

M-489155-03-5





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CA 8 ECOTOXICOLOGICAL STUDIES ON THE ACTIVE SUBSTANCE

INTRODUCTION

This document provides detailed summaries of new ecotoxicological studies which were not available at the time of the first EU review of mesosulfuron-methyl and were therefore not evaluated for the Annex I inclusion of this active substance. Existing studies already submitted for the first EU review are found evaluated in the Monograph or its Addenda in the present document these studies are therefore only briefly referenced, marked in grey shade. Complete reports to all studies are found included in the electronic dossier provided by Bayer CropScience. The numbering and the headlines correspond to latest EU requirements.

For transparent overall data interpretion and risk assessment, key entroints derived from both, old and new studies, are listed in the overview tables. For easy discrimination new information is printed black, whilst existing information is marked in gree shaded font.

Due to changes in triggers for metabolites to be further assessed additional metabolites are proposed to be included in the residue definition for the risk assessment (see Table CA 8-1). Accordingly, studies have been prepared to describe the ecoloxicological profile of these metabolites in the relevant environmental compartment.



*Justification for the residue definition for risk assessment is provided in MCA Sec.7, Point CA 7.4.1 and MCA Sec. 6, Point CA 6.7.1.



In addition to the studies on metabolites listed in Table CA 8-1 as being relevant for risk assessments of products, ecotoxicological tests have also been conducted on further components (BCS-CO60220, BCS-CV14885, BCS-CO60721) for specific purposes discussed in the respective document chapters [MCA Sec.7, Points CA 7.1.4.2, CA 7.2.2.3, and Document N4].

Metabolite designations

For historic reason, different coding or naming systems have been used for the designation metabolites in study reports and associated documents. Equivalence information for all substance designations appearing is provided in the list of metabolites (Document N3).

For better transparency and readability, a single primary identifier to each component will be used consistently throughout the present document To man tain comparability to documents from the first submission for Annex I inclusion, this will be (a) the AgrEvo/Aventis CropScience substance code (AE xxxxx), or, where newly assigned, (b) the Bayer CopScience substance code (BCS-XXxxx)).

Where applicable, substances will be addressed in the following compound sequence This applies for

Where applicable, substances will be addressed in the following compound sequence. This applies for tabulated information, as well as for the order of appearance of study summaries in the document text.

 1)
 mesosulfuron-methyl parent substance)

 2)
 AE F154851

 3)
 AE F160459

 4)
 AE F099095

 5)
 AE F092944

 6)
 AE F160450

 7)
 AE F140584

 8)
 AE F140584

 9)
 BCS-CO60720

 10)
 BCS-CO60720

 11)
 BCS-CO60721

 AE for aquatic organisms

 Data of the parent compound show that agoatic macrophytes are the clearly most sensitive group of organisms in the aquatic environment. The sensitivity of macrophyte species is clearly driving the risk

 organisms in the aquatic environment. The sensitivity of macrophyte species is clearly driving the risk assessment for mesosulfupon-methyl. All acute studies with fish and aquatic invertebrates led to effect doses above the highest tested concentration (100 mg/L). The most sensitive algae species was Pseudokirchneriella subcapitata (ErC₅₀>290 µg/L).

Based on the advatic sector pological profile of mesosulfuron-methyl, testing of metabolites was confined to *Lemna-gibba* and *Pseudokirchneriella subcapitata*. Only for the terminal product AE F092944, shared with other sulfonylurea-type herbicides, additional acute tests with fish and daphnia were performed, but did not reveal notable activity.



Metabolite testing for soil organisms

The sensitivity of soil macro- and microorganisms to the active ingredient mesosulfuron-method is generally low. The No Observed Effect Concentrations were above the highest tested concentration for collembola, soil mites and N-transformation. The NOEC for the earthworm Desenia fetida was about high with 125 mg a.s./kg dws. Consequently, the most sensitive species for the active ingredient is Eisenia fetida. As the NOEC for collembolan Folsomia candida for the representative formulation is 17 mg/kg dws, collembola is the most sensitive species pegarding the formulation. Therefore all sol metabolites were tested with earthworms, Folsomia candida, and N-transformation is soil addition, the last metabolite in the pathway, AE F092944 with an occurrence of 10.1% was tested with the predatory mite Hypaspis aculeifer.

Effects on birds and other terrestriaky CA 8.1

CA 8.1.1 **Effects on Birds**

Acute oral toxicity to birds CA 8.1.1.1

restriat vertebrates Two acute studies on non-related bird species, bobwhite quail and mallard duck, were performed. The highest tested dose level in both studies was 2000 mg/rg bw. No portality occurred. Details of the studies are provided in the following table.

Avial acute or al tozicity data of mesosulfuron-methyl presented in this chapter Table CA 8.1.1.1-1:

Test species	Fest design	Ecotoxicologicatondpoint	Reference
Bobwhite quait	actor, oralO	LD ₅₀ (72000 ¹⁾ mg as kg bw	, 1998 M-180378-01-1 KCA 8.1.1.1 /01
Mallard		LD ₅₀ LD ₅₀ Strapol 3776 ²⁾ Ang as/kg bw	, 1998 M-147788-01-1 KCA 8.1.1.1/02
¹⁾ 10 birds per group			

²⁾ LD₅₀ extrapolated according to SFSA (2) Birds & Manmals (2009) by applying a factor of 1.888 to the top dose in case 10 primals have been tested and no mortality occurred

Bold letters: Values	considered	relevant	formisk	assessmen	ntôn	the MCP	document
4	O ^r	~O`	4.54	1000	añ		

Report: x, 1928, M-180378-01
Title: Bobyonite qual acuto ral texperity test AE F130060 substance, technical Code: AE
F1 3Q06 0 0 Α βC95 Q 001 <
Report No: $C000232^{\circ}$
Document $No(s)$ M-180078-01-Q
Guidelines: O Gu
GLP/GEP: yeo yeo yeo
Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):
$\Delta = 1000 \text{ mg as/kg bw}$
Study Samary and RMS evaluation copied from the original Monograph:
\square Pafaranaa 100% 8.1.1/1
\square NUCLEUR. $(1)/(0, 0.1.1/1)$

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

- **Test guideline**: US-EPA Pesticide Assessment Guidelines, Subdivision E, series 71, §71-1 (1982) and OECD Draft Guideline for testing of chemicals "Avian acute toxicity test-oral toxicity" (1992).
- **GLP compliance**: Yes.
- **Methods**: The acute oral toxicity of AE F130060 technical (94,6% w/w) was d quail aged, at the start of the study, of approximately 8 months. A single dose of the test substance was administered by oral gavage to a group of 10 (5 males + 5 females) birds at the fate of 2 000 mg a.s. g book weight. During a 15 day-observation period, any sign of Oxicity, morth by rate and the of Nath vare recorded. The birds were weighted individually on days 1, 8 and 15 after treatment. Four conservation period, was the recorded for down 1.4.4.8 and 8.15 after the absence time recorded for down 1.4.4.8 and 8.15 after the ab recorded for days 1-4, 4-8 and 8-15 of the observation reviod. All birds, Pere finally dispeted to macroscopic observations. Control consisted in birds administered to vehicle (dei obsed water) onto

 Results: No clinical signs, or effects on body weight, food conserptions of no complex Ngical changes are recorded.
 LD50 > 2 000 mg/kg b.w. NOEL = 2 000 mg/kg b.w.
 Comments (RMS): the study is accessible
 Further study information supprementing the original Motograph superimeters are superimeters. Analysis of trial mix 8 (5 and 25 & w/v of the set sulf ance in douOe disc water) showed that they were homogenous and table after a period of Abours According to the report of Analytical Toxikology from July 8, 1999 the achiev & concentrations were entirely acceptable (95 to 99 % of nominal). Defend a stylic Oresult are presented in the Ollov ag table.

Table CA 34.1.1-2:	Fom	ogeneity	e di stabi	lityof sial	micos	~~	
vehicle	» Chinc. »	<mark>Ønc.</mark>	samples	found in	mg/mIs	found in %	of nominal
\$ \$	<mark>9ng/mľ</mark>	<mark>%</mark>	Ŏ,	‰ <mark>0 h</mark> 0	$\frac{5}{h}$	<mark>0 h</mark>	<mark>5 h</mark>
Į,	ĨQ.	2m	گر کرچ	482	D.	<mark>96</mark>	<mark>96</mark>
Double dist.	8 <mark>%</mark>	ັງ <mark>5</mark> ຈ		, <mark>49.5</mark>	4 <u>8.8</u>	<mark>99</mark>	<mark>98</mark>
Å	ð	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		6 ⁹ 48.8	48.8 <mark>48.8</mark>	<mark>98</mark>	<mark>98</mark>
^o ^r		Q,	0 ['] A	24	<mark>245</mark>	<mark>96</mark>	<mark>98</mark>
Double dist. water	250 A	, [°] <mark>25</mark>		* <mark>742</mark>	<mark>240</mark>	<mark>97</mark>	<mark>96</mark>
<u>~</u>		Ň		239	<mark>238</mark>	<mark>96</mark>	<mark>95</mark>

Le base of one determination and have not been corrected for Remark: The recoveries.

tity and no clinical signs of toxicity were observed. Body weight and food There 🔊 no fetted by the test substance. No macroscopically visible findings were seen at



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl



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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

- **Test guideline:** US-EPA Pesticide Assessment Guidelines, Subdivision E, series 71, §71-1 (1982) and OECD Draft Guideline for testing of chemicals "avian acute toxicity test-oral toxicity" (1992).
- **GLP compliance**: Yes.
- □ Methods: The acute oral toxicity of AE F130060 technical (94.6% w/w) was @dermined in adult n ducks aged, at the start of the study, of approximately 4 months. A single dose of the test substance was administered by oral gavage to a group of 10 (5 males + 5 females) birds at the fate of 2 000 mg a s, g book weight. During a 15 day-observation period, any sign of Oxicity, morth by rate and the of Nath vare recorded. The birds were weighted individually on days 1, 8 and 15 after treatment. Four conservation period, was the fate of a group of 2 one of the study of the advectory of the study of the advectory of the study of the advectory of the study of recorded for days 1-4, 4-8 and 8-15 of the observation period. All birds, Pere finally dispected to macro copie observations. Control consisted in birds administered to vehicle (deigo sed water) onto

 Analytical findings

 Analytical findin

vehicle	cooc.	Zonc.	amples	four in	mSmL	Wund in %	of nominal
	my/mL*	2 <mark>%</mark>			<mark>5 h</mark>	/ <mark>0 h</mark>	<mark>5 h</mark>
		Ĩ.		∕ <mark>∕∕ 48.2</mark> O	ž <mark>4%)</mark>	<mark>96</mark>	<mark>96</mark>
Double dist. water	Â,	, S ⁵	^o B	48 ⁹	<mark>\$8.8</mark>	<mark>99</mark>	<mark>98</mark>
~\$	Ŭ _v o			≥2 <mark>%8.8</mark> *∂	<mark>48.8</mark>	<mark>98</mark>	<mark>98</mark>
A	O A	2°		\$ [*] 241	<mark>245</mark>	<mark>96</mark>	<mark>98</mark>
Double St. water	* <mark>2,50</mark>	R <mark>25</mark>	B	<mark>Š</mark>	<mark>240</mark>	<mark>97</mark>	<mark>96</mark>
, ≪		r . O		م ^م <mark>گ²39</mark>	<mark>238</mark>	<mark>96</mark>	<mark>95</mark>

the base poine determination and have not been corrected for Remark: The result recoveries.

Biological Neither roortalit Conical Agens of toxicity were observed. Body weight and food consumption the test substance. No macroscopically visible findings were seen at necropsy.



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl



Two short-term dietary studies on non-related bird species, bobwhite quail and mallard duck, were performed. The lowest LC_{50} was determined to be ≥ 5000 ppm corresponding to an LDD₅₀ of 1359 mg a.s./kg bw/d Details of the studies are provided in the following table.



Table CA 8.1.1.2- 1:	Avian short-term dietary toxicity data of mesosulfuron-methyl presented in this
abantar	\mathbb{Q}

chapte	r				
Test species	Test design	Ecotoxicologic	al endpoint	ŕ	Reference 💦
		LC ₅₀	> 5000 ¹⁾	ppm	, 1999
Bobwhite quail	5-day dietary	$\equiv LDD_{50}$	\geq 720	mg as/kg bw�	M-184416-01-1
		LDD ₅₀ extrapol ²⁾	1359	mg as/kg <u>b</u> w/d	KCA 8.1 ¥.2 /0
		LC_{50}	$> 5000^{(1)}$	ppm	1998 7
Mallard duck	5-day dietary	$\equiv LDD_{50}$	≥ 121	mg as @ g bw	M-181332-91-1
1) 401 4 1		LDD ₅₀ extrapol ²	2284	mg skg bw/d	K CA 8.1 52 /02
$^{(1)}$ 10 birds per gro	oup; no mortality of	curred during stu	dy <i>O</i>		
⁻ LD50 and LDD	50 extrapolated ac	cording EFSA GL		$$ $$	
		(J			
Report:		q; ;1	99999M-184446-	01 ~ ~ ~	
Title:	Bobwhite q	uail dietaryLC50	Budy ABF130	Q substance, tec	hnical@ode: @E F13(960
	00 1C95 00	01	Y N N	A	
Report No:	C002392	<u> </u>			
Document No(s):	M-184416-	01-1-2 &	- Q		
Guidelines:	OECD: 20	5; CSEPA = EPA	()% §71-2%Devia	sion nog specifical	
GLP/GEP:	yes				
Endpoint accord	ling to the Review	v Report for mes	osulfuron met		798/2003-Final):
Enupoint accord			Vmg a@kg foc		298/2903-Pinal):
	Q				×,
Study summar	v and RMS eval	uation copied fr	the obgin	Monograph	
Reference :	<mark>1999, 8.1.2.</mark>	<mark>8</mark> 3	× , ~ , 0	(<i>n</i> .	
			NY N	<u> </u>	
□ Test guidelin	US-SPA Pestiči	de Assessment Gu	ick ines, Subdiv	100 m E, series 71,	§71-2 (1982) and OECD
Draft Guid	ne for sting Che	emleals "awan die	yry toxiety tese	5°(198°	
GLP covinlia	nce Yes		¹⁰ 0	Ň	
2S			S.	0 ^Y	
□ Methods: Th	e short) term cymu	axive toxi ity of a	₩ F120060 tec	Mical (94.6% w/v	v) to bobwhite quail was
determined b	y poviding chick	with yood for	ked onth the a	i.s. for a 5-day	period. Bobwhite quails
(approximativ	a la days old si	the start of the s	tudy) were essi	gned at random to	7 groups of 10, each of
Control velo	nade up dup bate	concentration (0, .	(02.5, 60), 1 2	50, 2 500 or 5 00 d by a 3 day recov	0 mg/kg test substance).
untreated foo	d was provided a	mical some aver	mortaity rate w	ere recorded duri	ing the whole test period
Body reight	was checked at w	ys -3 ⊘i , 6 and 9 a	and lood consur	nption was recorded	ed for both exposure and
recorry perio	ods. At the end of the	ne study, the survis	ig chicks were	dissected for mac	roscopic observations.
<i>k</i>		v V a	1		
Results: No c	clinical signation of	ects on sody Bei	ght, food consur	nption and no mor	phological changes were
$\frac{1}{1}$ C 50 > 5 040					
NOEL = 20					
L.		, ~\$~			
Comercents (I	WIS): the stud os	acceptable.			
<u> </u>					
Further study i	inf@mation sup	plementing the	original Mon	o <mark>graph summ</mark> ar	<mark>y :</mark>
validiteria	<u>L.</u>				
fulfilled					



Analytical findings:

Directly after preparation three samples from each of the lowest and highest concentrations sere
analysed for achieved test substance content, homogeneity and, after 10 days storage a room
temperature, for stability. Directly prior to the start of treatment three samples for each conortration
were analysed for content at the start of administration. All samples which were stored deep for the
prior to analysis were analysed in duplicate to determine the content on the test subsance sy the
Analytical Toxicology.
The mean concentrations analysed for homogeneity, stability and achieved content \mathcal{O}
were in a range of 94 - 117 % of the nominal concentration and were Onus within the State of the second second
acceptable range of 80-120 %. The results (mean values) of cherocal analysistore summarison in the
following table. $Q^{O'} \sim Q^{O'} Q^$
Table CA 8.1.1.2- 2: Results (mean values) O'the clonical shalysis
Dose level A Control & Q A
(ppm) (% of nominal concentration of the second sec
Date of preparation Pre check Pre check Control at Cont
July 24, 1998 July 24, 1990 August 03, 1998 August 04, 1998
<u>5000</u>
* Ther Ways to rage at room simperature O' y 'y'
$= no 2 \text{ multiple en } x^2 = x^2 \text{ for a low of the example.}$
A, B, C C mples ken from the p, might and ottom f the next
Biological Endings
No mortativy occurred is any use group. Based on these esults, the short-term dietary LC50 in the
Bobwhere quail was greater than 5000 perils, which was equivalent to a mean daily test substance
intake of approxing ely 72 mg/kg body, weight a second second second second second second second second second
No clinical sign of to icity curred in an dose grou Oat any time during the study up to and
including the 5000 pportiet γ' level γ'' $\gamma''' \gamma''''''''''''''''''''''''''$
Food consumption and body weight of a regraine counaffected by the test substance up to and
including the 5000 ppm dietary zvel.
Dissection of the surving checks killed ache edit of the study revealed no macroscopically visible
morphological abnormality of Q
ĉ



Mesosulfuron-methyl





Test guideline: US-EPA Pesticide Assessment Guidelines, Subdivision E, series 71, §71-2 (1982) and O Draft Guideline for testing of chemicals "avian dietary toxicity test" (1984).

GLP compliance: Yes.

- Methods: The short-term cumulative toxicity of AE F130060 technical (94.6% w/w) to maked determined by providing ducklings with food spiked with the a.s. for a 4-day period. Kobwhi quark (approximately 10 days old at the start of the study) were as 2 and at random o 7 groups of 0, each of when was offered one dietary concentration (0, 312.5, 625, 1 250, 2 500 or 5 000 mg/kg test substance. Some was made in duplicate. The exposure period was followed by a 3-day recovery period during which ontreach food was provided. Clinical signs and mortality rate were accorded during of whole test period. Body weight we checked at days -3, 1, 6 and 9 and food consumption was recorded for both sposu Q and robvery periods. At the end of the study, the surviving chicks were dissorted for macroscopic observations.

Ine end of the study, the surviving chicks were dissolved for macro poper observations.
Results: No clinical signs, effects on body reight and to morphologic change were recorded. Food consumption was lower in all groups exposed to morphologic change were recorded. Food consumption was lower in all groups exposed to morphologic change were recorded. Food consumption was lower in all groups exposed to morphologic change were recorded. Food consumption was lower in all groups exposed to morphologic change were recorded. Food consumption was lower in all groups exposed to morphologic change were recorded. Food assigned to this observation. LCS0 > 5 000 mg/kg. NOEL = 5 000 mg/kg.
Comments (RMS): the study is complete.
Further study information Suplementing the original Mong Suph examples.
Validity Criteria findinges.
Directly after proparation three samples from each of the lower and highest concentrations were analysed for context at the stander administration. As samples which were stored deep frozen prior to standing were analysed for context at the stander administration. As samples which were stored deep frozen prior to the fact of the content of the test substance by the Analytical Toxicology.

The mean concentrations analyted expreparation were to a range of 92 -104 % of the nominal concentration and way the within the Acceptate range of 80-120 %. The stability of the test

concentration and we thus withe the Sceptolic range of 80-120 %. The stability of the test substance in the discutter of days storage at room temperature was also acceptable (98 and 93 % of the nomin A at the lowest and highest or centrations, despectively). Sampling and analysis, regime of the test day mixed are summarised in the following Tables



Mesosulfuron-methyl

Table CA 8.1	l.1.2- 4: Sa	ampling and a	nalysis re	egimes of t	<mark>he test di</mark>	<mark>et mixes</mark>			o
<mark>Dose level</mark> (ppm)		C (% of nomin	ontent ial concen	itration			,		AL A
	Pre check	: Pre c	heck lity*	Con adminis	tent at tration**		<u>S</u>	Ş	
312.5	98	9 9	8	u u u u u u u u u u u u u u u u u u u)9 04		A	Ő ^g	
625 1250	_			1	04)©		<i>پ</i> ″		
2500 5000	<mark>-</mark> 97	9	3	L	<mark>)5</mark>	<u> </u>	L.	, ₂ 9.	
*	= after 12 day	s storage at ro	om tempe	ratur		Q b		4	
-	= no sample t	aken			ð				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
A, B, C	= samples tak	en from the to	p, middl&	and bogon	n of Ore n		r F		1
Biological f	indings:		A		v <		Å.	0' 0	
No mortalit Mallard due	y occurred in	any dose gr	of Bas		ese result	ts, Azé sh	a dail@tes	lietazy, LC	of intake
of approx. 1	210 mg/kg bo	dy weight							
No clinical	signs of toxi	city occorre	<mark>d in any</mark>	<mark>zdose 🏹</mark>	oup a a	ny Ome		e study u	p to and
including th	e 5000 ppm d mption was lo	weight all de	sin ^S ro		mared	Q Vith the c	onteols du	uring the t	reatment
period; no d	lifferences we	ronoted of ur	in the re	Overy p	eriod. In	thestbse	nt of any	dose-dep	bendency
and any imp	pairment of the	e body weig	ht dever	opment no	o bologi	cal sign [®]	Deance Co	uld be ass	signed to
this observa	of the Wickli	ngs kilæ	ut de en	Sof the	study 1	revealed	no ^w macro	scopically	v visible
abnormalitie	es. S			, <u>"</u>	D'	Ó S	Ø ÿ		
Table CA 8.1		loz Qlity, body	weight, f	ood and	St subor	s s	Imption		
Dose group	Mortality r	ate Bodyw	wight 8	Relativof	oodconsu	ingtion	Substanc	e intake	
Ê,	Day@-9	Day 1			My 1-6	\mathcal{T}	(mg/kg Day	/day) <mark>1-6</mark>	
Control 1	\$ <mark>910</mark>	~ <u>160.7</u>	282.2 n		0.342		-		
Control 2		, 2 <mark>862.6</mark>	285.7 4 ⁻		0,955 0,955		- 77	5	
625 ppm			209.0	à à	0.232		145	<u>.1</u>	
1250 ppr		<u> </u>	264.9		0.261		326	.3	
2500 pcm 5000 ppm		×1547	2/9/5	× ×	0.218		545 1210	.0).0	
<u> </u>				¥.					
Conclusion	s: 0'A	Í J	, Q						
The dietary	C50 OF XE F	180060; subs	state, te	chnical in	the Mal	lard duck	was great	ter than 50)0 <mark>0 ppm,</mark>

equivalent to a normal data test substance intake of greater than approx. 1210 mg/kg body weight. The No Observed Adverse offect Level (NOAEL) was considered to be 5000 ppm, the regulatory limit cose.



Table CA 8	8.1.1.1- 9: Si	ummary table		
Reference	<mark>Followed</mark>	Guidance currently	Differences	Critical assessment of the study / Deviatice /
	guidance	in force		conclusion about its Reliability
<mark>M-</mark>	<mark>US-EPA</mark>	(not EU-relevant)	N/A	N/A 🌫
<mark>181332-</mark>	Pesticide			
<mark>01-1</mark>	Assessment			
	Guidelines,			A OF A O
KCA	Subdivision		ě	
<mark>8.1.1.2</mark>	E, series 71,			
<mark>/02</mark>	<u>§71-2 (1982)</u>		ÿ	
	<mark>OECD Draft</mark>	OECD Guideline	No	The study is in compliance with the gue eline
	Guideline for	for testing of	changes	
	testing of	chemicals No. 205	RO .	
	chemicals No.	"avian dietary	u ka	
	205 "avian	toxicity test "	Š OŠ	
	dietary	(<u>1984)</u>		
	toxicity test "	$\langle \rangle$		
	<mark>(1984)</mark>			
		~ ~ ~		

Sub-chronic and reproductive toxicity to birds CA 8.1.1.3

CA 8.1.1.3 Sub-curronic and reproductive studies on non-related bird species, boowhite quar and mallard duck were performed. The lowest NOEL was determined to be 93 mg a.s. kg by/d. Details of the studies are provided in the following table.

Avian reproductive toxicity data of mesosulfuron-methyl presented in this chapter Table CA 8.1.1.3-1:

Test species	Test design	Ecotoxicological endpoint O'	Reference
Bobwhite quail	or-week feeding chronic, 4 repuduction	NOEC 1990 5 10 m 4 m 4 m 4 m 4 m 4 m 4 m 4 m 4 m 4 m	, 2000 M-198082-01-1 KCA 8.1.1.3 /01
Mallard duck	20 weeks feeding chronic reproduction	NAEC 1000 ppp NOEL 126 yg as/kg bw/d	et al., 1999 M-191369-01-1 KCA 8.1.1.3 /02

Bold letters: Values considered relevant for risk assessment in the MOP document

Ę,	
Report:	€ ;20@°;M-198082-01
Title:	Bob Chite chail dietary reproduction study AE F130060 substance technical Code: AE
A	F139060 191C954901 6
Report Ng	
Document No(s):	M-198082-01→ 2 ~ ~ ~
Guidennes: 🐇	OECO: 296, 1984, USERC (=EPA): §71-4; Deviation not specified
GLP/GEP:	yeo o
Q1	

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): NOPEC = 1000 mg as/kg food

Study Smm Sy an ARM aluation copied from the original Monograph:

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

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Reference: 2000, 8.1.3.1/1.

- Test guideline: US-EPA Pesticide Assessment Guidelines, Subdivision E, series 71, §71-4 (1982) an Draft Guideline for testing of chemicals "avian reproduction test" (1984).
- **GLP compliance**: Yes.
- **Methods**: Effects of AE F130060 technical (94.6% w/w) on the reproduction of boltabilite dual was determined by exposing chicks (F0) to the a.s. via the diet for 00 weeks. Boltabilite quails was approximately months old at the start of the study. A total of 4 test groups of 16 pairs pere constituted each 2 which was offered one dietary concentration (0, 40, 200, or 1 000 mg a.s./kg). Bedaviour, general health and mortality, were checked daily. Body weight was recorded at the start of the accordinatisation period and every transfer finally dissected at the end of the study for macroscopical and resolutions and orden's transfer (heart, liver, spleen, testes and oviduct) was wasured Effects on reproduction were assessed through the hatching rate of eggs, the surveal of cocks, bey weight and food coolumpt in over the first two weeks after hatching. General hearth observations, were promoted.
- Results: There were no effects of a log terre detary poster of add boby the question holds, body weight gain, food consumption and egg production viability of endryos as undected acept is groups exposed to 40 and 1 000 mg a.s./kg food, bQ the difference observed was significant in the last group willy, and was assumed to rather reflect the exceptional fertility that "curredo" controls (950°, carOared to usual 75-90% fertility rates). No effects were observed on hatching survival, head a body weight and food consumption in F1. A summary of reproduction data is proceed in the Bolt 1.3.1-the Table B.9.1.3.1-1. Reproduction data on *Slinux reginiterus*.

	NO NO		
Dietary concentration	Control 4 ppm &	200 pm	<mark>1 000 ppm</mark>
Eggs laid	ا 1 8 <mark>820 ا 850</mark>	∕ <mark>≫13</mark>	<mark>875</mark>
Eggs laid per fen	53 k	@ <mark>54.21</mark>	<mark>54.7</mark>
Eggs damaged			<mark>17</mark>
Eggs damag Oof egg Oud (%)	0.84 (<u>*13</u>	0.53	<mark>2.1</mark>
Mean egg shell thic press (rem)	0.200 00.214	0.217	<mark>0.214</mark>
Eggs set	03 846	<mark>809</mark>	<mark>854</mark>
Viable Winbryos	207 - C - M	<mark>717</mark>	<mark>689</mark>
Vig Vig embryos of egg set (%0)	© ^v <mark>88.0</mark> % <u>, 98.9</u>	<mark>88.6</mark>	<mark>80.7*</mark>
Live 3-wk embryos	👷 🔬 🖉 <mark>653</mark>	<mark>714</mark>	<mark>670</mark>
Live 3-wk embry of viable embry s (%)	<u> 97.8</u>	<mark>99.6</mark>	<mark>97.2</mark>
Normal hatchli		<mark>675</mark>	<mark>617</mark>
Normal hateling of Orle end yos (%)	91.8 ⁶ 87.6	<mark>94.1</mark>	<mark>89.6</mark>
Normal heighling office 3-6 embry of (%)	<mark>89.6</mark> 89.6	<mark>94.5</mark>	<mark>92.1</mark>
14-d old survivors O O	5 02	<mark>600</mark>	<mark>559</mark>
14-d & Survivors of east laid (S) C	, [≪] <mark>63.2</mark> <u>59.1</u>	<mark>73.8</mark>	<mark>63.9</mark>
14-Sild survivors of Armal hat nling (%)	<mark>⊕[∦] 78.9 85.8</mark>	<mark>88.9</mark>	<mark>90.6</mark>
d old survivors of female,	[*] <u>32.0</u> <u>31.4</u>	<mark>40.0</mark>	<mark>34.9</mark>
Nick bodyweight at hate Mig (g)	6.7 6.7	<mark>6.8</mark>	<mark>6.9</mark>
Chick bodyweight at 14 d (g)	28.0 27.6	<mark>28.5</mark>	<mark>30.0</mark>
* significantly different from the convol at $p \ll 0.05$.			
15 femal			
NOFC 20 w/S = 1 00 mg a kg die (nominal o	concentration).		
Cocynents (KMS) the story is acceptable.			

Further stady information supplementing the original Monograph summary :

Validity Criteria:

The definitive test criteria for control groups as set out in the respective testing guidelines and the corresponding values obtained in this study are shown in the table below.





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Table CA 8.1.1.3- 4: Group body weight, food	l consum	ption and	test substar	ice intake	
Parameter	<mark>0 ppm</mark>	40 ppm	<mark>200 ppm</mark>	<mark>1000 ppm</mark>	ໄ <u></u> ຂໍຈ
Male body weight at termination (g)	<mark>222</mark>	<mark>229</mark>	<mark>218</mark>	<mark>222</mark>	
Female body weight at termination (g)	<mark>248</mark>	<mark>247</mark>	<mark>248</mark>	<mark>2%7</mark>	
Group mean food consumption (g/bird/day)	<mark>19.4</mark>	<mark>19.6</mark>	<mark>21.5</mark>	<mark>\$9.9</mark>	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	207	20.2	10.0	A 200	- 5 ⁴ 5 ⁴ 5
Group mean food consumption (g/pen/day) Group mean body weight (g/replicate/day)	38.7 421.4	<u>39.2</u> <u>1035</u>	42.9 ×	<mark>39.8 % مر</mark> 428.0	
Replicate food consumption (g/1 OOg bw/day)	9.2	V .1	10,0	9.3	
Test substance intake (mg/kg bw/day)	-	الاني <mark>3.7</mark>	203	<mark>93.0</mark> 0	
	A	Ĵ	Q' A	° A	
Necropsy, including gastrointestinal tract and	thenaj	or organs	vf the Wrd	s which ha	died or of tose
killed during or at termination of the study, i	icdicated	ono patro	ological ch	enges at Oil	outable to the test
substance. In particular, no changes in the rep	Poduczi	e organs v	v det 🗞	ed.	A A C
	, Ø	\sim	Q A	S.	
Statistical analysis of absolute and relative w	eights o	Meart Q	ver, spleen	stestes and	oviduct (vsrhout
developing eggs) revealed no significant cha	<mark>gges.</mark> K	summer	, ikujs conž	fuded What	the test substance
caused no specific effects on the organ weigh	ts. 🕎	_ \$\begin{array}{c} & & & & & & \\ & & & & & & & \\ & & & &	y S	8 5	, L
Table CA 8 1 1 3 5t The relation		ÿ õ			*~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Organ Ser Vanny a	0 nnm				×
(cog vol)					
Heart (%) Male 0.55	K 25	0 <u>5</u> 4	K g	<mark>Ş</mark> X	
	<u>8.43</u> 0			<mark>41</mark>	
Liver (%) I contain a cont	2.5	× 2.2			
Spleen (%)	<mark>9.9</mark> €042 ∘~	₽ <mark>0,694</mark>		Q 15	
<u> </u>	<mark>ه.029</mark>	<mark>0.033</mark>		0 <mark>31</mark>	
Testes (%) From ale 0.0 k	1.02	0.92		.91	
No statistically significant difference from ontro	$\mathbb{Q}^{(n<0)}$	b) obs@ve	d in Ony par	ameter	
	Ô	×.	0		
Adult birds (Fogen Ation & Ren duction to	xicily:	& A	Y		
Egg production was unaffected in all weating	arou	Os. Thom	umbers of o	eggs laid, b	roken or cracked
eggs and abnormal eggs as will as the eggs	veighai	nd Well th	nickness in	dicated no	substance-related
changes. The group Igg dao (per yean) we s	unimari	sd in the	following	table:	
	Ô, ¹	Ŭ			
Table CA 9.1.1.3-6: Qoup Qg data (pen pg	an) 🕎				
Parameter Y0 ppy	4 ypn	1 200 p	pm 100	0 ppm	
Cracked eggs/number laid %	$0^{0.13}$	0.5	2 2	2 1	
Number normal temals	52.9	53.0	9 4	3.4	
Mean eggsley thick yess (northern the first of the first	0.214	0.21	7 0	.214	
Mean egg yeight 2 2 3 981	<mark>9.88</mark>	9.8	9) <mark>.94</mark>	
No static cally gnificant diff. Once from contro	ols (p<0.0)5) observe	d in any par	ameter.	
Traiment op to and inceding 1000 ppm had	d no adv	erse effec	ts on fertil	ity, embryo	onic development
and hat Oibility.			1 0 11		
The group mean incubation data (pen mean) a	re sumn	narised in	the follow:	ing table:	

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Table CA 8.1.1.3-7: Group mean incut	pation da	ta (nen me	ean)		
Parameter	0 ppm	40 ppm	200 ppm	1000 ppm	ø° 🗞
Fertile eggs/eggs incubated (%)	95.4	85.6	<mark>96.0</mark>	87.5	
Live 3-week embryos/fertile eggs (%)	<mark>98.7</mark>	<mark>97.8</mark>	<mark>99.6</mark>	97.2 🐎	
Chicks hatched/live 3-week embryos (%)	93.0	89.6	<mark>94.5</mark>	92.1	4 . P
Chicks hatched/eggs incubated (%)	87.6	75.0	90.4	78 <u>4</u>	
Examination of the unhatched eggs rev	ealed ful	ly devel	ed chicks	in@post_cases	which ded showy
before or during batching after packing	the error	hell and y	very few lat	Ambryonic (Buthe
before of during natering after pecking	the eggs				
Chiele (Francestien)		A	Q'	6° 4	
Chicks (F ₁ generation):	141		14		
No changes in benaviour, general hea	Ith cond	ition and	14-out su	rval ate w	se observed in the
hatchlings of the treated groups. In	addito	n, th o re y	we no da	creased nuts	ber of chicks with
malformations, e.g. of the pelvis.	2		v Q		
The descriptive overall statistical param	eter for	product	ive Srform	anyce (e©yress	ed as percentaces of
14-day survivors / eggs set and compared	Using all	coreste	ps of emlo	yonig and of	spring, development
such as fertility, embryonic develop	ent, Satcl	hir@and^	Sability of	the offstern	g) So indicated no
substance-related changes in any to atec	l group.				
The chick data (pen mean) are symmatic	Sed in 🖧	e followir	n <mark>g Alle.</mark> 📈	Š Š "C	
Table CA 8.1.1.3-8: Chick doga (per ya	iean)	<i>®</i>	<u> </u>		. 0
Parameter 👋 🌾	0 ôpm	<mark>∦∮0 ppn</mark> ⊘	200 pm	<mark>~j.000 lom</mark>	Ô
14-day survivors / female $\overset{\Lambda}{\sim}$	ه <mark>ک²2.0 ک</mark>	<mark>, 31,4</mark>	<mark>40.0</mark> 🔬	¥ <mark>36</mark> 9 _ 3	ý ^s
14-day survivors / chicks hatched(%)	* <mark>79.5</mark> 5	<u></u>	6 ^{°°} 89.8	* <mark>90.2</mark> 🏹	
14-day survivors / fert (seggs (b))	<mark>64.8</mark>	22 <mark>53.7</mark>	7 <mark>60</mark>	× <mark>64.2</mark> ×	
14-day survivors / eggs incubated (<mark>\$9.6</mark> '	<u> 64, 1</u> 2	<mark>%_0.6</mark>	69.5	
A : statistically not xamirQi;			N. O		
The statistically grint grid difference in the	Concors		P AS	ny porameter.	
	4		0~ *		
Chick bod weights at hatching and	hat do	14 were	matter	d by treatme	ent. There were no
statistic ty significant Change in any	treated	growp at	Jatching" o	r after compl	etion of the 14-day
rearing period as shown in the following	g töbile.	7 4	S		
	7 0	Ő (ð		
Table CA 8.1.1.3- %. Tick bey weight			<u>Ç</u>		1
Parameter & C' C App			200 ppm	1000 ppm	
Chick weight at hatching (6.8 28.5	6.9	
Chick weight on day 14 (g)			28.5	30.0	
No statesically significant difference from	consols	<u>(60.05) o</u>	bserved in ai	ny parameter.	
		¥			
Food consumption during the O-day re	earing	riod deter	rmined roug	ghly as total f	eed consumption by
group and prepented as dail food for	nsurQotio	n per 14-	day chick,	was not indi	cative of treatment-
related chan Qs.	Ø				
	Ŷ				
Table C.S.1.1.3010: Group Ood consu	mption as	s daily foo	<mark>d consumpt</mark> i	on per-day ch	ick
Parameter of A	<mark>) ppm</mark> 2	10 ppm	200 ppm 1	<mark>.000 ppm</mark>	
Graph food onsurption (whick/day)	<mark>2.6</mark>	<mark>2.5</mark>	<mark>2.6</mark>	<mark>2.8</mark>	
···* (3.					
Concl Cons:					
The NOEL of AE E120060 technical	in this 20) week re	production	study with a	dult Robychite Quail
The WOLL of AL F150000, technical i	m m s 20	J-week re	production	study with a	un Boowinte Quan

was 1000 ppm (diet) which is the limit dose according to the relevant OECD testing guideline.

was 1000 ppm	(diet) which	n is the limit dose ad	cording to th	e relevant OECD testing guideline.
Table CA 8.1.1	.1- 10: Su	mmary table		
Reference Fo	llowed idance	Guidance currently in force	Differences	Critical assessment of the study / Degrins, conclusion about it Seliability
M- US 198082- Per 01-1 As Gu Gu KCA Su 8.1.1.3 E, /01 §7	-EPA sticide sessment idelines, bdivision series 71, 1-4 (1982)	(not EU-relevant)	Les de	
OE Gu tes chc 200 rep tes	CD Draft ideline for ting of emicals No. 6 "avian production t" (1984)	OECD guideline 205 for testing of chemicals "Avian Dietary Toxicity Test (1984)		The Kudy on compliance with the guide thes
Devert				

Keport.	· · · · · · · · · · · · · · · · · · ·
Title:	Mallard duck dietary Coproduction togicity study AE V130000 substance technical Code:
	AF \$30060001650000
Report No:	C005103A
Document No:	M-191209-01
Guidelines:	OECD: 206 SEP (=EP3): §713; Deviation not specified
GLP/GEP:	S yeb in the interval

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): NOEC = 1000 mg/as/kg food \ll

Monograph: ummary an

- **Reference**:
- CD Guideline 206 and the A.S.T.M. guideline "Standard Test guidel@e: U practice for condu cies" (1983).

99**9**, 8.1.**&**2/1

- GLI Simpliance:
- Abthods: Effects of Ac 13000 technical (6.6% w/w) on the reproduction of the mallard duck was determined by exposing ducklogs (F0) to the Otive substance via the diet, over a 22 weeks period. All birds were approxidately 24 weeks old atopst inition. A total of 4 test groups of 16 pairs were constituted, each of were approximately 24 week old an est initiation. A total of 4 test groups of 16 pairs were constituted, each of which was fifered the diverse constituted, each of mortality were ducked fully. Body wornt was recorded at the start of the acclimatisation period and every two works units week of and the on week 22. Food consumption was checked weekly. First generation quails were finally dissected at the end of the study for macroscopical and pathological observations. Effects on reproduction were discussed through the number and quality of the eggs produced (visual observations, shell Sckness. Effect on the F1 were assessed through the hatching rate of eggs, the survival of chicks, body weight and food consumption over the first two weeks after hatching. General health observations were perto, med.
- **Results**: There were no effects of a long term dietary exposure of adult mallard ducks on their health, body weight gain and food consumption. A slight but significant increase in male body weight was observed in the 1

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000 mg/kg exposed group ($p < 0.01$), but was significant decrease in food consumption was rec could not be interpreted as treatment-related. Eg survival, health, bodyweight and food consumption during the embryonic stage and in the hatchling	not found to be o corded in the 40 mg g production was u on in F1. Slight diffe g rate, that could no	f biological signigfic /kg exposed group d naffected and neither rences were recorded of be interpret as t	cance. Similarily, a uring week 16 Onat was hatchigg rate. In the sur of al rate reatment clated of
summary of reproduction data is proposed in table Table B.9.1.3.1-2. Reproduction data on <i>Anas pla</i> Dietary concentration Eggs laid Eggs laid per female Eggs damaged	B.9.1.3.1-2.	0 ⁴ 200 ppm © 40 693 2 2 0 43 4 2 0 0 0 0 0 0 0	57 57 57 57 57 57 51 57 57 51 57 57 51 57 57 50 10 50
Ligs callinged of eggs rate (vo) Mean egg shell thickness (mm) Eggs set Viable embryos Viable embryos of eggs set (%) Live 3-wk embryos Live 3-wk embryos of viable embryos (%) Normal hatchling Normal hatchling			
Normal hatchling of live 3-wk embryos (%) 14-d old survivors 14-d old survivors of eggs laid %) 14-d old survivors of normal hatchling %) 14-d old survivors per fer % e Ducklings bodyweight at hatching (g) Ducklings bodyweight at hatching (g) Ducklings bodyweight at 14 c/2 * significantly different from the control $\infty < 0.0$			87.1 513 64.0 99.6 32.1 35.0 274.0
** significantly SrferenOrom the control at p 15 females NOEC -22 wks ² 1 000 mg a.c/kg digt (nomin Corrections (RMS) accessed			
alidity Critery his study was of excelled Gecht val que ity as the control pairs, which was of the opper 1 m espective testing guivaines. In particular free surfaces (hen () was the 10 merge will the	Vider de typical l vider de typical l it of the typical l boff the test criteria	raph summary : ry high reproductiv biological range as to for acceptability of the adult morta	We performance of s specified in the of the test, i.e. 14- lity ($\leq 10^{9}$) were
anity met by the control group nalytical fiolings he quantification of the est substance in the di V-detection) Corganic solution (acetonitrile) e	et was performed extracts of the test	by HPLC separations and the separation of the test substance.	ns (reverse phase, tures.
de at room temperatie were confirmed as a	cceptable, i.e. in th	ie range of 83-107	% of nominal.

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Table CA 8.1.1.3- 11:	Mean values (in % examination times) of the nomina	l content of the	test substance at	the individual	\sim
	Conce	ntration of AE F1	30060 in the di	et (mean % of nor	ninal)	Ş
Diet concentration	Pre study	Week 1	Reproduction	study		
Control	Day 0 Day 7 n.d. n.d.	Day 0 Day ´ n.d. n.d.	7 Week 4ª <u>n.d.</u>	Week 8 Wee	k 125 Weck 20 1 ~	2
$\frac{40 \text{ mg/kg}}{200 \text{ mg/kg}}$	94 ^b 90 ^b	88 ^b 83 ^b	93 97	0 ³⁷ 8		S.
1000 mg/kg	106b 95 ^b	90 ^b 900	99 5	$\frac{106}{2}$,
^a diets prepared from the samples collected from	ne first premix and s m the top, middle a	stored for deep fr nd bottom layers	ozen for 4 weeks of feed from the	veeder to deter	nine Komoger Gity,	
n.d. = not detectable (e)	stimated detection l	imit = Kng/kg Q				
				4.0 ⁵ ~		
<u>Biological findings:</u>	Ŕ					
Adult Birds						
There were no mortal	ities in any of the	featmont or of	htrol & Sups &	any Ome dioing	o test.	
No clinical signs of observations such as	toxicity wate s	es at any of	We concentration	Nons rested. Or	cidental clinical	
wear or interactions a	Mong ponnate (2)	vere Observor	Other clinical s	signs such is lar	neness and lower	
limb weakness also	ented occasion	ha@y, and ypic Dirds appear @	norma through	Qted wyth the in hout Que test. The first section was a section of the section of	icidental injuries.	
treatment-relate				the concentrat	ions tastad Any	
differences in female	body weig a bet	deen te contro	group and a	Ch of the treat	nent groups were	
not statistically signif (p<0.0 vincrease in x	iont at ony of a sale bary weight	in Che 1900 pp	in Evals X s m treatment gr	light, but statist	ically significant mination was not	
considered to be of a	iy biologica sign	Scance Since	Me difference of	observed was sli	ght (< 10%), and	
represented an ingreas		it was consider	of to be tre	eatment-related.		
Due to wastage by so treatment of ated effe	me ords, ford co	Qumpton wa	Variable amor 40, 200 or 100	ng pens. Howev	er, there were no entrations. At the	
40 ppm Est concentr	nion, there was a	slight de ase	in feed consu	mption during V	Veek 16 that was	
test concentration was	t at $r = 0.0308 \text{mc}$ s n@ consettent of	er the distrement	e from the cont od and was no	rol group observ	dependent, it was	
not considered be t	reatment relater.	An Other diffe	rences in feed	consumption be	tween the control	
		Q	Sinnount.			
The estimated 45t sul F13000 /Kg90dy 20	stance Otakes fo	r mallard ducks 0, 200 and 100	s during the tes 0 ppm treatmer	st were 4.6, 25.8 it groups, respec	and 126 mg AE tively.	
	were subjected to	groce neeropeu	following edu	It termination	All findings were	
considered incidental	to treatment. In pa	articular, no fine	dings were obs	erved in the repr	oductive organs.	
Reproduction data						

BAYER Bayer CropScience

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

There were no treatment-related effects upon reproductive performance in the 40, 200 or 1000 ppm
treatment groups. There was a slight decrease in live three-week embryos as a percentage of x ble 🖉
embryos in the 40 ppm treatment group that was statistically different from the control value of p
0.05. However, the difference was due, primarily, to exceptional performance by the conter group
(100%). Since the percentage of live three-week embryos was consistent with the historical control
value of 98%, and the reduction observed was not concentration-dependent, the difference fight the
control value was not considered to be treatment-related.
Additionally, at the 40 ppm test concentration there was vight decrease in hatchlings as overceasing a
of live three-week embryos that was statistically different from the Control group at p 30.05 , spaine 0^{7}
the difference observed was primarily the result & exceptional performance by the control group
which achieved 93% hatchability. Hatchability is the 40 ppm watme group 76% was comparely in
to the historical control value for this parameter of 73 + 13% Since the slip reduction in natche vility
was not concentration-dependant, and hatch Oility Withe Appm Peatro at graph was comparable to
the historical control value, the difference Asery was for conscienced to be reatment related.
Any other differences between the control group and my of the treatment eloups were not statistically
significant for any of the other reproductive commences measured, 0
There were no treatment-related effects upon egg shell this ness of the 4, 206, or 1900 ppm test
concentrations, and any differences from the control Soup cere no statis cally gnife ant.
There were no treatment-related effects upon the ody weights of hat ling of 14-any old survivors at
any of the concentrations vested. Any differences between the control group and any of the treatments
groups were not statistically somethic of the second statistically somethic of the second statistically somethic of the second statistical
Conclusions: 5 5 2 2 2 2 2 2
The no observed effect concentration for mallary such a treate Swith AF F130060 in the diet during
this reproduction stary way 000 ppm (equivalent to a achie daily intake of 126 mg AF F130060
/kg hody washt/day)
J J J J J J J J J J J J J J J J J J J





Table CA 8.1.2.1- 5 Mammatian acute orat foxicity data of mesosulfuron-methyl presented in this chapter

Test species Pest design 🔊	Ecotoxicological endpoint	Reference
Rat acute, oral @	Q LD ₅₀ Z > 5000 ¹⁾ mg as/kg bw	, 1996 M-140405-01-1 KCA 5.2.1 /01

Bold Vetters: Values considered relevant for isk as essment in the MCP document ¹⁾ 10 rats per group, no mortality occurred

Endpoint according to the Keview Report for mesosulfuron-methyl (SANCO/10298/2003-Final): $D_{50} > 5000 \text{ mg as/kg bw}$

CA 8.1.2.2 Congreterm and reproduction toxicity to mammals

Several subchronic and chronic studies were performed with mesosulfuron-methyl. As the 90-day dietary as well as the long-term carcinogenesis study resulted in endpoints equal or greater than the highest tested concentration of the two generation reproduction study, 12000 and 16000 ppm, respectively, there is no reason to deviate from the reproduction study as endpoint for risk assessment.



The reproduction study resulted - like the long-term carcinogenesis study - in an endpoint equal or greater than 16000 ppm, the highest tested concentration. According to the slightly higher food uptake in the reproduction study the corresponding NOEL is also slightly higher than in the long-term carcinogenesis study, underlining the low toxicity of mesosulfuron-methyl. Details of the studies are provided in the following table.

1

Table CA 8.1.2.2- 1:	Mammalian reproductive toxicity d	lata of mesosulfur on-metl	hyl presented iy
	-		

cha	pter			
Test species	Test design	Ecotoxicological endpoint	ĴÕ [¥]	Reference S ()
Rat	90-d chronic dietary	NOEC 12000 \equiv NOEL _{male} 7.5 \equiv NOEL _{female} 76.5 NOEL _{geomean} 941	ppmQ mg as/kg w/d Qg as/kg bw/d Ang ag kg bw/d	M 187497-01-1 (@A 5.3-7/01
Rat	Combined, chronic (long-term, carcinogenesis study)	NOEC 3 5600 \equiv NOEL 3 956	ppin org as/kg bw/sl	M-198434-01-1
Rat	2-generation dietary reproduction study	$NOF \bigcirc 0000 = 000 \text{ More } 0000 \text{ More } 00000 \text{ More } 000000 \text{ More } 000000 \text{ More } 00000000000000000000000000000000000$	mg askg bw/d mg askg bw/d mg skg bw/d	2000 MC/198366¢01-1 QCA & 6.1 /02

Bold letters: Values considered relevant for risk assessment in the MCP document

NOEC values (12000 ppm and 16000 ppm) of the studies of **Sectors** (1999) and **Sectors** (2000) on rats were listed as ecotoxic orgical endpoints in the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final). For the reasons discussed above, it is proposed for the updated list of endpoints to specify as endpoint relevant for long-term mampalian risk assessment the geomean NOEL value of 1277 mg as/kg bw/day derived from the results of the 2 generation dietary reproduction study.

CA 8.1.3 Effects of active substance bioconcentration on prey of birds and mammals

As the log Proof the active substance mesosulfuron-methyl is below the trigger (< 3), no evaluation of secondary poisoning is needed. 2

CA 8.1.4 Effects on texrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)

Since mesosulfuron-methyl is of low toxicity to birds and laboratory rodents, no risk for reptiles and amphibians is to be expected in the second sec

CA 8.1.5 Kadocrine disrupting properties

Following EU regulation 1.07/2009, an assessment has to be provided concerning potential endocrine disrupting properties of the active substance concerned.

WHO/IPCS (2002)¹ provided the currently widely accepted definition "An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations." An adverse effect has been defined also by WHO/IPCS (2009)²: "Change in the morphology physiology growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences."

Both definitions were used as the basis for evaluating the potential impact of mesosulfuron methyle wildlife presented below.

Wild Mammals

Potential endocrine activity and potential population relevant effects of mescoulfuron-methyl on mammals were studied in 90-d, chronic, and multi-generation studies in fats, 90-d and chronic studies in mice, 90-d and 1-year studies in dogs, and in terratolog@studies in rats and rabbits. In note of these studies any observations of effects were observed that could be related to primary endocrine activity. Based on the absence of any indication of relevant effects it can be concluded that mesos furonmethyl is not an endocrine disrupter.

Birds

Birds The population relevant effects of mesosulfuron-methyl on birds were studied in reproductive toxicity studies on bobwhite quail and matterid ducks. For both@species there were no effects on reproductive parameters up to and including the highest tested dietary concentration of 1900 ppm a.s.

As reproduction was not affected in other species, is concluded that there are no population relevant adverse effects of mesosulfuron-methyl. No additional studies seem recessary.

Amphibians and Reptile

Currently no test methods are established to assess the population relevant effects of chemicals to amphibians or reptiles. While an amphibian measure prophosis test method exists, this test was developed to evaluate to potential effect on the thyroid system, and not to measure population relevant effects. Therefore no further studies can be suggested at this time for this group of organisms.

Conclusion

Neither in manmak nor Birds were any indrations for adverse endocrine activity observed. Therefore further special esting for enderrine disrupting behaviour is not warranted.

Effects on aquatic organisms CA 8.2

Aquatic organisms have been rested with the active substance and the metabolites included in the residue definition for aquatic isk assessment (see MCA Section CA 7.4.1).

Metabolite testing in each case include *Lemna*, which represents the standard aquatic organism by far the most sensitive to the parent active substance mesosulfuron-methyl. Moreover, green algae (Pseudokirchteriella, subcapitata and Scenedesmus subspicatus) were tested in addition for all but two

¹ WHO/PCS (World Health Organization/International Programme on Chemical Safety), 2002. Global Assessment of the State-of-thescience of Endocrine Disruptors. WHO/PCS/EDC/02.2, 180 pp.

² WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2009. Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria 240. 689 pp.

intermediate components, as a standard aquatic testing organism of general relevance for herbicides. Nevertheless, in case of mesosulfuron-methyl, algae were found significantly less sensitive to parent active substance than aquatic vascular plant.

The terminal metabolite AE F092944 is a degradate shared with several sulfary urea type herbicides Tests with further aquatic species (Fish, Daphnia) have been performed on this metabolite

In addition, Lemna and algae tests have been conducted in two components BCS-CO60726 and BCS-CO60721, supportive to evaluation of artifact degradates that were observed in a water/sediment O study, but not considered relevant for inclusion in the aquatic residue definition. Details hereon are summarised in document MCA Section 7.2.2.3.

CA 8.2.1 Acute toxicity to fish

For mesosulfuron-methyl, three acute toxicity studies on three different fish species were performed. The maximum tested dose level in all studies was 000 mg a.s./L No mortality or subtethal effects were observed in the treatments, resulting in an LCs of >100 mg a.s./L V For the metabolite AE F092944 one acute study on rainbox trout was conducted with test doses ranging from 18 to 1000 mg/L. The 96-hour-L G_{0} was 254 mg/L. Details of all studies are provided in the following table.

	, ch	apter			O ^Y K		S
Test species	Å.	Test system	<i>a</i> ,	Test	, 🗡 🕅 E 🖓 d po	int (Reference
		C Š	du 🖉	iration 🕽	(mg as	s/Ľ] [×]	
Mesosulfuron-me	¢0ñyl ∖C				N N		
Oncorhynchus	king O	.4 4	1.0			\swarrow'	et al., 1999
(rainbow trout)	NISS (S	static acute	× .	Số h	LCO	@>100	M-186666-01-1
(Talloow trout)	•0		A D	y O		, ,	KCA 8.2.1 /01
Lanomie	rus Õ		<i>"</i>		× ×		et al., 1999
(hluegill sunfish)		stanc acute	<u>م</u>	900 ×	LC	> 100	M-186597-01-1
(ordegin sumsil)	<u>~</u> 0	$\langle \rangle $		jr 🦕	A.		KCA 8.2.1 /02
	à a	U 4		<i>,</i> 0	ð		
Cyprinodon varies	atus 🔍 🎙	static acute		968 6	SI C.	> 100	, 2001
(sheephead minno	w) 👌 (w		\sim		J. EC30	> 100	M-238810-01-1
¥	(Q'	<u>à gr</u>			KCA 8.2.1 /03
AE F092944		<u> </u>		<u> </u>			
Oncorh hchus my	biss N			~0~			, 1993
(rainbew trout)	K N	static acute	Ŭ,	98 h	LC_{50}	254	M-131422-01-1
(Turkoow trout)			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	N 1			KCA 8.2.1 /04

Table CA 8.2.1-1: Acrete toxicity days of mesosulfuron-methyl and metabolite to tash presented in this

Bold letters: Values considered relevant for risk assessment in the MCP document

Studies on Mesosulfaron-methyl

Report N	₄ v; ; ; ; ; ; ; ; ; ; 999;M-186666-01
Title:	Acute toxicity to rainbow trout (Oncorhynchus mykiss) AE F130060 substance, technical
	Contr. AE F130060 00 1C95 0001
Report NoC	C003718
Document No:	M-186666-01-1
Guidelines:	EU (=EEC): C.1; OECD: 203; USEPA (=EPA): E § 72-1; Deviation not specified
GLP/GEP:	yes



Endpoint according to the Review Report	for mesosulfuron-me	thyl (SANCO/10298/2	003-Final):
	$LC_{50} > 100 \text{ mg/L}$		
Study summary and RMS evaluation co	opied from the origin	nal Monograph 🏷	
	1000- 0.0.1.1/	, S	A S
□ Reference:	1999a, 8.2.1.1/	<mark>Ⅰ.</mark>	5 5 .Q
Test guideline : US-EPA Pesticide Asses	sment Guidelines Subo	livision E (series 72, §7.	1982 OECO
guideline no 203 (1992) and EU directive 9	92/69 Annex Part 2: C.1		
□ GLP compliance: Yes.	, O'		
D. Methoda: The casts torisity of AE E1200			
rainbow trouts exposed for 4 days under st	atic conditions, Fish y	e approximately 5 mon	is old at the start of
the study. Exposure was performed in 50 I	coordiners ontainity of	control and tot water res	pectively 0 and 10,
18, 32, 56 or 100 mg/l, nominal, in 50% randomly per container. Mortality and aba	tiltered to wate 50%	were recorded 24 h in	M wer Allocated
the exposure period.			L 5
A fine sediment was observed on the but after the start of the test. Analytical real	om af test cantainers wit	thig fie firs 48 h, tot ha	d Osappe Ocd 72 h
(above 87.9% of nominal a.s.).			
well as in control fish. Because of the	a Sence of mortality o	the range of concen	tations tested, no
concentration-effect relationship, o'd there	Sore nog C50, could be	establiched.	
LC50 - 96 h > 100 m/s/a.s./L, 9			
Comments (RMS) One study is activately			
Further study offormation supplementi	ing the original Mon	o aph Symmary :	
Validity Croperia:		The validity or	torion of our con
saturation above 60% fulling			terion of oxygen
		× *	
Analytical finding			
Chemical analysis of the freshly popare	ed and a d (96 hour	rs old) test solutions i	ndicated that the
actual expositive concentration ranged the	a 8/2% to 30.1% a	at the start of the test,	and ranged from
96.7% to 102.1% of the nomeal values.	Agall any ysed conc	entrations were above	80% of nominal.
the nominal concentrations vere wild for	peporting the results.		
Biological find @zs:	Q ^Y occurred in any	of the tested concentr	ations and in the
untreated carrol			anons and in the
The concentration of \$0% mostality of the	e test animals (LC ₅₀) i	s given below:	
Tak CA 8 9-2: Endpoint (LCso value)			

	<mark>24 - 96 hours</mark>
LC50 [mg test substance/L] nominal	<mark>> 100</mark>



Conclusions:

In a static-acute toxicity test (method EPA / OECD / EU) to determine the effect of AE F1 substance, technical, Code: AE F130060 00 1C95 0001 to rainbow trout (Oncorhynchus m lethal concentration for 50% of the test animals (LC₅₀) after 24-96 hours test \hat{O} ration was \hat{N} test substance/L (corresponding to 94.6 mg a.s./L). The concentration without mortality and without any observed effects (MOEC, no of concentration) was found at 100 mg animals (LC₅₀) after 24 - 96 hours test duration substance/L (corresponding to 94.6 mg a.s/L).

Table CA 8.2	2.1-3: Summary ta	ble	Ú,	<u> </u>	Ő	, ² % , O ^v	؟ ©_
Reference	Followed guidance	Guidance currently in force	W ifferences	Critical Ases	smont of the	study boughts Red o	ץ∕ ווונ
<mark>M-</mark> 186666-	OECD No. 203 (1992)	OECD No. 203 (1992)	no Qanger	no ceviatio	from Arren	nt grideline	م م
<mark>01-1</mark>	US EPA, E, § 72- 1	(not EU-releant)	X/A				Y
KCA 8.2.1 /01	92/69/EWG, C.1	(not releant)					
		L O	°∼y' W	\sim \sim	N S		

Report:	8; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ;
Title:	Acute toxicity to blues of sunfish (Lepomis macrochirs) AE F130060 substance, technical
	Code: AE F1 0060 AP 1C9 5 001
Report No:	C04,7682 Q Q Q A A A A A A A A A A A A A A A A
Document No:	M-18659 01-10 0 0 0 0 0
Guidelines:	ŒU (=@EC): MI; OECD: 200, USEPA (=EOA): E 72-1 Deviation not specified
GLP/GEP:	yes, & & V

The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2003 Final), but is available from the Monograph evaluation (B.9.2.1.2): 1000mg/L LC

Study symmary and al Monograph:

- **Reference**:
- Subdivision E, series 72, §72-1 (1982), OECD Test guide ne: guideline no 203 t C: C.1.

Rompliance

Acthods: The acute tox Sity of the F13Q60 (textinical substance, purity 94.6% w/w) was assessed in bluegill sunfish exposed for 4 days upper static conditions. Fish were approximately 9 months old at the start of the study. Exposure was performed to 50 IQcontainers containing control and a limit test concentration, respective 0 and 70 mgs (nominal, propared in 50% filtered tap water/50% deionised water). Ten fish were allocated and day per Sintain and the limit concentration was tested in triplicate. Mortality and abnormal responers of the were cord Pat 24h intervals throughout the exposure period.

Results: ty and ho abnormal behaviour were recorded in fish exposed to mesosulfuron-methyl, as ell as on control fishe Because of the absence of mortality over the range of concentrations tested, no once Pration-effect relationship, and therefore no LC50, could be established. LCO - 96 h > 100 mg a.s./l.

Comments (RMS): the study is acceptable.







Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Report:	3; ; ;200	1;M-238810-01	
Title:	96 Hour acute toxicity to the sheepshead minnow, Cypr	inodon variegatus, in a static	ĺ ô
	system AE F130060 technical 95.7 percent w/w		S
Report No:	B003157		"0"
Document No(s):	M-238810-01-1		<u>ڳ</u>
Guidelines:	OECD: 203; USEPA (=EPA): 72-3; Deviation not spe	ecified 🔍 🔊	-
GLP/GEP:	yes	A OF S	, Ôj

Ô

Executive Summary

The aim of the study was to determine the acute effects of mesosulfuron-methy AE FQ0060 AE F130060 00 1C95 0001; purity 95.7% w/w) to sheepshead minuow (Copringeon variegatus Juvenile Cyprinodon variegatus were exposed in a static system over a period of 96 hours to the nominal concentration of 100 mg a.s./L. In addition a dilution water control was tested. Mortality and sublethal behavioural effects were used to determine the endpoints. Based on analytical findings the biological endpoints are reported as nominal figures. The 96-hour LC50 of ACF F13,0060 technical to sheepshead minnows could not be determined under the conditions of this study and is greater than 100 mg/L. The no observed effect concentration (NOEC) was 100 mg/L. The lowest observed effect concentration (LOEC) could not be determined under the conditions of this study.

Material and Methods

Test item: AE F130060, technical, Batcle No.: 1/1. 35316; Code No. AE 1/30060 00 1C95 0001; Sample No.: ZBA806; Analysed purity: 5.7% /w; Certificate of Analysis /AZ 08063.

õ Juvenile sheepshead minnows (Cypenodon variegatus) were exposed AE F130060 in a static system over a period of 96 hours to a nominal concentration of 100 mg a.s./L in synthetic sea water (mean temperature of 22,1°C). In addition a dilution water control was cested, Each vessel (glass fish tanks; 20 L) served as one replicate filled with 15 L solution. 10 fish were used per test vessel (i. e., 30 fish per treatment level). Mean weight and length of fish taken at the end of the study were 0.307 g (range 0.169 to 0.502 g) and 2.2 cm trange 1.9 to 2.5 cm. The organism loading during the study was 0.205 gd. The test was conducted with 3 replicated per treatmen level.

Observations for death, absormal appearance and behavior were performed at 3, 6, 24, 48, 72, and 96 hours (± 1 hour).

For analytical verification of the test item concentrations samples were taken at test initiation and termination. All samples were analysed for AE F130960 by reverse-phase High Performance Liquid Chromatography with ultraviole detection (HPLC/UV) under isocratic conditions.

Test methodology was in agreement with QECD 203 and USEPA 72-3 guidelines.

Qune f 2000 – June 5, 2000 Dates of experimental work

Results:

Validity Criteria

The validity criterion of control mortality less than 10% is fulfilled. The validity criterion of oxygen saturation above 60% is fulfilled.

Analytical findings:

Results of analyses revealed that the AE F130060 concentration was 105% of nominal over the course of the study. There was no AE F130060 residues found in the dilution water or control samples greater than the limit of quantitation (5.0 mg/L). All toxicity values were calculated based on the nominal



u in the concentrations of test substance added to the test water. Detailed analytical results are presented in the following table:

Table CA 8.2.1- 6:	measured concentrations of AE F130060					
Sample identification	Measured AE F130060 Concentration (mg/L)					
(mg/L)	on day 0	on day 4	Mean	% Nominal 🔬		
			(combined)			
Dilution water	< LOQ*	< LOQ	< LOQ	07		
Control	< LOQ	< LOQ	< LOQ	-04		
100	107.3780	101.7925	104.59	(Std. Dev. = 3)%)		

^a Limit of Quantitation (5.0 mg/L)

Biological findings:

<u>)</u> No mortality or sublethal effects were obstudy.

Conclusion

The 96-hour LC₅₀ of mesosulfuron methyl technical to sheep head minnows could not be determined under the conditions of this study, and is greater than 100 mg/L. The no observed effect concentration (NOEC) was 100 mg/L. The lowest observed effect concentration (LOEC) could not be determined under the conditions of this study. y y y y y under the conditions of this study

Studies on the metabolite

AE F092944

C			, Y ~		
Report: 🔗		9Ç;	;19 9 3;M-12042	2-0	
Title:	¹⁰ Hoe 0929	44) substance, to	ectmical (Proe 0)	92944 0 ZD99 0001) Effect to	
×~	Oreorhyn	chus mybiss (Ra	mbow trout) in	Static Acute Toxicity Test (m	ethod
Ê,	ØECD)			、 O″	
Report No:	A50396		<u> </u>	4 V	
Document No:	∭ M-131422	2-691-1 >>	ά ο «	<u>.</u>	
Guidelines:	Q QECD: 2	93 (1984);Devia	tion pot specifi	řed	
GLP/GEP:	, joës en and and a second				
		**			

Executive Summary:

The aim of the study was to determine the active effects of metabolite AE F092944 (2-amino-4,6dimethoxypyrimidine, metabolite of mesosulfuton-methyl; code: AE F092944 00 ZD99 0001; further code: Hoe 092944; purity >99 (9%) to rainbox trout (Oncorhynchus mykiss).

Oncorhynchus mykiss (5 months of) were exposed in a static system over a period of 96 hours to nominal concentrations of 8, 32, 56, 100, 180, 320, 560, and 1000 mg/L. In addition a water control was tested.

Mortality and sublethal behavioural effects were used to determine the endpoints. Based on analytical findings the piological endpoints are reported as nominal figures. The 96-hour-LC₅₀ was 254 mg/L (95%) confidence limits 202 - 317 mg/L), the 96-hour-NOEC was determined to be 100 mg/L.



Materials and Methods:

Test item: Hoe 092944 – substance, technical (synonym: AE F092944); identification code 092944 00 ZD99 0001; common name: 2-amino-4,6-dimethoxypyrimidine; analysed purity: w/w; analytical certificate No.: AZ 04888.

Oncorhynchus mykiss (5 months old) were exposed to AE F092944 in a static system over a period of 96 hours. Nominal concentrations were 18, 32, 56, 100, 280, 320, 560, and 1000 mg/L. In addition a water control was tested. Each vessel (stainless steel tanks; 300 L) seved as one replicate filled with 200 L Test water was a well aerated water mixture of 80% filtered tap water and 40% deponized water passed through sand and activated charcoal filters to fishes were used per replicate Length of fishes at test start was 5.83 cm (mean of ten fishes). Body weight of fishes at test start was 3.03 g (mean of ten fishes). The static biological loading was \$15 g/Lor 0.29 cm/L. The test was conducted with one replicate per treatment level.

For analytical verification of the test item concentrations samples were taken at days 0,2 and a from systems exposed to concentration of 18, 100 and High-performance ້10069√mg/ໄ≿້ liquid chromatography (HPLC) was used as analorical method.

eptember Ø,

Dates of experimental wor

Results:

Validity Criteria: The validity criterion of control mortality less the fulfilled. The validity criterion of oxygen saturation above 60% is fulfilled.

Analytical findings Biological results are reported as nominal. Derailed malytical resplits are presented in the following table:

Nominal test comentrations		© 100 mg/L	1000 mg/L
Nominal a.i. (mg/L)		9 9	990
Day 0	8.012		494.1
Day 2	F18.25 -	104.4	879.8
Day 4 🖉 🔆	17,029	102.5	
Mean a.i.	28.07	85.25	686.95
% fecovery day 0	× %101.6×	49.3	49.9
% recovery day	102.5	105.5	88.9
% recovery day 4	2 ,00.6	103.5	
% recovery mean	¥101.4	86.1	69.4

Nominal and measured concentrations of AE F092944 Table CA 8.2.1- 7: ~


Biological findings:

Mortality was observ	red as listed belo	OW.			
Table CA 8.2.1- 8:	Effect of AE l	F092944 on morta	ality of <i>Oncorhyn</i>	chus mykiss	
Exposure time	24 h	48 h	72 h	- O	96 h 👋 √ 🌾
Test level mg / L	no. of dead	no. of dead	no. of dead	no of dead	S dead
Control	0	0	0	<u>کې</u> 0	× ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
18	0	0	¥ 0	Q 0 (
32	0	0		0	
56	0	0 1	0 %	⊳° 0 √	
100	0	0 0	0 🔊		
180	0	0 炎	6° br ×	j _n g jo	[×] × 10 ×
320	5	60°		~~ 8 ~	2 80 0
560	10	A10 0	2 10 Q	4 1 0	
1000	10				100

Biological endpoints derived:

From the results presented above the following biological energy

96-hour-figures:

highest concentration with no effect):@1

confidence limits - 317 mg/L)

 \bigcirc

Conclusions:

Ê

The acute effect of AEV 092944 (2-amino-4, 6-dimenoxypyrimidine; AE 092944 00 ZD99 0001) on rainbow trout *Concornynchus mytoss*) can be quantified as a 96-hour-LC₅₀ of 254 mg/L (95% confidence limits 202 - 317 mg/L). The highest concentration with no observed mortality and no sublethal behavioural effects can be septo 100 mg/L

Long-term and chronic toxicity to fish CA 8.2.2

One chronic study on Rainbox troug was performed. The maximum tested dose level was 32 mg a.s./L. No relevant treatment related effects were observed at the maximum dose level, resulting in a NOEC of 32 mg a.s./L. Details of the story are provided in the following table.

Chronic toxicity data of mesosulfuron-methyl to fish presented in this chapter Table CA 8.2.2- 1:

Test species	, s	Test system	auration	Endpoi [mg as/	nt L]	Reference
Oncorhynchus y (rainbow troug)	ykiss	Oronic ²	28 d	NOEC	32	et al., 2000 M-187567-01-1 KCA 8.2.2 /01

Bold letters: Values considered relevant for risk assessment in the MCP document



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Report:	;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;
Title:	Effects on juvenile growth of rainbow trout (Oncorhynchus mykiss) in a 28 days st
	renewal system AE F130060 substance, technical Code: AE F130060 00 1C95 00 7
Report No:	C004237
Document No:	M-187567-01-1
Guidelines:	ISO: 10229; OECD: Draft, No. 204; Deviation not specified
GLP/GEP:	yes A O ^y X ^y Q
Endpoint accordin	ng to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):
Study summary	and RMS evaluation copied from the original Monography
Reference:	
☐ Test guideline: (Nov. 1994), IS	SO 10229
GLP complian	
Methods: The trout was asses months old at t test water was 0.32, 1, 1.32, 1 were recorded of	effects of AE F13060, to hnical ubstate (puri 94.6° Ow/w) of growth of jurshile rainbow ssed in a static eneway system over 528-date exposed period. Fighwere approximately 2 the start of teasing. Exposure was performed fix 50 L Containers of which 1/Oof the volume of renewed daily. In each of these containers overly itsh were randomly allocated to 0 (control) 10 and 32 Ag/l (nominal). No treatment was replicated, Northing and Constation symptoms daily throughout the study and the growth rates are calculated of the test.
 Results: No mover the exposed fish for NOEC 28 d and the exposed fish for	ortory and no interaction ymptons were observed in fOn exposed to mesosulfuron-methyl in period the structure of the test fill ovas no statistically deterent in mesosulfuron-methyl in the yowth are in the control 22 mg s./l. MS): the study is a ceptral s
Further study in	in South of the superior of the second
more than \pm 1°C Concentronomic of	between charge berg drama for the end of the test species. f test ign were above 80% of nonfinal.
Analyses of test Analyses of test measured conc for fresh wa measured concen the result	substance concentrations which were based on AE F130060 revealed that mean trations over the type of opposure ranged from 92.1% to 107.8% of nominal values and range from 93.3% to 108.9% of nominal values for aged water. As all mean transferred water are sove 80% of nominal, nominal concentrations were used for reporting
Biological (Oding Normortably and The coordination was far above the	no intoxication symptoms of the fish were observed during the time of study. n of test substance lethal to 50% of the test animals (LC ₅₀) after 28 days test duration highest tested concentration of 32 mg/L.

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

At the start of the test, there was no signed test fish between the test concentrations	nificant difference (alp and the control. After	bha = 0.05) in length a r 28 days test duration th (± 27.9) approach	and weight of the the test fish@ad
was no significant difference (alpha = 0	.05) in weight and leng	gth of the test fire at t	he end of the test
compared to the control. Pseudo-specific growth rates for length	(growth rate based or	n individual end lengt	th and mean start
length) and relative increase in length	did not show any dif	ference of theatments	coopare to the
control. Pseudo-specific growth rate on the control	weight did not show ar	ny difference of treatm	Kuts campared to
The highest concentration of no observe	ed effects, NGC, (with	thout Piortality, interi	cation syme oms
effects on growth) was 32 mg/L.			
Table CA 8.2.2- 2: Endpoint (LC50)			
	O ^V Af@r 1 - 2vd	ays of F	A A s
LC ₅₀ [mg test substance/L] nominal			
Conclusions:			
In a static renewal system (method 920) technical Code: AE E130060 000 (29	D MSO to determine	the effort's of SEFL	(Question Control Cont
<i>mykiss</i>) the highest concentration of a	obraved greets	IOES (wibout corta	ality, intoxication
symptoms, effects on growth Sas 32 Ma		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	\bigcirc^{ν}
Table CA 8.2.2- 3: Summa Qtable			
Reference Followed Suidance	in force	Critical assessmed of t	he study / about its Reliability
M- OECD 204 197577	NA 5	, <mark>N/A</mark>	
01-1 C C C C C C C C C C C C C C C C C C	Appy 25		
KCA OFCD OF FIST OFCD N	215. ~ noné	Stark from day 19, the	e test water was
8.2.2 /01 Suvenile Growth		add@ional aerated in the	e treated tanks, due
		Selow 60%. The aeratic	on has not effected
ISO 6229 (A94) 510 102		the test substance analy N/A	ses. Study reliable.
CA 8.2.23 Fish carly life stage toxici	tytest		
One chronic study on early life stage of	posure with fathead r	ninnow was performe	d. The maximum
tested mean measured concentration	as 95 mg a.s./L. No	relevant treatment rel	ated effects were
observed at this maximum dose level, r	esulting in a NOEC of \mathbb{Q}	f 95 mg a.s./L. Detail	s of the study are
)		

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Test species	Test system	Test	Endpoint	Reference
		duration	[mg as/L]	
Pimephales promelas (fathead minnow)	Early Life Stage flow-through	32 d	NOEC 95	B004569 M-241475-01-1
Report:	a:	:2003@	₩ ₩ -241475-01.0 [%]	
Title:	Mesosulfuron - The To Early Life-Stage Expos	xicity to Eathe	ead Minnow Pimepha	les promelas) During an
Report No:	B004569	40		
Document No(s):	M-241475-01-1	K Q		
Guidelines:	USEPA (=EPA): FIFF	RA92-4, OPP	TS \$50.1400; Deviatio	on n@ specified 🔬 💡
GLP/GEP:	yes 🔎	1.0	V Q A	

Executive Summary

The aim of the study was to determine the effects of mesosulfuson-methyl (code: Af F13060; purity 96.7%) on fathead minnow (*Pimephales promelas*) embryos and arvae during continuos aqueous exposure.

Eggs and fry of *Pimephales promelas* were exposed in a flow through system over a period of 32 days to nominal concentrations of 6.3, 03, 25, 30 and 100 mg a.s./L (corresponding to analytically verified concentrations of 6.6, 10, 25, 46 and 95 mg as /L (77 to 110% of nominal). In addition a water control was tested.

Hatching rates, sublethal symptoms, survoval and growth (length and wet and dry weight) were used to determine the endpoints Based on analytical findings the biological endpoints are reported as mean measured figures. The overall NOEC was determined to be 95 mg a.s./L.

Materials and Methods.

Test material: Mesos difuror methyl, Synonym: AE F130060; Batch No.: AAIC00961, CAS No.: 208465-21-8; purit@96.7%

Fathead Minnow (*Ponephales promelas*) eggs starting at ≤ 24 hours old were exposed to mesosulfuron methyl (code AE £130060, purity 96.7%) in a flow through system over a period of 32 days. Test vessels were dosed via a proportional diluter with a renewal rate of 6.6 aquarium volumes per 24-hour period; 90% replacement time of approximately 8 hours. Nominal concentrations were 6.3, 13, 25, 50 and 100 me a.i./L in addition a dilution water control was tested. Each vessel (glass aquaria; 39 x 20 x 25 cm) served as one replicate containing legg cup(s) and filled with approximately 15 L well water 40 organisms were used per replicate (80 organisms per treatment level). Thinning of surplus alevin took place at day 4, the post-hatch phase started at day 4 (when no more than 10% unhatched viable embryos remained in any control or treatment level egg incubation cup). The dynamic biological loading did not exceed 0.14 g/L/day in any replicate exposure aquarium. The test was conducted with 2 replicates per treatment level.

During the post-hatch exposure period, observations of abnormal behavior, abnormal physical changes and were recorded daily. Larval survival was estimated at least twice weekly. At 28 days post-hatch exposure (test termination), the percentage of larval survival was determined.

For analytical verification of the test item concentrations and the control samples were taken at on days 0, 4, 11, 18, 25 and 32. Samples of the stock solution were also removed and analyzed on test day



0, 4, 11, 18, 25 and 32. High-performance liquid chromatography using ultraviolet detection (HPLC/UV) was used as analytical method.

Dates of in-life definitive exposure:

July 14, 2003 – August 15 2003

Results:

Validity Criteria

The overall survival of fertilised eggs in the controls was greater than the species-specific limits given in OECD 210 and OPPTS 850.1400. The oxygen saturation was above 60% (except some short-terms deviations). The water temperature did not differ by more than ± 1.5 °C between chambers or successive days. Concentrations of test item were within $\pm 20\%$ of nominal.

Analytical findings:

Analytical verification of test solutions revealed measured concentrations of 6.6,10, 25, 46 and 95 mg a.s./L (77 to 110% of the nominal) calculated as arithmetic mean Biological results are reported as mean measured. Detailed analytical results are presented in the following table:

		. v v	4	~ 7	(C)P	r.
Tabla CA 8 2 2 1 2.	nominal and	magging	annoantrations	of M F	F13MAGA	U
1 abic CA 0.2.2.1- 2.	пошпатану	a measureu	Concentrations	UNAL	T KJUUUU /	\sim
		S/ // O	// (C)			

Nominal	1	Meanmeas	sured cone	Ontration	(mg@.s./L)é ^y Ö	Mean (SD)	Percent of
Concentration	Day 0	Day 4	Day 🎼	Day 18	Day 25	Day 🕉 2		Nominal
(mg a.s./L)				Ĩ	0° 'Y			
Control	<0.88 %	<0.92	< <u>8</u> 3	€ [≪] 0.90€y	<0.84	×0.88	NACNA)	NA
6.3	6.2 ₆	6.6	l 6.2 Õ	, 72°,	€ 0.3 €	√ 7,1	6.6 (0.47)	110
13	100	Ø.5 🔊	, 10		©″10 [©]	tô [%]	لم (0.31)	77
25	24 24	§ 24)		26	° 25	26@	25 (0.80)	100
50	م 45 م	46	43 A	× 49×	A)5	©″ 49,5°	46 (2.4)	92
100	90	95 (9		\$ 95 ×	87	95 (3.2)	95

Biological findings: Larval survival, weight and size in the freatment levels were not statistically different from the respective figures of the control organisms.

	Table CA 8.2.2 🕭 3:	Effect of AE @330	066 on hatching	soccess and mortalit	y of Pimephales promelas
--	---------------------	-------------------	-----------------	----------------------	--------------------------

mean measured concentration (mg	mean survival at hatch 3%)	mean larval survaval at day 28	mean length (mm) at day 28 post-	mean dry weight (mg) at day 28
control	\$76 \$		30.3	81
6.6	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	73	30.7	83
10 🖉	15 0	85	30.0	80
25	A 678 V	83	30.4	81
46 🖉 🔬	85 ₁₀ ~C	86	31.4	90
ST OT		76	31.3	90

No sublethat behavioural changes were observed.

Biological endpoints derived:

From the results presented above the following biological endpoints can be derived:



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

NOEC (alevin survival day 4):	95 mg a.s./L
NOEC (fry survival day 32):	95 mg a.s./L
NOEC (percent hatch):	95 mg a.s./L
NOEC (growth in terms of length):	95 mg a.s./L
NOEC (growth in terms of weight):	95 mg a.s./L
NOEC (overall):	95 mg a.s./L

Conclusion:

The effect of mesosulfuron-methyl (AE F130060) on early life stages of fathead minnow Pimernal promelas) can be quantified as a no observed effect concentration of 95 mg a.s./L. The Lowest Maximum. Observed-Effect Concentration (LOEC) was 2095 mg a.s./L The geometric mean Acceptable-Toxicant Concentration (MATC) was determined wibe

CA 8.2.2.2 Fish full life cycle test

Sompound has no perential A fish full life cycle test with mesosulfaron-methyl is not traggered as for bioconcentration and is not persistent in water-sediment

CA 8.2.2.3 Bioconcentration in fish §

Due to the low Pow mesosulturon-methyl has no potential for bipeoncertration

m

Endocrine disrupting propertie CA 8.2.3

on endocrine discuption presented in Point CA 8.1.5 Based on the definition of the WHO/IPCS following results concerning relevant affverse effe of mesosulfuron-methyl on fish are presented below.

Fish

Population relevant effects of mesosphuron-methyl on fight were studied in an early life-stage test (ELS). No effects on embryocurvival at hatch or of survival and growth (wet weight, dry weight, and total length) of larvae at test termination were seen at the highest tested concentration of 95 mg/L.

No further testing is indicated to evaluate the indocrine disputer potential of mesosulfuron-methyl to fish.

Conclusion

There were no indications for adverse endocrine activity observed in fish. Therefore further special testing for endocrine disrupting behaviour is not warranted.

CA 8.2.4 te toxicit to aquatic invertebrates

Acute toxicity **(b)** Daphnia magna CA 8.2.4

For mesosulteron-methyl one acute study on Daphnia magna was performed. No mortality and no intext cation symptoms occurred at the tested dose level of 100 mg a.s./L, resulting in a NOEC of 100 mg a.s. \square and an EC₅₀ >100 mg a.s. /L.

For the metabolite AE F092944 one acute study on Daphnia magna was conducted. The tested dose level ranged from 10 to 560 mg/L, the determined EC_{50} was 233 mg/L.

Details of all studies are provided in the following table.



Test species	Test system	Test	Endpoint	Reference
Masasulfuran math	7]	duration	[mg as/L]	
Danhnia magna			/=	et 0 1998
(water flea)	static acute	48 h	EC ₅₀ >	M-186707-01-17 KCA©.2.4.401
AE F092944			Ŭ.	
Daphnia magna (water flea)	static acute	48	EC ₅₀ EC ³³	M-131582-01-1 KCA8.2.4.1/02
Bold letters: Values co	onsidered relevant for ri	isk assessmentoin	the DICP document	
Studies on mesosulfi	uron-methyl			
Report:	ü;		;	A-186797-01 ~ ^
Fitle:	Acute toxicity to wate F130060 00 1595 000	erflea (Dafrinia 1)	fogna) A F F130,60) sulfance Ochnical Code: AF
Report No:	C003741 😽 🥱	ý ý	<u> </u>	
Document No:	M-18670 01-1	"Ø Å		
Guidelines:	EU (= CC): 92/69 C	OECD: No.	202; USEPA (- @P.	A); E § 72-2, Deviation not
GLP/GEP:	ves 0			Š Z
Reference:	d O MS evaluation of	906 d frayh the 999b, Ø.4 Sent Golelines	Subsidiation E. se	aph: ries 72, §72-2 (1982), OECD
guideline no 202 GLP compliance:	784) and EU Stective	D/69 Annex Part	<mark>C: CÁ</mark> D S	
Methods: The ac waterflex exposed 200 g of test water control and test suit of daphnids was re	the target of the second secon	00600 technical contrains J pos 00 tg/l (terminal) ord is Orionised d the Orinit test co hrogonout the exp	substance, purity for oure was performed test substance, as a water. Ten daphnid oncentration was rep posure period.	94.6% w/w) was assessed in in 300 ml glass jars containing a limit test concentration. Both is were allocated randomly per peated 6 times. Immobilisation
Results: No offect mortality ver the could vestably he EC 048 h 000 r	An meanity we'reco lange concentration d ng a.s./] ; the didy is acceptable	rded at any of the tested, no concen	e concentrations test tration-effect relatio	ted. Because of the absence of onship, and therefore no LC50,
	1470-11			



Validity Criteria:

The validity criterion of control mortality less than 10% is fulfilled. The validity criterion of saturation above 60% is fulfilled.

Analytical findings:

Chemical analysis of the freshly prepared and aged (48 hours old) test solutions for AE indicated that actual exposure concentrations ranged from 97.4% to 102.7 at the start O the from 86.2% to 93.9% at the end. The mean measured concentrations over the time of exposure range nominal, nominal values based on 100 % purity of the test substance were used results.

Biological findings:

No immobilisation and no intoxication sy untreated control. 4 and Fafter 48 h Based on the absence of mortality an E effect relationship could not be plotted The concentration estimated to immediase 48 hours test duration was >100 mg/L.

6

The concentration without any observed effects NOE

Ø Table CA 8.2.4.1- 2: Endpoint () 50 value

 \bigcirc Ô

EC50 [mg test substance/L] normal

Conclusions: EUX dep min the effects of AE F130060: In a static-acute Skicity Oest (Interhod PPA [™]⊘EC \$ 95 00

0001 & Dapania magna (waterflea) the substance, technical, 🗞 \$13006 ode: ĂЕ concentration stim of to imobilize 50% of the test stimals (EC₅ after 48 hours test duration lay The high A concentration test with ut immobilization and without intoxication symptoms (NOEC. no observed effect concentration) after 48 cours of duration vary 100 mg/L.

and 48 hour

Table CA 8.2.4.1- 3 Summary tab ð

Ô

Reference Followed & Guidance Mifferences	Critical assessment of the study / Deviations / conclusion about its Reliability
M- 186707- M- 1984) M- 1984) M- 1984) M- M- 1984) M- 1984) M- 1986 M- 19	no deviations from current guideline
$\begin{array}{c c} 01-1 & \textcircled{O} & US EPA & \textcircled{O} & 72- \\ 2 & \swarrow & \textcircled{O} & \textcircled{O} & \textcircled{O} & \textcircled{O} & \swarrow \\ \end{array}$	N/A
KCAY 92/69/EWG, 62 Fot relevant) 0 N/A	N/A



Studies on the metabolites of mesosulfuron-methyl

AE E002044

AE F092944	abontes of mesosuraton metry:		
Report:	n; ;1993;M-131382-	01	e b
Title:	Hoe 092944 - substance, technical (Hoe 0929- magna (waterflea) in a Static -Acute Toxicity	14 00 ZD99 0001) Effec Test (method OECD)	t to Daphnia
Report No:	A50353	×,	
Document No:	M-131382-01-1		
Guidelines:	OECD: 202 (1984); Deviation not specified	Q. Q.	<u> </u>
GLP/GEP:	yes y		

Executive Summary:

The aim of the study was to determine 2-amino-4,6dimethoxypyrimidine; code: AE F092944 00 ZD99 0001 purity 99.0%, metabolite@f mesosulfuronmethyl) to Daphnia magna.

Daphnia magna (< 24 hour old neonates) were exposed in a static system over apperiod of 48 bours to nominal concentrations of 10, 18, 320 56, 100, 180, 320, and 560 mg/L corresponding to analytically verified concentrations of 100.4% In addition a water control and solvent control was tested. Immobilisation and sublethal behavioural effects were used to determine the endpoints. Based on analytical findings the biological endpoints are reported as norminal figures. The 40 hour-EC₅₀ was 223 mg/L (95% confidence limits 380 - 320 mg/L), the 48-hour-NOEC was determined to be 32 mg/L.

Materials and Methods:

Test item: Hoe 092944 z substance, technical (synonym: &E F092944); identification code: Hoe 092944 00 ZD99 0001; Common name. 2-amino-4;6-dimethoxypyrimidine; analysed purity: > 99 % w/w; analytical@ertificate No : AZ 048884

Daphnia magna (< 24 hour ord neonates) were exposed to AE \$092944 (2-amino-4,6-dimethoxypyrimidabe; code: AE f 0929 f 00 ZD99 0001; provide > 99.0% on a static system over a period of 48 hours. Nominal concentrations were 10, 68, 32, 56, 100, 180, 320, and 560 mg/L. In addition a water control and solvent control was dested Each dessel (glass jar; 300 mL) served as one replicate filled with 200 mL artificial mineral medium M4 (Elenger 1999), slightly modified. 10 daphnids were used per replicate biological loading rate was 20 mL/animal. The test was conducted with 2 replicates per treatment level. Immobilisation of dapanids intoxication symptoms and physical-chemical water parameters were assessed.

For analytical verification of the sest item consentrations samples were taken at 0 and 72 hours from 10 mg/L concentrations. High-performance Jiquid chromatography (HPLC) was used as analytical method.

erimental wor Dates of *exp*

November 10, 1992 – November 12, 1992

Results:

Validity Sriteria:

The validity criterion of control mortality less than 10% is fulfilled. The validity criterion of oxygen saturation above 60% is fulfilled. Analytical findings:



Analytical verification of test solutions revealed measured concentrations of 100.4% of nominal calculated as arithmetic mean. Biological results are reported as nominal. Detailed analytical results are presented in the following table:

Table CA 8.2.4.1- 4:	Nominal and measured concentrations of AE F092944
	i tommul unu meusul eu concenti utions of The Toyay II

Nominal	Concen-	Day 0	(New)	Day 2	(Old)	magan 🛇
Concen- tration	tration (mg/L)	Measured (mg a.i./L)	Percent Nominal	Measured (mg a.r./L)	Percent Nomenal	Measured (mg aû/L) Nominal
10 mg/L	9.9	9.849	98.5	10.237	102.4	10,043 100,4 0
				an		

Biological findings:

Observations on immobilisation and sublethal intoxication symptoms are listed as follows

Table CA 8.2.4.1- 5: Immobilization symptoms of Daphnia magnet

Nominal Test Concentration	💭 😽 Number of Immobilised Daphnids 🦧 🖉
mg/L	224 h. 27 485 ft. 27 485 ft. 27 28 10 20 20 20 20 20 20 20 20 20 20 20 20 20
Control	
Solvent control	
10	
18 🖉 🖉	
32 🔊 🔿	
56 🦻 🔬	
100 😓 🖉 🕯	
180	
	$\sqrt[3]{}$

No sublethat behavioural changes were abserved.

Biological endpoints derived. From the results presented above the following biological endpoints can be derived:

24-hour-figures:

247 mg/L (5% confidence) imits 215 - 283 mg/L)

48-hour-figures:

EC₅₀ 223 mg/L (95% confidence limits 180 - 320 mg/L)

Conclusions:

The acute effect of xE F092944 (2-amine-4,6-dimethoxypyrimidine; AE F092944 00 ZD99 0001) on *Daphnia magna* can be quantified as a 48-hour-EC₅₀ of 223 mg/L (95% confidence limits 180 - 320 mg/L). The highest concentration with no observed immobilisation and no sublethal behavioural effects can be set to 22 mg/L.

CA 8.2 $\mathcal{A}_{\mathcal{P}}^{\mathcal{P}}$ Acute toxicity to an additional aquatic invertebrate species

One acute study on *Mysidopsis bahia* was performed. No mortality or sublethal effects were observed at the concentration of 100 mg/L, resulting in a NOEC of 100 mg/L and a $LC_{50} > 100$ mg/L.

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Details of the study are provided in the following table.

Table CA 8.2.4.2- 1:	Acute toxicity data of mesosulfuron-methyl to Mysidopsis bahia presented in this	Ş
chapter		U

					())		
Test organism	Test system	Test duration	Endpoint	: [mg/L]	Reference		
<i>Mysidopsis bahia</i> (mysid shrimp)	static acute	96 h	LC ₅₀ NOEC	>100 100	et al. M-238811- KCA 8.2.4	, 2000 ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° °	
			T.				Ş

Report:	<u>KCA 8.2.4.2 /01;</u> $2006M-238811-06$
Title:	96 Hour Acute Toxicity to the Mysid Shring, Mysidopsis bahia, in a Static System
	AE F130060 Technical 95% w/ w/
Report No:	B003158
Document No(s):	M-238811-01-1
Guidelines:	USEPA (=EPA): 72,3; Deviation not specified
GLP/GEP:	yes a way of the second

Executive Summary:

The aim of the study was to determine the acute toxicity of necessarillaron-methyle (AE F130060, technical; code: AE F13006000 1C95 0000, purity: > 95.7%) to the mysid shrimp, *Mysidopsis bahia* Molenock.

Juvenile mysids (< 24 hour old neonates) were exposed in triplicate to nominal concentrations of 0 mg/L (control sample) and 100 mg/L of the test substance synthetic seawater for a 96-hour period. Results of analysis (evealed that jest item concentration was 111 % of nominal over the course of the study. All treatments had 10 mysids per test vessel (i.e., 30 mysids per treatment level). Test solutions were not renewed.

Mortality and Sublethal behavioral effects were used to determine the endpoints. The 96-hour LC_{50} of AE F130060 technical to mysic shrintly could not be determined under the conditions of this study, and is greater than 100 mg/b. The no observed effect concentration (NOEC) was 100 mg/L. The lowest observed effect concentration (LOEC) could not be determined under the conditions of this study.

Materials and Methods:

Test item AE F130060 – technical substance, Code No.: AE F130060 00 1C95 0001; Batch No.: Pfl. 35316; Sample No.: ZBA806; Analysed purity: >95.7 % w/w; analytical certificate No.: AZ 08063.

Juvenile mysids (\leq 24 hour old neonates) were exposed in triplicate to nominal concentrations of 100 mg/L of the test substance in synthetic seawater (mean temperature of 25.5°C) for a 96-hour period. In addition control treatments of dilution water were tested in triplicate. Each vessel (Pyrex[®] beaker, 1 Liter) served as one replicate, fulled with approx. 800 mL of solution. 10 mysids were tested for each replicate i.e. 30 organisms were tested for each treatment level. Mysids were fed concentrated *Artenna naupfit* twice daily, and the test solutions were not aerated during the study. Observations of motality and for abnormal appearance and behavior were performed at 3, 6, 24, 48, 72, and 96 hours (± 1 hour). Physico-chemical water parameters were also assessed.

Samples of the test solutions from each test chamber were taken at study initiation and at study termination. All samples were analyzed for AE F130060 by reverse-phase High Performance Liquid Chromatography with ultraviolet detection (HPLC/UV) under isocratic conditions.



Test methodology was in agreement with USEPA 72-3 guidelines.

Dates of experimental work: June 16, 2000 – June 20, 2000

Results:

Analytical findings:

Results of analyses revealed that the AE F130060 concentration was 111% of nominal over the course of the study. There were no AE F130060 residues found in the dilution water or control samples greater than the limit of quantitation (5.0 mg/L). At toxicity values were calculated based on the nominal concentrations of test substance added to the test water.

Detailed analytical results are presented in the following tak

Table CA 8.2.4.2	-2: me	asured concentrations of AE F130060 4 5 5
~ I	Meası	ired AE F130060 concentrations (mg/L)
Sample Identification (mg/L)	16JUN00	20JUN09 (combined) % Nominal
Dilution water	<loq<sup>a</loq<sup>	COO A SLOO A OA O
Control	ND ^b	LOQ & BLOQ & &
100	110.3012	110,7519 110,53 (Std. Dev. = 0.35)
a Limit of	Quantitation	

Biological find

One mysid in the control was not found during observations a 96 hours and was thought to have been a victim of cannabilism. No additional mortality or sublet feets were observed in the control or 100 mg/ treatments during to study.

Biological endpoints derived:

The 96-hour LC50 of SE F150060 rechnical to mysid shrimp could not be determined under the conditions of this study, and is greater than 100 mg/L. The no observed effect concentration (NOEC) was 100 mg/L. The lowest observed effect concentration (LOEC) could not be determined under the conditions of this study.

Conclusions:

The 96-hour L@ of mesosulturon thethyld AE F130060) technical to the mysid shrimp, Mysidopsis bahia, could not be determined under the conditions of this study, and is greater than 100 mg/L. The no observed effect/concentration (NOSC) was 100 mg/L. The lowest observed effect concentration (LOEC) Sould not be determined under the conditions of this study.

Long-term and chronic toxicity to aquatic invertebrates

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Reproductive and development toxicity to Daphnia magna CA 8.2.5.1

One reproductive study on Daphnia magna was performed. The active substance showed no cheonic effects on the survival of the water flea at a concentration of 100 mg/L. The NOEC for reproduction was 32 mg/L. The lowest NOEC (adult dry weight) was 1.8 mg/L. Details of the study are provided on the following table. Ò

Table CA 8.2.5.1-1:	Reproductive toxicity of	lata of mesoscilfuron-m	ethylto Daph	nia magna presented in	
this ob	anton		Ø	$\mathcal{O} = \mathcal{O}'$	

t	nis chapter		× _Q	
Test species	Test system	Test duration	Endpoint [mg as/L]	Référence &
Daphnia magna (water flea)	chronic	21 d	NOECregoduction: 32 NOEGweighte 1.8	M497785-92-2 KGA 8.2.51/01

Bold letters: Value	s considered relevant for risk assessment in the MCP document details and the second
Report:	7; ; ; 2000; X =1977 5 9-02 , X
Title:	Effects on growth and reproduction of Daynnia magna (waterfley) AE 103006(Oubstance
	technical Code ONE F159060.001C950001 0 5 5 6
Report No:	C008780 4 10 17 0 0 5 5
Document No:	M-197785-02-2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Guidelines:	EU (=EFF): C2; OECD: No. 102; USEPA (=PA): E § 72-Deviation not specified
GLP/GEP:	yes the stand of the stand

Endpoint according to the Review Report for pesosyfturon methyl (SANCO/10298/2003-Final): ØNOE©(21 j℃

* This is most likely a typing error, should read d" for day

Study summa onograph:

. 2008780. 6 and 100 mg test item/L):

- ence
- Test guidelin bdivision E, series 72, §72-4 (1982), OECD guideline no 202 (198 ~C

GLP compliance:

- 060 (technic substance, purity = 94.6% w/w) on the reproduction of *Daphnia* Methods: Effects *persona* was determined under serve static conditions over an exposure period of 21 d. Effects on survival and growth were assessed with 0 - (introl-, 9), 18 2, 56 or 100 mg test substance/ml in deionised water. Each treatment was repeated three times with 5 darks ids each. Effects on reproduction and growth were investigated in tests vessels conjuning Q0 millipst water of similar mesosulfuron-methyl concentrations and in which 10 adult dapleds were indicated allocate (10 test vessels containing one daphnid per concentration). For all concentrations distributed was belowed area times a week. The mortality of adults and the number of young were Corde Three times performed before renewal of the test media.
- Roults go impositisation of adult females was observed in any replicates, neither with single females nor with forcales kept in groups of five individuals. The number of living juvenile after 21 days was significantly owgoor exposure of 56 and 100 mg/l, but no mortality was observed in the neonates in any treatment level. Regarding to the length of females at test termination, the NOEC was estimated below the lower test concentration (10 mg/l) for both test designs. Regarding to their weight at this time, the NOEC was below 10 mg/l when females were tested by groups of five while it was 56 mg/l when females were tested individually.

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Mesosulfuron-methyl

NOEC 21 d = 32 mg a.s./l, based on the effects on reproduction.

Since the NOEC could, on the best, be estimated to be below the lower tested concentration, and regardin whe contradictory results achieved for the weight of females depending on the test design, it was decided to cordu a new study using lower concentrations.

8.2.5.1/2

- □ Comments (RMS): The RMS agrees that the NOEC is <NOEC 21 d < 10 mg a.s./ based on the effect size (weight and length) of females. Nevertheless, this study is not considered as valid because SNO not be estimated.
- 2nd Test run (C009791, CE97/098-2; treatment groups: 0, 1.0, 1.8,
- **Reference**:
- **S** □ Test guideline: US-EPA Pesticide Assessment Guidel guideline no 202 (1984) and EU directive 92/6 Annex
- **GLP compliance**: Yes.
- and Hong te and Hong te asicity, serves 72. 2-4 (\$982). Www.Var the period of 2 1. Substant Hurtis **Methods:** Effects of AE F130060 (technical culstance, purity 94.6) w/w) in the production of *Oaphnia* magna was determined under semi-Oile consistions over an exposure period of 21%. Effects on servival and growth were assessed with 0 -control-, 1.0, 9.8, 3.2, 5.6, 10 or 18 by test orbitation in a pointset ovater. Each treatment was repeated three times with orbitation of each offect on reproducting ond growth were investigated in tests vessels containing 100 hill test water of similar meson futuror onethyl concernations and in which 10 adult daphnids were individually allocated there times a weet of the mortality of act is and be number of young were recorded three times per week before the receival of the test media. **Results:** No immole isation was experted in any embigation point in the test media. □ Methods: Effects of AE F130060 (technical withstance, puritive
- were recorded three times per week before the receival at the test media.
 Results: No immobilisation was observed in any opplicate, neitor in sult fertiles nor in neonates. The number of living the ends are each may of the second and their comulative number after 21 days did not differ from the control if any operative revel these data conform the NOEC of 32 (Q/I that was determined in the first study, block on the effects of mesosith ron-retently on the reproduction. Regarding to the length of females, but test datings and to the NOEC determination of 5.6 as/I. Regarding to the length of females, but test datings and to the NOEC determination of 5.6 as/I. Regarding to the length of females, but test datings and to the NOEC determination of 5.6 as/I. Regarding to their weight, the NOEC was estimated to 00 mg/I in females that were applied in Soups but no concentration-effect relationship could be achieved regarding to the weight of the test of the males that were applied in a significant effects were recorded at 3.2 and 5 (mg/I) with not \$4.8 mg/I and \$2 mg/I). NOEC 21 d = 18 nt as/I. Answer on the effects on approximation. NOEC 21 d = 5 (Oig as.s.) based on the effects of the significant effects.

Comments (RMIS): Die NGSC of J mg/(veterme/ed on ble basis of the effects induced on the weight of females the were kept (dividenty is masticing). Indeed, significant effects were recorded in two consecutive concentrations 3.2, 21 5, 60 ge/1, by Onot at 98 mg/t and 10 mg/t, they may not be considered as "false continue". Therefore, they OEC fould be set as 0.8 mg/t. NOIS 21 d = 18 may 5.4, bioled on the effects on production. NOEC 21 d = 1.8 Set a.s. Abased of the orders of the size (weight and length) of females.

were less wan o

Further study information supplementing the original Monograph summary :

Validity Criteria:

No unforeseen circumstances were observed which may have affected the quality or integrity study. In both projects the validity criteria for this type of study are fulfilled:

- No mortality occurred in the control.
- The mean number of living offspring in the controls produced per tomale surviv of the test was ≥ 60 .
- No ephippia were produced by any test individuar. Deviations of temperature were less than 1°C deviations of Q1
 - the test period.

Analytical findings:

in oro linit of ing ince concentration in test The analyses of freshly prepared water for YE FF 0060 esultation in the sub-gance concentrations ranging from 89.8% to 109.8% of nominal values with men values performentiation between 92.4% and 103.8% of nominal. Analyses of the distribution of the sub-gance concentrations ranging from 88.2% to 199.1% of nominal values with men values with mean values performentiation between 93.1% and 105.3% of nomino. As all analysed concentrations and all main measured once that one were bove 50% concentrations are used for reporting.

As in test run 1 (= CE97/098-5 no inmobilitation as observed in the adult for lales or the neonates. In project test run 2 CE97/098-5 the assessment at day 90 vas postponed to day 10 for logistic reasons. At day 10 est neonates are observed at any reatment level. Therefore, results from test run 2 (= CE97/098-2) fre in the will those from the first project. The OEC regarding immobilisation as reported in test on 1 (CCE97/098-1) are confirmed and need not to be corrected. Ŷ

Reproducti**ĝ**a

Reproduction continue cuntil the last essessment at day 2 of all tratment levels. Nevertheless, a close inspection of the ray data is cate that even in the control reproductive some individuals had terminated their reproductive poise at tay 12 aread their reproductive Quee at Vay 1 calread

Data on living jugeniles per surviving temate on each day of assessment and data on the cumulative number of living juve sets hold the osume on of comognetity of variance according to Bartlett's test (p>0.05) with exception of day 12. The number of juveniles at each day of assessment and the cumulative number at day 21 40 not define to m the control at any treatment level. Since all higher treatment devels within dest rol 2 (=CE97298-2) did not differ significantly from the control, the difference at 1 mg/L and be regarded as a Galse Ositive". Therefore, the NOEC of 32 mg/L regarding reproduction as reported in estimated in the control of the

Length & weigh

While data over production from both projects (i.e. test run 1 and 2) were non contradictory, data on length and verify were officing to interpret. In test run 1 (= CE97/098-1) no NOEC regarding length of single fem to and those kept in groups could be achieved. Regarding weight the NOEC was 56 mg V in cross of styled. Smales and below the lowest treatment level of 10 mg/L in case of females kept of groups. This led to the decision to repeat the study with lower treatment levels.

In sest rue 2 (= CE97/098-2) data on length and weight of females from groups just failed the assummer on of homogeneity, (p-level just below 0.05). Regarding the length of females in singled females as well as in those kept in groups, a NOEC of 18 mg/L was obtained. This is in contradiction to test run 1 (CE97/098-1) where the treatment levels of 10 and 18 mg/L differed significantly from the control.



Weight of single females did not differ from the control at treatment levels of and above 56 mg \mathcal{O} in \mathcal{O}
was obtained. The treatment level of 10 mg/L was also within the same DNCAN-group as the
control, while the treatment levels of 3.2 and 5.6 mg/L differed significantly. Wis indicates the lack of
a clear dose response and justifies to determine the NOEC regarding the final weight of femates as
10 mg/L. This is in line with the data from females of test run 2 (CE97/095-2) kept in groups $\sqrt{2}$
Moreover, it should be mentioned that the weights of fergoles from the control replicates in its truct
(CE97/098-1) was 0.95 mg \pm 0.12 (single) and 0.91 mg \Rightarrow 0.10 (group) while in tegral 29 E9 A98- 2) females were considerably begins: 1.23 mg \pm 0.10 (group) and 1.06 mg \pm 0.1% group)
2) remains were considerably nearrer. 1.25 mg = 0.10 single) and set mg = 0.10 single of the set of
The above mentioned differences in body weight wetween both project did no refe of the final lody
length. Mean body length in the controls was between 4.26 form (CP 7/09 2; goaps) and 4.5 mm
(CE97/098-1; singles). Regarding the final logth of tematos a NOEC of 18 mS/L as achieved from
CE97/098-2 is in contradiction to the results from CE97/098, when the NOEC was the lowest
of females is considered to be 5.6 mg/L. This covers the findings from bottomore watering the share regul
An overview on the endpoints (over both to run is given in the following to e.
Table CA 8.2.5.1- 2: Endpoints (No. C and OEC ofter 2 days do ming for such val, epicodiction and growth
Parameter V NOEC nominal Concernation
Immobilisation of adults 9 0 2 4 100 2 2 2 2 -
Immobilisation of juveniles
Reproduction of the average of the second se
Weight $\sqrt{2}$
Conclusive: L L L A A A A
In a 21 Say reproducion to (metsod EPA / SECD) to decrimine the effects of AE F130060;
substance, technical Sode XE F30060 0 1 5 0001 on in Mobilization, growth and reproduction
of Daphnia magnessivere investigated. A of O
waterfleas after $21 days according to the trace above is 50 mg/L. A lower NOEC of 1.8 mg/L, and the$
lowest observed effect coventration (LAEC) was 3. Ong/L can be derived from table 6.7.2 on page
41 of the Aginal report

Table CA 8.2.5.1- 3: Sommary table		
Reference Followed Studance St	Differences	Critical assessment of the study /
guidance currendy in face		Deviations / conclusion about its Reliability
M- OKCD Ng 211 OKSD No. St	neonate sex	no deviation from current guideline
197785- <mark>(2012)</mark> (2012)	to be	
	determined	
US A, E, § 72- (not EU-relevant)	N/A	N/A
$ \frac{\text{KCA}}{\text{KCA}} \neq \frac{3}{2} \frac{4}{82} \frac{982}{2} \neq \frac{3}{2} \neq \frac$		
8.2.5 101 0 2 2		
li a a		



CA 8.2.5.2 Reproductive and development toxicity to an additional aquatic invertebrate species

Mesosulfuron-methyl has no insecticidal activity and no relevant chronic effects on *Daphnia nargna* have been observed. No additional chronic testing with aquatic invertebrate species is beemed necessary.

CA 8.2.5.3 Development and emergence in Chironomus species

Mesosulfuron-methyl has no insecticidal activity, is not a growth regulator, and no relevant chronic effects on *Daphnia magna* have been observed. No additional chronic resting with aquatic invertebrate of species is deemed necessary.

CA 8.2.5.4 Sediment dwelling organisms 🔬

Mesosulfuron-methyl is highly water soluble and does not accumulate in the sediment. No testing with sediment dwelling organisms is triggered

CA 8.2.6 Effects on algal growth

Potential effects of mesosulfuron methyl on algal growth were investigated with bur different algae species, a green alga, a blue green alga and a freshwarer and a marine datom. The effect of mesosulfuron-methyl on algae in general was found moderate to low, the numeric endpoint relevant for risk assessment derived from the study on green alga *Pseudokirchneric la subcapitata*, E_rC_{50} for this species is > 0.29 mg as./L.

For the metabolites E F160459, E F124851, E F029095, AE F02944, and AE F147447, studies were performed with green algae. All of these components were found devoid of notable effect on algae, EC_{50} in each case was above the highest tested dose level ($EC_{50} \times 10$ to > 560 mg/L).

In addition tests on green algae were conducted on two components BCS-CO60720 and BCS-CO60721, supportive to a discussion of artifact detects in a water sediment study (cf. document MCA Section 7.2.2.3). Also these components were found devoid of notable effect on algae.

Table CA 8.2.6 T: Growth effect data of mesosalfuron methyl and its metabolites to algae presented

110					
Test species	Test system	Test	Endpoi	nt	Reference
		duration	[mg as/	L]	
Mesosulfuron-methy	A. T. O				
		O ^y			et al., 1998
	growth in bition	∕72 h /96 h	$E_r C_{50}^{(1)}$	> 0.29	M-143500-01-1
Pseudokirchnervella 🔬 🔪					KCA 8.2.6.1 /01
subcapitata			-		2015
(green algant S	arrowth inhibition	<mark>72 h</mark>	ErC ₅₀	<mark>3.99</mark>	M-516540-01-1
		<mark>96 h</mark>	F.C.	4 43	KCA 8.2.6.1 /09
	KJ ^V	<mark></mark>		1.15	
Navisula polículosto	×				et al., 2000
(distom)	growth inhibition	72 h /96 h	$E_r C_{50}$ ¹⁾	> 74.9	M-187975-01-1
C ^O					KCA 8.2.6.2 /01



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Test species	Test system	Test	Endpoi	nt	Reference
		duration	[mg as/	L]	
Anabaena flos-aquae	2	50.1			
(blue-green algae)		72 h	$E_r C_{50}$	5.6	et al., 200
	growth inhibition	n			M-238869-01
		96 h	ErC50 ¹⁾	4.1	KCA 8.2.6,2/02
Skeletonema costatur	n		8.		2001
(marine diatom)	growth inhibition	ⁿ 72 h /96 h	E_rC_{50}	£100	M-238809-04-1
(test	R	¥ 1-50	Ş	KCA 8.2.6.2703
AE F154851				y.	
Pseudokirchneriella			- Q	Ô,	, 2005
subcapitata	growth inhibition	n 🕸 h	$E_r C_{50}$	§8.0	M-255087-991
(green alga)		\$, D	° 5 %		K@x 8.2.6 /04 2
AE F160459		O ^v "Ø ^v		Ň	The state of the s
Pseudokirchneriella		A . Ø	V Q	,	Det al. 2000
subcapitata	growth inhibition	₫ 72 fb/96 k	$E_r C ^{1)}$	$\rightarrow 1000^{\circ}$	M-198314-01-1
(green alga)	Ű				KQA 8.2 6/1 /02 2
AE F099095	, ⁶				
Pseudokirchneriella	<u>Á</u>			Ô Ô	\$20 05
subcapitata	growth inhibition	n 🛛 🦪 72 h 💭	$E_r O_{30}^{(1)}$	[°] > 199	M-254084-01-1
(green alga)					CA 8 2.6.1 /05
AE F092944			a' 4		
Scenedesmus subspic	atus 🖉 🔍 🔊				, 1993
(green alga)	growth inhibition	n 🗳 72 h 🗡	$E_{50}^{(1)}$	> 560	Xv-131421-01-1
			NY O		KCA 8.2.6.1 /06
AE F147447				0 4	
Pseudokirchneriell		\sim			et al., 2000
subcapitata	growth inhibition	n 72 h/96 h	$DC_{50}^{(1)} >$	1.20	M-199529-01-1
(green alga)				<i>î</i> 1	KCA 8.2.6.1 /03
BCS-CO60720	<u>v</u> v		y K	1	
Pseudokirchneriella					, 2011
subcapituta	growth inhosition		$E_{r} \mathcal{C}_{50}^{(1)} \mathcal{O}^{(2)} >$	· 10.0	M-414950-01-1
(green arga)	γ $\dot{\gamma}$ $\dot{\omega}$ \dot{c}	<u>× </u>	L A		KCA 8.2.6.1 /07
BCS-CO60721			<i>*</i>		
Pseudokirchneriella	J S. D.			10.0	, 2011
subcapitata	© [♥] growth infibition		$E_{50}^{(1)} >$	· 10.0	M-415112-01-1
(green alga) «Ç		5 ^v á 1	*		KCA 8.2.6.1 /08



³ EFSAOPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290



CA 8.2.6.1 Effects on growth of green algae

For mesosulfuron-methyl and its degradates AE F154851, AE F160459, AE F0999095, AE F092944 AE F147447, BCS-CO60720 and BCS-CO60721 aquatic toxicity studies on green algae, Pseudokirchneriella subcapitata or Scenedesmus subspicatus, were performed. An overview of studies is provided in Table CA 8.2.6-1.

Studies on mesosulfuron-methyl

		¥. O	
Report:	j, ;	; ; ;1998	8;M-14 35 00-01 5
Title:	Algal growth inhibition (Pseudo	kuchneriella subapitata) .	AE F 90060 substance,
	technical 94.6 percent Code: A	F130060 00 1C95 000	
Report No:	A59843		
Document No:	M-143500-01-1		
Guidelines:	EU (=EEC): 92/69 C.3; ECD	201; SEPASEPAS	§ 120-2; Deviation not
	specified A		
GLP/GEP:	yes		

10298/2003-Final): Endpoint according to the Review Report for mesosulfuron method (S $E_{0}C_{50} = 0.20 \text{ mg/L}$

The new aquatic guidance document (EFSA 2019) regards entropints b relevant. Accordingly, the listed entropint front front the second points b based on growth rates as

In the present study, due to the low top dose level tested no definite value but only 'greater than' information for ErC5@could be obtained: E_rC_{50} 72/96 h > 0.29 mg/l/(based on measured concentrations) $E_r C_{50}$ 72/96 h > 0.32 mg/f (based on nominal concentrations). 60 \bigcirc

A definite information on ErC50 for green algae Pseudokirchneriella subcapitata could however be derived from a repeat test reported under point KCA 8.2.6 \$ /09 below, using a higher dosing regime. It is therefore propose to base the new List of Endboints value for green algae on this latter study: (73 h) = 399 mgA

Study summOry an the original Monograph:

🗶 guideline: 🐼-EPA nent Syndelines, Subdivision J, §123-2 (1982), OECD guideline no 201 (1984) and EU dire vive 9 Part[©]: C.3.

8.2.6.1/1.

GLP compliance

ALS F130060 (technical substance, purity = 94.6%) to the green algae species riella subcariona was determined under static conditions over an exposure period of 96 h. The test was consucted a 300 with flasks filled with 100 ml test water, containing 0 (control), 0.032, 0.056, 0.1, 0.18 0.32 lig test oubstation/l. The cell density was 10⁴ cells/ml at the start of the test. Each concentration was epeat of three times, and control was repeated 6 times. Cell density was measured in 5 ml aliquots on every 24 h un \mathfrak{P} the end of the test.

Results: based on measured concentrations: $E_r C_{50}$ 72/96 h > 0.29 mg/l



$NOE_{r}C$ 96 h = 0.018 mg/l $E_b C_{50}$ 72 h = 0.18 mg/l; 95% CI = [0.16 - 0.29]mg/l E_bC_{50} 96 h = 0.21 mg/l; 95% CI =[0.16 - 0.29]mg/l.

E_bC_{50} 72 h = 0.18 mg/l; 95% E_bC_{50} 96 h = 0.21 mg/l; 95%	CI =[0.16 - 0.29]mg/l CI =[0.16 - 0.29]mg/l.		Y
□ Comments (RMS): analytical r 0.1 mg/l at the end of the test per mesosulfuron-methyl on algal co growth inhibition rate (i.e. as alg responsible for effects is difficu especially since the a.s. is system study is acceptable.	neasurements showed a low re- iod (14.9% to 87.4%). This phen ells. This hypothesis is acceptal gal density increases). However, alt to estimate (cell adsored a ic. Endpoints should then father l	covery rate for the active substance up of omenon was explained by the adsorption of ble as the requery rate increases which the the fraction of the active upstang that is s. may no induce to bological effects, be expressed as nominal once pation of he	.C.
E_rC_{50} /2/96 h > 0.32 mg/l NOE _r C 96 h = 0.032 mg/l E_bC_{50} 72 h = 0.20 mg/l E_bC_{50} 96 h = 0.23 mg/l. Further study information supp	lementing the brigger I MyG	P P P P P P P P P P P P P P P P P P P	
Validity Criteria: The validity criterion of cell de	of ty increase >16x in the	Antrolis fulfiled of a final fulfiled of a fin	
The additional validity crippin coefficient of variation for sect 2) and coefficient of variation (criterion 3)] are fulfilled.	defined in the recent very byn-by-section specific gro of deerage specific grow	sign of β ECD guideone 201 [mean with rates in Sontroj $\leq 35\%$ (criterion th rates in Feplicate controls $\leq 7\%$	
Analytical finding. Analyses of fronly propared wat from 90.7 to 90.6% of normal v	er or AF 13000 resulted i lues. Analyses of age water	v Sest substance concentrations ranging 96 b Gor AE F130060 at experimental	
termination esulted in test subs The mean measured volues over 0.041, 0.084, 0.165, and 0.292 mg The validation response and chro desired application: The lower analyte solution preport for H	ance Ancendations ranging the time of exposure adjuged of . Meromean red values we atograms demonstore suffic concentration level is ab the PLC are within the linearity	from 14.9 to 87.4% of nominal values. 1 50m 54.8 to 91.6% and were 0.018, 2 e used for reporting the results. cient reliability of the method for the the LOQ and all concentrations of the y range. The repeatability precision is	
sufficient expressed by a Ocan of The accuracy is within 80-120 y recovery ample on day 4, theores The specificity of the method is above the LOQ were recorded we cample results and its identity	of Aplicate determination recovery work a C < 20 % ults of days were corrected b Afficient. In Preferences of subtraction of the blank va	ns < 20 % for all concentration levels. Due to a dilution failure preparing the y the recovery determined on day 0. the determined compound with matrix lue of the blank control water from the games ponding certified	
reference substance. On day 0 th Plest roalts are with results of the low nominal conce concentration. Therefore, the Ori	nin 80 0120 % of the nomin ntration levels of 32, 56 and ability of the two lowest conc	al concentration, whereas on day 4 the 1 100 μ g/L are < 80 % of the nominal entration levels is >1.5.	

The reason for the deficiencies was strong growth of algae adsorbing considerable amounts of the test subschice, which porticing you influenced the results of the lower concentration level.

Ś Biologcal findings:

Significant inhibition of growth (significance level of alpha = 0.05) was observed in mean measured concentrations of 0.041 mg/L and above. Therefore, the no observed effect concentration (NOEC)

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defined as no significant growth inhibition and n	o cell deform	nation was 0	.018 mg/L.	_ 0
Table CA 8.2.6.1-1: Endpoints (EC ₅₀ values)				
	After 72	<mark>2 hours</mark>	Sfter 9	6 hours
	EbC50	ErC50	60 C 50	ErC50
EC50 [mg/L] (mean measured)	<mark>0.18</mark>	<mark>>0.29</mark>	<u>4</u> 0.21	\$ <mark>70.29</mark>
95% confidence limits in µg/L, low	<mark>0.16</mark>	- _	<mark>ب 0.16</mark>	
95% confidence limits in µg/L, high	0.29	<mark>-</mark>	0.29 Č	l of st a
Calculation method selected: binomial probability	Å	Ó,×	Å	
	A	Q [*] or		y' [©] [©]
Conclusions:				
substance technical 94.6% Code: AE E130		1001 de Pro	Sokir Cher	iella subcapitata
(Green alga) after 72 hours test duration, the	E B way	.18 mg/L	5% confider	$\sim 10^{\circ}$ 0.1
0.29 mg/L) and after 96 hours test duration 0.2	‰mg/L~γ95%	confidence	lippis 0.16	– 0.28 mg/29 in
comparison with the untreated control.				L L
The concentration for a 50% reducton of so	wth based of	n a sompara	son of slope	of the growth
curves (E_rC_{50}) in comparison with the updreat	control a	TRES /2 ACR	96 Dours &	st duration was
The no observed effect concertratics (NO?) at St 96 0	ours Mefin	as a sig	wificant growth
inhibition and no cell deformation) was 0.218 m	g/L.	Û ^Y . Ø	O O	
	ñ o			
Table CA 8.2.6.1-2: Summer table				
Reference Followed	Sefferences	critical as	ssessmont of the	ne study /
guidance 2 ° ° currently in force	St St	Reliabilit	v	about its
MOECL No. 20 / 2015	adortional	n veviat	of from curre	nt guideline.; the
143500- (1989) (200% corr. 2011)	Alidity	Quidy fixe	ills the new O	ECD validity
	Criter	N/X		
KCA 2 (1982)				
8.2.6.1 /2 92/69/EW C.3 (not revent)		, <mark>©/A</mark>		
	<u>}</u>	S.		
		,		
A repeat study on growth infibilition of green alog	Pseudokir	chneriella si	uhcanitata [K	CA 8 2 6 1 /09]

was conducted upon request of a countreauthority, to overcome concern over the analytical detect of a small amount of test item in control samples of the previous study KCA 8.2.6.1 /01 [cf. Table 6.2 of original teport].

Testing in the repeat study included higher top dose levels to enable the determination of a definite resung in the repeat study included higher top dose levels to enable the determination of a definite value for the risk assessment relevant parameter ErC50, where the dosing regime of the previous experiment allowed only for the derivation of a 'greater than' figure.





Mesosulfuron-methyl

Report:	k; ; ; 2015;M-516540-01
Title:	Pseudokirchneriella subcapitata growth inhibition test with mesosulfuron-methyl
Report No:	EBMMN130
Document No:	M-516540-01-1
Guidelines:	EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009 OCSPP Guideline
	850.4500: Algal Toxicity (January 2012);not specified A
GLP/GE P:	yes

Executive Summary:

The aim of this study was to determine the influence of the test item on exponentially growing populations of *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC, for growth rate of algae biomass (cells per volume). Algae were exposed in a chronic multigeneration test system for 72 hours with a prolongation to 96 hours to in order to cover OECD and OCSPP guideline under static exposure conditions to nominal concentrations of 0.143, 0.458, 1.46, 4.69 and 15.0 mg a.s./c. in comparison to control. Four replicate vessels per test level and six replicate vessels for the control were used. Cell numbers per volume fas as surrogate for biomass per volume) were estimated photometrically at day 1, 2, 3 and 4 of the exposure period. To detect possible alterations in algae cells that might influence extinction measurements, such as unusual cell size, pooled samples were examined under a microscope Based on analytical findings, the biological endpoints are reported as nominal figures. After 72 hours the E_rC_{50} for measuremental indings, the biological endpoints are reported as 3.99 mg a.s./L (95 % CI: 3.60 – 4.44 mg a.S./L) and the NOE₁C as 0.143 mg p.m./L

Material and methods:

Test item: mesosuffuron-methyl (tech.); Batch ID: EBME000144Sample description: TOX09287-01; Specification No. 102000013204; Purity: 97.4% www.

Pseudokirchneriella subcapitate (freshwater mieroalgae, formerly known as *Selenastrum capricorniuum*) were exposed in a chimic multigeneration test for 72 hours with a prolongation to 96 hours to in order to cover OPCD and OCSPP guideline under static exposure conditions to nominal concentrations of 0.043, 0.458, 1.46, 4.69 and 15.0 mg a.s./L in comparison to control. The test volume was 150 mL test medium per deplicate. 4 replicate vessels per test level and 6 replicate vessels per control were used during the test. The pH values ranged from 7.9 to 9.2 in the control replicates and the incubation temperature ranged from 22.3 °C to 23 J. °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 4.76 Klux (mean value). Quantitative amounts of mesosulfuron-methyl were measured in all treatment groups and in the control at test start, after 72 hours and test end (96 hours). HPLC was used as analytical method.

Dates of experimental works January 09,2015 to February 18, 2015

Results:

Validity criteria

The study conditions met all validity criteria, requested by the OECD guideline 201: Biomass increased to the control by a factor of at least 16 within the evaluation period (factor of 80.9). The mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35% (27.4%). The percent coefficient of variation of the average growth rate in each control replicate did not exceed 7% (0.7%).



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For the test to be valid according to OCSPP Guideline No. 850.4500, Biomass increased in the control exponentially by a factor of at least 100 within the 96 hours test (factor of 248.8). The coefficient of variation for mean control yield at day 4 did not exceed 15% (4.5%). The percent coefficient of variation for average specific growth rate of controls at test termination did not exceed 15% (

Analytical findings:

The analytical findings of mesosulfuron-methyl in the treatment levels found on day 0 were 99.3 % is 109 % of nominal (average 104 %). After 72 hours analytical findings of 96.7 % to 408 % of nominal (average 105 %) were found and after 96 hours analytical finding of 101 % to 107 b of nomina (average 105 %) were found. All results are based on nominal test concentrations of the test substan

					L.	20		. Ø	×		, Q	<u> </u>
Table: Sui	nmary o	f analytic	cal result	<mark>.S</mark>	(a	× ¢°	, P	*	O '	∂^` %		Y Y
Nominal					Actual	oncentre	tion (mg	mm /I		×,	4	
concentr					a a a a a a a a a a a a a a a a a a a			Ċ	<u>, '0'</u>	- A		, °
ation		<mark>0 ho</mark> i	urs	0	$A \sim$	() 72 h	ours 🚿	'.1	L.	<mark>96 h</mark> a	urs .	Ŵ.
[mg	Determ	nination	Avera	0/	Detery	nination	Averag		Determ	ination _	Ävera	<mark>%</mark>
p.m./L]	<mark>1.</mark>	<mark>2.</mark>	ge			43 .	°∕ ~e ∉	P ^v	x <mark>1.</mark> 0	[*] <mark>2.</mark>	້ <mark>g</mark> ເວົ້	<mark>/ 0</mark>
control	<0.00	<mark><0.00</mark>	<mark><0.00</mark>	,Ô [¥]	\$9.00	§ 6.00	\$ <mark><0.000</mark>	*	× <0.00	< 0.90	B.00	
	<mark>010</mark>	<mark>010</mark>	<mark>010</mark>	y =	" [©] " <mark>010</mark>	^w 010		Ö	CIO		≪ <mark>010</mark>	
0.143	0.152	0.153	0.153	107	0.153	0.154	ØØ\$54	£ 108	9.154	0.152	[≫] 0.153	<u>107</u>
<mark>0.458</mark>	<mark>0.493</mark>	0.501	0.497	109	0.492	00492	£0.492	3 107	0.49 2	0.492	0.492	107
<mark>1.46</mark>	1.52	1.52	×¥ <u>₽.</u> 52	2. <mark>104</mark>	₽ ¥.55	1.56 🔊	1.56	107	[₽] 1 <i>5</i> 4	1.54	1.54	105
<mark>4.69</mark>	<mark>4.82</mark>	<mark>4.87</mark> (ծ <mark>4.85</mark> Օ	ຶ <mark>103</mark> ຈັ	<mark>۶ 4.86</mark>	4.87 ⁰	4.87	~©0 4	Å 83	4.81	<mark>4.82</mark>	<u>103</u>
<mark>15.0</mark>	14.5	14.7	14.	<mark>97.3</mark>	12.6	A .4	0 <mark>14.5</mark>	[≫] 96. ∦ <mark>≹</mark> ∕	⁴ 15.2	[*] 15.1	<mark>15.2</mark>	<mark>101</mark>
		S.	Mean	<mark>∛104</mark>		\$ %	Mean	105	{\		Mean	<u>105</u>
		~~~ \	. 0		y ···	- N	(A)		_			

**Biological findin** Observations are listed as follo

# 

Nominal concentration	n	* . O 724h average spec , C 4 growth rates [day , C 5, 2 , C 7, 2 , C 7	cific Inhibition of average ys ⁻¹ ] specific growth rate [%]
control 🖓 🔒	۵ <mark>۵۵ - 800 م</mark> رکز ال	×	<mark>0.0</mark>
<b>0.14</b>	)* <u>^*</u> *88 000	<u> </u>	0.7
0.458	<mark>,                                    </mark>	<u>ک</u> 1.304	<mark>11.0*</mark>
<b>4</b> ,46	<b>254 000</b> s	2 <u>1.078</u>	<mark>26.4*</mark>
<b>4.69</b>	🧏 📿 <mark>63 000</mark> 🔬	<b>0.611</b>	<mark>58.3*</mark>
15.0	A 32 000 Y	°~~ 0.382	<mark>73.9*</mark>

Test pitiation with 10 000 cells/mL Ą, Ś

Significantly (a=0.05, one-sided smaller) reduced, based on Welch-t test for inhomogeneous variances with Bonferroni-Holm, adjustment



**Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

Nominal concentration	Cell number	72 h average specific	Inhibition of average
[mg a.s./L]	after 72 h	growth rates [days ⁻¹ ]	specific growth rate [%]
	(means) per mL	1.270	
control	2 488 000	1.379	
0.143	2 464 000	1.376	
0.458	1 899 000	1.312	<b>1</b>
<u>1.46</u>	872 000	<u> </u>	<b>19.0*</b>
<mark>4.69</mark>	<u>127 000</u>	<u> </u>	<u> </u>
<u>15.0</u>	31 000	<u>0.282</u>	<u> </u>
Test initiation with 10 000 ce	lls/mL		
* Significantly (α=0.05, one-s	sided smaller) reduced, bas	an Welch-t test for ignom	ogeneous variances with
Bonferroni-Holm adjustment			
	&,		
No morphological change	in algae was observed in	Any test concentration	O A A .
a manage and a manage			~ O ^V D ^V A
	L' L'A		
<b>Conclusions:</b>			
After 72 hours the E ₂ C ₅₀ fo	or mesosulforon-methyl	tech was determined as	3.99 mg @s /L (95 % CI
$P_{4}(0) = 4.44 \text{ mg a s} (I)$ and	the NOR $\alpha$ of $\alpha$		
5.00 - 4.44  mg a.s./L and	the NOF as 0.945 mg		
After 96 hours the $E_r C_{50}$ for	or mesosulturon-methyl	(teen.) was determined as	4.4.6 mg a.s./L (95 % CI:
4.16 - 4.72  mg a.s./L and	the OErCas 0.143 mg	p?m./L	U ON
~			L.
~			2 C
Studies on the metabolites	of presosulfuron-methyl		
Ő,			¥.
AE F154851			
		<u>in st of st</u>	
Report:		2005;M-255087-01	
fitle: Of Pseud	kokirchneriella subcapitata	- growth inhoition est with	AE F154851 00 1B96
<u></u>			
Report No: EBM	MX093		
Ocument No:	5087-01-1		
Guidelines: 🔬 Draf	Proposal for Opdating (	OECO Guideline 201: "Fres	hwater Alga and
	iobacteria, Growth Inhib	oition Tes <b>e'' (</b> Feb. 18 <u>,</u> 2004);1	none
GLP/GEP: yes		G S	
		) <u>"O"</u>	
Executive Summary: 🔊		ð	

The aim of the study was to determine the influence of AE F154851 (metabolite of mesosulfuronmethyl) on exponentially growing of the green algae Pseudokirchneriella subcapitata expressed as NOEC, LOEC and EG for growth rate of algal biomass (cells per volume). Cultures of Pseudokirchnervella subcapitota (feshwater microalgae) with an initial cell density of 10 000 cells/mL were exposed in a chronic multi-generation test for 3 days under static exposure conditions to the nominal concentration of 6.25, 12.2 25, 50 and 100 mg p.m. (pure metabolite)/L in comparison to an untreated control. Three replicate vessels per test level and six replicate vessels per control were used. Cell numbers per votume (as a surrogate for biomass per volume) were estimated photometrically at day 5/2 and 3 of the exposure period. To detect possible alterations in algae cells that might influence extinction measurements, such as unusual cell size, samples were examined under a microscope. The (0-72h) for the metabolite AE F154851 is 38.0 mg p.m./L based on the geometric mean of measured concentrations.



## **Materials and Methods:**

Test item: AE F154851 00 1B96 0001; Analytical ref.: 0107127; Batch No.: LOR 21029; Chemica code name: AE F154851; purity: 96.1 % w/w; certificate of analysis no.: AZ 09181.

Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as Selenastrum capricornutum) were exposed in a chronic multigeneration test for 3 tays under static exposure? conditions to the nominal concentrations of 6.25, 12.5, 2\$50 and 100 mg p.m. (pure metabolite)/[m comparison to control(s). The pH values ranged from 7.8 to 8.5 in the controls and the incubation temperature ranged from 22.2°C to 23.4°C (measured in an additional incubated as vessel) wer the whole period of testing at a continuous illumination of 6341 lux.
Quantitative amounts of AE F154851 were measured in all treatment groups and in the control(s) on day 0 and day 3 of the exposure period.
Dates of experimental work:
January 27, 2005 – May 30, 2005
Results:
<u>Validity Criteria:</u>
Test conditions met all validity criteria given by the mentioned guideline(s).
<u>Analytical findings:</u> whole period of testing at a continuous illumination of 6341 lux.

## Analytical findings:

ŕ The analytical findings of AE F154850 in the treatment levels found on day of where 64 to 81 % of nominal (average 72.22%). On day 32 analytical findings of 60 to 89 % of nominal (average 73.0 %) were found. All results are based on the geometric mean of measured test concentrations. Detailed analytical results are presented in the following table.

### Concentrations of AF F154851 in the test solutions at day 0 Table CA 8.2.6. - 1:

		Day 🖓 🕺 🔬	<u> </u>	
Nominal Concentration	Actual C	oncentration (mg AP	F154851/L)	
in mg p.m./L	8 A.			
	Determination	Determination	Average	%
Control	€0.0 <b>95</b> \$2 @	0<0.00562	< 0.00562	
6.25 🖗 🌧	338	2 4 CH	4.00	64
1200	^م ر مر 40.2 م	O [*] 00.2	10.2	81
235 0	16.05 0	15.9 گ	16.0	64
50	37.0	37.0	37.0	74
100	Q 79.4 S	مَحْ 79.1	79.3	79
			Mean	72.4
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	' x Q X	2		
L	ý sĩ Q			
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
	Õ			
× G A	S.			
	×			
c ^o '				
<b>V</b>				



Concentrations of AE F154851 in the test solutions at day 3								
Day 3								
Nominal Concentration	Actual Concentration (mg AE F154851/L)							
in mg p.m./L	1. Determination							
Control	< 0.00562	< 0.00562	< 0.00562	-				
6.25	4.74	4.69	4.71	35				
12.5	7.48	7.46	7.47	× 60				
25	18.6	8.0	JE 18.3 C	∑ 73©				
50	33.8	34.5	S 34.1 S	E S				
100	90.7	88.2	895	880 <u></u>				
			Aran 4	73.0				

**Biological findings:** 

Observations on growth rates are listed as follows:

### Effect of AE F154851 on growth mhibition of Eseudokirchneriella subcapitate Table CA 8.2.6.1-3:

Geometric mean concentration (mg p.m./L)	Cell number after 72 h (mean) per mL	(0-72h) Average specific growth rates 7 [day]	Inhibition of average specific growth rate (%)	Doubling time of algae cells
Control	669 000 ×	1699	<u> -</u> ~	Sec. 495
4.34	≪ <b>5</b> 26 000 ≈	1.321	£ \$.6	0.525
8.72	స్త 390 000 నా	@ [*] 1.221 ^{*0*}	~~12.7~~	0.568
17.1	َ [*] 192 000 [©]	\$ 0.9 <b>\$</b> 5 C	29,6	0.704
35.5	AT 000 00	0 <b>6</b> 579 0	\$ 51.5	1.021
84.2		\$9.443 ×	68.3	1.565

* test initiation with 10 000 colls/mL

A morphological change in agae was observed in test concentrations of 35.5 and 84.2 mg p.m./L.

## Conclusions:

The influence of AF F154851 (messosulfaron-methyl metabolite) on the growth of the green algae *Pseudokirchnerielle subcapitato* can be quantified as a (0-72h)-E_rC₅₀ of 38 mg p.m./L (95%) confidence limits 31.2 748.0 mg/L) based on the geometric mean of measured concentrations.

## AE F16045

Report: 🛇	,<;	· · · · · · · · · · · · · · · · · · ·	;2000;M-198314-01
Title: 🔍 🖌	Algaterowtoinhib	ision - Recudokirchner	iella subcapitata AE F160459 (metabolite of AE
· ¥	F100060) Substance	e, pur O ode: AE F16	0459 00 1B97 0001
Report No:	Ç01006		
Document No:	∠		
Guidelines: 🖉 🔬	EUSEEC): 92/68	C.3; OECD: 201; U	SEPA (=EPA): J § 123-2; Deviation not
	specified	8	
GLP/GRON:	Ayes o		
	S N		
		1.0 10	(1, 1) (0 ANICO (10000 (2002 $T', 1))$

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):  $E_bC_{50}$  (72h) = 92 mg/L.

The new aquatic guidance document (EFSA 2013) only regards endpoints based on growth rates as relevant. Accordingly, the listed endpoint should be revised to:

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

$E_r C_{50} > 100 \text{ mg/L}.$
Study summary and RMS evaluation copied from the original Monograph:
Comparison         2000d, 8.2.6.3.1/1.         Organization
□ Test guideline: US-EPA Pesticide Assessment Guidelines, Subdivision J, §12, (1982), OE (1982) guideline ne 201 (1984) and EU directive 92/69 Annex Part C: C 3
GLP compliance: Yes.
<ul> <li>Methods: The toxicity of AE F160459 (purity = 0.8%) to the green that supersisting the state of the end of t</li></ul>
Validity Critefia:
The validity criterion of cell deposity unreased low in the ontrol of fulfilled. The additional validity criteria connection for section-by-section specific growth rates (criterion 2) and coefficient of variation of average specific growth rates (criterion 3) are fulfilled.
Analytical findings: Analyses of Seshly Prepared water for $\Sigma$ F16,459 soulted in test substance concentrations ranging from 96.7Å to 103.2% of nonlinal values Analytes of aged water (96 h) for AE F160459 at experime tal termination resided in test substance concentrations ranging from 98.2% to 103.4% of nominal values. The case measured values over the time of exposure ranged from 98.8% to 102.8%. The core the mean measured exteent prome $\Sigma$ AE F160459 were within $\pm$ 20% of nominal at the start and the end of the study, $\Sigma$ effect concentrations were based on nominal initial test concentrations
Biological finding: Significant inhightion of group based on a comparison of areas under the growth curves (significance level of alpho = 0.(5) was observed at the highest tested concentration of 100 mg/L after 72 and 96 bars to duration. Somificant inhibition of specific growth rate based on a comparison of slopes of the growth curves (significance level of alpha = 0.05) was also observed in the highest tested concertation of 100 mg/L after 72 and 96 hours test duration.

72 hour- and 96 hour growth rates at 10 mg/L did not differ significantly from the control. At treatment levels between 18 and 56 mg/L a slight growth promotion was observed. A significant

**BAYER** Bayer CropScience Document MCA: Section 8 Ecotoxicological studies

Mesosulfuron-methyl

growth inh	ibition occurr	ed at 100	mg/L.				@.°	*
Table CA 8.2	2.6.1-3: Endp	oints (EC ₅₀	values)					Ş
			After 7	2 hours	4	Aft <mark>@</mark> 96 hou	irs 🧖 👗	"0"
			E _b C ₅₀	ErC50	E _b C5	S I	ErC3	)
	EC ₅₀ [mg/L]		<mark>92</mark>	>100	2		<mark>\$900</mark>	Ø
				Ĉs	L.	°' K		U'
Conclusion	18: the Induitation	Test (mes	the LEDA / OF					
In a Grow	n innibition	1  est (me	21100 EPA / UE	$CD \in EU$ to	kir knoriella	le enege of	Grad alg	k ^o ʻ
the nomina	al concentrat	ion of th	e test substance	hibiting t	he Frow a	ide res	alting ExCsoli	⊉` n
comparisor	n with the ur	ntreated c	control after $72^{\circ}$	and 96 hours	was and	98 mà te	st apostare/L	
respectivel	y.		<i>w</i>				N N	2
The nomin	nal concentra	ation of	test substance	iphroitine, the	e wowth an	d the rest	lting TrC50 i	<mark>a</mark>
comparisor	n with the unt	reated cor	ntrol after 2 and	1096 holles wa	s 🖗 100 mg te	sc substanc	e/L	
Therefore,	the no obser	ved adve	rse effect conce	ntración (NC)	AEC defined	as no sig	cant Sowt	h
inhibition a	ind no cell de	formation	n aft@96 bovrs v	was 56 mg/L.	* 0		Şa VO	
			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~				, L	
Table CA 8.2	2.6.1-4: Sumn	hary table					^≫	
Reference	Followed			L'éverence.	Corical as s	smort of the	study /	
	Buildance				Reliabyity			
M-	OECD No. 2	01 ⁰	CD No. 201	additional	no deviation	from & fren	t guideline.; the	
<mark>198314-</mark>	<mark>(1984)</mark>	, į 🗩	006 corr. 2641)	voidity	ctudy fulfills	the www.OE	CD validity	
<mark>01-1</mark>	US EPA	$\frac{123}{123}$	CELI-re Want	N/A		Ś		_
KCA	2 (198							
<mark>8.2.6.1 /02</mark>	92/60EW6	<mark>C.3</mark> <mark>Yn</mark>	ot clevant	A N				
	ð s	« ⁰	Ŭ Ý		Č.			
	ġ.	4 1 KI		TO DI				
AE F0990	n) _{(S}		ST ST	<u> </u>			
Report:		A	*:	;2005;M-254	084-01		5 00 1000	
Title:	Ps 00		deriella subcapitat	a - growth infi	bition test with	AE F09909	95 00 IB99	
Report No:		MMX092	2 60 3	<u> </u>				
Document N	o: M	-254984-0	197 - y ja					
Guidelines:		adr Propo	sal for C pdating	OECD Guide	line 201: "Fre	shwater Alg	ga and	
	, ⁷ Ca	anobacte	ria, Growth Jnhi	bition Test" (F	eb. 18, 2004);	none		
	ye	<u> </u>		<u>)</u>				
Executive	Summary:	ô, ô	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~					

The aim of this study was to determine the influence of AE F099095 (metabolite of mesosulfuronmethyl) on exponentially prowing *Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selengstrum (apriconutum*) expressed as NOEC; LOEC and EC_x for growth rate of algal biomass (cells per volume). The study was designed to meet OECD criteria. *Pseudokirchneriella subcapitata* were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nonunal concentrations of 6.25, 12.5, 25, 50 and 100 mg p.m.(pure metabolite)/L in comparison to an unreated control. Three replicate vessels per test level and six replicate vessels for the control were used.



Cell numbers per volume (as a surrogate for biomass per volume) were estimated photometrically at day 1, 2 and 3 of the exposure period. To detect possible cell deformations, samples were examined under a microscope. Based on analytical findings, the biological endpoints are reported as porninal figures. The (0 - 72 h)-E_rC₅₀ was > 100 mg p.m./L, the (0 - 72 h)-NOE_rC was determined to be 25 mg p.m./L.

Material and methods:

Test item. AE F099095 00 1B99 0001; Batch No.: KR363/364; party: 99.6 analysis-No.: AZ 10810; Analytical reference-No.: 0305473.

Pseudokirchneriella subcapitata (freshwater microalgae formerly known \ Selenastrum as capricornutum) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nominal concentrations of 6.25, 10.5, 25050 app 100 mg p.m. pure metabolite)/L in comparison to control(s). The pH values ranged from 7.7 to 8.5 in the controls and the neubation temperature ranged from 22.4°C to 23.4°C (measured) in an additional incubated glass vessel) over the whole period of testing at a continuou cillumination of 6610 lux. Quantitative amounts of AE F099095 were measured in all treatment groups and in the control(s) on day 0 and day 3 of the exposure period.

Dates of experimental w

Results:

Validity Criteria: criteria. nemfoned guidelige. The test conditions met all validity

Analytical finding The analytical findings of AE F@99095 in the reatment levels found on day 0 were 96 to 102 % of nominal (average 98.0 %). Operatory 3 analytical findings of 96 to 903 % of nominal (average 99.6 %) were found. All results are based on nominal test concentrations

Table CA 8.2.6.1-42 Boncentration, of AE 4099095 in the sest solutions at day 0					
Ô, Ĉ					
Nominal Concentration A Actual Concentration (mg AE F099095/L)					
in mg p.m./L		<u> </u>			
Č.	🖗 Determination	Determination	Average	%	
Control	9 .0110	<0.0110	< 0.0110		
6.25	6.00 S	5.92	5.99	96	
12.5		12.3	12.2	97	
25	 <!--</td--><td>25.4</td><td>25.4</td><td>102</td>	25.4	25.4	102	
	49.4 ₀	48.7	49.1	98	
A00 2	_Õ _ ≰ 97.Q	96.1	96.5	97	
			Mean	98.0	
	, Î				
	No.				



Day 5				
Nominal Concentration	Actual C	Concentration (mg AE	F099095/L)	
in mg p.m./L			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
	1.	2.	S	
	Determination	Determination	Average	
Control	< 0.0110	< 0.0110	<0.0110 . 0*	
6.25	6.14	¢232	6.23	
12.5	12.0	₹₹2.1	12.0	
25	25.0	24.9	25.Q	
50	51.8	¢ 50.7 ↔	″ <u>5</u> <u>1</u> © ~~	
100	98.6	99 2		

Concentrations of AE F099095 in the test solutions at day 3

Day 3

Table CA 8.2.6.1- 5:

Biological findings: Observations on growth rates are listed as follows:

Table CA 8.2.6.1- 6:	Inhibitory effects o	of AE/F099095		
Nominal initial	Cell Number	0-72h)-Average	Anhibition of S	Boubling time of
Concentration	after 722h	Specific Growth	Average Specific	algae cells
(mg p.m./L)	(means) per mL	Rates (days-1)	Growth Rate (%) (🖉 🔏 (days)
Control	8×1Q×000 °∽>	1.466		0.473
6.25	751 000	^{رم} الإطاعة الم	~ 18 Q	0.482
12.5	َدِّ \$\$06 000 دَرُّ	1.463	× × 0.2 × ×	0.474
25	788000	1.455 A	0.7∜″ న	v 0.476
50		1,028	× 45 ×	0.485
100	660 0 00	Ø 🔊 🖉	Q.7 🕎	0.497

test initiation with 1000 celk/mI

Conclusions: Conclusions: Co pure metabolite /L (based on opmina initial concentrations).

AE F 092944	
Report:	;1993;M ₇ ;31421-01
Title:	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to
.4	Scendesmos subspicatus (Freen alga) in a Growth Inhibition Test (method OECD)
Report No	A50395 N 01 N N
Document No:	<u>M</u> ² -13142 ³ ⁴ -01 _− 1
Guidelines: 🛛 💡	OECD: 201 (1984): Deviation not specified
GLP/GEP:	

Executive Summary:

The aim of the story was to determine the effects of AE F092944 (metabolite of mesosulfuron-methyl; code: A0 092944 00 ZD990001; further code: Hoe 092944; purity > 99.0%) to Scenedesmus subspicatus.

Cultures of Scenedesmus subspicatus with an initial cell density of 10 000 cells/mL were exposed in a static system over a period of 72 hours to nominal concentrations of 10, 18, 32, 56, 100, 180, 320, and 560 mg/L. In addition a water control and a solvent control were tested.

24, 48 and 72 hour growth rate based on cell density and visual assessment of potential cell deformations were used to determine the endpoints. Based on analytical findings the biological endpoints are reported as nominal figures. The 72-hour- E_rC_{50} was > 560 mg/L, the 72-hour-NOEC was determined to be 56 mg/L.

Materials and Methods:

Test material: Hoe 092944 technical (synonym: AE F092944); purity: > 99,0%, Code: Hee 0 ZD99 0001; Analytical certificate No.: AZ 04888;

Green alga (Scenedesmus subspicatus) was exposed to AE 092944 in a static system over a period of 72 hours. Nominal concentrations were 10, 18, 32, 55, 100, 180, 320, and 560 mg/L. In addition, a water control and a solvent control were tested. Each vessel (Erlenmeger flasks; 300 mL) served as one replicate filled with 100 mL test solution. Aftest initiation the cell density was 10 000 cells mL. The test was conducted with 3 replicates per treatmenfaevel. In the controls 6 replicates were tested. For analytical verification samples were taken at and and and a hours from all concentrations from test solutions with 18 mg/L. High-performance liquid chromatography (HPLC) was used a analytical method.

partimeters were assessed Growth rates, observation on cell abnormalities and physical as indicated below in the result section.

Dates of experimental worl

Results:

Validity criteria: ntrol is fulfiled. The validity criterion of cell density increase >16

Analytical findings

Analytical indings: Analytical vertication of test solutions rescaled measured concentrations of AE F092944, calculated as an arithmetic mean. Biological results are reported as nominal. Detailed analytical results are presented in the following table

Nominal	Concentra	Day	New)	Day 3	(Old)	М	ean
concentration	¢ tiqQ	Measured	Dercent O	Measured	Percent	Measured	Percent
~~	(mg/L) 🔊	D(mg∕a,j./L)	Nominal	(fing a.i./L)	Nominal	(mg a.i./L)	Nominal
18 mg/L	17.82	J7.5	98,2	l 17.11	96.0	17.31	97.1
Ő		Q.		1			

Nominal and measured concentrations of AE F092944 Table CA 8.2.6.1- 7:

Discretal tindings Biological findings



Table CA 8.2.6.1- 8: Ef	able CA 8.2.6.1-8: Effect of AE F092944 on growth-inhibition of <i>Scenedesmus subspicatus</i>						
Nominal treatment level	% inhibition according to mean area	% inhibition according to mean growth					
(mg/L)	under the growth curve after 72 h	rate after 72 h					
Control	-	- 8 6					
Solvent control	-0.02	2.5					
32	-1.9						
56	-3.6						
100	-7.4						
180	22.4	7.964					
320	37.4						
560	67.6						

concentrations equal to and higher After 48 hours test duration enlarged cells could be obser than 100 mg/L.

Biological endpoints derived:

From the results presented above the allowing biologi M

72-hour-figures (growth rate):

 EC_{50} - area under the growth curve. .∕ÅØ3 mg/Ľ 95% Sonfidence limes EC₅₀ - growth rate: 560 mg/I NOEC:

Conclusions:

The effect of AE F092944 on Scoredesma subspicatus can be quantified as 72-hour-ErC₅₀ of > 560 mg/L. The highest concentration with no observed growth inhibition and go cell deformations can be set to 56 mg/L. $\mathbb{E}_{50} = 403 \text{ mg/L}$

AE F14744

×~ .*			
Report:		;	;2000;M-199529-01
Title:	Algal growth	inhibiti 📭 - Pseu	okirchneriel subcapitata AE F147447 (metabolite of AE
	~Q F136960) sc	stance, echnical	Code AE F147447 00 1C93 0001
Report No:	СД09927 °		
Document No:	4Q -1995 39 -01	1-40 2	
Guidelines:	(EU (EEC)	%2/69,~ C .3; OE	D: 201; USEPA (=EPA): J § 123-2; Deviation not
\$	specified		
GLP/GEP	yes a		2×
~			

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):

$$\mathbb{E}_b \mathbb{C}_{50} \mathbb{Q}^{72h} = 92 \text{ mg/L}$$

The new aquatic guidance rocument (EFSÅ 2013) only regards endpoints based on growth rates as dingly, the listed endpoint should be revised to: relevant.

$$E_rC_{50} > 100 \text{ mg/L}.$$

evaluation copied from the original Monograph:

- rence
- Test guideline: US-EPA Pesticide Assessment Guidelines, Subdivision J, §123-2 (1982), OECD guideline no 201 (1984) and EU directive 92/69 Annex Part C: C.3.

2000e, 8.2.6.3.1/2.



GLP compliance: Yes.

- Methods: The toxicity of AE F147447 (technical substance, purity = 93.1%) to the green algae pecies *Pseudokirchneriella subcapitata* was determined under static conditions over an explosure period of \mathbb{Q}_0 h. To test was conducted in 300 ml flasks filled with 100 ml test water, containing 0 (cor \mathbb{Q}_0), 10, 18, 32, 36 as \mathbb{Q}_0 00 mg test substance/l. The cell density was 10⁴ cells/ml at the start of the test. Each concentration was three times, and control was repeated 6 times. Cell density was measured in 040 to 1 ml aliquate on sy Created Og until the end of the test.

Inclusion of the test
a. Results: After 72 h test duration, a significant growth tabibition was observed at the extent promoted and 100 mg/l, based on the results of both the area under the growth curve and the slope of the growth curve of these differences were not recorded after 96 h test duration. NOTE 72 h that the best to 2 mg/l Based to 100 mg/l, based on the results of both the area under the growth curve and the slope of the growth curve of these differences were not recorded after 96 h test duration. NOTE 72 h that the best to 2 mg/l Based to 100 mg/l, NOTE 72 h = 32 mg/l, NOTE 72 h = 32 mg/l, NOTE 72 h = 32 mg/l, NOTE 76 h = 100 mg/l, ECSO 72.96 h > 100 mg/l,

After 72 h test duration a securificant inhibition of growth based on a comparison of both the growth rates and the areas under the growth curves (somificance level of alpha = 0.05) was observed at the concentrations of 36 and 100 kg/L. After 96 h test duration no genificant inhibition of growth based on a comparison of both the growth rates and the areas under the growth curves (significance level of alpha = 0.05) was observed at any treatment of velocity of 100 mg/L the highest concentration tested.

There we, the obvious of the concentration (NOEC), defined as the concentration which had no sign Scant Gect of grov ty inhibition or cell morphology after 72 and 96 hours was 32 and 100 mg/L, respectively

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.2.6.1- 5: Endpoints (EC50 values)				0
	After 7	<mark>2 hours</mark>	After 9	6 hours
	<mark>ЕьС50</mark>	ErC50	EbC50	ErC5
EC ₅₀ [mg/L]	<mark>>100</mark>	<mark>>100</mark>	<mark>>00</mark>	<mark>>]@</mark>
			O,	
		J	A	
Conclusions:	Ś	Ś	, , , , , , , , , , , , , , , , , , ,	
In a Growth Inhibition Test (method EPA / O	ECD / 🔊	to determede	the effect	of Alof 147447;
substance, technical, Code: AE F147447 00 10	C93 0001 to	Pseud	neriella Sub	capiata Green O
alga) the nominal concentration of test substan	nce Chibitin	g the growth	and the re	sulting b C50
comparison with the untreated control after	72 and 96	hours' test of	lurat@n_w&	> 100 mg (st
substance/L.		D' Y		
The nominal concentration of test substants	inhighting	the growth	and the res	Sulting $E_r \mathfrak{C}_{50}$ in
comparison with the untreated control after	/2 and 96	hours test	ruration was	sy > 100-yng test
substance/L.		A.		
The no observed effect concentration (SQ)EC (S	yerined as no	Significant g	sowth uppild	ition and the cell
deformation after /2 and 96 hours ways2 and 10		eculery.		
Table CA 82.6.1. 6. Summany table			, S	ž Q
Pafarence Fallowed Cuidene				No other (
ruidance surreity in force	Dicterence		s concusion	a study /
		Relia	i là	yoour ns
M- OECD No. 2016 OOCD No 201	additional	no a viatio	Nom wheel	nt guideline.; the
199529- (1984) 🔊 J2006, corr. 20 🔊	v dity	study ful	Us the WW O	ECD validity
	O iteria	Ateria	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
US EPA \$ 123-0 (new U-re@vant)	Ś <mark>™∕A</mark> 💭		~~ "	
KCA 2 (1982) 4 . 0 . 5			Ø	
8.2.6.1 /03 92/6 2WG, C.3 (not relevant)	<u>NA</u> S		¥	
	× ò	Stat.		
BCS-CO60720				
	Ô ^v V			
Keport: Image: Comparison of the second se	MA14950	J-DV	th DCS COCO	720 limit toot
Report No: FEMMIL (NG V V			ui BC2-CO60	720 - fimit test
Document No:	s s			
Guidelines: O CECD Guideline 2014 "Fre	Water Alos	and Cyanobs	acteria. Grow	th Inhibition
Test March 23, 2006):none		and Cyanoba		
GLP/GEP® yes of O	, N			
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			

S. Executive Summary: methyl) on exponentially growing of the green algae Pseudokirchneriella subcapitata expressed as NOEC, LOSC and ECx for growth rate of algal biomass (cells per volume). The study was designed to meet OECD criteria. Cultures of Pseudokirchneriella subcapitata (freshwater microalgae) with an initial cell density of 10 000 cells/mL were exposed in a chronic multi-generation limit test for 3 days under static exposure conditions to the nominal concentration of 10.0 mg pure metabolite (p.m.)/L in comparison to an untreated control and a solvent control. Six replicate vessels per test level and control were used.

Cell numbers per volume (as a surrogate for biomass per volume) were estimated photometrically at day 1, 2 and 3 of the exposure period. To detect possible alterations in algae cells that might influence

extinction measurements, such as unusual cell size, samples were examined under a microscope. The (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)-E_rC₅₀ for the metabolite BCS-CO60720 was determined to be > 10.0 mg p.m./L and the (0-72h)72h)-NOE_rC was  $\geq$  10.0 mg p.m./L.

## **Materials and Methods:**

Test item: BCS-CO60720; Origin batch No.: SES 10689-26-2; Batch code: BCS-CO TOX-No.: 08551-00; Analysed purity: 98.3 % w/w; LIMS2No.: 10087553 analytical continuer no. 16515.

Pseudokirchneriella subcapitata (freshwater picroalgae, formerty known Selenastrum Pseudokirchneriella subcapitata (freshwater picroalgae, formerly known as Selenastrum capricornutum) were exposed in a chronic multigeneration test for 3 days under static exposure conditions to the nominal concentration of 40.0 mg pure metabolite (p.m.) in comparison to controls. The pH values ranged from 7.8 to 8.2 in the controls and the ocubation temperature ranged from 21.3°C to 22.3°C (measured in an additional incubated glass ressel) over the whole period of groups and in the control on testing at a continuous illumination of 7481 lux Quantitative amounts of BCS-CO60720 were measured in all day 0 and day 3 of the exposure period.

## Dates of experimental wor

## **Results:**

Validity Criteria: mentioned guideline(s) Test conditions met an validity criteria. giæen by 

## Analytical findings

The analytical findings of BCS-CO60720 in the treatment levels found on day 0 were 102 % of nominal. On day 3 analytical findings of 103% of nominal were found. All results are based on nominal test concentrations of the metabolite. Detailed analytical results are presented in the following table: 🖄

### Concentrations of BCS-CO60720 in the test solutions at day 0 Table CA 8.2.6.1-Ø

		Day 0 🔊		
Nominal Concentration Actual Concentration (mg BCS-CO60720/L)				
in mg p.m./L 🔗		<u> </u>		
je v v v v v v v v v v v v v v v v v v v	Determination	Determination	Average	%
Control	∞ ∞0.632	<i>© ≤</i> 0.632	< 0.632	
Solvent control	<0.63	≈ <0.632	< 0.632	
y 10.0 v		10.19	10.20	102

## Table CA 8.2.01-10 Concentrations of BCS-CO60720 in the test solutions at day 3

$\sim$ $\sim$ $\sim$ $\sim$ $\sim$ $\sim$ Day 3						
Nominal Concentration Actual Concentration (mg BCS-CO60720/L)						
	1.	2.	A	0/		
	Determination	Determination	Average	%0		
Control	< 0.632	< 0.632	< 0.632			
Solvent control	< 0.632	< 0.632	< 0.632			
10.0	10.25	10.31	10.28	103		



## **Biological findings:**

Observations on growth rates are listed as follows:

## Table CA 8.2.6.1-11: Effect of BCS-CO60720 on growth-inhibition of Pseudokir@neriella subcapitata

Nominal concentration [mg p.m./L]	Cell number after 72 h (mean) per mL	(0-72h) Average specific growth rates [day ⁻¹ ]	Sinhibition of average specific growth rate
control	741 000	گې 1.435 کې	× - × ×
solvent control	733 000	1.432	
pooled controls	737 000	↓ 1.4330 [♥]	× ~ ~ ~ ~
10.0	728 000	1.40%	0.3 0

* test initiation with 10 000 cells/mL

No morphological change in algae was observed in any test concentration

## **Conclusions:**

The influence of BCS-CO60720 on the growth of the green algae Bseudot dress fields albeap hata can be quantified as a (0-72h)- $E_rC_{50}$  of  $\gtrsim 10.0$  mg p.m. and the (0-2h)- $NOE_rC$  is  $\geq 10.0$  mg p.m./L.

## BCS-CO60721

<b>Report:</b>	;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;
Title:	Pseucokirch@riella@bcapi@ta growth inhibition test with DCS-CG60721 - limit test
Report No:	EBIMML043
Document No:	Au 4151 Ag-01-1 Q Q X X X X X
<b>Guidelines:</b>	OECD Guideline 2012 "Freshwater Alga and Cyanobacteria, Growth Inhibition
	Test (March 23, 2006); none , a g
GLP/GEP:	yes in the second secon

## Executive Summary?

The aim of the study was to determine the influence of BES-CO60721 (degradate of mesosulfuronmethyl) on exponentially growing of the green argae *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algar biomass (cells per volume). Cultures of *Pseudokirchneriella subcapitata* (freshwater microalgae) with an initial cell density of 10 000 cells/mL were exposed in a chronic multi-generation test for 3 days under static exposure conditions to the nominal concentration of 10.0 mg pure metabolite (p.m.)/L in comparison to an untreated control and a solvent control. Six replicate vessels per rest level and control were used.

Cell numbers per volume (as a surrogate for biomass per volume) were estimated photometrically at day 1 $\leq$ 2 and 3 of the exposure period. To detect possible alterations in algae cells that might influence extinction measurements such as unusual cells size, samples were examined under a microscope. The (0-72h)-E_rC₅₀ for the metabolite BCS-CO60721 was determined to be > 10.0 mg p.m./L and the (0-72h)-NOE_rC as  $\geq$  10.0 mg p.m./L.

## Materials and Methods:

Test frem: BCS-CC60721, Origin batch No.: SES 10798-12-3; Batch code: BCS-CO60721-01-01; analysed purity: 95.1 % W; analytical certificate no.: AZ 16765.

Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as Selenastrum capricornutum) were exposed in a chronic multigeneration test for 3 days under static exposure


conditions to the nominal concentration of 10.0 mg pure metabolite (p.m.)/L in comparison to controls. The pH values ranged from 7.8 to 8.3 in the controls and the incubation temperature ranged ______ from 21.4°C to 22.0°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8260 lux.

Quantitative amounts of BCS-CO60721 were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

## **Dates of experimental work:**

April 01, 2011 – May 18, 20

#### **Results:**

Validity Criteria:

Test conditions met all validity criteria, given by the mentioned guideline (s). 

e control on of the second of Analytical findings: The analytical findings of BCS-CO60721 in the treatment levels found on day 0 were 104% of nominal. On day 3 analytical findings of 103 % of nominal were found. All results are based on nominal test concentrations of the metabolite. Detailed analytical results are presented in the following table:

Table CA 8.2.6.1- 12:	Concentrations	of BCS-CQ6	0721 in the	test solutions at	t day 0

()		Day 0 👋	S Z Z	
Nominal Concentration 🔊	Actual So	ncentration (mg BCS	-CO60721/b0	
in mg p.m./L 🔬				
	[©] Determination	Determination	Average	%
Control 🖉 🖌		~0.52 [©]	<i>Q</i> <0.522	
Solvent control	<i>x</i> ≤0.522 <i>x</i> ×		<0.522	
1000	^م ن 4.0 ⁽¹⁾	× × 0.4	10.4	104
			Ø	

#### Concentrations of BCS CO60721 in the test solutions at day 3 Table CA **8.2**.6.1-13:

$\sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i=1}^{n} \sum_{i=1}^{n} \sum_{i=1}^{n} \sum_{i=1}^{n} \sum_{i$						
Nominal Concentration	🖌 🔬 Actual Co	ncentration (mg/BCS-	CO60721/L)			
in mg p.m. 🖓 🌷 🐴						
	Determination	20 Determination	Average	%		
Control 🖉 🔬	×0.522×	> \$0.522	< 0.522			
Solyent control	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<0.522	<0.522			
@*10.0 Ø	10/2	s 10.3	10.3	103		

Biological finding Observations on growth rates are listed as follows:

#### Effect of BCS-CQ60721 on growth-inhibition of Pseudokirchneriella subcapitata Table CA 8.2.6.1-1

Nominal concentration	Sell number after 72 h	(0-72h) Average	Inhibition of average
mg p.m./L]	O (mean) per mL	specific growth rates	specific growth rate
	N N	[day ⁻¹ ]	[%]
wintrol 🖓 🔪	800 000	1.460	-
solvent control	802 000	1.462	-
appoled controls	801 000	1.461	-
10.0	820 000	1.469	-0.5

* test initiation with 10 000 cells/mL

-% inhibition: increase in growth relative to the control

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

#### **Conclusions:**

The influence of BCS-CO60721 on the growth of the green algae Pseudokirchneriella subcapitato

The influence of BCS-CO60721 on the growth of the green argae *r seudoric chief relat superprivate call* be quantified as a (0-72h)- $E_rC_{50}$  of > 10.0 mg p.m./L and the (0-72h)-NOE is  $\geq$  10.0 mg p.m./d. **CA 8.2.6.2 Effects on growth of an additional algal species** For mesosulfuron-methyl, aquatic toxicity studies on three additional algal species, *Anabaena flog aquae*, *Navicula pelliculosa* and *Skeletonema constitum*, were performed

#### Studies on mesosulfuron-methyl

Report:	8; ; <b>42</b> ,000; <b>M</b> 87975-01
Title:	Algal growth inhibition - Navicul rellicutosa AF 130069 substance, technical rode: AE
	F130060 00 1C900001 4 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Report No:	C004457
Document No:	M-187975-00-1
Guidelines:	EU (=EE6): 92/65 EWC C.3; CCD: 201; USSPA (-SPA); O § 123-2; Deviation not
	specified 's a of the of the of the
GLP/GEP:	yes & D & g & Y & g

Study endpoints according to Monograph evaluation Point B.9.

100mg/l (norfunal) or > 74.9 mg/l (mean measured).

 $NOAE_{r}C 96 = 10$  mg/l  $E_{6}C_{50}$  96 h > 100 mg/l

not mentioned in the Res The endpoint from this staid iew Report for mesosulfuron-methyl (SANCO/10298/2003-Final).

**Monograph: Symmar** 

- Reference
- ubdivision J, §123-2 (1982), OECD guideline no Test guide

mnliance

0060 Oechnic substance, purity = 94.6%) to the diatom species Navicula **Methods**: The to *pelliculosa* was determined un er static conditions over an exposure period of 96 h. The test was conducted in 300 ml flaste filled with 106 ml tes water, Qintaining 0 (control), 10, 18, 32, 56 and 100 mg test substance/l. The cell orisity and 104 cells/m at the start of the test. Each concentration was repeated three times, and control was repeated 6 to res. Call dension was measured in 5 ml aliquots on every 24 h until the end of the test. Ø)

Streather to higher cell densities in comparison with the untreated control. Analytical its shared receivery rates below 80% at the end of the test period: from 75.5% to 79.3%. Endpoints suren Fre they also Expressed as corrected concentrations, using the overall recovery rate of 74.9% which orres and s to the lowest recovery rate that was recorded over the duration of the test.

C rC50 96 h > 100mg/l (nominal) or > 74.9 mg/l (mean measured).

NOAErC 96 h = 100 mg/l

EbC50 96 h > 100 mg/l

**Bayer CropScience Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

#### **Comments (RMS):** the study is acceptable.



## Table CA 8.2.6.2- 2: Summary table

	5			0
Reference	Followed	Guidance	Differences	Critical assessment of the study /
	guidance	currently in force		Deviations / conclusion about its 🔊 🚽
				Reliability
<mark>M-</mark>	OECD No. 201	OECD No. 201	additional	the study does of fulfill the not OEC
<mark>187975-</mark>	<mark>(1984)</mark>	(2006, corr. 2011)	validity	validity criteria validity cri
<mark>01-1</mark>			<mark>criteria</mark>	nevertheles considered to fovide seliable
			Ĉa	results synable for risk asvessmess. (see
KCA				explan we comment frow
8.2.6.2 /01	US EPA, J, § 123-	(not EU-relevant)	N/A	N/A CY J A A
	<mark>2 (1982)</mark>		.Ô	
	92/69/EWG, C.3	(not relevant)	A	
		la l	ĥ	

Comment on validity criteria: Algae studies performed before 2006 were technically not designed to optimally address the additional validity criteria set up in the revision of the DECD 201 Guideline version in 2006 [mean coefficient of variation for section-by-section specific growth rates in control  $\leq$ 35% (criterion 2) and coefficient of variation of average specific growth rates in replicate controls  $\leq$ 7% (criterion 3). Nevertheless they still can be scientifically robust and valid. One important issue is the sectional growth rate. This criterion is heavily influenced by the time of algae cell number measurement. As before 2006 this criterion did not exist, the relevance of checking the cell counts daily at the same time was not given. This is one reason why studies performed before 2006 frequently fail this criterion. Nevertheless, as long as the algae in the controls are still growing and expessure is given during the experiment the data are still delivering robust endpoints. This is even more the case as the old studies in most cases have been based on biomass related endpoints which in general are lower compared to growth rate related figures. Therefore these values represent a worst case and should be acceptable for the risk assessment.

The new Aquatic Buildance Document states as well that studies according to US guidelines can be used in the risk assessment. If this is the case, than old studies based on biomass values should be acceptable as well. For the present case of mesosulfaron-methyl this is oven more the case as the aquatic risk is clearly

For the present case of mesosulforon-methyl this is even more the case as the aquatic risk is clearly driven by aquatic macrophytes (Lempaceae). This study clearly indicates that mesosulfuron-methyl has no effect on *Navi an pelluculosa*.

Q		$\tilde{a} \sim \tilde{a}$	Â,	
Report:		j; Î;	;2	2001;M-238869-01
Title:	Effect to Anabae	ena flos-aquae (Bh	Green Alga) ii	n a Growth Inhibition Test, AE
	F130060 Sechni	ear, 95.7% w/w		
Report Xo:	₩\$00322			
Document No:	∭M-233869-01			
Guidelines:	OFCD: 2017, US	SERA (=ÊPA): 13	2-2;Deviation n	ot specified
GLP/GEP:	yes 🛴 (			

# Executive sommary:

The toxicity of mesosulturon methyl (AE F130060) technical to the blue-green alga, Anabaena flosaquae was assessed in a static system over a 96 hour exposure period.

Tripheate a gal cubures with an initial nominal cell count of approximately  $1.0 \times 10^4$  cells/mL were exposed to the nominal concentration of 0.5, 1.0, 2.0, 4.0, and 8.0 mg/L of the test substance (corresponding to mean measured concentrations of 0.55, 1.1, 2.1, 4.25, and 8.6 mg/L of the test substance) in Algal Assay Procedure (AAP) media for a 96-hour period. Six replicate algal cultures were cultured without test substance as the control treatment. Cell density of each culture was counted



under a microscope at 48, 72, and 96 hours. Average specific growth rate and biomass were both calculated at each timepoint. Inhibition of growth was calculated relative to the control group. Water samples of each treatment at test initiation and at test termination were analysed by High Performance Liquid Chromatography (HPLC) with ultraviolet detection (UV) for quantification of AE F130060. Based on analytical findings the biological endpoints are reported as normal figures. The  $E_{50}C_{50}$ (biomass) values for 72 and 96 hours were calculated as 2.8 mg/L and 24 mg/L, respectively. The  $E_rC_{50}$  (growth rate) values for 72 and 96 hours were calculated as 5.6 mg/L and 4.1 mg/L. The no observed effect concentration (NOEC) and lowest observed effect concentration (POECo baesd on biomass at 96 hours, were 1.0 mg/L and 2.0 mg/L, respectively.

#### **Materials and Methods:**

AE F120060 00/1C95 0001; Test material: AE F130060, technical; Batch bo .: Pf1 35316 Code , parity: 95.7% w/w; Certificate of analysis. Sample number: ZBA806, CAS number: 208465421-8 AZ 08063.

Triplicate algal cultures with an initial norminal cell count of approximately 1.0 x 104 cells/mL were exposed to the nominal concentration of 03, 1.0, 2.0, 4.0, and 8.0 mg/L of the test substance in Algal Assay Procedure (AAP) media for a 96 pour period. Six replosate algal cultures were cultured without test substance as the control treatment. The cell density (cells/mL) of each culture was counted under a microscope using a hemacytometer at 48,72, and 96 hours, average specific growth rate (rate of change in cell number with time and biomass (the productivity of the culture determined as area under the growth curves) were both calculated at each timepoint. Inhibition of growth was calculated relative to the control group.

Water samples for chemical analysis of each treatment were taken at test initiation (0 hours) and at test termination (96 bours). A test mitiation, samples were taken from the orginal parent stock solutions prior to the addition of alga. Samples addtest tormination were taken as composite samples and centrifuged at 1000 g for 10 minutes prior to analysis to remove alga and any undissolved particulates. All samples were analyzed by High Berformance Liquid Chromatography (HPLC) with ultraviolet detection (UV) for quantification of AE F130060. \$ 1

Test methodology was in agreement with DECD 201 and USEPA 123-2 guidelines.

Dates of experimentativork June 2, 2000 to Jose 16, 2000 Results: Analytical findings:

The method efficiency from fortified study metha with AE F130060 had a mean percent recovery of 111% (SD= 12.3%). The mean measured test concentrations for AE F130060 were 0.55, 1.1, 2.1, 4.25, and 8.6 mg/L (105 to 112% ) nominal). There were no residues of AE F130060 in the dilution water and control samples greater than the limit of quantitation (0.5 mg/L).

The measured concentration of XE F130060 indicated that the nominal concentration was achieved at test initiation and remained stable throughout the study. All toxicity values were calculated based on the nominal concentrations Detailed analytical results are presented in the following table:

L.



1 able CA 8.2.6.2- 1:	Nominal and measured concentrations of AE F 130060					
Sample identification	nominal concentration	measured concentrations (mg a.s./L)				
	(mg a.s./L)	day 0	day 4	mean	Combined percent of nominal	
Dilution water	0	<loq<sup>a</loq<sup>	<loq<sup>a</loq<sup>	<loq<sup>a</loq<sup>		
Control	0	<loq<sup>a</loq<sup>	<i>≽</i> LOQ ^a	$<$ L $OQ^{a}$	A RECORD AND	
0.5	0.5	0.5	<b>V</b> 0.6	Ø0.6	Č 120 × V	
1.0	1.0	1.0	الم الم الم	O [♥] 1.1	~ J10 ~ w	
2.0	2.0	1.9 🔬	2.3 Q	2.1	105 C C	
4.0	4.0	3.8 0	4.7~	_ <b>⊘</b> Ă.3		
8.0	8.0	7.8	60° 9,4° ×	8.60		
a LOO = Limit of Quar	ntitation (0.5 mg/L)	0 _ (		~07	O L A	

**Biological findings:** 

The control algal growth increased by factor of at 4east 16/from test initiation @ 96 hours. AP72 and 96 hours, the control group had average cell densities of \$ 97 x 104 and 2.34 x 10 cells/mL, respectively. The nominal concentrations of 0.5, 1.0, 29, 4.0, and 8, Omg/L and a 22 hour average cell densities of 8.67 x  $10^4$ , 8.37  $200^4$ , 6.4 x  $10^6$ , 3.6  $10^4$ , and 2.5 x  $10^4$  cells mL, respectively. The nominal concentrations of 0.5 1.0, 2.0, 4.6 and 8.0 mg/L had a 96 hour average cell densities of 3.08 x 10⁵, 2.37 x 10⁵, 1.29 x 10⁵, 5.3  $\infty$  10⁴, and 2 x  $20^4$  cells/mL, respectively. This it of biomass at 96 hours, relative to the control, ranged from 0.50 89%? Inhibition of specific growth rate at 96 hours, relative to the control ranged from 0 % 77%.

The No Observed Effect Concentration (COEC) and Lowest Observed Effect Concentration (LOEC) are presented in the following table:

Table CA 8.2.62-2: S NOFC and EOEC of AE B 30060 at different times of observation						
. Q	Specific Gro	wth Rate (µ)	🖉 Biomass – Area	Under Curve (A)		
Time	CNOEC &	LOEC	NOEC	LOEC		
(Hours)	(mg/L) 🔬	(mg/4)	(mg/L)	(mg/L)		
48	j 1.0 j	20 0	1.0	2.0		
72	2.0	¢ ~4.0 €	S 1.0	2.0		
96 🔊	l co' b° `sγ		1.0	2.0		
× A						

The ErCs@(Specifi	c Grow	vth Rate	) and	EbCor	(Area under	the Curve)	are	presented	in the	following
table:		.1 >>	$\searrow$	, S				-		_

0		
		. 1.66
	Ettoot estoontrotions of A F FI KIIIKII a	at dittarant times at absorvation
1 addie U.A. 0.2.0.2- J	INTELL CONCENTRALIONS OF ALL FISTORY	IL UITTELEITT TIMES OF ODSELVATION

Time (Hours)	A SEC 50 Tethod A	ErC ₅₀ (95% CL) (mg/L)	EbC50 (95% CL) (mg/L)
48	Nonlinear Regression	3.1 (2.2 to 4.4)	2.4 (1.5 to 3.8)
72 炎	Nonthear Regression	5.6 (4.8 to 6.6)	2.8 (2.1 to 3.7)
26 2	Nonlinear Regression	4.1 (3.6 to 4.6)	2.4 (1.8 to 3.1)
AY R	2. ~~		

## Conclusion;

The  $E_{\mathbb{P}}\mathbb{Q}_{0}^{\mathbb{P}}$  (biomass) values for 72 and 96 hours, as determined by nonlinear regression, were calculated as 2.8 mg/L (95% CL = 2.1 to 3.7 mg/L) and 2.4 mg/L (95% CL = 1.8 to 3.1 mg/L), respectively. The  $E_r C_{50}$  (growth rate) values for 72 and 96 hours, as determined by nonlinear regression, were calculated as 5.6 mg/L (95% CL = 4.8 to 6.6 mg/L) and 4.1 mg/L (95% CL = 3.6 to 4.6 mg/L), respectively. The no observed effect concentration (NOEC) and lowest observed effect concentration (LOEC), based on biomass (area under curve) at 96 hours, were 1.0 mg/L and 2.0 mg/L

		1	
Report:	• -	;2001;M-23 <b>8809-0</b> 1	
Title:	Effect to Skeletonema costatum (Mari	Diatom) in a Growth I	nhibition Test AE
	F130060 Technical 95.7% w/w	i Q	
Report No:	B003156	L.	
Document No(s):	M-238809-01-1	Q' e A	
Guidelines:	OECD: 201; USEPA (=EPA) 123-2	;Deviation not pecified	
GLP/GEP:	yes yes		

## **Executive Summary:**

Aim of this study was to determine the taxicity of mesosulfuren-metbyl (AE F130060) technical to the marine diatom, *Skeletonema costatum* in a static system over a 96 four exposure period. Triplicate diatom cultures with an initial nominal cell count of approximately  $10 \times 10^{4}$  cells/mL were exposed to the nominal concentration of 13, 22, 36, 60, and 100 mgC of the test substance in Marine Algal Assay (MAA) media for a 96-hour period (corresponding to mean measured concentrations of 12.25, 22.55, 37.25, 62.25, and 106.2 mga.s./L). In addition, six replicate cultures were tested as untreated control. At 24-hour intervals, the cell density of each culture was counted. Average specific growth rate and biomass were counted at each timepoint. Inhibition of growth was calculated relative to the control group. Based on analytical findings the biological endpoints are reported as nominal figures. The  $E_bC_{50}$  (values for 72 and 96 hours were calculated as 82 mg/L and 93 mg/L, respectively. The  $E_rC_{50}$  (growth rate) calues for 72 and 96 hours were both calculated as > 100 mg/L. The no observed effect concentration (NOEC) and lowest observed effect concentration (LOEC), based on biomass (area under curve) at 96 hours, were 36 mg/L and 60 mg/L, respectively.

## Materials and Methods:

Test material: AE F130060, technical; Batch No.: Pfl 35316; Code No.: AE F130060 00 1C95 0001; Sample No.: ZBA306; CAS No 208465-21-8, Purity. 95.7% w/w.

Triplicate dialom cultures (*Skeletorema costatum*) with an initial nominal cell count of approximately 1.0 x 10⁴ calls/mL were exposed to the nominal concentration of 13, 22, 36, 60, and 100 mg/L of AE F130060 in Marine Algal Asaay (MAA) for a 36-hour period. Six replicate diatom cultures were cultured without test substance as the control treatment. Each vessel (Erlenmeyer flasks; 250 mL) served as one replicate field with 100 mL MAA (Marine Algal Assay) nutrient medium. Cell density determinations were made on each flask at study initiation, 24, 48, 72, and 96 hours during the study. Average specific growth rate (rate of change in cell number with time) and biomass (the productivity of the culture determined as area under the growth curves) were both calculated at each timepoint. Inhibition of growth was calculated relative to the control group.

Water samples for chemical malysis of each treatment were taken at test initiation (0 hours) and at test termination (0 hours). At test initiation, samples were taken from the original parent stock solutions prior to the addition of diatoms. Samples at test termination were taken as composite samples and centrifuged at 1000 g for 10 minutes prior to analysis to remove diatoms and any undissolved particulates. All samples were analyzed by High Performance Liquid Chromatography (HPLC) with



ultraviolet detection (UV) for quantification of AE F130060. Test methodology was in agreement with OECD 201 and USEPA 123-2 guidelines.

#### Dates of experimental work: June 5, 2000 to June 9, 2000

#### **Results:**

#### Analytical findings:

The method efficiency from fortified study media with AE F130060 had a mean percent pecovery of 105% (SD = 7.8%). The mean measured test concentrations for AE 130060 were 12.25, 22.55 87.25 62.25, and 106.2 mg/L (94 to 106% of nominal). There were no residues of AE 130060 in the dilution water and control samples greater than the limit of quantitation (5.0 mg/L). The measured concentration of AE F130060 indicated that the nominal concentration was achieved at test initiation and remained stable throughout the study. All toxicity values were calculated based on the nominal concentrations. Detailed analytical results are presented in the following table:

# Table CA 8.2.6.2- 4: Analytically measured concentrations

Nominal concentration	2 Measured concentrations (mgR.s./L)					
(mg a.s./L)	Q05JUN00 (Eccsh)		A Measure	Combined percent		
Control	< LOQ	<loq q<="" td=""><td>ૢૢ૾ૢૢૢ૾૾ૼ૾ૢૢૺૺૺLOQ</td><td>Õ</td></loq>	ૢૢ૾ૢૢૢ૾૾ૼ૾ૢૢૺૺૺLOQ	Õ		
13		PI.7	12.25	§ 94%		
22 🔊	1 23 5	22. L	22,55 ~	103%		
36 🔬 🐇	\$ \$38 O	37,9	v Q7.75 ~	105%		
60 6	<u>62.2</u>	\$2.3	©62.25∜	104%		
100 5	2 1 <b>65</b> .7	¢106.6¢	Ly 106.45	106%		
LOQ = Limit of Quantitation (5.0 mg/L)	× «					

Biological findings:

Diatom cell numbers in the control increased by a factor of at least 16 from test initiation to 72 hours. At 72 and 96 hours, the control group had average cell densities of  $5.34 \times 10^5$  and  $7.31 \times 10^5$  cells/mL, respectively. The nominal concentrations of 13, 22, 36, 60, and 100 mg/L had a 72 hour average cell densities of  $5.48 \times 10^5$ ,  $5.74 \times 10^5$ ,  $5.65 \times 10^5$ ,  $4.23 \times 10^5$ , and  $1.94 \times 10^5$  cells/mL, respectively. Inhibition of biomass of 72 hours, relative to the control granged from 0 to 63%. Inhibition of specific growth rate at 72 hours, relative to the control granged from 0 to 25%. The nominal concentrations of 13, 22, 36, 60, and 100 mg/L had a 96 hours average cell densities of 7.26  $\times 10^5$ ,  $7.33 \times 10^5$ ,  $7.66 \times 10^5$ ,  $7.23 \times 10^5$ , and  $1.94 \times 10^5$  cells/mL, respectively. Inhibition of biomass at 72 hours, relative to the control granged from 0 to 25%. The nominal concentrations of 13, 22, 36, 60, and 100 mg/L had a 96 hour average cell densities of  $7.26 \times 10^5$ ,  $7.33 \times 10^5$ ,  $7.66 \times 10^5$ ,  $7.23 \times 10^5$ , and  $4.47 \times 10^5$  cells/mL, respectively. Inhibition of biomass at 96 hours, relative to the control granged from 0 to 25%. Inhibition of specific growth rate at 96 hours, relative to the control, ranged from 0 to 12%.

The No Observed Effect Concentration (NOPC) and Lowest Observed Effect Concentration (LOEC) are presented on the following table.



Table CA 8.2.6.2- 5:       NOEC and LOEC at different times of observation					
Time (hours)	Specific gro	wth rate (µ)	Biomass - Area under the curve		
	NOEC	LOEC	NOEC	LOPC	
	(mg a.s./L)	(mg a.s./L)	(mg a.s./	(mg a s./L)	
24	36	60	36	×60 , ~~	
48	36	60	<u>3</u> 6	\$ 60¢ a	
72	60	100	×36	x x	
96	60	198	<u>36</u>		

The  $E_rC_{50}$  (Specific Growth Rate) and  $E_bC_{50}$  (Area under the curve) are presented in the following table:

Table CA 8.2.0.2-0. Effect concentrations at unierent times of observation	
Time $E_{C_{50}} = E_{r}C_{50} + E_{r}C_{50$	$E_bC_{57}(95\% CL)$
24 Nontinear regression 78 (68 to 90)	66 ( <b>2</b> 4* to 81)
48 Nonlinear regression	78 (69 to 38)
72 $(Nonlinear regression)$ $(V > 100)$	\$2 (75 to 91)
96 Nontinear regression > 30	بَنْ (\$6 to 100)

#### **Conclusion:**

The  $E_bC_{50}$  (biomass) values for 52 and 96 hours, as determined by nonlinear regression, were calculated as 82 mg/L (95% CL = 760 to 95 mg/L) and 93 mg/L (95% CL = 86 to 100 mg/L), respectively. The  $E_r C_{59}$  (growth rate) values for 72 and 96 hours, as determined by nonlinear regression, were both calculated as 100 mg/L 95% 2L = unable to determine). The no observed effect concentration (NOEC) and lowest observed offect efficientration (LOEC), based on biomass (area under curve) at 96 hours, were 26 mg/L and 60 mg/L; Fespectively

# CA 8.2.7

Effects on aquatic macrophytes

For mesosulfuron methyl, toxicity studies on aquatic macrophytes clearly indicated vascular plant to represent the overall most sensitive group of aquatic organisms. To provide a thorough description of susceptibility on terms of species sensitivity distribution, and of the influence of temporal aspects of the exposure, a number of specifically designed higher tier studies on aquatic macrophytes were performent to complement the results of the standard static exposure laboratory test on Lemna gibba.

The following tests on active substance will be described in the following:

Standard test;	
KC4 8.2.7 01:	Standard Lemna growth inhibition test with 7 days exposure time
Investigations on the influence	
бу KGK 8.2.7906: "Ху	Lemna laboratory growth inhibition & recovery test with
	4 days exposure phase followed by 7 days recovery phase
KCA 8.2.7 /07:	Lemna laboratory growth inhibition & recovery test with

Lemna laboratory growth inhibition & recovery test with 7 days exposure phase followed by 7 days recovery phase

**Bayer CropScience Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

Investigations on species sensitivity distribution:

8 week multispecies outdoor growth inhibition test in pond systems KCA 8.2.7 /08: 9 species

8 week Lemna multigeneration laboratory test mimicking the KCA 8.2.7 /09: exposure situation in the pond systems of study KCA 8.2

Moreover, laboratory studies investigating the toxicity to Lemma gibba were performed for alk metabolites of the residue definition for risk assessment in surface water Even though Lemma represents the most sensitive aquatic macrophyte species for mesosulfuron-methyl, effect of all metabolites was found orders of magnitude lower thank of parent substances or fully absent Ö

In addition, tests on *Lemna* were conducted on the components BCS-CO60720 and BCSEC supportive to a discussion of artifact furthings in a water/sedment study (sf. document MCA 7.2.2.3). Also these components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort on terminal to the components were build devoid of notable effort. The components were build devoid of notable effort on terminal to the components were build devoid of notable effort. The components were build devoid of notable effort on terminal to the components were build devoid of notable effort. The components were build devoid of notable effort on terminal to the components were build devoid of notable effort. The components were build devoid of notable effort on terminal ter In addition, tests on Lemna were conducted on two components BCS-CO60720 and BCSCO60721, supportive to a discussion of artifact findings in a water/sechment study (ef. document MCA Section

Test species	Test system	Test	End	point	Reference
Mesosulfuron_meths	7	uuration	ling		
Lemna gibha				<i>\Q^*</i>	
(duck weed)	growth		$E_r C_{50}^{(1)}$	> 0.0010	2000 0 0
()	inhibition,	7 d	NÔÆC	\$00018	M#185398-01-1
	static		- The second sec	U. COLORIDO	K A 8 0 /01 /
Lemna oihha			de exposur	a norica: »	2001
duck weed)				00.00100 (nom ⁶	M-201731-01-1
			$\mathbb{A}$ $d E_r C_{50}$	0.00159 (11014)	K64 8 2 7 /06
	growth		4 d  NOFC	0.00151 (IIII)	
	inhibition +	4 d + 7 d		withase:	$\mathcal{O}^{\cdot} \sim \mathcal{V}^{\circ} \sim \mathcal{V}^{\circ}$
	recovery	0'		V D Dav (nom	a a .
		A	0.7 d E = 0.1	$\ll 0.0032$ (non)	O' Q' A
				$\alpha 00038 (mm)$	
l amna aibha		0 in			
duck weed)	, and the second s			$\sim 0.00308 (note)$	200
(uuck weeu)	4	° O	$7 d E C co^{1}$	0.00250 (num)	M=206844-01-1
	growth $Q^{*}$	6	7 PNOE	0.00172 (mm)	KCA 82.7 /07
	inhibition	<b>≪</b> J°d + 7⁄dr°	dast 4 days of r	Qovery phase	×.
	recovery		$7 \text{ d} \text{E} \text{C} \text{s}^{1)}$	> 0 for $0$ (nom)	$\circ$
			$7 d C_{50}^{1}$	>0.00004 [%mm)	Ò
		6		\$00141 mm	¥*
Aquatic macrophytes			Er@50 (d	weight)	2009
(9 species)		a.	Flodes ranadens		M-329474-01-1
Lemna bioassay not			Potanogeton p@tina	tus 0.0071	KCA 8.2.7 /08
considered; replaced	outdoor growth	w N	Pontederia Cordata	0.9021	
by 8-week Lemp	inhibition, 🔬	8 weeks	Nymphaea Bdorata		
study; see below	static O	K	Ceral demerran	<i>a</i> 20.023	
Čo - (		1	Gpzeria maxima	>0.025	
°N			Mentha advatica		
Lemna Sibha			-dave	dum 0.022	2013
(duck weed)		. 0 4	F C (1 + 1)	0.00161 (nom)	, 2013 M 445130 01 1
(uuck weed)	mowth 0	N. O	Free controndnumber	0.00101 (nom)	$KC \wedge 8 2 7 / 00$
Q	Whibition		NOFC	0.00129 (nom) 0.00039 (nom)	KCA 0.2.7709
Ø	»Pmimi@ing `~	8 weeks	8-week endpoint	s based on initial	
~~~	exposure of		a forminal con	ncentrations	
A	outdoor study		ExControndnumber 1)	0.00190 (nom)	
			$\mathbb{Z}_{rC_{50 \text{frondarea}}}^{1}$	0.00210 (nom)	
		and a	NOEC	0.00039 (nom)	
Lemma gibba	statement: ration	ale for the	*		, 2014
(duck weed)	replacement of t	he old Z			M-487405-01-1
L.	a day Leona grow	th 🖓			KCA 8.2.7 /10
_O' ~	inhibition study	(
	2000; M	195390-	ErC _{50frondarea} 0	.00129 (nom)	
	01-1 with the 7	-day			
N R	Aendpounts from t	he <i>Lemna</i>			
Á , Ő Å	study (20	13; M-			
<u>E R</u>	448¥139-01-1)				
Lemna Sob a	growth				, 2000
duck weed)	inhibition,	7 d	no inhibitory e	ffects observed	M-197850-01-1
	leachate water	/ u	no minoitory c		KCA 8.2.7 /02
	of Lysimeter				



Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Test species	Test system	Test duration	Endpoint [mg as/L]	Reference
	study,			
AF F154851	semi-static			
Lemna gibba (duck weed)	growth inhibition	7 d	$E_r C_{50}^{1)}$ 0.11 NOErC 0.03	DorherJoh, 2005 M-255283-054 KCA8 2 7441
AE F160459				
Lemna gibba (duck weed)	growth inhibition	7 d	E _r C ₅₀ ¹⁾ 2.6 NOEC 2.6	20000 % 0 MA98076-01-1 KCA 8 2% /03
AE F099095		<u> </u>		
Lemna gibba (duck weed)	growth inhibition	7.4d	$ \begin{array}{c} & & & \\ & & & & \\ & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & $	³ <u>μ</u> , 2005 MO ³ 54496001-1 , KCA 8.2.7 /12
AE F092944				
<i>Lemna gibba</i> (duck weed)	growth inhibition	Pd C	$\frac{100}{2}$, 2000 , M-186946-01-1 KCA 8.2.7/13
AE F160460				<u> </u>
<i>Lemna gibba</i> (duck weed)	growth inhibition		ErCso ¹⁾	, 2000 M-199266-01-1 KCA 8.2.7 /04
AE F140584				
(duck weed)	growth c		$\begin{array}{c} & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & &$, 2014 M-486658-01-1 KCA 8.2.7 /14
AE F147447		<u>, </u>		
Lemna gibha (duck værd)	arowtho inhibition		$\begin{array}{c} & & & & \\ & & & & \\ & & & & \\ & & & \\ & & & \\ & & & \\ & & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\$, 2000 M-198273-01-1 KCA 8.2.7 /05
BCS-CO60720 🖗		<u>ğ x</u>		
Lemna gibba (duck weed)	growth inhibition		$\sum_{r=1}^{n} E_r C_{50}^{1} > 11.8$, 2013 M-449110-01-1 KCA 8.2.7 /15
BCS-CQ60721	NO Q			
Lemna gibba (duck weed)	growth inhibition	Q 7 d 0	$\begin{array}{c} E_{r}C_{50}^{1)} \\ NOE_{r}C \end{array} > 10.0 \\ \ge 10.0 \end{array}$, 2013 M-445154-01-1 KCA 8.2.7 /16

Bold letters: Varies considered elevant for riscassessment in the MCP document mm = mean measured, non prominal $¹⁾ Since the new actuatic GD focusses on Gldpoints based on growth rates the old <math>E_bC_{50}$ figures were omitted from the table above.



Studies on mesosulfuron-methyl

Studies on mesosun	<u>uron-mettryr</u>	<i>Q</i> ¹	
Report:	p [.] · · · · 2000·N	4-195390-01	
Title:	Duckweed (Lemna gibba G3) growth inhibitio	on test AE F1300 substance, te Dical	®
	95.3 % Code: AE F130060 00 1C95 0001		
Report No:	C007190		
Document No:	M-195390-01-1		Ô,
Guidelines:	ASTM: E 1415-91; OECD: draft June 1998	8; USEP4 (=EPA): J § 128-2;Deviation3	iot
	specified		
GLP/GEP:	yes		, O ^v
Endpoint according The new aquatic gurelevant. According	to the Review Report for mesospil furon-met $E_bC_{50} = 600062 \text{ mg/L}$ idance document (EFSA 2013) only tegar ly, this study endpoint should be revised to $E_rC_{50} > 0.001 \text{ mg/L}$ id RMS evaluation cooled from the rigin	hýh (SA&CO/10298/2003-Final):	;
Reference :	1		
Test guideline: guideline for testi guide for conduct	US-EPA Pesticity Associate Suideloes, Sui ng of comicals on <i>Legha gifea</i> , growth inhibiti ng static toxidity test with <i>Legha gifea</i> " G3-415	Viivisity J, \$ 23-2 (1982), OECD draft on (Apple 1997) and ASTM "Standard 5-21 (1991)	
□ GLP compliance □ Methods: The first state of the state	ects of AE 4/30060 (technical substance, parity deciminat under Snews Conditions. Prats wer	5.3% $5.3%$ $5%$ $5%$ $5%$ $5%$ $5%$ $5%$ $5%$ 5	
flasks filled with	30 mkof test water, that configured (Control	0 1 9 18 0 32 0 56 or 1 0 microg test	

Lemna gible Ovas de Finined under Enewa Conditions. Pleats were exposed to the active substance in 300 ml flasks filled with 20 ml of test water, that conditions. Pleats were exposed to the active substance in 300 ml substance. A total of 12 frond, 3-5 pleats) were allocated peoplask. Each concentration and the control were repeated three times. Ost ways was referred on day of and Coefford at checks. Effects on growth rate were assessed through 10 number of fronds creasured after 3, 5 and 7 days test duration. Any abnormal morphological size was acto recorded.

Results: A significant which is a signific

 $\begin{array}{c} & \text{Based on nominal concentrations:} \\ & \text{E}_{r}\text{C}_{50} \ 7 \ \text{d}_{2} \\ & \text{NOE}_{r}\text{C} \\ & \text{Odays} \\ & \text{All particular} \\ \end{array} \\ \begin{array}{c} & \text{Odays} \\ & \text{Herrory} \\ & \text{Herory} \\ & \text{Herrory} \\ & \text{Herory} \\ & \text{Herrory}$

 E_6C_5 \mathcal{C} days $\cancel{0.62}$ \mathcal{C} rog/ $\cancel{0.56}$ – 1.0]microg/l.

Further addy information supplementing the original Monograph summary :

<u>Validity Criteria:</u> The validity criterion of a doubling time less than 60 hours (2.5 days) in the control is fulfilled.



Analytical findings:

Analyses of freshly prepared water for AE F130060 resulted in test substance concentrations 🛤 from 112.5 to 124.6% of mean nominal values. Analyses of aged water for AE F13 9060 experimental termination resulted in test substance concentrations ranging Som 93.1 to \$4.1 mean nominal values. Therefore, nominal values were used for reporting the results. The test results for fresh water are partly above the range of 80-120% of the nominal Oncent although the variability is < 1.5 - due to recalculation with a recovery slightly above or by (but still in the accetable range of 80 -120%) for which no reasoning ion vailable. For the control sample (and thus for the spiked control sample for Ocovery evaluation) is well the concentration level of 320 μg/L on day 5 no resolute are available due to strong interference cannot be explained. Therefore, the mean recover of days 0 and 3 were used or reoliculation of

Biological findings: Mean values of absolute and percentual provide with mhilting is comparison of presented in the following table:

Table CA 8.2.7- 2:	Mean values of	absolute	an	ercentral g	r 🐼 th in 📢	ntion 2	paredio	the	ent Antrol
		231	0 -	v -	~ /	(())	- C.		XX //

Treatment level	Mean goowth rate	SPerce Qual	MeapOncreatin	Ô Pêrzentual
[µg/L]	[d-1]] 🖉 🥤 🖞	🗘 <mark>inhikson of</mark> 🤇	<mark>Bioma </mark>	Application of
		growth rate		b@mass increase
<mark>control</mark>	× 1 8976	م 0.00	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u>کې 0.00</u>
<mark>0.10</mark> %	y ₄ 0.376		× √ <mark>15.5</mark>	^{1.27}
<mark>0.18</mark> 🔬	مَنَّ <mark>0.3</mark>	∿	<u>k</u> y <mark>1<u>8</u>.2 . ∽</mark>	<mark>3.18</mark>
0.32	, <mark>224</mark> , Q	S 14.02	Q.0 4	<mark>30.08</mark>
<mark>0.56</mark>	م <mark>ب 286</mark> م	, <mark>2,2,90</mark> , ¢	× 8.2	<mark>48.09</mark>
	[∧] 0.2%9	/ ~~	2 6 %	<mark>58.47</mark>
	0 0 %			

The level (50%) growth inhibition regarding from number (E₆($_{30}$)) after 7 days was calculated as 0.62 µg 12 substance ((95%) configure limits 0.66 - 1.6µg/l $_{30}$ like level of 50% growth inhibition regarding biomass (F (5_{30})) after 7 days was calculated above 1.9µg test substance /L. A significant inhibition of growth relate (on fixed number was observed in nominal concentrations of 0.32 µg/L and above. A significant whibition of biomaco increase (dry weight) was observed in nominal concentrations of 0.32 µg/L and above. A significant whibition of biomaco increase (dry weight) was observed in nominal concentrations of 0.32 µg/L and above. A significant whibition of biomaco increase (dry weight) was observed in nominal concentrations of 0.32 µg/L and above. Since intoxic from somptory (yellow consured from a biomaco) were observed at concentrations of and above nominal 0.22 µg/L, the 10 observed above concentration (NOEC) defined as no significant growth inhibition (NOEC) defined as no signifi

inhibition and no changes in part appearan and development was set to nominal 0.18 µg/L.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		~9`	
Table 🖏 8.2.7- 3:	Cidpoints (EC50 Oalues)	y v	
		<mark>ЕьС50</mark>	ErC ₅₀
EC-values after	7 days in µg@ (not Stal)	0.62	> 1.0
95% conference	e innits i gig/L, high	<mark>0.56</mark>	-
95% confiden	Fimiton µg/Solow	1.0	-

EC50 ca zulation One binomial regression method.

Calciusians:

In a Growth Inhibition Test (method EPA / OECD / ASTM) to determine the effect of AE F130060; substance, technical, 95.3%, Code: AE F130060 00 1C95 0001 to Lemna gibba (Duckweed) the concentration of test substance inhibiting the growth ( $\mu$ , frond numbers) and the resulting  $E_{b}C_{50}$  in comparison with the untreated control after 7 days test duration was nominal 0.62 ug/L

# **BAYER** Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

(95% confidence limits 0.56 - 1.0  $\mu$ g/L). The E_rC₅₀ was nominal >1.0  $\mu$ g/L and the NOEC nominal 0.18  $\mu$ g/L.

Table CA 8.2	2.7-4: Summary tal	ble			8		Ĩ
Reference	Followed	Guidance	Differences	Critical assess	to the stud		<b>?</b> )
	guidance	currently in force		Deviations / co	nclusion about	its Religion	lity
M-	US EPA, J, § 123-	(not EU relevant)	N/A	N/A	°∕°″	n de la companya de l	L.
<mark>195390-</mark>	2 (1982)		Ĉ\$	Å	≪″		J a
<mark>01-1</mark>	<mark>US EPA, OPPTS</mark>	(not EU relevant)	<mark>n/a</mark> 😵	N/A		9″ ~Ű	
	850.4400 (1996)		L.	.0×	«ĭ ~		a Q'
KCA 8.2.7 /01	ASTM, E 1415-91 (1991)	(not EU relevant)	N. A	NOT CO	di di		,0 7
	OECD Draft,	OECD 221,	<b>none</b>	No deviation fr	om current guid	cline	
	inhibition (1997)	inhibition (200			S L	A	0
		4			0	(M) " ~	1

Since the study dosing regime did not glow for the derivation of a definite numeric result for  $EC_{50}$  (only a 'greater than' figure) and comparable growth inhibition data is available from several further 7-day exposure tests on *Lemna gibba*, it is proposed to use these infomation as a basis for a definite number  $E_rC_{50}$  value to be included in the updated list of endpoints ( $E_rC_{50} = 0.00120$  mg/L). A review of the data available, and a reasoned proposal is presented in KCA 8.2.7/10 below.

Report:	_; <b>20</b> 01; <b>M</b> ,2017; <b>2</b> 01
Title:	Buckweed (Lenna gibba G3) gowth inhibition test with recovery phase AE
	F130060 substance, por Coder AE F130060 00 1B98 0002 4
Report No:	C016099 . O
Document No:	M 20173 2-01-1 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Guidelines: 🔊 🔊	@STM: E 1415-91; QBCD: draft 1998; USEPA (=EPA): 123-2; Deviation not
O* n	specified , a co co co
GLP/GEP; 🖗	yes, she are the the the the the the the the the th
Executive Summary	

Aim of this study was to determine the effects of the test item AE F130060 (mesosulfuron-methyl) on growth inhibition of *Jemna Sibba* is a 4-day exposure jest with subsequent 7-day recovery period under semi-static conditions according to draft OECD guideline, US-EPA Pesticide Assessment Guidelines J 123-2 and according to ASTMF E 1405-91 guideline under GLP. Triplicate *Lemna* cultures with an initial front number of 12 fronds per replicate were exposed to the test substance in 20X-AAP medium at five nominal treatment lexets (i.e. 0.32, 0.56, 1.0, 1.8 and 3.2  $\mu$ g/L). During the treatment phase growth and abnormal appearance of fronds were determined on test days 3 and 4. At day 4 the test continued with untreated netrient solutions (recovery phase). Growth and abnormal appearance of fronds were tested per treatment level. One control replicate was omitted from the evaluations of the recovery phase since symptoms were observed at these plants.

While provide the syndromes were observed during the exposure phase and at the beginning of the recovery phase, at the end of the recovery phase fronds recovered from all intoxication symptoms.

Mean measured levels of 50% growth inhibition during the seven-day recovery phase after the four day exposure period were calculated as follows:



7 d E _r C ₅₀	$> 3.8 \ \mu g/L$
7 d E _b C ₅₀	$> 3.8 \ \mu g/L$
7 d NOEC	0.44 μg/L

#### Material and methods:

Test item: AE F130060; Code: AE F130060 00 1B98 0002; Analysed purily: 98.1 % wo No.: AZ 07726.

Lemna cultures with an initial frond number of 12 fronds per replicate were exposed to the test them in 20X-AAP medium at five nominal treatment levels (i.e. 0.32, 0.5@ 1.0, 1.8 and 3.2 ug/L). During the treatment phase growth and abnormal appearance of fronds were determined on text days and #At day 4 the test continued with untreated nutrient solutions (recovery plase), Rgain, growth and abnormal appearance of fronds were determined at days 7,79 and 71. These reportates were tested per treatment level. One control replicate was omitted from the evaluations of the recovery phase spice symptoms were observed at these plants Chemical analyses were conducted on day Q and & from thesh water and on day 3 and 4 from aged water from all tested concentration by chromatographic determination. The binit of detection (LOD) was 0.008 µg/L, the limit of quantification (LOQ) was@.014

#### Dates of experimental wor

August 17, 2001. September

#### **Results:**

Analytical findings:

Analyses of freshly prepared water for AE F130060 resulted in concentrations ranging from 88.0% to 136.3% of nominal values at day 0 and between 72.8% and 109.4% at day 3. Analyses of aged water for AE F130060 at day 3 resulted in concentrations ranging from 58.7% to 99.3% of nominal values. Analyses from age@ water at day 4 were regarded as not reliable and were omitted from further evaluations. The mean measured concentrations between day 0 and day 3 ranged between 77.0 and 118.7% A summary of the analytical findings are presented in the following table:

Table CA 8.2.7- 5:	Qverall survey of analytical res	tilts as‰ of nomi	nal	
Nominal conc.	Q0.32 µg/L 0 0.56/µg/L	£0 μg/L	1.8 μg/L	3.2 μg/L
Day 0 fresh water	29.6 ~ ~ ~ 101.1~	88.0	93.3	136.3
Day 3 aged water		<b>90.3</b>	81.8	99.3
Mean day 0 - 3	79.0 79.9 4	89.2	87.6	117.8
Day 3 feesh water	2~ 73.3 × × × × × × × × × × × × × × × × × ×	92.8	95.5	109.4

#### **Biological findings:**

Inhibitory effects during the exposure and recovery phase were observed as follows:

# Table CA 8.2.7- 6: Mean values of absolute and percentual growth inhibition @AE F130060 compared to the control during the treatment phase Image: Compared to the control during the treatment phase

······································								
Treatment level (μg/L)	Mean growth rate (d ⁻¹ )	Percentual inhibition of growth rates	Mean increase in biomass (mg)	Percentual inhibițion of biomass increase				
untreated control	0.36970	0.00	0.022					
0.32	0.36569	1.08	⁰ 7.254 «	<u>~</u> 3.29 ~ ( ⁰				
0.56	0.33032	10.65	7.143	~-1.76 Q				
1.0	0.27636	25.25	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	-2,43				
1.8	0.17669	\$52.21	× ×4.632	&A.04 ~				
3.2	0.13584	× 63 20 ~	4.933	×29.76				

Table CA 8.2.7- 7:	Mean values of absolute	and percentual g	rowth inhi	, bition of	AE F130069	, c
compar	ed to the control during t	the recovery phas	ě	<u> </u>	×	s S

Treatment level (μg/L)	Mean growth Gate	Percentual inhibition of growth rate	Mean increase an biomass (mg)	BercenOal Inhibition of Siomass increase
untreated control	0.35777 🖉	\$ 0.00° \$	23.23500	×0.00
0.32	<b>A</b> \$4957	2029 L	Q 24.62000	-5.96
0.56	ר.33682 🏾 🖓	5.86	22.97333	5.00
1.0	الله 0.32	8.48 ⁰	~20.62333	11.24
1.8	°~ 0,32751 @	\$ 8.46	×18.63000	19.82
3.2 🔬	, <b>A</b> 324470 C	S & 31 O	k 18,42000	20.72
			0 2 13	

Due to the high variability of individual data no significant inhibition of growth related on biomass during the four-day treatment phase at a significance level of alpha = 0.05 was observed at any treatment levels up to nominal 3.2  $\mu$ g/L (mean measured 3.8  $\mu$ g/L).

No significant inhibition of growth related on frond number during the 7 day-recovery phase at a significance level of alpha = 0.05 was observed at all treatment levels up to nominal 0.56  $\mu$ g/L (mean measured 0.44 $\mu$ g/L).

No significant inhibition of growth related on biomass during the 7 day-recovery phase at a significance level of alpha = 0.05 was observed at any treatment levels up to nominal 3.2  $\mu$ g/L (mean measured 3.8  $\mu$ g/L).

Non-separating fronds were observed in all replicates from the two highest treatment levels at day 3 and day 4 but not in the consecutive recovery phase. Vaulted fronds were observed at the highest treatment level during the treatment phase and at the first assessment during the recovery phase (day 7). Moreover, tronds had nearly no root at day 7 in all replicates of the highest treatment level. All these inforced by the phase. Thus, up to  $3.2 \mu g/L$  fronds recovered from all intoxication symptoms acquired during a four-day treatment phase.



#### **Conclusions:**

Nominal levels of 50% growth inhibition during the four-day treatment phase were calculated as follows: follows: (95% confidence limits 1.513 - 3.188 µg/L)  $4 d E_r C_{50}$ 1.989 ug/L Mean measured levels of 50% growth inbibition during the seven-day recovery phase were calculated as follows:  $7 \text{ d } \text{E}_{r}\text{C}_{50}$   $7 \text{ d } \text{E}_{r}\text{C}_{50}$   $3.8 \mu g/L$   $3.8 \mu s/L$ 7 d E_bC₅₀ 3.8 mg/L Ô 7 d NOE 0.44 2002;MQ06814-01 **Report:** Duckweed (Benna gibba G3) - Growth inhibition test with recovery phase AE Title: F1 00060 substance, pure Søde: AE F130060 00 1398 0002 Report No: **©0**18852 s i ∭M-206®14-01-₽ Document No: Guidelines: 🔊 ASTM: E 1015-91, OECD draft June 1998; USEPA (=EPA): E § 123-2; Deviation not specified GLP/GEP øes Å X

## Executive Summary:

Aim of this study was to determine the effects of the testatem AE F130060 (mesosulfuron-methyl) on growth inhibition of *Lemua gibbo* in a 7-day exposite test with subsequent 7-day recovery period under senti-static conditions, according to draft QECD guideline, US-EPA Pesticide Assessment Guidelines J 123-2 and according to ASTM E 1415-91 guideline under GLP. *Lemna* cultures were exposed to the test substance in 20X-AAP medium at five nominal treatment levels (i.e. 1.0, 1.8, 3.2, 5.6 and 10  $\mu$ g/L). During the treatment phase six replicates were involved in which growth and abnormal appearance of fronts were determined on test days 3, 5 and 7. At day 7 the test continued with three replicates but with untreated nutrient solutions (recovery phase). Again, growth and abnormal appearance of fronts were determined at days 10, 12 and 14.

Vaulted and yellow coloured fronds were observed as severe intoxication symptoms. Moreover, slight changes in plant appearance like spread fronds, small fronds and shortened roots were observed.

At treatment level of and above 1.8  $\mu$ g/L the growth was obviously inhibited during the first three days of the recovery phase, only. During the period between day 3 and day 7 of the recovery phase the growth curves obviously run more or less parallel to the control. This is likely to be linked to the observed occurrence of the test item during the first days of the recovery phase. Therefore, the evaluation of data obtained during the recovery phase were separately analysed for the whole seven-



day recovery phase and the last four days of the recovery phase. For the last four days of the seven-day Analysed purito static renewal recovery phase the following endpoints were observed:

Figures based on time-weighted average concentrations during:

7 d E _r C ₅₀	> 9.41 μg/L
7 d NOEC	9.41 μg/L
7 d NOEC	1.41 µg/L

regarding growth rate (frond number) regarding severe intoxication symptoms

## Material and methods:

Test item: AE F130060 (mesosulfuron-methyl); Code: AE F130060 00 1B98 0002 98.1 % w/w; Certificate No.: AZ 07726.

Lemna cultures with an initial frond number of 12 fronds per replicate were exposed to the test item in 20X-AAP medium at five nominal treatment levels (i.e. @.0, 1. 2, 3.2, 5.6 and 10 µg/L). Additionally an untreated control was tested. During the treatment phase six replicated were involved in which growth and abnormal appearance of frends were determined on test days 3, 5 and 7. Adday 70he test continued with three replicates but with untreated nutrient solutions (recovery phase). Again, growth and abnormal appearance of frond were determined at days 10, 12 and 14.

Chemical analyses were conducted on day 0, & and & from fresh water and on day 3, 5 and 7 of aged water from all tested concentration by chromatographic determination Additional chemical analyses were conducted on day 10 and 12 of aged water of the untreated control, the concentration levels 5.6 mg/L and 10 mg/L by chromatographic determination of AE F130060. The limit of detection (LOD) was 0.05 µg/k for the treatment phase and 0.15 µg/L for the recovery phase, the limit of quantification (LOQ) was 0.08 µg/ for the treatment phase and 0.25 0g/L for the recovery phase.

Dates of experimental work: January 11,2002 – January 27,2002

## **Results:**

## Analytical findings:

Analyses of freshly prepared water for AE 130060 resulted in the means of the measured concentrations ranging from 820% to 93.3% of nominal values. The variability was < 1.5% at all treatment levels. Analoses of aged water for AEF130660 resulted in the means of the measured concentrations ranging from 692% to 1033% of nominal values. Time-weighted average concentrations for 1.0, 1.0, 3.2, 6 and 10 µg/2 were 77.36%, 78.42%, 95.71%, 90.36% and 94.06% of nominal, respectively. Since time-weighted average concentrations were below 80% of nominal at the two lowest treatments levels the bological results were based on time-weighted average concentrations.

Since plants were transferred from treated lest solutions to untreated nutrient medium at start of the recovery phase, samples from the two highest treatment levels were analysed for AE F130060. Aged water from day 10 (day 3 of the recovery phase) contained 10.1% and 4.8% of the respective nominal concentrations of the foregoing treatment phase (5.6 and 10 µg/L, respectively). Aged water from day 12 (day 5 of the recovery phase) contained no test item anymore. Therefore, no further analytical measurements have been conducted during the recovery phase.

## Biological findings:

Vaulted and/or yellow coloured fronds were observed in concentrations of and above 1.0 ug/L.



A significant inhibition at a significance level of alpha = 0.05 of growth both related on frond number and of biomass increase (dry weight) was observed at concentrations of and above nominal 1.0  $\mu$ g/L  $\sim$ (time-weighted average 0.77  $\mu$ g/L) after 7 days test duration. Inhibitory effects during the exposure phase were observed as follows:

compared to the control during the treatment phase 🗸 👋 🔬 💭									
Treatment level (μg/L)	Mean growth rate (d ⁻¹ )	Percentual inhibition of growth rate	Mean mcrease in bomass (mg)	Dercentual inhibition of biomass increases					
Control	0.394	00	Q 26.70 K	L 0.00					
1.0	0.298	24.43	× Ø8.87 ×	O 29.34 0					
1.8	0.212	¥46.22°	14.030 2	47.44					
3.2	0.154	6b00 x	L 12 3 S	54.56					
5.6	0.130	<b>66</b> .96	10.20	64,580 °					
10	0.108	72.65	9.43	<b>64</b> .67					
	a -								

# Table CA 8.2.7- 8: Mean values of absolute and percentual growth inhibition of AE F130060 compared to the control during the treatment phase

At treatment levels of and above 1.8 ug/L the growth was obviously inhibited during the first three days of the recovery phase, only. During the period between day 3 and day 7 of the recovery phase the growth curves obviously run more or less parallel to the control. Phis iolikely to be linked to the observed occurrence of the test item during the first days of the recovery phase. Therefore, the evaluation of data obtained during the recovery phase were separately analysed for the whole sevenday recovery phase and the last four days of the recovery phase.

During the whole recovery phase (test day 3 to 140 a significant inhibition at a significance level of alpha = 0.05 of growth both related to frond number, and of biomass increase (dry weight) was observed at concentrations of an above nominal 1.8 gg/L. During day 10 to 14 (the last four days of the recovery phase) a significant inhibition at a significance level of alpha = 0.05 of growth related to frond number increase was observed at concentrations of and above nominal 10  $\mu$ g/L / time-weighted average 9.41  $\mu$ g/L.

Vaulted and yellow coloured fronds were observed as severe intoxization symptoms. Moreover, slight changes in plant appearance the spread fronds, small fronds and hortened roots were observed. Inhibitory effects during the recovery phase were observed as follows:

2 compared to the control during the recovery phase								
Treatment level(µg/L)	Mean grooth rate	Percentual inbibition of growth rate	Mean growth rate (d ⁻¹ )	Percentual inhibition of growth rate	Mean increase in biomass (mg)	Percentual inhibition of biomass increase in biomass Day 7 to 14		
	🖉 🔒 🐧 🖉	to 14 Q	Day 10	) to 14	Day 7	7 to 14		
Control 💭	~9,38007	×0.00 @	0.33117	0.00	23.0	0.00		
1.0	×0.396@	<i>ي</i> ≪ -4.36¢	0.35325	-6.67	22.6	1.74		
1.80	0.34 <b>2</b> 50 (	9.88	0.39191	-18.34	17.0	26.09		
XX Q	0, <b>3</b> 4558,^\$	9.07	0.36161	-9.19	18.7	18.70		
×9.6 V	0:35528	6.52	0.36800	-11.12	20.3	11.74		
10	0.31242	17.80	0.38237	-15.46	15.1	34.35		

#### Table CA 8.2.7-9: Mean values of absolute and percentical growth inhibition of AE F130060 compared to the control during the recovery phase

## **Conclusions:**

The following endpoints were obtained:

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Figures based on time-weighted average concentrations during the seven-day static renewal treatment phase:  $\begin{array}{c} 7 \text{ d } \text{NOEC} & < 1.0 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 1.0 \ \mu\text{g/L} \\ 7 \text{ d } \text{E}_{b}\text{C}_{50} \\ 1.717 \ \mu\text{g/L} \\ 7 \text{ d } \text{E}_{b}\text{C}_{50} \\ 1.863 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{NOEC} & < 0.77 \ \mu\text{g/L} \\ 7 \text{ d } \text{d } \text{$ Nominal figures during the seven-day static renewal treatment phase: served. Threfore, the recovery-Nominal figures during the last four days of the seven day static renewal > 10.0 µg/1  $7 \text{ d} \text{E}_{r}\text{C}_{50}$ \$0.0 μg/L  $7 \text{ d} E_b C_{50}$ Gregarding growth rate (frond mimber) 7 d NOEC 10.0 **ug**/L 1.8 µg/L 🔊 7 d NOEC 🖗 regarding severe intoxication symptoms 7 d NOEC **≤1**,0 μg/L regarding gight changes in plant appearance during the last four days of the seven-day Figures based on time-weighted overage ations static renewal recovery plase: d Er 9.41 μg/L ©9.41 µg/L  $E_{50}$ regarding growth rate (frond humber) 941 d NOEC ©gg/L regarding severe intoxication symptoms egarding slight change On plant appearance 2009 M-329474-01 **Report:** Outsoor growth inhightion an aquation plants exposed to Mesosulfuron-methyl Title: Report No: 13798.6220 Ś M-32944-01-1 Document No: **Guidelines:** special design Deviation not specified GLP#GEP: ves Executive Sumary

The objective of this study was to evaluate the toxicity of mesosulfuron-methyl to nine aquatic plant species curiivated in outdoor food systems under natural atmospheric conditions, over a study period of 8 weeks. The plants were placed in the ponds for a 2 to 4 week acclimation period prior to exposure to the test substance. Normal test concentrations were 0.40, 0.78, 1.6, 3.1, 6.3, 13 and 25 µg a.s./L, and were confirmed by analytical measurement: 0.45, 0.82, 1.9, 3.1, 6.7, 14, 25 µg a.s./L (arithmetic mean values of 3-4 replicate ponds per test concentration). During the test period, a continuous dissipation of the test substance was observed in the ponds, as to be expected for mesosulfuron-methyl in a static water body.



In addition to the nine species cultivated in the ponds, the sensitivity of the duckweed, Lemna geba, was evaluated during weeks 0, 2 and 7 in an environmental chamber, by exposing the plants for days to nutrient enriched water samples taken from treated and control ponds. For biological reason Lemma could not be grown directly in the pond systems. Results of this test reflect Lemna response to the actual pond water exposure situation in a particular test week, however are not equivalent endpoints to those of the species grown over the full 8-week period in the ponds.

Results are reported as the percent reduction in growth (mean show length, mean dry proof wight and the respective growth rates) of plants exposed to the test substance as compared with growth of solvent controls. For Lemna gibba, results are expressed as the percent reduction in growth (frond I get the second show the second seco density, frond dry weight), and the respective growth rates. Visual observations for symptons of toxicity, when present, were also made. Results are Gased on noninal concentrations; EC10, EC25 and EC50 values and the No-Observed-Effect-Concentration WOEC were determined for eachendpoint for each species tested. For tests with Lemma gibba conducted in the Paboratory, the biological endpoints assessed for effects were Zday frond numbers density), frond dry weight biomass and growth rate based on frond density and dry weight

Key endpoints of the study, expressed as lowest Eres (8-week) based for the nine species maintained in the ponds



## Material and methods

E E 30060 technical; Batch No.: EFME000042; CAS Test item: Mesosulfur - methyl; Synonym No.: 208465-01-8; Analysee purity 98.1%

Test species: Monocotytedon; Water Weed (Flodea Lanadensis), Sago pondweed (Stuckenia pectinata, formerly Potamogeton pectinatus) Reed sweetgrass (Glyceria maxima), Pickerel weed (Pontederia cordata), duckweed (Lemia gibba). Decotyledon: Water lily (Nymphaea odorata), Coontail weed (Ceratophyllum_a demersum), Variable milf& (Myriophyllum heterophyllum), Water mint (Mentha aquatica), Farwort (Cabomba careliniana).

Thirty-one, Square 3000-1, outdoor, freshwater ponds (inside dimensions 230 cm x 230 cm x 60 cm deep) comaining a 5 cm layer of sandy loam soil to serve as sediment were used. The percent sand:silt clay of the soil was determined to be 65:24:11%, respectively, the percent organic matter was 9.4% and the pH was 4.3. Each pond was filled with approximately 1850 L (35 cm depth) of unchloringted well water and fortified in hardness to approximately 180 mg/L as CaCO₃. The ponds received full sunlight throughout the day. Covers were temporarily installed over the ponds when heavy rain was forecast, in order to prevent major dilution of the test solutions.



Plants were placed in the ponds for a 2 to 4 week acclimation period prior to exposure to the test substance. After the acclimation phase the ponds were dosed with the test substance at normal concentrations of 0.40, 0.78, 1.6, 3.1, 6.3, 13 and 25 µg a.s./L in addition with a solvent control (18.5) mL of acetone in 1850 L of pond water in each solvent control pond). Six solvent control policates were established. Four replicates were established for the four lowest conceptrations (0.40, 0.78, 4.6)and 3.1 µg a.s./L), while three replicates were established for the three highest concentrations (\$3, 13@ and 25  $\mu$ g a.s./L).

During the exposure, health observations were performed on emergent and, as the as possible, on submerged plants during weeks 2, 4, 6 and 8. The test was terminated after eight weeks of exposure Plants were harvested and mean shoot length and mean shoot do weight were determined for each species separately. Endpoints were calculated as reduction of mean shoot length and mean shoot diry weight compared to the control and as reduction of the respective growth rates.

Additionally, the sensitivity of the duckweed, Demn & was explusive during weeks 0, 2 and 7, by exposing the plants in an environmental chamber for 7 days to nutrient enriched samples from treated and control ponds. The culture medium used was sterile 20X0Algal(Assay Procedure (AAP) medium adjusted to pH 7.5  $\pm$  0.1. The biological endpoints assessed were 7-day frond numbers (densit), frond dry weight biomass and growth rate based on frond density and dry weight.

Analytical samples of each pond were taken at test initiation and on day 16 day 28 and test termination (day 54). HPLC was used as analytical method.

## Dates of experimental work (including dry weight defermination)

June 4, 2008 - August 21, 2008 (outdoor exposure of nine aquatic plants Č O June 5, 2008 June 16, 2008 Lemna gibbo Test 1) June 19, 2008 – July 2, 2008 (Lepana gibba Test 2) July 24, 2698 – Angust 4, 2008 Lemma gibbo Test 3

#### **Results:**

Environmental conditions. The environmental conditions maintained throughout the best period were within acceptable limits for the growth and survival of the test species. Rainfall during the exposure period was 9.0 cm for June 2008 and 12.4 cm for July 2008. Approximately 6.4 cm of rainfall was prevented from entering the ponds on 24 to 25 July 2008 since the ponds were covered. The remaining rainfall entering the ponds generally replenished water evaporated during the study.

## Analytical results:

The day 0 measured concentrations spesely approximated the desired nominal concentrations indicating the ponds were dosed as intended in all ponds, concentrations of mesosulfuron-methyl slowly decreased over the & week exposure period. Endpoints, however, are given in terms of nominal concentrations, since they will be used in risk assessments in combination with initial or maximum PEC-figures. Details of analytical measurements are presented in the following table:

# Bayer CropScience **Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

Table CA 8.2.7-10:       Concentrations of mesosulfuron-methyl measured in the pond water at test start										
and three timepoints over the eight week test period										
Non	ninal			a a a a a a a a a a a a a a a a a a a						
Concen (µg a	ntration n.s./L)	Day 0	Day 14	Day 28	Day 54		)			
Solvent	control ^a	<0.10	< 0.021	<0.021	<0.019		Ô			
	A	0.46	0.18	S 0.41 🖇	< 0.019 (	S S	ĩ 0.			
	В	0.43	0.20	v 0.34	<0.019	₽´ «Ű	Ś			
0.40	C	0.47	0.23	0.46 🔊	<0.019	S S	« ^O			
	D	0.44	0.15	0.29	<u>&lt;00019 ≫</u>	0,0	$\boldsymbol{v}^{*}$			
	Mean	0.45	0.19		0:0093*S	a ar				
	SD A	0.020	<b>0.62</b>			× .~~				
	A B	0.79		<u>~~~0.52</u>						
	C	0.87		0.05	0.48	and a	0			
0.78	D	0.78	0.43		\$ 0.45 K					
	Mean	0.82	.044	0.56	°~ 0.45 × /					
	SD	0.042	<u>, ≪0.038</u> ≪	× 0.049	Ø.031 S	Õ				
	А	2.1 0	1.2	× 191 . ~	\$0.78	Ô				
	В	2.0	1.2	1.1 0	× %0.86 گ	٧ [°]				
16	C	1.7 5	<u>\$ 9.1 °</u>	<u> </u>	<u> </u>					
1.0	D		1.1 8	1	09.74					
	Mean	≪ [™] 1.9		<u> </u>	0.78					
	SD	0.18	<u>~ 0,076 '0'</u>	0.018	<u>~ 0.053</u>					
	A °	<u>3.2</u>		1.9						
			2.5		<u>0</u> 1.4					
3.1		3.2		- 22	1.4					
	Mem	3 3 V X			© 14					
	SD	0x12 ⊛	>> 0.13€	N 0.14 2	0.054					
	A	$\bigcirc 6.4 \bigcirc^{\nu}$		r <u>\$\$.5</u>	2.5					
63 . (		66 4		<u> </u>	2.4					
	Nean Ũ	× 7 ×	4.6	× 3.6	2.4					
R.Y.	SD %	°a.41.	(°) 0:23	×0.28	0.038					
	AQ	4 15 .	<u> </u>	A 8.0	4.8					
	B A	L LA V	9.4		4.9					
13	Č Q	× 514 0	× 11\$	S 7.6	5.3					
	Mean	<u>گَ 14 کې</u>		^r 7.8	5.0					
a	[♥] SD [♥]	<b>∂ 0.</b> 2) ¹	<u>0″ (\$\$8 Ö`</u>	0.23	0.25					
	A	34 6,	<u>**18 x</u>	14	8.5					
	B S	~25		15	8.3					
25		<u>A</u> 25 Y		15	9.2					
s s	Mean SD			15	8.6					
a) Composito	some of all r	r www.		0.93	0.48	I				

^{b)} When the measured concentration decreased to below the limit of quantitation (LOQ), one-half of the LOQ value was used in the calculation of the mean measured concentration.

$$NA = Not Applicable.$$
  
SD = Standard Deviation.

# P

Biological results:

The nine species grown in the outdoor ponds showed a wide range of sensitivity to mesosulfuronmethyl. While Glyceria maxima and Cabomba carolinea were not affected even at 25 µg a.s./L (based



on nominal concentrations), the lowest EC₅₀ of 2.1  $\mu$ g a.s./L (based on nominal concentrations) were obtained for growth rate of mean shoot length in case of *Ponteteria cordata*. The lowest NOFC of 0.78  $\mu$ g a.s./L (based on nominal concentrations; analytically measured: 0.82  $\mu$ g/L) were achieved for *Potamogeton pectinatus*.

 $EC_{50}$  values and the NOEC for the different response variables and each species tested are summarized in the following table.

	1	aquatic macro	ophytes ex	kposed to mes	osulturon	-methyl in outo	ioor pond	s for eight
	1	weeks.			~	1 (	> <u>~</u>	
			Ba	sed og Nomin	al Conce	ntrations 🖉	Å	. 4
				(μg	a.s./🕼		<u> </u>	
			Week	& Growth °	5		🖉 Week	8 Grewth
Evenogumo	Weel	x 8 Mean	(	Bate 🖉	Week 8	MeanShoot		Rate
Dariad	Shoo	t Length	Based	lon Mean 🧷	,Dry	Weight	Base	d on Dry 🗸
reriou		_	Shoo	t Length 🥎	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	A	, W	Fight 🖉
	NOEC	EC50 (95% CL)	NOEC	EC (95%-CL)	<b>NOE</b> C	EC50 (95% CL)	NOE	ESC 50 (95% CL)
Elodea	NG					~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Ø 3.8
canadensis	NCª	NC Q	NC ^O		50	(1.5-1\$)	J.6 1	(1.3-5.8)
Potamogeton	16	>25	SAC 4	r 18€?	00 70	× 🖏 🗸		7.1
pectinatus	1.0	$(\mathbb{N} \otimes \mathbb{P})$	$\gg^{1.0}$	° (13°223) ≉		(5.3-13) [©]	0.12	(4.7-11)
Pontederia	16	≫3.1 &	10	£2.1	1	× 2.7 Ø	æ1 6	2.6
cordata	1.0	` (\$NA) ( [♥]		(1.5-3,0)	1.0	\$(2.1 <b>-3</b> ¥)		(1.9-3.0)
Nymphaea	250	>25	250	<u>}</u> >25	\$ 150°	×235 🔬	25	>25
odorata	23° 🔬	(NCA)	\$ ²³ 0	(()A) %	$\mathcal{O}^{23}$	((NA) ∖	23	(NA)
Cabomba	1	925 d	าย	\$≥25"	25	© [♥] >25√√	25	>25
caroliniana		$\sqrt{(NA)}$		(NA)	<u></u>	$(N_{A})$	23	(NA)
Ceratophyllum	062	^O >26, [™]	6 2 1	× 5°.5×	S 25 0	^ <b>\$</b> 25	NDd	ND
demersum 🔊		(NÁ)		2.8-9.7 嶡	23.03	NA)	ND	ND
Glyceria [©]		ي≥25 _	25	\$\$>25 ¢	Q	_ ⊘ >25	25	>25
maxima 🖏	29	(NA)		(NA)		(NA)	23	(NA)
Mentha	13	20			× 25	16	25	15
aquatiça		(12)25)	× 13	<u>(</u> 300-18) ×	· 230	(2.4-24)	23	(2.1-24)
Myriophyllum	÷ مو	£y ^{\$} 25 €	° O V	<i>ير</i> [¥] >25 [€] √	25	>25	25	22
heterophyllum	N.	(NAQ)	K J	(NA)	2 <i>5</i>	(NA)	23	(18-25)

Table CA 8.2.7-11:Summary of NOEC and EC50 values based on notifinal concentrations, for nineaquatic macrophytes exposed to mesosulfuron-methyl in outdoor ponds for eight

NC = Not calculated. Due to the constant branching observed and the fact that stems could not be associated with unique plant plant lengths were not measured for E. canadensis.

^b NA = Not applicable

с

Mean shoot length for water lily may not be a good indicator of sensitivity since mean shoot length is junited by the water column depth.

ND = Not determined. Test termination plant by weights were less than the initial weight, resulting in negative growth rates for the solvern control and each treatment; therefore, the EC and NOEC values were not calculated for shoot dry weight powth rates.

The following observations concerning plant health were made at test termination: *Elodea canadensis* plants exposed to the 6.2, 13 and 25  $\mu$ g a.s./L treatments were stunted, exhibited shortened branches and shortened and necrotic baves. *Potamogeton pectinatus* plants exposed to  $\geq 0.78 \ \mu$ g a.s./L were generally chlorotic or necrotic. *Glyceria maxima* plants in all treatments and the solvent control were noted as healthy. *Pontederia cordata* plants exposed to replicates A and B of the 6.3  $\mu$ g a.s./L treatment and all plants exposed to the 13 and 25  $\mu$ g a.s./L treatments were dead. Surviving plants exposed to 3.1 and 6.3  $\mu$ g a.s./L were generally necrotic at test termination. For *Nymphaea odorata* replicate B plants exposed to the 1.6  $\mu$ g a.s./L treatment had not emerged, while in replicate D, one plant did not emerge and one plant died during the exposure. *Mentha aquatica* plants exposed to



higher concentrations of mesosulfuron-methyl were more fragile and contained less biomass then the solvent control. Branching was observed to be stunted and the leaves were smaller then solvent control leaves. The solvent control and the lower treatment levels of the Cabomba caroliniana replicates were observed to have less biomass than the higher treatment levels and may be attributable 100 greater competition for space and nutrients at the lower treatment levels.

The results from the three seven-day Lemna-bioassays are not reported in this summary for following reasons:

- 1. The 7-day tests in nutrient-enriched pond water samples do not provide any new information of effects of mesosulfuron on Lemna compared to standar aboratory studies
- 2. In order to obtain a Lemna-endpoint which is directly comparable to the endpoints from this outdoor study a 8-week Lemna study was performed in the Jaboratory under sterile conditions while mimicking the dissipation of mesosurfuron as observed in the poind study (see KCA 8.2.7/09 below).

**Conclusions:** Seven of the nine aquatic macrophytes tested indicated sensitivity in reduced mean shoot length, dry weight, growth rates, or morphological abnormalities a mesosulfuron-metoyl over the range of tested concentrations, 0.4 to 25 µg a.s.L. EQ50 and NOEC values for all species and response wariables were reported in Table CA 8.2.7- ¥l above. Based on the lowest EC20 value, 2.1 gg a.s./L for growth rate based on mean shoot length, pickerel werd (Portederia cordata) was the most sensitive species tested. In general, the health and survival of the control plants for each species indicated the exposures systems were appropriate for ise. Additionally, the results demonstrated that the plant species selected were appropriate to detect responses to the test substance.

~0		O' 4'		A V	
Report:	E.	**	;2093;M-4951.	39- <b>0</b> 1	
Title:	Lemna git	ba G3 - Prolo	ngga growth inhi	bition test with mesosulfu	ron-methyl (AE
	F030060	with stepwise	decreasing cone	intrations over an 8 week	test duration
Report No.	EBMMLO	17			
Document No:	M-44≸j139	)-001 20			
<b>Guidelines:</b>	OECD - 2	A (March 2	3, 2006);none	ð	
GLP/GEP:	َّ <b>يَ</b> الْعَجْدِ الْ			Ø	

## **Executive Summary:**

The ain of the study was to determine the long form influence over a total period of eight weeks of mesosulfuron-methy (AE A 3006) on exponentially growing Lemna gibba G3 expressed as NOEC, LOEC and EC_x for grow frate of the response variables, frond number and total frond area of plants. The study is intended to complement the dataset of a multispecies growth inhibition study in outdoor 2009; M₂₃29474-01-1) by the generation of a corresponding 8-week ponds (KCA 8.2.7408) growth inhibition endpoint for *Lemna*. This species could not be grown directly in the pond systems for biological reason.

3 x 12 from s of Lemna globa G3 per test concentration were exposed in a chronic multi-generation test for eight times 7 days under static exposure conditions, starting at nominal initial test item concentrations of 0.194, 0.388, 0.755, 1.55, and  $3.1 \,\mu g/L$  (100% levels, week 1). These concentrations were stepwise decreased week after week of the test period, targeting levels of 84.1% (week 2), 70.7% (week 3), 63.2% (week 4), 56.5% (week 5), 50.2% (week 6), 44.7% (week 7), and



39.7% (week 8), to mimick under laboratory conditions the dissipation of mesosulfuron-methyl observed in the outdoor pond systems of study KCA 8.2.7/08. The Lemna plants were transferred into new test solutions of the next concentration level every 7 days, using 12 fronds from the respective? treatment level of the preceding week.

treatment level of the	e preceding week.		S.	4 <u>,</u> 9
Table CA 8.2.7- 12:	Key endpoints of the stud	y, expressed as ErC50 (	8-week) for Lemna	gjaba: 🚿 🗞
	mea	an growth rate	N N	
	effect on frond no.	effect on total frond	l area of plants 👗	'. N Ø ,0
	[µg a.s./L]	μg a.s.	Q Q	
ErC ₅₀ (8 week)	1.90	2.10		Q O Y
		A Q'	a' Á á	
			, 0° ~~ \0'	Ś Ś
Material and metho	ods:			
Test item: Mesosulf	uron-methyl (AE F130060)	, substance technical	l; Batch code: AE	F130000-0152;
Batch No.: EFME00	00144; Specification ^x No.: 1	0200001/3204; Tox	No.: 08878-00; A	nalysed parity:
97.4% w/w; Certifica	ate No.: AZ16385.			

3 x 12 fronds of Lemna gibba G3 per test concentration were exposed in chronic multi-generation test for eight times 7 days under static exposure conditions to the nonpeal concentrations listed in Table CA 8.2.7- 13. These concentration profile were derived from the analytical results of an 2009 M-329474-01-1). Lemna gibba could not be tested under outdooroutdoor pond-study ( conditions.

The objective of this study is to obtain 8-week endpoints for Lenna gibba by minicking the outdoorconcentration curves ander laboratory conditions  $\cap$ 

After each week preferably 12 fronds were transferred into the respective following concentration (e.g. fronds from the samples of 3.40 µg/L, the highest concentration of week 1, were transferred into the replicates of 201 µg/L, the higher concentration of work 2 Fronds from the test concentration of 0.194 µg/L the lowest concentration of week 1 were pansferred into the replicates of 0.163 µg/L, the lowest concentration of week 2, etc. In cases where the number of fronds after a 7-day period was below 12 due to damages caused by the tested substance, only the remaining fronds were transferred.

Samples were analosed for the actual concentration of mesosulfuron-methyl present in all freshly prepared test levels at the start day and in all aged test ferels after 7 days of the exposure period.





<b>Table CA 8.2.7-</b>	13: Sui	mmary of te	st concentra	ntions and ex	xperimental	conditions		0	_
Nominal initial								Q .	6
test levels									No.
mesosulfuron-						~		<i>б</i> . '0'	
methyl	Week 1	Week 2	Week 3	Week 4	Week 5	Week	Week 7 🔍	Weelos	
[µg /L]						- O'	2		
% of week 1	100	84.1	70.7	63.2	56.5	50.2	44	\$\$\$9.7 Ø	
0.194	0.194	0.163	0.137	0.122	0.109	<b>ð 0</b> .0970	0,0870	$\sim 0.0770^{\circ}$	
0.388	0.388	0.326	0.274	0.245	0.219	0.195	0.173	0.18Å	_C
0.775	0.775	0.652	0.548	0.490	0.438	0.389	©0.34	<b>0</b> 308 0	Š¥.
1.55	1.55	1.30	1.10	<b>969</b> 79	0.875	0.778 C	0.69\$	JOU.616	
3.10	3.10	2.61	2.19	A.96	1.75	©°1.56∱	1,38	1.23	
pН	7.5 - 8.7	7.5 - 8.7	7.5 – 8.7 «	© ⁷ .5 − 8.7	7.5/-8.7	7.5 – 8.7	<u>√.5</u> – 8,79	7.5 8.7	
Temperature	23.3 -	23.3 -	23.3 - 🌾	2368°-	⇒24.1 ⊀)	238-	©°23.9~~	≪2Å.0 –	
range	23.8°C	24.1°C	23.9°©	2 <b>₫</b> .4°C ×	J_24.4€€	<b>04</b> .4°C	24 ₆ 3°C	≰ 24.1°C	
Light intensity	8610	8000	900	@ 8760@	\$ <del>9</del> 60 .	8436		82200	
(lux)	0010	0000							l
			~ . 7	' <b>S</b> Y		No.			

(lux)	8610	8000	2080	8760	8760	8420	8090 8220			
Dates of experimental work:										
<b>Results:</b>		Q.				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Ŭ v			
Validity criteri	a:		Y da '		Ú ^V	\$ \$	$O^{*}$			
Test conditions	met all vali	dity criteri	a. given by the	mention	ned guidelin	he. 🔊	Ô			
Analytical resu Analytical resu Table CA 8.2.7-	Analytical results: Analytical results are summarized for the following table									
2		O DaØ		ð		Day '	7			
Week 1	Ø 68 a	nd 95% (ave	erage 79%)		79) ai	nd 116% (av	verage 93%)			
Week 2 🔊	<u>9</u> 2 aı	nd 98% (ave	ngge 95%),		🦉 🔍 🖗 an	d 102% (av	erage 100%)			
Week		nd 96% (av	) nage 94%)	° 4J	0 [°] 96 an	id 108% (av	erage 100%)			
Week 4	96 ar	dM04%(av	erage 99%) 🗡	<u>(</u>	^y 101 ai	nd 110% (av	verage 104%)			
Week 5	93 a	nd 97% (ave	eråge 96%	0 🍦	103 ai	nd 108% (av	verage 105%)			
Week 6	🤉 94 ar	id 1@% (ay	erage 98%)		97 an	id 115% (av	erage 103%)			
	~Q.	W /20 '		<i>a "</i>		1 1 0 - 0 / /	1010()			
Week 7	<u>z (89 a</u>	nd 95% (au	$\operatorname{erage}(\mathfrak{M}^{2}) \cap \mathcal{O}^{*}$	Ø	93 an	<u>id 107% (av</u>	erage 101%)			

to the objective of this study the endpoints were referred to nominal initial test According concentrations and not to weekly theatment levels

# $\frac{Biological results:}{Growth rate offects of the test item on Lemna gibba are presented in the following tables.}$

# Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.2.7-15	: Weel	dy inhibitio	n with reg	ard to the m	ean growth	rates of fror	nd numbers	<u>,</u>			
Nominal <b>initial</b> test levels		% inhibition of mean growth rate of <b>frond numbers</b>									
Mesosulfuron- methyl [µg /L]	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8			
% of week 1	100	84.1	70.7	63.2	56.5	50.2	<b>44.7</b>	39.7			
Control				{\$\vec{v}}	@	<i>–</i>	Ù N				
0.194	0.4	-0.6	-6.3	3.0	8.8	1.4 🦋	15	2.6,0			
0.388	2.1	1.1	-1.1	<b>₄</b> €5.5	5.91	-1.0 _c O	3.1	O 3.3			
0.775	32.7	15.1	11.7	8.6	12:4	3.95	3.5	10,3			
1.55	51.1	65.7	43.2 🖉	53.7	39.2∞	27.5	21,2%	<b>0.8</b>			
3.10	67.5	74.8	89.5	¥7.2 .	° 10,‰″	×100 ×	99,0	<b>∜</b> 102			
NOEC	0.388	0.775	0.3	J. 9.388	<02194	Q0.77 <b>5</b>	Q,775 🔬	0.388			
EC ₁₀	0.376	0.538	0.811	₯ 0.82 <b>%</b>	Q.05	1,28	01.39	\$,54			
EC ₅₀	1.61	1.42	1.65	h47	> 1.68	072     ≪	1.85	<b>A</b> 1.90			
Table CA 8.2.7- 16	: Weel	dy inhibitio	n with reg	auce to the Om	ean growth.	sates of Grou	nd addreas	er C			

1 able CA 8.2.7-10	weekiy mindenan wen'i	egard to the mean growth	falles of aron	iu ageas	
Nominal initial		% inhibition of 🖉			
test levels		mean growth rate of frond	area		
Mesosulfuron-			N N	02	
methyl [µg /L]	Week 1 Week 2 Week	3 Week ₹	Week 6	Week 7	Week 8
% of week 1		\$3.2 \$ 56.5	\$50.25	44.7	39.7
Control		<u> </u>			
0.194	©0.7 L 07 -3.4	→ -106 0 3.3	-1.6	0.6	1.5
0.388	€ -1,5 ⁰ 20.7 ¥ -2.2		1.3	0.2	5.4
0.775	30.9 16.4 67.8	5.4	2.8	1.0	5.8
1.55	€58.1 ₩ 74.3 77.2	$6450$ $0_{15.0}$	21.5	16.7	10.5
3.10	80,60 888.1 95.9	97.7 40	97.5	98.9	94.6
NØEC	QC88 ) 0.388 A388	3 0°0.388° 0.388	0.775	0.775	0.775
EC ₁₀	0.402 / 0.652 0.800	<b>∞</b> 0. <b>86</b> 9 ▲ 1.50	1.37	1.45	1.54
EC50 (	1.29	1.368 1.78	1.89	1.90	2.10
<i>.</i>					

Lemna exposed to initial nominal concentrations of 0.194 and 0.388 µg/L (and lower concentrations in the consecutive weeks) were inhibited to less than 10% during the whole study period of eight weeks. Lemna exposed to the initial nominal concentration of 0.775 µg/L were inhibited by 32.7% and 35.9% with regard to front number and front area, respectively. In the following weeks the inhibition percentages steadily dropped to 10.3% and 55% during the last week of the test. Lemna exposed to the initial nominal concentration of 1.35 µg/L were inhibited by 51.1% and 58.1% with regard to front number and front area in week 3), to then decrease again to levels of 10.8% and 10.5% during the last week of the test. Lemna exposed to a maximum of 77.2% thront area in week 3), to then decrease again to levels of 10.8% and 10.5% during the last week of the test. Lemna exposed to the initial nominal concentration of 3.1 µg/L were inhibited by 67.5% and 80.0% with regard to front number and front area, respectively. In the formulation of 3.1 µg/L were inhibited by 67.5% and 80.0% with regard to front number and front area, respectively. In the following weeks the inhibition of 3.1 µg/L were inhibited by 67.5% and 80.0% with regard to front number and front area, respectively. In the following weeks the inhibition percentages increased to figures greater than 95% from week 4 onwards No recovery was observed at this highest treatment level.

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<b>Table CA 8.2.7-</b> 1	l7: 0	bserved vi	sual effect	s on <i>Lemna</i>	gibba			<u> </u>	
nominal <b>initial</b> test levels mesosulfuron- methyl [µg /L]	week 1	week 2	week 3	week 4	week 5	week 6	week 7	Öyeek 8	
0.194	-	-	-	-	-		, - 0	\$ <del>7</del> - \$	)
0.388	-	-	1	-	Č5 -	£-	× ×	7 - 5	<i>.</i>
0.775	1, 2,4	4	-	-	- 🌾	3	<i>0</i> - <i>0</i>		L.
1.55	1, 3	4, 5	6	7, 10, 1 🕵	12	<u> </u>	3	\$3 6	)″
3.10	1	1	7, 8	7, 10	7, 13, 14	15, 16(A+B) 17@C), 18	3,15	6 ³ , 15	

1. Overlapping fronds
2. Plants with 2 and 3 fronds
3. Small fronds
4. Thin ligaments between fronds
5. Fronds mostly of similar size, some individual trands extremely small
6. Triny narrow fronds with ligaments connected to big fronds
7. Big yellowish fronds
8. Small fronds of a deep green colour
9. Connections between fronds
10. Detached curled roots
11. Small fronds with elongated ligaments
12. Come curly roots
13. No new root growth
14. Roots brownish
15. Isolated fronds
16. Nearly no green fronds
17. Some green fronds
18. Brownish plant parts arthe bottom of the test vesel
Conclusions:
The effects of mesogal fluren-methyl (AE F130060) to growth Canhibition of Lemna gibba during a 8-week period simulating a steady dissignation in a static water bodycan be quantified by the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final initial concentrations of the following endpoints based on non-final init endpoints based on normal initial concentrations:

K,

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Table CA	Table CA 8.2.7-18: EC50 for mean growth based on nominal initial concentrations							
	Q	🕹 🖉 🖉 📩 Mean g	rowth rate					
Endpoint	Timenania	Effection frond no.	Effect on total frond area of plants					
	i tige period		[µg a.s./L]					
EC ₅₀	A week 1		1.29					
(CI 95%)	🎾 0-7 d 🔍	(1.06 - 2.03)	(0.866 - 1.98)					
EC ₅₀	week 2	1.42 · · · · · · · · · · · · · · · · · · ·	1.19					
(CI 95%)	7-14 đ∜″	\$0.718 3.02 ×	(0.912 - 1.52)					
$EC_{50}^{\prime\prime}$	week 3		1.22					
(CI 95%)	14 🖉 1 d	(1, 49 - 1, 62)	(1.12 - 1.31)					
EC50	oveek 4 🦈	S ~ 1.47 *	1.37					
(CI 95%)	\$21-28¢d		(1.31 - 1.42)					
EC50	week 5	ũ 🔊 1.68	1.78					
(CI 95%)	2 <b>8∋</b> 35 d	~ (n.d.)	(n.d.)					
EC	week 6 🖓	م ^ع ر 1.72	1.89					
(C <b>J_93%</b> )	<u>්ර</u> 35-42 අ	(n.d.)	(1.78 - 2.11)					
ËC ₅₀	week 7	1.85	1.90					
(CI 95%)	42-49 d	(1.68 – 16174)	(1.84 - 2.01)					
EC ₅₀	week 8	1.90	2.10					
(CI 95%)	49-56 d	(n.d.)	(1.77 – 2.73)					

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



Report:	g; ;201	4;M-487405-01		ð	
Title:	Mesosulfuron-methyl rationa	le for the replace	ment of the old	🖗 day Lemna g	with s
	inhibition study (	2000; M-19	95390-01-1) wit	h the 7-day enc	lpoints
	from the Lemna study (	2013; M-4451	39-01-1)	° 0 v	
Report No:	M-487405-01-1	Ĉs	Å	, K	
Document No:	M-487405-01-1	- Ar			
Guidelines:	not specified;not specified	L.	, O¥		
GLP/GEP:	n.a.		Ô ·		
				AL /	-

#### **Executive Summary:**

The inhibition on **7-day growth rate-figures** has been studied within three Lemna-tests with mesosulfuron-methyl a.i (see Table CA 8.27-16). The first one is a 7-day study conducted in 2006 by according the OECD draft guideline (Dane 1998). Frond numbers and frond biomass was assessed during the study. While growth rate inhibition was calculated from frond numbers (N), the effects on biomass were simply evaluated from biomass increase (Ab) between day 0 and day 7.

The EbC50 calculated from biomass inhibition percentages was  $p.62 \ \mu g$  a.i./L and has been listed in the Review Report for mesosulfuton-metor (SANCO/10298/2003-Final) as bowest Lemna-endpoint. Nowadays a 7-day ErC50 based on growth rate inhibition is used for risk assessments. The ErC50 for frond number was > 1.0  $\mu g$  a.i.A in that study.

Table CA 8.2.7- 195	Survey of ErCso-figures	obtained from static <b>F</b> furon-methyl a.i.	mna-growth inhibition tests

Test system 🏷 🍐	Duration of exposure Results ag a. A.	Reference
growth inhibition	$E_{r} C_{0} (\text{frond Fighter}): $	(2000); M-195390-01-1
growth inhibition day the exposure phase of a recovery study	$ \begin{array}{c} & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & & \\ & & & \\ & & & & \\ & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & $	(2002); M-206814-01-1
growth inhibition,	ErC50 (frond area) 1.61	, 2013
outdoor study	Sweeks C for (frond number) 1.90 ErC 50 (frond area) 2.10	M-445139-01-1

The new *Lengta* study (2019) shall replace the study by (2000) to derive a definite value for *ErC50* (2000) suitable for risk assessment purposes, for the following reasons:

1. If the new study two endpoints, frond number and frond area, were measured.

25 The new study has been conducted on the currently valid guideline OECD 221 (2006).

3. Within a risk assessment, sensitivities of different plant species are compared. As their growth, the test durations, and the test designs are different, a comparison of sensitivities only makes sense when growth rate related endpoints are used. This is reflected in the current



versions of the OECD guidelines for algae and *Lemna*, stating that the growth rate related endpoints are preferred.

endpoints are	preferred.
Consequently the Re-	view Report endpoint of 0.62 $\mu$ g/L, based on frond biomas (data of study)
KCA 8.2.7/01) shall	be replaced by the lowest 7-day ErC50 definitive value of the studies available,
which is 1.29 µg a.i./	L based on frond area (data of study KCA 8.2.7/09).
Report:	0; ;2000;M-197850-01 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Title:	Duckweed (Lemna gibba G3) growth inhibition that. Leachate worer from the O
	lysimeterstudy Covance Muenster, 1490-001 with AE 5130060 Code: AE F130060
Report No:	$C008847 \qquad \qquad$
Document No:	M-197850-01-1
Guidelines:	ASTM: E 1415-91; OEO: drag Jung 1998; ESEPAGEEPAGE EPAGE J § 123-2; Deviation not
	specified
GLP/GEP:	yes A A A

The results of this study were not mentioned of the Review Report for mesosalfuron-methyl (SANCO/10298/2003-Final). A study evaluation is however available in the Monograph (B.9.2.8.6); it was concluded that leachates collected from the lysideter exerted no significant berbicidal activity.

Study summary and ation c

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- **Reference**:
- Test guideline: (1982), OECD draft esticide Subdivisi Gion test (April 1997) and ASTM "Standard guideline for test g of a femical On guide for conducting star
- GLP comp@ance
- Methods: The effect of leavate wer from the logimete study sovance **Method:** The effect of leachate weer from the legimeter dudy Sovance **1490-001** (study no 7.1 %/01) on the week of the duckweed *LemnOgibba* was determined under renewal conditions. In the leaching study, to active substance (as WR20 formulation mixed with metenpyr-diethyl as an EW10 formulation, rat of 14C AE F 00060 and AF 010789 of 13, w/w) was applied twice on the lysimeters, in spring, at 12 months interval. The dure substance was accured at the recommended field rate (15 g/ha). Analyses the were Offormed from the leachates role and dat AE F130060 was below the limit of detection (0.003 to 0009 microg/LQ, or equivalent). Two detabodies, M1 and M2, slightly exceeded 0.1 microg/l. The majoritz of the not identified phoactively was off ver polar nature. Leachates were pooled in 4 samples in order Q constitute matching of half year sangles. Sive samples of both type were constituted. Plants were exposed to the test plostance (leach test) in 000 microg/-5 plants) were allocated per flask. Each concentration and the control were repeated three three three of 15 months of 5 plants) were allocated per flask. Each concentration and the control were repeated three three of 16 months of 5 plants) were allocated per flask. Each concentration and the control were repeated three three of 16 months of 5 plants) were allocated per flask. Each concentration and the control were repeated three three of 5 months of 5 plants measured after 3, 5 and 7 days test duration. Any abnormal perplometers is was two recorded. 1490-001 (study no abnormal prophological sign was the recorded.

\$ 1  $\sim$ was gomoted significantly in each treatment compared to the control, of 1.75 and □ Result grow nonthly samples and of 4.75 and 5.05% in the half year samples (growth rate). According to 4@ in the ass, someth we promoted of 4.99 and 8.21% in the monthly samples and of 10.85 and 12.02% in the half Fir sangles. The phenomenant was explained by the presence of unidentified compounds in leachates. It was oncluged that leachates exerted no significant herbicidal activity.

**Comments (RMS):** the study is acceptable.

Bayer CropScience

#### **Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl



Probably des to unknown ingregents in the Stchate Lenga growth was promoted significantly in each treatment compared to the control of the co

## Conclusion

CEC / ASM) was performed under semi-static conditions A Growth Inhibition Testomethor EP

in order to determine the effect of let  $\phi$  be  $\phi$  (140 H) was performed under some state conditions of  $\phi$  of let  $\phi$  be  $\phi$  (D) with AE F130060 to Lemma gisba (D) to be  $\phi$ . Group was promoved at  $\phi$  four the determined to the control. Percentual inhibition rates were between -1.75 and -5.0  $\phi$  according  $\phi$  growth rate and -4.99% and -12.02% according to biomass increased biomass increas. Ż

The lack of one with the second secon



Mesosulfuron-methyl

#### Table CA 8.2.7-21: Summary table Reference Followed Guidance Differences Critical assessment of the study / De guidance currently in force conclusion about its Reliability M-US EPA, J (not EU-relevant) N/A N/A 197850-123-2 (1982) 01-1 US EPA, OPPTS (not EU-relevant) N/A N/A 850.4400 (1996) Č V KCA ASTM, E 1415-(not EU-relevant) N/A N/A 8.2.7 /02 91 (1991) OECO 221 Cemna sp. Growth Inhibition Test Revised Proposal for a New **Guidelines:** Guideline (April 2004); only minor (initial pH in the lowest test level was slightly Bolow (03 units) the guideline recommendations, which did not influence the outcome of this study negatively

# Executive Summars?

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**GLP/GEP:** 

The aim of the study was to determine the influence of the test item AE F154851 (metabolite of mesosulturon-methyl) on exponentially growing Lemna gibba, G3 expressed as NOEC, LOEC and EC_x for growth rate of both response variables, from number and total from area of plants. This test was conducted according to the OECD Guideline 221. As prinor deviation the initial pH in the lowest test level was gightly below (0.3 units) the recommendations of the guideline. This did not influence the outcome of the study negatively.

3 x 12 front s of *Lemna gibba* GP per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to the nominal concentrations of 0.003, 0.01, 0.03, 0.10, 0.31, 0.98, 3.13, and 10.0 mg pure methodited in comparison to control. Plant frond numbers and total frond area of plants are accorded at the beginning of the test, at test termination, and at two occasions during the 7 day period. Growth and growth inhibition were calculated.

The most sensitive endpoint in this study with AE F154851 was frond area of plants, resulting in a (0-7-day) -  $E_{1}C_{20}$  of  $E_{11}$  mcp.m./L. The NOEC was 0.03 mg p.m./L.

# Material and methods:

Test item RE F154851, Code: AE F154851 00 1B96 0001; Batch No.: LOR 21029; Analysed purity: 96.1% www. AZ No.: 09181.

3 x 12 fronds of Lemna gibba G3 per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to the nominal concentrations of 0.003, 0.01, 0.03, 210, 0.31, 0.98, 3.13, and 10.0 mg pure metabolite/L in comparison to control. The pH values ranged from 7.4 to 8.8 in the control and the incubation temperature ranged from 23.7°C to 24.0°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of

 

 Analytical findings:

 The test levels 0.003 and 0.01 mg pure metabolite/L were not analyted because they were below the (0-7-day)-NOErC.

 (0-7-day)-NOE_rC. The analytical findings of AE 454851 found in the freshter prepared test levels  $0.03 \times 3.13$  mg pure

metabolite/L on day 0 in reference to nominal concentrations ranged between 101 and 109% (average 105%). In the same aged test levels on days 7 there were analytical findings between 97 and 106% (average 101%) of nominal. The analysed quantity of AE 154851 in the highest treatment level 10 mg pure metabolite/L found on day Q and day 7 was only \$1% and 62% of nominal.

All results are based on nominal pritial concentrations of the pure metabolite, whereas the test level 10.0 mg p.m./L was excluded from  $EC_{50}$ -calculations due to potential exceedance of water solubility.

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I able	CA 8.2. /- 22: Concentratio	ns of AE F154851	in the test solutio	ons	<u> </u>
Day	Nominal concentration	A	Actual concentrat	ion of AE F1548	851 🖉 🏾
Day	Nominal concentration	Detection 1	Detection 2	Mean	% of nominal 🛇
	In mg AE F154851/L	[mg /L]	[mg /L]	[mg/L	
0	Control	< 0.001349	< 0.001349	< 0.001349	
7		< 0.001349	< 0.001349	< 0.009349	~- ~~
0	0.003	*	*		ð × .
7		*	*	* *	
0	0.01	*	*	<u> </u>	
7		*	**	Q *Q	ĩ 3 ⁻ 8 lâ
0	0.03	0.0330	0.0325	0.0327	~ 1090° v
7		0.0321	0.0316	© 0.0318	L 100 L
0	0.10	0.102	0.1010	0.10¥ 🔪	
7		0.0975	o 0.0 <b>20</b> 7	🕅 0. <b>09</b> 71 🏷	97
0	0.31	0.32	¢ \$\$332 ~{	Ø.335 S	108
7		0.318 🗸	Ø.316	© 0.317	
0	0.98	سن 1067 ×	1.031	1.049	& 07 V
7		× 1.015×	× 1,095 Å	× % 010 ~~	103
0	3.13	<u> </u>	3 3 73	3.176	\$ 10P
7		0° <u>3</u> .400 .	3.078	<u>م</u> 3.089	89
0	10.00**	6.065	6.053	O 6.059	× × 61
7		<u>\$</u> 6.1949	§ 6.053 K	× 179	[*] ¥ 62
Laurant	standard salution of AE E1 4051	and fam istance	24: and 2400 al		× .

#### Table CA 9 2 7 22 ~

lowest standard solution of AE F154851 used for determination; * not determined

* not determined ** excluded from EC50-calculations are to potential exceedence of water solutions

## Biological findings:

Effects are summarized in the following table.

#### L Effects of AE/E154851 on Lemna gibba in a static 74day test Table CA 8.2.7- 23.

Nominal test	Final frond no.	O Total frond area of	% inhibition*	
concentration	🖉 (replicate 🔊	plants (replicate means)	Mean growth	Mean growth rate for
[mg p.m./L]	means, day (7)		rate for frond	total frond area of
2 S			^y no.	plants
control	▲ 167% <	1377 4	s	
0.003	j 167 🔊	j~y ∦393 O [™] ∧	-0.1	0.9
0.01	A159 S	× 1265	2.0	3.1
0.03	0 ⁵⁶ 180 ⁵⁰	C 0 1440 0	-2.9	1.9
0.10 🔊	° 40 ~	307 8	54.3	60.9
0.31	92 S	4 ⁵⁴ 0190 0	77.7	79.4
0,98	Q 20	Ø 175 W	81.3	85.5
3.13	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	× ~ 140	85.7	89.3
¥0.0**		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	89.2	91.8

* negative value means growth striptilation ** excluded from EC calculations due to potential exceedable of water solubility
# BAYER Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.2.7- 24:	Summary of the observed visual effects of AE F154851
Test level	Observations 🖉 🏷
[mg p.m.//L]	
Control	
0.003	no visual affacts observed
0.01	
0.03	
0.10	fronds grown together on days 25,5 and 7
0.31	fronds small and grown together on day 2;
0.98	fronds grown together on days 5 and 7 $\mathcal{O}$ $\mathcal{D}$
2 1 2	no visual effects observed on days 2 and 5
5.15	fronds grown together and slightly chlorotic of day 7 C
10.0	Single fronds on day $\mathcal{D}$ , $\mathcal{D}$ $\mathcal{D}$
10.0	slight chlorosis and sing@ fronds on dags 5 and 3

			e,		10° 1	2	_ 0
Table CA 8.2.7- 25:	Results based on n	ominal conce	entrations	of AE F1548	51 (test lev <i>e</i> l 10	.0 m/s/1	L
14010 011 0120 200	ites and subta on n	Carlor Cyper		······································			@.V

	excluded) 🔬		s'A	Ô ^v	
Endpoint	Effect on mean growth sate	of frond no,	Effect on mea	n growth rate o	Ctotal frond
(0-7 dav)	[mg p.mOL]			area of plants S	y O
		¥ ~\$ 4	Y N N	mg p.m./L	Ċ,
$E_rC_{50}$	0.12		Nº O	<b>0.11</b>	
(CI 95%)	$(0,04^{\circ} - 0,34)$			(J.06_0.23)	/
LOErC	~~ 0.10 <del>%</del>	~ 0 /		0.90	,
NOErC	^س هر93 ک	y y w		\$\$Q.03	
	à O N				

### **Conclusions:**

The most sensitive endpoint in this study with AE F154851 was from Darea of plants, resulting in a (0-7-day) -  $E_rC_{50}$  of 0.51 mg/s.m./L. The NOEC (0.03 mg/s.m./L) was based on statistical analysis.

### AE F160459

0, 4		s v	0 . 0	
Report:	1	· · · · · · · · · · · · · · · · · · ·	;2000;M-19807	5-01
Title:	Duckweed (Le	mna gi <b>(b</b> a G3) g	rowth inhibition test A	AE F160459 (metabolite of AE
	2 F136960) sets	tance, pure & de	: AFF1604 <del>5</del> 9 00 1B9	07 0001
Report No:	CA09078		Č,	
Document No:	<b>1980</b> , 1980, 01-		9 Å	
Guidelines: 🔊	ASTAC: E 14	5-91; OECD; M	raft June 1998; USE	PA (=EPA): J § 123-2; Deviation not
*	specified			
GLP/GEP	yes a	Ű, X.	*	
N.			$\lor$	

Endpoint according to the Review Report or mesosulfuron-methyl (SANCO/10298/2003-Final):  $E_b C_0 = 1.7 \text{ mg/L}$ 

The new aquatic guidance document (EFSA 2013) only regards endpoints based on growth rates as relevant. Accordingly, the listed endpoint should be revised to

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### **Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

□ Test guideline: US-EPA Pesticide Assessment Guidelines, Subdivision J, §123-2 (1982), OECD draft guideline for testing of chemicals on Lemna gibba, growth inhibition test (April 1997) and ASTM "Stargerd guide for conducting static toxicity test with *Lemna gibba*" G3 1415-91 (1991).

### **GLP compliance**: Yes.

- Methods: The effects of AE F160459 (purity = 96.8%) on the growth of the duckweed *Lergia gives* was determined under renewal conditions. Plants were exposed to the active substance in 300 mbd tasks filled with 150 ml of test water, that contained 0 (control), 0.1, 0.18, 0 20.56, 1.0, 1.8 2.2, 5.6 or 10 by test work and A total of 12 fronds (3-5 plants) were allocated per flask. Each concent of and the outrol of the erected three times. Test water was renewed on days 3 and 5, before data checks diffects on growth ratio were accessed through the number of fronds measured after 3, 5 and days test durofon. Any abnormal morphological sign was also recorded. was also recorded.
- ed at the end of the **Results**: A significant inhibition of both grow krate a bion toming) o test for concentrations of 1.0 mg/l and above. Desed on original Mono Wap P ErC50 7 days > 2.6 mg/l, 95% CI =[1.84, 3.2]r@1 NOErC 7 days = 0.56 mg/l EbC50 7 days = 1.7 mg/l, 95% C
- **Comments (RMS)**: the study is acce Q

\$ Ø Further study information Stoplementing Validity Criteria:

Ò

The validity criterion of a dou is fulfilled. Analytical findings

MAN 045 Analyses of freshby prepoed sulte in coventra ons ranging from 91.9% to 7.7% to 10.9% nongoal values. Therefore, nominal of 115.1% of normal values Se al nging from \$7 resulted in corcentr ge reparted is this stor treatment legels of A E F1604

findings: Biolog in comparison to the solvent control are Mean values of abolite presented in the fail owin S

6 perceptual growth inhibition compared to the solvent control Table CA 8.2.2 ab%lute %

Treatment level	O ∧ <mark>⊘∕lean</mark> 4,	Perc@tual	<mark>Mean increase</mark>	<b>Percentual</b>
Orig/L]	Sowth Cate	inhibiton of	<mark>in biomass</mark>	inhibition of
		<b>SOwth rate</b>	[mg]	biomass increase
Untreated control		<b>0.00</b>	<mark>22.0</mark>	0.00
0.10	0.39 <mark>5</mark>	♥ [≠] 0.12	<mark>21.9</mark>	<mark>0.61</mark>
0.1 <mark>8</mark>	Q <mark>0,%</mark> Q	0.20	21.7	1.52
	0.393 Ø	<mark>0.59</mark>	<mark>21.7</mark>	1.52
<b>7.56</b>	ి <mark>0.384</mark>	<mark>2.89</mark>	<mark>21.3</mark>	<mark>3.33</mark>
~ <mark>1.0</mark> ~	0.377	<mark>4.75</mark>	<mark>20.5</mark>	<mark>6.82</mark>
	<b>0.247</b>	37.58	<mark>9.4</mark>	<mark>57.12</mark>
4 2 <mark>3.2</mark> 4	• 0.171	<mark>56.71</mark>	<mark>4.3</mark>	80.45
گ ^{0`} <mark>5.6</mark>	<mark>0.119</mark>	<mark>69086</mark>	<mark>4.4</mark>	80.15
<mark>10.0</mark>	<mark>0.093</mark>	<mark>76.61</mark>	<mark>2.5</mark>	<mark>88.64</mark>

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### Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

The concentration of test substance leading to a 50% inhibition ( $\mu$ ) in comparison to the untreated control ( $E_rC_{50}$ ) after 7 day (95% confidence limits 1.8 - 3.2 mg/L). The concentration of test substance leading to a 50% inhibitio weight) increase ( $\Delta$ b) in comparison to the untreated control nominal 1.7 mg/L (95% confidence limits 1.0-1.8 mg/L). Intoxication symptoms (yellow coloured fronds / fronds do observed at concentrations of and above nominal 1.0 mg/C). A significant inhibition at a significance level of alpha = 0.05 was observed at nominal concentrations of 1.0 mg/L and above. The no observed effect concentration (NOEC) defined as the changes in plant appearance and development was series on optimized the concentration of the series of the concentration of the concentration of the series of the concentration of the conce	of the growth regarding frond numbers ys test duration was nominal 2.6 rg/L n of the growth gearding bior bs (dry ( $E_bC_{50}$ ) after 2 days test duration as not fully scharate, plant aulted were of growth both relate on food number of growth both relate on food number sign deant growth inhibition and no al 0.66 mg/L.
The following table shows the EC ₅₀ value, after Adays, the caprobability.	Iculation method selected we bin Gial
EC-values after 7 days in mg/L     Over the second se	
<b>Conclusions:</b> In a Growth Inhibition JOst (monod EYA / SECD ASTLY is substance, pure Code AE F1604.49 00 1297 0091 (metabolic (Duckweed), Ore E(S) and P _b C ₅₀ after 7 says tot dury on we limits 1.8 - 6.2 mg/L) and noming 1.7 Ag/L (S% cooldence I The no observed effect concercention PIOEC) was comine (0.5)	to determine the effect of AE F160459, bloc of AL F130060) to <i>Lemna gibba</i> be nowinal 2.6 mg/L (95% confidence imit 2.0-1.8 mg/L), respectively.
Table CA 8.2.7-28:     mmax table       Reference     Folloged     Difference       guidance     Curracian for the folloged     Curracian for the folloged	Critical assessment of the study / Deviations / conclusion about its Reliability
M- 198076- 01-1 01-1 M- 2 (1982) M- 2 (19	N/A N/A
$\begin{array}{c} & \text{SSU4400} (996) \\ \hline \text{KCA} \\ & \text{ASTM} \\ \hline \text{MSTM} \\ \hline \ \ \ \text{MSTM} \\ \hline \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	N/A no deviations from current guideline
Lenna grawth nibition (1992) [phibition 2006]	



### AE F099095

Report:	; ; ;2005;M-254496-01	Ì
Title:	Lemna gibba G3 - growth inhibition test with AE F099095 under static conditions	
	(Code: AE F099095 00 1B99 0001)	
Report No:	EBMMX091	
Document No:	M-254496-01-1	
Guidelines:	OECD 221 "Lemna sp. Growth Inhibition Test" Revised Proposal for a New 🗸	
	Guideline (April 2004); only minor (see temperature measurements) not 🦯 🔗	(a)
	influencing the outcome of this study negatively	,© 1
GLP/GEP:	yes $\Delta $ $O^{\circ}$ $\Delta$ $\Delta^{\circ}$ $\Delta^{\circ}$	

### **Executive Summary:**

The aim of the study was to determine the influence of AE F099095 (metabolite of mesosuffuronmethyl) on exponentially growing *Lemna gibba* G2 expressed ap NOEC, LOEC and EC_x for growth rate of both response variables, frond number and total frond area of plants. The pH values ranged from 7.4 to 8.5 in the control and the incubation temperature ranged from 23.4 °C to 26.2 °C (measured in one additional incubated glass vesse) filled with the same amount of de-ionised water as in the test vessels) over the whole period of testing at a continuous flumination of 7.03 kbx. The measured values for the temperature ranged within which the recommendations. This full not influence the outcome of the study negatively. Plant frond numbers and total frond area of plants are recorded at the beginning of the test, at test termination, and at two occasions during the 7 day period. Growth and growth inhibition were calculated. The concentration which which which which which which which which species by 50 percent (EC₅₀) was determined where possible. The overall ErC₅₀ for AE F090095 was > 100 mg/L and the NOEC was <100 mg/L.

### Material and methods

AE F099095, (code? AE F099095 00 1899 0001) pupity: 99.6 % was tested, specified by batch-no.: KR363/364, certificate of analysis: AZ010810.

3 x 12 fronds of *Lemna gibba* G3 per test concentration were exposed in a chronic multigeneration test for 7days under static exposure conditions to the nominal concentration of 100 mg pure metabolite/L in comparison to control. The pH calues anged from 24 to 8.5 in the control and the incubation temperature ranged from  $29.4^{\circ}$ C to 26.2 C (measured in an additional incubated glass vessel) over the whole period of testing at a communus filumination of 7.03 klx.

Quantitative amounts of AE 1099095 were measured in all freshly prepared test levels on day 0 and additionally in all aged test levels on day 0 of the exposure period.

## Dates of experimental work Janoary 26, 2005 – May 24, 2005

### **Results:**

### Validity Criteria

Test conditions met all validity criteria, given by the mentioned guideline.

### Analytical findings:

The analysed quantity of AE F099095 in the treatment level found on day 0 was 102 % of nominal. On day 7 an amount of 107 % of nominal was found.

Ø1



All reported results are based on nominal initial values of the pure metabolite.

	Nominal concentration	Actu	al concentration	of AE 099095	
Day	[mg/L]	Detection 1	Detection 2	Mean	<b>%</b> of <b>%</b>
		[mg/L]	[mg/L]	[mg/L]	Snominal
0	Control	< 0.01102	م < 0.01102 €	∳ < 0.01102 ک	
7		< 0.01102	♥ <0.01102	< 0.0110	
0	100.000	100.950 🛴	103.126	102.038	× 102×
7		106.563 ( [®]	106,65%	. 106.009	× 197 .0
west sta	ndard solution of AE F0990	95 used for determine	ination: < 0.01	02 mg/L 🔊	in an

Results for the effects of the static 7 day growth individual and listed in the table below.

### Survey of biological findings and the derived inhibitions of growth rate Table CA 8.2.7-30:

Nominal test	Final frond no.	Total frond area of plan	s & Wind bition
levels	(replicate	(replicate means) [mm2	Average growth & Average growth rate
[mg/L]	means, day 7)		rate for frond no. for total frond area of
	~		<b>Plants</b>
control	87 🐇	& 205 L	
100	72 🔪 🖗	O* ~572 ~	9, 9, 7.9

Observed visual effect

Observed visual effects are listed of the table below.

Table CA 8.2.7	<u>l-01:</u>	Survey	of visual	effe@s
	$\sim$			

O"	Test level [mg/L]
	Control
- Ky	

The results based on noninal soncentrations of the test item are shown in the table below.

Table CA 8.2.7- 32:	Storvey of 7-day	y endpoints for AP	F099095
End point (0-7 day)	& Effect	🔊 frond no. 🗸	Effect on total frond area of plants
		[mg/£) ~0	[mg/L]
ErC50		> 400	> 100
LOErC			100
NOE _r C		~ 1005	< 100
× 4		¥	

Conclusion

The overall  $E_r S_0^{\omega}$  for AE F099095 was > 100 mg/L in this study. 6 100 mg/L) was based on statistical analysis. The NOI

AE F092944

### Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Report:	5; ;; ;; ;; ;; ;; ;; ;; ;; ;; ;; ;; ;; ;	
Title:	Duckweed (Lemna gibba G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1000	) ) ?
Report No:	C003865	
Document No:	M-186916-01-1	
Guidelines:	ASTM: E 1415-91; OECD: Draft June 1998; USEPA (ﷺ 123)	
	2;Deviation not specified	
GLP/GEP:	ves a n n n n	.C

### **Executive Summary:**

The objective of this test was conducted to determine the effect of AE F092944 (metabolite of mesosulfuron-methyl) on a higher freshwater plant under semi-static condition according to draft OECD guideline, US-EPA Pesticide Assessment Guideline, J 123 2 and according to ASTM₄E 1415-91 guideline under GLP.

Triplicate *Lemna* cultures with an initial frond number of 12 frond per replicate were exposed to the test substance in 20X-AAP medium at five nominal treatment levels (i.e. 16, 18, 52, 56 and 100 mg/L). Growth and abnormal appearance of fronds in each replicate were determined on test days 3, 5 and 7.

Analyses of freshly prepared water for AE F092944 resulted in concentrations ranging from 94.0% to 103.2% of nominal values. Analyses of aged water for AE F092944 at experimental termination resulted in concentrations ranging from 93.9% to 402.6% of nominal values. Therefore, nominal treatment levels of AE F092944 are reported in this study.

The concentration of the test substance reading to a 50% inhibition of the growth regarding frond numbers ( $\mu$ ) in comparison to the untreated control (E_rC₅₀) after 7 days test duration was nominal >100 mg/L. The concentration of the test substance leading to a 50% inhibition of the growth regarding biomass (dry weight) increase ( $\Delta b$ ) in comparison to the untreated control (E_bC₅₀) after 7 days test duration was nominal >100 mg/L. Or the duration was nominal >100 mg/L. Or the untreated control (E_bC₅₀) after 7 days test duration was nominal >100 mg/L. Or the duration was nominal >100 mg/L.

A significant inhibition of growth both related on front number or total biomass increase was not observed at a significance level of alpha -0.05 at any greatment level.

The no observed effect concempation (NOE@), defined as no significant growth inhibition and no changes in plant appearance and development, was set to rominal 100 mg/L.

## Material and methods: 🕅

Test item AE F092946, Code AE F092946 00 1699 0001; content: 99.8 % w/w; certificate No.: AZ 06326

Three replicate of *Lemna gipba* GS per test concentration with 12 fronds were exposed for 7 days under semi-static conditions to the nominal concentrations of 10, 18, 32, 56 and 100 mg/L in comparison to untreated control. Separate vessels were prepared for chemical analysis of the test substance. The dest media were analysed for chemical and physical parameters (pH, temperature, oxygen content and conductivity) on day 0, 3, 5 and 7.

Although the freshly prepared test water was adjusted to pH 7.5 there was a deviation to pH 8.6 to 9.0 in the agent test water. The temperature ranged from 24.5°C to 25.0°C at a constant light intensity of  $59.7 \,\mu$ Fm-2*s-1.

Growth and abnormal appearance of fronds in each replicate were determined on test days 3, 5 and 7.

### **Dates of experimental work:**

February 19, 1999 - February 26, 1999

### **Results:**

The validation results and chromatograms demonstrate sufficient reliability of the method for the desired application. The lowest concentration level is a law of the reliability of the method for the desired application: The lowest concentration level is above the LOQ and all concentration of the? analyte solution prepared for HPLC are within the linearity range. The repeatability precision is sufficient expressed by a mean CV of duplicate determinations < 20% for all concentration levels. The accuracy is within 80 - 120 % recovery with a CV < 20 %. The specificity of the method is sufficient: The chromatograms display no matrix interference > LOQ of the determined compound and their identity is established by co-chromatography with the corresponding certified reference substance.

Analytical findings: Analyses of freshly prepared water for AE F092944 esuited in concentrations ranging from 940% to 103.2% of nominal values. Analyses of aged water for AE F092944 at exerimental termination resulted in concentrations ranging from 95.9% to 102.6% of nominal values. Therefore, nominal treatment levels of AE F092944 are reported industry. Analytical findings: Analyses of freshly prepared water for SE F092944 resulted in concentrations ranging from 940% to



Table CA 8.2.7- 33:	Analytical findings of AE F092944 in test solutions						
Nominal concentration	Day	Fresh	Fresh water				
[µg a.s./L]		[mg test item/L]	% of nominal	[mg test item/L]	% of <b>no</b> minal		
Control	0	0.00	96.7*	0.00	97.5*		
	3	0.00	97.5*	0000	98.0*		
	5	0.00	98.6*	0.00	6 ⁵⁷ 9938 6		
	Mean	0.00	<u>9</u> 7.6*	0.00			
	Variability			<u>i</u> č	ý , Ú		
10.00	0	9.98	í 100.0	9.67 V	S 96.9		
	3	9.38	94.0 🗸	9.37	~ 9 <b>30</b> °		
	5	10.23	102.5 🖓	6° 9.39 (	94.1		
	Mean	9.86	98.8	0° 9.48 0	\$95.0 °		
	Variability	1.09		y Qr.03	× ×		
18.00	0	17.€	\$96.9	~~ 17.7 <b>%</b>	99.0		
	3	17.63	Ø 98.1 Q	0* 17.76	<b>9</b> 8.9 A		
	5	×J8.35 ~	✓ 102.2 *	\$ 13.80	\$99.1		
	Mean	17.8Q [♥]	e ^y 991 Å	°7.79,	≪J 99.€ [™]		
	Variability	Q 1,85 🔬	× ×	0 1.00 <i>d</i>	$\varphi  \underline{\circ}$		
32.00	0	20.73 ×	≪ ³ 96.2	J 30075 J	<i>9</i> 96.3		
	3 🔍	32.30	> 10,10r (	P A.16	× 97.6 v		
	5 _Q	<u>س</u> رة 32.12 م	× 100.6	<u>31.010</u>	97.1		
	Mean	× 31.72 °°	<u>√</u> 99.3 0×	<u>à</u> 30.99	[♥] 97.0		
	Variability	<u>0</u> .05 <u></u>	~	<u>مَحْ الْعُوْا</u>			
56.00		54.66	97.8	× ~ \$5.56 ×	99.4		
	3 4	55 👫 🧋	° 899.9 ((. )	^{∞°} 52.52	94.1		
A	s ar s	55.69 0	<u>\$99.7</u>	\$\$.00 \$	98.5		
Ő	Mean 🔨	Ø5.40 Š	99.1	© 5¥.40	97.3		
	<b>Variability</b>	<u>سٌ</u> 1.02		@1.06			
100.00 کُ		& 98.44 <i>C</i>	<b>3</b> 8.6	<b>102.41</b>	102.6		
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	ji di (	Ď [×] ₫03.02 ∞	⊘ 103.2	99.34	99.5		
Č O	′ <u>₩5</u>	98.71	~~ 98.99 _×	98.45	98.6		
	🔬 Mean	100.000	<u> </u>	100.07	100.3		
¢¢″	Variability	S 1.05 S	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	1.04			

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* Concurrent recovery rate of laboratory fortifications prepared

 $\sqrt{2}$ f the nominal concentration and the variability is < 1.5. The test results are within 80

Biological findings:

Ø The concentration of the test substance leading to a 50% inhibition of the growth regarding frond numbers (μ) in comparison to the untreated control (E_rC₅₀) after 7 days test duration was nominal Ø >100 mg/L.Ń

The concentration of the test substance leading to a 50% inhibition of the growth regarding biomass The concentration of the test prostance leading to a 50% inhibition of the growth regarding biomass (dry weight) increase (Δb) increase (



Table CA 8.2.7-34: Mean values of absolute and percentual growth inhibition compared to the solvent

control				
treatment level	mean growth	percentual inhibition	mean increase in	percentual inhibition of
(mg/L)	rate (d-1)	of growth rate	biomass (mg)	😞 biomass increase
untreated	0.374	0.00	19.4	0.00 (C)
control				
10	0.373	0.31	20.3	-646 \$ \$
18	0.369	1.26	19.8	×2.06 ×
32	0.370	1.03	19.3	0.69 0.00
56	0.387	-3.48	21.7	
100	0.377	-0.81	21.2	-892 0
		. 9 -		

No intoxication symptoms were observed.

A significant inhibition of growth both related on frond number of total biomass increase was not observed at a significance level of alpha = 0.05 at any treatment level. The no observed effect concentration (NOEC) defined as no significant growth inhibition and no changes in plant appearance and development was set to nominal 100 mg/12

Comparison of specific growth rates (µ), doubling times (Dd) and biomass increase Table CA 8.2.7-35: (Δb) after 7 days test duration with DUNGAN's Multiple Range Test at a significance level

or arph	a – 0.05. 🖉 🕺 🤫			
Concentration in	growth rate µ "	doubling time	change of bioma	ss Δb (mg)
mg/L		(d) 🔧 🕎		
untreated control	.s		A.9.4	А
10	0.373 A	° _∞ @/.861 ° _≪ A [∞]	20.3	А
18	0,569 J A	1.8797 O A	19.8 🔗	А
32 🖉	0.370	\sim 1.859 α A ^O	19.3	А
56	, 0°0.387 √A ∧	, 1995 & A	21.7	А
100	0.3777 & A	AJ1.840 ~ A X	21.2	A

Concentrations with the same letter within each column are not significantly different.

Conclusions:

The concentration of AE F092944 leading to a 50% inhibition of the growth regarding frond numbers (μ) in comparison to the untreated control ($E_{r}C_{6}$) after 7 days test duration was nominal >100 mg/L.

The concentration of test substance leading to a 50% inhibition of the growth regarding biomass (dry weight) increase (Δb) in comparison to the unneated control (E_bC_{50}) after 7 days test duration was nominal >100 mg/L.

A significant inhibition at a significance level of appha = 0.05 of growth both related on both frond number and biomasson crease was not observed up to a nominal concentration of 100 mg/L. which was the highest tested treatment level Q,

The no observed effect concentration (NOEC), defined as no significant growth inhibition and no



AE F160460

Damart	2. 2000.N4 1002// 01
Keport:	Dualayaad (Lampa gibba C2) growth inhibition toot AE E1(04(0 (mothelity of the
i itte:	F130060) substance, pure Code: AE F160460 00 1B96 0001
Report No:	C009792
Document No:	M-199266-01-1
Guidelines:	ASTM: E 1415-91; OECD: draft June 1998; USEPAAFEPA): J § 129-2; De Pation not
	specified
GLP/GEP:	yes v y y
Endpoint according	to the Review Report for mesosuffuron-methyd (SANCO/10298/2003-Final): $E_bC_{50} \ge 000 \text{ mg/L}$. uidance document (EFSA 2013) why revards and points based on growth rates as
relevant. According	gly, the listed endpoint should be revised to: \bigcirc
Study summary a	nd RMS evaluation consider the Sigin Monographs
Reference :	200c, 8 %.2.1/2 57 5 57 57 57 57 57 57 57 57 57 57 57 5
Test guideline: guideline for test guide for conduct	US-EPA & sticigle Assocration Guidelines, Subdivision 9, §123-2 (1982), OECD draft ing of chemicals in <i>Lengra gible</i> , growth inhibition tao, April 997), Gd ASTM "Standard ting stary toxicity test With <i>Lengra gible</i> ," G3 (415-91) (991)
□ GLP compliance	
Methods: The S gibba was defen filled with So m 12 fronds (3-5 pl Test water was re num So of fronds recorded.	ects co VE F (\$9460 (\$465tanes, purs, purity \$96.1% on the footh of the duckweed <i>Lemna</i> nine) under renewak conditions. Places were exposed to the otive substance in 300 ml flasks locaest worr, tha Oontaiked 0 (control). O, 18, 35 56 and 100 mg test substance/l. A total of dots) were allocated per flask, such control and the control were repeated three times, mewer on day 3 and 5 before data checks. [Oects of growth rate were assessed through the s me sured other 3.5 and 7 days for duration. A 5 abnormal morphological sign was also
 Results: No information in the second second	ication symposis with observed. Based on Ominal concentrations: 10 Ang/l -0 00 mOt 100 mOt S) we study is acceptabled
Further study Or	ormation sopplementing the original Monograph summary :
Analytical frames Analytical frames Analyses of reshly	on of doubing time less than 60 hours (2.5 days) in the control is fulfilled.
resulte in concent treatment levels of	trations ranging from 89.0% to 102.7% of nominal values. Therefore, nominal AE F160460 are reported in this study.



Biological findings					^	
Mean values of absolute	and nercentual grov	wth inhibition	in comparison	to the solve	ent control are	Ş
presented in the following	g table:		in companion	à		0*
				S	4 . A	
Table CA 8.2.7-36: Mean v	values of absolute and pe	rcentual growth	inhibition compa	red to the solv	enscontro (<i>R</i> a
<mark>Treatment level</mark>	Mean	Percentual	Mean in co	ase 🧏	Orcent al	
[mg/L]	growth rate	inhibiton 🚱	in bioryas	s 🦂	hibition of	,O
Untrooted control		growth rate			magy ncrease	Ő
	0.20025					×
10	0.39025					
18	0.39073	20 ⁻ -0.47				
32	0.39302				∼ <mark>∕0.9/</mark> ≈	
56	0.38597				, <mark>- . 4</mark> , °	
<mark>100</mark>	0.39506	• <mark>-1.54</mark>	2 <u>4.10</u>			
The construction of the st						
The concentration of test (u) in comparison to the u	substance leading to		on owne grew	th regarding	stond Mambers	
The concentration of test	substan@leading to	a 50% inhibit	ian of the grou	v Shioning in	•hiomass (dry	
weight) increase (Δb) in	comparison to the	atreat con	$P(E_{1})$ at	r 7 dQ/s tes	t duration was	
nominal >100 mg/L.				O O	1	
Intoxication symptoms w	ere not observed	à T		a 2.		
A significant inhibition ₈	of growth both relate	🔊 on frond n	umber of total	Spion in	crease was not	
observed at a significance	e level of alpha = 0	at any treaton	ent kyel.	6		
The no observed effort	comentration (NOE	C) Settined as	noOsignitivant	f growth inh	ibition and no	
changes in plant appearan	and gvelor crent	was set wrom	al 100 mg/L	Dy .		
The following terle slow	s the Cos salues at	er 7 Avs The	al ation the	ethod selecter	d was hinomial	
probability 0 -				lifed selected		
Table CA 8 2.7- 37: EC50 7						
	1 1 ST			minal		
		st st	EC50	E ₁	<mark>,C₅₀</mark>	
EC-values after Suays in	mg/L & x		<mark>≥ 100</mark>	>	100	
e pot		O O				
Lin a Grouth Inhibition	est (asthod DA) to determine	the effect of	F A E E 160460	
substance pure Cad	AF FIGONO 004 PC	6901 (meta	bolite of AF	F130060 to	Lemna gibba	
(Duckweed), the Eress an	Conter Mays	C duration w	ere both nomir	ral > 100 mg/	L.	
The no observed affect co	ncentetion NOE	was nominal 1	00 mg/L.			
	a sa Q					





Mesosulfuron-methyl

Table CA 8.2.7- 38: Summary table

				0
Reference	Followed guidance	Guidance currently in force	Differences	Critical assessment of the study / Deviations / conclusion about its Rability
<mark>M-</mark> 199266-	US EPA, J, § 123- 2 (1982)	(not EU-relevant)	N/A	
<mark>01-1</mark>	US EPA, OPPTS 850.4400 (1996)	(not EU-relevant)	N/A	N/A OF ST S
KCA 8.2.7 /04	ASTM, E 1415-91 (1991)	(not EU-relevant)	N/A	
	OECD Draft, <i>Lemna</i> growth inhibition (1997)	OECD 221, <i>Lemna</i> growth inhibition (2006)	nong	no de ations from en tent e delina
AE F1405	84	k St		

AE F140584

Report:	o; ;2013;M-486658-01 A A A
Title:	Lemna gibba G3 - Growth inhibition test with BCS AU66443 (AEF 140584) under
	semi static conditions & & & & & & & & & & & & & & & & & & &
Report No:	EBMMN119 OV NY
Document No:	M-486658-0161
Guidelines:	OECD Guideline 221 (March 23, 2006)
	US EPA OCSPP 850.4400; a slight deviation (01) of pH is explained and
	discussed with the preparation of the nutrient medium
GLP/GEP:	yes of of of of the second sec

Executive Summary

The objective of this growth inhibition test was to verify the assumption that the test item AE F140584 (metabolite of mesosulfuron-methyl) will cause no adverse effects on the growth of Lemna gibba G3 at the only test item concentration of 10 mg pure metabolite (p.m.)/L. This test was conducted according to the OFCD Guideline 221 (2006) and is also based on US EPA Ecological Effects Test Guideline ØCSPP850.4400 (2012).

6 x 12 fonds of Lemma gibba 3 per test conceptation were exposed in a chronic multigeneration test for 7 days under semi static exposure conditions to the nominal concentration of 10.0 mg p.m./L in ×,° comparison to a control

Plant frond numbers and total frond area of plant were seconded at the beginning of the test, at test termination, and at two casions during the day period. Growth and growth inhibition were calculated The E_rC_{50} was 10 pmg pm./L and the C_rC was >10.0 mg p.m./L.

Material and methods:

ė

Test item: AE F140584; Batchcode; AE F140584-01-01; Origin Batch No.: SES 10678-15-2; TOX No.: 10305-00 Analysed a.s content: 98.4% w/w AE F140584; certificate No.: AZ 19035.

6 x 12 fronds of Lemna gibba \$3 were exposed in a chronic multigeneration test for 7 days under semi static exposure conditions to the nominal concentration of 10.0 mg p.m./L in comparison to a control.

The pH value range from 7.5 to 8.7 in the control and the incubation temperature ranged from 24.0°C to 24.1°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 6603 lux (average of nine measurements).

Quantitative amounts of AE F140584 were measured in all freshly prepared test levels on day 0, 1, 2, 3, 4, 5 and 6 and additionally in all aged test levels on day 1, 2, 3, 4, 5, 6 and 7 of the exposure period.

Dates of experimental work:

April 22, 2014 - May 20, 2014

Results:

Validity Criteria:

The doubling time of frond number in the control was 1.8, corresponding to a 15.4 fold increase. The control coefficient of variation (CV) for yield and growth rate is < 20% at test termination. Therefore, the study met all validity criteria, requested by the mentioned guidelines.

Analytical findings:

The analytical findings of AE F140584 in all freshty prepared test levels ranged between 85 and 101 % of nominal. In all aged test levels analytical findings ranged between 0 and 1 % of nominal due to rapid degradation of the test substance. However, all reported results are based on nominal concentrations. During the test all efforts were made to establish a constant exposure concentration by performing a daily water exchange.

Table CA 8.2.7-39: Measured concentrations of AE F144584 in test solutions

	Nominal concentration	Acte	al concentration	of AD F140584	
Day	[mg p.m./L] 🖓	6 Detection 1	Detection 2	Meato	🔊 % of
		(mg/L)	Ű [mgŒ]	[©] [nng/L] ዿ	, nominal
0		°S≪ 0.672	<i>≤</i> 0.672	<i>⊚</i> 0.672 ⁰	
1 aged	Ô ^x	ِيَّ < 0.672 ^{°0}	< 0.672	× 0.672	
1 new	× A	30 .672	\$ < 0.672 ×	J < 0 .072	
2 aged		€ 0.67	< 672 kg	×0.672	
2 new		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	€0.672 ^{©*}	‴≪ 0.672	
3 aged		≪ 0 .672, ~ ♥	Q < 0.672	♥ <0.672	
3 new	C Ontrole	×0.672	~ < Q 672	<pre>✓ < 0.672</pre>	
4 aged		≪ < 0.672 C	60.672	< 0.672	
4 new 💊		, ∠, < 0 ,672 °	0.672^{j}	< 0.672	
5 aged		< 0.672	\$\$ < 0 672	< 0.672	
5 new		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	× 0.672	< 0.672	
6 aged		× < \$672 °	≈ ≈ 0.672	< 0.672	
6 new		پ _ ≮0.672	©* < 0.672	< 0.672	
7		\bigcirc $< 0.6 \%$	× < 0.672	< 0.672	
0			10.2	10.2	102
1 aged 🎢		₹ ⁹ .672	< 0.672		
1 new®		9.50	9.71	9.61	96
2 agod		$0^{9} < 0.672$	< 0.672		
2 new	, Frank	× 0.60	9.61	9.61	96
3 aged		0.672	< 0.672	< 0.672	
3 new		9.80	9.61	9.71	97
4 aged 🦼		Q < 0.672	< 0.672		
4 new 🖉		8.58	8.50	8.54	85
5 aged		< 0.672	< 0.672		
5 new		9.95	9.43	9.69	97
6 aged C		< 0.672	< 0.672		
6 net		9.57	9.57	9.57	96
7		< 0.672	< 0.672		



Biological find	ings:			٥
Effects are sum	nmarized in the follow	ing table.		
Table CA 8.2.7-	40: Effects of AE	F140584 on Lemna gibb	a in a static 7-day te	esto o a
Nominal test	Frond no. (day 7)	Total frond area of	% %	whibition 🔗 🖓
concentration	mean values from	plants (day 7)	Mean growth ®	Mean growth rate for
[mg p.m./L]	6 replicates	Mean values from 6	rate for frond no.	total frond area of
		replicates [mm ²] (2)		<u>plants y sy</u>
Control	185	1641	0	
10.0	193	1678	-195	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>
-% inhibition: ind	crease in growth relative	to the control	Q' p°	
		Q0".	~>~. Ŭ [*]	
No sublethal ef	ffects on Lemna gibba	were observed		
No remarkable	observations of the	test itemon the dest m	edium were record	led Over the whole test
period, the med	lia were clear and colo	ourless of o		
•			A.Ô	
Table CA 8.2.7-	41: Results based	on nominal concentrati	ons of AD F140584	
			Effect on mean gro	with rate of total frond
Endpoint	Effect on mean grow	th rate of frond no.	S Sarea	of planes 2
(0-7 day)	[mg@:	m./Lj	<u>s</u> o m	g p.mĉĽ] 🍾
E_rC_{50}	_@>10			>1,0,0 《
LOErC	×_>10			≥10.0 0°
NOE _r C				Ø10.0
The $E_r C_{50}$, LOE_r	C and NOE C determina	tion is based on statistica	ul data analysis 🔊	
		a 5° 2° . 0		. 63
Conclusions:				
				,
AE F140584 c	aused no adverse effe	ects on the growth of	Læmna zibba G3	up to the limit test item
concentration of	of 40 mg pure metabol	ite/L.	S S	
Š	j S O C		Ő.	
Ô		ANT		
	õ sõ j		× ×	
AL 114/44/			<u>~</u>	
Report:	<u>~</u>) '],	; ;20	00;M-198273-01	
Title:	Duckwee@Ler	nga gibba Ø3) growth ini	bition test AE F147	7447, substance, technical
	Oletabodie of	@ F130060) Code: AEQ	147447 00 1C93 00 1C93 00	01
Report No:	C009205 ~			
Document No:	M-198273-01-1			
Guidelines	ASTM: 51415	5-91; OECO: draft june	1998; USEPA (=EF	PA): J §123-2;Deviation not
	specific			
GLP/GEP:	yes A			
		× Sr		
		Q A		
Endpoint accor	ding to the Review Re	port for mesosulfuron	-methyl (SANCO/	10298/2003-Final):

The new aquatic guidance document (EFSA 2013) only regards endpoints based on growth rates as relevant. Accordingly, the bited endpoint should be revised to

 $E_rC_{50} > 100 \text{ mg/L}.$

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Ser Bayer CropScience

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl





Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl



Executive Summary

The objective of this growth inhibition test was to verify the assumption that the test item BCS-CO60720 (metabolite of mesosulfuron-methyl) will cause no adverse effects on the growth of *Lemna gibba* G3 up to a test item concentration of 11.8 mg pure metabolite (p.m.)/L. This test was conducted according to the OECD Guideline 221.



6 x 12 fronds of Lemna gibba G3 per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to a nominal concentration of 11.8 mg p.m. in comparison to a water control.

Plant frond numbers and total frond area of plants were recorded at the beginning of the test, at test termination, and at two occasions during the 7 day period. Growth and growth inhibition, were calculated. The E_rC_{50} was > 11.8 mg pure metabolite (p.m.)/L and the NOE was > 11.8 mg

Material and methods:

Test item: BCS-CO60720; Batch Code: BCS-CO60720-01-01; Gingin batch no TOX no.: 08551-00; Analysed purity: 98.3% w/w; certificate No.: AZ 16515.

6 x 12 fronds of Lemna gibba G3 were exposed in a chronic multigeneration test for 7 days under static exposure conditions to a nominal concentration of M/8 mg p.m./L m comparison to a water control. The pH value at day 0 was 7.5 in the controls and the incubation temperature ranged from 23.5°C to 23@°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7824 lux.

editest levels on day 0 and Quantitative amounts of BCS-CO60720 were measured in all freshly additionally in all aged test levels on day of the exposure period

Dates of experimental

Results:

Analytical finder

Validity Criteria: The study met all validity criteria, ned guidetine

The analytical finding of BCS-CO60720 found on day 0 was 108% of nominal and 112% of nominal on day 7 All reported results are based on nominal values of the test item.

A.			
Nominal Concentration	Actual Concentration (mg BC	S-CO60720/L)	
in mg.m./L			
l j	Determination Determination	Average	%
Control 🗞	<0.632	< 0.632	
10.0 ×	12.7 2 12.8	12.8	108

Table CA Q 2 S_@060728.in

Concentrations of BCS CO60720 in the test solutions at day 7 Table CA 8.2.7-46;

		Day 7			
Nominal Concentration A Actual Concentration (mg BCS-CO60720/L)					
in mg p.m. (L	~ h Q	2.			
	Determination	Determination	Average	%	
Control A a	> <0.632	< 0.632	< 0.632		
Ly 10.0 Ly	13.2	13.2	13.2	112	

Biological findings:

Effects are summarized in the following table.

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.2.7-	- 47:	7: Effects of BCS-CO60720 on <i>Lemna gibba</i> in a static 7-day test							
Naminal tag	4	Final frond			%	inhibition	Ø D		
Nominal test concentration [mg p.m./L]		no. (replicate means, day 7)	Final total frond area of plants (replicate means) [mm ²]		Mean growth rate for frond no.	Mean growth ra total frond are plants	te for a of		
Control		182.8	1318.7		1	<u> </u>	y b		
11.8		188.3	1323.3	æ.	-2.7	مَرْ 1.0 مَرْ	- North Contraction of the second sec		
There were no visual effects observed in any of the test concentrations.									
Endpoint (0-7 day)	Ef	fect on mean gro	with rate of frond no. ° p.m./L]		fect on mean grow area o	vth rate of total fre f plants >> @n.L] 2	and /		
E_rC_{50}		>	<u>11.8 A . O . (</u>	Ų		1.8 0	Ű.		
LOErC		>	$11.8 \qquad \qquad$	Ĩ	\rightarrow \rightarrow \sim	1.80	Ş		
NOE _r C		2	<u>11.80° v v</u>		$0 \le 1$	by a o			
The LOE _r C determination is based on statistical data analysis									
BCS-CO60720	ca	used no advers	e effects on the grov	vth c	of Vemna gibba	G3 up to a test	item		
BCS-CO6072	1								

BCS-CO60721

Report:	₽ ;20₽3;M-4₽5154-01 ♥ ♥
Title:	Lemna gibbs G3 - Growth inhibition test with BCS-CO60921 under static conditions
Report No:	EBMMLOWI & Y & Y & Y
Document No: 🐎	M-445054-01-O' & D' D' D' D'
Guidelines:	OECD - 221 (March 23, 2006); Deviations: The documentation of a 7-10 day old
	pre-culture is missing for this study. Of the basis of the photo-documentation of
<u>i</u>	Lemna plants within the study and the fulfilled validity criteria it can be stated
× ¥	That this deviation from the guideline had no impact on the study results and
	therefore on the validity of the study. The deviations from the guideline are
Ę,	documented within the taw data.
Q)	The pH values were not determined on day 7. Based on the normal control
~Q~	growth it can be assumed that the pH values on day 7 were in line with the
4	gui@ine.requirements.
GLP/GEP	
Å.	
Executive Summar	$\mathbf{y}_{\mathbf{i}}$ \mathcal{A} \mathcal{O}' \mathcal{Q}' \mathcal{X}'
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	

Executive Summary: CO60721 (metabolite of mesosulfaron-methyl) will cause no adverse effects on the growth of Lemna gibba G3 up to a test item concentration of 10 mg pure metabolite (p.m.)/L. This test was conducted according to the DECD Guideline 221. As deviation from the defined guideline recommendations the documentation of a 2,10 day old pre-culture is missing for this study. On the basis of the photodocumentation of *Lemna* plants within the study and the fulfilled validity criteria it can be stated that this deviation from the guideline had no impact on the study results and therefore on the validity of the study. The deviations from the guideline are documented within the raw data. The pH values were not determined on day 7. Based on the normal control growth it can be assumed that the pH values on day 7 were in line with the guideline requirements.



6 x 12 fronds of *Lemna gibba* G3 per test concentration were exposed in a chronic multigeneration test for 7 days under static exposure conditions to a nominal concentration of 10.0 mg p.m. (i) in comparison to a water control.

Plant frond numbers and total frond area of plants were recorded at the beginning of the test termination, and at two occasions during the 7 day period. Growth and growth inhibition server calculated. The  $E_rC_{50}$  was > 10 mg p.m./L and the NOE_rC was  $\ge 10$  mg p.m/L.

### Material and methods:

Test item: BCS-CO60721; Batch Code: BCS-CO60721-01-01; Origin batch No.: SES 10798-12 Customer order no.: TOX08552-00; Analysed purity 95.1% w/w; Certificate no?: AZ 46765.

6 x 12 fronds of *Lemna gibba* G3 were exposed in a chaonic multigeneration test for 7 days under static exposure conditions to a nominal concentration of 10.0 mg p.m./L in comparison to a water control. The pH value at day 0 was 7.5 in the control and the incubation temperature ranged from 23.5 °C to 23.6 °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7824 lux. Quantitative amounts of BCS-CO60721 were measured in all freshly prepared test levels on day 0 and additionally in all aged test levels on day 7 of the exposure period.

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### Dates of experimental work

### **Results:**

Validity Criteria:

The study met all valuatity criteria requested by the mentioned guideline.

Analytical findings:

The analytical finding of BCS-CO60721 found on day 0 was 97% of nominal and 101% of nominal on day 7. All reported results are based on nominal values of the test item.

Table CA 8.2.7- 49:		aceutra	tions of	f <b>BCS-C</b>	00721	in the test	solutions at day	0
	·	"	SY 11	$\sim "$	N/ //			

Nominal Concentration	Actual Concentration mg BCS	-CO60721/L)	
in mg p.m./L	Determination	Average	%
Çontrol 🔗		< 0.652	
10.0	<u>5</u> 964 55 9.68	9.66	97

Table CA 8.2.7- 50: Concentrations of BCS-CO60721 in the test solutions at day 7

· *	- OF		Day 7		
Nominal Concentration					
in mg p/m./L	A` Æ	≪ [™] 1. [™]	2.		
	Y. Z	Determination	Determination	Average	%
Contros	Ô á	<del>گ &lt;0.65</del> 2	< 0.652	< 0.652	
10 <b>_0</b> ∽	1 ~0	10.1	10.2	10.1	101

Biological Indings:

### Survey of biological results and derived inhibition percentages of BCS-CO60721 Table CA 8.2.7- 51:

according to growth rates							
Nominal tost	Final frond		<b>%</b>	inhibition			
concentration [mg p.m./L]	no. (replicate means, day 7)	Final total frond area of plants (replicate means) [mm ² ]	Mean growth ( rate for frond	Mean growth rate for total from area of			
			110.	Maints S			
control	182.8	1318.7	& "				
10.0	187.2	1264.5	-67				
There were no visual effects observed in any of the test concentrations.							
Table CA 8 2 7 52: Results based on nominal incontrations of BCS $CO(0721)$							
1 abit CA 0.2.7 - 32.	IXCSUITS DAS	cu on noninnai concenti ationy					

Table CA 8.2.7-	52:	Results based on	nominal conc	entrations	of BCS	CO60721	~\ ^	 ž
			^				11 12	 _

Endpoint (0-7 day)	Effect on mean growth rate of frond of. [mg p.m./L]	Effect on mean growth rate of total frond Area of plants A [mg.p.m./LP 2 4
ErC50	>10.0 20 000	>10.6c
LOErC		$\sim 100^{\circ}$ $\sim 100^{\circ}$ $\sim 100^{\circ}$
NOErC	$\geq 10$ $\sim$ $\sim$ $\sim$ $\sim$	
The LOE C date	mention to be and an effective of a state of the second seco	

The LOE_rC determination is based on statistical data analysis

### **Conclusions:**

on the growth of Lemma BCS-CO60721 caused no adverse effects gup to a test item concentration of 10 mg pare metabolite D.

### Further testing on Aquatic organisms CA 8.2.8

One acute study under flow through conditions on Eastern Ster Crassostrea virginica) was performed. Details of the study are provided in the following table. ×,®

Table CA <b>8,2.8-1</b> :	Kffect data o	f mesosulfuron	-methyl to@qu	aticorganisms pres	sented in this chapter

Test species		ystema v	Test duration	E Colp Ang as	oint s/L]	Reference
Mesosulfuron-me	hyl /		N O			
Crassostrea virgina (eastern oyster)	ca	hrough		© EC ₅₀ NOEC	> 100 100	, 2000 B003104 M-238739-02-1 KCA 8.2.8 /01

Report:	:; 2000;M-238739-02; Amended: 2000-12-07
Title:	AE F130000 00 JC96 0004 - Acute Toxicity to Eastern Oysters (Crassostrea
L. L.	virginia Under Flow Phrough Conditions
Report No: 🔎 🔦	B003604 Q
Document Nors):	M8739_402-1 ~
Guideline	USEPA EPA): FIFRA 72-3, OPPTS 850.1025; Deviation not specified
GLP/GEP:	yes S

# Executive Summary:

The air of the study was to estimate the acute toxicity of mesosulfuron-methyl (AE F130060) technical to Eastern oysters (Crassostrea virginica) under flow-through conditions.



Crassostrea virginica (mean valve height  $37 \pm 4.0$  mm) were exposed in a flow-through system over a period of 96 hours to nominal concentrations of 13, 22, 36, 60 and 100 mg a.s./L (corresponding to mean measured concentrations of 13, 20, 37, 57 and 100 mg a.s./L). In addition a dilution water control (natural unfiltered seawater) was tested. Shell deposition, mortality an Sublethal becavioural effects were used to determine the endpoints. Based on analytical findings the biological endpoints are reported as mean measured figures. The 96-hour-EC₅₀ was > 100 mg a.s., the 96-hour-NOEC was determined to be 100 mg a.s./L.

### Material and methods:

Test item: AE F130060, technical (mesosulfuron methyl); Code: AE 5130060 00 1096 0004 No.: 208465-21-8; Batch No.: OP 3/99, Purity: 996% w/w; Certificate of Analysis; XZ 08196.

Crassostrea virginica (mean valve height  $37 \pm 40$  mm) were exposed to the test stem in a flowthrough system over a period of 96 hours. Nominal concentrations were 13, 22, 35, 60 and 100 mg a.s./L (corresponding to mean measured concentrations of 13, 20, 37, 57 and 100 mg as./L). In addition a dilution water control (natural unfiltered seawater) was tested. Each vessel (glass aquaria measuring 49.5 x 25.5 x 29 cm) served as one replicate filled with 18 Loff test solution. Natural unfiltered seawater was used as diffution water The seawater used for these solutions had a salinity of 32‰ and a pH of 8.0. 20 ovsters were placed in each test apparium. The temperature of the test solution was regulated at  $20^{\circ} \pm 2^{\circ}$  The test was conducted with 2 replicates per treatment level and the control. Prior to the test initiation, each ovster was ground with a time-grit grinding wheel to remove approximately 3 to 5 mm of shell and for a blort edge. Observations of stress, abnormal behavioural activity and mortality were made at the start of the Ost and after 24, 48, 72, and 96 hours. Oyster shell deposition was measured microscopically at the god of the study.

For analytical verification of the test item concentrations sample were taken at 0 and 96 hours from all concentrations. High-performance liquid chromatography with ultraviolet detection (HPLC/UV) was used as analytical method.

September 14, 2000 to September 18, 2000 Dates of experimental work

### **Results:**

### Validity Criteria:

shell growth > 2 mm was fulfilled. The validity criterion of oxygen saturation above 60% was fulfilled. fulfilled

### Analytical Findings:

Results of the RE E130060 technical analyses established that the measured concentrations were consistent between sampling intervals and defined the exposure concentrations as 13, 20, 37, 57 and 100 mg a.i.D. Detailed analyticat results are presented in the following table:

La Sa Car



### Table CA 8.2.8-2: Concentrations of AE F1 30060 technical measured in the exposure solutions during the 96-hour exposure of Eastern ovsters (Crassostrea virginica).

	concentrations of the first booton technical incusation in the exposure solutions							
during the 96-hour exposure of Eastern oysters ( <i>Crassostrea virginica</i> ).								
	Ν	<b>Ieasured concentration</b>	n (mg a.s./L) ¹					
Nominal			~	Bowoont of mominal				
Concentration	0-Hour	96-Hour	Mean 🖉	Percent or nonnau				
(mg a.s./L)			<i>©</i>					
Control	< 2.3	< 2.6	NA A	Ô ^y NA ŷ				
13	12	13	13	× 964				
22	20	21 /		0° 28° 0° 10				
36	38	36	i Br	Q 3100 0 5				
60	56	58 🖉	457 <u> </u>					
100	98	105	~~100 @ ° ~~	L 100 L				
Analytical values are ren	artad to two aignifian	nt figures						

Analytical values are reported to two significant figures NA = not applicable

### **Biological results:**

exposed to all AE F120060 The percent reduction in shell growth did not exceed 12 6 for oysters technical concentrations tested. No sublethal effects, were observed among any of the exposed systers throughout the tested concentration range.

### Effects of AE F130060 technication the shell deposition of Eastern oysters Table CA 8.2.8-3: strea virginica) after 96 hours of ex

	(Crussesareu vaş	ance) and ronours of expass		$\wedge$
Mean measured concentration (mg a.i./L)	Mortalito%	Mean Mell deposition		Percent of control ²
Control 🔬		0 0.4 0	( 1.0 )	NA
13		Q \$\$ 3.5 \$	0° 1.2	0 (+6)
22			d.1	3
36	O QY	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~©0.9	10
60,0 0	Ň O O	10 L 2.9 ~ 5	1.2	12
100°		× <u></u> 3.3 ~ O	<i>©</i> 1.2	< 1



### Bayer CropScience BA F Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

### CA 8.3 Effect on arthropods

### Effects on bees CA 8.3.1

CA 0.5	Effect on artifiopous		
CA 8.3.1	Effects on bees		. 4
		*	
Table CA 8.3.1- 1	: Toxicity endpoints of/for	mesosulfuron-methyl (tech.)	
Test	Ecotoxicological endpoint		Reference
substance		<u> </u>	5° 25' 6
Acute oral and c	ontact toxicity for honey bees		
M	· · · ·		, 199,
methyl tech	LD ₅₀ -oral, 72 h	LD ₅₀ 5.6 µg a.s./bee	M441738901-1 0
metnyi, teen.		, O ^Y , S ^Y	©CA 8.3%.1.1.01
Mesosulfuron-			, 199 <b>X</b>
methyl tech	LD ₅₀ -contact, 48/72 h	$0.5_{50} > 13 \ \mu g \ a.s./bee. $	M-143107-691-1
memyi, teen.	%		KOA 8.3 J.1.2 / 4 J
Mesosulfuron-	LD ₅₀ -oral, 96 h $\bigcirc$	LD% > 105.6 μg a 3./bee_Ο	, 2012
methyl, tech.	LD ₅₀ -contact, 96 h	$L_{D_{50}} > 100 \ \mu g \ \text{a}$ , bee	M-4₿\$998-@₽1
	NOED (oral/contact) % h	NOER ≥ 105;6/100 µg a.s./b@ [×]	KCA 8.3.1.1 /01
Acute contact to	xicity for bumble bees 🖉 👔		
Mesosulfuron-	LD ₅₀ -contact. 480	$L_{1} = 100 \ \mu g \ a/00 \ hee \ s$	2014
methyl WG 75	NOED (contact), 48 h	NOED $\geq 100 \text{ µsg} \text{ a.s./bsg}$	M-4\$5279-01-1
<u> </u>			KGA 8.3 1/02
Chronic toxicity	for adult honey bees v '0		
Mesosulfuron-	10 d chronic adult feeding	$LC_{50} > 120 \text{ mg ds./kg}$	, 2014
methyl, tech.	studyo O S	$QNOEC \ge 120 \text{ mg a.s.} Rg$	M& 82655-01-1
Honor has hused	I fooding tost		Sec A 8.3.1.2 /01
noney bee brood		Mandyars affect on a stat baa	2
		whortality beedrood development	
1		(explored arvae ald large	
Mesosulfuron-		pupae), behaviour colony	
methyl WG 75	Boney bee brow feeding	strength and colony development,	, 2013
(+Mefenpyr,dieth	$et qd_{1}, 1992$	by feeding honey beecolonies	M-465325-01-1
WG 15)		sugar syrup at a mesosulfuron-	KCA 8.5.1.5 /01
É G		methyl concentration typically	
~ ¥		present in the spray tank (37.5	
		ppm)	
	Semi-field honey bee brood	No adverse offects on mortality of	
Mesosulfuron-	Quidy (OECD-No. 75; O	adult bees and brood, flight	2015
methyl WG 75	forced exposure conditions)	development (brood termination	, 2013 M 510267 01 1
(+Mefenpyi) dieth	ıyl <mark>in <i>Phacelia</i> Sapplication</mark> , Q	rate brood index, compensation	KCA 8 3 1 3 / 03
WG 15)	diffing fut-bloom and bees	index) and colony vitality at 15 g	KCA 8.5.1.5705
× 1	actively foraging	mesosulfuron-methyl/ha	
- K		y	
a			
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A.			
<u>5</u>			
	O' in		
A A	3		
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reflected in the new List of Endpoints.

In addition to the already available acute laboratory studies with technical mesosulfuron-methyl ( ; 1996, Doc.-No.: M-141738-01-1 and 1997, M-143107-01-1; KCA 8.3.1.1.1/01 and KCA 8.3.1.1.2/01), a further laboratory study on the acute oral and contact toxicity to honey bees has been performed with technical mesosulfuron-methyl according to current gordelines and requirements. Moreover, an acute contact toxicity study with Mesosuburon-methyl WG 25 in bumble bees has been conducted (KCA 8.3.1.1 /02) in order to benchmark potential mesosulfuron-@ methyl - inherent sensitivity differences to honey bees. Ś In addition, a chronic 10 day adult feeding limit test was conducted with technical mesosulfition. methyl (KCA 8.3.1.2 /01). The respective study summaries are presented below. (1996, 1997) and when comparing When considering the acute toxity findings from these endpoints with the endpoints as obtained in the recent widy by (2012) according to current guideline requirements, the findings of an 2050-contact of >13 org a.s bee ( 2012) with 0% corrected mortality in both studies at any 1997) and of >100  $\mu$ g a.s./bee ( point in time are fully consistent and the numerical difference is just to be attributed to the different doses tested. As such, the intrinsic acute contact toxicity of technical mesosurfuron methy can be concluded to be actually >100 µg os./bee, which should also be appropriately reflected in the new List of Endpoints. When comparing the findings regarding the intrinsic oral toxicity the old study . 1996) revealed a LD50 of 184.8 µg w.s./bee after 24 and 48 h, however, after 22 h, & marked decrease of the LD₅₀ to apparently 5.6  $\mu$ g  $\alpha$ s./bee@vas observed@ In order to investigate, whether there is any potential mesosulfuron-methyl inberent delayed toxicity 2012) was deliberately prolonged to the maximum guidelineeffect, the new study ( complient study duration of 96 h although this was not triggered by the actual study results. The new 2012), according to the latest OFCD guideline requirements, revaled a LD50-oral of study ( >105.6 µg a.s bee after 24, 48, 72 and 96 always associated with 0% mortality, respectively. (2014) The bees were continuously fed ad Moreover, in the the 10 day chronic feeding andy ( libitum over a period ov 10 days with technical mesosulfupon-methyl at a concentration of 120 ppm which was verified by daily chemical apalysis which resulted in 0% mortality after 10 days of consecutive feeding. In the old acute study by (1996), treatment levels of 10 and 100 ppm after a one-time feeding went resulted in a mortality of 22/50 (=44%) at 10 ppm (=0.001%) and in a mortality of  $23/50^{\circ}(=46^{\circ})$  at  $40^{\circ}$  ppn (=0.01%) after 72 h. In addition in the bee brood Beding study 2013), where entire honey bee colonies were exposed to Mesosulfuron-methyl WG 75 at a mesosulfuron-methyl concentration corresponding to 37.5 ppm, also no effects on honey bee mortality were observed. Overall, when accounting for the findings of (i) the new acute oral toxity study with technical , 12), Which was deliberately prolonged to 96 h without any mesosulfuron-methyl₄ ( mortality, the findings of (a) the new chonic oral toxicity study (1996, 2014), with a daily analytical confirmation of the exposure concentration and (iii) the findings of the bee brood feeding study ( 2013) in comparision to the old acute oral toxity study by (1996), it appears that the observed significant increase in mortality in the study by (1996) during 48 to 72 h must be attributed to study interent technical shortcomings, rather than to mesosulfuron-methyl inherent substance properties. As such, it can be concluded that the the intrinsic acute oral toxicity of technical mesosulfuron-methyl is actually >105.6 µg a.s./bee, which should also be appropriately

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### CA 8.3.1.1 Acute toxicity to bees

Study with mesosulfuron-methyl

			S.	L.	
Report:	V;	;2012;M-433998-01	103	~ Í	
Title:	Effects of mesosulfuron	-methyl tech. (Acute contact	and oral)	, Ô [°] â	
	on honey bees (Apis me	ellifera L.) in the laboratory			
Report No:	72941035		<u>v</u>		
Document No:	M-433998-01-1	í Ó	4		
Guidelines:	OECD 213 and 214 (19	998);The test was prolonged	d up to 96 hour	s 🖓 🔎	
GLP/GEP:	yes	A Y	Ø Å	Å V	<i>Y</i>

### **Executive Summary:**

The aim of this study was to determine the acute contact and oral toxicity of mesosulfuron-methyl tech. to the honey bee (*A. mellifera* L.) under laboratory conditions. For this purpose 50 female worker bees were exposed for 96 hours to a single dose of 100.0  $\mu$ g as. per bee by topical application contact limit test) and to a single dose of 105.6  $\mu$ g as. per bee by feeding (oral limit test, value based on the actual intake of the test item). As deviation to the OECD Guideline 210 and 214 the test was prolonged up to 96 hours. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed. The contact LD₅₀ (96 h) was > 100.0  $\mu$ g as bees. The oral LD₃₀ (96 b) was > 105.6  $\mu$ g a.s./bee. The

The contact  $LD_{50}$  (96 h) was > 100,0 µg as bee. The oral  $LD_{30}$  (96 h) was > 105,6 µg a.s./bee. The contact NOED was > 100 µg a.s./bee. The oral NOED was > 105.6 µg a.s./bee.

### Material and methods:

Test item: Mesosalfuron methyl, technical, Batch code AE F130060-01-02; Origin batch no.: EFME000144; EIMS po.: 11013375, TOX po: 09287-00; Spectrication no.: 102000013204; Article no.: 05748967; Analysed content: 97.4% www; Certificate of Analysis No.: AZ 17171.

Test units were stainless steel eages of 10 cm x 8.5 cm x 5.5 cm dength x height x width). 10 bees were used per test unit 5 test unit 5 test units for were used per test item dose level, control and reference item dose level, respectively. 50 worker bees were exposed for 96 hours to a single dose of 100.0  $\mu$ g a.s. per bee by topical apphration (contact limit test) and 50 worker bees were exposed for 96 hours to a single dose of 105.6  $\mu$ g a.s. per bee by feeding (oral limit test, value based on the actual intake of the test item).

For the contact test o single a single 5 µL droptet of mesosulfuron-methyl tech. in an appropriate carrier (acetone 90% + DMSO 10%) was placed on the dorsal bee thorax, likewise for the toxic reference (dimethoate made up in acetone) the control (tap water containing 0.5% Adhäsit) and solvent control (acetone 90% + DMSO 10%). For the oral test the final test item feeding solution was appropriate amounts of mesosulfuron-methyl dilutions mixed with 95% (w/w) ready-to-use syrup (30% sucrose, 31% glucose, 39% fructose) with solvent (2.5% acetone, 2.5% DMSO, 95% ready-to-use syrup); the feeding solution of the solvent control had the identical composition (i.e. 2.5% acetone, 2.5% DMSO, 95% ready-to-use syrup). The water control consisted of 50% (w/w) aqueous syrup solution (50% tap water, 50% ready-to-use syrup). The reference item was solved in pure acetone (5%) and thereafter mixed with water (45%) and syrup (50%). The treated food was offered in syringes, which were weighted before and after introduction into the cages. After a maximum of 4 hours 20 pointes, the uptake was complete and the syringes were removed, weighted and replaced by ones containing fresh, untreated food.

The number of dead bees was recorded after 4 ( $\pm$  0.5 h) hours (first day); 24, 48, 72 and 96 ( $\pm$  2 h) hours. Behavioural abnormalities (e.g. vomiting, apathy, intensive cleaning) were assessed after 4 ( $\pm$ 



0.5 h) hours (first day); 24, 48, 72 and 96 ( $\pm$  2 h) hours. Temperature during the test was 25 °C; relative humidity was 50 - 75% for both tests. Bees were kept in darkness (except during observation).

### **Dates of experimental work:**

### **Results:**

Dates of experimental	work:	May 14, 2012 – May 19, 2012	
Results:		4	A OF ST Q
Table CA 8.3.1.1- 1:	Validity criteria	Č Š	
Validity Criteria		Recommended O	Abtained 🔬 🖑
		Contact Test	
Γ	CO ₂ /water control	<u> </u>	· 2.0% C C
Γ	CO ₂ /acetone/DMSO		
	control:		
Control mortality		Qraf Test	
	water/sugar syrup		
	control		
	Acetone/DMSO		
	syrup control		
	Ő¥	🕵 🖉 🚱 🏹	
LD ₅₀ of reference		0.10 - 0.30 μg á. 9./bee 🖉	0.2 μg a. bee
item (24 h)	<u>v</u> y	Oro Oro Test	
		0.10 0.35 ug a.s./loe	b.10 µg/a.s./bee

All validity criteria for the study were me **Biological results**:

### Contact Test:

<u>Contact Test:</u> At the end of the contact toxicity test (96 hours after application), there was 2.0% mortality at 100.0 µg a.s./bcs. Also 2.0% mortality occurred in the water control group (water + 0.5% Adhäsit) and there was no mortality in the solvent control group (accone + OMSOV)

### Oral Test

In the oral toxicity stest, the maximum nonional test level of mesosulfuron-methyl tech. (i.e. 100 μg a.s./bee) corresponded to an actual jorake of 105,6 μg a.s./bee. This dose level led to no mortality after 96 hours

L

Also no mortality occurred in the solvent control group (acetone + DMSO) and in the water control group (50% sugar solution), respectivel

No test item induced behavioural effects were observed at any time in both toxicity tests.

### Acute toxicity of mesosplifuron-methyl to honey bees; contact and oral laboratory Table CA 8.3.1.1-2; test Q, Ĺ

Test Item	Mesosulfuron	-methyl tech.
Test Object	Apis me	ellifera
Exposure Q	contact (Acetone/DMSO solution)	oral (sugar/acetone/DMSO/water solution)
Application rate µg a.s./bee	100.0	105.6
$LD_{50} \mu g @.s./bee$	> 100.0	> 105.6
LD ₂₀ µg a.s./bee	> 100.0	> 105.6
LD ₁₀ µg a.s./bee	> 100.0	> 105.6
NOED µg a.s./bee*	≥ 100.0	≥ 105.6

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

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

The contact and oral LD₅₀ (24 h) values of the reference item (dimethoate) were calculated to be 0.2 and 0.10 µg a.i./bee, respectively.

### **Conclusions:**

The toxicity of mesosulfuron-methyl tech. was tested in both, an acute contact and an acute or toxicity test on honey bees. The contact  $LD_{50}$  (96 h) was 100.0 µg a. bee. The or  $LD_{50}$  (96 h) was 2100.0 µg a. bee.

Report:	t; ;2004;M-485279 01 3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5
Title:	Mesosulfuron-methyl WCK75 W: Acute contact toxicity to the buyble beer Bombus
	terrestris L. under laboratory conditions a second se
Report No:	S13-01778
Document No:	M-485279-01-1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Guidelines:	No specific guidebies are available. The test design is based of OEPP/EPPO 170
	(4) (2010) and GECD Guideline 214 (1998), and on the review article of VAN
	DER STEEN(2001) pot specified 🗸 🧹 🖉 🖉
GLP/GEP:	ves Q a a a a a a a a a a a a a a a a a a

### **Executive summary:**

The contact toxicity of Mesosulfuron-methyl WG 75 W to the bumble bee Bombus terrestris L.) was determined in a limit test according to OEPP/EPPO 170 (4) (2010), the OECP Guideline No. 214 (1998) and the review article of according (2001) in the ost item treatment group, no mortality and no sub-lethal offects were observed until the final assessment 48 hours after start of the experimental phase. The 48 hour contact  $DD_{50}$  value for Mesosulfuron-methyl WG 75 W was determined to be > 100 µg mesosulfuron-methyl a s/bumble bee

Material and methods:
Kest item: 🔬 🖉 Name 🕺 💦 Mesosulfaron-methyl WG /5 W
$\sqrt{7}$ TQX-No $\sqrt{7}$ $\sqrt{9721-41}$ $\sqrt{7}$
$2^{2}$ Batch $10^{2}$ . $2^{2}$ 2012-001670
Specification No.: ~ 102000027087
Content of a.s.: 74,8 % w/w (analysed)

The contact toxicity of Alesost Huron methy WG 75 W to the bumble bee (*Bombus terrestris* L.) was determined in a limit, test according to ØEPP/E0PO 170 (4) (2010), the OECD Guideline No. 214 (1998) and the review article of the second (2001).

In the laboratory, bumble bees were exposed to 100  $\mu$ g mesosulfuron-methyl a.s./bumble bee by topical application. Mortality and sub-lethar effects were assessed 24 and 48 hours after application. The control group was exposed for the same period of time under identical conditions to tap water.

Dates of work: 06 Sovember 2013 – 08 November 2013

## Findings:

In the control group, treated with tap water, no mortality was observed during the 48 h test period.

# **Bayer CropScience Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

In the reference item group, mortality was  $\geq$  50 % at the end of the test. Thus, the test was considered, to be valid.

Table CA 8.3.1.1-3: LD₅₀ values in the bumble bee contact toxicity test with Mesosulfuronmethyl WG 75 W Þ

Mesosulfuron-methyl WG 75 W	Contact toxicity test [µg a.s)	ble beel
LD ₅₀ (24 h)	> 100	
LD ₅₀ (48 h)	$\sim$ > 100	

In the test item treatment group, no mortality and no sub-lethal effects were observed until the final assessment 48 hours after start of the experimental phase. Thus, a carbe concluded that the topical application of Mesosulfuron-methyl WG 75 Woon bumble pees at the treatment level of 100 µg mesosulfuron-methyl a.s./bumble bee, caused to adverse effects regarding mortality, sub-tethal effects and behaviour.

The 48 hour contact LD₅₀ value for vesosulfuron methy WG 75 W wess determined to be >100 μg mesosulfuron-methyl a.s./bumble bee.

Report: x; (1996; M-1417) 8-01 4	
Title: Cody Hoe 00060 2C96 0002 Oral to LD 50 to honey bees (Apis mellifera L	J.)
Report No: Av8014 Av Av Av Av Av	
Document No: O Di-141738-01- V O L V O	
Guidelines: C EPPQ: 170; Deviation not specified O	
GLP/GEP: Q yes, L A O Q Q	

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):  $^{\prime}2 h_{\star}D_{50}$ -oral = 5 o µg a.s./bee

It is proposed to repeate this endpoint by the following endpoint derived from new study KCA 8.3.1.1/01:  $h_{4.5} = 105.6 \ \mu g \ a.s./bee$ 

For an indepth evaluation of the old and new findings according to the provisions of current guidelines and requirements, please refer to the explanative text at the introduction of Section CA 8.3.1.

Study sumpory and RM Sevaluation opied from the original Monograph:
<b>Reference:</b> 1996, 8.3.1.1.1/1.
<b>D T</b> ( <b>x</b> t gui@ine: F) <b>PO 1F</b> (1992).
GLPOompliance: Yes.
0

**Methods**: Lethal effect of AE F130060 (technical substance, purity = 96.0%) to bees were assessed through oral exposure. The test substance was added to diet paste at the rate of 0 (control), 0.0001, 0.001, 0.01, 0.1 and

### **Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

	1% (w/w), corresponding to 0, 0.0204, 0.2038, 1.4994, 15.808 and 184.81 microg a.s./bee. control was repeated 5 times on groups of 10 bees each. Mortality and behavioural abn lethargy and uncoordinated movements, were checked daily for a 72 hours test period.	Each dose and the ormalities, success
	Results: Oral LD50 - 72 h = 5.6 microg a.s./becImage: Comparison of the second	
	<b>Comments (RMS):</b> no mortality among exposed bees occured during the first 48 hours. T at 24 and 48 h (> 184.81 microg/bee) are greater than the 1950 72h. An additional assess would perhaps have lead to a lower LD50 value. The proposed endpoint will therefore a	have fore strong LD % Sent all \$ 96 h \$ 5 used She strong is
	acceptable.	
r u D	Results: 1. Hoe 130060 00 ZC96 0002	
	% a.i. in diet mean ng ingested dose 5 % mortaling after	
	food per bee consumption (µga.i.)	72h
	Control $0.024$ $0^{7}$ $0^{7}$ $0^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ $3^{7}$ <	4 :
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	22 23
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	30 33

The 72-hour LD₅₀ while of  $50 \text{ }\mu$  sc.s/be as given in the styly report and the DAR does not appear plausible when coordering that we at the hypest tot does of 184.81 µg a.s/bee a total mortality of 33% was observed, when is Sarly celow 50% nortality. The statistical analysis as presented in the report appear componised and institutiole. When effecting the data into a currently available statistical program (i.e. Porbit analysis 2 ith T ARatho Version 2.10) then an 72-hour LD₅₀ value of greater than the 184.85 µg g. /bee a decided. Therefore, the oral 72-hour LD₅₀ value should be corrected and presented as  $>184.81 \text{ }\mu$ g a.s/bee. The 72-hour LD₅₀ while of 9.6 µ x a.s./b as given in the study report and the DAR does not appear







criterion of average mortality for the total number of controls must not exceed 10 per alidi cent at to end of the test, as described in OECD 213, was met. However, the validity criterion that the LD₅₀ of the toxic standard meets the specified range as described in OECD 213 cannot be confirmed. In the current study Triazophos was used and an  $LD_{50}$  of 0.013µg a.s./bee was determined. OECD 213 defines dimethoate as preferred toxic standard but also allows the use of others.



A large number of deviations from the currently valid OECD guideline 213 were determined for this study and are described in detail in Table CA 8.3.1.1.1-1 below. It is concluded that the validity whe study is no longer given.

### Analytical findings:

28°C. Chumi Vy of O - O Chumi Vy of O Chum Vy of O The diet mix (containing the test item) was offered to the bees for 5 hours. After the end the tubes were reweighed and the ingested substance quantity calculated fug a.s. / bee The experiment was performed in a room at an average to perature of 06.5 – 28°C, 76% and a lighting period of 16 hours light : 8 hours darkness.

**Biological findings:** 

Table CA 8.3.1.1.1-1	: Acute oral LD50 values after up to 2 house for explorer table test and reference if the
h	
	Hoe 130060 00ZC96 0002
Time	(treatment = mesosulfurtha-met(yi) reference item = Tricophos 40EC
<mark>(hours)</mark>	10 50 (95 y fiducity limit 9 [µg//yer
<mark>24</mark>	> 184.81 μQ.s./bes 2000 -0.63) μg od./bes 0
<mark>48</mark>	> 184.8 $\mu_{g}$ g a.s. $\mathcal{O}$
<mark>72</mark>	> 184.8 Mug 200/bee 🖉 🖓 🖓 0.012 ( ), Oprod Gee 🦄

### **Conclusions:**

In a laboratory study to deter 060 00 ZC96 0002)

technical substance, is <i>Apis relinger</i> , the 2 holes and substance to be 184.81 µg a.s./bee.	ee.
Table CA 8.3.1.1.C 2: Nummery table	
Reference For wed & Oguida Ce & Offferer Oes Stical essessment of the study / Deviations guidance Currently in force & Concerned on about its Reliability	iations
M- 141738- 01-1 KCA 8.3.1.1.1 (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (01) (	ximum was be 50- held of 16 er eport. d of 6
CA 8.3.1.1.2 Acorte contract toxicity	



### Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Report:	u; ;1997;M-1	143107-01
Title:	Code: Hoe 130060 00 ZC96 0002; identical to r	new AgrEvo code: AE F130060 00 @96
Report No:	0002 - Contact toxicity (LD50) to honey bees (A	Apis mellitera L.)
Document No:	M-143107-01-1	
Guidelines:	EPPO: 170; USEPA (=EPA): L 141-1;Deviat	ion not specified
GLP/GEP:	yes	A Ó í g
GLP/GEP: Endpoint according to It is proposed to rep 8.3.1.1/01 : For an indepth evalua and requirements, ple Study summary and Reference: Test guideline: EPI GLP compliance: Methods: Lethal eff contact exposure. B (control), 0.04, (Grepeated 5 tims) or discoordinate movies Contact, 2D50 - 721 Results: Contact, 2D50 - 721 Comments (RMS) Further study inform Validity CAteria: No unfor Seen circums study. Analytical findious: The experiment was 73%. During the software Study and the	yes the Review Report for mesosulfuron-methy 72 h-LD ₅₀ -contact > 13 µg as/b place this endpoint by the following endp 96 h-LD ₅₀ -contact > 100 µg as/b tion of the old and new findings according to ase refer to the explanative text at the introde <b>RMS evaluation copied from the original</b> 16, 8.3.1, 2/1 0 170 (19) (es 10, 0.10, 0.10, 0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0.0	Al (SANCO/10298/2003-Email): ee offit derived from new study KCA bee offic provisions of cutrent shidelines action of Section CA 8.3.4 <b>Conotsuph:</b> 95 %) to be were assessed through test assamp, at an individual rate of 0 cetone. Each dose and the control was at abremalities, such as lethargy and d and and and and and and an



### Biological findings:

<u>Diological Illi</u>	<u>ungs.</u>	Q° 🐎
Table CA 8.3.1.1	1.2-1: Acute contact LD50 values after	exposure to test and reference item
	Hae 130060 007C96 0002	Hoe 002960 00 EC40 (063
Time	(treatment = mesosulfuron-methyl)	(reference item = Triazon yos 40EC)
<mark>(hours)</mark>	LD ₅₀ (95% fiducia	al limits) [µg/bee]
<mark>24</mark>	> 13.0 μg a.s./bee	0.250 (0.115-0.336) ug prod./bee
<mark>48</mark>	> 13.0 μg a.s./bee	<b>α</b> 249 (0.094-0 <b>2</b> 3) μg prod./b <b>6</b>
<mark>72</mark>	> 13.0 μg a.s./bee	<u>Д 0.242 (0.080-Ф.52) µg prod Dec</u>
	Ä	
Conclusions:		
In a laborator	y study to determine the toxicit so f m	egsulfy m-metryl (Iwe 130 00 2C96 4002).
technical subs	tance, to Apis mellifera, the 7 $\mathcal{D}$ hour	D ₅₀ was dearmined to be greater than 3.0 µg
a.s./bee.		
Table CA 8.3.1	.1.2- 2: Summary table	
Reference Fo	llowed Guidacce &	ferences Syncal Sessmer of the Study Deviations
M FP	PO No. 170 (The CD ) 214 (The a) th	A second of the of the second
143107-	(92)	idard $\checkmark$ trie@phose
01-1		limmic b) I emporture should be 25±2°C but was
	and the second secon	ditions 26.2-27 S°C Calative unidity should be
KCA		$2^{\circ}$ 50.70% but Mas 64.8%.
8.3.1.1.2 EP	A-540/9-95- (mot Fyrelevant)	
Se		N D D IS
<mark>19</mark>		
, a		
CA 8.3	Chronic toxicity to bees ~ . O	
		k, A ^Y
Study with me	esosupuron-metnyl	
Report:	£2014	×M-48\$\$55-01
Title:	Mesosulfuron-methyl (lech.) -A	ssessifient of chronic effects to the honeybee, Apis
Report Not	S13-00143	
Document No	: M-4856\$5-01-1	₩ १
Guidelines:	not applicable; not applicable	
GL'R/GEP:	yes yes a	

## Executive summary

The chronic effects of the test item mesosulfuron-methyl (tech.) on the honey bee, *Apis mellifera* L., were assessed in a 10 days continuous feeding test in the laboratory. The continuous *ad libitum* feeding of honey bees in the laboratory over a period of 10 consecutive days with the test item mesosulfuron-methyl (tech.) at the treatment level of 120 mg a.s./kg caused no adverse effect regarding mortality, sub-lethal effects and behaviour. No repellent effect of the test item at the treatment level of 120 mg a.s./kg was observed.

L.

The NOEC for mortality was determined at the end of the test period to be 120 mg a.s./kg (nominal). The  $LC_{50}$  was determined to be >120 mg a.s./kg (nominal).



### Material and methods:

Test item:

Name: Tox No.: Origin Batch No.: Purity:

Mesosulfuron-methyl (tech.) 09287-01 EFME000144 97.4 % w/w (analysed)

Over a period of 10 days, honey bees were exposed to 50 % (w/s) aqueous subrose application solution, containing nominally 120 mg a.s./kg of the test item mesosulfuron method (tech) by continuous and ad libitum feeding. Because the test item was dirst dissolved in agetone and the diluted with aqueous sucrose solution, the final test item application solution contained 3 % acetore. The control group was exposed for the same period of time under identical exposure conditions to untreated 50 % (w/v) aqueous sucrose application solution, also containing 3 % acetone. Mortality, sub-lethal effects and behavioural observations were sessed every day throughout the 10 days exposure period. Furthermore, the daily food uptake was determined

Samples of the application (feeding) solutions prepared reshly every day throughout the 10 days continuous feeding period were taken daily for subsequent chemical analysis in order to reveal the actual concentration of the test item. 

# Dates of work (biology):

### **Findings:**

After 10 days of continuous exposure, mortality at the test arem treatmen level of 120 mg a.s./kg of mesosulfuron-methyl (tech.) was not statistically significantly different when compared to the control group.

The cumulative control wortality was 0.0 %, as determined at the final assessment after 10 days. The cumulative mortality at the treatment level of 120 mg a.s kg mesosulfuron-methyl (tech.) was also 0.0 % at the final assessment. L, 0

At 120 mg a.s./kg mesosulfucon-methyl (teeh.), no sub-tethal effects or behavioural abnormalities were observed@hrougDout the entire observation period of 10 days.

After 10 days of continuous exposure, by considering the actual food consumption of the honey bees, the accurulated nominal intake of the test item mesosulfuron-methyl (tech.) at the treatment level of 120 mg a.s./kg was 48.5 µg as./bee the corresponding average daily dose was therefore 4.85 µg a.s./bee.

The overall mean consumption of the aqueous sucrose application (feeding) solution (i.e. the average value over 10 days in the set item treatment group was not statistically significantly different when compared to the untreated control group (40.2 mg/bee at 120 mg a.s./kg, compared to 38.4 mg/bee in the control group).

The mean daily consumption of the aqueous sucrose application (feeding) solution was not statistically significantly different (lower) between the control group and the test item treatment group throughout the entire testing period (day-by-day comparison).



# Table CA 8.3.1.2- 1: Mean consumption of application (feeding) solution, mean nominal intake of test item accumulated over all test days, average daily dose, cumulative mortality after ten days of continuous exposure (test end) as well as the LC50 and NOEC

Treatment Level	Control ¹	Mesosulfuron-methyl
Cumulative mortality after ten days of continuous exposure [%]	0.0	
Overall mean daily consumption of application (feeding) solution [mg/bee] ³	<u>کې</u> 38.4 کې	40.2
Mean nominal intake accumulated over ten test days [µg a.s./bee/10 d]		48,448 57 0
Average daily dose (nominal) throughout ten days of continuous exposure [µg a.s./bee/d]		Q 04.85 0 V
LC ₅₀	َ مَنْ الْحَدَّةُ مَنْ مَنْ أَنْ مَنْ مَنْ أَنْ مَنْ مَنْ أَنْ مَنْ مَنْ مَنْ مَنْ مَنْ مَنْ مَنْ م	(nopinal)
NOEC ⁴	2 C 120 mg ./	kg (frominally A o

¹ Application (feeding) solution: 50 % (w/v) aqueous sucrose solution containing 3.4% acetor

² Application (feeding) solution: 50 % (w/v) aqueous sucrose solution containing by % acetone and presosulfuron-methyl (tech.)

³ The mean values per replicate over the test period (non-rounded values) were used for the calculation of the overall mean daily consumption of application (feeding) solution per treatment

⁴ Determined to be the NOEC based on portality (not statistically significantly different compared to the control; Fisher's Exact Test, Bonferroni-Holms corrected, one sided, b ≤ 0.055 a.s. = active substance

## **Conclusions:**

It can be concluded that the continuous *ad libition* feeding of broney bees in the laboratory over a period of 10 consecutive days with the test item mesosulfuron-methyP(tech.) at the treatment level of 120 mg a.s./kg caused no adverse effect regarding mortality sub-lethal effects and behaviour.

The overall mean daily consumption of the aqueous sucrose application (feeding) solution (i.e. the average value over 6 days) in the test item treatment group was not statistically significantly different when compared to the untreated control group. Further on every single day during the 10 day continuous exposure period, the mean food consumption per Dee was not statistically significantly different (lower) in the test item treatment group compared to the control group. Therefore, it can be concluded that there was no repetient effect of the test item at the treatment level of 120 mg a.s./kg.

The NOEC for mortality was determined at the end of the test period to be 120 mg a.s./kg (nominal). The  $LC_{50}$  was determined to be 120 mg a.s./kg (nominal).

## CA 8:3/1.3 Effects on honeybee development and other honeybee life stages

Report:	₹,2013;M-465325-01
Title:	Mesos@furon wethyl & G 75 - A honeybee brood feeding study to evaluate potential
	effection brood development and mortality of the honeybee, Apis mellifera L.
	(HOmenoptera: Aprilae)
Report No.	201101
Document No	M-465925-01-1
Guidelines:	(1992). Method for
A A	honeybee brood feeding tests with insect growth-regulating
⊳O ^v	insecticides. EPPO Bulletin, 22, 613-616 [1].;not specified
GLP/GEP:	yes



### **Executive Summary:**

The purpose of the honey bee brood feeding study was to evaluate potential effects of Mesosulfuronmethyl WG 75 administered together with the herbicide safener Mefenpyr-diethyl WG 15 W or brood development and mortality of adult worker honey bees, *Apis mellifera*.

The test item was administered in 1 L 50% (w/v) aqueous sucrose solution at a concentration of 0.050 g formulated test item/L (=0.0375 g mesosulfuron-methyl/L) + 0.712 g formulated herbicide safener/L (0.1125 g mefenpyr-diethyl/L) per colony in summer 2012. No adverse effects on any endpoints assessed were observed (i.e. on the survival of adult beec eggs, larvae and pupae, brood development of the honey bee brood is based on the method of **10.050** and **10.050**. The administration of Mesosulfuron-methyl WG 5 + the herbicide safener. Mefenpyr-diethyl WG 15 W to honey colonies caused no adverse effects on any endpoints assessed were observed (i.e. on the survival of adult beck eggs, larvae and brood development. No adverse effects on any endpoints assessed were observed (i.e. on the survival of adult beck eggs, larvae and pupae, brood development, behaviour, colony strength and colony conditions).

### Materials and Methods:

Test item: Mesosulfuron-methyl WG 75; Sample code: 12005180; Specification pol: 102000027087; Batch no.: 2012-001670; Sample description: A.1200302; AS pol: 20865-2108; Content of active ingredient (nominal): 750 g/kg. Content of active ingredient (analysed): 748 g/kg.

Herbicide safener: Metenpyr-diethyl WG 5 W Sample code: 12006070 Specification no.: 102000027139; Batch no.: 2012-002193; Sample description A.12000401; CAS no.: 1322-93-6; Content of active ingredient (nominal): 150 g/kg Content of active ingredient (analysed): 158 g/kg.

Three healthy queer right bee colonies were used per treatment group (control, test item treatment administered with the herbicide safener) and seterence item). In total, nine colonies were treated. All treatments were administered in 1 L 50% (w/v) aqueous sucrose solution per colony. Test condition:

Natural field conditions with two different periods:

- Pre-treatment phase: In general stable conditions with some rain; overall favourable conditions during becactivity on an days.
- Exposure phase: to general favourable conditions for bee activity with some rain.

### Treatments:

*Test item:* 0.0375 g mes@ulfuron-methyl a.i.@, corresponding to 0.050 g⁴ Mesosulfuron-methyl WG 75 in 1 L 50% (@/v) aqueous sucrose solution.

Safener:_0.1  $\bigcirc$  5 g metenpyediethy a.i./L, corresponding to 0.712 g¹ Metenpyr-diethyl WG 15 W in 1 L 50% (w/x) aqueous success solution.

The test them and the herbicide safener were mixed and set up together.

*Reference item* 0.75 g fenoxycarb a.s./L, corresponding to 3.0 g⁵ Insegar[®] 25 WG in 1 L 50% (w/v) aqueous sugress solution.

⁴ Calculation based on the analysed active ingredient

⁵ Calculation based on the nominal active ingredient


*Control:* Untreated 50% (w/v) aqueous sucrose solution, 1 L per colony.

The feeding solutions were prepared 3 hours before administration to the honey bee colonies (IVL per colony). Due to rainy weather and low flight activity of the honey bees the treatments were administered in the afternoon simultaneously to all hives via commercial bee feeder as a single treatment. The feeder was placed beneath the hive roof over the hole on top of the crown board. The bee feeders were left at the colonies until total consumption of the feeding solution.

#### Endpoints:

Mortality of worker bees, larvae and pupae: between 3 days before to a days after application (= and the second se of the trial) in the bee traps;

Behaviour around the hive: between 3 days before to 21 days after application (Find of the trial); Condition of the colonies was assessed two times during the study: 2 days before and 20 days after application (study termination);

Detailed brood assessments (brood termination rate, brood index, and brood compensation index of 197 to 210 marked eggs, 150 to 200 young barvae and 199 to 200 old latvae): ope day before = BFD0) and 5 (= BFD 6), 10 (= BFD 11),  $40^{+}$  (= BFD 15), 20 (= BFD 20) days after the application

here 08 2012 (pre-treatment phase, DAT _& to 0) June 05, 2012 **Dates of work:** June 09, 2012 – June 29, 2012 (exposure phase (DXT 140-21)

#### **Results:**

# Validity criteria:Č

The overall day mean adul and papae mortality of the deference item was significantly greater when compared to the control, indicating that sufficient exposure of the horrey bees had taken place and thus the suitability of the test system to detect potential effects on the bee brood. The daily mean mortality of adult honey bees (1.2 bees/colony) and pupae (0.5 pupae solony) in the control treatment during the course of the study remained low. In addition the mean brood termination rate in the toxic reference treatment of all monitored brood stages on BFD 21 (eggs: 85.4%, young larvae: 43.9%, old larvae: 51.8% was considerable increased and stanstically significantly greater when compared to the control (eggs. 41.1%, young larvae: 7.7%, old darvae 5%). Regarding the overall performance of the reference item and control treatment, the study validity criteria were fulfilled.

the study valies of the st



#### **Biological results:**

Table CA 8.3.1.3- 1: bee m	Effects of mesosulfuron- ortality and honey bee bro	nethyl WG 75 (+ m ood development	efenpyr-diethyl WG	15 W) on Honey 7
Test item	Mesosulfuror	n-methyl WG 75 (+	Mefenpyr-diethyl Wo	G 15 W)
Test object	Honey	ybee Apis mellifera	L. (complete colonies	
Exposure	Via tre	eated 50 % (xy/v) aq	ueous sucrose solutio	ng z z
			<u> </u>	
Asses	ssment	n = 3	Test item $\bigcirc$ $\bigcirc$ $n = 3$	Reference $1 \text{ tem}$
		/ Mean mortany o	f worker bees + freshl Øbees/golony ±ØD	y emerged worker
Pre-application(DAT -3	to 0)	22.8≠6.5	₹27.8±€¥.7	$3100 \pm 1600$
Post-application(DAT 1	to 21)	19.2 ± 0.9	0 12,0 ¥ 2.8 5	$23.6 \pm 3.4^{a}$
		S Mean	mortality of pupae/c	elony o
Pre-application(DAT -3	to 0) Q 6	0%±0.1	0.2 +0.1	° 40.2 ± 0.3
Post-application(DAT 1	to 21) 0 21	0.5 ± 0.2	Q 0.2±0.2	$34.8 \pm 17.9^{a}$
		Alean vất	ies of brood developn	nent (eggs)
Brood termination rate (	%), at BFD 21 (DAG 20)	41(1 ± 33.2%	14.7° 5.6 °	$85.4 \pm 10.9^{b}$
Brood index at BFD 21	(DAT 20)	3.0 ± 0.7	$4.3 \pm 0.3^{\circ}$	0.7 ± 0.5
Compensation index &	3FD 21 (DAF 20)	3.85±0.7	$O_{4.4 \pm 0.3}^{4}$	$1.0 \pm 0.8$
		Mean values o	forood development	(young larvae)
Brood termination rate	%) at BFD 210DAT(29)	₹ 7.7 4.5 €	7.3 ± 4.2	$43.9\pm35.6^{b}$
Brood index at BFD 21 (	(DAT 20) 🖗 🔬 🔬	476 ± 0.2	4.6±0.2	$2.8 \pm 1.7$
Compensation index at I	SFD 21 (DAT 20)	~4.8±071	$4.7 \pm 0.2$	$2.9 \pm 1.8$
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Alean values	of brood developmer	nt (old larvae)
Brood termination rate (A at BF 21 (DAT 20)	5.0 ± 43,	6.7 ± 5.5	51.8 ± 13.4^{b}
Brood index at BFD 26		0 ⁵ 4.7 £0.2	4.7 ± 0.3	$2.4\pm0.7^{\rm c}$
Compensation index at H	3Fp 21 (DAY 20), Q	4 8 ± 0.2	4.8 ± 0.2	$2.8 \pm 0.3^{\circ}$

Values are $mean \pm SD$ V Ò Statistically significantly greater when compared to the control (Mann-Whitney, a=0.05, alternative one-sided

Statistically significantly greater when compared by the control (Fisher's exact test, α =0.05, alternative one-sided smaller)

с

Statistically significantly smaller when composed to the control (t-test, α =0.05, alternative one-sided greater)

Days After Treatment DAT

BFD Brood area Fixing Day SDStandard Deviation

SD Standard Dextation Mortality (adult and young worker bees)

The overall daily mean bee mortality observed on the days before application was similar in all treatments (22.8 to 31 bees per colony per day), indicating well adapted colonies. The overall daily mean bee mortality after application of all treatments was 11.2, 12.0 and 23.6 in the control, test item and reference item treatment, respectively. Only the reference item treatment was statistically

significantly greater when compared to the control. Furthermore, the mean mortality was statistically significantly increased on DAT 5, 7 and 19 (reference item) when compared to the control treatment.

Mortality (*pupae*)

The overall daily mean pupae mortality observed on the days before application was low and similar in all treatments (0.1 to 0.2 pupae per colony per day). The overall daily mean pupae portality after application of all treatments was 0.5, 0.2 and 34.8 in the control, fest item and reference item? treatment, respectively. Only the reference item treatment was statistically significantly greater when compared to the control. Furthermore, statistically significant increased mean pupae mortality was C observed on DAT 10 to 21 (6.7 to 105 pupae per colony) in the reference tem treatment. This indicated that honey bee brood was well exposed during the test and that the test system was sensible to detect potential brood effects of plant protection products

Denaviour In all treatments, no abnormal behavioural symptoms were observed during the whole study period. *Colonv strength*

Colony strength

The mean colony strength before the atment administration was 3600 1776 and \$267 bees/colony in the control, test item and reference item greatment, respectively, and was thus similar in all treatments. During the course of the study, the mean colony strength in the controly test item and reference item treatment displayed a relative increase of 22%, 48% and -27% respectively and was at study termination 16617, 96267 and 9700 bees per colony, respectively. Not distinct differences between the control and test item treatment were observed

Brood nest (eggs/lagae/pupae)

At the 1st assessment a Gealthy queen was present and the brood nest was similar in all colonies indicating healthy colonies. During the course of the study, the proportion of the brood nest in the control, test item and reference item displayed a gelative increase of -13%, 11% and -41%, respectivel? The brood nest in both the control and the test iten treatment remained similar when compared to the pre-treatment values, whereas the reference item showed a distinct decrease when compared to the control and the pre-treatment assessment.

Stores (pollen/nectar/honey)

At the 1st assessment (DATC2) a sufficient amount of nectar, honey and pollen was available in all colonies. During the course of the study the proportion of stores in the control, test item and reference item displayed a relative decrease of 0%, 12% and 4%, respectively. Thus, stores remained similar in all treatments during the course of the study

Brood termination rate

In the test item freatment, the brood germingtion was not statistically significantly different in all brood stages when Compared to the control. In contrast, the reference item treatment was statistically significantly higher in a selected brood stages (eggs, young and old larvae) when compared to the control. The performance of the reference item treatment indicated that the test system was sensitive to detect potential broad effects of plant protection products.

Brood index

Brood indices generally correlate with the termination rates: the higher the termination rates the lower the brood indices and vice versa. Overall, the brood indices of the control and test item displayed a continuous and comparable increase, indicating a successful development of the brood. In contrast, the mean brood indices of the reference item were distinctly lower when compared to the control and was statistically significantly smaller for the old larvae.

Brood compensation index

Generally the brood compensation indices of all treatments were slightly higher than the corresponding brood-indices at all days indicating that cells with terminated brood were a least partially refilled with new eggs, which developed successfully. Overall, the brood, indices of the control and test item displayed a continuous and comparable increase, indicating accurces ful development of the brood. In contrast, the mean brood indices of the reference tem were distinctly lower when compared to the control and was statistically significantly smaller for the old larvae

Conclusions:

The administration of Mesosulfuron-methyl WG 75+ the derbic de saferer Merenpyr diethyf WG 15 W to honey colonies caused no adverse effects on honey bee colonies and brood development No adverse effects on any endpoints assessed were observed the op the survival of adult bees eggs, larvae and pupae, brood development behaviour, cotony strength and cotony conditions).

	°° √° √°
Report: 2015:M-510040-01	
Title: Expert statement upgesponent request - Mesoculfuson-	methyl WC275 - A honeybee
bread feeding study to evaluate patential effects du bro	of development and mortality
of the horeybee, Apis mellifera Q. (Hymenoptera: Apid	ae)
Report No: 20110174 2 2 2 2 0 2	
Document No: M-510060-01 N N	*¥
Guidelines: S noCapplicable;nőt/applicable S &	~
GLP/GEP: O ALA. A & X X X X	X
Executive summary: O A AY AY	

In 2012 a honey beg brood feeding study (2013, 2013; Me465325-01-1; KCA 8.3.1.3/01) was performed with Mesosulfuron-methyl WS 75 to evaluate patential effects of Mesosulfuron-methyl WG 75 administened together with the herbicide safener. Mefenpyr-diethyl WG 15 W on brood development and mortability of adult worker honey bees, Apps mellifera.

The present re-evaluation solely concerns statistical revisions of the electronically documented data gathered during digital bood assessments, i.e. brood termination rates, brood indices and brood compensation indices. Ipon Spons for request, only the subset of the data of selected eggs was inspected under exclusion of control colory replacate no. 3 (that exhibited comparatively high brood termination rates for selected easy). The aim of the re-evaluation is to determine if the findings on statistically significant differences for the test item treatment would change when brood termination rate, brood index and compensation index are determined without considering the data from the control replicate performing comparatively weakest.

ñ Ĉ Material and Methods:

In order to re-assess potential treatment effects on brood development, specifically selected eggs, one of the three replicates of the control group (replicate no. 3) has been excluded from the original data subset for the present data re-evaluation. The rationale of this approach is that control replicate no. 3 exhibited the highest brood termination rate for eggs out of all control replicates (no. 1: 39.7%, no. 2: 8.6%, no 3: 75%).

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Comparisons of treatment-specific brood termination rates with the control were performed for all consecutive BFD assessments using Fisher's exact tests (count data for each colony replicate).

Assumptions of population normality of the data were tested using the Shapiro-Wilk test and found being fulfilled throughout. Accordingly, brood indices and brood compensation indices of the test item and reference item treatments were analysed for individual BFD assessments using Welsh two sample t-tests in comparison to the control.

For the Fisher's exact test the test direction was one-sidear greater and for t-tests the test direction was one-sidear greater and for t-tests the test direction was one-sidear smaller. For all tests the significance level was $\alpha = 0.05$.

All statistical calculations were carried out using R R Development Core Team 2012

The Fisher's exact test used for assessing brood termination rates is based on count data (brood cells including selected eggs) pooled across colory represented and can be considered relatively robust regarding unbalanced sample sizes.

For all two-sample comparisons regarding brood indices and brood compensation indices using crests, however, it has to be noted that statistical power is vastly similar with a sample size of N=2 in the control group. Therefore, the outcomes of these statistical tests should be treated conservatively.

Results:

All revised statistical results regarding brood development of selected eggs, are presented in combination with the revised tables and figures. Only statistically significant differences as compared to the control are highlighted, as well as any result diverging from findings presented in the original final report (1993; M-465325-01-1; KCA 83.1.3/07).

 Table CA 8.3.1 - 2:
 Summary table of effects of Mesosulf pon-methyl WG 75 (+ Mefenpyr-diethyl WG 15

 W) on honey bee brood development of selected eggs

	Assassment		Jan O	Control	Test Item	Reference Item
	ASSESSMERT			ູ 🛍 2 🖑 🚶	n = 3	<mark>n = 3</mark>
Γ	Brood termination	rate (%) at BFD 2	۲ <u>۵</u> ۵	2 <u>4.2 ± 222,0</u> ▲	5^{\prime} 14.7 ± 5.6	<mark>85.4 ± 10.9*</mark>
	(DAT 20)			r O _O		
	Brood index at BF	D 21 (DAT 20)		<mark>3.8≇1.1</mark> 🌮	4.3 ± 0.3	0.7 ± 0.5
Γ	Compensation inde	x & BFD 1 (DA	<mark>》20)</mark>	40 ± 0.8	4.4 ± 0.3	$1.0 \pm 0.8^{**}$
*	Ctatistically signifi	agently and the agent	man and to the	Poontrol (Lichor)	a awaat taat. D<0.001	

* Statistically significantly goater as compared to the control (Fisher's exact test; P < 0.001). ** Statistically significantly smaller as compared to the control (Welsh two sample t-test; t = 4.0452, df = 2.275, P=0.023

Table [®] CA 8	3.1.3- <u>3</u> : E	Brood te	minatio	on rate	(Ø) of	selected (eggs record	ed during	the study
A.		Â							

	L.	Control	× 01	Ş		Test I	tem]	Referen	ice Item	<i>.</i>	
DAT	Replicate				Replicat	te a	Maar		CD	I F	Replicat	e a	Marr		CD
	<mark>1</mark> _ [™] 2	Mean	<u></u> ∰_, <mark>2D</mark> %	J I	° Ç	.	wean	<u>±</u>	<mark>50</mark>	1	<mark>_</mark>	.	Mean	<u>±</u>	<mark>SD</mark>
<mark>6</mark>	265 6.2	16.4	0 140	∲ <mark>7.5</mark>	<mark>11.5</mark>	<mark>7.5</mark>	<mark>8.8</mark>	±	<mark>2.3</mark>	<mark>36.0</mark>	<mark>64.8</mark>	<mark>40.1</mark>	<mark>47.0</mark>	±	<mark>15.6*</mark>
11	39.2 3 9.6	2000	<mark>-</mark> ≇∼21.6	<mark>10.0</mark>	<mark>12.5</mark>	<mark>20.5</mark>	<mark>14.3</mark>	±	<mark>5.5</mark>	<mark>73.5</mark>	<mark>88.6</mark>	<mark>46.7</mark>	<mark>69.6</mark>	±	<mark>21.2*</mark>
	39 8.6	<mark>24.2</mark>	🗳 <mark>22.0</mark>	<mark>10.5</mark>	<mark>12.5</mark>	<mark>21.0</mark>	<mark>14.7</mark>	±	<mark>5.6</mark>	<mark>76.5</mark>	<mark>97.6</mark>	<mark>82.2</mark>	<mark>85.4</mark>	±	<mark>10.9*</mark>
21	8.6 8 .6	<mark>24.2</mark>	± 22.0	10.5	12.5	21.0	<mark>14.7</mark>	±	<mark>5.6</mark>	<mark>76.5</mark>	<mark>97.6</mark>	<mark>82.2</mark>	<mark>85.4</mark>	±	10.9*

* Statistically significantly greater as compared to the control (Fisher's exact test; for all tests *P*<0.001). The adjusted dataset had no impact on significant results.



Mesosulfuron-methyl

Table (Table CA 8.3.1.3-4: Brood index of selected eggs																
		(<mark>Control</mark>					<mark>Test</mark>	<mark>: Item</mark>				R	efere	nce Item	Å.	Ø 🖇
<mark>DAT</mark>	Repl	icate				R	eplica	te				R	eplica	ite		, N	
	1	2	<mark>Mean</mark>	±	<mark>SD</mark>	1	2 2	<mark>3</mark>	<mark>Mean</mark>	±	<mark>SD</mark>	1	2	3 3	<mark>Mean</mark>	_ <mark>∉</mark> ∕ [⊅] S	<mark>D</mark> e
<mark>6</mark>	<mark>2.2</mark>	<mark>2.6</mark>	<mark>2.4</mark>	±	<mark>0.3</mark>	<mark>2.9</mark>	<mark>3.1</mark>	<mark>3.2</mark>	<mark>3.1</mark>	±	<mark>0.2</mark>	<mark>1.6</mark>	1.20	2.0	1.6	* <mark>+ 0</mark>	A .
<mark>11</mark>	<mark>2.4</mark>	<mark>3.7</mark>	<mark>3.1</mark>	±	<mark>0.9</mark>	<mark>3.6</mark>	<mark>3.5</mark>	<mark>3.2</mark>	<mark>3.4</mark>	, <mark>±</mark>	<mark>0.2</mark>	<mark>1.1</mark> ×	0 <mark>.5</mark>	<mark>2.1</mark>	_ <mark>%</mark> 2		. <mark>8</mark> 🖉
<mark>15</mark>	<mark>2.4</mark>	<mark>3.7</mark>	<mark>3.1</mark>	±	<mark>0.9</mark>	<mark>3.6</mark>	<mark>3.5</mark>	<mark>3.2</mark>	3.4	[≫] <mark>±</mark>	<mark>0.2</mark>	00	<mark>0.1</mark>	<mark>0.7</mark>	0.6	<mark>⊯ 0</mark>	Ø
<mark>21</mark>	<mark>3.0</mark>	<mark>4.6</mark>	<mark>3.8</mark>	±	<u>1.1</u>	<mark>4.5</mark>	<mark>4.4</mark>	<mark>4.0</mark>	<mark>4.3</mark>	±	<mark>0.3</mark>	<mark>∂¥2</mark>	<mark>0.1</mark>	<mark>0,9</mark> (<mark>/ 0.7</mark> ූ	<u>+</u>	^ک نی <mark>6</mark>
The adj	usted d	lataset	had no i	mpa	ct on s	signifi	cant r	esults	. C		Ô	1	0	⁰	, ×	°,	Ĩ
								, (7		×,		d	Ŷ,	Ô (à	and a
Table (CA 8.3.	1.3-5	Brood	l cor	npens	ation	index	of sel	ected eg	gs	<u>}"</u>	\sim					×
		(<mark>Control</mark>				C	Sest	<mark>: Irem</mark>	Ś	Å			Refer	ence Iter	n [~]	
DAT	Repl	icate				R	eplica	te 🕺)		ß	éplica	te	õ ^y	õ,	s °
	1	2	Mean	±	<mark>SD</mark>	1	× ?	3 , °	Mean	_ <mark>+</mark> _	SD	4	25	<mark>3</mark>	<mark>Mean</mark>) [*] ±	<u>ŞD</u>
<mark>6</mark>	<mark>2.2</mark>	<mark>2.6</mark>	<mark>2.4</mark>	±	<mark>0.3</mark>	<mark>2.9</mark> 0	3.1	≫ <mark>3.2</mark>	<mark>. 9.1</mark>		0.2	1.6 1.6	<mark>].2</mark>	20		±Ő	<mark>0.4</mark>
<mark>11</mark>	<mark>2.4</mark>	<mark>3.7</mark>	<mark>3.1</mark>	±	<mark>0.9</mark>	(<mark>3.6</mark>	B	<mark>3.2</mark>	° <mark>3.4</mark> €	, t	<mark>9.2</mark>		0.5	2.1 [°]	\$ <mark>1.2</mark>	© <mark>⊥</mark>	<mark>0.8</mark>
<mark>15</mark>	<mark>2.4</mark>	<mark>3.7</mark>	<mark>3.1</mark>	±	<mark>0.9</mark>	<mark>3.6</mark>	₀ <mark>3.5</mark>	<mark>&2</mark>	<u>84</u>	6	ື <mark>0.2</mark>	<mark>Q.0</mark>	Øĭ	<mark>0.7</mark> 0	0.6×	_	<mark>0.5</mark>
<mark>21</mark>	<mark>3.4</mark>	<mark>4.6</mark>	<mark>4.0</mark>	±	<mark>Ø/8</mark>	4.0	<mark>4.5</mark> ⁴	0 <mark>4.1</mark>	<mark>\$4.4</mark>	,@ <u>+</u> ″	<mark>0.Ø</mark>	<mark>1.2</mark>	9 <mark>0.1</mark>	∛ 7	<u>\$,0</u>	<mark>± 0</mark>	. <mark>8**</mark>
** Statis	tically	signif	icantly si	nak	r as g	ompa	recto	the co	ontrol (Ŵ	elsl	1 t₩0	sampl	e t-tes	t; t =	<mark>4.04</mark> 52, d	$ \mathbf{f} = 2.2 $	<mark>75,</mark>
P=0.023	3). odiust	ad date	sot statis	Real		∀ nifia@	St off		U.	ronð	o itan	S.		tod &		hut n	<mark></mark>
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Executive summary:

A higher tier semi-field honey bee brood study according to the provisions of the OECD Guidance Document 75) was conducted while forced confined exposure conditions, by applying the rate (20.11 g product in 400 L tap water/hat corresponding to 15 g mesosulfuron-methyl/ha) of Mesosulfuron methyk WG 72 (750 g kg) under tunnel conditions to the full flowering and highly bee attractive suppogate or op Phacelia tanaceufolia.

The test was designed as a replicated tunnel study to assess potential effects of mesosulfuron-methyl to hone bee colonies, including a very detailed assessment of brood development. Tunnels (25 m length x 5.0 m width x 2.5 m height) were set up on a ca. 80 m² plot of *Phacelia tanacetifolia* (2 x 40 m²). Spall bee colonies were introduced to the tunnels 4 days before the application. One honey bee colory was used per tunnel. The test item, water and a reference item were applied on the whole plot of plants in two operations, with foraging bees present. The trial was carried out using four tunnels (i.e. replicates) for the test item treatment, the control and the reference item treatment (Insegar, 250 g/kg fenoxycarb), respectively. The confined exposure phase of the honey bees inside



the treated crop was 4 days following the test item application. At the end of the 4th day after application, due to the herbicide mode of action of the test item, the *Phacelia*-crop was no longer attractive to bees (faded crop) and did not longer support the confined colonies. Thus, all bee coronies (i.e. the colonies from the test item, the water and the reference item group, respectively) were relocated after 4 complete days of confined exposure from their respective minnels and placed in an area with no main flowering, bee attractive crops. Applications were conducted during daytine and during full flowering of the *Phacelia*-crop (BBCH 65), with confined honey bees actively foraging on the crop during application. After foliar (spray) application of the water (control) test item (Mesosulfuron-methyl WG 75 (750 g/kg)) and the steference iter (fenoxycark), ontogenesis of a defined number of honey bee eggs was observed for each group and colony. Mortality of adult bee and pupae/larvae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial. Ontogenesis of the bees from egg to adult workers was observed for a period of 22 day (i.e. one complete honey be brood cycle). This was done one day before the application by takingoout one one more brood combs and taking a digital picture of the brood combs. After saving the file on a computer, 200 eggs per colony were marked at this first brood area fixing day BFD0 (BFD) Brood Area Fixing Day). For each subsequent brood assessment (BFDn), again, the respective combs were taken out of the nive and another digital photo was taken in order to investigate the progress of the brood development with day 21 following the application (BFD22 following BFD0) Statistical evaluation was done for mortality, for a ging activity, colony strength, brood termination rate and brood indices using Shapir@Wilk's test (Check for normal distribution), Levene's test (check for homogeneity of variance), Student t-test (pairwise comparison) or Welch t- test (pairwise comparison, inhomogeneous variance). ~C Ľ No adverse effects on mortality of worker of pupae, foraging activity, behaviour, nectar- and pollen

storage as well as on queen surgival were observed. No effects on colony development, colony strength or bee brood were observed. Based on the results of this study, it can be concluded that Mesosulfuron-methyl WG 75 (750 g/kg) does not adversely affect honey bees and honey bee brood when applied a rate of 20,91 g product in 400% tap water/ha (corresponding to 15 g mesosulfuronmethyl/ha), gduring honey bees, getively for a for a bee-attractive, flowering crop. The observed, characteristic brood effects of the reference item Insegar (9.5. fenoxycarb) in terms of typicality, time of occurrence and extent, showed that the prevailing test conditions allowed for a profound detection of effects on immature honey beg life :

Material and Methous

Test Item: 🔬

Mesosulfuron-methyl WG 75 (750 g/g); Short name: Mesosulfuron-methyl WG 75 W: mesosulfuron-methy) (AE 3130060): 746 % www (746 g/kg) (analysed); Batch No.: 2014-004600; Sample Description: TOX10512-00; Specification No.: 102000027087.

Test Species

~^© Honey boos (Approx methifera Farnica L.); small bee colonies, maintained according to normal beekeeping practice, containing 9 combs with honey, pollen and brood. The preliminary brood check indicated healthy colonies with all brood stages present and a minimum reserve of food (uncontaminated nectar and pollen). The mean strength of the colonies per treatment group, one day before the application ranged between 7605 and 8066 adult bees per colony.

×,

Test Design:



The test was conducted under forced/confined exposure conditions (tunnel), in order to assess potential effects of Mesosulfuron-methyl WG 75 (750 g/kg) to honey bee colonies including beood development under semi-field conditions. Tunnels (25 m length x 5.0 m width x 2.5 m height) were set up on a ca. 80 m² plot of *Phacelia tanacetifolia* (2 x 40 m²). Small bee colonies were introduced to the tunnels 4 days before the application. One honey bee colony was used per tunnel.

The test item, water and a reference item were applied on the whole plot of plants in two operations with foraging bees present. The trial was carried out using your tunnels five. replicates for the test item treatment, the control and the reference item treatment (Insegar, 25@g/kg fenoxy@arb), respectively. The confined exposure phase of the honey bees inside the treated frop was 4 days following the test item application. At the end of the 4th day after application, due to the kerbicide mode of action of the test item, the Phacelia-crop was no longer attractive to bees (faded crop) and did not longer support the confined colonies. Thus, all bee colonies (i.e. the colonnes from the test item, the water and the reference item group, respectively) were relocated after a complete days of confined exposure from their respective tunnels and placed in an area with no main flowering, bee attractive crops.

After foliar (spray) application of the water (control), test item and the reference frem, ontogenesis of a defined number of honey bee eggs was observed for each group and colony. Mortality of adult bees and pupae/larvae as well as foraging activity of the adult bees was also assessed. The condition of the colonies was assessed in regular intervals until the end of the trial.

Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days (i.e. one complete honey bee brood cycle) This was done one day before the application by taking out one or more brood combs and taking addigital picture of the prood combs. After saving the file on a computer, 200 eggs per colony were marked at this first brood area fixing day BKD0 (BFD = Brood Area Fixing Day). For each subsequent brood assessment (BPDn), again, the respective comb was taken out of the hive and another training the brood development until day 21 following the application (BFD22 following BFD0)

Test Parameters:

- and pupace 3 days before to 27 days after application (= end of the Mortality of adult be trial); 0
- Behavioural abnormatives: 3 days before to 27 days after application (= end of the trial); \bigcirc
- Forasing activity of the bees: 3 days before to 4 days after application;
- Condition of the colorbes (food stores, brood status and colory strength): 1 day before and 4, 9, 15, 21 and 27 days after application; ~
- (N) Bee brood development (eggs): day before (= BFD0) and 4 (= BFD 5), 9 (= BFD 10), 15 (= BFD 16, 21 (= BFD 22) days after the application.

Application Rates

Control 400 L tap water/ha

Test Kem: 15 g mesosulfuroh-methyl a.s./ha via 400 L spray solution/ha; 20.11 g product in 400 L tap water/ha (corresponding to 0.050 g product/L),

Reference⁷Item: 300 g fenoxycarb a.s. (1200 g product)/ha in 400 L spray solution/ha (corresponding to nominally 3.00 g product/L).

All applied during full flowering of the crop when honey bees were actively foraging on the Phaceliacrop.

Test Conditions:

Natural field conditions. On the application day, due to the warm and sunny weather, there was honeybee foraging activity on the crop within the tunnels. Mean temperature during the whole experiment was between 16.3 and 27.5°C. First precipitation after application (1 mm) occurred on day 3 (ca. 72 hours following the application). Thereafter rain occurred on day 4 (27 mm), 5 (22 mm), 8 (1, mm), 12 (2 mm), 13 (16 mm), 17 (1 mm), 18 (22 mg%, 19 (11 mm), 21 (3 mm), 23 (6 mm), 25 7 mm and 27 (4 mm).

Statistics:

Statistical evaluation was done for mortality, foraging activity, colony, strength, brooptermination ate and brood indices using Shapiro-Wilk's test (check for normal distribution). Levere's test (check for homogeneity of variance), Student t-dest (pairwise comparison), Welch t-test (pairwise comparison, homogeneity of variance), Student t-dest (parwise comparison), Welch t-test (pairwise comparison, inhomogeneous variance); (software: TOX Rat Professional, Version 2.10.05, @ ToxRat Solutions GmbH). Dates of work: July 14, 2014, August 13 2014 Results: Mortality of the adult bees (worker bees) Pre-application phase (ray- 3 to day () before application); Mortality of the pre-application phase in the control and test item group was 35.1 and 69.8 dead

Mortality of the pre-application phase in the control and test item group was 35.1 and 69.8 dead bees/colory/day, respectively This was not statistically significantly different compared to the water control (Student t-test, pairwise comparison, two-sided, $\alpha = 0.05$). The mortality in the reference item group was 75.6 dead bees colony day. This was stansfically significantly different compared to the water control (Student Frest, pairwise comparison, two-sided, $\alpha = 0.05$) but can be considered within normal mortality leven under a contribed exposure scenario.

S ~ Exposure plase in the typnels day 0 offer application to day 4):

Mortality in the test them group was stand tically significantly increased on day 0, 3 and 4 after the application (Student t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$). However, the overall comparison of the mean number of dead bees found on the strips and in the traps after the application from day 0 to day 4 did not show a statistical significant difference between the control and the Mesosulfuron-methyl W6 75 (250 g/Q) treatment group. Average control mortality of adult bees during the exposition phase (day 0 to day 4 following the application) was 53.8 dead bees/colony/day. The average mortality in the test item group was higher with 83.9 dead bees/colony/day but not statistically significant different to the control group (Student t-test, pairwise comparison, one-sided greater, $\mathcal{L} = 0.05$). Reference Item mortality was 71.2 dead bees/colony/day (not statistically significantly different to the control, Student t-test, pairwise comparison one-sided greater, $\alpha = 0.05$).

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Phase outside the tunnels (day 5 after application to day 27):

An overall comparison of the mean number of dead bees found in the traps after the application from day 5 to day 27 did not show a statistical significant difference between the control and the Mesosulfuron-methyl WG 75 (750 g/kg) treatment group (Student t-test, patrwise comparison, onesided greater, $\alpha = 0.05$). A mean of 16.7 and 14.4 dead bees per day was found in the period from day. 5 to day 27 after treatment in the control and test item group, respectively. Neither did the overall evaluation of the post-application period from day 0 to day 27 show a statistical significant difference between the control and the test item treatment (23.4 dead bees/colony/day in the control and 26.8 dead bees/colony/day in the test item group, respectively) (Student t-test, pairoise comparison, α 0.05, one-sided greater).

0.05, one-sided greater). Mortality in the reference item group was statistically significantly increased on day 14, 18 and 19 after the application (Student t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$). But overall the reference item showed no impact on the adult bee mortality Mortality of pupae Pre-application phase (day -3 to day O before application).

During the pre-application phase only one dead pup was found in the control group on day -3 and none in the test item and reference, item group, respectively resulting in mean of 0.25 dead pupae/day/colony. There was no statistically significant difference, between the treatment groups (Student t-test, pairwise comparison to the control, two-sided, $\alpha = 0.05$).

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Ő Exposure phase in the unnels (day @ after application to day 4): \bigcirc

During the exposure phase in the sunnels in total 3 dead pupe were found in the control and the test item group, respectively. Mean pupae montality during exposure phase in the control and test item group was both 0.15 dead pupae/day/colony. Accordingly, the test item group was not statistically significantly different to the control group (Student t-test, pairwise comparison, one-sided greater, $\alpha =$ 0.05). In the reference item group a total of 11 dead pupae and a mean of 0.55 dead pupae/day/colony was found (no statistically Significant difference compared to the control group, Student t-test, pairwise comparison, one-sided greater, q = 0.05).

Phase outside the tungers (day 5 after application o day 20):

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During the phase outside the turnels in the stal 1 and 8 dead pupae were found in the control and the test item group, respectively Mean pupae mortality from day 5 to day 27 was 0.09 dead pupae/colony/day in the test item group, which was statistically senificantly different compared to the control group (0.04 dead pupae/colony/day) (Student test, pairwise comparison, one-sided greater, $\alpha = 0.05$). The overall post-exposure pupae mortality resulted in total in 4 and 11 dead pupae for control and test item, and consequently in an overally mean pupae mortality from day 0 to day 27 of 0.04 and 0.10 dead pupae/coloneday in the control and lest item group, respectively. This was not statistically significantly different to the control group (Student t-test, pairwise comparison, one-sided greater, $\alpha =$ 0.05). Pupae portality was generally low for control and test item throughout this study. When considering that in the control as well as in the test item treatment group 0.15 pupae/day/colony were found during the exposure phase in the tunnels, the value of 0.10 dead pupae/day/colony in the test item group over the entire post-application period is low and must be considered as biological irrelevant. Pupae mortality in the reference item group was increased and statistically significant different to the control group. The reference item induced pupae mortality of in total 430 pupae, being

4.55 dead pupae/colony/day from day 5 to day 27 and 3.84 dead pupae/colony/day from day 0 to day 27 after the day of application. In both cases, this was statistically significantly different to the control group (Student t-test or Welch t-test, pairwise comparison, one-sided greater, $\alpha = 0.05$).

Foraging Activity

Pre-application phase (day -3 to day 0 before application)

The mean foraging activity in the intended test item and reference them groups was comparable or even higher as the control group, resulting in overall daily mean values of 23.3, 26.3 and 24 bees/m²/day in the control, test item group and reference item groups respectively. No statistically significant differences were found between the control, the test item and reference item treatment groups at the overall daily mean comparison of this period (Student's t-test a = 0.05, two-sided).

Exposure phase in the tunnels (day 0 after application to day 4);

Overall, the mean foraging activity in the test item and reference item group from day of to day 4 after application were comparable to the control values on these days. The daily mean for aging activity from day 0 to day 4 were 19.3 bees/m2/day in the control group, 06.4 bees/m2/day in the test item group and 20.0 bees/m²/day is the reference item group, respectively. This was not statistically significantly different when compared to the control group (Student test of Welch t-test, pair-wise comparison, one-sided smaller, $\alpha \ominus 0.05$

Behavioural abnormatities 🌧

After application of Mesosulfuron methy WG 75 (756 g/kg) to behavioural abnormalities occurred at any time during the whole assessment period (up to day 27). No behavioural abnormalities were observed in the control group and in the reference item group.

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Condition of the Colonies

At the beginning of the triak, all queens and all brood stages (eggs, larvae and closed brood) were found in all colonies as an indication of healing and queen right colonies. Moreover the amount of food reserves (uncontaminated nectational potten) was sufficient to ensure colony viability and brood status but also allowed that wough space was available for exposure of the brood to new food sources. All queens and/or a sufficient presence of eggs were found in the test item treated colonies during all brood checks indicating that the queens were alive and healthy.

In the 5 assessments performed after application of a test item related effect on the condition of the colonies was observed. All colonies exposed to the test item remained vital with increasing bee numbers and healthy brood. There was no indication of any effect of the test item on the condition of the bee colorbes.

Colony Strength

The mean number of hone Bees per colony in all treatment groups was very similar one day before application, and did not differ statistically significantly (mean of 7605 to 8066 per colony). The subsequent development of the colony strength among the colonies in the control and test item treatment group followed the same pattern. In general, there was an overall increase of colony strength in the control and test item group observable throughout the course of the study. On the last colony strength assessment day +28 the increase in the test item group was even higher (133%) when



compared to the control group (115%). No statistically significant difference in the colony strength between the test item treated colonies and the control colonies occurred at any assessment state. Overall, no adverse effects of the test item on colony strength and population development have been ď observed throughout the study. Ĩ

Considering the initial mean number of bees per treatment group before the application as 100 % following relative mean numbers of bees were determined: , A

			8	ſŬ		
<mark>Treatment</mark> Group	Day -1 ¹	<mark>Day +4</mark>	Day +9	Day +15	Day +21	Day 27
Control	<mark>100%</mark>	<mark>109%</mark>	11,0%	127%	118%	
Test Item	<mark>100%</mark>	116% (n.s.)	122% (n.s.)	123% (n.s.)	116% (n.s.)	1 <u>33% (n</u> , 1)
Reference Item	<mark>100%</mark>	115% (n.s.)	ح <mark>133% (n.s.)</mark> ک	2127% (n.s.)	115% (n.s.)	118 <u>%</u> (n.s.)
1 to an text of a state of		2		\sim	a. 0	in in

in relation to the application

n.s. = not statistically significant to the control,

Development of Bee Brood

Brood Termination Rate:

Following the assessment of single cells from the egg stage to the successfully hatched worker bee, the mean termination rate at BFD (Brood Fixing Day) 22 in the test item group was 31.5 % which was comparable to the control group (29.3 %). This slight increase of the Brood Termination Rate in the test item group was not statistically significantly different compared to the control group (Student ttest, pairwise comparison, one-sided greater, $\alpha = 0.05$ Ø1

Treatment with the reference item Insegar (a.s. ferrexycarby caused a decrease of brood development of the marked eggs, resulting in a termination rate of 96,1%. This decrease was statistically significantly different compared to the control group (Studer Dt-test Chairwise comparison, one-sided greater, $\alpha = 0.05$).

Brood Compensation Index

The Brood Compensation Index is aromdication for recovery and shows the development of the brood at each assessment. A continuous brood development was observed in the test item group as well as in the control group. The Brood Compensation Indices following the labelling of the egg stage up to day 21 after application (BED+22) were other identical or slightly lower in the test item group compared to the control. Differences in the Brood Compensation Index between the test item and control were not statistically significant. At the end of the assessment period the Brood Compensation Index of the test item group was comparable to the control group (4.0 vs 4.2) and no statistical significant difference was detected. The higher Brood formination rate of the marked cells after treatment with the reference it is Insegar (a.s. fenoxycarb) as also reflected by the statistically significantly lower Brood Compensation Indices in the reference item group when compared to the control.

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

<mark>Treatment</mark> Group	BFD +5	BFD +10	BFD +16	BFD +22
Control	<mark>1.9</mark>	<mark>3.1</mark>	3.2	4.2 5 5
Test Item	1.9 (n.s.)	3.0 (n.s.)	3.1 (n.s.)	4.0 (n . s.)
Reference Item	<mark>0.2 (*)</mark>	<mark>0.6 (*)</mark>	1.5 (*)	

n.s. = not statistically significant to the control, * = statistically significant to the control, Student one-sided smaller

Brood Index:

The Brood Index as an additional indicator for the bee brood development facilitates, a comparison between the different treatments. Following the labeling of the egg stage the Brood Indices of the test item group were either identical or slightly lower compared to the control values. Differences in the Brood Index between the test item and control were not statistically significant. On the last assessment day (BFD+22) the Brood Index of 3. Win the test ifem group way comparable to the control group (3.5). The higher brood termination rate of the marked sells after treatment with the reference item Insegar (a.s.: fenoxycarb) is also reflected by the statistically significantly lower Brood Indices in the , S reference item group when compared to the control.

		0
Treatment Group	BFD +50 57 BFD +10 2 BFD +16	BFD +22
Control		3.5
Test Item	2.8 (n.s.) 2.8 (n.s.) 2.7 (n.s.)	<mark>3.4 (n.s.)</mark>
Reference Item		<mark>0.2 (*)</mark>

n.s. = not statistically significant to the control, ** statistically significant to the control, Student t-test, α=0.05, pairwise; one-sided smaller

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Accordingly, no adverse effects of the test item on brood development have been observed throughout the study, following the labelling of the egg stage up to day 21 after application (BFD+22).

Table CA 8.3.1.3- 6: Effects of Mesosulfuron-methyl WG 75 (750 g/kg) on honey bees under semi-field

ParameterTreatment group?Mean mortality of worker bees / colony / day [n] during pre-application phase 2 $35.1 \pm 15.0^{\circ}$ 69.8 ± 24.5 (n.s.)Reference film uscar10.3 kg acs./halMean mortality of worker bees / colony / day [n] during pre-application phase 2 $35.1 \pm 15.0^{\circ}$ 69.8 ± 24.5 (n.s.) 75.6 ± 31.2 (2%)worsul after application pre-application phase 1 23.42 ± 19.3 $26.8 \pm 29.3^{\circ}$ (n.s.) 71.2 ± 44.0 (α_{5})Total mortality of pupae [n] during pre-application phase 1 16.7 ± 8.1 $14\% \pm 7.6$ (n.s.) 17.8 ± 13.1 (h.s.)Total mortality of pupae [n] during pre-application phase 1 $90(0.60 \pm 0.89)$ $30(0.60 \pm 0.89)$ $14.0(18.22p^{-2}31.16)$ Overall after application 23.42 ± 19.3 $11(0.94\pm 0.26)$ 40.94 ± 0.96 $430(15.5\pm 25.8)$ Daily mean mortality of pupae [n] during pre-application phase 9 $0.060 \pm 0.13^{\circ}$ $0.05\pm 0.13^{\circ}$ $0.05\pm 0.51^{\circ}$ $410(18.22p^{-2}31.16)$ Daily mean mortality of pupae [n] during pre-application phase 9 $0.062 \pm 0.13^{\circ}$ $0.05\pm 0.05^{\circ}$ $410(18.22p^{-2}31.16)$ Daily mean mortality of pupae [n] during pre-application phase 9 $0.06\pm 0.13^{\circ}$ $0.05\pm 0.05^{\circ}$ $410(18.22p^{-2}7.16)^{\circ}$ Daily mean mortality of pupae [n] during pre-application phase 9 $0.06\pm 0.13^{\circ}$ $0.05\pm 0.05^{\circ}$ $42.5\pm 0.50^{\circ}$ Daily mean mortality of pupae [n] during pre-application phase 9 $0.06\pm 0.13^{\circ}$ $0.05\pm 0.13^{\circ}$ 22.1 ± 5.3 (n.s.)Mean foraging activity / m² / colony / day [n] during pre-application phase 29.7	conditions (Tunnel Test)		<u> </u>
ParameterControlTest ItemReference item Insegar [0.3 kg ass/ha]Mean mortality of worker bees / colony / day [n] during pre-application phase 2] 35.1 ± 15.0 69.8 ± 34.5 (n.s.) 75.6 ± 37.2 (s) 75.6 ± 37.2 (s)exposure phase in the tunnels 2] 35.1 ± 15.0 69.8 ± 34.5 (n.s.) 75.6 ± 37.2 (s) $77.8 \pm 13.4 \pm 7.6$ (n.s.) 75.6 ± 37.2 (s) $77.8 \pm 13.4 \pm 7.6$ (n.s.)phase outside the tunnels 3] $16.7, 78.1$ 19.45 ± 7.6 (n.s.) $77.8 \pm 33.4 \pm 3.5$ (n.s.)overall after application 23.42 ± 19.3 2068 ± 349.5 (n.s.) 71.2 ± 34.0 (ms)Total mortality of pupae [n] during pre-application phase 9] 10.07 ± 0.25 90.00 ± 0.09 exposure phase in the tunnels 9 overall after application $4(0,44 \pm 0.45)$ $11.(0.39 \pm 0.65)$ $410.(18.22\pm 31.16)$ Daily mean mortality of pupae [n] during pre-application phase 9] 0.00 ± 0.25 0.00 ± 0.00 $430.(15.56 \pm 22.85)$ Daily mean mortality of pupae [n] during pre-application phase 9] 0.00 ± 0.25 0.00 ± 0.05 $410.(18.22\pm 31.16)$ Daily mean foraging activity / m² / côlony / day [n] during [n] during 0.05 ± 0.72 0.00 ± 0.07 4.55 ± 0.78 Daily mean mortality of pupae [n] during pre-application phase 9] 0.00 ± 0.25 0.00 ± 0.01 4.55 ± 0.78 Daily mean mortality of pupae [n] during [n] during [n] during [n] during 0.07 ± 0.22 0.07 ± 0.05 4.53 ± 0.78 Daily mean mortality of pupae [n] during [n] during [n] during [n] during 0.07 ± 0.22 0.07 ± 0.05 4.53 ± 0			Treatment group ¹⁾	
ControlTest ItemInsegar (0.3 kg) ass./halMean mortality of worker bees / colony / day [n] during pre-application phase 2] $35.1 \pm 15.0^\circ$ 69.8 ± 24.5 (n.s.) 75.6 ± 31.2 (2)exposure phase in the tunnels 2] 53.8 ± 27.0 83.99 ± 31.6 (n.s.) 71.2 ± 44.0 (n.s.)phase outside the tunnels 3] 16.7 ± 28.1 14.4 ± 7.6 (n.s.) 71.2 ± 44.0 (n.s.)overall after application 23.4 ± 19.3 208 ± 343 (n.s.) 27.4 ± 29.3 (n.s.)re-application phase 1] 20.4 ± 19.3 208 ± 343 (n.s.) 27.4 ± 29.3 (n.s.)re-application phase 1] 20.6 ± 343 11.2 ± 34.0 (n.s.) 11.2 ± 34.0 (n.s.)re-application phase 1] 20.4 ± 19.3 208 ± 343 (n.s.) 27.3 ± 29.3 (n.s.)re-application phase 1] $11.0.04 \pm 0.24$ 0.000 ± 0.09 $11.2 \pm 34.22 \pm 31.16$ overall after application $4.09.4 \pm 0.45$ $11.0.39 \pm 0.69$ $430.(15.56 \pm 22.85)$ Daily mean mortality of pupae [n] during pre-application phase 9 0.005 ± 0.13 0.002 ± 0.10 overall after application 0.072 ± 0.22 0.15 ± 0.222 (n.s.)Daily mean mortality of pupae [n] during pre-application phase 9 0.002 ± 0.25 0.002 ± 0.10 overall after application 0.072 ± 0.25 0.022 ± 0.59 4.55 ± 0.78 overall after application 0.072 ± 0.25 0.022 ± 0.59 4.55 ± 0.78 overall after application 0.072 ± 0.25 0.022 ± 0.10 4.55 ± 0.78 overall after application 0.01 ± 0.25 0.02 ± 0.10 4.55 ± 0.78 </th <th>Parameter</th> <th></th> <th><u> </u></th> <th>Reference Item</th>	Parameter		<u> </u>	Reference Item
Mean mortality of worker bees / colony / day [n] during pre-application phase 2^{1} $35.1 \pm 15.0^{\circ}$ 69.8 ± 21.5 (n.s.) 83.92 ± 21.5 (n.s.) 75.6 ± 91.2 (%) 71.2 ± 44.0 (ns.) 71.2 ± 44.0 (ns.) $71.0 \pm 4.0 $		Control	Test Item S	Insegar 0.3 kg
day [n] during pre-application phase 2^{1} $35.1 \pm 15.6^{\circ}$ 98 ± 24.5 (n.s.) 83.92 ± 51.6 (n.s.) 75.6 ± 31.2 (s) 71.2 ± 34.0 (ns.)Total mortality of pupae [n] during pre-application phase 4^{1} 16.7 ± 8.1 1268 ± 34.3 (n.s.) 17.8 ± 29.3 (n.s.)Total mortality of pupae [n] during pre-application phase 4^{1} 10.025 ± 0.50 $0.6(0 \pm 0.9)$ 0.000 ± 0.90 Abase outside the tunnels 4^{1} 0.06 ± 0.89 $36.06.290.89$ $11 (2.20 \pm 1.92)$ phase outside the tunnels 4^{1} 0.06 ± 0.89 $36.06.290.89$ $419 (18.22) \pm 1.92$ phase outside the tunnels 4^{1} 0.06 ± 0.29 $36.06.290.89$ $419 (18.22) \pm 31.16$ porcent phase in the tunnels 4^{1} 0.06 ± 0.29 $36.06.290.89$ $419 (18.22) \pm 31.16$ phase outside the tunnels 5^{1} 10.09 ± 0.20 $430 (15.56 \pm 28.85)$ Daily mean mortality of pupae [n] during pre-application phase 9^{1} 0.06 ± 0.13 0.05 ± 0.22 (ns.)overall after application 90.1 ± 0.95 $0.002 \pm 0.16(5^{++})$ 45.5 ± 0.48 (n.s.)phase outside the tunnels 7^{1} 0.04 ± 0.11 0.04 ± 0.17 (n.s.) 38.4 ± 7.21 (*)Mean foraging activity / m² / colony / day [n] during pre-application phase 819.3 ± 31.7 $36.4 \pm 9.4 (n.s.)$ 20.0 ± 11.8 (n.s.)Mean brood termination factor phase 97.4 ± 28.3 $31.5 (n.s.)$ 22.1 ± 5.3 (n.s.)exposure phase in the tunnels 819.3 ± 31.7 $36.4 \pm 9.4 (n.s.)$ 20.0 ± 11.8 (n.s.)Mean brood termination factor phase 819.3 ± 31.7 $31.5 (n.$	Mean mortality of worker bees / colony /			
pre-application phase 2^{1} $35.1 \pm 15.0^{\circ}$ 69.8 ± 34.5 (n.s.) $(75.6 \pm 31.2$ (*)exposure phase in the tunnels 3^{1} 16.7 ± 81.1 144 ± 7.6 (n.s.) (71.2 ± 34.4) (n.s.)overall after application 23.4 ± 19.3 268 ± 34.3 (n.s.) 27.8 ± 13.1 (n.s.)Total mortality of pupae [n] during pre-application phase 4^{1} (0.25 ± 6.50) $0.(9.0 \pm 0.9)$ $0.000 \pm 0.0)$ swpsure phase in the tunnels 4^{1} (0.25 ± 6.50) $0.(9.0 \pm 0.9)$ $0.000 \pm 0.0)$ phase outside the tunnels 4^{1} (0.04 ± 0.24) $8(0.35 \pm 0.65)$ $11.(2.20 \pm 1.92)$ phase outside the tunnels 5^{1} 10.04 ± 0.24 $8(0.35 \pm 0.65)$ $410.(18.22) \pm 31.16)$ overall after application $4(0.74 \pm 0.45)$ $11.(0.39 \pm 0.6)$ $430.(15.36 \pm 28.5)$ Daily mean mortality of pupae [n] during pre-application phase 9^{1} 0.066 ± 0.13 0.15 ± 0.22 (n.s.)phase outside the tunnels 7^{1} 0.066 ± 0.13 0.15 ± 0.22 (n.s.)overall after application 0.066 ± 0.13 $0.092 \pm 0.16(6^{10})$ 4.55 ± 7.79 (*)phase outside the tunnels 7^{1} 0.01 ± 0.25 $0.092 \pm 0.16(6^{10})$ 4.55 ± 7.79 (*)overall after application 0.04 ± 0.11 0.492 ± 0.21 (n.s.) 22.1 ± 5.3 (n.s.)phase outside the tunnels 9^{1} 0.04 ± 0.11 0.492 ± 0.10 (n.s.) 22.1 ± 5.3 (n.s.)phase outside the tunnels 9^{1} 9.01 ± 0.22 0.15 ± 0.22 (n.s.) 22.1 ± 5.3 (n.s.)phase outside the tunnels 9^{1} 9.02 ± 0.21 9.02 ± 0.21 (*) $9.02 $	day [n] during	ڻ ا	<u> </u>	
exposure phase in the tunnels 2 53.8 ± 27.0 $83.9 \oplus 51.6$ (n.s.) 71.2 ± 34.0 (d.s.) 71.2 ± 34.0 (d.s.)phase outside the tunnels 3 16.7 ± 81.1 12.4 ± 7.6 (n.s.) 17.8 ± 13.1 (n.s.)overall after application 23.4 ± 919.3 26.8 ± 34.3 (n.s.) 27.8 ± 29.3 (n.s.)Total mortality of pupae [n] during 27.8 ± 30.3 (n.s.) 27.8 ± 29.3 (n.s.)pre-application phase 4 80.060 ± 0.89 30.60 ± 0.99 $11.(2.20 \pm 1.92)$ phase outside the tunnels 5 10.04 ± 0.24 30.60 ± 0.89 $11.(2.20 \pm 1.92)$ phase outside the tunnels 6 $11.0.94 \pm 0.24$ 30.60 ± 0.89 $11.(2.20 \pm 1.92)$ phase outside the tunnels 7 0.06 ± 0.13 10.04 ± 0.24 $419.(18.22) \pm 31.16)$ overall after application 0.06 ± 0.13 10.04 ± 0.24 $419.(18.22) \pm 31.16)$ phase outside the tunnels 6 0.06 ± 0.13 10.04 ± 0.24 $419.(18.22) \pm 31.16)$ phase outside the tunnels 7 0.06 ± 0.13 0.06 ± 0.24 0.55 ± 0.48 phase outside the tunnels 7 0.06 ± 0.24 0.06 ± 0.24 0.55 ± 0.48 phase outside the tunnels 7 0.04 ± 0.24 0.84 ± 0.12 0.85 ± 0.78 phase outside the tunnels 7 0.04 ± 0.24 0.84 ± 0.24 0.85 ± 0.78 phase outside the tunnels 7 0.04 ± 0.24 0.84 ± 0.12 $0.84 \pm 7.21 (*)$ Mean foraging activity / m² / colony / day 19.3 ± 21.7 $21.92 \pm 5.5 (s.s.)$ 22.1 ± 5.3 (n.s.)pre-application phase 20.7 ± 2.8 $21.92 \pm 5.5 \text{ (s.s.)$ 20.0 ± 11.8	pre-application phase ²⁾	<mark>35.1 ± 15.00</mark> 7	<mark>69.8 ± 4.5 (n.s.)</mark>	Q75.6 ±Q1.2 (*)
phase outside the tunnels 3 overall after application16.7 \neq 8.1 23.4 \neq 19.314.7 \neq 4 = 7.6 (n.s.) 26.8 \pm 34.93 (n.s.)17.8 \neq 13.1 (n.s.) 	exposure phase in the tunnels ²⁾	53.8 ± 27.0	<mark>83.9 🕉 51.6 (n.s.)</mark>	71.2 ± 4.0 (𝔅 s.) 0 [°]
overall after application 23.4 ± 19.3 268 ± 34.3 (n.s.) 27.8 ± 29.3 (n.s.)Total mortality of pupae [n] during pre-application phase 41 10.02 ± 0.50 0.00 ± 0.9 0.00 ± 0.9 phase outside the tunnels 51 10.09 ± 0.29 $3(0.60 \pm 0.89)$ $11.(2.20 \pm 1.92)$ phase outside the tunnels 51 10.09 ± 0.29 $3(0.35 \pm 0.65)$ $419.(18.22 \pm 31.16)$ overall after application $4(9.34 \pm 0.45)$ $11.(0.39 \pm 0.69)$ 40.0 (n.d.)pre-application phase 61 0.06 ± 0.13 0.09 ± 0.22 4.55 ± 0.48 (n.s.)phase outside the tunnels 61 0.06 ± 0.13 0.09 ± 0.16 4.55 ± 0.48 (n.s.)phase outside the tunnels 71 0.06 ± 0.13 0.09 ± 0.10 (n.d.) 4.55 ± 0.72 (n.s.)phase outside the tunnels 71 0.06 ± 0.13 0.09 ± 0.10 (n.d.) 4.55 ± 0.79 (*)overall after application 0.04 ± 0.21 0.40 ± 0.10 (n.s.) 3.84 ± 7.21 (*)Mean foraging activity / m² / colorny / day 19.3 ± 11.7 16.4 ± 9.4 (n.s.) 20.0 ± 11.8 (n.s.)pre-application phase 90.7 ± 2.8 21.9 ± 5.5 (n.s.) 20.0 ± 11.8 (n.s.)mean brood termination rate [%] 81 99.3 31.5 (n.s.) 20.0 ± 11.8 (n.s.) 9 ach with four tunnels (replicate) 9.3 ± 0.07 31.5 (n.s.) 96.1 (*) 9 ach with four tunnels (replicate) 9.3 ± 0.07 31.5 (n.s.) 96.1 (*) 9 ach with four tunnels (replicate) 9.3 ± 0.07 31.5 (n.s.) 96.1 (*) 9 ach with four tunnels (re	phase outside the tunnels ³⁾	<mark>16.7 ,⊉8.1</mark>	14.4 ± 7.6 (n.s.)	^{17.8} ¥ 13.1. € n.s.)
Total mortality of pupae [n] during pre-application phase 41 exposure phase in the tunnels 41 phase outside the tunnels 51 overall after application $1 (0.25 \pm 0.50)$ $3 (0.60 \pm 0.89)$ $4 (0.35 \pm 0.65)$ $4 (0.14 \pm 0.45)$ $11 (0.39 \pm 0.69)$ $4 (0.14 \pm 0.45)$ $11 (0.39 \pm 0.69)$ $4 (0.14 \pm 0.45)$ $11 (0.39 \pm 0.69)$ $4 (0.15 \pm 0.22)$ $4 (0.16 \pm 0.13)$ $4 (0.55 \pm 0.48)$ $4 (0.16 \pm 0.13)$ $4 (0.14 \pm 0.14)$ $4 (0.16 \pm 0.13)$ $4 (0.15 \pm 0.22)$ $4 (0.16 \pm 0.13)$ $4 (0.14 \pm 0.14)$ $4 (0.14 \pm 0.14)$ $4 (0.14 \pm 0.14)$ Daily mean mortality of pupae [n] during pre-application phase 91 $0 = 0.00 \pm 0.13$ $0 = 0.00 \pm 0.16$ $0 = 0.00 \pm 0.16$ $1 = 0.00 \pm 0.16$ <br< th=""><th>overall after application</th><th>23.4≇>19.3</th><th>26.8 ± 36.3 (n.s.)</th><th>27.3 ± 29.3 (n.s.)</th></br<>	overall after application	23.4≇>19.3	26.8 ± 36.3 (n.s.)	27.3 ± 29.3 (n.s.)
pre-application phase 41 $1(0,25\pm0,50)$ $0(0,0\pm0,09)$ $0(0,0\pm0,09)$ $1(2,20\pm1,92)$ phase outside the tunnels 51 $1(0,0,4\pm0,24)$ $8(0,35\pm0,65)$ $11(2,20\pm1,92)$ overall after application $4(0,4\pm0,45)$ $11(0,39\pm0,69)$ $410(18,22,431,14)$ Daily mean mortality of pupae [n] during pre-application phase 91 0.06 ± 0.13 0.0 ± 0.13 0.0 ± 0.00 phase outside the tunnels 91 0.06 ± 0.13 0.05 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 phase outside the tunnels 91 0.05 ± 0.13 0.09 ± 0.16 0.55 ± 0.24 0.55 ± 0.48 phase outside the tunnels 91 0.05 ± 0.22 0.15 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 phase outside the tunnels 91 0.07 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 0.55 ± 0.48 phase outside the tunnels 91 0.07 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 0.55 ± 0.48 phase outside the tunnels 91 0.07 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 0.55 ± 0.48 phase outside the tunnels 91 0.07 ± 0.22 0.15 ± 0.22 0.15 ± 0.22 0.55 ± 0.48 phase outside the tunnels 91 0.07 ± 0.22 0.12 ± 0.24 0.55 ± 0.22 0.20 ± 0.11 pre-application phase 0.07 ± 0.22 0.12 ± 0.24 0.20 ± 0.24 0.20 ± 0.24 pre-application phase 0.07 ± 2.8 21.02 ± 5.5 22.1 ± 5.3 $0.2.1\pm5.3$ phase in the tunnels 0.7 ± 2.8 21.02 ± 5.5 0.00 ± 1.18 0.00 ± 1.18 mean number of dead honey bees per day and colony found in dead beet traps and on gauze strips in the tunnels10each with four tunne	Total mortality of pupae [n] during	- Q°		
exposure phase in the tunnels 4 $(0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,$	pre-application phase ⁴⁾	$\frac{1}{(0.25 \pm 0.50)}$	0.0 ± 0.0	$0^{\circ} 0^{\circ} 0^{\circ} 0^{\circ} \pm 0^{\circ} 0^{\circ}$
phase outside the tunnels ³ overall after application $1 (0.04 \pm 0.20)$ $3 (0.35 \pm 0.65)$ $4 (0.35 \pm 0.65)$ $4 (0.35 \pm 0.65)$ $4 (0.35 \pm 0.65)$ $1 (0.39 \pm 0.65)$ $4 (0.35 \pm 0.65)$ $1 (0.39 \pm 0.65)$ $4 (0.30 \pm 28.33)$ Daily mean mortality of pupae [n] during 0 0.06 ± 0.13 $0.00 \pm 0.00(n.d.)$ $0.00 \pm 0.0 (n.d.)$ exposure phase in the tunnels 9 0.06 ± 0.22 0.15 ± 0.22 0.5 ± 0.48 (n.s.) phase outside the tunnels 1 0.15 ± 0.22 0.15 ± 0.22 0.5 ± 0.48 (n.s.) phase outside the tunnels 1 0.04 ± 0.11 0.09 ± 0.160^{46} 4.55 ± 7.79 (*) overall after application 0 0.04 ± 0.11 0.09 ± 0.160^{46} 4.55 ± 7.79 (*) as a foraging activity / m ² / colorly / day [n] during pre-application phase 0 0.07 ± 2.8 21.9 ± 5.566 (s.) 22.1 ± 5.3 (n.s.) exposure phase in the tunnels 19.3 ± 11.7 16.4 ± 9.4 (n.s.) 20.0 ± 11.8 (n.s.) Mean brood termination rate 19.7^{80} 39.3 31.5 (n.s.) 20.0 ± 11.8 (n.s.) 19.3 ± 11.7 31.5 (n.s.) 20.0 ± 11.8 (n.s.) 96.1 (*) 19 each with four tunnels (replicate) 2^{10} mean number of dead horey bees per day and colorly found in dead bee traps and on gauze strips in the tunnels 3^{10} mean number of dead horey bees per day and colorly found in dead bee traps and on gauze strips in the tunnels 3^{10} mean number of dead horey bees per day and colorly found in dead bee traps only 4^{10} (nean values and standard deviation)	exposure phase in the tunnels ⁴⁾	<mark>⊚(0.60 ∉∕0.89)</mark> ,≪	<mark>3 \$0.60 ±09.89)</mark>	$11(2.20 \pm 1.92)$
overall after application4 (0; 4 ± 0.45)11 (0.39 ± 0.69)430 (15.36 ± 28.83)Daily mean mortality of pupae [n] during pre-application phase 90.06 ± 0.130.0 ± 0.0 (n.d.)0.0 ± 0.0 (n.d.)exposure phase in the tunnels 90.15 ± 0.220.15 ± 0.22 (n.s.)0.55 ± 0.48 (n.s.)phase outside the tunnels 70.01 ± 0.950.092 ± 0.16 (n.s.)4.55 ± 7.79 (*)overall after application0.04 ± 0.110.40 ± 0.10 (n.s.)3.84 ± 7.21 (*)Mean foraging activity / m² / colony / day [n] during pre-application phase30.7 ± 2.821.9 ± 5.5 (n.s.)22.1 ± 5.3 (n.s.)exposure phase in the tunnels19.3 ± 11.716.4 ± 9.4 (n.s.)20.0 ± 11.8 (n.s.)Mean brood termination rate [%] 829.30.31 ± (n.s.)96.1 (*)***********************************	phase outside the tunnels ⁵⁾	$1(0.04 \pm 0.2)$	0.35 = 0.65	<mark>41∲ (18.22) ± 31.1∕6)</mark>
Daily mean mortality of pupae [n] during pre-application phase 0 exposure phase in the tunnels 0 phase outside the tunnels 7 overall after application 0.15 ± 0.22 (ns) 0.00 ± 0.0 (n.d.) 0.15 ± 0.22 (ns) 0.09 ± 0.16 (ns.) 0.09 ± 0.16 (ns.) 0.49 ± 0.10 (ns.) 0.15 ± 0.22 (ns.) 0.49 ± 0.10 (ns.) 0.49 ± 0.10 (ns.) 0.10 ± 11.8 (ns.) 0.00 ± 11.8 (ns.) $0.01 \pm 0.99 \pm 0.10$ (ns.) 0.10 ± 11.8 (ns.) $0.01 \pm 0.99 \pm 0.10$ (ns.) 0.10 ± 11.8 (ns.) $0.01 \pm 0.99 \pm 0.10$ (ns.) 0.10 ± 11.8 (ns.) $0.01 \pm 0.99 \pm 0.10$ (ns.) $0.01 \pm $	overall after application	$\sqrt{9} \frac{4}{(0.14 \pm 0.45)}$	$\frac{11}{9} \frac{11}{9} \frac{10}{9} \frac{10}{9}$	$430(15.56 \pm 28.83)$
pre-application phase 6 exposure phase in the tunnels 6 phase outside the tunnels 7 overall after application 0 0 0 0 0 0 0 0 0 0	Daily mean mortality of pupae [n] during $\mathbb{Q}^{\mathbb{Y}}$			
exposure phase in the tunnels ⁶ phase outside the tunnels ⁷ overall after application Mean foraging activity / m ² / colony / day [n] during pre-application phase exposure phase in the tunnels Mean brood termination rate [%] ⁸ ¹ each with four tunnels (replicate) ¹ each with four tunnels (replicate) ¹ each with four tunnels (replicate) ¹ total number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels ¹ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels ¹ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	pre-application phase ⁶	≰ [™] <mark>0.06⊕ 0.13</mark> (۲	0.0 ± 0.0 (n.d.)	$0.0 \pm 0.0 \text{ (n.d.)}$
phase outside the tunnels 7 overall after application 0.01 ± 0.05 0.04 ± 0.11 0.47 ± 0.10 (n.s.) 3.84 ± 7.21 (*) Mean foraging activity / m ² / cobony / day [n] during pre-application phase 0.7 ± 2.8 exposure phase in the tunnels 19.3 ± 11.7 10.4 ± 9.4 (n.s.) 20.0 ± 11.8 (n.s.) Mean brood termination rate [%] 8 19.3 ± 11.7 $0^3 31 5 (n.s.)$ 20.0 ± 11.8 (n.s.) Mean brood termination rate [%] 8 29.3 $0^3 31 5 (n.s.)$ 96.1 (*) 1^9 mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^9 mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^9 mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^9 mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^9 mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^9 mean number of dead honey bees per day and colony found in dead bee traps only 4^9 total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	exposure phase in the tunnels 6	[™] 0.15⁄± 0.22 3	0.15 ± 0.22 (n.s.)	48(n.s.)
overall after application $(0,04 \pm 0.11)$ $(0,47 \pm 0.10)$ (n.s.) $3(84 \pm 7.21)$ (*)Mean foraging activity / m² / cobony / day $(0,04 \pm 0.10)$ (n.s.) $3(84 \pm 7.21)$ (*)In during $(0,7 \pm 2.8)$ (21.9 ± 5.5) (res.) (22.1 ± 5.3) (n.s.)pre-application phase $(0,7 \pm 2.8)$ (21.9 ± 5.5) (res.) (22.1 ± 5.3) (n.s.)exposure phase in the tunnels (19.3 ± 0.17) (16.4 ± 9.4) (n.s.) (20.0 ± 11.8) (n.s.)Mean brood termination rate [%] % (29.3) (31.5) (n.s.) (96.1) (*)************************************	phase outside the tunnels $\frac{7}{2}$	<mark>0}01 ± 0€95</mark> ▲	[™] 0.090 0.160 ^{**B})	ć <mark>4.55⁄≱ 7.79 (*)</mark>
Mean foraging activity / m² / côteny / day [n] during pre-application phase exposure phase in the tunnels Mean brood termination rate [%] * 19.3 ± 11.7 19.3 ± 11.7 10.4 ± 9.4 (n.s.) 10.4 ± 9.4 (overall after application	0 <mark>0.04 ±0.11</mark> _℃	0.10 ± 0.10 (n.s.)	3.84 ± 7.21 (*)
[n] during pre-application phase exposure phase in the tunnels Mean brood termination rate [%] * ¹ each with four tunnels (replicate) ² mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels ³ mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels ⁴ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	Mean foraging activity / m ² / colony / day	Å.		O ^v
pre-application phase 20.7 ± 2.8 21.9 ± 5.5 (n.s.) 22.1 ± 5.3 (n.s.) exposure phase in the tunnels 19.3 ± 11.7 31.5 (n.s.) 20.0 ± 11.8 (n.s.) Mean brood termination rate 12.9 3 29.3 31.5 (n.s.) 96.1 (*) 1^{0} each with four tunnels (replicate) 3^{0} 29.3 3^{0} 31.5 (n.s.) 96.1 (*) 1^{0} mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^{0} mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^{0} mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels 3^{0} total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	[n] during			Č)
exposure phase in the tunnels 19.3 ± 11.7 16.4 ± 9.4 (n.s.) 20.0 ± 11.8 (n.s.) Mean brood termination rate $[27]^{8}$ 9.3 96.1 (*) ¹⁾ each with four tunnels (replicate) ²⁾ mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels ³⁾ mean number of dead honey bees per day and colony found in dead bee traps, only ⁴⁾ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	pre-application phase	20.7 ± 2.8	21,9, ± 5.5 (m.s.)	$\sqrt[3]{22.1 \pm 5.3 \text{ (n.s.)}}$
Mean brood termination rate [%] ⁸ ¹⁾ each with four tunnels (replicate) ²⁾ mean number of dead honey bees per day and colony found in the debet raps and on gauze strips in the tunnels ³⁾ mean number of dead honey bees per day and colony found in dead bee traps, only ⁴⁾ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	exposure phase in the tunnels	لا <mark>19.3 ⊉11.7</mark> م	$\frac{16.4 \pm 9.4}{(n.s.)}$	^{20.0 \pm 11.8 (n.s.)}
 ¹⁾ each with four tungers (replicate) ²⁾ mean number of dead honey bees per day and colony found in dead bee traps and on gauze strips in the tunnels ³⁾ mean number of dead honey bees per day and colony found in dead bee traps, only ⁴⁾ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels and standard deviation) 	Mean brood termination rate [%] ⁸⁾	U 3 ^{29.3} 27	0 31 (n.s.)	<mark>96.1 (*)</mark>
 ²⁾ mean number of dead honey bees, per day and colony found in dead bee traps and on gauze strips in the tunnels ³⁾ mean number of dead honey bees per day and colony found in dead bee traps, only ⁴⁾ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation) 	¹⁾ each with four tungers (replicate)		, a a	
³⁾ mean number of dead honey bees per day and colony found in dead the traps, only ⁴⁾ total number of dead pupae found in dead bee traps and on gauze strips in the tunnels (mean values and standard deviation)	²⁾ mean number of dead honey bees per day ar	nd colony found in dead	l be@traps and on gau	ze strips in the tunnels
⁴⁾ total number of dead pupae found in dead bet traps and on gauze sorps in the tunnels (mean values and standard deviation)	³⁾ mean number of dead torney bees per day ar	doolony found in dead	l hee traps, only	
standard devotation)	⁴⁾ total number of dead pupae found in dead be	traps and on gauze st	Tips in the tunnels (m	ean values and
	standard devotation)	NY O' a,	w w	

total number of dead pupple found in deal bee traps, only (mean aluss and standard deviation)

⁶⁾ mean sumber of dead supae, per day and colony found in dead bee traps and on gauze strips in the tunnels ⁷⁾ mean number of dead pupae per day and coonly found in dead beedraps, only ⁸⁾ at BFD 22

⁸⁾ at BFD 22 <u>Statistic:</u> Student of Welch rest, and an environmentation: Student of Welch rest, and a statistic student of welch res

Statistic: Student of Welch Ptest, g = 0.05 pairwise; before application: two-studed, after application: one-stude greater (mortality and termination rate) one-sided smaller (foraging activity); n.s. = not statistically significant compared to the control; * δ statistically significant compared to the control, n.d. = not determined *^B = statistically significant compared to the control but not biologically relevant **Conclusions:**

To assess the potential effects of Mesosulfuron-methyl WG 75 (750 g/kg) on honey bee colonies including brood development, 2011 g, product in 400 L tap water/ha (corresponding to 15 g mesosulfuron-methyl/ha) tap water for the control and a reference item were applied to a fullflowering and mighly bee-athractive crop (i.e. Phacelia tanacetifolia) under semi-field (tunnel) condition during bee flight

No adverse effects on mortality of worker or pupae, foraging activity, behaviour, nectar- and pollen storage as well as on queen survival were observed.

No effects on colony development, colony strength or bee brood were observed.

Based on the results of this study, it can be concluded that Mesosulfuron-methyl WG 75 (750 g/kg) does not adversely affect honey bees and honey bee brood when applied at a rate of 20.11 g product in



400 L tap water/ha (corresponding to 15 g mesosulfuron-methyl/ha), during honey bees actively The observed, characteristic brood effects of the reference item Insegar (a.s.: fenoxycarb) in terms of typicality, time of occurrence and extent showed that the remaining the statement iteration is the statement of the statement iteration in terms of the statement is a statement of the statement of th foraging on a bee-attractive, flowering crop. typicality, time of occurrence and extent, showed that the prevailing test conditions allowed for a



CA 8.3.2 Effects on non-target arthropods other than bees

Since the new representative formulation IMS+MSM+MPR OD 42 is a mixed-type product containing a second active substance, the tests on non-target arthropods other than bees with this formulation are clearly product related data and as such reported in document MCP.

Studies with the previous representative formulation containing mesosulfuron-methyl + safener mefenpyr-diethyl (MSM + MPR OD 120) are reported in the baseline cossier. These studies may be considered to allow for a general conclusion on the absence of relevant effects caused by the active substance mesosulfuron-methyl at its maximum intended use rate of 15 g a.s./ha th the contexp of the present application for EU approval renewal of mesosulfuron-methyl, however, these studies are considered 'supportive information', not relevant for risk assessments.

Report:	*;
Title:	Toxicity to the grand dw Aling predator Pardosa App. (Kborator) according to OBC
	Guideline (et 4) 1998 Code, C F120660 04 (K12 703
Report No:	C005107 & & X & X & X
Document No:	M-191378-01×1 & & & & & & & & & & & & & & & & & &
Guidelines:	ESCORT Recommendation (eval. 1994); IOBC:
	1998; Reviation not specified
GLP/GEP:	yes a a a a a a a a

Endpoints according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final):

Ano adorse effects on feeding rate (15 g.a.s./ha)

<u>Note:</u> In the context of application for EU approval renewal of mesosulfuron-methyl, these endpoints are ranked supportive information only. For the updated List of Endpoints, only the corresponding data for the new representative formulation IMS+MSM+MER OD 2 will be considered.

	S ^H	4	Ĩ I		
Report:	Ş		q;		;2000, 1-197173-01
Title:	U "	Oloxico	to the fol	iage@wellin	g predator Chrysoperla carnea Steph. (Neuroptera,
~Q	U U	Chr.Qopi	idaey in th	aboratory	AE 130060 + AE F107892 oil flowable 30 + 90 g/L Code:
A		AE F130	01 14	12 A 793	
Report No	0	@ 08080			
Document No:	Ŕ	»M-19717	/3-01→}		
Guidelines:	Ŵ	IOKE ;;I	Dexiation	Oot spectio	ed
GLP/GEP:		yes	,°°	× O	
	(//)			ON NOT	

Endpoints according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): -2 % mortality at the highest concentration tested, no adverse effects on reproduction (15 g a.s./ha)

<u>Note:</u> If the context of application for EU approval renewal of mesosulfuron-methyl, these endpoints are conked apportive information only. For the updated List of Endpoints, only the corresponding data for the new representative formulation IMS+MSM+MPR OD 42 will be considered.

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CA 8.3.2.1 Effects on Aphidius rhopalosiphi

For studies with the n	ew representative formulation	n IMS+MSM+MPR (DD 42 please	refer to the M	ICP.
				ð	
Report:	p;	;1999;M-194264-01			
Title:	Effects of AE F130060 01	1 1K12 A703 on the p	arasitoid Aph	idius rhopalo	siphi a
	(Hymenoptera, Aphidiida	e) in the laboratory C	ode: AE FT 80	060 01 1K 19	A7030 4
Report No:	C006599	Ś	Š	S.	
Document No:	M-194264-01-1	N N N N N N N N N N N N N N N N N N N			S' & 4
Guidelines:	IOBC/WPRS: 1988;Dev	iation not specified	,0×	× ó	
GLP/GEP:	yes	<u></u>			

Endpoints according to the Review Report for mesosulfuron-methyl (SANCQ/10298/2003 17.5 % mortality at the highest concentration tested,

no adverse effects on reproduction (15% a.s./ba)

Note: In the context of application for FU approval renewal of messful furon-methyl, these endooints are ranked supportive information only. For the updated Dist of Endpoints, only the corresponding data for the new representative formulation MS+MSM+MPR OF 42 will be considered.

Effects on Typhlodcomus p CA 8.3.2.2

For studies with the new representative formulation IMS WISM-OIPR QD 42 please reper to the MCP.

Report:	0; ,1999;24-1937;55-01
Title:	FiOcts on the predatory mite Thyphlodrodus py Scheuten (Acari, Phytoseiidae) in the
	aboratory Code: AE F130060 4 1K12 A703 4
Report No:	\$C006.005 O \$ \$ \$
Document No:	M-193755-001-1 A A A
Guideline	Deviation hot specified
GLP/GKP.	

Endpoints according to the Review Report for mesosulturon-methyl (SANCO/10298/2003-Final): 8.33 morality at the highest concentration tested,

no adverse effects on reproduction (15 g a.s./ha)

Note: In the context of application for EU approval renewal of mesosulfuron-methyl, these endpoints are ranked supportive information only. For the opdated List of Endpoints, only the corresponding data for the new representative formulation IMSPMSM+MPR OD 42 will be considered.

Effects of non-target soil meso and macrofauna CA 8.4

In the new European dossier format/data requirements there is no data point that corresponds to acute toxicity to earthworks. Nevertheless, four acute studies (on the active substance and metabolites AE F154851, SE F160459 and AE F099095) are mentioned here as supportive information, since they are contained in the baseline dossier and in the List of Endpoints from the first EU review.



Mesosulfuron-methyl

	•		
Report:	8; ;1998;M-142933-01		. Å . Ø
Title:	Acute toxicity to earthworms (Eisenia fetida) AE	F130060 substance,	technical Sode: AB
	F130060 00 1C95 0001	Ď	, ^e b
Report No:	A59244	- A	×
Document No:	M-142933-01-1	.1	
Guidelines:	EU (=EEC): 92/69; OECD: 207; Deviation not	specified	
GLP/GEP:	yes 🖉		
	· · · · · · · · · · · · · · · · · · ·		

Endpoint according to the Review Report for mesosulfuron-methyl SANCO/10298/2003 Final 14 d-LC₅₀ > 4000 mg/kg

Note: In context of application for EU approval renewal of mesosulfuron-methyl, this endpoint is ranked as supportive information, since acute carthworm testing is to longer a data requirement under Regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding chronic earthworm test.

AE F154851

Report:	k; ; ; ; ; 200 2 M-21 3 90-01Õ \sim
Title:	Acute to serily to earth forms (Elsenia forida) Joe Sosul for on (provisio ly approved ISO)
	substance, pute metal lite of mesos of furon-methyl (xE F139060) Code: AE F154851 00
	1B9@0001 O
Report No:	C022594A
Document No:	M-213390-014
Guidelines:	EU (=EEC) 2/69/2WG; CCD; 77; Deviation Pot specified
GLP/GEP:	the year of the the second sec

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): 14 d-LC > 1000 mg/kg

Note: In context of application for EC approval renewal et mesosulfuron-methyl, this endpoint is ranked as supportive information, since agite earthworm testing is no longer a data requirement under Regulation 1107/2009. The updated List of Enopoints will include only data from a corresponding chronic earthworm test

AE F160459

4	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
Report: 🖉	i;	;2002;M-214487-01
Title:	Acute toxicity	to earthworms Eisenia fetida) AE F160459 substance, pure metabolite of
L.	w megosulfuroff-r	methor (AE 5,30060) Code: AE F160459 00 1B97 0001
Report No:	CO23169	
Document No: 🖉	M-214487-01	
Guidelines: 🔊	EU (SEC).	2/69/FWG; OECD: 207; Deviation not specified
GLP/GEP:	≪ yeg v	

Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): $14 \text{ d-LC}_{50} > 1000 \text{ mg/kg}$

Note: Incontext of application for EU approval renewal of mesosulfuron-methyl, this endpoint is ranked as supportive information, since acute earthworm testing is no longer a data requirement under Regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding chronic earthworm test.

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Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

AE F099095

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Report:	§; ; ; ; ; ; 2002;M-213404-02; Amended: 2	011-12-05
Title:	Acute toxicity to earthworms (Eisenia fetida) AE F099095; sugarce,	pure; petabolio of
	mesosulfuron (AE F130060)	
Report No:	CE02/031	
Document No:	M-213404-02-1	
Guidelines:	EU (=EEC): 92/69/EWG; OECD: 2, 2, Deviation no specified	
GLP/GEP:	yes Q Q	

Endpoint according to the Review Report for mesosulfuron-methy (SANCO/10298/2003-Final): Ż 14 d-LC5 1000 mg/kg

Note: In context of application for EU approval renegal of mesosylfuron methyl, this endpoint is <u>Note</u>: In context of application for EU approval renewal of mesosurfuron methyly this endpoint is ranked as supportive information, since acute earthworm testing is no longer a data requirement under Regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding chronic earthworm test.
 CA 8.4.1 Earthworm, sub-lethal effects
 For mesosulfuron-methyl and its metabolites AE F154851, AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, and AF F14447 reproductive toxicity studies on Encoring for ide upon.

AE F160460, AE F140584, and AE F149447, reproductive toxicity studies on Esenia fetida were ALE F100400, AE F14040, and AE F140447, deproductive toxicity studies on *Elsenia fetida* were performed. In these studies, no mortality occurred. No Observable-Effect evels anged from 10 mg/kg dws for the metabolite AE F092944, at to 129 mg/kg dws for the parent compound. An overview of all studies is provided in the following table. performed. In these studies, no mortality occurred. No Observable-Effect levels ranged from 10 mg/kg



Table CA 8.4.1- 1:	Reproductive toxicity dat	a of mesosulfuron-methyl and m	etabolites to <i>Eisenia</i>
Test item	Test species, test design	Ecotoxicological endpoint	Reference
Mesosulfuron-methyl (tech.)	Eisenia fetida reproduction, 56 d (10% peat in test soil), test item sprayed on soil surface	NOEC ≥150 g a.s./ha	et al. (2000) M-19827 01-1 5 KCA 8 41 /01
Mesosulfuron-methyl (tech.)	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item mixed into soil	NQC 125 mg d.s./kg dws	(2010) M-392544-01-1 KCA 9.4.1/03
AE F154851	Eisenia fetida reproduction, 56 d (5% peat in test soil), test item mixed into soil	NOPC 393.9 mg/kg elys*	(2012) M-425013-01 KCA 8.4.1
AE F160459	Eisenia fetida reproduction, 56 (5% peat in test coll), test item mixed into soll	NOEC 30 mg/kg dw.	@012) \$ M-429997-0121 KÇ&8.4.1 94
AE F099095	Eisenia fetida reproduction, 56 k (10% peat in test soil) test item mixed into soil	NOEC ¹ ≥100 fig/kg dws	©013) M-473Q17-01-1 KCA 8.4.1 /05
AE F092944	Eisenia fetida reproduction, 560 (10% peat in test soil) test item mixed into foil	AØEC 7 10 mg/kg dws	(2013) M-461051-01-1 KCA 8.4.1 /06
AE F160460	Eisenia ferida oproduction, 56 d \$10% peat in test soil,\$ test item miked into soil \$	NOEC → ≥100 mg/kg dws	(2013) M-468911-01-1 KCA 8.4.1 /07
AE F140384	Eisenia feida ©production, 56 d 10% peat in test soil) test item mixed into soil	SOEC ≥1f3/mg/kg dws	(2013) M-468921-01-1 KCA 8.4.1 /08
ي AE F147447 ک	Effernia feeda Ceproduction, 50 d (5% Ceat in rest soil) test nem mysed into soil	NOEC 90 mg/kg dws	(2012) M-428651-01-1 KCA 8.4.1 /09
dws = dry weight soil; Bold letters: Values a * corrected to an ana	a \mathcal{Q} = active substance insidered relevant for risk asse lysed putrity of 93.9%	Soment in the MCP document	
Studies on mesosulfi	uron-methyl S Q		
Report: X	d; ;; Effects of growth and repro	; ; ;2000;M-193 duction of earthworms (Eisenia fe 0 00 1C95 0001	8271-01 stida) AE F130060 substance
Reports No: Doctiment 29(s): Guideling:	C009244 Ma 98271-01-1 BBA: VI, 2-2 (1994);Devia	tion not specified	
GLP/GPP:	yes		



Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): 56 d-NOEC = 150 g a.s./ha

Note: This study was conducted as a limit test with spray application, using two dose levels of thand in the maximum areal field use rate of mesosulfuron-methyl. A new dose restricted to the stand of the second state of the se 10x the maximum areal field use rate of mesosulfuron-methyl. A new dose-response study with standard soil incorporation test design is as well available for mesosulfuron-methyl, and resulted in definite endpoint value, see summarised as KCA 8.4.1/02 below. It is therefore proposed to update the List of Endpoints entry for chronic earthworm toxicity based on the results of this latter test: NOEC_{Reproduction} = 125 mg test item/kg dry weight artificial soil

Study summary and RMS evaluation copied from the original Monograph:

- **Reference**:
- Test guideline: BBA VI 2-2 (1994).
- GLP compliance: Yes.
- pied from the original Monograph: 2000_{9} 4.2/1 **Methods:** The effects of AE F130060 (Chni al Substance, perify = 95%) or the reproducting of ear worms was assessed in a 56 days laborator best. The test rate conjuncted with at least 2 results of ear worms, in 2.81 glass jars (10 cm diameter 19 cm neight) containing by g opertificity soil, since with the test substance at the rate of 0 (control) 15 and 150 cm.s./ha@noming). The est substance is prepared in water. Ten worms were randomly spected for control and each dise and each of the was specified 4 times. Exposure of adults lasted for 5 days after which mortality, biomass and integration symptops were recorded. The jars were hold 4 additional works in der to assess the possible effects of pressure jurn-methyl on the development of offspring. development of offspring
- A slight deviation is the anglent temperature $(0.3, 5^{\circ}C)$ was recorded in the test producing the lowest dose, for about 30 hour observed day S and S is a station is not expected to have induced bias in the results. For techsical resons, M lest versels were transferred S a sectrated from for 7 days, which did not affect the amount temperature over a 20±0.2 S range Also was deviation is not expected to have induced bias in the results. Finally, the analyse of the stock bolution used S prepare the lowest dose soil supports (15 g a.s./ha) revealed a resonance of 54.5%. The results are consistent with the results recorded at a 10 fold higher rate
- HIS A REAL AND A REAL Results: There was no moved by a point wears up to a rate of 150 g a.s./ha. No significant changes in feeding behavior was recorded A significant changes in body weight in worms exposed to the ower all se (15 g a.s./o). No effect on body weight was observed in worms exposed to be higher dose 150 g a.s./here the simpler of offspring was not influenced by the exposure to hesose furon. Bethylere

Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Report:	n; ; ;2010;M-392544-01		
Title:	Mesosulfuron-methyl - Reproduction toxicity to the earthworm Eisenia fetida in an \mathbb{Q}		
	artificial soil test		
Report No:	10P30RR		
Document No:	M-392544-01-1		
Guidelines:	OECD Guideline No. 222 for the Testing of Chemicals "Karthworm Reproduction		
	Test (Eisenia fetida/Eisenia andrei)'' adopted April 13,2004;		
	ISO Guideline 11268-2 "Soil quality Effects of pollutants on earth forms Eisenia"		
	fetida) Part 2: Determination of effects on reproduction" adopted July (1998.; The soil		
	moisture was at the start of the test at one treatment and at the end of the test at five		
	treatments slightly higher than sequired by the guideline. At the end of the tost the		
	pH-value was in one treatment 0.1 units higher than required by the guideline.		
	However, study results of the test have not been inpracted.		
GLP/GEP:	yes v v v v v		

Executive Summary:

The purpose of this study was to determine a NOFC/LOEC and or an EC, for the effects of mesosulfuron-methyl (AE F130060) of the teproduction (36 days after application), mortality and the biomass development (28 days after application) of the earthworm Evenia fetida (cumbraidae) by dermal and alimentary uptake using a standardised artificial soil. The test was performed according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004). As deviation from the guideline the soil moisture was at the start of the test at one treatment and at the end of the test at five treatments slightly higher than required by the guideline. At the end of the test the pH-value was in one treatment 0.1 units higher than required by the guideline. However, study results of the test have not been impacted.

Ten Eisenia fetida (atellate adults) per replicates 8 for the control, 4 per test item concentration) were exposed in artificial soil (with 10% pear content) to an unpeated deionised water control and to the test item for 28 days at nominal concentrations of \$3, 125, 250, 500 and 1000 mg a.s./ kg dry weight artificial soil. After 28 days of exposure, the adult worms were removed and the cocoons produced by these animals were kept for a forther 28 days in the treated artificial soil. Mortality, biomass and morphological and/or behavioural changes of the adult worms were assessed after 28 days. The number of juvenile earthworms was assessed after 56 days.

Based on the biological and statistical significance observed on biomass and reproduction, the overall No-Observed-Effect-Concentration (SOEC) was determined to be 125 mg test item/ kg dry weight artificial soil The overall Dowest-Observed-Effect-Concentration (LOEC) was determined to be 250 mg test item/kg dry worght antificial soil. The valiety criteria of the test according to the guideline were fulfined.

Materials and Methods: Sample description: TOX 0887&00; Specification No.: 102000013204; purity: 97.4 % w/w; Certificate of analysis No AZ 46385.

Ten Eisenia ferda (chtellate adults) per replicate (8 for the control, 4 per test item concentration) were exposed for 28 days in artificial soil (with 10 % peat content) to an untreated deionised water control and to mesosulfuron-methyl at nominal concentrations of 63, 125, 250, 500 and 1000 mg test item/kg artificial soil dry weight at 19.1 - 21.0°C and 428 - 788 lx. After 28 days of exposure, the adult worms were removed and the cocoons produced by these animals were kept for a further 28 days in the treated artificial soil. At the end of the test period (i.e. after 56 days) the juvenile worms hatched from



these cocoons were extracted from the artificial soil. Mortality, biomass and morphological and/or behavioural changes of the adult worms were assessed after 28 days. The number of juvenile earthworms was assessed after 56 days.

As deviation from the guideline the soil moisture was at the start of the test at one treatment and at the end of the test at five treatments slightly higher than required by the guideline. At the end of the rest the pH-value was in one treatment 0.1 units higher than required by the guideline. However, Study results of the test have not been impacted.

Toxic standard: Carbendazim (Derosal 360g/L SC): 4,0, 3.0 and 500 mg a.s./kg dry weight artificial soil moistened with deionised water, solven control: none, and the solution of the solution

Table CA 8.4.1- 2:	Validity criteria				
Validity criteria	Q. X	/ Kecom	mended	ŠŲ 🖉 Ob	reained ^O
Mortality of adults in th	e control		10 % 8		.25 % ^Q
Mean (± sd) number of control	juveniles per replicate in t			° ~ 420	1±69.6
Coefficient of variation in the control	for the number of juvenile	es of	30 %)* 6.6 %
The validity criteria of th	e test according to the gui	deline were ful	filled. 🖑 .		

In a separate toxic spindard reference study (EST Study No.: IRR1007, performed from July 28 to September 22, 2000), the NOE Reproduction xalue for carbondazing, was \$.0 mg a.s./kg dry weight artificial soil. The LOE CReproduction value for Carbendazim tested as a reference item was 3.0 mg a.s./kg dry weight artificial soil. Significant reduction in reproduction compared to the control was found at the concentrations of 3 and 5 mg a.s./kg dry weight artificial soil. The observed effect is within the expected ringe from literature. The effects of carbendarian confirm suitable sensitivity of the test system.

Affects on mortality, bromass and reproduction on Eisenia fetida Table CA 8.4.1-32

 \bigcirc

Concentration	ality Biomass*	Number of juveniles**
[mg test item/kg soil d.w.] 🖉 💫 🎊	[% of initial weight]	[% of control]
Control 7 6 2 0 21.25,	154.8	100.0
	159.5	89.9
	149.6	92.3
	153.8	83.8#
500	154.7	83.1#
	150.2	82.6#
LC ₅₀ /EC ₅₀ for g test trem/kg soil d w -	-	-
NOEC [ung test item/kg soil d.w.] -	≥ 1000	125
LOEC fung test tem/kg soil dw?] -	> 1000	250

- not applicable; * After 28 days of exposure; ** After 56 days of exposure; # Significantly different to control (Williams tetest; 1-sided, $p \approx 0.05$)

Mortality:

At the control 1.25% mortality was observed. No mortality was observed at all concentrations of the test item tested except in the concentration of 250 mg test item/kg dry weight artificial soil in which 2.5% mortality was determined. No statistical analysis was performed.

Biomass:

Statistical analysis showed no significant difference (Williams t-test; 2-sided, p < 0.05) oncertified the biomass of the adult worms after 28 days in all concentrations of the test item tested compared to the control.

Therefore, the NOEC_{Biomass} was considered to be > 1000 mg test item/kg dry weight artificial soft. The LOEC_{Biomass} could not be determined and was regarded as > 1000 mg test item/kg dry weight artificial soil.

Reproduction:

Concerning the number of juveniles statistical analysis (Williams t-test; 1-sided, p O0.05) shows a significant difference between the control and the concentrations of 250, 500 and 1000 mg test item/kg soil (dw).

Therefore, the NOEC_{Reproduction}. was determined as 125 mg test tem/kg dry weight artificial soil and accordingly the LOEC_{Reproduction} was determined as 250 mg test item/kg dry weight artificial soil.

Conclusions:

Overall, based on the biological and statistical significance of the effects observed on biomass and reproduction, it is concluded, that the NOEC for this study is 125 mg test item by dry weight artificial soil. Thus, the overall OEC is determined to be 250 mg jest item/kg dry weight artificial soil.

Studies on the netabolites of mesosulfuron method

AE F154851	
Report:	2012;M-425013-01
Title:	AE F154850? Reproduction toxicity to the earthworm Eisenia fetida in an artificial soil test
Report No: 🛛 🖗	
Document No: 🔊	₩-4250¥3-01-€ 0 [×] 0 [×]
Guidelines: 🛷	OECO Guideline No. 222 for the Testing of Chemicals "Earthworm Reproduction
1	Test (Eiseona fetida Eiseona andrei)" adopted April 13, 2004; ISO Guideline 11268-2
Ö, v	'Soil quality - Metects of pollutants on earthworms
	(Éisenia fetida) Part 2. Determination of effects on reproduction" adopted July
×	27 1998 pone & O Y
GLP/GEP:	yes a v
_@`	

Executive Summary.

The purpose of this study was to determine effects of the test item AE F154851 (metabolite of mesosulturon-methyl) on the eproduction (56 days after application) of the earthworm *Eisenia fetida* (Lumbricidae) by dormal and alimentary uptake using a standardised artificial soil. The test was performed as a limit test according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004),

Ten *Eisenia fetida* (adult worms with clithellum) per replicate (8 for the control, 8 for each test item concentration) were exposed in artificial soil (with 5 % peat content) to the test item at the concentration of 100 mg test item/kg dry weight artificial soil. The test item was applied once at the



beginning of the test. The duration of the test period (exposure of earthworms to the artificial soil containing the test item) was 56 days. The adult worms were removed from the substrate after 28 days. After 28 days mortality and biomass were determined. After 56 days reproduction was determined. The NOEC_{Biomass} and the NOEC_{Reproduction} were demonstrated to be \geq 100 mg fost item/kg do weight artificial soil and accordingly the LOEC_{Biomass} and the LOEC_{Reproduction} can be considered as \geq 100 mg test item/kg dry weight artificial soil. The validity criteria of the test according to the guideline were fulfilled.

Materials and Methods:

Test item: AE F154851; batch code: AE F154851 00 1B96 0001; origin batch Nov: LOR 21029 Certificate of Analysis No.: AZ 16603; purity: 939 % w/w.

Ten adults worms *Eisenia fetida* (with clitellum, fresh weight between 20 and 600 mg) per replicate (8 for the control, 8 for each test item concentration) were exposed in artificial soil (with 5 % beat content) to AE F154851 at the concentration of 100 mg test tem/kg artificial soil dry weight. The test item was applied once at the beginning of the test. The duration of the test period (exposure of earthworms to the artificial soil cortaining the test item) was 56 days. The adult worms were removed from the substrate after 28 days. After 28 days mortal by and biomass were determined. After 56 days reproduction was determined.

Temperature during the test ranged between 18 t and 21.4 °C (rec. 20 ± 2 %); the moisture content ranged from 54.4 – 56.0% (study initiation) to 52.4 – 56.7% (study termination), the pH value of the test substrate was 6.3 – 6.4 at test initiation and 6 6 at experimental termination, the photoperiod was 16 hours light : 8 hours dark and the light intensity was between recommended 400 – 800 Lux.

Toxic standard: Sarbendazim Derosal 360 g/L SEX: 1.053.0 and 5.0 mg a.s./kg artificial soil dry weight, control artificial soil solvent control. none

Dates of experimental work: Detrober 25, 2011 – December 22, 2011

Results:

Table CA 8.4.1- 42 Aaliditx criteria	
Validity criteria	Obtained
Mortality of adults in the control $\sqrt{2}$ $\sqrt{2}$ $\sqrt{2} \le 10$ %	1.25 %
Mean (\pm SP) number of juveniles per replicate in the control 230	216.0±32.8
Coefficient of variation for the number of jupeniles $\leq 30\%$	15.2 %

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

In a separate toxic standard reference study (ECT Study No.: IRR1105, performed from May 18 to July 13, 2011), The LOEC_{Reproduction} value for carbendazim tested as a reference item was 1.0 mg a.s./kg artificial soil dry weight. The observed effect is within the expected range from the guideline (1-5 mg Carbendazim/kg soil d.w.) and hence acceptable sensitivity of the test system is assured.

BAYER Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.4.1- 5:	Effects of AE F154851 on mortality, biomass and reproduction on <i>Eisenia fetida</i>
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Concentration [mg test item/kg soil d.w.]	Adult mortality [%]	Biomass*	Number of juveniles [% of comrol]
Control	1.25	163.0	100.0
100	0.0	167.3 O ^v	81.5
		4	
NOEC [mg test item/kg soil d.w.]	-	$\geq 100^{2}$	$\sim 100^{\circ}$
LOEC [mg test item/kg soil d.w.]		2 > 100	

In the control 1.25% mortality was observed. No mortality was observed at the only concentration of the test item.

Statistical analysis showed no significant difference concerning biomass development of individual adults over 28 days (Student-t test, 2-sided; $p \le 0.05$) and concerning the number of individual days between the control and the only concerning of the test item tested.

Conclusions:

The NOEC_{Biomass} and the NOEC_{Repoduction} were demonstrated to be ≥ 000 mg test item/kg artificial soil dry weight and accordingly the COEC_{Biomass} and the COEC_{Reproduction} can be considered as > 100 mg test item/kg artificial soil dry weight.

AE F160459

Report:	;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;
Title:	AE F160459 Reproduction foxicity of the earthwork Eisenia fetida in an artificial soil test
Report No:	11 $R^{3}2RR$ γ γ γ γ γ γ γ γ
Document No:	A-42909∮-01-1 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Guidelines: 🔊	The OECD Godeline No. 222 for the Testing of Chemicals "Earthworm Reproduction
,	Test (Eisenia fetida/Eisenia andrei)" adopted April 13, 2004;
	ISO Guideline 11268-2 Soil quality - Effects of pollutants on earthworms
SQ1	(Disenia Tetida) Part 2: Determination of effects on reproduction" adopted July
	1998: At few short time intervals the temperature dropped down to
<u>\$</u> 9	17.2 C in the second test run and was therefore, slightly below the range
No.	required by the guideline. However, study results of the test have not been
×	impacted. D by S S
GLP/GEP:	yes of in the second se

Executive Summary:

The purpose of this study was to determine effects of AE F160459 (metabolite of mesosulfuronmethyl) on reproduction (56 days after application) of the earthworm *Eisenia fetida* (Lumbricidae) by dermal and alimentary uptake using a standardised artificial soil. The study was performed as a limit test (1st test run) and a full dose-response test (2nd test run) according to the guideline ISO 11268-2 (1998) and the OKCD Condeline 222 (2004). As deviation from the guideline the temperature was slightly below the range required by the guideline at few short time intervals in the second test run. However, the tudy results of the test have not been impacted.

In the first fun adult *Eisenia fetida* (8×10 replicates for each treatment level) were exposed in artificial soil (with 5 % peat content) to the concentration of 100 mg test item/kg artificial soil dry weight

In the second run adult *Eisenia fetida* (8×10 replicates for the control group and 4×10 replicates for the treatment groups) were exposed in artificial soil (with 5 % peat content) to the concentrations of 9,



16, 28, 51 and 90 mg test item/ kg dry weight artificial soil. The test item was mixed into the soil at the beginning of each test run. Mortality and biomass was determined after 28 days. After 56 days, c reproduction was determined.

Considering both test runs together, the No-Observed-Effect-Concentration (NOEC) for reproduction was 90 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LQEC) for reproduction could be assumed to be 100 mg test item/kg dry weight artificial soil. The Stidity criteria of the test according to the guideline were fulfilled.

Materials and Methods:

Test item: AE F160459; Batch code: AE F160459 00 1B96 001; Origin batch No.: 2ER0125 Certificate of analysis No.: AZ 16306; Purity: 95% % w/w.

Adult earthworms (*Eisenia fetida*, with clitellum tresh weight between 250 and 600 mg, at least 2 months old) were exposed in an artificial soll in two test runs

months old) were exposed in an artificial sold in two test tuns. In the first run adults of *Eisenia fetida* ($\$ \times 10$ replicates for the control group and $\$ \times 10$ replicates for the treatment group) were exposed in artificial sold (with 5 % peat content) to AE \$160459 at the concentration of 100 mg test item/kg artificial sold dry weight. Temperature during the first test run ranged between 18.1 and 21.4°C (rec. $20 \pm 2\%$ C); the moisture content ranged from 53.8 – 54.6% (study initiation) to 55.4 – 57.3% (study termination); the photoperiod was 16 hours light : 8 hours dark and the light intensity was between recommended 400 – 800 Lux.

In the first test run statistically significant effects on the number of juveniles have been observed and it could not be demonstrated that the NOEC for reproduction in greater than the limit concentration. Therefore, a second test run was performed using five lower concentrations.

In the second run adult *Eisenia fetida* (8×10 replicates for the control group and 4×10 replicates for the treatment groups) were exposed in artificial soil (with 5 % peat content) to AE F160459 at the concentrations of 9,076, 28,51 and 90 mg test item/ kg dry weight artificial soil. Temperature during the second test run ranged between 17,5 and 29.4°C (rec. 20) 2 °C, the moisture content ranged from 53.9 – 56.7% (study initiation to 52.3 – 62.9% (midy termination); the pH value of the test substrate was 6.1 – 6.5 at test initiation and 6.9 – 70 at experimental termination; the photoperiod was 16 hours light : 8 hours dark and the light intensity was between recommended 400 – 800 Lux.

The test item was applied once at the beginning of each test run. The duration of the test period (exposure of carthworms to the artificial soil containing the test item) was 56 days. The adult worms were removed from the substrate after 28 days. After 28 days mortality and biomass were determined. After 56 days reproduction was determined.

As deviation from the guideline the temperature dropped down to 17.2°C at few short time intervals in the second test run and was therefore, slightly below the range required by the guideline. However, study results of the test have not been mpacted.

Toxic standard: Carbendarim (Derosal 560 g/L SC): 1.0, 3.0 and 5.0 mg a.s./kg dry weight artificial soil, control: artificial soil, solvent control: none.

Dates of exposure periode

October 25, 2011 – December 20, 2011 (first run) January 17, 2012 – March 13, 2012 (second run)



Results:

Table CA 8.4.1- 6:Validity criteriaValidity criteria	Recommended	Obtained 1 st run	Obtained 2 rd run
Mortality of adults in the control	≤ 10 %	2.5 %	
Mean number of juveniles in the control (\pm standard deviation)	≥ 30	136.4 ± 28.5	1498.6 ±49.8
Coefficient of variance for the number of juveniles in the control	≤ 30 % Õ	20	23,8%

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

In a separate toxic standard reference study (ECT Study No.: IRR1105 performed from May 18 - July 13, 2011), the LOEC_{Reproduction} value for carbendazim was determined as 10 mg/kg artificial sold dry weight. The NOEC_{Reproduction} was considered m < 1.0 mg/kg artificial sold dry weight. These observed effects are within the range expected from the guideline (1-5 mg carbendazim/kg artificial soil dry weight) and hence acceptable sensitivity of the test system is assured.

First test run:

 $\overline{2.5\%}$ mortality was observed in the control and at the limit concentration of 100 mg test tem/kg dry weight artificial soil.

No statistically significant difference Student test 2-sided, $p \leq 0.05$) concerning biomass development of individual adults over 28 days between the control and the limit concentration of the test item was determined.

Statistical analysis Student-t test, 1-sided, $p \le 0.05$ showed a significant difference concerning the number of juventies between the control and the limit concentration of the test item.

Therefore, with this first test run it could not be demonstrated that the NOEC for reproduction is greater than the limit concentration of 900 mg test item/kg gry weight artificial soil.

Elsenia fetida 🖉 📣 👘		
Concentration	Biomass [% of initial weight]	Number of juveniles [% of control]
Control & A A A A A A A A A A A A A A A A A A	160.7	100.0
	164.3	77.9#

Table CA 8.4.1- 7: First test run: Effects of AE F160459 on mortality, biomass and reproduction of

[#] significantly different to control (Student-fest; losided, $p \le 0.05$)

Second test ran? No mortality was observed in the control and in the concentrations of 16, 28 and 90 mg test item/ kg dry weight artificial soil and 3.5 % mortality at the concentrations of 9 and 51 mg test item/ kg dry weight artificial soil A

No statistically significant differences (Williams-t test; 2-sided, $p \le 0.05$) concerning the biomass development of individual adults after 28 days were determined between the control and all concentrations of the test item tested.



Statistical analysis (Welch-t test; 1-sided, $p \le 0.05$) showed no significant difference concerning the number of juveniles between the control and all concentrations of the test item tested.

Therefore, it could be demonstrated that the NOEC for reproduction is greater than the highest concentration (90 mg test item/kg dry weight artificial soil) of the test item/ested in this second test run.

Table CA 8.4.1- 8:	Second test run:	Effects of AE	F160459 on	n mortality, l	viomass and	reprødi	iction
Eisenia	fetida		ا	õ¥		- St	, C

Concentration [mg test item/kg soil d.w.]	Adult mortality	Biomass [% of initial weight [% of control]
Control	0 0. 0	17806 2 100,0
9	1 2.5 0	Q 174.1 0° 20.5
16		A 79.3 S 2.4 S
28	, × 0.00 × √	× 181,0× × 97.0×
51 Q	4 25 A	1764 95.5
90	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	× 280.9 5 2 99.0
Q'	6 6	

Conclusions:

If considering both test runs together it can be concluded that the NOFC Reproduction is 90 mg test item/kg dry weight artificial soil and accordinary the LOEC Reproduction could be assumed to be 100 mg test item/kg dry weight artificial soft

AE F099095

Report: (2013;M-4/9217-0)
Title: AE F099095 (BCS-AB40283) Effects on survey val, growth and reproduction of the
earthworm Eisenia fetida tested in astificial soil
Report Nos kta/Rg-R $58/13$ $\%$ $\%$ $\%$
Documencial 14-4732 7-01-1
Guidelines: %EU Divective 91/414 PEC %
Regulation (EC) No. 1107/2009
US EPA CSPE Not Applicable; none
GLP/GEP:

Executive Summary:

The purpose of this study was to assess the effect of AE F099095 (metabolite of mesosulfuron-methyl) on survival, growth and reproduction on the earthworm *Eisenia fetida* during an exposure in an artificial soil with five different est concentrations.

Adult *Eisenia fetida* (approx 8 manufis oldo 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in artificial soil (with 10 % peat content) to the nominal test concentrations of 10, 18, 32, 56 and 100 mg test item/ kg dry weight artificial soil. The test term was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined. The test was performed according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004).

Based on the biological and statistical significance observed on growth and reproduction, the overall No-Observed-Effect-Concentration (NOEC) was determined to be ≥ 100 mg test item/ kg dry weight artificial soil. The overall Lowest-Observed-Effect-Concentration (LOEC) was determined to be

> 100 mg test item/kg dry weight artificial soil. The validity criteria of the test according to the guideline were fulfilled.

Materials and Methods:

Test item: AE F099095; BCS code: BCS-AB40283; Batch code: AE F099095 00 1B98 0001; PMS No.: 1035243; Origin Batch No. 2ER0131; purity: 97.7 %w/w.

Adult *Eisenia fetida* (approx. 8 months old, 8×10 replicates for the control group and $4 \approx 10$ replicates per test concentration of the treatment group) were exposed in an artificial sol (with 10 %) peat content) to the nominal test concentrations of 10, 18, 32, 56 and 100 mg test item/kg dry weight artificial soil. The test item was mixed into the sol. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Toxic standard (Carbendazim EC 360 G): 125 - 2.5 - 50 mg a.s./kg dry weight artificial soil (corresponds to 3.94 - 7.89 - 15.78 fog test item/kg dry weight artificial soil control: quartz sand, solvent control: none.

Dates of experimental work: September 64, 2016 – November 08, 2003

Results:

Table CA 8.4.1- 9:		terzia 🗸			. 5
Validity criteria	N O		S Recom	mended 🥍 🧳	C ^Y Obtained
Mortality of adults	the constrol			10% j @	0 %
Mean number of uv	entres in the cont	trong of		365	270, 232, 253, 236, 202, 202, 231, 236
Coefficient of variar in the control	for the number	er of juveniles			9.9%
The set is the set of	Cal Clark Stati	S 11	C C C C C C C C C C C C C C C C C C C		

The validity criteria of the lest according to the guideling were turfilled \bigcirc^2

In a most recent toxic standard reference test (Study No. Rg-R-Ref 19/12, Report No.: kra-Rg-R-Ref 19/12; Non-GLP, performed from September 21 to November 28, 2012), the EC₁₀, EC₂₀ and EC₅₀ (reproduction) of the reference item Carbendazim EC 360 G were calculated to be 3.06, 3.22 or 3.54 mg a.s./kg artificial soil draweight. The results of the reference test indicated that the test system was sensitive to the reference item.





Table CA 8.4.1- 10: Effects of AE F099095 on mortality and changes in body weight of the adults of Eisenia fetida after an exposure period of 28 days and the number of offspring per test vessel after 56 days (values in this table are rounded values)

Test object	est object					S 0
Test item	Control		AE F099	095 (BCS-A	AB40283) «	
mg test item/kg dry weight artificial soil		10	18	2.3.7 2.2.7	560 ⁵⁷	A00 G
Mortality of adult earthworms [%] after 28 days	0	0 😵	0	0		
Mean change of body weight of the adults from day 0 to day $28 [\%]^*$	27.55	30 .60	28.9	34.64 ×	24.74 0	C _{32.20}
Standard Deviation	5.07 🐇	6. 0 9°	\$3.30 ×	429	6.70	4.22
Mean number of offspring per test vessel after 56 days **	232.8	206.5 V	203.0	1895	215.8	214/8
Standard Deviation	Q 23.0 4	×9.3	36%	235.7 Č	14 14 14 14 14 14 14 14 14 14 14 14 14 1	0 _{12.7}
Coefficient of variance (%) Q	10 10 10 10 10 10 10 10			,1⊗.8	0 16.7 ×	5.9
% of control		بر م لا	87.2 ×	81.40	92.7	92.3
			\$ \$ { (Reproduct	ion
NOEC (mg test item/kg dry weight sol) \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc 2100						
EC10 (mg test item fig dry @eight seil 1) (93% confidence fimits) / d.						
EC20 (mg test item/kg dy weight soil) (95% Confi	dence limits		7	n. d.	

* no statistical significance compared to the control (Williams Multiple Sequential t-test, two-sided, $\alpha = 0.05$) ** no statistical significance compared to the control (Waliams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$)

¹⁾ Probit analysis

n. d. not determine@due te hnathematical jeasons

Mortality

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

Effects on growth

Statistically significant different values for the growth relative to the control were not observed.

Therefore based on biological and statistical significance (for both test runs):

 \geq 100 mg test item/kg dry weight artificial soil

> 100 mg test item/kg dry weight artificial soil

Effects of reproduction

NOEC related to growth: LOEC related to growth:

No statistically significant different values for the number of juveniles per test vessel relative to the control were observed.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to reproduction: LOEC related to reproduction: ≥ 100 mg test item/kg dry weight artificial soil > 100 mg test item/kg dry weight artificial soil

Conclusions:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is ≥ 100 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be > 100 mg test item/kg dry weight artificial soil.

AE F092944

Report:	n; ;2013; M-461051-01(, , , , , , , , , , , , , , , , , , ,
Title:	AE F092944 (BCS-AA25052) AFfects on survival, growth and reproduction of the
	earthworm Eisenia fertida tester in artificial soil
Report No:	kra/Rg-R-147/13 🗸 🔨 🏹 🖉
Document No:	M-461051-01-1 4 4 4 4 4 4 4 6 6 6 6 6 6 6 6 6 6 6 6
Guidelines:	EU Directive 90414/EEC; Regulation (EC) No. 1107/2009 US ERA OCSPP Not
	Applicable; pone " , , , , , , , , , , , , , , , , , ,
GLP/GEP:	yes yes a co co co co co

Executive Summary:

The purpose of this study was to determine effects of AE F092944 (metabolite of mesosulfuronmethyl) on survival, growth and reproduction of the earthworm *Eisenja fetida* during an exposure in an artificial soil with one test concentration in the 1st run and 5 different test concentrations in the 2nd run.

In the first run adult *Eisenia fenda* (approx: 6 months old; 8×10^{4} feplicates for control and treatment group) were exposed in artitorial soft (with 10 % peat content) of the nominal concentration of 100 mg test item/kg artificial soil dry weight.

In the second run adult *Eisenia fetide* (approx. 5 months old, 8 10 replicates for the control group and 4 10 replicates per test concentration of the reatment group) were exposed in artificial soil (with 10 % peat content) to nominal concentrations of 5.6 10, 18, 32 and 56 mg test item/ kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then temoved from the artificial soil. After further 28 days, the number of offspring was determined. They test was performed according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004).

Based on the biological and statistical significance of the effects observed on growth and reproduction, the overall No-Observed-Effect-Concentration (NOEC) was determined to be 10 mg test item/ kg dry weight artificial soil. The overall Lowest-Observed-Effect-Concentration (LOEC) was determined to be 18 mg test frem/kg dry weight artificial soil. The validity criteria of the test according to the guideline were fulfilled.

Materials and Methods:

Test item: Ap F092944 (BCS-AA25052); Batch Code: AE F092944 00 1B99 0002; Origin Batch No.: 23503LR; EIMS No.: 1034970; Content of a.s. analysed: 99.8 %w/w; Certificate No.: AZ 17077.

Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

In the 1st test run adult *Eisenia fetida* (approx. 6 months old, 8×10 replicates for control and treatment group) were exposed in an artificial soil (10 % peat content) to the nominal test concentration of 100 mg test item/kg dry weight artificial soil.

In the 2nd test run adult *Eisenia fetida* (approx. 5 months old, 8×10 replicates for the control group and 4×10 replicates per test concentration of the treatment group) were exposed in an artificial soil (10 % peat content) to the nominal test concentrations of 5.6, 10, 18, 32 and 56 mg test item kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the antificial soil. After further 28 days, the number of offspring was determined.

Toxic standard (Carbendazim EC 360 G): 1.25 25 – 5.0 mg a.s./kg coil d.w. (corresponds to 3.94 7.89 – 15.78 mg test item/ kg soil d.w.); control: quartz sand, solvent control none Dates of experimental work: North 12, 2012 September 17, 2013 (hirst run) April 12, 2013 – June 14, 2913 (second zun)

Table CA 8.4.1-11:	Validitz eriteria	S O			× ×
Validity criteria	Ĵ,	Recom	mended	Obtained 1st run	Øbtained 2 nd run
Mortality of adults in th	e çoğarol		0%	\$0 % \$Y	0 %
Rate of reproduction of	juveniles	Les a	m a	[*] 391, 335, 260, 313	246, 350, 278, 228,
(earthworms per control	vessel)	0 2		330, 399, 371, 387	285,232, 254, 287
Coefficient of varian	of reproduction				147%
in the control					14.7 70

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

In a separate study (Study Nos Rg-R-Ref 19/12; Report No. Kra-Rg-R-Ref 19/12; NON-GLP, performed from September 21 to November 28, 2012) the EC10, EC20 and EC50 values for reproduction were calculated to be 9.06, 3 22 or 3.54 no a.s. kg dry weight stificial soil, respectively. Confidence



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Table CA 8.4.1-12: Effects of AE F092944 on mortality and changes in body weight of the adults of Eisenia fetida after an exposure period of 28 days and the number of offspring per test 🖉 after 56 des a in thi a (walu tabl L.L

Test object	Eisenia fetida								
	1 st	run	2 nd cm						
Test item	Control	AE F092944	Control		A	﴾ کد F0929،	4468		
mg test item/kg dry weight artificial soil	-	100		5.6	©10	18 8	32	C.	Ş
Mortality of adult earthworms [%] after 28 days	0	0	1 0	000	0 ©				<i>)</i>
Mean change of body weight of the adults from day 0 to day 28 [%] *	31.75	39.10 [*]	13°17	6.14*×	9.75 ⁰	1709	°14.30	£12.72	
Standard Deviation	4.05	×13~	3:3	6.27	2.82 á	5.52 °	8.29	281	
Mean number of offspring per test vessel after 56 days **	348.3	312.5	270.0	2748	267.8	£91.8**	232.3**	223.5**	
Standard Deviation	47:8	¢ 42 ¢	9 9.7	\$ 55.2 0	23		20.6	10.7	
Coefficient of variance (%)	13,7 0	213.5 J	14-7	2x0.3	×8.7	9.9	8.9	4.8	
% of control	Å - 0	89.7		100.6	99.2 99.2	ð 3 4.7	86.0	82.8	
	. Š ⁴ .	g J				eproductio	on		
NOEC (mg test item/kg dry weight soil)									
EC10 (mg test ftem/kg dry weight soil)) (95% confidence lights)									
EC ₂₀ (mg test item/kg dry weight soil ¹) 05% confidence limits 54.06 (n.d.)									
EC ₅₀ (mg test item/kg dry weight soik)) (95% confidence limits) n. d.									

* statistical significance compared of the control (10 run: Student t-test; 2nd run: Williams mult. sequent. t-test, two-sided, $\alpha = 0.05^\circ$

** statistical signaticance compared to the control (1st Qm: Student t-test; 2nd run: Williams mult. sequent. t-test, one-sided smaller, $\alpha = 0.05$

¹⁾ Probit analysis n.d. not determined due to mathematical reasons of inappropriate data ¢,

S

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

Effects on growt

Statistically significant different values for the growth relative to the control were observed in the 1st run and the lowest concentration of the 2nd run. Since in all higher concentrations of the test item no significant differences to the control were observed this is considered not to be treatment related.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to growth: 56 mg test item/kg dry weight artificial soil LOEC related to growth:

100 mg test item/kg dry weight artificial soil

Effects on reproduction

No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the test concentrations of 5.6 and 10 mg test item/k@dry weight artificial soil (2nd run). Statistically significant different values for the number of juveniles per test vessel relative to the control were observed in the three highest test concentrations of the 2th run.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to reproduction: LOEC related to reproduction:

10 mg test iten kg dry weight artificial sof 18 mg test ifem/kg dry weight and ficial soil

Conclusions:

Overall, based on the biological and statistical significance of the affects observed on growth and reproduction, it is concluded, that the MDEC for this study is 10 mg test nem/kg ary weight and ficial soil. Thus, the overall LOEC is determined to be 18 mg test item/kg dry weight artificial soil.

AE F160460

Report:	;2@13;M-468911
Title:	Mesosulfuron methyle RE F160460: Effects on survival, growth and reproduction of the
	earthworm Rosenia tenda tested in artificial soil
Report No:	krankg-R-156/13
Document No:	$M-4689$ $1^{2}01-10$ 0 5^{2} 10^{2} 10^{2}
Guidelines:	EU Directive 91/4147EEC; Regulation (EC) No. 1007/2009; US EPA OCSPP Not
	Applicable ASO 1268-2: 1998 (E); OEC 222; April 13, 2004; none
GLP/GEP:	yes in the state of the

Executive Summars:

The purpose of this study was to assess the effect of AE F160460 (metabolite of mesosulfuron-methyl) on survival, growth and reproduction on the earthworm Eisenia fetida during an exposure in an artificial soil with the different test concentrations.

Adult Eisenia fetala (approx. A months old & x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in artificial soil (with 10 % peat content) to the nominal test concentrations of 10, 18, 32, 36 and 100 mg test item/ kg dry weight artificial soil. The test item was mixed into the soil After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined. The test was performed according to the guideline ISO 11268-2 (1998) and the OECD G@deline 222 (2004).

Based on the blogical and statistical significance observed on growth and reproduction, the overall No-Observed Effect Concentration (NOFC) was determined to be ≥ 100 mg test item/ kg dry weight artificial soil. The overall Lowest-Observed-Effect-Concentration (LOEC) was determined to be > 100 mg test fem/kg dry wight artificial soil. The validity criteria of the test according to the guideline were fulfilled.



Materials and Methods:

Test item: AE F160460 (BCS-AU84908); Customer order no.: TOX-No. 09538-00; Batch code F160460-01-02; Origin Batch No. SES 11562-12-4; Purity: 96.7 %w/w; Certificate No.: AZ 1707/

Adult *Eisenia fetida* (approx. 4 months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in artificial soft (with 10 % peat content) to the nominal test concentrations of 10, 18, 32, 56 and 100 mg test itenty kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of serviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

a.s./kg dry weight artificial soil Toxic standard (Carbendazim EC 360 G): \$25 (corresponds to 3.94 - 7.89 - 15.78 mg test item/40g dry weigh (artifical soil), control: quartz sand, solvent control: none.

Dates of experimental work:

Results:

Table CA 8.4.1- 13:	Validity criteria	.0 	The second secon	<u></u>	ČA	ð	0 [×]
Validity criteria	× 4 .	O L	/ Reco	mmende₫	¥ .		Obtained
Mortality of adults in the	ne control 🖉 🧔		S E	5 NO % 🔊	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	1.25 %
Mean number of juven	tes in the control			≥ 36)))))))))))))))))))	76, 139, 173, 192, 181, 179, 168
Coefficient of variance	for the number of juc	eniles *		30 % L		<i>y</i>	12.3 %
The validity arite of the	a fact according to the	andalin	avera fulf	llad	K)		

In a most recent toxic standard reference test Study No. Re-R-Ref 19/12, Report No.: kra-Rg-R-Ref 19/12; Non-GLP; performed from September 21 to November 28, 2012), the EC10, EC20 and EC50 (reproduction) of the reference item Carbendazim FC 360 S were calculated to be 3.06, 3.22 or 3.54 mg a.s./kg arthrcial soil droweight? The results of the reference test indicated that the test system
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Table CA 8.4.1-14: Effects of AE F160460 on mortality and changes in body weight of the adults of Eisenia fetida after an exposure period of 28 days and the number of offspring per test

vesser after 50 days (v	alues in this	table are ro	unueu value	:5)		
Test object		Eisenia fetida 💫 🔊				
Test item	Control			AE F16046) 4	
mg test item/kg dry weight artificial soil		10	18	132 232	56	
Mortality of adult earthworms [%] after 28 days	1.25	0	0	0		
Mean change of body weight of the adults from day 0 to day 28 [%] *	38.77	3 7 .92	37.6	36.43 ×	3 1 ,73	037.42 ⁰
Standard Deviation	9.23 🐇	2.8a°	25.24 2 2	437	4.53	×2.74
Mean number of offspring per test vessel after 56 days **	178.1	186.5			184.5 ¢	167.3
Standard Deviation	Q 22.0 4	1.9 1.9		25.6 ¢	256	0 ^{20.1}
Coefficient of variance (%) Q^{2}	\$2.3 ¢		7.8 °	,1 <u>8</u> .1	0 ² 13.9 ³	12.0
% of control		یں 104.7	164.6	279. 6 0	103.6	93.9
			\$ \$ 4.		Reproduct	tion
NOEC (mg test item/kg dry weight soit	Ň _Q				≥100	
EC10 (mg test item fig dry @eight soil 1)) (93% confi	dence Pimits	Ê Ó	Å.	n. d.	
EC20 (mg test icm/kg dy weight soil) (95% Confi	dence limits		%)" 7)	n. d.	
	0					

* no statistical significance compared to the control William's Multiple Sequential t-test, two-sided, $\alpha = 0.05$) ** no statistical significance compared to the control (Williams Multiply Sequential t-test, one-sided smaller, α = 0.05)

1) Probit analysis

 \bigcirc inappropriatedata n. d. not determine@due to

Mortality

ontrol group and no mortality was observed at any test After 28 days of exposure no in the item concentration

Effects on growth

Statistically significant different values for the growth relative to the control were not observed.

Therefore based on biological and statistical significance (for both test runs):

 \geq 100 mg test item/kg dry weight artificial soil

> 100 mg test item/kg dry weight artificial soil

Effects m reproduction

NOEC related to growth:

LOEC related to growth: «

No statistically significant different values for the number of juveniles per test vessel relative to the control were observed.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to reproduction: LOEC related to reproduction: \geq 100 mg test item/kg dry weight artificial soil

> 100 mg test item/kg dry weight artificial soil

Conclusions:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is ≥ 100 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be > 100 mg test item/kg dry weight artificial soil.

AE F140584

Report:	•; ;20, 3, M-46, \$921-00, 20, 20, 20, 20, 20, 20, 20, 20, 20,
Title:	Mesosulfuron-methyl-AE F140584 (BCS-AU66443): Effects on survival, growth and
	reproduction of the earthworn Eisenia fetida tested in artifical soil
Report No:	kra/Rg-R-155/13 🗸 🔨 🏈 🎸 🖉
Document No:	M-468921-01-1
Guidelines:	EU Directive 90414/EEC; Regulation (EC) No. 1107/2009 US ERA OCSPP Not
	Applicable; ISO 11268-2: 1998(E); OECD 222: April 13 2004; For the three highest
	application rates 422.55 gary weight antificial soil were used and at test end soil
	moisture was above 60 percent of WHCmax Q &
GLP/GEP:	yes w w w w w

Executive Summary:

The purpose of this study was to assess the effect of AE F140584 (BCS_AU66443; metabolite of mesosulfuron-method) on survival growth and reproduction on the earthworm *Eisenia fetida* during an exposure in an artificial soil with five different test concentrations

Adult *Eisenia Guida* (approx 7 months oldo 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in artificial soil (with 10 % peat content) to the nominal test concentrations of 10, 18, 37, 66 and 117 mg test item/ kg dry weight artificial soil. The test trem was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined. The test was performed according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004). As deviation from the guideline 422.55 g dry weight artificial soil were used for the three highest application rates and soil moisture was above 60 of WHC_{max} at test end.

Based on the biological and statistical significance observed on growth and reproduction, the overall No-Observed-Effect Concentration (NOFC) was determined to be ≥ 117 mg test item/ kg dry weight artificial soil. The overall Lowest-Observed Effect-Concentration (LOEC) was determined to be ≥ 117 mg test item/kg dry weight artificial soil. The validity criteria of the test according to the guideline were fulfilled.

Material and Methods.

Test item: AL F140584 (BCS-AU66443); Batch code: AE F140584 00 1B96 0001; Origin Batch No.: LOP 21036, CAS No.: \$93509-80-3; LIMS No.: 1213360; purity: 95.5 %w/w; Certificate No.: AZ 18036.

Adult *Eisenia fetida* (approx. 7 months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in artificial soil (with 10 % peat content)



to the nominal test concentrations of 10, 18, 37, 66 and 117 mg test item/ kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, they number of offspring was determined. The test was performed according to the guideline ISO212682 (1998) and the OECD Guideline 222 (2004). As deviation from the guideline 422.55 g dry weight artificial soil were used for the three highest application rates and soil moisture was above 50 WHC_{max} at test end.

Toxic standard (Carbendazim EC 360 G): 1.25 - 2,5 - 5.0 mg A.s./kg dry weight attificial soil (corresponds to 3.94 - 7.89 - 15.78 mg test item/kg dry weight@rtificial soil); control: quadz sand solvent control: none.

Dates of experimental work:

July 29

Results:

Table CA 8.4.1- 15:	Validity criteria		2		Š	Ĩ	Â, C)
Validity criteria	0		k V	Le commende	d S	Š Ś	Obtained	l
Mortality of adults in th	e control	Q Q	ð	<u>چې</u> و کې			°0⁄%	
Mean number of juveni	les in the control		<u>o</u> r	$4 \ge 300^{\circ}$		3, 2 2	44, 250, 2 [°] 92, 274, 3	78, 321, 00
Coefficient of variance in the control	for the number of	juveniles (, "O 4	≤ 30 % √			9.9%	
The validity criteria of the	e test according@	the goddeli	newere	fulfilled.	<u> </u>	<u>, 67</u>		

In a most recent toxic standard reference test (Study No. Rg R-Ref 19/12 Report No.: kra-Rg-R-Ref 19/12; Non-GLE performed from September 21 to November 28, 2012), the EC10, EC20 and EC50 (reproduction) of the reference item Carbondazin EC360 @were calculated to be 3.06, 3.22 or 3.54 mg a.s./kg artificial soil dry weight. The results of the reference test indicated that the test system

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Table CA 8.4.1- 16: Effects of AE F140584 on mortality and changes in body weight of the adults of *Eisenia fetida* after an exposure period of 28 days and the number of offspring per test 0 vessel after 56 days (values in this table are rounded values) 0

vessel after 56 days (va	alues in this	table are ro	unded value	es)		
Test object			Eisenie	a fetida 🛛 嶡	,	
Test item	Control		AE F140	9584 (BCS-A	AU66443) 🖗	
mg test item/kg dry weight artificial soil		10	18	37***	660 [°]	\$17 \$
Mortality of adult earthworms [%] after 28 days	0	0 🗇	0	0		
Mean change of body weight of the adults from day 0 to day 28 [%] *	1.40	A 61	1.68	5.89	2(88 0 2	
Standard Deviation	4.17 💃	5.¢4°	21.73×2	5.37 200	5.94	¥.75
Mean number of offspring per test vessel after 56 days **	281.5	275.3°	241.8		264.3	258.5
Standard Deviation	Q 27 8 7	48 .5	384	25.7 ¢	249.8	0 ^{44.8}
Coefficient of variance (%) Q^{*}			\$15.9 \$		0°7.9°%	17.5
% of control		بر مرجع 97.8	8 59.9	× 102¢	93.9	90.8
			\$ [°] «,	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Reproduct	tion
EC10 (mg test item/kg fry weight soil) (95% confi	dence limits			n. d.	
EC20 (mg test item g dry @eight soil 1)) (93% confi	dence Pimits	Ê Ó	Å.	n. d.	

* no statistical significance compared to the control (Williams Multiple Sequential t-test, two-sided, $\alpha = 0.05$) ** no statistical significance compared to the control (Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$) = 0.05)

*** three replicates instead of for were tested

1) Probit analysis

n. d. not determined de to mathematica reasons or inappropriate data

Mortality:

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

Effects on growth 2^{1} 2^{2} 2^{2} 2^{2} Statistically significant different values for the growth relative to the control were not observed.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to growth: ≥ 117 mg test item/kg dry weight artificial soil

LOEQ related to growth: > 117 mg test item/kg dry weight artificial soil

Effects or preproduction

No statistically significant different values for the number of juveniles per test vessel relative to the control were observed.

Therefore, based on biological and statistical significance (for both test runs):

NOEC related to reproduction: LOEC related to reproduction: ≥ 117 mg test item/kg dry weight artificial soil > 117 mg test item/kg dry weight artificial soil

Conclusions:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is ≥ 117 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be > 117 mg test item/kg dry weight artificial soil.

AE F147447

Report:	6; ,2012() -428691-01
Title:	AE F147447: Reproduction to worty to the earth form Esenia felida in an artificial soil test
Report No:	11P34RR
Document No:	M-428651-01-1 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Guidelines:	the OECD Guidefine No, 222 for the Festing of Chemicals "Earthworm Reproduction
	Test (Eisenia fenda/Eisenia andrei), adopted April 13, 2009; the International
	Standard ISO 11268 Part 2 (1998) "Soil Qualito- Effects of Pollutants on
	Earthworms (Eisenia fetilia) - Part 2: Determination DEffects on Reproduction";At
	few short time intervals the temperature dropped down to a
	17.2°Cin the second test rup and was therefore, slightly below the range
	required by the guideline. However, study results of the test have not been
	impacted, Q Q Q Q V V
GLP/GEP:	yes A & C & C & C

Executive Summary:

The purpose of this study was to determine effects of AE F147447 (metabolite of mesosulfuronmethyl) on the reproduction 56 days after application) of the carthworm *Eisenia fetida* (Lumbricidae) by dermal and alimentary uptake using a standardised artificial soft. The study was performed as a limit test (Pst test run) and a fall dose response test (2nd test run) according to the guideline ISO 11268-2 (1998) and the OECD Guideline 222 (2004). As deviation from the guideline the temperature was slightly below the range required by the guideline at few short time intervals in the second test run. However, study results of the test have not been impacted.

In the first rule adult *Eisensi fetida* (8 010 replicates for each treatment level) were exposed in artificial soil in artificial soil (with 5 % peat content) to the concentration of 100 mg test item/kg artificial soil dry weight

In the second run adult *Eisenia fetida* (8 × 10 replicates for the control group and 4 × 10 replicates for the treatment groups) were exposed in artificial soil (with 5 % peat content) to the concentrations of 9, 16, 28, 51 and 90 mg test item/deg dry weight artificial soil. Mortality and biomass were assessed after 28 days. The number of juvenie earthworms was assessed after 56 days.

The No-Observed-Effect-Concentration (NOEC) was determined to be 90 mg test item/ kg dry weight artificial soil. The overal Lowest-Observed-Effect-Concentration (LOEC) was determined to be 100 mg test item/kg dry weight artificial soil. The validity criteria of the test according to the guideline were fulfilled.

Materian and Methods:

Test item: AE F147447; Batch code: AE F147447 00 1B98 0001; Origin batch No.: 33400-93/2; Certificate of analysis No.: AZ 16208; purity: 98.1 % w/w.

Bayer CropScience Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

months old) were exposed in an artificial soil in two test runs. Ô In the first run adults of *Eisenia fetida* (8×10 replicates for the control group and 8×10 replicates for the treatment group) were exposed in artificial soil (with 5 % peat content) to AE F147447 at the concentration of 100 mg test item/kg artificial soil dry weight. Temperature during the first test rung ranged between 18.1 and 21.4°C (rec. 20 ± 2 °C); the moisture content ranged from 55.0 \times 57.1% (study initiation) to 58.3 – 58.5% (study termination); the pH value of the test substrate was 6.3 at lest initiation and 6.7 at experimental termination; the photoperiod was Q6 hours light. 8 hours dark and the light intensity was between recommended 400 – \$60 Lux. In the first test run statistically significant effects of the number of juveniles have been observed and it could not be demonstrated that the NOEC for reproduction is greater than the dimit concentration. Therefore, a second test run was performed using five lower conceptrations. In the second run adult Eisenia fetida (8 × 10 replicates for the Control group and 4 × 10 replicates for the treatment groups) were exposed in artificial soil with 50% peat content) to 4 E F147447 at the concentrations of 9, 16, 28, 51 and 90 mg test item, kg dry weigh artificial soil. Temperatureduring the second test run ranged between 10.2 and 21.4°C (rec. 20 ± 2 °C); the moisture content ranged from 54.9 - 58.5% (study initiation) to 47.4 - 54.6% (study termination); the pH value of the test substrate was 6.3 - 6.4 at test initiation and 7.0×7.2 at experimental derivingtion; the photoperiod was 16 hours light : 8 hours dark and the light intensity was between recommended 400 - 800 Lux. \bigcirc The test item was applied once at the beginning of each test run. The dyration of the test period (exposure of earthworms to the artificial soil containing the test item) was 56 days. The adult worms were removed from the substrate after 28 days. After 28 days mortality and biomass were determined. After 56 days reproduction was determined.

Adult earthworms (Eisenia fetida, with clitellum, fresh weight between 250 and 600 mg, at least 2

As deviation from the guideline the temperature dropped down to 10.2°C & few short time intervals in the second test fun and was therefore, slightly below the range required by the guideline. However, study results of the test have not been impacted.

Toxic standard: Carberdazin: Derosal 360 g/L SQ: 1.0, 9.0 and 5.0 mg a.s./kg dry weight artificial soil, control: artificial soil, solvent control none

October 27, 2011 December 22, 2011 (first run) January 19, 2012 March 14, 2012 (seccercl Dates of exposure period:

Table CA 8.4.1- 17: A Validity criteria			
Validity criteria	Recommended	Obtained 1 st run	Obtained 2 nd run
Mortality of adults in the control	<i>x</i> ≤ 10 %	0 %	7.5 %
Mean number of juveniles per replicate in the control (± standard deviation)	≥ 30	200.4 ± 29.8	136.0 ± 39.4
Coefficient of variance for the number of juvenites in the control	<i>≤</i> 30 %	14.6 %	29.0 %

The validity crueria of the tesk according to the guideline were fulfilled.

In a separate toxic standard reference study (ECT Study No.: IRR1105, performed from May 18 to July 13, 2011), the LOEC_{Reproduction} value for carbendazim was determined as 1.0 mg/kg dry weight artificial soil. The NOEC_{Reproduction} was considered as < 1.0 mg/kg dry weight artificial soil. These observed effects are within the range expected from the guideline (1-5 mg carbendazim/kg soil dry weight) and hence acceptable sensitivity of the test system is assured.

First test run:

No mortality was observed in the control and 3.8% at the concentration of 200 mg test iter weight artificial soil.

0.05) conferming A statistically significant difference (Student-t test 2-sided, p development of individual adults over 28 days between the control and the limit concentration of test item was determined.

Statistical analysis (Student-t test; 1-sided, $p \ge 0.05$) showed a significant difference concerning the number of juveniles between the control and the limit concentration of the test item.

Therefore, with this first test run it could not be demonstrate that the is greater than the fimit concentration of 100 mg test item/kg de weight artificial seil.

First test ron: Effects of AE F147447 on portality, biomess and reproduction of Table CA 8.4.1-18: Eisenia fetida O

Concentration 🏑 [mg test item/kg soiled.w.	Adult mort	alify o	Biomass Sof initial weight	Number of juveniles
Contre	0 00	×	× 163.9 ×	100.0
100	\$3.8	s l	Ů Ď7.7# √	73.8#

[#] significantly different to control (Student) est; 2-sided for biomass, 1-sided for coproduction, $p \le 0.05$)

Second test ru

7.5% mortality was observed in the control, 25% at the concentrations of 51 mg test item/ kg dry weight artificial soil and no mortality all other concentrations of the test item tested.

No statistically significant differences Williams-t test; 2-sided, $p \le 0.05$) concerning the biomass development of individual adults after 28 days were determined between the control and all concentrations of the tost item tested

Statistical analysis (Williams-t test; 1-staded, p 20.05) showed no significant difference concerning the number of juveniles between the control and all concentrations of the test item tested.

Justicentrations of the test item tested. Justicentration is greater than the highest Justicentration (90 mg test item/kg dry weight artificial soil) of the test item tested in this second test run. Therefore, it could be demonstrated that the NOEC for reproduction is greater than the highest concentration (90 m run.

Table CA 8.4.1- 19:	Second test run: Effects of AE F147447 on mortality, biomass and reproduc	tion of	
Eisenia	fetida	añ	~

Concentration	Adult mortality	Biomass	Number of juven Ø es
[mg test item/kg soil d.w.]	[%]	[% of initial weight] 🔗	[% of control
Control	7.5	172.5	\$100. 0 \$
9	0.0	175.4	× 1111 ×
16	0.0	129.9	<u>Č</u> (08.7 Č
28	0.0	\$74.9	Ø 582.2 ×
51	2.5	183.9	Q 75.00 S
90	0-0	182.2	L 102.4 L
	- AD	N. 0° N	

Conclusions:

production is 96 mg test item &g If considering both test runs together it can be concluded that assumed to be 100 mg test dry weight artificial soil and according yo the ÊØE item/kg dry weight artificial soil.

Effects on non-target soil meso and macrofauna (other CA 8.4.2

CA 8.4.2.1 Species level testing

For mesosulfuron-methyl and ats metabolites AE F154851, AE F160459, AE F092944 and AE F147447 reproductive toxicity studies on Folgomia andida were performed. In addition, for mesosulfuron-methyl and its terminal metabolite AF F092934 reproductive toxicity studies on Hypoaspis aculifer were performed.

In the tests with the collembolan species Folsomia sandida and the soil mite Hyposapis aculeifer no effects were observed at the highest tested dose levels when either the parent compound or the metabolites were tested. Resulting NOEC values were \$1000 mg a.s. kg dws for mesosulfuron-methyl and ≥ 100 mg/kg dws for the solution that for the solution of all or and ≥ 100 mg/kg dws for the solution that the solution of all or an and ≥ 100 mg/kg dws for the solution that the solution of the

L.

Based on the consistent absence of effect observed in all studies covering the parent active substance, its initial and terminal metabolices, it was deened justified to conclude absence of relevant toxicity to non-target soil meso and macrofaun (other than carthy fins) as well for the transient intermediate

non-target soil meso and macrofaung (other than earthy ofms) as well for the transient intermediate components in the soil metabolic pathway of mesosulfuron-methyl. No further testing was therefore considered necessary.

Table CA 8.4.2.1-1: Reproductive toxicity data of mesosulfuron-methyl and metabolites to other non \mathcal{Q}_i

targe			
Test substance	Test species	Endpoint	Reference
Managelfunge	Hypoaspis aculeifer	NOEC ≥1000 mg a.s./kg dy	M-4293%6-01-1 KCA&4.2.1/0
methyl	Folsomia candida	NOEC Set ≥1000 mg as kg dws	2012 M-426538-01 KCA8.4.2.1402
AE F154851	Folsomia candida	$NOFC \geq 100 \text{ mg/kg dws}$	2013 © M ² 462785-01-1 KCA&A.2.1/0
AE F160459	Folsomia candida	NQEC Č≥100 mg/kg dws ở	, 20¥3 M£462786-01-1 KČA 8,422.1/04
AE F092944	Hypoaspis aculeder	NOEC → 100 mg/kg dws	M-454043-61-1 KCA 8.4.2.1/05 M-454/142-01-1 KCA 8.4.2.1/06
AE F147447	Folsomia condida	$\int \Theta EC = \frac{1}{2} \int \Theta $	M-462782-01-1 KCA 8.4.2.1/07
dws = dry weight soil		^N L ^V , Õ ^V & , , ^V Õ ^V	
Bold letters: Values co	onsidered relevant for risk as	sessment in the MCB document	
Studies on mesosul	uron-methyl		
Report:	у;	<u>\$2012;</u> ₩-4293, 6-01	
Title:	Mesosulfuron-methyl (AE	F30060. Influence or mortality and re	eproduction on the soil
~~~~	mite species Hypospis ad	Meifer tested intertificial soil	
Report No	KRA-HA2-67/12		

 

 Document No:
 M-4293/6-01-1

 Guidelines:
 OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals -Predators mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil;not

 GLP/GEP:
 yes
 yes

#### ExecutiveSummary; 🖗

The purpose of this study was to asset the effect of active substance mesosulfuron-methyl (AE F130060) on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested during an exposure of 14 days in an artificial soil comparing control and treatment. Ten adult, fertilized, female *Hypoaspis aculeifer* per repricate (8 replicates for each application rate) were exposed to control and one treatment. The concentration of 1000 mg test item/kg dry weight artificial soil was tested. After a period of 14 days, the surviving adults and living juveniles were extracted and counted under a binocular.

The  $DC_{50}$  could not be calculated and it is considered to be > 1000 mg test item/kg dry weight artificial soil. The No-Observed-Effect-Concentration (NOEC) for reproduction was  $\geq$  1000 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction was > 1000 mg test item/kg dry weight artificial soil. The EC_x-values could not be calculated. All validity criteria (for the untreated controls) according to the guideline were met.



#### **Materials and Methods:**

Test item: mesosulfuron-methyl (AE F130060); Batch code: AE F130060-01-02; Origin Batch No.. EFME000144; LIMS No.: 1101337; Specification No.: 102000013204; Certoricate No.: AZ 17129; Customer order No.: Tox-No. 09287-00; purity: 97.4 %w/w.

Ten adult, fertilized, female *Hypoaspis aculeifer* per replicate (8 replicates for each application rate) were exposed to control and to the concentration of one treatment. The concentration of 1000 mg test item/kg dry weight artificial soil was tested. In each test vessel 20 g dry weight artificial soil were weighed in. The *Hypoaspis aculeifer* were of a uniform age not differing more than three days (28 days after start of egg laying). During the test, they were fed with cheese mites bred on brower's yeast. During the study a temperature of  $20 \pm 2$  °C and light regime of 400 - 800 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 74,8 % time quartz sand, 5% sphagnum pear, air dried and finely ground, 20 % kaolin clay and approximately 0.2 % calcium carbonate (SaCO3). After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyet Apparatus. Extracted mites were collected in a fixing solution (20 % ethylene glycol, 80 % defenised water 2 g detargent P fixing solution were added). All Hypoaspis aculeifer were counted under a binocular.

Toxic reference: (Dimetheate EO400FG): 0.990 - 1.780 - 3.156 - 5.517 - 9.853 mg a.s./kg dry weight artificial soil; control: quartz sand with deion and worker, solvent control: gone.

Dates of experim	mental we	ork:	Jan	uary 06, 2	912 - Janu	iarg 26, 2012
		• 📎	<i>//</i> •	× •		

#### **Results:**

Table CA 84.2.1-2: Validity criterity		
Validity criteria (control values)	Recommended	Obtained
Mean adult female wrtality	$\leq 20 \%$	0 %
Mean number of faveniles per repricate with 10 adult females introduced)	≥ 50	283.9
Coefficient of Cariation Calculated for the number of provenile thites per replicate	≤ 30 %	13.7 %

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

In a separate non GLP study (method was calculated to be 4.051 mg a.s./kg dry weight artificial soil. The NOFC reproduction was calculated to be 3.156 mg a.s./kg dry weight artificial soil and accordingly the LOFC reproduction is 5.517 mg a.s./kg dry weight artificial soil. Dimethoate showed a EC₅₀ (reproduction) of 6.445 mg a.s./kg dry weight artificial soil. This shows that the test organisms are sufficiently ensitive.

and the second s



Table CA 8.4.2.1- 3:       Effects on mortality and reproduction of Hypoaspis aculeifer					
Test item	Mesosulfuron-methyl (AE F130060) a.s.				
Test object	Hypoaspis aculeifer				
Exposure		Art	ificial soil	<b>~</b>	· · · ·
mg test item/kg dry weight	% mortality	Mean num	ber of juve	ni <b>les</b> per	Reproduction
artificial soil	(Adults)	test vesse	el ± standaı	dððev.	(% of control)
Control	0	283.9	± A	38.8	ô* \$\$ .\$
1000	2.5	311.9	± " Š	34.7 🦼	× .9.9
NOEC (mg test item/kg dry weight a	artificial soil)	<i>₹</i>	Ű	Õ	
LOEC (mg test item/kg dry weight a	artificial soil)	<u>_</u>	Ö [%]	<u> </u>	

No statistical significance (Student t-test for homogeneous variances, on Q sided smaller Q = 0.05) was found

#### Mortality

In the control group 0 % of the adult *Hypoarpis active* if the divergence of  $\leq 20$  % mortality. The LC50 could not be calculated.

#### Reproduction

Concerning the number of juvenile statistical analysis (Student t-test for homogeneous variances, one-sided smaller,  $\alpha = 0.05$ ) revealed no significant difference between control and the concentration of 1000 mg test item/kg dry weight artificial soil. Therefore the No-Observed Effect-Concentration (NOEC) for reproduction is 21000 mg test item/kg dry weight artificial soil. The Lowest Observed-Effect-Concentration (LOEC) for reproduction s > 1000 mg test item/kg dry weight artificial soil. ECx-values could not be calculated.

#### **Conclusions:**

The No-Observed-Effect-Concentration (NOEC) for reproduction is 2 1000 mg test item/kg dry weight artificial soil, and the Lowest-Observed-EffectConcentration (LOEC) for reproduction is > 1000 mg test item/kg dry weight artificial soil.

Report	š; ;2012;M-420538-01
Title:	Mesesulfuron meth (AE F) 3006(0) a.s.: Influence on the reproduction of the collembolan
D.	species Forsomia candida @sted in artificial soil
Report No:	FRM-CGEL-13@12 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Document No: 2	OM-426538-04-
Guidelines:	OE 232 adopted, September 10, 2009: OECD Guidelines for Testing Chemicals -
4	Collembolan Reproduction Test in Soil;none
GLP/GE	Nes Q Q X

#### Executive Summary:

The purpose of this study was to assess the effect of the active substance mesosulfuron-methyl (AE F130060) or survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil, by comparing control and treatment.

10 collembolans (11 - 12 day old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 100, 178, 316, 562 and 1000 mg test items kg archicial soil day weight. After a period of 28 days, mortality and reproduction were determined.

The No-Observed-Effect-Concentration (NOEC) for reproduction is  $\geq$  1000 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is > 1000



mg test item/kg dry weight artificial soil. All validity criteria for the untreated control of the study according to the OECD Guideline 232 have been fulfilled.

#### **Materials and Methods:**

Test item: mesosulfuron-methyl (AE F130060) a.s.; analytical findings: 97,4% w/w; origin batch EFME000144; customer order no.: TOX-No. 09287-00; specification not 102000013204; 1101337; batch code: AE F130060-01-02.

10 collembolans (11 - 12 days old) were exposed to untreated control and to concentrations of 100% 178, 316, 562 and 1000 mg test item/kg dry weight artificial soil containing 74/8 % fine quartz said, 20 % kaolin clay, 5 % sphagnum peat, air dred and finely ground, and 0.2 % CaCP₃ for the adjustment to pH to  $6.0 \pm 0.5$ , at  $20 \pm 2$  °C, 400 - 800 fux, with a photoperiod: light : dark = 16 h : 8 h. Each test vessel of the 8 control and the 4 treatment replicas plus the one for measurement purpose .cq with veight; control: quartz sand was filled up with 30±1 g wet weight antificial soil. During the test the collembolans were fed with granulated dry yeast. Mortality and reproduction were deternined after 28 days

Toxic reference: 44 - 67 - 100 - \$50 - 225 mg boric acid/kg/so moistened with deionised water, solventoontroonne

### December 16, 2011 – January 1 Dates of experimental wor

#### **Results:**

Table CA 8.4.2.1-4: SValidity criteria		
Validity criteria (untreated control)	Recommended	Obtained
Mean adult mortality ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		20 %
Mean number juve files per Peplicale (with 10 collembolars introduced)	$\geq 100$	977
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30 %	14.6 %
	•	

All validity criteria for the study were met. Therefore the study is valid

In a separate mosphecent non-QLP study (FRM-ColPRef 45/11, . March 08, 2011) the EC₅₀ of the reference item boric acid was calculated to be 91 mg test item/kg artificial soil dry weight for reproduction. The NOE reproduction was calculated to be 44 mg test item/kg artificial soil dry weight and accordingly the LORO reproduction is 67 mg test item /kg artificial soil dry weight. This shows





nd reproduction of 。
nd reproduction of

Folsomia candida				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Test item	Me	sosulfuron-methyl (	AE F130060) a.	s. 🔊 🖉
Test object	Folsomia candida 💊 🖏			
Exposure		Artificial	soil	
mg test item/kg soil dry weight			O ^r	
	Adult mortality	Mean number of	juvéniles±SD	Reproduction
nominal concentration	(%)	A.	W.	% of controll
Control	20.0	77.3 ±	142.6	
100	10.0	1260.0	131.4	₹28.9
178	20.0	∱ 1127.5 L ±	165	Q 115.€ ^{¥.s.}
316	12.5	, 1086 Q° ±	° 192,4	11 M n.s.
562	30.0	1179~#	j∛ f <b>6</b> 9.7 ∖O	\$20.6 ^{n.s}
1000	22.5	∘ 1085 <b>8</b> , ¥	\$1.5 [°]	s≪111.1
NOEC _{reproduction} (mg test item/kg	soil dry weight)			≥1000
LOEC _{reproduction} (mg test item/kg	soil dry weight) 🔊	Q.	Ů _~ Č	× 2000

The calculations were performed with un-rounded values

SD = Standard deviation

n.s. = statistically not significant (William &-t test one-sided-smalle

#### Mortality

In the control group 20 % of the adult Folsomia candida died and therefore metche allowed maximum of  $\leq 20$  % mortality. A LCs could not be calculated and is considered to be > 1000 mg test item/kg artificial soil dry weight.

#### Reproduction

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

Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is ≥1000 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is >1000 mg fest item/kg attificiat soil dry weight. An EC 50 could not be calculated and is considered to be > 1000 mg test item kg artificial soll dry wei

#### **Conclusions:**

The No-Observed-Effect-Concentration NOEC for reproduction is ≥ 1000 mg test item/kg dry weight artificial soil, anothe Lowest-Observed-Effect-Concentration (LOEC) for reproduction is > 1000 mg @st item/ kg dpy weight artificial sor.

Studies on the metabolites of mes osulfuron-ma

AE F154851	
Report:	"; ;2013;M-462785-01
Title:	Mesosulfacon-methyl-AE F154851 (BCS-AU80405): Effects on the reproduction of the
	collembolan Folsomia candida
Report No: 6	13 10 78 104 S
Document No.	M-462785-01-1
Guideline	OECD 232 (2009), ISO 11267 (1999);none
GLP/GEP:	yes

#### **Executive Summary:**

The purpose of this study was to determine potential effects of the metabolite AE F154851 (BCS-AU80405; metabolite of mesosulfuron-methyl) on the reproductive output of the collembolan *Folsomia candida* as a representative of soil micro-arthropods during a test period of 28 days 10 juvenile collembolans (9-12 days old) per replicate (8 replicates for the control group and 8 replicates for each treatment group) were exposed to untreated control and to 100 mg test item/kg soil day weight. After 4 weeks the number of juveniles and surviving parental collembolans were counted. The test was performed as a limit test in accordance with the OECD Guideline 232 (2009) and the metabolic of the formational Standard ISO 11267 (1999).

The overall No-Observed-Effect-Concentration (NOEC) was determined to be  $\geq$  100 mg test item 4 g soil dry weight, and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be  $\approx$  100 mg test item/kg soil dry weight. The validity criteria for the control group of the study were accomplished.

#### **Materials and Methods:**

Test item: AE F154851, BCS-code BCS AU80405, Batch code: AE F154851-01 df, Origin Batch No.: SES 11372-3-4, LIMS No.: b10285, Customer order No.: TOX No: (9197-6), analysed purity: 97.1 % w/w.

10 *Collembola* (9-12 days old) were exposed to 100 mg/est item/kg div weight of soil containing 74.7 % quartz sand, 20 % kaolin clay, 5 % spherinum peat and 0.3 % CaSO3,  $12.1 - 20.6^{\circ}$ C and a photoperiod: light : dark = 16 h : 8 h (500 lx) and were feet weekly with granulated dry yeast. Mortality and reproduction were determined after 28 days.

Toxic standard 44 - 6 100 - 150 - 225 mg boric acid kg sol dry weight; control: quartz sand, solvent control none

Dates of experimental work May 07, 2013 - June 04, 201

#### **Results:**

Table CA 8.4.2.1- 6: Nalidity criteria 📈 🖉		
Validity criteria (coppol group)	Recommended	Obtained
Mean adult mortality & A & A	$\leq 20 \%$	6.3 %
Mean number of juveniles per replicate	≥ 100	1146
Coefficient of variation (mean number of jurchiles per replicate)	< 30 %	10.3 %

All validity criteria for the soldy were met. Therefore this study is valid.

The requirement of the ISO guideline concerning the precision of the counting method (average error <10 %) was fulfilled, the determined overall error of counting amounted to 3.6 %.

In the most recent study (BioChem, project No. R 13 10 48 004 S, dated July 16, 2013) the EC₅₀ of the reference item boric acid, was determined to be 108 mg a.s./kg soil dry weight. The LC₅₀ was determined to be 102 mg a.s./kg soil dry weight. The NOEC for mortality and for reproduction was determined to be 100 and 44 mg a.s./kg soil dry weight, respectively.

The  $E_{50}^{C}$  value for the reproduction was close to the value of 100 mg a.s./kg soil dry weight as stated in OECD 232 (2009). The EC₅₀ therefore showed that the test system was sensitive.



Table CA 8.4.2.1- 7:	Effects of AE F154851	on mortality and i	reproduction of <i>Folsomia candida</i>
Test item	AE F154851 Folsomia candida Artificial soil		
Exposure	Adult mortality	Reproduction	n A A A
	(mg test item/kg soil d.w.)		
LOEC	> 100	> 100	
NOEC	$\geq$ 100	≥100	
LC50/EC50	> 100	A)> 100	
95 % confidence limit	-		

Table CA 8.4.2.1-8: Effects of AE F154851 on mortality of parental collectibolans and on number of

juvenile collemb	olans A , & , & , , , , , , , , , , , , , , ,
Endpoint	(mg test ite to kg soft/d.w.)
Mortality of parental	
collembolans after 4 weeks (%)	
Mean number of juveniles after	
4 weeks	
CV %	\$\ 1\9.3 \$\frac{1}{3} \00 \$\frac{1}{3.6} \$\frac{1}{3} \$\f
Depreduction (0/ to control)	

Reproduction (% to control)  $\alpha$  100  $\beta$  100  $\beta$  105  $\beta$  105

Calculations were done using unromoded values

Percent reproduction:  $(R_{\odot}, R_c) * 100 \%$ 

 $R_t = mean number of juveniles ObserveOin the treated proups of$ 

 $R_c$  = mean number of juveniles observed in the control group.

The test item caused 5.0 % parental mortality at a concentration of 100 mg test item/kg soil dry weight. 6.3 % parental mortality was observed in the control.

No statistically significant effect (Fisher's Fract Binomial Test,  $\alpha = 0.05$ , one-sided greater) on parental mortality was bund for the concentration fested

No effects on Dehaviour of the collembolans were observed during the test.

The mean number of juvenile springrails, counted four weeks after introduction of the parental collemborans into the test vessels was 1146 in the control and 1205 at 100 mg test item/kg soil dry weight. No statistically significant effects (Student-t-test,  $\alpha = 0.05$ , one-sided smaller) on the number of juveniles compared to the control group were found at 100 mg test item/kg soil dry weight.

The No-Observed-Effect-Concentration (NOEC) was determined to be  $\geq 100$  mg test item/kg dry weight.

### Conclusions:

AE 55485 (BCS AU80405) showed no statistically significantly adverse effects on adult mortality and reproduction of the collembolan *Folsomia candida* in artificial soil at 100 mg test item/kg dry weight



Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be  $\geq 100$  mg test item/kg dry weight, and the Lowest-Observed-Effect-Concentration (LOEC) was determined as be > 100 mg test item/kg dry weight.

#### AE F160459

Report:	;;;;2013;M-462	.786-01	
Title:	Mesosulfuron-methyl-AE F160459 (Bes-AU	J84907): Effects on the re	production of the
	collembolan Folsomia candida 🛛 🚿	Ű.	
Report No:	13 10 48 103 S		
Document No:	M-462786-01-1	Å O	
Guidelines:	OECD 232 (2009), ISO 11267(1999);none		
GLP/GEP:	yes 🖗		
	o ."(		. ~ , ~

#### **Executive Summary:**

The purpose of this study was to determine potential effects of the metabolite AE F166459 (BCS-AU84907; metabolite of mesosulfurger-metayl) on the reproductive output of the collection Folsomia candida as a representative of soil micro-arthropods during a test period of 28 days. 10 juvenile collembolans (9-12 days and per replicate (8 replicates for the control group and 8 replicates for each treatment group) were exposed to untreated control and to 100 mg test item/kg soil dry weight. After 4 weeks the number of juveniles and surviving parental collembolans were counted. The test was performed as a limit test in accordance with the OECD Guideline 232 (2009) and the International Standard ISO 1267 (1999)

The overall No-Observed-Effect Concentration (NQEC) was determined to be 100 mg test item/kg soil dry weight, and the Lovest-Observed Effect Concentration (LOEC) was determined to be > 100 mg test item/kg soil dry weight The validity criteria for the control group of the study were accomplished.

#### Materials and Methods:

AU84907 Batch code AE F160459 00 1B96 0001, Origin Test item AE F16045@ BCS code: BCS 0936149, analysed purity: 95,4 % w/w, Certificate of analysis: AZ Batch No.: 2ER0125 16306.

weight of soil containing 74. and 0.3 % CaCO₃, 18.5 – 20.9 °C and a and were fed weekly with granulated dry yeast. are determined after 28 days. are standard 44 – 67² 100² 150 – 225 mg boric acid/kg soil dry weight; control: quartz sand, solvent control none photoperiod: light : dark =  $10^{\circ}$  h : 8 h (540 lx) and were fed weekly with granulated dry yeast.

solvent controk. non



#### **Dates of experimental work:**

April 11, 2013 - May 09, 2013

#### **Results:**

Table CA 8.4.2.1- 9:   Validity criteria		
Validity criteria (control group)	Recommended	Obtained
Mean adult mortality	ي 20 % ي	0 <u>3</u> 8% (
Mean number of juveniles per replicate (with 10 collembolans introduced)	© ^y ≥100 č	→ ⁹²⁶
Coefficient of variation (mean number of juveniles per replicate)	< 30 % [©]	J 13.9% ()
	. 0	

All validity criteria for the study were met. Therefore this study isoalid. The requirement of the ISO guideline concerning the precision of the counting method (average error <10%) was fulfilled, the determined overall error of counting amounted to 25%.

In the most recent study (BioChem, project No. R.73 10 48 004 S, dated July 16, 201S) the  $FC_{50}$  of the reference item boric acid was determined to be 108 mg as./kg soil do weight. The LC , was determined to be 192 mg a.s./kg soil dry weight. The NOFC for mortality and for reproduction was determined to be 100 and 44 mg a.s./kg soil dry weight, respectively.



#### Table CA 8.4.2.1-11: Effects of AE F160459 on mortality of parental collembolans and on number of iuvenile collembolans

juvenne conclusionalis				
Endpoint	AE F160459 (mg test item/kg soil d.w.)			
	control	100	Q	
Mortality of parental collembolans after 4 weeks (%)	3.8	2.5	4	
Mean number of juveniles after 4 weeks	926	<u>گ</u> 930		
CV %	13.9	9.4	Ŝ	
Reproduction (% to control)	100	100	. (	

No statistically significant differences compared to the control were calculated for mortality (Fisher's Exact Binomial Test,  $\alpha = 0.05$ , one-sided greater) and reproduction (Studen 4-test,  $\alpha = 0.05$ , one-sided smaller) CV: coefficient of variation, d.w.: dry weight (of artificial sojf) Calculations were done using unrounded values  $\bigcirc$ 

Percent reproduction:  $(R_t / R_c) * 100 \%$ 

 $R_t$  = mean number of juveniles observed in the treated groups  $R_t$  = mean number of juveniles observed in the treated groups

 $R_c$  = mean number of juveniles observed in the control group

The test item caused 2.5 % parental mortality at a concentration of 100 mg test item/sg soil .w. 3.8 % parental mortality was observed in the control.  $\alpha$  is the control of  $\alpha = 0.05$ , one-sided greater) on statistically significant effect (Fisher's Exact Dinomial Test,  $\alpha = 0.05$ , one-sided greater) on

Ô

parental mortality was found for the concentration tested

No effects on behaviour of the collembolans were observed during the test

The mean number of juvenile springtails sounted four weeks after introduction of the parental collembolans into the test vessels was 926 in the control and 930 at 100 mg test item/kg soil dry weight. No statistically significant effects (Student-t-test,  $\alpha = 0.05$ , one-sided smaller) on the number of juveniles compared to the control group were found at 100 mg test item kg soil dry weight.

The No-Observed-Effect-Concentration (NOEC), was determined to be  $\geq 100$  mg test item/kg dry weight.

#### Conclusions:

J84907) showed to statisticall@significantly adverse effects on adult mortality AE F160459 (BCS)A and reproduction of the collembolan Dolsomia candida in artificial soil at 100 mg test item/kg soil dry O weight.

Therefore, the overall NoObserved-Effect-Concentration (NOEC) was determined to be  $\geq 100$  mg test item/kg soil dry weight, and the Cowesco bserved-Effect-Concentration (LOEC) was determined to be > 100 mg test item/kg soil dry weight

#### AE F092944

<b>Report:</b>		ó; ;2013;M-454043-01
Title:		AE \$992944 (BCS \$A25052): Effects on the reproduction of the predatory mite
		Hypoaspis aculeifer
Report No		13 10 40044 S
Document	No:	TM-454043-01-1
Guideline	s:~ 0	OECD 226 (2008);none
GLP/GEI	Ç ^a	yes
A	)	

#### **Executive Summary:**

The purpose of this study was to determine potential effects of AE F092944 (metabolite of mesosulfuron-methyl) on the mortality and the reproductive output of the soil mite species Hypoaspis aculeifer (CANESTRINI) as a representative of soil micro-arthropods during a test period of 14 days 10 adult soil mites (females) per replicate (8 replicates for the control group and 8 replicates for each treatment group) were exposed to 100 mg test item/kg soil dry weight. Two weeks after start of exposure, the number of juveniles and surviving parental mites was determined. The lest performed as a limit test in accordance with the OECD Guideline 226 2008). The overall No-Observed-Effect-Concentration (NOFC) was determined to be 2100 mg test (Dem/kg soil dry weight. The Lowest-Observed-Effect-Concentration (LOBC) was determined to be > 100 mg test item/kg soil dry weight. The validity criteria for the control group of the study were accomplished.

#### **Materials and Methods:**

Test item. AE F092944 (BCS-AA25052), Batch code. XE F092944 00 1B99 0002; Origin Batch No.: %w/w; certificate No.: 23503LR; CAS No.: 36315-01-2; LIMS No; 10349 %; analysed, parity 99.8 AZ 17077.

Per test vessel 10 adult soil mites (females) were exposed to untreated control and to 100 mg test item/kg dry weight of soil containing 74.7% quartz sand, 20 % kaoling clay, 5% splagnum peat and 0.3 % CaCO₃, at 19.5 – 21.5 °C and a photoperiod: light : dark = 16 h : 8 h (580 lx) and were fed ... were determined -8,00 - 40.00 reg a.s./kg soil d.w.; control: every 2 days with Tyrophogus putrescentiae (SCHRANK). Mortality and reproduction were determined after 14 days of exposure.

Toxic standard (Dimethoate EC 400): 4,10 quartz sand, solvent control: none.

ry 15, 2013 – February 🖗 Dates of work:

#### Resu

#### Table CA 8.4.2.1- 1.2 Validity priteria

Validity criteria for the control group	Recommended	Obtained
Mean mortality of adapt females	$\leq 20 \%$	7.5 %
Mean number of juveniles per replicate	≥ 50	263.9
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30 %	16.4 %

All validity criteria for the study weremet.

In a separate study (BioCherry project NooR 13 10 48 001 S, dated February 04, 2013), the EC₅₀ (reproduction) of the reference item, Dimethoate EC 400, was calculated to be 6.64 mg a.s./kg soil dry weight. The results of the reference test demonstrate sensitivity of the test system.



Table CA 8.4.2.1-13:	Effects of AE F09294	44 on mortality and	reproduction of <i>Hypoaspis aculeifer</i>
Test item Test object Exposure	AE F0 <i>Hypoaspis</i> Artific	92944 s <i>aculeifer</i> ial soil	
Exposure	Adult mortality	Reproduction	
	(mg test item	/kg soil d.w.)	
NOEC	$\geq 100$	$\geq 100$ rs	
LOEC	> 100	> 100	
$EC_{10}$	-	- "	
$EC_{20}$	-	.Ô	
LC50/EC50	> 100	<b>≥</b> 100	
95 % confidence limit	-		

Table CA 8.4.2.1- 14:	Effects of AE F092944@	n mortality of parent	al collettrobolans and	on number of

juvenile collembolan	s A	(M)	Ø Q	0	$\sim$	0' 2	, V
Endpoint	(mg met	ÅE F929 abolitøks rol	44 g soikd.w.)				OF STOR
Mortality of soil mites after 14 days (%)	®"7.5		∞ 8.8	1 A		Ş Q	
Mean number of juveniles after 14 days	<u>ک</u> 263	9 D	2443		) ₍ )	°~y~	
CV %	₽° 1°0.	4	10.4	Da Qa	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<b>%</b>	
Reproduction (% to control)	~©100	)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Č ()		O`	

No statistically significant differences compared to the control were calculated (Chi²  $3\times 2$  Test for mortality,  $\alpha =$ 0.05; Student t-test for reproduction;  $\alpha = 0.05$ ) 

CV: coefficient of variation, d.w. dry weight (of ortificing Goil)

Calculations were done using non-rounded values

Percent reproduction:  $(\mathbf{R}_t / \mathbf{R}_g) * 100$ 

 $R_t$  = mean number of juvenity mites in the treated group(s)  $R_c$  = mean number of juvenity mites in the treated group(s)

In the control group and in the test item treatment group a parental mortality of 7.5 % and 8.8 %, respectively, could be observed at the end of the 14 day exposure period.

Fourteen days after introduction of the parental mites into the test vessels, the mean number of juveniles was 263. 29n the control and 244.3 in the test item treatment group.

The test item caused no statistically significantly adverse effects on adult mortality (Chi² 2x2 Test,  $\alpha = 0.05$ , one sided greater) and reproduction (Studen t-test,  $\alpha = 0.05$ , one-sided smaller) of the predatory mite Hypoaspis aculeifer in artificial soil at 000 mg test item/kg soil dry weight.

#### Conclusions:

The test item AE F092944 showed no satisfically significantly adverse effects on adult mortality and reproduction of the predatory mite Hypoaspis aculeifer in artificial soil at 100 mg test item/kg soil dry weight. Therefore, the overall No Observed-Effect-Concentration (NOEC) was determined to be  $\geq$  100 mg test item/kg soil dry weight and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be 100 mg test item/kg soil dry weight.

## BAYER Bayer CropScience Document MCA: Section 8 Ecotoxicological studies

Mesosulfuron-methyl	
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Report:	;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;	)1	0
Title:	AE F092944 (BCS-AA25052): Effects on the rep	roduction of the col	lembolanFols@nia 🖔
	candida		, S S
Report No:	13 10 48 045 S	~	
Document No:	M-451142-01-1	Â.	
Guidelines:	OECD 232 (2009), ISO 11267 (1999);none	O,	
GLP/GEP:	yes	4	

#### **Executive Summary:**

The purpose of this study was to determine potential effects of the test item AE 6092942 (metabolite of mesosulfuron-methyl) on the reproductive output of the collembolan *Folsomic candida* as a representative of soil micro-arthropods during a test period of 28 days 10 juvenile collembolans (9-12 days old) per replicate (8 replicates for the control group and 8 replicates for each treatment group) were exposed to untreated control and to 100 mg test item/kg soil dry weight. After 4 weeks the number of offspring (juveniles) and surviving parental contembolans was counted. The test was performed as a limit test in accordance with the QECD Guideline 232

(2009) and the International Standard SO 1/267 (1999). The overall No-Observed-Effect-Concentration (NOEC) was determined to  $be \ge 100$  mg test item/kg soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) was determined to  $be \ge 100$  mg test item/kg soil dry weight. The Validity criteria for the control group of the study were accomplished.

#### Materials and Methods; 🖗

Test item: AE F092944 (BCS AA25052); Sobstance code AE F092944; Batch code: AE F092944 00 1B99 0002; Origin Batch No.: 2350 LR; CAS No.: 36345-01-2, LIMS No.: 4034970; analysed purity: 99.8 % w/w; certificate No.: AZ 90772

10 juvenile coverbotans (9.02 day old) per test vessel were exposed to untreated control and to 100 mg test item/kg dry weight of soil containing 74.7 % quartz sand 20 % kaolin clay, 5 % sphagnum peat and 0.3 % CaCO₃, at 19.1  $\stackrel{<}{\sim}$  20.7  $\stackrel{<}{\sim}$  C and a photoperiod, light, dark = 16 h : 8 h (580 lx) and were fed weekly with granulated de yeast. Mortality and reproduction were determined after 28 days.

Toxic standard:  $44 - 67 + 100^{4} + 150^{4} + 225^{4}$  mg boric aciditg soil d.w.; control: quartz sand, solvent control: none.

Dates of work: February 01, 2013 - March 04, 2013

#### Results:

Table CA 8.4.2.1-15: Validity criteria		
Validity critenia (for the control group)	Recommended	Obtained
Mean adult portalify	≤ 20 %	2.5 %
Mean number of fuveniles per replicate	≥ 100	563
Coefficient of ariation (mean number of juveniles per replicate)	< 30 %	7.6 %

All wondity onteria for the study were met.

In a separate study (BioChem project No. R 12 10 48 003 S, dated May 24, 2012), the  $EC_{50}$  (reproduction) of the reference item boric acid was calculated to be 104 mg/kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system.

Table CA 8.4.2.1-16:	Effects of AE F092944	on mortality and repro	oduction of Folsomia candida 🖉 👌
Test item	AE FO Folsomia Artific	992944 a candida sial soil	
Exposure	Adult mortality	Reproduction	
	(mg test item	/kg soil d.w.)	
LOEC	> 100	> 100	
NOEC	≥ 100	100	
LC ₅₀ /EC ₅₀	> 100		
95 % confidence limit	-		

Table CA 8.4.2.1-17:	Effects of AE F092944	on mortality of	parental colle	mbolans and	n number of
:	wanila aallamhalana 🔌		A.	No. 1	

	juvenne cone	
Enders's 4		AE@092944 (mg test item kg sojQl.w.)
	Endpoint	Souther the second seco
	Mortality of parental	
	collembolans after 4 weeks (%)	
Mean number of juveniles after		
	4 weeks 🛷	
	CV %	14.3 × × ×
	<b>Deproduction</b> (% to control)	

No statistically significant differences compared the control were calculated for mortality (Fisher's Exact Binomial Test,  $\alpha = 0.05$  one-sided greater) and reproduction (Student-t-test, 0 = 0.05 one-sided smaller)

CV: coefficient of variation d.w.: er weight (of artificial soil)

Calculations were done using unrounded values

Percent reproduction: (Rt / Rc) @ 100 @

Rt = mean number of fuveniles observed in the treated groups

Rc = mean number of juveniles observed of the control group

The test item cause 2.5 % parental mortality at a concentration of 100 mg test item/kg soil d.w. 2.5 % parental mortalit was abserved in the control.

No statistically significant effect (Fisher Exact Binomial Test,  $\alpha = 0.05$ , one-sided greater) on parental mortality was found for the concentration tested.

No effects on behaviour of the collembolans were observed during the test.

The mean number of juvenile springtails counted four weeks after introduction of the parental collembolans into the test vessels was of average 563 in the control and 580 at 100 mg test item/kg soil d.w. No statistically significant effects (Sudent-t-test,  $\alpha = 0.05$ , one-sided smaller) on the number of juveniles compared to the control group were found at 100 mg test item/kg soil d.w.

The No-Observed Effect-Concentration (NOEC) was determined to be  $\geq 100$  mg test item/kg dry weight.

#### Conclusions.

The test item AE F092944 (BCS-AA25052) showed no statistically significant adverse effects on adult mortality and reproduction of the collembolan Folsomia candida in artificial soil at 100 mg test item/kg soil d.w. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined

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to be  $\geq$  100 mg test item/kg soil d.w., and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be > 100 mg test item/kg soil d.w.

#### AE F147447

Report:	b; ;2013;M-462782-0	
Title:	Mesosulfuron-methyl-AE F147447 (BCS-AU7362	25): Effects on the reproduction of the co
	collembolan Folsomia candida	
Report No:	13 10 48 105 S	
Document No:	M-462782-01-1	
Guidelines:	OECD 232 (2009), ISO 11267 (1999);none	
GLP/GEP:	yes A	

#### **Executive Summary:**

The purpose of this study was to determine potential effects of the notabolite AE \$1474\$ (BCS-AU73625; metabolite of mesosulfuron methyly on the reproductive output of the collembolan Folsomia candida as a representative of soil micro-arthropods during a test period of 28 days. 10 juvenile collembolans (9-12 days old) per replicate 8 replicates for the control group and 8 replicates for each treatment group/were exposed to untreated controband to 100 mg test item/kg soil dry weight. After 4 weeks the number of juverfles and survioing parental collembolans were counted. The test was performed as a timit test in accordance with the OFCD Guideline 232 (2009) and the International Standard ISO 11267 (1999).

The overall No-Observed-Effect-Concentration (NOEC) was determined to be 200 mg test item/kg soil dry weight, and the Lowest Observed-Effect-Concentration (LOEC) was determined to be > 100 mg test item/kg soik dry weight The validity criteria for the control group of the study were accomplished.

#### Materials and Methods:

Test item; &E F147447, BCS-code: BCS-A& 3625, Batch, code; XE F147447-01-01, Origin Batch Customer order No.: DOX No: 09196-01, analysed purity: No.: SES 10681-2-3 NG: 1310201, 98.9 % W/w. Š

standard: 444, 67 + 100 - 150 - 225 mg boric acid/kg soil d.w.; control: quartz sand, solvent control: none.



**Dates of work:** May 07, 2013 – June 04, 2013

#### **Results:**

Table CA 8.4.2.1- 18:    Validity criteria	Å,	
Validity criteria (control group)	Recommended	Obtained
Mean adult mortality	ي 20 %	
Mean number of juveniles per replicate (with 10 collembolans introduced)		~1146°° (C
Coefficient of variation (mean number of juveniles per replicate)	< 30 %	J 10.2%
	Ô	N AN

All validity criteria for the study were met. Therefore this study is valid.  $2^{\circ}$  and  $2^{\circ}$  and

In the most recent study (BioChem, project No  $\mathcal{R}$  13  $\mathcal{O}$  48  $\mathcal{O}$ 48  $\mathcal{O}$ 4 S, dated July 16 2013 the EC₅₀ (reproduction) of the reference item bonc acid was calculated to be 108 mg a.s./kg soil dry weight. The LC₅₀ was determined to be 192 mg as /kg soil dry weight. The NOEC for mortality and for reproduction was determined to be 100 and 44 mg a.s./kg soil droweight, respectively. The EC₅₀ value for the reproduction was close to the value of 100 mg a.s./kg soil dry weight as stated in OECD 232 (2009). The EC₅₀ therefore showed that the test system was censitive.



### **Bayer CropScience Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

#### Table CA 8.4.2.1-20: Effects of AE F147447 on mortality of parental collembolans and on number of

juvenile			
Fndpoint	AE F (mg test iten	147447 n/kg soil d.w.)	
Endpoint	control	100	
Mortality of parental collembolans after 4 weeks (%)	6.3	5.0	
Mean number of juveniles after 4 weeks	1146	<u>ک</u> 1173	
CV %	10.3	10.2 🔗	
Reproduction (% to control)	100 .0	102	

No statistically significant differences compared to the control were calculated for mortanty (Fisher's Exact Binomial Test,  $\alpha = 0.05$ , one-sided greater) and reproduction (Student 4-test,  $\alpha = 0.05$ , one-sided smaller). CV: coefficient of variation, d.w.: dry weight (of agificial sojf) Calculations were done using unrounded values  $\bigcirc$ 

Percent reproduction:  $(R_t / R_c) * 100 \%$ 

 $R_t = mean number of juveniles observed in the treated groups$ 

 $R_c$  = mean number of juveniles observed in the control group

The test item caused 5.0 % parental moreality at a concentration of 100 mg test item kg soil dry weight. 6.3 % parental mortality was observed in the control. No statistically significant effect (Fisher's Exact Binomial Test  $\mathcal{G}_{\alpha} = 0.05$ , one side  $\mathcal{G}_{\beta}$  greate  $\mathcal{G}_{\beta}$  on parental mortanty was found for the concentration tested.

No effects on behaviour of the collembolans were observed during the test

The mean number of juvenile springtails sounted four weeks after introduction of the parental collembolans into the test vessels was 1146 in the control and 173 by 100 mg test item/kg soil dry weight. No statistically significant effects (Student-t-test,  $\alpha = 0.05$ , one-sided smaller) on the number of juveniles compared to the control group were found at 100 mg test item kg soil dry weight.

Therefore the Oldo-Observed-Effect Concentration (NOEC) was determined to be  $\geq 100$  mg test item/kg soil dry weight.

#### Conclusions:

R

AE F147447 (BCSAU73625) showed no statisticall significantly adverse effects on adult mortality and reproduction of the collembolan Bolsomia candida in artificial soil at 100 mg test item/kg soil dry  $\odot$ weight.

Therefore, the overall NooDsecoed-Effect-Concentration (NOEC) was determined to be  $\geq 100 \text{ mg}$ test item/kg soil dry weight, and the Cowescobserved-Effect-Concentration (LOEC) was determined to be > 100 mg test item/kg soil dr

#### Effects on set nitrogen transformation CA 8.5

For mesosulfuron methy Dand its metabolites AE F154851, AE F160459, AE F099095, AE F092944, and AE 174744, studies on the effect on soil nitrogen transformation were performed. In none of the studies unacceptable effects were found at the highest tested dose level which ranged from 0.057 mg/kg dws/to 0.13 mg/kg dws. Details of all studies are provided in the following table.

Based In the consistent absence of toxicity observed in all studies covering the parent active substance, its initial and terminal metabolites, it was deemed justified to conclude absence of relevant

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effect on soil nitrogen transformation as well for the transient intermediate components in the soil and a metabolic pathway of mesosulfuron-methyl. No further testing was therefore considered necessary

P	esenteu in tins enupte		2	
Test item	Test design	Ecotoxicological endpoint	L'Y V	Reference?
N-transformation		Å.	,0 ⁹ ×	
Mesosulfuron- methyl (tech.)	28 d	no unacceptable ≥0.1 mg as effects	s./kg@ws	(1983) M 143358-01-1 RCA & 701
AE F154851	28 d	no vinacceptable vinacceptable	dwô ^r ^A	(2 <u>0</u> 02) <b>10-2140@0-01-1</b> KCA 85/02
AE F160459	42 d	no y unacceptable 3.1 mg/kg effects		(2002) AT-2140%6-01-1 KCA&55/03
AE F099095		no unwcceptable ≥0.1 me/kg stfects	y 67 69 ; dw9 69 57 67 4	(2002) M-214088-01-1 KCA 8.5/04
AE F092944	2850 L	no variable 20.137mg/ unacceptable 20.137mg/	kg dws	(2013) M-453511-01-1 KCA 8.5/09
AE F147447		no unavceptable ≥0.057 mg/ effects	kg days	(2013) M-460668-01-1 KCA 8.5/10
dws = dry weight soi	10 0		, V	
Bold letters: Values	considered relevant fai	wisk assessment in the MCP de	w weiment	
Studies on mesosul	féron-methyl		y <b>-                                   </b>	

Table CA 8.5- 1:	Toxicity data of mesosulfuron-methyl and metabolite	es to soil non-target	micro-organisms
	presented in this chapter	<i>n</i>	

ME F139060; Wostang, techoral Title: 1C96 0002 - Effects on soil AE F 130060 00 Øðé mial activity (nivogen, turn-over) Report No: QK96 Document MD-143358 -01-1 Guidelines: ADeviation not Decified GLP/SEP: Ľ

14335

0 Endpoint according to the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final): Deviation of less than 25% for application rate up to 75 g a.s./ha

(equivalent to  $\geq 0.10 \text{ mg a.s./kg dws}$ ).

aluation copied from the original Monograph: Studysymm

98b, 8.5.1/1.

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- **Fewguideline**: BBA guideline VI, 1-1 (1990).
- **GLP compliance**: Yes.

**Report:** 

Bayer CropScience B/ **Document MCA: Section 8 Ecotoxicological studies** Mesosulfuron-methyl

<b>Methods</b> : The influence of AE F130060 (technical substance, purity = 96.0%) on	soil microflora nitr@en
turn was assessed in a laboratory test. The test was conducted in 2 L stainless	steel containers 💭 cm 🖓
diameter $\times$ 10 cm height). The effects were measured at day 0, 14 and 28 after test	initiation in a by sand
and a loamy silt mixed with the test substance at the rate of 0 (control), 15 and	5 g a.s./ha (preparedOn
water, nominal). Three replicates were made for each dose and control. (Ora	imeters measured vere
ammonium and nitrate soil concentrations on 40 g soil aliquots.	
<b>Results:</b> Mesosulfuron-methyl applied at 1 (15 g/ha) an (2 (75 g/ha)) whe field	rate d no ause av
statistically significant effects greater than + 25% with respect to control y	alue on Sil niteren
transformations.	
$\Box$ Comments (RMS): the study is acceptable.	
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	Š. A.
Further study information supplementing the original Gonograph Sommar	
A A F	
Analytical findings:	
The study was conducted in a control of engineering room at $20 \times 2 \pm 200$.	
The water content of the soil subtrate fors manytained throughout the tex of	v receipting the test
containers weekly and replenishing lost mater in adding deighted were.	
The pH values on day 28 were @ and 9.9 for the controls. @specto elv.	
Biological findings:	Ô
AF F1 30060 00 1 C96 0002 when applied at field rate (1560 ha) and at the 5 tic	(3) field rate (75 g/ha)
had a negligible effect in nit onen ton-ove $9(< \pm 05\%)$ deviation of the control	treatment) on day 28
after treatment in the cilty and Wil 1) and 12 my (2) (coil 2). HObest Wil	ation of total minoral
after treatment in boosticy said son 1 said formy set (son 2). Therese devices	
ninogen compared to the contrar was + 9.3%. I sha difference ta the sinto	i was statistically not
significant.	
Table CA 8 62. Effects of AE F150 67 00 1290 000 211 fill/02eff transformer 900	
Soit Treatment Devision of total meral ptrogo (N-min) from	the control at different
times (Says) as er application of AE F130060 0	0 1C96 0002 to soil
a A S aday of day of day 14	day 28
Soil 1 . P 1529na C . So C 1.4	+ 0.8
silty sand 75 g/ha 258 g -38	- 2.1
	_ 1.5
	- 1.5
	<mark>+ 9.1</mark>
Conclusions:	
Application & AE # 300 00 996 0002 when applied at a rate equiva	lent to the maximum
recommended $(15\%/ha)$ at a grate Quivalent to 5 times the maximum recom	mended (75 g/ha) had
a negligible effection the nitro en turn-over in a silty sand and a loamy silt soil.	
\bigcirc	







Studies on the metabolites of mesosulfuron-methyl

AE F154851

Report:	3;	;2002;M-214090,0M	
Title:	Soil microorganisms: Nitrogen transformati	on test Code: AE F154851	00 1B96 0001
Report No:	C027822	-	
Document No:	M-214090-01-1		
Guidelines:	OECD: 216; Deviation not specified	Ŭ <u>Ŭ</u>	
GLP/GEP:	yes		N Q O

The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final). The study is filed in this document on the "List of studies, which were submitted during the evaluation process and were not cited in the draft assessment report"

Study summary and RMS evaluation content from the Griginal Monography

None available; Study is filed in "List of studies when were subported during be evaluation focess and were not cited in the draft excession report "S Approvidix of to SU reference to report for mesosulfuron-methyl (SANCO/1028/2009-Final).

Further study information & pplementics the original Monograph ammary

Executive Summary:

The purpose of this study way to determine the exects of AE O 548 & (metabolite of mesosulfuronmethyl) on the activity of soil may offlow with regard to nitrogen transformation in a laboratory test. The test was performed On accordance with SECD, suidely a 215 (2000 by measuring the nitrogen turnover.

A sandy loan Coil was explained for 28 days to concern thiom of 15 and 75 g test item/ha dry weight which refers to the one-fold and five-fold recommended use rate of parent active substance mesosulficon-methyl. A suming a upform soil incorporation depyh of 5 cm and a soil bulk density of 1.5 g/cm, the 15 as 75 s of st item/ha coplication rates were equivalent to 0.02 and 0.10 mg test item/kg soil dry weight, respectively.

The reference so was closed with soubstance (Nutrification Inhibitor Formula 2533TM) known to inhibit nitrification at Q once ratio Q 00 mg/kg dQ weigQ.

Powdered altona (*Monicage sativa*) was suded to sieved soil and this mixture was then be divided into appropriate batches for the corool, reprener and to atment groups. After 0, 5, 14 and 28 days of incubation samples obtreated and antrol soils of re extracted and the quantities of nitrate in the extracts were determined. The ansunt of thirate obrmed in the treated soil samples was compared to that the control soil samples and the presence of deviation from the control was calculated.

No long-term [4] luence of 5° F15,551 ∞ nitrogen transformation in soil (difference to control < 25%, OECD 5(6) with the observed in both test concentrations (0.02 mg/kg dry soil and 0.10 mg/kg dry soil) after 28 ways. Fiftereares from the control of +13.3% (test concentration 0.02 mg/kg dry soil) and 6.7% test concentration 0.10 mg /kg dry soil) were measured at the end of the 28-day incubation percent (day 28) 5°

Meerial Ad methods:

Test iter AE F154851 (AE F154851 00 1B96 0001, metabolite of mesosulfuron-methyl); Batch No: LOR 21029; Analysed purity: 96.1% w/w.

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A sandy loam soil was exposed for 28 days to 0.02 and 0.10 mg test item/kg soil dry weight. Application rates were equivalent to 15 and 75 g test item/ha which refers to the one-fold and five Cold recommended use rate of the parent active substance mesosulfuron-methyl. In addition, an unscated control and a reference toxicant group was tested. Each group contained three rolicates. Determination of the nitrogen transformation (nitrate formation, expressed in signitrate/kg signitrate/kg soil/day) in soil enriched with alfalfa powder (concentration in soil 5 g/kg soil dry signitized) conducted at different sampling intervals (0, 5, 14 and 28 days after treatment). In addition, sare each soil were removed at each sampling interval for percent moisture determinations The samples of the test soils were extracted, centrifuged and the liquid phase was a hyse for night The samples of the test soils were extracted, centrifuged and the inquippinase was approved on the inquippinase. The inquippinase wa

Validity Criteria:

Validity Criteria:Criterion: Coefficients of variation in One coefficients should be device most than 5%. The coefficients of variation in the control (nitrate formation) raised from 4.25% 5.3%. (5) day 5%, the maximum CV of the three control replicables was 17.6% which slightly occeeds the Grandon range (≤ 15%). However, on day 28 the deviation was only 56%, one represence oxice occured an effect on nitrogen transformation of approx. +26.7% of 100 mg reference of the soil dry oveight, 28 days after applicationNitrogen transformation:Nitrogen transformation:No long-term influence of AE For 1851 cm nitrogen transformation in soil could be observed in both test concentrations (0.020 mg/kg dry soil and 0.10 mg/kg dry soil) and 5.7% (test concentration 0.10 mg/kg dry soil) and 5.7% (test concentration 0.10 mg/kg dry soil) were cheasted at the end of the 2-day includence of device of the 2-day includence of device of the 2-day includence of device of the 2-day includence of the 2-day in

	~9 ″	A d	Q~~~		×							
Table CA 8.5- 4: J	Fiects g	<u>nitro</u>	n træsf	ormation i	n soil a	I	r treati	nent with A	E F15	<mark>485</mark>	1	
Sample date		0.0 mg t	est Hem//	kiQoil dw Va dw	0.10 f	g te lent	<mark>st item/</mark> t to 75 g	<mark>kg soil dw,</mark> /ha dw	<mark>100 m</mark> soil dv	<mark>g re</mark> v	<mark>ference</mark>	item/kg
(Day) Kitrate ¹		Nitra ¹⁾	Ő.	Control	Nitrat	e ¹⁾		<mark>%</mark> deviation to control	<mark>Nitrat</mark>	<mark>e ¹⁾</mark>		<mark>%</mark> deviation to control
5 1.68	0.05		0.22 ⁰		<mark>1.30</mark>		<mark>0.15</mark>	<mark>+22.6</mark>	<mark>0.95</mark>	+	<mark>0.04</mark>	<mark>+43.5</mark>
14 0.73	0.25%	0.80 ±		Q <mark>-9.6</mark>	<mark>0.68</mark>		<mark>0.14</mark>	<mark>+6.8</mark>	<mark>0.68</mark>	±	<mark>0.54</mark>	<mark>+6.8</mark>
28 0 4	<mark>.05</mark>	8 ³⁹ 2	, <mark>0.05</mark> Ç	¹ +13.3 ^{ns}	<mark>0.48</mark>	±	<mark>0.05</mark>	-6.7 ^{ns}	0.33	±	0.08	+26.7 ^{ns}

nitzee forration rate, in rackg soil dry weight/day, mean of 3 replicates and standard deviation ns = stauficall of significant different from control (rate differences judged at the 0.05 significance level)

AE F150351 had no long-term influence (difference in the rates of nitrate formation between the treatment and the control <25%, OECD 216) on nitrogen transformation in soils (measured as nitrate production) at the end of the 28-day incubation period. The study was performed in a field soil at a

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concentration of up to 0.10 mg test item/kg soil dry weight, which is equivalent to an application rate of up to 75 g test item/ha.

Table CA 8.	5-5: Summary	table		ð	
Reference	Followed	Guidance	Differences	Critical assessments of the study	/ Deviations
	guidance	currently in force		/ conclusion about its Reliabilit	
M- 214090- 01-1 KCA 8.5	OECD Guideline No. 216 (2000)	OECD Guideline No. 216 (2000)	none	The study rectives are in line Or guideline.	h theorem of the second s

AE F160459

		. 1			
Report:	Ö;	- *	;2002; M -1	2140\$6-01	
Title:	Soil microorganisms	Nitrogen traps	formation test 2 od	e: 🗛 E F160459 00	1B97 (2001
Report No:	C027820				0
Document No:	M-214086-01				Ŵ.
Guidelines:	OECD: 216@eviati	on not specifie			
GLP/GEP:	yes a si				V
		<i>w</i>		O Y	

Study endpoint: Deviation of less than 25 % for application rate up to 75 g p.m./ha

The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final). The study is fried in this doctment on the List of studies which were submitted during the evaluation process and were not cited in the graft assessment report".

Study sumpary and RMS evaluation copied from the original Manograph:

None a flable; Studyors file on "List of studies onich were submitted during the evaluation process and were not cited in the drag associment report - Appendix III to EU review report for mesosulfuron-metall (SANCO 298, 303-F Gal).

Further study information supplementing the original Monograph summary :

Execution Summary of

The on prose of this study was to determine the effects of AE F160459 (metabolite of mesosulfuronmethyl) on the activity of soil oncroflora with regard to nitrogen transformation in a laboratory test. The test was reformed in a cordence with OECD guideline 216 (2000) by measuring the nitrogen turnover.

turnover. A sandy loom sof was possed or 42 hays to concentrations of 15 and 75 g test item/ha dry weight which refers 10 the one-form and five-fold recommended use rate. Assuming a uniform soil incorporation septh of 5 confined a soil bulk density of 1.5 g/cm³, the 15 and 75 g a.s./ha application rates and 0.10 mg a.s./kg soil dry weight, respectively.

The reference soil was dosed with a substance (Nitrification Inhibitor Formula 2533^{TM}) known to inhibit $\alpha_{\text{Prification}}$ at a concentration 100 mg/kg dry weight.

Powdered alfalfa (*Medicago sativa*) was added to sieved soil and this mixture was then be divided into appropriate batches for the control, reference and treatment groups. After 0, 5, 14, 28 and 42 days of incubation, samples of treated and control soils were extracted and the quantities of nitrate in the

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extracts were determined. The amount of nitrate formed in the treated soil samples was compared to that of the control soil samples and the percentage of deviation from the control was calculated.

No long-term influence of AE F160459 on nitrogen transformation in soil (Afference to Antropy Strol 25%, OECD 216) could be observed in both test concentrations (0.02 mg/kg Sy soil and 450 mg dry soil) after 42 days. Differences from the control of -9.5% (test concentration 0.02 mg/kg dry soil and -9.5% (test concentration 0.10 mg /kg dry soil) were measured at the the the 42-Qy inco period (day 42).

metabolite.

sosulfur

Material and methods:

Test item. AE F160459 (AE F160459 00 1B97 000 25117/2; Analysed purity: 96.8% w/w.

A sandy loam soil was exposed for 42 daw to 0 dry weight and 0 10 Application rates were equivalent to 15 and 75 g to the vite of 2 and 0.10 or 12 and 0.10 or 10 or 12 and 0.10 Ad an twe-fold onereference to Greant group was to Ged. in menitras kg dry weight g/s soil ry w@ght) was conducted at different sampling Qitervals (0, 5, 14, 28 and 42 dors aff treashent) in addition, samples of each soil were removed at each sarepling Stervar or povent roustus Aeterninations. The samples of the test soils were extracted centrifuged and the oquid chase was ano sed for nitrates using High Performance Liquid Geroma graphy (HPIC). The data was statistically analysed using SAS institute, Inc. (SAS), NC ANOVO programe (An F-test way used to determine if there were significant differences, between the untreated control and deference toxicant group were statistically onalysed using a t-test to determine if there were significant differences between the untreated control and deferences between the untreated control and the reference toxicant replicates.

Dates of experimenta

Results: Validity Ateria:

Validity Enteria: Criterion Coefficient of variation in the control hould not twiate more than 15%. The CV in this study slightly exc os 15%. However, to adverse effects for the test item were proven within this study indicating to contern or the Miranatormation. Due reference toxicant caused an effect on nitrogen transformation of approx. (P - +7 7% approx 100 mp reference item per kg soil dry weight, 5 -42 days after application Nitrogen transformation. No king-term influence of the F 90455 on nigr/gen transformation in soil could be observed in both test concentrations (0.02 mg/kg/dry soil) and 910 mg/kg dry soil) after 42 days. Differences from the control of -9.5% (test concentration 0.10 mg/kg dry soil) wero mea ared at the end of the 42-day incubation period (on day 42). AE F160459 had no

dry soil) wer measured a she end of the 42-day incubation period (on day 42). AE F160459 had no long-term (filuenty (difference to corrol <25%, OECD 216) on the soil nitrogen transformation (measure@as ni@ite productio) at the end of the 42-day incubation period. ົ

Table	A 8, @ 6: Effects	or ritrogen transf	ormation	in soil after trea	tment with	n AE F160459 00 11	<mark>397 0001</mark>
Sample date	Øontrol	0.02 mg test item/l dry weight equival 15 g test item/ha	cg soil lent to	0.10 mg test item/ dry weight equiva 75 g test item/ha	لال soil alent to	100 mg reference ite dry weight	<mark>m/kg soil</mark>
<mark>(Day)</mark>	Nitrate ¹⁾	Nitrate ¹⁾	% deviat. to control	Nitrate ¹⁾	% deviat. to control	Nitrate ¹⁾	<mark>% deviat.</mark> to control

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

5 0.61* ± 0.01 0.44 ± 0.23 +27.9 0.68 ± 0.37 -11.5 0.13 ± 0.07 +78.3
14 0.37* ± 0.01 0.24 ± 0.12 +35.1 0.26 ± 0.14 +29.7 0.15 ± 0.15
28 0.17* ± 0.00 0.14 ± 0.15 ±17.6 0.23 ± 0.00 ±35.3 0.27 ± 0.06 € ±110
42 0.21 ± 0.02 0.11 ± 0.05 -9.5 ¹⁵ 0.23 ± 0.03 -9.5 ¹⁶ 0.21 ± 0.00
¹⁾ Soil nitrate formation rate, in mg/kg soil dry weight/day, mean of 3 reglicates and standard deviation
* One of the control replicates (no.3) was excluded of the mean / stars d deviation capitation. Exclude rates
$ns = statistically not significantly different from control (rate differences judged at the 0.05 significable level \delta$
AE E160459 had no long-term influence (difference to contro@25% DEC@216 son the will nit Seen
transformation (measured as nitrate production) at the end of the 4Q-day probably period. The study
was performed in a field soil at a concentration of up to 0.10 fig a sokg soil dry deight whick is
equivalent to an application rate of up to 25 g a. At a 34 and 35 g a. At a 34 and
Table CA 8.5-7: Summary table
Reference Followed Guidage & Afterents Cal Sessmed of the Study Deviations
guidance currQily in force Conclosion about its Chiability
$\frac{M}{214086} = N_0.216 (2000) \qquad (Solution) \qquad M = M_0 + M_0$
KCARS NO A A A A A A A
AE F099095 0 2 4 4 7 4 2 5 4 2 5
Report: (2002/M-214088-01
Report No. 2027820 A A A A A A A A A A A A A A A A A A A
Document No: 44988-01-1 0 0 0
Guidelines: OECD: 21 DeviatOn not specifica
GLP/GEP: yes of the second sec
Study endpoint: Deviation of less than 25% for application rate up to 75 g p.m./ha
gquivagent to 0.10 pg p.m./kg dws).
The sudpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl
(SANCO/10298/2003-Final). The study is filed in this document on the "List of studies which were
submitted during the evaluation process and were not cited in the draft assessment report".
Study sum ary and RMS evaluation Oppied from the original Monograph:
None available Study is files in "List of studies which were submitted during the evaluation process
and were 100° cluby in the drait assessment report - Appendix III to EU review report for methyl (SeNCO/10298/2003-Final)
South and the second by the se
Cĩ.

Further study information supplementing the original Monograph summary :



Executive Summary:

The purpose of this study was to determine the effects of AE F099095 (metabolite of mesosultion) methyl) on the activity of soil microflora with regard to nitrogen transformation in a laborated test. The test was performed in accordance with OECD guideline 216 (2000) by Reasuring the artrophysical turnover. A sandy loam soil was exposed for 28 days to concentrations of 15 and 🔏 g test item 🖓 dry which refers to the one-fold and five-fold recommended use rate. Assuming a unit on so incorporation depth of 5 cm and a soil bulk density a 1.5 g/cm³ one 15 and 6 g to iter application rates were equivalent to 0.02 and 0.10 mg test item/kg so ary weight a spect bely. The reference soil was dosed with a substance (Norffication Infoitor Formuo 2533 w) keOwn inhibit nitrification at a concentration 100 mg/kg daweight. inhibit nitrification at a concentration 100 flig/kg or weight. Powdered alfalfa (*Medicago sativa*) was added to sieved soil and this fixture was then be svided into appropriate batches for the control, reference and traitment groups. After 0, 5,14 and 28 days of incubation, samples of treated and control Sils whe expacted and be quarteries of nitrate in the extracts were determined. The amount of Aitrate Ormed on the Seated soil comples was compare to that of the control soil samples and the procent of diviation of the control soil samples and the procent of diviation of the control soil samples and the procent of diviation of the control soil samples and the procent of diviation of the control soil samples and the procent of the control soil samples and the procent of the control soil samples are the control soil samples and the procent of the control soil samples and the procent of the control soil samples are the control soil samples and the procent of the control soil samples are the control soil samples are the control soil samples and the procent of the control soil samples are the control son soil samples No long-term influence of AE F09905 00 4999 001 of Sitrog transformation in sell (difference to control < 25%, OECD 216) could be observed in both test concentrations 0.02 52/kg 4y soil and 0.10 mg/kg dry soil) after 28 days. Difference 3 from the control 4 +17 % (to concentration 0.02 mg/kg dry soil) and -5.9% (to concentration 0.10 mg /kc dry sol) were measured at the end of the 28-day incubation period (day 28) to the control of the end of the end of the control o Test item: AE F0990 (AE \$99905 00 1899 of mesosulfer n-methyl); Batch No: sabol16 KR363/364; Analys purity: 99.53 w/w@ O Ś A sandy loam foil way exposed for 28 days to 0.02 and 0.19 mg ost item/kg soil dry weight. Application roots were equivalent for 15 and 75 2 a.s. for which refers to the one-fold and five-fold recommended use file. In addition, an untreased control and a reference toxicant group was tested. Each group contained there replicates for Ô Each group contained there replicates a subscript of the concentration of the progenor ansformation (nitroe for writion expressed in mg nitrate/kg dry weight soil/day) in soil enclosed with a subscript and a weight was soil/day) in soil encoded with a hilfs of wder, concentration in soil 5 g/kg soil dry weight) was conducted at diffeont sampling nervel (0, 564 an 028 days after treatment). In addition, samples of each soil were remove on each sampling interval to peroon moisture determinations. The samples of the test soils were encoded control used and the liquid phase was analysed for nitrates using High Performance Liquid Chronatogramy (IOLC) one door was statistically analysed using SAS institute, Inc. (SAS) NC ANOVA projecture An E test was used to determine if there were significant differences between the untrated control and the treatment replicates. In addition, the untreated differences between we units and control and be treatment replicates. In addition, the unit cated control and reference toxical group was datisically analysed using a t-test to determine if there were significant differences between be untracted ontrol and the reference toxicant replicates. Dates of experimental work. August 26, 2002 – October 01, 2002 Results:

Validit Striters Control should not deviate more than 15%. The CV in this stuce slightly exceeds 15%. However, no adverse effects for the test item were proven within this study indeating no concern on the N-Transformation.

The reference toxicant caused an effect on nitrogen transformation of approx. +11.8% at 100 mg reference item per kg soil dry weight, 28 days after application



Nitrogen transformation:

No long-term influence of AE F099095 on nitrogen transformation in soil could be observed in oth test concentrations (0.02 mg/kg dry soil and 0.10 mg/kg dry soil) after 28 days. Differences from the control of +17.6% (test concentration 0.02 mg/kg dry soil) and -5.9% (test concentration 0.10 mg/kg dry soil) were measured at the end of the 28-day incubation period (on day 28). AE F099005 had to long-term influence (difference to control <25%, OECD 216) on the soil nitrogen transformation (measured as nitrate production) at the end of the 28-day incubation period.

Tabla C /	Q 5 Q. Effor	ts on nitrogon transformation	n in soil Witon trop	tmoo	AF FOOD 05		¢
Sample date	Control	0.02 mg test item/kg soil dry weight equivalent to 15 g test item/ha	0.14 mg test item/ weight equiv	tree of the second seco	100 ny refered	e iten og soik	Ĵ¥
<mark>(Day)</mark>	Nitrate ¹⁾	Nitrate ¹⁾ v diff. co @rol	Nito te 1 5	<mark>% diff.</mark> ↓ to ↓ ↓ contr@	Nitrat ^O	Control	
<mark>5</mark>	0.61* ± 0.	$01 0.75 \pm 0.28$	0.10	4.9		20 ⁰ + 201	
14	0.36* ± 0.	01 0.10 ± 0.02 +73	0, @ +, <mark>%.03</mark>	0 ^{481.1}	0.15	⁷⁵ 4 ⁵ 59.5	
28	0.17* ± 0.	00 0.07 ± 0.07	9.18 0.070	/ <mark></mark>	S 20.0	6	
¹⁾ Soil nitra * Mean of and was ns = statist Conclus	te formation ra two replicates, omitted from th ically not signif	te, in mg/kg sorQry weight/day a Control replicate 3 weight/day a te calculate for the yean and stan icantly difference from control (rate	nean (2) (2) for the c y de Anined (2) be si da Odevia (2) ho (differences judge) a	t the 105 sig	fles and Handa's ffer Offongrep cyficance level)	Sdeviation licates 1 & 2	
AE F099 treatmen productio concentr	9095 had no t and the co on) at the ations who	Ang-tech influence Riffe frol <2%, CD @6) or nd of the 29 day optibation 0 N mg that item/kg soil dry	roce is the ray the solution introgen people. The stury y wight, which	s of nitrat traQ form dy was oc ye equival	Prmation from (measur formed in a ent to applica	between the ed as nitrate field soil at tion rates up	
to 75 g to Table CA Referen	est it ha. 859: Su Followed		Torento Co	Cal assessme	ent of the study	y / Deviations	
M- 214088- 01-1 KCA 8.5 /04	OECD No. 29 (2 ~ V	ideline 00 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	none 5 5 5 5 5 5 5 5 5 5 5 5 5	results are in eline.	1 line with the	current	
AE F092	َ 2944 گ						
Report:		gi ;201	3;M-453511-01	41-14	1 mi ana (1 (2	Titus and	
Title:		ALAS 92944 (BCS 4A25052 transformation test)	2): Effects on the ac	ctivity of soi	i microflora (N	Nitrogen	
Report N		4 13 10 4©018 N					
Documen	t No:	M-453311-01-1					
Guidelin	es: J	OECD 216 adopted Januar Chemicals, Soil Microorgan	y 21, 200 <mark>0, OECD</mark> usms: Nitrogen Tr	Guideline	for the Testin	g of able	
GLP/GE	P:	yes		ansiormati	on,not applic		



Executive Summary:

The purpose of this study was to determine the effects of AE F092944 (metabolite of mesosultarion methyl) on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

A loamy sand soil (DIN 4220) was exposed for 28 d to concentrations of 0.028 and 0.137 mg test item/kg soil dry weight. Application rates were equivalent to 0.021 and 0.103 kg test item/ma, Lucerne meal was added to the soil (concentration in soil 0.5%) to stimulate nitrogen transformation. No adverse effects of AE F092944 (BCS-AA25052) on putrogen transformation in soil could be observed in both test concentrations (0.028 mg/kg dry soil and 0.137 mg/kg dry soil) after 28 days. Differences from the control of +7.9% (test concentration 0.028 mg/kg dry soil) and +9.2% (test concentration 0.137 mg /kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28). AE F092944 (BCS-AA25052) caused no adverse effects (difference to control <25% OECP 216) on the soil nitrogen transformation (measured as NO₃-N production) at the end of the 28-day incubation period.

Material and methods:

Test item. AE F092944 (BCS-AA25052); BES-code: BCS-AA25052; Batch code: AE F092944 00 1B99 0002; Origin batch No. 23503LR; CAS No.: 36315-06-2; LIMS No.: 1034970; Analysed purity: 99.8 % w/w; certificate of analysis No.: 62 17077.

A loamy sand soil (DIN 4220) was expose of a 28 days 0.028 and 0.137 mg test item/kg soil dry weight. Application rates were equivalent to 0.021 and 0.103 kg teo item/ba. Determination of the nitrogen transformation (SO_3 -nitrogen production) in soil enriched with facerne meal (concentration in soil 0.5 %) OH_4 -nitrogen NO₃- and NO_2 -nitrogen were determined using the Autoanalyser (BRAN+LUEBBE) ard different sampling mervals (0, 7, 04 and 28 days after treatment).

Dates of work: January 17, 2013 – February 14, 2013

Results:

Validity Criteria:

The coefficients of variation in the control (NQ₃-N), were, maximum, 5.1 % and thus fulfilled the demanded range (≤ 15 %)

In a separate study the reference item Dinoterb BioChem study code: R 13 10 48 001 N) caused a stimulation of nitrogen transformation of +33% and +42.6% at 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, 28 days after application and thus demonstrates the sensitivity of the test system $\sqrt{2}$

Nitrogen transformation

No adverse effects of AE 092944 (BCS-AA25052) on nitrogen transformation in soil could be observed at both test concentrations (0.028 mg/kg dry soil and 0.137 mg /kg dry soil) after 28 days. Differences from the control of +7.9 % (test concentration 0.028 mg/kg dry soil) and +9.2 % (test concentration 0.137 mg /kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28).


Table CA o.	3-10. E	ui AL	FU72744	â								
Time				0.02	8 mg t	est item/	'kg soil dry	0.137 mg test item/kg soil dr				ð
Interval	Control				weight				weight 🔬			
(days)				equivalent to 0.021 kg test item/ha			equiva	lent to	<u>0.103 kg</u>	test item/ha	0	
							%		Q		2%	
	Nitrate-N ¹⁾			Ni	trate-l	N ¹⁾	difference to	Nitrate-N ¹⁾			difference	
							control		1	Č	to control	Ô
0-7	3.16	±	0.29	3.23	±	0.05	+2,3 n.s.	3.35) [*] ±	0.09	+ 3 .9 n.s.	, Ø
7-14	1.30	±	0.15	1.26	±	0.24	-3.3 ^{n.s.}	526	±	Ø.33	3 -3.3 ^{ky}	0
14-28	0.93	±	0.04	1.00	±	0.14	+ 7.9 ^{n.s.} 《	1.02	, ± 4	0.15	+9.2 n.s.	,¥

Table CA 8.5- 10: Effects on nitrogen transformation in soil after treatment with AE F092944

The calculations were performed with unrounded values

¹⁾ Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation $\sqrt{2}$ n.s. = No statistically significant difference to the control (Students) test for homogeneous variances, 2-sided, p \leq 0.05)

Conclusions:

AE F092944 caused no adverse effects (difference to control < 25%, OFCD 216) on the soil hitrogen transformation (measured as NO₃-N production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 6137 mg test icm/kg foil dry weight, which are equivalent to application rates up to 0.103 kg test item/ha.

AE F147447

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Report:		§ ;	2013;M-46	0668901		•
Title:	Mesosul	uron-methyl-	AE F142447 (B&S-AU7362:	5) Effects on t	he activity of soil
	microflor	a (ntrogen &	ansformation	est)	O' 4	
Report No:	13 19 48	0782N 25	~ <u>~</u>			
Document No:	M-46066	§-01-1		N Q	Å.	
Guidelines: 🔊	ØECD 2	16; adopted .	lánuary 21, 2	990, OECĎ G	uideline for th	e Testing of
Ů	Chemica	ls, Soil Micro	organisms: 4	vitrogen Tran	Formation;no	one
GLP/GEP; 🖗	yes		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Q . T	<i>"</i>	
	Č Å		Â,	No N		

Executive Summary,

The purpose of this study was \mathcal{O} determine the effects of $\mathcal{O} \to F147447$ (metabolite of mesosulfuronmethyl) on the activity of soft microffora with regard to introgen transformation in a laboratory test. The test was performed in accordance with $\mathcal{O}F\mathcal{O}D$ guideline 216 (2000) by measuring the nitrogen turnover.

A loamy sand soil (DIV 4220) was exposed for 28 days to 0.012 and 0.057 mg test item/kg soil dry weight. Application rates were equivalent to 0.009 and 0.043 kg test item/ha. Lucerne meal was added to the soil (concentration in soil 0.8%) to stimulate nitrogen transformation. The test item AE F147447 caused a temporary inhibition of the daily nitrate rate at the tested concentration of 0.057 mg/kg at time interval 7-14 days after application. However, no adverse effects of AE F147447 on nitrogen transformation is soil could be observed at both test concentrations (0.012 mg/kg dry soil) at the end of the 28-day experiment. Differences from the control of -7.7% (test concentration 0.057 mg/kg dry soil) and +7.0% (test concentration 0.057 mg/kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28).



Materials and Methods:

Test item. AE F147447; BCS-code: BCS- AU73625; Batch code: AE F147447-01-01; Origin Patch No.: SES 10681-2-3; Customer order No.: TOX-No.: 09196-01; LIMS No.: 1310201; Certificate AZ 18638, analysed purity: 98.9 % w/w.

A loamy sand soil (DIN 4220) was exposed for 28 days to 0.012 and 0.057 mg test item/kg fil dry weight. Application rates were equivalent to 0.009 and 0.043 kg/test item/ha/ The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 05%). WH nitrogen, NO3- and NO2-nitrogen were determined by an Autoanalyzer at different sampling joervals (0, 7, 14 and 28 days after treatment). A Charles and Char

Dates of work:

May 31, 2013 – June 2

Results:

Validity Criteria:

wore maximum 7.0 % and wus fulfill The coefficients of variation in the control and thus fulfilled the demanded range (≤ 15 %).

In a separate study the reference item Dinoterb (BioChem study & de: B 13 10 48 00 N, carried out from 04.01. to 01.02.2013) caused a stimulation of nitrogen transformation of +327 % and +42.6 % (required ≥25 %) at 16.09 mg and 27.00 mg Dinoteth per kg soil dry weight, respectively, 28 days after application and thus demonstrates the sensitivity of the test system.

Nitrogen transformation:

The test item AE F147447 caused a temporary inhibition of the daily nitrate rate at the tested concentration of 0.050 mg/kg at time interval 7-14 days after application. However, no adverse effects of AE F147447 on introgen transformation in soil could be observed at both test concentrations (0.012 mg/kg dry soil and 0.057 mg/kg dry soil) at the end of the 28-day experiment. Differences from the control of -7.7 % (test concentration 0.012 mg/kg ary soil) and +7.0 % (test concentration 0.057 mg/kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28).

Effects on hirogen Pansformation in soil after treatment with AE F147447 Table CA 8.5-

Time A Intervator (days)	Contro	ol Q	0.012 n equiv	ng test	itena(kg s 0009 kg	oil dry weight g test item/ha	0.057 mg test item/kg soil dry weight equivalent to 0.043 kg test item/ha			
2	Nitrate (N)					% difference to control	Nitrate-N ¹⁾			% difference to control
0-7	\$.53 ±	037	£.13	Ŷ	0.46	+17.0 ^{n.s.}	4.29	±	0.09	+21.3 *s.
7-14	2.30 ±	0.39%	2.07	±	0.31	-10.3 ^{n.s.}	1.10	Ħ	0.55	-52.1 *s
14-28	D:26		11.7	±	0.15	-7.7 ^{n.s.}	1.35	±	0.32	+7.0 ^{n.s.}

The calculation were performed with unrounded values

& Rate: Marate-N in mg/kgsoil dry weight/time interval/day, mean of 3 replicates and standard deviation

storestically significantly different to control (Student-t-test for homogeneous variances, 2-sided, $p \le 0.05$)

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

Conclusion:

AE F147447 caused no adverse effects (difference to control < 25 %, OECD 216) in a field soil at concentrations up to 0.057 mg test item/kg soil dry weight on the soil nitrogen transformation (expressed as NO₃-N production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 0.057 mg test item/kg soil dry weight.

Supportive information: In the new European dossier format/data requirements there is no data point that corresponds to soil carbon transformation studies. Nevertheless, four studies (on the active substance and metabolites AE F154851, AE F160499, and AE F099095 are mentioned here as supportive information, since they are contained in the baseline dossier and the baseline dossie from the first EU review.

Studies on mesosulfuron-methyl

Report:	j; (998; NJ-14333) -01 () () ()
Title:	AE F130060; postance technical; Code: AE 193006000 1056 00025 Effects on soil
	microbial activity (short-term respiration) a contract of the second s
Report No:	A59695 a 4 m A a a A A A A
Document No:	M-143359-01-1 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Guidelines:	BBA: M, 1-& Deviation not specified
GLP/GEP:	yes Q O D Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q Q

Endpoint according to the Reserve Report for mesocalfuron-methyl (SANCO/10298/2003-Final): Deviation of less than 23 % for application rate up to 75 g a.s./ha

Lequivalent to >0.10 mg a.sokg dws).

Note: In contex of application for ED approval reprewal of mesosulfuron-methyl, this endpoint is ranked supportive information as soil carbon trapsformation testing is no longer a data requirement under regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding soil nitrogen transformation test

Studies on the me

AE F15485

Report: 2002;M-214092-01
Title: Soil microorganisms: Carbon Qansformation test Code: AE F154851 00 1B96 0001
Report No: $\sqrt{C0}$ C02723 $\sqrt{C0}$
Document No: $M\mathcal{Q}^1409\mathcal{Q}_{\mathcal{J}}01-1$
Guidelines: @ QECD 217; Deviation of specified
GLP/GEP: Ves & V
Study Adoption of less than 25 % for application rate up to 75 g p.m./ha
\mathcal{F} \mathcal{F} (equivalent to ≥ 0.10 mg p.m./kg dws).



The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final). The study is filed in this document on the "List of studies which were submitted during the evaluation process and were not cited in the draft assessment report".

ranked supportive information as soil carbon transformation testing is no longer a data requirement under regulation 1107/2009. The updated List of Endpoints will include or the data from c only data from $a O^{*}$, \tilde{O}^{*} , corresponding soil nitrogen transformation test.

AE F160459

		072	·		
Report:	5;		2002:NF-2121	02-01	
Title:	Soil microorganisms: carbon	transformation	test Code: AE	F1604 🔊 00	1897 006U
Report No:	C026800		Å ~0	ñ.	. 1
Document No:	M-212102-01-1	ŵ.Ű	Q.	~ Ö	
Guidelines:	OECD: 217;Deviation not	specified >	, A. (
GLP/GEP:	yes 🖉 🖓	.0' .4	0× 47	S.	L L

Study endpoint: Deviation of less than 25% for apple ation ate up to 75 gp.m./ba (equivalent to 20.10 nor p.m Arg dws)

The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2003-Final). The study is filed in this document on the "List of studies which were submitted during the evaluation process and were not cited in the draft assessment report". \bigcirc

Note: In context of application for EU approval revewak of mesosulfuron-methyl, this endpoint is ranked supportive information as will call on transformation testing is no longer a data requirement under regulation 107/2009. The updated List of Endpoints will include only data from a corresponding wil nitiogen transformation wst. (N 1)

, Q	
AE F099095	
Report:	م 2002;M-212100-01
Title:	Soil micro@ganisms: carl/on trans@ormagion test Code: AE F099095 00 1B99 0001
Report No:	Q D126792 0 2 Q Q
Document No:	M-212000-04-9 0 0
Guidelines:	OF D: 21 Deviation not pecificit
GLP/GEP	yes of the second s
0	

Study end soint: Deviation of less than 25 % for application rate up to 75 g p.m./ha (equivalent to 0.10 mg p.m./kg dws).

The endpoint from this study was not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298/2008-Find). The study is filed in this document on the "List of studies which were submitted during the evaluation process and were not cited in the draft assessment report".

Note: In context of application for EU approval renewal of mesosulfuron-methyl, this endpoint is ranked supportive information as soil carbon transformation testing is no longer a data requirement under regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding soil nitrogen transformation test.

CA 8.6 Effects on terrestrial non-target higher plants

CA 8.6.1 Summary of screening data

For mesosulfuron-methyl, greenhouse screening was performed on a number of higher plant species including crops, broadleaf and grass weeds (KCA 8.6.1 /01). As expected for a sulfonyl mea herbicide, the compound showed significant herbicidal activity to several plants, in both pre- and postemergence applications. The tests indicated excellent control in particular of grass weeds of high economical importance.

For BCS-CV14885, a component identified in a pecific non-guideline test for the retrospective structure assignment to polar leachate radioactivity observed in lysimeter studies (KOA 7,1.4.2 /05), absence of herbicidal activity was confirmed in comparative tests with parent active substance (ISCA 8.6.1 /02: pre-emergence application, KCA 8 6.1 /03, post-emergence application). Information from these tests is required for assessing the potential relevance if groundwater of component BGS-CV14885, cf. Document N4.

Soil metabolites AE F154851, AE F160450, AE F099095 AE F09294C AE F160460, AE F140584, AE F147447 were screened for herbicidal activity in greenhouse assays, at highly exaggerated test rates, with dosing pre- and/or post-engergence. Note of the components revealed a pronounced Details of all studies are provided in the following table. herbicidal effect comparable to that of the parent active substance. For metabolites AP F160459 and AE F147447, this information is required for assessing the potential relevance of these metabolites in



Table CA 8.6.1-1:	Screening data fo	or effect of mesosulfuron-methyl and selected	l metabolites to higher
	terrestrial plants		
Test design	Test species	Ecotoxicological endpoint	Reference
Mesosulfuron-methy	yl, formulated as WP	20	
Greenhouse,	Crop plants (6 ¹ -8 ²	Mesosulfuron-methyl is active pre-	, 1999 , 2
seedling emergence	species)	emergence as well as post-emergence to	M-186426-01-1
and growth, 26-28 d	Broadleaf plants	grass plants and broadleaf plants. Affower	KCA 80.1/06
	$(13^2 - 14^1 - \text{species})$	use rates below 2 grams, many plants are	× ~ §
	Grass plants (13 ^{1,2}	not susceptible to this herbicide	
	species)	particulary among the broadlowes and	
		More so and post-emergence use.	
		its good of tivity against tome gives plant	
		especially theopies why h are worldwide	
		ecoromical@impotent weeks in coreal	
		crops.	
BCS-CV14885, form	nulated as WP20	XXXXX A O	
Greenhouse,	Weed species	After pre-emorgence application, BCS-	, 2013 S
seedling emergence	(12 species)	CV14885 showed no biological activity of	M-460393-01-1
and growth, 28 d		the tange of weeds tested a start	KC 8.6.1002
Greenhouse,	Weed species	After post-emergence application, BCS	, 2013
seedling emergence	(12 species)	CV 14585 showed no biological activity on (DM-460647-01-1
and growth, 21 d		the range of weeds usited a second se	KCA 8.6.1 /03
AE F154851, AE F1	60459, AE F 099095, J	ALC F 092944, AE p 1604607, AE F 405842AI	1000
seedling emergence	leaver planks	actively at 86 4 / has a pre-amergent of or	, 1999 M 185252 01 1
and growth	(Wispeciel)	no generornce tests against a wide range	M-185253-01-1
und growin	S Species Street	of grass and browl-leaved plantOpecies	KCA 5.0/05
Ŕ	F 4 . 6 .	AE F160459 and AE 460460: only@light	
		to moderate reffects pre-en@rgenceOt	
		highly exaggerate dose rate of 330 g / ha.	
O'		This level of activity is 00-100@old less	
, Ô		than that of AC F130060 its ft.	
		AE F0990 S: Princery pre-synergence	
li sa		glasshou@screening found that it has no	
		Oerbickdal activuty at 3000 g/ha.	
l õ		AE re92944.9 almost herbicidally macuve	
<i>Q</i> ,		A F14084: In Gimary pre- and post-	
~0		mergence scheming this metabolite was	
1		herbiodally, Cactive at rates between 1250	
Ĩ,		and 3000 g.ma.	
		F14947: In primary pre- and post-	
		emergevice screening, both it was	
×		herbOidally inactive at 1250 g/ha.	
¹ post-emergent applic	cation of the test item	Ž [*]	
² pre-emergent application	attion of the test stom	~ Ø	
	i _n õi 🔬 🍕	$\sum_{i=1}^{n}$	
L ^Y Å	A S		
	¥ x¥		
A A	L.		
¢° ^v			
\bigcirc			



Studies on mesosulfuron-methyl

Report:	0; ;199	99;M-186436-01	Ĭ,
Title:	Effectivity of the herbicide AE F13	30060 on higher plant specie	as applied und
	greenhouse conditions	- A A A A A A A A A A A A A A A A A A A	
Report No:	C003598	10°	
Document No:	M-186436-01-1	A	
Guidelines:	Deviation not specified	Ča du	
GLP/GEP:	no		

The endpoint from this study was not mentioned in the Review Report for mesosulfuron methy (SANCO/10298/2003-Final) A study evaluation intermediate in the review of the study evaluation intermediate in the study evaluation Studies on the metabolites of mesosulfuron-method

BCS-CV14885

Report:	₹ 20 13;M≤460395 , 01 ↔ 5 ,5 ,5 ,5
Title:	Evaluation of the pre-emergence bological activit of merosulfuron and its metabolite
	BCS-CV #4885 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Report No:	FFS135005 7 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Document No:	M-460393-0 KA O A O A O
Guidelines:	not applicable; not applicable 2 2 2 2
GLP/GEP:	no A a a a a a a a a a a a a a a a a a a

Executive Summary:

This pre-emergence text was conducted to determine differences in the biological activity of mesosulfuron methyland it Odegra ate BCS-CV 4885 The stady was conducted under standardized glasshouse conditions using WO20 formulations of both mesoscilfuron-methyl and its degradate BCS-CV14885. Seeds of the weed precies (EPPO code) Zea mays (ZEAMA), Triticum aestivum (TRZAS), Triticum Lestiver (TRZAW), Horder vulgare (ORVS), Secale cereale ((SECCW), Lolium multiflorum (LOUMU); Beta Sulgaris (BEAVA), Brassica napus (BRSNS), Helianthus annuus (HELAN), Linum usitenssimum (LEUUT), PhaseQus vulgaris (PHSVN) and Pisum sativum (PIBST) were planted in posts and post-emergence applications of mesosulfuron-methyl and BCS-CV14885 were applied st rates of 15, 3.75 and 1.875 g a.s./ha. Furthermore, "Blindformulierung WP20" [blind formulation containing no active substance] was applied at rates of 60, 30, 15 and 7.5 g as that Effects were assessed visually two and four weeks after application. BCS-CV14885 showed no biological activity of the range of weeds tested.

Materials and Methods:

Test materia. 2013 000567 mesosulfuren-methyl; 2013-000563 BCS-CV14885; Blindformulierung [english translation] WP20.

Test species [12 weed species (EPPO code): Zea mays (ZEAMA), Triticum aestivum (TRZAS), Tracestivum (TREAW), Hordeum vulgare (HORVS), Secale cereale ((SECCW), Lolium multifler m (LOLMU); Beta vulgaris (BEAVA), Brassica napus (BRSNS), Helianthus annuus (HELAN), Linum usitatissimum (LIUUT), Phaseolus vulgaris (PHSVN), Pisum sativum (PIBST).



Jiffy pots (7 cm diameter) were filled to within 2 cm of the top with a silt-loam soil (20% sand, 57% silt, 23% clay, pH 6.8 and 1.4% organic matter). Seeds of the weed species were sown into these bots and covered with 0.5 to 1 cm of the same soil mixed 1 to 1 with sharp sand. The sowing density was selected based on prior experience to provide approximately 60-70% soil giver by the plants at application timing. After sowing the pots were watered slightly.

All compounds used in the test were dissolved in deionized water and diluted to obtain the required dose rates. The pre-emergence application (06 February 2013) was made using a track sprayer with a spray volume of 300 L/ha via a flat fan nozzle (TeeJer 8001). Messulfuron-methyl and BCS-CV 14885 were applied at rates of 15, 7.5, 3.75 and 1.875 g a.s./ha Blindformulerung WP20 was applied at rates of 60, 30, 15 and 7.5 g a.s./ha.

After application, the pots were placed into a gasshouse set $21^{\circ}C + \sqrt{2}^{\circ}C$ day and $\mathbb{Q}^{\circ}C + \sqrt{2}^{\circ}C$ night and watered according to need. High pressure sodium tamps $400^{\circ}V$ were used to augment day light during cloudy conditions and to extend the day lengt to 14 Hours $\sqrt{2}^{\circ}V$ and $\sqrt{2}^{\circ}V$

Two weeks and four weeks after application, the treated plants were visually assessed for inputy compared with the untreated control plants. The assessments were on a percentage basis ($0 \leq n$) effects, 100 = complete kill).

Dates of experimental work: February 6, 2013 to March 6, 2013

Results:

The results of the visual assessments are presented as means from the 2 ceplicates in the following tables:

				TOM	IIAD	CTOO)	DE	DD.	III	TTT	DIIG	DID	LOI
	lg a.s.	Z₽®.	I KZ	I KŹ	HOR	SEC	RFØ	RKX	HFF	LIU	PHS	LIR	LOL
	hal	MA	ÂS	AW	V 8	.€W	ŶĂ	NS	АŇ	UT	VN	ST	MU
2013-	Õ 1 5	\$0 ×	©55	© ₆₀ 9	لاي 0 الاي ال	80	¢ 55	60	D 75	55	55	90	85
000561	7.5	0		354	0	′40°°°	25	10	[′] 50	0	25	90	55
Mesosulfuro	3.75		Ĩ		0,	Í.	Ĵ.	O	10	0	0	63	0
n-methyl	1.875	~ 0		ي پ 0 ٍ (0	°, [™] 0 &	, 0 🔬	$\gg 0$	0	0	0	20	0
2013-	15	<u>04</u>	Ľ	<u> </u>	, Q		<u>ک</u>	0	0	0	0	0	0
000563	7,5		ð,	Û.	õ .	Õ°0	ÕÕ	0	0	0	0	0	0
BCS-CV	∾93.75	0 0	$0 \sim$		کې 0 کې		· 0	0	5	0	0	0	0
14885	1.875	8	and the second s	E ^F	NO S	, D	0	0	0	0	0	0	0
	60 🗋	Č [%] O		$\searrow 0$	$\sqrt[6]{0}$	0	0	0	0	0	0	0	0
Blindformul ierung WP 20	30 🐇	^ر 0			0~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	0	0	0	0	0	0	0	0
	£`	0	Q			0	0	0	0	0	0	0	0
	0 ⁷ .5 ~	Á) Ì		ي ⁶ 0	<u>0</u>	0	0	0	0	0	0	0	0

Table CA 8.6.1-2: Results of the first assessment (14DAT)

	Ľ	\approx 0	N.	· •			
	(selectivite)	éxcellent,	$\tilde{\mathcal{D}}$	good	sufficient	Side effects	Not sufficient/ gaps
ľ,		+++ (0-\$95-1	.00)	++ (6-10/90-94)	+ (11-15/80-89)	+- (16-20/60-79)	- (>20/<60)
	<u>م</u> "						

BAYER Bayer CropScience Document MCA: Section 8 Ecotoxicological studies

Mesosulfuron-methyl

Table CA 8.6	he seco	nd asses	sment (28 DAT	[]									
	[g a.s./	ZEA	TRZ	TRZ	HOR	SEC	BEA	BRS	HEL	LIU	PHS	PIB	IØĽ	ð
	haj	MA	AS	AW	VS	CW	VA	NS	AN	UT	VN	ST o	MU	Ş
2013- 000561	15	0	50	55	45	70	90	65	90	5 0,	30	980) 92 °	Í
	7.5	0	0	5	0	25	30	10	43	ÃÕ.	10	\$3		
Mesosulfuro	3.75	0	0	0	0	0	0	0	0 🤦	0	0	\$745 ू	S 28	ð
n-methyl	1.875	0	0	0	0	0	<u>ک</u> م	0	Č,	0	<u></u> ŽY	35		1
2013- 000563	15	0	0	0	0	0	₹0	0	0	0	\mathcal{O}_0	\$90°	N.	Å
	7.5	0	0	0	0	0,5	0		0		0 🤇	0	§ [™] 0 %	0 ¥
BCS-CV	3.75	0	0	0	0		0	ĺ °Ø∮	<i>S</i>		A A		a de la companya de	
14885	1.875	0	0	0	0 4	Ø 0						KO.	~Ş0	
	60	0	0	0	6		l a	0K		0,5	0	0	0	
Blindformul	30	0	0	0	<u>4</u> 0	<i>w</i>	\mathbb{Q}^{0}	~Q0	Ĩ		Ô	N.	O	
1erung WP 20	15	0	0	0	0°	$\sum_{i=1}^{N} 0$	گ 0 گ	× 0 ($\rightarrow 0$	0	0	0	\$ 0	
	7.5	0	0	B		Ŕ		e e	ø		00	0 Ĉ	0	
								-						
(selectivity/ efficacy) ++++ (0-5/95-100)					ood 8 \$490-94	کې ۲+ (۱۱	ifficient	89) + ₂	Sideeff	fects (60-79)	Not si 0 2 0 - (>2	aps 20/<60)	t/	

Conclusion:

In a direct comparison study under highly sensitive glasshouse screening conditions, the mesosulfuron-methyl degradate BCS-CV14885 showed no Biological activity on the range of weeds tested.

\$_ \$		
Report:	1; ;20\$; M-469647-	
Title:	Evaluation of the postcomergence biological	ctivity of mesosulfuron and its metabolite
~	BCS CV 14885 . O & X	
Report No:	FES135004 & 6	
Document No:	Q-460637-01-1° × ×	
Guidelines: 🔊	not applicable; not applicable	
GLP/GEP:	no or a construction of the construction of th	
A		

Executive Summary

This post-emergence test was conducted to determine differences in the biological activity of mesosulfuron-methyl and its degradate BCS-CV14885. The study was conducted under standardized glasshouse condition, using WP20 formulations of both mesosulfuron-methyl and its degradate BCS-CV14855. Seeds of the weed species (EPPO code) Zea mays (ZEAMA), Triticum aestivum (TRZAS), Triticum aestivum (TRZAW), Hordeum vulgare (HORVS), Secale cereale ((SECCW), Lolium multiforum (LOLNU); Beta vulgaris (BEAVA), Brassica napus (BRSNS), Helianthus annuus (HECAN), Einum usitatissimum (LIUUT), Phaseolus vulgaris (PHSVN) and Pisum sativum (PfBST) were planted in pots and post-emergence applications of mesosulfuron-methyl and BCS-CV14885 were made at rates of 15, 7.5, 3.75 and 1.875 g a.s./ha. Furthermore, "Blindformulierung WP20" [blind formulation not containing active substance] was applied at rates of



60, 30, 15 and 7.5 g a.s./ha. Effects were assessed visually one and three weeks after application. BCS-CV14885 showed no biological activity on the range of weeds tested.

Materials and Methods:

V14885; Blindformu Test materials: 2013-000561 mesosulfuron-methyl; 2013-000563 BCS-C WP20.

Test species: 12 weed species (EPPO code): Zea mays (ZEAMAQ, Triticum destivum) (TRZAS Triticum aestivum (TRZAW), Hordeum vulgare MORVS), Segale cereale (SECCW), Doliur multiflorum (LOLMU); Beta vulgaris (BEAVA) Brassica napus (BRSNS), Helianthus annuus (HELAN), Linum usitatissimum (LIUUT), PhaseOlus vulgaris, PHSVA), Pisum sativum (PBST)

Jiffy pots (7 cm diameter) were filled to within 2 son of the top with a Sit-loan soil (20% sand, 57% silt, 23% clay, pH 6.8 and 1.4% organic matter). Seeds of the weed species Wisted above) were sown into these pots and covered with 0.5 to frem of the same soil mixed to 1 with shorp sand. The sowing density was selected based on prior experience to provide approximately 60,40% sold cover by the plants at application timing. After sowing the pots were placed into a glass ouse set 162C+/-2°C at day and 12°C+/-2°C at night and watered according to need. High pressure softum lamps (400W) were used to augment daylight during cloudy conditions and to extend the day longth to 14 hours.

All compounds used in the test were dissolved in deionized water and diluted to obtain the required dose rates. The post-emergence application (06 February 2013) was made using actrack-sprayer with a spray volume of 300 L/ha via a flat fan norzle (TeeJet 8001), Mesosulfuror methyl and BCS-CV 14885 were applied of rates of 15, 7.5, 3.75 and 1.875 g a. Tha. "Blindformulierung WP20" was applied at rates of 60, 30, 15 and 53 g a. ha.

One week and three weeks after application, the treated plants were visually assessed for injury compared with the upreated control plants. The assessments were on a percentage basis (0 = no effects, 100 = comptote kill

Dates of experimental works, February 6, 2013 to February 28 2013 Results: The results of the visual assessments are presented as means from the 2 replicates in the following tables:

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Document MCA: Section 8 Ecotoxicological studies Mesosulfuron-methyl

Table CA 8.6	5.1-4:	Res	ults of t	he first	assessm	nent (7 I	DAT)	1	T	I	1		
	[g a.s./	ZEA MA	TRZ	TRZ AW	HOR VS	SEC CW	BEA VA	BRS	HEL		PHS VN	PIB ST .	
	15	3	0	0	0	0	70	25	73		20	200	10^{10}
2013-	7.5	0	0	0	0	0	70	15	70	 	10	20	AB)
Mesosulfuro	3.75	0	0	0	0	0	50	0	70 «	0	10 4	©20 ≈	×10
n-methyl	1.875	0	0	0	0	0	~ <u>3</u> 0	0	70	0	1.0×	20~	10
	15	0	0	0	0	0	∇_0	0	30	0			× B
2013-	7.5	0	0	0	0	0	0	0	10	0 🕺			
BCS-CV	3.75	0	0	0	0	<u></u>	0	Â,	رچ کچ	 ()/	<u>A</u>		a de la companya de
14885	1.875	0	0	0	0 4	\bigotimes_{0}^{0}	0				$\sqrt{0}$	Ê0	~~~~
	60	0	0	0	0	<u> </u>	l Qî	06		0,\$			
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enica	-y) ++	+ (0-5/9	≪_× 5-100)	 ≪++ (6-1	¢ \$/90-94	5 +(11	@ł 5/80-	89) +-	x X¥6-20/	60-79)	e - (>2	20/<60)	
) Q	y S						<u>y</u> J		
Table CA 8.6	5.1- 5:	Res	ults of t	heseco	nd @sses	sment (21 ØÅT		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<u> </u>	1	1	
	[g a.s./	QÆА Øма	TRZ AS	*PRZ Sawa	HOR	SEC SC	KBEA ▼V∆@		JAN -		PHS VN	PIB ST	LOL MU
	15	80	3			R R	68	36	80	0	45	35	55
2013-	~D5	<u>Š</u>	$\bigcirc 0$	Ő	e, 00	$\swarrow 0$	≈ <u>60</u>	\$20	75	0	33	20	40
Mesosulfuro	3.75						40		50	0	25	20	10
n-methyl	1.875	B	~07	do V	0		~20	~0/	40	0	15	10	0
- A	15	~ 0		. 0				$\sqrt[6]{10}$	20	0	0	0	0
2013-	7.5		0				Q	0	8	0	0	0	0
BCS-CV	3.75	Ó.	.4	<u> </u>	20	~		0	3	0	0	0	0
14885	0.875		Ŭ ₀	$\sim 0 \sim$		$\bigvee^{0} 0$	0	0	0	0	0	0	0
2	÷ 60	0	0.9	0-		00	0	0	0	0	0	0	0
Blindform	30	~~B	-Q		20	<u>~</u>	0	0	0	0	0	0	0
ierung WP	15 🔬	90			0	0	0	0	0	0	0	0	0
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Conclusion		Ĩ.											

In a direct comparison study under highly sensitive glasshouse screening conditions, the mesosulfuron-methyl degradate BCS-CV14885 showed no biological activity on the range of weeds tested.

AE F154851, AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, AE F147442

A study (M-185253-01-1) was submitted in the original EU dossier, under the efficacy section. It can be found under point KCA 3.6/03 of this dossier.

The endpoints from this study were not mentioned in the Review Report for mesosulturon methyl (SANCO/10298/2003-Final). A study evaluation is however available in the Monograph (B.397.5.3) CA 8.6.2 Testing on pion-target plants are product related determined. concluding that none of the identified metabolites showed significant herbicidal activity as compared

Test results of stadies on hon-target plants are product related date and as such reported in document MCP. Since the representative formulation INIS+MSM+MER OD42 is a mixed-type product containing a second herbieide active substance, no conclusion specifically relvant to the individual substance mesosulfuron the the results of these tests.

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Table CA 8.7- 1:	Effect data of means presented in this	sosulfuron-methyl WG 20 to entomology sc chapter	reening species
Test design	Test species	Ecotoxicological endpoint	Reference S
Mesosulfuron-methy	l, formulated as WG	20	
different treated stages (eggs, larvae, all stages), 6 d; additional root systemicity test on <i>Aphis fabae</i> ,	Spodoptera littoralis, Heliothis virescens, Aphis fabae, Nilaparvata lugens, Diabrotica undecimpunctata, Meloidogyne incognita, Tetranychus urticae, Vicia, faba, Aphis fabae (root systemic activity)	The test item is not effective on any test species.	M-198522-01-1*5 KCA 857/01 55 \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$
	, or a large state of the state		
Report:	\circ	;2000;M-198522-PI	
Title:	Effectivity of the he	Poicide nesos furon-Dethyl provisionally	pproved ISO) on
	entomology screeni	ng spečies Code: AR F1300 0	ř _v v
Report No:	C010158 (c	<u>i i y a y y y</u>	
Document No:	M-188522-00-1		<u> </u>
Guidelines:	EUX=EEC): 91/41	4;Devertion for specQied 💙 🖉	ÿ
GLP/GEP:)

 \bigcirc y chdpoin according to the Monograph evaluation (B.9.9.2): tesosulturon-methyl was not effective on any dested species.

was not mentioned in the Review Report for mesosulfuron-methyl The endpoint from his study (SANCO/10298/2003-Final)

Ő Effects on biological methods for sewage treatment CA 8.8

For mesosulfacon-mennyl, studies with activated sludge and Pseudomonas putida have been conducted. An overview of both studies is provided in the following table. Based on these test results,





Test species	Test design	Ecotoxicological endpoint	Reference
Mesosulfuron	-methyl		
Activated sludge	Respiration inhibition, 3 h, static (OECD 209)	Activated sludge, inhibition of respiratory actives : $EC_{20} > 1000 \text{ mg/L}$ $EC_{50} > 1000 \text{ mg/L}$ $EC_{80} > 1000 \text{ mg/L}$	Di996 M-141255-017 KCA 8.8. /04 S
Pseudomonas putida	Cell multiplication inhibition test, 16.5 h (DIN/EN/ISO 10712 (1996) (DEV- L8)	Pseudomonas putida, in bitory effect of water- soluble test substances. EC ₁₀ 75 mg/L (Confidence interval: 12-144 mg Φ , P = 95 %) EC ₅₀ 298 mg Φ (Confidence interval: 158-69 mg/L Φ = 95%) The EC ₅₀ the teg item is in the lange of >100 mg/L to 1000 mg/D	M-142398-04-5 KCO ⁸ 8.8.45 C ⁴ ² ² ² ² ² ² ² ² ² ²

Report:	(; ;1996; M-144) \$55-01
Title:	Testing of resumation phibiting to activated udge of Hoe 15060, Sostan Atechnical
	(Code: Hoe Q0060,00 ZC% 00022, 2 0 0 2 2 2
Report No:	A57673 0, 4, 0 0 4
Document No:	M-14135-01-17
Guidelines:	EU (=EEC): \$\$/302, C, OECD: 209 Deviation not specific
GLP/GEP:	yes Q O A Q A A A A

Study endpoint according to the Monograph evaluation (B.9:10.1): EC_{50} h > 1.000 mg h s./l; nominal concentration

	la l	Å			Ń		L C	7	
The results	from this	study '	were mot	mentio	ned	the Revi	ew Report	for	mesosulfuron-methyl
(SANCO/10	288/20024	Final	0×	\$\$ ¹⁰	S S	Ô Å			5

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Report	[0, 1]	
Title:	Determination of thornhibitory effect of water constituents on bacteria (Pseudomonas cell	
	🔊 multiplication inhibition toti) 🔘 😞	
Report No:	2 58780 5 m m La La	
Document No: 🖉	$0^{-14}23^{-9}8-01^{-9}$ 0^{-7} 0^{-7}	
Guidelines: 🌱	DINO10712-ISO: J712; Eviation not specified	
GLP/GEP	yes a start	

Study endpoint according to the Monograph evaluation (B.9.10.2): EC_{50} 16.5 $R \neq 298$ mg a.s. Q nominal concentration, 95% CI = [158-699] mg/l.

The results from this study were not mentioned in the Review Report for mesosulfuron-methyl (SANCO/10298 2003-Final)

Monitoring data CA 8

Nomonitoring data have been created by the notifier since no additional data was deemed necessary to completerisk assessments. No relevant and reliable monitoring studies were found in the required literature searches of the peer reviewed open literature.