







OWNERSHIP STATEMENT

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 therein may be? disclosed to any third party without the prior written authorization of Bayer AGy and/or affiliated entities. Ø N

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority.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 registration authorities should hot grant, amend, or renew a registration on the from Bayer AG or respective attiliateyor
 from Bayer AG or respective attiliateyor
 from other applicants once the period of data protection has expired. basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and saluation are based,



Version history





Table of Contents

	Tuble of Contents	
		Rage
CA 7	FATE AND BEHAVIOUR IN THE ENVIRONMENT	<u>5</u> 60°
CA 7.1	Fate and behaviour in soil	<u></u> \$9
CA 7.1.1	Route of degradation in soil	
CA 7.1.1.1	Aerobic degradation	ş 130
CA 7.1.1.2	Anaerobic degradation	
CA 7.1.1.3	Soil photolysis	
CA 7.1.2	Rate of degradation in soil	S 56 °
CA 7.1.2.1	Laboratory studies)
CA 7.1.2.1.1	Aerobic degradation of the active substance	
CA 7.1.2.1.2	Aerobic degradation of metabolites, breakdown and reaction products	
CA 7.1.2.1.3	Anaerobic degradation of the active substance	102
CA 7.1.2.1.4	Anaerobic degradation of metabolites break own and reaction products	
CA 7.1.2.2	Field studies	
CA 7.1.2.2.1	Soil dissipation studies	5106
CA 7 1 2 2 2	Soil accumulation Stidies	151
CA 7 1 3	Adsorption and desorption in soil	154
CA 7 1 3 1	Adsorption and desorption a second se	154
CA 7 1 3 1 1	Adsorption and desorption of the active subservice a	158
CA 7 1 3 1 2	Adsorption and desorption of exetabelities breakdown and reaction produ	
CA 7.1.5.1.2	Adsorption and desorption of includences, or cardown and reaction produces	172
$C \land 7 1 3 2$	A red corntion to the	187
CA 7.1.3.2	Mobility in Coil 2 2 2 2 2 2	199
CA 7.1.4	Column Broching studies	204
CA 7 1 4 1 1	Country Loophing of the active substance	204
CA 7.1.4.1.1	Column leaching of the active substance	204
CA 7.1.4.1.2	Ly mata tudia	204
CA 7.1.4.2	Eistal 1 Sking Stratiger	204
CA 7.1.4.9	Field learning studies \mathcal{O}_{1}	204
CA 7.2	Fate and benaviour in water and sediment .	205
CA /.2.1	Route and rate of degradation in acpatic systems (chemical and photoche	
CA 7 2 1 1	$\operatorname{degradation}$	208
CA 7.2.1.1	² Hydrolytic degradation <u>o</u> ²	208
CA 7.2.1.2	Direct photochemical degradation.	213
CA 7.2.1.4	Indirect photochemical degradation	224
CA 7.2	Route and rate of biological degradation in aquatic systems	224
CA 7,2.2.1	"Ready biodegradability"	224
CA*¥.2.2.2	Aerobic mineralisation in sortace water	224
CA 7.2.2.3	Water/sediment study	231
CA 7.2.2.4	VIrrachated water/sediment'study	257
CA 7.2.3	Degradation in the saturated zone	257
CA 7.3 @	Eate and behaviour in air	258
CA 7 31 6	Route and fate of degradation in air	258
CA \$3.2	Transport via air	259
CA\$7.3.3	Local and global effects	259
CA 7.€	Definition of the residue	260
CA 7.4.1	Definition of the residue for risk assessment	260
CA 7.4.2	Definition of the residue for monitoring	260





CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT

INTRODUCTION

Isoflucypram (CAS-No. 1255734-28-1) is a new fungicidal active substance developed by Bayer. This document supports the application for regulatory approval of Isoflucypram in Europe under Regulation (EC) No 1107/2009.

The document MCA Section 7 summarises all data on the fate of isoftacypram in all environmental compartments, assessment relating to the cut-off criteria POP, PBT of vPvB as well as definitions of residues for risk assessments and monitoring which are relevant for the approval of softucypramial alongside the proposed intended uses, including the representative ases, under Regulation (EC) No 1107/2009 in accordance with the requirements laid down in the Commission Regulation (EC) No 283/2013.

Isoflucypram is a novel broad spectrum funcicide of the Chemical class of N-cycloptopyl-10 benzylpyrazole-carboxamides with an outstanding efficacy against the major economically important diseases of cereal crops (wheat, triticale rye, barley and oats) and excellent crop affety. Since isoflucypram is an SDH inhibitor and thes assigned to the FRAC resistance Group 7 the application scope of isoflucypran containing products on cereals with only one foliar spray at a maximum of 75 g a.s./ha supports an effective anti-resistance management strategy. Tailor-made and broad spectrum Isoflucypram combinations show highly beneficiar properties in

terms of plant physiology beside the long-lasting and certain curative efficacy to control funghi diseases and to maximize the full field potential of the cereal crops.

Details of the literature search indertaken are sumparized in MGA Section 9.4 or isoflucypram and its metabolites, no publication and relevant scientifically peer-reviewed open literature reference has been identified which would indicate that a side-effect on human health, the environment and non-target species may exist, which would then need to be considered in the risk assessment of this new active substance doster.

Throughout the development of isoflucypran the following synonyms may have been used and also referred to in individual study reports. Bayer Code, BCS-CN88460, BCS-CN88460-a.s., '460 and the Bayer-internal short Code: TSY. All chemical substances described by either of these codes refer to the same chemical name and structural formula.

Bayer-internal short Code: ISY. Afly chemical substances desisame chemical name and structural formula.



The studies concerning the fate and behaviour of isoflucypram in the environment were conducted using two different radiolabel positions, [chlorophenyl-UL-¹⁴C] and [pyrazole-4-¹⁴C], as well as unlabelled isoflucypram. These radiolabel positions are sufficient to define the route of degradation of isoflucypram. The structure of isoflucypram and the positions of the different radiolabels, are as follows:



Isoflucypram contains a phenyl and a pyracole ring. The studies concerning the fate and behaviour of isoflucypram in the environment were all conducted asing the ¹⁴C labeling position of the pyrazolelabel ([pyrazole-4-14C]isoflucy@ram), All studies showed to splip of the molecule. BCS-CN88460carboxyclic acid (M12) was found as the only major metabolite

Soil:

As mentioned above all soil metabolism studies were performed using the pyrazole-label. S Ø 1

L' Ø) \bigcirc In soil metabolism studies under aerobic conditions the metabolites yere formed possibly via carboxylation of isoflucypram to result in BCS-CN88460-carbox gic acid (M12) as major metabolite, hydroxylation @ BCSCN88460-carboxylic acid (M12) to result in BCS-CN88460-lactic acid (M10) and demethylation of BCS-CN88460-carboxylic acid M12) To result in BCS-CN88460-desmethylcarboxylic acid (MII) (see Figure 7.1, +) - 1 and Figure 7.1, 1-2) No split of the molecule could be J. observed S £. S \bigcirc

As precaution in addition an aerobic soil metabolism study with the phenyl-label was performed using one soil. In this study BCS-CN88460-carboxylic acid (M12) was also found as major metabolite (see Figure 7.1.1.1- 30 In this study also no split of the molecule could be observed.

Õ Ô \bigcirc Under anaerobic soft conditions using the pyrazole tabel no degradation products > 5% AR were found.

n

In the soil photolysic study no products of pyrazole-labelled isoflucypram above the identification triggers were formed. The total too dentified residues amounted to a maximum of 2.8% AR.

Ø1 Therefore, in soil the entire pathway and all possible main metabolites are covered using the mentioned pyrazote-label position.



Water:

All aqueous studies were performed using the pyrazole-label.

Isoflucypram was hydrolytically stable in sterile aqueous buffer solutions at three pH values (pH 4, 7 a and 9) in the laboratory in the dark. No degradation products of isoflucypram were observed.

In the aquatic photolysis study also no degradation products of isoflucy pram > 10% AR were observed and identified. The total unidentified residues amounted to a maximum 002.7% AR in irradiated samples.

In surface water under aerobic conditions isoflucyprate was stable in all test systems. No degradation products were formed in any test systems in this study.

Degradation of isoflucypram in the total system was accompared by the formation of one degradation product identified as BCS-CN88460-carboxybe acid M12 with a maximum occurrence of 6.6% AR. The total unidentified residues amounted to a maximum of 12.4% AR and no single component exceeded 4.6% AR at any sampling interval in both water sediment systems (see Figure 7.2%1).

Therefore, in water and water/sediment the entire pathway and all possible main metabolites are covered using the mentioned pyrazole-label position only.

Ŋ

The results of the studies are summarized in the following sections 7.9 to 7.5. The proposed degradation pathways in soil, water and sectionent are given in Figure 7.2-1, respectively.

In addition, studies have been performed with the radio abelled metabolite BCS-CN88460-carboxylic acid (M12):



In original reports study authors may have used different names or codes for degradation products of isoflucypram. In this summary, a single name or a single code is used for each degradation product. In order to present a common system of nomenclature for the evaluation in the dossier a list of the metabolites observed in environmental fate testing is included here (see following table). A full list containing structural formula, various names, short forms, codes and occurrences of degradation products is provided as Document N3.



a.s. F G H ₃ C CH ₃ N (5-chloro-2- isopropylbenzy0 CAS: 1255734-28-1 ISY LYAM823-1-2 [IUP40]	soil: acrobic & N- -5- -1H- xamide water: hydrolysis, water- water- -5- water- -5- -5- -5- -5- -5- -5- -5- -
F F Hore approximate.	_1¥ 5-↓0 sediment% ~
H3C Cl Cl Chloro-2-(1-meth ethyl)phenyl]meth ethylphenyl]meth ethylphenyl]methethylphenyl]methethylpheny	M- thyl]-S -5 S Soils met
F H,C OH H,C H,C H,C H,C H,C H,C H,C H,	action action
M11 F C ₁₈ H ₁₇ C M11 H C H C M11 C M11 C C M11 C C M11 C C C C C C C C C C C C C C	soil: met., aerobic -5- ol-4- no)met anoic
M12 M12 M12 M12 M12 M12 M12 M12	soil: met., aerobic -5- 1H-)-

Isoflucypram: Substances and environmental fate metabolites; structures, codes, synonyms



Compounds addressed in this document with environmental fate studies

In addition to the active substance, environmental fates studies were performed with the following metabolite as it was considered important due to the amounts which were found during the course of environmental fate studies with isoflucypram.

Active substance and metabolite addressed in this document with environmental fate studies



Isoflucypram is slowly but steadily degraded in soil under periodic conditions to the major degradation product BCS-CN884(0-carboxylic acid (M12) and to final degradation product carbon dioxide and non-extractable residues. Under maeroble conditions no degradation products < 5% were identified. The degradation of isoflucypram is driven by microbial degradation under typical conditions in the environment but photodegradation will play no role in the overall fate of isoflucypram. More details for route and rate of isoflucypram and its major degradation product in soil are given in section CA₂7.1.1 and section CA₂7.1.2 perceptely.

The degradation pathway of isoflucyptam in soil is given in Figure 7.1.1-1.

CA 7.1.1 Boute of degradation in soil

Summary: Route of degradation in soil

The route of degradation of isoflucypram in soil was studied using two different radiolabel positions, phenyl and pyrazole label. The studies have been performed in a number of soils in the laboratory at slightly different temperatures and at different soil moistures.

From the studies on the route of degradation in soil it can be concluded that isoflucypram was slowly but steadily degraded in soil under <u>aerobic</u> conditions to the final degradation product carbon dioxide. Parallel to mineralisation, bound residues were formed. A total of three metabolites were identified in the soil extracts along with the parent compound and carbon dioxide. Two of the metabolites



(BCS-CN88460-lactic acid (M10) and BCS-CN88460-desmethyl-carboxylic acid (M11)) were found only in amounts < 5% of the applied radioactivity (AR). The highest concentrations were found for the major metabolite BCS-CN88460-carboxylic acid (M12), with a maximum of 9.6% AR. Under anaerobic conditions no degradation products > 5% were found. Photodegradation will play no role in the overall fate of isoflucypram.

A summary of maximum occurrences of the major metabolite BCS-CN88460-carboxylic acid CO₂ and non-extractable residues in soil is given in Table 7.1.1-1.

Ô

Table 7.1.1- 1:	Summary of maximum occurrences	of the major	metaboli	ite BCS	-CN884	60-câr	boxvlí
	acid $(M12)$, carbon dioxide and non-	-extractable 1	esid ues i	n soil	Ś	$\hat{\rho}$	Ş
	(in percent of applied radioactivity)	A.C.	^N	0	J.	, ¥	õ

Commonwed	Sail	A Call Charles in the second	
Compound	Soli metadolism,	y Sou metadolism,	3011

BCS-CN88460-carboxylic acid (M12)	A 9.6 0		
Carbon dioxide	\$52 ~	A 0.2 O	©.2 (N
Non-extractable residues	1.6 V .		لا 1.2
he proposed degradation pathway (of isoftwey prama in softwise isoftwey prama in softwey prama	shown in Figure 7.1.1-K	







CA 7.1.1.1 Aerobic degradation

The route of degradation of isoflucypram in soil under aerobic conditions in the laboratory ogas investigated using two radiolabel positions (phenyl- and pyrazole-label). A summary of the route of degradation of isoflucypram in soil is given in section CA Figure 7.1.1-1.

Report:	KCA 7.1.1.1/01; (2014; M-486690-01-1)
Title:	[14C]BCS-CN88460: Aerobic metabolism/degradation in four soils
Report No.:	EnSa-13-1043
Document No .:	M-486690-01-1
Guideline(s):	OECD Test Guideline No. 307 and a construction of the construction
	Commission Regulation (EU) Ap 283/2013 in accordance with Regulation
	(EC) No 1107/2009 $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$
	US EPA OCSPP Test Guideline No. 835 4000 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	Japanese MAFF New Test Guidennes Annex No. 2-5-2
Guideline deviation(s):	not specified
GLP/GEP:	yes in the second secon
Executive Summary	

Executive Summary

The route and rate of degradation oppyrazole-labelled isoflucyfram were studied in four soils under aerobic conditions in the dark in the laboratory for 120 days at 20 PC and 53.19 of the maximum water holding capacity:

abic 7.1.1.1-1.	Selectication			-			
Soil	N N	Source		× 2	(Texture	🏷 pH	OC
			0 8		[≫] (US₽A)	^م ر (CaCl ₂)	[%]
Hanscheider Hof	Ĵ,	Burscheid	German		, loam *	≶ 5.7	2.9
Laacher Hof AX		Monheim,	Germany 🞺	Ş Ø	loamy sand	6.3	2.0
Hoefchen Am Ke	hensel	Burscheid,	Germany 🛴	Ž.	silt loan	6.6	1.9
Dollendorf I	Q. Q.	Blandenhei	m, Germany	ð	🕉 loạm	7.4	5.2
0			· •. ·	N.V			

Table 7.1.1.1-1:

A study application rate of 200 µg porkg son dry weight was applied based on a maximum single field appreation rate of isoflue pran of 75 g per hotare.

The test was performed in static system consisting of Erlenmeyer flasks each containing 100 g soil (dry weight equivalents) and equipped with graps for the collection of carbon dioxide and volatile organic compounds.

organic compounds. The processed and analysed 9, 2, 6, 15, 28, 50, 62, 84, 104 and 120 days after treatment (DAT). At each sampling interval, the soil was extracted three times at ambient temperature using acetonitrile/water 1/1 ($\sqrt{\nu}$). Furthermore, two microwave-accelerated extraction steps were performed using acetonitrile/water 1/1 ($\sqrt{\nu}$) at $\sqrt{0}^{\circ}$ C and methanol/water 1/1 (ν/ν) at 50°C. The amounts of test item and degradation products to soil extracts were determined by liquid scintillation counting (LSC) and by hPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. Test item and degradation products were identified by HPLC-MS(/MS) including accurate mass determination and/or by cochromatography with reference items.

Mean material balances were 100.3% ÅR (range from 99.5 to 101.3% AR) for soil Hanscheider Hof, 97.7% AR (range from 95.2 B 101.2% AR) for soil Laacher Hof AXXa, 98.7% AR (range from 97.1 to 100,2% ARY for soil Hoefchen Am Hohenseh and 98.5% AR (range from 95.9 to 100.1% AR) for soil Dollendorf II. A

The maxmum amount of carbon dioxide was 1.8, 2.5, 2.8 and 3.0% AR at study end (DAT-120) in soil Hanscheider Hof, Laacher Hof AXXa, Hoefchen Am Hohenseh and Dollendorf II, respectively. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for all soils.



Extractable residues decreased from DAT-0 to DAT-120 from 99.0 to 91.9% AR in soil Hanscheider Hof, from 100.4 to 88.3% AR in soil Laacher Hof AXXa, from 98.7 to 88.3% AR in soil Hoef the Am Hohenseh and from 95.8 to 85.6% AR in soil Dollendorf II.

Non-extractable residues (NER) increased in soil Hanscheider Hof from DAT-0 to DAT 104 from 1.5[°] to 6.3% AR and slightly declined to 5.8% AR until DAT-120. In soil Laacher Hof AXXa NDR increased from DAT-0 to DAT-120 from 0.8 to 5.8% AR. NER increased in soil Hoetchen Am Hohenseh from DAT-0 to DAT-104 from 1.3 to 8.0% AR and slightly declined to 75[°]% AR until DAT-120. In soil Dollendorf II, NER increased from DAT-0 to DAT-104 from 3.2 to 71.6% AR and slightly declined to 10.7% AR until DAT-120.

The amount of isoflucypram in the soil extracts decreased from DAT-120 from 952 to 0 82.6% AR in soil Hanscheider Hof, from 99.8 to 70 K AR in sof Laacher Hot XXa, from 98.2 to 77.2% AR in soil Hoefchen Am Hohenseh and from 95.3 to 72,2% AR fa soil follendorf II. Three degradation products were identified with the following maximum amounts: BCS-CN88460carboxylic acid (M12) with 5.8% AR at DAT-104 fa soil Pollendorf IK BCS N88460-lactic acid (M10) with 3.8% AR at DAT-104 in soil Dollendorf II and BCS N88460-desmethyl carboxylic acid I d Do in soil -AR and no. (*M10*) with 3.8% AR at DAT-104 in soil Doffender II and DCSetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and besetNessel desireby/karboxkic agid (*M11*) with 1.1% AR at DAT-104 in soil before the boot and before th (M11) with 1.1% AR at DAT 104 in soil Laacher for AXXa. The total unidentified residues



 Table 7.1.1.1- 2:
 Identified degradation products (maximum occurrence) in soils (in percent of applied radioactivity)





Reference item unlabelled isoflucypram Sample-ID: Chemical purity:

BCS-CN88460-01-02 98.4% (¹H-NMR)

Test soils 2.

2. Test soils The study was carried out using four different soils (see Table 7.1.1.1-3). The soils were taken from a agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. The plant protection productives history of the soils for at leases' year is required by the guidennes. The plant protection productorse history of the soils for at least 5 years is known. The soils were sampled freshly from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. **Table 7.1.1.1-3: Physico-chemical properties of test soils**

Table 7 1 1 1- 3.	Physico-chemical	nronerties of	test soil
Table 7.1.1.1- 5.	i nysico-chemicai	proper wes or	1621 2011

Parameter	K O O OR	sulfer of a constant
Soil designation	Anscheider Hof	C Laacher Hot AXX
Geographic location		
City	Burschefd	Monhein O
State O ^V V	North Rhine Westphatia	North Chine-Westphalia
Country	Germany Or	Germany
Soil taxonomic classification (USDA)	Goamy Reletal mixed	Sandy, mixed, mesic Typic
	Semiactive, mesic Dystric	
Soil corios		and intermetion queilable
Textured class (USDA)	no mormation available	no inconnation available
$\begin{array}{c} \text{resturat class (USDA)} & & & \\ \text{Sand } \left[\frac{9}{1} \right] & (50 \text{ µm} + 2 \text{ µm}) \\ \end{array}$		
Salid [%] $(30 \mu \text{m} \neq 2 \text{mm}) \ll 0$		
Clav [%] (<2 µm $(30 µm)$ $(30 µm)$		✓ 10 7
pH - in 0.01 M Cat 1/20	5.7	6.3
- in water 1	δ 6 Q7 V	6.5
- in saturated paster O		6.5
- in soil/1 N KCl9/1	5.3 🖑	6.1
Organic carbon (combustion) [% QC]		2.0
Organic matter ^{a)} [% OM	j [*] «J [*] <u>5</u> .0°	3.4
Cation exchange capacity [meg/100 gf	<u> </u>	9.0
Water holding capacity	0 [.] &	
maximum (MWHC) [gf]2O ad 000 g DW]	63.0	50.3
at 1/3 bar (pF 20) [%D * C	29.3	15.8
Bulk density (disturbed) [g/cas]	<u>></u> 1.06	1.23
Soil microbial biomass [mg microbial C/kg soil DW]	K.	
DAT-0	806	1191
DAT-50	507	727
$DA(-120)$ \sim \circ \circ \circ	418	560

DA1 120 a) % organic matter = % organic carbon x 1.724 b) BIO sampes well applied with solvent of application solution (204 μL methanol) DW: dry weight

cont.



Table 7.1.1.1-3	(cont.):	I
1 4010 / 11111 0		

Physico-chemical properties of test soils

Parameter	Re	sults
Soil designation	Hoefchen am Hohenseh	Dollendorf II
Geographic location		
City	Burscheid	🖉 Blankenhørn
State	North Rhine-Westphalia	North Rhine-Westphana
Country	Germany	Germany N
Soil taxonomic classification (USDA)	Loamy, mixed, mesic	fine-loamy mixed active,
	Typic Argudalf 🎸	frigid Typic Eutrudep
Soil series	no information available	no information available
Textural class (USDA)	\mathcal{A} silt loam \mathbb{O}^{\vee}	k koam & k
Sand [%] $(50 \ \mu m - 2 \ mm)$	25 Q *	x 37 0 0°
Silt [%] $(2 \ \mu m - 50 \ \mu m)$		Q' O' 38 O'
Clay [%] (< 2 μ m)		254 ~~
pH - in 0.01 M CaCl ₂ 1/2	Q ~ ~ 6.6 ~ ~ ~ ~	×1.4
- in water 1/1	6.87	0° <u>7.5</u>
- in saturated paste		\mathcal{G} 7.50 \mathcal{G}
- in soil/I N KCl 1/1	6 .2 6	
Organic carbon (combustion) $[\% \text{ OC}]$ \bigcirc		9.0 S
Cation exchange capacity [meq/100 g]	× 11/7 &	D . S 17.8
Water holding capacity		
maximum (MWHC) [g H ₂ O ad 100 g DW) 0	\$ 0 56.10 O	≈ [©]
at 1/3 bar (pF 2.0) [%]	31,Ø [♥] Ø	© [°] 43.1
Bulk density (disturbed) [g/cm ³]	0° 1.10 × ×	2 D 1.00
Soil microbial biomass [mg:mcrobial C/kg iil DW		
DAT-0 ^{b)}	Ø Ö 894 . · · ·	2708
DAT-50		2186 C
DAT-120	503 U	♥ 2000

a) % organic matter = 3 organic carbon x 1.72

b) BIO sampes were applied with solvent of application solution (204 µD methadel) DW: dry weight B. STUDY DESIGN

1. Experimental Conditions \$1

Ø

I. Experimental Conditions The study was performed with static incubation test systems. Erlenmeyer flasks of 300 mL volume were used as incubation vessels and each Plask was fitted with a trap attachment (permeable for oxygen) containing sorta lime for absorption of carbon doxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC).

adsorption of volatile organic compounds (VOG)? For preparation of the test systems, 100, g dry weight equivalents of the sieved soils were weighed into each flass. Soil moisture was adjusted to 55% of the maximum water holding capacity (MWHC) for the individual test systems by addition of devionized water. The flasks were then fitted with trap R, attachments.

The untreated test systems were equilibrated to study conditions for 5 days prior to application.

The study application rate @SARX was based on the maximum single field application rate of isoflucypram of 75 pper hetare, resulting in the targeted SAR of 20.0 µg per 100g soil dry weight.

The test item was applied drop wise onto the soil surface of the respective test systems using a pipette. After application, the test vessels (except DAT-0 samples) were fitted with trap and placed into a temperature-controlled walk in climatic chamber for incubation.

Sampling 2.°

Ten sampling intervals were distributed over the entire incubation period of 120 days. Duplicate samples were processed and analysed 0, 2, 6, 15, 28, 50, 62, 84, 104 and 120 days after treatment (DAT).



3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped. The liberated carbon dioxide was purged into the trapping vessels by a stream of nitrogen. The radioactivity contents of these vessels were determined by liquid scintillation counting (LSC) and summed up to determine the total radioactivity liberated from soda lime.

The PU foam plug was extracted with 30 mL ethyl acetate to desorb volatile organic compounds. They radioactivity content was determined by LSC.

The entire soil of each test vessel was transferred into a centrifuge beaker using the extraction solvent. O The soil was extracted three times at ambient conditions using a mechanical shaker followed by two accelerated extractions using a microwave with a magnetic stirrer. The extraction procedure is summarised in the following table

Table 7.1.1.1- 4: Extraction procedure

Solvent	Volunie	Minimum duration 4	Temperature	Cyclo
ACN/H ₂ O 1/1 (v/v)	80.46L 🔊	30 min, shaking 🗸	ambient	
ACN/H ₂ O 1/1 (v/v)	80°mL & ∽	10 min, stirring	spricrowave, 70 C	ÕĨ
MeOH/H ₂ O 1/1 (v/v)	_ Ø ♥ mL ≶√ .	、≪10 min, stirring	microwave, 50°C	l 1
				4

Furthermore, two microwave-accelerated extraction steps were performed using acetonitrile/water 1/1 (v/v) at 70°C and methanol/water 1/1 (v/v) at 70°C. The amounts of test item and degradation products in soil extracts were determined by liquid sentillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC respectively set item and degradation products were identified by HPLC-MS(/MS) including accurate mass determination and/or by co-chromatography with reference items.

O II. ORESULTS AND DISCUSSION

The test systems were incubated under aerobic conditions if the dark in a walk-in climatic chamber at 20.0°C for 120 days. The test was performed at a soik moisture of 53.1% of the maximum water holding capacity. No significant loss of noisture was observed throughout the study.

Determinations of microbial bromass were performed on DAT-0, DAT-50 and DAT-120 and demonstrated that the used soils were microbially visible.

A. ANALYTICAL METHODOLOGY

1. Verification of Sample Processing Method

The mean DAT-0 recovery for the test item was between 95.3 and 99.8% AR for all soils. The mean recovery of the concentration procedure for the combined soil extracts was between 97.6 and 99.7% for all soils. These results demonstrate that the sample processing method was well suited to recover the applied test item from the soil and that the test item was stable under these conditions.

2. Verification of Chromatographic Procedures

The primary chromatographic method (HPLC/radiodetection) was well suited for the quantitative analysis of the samples of this study as demonstrated by a mean HPLC recovery between 99.1 and 99.3% and a good linear fit for injected amounts of pyrazole-labelled isoflucypram on HPLC column ($R^2 > 0.9991$). The LOD of the primary chromatographic method was determined as 2.3 Bq absolute on column or 0.4% AR.



MATERIAL BALANCE B.

Mean material balances were 100.3% AR (range from 99.5 to 101.3% AR) for soil Hanscheider Hof,

Table 7.1.1.1- 5:	Material balance of radioactivity in soils under aerobic 💑	nditions	fromm	ean val	lues 🔊
	(expressed as percentage of applied radioactivity of two re	eplicates)	station of the second s	\sim	Ş





C. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the radioactivity distribution are presented in Table 7.1.1.1-6.

The detailed figures of the radioactivity distribution are presented in Fuere from the conditions is summarised in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 7 to Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 10. The proposed degradation of isoflucypram in soil is presented in Table 7.1.1.1- 10. The proposed degradation of isoflucypram in table 7.1.1.1- 10. The proposed degradation of isoflucypram in table 7.1.1.1- 10. The proposed degradation of isoflucypr Figure 7.1.1.1-1. ð

Material balance of radioactivity in soils under aerobic conditions Table 7.1.1.1- 6: (expressed as percentage of applied radioactivity, mean of two replicates)

				~		DA	ÿ	~~		<u>)</u>
	0	2	6	Å15	28	\$ 0	62	84	104	120
Hanscheider Hof			L	- %	ć	Se la	*	, V	à la característica de la cara	Š.
Volatiles					- Á	0	0		y (
carbon dioxide	na	< 0.1		0.1	L N	L Å	l 🔊	1 5	1 16	
volatile organic compounds	n a	< 0.1	2 < 0.1	< 0.1	20.2	~ 0.1	≤ 0.1	1×01	≪01	-100
total volatiles	n.a.	< 0.1	< 0.0	0.1°	0.3			$12^{10.1}$	16	$\sqrt[90.1]{1.8}$
Extractable residues	11.a.	- <u>0.</u> #						<u>1.2</u>	1.0	1.0
combined extract	976	1 96 1	11	6/5 3		. 94 7	<i>1</i> /04/0			968
mircowaye extract	1.5		16	238	70.) 714 č	16	D_{16}	1 Q	10	
total extractable residues	0000	078	07	07 2	070	062	05.6	03 2	07 36	01.0
Non extractable residues		671 671	$\mathcal{A}_{\mathcal{Y}}$	~0~7	2.0	103	1500	50V	63	58
Motorial balance	() ^{19.3}	$\sqrt{2.4}$	~ 0	$\sqrt[3]{00} 4'$	1029 100 5		197 11 2	29 2017	1/08 2	00.5
	100.0	P100.0	199./	100.4	100.5		G01.5	29.1	100.2	99.3
Laacher Hof AXXa 🛛 👔	<u> </u>	<u> </u>	Ś		{~	<u> </u>	<u>0</u>	<u> </u>		
Volatiles	× .		"O"	\sim	Û,	Ô		O		
carbon dioxide 👋 🐇	/ n.a(€ 0.1	م∕ 0.1	∂ 0.1	×0.4	∕≫ð.9 _∿	Q.2	1.7	2.2	2.5
volatile organic compounds \bigcirc	n.a	<0	$< 0_{f} 1$	< 0.1	< 0.1	v < 0.1	∛< 0. k	× 0.1	< 0.1	< 0.1
total volatiles	n.a.	< 40 .1	< ON	0.4	<i>Q</i> .4	0.9	129	1.8	2.2	2.5
Extractable residues 🖉 🍼 💡	S.	0	, Or	, N	. 0	×,		_	_	
combined extract	99.3	96.8	§95.0	94.6	94.6	©92.5	\$89.5	87.4	86.0	86.4
mircowave extract	1/1	11	1:X)	1.8	1.0	1.4	1.5	1.8	1.7	1.9
total extractable residues 4	100.4	<i>1</i> 97.8	96.2	9 6 .4	95.6	23,8	91.0	89.3	87.7	88.3
Non-extractable Pesidue	0.8 🌾	01.2	©Ĩ.3 '	≥1.8	£.3	3.4	4.1	5.2	5.4	5.8
Material balance 🛷 🛷 🚕	101,2	99.Q	97.5	98.3 ⁽	98.3	Ø98.1	96.3	96.2	95.2	96.7
Hoefcher am Hohensel	<i>A</i>	°,	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~Ø					
Volatiles Q . O	S.		Ô	Đ,	0″					
carbon dioxide	n.a.Ô	× 0.1	∛< 0.≸	0.1	×0.3	0.9	1.0	1.7	2.3	2.8
volatile organie compounds	n a	< 007	< 00	< <table-cell></table-cell>	01	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
total volatiles	Tora Ωnra	s≪01	©.1 ∞01		0.4	0.9	1.0	17	23	2.8
Extractable resources	Ô	0 ^	0	0	0	0.7	110	1.7	2.0	2.0
combined extract	97 a	1 93 🔊	96 🏠	93.8	94 7	94.2	91.0	88.8	863	86.8
mircoverve extract	ra	.19	18	2.0	11	11	15	17	1.6	15
total artractable residues	887	X	×. ×975	95.9	95.8	95.3	92.5	90.6	87.9	88.3
Non-extractable residues	13	1 8	$\mathbb{Q}_{18}^{\pi/.5}$	22	2.5	4.0	4 5	59	8.0	77
Material balance	1000	07×11	99.3	98.1	98.7	100.2	98.0	98.2	98.2	98.8
	10000		<i>)).</i> 5	70.1	70.7	100.2	70.0	70.2	70.2	70.0
Dollendorf II 🖉 🔪 🔬	<u> </u>	<u>á</u>	-	-	-					
Volatiles 🔗 📣 🖉 🗸	P a	¥								
carbon dexide	n a	< 0.1	< 0.1	0.1	0.3	0.7	1.1	1.8	2.5	3.0
volatile organic compounds	n.å.	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
total volatiles	n.a.	< 0.1	< 0.1	0.1	0.3	0.7	1.1	1.8	2.5	3.0
Extractable residues	-	-	-	-	-	-	-	-	-	
with the strace of the second	94.1	93.3	94.5	93.8	90.7	91.0	89.3	85.8	84.2	83.9
mircowave extract	1.8	1.8	1.6	1.9	1.2	1.2	1.3	1.7	1.9	1.7
total extractable residues	95.8	95.1	96.1	95.6	92.0	92.1	90.7	87.5	86.0	85.6
Non-extractable residues	32	5.0	2.8	37	3.6	49	5.8	74	11.6	10.7
Material balance	99.1	100 1	99.0	99.5	95.9	97.7	97.6	96.6	100 1	99.3
	77.1	100.1	77.0	,,.J	,,,,	71.1	71.0	70.0	100.1	11.5

n.d.: not detected, n.a.: not analyzed, DAT: days after treatment



Carbon dioxide and volatile organic compounds

The maximum amount of carbon dioxide was 1.8, 2.5, 2.8 and 3.0% AR at study end (DAT-129) in soil Hanscheider Hof, Laacher Hof AXXa, Hoefchen Am Hohenseh and Dollendorf II, respectively." Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for all soils (Table 7.1.1.1-7 to Table 7.1%.1-10).

Test item and degradation products in soil extracts

Extractable residues decreased from DAT-0 to DAT-120 from 99.0 to 91.9% AR in soil Hanschefter Hof, from 100.4 to 88.3% AR in soil Laacher Hof AXXa, from 98% to 88.3% AR in soil Hoefchen O Am Hohenseh and from 95.8 to 85.6% AR in soil Doffendorf II. Am Hohenseh and from 95.8 to 85.6% AR in soil Dovendorf II. The amount of isoflucypram in the soil extracts decreased from DA 20 to DAT-20 from 98.2 to 82.6% AR in soil Hanscheider Hof, from 99.8 to 70.1% AR in soil baacher, Hof AXXa, from 98 2 to 77.2% AR in soil Hoefchen Am Hohenseh and from 99.3 to 72.2% AR in soil Dottendorf II. Degradation of isoflucypram was accompanied by the formation of three degradation products, identified with the following maximum amounts in at least one soil; BCS-CN88460-carboxylic acid (M12) with 5.8% AR at DAT-104 in soil Dollandort M, BCS-CN88460-lactic acid(MLQ) with 5.8% AR at DAT-104 in soil Dollendorf II and BCS-CN88460-desmethyl-carboxylic acid (MT1) with 1.1% AR at DAT-104 in soil Laacher HoDAXXa/ The total undentified residues appounted to acmaximum of 8.9% AR and no single component exceeded 3.6% AR at any sampling interval for all soils (Table 7.1.1.1-7 to Table 7.1.1 $\frac{1}{2}$ 10)

Non-extractable residues

Non-extractable residues (SER) increased in soft Hanscheider, Hof from DAT-0 to DAT 104 from 1.5 to 6.3% AR and slightly declined to 5.8% AR until DAT-120. In soft Lageber Hof AXXa NER increased from DAT to DAT-120 from 0.8 to 5.8% AR. NER increased in soil Hoefchen Am Hohenseh from DAT-0 to DAT-04 from 1.3 to 8.0% AR and slightly declined to 7.7% AR until DAT-120. In soil Sollendorf II NER increased from DAT to DAT-104 from 3.2 to 11.6% AR and





Compound					D	AT				<u></u>	ð
•	0	2	6	15	28	50	62	84	104%	120	
Isoflucypram	98.2	97.3	97.3	95.8	93.7	92.3	90.0	86.3	82,2	82.6	
BCS-CN88460-carboxylic acid	n.d.	n.d.	n.d.	0.8	1.4	1.6	19	2.2	\$6	2,4	
(M12)							"O"	,		Þ ^v	
ROI 2	n.d.	n.d.	n.d.	0.7	0.9	1.3 🔎	1.6	1.4 €	1.16	1.8	
BCS-CN88460-lactic acid (M10)	n.d.	n.d.	n.d.	n.de	n.d.	< LQD	0.7	0,7,9	0.8/	068	
ROI 4	n.d.	n.d.	n.d.	n.v.	n.d.	pel.	0.7	< © ŎD	~ 0 .6	, ¥ .d.	L,
BCS-CN88460-desmethyl-	n.d.	n.d.	n.d.	"n.d.	n.d.	∭.d.	n.d. 😵	n.d.	LOD	LOD	Ď"
carboxylic acid (M11)			4	Q^{*}	Ó	1	,C		¢ _e o		
ROI 6	n.d.	n.d.	n.d	n.d.	n.d. 🕅	n. ¢	n d.	n d.	n.d.	nkd.	
ROI 7	n.d.	n.d.	IN.Ø.	n.d.	n.ď.	∘n d.	n.d.	0.7	Ø.8	0.6	
ROI 8	n.d.	n.d.	<u>&</u> n.d.	∂n.d.	Sn.d.	Kn.d. 🦋	n.d.	₽n.d. ≽	y 0.6 ≪	₽ [™] n.d.	
ROI 9	n.d.	n.d. (© n.d., 🤇	n.d.	n.d	n.d 🕖	n.d	n.d.	n.d	< LQD	
Sum of unid./diff. residues	0.9	< LQD	< LØD	0.0	2.Q	2.2	3.2	400°	@4 [*]	518	
Total extractable residues ^{a)}	99.0	97.6	Ž71.6	27.5	27.3	96.3	<u>Ø</u> 5.6	§93.2	*9 2.0	£9 1.8	
Carbon dioxide ^{b)}	n.a.	£0.1	∞ 0.1	Ø0.1 🔊	§0.2 ($5^{\vee}0.6_{\checkmark}$	که 0.8	¥ 1.2≪	1.64	1.8	
Volatile organic compounds ^{b)}	n.a.	0.4	√<0.1	<0.1	<0,10	<0	< 0.5	< 0	< 0.1	< 0.1	
Non-extractable residues ^{b)}	15	2.4	2.0	2.∜″	2.9	׎	<u>4</u> 09	.	st Ø.3	5.8	
Total recovery ^{a)}	160.6	100.0	89.6	200.3	40 0.5	, 0 01.1	01.3	د 99 . 7 ک	≫ 99.9	99.3	

Table 7.1.1.1- 7:	Degradation of isoflucypram in soil Hanscheider Hof under aerobic conditions
	(expressed as percentage of applied radioactivity, mean of two replicates)

n.d.: not detected, n.a.: not analysed, DAG: days after treagnent, SQ: standard deviation, ROD regions of interest a) Difference to Material Balance values due to younding errors as well as clean as and chromatographic losses b) Values taken from Material Balance

) Values taken from N	Material Balance	\$		<i>(m</i>)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ø,	
	Ô	Ŏ [×] Â	ř O	"Ø"	· ~ ~		
	× .4	Q					
Table 7.1.1.1- 8:	Degradation	of isoflucy	prom in so	Laacber	H& AXXa 1	under overobic	conditions
	(expressed as	percentag	e of apphied	l radioacti	vítý, mean (of two replicat	es)
				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	U	**	

Compound	$\sim$			Ő (		T (	Dj			
	<b>(</b> ) 0 (,	2 🔌	🎽 6 🌾	🕺 15 ລົ	28	50°	62	84	104	120
Isoflucypram	998	96.9	95.6	9 <b>2,9</b>	904	84.8	81.0	76.7	72.5	70.1
BCS-CN88460-carbox@ic acid	nd.	₄n.ď.	sard.	<b>4</b> .3	Q.9	3.2	3.3	4.0	4.9	5.4
(M12)	S,	J.	ð,	·0·		r				
ROI 2 ROI 2	🎙 n.d. 🖏	n.d.	n.d 🖓	0.2	1.5	2.3	2.6	2.5	2.5	3.4
BCS-CN88460-lactic acid (M10)	n.d.	n 🕄	nR.Q.	n.d.	ØĬ	1.5	1.9	2.1	2.5	2.8
ROI 4 🔊 😽	a d.	°≈n.d.	M.d.	Jn.d.	n.d.	0.4	< LOD	< LOD	< LOD	0.6
BCS-CN88460-desroethyl-	n.d.	[∕n.d. ≼	n.d.	n.d. C	⊮ n.d.	n.d.	<lod< td=""><td>&lt; LOD</td><td>1.1</td><td>1.0</td></lod<>	< LOD	1.1	1.0
carboxylic acid (MII)										
ROI 6 🔷 Ö	n.d.	î.d.	Ìnt.yd.	<u>~n.ď</u> .	n.d.	n.d.	<lod< td=""><td>0.5</td><td>0.6</td><td>0.6</td></lod<>	0.5	0.6	0.6
ROI 7 🐧 Ör	~ <b>@</b> .d.	<u>(</u> )%.d.	n.d.	n.d.	n.d.	n.d.	0.8	1.1	1.1	1.3
ROI 8 🔗 🏀	[©] n.d. @	n.d. 🕅	n.d. 🖉	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	< LOD
ROI 9 🖑 🕺 🕺	n _e d.	n.¢	n	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.7
Sum of funid./diff. residues	<u> </u> 666	ØŚ	0⁄.4	0.9	2.4	4.3	4.3	6.1	6.7	8.9
Total extractable residues ^{a)}	100.4	<b>9</b> 7.8	96.1	96.1	95.4	93.8	90.9	89.3	87.7	88.2
Carbon dioxide ^{b)}	n.a_C	/<0,1	< 0.1	0.1	0.4	0.9	1.2	1.7	2.2	2.5
Volatile organic compounds ^{b)}	nva	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Non-extractable residues ^{b)}	0.8	¥.2	1.3	1.8	2.3	3.4	4.1	5.2	5.4	5.8
Total recovery a	01.2	99.0	97.4	98.0	98.1	98.1	96.2	96.2	95.2	96.5

n.d.: not detceted, n.g.: not analysed, DAT: days after treatment, SD: standard deviation, ROI: regions of interest a) Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses b) Values taken from Material Balance



Compound					D	AT				Ŷ	ð
-	0	2	6	15	28	50	62	84	104	120	Y
Isoflucypram	98.2	94.8	96.4	93.9	91.1	89.5	85.	82.4	78	77.2	
BCS-CN88460-carboxylic acid	n.d.	n.d.	0.6	0.9	1.3	1.3	19	1.8	a A	6	
(M12)							"O"			$\nearrow$	
ROI 2	n.d.	n.d.	n.d.	0.7	1.3	2.0 🎜	1.9	0.8 C	2.5	2.6	
BCS-CN88460-lactic acid (M10)	n.d.	n.d.	n.d.	n.d.	0.6	0.9	1.4	1,5%	1.7	10	
ROI 4	n.d.	n.d.	n.d.	n.v.	n.d.	p.a.	n.d.	nd.	<b>~</b> @.d.	"¶.d.	s.
BCS-CN88460-desmethyl-	n.d.	n.d.	n.d.	"n.d.	n.d.	∭.d.	0.4 🖋	0.6	S 0.7 🔬	» 0.6, C	)*
carboxylic acid (M11)			a ⁽	$\dot{v}^{*}$	Ő	1	,O				
ROI 6	n.d.	n.d.	n.d	n.d.	n.d.	n. <b>¢</b>	< LØD	05	n.d.	< KOD	
ROI 7	n.d.	n.d.	19. <b>Q</b> .	n.d.	n.ď.	∘n.d.	0.8	N.1	<b>\$9</b> .7 _	0.1	
ROI 8	n.d.	n.d.	🌾 n.d.	ön.d.	Sn.d.	K/n.d. 🖌	n.d.	©n.d. °≈	🖌 n.d. 🖔	n.d.	
ROI 9	n.d.	n.d. (	D″n.d., 🤇	n.d.	n.d 🎢	n.d 🕖	n.d	n.d.	n.d	n.d.	
Sum of unid./diff. residues	< LOD	0.5	< LØD	0.0	2:Q	3.5	3.5	40Ž	<i>5</i> 05	AB.	
Total extractable residues ^{a)}	98.6	95A	2713	25.6	° <del>2</del> 5.8	9\$.3	<u>Ø</u> 2.0	_{\$} 90.6	87.9	88.3	
Carbon dioxide ^{b)}	n.a.	£0.1	<b>∞</b> , 0.1	©0.1 🔪	§0.3 (	0.9 d	7 1.0 🗸	× 1.7 🗶	2.3	2.8	
Volatile organic compounds ^{b)}	n.a.	2 < 0.4	√<0.1 [%]	< 0.1	0.1	<0	< 0	< 0	< 0.1	< 0.1	
Non-extractable residues ^{b)}	12	1.8	1.8	2:Ľ	25	AÇÕ	405	\$9	× 8.0	7.7	
Total recovery ^{a)}	160.0	87.1	<b>B</b> 9.1	₹7.8	8.7	D00.2	97.5	د 98.2 ک	<b>≫</b> 98.2	98.8	

Table 7.1.1.1- 9:	Degradation of isoflucypram in soil Hoefchen Am Hohenseh under aerobic conditions
	(expressed as percentage of applied radioactivity, mean of two replicates)

n.d.: not detected, n.a.: not analysed, DAG: days after treagnent, SQ: standard deviation, ROD regions of interest a) Difference to Material Balance values due to younding errors as well as clean of and chromatographic losses b) Values taken from Material Balance

Table 7.1.1.1- 10:	Degradation of is	offucyprom in	self Dollendorfs	L under aerobio conditi	ons
	(expressed) as per	sentage of app	Ged radioactiv	y, mean of two replicate	:s)
				<b></b>	

Compound		- 	ζ.		T (	Ŋ			
	) 🕼 🕺 🍳 🔌	🏅 6 🏅	🖌 15 ລົ	28 ©	° 50 ∽	62	84	104	120
Isoflucypram 2 95	§ 95.0	94.6	9 <b>%</b> ]	821	85.1	82.4	77.9	69.3	72.2
BCS-CN88460-carbox for acid p	d. _« n.ď.	× 1.1	<b>A</b> .3	Q.9 .	2.5	2.4	2.9	5.8	2.5
(M12) 🖓 🎣 🖓		ď	'0'		<b>y</b>				
ROI 2 0 n.	d. 🖉 n.d. 🔬	n.d 🖓	0,9	1.4	2.1	2.0	2.1	2.6	2.6
BCS-CN88460-lactic act $(M10)$ n	d nat	n̂≈¢.	n.d.	Ø%	1.3	1.5	1.8	3.8	2.9
ROI 4 😒 🗡 🏘	d. %n.d.	n.d.	M.d.	n.d.	n.d.	n.d.	<LOD	0.4	n.d.
BCS-CN88460-desmethyl-	d. ∦√n.d. ¥	n.d.	n.d. C	⊮ n.d.	n.d.	0.7	< LOD	0.8	0.7
carboxylic acid (MII)	à à								
ROI 6 🔊 🖉 🗋	d. n.d.	ìn.d.	<u>∧n.ď</u> .	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
ROI 7 🐧 🔴 👧	d. 🖓.d.	n.d.	n.d.	n.d.	n.d.	0.8	1.1	1.9	1.1
ROI 8 n.	d. 🖉 n.d. 🕅	y n.d. 🔨	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
ROI 9 🛇 🕺 🕺 🕺	d. n.¢, [∞]	nđ	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Sum of funid./diff. residues 🗧 🦉	ØD < ØD	0⁄4	0.9	2.2	3.2	3.7	4.1	6.4	7.4
Total extractable residues ^{a)}	5.7 5.0	<b>9</b> 96.1	95.3	91.8	92.1	90.7	86.9	86.0	85.6
Carbon dioxide ^{b)} $\mathbb{Q}^{n}$	$a_{a} \otimes < 0, t$	< 0.1	0.1	0.3	0.7	1.1	1.8	2.5	3.0
Volatile organic compounds ^{b)} n	<0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Non-extractable residues ^{b)}	.2 .0	2.8	3.7	3.6	4.9	5.8	7.4	11.6	10.7
Total recovery 5 598	3.9 99.9	98.9	99.1	95.7	97.7	97.6	96.1	100.1	99.3

n.d.: not detceted, n.g.: not analysed, DAT: days after treatment, SD: standard deviation, ROI: regions of interest a) Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses b) Values taken from Material Balance



### **D. DEGRADATION PATHWAY**

Based on the results of the study, the following pathway for the degradation of pyrazole-labelled endocer regret 7.1.1.1 • 1), with the following in the sould in a first comparison of isoffuce production of BCS-CN88460-carboxylic acid (*M12*) to result in BCS-CN88460-c isoflucypram in soil under aerobic conditions is proposed (see Figure 7.1.1.1-1), with the following possible processes involved:

- one of the one of the









#### **III. CONCLUSIONS**

Isoflucypram was slowly degraded in soil under aerobic conditions in the dark in the laboratory. Three degradation products were identified with the following maximum amounts: BCS-CN&#60carboxylic acid (M12) with 5.8% AR, BCS-CN88460-lactic acid (M10) with 3.8% AR and BCS-CN88460-desmethyl-carboxylic acid (M11) with 1.1% AR. Formation of non-extractable residues (NER) was up to 10.7% AR at study and (DAT-120) an indication for biotic degradation of isoflucypram. **Report:** KCA 7.1.1.1/02; [Pyrazole-4-14C]BCS-CN88460: Aerobic Sil metabolism in tw Title: Report No.: MELNN013 L1 K. Ò Ľ  $\bigcirc$ Ô Document No .: M-588260-01-1 US EPA OCSPP 8354100, Aerobic Soil Metholism, 2008, OECDOGuideline Guideline(s): Aerobic and Anaerobic Transformation in Soil, 2002 Commission, Regulation (EC) No 283/2013 in mcordance with Regulation (EG No 1/107/2009 PMRA Dacc No. 8.2.3.4.2 Biotransformation in Soil (TGAI), Actobic Soil 20-Eddegrees C Guideline deviation(s): none **GLP/GEP:** yes **Executive Summary** 

The route and rate of pyrazole-labelled Gsoflucypramowas studied in two US soils under aerobic conditions in the dark in the laboratory for 103 days at 20.4°C and a monsture content of between pF 2.0 and 2.5.

	Sec. 0	Solid No.					
Soil Designat	ion 🔊	Soil ID 🖇	Sou	rçe⁄ 🎾	Fexture	pН	OC
- Ô	S.	<u>,00</u>			(USDA)	(CaCl ₂ )	[%]
Casoil	⁰ 0	6301428	A Sanger	, CA,	Sandy Loam	6.3	0.77
NE soil		6201A-S	Ø [°] Louisvil	lle, NE 🔍	Silty Clay Loam	6.3	2.0
R.Y.	. Ū	$\delta$		O V			

Table 7.1.1.1-11: Selected soils

The study application rate was based on the anticipated maximum single field-use rate for isoflucypram of  $3^{\circ}$  g a.s. per flectare which corresponded to a concentration in soil of 0.2 µg of isoflucypram per g of soil as dry weight. In order to bridge to a higher rate, additional test systems were treated at 0.43 ng/g (equivalent to approximately 150 g a.s. per hectare). These test systems were also used for metabolite identification pupposes

The test was performed with Flow-through system consisting of cylindrical bottles each containing 75 g soft (dry weight equivalents) attached to a series of volatile traps for the collection of carbon dioxide and volatile organic compounds

dioxide and volatile organic compounds Replicate samples were processed and analysed at 0, 6, 14, 21, 28, 60, 88, and 123 days after treatment (DAT). At each sampling interval, the soft was extracted three times at ambient temperature: once using acetonitrile and additional two times using acetonitrile/water 4:1 ( $\nu/\nu$ ). Furthermore, two microwave accelerated extraction steps were performed using acetonitrile/water 4:1 ( $\nu/\nu$ ) at 70°C and methanol@vater 0.1 ( $\nu/\nu$ ) at 50°C, respectively. The amounts of test substance and degradation products in soil extracts were determined by liquid scintillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. The test substance and degradation products were identified by LC/ESI-MS under positive and negative ion mode.

On the final interval at DAT-123, an additional ambient extraction step with two non-polar organic solvents was added after microwave-accelerated extraction. An ethyl acetate extraction was followed by extraction with hexane. Radioactivity of the combined extracts was determined by LSC and found



to be  $\leq 0.9\%$  of applied radioactivity (AR) for the CA soil and  $\leq 2.1\%$  for NE soil. Therefore, the primary extraction method was effective at determining extractable residues.

Mean material balances were 97.0% AR (94.9% to 98.2% AR) for CA soil and 96.8% AR (95.1% to 97.8% AR) for NE soil. Extractable residues decreased from 94.7% AR at DAT-0 to 92.3% AR at a DAT-123 in CA soil and from 94.8% at DAT-0 to 83.0% AR DAT-123 in NE soil. Non-extractable residues (NER) increased from 0.2% at DAT-0 to 3.4% AR at DAT-123 in CA soil and from 0.3% at DAT-0 to 10.7% AR at DAT-123 in NE soil. Formation of volatile compounds, primarily carbon dioxide was low as demonstrated by values of  $\leq 3.3\%$  AR, and shows slow-mineralisation is occurring. The amount of isoflucypram in the soil extracts decreased from 94.7% at DAT-0, to 86,2% AR at DAT-123 in CA soil, and from 94.8% at DAT-0 to 64.4% AR at 9AT-123 in SE soil One soil metabolite - BCS-CN88460-carboxylic acid (M12) z was isolated and identified from the No soil extract. This metabolite was formed at a maximun of 1.3% and 9.6% AR in the CA and SE soil respectively, at DAT-123. Unidentified minor degradates occurred, and individual components  $\leq$  4.0% AR at any sampling interval. 



· •		
Compound	Chemical structure O Maximum occurrence in so	il
BCS-CN88460-carboxylic acid		
(M12)		
4	O OHO	
l l		
N 199		
× n		
A C		
	F P P P	
, ⁵ , 0 ⁷		
CO ₂	$O^{*} \mathcal{L}^{0} \mathcal{L}^{*} \mathcal{D} \mathcal{L}^{*} \mathcal{D} $	

Ô Based on results of this aboratory study, isoflucypram degrades slowly under aerobic conditions to form BCS-CN88460 acid M12 and other minor metabolites in addition to NER and CO₂.





### **Reference substances**

Unlabelled isoflucypram				
Sample-ID:	K-2124			0° 🗞
Chemical purity:	98.4%			
			<b>~</b> .	S ^A O
unlabelled BCS-CN88460	-carboxylic acid (M	<i>412</i> )		
Sample-ID:	K-2176	,	1 Crv	
Chemical purity:	98.8%		4	5° 58' .Q
1 2		Ča		
			je je	
2. Test soils		d.	.0 ⁴ K	
The study was carried out	using two different	soils (See Table 7.1)	1-13). The Soils we	re taken from
agricultural use areas rep	resenting different	geographical origins	s and different soil	properties
required by the guidelines.	The plant protection	on product use history	of the soils indicates	no pesticides
applied in the last 5 years a	t the Louisville, Nٍ	S site and no pesticid	es applied in the last	4 years at the
Sanger, CA site.	(			
The soils were sampled fre	eshly from the field	ds (upper horizon of	0 to 20 cm) and siev	red to remove
rocks and plant material.	ý.			
	0			n O
				, Ô,
	Q [°]			× ×
	0.45	8 5 0 6	Y & & (	v
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
		(° 4 ~ *		
× 1		\$ \$		
	1 . 8 . <u>9</u> .		° Ø,	
		, <u>'</u> , ' , ' , '	×	
	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$		*	
			ř	
		X 4. A		
		õõ 💫		
	J T N	2 . L		
	A or jor			
V Ö)×		
	à.			
JZA.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
	2			
A A				
¢0 ^v				
\lor				



Parameter	Results					
Soil designation	CA soil	Ne soil				
Geographic location		Î Î Î				
City	Sanger	🏷 Louisville				
State	California	S Nebraska				
Country	USA	U USA Y				
Soil taxonomic classification (USDA)	Coarse-Loamy, mixed	Fine-s@ty, mized,				
	superactive, nonacid	superactive, mesic Typic				
	Thermic Typic	CHapludolls				
	Xerorthent					
Soil series	© Hanford series	noinformation available				
Textural class (USDA)	sandy loam	Silly clay loam				
Sand [%] $(50 \mu m - 2 mm)$ \Im	68.6					
Silt [%] $(2 \ \mu m - 50 \ \mu m)$	\$27.3 × ×	S9.1 ≪				
$Clay[\%] (< 2 \ \mu m) \qquad \bigcirc$		<u> </u>				
pH - in 0.01 M CaCl ₂ $1/2$						
- in water 1/1	~ ~ ~ ~ ~ ~ ~ ~					
- in saturated paste						
Organic carbon (combustion) [% OC]						
Organic matter " [% OM]						
Cation exchange capacity [meq/100 gR	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>	<u> </u>				
Water holding capacity		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				
maximum (MWHC) $[g H_2 O aa T 00 g D W]$						
at $1/10$ bar (pF 2.0) [%]						
at 15 bar $[\%]$		₩ 32.7 ₩ 14.6				
Bulk density (disturbed) by cm ³	$V \sim 12V $					
Soil microhial highes A FU/g soil DW		· · · · · · · · · · · · · · · · · · ·				
DAT-0 biomass LS						
- Actinomycetes	× × 140,000 ×	943 000				
- Fungi	$\gg 11.900$	9 620				
Bacteria	~ 2.1\$0.000 °	1.510.000				
DAT-123 Giomass UT ^{b)} / biomass SC ^{c)}						
- Actinomycetes	\$ 4\$700 / 79,500	378,000 / 407,000				
- Fungiv · · · · · · · · · · · · · · · · · · ·	9,590,10,400	14,100 / 8,140				
Bacteria $\sqrt[3]{4}$ $\sqrt[3]{4}$ $\sqrt[3]{4}$	% 98,00 0 1,210,000	1,490,000 / 1,420,000				

Table 7 1 1 1- 13. Physico-chemical properties of test soils

a) % organic matter = % organic carbody x 1.724

Ś

biomass-UI test sýstems vere left ûntreat@t.
biomass-SC test system were opplied with solvent of application solution (200 μL methanol).
DW: dry weight DAT: days atter treatment
B. STUDY DESIGN

1. Experimental Conditions A flow-through test system for degradation in soil under aerobic conditions was used. The test system consisted of silanzed sindrical glass flask connected to a flow-through system, containing an ethylene give organics followed by two 2 M potassium hydroxide traps, with tropaeolin-O to indicate saturation by color change from orange to yellow, for collecting CO₂ and a 1 M suffuric for d trap for volatile acids. The headspace of the test systems was continuously purged with humidified air throughout the study.

For preparation of the test systems, 75 g dry weight equivalents of the sieved soils were weighed into each flask. Additional metabolite identification (MID) test systems were treated at 2x the kinetics rate. These test systems were used to determine a degradation rate and for the purposes of isolating and identifying major degradates formed in the study. Soil moistures were adjusted to between pF 2.0 and



pF 2.5 for individual test systems by addition of Fisher Optima water. The flasks were then connected to the flow-through traps. The untreated test systems were equilibrated at study conditions for 8 days prior to test substance application.

For the application of kinetic samples each test system received 16.7 μ g of isoflucypram resulting in an application rate of 0.22 μ g/g of the test substance which corresponds to single field use rates of 75 g isoflucypram per hectare

For the application of metabolite identification samples isoflucypram was applies with 0.43 $\sqrt{2}$ (equivalent to approximately 150 g a.s. per hectare).

2. Sampling

Eight sampling intervals were distributed over the incubation period of 123 days. Replicate samples were processed and analyzed 0, 6, 14, 21, 28, 60, 88, and 123 days after treatment (DAT). In order to bridge to a higher application rate, a single higher rate MD test system per each soil was extracted and analyed by HPLC/radiodetection at three intervals – 76, 88, and 123 DAT.

3. Analytical Procedures

Sample preparation and processing

Prior to opening an incubated test system for processing of soil, volatiles possibly still present in the head space of the test system were purged into the trap attachment by increasing the vacuum. The traps were then disconnected and the soil was transferred to a Tethon centrifuge bottle and extracted.

Processing of volatile traps:

The volume of the ethylene glycol and I M HSO4 traps were recorded. The two 2 M KOH traps were combined and volume recorded. Three 0.5 mL aliquous of each were radioassayed by LSC to determine the total radioactivity trapped

Processing of soil:

The entire soft content of each test system was transferred into a Teflon bottle using the extraction solvent. The soil was extracted three times at ambient conditions using a mechanical shaker followed by a two microwave extractions with emagnetic stirrer. The extraction procedure is summarised in the following table:

	- C - 1			
Solvent	Volume	Minimum duration	Temperature	Cycles
Acetonitrile	80,00Ľ	🖉 30 m@, shaking	ambient	1
Acetonitrile/Water (4:1, v/x)	80 mL >	30 min, shaking	ambient	2
Actonitrile/Water (4:1, 1/2)	80 mL 🖗	to min, stirring	microwave, 70°C	1
Methanol/Water (9:1, $\frac{1}{2}$ /v)	×80 ma	∿√10 min, stirring	microwave, 50°C	1
	, Q	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		

Table 7.1.1.1- 14: Extraction procedure

After each extraction step, the extract and soil were separated by centrifugation and decanted and filtered into a glass graduated cylinder. The volumes of the combined ambient and microwave soil extracts were determined. The radioactivity content of these extracts was determined by LSC and concentrated extracts were characterized for parent and degradates by HPLC/radiodetection.

On the graal interval at DAT-123, two additional extraction steps with non-polar solvents were included after the microwave extraction steps. The soil was extracted with 80 mL of ethyl acetate with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extraction with 80 mL of hexane with shaking for 15 mill followed by an extract and soil were separated by centrifugation and decanted, filtered, and combined into a glass graduated cylinder. The volumes of the combined soil extracts were determined. The radioactivity content of these extracts was determined by radioassay of replicate aliquots. However, these extracts were not included in the HPLC analysis due to very low amounts extractable.



The extracted soils were air-dried, homogenised and non extractable residues were determined by combustion/LSC.

II. RESULTS AND DISCUSSION

The test systems were incubated under aerobic conditions in the dark in a walk-in climatic chamber at 20.4°C for 123 days. The test was performed at a soil moisture level between pF 2.0 and pF 2.5 for each soil. Losses of moisture were observed throughout the study, so periodic moisture adjustments were made to specific test systems as necessary. Determinations of michobial biomass were performed on DAT-0and DAT-123 and demonstrated that the used soils were merobially viable, but the Cer soil C showed a significant decline in activity at the end of the study (Table 7.19.1-13). Under the conditions of a laboratory experiment a decrease of microbial biological activity is devitable ducto the absence of any further amendment of nutrients.

ANALYTICAL METHODOLOGY Α.

Verification of Sample Processing Method « 1.

The mean DAT-0 recovery for the test substance was 94.9% and 95.1% AR for CA and NE soils. The mean recovery of the concentration procedure for the combined Soil extracts was between 90.2% to 105.0% AR for all soils. These results deponstrate that the sample processing method was well suited to recover the applied test substance from the soil and that the test substance was stable under these conditions.

Verification of Chromatographic Procedures 2.

The purity of the treatment solution was checked by HPL2 prior to test system treatments. The HPLC analysis showed a radiochemical purity of 100%

The flow-through detector was found to have a near pesporse over a range of 240 dpm to 194,814 dpm with a coefficient of determination $\langle r^2 \rangle$ of 0.9999. The limit of detection (LOD) was 322 dpm or 00% AR The lonit of quantitation (COQ) was 484 dpm (rounded up to 500 dpm), which is 1.4% of AR.

B. MATERIAL BALANCE

Mean material balances were 900% AR (range from 94.9% 98.2% AR) for soil CA, and 96.8% AR (range from 95.1 to 97.8% AR for sol NE Table \$1.1.1 \$5 and Table 7.1.1.1 - 16).

The complete material balances found at all sampling intervals for all soils demonstrated that there was no significant loss of adioactivity from the test systems or during sample processing.

Table 7.1.1.1-15:	Materiakhalance of radiactivity in soils under aerobic conditions from mean values
×,	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	(expressed as percentage of applied radioactivity of two replicates)
×	

Soil & & @	Å	Material	balance	
Y A & X	Amin.	max.	mean	SD
CA Y S	Ø 94.9	98.2	97.0	1.2
ANE of a	95.1	97.8	96.8	1.0

### **AND COMPOSITION OF RESIDUES**

#### **Distribution of residues**

In the CA test systems, the extractable radioactive residues in the soil increased from an average of 94.9% at DAT-0 to 98.2% AR at DAT-14, and then decreased to 95.6% at DAT-88, remaining approximately constant at 97.6% AR at DAT-123. The unextractable or bound radioactive residues in



the soil increased from an average of 0.2% on DAT-0 to 3.4% AR on DAT-123. Total volatiles were 0.1% at DAT-6 increasing to 2.0% AR at DAT-123.

In the NE test systems, the extractable radioactive residues in the soil increased from an average of 95.1% at DAT-0 to 97.7% AR on DAT-6, and then decreasing to 97.0% AR at DAT-123. The unextractable or bound radioactive residues in the soil increased from an average of 0.3% on Dor T-0 to 10.7% AR on DAT-123. Total volatiles were 0.1% at DAT-6 increasing to 3.3% AR at DAT-23. The detailed figures of the radioactivity distribution are presented in Table 7. 21.1-16.

	)		1		A			Ś	, L
ble 7.1.1.1-16: Distribution of radio	oactivit	v in soils	undêr a	nerobic co	martio	15	±7 ≈	"N	S.
(expressed as percen	itage of	applied 1	adioac	tivity, me	an of t	wo replin	Gates) 🛇	)″	y k
			<b>§</b>	<u> </u>	×				
		L)	7	Sampun	g times	L,O	s v	õ	, O ^v
	0		14		©28	60 ^{a)}	0 ⁷ 88,¢	123	Ć 🖌
CA soil		× (	ີ ຄ	5 ×	× 4	, Ç	°≈y	Ð	ľ
Volatiles	(		Ő	<u> </u>	- SP	- Ož	Å.	A	e °
carbon dioxide		.0 <u>9</u>	~0.1	62	0.5	<b>€</b> 0.5	0.9 S	°1.9 (	Ũ
volatile organic compounds	£-	KOD ∕	<b>≫0</b> .1	C LOD	0.1	LOØ/	< LOD	0.1	Ī
total volatiles	Ø - 🔬	≫ 0.1 _≪	0.2	0.20	0%6/	0,5	<i>6</i> 9	ØÕ	
Extractable radioactivity	4 K	×.~	, Ç	, Ø		Ű.	Î,	ັກ	
ambient extract	93 <u>9</u> 1	94.7	94.9	<b>9</b> 4.0	<b>)</b> 92.7 (	<b>\$90.8</b>	88.06	87.9	
aggresive extract	Ø1.6	Q2.4	2.4	€ 3.0 ⁽	3.1C	3.3 ^O	3.7%	3.6	
ethyl acetate/hexane	y -	° - P		`_ <del>,</del> Q″		ð	×-	0.8	
subtotal extractable 🔊 👔	94,7	97.1	97.4	97.0	<b>9</b> 5.8	<del>6</del> 94.1	91.7	92.3	
Non-extractable residues	<u>_</u> 2	Ø.5	″Ø.7	0.9 ~	× 1.0 ×	j ^a 1.9 Q	3.0	3.4	
Material balance	<b>@</b> 4.9	§97.7 {	98.2 _C	, [∿] 98.1 ^{©°°}	97,4,3	96.5	95.6	97.6	
NE soil	) Ĉ		_`~)	×	& °				
Volatiles		S.	2 2	a,	0	4	_	_	
carbon dioxide	\$J [°] - 1	0.1,~	0.3 @	0.4	0.20	1.2	2.0	3.2	
volatile organic compounds	- ^	< LQD	0.₩	< L (9D	Q.Y	< LOD	< LOD	0.1	
total volatiles	& O	Ø,1	?⊕,3	<b>20</b> .4	0.3	1.3	2.0	3.3	
Extractable radio@tivity	.4		S.	_° √					
ambient extract	<b>9</b> 1.8	0°89.4	88.8	88.90	87.1	83.5	78.7	73.8	
interowave extract of a	3.0	6.3	5.7	60	5.8	7.0	6.5	7.5	
ethyl acetate/hexane	- S		-	~~- ~~	-	-	-	1.8	1
subtotal extractable ~	94.8	^{395.7}	×94.6	~94.9	92.9	90.5	85.2	83.0	
Non-extractable residues	₩ 0.3 🕊	1.9	2.00	2.5	3.2	6.0	8.4	10.7	
Material balance	95	959	9639	97.8	96.4	97.8	95.6	97.0	]

<b>Fable 7.1.1.1-16:</b>	Distribution of radioactivity in soils under aerobic conditions	L
	(expressed as percentage of applied radioactivity, mean of two replic	a

a) Only on replicate was analysed for the day 60 interval for NE soil

### Composition of residues

ñ

The foute of degradation of isoflucy fram in soil under aerobic conditions is summarised in Table 7.1.1.1-17 and Table 7.10.1-18. The poposed degradation of isoflucypram in soil is presented in Figure 7.1.1, 2 2

# Identification and characterisation of degradation products:

#### - Carbon dioxide and volatile organic compounds

The maximum amount of carbon dioxide was 1.9 and 3.2% AR at study end (DAT-123) in the CAsoil and the NE soil, respectively. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of  $\leq 0.1\%$  AR at all sampling intervals for both soils (Table 7.1.1.1- 17 and Table 7.1.1.1-18).



#### - Test item and degradation products in soil extracts

The amount of isoflucypram in the soil extracts decreased from DAT-0 to DAT-123 from 94.7 to 86.2% AR in CA soil and from 94.8 to 64.4% AR in NE soil.

No major degradation products were formed in the CA soil. However, one minor degradation product was BCS-CN88460-carboxylic acid (M12) and increased from 1.1% at DAT-60 to 1.3% AR at DAT-123. One additional unidentified minor degradate was also formed with the maximum amount for a single compound of  $\leq 4.0\%$  AR. Total unidentified radioactivity was  $\leq 40\%$  AR for any interval. One major degradation product was formed in the NE soil was identified as BCS-CN88460-carboxylic acid (M12), and it increased from 1.4% AR at DAT 21 to 9.6% AR at DAT 123. Two minor unidentified degradates were formed with the maximum amount for a single compound of 3.0% AR. Total unidentified radioactivity was  $\leq 7.2\%$  AR for any interval. c conditions The results are summarised in Table 7.1.1.1- 17 and Table 7.1.1.1- 28.

Table 7.1.1.1- 17:	Degradation of isoflucypram in CA soil under aerobic conditions
	(expressed as percentage of applied radioactivity mean of two replica

	•	st i	C	407	- A	"0"	~	A.
Compound	4	. 0	~Ű	Samplin	ıg times	Q	0″	¢'
				<u>کہ</u> [da	[ <b>y</b> \$] ू (	D' 🔬		° s
	×۲ 0 ×۸	¢`6_♥	14		28	60	88	125
Isoflucypram	94,7	97.1	9 <b>T</b> 4	97.0	<u>2\$.</u> 8	<b>20</b> .4	<b>Ø</b> .8	86.2
BCS-CN88460-carboxylic acid (MJ2)	< ØÓD	< DOD	< ^x EOD	<b>LOD</b>	SLOD	\$ ² 1.1 ,	\$LOD	<u>ا ا ا</u>
Unknown 2 👋	🕱 LOD	🏷 LOD	🕅 LOD	K LO⊅	LQD	2.6Ô	¯ 1.9°≫	4.0
Unknown 3	Ì< LO₿	< LQD	< L000	< LQD	< LØÐ	< DOD	< KOD	<LOD
Unidentified radioactivity	< 40 D	< LÕD	< LÕD	< COD	<¢OD	2.6	Q.9	4.0
Total extractable radioactivity	<b>4</b> .7	<b>9</b> 7.1	<b>Ø</b> 7.4	ັງ7.0 _~ (	<b>\$95.8</b> %	94.1 (	91.7	92.3
Carbon dioxide	6 - 4	🗣 0.1 🎣	0.1	№ 0.2≪J	0.5	0.5	0.9	1.9
Volatile organics	-0	< L	0.0	< KOD	_0.1	< 60 D	< LOD	0.1
Total volatile 🖉 🔗 🖋		.071	×0?2	<b>@</b> .2	Ø.6	ð.5	0.9	2.0
Bound residues 🖉 🔬 🖓 🗸	<b>0</b> .2	≈0.5 <u>j</u>	Ĵ0.7 (	0.9	^U 1.0	[*] 1.9	3.0	3.4
Total recovery 🕉 🔍 🖉 🚿 🤻	¢ 94.9	97.2	98. <i>2</i> 2	98	92	96.5	95.6	97.6
		J.,	$\sim$		17			

Table 7.1.1.1

- 18: Degradation of isoflucyprant in NE soil under aerobic conditions (expressed as percentage of applied radioactivity, mean of two replicates)

Compound , C , O		<u> </u>	чQ.	Samplir	ıg times			
	O ^v		, L 4	🖞 [da	iys]			
	<u>&gt; 0 (</u>	p 6 C	<u>14</u>	21	28	<b>60</b> ^{a)}	88	123
Isoflucypram	94.8	9408	9406	93.5	92.9	86.4	75.0	64.4
BCS-CN88460-carooxylicacid (M12)	≲QÓD	≲₽ÖD.	<"POD	1.4	< LOD	4.1	6.7	9.6
Unknown 2 🔗 🚿	<b>Ö</b> LOD	🎘 LOD	🕅 LOD	<LOD	< LOD	< LOD	3.6	4.0
Unknown 3	K≷ LQD	<lqd< td=""><td>&lt; LOD</td><td>&lt; LOD</td><td>&lt;LOD</td><td>&lt; LOD</td><td>&lt;LOD</td><td>3.2</td></lqd<>	< LOD	< LOD	<LOD	< LOD	<LOD	3.2
Unidentified radioactivity	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	3.6	7.2
Total extractable Solioactivity	94.8	• 4.8	94.6	94.9	92.9	90.5	85.2	83.0
Garbon dioxide 🔪 🚿 🦄	0~-~~	0.1	0.3	0.4	0.2	1.2	2.0	3.2
Volatile organies	-~	< LOD	0.1	<LOD	0.1	< LOD	<LOD	0.1
Total volatite 🔥 🖉 🍼	Ą.	0.1	0.3	0.4	0.3	1.3	2.0	3.3
Bound readues 🕎 🖉	@ ₁ 0.3	0.3	2.0	2.5	3.2	6.0	8.4	10.7
Total recovery O 🔬 🦄	95.1	95.1	96.9	97.8	96.4	97.8	95.6	97.0
Unknown 2 Unknown 3 Unidentified radioachvity Total extractable radioactivity Carbon dioxide Volatile organics Total volatile Bound residues Total residues	© LOD < LQD < LQD 24.8 - ~ - ~ - ~ - ~ - ~ - ~ - ~ - ~	LOD < LOD < 4 COD < 4 COD < 4 COD < 4 COD < 0.1 < LOD 0.1 0.3 95.1	<pre></pre>	< LOD < LOD 94.9 0.4 < LOD 0.4 2.5 97.8	< LOD < LOD 92.9 0.2 0.1 0.3 3.2 96.4	< LOD < LOD 90.5 1.2 < LOD 1.3 6.0 97.8	3.6 < LOD 3.6 85.2 2.0 < LOD 2.0 8.4 95.6	4.0 3.2 7.2 83.0 3.2 0.1 3.3 10.7 97.0

pricate was analysed for the day 60 interval 



#### **DEGRADATION PATHWAY** D.

Based on the results of the study, the pathway for the degradation of pyrazole-labelled isoflucypram in soil under aerobic conditions is proposed in Figure 7.1.1.1-2.

Under aerobic soil conditions, BCS-CN88460-carboxylic acid (M12) was formed. Furthermore CO (max 3.3%) and non-extractable residue (max 10.7%) were also formed during this study.





#### **III. CONCLUSIONS**

Isoflucypram degrades slowly under aerobic conditions in the laboratory. One soil metabolite, BCS-CN88460-carboxylic acid (M12), was isolated and identified from the NE^(C) soil extract. This metabolite was formed at a maximum of 9.6% AR in the NE soil but only 9.3% AR in the CA soil. Formation of non-extractable residues (NER) was  $\leq 10.7\%$  AR and formation of volatiles was low ( $\leq 3.3\%$  AR) in both soils, but shows further degradation and mineralisation of isoflucypram is occurring. Similar degradation rates and routes are seen at higher (2x) application rates.

Report:	KCA 7.1.1.1/03; ; ; 2017; M-\$99926; 1 · · · · · · · · · · · · · · · · · ·
Title:	[Phenyl-UL-14C]BCS-CN88460: Aerobic degradation metabolism in one soil
Report No.:	EnSa-16-0986
Document No.:	M-599926-01-1 $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$ $\mathcal{A}$
Guideline(s):	OECD Test Guideline No. 307; Commission Regulation (EU) to 283 2013 in
	accordance with Regulation (EC) No (107/2009; US CPA QCSPP Tot Guideline No.
	835.4100 / 85.4200 apanese MAFF Test Guidelines 12 Nousan \$47, No. 2-5-2
Guideline deviation(s):	none $\mathcal{Q}$ , $\mathcal{Q}$
GLP/GEP:	yes a the of the the the the

#### **Executive Summary**

Executive Summary The route and rate of degradation of phenyl abelled isoflycyprate were studied in one soil under aerobic conditions in the dark in the laboratory in the dark at 20 ± 2 °C and 55 ± 5% of the maximum water holding capacito for 125 days

Ŵ

		~	ř.	O	6
Table	7.1.1.1-	19:°°	Selec	ted	soi₩
			~ ~ ~ ~ ~	· /	~ ~ ~ ~ /

	. ()	0°					4.¥		
Soil	õ	Q.	× 0	Source	V Ö		Texture	pН	OC
	Ô	"U"		, Q _		- P	(\$\$DA)	(CaCl ₂ )	[%]
Laacher D	fof AXX	Ka 💍	¢.	Monheim,	Germany	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	To amy sand	5.8	1.6
- Ry		. Ø	<u> </u>			0	<u> </u>		

An actual study approaction rate of 18.8 12/kg soil dry weight was applied based on a maximum single field application rate of isoflucy fram of 75 g/ha.

The test was performed in staric systems consisting of Eplenmeyer flasks each containing 100 g soil (dry weight equivalents) and equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds Ô

Duplicate amples were processed and analysed Q 2, 6, 14, 28, 50, 65, 85, 100 and 125 days after treatment (DAT). At each sampling interval, the soil was extracted three times at ambient temperature using acetonitrile/water 1/(v/v) at 50° C. Furthermore, two microwave-assisted extraction steps were performed using acetometrile/water  $1/1^{\circ}(v/y)$  at 70°C and methanol/water 1/1(v/v) at 50°C. The amounts of test tem and degradation products in soil extracts were determined by liquid scintillation counting (LSO) and by HRSC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. Test item identity was confirmed by HACC-MSI/MSS including accurate mass determination and degradation products were identified by co-chromatography with reference items.

Mean material balances were 103% of the applied radioactivity (AR) (range from 101 to 105% AR).

The maximum amount of carbon dioxide was 5.2% AR at study end (DAT-125). Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of  $\leq 0.1\%$  AR at all sampling intervals.

Extractable residues decreased from DAT-0 to DAT-125 from 100 to 92.0% AR.

Non-extractable residues (NER) increased from DAT-0 to DAT 125 from 0.7 to 6.4% AR.



The amount of isoflucypram in the soil extracts decreased from DAT-0 to DAT-125 from 100 to 75.5% AR.

Besides the formation of carbon dioxide, BCS-CN88460-carboxylic acid (M12) was the only degradation product identified. Its maximum occurrence was 6.2% AR at DAT-125. The total  $\sim$ unidentified residues amounted to a maximum of 13.1% AR and no single component exceeded 5.9% AR at any sampling interval.

Table 7.1.1.1- 20:	Identified degradation products (max	ximum	occurrence) in soi
	(in percent of applied radioactivity)	Ò	A.

Compound	Chemical structure	Q	Maximum occurrence in soil
Compound		Ľ, Č	
BCS-CN88460-carboxylic acid ( <i>M12</i> )	F. F. & HJC		
CO ₂			<u> 57.2</u>
	L. MATERIALS AND MET	HODS 🛛	Ĵ A
to a f		o y	2 Alexandre and a second secon
A. MATERIALS		0°	e e e e e e e e e e e e e e e e e e e
1. Test and Reference Items			<b>V</b>
Test item 🔈 👸 🗸			
Phenyle belled isoflucturant		$\sim$	
Sample-ID:	ML 10238 ~ ~ ~ ~ ~	y Y	
Specific activity: $3^{4}$	MBaying ~ A	<i>v</i>	
Radiochemical purity:	8% (IPPLC with radioactively c	letector)	
Chemical purity:	98% CHPL 6 with 6 V-detoctor, 2	210 nm)	
Reference yems	F F S S		
unlabetted isoflucypram			
Batedy-ID:	ÇS⊕ČN88460-₽Ů≯01		
Chemical purity: 79	J1% (1H=NMR)		
O`.			
unlabelled BCS-CN88460 cart	poxylic acid (M12)		
Batch-ID	2 <b>S-CY26497-01-04</b>		
Chemical purits 0 98	8% (various methods)		
2 / Test (61)			

The study was carried out using one soil for the metabolism part and testing of the simplified extraction method (SEM) and one additions soil used for testing of the SEM, only (see Table 7.1.1.1-21). The soils are well characterised and the plant protection product use history of the soils for at least 5 years is known.


The soils were collected fresh from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of  $\leq 2$  mm. Soil collection and handling were in accordance to ISO 10381-6¹.

Table 7.1.1.1- 21:	Physico-chemical	properties	of test soils
	i nysieo enemieur	properties	or cese soms

		<u> </u>		
Parameter	Results 6 ¹			
Soil designation	Laacher Hof AXXA ^{a)}	Dollendorf II ^{b)}		
Geographic location		ð sa s		
City	Monheim 🔬	Blankenheim		
State	North Rhine-Westphalia	North Rhine-Westphalia		
Country	Germany 🖉	Eermany O		
Soil taxonomic classification (USDA)	sandy, mixed, active,	fine-Bamy, mixed, active,		
	fonacid, mesic Inceptic	fogid Typic Eutodept 🐇		
	🖞 Hapludad f 🄊			
Soil series	no information available	no information available		
Textural class (USDA)	° loapity sand	clax Joam 🖉		
sand [%] (50 $\mu$ m – 2 mm)	0° × 80 × ~~			
silt [%] $(2 \mu m - 50 \mu m)$				
clay [%] (< 2 $\mu$ m)	$\sim$ $4^{\times}$ $\Delta$			
pH - in soil/0.01 M CaCl ₂ $1/2$	5.8 4 5	J.1 5		
- in soil/water 1/1	$\mathcal{L}$ $\mathcal{L}$ $\mathcal{L}$	Q ^y Q7.3 O		
- in saturated paste		S 7.20		
- in soil/1 N KCl 1/1	<u>~</u>	<u>, 5, 69</u>		
Organic carbon (combustion) $[\% \text{ OC}]^*$	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	A.9		
Organic matter ^{c)} [% OM]		<u>○</u> <u>× 8.4</u>		
Cation exchange capacity [meq/100 g]	<u> </u>	<u>ک</u> 23.1		
Water holding capacity				
maximum (MWHC) [g $H_2^{\circ}$ ad 100 g DW	\$\$ 49.6 S	77.4		
at 1/3 bar (pF 2.0) [%] at 1/3 bar (pF 2.0) [%]		<u>,</u> 40.0		
Bulk density (disturbed) g/cm ³	<u></u>	ر» 0.97		
Soil microbial biomass [mg microbiaDC/kg soil DW]				
DAT-0 BIO-	ັ້ 🕉 6900 🥳 🖓	2287		
DAT-65 BIQ_OBIO+O` ` ` ` ` ` ` ` ` `	500 🖓 🕉	1627 / 1592		
DAT-125 BIQ-/BIQ+	مَنْ 40∰ 381 ¢	1511 / 1400		

a) Soil Laachen Hof AXXa was used for the metabolism study and testing of the SEM (simplified extraction method)

b) Soil Dollerdorf II was used for testing of the SEM, only

c) % organic matter = % organic cathon x 1.724

BIO- samples were left untreated

BIO+ samples were applied with solvent of application solution (40 μL methanol) DW: dry weight B. STUDY DESIGN

#### Experimental Conditions 1.

The study was performed with static incubation test systems. Erlenmeyer flasks of 300 mL volume were used as test vessels and each test vessel was fitted with a trap attachment (permeable for oxygen) containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of olatile organic compounds (VOC).

For preparation of the test systems, 100 dry weight equivalents of the sieved soils were weighed into each test@vessel@Soil moisture was adjusted to 55 + 5% of the maximum water holding capacity (MWHC) for the individual fest vessels by addition of de-ionized water. The test vessels were then fitted with trap attachments. le,

¹ International Organization for Standardization (2009):

ISO 10381-6:2009(E): Soil quality - Sampling - Part 6: Guidance on the collection, handling and storage of soil under aerobic conditions for the assessment of microbiological processes, biomass and diversity in the laboratory



The untreated test systems were equilibrated to study conditions for 5 days prior to application.

For the application of the degradation samples the study application rate (SAR) was based on the maximum single field application rate of isoflucypram of 75 g per hectare, resulting in the targeted SAR of 18.8  $\mu$ g per 100g soil dry weight (400  $\mu$ /test system).

The test item was applied dropwise onto the soil surface of the respective test stems using a pipete. After application, the test vessels (except DAT-0 samples) were fitted with trap attachments and placed into a walk-in climatic chamber for incubation.

The degradation product identification samples were prepared to generate lager amounts of degradation products for structure elucidation (2 samples). For this porpose a 3-fold SAR was applied, of After application the samples were handled as described for the degradation samples.

#### 2. Sampling

Ten sampling intervals were distributed over the entire incubation period of 125 days. Duplicate samples were processed and analysed 0, 4, 6, 14, 28, 59, 65, 85, 100 and 25 days after treatment (DAT).

Samples for testing of the simplified extraction method were processed and analysed 0, 65 and 125 days after treatment.

Microbial soil biomass was determined af start, middle and ord of the study (DAT-0, DAT-65 and DAT-125).

#### 3. Analytical Procedures[®]

Carbon dioxide absorbed by soda the was liberated with 18% aqueons hydrochlonic acid and trapped. The liberated carbon dioxide was purged into the trapping vessels by a stream of nitrogen. The radioactivity contents of these vessels were determined by liquid scintillation counting (LSC) and summed up to determine the total adioactivity liberated from soda lime.

The PU foam plug was extracted with 50 mD ethy facetate to desorb votatile organic compounds. The radioactivity content was deformined by LSC.

A

The entire soil of each test vessel was transferred into a centrifuge beaker using the extraction solvent. The soil was extracted three times at ambient conditions using a mechanical shaker followed by two accelerated extractions using a microwave with a magnetic stifter.

The extraction procedure is summarised in the following table:

	Solvent	<b>X</b> olume	Minimum duration	Temperature	Cycles
	$ACN/H_2O 1/1 (v/v)$	\$80 mJ	∿30 min≰ shaking	ambient	3
	$ACN/H_2O$ $M_2(v/v)$	🖗 80 mĽ	10 min, stirring	microwave, 70°C	1
L,	$MeOH/H_2OS/1$ (v/)	89.mL	10-prin, stirring	microwave, 50°C	1
<b>S</b>	- Ca.	N N			

# Table 7.1.1.1- 22: Extraction procedure

 $\bigcirc$ 

After each extraction step, extract and soil were separated by centrifugation and decantation. The volume of the combined first three ambient extracts was combined and filled up to 250 mL while both microwave extracts were filled up to 400 mL each using the respective extraction solvent. The radioactivity content of these extracts was determined by LSC. The exhaustively extracted soils were lyophilised, homogenised by a mortar grinder and non-extractable residues (NER) were determined by combination/LSC.



### II. RESULTS AND DISCUSSION

The test systems were incubated under aerobic conditions in the dark in a walk-in climatic chamber at a mean temperature of 19.4°C for 125 days. The test was performed at a soil moisture of 53.0% of the maximum water holding capacity. No significant loss of moisture was observed throughout the study. Determinations of microbial biomass were performed on DAT-0, DAT of and DAT-125 and demonstrated that the used soils were microbially viable.

### A. ANALYTICAL METHODOLOGY

#### 1. Verification of Sample Processing Method

The mean DAT-0 recovery for the test item was 400%. The plean recovery of the concentration procedure for the combined soil extracts was between 98.3%. These results demonstrate that the sample processing method was well suited to recover the applied test item from the soil and that the test item was stable under these conditions.

### 2. Verification of Chromatographic Procedures

The primary chromatographic method (HPLC/radiodetection) was well shited for the quantitative analysis of the samples of this study as demonstrated by a mean HPLC recovery 96.5% and a good linear fit for injected amounts of phenyl-labelled pollucy ram of column ( $R^2 = 0.999$ ). The LOD of the primary chromatographic method was determined as 7.5 Bo absolute on column of 0.7% AR.

### B. MATERIAL BALANCE

Mean material balances were 103% AR (range from 101 to 105% AR) (see Table 7.1.1.1-23). The complete material balances found at all sampling intervals for all soils demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing.

Table 7.1.1.1-23: Material balance of radioactivity in soils under aerobic conditions from mean values (expressed as percentage of applied radioactivity of two replicates)

			ν	× .	~ ¥			s s	
	Soil	Ž.	0	O,	£07	Š, Š	Material k	oalance	
	Å.	O ^v	Ś	ès 4	min.	, Sn	nax. 🔍	🔬 mean	RSD
°~	Q 2	×	) 🕺			-0		<u>0</u>	[%]
<i>z</i> S'	Laache	r Hof A	XXa		101.0		)¥.5 O	102.5	1.3
«\Y	RSD = 1	relative s	stañdard	deviation		$\mathbb{Y}$ i.	a V		
	4	<u>`</u>	N.	× %	U K	i 🎽	2		

# C. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the adioactivity distribution are presented in Table 7.1.1.1-24.

The route of degradation of Bofluc pramon solution aerobic conditions is summarised in Table 7.49.1-25.

The proposed degradation of isofluxypram in soil is presented in Figure 7.1.1.1-3.

## Carbon dioxide and volatile organic compounds

The maximum amount of carbon dioxide was 5.2% AR at study end (DAT-125) (Table 7.1.1.1-24). Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of  $\leq 0.1\%$  AR at all sampling intervals.

### Test item and degradation products in soil extracts

Extractable residues decreased from DAT-0 to DAT-125 from 100 to 92.0% AR (Table 7.1.1.1-24). The amount of isoflucypram in the soil extracts decreased from DAT-0 to DAT-125 from 100 to 75.5% AR. Degradation of isoflucypram was accompanied by the formation of BCS-CN88460-carboxylic acid (M12) with 6.2% AR at DAT-125. The total unidentified residues amounted to a

maximum of 13.1% AR and no single component exceeded 5.9% AR at any sampling interval.



#### Non-extractable residues

Non-extractable residues (NER) increased from DAT 0 to DAT 125 from 0.7 to 6.4% AR.

									0,		Ő
l'able 7.1.1.1-24: Material balan (expressed as r	ice of radi	ioactivi e of anr	ty in so olied ra	ils und dioacti	er aero vitv. m	bic con ean of f	ditions worren	licates		Y )	- Or
( <b>F</b>		PT			D 6				<u> </u>		1
	0	2	6	14	Days af	ter trea	attenent	85	Sinn #	$a^{2}$	Ro
Volatiles	U	4	U		20	<u> </u>	03	03	<u>),100</u>		Ĵ
carbon dioxide	n.a.	< 0.1	0.2	<b>9</b> .3	1.1	Â.3	2.9	8,5	Â¥	50	e (
volatile organic compounds	n.a.	< 0.1	< 0.1	< 0.1	< 0.1	\$ 0.1	< 0.1	Ø0.1	<b>30</b> .1	\$0.1	Ô
total volatiles	n.a.	< 0.1	0,2,4	0.3	1.1	2.4	2.90	3.5 🖉	¥4.4 (	5.2	×
Extractable residues			4		-Q	Ô	Å	Ś	0	L	
ambient extract	95.6	97.3∡	95.7	93.7	<b>9</b> 3.0 。	&ð.9	9¥.5	89.2	<i>8</i> Ø.7	8.85	
microwave extract 1	3.6	43	3.9	4.5	₽ 4.3 ₹	4.4	4.6	¢4.8 ∘	5.0	8.5	
microwave extract 2	1.1	102	104	1,32	14/	12	1.6	1.8	1.74	2.0	
total extractable residues	100.3	102.8	<b>101</b> .0	89.5	98.6	99.6	97.7	969	944	92.0	
Non-extractable residues	0.7	× 0.9°	1.2	¥1.5 ≽	2.2	3.2	3.8	5.6	\$.3	64	
Material balance	101.0	103.7	102A	101	102	° 101,≹≶	104.5	101.0	م104.1 <i>₄</i>	<b>₽</b> 03.7	
n.a.: not analysed	Â.	K.	, Q		d W	Ň		Ĩ	, O	/	

# as of modio and initial in soils and an association and it is an

Degradation of isoflucypramon soil Chacher Hof AXXa under activitions Table 7.1.1.1-25: (expressed aspercentage of applied radioactivity mean of two replicates)

M

	¥ ·	<u> </u>		"						
Compound 👋		O ^r	L.	_∭ Da	ys after	treatm	en 🕼	<i>R</i> o		
	<b>0</b> ′	Ň	6	<u>14</u>	ູ28 ູ	, 9 <b>5</b> 0 "	<b>\$</b> 65 4	<b>85</b>	100	125
Isoflucypram	<u>100.3</u>	102.84	N01.00	97.6	94,2	88.2	88.0	73.0	81.5	75.5
BCS-CN88460-carboxylic acid	n.d	n.d.	n.dO	1.3	22	247	3:0	5.8	4.2	6.2
(M12)	ŝ		- D	Q.		°	~			
Sum of unid./diff. resides	∘_n.d.	🖉 ŋ.d. 🍃	n.d. 🖍	©LOD,	1.9	ي 4.7 🕻	6.5	13.1	8.4	10.3
Total extractable residues.	∛100. <b>3</b>	102.8	⁷ 101.0	¢ 99.2	§ 98.3	95,6	97.5	91.9	94.1	92.0
Carbon dioxide ^b $\bigcirc$ $\bigcirc$	n.a	<0.0	0.2			2.3	2.9	3.5	4.3	5.2
Volatile organic compoands ^{b)} 🎸	n.a.	< 0.1	≈0.1	\$0.1	Ø _{0.1}	<b>0.1</b>	< 0.1	< 0.1	0.1	< 0.1
Non-extractable residues ^{b)}	×J0.7	<b>\$</b> 0.9	ð1.2	1.5	y 2.2 @	3.2	3.8	5.6	5.3	6.4
Total recovery ^{a)}	101.06	103.7	102	101	10	101.1	104.2	101.0	103.8	103.7

n.d.: not detected, n.a.: not analysed

n.d.: not detected, n.a.: not adjalysed
a) Difference to material malance values the to rounding errors as well as clean up and chromatographic losses
b) Values taken from material balance. b) Values taken from material balance

# D. DEGRADATION PATHWAY

Based on the results of the study, the following pathway for the degradation of phenyl-labelled isoflucypram in soil ander aerobic conditions is proposed (see Figure 7.1.1.1-3), with the following ssible processes involved a solution of isoflucy from to result in BCS N88460-carboxylic acid (M12); possible processes involved.

- •
- mineralisation (carbon dioxide formation), •

formation of non-extractable residues (NER).



#### Figure 7.1.1.1-3: Proposed degradation pathway of phenyl-labelled isoflucypram in soil under aerobic conditions



Formation of carbon dioxide was up to 5.2% AR at study end indicating the potential for a complete mineralisation of isoflycyprane and its degradation products.

Besides the formation of carbon dioxide, BCS-CN88460-carboxylic acid (M12) was the only degradation product identified. Its maximum occurrence was 6.2% AR at DAT-125.

Formation of non-extractable fesidue (NER) was up to 6.4% AR at study end, which is an indication for biotic degradation of isoffucypram.

The formation of non-extractable residues and carbon dioxide indicates a participation in the natural carbon cycle of soil and the potential for a complete mineralisation of isoflucypram.



## CA 7.1.1.2 Anaerobic degradation

The route of degradation of isoflucypram in soil under anaerobic conditions in the laboratory was investigated using the pyrazole-label.

A summary of the route of degradation of isoflucypram in soil is given in section CA 7.1.1.

Report:	KCA 7.1.1.2/01; (2015; M-512)56-01-1
Title:	[Pyrazole-4-14C]BCS-CN88460: Anaerobic degradation / metabolism in one soil
Report No.:	EnSa-14-0146
Document No .:	M-513456-01-1 (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c
Guideline(s):	OECD Test Guideline No. 307; Commission Regulation (EU) No 83/2019 in
	accordance with Regulation (EC) No 1107/2009 WS EPA OCSRP Test Suideling No
	835.4100 / 835.4200; Japanese AAFF Test Guidelines 12 Nousan 8147, No. 25-3
Guideline deviation(s):	none
GLP/GEP:	yes

#### **Executive Summary**

The route and rate of degradation of pyrazole-labelled soflucypram were studied m one soil under anaerobic conditions for 120 days, after an aerobic incubation phase of 30 days (total study duration of of 150 days).

Table 7.1.1.2-	1:	Selected	soil
----------------	----	----------	------

	son y	<i></i>	S S	$\mathcal{L}$	0	**
Soil	Source 📎		Textur	R .	фн	S OC
	w u	Å de	(USD)		(CaCl ₂ )	[/] [%]
Laacher Hof AXXa	Monheim, Geô	many 🖉	loamy	sand	6.7	1.6
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~						

A study application rate of $200^{\circ} \mu g$ for kg soil div weight was applied based on a maximum single field application rate of isoflucyprom of 78 g per vectore.

The test was performed in static systems consisting of Erlenmeyer flask each containing 100 g soil (dry weight equivalents) For the aerobic incubation phase the flasks were equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. For the anaerobic incubation phase, the traps were replaced by gas sampling bags for the collection of volatiles.

After application of the test itom, the test systems were incubated under aerobic conditions in the dark at 51.9% of the maximum water folding capacity for 30 days. Then, the soil of each test system was flooded with oxygen-depleted do ionized water, mimuking a field flooding scenario, and set under an atmosphere of nitrogen to achieve an arrobic conditions.

Duplicate samples were processed and analysed 0 and 30 days after treatment (DAT) during the aerobic incubation phase and at DAT 30, -32, -37, 44, -60, -92, -120 and 150 of the anaerobic incubation phase. The sampling intervals of the anaerobic incubation phase correspond to 0, 2, 7, 14, 30, 62, 90 and 120 days after soil flooding (DASE)

At each sampling interval of the aerobic incubation phase, the soil was extracted three times at ambient temperature using acetometrile/water 1/1 (ν/ν). Furthermore, two microwave-assisted extraction steps were performed using acetonitrile/water 1/1 (ν/ν) at 70°C and methanol at 50°C.

At each sampling interval of the anaerobic incubation phase (from DASF-0 onwards), the water was separated from the soil by decantation. Afterwards, the soil was extracted as described for the aerobic incubation phase.

The amounts of test item and degradation products in soil extracts and water were determined by liquid scipitillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. The test item was identified by HPLC-MS(/MS) including accurate mass determination.

Mean material balance was 101.3% AR (range from 98.6 to 104.5% AR).



The maximum amount of carbon dioxide formed was 0.2 % AR at the end of the aerobic incubation phase (DAT-30) and < 0.1% AR during the entire anaerobic incubation phase. Formation of volatile organic compounds (VOC) during the aerobic and anaerobic incubation phases was insignificant/as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals.

Extractable residues varied between 95.2 to 104.1% AR over the total study duration (150 days) Non-extractable residues (NER) increased during the aerobic incubation phase from pAT-0.000 DAT-30 from 0.4 to 1.5% AR. During the following anaerobic incubation phase, NER increased further until DASF-120 to 4.2% AR.

Within the aerobic incubation phase, the amount of isoflucypram decreased from DAT-0 to DAT from 104.1 to 92.6% AR. During the following anaerobic incubation phase the amount isoflucypram varied between 90.3 and 97.6% AR.

a attempts single compo of the Since no degradation products of isoflucypram > 5% AR were found, no identification attempts were made. The total unidentified residues amounted to a maximum of 4.7% AR and no single component exceeded 3.1% AR at any sampling interval.

THODS I.

MATERIALS А.

1. **Test and Reference Items**

Test item

Pyrazole-labelled isoflucypram KM₽ 971@ Sample-ID: 4.22 MBq/mg (13.922 Ci/mg) Specific activity: 98% (HPLC with adioactivity detector) Radiochemical purity 99% (TLC, scan)

99% (HPLC with UV detector Chemical puri

Roforonco

	av.	M -	2	7 (V))	
Unlabelled isofluc	ypram	v .Ø	1		Ű
Sample-10:	, s	BCS-	CN8846	50-01-02	¥ -
Chemical purity:	. Ű	<u>م</u> گُ	6 (H-N	MAR) Ö	Ť
<i>v</i> 1 5		N 4		y" ("N	1

2. **Test soil**

The study was carried out using one soil considered representative for agricultural soils (see Table 7.1.1,2-2). The plant protection product use history of the soils for at least 5 years is known. The soils were sampled freshly from the field (upper horizon of 0 to 20 cm) and sieved to a particle size of 🖄 mm.

The soil microbial bomass was determined at spart and end of the aerobic incubation phase. The soil microbial viability was determined at the endoff the anaerobic incubation phase (see Table 7.1.1.2-3 and Table 7.1



 Table 7.1.1.2- 2:
 Physico-chemical properties of the test soil





B. STUDY DESIGN

1. **Experimental Conditions**

The study was performed with static incubation test systems. Erlenmeyer flasks of 300 mL volume were used as incubation vessels. For the aerobic incubation phase each test vessel was fitted with a^{ℓ} trap attachment (permeable for oxygen) containing soda lime for absorption of carbon dioxide and polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC).

For the anaerobic incubation phase the trap attachments were replaced by sealable two-valye glass stoppers connected with gas sampling bags for the collection of votatiles. Additionally, the test systems were placed into a nitrogen flooded box in a water in climatic chamber. For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into C each test vessel. Soil moisture was adjusted to 55% of the maximum water holding capacity (MPWHG)

for the individual test systems by addition of de-ionized water. The study application rate (SAR) was based on the maximum single field application rate of isoflucypram of 75 g per hectare, resulting in the targeted SAR of 200 µg kg soil dry weight. The test item was applied dropwise onto the soil surface of the respective equilibrated test systems using a pipette. After application, the test vessels were fitted with that attachments and placed into a temperature-controlled walk-in climatic charaber for incubation.

Sampling 2.

Two sampling intervals were distributed over the entire activity incubation phase of 30 days. Eight sampling intervals were distributed over the entire anaeroble incubation phase of 120 days.

Duplicate samples were processed and malysed 0 and 30 days after treatment (DAT) during the aerobic incubation phase and at DAT 30, -32, -37, -44, -60, -92, 120 and -150 of the anaerobic incubation phase. The sampling intervals of the anacrobic incubation phase correspond to 0, 2, 7, 14, 30, 62, 90 and 120 days after soil flooding (DASF)

Analytical Procedures 3.

The amounts of test item and degradation products in soil extracts and water were determined by liquid scintillation counting (LSC) and by (PLC) adiod dection analysis. The amounts of volatiles and non-extractable residues were determined by DSC and combustion SC, respectively. The test item was identified by HPLC MS(MS) including accurate mass determination.

Carbon dioxide absorbed by soda line was liberated with 48% aqueous hydrochloric acid and the liberated carbon, dioxide was purged into the trapping vessels by a stream of nitrogen. The radioactivity contents of these versel overe determined by LSC and summed up to determine the total radioactivity liberated from Soda line.

The PU foam plug was extracted with 50 mg ethy acetate to desorb volatile organic compounds (VOC). The radioactivity content was determined by LSC.

The test vessel with the gas sampling bag was connected to the volatiles. Volatiles present in the gas sampling bag were slowly purged using a stream of nitrogen over a soda lime trap for absorption of carbon dioxide. The radioactivity contents of these vessels were determined by LSC.

After determination of redoc potential, pH value and oxygen content, the water was separated from the soil by decantation into a centrifuge braker. Then, the water was centrifuged. The clear supernatant was decanted and the volume determined. The radioactivity content of the water was determined by LSC. The solids after centrifogation were combined with the soil.

The entire soil of each test vessel was transferred into a centrifuge beaker used for the processing of the water containing already the solids for the water using the extraction solvent. The soil was extracted three times at ambient temperature using a mechanical shaker followed by two extraction steps using a microwave with a magnetic stirrer.

The extraction procedure is summarised in the following table:



Table 7.1.1.2- 5:	Extraction	procedure
1 4010 7 11 11 20	LAGaction	procedure

Solvent	Volume	Minimum duration	Temperature	Cycles
ACN/H ₂ O 1/1 (v/v)	80 mL	30 min, shaking	ambient 🔊	3
ACN/H ₂ O 1/1 (v/v)	80 mL	10 min, stirring	microwave, 70°C	
MeOH	80 mL	10 min, stirring	microwave, 60°C	1
			۵	

After each extraction step, extract and soil were separated by centrifugation and decantation. Afterwards, the combined ambient extracts were filled up to volumes of 250 mL (aerola samples) 300 mL (anaerobic samples except DASF 62) and 350 mL (DASF 2) using the extraction solvent The microwave soil extracts were filled up to a votime of 100 ful using the Despective explacitor solvent. The radioactivity content of these extracts was determined by L&C. The exhaustively extracted soil was lyophilized, homogenized and NER were combustion/LSC determined e contraction of the contraction combustion/LSC.

RESULTS AND DISCOSSION П.

The test systems were incubated in Ovalk to climatic chamber in the dark at 20.4 °C for a total study period of 150 days. The aerobic incubation phase was maintained for 30 days. After forcing the test systems to anaerobic conditions, the anaerobic incubation phase was maintained for 120 days.

The aerobic incubation phase was performed at a soft moisture of \$5% of the maximum water holding capacity. No significant loss of moisture was observed throughout the aerobic incubation phase.

The anaerobic incubation phase was performed under flooded conditions with oxygen-depleted deionized water.

Determinations of soil microbial biomass of viability were performed at start and end of the aerobic incubation phase and at the end of the anaerobic incubation phase. The results demonstrated that the used soil was mictobially viable and that an anaeroby microflora was established in the test systems during the anaerobic incubation phase, L Å

Oxygen contents in the water decreased from a maximum concentration of 8.9 mg/L at DASF-0 to < 1.5 mg/L from DASF-30 onwards. This demonstrated the shift from aerobic to anaerobic conditions.

ANALYTICAL METRÓDOLOG

Verification of Sample Focessing Method 1.

The mean recovery of the test item at DAT 0 was 104.1% AR. The overall mean recovery of the concentration procedures for water and combined soil extracts was 99.3%. These results demonstrate that the sample processing methods were well suited to recover the applied test item from the soil and that the test item was stable under these conditions

m' 2. Verification of Chromatographic Procedures

The primary chromatographic method (HEEC/radiodetection) was well suited for the quantitative analysis of the samples of this study as demonstrated by a mean HPLC recovery of 96.3% and a good linear fit for njected amounts of pyrazole-labelled isoflucypram on HPLC column ($R^2 > 0.9998$). The LOD of the primary chromatographic method was determined as 9.1 Bq absolute on column or 1.1% AR.

MATERIAL BALANCE **B**.

Mean material balances was 101.3% AR (range from 98.6 to 104.5% AR) (Table 7.1.1.2-6).

The complete material balances found at all sampling intervals demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing.



Table 7.1.1.2- 6:Material balance of radioactivity under anaerobic conditions after an aerobic
incubation phase (expressed as percentage of applied radioactivity)

Soil Material halance	and a start of the								
min max mean O BSD	.0								
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$									
RSD = relative standard deviation									
	Ô,								
C DISTRIBUTION AND COMPOSITION OF DESIDUES \mathcal{O}	s.								
C. DISTRIBUTION AND COMPOSITION OF RESIDUES	, Ô ^v								
The detailed figures of the radioactivity distribution are presented in Table 7.1.1.5%.	, Y								
The route of degradation of isoflucypram in som, under anaeropic conditions is summarised in	Í								
Table 7.1.1.2-8. Q°									
Table 7.1.1.2-7: Material balance of radioactivity under anaerobi@conditions after an aerobic 🕰									
incubation phase A & Q Q A									
(expressed as percentage of applied radioactivity, mean of two replicates)									
	٦								
DATO A LOO LOO LOO LOO LOO LOO LOO LOO LOO									
$DA \downarrow 0 7 30 7 30 7 30 7 32 0 37 57 44 5 60 592 020 150 0 120$									
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	_								
volatiles									
$[- volatiles of aerobic incubation purse \sqrt{2} (- \sqrt{2} \sqrt{2})$									
$\frac{\text{carbon dioxide}^{2}}{\text{volotilo organic compounds}^{2}} = \frac{1.3}{2} + \frac{0.2}{2} + $									
$\frac{1}{1}$									
10tal volatiles actobic pilase $11.a$ $10.a$ 10.2 0.2 0.2 0.2 0.2 0.2 0.2 0.2 0.2 0.2									
carbon diavide $\sqrt{2}$									
volatile organic compounds $\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{$									
total volatiles appendix phase \mathcal{I} N/A \mathcal{N}_{A}									
- total carbon dioxide \sqrt{n} a \sqrt{n} 0 2 $\sqrt{0}$ 2 $\sqrt{0}$ 0 2 \sqrt									
- total volatile operation for the second s									
- total volatiles $ -$									
Extractable residues 0 ∞ 0 0 0 0 0 0									
- water $\sqrt{2}$									
- soil of A of A of A of A									
ambient extract 3 3 3 3 3 3 3 3 3 3									
mircowave extract Q ,									
mircowave stract 2° \sim $0.9914.1811.21.41.71.71.92.21.9$									
total soil extractable residues 100,1 909 939 97.9 92.5 93.3 93.1 91.2 96.4 94.6									
- total extractable residues									
Non-extractable residues $0.4 \times 1.5 \times 1.7 = 1.4 = 1.7 = 2.2 = 3.0 = 3.8 = 4.0 = 4.2$									
Material balance 2 104 104 98 100.1 103.9 98.7 100.0 100.3 99.2 104.5 103.2	2								

N/A: not applicable, n.d.: not depected, ma.: not adalysed DAT: days after treatment, DASF: days after soil flooding
a) Formation of carbon dioxide and valatile organic compounds of the aerobic incubation phase were determined at DAT-30 and DASF-0 and the mean value was assumed focall other sampling intervals

Carbon doxid and voratile organic compounds

, O

The maximum amount of carbon dioxide formed was 0.2% AR at the end of the aerobic incubation phase (DATC30) and < 0.1% AR during the entire anaerobic incubation phase. Formation of volatile organic compounds (VOC) during the aerobic and anaerobic incubation phases was insignificant as demonstrated by values of $\le 0.1\%$ AR at all sampling intervals (Table 7.1.1.2-7 and Table 7.1.1.2-8).



Test item and degradation products in the entire system

Extractable residues varied between 95.2 to 104.1% AR over the total study duration (150 days). Within the aerobic incubation phase, the amount of isoflucypram decreased from DAT-0 to DAT-30 from 104.1 to 92.6% AR. During the following anaerobic incubation phase, the amount of isoflucypram varied between 90.3 and 97.6% AR (Table 7.1.1.2- 8). Since no degradation products of isoflucypram > 5% AR were found, no identification attempts were

made. The total unidentified residues amounted to a maximum of 4.7% AR and no single component exceeded 3.1% AR at any sampling interval (Table 7.1.1.2-8).

Non-extractable residues

Non-extractable residues (NER) increased during the aerobic incubation phase from DAT to C DAT-30 from 0.4 to 1.5% AR. During the following anaerobic incubation phase, NER increased further until DASF-120 to 4.2% AR (Table 7.1.1.2%).

 Table 7.1.1.2- 8:
 Degradation of isoflucypram under an aerobic condition cafter ar aerobic incubation phase (expressed as percentage of applied radioactivity, mean of two replicates)

	1.1		\sim	ž.	4	~	×		<u>s</u>	
Compound	~ ~		¥″	<i>j</i> 🔊 San	npting	interv	vals 🔊	7	Š	Ş
DAT 🦉	(Q >>	°30♥	30~	¥32 _	3 7	<u>~4</u> 4	60	92	120	150
DASE	K N		, AC	2	່ 7ຸ	©14	3 0	62	<u>,90</u>	120
Isoflucypram (entire system)	104.1	92.6	92.3	97.6	910	93.@	92.5	90.3	\$\$5.7	94.2
Sum of unid./diff. residues ^{a)} (entire system)	n.d.	3.5	¥.7	ó¥.3	3.8	30	3,0	2.8	3.0	4.0
Total extractable residues ^{b)} (entire Sytem)	104.9	96	97,0	101.9	₽95.7	96.0	5.6	93,2	98.7	98.1
Carbon dioxide ^{c)}		40 J	-0.2 -0.2	a la	0.2	0 0 0 C	a 0.2	\bigcirc	0.2	0.2
(sum aerobic and anaerobic)	Qi.a.	$v^{\wp.2}$	@ . 2	0.2	0.2%		0.2	0.2	0.2	0.2
Volatile organic compounds		< 0.1	< 0 a	× 0 1	\swarrow			< 0.1	< 0.1	< 0.1
(sum aerobic and anaerobic)	n.a.s		$\mathcal{O}_{\mathcal{O}}$	r∼ 0.1	< 0.1	∞0.1	$\mathcal{O}^{\mathbf{a}.1}$	< 0.1	< 0.1	< 0.1
Non-extractable residues 0	@0.4	Q.5	L1.7	1.	1.7	2.2	¥3.0	3.8	4.0	4.2
Total recovery ^{b)}	M04.5	∾97.8	98.8	b 03.5	<u>9</u> 7.5	98.5	98.7	97.2	102.9	102.5

n.d.: not detected, n.a. not anaDzed, DAT: days after treatment, DASF: days after soil flooding

a) Minor degradates are sponded up to sum of unidentified / duffuse restdues and with the sum of unidentified /

b) Difference to praterial Balance alues due to rounding errors as well as clean up and chromatographic losses

c) Values taken from Material Balance

D. DEGRADATION PATHWAN

At all sampling intervals, the amount of isoflucypramextractable from soil was > 90% AR. Therefore, a pathway for the degradation of pyrazole labelled, isoflucypram in soil under anaerobic conditions after an aerobic incubation period can not be proposed based on the results of the study.



Isoffucypram was not degraded in soil under an erobic conditions in the laboratory in the dark. Formation of carbon dioxide during the aerobic and the anaerobic incubation phase was insignificant with values of 0.2% AR and 0.1% AR, respectively.

Formation of non-extractable residues (MER) was up to 4.2% AR at study end. No degradation products 5% AR were identified.



CA 7.1.1.3 Soil photolysis

The photolytic route was investigated usir A summary of the Figure 7.1.1-1.	of degradation of isoflucypram in soil under aerobic conditions in the laboratory of the pyrazole-radiolabel). route of degradation of isoflucypram in soil is given in section CA 701 and
Report:	KCA 7.1.1.3/01; ; 2013; M-467307-01-4
Title:	[Pyrazole-4-14C]BCS-CN88460: Phototransformation on soil
Report No.:	EnSa-13-0200
Document No.:	M-467307-01-1
Guideline(s):	European Commission Regulation (EU) No 283/2013 in accordance with Regulation
	(EC) No 1107/2009; SETAC Procedures for Assessing the Environmental Fate and
	Ecotoxicity of Pesticides; QECD Draft Test Guidel Be: Phototransformation of
	Chamicals on Soil Surfaces USEDA OC D Test Cuid to No 25 21 M. Can dian

Chemicals on Soil Surfaces; US EPA OCSPP Test Guideone No 835.2410; Canadian PMRA Environmental Gremistry and Fate Guideline DACO 82.3.3.1 eviation(s): not specified

Guideline deviation(s): GLP/GEP:

Executive Summary

yes

The photolytic route and rate of degradation of pyrazole labelled soflue ypram was studied on one soil under exposure to simulated sunkith and aerobic conditions in the aboratory for 10 days at 20.0°C and a soil moisture of 51.7% of the maximum water holding capacity (53.3% for dark samples) in comparison to samples incubated in the dark.

Table 7.1.1.3- 1:	Selected soi
-------------------	--------------

abic 7.11.1.5-11	Scietted #0		Řa	s au	Ô	((j	Ĵ		
Soil	Ž	Sou	INCE		2	Toture 🌭	Ĩ	рН	OC
	<u> </u>			S.	5	(USDA) [©]	~~	(CaCl ₂)	[%]
Laacher Hof AX	XXX O	Mo	nheim, Ge	ermany 🔊		sandyloam	Ŵ	6.3	1.6
	C al	Ž	<u>(</u>		Ş		1		

A nominal test concentration of 7. Jug per test system was applied based on a single field use rate of isoflucypram of 75 g/ha.

Isotlucypram of 75 g/ha. The test was performed in static systems consisting of quartz glass vessels each containing 3 g soil (dry weight equivalents), resulting in a soil layer of approximately 3 mm in height, closed by quartz glass lids and equipped with traps for the collection of carbon dioxide and volatile organic compounds. The test systems were continuously exposed to artificial irradiation by a Xenon lamp with a < 290 nm cut-off filter (irradiance of 1307 W/m² for range from 300 to 2450 nm). In addition, samples were incubated in the dark

Duplicate samples were processed and analysed 0, 1, 2, 3, 6, 8, and 10 days after treatment for both irradiated and dark samples. 10 Days of continuous irradiation corresponded to 36.4 solar summer days at Phoenix, Arizona, USA. At each sampling interval, the soil was extracted three times at ambient temperature using ACN (water U/1, v_0), once by microwave-accelerated extraction at 70°C using ACN / water $(1/10^{\circ}v/v)$ and finally once by microwave-accelerated extraction at 50°C using methanol. The amounts of test item and possible degradation products in soil extracts were determined by liquid scintillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues (NFR) were determined by LSC and combustion/LSC, respectively. Test item was identified by HPLC and TLC co-chromatography with reference items and by HPLC/MS(/MS) including accurate mass determination.

Mean material balances were 102.4% AR (range of 100.7 to 107.0% AR) for irradiated samples and 102% AR (range of 99% to 107.5% AR) for dark samples.

The maximum amount of carbon dioxide was 0.2 and < 0.1% AR at study end (DAT-10) in irradiated and dark samples, respectively.

Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for both irradiated and dark samples.



Extractable residues remained constant from DAT-0 to DAT-10 (range 99.3 to 106.7% AR in irradiated samples and 99.1 to 107.4% AR in dark samples. NER increased from < 0.1% AR at DAT-0 to 1.2 and 0.2% AR at DAT-10 in irradiated and dark samples, respectively.

The amount of isoflucypram also remained constant from DAT-0 to DAT-10 (range).5 to 106.1% AR in irradiated samples and 97.4 to 107.4% AR in dark samples), indicating neither photolytic degradation nor a significant difference in irradiated and dark samples. Neither in the irradiated nor in the dark samples degradation products of pyrazole-labelled isoflucypram above the identification triggers were formed in this study. The total unidentified residues amounted to a maximum of 2.8% AR. N

It is concluded that the degradation of isoflucypram is driven by morobial degradation under topical O

It is concluded that the degradation of isoflucypram is driven by microbial degradation under typical conditions in the environment and photodegradation plays no role in the overall fate of isoflucypram.

2. Test spil The soft was sampled freshlo from the field and sieved to a particle size of ≤ 2 mm. The physico-chemical characteristics are shown in Table 7.14.3-2.4

Lote-labelled isoflucypram Sample-ID: KML 9480 Specific activity: 5.904Bq/mg (10504 µG/mg) Radiochemical purity: >99% (HPLC with 1UV detector, 210 nm) eference item mlabelled isoflucypram ample-ID: AZ 18080 Test soil softwas sampled/reshly/from the field and Sieved nical characteristics and showern Table 7.141 The sold was sampled freshlop from the field and sieved to a chemical characteristics and shown in Table 7.14(3-2.4)



 Table 7.1.1.3-2:
 Physico-chemical properties of the test soil

Parameter	Results	0
Soil designation	Laacher Hof AXXA	
Geographic location		
City	Monhem	
State	North Rhine Westphalia	
Country	Germany	
Soil taxonomic classification (USDA)	Sandy, mixed, mesic Typ@ [*]	
<u>Č</u>	Cambudoll	N S
Soil series	no information available 🔌	
Textural class (USDA)	S sandy loans	
Sand [%] (50 μ m – 2 mm)		<i>0</i> , <i>0</i>
Silt [%] $(2 \mu m - 50 \mu m)$		
$Clay [\%] (< 2 \mu m) \qquad $		
pH - in 0.01 M CaCl ₂ 1/2	× × × ×	×0'
- in water 1/1	0° 6.6 0°	A S
- in saturated paste		
- In SOII/I N KCI I/I		Ĩ, S ^{\$}
Organic carbon (combustion)) % OC		Ő
		ŝ
Cation exchange capacity med noo g) [*]
Water holding capacity		
maximum (MWHQ) [$g H_2 O$ at 100 g D χ_3		
Dull density (disturbed) a com ³		
Soil migrobial Remark and remark and Solar		
Soli inicioolat pioinass [ing notional 7/kg soli Dw]	× × × × × × ×	l
a) % organic matter - so organic carbour x 1.7.40		
	s. Ø	
	it was	

B. STUI

Experimental Conditions 1.

Quartz glass vessels (36 mm inner diameter, 25 mm keight, inner shrface area 10.2 cm²) were used as incubation wessels. The upper edge of vessel is beaded and provided with a ground joint and a glass neck with ground joint is attached to the side of the walk. The ground joint of the upper edge of each vessel was covered with vacuum grease and each vessel was closed with round quartz glass covers being 3 mm thick esealed with metallic clips Additionally the glass neck of each vessel was closed with a trap attachment opermeable for oxygen), containing soda lime for absorption of carbon dioxide and a polyurethane (PU) found plug for adsorption of volatile organic compounds.

The photolysis test systems were placed in a Suntest guint containing a xenon lamp simulating natural sunlight. The light emission was fiftered with a 290 nm cut-off UV-filter, which eliminated all wavelengths < 290 nm. The temperature inside the Suntest® unit was maintained by a cooling plate connected to a cryostat unit. The ortensite of the xenon lamp was determined at the beginning and the end of the overall test period.

For preparation of the test systems of the quivalents of the sieved soil were weighed into each test vessel. Soil moisture was adjusted to 55% of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The test vessels were then closed with quartz glass covers and fitted with trap attachments.

All test systems were incubated in the same Suntest® to guarantee the same light intensity for all samples. "?

50 μ L ∞ the application solutions were applied dropwise onto the soil surface of the respective test systems using a pipette to obtain the nominal test item concentration of 7.7 µg per test system (based on the single field use rate of isoflucypram of 75 g/ha. All test vessels were left open for 15 minutes to facilitate the evaporation of application solvent methanol.



After evaporation of the application solvent, the test vessels (except DAT-0 samples) were closed with quartz glass covers, weighed and fitted with trap attachments. The irradiated samples were placed into the Suntest® unit for irradiation and the dark samples in a temperature-controlled (irradiated: 20.0°C, dark: 19.6°C) walk-in climatic chamber.

2. Sampling

Seven sampling intervals were distributed over the entire incubation period of 10 days. Duplicate samples were processed and analysed after 0, 1, 2, 3, 6, 8, and 10 days of incubation for both irradiated and dark samples.samples were processed and analysed 0, 2, 6, 15, 28, 50, 62, 84, 104 and 120 days after treatment (DAT).

3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous by drochloric acid and trapped. The liberated carbon dioxide was purged into the trapping vessels by a stream of nitrogen. The radioactivity contents of these vessels were determined by liquid scintillation counting (LSC) and summed up to determine the total radioactivity liberated from sodalime.

The PU foam plug was extracted with SmL ethyl acetate to desorb olatile organic compounds. The radioactivity content was determined by LSC.

The entire soil of each test vesseb was transferred into a centrifuge Deaker using the first extraction solvent. The soil was extracted three times at ambient conditions using a mechanical shaker followed by two accelerated extraction deps using a microwave with a magnetic stirrer. The extraction procedure is summarised in the following table:

Table 7.1.1.3- 3: Extraction procedure

-	A			
Solvent	Volume	Minimum duration	Temperature	Cycles
$ACN/H_2O(1 (v/y))$	hQmL _	Ø 30. min, shaking	Cambient	3
ACN/H20 1/1 (17)	∞,10 mL√	10 min, Prring	nticrowale, 70°C	1
Methanol	∛10 mµL	√10 min, stirring	microwave, 50°C	1
	Č.		N G	

After each extraction step, extract and soil were separated by centrifugation and decantation. The volumes of the combined ambient soil extracts and the microwave soil extracts were determined separately. The radioactivity content of these extracts was determined by LSC. The exhaustive extracted soils were an drigg and NER were determined by combustion/LSC.

The test item was identified by HPDC and TLC co-chromatography with reference items and by HPLC-MS(/MS) including accurate mass determination.

QII. RESIDETS AND DISCUSSION

The irradiated and dark test systems were incubated in a Suntest® unit exposed to simulated sunlight and in a walk-in climatic charaber in the dark, respectively, under aerobic conditions at 20.0°C (dark test systems: 19.6°C) for 10 days. The average irradiance of irradiated samples was 814 W/m²).

The test was performed at soil moistures of 51.7% and 53.3% of the maximum water holding capacity in irradiated and dark samples, respectively (see Table 7.1.1.3-4). No significant loss of moisture was observed throughout the study



Table 7.1.1.3-4: Soil moisture during study incubation

Samples		Soil moistures [% MWHC]					
	mean	min	max				
Irradiated	51.7	48.4	55.0 🏷				
Dark	53.3	48.4	55.0Ç				

 max
 max

 48.4
 55.0

 53.3
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 48.4

 55.0
 50.4

 A
 ANALYTICAL METHODOLOGY

 A
 400.7

 A
 400.7

 A
 400.7

 A
 400.7

 A
 40.4

 A
 40.4

 A
 40.4

 A
 40.7

 A
 40.4

 A
 40 these conditions.

Verification of Chromatographic Procedures 🚿

2. Verification of Chromatographic Procedures The primary chromatographic method (HPLG/radiotetection) was wellosuited for the quantitative analysis of the samples of this study as demonstrated by a MPL Corecovery of 99.2% and a good linear fit for injected amounts of pyrazok-labelled isoffercyprom on HPLC column ($R^2 > 0.9999$). The LOD of the primary chromatographic method was determined as 15% Boyabsolute on column or 0.6% AR.

B. MATERIAL BALANCE

Mean material balances were 102.4% XR (range of 100.7 \$ 107.0% AR for irradiated samples and 102.9% AR (range of 99.3 to 107.5% AR) for dark samples (Take 7.1.1.3-5).

The complete material balances found at all sampling intervals for both irradiated and dark samples demonstrated that no significant portion of radioactivity dissipated from the test systems or was lost during sample processing.

Material balance of radioactivity in gradiated and dark samples Table 7.1.1.3- 5: (expressed as percentage of applied radioactivity, mean of two replicates)

Soil	Samples N		Material balan	ce	
*		Q'minQ' Omax.	mean	SD	RSD
Laacher Hot AXXa	irradiated	100.7 107.0	102.4	2.1	2.1%
L.	ð dark	107.5	102.9	2.9	2.8%
CD 1 1 1 1 1					

- Ali - Int -



C. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the radioactivity distribution are presented in Table 7.1.1.3-6. The route of degradation of isoflucypram in soil under aerobic irradiated and dark conditions, "is summarised in Table 7.1.1.3-7.

Material balance of radioactivity in irradiated and dark samples Table 7.1.1.3- 6: (expressed as percentage of applied radioactivity, mean of two replicates)

				DAT	x î *		<u>, 0</u> ,] ፈ້
	0	1	Č 2	$\begin{vmatrix} \mathbf{DAI} \\ 3 \end{vmatrix}$	6		1	Ő,
Irradiated samples		L	¥	, ô ^g		Ŵ,	N S	کی ک
Volatiles		(U)*		<u>A</u>	<u>ا</u>	<u>)</u>	¢ ₍)	Ň
carbon dioxide	n.a.	0.1	< 0.1	₩0.1	0.10	0.1	<u>0.2</u>	A.
volatile organic compounds	n.a.	∞0.1	< 0.1	< 0,	< 0.1		× × 0.1~	
total volatiles	n.a. 🖔	< 0.0	< 001	\$9.1	×0.1	0.1 %	¥ 0.2 [≪]	ľ
Extractable residues	. O"		Č	- 10 m	Ö Ö	× L	A	<i>°</i>
ambient extract	1.00.3	1091.5	Ø105.8 4	₽,101,2 [°]	98.6	9\$¢	48 .3	a y
mircowave extract 1	0.2 ∧	[≫] 0.6∼	0.7	1,17	、 ©Ž	‰ 1.4	1.2	
mircowave extract 2	0.1°	0,20	<u>~0.2</u>	. 0 .3	0.3	0.3	0.5	
total extractables	100,6	102.4	~€06.7	102.6	100,	99®	<u>99.9</u>	1
Non-extractable residues	₹00 .1	`∕∕0.3	© 0.3	0.7	0:9	. A Ž	× 1.2	1
Material balance	©100.7¢	102.	1070	103.4	€ 01.2	Q00.7 °	≫101.3	1
Dark samples	L' O	Ő	L.		Ő, Ý	, %	-	1
Volatiles	, se	L.	, ¹ 4) Ô	0		
carbon dioxide 🔗 🔿	n.a.	V < 0.1	< 0.1	<	گُڑ.1	0.1	< 0.1	
volatile organic compounds	n.a.	< 0, 1/	≪ 0 %.1	< 0.1	× 0.1×	≥ < 0.1	< 0.1	
total volatiles 🏑 🦧	n.Q	@9.1	° 0.1	K≪ 0.Ł	< 0,10	< 0.1	< 0.1	1
Extractable residues	()	S ×	C [#]		- L			
ambient extract	≸ ¶00.3	1022	10696	105.7	2 9.5	98.2	101.1	
mircowaye extract 9	027	0.4	6.6	Ø.5 鷔	Q 0.8	0.8	0.8	
mircow e extract 2	_00ł	ר.1 4	0.1	0.2	0.2	0.1	0.2	
total extractables	100.6	Q102.7	107.€	10,624	100.5	99.1	102.1	1
Non-extractable residues 🖉	< 0.1	0.10	0,1	0 .2	0.2	0.2	0.2	1
Material balance	0 100.7	102.9	AQ97.5	¥06.6	100.7	99.3	102.4	1
n & not detected: n al note a paysed: DA	T. dawe afa	iter@reatm	ant o	0				-

O'

Carbon dioxide and volatile organic compounds

The maximum amount of carbon dio de was 0.2 and < 0 P% AR at study end (DAT-10) in irradiated and dark samples, respectively. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values $\mathfrak{W} \leq 0.18^{\circ}$ AR \mathfrak{A} all sampling intervals for both irradiated and dark samples (Table 7.17.3-7). Ò

× i

Test item and degradation products in soil extracts

Extractable residues remained constant from DAT-0 to DAT-10 (range 99.3 to 106.7% AR in irradiated samples and 99.1 to 107.4% AR in dark samples.

The amount of isoflucyper also remained constant from DAT-0 to DAT-10 (range 96.5 to 106.1% AR in invadiated samples and 97.4 to 107.4% AR in dark samples), indicating neither photolytic degradation for a significant difference in irradiated and dark samples.

Neither in the irradiated for in the dark samples degradation products of pyrazole-labelled isoflueyprane above the identification triggers were formed in this study. The total unidentified resolutes appounted to a maximum of 2.8% AR (Table 7.1.1.3-7).

Non-extractable residues

0

Non-extractable residues (NER) increased from < 0.1% AR at DAT-0 to 1.2 and 0.2% AR at DAT-10 in irradiated and dark samples, respectively (Table 7.1.1.3-7).



Table 7.1.1.3- 7:	Degradation of isoflucypram in irradiated and dark samples
	(expressed as percentage of applied radioactivity, mean of two replicates)

Compound	Samples				DAT			Š	O ^y
I	···· 1 ···	0	1	2	3	<i>S</i>	8	ر آن گ	
Isoflucypram	irradiated	100.6	102.0	106.1	101.8	@98.8	96.5	× 97.9×	
	dark	100.6	102.7	107.4	106.4	99.5	97 A	10 0.7	Ô
Sum of unid./diff. residues ^{a)}	irradiated	n.d.	< LOD	< LOD	< LØD	1.3	°×2.8	≈ 2.0 ≈	Ĵ
	dark	n.d.	n.d	n.d.	Ød.	< LOD	0.6	× 1.50	(
Total extractable residues ^{b)}	irradiated	100.6	102.0	106.5	<i>€</i> 1 02.3	100,1	99.3	90,9	. 6
	dark	100.6	a)02.7	107.4	106.4	995	98 ∕1	D02.1	S
Carbon dioxide ^{c)}	irradiated	n.a.	⇒<0.1	< 0.1%	<@_1	ØY.1	گن∕0.1	0.2	/
	dark	n.a	< 0.1	\$9.1	~ Q 0.1	₹0.1	0 < 0, 1	2 < 0	
Volatile organic compounds ^{c)}	irradiated	Q.a.	E 0.1	چ 0.1 ک	©″< 0.1ℓ″	$\int_{D}^{D} < 0$	`<^()	KØ.1	
	dark	Qa.a.	, Ø 0.1	< 0.1	′< <u>,0</u> 07	< 0.1	< 0.1	<u>_</u> < 0.1	,
Non-extractable residues ^{c)}	irradiated 🔎	< 0.1	, 0.30	0.Q	0.7	0.9	© 1.2	0° 1.2%	
	dark 🖉	~~Q.V	Â,Î	39 .1	0.2	$\stackrel{\sim}{0}$ 0.2	0.2	QŽ	
Total recovery ^{b)}	irradiated	_Ĵ€00.6	€ 02.3	∱106.8C) 103 (l	1052	100.7	A01.3	
	dark	x 100.6.	×102:®	1075	106.6	29 .7	Ø98.3	102.4	

n.d.: not detected, n.a.: not analysed, DAT days affor treatment

a) Minor degradates are summed up to the identified residues and momatographic losses b) Difference to material malance values due to rounding error as we

c) Values taken from material balance

D. KINETIC ANALYSIS OF DATA

D. KINETIC ANALYSIS OF DATA The amount of isofluctor pramatine constant from DAV-0 to DAT-10 (range 96.5 to 106.1% AR in irradiated samples and 97.4 to 1074% Afr in dark samples), indicating neither photolytic degradation nor a significant difference in irradiated and dark samples. Thus kinetic analysis was not performed.



The amount of isoflucepram mained constant from DAP-0 to PAT-10 (range 96.5 to 106.1% AR in irradiated samples and 97 4, to 10 4% AR in dark samples), and icating neither photolytic degradation nor a significant difference in intradiated and dark samples.

The degradation of is the driven by microbial degradation under typical conditions in the





CA 7.1.2 Rate of degradation in soil

The degradation behaviour of isoflucypram in soil was investigated under aerobic and anaerobic conditions in the laboratory as well as under field conditions. The kinetic models and DT_{50} values in soil of isoflucypram and its major degradation product in soil are summarised in sections CA 7.1.2.2.

Modelling input values for the calculation of predicted environmental concentrations (PECs) of isoflucypram and its major soil and aquatic degradation product in soil (PECs_{oil}), groundwater (PECs_{oil}) and surface water (PECs_w) were derived from studies and kinetic evaluations (according to FOCKS (2006¹/2014²) and EFSA (2014³) summarised in the following and injections CA (21.3.1) and CA (7.2, 6) and are submitted within this Dossier.

The DT_{50} values and maximum occurrences / the fination fractions is soil and a quatic system of isoflucypram and its major degradation product used as modelling input values for the calculation of <u>PECs</u> are summarised in the following modelling coff info documents.

Ø

• PEC _{soil} Model	ling Core Info				
Report:	KCA 7.1.2/04/;	ĞŸ.	, W. 2017	7 3 - 6087	23-01-4
Title:	Isoflucypram (IS	SY): CorepECs	o@EUR Modell	ing core	nfo doeument for soil risk
	assessment in Et	wope O		° Or	8 ×
Report No.:	EnSa,17-0654			, Q	~ O'
Document No.:	M-608723-0∳-1		Ø ^v		
Guideline(s):	not applicable	\$ \$	L ~ ~ ~)	
Guideline deviation(s):	none		^y . Ô ^v & .	. %	Š.
GLP/GEP:	no 🖓 🗸		NY ON	× .	
Ű			S a.	0 *	Ý
Executive Summary			9 6 A	, 0	
The input parameters y	which are used in	the PEC soir &	alculations are s	ummaris	ed in the following table.
				, Ø	C C
Table 7.1.2-29: Inp	ut parameters re	hated to active	substance isoflar	ypram a	nd metabolite for PEC _{soil}
cal	contions &			••	
Compound	Molecular	^S Max Y	<u>ф</u> ФТ50		Value in accordance to
	mass	∿øccur <i>r</i> ence	O ^y [days]		EU endpoint y/n /
Q	A [gemol]	<u> </u>			Reference
Isoflucypram	<u>کې99.85 کې </u>		630		n.a.
~Q~ 0			Arigger, maxim	um lab,	
A	<u> </u>		🖉 not-normali	ised	
BCS-CH 88460-carbox	Ağı 者 🖉 🦉	Ø.6 🔪	113		
acid (MY2)	× 4 × ~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	trigger, maximi	um lab,	
L W			not-normali	ised	
n.a. [≇] not applicable for a	ne@ substance subn	nission O ^v			

¹ FOCUS Tinetics (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies of Desticities in Etc. Registration", Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sance /10058/2005 version 2.0, 434 pp.

- ² FOCUS, 2074: Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticid in EU Registration, Version: 1.1; Date: 18 December 2014
- ³ EFSA, 2014: Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil, European Food Safety Authority (EFSA), Parma, Italy, EFSA Journal 2014;12(5):3662



• Isoflucypram

Rate of degradation

The route and rate of degradation of isoflucypram under laboratory aerobic conditions was investigated in three different studies (; 2014; M-486690-01-1; ; 2017; M-588260-01-1; 2017: 🔊

599926-01-1).

a)

The laboratory degradation data of these studies were kinetically evaluated according to CUS Table 7 1 2- 2: Summary of aerobic degradation rates (non-normalised) for isoflucypram

Summary of aerobic degradation rates (non-pormatised) for isoflucypram , K , S laboratory studies trigger endpoints ≪.

				\bigcirc \lor	,×Q		°¥ ∧`	8	a
Soil name	Soil type	pН	temp.	MWHC	5T ₅₀		St.	Kinetic	Exaluated on
	(USDA)	(CaCl ₂)	[°CT)	<u></u>	days	[∞] [da <u>¥</u> s]	($\chi^2 err$)	model	EU level y/n /
			á.				~ [%] _		Reference
Hanscheider Hof, D ^{a)}	loam	5.7	Q 20 🕵	53	438	🖉 100 🖉	0.89	SFO	n,
Laacher Hof AXXa,	loamy	6.3	2000	Š3%.1	[©] 236	782	1:90	SFO ₅	(9 .; , ,
GER ^{a)}	sand	Q,	Ô	S Q	r S		o ,	õ 'n	W.; 2017; M-
Hoefchen am	silt loam	6 .6 🗞	20	⁶ 53.1	348	Q1000	1.16	SFQ	608255-01-1
Hohenseh, GER ^{a)}	×	J u	Ş	al a	~~~ ~		Ĉ	0	
Dollendorf II, GEr ^{a),e)}	loam	70	20	\$3.1	[©] 277	901		SFO	
Sanger, CA, USA ^{b)f)}	sandy	<u> </u>	20.4	§ 64.9	630	>1000%	0.68	SFO	
	toam				× (5× &			
Louisville, NE,	Sity clay	63	204	70.0 ^{d)}	224	743	2.30	SFO	
USA ^{b),g)}	loam		L'	~~~ <u>^</u>	, Q	A A	Q.		
Laacher Hof AXXa	hamy	∛5.8 🕵	20	55.0	263	873	2.74	SFO	
GER ^{c)}	sandC) Oʻ	s. S	6 I		l ()			
Geometric mean (n=7)	<u> </u>	D.	A	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	323				
pH dependency:	õ		Ç,	~	tto, v	Ň			

- <u>, M</u>-486690-0<u>1</u> 2014 2017: 14-588260-01 .
- b) ; 2017 M-599926-01-k c)
- Calculated based on study moistore and MWHC d)
- From modified pathway fit excluding the residue data of PAT e)
- From modified parent only speecluding the residue data of DAT From modified parent only speecluding the residue data of D From initial pathway fit including ab residue data . f)
- g)



• BCS-CN88460-carboxylic acid (M12)

Rate of degradation

The degradation of BCS-CN88460-carboxylic acid (M12) under laboratory aerobic conditions was investigated in the studies with the parent substance isoflucypram (2014; M-486690-01-1; 2017; M-588260-04

; 2017; M-599926-01-1).

The kinetic evaluation according to FOCUS (2006, 2014) was conducted by W.; 2017; M-608255-01-1. The non-normalised DT values ranged from 14.8 to 13 davs (Table 7.1.2-3). The maximum non-normalised DT₅₀ value of 113 days was taken oto account for the soil exposure assessment, together with the maximum becurrence of BCS-CN88460-carboxylicacid in soil of 9.6% AR. Q

Table 7.1.2- 3:	Summary of aerobic degradation	rates (non normatised)	and formation Tractions (f.f.)
	for BCS-CN88460-carboxy Rc acie	(<i>M12</i>) - laboratory st	dies trogger endpoints

				41	064		-		()	
Soil name	Soil type	рН	temp.	мүнс,	DT50	DToo	Kinetic	St.	∞f.f .	Evaluated on
	(USDA)	(CaCl ₂)	[°C]	@{%] _{&} `^	day	[days]	model	(X ² err)		EU level y/n /
			Ő		. 9 .	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		[%]	Ű	Reference
Hanscheider Hof, GER ^{a)}	Loam	5.7	ZŞ ^r	53.1	45.4		SÊO A	208 0	0 ³³⁰	بنائی G.;,
Laacher Hof AXXa, GER ^{a)}	Loamy sand	6.3	20 ≽ &	53.1 C	1103 	\$377 \$	SFQ SFQ	5.2P	0.257	W.; 2017; M- 608255-01-1
Hoefchen am Hohenseh, GER ^{a)}	Silt loam		90 >	\$ ^{3.1}	14.8		JFO &	8.70	¢ 9 .440	
Dollendorf II, GER ^{a),e)}	Loam	7.4	39	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	مَنْ 18.4 مَنْ مَنْ	61,2 \$	SFO	8:55 Ø	0.500	
Sanger, CA, USA ^{b)}	Sandy Aloam	6.3	20.4 0	, 64.9 ^d			SFOU	_f)	_f)	
Louisville, NE, USA ^{b)}	Silty clay loam		20.4	20.0 ^{d)}	7 n.r. 7	n.r.	SFO SFO	20.01	0.286	
Laacher thof AXXa, GER ^{c)}	Loamy sand	5.80) ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	20 20 20	5500°	s n.r.	n.r:~	SFO	16.05	0.255	
Geometric mea	an (n🐳)	AS			34.4	²				
Arithmetic me	angen=6) Č	y S	Ŭ,		, Ô ^v	0 ⁷			0.345	
pH dependenc	ÿ?	~~~	\sim		ono 🔗					
a)		; 2014;	M-486	90-01-1						

2007; M

\$\$260-01-1

c) ; 2047; M-599926-06 c) calculated based on study mosture and MWHQ e) From modified pathway fit excluding the residue date of DAT 104 f) Metabolite only found in two samples – parent only fit conducted n.r. = not reliable

;

b)



CONCLUSIONS

The maximum non-normalised DT₅₀ values based on laboratory studies of 630 days for isoflucypram and 113 days for the major soil metabolite BCS-CN88460-carboxylic acid (*M12*) were used in the soil software exposure assessment.





PEC_{gw} Modelling Core Info .

Report: Title: Report No.: Document No.: Guideline(s): Guideline deviation(s): GLP/GEP: Executive Summary The input parameters w	KC4 Isoff grou EnS M-6 not a none no	A 7.1.2/02; Core PECg Iucypram (ISY): Core PECg Indwater risk assessment in I a-17-0655 08724-02-1 applicable e	W.; 2017; M-60872 w EUR - Modelling core in Europe	4-02-1 fo document for
Table 7.1.2- 4: Inpu	it pa	rameters related to active s	ubstance isoflyeypram an	d metabolity for PECgw
calci	ulati	ons O		
Parameter		Lisoflucypram,	poind BCS-CN89460- carboxylicacid (M72)	Value in accordance with EU endpoint on / Reference
Molecular mass [g/mol]		,≪ 399.8 5 ° ~~	A29.8 6	₩3.
Water solubility [mg/L]		[√] 1.8 (20°C)	² 10,000 (20°C) ∧	n.a.
Saturated vapour pressure [[Pa]	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	2.6×10^{-10} (20°C)	n.a.
DT ₅₀ in soil [days]		Tier 1: 04 geometric mean leb, normalisation to pI2, 20°C with Q p of 2.58, n =70 Fier 2: 023 geometric mean lab and field, normalisation to pF2, 20°C with Q ₄ /of 2.58 n=13	Tiel/1: 34 4 geometric mean lab normatisation to pF2, 20°C with Q ₁₀ of 2.58 n=4 Tier 2: 840 geometric mean lab and tield, normalization to pF2, 20°C with Q ₁₀ of 2.58, 0n=10	n.a.
Transformation rate k	d O	ل 1:00022005	Tigs 1: 0.0201496	n.a.
K _{foc} / K _{fom} [mL/g]	A A	4,580 / 86.3 geometric mean, 3=7	$3\sqrt{3} / 21.5$ geometric mean, pH 7.5, n=2	n.a.
1/n ^{a)}	\$ ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	arithmetic mean, n=1	0.9424 \rightarrow arithmetic mean, pH 7.5, n=2	n.a.
Plant uptake factor		Default: 0 (Tier 12, Tier 2) Briegs estimate: 0,10 (Tig 1b)	Default: 0	n.a.
Formation fraction	N		Tier 1: 0.345 from parent Tier 2: 0.043 from parent	n.a.

n.a. = not applicable for a prev active substance substance substance and a substance substance



Rate of degradation

• Isoflucypram

Tier 1:

The route and rate of degradation of isoflucypram under laboratory acrobic conditions investigated in three different studies (2014; M-486690-01-4

2017; M-588260-01-1;

Ĉĥ

2017; M-599926-01-1). The laboratory degradation data of these studies were kinetically evaluated according to FOCUS (2006, 2014) by , G.; , W.; 2017; M-608255-01-1 DT₅₀ values were formalised to 20°C ($Q_{10} = 2.58$) and field capacity (pF2) following the standard procedure described in FOCUS (2000). The normalised DT₅₀ values ranged from 200 to 570 days (Table 7.2- 50 The geometric mean of 314 days was used in the leaching assessment at tief1.

Table 7.1.2- 5:	Summary of aerobic	degradation	rates før	isoflucy	pram f	from la	boratory	studies,	
	modelling endpoints			ð	A	, O ^v	×1	Nº A	ž

					(// 1			- Y	1 V V	
Soil name	Soil type	pН	Temp.	МЖНС	D € 1 50	Ď ¥90	DT50	St.	Kinetic	Evaluated on
	(USDA)	(CaCl ₂)	[°C]	[%]	[days]	[days]	(days)	($\chi^2 err)$	medel	E level y/n /
			Ŷ,	h ù	T	Â	20%,	[%]	õ, v	Reference
		Q	, K	t di	Š		ph /2 ⁿ /	ð 🖕	p (
Hanscheider	loam	5,7	20%	53,1	438	≶¥000	¢¥38 ©	0.89	SFO	n /,
Hof, GER ^{a)}		~~	×	Č ^v	y a				Ô	G.;
Laacher Hof	loamy	6.3	⁰ 20 ¢	53. K	236	782∿	236	°¶.00	ŠFO €	W.; 2017; M-
AXXa, GER ^{a)}	sand	í A	Ô	Ő	»	Ô		Č,		608255-01-1
Hoefchen am	silt loan	605	20	<i>5</i> 3.1	\$348 🔬	71000	0'348	1,16	SFO	
Hohenseh,		L.	6 ^	\$~~^		, O	ſ	<i>.</i> ,		
GER ^{a)}	N. N	Ć, Ò				No.	ŵ ~			
Dollendorf II, 🗼	O loam	7,4	26	53	z77 🦓	921	🖉 277 🖗	1.24	SFO	
GER ^{a),e)}		*		×	p ç	Ő				
Sanger, CA, 🖗	sandy 💡	6.3 🔬	20.4	, 64.9°	630	>1000	. 570	0.68	SFO	
USA ^{b)f)}	loam	S S		<u>م</u>	S.	Ŝ	Ň			
Louisville, NE,	silty chay	<u></u> 63	×20.4	\$0.0 ^d	224	743 🐔	200	2.30	SFO	
USA ^{b),g)}	loam		Ş 🔉							
Laacher Hof	føamy _	5.8	20	55.0	263	A 73	263	2.74	SFO	
AXXa, GER ^{c)}	🖉 sandõ 🖗	õ	۵°,	, 0 [×] .	Ô ^y	6 ⁷				
Geometric mean	n (n=7)		Y p		× ò		314			
pH dependency:	Č	, , , , , , , , , , , , , , , , , , ,	Ű,		. K		no			

a)

2014: M-486690-01



- Calculated base on study moisture and M&HC d)
- From modified pathway fit excluding the residue data of DAT 104 e)
- f) From modified parent only fit excluding the readue data of DAT 0
- From initial pathway fit incoding at residue pata g)
- Normalied using 2 Q10 of 2.58 and Walker equation coefficient of 0.7 h)

Tier 2:

The degradation of isoflucypram in the field was investigated by 2017; M-, B.; 2017; M-608370-595964-01-1. A kinetic evaluation was conducted by , G.; 01-1. The degradation kinetics were normalised to a soil moisture corresponding to field capacity (pF2) and a temperature of 20°C ($Q_{10} = 2.58$) following FOCUS (2000). The normalised DT₅₀ values



ranged from 137 to 649 days (Table 7.1.2-6).

Based on the EFSA endpoint selector (EFSA 2014) degradation rates of isoflucypram derived from laboratory and field degradation studies are not systematically different and can therefore be pooled to derive a DegT_{50matrix} value for input to simulation models. According to EFSA (2014), it may be acceptable not to perform a difference test between laboratory and field data if the geometric mean laboratory DegT_{50matrix} value is higher than 240 days.

and the service of the opening the service of the service of the opening the service of In this particular case the geometric mean laboratory $\text{DegT}_{50\text{matrix}}$ value of 314 days and the geometric mean field $\text{DegT}_{50\text{matrix}}$ value of 335 days are very close to each other. Providence of the second of th latoratory Deg I somans value is higher than 240 days. In this particular case the geometric mean laboratory Deg I somans, value of 314 days and the geometric mean field Deg I somans, value of 315 days are very close to each other. In other to make the set use of all available data DT₀ values have been pooled. Consequently, the geometric mean Deg I somans, value of 333 days derived from lab and field data (n=13) was used for the leaching assessment. In this particular case the geometric mean laboratory Deg I smarts, value of 34 days and mean field Deg I smarts, value of 335 days are very close to each other. In edger to make available data DT₅0 values have been pooled. Consequently, the geometric mean Deg **323 days** derived from lab and field data (n=13) was used for the leaching assessment. mean field DegT_{50matrix} value of 335 days are very close to each other. In order to make best use of all



Table 7.1.2- 6:	Summary of aerobic degradation rates for isoflucypram from laboratory and field
	studies, modelling endpoints

		Isoflu	icypram	, aerobic co	nditions		Ŵ
Soil name	Soil type (USDA)	pH (CaCl ₂)	Depth [cm] ⁱ⁾	DT50 matrix [days] norm ^{h)}	St. (χ²err) [%]	Method of calculation	Evaluated of EU level ym Reference
Laboratory stu	dies kinetic evalı	uation (, (G.;	, W.; 2017	7; M -60 8255-01-	
Hanscheider Hof, GER ^{a)}	loam	5.7	0-20	438	0.89	SFO SFO	, GØ , ¥;
Laacher Hof AXXa, GER ^{a)}	loamy sand	6.3	0-20	236	1.00	SFO Õ	2017, M-60 255-
Hoefchen am Hohenseh, GER ^{a)}	silt loam	6.6	0-20	9 348 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		SEO SEO SEO	
Dollendorf II, GER ^{a),e)}	loam	7.4	20	© 277 ©	1.24	SFQ,	
Sanger, CA, USA ^{b),f)}	sandy loam	6.3	0-20		×0.68	SSFO	
Louisville, NE, USA ^{b),g)}	silty clay loam	~Q.3	0-20	200	2:30	SIQ 6	
Laacher Hof AXXa, GER ^{c)}	loamy sand	5.8¥ &	0-20		2.74	SFO SFO	0 [¥]
Field dissipation	on studies kinetic	evaluatio	p (.,G.;		їВ.; 2097; М -6 9	8370-01-1)
Burscheid, GER ^{d)}	silt loam, bare soil	5.30 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0-600 Ø	281 . S	3. K	DFOP slow	n /, G.; , B.;
Great Chishill, UK ^{d)}	classioam		* 0-60		6.1 5	DF@P slow	2017; M-608370- 01-1
Parcay Meslay, F ^d	loam	50°	& 0 260	* 449 7 7		DFOP slow phase	
St. Etienne du Gres,	clay loam bare so	V 7.5 0	* 0-60 [*]	5 ¹³⁷ 2		HS slow phase	
Albaro, IT ^a	clay > (* bate soil		00-60		\$ <u>5</u> ?9	DFOP slow phase	
Vilobi, ESa	bare soll	× 5.80°	0-60	\$ ²⁵⁸ \$	/ 10.3	DFOP slow phase	
from combine	an (n=13) 🔗 d lab and field s	ordies 🗲					
pH dependency	/: <u>```</u>		R.	~0 [×]	no		
a) b) c) e) From modifie f) From modifie g) From mitial p h) Notmalised i) Experimental	d pathway fif excluded a second secon	01 PM-486 7; M-59992 7; M-59596 ding the res duding the g all residue and Walker n considered	26-00-21 24-01-1 residue data residue data equation to derive	of DAT 104 of DAT 104 ata of DAT 0 coefficient of total residues	0-01-1 0.7 s for kinetic	evaluation	



• BCS-CN88460-carboxylic acid (M12)

Tier 1:

The degradation of BCS-CN88460-carboxylic acid (*M12*) under laboratory aerobic conditions was investigated in the studies with the parent substance isoflucypram (**M12**), **M-486690-01-1**; **M-486690-01-1**; **M-486690-01-1**; **M-486690-01-1**;

; 2017; M-599926-01-1).

2017, M-386200-01-

The kinetic evaluation according to FOCUS (2006, 2014) and normalisation to 20° C ($Q_{0}^{\circ} = 2.58$) and field capacity (pF2) (FOCUS 2000) were conducted by **FOCUS**, G.; **FOCUS**, W.; 2017; M-608255-01-1.

The normalised DT_{50} values ranged from 14.8 to 113 days (Table 79.2-7). In tier 1 of the learning assessment, only the data from the laboratory studies were considered. Consequently, the geometric mean DT_{50} value of 34.4 days and the arithmetic mean formation fraction of 0.345 were taken into account.

Table 7.1.2- 7:Summary of aerobic degradation rates (normalised) and formation feaction (f.f.) for
BCS-CN88460-carboxy fic acid (M12) – laboratory studies modelling endpoints

Soil name	Soil	рH	Temp.	MWHC	DT 50	крт‰ '	Kinetic	DT	SE	f.F.	Evaluated
~	type	(CaCl ₂)	[°C]	Q%1	davs	davs	moder	[daws]	(gerr)	kt kdp	an EU level
	(USDA)	、 <i>、 、 、</i>						₩°C.		S . 4	v/n /
	` ´		a,				Ô,	Ç pF2₽			Reference
Hanscheider Hof, GER ^{a)}	loam	5.7	290 (°\$3.1 ₹∕	45.4	©151 Å ©	SFO	45,4	7.08	©330	n /, G.;,
Laacher Hof AXXa, GER ^{a)}	loamy sand	6.3	20 C	53¢)		877 ©	SFO SFO	³ 113 پر	5.24) 5.24)	0.257	W.; 2017; M- 608255-01-1
Hoefchen am Hohenseh, GER ^{a)}	silt loam	© 6.6 (20 8	53.15	14.8	4901	SFO C	14.8 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	^{\$\$} 8.70	0.440	
Dollendorf II, GER ^{a),e)}	loam Ø	6 ^{97.4} «	⁰ 20	© _{53.1} %		61.9 0	\$60	Ø8.4	8.55	0.500	
Sanger, CA	sandy sandy		20:4	(9 ^{d)}			SFO SFO	_f)	_f)	_f)	
Louisville, NE, USA ^{b)}	silty clay loam	9 6.3 4 Q	20.4 20.4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 0.4 2 2 2 2 0.4 2 2 2 0.4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	70:00		8.1. 7	ŚFO	n.r.	20.01	0.286	
Laacher Hof AXXa, GER ^{c)}	AQamy sand	05.8 0		55.0		tor.	SFO	n.r.	16.05	0.255	
Geometric m	ean (n=4)			7		,		34.4			
Arithmetic m	iean (n=ð)		, Q	S					0.345	
pH dependent	y: 🔊		Å		S.			no			
-)	~	201	A 1 4 0 0		\$						

a) ; 2014; M-486690-01-

d) Calculated based on study moisture and MWHC

e) From prodified on hway the excluding the residue data of DAT 104

f) Metabolite on found two samples - parent only fit conducted

g) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

n.r. = not reliable

C

Tier 2:

The degradation of BCS-CN88460-carboxylic acid (M12) in the field was investigated in study with



the parent substance (; 2017; M-595964-01-1) on six European soils. The kinetic evaluation according to FOCUS (2006, 2014) and normalisation to 20° C (Q₁₀ = 2.58) and field Based on the EFSA endpoint selector (EFSA 2014) degradation rates of BCS CN88460-carboxylic acid derived from laboratory and field degradation studies are not systematically different therefore be pooled to derive a D. T. capacity (pF2) (FOCUS 2000) were conducted by , G.; , B.; 2017; M-608370@1-Add and of the second of the s Autor the second the s therefore be pooled to derive a $\text{DegT}_{50\text{matrix}}$ value for input to simulation models. Consequently the geometric mean DegT50matrix value of 84.1 days derived from lab and field data was used for the



Summary of aerobic degradation rates and formation fractions for BCS-CN88460-Table 7.1.2-8: carboxylic acid (M12) from laboratory and field studies: Modelling endpoints

	BCS-CN88460-carboxylic acid, aerobic conditions									
Soil name	Soil type (USDA)	pH (CaCl ₂)	Depth [cm] ^{h)}	DT ₅₀ matrix [days] norm ^{g)}	St. (χ ² err) [%]	Method of cal- culation	f.f. k∂∕k _{dp}	Evaluated on EU		
Laboratory stu	dies kinetic evalu	uation (,	<i>G.;</i>	, W.; 201	7; M-60 \$25 3	5-01-1)			
Hanscheider Hof, GER ^{a)}	loam	5.7	0-20	45.4	7.08	SEO	0.330 گ ©	n /G.;		
Laacher Hof AXXa, GER ^{a)}	loamy sand	6.3	0-20		5.27	SFO SFO	0.057	2047; M-608255 01-1		
Hoefchen am Hohenseh, GER ^{a)}	silt loam	6.6	0-20	94.8 \$ \$	8.70	SFO	0.440			
Dollendorf II, GER ^{a),e)}	loam	7.4	0-20	~18.4 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	© 8.55 ~	SFO	©0.500			
Sanger, CA, USA ^{b)}	sandy loam	6.3	0-20 4			SFO				
Louisville, NE, USA ^{b)}	silty clay loam	6.2) ()	0-20	n.r.	20.00	AFO O	0.286°			
Laacher Hof AXXa, GER ^{c)}	loamy sand	~~5.8 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	¥ 0-20	n.r.	Å46.05 €	SFQ	0.255			
Field dissipati	on studies kineti	c eyaluati	ionô	, G.;	,	B‰2017,¶	-608370-0	01-1)		
Burscheid, GER ^{d)}	silt loam, bare soik	5.3 C	▶ 0-60Ć		4.3 %	SFO	.0 90 386	n / , G.; , B.;		
Great Chishill, UK ^{d)}	clay loam, dy bare soil	.7.90 	20+60	67.3	1398 2	SFO O	0.0563	2017; M-608370- 01-1		
Parcay Meslay, F ^{d)}	bare sont	5.9 Õ	0-600	340 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	8.9 5	SFŐ	0.0345			
St. Etienne du Gres, F ^d	clay loam, 👟 bare soil	\$9.5 89 - 6	60 ≁60	° 82.4 °		SFO	0.0651			
Albaro, IT ^{d)}	clay,	7.60 D	060 >>	228 & 7 0	23 <u>A</u> ×	SFO	0.0430			
Vilobi, ES ^{d)}	loam,	5.8	0-60		\$ 2 3.9	SFO	0.0183			
Geometric me	ean (n=10) 💍	2	R	84.1 ^{°°}	Arithmet	ic mean	0.043			
from combine	d lab and field st	udies (Ů 🌾		(n=6) fro	m field				
nU davandana	······································	× ~~		<u>~</u> 0′	studies					
pri dependency		1. NA 10611		<u>A</u>	10					
a) b) c) d)	; ; ; 2014 ; ; 2018 ; ; 2018 ; ; 2018	+;) (1 48669 ; 1 ; M-59 99 2 ; M-59596	6-01-1 4-0-1	© Ő17; M-58820	50-01-1					
 e) From modifie f) Metabolite on g) Normalised u h) Experimental 	ed pathway fitoxclu lly found in two san uning a Off of 2.58 soil sampling dept	ding the re opes – pare and Walke h considere	sidue data ent only f r equation d to deriv	a of DAT 104 it conducted a coefficient o ve total residu	f 0.7 es for kinet	ic evaluation				
	~									

.0

In addition a population test was also conducted for the kinetic formation fraction (f. f. k_f / k_{dp}) of BCS-CN88460-carboxylic acid. The arithmetic mean formation fraction in laboratory studies is 0.345 (n = 6) whereas the arithmetic mean formation fraction in field studies is 0.043 (n = 6). Based on the



ð

EFSA endpoint selector kinetic formation fraction of BCS-CN88460-carboxylic acid derived from laboratory and field degradation studies are systematically different. Consequently, the arithmetic mean value of **0.043** derived from field data was used for the leaching assessment at Tier 2. Sumpary of combined laboratory and field kinetic endpoints for modelling at Tier 2 is given in Table 7.1.2

Table 7.1.2- 9:	Summary of combined laboratory and field kinetic endpoints for m	odelling at Tier
-----------------	--	------------------

Parent / Transformation product	Rate of degradation in soil normalised geometric mean (if not pH dependent)	Kinetic Aprmation fraction (f, Skr /
Isoflucypram	323 d (n = 13) from combined labored field studies	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
BCS-CN88460-carboxylic acid (<i>M12</i>)	84.1 d (fr= 10) from combined lab and field studies	0.042 (n = 6) $\sqrt{2}$ $\sqrt{2}$ from field studies formed from parent
n.a. = not applicable		

Tiered approach

For PEC_{gw} assessments a tiered approach concerning the DT₅₀ alues of isolucyprain and its metabolite BCS-CN88460-carboxylic acid, the formation fraction of BCS-CN88460-carboxylic acid, and the PUF values should the considered. In Tiel 1 only laboratory data are considered for DT50 values and formation fractions, which can be modified by the BUF values. Field data are included in Tier 2 where a further modification by PUF values is not possible. A detailed description is presented in Table 7.1.2-10.

	((//))*					V 7	
Table 7 1 2_ 10.	- Alered An	nroach for	• Nother	nram and	its metabolit	e used for	modelling
1 abic 7.1.2-10.	ancicular		Joginucy	pi ani ang	no meaboli	c usequit	mouthing

Compound O		fier 1a			Ther 1b			Tier 2	
ð	D T ₅₀ ^{a)}	ff ^{a©}	P&F ^{d)}	(A)T 50 ^{a)}	ffe ^{r d}	P&Fe)	DT 50 ^{b)}	ff ^{c)}	PUF ^{d)}
Ò	^{"0} [days]"	<u></u>	A. 2	>[days	<i>a</i> .		[days]		
Isoflucypram	30Å	Çn.a.	0.0	3014	n.a.	0.1	323	n.a.	0.0
BCS-CN88460-	× 4.4 ×	0.345	(QQ)	\$4.4	0.3,45	0.0	84.1	0.043	0.0
carboxylic acid		S.	°						
a) From laboratory da	ta A								
b) rom laboratory and	field stata	y °C	Ó¥	. O [×] 4	de la compañía de la comp				
c) rom field data	0.0		\sim	× ×					
d) PUF representing v	vorst cas	ult	Ri						
e) PUF based on Brig	gs equation	S 6	F a						
la l		Q _ ~	, A						
. K	X A	Ĩ	Ĩ	NY NY					
Advention	~ ~	\sim	<i>D</i> ^	Q					

- c) rom field data
- Õ d) PUF representing worst case defau

Adsorption

toor toor Adsorption For the leaching calculations the adsorption of isoflucypram was described by the geometric mean K_{foc} value of 1580 mL/g ($K_{for} = 916.3$ mE/g) and the arithmetic mean Freundlich exponent 1/n of 0.9142. For the leaching assessment of SCS-CN88460-carboxylic acid (M12), only the realistic worst case (K_{fo} 37.1 ML/g, Mn = 0.9424) was taken into account.

A more detailed summary is given in chapter CA 7.1.3.1.



CONCLUSIONS

For isoflucypram the geometric mean (normalised to 20°C and pF2) of laboratory data of 314 days was used in the leaching assessment at Tier 1. For Tier 2 the geometric mean DegT_{50matrix} value of 323 days derived from lab and field data was used for the leaching assessment. A default plant uptake factor of zero was used at Tier 1a and Tier 2, and for Tier 1b the Bridge estimate of 0.10. For the leaching calculations, the adsorption of isoflucypram was described by the geometric mean K_{foc} value of 1580 mL/g ($K_{fom} = 916.3 \text{ mL/g}$) and the arithmetic mean Freundlich exponent $1/n_{s}$ 0.9142. In tier 1 of the leaching assessment of the major retabolite BCS CN88460-carboxylic acid only the data from the laboratory studies were considered. The geometric mean DT_{50} value (normalized to 20°C and PF2) of 34.4 days and the arithmetic mean formation fraction of 0.345 were only the realistic Forst case taken into account. For Tier 2 the geometric mean DegT_{50math} value of 844 days derived from fab and field data and a formation fraction of 0.043 were used For the leaching assessment of BCS-CN88469-carboxylic acid, only $(K_{foc} = 37.1 \text{ mL/g}, 1/n = 0.9424)$ was taken into account. ary the second of the second o



Table 7.1.2- 11:	Input parameters related to active substance isoflucypram and metabolite for
	PEC _{sw/sed} calculations

Parameter	Com	pound	Value in accordance with 🔗
	Isoflucypram	BCS-CN88460-	EU endpoint vn /
		carboxylic acid (M12)	S Reference
Molecular mass [g/mol]	399.85	429.8	n.a. S
Water solubility [mg/L]	1.8 (20°C)	10100 (20°C)	Ar.a. S
Saturated vapour pressure [Pa]	$1.2 \times 10^{-7} (20^{\circ} \text{C})$	$2.6 \times 10^{-13} (20^{\circ} \text{C})^{-13}$	× n.a. ×
Diffusion coefficient in water [m ² /d]	required for Steps 3-4: 4.3 $\times 10^{-5}$	not required	
Diffusion coefficient in air $[m^2/d]$	required for Steps 3-4:	not required	n.a. cy @
$K_{foc}/K_{fom} [mL/g]^{c)}$	1580 / 916.3 (geometric mean, n = 7)	37.1 / 20.5 (geometric) mean, pH 7.5, n = 2	h.a. J
1/n ^{c)}	0.9142 (arithmetic mean $n = 2$	0.924 (arithmetic mean, $p_{\rm H}$ 7.5, n = 2)	
Plant uptake factor			Le La
Wash off factor from crop [1/m]	required for Steps 3-4: 56	not required O	a Ona
DT ₅₀ in soil [days]	314 (geometric mean lab, normalisation to pF2, 20°G with Q_{10} of 2, 23°, n =7)	Q4.4 (geometric mean lab, normalisation@pF2, 20°C with Q1007 2.58 Q=4)	n.a.
DT ₅₀ in water [days] ^{d)}	354 (Stop 2) 354 ^{a)} /100 ^{b)} (Stop 3)		n.a.
DT ₅₀ in sediment [days] ^{d)}	54 (Step 2) 5 354 1000 @Step 35		n.a.
DT ₅₀ in total system [avys] ^{d)}	354 (Step 1)	§ § 1000 0	n.a.
Maximum occurrence observed (% motor basis with respect to parent)	© @vater:400 Sediment: 83.0~	varier: 5.4 sedimentz .3	n.a.
N N	total system: 190	total system: 6.6	

According of OCUS (2015) for subtances with a K between 100 and 2000 mD/g two options should be tested: a) DegTsosystem used for degradation in water, default DTso of 1000 days used for degradation in sediment b) DegTsosystem used for degradation in sediment default DTso of 0000 days used for degradation in water c) A more detailed summary is given in chapter CA 7.15.1 d) A more detailed summary given in chapter CA 7.2.3 n.a. = not applicable for a row active substance submission Rate of degradation in soil

• Isoflucypram 🖉

The route and	d rate	ofodeg	gradation	n 🕅	isoffucypram	under	laboratory	aerobic	conditions	was
investigated in	.182 mee di	fferent	studies	Ľ	•		; 2014;	M-48669	0-01-1;	
			"	; 201	7; M-588260-0)1-1;			; 2017	; M-
599926-01£P).	Z Z	Ő	Ð	Ŷ						

The laboratory degradation these studies were kinetically evaluated according to FOCUS (2006, 2014) (2006, 2014) (2006, 2014) (2007), W.; 2017; M-608255-01-1. DT₅₀ values were normalised to 20°C (Q_{10} 2.58) (2000). The normalised DT₅₀ values ranged from 200 to 570 days (Table 7.1.2- 12). The geometric mean of 314 days was used in the risk assessment.

	moue	ming end	points							
Soil name	Soil type (USDA)	pH (CaCl ₂)	Temp. [°C]	MWHC [%]	DT ₅₀ [days]	DT90 [days]	DT ₅₀ [days] 20°C, pF2 ^{h)}	St. (χ ² err) [%]	Kinetic model	Evaluated on EU level y/n Reference
Hanscheider Hof, GER ^{a)}	loam	5.7	20	53.1	438	>1000	438	0.89	SFO	G.;
Laacher Hof AXXa, GER ^{a)}	loamy sand	6.3	20	53.1	236	Ö 7 82	236	1.00	SFO	₩ <u>;</u> 2017;M- 608255;01-1
Hoefchen am Hohenseh, GER ^{a)}	silt loam	6.6	20	53.1	348	>1000	348 Q	° 1.16	SFO 4	
Dollendorf II, GER ^{a),e)}	loam	7.4	20	53.k	277,°	924 *	227	ر 1024 ۵	©8FO ∿	
Sanger, CA, USA ^{b)f)}	sandy loam	6.3	20.4	64.9 ^{d)}	~630 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	000ع کې	Q 570	0.68	SKO)	
Louisville, NE, USA ^{b),g)}	silty clay loam	6.3	20.40	70,00	2294 ©	74 8		2.30	SFO SFO	
Laacher Hof AXXa, GER ^{c)}	loamy sand	5.8	Q ²⁰	95.0	⁷ 263	873	× 260	264	SFO ,	
Geometric mean	n (n=7)	Å.	°~		\mathcal{O}_{λ}	K	314	Č		
pH dependency:	y/n		×		ș a	»	n N		ČA –	
a) b)	;	;2014; N	1-486694	01-1 € • 20₽ M	-58 8 60-	016	w v		Å.	

Table 7.1.2-12: Summary of aerobic degradation rates for isoflucypram from laboratory studies,

c)

; 2017; M-599926-01-1

c) calculated based on surdy moisture and MWHC System of DAT Q4
e) From modified pathway fit excluding the residue data of DAT Q4
f) From modified pathway fit excluding the residue data of DAT Q4

g) From initial patoway fit we luding all residue data

h) Normalised using a Quot 2.58 and Walker equation coefficient of 0.7

• BCS-CN88460-carboxylic acid (M12)

The degradation of BCS-ON88460-carboxylic acid (M12) under laboratory aerobic conditions was investigated in the studies with the parent substance isoflucopram (M-486690-01-dri ; 2017; M-588260-01-1; 92017; M-599926-01, 1).

; 2017; M-599926-(N-1). The kinetic evaluation according to FOCUS (2006, 2014) and normalisation to 20° C (Q₁₀ = 2.58) and field capacity (pF2) (FOCUS 2000) were conducted by , G.; , W.; 2017; M-608255-01-1. The rormalised DT walkes ranged from 14.8 to 113 days (Table 7.1.2-13). The geometric mean DT₅₀ value of 34.4 days was taken into account. The maximum occurrence of BCS-

geometric mean D150 varpe of 5*.4 days was baken into account. The n CN88460-carboxylic acid in soft in the laboratory studies was 9.6% AR.



		BCS-CN	88460-c	arboxylio	e acid (M	(12) – la	boratory	v studies n	nodellin	g endpo	oints
Soil name	Soil type (USDA)	pH (CaCl2)	Temp. [°C]	MWHC [%]	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic model	DT ₅₀ [days] 20°C, pF2 ^{g)}	St. (χ ² err) [%]	f.f. k _f /k _{dp}	Evaluted on KU level y/n / Reference
Hanscheider Hof, GER ^{a)}	loam	5.7	20	53.1	45.4	151	SFO	45.4	7.08	0.330	n / . G.,
Laacher Hof AXXa, GER ^{a)}	loamy sand	6.3	20	53.1	113	377¢	> SFO	00 11 28	5.27	B 257	W, 7, 2017, M- 608250, 01-1
Hoefchen am Hohenseh, GER ^{a)}	silt loam	6.6	20	53.1	14.8	49.1	SFOQ	14.8°	8:70 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0(440	
Dollendorf II, GER ^{a),e)}	loam	7.4	20	53.1	ð8.4	Ø51.2	SFO A	18.4	8,55	0,500	
Sanger, CA, USA ^{b)}	sandy loam	6.3	20.4	64.9 4			SEO			_f)	
Louisville, NE, USA ^{b)}	silty clay loam	6.3	20.4		yn.r. (n.r.~	SFQ	n Q		02286	Ģ
Laacher Hof AXXa, GER ^{c)}	loamy sand	5.8		~55.0	n.r.	Fn.r. ,	©SFO Ç	, n.r.	16,95	0%255	
Geometric m	ean (n=4)		2	Q		Ś.	S.	[©] 34.4			
Arithmetic m	ean (n=6) 🖉	S.	S.		Ĭ,		\$		0.345	
pH dependenc	:y:y/n	<u>°</u>			S'	<u> </u>		n	*¥		

Table 7.1.2- 13:	Summary of aerobic degradation rates (normalised) and formation fractions (f.f.) for
	BCS-CN88460-carboxylic acid $(M12)$ – laboratory studies modelling endpoints

M-588**26**0-01-1 [©] ; 2017;

b) (2017, M-599, 26-01-1)c) (2017, M-599, 26-01-4)d) Calculated based on study moisture and MWHC e) From modified pathway fit excluding the residue data oDAT 104 f) Metabolity only found in two samples – paratronly fit conducted g) Normalised using a Q100 (2.58 and Walker equation coefficient of 0.7) n.r. = not reliable Adsorption For the leaching calculations, the adsorption of isofurcypram was described by the geometric mean K_{foc} value of 1580 mL/g (K₁₀₀ = 916/3 mL/z) and the arithmetic mean Freundlich exponent 1/n of K_{foc} value of 1580 mLg ($K_{foc} = 9163$ mLg) and the arithmetic mean Freundlich exponent 1/n of 0.9142. ~Q'

For the leaching assessment of the major metabolite BCS-CN88460-carboxylic acid (M12), only the

For the leaching assessment of the major metabolite <u>BCS-CN88460-carbox</u> realistic worst case (K_{foc} \Rightarrow 37.1 mL/g, 1/n = 09424) was taken into account. A more detailed summary is given in chapter CA 7.1.3.1.



Degradation in aquatic systems

The geometric mean total system degradation DT₅₀ of 354 days for isoflucypram was used for all phases in the Steps 1-2 calculations. For FOCUS Step 3 degradation DT₅₀ for the single phasespare required. Since these are not available the geometric mean total system DT_{50} of 354 days was taken 4 into account. According to FOCUS (2015), for substances with a K_{foc} value between 100 and 2000 mL/g such as isoflucypram two options have to be tested to derive the worst case PEC value 1. The geometric mean total system DT_{50} of 354 days was used for the water phase and a default DT_{50}

- value of 1000 days was used for the sediment phase.
- 2. The geometric mean total system DT₅₀ of 354 days was used for the sediment phase and a default DT_{50} value of 1000 days was used for the water phase

For the major metabolite BCS-CN88460-carboxyle acid (M12) no reliable degradation harf-lives could derive from the aerobic water-sediment starty with the parent soflucy prant due to limited formation in aquatic systems. Therefore, the DT₅₀ in water, sediment, and total system was secto a conservative value of 1000 days for the use in FOCUS Steps 1-2 calculations. The maximum occurrence of BCS-CN88460-carboxylic acid in water/sedunent systems was 6.6%.

A more detailed summary is given in chapter

For isoflucypram the geometric mean mormalised to 20°C and ppp of laboratory soil data of 314 days was used for the risk assessments. Õ Ô Ø

The adsorption of isofluepram was described by the geometric mean K_{foc} value of 1580 mL/g $(K_{fom} = 916.3 \text{ mL/g})$ and the arithmetic mean freundtich exponent 1/n of 0.9142

The geometric mean total water/sediment system begradation DT50 of 354 days for isoflucypram was used for all phases of the Steps 12 calculations For FOCUS, Step 3 degradation DT₅₀ for the single phases are required. Since these are not available the geometric mean total system DT₅₀ of 354 days was taken into secount, According to FOCDS (2005), for substances with a K_{foc} value between 100 and 2000 mL such as isoftucypram two options have to be rested to derive the worst case PECsw values: n

- 1. The geometric mean total system DD_{50} of 354 days was used for the water phase and a default DT_{50} value of 1000 days was used for the sedument phase. 🖑 \cap
- 2. The geometric mean total system DT of 354 days was used for the sediment phase and a default DT 50 value of 1000 days was used for the water phase.

For the major metabolite <u>BOS-CN\$8460 carboxylic acid (M12)</u>, the geometric mean DT₅₀ value of 34.4 days (based on soil lab data) was aken into account. The maximum occurrence of BCS-CN88460-carboxylic acidan soil in the laboratory studies was 9.6% AR.

For the PEC_{sw/sed} categorian of BCS CN88460-carboxylic acid, only the realistic worst case $(K_{foc} \ll 37.1 \text{ mL/g}, 1)n = 0.9424)$ was taken into account.

For BCS-CN88460-carboxylic acid (M42) no reliable degradation half-lives could derive from the aerobic water-sediment study with the parent isoflucypram, due to limited formation in aquatic systems. Therefore, the DTs in water, sediment, and total system was set to a conservative value of 1000 days for the use in FOCUS Steps 0-2 calculations. The maximum occurrence of BCS-CN88460carboxylic acid in water sediment systems was 6.6%.


CA 7.1.2.1 Laboratory studies

The degradation rates of isoflucypram in soil were studied using two different radiolabel positions for the parent compound (phenyl- and pyrazole-label). The studies have been performed in a number of soils in the dark in the laboratory. For isoflucypram the not-normalised trigger endpoints are summarised in Table 7.1.2.1-1. The modelling endpoints not-normalised and cormalised to F2 and 20°C are summarised in Table 7.1.2.1- 2. For the major soil metabolite <u>BCS-CN88460-carboxylic acid (*M12*)</u> the not-normalised and endpoints are summarised in Table 7.1.2.1- 3. The modelling endpoints not-normalised and normalised to pF2 and 20°C are summarised in Table 7.1.2.1- 4.

Table 7.1.2.1- 1:	Soil degradation not-normalis	ed DØ50 valu	es of isoflucyp	ram to Prigg	ger additional
	studies (<u>trigger</u> endpoints)	Ä	~~ Ø		

	studies (<u>inggen</u> enupoints)		\sim	o" ~	<u>`</u> 0`	ò_U'
Study	(Soil °		Model futted	not-no	۳T ₅₀ ormalised اهمچه مر
01 - 1	; 2014; M-4866990-	Hanscheider Laachel Hof	Hof AXXa O	SFO SFO		¥38 236 ⊖
		Hoefchen an Dollendorf I	hHohenseh I	SFO SFO		348 \$77
; 2017; M-588260-01-1		Sanger CA Louisville, N	TE CY	SFO © SFO		530 224
; 1	; 2017; MS9992691-	Læacher Høf	AXXa	SFQ [*]		263
Geometric mean:			y or			323

Ø

Ô Soil degradation not-normalised and normalised (to pr2 and 20°C, Q10: 2.58) DEso values of isoflucypram for modelling purposes (<u>modelling</u> endpoints) Table 7.1.2.1- 2:

			2	
Study	Soil Soil	Modek	DT ₅₀	DT ₅₀
	\$ 5 \$ \$		[days]	[days]
; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ;	Hans Beider Høf 🌾	∭SFO	438	438
486690-01-1	Laacher Hol AXXa	» SFO	236	236
	Heefchen am Hohenseh	SFO	348	348
	Dollendorf IL 🕅 📎	SFO	277	277
· · · · · · · · · · · · · · · · · · ·	Sanger, ÇAQ	SFO	630	570
2017; M-588260-01-2	Louisvike, NE	SFO	224	200
; 20 ⁴ 7; M-0 599926-01-1	Laachor Hof AXXa	SFO	263	263
Geometric mean			323	314
	, ^e			



Table 7.1.2.1- 3:	Soil degradation not-normalised DT50 values of BCS-CN88460-carboxylic acid (M12)
	to trigger additional studies (<u>trigger</u> endpoints)

Report	Soil origin	Soil type	pH ^{a)}	Temp.	MWHC	DT ₅₀	DT ₉₀	f.f.	St.	Method
				[°C]	[%]	[days]	[days]	~	(χ ² err)	of cale
	Han-	loam	57	20	53.1	45.4	151	50 330	0.89	N STOC
; 2014;	scheider	iouin	5.7	20	00.1	10.1	.101	0,0.220	S	
M-486690-01-1	Hof, Germany				<i>Č</i> A				0 7 . ~	
	Laacher	loamy	6.3	20	53.1	113	0377	0.257	1.90	SFO K
	Hof	sand			â,	A C	22	Ň	Ŷ.	S ^a S ^a
	AXXa, Germany				N	, Qʻ	le l	á á		
	Hoefchen	silt loam	6.6	20	53.1	@14.8	≫49.1 _@	0.440	., 1 €.	S FO
	am Hohenseh			Ő,				S a	. A	
	Germany			, , , , , , , , , , , , , , , , , , ,		-Q		ç Ö		Û.
	Dollendorf	loam	74	<u>,</u> ,20	33.1 ×	⁰ 18.4	61.2	0.500	ي 1.24	SFO SFO
	II, Germanv ^{b)}	_	ŝ,							
	Sanger,	sandy Q	6.3	20.4	~64.9 ^{c)}	S ^{-d)}	<u>d</u>		×Q,68	SFO
;	CA, USA	loam	S.	<i>®</i>	Ş		Č do se	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~~~~
; 2017: M-588260-	Louisville, NE USA	silfy clay	° %.3	20.4	♥ 70.0°♥	rØ₽.♥	¢a,r.	0.286 O	2.30	SFO
01-1	×, 0011		<i>S</i>		 L ~					
;	Laacher	sandy	©5.8	0 ²⁰ 2	¢ 55.00°	ışçı,	n.r.	\$ 255	2.74	SFO
; 2017; M-599926-01-1	AXX			, S	2		Ŏ ^Ŷ	Ş″		
	Germany Ó		s and a second s		Ş Ş		~~~			
Geometric mean:	<u>ç ç</u> `				<u>~~~</u>	34.4	Ĩ₩4			
Arithmetic mean	- O ^y	<u> </u>	×		<u>~~</u>	0 4	<i>0</i>	0.345		
a) Measured in CaC	12		O'Y	0	7 .5					
b) From modified pa	athway thexc	luding the re	esidue da	ta of DAP	104 📎					
d) Metabolite only f	on stray mois	amples and very	whC ∪ rent ônlv	fit Conduc	tet 🔊					
,				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	y .Q					
~	×0, 1	Č N	,)´Oʻ	^o					
¥ .1	2		R	Č,	Ĩ,					
<u>F</u>		Q.	ø,		, ,					
. K		A								
<i>L</i>	, Ő		-Q	, O'Y						
Å	©`	Ő A	Ş 4	Ŷ						
S &	, A	J.								
	O L	×.								



Soil degradation not-normalised and normalised (to pF2 and 20°C, Q10: 2.58) Table 7.1.2.1-4: DT₅₀ values of BCS-CN88460-carboxylic acid (M12) for modelling purpose (modelling endpoints)

	(<u>modell</u>	<u>ing</u> end	points)								O A
Report	Soil origin	Soil type	pH ^{a)}	Temp. [°C]	MWHC [%]	DT50 [days]	DT90 [days]	f.f.	DT50 [days] 20°C,	St. (χ ² err) [%]	Method of calc.
						×		Ç,	pr 2/ 10 kPa e) %		
; 2014; M-486690-01-1	Han- scheider Hof, Germany	loam	5.7	20	53.1 V	\$ 45.4		0.330	45 Q		
	Laacher Hof AXXa, Germany	loamy sand	6.3	20 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	53.1 53.1		377	0.257 */ Ø		× 00	с SFO Су
	Hoefchen am Hohenseh, Germany	silt loam	6.6		× 53.1× ×			0.440 C			\$SFO
	Dollendorf II, Germany ^{b)}	loam	7.4 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	20 20	53 O			009J9	8.4	¥.24	SFO
	Sanger, CA, USA	andy loam	06.3 ₍	S20.4	0 [°] 64.9°	_d)	CB.		Z Z Z	0.68	SFO
; 2017; M-588260- 01-1	Louisville, NE, 58A	silty clay łoam		20.4		y n.r. C	≯n.r.∢	, 0.286	n.r.	2.30	SFO
; 2017; M-599926-01-1	Gaacher Hof AXXa, Germany	sanđy logm	548 0 2		55.0 5 6 7 7 7 7 7 7	n.r.	n.r. s	0.255	n.r.	2.74	SFO
Geometric mean:		<u> </u>			Ô ^v «	J 34.4 (ົ້ 114		34.4		
Arithmetic mean:		<u> </u>	ç v	O ^v K	j 🖕	<u> </u>		0.345			





CA 7.1.2.1.1 Aerobic degradation of the active substance

The degradation rates of isoflucypram in soil were studied using two different radiolabel positions for the parent compound (phenyl- and pyrazole-label). Three studies have been performed in a number of soils in the dark in the laboratory. In addition the data of these studies have been evaluated for trigger? and modelling endpoints according to FOCUS guidance (2006, 2014). ď A summary of the degradation rates of isoflucypram and its major degradation product in soil in the laboratory is given in section CA 7.1.2.1.

Studies soil metabolism, aerobic

Report:	KCA 7.1.2.1.1/01; (2014; M-4866) -01-1 (2014; M-4866)
Title:	[14C]BCS-CN88460: Aerobic metabolism/degradation°in for soils &
Report No.:	EnSa-13-1043 \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O}
Document No .:	M-486690-01-1
Guideline(s):	OECD Test Guideline No. 307 a A A A
	Commission Regulation (EU) No 283 2013 in accordance with Regulation 🖉 🔬
	(EC) No 1107/2009 \rightarrow \sim
	US EPA OCSPP Test Guideline No. 835 9100 🖉 💭 📩
	Japanese MAFE Wew Test Guidefines Annex No. 2-5-20 0 0 0
Guideline deviation(s):	not specified of the
GLP/GEP:	yes of the state o

Executive Summary

The degradation data of isofkucypram as reported in M-486690-01-1 2014 in section 7.1.1.1 (page 13) were metically evaluated according to FOCUS Kinetles report (FOCUS, 2006). The experimental data could be well described by a single first order (SFO) kinetic model. The half-life of isoflucypram under deroble conditions was 458, 239, 358 and 267 days in soil Hanscheider Hof; Laacher Hof AXXa; Hoefchen Am Hohenser and Pollendorf II, @spectively (Table 7.1.2.1.1-1).

Table 7.1.2.1.1- 1 Degradation kinetics of isoflucypham in soils under aerobic conditions

Soil 🔗 🗸	Texture	Best fit	D\$\$50	D T90	Chi ²	Visual
	(USDA) A	model ^{a)}	[days] ([days]	error	assessment ^{b)}
Hanse Geider Hof	boam 🖉 🔬	SFO 🖌	\$¥458 ₀ ₹	> 1000	0.7	+
Laacher Hof AXXa	loamy sand	≫SFQ_	239/	795	0.7	+
Hoefchen Am Höpenseh	sik Yoam 📎 👘	SFO	358	> 1000	0.9	+
Dollendorf II 🖗 🖂	koam 🖉 🔍 🗸	SFO	[©] 267	887	1.5	+
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	×			

a) SFO: single first ord b) Visual assessment

# AND METHODS

Details on the study conduct and its results are summarised under KCA 7.1.1.1/01, page 13.

The data for the test item were evaluated according to FOCUS kinetics (2006)¹ using the software KinGUI 2. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial total recovery (material balance) at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model  $DT_{50}$  and DT values were calculated from the resulting kinetic parameters.

Ô ()

Report of the FOCUS Work Group on Degradation Kinetics,

EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.

¹ FOCUS@hetics (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration",



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

The degradation of isoflucypram followed single first order (SFO) kinetics in all soils according to the lowest chi² error values and visual assessments. A summary of all kinetic data is given in Table 7.1.2.1.1-2, the best fits are fighlighted in bold testers there. The half-lives for isoflucypram were between 239 and 458 days in the tested soils inder probic conditions. Č V.

Table 7.1.2.1.1- 2:	Summary of the kinetic evaluat	tion (før trigger	values accor	ding to F(	DCQS)	of th
	degradation of isoflucypram in	soils under aero	obic condition	ns 🏑	s.	õ
	(best fits are highlighted in <b>bold</b> )	letters)		Q,	) N	-

	0	~~ '			
Soil	Kinetic 候	, DT _{®D} °	<b>D9</b> 90	≪Chi² error √	)° ∛yisual≪
(Texture (USDA)	model ^{a)} O ²	[days]	aterays]	× _{% ] ~~	assessment ^{b)}
Hanscheider Hof	SFQ	<b>@4</b> 58 _ (	Z> 100€	0.7	O' Q' Y
(loam)	FOM€ ^{c)} ≈	×448	> 12000	Q.70 ×	
	ØFOP [™]	45 <b>9</b>	(Jd)	O DI S	
Laacher Hof AXXa	SFO SFO	239	S 795 🔊	<b>0.</b> 7	V t
(loamy sand)	√ FOM 健	*>>285 *	> 1000	8 0.6 ×	S I
di la constante de la constante	DEOP ^{c)}	2380	898		v °∀+
Hoefchen Am Hohenseh	SFO '0	358	£1000	0.9 🏷	× +
(silt loam)	FOMC	353	> 1000	s 9 1.0	O +
<u>b</u>	DEOP	@ ⁷ 359 ¹⁰	_d) 2	~~ 0. <b>9</b>	Ŷ +
Dollendorf II	SFO 🔊	261/	887	~ <u>4</u> 5 ~~	+
(loam)	<i>∲</i> FOMCO	259 -	^{0°} 873 🖗	1.6	+
	🖉 DF 🖉 P	\$Ž67 🔬	× 888	0 [×] 1.74	+

a) SFO: Single first order, FQMC: Figborder multi compartment, DFO@ Double first order in parallel b) Visual assessment: + = good, o = moderate, - = poor

- c) Statistically pon-reliable kinetic evaluations

d)	Could	not	be cal	culated	/dete@ni	ined	O	K,	
			0	(A)	<i>4</i> 5			ν	0

tatistically por	i-reliable	kinetic é	valuatu	əns 🔊			
ould not be ca	lculated/a	letetinin	ed O	K.		Č,	je j
、 ●	°Oʻ	s	Ĉo	4	.~	S	O
. Q	~	, %		A	8	"0"	0, 1
	Õ			0.	~~~~ C	* ~	y N
Ľ,	. O	, Öř		∛ ∭۷	CONC	LUSIE	DNS O
- //	S	, N	×	Ő		4.	

Isoflucypram was slowly degraded in soil under aeroDic conditions in the dark in the laboratory. The

Isoflucypram was showly degraded in soil under aeroDic canditions in the dark calculated best fit half-fives were between 239 and 458 days in the tested soils.



Report:	KCA 7.1.2.1.1/02; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ;
	01-1
Title:	[Pyrazole-4-14C]BCS-CN88460: Aerobic soil metabolism in two US soils
Report No.:	MELNN013
Document No.:	M-588260-01-1
Guideline(s):	US EPA OCSPP 835.4100, Aerobic Soil Metabolism, 2008. @ECD: Guideli@ 307;
	Aerobic and Anaerobic Transformation in Soil, 2002 Composition Regulation (EU)
	No 283/2013 in accordance with Regulation (EC) No 1107/2009 PMRA Daco No.
	8.2.3.4.2 Biotransformation in Soil (TGAI), Aerobic Soft 20-30 degrees C S
Guideline deviation(s):	none & A A A
GLP/GEP:	yes v a a

#### **Executive Summary**

The degradation data of isoflucypram as reported in study

FOCUS Kinetics report (FOCUS, 2006). The experimental data could be well described by a single first order (SFO) kinetic model. The half-lives of isoflucy fram under according were 223 and 714 days in NE and CA soil, respectively. Table 7.1.2, 1.9-3)

Table 7.1.2.1.1- 3:	Degradation	kinetics of	f isofluc	ypcam	in søils	under	aerobic	conditio	ns
---------------------	-------------	-------------	-----------	-------	----------	-------	---------	----------	----

(USDA)     model ^a Hays     [days]     error     assess       CA     sandy loam     SFO     714///     \$1000     1.15       NE     silty clay loam     SFO     223     741     2.35       a) SFO: single first order     silty clay loam     SFO     223     741     2.35	Best fit DD50 DT90 Chi Sisual	oil Texture
CA     sandy loam     ✓ SFO     714//>223     × 1000     ≥ 1.15       NE     9     silty clay loam     SFO     223     741     2.35       a) SFO: single first order     9     9     9     9     9       b) Visual assessment: ** # good     9     9     9     9	model ^a (days) (days) error assessment ^b )	(USĎA)
NE     Silly clay bodin     SFO     223     741     235       a) SFO: single first order     A       b) Visual assessment: ★≠ good     A	× SFO 714 × 000 0 1.15 +	A sandy loam
a) SFO: single first order b) Visual assessment: * ≠ good y	n SFO 223 $741$ 235 +	IE 🔬 🖉 silt 🖓 clay 🛵 am
A MATERIALS AND METHODS S	RIALS AND METHODS	) SFO: single first order ) Visual assessment: * = good 5 , , , , , , , , , , , , , , , , , , ,

Details on the study conduct and its results are summarised under KCA 7.1.1.1/02, page 26. The data for the test item were evaluated according to FOCUS kinetics  $(2006)^1$  using the software KinGUL Model input datasets were the residual mounts found in each replicate test system at each sampling interval. The initial total tecovery (material balance) at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of Ot, the value was allowed to be estimated by the model.  $DT_{50}$  and  $DT_{90}$  values were calculated from the resulting kinetic parameters.

# A SH. RESULTS AND DISCUSSION

The degradation of forflucypram followed single first order (SFO) kinetics in all soils according to the lowest chi² error values and visual assessments

A summary of all kinetic data is given in Table 7.1.2.1.1-4, the best fits are highlighted in bold letters there. The half-lives for isotle cyprab were between 223 and 741 days in the tested soils under aerobic conditions.



¹ FOCUS The formation on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration",

Report of the FOCUS Work Group on Degradation Kinetics,

EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



# Table 7.1.2.1.1-4: Summary of the kinetic evaluation (for trigger values according to FOCUS) of the degradation of isoflucypram in soils under aerobic conditions (best fits are highlighted in **bold** letters)

(best fits are high	lighted in bolo	d letters)				Ø	°
Soil	Kinetic	DT50	DT90	Chi ² error		Visual	15
(Texture (USDA)	model ^{a)}	[days]	[days]	[%] 🗇	_≫ a	ssessment ^{b)}	102
CA soil	SFO	714	>1000	1.15 🛇		*	ク
(sandy loam)	FOMC ^{c)}	714	>1000	1.23			
	DFOP	714	>1000	1:33		Ö ^v + 8 ^v	Ŵ.
NE soil	SFO	223	് 741	×2.35	×.	× * × 4	<b>*</b>
(silty clay loam)	FOMC	223 🚿	741	2.51	Ô		" ()
	DFOP	223	740	_Ô [♥] 2.71	×,	$\hat{\mathcal{A}}^+$	C O
a) SFO: Single first order, FOMC: First	t order multi cor	npartment, 1	DFOP: Dou	he first order in	arallel		
b) Visual assessment: $+ = \text{good}, \text{ o} = \text{mod}$	derate, - = poor		A .		. 6		1
		~~				. 43° - 59°	
	×		, S			*~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
	III. Ø	DNCEUS	IØNS 🔬	, ₂ , 0	F L		0
	A		Ø, Q	.1 .5	O.		1
Isoflucypram was slowly degraded	l in soil unde	x aerobic	condition	s in the dark	in «the l	laboratorxTl	ne
calculated best fit half-lives were 2	23 and 714 d	lays in the	tested so	₽\$. <u>×</u> ″		çõõ	
			Ş, Ö			, B	
Â	\$~ ⁶ *	**** ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		ð ð	Ň		
		j _s	, S	~~~~~.	δ,	~	
		Or I	L 6.		× ×	, ¥	
Report: KCA [%] , 1.2.	k.1/03;	A		; 2017; M- <b>5</b> 999	926-01-	1	
Title: [Plonyl-UC	)14C]BCS-C]	<b>&amp;</b> 8460: A	erobic degr	adation / metab	olism ii	n one soil	
Report No.: EnSa-16-09	86 8		S.		Ş		
Document No.: M-599926-0		ð :	×	\$ N	>		
Guideline(s):	Guideline No.	. 397; Com	mission Re	egunation (EU)	No 283	/2013 in	
actordance	with Regulation	on (EC) No	11002009	SUS EPA OC	SPP Tes	st Guideline No	).
Cuidalina daviatio	335.4200; Japa	inese AyrAF	F Jest Gun	gelines 2 Nou	san 814	/, No. 2-5-2	
CL P/CEP: vos	Ő K	\$ X					
	4 2		0	L)			
Executive Summary	à ô	, -U	~~ ~'	Ø			
The designation data of isource	nram as ten	ortod in §	widy.	•		· 2017· N	<i>I</i> _
599926-01-1 in section 7 $1/1$ (na	e 35) Were k	vinetically	evaluated	, ,		, 2017, 1	1-
The experimental state could be the	st described	by a Sing	le first or	der (SEO) kir	etic m	odel The DT	
value of isoflucypram	c. Anditions	$w_{2} = \sqrt{2} 63$	two in the	tested soil (T	Che III	12115	50
value of isofice praintance agroup	Conditions	was=203 y	ays in the		able 7.	1.2.1.1-3).	
		× >					
Table 7.1.2.1.1-5: Degradation an	etics of isoffu	cypram in	soil under	r aerobic cond	itions		
	ture 🔊	<b>Best fit</b>	DT50	DT ₀₀	`hi²	Visual	
	PA) ô	model ^{a)}	[days]	[davs] e	ror	assessment ^{b)}	
I yacher Hof AXXa	v sand	SFO	263	873	2 7	0	
a) SFO: single first order		510	205	075	2.7	0	
b) Visual assessment $0 = moderate$							
	Ŷ						
	MATERIA	ALS AND	METHO	DDS			
Details on the stude conduct and its	s results are s	summarise	ed under K	CA 7.1.1.1/0	3, page	35.	
					) I ~O·		
Č ⁹							



The data for the test item were evaluated according to FOCUS kinetics (2006)¹ using the software KinGUI 2. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial total recovery (material balance) at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

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

The degradation of isoflucypram followed single first order (SFO) kinetics in all soils according lowest chi² error values and visual assessments.

A summary of all kinetic data is given in Table 7.1.2.1.1-6, the best fit is high the difference of the bold there. The DT₅₀ value of isoflucypram under aerobic conditions was 26% days in the tested soil

Table 7.1.2.1.1- 6:	Summary of the kinetic evadu	ation for tri	gger values	according to	FOCU	S) of the
	degradation of isoflucypram	in soil under	aerobic con	dutions	ã de la companya de l	
	(best fits are highlighted in <b>bol</b>	<b>d</b> detters)	L V	-S	0	E C

Soil	Konetic DT DT DT Konetic Visua
(Texture (USDA)	model? ^[] [days] [days] [%] & @ssessment ^b
Laacher Hof AXXa	SFOV 263 8737 2.76 5
(loamy sand)	FOMC $4250$ > $5000$ $20$ $20$ $4250$ > $5000$
	$\mathbb{Q} = \mathbb{Q} = $

a) SFO: Single first order, FOMC First order must compartment, DFOP: Double first order in parallel

= moderate, 😽 b) Visual assessment: + poor

ĭSÔ



¹ FOCUS@hetics (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration",

Report of the FOCUS Work Group on Degradation Kinetics,

EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



#### • Kinetic evaluation of the aerobic soil metabolism studies

Report:	KCA 7.1.2.1.1/04; G.; G.; W.; 2017; M-608255-01-1
Title:	Isoflucypram (ISY) and metabolite - Kinetic evaluation of the degradation in soit
	under aerobic laboratory conditions
Report No.:	EnSa-1/-0102
Cuideline(s):	INI-008255-01-1
Guideline deviation(s).	none
GLP/GEP:	
Executive Summary	
The route and rate	of degradation of isoflucypram under Aboratory activities was
investigated in three di	fferent studies ( $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, 2017$ ; $1, $
(01, 1) In the current re	, 2017, MI-588200-01-4, , , , , , , , , , , , , , , , , , ,
to derive kinetic param	poli, a kinetic analysis of restaue data of isofiucy fram was conducted in order
and environmental risk	assessments (modelling anthount)
	assessments (moderning chappend).
The model fit as well	as the statistical evaluation of the results were carried out with the in-house
developed software K	inGUI version 2.1 The selection of the most appropriate spheric model was
based on a detailed st	tatistical analysis including visual assessment $\gamma^2$ etc) statistics randomness of
residuals, and t-test sig	nificance following the $OCLS$ guidence (2006 ¹ , 2014 ² )
The resulting DT ₅₀ v	alues (i.e. Trigger and modelling endpoints) of isoflucymam are given in
Table 7.1.2.1.1- 7 and	Table 7.1,2.1.1- 8. 5 4 6 4 6 7 5 6
The parts concerning	the nonjor degradation product BCS-CN88460-carboxylic acid (M12) are
reported in section CA	7.1.2.9.2 of this document $\sqrt{2}$
Ô,	
e or	
No.	
ÊŠ ⁱ .	
, S ^Y	
1	
T.	
7	
L A	
<u>× 6 A</u>	

¹ FOCUS, 2006: Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticities in EU Registration. Report of the Work Group on Degradation Kinetics. EC Document Reference SANCO 10058/2005 version 2.0, 434 pp.

² FOCUS, 2014: Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.1.



Table 7.1.2.1.1- 7:	Soil degradation not-normalised DT ₅₀ values of isoflucypram to trigger additional
	studies ( <u>trigger</u> endpoints)

Report	Soil origin	Soil type	pH ^{a)}	Temp.	MWHC	DT ₅₀	DT ₉₀	St.	Method of
				ľCj	[%0]	[days]	[days]	(x ⁻ err) [%]	
;	Hanscheider	loam	5.7	20	53.1	438	>0000	0.89 '	SEC 2
; 2014; M-486690-01-1	Germany					*	<b>A</b>		
	Laacher Hof	loamy	6.3	20	©\$3.1	236	782	×4.00	SFQ
	Germany	Sand		, A	,	Ó	×		
	Hoefchen am Hohenseh,	silt loam	6.6	20	53.1	Q*348	> 1000	1.16 2	© SFQ.
	Germany	-	(	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		L.	<u>v</u>		Ĵ.
	Dollendorf II, Germany ^{b)}	loam	7.40		<b>\$3</b> .1	\$277 \$	921	1.24	SFO
	Sanger, CA, USA ^{c)}	sandy loam	×6.3	20.4	7 64.9°,	630 0 ×	ð1000,	0.68	SHO
; 2017; M-588260-	Louisville, NE, USA ^{d)}	silty clay	600 0	20 A	~~0.0 ^{e)}	224 Û		230	SFO
;	Laacher Hof	sa@dy 、 ×	້ 5.8 ໃ	6 <u>6</u> ř 205	<b>5</b> .0	<u></u> 263 (	0 ⁻ 0 873	2 <u>67</u> 4	SFO
; 2017; M-599926-01-1	AXXa, Germany	Toram	ŝ	Å. 1				0 [°]	
Geometric mean:		 	2 2			323 🐇	897	4	
a) Measured in CaC b) From modified pa	l2 🖉	ong the residu	e Øðta of	f D297 1045	ÌY Õ	× &			
<ul> <li>c) From modified particular d) From initial paths</li> </ul>	arent only fit exc	ludin One res	idule data	of DAT	ř _b o	Å	Ŵ.		
e) Calculated based	on study poistu	re and MWHO				y 5	2		
C Č			1 ×	à à	y Õ	L.			
		Frank and a start and a start	,» (	, S	Ĵ, ĉ	Y Y			
4 Y	à Â		Ő ^S		, s				
			Í 🖏	or o	A A				
~			$\sim$	ñ N N	,				
A A	o Ø	S' é							
	19 A	, ~ ~ ·	Ĩ						
			°,	<u>S</u>					
Ő.		ý "S	Q [*]						
			Ş						
		Ŭ V							
		,							
~									



Table 7.1.2.1.1- 8:	Soil degradation not-normalised and normalised (to pF2 and 20°C, Q10: 2.58)
	DT50 values of isoflucypram for modelling purpose (modelling endpoints)

Report	Soil origin	Soil type	pH ^{a)}	Temp.	MWHC	DT ₅₀	DT90	DT ₅₀	St.	Method
				[°C]	[%]	[days]	[days]	[days]	$(\chi^2 \text{err})$	of cale
								$20^{\circ}C,$		Ô
								10 kPa ^f		
;	Han-	loam	5.7	20	53.1	438	> 1,000	438	0.89 6	SFQ
; 2014;	scheider				Ò			×.		ŝ,
M-486690-01-1	Hof, Germany				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	, C	Ŷ	×,		
	Laacher	loamy	6.3	20	© 53.1	236	782	236	J.00	SF
	Hof	sand			, <b>V</b>	$\sim$ .	Ŵ	Q' $O'$	l Ø	Ŵ
	AXXa, Germany			\$	Q° Å	¢ ×				Ŝ
	Hoefchen	silt loam	6.6	⁰ 20 ×	53.0	3408	> 2000	<b>3</b> 48	1.16	SFO
	am Halanah		, L				A. (	G		
	Hohenseh, Germany		Ő							
	Dollendorf	loam	07.4	چ 20	53.	2017	<b>9</b> 21	\$277	1.24	SFO
	II, Germany ^{b)}	Ŵ	i B	i in i	8	Ĵ,				
	Sanger	contr	\$63		61 00	628	> 1000		0.68	SEO
2	CA, USA ^{c)}	loam &	* %0.3 Ĉ	20.4	♥ 04. <i>3</i> ≪y			\$ \$	° 0.08	510
;	Louisville	silty clay	63	2,0,4	70.0 ^{e)}	<ul><li>√ 224 </li></ul>	743	200	2.30	SFO
2017; M-588260-	NE, USAd)2	loam	Če		ê 5		d v	- S		
01-1						Ő	×,			
;	Laacher Hof	sañdy 泠	5.80	2.05*	55.0	263	©873 ' <i>@</i> ,	¥ 263	2.74	SFO
; 2017; M-599926-01-1	AXXa, \	ioani 🔊			× 5	Ĩ	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
WI 577720 01 1	Germany		× «	ď "Ú	ð		~~			
Geometric mean:	- O'	N Ø	.1		a a a a a a a a a a a a a a a a a a a	^O 323≪	897	314		
a) Measured in CaC	12		TO Y	<del>o</del> r (		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	•			

- a) Measured in CaCl²
  b) From modified pathway for excluding the residue data of DAO 104
  c) From modified parent only fit exclading the residue data of DAT 0
  d) From initial pathway to including all residue data
  e) Calculated based on study moisture and MWMO
  f) Normalised using a Q₁₀ of Q58 and Valker quation coefficient of 0, 7

~Q	0	<u> </u>		Y.		$\gg$
2		O' ~	Q´ A	\$ 0		Ũ
- OF Y	Ô	Ì	Ű.	_ I,≫	MET	HODS
Ľ,	° M	, R	▲.		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	

The objective of the work reported here was a kinetic evaluation of the degradation behaviour of isoflucypram in European and US soils und laboratory conditions in the dark. The evaluation was conducted to detrive kinetic parameters that are suitable to trigger additional studies (trigger endpoints) and for modelling and environmental risk assessments (modelling endpoints).

The kinetic parameters which lead to the appropriate fit of measured to calculated values were identified based on a mathematical optimisation algorithm and statistical analysis. The modelling analysis was based on residue data from three studies ( : 2014: M-486690-; 2017; M-588260-01-1; 01-1 \$2017 M-599926-01-1) covering different soil types. The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1. The soil metabolite BCS-CN88460-carboxylic acid (M12) was found at relevant amounts (> 5%) in the soils Laacher Hof AXXa and Dollendorf II in 2014; M-486690-01-1, in the soil Louisville, NE in 2017; M-588260-01-1,



as well as in the soil Laacher Hof in **Sector**; 2017; M-599926-01-1. Because residue data of BCS-CN88460-carboxylic acid was at sufficient data points above the limit of detection (LOD) in all soils in **Sector**; 2014; M-486690-01-1, the soil Louisville, NE (**Sector**; **Sector**; 2017; M-588260-01-1), and the soil Laacher Hof AXXa in **Sector**; 2017; M-59926-01-1, degradation of BCS-CN88460-carboxylic acid was also included into the pathway. In the soil Sanger, CA (**Sector**; 2017; M-588260-01-1), BCS-CN88460-carboxylic acid was found in concentrations above LOD only in two measurements; consequently, for this soil a parent only fit was conducted. Further metabolites were only observed in minor amounts 5% and were therefore not included in the kinetic evaluation.

The degradation behaviour of isoflucypram was investigated in several soils upder laboratory aerobic conditions in the dark. The compound was appred on soil at an application rate corresponding to 75 g/ha. In Table 7.1.2.1.1-9 the main parameters of soils and study conditions are summarised.

Table 7.1.2.1.1- 9:	Important charact	eristics	f aerobic	: kaborato	ory soil deg	gradation	studies with	, ,
	isoflucypram	Ĺ	~~/~	$\sim$ $i$		, O	×	Ś

		, s	i .0 .4	0″			
Report	Soil origin 🔗	×.	Soji Type ~	<b>pH</b> ^{a)}	Organie	Temp.	MWHC
	4	°°	(USDA) 🖑	<u></u>	🖓 carbon	<i>"</i> М°С] "	8 [%]
	Q' à	n (		Ŏ, Ŷ			
	Hanscheider Ho	f, Ø	loam	D.I	2.9 8	20	53.1
; 2014; M-	Germany	ŝ			Q D	O`	
486690-01-1	Laacher Hof AX	Tra,	Camy sand	6.30	2,0	20	53.1
2	Germany				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1	
~	Hoetchen and	Õ	silt@oam 📎	6.6	( <u>1.9</u> )	20	53.1
	Hohenselr, Gern	1000 y	S &		) [×] 4		
	Øollendorf II, 🖉	y ~	loam 🖓 🔗	7.4	_@5.2	20	53.1
	Germany 🔬	$\searrow$					
;	Sa@ger, CQ, US	AL 10°	sandy loam	6.3 🖉	0.77	20.4	64.9 ^{b)}
•	Louisville, NE	USA 🕺	silty chay loam	6.3	2.00	20.4	70.0 ^{b)}
2017; M 5 8 8 2 6 0 - 0 1 - 1		, O		$\sim$			
;	Laacher Hof AX	Xa,∿	sandy loam	°≈ ⁰ 5.8	1.6	20	55.0
; 2017; M-59992001-1	Germany	0× 2		\$			
a) in CaCl ₂	L L			•	•	•	

b) Calculated based on study moisture and MWHC

The kinetic evaluation of the laboratory degradation behaviour was done following a tiered approach, based on various model assumptions according to FOCUS kinetics (FOCUS 2006, 2014) using the software KinGUI 2.1 with four different kinetic models: Single First-Order (SFO) and the biexponential models FOMC (First-Order Multi-Compartment model), DFOP (double first order parallel) and HS (Hockeg Stick).

For the estimation of <u>trigger</u> endpoints the SFO model and the FOMC model are calculated. If the SFO model leads to an overall (visually and statistically) better fit, the SFO model is selected. If not the DFOP and HS models are calculated. The bi-phasic models are compared (visually and statistically) and the one model resulting in the better fit is chosen.

The aim of tagger indpoints is to obtain the curve that best interpolates the observed behaviour, and notio generate parameters for further calculations. Therefore, no assessment of parameter significance is performed, unless endpoints are extrapolated.

For <u>modelling</u> purposes the preferred model is the single first-order decay. If the SFO fit to parent data is visually acceptable and the  $\chi^2$ err does not significantly exceed 15%, the SFO fit and parameters are



#### accepted.

If  $\chi^2$ err is still significantly greater than 15%, then other models may be tested and/or model parameters may be fixed based on available information (*e.g.*, initial amount) on a case by case basis. The model with the smaller  $\chi^2$ err is finally chosen as the appropriate model. But the 15% threshold value for the scaled error should not be employed as absolute cut-off criteria as this value is strictly appropriate only for optimal experimental conditions. There can be cases where the error value to pass the  $\chi^2$ err test is higher than 15% but the model fit still represents a reasonable description of the degradation behaviour. However, the standard biphasic models recommended by FOCUS viz. DFOP and HS are recommended, if residues remain above 10% of the initial concentration. Then, a very conservative equivalent single first-order half-life can be calculated from the lower of the two kinetic rates. By this method the equivalent SFO-curve always overpredicts the residues. FOXTC model is only recommended, if residues reach less than 10% of the initial concentration. Then, an equivalent single first-order half-life is recalculated, based on DT_{90FOME} /3.32. By this method the equivalent SFO-curve meets the FOMC-curve at the time when DT₉₀ is reached and consequently overpredicts the residues before. It should be noted, however, that these corrected DL₅₀ values can only be used to simulate the leaching

It should be noted, however, that these corrected  $DE_{50}$  values can only be used to simulate the beaching of a parent compound alone, and they must not be used to simulate the tate of the parent and a metabolite in a linked model run, as such an approach does not assure worst-case situation for metabolites. In such cases, if the SFO model is not appropriate for the parent the parent should be fitted with an appropriate bi-phasic model which may be implemented in environmental models (FOCUS 2014)

The DT₅₀ values were normalised to the soil moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Temperature and moisture corresponding to field capacity and a temperature of 20°C and Q₀ = 2.58. Te



# Table 7.1.2.1.1-10:Normalisation correction factors for the soils used in the kinetic evaluation.<br/>"FOCUS field capacity, $\theta_{ref}$ " denotes the default values for reference soil moisture<br/>as given in FOCUS (2014)

Report	Soil origin	Soil	Study	Study	Study	Study	FOCUS	fe	frè	ferfr	¢,
		type	moist. MWHC [%]	soil MWHC g/100 g]	moist, θ [g/100 g]	temp. [°C]	field capacity, Ø _{ref} [g/100 g]				Þ
; 2014;	Hanscheider Hof, Germany	loam	53.1	63.0	§ 33.5	205 205	29.3		~1,00 0	1-00	Ļ
M-486690-01-1	Laacher Hof AXXa, Germany	loamy sand	53.1	50 \$r	26.7 Q	^O 20	15.8	1.00)	1.005	1.00	D.
	Hoefchen am Hohenseh, Germany	silt loam	53.1	56.1	29.8 5 29.8		3¥.7 ∑	9.00 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	00. C	Ø.00	
	Dollendorf II, Germany	loam	53.1	84.5	44.20°	20 A	43.1	ð.00	100 (	KOO	
,	Sanger, CA, USA	sandy loam	64.9%		, 4/8.9 ()	20.4 0	21.8	0,90	1.00	0.90	
; 2017; M- 588260-01-1	Louisville, NE, USA	silty clay loam ≪	70°.0ª)	°₹52.4 ×		20.4	č ⁴ 3.0	\$0.90* ```	J.00	0.90	
; 2017; M-599926-01-1	Laacher Hof 🔊 AXXa, Germany	sandy logm	<b>3</b> 5.0	49.6	27£		47.7	P.00	1.00	1.00	
a) Calculated base	d on study moisture a	nd MWH	C O		× ×	ő			•	<u>.</u>	

AIL RESULTS AND DISCUSSION

Results of the kinetic evaluation of three different studies (**1999**; **1999**; 2014; M-486690-01-1; **1999**; 2017; M-588260-01-1; 2017; M-5882600-01; 2017; M-5882600; M-5882600; M-5882600; M-5882600; M-

(MA) are given below in the current study, kinetic parameters were derived for trigger and modeling endpoint based on the pathway fit. For the evaluation of trigger endpoints, the comparison of the pathway fits using the SFO and FOMC models for the parent isoflucypram is provided for all soils among the statutes considered here.

The degradation rates were evaluated for the corresponding study conditions. For the soil Sanger, CA, a parent only fit was conducted as the metabolite BCS-CN88460-carboxylic acid was only found at concentrations above DOD at two time points.

# Study and and (2014)?

For derivation <u>a trigger</u> endpoints, the kinetic evaluation was started by comparing results of the SFO and FOMC models for isolucypram included in the pathway fit. For the soils Hanscheider Hof, Laacher Hof AXXa and Boefchen am Bohenseh the SFO model resulted in a similar fit compared to the FOM model (Table 7.1.2 P.1-11) and was therefore chosen for derivation of trigger endpoints.

For derivation of <u>modelling</u> endpoints, the kinetic evaluation was started by assuming a single firstorder (SFO) degradation. For residue data of the soils Hanscheider Hof, Laacher Hof AXXa and Hoefchen am Hohenseh the SFO fit was deemed acceptable as the residuals were well distributed and the error value of the  $\chi^2$ err test was very low (Table 7.1.2.1.1-11).

Inspection of parent and metabolite residue data of the soil Dollendorf II indicates an irregular behaviour at DAT 104. Parent residues at DAT 104 tend to be too low whereas residues of



BCS-CN88460-carboxylic acid are significantly too high (approximately factor 2 higher compared to determined residues at DAT 84 and DAT 120). This could be caused by an error in the analytical procedure. Thus, the kinetic evaluations for modelling as well as trigger endpoints have byen conducted in 2 steps, considering all data and excluding DAT 104 residues, respectively (Figure 7.1.2.1.1-1 and Figure 7.1.2.1.1-2).

As the fit was clearly improved by the exclusion of the DAT 104 residue data, kinetic parameters derived from the SFO pathway fit (Dollendorf II: modified pathway fit) were selected as trigger and modelling endpoints and are presented in Table 7.1.2.1.1-11.

Soil	Kinetic model	DT ₅₀ [days]	DT90 [days]	VA	xferr [%]	k₁ / α → [1/d / -]	ka / β , H/d / -]	¢ g ∧	t-test ky k2	MS
Hanscheider	SFO	438	> 1000	+ 《	0.89	0.001583		Å.	[≈] 0.001 [×]	[⊘] T/M
Hof	FOMC	440	> 1000	4	0.93	C 57.94	36540			s, °
Laacher Hof	SFO	236	782	Ś	×_00.1	0.002943	A . 6	*	< 6.001	₫/M
AXXa	FOMC	310	> 100@	× + °	y 0.9	. Ø7637 O	202,6	Ş		
Höfchen am	SFO	348	> 1000	×	<b>\$</b> \$\$\$	Ø.0019 <b>9</b> 3		Q.	< 0.001	T/M
Hohenseh	FOMC	348	2 ¹ 000	"Ŷ	1.22	2011	900900		2	
Dollendorf II	SFO ^{a)}	255 🧔	848	P + @	1.767	0.002715			< 0.001	
	FOMC ^{a)}	307	> 1000	đ,	1.79	√1.16®	ð78.2	0 O	8	
	SFO ^{b)}	277	921	j, ^c i	<u></u> 1.24 O	0.002501		ÇÎ,	< 0.001	T/M
	FOMC ^{b)}	مُ 463	> 1000	+ 4	1.14	<b>0</b> ,4861	146,5			

Table 7.1.2.1.1-11: Isoflucypram: kinetic and statistical results of the STO and FOM (pathway fit) best fits highlighted in bold letters  $\mathcal{A}$ 

a) Initial fit including all residue date

b) Modified fit excluding residue data for DAT 104

exaluation MS: Model selected (T; trigger evaluation; M. Cor model C. Or

Kingel results for isoflucypram in Soil Dollendorf II from the SFO pathway fit -Figure 7.1.2.1. initial fit Ò, 0





#### Figure 7.1.2.1.1- 2: KinGUI results for isoflucypram in soil Dollendorf II from the SFO pathway fit – modified fit



For derivation of trigger and modelling ondpoints, all cesidue data were included to a first step while in a modified approach residue data at DAT 0 were excluded from the fit (both replicates for Sanger, CA, second replicate only for Louisville, NE). It's the metabolite BCS-CNS8460 carbox fic acid was only found at two time points in concentrations above the LOD, the metabolice was not included in the assessment and a parent only figwas conducted for soil Sanger, CAO

For derivation of trigger endpoints the kipetic evaluation was started by comparing results of the SFO and FOMC models for isoflucypram included in the parent only fit (Sanger, CA) or the pathway fit (Louisville, NE). For all investigated soils the SIAC model resulted in a similar fit compared to the FOMC model (Table 9.1.2.1.9-12)

For derivation of modeling endpoints, the kinetic evaluation was started by assuming a single firstorder (SFO) degradation. For residue date of all soils the SKO fit was deemed acceptable as the residuals were well distributed and the error value of the  $\chi^2$  err lest was very low (Table 7.1.2.1.1-12).

For the soil Sanger, GA, the fit was clearly improved by excluding the residue data for DAT 0, visually as well as statistically (compare Figure 7.1.2.1.1- 3 and Figure 7.1.2.1.1- 4, Table 7.1.2.1.1- 12). Therefore kinetic parameters from the modified SFO parent only fit were selected as trigger and modelling endpoints.

For the soil Louisville, NE the exclusion of the DAT Oresidue date did not result in a significant improvement of the fit (Ompare Figure 7.1.2).1- Sand Figure 7.1.2.1.1- 6, Table 7.1.2.1.1- 12).





Table 7.1.2.1.1- 12:	Isoflucypram: kinetic and statistical results of the SFO and FOMC curve fits
	best fits highlighted in <b>bold letters</b>

Soil	Kinetic model	DT ₅₀ [days]	DT ₉₀ [days]	VA	χ²err [%]	k ₁ / α [1/d / -]	k ₂ / β [1/d / -]	g	t-test k1 / k2	MIS	ð,
Sanger, CA	SFO ^{a),b)}	709	> 1000	0	1.11	0.0009781		þ	< 0.001	Ó	
	FOMC ^{a),b)}	709	> 1000	0	1.18	2392	2446000		× .	S	
	SFO ^{a),c)}	630	> 1000	0	0.68	0.00110	A		ð 0.00	T/MØ	
	FOMC ^{a)c,)}	> 1000	> 1000	0	0.71	ار 🖉 🔊 0.3337	244.4	L.		-Q	0
Louisville, NE	SFO ^{b)}	224	743	0	2.30 🚿	0.003099	Q.		< <b>Q</b> 001	<b>Д/М</b>	Ś
	FOMC ^{b)}	224	744	0	2.45	1245 🔊	401600	Ň	Ŷ.Ô		)
	SFO ^{c)}	215	713	0	2.92	0.0032	ð° Ó	V 4	< 0.001	Ļ	
	FOMC ^{c)}	215	713	0	\$2.16	11420 <	\$536000		L. A	Q Q	
Denvert and Ct				Co	- Ro			0×		N.	

a) Parent only fit

b) Initial fit including all residue data

c) Modified fit excluding residue data for DAT 0

c) Modified fit excluding residue data for DAT 0 MS: Model selected (T: for trigger evaluation; M: for model has gevaluation

KinGUI results for is the cypram in sol om the SF O Oparent only fit -Figure 7.1.2.1.1- 3: Ľ

C



Figure 7.1.2.1.1- 4 5 Ç,









For derivation of <u>trigger</u> endpoints, the kinetic evaluation was started by comparing results of the SFO and FOMC models for isoflucyperm included for the pathway fit. For the soil Laacher Hof AXXa the SFO model resulted in a similar fit compared to the FOMC model (Table 7.1.2.1.1-13).

For derivation of <u>modelling</u> endpoints, the kinetic evaluation was started by assuming a single firstorder (SFQ) degradation. For residue, that of the sol Laacher Hof AXXa the SFO fit was deemed acceptable as the residuals were well distributed and the error value of the  $\chi^2$ err test was low (Figure 7.1.2.1.1-7, table  $\chi^2$ 1.2.1  $\chi^2$ 13).

However, the fits might have been deterinated by the residue data measured at DAT 85 where concentrations are exceptionally low for the parent substance, while concentrations of the metabolite are increased. If these data are removed from the fit the  $\chi^2$ err decreases, but no improvement of the visual assessment or the statistical significance of the t-test is observed (Figure 7.1.2.1.1-8, Table 7.4.2.1.1.4.3).

Consequently the degradation parameters derived from the initial SFO fit including all residue data was chosen for derivation of trigger and modelling endpoints (Table 7.1.2.1.1-13).



Table 7.1.2.1.1- 13:	Isoflucypram:	kinetic and statistical results of the SFO and FOMC curve fits
	(pathway fit)	best fits highlighted in <b>bold letters</b>

Soil	Kinetic model	DT ₅₀ [days]	DT90 [days]	VA	χ ² err [%]	k ₁ / α [1/d / -]	k ₂ / β [1/d / -]	g	t-test MIS k1 / k2
Laacher Hof	SFO ^{a)}	263	873	+	2.74	0.002639		) )	
AXXa	FOMC ^{a)}	397	> 1000	+	2.76	0.5611	162.7		
	SFO ^{b)}	295	981	+	0.98	0.002347	A		S 10.00
	FOMC ^{b)}	403	> 1000	+	0.96	0.7691	274.9	, K	

a) Initial fit including all residue data

b) Modified fit excluding residue data for DAT 85

MS: Model selected (T: for trigger evaluation; M: for modelling @aluation)





KinGUI results for isoffucypram in soil Lagener Hor AXXa from the SFO pathway fit - modified fit Figure 7.1.2.1.1 Fit





#### **III. CONCLUSIONS**

The trigger and modelling endpoints for isoflucypram are presented in Table 7.1.2.1.1- 14 and Table 7.1.2.1.1- 15, respectively.

Table 7.1.2.1.1- 14:	Soil degradation not-normalised DT50 values	s of isoflucyprate to trigger	· additional,
	studies ( <u>trigger</u> endpoints)	4	

				A.	0°	est C	)
Study		Soil 💦		Model	٦ 🌾 🖉		
				⊘'fitted	mot ng	rmalise	© ،
		×		) /	<u> </u>	ays]	Ď
;	; 2014; M-486690-01-	Hanscheider Ho	of of	SFO 🔍	o y	438°°°°°°	1
1		Laacher Hof A	XXa 🕺	SFOQ	, ô ^y -	236	
		Hoefchen am H	of Benseh 🔊	SFO		¥48 🏈	
	C	Dollendorf II 🔨		SFO a		277	
;	;	Sanger, CA	Q,	[©] SFO _☉	Ő	30° /	
2017; M-588260-01-1	Ļ,	Louisville, NE	ð Í	sfo"	$\mathcal{Q}$	224	
- 7	; 2017; M-599936-01-%	Laacher Hof A	XXa 🔊	SFO .		2630	
Geometric mean:						323	
	Q.		N O			, ,	•

 Table 7.1.2.1.1-15:
 Soil degradation not-normalised and normalised (to pF2 and 20°C, Q%: 2.58)

 DT50 values of isoflucypram for modelling purposes (modelling endpoints)

	A	*		0"			,
Study		Soil			Model fitted	DT ₅₀ not normalised	DT ₅₀ normalised
	A A	Ķ [®] a.	,,	$\langle \gamma \rangle$	0″	🖉 [days]	[days]
;	(2014; Ô	Hanschei	der Ĥof 🚕		ℤSFO_	438	438
M-486690-01-1	× V. A.	Laacher J	IOF AXXX	S.	SF	236	236
		Doefcher	am Hohense	Ð	STO .	348	348
<u>گ</u>	<u> </u>	Dollendo	rf 🌆 🖉	,×	SFO	277	277
ý,		Satuger, C	CA R	~~	SFQ	630	570
ž 2017; M-5	588260-01-9	Louisvill	ê, NE O'	ж,	sfo	224	200
; 599926-01-1	; 2017; M	Laacher I	Hof XXa		SFO	263	263
Geometric meany:		Ŭ Ö		Q.		323	314
				9			



# CA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products

BCS-CN88460-carboxylic acid (M12) was found as major soil metabolite in a soil metabolism studies with isoflucypram under aerobic conditions.

A summary of the degradation rates of isoflucypram and its major degradation product in soil in the laboratory is given in section CA 7.1.2.1 laboratory is given in section CA 7.1.2.1.

#### Kinetic evaluation of the aerobic soil metabolism studies

**Report:** Title:

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

#### **Executive Summary**

The route and rate of degradation of isoflucypram under laboratory aerobic conditions was ; 2014; M \$6690 01-1; investigated in three different studie

; 2017; M-588260-01, D 2017: M-599926-01-1). In the current report, a kinetic malysis of residue data was conducted in order to derive kinetic parameters suitable to trigger additional studies (trigger endpoints) and for modelling and environmental risk assessments (modelling endpoints) for the major metabolite BCS-CN88460carboxylic acid (M12).

C The metabolite BCS N88460-carboxylic acid was found at relevant amounts (> 5%) in the soils Laacher Hof AXXa and Dollendorf II inc ; 2014; M-486690-01-1, in the soil Louisville, NE ins 2017; M-588260-01-1, as well as in the soil Laach Hof XXa in ; 2007; M-599926-01-1. Because residue data of BCS-CN88460-carkoxylic acid was at sufficient data points above the limit of detection (LOD) ; 2012, M-486690@1-1, the soil Louisville, NE ( in all soils in (2017; M-58) (2000), and the soil Laacher Hof AXXa in ; 2017; M-599986-01-1, degradation of BCS CN88460-carboxylic acid was

also included into the pathway. In the soil Sanger, CA ( ; 2017; M-588260-00,1), BCS-CN88460-carboxolic act was found in concentrations above LOD

only in two measurements consequently, for this soil a parent only fit was conducted. Further metabolites were only observed in minor amounts (25%) and were therefore not included in the kinetic evaluation.

The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KingUI, version 24. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment,  $\chi^2$  err statistics, randomness of residuals, and test significance following the FOCUS guidance (2006, 2014).

The resulting DT values (i.e. modelling and trigger endpoints) of BCS-CN88460-carboxylic acid are given in Table 7.1.2.12- 1 and Table 7.1.2.1.2- 2.



Table 7.1.2.1.2- 1:	Soil degradation not-normalised DT ₅₀ values of BCS-CN88460-carboxylic acid (M12)
	to trigger additional studies ( <u>trigger</u> endpoints)

Report	Soil origin	Soil type	pH ^{a)}	Temp.	MWHC	DT50	<b>DT</b> ₉₀	f.f.	St.	Method O
				[°C]	[%]	[days]	[days]	~	$(\chi^2 \text{err})$	of cale
	Uon	loom	57	20	52.1	15 1	151	© © 220		
; 2014;	scheider	IUaiii	5.7	20	55.1	43.4	131	©*0.330	7.0ø	
M-486690-01-1	Hof,						, S	2		
	Germany	1	()	20	<u>Č</u>	112	Ŵ.,			<u> </u>
	Laacher Hof	sand	6.3	20	53%1	113	Q311	0.25	3¥1	SFU SFU
	AXXa,			Æ		Q ⁴	ê ^o		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
	Germany			R	. »	$\sim$	Ŵ.	Q' 0'		Ű.
	Hoefchen	silt loam	6.6	20*	53.1	014.8 ×	≯49.1 @	× 0.440		SFO SFO
	Hohenseh,			° "			~	Ô L		· · · · ·
	Germany					Reg	1	§ O	L.	<u></u>
	Dollendorf	loam	7.4	20	3.1	^{0°} 18.4 Å	61.2	0.500	<b>∢</b> §.55	SFO SFO
	II, Germany ^{b)}		R.			N N N	Ő			
	Sanger	sandy @	63	204	a64 9°	<u>_d</u> )	<u>d</u>			SFO
2	CA, USA	loam	L.	- <i>0</i> .	-9" Ø	5	6	~~~ (	~	51 0
;	Louisville,	silfy clay	۰،3 م	20.4	70.0%	pØr.	æ.r.	0.286 0	20.01	SFO
2017; M-588260-	NE, USA	loam 🖇	l S	Ĩ Î	Ø	4				
	Laacher	sand	<u>\$</u>		Q 55 00 S	h nor	n	A 255	16.05	SEO
; 2017;	Hof	loapn 🐇	\$2.0 }	0 20 %			\$ \$		10.05	510
M-599926-01-1	AXX,			~~ ³⁷		¢,		Y		
Contractor	Geomany									
Geometric mean:		_0 (	) }	<del>p' kj</del>	<u>~</u>	34.4	1N14 @	0 3 4 5		
n r = not reliable			Å		- Or a			0.343		
a) Measured in CaC			Ø	. 4	7.5	$\sim$				
<ul> <li>b) From modified particulated based</li> </ul>	athway fuexc	sture and M	esidue da	ta of DAD	104 📎					
d) Only two metabo	lite detect abo	ove $LOB \neq 0$	nly parei	nt on fit o	comucted					
		J.	, ^m		7 5					
~	° °°,				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~					
4	Č	,	A.		, Ø					
	ŝ.	Ŕ,	Ŵ		Ĩ					
a the	Ĵ,	A. P	í _v õ							
**	Ô			NO [×]						
Å	.0 7 4 `			Q ^y						
			~0							
Ċ,	A C		¥							
Ž ^A K	à à	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~								
		Y Y								
	45									
Õ										



0

 Table 7.1.2.1.2- 2:
 Soil degradation not-normalised and normalised (to pF2 and 20°C, Q10: 2.58)

 DT₅₀ values of BCS-CN88460-carboxylic acid (M12) for modelling purpose (modelling endpoints)

Report         Soil origin         Soil type         pH ^a bype         Temp. [PC]         MWHC [PG]         DTso [lays]         DTso [lays] <thdtso [lays]<="" th="">         DTso [lays]         <thdtso l<="" th=""><th></th><th>(<u>moucn</u></th><th><u>ing</u> chu</th><th>points)</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>Q</th></thdtso></thdtso>		( <u>moucn</u>	<u>ing</u> chu	points)								Q
type         [°C]         [%]         [days]         [days]         [days]         [days]         [days]         [days]         [20°C, pF2/ pF2/ 10 kPa         [94]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]         [14]	Report	Soil origin	Soil	pH ^{a)}	Temp.	MWHC	<b>DT</b> 50	<b>DT</b> 90	f.f.	DT50	St.	Method
Han- scheider Hof, Germany         Ioam         5.7         20         53.1         45.4         151         0.330         45.4         708         500           M-486690-01-1         Ioamy Hof, AXXa, Germany         Ioamy Ioamy Ioamy Hoefchen Hof AXXa, Germany         Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Ioamy Io			type		[°C]	[%]	[days]	[days]		[days]	(χ²err)	of calc.
Han- scheider Hof, Germany         Ioam         5.7         20         53.1         45.4         151         0.330         45.4         708         500           Laacher Hof, Germany         Ioamy         6.3         20         53.1         45.4         151         0.330         45.4         708         500           Laacher Hof, Germany         Ioamy         6.3         20         53.1         114         374         0.257         118         5.7         500           Har- Hof, Germany         Ioamy         6.3         20         53.1         114         374         0.257         118         5.7         500         53.4         14.3         490         0.490         14.8         8.70         500         500         68.4         8.55         5F0           Dollendorf         Ioam         7.4         20         53.4         16.4         602         650         68.4         8.55         SFO           Ioam         7.4         20         53.4         16.4         602         650         68.4         8.55         SFO           Ioam         7.4         20.6         53.4         16.4         602         600         68.4         8.55         SFO </td <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>≥ 20°C,</td> <td>[%]</td> <td></td>										≥ 20°C,	[%]	
Han- scheider Hof, Germany         Ioam         5.7         20         53.1         45.4         151         0.330         45.4         7.08         500           M-486690-01-1         Scheider Hof, Germany         Ioam         5.7         20         53.1         45.4         151         0.330         45.4         7.08         500           Laacher Hof, Germany         Ioamy         6.3         20         53.1         114         377         0.257         118         5.7         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500         500									4	pF2/	R.	
Han- scheider Hof, Germany         Ioam S.7         20         53.1         45.4         151         0.330         45.4         708         500           Laacher Hof AXXa, Germany         Ioam         5.7         20         53.1         45.4         151         0.330         45.4         708         500           Laacher Hof AXXa, Germany         Ioam         6.3         20         53.1         112         377         0.257         113         5.7         570           Hoef AXXa, Germany         Ioam         6.6         20         53.1         143         49.1         0.440         44.8         8.70         8F0           Hoefseh, Germany         Ioam         6.6         20         53.1         143         49.1         0.440         44.8         8.70         8F0           Jollendorf         Ioam         7.4         20         53.4         1634         60.2         6000         8.4         8.55         SFO           Lusissile         Sanger, Germany ^b Sanger, CA, USA         Ioam         7.4         20.4         64.9 ^{of} -0         40         9.4         9.4         9.4         9.4         9.4         8.5         SFO           Lusissite									×,	10 kPa	O ^v . (	
Han-scheider       Ioam       5.7       20       53.1       45.4       151.4       0.330       45.0       7.08       SPO         M-486690-01-1       Hof,       Germany       Ioam       6.3       20       53.1       114       377       0.257       119       527       SFO         M-486690-01-1       Laacher       Ioam       6.3       20       53.1       114       377       0.257       119       527       SFO         M-486690-01-1       Hof,       Sand       6.6       20       53.1       114       377       0.257       119       527       SFO         Hoefchen am       silt       6.6       20       53.1       1428       49.17       0.440       44.8       8.70       SFO         Moefchen seh,       Germany       Germany       6.6       20       53.4       14.8       49.17       0.440       44.8       8.55       SFO         Jollendorf       Ioam       7.4       20       53.4       16.4       61.2       6.900       68.4       8.55       SFO         Louisytile       Silty       6.3       20.4       64.9°       -0       4.4       4.4       4.4       4.4       5.						(	È <u>s</u>		<u>K</u>			
: 2014: M-486690-01-1       Scheider Hof, Germany       Image: Scheider Hof, Germany       Image: Scheider Hof, Germany       Image: Scheider Hof, Sand       Image: Scheider Hof, Germany		Han-	loam	5.7	20	53.1 🕎	\$ 45.4	151	0.330	45 🖤	7.08	S₽0
M-486690-01-1 Germany Laacher loamy 6.3 20 53.1 112 377 0.257 118 527 SFO AXXa, Germany Hoefchen silt loam Hohenseh, Germany Dollendorf loam 7.4 20 53 1 148 497 0.440 148 8.70 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 8.4 8.55 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 20 53 1 184 60 2 0.50 58.5 SFO II, Germany ^b 7.4 7 20 55 0.50 58.5 SFO II, II, Germany ^b 7.4 7 20 58.5 SFO II, II, Germany ^b 7.4 7 20 58.5 SFO II, II, Germany ^b 7.4 7 20 58.5 SFO II, II, II, II, II, II, II, II	; 2014;	scheider				Å		LO ^v		Ŵ	Q,	6° 4
Schmany       Laacher       loamy       6.3       20       53.1       113       377       0.257       113       5.77       \$FO         Hof       AXXa,       Germany       Germany       6.6       20       53.1       114       377       0.257       118       5.77       \$FO         Hoefchen       silt       6.6       20       53.1       143       490       0.440       1448       8.70       \$FO         Hoefchen       silt       6.6       20       53.4       143       490       0.440       1448       8.70       \$FO         Mohenseh,       Germany       Germany </td <td>M-486690-01-1</td> <td>П01, Germany</td> <td></td> <td></td> <td></td> <td>A</td> <td></td> <td>Q,</td> <td></td> <td>5 L</td> <td>Č</td> <td></td>	M-486690-01-1	П01, Germany				A		Q,		5 L	Č	
Laacher       loamy       6.3       20       53.1       112,5       374,6       0.20       115,5       4.27       540         Hof       sand       AXXa,       Germany       6.6       20       53.1       143,5       49,1       0.490       144,8       8.70       8FO         Hoefchen       silt       6.6       20       53.1       143,5       49,1       0.490       144,8       8.70       8FO         Mohenseh,       Germany       7.4       20       53.4       18,4       60,2       9500       68.4       8.55       SFO         Dollendorf       Ioam       7.4       20       53.4       18,4       60,2       9500       68.4       8.55       SFO         II,       Germany ^{b)} 7       7       20,7       53.4       18,4       60,2       9500       68.4       8.55       SFO         II,       Germany ^{b)} 7       7       20,7       7       500       68.4       8.55       SFO         2017; M-588260-       Ioam       63       20.4       64.95       -4       7       7       -4       570         10-1       Ioam       58       20,4 <t< td=""><td></td><td>T 1</td><td>1</td><td>()</td><td>20</td><td>0</td><td>112</td><td></td><td>0.257</td><td></td><td>5. Q</td><td>Ŵ</td></t<>		T 1	1	()	20	0	112		0.257		5. Q	Ŵ
101       AXXa, Germany       6.6       20       53.1       14.3       49.1       0.440       14.8       8.70       SFO         Hoefchen am Hohenseh, Germany       10am       7.4       20       53.4       16.4       61.2       9.500       68.4       8.55       SFO         Dollendorf       Ioam       7.4       20       53.4       16.4       61.2       9.500       68.4       8.55       SFO         Dollendorf       Ioam       7.4       20       53.4       16.4       61.2       9.500       68.4       8.55       SFO         Int, Germany ^{b)} Germany       6.3       20.4       64.9 ^{co} -d ¹ 4.4       8.70       SFO         Int, Germany ^{b)} Germany       6.3       20.4       64.9 ^{co} -d ¹ 4.4       8.55       SFO         Int, Horizan       Louisville, Value       Sift       6.3       20.4       64.9 ^{co} -d ¹ 4.4       8.70       SFO         Int, Horizan       Louisville, Value       Sift       6.3       20.4       64.9 ^{co} -d ¹ 4.4       4.4       1.4       4.4       1.4       4.4       1.4       1.4       1.4       1.4       <		Laacher	loamy	6.3	20	≫ 55.1 ⊘		3 14 g	0.23/		≈ 30.£/ ≈	STU
In First, Germany       Germ		AXXa	Sanu		Ő	, Ŭ	40	S.	Ő	S.	4	-
Hoefchen am Hohenseh, Germany       6.6       20       53.1       14.3       49.7       0.440       14.8       8.70       SFO         Dollendorf loam       7.4       20       53.4       18.4       60.2       9.00       8.4       8.55       SFO         Dollendorf loam       7.4       20       53.4       18.4       60.2       9.00       8.4       8.55       SFO         Louisville, Silf       6.3       20.4       64.9°       -d       -d       -d       -d       -d       -d       -d       SFO         Louisville, Silf       6.3       20.4       64.9°       -d       -d       -d       -d       -d       -d       SFO         Louisville, Silf       6.3       20.4       64.9°       -d       -d       -d       -d       -d       -d       SFO         2017; M-588260-       NE, FSA       clay       58       20.4       60.0°       n.r.       n.r.       0.286       n.r.       20.01       SFO         2017; M-599926-       Hof       Iaa       58       20       65.0       n.r.       16.05       SFO         2017; M-599926-       Axda, Germany       Axda       Axda       Axda		Germanv			1	m (			° ~	Ô		<i>A</i>
Incrementation       init       0.0       20       53.9       1.4       0.4       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10       0.10		Hoefchen	silt	6.6	$\sqrt[6]{20}$	53	1408	4971	0.490	1≰4/8	870	<b>S</b> FO
Hohenseh, Germany       A       20       53       164       60.2       9.00       8.4       8.55       SFO         Dollendorf Ioam II, Germany ^{b)} 7.4       20       53       164       60.2       9.00       8.4       8.55       SFO         Sanger, CA, USA       Sanger, Ioam       Sanger, CA, USA       Sanger, Ioam       Sanger, CA, USA       Sanger, Ioam       20.4       64.9c ¹ -0       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40		am	loam	0.0 <i>°</i>		<u> </u>		0	\$ \$	S.	K) (	
Germany       Germany       7.4       20       53       184       60       2       600       8.4       8.55       SFO         Dollendorf       Ioam       7.4       20       53       184       60       2       600       8.4       8.55       SFO         Germany ^{b)} Sanger, sandy       6.3       20.4       64.9°       -d       4       4       4       4       4       4       5       5       SFO         Louisyfile, silfer       6.3       20.4       64.9°       -d       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4 <td></td> <td>Hohenseh,</td> <td></td> <td>R</td> <td>Ŵ</td> <td></td> <td>Ç^y (</td> <td></td> <td>Û,</td> <td>, j</td> <td></td> <td>*</td>		Hohenseh,		R	Ŵ		Ç ^y (		Û,	, j		*
Dollendorf       loam       7.4       20       53       184       612       600       8.4       8.55       SFO         I,       Germany ^{b)} Sanger, candy       6.3       20.4       64.9°       -d       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40       40		Germany		Ś	°O″	°~y" ~ «	ř 🔿	Ĩ D			. 2	
II,       Germany ^{b)} <t< td=""><td></td><td>Dollendorf</td><td>loam</td><td>7.4</td><td>20 ⁽</td><td>53</td><td>18.4</td><td>61,2</td><td>0,500</td><td>8.4</td><td>8.55</td><td>SFO</td></t<>		Dollendorf	loam	7.4	20 ⁽	53	18.4	61,2	0,500	8.4	8.55	SFO
Germanyb)		II,		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	102	Ĩ		S'	Ū.	ð «	V	
Sanger, CA, USA loam       6.3       20.4       64.9°       -d       -d       SFO         2017; M-588260-       Louisville, Silfy clay       6.3       20.4       0.0°       n.r.       n.r.       0.286       n.r.       20.01       SFO         2017; M-588260-       NE, JSA       clay       20.4       0.0°       n.r.       n.r.       0.286       n.r.       20.01       SFO         2017; M-588260-       NE, JSA       clay       20.4       0.0°       n.r.       n.r.       0.286       n.r.       20.01       SFO         2017; M-599926-       Cacher       sandy       5.8       20       53.0       n.r.       0.255       n.r.       16.05       SFO         2017; M-599926-       AXXa, Germany       AXXa		Germany ^{b)}	L,	Q.,		de a	× L			Ŭ		
CA, USA       loam       Ioam	•	Sanger,	sandy	<u> </u>	¢20.4	64.9° ^{°°°}	_d)	<u> </u>	-en	<u> </u>	_d)	SFO
i       Louisville, silty       6.3       20.4       0.0°       n.r.       0.286       n.r.       20.01       SFO         01-1       Ioam       Ioam </td <td>. ,</td> <td>CA, USA 🆄</td> <td>loam</td> <td>Ű</td> <td></td> <td></td> <td>S.</td> <td></td> <td>L.</td> <td>Ś</td> <td></td> <td></td>	. ,	CA, USA 🆄	loam	Ű			S.		L.	Ś		
2017; M-588260- 01-1 Laacher baacher bandy 528 2017; M-599926- 01-1 Coometric broom	•	Louisville,	silt	6.3	20.4	Ø0.0 ^{c)} >	n.r.	∀n.r. &	0.286	n.r.	20.01	SFO
01-1 Laacher Sandy 5,8 20 53.0 h.r. h.r. 9.255 n.r. 16.05 SFO 2017; M-599926- 01-1 Germany Germany 6 6 6 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	2017; M-588260-	NE, ÉSA	clay	Š.	Į,			0				
Caacher       sandy       5.8       20       53.0       n.r.       n.r.       16.05       SFO         2017; M-599926- 01-1       AXXa, Germany,       Germany,       <	01-1		atoam,	$\mathcal{P}$	y a.		ß	L,				
$\begin{array}{c c} \hline \\ \hline \\ 1 \\ 01-1 \\ \hline \\ 0 \\ \hline \\ 0 \\ 0 \\ \hline \hline \\ 0 \\ \hline \\ 0 \\ \hline \\ 0 \\ \hline \hline \\ 0 \\ \hline \\ 0 \\ \hline \hline \\ 0 \\ \hline \\ 0 \\ \hline \hline \\ 0 \\ \hline \\ 0 \\ \hline \hline \hline \hline$		Kaacher \	sandy	5,8	20/	53.0	≈ĥ.r.	"n.r. 🔉	0.255	n.r.	16.05	SFO
2017; M-599926- 01-1 Germany,	; ; *	Hof 🖉	læm	0 [°]	X.0	× ò						
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	2017; M-599926-	AXXXX,		6			0	Ł				
Comparing Second $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$ $\mathcal{O}$ 114 24.4	01-1	Germany			> Or			NO -				
	Geometrie mean:		<u> </u>			<u> </u>	34.4	114		34.4		• •
Arithmetic mean: 2 4 2 2 4 4 0.345	Arithmetic mean:		~~ ~	¢ ¢ %	O' K	<u>, y</u>	A.		0.345		•	
n.r. = not reliable $\beta$	n.r. = not reliable	6 A		, K	, K		ð		•			
a) Measured in CaCl ² Q [*]	a) Measured in CaC		Š	Ŭ.	[°] N		A N					
b) From modified withway fit excluding the residue data of DAT 104	b) From modified	thway fit exc	luding th	ne residu	e data of I	2AT 104	"					
d) Metabolite ably found in two samples narent why a constructed	d) Metabolite control	on study more	amples	WIWHQ	) Khly fit	nduct						

e) Normalise using a  $Q_{10}$  of 258 amb Walker equation  $7.7 \approx$ 

.1 .1	

Soil residue data from the aerobic soil degradation studies of isoflucypram (_____; ____; 2014; 4.486690-01-0; ____; ____; 2017; M-588260-01-1;

Biology (2017; M-599926-01-1) were used. In these studies, the degradation of isoflucypram was studied in soil Hanscheider Hof (loam), soil Laacher Hof (loamy sand), soil Hötchen (soit loam), soil Dollendorf (loam), soil Sanger (sandy loam), soil Louisville (silty clay loam) and soil Baacher Hof (sandy loam with a test concentration of 75 g/ha.

Detailed information on the kinetic analysis is given in the corresponding chapter of the parent compound in section CA 7.1.2.1.1.



Table 7.1.2.1.2

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

; 2014 Results of the kinetic evaluation of three different studies ( 486690-01-1: ; 2017; M-588260-01-1;

; 2017; M-599926-01-1) concerning the metabolite BCS-CN88460-carboxylic acid(M12) are given below.

#### **Study Hellpointner and Junge (2014):**

The kinetic evaluation was started by assuming a single first-order (SFØ) degradation For the soils Hanscheider Hof, Laacher Hof AXXa, and Hoefchen and Hohenseh, the SFO pathway was visually and statistically acceptable as the residuals were were distributed and the error value the  $\chi^2$  err test was low. Q, Õ

Inspection of parent and metabolite residue data of the soft Doftendorf II indicates an irregular behaviour at DAT 104. Parent residues at DAT 104 tend to be too low whereas residues of BCS-CN88460-carboxylic acid are significantly towhigh (approximately factor 2 higher compared to determined residues at DAT 84 and DAT 120). This could be caused by an error in the analytical procedure. Thus, the kinetic evaluations have been conducted in 2 steps, considering all data and excluding DAT 104 residues, respectively (Rigure XI.2.12 4 and Figure 7.1.20.2- 5) The modified fit resulted visually and statistically  $\mathbb{O}$  a significant improved fit  $\mathbb{O}$ 

The degradation of the metabolite was described with the SFO modes following the recommendations of FOCUS (2006, 2014). Kinetic parameters derived from the pathway for for solls Hanscheider Hof, Laacher Hof AXXa, Hoefcher am Höhenseh, and Dollendørf II (modified fit) were selected as trigger and modelling endpoints and are presented in Table 7.1 21.2- 3. Ø

The metabolite fits are for all four soils very robust and lead to a reliable description of the measured residues. Residuals are clearly randomly scattered around the zero line without any systemetic deviation. Computed formation fractions are highly significant with generally how standard deviations (Table 7.1.2.1.2-3)

Ô	. 9	L)		101		9			
Soil Soil		DT 50 days	DT90 [days](	f.f.	N O	χ²err [%]	k1 / α [1/d / -]	t-test k1 / k2	MS
Hanscheider Hof 🔊 "	SFO-SEO	45.9	151	0.330±0.044	+	7.08	0.015280	< 0.001	T/M
Laacher Hof AX	SFO SFO	¥13 。	×377	0.257±0.022	+	5.27	0.006114	< 0.001	T/M
Höfchen am Hohenselo	SFQ-SFQ	¥14.8℃	[≫] 49,1€	0.440 <b>£0</b> .081	0	8.70	0.046870	< 0.001	T/M
Dollendorf IP	SPO-SEO ^{a)}	4709	159	0.307±0.101	0	32.13	0.014467	0.053	
	SFO-SFOb)	18.4	≈ <b>6</b> 1.2 °	\$500±0.068	+	8.55	0.037639	< 0.001	T/M

BCS-GN88466 carbo Wic and (M12): kinetic and statistical results of the SFO pathway curve fits

a) Initial fit including all residue data

b) Modified fit excluding residue data for DAT 2004

c) Kinetic formation fraction f.f. ± Standard Deviation STD

MS: Model selected (T: for trigger evaluation; M: for modelling evaluation)



Figure 7.1.2.1.2- 1: KinGUI results for BCS-CN88460-carboxylic acid (*M12*) in soil Hanscheider Hof from the SFO pathway fit – initial fit



Figure 7.1.2. 3: KinGUI regults for BCS-CN88460 carboxylic acid (M12) in soil Hoefchen am Hohensen from the SFG pathway fit initial fit









SFO pathway fit - modified fit



#### Study

2007; M=588260-01-1:

For the soil Sanger, KA, the metabolite BCS-CN88460-carboxylic acid was not considered as it had only been found in soncentrations above LOD at two time points.

For the soil Louisville NE, the kinetic evaluation was started by assuming a single first-order (SFO) degradation. As for the parent substance softweepran, an initial fit including all residue data and a modified fit excluding the residue data from DAT 0 2nd replicate) were conducted. In both cases, the pathway fit was visually acceptable (compare Figure 7.1.2.1.2- 6 and Figure 7.1.2.1.2- 7) but the derived rate constant was statistically not repable (Table 7.1.2.1.2- 4). Therefore, no reliable degradation parameters could be derived and the DT₅₀ was rejected for further evaluation.

The formation fraction of BCS-CN98460 arboxylic acid, however, was considered reliable as the visual fit was acceptable and the standard deviation was small. The steady increase of the metabolite residues is well described with residuals clearly randomly scattered around the zero line without any systemetic deviction. As the modified fit did not lead to clear improvements, the formation fraction from the initial fit was chosen.

Ô



Table 7.1.2.1.2- 4:	BCS-CN88460-carboxylic acid (M12): kinetic and statistical results of the SFO	
	pathway curve fits	

Soil		DT ₅₀	DT ₉₀	<b>f.f.</b> ^{c)}	VA	χ ² err	$k_1 / \alpha$	t-test	MS	
		[uays]	[uays]			[%0]	[1/ <b>a</b> / -]	K1 / K2	S O	
Sanger, CA	SFO-SFO	n.a.	n.a.	n.a.		n.a.	n	n.a.	<i>,U</i> ² <i>b</i>	
Louisville, NE	SFO-SFO ^{a)}	> 1000	> 1000	0.286±0.071	0	20.01	<b>∞0</b> .001	0.500		
	SFO-SFO ^{b)}	> 1000	> 1000	$0.274 \pm 0.067$	0	20.11	<b>≦</b> < 0.001	0.500		
a) Initial fit including all residue data										
b) Modified fit exclu	b) Modified fit excluding residue data for DAT 104									
c) Kinetic formation	fraction f.f. $\pm$	Standard	Deviation	STD		æ	(	ひょう		
n.a. Not available (Parent only fit for soil Sanger, CA)										
MS: Model selected (T: for trigger evaluation, M: for modelling evaluation)										

¢,



KinGUI results for BCS CN88460-carboxylic acid (M12) in soil Louisville, NE from the SFO pathway fit - modified fit Figure 7.1.2.1 27:





Study

; 2017; M-599926-01-1:

The kinetic evaluation was started by assuming a single first-order (SFO) degradation.

For the soil Laacher Hof AXXa the SFO pathway fit was visually good with well distributed residuals (Figure 7.1.2.1.2- 8) and an error value of the  $\chi^2$  err test acceptable for metabolites. However, the degradation half-life derived for BCS-CN88460-carboxylic acid is statistically not significant (t-test > 5%).

However, the fit might have been deteriorated by the residue data measured at DAT 85 where concentrations are exceptionally low for the parent substance, while concentrations of the metabolite are increased. If these data are removed from the fit the gerr decreases and the formation fraction fraction still reliable. The visual and statistical assessment, Nowever, is not improved and the derived metabolite half-life is still not significant (Figure 7.1.20.2-9, Table Q.I.2.1.2-5). Consequently, the DT₅₀ value was rejected for further evaluation. The formation fraction of BCS-CN88460-carboxylic acid, however, was considered reliable as the visual fit was acceptable and the standard deviation was small (Table 7.1.2.1.2.5). The steady increase of the metabolite residues is well described with residuals clearly randomly scattered around the zero tine without any systemetic deviation.

Table 7.1.2.1.2- 5:	BCS-CN88460-	carboxylic	acid M	(12): kin	etic and	statistic	cal res	ults of the	SHO
	pathway curve	fils «×		~		٥́ ٥		Ū.	0

<b>_</b>	·		°~	ÿ _s v .	~`0 [.]	s)	Nº E	,	
Soil	Q	DT 50	DT 90	<b>∞f.f.</b> ^{c)}	VA	∑²err		t∸test	MS
	Ŵ	[days]	[days]	S O		[%)	[1/d0]-]	$\mathbf{k}_{1} / \mathbf{k}_{2}$	
Laacher Hof AXXa II	SFQ-SFO ^{a)}	[~] 228	₹759 °	0.255±0.048		1605	0.003035	⊅0.188	
	SFO-SFQ♥	486	>1000	0.24 <b>5</b> £0.034	+ *	2.63	0.001427	0.288	
		1 Alexandre		<i>a</i> ()	~ ~//				

a) Initial fit including all residue data

b) Modified fit excluding residue tata for DAT 104

c) Kinetic formation fraction f.f. Standard Deviation STD MS: Model selected ( To for trigger evaluation; Me for modelling

ăluation) S.

Figure 7.1.2.1.2 8: Kinter UI results for BCS-ON88460-carboxylic ford (MIZ) in soil Laacher Hof AXXa from the SFO pathway fit – initial fit Ø









r the metabolite B presented in Table 7.1.2.1.2-6 and Table 7.1.2.1.2-7, respectively.

Table 7.1.2.1.2- 6: Soil degradation not-normalised DT50 yalues of BCS-CN88469-carboxylic acid (M12) to trigger additional studies (frigger endpoints) J Q ~

	°~~ .	Ø 1		×	
Study				Model &	DT50 not normalised [days]
;	; 2914; M-486	5690-01-1	Hanscheider Hof	_SFO	45.4
		° «?"	Lascher Hof AXX	[∞] SFO	113
	N V B		Hoefchen am Hohensel	SFO	14.8
			Dollendorf II 🖉 🔍	SFO	18.4
;	,	, \ %	Sanger, CA, USA	SFO	n.a.
2017; M-588260-0		/ <u>`</u>	Kouisville, NE, USA	SFO	n.r.
,	<b>2017: 1-5</b>	99926-01-4	Laacher Hof XXa	SFO	n.r.
Geometric mean	<u> </u>	0 0	O O O		34.4





#### Table 7.1.2.1.2-7: Soil degradation not-normalised and normalised (to pF2 and 20°C, Q10: 2.58) DT50 values (SFO fit) and formation fraction (f.f.) of BCS-CN88460-carboxylic acid (M12) for modelling purposes (modelling endpoints) $a^{\circ}$

StudySoilModel fittedDT50 not normalised [days]DT50 normalised [days]2014; M-486690-01-1Hanscheider Hof Laacher Hof AXXaSFO45.445.40,230Hoefchen am HohensehSFQ1131130,230Jollendorf IISFO14.814.80,400		· · ·		·			Or.
2014; M-486690-01-1       Hanscheider Hof       SFO       45.4       45.4       0.330         Laacher Hof AXXa       SFO       113       113       0.257       0.440         Hoefchen am Hohenseh       SFO       14.8       0.440       0.440         Dollendorf II       SFO       184       0.500       0	Study	Soil	Model fitted	DT50 not normalised [days]	DT50 normalised		N. N
2014; M-486690-01-1Laacher Hof AXXaSFO1131136257Hoefchen am HohensehSFQ14.814.80.440Dollendorf IISFO18464.40.500	; ; ;	Hanscheider Hof	SFO	45.4	45.4	× 0, ž30	
Hoefchen am HohensehSFQ14.814.80.440Dollendorf IISFO18.40.500	2014; M-486690-01-1	Laacher Hof AXXa	SFO	113 🔊	113	. 0257 ≪	)
Dollendorf II SFO 184 . 8.4 5 0.500		Hoefchen am Hohenseh	SFQ	14.8	14.8		¢
		Dollendorf II	SFO	184	1 <b>%</b> .4	0,500	Š
; Sanger, CA, USA Stro n.a. n.a.	;	Sanger, CA, USA	<b>SFO</b>	on.a.	On.a.	cn.a.	
; 2017; M- Louisville, NE, USA SFO n.r n.r 0.286 588260-01-1	; 2017; M- 588260-01-1	Louisville, NE, USA	SFO	n.r.g	n.o	0.286	
2017; M-599926-01-1 , Laacher Hof AXXa , SFO , An.r. , O.255	; <b>1</b> ; 2017; M-599926-01-1	Laacher Hof AXXa	SFO X		Sn.r.	0.255	
Geometric mean:	Geometric mean:			°∼ 3 <b>4</b> .4, Ô	.34.4	¢ "Q	
Arithmetic mean	Arithmetic mean					<b>6</b> 345	

n.a. = Not available (only two metabolite detects above LOD, all detects below 1990) 2 2 2 2
n.r. = Not reliable
CA 71212 Anonychia Land dation of the string and the second
CA 7.1.2.1.5 Anaerobic degradation of the active substance
<b>Report:</b> KCA 7.1.2.1.3401; <b>2015</b> ; <b>M-51</b> 3456-01-1
Title: [Pyrazole-404C]B@S-CN88460: Appaerobic degra@ation / phetabolism in one soil
Report No.: $\mathcal{E}$ Extra-14-0046 $\mathcal{A}$
Document No.: 2 WI-513456-01-1 2 2 2 2 2 2
Guideline(s): OOECD Test Guideline No. 307, Commission Regulation (EU) No 283/2013 in
accordance with Regulation (EC) No 1107 2009; 28 EPA OCSPP Test Guideline No.
835.4100 9835.4200; Japanese MAFF Test Guidelines 12 Nousan 8147, No. 2-5-3
Guideline diviation(s): mone and a construction of the second sec
GLP/GEP: $(ves, 0)$ $(ves, 0)$ $(ves, 0)$ $(ves, 0)$

## **Executive Summary**

Ś The degradation data Risoflugypran as reported in ; 2015; M-513456-01-1 in section 6A 7.10.2 were kinetically evaluated according to FOCUS Kinetics report (FOCUS, 2006). The experimental data coold be described by a single first order (SFO) kinetic model. The DT₅₀ value of isoflucypram under anaerobi@conditions was > 1000 days.

It is concluded that the significant degradation of isoflucypram will occur in soil under anaerobic conditions following an actobic incubation phase.

#### Table 7.1.2.1.3 (1: Degradation kinetics of isoflucypram in soil under anaerobic conditions

Soil C Texture C S S C S S S S S S S S S S S S S S S S	Best fit model ^{a)}	DT50 [days]	DT90 [days]	Chi² error [%]	Visual assessment ^{b)}
Laucher Hoff AXX	SFO	> 1000	> 1000	0.7	-

(a) SFO: angle first order

b) Viscal assessment: - = poor



#### I. **MATERIALS AND METHODS**

Details on the study conduct and its results are summarised under KCA 7.1.1.2/01, page 42. The data for the test item were evaluated according to FOCUS kinetics (2006)¹ using the software KinGUI 2. Model input datasets were the residual amounts found in each replicate test system  $at each^{\ell}$ sampling interval of the anaerobic phase.

For the evaluation of the data three different kinetic models (Single First Order model (SFO); First Order Multi Compartment model (FOMC) and Double First Order in Parallel model (DFOP) were tested in order to determine the best-fit kinetic model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits (diagrams of measured and calculated values vs. time, diagrams of residuals vs. time). DTs and DT₉₀ values (time until 50 or 90% degradation) were calculated from the resulting kinetic parameters

II. RESULTS AND DISCO

The degradation of isoflucypram under anaerobic conditions followed single forst order (SFC ) kinetics in all soils according to the lowest chi² error values and visual assessments of fits. A summary of all kinetic data is given in Table 7.1.2.1.3- 2, the best fits we highlighted in bold letters there. The half-life for isoflucypram was > 1000 days in the tested soil under apierobic conditions.

Table 7.1.2.1.3- 2:	Summary of the kinetic evaluation for trigger values according to FOCUS) of the degradation of isoflucy promin soil under an activity conditions	e
	(best fits are highlighted w bold etters)	

	S V			· · · · · · · · · · · · · · · · · · ·		1
Soil	N A	Kinetic	DT	_ <b>40</b> /T ₉₀ ∼	Chi2 error	Visual
(Texture (USDA)	K R	<b>g</b> nodel [®]	[tays]	Jdays 🖌	<u>«</u> [%] »	assessment ^{b)}
Laacher Hof AXXa		SFØ	\$100¢	> 1000 (	⊃ 1.8√	-
(loamy sand)		FOMC	> 1000	>2000	2@9	-
õ		[™] DFOP	p.d.	Nn.d. 🖉	<b>a</b> .d.	n.d.
n.d. = not detected	Or O	N LO	K >			

a) SFO: Single first order, FONC: First order multi compartment DFOP Double Girst order in parallel

- b) Visual assessment: + = good, o = moderate - = poor
- c) Could not be calculat

Isoflucypram was not degraded in soil under anaerobic conditions in the laboratory in the dark. The calculated best fit  $DT_{50}$  value was 1000 days in the jested soil.



FOCUS@hetics (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration".

Report of the FOCUS Work Group on Degradation Kinetics,

EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



### CA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products

As no major metabolites were found in the anaerobic soil metabolism study of isoflucypram ( ; 2015; M-513456-01-1) no kinetic evaluation was conducted to derive an ger and modelling endpoints according to FOCUS Guidance 2014 for isoflucyprammajor soil degradation products.

#### CA 7.1.2.2 **Field studies**

The trigger and modelling endpoints of isoflucyprant and its major soil metabolite BC carboxylic acid (M12) derived from field dissipation trials are summarised in Table 7.1.2.2- 2 and Table 7.1.2.2- 3 to Table 7.1.2.2- 4, respectively.

		×		$\sqrt{2}$		s s	£C.	- 7	
Table 7.1.2.2- 1:	Isoflucypram:	$\odot$	~	õ	a '	×0°	- Carlor - C	L.	A
	Field degradation endpo	ints for	rrigger	purpos	🗟 not-n	ormalis	ed; Eu	opean (	field sites
	(jc • Q?4c□u. A,; ü_sdc. ,	<b>Z</b> ; 201	7; M-593	964	1)		Ś		£G [™]
	ġ.Ÿ	Q		ala	۵Ÿ	"\\		× 1	450

1.

		<i>a</i> .				<u> </u>	
Location, country	Soil type ^{a)}	рЮ	Ø¢pth ^{b)} ≪	DT 50 actual	DT90 actual	St.	Method of
		(CaČl ₂ )	>[cm]	[days]	[days] 🏾	( $\chi^2 erg)$	catculation ^{c)}
				s S			<u></u>
Burscheid, Germany	silt loam,	5.3	<i>6</i> 60	× 143	Å 177 <b>4</b>	»O.2 и	trigger: DFOP
	bare soil	°~,	$\sim$			° Å	1
Great Chishill,	clay loam,	\$ 7.0	<u>کہ</u> 60	129 √	ୁ¥637 ୃ¢	5.6	trigger: DFOP
United Kingdom	bare Spoil	O' N				×,	
Parcay Meslay,	loam, A	5.9	£60	150	2344	\$2.4	trigger: DFOP
Northern France	bare sojł⊊″	<u></u>			1 4, 7	$\sum_{k}$	
St. Etienne du Gres,	člay loam,	~~7.5 _ C	605	×17.0	<b>6</b> 9.4 🖑	4.7	trigger: DFOP
Southern France	bare soil 💊	Ő "Ş			L. U		
Albaro di Ronco al	chay, 🖧	<i>7</i> .0	~60	୬ 7202°	Ø 20 <b>3</b> 6	5.8	trigger: DFOP
Adige, Italy	Gare soil	Ň 4	Ś.		× ~		
Vilobi d'Onyar, Spain	loam	5.8	602	\$25.1 O	%¶97	10.3	trigger: DFOP
	bare soil 🔬		ð,	°° (D).	Ť		
pH dependence	nô/ S		- L		Y		





Ø

ð

#### **Isoflucypram:** Table 7.1.2.2- 2:

Field matrix degradation endpoints for modelling purpose; normalised to 20°C, 100% field capacity,  $Q_{10} = 2.58$ ; European field sites ( $\cdot 2\square 26$  Gelp K sii 4xz L  $\cdot 2017 \cdot M$  505064 01 1) 4x7 L · 2017 · M-595964-01-1)

(	!⊡!0.00µ K, su.4	12, 2017	, 101-39390	+-01-1)			Ş
Location, country	Soil type ^{a)}	pH (CaCl ₂ )	Depth ^{b)} [cm]	DT _{50 matrix} norm ^{c)} [days]	St. (7 ² err)	Method of calculation ^d	l.
Burscheid, Germany	silt loam , bare soil	5.3	60 (ීය	281	3.1	DFOP slow phase	2
Great Chishill, United Kingdom	clay loam, bare soil	7.0	60 T	489	6.1	DFOR Now phase	ô
Parcay Meslay, Northern France	loam, bare soil	5.9	260	400	2.70	DFOP slow phase	1
St. Etienne du Gres, Southern France	clay loam, bare soil	7.5 🖉	60 இ	↓ 137 ↓ ↓ ↓	3.7	HS slow phase	
Albaro di Ronco all Adige, Italy	clay, bare soil	790°			5.95°	DEOP slow phase.	
Vilobi d'Onyar, Spain	loam, bare soil	5.8			010.3 x	DFOP slow porase	
Geometric mean:	²	K,		<b>33</b> 5 💭	IJ.	<u> </u>	
pH dependence	no	° `	<u> </u>	N N		S . L	

a) according to USDA

a) according to USDA
b) Experimental soil sampling depth considered to derive total sesidue dor kines evaluation

c) Normalised using a  $Q_{10}$  of 2.58 and Walker equation coefficient of 9.7

d) DFOP: double first order in parallel; IS: Hockey stick Ø Ô O

BCS-CN88469-carboxylicacid (M92): Field degradation endpoints for trigger purpose; not-normalised; European field sites Table 7.1.2.2- 3:

1 P

			<u> </u>	~Q 65			
Location, country	Sdil type 🧳	pН	Depth ^{b)}	DT 50 actual	DT90 actual	St.	Method of
		(GaCl2)	@ [cm/	[gays]	[days]	$(\chi^2 err)$	calculation ^{c)}
		Ro a		S O	<i>4</i> ,	[%]	
Burscheid, Germany	silt loam , «	5.3	۵۵	380	<b>@</b> 1291	10.7	trigger: SFO
	bate soil				×		
Great Chishill,	çlay loam,	× 7.0 Å	× 60	179 N	595	11.8	trigger: SFO
United Kingdom 🏻 🍣	bare soil	$\langle \rangle$					
Parcay Meslay,	loam,	529	<u>,</u> ≪60	690	2311	9.00	trigger: SFO
Northern France	bare soil	Ô					L
St. Etienne du @es, 0	clay loam,	X7.5 🚿	60>	72	239	8.69	trigger: SFO
Southern France	bar Soil 🔍		<u>s</u>				L
Albaro di Ronco all	chay, 🔊	700"	چ» 60 م	J 311	1032	21.7	trigger: SFO
Adige, Italy	b∕are soil∛	$\sim$ $\downarrow$					
Vilobi ØOnyar, Spain	loam	@ 5.8 @		211	702	24.6	trigger: SFO
· *	bang soil 🔊						
pH dependence 🖉 🔪	no 🖌		Å.				
a) according to LSDA			- V				
b) Experimenter soil same	bling depth cor	isidered to d	erive total r	esidues for kinet	ic evaluation		
c) SFO: single first order							
	N.						
¢°							



1

#### Table 7.1.2.2- 4: BCS-CN88460-carboxylic acid (M12): Field matrix degradation endpoints for modelling purpose; normalised to 20°C, 100% field capacity, Q10 = 2.58; European field sites

	$\mathbb{C}^{2}(0, \mathbb{V}^{t} \cdot \Box \mathbb{Z}^{u} \mathbb{A})$	; sp≤a.y,I	; 2017; M	-595964-01-1	)		S. S.
Location, country	Soil type ^{a)}	pH (CaCl ₂ )	Depth ^{b)} [cm]	DT _{50 matrix} norm ^{c)} [days]	St. (χ ² err) [%]	Formation Graction [©] k _f / k _{pd}	Method of calculation
Burscheid, Germany	silt loam , bare soil	5.3	60	172 (ීය	4.3	0.0386	
Great Chishill, United Kingdom	clay loam, bare soil	7.0	60	<b>67.3</b>	18.8	0.056	SFQ SFQ
Parcay Meslay, Northern France	loam, bare soil	5.9	60 C	340	× 8.9	00345	
St. Etienne du Gres, Southern France	clay loam, bare soil	7.5	<b>69</b> &	82.4	11.0		SEQ.
Albaro di Ronco all Adige, Italy	clay, bare soil	7.0			23	\$\$0430 \$\$	SFO .
Vilobi d'Onyar, Spain	loam, bare soil	5.8		172	23.9 0 4	0.0183	SEO
Geometric mean:				~ <b>3</b> 53			<i>i</i>
Arithmetic mean:		s o	~~~~ <u>~</u> ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	$\sim$	ð -	A 0.04	K)
pH dependence	no		0			) <u>(</u>	~~~

a) according to USDA

a) according to USDA
b) Experimental soil sampling depth considered to derive total residues for kinetic evaluation
c) Normalised using a Q₁₀ of 2.58 and Walker equation coefficient of 0.7
d) SFO: single first order

# CA 7.1.2.2.1 Soll dissipation studies

In Europe a total of ax field dissipation frials for with isofherypram, three conducted in Northern Europe and three conducted in Southern Europe using unlabelled Isoflucypram + Prothioconazole n D formulated as EC 200. ő O

In addition, kinetic evaluations of the degradation behaviour of isoflucypram and its major soil metabolite BCS-CD88460-carboxylic acid (MJ2) in Soil under field conditions have been performed according to FOCUS Rinetics (FOCUS 2006, 2014) to derive kinetic parameters suitable for environmental risk assessment and modelling purpose ( . G.: , B.; 2017; M-, B 2017; A-608370-01-1). 608368-01-1 ånd , G.;,

A summary of the degradation, rates of influcypram and its major degradation product

A summary of the degradation, rates of isoflucypram and its major degrad BCS CN88460-carboxylic acid (1012) in soil in the field is given in section CA 7.1.2.2.



#### • Terrestrial field dissipation study

<b>Report:</b> Title:	KCA 7.1.2.2.1/01; <b>Constant of Second Second</b>
	Germany, United Kingdom, France (North), France (South), Italy and Spain
Report No.:	14-2750
Document No .:	M-595964-01-1
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of
	21 October 2009 including Data Requirements SANC@ 1803/2010 Rev. 7 and Test 3
	Methods SANCO/11843/2010 Rev. 🏠
	EPA Fate, Transport and Transformation Test Guidelines OPPTS 35.6100
	Terrestrial Field Dissipation, October 2008
	NAFTA Guidance Document for Conducting Ferrestrial Field Dissipation Staties,
	DIR2006-01, March 2006 $\sqrt{2}$
Guideline deviation(s):	none
GLP/GEP:	yes & a a a a a a

#### **Executive Summary**

Soil dissipation of isoflucypram under European field conditions was investigated after application of Isoflucypram + Prothioconazole EC 200 on bare soil plots at six spes in Burscheid (Germany) Great Chishill (United Kingdom), Parcay Meslay (Northern France), St. Etienphe du Gres (Southern France), Albaro di Ronco all Adige (Italy) and Vilobi d'Onyar (Spain). The stress are located in the ecoregions Northern and Southern Europe. Isoflucypram + Prothioconazole EC 200 was sprayed once on 256 to 920 m² plots at a rate of

Isoflucypram + Prothioconazofe EC 200 was sprayed once onto 256 to  $920^{\circ}m^2$  plots at a rate of 2.00 L/ha, corresponding to nominal 100 g ha isoflucypram. The plots received approximately 10 mm water between DAT-0 and DATO, either by frigation post application of by rainfall. The control plots were at least 5 m away from the treated plots.

plots were at least 5 m away from the treated plots. Soil samples were taken from day 0 before application up to 749 days post-application to a maximum depth of 60 cm, domogenised and analysed for isoflucypran and its degradation product BCS CN88460-catboxylic acid (2012).

BCS CN88460-carboxylic acid (4/12). Sub-samples of homogenised soil (5 or 20 g) were extracted in a microwave extractor with a mixture of acetonitrile water/acetic acid (4000/1000/30, 4/v/v). Potential matrix effects were eliminated by using an internal standard solution of isotopically labelled reference items added to sample extracts. Following separation 60 fine particles from soil extracts by centrifugation, identification and quantitation of the analytes was performed by high performance iquid chromatography using MS/MS detection in the multiple reaction monitoring mode. The analytical method was validated using three different soils. The limit of quantitation (LOQ) was  $0.0 \mu_{\rm g}/kg$  and the limit of detection (LOD) was  $0.3 \mu_{\rm g}/kg$  for each analytic.

The amount of soflue pranchecreased from DAT 0 to study end (DAT-713) from 98.2 to 28.7 g/ha at Burscheid (Germany), from DAT 0 to DAT-749 onwards from 96.8 g/ha to 20.3 g/ha at Great Chishill (United Kingdom), from DAT 0 to DAT-701 from 88.1 to 31.2 g/ha at Parcay Meslay (Northern France), from DAT 0 to DAT-205 from 90.9 g/ha to 4.20 g/ha at St. Etienne du Gres (Southern France), from DAT 0 to DAT-728 from 90.1 g/ha to 21.0 g/ha at Albaro di Ronco all Adige (Italy) and from DAT-0 to DAT-714 from \$8.2 to 13.0 g/ha at Vilobi d'Onyar (Spain).

Residues of isoflucypram remained trainly in the top 0-40 cm of soil. Dissipation of isoflucypram from soil was moderately to fast with  $DT_{50}$  values ranging from 16.5 to 177 days for all test sites.

An overview of the results is given in the following table:



Soil	Soil type	pН	Best fit kinetic	DT ₅₀	DT ₉₀
	(USDA)	(CaCl ₂ ) ^{a)}	model ^{b)}	[days]	[ <b>dæv</b> s] Ĉ
Burscheid	silt loam (0-50 cm)	5.3	DFOP	143	×1000
(Germany)	loam (50-75 cm)		ĉ		
14-2750-01	sandy loam (75-100)		Ş	- S	
Great Chishill	clay loam (0-30 cm)	7.0	DFOP "O"	177	_>_* <b>1</b> ,000
(United Kingdom)	clay (30-100 cm)		A	, Ô ^y	6 J
14-2750-02		Ĉs	~		Y Q
Parcay Meslay	loam (0-50 cm)	~ <del>~</del> ?9	DØØP	047	>1000
(Northern France)	clay loam (50-100 cm)	al a	-Ô¥		
14-2750-03		Ů,		õ Y	
St. Etienne du Gres	clay loam (0-30 cm)	> 7.5	[™] DF@P	16,5	69.6
(Southern France)	silty clay loam (30-50 cm)	~			
14-2750-04	clay loam (50-75 cm)	6° A		$\mathcal{O}$	st start and sta
	clay (75-100 cm)	Ŭ 🔊			
Albaro di Ronco all Adige	clay (0-75 cm)	6	DFOP	F.6 0	> 1000
(Italy)	clay loam $(75 \times 100 \text{ cm})$	$\sim$ $\sim$	A O		
14-2750-05				$\sim$ $\sim$	A A A A A A A A A A A A A A A A A A A
Vilobi d'Onyar	loam (6-30 cm)	۲ <u>۶</u> ۶۶	≪ DFQP	Q [¥] 25,97	© 812
(Spain)	sandyQelay loam	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Ø. 3.	
14-2750-06	(30-100 cm)	<u>s</u>			
a) pH in 0-30 cm soil depth			A A		
b) DFOP: double first order in	parallel	r L		N X	

Table 7.1.2.2.1- 1:	Degradation of isoflue	cypram in soil
1 abic 7.1.2.2.1 ⁻ 1.	Degradation of isonu	cypram m son

Dissipation of isoflucypram was accompanied by the formation degradation product of∕≫îts BCS-CN88460-carboxylity acid (M12). L, L) The maximum amounts of BCS-CN88460 arborolic acid in the entire soil profiles were detected between DAT-30 and DAT-209 and ranged from 9.99 to 3.88 g/na. However, the transient character of

this metabolite is indicated by its decline to values below the COD towards the end of the study.

ATĚRIAĽS

AND METHODS

#### MATERIALS A.

# 1.

## Test item:

Test and Reference Items Isothecypron + Prothioconazole EC 200 ES 200 (PC: emulsifiable concentration) Test item name: Formulation type: Ô Batch no.: Content a.s. norminal AR 10.: 01785-00 Visofficypram, prothioconazole 20**0**Å-002032 150 g/L prothioconazole 50 g/L isoflucypram 151.5 g/L prothioconazole


# **Reference items:**

Name: Certificate of analysis:

Name: Certificate of analysis:

Name: Certificate of analysis:

Name: Certificate of analysis: isoflucypram (BCS-CN88460)

BCS-CN88460-carboxylic acid (BCS-CY26497) (M12) MZ 00913; MZ 00984; MZ 01697; MZ 01102 MZ 99188 [ds] BCS-CY26497 (BCN-CY26497 ISTC) KML 9812 2.2.1-2) which are typical for the end of subjected to erosion, floor ee of stones. A first 2. Test Sites Six sites were selected (see Table 7.1.2.2.1-2), which are typical for the ecoregions of Southern and Northern Europe. The sites were neither subjected to rosion, flooding not run-off. The test plots had no significant slope and were largely free of stones. A field soil dissipation trial consisted of a treated and an untreated plot at each test site. The control plots were pocated at leases meters away from the treated plots. The selected sites have not been treated with chernicals which could influence the dissipation behaviour of isofluceprant of which could interfere with the analysis of the tesidues in soil.





Site ID	14-2750-01	14-2750-02	14-2750-03 _°	
Site designation	Burscheid,	Great Chishill,	Parcay Mesla	ð
5	Germany	United Kingdom	France	
Geographic location:		ð		9
Latitude	51°04.110'N	52°03'17.07"N 🔊	47°27'47.0''N	
Longitude	07°05.690'E	0°08'33.78"E	0°45;11.9''£y	
Country	Germany	United Kingdom	<b>F</b> rance	Q.
Ecoregion	Northern EU	Northern EU	Northern EU	
Plot Size [m ² ]	306 📎	63	0 258	Ľ
Distance from weather station	in 2 km distance from the	< 1  km avor y from the	At trial location	0″
used for climatic measurements	plot 🔬 🦉	plot		8
Meteorological conditions	yes	yes ves	yes y	
compared to long-term average	~~~ ·			
within normal levels (yes/no)				
Site ID	14-2750-04 🖑	C 14-2750005	₩4-27 <b>50</b> +05 <u>(</u> °	
Site designation	St. Etienne du Gres, 🕎	Albaro di Ronco all	Vilobi Onya	
	France	Adige, Italy	Spain S	
Geographic location:				
Latitude	043°48 20.0 5 5 ×	7 49.345035 N	#1°52` <b>\$</b> 3,43"N	
Longitude	Q [*] 004°43'12.0"E	→11.18979'E C	~~°2°4 <b>4</b> * <b>5</b> 2,39" E	
Country	France	taly of	Spain	
Ecoregion	Southern EU @	Southern EU O	Southern EU	
Plot Size [m2]	<u>&amp; 2</u> 256 <u>(</u>	<u> </u>	296	
Distance from weather station	• at total location	in 0.1 km distance from .	fn 0.4 km distance	
used for climatic measurements		the plot $\mathcal{A}^{\circ}$	rom the plot	
Meteorological conditions	yes of the	y o ^{y yes} , y	yes	
compared to long-term average	E E 8 82 E			

Table 7.1.2.2.1- 2:	Location,	, site description	and climatic da	ta of test sites
---------------------	-----------	--------------------	-----------------	------------------



Test Site and	Soil depth	Soil type	pН	pН	Organic carbon
Trial No.	[cm]	[USDA]	(CaCl ₂ )	(H ₂ O)	[%] 🖉 👌
Burscheid	0-30	silt loam	5.3	5.4	1:0
(Germany)	30-50	silt loam	5.5	5 <u>8</u>	<b>A</b> 2
14-2750-01	50-75	loam	5.7	<b>\$</b> .0	L 0.1
	75-100	sandy loam	5.9	6.2	$0.0^{\circ}$
Great Chishill	0-30	clay loam	7.0	A 7.0	0° 20° , 9
(United Kingdom)	30-50	clay 🔊	7.5 🛴	7.7 🧹	Ŷ°¥.2 _ÇŸ
14-2750-02	50-75	clay 💎	7.6 🖉	7.9 🜔	~
	75-100	clay 🔬	7.60%	7.8 🖉	<u>~</u> " 1.90° _ 0″
Parcay Meslay	0-30	loam®	<u>5</u> 9	6,D	× 19° ×
(France)	30-50	loam	6.1 🛇	6.5	0.5
14-2750-03	50-75	clayloam	6.5	6.9	
	75-100	¢lay loana 🦂 🦯	or 6,4√	6.80	~~ 0. <b>D</b>
St. Etienne du Gres	0-30	@lay loan 🔊	1 75 %	or 7.86	£.3 °
(France)	30-50	silty clay loam	~Q7.6	.7.8 C	2.3
14-2750-04	50-75	✓ clayloam	≫ 7.6	°7.9 €	1.80
	75-100 🖉	🏹 💦 clay 🖉 🔬	v <u>70</u> °,	8.00	24
Albaro di Ronco all Adige	0-30 🖓	د کې دا <del>مې</del>	J.0 Č		2.1
(Italy)	30-50	🔗 x čhavy 🔊	<u>∽</u> 7.1 ~	A7.3 S	1.6
14-2750-05	50-78	b Clay 🗞	Č 7.30	0 7.5 Č	້∼yັ 0.7
	7 <i>5</i> @100 🕵	Chay loan 🖉	<u>5</u> 2	0°7,0	0.6
Vilobi d'Onyar	<b>Ø</b> -30	🔊 loam 🔦	Ø5.8 Ø	6.1 (	0.7
(Spain)	30-50√	Sandy Play loam	6.0	s_6.3 ⊘	0.4
14-2750-06	\$ 50-75	Sandy clay loam	\ 6x5	6.9	0.1
	75,100	sandy cla@loam	<u>6.5</u>	68	0.1

Table 7.1.2.2.1- 3: Properties of the soils from the test sites

## STUDY DESIG B.

1. Experimental conditions For the spray application onto the soil sarrace the representative formulation Isoflucypram + Prothiocomazole EC 200 was selected

Prothioconazole EC 200 was selected Isoflucypram + Prothioconazole EC 200 is an empisifiable concentrate formulation, containing 50 g/L isoflucypram. The product was used one with an application rate of 2 L/ha and 400 L/ha water, J. The second se corresponding to 100 g isoflucy fram/ha

The product was applied to base soil with two passages from opposite directions with each 50% of the total test item at all test sites. First soil samples were taken immediately after each spraying.

The plots received approximately 10 mps water between DAT-0 and DAT-3, either by irrigation post





Trial no. and	14-2750-01	14-2750-02	14-2750-03
test site	Burscheid	Great Chishill	Parcav Meslav
	(Germany)	(United Kingdom)	(Northern France)
Formulation	EC 200	EC 200 🔊	EC 200
Date of application	2014-04-04	2014-06-06	2014-06-16
Application rate of Isoflucypram &	2.00 L/ha	2.00 L/ha	2,00 L/ha
Prothioconazole EC 200 [kg/ha]		A	Ö ^y S ^y i
Water rate [L/ha]	600.0	400.0	× 600.0
Concentration of Isoflucypram &	0.333	0 <b>B</b> Ó0	Č Q333 V
Prothioconazole EC 200 in the spray liquid	al a	Ő¥ ×	
[%]	Ű ^Ÿ		
Concentration of isoflucypram a.s. in the	0.01 <del>6</del> 666	× 0.02,50	چ 0.016666 کې
spray liquid [%]			
Concentration of prothioconazole a.s. in the	پ ^{0.05} و °	g g.0750°0°	D ^x
spray liquid [%]			
Application rate of isoflucypram a.s. [g/ha]			
Application rate of prothioconazole a.s.			
[g/na]			
Wind speed [m/s] and direction			20
Painfall [mm] within 24 h after the		1.0 - 2.0 SE 3	
application			
Irrigation [mm] after application			$\sim 10$ (DAT 1)
		(DA1-5) *	09 (DA1-1)
Trial no. and	142750-04	14-2750-05	
test site	St. Frenne du Gres	Albaro di Ronco all	🖉 Vilobi d'Onyar
	(Southern France)	🔬 🕺 🖓 🖓 🖓 🖓 🖉	(Spain)
Formulation	$EC 200 \sqrt{3}$	$\bigcirc$ EC 200 $\swarrow$	EC 200
Date of application	× 2014-05-D2	2014-06-20	2014-05-12
Application rate of Dofluc Oram &	^2.00 €Zha _?		2 00 T/1
		Q.Z.00 Lena	2.00 L/ha
Prothioconazole & 200 kg/ha]			2.00 L/ha
Prothioconazole & 200 kg/ha] Water rate [L/h]		©2.00.0	600.0
Prothioconazole & 200 kg/ha] Water rate [L/ka] Concentration of Isoffacypram &	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	\$00.0 \$0.333	600.0 0.333
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	©2.00.44a <u>600.0</u> ~0.333	<u>600.0</u> 0.333
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothiocomazole EC 200 in the spray liquid [%]	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	©2.00.44a	2.00 L/ha 600.0 0.333
Prothioconazole C 200 kg/ha] Water rate [L/ka] Concentration of Isoffacypram & Prothiocomazole EC 200 in the spray liquid [%] Concentration of isofficypram a.s. in the concentration of isofficypram a.s. in the	5 0.0166666	0.016666	2.00 L/ha           600.0           0.333           0.016666
Prothioconazole & 200 kg/ha] Water rate [L/ka] Concentration of Isoffucypram & Prothiocomzole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of rothiocomzole in the	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	0.016666	2.00 L/ha <u>600.0</u> 0.333 0.016666
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole s.s. in the spray liquid [%]	× 4 × 500.0 × 0.3335 × 0.05 × 0.05	0.016666 0.05	2.00 L/ha <u>600.0</u> 0.333 0.016666 0.05
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application of isoffucypram a.s. [7]	× 4 × 5 × 0.00 × 0.333 × 0.05 × 0.05 × 0.05 × 0.05 × 0.05 × 0.00 × 0	0.016666 0.05	2.00 L/na <u>600.0</u> 0.333 0.016666 0.05 100
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s.	× 0,05 × 0,05 × 0,00 × 0,05 × 0,007	0.016666 0.05 100 300	2.00 L/na <u>600.0</u> 0.333 0.016666 0.05 <u>100</u> 300
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 if the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha]	× 4 × 0.00 × 0.333 × 0.05 × 0.00 × 0.333 × 0.00 × 0.333 × 0.00 × 0.333 × 0.00 × 0.00	0.016666 0.05 100 300	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of ptothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha]	× 5 × 0.00 × 0.3335 × 0.00 × 0.00 × 0.05 × 0.05 × 0.05 × 0.05 × 0.05 × 0.05 × 0.05 × 0.00 × 0.00	0.016666 0.05 100 29	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of ptothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] art direction	× 5 × 0.00 × 0.3335 × 0.05 × 0.00 × 0.05 × 0.00 × 0.05 × 0.00 × 0.00	2.00.4 ra 600.0 0.333 0.016666 0.05 100 300 29 no wind	2.00 L/ha <u>600.0</u> 0.333 0.016666 0.05 <u>100</u> 300 <u>15</u> 0.8 - 2.8 E
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spice liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] and directron Rainfall [mm] within 24 h after the	→ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	2.00.2 tra 600.0 0.333 0.016666 0.05 100 300 29 no wind no rain	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15 0.8 - 2.8 E 7.4
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spiral liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] and directron Rainfall [mm] within 24 h after the application	→ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	2.00.4 ra 600.0 0.333 0.016666 0.05 100 300 29 no wind no rain	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15 0.8 - 2.8 E 7.4
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole s.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole s.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] and direction Rainfall [mm] within 24 h after the application [mma after application	5 0.00 0.333 0.333 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.	2.00.4 ra 600.0 0.333 0.016666 0.05 100 300 29 no wind no rain 10 (DAT-0)	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15 0.8 - 2.8 E 7.4 4 (DAT-2)
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] and direction Rainfall [mm] within 24 h after the application [mm] after application	→ 0.05 → 0.0	2.00.4 ra 600.0 0.333 0.016666 0.05 100 300 29 no wind no rain 10 (DAT-0)	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15 0.8 - 2.8 E 7.4 4 (DAT-2)
Prothioconazole & 200 kg/ha] Water rate [L/ha] Concentration of Isoffucypram & Prothioconazole EC 200 in the spray liquid [%] Concentration of isoffucypram a.s. in the spray liquid [%] Concentration of prothioconazole a.s. in the spray liquid [%] Application rate of isoffucypram a.s. [g/ha] Application rate of prothioconazole a.s. [g/ha] Air temperature at application [°C] Wind speed [m/s] and direction Rainfall [mm] within 24 h after the application	→ 0,05 → 0,0	2.00.4 ra 600.0 0.333 0.016666 0.05 100 300 29 no wind no rain 10 (DAT-0)	2.00 L/ha 600.0 0.333 0.016666 0.05 100 300 15 0.8 - 2.8 E 7.4 4 (DAT-2)

## Table 7.1.2.2.1- 4: Data for spray application

# Sampling 2.

The treated pot of the triat was divided into four sub-plots. From each sub-plot of the treated plot four soit cores were taken and combined to a sample at each sampling interval.

Before application four soil cores were taken from untreated control plot to a depth of 10 cm with a soil piercer (Ø 100 mm). Immediately after application two times 16 soil cores were taken from the treated plot to a depth of 10 cm with a soil piercer (Ø 100 mm), respectively.



All subsequent samplings were performed using a "Wacker Hammer" (Ø 48 to 100 mm). At each sampling interval 16 cores from the treated plot were taken. From control plots 16 soil cores were taken.

The samples were taken to a maximum depth of 60 cm on the following occasions: 0, Fostapplication, 0-10 cm depth), 3-4, 7, 13-15, 27-30, 57-70, 88-111 (0-40 cm depth), 110-140, 103-168, 205-278, 345-402, 519-560, 701-749 (0-60 cm depth) days after treatment (DAT).

From the control plot samples were taken on the following occasions: 0 days before application and 345-402 days and 713-728 days after treatment. Ô

In addition, for characterization soil samples were taken before application from the treated plots to a depth of 100 cm (10 coil correct) depth of 100 cm (10 soil cores).

The samples were deep-frozen within 24 hours. The frozen soil cores were cut into 10 cm segments C and each horizon (laboratory samples) was milled separately in a hammer mill and earefully homogenized. An aliquot of each homogenized laboratory sample (analytical samples) was used for analysis. Soil cores and samples were stored at  $\leq 98^{\circ}$ C.

3. Analytical Procedures The analytical method 01432¹ was developed for the determination of isoflucyprate and its metabolite BCS-CN88460-carboxylic acid in/on soil. acetonitrile/water/acetic acid (4000/1000/30, v/v/v). The extracts were contributed to remove fine particles of the soil. Possible matrix effects of isoflucypean and the metabolite BCS-CN88460carboxylic acid are eliminated by using an internal standard solution of isotopically labelled reference items. Identification and quantitation of the active substance was done by high performance liquid chromatography using MS/MS detection in the Multiple Reaction Monitoring mode.

The limit of quantitation (LOQ) for each single analyte was 1.0 kg/kg ar soil. The limit of determination (LOD) for each single analyte was  $\rho \mathcal{G} \mu g/kg$ . Ô

During analysis of the samples concurrent recovery experiments were performed by spiking control

4. Kinetic evaluation

The degradation kinetics of the test iten was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with three different kinetic models Single first order (SFO), first order multi compartment (FOMC) and double first order in parallel (DPOP).

Model input datasets completed of the residual amounts found in each replicate test system at each sampling interval. The initial total recovery at DAT-9(2 samplings after incorporation) was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.



^{2014;} Analytical method 01432 for the determination of BCS-CN88460 and the metabolite BCS-CN88460carboxylic acid in soil and sediment by HPLC-MS/MS; M-499794-01-1 summarised in MCA 4.1.2



## II. **RESULTS AND DISCUSSION**

# A. ANALYTICAL RESULTS

# **Control samples**

Residues of isoflucypram and BCS-CN88460-carboxylic acid in control samples were < LOD samples taken.

# **Treated samples**

The measured initial mean concentrations (n = 4) for isoflucyprate were 98.2 c/ha Burscheid, Germany) 96.8 g/ha (Great Chichill United View) Germany), 96.8 g/ha (Great Chishill, United Kingdom), 88.1 g/ha (Carcay Meslay, Northern France), 90.9 g/ha (St. Etienne du Gres, Southern France), 90.1 g/ha (Albaro di Ronco all Adige, Italy) and 88.2 g/ha (Vilobi d'Onyar, Spain), representing 88 to 98% of the intended application ate.

Ø Residues of isoflucypram remained mainly in the top \$40 cm of soft. Dissuation of isoftucypram was ↓ ¢ accompanied by the formation of its degradation product BCS-CN8846(Farboxylic actd

gr. LN88646 JAT_209 avia Indicated by the in The maximum amounts of BCS-CN88040-carboxylic acid *fM124*, in the entire soil profiles were detected between DAT-30 and DAT-309 and fanged from 0.99 43.88 sha. However, the fansient character of this metabolite is indicated by its decime to values below the LOS towards the end of the study. The maximum amounts of BCS-CN88640-carboxylic acid M12/ in the entire soil profiles were



Subplot					Bursc	heid, G	ermany	(14-27	50-01)				<u></u>	2
						Days af	fter app	lication	l			ە	× i	Ş
	0	3	7	13	28	70	91	110	160	209	370	538C	713	
T1	97.3	88.9	103	97.4	91.8	61.3	49.6	60.0	38.4	390	32.2	33.3	2790	
T2	101	106	97.7	97.6	73.5	83.7	55.5	55.1	55.1	49.3	34.2	28.7	°22.2	
T3	92.6	88.2	86.5	86.5	84.3	50.3	43.1	50.4	37.5	47.6	38.8	D ^{27.9}	>30.2	P
T4	102	93.3	85.2	90.4	88.3	67.3	74.2	53.4	51.2	44.1	42.1×	33.8	35.2	
Mean	98.2	94.1	93.1	93.0	84.5	65.7	55,5	54.7	45%6	44.5	36,8	30.9	287	- L
	Great Chishill, United Kingdom (14-2750-02)													0″
	•	4	-	14	27	Days a	ter app	licatio	ເ" 1 1.0ຄິ	่าซึ่	403	ڻ ج (۵	ี 🥵	p
T1	07.2	4	/	14	72.9		<b>111</b> 91.6	140	1 <b>98</b>	24.0	40%	<u> 700</u>		-
11 T2	97.2	115	93.1 82.0	79.0 78.0	70.0	(77.0 (77.0	0,1.0 026.1	(199.9 (a) 20a)	×490.4 ×11.4 s	(201.0 (127.2 /	0.9	≫0.4 ≫12 °	$V_{127}^{2.9}$	
12 T3	100	85.6	62.0 114	70.9 88 1	03 1 C	77.2	71 12	_•0.20 ∕_ 	5180	* 37.3 A	* 32.2 33 <i>I</i>	*25.8 25 a	14.6	
13 T4	99.6	89.0	98.4	90.3	7729	57709	7907	1590°	38.8	46.3	30	4301	268	
17 Mean	96.8	97.4	96.9	90.5 84 1		2200 ≈71 1	~707	73.9 5	20.0		√33 0	30 2	0 3	-
Ivican	70.0	77.4	70.7	04.1	7			v.s V (		<b>3</b> /.0			×0.5	
				Parce	ay Mes	lay, No	thern I	rance	(14-275	0-03)	Í Í		<i>y</i>	
	0	3	7	A4	29	Days ai	ter≈app ∧ 88	incation			357	519	701	
T1	75.7	82.4	77.5 e	~~~	57.2	46.9	52.0	49.3 ⁴	37.7	44.6	33.4	29.3	28.9	
T2	86.4	71.3	86%	70.3	79.1	53.90	55.4	46	47.4	36.0	40	36.7	31.4	
Т3	86.4	74.8	86.8	84.6	65,0	5 <b>L</b> 6	46.0	41/3	53.1	390.0	35.6	33.8	32.2	
T4	104	112	Ø9.0	<b>\$6</b> .0	\$7.1	\$3.9	51.1	49.5	4.3	Å7.4 .	31.4	34.8	32.1	
Mean	88.1	85.1	82.5,5	79.2	64.6	53.1	51.1	46.6	45.6	¥41.9	35.1	33.7	31.2	
		Ż	Ş		0			E C	(See a					
		ŝ	100	St. Maie	enne du	Gres, S	Souther	n Franc Estat	e (J#-2	/50-04)				
	0	\$ 3 . (	6 ⁷ 7 3	×14 ×	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Days ai	92		 ∲151⊲	P 205				
T1	93	82%	58.2	59%6/	223	15.2	9.36	12.0	14:00	7.33				
Т2	881	75,9	6 D2	50.3	18,6	812	10.0	346	Zr.40	2.87				
Т3	85.9	80.2	69.6	<i>©</i> \$5.2	₹35.1 ¢	3.5	3.59	7.00	8.99	3.79				
T4 🌾	96.4	87.3	J 73.3☆	) 53.3 n	[©] 19.8 ⁽⁽	8.16	4.59	2.95	3.37	2.82				
Mean 🔊	90.9	81	670	54.6	24.0	110	7.39	<b>6.38</b> ″	7.44	4.20				
<i>v</i>		0	L.		uro di R	≫ ŏ¤co al	Adige	. Italy (	14-2750	)-05)				
	Ő	7 A		Ų 🗶		<b>B</b> ays af	ter app	hication		,				
	0 "	<u> </u>	75	14,0	28	62	89	122	157	209	369	531	728	
T1	A.5	87	88.9	<b>79</b> .7	AZ.2	63.4	44.9	53.2	45.6	34.2	33.4	30.2	17.9	
T2	§ 90.2	83.8	_ج 87	ರಿ36.6 ್ಲೆ	\$68.8	\$2.3	35.3	35.6	49.2	29.2	40.5	28.3	22.7	
T3	₩88.2	87.5	85.4	* 70.9°	87.5	33.6	41.6	43.2	35.2	26.7	37.7	35.4	23.1	
T4 🖑	90.3	90.9°	82.℃	119	40.5	-53×	32.9	27.6	30.5	29.7	40.6	29.8	20.2	
Mean	90.1	87.3	85.9	80.1	67.3	50.3	38.7	39.9	40.1	30.0	38.1	30.9	21.0	
$\sim$		, and the second s	ð é	Ŋ,	Vilobi	d'Onva	ır, Spaiı	n (14-27	750-06)					
	, O	*	a s		D.Y	Days af	ter app	lication	1					
	Ĩ		Ĩ	×45	<b>30</b>	57	99	120	158	224	345	533	714	
T1	\$75.6	\$ <b>1</b> 9.2 (	ð ð 7.4 🗴	×35.3 ک	Q44.5	31.9	31.9	30.9	30.1	27.2	22.5	12.4	13.6	
T2	96.4%	[∞] 96.7Ô	104	54.0	56.3	34.1	35.4	40.0	24.1	21.7	18.1	15.7	15.6	
T3 🎊	863	8 <u>6</u> 9	76.9	44.8	43.1	41.7	34.7	31.2	33.1	21.3	19.8	15.1	10.2	
T4 🔊	94?3	<b>Q</b> 2.8	\$\$8.9	48.3	47.8	36.1	40.8	37.8	26.6	28.6	25.8	14.8	12.5	
* `````		"(boo	1 /01 0		4 = 0	260	25 5		30 5	<b>A A B</b>	31 6		1 1 2 2	1

## Table 7.1.2.2.1- 5: Analytical results of isoflucypram preprocessed values in entire soil profiles (0-100 cm) [g/ha]

a) outlier, and not used for calculation



Subplot					Bursc	heid, G	ermany	(14-27	50-01)				Ŷ	ð
-						Days af	ter app	lication						S
	0	3	7	13	28	70	91	110	160	209	370	<b>538</b> Ö	ð 713 [°]	J.
T1	0.00	0.00	0.00	0.26	1.12	1.49	1.17	1.74	1.19	1.45	0.95	1.26	0,930	
T2	0.00	0.00	0.00	0.25	0.94	1.63	1.34	1.19	1.66	1958	1.12	1.23	° <b>0</b> ,94	
Т3	0.00	0.00	0.00	0.26	0.91	1.17	1.30	1.05	1.44	1.63	1.23	J1.18 👸	§1.04 ¢	ð
T4	0.00	0.00	0.00	0.25	1.02	1.96	2.08	1.06	2.16	2.17	1.76	1.77	1.66	_
Mean	0.00	0.00	0.00	0.26	1.00	1.56	1,47	1.26	1.61	1.63	127	1.36	104	a a
	Great Chishill, United Kingdom (14-2750-02)													
	0	4	7	14	27		111	140	۱6	278	402	560	749	
Т1	0.00	0.00	0.21	0.72	0.88	144	2 38	A-91	°2/05	a.51	a)\98	×0,89	~0~59	
T2	0.00	0.00	0.00	0.22	0.91	k√1.26 -	Q2.11	0.00 ^a	×1.30 ×	0.97 <i>"</i>	1.29	0.24	0.00	
T3	0.00	0.00	0.00	0.24	1.06 ^C	1.54	1.58	1.16	2.56	1.090	1.15	0.84	0.000	
T4	0.00	0.00	0.00	0.22	0,485	1.08	2.58	2.60	1,.49	131	1.60	1.88	0,86	
Mean	0.00	0.00	0.05	0.35	0.93	1.35	2.16	<u>.</u> @:89	1.85	<b>.</b>	<b>≪}</b> .26	0.78	<b>9</b> .36	
				Dava	U. M.		0 4 h a m 2	Y (	11 275	h 02) @	, Y	Č	)	
				race	ay mes	Daxs af	ter ann	lication	14-20	0-03	Ű	Ô		
	0	3	7	<b>A</b> 4	29	<b>63</b>	<b>88</b>	221	43	Â10	\$357	519	701	
T1	0.00	0.00	0.00	, 0.22 _%	<u>,</u> 0.88 (	1.194	×1.67	2.50	¥1.55℃	1.35	1.30	1.38	1.19	
T2	0.00	0.00	0.00	0.23	1,11	1.080	1.06	1.18	1.05	0.25	0.93	1.30	1.04	
Т3	0.00	0.00	0.18	Q.75	1.01	154	1,32	1:61	2.01	ू 1 <b>्</b> र्3्	1.49	1.62	1.64	
T4	0.00	0.00	Ø.00	<b>@</b> .22	<b>0</b> .87	¥.43	1.25	1.62	¥.49 🔊	7.83	0.99	1.39	1.25	
Mean	0.00	0.00	¥0.05 <u>1</u>	0.36	*0.97	*1.31	1.33	¥ 1.48	°1.53≪	r [∞] 1.20	¥ 1.18	1.42	1.28	
	St Hienne du Cres Southern France (12-2750.04)													
		Ű	L.	8		Days af	ter app	lication	- O	a.				
	0	<b>§</b> 3 (	D″7 ×	<u>y 14</u> *	<i>୰</i> 30 ∾	y 58 🔨	<u>7 92</u>	م 116 م	¥ 151	205			<u> </u>	
T1	0.00	0.20	1.45*	2.50	3.91	3.43/	2.50	2.00	1.5	1.25				
T2	0@0	008	1.61	2.60	3,65	3,73	2976	883	<u>6</u> 71	0.29				
T3	0.00	·Ø.21	F.41	©2.43	4.53	<b>4</b> .83	©Z.87	2.69	©1.71	1.02				
	0.00	0.22	1.04	2.240	**3.43 ×	3.29	3.75	2.86	2.01	0.33			ļ	
Mean 🖉	0.00	0.20	1.05	2.4*	3.88	3.82	2:90	2.00	1.75	0.72			<u>i                                    </u>	
		\$°	\$° .	Alba	k di R	onco al	L X dige	, Italy (	14-2750	-05)				
	Ô	y a			<u>í</u> " «	Bays af	ter app	hication						
		30		140	28	62	<u>89</u> >'	122	157	209	369	531	728	
T1	< DOD	< COD	824	027	1,20	*1,81	2.23	3.37	1.92	1.21	1.23	1.06	1.05	
T2	< LOD	< LOD	00.23	0.84	Q1.20	4.70	2.04	2.76	2.40	1.25	1.39	1.08	1.20	
	≪ LOD	< LOD	0.250		1.26	1.64	2.14	2.51	1.37	1.03	1.04	1.60	1.41	
		0.222	0.6%	1.09			1.96	1.98	1.27	0.24	1.30	0.82	1.20	
Mean _k	< LOD	×UN0	( <del>1</del> ,4,7)	/%/1/8 >>	0 ~	1,08	2.09	2.00	1./4	0.93	1.24	1.14	1.22	
Ÿ		\ \	° c		Vilob	d'Onya	r, Spai	n (14-27	/50-06)					
	s.	4 1	, Î		, Q	Days af	ter app	lication						
	Ö	<b>3</b>	Ĩ	≪¥∕5	<b>30</b> ″	57	99	120	158	224	345	533	714	
T1	§0.00 ×	<i>ب</i> 0.00 (	50.19 ≰	≫0.83¢	Q0.85	0.22	0.88	0.85	0.97	0.81	0.97	0.23	0.00	
	″ 0.00°	0.00	0.19	1.01	0.96	0.78	0.92	1.02	0.85	0.24	0.00	0.00	0.00	
	0,009	0.00	0,07	0.92	0.78	0.92	0.90	0.97	1.24	0.27	0.00	0.00	0.00	
	<b>\$</b> .00	40:00	10/18	1.04	0.96	0.86	1.04	0.89	0.88	0.24	0.84	0.24	0.00	
Mean	Q <b>0.00</b>	^{ال} 0.00 ل	ð″ <b>0.18</b>	0.95	0.89	0.70	0.94	0.93	0.99	0.39	0.45	0.12	0.00	

## Table 7.1.2.2.1- 6: Analytical results of BCS-CN88460-carboxylic acid preprocessed mean values [g/ha]

a) outlier, alue not used for calculation



# **B. KINETIC ANALYSIS**

The data for isoflucypram were evaluated. The measured initial concentration at day 0 was included in the parameter optimization procedure. Based on criterion for chi² error to be minimal and vigual assessment the best fit kinetic model was chosen for the evaluation of the dissipation time. The calculation considered the quantifiable residues for the whole soil profiles expressed in g/bs. The results are summarised in Table 7.1.2.2.1-7 with best fits highlighted in bold fetters. For the six test sites Burscheid (Germany), Great Chishill (United Kingdom), Parcay Meslay (Northern France), St. Etienne du Gres (Southern France), Albaro di Ronco all Adige (Italy) and Vilobi d'Onyar (Spain) the dissipation of isoflucypram could be described using biphasic kingues. In detail, the results are shown in Table 7.1.2.2.1-7.

The dissipation of isoflucypram showed a biphasic behaviour After treatment, isoflucypram dissipated in a first step very fast within a couple of days followed by a second sower step until study termination.

<b>h² error</b> <u>1%</u> 1698 3.502
1698 3.502
1 698 3.502
3.502
2.532
12.9
10.41
10.68
14.04
2.814
2.236
8.801
6.861
4.537
18.41
7.388
5.523
23.39
11.59
10.29

		×.,	S	$\sim$
Table 7.1.2.2.1- 7:	Isoflucypram: calcu	lation ^v of	distinat	ion/time

aerm

b) Best fits highlighted in hold letters

c) Visual assessment: + good, s moderate, - = moor

A	
~~	

Isoflucypram was moderately to last degraded in soil under the conditions of field testing at six trial sites in Northern and Southern Burope, The dissipation of isoflucypram could be described by biphasic kinetic models with calculated best fit half Qves between 16.5 and 177 days in the tested soils.

Residues of Soflueypram were shown to remain mainly in the top 0-40 cm soil layer with residue levels within the range of 2.2 to 31.2 g/ha at study end.

Dissipation of Soflucypram was accompanied by the formation of its degradation product BCS-CD88460 carbo ylic acid (M12) with maximum amounts in the entire soil profiles detected between DAT-30 and DAT-209 and ranged from 0.99 to 3.88 g/ha. BCS-CN88460-carboxylic acid was found in the top 0-20 cm only.



# Kinetic evaluations of field dissipation study

# Kinetic evaluation for trigger endpoints

Report	KCA 7 1 2 2 1/02:	B · 2017: M 608368 01 1	X X
Report	KCA 7.1.2.2.1/02, , O.,	, D., 2017, WI-600500-01-1	
Title:	Isoflucypram (ISY) and metabolite - Kineti	ic evaluation of the degradation i	n soil 🔘
	under field conditions for trigger purpose	O ^y	
Report No.:	EnSa-17-0634	A. OF	ô V
Document No .:	M-608368-01-1		
Guideline(s):	not applicable		Y ÔY O
Guideline deviation(s):	none	Q. O. T	
GLP/GEP:	no		
	A	R' 6° A A	C L

## **Executive Summary**

Non-normalised (not for temperature or moisture) dissipation DT values of isoflucy fram and its metabolite BCS-CN88460-carboxylic acid (MP2) in soil under European field conditions (

; 2017; M-595964-01-1) were derived for tragger purpose according to FOCUS guidance  $(2006^1, 2014^2).$  $\bigcirc$ In the experimental field dissipation stadies, the active substance has been applied onto bare soil at a nominal rate of 100 g/ha isoflucyprand in spring (April to June) 2014. Throughout the study period of approximately 2 years, irrigation activities were carried out.

In this evaluation, the initial soil conceptration was free fitter together with all degradation rates and formation fractions, based on the IRES erfor model (Instatively reweighted least square), using KinGUI 2. The selection of the kinetic model was based on a detailed statistical analysis including visual assessment,  $\chi^2$  statistic and significance of a t-test.

In all soils, the best fit for dissipation of isoflucy fram (parent and its metabolite BCS-CN88460-



FOCUS, 2006: Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the Work Group on Degradation Kinetics. EC Document Reference SANCO, 10058/2005 version 2.0, 434 pp.

² FOCUS, 2014: Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.1.



Table 7.1.2.2.1- 8:	Isoflucypram: field degradation endpoints for trigger purpose;
	non-normalised; European field sites

Location, country	Soil type ^{a)}	pН	Depth ^{b)}	DT50 actual	DT90 actual	St.	Methodof
		(CaCl ₂ )	[cm]	[days]	[days]	$(\chi^2 \text{err})$	calculation ^{c)}
Burscheid, Germany	silt loam , bare soil	5.3	60	143	1774	3.2	trigger: DFCP
Great Chishill, United Kingdom	clay loam, bare soil	7.0	60	129 Ča	1637-	5.6	Origger DFOP
Parcay Meslay, Northern France	loam, bare soil	5.9	60	~₹ <b>7</b> 50	2841	2.40	trigger: DFOP
St. Etienne du Gres, Southern France	clay loam, bare soil	7.5	60	Ø 17.0	69.4°	04.7	trigger. DFOP
Albaro di Ronco all Adige, Italy	clay, bare soil	7.0	60% &	72.2 ×	°.2036	5.8	trigger: DFOP
Vilobi d'Onyar, Spain	loam, bare soil	5.8		25 Y	J 7970	A10.3	trigger: DFOP
pH dependence	no	, K		N D	J.O	, L	

a) according to USDA

т	able 7 1 2 2 1 0 BCS (	N 99460 A	wybill a aid a	AU 20 Card	daradation	on Anginte Cor	# triagor
.,		Ô.	10° 'Y			õ "Š "	L [®]
Ś	DFOP: double first order in para	llel 🖉	×		o s		Ô
)	Experimental soil sampling dept	h consider a to c	lørive total r	sidues for kine	ene evaluation		Q
ı)	according to USDA		,°N	0.4			E.

		× (				l de la	
Location, country	Soil Øpe ^{a)}	©´pH,∾	Depth ^{b)}	DT 50 actual	DA 90 actural	"St.	Method of
	× A	(CaCl2)	em]	J [dass]	[days]	(gerr)	calculation ^{c)}
	$\swarrow$ $\varsigma$		0 0		1 Q, 7	<i>ू</i> [%]	
Burscheid, Germany	silt loam ,	\$\$.3 Q	60	389	D291 🔧	10.7	trigger: SFO
	bare soil 🔩	Ø. S	<b>A</b>		L O		
Great Chishill,	çlay loam∳	<b>7</b> .0	~60 L	× 1705	© 5 <b>95</b> %	11.8	trigger: SFO
United Kingdom	pare soil	Ő 4					
Parcay Meslay,	loam,	5.9	. 60 ²	§~696 ©	2311	9.00	trigger: SFO
Northern France	bare soil 🔬		ð	°°	Ø		
St. Etienne du Gres,	clay loans	Į,	<u>60</u>	72 C	> 239	8.69	trigger: SFO
Southern Prance 7/	bare soil	×, Å					
Albaro di Ronco all 🍣	clay,	♥ 7.0~	60	311	1032	21.7	trigger: SFO
Adige, Italy	bane soil		. 🖉	Ŭ Õ			
Vilobi d'Onyar, Spain	foram, N	5.8	گ 60 گ	<b>21</b>	702	24.6	trigger: SFO
	bare soil	$\sim$		s.			
pH dependence	no 🖉 🔍						





# I. METHODS

The behaviour of isoflucypram and its metabolite BCS-CN88460-carboxylic acid (*M12*) was investigated in a terrestrial field soil dissipation study designed to determine the dissipation onder representative European field conditions (**M12**); **M12**; 2017, M-595964-01(**D**). The study included trials at six sites at six geographic locations in Germany, the UK, France (taly and Spain (Table 7.1.2.2.1-10). Each test site received a single application at a nominal application rate of the active substance of 100 g/ in spring. However, the actual amount of isoflucypram applied was 88.1% to 98.2 g/ha (Table 7.1.2.2.1-11). Application was made on bare soil.

Table 7 1 2 2 1 10.	Coographical data	of the field	distinction	triald
1 able /.1.2.2.1-10:	Geographical data	of the field	dissipation	trials

	4	<u>م</u>		, C, U
Site	Trial no. 🏾 🌾	Latitude ^{a) V}	LongiQide ^{a)}	Elevation 🖌
Burscheid, Germany	14-2750-01	51°04.1 0 N	07°05.690'E	205 mC
Great Chishill, UK	14-2750-02	\$2°03'H.07''N	0°08'33.78 E	≫ 146 m
Parcay Meslay, Northern France	14-2750-03 🤸	47°28,47.0°	2 <b>€</b> 45'11. <b>9</b> ′'E ↓	l₄10 m ∘
St. Etienne du Gres, Southern France	14-2,45,0-04 @	43 48'20.0 N	₄ 4°43',12.0''E ©	al m
Albaro di Ronco Aldige, Italy	142750-05	45 ⁸ 34'5035"N	♪ 11°1®97.9‰	23 m
Vilobi d'Onyar, Spain	<b>14-</b> 275 <b>0-</b> 06	41°52,53.43"NO	2 44 52,39 E	~ 136m
a) by Google Earth				

a) by Google Earth

Table 7.1.2.2.1-11: _____ Application rates of isoffacypram in field dissipation mals

	Site & B &	Actual application rate
	Burseheid, Germany	\$\$8.2 \$\$
	Great Chiston, UK	$O^{*}$ & 96,8 $O^{*}$
	Parcay Meslay, Northern France	
£	St. Etienne du Gres, Southern France	<i>Q</i> 90.9
Ŷ	Albato di Robco Aldige, Italy	\$90.1
	Vilobi d'Onyar, Spain	88.2

The evaluation is conducted to derive kinetic parameters suitable for trigger purpose according to FOCUS kinetics (FOCUS 2006, 2004). The kinetic analysis was performed using the software KinGUS 1 with four different kinetic models. Single First-Order (SFO) and the bi-exponential models FOMC (First-Order Multi-Compartment model), DFOP (double first order parallel) and HS (Hockey-stick).

In case of a trigger evaluation, for a parent substance the best fit model should be evaluated based on a visual assessment, t-test and  $\chi^2$  test of SPO, FOMC or DFOP models. The best fit model of the parent is then obosen, and for the metabolite in the total system it is tested, whether SFO yields an appropriate fit based on visual assessment, t-test and  $\chi^2$  test. Generally, an error of  $\chi^2 < 15\%$  is considered as acceptable.

Otherwise, FOMC or DOOP could be assessed for a metabolite and the best-fit model be chosen. However, bi-phasic models for metabolites bear a complexity in formation and degradation in parallel, and consequently for the interpretation and comparison with effects in ecotoxicological studies. Thus, biphasic models typically are not used in case of metabolites.



# **II. RESULTS AND DISCUSSION**

Results of the simple first-order or bi-phasic kinetic evaluation of 6 field dissipation s including the active substance isoflucypram and its metabolite BCS-CN88460-carboxylic acid (*M12*) are given below according to FOCUS kinetics (FOCUS, 2006, 2014).

Dissipation rates are evaluated for the corresponding study conditions at the field site (not temperature



or moisture normalised).

For trigger purpose the best fit model is required (SFO, FOMC, DFOP) for a parent compound, based on the error of the  $\chi^2$  test and visual acceptability.

## **Degradation of isoflucypram** •

The non-normalised degradation DT₅₀ matrix values of isoflucyprant are summarised Table 7.1.2.2.1-12.

In all soils, the best fit for dissipation of isoflucypram for trigger purpose could be described assuming a DFOP model. The statistical assessment of the best fit model shows good results with relative errors  $\varepsilon$  of the  $\chi^2$  test below 15%. The visual inspection of the fill shows for each soft a good acceptability.

Site	Kinetic	DisT ₅₀ initial	Dist 90 infial	A-test	®St. 1	Visual
	model ^{a)}	[dax[s]	© [days	& kinitial	( $\gamma^2 er P$ )	fat ⁰⁵
					<b>[%</b> ]	
Burscheid,	SFO	269 ¢	× 894 ~	\$0.00 ×	Ø12.1 (	7 0 0
Germany	FOMC	0 [×] 149 [×] 2	\$ 7370	~ ~ 5 .5	3.6	, ÓQ
	DFOP 🖗	2 <u>1</u> 43	1774	< <u></u>	<b>3</b> ,2	°∼y+
Great Chishill,	SFQ	<u></u>	\$824 ©	Q 0.001	°S93.0 &	0
UK ^{c)}	FOMC	182	2308	4 <del>.</del> 8	10.4 ^O	+
	<b>€</b> € <b>€</b> <b>€</b> <b>€</b> <b>FOP</b> (	) <u>A</u> 80 0	1322	0.001	109	+
Great Chishill,	SFQ	238	<u>م</u> ر 189	× 0.00 ×	A2.6	0
UK ^{d)}	FOMC	لا 145	× 2844×		6.0	+
	<b>DFOP</b>	≶_~ <b>€2</b> 9 ~⊃	1637	⊘ <0.001	5.6	+
Parcay Mestay, 🔪	[©] SFQ [≫]	437	્રે [°] ¥450 ્રુ	\$0.00M	15.0	0
Northern Mance	FOMC	0 1490 x	€ ⁷ 479 <del>74</del>	- ¹	2.8	+
	<b>Ď</b> ŦOP	<u>150</u>	2341	^O <b>≪0.00</b> 1	2.4	+
St. Étienne du	SFQ	@18.4 ^O	61.2	0.001	8.8	0
Gres, Southern	FQMC	, ¹ 7,9 [°] ,	O [™] 70.8	- ~~	7.8	0
France $\Im$	<b>B</b> FOP C	× •17.0 ×	<b>6</b> 9%4	< 0.001	4.7	+
Albaro, Ital 🖗 🍦	SFQC	313	1041	< 0.001	19.7	0
	FOMC	× 900 .	O 828	-	7.4	+
	<b>%DFOP</b>	Ø2.2 Ø	2036	< 0.001	5.8	+
Vilosi, Spain 👌	SFQO	J 144 -	<b>√</b> 478	< 0.001	24.1	0
	FOMC 4	346 .4	2373	-	11.6	+
	<b>ØFOP</b>	<u>35.1</u>	797	< 0.001	10.3	+

Table 7.1.2.2.1- 12:	Estimated field n	natrix deg <b>ra</b>	ation of iso	flucypram for	trigger p	urpose¢
	non-normalised	( <b>bold</b> = best	fit model fo	Dtrigger purpo	99) 🔊	
		×.,	$\otimes$ $\sim$	, ~ *		19

a) SFO: single first order, FOMC: first-order multi-compartment model, DFOP: double first order in parallel

a) SFO: single first order, FOMC: first-order, multi-compar
b) Visual M: + = good, o phoderate - = poor
c) Initian fit including all esidue stata
d) Modified fit excluding parent residue stata for DAT 111



The selection of the most suitable model for trigger purpose is explained below. It should be noted that the given time is not the true experimental time but the transformed time based on the time step normalisation approach.

# **Burscheid**, Germany

The initial simple SFO fit performed statistically relative poor ( $\chi^2$  error of 12.1%). The visual assessment indicates systematic deviations in the residual plot between day 40 until end of study. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 3.2%). The visual assessment of the DFOP fit shows no systematic deviations until end of study (Figure 7.1.2.2.1-1). Residuals are clearly randomly scattered around the zero ine. Determined residue levels at end of study are well predicted by the fitted curve Following the FOGUS decision of tree the matrix degradation of isoflucypram is best described assuming the DFOP model for trigger purpose.





# Great Chishill, United Kingdom

The soil residues of the parent showed at day 111 of the Great Chishill trial a sudden unexpected increase not consistent with the stead parent decay. (Table 10 in the report) DAT 67 71%, DAT 111 80%, DAT 140 40% Parent soil residues at DAOT 111 are excluded for the presented final kinetic evaluations.

The initial simple SFQ fit performed statistically relative poor ( $\chi^2$  error of 12.6%). The visual assessment indicates some systematic deviations in the residual plot in the second phase of the study. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 5.6%). The visual assessment of the DFOP fit shows no systematic deviations until end of study (Figure 7.1.2.2.1-2). Residuals are clearly randomly scattered around the zero line. Determined residue fevels at end of study are well predicted by the fitted curve.





## Figure 7.1.2.2.1- 2: Great Chishill: DFOP kinetics selected for trigger purpose (modified fit)



Following the FOCUS decision tree the matrix degradation of isoffic ypram is best described assuming the DFOP model for trigger purpose. O Ù C 0

Additional DFOP evaluations with the full residue data of Great Chishill (inc). DAT, 111 of parents are Additional DFOP evaluations with the type restrict date of Orea Chight (inc). Dry 111 of parent are presented in the report. These fits did not change the principle outcome of the kinetic evaluation but lead to worsened statistics (e.g.  $\chi^2$  error of 10.9% compared to 5.5%).

# Parcay Meslay, Northern France

The initial simple SFO fit performed statistically relative poor (2 perror of 15.0%). The visual assessment indicates a systematic deviation in the residual plot during the study period. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 2.4%). The visual assessment of the DFOP fit shows no systematic deviations until end of study (Figure 7.1.2.2.1- 3) Residuals are clearly randomly scattered around the zero line. Determined residue levels at end of study are well predicted by the titted surve.

Ô

Following the FOCUS decision free the matrix degradation of isoffacypram is best described assuming the DFOP model for trigger purpos





# St. Etienne du Gres, Southern France

The initial simple SFO fit performed statistically relative poor ( $\chi^2$  error of 8.3%). The visual assessment indicates systematic deviations in the residual plot between day 40 until end of study. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 4.7%). The visual assessment of the DFOP fit shows no systematic deviations until end of study.





Residuals are clearly randoms scattered around the zero line. Determined residue devels at end of Albaro. Italy

assessment indicates a systematic deviation in the residual plot during the study period. The decline of the residues could be significantly better described assuming the piphasic DFOP model ( $\chi^2$  error of 5.8%). The visual assessment of the DFOP fit shows low residual level with no systematic deviations until end of study (Figure 7, 2.2.1-5). Residuals are clearly randomly scattered around the zero line. Determined residue Devels at end of study are well predicted by the fitted curve.

Following the FOCUS decision free the matrix degradation of isoflucypram is best described assuming the DFOP model for trager purpos



## Albaro DFOP Tinetics selected for trigger purpose Figure 7.1.2.2.1- 5:



# Vilobi, Spain

The initial simple SFO fit performed statistically very poor with an  $\chi^2$  error of 24.1%. The visual assessment indicates a systematic deviation in the residual plot during the study period. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of  $\chi^2$  10.3%). The visual assessment of the DFOP fit shows very low residual level with no systematic deviations until end of study (Figure 7.1.2.2.1- 6). Some scatter is visible in the very early residue data points but residuals are overall randomly scattered around the zero line. Determined residue levels at end of study are well predicted by the fitted curve.





## • Degradation of BCS-CN88460-carboxylic acid (M12)

Non-normalised field degradation parameter of metabolite BCS-CN88460-carboxylic acid (M12) are summarised in Table 7.1.2.2.1-13. The best and reasonable model for trigger purpose for the parent was chosen (bold) and the corresponding degradation rates and formation fractions for the metabolite were selected. For metabolite, only a SFO fit is tested.

Site         Kinetic model**         Dis T.s., initial [days]         Dis T.s., initial [days]         Dis T.s., initial (ays]         Sec. k         Formation (freer)         Visual fraction parent=>met           Burscheid, Germany         SFO         91.2         303         <0.001         1%6         0.0034         0           Burscheid, Germany         SFO         91.2         303         <0.001         1%6         0.0034         0           Burscheid, Germany         FOMC         382         1267         0.0010         11.0         0.0354         0           Great Chishill, UK°         SFO         51         169         0.001         13.2         0.1383         0         0           Great Chishill, UK°         SFO         163         541         0.000         13.3         0.0506         0           Great Chishill, UK°         SFO         426         0.001         129         0.1450         0           DFOP         0.128         426         0.000         11.9         0.0628         0           UK°         FOMC         602         2199         0.001         4.8         0.0689         0           Brone         FOMC         623         207         0.001         8.5 </th <th></th> <th></th> <th></th> <th>-</th> <th>(Pr)</th> <th>al .</th> <th></th> <th>N N</th> <th>2</th>				-	(Pr)	al .		N N	2
Induct         [days]         [varent]         [varent] <t< th=""><th>Site</th><th>Kinetic model^{a)}</th><th>DisT50, initial</th><th>DisT90, initial</th><th>artest,</th><th>St.</th><th>Formation</th><th>Visual</th><th>Å</th></t<>	Site	Kinetic model ^{a)}	DisT50, initial	DisT90, initial	artest,	St.	Formation	Visual	Å
Burscheid, Germany         SFO         91.2         303         < 0.001		parent	[uays]	[uays]	Ś ĸ	[%]	parent=>met		, O S
Germany         FOMC         382         1267         0.0017         1.0         0.0354         95           DFOP         389         F291         < 0.0017         10.7         0.0354         95           Great Chishill, UK°)         SFO         51         169         < 0.001         13.2         0.1833         0           Great Chishill, UK°)         SFO         51         169         < 0.005         43.3         0.0506         97           Great Chishill, UK ^{d)} SFO         410         0.005         43.3         0.0506         97           Great Chishill, UK ^{d)} SFO         490         462         9001         129         0.1450         0           Great Chishill, UK ^{d)} SFO         490         466         < 0.007         13.1         96636         0           OFOP         128         426         < 0.001         149         0.2446         0           Parcay Meslay, Northern France         SFO         49.9         166         < 0.001         48.9         0.0688         4           France         DFOP         2182         207         0.001         8.9         0.0648         4           Ibaro, Italy         SFO	Burscheid,	SFO	91.2	303	< 0.001	¥ 1 <b>₹</b> 26	0.0981	0	/
DFOP         389         291         < 0.001         210,7         0.0354         0           Great Chishill, UK°)         SFO         51         169         9.001         132         0.1283         0           Great Chishill, UK°)         FOMC         163         541         0.008         3.3.         0.0506         0           Great Chishill, UK ^{d)} SFO         42         585         < 0.001	Germany	FOMC	382	1267	0.001	_°≫1.0 ~~	Q.0354 K	<b>9</b> 9	
Great Chishill, UK°)       SFO       51       169 $0001$ 132 $0.133$ $0 \circ$ FOMC       163       541 $0.008$ $13.3$ $0.0506$ $07$ Great Chishill, UK°)       SFO       490 $162.5$ $< 0.001$ $13.3$ $0.0476$ $00$ Great Chishill, UK°)       SFO       490 $162.5$ $2001$ $11.8$ $0.0476$ $0$ Great Chishill, UK°)       SFO       490 $162.5$ $4001$ $11.8$ $0.0476$ $0$ Great Chishill, UK°)       SFO       490 $162.5$ $2001$ $13.2$ $0.0476$ $0$ Or       DFOP $128.5$ $416$ $<0.001$ $129$ $0.1450$ $0$ Or $DFOP$ $128.5$ $416$ $<0.001$ $11.9$ $0.0628$ $0$ Parcay Meslay, Northern France       SFO $49.9$ $166$ $2001$ $9.6$ $0.0330$ $0$ St. Etienne du Gres, Southern France       SFO $265$ $288.7$ $0.001$ $8.7$ $0.0648$ $+$ Albaro, Italy		DFOP	389	1291 _Q	< 0,001	لمركز 10.7	<b>\$0.0354</b>	4 0	
UK°         FOMC         163         541         0.008         43.3         0.056 $\sigma$ DFOP         179         595 $< < 0.001$ 11.8 $0.0476$ $\sigma$ Great Chishill, UK ^d SFO         490         162 $20.001$ 129 $0.1450$ $\sigma$ Mode         FOMC         425         416 $< 0.000$ $13.1$ $0.0628$ $\sigma$ Parcay Meslay, Northern France         SFO         49.9         166 $< 0.001$ 129 $0.2446$ $\sigma$ DFOP $0.228$ $0.0628$ $\sigma$ $0.0028$ $\sigma$ $0.0628$ $\sigma$ Northern France         FOMC $696$ $2311$ $0.601$ $9.00$ $4.8$ $0.0689$ $\sigma$ France         DFOP $72$ $239$ $< 0.001$ $8.5$ $0.0648$ $+$ Albaro, Italy         SFO $267$ $282$ $936$ $0.010$ $23.7$ $0.3790$ $\sigma$ OFOME $282$ $936$ $0.010$ $23.9$	Great Chishill,	SFO	51	169	. 001.Q	192	0.1283	o so	
DFOP         179         595         < 6001         11.8         0.0476         60           Great Chishill, UK ^{d)} SFO         490         162         9001         125         0.1450         0           FOMC         125         416         <0.000	UK ^{c)}	FOMC	163	( ³ 541)	0.00	3.3 0	Q.0506	, R	
Great Chishill, UKd)SFO490 $162$ $9001$ $129$ $0.1450$ $o$ FOMC $105$ $416$ $<0.000$ $3.1$ $90636$ $o$ DFOP $128$ $426$ $<0001$ $11.9$ $0.0628$ $o$ Parcay Meslay, Northern FranceSFO $49.9$ $166$ $<0.001$ $149$ $0.246$ $o$ DFOP $2128$ $426$ $<0001$ $149$ $0.246$ $o$ $o$ DFOP $662$ $2199$ $0.004$ $41.7$ $90328$ $o$ DFOP $666$ $2311$ $0.001$ $9.6$ $0.0330$ $o$ St. Etienne du Gres, Southern France $5FO$ $623$ $207$ $0.001$ $8.9$ $0.0689$ $o$ Albaro, Italy $5FO$ $265$ $288.7$ $0.001$ $23.7$ $0.3790$ $o$ DFOP $311$ $1632$ $<0.001$ $23.9$ $0.0422$ $o$ DFOP $311$ $1632$ $<0.001$ $23.9$ $0.0422$ $o$ Vilobi Spain $5FO$ $17.4$ $57.7$ $0.001$ $30.3$ $0.1532$ $o$ DFOP $211$ $702$ $<0.003$ $25.2$ $0.0186$ $+$		DFOP	179 🖉	ر پ <b>59</b> 5 ک	^V < <b>0.0</b> 01	0°11.8°	0.0476	<b>Ö</b> 0	
UKd       FOMC       125       416       < 0.000       13.1       0.0628       o         DFOP       128       426       < 0.001	Great Chishill,	SFO	490	162	<b>\$9</b> .001 0	13,9		0	
DFOP $128$ $426$ $< 0001$ $11.9$ $0.0628$ $o$ Parcay Meslay, Northern FranceSFO $49.9$ $166$ $< 0.001$ $129$ $0.2476$ $o$ FOM6 $662$ $2199$ $0.004$ $11.7$ $90328$ $o$ DFOP $696$ $2311$ $0.001$ $9.0$ $0.0330$ $o$ St. Etienne du Gres, Southern France $3FO$ $622$ $207$ $>0.001$ $8.8$ $0.0689$ $o$ DFOP $72$ $239$ $< 0.001$ $8.7$ $0.0648$ $+$ Albaro, ItalySFO $265$ $928$ $0.010$ $23.7$ $0.3790$ $o$ OFOMC $282$ $928$ $0.010$ $23.9$ $0.0422$ $o$ DFOP $311$ $H322$ $< 0001$ $21.7$ $0.0412$ $o$ Vilobis painSFO $17.4$ $57.7$ $< 0.003$ $25.2$ $0.0186$ $+$ DFOP $211$ $702$ $< 0001$ $24.6$ $0.0176$ $+$	UK ^{d)}	FOMC	£Q25	416	<0.00℃	93.1 Å	@@636~~~	0	
Parcay Meslay, Northern France       SFO $49.9^\circ$ $166$ $<0.001$ $109$ $0.2476$ $o$ FOM6 $662$ $2190$ $0.004$ $11.7$ $0.03328$ $o$ DFOP $696$ $2511$ $0.601$ $9.6$ $0.0330$ $o$ St. Etienne du Gres, Southern France       SFO $623$ $207$ $0.001$ $3.8$ $0.0689$ $o$ More $696$ $2311$ $0.601$ $9.6$ $0.0330$ $o$ St. Etienne du Gres, Southern France       SFO $623$ $207$ $0.0042$ $8.9$ $0.0688$ $+$ Albaro, Italy       SFO $267$ $72$ $239$ $< 0.001$ $23.7$ $0.3790$ $o$ More $282$ $928$ $0.010$ $23.9$ $0.0422$ $o$ Vilobi       Spain $SFO$ $211$ $57.7$ $0.001$ $30.3$ $0.1532$ $o$ Vilobi       Spain $5FO$ $211$ $57.7$ $0.003$ $25.2$ $0.0186$ $+$ $a$		DFOP	ً⊘ 128 ٍ ا	<b>4</b> 26	> < 0,001	0 ⁹ 11.90	~0.0628	0	
Northern France         FOM6         662         2109         0.004         1.7         00328         o           DFOP         696         2311         0.601         9.6         0.0330         o           St. Etienne du Gres, Southern France         SFO         62.3         207         9.001         8.8         0.0689         o           Main         OFOP         72         239         0.042         8.9         0.0648         +           Albaro, Italy         OFO         26.7         9.8         7.7         0.001         23.7         0.3790         o           Vilobit Spain         SFO         17.4         57.7         0.001         30.3         0.1532         o           DEOP         71.4         57.7         0.003         25.2         0.0186         +           OHOP         211         702         0.003         25.2         0.0186         +	Parcay Meslay,	SFO 🐇	49.9	S 166	< 0.001	1909	0.2496	0	
DFOP         696         11         0.601         9.6         0.0330         0           St. Etienne du Gres, Southern France         SFO         62.3         207         9.001         8.8         0.0689         0           Marce         SFO         62.3         207         9.001         8.8         0.0689         0           France         DFOP         72         239         <0.061	Northern France	FOM	662	2199	0.004	~\$1.7 ×	090328	0	
St. Etienne du Gres, Southern France       SFO       62,3       207       90.001       4,8       0.0689       0         Main       Mic       Size       210       0.042       8.9       0.0688       +         Mic       SFO       26,7       239       <0.001       8.7       0.0648       +         Albaro, Italy       SFO       26,7       88.7       <0.001       23.9       0.0422       0         Milobit Spain       SFO       26,7       88.7       <0.001       23.9       0.0422       0         Vilobit Spain       SFO       26,7       88.7       <0.001       21.7       0.0412       0         Vilobit Spain       SFO       17.4       57.7       <0.001       30.3       0.1532       0         DEOP       211       702       <0.003       25.2       0.0186       +		DFÔP	چ 696	<b>2</b> \$11	0.691	9.6	<b>\$0.0330</b>	0	
Gres, Southern $OMC$ $0.2$ $210^\circ$ $0.042$ $8.9$ $0.0688$ $+$ France       DFOP $72$ $239$ $< 0.001$ $8.7$ $0.0648$ $+$ Albaro, Italy $9FO$ $26^\circ$ $0.88.7$ $0.001$ $23.7$ $0.3790$ $o$ Momentary $9EO$ $26^\circ$ $938$ $0.010^\circ$ $23.7$ $0.3790$ $o$ Momentary $928$ $928$ $0.010^\circ$ $23.7$ $0.0422$ $o$ Momentary $980$ $26^\circ$ $938$ $0.010^\circ$ $23.7$ $0.0412$ $o$ Momentary $930^\circ$ $938$ $0.010^\circ$ $23.7$ $0.0412$ $o$ Momentary $930^\circ$ $938^\circ$ $0.010^\circ$ $23.9$ $0.0422$ $o$ Vilobit $9ain$ $83^\circ$ $605^\circ$ $0.003^\circ$ $25.2$ $0.0186$ $+$ DEOP $211^\circ$ $702^\circ$ $2001$ $24.6$ $0.0176$ $+$	St. Etienne du	SFO	S 6223	207	_≷%0.001 Õ	<b>A</b> 8 2	y 0.0689	0	
Prance       DFOP       72       239 $< 0.601$ 8.7       0.0648       +         Albaro, Italy       SFO       267 $88.7$ $< 0.001$ 23.7       0.3790       o         More that the second sec	Gres, Southern	<b><i>CFOMC</i></b>	<b>8</b> .2 ~	210	S 0.042	8.9	0.0688	+	
Albaro, Italy       SFO       26       88.72       0.001       23.7       0.3790       0         FOME       282       928       0.010       23.9       0.0422       0         DFOP       311       1032       <0.001       21.7       0.0412       0         Vilobit Spain       SFO       17.4       57.70       <0.003       25.2       0.0186       +         DFOP       211       702       <0001       24.6       0.0176       +	France	DĘŶP	🔊 72 🕬	<b>23</b> 9 s	< 0.001	8.7	0.0648	+	
OFOME         282         938         0.010         23.9         0.0422         0           DFOP         311         H032         <0.001         21.7         0.0412         0           Vilobit Spain         ØFO         17.4         57.7         <0.001         30.3         0.1532         0           FOME         483         605         0.003         25.2         0.0186         +           DEOP         211         702         <0001         24.6         0.0176         +	Albaro, Italy	SFO	26	6 7 88.7 J	≤,0.001	23.7	0.3790	0	
DFOP         311         H032         < 0.001         21.7         0.0412         o           Vilobit Spain         SFO         17.4         57.70         <0.001		∂FOM&	_م 282 م	938	\$ 0.010	23.9	0.0422	0	
Vilobic Spain         SFO         17.4         57.7         <0.001         30.3         0.1532         o           FOMC         483         605         0.003         25.2         0.0186         +           DEOP         211         702         <0001	<u>`</u>	DFOP	لي 311 €	1932 🔊	< 0.901 ~	21.7	0.0412	0	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Vilobi Spain	、SFO、	5 17.4	\$57,70	<b>₹0</b> .001	30.3	0.1532	0	
0 1000 211 $702 < 0001 24.6 0.0176 +$	<u> </u>	<b>ĢFOM€∕</b> [°]	ي 83 م	D 695	≶ 0.003	25.2	0.0186	+	
		DEOP	211 × ²	<b>∿</b> 702	< 00001	24.6	0.0176	+	

Table 7.1.2.2.1- 13:	Estimated field matrix degradation of the met	abolite BCS-CN	88460-carboxylie
	acid for trigger purpose, non-normalised		, O' , 67

a) SFO: single first order FOMC Pirst-offer multi-compariment model, DFOP: double first order in parallel

- b) Visual fit = good o = møderate \$poor
- Initial fit including all resoure data Modified fit excluding parent resoure data for DAJ c) Initial fit including all residue data
- d)

# Burscheid, Germany

Ś **Burscheid, Germany**  $\mathcal{F}$   $\mathcal{F}$   $\mathcal{F}$  Following the FOCUS decision tree for field degradation of isoflucypram at the Burscheid trial is best described assuming the DFOP model for trigger purpose. The kinetic evaluation of the metabolite BCS-CN88400-carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent and SFO kinetics for metabolite

Metabolite SEO evaluation reads to a statistical and visual acceptable fit. Calculated metabolite  $\chi^2$  error is 10% with an  $\chi^2$  error of 4.4% for the overall fit (parent and metabolite). Visual assessment indicates possible systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-7). The visible scatter in the residual plot is fully randomized and may be caused by the low residue level of the metabolite BCS-CN88460-carboxylic (< 2 g a.s. eq./ha). Determined residue levels at end of study are well predicted by the fitted curve.

Considering the statistical and visual assessment the field degradation of isoflucypram and the



metabolite BCS-CN88460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for trigger purpose.



Following the EFSA decision tree the field degradation of isoflucypam at the Great Chishill trial is best described assuming the DFQP model for preger purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolity fit with DFOP kinetics for parent and SFO kinetics for metabolite. &

Metabolite SFO evaluation leads to a statistical and visual acceptable fit. Calculated metabolite  $\chi^2$  error is 11.8% with an  $\chi^2$  error of 7.9% for the overall fit parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Migure 7.1.2.2.1-8). The visible scatter in the residual plot of fully randomized and may be caused by the low residue level of the metabolite BCS-CN88460-carbox dic (~2.4 g as. eq. ta). Determined residue levels at end of study are well predicted by the fitted curve

Considering the statistical and visual assessment the field degradation of isoflucypram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for trigger phrpose



Great Chishill: SFO fits of BCS CN88460-carboxylic acid Figure 7.1.2.2.1-8:

Additional metabolite evaluations with the full parent residue data of Great Chishill (incl. DAT 111) are presented in the report. These fits did not show any significant impact on the kinetic evaluation of the metabolite but increased the  $\chi^2$  error of the overall fit from 7.9% to 15.1%.



# **Parcay Meslay, Northern France**

Following the FOCUS decision tree the field degradation of isoflucypram at the Parcay Meslay trial is best described assuming the DFOP model for trigger purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent & and SFO kinetics for metabolite.

Metabolite SFO evaluation leads to a statistical and visual acceptable fit Calculated metabolite  $\chi^2$  error is 9.0% with an  $\chi^2$  error of 3.4% for the overall fit (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.12.2.1-3). The visible scatter in the residual plot is fully randomized and may be caused by the low residue level of the metabolite BCS-CN88460-carboxylic (< 1.9 g a.s. Q./ha). Determined residucitevels at end of study are well predicted by the fitted curve.

Considering the statistical and visual assessment the field degradation of soflucy pram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming DFOP SF derive input for trigger purpose.



Following the FOCUS decision tree the field degradation of isofucypram at the St. Etienne du Gres trial is best described assuming the DFOR mode of trigger perpose. The kinetic evaluation of the metabolite BCS-CN88460 carbox fic acc is based on parent and metabolite fit with DFOP kinetics for parent and SFO kinetics for metabolite. Metabolite SFO evaluation kinds to a statistical and visual acceptable fit. Calculated metabolite

 $\chi^2$  error is 8.7% with an  $\chi^2$  for or 5.4% for the overall fit (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-10). The visible scatter in the residual plot is fully randomized. Determined residue levels at end of study are wells predicted by the fitted curve. Maximum residue level of the metabolite BCS-CN88460carboxylic are higher compared to the other trial (< 4.5 g a.s. eq./ha) allowing a more robust fit of the metabolite decline.

Considering the statistical and visual assessment the field degradation of isoflucypram and the metabolite BSS-CN88460 carbox fic acid can be well described assuming a DFOP-SFO model to

derive input for trigger purpose 2







# Albaro, Italy

Following the FOCUS decision tree the field degradation of isoflug pramat the Albaro trial is best described assuming the DFOP model for trigger purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with DECP kinetics for parent and SFO kinetics for metabolite. K,

Metabolite SFO evaluation leads to asstatistical and visual acceptable dit. Calculated metabolite  $\chi^2$  error is 21.7% with an  $\chi^2$  error of  $\Re^2$ % for the overall fill (pareor and metabolice). The relative high metabolite  $\chi^2$  error seems to be caused by some scatter in the metabolite residue data and low metabolite residue levels ( $\leq 3.1$  ) a.s. eq./ha). Thus, the metabolite  $\chi^2$  error does also not improve considering other kinetic model for the parent. The visual assessment indicates no systematic deviation in the residual plot during the study period Orgur 7.1.2.29-11 Determined esidue levels at end of study are well predicted by the fitted curve,

Considering the softistical and osual assessment the field degradation of isoflucypram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for Origge Opurpose. Ľ



, all Hbaro SFO for of BCS -CN88460-carboxylic acid

# Vilobi, Spain

Following the EFSA decision tree the field degradation of isoflucypram at the Vilobi trial is best described assuming the DFOP model for trigger purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent and SFO kinetics for metabolite.

Metabolite SFO evaluation leads to a statistical and visual relative poor fit. Calculated metabolite



 $\chi^2$  error is 24.6% with an  $\chi^2$  error of 14.1% for the overall fit (parent and metabolite). The relative high metabolite  $\chi^2$  error seems to be caused by large scatter in the metabolite residue data and very low metabolite residue levels (< 1.2 g a.s. eq./ha). Thus, the metabolite  $\chi^2$  error does also not improve considering other kinetic model for the parent. The visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-12). Considering the statistical and visual assessment is somewhat questionable if the field degradation of the metabolite BCS-CN88460-carboxylic acid can be sufficiently reliable described to derive a metabolite DT₅₀ for trigger purpose. The resulting DT₅₀ may be still accepted as it lays rearly within

the range of the other trials. As the overall metabolite residue level is acceptable described by the fitted curve, the resulting metabolite formation fraction can be selected as reliable trigger input.



After the kinetic evaluation of field dissipation trials using simple first-order (SFO) and bi-phasic models in comparison, the best description of isoflucy fram could be given using an DFOP fit for 6 European trials (Table 7.1.2.2.1-32). The overall field degradation parameter for trigger purposes are summarised in Table 74.2.2 18 for the parent isoflue pram and in Table 7.1.2.2.1-9 for the metabolite BCS-CN88260-carboxylic acid





# Kinetic evaluations for modelling endpoints

The dissipation of isoflucypram in agricultural soils under natural field conditions was investigated in several trials in Europe. Based on these trials, a kinetic evaluation was performed to estimate normalised (20°C, pF 2) dissipation times (DT₅₀) for use in model simulations of environmental  $\sim$ exposures (modelling endpoints) for isoflucypram and its major metabolites BCS-CM88460⁴⁰ carboxylic acid (M12).

Report:	KCA 7.1.2.2.1/03;	, G.;	, B.; 2017; 🕰	-608370-01-10	
Title:	Isoflucypram (ISY)	) and metabolite - Kir	etic evaluation of	the degradation in	rsoil
	under field condition	ons for modelling pur	pose 🖉		×{
Report No.:	EnSa-17-0533	× ۱	Å.		
Document No .:	M-608370-01-1	.Ô ^Y	A		
Guideline(s):	not applicable	A	Q B°	A A	
Guideline deviation(s):	none		$\sim 0^{\circ}$	°¥ ∖0` ¢	, Q'
GLP/GEP:	no				<i>S</i> [*]
		O O X	ĭ Å "m	S.	4
			10° 'N	"O ~ ~	

# **Executive Summary**

Normalised (20°C, 100% field capacity) degradation DT₅₀ matrix-values of isoflucyprim and its metabolite BCS-CN88460-carboxylic acid (MJ2) in the soil matrix under European field conditions (**EXAMPLE**; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; 2017; studies (EFSA 2014³). Processes potentially occurring at the soil surface during the field study, e.g. photo-degradation and volatilisation should be stiminated to resul finally in a DegT_{50 matrix} representing the degradation in the soil. This was considered following the EFSA framework for evaluation of existing field studies not tailored for Deg T matrix (EFSA 2014, Section 2.3.2).

In the experimental field studies, the active substance has been applied only bare soil at a nominal rate of 100 g/ha isoflucypram in spring (April to June) 2014. Throughout the study period of approximately 2 years irrigation activities were carried out. Ô

Simulated (with PEARL) daily soil temperatures and moisture contents were used to normalise the evaluated parameters to reference conditions according to CUS groundwater assumptions (Arrhenius equation,  $Q_{10} = 2.58$ ; Walker equation, pF2) (FOCDS^{4.5}). The residue data together with the transformed involution times (transformed time approach, time step normalisation) were kinetically and statistically evaluated, based on the proceedure explained by FOCUS kinetics, using the software fool KinGUI 29. ~  $\bigcirc$ 

In the attempt to separate soil surface degradation processes, such as photo-degradation and volatilisation, from Bulk soil degradation, an important threshold for a kinetic evaluation might be the time point, when the sum of precipitation and irrigation equals or exceeds 10 mm (EFSA 2014,  $0^{*}$ Section 2.3.2) Õ Ô

Following the EFSA decision tree on field dissipation studies (EFSA 2014), an appropriate description of soil mathix degradation of isoflucypram could be derived using a DFOP model fit for 5 trials and HS model fit for one trial (Table 7.1.2.2.1.4.4). The corresponding  $DT_{50}$  and formation fractions (f.f.)

Ø

n

¹ FOCUS, 2006: Guidance Dominant of Estimating Peopstence and Degradation Kinetics from Environmental Fate Studies on Pesticides in FJJ Registration. Report of the Work Group on Degradation Kinetics. EC Document Reference SANCO/100582005 version 2.02434 pp

² FOCUS, 2010: Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version, 1.1.

³ EFSA, 2014: EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plast protection products and transformation products of these active substances in soil. 23.7.2014. EFSA Journ 2014; (2):362. www.efsa.europa.eu/efsajournal. European Food Safety Authority EFSA, Parma, Italy

⁴ FOCUS 2014: Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU: The Final Report of the Ground Water Work Group of FOCUS: EC Document Reference: Sanco/13144/2010 version 3, 613 pp.

⁵ FOCUS, 2014: Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2



for the metabolite BCS-CN88460-carboxylic acid (M12) are summarised in Table 7.1.2.2.1-15.

The overall geometric mean DT_{50 matrix} of isoflucypram, for modelling purposes according to FOGUS kinetics and EFSA (2014) based on these 6 values, can be given with 335 days and for the metabolite with 153 days (normalised to 20°C, 100% field capacity). The arithmetic mean formation fraction of the metabolite BCS-CN88460-carboxylic acid in soil under field conditions is 0.043. Ô

Table 7.1.2.2.1- 14:	Isoflucypram:	L.	
	Field matrix degradation endpoints for modellin	ng purpose;	
	normalised to 20°C, 100% field capacity, $Q_{10} = 2$	2,58; European	i field sites

			C			
Location, country	Soil type ^{a)}	pН	Depth ^{b)}	DT50 matrix	St.	Methodof
		(CaCl ₂ )	- [cm]	nowm ^{c)}	$(\chi^2 err)$	<b>Acalculation</b> ^{d)}
			0°	{{days]@*	[%]	
Burscheid, Germany	silt loam,	5.8	60	284	3.1	DFOP slowphase
	bare soil	Ŏ	, O ×			
Great Chishill,	clay loam,	<u> </u>	» 60 °	Q489 O*	6.1	DFOP stow phase
United Kingdom	bare soil	$\tilde{\omega}$		s A		
Parcay Meslay,	loam,	52Q, ⁹	Ø0 .	ζ 4 <b>49</b>	7 2.7.	DF@P slowphase
Northern France	bare soil Q	u S			Ű	
St. Etienne du Gres,	clay loam,	7.5 ×	[≫] 60√ [∞]	~137~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<b>3</b> .7	HS slow phase
Southern France	bare soil $Q^{\vee}$		ð	Å O	ÔÔ	
Albaro di Ronco all	clay, 🖉 📣	7.0	\$60	~ <b>64</b> 9 (	5,20	DFOP slow phase
Adige, Italy	bare sô		O L	a to.	O*	Ő -
Vilobi d'Onyar, Spain	loam, 🔍	گ 5.8 €	60	أ≪258 أ	s 90.3	DFOP slow phase
	bar@soil 🔘		.ſ			-
Geometric mean:		Ĩ,		v ₍₄ 335 ×		
pH dependence	no 🖓 📣			O ^V ^K	۶. ۲	
a) according to USDA		0.5		0	$\sim$	





Table 7.1.2.2.1- 15:	BCS-CN88460-carboxylic acid (M12):	
	Field matrix degradation endpoints for modelling purpose;	
	normalised to 20°C, 100% field capacity, $O_{10} = 2.58$ ; European field sites	<i>.</i>

							e co
Location, country	Soil type ^{a)}	pH (CaCl ₂ )	Depth ^{b)} [cm]	DT _{50 matrix} norm ^{c)} [days]	St. (χ ² err) [%]	Formation fraction 	Method of calculation ^{d)}
Burscheid, Germany	silt loam , bare soil	5.3	60	172	4.3	0.0386	SFO
Great Chishill, United Kingdom	clay loam, bare soil	7.0	60	67.3	13,8	0.0563	SFO C
Parcay Meslay, Northern France	loam, bare soil	5.9	ر هو هو	340	8.9	0.0345	SFO O
St. Etienne du Gres, Southern France	clay loam, bare soil	7.5		82.4		Q.0651	SFO A
Albaro di Ronco all Adige, Italy	clay, bare soil	7.0		° 228	×23.1		ץ SKØ ג ₀
Vilobi d'Onyar, Spain	loam, bare soil	5.8	68 68 68	©172 Q	23.9		SFO SFO
Geometric mean:		Ĩ,	, °~ _ C	<u>1</u> 53	Ő z?		
Arithmetic mean:		R &	y õ			Ø.043	à-
pH dependence	no	5 0°			ð.	õ, Š	, L

a) according to USDA

a) according to USDA
b) Experimental soil sampling depth opnsidered to derive total residues for kinetic evaluation 

c) Normalised using a  $Q_{10}$  of 2.58 and Walker equation coefficient of  $\theta_{10}$ 

d) SFO: single first order

The behaviour of isoflacypran and its metabolic BCS-CN88460-carboxylic acid (M12) was investigated in externestrial field soil dissipation study designed to determine the dissipation under representative European fiel@conditions ( ; 2017; M-595964-01-1)). The • study included trials at six sites at six geographic locations in Getmany, the UK, France, Italy and Spain (Table 7.1.2.2.1- 19). Each test site received a single application at a nominal application rate of the active substance of 100 goin spring. However, the actual amount of isoflucypram applied was 88.1 to 98.2 g/ha (Table  $\int \mathbb{P}.2.2 \int \mathbb{P} (17)$  Application was made on base soil. The evaluation is conducted to derive kinetic parameters suitable for modelling purpose according to

FOCUS kinetics (FOCOS 2006, 2014) and FFSA guidance on field dissipation studies (EFSA 2014). It includes a fime-step normalisation to standard reference conditions for soil temperature (20°C,  $Q_{10}$  of 2.58) and soil moisture (field capacity, pp2), as well as a quality check of the results. Processes potentially occurring at the soil surface, e.g. photo-degradation and volatilisation, during the field study should be eliminated to result finally in a DE% representing the degradation in the soil.

The kinetic analysis was performed seconding to FOCUS kinetics (2014) using the software KinOUI 2.1 with four different kinetic models: Single First-Order (SFO) and the bi-exponential models FOMC First-Order Multi-Compartment model), DFOP (double first order parallel) and HS (Hockey-stick)?

(Hockey-stick)? A seather data daily soil moisture and temperature were calculated using a data of a local soil and weather data daily soil moisture and temperature were calculated using a simulation model. The effect of soil moisture and temperature on degradation was included into the evaluation according to FOCUS (2014) using a reference temperature of 20°C and a soil moisture of 100% (field capacity (FC), *

The kinetic evaluation followed the recent guidance of EFSA (2014) on derivation of so-called  $\text{Deg}^{T}_{50,t}$  for use in exposure modelling.

In case a bi-phasic model was selected only the slow phase degradation was considered which leads to conservative kinetic endpoints.



Site	Trial no.	Latitude ^{a)}	Longitude ^{a)}	Elevation _。
Burscheid, Germany	14-2750-01	51°04.110'N	07°05.690'E	205 m
Great Chishill, UK	14-2750-02	52°03'17.07"N	0°08'33.78"E	146 คล
Parcay Meslay, Northern France	14-2750-03	47°27'47.0''N	0°45'11%;"E	1197m
St. Etienne du Gres, Southern France	14-2750-04	43°48'20.0''N	4°43'12.0''E	41 m 🔊
Albaro di Ronco Aldige, Italy	14-2750-05	45°34'50.35"N	11°18'97.9" E	23 m y
Vilobi d'Onyar, Spain	14-2750-06	41°52`53.43"N	2°44, 52,39" E	0 139m /
a) by Google Earth		Ĉa	L I	

Table 7 1 2 2 1- 16.	Geographical data	of the field	dissination	trials
1 abic /.1.2.2.1-10.	Geographical uata	of the neiu	uissipation	u lais

Table 7.1.2.2.1- 17:	Application rates of	isoflucypramin	field dissipation trials
----------------------	----------------------	----------------	--------------------------

1	14-2750-06	41°52`53.43"1	N 2° <b>4</b> 4,52	2,39" E	<b>○</b> " 139 m	
Application	rates of isofluevor	artin field dissi	a gion trials			
Application	ates of isofiucypi					, ev
Site		Actual A	application	ate o	/ ```` (	2 V
	~~				10° ~ C	ĩ
Burscheid, Geri	nany 🔬	Ø S	×98.2 ×	P	$\sim 10^{-1}$	
Great Chishill,	uk O 🧹		¥96.&Ø	R R	A.	0
Parcay Meslay	, Northern France	, d' Q	88.1	" Oʻ		2
St. Etienne du C	Gres, Southern Fran	ice 🗡 🏠	2 <del>0</del> ,9 0	, 		<i>9</i>
Albaro di Ronc	o Aldage, Italy	0 .4	90.1 N	Š	L L	
Vilobi d'Onyar	, Span 🖉		88.20	é é		
Â						

# Q1. RESULPŠ AND DISCUSSION

Normalised (20°C, 100% field apacity) degradation  $DT_{50}$  matrix values of isoflucypram and its metabolite BCS-CN88460 carboxylic and (M22) in the soil matrix under European field conditions were derived for modelling purpose according to FOCUS Innetice (FOCUS 2000) 2014) and the EFSA guidance on field dissipation studies (EFSA 2014). Processes potentially occurring at the soil surface, e.g. photo-degradation, volatilisation, during the field study should be eliminated to result finally in a DT50 matrix representing the degradation in the soil matrix or bulk.

Simulated (with PEARL) daily soil temperatures and moisture contents were used to normalise the evaluated parameters to reference conditions according to FOOUS groundwater assumptions (Arrhenius equation,  $Q_{10} = 2.58$ ; Walker equation, pF2). The residue data together with the transformed times (transformed time approach stime step pormalisation) were kinetically and statistically evaluated based on the procedure explained by FQCUS kinetics, using KinGUI 2.1.

In the attempt to separate soft surface degradation processes, such as photo-degradation and volatilisation, from bulk soil degradation, an important threshold to start a kinetic evaluation might be the time, when at least 10 mm precipitation (+ in gation have been fallen (EFSA 2014). Then, it is assumed that the active substance is sufficiently deep washed into the soil matrix.

# Degradation of icoflucypram

According to the EPSA decision free (EFSA 2014), the kinetic evaluation was started by assuming a simple first-order (SFO) dissipation for the parent compound in soil, excluding the first sample points, until the 10 mm rain criterio chas been reached (Table 7.1.2.2.1-18).

Further on, the bi-phasic models DFOP (double first order in parallel) and HS (hockey stick) were checked with the whole data for the field matrix degradation of isoflucypram in all soils, besides following the decision tree of FSA (2014) (Table 7.1.2.2.1-18).

Some main parameters fitted, as degradation rates k, DT_{50 matrix}, switch parameters g or t_b and some statistical parameters are summarised in Table 7.1.2.2.1-18. Finally selected values to be considered as modelling input are given in bold.

The  $D_{50}^{\text{matrix}}$  values are reported to be used for environmental fate modelling purposes. Therefore, where needed, recalculated DT₅₀ are mentioned as follows: for DFOP and HS, DT_{50 2nd phase} of slow phase.



Site	Kinetic	<b>k</b> _{fast}	k _{slow}	t-test,	t _b	$\mathbf{g}_{\text{fast}} =$	DT ₅₀	St.	Msual	Ŝ
	model ^{a)}	[1/d]	[1/d]	kfast / kslow	[d]	Ffield	matrix	(χ²err)s	fit ^{b)}	, ,
							≫[d]	[%]		
Burscheid,	SFO	-	0.004847	< 0.001	-	- /	143	10.25	, P	
Germany	DFOP	0.04892	0.002471	< 0.001 / < 0.001	-	0.3709	281	<b>3%.12</b> ≈	×+ 0	)
	HS	0.01259	0.002708	< 0.001 / < 0.001	40.17	s s	256 ^م	× 3.33	+~~	
Great	SFO	-	0.006008	<2e-16	-	<i>Q</i> -	1150	1.0.06	, Co	L
Chishill,	DFOP	0.01492	0.001417	0.0058 / 0.2186	- "(	0.6276	489	6.10	Ş ⁷ + ₆	Ś,
UK	HS	0.00842	0.002813	< 0.001 / 0.001	94.3Q	-0	£246 _£	5.43C	ഀഀ	
Parcay	SFO	-	0.002949	<	$\sim$	<u> </u>	° 2350°	10226	<u></u>	
Meslay,	DFOP	0.03813	0.001545	< 0,001/ < 0,001	S- ×	0.4128	449	∞2.74 ⊭	+	
Northern France	HS	0.01370	0.001834	< 9.001/ 0.001	38.5	8 ⁰	Ø <b>3</b> 78	, 3.13	+ 。	
St. Etienne	SFO	-	0.048852 🐋	~~ <u>~</u> ~ <u>~</u> ~ <u>~</u> ~ <u>~</u> ~~ <u>~</u> ~~~~~~~~~~~~~~~~	~ <del>~</del>	A - S	14.2	1510		
du Gres,	DFOP	0.06241	0.00131	<i>≲</i> %001/02342 、	<b>√</b> - Ó	0.9134	\$26	<b>∜</b> 3.89 ≜	+	
Southern France	HS	0.05392	0.005658	≪0.001¢0.036€	39,4		§ 137 Ĉ	3.68	+	
Albaro,	SFO	-	0.003383	€ 0.001	\$ ⁻	0 0.	265	\$15.59	0	
Italy	DFOP	0.02233	Ø.001068	< 0.001/ 0.019	e - Q	0.5324	<b>≈</b> 849 %	5.88	+	
	HS	0.00798	0.001134	S 0.001 / 0.004	1001.3	· ?- 0	611 0	4.97	+	
Vilobi,	SFO	, Ø	0.0005510	r _@0.001	<u> </u>	Ş - Z	128	23.84	0	
Spain	DFOP	0.14200	<b>40.002691</b>	<0.001/00.001	S -6	0.5315	258	10.28	+	
	HS	0,06729	0.003093	<0.001 0.001	10064	×- `	> 224	8.69	+	
DT _{50 matrix} hal a) SFO: single b) Visual fit:	f-lives for particular for the first order, $+ = go(\theta, 0)$	delling: DF DFOD dout = moderate,	OP SS: Dag De first order i → po@r	of slow phase S in parallel, HS Hocke	estick					

Table 7.1.2.2.1- 18:	Estimated field matrix degradation of isoflucypram for modelling purpose,
	normalised to 20°C, 100% field capacity

a) SFO: single first order, DFOD double first order in parallel, HS Hocke stick b) Visual fit: + = good, o = anderate, = poor The selection of the most suitable model for modelling purpose is explained below. It should be noted





# **Burscheid**, Germany

The initial simple SFO fit performed statistically relative poor ( $\chi^2$  error of 10.3%). The visual assessment indicates systematic deviations in the residual plot between day 40 until end of study. The decline of the residues could be significantly better described assuming the biphasic DFOP model  $(\chi^2 \text{ error of 3.1\%})$ . The visual assessment of the DFOP fit shows no systematic deviations untipled of study (Figure 7.1.2.2.1-13). The bi-phasic HS model could not improve the overall fit. Following the EFSA decision tree the matrix degradation of isoflucypram is best described assuming, the model for modelling purpose.





# Great Chishill, United Kingdom

The soil residues of the parent showed at day HI of the Great Chishill trial a sudden unexpected increase not consistent with the steady parent deeay (DAT-67, 71%, DAT-111: 80%, DAT-140: 40%). Parent soil residues at DAT-11 are excluded for the presented kinetic examinations.

The initial simple SIO fit performed statistically relative peor ( $\chi^{24}$  error of 10.1%). The visual assessment indicates some systematic deviations in the residual plot in the second phase of the study. The decline of the residues could be significantly better described assuming the biphasic DFOP model  $(\chi^2 \operatorname{error} 6.1\%)$ . The visual essessment of the DEOP fit shows no systematic deviations until end of study (Figure 7.1.2.2, 9-14), The bi-phasic HS model could not improve the overall fit especially considering the observed scatter in the residue data.

Following the EESA decision the the matrix degradation of isoflucypram is best described assuming the DFOP model for modelling purpose



## Great Conshill, DFOP, Mnetics selected for modelling purpose Figure 7.1.2.2.1-14:



# Parcay Meslay, Northern France

The initial simple SFO fit performed statistically relative poor ( $\chi^2$  error of 10.3%). The visual assessment indicates a systematic deviation in the residual plot during the study period. The decline of the residues could be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 2.7%). The visual assessment of the DFOP fit shows no systematic deviations until end of study (Figure 7.1.2.2.1-15). The bi-phasic HS model could not improve the overall fit.





St. Etienne du Gres, Southern France The initial simple SFO fit performed statistically relative poor ( $\chi^2$  error of 13.1%). The visual assessment indicate systematic deviations in the residual plot between day 40 until end of study. The decline of the restrices ould be significantly better described assuming the biphasic DFOP model ( $\chi^2$  error of 3.9%). The visual assessment of the DFOP fit shows no systematic deviations until end of study. The bi-phasic DS model resulted also to a good description of the residue decline with a slightly lower  $\chi^2$  error of 3.7%. The visual assessment of the DFOP fit is also slightly better compared to DFOP with an overall lower restricted and no systematic deviations until end of study (Figure 1.2.2.1-16)





It should be noted that residue levels at end of study are at St. Etienne du Gres clearly below 10% of initial amounts (ca. 3.3%). Thus, the use of the DFOP model should be considered with care especially extrapolating outside the experimental time period. In this situation the HS may be more suitable for modelling purpose. Furthermore the  $g_{fast}$  value of 0.91 resulting from the DFOP fit is outside the EFSA



validity range (> 75). Based on the EFSA framework for evaluation of existing field studies not tailored for DegT_{50 matrix} (EFSA 2014) the HS model is under this circumstance to be chosen to derive modelling input.

Following the EFSA decision tree the matrix degradation of isoflucypram is best described assuming the HS model for modelling purpose.

# Albaro, Italy

The initial simple SFO fit performed statistically poor, with an  $\chi^2$  error of 15.6%. The visual assessment indicates a systematic deviation in the residuar plot during the study period. The decline of the residues could be significantly better described assuming the burnaries DFOR model ( $\chi^2$  error of 5.9%). The visual assessment of the DFOP fit shows low residuablevel with no systematic deviations until end of study (Figure 7.1.2.2.1-17). The bi-phasic HS model could not improve the overall fit significantly.

best described assuming Following the EFSA decision tree the matrix degradation of soflucypram's the DFOP model for modelling purpose.





Vilobi, Spain

The initial simple SFO fur performed statistically very poor with an  $\chi^2$  error of 23.8%. The visual assessment indicates a systemate deviation in the residual plot during the study period. The decline of the residues could be again fightly better described assuming the biphasic DFOP model ( $\chi^2$  error of 10.3%). The stsual assessment of the DFOP fit shows very low residual level with no systematic deviations until end of story (Forure 7, 2.2.1, 18). Some scatter is visible in the very early residue data points. The bi-phasic HS model wild not improve the overall fit significantly.

Following the EFSA decision tree the matrix degradation of isoflucypram is best described assuming





### Figure 7.1.2.2.1-18: Vilobi: DFOP kinetics selected for modelling purpose



• Degradation of BCS-CN88460-carboxylic acid (M12) Normalised (20°C, 100% field capacity) degradation  $DT_{50}$  means values of metabolite BCS-CN88460-carboxylic acid (M12) are summarised in Table 7, 2.2.1, 19. The best and peasonable model for modelling nurpose for the parent year obtain (1994) and the second sec modelling purpose for the parent was chosen (bold) and the porresponding degradation rates and formation fractions for the metabolite were selected. For metabolite, only a SBO kiperic is tested. Details of the metabolite fits are discussed further below. It should be noted that the given time is not the true experimental time but the transformed time based on the type step normalisation approach. Only low residue level of the metabolite BCS-CN88460-carboxylic acid were found in the field trials (<4.5 g a.s. eq/ha) indicating a generally low metabolite formation under outdoor field conditions.





							0
Kinetic model ^{a)} parent	k [1/d]	t-test, k	DT _{50 matrix} [d]	St. (χ ² err) [%]	Formation fraction parept=>met	Visual fit ^{by}	
SFO	0.00827	< 0.001	83.8	15.92	0.0568	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ç)
DFOP	0.00404	< 0.001	172	4.27	0.0386	\$° 0 ₂ \$	r D
HS	0.00428	< 0.001	162	4.56 🐇	0.0405	re g	
SFO	0.02097	< 0.001	335,1	14.6	0.0102	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ô, Ô
DFOP	0.01031	< 0.001	<b>£67.3</b>	1.3.82	0.0563	0 \$	Ú.
HS	0.01050	< 0.001	<b>66.0</b>	Q1.47 °	0,0569	Ô	<u> </u>
SFO	0.00844	0.001	82.2	13.58	90.096°	jõg o	Ç,
DFOP	0.00204	0.004	ري ³ 40	8.89 🔬	0.0345 >	y 0 W	
HS	0.00217	< 0.001	319	8.08	000355 L	Â	L°
SFO	0.00958	\$0.001°	A724.3	10408	0.0 <u>68</u> 8	¢o ¢	D"
DFOP	0.00834	0.00J	@83.1, ~	ð 23 ý	0,0645	0,5	
HS	0.00841	< 9,001	82:4	<b>10.99</b>	<b>9</b> .0651	_©0	
SFO	0.01 <i>5</i> ®3	0.00169	₹43.8	263	0.1634	y o	
DFOP	0.00304	♥ < 0.001	\$ 228 V	<b>23.12</b> O	<b>9</b> 9430 🗶	0	
HS	0,00330	\$9,001 €	210	22.94	© 0.0459	0	
SFO	0.01 2	\$0.0204	45.5	27982	9 0.0566	0	
DFOP	0.00403	< 0.001	Ø ^Y 172 S	🔬 23.94 🖑	0,9183	-	
HS	@:00404	< 0.001	172	0 22.62	0.0182	-	
	Kinetic model ^{a)} parent SFO DFOP HS SFO DFOP HS SFO DFOP HS SFO DFOP HS SFO DFOP HS	Kinetic model ^a ) parent         k [1/d]           SFO         0.00827           DFOP         0.00404           HS         0.00428           SFO         0.02097           DFOP         0.01031           HS         0.01050           SFO         0.00844           DFOP         0.00204           HS         0.00217           SFO         0.00958           DFOP         0.00834           HS         0.00958           DFOP         0.0150           SFO         0.0152           DFOP         0.00330           SFO         0.01522           DFOP         0.00403           HS         0.001522           DFOP         0.00404	Kinetic model ^a ) parent         k [1/d]         t-test, k           SFO         0.00827         < 0.001	Kinetic model ^a ) parent         k [1/d]         t-test, k         DT _{50 matrix} [d]           SFO         0.00827         < 0.001	Kinetic modela) parentk [1/d]t-test, kDT $_{50 matrix}$ [d]St. ( $\chi^2$ err) [ $\%$ ]SFO0.00827< 0.001	Kinetic model ^{a)} parent         k [1/d]         t-test, k         DT _{50 matrix} [d]         St. (\chi_err) [\%]         Formation fraction parent=>met           SFO         0.00827         < 0.001	Kinetic model ^{a)} parent         k         t-test, k         DT _{50 matrix} [d]         St. (χ ² err) [%]         Formation fraction parent=>met         Visual fit ^b SFO         0.00827         < 0.001

Table 7.1.2.2.1- 19:	Estimated field matrix degradation of the metabolite BCS-CN88460-carboxylic
	acid for modelling purpose, normalised to 20°C, 100% field capacity

a) SFO: single first order, DFOP: double first order in parallel OHS: Hockey stick

b) Visual fit: + 2000, 7 moderate, - = poor

# Burscheid, Germany

Following the EFSA decision the the matrix degradation of isoftwypram at the Burscheid trial is best described assuming the DFOP model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent

and SFO kinetics for metabolite  $\chi^2$  error is 102% with an  $\chi^2$  error of 4.3% for the overall fit (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-19). The visible scatter in the residual plous fully randomized and may be caused by the low residue level of the metabolite BC\$ CN88460-carboxylic acid ( 2 g a.s. eq/ha).

Considering the statistical and visual essessment the matrix degradation of isoflucypram and the

Considering the statistical and wisual assessment the matrix degradation of isoflucypram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for modelling purpose.



# Figure 7.1.2.2.1-19: Burscheid: SFO fits of BCS-CN88460-carboxylic acid



## Great Chishill, United Kingdom

Following the EFSA decision tree the matrix degradation of isoflucypham active Great Chishill total is best described assuming the DFOP model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite of with DFOP kinetics for parent and SFO kinetics for metabolite.

Metabolite SFO evaluation leads to a statistical and visual acceptable fit. Calculated metabolite  $\chi^2$  error is 14.6% with an  $\chi^2$  error of 15.5% for the overall of (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-20). The visible scatter in the residual plot is fully randomized and may be caused by the low residue level of the metabolite BCS CN88460-carboxylic acid. 2.4 g a.s. eq/ha).

Considering the statistical and visual assessment the matrix degradation of soflucypram and the metabolite BCS-CN\$8460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for modelling purpose

## Residuals vs. Time BCSCY26497 **1** 2.5 Measured & Predicted Residues 2.0 0 0 0.2 0.2 0 -0.4 -0.6 -0.8 0 50 100 150 200 250 300 350 400 Time Parcay Meslay, Northern France

Figure 7.1.2.2. 20: Great Chishill: SFO fits of BCS-CN8846 carboxylic acid

Following the EFSA decision aree the matrix degradation of isoflucypram at the Parcay Meslay trial is best described assuming the DFOP model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460 carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent and SFO kinetics for metabolite.

Metabolite SFO evaluation leads to a statistical and visual acceptable fit. Calculated metabolite  $\chi^2$  error is 8.9% with an  $\chi^2$  error of 3.8% for the overall fit (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1- 21).



The visible scatter in the residual plot is fully randomized and may be caused by the low residue level of the metabolite BCS-CN88460-carboxylic acid (< 1.9 g a.s. eq/ha).

Considering the statistical and visual assessment the matrix degradation of isoflucypram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming a DFOP-SFO model to derive input for modelling purpose.





# St. Etienne du Gres, Southern France

Following the EFSA decision tree the matrix degradation of isoflucypram, at the St. Etienne du Gres trial is best described assuming the HS model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with HS kinetics for parent and SFO kinetics for metabolite.

Metabolite SFO expluation leads to a statistical and visual acceptable fit. Calculated metabolite  $\chi^2$  error is 11.0% with an  $\chi^2$  error of 5.1% for the overall fit (parent and metabolite). Visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-22). The visible scatter in the residual plot is fully randomized. Maximum residue level of the metabolite BCS-CN88460-carboxylic acid are higher compared to the other trial (< 4.5 g a.s. eq/ha) allowing a more robust fit of the metabolite decline.

Considering the statistical and visual assessment the matrix degradation of isoflucypram and the metabolite BCS-CN88460 carbox fic acid can be well described assuming a HS-SFO model to derive input for modelling purpose. ð



Ő SFØ fits St. @tienne Figure 7.1.2.2. - 22: of BCS-CN88460-carboxylic acid



# Albaro, Italy

Following the EFSA decision tree the matrix degradation of isoflucypram at the Albaro trial is best described assuming the DFOP model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460-carboxylic acid is based on parent and metabolite fit with DFOP kinetics for parent & and SFO kinetics for metabolite.

Metabolite SFO evaluation leads to a statistical and visual acceptable fit Calculated metabolite  $\chi^2$  error is 23.1% with an  $\chi^2$  error of 8.3% for the overall fit (parent and metabolite). The relative high metabolite  $\chi^2$  error seems to be caused by some scatter in the metabolite residue data and low? metabolite residue levels (< 3.1 g a.s. eq/ha). Thus, the metabolite  $\chi^2$  error does also not improve considering other kinetic model for the parent. The visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7. 1.2.2.1-23).

Considering the statistical and visual assessment the matrix degradation of pollucypram and the metabolite BCS-CN88460-carboxylic acid can be well described assuming & DFOP-SFQ model to derive input for modelling purpose.



# Vilobi, Spain

Following the EFSA decision free the matrix degradation of is Rucypram at the Vilobi trial is best described assuming the DFQP model for modelling purpose. The kinetic evaluation of the metabolite BCS-CN88460-car@xylic acid is based on patent and metabolite fit with DFOP kinetics for parent and SFO kinetics for metabolite ×, *Li

Metabolite SFQ evaluation leads to a statistical and visital relative poor fit. Calculated metabolite  $\chi^2$  error is 23.9% with an  $\chi^2_{\text{error}}$  of 14.1% for the overall fit (parent and metabolite). The relative high metabolite  $\chi^2$  error seems to be caused by large scatter in the metabolite residue data and very low metabolite residue levels (<  $\frac{1}{\sqrt{2}}$  g a. eq/ba). Thus, the metabolite  $\chi^2$  error does also not improve considering other kinetic model for the parent. The visual assessment indicates no systematic deviation in the residual plot during the study period (Figure 7.1.2.2.1-24).

Considering the statistical and usual assessment is somewhat questionable if the matrix degradation of the metabolity BCS-CN88460-carboxylic acid can be sufficiently reliable described to derive a metabolite D50 for modeling purpose. The resulting DT₅₀ may be still accepted as it lays clearly within the tange of the other trids. As the overall metabolite residue level is acceptable described by the fitted curve the resulting metabolite formation fraction can be selected as modelling input.



### Figure 7.1.2.2.1- 24: Vilobi: SFO fits of BCS-CN88460-carboxylic acid



# Formation of the metabolite BCS-CN88460-carboxylicacid in soil under field conditions

The metabolite formation fraction (f.f.) or formation rate (k) is an import modelling input factor. According to FOCUS kinetic the acceptability of the ditted formation fraction can be exeluated based on the robustness of the overall fit. The fitted formation fraction may be also compare to the observed maximum metabolite residue level and the computed standard deviation (STD).

Table 7.1.2.2.1- 20 summarises the formation data of BGS-CNS8460-Carbox dic acid. All given formation fractions are statistically reliable and can be used for modelling purpose.

Depending on the FOCUS exposure mode the metabolite formation fraction (f.f.) is directly used as model input (e.g. PEARL), Alternatively the corresponding metabolite formation rate (k_f) from the precursor to the metabolite may be employed as model input (e.g. PELMO). Both ways are identical as the two parameter are directly interlinked based on the equation  $k_f = f_s k_{dp} k_{dp}$  (with being the modelling degradation rate constant of the precursor). 0

The arithmetic mean formation fraction of the metabolite BCS-CN88460-carboxylic acid in soil under field conditions is 0.043 (Table 7.1.2.2.1 - 20A

Field matrix degradation endpoints for modeling purpose;										
avrmatised to 20°C, 100% field capacity, Q@= 2.58; European field sites										
Location, country	Soil type	Parent kap D/d]	Max. met. residue level gg a.s. eq/ha]	Met k _f [1/d]	f. f. k _f / k _{dp}	STD ^{a)}	Method of calculation (p-met)			
Burscheid, Germany	silt loom , bare soil	0%0024J	~~2.0	0.00403	0.0386	0.0042	DFOP-SFO			
Great Chishill, United Kingdom	cay loam, pare son	0.00 42	2.4	0.01030	0.0563	0.0099	DFOP-SFO			
Parcay, Meslay, Northern France	Toam bare soil	<b>6</b> 00154	1.9	0.00204	0.0345	0.0038	DFOP-SFO			
St. Etienne du Gres, Southern France	clay loant, bare soil	0.00506	4.5	0.00841	0.0651	0.0042	HS-SFO			
Albar, Italy	clay Bare soil	Ø.00107	3.1	0.00304	0.0430	0.0060	DFOP-SFO			
Vilobi, Sprin	loûm, bare soil	0.00269	1.2	0.00403	0.0183	0.0024	DFOP-SFO			
Arithmetic mean:	A A				0.043					

BCS-CN884	60-carb	oxylič	tcid (MA	2):	~ <u>~</u>
Eield matrix	degrad	ation	ndnoints	s for	ndellin
	A ANOC	1000/	r di an	S.	n = 1

deviation TD of metabolite f.f.

Table 7.1.2.2,1-20:


### **III. CONCLUSIONS**

After the kinetic evaluation of field dissipation trials using simple first-order (SFO) and bi-phasic models in comparison, the best description of isoflucypram could be given using a DFOP fit for 5 & European trials, and a HS fit for the one remaining trial (Table 7.1.2.2.1-18).

The overall geometric mean DT_{50 matrix} of isoflucypram, for modelling purposes according to FOCUS kinetics and EFSA (2014) based on these 6 values, can be given with 335-days and for the metabolite with 153 days (normalised to 20°C, 100% field capacity) (Table 7.1.2.2.1.-14 and Table 7.1.2.2.1.-14). The arithmetic mean formation fraction of the metabolite BCS-CN88460-carboxylic acid upsoil upder field conditions is 0.043 (Table 7.1.2.2.1-20).

### Storage stability in soil

The arithmetic mean for	ormation fraction of the metabolite BCS-CN88460-carboxylic acid in soil under
field conditions is 0.04	3 (Table 7.1.2.2.1-20).
Storage stability in so	
Storage stability in so	
Report:	KCA 7.1.2.2.1/04
Title:	Determination of the storage stability of BCS-CN88460 and the metal vite BCS-
	CN88460-car Xylic acid in soil for 24 months S
Report No.:	P641 14 1869 "" " " " " " " " " " " " " " " " " "
Document No.:	M-574766-01-1 & & & & & & & & & & & & & & & & & &
Guideline(s):	Regulation (EC) No 1109/2009 of the European Parliament and of the Council of 21
	October 2009 concepting the placing of plant protection products on
	the market and repeating Conneil Directives 79/117/EEC and 91/614/EEC,
	EC DGA: Appendix H - Storage(stability of residue samples, 72,2/VI/95 rev. 5 of 22
	, July 1997
a construction of the second sec	US EPA OCSUP 860.1380, Storage StabilitoData
Guideline deviation(s)	yes, see report of a a a
GLP/GEP:	$\mathbf{y}$

Executive Summary O O G this study was to determine the stability of isoflucypram and BCS-CN88460carboxylic acid (M12) in soil under freezer storage conditions.

Untreated soil samples of soid Höfchen (silt loam) and sou Dollendorf (clay loam) were fortified with isoflucypram and BGS-CN88460-carbox dic acid respectively

The fortified concentrations of isoflucypram and BCS CN88460-carboxylic acid were about 10 µg/kg. Soil samples were analysed for isoflocypram and BCS-CN88460-carboxylic acid on day 0 and after 93, 194, 308, 363, 539, and 20 days of storage below - 18°C. Due to a technical error on day 235, the temperature rose to an average of -12,00°C for 5 hours and 55 minutes. Never the less this had no impact on the stability of the compounds. Soil samples were analysed for isoflucypram and CS-CN88460-carboxylic acid by means of HPLCimpact on the stability of the compounds.

MS/MS according to method 01432. Sold samples of 20 g were extracted in a microwave extractor with 40 mL of a mixture of acetonitrile/water/acetic acid (4000+1000+30, v/v/v), respectively.

Possible matrix offects of isoffucyprain and BCS-CN88460-carboxylic acid are eliminated by using an internal standard solution of isotopically labeled reference items. This solution is added to the sample solutions after extraction. Then a subsample was centrifuged to remove fine particles of the soil. Identification and quantitation of the test item and its degradation products was done by high performance liquid chromatography using MS/MS detection in the Multiple Reaction Monitoring mode

The Hmit Dquantitation (LOQ) for each single analyte was 1 µg/kg in soil. The limit of determination (LOD) for each single analyte was 0.3  $\mu$ g/kg.

Mean concurrent recoveries for each soil typ were within the range of 100% to 102%. The relative standard deviations were within the range of 2.13% to 5.24%

The recovered amounts of isoflucypram and BCS-CN88460-carboxylic acid on day 0 and after



720 days were compared to the standardized recovery rates (day 0 = 100%).

Residue results were not corrected for the concurrent recoveries at the respective day of analysis, since the mean concurrent recoveries were within a range of 70 - 110% and thus fulfilled the requested analytical guideline requirements.

At all sampling intervals on average more than 70% of the fortified amount of isoflucypram and BCS-CN88460-carboxylic acid were recovered from the stored samples (not corrected for concurrent recoveries).

The mean recovered amount in the two soils after 720 days of freezer storage ranged from 104% to 105% for isoflucypram and BCS-CN88460-carboxylic acid. Altogether the study results demonstrate that isoflucypram and BCS-CN88460-carboxylic acid residues are stable in soil for at least 720 days of storage under frozen conditions.

## I.

### **MATERIALS** A.

#### **Reference Items and Internal Standards** 1.

### **Reference items:**

I. MATERIALS I. MATERIALS AND VIETHODS A. MATERIALS I. MATERIALS A. MATERIALS I. Reference Items and Internal Standards Reference items: Isoflucypram Batch code: BCS-CN88460-PU-01 Cerificate of analysis: Purity: BCS-CN88460-BCI-01 BCS-CN88460-PU-01 BCS-CN88460-PU
I. MATERIALS AND METHODS A. MATERIALS 1. Reference Items and Internal Standards Reference items: Isoflucypram Batch code: Cerificate of analysis: Purity: BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN88460-etil-01 BCS-CN26497-01-02 Certificate of analysis: MZ-00912 MZ-00984, MZ-01057 MZ 01102 MZ 01188 90% 98.8% 98.8% 98.8% 98.8%
I. MATERIALS AND METHODS         A. MATERIALS         1. Reference Items and Internal Standards         Reference Items and Internal Standards         Batch code:         BCS-CN88460-entbox/lic acid (M12)         Purity:         BCS-CN88460-entbox/lic acid (M12)         BCS-CY26497-01-01         BCS-CY26497-01-02         BCS-
I. MATERIALS AND METHODS
A. MATERIALS 1. Reference Items and Internal Standards Reference items: Isoflucypram Batch code: Cerificate of analysis; Purity: BCS-CN88460-earbox vHc acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Certificate of analysis; PURITY: BCS-CN88460-earbox vHc acid ( <i>M12</i> ) (BCS-CY26497) BCS-CY26497-01-01 BCS-CY26497-01-02 Certificate of analysis; MZ-00984, MZ-01057 MZ 01102 MZ 01188 9.0% 98.8% 98.8% 98.8% 98.8%
A. MATERIALS 1. Reference Items and Internal Standards Reference items: Isoflucypram Batch code: Cerificate of analysis: Purity: BCS-CN88460-earboxyHe acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Certificate of analysis: Purity: BCS-CN88460-earboxyHe acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Certificate of analysis: Purity: BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-CY26497-01-02 BCS-
A. MATERIALS1. Reference Items and Internal StandardsReference items:Isoflucypram Batch code:Batch code:BCS-CN88460-01-02 BCS-CN88460-PU-01 Certificate of analysis;AZ 1867 98.4%Purity:BCS-CN88460-earbox/Hc acid/( $M12$ ) (BCS-CY264970) BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-01 BCS-CY2649701-02Internal standards
1. Reference Items and Internal Standards         Reference items:         Isoflucypram         Batch code:       BCS-CN88460-01-02         Cerificate of analysis:       BCS-CN88460-PU-01         Purity:       BCS-CN88460-PU-01         BCS-CN88460-carboxylic acid (M12)       BCS-CY264970         BCS-CN88460-carboxylic acid (M12)       BCS-CY264970         BCS-CV2649701-01       BCS-CY2649701-01         BCS-CY26497-01-02       MZ 00913         Purity:       BCS-CY2649701-01         BCS-CY2649700-01       BCS-CY2649701-01         BCS-CY2649700-01       BCS-CY2649701-01         BCS-CY2649700-01       BCS-CY2649701-01         BCS-CY2649700-01       BCS-CY2649700-01         BCS-CY264
Reference items:         Isoflucypram         Batch code:         Cerificate of analysis;         Purity:         98.4%         98.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         99.4%         98.4%         98.8%         98.8%
Reference items:       Isoflucypram         Batch code:       BCS-CN88460-01-02         Cerificate of analysis:       AZ 1860         Purity:       98.4%         BCS-CN88460-carboxyHc acid       M12) (BCS-CY26497)         BCS-CN88460-carboxyHc acid       M12) (BCS-CY264970)         BcS-CY26497-01-01       BCS-CY2649701-01         BcS-CY26497.01-02       M200915         M200915       MZ 00984       MZ01057       MZ 01102       MZ 01188         Purity:       98.8%       98.8%       98.8%       98.8%       98.8%
Isoflucypram         Batch code:         Cerificate of analysis;         Purity:         BCS-CN88460-RU-01         AZ 18657         AZ 18657         AZ 18657         AZ 19352         AZ 20542         Purity:         BCS-CN88460-carboxylic acid         MI200915         BCS-CY26497-01-01         BCS-CY26497-01-02         Certificate of analysis:         Purity:         BCS-CY26497-01-02         BCS-02       BCS-02         BCS-02       BCS-02         BCS-02       BCS-02         BCS-02       BCS-02         BCS-02       BCS-02         BCS-
Isoflucypram Batch code: Cerificate of analysis: Purity: BCS-CN88460-earbox Hc acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Purity: Certificate of analysis: Purity: MZ 00915 MZ 00984, MZ 01057 MZ 01102 MZ 01188 98.0% 98.8% 98.8% 98.8% 98.8%
Batch code:       BCS-CN88460-01-02         Cerificate of analysis:       AZ 1860         Purity:       98.4%         98.4%       99.4%         99.4%       99.1%         BCS-CN88460-carboxylic acid       MI2) (BCS-CY26497)         BCS-CN88460-carboxylic acid       MI2) (BCS-CY2649701-01         BcS-CN88460-carboxylic acid       BCS-CY26497-01-02         BcS-CY26497-01-02       Certificate of analysis:         MZ 00913       MZ 00984         MZ 00913       MZ 00984         MZ 00913       MZ 00984         MZ 00984       98.8%         98.8%       98.8%         98.8%       98.8%
BCS-CN88460-PU-01         AZ 1867       AZ 10352         Purity:       98.4%       99.4%         BCS-CN88460-carbox/Hc acid       (M12)       (BCS-CY26497)         BCS-CN88460-carbox/Hc acid       (M12)       (BCS-CY26497)         BCS-CN88460-carbox/Hc acid       (M12)       (BCS-CY26497)         BCS-CN88460-carbox/Hc acid       (M12)       (BCS-CY26497-01-01)         BCS-CY26497-01-02       BCS-CY26497-01-02       (MZ 01102)         Certificate of analysis:       MZ 00913       MZ 00984       MZ 01102       MZ 01188         Purity:       99.0%       98.8%       98.8%       98.8%       98.8%         Internal standards       4       4       4       4       4
Certificate of analysis:       AZ 18667       AZ 19352       AZ 20562         Purity:       98.4%       99.4%       99.1%         BCS-CN88460-earboxyHc acid       (M12)       (BCS-CY26497)       99.1%         Batch code:       BCS-CY2649701-01       BCS-CY26497-01-02       0         BCS-CY26497-01-02       BCS-CY26497-01-02       0       0         Certificate of analysis:       MZ 00915       MZ 00984       MZ 01102       MZ 01188         Purity:       98.8%       98.8%       98.8%       98.8%       98.8%         Internal standards       4       4       4       4       4
Purity:       98.4%       99.4%       99.1%         BCS-CN88460-carboxyPic acid (M12) (BCS-CY26497)       99.1%         Batch code:       BCS-CY26497/01-01         BCS-CY26497-01-02       BCS-CY26497-01-02         Certificate of analysis:       MZ 00913       MZ 00984       MZ 01102       MZ 01188         Purity:       98.8%       98.8%       98.8%       98.8%       98.8%         Internal standards       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4       4 <t< th=""></t<>
BCS-CN88460-earboxylic acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Certificate of analysis: Purity: MZ 00913 MZ 00984, MZ 01057 MZ 01102 MZ 01188 99.0% 98.8% 98.8% 98.8% 98.8%
BCS-CN88460-earboxy4c acid ( <i>M12</i> ) (BCS-CY26497) Batch code: Certificate of analysis: Purity: Internal standards
Batch code: BCS-CY26497-01-02 Certificate of analysis: Purity: MZ-00915 MZ 00984, MZ 01057 MZ 01102 MZ 01188 98.8% 98.8% 98.8% 98.8%
Certificate of analysis: MZ 00913 MZ 00984 MZ 01057 MZ 01102 MZ 01188 Purity: 98.8% 98.8% 98.8% 98.8% 98.8%
Certificate of analysis:         A         MZ 00916* MZ 00984;         MZ 01102         MZ 01102         MZ 01188           Purity:         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%         98.8%
Internal standards
Internal standards
internal standardsy , by by by or a
[d5] BCS-CN88460 (BCN-C\$8884600ISTD) 2 2 2
Batch number $MXM 9255 24$
Purity: 99% 99% 2 6
[d ₅ ] BCS-CY26497 BCN- CY26497 ISTD)
Batch number: $\sqrt[3]{MX}$ $\sqrt[3]{MX}$ $\sqrt[3]{7360}$ $\sqrt[3]{-6}$
Purity: $\sqrt[3]{98\%} > 98\%$
$\mathcal{C}^{\Theta}$



#### 2. **Test Soils**

The control materials used for the storage stability experiments originated from two German soils Höfchen and Dollendorf. Two different soils were used for each analyte in order to assess a possible influence of different soil characteristics. The soil samples were classified according to DIN and/or a USDA specifications. Soil characteristics of the used soils are summarised in Table 7.1.2.2.1-

### Table 7.1.2.2.1-21: Soil characteristics

	4		<u> </u>
	r Soil Höfchen	Soil Dollendorf	
Description	Plot 4011:	Plot 20100433;	Û SÛ
	0-30 cm soil hayer	0-20 cm soiDlayer	
Textural description according to USDA [fraction			
clay (<0.002 mm)	ົ 19.4 _ ຜູ	Å Å 31 U	S.
silt (0.002-0.050 mm)	>> 76.3℃	× <u>38</u>	Ŵ.
sand (0.050-2.000 mm)	° ~ 43″ 4		Ø.
Soil type $O^{*}$	silt kam	Clay loam	_ 0
pH (in CaCl ₂ solution)	Q 6.7	0 [°] 7 <i>3</i> 0 [°]	a.
pH (in H ₂ O)	∑ ~ 7, <b>A</b> 0	× 19.1 2	
Organic carbon [%]	§ § 92 € 92	\$5 Å	
Organic matter [%] ^{a)}	~~~~1.58 Û	× × 8.6	
Cation exchange capacity[meq 400 g doy soil]	12.4	20.6	
Max. water holding capacity[g\$%100 gdry south (	) <u>6</u> 3 <u>9</u> <u>0</u>	Õ <b>79</b> .1	
a) organic matter = organic cate on $x_1$ .		8 4	-
	a w b	, Ö	

### **STUDY DESIG** B.

### Preparation of sample 1.

1. Preparation of samples To determine the storage stability of isoflucypram and BCS@N88460-carboxylic acid untreated soil samples of 20 g each were weighed into 100 mL glas bottles with screw caps. Each of the reference items was dissolved in acetonitrile to obtain fortification standard solutions with concentrations of about 1 mg/L of each compound. For the preparation of the storage stability samples 0.2 mL of the 1 mg/L fortification standard solution dissolved in acefonitrile was added to each of the corresponding sets of soil samples (A and B-samples). Ŝ

For the preparation of the samples used for the concurrent recovery experiments, 0.2 mL of the 1 mg/L fortification standard solution was added to each of the corresponding sets of soil samples. The resulting concentration in all soil samples was approximately 10 µg/kg soil.

## 2. Storage of bulk control material

Except for the time during subsampling and subsequent analysis, the homogeneous control matrices were maintained in deep-frozen storage (-48°C of below).

Ô

## 3. Sampling

Soil samples were analyses for isoflucypram and BCS-CN88460-carboxylic acid on day 0 and after 93, 194, 308, 363, 339, and 720 days of storage below -18°C. Due to a technical error on day 235, the temperature rose to an average of -12.2°C for 5 hours and 55 minutes. Never the less this had no impact on the tability of the compounds.



### 3. **Analytical procedures**

The analytical method 01432 ( ; 2014; M-499794-01-1, KCA 4.1.2) was developed for the determination of isoflucypram and the metabolite BCS-CN88460-carboxylic acid residues in/on@oil and sediment.

Soil and sediment samples of 20 g were extracted in a microwave extractor with a mixture of acetonitrile/water/acetic acid (4000/1000/30, v/v/v). The extracts were centryfuged to remove the particles of the soil. Possible matrix effects of isoflucypram and the metabolite BCS-CN88460carboxylic acid are eliminated by using an internal standard solution of isotopically labeled reference items. Identification and quantitation of the active substance was done by high performance liquid chromatography using MS/MS detection in the Multiple Reaction Monitoring mode "Doffendor The method was validated using three different soils, "Höfchen", OLaacher Hot an sediment "OECD 218/219". Õ

The limit of quantitation (LOQ) for each single analyte was The limit of determination (LOD) for each single analyte was  $0.3 \mu g/kg$ .

### RESU II.

### A. CONCURRENT RECOVERIES

concurrent recoveries were determined by In order to assess the accuracy of the residue analyses, analysing freshly fortified sample alongside with the stored fortified samples. At all storage intervals concurrent recoveries were determined at the bug/kg fortification level.

Table 7.1.2.2.1- 22: Isoflucypram, concurrent recoveries	Table 7.1.2.2.1- 22: Isoflucy	ram, concurrent	recoveries "	0°
----------------------------------------------------------	-------------------------------	-----------------	--------------	----

			- <i>k</i>	~	<u> </u>	<u> </u>		
Soil		Fortification level	U (	Recoy	eries	s i	Mean	RSD
		a [ng/kg]	Ç A	singlø	/alues)		<b>[%]</b>	[%]
	Ô`.			[%	<b>)</b> 0'	~		
Höfchen 🔊	·		୍ବ୍ୟୁହାଁ	<i>6</i> ,02	<b>A</b> 03	<b>10</b> 3	101	2.42
Ď		× & ~	<u>103</u>	0104 <u>(</u>	¢100 🖌	102		
~~	~~ .C		/ 10 <b>0</b> ~	99	99	98		
	or do		169	104	104	99		
	×		i04	Ø104	@04	101		
Ş,			\$101	√ ^v 100 _C	⁹ 101	101		
¥	s s		102	93	99	100		
Dollendorf		S NO M	<u>b</u> )2	§99	98	99	100	2.13
Ġ,	A		<u>101</u>	©104	105	104		
a,	Ô K		🕅 100	100	100	99		
~Ç	0 vo		100	100	100	99		
4	O,	2° 47° 6°	99	104	100	100		
Q'	, Ô		×101	102	99	100		
		× ~ ~	102	101	98	95		
*	J A							
~	O ^y							
Ű.	a \ (							
^ ^ ×	A &							
	, <i>°</i>	× ~						
	Õ	à i						
9 D	1 ~	×.						
″ O¥ .	∩>″ ≾ı°	•						



Soil	Fortification level		Recov	reries		Mean	RSD	_ 0
	[µg/kg]	(single values)			[%]	[%]	<u></u>	
			[%	<b>b</b> ]				
Höfchen	10	104	100	102	100	≥101	3.90	
		105	99	106	107		- L	
		103	104	104	1020			
		91	96	98	<b>10</b> 5		Ŭ,	
		102 🍙	100	100	<u>94</u>	~		
		98	97	95 C	° 101	Ú,	~0 [%]	<u>v</u>
		106	100	164	103	×.	Ň	S v
Dollendorf	10	_₄ <b>Ø∕</b> 05	100	<b>6</b> 96	100	_@02	<i>°</i> ≸⁄.24 ₍	
		100	106	100	¢109 "			
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	105	108	99	104		L.	
	4	bgi	, M	×92°	100			Ж ^и
	0	<i>2</i> 99	M02	~ 99 /	A 108	° °		~ c °
		ð 101 Ø	100	102	104	, 0	í "Ø	, ar
		' 14.9%	1293	103	100*	\$	~~~``	<u>s</u>
		v v	Å .	_0 [*]	Ň	ŝ		
		õ S	1 G		O .	Ë (Ŭ 🔊	-

Table 7.1.2.2.1-23: BCS-CN88460-carboxylic acid (M12), concurrent recoveries

B. STORAGE STABILITY The following tables show the levels for isoflucyprate and BCS-CF88460 carboxylic acid measured in the stored spiked samples of soil. In each table the recoveries determined in the stored spiked samples are uncorrected. In with the columns the results are normalised to day 0. Mean values were calculated with unrounded values therefore million deviations may occur when the values given in the table are used. table are used.

0 Table 7.1.2.2.1- 24: Recovered amounts of isoflucypram in percent of nominal added amount in soil

			· (//
Soil ~	Ç Day 🗸 🗡	Mean recovery 🖉	Standardised to
	`\$\$ \$\$	Mean 🔊	🐃 day 0
		Q (M) Õ	_⊘ [%]
, 🖗 Höfchen,		101 ₀₁	× 100
	× \$93	<u>~ 160</u> ° ~	99
	194		99
~9 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	308 *	لم 103 گ	102
a a	Q 363 (0	103	102
	× po 539 ×	S 168	102
	°∼y 7200	i04	103
Jollendor		9 99	100
	S 0.93 ~	ູ 🖉 102	103
	194	100 ×	101
× × A	308	y 104	105
	363	105	106
	, @539 Å	103	104
	× 720 [×]	104	105
	*O ~~Y		
Ĉ			



Table 7.1.2.2.1- 25: Recovered amounts of BCS-CN88460-carboxylic acid (M12) in percent of nominal added amount in soil

Soil	Day	Mean recovery	Standardised to	l d' de
		Mean	day 0	
		[%]	[%]	
Höfchen	0	98	10.0	
	93	101	103	
	194	102	104	0° 29 .9
	308	101	103	
	363		<u></u> 101 <u></u>	
	539	. ⁹⁸		
	720	104	106 0	
Dollendorf	0	98	\$ 106 ⁵	
	93	🖉 104 🖉	× 106 ×	
	194 候	چ گر 102 کې ي	\$ _{\$\$} 964 \$	
	308 O		2 103 A	
	363	100 Q	102 0	
	539 ~	× ~ >99 ~		
	20 ×	_©_105 √	× 107 ×	No N
	Q 4,4			
	s. a		N N S	, Q

The recovered amounts of isoffueypram and BCS ON88460-carboxylic acid on day of and after 720 days were compared to the standardized recovery rates day 0, 100%.

Residue results were not corrected for the concurrent recoveries at the respective day of analysis, since the mean concurrent recoveries were within a range of 70 - 110% and thus fulfilled the requested analytical guideline requirements.

At all sampling intervals on average more than 30% of the fortified amound of isoflucypram and BCS-CN88460-carboxylic acid were recovered from the stored samples (not corrected for concurrent

recoveries). The mean recovered anyount in the two soils after 720 days of freezer sporage ranged from 104% to 105% for isofl@yprar@and BCS-CN8846@carbexylic acid. Altogether, the study results demonstrate that isoflucypram and BCS-CN88460-carboxylic acid tesidue in soff for at least 720 days of storage under frozen conditions

ŃCLĂSIO

The mean recovered mount in the two sols afto 720 days of freezer storage ranged from 104% to





CA 7.1.2.2.2 Soil accumulation studies

Due to the use pattern and the degradation rates of isoflucypram no significant accumulation in soil would be expected.

The accumulation potential of isoflucypram and its metabolite BCS-CN88460-carboxylic acid after long term use was assessed in the PEC_{soil} calculation below.

Report:	KCA 7.1.2.2.2/01;	, G.;	. W.; 2017; M-6	508723-01-1 🖉	
Title:	Isoflucypram (ISY): C	ore PECsoil EUR - N	Aodelling core in	nfo document for	sofl risk≪
	assessment in Europe	Ś		s ' a	
Report No.:	EnSa-17-0654	- And	Ð.	<i>"</i> , "	' w k
Document No.:	M-608723-01-1	Å.	,0×	× N	
Guideline(s):	none	S. C	0		o ju
Guideline deviation(s):	none	A A A A A A A A A A A A A A A A A A A			
GLP/GEP:	no			i al wi	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
					<i>\$</i> 0'

Executive Summary The accumulation potential of isoflucypram and its metabolite BCS-CN88460-carboxylic acid (*NJ2*) after long term use was also assessed based on the maximum PEC_{sol,max} concentration of the compounds. The resulting soil accumulation factors (categolated as ration between PEC_{soil,Qotal} and PEC_{soil,max}) are 1.5 for isoflucypram and 1.63 for BCS-CN88460 carboxylic and and are independent from the evaluated use pattern. The results are summarised in the following tables:

Table 7.1.2.2.2- 1:	PECsoil of isoflucypram and its major degradation product BCS-CN89460-carboxylic
	acid (M12) for the uses assessed/taking the effect of accumulation into account

Use pattern		PEC _{vil} mg/kg]
	Jo J	BCS-CN88460- carboxylic acid <i>(M12)</i>
Cereals, early	Plateauconcentration (20 cm) after year 6 2,010 2	0.00007
1×75 g a.s./ha	PEGaccumulation (PECact + PEG soil plateau 00.036)	0.00224
Cereals, lạt🧞	Plateauconcentration (20 cm) after year 0.005	0.00003
1×75 g a Sha	PEC ac PEC soil plateau	0.00112

Soil accumulation factor of fooflucypram and BCS-CN88460-carboxylic acid (M12) for the user assessed Table 7.1.2.2.2-2

a.			
~Ç [®]	Use pattern	🎽 🔿 💦 Soil aceumu	lation factor
A CONTRACTOR		f Isoflueypran	BCS-CN88460- carboxylic acid <i>(M12)</i>
L.	Ceteals, early 1×75 g g s./ha		1.03
	Cereals, late 1×45 g a.s. aa	© § 1.50	1.03
		Ą	



I. METHODS

Application and GAP

The use of isoflucypram in cereals in Europe was assessed according to the Good Agricultural Practice (GAP) as summarised in Table 7.1.2.2.2-3.

				-0
Table 71333 2.	A l'astis data af :	a a fl a a a a a a di a A	La 4 l e a a a - 44	
Table /.T.Z.Z.Z- 5:	ADDIICATION GATA OF I	sonucybram ассоготпу і	lo lhe use dall	ern in rarodez
		sonae, pram accor ang .	to the use puty	

Individual crop	FOCUS crop	Rate [g a.s./ha]	Interval [days]	Plant Interception	BBCH stage	Amôunt reaching soil (ga.s./ha)
Cereals, early	cereals	1 × 75		80	<u>30 - 39</u>	
Cereals, late	cereals	1 × 75		20	40 4 9	D 187.5 D

The calculations were based on the maximum intended application rate logether with the maximum intended number of applications per season and (for multi-application sequences) the minimum interval between the applications. Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCKS (2014)¹. For the metabolite, the (pseudo) application rate is calculated based on the maximum amount of the metabolite observed in soil degradation studies and the molar mass correction (Table 7.9.2.2.2-4, Table 7.1.2.2.2-5).

Table 7.1.2.2.2- 4: Summary of properties for metabolite rate calculation?

	~ ~	<u> </u>			· //	•	\$//		
Parameter	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	A c		Isoř Ö	lucypra	m	BCS-©	88460-car (<i>M12</i>)	boxylic acid
Molar mass∉	@mol]		, Ø		99.85		0°	³ √ 429€8 ³	,
Correction	actor			~ .	1			1@749	
Maximum o	ccurrenc	e fa soil	%]	\mathbb{R}^{n}	100	L) A		£ ⁹ .6	
~0			``````	or .	Ś	\sim	AN NORTH		

Table 7.1.2.22- 5: Calculation of metabolite application rates

Crop: vate			Application		Application rate [g/ha]
				Isoflucypram	BCS-CN88460-carboxylic acid (M12)
Cereals, early	, 1×75 g a.s./b	ຊັູຈ		15	1.55
Cereals, late,	1×75 g a.s.@a	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	ANI 6	7.5	0.775
"Ø"	ČŐ.	2°	Ø X		

Calculation

All calculations and assumptions are done in accordance to the Guidance Document on Persistence of Soil (EU Commission 2000²) and according to FOCUS (1997)³.

Potential accumulation after Aong term use is assessed, based on the maximum PEC_{soil,max} concentration othe respective compound.

Ś

¹ FOCUS 2014: Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2

² EU Commission, 2000: Guidance Document on Persistence in Soil (Working Document) 9188/VI/97 rev 8

³ FOCUS, 1997: Soil persistence models and EU registration. Final report of the work off the Soil Modelling Work group of FOCUS



The compound and scenario input parameters as used for the calculation are given in Table 7.1.2.2.2- 6 and Table 7.1.2.2.2-7. A plateau mixing depth of 20 cm was used.

$1 a \beta \alpha \gamma \gamma \gamma \gamma \gamma \alpha \gamma \alpha \gamma \alpha \gamma \alpha \gamma \alpha \gamma \alpha \gamma \alpha$
--

Tuble 7.1.2.2.2 0. Compound input	parameters			~	6, "	0*
Compound	Molar mass Molar mass		Maximum		B T 50 ^{a)}	
	[g/mol]	correction factor	occur	rænce in soil	[days]>	
			A	[%]		Q
Isoflucypram	399.85	Cz 1	Å.	100 🔊	\$30	
BCS-CN88460-carboxylic acid (M12)	429.8	\$1.0749 (9.6	¶113	Å
a) worst case DT50 lab, not-normalised (, G.;	, W.\$2017; M-6082550)1-1)	Å,		v V
	a	A Q	<i>B</i> °	A 4		v
		✓	((// n	· 🖌 , 🔘		

Table 7.1.2.2.- 7: Scena

rio input param	eters		N M	Å,	5
Parameter	Ő.Ű		\$_~~		/ ^{\$} V 4
Soil bulk density	y [kg/L]		1.5 °	, Ô	D d'
Soil mixing dep	th [cm]		A S	Ý L	\$ \$
Tillage depth	r plateau [cm]		\bigcirc_{20}	<u> </u>	Ő
					L. Y
JI. RE	SULTS AND	DISCUSSI	ON S	2° &	•

Overview of maximum PEC_{soil} values of soflucypram and its metabolite for all use patterns under consideration is shown in table 79.2.2 8. The accumulation potential of soflucypram and its metabolite BCS-CN88468 carboxylic acid after long term use was also assessed, employing the larger sont depth for the calculation of the background concentration in cases where tillage is relevant. The results are presented in Table 7.1.2.2.2-9 and Table 7.1.2.2.2-16 Table 7.1.2.2.2-16 Ô

Table 7.1.2.2.2-8: Maximum PECsoil of isoflucypram and its meabolit for the uses assessed

			~ \			
	Use pattern			() () () () () () () () () () () () () (Iax PEC _{soil} [Ing/kg] BCS-CN88460- carboxylic acid (M12)	
~	Gereals early,	Q75 g°a	s./ha	× 0,020	0.00217	
4	Cereals, late,	ř×75 ₂ 00.	s./ha	\$ @ \$10	0.00109	
"Or"	Ô	Ž	Ċ X			

Table 7, 1.2.2.2-9: PEC soil of isoflue prant and its metabolite for the uses assessed, taking the effect of accumulation into account

	Use pattern			PEC _{soil} [mg/kg]
		Ŷ	Isoflucypram	BCS-CN88460- carboxylic acid <i>(M12)</i>
~	Gereals, Carly, 1875 g à s/ha	plateau (20 cm)	0.010	0.00007
Ľ.		total	0.030	0.00224
	Cereals, late, 1×75 g a.s./ha	plateau (20 cm)	0.005	0.00003
		total	0.015	0.00112



Table 7.1.2.2.2- 10: Soil accumulation factor of isoflucypram and BCS-CN88460-carboxylic acid (M12) for the uses assessed

F		a u		
L	se pattern	Soil accumu	lation factor	
		Isoflucypram	BCS-CN88460- carboxylic actor (M12)	
C	Cereals, early, 1×75 g a.s./ha	1.50	1.65	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
C	ereals, late, 1×75 g a.s./ha	1.50	<u>₹</u> .03	
The worst case isoflucypram a CA 7.1.3 CA 7.1.3.1	e accumulation factor calc and 1.03 for the metabolite Adsorption and deso Adsorption and deso	1.50 CONCLUSIONS ulated for the different us BCS-CN88460-carboxy rption in soil	A.03	P G G G G G G G G G G G G G G G G G G G
The mobility of	$\int_{\infty}^{\infty} dt = 0$	ai metabolite B	CN& 60-02 hove the ac	id M12) was
assessed in bat An overall sun	ch-equilibrium adsorption nmary is given in the follow	desorption.	odocuments: 8	∀ ∀
Report.	VCA 7 1 2 101.	W W		
Title [.]	$1 \approx 1 \times 10^{-1}$	Ø: Conserver EUR Ma	delling cord info document	for
THE.	√ groundwater risk	assessment in Europ		101
Report No.:	© EnSa@ 7-0655			
Document No.:	M_608724692-1			
Guideline(s):	ູລີ້ ເຫັ applicable 🌾			
Guideline devia GLP/GEP: (tion(s): The γ κ			
Report: 🔊	1/02	G : W ·	QUT 7. M-608725-02-1	
Title:	/Isoflucypram (PS)	(): Core PROSW EKK - Mo	Pelling core info document	for surface
«%	water risk assessn	nent in Europe (,	
Report No.:	EnSa-17-0656	Y O O A		
Document No.:	Q AM-608725-02-15			
Guideline(s):	© not applicable			
Guideline devis	tion(s). none			
GLP/GEP;	no y			
E				
Executive Sur	nmary	Fite matchalita	OCS CN99460 corboxyli	a and $(M12)$
which are used	1 in the PFC and PFC	calulations are summ	parised in the following t	able: $(M12)$



Table 7.1.3.1-1: Overall summary of adsorption constants K_{oc(ads)} in soils of isoflucypram and its major degradation product BCS-CN88460-carboxylic acid (M12)

Parameter	Com	pound	Value in accordance with 💍
	Isoflucypram	BCS-CN88460- carboxylic acid <i>(M12)</i>	EU endpoint 3 n / Reference
K _{foc} / K _{fom} [mL/g]	1580 / 916.3 geometric mean, n=7	37.1 / 21.5 geometric mean, pH 7.5, n=2	n.a. y
1/n	0.9142 arithmetic mean, n=7	0.9424 arithmetic mean, pH 7.5, $=2$	
n.a. = not applicable for a new	w active substance submission		

• Isoflucypram

	\sim 0	\sim	9		N A	1	
Soil name	[≫] Soil_type	OC S	N N	K f	Krec	∧¶/n	Evaluated on
L. L		[%] 	(GaCl ₂)	MmL/g	[m/L/g] ∘		EU level y/n / Reference
Laacher Hof AXXa, GER	toamy sand	2.1	<u></u> ,60	29.184	1389	0.8904	<u>n</u> /
Hoefchen am Hohefisch 4a GER	silt toam (6.3	29.812	1569.1	0.8788	;; 2014; M-
Hanscheider Hof, GER	loando	1 2.3 Å	5 A	32.430	≪1410.0	0.8972	499024-01-1
Dollendorf D, GER	łoam	5.1	J.2 ~	S8.71	1151.2	0.8690	
Sanger, CA, USA	sandy loam	.0%	6.2	[3,/	1394	1.0150	n /
Louisville, NE, USA 🖉 🏾	silt loan	مچ 1.8	65	25	1384	0.9101	; 2015;
Lawrence, KS, USA	silty cory loan	0.34	7.5 ¢	12	3594	0.9387	M-518345-01- 1
Geometric mean (n=7)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		× ~		1580		
Arithmetic mean (n=7)			- 1			0.9142	
pH-dependency					no		
	2.0		Y.				

Table 7.1.3.1-2: Summary of soil adsorption/desgrption/for isoflucypram

• BCS-CN88460-carboxylic acid (112)

The adsorption of BCS-CNS8460 arboxylic acid to soil was investigated in two batch equilibrium studies, one with five soils by the soil

; 2017; M-5898; 36-01-1. The K_{foc} values ranged from 28.1 to 289.8 mL/g, with Freundlich expenses between 0.8914 and 0.9604 (Table 7.1.3.1-3).

The adsorption of BCS-CN88460-carboxylic acid to soil is pH dependent following an S shaped curve which is typical for many ionic substances with a single ionisable functional group (Figure 7.1.3.1-1). A signed correlation analysis of pH and K_{foc} values with the Input Decision Tool version 3.3 resulted into a K_{foc} a of the dissociated BCS-CN88460-carboxylic acid of 37.7 mL/g considering an apparent pKa of 5.6 in soil. The apparent pKa in soil needs to be estimated as the pKa in soil is increased compared to the pKa determined in water as sorption processes are reducing the water available



substance amount.

The geometric mean K_{foc} value for soils at pH 7.5 is 37.1 mL/g, with an arithmetic mean Freundlich exponent of 0.9424 (Table 7.1.3.1- 5). The geometric mean K_{foc} value for weak acidic soils with appH of about 5.4 is 153.2 mL/g, with an arithmetic mean Freundlich exponent of 0.9169 (Table 7.1.3 + 4). EFSA (2013) and FOCUS groundwater (2014) recommend that Tier 1 leaching simulations for consideration of EU approval should select adsorption values, chosen to represent a realistic worst case considering the pH of the soils in the EU that are used for the production of the pertinent crop, which is in this case cereals. For a compound with a single ionisable functional group that follows ab typical S shaped relationship for adsorption with pH, such as a weak and, two contrasting pH values for which realistic best case and realistic worst case adsorption estimates may be selected to consider the impact of variable soil pH values relevant for the grop growing situation (*e.g.* pH of 7.5 and pH of 5.4 as relevant range for cereal growing conditions; with an optimum pH of about 6.5 for ereats). Thus, the adsorption of BCS-CN88460-carboxylic acid can be described

- by the geometric mean K_{foc} value of 37.1 mL/g and the arithmetic mean Freundlich exponent on of 0.9424 to represent a realistic worst case (neutral scal conditions around pH 7.5).
- by the geometric mean K_{foc} value of 153.2 mL/g and the arithmetic mean Freundlich exponent 1/n of 0.9169 to represent a realistic best case (weak acidi soil conditions around pH 9.4).

For the leaching assessment and for the PECs assessment, only the realistic work case $(K_{foc} = 37.1 \text{ mL/g}, 1/n = 0.9424)$ was taken into account 2 \times 2 \times

Soil type 🖇	OC S		_₽ Kr∳	Kfoc	1/n	Evaluated on
		CaCl ₂)	[mL/g]	mL/g	N.	EU level y/n /
	× 4	<u>ľ</u>	- ⁵ 4.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u>S</u>	Reference
sandy loam	KJ 1.9		°≫2.009 6 °	\$0.5.8	∲0.9297	n /
🖉 siltcloam 💍	200	Ĩ≈6.3 ⊅	0.7575	37.9	0.8952	2014 M
i o' y'			, s é			- 400602 01 1
loam	\$ 4.5	7,8	1.263	28.1	0.9243	499092-01-1
sandyJoam	0.7	\$6.7 S	0.2039	Ø38.4	0.9311	
silt loam	Ĵ77	6.6	122018	70.7	0.9185	
boamy sand	©0.94 N	6 9	\$2.7240 [°]	289.8	0.9497	n / ;
		N W	A			2017; M-
clay loam	2,40	õ 7.70 [°]	178, 178	49.1	0.9604	589856-01-1
	N N		Š			_
Sandy @am >>	0.29	\$.6	0.544	187.5	0.8966	
<u> </u>	<u>Q</u>					_
silty clay loam	Øł.80 🕎	\$ <u>5</u> %	1.727	95.9	0.8914	
	Y A	~9″		75.3		
) S >					0.9219	
10 L	0 4	, ,		yes		
	G G					
	Soil type	Soil type Soil type Soil type Silt loam Sandy loam Sandy loam Clay loam Sandy loam Clay loam Sandy loam	Soil type Soil type Sandy Learn Sandy Learn Sandy Learn CaCle Sandy Learn Sandy Learn CaCle Sandy Learn Sandy Le	Soil type OC pH K/ 201 201 6.3 0.7575 3 200 6.3 0.7575 3 1.0am 4.5 7.8 1.2635 3 3 0.7575 3 0.7575 3 1.0am 4.5 7.8 1.2635 3 3 0.7677 0.2689 silt loam 3 7 6.6 1/2018 3 3 0.94 59 2.7240 3 0.94 59 2.7240 3 3 0.94 59 2.7240 3 3 0.29 5.6 0.544 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 <td>Soil type OC pH Kr Kroc grindy loam 1.9 3 2.0095 105.8 siltdoam 20 6.3 0.7575 37.9 loam 4.5 7.8 1.2635 28/1 sandy loam 0.7 6.7 0.2689 238.4 silt loam 17 6.6 22018 70.7 pamy said 0.94 9 2.724 289.8 clay loam 22 5.6 0.544 187.5 silty clay loam 0.2 5.6 0.544 187.5</td> <td>Soil type OC pH K/ K/ K/ K/ I/n sindy loam 1.9 3 2.0094 405.8 0.9297 siltloam 2.00 6.3 0.7575 37.9 0.8952 loam 4.5 7.8 1.2635 2.0194 0.9243 sandy loam 0.7 6.6 22018 70.7 0.9185 sandy loam 0.7 6.6 22018 70.7 0.9185 oamy sold 0.94 9 2.724 289.8 0.9497 clay loam 2.40 7.7 1.178 49.1 0.9604 Sandy loam 0.20 3.6 0.544 187.5 0.8966 silty clay loam 0.20 3.6 0.544 187.5 0.8966 silty clay loam 0.20 3.6 0.544 187.5 0.8914 y y y y 1.727 95.9 0.8914 y y y y y 1.9219 y y y y y y</td>	Soil type OC pH Kr Kroc grindy loam 1.9 3 2.0095 105.8 siltdoam 20 6.3 0.7575 37.9 loam 4.5 7.8 1.2635 28/1 sandy loam 0.7 6.7 0.2689 238.4 silt loam 17 6.6 22018 70.7 pamy said 0.94 9 2.724 289.8 clay loam 22 5.6 0.544 187.5 silty clay loam 0.2 5.6 0.544 187.5	Soil type OC pH K/ K/ K/ K/ I/n sindy loam 1.9 3 2.0094 405.8 0.9297 siltloam 2.00 6.3 0.7575 37.9 0.8952 loam 4.5 7.8 1.2635 2.0194 0.9243 sandy loam 0.7 6.6 22018 70.7 0.9185 sandy loam 0.7 6.6 22018 70.7 0.9185 oamy sold 0.94 9 2.724 289.8 0.9497 clay loam 2.40 7.7 1.178 49.1 0.9604 Sandy loam 0.20 3.6 0.544 187.5 0.8966 silty clay loam 0.20 3.6 0.544 187.5 0.8966 silty clay loam 0.20 3.6 0.544 187.5 0.8914 y y y y 1.727 95.9 0.8914 y y y y y 1.9219 y y y y y y

	~	¥ Ø	Q	Ŭ,	65		, O	⁰	
Table 7.1.3.1- 3:	Summary of sol a	adsorption	1/desorptic	m for 🕻	₿ĆA-Q	N88460	-carbox	ylic agig	I (M12)



Figure 7.1.3.1-1: Koc-pHwater correlation for BCS-CN88460-carboxylic acid (M12) evaluated with **Input Decision Tool version 3.3**



Table 7.1.3.1-4: Soil adsorption/desorption for BCS-CN88460-carboxylic acid (M12) at weak acidic soil

	Nuttions (ai ou	er priger	/ R				
Soil name	Soil type		O [®] pH C (CaCh)	K Q [*] [m]L/g] (K _{foc} (mLy)		Evaluated on EU level y/n / Reference
Wurmwiese, GER	sandy loam		5.3 ×	2.00 9 4	05.8~C	0.9297	n / ; 2014; M- 499692-01-1
Northwood, North Dakota, USA	loamy sand	0.94 2	€¥.9	0°2.724	289.8	0.9497	n / ; 2017; M-589856-
Sanger, California, USA	sandy loam	0.29 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	5:6 ₇	0.544 Å	187.5	0.8966	01-1
Stilwell, Kansas, USA	sitty clay		×5.8 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	1,797	95.9	0.8914	
Geometric mean (n=4				ð	153.2		
Arithmetic mean (n=4	4) ₍₂ , N	<u> </u>	12 . V			0.9169	
pH-dependency		~ ~			yes – pH s	5.4	



Table 7.1.3.1- 5:	Soil adsorption/desorption for BCS-CN88460-carboxylic acid (M12) at neutral soil
	conditions (around pH 7.5)

Soil name	Soil type	OC [%]	pH (CaCl ₂)	K _f [mL/g]	K _{foc} [mL/g]	1/n	Evaluated on K level y/n / Reference
Dollendorf II, GER	loam	4.5	7.3	1.2635	28.1	0.9243	n / 2014; M-499692-00-1
Morris, Minnesota, USA	clay loam	2.40	7.7	1.178	49.1	0.9604	n / 2017; M-5898; 6-01-4
Geometric mean (n	i=2)				37.1	Ð	
Arithmetic mean (r	n=2)			Å	, Ô ⁵	0.9424	
pH-dependency				A	yes⊋pH	7.5	
			Ŕ	<u>o</u> , <u> </u>	~ ~	y Q	

CONCLUSIONS

For the leaching calculations, the adsorption of isoflucypram was described by the geometric mean K_{foc} value of 1580 mL/g ($K_{fom} = 9163$ mL/g) and the arithmetic mean freundlich exponent in of 0.9142.

For the leaching assessment of BCS-CN 88460-carbox Aic acid (M12), only the realistic worst case ($K_{foc} = 37.1 \text{ mL/g}, 1/n = 0.9424$) was taken into account:

CA 7.1.3.1.1 Adsorption and desorption of the active substance

The adsorption and desorption behaviour of isofficypram was assessed in two batch equilibrium studies using the pyracole labelled compound.

, and the second s	
Report:	₩CA 7,1,3.1.1/01; ; ; 2004; M-499024-01-1
Title:	OPyrazole-14 BCS-@N88460. Adsorption/@Sorption on four European soils
Report No.: O	y Enga-13-0521 y & O &
Document No:	M-499024201-1 A A O
Guideline (\$).	OECD test Gudeline No. 106 US ERA OCSPP Test Guideline No. 835.1230;
i i i i i i i i i i i i i i i i i i i	\bigcirc Canada PMRA Guideline DACO No \checkmark 2.4.2 \bigcirc
Guideline deviation(s)) not specified of a start sta

GLP/GEP:

Executive Summary

The adsorption behaviour of isofficypron was studied in four soils in batch equilibrium experiments in the dark at 20.2°C:

Soil	Source of	Texture (USDA)	pH (CaCl ₂)	OC [%]
Laacher Hot AXXa	MonheimGermany	loamy sand	6.0	2.1
Hoefchen am Horenseh 4a	Burscheid, Germany	silt loam	6.3	1.9
Hansebeider Hof	Burscheid, Germany	loam	5.4	2.3
Dollendorf Dr	Blankenheim, Germany	loam	7.2	5.1

Table 9.1.3.1.1- 1: Selected soils

The adsorption phase of the study was carried out using air-dried soils equilibrated in aqueous 0.01 MCaCl₂ solution with a soil-to-solution ratio of 1/20 for all soils. Isoflucypram was applied at nominal concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. Due to the low water solubility the test item was dissolved in 20 μ L methanol and added to 20 mL aqueous



solution (0.1% organic solvent). The desorption phase was performed by supplying pre adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution for one desorption cycle. Adsorption and the first desorption cycle took place for 24 hours. For the highest concentration, two additional desorption cycles were performed with 24 hours equilibration time each.

The aqueous supernatant after adsorption and desorption was separated by centrifugation and the test item amounts in the supernatants were analysed by liquid scintillation counting (LSC). After the last desorption step, the samples were extracted with acetone. The organic extracts were separated by centrifugation and the test item amounts in the supernatants were analysed by LSC. After the extraction, the soil was dried and combusted. The trapped carbon droxide after combustion was measured by LSC. The adsorption parameters were calculated using the Freuddlich adsorption isotherm.

The test item was sufficient stable throughout the study. The mean parental mass balances calculated as recovery of isoflucypram from aqueous supernation and soil extract in a project were 110.0, 1075, 103.0 and 104.8% of the applied radioactivity (AR) for soil Laacher Hof AXXa, Hoefchert am Hohenseh 4a, Hanscheider Hof and Dollendorr II, respectively.

Mean material balances were 104.7, 106.7, 107.0 and 006.1% AR for soil Laacher Hof AXXa, Hoefchen am Hohenseh 4a, Hanscheider Hof and Pollen forf II, respectively

In the definitive adsorption test 59.4 - 71.8% AR were adsorbed in soil Lacher Hof AXXa, 61.0 - 73.9% AR in soil Hoefchen am Hoherseh 4a, 63.12 - 74.6% AR in soil Hanscheider Hof an 76.8 - 87.1% AR in soil Dollendorf II.

The calculated adsorption constants K_{frads} of the Freundlich isotherms for the four test soils ranged from 29.184 to 58.711 mL/g (mean: 37.534 mL/g). The Freundlich exponents 1/rowere in the range of 0.8690 to 0.8972 (mean: 0.8839), indicating that the concentration of the test item affected the adsorption behavior in the examined concentration range

In general the organic matter in Soil, getermined as organic carbon content, is the most important component responsible for binding organic chemicals. Therefore, the adsorption coefficients $K_{f(ads)}$ were correlated with the organic carbon content of the soil, in order to get a comparability of the adsorption behavior in different soils. For isofkicypran the calculated $K_{oc(ads)}$ values varied between 1151.2 and 1569.1 mL/g (near) 380.0 mL/g

At the end of the adsorption and first desorption physe, 23.2 - 34.5%, 24.0 - 34.2%, 20.1 - 29.1% and 10.3 - 18.5% of the initially adsorbed amount were desorbed in soil Laacher Hof AXXa, Hoefchen am Hohenseh 4a, Hanscheider Hof and Dollendorf H, respectively.

The desorption $K_{f(des)}$ and the portmali (ed $K_{oc(des)}$ values were slightly higher (mean 1720.9 mL/g) than those obtained for the edsorption phase (mean 1380.0 mL/g).

There is no significant correlation between pH and adsorption for the investigated soils. The following table summarises the key data of this study:

Table	7.1.3.13 2:	Summe	bry of the adso	ption data o	<i>S</i> isofluc	ypram	
Soil	Tol I		Texture (USDA)	→ pH ≪ A (CaCa)	OC [%]	Clay [%]	K _{f(ads)} [mL/g]
		A 1 S2					

	(Co	Lexture	[»]рн 🔊	UC	Clay	I ∖ f(ads)	1/N	Noc(ads)
- A		(USDA)	(CaCD)	[%]	[%]	[mL/g]		[mL/g]
Laacher Hof AXX	Kaz A	loamy sand	6:9	2.1	9	29.184	0.8904	1389.7
Hoetchen am Hoh	enseh 4	silî loam 🔗	6.3	1.9	19	29.812	0.8788	1569.1
Hanscheider Hof	, ` .	Agam 🖉	5.4	2.3	21	32.430	0.8972	1410.0
Dollendorf II	A	loam	₹ 7.2	5.1	23	58.711	0.8690	1151.2
arith. mean &		* *				37.534	0.8839	1380.0
		A V						

12

According to Briggs¹ isoflucypram can be classified as immobile.

¹ Briggs, G. (1973)

A Simple Relationship Between Soil Adsorption of Organic Chemicals and their Octanol/Water Partition Coefficients *Proc.* 7th British Insecticide and Fungicide Conference, Nottingham/UK.



MATERIALS AND METHODS I.

A. MATERIALS

1. Test and Reference Items

A. MATERIALS	
1. Test and Reference Ite	ms a d d
Test item	
Pyrazole-labelled isofluc	ypram
Sample-ID:	KML 9427 😵 🥺 🖉 🖉
Specific activity:	3.90 MBq/mg (105.34 @Ci/mg)
Radiochemical purity:	> 99% (HPLC with radioactivity detector)
	>99% (TLC, scan)
Chemical purity:	> 98% (HPLC with UV-detector 210 nm)

Reference item

Reference items were not used.

Test Soils 2.

The study was carried out using four different sorts (see Pable The study was carried out using four different soils (see Pable 7.1.3.13). The soils were taken from agricultural use areas representing different geographical origin and different soils properties as required by the guidelines. The soils were samples freshes from the fields apper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 poin. O

Ø

		. 0)
Parameter & &	$\sqrt[n]{2}$ $\sqrt[n]{2}$ $\sqrt[n]{2}$ $\sqrt[n]{2}$ Res	ydrs
Soil designation	Fracher Bof AXXA	Hoefchen am Hohenseh 4a
Geographic location \mathcal{A}	× 5 0 %	
City City	Monheum 📎	Burscheid
State O S .	North Rhin Westphalia	North Rhine-Westphalia
Country 6	Germany 🖏	Germany
Soil taxonomic classification (USDA)	Sandy, noixed, mesic Typic	Loamy, mixed, mesic
		Typic Argudalf
Soil series $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$	no upformation available	no information available
Textural class (USDA)	Iopspry sand	silt loam
Sand [%] $(50 \mu m \text{mm})$ ~ 7	\$ \$ 83	25
Silt [%]50 µm 50 µm 50 ×		56
Clay [%] $(< 2 \mu m)$ $(< 2 \mu m)$	9	19
pH - in 0.41 M CaCl ₂ 1/2	6.0	6.3
- ipovater 1/1 🔍 Q	6.3	6.6
- in saturated paster 🔬 🏈 🚀	6.3	6.6
\swarrow in soil/1 N KCY 1/1 \checkmark \checkmark Q	5.8	6.0
Organic carbon (combustion) [% OC]	2.1	1.9
Organic matter ³ OM	3.6	3.3
Cation exchange capacity [meg/100 g]	9.5	10.8
Water holding capacity 0 2		
maximum (MWAC) [gH2O ad 100 g DW]	52.5	60.4
at 1/3 bar (pF2.0) [2]	15.6	26.4
Bulk density (disturbed) [g/cm ³]	1.22	1.09
a) a organic matter = % organic carbon x 1.724		

 \bigcirc Physico-chemical properties of test soils Table 7.1.3.1.1- 3:

DW: dry weight



Table 7.1.3.1.1- 3	(cont.):	Physico-chemical	properties of test soils
1 4010 / 110/11/1 0		i nysico chemicai	properties of test solis

Parameter	Re	sults 。
Soil designation	Hanscheider Hof	Dollendorf II
Geographic location		L. L
City	Burscheid	🐎 Blankenheim
State	North Rhine-Westphalia	North Rhine-Westphalin
Country	Germany	Germany
Soil taxonomic classification (USDA)	Loamy skeletal, mixed,	fine-loamy, noxed, active,
	semiactive, mesic Dystric	frigid Typic Eutrudept
	Tutrudept	
Soil series	no information available	no information available
Textural class (USDA)	loam y	loam o
Sand [%] 33		Q ⁴⁵
Silt [%] 50		
Clay [%] 17		° 23 V
pH - in 0.01 M CaCl ₂ $1/2$	× 5.4 6 ~	~ Z.2 A
- in water 1/1	© _ © 5.7 Q _	0 ^{7.4} 0 ⁷
- in saturated paste		
- in soil/1 N KCl 1/1		<u>7 </u>
Organic carbon (combustion) $[\% \text{ OC}]$		S. D.1
Organic matter ^{a)} [% OM]	~ 1.0	<u> </u>
Cation exchange capacity [meq/100g]		<u>ک</u> 20.6
Water holding capacity		
maximum (MWHC) [g H ₂ O ad 100 g DW]	~~60.7 ©~ ©	Ø9.3
at 1/3 bar (pF 2.0) [%]	y or 27.1% y	<u>\$</u> 6 41.4
Bulk density (disturbed) [g/em ³]	<u>1.04</u>	్ల టి 0.98
a) % organic matter = % organic carbon x 1.724		
DW: dry weight		
	\mathcal{F} \mathcal{F} a , O	* ¥

STUDY DESIG В.

1. Experimental Conditions For the pteriminary tests and for the definitive test the same equipment and experimental set-up was used. Important parameters for the test e.g. stability of the test itom, adsorption to vessel surface, soilto-solution ratio and equilibration time for adsorption were determined prior to the definitive test in preliminary tests.

In the definitive test, soil-to-solution ratios of 1/20 were osed. The corresponding amounts were 1 g soil (dry weight) and 20 mL colution (corrected for soil moisture). The equilibration time was 24 hours for adsorption and each desorption step.

ő Centrifuge tubes with screw cops (material fellow, volume 42 mL) were used as test vessels. They were shaken by a mechanical overhead straker in a walk-in climatic chamber at controlled temperature. R, Ô

Ľ

For the definitive test, the soil-to-colution ratio was 1 g soil (dry weight) and 20 mL aqueous 0.01 M CaCl₂ solution (corrected for soil moisture) for all soils. The nominal concentrations of the test item were 01, 003, 0 03, and 1, mg/L. 20 µL of the respective application solutions were pipetted into the suspensions consisting of 1 g soil (dry weight) and 20 mL aqueous 0.01 M CaCl₂ solution corrected for soil mosture), which were equilibrated for 72 hours.

Due to the stability of the test item, the partition of the test item was determined based on the amount of radioactivity in the supernatant. The experiments were performed in duplicate.



2. **Analytical Procedures**

In the definitive test, 1 g soil (dry weight) was weighed into the centrifuge tubes and 20 mL aqueous 0.01 M CaCl₂ solution (corrected for soil moisture) was added. After equilibration by shaking for 72 hours, 20 µL of the respective application solution was added. The adsorption measurements were 4 performed with five test item concentrations (0.01 to 1.0 mg/L) covering two orders of magnitude. The tubes were closed and the suspensions were agitated for a defined period of time using an overhead shaker at a constant temperature in the dark. The suspensions were centrifuged (10 min. at 4550 x g) and the supernatants were analysed by LSC. Additionally, the pH_yalues of the adsorption supernatants were determined.

For the desorption experiment the supernatants were centrifuged and decanted, weighed and replace by a corresponding volume of aqueous 0.01 M CaCl₂ solution.

After agitation for a defined period of time and centrifugation (14 min. at 4550 x g) the super matan was decanted, weighed and analysed as described above. 0

In case of the highest concentration, two additional desorption steps were performed. For the calculation of the mass balance, the remaining soil of the first replicates was extracted after the last desorption step with 10 mL acetone at ambient temperature boshaking for 30 minutes, centrifuged (10 min. at 4550 x g) and the supernatant was analysed by LSC. Afterwards, the soil was doed, combusted and analysed by LSC.

3. Calculations

analysis of the adsorption or Adsorption and desorption isotherms were calculated by line desorption data according to the Freundlich equation

RESULTS ĂNĐ ĎISCUSS

A. MATERIAL BAYANG

The recovery of radioactivity for a soils & presented in Table 7.1.3.19-4 Material balances, were 104.7, 106.7, 107.0 and 106.1% AR for soil Laacher Hof AXXa, Hoefchen am Hohenseh 4a, Hanscheider Hof and Dollendorf II. 4/

The complete material balance values found for all samples demonstrated that no significant portion of radioactivity dissipated from the cost systems of was lost during sample processing.

	Star hereinings of applied instructions, one re-	pineure)	
Conc. ID	Set Set		
	∠Laacher Hof XXXa HoefChen an Hohenseh 4a	Hanscheider Hof	Dollendorf II
A		101.8	98.2
B		108.0	105.8
Ű.	\$103.9 ⁽¹)	107.4	108.8
, d D	106 .8 7 7.9	108.5	108.6
Έ	102.9	109.1	108.9
Mean ^{a)}	🔊 104.7 K 🖉 🖉 106.7	107.0	106.1
SD 4	4 ± 2.5	± 2.6	± 4.1
a) maan famil			

Table 7.1.3.1.1- 4:	Recovery of radioactivity after adsorption. desorption and extraction	1
	(Vas noncontage of applied rodiogatility and raplicate)	
	³ (as percentage of applied factor (average)	

ADSORPTION RESULTS В.

The dest item was stable whether the test conditions (parental mass balance: > 103% AR). Therefore, the sorption behaviour was calculated based on the radioactivity measured in the supernatant only.

The text was performed using soil-to-solution ratios of 1/20 (1 g soil dry weight and 20 mL solution). The equilibration time for adsorption was 24 hours.



ð

In the definitive adsorption test 59.4 - 71.8% AR were adsorbed in soil Laacher Hof AXXa, 61.0 - 73.9% AR in soil Hoefchen am Hohenseh 4a, 63.1 - 74.6% AR in soil Hanscheider Hof and 76.8 - 87.1% AR in soil Dollendorf II. The respective concentrations in solution and in soil and the percentage of adsorbed test item are summarised in Table 7.1.3.1.1 - 5.

Table 7.1.3.1.1- 5:	Concentration of isoflucypram in the solid and liqu	id phases at t	he end of adsorptio
	equilibrium	-0	

Concentration	Soil	solution Solution	Percentage adsorbed
of isoflucypram	[mg/kg]	[mg/L]	mean SD 🖉
Laacher Hof AXXA		k O	
Control	N/A	N/AQ o	
0.012 mg/L	0.170	° 0.003 01	$\sqrt{2}$ $\sqrt{2}$ $\sqrt{8} \pm 0$
0.031 mg/L	0.437	° (0009 ° (0	y ≥0.7 ±4.6 , 9
0.09 mg/L	1.279		√℃ 70.3 ± 1.7
0.29 mg/L	3.883		67.94 ± 1.5
1.05 mg/L	12.480	Q.427 A	\$ [™] 59.4 ± € \$ [™]
Hoefchen am Hohenseh 4a			
Control		N/A Q	
0.012 mg/L	Q.175 0° ~	0,003	3.9 ± 0.4
0.031 mg/L	~~√0.45 0 g ∅		©72.7 ±¥1.7
0.09 mg/L	1. 39 2 "0"	0.02Q	∂ 71 5 ± 0.9
0.29 mg/L	مَنَّة 3.888 مَنْ مَنْ مَنْ عَلَيْهُ 3.888 مَنْ مَنْ مَنْ مَنْ مَنْ مَنْ مَنْ مَنْ	0.094	67.4 ± 0.5
1.05 mg/L	6 12.818 0 ⁹	0.410	\$\$1.0 ± 0.8
Hanscheider Hof			
0.012 mg/L		NOA &	
0.031 mg/L 🦉	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<i>₽</i> ,003 ⁰	[∞] 74.6 ± 1.9
0.09 mg/L	0.442°	\$\$\$0.009\$ \$	71.4 ± 0.6
0.29 mg/ 🖉 🔊	[™] ¥295 [™]	v [~] 0.0 26 v	71.1 ± 0.7
1.05 mg/L S	<u> </u>	0° 0,4990 _Q	68.7 ± 1.1
0.012 mg/L "0"	© 13.2 <u>6</u> 4	0.388 🖉	63.1 ± 1.9
Dollendorf II			
Control	N/A St in	, ÌN∌A	
0.012 mg/L 💭	× ~ 0.206 ~ ~	0.002	87.1 ± 0.6
0.031 mg/b	0,524	0.005	84.7 ± 0.8
0.09 mg/L	544 ° 0	v 0.014	84.8 ± 0.4
0.29 mg/L C	0 <u>4.74</u>	> 0.051	82.2 ± 0.4
1.05 mg/L	O () 16.148 ()	0.243	76.8 ± 1.1
		× ¥	

The adsorption behaviour of isofficyprom in the concentration range of two orders of magnitude (i.e. from 0.01 to 1.0 mg/L) was accurately described for all soils with the Freundlich equation. The correlation coefficients of the individual isofficements were 0.9963 to 0.9979 (mean: 0.9973).

The calculated adsorption constants $K_{f(G)}$ of the Freundlich isotherms for the four test soils ranged from 29.1% to 58 11 mD/g (mean: 37.334 mL/g). The Freundlich exponents 1/n were in the range of 0.8690 to 0.8972 (mean: 0.8839), indicating that the concentration of the test item affected the adsorption behaviour in the examined concentration range.

In general the organic matter in soil, determined as organic carbon content, is the most important component responsible for binding organic chemicals. Therefore, the adsorption coefficients $K_{f(ads)}$ were correlated with the organic carbon content of the soil, in order to get a comparability of the adsorption behaviour in different soils. For isoflucypram the calculated $K_{oc(ads)}$ values varied between 1151.2 and 1569.1 mL/g (mean: 1380.0 mL/g).

An overview of the results according to the Freundlich equation is presented in Table 7.1.3.1.1-6.



.1.3.1.1- 6: Adsorption con	stants of isofiu	cypram in solis		a °
Soil	K _{f(ads)}	1/n	Koc(ads)	r ²
Laacher Hof AXXa	29.184	0.8904	1389.7	0.9963
Hoefchen am Hohenseh 4a	29.812	0.8788	1569.1 🞯	0.9979
Hanscheider Hof	32.430	0.8972	1410,0	0.9978
Dollendorf II	58.711	0.8690	1151.2	0.9976
Arith. mean	37.534	0.8839	13380.0	(),9973
Geo. mean	•		371.6	
FSORPTION RESULTS	Q			

Table 7.1.3.1.1- 6: Adsorption constants of isoflucypram in soils

C. DESORPTION RESULTS

L, One desorption step was performed for each concentration. At the end of the first desorption phase, 23.2 - 34.7%, 21.0 - 34.2%, 20.1 - 29.1% and 10.3 - 18.5% of the initially adsorbed amount were desorbed in soil Laacher Hof AXXa, Hoefehen and Hohenseh 4a, Hanscheider Hof and Dollendorf II, respectively. For the highest concentration, two additional desorption steps were performed. At the end of the second desorption phase, 31,4, 31,8,27.0 and 17,9% of the adsorbed amounts after the first desorption phase were desorbed in sol's Lancher Hot AXXa, Hoefchen am Hobensel 4a, Hanscheider Hof and Dollendorf II, respectively. At the end of the third desorption phase, 286, 30%, 24.7 and





Table 7.1.3.1.1- 7:	Concentration of isoflucypram in the solid and liquid phases at the end of desorption
	equilibrium

Concentration	Soil	Solution	Percentage adsorbed
of isoflucypram	[mg/kg]	[mg/L]	mean SD S
Laacher Hof AXXA			
Control	N/A	N/A	
0.012 mg/L	0.130	0.002	23.2 - 0.4
0.031 mg/L	0.329	0.005	24,95 = 0.7 3
0.09 mg/L	0.968	0.016	24.4 ± 1.6
0.29 mg/L	2.866	0.051	
1.05 mg/L	8.151	0.216	34.7 20.5 0
Hoefchen am Hohenseh 4	la		
Control	N/A		
0.012 mg/L	0.138	0.002 ×	21.0 ± 0.3
0.031 mg/L	0.350		225 ± 1.2
0.09 mg/L	1.005	Q.015 ₫	
0.29 mg/L	2.894	9.050 %	25.6≠0.2
1.05 mg/L	8,452	× × 0.21	Ø 34 2 ± 0.7 ©
Hanscheider Hof			
0.012 mg/L	N/A⊘ ∅	A A C	
0.031 mg/L		0.002 °C	° 20,4 ± 1.6
0.09 mg/L	0.340	0.005	23.1 ± 0.7
0.29 mg/L	© 0.9985 _ O	0.015	22.9 ± 0.4
1.05 mg/L	× 2.980	\$ 0.049 × ×	24.7 ± 0.7
0.012 mg/L 🔬	9 2 917 O 6	0°0.190	s 0 29.1 ± 1.6
Dollendorf II			K ^v
Control	N/A ~	N/A y	,
0.012 mg/ 🖉 😞	 ✓ Qc185 		10.3 ± 0.6
0.031 mg/L _Q	Q.460 %	04003 "	12.2 ± 0.5
0.09 mg/L	۵۵ الگ الگ	0.009 🔊	12.3 ± 0.5
0.29 mg/L	4 66	0.034	14.5 ± 0.5
🖉 05 mg/L 🔍 🖉	13.158	° √° 0,190	18.5 ± 0.9
		& Å	

The correlation coefficients of the individual isotheons were 0.9947 to 0.9978 (mean: 0.9964). The calculated desorption constants $K_{f(ds)}$ of the Freundlich isotherms for the four test soils ranged from 35.114 to 72.535 mb g (mean: 46.831 mb/g), the exponents 1/n were in the range of 0.8669 to 0.9069 (mean: 0.8842). The $K_{c(des)}$ values of the soils ranged from 1422.3 to 1897.3 mL/g (mean: 1720.9 mL/g). The $K_{c(des)}$ values were slightly higher than the $K_{oc(ads)}$ values (mean 1380.0 mL/g). An overview about the results according to the fournam in soils

Table 7.1.3.1.1 ₇ 8:	Desorption	constants	or Soflucypram in soils	
---------------------------------	------------	-----------	-------------------------	--

	Soil Soil Soil Soil Soil Soil Soil Soil	mL/g]	1/n	K _{oc(des)} [mL/g]	r ²
	Caacher Hof AXXa	36.038	0.8926	0.9947	1716.1
, K	Hoefer am Mohensen 4a	35.114	0.8669	0.9956	1848.1
B	Hatescheider Hof	43.637	0.9069	0.9975	1897.3
	Dollendorf II	72.535	0.8703	0.9978	1422.3
(Arith. mean	46.831	0.8842	0.9964	1720.9



III. CONCLUSIONS

The adsorption constants K_{f(ads)} of isoflucypram for the four test soils calculated based on the Freundlich isotherms ranged from 29.184 to 58.711 mL/g (mean: 37.534 mL/g). The respective K_{recads} values were in the range of 1151.2 to 1569.1 mL/g (mean: 1380.0 mL/g). The desorption constants K_{f(des)} of isoflucypram were slightly higher than the respective adsorption constants. There was no significant correlation between pH and adsorption for the investigated soil isoflucypram was stable in the course of the study. The parental mass balance for the adsor desorption phase was $\geq 103.0\%$ AR. No major degradation product was observed. Using the Briggs classification for the estimation \mathcal{A} the mobility of crop protection agents in based on K_f and/or K_{oc} values, isoflucypram can be classified as immobile. L. The results are included in the summary of the adsorption and desorption behaviours of isoflucypram and its major degradation product in soil given in section (7.1.2). **Report:** KCA 7.1.3 BCS-C 888460 Adsorbon/I Soils and One Title: sorption on [Pvrazole-Sedimen 032774-1 Report No.: Document No .: M-51834501 OPCD Guideline for the Pesting of Chemicals, No. 106, Adsorption/Desorption, 2000 Guideline(s): Commission Regulation (EU) No 283 2013 in accordance with Regulation (EC) No 11072009 USEPA Fate, Transport and Transformation Test Guidelines, OCSPP 835.1230, Asorption/Desorption (Batch Equilibrium), 2008 Anot specified 🖗 Guideline deviation(s): **GLP/GEP:** Executive Summary The adsorption/desorption characteristics of pyra@le-labelled.joflucypram was examined using two

Soil/sediment		Source Q	Texture	pН	OC
		J A N	(USDA)	(CaCl ₂)	[%]
EFS-487 (soil)		Sanger, CA SA	sandy loam	6.2	0.9
EFS-488 (soil)		Logisville NE, USA	silt loam	6.5	1.8
EF8-511 (sedimer	nt)	Lawrence KS, SA	silty clay loam	7.5	0.34

Table 7.1.3.1.1.9: Selected soils and sediment

North American soils and one North American sediment:

Preliminary experiments determined that isoflucypram (test material) had slight adsorption to the glass test vessel surfaces. However, $\leq 3\%$ adhered to glass in the presence of soil. The preliminary soil-to-solution ratio experiment was conducted with all three soil/sediment types (active soil) at 1:10, 1:4, and 1:25 soil-to-solution ratios. HPLC analysis of the adsorption aqueous fraction showed no degradation in all test systems. A 1:10 soil-to-solution ratio with two soils and one sediment was determined to be appropriate for the definitive study. The equilibration time experiment showed that isoflucypram was stable at the 24-hour time point.

One adsorption experiment and one desorption experiment were performed using the batch equilibration method with two soils and one sediment at five concentrations covering three orders of magnitude (0.005, 0.015, 0.05, 0.15 and 0.5 μ g/mL) of the test substance in 0.01 M calcium chloride.



Ś

The percent of isoflucypram adsorbed during the adsorption cycle to each matrix was calculated at all five test solution concentrations. The average percentage sorbed to soil or sediment at the end of the adsorption test ranged from 54.9 to 79.3% of the applied radioactivity. At the end of the desorption period, 15.9 to 33.4% of the applied radioactivity was sorbed to soil or sediment. The following tables summarise key data of this study.

Table 7.1.3.1.1- 10:	Freundlich adsorption isotherms of isoflucypram
1 4010 / 1100 1111 101	i reunanen ausor prion isotner mis or isotnacy pram

Soil/sediment	Texture	pH	OC	Kef(ads)	1/n	Kockads)	
	(USDA)	(Cated)	[%]	@mL/g	Ö	miL/g	
EFS-487, Sanger (soil)	sandy loam	6.2	0.9	13	1,0450	^{مي} 1394	1.04
EFS-488, Louisville (soil)	silt loam	¢6.5	1.8	25	0 .9101	13,84	
EFS-511, Lawrence (sediment)	silty clay loam	⇒ 7.5	0.34	Ø12 ([≫] 0.938₩	3594	K
Arith. mean	Ŵ			≈ 16.7	0,9\$46	2124	2/ 7
	×.	Ô,	N X			× *	
	0΄			~O	F s.	1	_ 0

Table 7 1 3 1 1- 11.	Freundlich desorption	isotherm	of isath	icvnes
1 abic /.1.3.1.1-11.	r reunanen desorption	BOULEI	5 01 1509110	icypg

			, C	
Soil/sediment	Texture 🔨	_γµH DOC L	Kuden	1/n Koc(des)
	(USDA) v	CaCh) [%P	[mtL/g]	
EFS-487, Sanger (soil)	sondy loapn	6,2 0,9	23 s	1.0442 2591
EFS-488, Louisville (soil)	Silt loan	6.5 1.8	¢ 33 ℃	0,9116 📈 1810
EFS-511, Lawrence (sediment)	silty day loan	7.5 0.34C	19	9538 5479

Based on the results isoftweypram can be classified in the 'inamobiles' mobility class in all soils/sediment according to the Broggs1 classification

Ø MATERIA A. 1. Test and Reference Item Test item Pyrazole-labelled 252,999 (dpm/μg) Standard-ID: ut Mole: Specific activity Radiochemical purit Referenceitem Nonzlabelled isofl@prand Standard-ID: Chemical purity

¹ Briggs, G. G. (1973)

A Simple Relationship Between Soil Adsorption of Organic Chemicals and their Octanol/Water Partition Coefficients Proc. 7th British Insecticide and Fungicide Conference, Nottingham/UK.



Test Soils and Sediment 2.

The two soils and one sediment selected for the study are typical of agricultural growing regions in North America and provide a variety of soil characteristics and geographic diversity.

Table 7.1.3.1.1- 12:	Physico-chemical properties of test soils and sediment	
1 4010 / 11 00 11 1 1 1 1	Thysico chemical properties of test sons and seament	

· 1	-			
Parameter		Results	<u> </u>	
Soil	EFS-487 (soil)	EFS-488 (soil)	EFS-511 (sediment)	Č
Geographic location	ČA			
City	Sanger 💎	Louisville	Lawrence	Ø
State	California	Nebraska	Kansas	1
Country	USA	USĂ	USA O	
Latitude and longitude	N 36.7 0 232	N 4150365₽°	39.0471331,	Ś
	W 120 46355	W 996.14983	-95.4965612	ŢĽ.
Soil taxonomic classification (USDA)	k. o°	no information av	affable 🔊 👾 🗸	Ŷ
Soil series		no information or	ailable	
Textural class (USDA)	🔬 sandy loam 🖉	sQt loam O	silty Clay loan	Υ.
Sand [%]	¢% _6%8.5 _√	» 15.5-	6.8 ×	/
Silt [%]	28.4	مر 63€¢ ``	x x 63.5 x	
Clay [%]	3.1	× \$1.5 č	2957	
pH - in 0.01 M CaCl ₂ (1:1)		6.5	Š §1.5 , Q	
- 1:1 soil:water ration Q^{ν}	6.7	7.0	° ~ 7.9 ~	
- in saturated paste	6.6 S		<u>_0 77</u>	
Organic carbon [% OC]	0.900	OT * 8	634	
Organic matter [% OM] 🔌 🎉	C ^V 45 00	→ 3.2 ×	<u>©</u> 0.58	
Cation exchange capacity [meq/400 g]	6.7	16.0	y 20.1	
Water holding capacity (gm/100 gm)	£ 27,60°	64.4 W	51.7	
% moisture at 1/10 bar		3 8.6 &	<u>کې</u> 44.1	
% moisture at 2.0 F units		38.60	4	
% moisture at 145 bar 4 2		o 27.8 Q	, 34.9	
% moisture ar 2.5 pF units				
% moisture at 15 bar		M7.7	15.7	
Bulk density (dispribed) [gm/cc]	¥ <u>\$</u> 926 S	0 0.96	1.02	
		¢ ~		
		, 0 ⁷		
STUDY DESIGN N &	N N U	A Y		

1. Experimental Conditions The test system consisted of individual capper glass test vessels (50-mL glass test tubes with Teflon-lined caps) containing the soil and test solution. The soil-to-solution ratio was determined in preliminary experiments. During equilibration, the test system was continuously agitated (horizontally) using a mechanical device to keep the soil in suspension. All experiments were conducted in duplicate (unless otherwise ported) are temperature of 20°C in the dark.

The test substance was dissolved in aqueous solution (0.01 M CaCl₂) at concentrations of 0.005, 0.015, 0.05, 0.15 and 0.5 μ g/m². All samples containing analytes (with or without soil) were studied in duplicate unless otherwise noted. Preliminary experiments were conducted to determine suitability of the test method and to establish test conditions.

The Freundlich coefficients, $K_{f,ds}$ and $K_{f(des)}$, and the exponential constants, $1/n_{(ads)}$ and $1/n_{(des)}$, were calculated from add of desorption and desorption isotherm experiments in each soil. K_f as a function of organic matter content (Kron(ads) and Kfom(des)) and organic carbon content (Kfoc(ads) and Kfoc(des)) were also determined. Š



2. **Analytical Procedures**

Liquid scintillation counting analysis was performed on samples to quantify radioactivity.

Combustion of soil samples: Air-dried soil samples were combusted to determine ¹⁴C residues remaining in soil after the relevant tests. Approximately 0.1 g sub-samples of each extracted soll pellet were weighed in triplicate into ceramic combustion boats and combusted for 2 minutes. The generated ¹⁴CO₂ was collected directly into Harvey[™] scintillation cocktail and assayed [®] LSC. The efficiency of the oxidizer was determined daily by combusting soil blanks and spiking the generated scintillation cocktail vials with a known volume of a ¹⁴C uracil standard (vial spikes). Aliquots of the same standard were then spiked onto son replicates that were then combosted (spils spikes). The oxidizer efficiency was calculated by dividing the recovered radioactivity from the soil C spikes by the mean radioactivity in the vial spikes. This correction factor was applied to each sample combusted on that instrument that day. Acceptable xidizer recoveries were between and 102%

HPLC analyses were conducted on all samples and the radioactivity detected using an m-line radioactivity detector. Radioactivity was detected in the enduent ising a liquid scintillation cell. The effluent was passed through the UV detector and then through the radioactivity flow detector. Radioactivity in the effluent was detected and quantified with a radioactive flow detector. Percentages of radioactivity in the separated components were quantified by integrating the peaks.

3. Calculations

Adsorption and desorption isotherms were calculated by linear repression analysis of the adsorption or desorption data according to the Freundlich equation. 1 P

RESULTS AND DISCUSSION

A. MATERIAL BALANCE

The material balance for each soil was defermined on each sample at each test concentration. The material balance for each sample in the adsorption desorption experiment was determined as the sum of the amount of radioactivity in the agueous phase of the adsorption and desorption phases and the amount of radioactivity in the soil phase (sum of extract and post extraction solids combustion) divided by the amount of radioactivity applied to the sample. The average material balances for each test concentration ranged from 93.4-11102% for the Sanger, CA (EFS-487) soil, 79.3 - 102.9% for the Louisville, NE (EPS-488) soil and 93 7-96.8% for the Lawrence, KS (EFS-511) sediment. The soil extracts, one replicate from sach soft/sediment type from the highest test concentration following desorption, were analysed by HPLS. The radioactivity associated with the extract was 100% pyrazolelabelled isoflucypram.

Table 7.1.3.1.1-1	3: Determination of	the mass balance for	adsorption/desorption experiments
L.	(as percentage of	applied radioactivity	, mean of two replicates)

	Concentration		Soil/sediment	
	[µg/mL]	EFS 487, Sanger, CA,	EFS-488, Louisville,	EFS-511, Lawrence, KS,
		Sandy loam (Soil)	NE, silt loam (soil)	silty clay loam (sediment)
	Ø.005 C	ک 107.4 ک	102.9	96.8
	~~ 0.01 ~	111.2	89.8	94.7
	0.05	ູ 🔊 97.7	89.0	94.3
P	o 0.15 °	101.3	79.3	93.7
Ş	\$ 0.5	93.4	93.3	94.0
	24			



B. ADSORPTION RESULTS

The percent of isoflucypram adsorbed during the adsorption cycle was calculated for both soils and one sediment at all five test solution concentrations. A summary of the average percent adsorbed on each soil can be found in the table below.

Table 71211 14.	A	
1 able /.1.3.1.1-14:	Average dercent adsorbed of isoflucybram on each soil/sedwinent	

Soil	Perc	entage adso (average ^{a)})
EFS-487, Sanger, CA, sandy loam (soil)	Ű	54.9 Č
EFS-488, Louisville, NE, silt loam (soil)	õ	79.3 Ø
EFS-511, Lawrence, KS, silty clay loam (sedin@nt)	4 F	61,Ø

a) Calculations performed using the data from all concentrations 0.008-0.5 cp/mL

The values for the Freundlich adsorption and desorption is otherms, K_f , were derived from the Jinear form of the Freundlich equation.

A summary of the adsorption isotherms for each soil carbo found in the table below. The values for the Freundlich adsorption isotherms, $K_{f(rds)}$, ranged from 12 mb/g in the EFS511, Lawrence, KS silty clay loam sediment to 25 mL/g in the EFS488, Couisville, ND, silt foam soil. The Freundlich adsorption isotherms, $K_{f(ads)}$, were normalised for the organic matter and organic carbon content for each soil to calculate the soil sorption coefficients, $K_{fom(ads)}$ and $K_{f(cds)}$. The K_{founds} values ranged from 778 mL/g in the EFS-488, Louisville, NE silt loam soil to 210 mL/g in the EFS-488, Louisville, NE silt loam soil of 210 mL/g in the EFS-517, Lawrence, KS, silty clay loam sediment while the $K_{foc(ads)}$ values ranged from 1,384 mL/g in the EFS-488, Louisville, NE, silt loam soil of 3,594 mL/g in the EFS-511, Lawrence, KS, silty clay roam sediment.

			S S	. Q.	
Table 7.1.3.1.1-15:	Adsorption	stants of isofl	ucypram	im soils ()	
					~

	\sim		, 4	\bigcirc				
Soil		le le		Kf(ads)	Kfom(ads)	Koc(ards)	1/n	r ²
	Č,	<u>, Ö</u>	<u> </u>	[mL/g]	[ma/L/g]	[mJ _/g]		
EFS-487, Sanger, 🚱	l, sandy	loam (soi	l),	Ĩ.	⇒ [*] 837_© [*]	\$394	1.0150	0.9881
EFS-488, Louisx@e,	NEQilt	loam (soi	ib ^y co	×25 🎓	, 77 8 °	~1384	0.9101	0.9978
EFS-511, Lawrence,	K&, silty	Actay loan	m (sediment)	2 12 5	2007 🦼	Ø 3594	0.9387	0.9992
Arith. mean	Ŕ			16.7	@240,7°°	2124	0.9546	0.9950
Geo. mean	Ö.	S.				1907		
		\$, \$	~~··	۰. U				

C. DESORPTION RESULT

\$1

The percent of isoflucy pram desorbed from the ofl was calculated for each soil/sediment at each of the five test solution concentrations. A summary of the averaged percent desorption's for each soil can be found in the table below. The average values ranged from 15.9% in the EFS-488, Louisville, NE, silt loams oil to 33.4% in the EFS-487, Sanger, CA sandy loam soil.

Table 7.1.3.1.1- 16:	Average	percent	désørbed) f isoflucypramon	each soil/sediment
	9 0	1 (//	~~~	v 1	

Soil C C C C	Percentage desorbed (average ^{a)})
ECS-487, SangeOCA, sandy loan (soil)	33.4
EFS-498, Louisville, SE, silt loam (soil)	15.9
EFS 1, Lawrence KS, silty clay loam (sediment)	30.9

a) Calculations performed using the data from all concentrations 0.005-0.5 μ g/mL

A sumplify of the desorption isotherms for each soil can be found in the table below. The values for the Freundlich desorption isotherms, $K_{f(des)}$, ranged from 19 mL/g in the EFS-511, Lawrence, KS, silty clay loam sediment to 33 mL/g in the EFS-488, Louisville, NE, silt loam soil. The Freundlich



desorption isotherms, K_{f(des)}, were corrected for the organic matter and organic carbon content for each soil to calculate the soil sorption coefficients, K_{fom(des)} and K_{foc(des)}.

Table 7.1.3.1.1- 17:	Desorption	constants	of isc	oflucypram	in	soils

Table 7.1.3.1.1- 17: Desorption constants of isof	lucypram	in soils	~			ð,
Soil	K _{f(ads)} [mL/g]	K _{fom(ads)} [mL/g]	Koc(ads)	1/n	r^2	
EFS-487, Sanger, CA, sandy loam (soil)	23	1555	2591	1.044	09942	
EFS-488, Louisville, NE, silt loam (soil)	33	م 1018	1810	0.9116	×0.9978	
EFS-511, Lawrence, KS, silty clay loam (sediment)	19 🚿	3212	2 5479	@9538	∑ 0.99 03	"®

III. CONCLUSIONS

The adsorption constants K_{f(ads)} of isoflucyprate for two test soils and one sediment calculated based on the Freundlich isotherms ranged from 12 to 25 mL/g mean 16.7 pL/g). The respective Koc(ads) values were in the range of 1384 to 3594 mL/g (mean: 2194 mL/g). The desorption constants K_{f(des)} of isoflucyprane were slightly higher than the respective adsorption constants. There was no significant correlation between pH and adsorption for the investigated soils.

Using the Briggs classification for the estimation of the probility of crap protection agents in soil 0 6 based on Kf and/or Koc values soflueypram can be Classified as immobile.

based on Kr and/or K_e values, is oflueypram can be classified as itimobile. The results are included in the submary of the adsorption and desorption behaviours of isoflueypram and its major degradation product in soil gives in sector CV7.1.3.1.



CA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products

The adsorption and desorption behaviour of the major soil degradation product BCS-CN88660carboxylic acid (M12) was assessed in two batch equilibrium studies using the pyrazolyl- $kabelled_{0}$ compound.

Report:	KCA 7.1.3.1.2/01; 2014; M-499692-01,1
Title:	[pyrazolyl-4-14C] BCS-CY26497: Adsorption/desorption in five different soil
Report No.:	A\$357 O A A A A
Document No.:	M-499692-01-1
Guideline(s):	OECD Guideline for Testing of Chemicals, No 106" "Adsorption" - Sing &
	a Batch Equilibrium Method", an. 21, 2000
	US EPA, Fate, Transport and Fransformation Test Gadeling OPP \$ 835,1230
	Sediment and Soil Adsorption/Desorption/sothering January 1998
Guideline deviation(s):	not specified \hat{k} $\hat{\omega}^{\dagger}$ $\hat{\lambda}^{\dagger}$ $\hat{\omega}^{\dagger}$ $\hat{\omega}^{\dagger}$ $\hat{\omega}^{\dagger}$
GLP/GEP:	yes O' , A A A
	$A \widetilde{\sigma} \sigma$

Executive Summarv

The adsorption behaviour of BCS-CN 3460 carbox fit acid (M12) was studied in five so equilibrium experiments in the dark at 20.2 °C. ls in batch

Soil 🐇	Source S Texture pH	OC
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	[%]
Wurmwiese 📎	Monheim, Germany / Sandy toam / 5.3	1.9
Hoefchen am Hohenseh 4a	Burscheid, Germany 🖉 🖓 silt Høam 🌾 , 🔊 6.3	2.0
Dollendorf II	Blankenheim, Gernamy 🖉 Ioam 🔿 🦨 7.3	4.5
Guadelupe	CAUUSA 6.7	0.7
Springfield	NE, USA N S silt Gam S 6.6	1.7

Table 7.1.3.1.2-1: Selected soils

The adsorption phase of the study (definitive test) was carried out using pre-equilibrated air-dried soil with pyrazofyl-labelled BCS-CX88460 carboxylic acid (MIQ) at concentrations of nominal 1.00, 0.30, 0.10, 0.05, and 0.01 mg/L in the dark at 20°C for 24 hours. \bigcirc

The equilibration solution used was 0.01 M aquéons CaCl₂ solution for all soils.

After the preliminary test I following soil to solution ratios were defined to the soils: Wurmwiese, Höfchen am Hohenseh Dollensorf II and Springfield, NE 2 and Guadalupe, CA 1:1.

Desorption phase of the study was Garrie out bo supplying pre-adsorbed soil specimens with fresh 0.01 M aqueors $CaCH_2$ solution for one desorption cycle for 24 hours.

Ľ The aqueous supernatant after adsorption and desorption was separated by centrifugation and the BCS-CN88460-carboxylic acid residues in the supernatant were analysed by liquid scintillation counting (LSC). The adsorption/desorption@parameters were calculated using the Freundlich adsorption isotherm.

Test systems withour soil were used as control in preliminary test and did not show adsorption to the vessels or degradation.

For all soils the parental mass balance after 72 h showed that > 90% of applied pyrazolyl-labelled BCSECN88460-cafe oxylic acid could be recovered. This demonstrates that the test item was sufficient stable for test in these soils. Ĉ

The mass balance in the definitive test of the soils was determined by LSC of the supernatants after adsorption/desorption and by combustion of the remaining soils. The overall material balance for all



concentrations for individual specimens was in the range of 91.3 - 101.8%, 95.9 - 103.3%, 96.5 - 103.2%, 99.1 - 111.2% and 93.0 - 100.9% of the applied radioactivity in soils Wurmwiese, Höfchen am Hohenseh 4a, Dollendorf II, Guadalupe, CA and Springfield, NE, respectively.

and In the definitive adsorption test 48.9 - 58.4%, 26.0 - 38.3%, 37.3 - 47.0%, 19.3 - 6.8% 35.5 - 46.5% of the applied test material was adsorbed in soils Wurmwiese, Hötchen am Hohenseh an Dollendorf II, Guadalupe, CA, Springfield, NE, respectively.

The calculated adsorption constants $K_{f(ads)}$ of the Freundlich isotherms for the five test soils from 0.3 mL/g to 2.0 mL/g. The Freundlich exponents 1/n were in the range of 0.8952 indicating that the concentration of the test item did affect the adsorption behaviour.

At the end of one adsorption and one desorption phase, 24.7 - 34.2%, 34.2 397.2% 43.0 - 53.7% and 29.9 - 43.7% of the initially adsorbed amount were desorbed in soils Wurm Höfchen am Hohenseh 4a, Dollendorf II, Guadalupe, CA, Springfield, NE, respectively. The mean desorption $K_{f(des)}$ ranged from 0.2 2.2 m/g and and the normalised $K_{oc(des)}$ ranged from 34.5 – 116.3 mL/g.

The following table summarises the key soil propertie

Table 7.1.3.1.2- 2:	Summary of the a	dsorption data	of BCS-CN8	8460 carbox	Alic acid M12)	, Ô
	• • • •		~ //		·	. "

	0 .	~	Ň			N
Soil	Texture (USDA)	pH (CarCl ₂) ₅	ФС [%]	Kf(ado [mL/g]		Koc(ads) ∑[mL/g]
Wurmwiese	(sandy loam	£ 5.3 m	1.96	\$2,0	©0.9297	105.8
Hoefchen am Hohense 4a	Silt loann	6,3	2.0	\$0.8 °	0.8952	37.9
Dollendorf II 👋 🔬	loam 🔹 🔊	<i>ā</i> ,3	\$4.5	1.3	0.9243	28.1
Guadelupe 🖉 🖉	sandy loam	Ø6.7 s	0.7	Q.3	°≈ 0 .9311	38.4
Springfield	Şilt loat 🧳 🔬	6.6	1.7	Q.2 '	¥0.9185	70.7
Arith. mean		,~Q~		£y 1.1 €	0.9198	56.2
		e V	S) (

MATERIALS AND METHODS According to Briggs depending on the soft type the molotity of BCS -CN88460-carboxylic acid can be classified as mobile to inter mediate mobile in the tested soils

MATERI

1. Test and Reference Ite

Test iten

Pyrazolyl-labelled BCS-CN88460-carboxylie acid (M12)
Sample-ID: KOVIL 9692	
Specific activity: 3 2.92 MBq/mgQ105.97 µCi/m	ng)
Radiochemical purity: $\$ > 99\%$ by $\pounds LC$	

Briggs, G. G. (1973)

A Simple Relationship Between Soil Adsorption of Organic Chemicals and their Octanol/Water Partition Coefficients Proc. 7th British Insecticide and Fungicide Conference, Nottingham/UK.



Reference item

Non-labelled BCS-CN88460-carboxylic acid (M12) BCS-CY26497-01-01 Batch code: Chemical purity: 97.0%

Lest Soils
 Five test soils (three of European origin, two of USA origin) were used within this study, chosen to cover a representative range in soil physico-chemical properties. The physico-chemical properties of the test soils are given in the following table:
 Table 7.1.3.1.2- 3: Physico-chemical properties of test soils

Parameter Regults Regults Soil designation Wurgwiesse Herchensam Bollepdorf II, Hohensch 4a Geographic location Monheim Birscheid Blankeaheim State Norde Rhine, Westphalia Birscheid Blankeaheim Country Geographic Westphalia Cernany Gefrany Latitude and longitude Ni 512/64.857 N 81° 04.944 N 50° 22.599? Soil taxonomic classification(USDA) no information available Cernany Soil taxonomic classification(USDA) ano information available Od 324° De 06 24.001° Soil taxonomic classification(USDA) sand/loam silt loam Ioam Sand [%] (20 µm² 2 µm² 55 21 39 Silt [%] (2 µm² 50 µm² 55 21 39 Silt [%] (2 µm² 50 µm² 55 21 39 Silt [%] (2 µm² 50 µm² 56 6.6 7.5 Organic carbor (consustion) % 0 C? 1.9 2.0 4.5 Organic carbor (consustion) % 0 C? 1.9 3.4 7.74 Geographic (Deveryetar			× × ×
Soil designation Wurgwesse Heetchergam Dollepdorf II, Hohenseh 4a Geographic location Monkeim Barscheid Bankenteim State North Rhine Werstphalia Werstphalia Werstphalia Country Germany Germany Germany State Soil taxonomic classification (USDA) no information available North Rhine Soil series no information available North Rhine Soil taxonomic classification (USDA) no information available North Rhine Soil series no information available It oata Soil taxonomic available Soil taxonomic classification (USDA) sand Vloam silt loata It oata Sand [%] (2 µm 2 nmf) 55 32 63 7.3 Silt [%] (2 µm 2 nmf) 55 6.6 7.5 Organic carbor (combustion) % OC 1.9 2.0 4.5 Organic matter [% OM] 3.37 3.44 7.74 Garlon exchange capacit (mod/90 g] 9.9 11.0 19.8 Soil designation Gerdalupe Springfield NE Georaphic locatio	Parameter	<u> </u>	Results 0	
Geographic location Hohensen 4a Processor City Monpeim Barkcarbeim State Nordv Rhine- Westphalia Barkcarbeim Country Germany Germany Latitude and longitude RI 51° 04.857 Nof 204.014 Soil series no information available Soil 22.899° Soil series no information available Soil 22.899° Textural class (USDA) sandv loam silt loam Sand [%] (2 µm 50 am) 29° 65° Soil series no information available Iata PH - incGaCl 7.3 6.3 7.3 in watec 7.3 6.3 7.3 organic matter [% OM] 1.9° 2.0 4.5 Organic matter [% OM] 33° 6.6 7.5 Organic carbon (classificationf/USDA) Sind aluge CA Springfield NE Soil designapto Germany 9.9 11.0 19.8 Soil designapto Germany Germany 4.5 10.1° Soil designapto Germany Germany 5.6 6.6 7.5	Soil designation	O' Wunniwiese	Hoefchen am	Dollendorf II
Geographic location Monthelm Binscheid Bankcetheim State Nortb Rhine Westphalta Korth Rhine Country Germany Germany Germany Germany Latitude and longitude M 51 204.857 Noft 0.4041 M 50° 22.899' Soil taxonomic classification (USDA) no information available No and 0.4041 M 50° 22.899' Soil series 0 no information available No and 0.4041 M 50° 22.899' Textural class (USDA) sand Vloam silt loam silt loam Sand [%] (2 µm 50 µm) 29' (05 35 Clay [%] (2 µm 50 µm) 29' (05 35 Clay [%] (2 µm 50 µm) 29' (05 35 Clay [%] (2 µm 50 µm) 29' (05 35 Clay [%] (2 µm 50 µm) 29' 05 35 Clay [%] (2 µm 50 µm) 29' 05 35 Organic carbon (combustion) [% OC] 1.9' 2.0 4.5 Organic matter [% OM] Gerdalupe Springfield NE Nebraska			Piohenseh 4a	O' Q'
City Montperim Burscheite Mankeapeim State Norbo Rhines Westphala Westphala Country Germany Germany Germany Latitude and longitude No 19 04 857 No 19 04 924 850° 22.899° Soil taxonomic classified tion (USDA) no information available Ison 22.899° Soil series on information available Ison 22.899° Soil series on information available Ison 39 Sitt [%] (2 µm 20 µm) 55 24 39 Sitt [%] (2 µm 20 µm) 55 66 7.5 Organe carbor (combustion) % OC 1.9 2.0 4.5 pH - inCACl 5.6 6.6 7.5 6.6 7.5 Organe carbor (combustion) % OC 1.9 2.0 4.5 Organic matter [% OM] Gerdalupe Springfield NE Springfield NE Geographic Bocation Gerdalupe Springfield NE No 10.75 Organic matter [% OM] Gerdalupe Springfield NE No 10.72 Soil taxonomic class/tration (USDA) no information available <	Geographic location			
State Sorth Rame Controstmine- Sorth Rame Controstmine- Westphalia Germany Germany Germany Latitude and longitude N 51204.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 07° 06.324' DE 06° 43.001' Soil series N 51204.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 07° 06.324' DE 06° 43.001' Soil series N 51204.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 07° 06.324' DE 06° 43.001' Soil series N 51° 04.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 07° 06.324' DE 06° 43.001' Soil series N 51° 04.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 07° 06.324' DE 06° 43.001' Soil series N 51° 04.857 N 41° 04394' N 50° 22.899' E 06° 55.250 E 06° 43.001' Soil series N 51° 04.857 N 41° 040° N 41° 05° N 41°	City	Monheim	Borscheid	Blankerneim
Country Westphala Westphala Westphala Westphala Latitude and longitude N 51° 94.857° N 51° 94	State	North Rhine-	North Rame-	North Knine-
Contruy Certain	Country & W	«Westphana	Westphalla	westphaliz
Latitude and longitude $(Sin S1 Q4.85) = [Sin S1 Q4.85] = [Sin S1 Q4.85] = [Sin S1 Q4.85] = [Sin S1 Q4.85] = [Sin Q4.85] = [Sin$		Germany ~	· Germany U	Sermany
Soil taxonomic classification (USDA) no information available Soil series 0 no information available Textural class (USDA) sandyloam silt loam Sand [%] (60 µm 2 µm) 29 65 Silt [%] (2 µm 50 µm) 29 65 35 Clay [%] (2 µm 50 µm) 29 65 35 DPH - in CaCl- 7.3 6.3 7.3		E 060 55.250	1 0 0 0 0 1 0 1 0 1 1 0 1 1 1 1 1 1 1 1 1 1	©E 06° #3.001'
Soil seriesno information availableTextural class (USDA)sandy loamsilt loamSand [%](60 µm) 2 µm² 55 24993529 65 Clay [%](2 µm) 50 µm² 29 pH - in CaCl 53 6.3 - in CaCl 56 6.6 - in water 56 6.6 Organic carbon (combustion)[% OC] 1.9 29.9 21.0 4.5 Organic carbon (combustion) $1\% OC$ 1.9 29.9 21.0 4.5 Organic carbon (combustion) $1\% OC$ 1.9 29.9 21.0 4.5 Organic carbon (combustion) $1\% OC$ 1.9 29.9 21.0 1.0 29.9 21.0 1.0 29.6 29.9 11.0 29.6 29.9 11.0 29.6 29.9 29.7 11.0 29.7 29.7 29.7 29.7 20.6 29.9 20.6 29.9 20.6 29.9 20.6 29.9 20.6 29.9 20.6 29.9 20.6 29.9 20.6 29.9 20.6	Soil taxonomic classification (USDA)	no in	Normation availad	ble
Textural class (USDA)sand valuesilt loafaloamSand [%](50 µm 2 µm 30 µm)552139Silt [%](2 µm 50 µm)296535Clay [%](\leq µm)296535pH-in CACl,5.66.67.5Organic carbon (combustion) [% OC]1.9204.5Organic matter [% OM]3.273.447.74Cation exchange capacity (meq/400 g)9.911.019.8Soil designationGradalupeSpringfield NEGeographic SocationGradalupeSpringfield NECityGradalupeSpringfield NEGeographic Socation03.5%City03.5%Soil taxonomic classification0Soil series0012.7Sing [%]12.7Sing [%]12.7Sing [%]25Soil series0.080.860.80.860.80.91.12.72.72.77.20.66.66.66.67.27.27.20.526.50.60.80.90.91.12.9Cation exchange capacity [meq/100 g]16.116.1	Soil series	no įr	nformation availal	ole
Sand [%] (50 µm ² 2 µm ⁴) 55 21 39 Silt [%] (2 µm 50 µm) 29 65 35 Clay [%] (2 µm) 73 63 73 PH -in CaCl, 73 63 73 yowater 5.6 6.8 7.5 Organic carbon (combustion) [% OC] 1.9 20 4.5 Organic matter [% OM] 327 3.44 7.74 Gaion exchange capacity (med/400 g) 29.9 11.0 19.8 Soil designation Guadalupe CA Springfield NE Geographic focation Guadalupe Springfield NE Cubarty USA USA Latude and longitude 35° 00' 05.6'' N 96.15085 W 120° 36' W 41.03725 Soil taxonomic classification (USDA) no information available Textural class (USDA) Sandy loam Sandy loam silt loam Sandy [%] 32 Giain carbon (combustion) [% OC] 0.7 Organic matter [% OM] 1.1 2.7 7.2 Sht[%]	Textural class (USDA)	sandy loams	silt loator	🛇 loam
Silt [%] (2 µm ² 50 µm ³) 29 05 35 Clay [%] (< 4µm)	Sand [%] 🖉 50 µm 🖓 2 mp 🖗	ي 55 ∞	× 21 ×	39
Clay [%] (<3, m) 16 14 26 pH -in CaCl, 3.3 6.3 7.3 in water 5.6 6.6 7.5 Organic carbon (combustion) [% OC] 1.9 2.0 4.5 Organic matter [% OM] 327 3.44 7.74 Gation exchange capacity (med/00 g) 9.9.9 11.0 19.8 Soil designation Gatadalape CA Springfield NE Geographic location Gatadalape CA Springfield NE Contry USA USA USA Lattude and longitude 35° 60' 05.6'' N 96.15085 W 41.03725 Soil taxonomic classification (USDA) no information available Netraska Soil series 0 no information available Netraska Soil series 0 0 10.1'' 12.7 12.7 She [%] 3.2 60.8 60.8 60.8 60.8	Silt [%] (2 µm ² 50 µm ³) (2	29 × 29	65 4	35
pH- in CaCl: - in water7.3. in water. 5.6. 6.6Organic carbor (combustion) $[\% OC]$ 1.9Organic matter [% OM]. 327. 3.447.74Cation exchange capacity (meq/400 g). 9.9Soil designation. Guadalupe CASoil designation. GuadalupeCombry. USAUSA. USALatitude and longitude. 35° GP 05.6''N 96.15085. W 220° 36'W 120° 36'. W 41.03725. 10.1''. Sandy loamSoil taxonomic classification (USDA). no information availableSoil series. no information availableTextural class (USDA). sandy loamSandy [%]. 1.12.7. 2.7Sife [%]. 32.8. 6.6. 6.6. 7.2. 7.2. 7.2. 7.2. 7.2. 7.2. 7.3. 1.1. 2.9Cation exchange capacity (meq/100 g). 16.1. 16.1	Clay [%] 🖉 (<޵m), 🔊 🏷		14 _@	26
in water5.66.67.5Organic carbon (combustion)[% OC]1.92.04.5Organic matter[% OM]3.273.447.74Carlon exchange capacity (meq.400 g)9.911.019.8Soil designationGradalupe CASpringfield NEGeographic locationGradalupeSpringfield NECountryGradalupeSpringfieldStateCaliforniaNebraskaCountryUSAUSALatitude and longitude35° Gt' 05.6''N 96.15085W 120° 36'W 120° 36'W 41.03725Soil taxonomic classification (USDA)no information availableSoil seriesno information availableSand[%]5612.7State %60.8Glay [%]1.426.526.5pH6.66.66.66.87.2Oreanic carbon (combustion) [% OC]0.70.71.7Organic matter [% OM]1.12.9Cation exchange capacity (meq/100 g)16.116.1	pH - in CaCl ₂	× × × 3	0 ⁴ 6.3 9	7.3
Organic carbon (combustion) % OC 1.9 2.0 4.5 Organic matter % OM 3.27 3.44 7.74 Cation exchange capacity (meq.400 g) 9.9 11.0 19.8 Soil designation Gradalupe CA Springfield NE Geographic location Gradalupe Springfield NE Construct Gradalupe Springfield NE Geographic location Gradalupe Springfield NE Constry USA USA Latitude and longitude 35° Gt' 05.6'' N 96.15085 W 120° 36' W 120° 36' W 41.03725 Soil taxonomic classification (USDA) no information available Textural class (USDA) Sandy loam silt loam Sand[%] 56 12.7 12.7 Site (%) 323 60.8 60.8 Glay [%] D.4 26.5 26.5 Granic carbon (combustion) [% OC] 0.7 1.7 Organic matter [% OM] 1.1 2.9 Cation exchange capacity (meq/100 g) 16.1 16.1	- @ waterO	£ ⁹ 5.6	6.6	7.5
Organic matter [% OM] 3.27 3.44 7.74 Gation exchange capacity [meq/400 g] 9.9 11.0 19.8 Soil designation Guadalupe CA Springfield NE Geographic Scation Springfield NE Geographic Scation Guadalupe Springfield NE Springfield NE Geographic Scation Guadalupe Springfield NE Springfield NE Gata alupe Springfield Nebraska Nebraska Colliformation VISA USA USA Ladude and longitude N 35° Gt' 05.6'' N 96.15085 W 120° 36' W 41.03725 10.1'' Soil taxonomic classification (USDA) no information available Textural class (USDA) Sandy loam silt loam Sandp[%] 32.5 60.8 60.8 Gatay [%] U.4 26.5 26.5 Organic carbon (combustion) [% OC] 0.7 1.7 Organic matter [% OM] 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1	Organic carbon (condustion) [% OC]	,)~@ <u>2</u> .0	4.5
Carlon exchange capacity (meq.400 g) 9.9 11.0 19.8 Soil designation Cardalape CA Springfield NE Geographi Ocation Geadalupe Springfield NE City Geadalupe Springfield State California Nebraska Country USA USA Latude and longitude A 35° Ør 05.6'' N 96.15085 W 120° 36' W 120° 36' W 41.03725 Soil taxonomic classification (USDA) no information available Soil series No information available Textural class (USDA) sandy loam Sift [%] 323 60.8 60.8 Galay [%] 0.4 63.8 7.2 7.2 7.2 Oreanic carbon (combustion) [% OC] 0.7 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1	Organic matter [% OM]	~ 3.27 _Q	3.44	7.74
Soil designation Guadalupe CA Springfield NE Geographic location Gnadalupe Springfield City Gnadalupe Springfield State California Nebraska Commry USA USA Latitude and longitude N 35° 0° 05.6° N 96.15085 W 120° 36' W 41.03725 Joil taxonomic classification (USDA) no information available Soil series no information available Textural class (USDA) sandy loam Sift[%] 325 Go.8 60.8 Glay [%] 0.4 26.5 26.5 9H 6.6 6.8 7.2 7.2 7.2 Organic carbon (combustion) [% OC] 0.7 1.1 2.9 Cation exchange capacity [meg/100 g] 16.1	Cation exchange@apacity [meq/10 g]	\$9.9	× 11.0	19.8
Geographic Ocation Geodalupe Springfield City Geodalupe Springfield State California Nebraska Country USA USA Lattude and longitude N 35° 07' 05.6'' N 96.15085 W 120° 36' W 41.03725 Soil taxonomic classification (USDA) no information available Soil series no information available Textural class (USDA) Sandy loam Silt loam silt loam Sandp[%] 325 60.8 60.8 Glay [%] 1.4 26.5 26.5 9H 6.6 6.8 7.2 7.2 7.2 Oreanic carbon (combustion) [% OC] 0.7 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1	Soil designation	Guadaløpe CA 🔬	Springfield NE	
City StateGnadalupeSpringfield Nebraska USALatitude and longitudeVSAUSALatitude and longitudeVSCN 96.15085 V 120° 36'VV20° 36'W 41.03725 10.1''Soil taxonomic classificationN 000000000000000000000000000000000000	Geographic Socation	No No		
State Oaliformat Nebraska Country USA USA Lattude and longitude N 35° Qr' 05.6'' N 96.15085 W 120° 36' W 41.03725 Soil taxonomic classification (USDA) no information available Soil series no information available Textural class (USDA) sandy loam silt loam Sand[%] 56 60.8 60.8 Qay [%] Qay 66.6 66.6 M 20° 0.7 1.7 Site [%] 32.5 60.7 1.7 Site [%] 32.5 60.8 60.8 Qay [%] Qay 0.7 1.7 Organic carbon (combustion) [% OC] 0.7 1.7 Organic matter [% OM] 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1	City Q D S S O S	Gaadalupe	Springfield	
Country \bigcirc <	State \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O}	Oálifornúá	Nebraska	
Latitude and longitude 35° (4° 05.6''N 96.15085W 120° 36'W 41.03725Soil taxonomic classification (USDA)no information availableSoil series0Textural class (USDA)sandy loamSand [$\%$]5612.712.7Sift [$\%$]32.560.860.8Clay [$\%$]0.426.526.59H6.66.66.6987.27.27.2Organic carbon (combustion) [$\%$ OC]0.71.12.9Cation exchange capacity [meq/100 g]16.1	Country 0 0 0	USA V	USA	
Soil taxonomic classification (USDA)No information availableSoil seriesno information availableSoil seriessandy loamTextural class (USDA)sandy loamSand [%]5612.712.7Sand [%]32%60.860.8Clay [%]0.426.526.59H6.66.87.27.27.2Organic carbon (combustion) [% OC]0.71.12.9Cation exchange capacity [meq/100 g]16.1	Latitude and longitude	A 35° OU 05.6''	N 96.15085	
Soil taxonomic classification (USDA) no information available Soil series no information available Textural class (USDA) sandy loam Sand [%] 56 Sht [%] 325 Sht [%] 325 Organic carbon (combustion) [% OC] 0.7 Organic matter [% OM] 1.1 Cation exchange capacity [meq/100 g] 16.1		W 120° 36'	W 41.03725	
Soil taxonomic classification (USDA) ino information available Soil series ino information available Textural class (USDA) ino information available Sand [%] 56 Sife [%] 326 Glay [%] 0.4 Soil carbon (combustion) [% OC] 0.7 Organic matter [% OM] 1.1 Cation exchange capacity [meq/100 g] 16.1		, [™] 10.1 [™]		4
Soil seriesno information availableTextural class (USDA) \bigcirc Sand [%] 56 Sint [%] 326 Sint [%] 326 Gay [%] 0.4 Cation carbon (combustion) [% OC] 0.7 Organic carbon (combustion) [% OC] 0.7 Cation exchange capacity [meq/100 g] 16.1	Soil taxonomic classification (USDA)	no informatio	n available	
I extural class (USDA) \checkmark \checkmark sandy loam silt loam Sand [%] 56 12.7 12.7 Site [%] 32.9 60.8 60.8 Clay [%] 0.4 26.5 26.5 PH 6.6 6.6 P8 7.2 7.2 Organic carbon (combustion) [% OC] 0.7 1.7 Organic matter [% OM] 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1	Soil series	no informatio	n available	
Sance $[\%]$ 56 12.7 12.7 She $[\%]$ 325 60.8 60.8 Clay $[\%]$ 0.4 26.5 26.5 PH 60.8 6.6 6.6 0.8 7.2 7.2 Organic carbon (combustion) $[\% OC]$ 0.7 1.7 Organic matter $[\% OM]$ 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1	Textural class (USDA)	sandy loam	silt loam	
She [70] Sty 00.8 60.8 Gay [90] 0.4 26.5 26.5 H 6.6 6.6 6.6 0.8 7.2 7.2 Organic carbon (combustion) [90 OC] 0.7 1.7 Organic matter [90 OM] 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1		12.7	12.7	
Control Control <t< td=""><td>$\mathcal{S}_{\text{ATV}}^{\text{ATV}}[70] \rightarrow \mathcal{S}_{\text{ATV}}^{\text{ATV}} \rightarrow \mathcal{S}_{\text{ATV}}^{$</td><td>00.8</td><td>00.8</td><td></td></t<>	$\mathcal{S}_{\text{ATV}}^{\text{ATV}}[70] \rightarrow \mathcal{S}_{\text{ATV}}^{\text{ATV}} \rightarrow \mathcal{S}_{\text{ATV}}^{$	00.8	00.8	
0.0 0.0 0.0 0.8 7.2 7.2 Organic carbon (combustion) [% OC] 0.7 1.7 Organic matter [% OM] 1.1 2.9 Cation exchange capacity [meq/100 g] 16.1 16.1		20.3	20.3	{
Organic carbon (combustion) [% OC]0.71.7Organic matter [% OM]1.12.9Cation exchange capacity [meq/100 g]16.116.1		7.2	7.2	
Ørganic matter [% OM]1.12.9Cation exchange capacity [meq/100 g]16.116.1	Organic carbon (combustion) [% OC]	0.7	17	1
Cation exchange capacity [meg/100 g] 16.1 16.1	Organic matter [% OM]	1.1	2.9	
	Cation exchange capacity [meg/100 g]	16.1	16.1	1



B. STUDY DESIGN

1. Experimental Conditions

Important parameters for the test e.g. stability of the test item, soil-to-solution ratio and equilibration time for adsorption were determined prior to the definitive test in preliminary tests.

In the definitive test soil/solution ratios of 1:2 for the soils Wurmwiese, Horchen am Hohensch 4a, Dollendorf II and Springfield, NE and 1:1 for the soil Guadalupe, A and equiperation time (24 hours) established for each soil in the preliminary tests were used.

Borosilicate glass centrifuge tubes (42 or 83 mL) with Teflon®, lined screw were used as test verse They were shaken by an overhead shaker in the dark at controlled temperature (20°C).

Adsorption/desorption tests were conducted at nominal concentrations of 1.00, 0.30 0.40, 0.03 and 0.01 mg/L. For the preparation of the application solution if was taken into account that the final concentration of the test item was decreased by a factor of 0.0 after application into the equilibrated test system.

In the definitive test 10 g for the soils Wurmwiese Höfchen am Hohenseh 4a Dollendorf fr and Springfield, NE and 20 g for the soil Guadatupe, CA were weighed into centrifying tubes, anD18 mL of aqueous 0.01 M CaCl₂ stock solution were added. After pre-equilibration for \geq 16 hours, 2 mL of the respective application solution were spiked in.

The batches were equilibrated. Following the determined shaking period, the test vessels were centrifuged and the supernatant was completely decanted. The volumes were measured gravimetrically (density of the solution was set equivalent to 1 g/mL) and recorded, and aliquits of 2×1 mL from all soils were taken for LSC. The pH was measured in all supernatants,

One single point desorption was performed on all concentrations. The volume of solution removed was replaced by an equal volume of Stock Solution. The test vessels were then shaken for the predetermined period of 24 hours for single point desorption and handled as described in the previous section. The pH was measured in the test vessels containing ong/L

After the desorption cycle the soils were mixed with approximately 0.4 g cellulose / g soil, air-dried, homogenised and alignots were combusted. Mass balance was established on all specimens from the definitive tests.

2. Analytical Methodolog

Radioactivity determinations. The Fquid Opecimen's were measured with a liquid scintillation counter. Soil specimens were mixed with approximately 0.4 g cellulose/g soil, air dried, homogenised, and combusted in a Sample Oxidiser. Radioactivity was measured with a liquid scintillation counter.

The distribution of the radioactive regions of interest was measured with a Radio-HPLC-detector and quantified via manual evaluation of the area integrals and an evaluation program.

3. Cateulations

Adsorption and desorption sotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Preundlich emation.

. **RESULTS AND DISCUSSION**

A. MATERIAL BALANCE

The recovery of radioactivity for all soils is presented in Table 7.1.3.1.2-4.

à

The radioactive material balance in the test soils was calculated as sum of the radioactivity detected within the decanted supernatant solutions after the adsorption / desorption step and the radioactivity found in the air-dried and combusted soil residues. The total radioactivity recovery with respect to the individual vessel ranged from 91.3% to 111.2% of the applied radioactivity.



The complete material balance observed for all test systems therefore demonstrated that no significant amount of radioactivity dissipated from the test vessels or was lost upon processing.

Concentration			Soil	O,	
[mg/L]	Wurmwiese	Höfchen am Hohenseh 4a	Dollendorf II	Gu <u>a</u> dalupe	Springfield
0.97	99.25	103.5	193.15	@ 103.65 e	100.85
0.30	93.05	97.2	<u>ہ</u> 97.65	🖓 99.2 🖉	\$94,15
0.10	94.7	96.85	97.2 A	99.3	~ 94 Ø ×
0.03	91.95	96.0	97.2 🖓	© 100.25	§ 95.65 L
0.01	99.5	97.75 Q	99.5 🕎	€ 107.03	\$100.3
Mean ^{a)}	95.96	98.17 🐇	©°98.94	109.89	°~~ 97.04

B. ADSORPTION RESULTS

Ő In the definitive adsorption test 48.9 - 38.4% AR were adsorbed in Soil Wurmwiese, 26.9 - 38% AR in soil Hoefchen am Hohenseh $4a_{1}$, 34.47.0% AR for soil Dollenborf IK 19.3 26.8% in soil





Table 7.1.3.1.2- 5:	Concentration of BCS-CN88460-carboxylic acid in the solid and liquid phases at the
	end of adsorption period (mean of duplicates)

Concentration	Soil	Solution	Percentage adsorbed
[IIIg/L]	[mg/kg]	[IIIg/L]	i inean SD av
Wurmwiese			
0.010	0.011	0.004	57.7 ± 0.5
0.029	0.034	0.012	58.1 \$0.4 \$
0.098	0.113	0.042	57.0y±0.1
0.293	0.326	0.132	55,1 ± 0,1
0.962	0.953	0.491	@19.0 ±09.1
Hoefchen am Hohenseh 4a	1	je je .	
0.010	0.007	0,006	$2,365 \pm 1,1$
0.029	0.021		≥36.5 ±0.5
0.098	0.069	0, 0.064 ×	34.8 ± 0.0
0.292	0.192	U U 0.120 O	325 ± 0.5
0.961	0.506	Q.7M <u>A</u>	
Dollendorf II			
0.010	0,009	0.005 V	$460^{\circ} \pm 0.3$
0.029	\$9.027 ° >	× 0.045 %	45.2 ±40,9
0.097	[∞] 0.08 0 ∅	054 0	044.8 €0.3
0.290	0,255	\$ 0.16D O	6 43 € ± 0.3
0.953	0.728	0.5%	37.4 ± 0.1
Guadalupe			Y L
0.010	A. 0.003	Ø S0.007 V	25.6 ± 0.1
0.029	\$ \$0,008	× 0.031 %	26.3 ± 0.7
0.098	\$0.025	\$ Q.073 O	25.3 ± 0.5
0.292	0.042 ~	\$\$ \$0.220 \$ B	$7 24.5 \pm 0.4$
0.960	× Q(190 × /	0.775	19.5 ± 0.3
Springfield			
<u>0</u> 9010	, x, 0.009, or	0,0.005	46.0 ± 0.8
£ 0.029 Û	2 0 0 2 7	0.016	45.7 ± 0.2
0.098	2 0.088 St 2	0:954	43.9 ± 0.3
0.290	× \$ 0.254 ~	0.167	42.4 ± 0.1
0.054		© 0.611	36.0 ± 0.7

The adsorption behaviour of BCS-CN88460-carbox fic acid (M12) in the concentration range of two orders of magnitude. (i.e. from 0.01 to 1.0 mg/L) was accurately described for all soils with the Freundlich equation. The adsorption behaviour was accurately described by the Freundlich equation for all test soils, reflected in correlation coefficients of fit of calculated adsorption isotherms to the respective measured data close to one (0.9975 - 0.9988).

The calculated adsorption constants $K_{\text{f(ads)}}$ of the Freundlich isotherms for the five test soils ranged from 0.3 to 20 mL/g (mean) 1.1 mL/g). The Freundlich exponents 1/n were in the range of 0.8952 to 0.9311 (mean) 0.9198).

0.9311 (mean: 0.9198). In general the organic matter in soil, represented as organic carbon content, is the most important binding site for xenctivities. Therefore, the Freundlich adsorption coefficients (K_{fads}) were normalised for the percentage of organic carbon content of the test soils to obtain Freundlich K_{ocads} values as a general comparability basis of the test item adsorption behaviour. For the test item the calculated K_{ocads} values in the five soils varied between 28.1 and 105.8 mL/g (mean: 56.2 mL/g).

An overview of the results according to the Freundlich equation is presented in Table 7.1.3.1.2-6.



Soil	K _{f(ads)} [mL/g]	1/n	K _{oc(ads)} [mL/g]	r ²	e s
Wurmwiese	2.0	0.9297	105.8	0.9983	
Hoefchen am Hohenseh 4a	0.8	0.8952	37.9	0.9978	, A
Dollendorf II	1.3	0.9243	28.1	0.9988 😽	
Guadelupe	0.3	0.9311	38.4	0.997	
Springfield	1.2	0.9185	70,	0.9283	ý L
Arith. mean	1.1	0.9198	56.2	0.9981 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	ŝ, a
Geo. mean		"Y"			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
		Å	0 v		\$ <u>4</u> 0

C. DESORPTION RESULTS

Evaluations of the desorption experiments performed for all soils at five test concentrations are given in the following table:

Concentration of BCS-CN88460-casboxylic acid in the solid and liquid phases of the end of desorption period (mean of duplicates) Table 7.1.3.1.2- 7:

Concentration	Soil Soil	Solution ~	Percentage adsorbed	
[mg/L]	@mg/kg]		/ poeían - SD	
Wurmwiese			<u> </u>	
0.010	0.008		25.6 ± 1.0	
0.029	\$\vee\$0.025\\circ\$\vee\$	@ 0. 0 08 °	25.5 ± 1.1	
0.098	0.08	Q.027 V ~	26.9 ± 0.3	
0.293	0,235		27.9 ± 0.1	
0.962	Q 632	× 0.2588 ×	33.7±0.7	
Hoefchen am Hohensch 4a			¥	
0.010	0.0 69 ~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	34.6 ± 0.6	
0.029	× \$\$014		35.4 ± 0.8	
0.098			36.0 ± 0.2	
0292	\$ 0.120 ×	0.092	37.4 ± 1.0	
0.961	0,208	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	47.1 ± 0.2	
Dollendoy f II 🔍 🖉				
0.010 🔊	<i>L</i> ^y 20.0070° <i>L</i> ^y	<u>پ</u> ۵۹٬003	28.0 ± 0.4	
0.029		© ~0.009	28.2 ± 0.8	
0.097 🧳 📿	<u>يْنْ 9,062 مَنْ 6</u>	0.032	30.1 ± 0.2	
0.29	× × 0.176 ×	0.095	30.8 ± 0.2	
0,953	0.469	0.335	36.4 ± 0.0	
Guadalupa & & & &				
× 0.010	~ <u>0</u> .001 ~	0.004	43.6 ± 0.7	
م م 0.029 م	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0.011	43.8 ± 0.3	
0.098		0.036	44.5 ± 0.3	
0.292		0.107	45.5 ± 1.0	
0.960	ي <i>ش.088</i>	0.396	53.4 ± 0.5	
Springfield & & &				
Ø.010 5 0	<i>2</i> 0.006	0.003	34.4 ± 1.9	
×0.020 A	<u>مر</u> م 0.018	0.008	31.8 ± 0.9	
J 0.098 J	0.058	0.029	32.1 ± 0.0	
& \$ 290 is	0.163	0.087	34.9 ± 1.1	
<u>ک</u> 0.954	0.399	0.305	43.1 ± 0.8	



Desorption isotherms for desorption were calculated in analogy to the adsorption experiment. Correlation coefficients for desorption were in the range of 0.9920 –0.9980.

The Freundlich desorption coefficients K_{fdes} ranged from 0.2 mL/g (soil Guadalupe, CA) to 2.2 mL/g (soil Wurmwiese) with Freundlich exponents (1/n) ranging from 0.8632 to 0.9225. Normalisation to $\sqrt[\infty]{2}$ the soil organic carbon contents led to the following K_{focdes} values of 116.3 mL/g for soil Wurdwiese, 41.4 mL/g for soil Höfchen am Hohenseh 4a, 30.6 mL/g for soil Dollendor II, 34.5 mL/g for soil Guadalupe, CA and 78.3 mL/g for soil Springfield, NE, respectively. An overview of the results is presented in Table 7.1.3.1.2-8.

Ò

Soil 1/n Kf(des) Koc(des) [mL/g][mt]g] Wurmwiese 2.2093 0.9975 0.9225 ×116.3 Hoefchen am Hohenseh 4a 0.8286 Ø.8632 ©́41.4≪ 0.9948 Dollendorf II 1.3750 0.9101 30.6 0.2980 0.2417 0.8894 09920 Guadelupe 34.5 Springfield ₫,**3**306^ **~0.9055℃** 8.3 ≪/0.9957 0.9956 Arith. mean ©1.1970> 0.8981 60,2 QO CC Kint CONCLUSION

		1000	Ø
Table 7 1 3 1 2_ 8.	Desorption constants of BCS.	-CN88460-carh	ovulic field in soils
1 a D C / 1 D C 1 D C C C C C C C C C	Description constants of Des	$-C_1 + 0 + 0 + 0 + Car b$	UATING ALCU III SUIIS

The adsorption coefficients K_{fads} of BCS CN88460-carboxylic acid M120 in five test soils were determined to range from 0.3 mDg to 2.0 mLg based on Freundlich equation. The corresponding organic carbon normalised adsorption coefficients K focad ranged from 28.1 mL/g to 105.8 mL/g (mean 56.2 mL/g). The FreupPlich exponents 1/n were in the range of @ 8952 to 0.9311 indicating that the concentration of the test item affected the adsorption behaviour slightly, only.

 \bigcirc The desorption coefficients Kindes of BCS-ON88460-carboxylic acid were found to be in the same range as the respective adsorption coefficients (30 6 mL@ - 1163 mL/g).

n Based on the soil sorphion parameters measured in this study and classification of soil mobility potential according to Briggs depending on the soil type the mobility of [BCS-CN88460-carboxylic acid can be classified as mobile to intermediate mobile in the tested soils.

The results are included in the summary of the adsorption and desorption behaviours of isoflucypram





Report:	KCA 7.1.3.1.2/02; ; 2017; M-589856-01-1
Title:	[Pyrazolyl-4-14C]BCS-CY26497: Adsorption/desorption in four US soils
Report No.:	MELNN219
Document No.:	M-589856-01-1
Guideline(s):	OECD Guideline for the Testing of Chemicals, No. 106, Adsorption/Desorption, 2000
	Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No
	1107/2009
	US EPA Fate, Transport and Transformation Test Guidefines, OCSPP 95.1239,
	Adsorption/Desorption (Batch Equilibrium), 2008
Guideline deviation(s):	none
GLP/GEP:	yes λ O^{4} λ S^{7} Q^{0}

Executive Summary

The adsorption behaviour of BCS-CN88460-carboxylic acid (M gricuttural soils in batch equilibrium experiments in the dark at 20°C

1

7.1.3.1.2- 9:	Selected soils			× ,& ,	A.	Ô ^v K	<u>S</u>
Designation	Location			Texture O	^Z O ^Z	pH (CaCl2)	
END	Northwood, N	th Dakota, U	USĂ 🔊	loamy sand	Č,	ر 4.9 ک	0.94
MMN	Morris, Minnes	sota, ØSA 🥚		clayDoam 🗸	, Å	7.7	2.4
SCA	Sanger, Califor	nia, USA	Ø	sandy loans	¢.	506	₩0.29
SKS	Stilwell, Kansa	s, USA	2 0	silty clay loa	ina	۵5.8	1.8
			Ŵ.	~	Qʻ.	× ,0	

Table

The adsorption phase of the study was carried out using sieved (start may and air-dried soils equilibrated in aqueous 0.01 of CaC solution. Periminary tests were conducted for solubility of the test substance, adsorption to the test vessels, appropriate soil-to-solution ratio, equilibrium time, and stability of the test substance. Control test systems containing only 0.01 McCaCl2 were used in the test for solubility and adsorption of the test substance to the test vessels. In the pretest for parental mass balance, North vood, North Dakota (END), Morris, Mindesota (MMN), Sanger, California (SCA), and Stilwell, Kansas (SKS) test systems had 94.4, 95.0, 94.9 and 93.9% of applied radioactivity (AR) as the test substance, respectively at the ond of a 48-h period of shaking.

Ô For the definitive test, a sort-to-softwion ratio of 1.4 for END soil, 1:2 for MMN soil, 1:1 for SCA soil, and 1:2 for SKS soil were used. The nominal test concentrations of BCS-CN88460-carboxylic acid ranged over two order for magnitude and were 1.0, 0.3, 01, 0.03, 0.01 mg/L. All applications of the test substance were made in aqueous 0.09 M CaCl2 solution. The tests were conducted in 30-mL Teflon® centrifuge tubes with screw caps, in an environmental chamber in the dark at 20 ± 2 °C on a reciprocal shaker.

\$1

The aqueous supernatant after adsorption and desorption was separated by centrifugation, and the supernatant was radioassayed. Supernatants from representative samples were analysed by HPLC to determine the composition of fadioactive residues. Residues in the soils were determined by extraction followed by combustion and radioassay. The adsorption/desorption parameters were calculated using Freundlich assorption/desorption, isotherms. The test substance was sufficiently stable throughout the 48-h study period, with 000% test substance noted in HPLC analyses of adsorption supernatants and soil extracts.

Mean material balances for END, MMN, SCA, and SKS soils were 98.5% AR (range 96.2 to 101.9% (AR), 97.8% AR (range 96.2 to 100.2% AR), 97.9% AR (range 95.4 to 106.5% AR), and 98.6% R (range 95.0 to 102.6% AR), respectively. The overall mean material balance was 98.2% (SD = 2.3%).


In the definitive adsorption test, the mean % AR adsorbed to soil ranged from 40.4 to 46.7% in END soil, 36.1 to 41.3% in MMN soil, 35.8 to 48.0% in SCA soil, and 47.1 to 60.3% in SKS soil.

In the definitive desorption test, the mean % AR desorbed from the initially adsorbed amount ranged from 40.4 to 47.4% in END soil, 31.4 to 36.4% in MMN soil, 29.2 to 41.5% in SCA soil, and 2.4 to 33.5% in SKS soil.

The calculated adsorption constants K_{f-ads} of the Freundlich isotherms ranged from 0.5446 2.75 mL/g (mean 1.54 mL/g) for the four tested soils. The Freundlich exponents (1/n) were in the range of 0.8914 to 0.9604 (mean 0.9245), indicating that the concentration of the test substance minimally offected the adsorption behavior of the test substance in the examined concentration range.

In general, the organic matter in soil, determined as organic carbon content is the most important component responsible for binding organic chemicals. Therefore the adsorption coefficients (K₁) were correlated with the organic carbon content of the soil to compare the adsorption behavior in different soils. For BCS-CN88460-carboxylic acid, the K_{fox ads} values ranged from 49.1 to 289.8 mL/g (mean 155.6 mL/g). According to Briggs¹ classification scheme, the mobility of BCS-CN88460 carboxylic acid can be classified as 'Low' for two soils (BND and SCA), 'Intermediate' for one soil (SKS) and 'Mobile' for one soil (MMN).

The calculated desorption constants K_{f-des} of the Freundhich isotherms ranged from 1.322 to 4.870 mL/g (mean: 3.510 mL/g) for the tested matrices. The Freundlich exponents 1/n ranged from 0.8972 to 1.0434 (mean: 0.9459). The K_{focdes} values for desorption ranged from 2010 to 455.8 mL/g (mean 327.4 mL/g).

The following table summarises the adsorption and desorption data of BCS-CN88460-carboxylic acid:

		Adapta		i di ta	Decomption	
Soil texture (USDA)		Ausorption	No.		Desorption	
ð S		¥/n ୁઉ		S Kr-des	1/n _{des}	Kfoc-des
	[∞] [mL/g]					[mL/g]
(END) loamy sand	2 3/24	_≫ ®0.949₽	289.8	40.230	0.9403	450.0
(MM) Clay loam	B 178 🛇	0.9604	<u></u>	4.870	1.0434	202.9
(SCA) sandy loam	°∕0.544€)	B 8966 ^^	187.5	≫ 1.322	0.8990	455.8
(SKS) silty clay loam	1.73	<u>مَ</u> يْ 891 4 مَ	ØŠ.9 🔊	3.619	0.8972	201.1
Arith. mean:	1543	0.9245	155.6	3.510	0.9450	327.4
		_O' 、	O ^v O ^v			
~~ U	\sim \sim	Q ^Y Q ^Y				
A .			4.)			
	Q.	S.	N N			
	A		, P			
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	S N	$Q$ $\mathcal{Q}'$				
L .1 [\]	Û ^Y NŸ	rQj"				
		<u></u>				
	õ 🔬 í	-Q				
N R A	~9 [°]					
	2					
	Ê.					

Table 7.1.3.1.2- 10: Summary of the adsorption/desorption data of BCS-CN88460-carboxylic acid (M12)

¹ Briggs, G. G. (1973)

A Simple Relationship Between Soil Adsorption of Organic Chemicals and their Octanol/Water Partition Coefficients *Proc.* 7th *British Insecticide and Fungicide Conference, Nottingham/UK.* 



#### I. **MATERIALS AND METHODS**

I. MATERIALS AND METHODS					
A. MATERIALS			ø° %		
1. Test and Reference Items		ð			
Test item		and the second s			
Pyrazolyl-labelled BCS-CN88460-carboxylic acid (MI	2)	A			
Standard-ID: C-1202	Ċ5	4 4			
Specific activity: 3.73 MBq/mg (100.8 µCi/	ng) 🔍		\$ \$ \$		
Radiochemical purity: 100% by HPLC	A C	' Å	Q O H		
	Q'	\$ A A			
Reference item					
Reference substances were not used					
	D D	So or A	, A .°		
2. Test Soils					
Four test soils (USA origin) were used within this state	v. The soils w	vere taken from	aspicultural use		
areas representing different geographical regions and d	ifferent soil pr	operties The pl	Wsico-chemical		
properties of the test soils are given in the following tabl	é, N 8				
	R ^a sõ		°~y [™]		
Table 7.1.3.1.2-11: Physico-chemical properties of test s		· ° ~ ~	4		
Demonstration & C			,		
Soil designation	Morris MSV	Songer A	Stilwell KS		
System ID/	O'MMAN	SCO	SKS		
Soil ID & & & 050216-S	7 1002 D5-S	✓ 032615-S	122613-S		
Geographic location		n n			
City S O Y Northwood	Morris	Sanger	Stilwell		
Country	Minesota	× / L autornia			
	TRANS				
Soil coordinates	USÅ N 45.58333	USA N 36.70227	KS USA N 38.81528		
Soil coordinates	USA N 45.58333 XC95.86667	USA N 36.70227 W 119.46355	KS USA N 38.81528 W 94.66111		
Soil coordinates N 47:90093 W 97.51627 Texturat class (USDA)	V 45.58333 N 45.58333 V 95.86667 V clay Qam	USA N 36.70227 W 119.46355 sandy loam	KS USA N 38.81528 W 94.66111 silty clay loam		
Soil coordinates         N 47,70093           W 97.51697         W 97.51697           Texturat class (USDA)         Sand [%]           (50 µm - 2 µm)         83.8	N 45.58333 N 45.58333 N 95.86667 Clay Qam	With the second	KS USA N 38.81528 W 94.66111 silty clay loam 4.7		
Soil coordinates Soil coordinates N 4770093 W 97.51697 Ioamy soud Sand [%] (50 µm – 2 µm) Silt [%] (2 µm – 50 µm) Clave 19/1	V 45.58333 N 45.58333 V 95.86667 Clay IQam 39.8 39.8 28.6	W Cultonina USA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5 7	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9		
Soil coordinates       N 47,70093 $3000000000000000000000000000000000000$	N 45.58333 N 45.58333 V 95.86667 Clay Kam 31.6 39.8 28.6 7 7	USA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8		
Soil coordinates       N 4770093         Soil coordinates       N 4770093         Textural class (USDA)       N 4770093         Sand [%]       (50 $\mu$ m) – 2 $\mu$ m)         Silt [%]       (2 $\mu$ m) – 2 $\mu$ m)         Clay [%]       (2 $\mu$ m) – 50 $\mu$ m)         pH       - in caclo         - in water       - 537	N 45.58333 N 45.58333 V 95.86667 Clay Ioam 39.8 28.6 7.7 8.1	VSA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2		
Soil coordinates       N 4770093         Texturat class (USDA)       W 97.51697         Sand [%]       (50 $\mu$ m - 2 $\mu$ m)         Silt [%]       (2 $\mu$ m - 50 $\mu$ m)         PH       - in CaCl         - in water       - 4.90         - in saturated paste       - 5.37	N 45.58333 V 95.86667 Clay Ioam 39.8 28.6 7.7 8.1 7.9	V Cultionna USA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 6.2	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0		
Soil coordinates       N 4770093         Texturat of ass (USDA)       W 97.51697         Texturat of ass (USDA)       Ioamy smidth         Sand [%]       (50 $\mu$ m – 2 $\mu$ m)         Silt [%]       (2 $\mu$ m – 50 $\mu$ m)         Clay [%]       (2 $\mu$ m)         PH       - in cacl         - in saturated paste       53         Organic carbon (combustion) [%OC]       0.94	N 45.58333 N 45.58333 V 95.8667 Clay Kam 3P.6 39.8 28.6 7.7 8.1 7.9 2.4	USA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 6.2 0.29	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0 1.8		
Soil coordinates       N 4770093         Soil coordinates       N 4770093         Texturat class (USDA)       Ioamy soud         Sand [%]       (50 $\mu$ m) - 2 $\mu$ m)         Silt [%]       (2 $\mu$ m) - 50 $\mu$ m)         Clay [%]       (2 $\mu$ m) - 50 $\mu$ m)         pH       - in caCl         - in water       - 53         - in saturated paste       53         Organic carbon (combustion) [% OC]       0.94         Organic matter [% OM)       - 1.60	N 45.58333 N 45.58333 V 95.8667 Clay Kam 31.6 39.8 28.6 7.7 8.1 7.9 2.4 4.1	V Cultonia USA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 6.2 0.29 0.51	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0 1.8 3.1		
CountryOrganicSoil coordinatesN 4770093Soil coordinatesN 4770093Texturat class (USDA)Ioamy southSand [%](50 $\mu$ m – 2 $\mu$ m)Silt [%](2 $\mu$ m – 50 $\mu$ m)Clay [%](2 $\mu$ m – 50 $\mu$ m)pH- in CaCl- in water- 53- in saturated paste- 53Organic carbon (combustion) [% OC]0.94Organic matter [% OM]1.69Cation exchange capacity [mod/100 § a)40.4	N 45.58333 N 45.58333 V 95.8667 Clay Oam 39.8 28.6 7.7 8.1 7.9 2.4 4.1 19.2	VSA VSA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 0.29 0.51 4.9	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0 1.8 3.1 18.5		
Soil coordinates Soil coordinates N 4770093 W 97.51697 Texturat class (USDA) Sand [%] (50 $\mu$ m - 2 $\mu$ m) Sand [%] (2 $\mu$ m - 50 $\mu$ m) Clay [%] (2 $\mu$ m) PH - in CaCl - in water - in saturated paste Organic carbon (combustion) [%OC] Organic matter [% OM Clay [%] (2 $\mu$ m) - in saturated paste Organic carbon (combustion) [%OC] Clay [%] (2 $\mu$ m) - in saturated paste Organic carbon (combustion) [%OC] Clay [%] (2 $\mu$ m) - in saturated paste Organic carbon (combustion) [%OC] Organic matter [% OM - in saturated paste Organic matter [% OM - in saturated paste - in saturate	N 45.58333 N 45.58333 V 95.8667 Clay Kam 3P.6 39.8 28.6 7.7 8.1 7.9 2.4 4.1 19.2 0.97 N/A	VSA N 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 0.29 0.51 4.9 1.23 24.7	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0 1.8 3.1 18.5 0.97 35.2		
Soil coordinatesN 47 70093Soil coordinatesN 47 70093Texturacelass (USDA)Ioamy soulSand [%](50 $\mu$ m - 2 $\mu$ m)Silt [%](2 $\mu$ m - 50 $\mu$ m)Clay [%](2 $\mu$ m)PH- in CaCl- in water- 53- in saturated paste- 53Organic carbon (combustion) [% OC]0.94Organic matter [% OM]- 160Cation exchange capacity [mod/100 §]*40.4Bulk density [g/cm3]- 18.6	N 45.58333 N 45.58333 V 95.8667 Clay Kam 31.6 39.8 28.6 7.7 8.1 7.9 2.4 4.1 19.2 0.97 N/A 30.9	VSA V 36.70227 W 119.46355 sandy loam 67.1 27.2 5.7 5.6 6.2 6.2 0.29 0.51 4.9 1.23 24.7 14.8	KS USA N 38.81528 W 94.66111 silty clay loam 4.7 60.4 34.9 5.8 6.2 6.0 1.8 3.1 18.5 0.97 35.2 30.6		

Table 7.1.3.1.2- 11:	Physico-che	micalproj	perties of	test soils	, O
----------------------	-------------	-----------	------------	------------	-----

N/A = not @ailable

a) Gravinetric norsture content (gwater per 100 g dry soil) b) % organic matter = % Organic carbon x 1.724



### **B. STUDY DESIGN**

### **1. Experimental Conditions**

Preliminary tests were performed to determine solubility, adsorption to test vessel, stability and a equilibration time prior to the definitive test in order to optimise the test conditions.

The definitive test was performed in duplicate with five test substance concentrations (nominal 0.0) to 1.0 mg/L). A soil-to-solution ratio of 1:4 was used for END soil, 1:2 was used for MMD soil, 24 was used for SCA soil, and 1:2 was used for SKS soil. The equilibration time was 24 hours for adsorption and was followed by a a 24 hour desorption phase.

For the adsorption phase the test systems were set up with the appropriate amounts of soil and 0.01 M CaCl₂, and were pre-equilibrated by shaking overnight before treatment. A 1-mL aliquot of each application solution was added to the SCA test systems and a 2-mL aliquot was added to the END, MMN and SKS test systems. After application the test systems were shaken for approximately 24 hours. Test systems were removed, soil and supernatants were separated by centrifugation and the supernatants were decanted. The volumes of the supernatants were determined by weight and aliquots were taken for radioassay. The supernatants were placed by approximately the same weight of fresh 0.01 M CaCl₂ solution, and the test systems were placed on the reciprocal shaker. The pH of adsorption supernatants were measured. One replicate of adsorption supernatant at the highest test concentration per soil was analysed by HPLC.

After shaking for 24 hours for desorption equilibrium, test systems were removed from shaker, centrifuged, and supernatants were decanted. The volume of the supernatants was determined by weight and aliquots were analysection LSC.

Soils were extracted once with 15-mL acetometrile for 20 frin at ambient temperature on a benchtop shaker, centrifuged at 3,000 for 5 min, and superhatant was decanted and radioassayed. The volume of the extract was recorded. Soils were an dried, weighed, and aliquots were combusted.

## 2. Analytical Methodology

Radioactivity in samples was determined in trippicate by LSC.

The liquid specimens were measured with a liquid scintillation counter.

Solid samples (after extraction) were oxidized. The generated  ${}^{1}CO_{2}$  was radioassayed with 15 mL of Harvey Carbon-14 oxidizet cocktail. The samples were radioassayed for  ${}^{14}C$ -content by LSC, and the results were corrected for oxidizer efficiency.

## 3. Calculations

The amount of test substance adsorbed to soil was calculated by subtracting the equilibrium concentration in the solution from the initial concentration (applied concentration). By establishing the material balances and the stability of the test substance with HPLC/radiodetection it was verified that, besides the adsorption to soils no other significant processes had contributed to the decline of test substance measured in the supernatant.

Calculation of the Freundich constant and related K_{foc} was performed according to US EPA OCSPP Fate, Transport and Transformation Test Guideline No. 835.1230.

The radioactive contents determined in the supernatants of the adsorption and desorption steps at each equilibrium were used to calculate adsorption ( $K_{f-ads}$ ) and desorption isotherms ( $K_{f-des}$ ), respectively, as well as the organic carbon related distribution coefficients ( $K_{foc}$ ).



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

#### MATERIAL BALANCE A.

In the definitive test the overall mean material balances for END, MMN, SCA and SKS soils were 98.5% (individual replicate range 96.2 to 101.9%), 97.8% (96.2 to 100.2%), 97.9% (95.4 to 106.5%), and 98.6% (95.0 to 102.6%) AR, respectively. The overall mean material balance was  $982 \pm 2.5\%$ AR, which demonstrates the effectiveness of the extraction method. The recovery of radioactivity for all soils is presented in the following table.

Ô

Table 7.1.3.1.2- 12:	<b>Recovery of radioactivity</b>	-As	Q
	(as percentage of applied 1	adioactivity, mean	of two replicat

			<b>^</b>	<i>c O</i>	· ~ ~ (
Concentration		A h	Soil 🔧 👸		S S
[µg/mL]	END	MQIN	SCA		
1.07	96.35	& 96.4 jg	_S 9 <b>6</b> .9	× 296	.2 %
0.29	97.9	0 ⁹⁸ 3	<b>95</b> .85 🎽	S 87.	25 A
0.09	98.2	A 9707 .	Ø 6.35	98 ^Q	05 ° ô
0.03	98.6	Q7.0 🔨	× 97,0	<u></u> \$	.8
0.01	101.25	°∕≫99.85,©	100.25	¥101 (چ)	200
Mean	98.5	§ 97.8	<b>9</b> 7.9	98	¢ à

B. ADSORPTION RESULTS In the definitive adsorption test, the mean % AR sorbed to sol ranged from 40.4 to 46.7% in END soil, 36.1 to 41.3% in MMN soil 35.8 to 48.0% in SCA soil, and 47.1, to 60.3% in SKS soil. The respective concentrations in solution, in soil and the percentage of adsorbed test substance are shown in the following table



Concentration	Soil	Solution	Percentage adsorbed
[mg/L]	[mg/kg]	[mg/L]	mean SD 🚿 🎜
END	· · · · · · · · · · · · · · · · · · ·		
0.009	0.017	0.005	46.7 ± 0.2
0.028	0.051	0.016	45.2 ± 2.0
0.09	0.172	0.052	45.3 Q 1.3 Q x
0.29	0.493	گې 0.163	$430^{2} \pm 0.9^{2}$
1.07	1.723	0.636	€0.4 ± 20 ×
MMN		A IO	
0.009	0.008	<u>م</u> 0.00 ( ) م	$40.8 \pm 0.0$ $0$
0.028	0.023	0~017 ₀ ,	$4 \oplus 3 \pm 0 $
0.09	0.077	<u>، ۵</u> 0056 کې ۱	∂r >40.8 ± 0.1
0.29	0.228	0.172	39.8 ± 0.1
1.07	0.770		$3654 \pm 0.2$
SCA			
0.009	0.00	0.004	0.005 48.0
0.028	0.028	× × 0.013	© 0.01\$45.8
0.09	( <del>9</del> .09	× ~ 0.041 ~~	\$ 0. <b>6</b> 54 43 \$
0.29	Q 0.29	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	P 6.173 39 4
1.07		\$ 0 ^{0.382}	00.685 35.8
SKS			. 0, 0, 1
0.009	Ø.011 Or	0.004	$0.3 \pm 0.2$
0.028	0.034	@.012 × ~	≶
0.09	0,106	Ø 0.042	55.7 ± 0.1
0.29	Q ²⁹⁸	0.07 %	$52.1 \pm 0.1$
1.07	J. \$1.004 ~	<i>⊅ ∂</i> ,565	¥ 47.1 ± 0.3

Table 7.1.3.1.2- 13:	Concentration of BCS-CN88460-carboxylic acid in the solid and liquid phases at the
	end of adsorption period

The adsorption behaviour of BCS-CN88469-carboxylic acid (MQ2) in the concentration range of two orders of magnitude (i.e. from 0.01 to 1.0 mg/L) was accurately described for all soils with the Freundlich equation. The coefficients of determination ( $r^2$  value) for the individual adsorption isotherms ranged from 0.9989 0.9997 (mean: 0.9993).

The calculated adsorption constants  $K_{\text{fad}}$  of the Freundlich isotherms for the four test soils ranged from 0.544 to 2.724 mL/g (mean 1.543 mL/g). The Freundlich exponents 1/n were in the range of 0.8914 to 0.9604 (mean 0.9245), indicating that the concentration of the test substance minimally affected the adsorption behaviour in the examined Soncentration range.

In general, the organic matter in soil, determined as organic carbon content, is responsible for binding most organic chemicals. Therefore, the adsorption coefficients K_{fads} were correlated with the organic carbon content of the matrix to get a comparability of the adsorption behaviour in different soils. For

carbon content of the matrix to get a comparability of the adsorption behaviour in different soils. For BCS-CN88460-carboxylic acid (*ML2*), the calculated  $K_{ocads}$  values ranged from 49.1 to 289.8 mL/g (mean 155.6 mL/g). An overview of the results according to the Foundlich equation is presented in the following table:



Soil	K _{f(ads)} [mL/g]	1/n	K _{oc(ads)} [mL/g]	r ²	ð
END	2.724	0.9497	289.8	0.9989	Ş
MMN	1.178	0.9604	49.1	y 0.9992	,
SCA	0.544	0.8966	187.5	0.9997 😽 🖉	
SKS	1.727	0.8914	95.9	0.9995	»
Arith. mean	1.543	0.9245	155.6	0.9293	Q
Geo. mean		Č5	126.5		a
		-As	Q.		S

Table 7 1 3 1 2 14.	Adsorption constants of	FRCS CN88460 corbox	ulia agid in sails
1 abie /.1.3.1.2- 14:	Ausorption constants of	I DUS-UN00400-Carbox	yne aciu in sons

### C. DESORPTION RESULTS

In the definitive desorption test, the mean % AR desorbed from soil ranged from 40.4 to 47.4% in END soil, 31.4 to 36.4% in MMN soil, 29.2 to 41.5% in SCA soil, and 22.4 to 33.5% in SKS soil. The respective concentrations in solution, in soil and the percentage of desorbed test substance are shown in the following table.

Table 7.1.3.1.2- 15:	Concentration	of BCS-CN88460	-carboxxlic a	cid ^{Qn} the soli	d and li	quid phases	at the
	end of desorpti	ion period (mean	of dupQcates)				

Concentration	Q'Soil	Solution	Percentage desorbed
[mg/L]	[mg/kg]	A mg/L	_S Omean SD
END			N N N N N N N N N N N N N N N N N N N
0.009	© 0.010	0.002	40.4
0.028	× 0.039	~ ~0.005 V	40.7
0.09 🔬	0¢01 0 %		<u>41.1</u>
0.29	Ø.277 @ \$	ي ^س 0.054 م	§ 43.7
1.07	(y , 0) 0.9 <b>0</b> 6	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	47.4
MMN			
0.000		0,4901	36.4
0,028	الأي 0.01 <b>6</b> م	0.004	32.8
× 09.09	0,061		33.8
<u>کې</u> 0.29 کې	<u>َمْ (1.156 مَ مَ )</u>	° ≪ 0.096	31.6
1.07	L 0.5280 L	<u>لار م</u> راكا	31.4
SCA			
0.009		» 0.001	30.7
0. <b>6</b> 28 O		۵.004	29.2
<u>09</u>		0.012	29.9
©0.29	Q. 0.975 X 🔅	0.038	33.5
1.07	¥\$.223 .↓	0.158	41.5
SKŚ			
0.009	~~ QQ009 ~~	0.001	23.2
0.028	J.026	0.004	22.4
98 <b>9</b> 9 2,7		0.013	24.4
j¥.29 🛇 Č	0.216	0.041	27.6
~~ 1.075× A	0.668	0.168	33.5
	K,		

The  $\vec{r}$  value of the individual desorption isotherms ranged from 0.9951 to 0.9988 (mean: 0.9972). 1.322 mb g to 4.870 mL/g (mean: 3.510 mL/g). The Freundlich exponents 1/n ranged from 0.8972 to 1.0434 (mean: 0.9450). The calculated K_{ocdes} values ranged from 201.1 to 455.8 mL/g (mean: 327.4 mL/g). An overview of the results is presented in the following table.



Soil	K _{f(des)}	1/n	Koc(des)	r ²	° .
	[mL/g]		[mL/g]		
END	4.230	0.9403	450.0	0.9984	N 4
MMN	4.870	1.0434	202.9	, 0.9988	
SCA	1.322	0.8990	455.8	0.9951 😽	
SKS	3.619	0.8972	201.1	0.996	
Arith. mean	3.510	0.945	327 4	0.997	o L

 Table 7.1.3.1.2-16:
 Desorption constants of BCS-CN88460-carboxylic aicd in soils

## III. CONCLUSIONS

The adsorption coefficients  $K_{fads}$  of BCS-CN88460-carboxytic acid  $\mathcal{O}M12$ ) in four test poils were determined to range from 0.5 to 2.7 mL/g (mean 1:5 mL/g. The corresponding organic carbon normalised adsorption coefficients K focads ranged from 49.1 to 289 8/mL/grmean \$55.6 mL/g) The Freundlich exponents 1/n were in the range of 0.8914 to 0.0604 indicating that the concentration of the test item affected the adsorption behaviour slightly, only,

The desorption coefficients K_{focdes} of BCS-EN88460-carboxylic acid were to to times higher \$5.8 mD/g) indicating a strong compared as the respective adsorption coefficients (2011,1 mb/g binding of the test substance once adsorbed to the soil Õ

Using the Briggs classifications for the estimation of the mobility of chemicals in soil based on the mean Kf and/or Kfoc values BCS-GN88469-carboxylic and can be classified as mobile to low mobility for adsorption, and once sorbed will remain strongly sorbed

The results are included in the supprary of the accorption and desorption behaviours of isoflucypram

CA 7.1.3.2 Aged sorption Studies are not required under Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 3 07/2009.



## CA 7.1.4 Mobility in soil

The plant uptake factor and the transpiration stream concentration factor of <u>isoflucypram</u> in wheat were determined – default value and Briggs estimate (KCA 7.1.4/01). In addition studies on the plant uptake factor and the transpiration stream concentration factor of isoflucypram and BCS-CN88460-carboxylic-acid (*M12*) were performed (KCA 7.1.402 and KCA 7.1.1.1/03, respectively).

Report:	KCA 7.1.4/01;	, G.; , W.:	2017; M-60872	4-02-1 ×		L.
Title:	Isoflucypram (ISY	): Core PECgw E	Modelling cøre i	nfo document	for	S O
	groundwater risk a	assessment in Europe	Q.		2 ×	Ś
Report No.:	EnSa-17-0655	L.	0*	× č	S S	«O'
Document No .:	M-608724-02-1				× 0 .	Ŭ.
Guideline(s):	none	OT Y				Y
Guideline deviation(s):	none	~			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
GLP/GEP:	no				y w	
			a so	T L	A	, 0
		4 0		0'	@** ~	Л

### **Executive Summary**

The plant uptake factors of isoflucypram and its major metabolite BCS @N88460-carboxylic facid (M12) which are used in the **PEC**_{gw} calculations are symmetrized in the following fable  $\bigcirc$ 

Table 7.1.4- 1: Overall summary of the plant uptake factors of icollucy man and its major degradation product BCS-CN88460-earboxyle acid (112)

M

			"()" ala	av	$\bigcirc$	e i
Parameter	K)	«, [°] [°] [°] Ca	mpound		Value	in accordance with
	Ô (	Boflucybram		CS-CN88460-	A SE	endpoint y/n /
	× A		🔪 🖉 carbo	xylic acid (MAZ		Reference
Plant uptake factore	Defau	lt:0 (Tier 1a, Tier	\$ }	Default: 0%		n.a.
	Brig	os estimate: 0.10		<i>a</i> . O'	4	
		(Tier 1b)	, Ý	s s c	9	
n.a. = not applicable to	r a new active substa	ance submission	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	, Q		y Dr	AN ON		
		· · · ·	L.V	0		

Plant uptake factor (PLF/TSCF)

Plant ustake describer the amount of chemical taken up by the plant from soil during its growth and prior to harvesting. The EFSA (2013)¹ PPR panel has recognised in an opinion that plant uptake via roots is significant when calculating leaching exposure concentrations and has recommended the use of the plant uptake in exposure models if evidence for the actual occurrence of the process is demonstrated

According to EFSA (2013), the use of a worst case default transpiration stream concentration factor (TSCF) of zero in the leaching assessment is recommended as a first step. As a second step EFSA (2013) proposes the use a TSCF derived from the equation given by Briggs et al. (1982)² which is based on the relationship between plant uptake and octanol water partition coefficient (Table 7.1.4-2). This is also in line with the approach recommended by FOCUS (2014). It is also possible to consider experimentally determined TSCF.



¹ EFSA, 203: Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers, EFSA Journal 2013; 1(6):3291

² Briggs G.G., Bromilow R.H., and Evans A.A., (1982): Relationships between lipophilicity and root uptake and translocation of non-ionized chemicals by barley. *Pestic. Sci. 13, 495-504*



Table 7.1.4- 2: Plant uptake factors for isoflucypram and its metabolite derived from Briggs equation (Briggs et al. 1982)

Compound	log Pow ^{a)}	TSCF by Briggs	Reference log Por
Isoflucypram	4.0 (pH 4-9)	0.10	2014; M-484626-01- (summarised in) MCA section 2; CA2.7)
BCS-CN88460-carboxylic acid	at 23°C: 2.11 at pH 5 0.22 at pH 7 -1.1 at pH 9	0.75 0.29 0.03 0.03 0.03	2015 M-519996-01- Cummarsed in MGA section 2; CA 2.7)

a) Used for estimation of TSCI

The Briggs estimation leads for isoflucypram to a TSCF of \$10 (Table The plant uptake of isoflucypram has been also demonstrated experimentally (2017 M-587420-02-1). The experimental mean TSCF is 0.14. Consequently the Briggs estimated value of 0010 was used as refined input for the leaching assessment The Briggs estimated TSCF of BCS-CN88460 carboxylic acid is pp dependent. Thus, the default PUF of zero was considered as input for the leaching assessment?

Tiered approach

values of soflucypram and its For PEC_{gw} assessments a tieted approach concerning the DTS metabolite BCS-CN88460-carboxylic acid, the formation fraction of BCS-CN88460-carboxylic acid, and the PUF values should be considered. In Ther 1 only laboratory date are considered for DT₅₀ values and formation fractions, which can be modified by the PUF values. Field data are included in Tier 2 where a further modification by PUF value or not possible. A detailed description is presented in Table 7.1.4-3.

Compound	N N	Tier 1a	<u>م کم</u>	Y A	Tier B	×,		Tier 2	
	DT ₅₀ a) [days]	ff ^{a)}	PUF ^{d)}	DT ₅₀ a) [Onys] ×		PUF ^{e)}	DT ₅₀ b) [days]	ff ^{c)}	PUF ^{d)}
Isoflucypram	314 2	n a.	0.0	√314 🞸	n÷a.	0.1	323	n.a.	0.0
BCS-CN88460-	34 <u>4</u>	9.345 ×	, 0.0 K	* 34.4	@ <u>.</u> 345	0.0	84.1	0.043	0.0

Table 7.1.4- 3: Tiered approach for isoflucypram and its metabolite ised for modelling

a) From laboratory data

b) From laboratory and field data

- c) From field data
- d) PUF representing worst case default

Contraction of the second seco e) PUF based on Briggs Quation

CONCLUSIONS

The Briggs estimation leads for isoflucy pram to a TSCF of 0.10. The experimental plant uptake factor mean TSEF is QI4. Consequently, the Briggs estimated value of 0.10 was used as refined input for the leaching assement 2

The Briggs estimated TSCF of BCS-CN88460-carboxylic acid (M12) is pH dependent. Thus, the default PLF of zero was considered as input for the leaching assessment.



• Isoflucypram

Report:	KCA 7.1.4/02; ; 2017; M-587420-02-1
Title:	Determination of the plant uptake of [pyrazole-4-14C] BCS-CN88460 in whet plants
	- Report amendment 1
Report No.:	S16-05508
Document No.:	M-587420-02-1
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 110 2009
	of the European Parliament and of the Council of 21 October 2009 concerning the
	placing of plant protection products on the market and repealing Gouncil Directives
	79/117/EEC and 91/414/EEC
	The OECD Principles of Good aboratory Practice (QECD 1998) and respective
	national regulations
Guideline deviation(s):	none
GLP/GEP:	yes & & X & X & X

Executive Summary

The uptake of pyrazole-labelled isoflucionam was investigated in wheat plants (variety: *Thasos*) over a study duration of ten days under controlled temperature, humidity and light conditions (mean: 20.2°C, approx. 50% humidity and oday/night cycle of 16 h/8 h). The plant optake factor (PUF) and the transpiration stream concentration factor (TSCF) were determined. The test was performed in quadruplicates (four test systems) with additional triplicates of plant controls and pipicates of stability controls.

The initial test item concentration in the test solution was $91.79 \mu g/L$, corresponding to $30.94 \mu g$ test item per test vessel. Pre-grown wheat plants (BBCH code approx. 19) were either exposed to the test solution (half strengthened Horgland's No. 2 basal calt L mixture nutrition solution including the test item) or to nutrient solution only (controls) for the whole study duration of 10 days. Sample aliquots were analysed 0 (t_{sta}0, 2 (t₀), 4 (t₁) and 10 (t_{end}) days after treatment (DAT).

Wheat plants appeared healthy over the total study duration both in treated and untreated test systems. During the course of the study the wheat plants grew from BBCH 13 at t_{start} (application and start of equilibration) to BBCH 14-24 at t_{end} (end of study at DOT-10). Oxygen saturation for all experiments was always above 86% and pH values remained in an adequate range for treated (6.49 to 6.96) and control test systems (6.57 to 6.21).

Mean paterial balances were 6.2% ÅR for t_1 (range from 95.2 6 100.7% AR) and 92.2% AR for t_{end} (range from 88.7 to 9.4% ÅR). The total net transpiration rates at the end of the incubation phase (t_{end}) ranged from 51.0 to 69.5 mL

The total net transpiration rates at the end of the incubation phase (t_{end}) ranged from 51.0 to 69.5 mL for treated plants and 45.1 to 50.6 mD for control plants about 2.4 mL of the test solutions was lost due to evaporation, which was determined as the mean of 3 control replicates.

The mean initial concentrations \mathcal{K}_{tart} , DAT-0) of pyrazole-labelled isoflucypram in the test solutions amounted to 91.79 µg/L, increasing to 95.71 µg/L at t_1 (interim sampling at DAT-4) and decreasing to 89.74 µg/L at t_{end} (end of study at DAT-10). Root washing desorbed 0.209 µg of the test item from the roots at t_1 and 0.212 µg at t_{end} . These parade analysis of roots and shoots showed, that at t_1 40.7% and at t_{end} 43.0% of radioactivity taken µp was translocated from roots into shoots.

The PUF was calculated from the respective amount of test item in the test solution and the volume of the test solution each at the end of equilibration phase (t₀) and the end of the respective incubation phases (t₁, t_{sd}). The PUF in wheat for pyrazole-labelled isoflucypram amounted to 0.40 ± 0.10 (t₀-t₁) and 0.49 ± 0.06 (t₀-t_{end}). The mean PUF was determined as 0.44 ± 0.10 . The TSCF results from a calculation using the respective parameters present at the start of the study (t_{start}) and the end of incubation phases (t₁, t_{end}), additionally taking into account the radioactivity present in the plant shoot tissues, indicative for the uptake and translocation of the test item in correlation with the net amount of transpiration. The respective TSCFs were determined as 0.14 ± 0.01 (t_{start}-t₁) and 0.17 ± 0.02 (t_{start}-t_{end}) (see table below).



Replicate no.	PUI	wheat	TSC	Fwheat	0
	$t_0 - t_1$	to — t _{end}	t _{start} – t1	tstart - tend	0 2
1	0.27	0.45	0.12	0.13	
2	0.47	0.46	0.14	> 0.16	
3	0.32	0.60	0.15	\$ 0.16 K	²
4	0.55	0.46	0.15	0.19	Y
5	0.41	_*	0.14	<u>,-0` &</u>	Ŷ Ŵ
mean	0.40	0.49	0.14	0,1 7 ~	
SD	0.10	0.06	0.01°	¢0.02	
CV [%]	25.00	13.03	965	12.84	, o ^y
overall mean	0.	44	Å.		
SD	0.	10		ð á .	S.
CV [%]	21	.94 📎			
a) Replicate was a	not included into calcul	ations due to unusual ob	servation with respect	to growth 📎 🔨	, Y

Table 7.1.4- 4: PUF and TSCF values of isoflucypram in wheat

 I. MATERIALS AND METHODS
 A. MATERIALS
 I. Test Item
 Pyrazole-labelled isoflucyprant
 Sample-ID:
 KMK 10300
 Specific activity:
 4.22 MBq.ng
 Radiochemical purity:
 99%
 Chemical purity:
 99%
 Germination and early growth of wheat plants (variety: *Thasos*) was conducted on Perlite until plants reaching a BBCH stage of approx 11-12. The plants were cultivated under temperature, humidity and light conducted conditions in an incultation room. During germination and early growth, plants were poured with water on Perlite Substrate before particle of the method in the method. poured with water on Perlite Substrate before exposed to constant illumination using LED lights and pouring with nutrient solution (NS). The characteristics of the Perlite substrate, illumination and the composition of untreated nutries solution are given in the table below.

S

Table 7.1.4- 5% Te	est condition			
Perlite charact	eristics	Illudrination c	aracteristics	Nutrient solution
Granule Size d	Mass ps	day / night	Quantity	
[mm]	[kg/m ³]	[h ∕ þ ĭ	× [khux]	
			approx. 5 12.0	0.8 g Hoagland's No. 2 basal salt L mixture, 1.03 g MES buffer (2-(N-morpholino)-ethanesulfonic acid) and 0.75 mL of 15% Ferric EDTA (ethylenediaminetetraacetic acid) solution were dissolved in an appropriate amount of demineralized water. pH was adjusted to 6.5 using sodium hydroxide (KOH) and finally was filled up to 1 L with demineralized water.
	L.			

, O . ° . ° Ø



B. STUDY DESIGN

1. Use Pattern

The initial test item concentration in the test solution was 91.79 μ g/L, corresponding to 30.94 μ g test $\sqrt[3]{2}$ item per test vessel.

2. Experimental Conditions

The hydroponic test system for the PUF/TSCF experiment consisted of 10 brown class sessels (300 mL) filled with ~340 mL test solution and 2 plants each, 3 brown glass vessels filled with ~340 mL test solution only and 3 more brown glass vessels filled with ~340 mL cutrition solution (NS) and 2 plants each. Plants were gently fixed with elastomer form and staked with a wire spiral. All vessels were bubbled with air to maintain aerobic conditions. All used plants were pre-grown on Perlite and transferred at BBCH stage of approx. 11-12 to hydroponic conditions. Therefore, 2 plants for each brown glass vessels were selected based on health, morphology and size as suitable replicates. After acclimatisation to the new hydroponic growth conditions (10 days), plants were transferred into 10 brown glass vessels containing ~340 mL NS with 50.5 mL of MeOH. The latter corresponded to the organic solvent used for application of the test item. Throughout the whole experiment performed under hydroponic conditions, all used test vessels were bubbled with air to maintain aerobic conditions. Following a 10-day acclimatisation phase, plants were exposed to the test item for 2 days during the equilibration phase, before starting the incubation phase lasting for 2 (f) or 8 (tend), more days. All plants were monitored regulary and in unusual observation with respect to growth could be detected.

3. Sampling

The study was performed with two wheat plants per brown glass vessel. Analyses were conducted at $0 (t_{start})$, $2 (t_0)$, $4 (t_1)$ and $10 days (t_{end})$ after treatment. Samplings were performed at t_1 and t_{end} . Harvest of the plants were performed at t_1 and t_{end} . At all dates, radioactivity in the test solution, pH, oxygen saturation and volume of the solutions were determined. At a_{start} , t_1 and t_2 biomass of the plants was determined for all (t_{starb}) or harvested brown gras vessels (t_1 , t_{end}).

3. Analytical Procedures

At each date of analysis (t_{start} , t_1 , t_2), 3 aliquots of 0.5 mL were taken from each radioactive test system and the overall contained radioactivity was determined by liquid scintillation counting (LSC). Additionally, at the plant harvest after 40(1) and 10 days (t_{eff}) after treatment, radioactivity formerly attached to the root surfaces was quantified after external treatment with ACN/H₂O (4/1; v/v). The amount of radioactivity for the test solution as well as in the root wash solution was determined by LSC. Radioactivity taken up into root tissues as well as radioactivity allocated to the shoots was determined by combustion in an oxygen atmosphere using an oxidiser. The released carbon dioxide was trapped in an alkaline scintillation cocktant and the radioactivity was determined by LSC.

The purity of the stock solution, as well as the stability of respective aliquots used for application (application solution) before and after application were checked by High Performance Liquid Chromatography (HPLC) coupled with radiodetection.

, RESULTS AND DISCUSSION

A. **FROPERTIES OF TEST SYSTEM**

Oxygen saturation for all experiments was always above 86% and the pH of the test solutions during the course of study ranged from 6.49 to 6.96 for the treated and 6.51 to 6.91 for the untreated test systems.



B. PLANT CONTROLS

The health and growth of the wheat plants was visually assessed regularly. In parallel to the treated test systems untreated test systems (plant controls) were incubated to enable the detection of possible effects on plant growth and health induced by the test item. Wheat plants appeared healthy over the so total study duration both in treated and untreated test systems.

Besides an increase of biomass detectable for all treated (1.07 g) and untreated plants (1.30 g) at the end of the incubation phase, plant vigour was evident from the detectable plant development. This was reflected by BBCH stages of approx. 13 at the start of equilibration phase and BBCH stages of approx. 14 to 24 at the end of incubation phase.

C. ANALYTICAL RESULTS

Mean material balances were 96.2% AR for t_1 (range from 95.2 to 100, % AR) and 82.2% (range from 88.7 to 95.4% AR) (see Table 7.14-6). The complete material balances found at all sampling intervals for all test systems demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing. Ô 6 The total transpiration rates at the end of the incubation phase (Kend) ranged from 51.0 to (9.5 ml for treated plants and 45.1 to 50.6 mL for control plants. This corresponds with a pret transpiration of 17.2% of the initial volume (337.61 mb) for the test vessels, meeting the requirements of at least 15% **K** net transpiration (see Table 7.1.4-7) Ŵ

The concentration of isoflucypramon the test solution stayed nearly constant over the entire incubation phase of ten days. The mean initial concentration of pyrazole labelled isoffocypram in the test solutions at t_{start} amounted to 90.79 µg/L, increasing to 95.4 µg/L at t₁ and decreasing to 89.74 µg/L at t_{end} . The mass of the test item decreased from 30.94 µg at t_{start} to 29.76 µg at the and further decreased to 24.48 μg at t_{end}. (Table 7,1%-8). Ο Ľ

On average the root washing released 0.209 pg of the test item from the roots a_{1} and 0.212 µg at t_{end}

24.48 µg at t_{end}. (Table 7,19-8). On average the root washing released 0.209 ng of the test atem from the roots at y and 0.212 µg at t_{end} (see Table 7.1.4-9). The separate analysis of roots and shoots showed, that t₁ 40.7% and at t_{end} 45.0% of radioactivity taken up was transported from roots into shoots (see Table 7.1.4-9).



Table 7 1 4 6. Mass	halanaa	(in)	norcontogo	of applied)
1 able 7.1.4- 0: Mass	Dalance	(Ш	percentage	or appneu)

			Reco	overy			0
		si	ngle samp	les		mean	Ð,
Day 4 (t ₁)					~		Ô
Test solution t _{start}	100.0	100.0	100.0	100.0	Q* 100.0	1,000.0	Ô
Test solution t ₁	92.0	96.6	91.4	88.6	90.7	^م ر 9/1.9	Ç"
Root wash	0.7	0.5	0.5	0.9	0.6	S 0.6	Õ
Test solution + root wash	92.7	97.1	91.9	\$9.5	91.3%	92.9	
Aliquots	1.3	1.40	1.3	1.3	1,3	₹.3	a) ^y
Combustion shoots	0.8	0.9	1.1	Q 1.1	, CO	\$¥1.0 ≾	
Combustion roots	1.1	∂¥ .3	1.3	1.6	M.7 4	1.40	s and a second s
Translocation from roots to shoots	39.6	A 39.3	44 .	A1.6	§ 37.9¢	40.7	
Plant total	1.9 D	2.2	~2⁄₄.4 ∘	ov 2.7 🖄	∕ ⊋ .∅″	<u></u> \$2.4 (\tilde{v}^{*}
Total recovery radioactivity	96 ₆ 0 *	100.7	~95.6 _%	93.5		[©] 96.2	r
Day 10 (tend)	Ő			2°	Ê L	A	e °
Test solution t _{start}	A00.0	₽ 10Q.Ø	100.0	100.0	0.	£90.0	Ũ
Test solution t _{end}	85.5	88,5	ð 78.7 L	× 84.9	s de la companya de l	84.2	ſ
Root wash	Q.8/	× 0.6 ×	∫× 1.0°	26		0.5	
Test solution + root wash	\$6.1	© 89. ∱ ©	796	×84.9 ×		\$4.9	
Aliquots	©1.3	1.4	¥.3	D 1.4 C		l.4 €	
Combustion shoots) 2. <i>2</i>	<u>Ø</u> .5	ۍ 3.9 <i>ک</i> ړ	3.D	Ö.	≫ 3.0	
Combustion roots	3.3	@ ² .4	5 Q	3.8		3.7	
Translocation from roots to shoots	<u>ک</u> 9.9	51.1 "	4 3.5 «	Q45.5	0	45.0	
Plant total	5.5	5.0	<u>9.1</u>	6.9	<u></u>	6.6	
Total recovery radioactivity	930	\$95.4 <u>(</u>	≫ [∾] 88.7 [≪]	<u>91.8</u>		92.2	
le 7.1.4- 7: Wategaptake	y S				J)		

Commla	Stand Go	V A in the	NA initial			437
Sample	sample 1D	V Ustart Indulat	V Yend Interal		net Δv	Δν
				Start →tend	tstart →tend	t _{start} →t _{end}
O*	à tì .			<u>[ng]</u>	[mL]	[%]
Control plants	160818P1 🛒	3-38.93	285.36 ₀	\$3.57	50.63	14.94
	160818P2	338.62	_©290.5©	∕≫48.07	45.13	13.33
No al	160848P3	, [°] 338@A ∘,	O 287.63 🔅	50.91	47.97	14.17
	mean (P143)			50.85	47.91	14.15
Day 4 (t_1)	¥60818РТ7 🖉	\$35.14 O	315.90	19.24	18.05	5.36
	1608 (8 PT8)	~°335.76	S 317 S	18.61	17.42	5.17
	160818PT	~~ 33₹,25 °~	3,16.06	21.19	20.00	5.91
\$	160818PGF10	396.57	3 P1.19	25.38	24.19	7.16
	160818PT11	338.41	ू≪ॐ313.68	24.73	23.54	6.93
L.	mean (PT7-11)		Ő ^Y	21.83	20.64	6.10
Dax 10 (tend)	1,60818PT+12	y 33 4 /16	[*] 276.92	57.24	54.30	16.25
\sim	160818 113	338.36	284.41	53.95	51.01	15.08
. Ø	160818PT15	@342.76	270.29	72.41	69.47	20.27
4	160818PT16	335.23	274.77	60.46	57.52	17.16
	mean (PT\$2-16)			61.02	58.08	17.19
P1-P3 = matreated	plants, P7-P16 = rea	ated plants				
V tstart intitial = vo	dume of test soloion	at the start of the e	quilibrium after s	ampling, DAT-	0	
V ten initial zvol	lume of test solution a	at the end of the ex	periment, DAT-1	0		
	Ô, X					
E S	L'					
Č ^O [*]						



Date				Si	igle valu	ies				Mean	
	PT7	РТ8	РТ9	PT10	PT11	PT12	PT13	PT15	PT16	Q	, ·
Day 0 (tstart)										Z.	Ĩ
V t _{start} [mL]	335.14	335.76	337.25	336.57	338.41	334.16	338.3	342.7	335.2	2 7.06	Ô
c t _{start} [µg/L]	93.46	89.18	100.36	104.06	94.76	90.00	90.48	\$5.43	78.34	≫91.79	*
m t _{start} [µg]	31.32	29.94	33.84	35.02	32.07	30.07	30.62	29.28	26.26	30.04	Ô
Day 2 (t ₀)					Ĉs		Ľ,		~~~		Å C
V t ₀ [mL]	325.05	327.02	326.37	323.32	325.42	323.38	<i>3</i> 27.95	329.11	<u>©20.78</u>	325.38	Į ^v
c t ₀ [µg/L]	91.22	91.36	97.71	100.32	92.46	86.71	89.56	80.95	75.35	89.52	6
m t₀ [μg]	29.65	29.88	31.89	32.4 <i>3</i> C	30.09	28. Ø	29.37	26.64	24.17	29.13	Ň
Day 4 (t1)						××.	Ŷ	Ŷ,	Ő (ð (×
V t ₁ final [mL]	310.89	313.89	310.68	308.85	3°10.47≈	° '	Y Q	r ô		310.96	
c t ₁ [µg/L]	92.67	92.11	99.60	100.50	93.68	, s			c	95.71	
m t₁ [μg]	28.81	28.91	30,94	31 04	29,09	Ð.	0		Ž)	29 .76 🔬	Ŷ
Day 10 (tend)						à ć	4 . () V			,
V t _{end} final [mL]			Ý «	v _ (273, 🖗	281×20	264,59	27, 23	270.53	
c t _{end} [µg/L]		Ő		. \$		92,95	96.34	\$7.04	X .64	89.74	
m t _{end} [µg]			<i>w</i>		2	28.66	2 7.09 (23.03	\$22.1ٍ4≪	24.48	
PT7 - PT16 = treated	plants	~~	, Ô,	S C	ŷ Ó			0	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
$V t_{start} = volume of test$	t solution at	be start c	∲the equ	librium	fter samp	ling, DA	Г-0 О	ð	× .		
$c t_{start} = concentration$	of the test ite	m in the	test sonution	on at the s	start of th	e equilibi	has	e after sa	mpling, I	JA1-0	
$V t_0 = v_0 lume_0 f test s$	olution at the	e end of t	he muilib	i cominioi	r samnlin	σ DAT	inpring,		2		
$c t_0 = concentration of$	the test item	in the tes	st solution	at the en	d of the	quilibriu	n phase a	fter samr	oling, DA	Т-2	
$m t_0 = mass of test iten$	n in test solo	tion at the	e end oDe	quilityun	n phase at	ter samp	ling, DA	Г-20) Г	0,		
V t_1 final = volume of	est solution	at the int	erim şamı	oling, after	r samplin	g, 🖗 AT-4		Ç ^y			
$c t_1 = concentration of$	the test item	in the tes	st colution	at the in	edim sam	pling afte	er samplii	ıģ, DAT-	4		
$m t_1 = mass of test ten$	n in test solu	tron at the	whterm	ampling	after same	pling, 19/4	AT-4				
$v_{\text{tend}} = concentration c$	the test solutio	m in the t	nd of the	experime	nt aller sa	mpang, I	DAA 10	10			
$m t_{end} = mass of test in$	am in test sol	ution at t	he end of	theexper	iment aft	Sampli	M. DAT	-10			
Q		Q.	A 2		F a,		<i>,,,,,,,,,,,,,</i>				
	0. 5	×	· · ·	S		\sim					
ble 7,1.4-9: Concer			yprankn		asne	<u>کې</u>					
ite S	× *	, and the second		X) XI Dar	Single v	alues		a p		Mea	n
\			<u> 8 Pal</u>			I PII	2 PT1	3 PT1	5 PT1	0	
y 4 (t1) 🖉 💡	<u>, 67 80</u>		<u> </u>	<u> </u>	- O						
root wash [ug/L]	<u> </u>	2.8	3.0	4.3	3.9	1				3.87	7
t ₁ root wash [μg]	0.2	29 0.1	48[°] 0.1 ¢	8 0,34	0.18	1				0.20	9
y 10 (End)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	, ,,	, L								
end, root wash [µg]	× A	. *	Â,	ð.		2.7	1 2.1	6 1.12	2 3.2	6 2.50)
tend root wash [µg]	R I	Ň	× _ C			0.22	.9 0.17	8 0.09	0.28	0.21	2
7 – PT16 = treated plan	nts	<u>, 0</u>								-	

Table 7.1.4- 8: Concentrations of isoflucypram in test solutions

P17 – PT16 = treated plants c t₁ root wash = concentration of test item in root wash solution at the interim sampling, DAT-4 m t₁ root wash = concentration of test item in root wash solution at the interim sampling, DAT-4 c t_{end} root wash = concentration of test item in root wash solution at the end of the experiment, DAT-10 m t_{end} root cash = mass of test item in root wash solution at the end of the experiment, DAT-10



D. CALCULATION OF PUFs AND TSCFs

The mean PUF in wheat for pyrazole-labelled isoflucypram amounted to 0.40 ± 0.10 (t₀-t₁) and 0.49 ± 0.06 (t₀-t_{end}). The mean PUF in wheat for pyrazole-labelled isoflucypram accounted for 0.44 ± 0.10 , indicative for a slightly inhibited plant uptake of the test item in comparison to water with the test (see Table 7.1.4-10).



		PUFwheat		
	t_1	Fend	overall 👸	
single	0.27	0.45 J	R v	13 <i>X</i> . 6
samples	0.47	0.46		
	0.32	A 0.60 V	o° A A	
	0.55	0.46		
	0.41 🔬			
mean	0.40 O [*]	0 0.49	0.44	
SD	0.10	~ 006 Q	0,10 0	
CV [%]	25.00	¥3.03	A . OY.94 .	
SD = standard devia	ation 🆓 🔊	° ° . 4° ć		K X
CV = coefficient of	variation			y O
$t_1 = interim samplin$	ig, DATQ [®]			Ó
$t_{end} = final \ sampling$	g, DAT 10			

C

The mean TSCF in wheat for byrazele-labelled isoflucypram arounted to 0.04 ± 0.01 (t_{start}-t₁) and 0.17 ± 0.02 (t_{start}-t_{end}), indicative for the translocation of the test item (or equivalents) from root to shoot tissues. For all plants analysed, the relative amount of the test item that was taken up by the roots and allocated to the shoots ranged from 37.9 to 51.1% (see Table 7.1.4-14).

Table 7.1.4-11: Transpiration stream concentration factor (TSOF) for isoflucypram in wheat plants



The good plant health indicated by interse biomass increase and water consumption throughout the testing period demonstrated a retrable and robust test system for the determination of the Plant Uptake Factor (PUF) and the Transportion Stream Concentration Factor (TSCF) of the test item. This was supported by a pH of the test solutions between 6.49 and 6.96 for the treated test systems and continuous aerobic conditions during the experimental period. Deviations between the values of individual test replicates were low indicated by an overall coefficient of variation of 21.94% (PUF) and 14.25% (TSCF), respectively. Furthermore, the reliability of this plant uptake experiment was confirmed as the reduced test item amount in the test solution at the end of the incubation phase could be recovered in the plants with a recovery of 92.2%.



The mean PUF for pyrazole-labelled isoflucypram in wheat plants was determined as 0.44. The calculated TSCF values amounted to 0.14 ± 0.01 (t_{start} - t_1) and 0.17 ± 0.02 (t_{start} - t_{end}), indicative for the translocation of the test item (or equivalents) from root to shoot tissues. For all plants analysed, more than 37.9% of the test item taken up by the roots was allocated to the shoots.

BCS-CN88460-carboxylic acid (M12)

• BCS-CN88460-car	·boxylic acid (M12)
Report:	KCA 7.1.4/03; ; 2017; M-588284-021
Title:	Determination of the plant uptake of [pyrazole, #14C] BCS-CI 888460 carboxy hc acid
	in wheat plants - Report amendment 1
Report No.:	S16-05510
Document No.:	M-588284-02-1 () () () () () () () () () (
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
	of the European Parliament and of the Council of 21 October 2009 Sheering the
	placing of plant protection products on the market and repealing Council Directives
	79/117/EEC and 91/414/EEC a 2 2 2 2 2 2 2
	The OECD Principles of Good Laboratory Practice (OECD 1998) and respective
	national regulations 2 2 2 2 2 2 2 2 2
Guideline deviation(s):	none of the state
GLP/GEP:	ves a v a a v a v a v a v a v

Executive Summary

The uptake of pyrazolyl-labellecoBCS 2N88460-carboxylic acid (112) as investigated in wheat plants (variety: Thasos) over a study duration of ten days under controlled temperature, humidity and light conditions (mean, 22.5%, approx. 50% hundity and a day/night cycle of 16 h/8 h). The plant uptake factor (PUF) and the transpiration stream concentration factor (TSCF) were determined. The test was performed in gradrupticates (four test systems) with additional driplicates of plant controls and triplicates of stability controls. 2

The initial test item concentration in the test solution was $89.05 \ \mu g/L$ corresponding to $29.85 \ \mu g$ test item per test vessel. Pre-grown wheat plants (BBCH code approx. 43) were either exposed to the test solution (half strengthened Hoagland No. 2 basal salt L maxture nutrition solution including the test item) of to nutrient solution only (controls) for the whole study duration of 10 days. Sample aliquots were analysed 0 (t_{stm}), 2 (t_{stm}), 4 (t_{stm}), 4 (t_{stm}), days after treatment (DAT).

Wheat plants appeared healthy over the total study duration both in treated and untreated test systems. During the course of the study the wheat plants grow from BBCH 13 at tstart (application and start of equilibration) & BBCPI 14-CF at ten (end of study at DAT-10). Oxygen saturation for all experiments except for one sample (161023 PY11: 68%) was always above 79% and pH-values remained in an adequate range for treated (6.53) to 6.999 and controktest systems (6.48 to 7.06).

Mean material balances were 98.8% of the applied radioactivity (AR) for t1 (range from 97.5 to 99.4% AR) and 97.0% AR for tend frange from 95.9 to 28.1% AR).

The total net transpiration rates at the end of the incubation phase (tend) ranged from 46.6 to 59.7 mL for treated plants and 49.6 to \$8.4 pl for sontrol plants. About 2.5 mL of the test solutions was lost due to evaporation, which was determined as the mean of 3 control replicates.

The mean initial concentrations (t_{start}, DAT-0) of pyrazolyl-labelled BCS-CN88460-carboxylic acid in the test solutions amounted to $\$9.08 \ \mu g/L$, increasing to $91.82 \ \mu g/L$ at t_1 (interim sampling at DAT-4) and decreasing to 101.05 µg/2 at tend (end of study at DAT-10). Root washing desorbed 0.115 µg of the test item from the roots at t_1 and 0.079 µg at t_{end} . The separate analysis of roots and shoots showed, that at t_1 372% and at t_{en} 38.4% of radioactivity taken up was translocated from roots into shoots.

The PUF was calculated from the respective amount of test item in the test solution and the volume of the test solution each at the end of equilibration phase (t₀) and the end of the respective incubation phases (t₁, t_{end}). The PUFs in wheat for pyrazolyl-labelled BCS-CN88460-carboxylic acid amounted to



0.24 (t₀-t₁) and 0.26 (t₀-t_{end}). The mean PUF was determined as 0.25.

The TSCF results from a calculation using the respective parameters present at the start of the study (t_{start}) and the end of incubation phases (t_1, t_{end}) , additionally taking into account the radioactivity present in the plant shoot tissues, indicative for the uptake and translocation of the test item in correlation with the net amount of transpiration. The respective TSCF was determined as $0.070 f_{start} - t_1$ and 0.06 (t_{start}-t_{end}) (see table below).

Table 7.1.4- 1	2: PUF and T	SCF values	of BCS-CN88460-	carboxvlic acid	in wheat plants
			01 2 00 01 00 .00	ear song ne aere	and a second products

Replicate No.	PUI	wheat A	<u> </u>	TSCFwheet O
	t ₀ -t ₁	to-tend	$t_{m} t_1$	L tstartend
1	0.20	0.28	Ø.11	0 ⁶ 8.06 0 [°]
2	0.21	0.27	∾0.06⊘	0.07 K
3	0.22	0.25		
4	0.31	%0.29 گ [°]	∑ ×0,07 K	0° 20° ×0,06 ×5°
5	0.29	00.29 °	0.05	0.03
mean	0.24	A 0.26 0	Q 0.07	
SD	0.05	Q.04	⊘. 0.02 (O^{γ} \swarrow 0.02 O^{γ}
CV [%]	19.17	J 13.81 V .	مَّرَّبِي (A.25 مَرْبَ	1 27.48 A
overall mean	Ø.	25 6 0 0		
SD	LÖ.	04 ° y v		
CV [%]	≈16	.96, & &	K O .C	Ŭ ^N
SD = standard dev	iation CV = coefficient d	Swariation 4		a0 <i>u</i>

A.

1.

Â		'0' A	ÓN KA	0
*		L. a.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ô.
<i>R</i> e		0° (0°		S O
	I. MATER	AND M	ETHODŠ 🕺	y di
- W	A			
	(°, (Å O		× 4	
A. MATERIALS 🔊 🛛 🖉			0 👋	a y
Q'		N 5		. A
			n de la	D
. Test Item	L' , ~	Y , Y , N	U N	í.
Pyrazolyl-labelled RCS-CN	8460@arboxy¶i	c acted (MID)	S'a.	
Sample-ID: $\mathcal{O}^{v} \overset{v}{\sim}$	KML 10176	× \$	0 4	
Specificantivity	2 12 MDalma		, (?)	
specific activity.	o,∻o wingynig `			
Radiochemical purity	<u></u> 898%≪° _ ∖	Ô V	, O	
Chemical nurity:	97 7 % S	× /.	1 A	
		s s		
	OF 47	8° 0 🔊	,	
Tast Swatan	Y O AY	N N		
a resusystem 🔊 🕐				

2. Test System

Germination and early growth of wheat plants (varieto Thasos) was conducted on Perlite until plants reaching a BBCH stage of approx 11-12. The plants were cultivated under temperature, humidity and light controlled conditions in an incubation for During germination and early growth, plants were poured with water of Perlife substrate before exposed to constant illumination using LED lights and pouring with nutrient solution (NS). The characteristics of the Perlite substrate, illumination and the





Table 7.1.4-13: Test conditions

Illumination c	characteristics	Nutrient solution
day / night	Quantity	
[h/h]	[klux]	
16 / 8	approx. 12.0	exemplary: 0.8 g Hoagland's No. 2 basal saft L
		mixture, 1.03 g MES butter (2-(N-morpholino)
		ethanesulfonic acid) and 0.75 mL of 15% Ferric
		EDTA (ethylenediaminetetraacetic acid) solution
		were dissolved in an appropriate amount of
		mineralised water. pH was adjusted to 6.5 using
	C	sodium hydroxide (KOH) and finally was filled
	a)	up to 1 L with demineralised water Q
_	Illumination of day / night [h/h] 16 / 8	Illumination characteristics day / night Quantity [h/h] [klux] 16 / 8 approx. 12.0

B. STUDY DESIGN
1. Use Pattern The initial test item concentration in the test solution was 89%

Experimental Conditions 2.

The hydroponic test system for the PbJF/TSCF experiment consisted of 10 brown gass vessels (300 mL) filled with ~340 mc test solution and 2 plant each 3 brown glass vessels filled with ~340 mL test solution only and 3 more brown glass vessels filled with ~340 mL nutrition solution (NS) and 2 plants each. Plants were gently fixed with elastomer form and staked with a wire spiral. All vessels were bubbled with air to maintain aerobic conditions. d'i

All used plants were pre-grown on Perlito and ransferred at BBCH stage of approx. 11-12 to hydroponic conditions. Therefore a plants for each brown glass vessed were selected based on health, morphology and size as suitable replicates. After acclimatisation to the new hydroponic growth conditions (10 days), plants were transferred into 10 brown glass dessels containing ~340 mL NS with pyrazolyl-label@d BCS-CN88460-earboxy/0c acid at a final concentration of 89.08 µg/L, as well as into 3 brown glass test wessels containing 340 m NS with 47.6 µL of MeOH. The latter corresponded to the organic solvent used for application of the test term. Three more vessels contained NS with Gadiolabelled test item at the described Soncentration, but without plants. Throughout the whole experiment performed under hydroponic conditions, all used test vessels were bubbled with air to maintain aerobic conditions. Following a 10 day acclimatisation phase, plants were exposed to the test item for 2 days during the equilibration phase, before Starting the incubation phase lasting for 2 (t1) or 8 (tend) more days. All plants were monitored regularly and no unusual observation with respect to growth could be detected

3. Sampling

The study was performed with two wheat plants per brown glass vessel. Analyses were conducted at 0 (t_{fac}), 2 (t₀), 4 (t₁) and 10 days (t_{end}) after treatment. Harvest of plants were performed at t₁ and t_{end}. At all dates, radioactivity in the test solution pH, oxygen saturation and volume of the solutions were determined. At Istart, to and the biomass of the plants was determined for all (tstart) or harvested brown glass vessels (t1, tend)

Analytical Procedures 3.

At each date of analysis (that, to, t1, tend), 3 aliquots of 0.5 mL were taken from each radioactive test system and overall contained radioactivity was determined by liquid scintillation counting (LSC). Addition Φ , at the plant harvest after 4 (t₁) and 10 days (t_{end}) after treatment, radioactivity formerly attached to the root surfaces was quantified after external treatment with ACN/H₂O (4/1; ν/ν). The amount of radioactivity in the test solution as well as in the root wash solution was determined by LSC. Radioactivity taken up into root tissues as well as radioactivity allocated to the shoots was



determined by combustion in an oxygen atmosphere using an oxidiser. The released carbon dioxide was trapped in an alkaline scintillation cocktail and the radioactivity was determined by LSC.

The purity of the stock solution, as well as the stability of respective aliquots used for application (application solution) before and after application were checked by High Performance Liquid Chromatography (HPLC) coupled with radiodetection.

II. RESULTS AND DESCUSSION

A. PROPERTIES OF TEST SYSTEM

Oxygen saturation for all experiments except for one sample (161923PT11: 689) was always above 79% and pH of the test solutions during the course of study ranged from 6.56 to 6 89 for the treated and 6.48 to 7.06 for the untreated test system.

B. PLANT CONTROLS

The health and growth of the wheat plants was visually assessed regularly. In parallel to the treated test systems untreated test systems (plant controls) were insubated to enable the detection of possible effects on plant growth and health induced by the test item. Wheat plants appeared healthy over the total study duration both in treated and untreated test systems

Besides an increase of biomass detectable for all treated (0,57 g) and unscated plants (2.26 g) at the end of the incubation phase, plant vigour was evident from the detectable plant development. This was reflected by BBCH stages of approx. 110 the start of acclimatisation phase and BBCH stages of approx. 14 to 15 at the end of incubation phase

C. ANALYTICA RESULTS

C. ANALYTICA RESULTS Mean material balances were 98.8% AR for the (range from \$7.5 tg \$9.4% AR) and 97.0% AR for the (range from 95, 97 to 98, 1% AR) (see Table 7.1.4-44). The complete material balances found at all sampling intervals for all test systems demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing.

The total transpiration rates ab the end of the incubation phase (Pend) ranged from 46.6 to 59.7 mL for treated plants and 49.6 to \$8.4 nd for Ontrok Plants This Orresponded with a net transpiration of 15.6% of the initial volume (335.12 ml) for the test vessels at the end of incubation phase, meeting the requirements of at least 15% net transpiration (see Table 7.1.4-15).

The concentration of the test item in the test solution stayed nearly constant over the entire incubation phase of ten days. The men initial concentration of parazolyl-labelled BCS-CN88460-carboxylic acid in the test solutions at that amounted of 89.08 µg/L, increasing to 91.82 µg/L at t1 and 101.05 µg/L at t_{end} . The mass of the test item decreased from 29.85 µg at t_{start} to 28.75 µg at t_1 and further decreased to 27.88 (ug at tend (Table 7.1 4 16). 0

On average the root washing released 0.915μ of the test item from the roots at t_1 and 0.079 μ g at t_{end} (see Table 7.1.4217).

The separate analysis of roots and shoots showed, that at t₁ 37.2% and at t_{end} 38.4% of radioactivity taken up was translocated from roots into shoots (see Table 7.1.4-14).

anstocated from re



Table 7.1.4- 14:	Mass balance	(in percentage	of applied)
1 abic 7.1.7-17.	mass balance	(in percentage	or appricu)

			Reco	very			0
		siı	ıgle sampl	es		mean	
Day 4 (t ₁)					~		Ô
Test solution t _{start}	100.0	100.0	100.0	100.0	P 100.0	1,000.0	Ô
Test solution t ₁	96.6	95.8	96.7	96.5	94.9	96.1 🦿	
Root wash	0.3	0.4	0.4	0.4	0.4	S 0.4	Ô
Test solution + root wash	97.0	96.2	97.1	\$6.8	95.3	96.5	Ŵ
Aliquots	1.4	1.40	1.4	<i>1.4</i>	1,4	4	n v
Combustion shoots	0.5	0.4	0.3	0.4	. ØB	≫0.4 ∠	, (
Combustion roots	0.6	ØY.7	0.6	0.7	0.6	0.6	- K
Translocation from roots to shoots	45.8	A 36.2	36.Q	a33.9 /	§ 33.2	31.2	s.
Plant total	1.1	⁹ 1.0	≈0,9	of 1.1 🔗	× Q.9	@1.0	Û
Total recovery radioactivity	99 _{&} 4 *	98:6	~ ⁹⁹ 9.3 _%	× 99.3	Ø7.5 »	``98.8 ``	
Day 10 (tend)	Ő.			Å.	ά L	4	e °
Test solution t _{start}	A00.0	₹ 10Q.Ø	100.0	100.0	100.0	190.0	, , ,
Test solution t _{end}	93.4	94,3	گ 93.9 <i>گ</i>	∜ 9 <u>2</u> .©	93.8	93.6	
Root wash	0.3	× 0.2 ×	≫ 0.3°	xQ.3	0.2 ×	0.3	
Test solution + root wash	9 34	° 94.6°	9 4 ~2	J3.3 &	§ 94 Ø	93 9	
	- Y		- 0			(A) • · ·	
Aliquots	0°1.4	1.4	¥.4	5 1.40		≪1.4	
Aliquots Combustion shoots	0.92	1.4 •.1	7.4 6 1.4	5 1.40 1.40	0.5	≪1.4 [≫] 1.0	
Aliquots Combustion shoots Combustion roots	0.92 1.4		1.4 1.4 1.9	<u>) 1.4</u> <u>1.0</u> 2.0	0.5 0.5	×1.4 [∞] 1.0 1.6	
Aliquots Combustion shoots Combustion roots Translocation from roots to shoots	0.92 1.4 1.4	1.4 0.1 0.1 50.1	¥.4 0 1.4 1.9 41.7	2.0 2.0 2.0	0.5 0.5 1.4 24.0	×√1.4 [×] √1.0 1.6 38.4	
Aliquots Combustion shoots Combustion roots Translocation from roots to shoots Plant total	0 1.4 0 90 1.4 2 39.5 2.4 0	1.4 0.1 50.1 2.2	¥.4 5 1.4 1.9 41.7 3.3	2.0 3.2 3.2 3.2 3.2 3.2 3.2 3.2 3.2	0.5 0.5 24.0 29	× 1.4 × 1.0 1.6 38.4 2.6	

Sample	Sample ID	V t _{start} initial	W t _{end} initial	$\mathbb{Q}^{\gamma} \Delta V \mathbb{Q}^{\gamma}$	net ΔV	ΔV
~0		🔊 (ml@r ^{a)} 🔬	َ× [₄m]L]	Start → tend	$t_{start} \rightarrow t_{end}$	t _{start} →t _{end}
O^v				[@/L]	[mL]	[%]
Control plants	161018P1	36.7	Ø81.4 9 ,	\$5.31	52.16	15.49
	161018P2	338.33	. 276 : ₿	% 61.55	58.40	17.26
K Y	161048P3	340-92 👡	288.13	52.79	49.64	14.56
	mean (P1-P3)			56.55	53.40	15.77
Day 4 (t_1)	A61018PT7	≪J335.190°	319.90	15.29	13.90	4.13
	16104 8 PT8 5	332.93	\$ 312,65	20.28	18.89	5.65
	161018PT9	233.83 %	311.12	22.71	21.32	6.36
*	161018PD10	Q37.43	9 18.52	18.91	17.52	5.17
	16101&PT11	335.23	≪ 315.63	19.60	18.21	5.41
L.	mean (PT7-PK11)		Y	19.36	17.97	5.34
Dax 10 (tend)	161018PT+2	33 5.74 ×	283.77	51.97	48.82	14.54
	161018 P 13	\$39.06	289.29	49.77	46.62	13.75
a da	161018PT14	@ 334 9	273.16	61.03	57.88	17.32
Å	161018PT1	333.54	270.73	62.81	59.66	17.89
	161018P7016	\$34.10	283.31	50.79	47.64	14.26
	(PP12-PT)6)	Ŷ		55.27	52.13	15.55
P1-P3 suntreate	d plants, PT7-PD6 = tr	eated plants				
Vtstarkinitial + vol	lume of test solution at	the start of the equ	ilibration after sa	mpling, DAT-0)	
V ten initial vo	lume of test solution at	the end of the exp	eriment, DAT-10			
Gaart = start of equ	uilibration, DAT-0; tend =	= final sampling, I	DAT-10			
a) for 677-PT11	$t_{end} = t_1$					
Ű						



Date					Single	values					Mean]
	PT7	РТ8	PT9	PT10	PT11	PT12	PT13	PT14	PT15	PT16	Ľ	Ŝ
Dav 0 (t _{start})												S
V t _{start} [mL]	335.19	332.93	333.83	337.43	335.23	335.74	339.06	334.19	330.54	334.10	B 35.126	5
C t _{start} [µg/L]	89.12	89.54	89.28	89.17	89.54	89.71	88.96	88.61	88.43	88.45	89.08	
m t _{start} [µg]	29.87	29.8	29.80	30.09	30.02	30.12	30.16	29.61	29.49	29.55	29085	Ô
Day 2 (t ₀)						Ĉa		Ľ,	•		Å Å	Ų
V t ₀ initial [mL]	325.36	322.61	321.94	327.28	325.17	328.46	327.91	323.47	319.78	Q23.32	324.09	L
C t ₀ [µg/L]	90.23	90.38	91.57	90.71	89.78 🍃	91.12	90.81 (89.96	91.13	90.3	90060	ιÔ
m t₀ [μg]	29.36	29.16	29.48	29.69	29.19®	29.47	29.78	29.10	29 1	29.20	29.36	V
Dav 4 (t ₁)							~	Ŵ	Ŷ,	Ô,	ès de	
V t ₁ final [mL]	318.12	311.23	307.50	316.97	312.05	° .	Q ^r x		1 8		313,17	
C t ₁ [µg/L]	90.75	91.78	93.72	91.56	91.27	, K	Ś			e V	<i>s</i> 91.82	
m t ₁ [μg]	28.87	28.56	28.82	29.02	28,48			- Of		Ő	∂ 28.75€	
Day 10 (t _{end})							r d	A .	Ĵ ^v «	, ,		
V t _{end} final [mL]				Ŷ (¥	280.14	285,9	269,33	266,89	277.98	206.05	
C t _{end} [µg/L]			Ő		. \$	100,10	9953	109.22	102.70	£ 9.71	≥101.05	
m t _{end} [µg]				10%	ĽŸ,	28.04	28.46	27.80	27.41	\$ <u>27.7</u> 2%	y 27.88	
PT7-PT16 = treated	d plants			Q)			
V $t_{start} = volume of$ V t_0 initial = volume	test solut	ion at the	start of t	of these	vilibration	er sampli	ing, LAT	-0 ♥ D&T-2	õ	Ň		
V t ₁ final = volume	e of test so	olution af	ter sampl	ing D AT	-4 \$				Q,	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
V tend final = volu	ne of test	solation	at De end	l of the e	speriment	t after sar	npling, D	AT-10	, , , , , , , , , , , , , , , , , , ,	2		
$c t_{start} = concentration$	on of test	item in <u>t</u>	st solution	on at the	start of eq	uilibratic	on phase a	after sann	oling.@A	Т-0		
$c t_0 = concentration$	1 of testat	em in tes	t solution	at the h	d of the e	quilibrati	on before	e samplin	g, DAVI-2 ^∼	2		
$c t_1 = concentrationc t_{end} = concentration$	n allest	item in te	stadutio	at the fi	enthof the	eving and	en sænnprin ment DAT	-10				
$m t_{start} = mass of test$	st nem in	test solut	fon at the	start of	quilibrat	on phase	after sam	npling Ø	AT-0			
$m t_0 = mass of test$	tiem in te	st solutio	n at the e	nd of the	equilibra	tion befor	re sampli	ng, DAT	-2			
$m t_1 = mass of test$	item in te	st solatio	n at the in	nterin sa	mpling af	terSampl	ing DAT	-4 @p. 1	0			
$m t_{end} = mass of tes$	t item-in	testsoluti	ion at the	end of th	e experin	Weba after	sampling	goda I-I	0			
27			Ç 2	γ (y `							
able 7 .1.4 - 17: C	Concenti	rations	of BCS-0	CN8846	0-carboz	xyl ic aci	d (M12)	in root	wash			
Date	_ م	- Ç		<u> </u>	🔊 Sin	gie valu	és				Mean	
	🔊 РІ	Y P7	🖋 P4	9 PA	90 PT	1	12 PT	13 PT	14 PT	15 PT	16	
)av 4 (t_1) Q_1			, Ĉ		<u></u>	<i>a</i>						
$t_1 \left[\mu g/L \right] $	01.2	23 1 .4	2 1.3	35 1.4	15	7 77					1.44	
$n_{\text{root wash}} t_1 (\mathbf{h}g]$	0.0	99 0.1	9 0.k	08 Q.I	₽6 Q.P	16					0.115	
Day 10 (Bad)	· · ·	? . Q	- 0	, C			•					
tend. Mug]		A	A A	<u></u>	×	1.0	07 08	37 10	6 11	5 08	.99	
n root wash tend [ug]		Â,	× ×		Star I and a star in the star	0.0	87 0.0	68 0.0	84 0.0	95 0.0	70 0.079	
T7-PT11 = treated	plants				<i>»</i>							

Table 7.1.4- 16: Concentrations of BCS-CN88460-carboxylic acid (M12) in test solutions

P1/-P111 = treated plants c t₁ root wash = concentration of the item in root wash solution at the interim sampling, DAT-4 c t_{end} root wash = concentration of test item in root wash solution at the end of the experiment, DAT-10 m t₁ root wash = mass of test item in root wash solution at the interim sampling, DAT-4 m t_{end} root (c) = mass of test item is root wash solution at the end of the experiment, DAT-10



D. CALCULATION OF PUFs AND TSCFs

The PUF in wheat for pyrazolyl-labelled BCS-CN88460-carboxylic acid amounted to 0.24 ± 0.05 (t_0-t_1) and 0.26 ± 0.04 (t_0-t_{end}) . The mean PUF amounted for to 0.25 ± 0.04 , indicative for a slightly inhibited plant uptake of the test item in comparison to water uptake (see Table 7.1.4-18).

Table 7.1.4- 18: Plant uptake factor (PUF) for BCS-CN88460-carboxylic acid (M22) in wheat plants

		PUFwheat	A	
	t0-t1	tostend	, 🖉 overall	
single	0.20	28	Û (9, °0, °C, C
samples	0.21	0.27	R jû	
	0.22	0.19	.0	
	0.31	0.29	o° A	A U A
	0.29 4	0.29		
mean	0.24 🔬	°0.26,☆ ∡	0.25	
SD	0.05	0.04	~ 0.0 4	
CV [%]	19.17	1281 Q	^{Or} 16.96	
SD = standard deviation	ation: $CV = cdefficient$	of variation	1	

 \bigcirc

 $t_0 = end of equilibrium phase, DXT$

 $t_1 = interim sampling, DAT-4$

 $t_{end} = end of study at DAT-00$

The mean TSCFs in wheat for pyrazolyl-labelled BCS-CN88460-carboxyde acid amounted to 0.07 ± 0.02 (t_{start}-t₁) and 0.06 ± 0.02 (t_{start} find), indicative for the translocation of the test item (or equivalents) from root to shoot tisques (see Table 7.1.4-19). ~C For all plants analysed, the relative amount of the test item that was taken up by the roots and allocated to the shoots ranged from 24, Oto 50, P% 0

Table 7.1.4- 19: Teamspiration stream concentration factor (TSCF) for BCS CN88460-carboxylic acid (MA2) in wheat Mants 🔍 al a

				-
			SCFwheat	Q.
, Q	× 1	🗸 tstart-t1 🔿	tstart-tend	overall
2Q ¹	single 🖉 🧳	Ø .11	\$ Q.96 }	
<i>K</i> ∕y″	samples 3	🔬 0.06 🖓 👌	₩ 0.07 ×	
	\$° ~	~ 0. 0 4	0.07	
	6 A	¢ 0.07 k	0.06	
	<u>_`</u> \$'\$	😤 0.05 🖉	S 603	
~	Qmean O 🔍 🔿	م ^(*) 0.0 (*)	У _🏡 0.06	0.06
A	SD Ö		0.02	0.02
T'	CV [%]	₩ 123	27.44	32.12
	SD = standard devia	tion; CV = coefficient	∮ variation	
, Ku	tstart = start of equilib	ration, DATØ;	1	
\searrow	$t_1 = interim sampling$	2, 19AT-4 🖓 🔊 🔊		
	tend study at	PAT-10		
	L A V			
R			NCLUSIONS	

The good plant health indicated by intense biomass increase and water consumption throughout the testing period demonstrated a reliable and robust test system for the determination of the Plant Uptake Factor (POF) and the Transpiration Stream Concentration Factor (TSCF) of the test item. This was supported by a pH of the test solutions between 6.53 and 6.99 for the treated test systems and continuous aerobic conditions during the experimental period. Deviations between the values of individual test replicates were low indicated by an overall coefficient of variation of 16.96% (PUF) and 32.12% (TSCF), respectively. Furthermore, the reliability of this plant uptake experiment was



confirmed as the reduced test item amount in the test solution at the end of the incubation phase could be recovered in the plants with a recovery of 97.0%.

The PUF for pyrazolyl-labelled BCS-CN88460-carboxylic acid in wheat plants (variety: *Thasos)* and a second determined as 0.25 ± 0.04 . The calculated TSCF values amounted to 0.07 ± 0.02 (t_{start} t) and 3 0.06 ± 0.02 (t_{start}-t_{end}), indicative for the translocation of the test item (or equivalents) from boot to²⁰ shoot tissues. For all plants analysed, more than 24.0% of the test item taken up by the roots was allocated to the shoots.

Column leaching studies CA 7.1.4.1

CA 7.1.4.1.1 Column leaching of the active substance

No column leaching studies were performed for isoflucypram. The potential mobility j S determined from the adsorption/desorption studies described wider a 7.1, 91

CA 7.1.4.1.2 Column leaching of metabolites, preakdown and reaction products

No column leaching studies were performed for the major soil regradation product of isoflucypram. The potential mobility can be determined from the adsorption/desorption/studies described under CA 7.1.3.1.2.

Lysimeter studies CA 7.1.4.2

The leaching behaviour of is thur par and its more sei metabolite BCS-CN98460-carboxylic acid (M12) are addressed by standard focus goundwater modelling. Therefore, Hysimeter studies were not conducted.

Field leaching studies have not been conducted for the active substance as sufficient information can





CA 7.2 Fate and behaviour in water and sediment

Isoflucypram was hydrolytically stable in sterile aqueous buffer solutions at three pH values (pH 4.97and 9) in the laboratory in the dark. No degradation products of isoflucypram were observed. Hydrolytic degradation is unlikely to contribute to the degradation of isoflucypram under by pical conditions of the environment.

Photodegradation is unlikely to contribute to the degradation of isoflueypram under spice light conditions of the environment. Isoflucypram was slowly degraded in aqueous buffer solution at pH under exposure to simulated sunlight and aerobic conditions in the laboratory No degradation products > 10% AR were observed.

In surface water under aerobic conditions, isoflut ypram does not degrade

Isoflucypram dissipated rapidly from the water in water/setiment systems under aerobie conditions. One degradation product of isoflucypram was identified: BCS-CM88466 Parbox ic acid (MI2) with a maximum occurrence in the total system of 6.6% are (water laver 5.4%; sediment 1.3%, respectively). Formation of carbon dioxide accounted to \$0.3% AR or both watersediment systems. Nonextractable residues accounted for a maximum of 8.4% AR in 90th water/sediment systems. The proposed metabolic pathway of is much a gerobic water/sediment systems is shown in Figure 7.2-1.

A summary of maximum occurrences of the major metabolite BCS-CN88460-Carbox tric acid (M12), CO₂ and non-extractable residues in aquatic systems is given in Jable 72

O Summaries of half-lives for trigger evaluation and modelling purpose are shown in Table 7.2- 2 and Table 7.2-3, respectively. 0 \bigcirc

Ø 1

Summar of maximum occurrences of the major metabolite BCS-CN88460-carboxylic Table 7.2-1: acid (MV2), carbon dioxide and non-extractable residues in aquatic systems (in percent of applied radioactivity) $\hat{\mathbb{O}}$ Ø

		Ro I	× 27			
	Compound 🔬 🔬	Hydrolysis	Photolysis	🖉 Aerobic	Water-	sediment,
1		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	_{%] ~	mineralisation	ae	robic
K,			× /.	مْجَر[%]	[%]
	2° 4'				water	sediment
			or U	ð,	layer	
	BCS-CN88460 carboxyric	6 - 🚿	§- &	ž _	5.4	1.3
	acid (112)					
	Carbon dioxide 🖉 ๙			0.9		0.3
	Non-extractable residues	Û X				6.4

(3) Carbon dioxide and volatile organic compound were not collected





Summary of DT50 values in aquatic studies of isoflucypram and its major aquatic Table 7.2- 2: metabolite BCS-CN88460-carboxylic acid (M12) for trigger evaluation

Compound			DT50	<u> </u>			
			[days]				
		range	arith. mean	geo, mean			
Hydrolysis			- A	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
Isoflucypram		Isoflucypram	was stable at all	H values,			
	therefore $\operatorname{norm} DT_{50}$ and DT_{50} values were						
		S A	calculated 🖉				
Aquatic photolysis study							
Isoflucypram	, O ^V	150	, O Y				
	environmental days	484 (Phoenixog)					
		750 Athens					
BCS-CN88460-carboxylic acid (M12)	k B°	~~~~~~~~~~~~~~~~~~~~~~~~~~~~					
	environmental days			4			
Aerobic mineralisation in surface wat	er (pelagic test)		ST O'				
Isoflucypram	low concentration	^{ال} 1000 × 1000					
	high concentration	> 1000		Õ			
BCS-CN88460-carboxylic acid (M12)				Ô			
Water-sediment study, aerobic				× Y			
Isoflucypram	water O	Ø2.79 <u>D</u> 2.06		2.40			
	sediment	≫ 282⊈n.r. ⊘	oʻ	282			
	total System 🖉 🖉	211 - 593		354			
BCS-CN88460-carboxylic acrd (M12)	watter of the	<u>n.e</u>		n.e.			
	sediment 🖉	0 k.e.	. 8	n.e.			
Č Š ×	total system 🖉 🚽	M.r. M	л ^у	n.r.			
n.r. = Not fully reliable, wathematically por	significantly different from	n 0; pot usable					
n a - Not avaluable more sufficient date more			7/ n				

 Table 7.2- 3c
 Summary of input parameters of software and its major soil metabolite

 BCS-CN88460-carboxylic acid (M12) in water and sediment for modelling purpose (PECsw)

Compound	Risk >>	Compartment	≫DT ₅₀		Max. occurrence
	assessment		[days]	remark	observed ^{c)}
Isoflucypram	PEC _{sw} Step 1	total system	354	Seo. mean of total system	100
_Q	, O [×] Step 2	water O	<u>)</u> 354 Ø	geo. mean of total system	100
~\$	Ŭ _v õ	sediment	≫ 354	geo. mean of total system	83.0
A	Step 3 [*]	Water & S	3,500	geo. mean of total system	100
Q,	, ¢ , õ	U S	•1000 ^{b)}	default value	
		sediment &	©354 ^{a)}	geo. mean of total system	83.0
			≫ 1000 ^{b)}	default value	
BCS-CN88460-	Step 10	water 0	1000	default value	5.4
carboxylic acid	U & 2 V	sediment O	1000	default value	1.3
(M12)		tötal system	1000	default value	6.6

According to FOCUS (2015) for Substances with Koc between 100 and 2000 mL/g two options should be tested:

a) DegT50555tem used for degradation in sediment

a) Deg Forystem used for degradation in sediment, default D150 of 1000 days used for degradation in sediment
b) Deg Forystem used for degradation in sediment, default DT50 of 1000 days used for degradation in water
c) % month basis out respect to parent



Figure 7.2-1:





CA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

Statement on water treatment processes

The request, complex by nature, is to be found in EC Regulation 1107/2009. However, it was not subject to specification at EU and Member State level, for example, in times of occlusion into Commission Regulation 283/2013 defining actual data requirements of, in Commission Regulation 2013/C95/01 defining and specifying the tests to serve as the data basis for evaluation. Beyond the general data requirements there was no specific guidance or interpretation given in the EV or national context. Even if standardized and reliable data were available it would be another step to define the complete steps in risk assessment including results of potential tests, their interpretations and to draw conclusions based on realistic scenarios that remain to be developed.

In the absence of tests, guidelines and guidance it thus remains with some general principles as for any chemical reaction. The progress of transformation of 'organic residues' is dependent on a full tange of parameters of influence, for example: concentration of chemical (= residue) to be oxidised available, extent of other organic matter available for oxidation in water, potential catalytic influence of ions of heavy metals, the concentration of the oxidizing chemicals (ozone/chiofine) the contact time and temperature.

Dependent on parameters of influence the transformation of residues can be expected to range from no to even complete mineralisation

Again and with no tests specifying influence or test parameters realistically in more detail, an estimated outcome would remain fully speculative and thus not scientific. No evaluation can be made currently on the effect of water treatment processes on the nature of the residue.

In the absence of agreed and harmonised testing proceedings including guidance on evaluation and interpretation of results at EV level this request is clearly out of scope for a qualified reply in the current registration process of the active substance isofacypram.

In summary and in light of the absence of harmonised testing procedures as well as guidelines on evaluation and interpretation of these results and their use for risk assessments a scientifically qualified response to this complex requirement cannot be delivered to date.

CA 7.2.1.1	Hydrolytic degrad

Report:Title:Report No.:Document No.:Guideline(s):

accordance with Regulation (EC) No 1107/2009; US EPA OCSPP Test Guidelines No. 835, 2120 and No. 83, 2130; Japanese MAFF Test Guidelines 12 Nousan 8147, No. 2-621

GLP/GEP:

Executive Summary,

The hydrolytic route and rate of degradation of pyrazole-labelled isoflucypram were studied in sterile aqueous buffer solutions at three pH values (pH 4, 7 and 9) in the laboratory in the dark at 50.0°C for 7 days. The test concentrations were between 0.41 and 0.44 mg/L.

The text was performed in static systems consisting of 10 mL glass crimp-top vials each containing 5 mL of test solution closed by crimp caps with Teflon®-faced septa.

Duplicate samples were processed and analysed 0, 0.17 (4 hours), 1, 3 and 7 days after treatment



(DAT). At each sampling interval, the amount of test item in test solutions was determined by liquid scintillation counting (LSC) and by HPLC/radiodetection analysis. The test item was identified by HPLC-MS(/MS) including accurate mass determination.

Mean material balances were 100.8% AR for pH 4 (range from 97.1 to 106.9% AR), 102.8% AR for A pH 7 (range from 100.0 to 107.1% AR) and 103.2% AR for pH 9 (range from 100.0 to 106.3% AR). Carbon dioxide and volatile organic compounds were not collected.

The amount of isoflucypram in the test solutions ranged from DAT 0 to DAT 7 between 97 and 106.9% AR for pH 4, between 100.0 and 107.1% AR for pH 7 and between 100.0 and 106.3% pH 9. No degradation products of isoflucypram were observed.

Isoflucypram was stable at all pH values, therefore no D⁴²⁰ and DT₉₀ Affues were calculated

Isoflucypram was stable at all pH values, therefore no Dt₂₀ and DT₉₀ yalues were calculated It is concluded that hydrolytic degradation is unlikely to contribute to the degradation of soflucypram under typical conditions of the environment. I. MATERÍALS AND METHOPS A. MATERIALS I. Test and Reference Items Test item: Pyrazole-labelled isoflucypram Sample-ID: Sample-ID: Sample-ID: A. MAL 9803 Specific activity: A. 22 MBq/mg (112.92 µCV/mg) Radiochemical purity: > 98% (HPLC with radioactivity detector) > 98% (HPLC with radioactivity detector) > 98% (TLC, soan) > 98% (HPLC with V-detector, 210 nm) Radiochemical purity:

Chemical purity:

Reference item;

No reference items wede

2. **Buffer** Solutions

The study was carried out using three different buffer solutions of pH 4.0, pH 7.0 and pH 9.0. The buffer solutions were prepared with concentrations of 0.01 mol/L to minimise buffer reactions.

Tał	ole 7.2.1.1- 1:	Buffer solutions of the two of	
	~Q	pH Type and final molarities	
	A	4.0 acetate, 0.00 M	
	Ĩ,	, Q , Q .0 U , FRAS, 0.0 M	
	, ¹	√ 9.0 → Øorate, 9.01 M	
	\sim		
B.	STUDY DES		

1. Experimental Conditions

Glass crimp top ytals (e. 10 mL) closed by crimp caps with Teflon®-faced septa were used as test vessels, Carbon Gioxide and volatile organic compounds were not collected.

All glassware and aqueous buffer solutions were sterilised prior to use by autoclaving twice for 20 minutes at 121% and stored under a clean bench to prevent biodegradation of the test item during the study. The oxygen contained in the buffer solutions was depleted before sterilization by purging nitrogen through the buffer solutions.

For each pH value, 5 mL aliquots of the respective test solutions were distributed into the test vessels which were then closed with Teflon®-faced septa and placed in a temperature-controlled water bath. For DAT-0 samples, aliquots of the test solutions were processed and analysed immediately after



application.

The amounts of applied test item were determined at DAT 0 as 9193 Bq (equal to 0.44 mg/L) for pH 4, 8673 Bq (equal to 0.41 mg/L) for pH 7 and 8796 Bq (equal to 0.42 mg/L) for pH 9 see Table 7.2.1.1- 2). These values were set to 100% of applied radioactivity (AR) for the samples of the respective pH value.

The test systems were incubated in a temperature-controlled water bath in the cark at a temperature 50°C.

II II			
0.01 M buffer	Radioactivity applied	Fest concentration	
рН	[Bq] "Õ ^y	[mg/L]	
4	9193	\$ \$ 0.445 ×	
7	8673 🖉		
9	879 % @	S & Q.42	\sim
	0		

Ĉ

2. Sampling

Duplicate Samples Five sampling intervals were distributed over the entire incubation period of 7 were processed and analysed 0, 0.17 (Phours), 1, 32 and 7, Gays after treatmen

3. Analytical Methodolog

Sample preparation and processing

The pH values of the test solutions were determined at each sampling interval in the unprocessed test systems.

The sterility was checked at each sampling interval for all samples.

At each sampling interval, the radioactivity content of the samples was determined by LSC.

No isolation of degradation products was performed spice no degradation product was observed.

All LSC and HPCC/radiodetection measurements were carried out without concentration steps.

Sample analysis

0 Radioactivity contents in samples were determined generally in duplicate by LSC.

Radioactivity contents in liquid samples (test solutions and recordines) were determined using aliquots of up to 0.5 mL with 2 mL Quicks afe \mathbb{R} from the formation of \mathbb{R}^{5} water (sample counting time in general = 10) minutes, background = 12 - 14 g/m).

At each sampling interval sliquous of the test solutions were characterised by the primary chromatographic method (RICHPLC) radio detection system).

HPLC hyphenated to electrospray ionization mass spectrometry in single or multistage mode (ESI-MS(/MS)) and radiodetection was used for confirmation of the test item identity.

> RES LAS AND DISCUSSION

ANALYACALMETRODOCOGY Α.

Verification of Sample Processing Method 1.

The mean recovery of the test item at DAT 0 was 100% AR for all pH values demonstrating that the sample processing wethod was well suited to recover the applied test item from the test solution and that the test item was stable under these conditions.



2. Verification of Chromatographic Procedures

The primary chromatographic method (HPLC/radiodetection) was well suited for the quantitative analysis of the samples of this study as demonstrated by a mean HPLC recovery of 106.2% and a good linear fit for injected amounts of pyrazole-labelled isoflucypram from 8.8 to 1846 Bq absolute on column ($R^2 \ge 0.9996$).

The LOD of the primary chromatographic method was determined as 8.8 Bc absolute on column or 1.0% AR.

B. MATERIAL BALANCE

Mean material balances were 100.8% AR for pH 4 (range from 97.6 to 106.9% AR), 102.8% AR for pH 7 (range from 100.0 to 107.1% AR) and 103.2% AR for pH 8 (range from 000.0 to 106.3% AR) (Table 7.2.1.1-3).

(Table 7.2.1.1-3). The complete material balances found at all sampling intervals for all pH values demonstrated that there was no significant loss of radioactivity from the test systems of during sample processing.

Table 7.2.1.1- 3:	Material balance of	radioactivit	y in duffers	olutions at p	oH∱¥, 7 ag	ad 9 🖉
	(expressed as percer	itage of app	lied radioac	tivity, mean	s øf twor	eplicates)

Material		Buffer solution	
balance	∽ pH 4 [⊘] ~ ~ ~	рН 7	
Min	970 Q	0 1000 L	~ 100 A
Max 🔹	*106.9	8 107.1 S	10673
Mean 🐇	i00.85	102.8	4 03.2
RSD 🔊		2.4	2.1
RSD = relative stan	dard deviation		
		~~ 0' 4.	Ň

C. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the radioactivity distribution are presented in Table 7.2.1.1-4. The hydrolytic route of degradation of isoflucypram at three pH values is summarised in Table 7.2.1.1-5 (mean values).

Table 7,2,1.1-4:	Material Dalances	of radioaction under	hydrolytic condition at 50°C

	Buffer 🔊 Buffer	Replicate		Days at	fter treatme	nt	
	δ ² Α.	no. 🗸	~ 9 ~	0.10	1	3	7
	pH 4	N 10	\$98.3	103.1	102.4	98.9	94.6
			101,77	110.8	100.5	98.3	99.5
	A Ô	🛛 🔊 🖉 🖉	100.0	106.9	101.5	98.6	97.1
4	OpH 7 👸		jtøð.5	J 104.9	97.9	104.3	102.5
<i>a</i>		× 2	£99.50 [°]	109.2	105.4	99.8	104.2
A.		mean /	2 100 Ø	107.1	101.6	102.0	103.3
. A	рН9 🖉		1,000.0	103.6	105.6	102.5	104.3
	Į į		OP00.0	104.7	107.0	101.3	103.5
		mean	100.0	104.2	106.3	101.9	103.9
		y Z Z					



Ň

Table 7.2.1.1- 5:	Hydrolytic degradation of isoflucypram at 50°C
	(expressed as percentage of apllied radioactivity, mean of two replicates)

Buffer	Compound	Days after treatment					
solution		0	0.17	1	3	7 🐔	
pH 4	Isoflucypram	100.0	106.9	101.5	98.6	97 💭	40' A
	sum of unid,/diff. residues ^{a)}	n.d.	n.d.	n.d. 🖧	n.d.	nÇd.	
	total recovery ^{b)}	100.0	106.9	101.5	98.6	97.1	Y.
pH 7	Isoflucypram	100.0	107.1	10,1-6	102.0	O ^v 103.	, Q
	sum of unid,/diff. residues ^{a)}	n.d.	🗞 n.d.	nd.	n.d	n.đ%	<u></u>
	total recovery ^{b)}	100.0	107.1	¥01.6	10200	AØ3.3	
pH 9	Isoflucypram	100.0	104.2	Õ [™] 106.3	\$01.9	A03.9 K	°0, °
	sum of unid,/diff. residues ^{a)}	n.d.	n.d.	n.d.	On.d.	[™] n.d?	, Ô
	total recovery ^{b)}	100.0	104.2	Ø6.3 L	101	103.9	

n.d. = not detected

a) Minor degradates are summed up to sum of widentified ⁹/₂ diffuser residues

so residues well as clean up and charmatographic b) Difference to material balance values due to ounding errors a losses

Carbon dioxide and volatile organic compounds

Carbon dioxide and volatile organic compounds Carbon dioxide and volatile organic compounds were not collected Test item and degradation products in test solutions

Test item and degradation products in test solutions

The amount of isoflucypram in the test solutions ranged from DAT 0 to DAT 7 between 97.1 and 106.9% AR for pH 4, between 100.0 and 107 1% AR for pH 7 and between 100 L and 106.3% AR for pH 9 (see Table 7.2.1.1-5 above). No degradation product of isoflucypram web observed. \circ

D. DEGRADADON C

Isoflucypram was stable at all pH values, therefore to DT 50 and DT 90 values were calculated.

E. DEGRADATION PATHWA

therefore no degradation pathway is proposed. Isoflucypram was stable at all pH yalues J. O

III ČONELUSIONS

Hydrofytic degradation is unlikely to contribute to the degradation of isoflucypram under typical conditions of the environment



CA 7.2.1.2 Direct photochemical degradation

Report:	KCA 7 2 1 2/01	· 2013· M-	461939-01-1		
Title:	[Pyrazole-4-14C]BCS	S-CN88460: Determina	ation of the qu	antum yield a	nd assessment
	of the environmental J	half-life of the direct p	hoto-degradat	ion in water	
Report No.:	EnSa-13-0236			- C ^y	
Document No.:	M-461939-01-1		1		\$° \$\$' 60
Guideline(s):	Draft SANCO 11802/	2010/rev 7 in accordar	nce with Regu	lation (EC)	
	No 1107/2009, 2012;	OECD Test Guideline	101, 19 \$ ¥; O	ECD Test Gui	define 316
	2008	"\V"	Q,	a,	\$ × 4
Guideline deviation(s):	not specified	Å	0 ×	× 4	
GLP/GEP:	yes	A	Q [°] b°	Å 4	× Č _L O ^v

Executive Summary

The UV-VIS absorption spectrum of isoflucypram n physhate buffer pH 7/acetonitrile (4/1, v/v) showed two maxima at 195 nm (abs 1.38) and 218 nm (abs 0.598). The V-VIS absorption spectra of isoflucypram in acetate buffer pH 4/acetonitrile (4/1, \sqrt{v}), in borate buffer pH 9/acetonitrike (4/1, \sqrt{v}) and in water containing isoflucypram showed similar absorption properties. The medar extinction coefficient ε of isoflucypram in botter pH/7 / ACN (4/1, $\sqrt{2}$) at 290 new was determined to 86 L x mol⁻¹ cm⁻¹ and at 295 nm to $\sqrt{2}$ L x mol⁻¹ cm⁻². The quantum yield of the direct phototransformation of isoNucyprim was determined in buffered aqueous solutions using polychromatic light according to the ECET OC method. Degradation of isoflucypram in neutral aqueous solution in a range of 8 to 21% was measured by HPLCradiodetection after a maximum virradiation period of 500 minutes. This indicated moderate degradability of isoflucypram via direct phototransformation in weutral puffered solutions. A low mean quantum yield of $\Phi = 0.00077$ was calculated on the basis of UV absorption data and the degradation kinetics determined from both experiments O The estimates based on the two modeling concepts (Zepp & Cline, Frank & Kloepffer) were well comparable. Both estimates considered the quantum yield Φ and the absorption in the UV-VIS spectrum being in the range of wavelengths retevant for the environment (see tables below). EnvironmentaPhalf fives of sunlight exposed top surface water layers were estimated to 8 to 22 days for a direct phototransformation of isoflucypran during periods of main use in spring to fall.

Thus, direct phototransformation in neutral aqueous solution may contribute to the dissipation of isoflucy fram from the environment. This assessment does not consider other potential mechanisms which may enhance the degradation in natural water, e.g. by indirect photolytic processes. However, in neutral and alkaline aqueous solutions hydrolytic degradation is regarded as the predominant route of dissipation.

Season	Environmental OT 50 of the direct phototransformation of isoflucypram in buffer pH 7 [days]					
a a la construction de la constr	30 th degree lat.	40th degree lat.	50 th degree lat.	60 th degree lat.		
Spring A	8.20	8.8	9.8	12		
Summer 🖉 🖉	7.4 ~	7.5	7.7	8.2		
Fall	ර ූ∆¥2 °	15	21	39		
Winter S	15	23	45	138		

Table 7.2.1-2- 1: Zepp and Cline Modelling (GC Solar)

Marginal conditions pure surface water at 0-5 cm depth, 10th degree longitude, clear sky, typical ozone concentrations in the atmosphere, half-lives integrated over the entire day.

The common of the 50th degree of latitude is more or less relevant to the conditions of Central Europe.

Ĵ



Month	Photolysis constant [1/sec]	Environmental DT ₅₀ of the direct phototransformation of isoflucypram in buffer pH 7 [days]				
		minimum	mean 🔌	maximum		
January	0.692 x 10 ⁻⁷	55	120	5304		
February	0.144 x 10 ⁻⁶	27	56	240		
March	0.283 x 10 ⁻⁶	15	28			
April	0.475x 10 ⁻⁶	9.4 🕅	17.	× 768 7 ~		
May	0.605 x 10 ⁻⁶	8.3 🕎	18	0 520 v V		
June	0.678 x 10 ⁻⁶	7.9 ₁	,ÕM2	L A L L		
July	0.604x 10 ⁻⁶	8.8	× 13	0 <u>44</u> 0 V		
August	0.590 x 10 ⁻⁶	A	140	45		
September	0.342x 10 ⁻⁶	<i>∞</i> 14	2 ×2 ×	▲ 87/2 ~C		
October	0.188x 10 ⁻⁶	🤹 22 🕉 🔎	¢ 43 √	<u>~ 190 ~ </u>		
November	0.831 x 10 ⁻⁷	O 42 c	\$ 97 O	م 482 م		
December	0.436 x 10 ⁻⁷	1 m84 0	Q 180 a.	<u>0</u> 920 0 4		

Table 7.2.1.2- 2: Frank and Kloepffer Modelling

Marginal conditions: pure stagnant surface water at Q-3 cm depth, geographic and clim oc conditions of German (50th degree lat.), no ontribution of another meno- or bimolecular elimination process.

(50 th degree lat.), no gentribution of another metro- or psynolecular elimination process.
$I \sim MA_1 = KIALS A > D M < HO D > C > C > \gamma$
A. MATERIALS
1 Test and Defense as Harry Control of the second s
Test item: $Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q$
Demonster la helle de Churchener Churchener
Pyrazole-labelledpsoliug/pramy & ~ ~ ~ ~ ~ ~ ~
Sample-ID: \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O} \mathcal{O}
Sumple-iD.
Specific activity: \bigcirc
\mathbf{D} adjochomical multiple $\mathcal{D} > 0.00/$ (IDEC with radio stivity detection)
Radiocheruical purey > 96% (Hr LC why radioactivity detection)
\sim
Chemical purity: $\mathcal{O}_{1} = \mathcal{O}_{2} = O$

Pyrazole-labelled soflucypram as used for the determination of the quantum yield instead of a nonlabelled test item due to a solubility assue and thus detection issue: It was not possible to detect low concentrations of the test compound using V detection - using the ¹⁴C-labeled test item radiodetection was possible. radiodetection was possible.

Reference item:

Non fabelled isoffucyprate of a state of the second s
Certificate-ID: $\sqrt{2}$ $\sqrt{2}$ 18080 $\sqrt{2}$
Batch code: 1 March 200 BCS-CN8846Q-01-02
Certified as ay: 5 98.4% w/wg/1H-NMR spectroscopy)



Test Systems 2.

The study was carried out using three different buffer solutions of pH 4.0, pH 7.0 and pH 9.0.

рН	Buffer	\$
4	acetate buffer	Č,
7	phosphate buffer	O,
9	borate buffer	4

 $\frac{1}{2} \frac{1}{2} \frac{1}$ uranyl oxalate as chemical actinomedr. The merry go-round irradiation apparatus was warmed up for at least 15 minutes prior to the exposure of the samples in order to guarantee a constant radiation of the light source as well as the projected sample temperature of $25\% \pm 1^{\circ}$ already at the beginning of the experiment. Subsequently only the merry-go-found but not the lamp or the cycle cooling was switched off for adding or removing of samples. After the equilibration phase of the system, two measuring cells with 3.0 m of actinometry solution were first exposed in the system for 10 minutes. After that the measuring cells containing 3.0 and of test solutions each were swiftly placed onto the 10 positions of the merry go-round apparatus. Degradation samples were incubated for 500 minutes in maximum.

LC-MS(/MS) verification spectra for test item and reference item were performed in the positive-ion electrochemical Conisation mode (ESI).

Sampling 2.

One sample of each degradation experiment was taken and analysed after 0, 50, 100, 150, 200, 250, 300, 350, 400, 450 and 500 minutes. A

Analytical Procedures 3.

At each sampling intervation is plucypain concentration in the samples was determined by reversed phase HPLC and evaluation of the respective VV signal by means of external reference standard.

Each sample for actinometry was transferred into an Erlenmeyer flask and filled up with water to about 50 mL. Then 5 mL of solution was added to each sample. The mixture was slowly titrated with the titration solution under aditation by means of a magnetic stirrer, until the colour changed from colourless to pink. The consumption in mL was determined exactly to 0.05 mL and the mean of four

replicates was taken. The consumption of the titration solution in case of the unexposed actinometry solution was determined in the same way blank value).



RESULTS AND DISCUSSION П.

A. **UV-VIS ABSORPTION PROPERTIES**

The UV-VIS absorption spectrum of a solution of 11.12 mg/L isoflucypram in phosphate. Suffer @ pH 7/acetonitrile (4/1, v/v) showed two maxima at 195 nm (abs 1.38) and 218 nm (abs 0.50). The UV-VIS absorption spectra of isoflucypram in acetate buffer pH 4/acetonitrite (4/1, v/v) in borne buffer pH 9/acetonitrile (4/1, v/v) and in water containing 11.12 mg/L isoffacypram showed simplar absorption properties.

The molar extinction coefficient ε of isoflucypram in buffer pH 7/acetomitrile (4/1, v/y) at 290 nm was determined to 86 L x mol⁻¹ cm⁻¹ and at 295 nm to 75 L x mol⁻¹ cm⁻¹. In general, the absorption properties indicate a potential for direct photolyfic interactions isoflucypram with sunlight in aqueous solutions.

B. PHOTODEGRADATION OF PARENT COMPOUN Degradation of isoflucypram was measured by HPLC-radiodection during the maximum irradiation period of 500 minutes. For respective data see Table evaluation of data see Table 7.2.1.2-5.

Photodegradation of isoflucypram in buffer af pH Frexpressed as mg/I Table 7.2.1.2- 4:

		al.	2	~		a l'	\sim		~ ~	¥	
Experiment		@.	1 _Q	Dura	tion of	irradiati	ion¶min	utes	. 0	, "%	
_	0	~50	100	150	ZÕ 0	£250	\$ 3 00	350	0400 /	⊳∕450	500
#1	0.23 ^{a)}	[≪] Ø.25 ¢	0.21	0.22	0.22	0.23	0.21	0.20	0.23	0.21	0.21 ^{b)}
#2	0.240	0.220	0.22°	0.22	0.21	0.21	0,22	0.24	Q.22	0.20	0.19 ^{c)}
a) 100%	\sim	A	-	AN INCOMENT	a.	\$	~	K)	\$\$ \$		
b) 92%	K)	Č, V	,Òj	\bigcirc	° °		× 6	•	0)		
c) 79%	Ĩ,	°	s a	». A	¥ 4	` <i>`</i> % (C		/	1		

able 7.2.1.2- 5: 🖏	Statistics of photo	degration t	ests in byffer	раб ^у 7 29	V
60°			Éxperi #10	nent Ø #2	
ES .	No, of data pairs, Rate constant (k)	0,0,00	0+1 ~~~ 02 1/min 🙀		in
Č.	$\frac{\text{Half-Hee}(DT_{0})}{\text{t}_{10}}$	<u></u> 	05 min 炎	2511 min 382 min	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Cerrelation coeff	cient y -	<u>*5073</u>	-0.7993	

## C. QUANTUM YIELD OF THE DIRECT PHOTODEGRADATION

Based on both degradation experiments performed in buffer pH 7 quantum yields  $\Phi$  of 5.96 x 10⁻⁴ (experiment #1) and 9.44 (10-4 (experiment #2) were calculated. This results in a quite low mean quantum yield  $\Phi$  of 0.00077 for the direct plototransformation in neutral aqueous solution, when the test item is regarded most stable with respect to hydrolysis.

#### ASSESSMENT OF SO-CALLED ENVIRONMENTAL HALF-LIFE OF DIRECT D. PHOTO PEGRADATION IN WATER

Besides confound specific factors like the quantum yield  $\Phi$ , the extent of absorption of a compound in the relevant range of the tropospheric sunlight spectrum, the degradation by sunlight is influenced by geographic, climatic, seasonal and matrix-specific conditions.

The environmental half-life for different conditions can be assessed by means of arithmetic models. A prerequisite for the assessments made in the following is the presence of the substance in aqueous


 $\overline{a}$ 

solution, i.e. surface water, rain, fog or aerosols water so that exposure to sunlight is given. Moreover it is taken for granted that water constituents do not reduce the intensity of sunlight.

With the arithmetic model developed by Zepp & Cline¹ it is possible to transfer laboratory data concerning direct photodegradation in water to field conditions. The model estimates on the box of  $a^{0}$ clear summer sky with no influence of clouds. The half-lives calculated therefore may be regarded as minimum half-lives depending on frequency and extent of cover of sky by clouds. Based on a mean quantum yield of  $\Phi = 0.00077$  and the molar extinction coefficients determined for wavelengths of 297.5 to 490 nm, environmental half-lives-were calculated. The results are summarised in the following table.

Season	Environmen	tal direct photolysi	s half-life of isoflu	cypram\daysk
	30 th degree lat.	400 degree lat.	50th degree lat.	60 th degree lat.
Spring	8.2	Å <u>808</u>	Q 9.8	Q ² Q ²
Summer	7.4	7.5		Q [™] ≪ 8.2
Fall	12 🖉	د ۲۵ ^۲ ۲۵ ^۲	N O L	\$ 39
Winter	15	× 23 ~	r ~45 ~	JØ8 2

In contrast to the model approach by Zepp and Chine, the arithmetic model developed by Frank & Klöpffer² considers the influence of clouded sky for the region Central Europe, i.e. Germany. Using the mean quantum yield  $\Phi = 00007$  and the molar extinction coefficients from 292.5 to Using the mean quantum oncirculated as summatised in the following table.

Table 7.2.1.2- 7:	Frank &	Klöpfer	modell	ing 🔊
	s and a second s	Å *	J 4	

Month	Photolysis /Environmental DT50 of	the direct prototransfo	rmation of isoflucypram
	constant of the star	S [days]	
	🔰 [1/spec] 🗸 🕺 Minimum	🛇 Mean 🖉	Maximum
~~~	② pH7 <u>↓ ↓ ↓</u> → pH7 ℃ "	/ pH &	рН 7
January 🔊	0.692×10^{-7}	130 kg	530
February	0.144 × 10^{-6} × × 28 ×	56	240
March	0.2 10^{-6} 5 5	28	120
April	0.475x 10 3 9.4 5	1 7	68
May	$\mathfrak{A}.605 \times \mathfrak{A}^{\mathfrak{V}^{-6}}$	13	53
June	~\$0.678\${10 ⁻⁶ } ~\$ \$\$	12	47
July 🗳	0.604×10^{-60} 3 48.8 6	13	44
August 🖉	0.590 x 10^{-6} $0 9.1 \text{ x}$ 30^{-6}	14	45
September	0.342010^{-6}	23	87
October	0.188×10^{-6}	43	190
November	$0.831 \times 10^{10^{10^{10^{10^{10^{10^{10^{10^{10^{$	97	482
December	0.436 x 10 ⁻⁷ x 84Q	180	920

¹ Zepp, R.G. & Cline, D.M.: Environ. Sci. Technol. 11, 359 (1977).

² Frank, R. & Klöpffer, W.: UBA Research Report No. 10602046 (1985).



III. CONCLUSIONS

Degradation of isoflucypram in neutral aqueous solution in a range of 8 to 21% was measured by HPLC-radiodetection after a maximum irradiation period of 500 minutes. This indicated moderate degradability of isoflucypram via direct phototransformation in neutral buffered solutions A low mean quantum yield of $\Phi = 0.00077$ was calculated on the basis of UV absorption data and the degradation kinetics determined from both experiments. A comparison of the estimates derived from models of Zepp & Cline and Frank & Kloepffer shows that both approaches are well comparable. The two approaches considered the quantum yield and the absorption in a range of wavelengths relevant for the environment. Environmental half-live of sunlight exposed top surface water layers were estimated to 8 to 22 days for a chirect of phototransformation of isoflucypram during periods of main use in spring to fall.

Thus, direct phototransformation in neutral aqueous solution may contribute to the dissipation of isoflucypram from the environment. This assessment does not consider other potential mechanisms which may enhance the degradation in natural water, e.g. by indirect phototytic processes.

Report:

Title: Report No.: Document No.: Guideline(s): KCA 7.2.1.2 (Q?) [Pyrazole-4) 4C]BCS-CN88460: Phototransformation in Gater EnSa-14-1033 M-510627-01-4 OEC19 Test Guideline No. 316; Commission Regulation (EJ)) No 283/2013 in accordance with Regulation (EC) No 1107/2009 US EPA OCSPP/Test Guideline No. 835.2240; Japanese MALF Test Guidelines 12 Nousan 847, No. 2-6-2

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

 \bigcirc

Executive Summary

The photolytic mute and rate of degradation of pyrazole-labelled isoflueypram were studied in sterile aqueous buffer solution at pH 7 under exposure to simulated sunlight and aerobic conditions in the laboratory at 24.5°C for 10 days. In comparison, samples were incubated at 24.7°C in the dark for 13 days. The test concentration was 0.46 mg/L.

The test was performed in static systems consisting of quartz glass vessels each containing 10 mL of test solution and equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. The test systems were continuously exposed to artificial sunlight (Xenon lamp with a < 290 nm cut-off filter). 10 days of continuous irradiation were equivalent to 32.3 and 50.1 solar summer days in Phoenix (Arizona, USA) and Athens (Greece), respectively. For comparison additional samples were incubated in the dark.

Duplicate samples were processed and analysed 0, 1, 2, 3, 4, 7 and 10 days after treatment (DAT) for irradiated samples and 0, 1, 2, 3, 4, 7 and 3 days after treatment for dark samples. At each sampling interval, the amounts of test item and degradation products in test solutions were determined by liquid scintillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles were determined by USC. The identity of the test item was confirmed by HPLC-MS(/MS) including accurate mass determination.

Mean material batances were 96.3% AP for irradiated samples (range from 93.4 to 100.6% AR) and 95.6% AP for dark samples (range from 91.9 to 100.6% AR).

The maximum amount of carbon dioxide was 0.1% AR in irradiated and dark samples. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for irradiated and dark samples.

The another of isoflucypram in the test solutions decreased from DAT 0 to DAT 10 from 100.6 to 93.1% AR in irradiated samples and ranged from DAT 0 to DAT 13 between 91.8 and 100.6% AR in dark samples. The total unidentified residues amounted to a maximum of 2.7% AR in irradiated samples.



The DT₅₀ and DT₉₀ values of isoflucypram in irradiated samples were calculated using single first order (SFO) kinetics. The experimental half-life for isoflucypram was 150 days in irradiated samples. Due to the stability of isoflucypram in the dark, a kinetic evaluation could not be performed for da^{*} k samples. Therefore, the corresponding net photodegradation rate constant (difference between a irradiated and dark samples) could not be calculated. Based on the experimental DT_{50} (after other other samples) could not be calculated. 150 days for irradiated samples, the DT₅₀ value of isoflucypram under environmental conditions was calculated to be e.g. 484 solar summer days at Phoenix (Arizona, USA) or 100 solar summer days at Athens (Greece). Ô

It is concluded that photodegradation is unlikely to contribute to the degradation of isoffery under typical light conditions of the environment.

Test		_		SFO SFO
system	DT 50	DT90	Chi ²	Rate DT 50 under C Ner photodegradiation
	(exp.)	(exp.)	error	constant natural conditions or ate constant / DT50 .
	[days]	[days]	[%] 🦼	[days] [@ays] [Qay-1/ (tays]
Irradiated	150	497	1.6	0.095 484 (Phoenix, USA) O 2
			Ű	\sim 750 (Athen Greece) \sim \sim \sim \sim
Dark ^{b)}	n.c.	n.c.	AS.	N.c. N AC A A

Table 7.2.1.2- 8: Degradation	kinetics of isoflucypramin	irradiated and	dark°samples

n.c. = not calculated a) net rate constant of irradiated samples prate constant of the kark samples b) Due to the stability of isoflucyprany in the dark, a kinetic evaluation could not be performed for Cark samples

I. MATERIALS AND METHODS

MATERIALS A.

1. Test and Reference

Test item:

	·0 ~	Ĉ	4		(Const	
Pyrazole-labelled i	soflucy	orana	<i>A</i>	٣̈́٣́	' ⁰	D NO
Sample D:	Ö	≱ ML	9823		¥ 43	, vy
Specific activity:	s ?	≫4.22⊉	Bq/mg	[»] (11 3:9 2	2.34 μČi/	mg)
Radiochemical pur	эty: 🄊	′ > 98 %/	6 (HRLC	C with ra	dioactivi	ty detection)
Ŵ.	A	₹99%	6 (ĴLC,	scan)		ÿ
Chamical numitur	- Alexandre	× 000/	raidd a	With M	V date	(210 nm)

detector, 210 nm)

Reference-item:

No reference items were

2. Test System The study was carried out a pH J using a 0.01 M phosphate buffer solution. First, a buffer stock solution (0.04 M) was prepared. Therefore, 1.36 g of KH₂PO₄ were dissolved in 100 mL water, diluted with 74 mL of 0.04 M aqueous sodium hydroxide solution and made up to a final volume of 250 mL with water. After homogenisation, the pH of the solution was adjusted to a value of 7.0. Finally, this buffer stock solution was diluted (1/3, v/v) to result in the desired 0.01 M buffer solution.



B. STUDY DESIGN

1. **Experimental Conditions**

The test system for photolytic degradation in water consisted of Quartz glass vessels (50 mm x 26 mm x 16 mm) fitted with a trap attachment (permeable for oxygen), containing soda lime for absorption of 0 carbon dioxide and a polyurethane foam plug for adsorption of volatile organic compounds. glassware and the buffer solution were sterilised in an autoclave in order to prevent biodegradation of the test solutions during the study.

The test solution was prepared by pipetting 50 µL of stock solution (prepared in acetometrile) to 500 mL sterile phosphate buffer solution at pH 7. For preparation of the test system's the martz glass vessels were filled with 10 mL test solution. The test concentration was 0.46 mg/L and was set to 100% of applied radioactivity.

The irradiated and dark test systems were incubated under aerobic conditions for 10 days inva Suntest® unit under continuous exposure to simulated sunlight and for 13 days in a climatic cabinet in the dark, respectively. The incubation temperatures were 24.5°C and 24.9°C for irradiated and dark samples, respectively.

The light intensity of the Suntest® unit, used for artificial irradiation was constant throughout the incubation period. The spectral distribution of the artificial sunlight was similar to the distribution of natural sunlight. The average irradiance for pradiated samples was 1160 W/m². Do days of continuous irradiation at this light intensity was equivalent to 32, and 50.1 solar subimer days in Phoenix (Arizona, USA) and Athens (Greece), respectively.

2. Sampling

2. Sampling Seven sampling intervals were distributed over the entire incubation period of 10 days for irradiated samples and 13 days for dark samples. Duplicate samples were processed and analysed 0, 1, 2, 3, 4, 7 and 10 days after treatment (DAT) for irradiated samples and 0, 14, 2, 3, 4, 7 and 13 days after treatment for dark softilas treatment for dark samples,

Analytical Procedures 3.

The samples were monitored for aerobic conditions as DAT-0 and DAT-10 and the pH values were determined at each sampling interval @

The sterility was checked at all sampling intervals for each replicate. Therefore, 100 µL of the test solutions were applied onto agar plates and incubately in the dark for at least two weeks at ambient temperature. Then the plates were visually inspected.

Carbon dioxide absorbed by soda time was liberated with 18% aqueous hydrochloric acid and trapped. The liberated carbon diovide was purged into the papping vessels by a stream of nitrogen. The radioactivity contents of these vessels were determined by liquid scintillation counting (LSC) and summed up to determine the total radioactivity liberated from soda lime.

The PU foam plug was stracted with 20 mL thyl acetate to desorb volatile organic compounds. The radioactivity content was determined by LSC.

Samples were monitored for aerobic conditions at DAT-0 and DAT-10 and the pH values were determined at each sampling interval.

At each sampling interval, the amounts of test item and degradation products in test solutions were determined by liquid scincillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volations were determined by LSC. The identity of the test item was confirmed by HPLC-MS(/MS) including accurate mass determination.

No isolation of degradation products was performed since no degradation product > 10% AR was observed.



II. RESULTS AND DISCUSSION

The buffer and test solutions at pH 7.0 were prepared under sterile conditions with concentrations of $\leq 0.01 \text{ mol/L}$ to minimize buffer reactions.

The irradiated and dark test systems were incubated under aerobic conditions for 10 days in a Suntest® unit under continuous exposure to simulated sunlight and for 13 days in a climatic cabinet in the dark, respectively. The incubation temperatures were 24.5°C and 24.7°C for irradiated and dark samples, respectively.

The light intensity of the Suntest® unit used for artificial irradiation was constant throughout the C incubation period. The spectral distribution of the artificial sunlight was similar to the distribution of natural sunlight. The average irradiance for irradiated samples was 1160 W/m 10 days of continuous irradiation at this light intensity was equivalent to 32.3 and 50.1 solar summer days in Phoenix (Arizona, USA) and Athens (Greece), respectively.

The pH values of the test solutions for irradiated and dark samples were determined at each sampling interval as 7.0.

The oxygen contents were determined at OAT-0 and DAT-10 m irradiated samples and ranged between 7.7 and 8.7 mg/L.

The sterility tests at each sampling interval demonstrated that sterile conditions were maintained throughout the incubation period. No contamination was observed in the test solutions.

A. ANALYTICAL METHODOLOGY

1. Verification of Sample Processing Method

The mean DAT-0 recovery for the test item was 100.6% AR demonstrating that the sample processing method was well suited to recover the applied test item from the test solution and that the test item was stable under these conditions.

O

2. Verification of Chromatographic Procedures

The primary chromatographic method (HPLC/radiodetectron) was well suited for the quantitative analysis of the samples of this study as demonstrated by a mean HPLC recovery of 106.2% and a good linear fit for injected amounts of pyrazole-labelled is thucypram on column ($R^2 > 0.9996$). The LOD of the primary chromatographic method was determined as 8.8 Bq absolute on column or 0.9% AR.

B. MATERIAL BALANCE

Mean material balances were 96.3% AR (range of 93.4 to 100.6% AR) for irradiated samples and 95.6% AR (range of 93.4 to 100.6% AR) for dark samples (Table 7.2.1.2-9).

The complete material balances found a fall sampling intervals for both irradiated and dark samples demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing.

Table 7.2.10-9: Material Galance of radioactivity in irradiated and dark samples expressed as percentage of applied radioactivity, mean of two replicates)

Samples &		Material	balance	
	min.	max.	mean	RSD [%]
radiated	93.4	100.6	96.3	2.3
dark	91.9	100.6	95.6	3.0



C. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the radioactivity distribution are presented in Table 7.2.1.2-10. The route of degradation of isoflucypram in aqueous buffer solution at pH 7 under aerobic irradiated \square and dark conditions is summarised in Table 7.2.1.2-11.

Table 7.2.1.2-10: Material balance of radioactivity in irradiated and dark samples (avpressed as percentage of applied radioactivity, mean of two replicate

(expressed as pe	rcentage of a	ipneu rau	oactivity	, mean or	i ingo rep	ncates) PS	. 0
		1 .	I ĈA	DAT				
	0 ^{a)}	1	2	3 @	4	A S	¥0	¢ _C
Irradiated samples		Ś	8	^o				
Volatiles				õ ^y .	•		× õ	"Q [°]
carbon dioxide	n.a.	A .1	0.1	₹0.1	0.1^{10}	. 65	0.1	a,
volatile organic compounds	n.a.	∞ 0.1	< 0.1	0:4	≤ 0.1	0.1	€ 0.1≪	×
total volatiles	n.a.	0.10	<u>9</u> :P	<u>0</u> 1	×0.1 ,	0.1	0.1	
Solution	100.6	96,4	Ø 3 .6	@9 3.3 冷	Ø96.3 O	97. 5 ,	958	e °
Material balance	1490.6	9 6.5 "	Ø93.7 [¢]	93.4 [™]	964	99 <u>6</u>	\$5.9	Ŵ
Dark samples		$\sum $		<u>S</u>	N.		, Å	
Volatiles	0	, 2		× i	, l		O	
carbon dioxide	O ^v pa.	× Ø.1	×0.1	Ø 0.1 S	0,4	<u>0</u>	<i>©</i> 0.1	
volatile organic compounds	n.a.	< 0.1	<0	< 0	≤00.1	×0.1 ×	×0.1	
total volatiles	, 🖌 🖓 n.a.	» 0. 1	Q.P)	Q.1	°∂0.1 _ (0.1	/ < 0.1	
Solution	100.6 🕎	960.9	A92.3	91.8	96.4©	93.6	97.3	
Material balance	× 100.6	£96.9	s 92.4 🖉	91.9	965	93.7	97.4	
n.a.: nota analysed: DAT: days after	e Oreatment	<u> </u>	<u> </u>	Â,	\sim			

a) The same duplicates were used ass irradiated and dark DAT-0 samples

Ø Carbon dioxide and volatile organic compounds

The maximum amount of carbon dioxide was 0.1% AR in fradiated and dark samples. Formation of volatile organic compounds was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for both irradiated and dark samples (Table 7 \$1.2-19).

Ø 1

 \bigcirc

Test item and degradation products in test solution

 \bigcirc The amount of isoffosypram in the test solutions decreased from DAT-0 to DAT-10 from 100.6 to 93.1% AR in irradiated samples and ranged from DAD-0 to DAT-13 between 91.8 and 100.6% AR in dark samples. The total unidentified residues amounted to a maximum of 2.7% AR in irradiated samples (Table 7.2.1 & 1). No degradation prode is of coflucypram > 10% AR were observed.

solution and ranged from indentified residues an (11) No degradation produce (11) Ab d



				•		-		0	
Compound	Samples				DAT			<u></u>	ð
-	-	0 ^{a)}	1	2	3	4	7	10 13 ^{b)}	S
Isoflucypram	irradiated	100.6	96.4	93.6	93.3	95 ,6	95.3	93.1	"O"
	dark	100.0	96.9	92.3	91.8	% 6.4	93.6	97,2	
Sum of unid./diff. residues ^{c)}	irradiated	nd	n.d.	n.d.	n.d.	″∉ LOD	2,2	2.9	
	dark	n.a.	n.d.	n.d.	n.d 🌧	n.d.	, 1QÎ.	Ar.a.	Q.
Total residues in solution ^{d)}	irradiated	100 (96.4°s	93.6	92,3	96.3	∢ 97.5 _≈	≫95.8	
	dark	100.0	96.	92.3	A1.8	96.4	ڳ£93.	97.5	L.
Carbon dioxide ^{e)}	irradiated		Q .1	0.1	©₹0.1	0.K	61°	Q.1	, O″
	dark	n.a.	°0.1	0.10	0.1。	0.A	0.1	c× 0.1	F
Volatile organic compounds ^{e)}	irradiated		y ^y < 0.1	$\leq 0.1^{\circ}$	¢?	Q0.1	°~€ 0.1	< 0	
	dark	n.a.	< 0.1	®0.1	مُ 0.1 م	~ < 0.4	<0%	<q.1< td=""><td></td></q.1<>	
Total recovery ^{d)}	irradiated	Den (9 6.5 d	[©] 93.7 Ľ	93.4	960	97%	95.9	
	dark		ن 96.9°	92 Ø	969	96.5	\$93.7	⇔97.3	•
	DAT. 1			~~		\bigotimes			-

Table 7.2.1.2-11: Degradation of isoflucypram in irradiated and dark samples (expressed as percentage of applied radioactivity, mean of two replicates)

n.d.: not detected, n.a.: not analysed, DAT: days after treatment

a) The same duplicates were used as irradiated and dark DAT-0 samples

b) DAT-10 for irradiated samples, DAT-13 for dark samples

b) DAT-10 for irradiated samples, 2...
c) Minor degradates are summed up to unided iffed revidues as well as clean up and chroma difference to material balance of the rounding energy as well as clean up and chroma and chroma

D. KINETIC ANALYSIS OF BATA

The experimental DT₅₀ and DT₉₀ values of isofucypram in irradiated samples were calculated using single first order (SFO) kinetics. The table befow summarises the best fit results of the DT₅₀ and DT₉₀ calculations: O \bigcirc

Ø

	n i	Nº .				
Test	ð S	× _0	0 🐇		STO S	
system	DT 50	DT 90 🖗	Chi ²	Rate	DT50 under	Net photodegradation
\$ *>	(exp.)	(exp.)	ervor	constant	natural conditions	rate constant ^{a)} / DT ₅₀
Į,	[days]	[days]	[%]	_{[days}}*	(Øys]	[day ⁻¹ / days]
Irradiated	150	497	🖉 1.6 💍	0,005	484 (Phoenix, USA)	
	L. L.			. °	750 (Athens, Greece)	n.c. ^{b)}
Dark ^{b)}	n.e.	n.c.	126°E.	n.c.	n.c.	
n a = nat calor	ulorad (0			

Degradation kinetics of isofly cypramin irradiated and dark samples L, Table 7.2.1.2- 12:

a) net rate constant = rate constant of insadiated samples are constant of dark samples

b) Due to the stability of isoflicyprame the daily, a kinetic evaluation could not be performed for dark samples

The experimental half life for isoflucypran was 50 days in irradiated samples. Due to the stability of isoflueypram in the dark, a kineti@evaluation.goald not be performed for dark samples. Therefore, the corresponding net photodegradation rate constant (difference between irradiated and dark samples) could not be calculated. Based on the experimental DT₅₀ value of 150 days for irradiated samples, the DT₅₀ value of isofly yprasi under environmental conditions was calculated to be e.g. 484 solar summer days at Phoenix Arizona, USAO or 750 solar summer days at Athens (Greece).

DEGRADATION PATHWAY E.

No degradation products of isoflucy pram > 10% AR were observed and identified. Therefore, no degradation pathway is proposed.



III. CONCLUSIONS

Isoflucypram was slowly degraded in aqueous buffer solution at pH 7 under exposure to simulated sunlight and aerobic conditions in the laboratory. No degradation products > 10% AR were observed. The experimental half-life for isoflucypram was 150 days in irradiated samples Due to the stability of isoflucypram in the dark, a kinetic evaluation could not be performed for dark samples. Therefore, the corresponding net photodegradation rate constant (difference between irradiated and dark samples) could not be calculated. Based on the experimental DT_{50} value of 150 days for irradiated samples, the DT₅₀ value of isoflucypram under environmental conditions was calculated to be e.g. 484 solar summer days at Phoenix (Arizona, USA) or 750 solar summer days at Suhens (Greece). Photodegradation is unlikely to contribute to the degradation of soflucypram under spical light conditions of the environment.

Indirect photochemical degradation CA 7.2.1.3

No study for the determination of the photolytic route and rate of degradation of isoflacy prant in natural water has been performed and is not required under Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 1107/2009

CA 7.2.2 Route and rate of biological degradation

"Ready biodegradability" CA 7.2.2.1

of isofficypram was not performed. However, water-A study on the "Ready"Biodegradabinty" sediment studies under aerobic conditions was performed which are described in section CA 7.2.2.3.

M

Kerobic mineralisation in surface water CA 7.2.2.2

The route and rate of degradation of isoflues pram were studied in surface water under aerobic conditions using the pyrazole-label. A summary of the route and rate of degradation of isoflucypram in the aquatic environment is given in section CA 7.2 and Figure 7.2 1.

Report:

2017; M-582106-01-1 Title: S-CN88460: Aerobic mineralization in surface water vrazate Report No.: 1ELA\$\$Ň01.7 © Ô Document No. M-682106-01-1 OBCD Tot Guidenne No 309 0 Guideline(s) , Maria Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) Jo 1107/2009

Guideline deviation(s) GLP/GEP:

Executive Summary

The route and rate of degradation of ovrazole-labelled isoflucypram were studied in surface water under aerobic conditions pelasic test). Two test concentrations were incubated in the laboratory in the dark at 20 ± 2 ° for 61 days

Two study application rates were used and included 10.0 µg/L and 103.6 µg/L surface water for low and high concentration test systems, respectively. The test system consisted of a 250 mL flasks each containing 100 mL of surface water which was equipped with a static volatile trap (permeable to oxygen for the collection of carbon dioxide and volatile organic compounds. The surface water in the test systems was kept in motion during the entire study period to maintain aerobicity.

Duplicate test systems of each test concentration were processed and analysed at 0, 8, 14, 22, 29, 43,



48, and 61 days after treatment (DAT). Sterile test systems for both concentrations were processed and analysed at DAT-0 and 61. The amounts of test substance and degradation products in surface water were determined by liquid scintillation counting (LSC) and by HPLC/ radiodetection analysis. The amount of volatiles was determined by LSC. Identification was performed by HPLC-MS including & accurate mass determination and/or by co-chromatography with reference substances. The redox" potential, pH and oxygen content of the surface water were measured throughout the study of 0, 8, 9, 22, 29, 43, 48, and 61 days.

Mean material balances were 101.7% of the applied radioactivity (AR) for low concentration test systems (range from 98.5 to 103.9% AR) and 98.4% AR for high concentration test systems (range from 94.7 to 101.9% AR).

For all test systems in this study (low, high and sterile control test systems), the amount of CQ2 and C organic volatiles formed during this study was regligible, with the exception of DAT-1/4 (low concentration) which had a mean of 4.4% AR as $C\sqrt{2}$.

Isoflucypram was stable in all test systems, with a mean of 100,6% AR and 98.3% AR in low and high concentration test systems, respectively. No degradation products were formed in any test systems in this study. In sterile test systems, the mean amount of isoflucyprom in surface water at DAP 61 was 93.4% and 94.9% AR in the low and high concentration test systems, respectively.

The experimental data could be described by a single first order (SFQ) kinetic model. The DT₅₀ values of isoflucypram in the tested surface water under aerobic conditions were > 1000 days for both low and high concentrations.

		- · · · · · · · · · · · · · · · · · · ·		()
Concentration	Best fit kinetic model	D T 50	DT 50	Chi ² error
		[days]	felays 🖉 💡	⁽ ²]%]
Low	SFO SFO	$p^{V} > 1000$	> 1000 3	1.264
High 🔬	SFO C	>%1000	> 10000	1.62
	N. MATEMALS	AND METHE	DS _K y	
	O O' $(0'$ $(0')$		<i>.</i>	
A. MATERIALS		S O	*	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		"° @ _ (	ðr -	
1 Tablitam and Cant	rol Substand	7 <i>1</i> 7	<b>,</b>	
1. I est item and Contra				
~ ~ ~		& A'		
Test item:		0 ô		
Burazala laballad isat		, Q		
I yrazole-laberled isonuc	ypcan 0 0 0			
Sample ID: Sample Sam	$O^{-}C-H/3$ $Y$ $Y$	$\sim$		
Specific activity:	→ 45,950 mC1/mMole (1	_1 <b>3</b> .92 μCi/mg)		
Radiochemical purity.	100% (determined with	hin this study)		
		, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Control substance.				

Table 7.2.2.- 1: Degradation kenetics of isoflueypran in surface water under aeropic conditions

To confirm the microbial activity of the surface water in this study phenyl-UL-14C and carboxyl-¹⁴C-labelled benzoic acid was used as the control substance, and its degradability in surface water was measured an  $\mathcal{O}$  compared to an expected  $\mathcal{O}T_{90}$  of typically < 14 days. Radiolabelled benzoic acid was used in the aqueous treatment solution in order to obtain the appropriate concentration.

Phenyl UL-14G- and carbox 9-14C-labelled benzoic acid Sample ID: C-1189 Specific activity: 125.00 mCi/mMole Radiochemical purity: 100%



#### 2. **Test Water**

Natural surface water from a location known not to be exposed to discharges or effluents or near human activity was used.

Table 7.2.2.2- 2:	Physico-chemical properties of test water
	i nysieo enemieni pi oper nes or test water

ie 7.2.2.2-2. I hysico-chemical prop	erties of test water		
Parameter		Results 💞	
Water designation	Bear	ver Dam lake	<u>\$ 2</u> 5 .0
Origin	Wake Forest,	North Carolina, USX	
GPS coordinates	N 36°02'00	.2 [©] W 78°41'01 [©]	
Site description	North Carolina State	ark system, part of Fal	He Lake O
	Separated by a dam	, no gasoline@oats allo	wed O
pH ^{a)}			
<ul> <li>measured at sampling site</li> </ul>		9.95 ×	
<ul> <li>measured at Bayer CropScience</li> </ul>	4, 6° 5 4	/8.284 ^{/0} 0 ×	$\gamma$ $\psi$
Oxygen saturation [mg/L] ¹		<u>8</u> 70° 21.	1
Redox potential at 20°C, pH 6.9 Eobs [mV]		169.0 N	
Total organic carbon (TOC) [mg C/L]		A8.1 0 K	
Disolved organic carbon (DOC) [mg $OL$ ]		6.4 \$	
Biological oxygen demand (BOD)			<u>~</u>
Total nitrogen [mg/L]		80.4	L.
Total phosphorous [mg/L] 👋 🧑		0.60 0	$\searrow$
^{a)} determined on-site at day of sampling			

The surface water was collected fresh from the matural water system just below water surface. At the sampling site, temperature and pH were determined. The water was filtered through a 0.100 mm mesh at the test facility. Redox, pH and dissolved xyger were determined at the test facility two days after sampling.

#### B. STUDY DESIG

#### Experimental Conditions 1.

1. Experimental Conditions (permeable to oxygen) containing soda time for the collection of carbon dioxide and polyurethane foam for trapping splatile organic compounds For preparation of the test systems, 100 mL aliquots of the Surface water (filtered through a 0.100 mm

mesh) were added to each test vessel. The test vessels were then fitted with the trap attachments.

The untreated systems were equilibrated to study conditions for two days prior to application.

Study application rates of 10.0 pc/L and 103 & µg/L per test system were applied for the low and the high concentration, respectively.

The test item was applied onto the water surface of the respective equilibrated test systems using a gastight syringe. After application, the test vessels (except DAT-0 samples) were fitted with trap attachments and placed into a walk in incubator. The test systems were incubated in the dark for 62 days at  $20^{\circ}$ 

#### Sampling 2.

Eight sampling intervals were distributed over the entire incubation period of 61 days. Duplicate samples were processed and analysed 0, 8, 14, 22, 29, 43, 48 and 61 days after treatment (DAT) for both low and high concentration. Sterile controls were processed and analysed at DAT-61 for both concentrations, microbial activity samples at DAT-0, DAT-14 and DAT-39. Ĉ

#### 3. **Analytical Procedures**

The water was removed from the test systems with an additional rinse of 20 mL ACN. The amounts of isoflucypram and its degradation products in water were determined by liquid scintillation counting



(LSC) and by HPLC/radiodetection analysis. The amount of volatiles was determined by LSC. Identification was performed by HPLC-MS including accurate mass determination and/or by co-chromatography with reference substances.

At each sampling interval, pH, oxygen content and redox potential of the surface water were a determined.

#### 4. Calculations

Amounts of test substance and degradation products were calculated as percentage of applied radioactivity ([% AR]. Values are presented as single values and as means if replicates were made. The data for the test substance were evaluated according to FOCOS kinetics (2006) using the software KinGUI 2.

## II. RESULTS AND DISCUSSION

The pH in water ranged from 8.1 to 9.1 (mean: 8.6) in test systems with low concentration and from 8.0 to 8.8 (mean: 8.5) in test systems with high concentration.

The redox potential ( $E_H$ -values) in surface water were 376.0 (mean frange from 327.2 to 397.2) for low concentration test systems and 372.9 (mean, range from 343.7 to 394.2) for high concentration test systems. The redox potentials of the sterile samples were 362.1 in low concentration systems and 358.8 in the high concentration, averaged over two replicates

The oxygen contents in surface water samples were 8.8 mg/L (mean, range from 8.4 to 9.1 mg/L) in low concentration test systems an 8.9 mg/L (mean, range from 8.5 to 9.3 mg/L) in high concentration test systems. The oxygen contents of the sterift samples were in a similar range %

The values for the codox potentials and exygen contents indicate aerobic conditions throughout the entire incubation period for both concentrations.

The sterility ests for the sterile samples at DAC-61 demonstrated the absence of viable microorganisms in these samples during the entire incapation period.

## A. ANALYTICA METHODOLOGO

## 1. Verification of Sample Brocessing Method

The mean recovery of the test substance at DAT 0 was 98.5% and 94.7% AR for low concentration and high concentration samples, respectively.

These results demonstrate that the sample processing method was well suited to recover the applied test substance from the surface water and that the test substance was stable under these conditions.

## 2. Verification of Chromatographic Procedures

The HPLC method was used as the primary method for data evaluation. A good selectivity and reproducibility demonstrated the subability for separation and quantification.

The off-column HPLC recovery was measured on random samples, which averaged 96.3% in the low concentration (n = 8) test systems and 101.0% in the high concentration (n = 8) test systems, respectively.

¹ FOCUS (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp



#### **B**. MATERIAL BALANCE

Mean material balances were 101.7% AR for low concentration test systems (range from  $98.5\mu$ ) to 103.9% AR) and 98.4% AR for high concentration test systems (range from 94.7 to 101.9% AR). The complete material balances found at all sampling intervals for both concentrations demonstrated that there was no significant loss of radioactivity from the test systems or during sample processing

			40	
Table 7 2 2 2- 3.	Material halan	ce from mean values	- not including sterile s	samples of St 19
10010 / 20202 00	(			
	(expressed as %	% AK)		
		Materi	al balance 🔗	
		low concentration	high concentration	
	Min	98.5 🔿	<b>*9</b> 4.7 ©°	
	Max	103.	101.9	
	Mean	101.7 os°	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>	
	RSD	0.7 <u>v</u>	2.1 0	
	RSD = relative st	andard deviation	ΰ Q , O ,	
C. DISTRIBUTIO	N AND COM	QSITION OF RES	HOUES O	
The detailed figure	s of the radi	oactivity distributio	n are presented in	Table 7.2.2.2- 4 and
Table 7.2.2.2- 5. The	formation of a	urbon dioxide wasom	inimal in the study T	he formation of volatile
organic compounds w	as insignitican	t as demonstrated by	values of ≤0.1% AR	a all sampling intervals

organic compounds was insignificant as demonstrated by values of 20.1% AR a all sampling intervals for both concentrations. Therefore, no identification of the volatife organic compounds was performed.

The route of degradation of isoflucyprain in surface water under acrobic conditions is summarised in Table 7.2.2.2- 6 and Table 7.2.2.2- 7 No degradation products were observed in the surface water. Š O Ø L  $\bigcirc$ 

Table 7.2.2.2- 4:	Material balan	Re of radioactiv	ity in Surface	water under wro	oic conditions at low
		·			
	🗇 concentration ·	- including steri	le samples (ex)	pressed as /// AR	
C	Š Š				

Component O	Replicate	o c	) 🖓	, Ø	Days	after tree	<b>t</b> ment			
	no.	<b>0</b> ©	<u>_8</u>	<b>Å</b> ¥4	@ ² 2	<b>29 ∜</b>	43	48	61	61 sterile
Volatiles	õ	Å.	Ő	L.		$\sim$				
carbon dioxide	. X .	Dn.a.	[~] 0.6	6.90 [°]	0.9	° 9.7	1.0	1.0	0.9	0.8
	_{NO} B √	[≫] n.a _∞ ∞	0.0×	19	<b>&amp;0.</b> 7	۵.3 🖾	0.7	0.8	0.9	0.9
	🕅 mean	n@.	×0.6	<i>,</i> <b>04.</b> 4	0 ⁻ 0.8 _%	0.5	0.8	0.9	0.9	0.9
volatile organic [®]	AQ >	an.a.	Ø0.1 🗞	0.1	0.4	0.1	0.1	0.1	0.1	0.1
compounds @	B	Ön.a. 🗞	010	0. P`	0.9	0.1	0.1	0.1	0.1	0.1
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	mean	n.a. y	00, [%]	<b>Ø.</b> 1	0.1	0.1	0.1	0.1	0.1	0.1
total votatiles	Ą	Da.	Ø.7 3	27.0 x	1.1	0.7	1.1	1.1	1.1	0.9
	°,₿°	Qa.a.	0.6	2.0	0.8	0.4	0.8	0.9	1.0	1.0
× ,	🔊 🗊 ean 🔬	n.a.	0.7	47	0.9	0.6	0.9	1.0	1.0	1.0
Water	× A ×	97ू∰	102.7	\$98 .4	100.4	100.1	100.7	100.7	97.6	90.8
a	B ^v	99.9	<i>@</i> 102.2 <i>"</i>	100.3	101.8	99.8	102.8	101.4	100.7	96.0
	mean	@98.5 🔨	∑102.9Q	99.4	101.1	100.0	101.7	101.1	99.2	93.4
Material balance	NA S	[≈] 97.1	10474	105.5	101.5	100.8	101.7	101.8	98.6	91.8
	₩ B.Ô	9 5 .9	192.8	102.3	102.6	100.2	103.6	102.2	101.7	97.0
	mean	Ø 8.5	103.6	103.9	102.0	100.5	102.7	102.0	100.2	94.4

n.a. = not analysed a) includes accountrile finse, min 1.8% to max. 8.8% AR



			0		•			,		0	
Component	Replicate				Days	after trea	atment			Q	ð
-	no.	0	8	14	22	29	43	48	61	61 sterile	()
Volatiles								ð			-
carbon dioxide	Α	n.a.	0.1	0.2	0.1	0.1	0.1	Q 0 .1	0.1 🛦	0.1	
	В	n.a.	0.1	0.2	0.1	0.1	0.1	Ø 0.1	0.1	0,1	
	mean	n.a.	0.1	0.2	0.1	0.1	0.Þ	0.1	.00	0.1	2
volatile organic	Α	n.a.	< 0.1	< 0.1	< 0.1	< 0.1	≤ <u>0</u> .1	< 0.1	0.1	°≈y≤0.1	
compounds	В	n.a.	< 0.1	< 0.1	<0.1	< 0.1	@0.1	< 0.1	$\tilde{C} < 0.1_{C}$, [≫] < <u>0</u> ,∰′	s.
	mean	n.a.	< 0.1	< 0.1	0.1	< 0.1 Ĉ	≫< 0.1	< 0,1	′ < 0,£) [×]	₹9.1	Ô [%]
total volatiles	А	n.a.	0.1	0.2	V 0.1	0.14	0.1	QO	0.1	0.1 ×	7
	В	n.a.	0.1	0.2	0.1	0.1	\$	<i>ð</i> 7 .1	\$0 .1	0.1	
	mean	n.a.	0.1	0.2	0.1	Ø. 1 🦻	0.1	0.1	0.1		
Water ^{a)}	А	97.1	93.8	Q9.6	¢]01.4 🔬	≽99.1≮	98, 4 ,0	98 D	98:3	×9\$.5	
	В	95.5	99.9	Q101.9	€`99. <u>1</u> %	99,9/	2804	962Ž	97.0	<u> </u>	
	mean	94. 7	99.7	101	9921	90,2	98.3	_97.3	096.3	⊘ [™] 94, 9 √	
Material balance	Α	97.1	93*8⁄ ″	297	101.6	≉ 99.2€	€,98.5	^{98.4}	98.4 [®]	95,17	
	В	95.5	100.0	°40°2.2	©99.2 🗸	∕̃100.ੴ	98,5%	96®	9 <u>%</u> 1	<u>گ</u>	
	mean	94.7	\$9.8 (v)	[∞] 101.9	99.2	99.2	98.4	27.4	96.4	95.0	

Material balance of radioactivity in surface water under aerobic conditions at high Table 7.2.2.2- 5: concentration - including sterile samples (expressed as % AR)

n.a. = not analysed

n.a. = not analysed		2	67 67	\sim	V 83	s and the second	
a) includes acetonitrile	rinse, min 1.8%	toQnax. 8,8%	AR 🔊			0	\sim
	0					°, °	Ő /.
			0) L	Ş.	Ĵ Ĉ	y s
Table 7.2.2.2- 6:	Degradation o	of isoflucyp	kam in su	rface water	r under aer	obic cor	iditions
	(low concentra	ation, mean	n valuæs ar	nd 🔊 expr	essed as %	AR)	Ô
	· (//)			1	N ¹	~ //	

$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	Compound	Mean	N L	<u> </u>	A A	Ø Day	's after ti	ceatment	5	8	
Isoflucypram Man 98.5 408.7 99.4 101.1 100.0 101.7 101.1 99.2 93.4 Total water Mean 98.5 103.7 99.4 101.1 401.1 41.1 421.6 421.6	Ĩ	SD 🚿) 0 Š	× 8Q	14		∼ ⁰ 29	√ 43‰	48	61	61 sterile
SD 41.4 $20.0 \times \pm 1.0$ ± 0.7 ± 0.1 $4.1.1$ (2 ± 0.3) ± 1.6 ± 2.6 Total water Mean 98.5 103.7 99.4 101.1 400.0 401.1 400.3 ± 1.6 ± 2.6 Carbon dioxide Mean $n.4$ 0.5 4.4 0.8 0.5 0.8 0.9 0.9 0.9 SD ± 1.2 ± 0.0 ± 2.5 ± 0.1 ± 0.2 ± 0.1 ± 0.3 ± 1.6 ± 2.6 Carbon dioxide Mean $n.4$ 0.5 4.4 0.8 0.5 0.8 0.9 0.9 0.9 Volatile organic Mean $n.4$ 0.4 0.3 0.1 <td>Isoflucypram</td> <td>Mean</td> <td>98.5</td> <td>103.7</td> <td>@9.4 🔬</td> <td>\$101.1\$</td> <td>100,0</td> <td>10 🖓</td> <td>104.1</td> <td>99.2</td> <td>93.4</td>	Isoflucypram	Mean	98.5	103 .7	@ 9.4 🔬	\$101.1\$	100,0	10 🖓	104.1	99.2	93.4
Total water residues Mean 98.5 102.7 99.4 107.1 100.0 (101.7) 101.1 99.2 93.4 SD ± 1.6 ± 0.0 ± 1.0 ± 0.0 ± 0.7 ± 0.4 ± 1.1 ± 0.3 ± 1.6 ± 2.6 Carbon dioxide Mean n.a. 0.5 4.4 0.8 0.5 4.8 0.9 0.9 0.9 Volatile organic compounds Mean n.a. 0.1 ± 2.5 ± 0.1 ± 0.2 $4^{\circ}0.1$ ± 0.1 ± 0.0 ± 0.2 ± 1.5 ± 2.6 Material balance Mean 98.5 $5^{\circ}04.4$ 103.9 102.0 100.2 ± 1.5 ± 2.6 n.a. = not analysed SD 5° 5° 5° 5° <		SD.	£1.4 °	$\gg 0.0$	1 ± 1	±.00	±29.1	€ 1.1	@ ≠ 0.3	± 1.6	± 2.6
residues SD ± 1.24 ± 0.06 $\pm 4.0.7$ $\pm 2.0.18$ ± 1.1 ± 0.3 ± 1.66 ± 2.6 Carbon dioxide Mean m.a. 0.5 4.4 0.85 0.5 4.8 0.9 0.9 0.9 SD \checkmark ± 0.17 ± 2.5 ± 0.1 ± 0.2 20.1 ± 0.1 ± 0.0 ± 0.2 ± 1.5 ± 2.6 Material balance Mean 98.5 Y04.4 ± 10.6 ± 1.6 ± 0.5 ± 0.3 ± 0.9 ± 0.2 ± 1.5 ± 2.6 <th< td=""><td>Total water</td><td>Mean</td><td><u>98.5</u> 4</td><td>103.7</td><td>99.∳″</td><td>101.1</td><td>100.0 J</td><td>J01.7</td><td>¥ 101.1</td><td>99.2</td><td>93.4</td></th<>	Total water	Mean	<u>98.5</u> 4	103.7	9 9. ∳″	101.1	100.0 J	J01.7	¥ 101.1	99.2	93.4
Carbon dioxide Mean n.a. 0.5 4.4 0.8 0.5 40 0.9 0.0 ± 0.0 ± 0.2 ± 1.5 ± 2.6 n.a. n.a. 0.9 0.9 0.9 0.2 ± 1.5 ± 2.6 n.a. 0.9 0.9 0.9 0.9	residues	SD	r ± 1⊘	±®ð	(¢∰1.0	ٍ¥́ 0.7 ¢	$y \pm 0.1$	± 1.1	± 0.3	± 1.6	± 2.6
SD \checkmark \pm 0.1	Carbon dioxide	Mean	ň.a.	چ0.5 ک	4.4 °	0.8	0.5	×0.8	0.9	0.9	0.9
Volatile branic compounds Mean n.a. 0.1 0.0 ± 0.0 ± 0.0 ± 0.0 ± 1.0 ± 0.0 ± 1.0 ± 0.0 ± 1.0 ± 0.2 ± 1.5 ± 2.6 $= 0.3$ ± 0.9 ± 0.2 ± 1.5 ± 2.6 $= 0.4$ $= 0.4$ $= 0.4$ $= 0.4$ $= 0.4$ $= 0.4$ $= 0.4$ $= 0.4$	<u>~</u>	SD		$\forall \pm 0.1$	[™] ± 2.9 [™]	± 0.1	<u>_</u> #@.2 ,	@ 0.1	± 0.1	± 0.0	± 0.0
compounds SD \checkmark $\pounds 0.0$ ± 1.4 ± 0.0 ± 1.4 ± 0.0 ± 0.0 ± 0.2 ± 1.5 ± 2.6 n.a. = not analysect SD = 30 indard deviation 0	Volatile organic	Mean	n.a 🔊	0.1	0.1	Ø.1	گ [%] 0.1_ (0.1	0.1	0.1	0.1
Material balance Mean 98.5 103.9 1020° 100.5 102.7 102.0 100.2 94.4 SD $\pm 1.45 \pm 0.6$ ± 16 ± 0.5 $60.3 \pm 0.9 \pm 0.2 \pm 1.5 \pm 2.6$ n.a. = not analysed SD = Condard deviation	compounds	SD	, Y'	₩0 .0	ð 0.0 x	>>± 0.0	$\pm 0.0\%$	± 0.0	± 0.0	± 0.0	± 0.0
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Material balance	Mean	98.5	2¥04.4	103.9	10200	100.5	102.7	102.0	100.2	94.4
n.a. = not analyse¢, SD = @mdard & viation		∕\$SD _	5¥1.4≲	$ \pm 0.0 $	±,1.6	±0.5	0.3	± 0.9	± 0.2	± 1.5	± 2.6
Ċ [°]											



	ν U		<i>,</i>			-					
Compound	Mean				Day	s after ti	reatment			<u>ø</u>	ð
-	SD	0	8	14	22	29	43	48	61	61 sterile	Ş
Isoflucypram	Mean	94.7	99.7	101.7	99.1	99.2	98.3	97.3	96.3	94.9	J.
	SD	± 0.8	± 0.2	± 0.3	± 0.0	± 0.8	± 0.1	± 19	± 0.7	√y±2.5	
Total water	Mean	94.7	99.7	101.7	99.1	99.2	98.3	97.3	96.3	⇒ 94°9⁄°	
residues	SD	± 0.8	± 0.2	± 0.3	± 0.0	± 0.8	± 0.1	4 1.1	$\pm 0,70$	±2.5	Q
Carbon dioxide	Mean	n.a.	0.1	0.2	0.1	گ0.1	0.1 🗸	0.1	0KI 7	~~0.1 ~~	a
	SD		± 0.0	± 0.0	$\pm 0.0^{-10}$	$\sqrt[6]{t} \pm 0.0$	± 0.0	± 0.0	£0 .0	0 ± 0.0	L.
Volatile organic	Mean	n.a.	< 0.1	< 0.1	< 0.1	< 0.1	≤ Ø.1	< 0.1	K× 0.1	^y <0,1 (O″
compounds	SD		± 0.0	± 0.0	± 0.0	± 0.0	0.0	$_{\circ} \pm 0.0$	$\pm 0.0^{\circ}$	⊕0.0 ©	1
Material balance	Mean	94.7	99.8	101.9	@9.2	99.2	^{98.4}	97.Q*	.96.4	95.0	
	SD	± 0.8	± 0.2	± 0.3	$\gg_{\pm 0.0}$.	± 0	±0,1	₩1.ĺ	± 0.7 ≈	5 ± 20	
n.a. = not analysed,	SD = stat	ndard devi	ation	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u> </u>	N. N.		K (

Table 7.2.2.2-7: Degradation of isoflucypram in surface water under aerobic conditions (high concentration, mean values and SD expressed as % AR)

D. DEGRADATION PATHWAY

in surface water under derobic Hucypram does not degrade in Based on the results of the study, is conditions.

E. KINETIC ANALYSIS

The degradation of isoflucyprane followed single first order (SFG) kinetics. The table below summarises the results of the $D \mathbb{D}_{0}$ and $D \mathbb{T}_{0}$ calculations. The $D \mathbb{D}_{0}$ values of software water under aerobic conditions were 2000 cays for both low and high concentrations. **Table 7.2.2.- 8: Degradation of isoflucypram in surface water under aerobic conditions**

				<u>_</u>	-
	Concentration	Best fit			Chi ² error
	$O \land$	Agnetic model	🖉 [days] 🔌		۶ [⁷ 0]
~	Pow & O	SFO &	×1000 >>	£1000	1.264
<i>R</i> ₂	High 🖉 🔍	SFO SFO	مَح 100 <u>0</u>	0 1000	1.62
	SFO = single first	order		Q Q	
je G		Y & .			
	\$ X			^N	
	\$° 4	S 11.	CONCLUSIO	DNS	
	a a			°∕~	

Isoflucypram was degraded minimally at oth the low test concentration and high concentration to CO_2 . The DP₅₀ values of Osoflucy pram in the rested surface water under aerobic conditions were > 1000 days for both low and high concentrations.

Formation of volatiles such accarbon dioxide was prinimal and the interval mean reached a maximum





CA 7.2.2.3 Water/sediment study

The route and rate of degradation of isoflucypram in water/sediment systems under aerobic conditions were investigated using the pyrazole-label. A summary of the route and rate of degradation of isoflucypram in water and sediment is given in section CA 7.2 and Figure 7.2-1. 2017; M-580411-01, A summary of the data of the water/sediment study of which are used in PEC_{sw/sed} calculations is given in the following Modelling core info document:

PEC_{sw} Modelling Core Info

KCA 7.2.2.3/01; G.; KUK, SU17 M-608725-02 G Isoflucypram (ISY): Core PECs EUR - Modelting core info document for surface water risk assessment in Europe EnSa-17-0656 M-608725-02-1 not applicable none no **Report:** Title: Report No .: Document No .: Guideline(s): Guideline deviation(s): **GLP/GEP:**

Executive Summary

The input parameters of the water/sediment/study of which are used in the PECsw/sed catoulations are summarised in the following table Q. °, Ś P ò

Table 7.2.2.3-1:	Input parameters,	related to a	ctive su	bstance	isoflucypi	and and	metabolite
	for PECswsed calcu	Pations	Ű.	Ø		, s	Q,

			×)
Parameter	A S Com	Sound S &	Xalue in accordance with
L. L	S Isoflucypram	NRCS-ON88460	EU endpoint y/n /
		carboxylic acid (M12)	Reference
DT ₅₀ in water [days]	354 (Step 2) →		n.a.
	354 ^a /\$000 ^b) (Step 3)		
DT ₅₀ in sedimen days	354 (Step 2) (5)		n.a.
	35(a ^a)/1000 ^b (Step 3)		
DT50 in total system [days]	35@ (Step 1)	<u> </u>	n.a.
Maximum occurrence	water: \$90 ~	water: 5.4	n.a.
observed (% molar basis with	Gediment: 83.0	sediment: 1.3	
respect to parent)	total system: 100	total system: 6.6	

According to FOCUS (2015) for substances with a K between 100 and 2000 mL/g two options should be tested: a) DegT₅₀system used for degradation in water, default DT₅₀ of 1000 days used for degradation in sediment b) DegT₅₀system used for degradation in rediment default DT_{50} of 1000 days used for degradation in water n.a. = not applicable for a new active substance submission

Degradation in aquatic system

• Isoflucypram

The degradation and dissipation behaviour of isoflucypram was characterised by data from a laboratory acrobic water sediment study by ; 2017; M-580411-01-1 including two water sediment systems. The kinetic evaluation was conducted by . G.: . W.: 2017; \$6083\$6-02-1 according to FOCUS (2006, 2014). Resulting simple first order DT₅₀ values are shown in Table 7.2



The geometric mean total system degradation DT_{50} of 354 days for isoflucypram was used for all phases in the Steps 1-2 calculations. For FOCUS Step 3 degradation DT_{50} for the single phases are required. Since these are not available the geometric mean total system DT_{50} of 354 days was taken into account. According to FOCUS (2015), for substances with a K_{foc} value between 100 and 2000 mL/g such as isoflucypram two options have to be tested to derive the worst case PEC_{sw} values: 1. The geometric mean total system DT_{50} of 354 days was used for the water phase and a default $D\Phi_{50}$

value of 1000 days was used for the sediment phase. 2. The geometric mean total system DT₅₀ of 354 days was used for the sediment phase and a sefault

1 abic 7.2.2.5- 2.	Sum	inary or	ucgi auan					cuve su	Diang	130114	
Isoflucypram	Distrib Max. ir	ution: 1 sedime	nt 83.0%	⁾ after 5		ehltalsp	exre)		Â m î		
Water / sediment system	pH water / sed	DegT50 whole sys. [days]	DegT90 whole sys. [days]	Kinetic fit	DisT5 water [days]	DisT ₉ 6 water [days]	Kinetî c fît	DisTs sec [days]	DisT setD [days]	Kinetie fit	Evaluated on EU level y/n Reference
Anglersee, sand ^{a)}	7.1 / 6.6	211	702	U SFO	22.3	74.2	FOM recorde	285	938	SEQ	n /
Wiehltalsperre, loam ^{a)}	7.3 / 5.1	593	> 1000 ~ ~ ~	SFO		39.6		n.r.	Çh.r.	7, - <i>S</i>	2017; M- 608356-02-1
Geometric mean 20ºC	at	354	0 [×]		¥\$.3	8		* 2 82 .	N N	D,	

	~ ~ ~ ~ ~ ~	i den a	$ O^{\gamma} $	
Table 7.2.2.3- 2:	Summary of degradation in wa	ater / sediment of	the active subst	ance isoflucionra
	Summing of acgradation in we	acci , spannent or	mente subst	may isonaly pra

n.r. Not fully reliable, mathematicalle not significantly different from Oriot usable

DT50 value of 1000 days was used for the water phase real

a) ; 2017; M \$8041101-1

• BCS-CN88469-carboxylic acid (4412)

The degradation and dissipation behaviour of BCS-CN88460 carboxylic acid was investigated in the laboratory aerobic water-sediment study with the parent substance (soflucypram (software); software); 2017; M-580411-0(-1). The kinetic evaluation was conducted by software), G.; Software), W.; 2017; M-608356-02- according to FOCOS (2006, 2014). However, due to its limited formation in aquatic systems, no reliable degradation half-lives for BCS-CN88460-carboxylic acid could be derived. Consequently, the DT- in water, sediment, and total system was set to a conservative value of 1000 days for the use in FOCUS Steps 1-2 calculations.

The maximum occurrence of BCS-CN88460-catboxylic acid in water/sediment systems was 6.6% AR observed after 100 days in the system Anglersee (**Generative**; **Generative**; 2017; M-580411-01-1).

		Ŷ,		
AN AN			CONFLUSIONS	1
. A	N Or			,

The geometric mean total weer/sectiment system degradation DT_{50} of 354 days for <u>isoflucypram</u> was used for all phases in the Steps 1-2 calculations. For FOCUS Step 3 degradation DT_{50} for the single phases are required. Since these are not available the geometric mean total system DT_{50} of 354 days was taken into account. According to FOCUS (2015), for substances with a K_{foc} value between 100 and 2000 mL such as isoflucypram two options have to be tested to derive the worst case PEC_{sw} values.

- 1. The geometric mean total system DT_{50} of 354 days was used for the water phase and a default DT_{50} value of 1000 days was used for the sediment phase.
- 2. The geometric mean total system DT_{50} of 354 days was used for the sediment phase and a default DT_{50} value of 1000 days was used for the water phase.



For BCS-CN88460-carboxylic acid (M12) no reliable degradation half-lives could derive from the aerobic water-sediment study with the parent isoflucypram, due to limited formation in aquatic systems. Therefore, the DT_{50} in water, sediment, and total system was set to a conservative value of 1000 days for the use in FOCUS Steps 1-2 calculations. The maximum occurrence of BCS-CN88460carboxylic acid in water/sediment systems was 6.6%.

Study water/sediment, aerobic

Report:	KCA 7.2.2.3/02; ; ; ; 2017 M-580411-01 P
Title:	[pyrazole-4-14C]BCS-CN88460: Aerobic aquatic metabolism
Report No.:	EnSa-15-0965
Document No.:	M-580411-01-1 & @ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Guideline(s):	OECD Test Guideline No. 308° \sim
	Commission Regulation (EU) No 280/2013 @ accordance with Regulation (EU) No 280/2013
	(EC) No 1107/2009
	US EPA OCSPP Test Guideline No. 835 A300 835.4400 a 2 2
Guideline deviation(s):	none Q Q Q A A A A A A A A A A A A A A A A
GLP/GEP:	yes \mathcal{A} \mathcal{A} \mathcal{A} \mathcal{A} \mathcal{A} \mathcal{A} \mathcal{A} \mathcal{A}

Executive Summary

The route and rate of degradation of pyrazole-labelled isofly@yprame were studied in two watersediment systems under aerobic conditions in the aboratory in the dart at 20 °C for 100 days:

Table 7.2.2.3- 3:	Water-sediment s	systêms used
-------------------	------------------	--------------

	2.7	"O" _~			0	ື້		
Water-sediment	System	Source	Ž Č	Textore ^{a)}	0,	pH 🚿	Т	OC
system	₿ DO	۶.	$\swarrow^{*} \sim$	(CSDA)	water ⁶	sediment ^{c)}	water ^{d)}	sediment ^{e)}
Ĺ		Å \{					[mg/L]	[g/kg]
Anglersee	Ă	Deverkus	en, Germany	san	A.1	6.6	< 2	8.8
Wiehltalsperre	W W	Nespon, C	Germany 🔊	løam	7.3 🔊	5.1	< 2	58.5
TOC + + 1 & X	1	St I		0				

TOC: total organic carbon

a) sediment textural class water pH value determined on site immediately after sampling b)

4

- sediment value der od from squeous 0.01 M CaCl2 suspensions c)
- d) water TOC determined at start of study (application of test item)
- sediment TOC determined at starf of stud @application of lest item C e)

A nominal study application rate of 1205 µg/lost system (corresponding to 37.5 µg/L) was applied based on a 5 fold maximum single field application rate of isoflucypram of 75 g/ha due to analytical reasons

The test was performed in systems consisting of cylindrical glass containers containing a water-tosediment volume ratio of approx. $3/1 (\sqrt{v})$ and equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. During incubation, the water was in smooth motion Ľ

Duplicate samples were processed and malysed 0, 3, 7, 14, 29, 51, 72 and 100 days after treatment (DAT). Af each sampling integral, the water was separated from the sediment by centrifugation and decantation. The sediment was extracted three times at ambient temperature, once using acetonitrile and twice using accountrie water 4/1 (v/v). Furthermore, two microwave-assisted extraction steps were performed using accionitrile/water 4/1 (v/v) at 70 °C and methanol/water 1/1 (v/v) at 50°C. The amounts of test item and degradation products in water and sediment extracts were determined by liquid Seintillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. Test item and degradation products were identified by HPLC-MS/MS) including accurate mass determination and/or



by NMR.

Mean material balances were 95.4% AR for system Anglersee (range from 93.0 to 97.9% AR) and 96.0% AR for system Wiehltalsperre (range from 92.9 to 98.3% AR).

The maximum amounts of carbon dioxide were 0.3 and 0.1% AR at any sampling interval in system Anglersee and Wiehltalsperre, respectively. Formation of volatile organic compounds (VOG) was insignificant as demonstrated by values of < 0.1% AR at all sampling intervals for both water/sediment systems.

Residues in water decreased from DAT-0 to DAT-100 from 82.3 to 20.6% AR in system Appresee and from 78.4 to 6.5% AR in system Wiehltalsperre.

Extractable residues in sediment of system Anglersee increased from SAT-0 to DAC-29 from 15. V to 76.2% AR and then decreased to 70.6% AR at DAT 100. Extractable residues in sediment of system © Wiehltalsperre increased from DAT-0 to DAT-51 from 17.6 to 84.6% AR and then decreased to 82.7% AR at DAT 100. Q,

Extractable residues in the total system (water and sediment extracts) decreased from DATO to DAT-100 from 97.5 to 91.2% AR in system Anglersee and from 96.0 to 89.2% AR in system 8 n Wiehltalsperre.

Non-extractable residues (NER) increased from DAT-0 6 DAT-100 from 00 to 6.4% AR in system Anglersee and from 0.7 to 6.2% AR in system Wiehltatsperre L 1

Isoflucypram dissipated from the water due to degradation and translocation into the sediment. The amount of isoflucypram in the water decreased from DAT-0 to DAT 500 from 82,5 to 8,2% AR in system Anglersee and from 78.4 to 4.4% AR in system Wiehltalsperre?

The amount of isoflucypram in the sedment extracts increased in system Angle see from DAT-0 to DAT-29 from 15.2 to 76.2% AR and decreased then to 62% AR at DAT 00. In system Wiehltalsperre, the amount of isoffacypram in the sediment extracts increased from DAT-0 to DAT-51 from 17.6 to 83.0% AR and decreased then to \$0.1% AR at DAT-100.

The amount of isoflucypram in the total system decreased from DAT of to DAT-100 from 97.5 to 71.4% AR in system Anglersee and from 96.0 to \$9.5% AR in system Wiehltansperre.

Degradation of isofl@cypram in the total system was accompanied by the formation of one degradation product identified as BCS-CN88460-carboxylic acid M12) with a maximum occurrence of 6.6% AR at DAT-100 in System Anglersee (see Table 7.2.2 3, 4). The total unidentified residues amounted to a maximum of 2.4% AR and no single component exceeded 4.6% AR at any sampling interval in both water/sediment systems.

The experimental data could be best described by a first order quilti compartment (FOMC) kinetic model for dissipation from the water and a single first order (SPO) kinetic model for degradation in the total system. The DT is values for the dissipation of isoflucypram from the water were 2.0 and 1.8 days in system Anglersee and Wiehltalsperfe, respectively. The DT₅₀ values for the degradation of





Compound	Chemical structure	Maximum occurrence in total system
BCS-CN88460-carboxylic acid (M12)	F F O H ₃ C OH N F O OH H ₃ C OH	

Table 7.2.2.3- 4:	Identified degradation product (maximum occurrence in total system)
-------------------	---

Table 7.2.2.3- 5:	Degradation kinetics	of isofluc	ypræm	in Wate	er-seqim	ent sys	stems	unde	ierobie "	O
	conditions	N,		× ×	s.	A	Ő	A 11	ġ.	, C

			× do	<u>~</u>	<u>v</u>	<u> </u>
Water-sediment sy	stem	Best fit kinetio	D F 50 🐇	⊖DT98	Che	Wisual
		* modela)	Jdays] ()	[days]	error (%)	assessment ^{b)}
Anglersee	water layer	FOMAC	200	£ 89.5 ¢	4.5	, [*] +
	total system 🗞	SFO 🔗	218	₽ 725	2.0	× +
Wiehltalsperre	water layer 🔬	FOMC	1.8 🎸	41,4	<i>8</i> .6	+
	totadsystem	SFQU	681	×\$1000	¥1.3 🗶	Q +

a) SFO = single first order FOMC = first order muti comparament

b) Visual assessment: $\frac{1}{\sqrt{2}} = \text{good}$

A.

Test item

NO ATERNALS AND METHONS
A. MATERYALS
1. Test and Reference Items & S S
Test item $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$
Pyrazole-labelled isotheyprasi
Sample ID: \mathcal{O}^{\vee} \mathcal{O}^{\vee} \mathcal{O}^{\vee} \mathcal{O}^{\vee} \mathcal{O}^{\vee} \mathcal{O}^{\vee}
Specific activity: 4 22MBq/mg (11/2 92 µOi/mg)
Radiochemical purity: >08% (PPI Couth radioactivity detector)
× × 99% (TLC stan)
Chemical purity: 299% (HPCC with/UV-detector, 210 nm)
Reference item
Reference substances were por used

Test Systems 2.

The study was carried our using two different natural water-sediment systems (Anglersee and Wightalspore). Water and sediment were sampled fresh. The natural systems were characterised at the site of collection with respect to temperature, pH and redox potential of the water and sediment as well as wygen content of the water.

Water and sediment were taken in approximately 0.5 m water depth and filled separately in plastic containers. Sediment was obtained from the upper sediment layer.



In the laboratory, the sediments were sieved to ≤ 2 mm, filled into plastic trays and stored at ambient temperature overnight for sedimentation. The water was filtered through a 0.063 mm mesh before preparation of the test systems.

Aliquots of the water/sediment systems were characterized with respect to the total organic carbon of the water and the sediment. In addition, aliquots of both sediments were characterised with respect to textural class, pH, and cation exchange. The results of the characterisation are presented on Table 7.2.2.3- 6. The sediment microbial activity was determined at start opequilibration as well as start and end of the study (Table 7.2.2.3-7).

ĈŊ

AnglerseeWichliftisperreProperties of water Temperature [°C]9.96.3pH7.17.3Redox potential [mV]241Oxygen saturation [%]102Total organic carbon (TOC) [mg/b)starf of the studyCall organic carbon (TOC) [mg/b)starf of the studyProperties of sediment3.4Textural class (USDA)andsand [%]97sitt [%]2.4clay [%]8.6pH (sediment / 0.01 M CaCl ² 1/2)pH (sediment / 1/1pH (sediment / 1/1pH (sediment / 1/1pH (sediment / 1/1pH (sediment / 0.01 M CaCl ² 1/2)pH (sediment / 1/1pH (sediment / 1/2pH (sediment / 1/2pH (sediment / 1/2pH (sediment / 1/2pH (sediment / 1/2<	Parameter	.Ô	R	esulta 🖓 🔬	Ď ^y
Properties of water Temperature [°C]Temperature [°C]9.96.3pH7.17.3Redox potential [mV]241257Oxygen saturation [%]405102Total organic carbon (TOC) [mg/b)starf of the study2.2Properties of sediment3.42.3Textural class (USDA)9749silt [%]9749silt [%]6.65.1pH (sediment / 0.01 M CaCl_21/2)6.65.1pH (sediment / 0.01 M CaCl_21/2)5.3OC [%]4.47.7Redox potential mV]4.40.85.8Cation exchange capacity med/100g]4.40.85.8Cation exchange capacity med/100g]4.40.85.8Cation exchange capacity med/100g]4.40.85.8Cation exchange capacity med/100g]4.40.85.8Cation exchange capacity med/100g]4.1a) = application of the test item41		A	Anglersee	Wiehltalsperre	
Temperature [°C] 9.9 6.3 pH 7.1 7.3 Redox potential [mV] 241 257 Oxygen saturation [%] 405 102 Total organic carbon (TOC) [mg/g] start of the study 22 2 Properties of sediment 3.4 27 27 Textural class (USDA) 3.4 27 49 sand [%] 9 9 6.6 5.1 pH (sediment / 0.01 M CaCl2 1/2) 6.6 5.1 9 pH (sediment/water 1/1 7.0 5.3 5 ph (sediment/water 1/1 7.7 7.2 7.42 ph (sediment/water 1/1 7.7 7.7 7.7 ph (sediment/water 1/1 7.7 7.7 7.7 ph (sediment/water 1/1 7.7	Properties of water				
pH 7.1 7.3 A Redox potential [mV] 241 257 A Oxygen saturation [%] 405 102 Total organic carbon (TOC) [mg/b] start of the study % 2.2 2 Properties of sediment 3.4 20 Textural class (USDA) and Joand Joand sand [%] 2.0 49 3.4 20 silt [%] 2.0 49 3.4 20 pH (sediment / 0.01 M CaCl_21/2) 8.6 5.1 9 pH (sediment/water 1/1 7.0 5.3 5.3 TOC [g/kg dw] start of the study a) 8.8 58.5 Cator [%] 4.4 7.7 Redox portential [mV] 2.37 42 Moisture [g H2O ad f00 g dty weight] 41 139 a) = application of the test item 41 139	Temperature [°C]	\$, 0° ~	×9.9 ×	6.3%	Š
Redox potential [mV] 241 257 Oxygen saturation [%] H05 102 Total organic carbon (TOC) [mg/b] start of the study 2 2 Properties of sediment Study onl 3.4 27 Textural class (USDA) Study onl 3.4 27 sand [%] 97 49 silt [%] 2 92 pH (sediment / 0.01 M CaCl_21/2) 8.6 5.1 pH (sediment/water 1/1 7.0 5.3 OC [%] Start of the study ^a 8.8 58.5 Cation exchange capacity (meq/100g) 4.4 7.7 Redox potential [mV] 4.4 7.7 Addition exchange capacity (meq/100g] 4.4 7.7 Addition exchange capacity (meq/100g) 4.4 7.7 Addition of the test item 4.1 139 <td>pH</td> <td>O Q X</td> <td>7.1.0</td> <td>[™] 7,3 A</td> <td></td>	pH	O Q X	7.1.0	[™] 7,3 A	
Oxygen saturation [%] Hb5 102 Total organic carbon (TOC) [mg/b] start of the study % 2 2 2 2 Properties of sediment Study end 3.4 2 2 3 Textural class (USDA) and loam 10am sand [%] and loam 97 49 silt [%] 2 02 02 clay [%] 2 02 02 pH (sediment / 0.01 M CaCl ² 1/2) 6.6 5.1 pH (sediment/water 1/1 7.0 5.3 OC [%] start of the straty % 8 8 58.5 clay end 7.9 51.3 OC [%] 4.4 7.7 Redox potential (mV] 4.4 7.7 Redox potential (mV] 4.4 7.7 Addition of the test item 237 42	Redox potential [mV]	A . 7 . 0	Q 241	0 \$7 0 *7	
Total organic carbon (TOC) [mg/b] start of the study 2 -	Oxygen saturation [%]		, 1 0 5 Ô	102 🛇	Ŕ
Properties of sediment 3.4 27 Textural class (USDA) and loam sand [%] 97 49 silt [%] 97 49 clay [%] 7.0 5.3 pH (sediment/vater 1/1 7.0 5.3 TOC [g/kg dw] start of the struty ^a) 8% 58.5 0C [%] 0.8 5.8 Cation exchange capacity (meq/100g) 4.44 7.7 Redox potentiat [mV] 237 42 Moisture [g H2O ad 100 g dey weight] 4.1 139	Total organic carbon (TOC) [mg/b)	start of the study		< 2 🖉 🚽	
Properties of sediment Textural class (USDA)One of the sediment of the sediment / 0.01 M CaCl2 1/2)One of the sediment / 0.01 M CaC	Q	🔬 study end 💫	3.40	2 2 3	0
Textural class (USDA)Image: Constraint of the structure is integrable.Image: Constraint of the structure is integrable.sand [%]9749silt [%]2097clay [%]2097pH (sediment / 0.01 M CaCl 21/2)8.65.1pH (sediment/water 1/17.05.3TOC [g/kg dw]start of the structy and start of the struct of the s	Properties of sediment	\mathcal{O}_{1} \mathcal{O}_{2} \mathcal{O}_{1} \mathcal{O}_{2}			
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Textural class (USDA)		l gond	© Toam∿~	
silt [%] clay [%] pH (sediment / 0.01 M CaCl 91/2) pH (sediment/water 1/1 TOC [g/kg dw] 3 start of the straty ^a) 3 straty ^a) started straty ^a) 3 start of the stratya stratya	sand [%]	<u> </u>	0 ^{×97} 0	<u>∼</u> 42	
clay [%] 4 9 pH (sediment / 0.01 M CaCl 1/2) 8.6 5.1 pH (sediment/water 1/1 7.0 5.3 TOC [g/kg dw]start of the structy ^a) 8.8 7.0 5.3 TOC [g/kg dw] 9 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.3 7.0 5.8 7.0 7.9 7.1 7.7 <	silt [%]		<u></u> 20	, ⊕2´	
pH (sediment / 0.01 M CaCl $21/2$) pH (sediment/water $1/1$ TOC [g/kg dw] OC [g/kg dw]	clay [%]	<u>C' A P</u>		9	
pH (sediment/water $1/1$ TOC [g/kg dw]start of the stricty ^a TOC [g/kg dw]start of the stricty ^a Start of the stricty ^a 8%Start of the stricty ^a 58.5OC [%] 0.8 Start of the stricty ^a 0.8	pH (sediment / 0.01 M CaCl ₂ 1/2)		<u> 18.6</u> ~~~	\$v* 5.1	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	pH (sediment/water 1/1		≪ 7.0 ∞	5.3	
OC [%]Study end7.9 51.3 OC [%] 0.8 5.8 Cation exchange capacity meq/100g] 4.4 7.7 Redox potential mV] 237 42 Moisture [g H20 ad 100 g day weight] 41 139	TOC [g/kg dw]	start of the study ^a	O' 8.%	58.5	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $		study end	7.9	\$ 51.3	
Cation exchange capacity meqc[00g] \sim \sim 4.4 7.7 Redox potential mV] \circ \sim 237 42 Moisture [g H2O ad 100 g day weight] \sim $$ $$ $$ a) = application of the test inten \sim $$ $$ $$			<u> </u>	5.8	
Redox potentials $[mV]$ ImV Im	Cation exchange capacity meq(100g		4.4	7.7	
$\frac{\text{Moisture [g H2O ad 190 g dev weight]}}{\text{a}) \approx 3 \text{ application of the test item}} \qquad $	Redox potential mV] O		237 D	42	
a) \approx application of the test integration \mathcal{A}^{μ} \mathcal{A}^{μ} \mathcal{A}^{μ} \mathcal{A}^{μ}	Moisture [g HQO ad 190 g dry weight	t <u>j zv öř</u>	r sti	139	
	a) = application of the test item		\sim		

Table 7 2 2 3_ 6.	Physica_chemical characteristics of th	e water_sediment systems
1 abit 7.2.2.5-0.	i nysico-chemical characteristics of th	c water-scumence systems

Table 7.2.2.3-7: Results of microbial action determinations (expressed as not microbial carbon dioxide per hour per kg of sediment dry weight)

		~	
	System of a or	Sampling date	
~	Starryf	DAT-1	DAT-100
.1	َ اللهُ ا	Bio1-	Bio2- / Bio2+
<u>S</u>	Anglersee A to the Anglersee	9.7	5.5 / 3.9
le la	Wiehltalsperre 82.50	64.8	49.2 / 73.5
\bigcirc	BIO- samples were leftoantreated		

samples were applied with solvent of application solution (229 µL methanol)

В. STUDX DE

Experimental Conditions 1.

Special cylindrical glass, containers (volume approx. 1000 mL, inner diameter approx. 10.5 cm, surface area approx. 86.6 cm²) were used as test vessels and each container was fitted with trap attachments (permeable for oxygen) containing soda lime for absorption of carbon dioxide and a polyurethane foam plug for adsorption of volatile organic compounds.

For preparation of the test systems a water-to-sediment volume ratio of approx. 3/1 was used corresponding to a water layer of approximately 6 cm and a sediment layer of approximately 2 cm.



Therefore, wet sediment with a weight equivalent to a volume of 175 mL was weighed into each vessel and 520 mL of the corresponding water were added. The flasks were then fitted with trap attachments, valves and stirrers.

A nominal study application rate of 19.5 μ g/test system (corresponding to 37.5 μ g/L) was applied based on a 5 fold maximum single field application rate of isoflucypram of 75 g/ha due to applytical[©] reasons.

The test item was applied dropwise onto the water surface of the respective equilibrated test systems. After application, the test vessels were fitted with trap attachments (except of DAT-0 samples). The test systems were incubated in the dark for 100 days at 20°C in walk-in climatic chamber.

2. Sampling

Eight sampling intervals were distributed over the Entire incubation period of 0100 days. Deplicate samples were processed and analysed 0, 1, 3, 7, 1429, 51, 72 and 100 days after treatment (DAT) Microbial activity was determined at start of equilibration as well as start (DAT V) and end of the study (DAT-100).

Analytical Procedures 3.

At each sampling interval, the water was separated from the sediment by centrifugation and decantation. The sediment was extracted three times at ambient temperature, once using accontrile and twice using acetonitrile/water OV (v/y). Furthermore, two@microwave-assisted extraction steps were performed using acetonitrile vater 4/1 (v/v) at 70°C and methabol/water 1/1 v/v) at 50°C. The amounts of test item and degradation products in water and sediment extracts were determined by liquid scintillation counting (LSC) and by HPLC/radiodetection analysis. The amounts of volatiles and non-extractable residues were determined by LSC and combustion/LSC, respectively. Test item and degradation products were identified by HPLC-MS(/MS) including accurate mass determination and/or by NMR.

Determination of Degradation Kinetics 4.

The degradation kinetics of the test item was determined according to FQCUS kinetics (2006¹) using the software KulGUI 2. Model input datasets were the residual mounts found in each replicate test system at each sampling interval. The initial recovery (paterial balance) at DAT-0 was included in the parameter optimization procedure, but for optimal poodness of fit, the value was allowed to be estimated by the model PT₅₀ and DT ovalues were calculated from the resulting kinetic parameters.

RESULTS AND DISCUSSION

The test systems were incubated under aerobic conditions in the dark in a walk-in climatic chamber at a mean temperature of 204°C for 100 days. Determinations of microbial activity were performed at start of equilibration as well as start (DAT-1) and end of the study (DAT-100) and demonstrated that the used sediments were microbially viable.

The pH values in the water ranged from 7.8 to 8.6 in Anglersee test systems and from 6.4 to 8.3 in Wiel stalsperre test systems. The corresponding pH values in the sediment ranged from 6.3 to 7.4 in Anglersee test sestems and from 6.0 for 7.0 in Wiehltalsperre test systems.

The oxygep contents in the water, ranged from 8.0 to 8.6 mg/L in Anglersee test systems and from 7.8 to 8.8 mg/L in Wiehltausperre test systems. The redox potentials determined in water and sediment were at highly positive E_H-values during the incubation period. However, variations between different test systems, were observed. In Anglersee test systems, the E_H-values in water ranged from +365 to

FOCUS (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



+423 mV. The corresponding E_{H} -values in sediment were between +159 and +536 mV. In Wiehltalsperre test systems, the E_{H} -values in water ranged from +352 to +446 mV. The corresponding E_{H} -values in sediment were between +242 and +410 mV.

The clearly positive values for the redox potentials and the oxygen contents indicate activity conditions during the incubation period.

A. MATERIAL BALANCE

Mean material balances were 95.4% AR for system Anglersee (range from 93.0 to 97.9% AR) and 96.0% AR for system Wiehltalsperre (range from 92.9 to 98.3% AR) (Table 7.2.2.3-8, and Table 7.2.2.3-9).

The complete material balances found at all sampling intervals for both water/sediment systems demonstrated that there was no significant loss of radioactivity from the test softens of during sample processing.

B. DISTRIBUTION AND COMPOSITION OF RESIDUES

The detailed figures of the radioactivity distribution are presented in Table 7.2.2.3- & and Table 7.2.2.3- 9. The route of degradation of isoflucipram in Anglersee and Wiehltalsperre water-sediment systems

under aerobic conditions is summarised in Table 7.2.2.3- 8 and Pable 2.2.3-9. The proposed degradation pathway is presented in Figure 7.2.2.3-1

Carbon dioxide and volatile organic compounds

The maximum amounts of carbon dioxide were 0.3 and 0.1% AR at any sampling interval in system Anglersee and Wiehltalsperre respectively Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of 0.1% AR at all sampling intervals for both water/sediment systems (Table 7.22.3-8 and Table 7.22.3-9).

Test item and degradation products in the water

Residues in voter decreased from DAT-0 to DAT-100 from \$2.3 to 20.6% AR in system Anglersee and from 78,4 to 6.5% AR in system Wighltalsperre.

Isoflucypram dissipated from the water due to degradation and translocation into the sediment. The amount of isoflucypram in the water decreased from DAT-0 to DAT-100 from 82.3 to 8.2% AR in system Anglersee and from 78.4 to 4.4% QR in system Wiehltalsperre.

Degradation of isoflucypram in the water was accompanied by the formation of one degradation product identified as BOS-CN 8460-carboxylic act (M/2), with a maximum occurrence of 5.4% AR at DAT-100 in the water of system Anglersee. The total unidentified residues in the water amounted to a maximum of 7.1% AR at any sampling interval for both water/sediment systems and no single compound exceeded 2.5% AR Clable (2.2.3) and Table 7.2.2.3-9).

Test item and degradation products in the sediment

Extractable residues in sediment of system Anglersee increased from DAT-0 to DAT-29 from 15.2 to 76.2% AR and then decreased to 70.6% AB at DAT-100. Extractable residues in sediment of system Wiehltalspere increased from DAT-0 to DAT-51 from 17.6 to 84.6% AR and then decreased to 82.7% AR at DAT-100.

The amount of isoflucypram in the sediment extracts increased in system Anglersee from DAT-0 to DAT-29, from 15.2 to 76.2% AR and decreased then to 63.2% AR at DAT-100. In system Wiehkalsperre, the amount of isoflucypram in the sediment extracts increased from DAT-0 to DAT-51 from 17.6 to 83.0% AR and decreased then to 80.1% AR at DAT-100.

Degradation of isoflucypram in the sediment was accompanied by the formation of one degradation product identified as BCS-CN88460-carboxylic acid (M12), with a maximum occurrence of 1.3% AR at DAT-100 in the sediment extracts of system Anglersee. The total unidentified residues in the sediment extracts amounted to a maximum of 5.3% AR at any sampling interval for both



water/sediment systems and no single compound exceeded 2.7% AR (Table 7.2.2.3- 8 and Table 7.2.2.3- 9).

Test item and degradation products in the total water-sediment system

Extractable residues in the total system (water and sediment extracts) decreased from DAT-000 DAT- 100 from 97.5 to 91.2% AR in system Anglersee and from 96.0 to 89.2% AR in system Wiehltalsperre.

The amount of isoflucypram in the total system decreased from DAT-0 to DAT-109 from 97.5 to 71.4% AR in system Anglersee and from 96.0 to 84.5% AR in system Wiehltalsperred Degradation of isoflucypram in the total system was accompanied by the formation of one degradation of product identified as BCS-CN88460-carboxylic acid (M12) with a maximum occurrence of 6.6% AR at DAT-100 in system Anglersee. The total unidentified residues amounted to a maximum of 12.4% AR and no single component exceeded 4.6% AR at any sampling interval in both water/sediment systems (Table 7.2.2.3- 8 and Table 7.2.2.3- 9).

Non-extractable residues

Non-extractable residues (NER) increased from DAT 9 to DAT-100 from 9.4 to \$4% AR in Stem Anglersee and from 0.7 to 6.2% AR in System Wiehtalsperse (Table 7.2,23-8 and Table 7.2.23-9).

Table 7.2.2.3- 8:	Degradation of isoflucypram in system	Anglersee	under :	aerobic	conditions
	(expressed as porcentage of applied rad	lioa¢©wity)	Õ.	°° i	~~ ~~

Compound	Source (~~	L, i	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	€ Đ√	M D) .	Ĵ	
•	B O A	۵ 🖉	3	ື 7 ຸ	14	22	5Î	72	100
Isoflucypram	Water 🔬 💡	82	40.4	32 A	24.9	\$4.3	2. 5	10.3	8.2
2	sediment	19.2	St .9	≈ 60 .8	∞ €8.7 ≬	_76.2 %	65.3	65.7	63.2
	entire system ^{d)}	Ø97.5 💒	\$92.3 ×	93.1	[©] 93.6©	[∞] 90.6∳	77.8	76.0	71.4
BCS-CN88460-carboxylic	water N	n.d.	n.do	n.d	n,d.	109	2.4	3.2	5.4
acid (M12)	sediment	nd.	p.d.	Dd.	Ø.d.	∕ ₽.d.	< LOD	1.2	1.3
	entire system ¹⁾	6 0 .d.	Kn.d. 4	n.d. 🦼	n.d.	[∞] 1.9	3.0	4.4	6.6
Sum of unid./diff.	water	[™] n.d _s	🖗 n.d. 🔍	ĭ≪ LOD	∼ n.d.©	< LOD	5.7	5.6	7.1
residues ^{a)}	şediment 🖂	n.đ	n.đ.	< I @D	nz.	n.d.	2.0	2.3	5.3
	entire system	n.d.	A.d.	Ś€OD	n.d.	< LOD	7.7	7.9	12.4
Total extractable residues ^{b)}	water	\$2.3	40.4	[∞] 32.4 [°]	24.9	16.8	20.7	19.1	20.6
\$9 [′]	sediment	P 15.2%	51. 2 √	60.8	68.7	76.2	67.8	69.2	69.8
	entire stem	97.5	92.3	961	93.6	93.0	88.5	88.3	90.4
Carbon dioxide ^{c)}		Ĵî≱a.	\$0.1	0 .1	< 0.1	< 0.1	0.3	0.1	0.1
Volatile organic compound	s ^c)	n.a. 🍾	y< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	n.d.	< 0.1
Non-extractable residues ^{c)}		0.4	0.8	1.5	1.9	2.8	3.6	4.6	6.4
Total recovery ^{b)}	a di	9.7×9	\$99.2	94.6	95.5	95.9	92.3	93.0	96.9

n.d.: not detected, n.a.: not analysed, DAT: days after treatment, SD: standard deviation,

LOD: limit of detection (1.0% AR)

a) Minor degradates are sumped up to sum of buildentified / diffuse residues (single max. < 5 %AR in the entire system)

b) Difference to material balance values due to rounding errors as well as clean up and chromatographic losses
 c) Values taken from material balance

d) Mean values of the entire system could be unequal compared to the sum of the mean values of water and sediment, as values of the entire system are calculated individually for each replicate by summation of values from water and sediment before averaging the entire system values



Table 7.2.2.3- 9:	Degradation of isoflucypram in system Wiehltalsperre under aerobic conditions
	(expressed as percentage of applied radioactivity)

Compound	Source			Q	ð					
•		0	3	7	14	29	51	72	A00	Š
Isoflucypram	water	78.4	37.7	26.7	17.4	12.2 🐐	> 8.5	7.5) 4.4 s	0.
	sediment	17.6	53.5	67.2	75.2	80.2	83.0	80.5	80.	
	entire system ^{d)}	96.0	91.2	93.9	92.6	92.4	91.4	88.0	84.5	
BCS-CN88460-carboxylic	water	n.d.	n.d.	n.d.	n.d.	≪–LOD	< LOD	©LOD	LOD	la International
acid (M12)	sediment	n.d.	n.d.	⊳ _{&} n.d.	n.d. 🖈	n.d.	< LQD	K⊂ LQD	<lqd< td=""><td></td></lqd<>	
	entire system ^{d)}	n.d.	n.d.📎	n.d.	n.d_©	< LOD	< LØD	13	< LØD	¢.
Sum of unid./diff.	water	n.d.	n,d.	n.d.	nð.	n.d.	<i>s</i> l,OD	≲₽OD	A.7	Ů,
residues ^{a)}	sediment	n.d.	"Rð.	n.d.	∫tr.d.	n.d.	©LOD	≪LOD	Q LOD	×
	entire system ^{d)}	n.d.	an.d.	n.d.	n.d. 🤇	n.d,	<lod< td=""><td>< LOD</td><td>2.2</td><td></td></lod<>	< LOD	2.2	
Total extractable residues ^{b)}	water	78.4	37.7	262	17,4	12.8	8.5	\$P	~6,0	
	sediment	17.6	5 🏹 🔊	6352	7 5.2	-80.2	\$3.0	°∻§¥1.1	≪80.6	
	entire system ^{d)}	\$6 .0	94 .2	\$93.9	9 2.6 🔊	Ø93.0 <i>4</i>	91.4	89.2	86.6。	
Carbon dioxide ^{c)}		🛆 n.a. 🛛	× 0.1 (< 0.14	₹ < 0.1	< 0,1	< 0.	$< QO^{2}$	0.1	
Volatile organic compounds	S ^{c)}	n.a. 🔿	< 0.1	< 0.1	< Ø .],	<01	≨0.1	n.d.	£0.1	
Non-extractable residues ^{c)}	Ű	0.7	, WÎ	<u>, 2</u> 2	<u>ð</u> .4	¥ .1	\$3.8	¥4.5	6.2	
Total recovery ^{b)}	Q	¢ 96 .7	≫ 2.9 ∝	9 6.1	95.1	97.2	95.3	93.7	92.9	

n.d.: not detected, n.a.: not analysed, DAL, days aper treatment, SB/standard deviation, LQD limit of detection (1.0% AR)

a) Minor degradates are summed up to sum of unidentified / diffuse restrictes (stogle may < 2 **(OR** in the entire Ø system)

b) Difference to material balance values due to rate ding errors as well as citizen up and chromatographic losses
c) Values taken from material balance values of the company of the company. The company of the company of the company of the comp

a) minor degradues are summed upper singly minor queres induces togete minor 2 and in the clinic system
b) Difference to material balance values due to rehabiling errors as well as clean up and chromatographic losses
c) Values taken from material balance values due to rehabiling errors as well as clean up and chromatographic losses
d) Mean values of the entire system aceluated individually for each opticate by summation of sulues from water and sediment before averaging the minor explored by the entire system aceluated individually for each opticate by summation of sulues from water and sediment before averaging the minor explored by the entire system and explored by the entire system aceluated individually for each opticate by summation of sulues from water and sediment before averaging the minor explored by the entire system and explored by the entire system and explored by the entire system and explored by the entire system are calculated individually for each opticate by summation of sulues from water and sediment before averaging the minor explored by the entire system and the entire sy







Dissipation kinetics of isoflucypram from the water

The dissipation of isoflucyprain from the water followed first order multi compartment (FOMC) kinetics in both water/sediment systems according to the lowest chi2 error values and visual assessments. The table below summarises the best fit results of the DT₅₀ and DT₉₀ calculations for the

dissipation of isoflucypram from the water. \bigcirc The DT₅₀ values for isoflucypram were 20 and 1.8 days in the water of the tested water/sediment systems under aerobie conditions.

Table	7.2.2.3-	10 Dissipat	ion @isoflucypra	m from the w	ater phase
		· >>/ 4/1			1

Water-sediment system	Best fit kinetic model ^{a)}	DT50 [days]	DT90 [days]	Chi ² error [%]	Visual assessment ^{b)}
Anglerses (sand)	FOMC	2.0	89.5	4.5	+
Wiehlasperre (loam)	FOMC	1.8	41.4	2.6	+

a) FOMC: first order multi compartment

b) visual assessment: + = good



Degradation kinetics of isoflucypram in the entire water-sediment system

The degradation of isoflucypram in the total system followed single first order (SFO kinetics in system Anglersee and Wiehltalsperre, respectively, according to the lowest chi² error values and visual assessments. The table below summarises the best fit results of the DT_{50} and DT_{90} calculations for the degradation of isoflucypram in the total system.

Ĉa

The DT_{50} values for isoflucypram were 218 and 681 days in the total system of the tested watersediment systems under aerobic conditions.

Table 7.2.2.3-11: Degradation	of isoflucypram in	the entire v	vater-sedin@) it system	
Water-sediment system	Best fit	DØ 50		Chi ² ergor	Visual X
(sediment texture (USDA))	kinetic model ^{a)}	[days]	[days]	° [%)	~assessment ^{b)}
Anglersee (sand)	SFO	218	725 👡	2.1	
Wiehltalsperre (loam)	SFO 候	, 685)°	ِيْ 100¢¢	1.3	' °∼y + ≪v
a) SFO: single first order	O'			S õ	L A
b) visual assessment: + = good		DNEEUSI	NS S		
Isoflucypram dissipated rapidl	y from the water	jn water/se	diment system	ms Onder der	robic conditions in
the laboratory in the dark. The	calculated best f	it DT val	les for the di	ssipation of	isoflucypram from
water were 2.0 and 1.8 days	the tested water	/sediment s	ystems. In th	e total water	r-sediment system,
isoflucypram was degraded sl	owly. The calcula	and best fit	DT ₅₀ values	for the tota	system were 218
and 681 days in the tested wat	er-sediment syster	ms. 🔬			
Formation of carbon dioxide a	Second to ≤ 0.3	% AR in be	h water/sedi	ment system	18.
Non-extractable residues acco	unted for a maxin	num of 644	6 AR in both	watef/sedim	ent systems.
One degradation product of is	ofluevprany was id	dentified: B	CS4CN8846)-carboxylic	acid $(M12)$ with a
maximum occurrence of 8.6%	AR in the total sy	vstem	5° 0	~~~	
• Kinetic evaluation of		A A A A A A A A A A A A A A A A A A A		Ű,	
			i sigay		
Report: 6 ACA 7	A 3/02:	G	W · 2017	M-608356-0	2-1
Title:	vpram@ISY) and m	etabolite A	inetic evaluati	on of aerobic	aquatic metabolism
	r/sediment_systems	$\gamma \sim$			uquuit interaconom
Report No.:	7-0356 2 0				
Document No.: @M-608	336-02-Ŵ ×	, s			
Guideline(s):	ficable \mathcal{L}°	~0 [°]			
Guideline deviation(s) note					
GLP/GEP: NO	er ro	Ť			
Executive Summary					

The degradation behavious of isoflucyprim in water-sediment systems was investigated in two aerobic laboratory water sediment test systems in one experimental studies at 20°C in the dark (2007; M-580411-01-1).

The objective of this study was to obtain degradation or dissipation half-lives of and its aquatic metabolite BCS-CN88460-carboxylic acid (M12) in the water phase, sediment phase as well as in the total system of water and sediment in the dark.

The evaluation was conducted to derive kinetic parameters that are suitable to trigger additional



studies (trigger endpoints) and for modelling and environmental risk assessments (modelling endpoints), according to FOCUS kinetics (FOCUS 2006¹, 2014²). The kinetic modelling analysis was conducted using the software tool KinGUI 2.1, implementing the IRLS error model (Iteratively reweighted least square). The identification of the appropriate kinetic model followed the recommendations given by the FOCUS Degradation Kinetics Workgroup (FOCUS 2006, 201) based on a detailed statistical analysis including visual assessment, chi2err statistica significance test and correlation analysis.

The FOCUS kinetics report distinguishes between two levels of kinetics: At Level 1 a single compartment is used to derive (i) degradation endpoints from the total system or (ii) dissipation or decline endpoints from each compartment separately in water, sediment or total system from maximum onwards. Level 2 considers two-compartmental approaches to estimate the real degradation C in water and sediment, in parallel, considering exchange rates between water and gediment. The resulting degradation and dissipation half-lives in total system, water or cediment phase (trigger and modelling purpose) and formation fractions of isoflucypram and its metabolite are given in Ô Table 7.2.2.3- 12 to Table 7.2.2.3- 16. K. Ľ

For metabolite BCS-CN88460-carboxylic acid, no fully reliable and statistically significant dissipation kinetics in water or in total system could be derived based on chi²err ertor, t-test) for modeling purpose. Only a formation fraction for the total system could be derived for the system Anglersee

Table 7.2.2.3- 12:	Degradation and dissipa	tion in wat	er / sæðin	nent systems:	trigger	endpoints of	Ì
	isoflucypram, Level P-L		ð	R O	<u> </u>	õ v	

			M.	<u> </u>			¥ Öř	<u> </u>	80	
Isoflucypram	Distrib	ution: m	ax. in s	diment 84.5	5% afte	1 51 days (Wiehlta	lsperre)	Ň	
Water /	pН	pH sed	Temp.	DT 🕡 DT 🖉	St. 🔗	DT50/	^st.	ВУТ 50 / Д	St.	Method of
sediment system	water	(Ca€l ₂)	[@]	whole sys.	$(\chi^2 err)$	DT90	(y ² err)	ŷ DT‱	(χ ² err)	calculation
	phase	· *	A.	(days)	\$	water	ັ [%]∕ິ	sed	[%]	whole sys. /
	×				Ŏ,	[days]	×,	[days]		water / sed
Anglersee, sand ^{b)}	7 🖉	6.6	20	2 / / 702	2.09	2,79/	2.78	282 /	3.25	SFO /
		. 64	\sim	«گ(SFØ)	~ <u>^</u>	Ø4.2 A		938		FOMC
	Ô,	∧	V &	\sim	L, V	FOME	Š	(SFO)		recalc /
8		, O	O ^y		Ý Ò		a			SFO
Wiehltalsperre	7.3	5.1	<i>©</i> 20	593 / >1000	0.88	2.06 / 3	£2.10	n.r.	-	SFO /
loam ^{b)}			K,	(SFO)		39.6	۴			FOMC
<u></u>	. 0	r . 8	r k		Ő ^y 4	(FOMO)				recalc / -
Geometric mean	at 20%		2	<u>,</u> 0354 √}		2.40		282		

n.r. = Not fully reliable mathematically for significantly different from Opot usable



FOCUS, 2006: Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticities in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics. EC Document Reference Sanco/40058/2005, v.2.0, June 2006

² FOCUS, 2014: Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. v1.1., 18. Dec. 2014. EU Document



Table 7.2.2.3- 13: Degradation and dissipation in water / sediment systems: modelling endpoints of isoflucypram, Level P-I

Isoflucypram	Distrib	ution: m	ax. in sec	liment 84.5%	⁄o ^{a)} after	51 days (V	Viehltals	perre)			ð
Water / sediment system	pH water phase	pH sed (CaCl2)	Temp. [°C]	DT ₅₀ / DT ₉₀ whole sys. [days]	St. (χ²err) [%]	DT ₅₀ / DT ₉₀ water [days]	St. (χ ² err) [%]	DT ₅₀ / DT ₉₀ Sed [days]	St. (χ ² err) [%]	Method of calculation whole sys. / water / sed	Y Y
Anglersee, sand ^{b)}	7.1	6.6	20	211 / 702 (SFO)	2.09	22.3 / 74.2 (FOMC recalc)	2.78 0 0 0	282 / 938 (SFO)		• SFO / 2 • FOMS recalc / SFO (
Wiehltalsperre, loam ^{b)}	7.3	5.1	20	593 / >1000 (SFQ)	20.88	11.9 Q 39,6 (FØMC (Tecalc)		N.F.		©SFO/© FOMC recarc / -	
Geometric mean	at 20°C			354		163	ð	282	Ő		

n.r. = Not fully reliable, mathematically not significantly different from 0; no

a) maximum value of a single replicate b)

a) maximum value of a single replicate b) **Table 7.2.2.3- 14: Degradation in water and sediment:** modelling endpoints of soflue pram, Level P-II

							9			
Isoflucypram	Distrib	ution: m	ax. in se	diment 84.5	% ^{a)} afte	r 51 da <i>ys</i> (Wiehlta	lsperre)	0×	
Water /	pН	pH sed	Temp.	DT / DT	f St. Ø	DT50/	St.	DT 50 / C	St.	Method of
sediment system	water	(CaCl ₂)	[°C]	whole sys.	$(\chi^2 err)$		(x²err)	DT	(χ^2 err)	calculation
	phase			[daxs]	\$%]	Owater	[%]	sed	[%]	water / sed
	, C					[days]		[days]		
Anglersee, sand ^{b)}	7,0	£ .6	, ÔÝ	~∽n.r. ∼		Øvr.	- 0	n.r.	-	- / -
Wiehltalsperre,	£7.3	\$.1 ,	²⁰	na	۶×	ۍ n.r.	-~~	n.r.	-	- / -
loam ^{b)}	Þ))	í 🔊		jy »		Ŵ			
Geometric mean	at 2000		Ča		Ś	0				





Table 7.2.2.3- 15: Degradation and dissipation in water / sediment systems: trigger endpoints of BCS-CN88460-carboxylic acid (M12), Level M-I

Water / sediment systempH water phasepH sed (CaCl2)Temp. [°C] DT_{50} / DT_{90} whole sys. [days]St. ($\chi^2 err)$ DT_{50} / DT_{90} DT_{90} water [%]St. DT_{90} ($\chi^2 err)$ DT_{50} / DT_{90} ($\chi^2 err)$ St. DT_{90} ($\chi^2 err)$ DT_{50} / DT_{90} ($\chi^2 err)$ St. DT_{90} ($\chi^2 err)$ DT_{90} / DT_{90} ($\chi^2 err)$ St. DT_{90} ($\chi^2 err)$ DT_{90} / DT_{90} ($\chi^2 err)$ St. DT_{90} ($\chi^2 err)$ DT_{90} / DT_{90} ($\chi^2 err)$ $DT_{90} / DT_{90} / DT_{90}$ ($\chi^2 err)$ $DT_{90} / DT_{90} /$	Metabolite BCS-CN88460- carboxylic acid <i>(M12)</i>	Distrib Kinetic	ribution: max in total system 6.6 % after 100 d (Anglersee) max in water 5.4 % after 100 d (Anglersee) max in sediment 1.3 % after 100 d (Anglersee) etic formation fraction (k _f /k _{dp}) from parent in total system: ff 0.228 (n=1)										
Anglersee, sanda)7.16.620n.r.n.e. \frown n.e. \frown n.e. \frown	Water / sediment system	pH water phase	pH sed (CaCl2)	Temp. [°C]	DT ₅₀ / DT ₉₀ whole sys. [days]	St. (χ ² err) [%] ζ	DT ₅₀ / DT ₉₀ water [days]	St. (χ ² er.r)) [%]	DT ₅₀ / DT ₉₀ sed [days]	St, (χ ² cOr) (³ / ₀]	Method of cabeulation		
Wiehltalsperre, 7.3 5.1 20 n.r. A - n.e. Q e° n.e. Q e° n.e. Q	Anglersee, sand ^{a)}	7.1	6.6	20	n.r.	2	n.e.	Þ [∞] -	n.e.	-Q,	-\$- / - &	Þ″	
	Wiehltalsperre, loam ^{a)}	7.3	5.1	20	n.r.	- (n.e.Q	Ô	nce.	с- О	Ŭ-/-/-@*		
Geometric mean at 20°C n.r. o are a n.e. n.e.	Geometric mean	at 20°C	r Ý		n.r	Ô	 a.e. 🗴		n.e.Ò		C ~		

n.r. = Not fully reliable, mathematically not significantly Offeren from 0 pot usable

Table 7.2.2.3- 16: Degradation and dispation in water / sediment systems; modeling endpoints of BCS-CN88460-carboxylic acid (M12), Level My (pathway fit)

			~~~		Ö	~ ~		õ (	', '^	1
Metabolite	Distrib	ution: r	@ax in	total system	6.6% a	ftee 100 d	Angler	ěe) 🔊	K,	
BCS-CN88460-		Ĵ,	ňax in'	water 5.4 %	after 10	0 d (Angle	rsee	Ŷ	$\bigcirc^{r}$	
carboxylic acid		ŗ~r	naxun	sediment 1,	3∮% aft@	r 100 d (An	glersee)		Ĉa	
(M12)	Kinetic	formati	on fra	ction (k _f /k _{or} )	from pa	arent in tot	al system	n: ff = Ø.	<b>Ž28 (n=</b> ]	l)
Water /	рН	pH sed	≜Tem	DT 50 / DT 90	st.	DT50 ¢	Št. 🕷	DT	St.	Method of
sediment system	water	CaCa	D×/	whole svs.	(Perr)	DT	$(\gamma^2 e r)$	<b>Ď</b> ¥90	$(\gamma^2 err)$	calculation
	phase	(	19CT	davsl 🐔	<b>1%</b>	water		Sed	[%]	whole svs. /
		Ô ^y				[@ays]		[days]	L)	water / sed
Anglersee, sanda	°7.1 ≈	6.6	20%	nz	~-~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	n.e.	<u> </u>	n.e.	-	- / - / -
Wiehltalsperre,	7 5	۶.P	20	n.r. s	- ~	n@.	. @-	n.e.	-	-/-/-
loam ^{a)}	40.			A S	- O	0, 0				
Geometric mean	at 20°C			n.r.		S'n.e.		n.e.		
n r = Not fully reliant	ble mat	ematical	v nøt ci	anificantly dif	Serent from	n 0: nat visat	le			

n.r. = Not fully reliable, mathematically not significantly different from 0; not usable n.e. = Not evaluable, not sufficient data points

a)

# . METHODS

The objective of this study was to obtain degradation or dissipation half-lives of isoflucypram and its aquatic metabolite BCS-CW88460 carboxylic acid (M12) in the water phase, sediment phase as well as in the total system of water and sediment in the dark. The evaluation was conducted to derive kinetic parameters that are suitable trigger additional studies (trigger endpoints) and for modelling and environmental risk assessments (modelling endpoints), according to FOCUS kinetics (FOCUS 2006, 2014).

The FOCUS kaletics report distinguishes between two levels of kinetics: At Level 1 a single compartment is used to derive (i) degradation endpoints from the total system or (ii) dissipation or decline endpoints from each compartment separately, in water, sediment or total system from maximum onwards. Level 2 considers two-compartmental approaches to estimate the real degradation in water and sediment, in parallel, considering exchange rates between water and sediment.

Isoflucypram and its aquatic metabolite BCS-CN88460-carboxylic acid were addressed for the total system, water and sediment phases.



The degradation behaviour of isoflucypram in water-sediment systems was investigated in two aerobic laboratory water/sediment test systems in one experimental study at 20°C in the dark (

; 2017; M-580411-01-1). Duplicate samples were taken at 0, 3, 7, 14, 29, 51, 72, and 100 days after treatment (DAT). In all trials, the parent substance isoflucypram was applied. ram of the second secon Further information on study conditions, observed metabolites and physico-chemical propertie Dis summarised in Table 7.2.2.3-17.

	G 11.6 /1		
Table 7.2.2.3-17:	General information on a	erobic aquatic laboratory	studies with isoflucypram
10010 / 121210 1/1	General million mation on a	ei obie aquate apoi atorj	Studies with isonacy py and

Water-sediment system	Texture of sediment	Radioactive label	Duration [days]	Metabolites observed	Reference y
Anglersee, GER	sand	pyrazole-label	100	BCS-@ 88460.	;
Wiehltalsperre, GER	loam		<i>Q</i> ⁰	carboxylic acid (M12)	Q20170M-580411-0167

The kinetic evaluation of the laboratory degradation behaviour way done following a tiered approach, based on various model assumptions according to FOCUS kinetics (FOCUS 2006 2014) asing the software KinGUI 2.1 with four different kinetic models: Single First-Order (SFO) and the biexponential models FOMC (First-Order Multi-Compartment model), PFOP (double first order parallel) and HS (Hockey-stick). (L For the kinetic evaluation of water sediment studies FOCUS (2906, 2014) distinguishes two levels of

- kinetics: - Level I: One compartmental approach to estimate the dissipation from the water column, the sediment (from maximum onwards) of the degradation from the total system, as a single Ŵ compartment. Ľ  $\bigcirc$
- Level II: Multi-compartmental approach to estimate the degradation in the water column and sediment compartments in parallelo including partitioning processes via reaction rates or sorption isotherms.

For the aquatic exposure assessment, a Level I evaluation is not mandatory. FOCUS recommends e.g. for parent compound to use the Level I total-system degradation half-life for both compartments at Step 2 level, or in combination with the conservative word-case default degradation half-life of 1000 days for the respective other compartment at Step Devel For lower tier calculations or the comparison with trigge values often & Level I evaluation of the dissipation is appropriate.

## Dissipation kinetic

Dissipation half-laves of the patient compound and metabolites, separately for the water- and sediment phase, as well as for the total system, mainly for metabolites, can be derived starting from the maximum onwards. The time axis might be shifted by the time t_{max}, where the maximum occurred. Generally, free fitting of the inited amount is used as default for all substances or phases.

## Degradation kinetics

- Level P-I degradation: Additionally, overall degradation rates of each substance from the total watersediment system should be defived from an overall compartment modelling approach.
- The proposed metabolic oute of isofficypram in water-sediment systems was converted into compartment systems. The compartments were associated with the sum of measured amounts in the water and the sediment phase of the compounds. No values were associated with sink compartment. If obviously to kinetic evaluation of a metabolite was possible, e.g. too low measurements or no significant decay during the duration of the study, the compartment system can be simplified correspondingly. Correspondingly, if a degradation pathway is observed not to be significant or relevant sit can be deleted in a further evaluation.
- Lever P-II degradation: A 2-compartmental approach was taken into account to estimate the degradation in the water column and sediment compartments, in parallel, inclusive partitioning processes via reaction rates. Simple first-order (SFO) kinetics was used to describe degradation



separately in the water and the sediment phase as well as reversible transfer between these compartments.

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

A summary of all results for modelling and trigger purpose is given in the executive summary (page 242). The most appropriate kinetic parameters are summarised per water-sediment system, for modelling and trigger purpose, for parent isoflucypram and its metabolite BCS-CN88460-carboxylic acid.

#### **Dissipation kinetics**

## Dissipation from water, isoflucypram (level P-I)

Residues of isoflucypram in water have been measured at study end in both trials below 10% of the initial residues. So, for modelling purpose,  $DT_{50 \text{ mod}}$  from biphasic models is estimated by  $DT_{90} / 3.2$ .

Kinetic model	DT 50 trigger [days]	DT90 trigger [days]		VA	~ <b>y²err</b> ^ [%k]	k1/aO [1/d]-]	κ,β , ¶/d/-] < , ~	tb/g	f t-test of kr/k2	M
Anglersee			<u>~</u> " a	ò	<u>ó</u> ô	<u>&gt; 8</u>		<u> </u>	<u>~~~~</u>	
SFO ^{a)}	4.60	15.3	4.60	-	© 30.3 S	0.1807	Q ^Y C		< 🕵 001	
FOMC ^{a)}	2.03	89:5	26.9	Ŕ	4 _€ 54	0.4536	0.5622	Ô	0	M/T
DFOP ^{a)}	2.13	<b>65</b> .6 ≫	Q20.1	0°+	Ø.03	0.6079	0.00782	07.6726	€ 0.001 / < 0.001	
HS ^{a)}	2.35 🐇	65,5	19,6	o ©	7 AQ 23	0,2955	0.01889	3.8833 4	< 0.001 / < 0.001	
SFO ^{b)}	593	ر 19.7 ک	₹.93¢	- /	25.4	0.11658		ł.	< 0.001	
FOMC ^{b)}	<b>∂</b> 2.79 ≿	74.2	2243	. 10	2.78	0.5452	\$1.07 <b>8</b>			
DFOP ^{b)}	3.84	739	22.3	S#		9.2734 0	0.01233	0.7514	< 0.001 / 0.005	
HS ^{b)}	4.38	71.2	21	o Q	6.0\$	05 <b>\$</b> 382	Ø.01444	8.866	< 0.001 / 0.001	
Wiehltalsp	Wiehltalsperre									
SFO ^{a)}	3.32	₽11.0€	3.32	•~~	26,8,	0,2988			< 0.001	
FOMC ^{a)}	2 1.76 ⁰	4104	12.5	, Q'	<u>∘2,80</u>	0.5696	0.74043			M/T
DFOP ^{a)}	2.06	@7.4 ~	14.3	) + 	\$5.51	0.5261	0.02025	0.7388	< 0.001 / < 0.001	
HS*	2.20	46.2	13.9	Ĩ	6 <b>6</b> 8	0.3146	0.02285	4.276	< 0.001 / < 0.001	
SFO ^{b)}	4.52	015.0 0	4.52	r	O ^v 22.5	0.1534			< 0.001	
FOMC ^{b)}	2.06	396	<b>1(</b> )9	Ŵ	2.10	0.6231	1.0081			
DFOP ^{b)}	3.16	<b>6</b> .9	14.1 (	2+	1.81	0.3007	0.0148	0.8001	< 0.001 / < 0.001	
HSb	Ø3.77	47.80	14.4	-	2.42	0.1837	0.01615	9.137	< 0.001 / < 0.001	

Table 7.2.2.3- 18: Isoflucypram: kinetic and statistical results of dissipation from water of

*DT_{50 mo} Half of for modelling before normalisation

MS: Model selected (T: for trigger evaluation; M: for modelling evaluation)

a) Initial fit including all residue data

b) Modified fit excluding the residue data of DAT 3

For both systems, initially all data points were included in the kinetic evaluation. In a modified



approach, the residue data of DAT 3 were excluded from the fit as the concentrations are noticeable decreased at this day in both systems. The statistics (chi² err) were improved for most of the fits (compare Figure 7.2.2.3- 2 and Figure 7.2.2.3- 3 for system Anglersee; Figure 7.2.2.3- 4 ond Figure 7.2.2.3- 5 for system Wiehltalsperre). For derivation of modelling and trigger endpoints, the modified fits were taken into account.

For both systems, SFO resulted in a visually not acceptable fit as the later data points were clearly underestimated and the residuals not systematically distributed. FOMC fits resulted in the best chi² tests and best visual assessments. FOMC results were therefore proposed for trigger and modelling purpose.

Figure 7.2.2.3-2: KinGUI results for dissipation from water of isoflacypram at level P-I (FOMC parent only fit), system Anglersee (initiaQiit)



Figure 7.2.2.3- 3: KinGUI results for dissipation from watch of isoflucypram at level P-I (FOMC parent only fit), system anglers e (modified fit)









KinGUI results for dissipation from water, of isofucypren at level P Figure 7.2.2.3- 5: (FOMC parent only fit), system Wiehlt asperre modified fit)



isoflucypram (level)P Dissipation from sectiment, Ô Ũ

Table 7,2,3.3-19: Isoflugyprans kinetic and statistical results of dissipation from water

ð

Kinetic model	D'IG0 Asigger	DT 90	DT 50°	<b>WA</b>	Verr	√ k₁/α [1/αb/-]	k₂/β [1/d/-]	tb/g [d/-]	t-test of k ₁ /k ₂	MS
C	[days]	days	[days]			and a second sec				
Anglersée	0	Ň		Y	6	<b>&gt;</b>				
SFO A	282	938 న	282	0%	\$ 3.25	0	0.002455		0.0079	M/T
FOME	>1000	>1000	≥1000	Ĩ,	1. JA	0.02415	0.04785			
Wiehltalsperre A A A A										
SFO	>1000	®1000C	>1000	၀၂	0'0.623		0.000069		0.0623	
FOMC 🦼	×1000 «	> 1000	>1000	R'	n.e.	0.005904	0.131686			

*  $DT_{50 \text{ mod}}$  Half-life/for modelling: if residu@vat end < 10 %,  $DT_{50} = DT_{90} / 3.32$ ; otherwise  $DT_{50}$  of slow phase n.e. = Not evaluable, not sufficient data points

MS: Model selected (T: for trigger evaluation; M: for modelling evaluation)

For the system Anglersee the SFO fit is statistically acceptable but visually borderline based on the low number of available data points (four, each with two replicates). While the fit was visually improve using the FOMC model, no degradation parameters could be derived. Thus the SFO model is considered appropriate for trigger and modelling purpose.

For the system Wiehltalsperre only three data points (each with two replicates) from the maximum onwards were available. Based on these low numbers and some scattering of the data no reliable



degradation parameters could be derived.

## Dissipation from water or sediment, BCS-CN88460-carboxylic acid, decline (level M-I) The dissipation of the metabolite BCS-CN88460-carboxylic acid in water or sediment phase was tried

to evaluate from the observed maximum onwards. However, in the system Anglersee an evaluation was not possible, due to the fact that the Degradation kinetics Degradation in total system, isoflucypram (level P.f)

able 7.2.2.3- 2	20: 1	sonucypr	am: Kine			ar resums	or degrada	tion in ų	otal syster	n sy
Kinetic model	DT50 trigger [days]	DT90 trigger [days]	DT ₅₀ mode [days]	VA	x ² erτ [%]	kî/u D/d/-l	x, k2/β × F [1/d/3]	tb/@ [ef=]	t-test ot kı/k2	MS Ø
Anglersee			v	2	o S		S C	ř "Ô	, , &,	
SFO ^{a)}	222	736	222	× V	2,23	0.003128	Û ^Y Q		< <b>0</b> .001	
FOMC ^{a)}	222	738	222	50	<b>2</b> .41	©390.8	124900		ĊQ.	
SFO ^{b)}	211	`^7702 _≦	211	0	2.09	0.00\$281			< 0.001	M/T
FOMC ^{b)}	211	J 702	2,1	0	2	^{*1} 2850	3916000	s S		
Wiehltalsp	erre 🖉	d.	22		2	х С	0	N N		
SFO ^{a)}	631		🎽 681 🖗	0	7 1.43	0.00 018	ê s		< 0.001	
FOMC ^{a)}	O 681 Ĉ	»>1000 ″	ő	() ()	1,54	3491E+5	3.429E+8			
SFO ^{b)}	5930	>1'900	ه593 ₄	0	° 9.88	<b>9</b> .0011 <b>68</b>	L.		< 0.001	M/T
FOMC	593	×1000 ×	y - 6	0	© 0.97	3.66 <b>9</b> E+6.	3.937E+9			

* DT $_{0,mod}$  = Half-life 0 model mg: if residues at end < 0%, DF $_{0,mod}$  = DT $_{0,mod}$  3.32; otherwise DT₅₀ of slow phase MS: Model selected (1) for trigger evaluation (1): for modelling evaluation)

a) Initial fit including all residue data

b) Modified fit cocluding the residue data of DATS

0 For the systems Anglerse and Wiehltabperre a pathway fit of isoflucypram with BCS-CN88460carboxylic acid has been carried out. Initially all data points were included in the kinetic evaluation. As the residue data measured at DAT 3 are low compared to those measured before and afterwards, a modified fit was conducted additionally where the residue data measured at DAT 3 were excluded. For derivation of modelling and trigger endpoints, the modified fits were taken into account as the statistical significance (chi2erf) was clearly improved. The SFO fit is visually and statistically acceptable. As the FQMC nodel does not significantly improve the fit the SFO model is chosen for derivation of modelling and trigger endpoints.

The second secon







KinGUI results for dissipation from water of isoffucypram at level P (SFO pathway fit), system, Anglersee (modified at) **′-K** Figure 7.2.2.3- 7:



KinGUI tosults for dissipation from water of soflucypram at level P-I (SFO pathway fit), system Wighltalsperre (initial fit) Figure 7.2.2.3-8:









# Degradation in total system, BCS-CN88460-carboxylicacid (\$12), pathway (lever M-1)

In general, the kinetic evaluation of total system degradation of the notabolite BCS-CN88460carboxylic acid was based on the pathway fit in combination with the parent compound soflue pram. For the metabolite always an SFO kinstic model was chosen in the pathway fit Finally the metabolite results reported here are based on the corresponding appropriate parent it, for modeling (m) or trigger purpose (p).

It should be noted, that the 15% threshold value for the scaled error  $\varepsilon$  of the choerr test should not be employed as absolute cut off criterion, as this value is strictly appropriate only for optimal experimental conditions. Is might be that the eror to pass the chi² er test is higher than 15%, but the model fit still represents a reasonable description of the degradation behaviour Especially in case of field data or for metabolite at may be sistified to accept farger values due to generally low measurements compared to the mean of alt measurements, which strongly influences the chi² err test.

Construction system, particularly and a construction of the constr											
Kinetic 👡	<b>DT</b> 50	<b>QT</b> 90	<b>DT</b> 50	, def	VA	Øerr	ak1/α	$k_2/\beta$	tb/g	t-test	MS
model of 🔿	trigger	Grigger	mod	, <u></u>		<b>[%]</b>	<b>[1/d/-]</b>	[1/d/-]	[d/-]	of	
parent 🔊	[days]	days	[days]		, ~~	ŝ				<b>k</b> ₁ / <b>k</b> ₂	
Anglersee a francisco a franci											
SFO-SFO ^{a)}	> 100 ⁶ .r.	>_000 ^{n.r.}	≥ 1000°.	$0.240 \pm 0.027$	+_(	8.71	2.250E-14			0.5	
SFO-SFO ^{b)}	$>1000^{n.r.}$	\$91000G	$> 1000^{n.r.}$	0.228 ± 0.056	4	8.84	2.295E-14			0.5	
Wiehltalsperre & A A A											
SFO-SFO	12.0	<u>,</u> Ø9.7 ∫	[™] 12.00°	$0.632 \pm 0.811$	-	31.1	0.05799			0.248	
SFO-SFO ^{b)}	12.2 🛸	40.6	12/2	<b>\$</b> 38 <b>± 0</b> 675	-	31.1	0.05671			0.247	

<b>Fable 7.2.2.3-21</b>	<b>BCS-CN88460</b> (carboxy) ic acid, kinetic and statistical results of degradatio	on in
~0	Total soften Othy to Sty dog Hation	
O ^r	Stotal system, pathway in. 550 ucg adaluan	

n.r. Not fully reliable, mathematically not significantly different from 0, not usable n.e. = Not evaluated, not enough data wints for kinetic evaluation available

MS: Model selected (T: for trigger valuation; M: for modelling evaluation)

* DT_{50 mod} Half-he for modelling before normalisation

a) Initial fit including all residue data

b) Modified bit excluding the residue data of DAT 3

For the system Angle see, even though the visual fit is good the degradation rate is not significantly different from zero and statistically not reliable. Consequently, no reliable degradation half-life could be estimated. The formation fraction, however, is considered reliable based on the good fit and an acceptable standard deviation.


For the system Wiehltalsperre, residue data of BCS-CN88460-carboxylic acid were included in the pathway fit even though the metabolite had only been detected in three samples. However, it was not and and a second possible to derive reliable degradation half-lives or formation fractions from these data.

and the second the second seco A 2-compartmental approach was taken into account to estimate the degradation of isoflucyprapi in water and sediment compartment, in parallel including partitioning Degradation in water and sediment phase (level P-11) A 2-compartmental approach was taken into account to estimate the degradation of isofluxypray in water and sediment compartment, in parallel, including partitioning processes via reaction takes. As simple first-order (SFO) kinetics was used to describe, degradation, geparately in the sediment phase, as well as reversible transfer or partitioning between these compartments. A transfer or partitioning between these compartments of the sediment phase, as well as reversible transfer or partitioning between these compartments. A transfer of the transfer or partitioning between these compartments of the transfer of the transfer or partitioning between these compartments of the transfer or partitioning between these compartments of the transfer or water and sediment compartment, in parallel, including partitioning processes via reaction rates. A@



Test system	Compartment	M ₀	DT ₅₀ [days]	DT ₉₀ [days]	VA	χ ² err [%]	k [1/d/-]	t-test of k
Anglersee ^{a)}	water	97.90	63.8 ^{n.r.}	212 ^{n.r.}	+	14.93	0.01086	@0.327
C	sediment	0	> 1000 ^{n.r.}	> 1000 ^{n.r.}	+	5.31	< 0.001	0.500
Anglersee ^{b)}	water	97.90	59.9 ^{n.r.}	199 ^{n.r.}	+	8-30	0.0115	20A60 0
	sediment	0	756 ^{n.r.}	$> 1000^{\text{ n.r.}}$	+	3.56	0.0009	`≫0.362⊘
Anglersee ^{c)}	water	97.90	> 1000 ^{n.r.}	> 1000 ^{n.r.}	+ _(	14.37	n.e. S	n e
	sediment	0	267	\$ 888	±,0	5.41	0.0025992	<del>6</del> 9.001 %
Anglersee ^{d)}	water	97.90	> 1000 -	> 1000 ^{n.r.}	₽\$°	67.88	nko.	n.e.
	sediment	0	1990	644	, ¥ + _∿ "	3.91	0.003578	< 0,001
Wiehltalsperre ^{a)}	water	96.75	> 1000 n.r.	2 1000 ^{04.}	Ł	15,99	QS< 0.00₽	0.500
	sediment	0	>1000	> 1000 ^{n.r.}	<u>A</u>	3.35	3.012E-14	~0.50@°
Wiehltalsperre ^{b)}	water	96.75 <b>K</b>	169 ^{°°r.}	×1000 p.r.	+ _	10.0	9.004101 [©]	0,223
	sediment	0	≥1000 ^{n.r.}	▷ 1000 ^{(ŋ.r.}	, Ô ^y	2,20	<\$ [™] < 0.0€¥	500
<b></b>					<del>N</del> -			<u> </u>
Test system	Partitioning	Kavat-sed	Ksed-wat	t-test of k	Fse	d modelling	Sed theoreti	žal
	compartment @	γ1/u/-26 √√			Å	`~~`~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
Anglersee ^{a)}	water	0.2638		< 0.001		0.\$10	0.775	
-	sediment 🔊	Č, Č	0.06203	20.001	×	×	19 1	
Anglersee ^{b)}	water 🗡 🕰	0.1616	Å, Ó	< 0,001		0.836	0.775	
	sediment	N.	0.03163	\$0.001 (	Ď×	<u>× ,</u> ×	7	
Anglersee ^{c)}	water L	0.267T	~~~	× 0.00	C	0.812	0.775	
	sediment	/ 🔊	0.06185	< 0,001	Ĩ	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
Anglersee ^{d)}	water	6.1658 g	Ø L	چ0.001 🚓	Ç,	0.843	0.775	
	sedunent 🖑	<i>в</i> .,	0,03083	\$ 0.001 ⁰	Ś	9		
Wiehltalsperre ^{a)}	water	0.2849		< 0,001	$\sim$	0.874	0.909	
	sediptent		0.0410	_<0.001 %	ĮO V			
Wiehltalsperre ^{b)}	wätter 😽	©0.19 <b>56</b>		× 0.001		0.893	0.909	
	Sediment &		0/02341	< 0.901	1			

Table 7.2.2.3- 22:	Estimated (SFO) parameters for degradation and partitioning of isoflucypram in
	water and sediment, separately (level P-II)

n.r. = Not fully reliable, mithematically not significantly different from 0; not usable

n.e. = Not evaluated (pathway watter -> sink deleted/from kinetic model)

a) Initial approach including a Preside data and with all parameters free

b) Modified approach excluding the residue to a from DAT 3 and with all parameters free

c Modified approach including all visible data and fixing the transformation fraction from water to sediment to 1 (pathway water -> sink excluded)

d) Modified approach excluding the residue date from DAT 3 and fixing the transformation fraction from water to sediment to 1 (pathway water -> sink excluded)

For the system Anglersee, the initial approach (all parameters free) did not result in reliable degradation parameters as the trest indicated that the degradation rates were not significantly different from zero. This is also valid in the residue data of DAT 3 are excluded from the fit, even though the chi²err is significantly decreased by this procedure. In a modified approach (fixing the transformation fraction from water to 1) a statistically reliable half-life for the sediment could be derived, independent of the inclusion or exclusion of DAT 3 residue data.

Additionally, the  $F_{sed}$  test according to FOCUS kinetics was carried out to assess the reliability of the modelled parameters. The fraction of parent compound that transfers into the sediment at equilibrium ( $F_{sed}$ ) is calculated using: 1. fitted Level P-II model parameters ( $F_{sed, modelling}$ ) as well as 2. conditions of the study or tabled values ( $F_{sed, theoretical}$ ). Theoretical and modelled  $F_{sed}$  values show a moderate to



excellent conformity, which might confirm the reliability of estimated partitioning rates (Table 7.2.2.3-22).

For the system Wiehltalsperre, the degradation rates were not significantly different from zero ond statistically not reliable.

As no separate degradation rates for water and sediment could be derived, a finither attempt was made to describe the degradation of isoflucypram occurring in water-sediment systems. Therefore the initial degradation rate constants for sediment were fixed to the DegT₅₀ values estimated for the degradation in total system (level P-I) while the initial degradation in water was fixed to 1000 days. This resulted in a good visual fit with reliable transition rates between water and sediment (Figure 7.2.2.3- 10 and Figure 7.2.2.3- 11 for systems Anglersee and Wiehltalsperre, respectively). It is hereby shown that significant degradation occurs in the sediment phase which is at least as fast as given by the total system DT₅₀ values. Residue data in the water phase show a higher degradation as estimated by using a DT₅₀ value of 1000 days. While it is not possible to derive degradation parameters from these fits, it is nevertheless possible to conclude that significant degradation of isoflucypram occurs in the water and sediment phases.











presented in Table 7.2.2.3- 23 and Table 7.2.2.3 4 to Table 7 2.3- 25, respectively

For metabolite BCSCN88460-carboxylic acident full freliable and statistically significant dissipation kinetics in water or in total system gould be derived (pased of  $\chi^2$  err error, t-test) for modelling purpose Only a formation fraction for the total system (f = 0.028) could be derived for the system Anglersee. S" **X** Į, O

Table 7.2.2.3 - 23: Degradation and dissipation in water / sediment systems: trigger endpoints of isoflucypram, Level P-I ۸Ő N ~

	×			$) _{0}$	٢				
Water / sediment		Whole sy	stem 🔍		Wat	er		Sedime	ent
system	<b>DT</b> 50	<b>B</b> T90	Method of	DT 50	DT90	Method of	DT50	DT90	Method of
. K	[days]=	[days]	calcolation	[days]	[days]	calculation	[days]	[days]	calculation
Anglersee	214	702	SFO O	2.79	74.2	FOMC	282	938	SFO
<u></u>		Â. A				recalc.			
Wiehltalsperre	<i>₽</i> \$93 ₹	€1000≪	SF₀	2.06	39.6	FOMC	n.r.	n.r.	-
	j de	1	~~			recalc.			
Geometric mean 🔊	354	2°		2.40			282		



# Table 7.2.2.3- 24: Degradation and dissipation in water / sediment systems: modelling endpoints of isoflucypram, Level P-I

Water / sediment	Whole system				Wat	er	Sediment 🖉 🖉			
system	DT50 [days]	DT90 [days]	Method of calculation	DT50 [days]	DT90 [days]	Method of calculation	DT50 [days]	DT90 [days]	Method of	
Anglersee	211	702	SFO	22.3	74.2	FOMC recalc.	Â282	938	SPO S	2
Wiehltalsperre	593	> 1000	SFO	11.9	39.6	FOMC	n.r.	nr.		
Geometric mean	354			16.3 ₁	Ŷ	, Ó ^Q	282		S.	6¥
	•	•			•		L.		ο, [©]	1

Table 7.2.2.3- 25: Degradation and dissipation	in water	/ sedin	nent systems.	modéling	endpoints of	_
isoflucypram, Level P-II	, **	~ °	No N	0 1		ŗ,

	J <b>I</b>		×	, Q	Ň	Ň	Ś		$\sim$	N N
Water / sediment		Whole sy	vstem O	×2	Wat	er	S.	O.	Sedime	nt °
system	DT50	DT90	Method of	DT 50	<b>D</b> T90	Metho	d of	<b>D</b> T50	DT90	Method of
	[days]	[days]	caleulation	(days)	∕[days₽	calcula	ition	days	[days]	calculation
Anglersee	n.r.	n.r.	Q - 4	n'i	A.P.	2-	Ö	nÇ.	jA.	0_
Wiehltalsperre	n.r.	n.r.		°∕µ.r.	≪n.r. ^			"Ĵñ.r.	§n.r. 🖉	Q _
							Сл Сл			

## Irradiated water/sediment study CA 7.2.2.4

The route and rate of degradation of softwypram in water and sediment were comprehensively studied in sections CA 7.2.1, A 7.22.2 and CA 2.2.3. Pherefore, the route and rate of degradation of isoflucypram in irradiated water sediment systems were not studied. A summary of the route and rate of degradation of sofluc pram in water and sediment is given in section CA 7.2 and Figure 7.2-1.

CA 7.2.3 Degradation in the saturated zone was not studied since isoflucypram is not expected to reach the saturated zone after its use according to good agricultural practices. A summary of the route and rate of degradation of isoflucypram in water and sediment is given in section CA 7.2 and Figure 7.2 a.



### CA 7.3 Fate and behaviour in air

Isoflucypram has a very low vapour pressure of  $1.2 \times 10^{-7}$  Pa ( ; 2014; M-488244-01-1, summarised in MCA section 2, CA 2.2). Therefore, it can be concluded that significant volation of isoflucypram is not to be expected. Õ

In addition, estimates of the chemical lifetime in the troposphere resulted in half-lives < 2 days for isoflucypram. 

## CA 7.3.1 Route and rate of degradation in air 1⁰

Report:	KCA 7.3.1/01; ; 2015; M-54#687 ₅ 0 ¹⁰ /
Title:	BCS-CN88460: Calculation of the chemical halfelife in the trop ophere
Report No.:	EnSa-15-1015
Document No.:	M-544687-01-1
Guideline(s):	Commission Regulation (EV) No 283/2013 in accordance with Regulation (EC) No
	1107/2009
	US EPA OCSPB Test Quideline N/A y a g Q Q Q
Guideline deviation(s):	none OV X X X X X X X
GLP/GEP:	no or the star of or start

# **Executive Summary**

Based on the estimation according to structure activity relationship (SAR) methods developed by Atkinson et al., the half-life time in an of isoflucypram was assessed with the computer program AOPWINTM (version 1.92). The half-life time (1) was estimated with 0.3 d days (long term scenario) assuming the typical OH radical concentration averaged over  $24^{\circ}$  hours (0.5 x)  $10^{\circ}$  radicals/cm³). The half-life time  $(t_{1/2})$  was estimated with 0.229 Gays (long-term scenario) assuming the typical OH radical concentration averaged over 12 hours (13 x 10 radicals/cm)

METHODS The objective of this report is the assessment of the potential chemical half-life (t1/2) of isoflucypram in the troposphere The model calculation was based on structure-activity relationship (SAR) methods developed by Atkinsco et al and available as the computer program AOPWIN ("Atmospheric

Oxidation Program for Microsoft Window?), version 1.92a. The program is able to estimate reaction rate constants in the atmospheric gas-phase between lightand thus photochemically generated hydroxyl radicals and organic chemicals. It is also able to estimate

rate constants for gas phase reactions between ozone and compounds containing double (olefinic) or triple (acetylenic) bords. The rate constants estimated by the program are used in the following for the calculation of half-lives of organic compounds in the atmosphere on the basis of average atmospheric concentrations of hydroxyl radicals and ozone. AOPWINTM requires only the chemical structure and atmospheric concentrations of the potential reaction partners as inputs.

Considering the chemical structure of isoflucypram, it can be concluded that reactions with photochemical produced hydroxyl radicals will mainly determine its degradation rate (Ktotal, indirect photoseaction & kOH) in the air.

No ozone reaction is expected and therefore not included for the determination of isoflucypram. Ŀ, Ő

The AQDWIN program allows the user to select 12 or 24 hour time frames and any average hydroxyl radical concentrations. For the current report the  $0.5 \times 10^6$  radicals/cm³ per day (24-h) was taken for the long term estimations.



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

The overall reaction rate of isoflucypram with hydroxyl radicals is estimated at 46.6558 x 10⁻¹² cm³ x molecule⁻¹ x s⁻¹. This rate is derived mainly from incremental reactions like hydrogen abstraction (6.5543 x 10⁻¹² cm³ x molecule⁻¹ x s⁻¹) and an addition reaction to the aromatic ring (assumed value of 40.1015 x 10⁻¹² cm³ x molecule⁻¹ x s⁻¹, value estimated).

Based on the overall hydroxyl radical reaction rate constant in combination with the "long term concentration of these radicals in the atmosphere (*i.e.* 24 h day, 0.5 x  $10^6$  OH radicals/cm 12 h  $4^7$ 1.5 x 10⁶ OH radicals/cm³) the half-life ( $t_{1/2}$ ) of isoflucypram in air isoferived to:

- Half-life  $(t_{1/2}) = 0.344$  days (24 h day)
- Half-life  $(t_{1/2}) = 0.229$  days (12 h day)

That estimate should be regarded as worst-case assumption as the approach does not consider the contribution of any other reactive species to the overall atmospheric degradation of isoflacypram in air.

M Isoflucypram is considered to be susceptible to reactions with warroxyl radicals which contribute to the overall degradation of the substance in the autoosphere. Two parts of the molecule were identified as potential targets for radical reactions. An attack by hydroxyl radicals should result in the formation of multiple primary radicals. Their formation may be followed by secondary addation products that can be eliminated from the atprosphere by wet and or dry deposition.

## Transport via ai CA 7.3.2

was not studied since its vapour pressure is below the trigger The transport via air of value of 10⁵ Pa.

CA 7.3.3 Local and global effects. On account of the short chemical lifetime of isoflucypram in the air it is to be expected that the substances cannot be transported in the gaseous phase over large distances or can accumulate in the air. Thus no difference in the behaviour isoftweypran and other organic substances emitted into the air from natural sources (e.g. from plants and soil) is ordicated.





### **Definition of the residue** CA 7.4

### CA 7.4.1 Definition of the residue for risk assessment

The proposed residue definitions relevant for risk assessment for each compartment are summarised in the following table:

e 7.4.1-1: Proposed	residue definitions relevant for risk assessment					
Compartment	Residue definition for risk assessment					
Soil	Isoflucypram and					
	BCS-CN88460-carboxylic acid (M12)					
Groundwater	Isoflucypram and					
	BCS-CN88460-carboxylic acid (M12)					
Surface water	Isoflucypram and					
	BCS-CN88460-carboxylic acide (M12) S					
Sediment	Isoflucypram and O C C C C C C C C C C C C C C C C C C					
	BCS-CN88460-cathoxylicacid (MU2)					
Air	Isoflucypram $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2}$					
712 Definitio	on of the residue for monitoring y a start					
7.4.2 Demini						
enforcement method	for sort includes the active substance on the section of the secti					
enforcement method	for water includes the settive substance only					
elevant residue with reason to apartification wair is the parent compound only						

### CA 7.4.2 Definition of the residue for monitoring

The enforcement method for soft includes the active substance on  $\beta$ 

The enforcement method for water includes the active substance only. The substance only  $\frac{1}{\sqrt{2}}$ 

s the parent compound only. The relevant residue with regard to guantification in ain L,

CA 7.5 Monitoring data