bee by feeding (oral limit test, value based on the actual intake of the test item).

Dates of experimental work: May 12, 2014 to May 17, 2014



II. RESULTS AND DISCUSSION:

Toxicity to Honey Bees; laboratory tests

Test Item	Fluopicolide + Propamocarb-H		
Test Species	Apis mell		
Exposure	contact		
	(solution in Adhäsit (0.5 %)/water)	(sucrose solution)	
Application rate µg prod./bee	200.0	233.2	
LD ₅₀ µg prod./bee	> 200.0	>@33.2 🜔	
LD ₂₀ µg prod./bee	> 200.0	© [∞] 233.2	
LD ₁₀ µg prod./bee	> 200.0 v	م > 233.2 ,0	
NOED µg prod./bee*	≥ 200.0	≥⊉33.2 0	

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

The NOED was estimated using risket a second second

At the end of the contact toxicity test (48 hours after application), there was no mortality at 200.0 µg product/bee. Also, no mortality occurred in the control group (water +0.5 % Adhäsit). There were no behavioural abnormalities of the bees during the entire trial at 200.0 urg product/bee?

\$ \$°		Ö 🗞 /	¥ 4.	\sim
	$\begin{array}{c} & \bigcirc \\ & \bigcirc \\ \hline \mathbf{Total @umber} \\ \hline 2 & 4 & \mathbf{b} \\ \hline & & \bigcirc \\ & 0 & \bigcirc \\ \hline & & \bigcirc \\ & & & &$	of dead bees (a	nd m@tality	🙀 %) after
	4 h	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		48 h
Control	$\begin{array}{c} 2 4 \mathbf{h}_{2} \\ \hline 0 \\ (0) \\ \hline \end{array}$	<u>کې</u> 0.00		0 (0)
Test item [µg@rodu@bee]			× ·	
200	0 (0)	\bigcirc \bigcirc \bigcirc \bigcirc \bigcirc		0 (0)
Control Test item [µg product/bee] 200 Reference/item [µg a.s./bee] 0.30 0.20 0.15		of deate/bees (à 24 b 24 b 20 0 0 20 0 0 20 0 0 20 0 0 20 0 0	, O	
0.30	286)	\$ 38(76)	Ň	40 (80)
0.20	1(2)	27 (54)	/	37 (74)
0.15 🔊 🗸	1 (2)	17 (34)		25 (50)
0.10	1.2	10		3 (6)
Test item [µg.product/bee] 200 Reference/item [µg a.s./bee] 0.30 0.20 0.15 0.10 0.4 0.10	9 (0) 7 0 (0) 7 2 (6) 1 (2) 7 1 (2) 7 7 7 7 7 7 7 7 7 7 7 7 7 7			



Oral Test:

In the oral toxicity test, the maximum nominal test level of Fluopicolide + Propamocarb-HCl SC 687.5 (62.5+625) G (i.e. 200 µg product/bee) corresponded to an actual intake of 233.2 µg product/bee, This dose level led to 2.0% mortality after 48 hours. No mortality occurred in the control group (50% w/v sucrose solution = 500 g sucrose/L tap water). One single bee was found to be affected during the hours assessment (before dying) at the 233.2 µg product/bee dose level.

	Total number of	dead bees (a	and mortality	v in %) after	
	4 h	h	Ũ	48 h	JY O O
Control	0 (0)	(0)	R.	0 (0) @	
Test item [µg product/bee]		a' l	Å		
233.2	0(0)	1 (2)	Q &	1/2) 2	
Reference item [µg a.s./bee]			y . O		
0.33	10 (20)	6° 50 (190		50 (1000)	
0.17	2 (4)	0 41 (82)	à số	41 (82)	
0.08	0(0)	6,12)	Q O	8 (16)	
0.06	0 (0) 💭 🔊	A (2)	4 4	1 (2)	
					the second secon

Validity criteria:

Validity criteria (OECD 213 and Q14, 1998)	ð	2	Obtained in this study
Control mortality should not exceed 10 % at testend	Å.	Ŭ Â	Condict test 0%
	'0' - 4y	, Û ^y	Oral test: 0%
LD50 of the reference item should be in the specified	range	~~	Contact lest: 0 19 µg a.s./bee

(contact test: 0.10 - 0.30 up a.s./bee, oral test: Orablest: 0.14 jug a.s./bee

WII. CONCLUSION The toxicity of Ruopicolide + Propanocarb HCl SC 687.5 62. 625) was tested in both, an acute contact and an acute oral toxicity teo on honey bees.

The contact LD_{50} (48 h) was > 209.0 µg product bee. The oral LD_{50} (48 h) was > 233.2 µg product/bee.

X

Assessment and conclusion by applicant:

This study is considered reliable for isk assessment and the endpoints are: LD_{50} contact (48 h) $\gtrsim 200.0$ fg product/bee LD_{50} oral (48 h) > 23.2 (2 product/bee)



Data Point:	KCP 10.3.1.1.1/03
Report Author:	
Report Year:	2017
Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5 + 625) G: Effects
-	(Acute contact and oral) on bumble bees (Bombus terrestric L.) in the laboratory
Report No:	118591105 M-581093-01-1 EC) No. 1107/2009 Directive 2003-01 (Canada/PMRA) US EPA OCSPP 850.SUPP OECD 213 and OECD 214 (1998) Van der Steen (2001) ICPPR non-apis group (2013) and 2016) Current Guidelines: OECD 246 (2017) and 247 (2017) A 5 μL droplet was chosen in the contact to xierty test in deviation to the guideline recommendation of OL uL (contact border a bit her a fitting of the second contact to xierty test in deviation to the guideline
Document No:	M-581093-01-1
Guideline(s) followed in	EC) No. 1107/2009
study:	Directive 2003-01 (Canada/PMRA)
-	US EPA OCSPP 850.SUPP
	Directive 2003-01 (Canada/PMRA) US EPA OCSPP 850.SUPP OECD 213 and OECD 214 (1998) Van der Steen (2001) ICPPR non-anis group (2015) and 2016)
	Van der Steen (2001) $\sqrt[6]{2}$
	ICPPR non-apis group (2013) and 2016)
Deviations from current	Current Guidelines: OECD 246 (2017) and 247 (2017)
test guideline:	A 5 μL droplet was classen in the contact to xis it to the guideline
	recommendation of a put inopicit since a presence of surced inore matrice of
	dispersion of the test item and allows for esting higher application voluties.
	Analytical determination of the test item was not conducted, but the study was performed before the guideline implementation and ite analytical dose
	performed before the guideline implementation and no analytical dose
	verification was foreseen at that pourt in time. Moreover, since it is a limit test
	with a single dosing of the test item this deviation is not proceed to have
	impacte@fhe study results.
Previous evaluation:	No, not previously submitted
GLP/Officially	Yes, conducted under GLP/Offiejally recognised testing facilities
recognised testing	
facilities:	Yes, conducted under GEP/Officially recognised testing facilities
Acceptability/Reliability	

Executive Summary

Executive Summary The purpose of this study way to determine the acute oral and contact toxicity of fluopicolide + propartocarb-hydrochloride SC 687.5 to the bumble bee (*Bombus terrestris* L.) in the laboratory. Mortality of the burnele bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

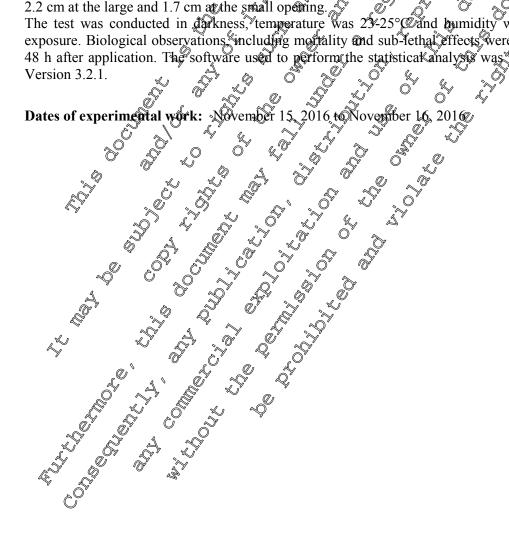
Therefore, under laboratory onditions 50 pumble Bees (Bombus terrestris) were exposed for 48 hours to a single dose of \$20 µg prod./bumble bee, by topical application of 5 µL, in a contact limit test and to a single dose of 345.4 ug prov. bundole bee By feeding iron oral limit test. At the end of the contact toxicity test (48 hours after application) no mortality occurred in the 320 µg prod./bumble bee treatment group. Mortabily of 20% occurred in the water control group (48 hours). After 48 hours there was no mortality in the 345.4 µg prod bumble bee test item group. No mortality occurred also in the water control group. The moreality in the reference item group in the contact and oral test was 100% at rates of 12 µg dimethoate/bumble bee (contact) and 4,30 g dimethoate/bumble bee (oral). All validity criteria

ot 12 µg dimethoate/bumble bee (contact) and 4.30 g dimethoate/bumble bee (oral). All validity criteria of the test were met. The contact UD_{50} (48 h) was > 320 µg product/bee. The oral LD_{50} (48 h) was > 345.5 µg product/bee.



I. MATERIAL AND METHODS:

Test item: Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G: 5.96% fluopicolide (analytical), 55.4% propamocarb-hydrochloride (analytical), Supplier batch No: EV58002080, Saupple description: FAR30060-00, Specification No.: 102000027553. Test organism: female worker bumble bees (*B. terrestris*), obtained from a healthy and queen-right colony, bred by a commercial bumble bee breeding company (Under laboratory conditions worker bumble bees were exposed for 48 hours to a single dose of 320 µg prod./bumble bee, by topical application of 5 μ L, in a contact limit test and to a single dose of 345.4 μ g/ prod./bumble bee by feeding in an oral limit test (value based on the actual intake of the test item). Furthermore, each test consisted of a control and a reference item group. In the contact light test tap water containing 0.1% v/v Triton X-100 was used as control. In the Oral limit test a 50% w/v sperose solution (500 g sucrose/L tap water) was used as control. In both limit tests, BAS 152 11 C (active ingredient 420.3 g/L dimethoate, batch No: FRE (1226) was used as reference item Each treatment group, control and reference in the acute oral and contact toxicity test consisted out of 50 bumble bees Ő with 1 bumble bee per test unit (replicate). 1 Ŵ For the acute oral toxicity test from the 50 bumble bees per treatment group/control only those were taken into consideration which achieved at Teast 80% of the mean food uptake per treatment group For the 345.4 µg prod./bumble bee test item treatment group AT bund he bees were considered for the evaluation. For the water control (50% w/v sucrose solution) and the reference fiem treatment groups 50 and 47 bumble bees were considered for the evaluation, respectively. Test units were cylindrical, lattice plastic cages with blength of appoximately 7 m and a diameter of 2.2 cm at the large and 1.7 cm at the small opening. The test was conducted in darkness, temperature was 23-25° and bumidity was 50-64 % during exposure. Biological observations including motivality and sub-lethal effects were recorded 4, 24 and 48 h after application. The software used to perform the statistical analysis was PoxRat Professional





II. RESULTS AND DISCUSSION:

Biological findings:

Test itemFluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G						
Test object	Bombus te	errestris L. 👡				
	Contact (CO ₂ / tap water containing 0.1% v/v Triton X-	Oral (50% w/v sucrose solution) (based on recorded consumption				
Exposure	100)	considering bumble bees with				
		food uptake of ≥ 80% of the mean Øiptake per treatment group Ø				
Dose rate [µg prod./bumble bee]	320	Q45.4 2 (Q45.4 2)				
LD ₅₀ [µg prod./bumble bee] ^{1,4}	24 hours: 220 48 hours: 320	24 bours: >\$45.4, 0 6 48 hours: > 345.4				
LD ₂₀ [µg prod./bumble bee] ^{1,4}	24 hours: > 320 48(hours: >>>20	24 hours: > 349.4 48 bours: > 345.4				
LD ₁₀ [µg prod./bumble bee] ^{1,4}	24 hours: 320 48 hours: > 320	24% hours > 345.4				
NOED [µg prod./bumble bee] ^{2,4}	24 hours: ≥320 0 48 bours: 2320 0 24 hours: 2320 0 25 hours: 2320 0 26 hours: 2320 0 27 hours: 2	$24 \text{ hours: } \ge 345.4$ $4860 \text{ ours: } \ge 345.4$				
LOEC [µg prod./bumble bee] ^{2,4}	0 % % hours > 320 % 0 √ % 48 hours > 320 %	24 hour > 345.4 248 hours: > 345.4				
As the test item treatment groups did no	ot show in tality bove 50% no stopstical e	valuation on the D ₅₀ , LD ₂₀ and LD ₁₀ was				

1 carried out.

² The NOED/LOED was determined using Fisher's Exact Test after Bonferroni, floim (pairwise comparison, one-sided greater, $\alpha = 0.05$). $\alpha = 0.05$). ³ For the 345.4 µg prod./bumble free test frem treatment group 41 pumble bees were considered for the evaluation. ⁴ Results obtained from test item treated group were compared to those obtained from the water control treated group. **Observations**

Contact test

At the end of the contact toxicity test (48 hours after application) no mortality occurred in the 320 µg prod./bumble bee treatment group. Mortality of 2.0% occurred in the water control group (tap water containing 0.1% v/v Tyton X 100) at test termination (48 hours). The mortality in the reference item group was 100% at test end During the first 4 hours assessment one affected bumble bee was observed in the water control group (tap water containing 0.1% Triton X-100). No test item induced behavioural effects were observed at any time in the 320 pg prod,/bumble bee treatment group. َں ہ Ő¥ õ (A) n

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u>0     0                              </u>	$\underline{\gamma}$	<u>N A</u>			
	ÔAfte	hours?	🤊 🧷 After	24 hours	After	48 hours
Treatment group	Mortalit	apnormaintes	Mortality	Behavioral abnormalities	Mortality	Behavioral abnormalities
. KU K	Smean %	~mean %	Smean %	mean %	mean %	mean %
Test item	Ŵ.		2			
320 μg product	0.0 K	Q0.0 ×	0.0	0.0	0.0	0.0
bumble bee						
Water control	0.0	2	2.0	0.0	2.0	0.0
Reference/item						
12 µg dimethoare/	10.00	33.3	100.0	-	100.0	-
bumble bee						

Test item: Flopicol de + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G

Rehav. absorm mean = Behavioural abnormalities; mean = mean of 50 individual per treatment group

Water  $control = CO_2 / tap water containing 0.1% Triton X-100$ 



#### Oral test

After 48 hours there was no mortality in the 345.4 µg prod./bumble bee test item group. No mortality occurred also in the water control group (50 % w/v sucrose solution). The mortality in the reference item group was 100% at test end.

					ð	
	After 4 hou	rs	After 24 h	ours	After 48 h	iours 5
Treatment	Mortality mean %	Behavioural abnormalities mean %	Mortalit y mean	Behavioural abnormalities mean %	mean %	Séhavioural abnormalities mean %
Test item 354.4 µg product/ bumble bee	0.0	0.0	0.04	()) o	0.0 2	
Water control	0.0	0.0	0.0	0.0		0.0
Reference item 4.3 µg dimethoate/ bumble bee	48.9		100 ×			
Test item: Fluopicolic Mortality mean = Me Behav. abnorm mean Water control = 50%	an of 41-50 indi = Mean of livin	viduals per treatmen g individuals per tre	687.5 62.5+ at group			
/alidity criteria: All validity criteria (	of the test we	romet. S	y o		- 0	4
Validity criteria (C	DECD 246 an	d 247, 2017)		Obtained in this	ştûdy	

Validity criteria (OECD 246 and 247, 2017) 💦 √ Obtained in this study
Control mortality hould not exceed 10 % at test end
Mortality of the reference item should be $\geq 50\%$ at test end Contact test. $\pm 00\%$
Nortanty of the relevance from should be 20 % at test end Oral test: \$00%

IN. CONCLUSIONS:

The 48-h contact  $D_{50}$  of fluopicolide + propamorarb-hydrochloride SC 687.5 (62.5 + 625) was estimated to be 200 µg prod bumble bee. The 48 oral LI250 of fluopicolide + propamorarb-hydrochloride SC 687.5 (62.5 + 625) was estimated to be > 345.4 µg prod. bumble bee.

Assessment and conclusion by applicant:

This study is considered reliable for risk as essment and the endpoints are:  $LD_{50}$  contact (48 h) > 320 µc product/bumble bee  $LD_{50}$  oral (48 h) > 345.4 µc product/bumble bee



# CP 10.3.1.1.2 Acute contact toxicity to bees

	e e e e e e e e e e e e e e e e e e e
Data Point:	KCP 10.3.1.1.2/01
Report Author:	
Report Year:	
Report Title:	Amendment no. 01: Contact Toxicity (LD50) to honey bees (Apis mellifera L) propamocarb hydrochloride + AE C68206 - Water miscible suspension concentrate 634 + 64.7 g/L
Report No:	CW02/054
Document No:	<u>M-213107-02-1</u>
Guideline(s) followed in	EPPO 170 (1992); OECD: 210 (1998)
study:	
Deviations from current	Current Guideline: OECO214 (1998)
test guideline:	Triazophos was used as reference item instead of dimethoate as recommended in the mideline. The second for a filler of the text form door was itely to have the
	the guideline. The spacing factor of the test frem doors was slightly above the maximum of 2.2 recommended in the guideline between the two towest test items doses only. These deviations are not expected to have impacted the study results.
Previous evaluation:	yes, evaluated and accepted
GLP/Officially	Yes, conducted upder GLP Officially recognised testing facilities
recognised testing facilities:	Yes, conducted under GEP Officially recognised testing facilities
Acceptability/Reliability:	Yes vy v v v v
Frecutive Summary	

#### **Executive Summary**

The purpose of this study was to determine the accele contact toxicity of Proparadicarb hydrochloride + AE C638206 to the honeybee (A. mellifera L.) in the laboratory. Mortality of the bees was used as toxic endpoint. Therefore, under laboratory conditions Apis mellifera worker bees were exposed to the test item, reference item and a control by topical application of a single dose of 1.0  $\mu$ L to the ventral thorax. The five dose rates of the test substance were 14.3, 35.8, 71.5, 107.3 and 143.1  $\mu$ g product/bee.

Each treatment group consisted of 5 replicates (lest units) with 10 bees per replicate. The tests were conducted in darkness, temperature was 24 - 26 C and relative humidity was between 57 and 66 %.

The number of dead bees in each case was assessed 24, 48 and 72 hours after application. Contact  $LD_{50}$  values were calculated with the aid of SAS probit – analysis. The  $LD_{50}$  of the reference item was calculated to be 0.104 µg product bee. All validity criteria of the test were met. The  $LD_{50}$  (72 h) for honeybees was >343.1 4g product/bee in the contact toxicity test.

# 1. Materia AND METHODS:

Test item, Propamocarb hydrochloride # AE C638206: 634 g/L propamocarb hydrochloride, 64.7 g/L AE C638206 g/L, density: 1.129 g/L, Identification code: AE B066752 04 SC61 A102, Certificate of Analysis: AGF2002-0022-01 (dated 19 February 2002).

Test organism: female worker honeybers (*Aprs mellifera*), obtained from a healthy and queen-right colony.

Under laboratory conditions *Apis mellifera* worker bees were exposed to the test item, reference item and control by topical application of a single dose of  $1.0 \,\mu\text{L}$  to the ventral thorax. The control bees were treated with 1.0  $\mu\text{L}$  drinking water. The five dose rates of the test substance were 14.3, 35.8, 71.5, 107.3 and 143  $\mu$  µg product/bee. The reference item (triazophos 40.9% w/w) prepared in water was tested in 3 dose rates 0.2, 0.3 and  $0.4 \,\mu\text{g}$  product/bee. Before application, the bees were slightly anaesthetized with CO₂.

Each treatment group consisted of 5 replicates (test units) with 10 bees per replicate. Test units were 12-13 cm high cylindrical test cages with a diameter of 5 cm.



The tests were conducted in darkness, temperature was  $24 - 26^{\circ}$ C and relative humidity was between 57 and 66 %. The number of dead bees in each cage was assessed 24, 48 and 72 hours after application. Contact LD₅₀ values were calculated with the aid of SAS probit – analysis. One dead bee was found in the control after 24 hours. In the test item group 3, 1 and 2 dead bees were found in the test item concentrations with 14.3, 35.8 and 71.5 µg product/bee after 24 hours. No more dead bees were found in the test item group 3, 42 and 46 dead bees were found after 72 hours in the concentrations with 0.2, 0.3 and 0.4 µg product/bee respectively.

### II. RESULTS AND DISCUSSION:

#### **Observations**

One dead bee was found in the control after 24 hours. No more bees died in the control till the end of the study. In the test item group 3, 1 and 2 dead bees were found in the test concentrations with 4.3, 35.8 and 71.5 µg product/bee after 24 hours. No more dead bees were found in the test item concentrations till end of the study. In the test with the reference item group 5, 42 and 46 dead bees were found after 72 hours in the concentrations with 0.2, 0.3 and 0.4 µg product/bee, respectively.

Q Toral number of dead	d bees after 72 fr
24m × 48	$\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}{\sqrt{1-\frac{1}}{1-\frac{1}}}}}}}}}}}}}}}}}}}}}}}}}}$
Control Q al a a	
Control	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	
Reference item füg product/bree]	L O
Reference item fug product/beel         4         5           0.2         4         4         4           0.3         4         4         4         4	
	42
	<u>3 2 46</u>
35.8       1         71.5       2         107.3       0         143.1       0         0.2       4         0.4       4         0.4       4         Test substance       7         Propamocarb hydrochloride + AE C638206       24-72 h LD ₅₀ [µs]         Validity criteria:       7	
Biological findings	
Test substance       Endpoint         Propamorarb hydrochloside + AE C638206       24-72 h LD ₅₀ Reference item       720 LD ₅₀ [μg         Validity criteria:       4         All validity criteria of the test were met.       4	
Test substance Q & S 20 N Kndpoint	
Propamocarb hydrochlofide + AE C638206 24-72 h LD ₅₀	$[\mu g \text{ product/bee}] > 143.1$
Reference item $\bigcirc$ $\bigcirc$ $\bigcirc$ $?$ $\bigcirc$ $?$ $?$ $2$ $\bigcirc$ $?$ $2$ $\bigcirc$ $2$ $0$ $2$ $0$ $2$ $0$ $0$ $0$ $0$ $0$ $0$ $0$ $0$ $0$ $0$	g product/bee] 0.255
Validity criteria:	
All validity criteria of the test vore met.	
Validity coteria (OECI) 214, 1998)	Obtained in this study
Propamocarb hydrochlofide + AE C638206       24-72 n LD ₅₀ Reference item       72 h LD ₅₀ [µ4         Validity criteria:       72 h LD ₅₀ [µ4	2 %
$LD_{50}$ of the reference item fould be in the specified range	0.104 μg a.s./bee*
(coptact test, 0.10 0.30/µg a.s./bee)	1.0.000
*0.253 μg product/bee × 40.9 % w/w triazophos	

**III. CONCLUSIONS:** 

The LD₅₀ (72 h) was > 143.1  $\mu$ g product/bee in the contact toxicity test.



#### Assessment and conclusion by applicant:

This study is considered reliable for risk assessment and the endpoint is:  $LD_{50}$  contact (72 h) > 143.1 µg product/bee.

#### CP 10.3.1.2 Chronic toxicity to bees

Bala Folin.       RCF 10.5.1.2/01         Report Author:       2020         Report Year:       2020         Report Title:       Fluopicolide + propamocath hydrochloride SC 687.5 (62.5) 62.5 g/L): Chronic toxicity to the honey best op is mellifera L, under aboratory conditions         Report No:       19 48 BAC 0030         Document No:       M-682991-01-1         Guideline(s) followed in study:       Regulation (EC) No 1107/2009 (2009)         OECD TG 245 (2017)       0         Deviations from current test guideline:       No deviation         No, not proviously submitted       0         GLP/Officially       Yes, conducted under GLP/Officially second testing facilities:         Acceptability/Reliability:       Yes	LD ₅₀ contact $(72 \text{ h}) > 1$	143.1 μg product/bee.
Data Font.       RCF 10.5.1.2/01         Report Author:       2020         Report Year:       2020         Report Title:       Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 62.5) 6	CP 10.3.1.2 Chro	
Report Author:       2020         Report Year:       2020         Report Title:       Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5 + 625 + L): Chronic toxicity to the honey bee Spis melliferal, under aboratory conditions         Report No:       19 48 BAC 0030         Document No:       M-682991-01-1         Guideline(s) followed in study:       OECD TG 245 (2017)         Deviations from current test guideline:       No deviation         Previous evaluation:       No, not previously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under GLP/Officially occognised testing facilities         Acceptability/Reliability:       Xes	Data Point:	KCF 10.5.1.2/01
Report Title:       Fluopicolide + propamocarb hydrochloride C 687.5 (62.5 625 gL): Chronic toxicity to the honey bee topis mellifera L under taboratory conditions         Report No:       19 48 BAC 0030         Document No:       M-682991-01-1         Guideline(s) followed in study:       Regulation (EC) No 1107/2009 (2009)         Deviations from current test guideline:       No deviation         Previous evaluation:       No, not proviously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under CLP/Officially cognised testing facilities         Acceptability/Reliability:       Yes	Report Author:	
Report No:       19 48 BAC 0030         Document No:       M-682991-01-1         Guideline(s) followed in study:       Regulation (EC) No 1107/2009 (2009)         OECD TG 245 (2017)       OECD TG 245 (2017)         Deviations from current test guideline:       Current Guideline: OECD 245 (2017)         Previous evaluation:       No, not proviously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under OLP/Officially Occognised testing facilities         Acceptability/Reliability:       Yes	Report Year:	
Report No:       19 48 BAC 0030         Document No:       M-682991-01-1         Guideline(s) followed in study:       Regulation (EC) No 1107/2009 (2009)         OECD TG 245 (2017)       OECD TG 245 (2017)         Deviations from current test guideline:       Current Guideline: OECD 245 (2017)         Previous evaluation:       No, not proviously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under OLP/Officially Occognised testing facilities         Acceptability/Reliability:       Yes	Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5+625 g/L): Chionic toxicity to the honey bee Apis mellifera L, under aboratory conditions
Document No.       Medo22991-0141         Guideline(s) followed in study:       Regulation (EC) No 1107/2009 (2009)         Deviations from current test guideline:       OECD TG 245 (2017)         Deviations from current test guideline:       Current Guideline: OECD 245 (2017)         Previous evaluation:       No, not previously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under OLP/Officially becognised testing facilities         Acceptability/Reliability:       Yes	Report No:	19 48 BAC 0030
study:       OECD TG 245 (2017)         Deviations from current test guideline:       Current Guideline: OECD 245 (2017)         Previous evaluation:       No deviation         GLP/Officially recognised testing facilities:       Yes, conducted under CLP/Officially occognised testing facilities         Acceptability/Reliability:       Yes	Document No:	
Deviations from current test guideline:       Current Guideline: OEGD 245 (2017)         No deviation       No deviation         Previous evaluation:       No, not previously submitted         GLP/Officially recognised testing facilities:       Yes, conducted under GLP/Officially becognised testing facilities         Acceptability/Reliability:       Yes		OECD TG 245 (2017) . O . O . O . O . O . O . O . O . O .
Previous evaluation:     No, not previously submitted       GLP/Officially recognised testing facilities:     Yes, conducted under OLP/Officially occognised testing facilities       Acceptability/Reliability:     Yes	test guideline:	Current Guideline: OFCD 24 (2017) (7
recognised testing facilities:	Previous evaluation:	No, not provide submitted in the second
Acceptability/Reliability: Ses of a contract of the second	recognised testing facilities:	Yes, conducte@under@LP/Officially@cognised testing facilities
		$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

#### Executive summary

The purpose of this study was to determine the chronic oral toxicity (LDD50/LC50 and NOEDD/NOEC) of Fluopicolide + Propane carb hydrochloride &C 6875 (62,5+6250/L) applied on ten consecutive days to young adults of the boney bee (Apis melbifera L.Y. Martality of bees was used as the toxic endpoint. Sublethal effects, such as changes in behavior, were also assested.

In a 10-day chronic toxicity feeding test max. 2 days of worker honey bees (Apis mellifera L. subspected Buckfast) were exposed to a daily application of Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5+625 g/L) diffuted by the bee food (50%, (w/v) aqueous sucrose solution + 0.1% (w/v) xanthan). The chronic toxicity of the test item was determined at nominal doses of 165, 82.5, 41.3, 20.6 and 10.3 µg product/bee day corresponding to concentrations of 4202, 2101, 1050, 525 and 263 mg product/kg food, respectively.

Additionally, honey bees were toated with Dimethome EC 400 as toxic standard at a nominal dose of 27.3 ng a bee/day. Uptreated 50% (w/v) aqueous sucrose solution (AC) and 50% (w/v) aqueous sucrose solution + 0.1% (w/v) xanthan (BC) served as control.

Assessments of mortality and behavioral abnormalities were done daily. The daily food consumption was corrected by subtracting the measure vaporation figure of each day of application.

A mean mortality of 6.7% was observed in control group AC and 13.3% in control group BC at end of the test. In the test item group been effectively consumed doses of 119, 77.8, 43.0, 19.3 and 11.0 µg peduct dee/day which caused mortalities of 13.3, 13.3, 6.7, 3.3 and 6.7%, respectively, after 10 days, None of the obtained mortalities was statistically significantly increased compared to the control group BC.

No treatment related abnormal behaviour was observed in any of the test item groups during the test.

The analysed concentrations of the active substance fluopicolide in the feeding solutions ranged between 90% and 101%. The analysed concentrations of the active substance propamocarb-hydrochloride in the feeding solutions ranged between 101% and 103%.



Due to low obtained mortalities, the LDD₅₀, LDD₂₀ and LDD₁₀ are considered to be higher than 119  $\mu$ g consumed product/bee/day and the LC₅₀, LC₂₀ and LC₁₀ to be higher than 4202 mg product/kg food.

The NOEDD was determined to be higher than or equal to 119  $\mu$ g consumed product/bee/day and the NOEC to be higher than or equal to 4202 mg product/kg food.

The study fulfilled all validity criteria of the current OECD 245 guideline.

# I. MATERIAL AND METHODS

<u>Test item:</u> Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5+625 g/L), supplier batch no.: EV57002753, sample description: TOX21332-00 specification no.: 1/2000027553, active substances: Fluopicolide 62.5 g/L (nominal), 5.66% w/w corresponding to 64.04 g/L (analysed) and Propamocarb-hydrochloride 625 g/L (nominal), 54.6% w/w corresponding to 61.80 g/L

<u>Test species:</u> Honey bee (*Apis mellifera* L, subspecies Buckfast); young female worker bees (max awo days old), healthy, disease-free and queen-right boney bee colonies of the second state of the second s

<u>Test concentrations</u>: The chronic toxic by of the test item was determined at nonunal doces of 165, 82.5, 41.3, 20.6 and 10.3  $\mu$ g product/bee day, corresponding to concentrations of 4202, 2101, 1050, 525 and 263 mg product/kg food, respectively.

Additionally, honey bees were treated with Dimethoate EC 300 as toxic standard at a nominal dose of 27.3 ng a.s./bee/day. Untreated 56% (w/v) aqueous success solution (AC) and 50% (w/v) aqueous success solution 0.1% (w/v) xanthan (BC) served as control.

Each group (test item, controls and reference item comprised there replicates containing ten bees.

<u>Test design</u>: In a 10-day chronic to ficity feeding test max. 2 days old worker honey bees (*Apis mellifera* L. subspecies Buckfast) were exposed to a daily application of Fhiopicolide + Propamocarbhydrochloride se 6875 (62.5+625 g/L) dilated in the bee food (50% (%%) aqueous sucrose solution + 0.1% (w/v) xanthan)

For the collection of honey bees, broad combs with capped cells were taken from outside hives and different colonies. Sufficient food supply was ensured either bohoney and pollen which was on the same broad comb or by an additional comb containing food. These frames were placed without adult worker bees in a "five comb hive body" and incubated under controlled environmental conditions in a climatic chamber at  $33 \pm 2$  °C to darkness. Afterwards, thereway hatched worker bees were transferred into the test cages in groups of ten bees per cage. For the following  $24 \pm 2$  h the bees were held in the test cages at  $33 \pm 2$  °C and 50 - 70% relative humidit and provided with 50% (w/v) sucrose solution for acclimatization to the test conditions.

Test item solutions were prepared daily just before the administration of food. Daily dose rates were based on a theoretical food consumption of 33 th/bee. The reference item stock solution was prepared once for the whole feeding period and the respective feeding solutions at least every 4 days and stored in the refrigerator at about 6 %. The respective feeding solutions (test item, control and reference item) were provide *ad libitum* in a plastic syringe, which had been weighed before application. The feeders remained in the cases for bout 24 h (±  $\Omega$ h). The actual consumption was determined by reweighing the syringe containing the temaning test solution each day after removal from the test units. Any unconsumed food was discarded.

Assessments of moltality and behavioral abnormalities were done daily. The daily food consumption was corrected by subtracting the mean evaporation figure of each day of application.

Test conditions:

Temperature: 31.6 - 33.6 °C, Relative Humidity: 54.1 – 63.2 %; Photoperiod: 24 h darkness.



Analytics: For verification of the exposure concentration, all test item solutions as well as control solution were sampled in duplicate as specimens for analysis and retain directly after preparation on each day (D0-D9) of application. Samples were quantified by reversed phase High Performance Liquid Chromatography (HPLC), coupled with electrospray and mass spectrometry (MS/MS) detection.

Statistics: The statistical calculations were performed with the computer program ToxRat Professional 3.2.1 (2015). Fisher's Exact Binomial Test with Bonferroni Correction was used for mortality data (onesided greater,  $\alpha = 0.05$ ) and determination of NOEDD/NOEC (no observed effect dictary dose/concentration). Due to low obtained mortalities the LDD_{50/20/10} and LO_{50/20/10} are considered to be higher than the highest dose/concentration.

Dates of work: September 3, 2019 to February 02, 2020

#### II. RESULTS AND DISCU

Analytical results:

<u>Analytical results:</u> The mean recovery of fluopicolide ranged between 90% and 101% and the mean recovery of propamocarb ranged between 101% and 103% in the final diets. No residues of Fluopicolide (COQ = 6.86 mg/kg) and propamocarb (LOQ 66.2 mg/kg) above the limit of detection were found in any of the control samples.

The mean measured concentrations of the test item in the larger diet were within  $\pm 20\%$  of the nominal. Therefore, the concentrations of the test item in the larval diet were confirmed and the endpoints are based on nominal concentrations. &

Treatment	Timing	Nominal*	Analysed	Recovery	Mean
Group		Nominal* 5 Concentration of a	Concentration of Shuopicolide		recovery
		Nominal* Concentration of fluopicolide Dig a.s./g diet	[mg a k/kg diet]	[%]	[%]
, Ø	D0 D0		© ≤ 30% LOQ	-	
	D0 D0 CD1 D2 C		∑ < 30% LOQ	-	
*7	491 D2 493 O D4 D 9		≪< <200% LOQ	-	
Q	A)3 C D4 C A)3			-	
	0° D4 0		⁽²⁾ < 30% LOQ	-	
Control	D\$		< 30% LOQ	-	
	<u>∿</u> , D6 -Q		< 30% LOQ	-	
Controls A A A A A A A A A A A A A A A A A A A	D6 D7 D7 D8 C D9 D9 D9 D9 D9 D9 D9 D9 D9 D9		< 30% LOQ	-	
7 Ø1	D8 (		< 30% LOQ	-	
	Å D9 0		< 30% LOQ	-	
		r Q	236.7	100	
	D1	9	237.0	100	
	D2	227.8	239.0	101	101
⁴ ⁴ ⁴ ⁴ ⁴ ⁴ ⁴ ⁴ ⁴ ⁴	D1 00 D1 00 D3	237.8	242.9	102	101
Ű	D4		228.9	96	
	D5		242.3	102	

Analysis results for fluopicolide in final diets

Ô

O



#### Page 203 of 299 2020-08-11 Document MCP – Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

Treatment Group	Timing	Nominal* concentration of fluopicolide	Analysed concentration of fluopicolide	Recovery	Mean recovery
		[mg a.s./kg diet]	[mg a.s./kg diet]	[%]	189 à
	D6		251.6	<b>2</b> 106	
	D7		230.7	97	
	D8		251.7	106 5	Ô' JN
	D9		245.5	103	
	D0	Ő	∫ 106.2 ⁰ √	103 103 ×89	
	D1		114.4 Q°	96 fy	
	D2	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	·	× ~82 .×	
	D3	Ŏ [,]		104 c	4
	D4	A T	108.5	\$ 91 ⁰	
	D5		× 121.5 × ×	\$ 91 ⁰	
	D6		1201.0	\$ 102°	¢,
	D7		A12.50	<u> </u>	J [*]
	D8 ~			°°100%	
			6 114.9 V	P 27	
	ĎØ		43.06	~~ 72	
	D1		56.87	s≫ 92	
	DZ .		£ 258.36	98	
Ô	~D3 ~		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	100	
	\$ D4		\$4.07_®	91	
EG EG	105	\$9.45 °	D 58,24	98	90
Ê, ^g '	, © D6 , ∽		×58.29	98	
	D7		48.68	82	
Q			48.61	82	
~Q	C D90		<i>4</i> 9.28 €	83	
A			28.51	96	
	D1	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	27.72	93	
L.			28.97	97	
, O	D3		29.83	100	
Į,		w ^y w ^y	29.82	100	
		≪ ~ <b>Q</b> 9.73	24.55	83	93
J Z	A D6, 9	A G G G G G G G G G G G G G G G G G G G	24.30	82	
S O	D D		30.05	101	
	D8		24.03	81	
	D9		29.50	99	
	D0	14.86	14.67	99	99



#### Page 204 of 299 2020-08-11 Document MCP – Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

Image is a single in the single in the single is a single in the sing	Treatment Group	Timing	Nominal* concentration of fluopicolide	Analysed concentration of fluopicolide	Recovery	Mean recovery
D8     14,7     99 f       D9     190     190       OQ = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts     based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)       nalysis results for propamocarb infinal diets     Anatysed     Recovery       Treatment Group     Timing     Nominal*     Anatysed       Image: Scheduler of analysis (5.66% w/w)     Nominal*     Anatysed     Recovery       Image: Scheduler of analysis (5.66% w/w)     Image: Scheduler of analysed content of propamocarb according concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb       Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb       Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb       Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb       Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration of propamocarb       Image: Scheduler of analysed concentration of propamocarb     Image: Scheduler of analysed concentration			[mg a.s./kg diet]	[mg a.s./kg diet]		L KAT (
D8     14,7     99       D9     1903     101       OQ = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts, based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinalatiets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery     Mean recovery       Image: a.s./kg/diet]     Image: a		D1		13.95	<u></u> 94	
D8     14,7     99       D9     190     190       Q = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts, based on analysed content of propamocarb according ecriticate of analysis (5.66% w/w)     nalysis results for propamocarb infinal gliets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery     Mean recovery       Image: a.s./kg/diet]     Image: a.s./		D2		15.10	0 102	
D8     14,7     99       D9     1903     101       OQ = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts, based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinalatiets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery     Mean recovery       Image: a.s./kg/diet]     Image: a		D3			100 5	
D8     14,7     99       D9     190     190       D0 = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinalatiets       Treatment Group     Timing Nominal* concentration of propamocarb     Anatysed concentration of propamocarb       Image: S./kg diet]     Image: S./kg diet]     Image: S./kg diet]       D0     Image: S./kg diet]     Image: S./kg diet]       D1     Image: S./kg diet]     Image: S./kg diet]       D2     Image: S./kg diet]     Image: S./kg diet]       D2     Image: S./kg diet]     Image: S./kg diet]       D2     Image: S./kg diet]     Image: S./kg diet]       D3     Image: S./kg diet]     Image: S./kg diet]       D3     Image: S./kg diet]     Image: S./kg diet]       D4     Image: S./kg diet]     Image: S./kg diet]       D3     Image: S./kg diet]     Image: S./kg diet]       D4     Image: S./kg diet]     Image: S./kg diet]       D3     Image: S./kg diet]     Image: S./kg diet]       D4     Image: S./kg diet]     Image: S./kg diet]       D4     Image: S./kg diet]     Image: S./kg diet]       D5     Image: S./kg diet]     Image: S./kg diet]       D4     Image: S./kg diet]     Image: S./kg die		D4		<u>7</u> 13.90 0 [°]	98	
D8     14,7     99       D9     1903     101       OQ = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts, based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinalatiets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery     Mean recovery       Image: a.s./kg/diet]     Image: a		D5	, Ø	5 14.82 ⁰⁵	¥00 _Q	
D8     14,7     99       D9     190     190       D0 = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts, based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinalatiets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery propamocarb       Image: a.s./kg/diet]     Image: a.s./kg/diet] <td></td> <td>D6</td> <td>A A</td> <td>15.20 g°</td> <td>⁵ 1025</td> <td></td>		D6	A A	15.20 g°	⁵ 1025	
D8     14,7     99 f       D9     190     190       D0 = 6.86 mg/kg, corresponding to 6.75 µg/L if, diluted extracts based on analysed content of propamocarb according e certificate of analysis (5.66% w/w)     nalysis results for propamocarb infinal diets       Treatment Group     Timing     Nominal* concentration of propamocarb     Anatysed     Recovery     Mean recovery       Ing a.s./kg diet1     0     [%]     [%]     [%]     [%]       D0     30% LOQ     -     30% LOQ     -       D1     D2     30% LOQ     -     -       D2     04     -     -     -       D3     -     -     -     -       D4     -     -     -     -       D3     -     -     -     -       D4     -     -     -     -       D3     -     -     -     -       D4     -     -     -     -       D3     -     -     -     -       D4     -     -     -     -       D3     -     -     -     -       D4     -     -     -     -       D3     -     -     -     -       D4     -     -     -		D7		<u> </u>	× vov ×	
Treatment Group       Timing Propamocarb Propamocarb       Nominal* concentration of propamocarb       Anabysed concentration of propamocarb       Recovery       Mean recovery         D0       [mg a.s./kg diet]       [%]       [%]       [%]       [%]         D0       [mg a.s./kg diet]       [%]       [%]       [%]       [%]         D0       [mg a.s./kg diet]       [%]       [%]       [%]         D1       [%]       [%]       [%]       [%]         D2       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]<		D8	o ^r _k g	<u> </u>	\$ 99 £	4 60
Treatment Group       Timing Propamocarb Propamocarb       Nominal* concentration of propamocarb       Anatysed concentration of propamocarb       Recovery       Mean recovery         D0       [mg a.s./kg diet]       [mg a.s./kg diet]       [%]       [%]       [%]         D0       [mg a.s./kg diet]       [%]       [%]       [%]       [%]         D1       [%]       [%]       [%]       [%]       [%]         D2       [%]       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]       [%]         D6				<u>15:03</u>	¢ 10 [°] ،	¢´¢
Treatment Group       Timing Propamocarb Propamocarb       Nominal* concentration of propamocarb       Anabysed concentration of propamocarb       Recovery       Mean recovery         D0       [mg a.s./kcdiet]       [mg a.s./kcdiet]       [mg a.s./kcdiet]       [%]       [%]         D0       [mg a.s./kcdiet]       [mg a.s./kcdiet]       [%]       [%]       [%]         D0       [%]       [%]       [%]       [%]       [%]         D1       [%]       [%]       [%]       [%]         D2       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%] <td< th=""><th>OQ = 6.86  mg/kg, cone of analys</th><th>responding to 6 is (5.66% w/w)</th><th>5.75 μg/L in diluted extract</th><th>s based on analysed conte</th><th>nt of propamocar</th><th>b according to</th></td<>	OQ = 6.86  mg/kg, cone of analys	responding to 6 is (5.66% w/w)	5.75 μg/L in diluted extract	s based on analysed conte	nt of propamocar	b according to
Treatment Group       Timing Propamocarb Propamocarb       Nominal* concentration of propamocarb       Anabysed concentration of propamocarb       Recovery       Mean recovery         D0       [mg a.s./kg diet]       [%]       [%]       [%]       [%]         D0       [mg a.s./kg diet]       [%]       [%]       [%]       [%]         D0       [mg a.s./kg diet]       [%]       [%]       [%]         D1       [%]       [%]       [%]       [%]         D2       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D3       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]       [%]       [%]       [%]         D4       [%]       [%]       [%]       [%]       [%]         D5       [%]       [%]<	nalysis results for	propamocarl	o infinal@iets			Ĵ,
Group         concentration of propamocarb         concentration of propamocarb         concentration of propamocarb         recovery           Img a.s./kg diet]         <	Treatment	Timing				
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Group		concentration of	concentration of		recovery
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$						50/1
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			<pre>% [nog a.s./k@diet]</pre>		<u>, 0) [%]</u>	[%]
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Å			$\sim < 30\% LOQ$	-	
O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O       O <tho< th=""> <tho< th=""> <tho< th=""></tho<></tho<></tho<>	le la				-	
D3       30% 190       -         D4       -       -         D5       -       -         D6       -       -         D6       -       -         D7       -       -         D8       -       -         D9       -       -         230% LOQ       -         -       -       -         09       -       -         09       -       -         230% LOQ       -       -         230% LOQ       -       -         D9       -       -       -         210       -       230% LOQ       -         230% LOQ       -       -       -         D9       -       -       230% LOQ       -         2316       101       2389       104       103         05       -       -       2375       104       103         06       05       104       105       104	ð			~ < 30% LOQ	-	
Optimized     Optim	1 N			<u>⊗ &lt; 30% LOQ</u>	-	
D3       D3       C       S0       -         D6       0       0       0       -       0       30% LOQ       -         D8       0       0       0       0       -       0       30% LOQ       -         D8       0       0       0       0       -       0       30% LOQ       -         D9       0       0       0       0       -       0       20% LOQ       -         D9       0       0       0       0       0       -       0       20% LOQ       -         D9       0       0       0       0       0       -       0       20% LOQ       -         D0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0       0				× × 30% LOO	-	-
D0     -       D7     -       D8     -       D9     -       C     30% LOQ       C     -       C     30% LOQ       C     -       C     -       D9     -       C     -       C     -       C     -       D9     -       D9     -       D9     -       C     -       D9     -       D9     -       D1     -       D2     -       D1     -       D2     -       D3     -       D4     2294       2316     101       D3     -       D4     2294       2313     101       103       D6     -	* *				-	
DS     DS     C     SO 0     C       DS     DS     C     30% LOQ     -       C     S0% LOQ       S0%	Q M			0 < 200/ LOQ	-	
Do     Do     C     S0% LOQ     -       D9     D9     C     S0% LOQ     -       D0     D0     C     S0% LOQ     -       D0     D0     C     S0% LOQ     -       D0     D2     D1     S258     98       D1     D2     D2     D3     D4       D2     D4     D2     D3     D4       D4     D2     D3     D4     D3       D3     D4     D4     D2     D4       D4     D4     D2     D4     D4       D6     D6     D4     D1	~Ÿ				-	
DQ     DQ     DQ     DQ       DQ     DQ     DQ     DQ <td>A A</td> <td></td> <td></td> <td>&lt; 200/ LOQ</td> <td>-</td> <td>   </td>	A A			< 200/ LOQ	-	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	~~~			> 50% LOQ		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$				22.30	70	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		DQ R		2427	107	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		Bi Contraction		2427		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		DOA DI A D2		2427 2316	101	
2375 104 2416 105		$\begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} $		2427 2316 2389	101 104	
^v D6 2416 105		$\begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} $	2294	2313	101 104 101	103
		DQ D1 D2 D2 D4 D4 D4 D4 D4 D4	2294	2313	101 104 101 104	103
D7         2339         102           D8         2446         107		$ \begin{array}{c} \begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\$	2294	2313 2375 2416	101 104 101 104 105	103

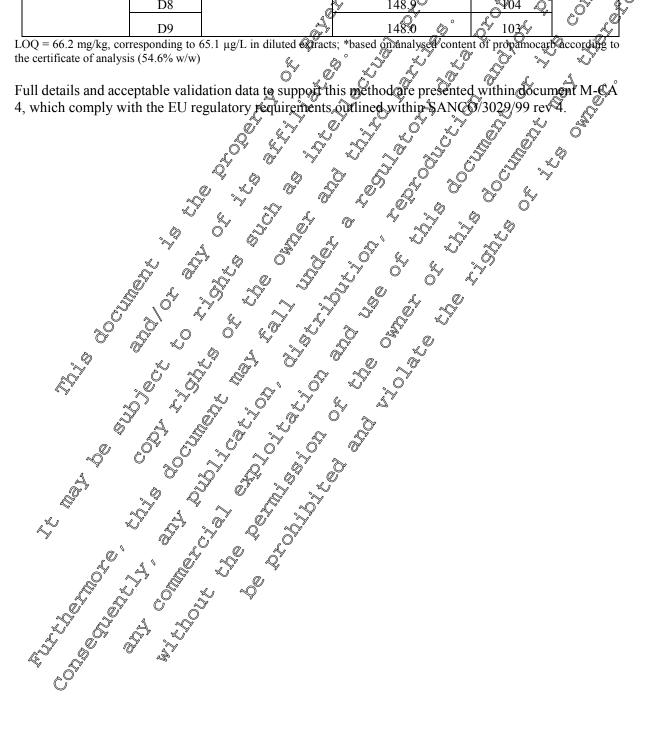


#### Page 205 of 299 2020-08-11 Document MCP – Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

Treatment Group	Timing	Nominal* concentration of	Analysed concentration of	Recovery	Mean recovery
		propamocarb	propamocarb	Г0/ <b>Т</b>	F0 A
	D9	[mg a.s./kg diet]	[mg a.s./kg diet] 2457	[%]	
	D9 D0		1157	4 V	
	D0		1110	97 2	
	D1 D2		O S	107	
	D2 D3		<u>√</u> 1160 0° √ 1260 0°	100 x	
	D3			98 × 9	
	D4 D5	1147	·		¢ 103
	D3 D6			204 ×	
	D0	A. W			
	D7 D8		1216	\$ 103 \$ 103 \$ 105	
	D8 D9				0°
	D0		× × × × × × ×	<u>d</u> 03 ~	<u>y</u>
	D1		3. 55 <b>4</b>	° 97 % €	
	D2 🖏		~ 568.1 ×	2 <u>89</u>	
	D2 D3		\$ 593.9 \$ \$	~~104	
	~D4	4 500.5 5 ⁴ 6 57 6 6 57 6 7 570.5 5 ⁴	2 560.5 K	2×7 98	
	<u> </u>	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		99	101
Ő			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	100	
ST CO	D720		\$ \$04.5 ¢	105	
	×D8 _3		© 597.6	104	
Ê	*D8 . @ D9. )		× \$\$5.5	106	
try'			297.9	104	
Q			\$ 272.4	95	
~	D9.07 D0 D0 D1 5 D20		297.4	104	
	D3		298.7	104	
W.	$\sim D4$		304.6	106	
			280.5	98	101
, O `			281.7	98	
	DZ		296.6	103	
			288.8	101	
J R			286.8	100	
	Č LŽ		145.2	101	
	D1		137.7	96	
$\bigcirc$	D2	143.4	149.5	104	102
	D3		148.3	103	



Treatment Group	Timing	Nominal* concentration of propamocarb	Analysed concentration of propamocarb	Recovery	Mean recovery
		[mg a.s./kg diet]	[mg a.s./kg diet]	[%]	18 A
	D4		144.5	<b>D</b> 101	
	D5		144.9	101	
	D6		146.5	102 5	
	D7		148.1 V	100 .	
	D8		148.90		
	D9	4	148.0 Ø	103	Ŭ d





#### **Biological results:**

Summary	of mean	mortality an	d toxicity of	f Fluopicolide +	Propamoca	rb-hydroch	loride SC 687.5	NO S
(62.5+625 g	g/L) to ad	ult honey bees	after 10 days	of chronic expos	ure		N C	d y
						After 10 da	iys L S	
Treat-	Treat	Daily	dose	Concentration	Mean m	ortality	Number of	₽ _⊂
ment	ment				L.	÷	bees showing	2
group	group	nominal	consumed	Ó	absolute	corrected		Q1
	ID	[µg produc	t/hee/davl	[mg product/k	100 ⁹	[%]	abiormalities	6
		ing produc	ubee/day]	g food]				¥
Control	AC	=	-	~~	6.7 ° 1953	ý - ý	0 out of $28^{\circ}$ $\sim 9$ out of $26^{\circ}$	
Control	BC		- (	5 B A	1363 🐇	g - D`	°∼9 out of 26	
	AT	165	119	4202 4202 2104 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4202 4002 400 400	Q13.3 0		0 met of 26	
	BT	82.5	77.8	2104	13(3)	0.0 ×	0 out of 26	
Test item	CT	41.3	Q 19.3	\$1050~C*	Q ^{43.3} 13(3) 6.7 2 5 6.7 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		0 out of 28	
	DT	20.6	Q 19.3	Q 585 6	3.0	0.0	• 0, out of 29	
	ET	10.3	~11.0	263 L	<b>\$</b> .7		9 0 out of 28	
		, <b>frig</b> a.s./h	ee/day	mag a.s./ by foo				
Referen ce item	AR	\$ 27.30 5 5	19.2 19.2		90.0 ⁴	\$9.3	0 out of 3	
			Endpoints			// 10 d		
Test i	item	DD 5900/10 [µ	g consumed p	rodact/bee day]		>119		
dos	er ser ser ser ser ser ser ser ser ser s	NOEDD Ing consomed prod		duct/bee/day	2 D	≥119		
Test i	item 🐊	\$ \$\$\$\$50/20/	mg product	/kg tood		> 4202		
concent	rations	A NOE	[mg product/]	g food]		≥ 4202		

Results are averages based on 3 reprisentes, containing 10 bee Each; Calculations are performed with non-rounded values and corrected for exportation corrected for exporation Õ

corrected: conjected mortality (according to SCANEIDER WRELLI W47), negative values are treated as "0"; test item treatment group was corrected for magality of untreated control BC; scelerence item treatment group was corrected for mortality of untreated control AC

- Number of bees with behavioural abnormalities referring to number of remaining bees
- No observed effect dietary dose concernation 1 was calculated using Fisher's Exact Binomial Test with Bonferroni Correction; a = 0.05; and sided greater

A mean mortality of 6.7% was observed in control group AC and 13.3% in control group BC. In the test item group bees effectively consumed doses of 119, 77.8, 43.0, 19.3 and 11.0 µg product/bee/day which caused mortalities of 13.3/13.3, 6.7, 3.3 and 6.7%, respectively, after 10 days. None of the obtained montalities was statistically significantly increased compared to the control group BC. The reference dosage tested in the study was 27.3 ng a.s./bee/day (actual consumption on average per day: 19.2 ng a.s./bee), which caused a mean mortality of 90.0%.

In the test item group, the food consumption ranged between 28.4 and 41.9 mg solution per bee per day



 $\bigcirc$ 

with a tendency of higher food uptake in the lower concentrations.

The mean daily amount of evaporated feeding solution AC ranged between 38.7 and 50.0 mg per day per feeding tube and of BC between 34.7 and 44.7 mg per day per feeding tube.

In the course of the test as well as in the final assessment on the last day of the test no treatment elated abnormal behaviour was observed in any of the test item groups. 

#### Validity criteria:

All validity criteria according to the guideline OECD 24% were met in this study.

M			0	ĭ 🖓	_O' _×
Validity Criteria (OECD 245, 2017)		Recommended	Q	Obtained	
Mortality after 10 days of exposure	Control &°	$\leq 15\%$	Ø	0.7 % and 1	3.2%
Mortality after 10 days of exposure	Dimethoate	\$50%	Ô	90.6.%	<u> </u>
*			S.		

CONCLUSIO

L

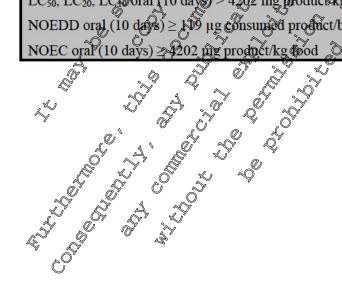
The chronic oral toxicity of Fluppicolide + Propangearb-hydrochloride Se 687 (62.5+625 g/L) on young adult honey bees (Apis mellifers L.) was investigated in a Brday chronic, dose-response feeding ¢, study under laboratory conditions. & m

Due to low obtained mortalities, the LDD 50, LDD 20 and LDD 30 are considered to be higher than 119 µg consumed product/bee/day and the LG50, LC5 and LC10 to De higher than 4202 mg product/kg food.

The NOEDD was derivined to be higher than of equat to 119 µg consumed product/bee/day and the NOEC to be higher than of equal to 4200 mg product of food

Assessment and conclusion by applicant: 0

S This study is considered reliable for risk assessment and the endpoints are: LDD3, LDD20, LDD10 oral (10 days) > 19 µg product/bee/day LC50, LC20, LC10 oral (10 days) > 4202 mg product Rg food NOEDD oral (10 days)  $\geq 109$  µg consumed product/bes/day





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

Data Point:	KCP 10.3.1.3/01
Report Author:	
Report Year:	2020
Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (625 + 625 g/L) - Repeated
	exposure to honey bee larvae (Apis mellifera L.) under laboratory conditions
Report No:	19 48 BLC 0035
Document No:	<u>M-682868-01-1</u>
Guideline(s) followed in	OECD Guidance Document 239 (2016)
study:	
Deviations from current	Current Guideline: OECD G 239 (2016)
test guideline:	The relative humidity between D8 and D15 was below $80 \pm 5\%$ due to a
	malfunction of the climate chamber. There was no impact assumed on the study
	outcome as no effects occurred in the untreated control?
Previous evaluation:	No, not previously sometime of the second se
GLP/Officially	Yes, conducted under GAP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes 0 2 2 2 2 2 2 2

#### **Executive summary**

The purpose of this study was to determine the chronic toxicity (NOED, LOED, NOEC and LOEC for adult emergence up to D222 and  $DD_{10}$ ,  $DD_{20}$ ,  $ED_{50}$  if possible) of the rest item to the honey bee larvae, *Apis mellifera* L., in a laboratory test after repeated sposure

First instar honey bec harvacoof *Apps mellifera* L were transferred from brood combs to polystyrene grafting cells in 48 well cell culture plates 2 days before the start of the exposure period (D1, grafting). Larvae were exposed to Onominal concentrations of 1153, 1613, 2257, 3162 and 4426 mg product/kg food (corresponding to a nominal cumulative dose of 182, 255, 357, 500 and 700 µg product/larva) via the larval diet on 4 consecutive days (D3 to D6). No additional feeding of the larvae took place after D6.

Additionally, a reference item dimethoate tech. at a cumulative nominal dose of 7.6 µg a.s./larva) and an untreated control were included in the experimental design. Each treatment group comprised 3 replicates including 12 larvae each. Assessments of larval mortality were done on D4, D5, D6, D7 and D8. Additionally other observations such as small body size or unconsumed food on D8 were noted. Pupal mortality was assessed on D15 and energence of adults was evaluated on D22.

Concentration of the active substances thopicopide and propamocarb-hydrochloride was determined in the larval thet of each day of the exposure period.

On D8, charval mortality of 28% was observed in the control. In the test item group larval mortalities on D8 were 36.1% 1.1% 5.6% 0.0% and 0.0% following a treatment with 700, 500, 357, 255 and 182 µg product/larva, respectively. In the Final assessment on D22, larvae treated with 700 µg product/larva showed an emergence rate of 55.6% which was statistically significantly different compared to the control (77.8%).

The mean recovery of fluppicolide and propamocarb-hydrochloride ranged between 82% and 104% in the final diets.

The NOED and LQED were determined to be 500  $\mu$ g and 700  $\mu$ g product/larva (based on adult emergence) respectively. The NOEC and LOEC were 3162 mg and 4426 mg product/kg food, respectively.

The  $E\widehat{\mathbb{D}_{30}}$ ,  $ED_{20}$  and  $ED_{10}$  values (based on adult emergence) were determined to be >700 µg, 613 µg and 351 µg product/larva, respectively. The  $EC_{50}$ ,  $EC_{20}$  and  $EC_{10}$  values were determined to be >4426 mg, 3876 mg and 2219 mg product/kg food, respectively.



The study fulfilled all validity criteria until day 8 of the current OECD guidance document 239 (2016).

#### I. MATERIAL AND METHODS

<u>Test item:</u> FLC + PCH SC 687.5 (62.5 + 625 g/L), supplier batch no.: EV57002793, sample description: certificate of analysis; TOX21332-00, specification no.: 102000027553, content of fluopicolide; 62.5 g/L (nominal), 5.66% w/w corresponding to 64.04 g/L (analysed) and propamocarb-hydrochloride; 625 g/L (nominal), 54.6% w/w corresponding to 618.0 g/L (analysed).

<u>Test species</u>: Honey bee larvae (Hymenoptera, Apoidea), *Apis mellifera* L. subspecies Buckfast, commonly known as Buckfast bees, synchronized first instar (L1, one day-old) larvae originating from three adequately fed, healthy (free of clinical symptoms of any disease) and queen-right bee colonies. The larvae were taken from hives that had not received treatments with chemical substances for a least one month.

<u>Test concentrations</u>: Larvae were exposed to 5 concentrations of the test item 1153, 0613, 2057, 3162 and 4426 mg product/kg food (nominal), equivalent to a cumulative dose of 182, 255, 357, 500 and 700  $\mu$ g product/larva (nominal), and one reference item group with 48.0 mg dimethoate/kg food, equivalent to a cumulative nominal dose of 6  $\mu$ g dimethoate/larva.

One untreated control group (feeding diet) was also assessed.

Each treatment group comprised 3 replicates; including 12 darvae each.

<u>Test design</u>: Larvae were exposed to 5 concentrations of the test item via the Jarval diet on 4 consecutive days (D3 to D6). No additional feeding of the darvae took place after D6 the aqueous sugar solution (ASS-A) as one component of the artificial diet A was prepared freshly on D1. ASS-B and ASS-C were prepared prior to the test and thereafter stored in a prepared freshly on D3, D4, D5 and D6. The sugar solution was thixed with royal jelly every day before each feeding occasion. The volumes and contents of diets A B anOC are presented below.

. 0			,	49	Ś		
Test day					4 ²	5 ²	6 ²
Artificial		A A	ې . چ	Ø BY	С	С	С
Volume of diet per	·lanva 🏷 🖉	A μL >		20 μL	30 µL	40 µL	50 µL
Composition of di				) )			
Royal jelly		50% w/w	5 - 8	50% w/w		50% w/w	
Sugar solution		\$0% w/\$	Ď.	50% w/w		50% w/w	
Composition of sug	gar soution a	<u>60% w/@</u>					
Glucose	S A P	12% w/v	ļ	15% w/v		18% w/v	
Fructose	Ĩ Î Î	12% <b>v</b>	-	15% w/v		18% w/v	
Yeast extract		2%w/v		3% w/v		4% w/v	
		day of graft	ing	² days o	of exposure		

On D1 the coops containing the L1 larvae were transported from the hives to an acclimatized laboratory room Larvae were transferred from the combs to the cells. The larvae were placed on the surface of the artificial thet within the grafting cells. Assessments of larval mortality were done on D4, D5, D6, D7 and D8. Additionally, other observations such as small body size or unconsumed food on D8 were noted. Pupal mortality was assessed on D15 and emergence of adults was evaluated on D22. In the analytical phase of the study, the concentration of the active substances fluopicolide and propamocarb-hydrochloride was determined in the larval diet of each day of the exposure period.



<u>Test conditions:</u> Temperature: 34.0 – 35.0°C, Relative Humidity: D1 – D8: 90 – 100%, D8 – D15: 30 – 70%, D15 – D22: 56 – 63%, Photoperiod: 24h darkness (diffuse artificial light only during handling and assessments).

Statistics: The Step-down Cochran-Armitage Test was used for statistical analysis of the adult emergence data and the estimation of the NOEC/NOED and LOEC/LOED. The accepted significance level was  $\alpha = 0.05$  (one-sided greater). The ED/EC_{10/20/50} values were determined with the Weibull analyses using linear maximum likelihood regression.

The statistical calculations were performed with the statistical program ToxRat Professional (Ratte, 2018).

Analytics: All final diets were sampled in duplicate as retain (-R) samples after proparation and as analysis (-A) samples right after feeding on D3, D4 D5 and D6. The chemical analysis were performed by using reversed phase High Performance Liquid Chromatograph (HPIDE) coupled with MS/MS detection.

Dates of work: September 09, 2019 to September

#### Analytical findings:

The mean recovery of fluopieolide ranged between 82% and 500% and the mean recovery of propamocarb ranged between 9% and 104% in the final dists. Notesidues of fluopicobile (LOQ = 30.6 mg/kg) and propamocarb (LOQ = 295.4 rog/kg) above the limit of detection were found in any of the control samples.

The mean measured concentrations of the test item of the loval diet were within 20% of the nominal content. Therefore, the concentrations of the test item in the larvaOdiet were confirmed and the endpoints are based on nominal concentrations.

Treatment	Timing	Nominal*	Analysed concentration of	Recovery	Mean
Group	Timing	fluopicolide 0	concentration of		recovery
~	ý) ý	mg.a. 0/kg diet	[mg=a.s./kg diet]	[%]	[%]
Į,	<u>Å</u> 3		30% LOQ	-	_
	6 ⁹ D4 0		@ ³ < 30% LOQ	-	-
Contrôl	DS	$\begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \end{array} \\ \begin{array}{c} \end{array} \\ \end{array} $	Ø″ < 30% LOQ	-	-
	≿\$D6 <		< 30% LOQ	-	
, KU 5	D D D 4 L		261	104	-
	D4		254	101	100
Ó ^y .	A D5	25005	237	95	100
	D4 D5 D5	ky ~Q	255	102	
Fluppicolide	D3 04	ŕ	173	97	
	\$ D4	170.0	161	90	
	D5	179.0	153	86	89
G	D6		148	83	
	D3	127.8	118	92	86

### Analysis results for flugpicolide in final diets

C



#### Page 212 of 299 2020-08-11 Document MCP – Section 10: Ecotoxicological studies Fluopicolide + Propamocarb-hydrochloride SC 687.5

Treatment Group	Timing	Nominal* concentration of fluopicolide	Analysed concentration of fluopicolide	Recovery	Mean recovery
		[mg a.s./kg diet]	[mg a.s./kg diet]	[%]	<u>k</u>
	D4		108	84	
	D5		110	86	
	D6		107	84 ×	
	D3		76.8	840	
	D4	01.2	√ 73.7 ^{√ √} √	×81 Q	
	D5	91.3	73.2° ©	2 ⁵⁴ 80 ⁴	C82 @
	D6		<u>. 017.4 × 0</u>	× 285 .×	
	D3		<u>59</u> 59	\$ 91 £	A
	D4		52.9	\$ 81 ⁰	
	D5		52. 6 52. 6 J	\$80 X	
	D6	6.05 Mg/L in Ciluted extrac	55.2	850 Int of flugpicolist	ò
e certificate of analys nalysis results for	propamoeart	b in final diets			,
Treatment	Timing	Nominal	Analysed	Recovery	Mean
Group	* \$	concentration of	concentration of proponocarb	63	recovery
				* ¥	
		propamocarb		· ¥ ¥ [%]	[%]
Č		fing a st./kg diet	[mga.s./kg diet]	°∛ ∀ [%] -	[%]
	0 0 0 0 0 0 0 0 0 0 0 0 0 0		5 [m@a.s./kg diet] ~ 30% LOQ	- - -	[%]
Control	•		∑ [m@a.s./kg diet]	- - -	[%]
Control	XD5		∑ [m@a.s./kg diet]	- - - -	[%] -
E	105 © D6. 0		∑ [m@a.s./kg diet]	[%] - - - - 107	[%] -
	205 . @ D6		∑ [m@a.s./kg diet]	- - - - - 107	
	25 C D6, $CD3D3D4CD5$		∑ [m@a.s./kg diet]	- - - 107 103	[%] - 104
	25 C D6, $CD3D3D4CD5$		∑ [m@a.s./kg diet]	- - - - 107 103 102	
	205 . @ D6		∑ [m@a.s./kg diet]	- - - 107 103	
	D5 D6 D3 D4 D5 D5 D6 D6		∑ [m@a.s./kg diet]	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6		∑ [m@a.s./kg diet]	- - - - - - - - - - - - - - - - - - -	
	D5 D6 D3 D4 D5 D5 D6 D6		∑ [m@a.s./kg diet]	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6		[m@a.s./kg diet]         30% LOQ         30% LOQ         30% LOQ         30% LOQ         30% LOQ         230% LOQ         230% LOQ         2577         2495         2477         2550         1846         1809         1766         1755	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6		[m@a.s./kg diet]         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~         ~	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6		[m@a.s./kg diet]         30% LOQ         30% LOQ         30% LOQ         30% LOQ         30% LOQ         230% LOQ         2577         2495         2477         2550         1846         1809         1766         1755         1260         1222	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6	Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 241664       Öğimg 241664	[m@a.s./kg diet]         30% LOQ         30% LOQ         30% LOQ         30% LOQ         30% LOQ         230% LOQ         230% LOQ         2577         2495         2477         2550         1846         1809         1766         1755         1260         1222         1264	- - - - - - - - - - - - - - - - - - -	- 104
	D5 D6 D3 D4 D5 D5 D6 D6	Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 25%/kg dieti       Öğimg 241664       Öğimg 241664	[m@a.s./kg diet]         30% LOQ         30% LOQ         30% LOQ         30% LOQ         30% LOQ         230% LOQ         2577         2495         2477         2550         1846         1809         1766         1755         1260         1222	- - - - - - - - - - - - - - - - - - -	- 104



Treatment Group	Timing	TimingNominal*Analysedconcentration of propamocarbconcentration of propamocarb		Recovery	Mean recovery
		[mg a.s./kg diet]	[mg a.s./kg diet]	[%]	18 j
	D5		864.5	<b>98</b>	
	D6		883.8	100	
	D3		641.0	102 -	
	D4		634.1		
	D5	629.29	604.40	×96 Q	
- 205 4 mg/ltg a	D6	A	609.5 Ø	م 97 الم	Ŭ d

LOQ = 295.4 mg/kg, corresponding to 58.1 µg/L in diluted extracts; *based on/analysed content of propamocarbaccording to the certificate of analysis (54.6% w/w)

Biological findings: Biological observations On D8, a larval mortality of 2.8% was observed in the control (AG). In the test stem group larval mortalities on D8 wars 36.1% 11/2% 5.6% 0.6% on 200 % Objective a transmit with 700, 500, 257 mortalities on D8 were 36.1%, 11.9%, 5.6%, 0.8% and 0.0% following a treatment with 700, 500, 357, 255 and 182 µg product/larva @espectively. Mortality of the reference item treated group (AR) was above 50% on D8.

#### **Other observations**

Other observations of the remaining farvae areated with the test ice wete observed to have food left and/or a smaller body size.

Adult emergence In the final assessment on D22, an adult emergence rate of 77.8% was determined for the honey bees in the control group. In the test atem treated group, the adult hone obees cherged at rates of 55.6%, 69.4%, 88.9%, 75, 9% and 86.1% exposed to a cumularive dose 70%, 500, 357, 255 and 182 μg product/larva, respectively, during the larval stages. On D22, larvae treated with 700 µg product/larva, showed an

respectively, during the larvat stages. On D22, larvae treated with 700 µg product/la emergence rate, which was statistically significantly different compared to the control.



•					-		-	-	-	
			Concen-		On D8			On D2	22^	
Treat- ment group	Treat- ment ID	Cumu- lative Dose (nominal) [µg	tration (nomi- nal)		nortality o D8	Mean OO	Total m D3-		Adia emergence rate	
		product/ larva]	[mg pro- duct/ kg food]	[% abs.		[%]	Jenson Contraction of the second seco	6] S		
Control	AC	_	-	2.8	Ø.0	0.0	22.2		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
	AT	700	4426	36.1Q	34.3	0.9	Q4.4	Q _{28.6} 0	* 158 55.6* ⁽¹⁾ ** 69.4	/
	BT	500	3162	1	8.6	~~0.0 ×	30,6	10.7	° 69.4	
Test item	СТ	357	2257	A, 5.6, 4	or 2,20	0.0	م ۱۱.1 م	≥ 0.0 Ô	88.9	0
	DT	255	1613	0.0	Ø.0 .	\$0.0 Ó	25,0	\$.6	گ [°] 754€	
	ET	182	1193	¢ ₩0.0 %	\$ 0.0\$	× QO	~D3.9	5 0.0 ¢	\$\$6.1	
Reference		[µg a.s./larva]	woul							
item	AR	7.6	48	88.9	\$8.6	\$33.3 ×	97,Q	26.4	2.8	

#### Mortality and other observations of larvae and adult emergence in the repeated exposure toxicity test

Results are averages based on 3 replicates (kives), containing 2 larvac each; corf.: concected mostality (according to SCHNEIDER-ORELLI 1947); mortality in test and reference item treated groups were concected by the mortality of the control (AC); abs.: absolute mostality as counted from the results; calculation were performed with non-rounded values; OO: Other observations (e.g. remaining tood); negative values were set to 30 and 50 and 5

Ô

# Calculated endpoints of the repeated exposure larvae toxicity test

Treatment	S Endprint: Adult emergence	at D22
S,	ED6/µg product/larva] ^{2,3}	>700
	ED ₂₀ frg product/larea] (95% CL) ²	613 (440 - 854)
Test item cumulative doses	ED ₁₀ [μgproduce/Jarva] @5% CL) ²	351 (274 - 450)
	LOED [us product/larva] 1	700
↓ ↓ ↓	NOED [µg product/larva] ¹	500
	EC ₅ @[mg product/kg food] ^{2,3}	>4426
Test item	$EC_{20}$ [mg product/kg food] (95% CL) ²	3876 (2786 - 5394)
Test item	$EG_{10}$ [mg product/kg food] (95% CL) ²	2219 (1732 - 2844)
	LOEC [mg product/kg food] ¹	4426
concentrations	NOEC [mg product/kg food] ¹	3162

¹ Step-down Cochran-Armitage Test;  $\alpha$ =0.05; one-sided greater

²Weib analyses using linear maximum likelihood regression

³ Value was extrapolated to be outside of the tested range

CL...Confidence limits



#### Validity criteria:

All validity criteria were met in this study.

Validity Criteria (OECD GD 239, 2016)		Recommended	Opgained (5)
Cumulative larval mortality from day 3 to 8 in the control groups	Control	<u>≤1</u> 5%	5 2.85 p
Adult emergence rate until day 2	Control	© ⁴ ≥70%	77.8%
Cumulative larval mortality from day 3 to 8 in the reference group	Dintethoate		Q 88.0%
III.	Conclusion		

In a repeated exposure larval toxicity study performed in Fdose-Fspone design with FLC + CH SC 687.5 (62.5 + 625 g/L), the NOED and LOED was determined to be 500 µg and 700 µg product/farva (based on adult emergence), respectively The NOEC and LOEC were 3162 mg and #426 mg product/kg food, respectively.

The ED50, ED20 and ED10 values based on adult emergence) were determined to be >700 µg, 613 µg and 351 µg product/larva, respectively. The EG50, EG50 and CC10 values were decormined to be >4426 mg, 3876 mg and 2219 mg product/kg food, respectively. O

A,

×,

Assessment and conclusion by applicant: This study is considered reliable for risk assessment and the endpoints are; NOED (emergence) = 500 μg product/larva LOED (emergence) = 000 μg product/larva NOEC (emergence) = 3162 mg product/kg food
Assessment and conclusion by applicant: This study is considered reliable for risk assessment and the endpoints are: NOED (emergence) = 500 $\mu$ g product darva
NOED (emergence) = 500 ug productory
NOED (emergence) = 500 $\mu$ g product/arva $\sim$
LOED (emergence) = $000 \ \mu g \ product/larva > 0 NOEC (emergence) = 3162 \ m g \ product/kg \ food > 0 LOEC (emergence) = 4426 \ m g \ product/kg \ food > 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 $
NOEC (emergence) 3162 mg product/kg 100d 3
NOEC (emergence) = 3162 mg product/kg food LOEC (emergence) = 4426 mg product/kg food
ED ₅₀ (emergence) > $\frac{1}{200}$ µg productiarva
LOEC (emergence) = 4428 mg product/kg ford $ED_{50}$ (emergence) > $\frac{2}{000} \mu$ product/larva $ED_{26}$ (emergence) = $\frac{6}{613} \mu$ product/larva $ED_{10}$ (emergence) = $\frac{3518}{42} \mu$ product/larva
$ED_{10}$ (emergence) = 35 Kng product/Japva $\swarrow$
EC ₅₀ (emergence) 2426 pg product/kg food 2
EC20 (emergence) = 3876 mg product/kg food
$EC_{10}$ (engergence) = 2209 mg product kg food
$ED_{50} (emergence) > 700 \ \mu g \ product Harva \\ ED_{20} (emergence) = 613 \ \mu g \ product/larva \\ ED_{10} (emergence) = 351 \ \mu g \ product/larva \\ EC_{50} (emergence) = 4426 \ m g \ product/kg \ food \\ EC_{20} (emergence) = 3876 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 2209 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ product/kg \ food \\ EC_{10} (emergence) = 200 \ m g \ pro$

#### Sub-lethal effects CP 10.3.1.4

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



Data Point:	KCP 10.3.1.5/01
Report Author:	
Report Year:	2019
Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (625 + 625) G: Texicity
	testing on honey bees (Apis mellifera L.) under semi-field conditions in Germany
	- Tunnel test
Report No:	122691037
Document No:	<u>M-651105-01-1</u>
Guideline(s) followed in	Regulation (EC) No. 1107/2009
study:	Directive 2003-01 (Canada/PAIRA)
	US EPA OCSPP Not Applicable
	US EPA OCSPP Not Appleable
Deviations from current	Current Guideline: EPPO 170 (4) (2014)
test guideline:	No deviations
Previous evaluation:	No, not previously submitted
GLP/Officially	Yes, conducted under OLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes Q A A A A A A A A A A A A A A A A A A
Executive Summary	

#### **CP 10.3.1.5** Cage and tunnel tests

### Executive Summary

The purpose of this semi-field study in Germany was to conduct a test under forced confined exposure conditions (tunnel), in order to assess potential effects of Ruopicolide + Propanocarb-hydrochloride SC 687.5 (62.5 + 625) G on honey bees and honey Bee cotonies Four funnels for each treatment group (20 m length  $\times$  5.0 pewidth  $\times$  2.5 th height were set up on a *cg*. 80 m plot of *Phacelia tanacetifolia* (2 × 40 m²). Small be colornes were introduced to the turnels ordays before the daytime application of the test item, the control and reference item, respectively. One honey bee colony was used per tunnel. Four tunnels were wated av 1.965 L/ha during full flowering without honey bees present. On the following day a second test item application was performed at 1% L/ha during full flowering of the crop while honey bees were actively for aging (daytime application). For the control and the reference item the reatment with tap water and dimethoate Despectively, was done at full flowering at daytime, when bees foraged actively. In addition the 12 turnels being treated with the test item, water and reference item, three further turnels were setoup. These tupnels were treated with the test item and thereafter exclusively used for moniforing and collecting residues. Test parameters were mortality of adult bees, behavioural abnothalities, foraging activity of the bees and assessment of brood status. Mean temperature during the continement period (day  $\sqrt{3}$  to day + 7) ranged between 16.3 and 26.6°C. No rain occurred during the exposure phase of the bess to the treated crop in the tunnels for the first 5 days. No effects on mortality of adult and immature honey bees were observed. Foraging activity, behaviour, nectar, and pollen storage as wellows queen survival was not affected. There was no effect on overall colony development, development of brood and colony strength observed. Based on the study results it can be concluded that Fluopicolide Propanocarb-hydrochloride SC 687.5 (62.5 + 625) G does not adversely affect honey bee behaviour, brood development, colony strength and queen survival when applied twice, at a rate of 5.965 L product/ha and at 1.6 L product/ha in 400 L water/ha under the above described conditions.



#### I. MATERIAL AND METHODS:

Test Item:

Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G (FLC + PCH SC 687.5 (62.5 + 625) G): fluopicolide (AE C638206): 5.96 % w/w, 67.42 g/L, propamocarb-hydrochloride (AE B066752): 55.4 % w/w, 627.6 g/L (all analysed values); Supplier Batch No.: EV58002080; Sample Description: FAR30060-00; Specification No.: 102000027553; Sample ID: FAR30060-00; All analysed values); Supplier Batch No.: EV58002080; Sample Description: FAR30060-00; Specification No.: 102000027553; Sample ID: FAR30060-00; All analysed values); Supplier Batch No.: EV58002080; Sample Description: FAR30060-00; Specification No.: 102000027553; Sample ID: FAR30060-00; All analysed values); Supplier Batch No.: EV58002080; Sample Description: FAR30060-00; Specification No.: 102000027553; Sample ID: FAR30060-00; All analysed values); Supplier Batch No.: EV58002080; All analysed values); Supplier Batch No.: EV58002080; Sample Description: FAR30060-00; Specification No.: 102000027553; Sample ID: FAR30060-00; All analysed values); Supplier Batch No.: EV58002080; All analysed values; All analysed values; All analysed values; All analysed values; A

#### Test Species:

Honey bees (*Apis mellifera carnica* L.); small bee colopies, maintained according to formal beekeeping practice, containing 11 combs with honey, pollen and 7 – 7 brood combs (eggs, lavae and pupa). They preliminary brood check indicated healthy colonies, with all brood stages present and a sufficient amount of pollen and honey to guarantee colory viability. The mean strength of the colonies per treatment group, three days before the daytime application, was similar and range between 47% and 6233 adult bees per colony. No medical treatments were used in the three weeks prior to the experimental start.

#### Test Design:

The test was conducted under forced confined exposure conditions (tunnel), in order to assess potential effects of Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G on honey bees and honey bee colonies under semi-field conditions. Four tunnels for each treatment group (20 m length  $\times$  5.0 m width  $\times$  2.5 m height) were set up on a *ca*. 80 m² plot of *Phacelia Ganacetifolia* (2 × 40 m²). Small bee colonies were introduced to the tunnels 6 days before the daytime application of the test item, the control and reference item, respectively. One honey bee colony was used performed.

The following application scenarios were performed a second state of the second state

- a) four tunnels (with one colony per tunnel) were treated twice with the test item: once at 1.965 L/ha during full flowering of the crop (BBCH 65) in the ovening (evening application; without honey bees present). On the following day a second test item application was performed at 1.6 L/ha during full flowering of the crop (BBCH 65) while honey bees are actively foraging during daytime (daytime application).
- b) four whinels (with one colory per tranel) were to ated with tap water (serving as controls) during full flowering of the grop while hopey bees were actively foraging during daytime.
- a) four tunnels (with one colory per tunnel) were treated with a reference item during full flowering of the crop while honey beer were actively foraging during daytime (a.s. dimethoate, 1.2 L BAS 152 11 I/ha).

The confined exposure phase of the honey bees to the control (water) and reference item treated crop inside the tunnels was 7 days following the daytime application. In the evening of the 7th day after daytime application, all be colonies (*i.e.* the colonies from the test item, the control and the reference item group, respectively) were relocated after 7 days of confined exposure from their respective tunnels and placed in an area with no main flowering, bee attractive crops.

After foliar (spray) application of the water (control), test item and the reference item, mortality as well as foraging activity of the bees was assessed. Mortality and foraging activity of the bees were assessed before and after the daytime application (corresponding to Day of Daytime Application = DDA0). The condition of the colonies including assessment of brood status was assessed in regular intervals until the end of the trial.

In addition to the 12 tunnels being treated with the test item, water and reference item, three further tunnels were set up. These tunnels were treated with the test item and thereafter were exclusively used for monitoring and collecting residues ("residue tunnels") to describe exposure. Three tunnels (with one



colony per tunnel) were treated twice with the test item: once at 1.965 L/ha during full flowering of the crop in the evening (without honey bees present). On the following day a second test item application was performed at 1.6 L/ha during full flowering of the crop while honey bees are actively foraging during daytime. The following specimens were collected from each of the three test item residue turnels, separately:

- pollen and nectar via foraging bees on DDA0 (ca. 2 hours after application) and on DDA

No biological assessments were performed in the three-test item "residue tunnels" after application at any time during the confinement period.

In order to verify application and exposure of the bees, a duplicate sample of the spray solution was taken out of the spray tank before each application and exposure of the spray each tunnel separately:

- 2 × approx. 80 mL sample from the test item spraying solution following evening application (DDA-1), out of the spray tank for each test item tunnel separately ( $-4 \times biological tunnels + 3$ ) residue tunnels = 7 tunnels).
- 2 × approx. 80 mL sample from the test item spraying solution following dayting application (DDA0), out of the spray tank for each test item tunnel separately  $4 \times 10^{-10}$  application (DDA0), residue tunnels = 7 tunnels).

Afterwards all samples were transported deep-frozen ( $\leq -20$  °C) to the ibacon laboratory in Rossdorf, Germany. In the laboratory of the ibacon test facility, the collected for doing bees were further processed (pollen and nectar extraction). The residue samples of the spray solution(s) were stored deep frozen ( $\leq -20$  °C) until further shipment, only.

After processing the samples (including residue samples of the spray solution(s)) were send (deepfrozen,  $\leq$  -20 °C) to Bayer AG - Crop Science Division - in Monheim, Gerthany, for the analytical phase of the study. After transfer of the deep-frozer samples from ibacen to Bayer AG, residue analysis of the active ingredient contained in test item in the samples was Onducted at Bayer AG - Crop Science Division -, fluman Safety - Residue Analysis The analytical phase report is added to the final report (ibacon 122691037).

#### Test Parameters:

Mortality of adult bees 3 days before to 42 days after daytone application (2 brood cycles).

Behavioural althormanies: Edays before to 42 days after daytime application (2 brood cycles).

Foraging activity of the bees: 3 days before to Talays after daytime application

Colony assessments including assessment of broad status (food stores, colony strength and hive populations): once before application on day -3 and on days 7, 14, 21, 28, 34, 41 (2 broad cycles and end of the trial).

### Application Rates:

Control: 4000 tap water/ha, during bees actively foraging on the crop.

**Test Item evening application:** 1.965 L product in 400 L water/ha corresponding to 2.224 kg product/La¹⁷ and to 5.56 g product/L, without bees present.

¹⁷ Considering a density of 1.132 g/mL according to Certificate of Analysis.



**Test Item daytime application:** 1.6 L product in 400 L water/ha corresponding to 1.811 kg product/ha and to 4.53 g product/L (considering a density of 1.132 g/mL), during bees actively foraging on the crop.

Reference Item: nominally 1.2 L BAS 152 11 I in 400 L water/ha (corresponding to 3.0 mL/L of 2.22) g/L), during bees actively foraging on the crop.

#### Test Conditions:

The© The period before daytime application was characterized by unsettled weather with some rain weather stabilised on the day of the evening application and during the evening and daytime application. the weather was warm and sunny. On the day of the daythere application doneybee for aging activity was sufficient on the crop within the tunnels.

Mean temperature during the confinement period ( $dage^2 3$  to day + 3) ranged between 16.3 and 26.6No rain occurred during the exposure phase of the reated crop in the tunnels for the fi days. First precipitation (4 mm) occurred on day 8.

#### Statistics:

C Statistical evaluation was done for mortality, for aging activity and colony strength using Shapiro-Witk's test (check for normal distribution), Levene's test (check for homogeneity of cariance), Student or Welch t-test and Mann- Whitney U-test (parwise comparison), (software TOX Rat Professional, Version 3.2.1, ® ToxRat Solutions (mbH) Dates of experimental work:

Mortality of the adult worke

Pre-application hase day - 3 to day + before day the application. Mortality before dagtime application in the control, test item and reference item group was 43.2, 42.4 and 42.6 dead bees/colory/day respectively. This was not statistically significantly different compared to the water control (Student Fest, pairwise comparison to the control, two-sided,  $\alpha = 0.05$ ).

Q.

Exposure phase in the tunnels (day 0 after day time application to day 7):

Mean mortality of admit bees in the test item treatment during the exposure phase was similar or even lower to the control group any assessment day. There was no sign of any acute effect on mortality of the adult honey bees at any time after exposure to the treated crops in the tunnels. The comparison of the daily and the overall mortanty values (day 0 to day 7) between the test item treatment and the control group showed no statistically significant difference to the control (Student t-test [day wise] or Mann-Whitney U-test [overall], pairwise comparison one-sided greater,  $\alpha = 0.05$ ). Average control mortality of adult bees during the exposure phase (day 0 to day 7 following the daytime application) was 42.6 dead bees/colony/day. The acrage portality in the test item group was distinctly lower with 25.0 dead bees/colony/day.

In contrast, application of the reference item (dimethoate at a rate of 480 g/ha) resulted in a markedly increased number of the debes found in the traps and on the gauze strips during the confinement period. Following the application on day 0, mortality in the reference item group increased up to ca.  $72 \times$  the mortality levels of the control group. From day 0 to day 3 following the application the number of dead bees found in the reference item treatment was statistically significantly increased compared to the control values (Student t-test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). The average mortality during the exposure phase (day 0 to day 7) in the reference item group was 246.1 dead bees/colony/day vs 42.6 dead bees/colony/day in the control group.



Phase outside the tunnels (day 8 after daytime application to day 21 [1st brood cycle]):

Overall, the number of dead bees in the test item treatment was low with a mean of 8.4 dead bees per day and colony during the period from day 8 to day 21 after treatment. This was lower and accordingly not statistically significant different to the control (14.6 dead bees/day/colony) (overall comparison with Mann-Whitney U-test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). Mortality levels in the test item group were not statistically significant different to the control at any time when subjected to a day wise comparison (Student t-test, pairwise comparison, one-sided greater, d = 0.05).

Phase outside the tunnels (day 22 after daytime application to day 42 day brood cycle)

The overall comparison from day 22 to day 42 showed that the number of dead bees found in the tes item treatment (4.9 dead bees/day/colony) was lower and thus not statistical significant compared to the number of dead bees found in the control group (5.8 dead bees/day colony (Mann-Whitney U test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). The pairwise comparison on every day displayed no statistically significant difference of the test item group to the control. The relative low amounts of dead bees in the reference item group during the phase outside the tunnels

(days 8 - 42) is the result of the high effects on bees caused by dimethoate during the exposure phase. Half of the bees in the colonies were lost during the exposure phase in the reference item.

**Foraging Activity** 

Pre-application phase (day -3 for day Tbefore, daytime application

The mean foraging activity in the intended test term and reference item groups was comparable to the control group, resulting invoverall daily mean values of 13.0 12.4 and 13.8 bees on 2/day in the control, test item group and reforence tem groups, respectively. Day -Zwas excluded from evaluation as no flight activity occurred due to enduring rain. No statistically significant differences were found between the control, the test and reference item treatment groups at the overall daily mean comparison of this period (Welch t-test,  $\alpha \neq 0.05$ , two-sided).

Exposure phase in the tunnels (day 0 after daytime application to day./):

Overall from day 0 to day 7; mean for aging activities in the test item group were comparable to the control values (16.1, bees/m²/day, and 16.8 bees/m²/day, respectively), and thus not statistically significantly different (Welch t-test, pairwise, one-sided smaller,  $\alpha = 0.05$ ).

After application of the reference item (dimethoate), foraging broke down and was statistically significantly reduced compared to the control group (Work t-test, pairwise, one-sided smaller,  $\alpha =$ 0.05). The overall daily mean foraging activity from day 0 to day 7 in the reference item group was 0.1 bees/m²/day, which was statistically significantly reduced compared to the control group (Welch t-test, pairwise one-sided smaller,  $\alpha \approx 0.05$  ?

Behavioural abnormalitie

No behavioural@bnormalities occurred in the test item treated group and in the control group at any assessment day? The reference iter caused behavioural abnormalities (moribund and affected bees) for three days following day &

C

Ŵ Condition of the colonies:

Condition of the coronies was assessed over two complete brood cycles of the honey bees (*i.e.* 42 days  $[2 \times 21 \text{ days}]$ ). At the beginning of the trial all colonies to be used for the test were similar according to the season. All queens (or eggs) and brood stages (eggs, larvae and closed brood) were found in all colonies as an indication of healthy colonies. Moreover, the amount of food reserves (uncontaminated



nectar and pollen) was sufficient to ensure colony viability and brood status but also allowed that enough space was available for exposure of the brood to new food sources.

At the end of the 7th day after daytime application, the hives were relocated from their tunnels. In general, the test item treatment group colonies developed in the same manner as the control colonies. Compared to the control, a similar amount of brood could be found during the assessments with not indication of a test item related effect. All colonies exposed to the test item remained stal with increasing bee numbers and healthy brood. The amount of individual brood stages (eggs, larvag and pupae) present in the colonies of the different treatment groups fluctuated and was alternating higher in the different treatment groups on the different assessment days. All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all following brood checks indicating that the queens were alive and healthy.

There was no indication of any effect of the test item on the condition of the bee olonies:

#### Colony strength:

Three days before daytime application the mean number of hones bees for colory was between 4770 and 6233 in all treatment groups. The subsequent development of the colony strength apong the colones in the control and test item treatment groups followed the same pattern. Following re-movement of the colonies from the tunnels, (beside a short decrease within the confinement period) there was a continuous increase of colony strength observable. The relative increase of bee population in the control group was slightly higher and is explainable by the slightly lower becommbers in the control colonies at the beginning of the trial. No statistically signaticant difference in the colory strength between the test item treated colonies and the control colonies occurred at any assessment date (Student Vtest, pair-wise comparison to the control, one sided smaller,  $\alpha = 0.05$ ). Overall, no adverse effects of the test item on colony strength and population development have been observed throughout the study. Development in the reference item group was slightly decreased which was statistically significantly different to the control on days 7 and 28.

Ø Considering the initial mean number of bees per treatment group before the application as 100 %, the following relative mean numbers of bees were determined:

Treatment Group	Day 1 -1 Day 7 Day 2	10 Day 28	Day 34	Day 41
Control		b 163%	190%	198%
Test Item	96% 118% 0136% (n.s.) (n.s.) (n.s.)		141% (n.s.)	154% (n.s.)
Reference Item			137% (n.s.)	140% (n.s.)

¹ time in relation to the daytime application

n.s. = not statistically significant to the control; Student t-test,  $\alpha$ =0.05, pairwise; onesided smaller.

Les Control, *. * statis



#### Summarised mortality and foraging activity data of the honey bees

		Treatment group	1)
Parameter	Control	Fluopicolide + propamocarb- hydrochloride SCO 687.5 (62.5 + 625)G	Reference Item BAS 152 0 I [0.48 kg. s./ha]
Mean mortality of worker bees / colony / day [n] during pre-application phase day -3 - 1 ²⁾	43.2 ± 14.7	$42.4 \pm 1340$ (n.s.)	
exposure phase in the tunnels day $0 - 7^{2}$ phase outside the tunnels day $8 - 21^{3}$	$43.2 \pm 14.1 = 42.6 \pm 23.9$ $14.6 \pm 97$	$42.4 \pm 130$ (n.s.) $25.0 \pm 28$ (n.s.) $8.4 \pm 4.7$ (n.s.)	$246.1 \pm 30.5 (\text{ms.})$ 5.5 $\oplus$ 5.0 (ms.)
phase outside the tunnels day 22 - 42 ⁴⁾ overall after application day 0 -42	5.8 ± 2.6 15 ℃± 6.6	$4.0 \pm 0.8 \text{ (ms.)}$	$4.6 \pm 1.5$ (n.s.) $0^{2}$
Mean foraging activity / m² / colony / day [n] during pre-application phase	(4, 0°) 0 0° 0° 13.0 ± 8.4 0°	0 124±9.30(n.s.)	$b = 1 b \overline{p} (n.s.) c^{\circ}$
exposure phase in the tunnels	16.8±7.8	$16.1 \pm 14$ (n.s)	0.1 ±9.1 (*)

Statistical evaluation:

Mortality: before application: Student t-test, 90.05 (two-sided, after application: Student t-test bay wis for Mann-Whitney U-test [overall], pairwise, one-sided greater 1 m Foraging Activity: before application: WOCh t-test, a = 0.05, two-sided; atter application: Welch trest, pairwise, one-sided

smaller (No flight activity occurred on day -2 due to enduring rain, therefore day 4 was excluded from evaluation). n.s. = not smaller (No flight activity occurred on day -2 can to charge and the control statistically significant compared to the control = statistically significant compared to the control

1) each with four tunnels (replicate)

2) mean number of dead honey bees per day and coord in dead bee traps and or gauze strips in the tunnels

3) mean number of dead hones bees per day and colony found in dead bee traps (1 brood cycle; day 8 to day 21)

4) mean number of dead honey bees per day and colong found in dead ber traps (2nd brood cycle; By 22 to day 42) 0

#### Analytical findings

The exposure of the hone bees to the test item was confirmed by malytical measurement of the active substances fluopicolide and propanocarb-hydrochloride in the spray solution samples taken from the biological assessment tunnels and the extra residue tunnels. The concentration of fluopicolide and propamocarb-hydrochloride in both groups of sunnels was in a comparable range so that it is assumed that the exposure conditions were comparable in all tunnels treated with the test item. In those tunnels allocated to residue determination, honeybees were used as sampling device. The concentration of fluopicolide and propamocarb-hydrochloride measured in the collected pollen and nectar samples of the day of daytime application and the day after allows for confirmation of the exposure of the bees inside No. Ő the tunnels. Õ O

The following table gives an overview of the concentration of fluopicolide and propamocarbhydrochloride in the analysed sample materials

5 E 0				Fluopicolide					
Sample Material	Ost Item	Sampling Day	Source	Concentration [mg/kg]	Mean Concentration [mg/kg]	Recovery from Target* [%]	Mean Recovery from Target* [%]		
Pollen		DDCA0	T1 - T3	19 - 27	24	-1			
Poller	Fhiopicolitie +	DDA1	T1 - T3	2.3 - 2.5	2.4	-	121		
A.	Fhiopicolfte + Poopamocarb- hydrochloride	DDA0	T1 - T3	0.22 - 0.32	0.28	-1	1. I I		
Nectar	SC 687.5 (62.5 + 625) G	DDA1	T1 - T3	0.028 - 0.068	0.047		( <u>-</u> )		
			TSE: T1 - T4	265 - 273	269	80 - 82	81		
	ða á á	DDA-1	TRE: T5 - T7	248 - 288	268	75 - 87	81		

#### Residue summary in on pollen, nectar and sprax solution



					Fluopie	colide	
Sample Material Test Item		Sampling Day	Source	Concentration [mg/kg]	Mean Concentration [mg/kg]	Recovery from Target* [%]	Mean Recovery from Target*
C			TSD: T1 - T4	196 - 231	214	73 - 86	
Spray Solution		DDA0	TRD: T5 - T7	222 - 242	234	73 - 86 82 - 90	87. 5
		3		]	Propamocarb-	ydrochloride	
Deller		DDA0	T1 - T3	323 - 474	410	- 🖉	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Pollen		DDA1	T1 - T3	41 - 50	45	- 0	- ×
Maatan		DDA0	T1 - T3	11@13	42	Õ	
Nectar		DDA1	T1 - T3	0.73 - 1.5	Y.1 Q	Q A	· · ·
		DDA-1	TSE: T1 - T4	2470 - 2960	Y.1 2 2648y	80 - 20	- 4 - 4 - 4 - 4 - 4 - 4 - 4 - 4 - 4 - 4
G		DDA-1	TRE: T5 - T7	2520 2680 ×	2590	82 87	84
Spray Solution		TSD: T1 - T4		2010	75-83		
		DDA0	TRD: 75 -	2080 - 2110	20.00 ×	0 ⁸ 83 - <b>8</b> 4	83

Pollen/Nectar: T1 to T3 description for samples from tunnels used for Residue Analysis Spray Solution: TSE = Test Item Evening Spray Solution from Tunnels used for Biological Accessments, TRE = Test Item Evening Spray Solution from Tunnels used for Residue Analysis (SD = Test Item Daytime Spray Solution from Tunnels used for Biological Assessments, TRP = Test Item Daytime Spray Solution from Tunnels T-1 to T-4 description are samples from tunnels used for Biological Assessments, T5 to 37 descriptions are samples from tunnels used for Residue Analysis

tunnels used for Residue Analysis

Mean concentrations were calculated using unrounded values. *The target concentration in the spray solution for fluopicolide ors 331 mg/kg for DDA-1 and 270 mg/kg for DDA0, and for propamocarb-hydrochloride 3080 mg/kg for DDA-1 and 2510 mg/kg for DDA0

propanice and hydrochloride solution in the grant of  $DDA^{-1}$  and 2310 a

III. Conclusions: III. Conclusions: III. Conclusions: G to honey bee colonies, honey bees were exposed under realistic but severe (forced) exposure conditions in a semicifield test (confinement in tunnels). The test item was applied twice: once at 1.965 L product/ha during full flowering of the surrogate crop *Phacelia tanacetifolia* in the evening (without honey bees present) and subsequently the next day Guring Caytime at 1.6 L product/ha in 400 L water/ha, during full flowering of the Grop (BBCH 65) while honey bees were actively foraging.

Concurrently to the second test item application, the control (tap water) and reference item applications (dimethone) were conducted on the full flowering *Phacelia tanacetifolia* crop (BBCH 65), during daytime and with honey bees actively for a ging on the crop.

No effects on mortality of adult and impature boney bees were observed. Foraging activity, behaviour, nectar- and pollen storage as well as queen survival was not affected. There was no effect on overall colony development, development of brood and colony strength observed.

Based on the results of this Study,  $4^{\circ}$  can be concluded that Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 62.5) Goloes not advessely affect honey bee behaviour, brood development, colony strength and queen survival when applied twice, at a rate of 1.965 L product/ha and at 1.6 L product/ha in 400 L water ha under the above described conditions.



Report Author:	
Report Year:	2019
Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5 + 625) G: Toxicit
	testing on honey bees (Apis mellifera L.) under semi-field conditions in Spain -
	Tunnel test - Final report -
Report No:	121561037
Document No:	<u>M-653952-01-1</u>
Guideline(s) followed in	Regulation (EC) No. 1107/2009
study:	Directive 2003-01 (Canada/PMR A)
	US EPA OCSPP - Not Applicable
	OEPP/EPPO guideline No. 170 (4) (2010)
Deviations from current	Current Guideline: EPPO 17 $\mathcal{O}(4)$ (2010)
test guideline:	No deviations
Previous evaluation:	No, not previously submitted
GLP/Officially	Yes, conducted und GLP/Officially recognised teching facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$ $\tilde{\mathcal{A}}$

#### **Executive Summary**

The purpose of this semi-field study in Spain was to conduct a test under forced/confined exposure conditions (tunnel), in order to assess potential effects of Fluopreolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G on honey bees and honey bee colonies. Four tunnels for each treatment group ( $25 \text{ m} \text{ length} \times 5.5 \text{ m} \text{ width} \times 3.5 \text{ m} \text{ height}$ ) were set up on a ca. 80 m² plot of *Phacelia tanacetifolia* ( $2 \times 40 \text{ m}^2$ ). One honey bee colonies was antroduced to each tunnel, in the morning, at BBCH 65, two days before the evening application of the test item and three days before the daytime applications of the control (water), second test item application and the reference term.

Four tunnels were freated at 1.965 L/ha during full frowering (BBCH 65) in the evening without honey bees present. On the following day a second test item application was performed at 1.6 L/ha during full flowering of the crop (BBCH 65) while honey bees were actively foraging. For the control and the reference item the treatment with tap water and dimethoate, respectively, was done at full flowering at daytime, when bees foraged actively in addition to the 12 tunnels being treated with the test item, water and reference item, three further tunnels were set up. These turnels were treated with the test item and thereafter exclusively used for monitoring and collecting residues. Test parameters were mortality of adult bees, behavioural abnormalities foraging activity of the bees and colony assessments including assessment of brood status. Mean temperature during the confinement period (day- 3 to day + 7) ranged between 18.1 and 25.5 °C. During the exposure phase inside the tunnels and the following monitoring phase outside the tunnels, weather was very warm and no rain occurred until study end.

Overall, the mortality and foraging activity were comparable to the control throughout the study duration and no test item related effects on adult and immature honey bees were observed. Behaviour of the bees, nectar- and pollen storage well as queen survival was not affected. There were no observable effects on overall colony development development of brood and colony strength.

Based on the study results it can be concluded that Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) O does not adversely affect honey bee behaviour, brood development, colony strength and queen survival when applied twice, at a rate of 1.965 L product/ha and at 1.6 L product/ha in 400 L water/ha under the above described conditions.

# Test Iter

#### I. MATERIAL AND METHODS:

Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G (FLC + PCH SC 687.5 (62.5 + 625) G): fluopicolide (AE C638206): 5.96 % w/w, 67.42 g/L, propamocarb-hydrochloride (AE B066752): 55.4 % w/w, 627.6 g/L (all analysed values); Supplier Batch No.: EV58002080; Sample



Description: FAR30060-00; Specification No.: 102000027553; Sample ID: M16000539001; density: 1.132 g/cm³.

#### Test Species:

Honey bees (*Apis mellifera iberica* L.); Healthy, well-fed and queen-right colonies were used for the test. Colonies were free of obvious bee diseases. Small honey bee colonies, equipped with 6 conves containing at least 5-6 brood combs with all brood stages present (eggs, larvae and pupae) and at least 1 comb with an appropriate amount of nectar and pollen. The queen-right colonies consisted of a mean of 7101 to 7524 honey bees/colony. No medical treatments were used in the hives 4 weeks prior to the experimental start.

#### Test Design:

The test was conducted under forced/confined exposure conditions (tunnel), inorder to assess potential effects of Fluopicolide + propamocarb-hydrochloride SC 687.5762.5 + 625) G on honey bees and knewy bee colonies under semi field conditions. Four tunnels for each treatment group (25 m length  $\times$  5.5 m width  $\times$  3.5 m height) were set up on a *ca.* 80 m² plot of *Phacelig tanacutfolia* (2 × 40 tr²). One honey bee colony was introduced to each tunnel, in the morning, at BBCH 65, two days before the evening application of the test item and three days before the daytime applications of the control (water), second test item application and the reference frem. The study was carried out according to the following test design:

- four tunnels (with one colony per tunnel) were treated twice with the ten item: once at 1.965 L/ha during full flowering of *Phacelia tandcetifolia* crop (BBCH 65) in the evening (without honey bees present). On the following day a second test item application was performed at 1.6 L/ha during full flowering of the crop (BBCH 65) while honey bees were actively foraging during daytime;
- four tunnel (with one colony per tunnel) were (concurrently to the test item daytime application) treated with tap water, while hone bees were actively toraging on the crop (serving as controls);
- four tunnels (with one colony per turnel) were treated with a reference item during full flowering of the crop while honey bees were actively foraging during daytime (a.s. dimethoate, 4.2 L BAS 152/11 1/1a), while honey bees were actively foraging on the crop.

The confined exposure phase of the honey bees to the control (water) and reference item treated crop inside the tunnels was "days following the application day DDA0¹⁸ (during full flowering (BBCH 65) and honey bees actively for ging on the crop). The confined exposure phase of the honey bees to the test item-treated crop inside the funnels started in the giorning of DDA0 when the bees started to for age on the test item treated grop after the first test item application in the evening on DDA-1.

In the morning of DDA8, all honey bee colonies were removed from the tunnels to an area with no main flowering crops in the surroundings. The condition of the colonies and the mortality were examined until day 42 following DDA0 (Send of study).

In addition to the 12 tunnels being treated with the test item, water and reference item, three further tunnels were set up. These three tunnels were also treated with the test item and thereafter were exclusively used for monitoring and collecting residues ("residue tunnels") to describe exposure. Three tunnels (with one colory per tunnel) were treated twice with the test item: once at 1.965 L/ha during full

¹⁸ In the following, the point in time refers to the control, second test item application and reference item application during full flowering (BBCH 65) and honey bees actively foraging on the crop (= Day of Daytime Application, DDA0).



flowering of the crop (BBCH 65) in the evening (without honey bees present). On the following day a second test item application was performed at 1.6 L/ha during full flowering of the crop (BBCH 65) while honey bees were actively foraging during daytime.

The following samples were collected from each of the three test item residue tunnels, separated

• pollen and nectar via foraging bees: DDA0 approx. 2 hours after the test item application and on DDA1

No biological assessments were performed in the three-test item "residue tunnels" offer application at any time during the confinement period. In order to verify application and exposure of the bees, a duplicate sample of the spray solution was taken out of the spray tank before each application in each tunnel separately:

- 2 × approx. 100 mL from the test item spraying solution on DDA, out of the spray tank for each test item tunnel separately (= 4 × biological tunnels 3 × residue tunnels 7 tunnels) 4°
- 2 × approx. 100 mL from the test item spraying solution on DDA0, out of the spray tank for each test item tunnel separately (= 4 vbiological tunnels * 3 × residue tunnels 7 tunnels)

All collected samples were stored in a freezer ( $\ge -20$   $\odot$ ) located near the experimental field site. After all samples were collected during the experimental field phase, they were dispatched deep-frozen ( $\le -20$  °C) to the ibacon laborator in Leverkuser, Germany. There, the collected foraging bees were further processed (pollen and nector extraction) and the residue samples of the spray solution(s) were stored deep-frozen ( $\le -20$  °C).

In the end, all samples were shipped deep-frozen (S-20 °C) to Bayer AG - Crop Science Division - in Monheim, Germany for the analytical phase of the study. The analytical phase report is added to this final report.

#### Test Parameters

Mortality of adult bes: DDA-3 to DDA42;

Behavioural abnormalities: DDA-3 to DDA42,

Foraging activity of the bees: DDA-3 to DDA7;

Colony assessments including assessment of brood status flood stores, colony strength and hive populations): once before the application days on DDA-1 and on DDA9, DDA13, DDA21, DDA28, DDA35 and DDA42.

### Application Rates:

Control: 400 L tap water/ha

#### Test Ittem:

1) Evening application rate (without bees present): 1.965 L product in 400 L water/ha. This corresponded to 2.22 kg product/ha and to 5.56 g product/L, considering a density of 1.132 g/mL according to Certificate of Analysis.

2) Daytime application rate (during beeflight): 1.6 L product in 400 L water/ha. This corresponded to 1.81 kg product/ha and 64.53 product/L, considering a density of 1.132 g/mL according to Certificate of Analysis.

**Reference Item:** nominally 1.2 L BAS 152 II (Dimethoate) in 400 L water/ha (corresponding to 3.0 mL/L or 0.22 g/L.



#### Test Conditions:

Natural field conditions. On the day of the test item evening application (DDA-1), weather conditions were good, and no rain occurred. On the following day during the daytime applications of the control, test item and reference item on DDA0, the sky was cloudy (80%) but the temperature was warm, Mean & temperature during the confinement period (day- 3 to day + 7) ranged between 18.1 and 25.5°C  $\mathcal{O}$  uring the exposure phase inside the tunnels and the following monitoring phase outside the tunnels, the weather was very warm and no rain occurred until study end.

#### Statistics:

Statistical evaluation was done for mortality, foraging activity and cology strength using Shapiro-Wilk test (check for normal distribution), Levene's test (check for homogeneity of variance), Student Fiest ok Welch t-test (pairwise comparison); (software: TOX Rat Professional; Version 3,2.1, ® ToxRat Solutions GmbH. Solutions GmbH.

#### **Dates of experimental work:**

#### Mortality of the adult (worker bees)

Pre-application phase (DDA-300 DDA-1)

Résultts AND Discussion: Mortality of the pre-application phase in the control, test item and reference item group was 11.9, 12.9 and 12.3 dead bees/colony/day, respectively. This was not statistically significantly different compared to the water control (Welch t-test, partwise comparison to the control, two-side  $\Omega = 0.05$ ). S

## Exposure phase (DOA-0 to DDA

At start of foraging activity on DDAO, the honey bees in the test tem treatment group were exposed to residues of the first application of the test item (ODA-I). Following this exposure, the mean mortality in the test item group was slightly higher with 26.8 dead bees/colony/day and resulted to be statistical significant different compared to the water control (mean of 7.3 dead bees/colony/day) at DDA0 before the second test item application during dataime (Welch t-test, pairwise comparison to the control, onesided greater,  $\alpha = 0.05$ ). These statistically significance was caused by time management of the mortality assessments before daytime application (two hour difference between assessments in the control and test item group) and was not related. Moreover, after the daytime application of the water control and test iten (DDA), mean mortality of adult bees in the test item group was slightly lower compared to the control group (205 ys, 29.0 dead beeg colony/day in the control and the test item group,respectively. Thus, this was not statistically significantly different compared to the control (Welch ttest, pairwise, one-sided greater,  $\alpha < 0.05$ 

The overall evaluation of the mean mortality, level of the exposure days from DDA0 to DDA7, resulted in a statistically significant difference compared to the control group (Welch t-test, pairwise comparison, one-sided greater, a 0.05) Average control mortality of adult bees during the exposure phase (DDA0 to DDA7) was 22 dead bees/colony/day whilst the average mortality in the test item group was slightly increased with 2.5 dead bees colony/day, respectively. The higher mortality levels in the test item group were mostly driven by one replicate (tunnel 4) with increased mortalities. However, the overall mortabity levels observed in the test item group were negligible and within a normal range considering the starting colony strength of 7101 bees/colony in the test item group and an increase of 120% (8515 bees/colony) at test end (DDA42).

In contrast, application of the reference item (dimethoate at a rate of 480 g/ha) resulted in a markedly increased number of dead bees found in the traps and on the gauze strips during the assessments



performed after the daytime application on DDA0. Following the application, mortality in the reference item group increased up to ca. 41 × the mortality levels of the control group on day DDA0. The average mortality during the exposure phase (DDA0 to DDA7) in the reference item group was statistically significantly increased, with a mean mortality of 311.1 dead bees/colony/day (Welch t-test, pairwise comparison to the control, one-sided greater,  $\alpha = 0.05$ ).

Phase outside the tunnels (DDA8 after application to DDA21 [1st brood cycle])

After the confined exposure phase inside the tunnels, a day wise comparison from DDA8 to DDA21 did not indicate a statistically significant difference of the test item mortality and the control mortality (Welch t-test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). Overall, the number of dead bees in the test item group was very low with a mean of 20 dead bees/colony/day during the period from DDA8 to DDA21 after the test item treatments. This was comparable and accordingly not statistically significant different to the control group (2.1 dead bees/day/colony) (Welch t-test, pairwise comparison to the control, one-sided greater,  $\alpha = 0.05$ ). In the reference item group, the mortality of adult worker bees was considerably increased from DDA8 to DDA14 but was not reflected in statistically significant differences compared to the control group (Welch t-test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). The increased mortality was only detected in two out of the four reference item replicates. This variation within the reference item group resulted in a high standard deviation following DDA15 the mean mortality levels in the reference item group were comparable to those of the control and even of the test item group

Phase outside the tunnels (DDA22 after application & DDA42 [2rd brood cycle).

The overall comparison from DDA22 to DDA42 showed very low mortality revels with a mean of 0.9 dead bees/colony/day found in the test item group. This was not statistically significant different compared to the also very low mean mortality revel bound in the control group of 1.9 dead bees/day/colony, respectively (Welch t-test, pairwise comparison to the control, one-sided greater,  $\alpha = 0.05$ ). Moreover, the overall mortalities from DDA0 to DDA24 and from DDA0 to DDA42 did also not show statistically significant differences between the test item and control group (Welch t-test, pairwise comparison, one sided greater,  $\alpha = 0.05$ ).

The very low amounts of dead bees in the reference item group from IDA22 to DDA42 were the result of the high effects on bees caused mainly by dimethoate during the exposure phase. An overall comparison showed a mortality in the reference item groups of 2. Dead bees/day/colony which was not significantly different to the control group with a mortality of 1.9 dead bees/day/colony (Student t-test, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ). In contrast, the overall mortalities from DDA0 to DDA21 and from DDA0 to DDA42 did show statistically somificant differences between the reference item and the control group (Walch treast, pairwise comparison, one-sided greater,  $\alpha = 0.05$ ).

Foraging Activity

Pre-application phase (DDA-3 to DDA0)

The mean foraging activities from DDA-3 to  $\overline{DDA}$ -1 were comparable in all three treatment groups with 9.3, 9.1 and 7.9 bees/m²/day if the control, test item and reference item group, respectively. Therefore, no statistical differences were found between the test item and reference item compared to the control (Student t-test, pairwise, two-sided,  $\alpha = 0.05$ ).

Exposure phase (DDA0 to PDA7):

At start of toraging activity on DDA0 and thus exposure to fresh residues in the test item group, the first assessment of the mean foraging activity in the test item group was performed shortly before the daytime application around noon. The high foraging activity of 23.3 bees/m²/day in the test item group was not statistically significantly different compared to the lower foraging activity value of 14.8 bees/m²/day in the control group assessed approx. 2 hours earlier in the morning of that day (Student t-test, pairwise,



one-sided smaller,  $\alpha = 0.05$ ). On DDA0, after the second test item daytime application, the mean foraging activity of 12.2 bees/m²/day in the test item group showed a statistically significant difference compared to the mean foraging activity of 14.5 bees/m²/day in the control group (Student t-test, pairwise, one-sided smaller,  $\alpha = 0.05$ ). This was caused by displaced application timings and consequently different assessment timings between the control and test item groups and thus, is not considered to be treatment related. Moreover, the mean foraging activity on DDA1 in the test item group was with 106 bees/m²/day slightly higher compared to 15.8 bees/m²/day in the control group and thus not statistical different (Student t-test, pairwise comparison to the control, one-sided smaller,  $\alpha = 0.05$ ).

Overall, from DDA0 to DDA7, mean foraging activity in the test item group was slightly higher compared to the control values (20.6 bees/m²/day vs. 19.9 bees/m²/day), and thus not statistically significantly different (Student t-test, pairwise, one-sided smaller  $\alpha = 0.05$ ). On DDA0 before the daytime application, the mean foraging activity of 20.0 bees/m²/day resulted to be statistically significantly increased in the reference item group compared to the mean foraging activity of 4.8 bees/m²/day in the control group, respectively (Student t-test) pairwise, one-sided smaller,  $\alpha = 0.05$ ). Again, this was caused by displaced application timings and consequently different assessment timings between the control and reference item groups.

Following DDA0 after application of the reference item (dimethoat), almost no fright was recorded on any of the assessment days. This resolved in an overall daily mean foraging activity of 0.0 bees/m²/day from DDA0 to DDA7.

#### Behavioural abnormalities:

No behavioural abnormalities occurred in the test item treated group and in the control group at any assessment day. There were also no noticeable behavioural abnormalities recorded in the reference item group as the impact of the application with dimethodic way mainly reflected in the high mortality rates after DDA0.

#### Condition of the Monies?

Condition of the colories was assessed over two complete brood cycles of the honey bees (i.e. 42 days  $[2 \times 21 \text{ days}]$ ).

At the beginning of the trial of colonies assigned for the test were similar according to the season. All queens (or eggs) and brood stages (eggs) farvae and closed brood) were found in all colonies as an indication of healthy colonies. Moreover, the amount of food reserves (uncontaminated nectar and pollen) was sufficient to ensure colony viability and brood status but also allowed that enough space was available for exposure of the brood to new food sources.

In the morning of DDA8, all honey bee hives were relocated from their tunnels to a monitoring site (approx 42 km distance from the field site) in general, the test item treatment group colonies developed in the same manner as the control colonies. Compared to the control, a similar amount of brood was found during the assessments with no indication of a test item related effect. All colonies exposed to the test item remained vital with healthy prood. The amount of individual brood stages (eggs, larvae and pupae) present in the colonies of the control and test item treatment groups fluctuated and slightly alternated on the different assessment days. All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all following brood checks indicating that the queens were alive and healthy. There was no indication of any effect of the test item on the condition of the bee colonies.

On DDA28 after expert adgement (beekeeper) colonies used for the biological assessments showed low food stores and all honey bee colonies assigned to the control, test item and reference item groups were additionally fed with 1.0 kg commercial ready-to-use syrup (Apicar Pro) in order to avoid artefacts from insufficient food supply (food uptake from DDA28 to DDA29).



The colonies in the reference item group showed a decrease in the total amount of brood during the assessment days after DDA0. This was a result of the high effects on bees caused by dimethoate during the exposure phase.

#### Colony strength:

The mean number of honey bees per colony in all treatment groups was signifar one day before the daytime application (DDA0) and did not differ statistically significantly (mean of 7101 to 7524) per colony). Following re-movement of the colonies from the tunnels a short decrease was observed during? the assessment on DDA9 in the test item group (86%). But overall there was an increase of colony strength observable and even stronger compared to the control group from DDA13 DDA42 (120%) (= last assessment day after two brood cycles). Thus, no statistically significant differences the colony strength between the test item treated colonies and the control colonies occurred at any assessment daff (Student t-test, pair-wise comparison to the control, one-sided smaller  $\alpha = 0.95$ ). Querall, go adverse effects of the test item on colony strength and population development were observed throughout the study.

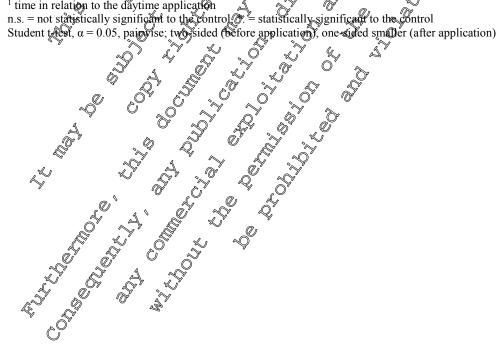
The development of the colony strength in the reference item group was statistically significantly decreased on all assessment days after DDA0 except on DDA9 (Student t-test pair-wise comparison to O Charles the control, one-sided smaller,  $\alpha = 0.05$ 

Considering the initial mean number of bees per treatment group before the application as 100 %, the following relative mean numbers of beeswere determined:

				lf .	O ^V O	<u> </u>	
Treatment Group	DDA ¹ -Į 🌾	DDA9		DDA21	<b>DP</b> A28	DDA35	DDA42
Control	100	£103%	129%	ž Ž8%	Ő A	86%	86%
Test Item	300% O	8005 (*)	(n.s)	√112%© ∀ (n.s.)	104% (n.s.)	111% (n.s.)	120% (n.s.)
Reference		90% 🖉	. 6% 3	52% A	\$ 50%	44%	40%
Item C		$\int_{1}^{0} (n.s.)$	(*)		<b>(</b> )	(*)	(*)

¹ time in relation to the daytime application

n.s. = not statistically significant to the control @. = statistically significant to the control





		Foraging activity								Mortality														
	water treat				water treated control				Т	est Iter	n		Ref	erence	Item	water trea	ated c	ontrol	R	Test Item	ı.	Ret	erence Įte	
time ^a			ber of m² ^b			ber of m² ^b	statistics			nber of r nf ^b	statistics	total dead bees ^b	ł	SD	total dead bees ^b	SD	tastistics	total dead bees ^b	en la	statistics				
DDA-3	0.7		0.4	0.5	±	0.8	14-	0.4	±	0.4		1.0	±	0.8	2.0	± 0,8	- 1	2.3	# 0.5					
DDA-2	15.8	±	3.6	14.0	±	5.8	-	11.5	±	3.5	-	19.0	±	11.6	13.0	± 10	-	19.5	± 4.4	and a start				
DDA-1	11.3	±	2.5	12.9	±	2.8	-	11.9	±	1.9	-	15.8	±	5.7	23.8	₹ 11.3	-	15.0 C	7± 3.8	¥-				
Daily mean DDA-3 to DDA-1	9.3	±	7.8	9.1	±	7.5	n.s.	7.9	±	6.5	<b>n</b> .s.	11.9	±	9.6	12.9	£ 10.9	n.s.	ju ka	± 08.99	n.s.				
DDA0 b.a.	14.8	±	0.2	23.3	±	4.5	n.s.	20.0	±	1.6	* ¹⁾	17.3	±	5.1	200	± 7.9	÷	Ú 12.5 ♠	2.1	1				
mean DDA0 a.a.	14.5	±	1.1	12.2	±	1.9	*	0.0	±	0.0	* @	27.0	±	5.3	53.5	± 8.7	n.s. C	1107.5	+ 424.3	*				
DDA1	15.8	±	1.7	17.6	±	2.1	n.s.	0.1	±	0.1	*	17.0	±	4.8	18.8	± 6.1	n's.	6050	± 323					
DDA2	20.8	±	1.0	20.0	±	2.3	n.s.	0.0	±	0.0	Ű	30.8	±	11	41.5	e ± 12.8	SQ.	232.5	= 120.	* (1)				
DDA3	13.0	±	2.4	13.6	±	5.1	n.s.	0.1	±	0.2	4	16.8	±	621	3360	± 21 5	ns	\$171.0	± 89.2	*1				
DDA4	20.3	±	2.6	20.4	±	2.7	n.s.	0.0	±	0.0	0.0	17.5		7.1	08	± 16.2	n.s.	69.3	C 22.8	()				
DDA5	22.1	±	3.2	23.5	±	6.1	n.s.	0.0	±	0.0	V 🔹	14.5	(The	\$ 5.9	° 15.8	± 8.2	n.s.	44.3 %	₹ 29.4 @	Mys.				
DDA6	28.4	±	4.1	30.8	±	1.8	n.s.	0.0	±	00	* 10	° 19.3	Ø.	14.6	42.0	# 93.1	Č,	10P9 158.5	± 64.8%	J**				
DDA7	24.3	±	2.0	26.6	±	4.4	n.s.	0.0	±	2		33.5	¥±	7.0.0	50.3	\$ 15.1 15.1	- A	158.5	± 147.9	n.s.				
Daily mean DDA0 to DDA7 a.a.	19.9	±	5.2	20.6	±	6.3	n.s.	0.0	T.	0.1	, ^d	<u> </u>	±	Ţ	31.0	± 12.2	÷	O ^{41.1}	+757.1	s,				
Daily mean DDA8 to DDA21 a.a.								Ś				2.1		1.7	¥ 2.5	2.5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2 Contraction	278	± 39.0	\$*.				
Daily mean DDA22 to DDA42 a.a.							Ś	\$	K V				×	<b>0.6</b>	<b>N</b>	± 0,5	n.s.	Q 2.1	£94.0	<b>n</b> .s.				
Daily mean DDA0 to DDA21 a.a.						Ś		4) 7		<i>S</i>		9.4	S±	10.7d		õ	20 C		± 255.6	÷				
Daily mean DDA0 to DDA42 a.a.						Š	\$	¥ 	Ś	y 	4	0 ^{5.7}	¥	Ø.6	and and a	± 1200	Ŭ	0 68.0	± 192.1	*				

#### Summarised mortality and foraging activity data of the honey bees

Day of evening application of the test from group only BBCH (B): May 00; 2047 = DDA-T

Day of daytime application of control, test item and reference frem group (BBCH 65): May 31, 2917 = DDA0  $^{\text{A}}$  DDA-3 to DDA-1 = days before application DDA9, DDA9 to DDA7 = days after application DDA0

^B Mean values (roundee) of four tunnels per treatment group

b.a. = before daytime application (DDA0)

a.a. = after daytim Opplication (DDA0)

n.s. = not statistically significant compared to the control; * statistically significant compared to the control; "-" = no statistics were performed statistics (for aging activity): Student t-test pairwise;  $\alpha = 0.05$ ; before DDA0; two-sided (control, reference item), one-sided statistics (refuging det ry). Side in the day pairwee, a 200, or 100 m 200, we sided (control, reference item) statistics (mortality): Welch, lest; pairwise; 6 = 0.05; before DDA0; two-sided control, reference item), one-sided greater (test item), after DDA0: one-sided preater (control, GSt item, reference item)  $\sim$ ¹⁾ Statistically significantly increased compared to the control Weight-test; pairwise;  $\alpha = 0.05$ ; two-sided) Analytical findings

Analytical findings

The exposure of the honey ores to the test item sizes confirmed by analytical measurement of the active substances fluopicolide and propamocare-hydrochlofde in the spray solution samples taken from the biological assessment tunnels and the extra residue tunnels. The concentration of fluopicolide and propamocarb-hydrochloride in both groups of turnels was in a comparable range so that it is assumed that the exposure conditions were comparable or all tunnels treated with the test item. In those tunnels allocated to residue determination, honeybees were used as sampling device. The concentration of fluopicolide and propamocate-hydrochloride measured in the collected pollen and nectar samples on the day of davine application and the dag after allows a confirmation of the exposure of the bees inside the tunnels

The following cable gives of overview of the concentration of fluopicolide and propamocarbhydrochlorid on the analysed sample materials.



				Fluopicolide			
Sample Material	Test Item	Sampling Day	Source	Concentration [mg/kg]	Mean Concentration [mg/kg]	Recovery from Target* [%]	Mean Recovery from Parget
Pollen		DDA0	T1-T3	27-30	28 🔬	- 8	
Folieli		DDA1	T1-T3	1.4-2.3	2.0 🖑 "	- `~	<u>, , , , , , , , , , , , , , , , , , , </u>
Nectar		DDA0	T1-T3	0.15 - 0.2	0.68	Ď,	<u>~ - @</u>
rtootar	FLC+	DDA1	T1-T3	0.10-0.14	<b>6 1</b>	Ų,	
	PCH SC 687.5	DDA-1	TSE: T1- T4 TRE: T5-	260 270	260 °	$\sqrt{99-80}$	299° °
Spray Solution	(62.5+	DDA0	T7 TSD: T1- T4 TRD: T5- T7	$210^{2} 230^{2}$	220 0 220 0 220 0 210 0	74-80 74-80	\$ 805 A 79 C 755
			Propan	iocarb-itydrochiør	ide 🖉 🕺	<u> </u>	Õ
Sample Material	Test Item	Sampling Day	Source	Goncentration	Mean Concentration Ging/kg	Recovery from * Parget*	Mean Recovery from Target* [%]
Pollen		DDA0 DDA1	<u>11-T3</u> T1- <b>F3</b>	2390 - 500	×42 ×	<u>s</u>	-
			Tab T3 (	$5^{-12}$ $12^{-11}$ $0^{-18}$	<u> </u>	<u> </u>	-
Nectar	FLC+	\$DDA10	¶1-T3	0 − 1×9 [×]	0 bo L	-	-
	PCH SC		67 SE: 407- У Т4У ≈	2480-02910		81 – 94	85
Spray	68 <b>5</b> .5 (@2.5+		TRE: T5-0 0 T7	2470-2670	2560	80 - 87	83
Solution	625) G	ÔDA029	GTSD: T1-	2040 -2120 2120	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	81 - 84	83
			TRĐ: T5- ≪ T7 Ô	2080-2220	2130	83 - 88	85

#### **Residue summary in/on pollen, nectar and spray solution**

DDA: Day of Daytime Application; Pollen/Nectar. T1 to 3 description for samples from tunnels used for Residue Analysis DDA: Day of Daytime Application; Pollen/Necta? 11 to 3 description for samples from tunnels used for Residue Analysis Spray Solution: TSE Test Item Evening Spray Solution from Tunnels used for Biological Assessments, TRE = Test Item Evening Spray Solution from Tunnels used for Residue Analysis, TSD Test Item Daytime Spray Solution from Tunnels used for Biological Assessments RD = Test Item Daytime Spray Solution from Tunnels used for Residue Analysis T1 to T4 description are samples from tannels used for biological assessments, T5 to T7 descriptions are samples from tunnels used for residue analysis. Mean concentrations were calculated using unrounded values. * The target concentration in the spray solution for floppicolide was 331 mg/kg for DDA-1 and 270 mg/kg for DDA0 and for propamocarb-hydrochlorite 3080 mg/kg for DDA-1 and 2510 mg/kg for DDA0. LOQ Limit of Quantification 2001 mg/kg (= 10 µg/kg ~ 10 ppb) for fluopicolide and propamocarb-hydrochloride LOD = Limit of Detection = 02003 mg/kg (3 µg/kg = 3 µpb) for fluopicolide and propamocarb-hydrochloride

## **AIII.** CONCLUSIONS:

In order to assess the potential of sk of Fluopicolide + Propamocarb-hydrochloride SC 687.5 (62.5 + 625) G to koney bee colonies, honey bees were exposed under realistic but severe (forced) exposure conditions in semi-field test (confinement in tunnels). The test item was applied twice: once at 1.965 L product ha during full flowering of the surrogate crop Phacelia tanacetifolia (BBCH 65) in the evening without honey bees present) and, during daytime on the following day at 1.6 L product/ha, during full flowering of the crop (BBCH 65) while honey bees were actively foraging.



Concurrently to the second test item application, the control (tap water) and reference item applications (dimethoate) were conducted on the full flowering *Phacelia tanacetifolia* crop (BBCH 65), during daytime and with honey bees actively foraging on the crop.

Overall, the mortality and foraging activity were comparable to the control throughout the study duration and no test item related effects on adult and immature honey bees were observed. Behaviour of the bees, nectar- and pollen storage as well as queen survival was not affected. There were no observable effects on overall colony development, development of brood and colony strength.

Based on the results of this study, it can be concluded that Fluopicolide + Bropamocarb-Bydrochoride SC 687.5 (62.5 + 625) G does not adversely affect honey bee behaviour brood development, colory strength and queen survival when applied twice at a rate of 1.965 L in 400 L/ha (corresponding to 2222 kg product/ha) in the evening after bee flight and at a rate of 1.6 L/ha (corresponding to 1.81 kg  $^{\circ}$  product/ha) during daytime and foraging activity, under the above described conditions.

### CP 10.3.1.6 Field tests with honeybees

Not necessary when considering the outcome of the risk assessment and the results of the lower-tieted studies.

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

The risk assessment was performed according to Guidance Document on regulatory testing and isk assessment procedures for plant protection products with non-farget arthropods (ESCORT 2, Candolfi et al. 2000¹⁹).

Test Species,	Tested Formulation, Study type,	Ecotoxico	logical Endpoint
Test Species, Dossier-file-No.	Duration Exposure		
Aphidius rhopal@iphi	PLC + PCH S662.5 ± 625 G		
Ô	Laboratory, spray deposits on glass		
2002 (%)	plates $\sqrt{3}$ $\rightarrow$ $\rightarrow$	° a . °	
M-217140-01-1		Cort. Mortality [%]	Effect on Reproduction [%]
Rep.No. CW02/078	977.1 m product/ha	AQ.1 A	8.3
KCP 10.3.2.1/03	477.1 m product/ha 334.3 mL product/ha	<u>ک</u> ۵.0	10.5
Aphidius rhopalosiphi	$\mathbf{F} \mathbf{H}^{\alpha} + \mathbf{D} \mathbf{C} \mathbf{H}^{\alpha} \mathbf{S} \mathbf{C} \mathbf{G} \mathbf{S}^{\alpha} \mathbf{S}^{\beta} + \mathbf{G} \mathbf{S}^{\alpha} \mathbf{G}^{\alpha}$	C LR ₅₀ [mL]	product/ha]: 2482
4	Platos v spray deposits on gass	ER ₅₀ [mL	product/ha] > 427
2003 🔊 🔊	plates y n	•0	
M-221752-01-Ĭ		Corr. Mortality [%]	Effect on Reproduction [%]
Rep.No: C 3003/009	427 mL product/ba	16.9	47.4
KCP 10 2.1/01	427 mL product/ha 1541 mL product/ha 5564 mL product/ha	11.9	73.0
, KU - K.	1541 mL product/ha	47.5	n.a. ^C
Š	292) mL product/hav	44.1	89.7
Q	5564 mL productha	76.3	n.a. ^C
E di			
	The second se		
	$\sim$		

Table 10.3.2- 1:	Toxicological endpo	ints for arthropod	s other than bees (F	TLÇ ¥ PCH SC 62.5 + 625 G)
				×

¹⁹ Candolf et al.: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001



Test Species,	Tested Formulation, Study type,	Ecotoxicological Endpoint
Dossier-file-No.	Duration, Exposure	Ecotoxicological Enupoint
Typholodromus pyri	FLC + PCH SC 62.5 + 625 G	LR ₅₀ [mL product/ha]: 3238
1 ypholour omus pyri	Laboratory, spray deposits on glass	
2003	plates.	
M-221754-01-1	P	Mortality [%] Effect on Reproduction [%]
Rep.No: CW03/011	397 mL product/ha	2.5 $3$ $7.9$ $4$
KCP 10.3.2.1/02	716 mL product/ha	5.0
	1287 mL product/ha	
	2318 mL product/ha	© 38.8 4 ×49.4~
	4173 mL product/ha	56.3 0 86.19 W
Chrysoperla carnea	FLC + PCH SC 62.5 + 625 G	$LR_{\rm s} P[\text{mL product/ha}] > 6600 \text{ for } 4000 \text{ for } 40000 \text{ for } 400000 \text{ for } 400000 \text{ for } 400000000000000000000000000000000000$
2003	Laboratory, spray deposits on glass	EBS ₀ [mL productiona]: $> 6400$ $\bigcirc$ $_{\sim}$
M-225401-01-1	plates.	
Rep.No: C038632		Corr. Mortality Eggs Female Hatching
KCP 10.3.2.2/01	&	Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q
1101 10.0.2.2,01	Control O [*]	
	1600 mL product/ha	
	4320 mL product/ha	
	6400 mL product has a grad	× × × × × × × × × × × × × × × × × × ×
Aphidius rhopalosiphi	FLC + PCH SC $62.5 + 625$ G	AR50 [mt product/ha]; \$8000
2003	Extended laboratory, spray	$\sim$
M-225402-01-1	deposits on potted wheat plants	
Rep.No: C038633		Coff. Mortality [%) Effect on Reproduction [%]
KCP 10.3.2.2/02	500 mk product/ha	
	1000 mL product/ha	
	2009 mL product/ha	
	4000 mL product/ha	50.0 Star 50.0
	\$000 m [°] product/ha	90 × 98.7
Typholodromus pyri	FLC4+ PCHOC 62,54+ 625 G	$\mathbb{Q}_{1}$ I.P. [m] product/hal: $> 1172$
Typholoar olmus pyric	Extended Jaboratory, freshly dried	$\sum_{n=1}^{\infty} ER_{50} \text{ [mL product/ha]:} > 4173$
2003	esidues on detached leaves of	
M-221756-01-	thean O C C C	
Rep.No: CW93/017		Corr, Mortality [%] Effect on Reproduction [%]
KCP 10.3.2.2/03	397 mL product/h	7:5 12.9
Ê.	<b>a</b> 6 mI (b) roduct/ba	× 19.3 17.9
** *	1287 mL product/ha	Å Ž.5 27.6
	2318 mL product/ha	11.3 29.8
Ŵ.		12.0 24.2
Coccinella 🖉 🎾	PLC + BCH SC 62.5 + 625 G O	$C^{*}$ LR ₅₀ [mL product / ha]: > 4800
septempunctata	Extended laby spray deposits on	$ER_{50} [mL product / ha]: > 4800$
2005	detached bean leaves	
M-25634-01-1		Corr. Mortality Eggs/Female/ Hatching
Rep.No.: 23841012		[%] Day [%]
KCP 10.3.2.2/04	Control ~ ~	- 15.3 65.4
// (\)	PLC + OCH SC 62.5 + 625 G Extended lab, spray deposits on detached bean leaves Control 300 mL product/ha 600 mL product/ha	0 15.3 72.6
Ĵ.	600 mI product ha	9.7 19.8 76.7
	1200 grd product/ha	-9.7 ^A 8.9 76.5
se si	240 mL ptoduct/ha	9.7 17.6 73.1
	4800 mL product/ha	-6.5 11.6 81.1
KCR210.3.2.2/04	Á ÁG	
G ^{ir} Q ^{ir}		
Ű		



	110	ispiconde + 1 topaniocar b-nyur benior ide Se 007.5
Test Species,	Tested Formulation, Study type,	Ecotoxicological Endpoint
Dossier-file-No.	Duration, Exposure	
Aphidius rhopalosiphi	FLC + PCH SC 62.5 + 625 G	
2014	Aged residues spray deposits on	
M-503125-01-1	barley plants,	
Rep.No: BAY-14-1	$2 \times 2800$ mL prod./ha	
KCP 10.3.2.2/05	(7-day interval)	
		Corr. Mortality [%] Effect on Reproduction [%]
	residues aged for 0 d:	$3.3$ $-20^{\nu}B$ $\sqrt{\nu}$
	residues aged for 7 d:	
	residues aged for 14 d:	
A: a negative value indic	ates a higher mortality rate in the control	than in the treatmont $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$
	ates a higher reproduction rate in the treat	ment than in the control
C: not applicable, reprod	uction was not assessed	
	40	
701		iven in Table 10- 1 The product FLC + PCH SC
		/hag1-4 applications in potatoes 1-2 applications
in lettuce).		
According to ESCO	RT 2 and the Terrestrial Guidance	Document SANCO/10329/20029 the conosure
is calculated as:		
15 culculated as.	L & V Y	
in-field: App	lication rate MAF	
off field: Max	lication rate × MAF single application rate × MAF	drift factor DF & correction factor
Application rates 16	I my duct/ho in all groups	
Application rate. 1.0		
MAF (multiple appl	L product tha in all crops	s) 2.3 (3 applications) 2.7 (4 applications)
Drift factor = $0.02$	7. 90 th percentile for one applicant	on, 0.0238, 82 nd percentile for two applications;
0 0201 77 th percenti	le for three applications 9 0185	^{74nd} percentile for four applications (according to
Ganzelmeier)		> Percentry rocky an approximents (according to
		A O V
VDF = vegetation d	istribution factor $= 10$ (stadies where the state is the state of th	th 2D exposure system) and 1 (studies with 3D
exposure system)		
	(0)(Tier Y) and 5 (Tier 2)	
Correction factor =		

The risk is considered acceptable if the calculated Q is

1	O,	~Q	A St	, Ô	Ũ	
Table 103.2- 2:	E Ô	×.		No.		t (Tier 1 and 2)
Table 10.3.2- 2:	Exposure	calculat	ion for	our-field	rassessment	(11  er  1  and  2)

Crop	Novof appl.	(D) prod./haj	MAF	PER _{in-field} [L prod./ha]
Potatoes		Q 1.6	2.7	4.320
Potatoes		<b>2</b> 1.6	2.3	3.680
Potatoes, letruce		1.6	1.7	2.720
Potatoes, Dettuce	1 ~~	1.6	1.0	1.600

MAF: Multiple pplication factor, PER: Predicted environmental rate



Сгор	No. of appl.	Appl. rate [L prod./ha]	MAF	Drift [%]	VDF	Correction factor	PER _{off-field}
Potatoes	4	1.6	2.7	1.85	10	10	0.080
Potatoes	3	1.6	2.3	2.01	10	100	0,@4
Potatoes, lettuce	2	1.6	1.7	2.38	10	đ	0.065
Potatoes, lettuce	1	1.6	1.0	2.77	10	<u> </u>	0.042 ×

Exposure calculation for the off-field scenario (Tier 1) Table 10.3.2-3:

MAF: Multiple application factor; VDF: Vegetation distribution factor PER: Predicted environmental rat 

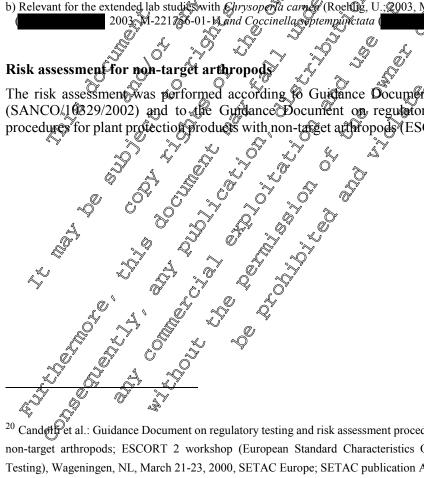
		<i>_</i>
Table 10.3.2- 4:	Exposure calculation for the off-field scenario	(Tide 2)
1 abic 10.3.2- 4.	Exposure calculation for the on-new scenario	(1 (0) 4)

Сгор	No. of appl.	Appl. rate [L prod./ha]	MAF	Drift [%]	Test system	<b>∼_VD</b> F ⊘	factor 🍌	PEBoff-field
Potatoes	4	1.6	2.7	P.85 *	2DØ	Q10	\$ 5 \$ \$ \$	0.400 0 0.400
Potatoes	3	1.6	2.3	2.01	3D ^{a)}			0.370 (S ² ) (S ² ) 0.0 (D ² )
Potatoes, lettuce	2	1.6	Q 1.7	2.38 Ø	BD "	7 1 100		\$ 0\$24 \$~0.032
Potatoes, lettuce	1	1.6	120 201	2.77	$\frac{\sqrt[3]{3D^{a}}}{2D^{b}}$	Q ~ 10 ~	85 5 00 8 8	& 0.222 0.022

MAF: Multiple application factor, VDF: regetation distribution factor; PER: Prediced environmental rate

a) Relevant for the extended lab study with *Aphidius rhopalosiph* (Roehlin, U.; 2003, M-225402-01-1) b) <u>Relevant for the extended lab studies with *Ghrysop Ta carner* (Roehling, U.; 2003, M-225401-05-1), *Typholodromus pyri*</u> 2003 M-2217 8-01- Mand Coccinella ptempunctata 2005, M2256344-01-1)

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target atthropode (ESCORT 2, Candolfi et al. 2000²⁰).



²⁰ Cand de Det al.: Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001



#### Tier 1 in-field risk assessment for non-target arthropods

Crop and application rate	Species	PER _{in-field} [L prod./ha]	LR50 [L prod./ha]	HQ	Trigger
Potatoes	Aphidius rhopalosiphi	4.320	2.482	<b>4</b> 74	
$4 \times 1.6$ L prod./ha	Typhlodromus pyri	4.320	3.238	@1.33	
Potatoes	Aphidius rhopalosiphi	2 680	2.482	1.48	
$3 \times 1.6$ L prod./ha	Typhlodromus pyri	3.680	چ 3.238	1.14 🔬	
Potatoes, lettuce	Aphidius rhopalosiphi	2 720 6	2.482	1.10	
$2 \times 1.6$ L prod./ha	Typhlodromus pyri	2.720	3.23	0.84	
Potatoes, lettuce	Aphidius rhopalosiphi	1 - 200	2.482	° (64 🖓	
$1 \times 1.6$ L prod./ha	Typhlodromus pyri		3.238 ×	0.49	

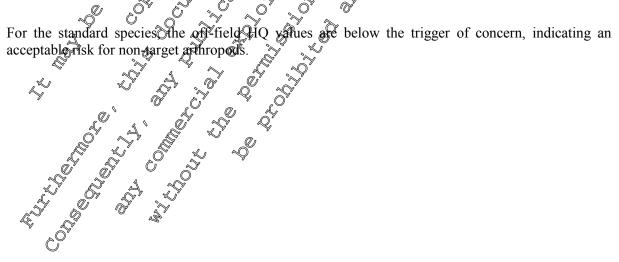
PER: Predicted environmental rate; HQ: Hazard quotient

igger, of concern, indicating an For the standard species, the in-field HC acceptable risk for non-target arthropode

# Tier 1 off-field risk assessment for non-targer arthropods

Tier 1 off-field risk assessment for non-target atthropods Table 10.3.2- 6:

Crop and application rate	Species A	PERoff-field	LRso LRso LRso		Trigger
Potatoes	Aptildius raopalosiphi	0.5980 ~	y 2 <b>⊙</b> \$82 %y	°∼9.03	2
$4 \times 1.6$ L prod./ha	Gyphlodromus Fri 🛷		3.238	0.02	2
Potatoes	Aphianus rhopalosiphi	0.074	S 2.487 ~	0.03	2
$3 \times 1.6 \text{ L prod}/ha$	Typhlodromus pyr		<u> </u>	0.02	2
	Ophidius rhopalosiphi	ð.065 P	9.482	0.03	2
$2 \times 1.6$ L prod./ha	Typhtedromas pyri 🐨	.0.065 .0	3.238	0.02	2
Potatoes, Jettuce	Appidius Appalosiphi	N 00011	J _2.982	0.02	2
$1 \times 1.6$ L prod./ha $\approx$	Øvphlodvomusævri 🔍 🔍		3.238	0.01	2
PER: Predicted environ	mental rate; HQ Hazard quo	tient	ð		





#### Tier 2 in-field risk assessment for non-target arthropods

Table 10.3.2- 7:	Tier 2 in-field risk assessment for non-target arthropods
1 abit 10.5.4- /.	The 2 m-menu risk assessment for non-target artificitudes

Crop and application rate	Species	PER _{in-field} [L prod./ha]	LR50/ER50 [L prod./ha]	PERin-field below rate with ≤ 50% effect
	Chrysoperla carnea		> 6.400	Yes O
Potatoes	Aphidius rhopalosiphi	4.320	~ 4.000	No No
$4 \times 1.6$ L prod./ha	Typhlodromus pyri	4.320	> 4.173	No 6 4
	Coccinella septempunctata	Ò	> 4.800	X Yes S
	Chrysoperla carnea	. ¥	> Q400	V YES L
Potatoes	Aphidius rhopalosiphi	a de con	Jy 4.000	O Res O
$3 \times 1.6$ L prod./ha	Typhlodromus pyri	5.680	→> 4.1233	Q Yes
	Coccinella septempunctata		>*4,800	Yes S
	Chrysoperla carnea		6.400	Yes Yes
Potatoes, lettuce	Aphidius rhopalosiphi 🛒		~ 4.000	Yes y
$2 \times 1.6$ L prod./ha	Typhlodromus pyri 🔊	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	>4,173	Yes o
	Coccinella septempulicitata		Q 4.800	S Yes S
	Chrysoperla carn		$0^{\circ} > 6,490$	Yes
Potatoes, lettuce	Aphidius rhopatosiphi		~ <del>.</del> 000 Ĉ	Xes 1
$1 \times 1.6$ L prod./ha	Typhlodrom pyri 🖉		<i>4.17</i> €	V (Yes
	Coccinella Septempunctato		© > 4.800	O Yes
PER: Predicted enviro				

The PER_{in-field} is below the rate with  $\leq 50\%$  effect for all species and uses, except for *Aphidius rhopalosiphi* and *Tephlodromus pyri* for the application of 4% 1.6 L prod/ha in potatoes. Taking the results from studies on glass plates and natural substrates into account, *Aphidius rhopalosiphi* is considered to be the most sensitive species to FLC++ PCH SC 52.5 + 625 G. Hence, an aged residue study with A. *Phopalosiphi* is presented to demonstrate the potential for recovery of in-field non-target arthropod populations and thus no unacceptable risk.

				Ö 🔊	
Crop		Species 5	PERin-field	Rate with ≤ 50 % effect ℃L/ha) at 0 DALT	PER _{in-field} below rate with ≤ 50 % effect?
Potatoes $4 \times 1.6 \text{ L pro}$	d./ha	Aphidius rhopalosiphi	4.320	2 × 2.8 ^A	Yes

Table 10.3.2-8: Tier 2 in field risk assessment for non-target arthropods

PER: Predeted environmental rate; DALT: Days after last treatment.

^A 2 × 1.6 L/ha can be expressed as 1.7 (MAD/ for 2 applications) × 1.6 L/ha = 2.72 L/ha, therefore the tested 2 × 2.8 L/ha cover the use pattern of 4 × 1.6 L/ha; 2 × 2.8 L/ha would be equivalent to 1.7 (MAF for 2 applications) × 2.8 L/ha = 4.76 L/ha, which is > the PER

The PER_{in-f} is below the rate with  $\leq 50\%$  effect for all species and uses indicating an acceptable risk for non-target arthropods

for non-target arthropods.



Table 10.3.2- 9:	Tier 2 off-field risk assessm	ent for non-target a	in this oppose	
Crop and application rate	Species	Off-field PER _{max.} [L prod./ha]	LR50/ER50 [L prod./ha]	$\frac{\text{PER}_{\text{off-field}} \text{ below faite}}{\text{with} \leq 50\% \text{ effect}}$
	Chrysoperla carnea	0.040	> 6.400	Yes (
Potatoes	Aphidius rhopalosiphi	0.400	~ 4.000	Yes
$4 \times 1.6$ L prod./ha	Typhlodromus pyri	0.040	> 4.172	, Yes of A
	Coccinella septempunctata	0.0400	> 4,800	Yes
	Chrysoperla carnea	0.037	> \$400	V Yes X
Potatoes	Aphidius rhopalosiphi	<b>2</b> 370	4.000	O Yes O
$3 \times 1.6$ L prod./ha	Typhlodromus pyri	0.037	> 4 \$73	Q ^Y Yes
	Coccinella septempunctata	0.037	>*4.800	Yes v
	Chrysoperla carnea	Ø 032 ×	6.400	Yes 4
Potatoes, lettuce	Aphidius rhopalosiphi 🔬	0.324	Q ~ 4.090	O ^Y Yes
$2 \times 1.6$ L prod./ha	Typhlodromus pyri	× 0.032 ~~	≥4173 0	Yes or
	Coccinella septempulicitata	× 0.032 ×	4.800	A stes
Potatoes, lettuce 1 × 1.6 L prod./ha	Chrysoperla carn	~~~~0.02 <b>2</b> ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0 > 6,400	Yes
	Aphidius rhopaQsiphi	0,222	-0.000 C	Yes
	Typhlodrom 🕲 pyrį 🔊	¢ 022 ¢	¥4.17\$¥	Yes Ves
	Coccinella Septempunctata	0.022	© > 4.800	OYes
PER: Predicted environ		<u>O</u> O		

#### Tier 2 off-field risk assessment for non-target arthropods

Table 10.3.2- 9:	Tier 2 off-field risk assessment for non-target arthropods
------------------	------------------------------------------------------------

The PER_{off-field} is below the rate with  $\leq$  50% effection alk species and uses indicating an acceptable risk for non-target arthropods.

CP 10.3.2,1 Stand	lard laboratory testing for non-target arthropods
	aru lagoratury testing top non-targes artin opous
Data Point:	KCP 103.2.1/00 2 4 A
Report Author:	
Report Year:	200
Report Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez)
	Hymensptera; Bracondae) in the laboratory Propamocarb hydrochloride + AE
	C638296 water misciple suspension concentrate 625 + 62.5 g/l Code: AE
	B060752 04 SC61 & 102
Report No:	
Document No:	Q <u>1-221</u> Z <u>2-01</u>
Guideline(s) followed in	IOB Mead Briggs et al. 2000
study:	
Deviations from current	Surrent Guideline: Mead-Briggs et al. (2000)
test guideline. 🗸	No deviations Q
Previous evaluation:	yes Valuated and accepted
A PA	DAX 2005
	for Propamocarb RAR June 2017
	Yes, conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities.	
Acceptability/Reliability:	Yes



#### **Executive Summary**

The objective of this laboratory study was to investigate the lethal and sublethal effects of FLC + PCH SC 687.5 on the parasitoid wasp *Aphidius rhopalosiphi* when exposed on a glass surface. The test substance was applied at rates of 27.6, 52.5, 99.7, 189 and 360 g fluopicolide/ha (equivalent to 0.43, 0.81, 1.54, 2.92 and 5.56 L product/ha) and the effects were compared to 5 toxic reference (a5: dimethoate) applied at 0.12 g a.s./ha and a water treated control. Mortality of 60 adults was assessed 24 and 48 hours after exposure. From the water control and the 0.43, 0.81 and 2.92 L product/FLC PCH SC 687.5)/ha treated groups, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated cereal plants infested with *Rhopalosiphum padi* for a period of 24 hours. The number of mummies was assessed 11 days later. All validity criteria were met. The LB₅₀ was 760.6 g fluopicolide/ha (equivalent to 2.48 L product/ha). Sublethal effects lower than 50% were observed at the rate of 0.43 L product/ha.

## I. MATERIAL AND METHODS

Test item: Infinito SC Fungicide (FLC + POH SC 687.5), Batch No.: OP220639, density 1829 g/cm³, a fungicide SC type product containing Flaopicol de + Propanto carb HCl (measured concentrations 64.7 g/L + 634 g/L, respectively) as active or greatents.

The test substance was applied at rates of 27.6, 52.5, 99.7, 189 and 366 P Fluopicolide ha (convalent to 0.43, 0.81, 1.54, 2.92 and 5.56 L product/ha) and the effects were compared to a faxic reference (a.s.: dimethoate) applied at 0.12 g.a.s./ha and a water treated control.

Mortality of 60 adults was assessed 24 and 48 hours after exposure.

From the water control and the 0.40, 0.81 and 2.92 L product (Infinite SC Fungicide) ha treated groups, 15 impartially chosen females per treatment were such transferred to a cylinder containing untreated cereal plants infested with *Rhopalosiphum padi* for a period of 24 hours. The number of mummies was assessed 11 days later.

Dates of experimental work: May 26, 2009 to July 14, 2003

IE RESULTS AND DISCUSSION?

In this laboratory test the effects of Infinito SC Fungicide residues on the survival of *Aphidius rhopalosiphi* were determined a 0.43, 0.81, 1.34, 2.92 and 556 L product/ha), applied to glass plates. In the highest dose rate of 5.56 L product/ha, a mortality of 76.3% was observed. At the other rates of 0.43, 0.81, 1.34 and 2.92 b product/ha mortality percentages lower than 50% (16.9, 11.9, 47.5 and 44.1%, respectively).

The reduction in reproductive success relative to the control at the dose rates of 0.43, 0.81 and 2.92 L product/ha was 47.4%, 73.0% and 89.7, respectively.

product/ha was 47.4%, 73.0% and 89.7, respectively.



#### Mortality / Reproduction - 48 hours after treatment

	Mo	ortality [9	6]	03	Reproduc	tion
Infinito SC Fungicide (L/ha)	Uncorrected	Abbott	P-Value(*)	Rate	% to Control	P-Valve(#)
0 (control)	1.7	0		7.7	0	S C
0.43	18.3	16.9	0.008	4.1	47.4	S.0010
0.81	13.3	11.9	0.032	20	73.0	<.001
1.54	48.3	47.5	<.001	<u>n</u> .d.**	n.d.**	n,d.**
2.92	45.0	44.1	<.001	0.8	89.7	∞≲001 ∞
5.56	76.7	76.9	<.001	n.d.	p.d.	Nn.d. 0
Reference item 0.12 g a.s./ha	100	100	<.004Q	n.d.	On.d.	n.đ.

LR50: 160.6 g a.s. fluopicolide /ha; 95 % Confidence Interval: (14-243), equivalent to LR50=2.48 L prod./ha * Fisher's Exact test, two-sided, p-values are adjusted according to Bonferroni-Holm ** not detected because 10 females (instead of 15) were available after the mortality place le after the montality phase of the study # one-way ANOVA, p-values are adjusted according to founnett n.d.: not detected

#### Validity criteria:

17	
Validity criteria (Mead-	O L Gindeline J J J Test result
Briggs et al., 2000):	
Control mortality	Not more than 5 out of 40 was 2 (12.5%) 0 - 50% $0 - 50%$ $0 - 1.7%$
Toxic reference mortality	
(according to study protocol)	
Reproduction rate	5 mmmies/female 7, 77.7 mmmies/female
	2 $2$ $2$ $2$ $2$ $2$ $2$ $2$ $2$ $2$
Ũ,	S OHI. CONCLUSIONS:
	S AND A CONCILCATIONS A

The LR₅₀ (median lethal rate) of anfinito SC Eungicide to the central aphid parasitoid Aphidius rhopalosiphi was 1600 g fluopicolide/ha (equivalent to 248 L product/ha).

Sublethal effects lower than 50% were observed at the rate of 0.43 L product/ha.

The study is considered reliable. LR  $_{50}$  = 2.48 L/ha and ER  $_{50}$  > 0.43 L/ha are the relevant endpoints

the second secon



Data Point:	KCP 10.3.2.1/02	
Report Author:		
Report Year:	2003	
Report Title:	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseidae) in the laboratory Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate 625 + 62.5 g/l Code: AE 8966752 04 SC6 A102	-0 
Report No:	C036921	
Document No:	<u>M-221754-01-1</u>	8-
Guideline(s) followed in	IOBC: Blümel et al. 2000	2
study:	C & J J S	
Deviations from current test guideline:	Current Guideline: Blümel et al. (2000) No deviations	Ó
Previous evaluation:	yes, evaluated and accepted DAR 2005 for Propamocarb RAR June 2017	1
GLP/Officially	Yes, conducted under GLP/Otocially coopyied testing facilities	
recognised testing facilities:		
Acceptability/Reliability:	Yes A A O K	

### **Executive Summary**

The objective of this laboratory study was to investigate the lethal and sublethal toxicity of PLC + PCH SC 687.5 to the predatory mite *Typhledromus pyri* when exposed to a treated class surface. The test item was applied at rates of 25 7; 46.3, 83 3, 150 and 270 g a.s. (related to fluopicolide)/ha (equivalent to 0.40, 0.72, 1.29, 2.32 and 4.17 L product/ha) and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 6 g a.s./ha, and a water treated control. Mortality of 80 protonymphs was assessed 1, 3, 7, 10, 12 and 14 days after exposure. The perioduction rate of the surfaving mites was then evaluated over the period 7-14 days after treatment by counting the total number of offspring (eggs and larvae) produced. All validity criteria were met. The LR₅₀ to the predatory that *Typhlodromus pyri* was 209.5 g fluopicolide/ha (equivalent to 3.24 L product/ha). Subtethal effects lower than 50% were observed at the rate of 2.32 D product/ha.

## L.MATERIAL AND MECHODS

Test item: Infinito SC Fungivide (FLC + CH SC 687.5), Baten No.: OP220159, density 1.129 g/cm³, a fungicide SC type product containing Fluopicolide + Propagocarb-HCl (measured concentrations 64.7 g/kg + 634 g/L, respectively) as active ingredients  $\sim$ 

The test substance was applied at rates of 25.7; 46, 3; 83, 3; 150 and 270 g a.s. (related to fluopicolide)/ha (equivalent to 0.40, 0.72, 0.29, 0.32 and 4.17, product/ha) and the effects were compared to a toxic reference (a.s.: dimethorate) applied at 6 g a, that and a water treated control.

Mortality of 80 protonymphs was assessed, 3, 7, 10, 12 and 14 days after exposure. The reproduction rate of the surviving mites was then evaluated over the period 7-14 days after treatment by counting the total number of offspring (eggs and lawae) ptoduced.

Dates of experimental work: June 03, 2003 to June 17, 2003



#### **II. RESULTS AND DISCUSSION:**

The mortality / escaping rate in the control chambers up to day 7 after treatment was 0%. The mean corrected mortality of the nymphs, and the mean reproduction rate of the surviving females exposed to the test material and the toxic reference is given below: 0

In the highest dose rate of 4.17 L product/ha there was 56.3% corrected morehity. The reduction in reproductive success relative to the control at this rate was 86%. At the lower rates of 0.40, 0.72, 1.29 and 2.32 L product/ha the corrected mortality and the reduction of reproduction were <50%.

Iortality / Reproduction - 7 o			- The second sec	Reproductio	. [0/]	
	Mortality [%	2	, A	e e e		
		40	Ų"	Total No.	ReOto	
Infinito SC Fungicide (L/ha)	Uncorr.	Abbott	P-Value (*)	of offspring	<b>Gontrol</b>	P-Value (#)
0.0 (control)	0.0	0.0		11.70	0× \	
0.40	2.5	2.5 %	Q.497	19.8	7.9 0° %	0.976
0.72	5.0	5.00	0.241	24 0	19	0.526
1.29	26.3	26.3	<.00	6.9 0	40.8	0.023
2.32	38.8	38.8 ~	<.001	5.9	49.4	0.025 A
4.17	56.3	56.3	F.001 L	1.8	86.1 %	<.001°
Toxic reference item	73.8 Q	73.8	<.001	w.d.	n G. C.	0
6 g a.s./ha	,0*		Nº Nº		S S	Ô,

* Fisher's Exact test, two-sided, p-values are adjusted according to Bonferoni-Ho # one-way ANOVA, p-values are adjusted according to Dunnet

Validity criteria:

Validity criteria Blüme et al. 2000)	Test result
Montality rate 5 5 Mean montality (dead + escaped)	0 %
Toxic reference mean mortality of Between 50 and 100 % protonynoms at day 7 (control corrected)	55 %
The control from day 700 14)	11.7

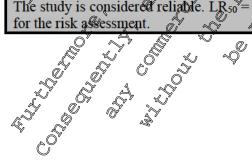
JIII. CONCLOSIONS;

The LR50 (median lether rate) of Intinito SC Fungicide of the predatory mite Typhlodromus pyri was 209.5 g fluop colide/ha (equivalent to 3.24 L product/ha).

Sublethal effects lower than 50% were observed at the rate of 2.32 L product/ha.

## Assessment and Conclusion by applicant:

The study is considered reliable. LR50  $3_{g}$  L/ha and ER₅₀ > 2.32 L/ha are the relevant endpoints





Data Point:	KCP 10.3.2.1/03
Report Author:	
Report Year:	2003
Report Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez)
	(Hymenoptera: Braconidae) in the laboratory Propamocarb hydrochloride + XE
	C638206 water miscible suspension concentrate $625 + 62$ $g/L$ Code: AF
	B066752 04 SC61 A102
Report No:	C029419
Document No:	<u>M-217140-01-1</u>
Guideline(s) followed in	ESCORT: Candolfi et al., 2000; IOBC: Mead-Briggs et al., 2000
study:	
Deviations from current	Current Guideline: Mead-Briggs et al. (2000)
test guideline:	No deviations.
Previous evaluation:	No, not previously submitted
	for Propamocarb RAR from 2017
GLP/Officially	Yes, conducted under GLP/Officially becognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes N N N A O X

### **Executive Summary**

The objective of this laboratory study was to investigate the left al an Osuble that to dicity of FLC + PCH SC 687.5 on the parasitoid was Aphidius rhopalosiphi when exposed on a treated glass surface. The test substance was applied at rates of 200 and 400 g product/ha (corresponding to 1779) and 354.3 mL product/ha, respectively) and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 0.12 g a.s./ha, and a water treated control. Mortality of the adults was assessed 24 and 48 hours after exposure. From the water control and both terrates of test item impartially chosen females per treatment were each transferred to a cylinder containing untreated coreal plants infested with Rhopalosiphum padi for a period of 24 thours. This parasitation period provided a measure of reproductive success. The number of mumpies was assessed 14 days later. All validity criteria were met. In both dose rates there was no mortalio. The deduction in reproductive success relative to the control at the 200 g product/ha rate (177.1 mL product/ha) was 8.3% and that of the 400 g product/ha rate (354.3 mL product/ha) was 10.5%.

Test item: Infinite SC Fungicide (FLC+PCHSC 689.5), Batch No.: OP220159, density 1.129 g/cm³, a fungicide SC type product containing Fluopicolide Propamocarb-HCl (measured concentrations 64.7 g/L + 634 g/L respectively as active ingredients?

The toxicity of freshly dried residues of the product AE B066752 04 SC61 A102 applied onto glass plates, to the parasitoid wasp aphidius rhopalosiphi was examined. The test substance was applied at rates of 200 and 400 g product/ha/corresponding to 177.1 and 354.3 mL product/ha, respectively) and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 0.12 g a.s./ha, and a water treated control.

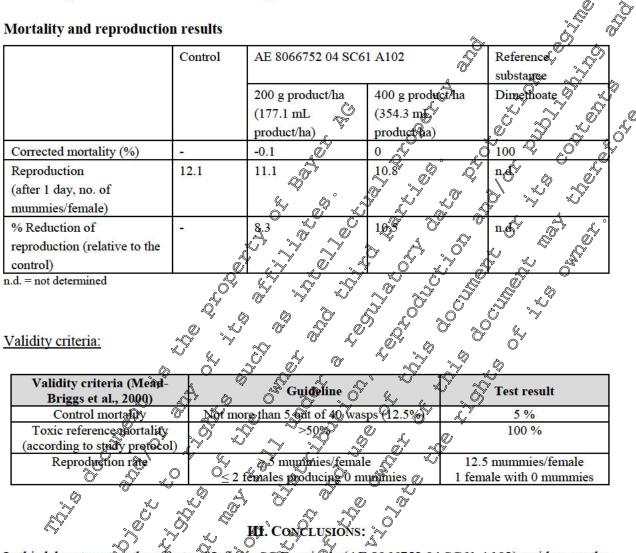
Mortality of the adults was sessed 24 and 48 hours after exposure. From the water control and both test rates of XE 8066752 of SCGL A1020 mpartially chosen females per treatment were each transferred to a cylinder containing untreated cereal plants infested with Rhopalosiphum padi for a period of 24h hours, This parasitation period provided a measure of reproductive success. The number of mummies was assessed 14 days latery

Dates of experimental work: March 09, 2005 to July 28, 2005



#### II. RESULTS AND DISCUSSION:

The findings are summarized in the following table.



In this laboratory test the effects of Infinito SC/Fungiede (AE 8066752 04 SC61 A102) residues on the survival of *Aphidius rhopalosphi* we'e determined at 200 and 400 g product/ha, applied to glass plates. In both dose rates there was no mortality. The reduction in reproductive success relative to the control at the 200 gproduct/ha rate (177 mL product/ha) was 8.3% and that of the 400 g product/ha rate (354.3 mL product/ha) was 105%.

## Assessment and conclusion by applicant

The study  $\Omega$  considered reliable. No effects on survival and reproduction were observed at both application rates tested leading to  $LR_{50}$  and  $ER_{50} > 354.3$  mL/ha. These endpoints are not further considered in the risk assessment as a higher dosed study is available providing more relevant information for the risk assessment (KCP 10.3.2.1/01; Waltersdorfer, 2003; M-221754-01-1).



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

Data Point:	KCP 10.3.2.2/01
Report Author:	
Report Year:	
Report Title:	Toxicity of AE B066752 04 SC61 A102 to larvae of the green lacewing
	Chrysoperla carnea (Steph.) under laboratory conditions
Report No:	C038632
Document No:	<u>M-225401-01-1</u>
Guideline(s) followed in	IOBC: Vogt et al. (2000) $\mathcal{A}$
study:	
Deviations from current	Current Guideline: Vogt erail: (2000)
test guideline:	Exposure on glass plates
Previous evaluation:	yes, evaluated and accepted of the second se
	for Propamocarb RAR June 2017 Q Q O O Q
GLP/Officially	Yes, conducted mider GDP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes 7 7 7 7 7 7 7 7 7 7 7 7
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$
E 6 6	

### **Executive Summary**

The purpose of this study was to determine the left al and sublet hal effects of PLC + PCH SC 687.5 on larvae of the green lacewing *Chrysopetia cantea* STEPH. in a laboratory test. Lacewing larvae were exposed to dried residues of 1.6, 4.32 and 6.4 L product/hom 200 L deionized oater/ha and a control. The different application rates of the test item were applied onto glass plates. Dimethoate EC 400 (30 mL product/ha in 200 L/ha of water) was used as a toxic reference treatment. Larvae of *Chrysoperla cannea* (Steph.) were exposed in 40 replicates of 1 larva (per freatment group) to the residues of the test item, reference trem and control, respectively. During the assessments the larvae were fed with UVsterilized eggs of *Sitotroga greatella*. The number of surviving larvae and hatched adults as well as the number of eggs laid, and larvae hatched (F₁) were recorded over a period of 42 days. From these data the endpoints mortality differences in mortality were observed in all test item treatment groups. No abnormalities regarding larvae or hatched adults were observed in any treatment group during the test.

# 

Test item, Infinito SC Eurgicico (FLG  $\neq$  PCLFSC 687.5), Batch No.: OP220159, density 1.129 g/cm³, a fungicide SC type product containing Fluopicolide + Propamocarb-HCl (measured concentrations 64.7 g/kg  $\neq$  634 g/L, respectively) as active ingredients.

The product was tested on larvae of the green lacewing *Chrysoperla carnea* (Steph.) under laboratory conditions after fesidual conditions after fes

Larvae of *Christopeful carnea* (Steph.) were exposed in 40 replicates of 1 larva (per treatment group) to the residue of the test item, reference item and control, respectively. During the assessments the larvae were fed with UV-sterilized eggs of *Sitotroga cerealella*. The number of surviving larvae and hatched adults as well as the number of eggs laid and larvae hatched (F₁) were recorded over a period of 42 days. From these data the endpoints mortality and reproductive performance were calculated.



#### Dates of experimental work: August 26, 2003 to October 07, 2003

The toxic reference to Mortality and repro	II. F reatment resulted in oduction results	RESULTS AND DISCUSSION: n 52.8 % corrected mortality (57.5 % mortality) after 21 days.
Test item	Infinito SC Fungio	cide A O S Q
Test object	Chrysoperla carned	a (Steph.)
Exposure	Dried spray deposit	ts on glass plates 🔬 🖉 👸 🖉
Treatment	Mortality after 21 days [%]	Reproduction     Fertility       Fecundity     Fertility       mean number of eggs/female/day     reduction       interview     relative to       interview     interview       interview     interview       interview     interview       interview     interview       interview     interview
Control	10	
Application rate [L product/ha]	Corrected mortality [%]	
1.6 4.32		$\begin{array}{c ccccccccccccccccccccccccccccccccccc$
6.4	2.8	182 0 (+1.2) 1708 7 2.7 7 79 2 2 2.5
Reference item Dimethoate EC 400 30 mL product/ha	52.8 0 × 4	

No statistically significantly differences in portality were observed in all test fem treatment groups compared to control group.

compared to control group. The reproductive entropy of the

Validity criteria Vogt of al., 2000) 7 5 5 Guideline	Test result
Mortality rate $\leq 20\%$	10%
Toxic reference mean mortality of Between 50 and 100 %	57.5%
Fectuality in the control (ntern number of $\mathcal{O}$ $\mathcal{A}$ $\geq 15 \%$ eggs/female and day) $\mathcal{O}$ $\mathcal{O}$	18.3%
Fertility in the control (mean patching rate) $\bigcirc$ $\ge 70 \%$	81%

#### **III.** CONCLUSIONS:

The fingicide product Infinito SC Fungicide did not induce any noticeable mortality (max corrected mortality 23%) to the green lacewing *Chrysoperla carnea* exposed to dose rates up to 6.4 L product/ha on glass plates. No noticeable sublethal effects on reproduction were observed up to the maximal rate of 6.4 L product/ha (2.5% reduction, only).



#### Assessment and conclusion by applicant:

The study is considered reliable. The relevant endpoints for the risk assessment are  $LR_{50}$  and  $ER_{50}$ >6.4 L/ha.

	and the second sec
Data Point:	KCP 10.3.2.2/02
Report Author:	
Report Year:	
Report Title:	Acute dose-response toxicity (LR50) of AE B066752 04 SCOP A1020to the Greal aphid parasitoid Aphidius rhopalosiphi (DeSefani-Perrez) under extended laboratory conditions
Report No:	
Document No:	C038633 ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° °
Guideline(s) followed in study:	IOBC: Mead-Briggs et al. (2000)
Deviations from current test guideline:	Current Guideline: Mead-Briggs et al. (2000)
Previous evaluation:	Current Guideline: Mead-Briggs et al. (2000)
GLP/Officially recognised testing facilities:	Yes Conducted under GLP Officially recognised testing facilities
Acceptability/Reliability:	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
× 1	

#### **Executive Summary**

The purpose of this study was to investigate the lethal and sublethal boxicity of FLC + PCH SC 687.5 to the cereal aphid parasited Aphidius rhopalosiphi (DESTEFANI-REREZ) in an extended laboratory test. Wasps were exposed to dried residues with rate of 0.5.1, 2, and 80 product/ha in 200 L deionized water/ha applied on potted wheat plants. The control was treated with deionized water (200 L/ha). Dimethoate EC 400 (10 mL product/ha in 200 L/ha of water) was used as a toxic reference treatment. Adults of Aphidius rhepalosiphi were exposed in a replicates of 5 female wasps (per treatment group) to the residues of the test item, reference item fonly Freplicate) and control, respectively. During the mortality test, the wasps were feel with aqueous fructose solution (25 % w/v). The number of surviving wasps, behaviour and position and the number of parasitised aphids (mummies) were recorded over a period of 14 days. From these data the endpoints mortality and fecundity were calculated. All validity criteria were met. The LRG (median lethal rate) of Indinito SC Fungicide to the cereal aphid parasitoid Aphidius Phopalosiphi was estimated to be 8 L product/ha. Sublethal effects lower than 50% were observed at the max sate of 4 L product/ha \$

# I MATERIAL AND METHODS:

Test item: Infinito Sé Fungieride (FEC + PCH SC 687.5), Batch No.: OP220159, density 1.129 g/cm³, a fungicide SC type product containing Guopicolide + Propamocarb-HCl (measured concentrations 64.7 g/kg + 63@ g/L, respectively) a active ingredients.

The product was tested under extended laboratory conditions after residual contact exposure of adults of the cereal aphid parasitoid Aphidius rhopalosiphi to spray residues with rates of 0.5, 1, 2, 4 and 8 L product/h@in 200 L deionized water/ha applied on potted wheat plants.

The courol was treated with deionized water (200 L/ha). Dimethoate EC 400 (10 mL product/ha in 200 L/ha of water) was used as a toxic reference treatment.



Adults of *Aphidius rhopalosiphi* were exposed in 4 replicates of 5 female wasps (per treatment group) to the residues of the test item, reference item (only 1 replicate) and control, respectively. During the mortality test, the wasps were fed with aqueous fructose solution (25 % w/v). The number of surviving wasps, behaviour and position and the number of parasitised aphids (mummies) were recorded over a period of 14 days. From these data the endpoints mortality and feoundity wore calculated

period of 14 days. From t	hese data the endpoints mortality and fecundity were calculated.	
Dates of experimental w	ork: September 22, 2003 to October 06, 2003	
<b>r</b>		
	II. RESULTS AND DISCUSSION:	")
The toxic reference treatm	pent resulted in 100 % corrected mortality within 24 hours	
	Them resulted in 100 /0 concept montanty patinin 24 nourse of a second sec	
Mortality and reproduc	hese data the endpoints mortality and fecundity were calculated. ork: September 22, 2003 to October 06, 2003 II. RESULTS AND DISCUSSION: ment resulted in 100 % corrected mortality within 24 hours tion results Infinito SC Fungicide	
Test item	Infinito SC Fungicide	
Test object	Aphidius rhopalosiphi (Des EFAN PEREZ)	
Exposure	Dried spray deposits on ported wheat planes	
Treatment	$\mathbb{A}$	
	Mortality after 48 hours [%] [%] Second and second a	
	Mortality after 48 hours of munipries/ control frelative to	
Control		
Application rate		
[L product/ha]		
0.5		
1	$0 \xrightarrow{1} 0 \xrightarrow{1} $	
2	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	
4 Q ^v	5 5 50.0 50.0 50.0 50.0	
8	$10^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$ $3^{10}$	
	not determinable y y y	
4         8 <b>LR</b> 50         0           [CL 95 %]         0           Reference item         0	not determinable	
Reference item		
Dimethoate EC 400	100 - not assessed	
10 mL product/ha		
* statistically significantly differ	$reprint (p < 0.05) \qquad \qquad$	

No statistically significant differences in mortality were observed in all test item treatment groups, compared to the control group. °~

The behaviour assessments showed only a statistically significant difference in the 8 L product/ha test item treatment group compared to the control group 30 minutes after exposure. This effect on behaviour was not anymore observed 2 hours after the application.

A statistically significant difference in reproduction (mean number of mummies/female), was observed in the 4 and 8 l product/ha test them groups, when compared to the control group.

Because of not or low mortality in all test tem treatment groups, a calculation of the LR₅₀ was not possible.

The LR₅₀ has to be regarded above the highest tested application rate of the test item (8 L product/ha).



#### Validity criteria:

Validity criteria (Mea Briggs et al., 2000)	Id- Guideline	Test result
Control mortality	Not more than 5 out of 40 wasps	0%
	(12.5 %)	Č V S
Toxic reference mortal		J 100 % 4 5
(according to study proto		
Reproduction rate	$\geq$ 5 mummies/female	15.8 munumes/female
	$\leq 2$ females producing@mummies	1 female with 0 mummies
	III. Concentrations: I rate) of Infinito SC Fungicide to the cereal ed to be > 8 L product/ha. an 50 % were observed at the max. rate of 4 L pro- usion by applicant: I reliable. Endpoints for the ask as essment are to a set the set of t	1 female with 0 mummies
The LR ₅₀ (median letha	1 rate) of Infinito SC Fungicide to the corea	1 aphid parasiterid Aphidius
rhopalosiphi was estimate	ed to be > 8 L product ha.	
Sublethal effects lower th	an 50 % were observed at the max, rate of 4 L of	oduct/ha
Assessment and concl	usion by applicant: 7 5 5	
The study is considered	l reliable. Endpoints for the osk assessment are f	$R_{50} > 8$ L/ha and ER ₅₀ of 4
L/ha.		
2		J ~ A
Data Point:	KCP 103 2.2/02 ~ ~ ~	~~~
Report Author:		<b>V</b>
Report Year:		9
Report Title:	Toxicity to the predatory mite Tophlodromus pyri So	CHEUTEN (Acari,
<i>6</i> 7	Phytoseiidae) using an extended laboratory text Prop	amocarb hydrochloride + AE
	C638206 water miscible suspension Concentrate 625	+ 62.5 g/l Code: AE
	B066752 04 SC61 A102	
Report No:	C036922	
Document No:	M-22176-014	
Guideline(s) followed in	IOB Blümer et al. 2000	
study:		
Deviations from current test guideline:	Ourrent Guideling. Blüngel et al. (2000)	
	vs.,⊋aluat@ and accepted.	
Previous or aluation:	DAR 2005.	
	for Propomocar RAR Date 2017	
GLP/Officially	Yes, conducted under GLP/Officially recognised test	ting facilities
recognised testing		ing mentices
facilities:		
Acceptability Reliability:		
A A A	Star & Star	
Executive Sucemary	~G~	

## Executive Supernary

The aim of the study was to determine the toxicity of freshly dried residues FLC + PCH SC 687.5 applied onto leaves of *Phaseolus vulgaris* var. *nanus*, to the predatory mite *Typhlodromus pyri*. The test item was applied at rates of 25.7, 46.3, 83.3, 50 and 270 g a.s. (related to fluopicolide)/ha (equivalent to 0.40, 0.72, 1.29, 2.32 and 4.17 L product/ha) and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 35 g a.s./ha, and a water treated control. Mortality of 80 protonymphs was



assessed 1, 3, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The reproduction rate of the surviving mites was then evaluated over the period 7-14 days after treatment by counting the total number of offspring (eggs and larvae) produced. All validity criteria were met. The LR50 of test item to the predatory mite Typhlodromus pyri was > 4.17 L product/ha. Sublethal effects lower than 50% were observed at the maximal rate of 4.17 L product/ha.

#### I. MATERIAL AND METHODS:

Test item: Infinito SC Fungicide (FLC + PCH SC 687.5), Batch No.: OR220159, density a fungicide SC type product containing Fluopicolide + Propamocarb-HCL measured concentrations 6 g/L + 634 g/L, respectively) as active ingredients.

The test substance was applied on bean leaves (Phaselus vulgaris) at rates of 250, 46.3, \$3.3, \$0 and 270 g a.s. (related to fluopicolide)/ha (equivalent to 0.40, 0.72, 1.29, 2.92 and 1.17 L product/ha) and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 35 g a.s./ha and a water treated control.

Mortality of 80 protonymphs was assessed 1, 3, 7, 10, 12 and 14 days after exposure by compring the number of living and dead mites. The reproduction rate of the surviving mites was then evaluated over the period 7-14 days after treatment by counting the total number offspring (eggs and harvae) produced.

## Dates of experimental work: September 09, 2003 to September 2

(II. RESPLTS AND DISCUSSIO

The mortality / escaping rate in the confiol chambers up to day 7 after treatment was > 4 %. The mean corrected mortality of the nynolis, and the mean reproduction rate of the surviving females exposed to the test material and the toxic reference is given below:

In the highest dose rate of 4.17, P product/ha there was 13,5% corrected@nortality. The reduction in reproductive success relative to the control at this highest tested rate was 34.3 %. At the lower rates of 0.40, 0.72, 1.29 and 2.32 L product ha the corrected mortality and the reduction of reproduction were also < 50 %

	Monality	[%] ~~	Reproduc	tion [%]
Infinito SC Fungicide (6 na)	C Shcort.	Abott	Rate	Relative to Control
0.0 (control)	0.0	0.0	7.5	0
			6.6	12.9
	2 (11.3 ° )	11.3	6.2	17.9
	2.50	2.5	5.4	27.6
2.32 <u>A</u>	A.3	11.3	5.3	29.8
2.32 4.17	~ 13.8	13.8	4.9	34.3
Toxic reference from	96.3	96.3	n.d.	n.d.
6 g a.s. Tra				

## Mortality / Reproduction - Adays after treatment



#### Validity criteria:

Validity criteria (B	lümel et al., 2000)	Guideline	Test result
Mortali	ty rate	Mean mortality (dead + escaped) $\leq 20\%$ at day 7 $\%$	0 %
Toxic reference n protonymphs at day 7		Between 50 and 100 %	96.3 %
Reproduction (number the control from	of eggs per female in		
The LR50 (median lethal	III. C rate) of Infinito SC Fu	ONCLUSIONS:	Aromus pyriseas >
roduct/ha.			
Assessment and conc The study is considered 4.17 L/ha.	lusion by applicant: ed reliable. Relevant e	ndpoints for the risk assessment are	$E LBS and ER_{50} >$
			0 [×]
Data Point: Report Author:	RCP 10.3.2.2/04		
Report Year:			
Report Title:		Propanocarb SC 62.5+ 625 on the	advhird beetle
	Coccinella sentempino	tata, exended aboratory stude - dose r	esponse test -
Report No:	2384 1012 6		
Document No	M@25634@01-1 %		
Guideline(s) followe@in	Schmuck et al. 2000		
study: 🔪 🗴			
Deviations from current	Current Guideline: Sch	$mu \leq et al_{(2000)}$	
test guideline:	No deviations.	Y U Y	
Previous evaluation	yes, evaluated and acc DAR 2005	, , , , , , , , , , , , , , , , , , , ,	
GLP/Officially	Yes, conducted under	GL& Officially recognised testing facilit	ties
recognised teeping			
facilities: Acceptabaity/Reliability			

A Q FLC + PCH SC 683.5 on the ladybird beetle larvae and pupae Coccinella septempunctata L. by contacting substance treated leaf surface (exposure period) compared to a water treated control and a toxic standard. Additionally, an assessment for sublethal effects on reproduction of the survivors (reproduction) was made. Approximately 4-day old larvae of C. septempunctata (1 larva per replicate) were exposed to dried sprace deposits of 300, 600, 1200, 2400, and 4800 mL product/ha (diluted in 200 L defonised water/Ha) on freated bean leaves (Phaseolus vulgaris; 40 replicates per treatment group). Defonised water was used as a control treatment and Perfekthion (50 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. The duration of the pre-imaginal mortality part was 15 -16 days (toxic standard only 1 day). The reproductive performance of the survivors was examined over 2 weeks (oviposition period) using adults from the control and from those test item concentrations where



the corrected mortality was < 50.0 %. All validity criteria were met. The LR₅₀ (median lethal rate) of the test item to the ladybird beetle C. septempuncta was > 4.8 L product/ha. Sublethal effects lower than 50% were observed at the maximal rate of 4.8 L product/ha.

## I. MATERIAL AND METHODS:

Fluopicolide + Propamocarb SC 62.5 + 625 [active ingredients: Fluopicolide (SE C638206) \$3.00 g Propamocarb-HCl 640.13 g/L; batch no.: 08490/0012(0001), sample no.: TQX06993-00, acticle por 00-00 06373046, development no.: 30-00312153]; under extended laboratory conditions approximately 4 day old larvae of Coccinella septempunctata (1 larva per replicate) were exposed to dried spray deposite of 300, 600, 1200, 2400, and 4800 mL product/ha (diluted in 200 L dependent water ha) on treated bean leaves (Phaseolus vulgaris; 40 replicates per treatment group). Defenised water was used as a control treatment and Perfekthion (50 mL product/ha divided in 200 L deionised water/ha) as a reference treatment.

The duration of the pre-imaginal mortality part was 15 - 15 days (toxic standard only 1 day). The reproductive performance of the survivors was examined over 2 weeks (oviposition period) using adults ality wa from the control and from those test iter concentrations where the correct of mortality was < 50.0%. The toxic standard treatment caused a 100% correcte Cinortality.

## Dates of experimental work: March 09, 2005 to August 15, Ô

## Ô II. RESULTS AND DISCUSSION.

In the highest dose rate of 4.8 Loroducina there was-6.5% corrected mortality? The reproductive success was not significantly lower compared to the control at this highest tested ate. Ĉ  $\bigcirc$ 

			X O		
Treatment 🖉	Pre-imaginal	Corrected	Eggs per	<b>Fertile</b> eggs	Larval
[mL product/ha]	mortality a	mortality	female per	perofemale	hatching rate ^b
	~{ <b>%</b> ]	~[%]	May b	per day ^b	[%]
Control	0 22.50	40° - 20°	> 15.2	10.1	65.4
300	22.5 n.s.	28	9 15.3 n.s. 🧹	11.2 n.s.	72.6 n.s.
× 800 x	300 n.s.	0.7	1 28 n.s. 0	15.3 n.s.	76.7 *
1200 U	3.0 n.s	9.7	8.9 n.s	6.9 n.s.	76.5 *
2400	~ 30.0 n.s.	\$ 9.7	17.6 ms.	13.2 n.s.	73.1 n.s.
4800	17. Sn.s. %	40.5	11.6 n.s.	9.4 n.s.	81.1 *
Toxic reference		K)			
50 mL Perfekthion/hav	N00.0	¥100.6	n.a.	n.a.	n.a.

an.s. = not significant, * Significant; Fisher Exact Test, a 0.05 ^bn.s. = not significant, * = significant; Dunnett-Test, α n.a. = not assessed

Validity criteria:

A

Validity vriteria (Schmuck et @., 2000)	Guideline	Test result
Average pre-imaginal nortality on the control	$\leq$ 30 %	22.5 %
Agre-imaginal mortality of the reference treatment	> 40 %	100 %
Number of eggs/female/day on the control	>2	10.1



## **III.** CONCLUSIONS:

The LR₅₀ (median lethal rate) of AE B066752 04 SC61 A102 to the ladybird beetle Coccinella septempuncta was > 4.8 L product/ha. Sublethal effects lower than 50 % were observed at the maximal rate of 4.8 L product/ha. Ĩ

Assessment and conclusion by applicant: The study is considered reliable Relevant endpoints for the risk assessment are  $LR_{50}$  and  $ER_{50} > 4.8$  L/ha. Data Point: KCP 10.3.2.2/05 Report Author: Report Year: 2014 Ø Fluopicolide + propaniocarb mydrochloride & 687 (62 .5+625 Report Title: g/L): Agedresidue extended laboratory tests to determine effects on the parasitic wasp Aphidius rhopalosiphi (Hymenøptera, Braconidae) Report No: **BAY-14-1** Document No: M-503125-04-1 Mead-Briggs et al (2009). An extended laboratory test for evaluating the effects of Guideline(s) followed in study: plant protection products on the parasities wasp aphidites rhopalosiphi De Stefani-Perez) Ô Ò (Hypernoptera, Braconidae) Current Guideline Mead Briggs et al. Deviations from current test guideline: No deviations. Previous evaluation: No, not previously sugmitted for Ropamoearb RAR June 2017 GLP/Officially Yes, conducted under GLE/Officially recognised testing facilities recognised testing facilities: Acceptability/Reliabilit

## **Executive Summary**

The objective of this extende Daboratory study want investigate the lethal and sublethal effects of FLC + PCH SC 687.5 out he parasitoid wasp. Dhidius rhophosiphe when exposed of both freshly-dried and field-aged residues of this test item. The test item was applied at a treatment rate of 2.8 L product/ha to pots of seedling barley plants on two occasions (TLT2) with 7 days in-between. A control treatment of water and a toxic reference reatment (BAS 152 1 I, containing nominally 400 g/L dimethoate) were applied to barley plants and a rate of 10 and product/na. An initial bioassay on freshly-dried residues commenced following the applications at time, T2, hereafter referred to as 0 days after treatment (DAT), with subsequent bioassays commencing at and of DAT. Five wasps were confined in each pot, with six replicates (i.e. actoral of \$0 wasps) prepared for each treatment. Wasp survival was assessed over a period of 48 h. To assessminy significant sub-Othal effects on the reproductive capacity of the exposed wasps, further assessments were then carried out in bioassays where the test-item treatment had resulted in < 50% corrected indicate 48 1/ Fifteen surviving female wasps from the treatment rate and control were confined individually for 24 hover untreated barley plants infested with the cereal aphids, Metopolophium prhodien and Rhopalosiphum padi. The wasps were then removed, and the plants left for a further 10 days before the number of 'mummies' (parasitised aphids containing wasp pupae) that had developed was pecorded. All validity criteria were met. The corrected mortality did not exceed 3.3% and the effect on reproduction was less than or equal to 1.6% throughout all of the bioassays. No statisticadly significant repellent effect of the test item was observed during the initial 3 hours of any of the bioassays and the percentage of wasps which settled on treated plants was 24.7%, 32.7% and 38.0% in the bioassays initiated 0, 7 and 14 DAT respectively.



## I. MATERIAL AND METHODS:

Test item: Fluopicolide + Propamocarb-HCl SC 687.5 (62.5+625) G: Fluopicolide 5.18 % w/w, 58.14 g/L; Propamocarb-HCl: 55.8 % w/w, 627.0 g/L; (all values analytical); Batch ID.: EM4L01, 80; Sample Description: FAR01771-00; Specification No.: 102000027553; density: 1.123 g/mL (2000). A single treatment rate of FLC+PCH SC 687.5 (62.5+625 g/L) equivalent to 2.8 L produce ha, was applied to pots of seedling barley plants on two occasions (T1, T2) with 7 days in-between. A control treatment of water and a toxic reference treatment (BAS 152 11 I, containing nominally 400 g/L@ dimethoate) were applied to barley plants at a rate of 10 mJ, product/ha. An initial bioassay on freshky dried residues commenced following the applications at time T2, hereafter referred to as addays after treatment (DAT), with subsequent bioassays commencing at 7 and 10 DAT. Five wasps were confined in each pot, with six replicates (i.e. a total of 30 wasps) prepared for each treatment. Wasp survival was assessed over a period of 48 h. To assess any significant sub-lethal effects on the reproductive capacity of the exposed wasps, further assessments were then carried out in bioassays where the test item treatment had resulted in < 50% corrected mortality at 48 h. Fifteen surviving female wasps from the treatment rate and control were confined individually for 24 h over untreated barley plants intested with the cereal aphids, Metopolophium dirhodum and Rhopolosiphum path? The wasps were then repoved and the plants left for a further 10 days before the number of mumphies' (parasitised apprds containing wasp pupae) that had developed was recorded. 

Dates of experimental work: July 16,2014

1. RESULTS AND DISCUSSION

Mortality and reproduction of Aphidius repopulosiphi after expositive to Fluopicolide + Propamocarb-HClSC 687.5 (62,5+625,2/L) P (N n

Bioassay	Treatmen	t Nate of	Mean %	Corrected	wasps	Mean No.	Effect on
initiated	~ ⁰	fmL/ha x	mortadity 1	×mortality ²	settled on	mummies	reproduction ⁵
	Ča.	number of	at 48 h	at 48 h	treated plants	per	
		applications	j o		during initial 3 hours ³	surviving female ⁴	
	Ç.			<del>```</del>	<u>a alours -</u>	Temate	
0 DAT ^{«×}	Control		y 89 ,	× ~ .	xx 32.7	18.5	-
	Test Item	דע 2800 x 2 א	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	• • • • • • • • • • • • • • • • • • •	24.7	18.9	-2.1
	Toxic ref.	<u></u>	96.7×	\$ ^{\$7} 96.7	20.0 *	~	~
7 DAT	Control		× 2%0	y do	44.0	27.5	-
	Test Item	2800 x 25	0.0°	ູ 🗶 0.0	32.7	32.1	-16.5
4	Toxic ref.			~O [°] 100	24.0 *	~	~
14 DAT	Control		Q3.3 ~	<i>*</i> -	44.0	45.5	-
	Test Item	2800 x 2		0.0	38.0	44.8	1.6
	Toxio ref.		\$6.7 *	86.2	22.7 *	~	~

¹ For each bio stay, in d = 0.05. Values that differed significantly from theil respective control are marked with an asterisk.

² Derived psing Adoott's formula

³ For each bioassay, treatments were compared to the control by one-way ANOVA and Dunnett's t-test ( $\alpha = 0.05$ ). An asterisk indicates where the results were significant.

⁴ For each broassay, results were compared by t-test for independent samples ( $\alpha = 0.05$ ), but there were no significant differences.

⁵ Reproduction relative to respective control treatment. A positive value indicates a decrease in reproduction, and a negative value an increase.

[~] No reproduction assessments were carried out.



Ø1

## Validity criteria:

	, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~_, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~, ~~~, ~~, ~~_, ~~, ~~, ~~, ~~, ~~, ~~, ~
Guideline	Test result
Not more than 5 out of 40 wasps (12.5%)	3.3 %
>50%	86.7%
$\geq$ 5 mummies/featale $\leq$ 2 females producing 0 mummies Q	45.50 minimies temale 0 female with 0 prumpies
	Not more than 5 out of 40 wasps (12.5%) >50% $\ge 5$ mummies/featale $\le 2$ females producing 0 mummies

The residues of FLC + PCH SC 687.5 (62.5+@5 g/L@had up harmful effects after application of 2 x 2.8 L/ha on either the survival or reproductive capacity of the was Aphidius rhopalosion in Obioassay initiated 0 DAT, and this was confirmed by further bioassays initiated at 7 and 14 DAT. The conjected mortality did not exceed 3.3% and the effect on reproduction was less than or equal to 1.6% throughout all of the bioassays. No statistically significant repellent effect of the test tem was observed during the initial 3 hours of any of the bioassays and the percentage of wasps which settled on preated plants was 24.7%, 32.7% and 38.0% in the bioassays initiated 0, Dand 16 DAT respectively.

## Assessment and conclusion by applicant:

n The study is considered reliable. The relevant endpoints for the risk assessment are LR50 and ER50 > 2 x 2.8 L/ha.

Ô

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

above, no semi-field studies were deemed necessary. In view of the esults presented

### CP 10.3.2.4 tudies with pon-target arthropods

field studies were deemed necessary. In view of the results expo

## Other routes of exposure for non-target arthropods CP 10.3.2

No relevant exposure of non-target arthropods is expected by other routes of exposure.



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

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev. 2 final, 2002). Predicted environmental concentrations used in risk assessment For details of PEC_{soil} calculations refer to MCP Summary Section 9, Point 9, 1.3. Table 10.4- 1: Maximum PEC_{soil} values for fluopicolide its metabolites and the product FLC+ PCF SC 687.5 in potatoes (for details see MCP Section 9, Point 9.1.3)

Table 10.4- 1:	Maximum PEC _{soil} values for fluopicolideoits metabolites and the SC 687.5 in potatoes (for details see MCP Section 9, Point 9.1.3)	product FLC
	SC 687.5 in potatoes (for details see MCP Section 9, Point 9.1.3)	
	<b>I</b>	, U SI

Compound	Potatoes	A.	
	PECsoil, initial	PECsoil, plateau, 20 cm	RC soil, Gu*
	[mg/kg]		
	4 8 100	ga.s./ha	
Fluopicolide	0.144	<b>g.g.s./ha</b> 2 4 4 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	0,192
M-01 (AE C653711)	0.034		0,192 0 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
M-02 (AE C657188)	0.007	0.001 × × × × × × × × × × × × × × × × × ×	0,007
M-03 (AE 0608000)	0.016	0.014	<b>9</b> .030 5 5
	<u>کې کې 3 %100</u>	gas./ha	
Fluopicolide	0.125 6 2	0.042	<b>9</b> 167 ^O
M-01 (AE C653711)	QQ030 O Q Q	0.007	0.036
M-02 (AE C657188)	$0.007$ $\sim$ $0$	\$0.0010° & k	0.007
M-03 (AE 0608000)			9.026
	^م ر ک ^س کر کر	gass./ha	
Fluopicolide	0.186 8 6	0.036	0.142
M-01 (AE C653711)	0.025 0 1 2	0.0006	0.031
M-02 (AF \$657188)		\$100.0°	0.007
M-03 (ÅĚ 0608000)	0,012 5 5	0.010	0.022
6 ⁶ 4		g a.s./ha	
Fluopicolide	0.053 .0 0 .0	0.0180	0.071
M-01 (AE C653711)		0.003	0.016
M-02 (AF@C657188)	0.005	≥0.001	0.005
M-03 (AE 0608000)		0.005	0.011
		, prod./ha	
FLC + PCH SC 687.5	2.685 ¹⁾ 25 9	-	-
FLC + PCH SC(87.5 A)			



		3 × 1.6 L prod./ha		
FLC + PCH SC 687.5	2.276 ²⁾	-	-	°
	·	2 × 1.6 L prod./ha		
FLC + PCH SC 687.5	1.917 ³⁾	-	- 8	
	·	1 × 1.6 L prod./ha	- Ali	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
FLC + PCH SC 687.5	0.958 4)	-	-	. ⁶⁷ 67 19
* PECsoil, accu means th	e sum of PECsoil, in	itial and PECsoil, plateau	4	

The PEC_{soil} accu means the sum of PEC_{soil}, initial and PEC_{soil}, plateau The PEC_{soil} value for the product FLC + PCH SC 687.5 is calculated based on the initial rate of the product (1.6 Juna) 1) in a four times application, the portion reaching soil (BBCH 21 - 40, worst case interception of  $2 \times 60$  and  $2 \times 85\%$  for potatoes), the standard soil density (1.5 g/cm³), the standard soil depth (5 cm) and the density of the formulation %C (1.123 g/mL).

The PECsoil value for the product FLC + PCH SC 687 is calculated based on the initial date of the product (1.6 [fra) 2) in a three times application, the portion reaching solf (BBCH 21 – 40) worst case interception of  $2 \times 60^{\circ}$  and  $1^{\circ}$ 85% for potatoes), the standard soil density (1.5 (cm³), the standard soil depth (5 cm³ and the density of the 4

formulation (1.123 g/mL). The PEC_{soil} value for the product FLC + PCH SC 687.5 is calculated based on the initial rate of the product (1.6 L4ba) in a two times application, the portion reaching soil (BBCH²), worst case interception of  $2 \times 60\%$  for solatoes) the standard soil density (1.5 g/cm³), the standard soil depth (5 orn) and the density of the formulation (1,123 g/mL). The PEC_{soil} value for the product FLC + PCH SC 687.5 is calculated based on the unital rate of the product (1.6 L4ba) in a two times application, the portion reaching soil (BBCH²), worst case interception of  $2 \times 60\%$  for solatoes) the standard soil density (1.5 g/cm³), the standard soil density (5 orn) and the density of the formulation (1,123 g/mL). 3)

4) in a single application, the portion reaching skil (BBCIC 21, worst case merception of 1 100% for potatoes), the standard soil density (1.5 g/cm3), the standard soil depth (5 cm) and the density of the tormulation (1.123 g/mL).

Table 10.4.1- 1:	Maximum, RECsoil values for fluopicolide, its metabolites and the product FLC + PCH
	SC 687.5 in lettice (for details see MOP Section 9, Point 9.1.3)

Compound	Lettuce		
	DEC	PEC, soik plateau (2) cm (4) [mg/kg]	PECsoil, accu*
		[mg%kg]	♥
		rays./ha	
Fluopicolide M-01 (AE C653711) M-02 (AE C657188)	0.080 0 40 2		0.107
M-01 (AE C653711)			0.023
M-02 (AF 657188)		× 100.08	0.005
M-03 (AÉ 0608000)	0,009 ~ 67 ,7	0.008	0.016
67 1		g a.s./ha 🏷	
Fluopicolide		0.034	0.134
M-01 (AE C653711)		0.095	0.029
M-02 (AFC657188)	0.016	\$0.001	0.010
M-03 (AE 0608000)		0.010	0.021
		prod./ha	
FLC + PCH SC 87.5	1.467 ¹⁾ 5 9		
	് പ് എ 1 × 1.6 L	prod./ha	
FLC + PGH SC 697.5	1.790 ²⁾		
* DEC	und df DEC and DEC		

PECsoil, a means the sum of PECsoil, initial and PECsoil, plateau

The Presoil value for the product FLC + PCH SC 687.5 is calculated based on the initial rate of the product (1.6 L/ha) 1) in a dauble application, the portion reaching soil (BBCH 40-49, worst case interception of 70 % for lettuce), the standard soil density (1.5 g/cm³), the standard soil depth (5 cm) and the density of the formulation (1.123 g/mL).

He PEC_{soil} value for the product FLC + PCH SC 687.5 is calculated based on the initial rate of the product (1.6 L/ha) 2) in a single application, the portion reaching soil (BBCH 13, worst case interception of 25 % for lettuce), the standard soil density (1.5 g/cm³), the standard soil depth (5 cm) and the density of the formulation (1.123 g/mL).



 $\gg$ 

### **CP 10.4.1 Earthworms**

The risk assessment (calculation of TER values) was based on the NOEC values calculated from the studies performed with the product and the metabolites.

enia fetida roduction d, mixed into sojt enia fetida roduction d, mixed into soil	Ecotoxicological endpointReferenceNOEC30 L prod./ha $2002 \cdot M-2180 \cdot 29-01 \cdot K K C 10.4.1 \cdot 1/01 \cdot 10.1 \cdot $
roduction <u>a</u> , mixed into soil <i>enia fetida</i> roduction <u>a</u> , mixed into soil <i>enia fetida</i> roduction <u>a</u> , mixed into soil <u>a</u> , mixed into soil	NOEC $\ge 500 \text{ mg pcod./kg/dws}^{47}$ EC _{10/20} Calculation not possible $\xrightarrow{542464-01-1}$ NOEC 31.25 mg a.s./kg dws ⁴⁰ EC _{10/20} Calculation not possible $\xrightarrow{642464-01-1}$ NOEC 250 mg p.m./kg dws ⁴⁰ $\xrightarrow{642464-01-1}$ NOEC 22003 $\xrightarrow{642464-01-1}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$ $\xrightarrow{72003}$
roduction 1, mixed into soit <i>enia fetida</i> roduction 1, mixed into soil	2003 04- 250 mg p.m./kg dwc 250 mg p.m./kg dwc 2003 04- 2003 04- 2004 0
oduction	Calculation at normalia
min fatida	
oduction	NOEC $100$ for p.m. kg dw $2016$ ; M- SC _{10/20} Calculation for possible KCA 8.4.1/08
fia fetica	NQC $\gtrsim$ 50 mg.p.m./kg/dws, $\sim$ 2016; M- 57/57-01-1 Calcutation not possible $\sim$ A 8.4.1/07
bduct: a = active si	substance: n no nure nortabolite
	lic substance flog Port 2)
	l, mixed into soil lent

DER calculation for earthworkins for the product FLC + PCH SC 687.5 Table 10.4.1-3:

<u>````</u>			1	-	
Compound 🖗	Species, study type	Endpoint	PECsoil	TERLT	Trigger
		[mg prod./kg]	[mg prod./kg]		
Potatoes, 4 × 1.6 L pro	od./ha				
FLC + PQP SC 687.5		NOEC $\geq 500$	2.635	$\geq$ 190	5
Potatoes, 3 × 1.6 L pr	d./ha				
0	Earthworm, reproduction	NOEC $\geq 500$	2.276	$\geq$ 220	5
Potatoes, 2 × 1,6 L pro	ads/ha 🖉 🦿				
	Earthworm, reproduction	NOEC $\geq 500$	1.917	$\geq 261$	5
Potatoes X × 1.6 Pro	od. Ma				
FLC + PCH SO 87.5	Earth orm, reproduction	NOEC $\geq 500$	0.958	$\geq$ 522	5
Lectuce, 2 21.6 L pro	d./ha				
FLC + PCH SC 687.5	Earthworm, reproduction	NOEC $\geq 500$	1.437	≥ 348	5
Lettuce, 1 × 1.6 L pro	d./ha				
FLC + PCH SC 687.5	Earthworm, reproduction	NOEC $\geq 500$	1.797	$\geq$ 278	5



Compound	Species, study type	Endpoint	PECsoil	TERLT	Trigger
•		[mg/kg]	[mg/kg]		j j
Potatoes, 4 × 1.6 L p	rod./ha		Ş	9. 0.	
Fluopicolide	Earthworm, reproduction	NOEC 31.25	0.192	161	5
M-01 (AE C653711)	Earthworm, reproduction	NOEC	0.04	5952	
M-02 (AEC657188)	Earthworm, reproduction	NOE $\geq 100$	g 007	Ø14286	5 0
M-03 (AE0608000)	Earthworm, reproduction	$NOEC$ $\geq 50$	0.030	≥.1067 ×	\$5 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Potatoes, 3 × 1.6 L p	rod./ha		8 8 ·	di di ca	2
Fluopicolide	Earthworm, reproduction	NOEC 31.25	0.167	187	\$5 \$5
M-01 (AE C653711)	Earthworm, reproduction		\$0.036 Č	6944	5
M-02 (AEC657188)	Earthworm	$300 \text{EC}^{\circ} \ge 100^{\circ}$	0,007	>04286 *>	5
M-03 (AE0608000)	Earthworm, reproduction	$\begin{array}{c} NOEC \\ O \\ O \\ O \end{array} \geq 50 $	0.026	≥ 1923	5
Potatoes, 2 × 1.6 L p	rod./http://	S & a	S.		
Fluopicolide	Farthworm, C	NOTC 31.25 0	0.142	220	5
M-01 (AE C653711)	Eacthworm	NOEC 250	031	8065	5
M-02 (AEC657188)	Earth@orm, O &	NOEC $\sim 100^{10}$	~	≥ 14286	5
M-03 (AE0608000)	Earthworth, Construction	NOKC 250	0.022	2273	5
Potatoes, 1 × 1.6 L p				_	
Fluopicolide	Farthworn, V	NOFE 30,25	0.071	440	5
M-01 ^(AE C6537,11)	Eartoworm reproduction	\$0EC 250	0.016	15625	5
M-02 (AEC657188)	Searthworm,	$\mathbf{NOPC} \ge 100$	0.005	20000	5
M-05y (AE0608000)	Eatthworm Q	$\dot{O}$ NOEC $\geq 50$	0.011	4545	5
Lettuce, 2 × 1 of L pr	oð,/ha				
Fluopicolide	Earthworm, ~ reproduction	NOEC 31.25	0.107	292	5
M-01 (AE \$5371)	Earthworm, reproduction	NOEC 250	0.023	10870	5
M 402 (AE C65 (0188)	Earthworm, reproduction	NOEC $\geq 100$	0.005	$\geq$ 20000	5
M-03 (AE0608000)	Earthworm, reproduction	NOEC $\geq 50$	0.016	≥ 3125	5

 Table 10.4.1-4:
 TER calculations for earthworms for fluopicolide and its metabolites



Compound	Species, study type	Endpoin [mg/kg]	it	PEC _{soil} [mg/kg]	TERLT	Trigger
Lettuce, 1 × 1.6 L	prod./ha					Ŷ
Fluopicolide	Earthworm, reproduction	NOEC	31.25	0.134	233	5
M-01 (AE C653711)	Earthworm, reproduction	NOEC	250	0.029	8621	
M-02 (AEC657188)	Earthworm, reproduction	NOEC	£100	0.010	≥ 10000	
M-03 (AE0608000)	Earthworm, reproduction	NOEC	¥.	0.021	≥2381	

The TER values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of FLC+ PCF SC 687.5 in potatoes and lettuce.

Qà

	KCP 104 QM S S S S S
Data Point:	KCP 10.4, Q01 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Report Author:	
Report Year:	
Report Title:	AE 638206 & propamocaro SC 62,5 & 635 (Code: AE B066752,04 SC61 A1):
	Acute toxicity to carthworms (Eisenia fetta)
Report No:	©03516© ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Document No:	©03516© ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
study: Deviations from current test guideline:	
Deviations from current	Current Guideffine: OECD 20771984) @ No deviations
test guideline:	No deviations
revious evaluation:	yes, evaluated and accepted In the DAR (2005) Yes, conducted under CLP/Officially recognized testing facilities
O**	In the DAR (2005)
GLP/Officially	Yes, conducted under CLP/Officially recognized testing facilities
recognised resting	
facilities:	
Acceptability/Reliability:	Xies X O' X & A'

## Executive Summary

The purpose of this study was to assess the effect of Euopicolide + Propamocarb SC 687.5 on survival of the earthworm *Eisenia fetida* during an exposure into an artificial soil at 5 different application rates. Adult earthworms (*Eisenia fetida*) were exposed for 14 days in groups of 40 (four replicates of 10 worms per concentration) to concentrations of 10, 32, 400, 316 and 1000 mg test item/kg dry weight mixed into artificial soil. The assessment (4) the number of surviving earthworms and observations were made on day 7 and day 4. Earthworms were weighed initially and at end of the test. The validity criteria were met. The motality of earthworms was 0% in the control and in all treatments with the test substance. The weight change of the earthworms ranged between -9 and 4% in the treated groups and was 2% in the control. The 4-day LC₅₀ for the test material to earthworms (*Eisenia fetida*) based on nominal test concentrations was 1000 mg/kg soil d.w. The No Observed Effect Concentration was 316 mg/kg soil d.w.

## I. MATERIAL AND METHODS:

Test item: Fluopicolide + Propamocarb SC 687.5 (62.5 + 625), Short name: FLC + PCH SC 687.5 (62.5 + 625) (Code: AE B066752 04 SC 61 A1, analysed contents of a.s.: 64.7 g/L fluopicolide and 634 g/L



propamocarb, density: 1.129 g/mL. Adult earthworms (Eisenia fetida) were exposed for 14 days in groups of 40 (four replicates of 10 worms per concentration) to concentrations of 10 - 32 - 100 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 316 - 31and 1000 mg test item/kg dry weight mixed into artificial soil containing 69 % quartz sand, 20 % kaolin clay, 10 % sphagnum peat and about 0.2 - 1% CaCO₃. The assessment of the number of surviving earthworms and observations were made on day 7 and day 14. Earthworms were weighed initially and at end of the test. Toxic standard: 2-chloroacetamide, separate study at concentrations of 5.6, 18,04 and 32 mg/kg soil d.w.; control: untreated, solvent control: none.

Dates of work: March 26, 2003 - April 10, 2003

## **II. RESULTS AND DISCUSSION:**

**Biological findings:** 

Effects on mortality and growth of the earthworns are shown in the following table

Test item	Fluopicolide + Propamocarb SC 687,5 (62.5, 625)
Test object	Eisenia fetida
Exposure	Artificial soil
	Eisenia fetida Artificial soil Mortality Img test item/kg soil d R & Y & Y & Y 316
	Img test item/kg soil d a grad
NOEC	Mortality     A     A       [mg test item/kg soil down     4     4       316     4     4       1000     4     4
LOEC	
LC ₅₀	

		r Úr	10%	$\sim$ $\sim$		
	ġ,	Fluopicolie	le + Propam m/kgSoil d%	očarb SÇ 68	7.5 62.5 + 6	25)
	Control	og testate	em/kgQsoil d%	w.]	, Ô ^v	
S O		v10 🔊	<b>30</b> 0	100	316	1000
% Mortality of addit worths after 14 days	¢ ¢				0	0
Biomass charge in Achange in fresh weight after 4 days relative to mitial fresh weight)				la El	1	-9*

* Statistically significant coppared is control U-Test of Wiles xon, a 0.05, two-sided) d.w.: dry weight (of artificial soil) L,

The mortality of carthworms was 0% in the control and in all treatments with the test substance. The between and \$% in the treated groups and was 2% in the weight change of the earthworn's ranged control.

of the fest according to OECD guideline 207 were fulfilled. The validity criteria

a

Validity criteria (Off.CD 207, 1984)	Recommended	Obtained
Mortality of the adults in the control	≤ 10 %	0 %
Average loss of biomass in the control	$\leq 20 \%$	- 2 %

To verify the sensitivity of the test system, the reference item chloroacetamide was tested at concentrations of 5.6, 10, 18, 24 and 32 mg/kg soil d.w. The result of this positive control study gave a 14-day L(50 for 2-chloroacetamide of 23 mg/kg soil d.w.



## **III.** CONCLUSIONS:

Fluopicolide + propamocarb SC 687.5 (62.5 + 625) showed no effects on survival of the earthworm *Eisenia fetida* in artificial soil at the highest treatment at 1000 mg test item/kg soil d.w. The 14-day *QC*₅₀ for the test material to earthworms (Eisenia fetida) based on nominal test concentrations was 1000 mg/kg soil d.w. The No Observed Effect Concentration was 316 mg/kg soil d.w

## Assessment and conclusion by applicant:

The study is considered reliable. However, acute earthworm studies are no tonger a requirement, therefore, this study is not further considered in the risk account of the rest account of the risk account of requirement, therefore, this study is not further considered in the riskassessment.

### CP 10.4.1.1 Earthworms sub-lethal effec

The study is conside	red reliable. However, acute earthworm studies are no tonger a data this study is not further considered in the risk assessment.
requirement, therefore,	this study is not further considered in the riskowssessment.
	red reliable. However, acute earthworm studies are no honger a data this study is not further considered in the risk assessment.
Data Point:	KCP 10.4.1.1/01 A @ @ Q O O O O
Report Author:	
Report Year:	
Report Title:	Effects of ARB066752 04 SC61 Ad on reproduction and growth of earthworms Eisenia fetuda in applicial soil with 5 percent peac in the test substrate
Report No:	C03553-Q & & & & O & & ~
Document No:	<u>M-218629-04 1</u> 0 0 0
Guideline(s) followed in study:	BBA: V12-27, 1994, ISO: 11268 pair 2 (1998)
Deviations from current test guideline:	The number of replicates in the control was 4 instead of 8 as recommended by the guideline.
Previous evaluation	yes, examinated and accepted accepte
GLP/Officially recognised testing facilities:	Yes, conducted under GL2/Officially recognised testing facilities
Executive Summary	$Yes G \qquad G $

The purpose of this study was b investigate the effects of Ruopicolide + Propamocarb SC 687.5 on the mortality, body weight, feeding activity and reproduction of the earthworm Eisenia fetida. Adult earthworms (40 worms per treatment group and control) were exposed in artificial soil to the spraying rates of 2 10, 4.32, 10.8, 21.6 and 30.0 product/ha After 28 day, the number of surviving animals and their weight change was determined. After further 28 days, the number of off-spring was determined. Endpoints were mortality, growth and reproduction.

All validity criteria were met. During the 4 weeks of exposure, a slight mortality (2.5%) was observed among the control adult earthworms No dear adult earthworms were observed in any of the treated test groups. The Dody weights of adult worms in the treatment groups increased by 48.6% to 57.5% compared to 57.2% in the control. The reproduction ranged from 386 to 441 juvenile worms in the groups treated with test item 374 juvenile earthworms were found in the control. Weight changes and reproduction ones in the treatments were not significantly different compared to the control group.

No statistically significant effects (p < 0.05) were observed in mortality and reproduction of treated earthworks and hence the NOEL based on mortality (28 days) and the NOEL based on reproduction (56 dat) is 30 L product/ha.



## I. MATERIAL AND METHODS:

Test item: Infinito SC Fungicide (FLC+ PCH SC 687.5), Batch No.: OP220159, density 1.129 g/cm³, a fungicide SC type product containing Fluopicolide + Propamocarb-HCl (measured concentrations 4.7 g/kg + 634 g/L, respectively) as active ingredients.

240 adult earthworms *Eisenia fetida* (approximately 11 months old, 4 x 10 animals per test group) were exposed in an artificial soil by spray application at rates of 2.16, 4.32, 10.8, 21% and 30.0 L product/ha. After 28 days, the number of surviving animals and their weight change were determined. They were then removed from the artificial soil. After further 28 days the number of off-spring was determined.

The most recent reference test with Carbendazim (360 g a.s./L; trade name "Derosal \$2,360" was of performed from August to October 2002. The test onsured that the laboratory dest conditions were adequate and verified that the response of the test organisms did not charge significantly over time of the test organisms did not charge significantly over time of the test organisms did not charge significantly over time of the test organisms did not charge significantly over time of the test organisms did not charge significantly over time of the test organisms did not charge significantly over time of the test of test of the test of test o

## Dates of experimental work: May 06, 2003 6 July 2, 20

# II. RESULTS AND DISCUSSION

During the 4 weeks of exposure, a slight mortality (2.5%) was observed among the control adult earthworms. No dead adult earthworms were observed in any of the treated test groups

The body weights of adult worms in the treatment groups increased by 48.5% to 57.5% compared to 57.2% in the control. None of the weight changes was significantly different compared to the control group (Dunnett-test,  $\alpha = 0.05$ )

The reproduction ranged from 386 to 441 juvenile worms in the groups dreated with test item. The reproduction was not significantly different compared to the control group, where 374 juvenile worms were found (Dunnett test test  $\alpha = 0.05$ ).

The quantity of food added (which roughly reflects the amount of food eaten) was 25.0 in all the control and treatment groups.

Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of off-spring after \$6 days

		6 A			
	le fisenia	fetida 🦷 🗍			
Test substance		Infi	nito SC Fungic	eide	
Application rates C	⊘72.16	<b>A</b> .32	10.8	21.6	30.0
(L product/ha)		$\sim$			
Mortality of adults 🔍 🔊 🖉	S OF .	0	0	0	0
aft@28 days (%) 🖉 🖉					
Mean change of adult body +57,2	_↓ 56.	+52.2	+55.2	+57.5	+48.6
weights (%)					
Standard deviation 8.7	<u>+0</u> 3.5	<u>+</u> 7.7	<u>+</u> 6.8	<u>+</u> 6.8	<u>+</u> 9.6
Statistical comparison to	n.s.	n.s.	n.s.	n.s.	n.s.
the control*	· ·				
Number of off-spring per 374	<b>409</b>	386	390	441	410
group by	¥				
~~(56 days)					
Standar deviation + 44	<u>+</u> 53	<u>+</u> 46	<u>+</u> 18	<u>+</u> 27	<u>+</u> 19
Statistical comparison to	n.s.	n.s.	n.s.	n.s.	n.s.
the control*					

* Result of a Dunnett's multiple t-test, one sided smaller,  $\alpha = 0.05$ 

n.s.: mean value not statistically significantly different compared to the control ( $p \ge 0.05$ )



ò

O

The calculation of an ECx-curve was not possible due to the lack of a significant dose-response relationship.

Results of the most recent test with the reference substance (Carbendazim 360 g a.s./L): The ES for S reproduction was calculated as 1.9 mg carbendazim/kg dry soil. The reproduction rate was significantly reduced at the application rates of 1.6 mg a.s./kg dry substrate.

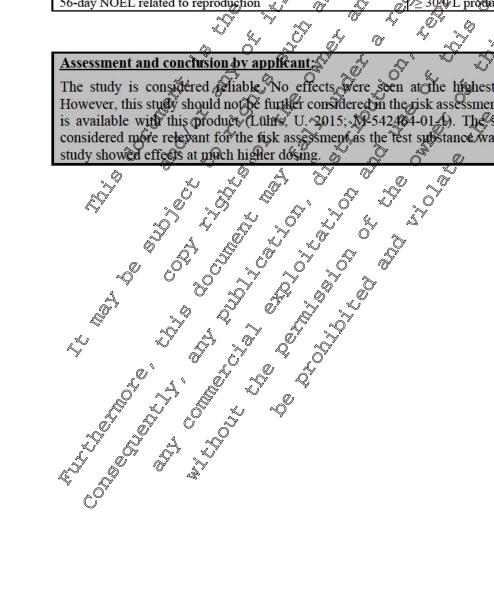
Validity criteria:	۵.	S x
Validity criteria (OECD 222, 2004)	Recommended	Obtained
Adult control mortality	$\leq 10\%$	5 % (after 4 week
Number of juveniles per control replicate	_ 230 ∽	374 (m@an)
Coefficient of variation of reproduction in the control	Q ≤ 30%	

# III. Concuision

Fungicid to the earthworm m Eisenia Under the conditions of the test, the chroppic toxicity of Infin fetida, is defined as follows:

	Ú	- X - X		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
28-day NOEL related to mortality	d growth	of adult	5	30.0	Oproduct ha
56-day NOEL related to reproduction					L product/ha
	9.				

The study is considered pliable. No effects were seen at the highest application rate tested. However, this study should not be further considered on the risk assessment as a higher dosed study is available with this product (Lührs, U. 2015; N-542464-01-1). The study of Lührs (2015) is considered more relevant for the risk assessment as the test substance was mixed into soil and the





KCP 10.4.1.1/02
2015
Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5+625) G: Effects of
reproduction and growth of earthworms Eisenia fetida in artificial soil
99761022
<u>M-542464-01-1</u>
OECD, Guideline for the testing of chemicals No. 222, Earthworm, Reproduction
Test (adopted April 13, 2004)
ISO-Guideline 11268-2, Soil quality - Effects of pollutants on earthworms? Part
2: Determination of effects on reproduction of Esenia fetida/Eisenia anorei,
International Organization for Standardization 2012
Current Guideline: OECD $22$ (2004)
No deviations
No, not previously submyred
Yes, conducted und GLP/Officially recognised testing facilities
Yes of the the second s

**Executive Summary** The purpose of this study was to investigate the offect of Fluppicolice + Propamocarb SC 687.5 on the mortality, body weight, feeding activity and reproduction of the earthworm Eisenbar fetida. Adult earthworms (40 worms per treatment group and 80 per control) were exposed in artificial soil to concentrations of 100, 1782316, 562 and 2000 pre product/kg dws mixed into soil Assessment of adult worm mortality, behavioural effects and biomass development was carried out other 28 days exposure of adult worms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application). All validity criteria were met. During the 4 weeks of exposure, no dead adult earthworms were observed in the treaments and in the control. The body weight changes and reproduction rates of the earth worms after 4 weeks of exposure were not statistically different compared to the control at all tested conceptrations. No behavioural abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control. The No Observed Effect Concentration (NOEC) for mortality, growth and reproduction of the earthworm Eisenia ferda was determined to be 1000 mg test item/kg soil and the LOEC was determined to be 1000 mg test tem/kg soil

# J. MAJERIAL AND METHODS:

Test material: Fluopicolide Propanocarb-hydrochloride SC 687.5 (62.5+625) G; batch ID: EM4L0@180; sample description: FAR01@1-00 specification no.: 102000027553; Fluopicolide (AE C638206, BCS-AM59797, 5.18% w/w, 68.14 g/L; Propamocarb hydrochloride (AE B066752, BCS-AV64527): 55.8% w/w 627.0 gA2, density: 1.023 g/mL.

Adult earthworks (Eisenia ferida, & 9 months old) were exposed to control, 100, 178, 316, 562 and 1000 mg Flugpicolide+ Propamočarb-hydrochloride SC 687.5 (62.5+625) G/kg soil.

Different concentrations of the test item were incorporated into the soil; 5 test item concentrations and one control were tested; 4 replicates for the test item treatments and 8 replicates for the control with 10 worms each. 🔗 A Xì

Assessment of adu@worm mortality, behavioural effects and biomass development was carried out after 28 days posure of adult worms in treated artificial soil. Reproduction rate (number of offspring) was assessed/after additional 28 days (assessed 56 days after application).

Test test conditions were, artificial soil according to OECD 222 (10% peat content); initial pH 5.8 to 6.1, pH at experimental end 6.1 to 6.4; water content 28.6% to 29.2% (54.0% to 55.1% of maximum



water holding capacity, WHC) at experimental start and 28.1% to 30.8% (53.0% to 58.2% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux.

The effects of the reference item were investigated in a separate study (Carbendazim 600 g/L SC (600 S g/L nominal)).

## Dates of work:

September 29 to November 25, 2015

## II. RESULTS AND DISCUSSION:

No mortality was observed in any treatment group.

The body weight changes of the earthworms after A weeks exposure to Fluopicolide + Propanocart hydrochloride SC 687.5 (62.5+625) G were not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg test item/kg will (Williams t-test,  $\alpha = 0.05$ , two-sided).

The reproduction rates were not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg test item test item test,  $\alpha = 0.05$  one-sided smaller).

No behavioural abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control.

Effect of Fluopicolide + Propanocarb-hydrochloride SC 687.5 (62,54625) Con earthworms (*Eisenia fetida*) in a 56-day reproduction study

Fluonicolide + Pronamocarb-	2 1000
hydrochloride SC 687 5 (62.5 625) G Control 100 178 316 562 [mg/kg soil dry weight] 562	1000
Mortality (day 28) $(3^{\circ})$ $(3^{\circ$	0
	-
Body weight change (they 28) [%] O (33.1 31 31 35.5 27.4	4 26.7
Statistical Significance ¹⁾	. n.s.
Mean No. of juveniles (dg/ 56) 248 261 261 209 255 229	215
Statistical Significance of the second secon	. n.s.
Reproduction in [%] of control (day \$6) - 7 405 405 384.2 103 92.1	2 86.5
S S S S S S S S S S S S S S S S S S S	
NOEC (day 28 mertality and weight)	
LOEC (day 28 mortal it) and weight) $\bigcirc$	
NOEC (day 50 reproduction 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
LOEC (dax 56 reproduction) >1000	

The results represent rounded values calculated on the exact raw data.

- = not applicable

n.s. 7 not significantly different compared to the control

¹⁾ Williams t-test,  $\alpha = 0.05$ , two-sided for weight enanges and one-sided smaller for reproduction

The calculation of an EQS curve was not possible due to the lack of a significant dose-response relationship.

## Reference tem Test:

In the most recent test with the reference item Carbendazim 600 g/L SC (performed under ibacon Study Number 105861022 from June to August 2015), there were statistically significant effects on reproduction at a concentration of 2.08 mg a.s./kg soil and higher, which is in line with the guideline OECD 222 (effects should be observed between 1 and 5 mg a.s./kg soil). The EC₅₀ for reproduction was



calculated as 1.91 mg a.s./kg soil.

Validity criteria:			^ ^
Validity criteria (OECD 222, 2004)	Recommended	Obtained	19 59
Control mortality	≤10%	0%	
Number of juveniles per replicate	≥ 30	173 to 311	× .~ ~
Coefficient of variation of reproduction	< 30%	17.3%	
	Ŭ,		

## **III. CONCLUSIONS:**

In an earthworm reproduction and growth study with Fluopicolide Propamocorb-hydrochloode Sc 687.5 (62,5+625) G the No Observed Effect Concentration (NOEC) for mortality, growth and reproduction of the earthworm Eisenia fetida was determined to be 1000 mg test item kg soil and, accordingly, the LOEC was determined to be \$1000 mg test item/kg soil, Ke. the highest concentration tested.

## Assessment and conclusion by applicant

≥1000 mg/to dws should be used in the @sk assessment The study is considered reliable. The NOEC for earthworms.

## Earthworms field studies, CP 10.4.1.2

In view of the results presented above, no field studie Ő

## Effects on non-target soil meso- and macrofaunt (other than CP 10.4.2 earthworms) Ô

The risk assessment calculation of TER values was based on the NOEC values calculated from the re used for the calculations of TER values. studies performed with the protect anothe metabolites. In case ECF values were lower than the NOEC

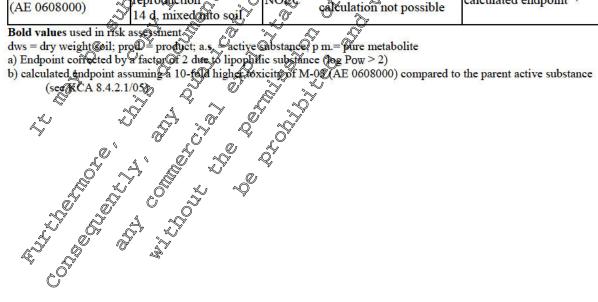
Ô

was based in mey were used for the catching the contract of the catching t



Test item	Test species, test design	Ecotoxicological endpoint	Reference 🖉 °
FLC + PCH SC 687.5	Folsomia candida reproduction 28 d, mixed into soil	NOEC ≥ 500 mg prod./kg dws ^{a)}	<u>2015: M-</u> <u>522-70-01-1</u> KCP 10.4.2.1/04
FLC + PCH SC 687.5	<i>Hypoaspis aculeifer</i> reproduction 14 d, mixed into soil	NOEC ≥ 500 mg prod./kg dws	2015 M- 521222-01-0 KCP 10.42.1/02
Fluopicolide	<i>Folsomia candida</i> reproduction 28 d, mixed into soil	NOEC $\sqrt{91.25}$ mg a.s./ $\sqrt{6}$ dws ^{a)} . EC ₁₀ $\sqrt{7}$ <b>16.44 mg a.s./kg dws</b> ^{a)}	$\frac{M-24\sqrt{194-00-1}}{K(2A 8.4.2.1/01} \bigcirc 0$ $\frac{2030}{M-2} \bigcirc 0$ $\frac{2030}{M-2} \bigcirc 0$
Fluopicolide	Hypoaspis aculeifer reproduction 14 d, mixed into soil	NOEC $\geq$ 500 mg a.Qkg dws ^(a) EC ₁₀ calculation not possible	Colf: M-54804C-01-1
M-01 (AE C653711)	Folsomia candida reproduction 28 d, mixed into soil	$\mathcal{O}$ EC $25 \text{ mg p.m./kg dws}$ EC $10 \sim 25 \text{ calculation not possible}$	2003: M 41195-01-1 KCA & 2.2.1/02
M-01 (AE C653711)	Hypoaspis aculeifer reproduction × 14 d, mixed into soil (	NOEC $5100 \text{ µmg p mQxg dws}$ $C_{10}$ calculation por possible	2045: M-538626-01-1 &CA 8.4.2.1/06
M-02 (AE C657188)	Folsonnia candida S reproduction 2841, mixed into Soil	NGEC <b>5/100 mg p m./kg dws</b> E0 10 Calculation not possible	<u>2016; M-</u> 555332-01-1 K A 8.4.2.1/04
M-02 (AE C657188)	Hypoaspis acheifer reproduction 14 d, mixed into soil	NOEC <b>300 mg/p.m./kg dws</b> EC76 valculation not possible	<u>2016; M-</u> <u>557987-01-1</u> KCA 8.4.2.1/07
M-03 (AE 0608000)	Folsom a candida reproduction 3 28 Amixed into soft	NOE > 50 mg pon./kg dws ^{a)} E calculation not possible	<u>2016; M-</u> <u>558337-01-1</u> KCA 8.4.2.1/03
M-03 (AE 0608000)	Bypoasperaculeifer reproduction 14 d. mixed for soil	NOFC ≥50 mg p m./kg dws ^{a) b)}	calculated endpoint ^{b)}

Table 10.4.2-1:	Endpoints used in risk assessment
-----------------	-----------------------------------





~

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

	ER calculations for the d macrofauna	product FLC + PCH S	C 687.5 for other	non-target :	soil meso-
Compound	Species	Endpoint [mg prod./kg]	PEC _{soil}		Trigger
Potatoes, 4 × 1.6 L pro	od./ha	\$	Z,		
FLC + PCH SC 687.5	Folsomia candida	NOEC 200	2.63	≥0190 _	5
FLC + PCH SC 687.5	Hypoaspis aculeifer	NOEC	2,635 *	≥ 1900°	558 \$
Potatoes, 3 × 1.6 L pro	od./ha			Å ,	
FLC + PCH SC 687.5	Folsomia candida	NOEC ≥ 500 g	2.2%6	219 %	5,~~
FLC + PCH SC 687.5	Hypoaspis aculeifer	NOEC_@ ≥ 500	\$1276 J J	$\geq 219$	45
Potatoes, 2 × 1.6 L pro	od./ha		1 5	Ö 🦉	
FLC + PCH SC 687.5	Folsomia candida	NQEC @2 5006	6917	≥26₩	53
FLC + PCH SC 687.5	Hypoaspis acuteder	©OEÇ.© ≥500 0	1.917	≥ <b>26</b> 1	5
Potatoes, 1 × 1.6 L pro	od./ha			ê v	
FLC + PCH SC 687.5	Folsomideandida	NOEC 2500	Q.958 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	$\geq$ 522	5
FLC + PCH SC 687.5	Hypoaspis deuleifer (	NOE 500 4	0.938	≥ 522	5
Lettuce, 2 × 1.6 L proc			N J C	, ,	
FLC + PCH SC 687.5	Folsopha canduda	ROEC 2500	1.43%	≥ 348	5
FLC + PCH SC 687	Hypoaspis of uleifer	NOEC 500	1,437	≥ 348	5
Lettuce, 1 × 1.6 Kprod			Ç ⁱ Z ^ç		·
FLC + PCH S0687.5	Folsonia candida 🧏	NOE	1.707	$\geq$ 278	5
FLC + PCH SC 687.5	Hypoaspis aculeiter	NOEC $\geq 50\%$	10797	≥278	5
			) )		<u>.                                    </u>

 K
 K
 K
 K

 FLC + PCH SC 687.5
 Folsonia candida
 NOEC
 500

 FLC + PCH SC 687.5
 Hapoaspisaculester
 NOEC
 500



Table 10.4.2- 3:	TER calculations for fluopicolide and its metabolites for other non-target soil meso-
	and macrofauna

Compound	Species	Endpoint [mg/kg]	PEC _{soil} [mg/kg]	TER _{LT}	Trieger
Potatoes, 4 × 1.6 L p	rod./ha		ð		
Fluopicolide	Folsomia candida	EC ₁₀ 16.44	0.192	85.63	5 5
Fluopicolide	Hypoaspis aculeifer	NOEC $\geq 500$	0.192	26040	B X
M-01 (AE C653711)	Folsomia candida	NOEC 25	0.042	585 2	5
M-01 (AE C653711)	Hypoaspis aculeifer	NOEC ≥100	9 <b>0</b> 42 ×	2381	5.47
M-02 (AE C657188)	Folsomia candida	NOEC A 100	0.007,° 5	14286	Ğ, Ö
M-02 (AE C657188)	Hypoaspis aculeifer	NOEC $\gg \geq 100$	0:907	14286 J	5
M-03 (AE 0608000)	Folsomia candida	NOE 30 x	0.030	1667	\$ ⁵
M-03 (AE 0608000)	Hypoaspis aculeifer	NOEC $\gg \geq 50^{\circ}$	0.030	1667	5
Potatoes, 3 × 1.6 L p	rod./ha				No.
Fluopicolide	Folsomia candida	EC.0 \$16.44	0.1620	98	5
Fluopicolide	Hypoaspis acutelfer	NOEC 2500	0,007	2994. V	5
M-01 (AE C653711)	Folsomia candida 🐇		0.036 ° ~~ ~~	694	5
M-01 (AE C653711)	Hypoaspits aculaifer	NOEC $\gtrsim \geq 100$ $\ll$	0.036	2778	5
M-02 (AE C657188)	Folsomia canaida	NOEC = 100	0007	14286	5
M-02 (AE C657188)	Hypoaspisaculeife		0.007	14286	5
M-03 (AE 0608000)	Folsomia canata	NOEC 2 ≥ 50	0.026	1923	5
M-03 (AE 0608000)	Hypoaspis aculeifer	NOEC \$ 50 a)	Ø.026 Ç	1923	5
Potatoes, 2 × 1.6 L p	r.ou./ha_O				
Fluopicolid	Folsomia candida 🔎	EC10 16.44	<b>§</b> 142	116	5
Fluopic	Hypoaspis aculeifer	NOEC 500 0	0.142	3521	5
M-01 (AE C653711)	Folsomija candida	\$DEC 254 254	0.031	806	5
M-01 (AE C653710)	Hypoaspis aculeifer	$NQEQ \geq 100$	0.031	3226	5
M-02 (AE C65 488)		$\frac{1000}{100} = 1000$	0.007	14286	5
M-02 (AE <u>G</u> 657188)	Hypoospis a leifer		0.007	14286	5
M-03 (AE 0608000)		NOT $\sim 50$	0.022	2273	5
	Hypocspis acuteifer	$\overset{\circ}{\operatorname{VOEC}} \overset{\circ}{\overset{\circ}} \overset{\circ}{\overset{\circ}} \overset{\circ}{\overset{\circ}} \geq 50^{\mathrm{a}}$	0.022	2273	5
Potatoes, 1× 1.6 L pi	rod./ha	* <u>0</u> .			
Fluopicolide	Polsoma candida	EC ₁₀ 16.44	0.071	232	5
Fluopicolide	Hyp@spis aculeifer	NOEC $\geq 500$	0.071	7042	5
M-01 (AC C653511)	Folsomia çandida	NOEC 25	0.016	1563	5
M-01 (AE C 3711)		NOEC $\geq 100$	0.016	6250	5
M-02 (AEC657188)	Folsomia candida	NOEC $\geq 100$	0.005	20000	5
M-02 (AE C657188)	Hypoaspis aculeifer	NOEC $\geq 100$	0.005	20000	5
M-03 (AE 0608000)	Folsomia candida	NOEC $\geq 50$	0.011	4545	5



Compound	Species	Endpoint [mg/kg]	PEC _{soil} [mg/kg]	TERLT	Trigger
M-03 (AE 0608000)	Hypoaspis aculeifer	NOEC $\geq 50^{a}$	0.011	4545	5 °
Lettuce, 2 × 1.6 L pr	od./ha				Nº ¢
Fluopicolide	Folsomia candida	EC ₁₀ 16.44	0.107	154	5 0
Fluopicolide	Hypoaspis aculeifer	NOEC $\geq 500$	0.107	4673	5
M-01 (AE C653711)	Folsomia candida	NOEC 25	0.023	1087	
M-01 (AE C653711)	Hypoaspis aculeifer		0.03	<b>Å</b> 348 S	5
M-02 (AE C657188)	Folsomia candida	NOEC	0,005	20000	50
M-02 (AE C657188)	Hypoaspis aculeifer	NOEC 2 100	0.00 2	20000	5
M-03 (AE 0608000)	Folsomia candida	NOEC ≥50 5	0.016 0 2	3125	5,5
M-03 (AE 0608000)	Hypoaspis aculeifer		0.016 0	3125	<u>15</u> °
Lettuce, 1 × 1.6 L pr	od./ha		A. 8 .	, <del>(</del>	
Fluopicolide	Folsomia candida	EC10 2 10.44	<b>O</b> .134	123	Ň
Fluopicolide	Hypoaspis aculeifer	NQEC $\sim 2500^{\circ}$	0.133	3531 0	
M-01 (AE C653711)	Folsomia canalda	NOEC 25 S	0.029	862 🥎	5
M-01 (AE C653711)	Hypoaspisaculeifer		90.029	3448	5
M-02 (AE C657188)	Folsomia candida	NOEC $2^{4} \geq 100$	0,000 .	J0000	5
M-02 (AE C657188)	Hypodspis aculeifer	NOE	0.010	10000	5
M-03 (AE 0608000)	Folsomic Fandida	NOEC $\sim 250^{\circ}$ $\sim$	0.024	2381	5
M-03 (AE 0608000)	Hypodspis activiter		P.021	2381	5

a) calculated endpoint for *Hopoaspis aculeife* assuming a 10-fold higher toxicity compared to the parent active substance

A Hypoaspis aculetter reproduction study is not available for the metabolite M-03 (AE 0608000). However, the toxicity of the parent active orbstance fluopicolide and of all other metabolites to Hypoaspis aculeifer is very low. Even if a 10-fold higher toxicity compared to the parent active substance would be assumed, the tier 1 rist assessment would still indicate a low risk to soil mites with a high margin of safety (TER  $\ge$  1667). Mence, no unacceptable risk can be concluded for the metabolite M-03 (AE 0608060) in the risk assessment for soil mites.

M-03 has been observed only in soil matrices where it can exceed 5% AR in acidic soils dosed with parent. The metabolite is cadily degraded in acidic soils and very rapidly degraded in soils at neutral or slightly alkaline soil pH. No information on the composition of possible enantiomers of M 03 formed in soil of their individual transformation or interconversion is available. M-03 has not been observed as a metabolite in plant, animation water matrices.

Ecotoxicological studies for M-03 are available with the soil organisms *Eisenia fetida* and *Folsomia candida*, and on microbial nervogen transformation. No effects on survival and reproduction were seen for *E. fetida* and *F. candida* by to 100 mg/kg, the highest concentration tested. For *Hypoaspis aculeifer* no ecotoxicological stud with M-03 is available. However, an endpoint is extrapolated from the study with the parent active substance assuming 10-fold higher toxicity compared to the parent active substance (see above paragraph). Endpoints are corrected by a factor of 2 as the Log P for M-03 is > 2. The process of microbial nitrogen transformation was not adversely impacted up to 2.78 mg/kg (effects on nitrate formation rate < 25%), the highest concentration tested.

Information is not available on whether a specific stereoisomer of M-03 is enriched in the ecotoxicological studies listed above and/or whether the ecotoxicity properties of M-03 stereoisomers are comparable. For this case EFSA (2019) proposes an uncertainty factor is used in the ecotoxicological



Ò

risk assessment. For two isomers the EFSA guidance document (EFSA, 2019) advises the No Observed Effects Concentration (NOEC) can be divided by 2 provided the TER is exceeded. Considering an additional safety factor of 2 the risk assessment would still indicate no unacceptable risk for oil organisms. The risk assessment shows a high margin of safety.

# Table 10.4.2- 4:Applying an additional safety factor = 2 on ecotoxicological ordpoints to account for<br/>remaining uncertainty with regard to potential isomerization of M-03 (AC 0608000)

Ecotoxicological end	point ^b	O PECsoil	TER	Critical trigger
E. fetida	NOEC _{corr} $\geq$ 25 mg/kg ^{a, b} (with uncertainty factor)	0.030 mg/kgQ	≥833.3 @	
F. candida	NOEC _{corr} $\geq$ 25 mg/kg ^{a, b} (with uncertainty factor)	0.030 mg/kg	°≥83 <b>3</b> 3	
H. aculeifer	NOEC _{corr} = 25 mg/kg * $\frac{1}{2}$ (with uncertainty factor)	() 408	*3833.3 O	
N-transformation	Effects < 25% at 1.30 mg/kg@ (with uncertainty factor)	©0.030 mg/kg	≥ <b>46</b> .3	

* NOEC extrapolated from Hypoaspis aculeifor reproduction study with the active substance (NOEC  $\geq$  000 mc a.s./kg), assuming 10x higher toxicity of M-03 compared to the parent active substance a As LogP for M-03 is >2 the ecotoxicological endpoints for *E. fetida* and *P. candido* are divided by a correction factor of 2 (NOEC_{corr.} = NOEC corrected) ^b Endpoint corrected by an additional safety factor of 2 to accound for uncertainty with regard to obtential isomerization of M-03 (EFSA, 2019)

No unacceptable risk to soil organisms is concluded from enanthemers of M-03 forming from fluopicolide.

All TER values clearly exceed the frigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms aro to be expected from the intended use of FLC + PCH SC 687.5 in potatoes, lettuce and cucumber.

 $\bigcirc$ 

Ø

	ion in the second se	Ares level testing
CP 10.4	2.1 Spe	fies level testing $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$
* 7	$\sim$	ies level testing
	J.	
Data Poir		KCP10.429/01 ~ ~ ~
Report A	uthor c	
Report Y		
Report T	ifter.	Fluoprolide F propunocarts hydrochloride SC 687.5 (62.5+625) G: Effects on
- A		reproduction of the Collembola Folsomia candida in artificial soil with 5 percent
K)	× 1 ⁻	
Report N		\$99761016 Q S
Documer		<u>M-522170-01-1</u>
	e(s) fallowed in	GCP compliant study based on OECD 232, 2009 and ISO 11267, 1999
study:	<u></u>	
Deviation	notion current	Current Guiderine: OECD 232 (2016)
	SPILIE. W/	Nogeviations
Previous	evaluation:	No, not previously submitted
	<u>_0``~~``~``</u>	×
G&P/Off	cually	Yes, conducted under GLP/Officially recognised testing facilities
recognice		
facilities:		
Acceptab	oility/Reliability:	Yes



## **Executive Summary**

The purpose of the study was to determine the effects of Fluopicolide + Propamocarb-HCl SC 687.5 (62,5 + 625) G on mortality and reproduction of the Collembola *Folsomia candida* in artificial soil (0 collembolans (approximately 9 - 11 days) per replicate were exposed to control (8 replicates) and treatments (4 replicates) with concentrations of 18, 32, 56, 100, 178, 316, 562 and 1000 mg Fluopicolide + Propamocarb-HCl SC 687.5/kg dry weight soil. The different concentrations of the test men were mixed homogeneously into the soil which was placed into glass vessels before the colleptibolar were introduced on top of the soil. Assessment of adult mortality, behavioural effects and reproduction was performed after 28 days. All validity criteria were met. A mortality of up to 10% was observed in the test item treated groups, which was not statistically significantly different compared to the control at any test concentration. No behavioural abnormalities were observed in any of the treatment groups. Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be 2 1000 mg test item/kg soil.

# MATERIAL AND METHODS

Test item: Fluopicolide + Propamocarb-HCl SC 687.5 (62,5+625) G batch D: ENALO14180; sample description: FAR01771-00; specification no.: 102000027552; Fluopicolide (AE 638206): 5.18% w/w, 58.14 g/L; Propamocarb-HCk (AE 8066752): 55.8% w/w, 627.0 g/L, deasity: 1.123 g/nL.

Ten collembolans per replicate (8 control replicates and 4 replicates for each application rate) were exposed to control (untreated) and treatments. The collembolans were of a uniform age (approximately 9-11 days). Concentrations of 98, 32, 96, 100, 178, 916, 562 and 5000 mg Fluopicolide + Propamocarb-HCl SC 687.5 (62,5,2625) G/kg dt weight soil were tested.

The different concentrations of the test item were mixed homogeneously into the soil which was placed into glass vessely before the collembolan were introduced on top of the soil. The collembolans were fed with approximately 2 mg dry yeast for each test vessel at the beginning of the test and on day 14. Assessment of adult mortality, behavioural effects and reproduction was performed after 28 days.

Test conditions: Artificial soft according to OECP 232, pH at experimental start 5.7 to 5.8, pH at experimental end 5.8 to 6.0° water content at experimental start 21.5% to 22.0% (51.2% to 52.4% of the maximum water holding capacity); at experimental end 18.6% to 21.6% (44.3% to 51.3% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark flight intensity within the range of 400 to 800 lux. After a period of 14 days, the surviving adults and the number living juveriles were detected.

Boric acide was applied as positive comool. The effects of the reference item are investigated in a separate study.

# Dates of experimental work: March 16, 2019 to April 27, 2015

## II. Results and Discussion:

A mortality of up to 10% was observed in one of the test item treated groups, which was not statistically significantly different compared to the control, where 11% of the collembolans died (Fisher's Exact test,  $\alpha = 0.05$ , one-sided greater). The reproduction of the collembolan exposed to Fluopicolide + Propamocarb-HCl SC 687.5 (62,5+625) G was not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg test item/kg soil (Williams t-test,  $\alpha = 0.05$ , one-sided smaller). No behavioural abnormalities were observed in any of the treatment groups. In a separate study (study code 61406016) the reference item Boric acid showed statistically



_ب ب

ð

significant effects on reproduction at concentrations of  $\geq$  48.8 mg/kg soil; the EC₅₀ for reproduction was calculated to be 145.1 mg/kg soil.

Effect of Fluopicolide + Propamocarb-HCl SC 687.5 (62.5+625) G on Colle	mbola ( <i>Folsomi</i>	a candida) in a
28-day reproduction study	ð	

						Ģ	1	L	
Fluopicolide + Propamocarb- HCl SC 687.5 (62.5+625) G [mg/kg soil dry weight]	Control	18	32	56 ර්ර	100	A78	316	0 <b>562</b> 2	\$1000 5
Mortality (day 28) [%]	11	8	0	0	5%	5	× KO	200	
Statistical significance1	( <del></del> )	n.s.	A.S.	n.s.	Qn.s.	on.s.	O _{n.s.}	n.s. Ö	n.s.Ø
No. of juveniles (day 14)	729	734 🗸	819	791	782	762	929	825	192
Reproduction in [%] of control (day 14)	-	101	12/2	209	2107 a	~105 /		113	99 &
Statistical significance ²	- *	n.s, *	n.s.	n.s	n.s.	no	n.s.	ns.	Q.S.
			Endp	oints [m	g/kg soil	dry wei	ght]	ÿ Ő	)
NOEC		Ø.	× *		≥1008 [°]		ght]	L.	
LOEC		<i>S</i>	ţ,	, B	>1000	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Ĩ~∕	

n.s. = not statistically significantly different compared to the control

¹ Fisher's Exact Test,  $\alpha = 0.05$ , one-sided greater  $\bigcirc$ 

² Williams t-test,  $\alpha = 0.05$ , one-coded smaller

- not applicable

The calculation of an ECx-curve was not possible due to the lack of a significant dose-response relationship.

Validity centeria (OECD 232, 2096)	Achieved
Control Mortality	11 %
Control Reproduction (Juveniles per Contriner) $\phi$ $\circ$ $> 50$	402 to 918
Coefficient of Variation of the Control Reproduction - 30%	23.2 %

Fluopicolide + Propanocarb-HCl'SC 6875 (62, 9625) G caused no statistically significant effects on mortality and reproduction of *Folsomia Candid* up to and including the concentration of 1000 mg test item/kg soil. Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be

item/kg soil. Therefore, the overall № Observed Effect Concentration (NOEC) was determined to be ≥1000 mg test them/kg soil. The overall Lowest Observed Effect Concentration (LOEC) was determined to be greatec than 1000 mg test item/kg soil.

## Assessment and conclusion by applicant:

The study is considered reliable. The NOEC  $\geq$  1000 mg/kg dws should be used in the risk assessment for *Folsomia candida*.



Data Point:	KCP 10.4.2.1/02	
Report Author:		
Report Year:	2015	
Report Title:	Fluopicolide + propamocarb-hydrochloride SC 687.5 (62.5+625) G: Effects of reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5percent peat	Ŏ,
Report No:	99761089	
Document No:	M-521222-01-1	
Guideline(s) followed in	OECD 226 (2008)	
study:	$G \qquad \mathcal{A} \qquad \mathcal{A} \qquad \mathcal{A} \qquad \mathcal{A}$	a
Deviations from current test guideline:	Current Guideline: OECD 226 (2016) No deviations	Ś
Previous evaluation:	No, not previously submitted	
GLP/Officially	Yes, conducted under GEP/Officially recognised testing facilities	
recognised testing		
facilities:		
Acceptability/Reliability:	Yes $A$ $\phi$ $Q$ $Q$ $\phi$ $O'$ $\phi'$ $\phi'$	
Executive Summary		

## Executive Summary

Ê.

The purpose of the study was to determine the effects of Fluopicolide 4 Propamocarb-HCFSC 687.5 (62.5+625) G on mortality and reproduction of the predatory of the *Hypoaspia aculeifer* tested during an exposure of 14 days in artificial soil comparing control and treatment. Ten adults, fettilized, female *Hypoaspis aculeifer* per replicate (8 control and 4 replicates for each application rate) were exposed to control (8 replicates) and treatments (4 replicates). Concentrations of 98, 32, 36, 100, 178, 316, 562 and 1000 mg a.s./dry weight soil were tested. The test item was mixed into soil. After a period of 14 days, the surviving adults and the living juveniles were detected All *Hypoaspis aculeifer* were counted under a binocular. All valuative criteria were met. Fluopicolide + Propamocarb-HCI SC 687.5 (62,5+625) G caused no statistically significant effects on mortality or reproduction of *Hypoaspis aculeifer* up to and including the concentration of 1000 mg test item/kg soil. The overall No Observed Effect Concentration (LQEC) was estimated to be greater than 1000 mg test item/kg soil.

A. MATERIAL/AND/METHODS:

Test item: Fluoppoolide A Propanocarb-HCLSC 687.5 (62,54-625) G; batch ID: EM4L011180; sample description: FAR01775-00; specification no. 102000027553; Fluopicolide (AE C638206): 5.18% w/w, 58.14 g/L; Propamocarb-HOI (AE B066752): 55,8% w/w 627.0 g/L.

Ten adults fertilized, female *Hypoaspis acule fer* per replicate (8 control replicates and 4 replicates for each application rate) were exposed to control (water treated) and treatments. Concentrations of 18, 32 56, 100, 178, 316, 562, 1000, mg test itentikg dry weight soil were tested. The test item was mixed into soil. The *Hypoaspis acule fer* were of a uniform age (approximately 14 days after reaching the adult stage, 35 days after placing the adult females in clean rearing vessels). They were fed with cheese mites (*Tyrophagus Outrescentiae) ad libitum* at jest start and on day 2, 4, 7, 9, and 11.

Test Conditions: attificial soil based on ØECD 226; initial pH 6.1 to 6.5, pH at experimental end 5.8 to 5.9; water content at experimental start 19.6% to 22.0% (47% to 53% of the maximum water holding capacity); at experimental end 20.5% to 21.9% (49% to 52% of the maximum water holding capacity); temperature within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark (within the range of 400 to 809 lux).

After a period of 14 days, the surviving adults and the number living juveniles were detected.

Perfekthion (a.s. dimethoate, 400.0 g/L, nominal) was applied as positive control. The effects of the reference item are investigated at least once a year in a separate study.



Ů

Dates of experimental work: March 16, 2015 to April 01, 2015

## **II. RESULTS AND DISCUSSION:**

LISC ST. Control of the second state of the s A slight mortality of up to 7.5% was observed in one of the test item treated groups, whick was not statistically significantly different compared to the control, where 5% of the adult mites died (Fisher's The reference item dimethoate showed statistically significant effects on reproduction at a concentration of 4.5 mg dimethoate/kg soil and above. The EC so for eproduction was 5.5 mg dimethoate/kg soil.



Effect of Fluopicolide + Propamocarb-HCl SC 687.5 (62.5+625) G on the Predatory Mite Hypoaspis aculeifer in a 14-day reproduction study

Fluopicolide + Propamocarb- HCl SC 687.5 (62.5+625) G [mg/kg soil dry weight]	Control	18	32	56	100	178	316	562 5000 5
Mortality (day 14) [%]	5.0	2.5	2.5	5.0	2.5	7.5	2.5	5.0 . 25
Statistical significance ¹	14.0	n.s.	n.s.	n.s.	n.s.	Thes.	n.s. 🗞	On.s. On.s.
No. of juveniles (day 14)	239	230	236	²⁵⁰	224	223	237	253 265
Reproduction in [%] of control (day 14)	<b>1</b> 30	96.5	9858	104.6	<b>94.1</b>	93.4 °	399.2	Q05.9 998.7 4
Statistical significance ²	1.70	n.s. 🗶		n.s.	n.s.Ø		n so	ILS. ICS.
Endpoints [mg/kg soil dry weight]								
NOEC		A.	Å,	0 A	21000		Ő	
LOEC	, second se			Ô	> 1000		No.	

n.s. = not statistically significantly different compared to the control

r isher's Exact Test, α = 0.05, one-sided greater
 ² Williams t-test, α = 0.05, one-sided smatter
 - not applicable
 The calculation of an ECx-curve was not possible due to the block of a significant dose-response relationship.
 Validity criteria:

Control Mortality $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ Control Reproduction (Juvennies per Container) $5^{\circ}$ $5^{\circ}$ $5^{\circ}$ $5^{\circ}$	Archieved
Control Reproduction (Juvennies per Container) $\gamma$ ( $\gamma \ge 50$	5 %
	195 to 278
Coefficient of Variation of the Control Reproduction: $\bigcirc \bigcirc \le 30\%$	13.0 %

MI. CONCLUSIONS:

Fluopicolate + Propamocarb-HCl SC 87.5 (62.5+625) G caused no statistically significant effects on mortality or reproduction of Hypothespis active ifer up to and including the concentration of 1000 mg test item kg soil. Therefore, the overal No observed Effect Concentration (NOEC) was determined to be  $\geq$ 1000 mg test item/kg soil. The overall Lowest Observed Effect Concentration (LOEC) was estimated to be greater than 1000 mg test frem/kg soil.

## Assessment and conclusion by applicant:

The study is considered reliable. The NOEC ≥1000 mg/kg dws should be used in the risk assessment Hypo@spis achleifer

## CP 10.4.2.2 Higher tier testing

In view of the results presented in Section CP 10.4.2, no further testing is necessary.



CP 10.5 E	ffects on soil	nitrogen transformation	Reference 2
Table 10.5-1: Endp	oints used in ris	k assessment	
Test item	Test design	Endpoint	Reference
FLC + PCH SC 687.5	Study duration: 28 days	No unacceptable effects at an appl. 241 mg prod./kg/dws rate of:	200327/1-218267-0167 KC@ 10.5 82
Fluopicolide	Study duration: 28 days	No unacceptable effects at an approx 1.77 mg a.s. kg days rate of:	2003:44-230023-01-1 KC48.5/012
M-01 (AE C653711)	Study duration: 28 days	No unacceptable $0.92$ mg p $1.1$ kg d $0.92$ mg p $1.1$ kg d $0.92$ kg $2$	2004; <u>1-235991-01-1</u>
M-01 (AE C653711)	Study duration:	rate of: No unacceptable effects at an appl rate of no unacceptable effects at an appl of no unacceptable effects at an appl No unacceptable	<u>1956; M-2≩4312-01-1</u> √SCA &5/02
M-02 (AE C657188)	Study duration: 28 days	No unsceeptable effects at an oppl. <b>0.89 mg p.m. kg dws</b>	<u>2016; M-</u> <u>557010-01-1</u> KCA 8.5/07
M-03 (AE 0608000)	Study doration; 28 days		<u>2016; M-</u> <u>555852-01-1</u> KCA 8.5/06
Bold values: endpoints us dws = dry weight soft, pro	ed for risk assessm of product, a.s.	ent active substance; p m. = pure metholite	
		effects, at an appl. 2,78 mg p.m./kg flws rate of: ent active substance: p m = pure met bolite	



## **Risk assessment for Soil Nitrogen Transformation**

Compound	Species	Endpoint [mg prod./kg]	PECsoil, max	Refinement required
Potatoes, 4 × 1.6 L prod./ha			2	
FLC + PCH SC 687.5	Soil micro-organisms	24.1	2.635	No No
Potatoes, 3 × 1.6 L prod./ha		- The second sec	Q Q	
FLC + PCH SC 687.5	Soil micro-organisms	24.1	2.276	No O
Potatoes, 2 × 1.6 L prod./ha			R Q .C	
FLC + PCH SC 687.5	Soil micro-organisms	24.1 5	J.917 0 D	No 25
Potatoes, 1 × 1.6 L prod./ha				S A d.º
FLC + PCH SC 687.5	Soil micro-organisms	241	Ø.958 5 ×	No & Q
Lettuce, 2 × 1.6 L prod./ha				L. O
FLC + PCH SC 687.5	Soji micro-organisms	2425 ~	1,497 5	No ©
Lettuce, 1 × 1.6 L prod./ha				`~\ ^\
FLC + PCH SC 687.5	Soil micro-organismo	24.15	1.797	No

Table 10.5- 3: Risk Assessment for fluopie lide and its metabolites for soil micro-organisms

				1
Compound	Species 5	Endpoint	PDC soil, max	Refinement
		mg/kg	[mg/kg]	required
Potatoes, 4 × 1.6 🗘 prod ha 🕺				
Fluopicolide	Soft micro-organisms	1.07 5	@192	No
M-01 (AE C653711)	Soil mero-organisms		0.042	No
M-02 (AE C657188)	Soil micto-organisms	\$\$.89 Å	0.007	No
M-03 (AE 0608000)	Soil micro-organisms	2.785	0.030	No
Potatoes, 3 × 1.6 L prod./ha				
Fluopicolide	Soil micro-etganisms	1.77	0.167	No
M-01 (AE4C653711)	Soil mic -organisms	0.92	0.036	No
M-02 (AE C657188)	Soil micro organisms	1.89	0.007	No
M-03 (AE 0608000)	Soil moro-organisms	2.78	0.026	No
Potatoes 2 × 1 & L prod./ha				
Fluggicolide of in	Soil micro-organisms	1.77	0.142	No
M-01 (AE C©3711)	Soil micro-organisms	0.92	0.031	No
M-02 (AE C657188)	Soil micro-organisms	1.89	0.007	No



Compound	Species	Endpoint [mg/kg]	PECsoil, max [mg/kg]	Refinement required
M-03 (AE 0608000)	Soil micro-organisms	2.78	0.022	No 🖉
Potatoes, 1 × 1.6 L prod./ha			ð	
Fluopicolide	Soil micro-organisms	1.77	0.071	No ~ ~
M-01 (AE C653711)	Soil micro-organisms	0.92	0.016	
M-02 (AE C657188)	Soil micro-organisms	1.89	0005 ×	No S S
M-03 (AE 0608000)	Soil micro-organisms	2.78		No v v
Lettuce 2 × 1.6 L prod. /ha	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		NY W N	
Fluopicolide	Soil micro-organisms	1.77		No A .
M-01 (AE C653711)	Soil micro organisms	¢.92	0-023 0 ⁵⁷ 4	No S
M-02 (AE C657188)	Soil nicro organisms	1.890	0.005	ØNO ØNO
M-03 (AE 0608000)	Soil micro-organisms	0.78	9.016	No ^y
Lettuce, 1 × 1.6 L prod./ha 🔩				¢″
Fluopicolide		1.77	134 Jan 134	) No
M-01 (AE C653711)	Soil@nicro-ocganistos	0.920 %	0.029	No
M-02 (AE C657188)	Soil moro-organisms	\$.89 \$.89	0.010	No
M-03 (AE 0608000)	Sol micro-brganisms		0.021	No
			Ø	

According to regulatory requirements, the risk is acceptable if the effect on nitrogen transformation at the maximum PEC, values is < 25% after 28 days (latest 100 days). In no case, deviations from the control exceeded 25% at concentrations whickare clearly higher than the PECs in soil, indicating low risk to soil micro organisms.



Data Point:	KCP 10.5/01	
Report Author:		
Report Year:	2003	
Report Title:	AE C638206 & propamocarb SC 62.5 + 625 (AE B066752 04 SC61 A1):	Ş
	Determination of effects on carbon transformation in soil	Y
Report No:	C035158	
Document No:	<u>M-218265-01-1</u>	
Guideline(s) followed in	OECD 217 (2000)	
study:		V
Deviations from current	Current Guideline: OECD 217 (2009)	$\cap$
test guideline:	Not evaluated	Ľ
Previous evaluation:	yes, evaluated and accepted $\mathcal{A}$ $\mathcal{O}^{\vee}$ $\mathcal{A}^{\vee}$ $\mathcal{O}^{\vee}$	),
	In the DAR (2005)	
GLP/Officially	Yes, conducted under GL Officially recognised festing facilities	
recognised testing		
facilities:		
Acceptability/Reliability:	Yes O' d' a a a	

## **Executive Summary**

The purpose of this study was to determine the effects of Fulopic filde + proparticarby C 687.5 on the activity of soil microflora with regard to carbon transformation in a laboratory test. A filty sand soil was exposed for 30 d to concentrations of 2.13 and 21.33  $\mu$ D Fluopicolide + Proparticarb SC 687.5/kg soil. This is equivalent to a concentration of 2.41 mg product/kg and 24.1 mg product/kg dry weight soil, respectively, considering a product density of 1.129 g/mL. Glucose was added to the soil samples to induce maximum respiration rate (3 g/kg dry weight/soil). No adverse effects of Fluopicolide + Proparticarb SC 687.5 on carbon transformation in soil were observed at both test concentrations (2.41 mg test item/kg dry weight soil and 24.1 mg test item/kg dry weight soil) and 0.43% (test concentration 24.1 mg test item/kg dry weight soil) and 0.43% (test concentration 24.1 mg test item/kg dry weight soil) and 0.43% (test concentration 24.1 mg test item/kg dry weight soil) and 0.43% (test concentration 24.1 mg test item/kg dry weight soil) and 0.43% (test concentration 24.1 mg test item/kg dry weight soil) are measured at the end of the 28-day incubation period. Fluopicolide + Propamocarb SC 687.5 caused no adverse effects deviation from control < 25%, OECD 217) on the soil carbon transformation in the end of the 28-day incubation period. Fluopicolide + application rates up to 164 test form/ha.

# 4. Morerial And Methods:

Test item: Fluopicolide Propanocarl SC 687.5 (62.5 + 625), Short name: FLC + PCH SC 687.5 (62.5 + 625) (Code AE B666752 04 SC61 AL development No.: 3000312153, batch No.: OP220159, analysed computer of a.s.: 667 g/L fluopicolide and 634 g/L propamocarb, density 1.129 g/mL. A silty sand soil was exposed for 30 d to concentrations of 2.41 and 24.1 mg Fluopicolide + Propamocarb

A silty sand soil was exposed for 30 d to concentration for 2.41 and 24.1 mg Fluopicolide + Propamocarb SC 687.5 (application rates were equivalent to 1.6 and 16.0 L Fluopicolide + Propamocarb SC 687.5), which is equivalent to 1 × and 10 × recommended field rate, respectively.

Glucose was added to the soil samples to induce maximum respiration rate (3 g/kg dry weight soil).

Dates of work: #ebruary 25 2003 March 7, 2003

UI. RESULTS AND DISCUSSION:

No adverse effects of Fluopicolide + Propamocarb SC 687.5 on carbon transformation in soil were observed at both test concentrations (2.13 mg test item/kg dry weight soil and 21.33 mg test item/kg soil dry weight soil) after 28 days. Differences from the control of 10.54% (test concentration 2.41 mg test item/kg dry weight soil) and -0.43% (test concentration 24.1 mg test item/kg dry weight soil) were measured at the end of the 28 day incubation period.



Sampling	Control	2.41 mg test item/kg dws equiv. to 1.6 L test item/ha		24.1 mg test item/kg soil dws equiv. to 16 L test item/ha		
date	[mg CO2 / hour / kg dws]	[mg CO2 / hour / kg dws]	% difference to control [#]	[mg CO ₂ / hour / kg dws]	% difference • to control	
0	216.03	186.63*	13.61	195.52	9.49	
8	221.54	193.73	12.55	199.92	9.76	
14	215.56	190.02	11.85	193.17	10,39	
28	151.02	135.11	10.54	151.68	Q43 6 x	

* Significant difference between treated and untreated soil samples (t- 🕼 with 5% probability of error) # Exact Values not given in study report; calculated on the basis of the mg CO₂/hour kg dws values given in the table

dws = dry weight soil

Ó In a separate study the reference item sodium chloride was used as a reference standard. In tests (pon-GLP) with the agricultural soil described above, 16 g NaCl/kg dry weight soil had distinct and longterm (> 28 days) influences on microbial mineralization of carbon.

Validity criteria:

The validity criteria of the test according to OECD suideline 7 were fulfill 6

### Recommended Obtained Validity criteria (OECD 217, 2000)

Ô

Coefficients of variation in the control 3.5 %00 15 % ¢,

Fluopicolide + Propano carb & 68% caused no averse effects deviation from control < 25 %, OECD 217) on the soil carbon transformation at the end of the 28-day incubation period. The study was performed in a field soft at concentrations up to 29.1 mg test rem/kg soil dry weight, which are

W

O

The study is considered reliable. However, capon transformation studies are no longer a data requirement, therefore, this study is not further considered in the risk assessment.



KCP 10.5/02
2003
AE C638206 & propamocarb SC 62.5 + 625 (AE B066752 04 SC61 A1):
Determination of effects on nitrogen transformation in soil
C035160
<u>M-218267-01-1</u>
OECD 216 (2000)
Current Guideline: OECD 216 (2009)
Sampling interval was 0, 8, 14 and 28 days instead of 0, 7, 14 and 28 days as $\sqrt{2}$
recommended by the guideline. This deviation not expected to have impacted a state of the state
the study results.
yes, evaluated and accepted in the second seco
In the DAR (2005)
for Propamocarb in RAR June 2017 5 5 4 4 5 5 5
Yes, conducted under GLP/Officially recognised testing fagilities
Yes $\partial \gamma$ $\gamma$ $\partial \gamma$ $\gamma$ $\gamma$ $\gamma$ $\beta$
· · · · · ·

## **Executive Summary**

The purpose of this study was to determine the effect of FIG+ PCH SC 687,5 or the activity of soil microflora with regard to nitrogen transformation in a laboratory test. A silty said soil was exposed for 28 days to concentrations of 2.43 and 21.33 pL Infinito SC Fungiolde/kg dry weight soil. Each treatment consisted of 3 replicates. Application rates were equivalent to 1.6 and 16.0 L Infinite SC Fungicide/ha, which is equivalent to 1x and 10x maximum field rate, respectively. The nitrogen transformation was determined in soil enriched with luceme meal. NHOnitrogen, NOV and NO₂-nitrogen were determined by an autoanalyzer at different sampling intervals (0, & 14 and 28 days after treatment). A reference item is not required by the guideline. Nevertheless, softum chloride was used as a reference. During the 28-day experiment, the maximum field rate of Infinito SC Fungicide (1, 6 L/ha) and 10-fold this field rate of Infinito SC (21,33  $\mu$ L/kg dry weigh Soil = 24.1 ing/kg dry weight soil) had no influence on the microbial mineralization of nitrogen to a silty said amended with lucerne-grass-green meal.

# I. MATERIAL OND METHODS:

Test item: Infinito SC Fungicide (AE B066752 04 SC61 Ål, FLC+ PCH SC 687,5), Batch No.: OP220159, density 1.129, g/cm, a fungicide SC type product containing fluopicolide + propamocarb-HCl (measure@conce@rations 64.7 g/kg + 634 g/D respectively) as active ingredients.

A silty sand soil was exposed for 28 days to concentrations of 2.41 and 24.1 mg Infinito SC Fungicide/kg dry weight soil (application rates were equivalent to 1.6 and 16.0 L Infinito SC Fungicide/ha, which is equivalent to 1x and 10x maximum field rate, respectively).

Lucerne-grass-green meal is g/kg/dry weight soil) was added to soil samples to stimulate nitrogen transformation.

## Dates of experimental work: February 25, 2003 to March 25, 2003

II. RESULTS AND DISCUSSION:

The finding care presented in the following table.



## Effects on non-target soil micro-organisms

Test substance	Infinito SC Fungicide				
Test object	soil micro-organisms Nitrogen transformation (silty san	id soil)			
Exposure	28 days				
mg/kg dry weight soil	2.41	24.1			
L/ha (equivalent)	1.6 (recommended field rate)	16.0 (10x recommended weld rate)			
Final result after 28 days	Difference to control: (%) (<25%)				

Validity criteria: All validity criteria were met in this study. Validity criteria (OECD 216, 2000) The coefficient of variation in the control for NO₃-N₂ 15 % III, CONCLUSION Uning the 28-day experiment, the maximum field rate of Infinity SC Stingicide (1.62/ha) and 10-fold this field rate of Infinito SC (21.33 µL/kg/dry weight solt = 245 mg/kg/dry.steight solt) haddoo influence

this field rate of Infinito SC (21.33 µL/kg/dry weight sol = 245 mg/kg/dry weight sol) had no influence on the microbial mineralization of nitrogen to a silty and soil amonded with lucerne-grass-green meal.

The study is considered reliable. The relevant endpoint maximum concentration with effects <

And a set any decide with the set of the set



## CP 10.6 Effects on terrestrial non-target higher plants

For the product FLC + PCH SC 687.5 two single dose studies on Terrestrial Plant Vegetative Vigour (testing 6 and 10 test species, respectively) and two single dose studies on Terrestrial Plant See Ung Emergence (testing 6 and 10 test species, respectively) were conducted to determine possible effects on terrestrial non-target higher plants.

Table 10.6- 1:	Effect values relevant for the risk assessment product FLC + PCH SC 687.5	for non-target terrestrial	plants for the
	product FLC + PCH SC 687.5		

Test organism	Study type	Max. effects 💎	Most sensitive species	Beferences
Application rate	: 2.13 L product/ha (≙ 62	2.5 g FLC/ha)		
Terrestrial non- target plants; 6 species	Seedling emergence; Tier 1 single dose 21 days	No effect© 50 % at an appl. rate of 2.13 L/ha ♀ ♀	Allium centre.	<u>208</u> <u>M-235772-0271</u> KCP 10.62/02
Terrestrial non- target plants; 6 species	Vegetative vigour; Tier 1 single dose 21 days	No effect $\geq 50$ at an apply rate of 2.13 L/ha		Į.
Application rate	: 1.6 L product/ha ( 88.	5 gGFLC/ha) a)	N N N	5.4
Terrestrial non- target plants; 10 species	Seedling emer@ence; Tier 1 single dose 21 days	No effects 50 % at au appl. rate of 1.6 Dha	shoot dry weight	2019; <u>M-652842-</u> 02-1 KCP 10.6.2/05
Terrestrial non- target plants; 10 species	Vegetative viewur; Tier singte dose 2. days	an appl. care of 1.5	410 % reduction of shoot dry weight	2019; M-652843- 02-1 KCP 10.6.2/06

a) Based on an FLC content of 62.5 gL and a product density: 1.13 g/cm

In the case of FLC + PCH SC 687.5, the Tier 1 vegetative vigous studies and seedling emergence studies showed no phytotoxic effects > 50 % at the tested rates of 2.03 and 0.6 L product/ha (equivalent to 62.5 and 88.5 FLC/ha).

# Risk assessment for Terrestrial Non-Farget Higher Plants

The risk assessment is based of the Guidance Bocument on Terrestrial Ecotoxicology", (SANCO/10339/2000 rev. 2 final, 2002) It is restricted to off-field situations, as non-target plants are defined as non-crop plants located outside the freated area. Effects on non-target plants are of concern in the off-field environment, where non-target plants may be exposed to spray drift.

As the single application rate of 106 L product/br (corresponding to 62.5 g FLC/ha) does not result in effects  $\geq 50$  %, according, to the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/103292002 rev. 2 final, 2092), no risk for non-target terrestrial plants is expected. Thus, no further risk as essment is required and the need for risk mitigation measures is excluded.

## Conclusion:

From the date presented above, it is concluded that unacceptable effects of FLC + PCH SC 687.5 on non-target tertestrice plants are not to be expected when the product is used as recommended.



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

Not necessary as guideline GLP studies for terrestrial non-target plants are available (see Point 10.6,2 in this MCP Summary). 

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

Data Point:	
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$
Report Author:	
Report Year:	
Report Title:	Non-target terrestrial plants: An evaluation of the offects of AE B666752 04 SC61
	A102 in the vegetative vogour test (Tier 1)
Report No:	
Document No:	M-235779-01-1
Guideline(s) followed in	OECD 208 B (draft, 2000) Q Q Q
study:	
Deviations from current	OECD 208 B (draft, 2000) Current Guidebre: OECD 227 (2006) Seedling emogence of control plants humidity and light intensity are not reported. Plant density was 5 plants per poinstead of 2 plants per pot for larger species. Used pots were smaller than 15 cm in chamter These deviations are not expected to have impacted the studyresults
test guideline:	Seedling emergence of control plants humidity and light intensity are not
-	reported. Plant density was 5 plants per populatead of 2 plants per pot for larger
	species. Dised pots were smaller than 15 cm in drameter
	These deviations are not expected to have impacted the study results.
Previous evaluation:	yes evaluated and accepted and accepted and accepted and accepted and accepted and accepted a
	In the DAR (200)
	ther Pronomocarto in RAQ lune 2017
GLP/Officially	No. not conducted under GL POfficially recognised testing acilities
recognised testing	
facilities:	
Acceptability/Reliability:	Nes O S a c a

## EXECUTIVE SLOTMARO

The purpose of this specific study was to evaluate the prect of Fluopicolide + Propamocarb SC 687.5 on the vegetative vigont of six non-target terrestrial plant species following a post-emergence application of 2.13 L product/m at the 2-4 leaf stage. The selected six non-target terrestrial plant species were sown in a standard soil fertilized with 2.4 g Blaukorn peol and grown in a greenhouse in 10 and 13 cm pots. The test item was dissolved in defonized water and was applied 2 times at 200 L/ha to the plant foliage using a speay chapter equipped with an overbead nozzle.

Plants were grown under controlled greenhouse conditions. Assessments were made 7, 14 and 21 days after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage and fresh weight. () ()

There were no significant adverse offects in the vegetative vigour of the six plant species tested after the treatment with Fluopicoline + Propamocarb So 687.5 at an application rate of 2.13 L product/ha.

## I. M&TERIAL AND METHODS:

Test item Fluor colide + Prosamocarb SC 687.5 (62.5 + 625); Short code: FLC + PCH SC 687.5 (62.5 + 625 Code E B66675204 SC 61 A102), batch No: OP220159, analysed contents of a.s.: 64.7 g/L fluopicolide and 634 g/L propamocarb, density: 1.129 g/mL.

Test species: 4 dicotyledonous and 2 monocotyledonous species representing 6 different plant families (EPPO code): Lactuca sativa (LACSA), Brassica napus (BRSNW), Cucumis sativus (CUMSA), *Glycine max* (GLXMA), *Avena sativa* (AVESA), *Allium cepa* (ALLCE).



In order to reach the 2-4 leaf stage at the start of testing, the selected six non-target terrestrial plant species were sown in a standard soil (14.2% sand, 65.1% silt and 20.7% clay, organic carbon: 1.19%) fertilized with 2.4 g Blaukorn per L and grown in grown in a greenhouse in 10 and 13 cm pots.

The plant species were treated at the 2-4 leaf stage with an application rate of 213 L product and a water control (400 L/ha of deionised water), respectively. The test item was dissolved in in deionized water and was applied 2 times at 200 L/ha using a spray chamber equipped with an overlead no class to a the plant foliage. There were 5 plants per pot and 4 replicate pots, giving a total of 20 plants per control and treatment.

Following application, the pots with plants were maintained under greenhouse conditions with temperature of  $23 \pm 5^{\circ}$ C during day time and  $18 \pm 5^{\circ}$ C during night time. The photoperiod was 16 h light and 8 h dark. Natural daylight was supplemented by artificial lighting to provide the required photoperiod.

Å nents were made for plant Assessments were made 7, 14 and 21 days after application. survival, visual phytotoxicity, plant growth stage and fresh

ÍLTS ÁND

## **Biological findings:**

There were no visible sympton's of phytotoxicity in any species. Growth the emerged plants was not influenced by the test compound for any of the tested

Ľ eigh. ical, fresh weight, phytotoxically and growth stage are Detailed results for effects of the test frem on surv given below.

	i në	_ ·¥	' (N	$\sim$
	Mean %	portality of	n day 21	ð.
Species	Control	₹2.13	L <b>(ha</b>	
Lactuca sativa	) jy	Š, Õ		<b>%</b>
Brassica napus 🔊		0 🔨 🕺	<i>"</i> Ø [°]	Oʻ į
Cucumis sativus			<u>~~~~</u>	Ś
Glycine max		$\sim \sim$		 &
Avena sativa	ðð "		<u>s</u>	Ŵ
Allium Copa				Į

Effects of the test item on surviva

Effects of the test item on fresh weight

	Mean fre	sh weight (g) po	er plant on day 21
Species	Control	2.13 [°] L/ha	% of control
Lactuça sativa	12.501	13.343	107
Brassica napus 🔗	24,009	21.284	101
Eucumic sativus	23.297	27.249	117
Glycine max	7.238	7.512	104
Avena sativa	7.279	7.130	98
Allium cepa	1.180	1.195	101

O

Ô



Species	Mean phytotoxicity (%) on day 21		Growth stag	ge on day 21
	Control	2.13 L/ha	Control	2.13 L/h
Lactuca sativa	0	0	20-22	21-22
Brassica napus	0	0	16-18	1618
Cucumis sativus	0	0	61	× 761 ~~ Q
Glycine max	0	0 🗇	51 6	0 51-26
Avena sativa	0	0 🔏	20-47	
Allium cepa	0	<u>Q</u> _	Q13-14 •	13-14 C C

## Phytotoxicity and growth stage of the test item

# III. CONCLAUSIONS

In a Tier 1 seedling emergence study Fluopicolide Propamocarb SC 687.5 way tested under greenhouse conditions for effects on survival, fresh weight, and phytotopicity and growth stoge of six non-starget terrestrial plant species. There were no adverse effects in the vegetative rigour of the six tested plant species after the treatment with Fluopicolide + Propamocarb SC 687.5 at an application rate of 2.13 L product/ha.

## Assessment and conclusion by applicant:

There were no adverse effection the vegetative vigour of the Six tested plant species after the treatment with Fluopicolide + Propamocarb SC 687.5 ar an application rate of 2.13 L product/ha. The study is considered reliable.

Data Point:	KCP 10.6.2/02
Report Autlor:	
Report Year:	
Report Title:	Non-target terrestrial planes: An evaluation of the effects of AE B066752 04 SC61
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	A102 in the seedling entergence and growth test (Tier 1)
Report No:	C040
Document No:	<u>M-255772-02-1</u> × × ×
Guideline(s) followed an	QECD 20\$ A (draft, 2000
study:	
Deviations from current	Current Guideline: QECD 208 (2006)
test guideline:	Humodity and light intensity are not reported. Plant density was 5 plants per pot
test guideline:	instead of 2 plants per por for larger species. Used pots were smaller than 15 cm in
	diameter. Q S
	These deviations are not expected to have impacted the study results.
Previous evaluation:	ye@evaluated andQccepted
	(2005) (2005)
	for Propamocarb in RAR June 2017
GLP/Off@ally	No pot conducted under GLP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	Yes
*	

Executive Summary

The purpose of this specific study was to evaluate the effect of Fluopicolide + Propamocarb SC 687.5 on the seedling emergence and seedling growth of six non-target terrestrial plant species following a



pre-emergence application of 2.13 L product/ha. The day before application, 5 seeds per pot with 4 pots per control and treatment, respectively, were planted. The seeds were manually introduced in sterilised standard soil. Q_{μ}°

The spray solution was applied to the soil surface using a spray chamber equipped with an overhead nozzle. Plants were grown under controlled greenhouse conditions. Plants were assessed for emergence, survival and rated for phytotoxicity on days 7, 14 and 21 days. At study termination, biomass indpoint determinations were performed for plant fresh weights. The validity criteria of the study were fulfiled for all species, except for oilseed rape. For oilseed rape, two control plants died during the duration of the study resulting in 11% mortality and therefore breaching the validity criterium of 90% stavival approximation.

There were no significant adverse effects in the seedling emergence of the six crops tested after the treatment with Fluopicolide + Propamocarb SC 687. Fat an application rate of 2.10 L product/hQ

I. MATERIAL AND METHOD

Test item: Fluopicolide + Propamocarb SC 687.5 (62.5 + 625); Short code: FLC + PCH SC 687.5 (62.5 + 625) (Code AE B066752 04 SC 61 A102), batch No: OP220159, analysed contents of a set 64 *Fg/L* fluopicolide and 634 g/L propamocarb. density: 1.129 mL

Test species: 4 dicotyledonous and 2 monosotyledonous species representing 6 different plant families (EPPO code): Lactuca sativa (EACSA), Brassica napus (BRSNN), Cucumis Sativas (CUMSA), Glycine max (GLXMA), Avena ativa (AVESA), Alfrim cepa (ALECE).

The day before application, 5 seeds per pet with 4 potsper control and treatment respectively, were planted by manually introducing the seeds in sterilised standard soil (14.2% and 65.1% silt and 20.7% clay; pH 7.4 and organic carbon 1.19%). The spray colution was applied to the soil surface. The blank control spray solution was defonized water. The test item was dissolved in dejonized water and applied 2 times at 200 L/hausing a spray chamber equipped with an overhead nozzle; a nominal rate of 2.13 L product/ha was applied.

Following application the poly with seeds were maintained under greenhouse conditions with a photoperiod of 16 h light and 8 dark, a day temperature of $23 \pm 5^{\circ}$ C and a night temperature of $18 \pm 5^{\circ}$ C. Natural daylight was supplemented by artificial lighting to provide the required photoperiod. Plants were assessed for emergence, survival and rated for phytotoxicity on days 7, 14 and 21 days. At

study termination, biomass endpoint determinations were performed for plant fresh weights.

RESILTS AND DISCUSSION:

Validity criteria:

The germination rate of the seeds used in this study was $\geq 70\%$.

The validity criterion of at leasy 90% survival of the plants during the study period was achieved for the untreated controls for all species tested except for oilseed rape. The control mortality for this species was 14%. It has to be noted that no mortality was detected in the treatment group of oilseed rape.

Biological findings:

There were no major effects on emergence and survival for any of the six plant species tested and all plants exhibited normal provide

There were no major effects on fresh weight for all six of the crops tested (see second table below). Fresh weights were recorded for each replicate and the final data corrected on a per plant basis.

There were no visible symptoms of phytotoxicity in any species. Growth of the emerged plants was not influenced by the test compound for any of the species except for lettuce which showed a slight growth delay, however appeared normal.



Detailed results for effects of the test item on emergence, survival, fresh weight, phytotoxicity and growth stage are given below.

8						
Mean %	Emergence	Mean % S	Survivation day 21			
Control	2.13 L/ha	Control	A 2.13 L/ha			
70	60	93	2.13 L/ha 75 100 89 0 0 0 0 0 0 0 0 0 0 0 0 0			
80	80	89				
85	90 🔬	100	89			
85	95 ₄ 0	100				
100	296 V	100				
80	55 °	@ ¹ 00 ~	$\begin{array}{c} 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 $			
Effects of the test item on fresh weight A						
	it (gyper plane on da	<u>y 21 - </u>				
	L/ha 📎% of con	trol ^o				
	32 6 88	<u>r</u> ,0				
	81 1 99 @					
4.863 5.7	118					
	Control 70 80 85 85 100 80 em on fresh weight Mean fresh weight 0.830 0.7 3.514 34	Mean % Emergence Control 2.13 L/ha 70 60 80 80 85 90 85 95 100 95 80 55 90 55 90 60 80 85 90 95 100 95 80 55 90 95 90	Mean % Emergence Mean % Control 2.13 L/ha Control 70 60 93 80 80 89 85 90 100 80 5 90 100 95 100 80 55 9100 100 95 100 80 55 9100 100 95 100 80 55 9100 100 95 100 80 55 9100 100 95 100 80 55 9100 0.80 0.732 88 3.514 3.481 99 4.863 5.729 118			

Effects of the test item on fresh weight

Effects of the test it	tem on fresh	weight			ð A Å	
	Mean fres	sh weight (g) pe	r plant on da	ý 21* Ô		
Species	Control	213 L/ha	S of con	trol		
Lactuca sativa	0.830	Q 0.732	88	2°	ັດັ	, S
Brassica napus	3.514	<u></u> , 3€ Å81 ⊘	\$ 99.0		ð	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Cucumis sativus	4.863	5.729	118		. Q /	» (
Glycine max	3,846	3.38	Q 888	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		ġ Q
Avena sativa	°∱⁄742	1.413	81		, S	
Allium cepa	K 0.102	Ø.112 O	<u> </u>) <u>\$</u>	<u> </u>	, OŠ

*On a per plant basis, and vatistical analysis using the Willights Test vevealed no significant differences between control and treatment for any species at the 1% level

Phytotoxicity and growth stage of the test item

L.	Mean phytomxicity (%) op day 24	Growth stag	ge on day 21
Species 🔊	Control 2413 L/ha	لم الم الم الم الم الم الم الم الم الم ا	2.13 L/ha
Lactuca sativa 🔊		¥ 12-14	10-14
Brassica napus	8 50 C 57 8 57	14	14
Cucumis sativus		12	12
Glycine max		12-13	12-13
Avena ativa		13	13
Allium cepa		11-12	11-12
Å,	THE AND A CONTRACT OF A CONTRACT.		
Ŵ	III CONCLUSIONS		

In a Tier 1 Seedling emergence study Fluopicolide + Propamocarb SC 687.5 was tested under greenhouse conditions for effects on emergence, survival, fresh weight, visual phytotoxicity and growth of six non-targer terrestrial pant species. There were no significant adverse effects in the seedling emergence of the six species tested after the treatment with Fluopicolide + Propamocarb SC 687.5 at an application rate of 2.13 L product/ha.



Assessment and conclusion by applicant:

There were no significant adverse effects in the seedling emergence of the six species tested after the treatment with Fluopicolide + Propamocarb SC 687.5 at an application rate of 2.13 L product that. The study is considered reliable.

Data Point:	KCP 10.6.2/03
Report Author:	
Report Year:	
Report Title:	Fluopicolide + propamocarb \$6 687.5 (62.5+625 g/L): Effects on the seedling
Report No:	S18-02177 M-652842-02-1
Document No:	<u>M-652842-02-1</u>
Guideline(s) followed in study:	M-652842-02-1 EU Directive 91/414/EEC Regulation (EC) no. 1107/2009 US EPA OCSPP \$50.4100 (2012) OECD 208 (2006) Current Guid@ne: OECD 208 (2006)
Deviations from current test guideline:	Current Guid@ine: OFCD 208 (2006) The light intensity was higher than required by the guideline (81@ 1150 µmol/m ² /s). Higher light intensities (above 400 µmol/m ² /s) are not considered as deviations as experience show that higher light intensity has no negative influence on phytotocicity, growth @ morphology.
Previous evaluation:	No not previously submitted of a contract of
GLP/Officially	Yes, conducted under CLP/Officially recognised testing facilities
recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing factitutes
Acceptability/Reliability:	Yes XY XY XY O Y
S .	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

EXECUTIVE SIOIMARO

The purpose of this specific study was to evaluate the effect of fluepicolide + propamocarb SC 687.5 on the seedling emergence of ten ron-target terrestrial plant species following a pre-emergence application of 1.6 L productora. The selected terronon-target terrestrial plant species were sown in a loamy sand and grown in a greenhouse in 15 cm pots. The test item was dissolved in deionised water and was applied one time at an overage spray colume of 218 L/ha to the bare soil surface after sowing of the plants using a spray chapter equipped with an overlead nozzle.

Plants were grown under controlled greenhouse conditions. Assessments were made 7, 14 and 21 days after application. Assessments were made for seedling emergence, phytotoxicity and post-emergence mortality Plant growth stage and show dry weight were assessed only at day 21. The validity criteria were fulfilled for all species.

There were no adverse effects > 50% on sorvival phytotoxicity, emergence, growth stage and shoot dry weight after the treatment with Huopicoride propamocarb SC 687.5 at an application rate of 1.6 L product/ha.

I. MATERIAL AND METHODS:

Test item: Flugnicolide + Propamocarb SC 687.5 (62.5 + 625); Short code: FLC + PCH SC 687.5 (62.5 + 625); specification No: 102000027553, Sample description: TOX20899-00, batch No: 2018-002211-01 analysed contents of a S.: 65.91 g/L fluopicolide and 612.4 g/L propamocarb, density: 1.133 g/mL.

Test species: 7 dicotyledonous and 3 monocotyledonous species representing 8 different plant families (EPPO code): *Beta vulgaris* (BEAVX), *Brassica napus* (BRSNW), *Cucumis sativus* (CUMSA), *Glycine*



max (GLXMA), Helianthus annuus (HELAN), Lactuca sativa (LACSA), Solanum lycopersicum (LYPES), Allium cepa (ALLCE), Triticum aestivum (TRZAX), Zea mays (ZEAMX).

The selected ten non-target terrestrial plant species were sown in a soil (loamy sand) composed of 77.11% sand, 18% silt and 4.89% clay, with a pH of 7.64, a total organic carbon content of 0.40% (0.69% organic matter) and an electronic conductivity of 133.9 µS/cm. Plants were grown into a greenhouse in 15 cm pots.

Treatment was done at the day of sowing with an application rate of 1.6 L product/ha and a water control (average 218 L/ha of deionised water), respectively. The test item was dissolved in defonised water and was applied once using a spray chamber equipped with an overhead nozzle to the soil subface. There were 2 plants per pot and 10 replicate pots for all dicco ledonous species and for the monocotyledonous test species *Zea mays*. For the two monocotyledonous species *Allium cepa* and *Viticum aestivum* there were 4 plants per pot and 5 replicates pots. In total 20 plants per control and treatment were tested for each species.

Following application, the pots with plants were maintained under greenhouse conditions with a temperature of 17.45 - 29.96 °C and relative air humidity of 52.55 - 87.83%. The photoperiod was 16 h light and 8 h dark and the light intensite was between 810 - 1150 µmol/m²/s. Plants were assessed for seedling emergence, post-emergence motality and phototoxicity symptoms 7, 14 and 21 days after at least 50% emergence of the seedlings in the control group Additionally, the BBCH growth stage was determined for all treatment groups on day 21. The effects on plant shoot dry weight were determined for day 21.

II. RESULTS AND DISCRSSION:

Validity criteria:

The germination rate of the seeds used in this study was $\geq 70\%$.

The validity criterion of at least 90% survival of the plants during the study period was achieved for the untreated compose for all species terred.

The control seedlings of each species did not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and control plants exhibited normal variation in growth and morphology for that particular species.

Biological finding

No post-emergence mortality occurred for any of the plant species tested.

No symptoms of phytotoxicity were observed during the course of this study. Thus, the phytotoxic grade for all plant species is 1 (normal plant appearance)

Detailed results for effects of the test item on seedling emergence, growth stage, and shoot dry weight are given below

No statisticately significant effects on seeding emergence were observed for any of the plant species tested at the last assessment day. The highest inhibition for seeding emergence occurred for *Beta vulgaris* with 15.8% compared to the control group.



	% emerged p	lants on day 21	Inhibition compared to the control [%]**	
Species	Control	1.6 L/ha	~	
Beta vulgaris	95	80	15.8	
Brassica napus	100	100	0	
Cucumis sativus	95	95	0	
Glycine max	95	85 _	10.5	
Helianthus annuus	100	95	Å.	
Lactuca sativa	100	100		
Solanum lycopersicum	95	1.00,	[∞] -5.8 ₆ ° [∞]	
Allium cepa	75	\$80	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
Triticum aestivum	95	<u>لام</u> 95 ه		P v v
Zea mays	90		~ ~ - 11 % O	A A C

Effects of the test item on seedling emergence

* Negative values indicate that there was an increase compary

No differences in growth stage between the control and the text iten treated plants were observed at the final assessment day (21 DA50E).

Effects	on	growth	stage	of	thetest	item
---------	----	--------	-------	----	---------	------

		Gro Gro	wth stage on Aximum BB	day 21	
Species	2 2	Control			
Beta vulgaris Brassica napus Cucumis sativas		v 14 L d 4	N S	<i>a</i> 14/94	~~
Brassica napus 🔊		14%14		<u>~</u> 147 14 ~	Č,
Cucumis sativas	<u>D</u>	\$\$3 / 13		\$973 / 13 ⁵) [*]
Glycine max	₽~~~	16/16			
HelianthuQannuus	×, ×,	16416		16 16	
Lactuça sativa		£\$ / 15		\$ 15/15	
Solanum lycopersici	my x x	14/18		× 14 / 14	
Allium cepa 🔬 🔊		13 13 13	δy φ	13 / 13	
Triticum aestivum		22 / 22		22 / 22	
Zea mays 🦉	, <u> </u>	96/20		16 / 16	
		<u>, 0</u>	<u>o' o</u> r		•

The application of the test item resulted in statistically significant differences on shoot dry weight compared to the control of 15.0% and 13.5% respectively, for *Brassica napus* and *Solanum lycopevsicum*. The highest non-significant inhibition occurred for *Allium cepa* with 24.3% inhibition compared to the control group.



	36740	eight on day 21 [g] ± SD)	Inhibition (% compared to control)**
Species	Control	1.6 L/ha	
Beta vulgaris	0.315 ± 0.046	0.422 ± 0.090	-34.0 27 27
Brassica napus	0.602 ± 0.086	0.512 ± 0.082	× 15.0* × × ×
Cucumis sativus	0.912 ± 0.226	0.940 0.253	<u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u></u>
Glycine max	1.507 ± 0.287	1.556 ± 0.751	
Helianthus annuus	0.608 ± 0.079	079 ± 0.464	$\begin{array}{c} 0^{4} & -3.5^{4} & 5^{4} \\ \hline & -203 & 5^{4} \\ \hline & 0^{2}7.6 & 9 $
Lactuca sativa	0.254 ± 0.038	0.237 ± 0.056	Q 0 6.7 4
Solanum lycopersicum	0.466 ± 0.077	Ø 0.403 ± 0.066 %	
Allium cepa	0.037 ± 0.005 ^A	00028±,0009	
Triticum aestivum	0.191 ± 0.010	≪0.177€0.0150	7.3 L ~
Zea mays	1.197 ± 0.21	1.084 ± 0,245	<u>8</u> 9.4 8 0 ⁴

Effects on shoot dry weight of the test item

^A The shoot dry weight of *Allium cepa* replicate $8 \, \mu$. 1 in the control group was detected as statistical Outlier (Dixon & Harley test, $\alpha = 0.05$). Hence this replicate was not considered for the evaluation of shoot dry weight. *Significantly different compared to control (Student st-test: fest one-sided smaller, a = 9.05)

**Negative values indicate that there was an increase compared to the control.

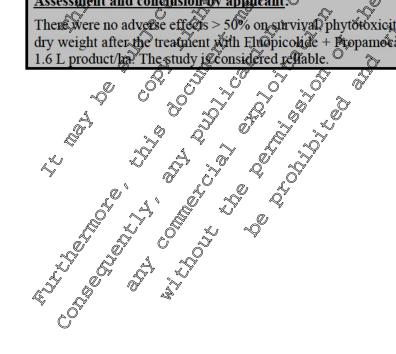
III. CONCLUSIONS In a Tier 1 seedling emergence study fluopicolide proprinocarb SC 687.5 was tested under greenhouse conditions for effects on survival, phytoloxicity seedling emergence, growil stage and shoot dry weight of ten non-target teneestrial plant species. There were no adverse effects 50% on survival, phytotoxicity, emergence, growth stage and shoot dry weight after the treatment with Fluopicolide +

Propamocarb SC 687.5 at an application rate of 1.6 L production.

Assessment and conclusion by applicant

There were no adverse effects > 50% on survival phytotoxicity, emergence, growth stage and shoot dry weight after the treatment with Eluopicolide + Propamorarb SC 687.5 at an application rate of 1.6 L product/ha. The study icconsidered reflable.

Ø





Data Point:	KCP 10.6.2/04
Report Author:	
Report Year:	2019
Report Title:	Fluopicolide + propamocarb SC 687.5 (62.5+625 g/L): Effects on the vegetative vigour of ten non-target terrestrial plant species (tier 1)
Report No:	S18-02178
Document No:	<u>M-652843-02-1</u>
Guideline(s) followed in	EU Directive 91/414/EEC
study:	Regulation (EC) no. 1107/2009 \swarrow
	US EPA OCSPP 850.4150 (2012)
Deviations from current	Current Guideline: OECD 227(2006)
test guideline:	The light intensity was higher than required by the guideline (460 - 910
	µmol/m ² /s). Higher light intensities (above 400 µmol/m ² /s) are not considered as
	μ mol/m ² /s). Higher light intensities (above 400 μ mol/m ² /s) are not considered as deviations as experience shows that higher light intensity has no negative
	influence on phytotoxicity, growth or prorphology.
Previous evaluation:	No, not previously submitted a solution of the
	$\Delta \phi \psi Q \sim 0' \phi' \phi$
GLP/Officially	Yes, conducted under ODP/Officially recognised testing facilities
recognised testing	
facilities:	
Acceptability/Reliability:	$Yes \qquad \qquad$

EXECUTIVE SUMMARY

The purpose of this specific study was to evaluate the effect of fluopicolide φ propamocarb SC 687.5 on the vegetative vigour of ten non-target derrestrial plant species following a post-emergence application of 1.6 L product/hast the 2-4 leaf stage. The selected ten non-target derrestrial plant species were sown in a loamy sand and grown in a greenhouse in 15 cm pots. The test item was dissolved in deionised water and was applied once at 12 L/ha to the plant foliage using a spray chamber equipped with an overhead tozzle. Plants were grown under controlled greenhouse conditions. Assessments were made 7, 14 and 21 days

Plants were grown under controlled greenhouse conditions. Assessments were made 7, 14 and 21 days after application. Assessments were made for plane survival and visual phytotoxicity. Plant growth stage and shoot day weight were only assessed at day 21. The validity criteria were fulfilled for all species. There were no significant adverse effects > 50% in the vegetative vigour of the ten plant species tested after the freatment with Fluoppolide + Programoear SC 687.5 at an application rate of 1.6 L product/ha.



Test item: Fluopicolide + Bropanocarb SC 687 (62.5 + 625); Short code: FLC + PCH SC 687.5 (62.5 + 625), Sample description: TQX2089 00, Specification No. 102000027553, batch No: 2018-002211-01, analysed contents of a.s.: 65.91 g/L fluopicolide and 612.4 g/L propamocarb, density: 1.133 g/mL.

Test species: 7 dicotyledonous and 3 monocotyledonous species representing 8 different plant families (EPPO code): Beta vulgaris (BEAVX), Brassica napus (BRSNW), Cucumis sativus (CUMSA), Glycine max (GLXMA), Helianthus annuus (HECAN), Lactuca sativa (LACSA), Solanum lycopersicum (LYPES), Alium copa (ASLCE), Triticom aestivum (TRZAX), Zea mays (ZEAMX).

In order to reach the 2-4 leaf stage at the start of testing the selected ten non-target terrestrial plant species were sown for a soft (loamy sand) composed of 77.11% sand, 18% silt and 4.89% clay, with a pHz of 7.6%, a total organic carbon content of 0.40% (0.69% organic matter) and an electronic conductivity of 133.9 μ S/cm. Plants were grown in a greenhouse in 15 cm pots.



The pots with plants were maintained under greenhouse conditions with a temperature of 17.97 – 28.60°C and relative air humidity of 46.95 – 78.65%. The photoperiod was 16 h light and 8 h dark and the light intensity was between $460 - 910 \,\mu mol/m^2/s$.

The plant species were treated at the 2-4 leaf stage with an application rate of 1.6 L product/ka and a water control (average 212 L/ha of deionised water), respectively. The test fem was discolved on deionised water and was applied once using a spray chamber equipped with m overhead nozzle to the plant foliage. There were 2 plants per pot and 10 replicate pots for all dicatyledonous species and for the monocotyledonous test species Zea mays. For the two monocotyledonous species Allium cepa and Triticum aestivum there were 4 plants per pot and 5 replicates pots. In otal 20 plants per control and treatment were tested for each species.

The plants were assessed for mortality and signs of phytotoxicity 7, 14 and 25 days after application. BBCH-growth stage and shoot dry weight were assessed for day 21. **II. RESULTS AND DISCUSSION:** <u>Validity criteria:</u> The germination rate of the seeds used in this study was $\geq 0\%$. The validity criterion of at least 90% survival of the plants during the andy period was achieved for the untreated controls for all species tested.

untreated controls for all species tested. wilting, leaf and stem deformations) and control plants exhibited normal variation in growth and morphology for that particular species.

Biological findings:

No mortality occurred for any species tested

No symptoms of phytotoxicity were observed during the course of this study. Thus, the phytotoxic grade for all plant species is 1 (normal plant appearance). Ø

Ø Detailed tesults for effects of the test tem on growth stage and shoot dry weight are given below.

Ĵ, Ľ Å No differences in the BBCH growth stage between the treatment group and the control group were

No differences in the BBCH growth stage between the treatment group and the observed for any of the plant species tested on the last assessment day (day 21).



	Growth s (Minimum / Maxim		
Species	Control	1.6 L/ha	
Beta vulgaris	17 / 17	17 / 17	
Brassica napus	17 / 17	17/17	
Cucumis sativus	63 / 63	63 / 63	
Glycine max	64 / 64	64/64	
Helianthus annuus	18 / 18	18/18	
Lactuca sativa	16 / 16	16/16	
Solanum lycopersicum	17/17		
Allium cepa	14 / 14		
Triticum aestivum	23 / 23	23/23 ×	
Zea mays	17 / 17		

Effects on growth stage of the test item

An application of the test item resulted in statistically significant effects on short dry weight for the plant species *Allium cepa* and *Zea pays*. The highest individual of short dry weight compared to the control was determined for *Allium cepa* with 41.5% followed by *Zea pays* with 12.1% at the test item rate of 1.6 L product/ha.

Mean shoot dry weight on day 21 [g] Mean shoot dry weight on day 21 [g] Mean ± SD) Mean ± SD)				
Species	6 Control	2.6 L/hg	control)**	
Beta vulgaris 🔊 🔪	1.714 ± 0.309	3.234 ± 0.195 ℃	-30.3	
Brassica napu® O Cucumis sativus no	3.376 0.6360	4.027 ± 0.44	-19.3	
Cucumis sativus	≪ 3.993 ± 0.634	3.692±0.938	7.5	
Glycine max s	3962±0396 O	4.802 ±@.731	-21.2	
Helian Hus annuus	€.109±0.202	0.19€	-5.7	
Lactuca sativa	1.5 16 ± 0.3 6	1558 ± 0.343	-2.8	
Solanum lycopersicum	2.278±0.319	2Q 473 ±0 .389	-10.5	
Allium cepa 🛛 🖉 🖉	0.275 ±0.055	\$0.161\$0.029	41.5*	
Triticum agentrum	0.708 ± 0.085	$\sim 0.780 \pm 0.041$	-10.2	
Zea mays	O 3.881 ± 0.285	2,411 ± 0.488	12.1*	

Effects on shoot dry weight of the test item

* Significantly different compared to control (Brudent St-test; test one-sided smaller, $\alpha = 0.05$)

**Negative values indicate that there was an increase compared to the control.

In a Tier 1 vegetative vigoue study thuopiconde + propamocarb SC 687.5 was tested under greenhouse conditions for effects on privial, phytoroxicity, growth stage and shoot dry weight of ten non-target terrestrial plant species. There were no adverse effects > 50% on survival and shoot dry weight after the treatment with thuopicolide + propamocarb SC 687.5 at an application rate of 1.6 L product/ha.

Assessment and conclusion by applicant:

There were no adverse effects > 50% on survival and shoot dry weight after the treatment with fluopicolide + propamocarb SC 687.5 at an application rate of 1.6 L product/ha. The study is considered reliable.



CP 10.6.3 Extended laboratory studies on non-target plants

In view of the results presented under Point CP 10.6.2 above, no further studies are deemed necessary.

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

In view of the results presented under Point CP 10.6.2 above, no further studies are deemed ne

CP 10.7 Effects on other terrestrial organisms (flore and fauna) and chronic ecotoxicity of fluopicolide + propans arb-hydrochloride & 687. Sas prosented under the

No monitoring data has been collected by the applicant nor have they been reported in any of the public literature references as evaluated in Document MGA, Section & Due 10 the loss to moderate acute and chronic ecotoxicity of fluopicolide + propamocarb-hodrochtoride SC 6875 as presented under the Points CP 10.1 to CP 10.7, no monitoring of non-target organisms is deened to be necessary.

