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In agreement with the Rapporteur Member State, the product dossier is submitted following the dRR format. All points required under the SANCO 10181/2013 are covered, although their naming might differ slightly.

IIIA 10 ECOTOXICOLOGICAL STUDIES

This document reviews risk assessment for Non-Target Organisms for the plant protection product of IMS + MSM + MPR OD 42 which contains the active substances iodosulfuron-methyl-sodium (IMS) and mesosulfuron-methyl (MSM), and the crop saferer mefenpyr-dethyl (MPR).

This product is the representative formulation for the inclusion of mesosulfuron-methyl at European level. In its function as Document MCP for the EU review process, the assessment will focus on only the active substance mesosulfuron-methyl. A comprete assessment to cover all active substances of the formulation will be provided at a later stage, as part of the post AIR process for rerewal of authorisations at member state level, once mesosulfuron-methyl is re-approved under Regulation (EU) 1107/2009.

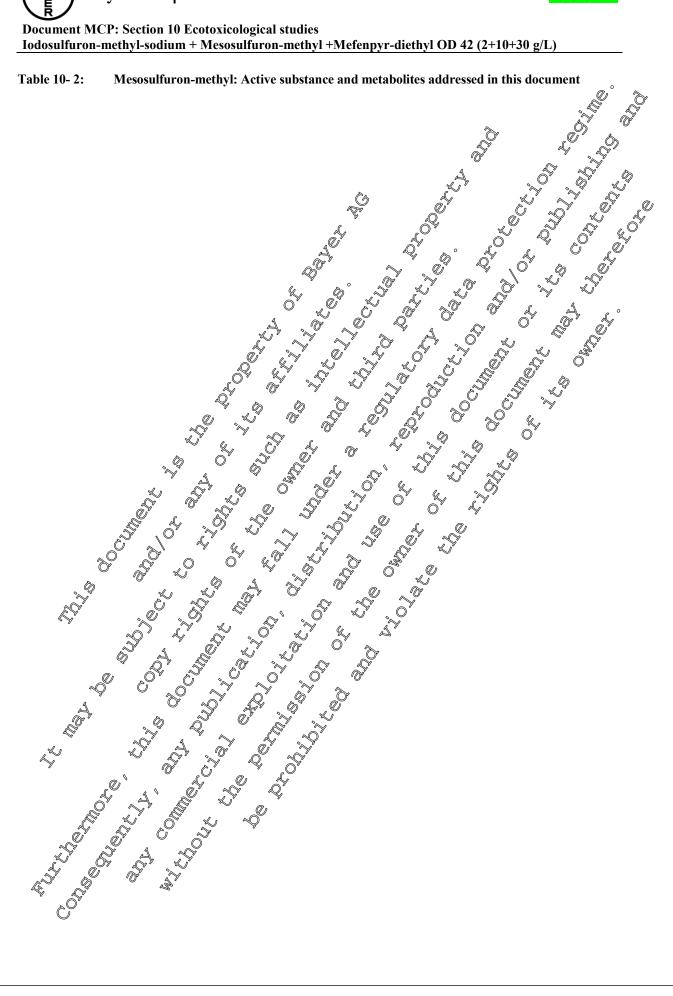
In general, formulants (inactive ingredients) present in a product de not influence to a relevant extent the behaviour of the active substances in the environment. An exemption is for slow release formulations but this is not the case for the present product. Therefore, data derived from tests with the individual active substances are considered representative for the behaviour of these substances in product IMS+MSM+MPR OD 42. This assumption has been supported by testing as well the formulated product on a selection of organisms.

Intended application pattern

The formulation is intended for use as a post-emergent herbicide to control weeds in winter and spring cereals. The critical use pattern for this formulation is summarised as follows. A detailed use pattern can be found in Document D-1 of this dossier.

Table 10-1: Intended application pattern for the representative uses of mesosulfuron-methyl in product MS+NSM+APR OD 42

Crop &	Timing of Q	applications	Application interval [days]	Maximum label rate [L/ha]	Maximum ap individual [g a.s iodosulfuron- methyl-sodium	
Winter wheat	BRCH 20 2 and of voiter, beginning of vegetation		ı	1.5	3	15
Winter ry	BECH 20-32 end of winter, beginning of vegetation	1	-	0.6	1.2	6



Compound / Codes	Chemical Structure	Explanation for Consideration	Considered for .
Mesosulfuron -methyl / AE F130060	H ₃ C SO ₂ H SO ₂ H N OCH ₃	active substance	PEC _{soil} O PEC _{gw} O PEC _{sw} & PEC _{sed}
AE F154851	H ₃ C Số ₂ Số ₂ N OCH ₃ OCH ₃	aerobic soil: >109 anaerobic soil: < 59 soil photolysis: 4d. water/sediment: <5% hydrolysis: <5% aqu. photolysis: nor.	PEC _{sw} PEC _{sw}
AE F160459	H ₃ C Số ₂ H OCH3	serobic coil: >5% naerobic soil: >10 soil photolysts: n.d. water/sediment: >10 bydrolysts: n.d. aqu. photolysis: n.d.	PEC _{sw} PEC _{sed}
AE F099095	H.N N OCH	acrobic soil: >10% anaerobic soil: <5% soil photolysis: n.d. wa@r/sediment: *5% hydrolysis: n.d. aqu. photolysis: n.d.	PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed}
AE F092944		aerobic soil: >10% anderobic soil: <5% soil photolysis: n.d. water sediment: <5% hydrolysis: >10% aqu. photolysis: n.d.	PEC _{gw} PEC _{sw} & PEC _{sed}
AE F160460	H ₃ C N N N OH N OCH ₃	aerobic soil: >5% anaerobic soil: >5% soil photolysis: n.d. water/sediment: >5% hydrolysis: n.d. aqu. photolysis: n.d.	PEC _{gw} PEC _{sw} & PEC _{sed}
AE F140584	H ₃ C SÓ ₂ NH ₂ SÓ ₂	aerobic soil: >5% anaerobic soil: <5% soil photolysis: n.d. water/sediment: <5% hydrolysis: >10% aqu. photolysis: n.d.	PEC _{gw} PEC _{sw} & PEC _{sed}

Compound / Codes	Chemical Structure	Explanation for Consideration	Considered for .
AE F147447	H ₃ C NH SÓ ₂	aerobic soil: anaerobic soil: soil photolysis: n.d. water/sediment: hydrolysis: aqu. photolysis: n.d.	PEC _{soil} PEC _{sex} PEC _{sed}
	Chemical Structure H ₃ C Số ₂ NH Số ² NH		

IIIA 10.1 Effects on Birds

Ecotoxicological endpoints used in risk assessment

Table 10.1-1: Endpoints of the <u>formulation</u> IMS + MSM + MPR OD 42 used in risk assessment.

Test substance	Endpoint A S S
IMS + MSM + MPR OD 42	Mesosulfuron-methyl is of low acute oral exicity to Bobylinte quail and Wallard suck, with LD ₅₀ values in excess of 2000 mg a.s./kg bw. For animal welfare reason, acute oral studies with formulations are routinely not conducted for birds, where the individual active substance tests indicated low toxicity to birds. Based of the active ingredient data, the toxicity of the formulation can be reliably predicted in the present case, considering that avian LD ₅₀ of iodosulfuron-methyl-softum is 2000 ang a.s./kg bw ¹⁾ and LD ₅₀ of mefenpyr-diethyl is >2000 mg a.s./kg bw ²⁾ , it is reasonable to assume that the product would also be practically non-toxic to birds.

¹⁾ EU list of endpoints for iodosulfuron-methyl-sodium [SANCO/19166/2009-Final]

2 (1991, amended 1994) M-129350-02-17 Mefengyr DAR une 2014, available on ORCA (Archive individual substances – Mefenpyr-dichyl(saferier)).

Table 10.1-2: Endpoints for the active substance mesosulfuron-methyl used in risk assessment

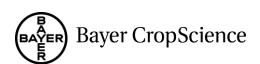
Test substance	Test organism Stud@type Endpoin®	Reference
	Acute Exicity to bird Y Y Z Z	
	Bobwhite quaid, Madard dusk oral LD ₅₀ > 2000 mg as/kg bw	(1998) M-180378-01-1 KCA 8.1.1.1 /01 (1998)
methyl		M-147788-01-1 KCA 8.1.1.1 /02
(Long-form toxicity to bird	
	NOEC 1000 ppm	(2000) M-198082-01-1
	Bobwhite quaid fooding WOEL 93 mg as/kg bw/d	KCA 8.1.1.3 /01

All above endpoints used in risk assessment are consistent with the *proposed* EU endpoints listed in Document N2 for mesosulfurent methyl.

Risk assessment for birds

The risk assessment procedure follows the EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009).

The risk assessment follows a tiered approach to assess the effects of plant protection products on birds based on current regulatory requirements. The risk is considered acceptable, if the 'Toxicity Exposure Ratio' (TER) value pass the trigger values of 10 for acute exposure and 5 for chronic



exposure. If the TER values are below the trigger values in certain areas, a refined risk assessment based on more relevant and realistic conditions is performed for those particular areas.

Calculation of Toxicity Exposure Ratio (TER)

According to the EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009) the calculation of acute and long-term Toxicity to Exposure Ratio (TER) is defined as follows:

Acute risk: $TER_A = LD_{50} [mg \ as/kg \ w] / DDD$

Long-term risk: $TER_{LT} = NO(A)EL$ [mg as/kg bw/d]

The endpoints for acute and long-term risk assessment derive from acute and reproductions addies respectively, and are expressed as dose in ner kilogram had weight for doing.

Calculation of Daily Dietary Dose (I

Acute exposure:

ven by the following equal The daily dietary dose for cosingle application is gi

Long-term exposition

the following equation: For a single application the dai

ngle application the daily dietary dose is given by the following equation:
$$DDD_{\text{single application}} = \text{application rate}(kg/ha) \times \text{shortcut value}(SV_m) \times TWA$$

Where

Time weighted average factor (= ftwa) based on a default time window of

21 days and a DT of to days leading to a value of 0.53

SV = FXX/bw x RUD Value for exposure estimate based on species and crop.

Residue per unit dose: residues on feed items normalized on an application

th percentile values for acute exposure, extension for RUD and SV mean values for reproductive/long-term exposure, extension for RUD and SV

Standard exposure scenario for risk assessment on screening level

The main potential exposure route for birds is expected to be consumption of contaminated feed.



The risk assessment on screening level is based on standard scenarios, i.e. combination of indicator species and crop.

Default ("shortcut"-) values for the exposure estimate will be used as provided in Appendix A of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009) representing a worst case assessment.

It is assumed that

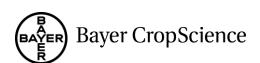
- animals satisfy their entire food demand in the treated area (PT
- animals feed on a single food type only (PD = 1)
- over an acute time frame (hours) the animals feed on items containing maximum residues (90th percentile), whereas they would ingest food containing mean residues over a long-term period (days to weeks),
- long-term predicted environmental concentrations to be compared with chronic endpoints can be calculated as the time-weighted average concentration. Default assumptions are a time window of 21 days and a DT₅₀ of 10 days leading to a time weighted average factor (= \$\mathbb{U}_{va}\$) of \$\mathbb{D}\$.53. This factor is equally valid for feed items consisting of vegetation as well as of athropods.
- The 'indicator species' used on screening level is not a real species but By virtue of its size and feeding habits is considered to have higher exposure than other species that occur is a particular crop at a particular time and is therefore protective for all other species in that particular crop.

Avian indicator species for fisk assessment on screening leved

The product IMS + MSM + MPR OD 42 is intended to be used in winter wheat for a single application between BBCH 20 and 32 at an application rate of 1.52/ha, corresponding to 0.015 kg mesosulfuron methyllia, and in winter rye for a single application between BBCH 20 and 32 at an application rate of 0.6 L/ha, corresponding to 0.006 kg/mesosulfuron-methyl/ha. According to the EFSA Goodance Document of Risk Assessment for Birds & Mammals (2009) the following indicator species have to be addressed in risk assessment of screening level.

Table 10.1-3: Relevant avian indicator species for isk as ssment on screening level

		Shortcu	ıt value
Crop	Indicator species		For acute RA based on RUD%
Gereals	Small, omning orous bird	64.8	158.8



Summary of calculated TER values for birds

Table 10.1-4: Summary of all acute TER calculations as given under point 10.1.1

Crop / Compound	Indicator species	SV90	TERA	Trigger	Refinement
Winter wheat, 1 × 15 g a.s.	/ha		.4	<i>*O</i> *	S S
Mesosulfuron-methyl	Small omnivorous bird	158.8	>840 🗸	10	y ng 🛴
Winter rye, 1 × 6 g a.s./ha		4		Ö	
Mesosulfuron-methyl	Small omnivorous bird	\$ 158.8	2105	16	ng (

Table 10.1-5: Summary of all reproductive (long-term) TER calculations as given under point 10.1.

Crop / Compound	Indicator species SVmean Trigger Refinement model?
Winter wheat, 1 × 15 g a.s.	/ha
Mesosulfuron-methyl	Small ompoworous Fird 64.87 0181 0 0 10
Winter rye, 1 × 6 g a.s./ha	
Mesosulfuron-methyl	Small omnix rous bind 64.8

Conclusion: According to the presented risk assessment, the risk to birds from the use of the product in cereals is acceptable.

IIIA 10.1.1 Agorte toxicity exposure ratio (TERA)

Acute toxicity exposure ratio on screening level for birds

Table 10.1.1. 1: Acute DDD and TER calculation (active substance mesosulfuron-methyl) on screening level for birds

Crop /		~ ~ . (ADDD .				
Compound S	Indicator species	I nig/kg/gw]	Appl. rate [kg/hap	SV90	MAF90	DDD	TERA	Trigger
Winter wheat # 1	5 Pa.s./hat							
Mesosulfuron- metryl		>2000	© ©0.015	158.8	1	2.38	>840	10
Winter rye, 1 × 6 g a Sc/ha								
Mesosulfuron- methyl	Small omnicorous bigs	· . ()	0.006	158.8	1	0.95	>2105	10

All TER values are above the required trigger of 10 for acute exposure. Acute risk to birds is therefore acceptable for the intended product uses.

Acute risk assessment for birds drinking contaminated water

An assessment of the risk potentially posed by consumption of contaminated drinking water is required according to the EFSA Guidance Document for Birds and Mammals (2009). For details see point 10.1.2 of this dossier.

As formulation IMS + MSM + MPR OD 42 is applied in cereals, no poole in leaf axils where a facute exposure possibly might occur are to be expected.

The acute risk from water in puddles formed on the soil surface of a field when a cheavy) rainfall event follows the application of a pesticide to a cross or bare soil is covered by the long-termerisk assessment under Point 10.1.2 of this dossier.

IIIA 10.1.2 Short and long-term toxicity exposure ratio (TERst, TERLT)

Short-term toxicity exposure ratio for birds

According to the risk assessment scheme of EFSA GD birds and mampals (2009) a short-term risk assessment is not required. However, the endpoint from short-term dictary studies & g. 5-day dietary study in birds (OECD 205) should be used in an acute risk assessment when indicating a higher toxicity via the dietary exposure route (lower LDD₅₀).

Situation for mesosulfuror methyl. Short term detary studies for mesosulfuror methyl gave no indication for higher toxicity via the dietary sposure router compared to one application via gavage in the acute oral studies.

Long-term toxicity exposure ration screening level for birds

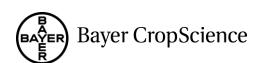
Table 10.1.261: Long-term DDD and TER calculation (active substance mesosulfuron-methyl) on screening level for birds

I	Indicator species	NO(A)EĹ [mg/kg hw]	Appl. rate [kg/ha]	ŠV _m	MAFm	f _{twa}	DDD	TER _{LT}	Trigger
Winter wheat, 1 ×	Winter wheat, 1 215 g. s. /ha 5 5 5								
Mesosulfuron- methyl	Small onniverous bird	93	1 0015	64.8	1	0.53	0.52	181	5
Winter Se, 1 × 6 g a.s. ha									
Me sosulfuron- methyl	Small omniverous bird C	930	0.006	64.8	1	0.53	0.21	451	5

All TER values are above the required tregger of 5 for reproductive/long-term exposure. Long-term risk to birds is therefore acceptable for the intended product uses.

Long-term risk assessment for birds drinking contaminated water

An assessment of the risk potentially posed by consumption of contaminated drinking water is required according to the EFSA Guidance Document for Birds and Mammals (2009). Two scenarios



were identified as relevant for assessing the risk of pesticides via drinking water to birds and mammals:

- Leaf scenario, only relevant for birds possibly drinking water from puddles in leaf whorls after application of a pesticide to a crop and subsequent rainfall or in gation. This scenario is only relevant for acute exposure.
 - As IMS + MSM + MPR OD 42 is applied in cereals, no pools in leaf axils where an acute exposure possibly might occur are to be expected.
- Puddle scenario. Birds and mammals taking water from preddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. This scenario is relevant for acute and long-term exposure.

An "escape clause" recommended in the EFSO Guidance Document for Bords and Mammals (2009) allows for screening the need for a quantitative risto assessment by a comparison between the application rate and the toxicity of the respective substance. This escape clause specifies that "due to the characteristics of the exposure scenario the connection with the standard assumptions for water uptake by animals ..., no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not esceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc > 500 L/kg)." \(\)

Table 10.1.2- 2: Evaluation of potential concern for sposure of birds drinking water (escape clause)

Crop / Koe Application NO(A)EIO Ratio (Application rate ID kg [g as ha] kg bw/d / NQ(A)EL	"Escape clause" No concern if ratio	Conclusion
Winter wheat, 1 × 15 g a,s./ha		
Mesocolfuron- methyl Mesocolfuron- methyl	≤ 50	No concern
Winter rye, 1 × 6 ga.s./ha		
Winter rye, 1 × 6 ga.s./ha Mesosulfuron- methyl 0.06	≤ 50	No concern

median value, MCA 7.1.3.1, mososulfmon Review Report (SANCO/10298/2003 final)

This evaluation confirms that the risk for bods from drinking water that may contain residues from the use of IMS + MSM MPR OD 42 is acceptable.

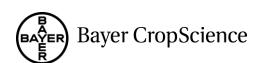
IIIA 10.1.2 Baits: Concentration of active ingredient in bait in mg/kg

Not applicable for spray application.

IIIA 10.44 Pellets, granules, prills or treated seed

Not applicable for spray application.

¹ EFSA (2009): Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA, p. 66



IIIA 10.1.4.1 Amount of active ingredient in or on each item

Not applicable for spray application.

IIIA 10.1.4.2 Proportion of active ingredient LDsceper 100 items and per gram of items.

Not applicable for spray application.

IIIA 10.1.5 Size and shape of pellet, granule or prill?

Not applicable for spray application.

IIIA 10.1.6 Acute toxicity of the formulation.

For animal welfare reason acute or structure and structure in the structur

For animal welfare reason, acute oral studies with formulations are roomely not conducted for birds, when the individual active ingredients have been shown to clearly be devoid of relevant toxicity to birds.

Based on LD₅₀ of both active substances and the afener contained in formulation IMS + MSM + MPR OD 42 consistently 2000 a.s./kg/bw, it is reasonable to assume that the product would not pose an unacceptable risk to birds. Therefore it is fustified to wave the acute test with the formulation in birds.

Supervised cage or field trials

The risk assessment based on the active substances indicate acceptable acute, short-term and longterm risks to birds (see Points) 0.1.1 and 10.1.2 of this dossier). For this reason and also considering field study with the preparation was deemed necessary. animal welfare, no Opervised cage or

treated seeds (palatability testing)

Not applicable for spray application

Effects of secondary poisoning IIIA 10.1.9

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeting on contaminated prey like fish or earthworms. For organic chemicals, a log Pow 25 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

of mesosulfaton-methyl was determined to be significantly below that trigger (see Table

Thus a risk assessment for a generic earthworm eating bird and a generic fish eating bird is not required since bioaccumulation of the substance is not to be expected.

Compound	log Pow	Reference	- O'
Mesosulfuron-methyl	-0.48 (pH 7)*	Reference (1996) M-142043-02 J CA 2.7	
Able 10.1.9-1: Log Pow values of more Compound Mesosulfuron Review Report (SANCO/10) Mesosulfu	0298/2003 final)	Reference (1996) (M-142043-02-1) (CA 2.7) (M-142043-02-1) (CA 2.7) (M-142043-02-1) (M-142043-0	
Q J			,

IIIA 10.2 Effects on aquatic organisms

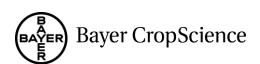
Ecotoxicological endpoints used in risk assessment

Table 10.2-1:

IIIA 10.2	Effects on aquatic or	ganisms		Q° &
Ecotoxicologica	al endpoints used in risl	k assessment		
Гable 10.2- 1:	Endpoints of the <u>formula</u>	<u>tion</u> IMS + MSN	M + MPR OD 4 2	2 used in risk assessment 💞 💍
Test substance	Test organism	Study type	Endpoint [mg/L]	2 used in risk assessment References
	Fish, acute		Ĉ ₃	A V A G
	Oncorhynchus mykiss (rainbow trout)	static acute, 96 h	LC ₅₀	C038/44 MQ25670-01-1 G1IIA 16/2.2.1/01
	Aquatic invertebrates,	acute 🛇		
IMS + MSM +	Daphnia magna (water flea)	statioacute,	EC 7.6	© 3815 k M-224 © 6-01-0 KIIIA, 10.2.2.2701
MPR OD 42	Algae			
	Pseudokirchneriella Subcapitata (green alga)	growth \$\frac{1}{2}\$ inhibition, \$\frac{1}{2}\$	l .0 .0"	(2003) (2003)
	Aquatic macrophytes	~ ~ · · · · · · · · · · · · · · · · · ·		
	Lemna giboa (duckweed)	growth inhibition,	10° ~	(2003) C0 7713 M 223377-01-1 KIIIA 10.8.2.1/01

Endpoints for the active substance mesosulfuron-methyl and metabolites used in **Table 10.2- 2:** risk

Test substance	Test organism	Testoystem	En o point [1	org/L]	References
	FishCacute O	~	<i>\(\)</i>		
Mesosulfuron-	Lepomis macrochirus (bluegill sunfish) Cyprinodon variegates (sheepshead minnow)	Acute station 96 by	LC ₅₀	> 100	et al. (1999) M-186666-01-1 KCA 8.2.1 /01 et al. (1999) M-186597-01-1 KCA 8.2.1 /02 (2001) M-238810-01-1 KCA 8.2.1 /02
	Fish, chronic	7)			
	Oncortoynchus mykiss (rainbow trout)	chronic, 28d	NOEC	32	et al. (2000) M-187567-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, a	icute			



Test substance	Test organism	Test system	Endpoint [mg/L]	References
	Daphnia magna (water flea)	Acute, static, 48 h	EC ₅₀ >100	et al. (1999) W186707-01-10 KCA 8.2.4.1 /01
	Mysidopsis bahia (mysid shrimp)	Acute, static, 96 h	LC ₅₀ >100	Abedi et al 2001 M-2388 V-01-1 KCA 8 2.4.2 DV
	Aquatic invertebrates, c	hronic 🙏	, , ,	
	Daphnia magna (water flea)	chronic, semi static, 21 d	NOEC 1.8	et al. (2000) M-197085-02 ₆ 2 KCA 8.2.5 1401
	Algae	Õ .Ü		
	Pseudokirchneriella & subcapitata (green alga)	Growth 96 h Growth inhibition 72 h	E _r C ₅₀ 3.99	
	Aquatic plant			<u> </u>
	Lemino gibba (duck weed)	Growth inhibition	£;C ₅₀ 0 0.00129	(2013) MA45139-01-1 CA 8.2.7 /09
		y/ d		M-487405-01-1 KCA 8.2.7 /10
	Aquatic plants (SSD whalys) based on daw for 11 species)	Growth inhibition	HCC 00017	M-329474-01-1 KCA 8.2.7 /08 (2013) M-445139-01-1
				KCA 8.2.7 /09
	Algae			<u> </u>
AE F\$34851	Psendokinomerilla subcapitata (green alga)	Growth inhibition, 724	E _r C ₅₀ 38.0	(2005) M-255087-01-1 KCA 8.2.6.1 /04
AE F\(34051	Aquatic plant	\$`.\$'_		T
4	Lemna gibba	Growth inhibition, static, 7 d	E _r C ₅₀ 0.11	(2005) M-255283-01-1 KCA 8.2.7 /11
	Algae	U		
ATE F1667359	Pseudôkirchnevilla subcapitata (ggen alga)	Growth inhibition, 96 h	$E_rC_{50} > 100$	et al. (2000) M-198314-01-1 KCA 8.2.6.1 /02
Æ F16 €4 59	Aquaticplant	1		1
S. S	Lemna gibba (duck weed)	Growth inhibition, static, 7 d	E _r C ₅₀ 2.6	(2000) M-198076-01-1 KCA 8.2.7 /03



Test substance	Test organism	Test system	Endpoint [mg/L]	References
substance	Algae	<u> </u>	<u> </u>	1
AE F099095	Pseudokirchnerilla subcapitata (green alga)	Growth inhibition, 72 h	$E_r C_{50}$ > 100	(2005) WI-254084-014 KCA 8.2.6 1,05
AL FUZZUZZ	Aquatic plant			
	Lemna gibba (duck weed)	Growth inhibition, static, 7 d	E _r C ₅₀ >Q0	M-279496-09-1 K 8.2.7012
	Fish, acute		Y &	
	Oncorhynchus mykiss (rainbow trout)	Acute, static	LC ₃ S 254	(1993) M = \$1422-\$1-1 K&A 8.241 /04
	Aquatic invertebrates, a	ıçirte		
	Daphnia magna (water flea)	Acute, static	EC. 233	(1993) W131382-01-1 XCA 2.4.1 /02
AE F092944	Algae			
122 2 4/2/11	Desmodesmus & Subspicatus & Su	Growth Cathibition,	₽ _r C ₅₀ + > 500	© (0993) • M-131421-01-1
	subspicatus) O (green alga)	72 h		KGA 8.2.6.1 /06
	Aquatic plant Lemna etha (duck weed)	Growth inhibition, static, 7 d	E _r C	M-186916-01-1 KCA 8.2.7/13
	Aggratic plant			11011 0.2.7 715
<i>i</i>	Agratic plant			(2000)
AE F160460	Lemna gibba (duck weed)	Growth inhibition static, 7.0	E1 50 > 100	(2000) M-199266-01-1 KCA 8.2.7 /04
	Aquatic plant		%	
AE F140584	Lemma gibbo	Growth inhibition static Tvl	©C ₅₀ > 10	(2014) M-486658-01-1 KCA 8.2.7 /14
<u> </u>	Algae	Station C	<u>p'</u>	1-2012 0.2.7711
	Pseudokirchnerilla	Growth 7	$E_rC_{50} > 100$	(2000) M-199529-01-1
Ÿ	(green atga)	, 96 h		KCA 8.2.6.1 /03
AE F147447 @	Aquatic plant		I	1
		Growth inhibition,	$E_rC_{50} > 100$	(2000) M-198273-01-1
- 5 S	A S	static, 7 d		KCA 8.2.7 /05

All above endpoints used in risk assessment are consistent with the *proposed* EU endpoints listed in Document N2 for mesosulfuron-methyl.

IIIA 10.2.1 Toxicity exposure ratios

Predicted Environmental Concentrations used in risk assessment

Formulated product:

Spray drift represents the only route that might lead to exposure of surface water to the formulated product. Since integrity of the formulation will be lost upon soil contact, indirect entry route such as run-off or drainage processes are not of relevance for formulation task assessment.

As a tier 1 approach, drift PECsw of the product is calculated sonsidering standard standard water body, which is 30 cm deep and without riparian vegetation

Table 10.2.1-1: Initial maximum PECsw values of the formulation, considering spray drift after one application as poute of entry relevant for the product

Compound	Scenario (arable crops) Scenario (arable crops) PECsw, max [µg/L] Winter vereat, 1 x 1,5 L/ha 1 x 9,6 L/ha PECsw, max [µg/L]
IMS + MSM + MPR OD 42	small static ditch, at the edge of the treated field, safer depth 0.3 m

PEC derived from calculation of entry in standard ditch via spray drift (water body of 30 cm depth), according to BBA (2006)², taking into account the specified density of the product (1.000 g/mI@ Bold values were used for risk assessment

Predicted invironmental concentrations for the active substance and its metabolites relevant for risk assessment were calculated in surface water (PECsw) and in sediment (PECsed) according to FOCUS surface water scenarios as described in detail in Point IIA 9.7 (active substance) and IIIA 9.8 (metabolites) of this MOP document.

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

ou for FER & our wisk assessments.

^{., (2006)} Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden, http://www.jki.bund.de/de/startseite/institute/anwendungstechnik/abdrifteckwerte.html

Table 10.2.1-2: Initial maximum PECsw values for mesosulfuron-methyl and its metabolites at FOCUS Steps 1 & 2

(a) originally submitted simulation – KIIIA 9.7/01 and KIIIA 9.7/01

nally submitted simulat	ion – KIIIA 9.7/01 and KIIIA 9.'	<mark>7/01</mark>	
Compound	FOCUS Scenario	Winter wheat, 1 × 15 g a.s./ha © PEC _{sw, max}	Winter ryes 1 × 6 g a.s./ha PEC max [µg/L] 0.395 0.481 0.069 0.069
	CTED 1	[μg/L] [*]	[μg/L] ***
Mesosulfuron-methyl	STEP 1	4.83 © * 1.202	0.481
	STEP 2 – Northern Scenario STEP 2 – Southern Scenario	1 202 1 2986	0.39\$
	STEP 1	0.7286°	\$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
AE F154851	STEP 2 – Northern Scenario	~ 0.178 °	9.069, Q
AE F154851	STEP 2 – Southern Scenario	90,40	0.056
	STEP 1 O Z	¥ 29.449 0°	\$ 0.180 a
AE F160459	STEP 2 – Northern Spenario	Q 0.128 C	0.043 0 0.043
	STEP 2 - Southern Scenario	O.1+08	0.043
	STEP 1 V V V	₹ £326 ×	0.120
AE F099095	STEP 2 Northern Scenario	0.079	0.032
	STEP 2 – Somethern Scenario	0.00	©.025 ©
A F F002044	STEP 1	0.099 0.024	0.040
AE F092944	STEP 2 North on Scenario (STEP 2 Southern Scenario	9/ ////	0.010
AE F160460	CTION 1 CT &	N 0 1800 0	0.164
	STEP 2 — Northern Scenario	Q 700	№ 0.104
	STEP 2 – Southern Scenario	0.082	0.033
AE F14@84	STER 1	0.229/	0.092
	STIP 2 - Northern Scenario	0.028	0.011
	STEP 2 Southern Scenario	№ 023 №	0.009
	STEPA Y	0.195	0.078
A F147477 0	STEID2 – Northern Seenario	0.054	0.022
	SIPP 2 – Southern Scenario	9(045	0.018
	STEP 2 — Northern Scenario STEP 3 — Northern Scenario STEP 4 — Northern Scenario STEP 4 — Northern Scenario STEP 2 — Northern Scenario STEP 2 — Northern Scenario STEP 2 — Southern Scenario STEP 3 — Northern Scenario STEP 3 — Northern Scenario STEP 4 — Northern Scenario STEP 4 — Northern Scenario STEP 3 — Northern Scenario STEP 4 — Northern Scenario STEP 3 — Northern Scenario STEP 4 — Northern Scenario STEP 4 — Northern Scenario STEP 5 — Northern Scenario STEP 6 — Northern Scenario STEP 6 — Northern Scenario STEP 7 — Northern Scenario STEP 8 — Northern Scenario STEP 8 — Northern Scenario STEP 9 — Northern Sce		

(b) alternative simulation using RMS requested modelling parameters- KIIIA 9.7/02 and KIIIA 9.8/02

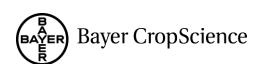
	, in its requested modeling para		
		Winter wheat,	Winter rye,
Compound	FOCUS Scenario	1 × 15 g a.s./ha	1 × 6 g a.s./ha
		PEC _{sw, max}	PECsw, max
		[μg/L]	γ [μg/L] γ , ζγ ,
	STEP 1	4.745	1.8987 7 6
Mesosulfuron-methyl	STEP 2 – Northern Scenario	1.849 🗸	0.740 . 9 27
	STEP 2 – Southern Scenario	1.504	\$\\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	STEP 1	0.701	0 0.293
AE F154851	STEP 2 – Northern Scenario	9.281	0.110
	STEP 2 – Southern Scenario	₹0.226 , ∘	2 0,090 C C
	STEP 1	0.45%	1.898 0.736 0.602 0.110 0.090 0.180
AE F160459	STEP 2 – Northern Scenario	© 0,191 ©	
	STEP 2 – Southern Scenario	0158	0.063
	STEP 1	0.158	0.061 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
AE F099095	STEP 2 – Northern Scenario	0.153	7 0.061
	STEP 2 - Southern Scenario	Q <u>Q Q 22</u>	© 0.049 ©
	STEP 1	9.109 0.041	0.0044 O
AE F092944	STEPO - Northern Scenario	© 0.0415 2	6017 🖔
	STEP 2 – Southern Scenario		0.013
	STEP 1 9 9 9	<u> </u>	0.164
AE F160460	STEP 2 Northern Scenario	∂ , 9.156	0.063
<u> </u>	STEP 2 – Southern Scenario	√ <mark>0.127 ∂</mark>	0.051
, Q	STOP 1 S C	0.049	√ 0.092
AE F140584 🥍		0.049 🏈	0.020
₩ .	STEP 2 — Southern Sconario	() ()	
AE F1. 447		0.105	
AE F1. 447	STOP 2 - Northern Scenario	Q.074 Q ,	0.030
	STEP 2 – Southern Scenario	Ø .061, \$	0.024
Dan valuara	road for Walt as Comparet	W.V.	

STEP 2 — Southern Scenario Q.074

STEP 2 — Southern Scenario Q.074

STEP 3 — Southern Scenario Q.074

STEP 3



Bold values were used for risk assessment.

B

Document MCP: Section 10 Ecotoxicological studies Iodosulfuron-methyl-sodium + Mesosulfuron-methyl +Mefenpyr-diethyl OD 42 (2+10+30 g/L)

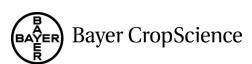
Table 10.2.1-3: Initial maximum PECsw values for mesosulfuron-methyl at FOCUS Step 3

(a) originally submitted simulation – KIIIA 9.7/01 and KIIIA 9.7/01) Mesosulfuron-methyl Winter rye, Winter wheat, **FOCUS** scenario 1×15 g a.s./ha 1 6 g a.s./ha PECsw, max PECsw, max [µg/L] Step 3 D1 (ditch) 0.161 0.063 0.047 0.118 D1 (stream) D2 (ditch) 1.601@ 0.376 D2 (stream) 1.010 **©0.366**© 0.096 D3 (ditch) 0.038 0.008 D4 (pond) 0.024 **√0.079**° D4 (stream) *-*0.031 D5 (pond) 0.011 0.0040.078 D5 (stream) 0.03/1 D6 (ditch) **0.102** ² 0.041 -0.002≥ R1 (pond) 0.006 0.140 R1 (stream) 0.043 $0.\overline{325}$ 0.130 R3 (stream) R4 (stream) ©.246 ^ℤ **©**.100

(b) alternative simulation using RMS requested modelling parameters— KIVIA 9.7/02 and KIIIA 9.8/02

	4.9		- A/V		01.
	FOCUS scendario		Mesosi	Afuron Chethal	0
	FOCUS scenario	O Wind	ter whoat, 5 & ax./ha		Winter rye,
	\$ Q \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \				× 6 g a.s./ha
	Step 3 D1 (ditch) D1 (stream)	Ö J× 1	Ccsw, max		PECsw, max [µg/L]
	Step 3			3	N O I
	D1 (ditch)			₩	0.075
	D1 (ditch) D1 (stream) D2 (ditch) D3 (stream)		0.187 0 7 0.132 \$ \$ 1.328 0 0		0.053
	D2 (ditch)		2.328 O' 'O'		0.510
			0.837		0.322
		P F	UNITYO & I		0.038
	D4 (sond)		6 035		0.013
	D4 (stream) D5 (pond)		0.080		0.032
R	D4 (stream) D5 (pond) D5 (stream)	`~\ Q	0.0 16 ″		0.006
	D5 (stream)		0.081		0.032
		/ N (N (N (N (N (N (N (N (N (N	Q 102		0.041
	RI (non/U) ~ ~ ~ ~ ~		0.007		0.003
	R1 (pont) R1 (stream) R3 (Gream)		0.111		0.045
		\ //	0.327		0.130
	R4 (stream) A Sold values were used for r	Y	0.266		0.108
	Bald valles were used for r	ick accecement		•	

Risk assessment



The risk assessment has been performed according to "Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC" (Sanco/3268/2001 rev.4 (final) 17 October 2002). The "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edgeof-field surface waters" (EFSA Panel on Plant Protection Products and their Residues, 2013, FSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290) has been considered where appropriate.

Toxicity exposure ratios (TER_A or TER_{LT} values) are calculated based on endpoints of the most sensitive species per organims group, and worst-case DEC_{SW} values

Summary of TER values for aquatic organisms

Table 10.2.1- 4: TER overview summary for formulated product, as detailed under points 19.2.1. Ltd 10.2.11

Crop / Organism Fine-seals | FOOTIGE 523

C /		Time-scale	FOCUS Step	TERO	rigger	Refinemen Qused?
Crop /	Organism	rime-scale	Fee US Step	TERO	grigger,	Refinemen
Compound	group	<u> </u>		y 8°		√
Winter wheat,	1× 1.5 L product/hå	N & C		638		~
IMS + MSM +	Fish @	, ≪a/cute "∅	I I CA I UI I II	0.038	~100 %	NO
MPR OD 42	Invertebrates	acuto	Tier 1 drift	© ¥ 5,490g	1000	No
	Green algae	√ long√erm	Tier l©drift		16	No
	Aquatic plants	long-term	Tier 1 drift	₹6 .38# ₽	'] \$\tag{9}0	No
Winter rye, 1×	0.6 L product/þa	lor@-term		% /.		
IMS + MSM +	Fish O	acute a	√Tier 1⁄drift	0 1 5 4	.r // 100	No
MPR OD 42	davertebrates &	acorte	Tier Vdrift @		100	No
	Green Qalgae 7	long-term	Tier 1 drift	# 211c	10	No
. (Green algae Aquaric plants sment on ductor at pro	Aong-terph	/Mer 1 drift	1 372 7 211 15.96	10	No
) no refined asses	smentsconducted at pro	duct level refin	erent at #Orive subs	tance 18/el will	cover the situati	ion for product
) no remied dissess	oment gondaetest at pro) A s	y of o	stance jever win	cover the situat	ion for product
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^{*)} no refined assessment conducted at product level, refinement at conve substance level will cover the situation for product.

Table 10.2.1- 5: TER overview summary for active substance mesosulfuron-methyl and detailed under points 10.2.1.1 to 10.2.1.11

6 /	detaned under point	m	DO CTTC		,	
Crop /	Organism	Time-scale	FOCUS	TER	Trigger	Refinement
Compound	group		Step	4 A	<u> </u>	used?!
Winter wheat,	1 × 15 g a.s./ha	4 -	G4 2	> 02 10	1000	
	Fish	acute	Step 2	> 83 195 26 622	100%	Now Now
		long-term	Step 2	₹ 200₩ > 27905		
İ	Invertebrates	acute	Step 2	> 85 \$95 498	100	
ı	Croon algae	long-term	Step 2	241 ©	10 V	ONO OF
ı	Green algae	long-term	Step 2		10	No No
		Flong-term		D1 (ditch) 7.27 D1 stream 9.92	2 ° ×	
İ		%		(ditch) 0.73		, W
		4		52 (stroam) 1.16		a co
M 1C				D3 (ditch) 12.79		
Mesosulfuron-		4 .^		D4 (pond) 48.75		
methyl				DA (stream) 14.81		O
İ	Aquatic plants	Song tom	Ston 2	D5 (poled) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		Yes
	Aquatic plants	Nong-worm	step 3	D3 (ditch) 1239 D4 (pond) 48.75 D4 (stream) 14.81 D5 (pond) 96.36 D5 (stream) 3.00 D6 (ditch) 11.47		y res
	a s		atep 3	DSOstream) \$3.00		
			O'	D 6 (ditch) 11.47©		
	W' (4 6	Ř1 (pond)		
	, Ø O			R1 (pond) 195.00 Ro (stream) 10.64	L.S	
	~ 4		, Ø,	Rat (stream) 70.64		
				R4 (stream) 3.60 R4 (stream) 4.76		
	Green algae	long-term	Step	R4 (stream) 4.76 4.76 219 653	10	No
AE F154851	Aquationlants	long-term		\$21,9 033 \$\infty\$636 \times\$	10	No
	Green algae	Long-term	Step 2	\$781 250	10	No
AE F160459	Agratic plants	long-term	Step 2		10	No
- Co	Green algae	long-term	Step	> 1265 823	10	No
AE F099695	91 007 41840 4 1	/AS.2//		- W // '' '' '' '' '' '' '' '' '' '' '' ''	10	No
	Fish	acute	Step 2	90 583 333	100	No
	Amvertebfates 2	acute *	Step	9 708 333	100	No
AE F092944	Green algae	long-term	Step 2	> 23 333 333	10	No
	Aquaric plants	Ming-term	Step 2	> 4 166 667	10	No
AE F160460	Aguatic plants	longsterm	Step 2	> 1 000 000	10	No
AE F140584	Aquatic lants	lon@term	Step	> 357	10	No
A E E1 45 0 5	Green algae	lorig-term	Step 2	> 1 851 852	10	No
AE F14/4/	Aquetic plants	long-term	Step 2	> 1 851 852	10	No
.*	29 A 0				•	
4		Q	7			
.(w`					
A STATE OF THE STA	, A & &	J 4				
		*				
	Aquatic plants Green algae Aquatic plants Aquatic plants Aquatic plants Aquatic plants Green algae Aquatic plants					



Crop /	Organism	Time-scale	FOCUS	TER	Trigger	Refinement
Compound	group		Step			used?
Winter rye, 1 ×	6 g a.s./ha		1		1	
	Fish	acute	Step 2	> 207 900	100	©No S
	1 1511	long-term	Step 2	66 528	10	√ No O
	Invertebrates	acute	Step 2	> 207 900	100	Ney
		long-term	Step 2	3 742	10 0	No (
	Green algae	long-term	Step 2	603	10,5	No No
Mesosulfuron- methyl	Aquatic plants	long-term	Step 3	D1 (ditch) 18.57 D1 (stream) 24.89 D2 (ditch) 30.79 D3 (ditch) 30.79 D4 (stream) 37.74 D5 (pond) 292.50 D5 (stream) 37.74 D6 (ditch) 28 R1 (pond) 27.21 R3 (stream) 79.00 R4 (stream) 71.79		Yes Yes
AE F154851	Green algae	long term	Step 2	5500725	0 10 3	NO
	Aquatic plant Green algae	Jong-term© long-teom	Step 2	960 2 84	100	No No
AE F160459	Aquatic plants	long-term	Step 2	50,080	©10	No
	Green algae	long-term	10/	> 3 4 2 5 000	10	No
AE F099095	Aquatic plants	bang-term	Step 2	© *3 125,000 ©	10	No
	Fish O	acute	Step 2	25 400 000 °C	100	No
	Avertebrates	acore	Step 2	© 23 300 000	100	No
AE F092944	Green Palgae	long-term	Step 2	25 300 000 27 > 56,000 Q00	100	No
	Aquatic plants	Aprig-term	Step 2	\$\frac{1}{2}\tau 000 \frac{1}{2}\tau 000 \frac	10	No
AE F160460	Aquatic plants Aquatic plants	long-term	Step 2	2 500,000	10	No
AE F14058	Aquatic plants	long-term	Step 2	\$909	10	No
~	Green algae	long-term	Step 2	(// n	10	No
AE F145047	A affection plants	Tong term	Oen 2 ×	J . O1 515 155	10	No
IIIA 10.2.1.© Table 10.2.1.1:	TERA for tish TERA calculations	(for mulated	product) for	24 545 455 4 545 455 or fish based on Tier 1 dr	ift calculat	ion
Crow / Compou	*		Endpoint	PEC _{sw,max}	TFR	Trigger

		point g/L]	PEC _{sw,max} [μg/L]	TERA	Trigger			
Winter wheat, 1×1.5 L product/ha								
IMS + MSM + MPR QD 42 mykis	EC50	8 830	13.85	638	100			
Winter ryca × 0.6 L product/ha								
IMS + MSM + MPR OD 42 O Tykiss	LC ₅₀	8 830	5.54	1 594	100			

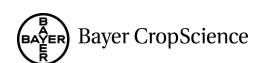


Table 10.2.1.1-2: TERA calculations (<u>active substance mesosulfuron-methyl and metabolites</u>) for fish based on FOCUS Step 2

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species	Endpoint [µg/L]	PEC _{sw,max} [μg/L]	TERA	Trigger
Winter wheat, 1 × 15 g	a.s./ha			, O	
Mesosulfuron-methyl	O. mykiss L. macrochirus C. variegates	LC ₅₀ > 100,000	1.262	> 83 495	100
AE F092944	O. mykiss	LC ₅₀ 254 000	Q0.024 °	10 583 333	Ĉ 100,€
Winter rye, 1 × 6 g a.s.	/ha	Q .			
Mesosulfuron-methyl	O. mykiss L. macrochirus C. variegates	LC 2100 000	0.481	\$207 900 \$\int \text{2}	100 .
AE F092944	O. mykiss	LC ₅₀ 254 000	y 02010 Q	25 400 000	200

b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

	, , , , , , , , , , , , , , , , , , , 	h <u>Go</u>				
Crop / Compound	Species	Endpe [μgA		PACsw,may	TER%,	Trigger
Winter wheat, 1 × 15 g			0		P &	
Mesosulfuron-methyl	L. maetochirus C. vaniegates	L _O 50	100,000	4 1.849	5 54 083	100
AE F092944	OL mykiss (*)	C LC ₅₀	254 000 ©	0.041	6 195 122	100
Winter rye, 1 × 6 g a.s./	ha & «		i Ji			
Mesosul furon-methy	L. Macrochirus G. vari eg ates	LC: D	1960 0000 P	Q 40	> 135 135	100
AE F0/2944	O. mokiss	LC ₅₀	254 000	0.017	14 941 177	100

All TERA values meet the required to gger of 100 bidicating an acceptable acute risk to fish for the intended uses

IIIA 40.2.1.2 TERLT for fish

Table 10.2.1.2-1: TERL calculations (active substance mesosulfuron-methyl) for fish based on

a) risk assessment based on PEC values of Figinally submitted simulation

	M S/ h	Endj [µg	ooint /L]	PEC _{sw,max} [μg/L]	TER _{LT}	Trigger
Winter wheat, 1 × 3/5	g a¸s√ha					
().	O. mykiss	NOEC	32 000	1.202	26 622	10
Winter rye, 1 × 6 g a.s	./ha					
Mesosulfuron-methyl	O. mykiss	NOEC	32 000	0.481	66 528	10



b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

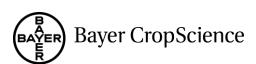
Crop / Compound	Species	End [μg	point g/L]	PEC _{sw,max} [μg/L]	TERLT	Exigger
Winter wheat, 1 × 15	g a.s./ha				Q,	
Mesosulfuron-methyl	O. mykiss	NOEC	32 000	1.849	17.306	7 719
Winter rye, 1 × 6 g a.	s./ha				° 0	
Mesosulfuron-methyl	O. mykiss	NOEC	32 000	0.746	43 243	10

Winter rye, 1×6 g a						
Mesosulfuron-methyl	O. mykiss	NOEC	32 000	0.740	43 243	10
			K	, É		
				Õ		
The TER _{LT} values more intended uses.	eet the required	trigger of 10,	indicating ar	n acceptable lo	ng-term fisk t	o fish for∜
ne intended uses.		()	e ·			j J
						.1
		4				
			r . W	~	\sim	
IIA 10.2.1.3 TEF	Ra for Daphni	ia 🔑 💸				
IIA 10.2.1.3 TEF	Ra for Daphni	ia J			S L L	
HA 10.2.1.3 TER Table 10.2.1.3-1: TER	RA for Daphni RA calculations (based on Tie	ia formulated pro drift calculated			tes F	
HA 10.2.1.3 TEF Table 10.2.1.3-1: TEF Crop / Compound	RA for Daphni RA calculations (based on Tie	formulated production of the p			tes O O	
HA 10.2.1.3 TEF Cable 10.2.1.3-1: TEF Crop / Compound Winter wheat, 1×1.5		formulated production of the p	delet) for aque from	PEOsw,max	tes O G	
	L product/ha	formulated pro O drift calculated bond (a)	delet) for aque from	PEOsw,max	tes FER	
Winter wheat, 1× 1.5	L product/ha	formulated pro-	dúct) for aqu	PEOsw,max		Trigger

TER calculations (active substance mesosulfuron methykand metabolites) for aquatic invertebrates based on FQCUS Step 2

a) risk assessment based on PEC yafues of originally submitted simulation

Crop Compound		Enapoint S	PEC _{sw,max} [μg/L]	TERA	Trigger
Winter wheat, 1 × 5 g a	s./ha 🖉 🦼				
Mesosulfuron-methyl Q	Domagna 0	1 Foc 50 5 100500	1.202	> 83 195	100
AE F09294 4 ♥ 🏻 💆	No. magna		0.024	9 708 333	100
Winter rye, 1 × 6 g a.s./h	a S				
Mesosur@uron-methyl &	Danaona	100 000	0.481	> 207 900	100
AE R092944	D. magna	©EC ₅₀ 233 000	0.010	23 300 000	100
AE 1092944					



b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

Crop / Compound	Species		idpoint μg/L]	PEC _{sw,max} [μg/L]	TER _A	Exigger
Winter wheat, 1 × 15 g a.s	<mark>./ha</mark>				O	
Mesosulfuron-methyl	D. magna	EC_{50}	> 100 000	1.849	> 54 083	100
AE F092944	D. magna	EC_{50}	233 000	0.041	5 682 92 °	į ⊗ <mark>100</mark> √9
Winter rye, 1 × 6 g a.s./ha			Ö	0,1		
Mesosulfuron-methyl	D. magna	EC_{50}	> 100,000	0.740	> 195 135	100
AE F092944	D. magna	EC_{50}	₄ 23 3 000	9 .017	1®705 882	P <mark>100</mark>

All TER_A values meet the required trigger of 00, indicating an acceptable acute 0 invertebrates for the intended uses.

IIIA 10.2.1.4 TERLT for Daphpa

Table 10.2.1.4-1: TERLT calculations (active substance mesosulfur on-methyl and metabolites) for aquatic overtebrates based on FOCUS Step 3

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species 4	Endpoint	Sw,max SYE	
Winter wheat, 1 × 15	g a.s./ha		Ö 47	
1	Ponagnà y	NOES 1-89	.202 1 4	198 10
Winter rye, 1 6 g a			W Qı	
Mesosulfuron-methyl	D. magna 🛇	NOE 1 800	481 3 7	742 10

b) risk assessment based on REC values of alternative simulation using RMS requested parameters

Crop / Compound Species Endpoint	PECsw,max [µg/L]	TER _{LT}	Trigger
Winter wheat, 1 × 15 g a.s. ha			
Mesosulturon-methyl D. magna V NOSC 1800	1.849	973	10
Winter rye, 1 × 6 g/3/s./ha			
Mesosulfuron-methyl D. magnet NOR 1800	0.740	2 432	10

The TER_{LT} values meet the required trigger of 10, indicating an acceptable long-term risk to aquatic invertebrates for the intended uses.

IIIA 10.21.5 TERA for aquatic insect

No specific studies on the acute toxicity of the product to aquatic insect species were conducted. The product is not an insecticide.



IIIA 10.2.1.6 TERLT for aquatic insect

No specific studies on the long-term toxicity of the product to aquatic insect species were conducted The product is not an insecticide.

IIIA 10.2.1.7 TERA for aquatic crustacean

No specific studies on the acute toxicity of the product to aquatic crustacean species were

IIIA 10.2.1.8 TERLT for aquatic crustacean

No specific studies on the long-term toxicity of the product to aqua conducted.

IIIA 10.2.1.10 TERLT for aquatic gastropod mollusc

No specific studies on the long-term toxicity of the product to aquatic gastropod pollusc species were conducted.

IIIA 10.2.1.11 TERET for algae.

Table 10.2.1.11-1:

TKR_{LT} calcollation (formulated product) for algae based on Tier 1 drift calculation

Crop / Compound Species Winter wheat, 1× 1.5 L product/ka	Endphint ([µg/L]	ECswanax [µg/L]	TER _{LT}	Trigger
Winter wheat, 1× 1.5 L product/ha				
THE CALL OF THE CA	,, •	13.85	484	10
Winter rye, 1 × 0.60 product/ha				
IMS + MSM + MPR OD 42	E ₁ C ₅₀ 6710 7	5.54	1 211	10
Winter wheat, 1× 1.5 L product/ha IMS + M\$M + MPR OD 42 Winter rye, 1 × 0.6 product/ha IMS + MSM + MPR OD 42 Subcapitata Subcapitata OD 42				

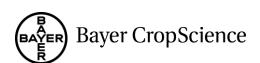


Table 10.2.1.11- 2: TER_{LT} calculations (<u>active substance mesosulfuron-methyl and metabolites</u>) for algae based on FOCUS Step 2

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species		lpoint g/L]	PEC _{sw,max} [μg/L]	TERLT	Trigger
Winter wheat, 1 × 15 g a.s./ha				X.	* O*	
Mesosulfuron-methyl	P. subcapitata	E_rC_{50}	<mark>>290</mark> 3 990 ♥	1.200	3349 ×	100
AE F154851	P. subcapitata	E _r C ₅₀	38 .9 90	0.173	249 653Q	30
AE F160459	P. subcapitata	E _r C ₅₀	2 00 000	₹0.12 % °	<i>₹</i> 781 2 50	0 10
AE F099095	P. subcapitata	E _r C ₅₀	♦ 100 000 6 6 6 6 6 6 6 6	0,099	× 1,265 823,	J 70
AE F092944	P. subcapitata	E _r C ₅₀	> 560 000	0.024	> 25, 333 338	10
AE F147447	P. subcapitata	E _r C ₅₀	×100 000	© 0.05 ©	×1 851 852	→ 10 <u>,</u> °
Winter rye, 1 × 6 g a.s	s./ha			, A. C		
Mesosulfuron-methyl	P. subcapitata	E _r Cy	290 2990	0.481	8 2965	0 10
AE F154851	P. subcapitato	ErC ₅₀	38 000	0.009	550 725 4	10
AE F160459	P. subcapitata	E_rC_{5}		Q .051	≥ 6960 784	10
AE F099095	P. subçaritata	$\mathcal{F}_{\mathbf{E}_{\mathbf{S}_{0}}}$	>900 000	0.032	93 125 0 00	10
AE F092944	P. sybcapitate/	EC 50	> 560 0 000	QQY0 -	> 56 6 00 000	10
AE F147447	P. subcapitata	©E _r C ₅₀	> 100 000	19.022 P	345 455	10

b) risk assessment based on PEC values of atternative simulation asing RMS requested parameters

Crop / Endpoint Compound Compo	EC _{swant} [μg/L]	TERLT	Trigger
Winter wheat, 1 × 19 g a.s. ha			
Mesosulfüron-methyl P subcapitata ErCs0 3-990	1.849	3 319	10
AE F194851 P. subcapitata	0.281	135 231	10
AE F160459 $P.$ subcapitata $\sim E_rC_{50} \sim > 100 \checkmark 000$	0.191	> 523 560	10
AE F099095 Q E. subcapitata E. E. 100 000	0.153	> 653 595	10
AE F092944 P. subgapitato SC 50 560 000	0.041	> 13 658 537	10
AE F147447 P. Subcapitala SE _r C ₅₀ > 199 000	0.074	> 1 351 351	10
Winter Oc, 1 × 6 g a,s. Apa			
Mesosulfuron-methy P. subcapitala C ₅₀ 3 990	0.740	5 392	10
AE V 154851 P Subcapitata PErCs 38 000	0.112	339 286	10
AE F160459 P. subclipitata E. S. > 100 000	0.076	> 1 315 789	10
AE F099095 P . subcapitata $E_1C_{50} > 100 000$	0.061	> 1 639 344	10
AE F092944	0.017	> 32 941 176	10
AE F14.7447 \mathcal{Q} P . subcapitata $\mathbb{E}_{r}\mathbb{C}_{50}$ > 100 000	0.030	> 3 333 333	10
	•		

The TERO's values meet the required trigger of 10, indicating an acceptable long-term risk to algae for the intended uses.

TER for aquatic plants

Table 10.2.1.11-3: TERLT calculations (formulated product) for aquatic plant based on Tier 1 drift calculation

Crop / Compound	Species	Endpoint [μg/L]		PEC _{sw,max} [µg/L]	TERLT	Trigger
Winter wheat, 1× 1.5	L product/ha				, O	
IMS + MSM + MPR OD 42	L. gibba	E _r C ₅₀ 88	3.4	13.85	6.38	100
Winter rye, 1× 0.6 L	product/ha		. Ĉ	Ž.		
IMS + MSM + MPR OD 42	L. gibba	E _r C ₅₀	3.4	5.56	Q 15.06	100

Bold values: trigger is not met and further refinement is required

Refined risk assessment for the formulated product.

For the drift entry of the fermion of the f For the drift entry of the formulated product to higher tier exposure calculations are available. DOCUS surface water calculations can only be performed for the individual active substances

PEC_{sw} calculations (tier 1 as well as FOGUS surface water) are based on the scenario of immediate equal distribution of the active substance in the water body. Under these conditions - instant and equal dilution in a big water volume - it can be assumed that the properties of the formulants will no longer influence the behaviour of the active substances. The same scenarious also reflected in laboratory tests on aquatic plants, where the test item is equally distributed in the test solution before test organisms are put in the system and where the formulation additionally decomposes over the test period of a 7day static test.

Given the well-known exceptional toxicity of sulfonyl brea type (ALS inhibitor) herbicides to aquatic plants, especially to Lengua gibbel, it is justified to assume that the Exicity of the formulated product originates exclusively from a ditive effects of its contained active substances mesosulfuron-methyl and iodosulfuron-methyl-sodium for confirmation of this hypothesis, an expected endpoint for the fractional active substance composition of the product was calculated based on the individual substance endpoints, and found to be matching the actually measured formulation endpoint within 98.4 μ g/L vs. measured product E_rC₅₀ =88.4 natural biological variance calculated expected ErC μg/L; cf. Table 10.2.1.14

Calculation of the acut mixed toxicity of the formulation according to Finney

	Mesosulfuron-methyl	Iodosulfuron-methyl-	IMS + MSM + MPR				
		sodium	OD 42				
Content within the product[%]	¥ 1.0	0.2	-				
	Effects on Lemna (L. gibba)						
ErC50 Mag as/16	1.29	0.83#					
ErCy – added toxicov	Calculated ex	epected ErC50	Measured E _r C ₅₀				
[pg prodoct/L]	98	88.4					

^{*)} EU list of endpoints for iodosulfuron-methyl-sodium [SANCO/10166/2003-Final]

The risk assessment for aquatic plant can therefore safely be performed on individual active substance basis; any refinements made in these assessments will apply for the formulated product as well.

For the purpose of the present MCP document, however, assessments will only address the active substance mesosulfuron-methyl eligible for Approval renewal. Assessments for the second active substance, iodosulfuron-methyl-sodium, will be provided at a later stage as part of the post process.

Table 10.2.1.11-5: TERLT calculations (active substance mesosulfuron-methyl aquatic plant based on FOCUS Step 2

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species	Eng.	point g/L]	PEC _{sw,max}	av skr	Trigger
Winter wheat, 1 × 15 g	g a.s./ha			01.200		O
Mesosulfuron-methyl	L. gibba	F. 50	£29 \$	1.200	1.95	3 10
AE F154851	L. gibba 🍳	E_rC_{50}	110%	0073	∱ 6 636 ~	10
AE F160459	L. gibba 🔍 🧸	E _r C ₅₀	2,600	″I ⊿00 128 🖤	20313	10
AE F099095	L. gibba 👢	E 50	> 100 000	0.079	> 1 265 823	10
AE F092944	L, gabba O	$\mathbb{Z}_{r}C_{50}$	> 100 000	0,924	> 4 66 667	10
AE F160460	L. gibba	E _r C	≥ 3 00 00€	0.100	\$ 000 000	10
AE F140584	L. gibtor 🙏	$E_{r}C_{50}$	(*) 10 (*)	0.028	> 357	10
AE F147447	L. 🖏 ba 💍	$\mathcal{L}_{r}C_{50}$	`> 10469≥0000 (0	0.054	> 1 851 852	10
Winter rye, 1 × 6 g a.s			N S			
Mesosulfuron methyl	L. gib © a O	E C 50	1100	0.481	2.68	10
AE F154856	L. gibba 🔎	$\Delta E_r C_5$	1100	6 .069	1 594	10
AE F160439	C gibb _o C ,	E_rC_{50}	2 (\$00 \(\sqrt{\sin}}}\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sq}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}	2 0.051	50 980	10
AE F099095	L. gibba	EC 50 %	> 100 000	0.032	> 3 125 000	10
AE F092944	L. gibba 🧳	$\sum_{r} E_r C_{50}$	> 100 000	0.010	> 10 000 000	10
AE F160460	6. gibbe	E_r	×100 000	0.040	> 2 500 000	10
AE F140584	L. gibba 🤝	≈E,C ₅₀ %	> 10	0.011	> 909	10
AE F147447	W	E _r C ₅₀₀	> 1000 000	0.022	> 4 545 455	10
AE F147447 old value of rigger is not n	and the there rely	Makement 13 req				

b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

Crop / Compound	Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	TER _{LT}	Exigger
Winter wheat, 1 × 15	g a.s./ha			\$\frac{1}{2} \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qquad \qqquad \qqqqq \qqqqqqqqqqqqqqqqqqqqqqqqqqqqq	
Mesosulfuron-methyl	L. gibba	E_rC_{50} 1.29	1.849	0.70	1
AE F154851	L. gibba	E_rC_{50} 110	0.281	391, O	Ø 10 Ø
AE F160459	L. gibba	E _r C ₅₀ 2 600	0.191	13 643	10,5
AE F099095	L. gibba	E_rC_{50} > 100 000	0.433	65 % 595	
AE F092944	L. gibba	E_rC_{50} ≥ 100000	Q.041	2 39 024 √	O 10 (V)
AE F160460	L. gibba	E _r C ₅₀ 700 000	0.15	Q 641 Q 6	
AE F140584	L. gibba	E_rC_{50} > 10 .	0.049 0	, <mark>204</mark> . «	
AE F147447	L. gibba	E _r C ₅₀ > \$00 000	9.074	351 351 x	10
Winter rye, 1 × 6 g a.s	s./ha	A			O V
Mesosulfuron-methyl	L. gibba	1.29 1.29	ð <mark>0√740</mark> √	` ₄1 ,74	
AE F154851	L. gibba	ErCso 130	0.112	Ø 982 F	10
AE F160459	L. gibba	E ₆ C ₅₀ × 2600 × 3	0.070	§ 34.291 J	10
AE F099095	L. gibba 🗣	$E_rC_{50} \gtrsim 200000$	0061	1 6 3 344	10
AE F092944	L. gibba	ErC50 > 00 000	0.017	882 353	<mark>10</mark>
AE F160460	L. gibba 👢	$E_{50} > 100,000$	√ 0.063 (1 587 302	10
AE F140584	L. goba O'	E _r C ₅₀ ≥ 10	\ \ \ 0 \\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	′ √ 500	10
AE F147447	L. gibba	ErC 2000 000	6.030 0.030	333 333	10

Bold values: trigger is not met and withher retinement is require

The TER_{LT} values for the parent active substance mesosulforon-methyl do not meet the trigger of 10 based on FOCUS Step 2 PEG values The trigger to met for all metabolites.

Therefore, in the next step, TER values are calculated based on more realistic FOCUS Step 3 PEC values, for the parent active substance only.

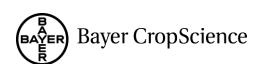


Table 10.2.1.11-6: TER_{LT} calculations (<u>active substance mesosulfuron-methyl</u>) for aquatic plant based on FOCUS Step 3

a) risk assessment based on PEC values of originally submitted simulation

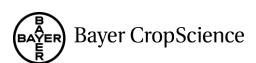
Crop / Compound	Species	Endpoint [μg/L]	Focus scenario	PEC _{sw,max} [μg/L]	TER _{LT}	Trigger
Winter wheat	, 1 × 15 g a.s	s./ha		<u> </u>)	
			D1 (ditch©	0.161	8.01	
			D1 (stream)	0.148	10.93	
			D2 (dich)	1 .601	(0)81	
			D2 stream)	1.010 Q	Q1.28 O	
			D3 (ditch)	© 0.9 %	_∂ 13•4	
			D4 (gond) 🔬	0024	55.75	.1
Mesosulfuron	L. gibba	F.C. 1.20 ♣	D4 stream	Q0.079	16.33	
-methyl	L. gioda	E_rC_{50} 1.29	D5 (pond)	0.Qf	O 117Q7	
		,	D5 (stream)	.0978 ×	16 .54	
			D6 (ditck)	~0.102°	\$\text{12.65}	
		Q [*] &	R1 (pand)	0.006	© 215@0	~~~
			R1 (stream)	1 0 110 °	D.73 &	
		J 4, 5	R3 (stream)	L 0.325	⊘ 3.97	
	٥,	E _r C ₅₀ 1.29	4 (stream)	0.246	× 5.24	
Winter rye, 1	× 6 g a.s./ha			v		
	Ģ		Dr (ditch)	00.063∜	2 0.48	
			DI (stream)	© 0,047	, * 27.45	
		4 4, 2	D2 (Witch)	Ø .576, \$	2.24	
7			D2 (stream)	0.366	3.52	
Massay	100		Ď3 (dájeh)	0.638	33.95	
	Š		D4((pond)	% .008	161.25	
Mesosulfuron	I gibeh		D4 (stream)	0.031	41.61	10
-methyl	L. galoya		D5 (pond)	0.004	322.50	10
			D5 (stream)	0.031	41.61	
~C			Do (ditch)	0.041	31.46	
4			R1 (pond)	0.002	645.00	
	, Q		R1 (stream)	0.043	30.00	
***		A' A' O'	(stream)	0.130	9.92	
		Y ZY Q	R4 (stream)	0.100	12.90	

Bold values: trigges is not met and further refurement so required

The following scenarios do not pass the fisk assessment for mesosulfuron-methyl at FOCUS Step 3 and require a reffred risk assessment:

for intended use an winter wheat, 1×1.5 L prod./ha = 1×15 g a.s./ha

- D1 ditch
- D2, ditch & stream
- R3, stream

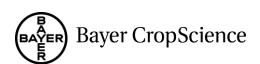


- R4, stream

• R4, stream			Q° 🎘
 R4, stream for intended use on winter rye, 1× 0.6 D2, ditch & stream R3, stream b) risk assessment based on PEC values of alternative Crop / Compound Species Endpoint [µg/L] 	6 L prod./ha = 1×6 g a.s./ha	Ş	
b) risk assessment based on PEC values of alter	native simulation using RMS req	uested parame	
Crop / Species Endpoint [µg/L]	Focus scenario PECsw.max	TER _{LT}	Træger
Winter wheat, 1 × 15 g a.s./ha	\$\frac{1}{\sqrt{2}} \frac{1}{\sqrt{2}} \frac{1}{\sq		
		9.77 5 5 0.97 1.584	
Mesosulfuron Toribba	D3 (ditcl) 0.096 0.096 0.038 0	\$3.44 © \$36.86 . \$4013 &	10
-methyl	D5 (pond) \(\text{Q0.016} \) \[\begin{align*} \text{D6 (stream)} & 0.984 \\ \text{D6 (stream)} & 0.102 \\ \text{D6 (stream)} & \text{D6 (stream)} \\ \text{D6 (stream)} & \text{D7 (stream)} \\ \text{D6 (stream)} & \text{D7 (stream)} \\ \text{D7 (stream)} & \text{D7 (stream)} \\ \t	80.63 O' 15.92 12.65	
	R (pond) 0.00	11.62 3.94	
Winter rye, 1 × 6 g 25./ha	R4 (stream) \$0.266	4.85	
Mesosulfuron -methyl Winter rye, 1 × 6 g a.s./ha Mesosulfuron -methyl L. gibba L. gibba 1. 29	D1 (ditch) 0075 DC(stream) 0.053 D2 (ditch) 0.510	17.20 24.34 2.53	
	D2 (stream) 0.322 D3 (ditch) 0.038 D4 (pord) 0.013 D4 (stream) 0.032	4.01 33.95 99.23 40.31	
Mesosulfaron -methyf	(pond) 0.006 (pond) 0.006 (0.032) 0.032	215.00 40.31	10
	D6 (ditch) 0.041 R1 (pond) 0.003	31.46 430.00	
	R1 (stream) 0.045 R3 (stream) 0.130	28.67 9.92	
	R4 (stream) 0.108	11.94	

Bold Mues: tregger is not met and further refinement is required

The following scenarios do not pass the risk assessment for mesosulfuron-methyl at FOCUS Step 3 and require a refined risk assessment:



- Refined aquatic risk assessment for active substance mesosulfuron-methyl:

 probabilistic assessment species sensitivity distribution and HCs approach

 in addition to the tier 1 laboratory 7-gay endpoint for Lemma gibba (ErC\$0 of k29 µg @8./L).

 An outdoor growth inhibition study with nine macrophytess (KCA 8.2.7 /08) tested sensitivity tomesosulfuron-methyl systems representing a typical stage water body)

 Since for biological reason Lemma could an analogous 8-week laboratory

 2013; MA445139-01

 was mimicked in endpoint endpoints from the outdoor study.

The results of these two studies allow for species sensitivity distribution (SSD) analysis. E_rC_{50} values for the nime species tested in the outdoor ponds ranged from 2.1 µg a.s./L (Pontederia cordata) to > 25 ug a.s./Nymphaea Bdorata Cabomba carolinia a, Glyceria maxima). The lowest endpoint for week 8 in the Lemma gibba bioas any was 9.9 μg a.s./L E_rC₅₀ for frond number).

The complete data set from both studies was used for calculation of the EC50-based median HC5 value $(2090)^3$. Endpoints that are not discrete numbers according to

("greater-than" figures for Nymphaea of grata Cabomba caroliniana, Glyceria maxima) were thereby ignored.

Table 10.2.1.11-7: Survey of aquatic plant endpoints used for the calculation of the HC5

Species A Q	ErC ₅₀ (μg/L)	
Lemna gibba (8 week)		
Pontederid cordetti o	2.1	W WG 445 7
Elodeg Fanadensis 🔬 🧳	3.8	median HC ₅ = 1.17 μg/L
Ceresophyllam demersum	5.3	n=7
Pojamogelin pectinatus	7.1	
Mentha aquatica	12	

^{(2000):} Uncertainty of the hazardous concentration and fraction affected for normal species sensitivity distributions. Ecotoxicology and Environmental Safety, 46: 1-18.

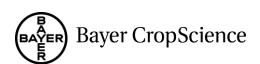
Myriophyllum heterophyllum	22	
Nymphaea odorata	(>25)	('greater than' figures were omitted from
Cabomba caroliniana	(>25)	the calculation; the HC5 will increase if the
Glyceria maxima	(>25)	'greater than' figures are include

Cabomba caroliniana (-25) the calculation; the HCS will increase if the greater than figures are metadeful from the lowest Ecol figure as reactions from the uniterest from the uniteres

Table 10.2.1.11-8: Refined TER_{LT} calculations (<u>active substance mesosulfuron-methyl</u>) for aquatic plant based on FOCUS Step 3 and median HC₅

a) risk assessment based on PEC values of originally submitted simulation

Compound	Species	Endpoint [μg/L]	Focus scenario	PEC _{sw,max} [μg/L]	TERLT	Trigger
	1 × 15 g a.s./ha	[F-8]		<u> </u>	<u> </u>	N W
·			D1 (dich)	0.161	7.27	
			D1 (stream)	0.108	9.9%	
			Da (ditch)	4 √601	(C73	
			(stream)	1.010	Q1.16 O	
			D3 (ditch) Q	0,096	_∞ 12≱3	
		\$	Da (pond)	0.024	48.75	[
Mesosulfuron-	Aquatic	HC. 1.4	4 (str@m)	0.079	14.81	
methyl	macrophytes	HC ₅ Liv	D5 (pond)	0.014	© 106√3/6	
			D5 (stream)	9 .078 %	6.00	
			D6 (ditch)	0.102	Ñ1.47	
		Q' O Q	R1%pond)	0,0006	[©] 195 . 00	
			R (stream)	Ø.110 [©]	% 0.64 €	1
	4		R3 (stream)	0.325	3.60	
			R4 (stream)	0.246	¥ 4.76	
Winter rye, 1 ×	6 g a.s./ha					T
			D1 (diteh)	0.063/	18.57	<u> </u>
			D1 (Stream)		, 24.89	 -
		Y & ?	DZ (ditolo)	Ø.576 \$	2.03	 -
8			D2 (stoam)	0.366	3.20	
	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		D3 (ditch)	0.038	30.79	
			DA (pond)	0.008	146.25	
Mesosulfuron-	Aquatic 🔊	#C 017 4	D4 (stream)	0.031	37.74	3
4 1	1 00 1 00					
methyl	macrophytes		D5(pond)	0.004	292.50	
methyl	magrophyles		D5 (stream)	0.031	37.74	
methyl	macrophyles		D5 (pond) D5 (stream) D6 (ditch)	0.031 0.041	37.74 28.54	
methyl	macrophyles		D5 (pond) D5 (stream) D6 (ditch) R1 (pond)	0.031 0.041 0.002	37.74 28.54 585.00	
methyl	magrophyles		D5 (stream) D6 (ditch) R1 (pond) R (stream)	0.031 0.041 0.002 0.043	37.74 28.54 585.00 27.21	
methyl	macrophyles		D5 (pond) D5 (stream) D6 (ditch) R (pond) R (stream) R3 (stream)	0.031 0.041 0.002	37.74 28.54 585.00	



b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

Crop / Compound	Species	Endpoint [µg/L]	Focus scenario	PEC _{sw,max} [µg/L]	TER _{LT}	Triggor Control of the control of th
Winter wheat,	1 × 15 g a.s./ha				6.26	
			D1 (ditch)	0.187	© 6.26	
			D1 (stream)	0.132	» <mark>8.86</mark> ₅	
			D2 (disch)	1.328	0.88 🛫	
			D2 (stream)	0.837	8.86 0.88 1.40	
			D& (ditch)	9 .096	1019	
			P4 (pond)	0.035	33.43	
Mesosulfuron- nethyl	Aquatic macrophytes	HC₅ 1.17 &	, <u> </u>	\$.016	75.13	3 3 1
inctify!	macrophytes	O	Do (ponet) 75 (str@m)	Q 0.081	14.440	
			D6 (ditch)	V	0 11:47	
			RI (pond)	9.007	16714	
			XI (stream)		10.54	<u></u>
			R3 (Stream)		3.53	
	all a		RA (stream)	0.266	10.54 10.54 3.58	
Winter rye, 1	× 6 g a.s./ha		4 02	0.027	Ca	
	~ Q	O' B' E	Dl (ditch)	Q.975 ~	× 15.60	
	\ \%\\ \%\\\\		DW (stream)	0.053	37 .08	
			D2 (ditch)	0.510/	2.29	
			D2 Gtream	Q.322		
, (D3 (ditch)	0.038	30.79	
Ĉ			D4 (pond)	0.013	90.00	
Mesosulfur@n-	Aquatic	HC 5 € 1.17 ©	D4 (stream)	0.006	36.56 195.00	3
nethyl (*)	W S		(ctreen)	0.006 0.032	36.56	
·			De ditch	0.032	28.54	
			Rel (north)	0.003	390.00	-
	ن کی کی		R1 (stream)	0.045	26.00	
.4			R3@stream)	0.130	9.00	
		HC: WALLT	RA (stream)	0.108	10.83	
	29 1		-	•		

The refined risk assessment of mesos affuror methyl passes all Focus Step 3 scenarios, except D2. Since the PEC values simulated for scenario D2 are driven by the entry route drainage (cf. Document MCP, Section 9.7) mitigation options as implemented in FOCUS Step 4 (e.g. drift buffer zones, vegetated filter drips) would not reduce the aquatic exposure to mesosulfuron-methyl for this particular scenario struction. Therefore, no further risk assessment based on FOCUS Step 4 calculations is presented in the MSs concerned with the D2 scenario, a local restriction of product use on drained fields during drainage season will be proposed in the national dossiers submitted in the post Approval re-registration process.



Supplemental information: Comparison of predicted exposure profiles versus exposure regime tested in the higher tier studies

For the following GAP and FOCUSsw scenario situations, a refined endpoint (HC5) from higher tied studies on aquatic macrophytes was used to resolve the risk assessment:

• for intended use on winter wheat, 1×1.5 L prod/ha = 1×15 g s/s/ha
• D1, ditch
• R3, stream
• R4, stream

• D2, stream
• R3, stream
• R3, stream
• R3, stream
• R3, stream
• R3, stream
• R3, stream

According to the Aquatic Guidance Document⁴, For a straightforward risk and effect assessment, the exposure regime of the PRP in the ecotogicological test should be realistic to worst case relative to the predicted exposure regime in the edge of-field surface water under consideration. An evaluation of this criterium for the higher approach used is made below.

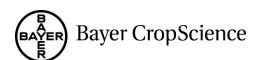
Exposure regime underlying the higher tier studies used for HC5 derivation:

For mesosulfuron-methyl, an outdoor growth inhibition study with nife macrophytes over 8 weeks has been performed (2009; M-329474-01 Q, KCA 8.2.7008). The climatic conditions during the outdoor test at the site of Smithers Viscient (formerly Smithers Springborn) in Massachusetts resemble the conditions in middle Estrope. Analytical measurements were made during the study and indicate a dissipation of mesosulfuron-methyl similar to that in water sediment studies investigating the environmental fate and behavior of the compound in order to also address the effects on Lemna gibba⁵ for an analogous exposure regime the dissipation of mesosulfuron-methyl observed during the outdoor growth inhibition study was mimicked on a weekly base under sterile conditions in the laboratory (2013; M-445139-01-1 &CA 80.7 /09).

For this test, the exposure regime was derived to follows: The mean percentage levels of mesosulfuron-methyl analytically determined for the three highest treatment levels of the pond study were 100 %, 70.70 % 56.48% and 35.31 % for day 0, day 14, day 28, and day 54, respectively. Based on these measured values Figures, for dos 7, 21, 35, 42, and 49 were interpolated, and a stepwise weekly reduction in test item concentration was used to mimic the outdoor dissipation of mesosal furon methyt in the laboratory study on Lemna gibba (cf. Table 10.2.1.11-9). After each 7-

⁴ "Guidance" on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters' QEFSA Panel on Plant Protection Products and their Residues, 2013, EFSA Journal 2013)

⁵ For biological reason, this species could not be cultivated simultaneously in the pond systems of the above study.



day-period an aliquot of fronds were transferred to freshly prepared test medium of the subsequent concentration level. *Lemna* clearly represented the most sensitive of all macrophytes tested, cf. Table 10.2.1.11-7.

Table 10.2.1.11- 9: Study exposure timecourse of mesosulfuron-methyloased on the analytical findings of the outdoor growth inhibition study, and weekly interpolated values used for laboratory test on Lemna gibba

<mark>day</mark>	<mark>%</mark>	comment of the commen
Day 0	100.00	Mean of measured recoveries at the three highest concentrations
Day 7	84.08	Geometric mean between day 0 and day 14 figure
Day 14	<mark>70.70</mark>	Mean of measure recoveries at the three highest concentrations
Day 21	63.19	Geometric mean between day 14 and day 28 figure
Day 28	56.48	Mean of measured recoveries at the three highest concentrations
Day 35	50.22	Geometric mean between day 28 and day 42 figure
Day 42	<mark>44.66</mark>	Geometric mean between day 28 and day so figure
Day 49	39.71	Georgetric mean between day 42 and day 56 figure
Day 56	35.31	Mean of measured recoveries at the three highest concentrations

Comparison of predicted surface water concentration profiles versus study exposure regime:

To compare the predicted exposure profiles for the critical FOCUSsy scenarios with the exposure regime of the ecotoxicological tests, a graphical visualisation is provided in Figures 10.2.1.11-1 to 10.2.1.11-4 as follows:

red line: Simulated aquatic exposure profile: concentration over time resulting from Step 3

FOCUS of calculation (cf. singulation) reported in KIIIA 9.7 /01, plots reported in KIIIA 9.7 /02. The diagraphs show a time frame focusing 1 week before maximum to 8 weeks after maximum.

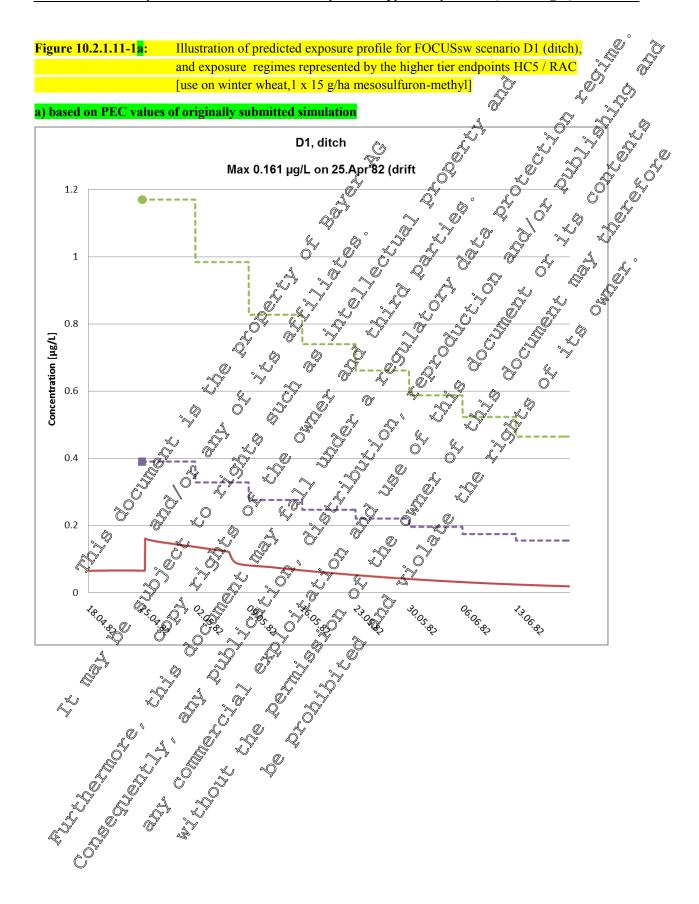
green dot: μ 05 value = $1\sqrt{7} \mu g/b$ (derived acc. Tables) 0.2.1.11-7)

violet square: RAC value 0.39 pg/L (Based on HC5 value divided by assessment factor of 3).

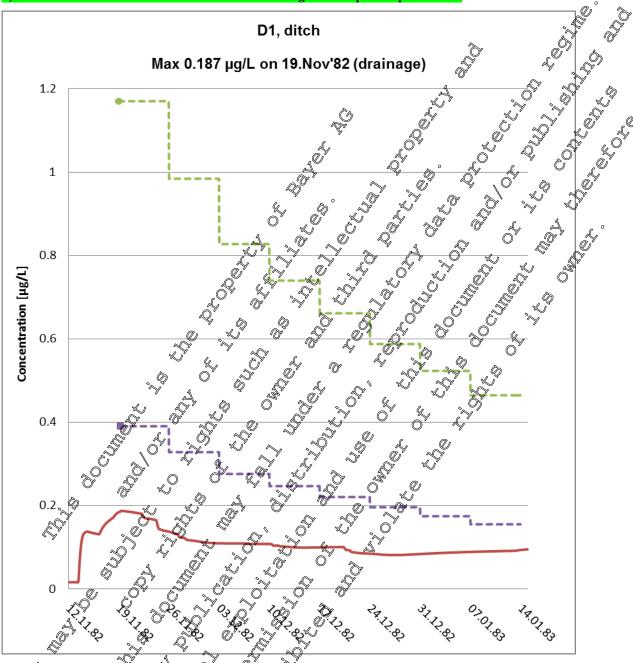
dashed green one: Relative flustration of the exposure regime in the studies used for derivation of the HC5 endpoint. For resualisation, a time is plotted starting at HC5 level at the time of PEC_{sw,mo}, with stepwise decrease according to the percentual figures in Table 19.2.1.14-9, based on the analytical results of the pond study.

dashed violet line. Analogous of green dashed line, but relative to the RAC value.

Note that only the specific data point of the HC5 and/or RAC value is the relevant endpoint for use in straightforward risk assessment via comparison with PEC_{sw, max.} Technically, these HC5 and/or RAC endpoints represent the integral exposure regime over an 8 week period that may be described as the area under the dotted line graphs. Therefore, the most relevant parameter for comparison of study exposure regime vs. predicted exposure profiles is the areas under the curves.



b) based on PEC values of alternative simulation using RMS requested parameters



Interpretation: PEC_{sw, max} is clearly below RAC (HC5 divided by AF=3). The integral of predicted exposure over time does clearly not exceed the exposure × time regime represented by the higher tier endpoints. Therefore, the cotoxicological test exposure regime was worst case relative to the predicted exposure regime in the edge-of-field surface water under consideration for scenario

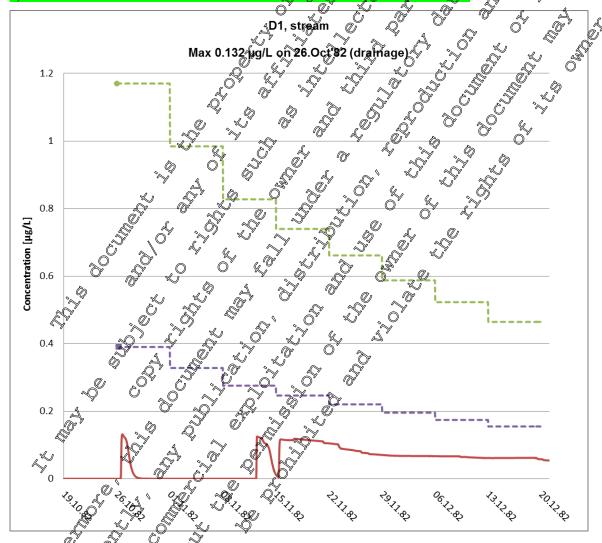
Figure 10.2.1.11-1b:

a) based on PEC values of originally submitted simulation

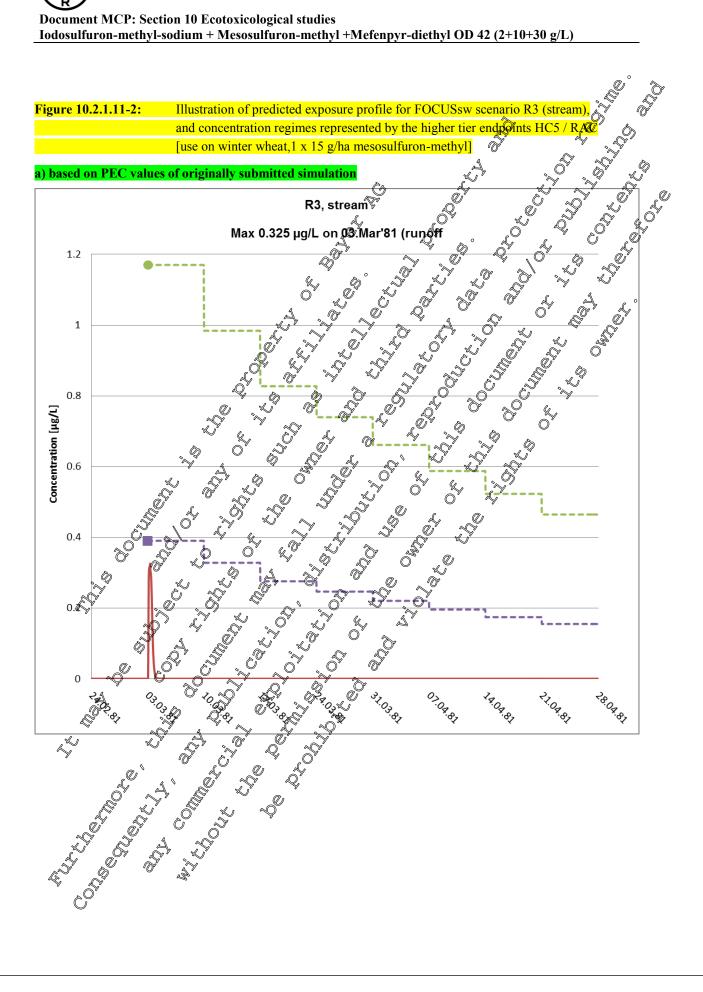
a) based on PEC values of originally submitted simulation

No refinement based on pond study endpoint was needed to pass risk assessment for scenario Destream when using PEC values of the originally submitted simulation; a comparison of FOC study exposure regime is therefore not required.

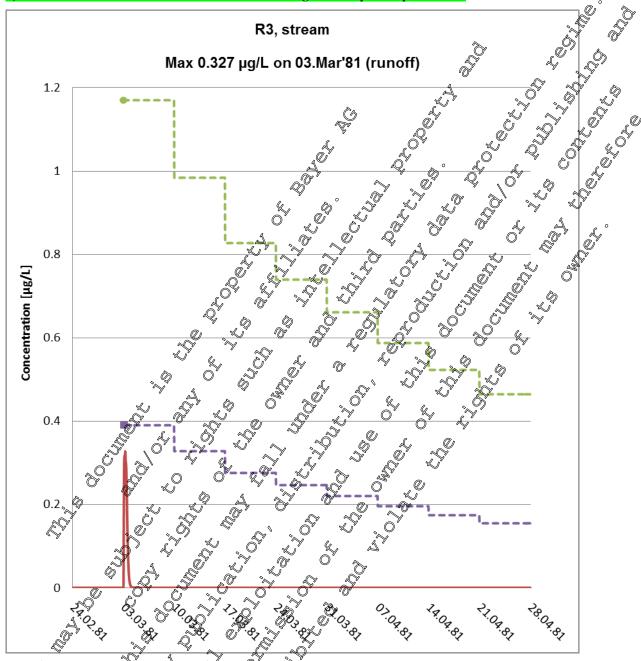
b) based on PEC values of alternative simulation using RMS requested parameters



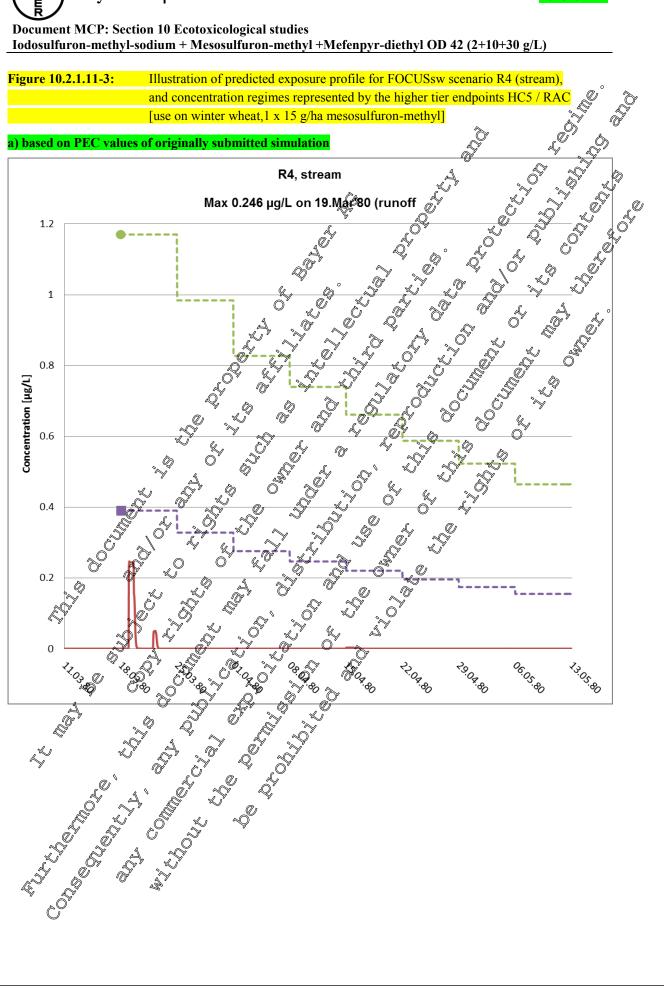
Interpretation FEC hax is crearly below RAC (HC5 divided by AF=3). The integral of predicted exposure over time does. Tearly not exceed the exposure × time regime represented by the higher tier endpoints Therefore, the ecotoxicological test exposure regime was worst case relative to the predicted exposure regime in the edge-of-field surface water under consideration for scenario D1 (stream).



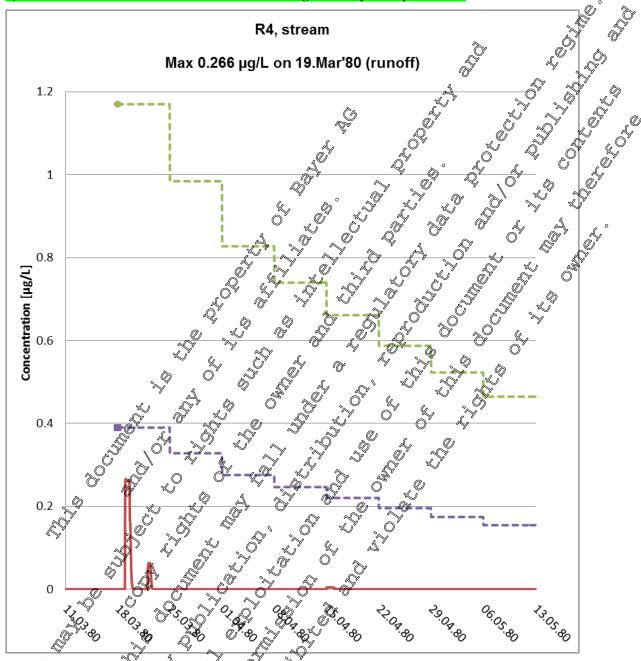
b) based on PEC values of alternative simulation using RMS requested parameters



Interpretation: PEC_{sw, max} clearly below RAO (HC5 divided by AF=3). The integral of predicted exposure over time does clearly not exceed the exposure × time regime represented by the higher tier endpoints. It should be noted that in fact the predicted exposure in scenario R3 (stream) is confined to a very short pulse below the RAC and lasting approximately a single day only. Therefore, the ecotoxicological test exposure regime was by far worst case relative to the predicted exposure regime in the edge-or-field surface water under consideration for scenario R3 (stream).

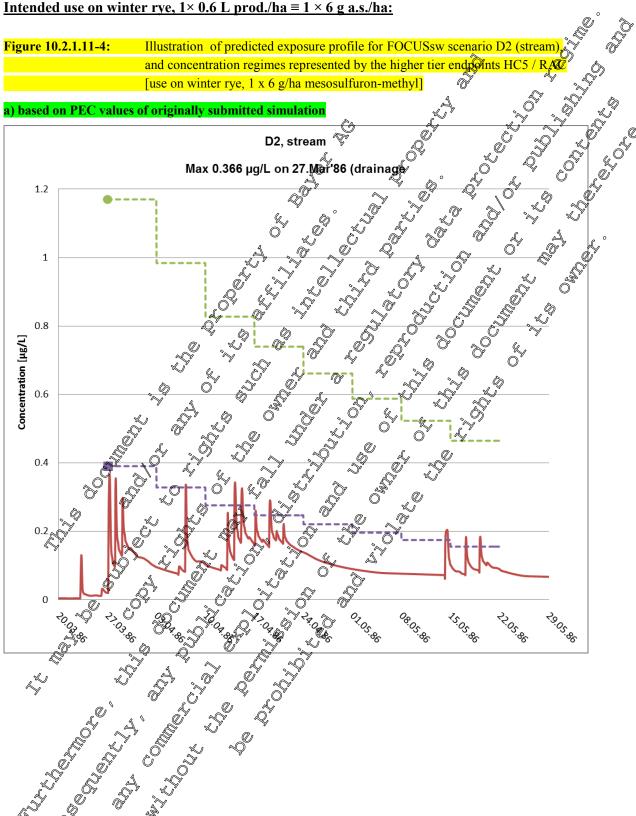


b) based on PEC values of alternative simulation using RMS requested parameters

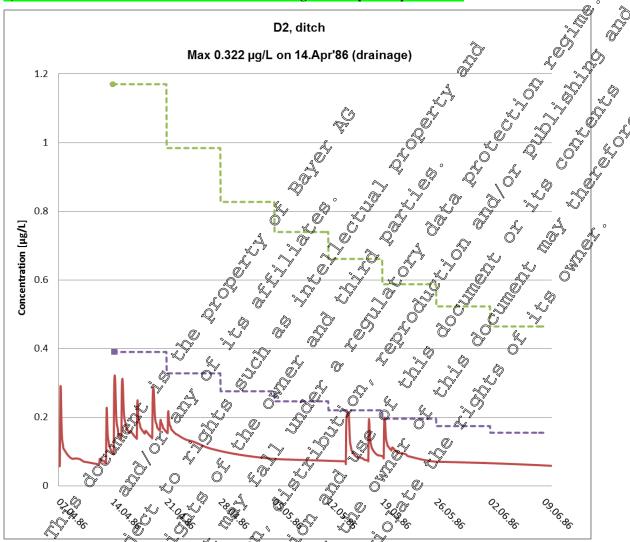


Interpretation: PEC_{sw, max} is clearly below RAC (HC5 divided by AF=3). The integral of predicted exposure over time does clearly not exceed the exposure × time regime represented by the higher tier endpoints. In fact, it should be noted that the predicted exposure in scenario R4 (stream) is confined to a very short pulse followed by allower second pulse, both below the RAC and each lasting approximately a single day only. Therefore, the ecotoxicological test exposure regime was by far worst case relative to the predicted exposure regime in the edge-of-field surface water under consideration for scenario R4 (stream).

Intended use on winter rye, 1×0.6 L prod./ha = 1×6 g a.s./ha:



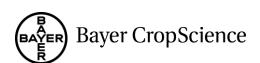
b) based on PEC values of alternative simulation using RMS requested parameters



Interpretation: PIC sw, may is below RAC (HC5 divided by AC=3). The integral of predicted exposure over time does not exceed the exposure × time regime represented by the higher tier endpoints. With regard to daily exposure levels, some slight and short-form breaches of the violet line are observed but for the most time the predicted exposure profile remains below the exposure regime underlying the RAC derivation, and a significantly below the exposure regime underlying the HC5 definition over the entire time period considered.

Despite these exceedances of the exposure regime underlying the RAC derivation it can be safely concluded that a risk assessment based on PEC_{sw, max} versus RAC is protective for aquatic macrophaes in the FOCUS segnario situation of D2 (stream), due to the fact that

- the broaches are peak exposure events of only very short duration (≤ 1 day),
- their peak reights only slightly breaches the equivalent concentration line projected from RAC and never reaches the equivalent concentration line projected from HC5, and
- The area under the predicted exposure curve is significantly below the area under the equivalent concentration line projected from HC5.



R3 (stream): Concerning exposure timecourse discussion for scenario R3 (stream), reference is made to the above assessment on the same scenario in context of the intended use on winter cereals, a.s./ha, which covers the situation as well for the intended use on winter rye, 1 g a.s./ha (see Fig 10.2.1.11-2).

Conclusion:

Overall, it can be concluded that the Guideline criteria for an acceptable risk despends the higher tier endpoint is fulfilled, since the exposure regime in the ecotoxicological tests was realistic to the exposure regime in the edge of field surface water under Overall, it can be concluded that the Guideline criteria for an acceptable risk assessment based on the consideration for all FOCUS scenarios that were resolved via this higher ther assessment route.

IIIA 10.2.2 Acute toxicity of the formulation

IIIA 10.2.2.1 Fish

Report:	©, 2003, M-229670-p
Title:	Agute toxicity of AE F130081 + Iodosulfuron-methyl-sodium + Mefenpyr-
	diethy OD 10 + 2 + 20 to fish (Oncorhynchus miskiss) (Groduct code: AE
*	F115008 0600D04X104) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Report No:	CQ58744Q 0 0 0 0 0 0 0
Document No(s):	M-225670-01g \$ \$
Document No(s): Guidelines:	EU (=EEC); 92/69/EEC 6.1 (1992); OECD: 203 (rev.1992); USEPA (=EPA); 72-1/SEP-EPA-540/9-85-006 (1982) 985), OPPTS 850.1075
	(=KPA); 72-1/SKP-EPA-540/9-85-006 (1982/1985), OPPTS 850.1075
GLP/GEP:	(public draft); Deviation not specified
GLP/GEP:	Kyes & S O S

Objective

The aim of the study was to determine the effects of formulation IMS + MSM + MPR OD 42 (Atlantis®OD, AE) 115008 06 (D04 A104) to Oncorhynchus mykiss. The study was designed to meet both, OECD and EPA priterial.

Material and Methods

The study was conducted under static conditions. Nominal concentrations were 0.94, 1.88, 3.75, 7.50, 15.0 and 30.0 mg product. In addition an universated control was tested. 10 fish were used per treatment level a volume of 40 L test water. Mean weight was 0.7 g, mean length was 4.3 cm. Static biological loading was 0.18. The mean water temperature was 10.1 to 11.2 °C. The daily illumination period lasted 16 hours. pD varied between 6.9 and 7.1. Oxygen concentration varied between 97 and At test start total hardiess was 40 to 60 mg/L as CaCO₃.

Analytical measurements for mesosulfuron-methyl (sodium salt) resulted in concentrations between 95% and 101% of nominal treatment levels. Biological results are reported as nominal.

Percent mortality is summarised in the following table.

Table 10.2.2.1-1: Acute toxicity to Oncorhynchus mykiss (based on nominal concentrations)

Nominal	24 hrs	48 hrs	72 hrs 💞	96 hrs 📡
(mg product/L)			2	
Untreated control	0	_ 0	(W) (
0.94	0	0 🔘	<i>~</i> ~0	
1.88	0	0 %	Q 0	
3.75	0	1	10	/ Q 10 0 \$
7.5	0	<u> </u>	Q' 10 K	100
15	100	100	√ 01°00 ~	\O' \ \$90 \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
30	100	1000	100 m	, 400

The following intoxication symptoms were observed in the surviving fish: swimming at the surface lethargic behaviour, loss of equilibrium and enhanced respiration.

Conclusions:

The acute toxicity of formulation IMS + MSM MPR OD 42 Atlantis CD, AE 5115008 06 OD04 A104) to *Oncorhynchus mykis* under static conditions based on coming figures are acfollows:

24 h LC₅₀ = 10.2 mg product/ $\sqrt{95}$ % confidence limits 8.87 - 11.8 mg product/ $\sqrt{95}$ %

48 h LC₅₀ = 8.832 mg product/L (95% confidence limits 6.90, 11.3 mg product/L)

96 h LC_{50} = 8.832 mg product/L 95% confidence limits 6.90-112 mg product/L)

96 h NOEC = 1.88 mg product

IIIA 10.2.2.2 Aquatic invertebrates (Daphnia

Report:	b; 2003;M-224326-01
Title:	Acute Toxicit of AEF 130681 & iodosulfuron-methyl-sodium & mefenpyr-
	dietbyl OPU0 + 2 30 to the waterflea Daphnia magna Code: AE F115008
	060D04A104V S S
Report No:	038154 ~ 2
	M-2Q4326-02-1 05 0
Guidelfores:	OF D No 202 April 1984 and corresponding revised draft
Guidelores:	document, & .V
	dated October 2000, EEC Directive 92/69/EWG, part C.2; U.S. EPA
	Pesticide Assessment Guidelines, Subdivision E, § 72 2; OPPTS
	Guideline 850 (2010 public draft 1996 (modified); Deviation not specified
GLP/GEPO"	ves v

Objective

The aim of the study was to determine the effects of formulation IMS + MSM + MPR OD 42 (Attantis® QD, AE F115008 06 OD04 A104) to *Daphnia magna*. The study was designed to meet both, OECD and EPA criteria.

Material and Methods

The study was conducted under static conditions. Nominal concentrations were 0.13, 0.25, 0.50, 1 2.0, 4.0, 8.0 and 16.0 mg product/L. In addition an untreated control was tested. 6 replicates with 5 individuals each were used per treatment level. Maximum age of test animals was 24 hours. The mean water temperature was 21 ± 1 °C. pH varied between 7.8 and 8.0. Oxygen concentration between 8.0 and 9.1 mg/L.

hetween 8.0 and 9.1 mg/I
octween 6.0 and 7.1 mg/L.
Findings Analytical measurements for AE F130081 (mesosulforon-methyl, sodium salt) resulted in concentrations between 91% and 103% of nominal preatment levels. Biological esults are reported as nominal. Mortality and intoxication symptoms are summarised in the following table. Table 10.2.2.2-1: Toxicity to Daphnia magna (based on nominal concentrations) Nominal (mg product/L) (mg product/L
Findings () () () () () () () () () (
Analytical measurements for AE F130081 (mesosulf@on-methyl, sodium salt) resulted in
concentrations between 91% and 103% of nominal reatment levels. Big ogical results are reported as
nominal.
Martality and intovication symptoms are symmetrized in the fall Sking toklo
Wortanty and intoxication symptoms are similarised in the following table.
Table 10.2.2.2-1: Toxicity to Daphysa magna (based on noviinal concentrations)
Nominal Q 24 hrs. 24 hrs.
(mg product/L)
Untreated control
0.25
3
8 5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
16 × × × × 57 ° × × 7 87

The following intoxication symptoms were observed in the surviving organisms: Dwelling near the bottom, lethargic behaviour and moving erration gyrating.

Conclusion

The acute toxicity endpoints of Termulation IMS + MSM + MPR OD 42 (AE F115008 06 OD04 A104) to Daphnia magna under static conditions based on nominal figures are as follows:

13.6 mg@roduct/L (95% confidence limits 10.8 - 17.0 mg product/L) $24-h EC_{50} =$ 9.6 mg product/L (% confidence limits 6.4 - 9.0 mg product/L) $48-h EC_{50} =$

48-h NOE

IIIA 10.2.2.3 Algae

Report:	° ;	;200	3;M-224329-0)1	
Title:	Influence of mesosulfu				
	mefenpyr-diethyl OD	10 + 2 + 30 (Atla	ntis liquid) on	the growth of	green 🕏
	alga, Pseudokirchnerie	ella subcapitata C	Code: AE F1075	5008 06 OD04	A1937
Report No:	C038152		,4	. 0	
Document No(s):	M-224329-01-1	Ĉ			
Guidelines:	OECD: 201;Deviation	n not specified	<u> V</u>		/
GLP/GEP:	yes	√	, OY		\$ 4

Objective

The aim of the study was to determine the effects of formulation IMS + MSM + MPR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104) to the growth of Pseudokiroluberiello subcapitata. The study was designed to meet OECD criteria.

Material and Methods

Algal cultures with an initial cell density of 10,000 algal cells/mix were incubated in synthetic medium for 72 hours at 1.56, 3.13, 6.25 12.5 and 25.0 mg fromulation/L. Hoaddition an unitreated control was tested. 3 replicates were used per treatment level, the eplicate number in the control was twice as high. The mean water temperature was 2½ ± 1 %. pH varied between 7.8 and 8.6. The mean light intensity during the test was 7744 tax.

Findings

Analytical measurements for AEF 30060 resulted in concentrations between 94% and 104% of nominal treatment levels at test start and between 92% and 102% of nominal treatment levels at test termination. Biological results are reported as nominal.

Inhibitor effects and infoxication symptoms are summarised in the following table.

Table 10.2.2.3-12 Cell number, growth rates in *Pseudokire Ineriella subcapitata* cultures treated with the test item and their % deviation relative to that of the control

	/	
Nominal 72 hours	72 hours	72 hours
(mg formulation/L) (cell@rumber)	(average growth rate)	(growth inhibition in %)
Control 3 398 000 3	1.225	
1.56 435,000 435,000	1.257	-2.6
3.13	1.107	9.6
3.13 282 000 4 6.25 4 93 000 4	0.732	40.3
12 860	0.045	96.3
25 7 0 10 000	0.000	100

^{-%} inhibition: increase in growth relative to the control

Novell deformation was observed.



Conclusion

The effect of formulation IMS + MSM + MPR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104 on the growth inhibition of *Pseudokirchneriella subcapitata* based on nominal figures are as follows:

72-h E_rC_{50} = 6.71 mg formulation/L 72 h $E_{logb}C_{50}$ = 6.25 mg formulation/L 72-h NOEC = 3.13 mg formulation/L

IIIA 10.2.2.4 Marine or estuarine organisms

This is not an EC data requirement / not required by Directive 1/4147EEC,

IIIA 10.2.2.5 Marine sediment invertebrates

This is not an EC data requirement / not required by Directive 91/414/EFG

IIIA 10.2.3 Microcosm of mesocosm study

No microcosm or mesocosm studies were performed with the formulated product. Based on the toxicity data and application rate of the product, the risk assessment (TER calculations) presented above indicates acceptable risk to aquatic organisms. Therefore, microcosm or mesocosm studies with the formulated product are not deeped necessary.

IIIA 10.2.4 Residue data in fish

Based on the triggers gated in the Aquatic Guidance Document of fish BCF-study for the product was not conducted.

The octanol / water profition coefficient Log Pow of mesoval furon-methyl and its metabolites are well below the trigger value of 2000 and 1000 and 1000 are well below the trigger value of 2000 and 1000 are well and 1000 are well below the trigger value of 2000 and 1000 are well and 1000 are well and 1000 are well and 1000 are well are well and 1000 are well ar

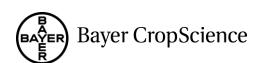
Therefore considerable accumulation (Froconcentration) of residues of the parent compounds and/or the metabolites in fishes unlikely, and a BCF-study is not required.

IIIA 10.2.5 Chronic toxicity to fish

Based on the triggers stated in the Aquade Guidance Document, further chronic studies with the formulated product are not considered necessary, as the relevant information can be obtained from studies with the active ingredient.

IIIA 10.2.5.1 28 day study

Please refer to point IIIA 10.2.5.



IIIA 10.2.5.2 Fish early life stage test

Please refer to point IIIA 10.2.5.

IIIA 10.2.5.3 Fish life cycle test

Please refer to point IIIA 10.2.5.

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

Based on the triggers stated in the Aquatic Guidance Document, for therefronic studies with the formulated product are not considered necessary. at III 4 10.26

Accumulation in advante from tabelities in agentic organisms

rmation given under Poure IIIA. 10.2.4. Considerable accurabolities in agentic organisms is under the pour interest of the property of the prope Based on the triggers stated in the Aquatic Guidance Document, further effornic studies with the formulated product are not considered necessary. If the relevant information can be obtained from studies with the active ingredient.

IIIA 10.2.6.1 21 day test (Daphnia magna)

Please refer to point IIIA 10.2.6.

IIIA 10.2.6.3 Aquatic gastropod molfusc

Please refer to point IIIA 10.2.6.

IIIA 10.2.7 Accumulation in aquatic non-target organisms

IIIA 10.2.7

Based on the ifformation given under Point IIIA 9.2.4, considerable accumulation of residues of the Based on the information given under Point IIIA (0.2.4, considerable product and/or metabolites in agratic organisms is unlikely to occur.

IIIA 10.3 Effects on terrestrial vertebrates other than birds

Ecotoxicological endpoints used in risk assessment

Table 10.3-1: Endpoints of the <u>formulation</u> IMS + MSM + MPR OD 42 used in risk assessment

Test substance	Test organism	Study type		Endpoint	Reference
IMC + MCM	Acute toxicity to	mammals	Ď		
IMS + MSM + MPR OD 42	Rat	acute, oral	1 50	≥ 5000 mg/kg bw	(2003) MQ225486-01-1 KIIIA 7.1.1/01

Table 10.3-2: Endpoints of the active substance mesosulfuron-methyl used in risk assessment

Test substance	Test organism Study type Endpoint Reference	organism St	Reference
	Acute toxicity to manufals	toxicity to map	
Mesosulfuron- methyl	Rat LD ₅₀ 5000 mg as/lc bw M-140405-01-1 KCA 5.2.1 /01		0405-01-1
	Part Company NOE 16000 ppm (2000) Rat reproduction Study NOEL 1277 mg as kg bw/d KCA 5.6.1/02	Řat 🔬 🔭	8366-01-1

All above endpoints used in risk assessment are consistent with the proposed EU endpoints listed in Document N2 for mesosulfuron-methyl.

Risk Assessment for mammals

The risk assessment procedure for wild mammals follows the EFSA Guidance Document on Risk Assessment for Bards & Mammals (2009); principles see described under point 10.1 for birds.

Mammalian indicator species for risk assessment of screening level

The product IMS + MSM + MPR OD 42 is intended to be used in winter wheat for a single application between BBCH 20 and 32 at an application rate of 1.5 L/ha, corresponding to 0.015 kg mesosulfuron-methyl/ha and in winter rye for single application between BBCH 20 and 32 at an application rate of 0.6 L/ha, corresponding of 0.006 kg mesosulfuron-methyl/ha. According to the EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009) the following indicator species have to be addressed in risk assessment on screening level.

Table 10.3-3: Relevant mammalian indicator species for risk assessment on screening level

		Shorter	ut value
Crop	Indicator species	For long-term RA based on RUD	based on RUD
		mean	90th perc.
Cereals	Small herbivorous mammal	48.3	118.4

Toxicity exposure ratios IIIA 10.3.1

Table 10.3.1-1: Summary of TER values for acute exicity

				me	an) perc.	, ~y	
	Cereals	Small l	nerbivorous mammal	48	.3	1	118.4		
S	ummary of calcu	ılated Tl	xposure ratios ER values for mamm f TER values for acute	- Or y		- 6			. © 4
	Crop / Compound		Indicator species			EERA 1	Trigger	Refinement used 2°	
1	Winter wheat, 1 × 1	15 g a.s./h	a Z	Y ZY	> A		& 1		
	Mesosulfuron-me	ethyl	Small herbitorous nan	nma¶″ "I	√8.4	2809	\$10 &	no	
1	Winter rye, 1 × 6 g	a.s./ha				S S			
	Mesosulfuron-me	ethyl	Small@erbivorous mar		1894	7043	TO O	no	

Table 10.3.1-2: Summary of TER values for long-term toxicity

Crop / Compound	Indication		Mean "	TERLT	Trigger	Refinement used ?
Winter wheat, 1 × 15	a.s./ha ^{Dy}	v \$ 2	7 0		7	
Mesosulfuron-menyl		rous mammal\$	6 5.3	336 %	5	no
Winter rye, 1 × g a.s.?	ha y	, O 4 5		W.		
Mesosulfuron-methy	Small herbivoi	rous manmal	480	©8513	5	no

Conclusion: According to the presented risk assessment, the risk to mammals from the use of the product in cereals is acceptable.

IIIA 10.3.1.9 Acute toxicity exposure ratio (TERA)

Acute toxicity exposure ratio on screening level for mammals

The risk assessment on screening level has been performed for cereals for an application rate of 1.5 L product/ha corresponding to 0.013 kg mesosyburon-methyl/ha and for an application rate of 0.6 L product/ha corresponding to 6,006 kg/mesosyll furon-methyl/ha.

Table 10.3.1.1-1: Acute DDD and TER calculation (active substance mesosulfuron-methyl) on screening level for mammals

Crop /		LD ₅₀		DDD				٦
Compound	Indicator species	[mg/kg bw]	Appl. rate [kg/ha]	SV ₉₀	MAP	DDD	TERA Trigger	
Winter wheat, 1 × 1	5 g a.s./ha				_A	۰. (1
Mesosulfuron- methyl	Small herbivorous mammal	> 5000	0.0	118.4 🖉	, 1	1.78	> 2809 70	V
Winter rye, 1 × 6 g	a.s./ha		Q.Y	Y O A				
Mesosulfuron- methyl	Small herbivorous mammal	> 5000	0.006	118.4	12	0.76	> 7042 10	

All TER values are above the required trigger of 10 for therefore acceptable for the intended product uses

Acute risk assessment for mammals drinking contaminated water.

For further details reference is For further details, reference is made to Point 19.1.1 of this dossier Glower, according to EFSA Guidance Document for Birds and Marnmals (2009), unlike for brids the scenario of pools formed in leaf axils is not relevant for mammals. Therefore the risk assessment for mammals is limited to the scenario of puddles formed on the ground after application.

The acute risk from water in puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a coop or bare soil is covered by the long-term risk assessment under Boint, 10.3.1.3 of this dossier

IIIA 10.3. 2.2 Short-term toxicity exposore ratio (TER

Not required according to

IIIA 10.3.1.3 Long term foxicity exposure catio (FERLT)

Reproductive/long-term toxicity exposure ratio on screening level for mammals

The risk assessment on screening level has been performed for cereals for an application rate of 1.5 L ng mg ng to 0,000 kg mes product/ha corresponding to 0.0150kg mcsosulfuron-methyl/ha and for an application rate of 0.6 L product/ha corresponding to 0,006 kg mesosufuron-methyl/ha.

Table 10.3.1.3-1: Long-term DDD and TER calculation (active substance mesosulfuron-methyl) on screening level for mammals

Crop / Compound	Indicator species	NO(A)EL [mg/kg bw]	Appl. rate [kg/ha]	SVm	MAFm	ftwo	DDD	TERO Trigger
Winter wheat, 1 × 15	g a.s./ha					T		
Mesosulfuron- methyl	Small herbivorous mammal	1277	0.01	48.3		0.53	0.38	326Y 5
Winter rye, 1 × 6 g a.	s./ha		Z Z	, A	/ /	, C		
Mesosulfuron- methyl	Small herbivorous mammal	1277	0.006	48.3		9.53	0.15	\$513 \$\tilde{5}\$5

All TER values are above the required trigger of 5 for reproductive/long-term exposure. Long-term risk to mammals is therefore acceptable for the intended product uses

Long-term risk assessment for nammals drinking contaminated water

For further details, reference is made to Point 20.1.1 of this cossier.

Table 10.3.1.3- 2: Evaluation of potential concern for exposure via drinking water of mammals (escape elause)

Crop / Compound			NO(A)EL Img as (kg bw/d)	(Application rate)	Escape clause" No concern if ratio	Conclusion
Winter wheat, 1 × 1	l∕ 5 g a.s.∕Ab	a o				
Mesosukturon-	× 1	150	1277		≤ 50	No concern
Winter rye, 1 × 6 g	as./ha 🎸			, Š		
Mesosulfuron-		5 65	1277	0.005	≤ 50	No concern

median value; QCA 7. Q.1, mcsosulfuron Review Report SANCO/10298/2003 final)

This evaluation confirms that the risk for mammals from drinking water that may contain residues I mis evanation continue that the risk for manmals from different the use of IMS MSM + MRR ODA2 is acceptable.

IIIA 10.3.2 Other studies

IIIA 10.3.2.1 Acute oral toxicity of the preparation

Table 10.3.2.1-1: Toxicological profile of IMS + MSM + MPR OD 42

Test system	Test species	ID ₅₀ [mg product/kg bw]	Reference (See III A Point D)
Acute oral	rat	≥ 5000	(2003) (0 M-22548001-1

The study confirmed a low acute oral toxicity of the formulated product, reflecting the low toxicity the active substances. It is therefore reasonable to assume that the product would not pose an unacceptable risk to mammals, as indicated by the isk assessment performed (see Points 10.3.1.1 and 10.3.1.3).

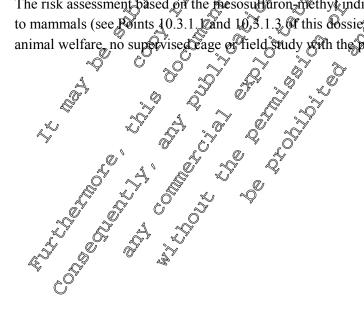
IIIA 10.3.2.2 Acceptance of bait, granules or treated seed

IIIA 10.3.2.3 Effects of secondary poisoning

The log K_{OW} values for mesosulfuron-methyl (log K_{OW} \$\subseteq 0.48 at pH 7) is below the trigger value indicating a very low risk of secondary poisoning. For details regarding log Kow of the active substance refer to IIIA 10.1.9.

Supervised eage of field trials IIIA 10.3.3

The risk assessment based on the mesosulturon, methyl indicates acceptable acute and long-term risks to mammals (see Points 10.3.1. Land 10.3.1.3 of this cossie). For this reason and also considering strage of field study with the preparation was deemed necessary.



IIIA 10.4 Effects on bees

Ecotoxicological endpoints used in risk assessment

Test substance	Test organism	Study type	Ò	Endpoint Endpoint	Reference (2003) M-222991-01-1 RHIIA 1024.2 1.01
IMS + MSM	Acute toxicity for	r honey bees			(<u>(</u> (<u>(</u> (<u>(</u> (<u>(</u> ()))))))
+ MPR	Anis mellifera	oral, 48 h	100 50	234 gg product/be	(2 003) (3 003) (3 003) (3 003)
OD 42	I I I I I I I I I I I I I I I I I I I	contact, 48 h	LD ₅₀	498 μg p@duct/be	PIIA 100.4.2.1 01
	Test organism Acute toxicity for Apis mellifera				Per (2003) M4222991-01-1 M1IIA 1424.2 1/41

Table 10.4-2: Endpoints of/for the active substance mesosulfuron-methyl

Test	Test organism	Study type	Endpoint	Reference \$
substance	Ü	* * * *	•	
	Acute toxicity for	honey bees		
	Apis mellifera	oral, 96 h	LD ₅₀ > 105.6 μg a.s./bec (NOED) (≥ 105.6 μg a.s./bee)	2012 M-403998-0321
Mesosulfuron-		contact, 96 h	LD ₅₀ > 100 μg a.s./bee (NOED) (≥ 100 μg a.g./bee)	KCA 8.3.171./01
methyl	Chronic toxicity f	or honey bees		
	Apis mellifera	10 d chronic adult feeding study	$DC_{50} > 120$ mg a.s./kg $NOEC \ge D0$ mg a.s./kg	2014 M-485655-01-10 KCA 8-3.1.2,797
Mesosulfuron-	Acute toxicity for	bumble bees		
methyl WG 75	Bombus terrestris	confact, 96 h	LD > 000 µg(a.s./bee (NGED)	M-485279-01 KG 8.3.1 P/02
	Honey bee brood	feeding test		
Mesosulfuron- methyl	Apis mellifera	Oomen er al., 1993	No adverse offects on adulthee mortality. Gee broad development (eggs, young lawae, old larvae, pupaen behaviour, calony strength and colony development by deeding honey bee colonies sugar syrup at mesosulfuron methyl concentration typically present in the spray tank (\$\mathcal{D}\$.5 ppm)	, 2013 M-465325-01-1 KCA 8.3.1.3/01
WG 75 (+Mefenpyr diethyd WG 25)	Apis melliferal	honey bee brood study OECD No. 75; forced exposure	No adverse effects on mortality of adult bees and brood, flight intensity, behaviour, brood development (brood termination rate, brood index, compensation index) and colony vitality at 15 g mesosulfuron-methyl/ha	, 2015 M-510267-01-1 KCA 8.3.1.3 /03

All above listed endpoints are considered for the risk assessment and are consistent with the *proposed* EU endpoints isted in Document N2 for mesosulfuron-methyl.

IIIA 10.4.1 Hazard quotients for bees

An indication of hazard (Plazard Quotient or Q_H) can be derived according to the EPPO risk assessment scheme, by calculating the ratio between the application rate (expressed in g a.s./ha or in g product/ha) and the laboratory contact and oral LD_{50} (expressed in μg a.s./bee or in μg product/bee).



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

Hazard Quotient, oral:
$$Q_{HO} = \frac{\text{maximum applicatio n rate}}{\text{LD appl}} = \frac{[\text{g a.s./ha or g/product/ha}]}{[\text{LD appl}]} = \frac{[\text{g a.s./ha or g/product/ha}]}{[\text{LD appl}]}$$

Hazard Quotient, contact:
$$Q_{HC} = \frac{\text{maximum application rate}}{\text{LD}_{co} \text{ contact}} = \frac{[g \text{ a.s./ha or g product/ha}]}{[g \text{ a.s./hee or up product/hee}]}$$

IIIA 10.4.1.1 Oral exposure QHO

Table 10.4.1.1- 1: Hazard quotients (formulated product

Hazard Quotient, oral:	o _ maximum applicatio n rate _ [g a.s./ha or g product/ha]			
,	$Q_{HO} = \frac{\text{HEASTMAIN application is rate}}{\text{LD}_{50} \text{ oral}} = \frac{15}{[\mu \text{g a.s./bee}]} \frac{\text{product/bee}}{\mu \text{g product/bee}}$			
Hazard Quotient, contact:	$Q_{HO} = \frac{\text{maximum applicatio n rate}}{\text{LD}_{50} \text{ oral}} = \frac{[\text{g a.s./ha or g'product/ha}]}{[\text{µg a.s./bee on µg product/bee}]}$ $\vdots \qquad Q_{HC} = \frac{\text{maximum applicatio n rate}}{\text{LD}_{50} \text{ contact/ha}} = \frac{[\text{g a.s./ha or g'product/ha}]}{[\text{µg a.s./bee or µg product/bee}]}$			
Table 10.4.1.1- 1: Hazard quotients (<u>formulated product</u>) for bees – oral exposure Test item Oral D ₅₀ Max. application rate quotient quotient risk for adult bees Winter wheat, 1× 1.5 L product/ha				
Test item	Orald D50 @ Max. application sate Bazard Trigger A-priori			
	Q Q Q Q Q Q quotient S acceptable risk for			
	[µgproduct/bee] [gproduct/ha]#@ QHO adult bees			
Winter wheat, 1× 1.5 L p				
IMS + MSM + MPR OD 42	234 50 yes			
Winter rye, 1× 0.6 pro	duct/ha duct/h			
IMS + MSM + MPR OD 42	duct/ha 234			

^{*)} specified density for product IMS + MMPR OD 42. 1.000 / mL

Table 10.4.1.1-2: Hazard quotients (active substance mesosulfurous methyl) for bees – oral exposure

Test item Opal LD59 Max. application rate [µg a./.bee] [gas./.ha]	Hazard quotient Q _{HO}	Trigger	A-priori acceptable risk for adult bees
Winter wheat, 1 × 15 g.a.s./ha			
Mesøsulfuron-methyl 2 > 105.6 15	< 0.1	50	yes
Winter rye, 1 6 g a.s./ha			
Mesosulfuron-methyl > 105.6 6	< 0.1	50	yes

The hazard quotient for oral exposure is below the validated trigger value for higher tier testing (i.e. Q₁ S 50) Risk to bees from oral exposure is therefore acceptable for the intended product uses.

IIIA 10.4.1.2 Contact exposure QHC

Table 10.4.1.2- 1: Hazard quotients (formulated product) for bees – contact exposur

Test item	Contact LD ₅₀	Max. application rate	Hazard	Trigger	A-priori
			quotient		acceptable ∂ risk for ✓
	[µg product/bee]	[g product/ha]#	Д НО		adult bees
Winter wheat, 1× 1.5 L	prod./ha		Ř.	- V	
IMS + MSM + MPR OD 42	498	1500	, & .0	500	yes y
Winter rye, 1× 0.6 L prod./ha					
IMS + MSM + MPR OD 42	498		9.2 A 5	56	yes 4°

^{#)} specified density for product IMS + MSM + MPR OD 42: 1.000 g/mL

Table 10.4.1.2- 2: Hazard quotients (active substance mesosulfuron methy) for bees - contact exposure

Test item	Contact LD 50	Max. application rate	qpotient	Trigger	A-priori acceptable risk for
	🍳 [μg æs./bee	g a.s./ha]	QHO Q		adult bees
Winter wheat, 1 × 15 g a	n.s./ha		<i>1.</i> • •	5	
Mesosulfuron-meth	\$ \$\frac{1}{2}\text{00}\$		<0.2	50	yes
Winter rye, 1 86 g a. ha					
Mesosulfuron-methyl	2100	7 76	<0.1	50	yes

The hazard quotient for contact exposure is below the alidated trigger value for higher tier testing (i.e. $Q_{HC} < 50$). Risk to bees from contact exposure is therefore acceptable for the intended product uses.

Further Considerations for the risk assessment

In addition to acute laboratory studies with adult honey bees, mesosulfuron-methyl was further subjected to topical acute bumble bee testing [KCA 8.3.1.1 /02]. The study did not reveal sensitivity differences between honey bee and bumble bee foragers.

In addition, messfulfuror-methyl was subjected to chronic laboratory testing with adult honey bees [KCA § 3.1.2 [91]. This chronic study was designed as a limit test by exposing adult honey bees for 10 consecutive days to a concentration of nominally 120 mg mesosulfuron-methyl per kg aqueous sugar solution (120 ppm). Thus, the nominal employed test concentration exceeded the concentration of mesosulfuron-methyl as usually present in the spray tank. No adverse lethal-, sub-lethal, behavioural or delayed effects were found by exposing adult honey bees for ten consecutive days exclusively to sugar solution, containing 120 ppm mesosulfuron-methyl (nominal).



In order to reveal whether mesosulfuron-methyl poses a risk to immature honey bee life stages, a bee brood feeding study [KCA 8.3.1.3/01] has been conducted by following the provisions/method of Oomen P.A., de Ruijter, A. & van der Steen, J. (OEPP/EPPO Bulletin 22:613-636 (1992)), which require, amongst other parameters to "...use formulated products only... products are fed at a concentration recommended for high-volume use...". The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the high with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, soung & old lavae by employing digital photo imaging technology.

This particular study tested formulated mesosol furon methyl (via Mesosuburon methyl WG 75) together with formulated crop safener mesosulfuron-methyl (as Mesosuburon-diethyl WG 150). The actual test concentration of mesosulfuron-methyl was 37.5 mg/L 37.5 ppm), which corresponds to a typical concentration of mesosulfuron-methyl present in the spray tank when using product IMS+ MSM+ MPR OD 42. The administration of litre sugar solution per colony, containing 37.5 ppm (as mesosulfuron-methyl, has not resulted in adverse effects. These were neither adverse acute or chronic effects on adult honey bees nor adverse effects on immature honey bee life stages (eggs young larvae, old larvae, pupae) or on the colony itself. Neither mortality of worker bees and pupae (as assessed via dead bee traps) nor the termination rate of eggs young larvae and old larvae (as assessed via digital imaging of individual marked cells) was statistically significantly different from the untreated control.

In order to investigate brood development under actual use conditions of mesosulfuron-methyl, a higher tier semi-field honey bee brood study [KCA8.3.1.3/03] (according to the provisions of the OECD Guidance Document 75) was conducted under forced/confined exposure conditions, by applying the rate of 20.11 g Mesosulfuron-methyl WG75 per hectare, corresponding to 15 g mesosulfuron-methyl/ha, under tunnel conditions to the full flowering and highly bee attractive surrogate crop Phacella tangettifolia.

The test was designed as a seplicated tunnel study to assess potential effects of mesosulfuron-methyl

to honey bee cologies, including a very detailed assessment of brood development. Tunnels (25 m length x 5 m width x 2.9 m height) were set up on Sca. 80 m² plot of Phacelia tanacetifolia. Small bee colonies were introduced to the tuingels 4 days before the application. One honey bee colony was used per tunnel. The test item, water and a reference frem was applied during honey bees actively foraging on the crow. The trial was carried out using four tunnels (i.e. replicates) for the test item treatment, the control and the reference item treatment (Insegar 050 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 them test item, the *Phace Bu*-crop was no longer attractive to bees (faded crop) and did not longer support the confined colonies. Thus, all the colonies fire, 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 tunnels and placed in an area with no main flowering, bee attractive crops. The test item was applied under option foraging conditions. After foliar (spray) application of the water (control), teasitem Mesosulfuron-methyl WG 75) and the reference item (fenoxycarb), ontogenesis of a defined number of homey bee eggs was observed for each group and colony. Mortality of adult bees and pupal 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 a brood comb and taking a digital picture of the



brood comb. 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 comb was taken out of the hive and another digital photo was taken in order to investigate the progress of the brood development until day 21 following the application (BFD22 following BFD0). Statistical evaluation was done for mortality, foraging activity, colony strength and the brood termination rate using Shapiro-Wilk's test (check for normal distribution). Levene's test (check for homogeneity of variance), Student or Welch t- test (pairwise comparison). No adverse effects on mortality of worker or pupae, foraging activity, behaviour, nector-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 oney bees and honey bee brood when applied at a rate of 20.11 g product/ha (corresponding to 15 g mesosulfuron-mediyl/ha) in 406/L tap water/ha, during honey bees actively foraging on a bee-attractive. Howevery crop. The observed, characteristic brood effects of the reference item Insepar (a.s. 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 bee life stages

Synopsis

Mesosulfuron-methyl has a low acute toxicity to honey bees, with D₅₀ foral and contact) above the highest tested dose level (oral: LD 1056 µg & s./bee, Contact: LD 100 µg a.s. bee). The calculated Hazard Quotients for both, mesosulturon-methylas well as for MS + MSM + MPR OD 42 are well below the validated this ger value which would indicate the need for a refined risk assessment; no adverse effects of honey bee mortality are to be expected. This conclusion is confirmed by the results of the bee brood feeding study.

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

Regarding potential side effects of measulfuron-methyl or mmature honey bee life stages as well as

on colony development, 37.5 ppm mesosulfuron-methyl, a concentration which corresponds to a typical concentration of mesosulforon-methyl yea IMS MSMP+ MPR OD 42 present in the spray tank, has not resulted in adverse statistical significant effects on mortality of worker bees and pupae nor in adverse statistically significant effects on the termination rate of eggs, young larvae and old larvae (as assessed via digital imaging opindividually parked cells) in the bee brood feeding study on colony level. Even at this very high concentration under the worst case conditions of the honey bee brood feeding test, no adverse effects on insmature honey bee life stages were found; the findings in this study regarding the absence of chronic/delayed effects on adults honey bees are in line with the absence of adverse chronic effects on adult bees in the chronic 10 day laboratory feeding test with adult honey best under laboratory conditions (at 120 ppm).

In order to investigate potential effects of mesosulfuron-methyl under confined semi-field testing conditions (according to the provisions of OECD Guidance Document No. 75), Mesosulfuron-methyl WG 75 (750 g/kg) was applied at a rate corresponding to 15 g a.s./ha in 400 L water/ha to fullflowering *Phacelia* during honey bees actively foraging on the crop. This study design, although being conservative for an actual exposure situation of honey bees in cereals, is from an apidological and apicultural point of view more realistic than an in-hive feeding of the test compound via a treated sugar solution, which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration). The results of this higher tier semi-field study confirmed the conclusions made above on the basis of the outcome of the lower-tiered studies, as no adverse



direct or delayed effects on mortality of worker bees or pupae, foraging activity, behaviour, nectarand pollen storage, queen survival, colony strength, colony development as well as the development of bee brood were observed, even under aggravated, forced exposure conditions and by digitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.

Overall, it can be concluded that mesosulfuron-methyl, when applied at the maximum application rate of 15 g a.s./ha even during the flowering period of potentially bee-attractive weeds inside the cereal cropping area, does not pose an unacceptable risk to hone bees and honey bee colonies.

Acute toxicity of the formulation to bees, **IIIA 10.4.2**

IIIA 10.4.2.1 Oral

Report:	9; (2003;M-222991,01 O O O
Title:	Effects of AFF115008 06 QD04 10104 (active confact and oral) on honey
	bees (Apis mellitera L.) in the laborator of the laborato
Report No:	C0374870
Document No:	M-222991-01-P
Guidelines:	OECD: 213/2214; Deviation not specified
GLP/GEP:	yes w

Objective

The aim of the study was to determine the oral and intact oxicity of IMS + MSM + MPR OD 42 (Atlantis®OD, AE F153008 % ODOF A104) to Abis mellifera. The study was designed to meet OECD criteria.

Material and Methods

Acute ord test

Worker bees, 4-6 weeks old were weated with 63, 127, 245, 495 and 986 μg product/bee. Test duration was 48 hrs. In addition an untreated control was tested Moreover, Perfekthion EC was tested as a toxic standard. 3 replicates with 30 bees were used per treatment level. Bees starved during a period of 0.5 hours prior to test start. The temperature was 25 °C. Relative air humidity varied between 60 and 76 %. The bees were maintained at dark during the test.

Acute contact test 2

Worker bees, 4-6 weeks old were treated with 16, 232, 463, 926 and 1389 µg product/bee. Test duration was 96 hrs. In addition, an intreated control was tested. Moreover, Perfekthion EC was tested as a toxic standard. Freplicates with 10 less each were used per treatment level. The temperature was 25°C. Relative aic numicity varied between 60 and 76 %.

Findings

Acute oral test: Mortality and intoxication symptoms were observed as follows:

1 20000 01 01 00 000 1:101 001111	una monication sympt	onis were observed as ro	110 1100
Actual intake	4 hrs	24 hrs	48 hrs 🖒
(µg product/bee)	(% mortality)	(% mortality)	(% mortality)
Control	0	0	
63	0	<u>څ</u> 6.7	6.27
127	0	10.0	
245	0	43.3	Q6.7 0 S
495	0	93°.3° ©	\$ \$\ 96.7 ° \$
986	0	20.0	
	Koxic s	\$0.0 \$\tag{50.0}	
0.04			3.3
0.08	0 5	23.3	360
0.16	307	Ø \$36.70°	360
0.33	A 0.0 ()	567 0	Ø 96.7

Acute contact test: Mortality and into acation symptoms were observed as follows:

μg product/bee	24 hrs (1)	48 days	96 hrs
	(% mortativy)	⊚ (% mortality) 🛴 🤻	% mortality)
Control	I49 &	3.3 3.3 3.3 3.3 3.3 3.3 3.3 3.3 3.3 3.3	(% mortality) 6.7
116	3.3	343	33.3
		93.3 N	20.0
463		S & 6.7L W	16.7
926	40.0 × 4.		90.0
1389	0 0 63.3		96.7
	63.3	taodard S	
0.1	6.7	433	70.0
0.2	90.0	2×93.3	96.7
0.3	93.7	93.3	96.7

The following &bservations were made: aparty and discoordinated movement.

Conclusion

The effect of of IMS + MSM + MRR OD 42 (Athatis®OD, AE F115008 06 OD04 A104) after oral and contact exposure on the mortality of Apis mellifera based on nominal figures are as follows:

Acute oral testa

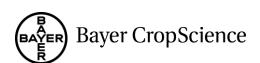
24h LD₅₀ = $\frac{262 \text{ μg product/bee}}{262 \text{ μg product/bee}}$ (95% confidence limits 213 - 319 μg product/bee)

48h LD₅₀ 284 μg product/bee (95% confidence limits 197 - 280 μg product/bee)

Acute contact test

486 $\cancel{\text{ED}}_{50} = 970$ µg product/bee (95% confidence limits 771 - 1220 µg product/bee)

96h LD_s 498 μg product/bee (95% confidence were not determined)



IIIA 10.4.2.2 Contact

The acute contact toxicity studies on honey bees with the product are summarised in Point 10.4

Effects on bees of residues on crops IIIA 10.4.3

A honey bee brood feeding study according to the provisions of 465325-01) as well as a semi-field brood tunnel study according to the provisions of the OECE , 2015, M-510267-07-1) have been conducted. These soldies Guidance Document 75 (summarized under KCA 8.3.1.3 /01 and KCA 8.3.1.3 /03, respe

IIIA 10.4.4 Cage tests

A semi-field brood tunnel study according to the provi , 2015, M-510267-01-1) has been Not necessary considering the outcome of the risk assessment and the results of lower-tiered studies.

IIIA 10.4.6 Investigation into special effects
Please refer to point IIIA 10.4.3.

IIIA 10.4.6.1 Larval toxicity
Please refer to point IIIA 10.4.3.

IIIA 10.4.6.2 Long residual effects
Please refer to point IIIA 10.4.3.

IIIA 10.4.6.3 Disorienting effects on bees
Please refer to point IIIA 10.4.3.

IIIA 10.4.7 Tunner tests

Not necessary considering the outcome of the risk assessment and the results of lower-tiered studies. 8.3.1.3 /03.

IIIA 10.5 Effects on arthropods other than bees

Toxicity tests on non-target arthropods were conducted with IMS + MSM + MPR OD 42 on the sensitive standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi* and on *Chrysoperla carnea*. A summary of the results is provided in Table 10.5-1.

Table 10.5- 1: Endpoints of the formulation IMS + MSM + MPR OD 42 used in risk assessment

Test species	Tested formulation, study	Ecoto Ecoto	xeological endpoint
Reference	type, duration, exposure	<u> </u>	xCological endpoint
Aphidius	IMS + MSM + MPR OD 42	$LR_{50} = 277.3 \text{ mL/ha}$	
rhopalosiphi	lab., glass plates,		
	[mL/ha]	corr. Mortality [%] 0	Exploring Parasitation Explicience A [%]
(2003)	375	corr. Mortality [%]	-2.2
C036547	530	2.6 4 0 0	5.00
M-220929-01-1	750	,56.4 0	
KIIIA 10.5.1/01	1061	59.0	
	1500	corr. Mortality [%] 2.6 56.4 59.0 87.2 1.8 so \$1500 par/ha \$2500	
Aphidius	750 1061 1500 IMS + MSM + MPR 30 42 ext. lab., barley seed lings [mL/ha] 750	ĽR ₅₀ ≈ 500 mΩ/ha	Effect on Parasitation Efficiency [%]
rhopalosiphi	ext. lab., barley sectlings O		
(2003)	[mL/ha]	com. Mortality [%]	Effecton Parasitation Efficiency [%]
C037712	750		25.8
M-223374-01-1	1500	N 1 1 1	8.7
KIIIA 10.5.2/01		Coop. Mortality [%]	
Typhlodromus	IMS + MSM + MPR O 2042	LR 50 > 1300 mL/ha corr Mortality [%] 0	
pyri	lab., glass plate [mL ha] 7 7 150 257 257 257 257 257 257 257 257 257 257		
	[mLaa] 6 4	corr Mortality [%] O	Effect on Reproduction ^B [%]
(2003)	1500	13.5	[-¶.2 [~]
C036098	[mLAsa] 7 2 150 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	13.50 8.4 93.9 L	4.9
M-219955-01-1	Å74 🔊 🖖 🐇 🔏	33.9 L	-400
KIIIA 10.5.17	844 1500 × 2	8.4 93.9 40.7 32	19.8
	15000 🐃 👸 🧸	32 7 9	12.3
Chrysopexia	IMS + MSM + MPR QD 42	IDX 50 > 1500 mI@na	
carnea 🤝	ext. lab., maize leaves		
	[mkma] 😽 🛴 Ş	cori Mortality [%]	Eggs/Female/Day Hatching [%]
(2003)	Control 🖖 💍 🦠		30.7 87.7
C038055	350 A & &'		32.6 90.6
M-224105-02-1	[mk/ha] Control 50 1500 1500 1500 1500 1500 1500 1500	33.9 40.7 32 198 ₅₀ > 1500 ml@ha corft Mortality [%]	34.4 89.4
KIIIA 10.5.2002			

A negative value means increased pagasitation efficiency compared to the control

All above endpoints used in risk assessment are consistent with the *proposed* EU endpoints listed in Document N2 for mesosulfuron-methol.

Risk assessment procedures

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/19329/2002) and to the Guidance Document on regulatory testing and risk assessment

B negative value indicates increased reproduction compared to the control



procedures for plant protection products with non-target arthropods (ESCORT 2, Candolfi et al. 2000^6).

The following equation was used to calculate the hazard quotient (HQ) for the in-field scenario.

In field-HQ = max. single application rate * MAF(LR₅₀)

IMS + MSM + MPR OD 42 is intended to be applied once with an application rate of 1500 mL/km in winter wheat and with an application rate of 600 mL ha in winter we. Resulting ho values are presented in the following table. The risk is considered acceptable if the calculated HQ is

Table 10.5-2: HQ for terrestrial non-tanget anthropods for the in-field scenario

Crop /	Species Appl. rate MAF Lakso H.	rigger
Compound Winter wheat 1		, <u> </u>
IMS + MSM +		1 2
MPR OD 42	T. pyri	2
Winter rye, 1 × 0	0.6 productha	
IMS + MSM +	$ \mathcal{A} _{\text{nvris}}$ $ \mathcal{A} _{\text{constant}} \mathcal{A} _{$	2
MPR OD 42	A. rhopalosifyhi 600 1 2 877.3 0.68	2

Conclusion For the standard species, the in-field HO values are below the trigger of concern, indicating an accepta

Off-field hazard quotient (HQ) tier I risk assessment

The following equation was use to calculate the hazard quotient (HQ) for the off-field scenario:

Eld HQ = max. single application rate MAF * (drift factor/VDF)*correction factor / LR₅₀

MAF = multiple application factor

Drift factor = 1 0.02\forall , 90\forall perceptile for one application (according to Ganzelmeier)

VDF = vegetation distribution factor

Vegetation distribution factor 10

⁶ Candoln et al.: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001

Correction factor = 10 (uncertainty factor for the extrapolation from indicator species to other off-field non-target arthropods; default value for tier 1 risk assessment according to the Terrestrial Guidange Document)

Table 10.5-3: HQ for terrestrial non-target arthropods for the off-field scenario

Guidance
× 1 0,
\$ \$. Q
HQ Trigger
<0.03 2
Q 5 2
×0.02 2
* * * ·

Conclusion: The estimated HQ is below the trigger of concern, indicating no unacceptable risk for non-target arthropods.

IIIA 10.5.1 Using artificial substrates

Report:	;2005,M-220929-01
Title:	Fifects of AE F115008 06 QD04 A104 on the parasitoid Aphidius rhopalosiphi in
	the laboratory - dose response test Code: AE F105008 06 OD04 A104
Report No	CQ36547, A A A A A A A A A A A A A A A A A A A
Document No:	100-2209 2 9-01-
Guidelines:	IOBS: WPRS 2000 Deviation not specified
GLP/GEP:	yes y y y

Objective

The aim of the study was to determine the effects of formulation IMS + MSM + MPR OD 42 (Atlantis D), AE F115008 06 D04 104 to mortality and parasitisation efficiency of parasitoid The standard laboratory study was designed to meet IOBC criteria. wasps (Aphidius rhap dosiphi)?

Material and Methods

Wasps were treated with 375 530, 1061 and 1500 mL product/ha with an application volume of 200 L/ha op glass plates. Foreover, Pertekthion EC was tested as a toxic standard with a dosage of 0.3 mL/ha. The exposure duration was 48 hours. In the course of the exposure phase 4 replicates with 10 (7 females and makes) were used per treatment level. The wasps were introduced into the test systems 20% 60 minutes after the application.

A consecutive parasitisation test was performed at treatment levels with mortality rates less than 50%. Untreated pots with barley seedlings infested with aphids (Rhopalosiphum padi) served as postexposure units, 20 replicates with one female each were used during the post-exposure period. The 24hour-parasitation period was followed by a post-parasitisation period of 12 days.

The temperature varied between 20 to 24°C during the whole study period. Relative air humidity varied between 60 to 88% and 60 to 67 % during the exposure and the post-exposure period, respectively. The test systems were exposed to 1370 to 1800 lux during the exposure period and 4000 © to 10000 lux over the post-exposure period. The light period during the whole test was 16 hours.

Findings

All validity criteria according to control mortality, effects of the toxic reference and the parasitisation rates are fulfilled.

Mortality and parasitisation rate are summarised in the following table.

Percent mortality and parasitisation efficiency of Aphiatis rhofulosiphi Table 10.5.1- 1:

mL product/ha	48 h % corrected Significance % reduction of paralue
	mortality V V Darasitisation S S
Control	
375	0.0 % n.s. \$\frac{1}{2} \times 2.2 \times \frac{1}{2} \times \frac{1}{
530	26
750	56.4 'Y & Da. O *
1061	59.0 × V × V h.a. V × *
1500	87,2 0 1 1 1 n.a. 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Toxic standard	* Note: O & O & O & A A A A A A A A A A A A A A

n.s. = not significant

n.a. = not applicable

ons were made: affected and morbund individuals were observed after 2 eer 750 and 1500 mL product/ha. hours at treament leve

Conclusion

The effect of the formulation IMS + MPR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104) on mortality and the parasitisation rate phidius hopalosiphi are as follows:

©nfidence limits 791.6 - 972.3 mL/ha) 48 h LD₅₀

Report:	n; ;2003;M-219955-01
Title:	Effects of AE F115008 06 OD04 A104 on the predatory mite Typhlodromus pyri in
	the aboratory dose response test
Report No: 0	C03608
Document No:	M-219955-01-1
Gnidelines:	IQBC: ESCORT 1994; Deviation not specified
CLP/CEP:	yes
8	

Objective

The aim of the study was to determine the effects of the formulation IMS + MSM + MPR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104) to mortality and reproduction of predatory mites (*Typhlodromus pyri*). The standard laboratory study was designed to meet IOB Criteria.

Material and Methods

Mites were treated with 150, 267, 474, 844 and 1500 mL product/ha with an application volume of 200 L/ha on glass plates. Moreover, Perfekthion EC was tested as a toxic standard with a dosage of 8 mL product/ha. Test duration was 14 days. 3 replicates with 20 protonymphs were used per treatment. level. The protonymphs were introduced into the tox systems 25 to 40 prinutes after the application. The temperature varied between 24°C and 26°C. Relative air kumidity varied between 61% and 89°C. The test systems were exposed to 250 to 590 by. The light seriod during the whole test was 16 hours

Findings

All validity criteria according to control mortal The second control of the second control of rates in the control are fulfilled.

Mortality and reproduction are summaris

Table 10.5.1- 2:

mL product/ha	Day 7 to 14	Significance
mL product/ha	reduction of	
(% corrected (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)	production)	
Control O O O O O O O O O O O O O O O O O O O	& '	
150 0 × 13.5 n.s. 5	<u></u>	n.s.
267 & 84	4.9	n.s.
\$\hat{\pi}\frac{\pi}{2}\p	-4.9	n.s.
844	19.8	n.s.
1500 3 320 4 * 0	12.3	n.s.
1500 324 4 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	n.a.	n.a.

No intoxication symptom

Conclusion

The effect of IMS + MSM MPR OD 42 (Atantis®OD, AE F115008 06 OD04 A104) on mortality Bphlodromus Pyri are as follows:

1500 mEproduct/ha 1500 mL product/ha

IIIA 10.5.2 Extended laboratory studies

Report:	p; \$2003;M-223374-01	, Ç Q
Title:	Effects of AE F115008 06 OD04 A104 on the parasi	itoid Aphidius rhopalos phi - 🏻
	extended laboratory study	
Report No:	C037712	
Document No:	M-223374-01-1	
Guidelines:	IOBC: Mead-Briggs et al. 2000; Deviation not spe	cified y y y
GLP/GEP:	yes	

Objective

The aim of the study was to determine the effects of the formulation IMS + MSM + MPR QD 42 (Atlantis®OD, AE F115008 06 OD04 A104) to mortality and parasitisation efficiency of parasitoid wasps (*Aphidius rhopalosiphi*). The extended aboratory study was designed to meet IQBC criteria.

Material and Methods

Wasps were treated with 750 and 1500 mL product that with an application volume of 400 L/ha on barley seedlings. Moreover, Perfection EC was tested as a toxic standard with a dosage of 10.0 mL product/ha. The exposure duration was 48 hours. In the course of the exposure phase 6 replicates with 5 females were used per treatment level. The wasps were introduced into the test systems 15 to 20 minutes after the application.

A consecutive parasitisation test was performed at treatment levels with mortality rates less than 50%. Untreated pots with batley seedlings infested with aphids (hop dissiplum padi) served as post-exposure units. 20 replicates with one feptile each were used during the post-exposure period. The 24-hour parasitisation period was followed by a post-parasitisation period of \$1\$ days.

The temperature varied between 18 22°C during the whole study period! Relative air humidity varied between 60 to 83% and 66% during the exposure and the post exposure period, respectively. The test systems were exposed to 1230 4960 have during the exposure period and 6830 - 11500 lux over the post-exposure period, the light period during the whole test was 96 hours.

Findings

All validity criteria according to control mortality of fects of the toxic reference and the parasitation rates are fulfilled.

Mortality and parasitisation rate are summarised in the following table.

Table 10.5.2- 1 Percent mortality and parasitisation efficiency of Aphidius rhopalosiphi

	48 h % m@tality	Mummies per female	% reduction of parasitisation
Contrat	0.0	28.7	•
	0.0 n.s.	21.3 n.s.	25.8
1/500 mL product/ha	13.3 n.s.	26.2 n.s.	8.7
Toxic	100.0	n.a.	n.a.

No sigificant mortality compared to the control and no repellent effects were observed.

The effect of formulation IMS + MSM + MPR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104) on mortality and the parasitisation rate of *Aphidius rhopalosiphi* are as follows:

The effect of formula	tion IMS + MSM + MPR OD 42 (Atlantis OD, AE F115008 06 OD04 A 1041) on 6
mortality and the para	asitisation rate of <i>Aphidius rhopalosiphi</i> are as follows:
48 h LD ₅₀ > 1500 NOEC≥1500 mL pro	mL product/ha duct/ha
Report:	;; ;2003; M-22410, 203; Agnended 2004-02-19;
Title:	Effects of AE F115008 06 D04 A104 on the Jazewing Chrysoperla carneg
	extended laboratory study Revised final report no. 1
Report No:	C040071
Document No:	M-224105-03-1
Guidelines:	IOBC: Vogt et al 2000; Deviation not specified >
GLP/GEP:	yes Q V Z Z Z Z Z Z Z Z Z Z Z Z Z Z Z Z Z Z

Objective

The aim of the study was to determine the effects of the formulation IMS + MSW+ MIR OD 42 (Atlantis®OD, AE F115008 06 OD04 A104) to latval mortality and reproduction of lacewings (Chrysoperla carnea). The extended laboratory study was designed to meet OBC oriteria.

Material and Method's

2 to 3 days old larger were treated with 30 and 1500 on L product/ba with an application volume of 200 L/ha on maize leaves. Moreover Perfektion EC was tested as a toxic standard with a dosage of 60 mL productha. 50 replicates were used per treatment level the large a were introduced into the test systems 50 to 55 minutes after the application. The larvae were fed with UV-sterilised eggs of Sitotroga Gerealella. The duration of the exposure phase was 12 to 17 days.

The reproduction phase lasted 7 to 12 days (pre oviposition) and 1 week with 2 checks (oviposition period). The temperature varied between 23°C and 26°C. Relative air humidity varied between 61% sed to 1070 to 2230 Tux. The light period during the whole test and 88 %. The test systems was 16 hours

All validity criteria according to control portality, effects of the toxic reference and the reproduction rates in the control are filled. Mortality and reproduction are summarised in the following table.

Mortality and reproduction of adult Chrysoperla carnea Table 10.5.2- 2:

	% corrected mortality	Mean number of	Mean larval hatchire rate
		eggs/female/day	
Control		30.7	87,7 (2)
750 mL product/ha	0.0	32.6	99.6
1500 mL product/ha	0.0	34.4	894 6
Toxic reference	57.4		
Toxic reference To mortality and reproduct the formulation of the formulation mortality and the reproduct to $D_{50} > 1500 \text{ mL}$ product $O_{50} > 1500 \text{ mL}$ product $O_{50} > 1500 \text{ mL}$ product $O_{50} > 1500 \text{ mL}$ product	ts on IMS + MSM + MPR Coduction rate of Chrysopolis ha t/ha ts orred under 10.5.1, and ba been conducted.	42 (Allantis OD, AE F la camea is as follows:	F115008 06 OD04 A104)

IIIA 10.6 Effects on earthworms and other soil non-target macro-organisms

Ecotoxicological endpoints used in risk assessment

Table.10.6-1: Endpoints of the <u>formulation</u> IMS + MSM + MPR OD 42 used in risk assessment

Test substance	Test organism	Study type	Endpoint [mg/kg dws]		References	
	Earthworm, chi	ronic	Ĉ	Å,	. W ~	N Q
IMS + MSM + MPR OD 42	Eisenia fetida	reproduction, 56 d (10% peat in test soil) test item mixed into soil		,	(20)4 M-8/3205-Q1-1 KUIIA 10.6.3/01	

dws = dry weight soil

Table.10.6-2: Endpoints of the active substance mesosulfuron-methyl and metabolites used in risk assessment

Test substance	Test organism	Studytype	Endpoint O	References
			[mg/kg dms]	
Earthworm, chi	ronic			
Mesosulfuron- methyl	Eisenia fetida (reproduction of d (10% peat in test soil), test item based into	NOTEC STATE OF THE PROPERTY OF	(2010) M-392544-01-1 KC 428.4.1 /02
AE F154851	Eiseging fetida	reproduction so d (5% peat intest soll) test item mixed into	NOEC \$\frac{1}{2} \geq 293\color{10}{2}\$	©012) M-425013-01-1 KCA 8.4.1 /03
AE F160459	Eisgriia fetiga	reproduction 56 d. (5% peat in test soil), test item mixed into soil	SOEC SOOC	(2012) M-429097-01-1 KCA 8.4.1 /04
	ESenia fétida	reproduction, 56 O 20% por in test soil), test item mixer into O soil	NOECS ≥100	(2013) M-473217-01-1 KCA 8.4.1 /05
AE F092944	Eisenia Jorida	reproduction, 56 0 (10% peat in test soil) test item mixed into soil	9	(2013) M-461051-01-1 KCA 8.4.1 /06
AEF160460	Eisenia Fiida	fewroduction, 56 d 10% poat in 40st soil), test item mixed into soil	NOEC ≥100	(2013) M-468911-01-1 KCA 8.4.1 /07
AE F140554	Fisenia Getida Z	reproduction, 56 d (10% Peat in test soil), test item mixed into soil	NOEC ≥117	(2013) M-468921-01-1 KCA 8.4.1 /08
AF F147477	Eisenia Jetida	reproduction, 56 d (5% peat in test soil), test item mixed into soil	NOEC 90	(2012) M-428651-01-1 KCA 8.4.1 /09

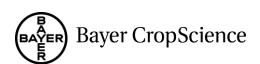


* corrected to an anal dws = dry weight soi	
All above endpoint	is used in risk assessment are consistent with the <i>proposed</i> Elemonomics listed in
Document N2 for r	ts used in risk assessment are consistent with the <i>proposed</i> Elemander in the mesosulfuron-methyl.
	est used in risk assessment are consistent with the proposed Ethendpoints listed in mesosulfuron-methyl. **Description** **
Predicted Enviror	nmental Concentrations used in risk assessment
Formulated produc	
•	
Predicted environm	nental concentrations in Soil (PEC soil) Values were calculated for the formulation
pased on the standa	ard assumptions of distribution in a soil layer of 5 km with a bulk density of
1.5 g/cm ³ ; a crop ir	ard assumptions of distribution in a will layer of 5 km with a bulk density of the interception of 50% was taken into account.
ГаЫе 10 6 1- 1· Ini	itial PECsoil values of the formulation
Crop / Compound	Scenario Winter wheat, Winter rye, 1 1 1.5 L/ha 1 x 0.6 L/ha
Compound	PECon, max PECon, max
	[mg/kg] (mg/kg] (mg/kg)
	sold layer of cm
IMS + MSM +	soit densition 1.5 g cm L 1.000 L 0.400
MPR OD 42	product density: 1.000 g/ml # 1.000 g/ml # 0.400 crop interception: 50%
Bold values: worst c	rest Vancidared in Oily assessment
) specified desity for	product IMS + M9M + MPR ODAY: 1.000g/mL

Predicted environmental concentrations for the active Substance and its metabolites were calculated in Point IIIA 9.4 (active substance) and IIIA 9.5 (metabolites) of this MCP document. The relevant PEC values considered for TER calculations are summarised in the tables below. Maximum values are used for risk assessments. Point IIIA 9.4 (active sobstance) and DIA 9.5 (metabolites) of this MCP document. The relevant PEC

^{*} corrected to an analysed purity of 93.9 %

^{*)} specified dossity for product IMS + MSM + MPR OD 1. 1.000 g/mL



Crop / Compound	Winter v		Winte	er rye,	its metabolites
	1 x 1.5 PECsoil, initial	PEC _{soil, accu}	1 x 0.6 PECsoil, initial	PEC _{soil}	
	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	
Mesosulfuron-methyl	0.010	0.011	0.004	Q.004	
AE F154851	0.002	-	⊘ €0.001	√ -	
AE F160459	< 0.001	0.001	% <0.001	<0.001	
AE F099095	0.001	0.002	<0.001	○ <0.001 3	
AE F092944	< 0.001	- 4	<0.001	, , C	
AE F160460	< 0.001	- 6	<0.001	- Q	
AE F140584	< 0.001		<0.001	700	
AE F147447	< 0.001	\$6,001	\$ 0.0 01	<0.001 (
values: worst case con	nsidered in risk ass	sessment &			

Crop / Compound	Winter v	v <mark>heat, 🎺</mark> L ^o ha	Wonter	r rye,
	PECsoil, initial, Q	PE Coil, accu	PECO, initial C	PECoil, accu [mg/kg]
Mesosulfuron-methyl	₹ 0.0 1 6	0.020	0.006	∞ 0.008 0.0
AE F154851	© 0.063 ×	0.004	0.001	0.001
AE F160459 \$	g.001 Q	0.002	₹0 ₹001 [™]	<0,001 ≪
AE F099095 ≪ _J	©.002 ©	○ <u>0.003</u> >	° 20.001 €/	0.001
AE F092944 🝣	© <mark><0.00</mark>	7) - S	√√′<0.001 ″	
AE F160460	√ <mark>0.001</mark> ,^S		<0001	
AE F1405	€0.001		59.001 3	Z.
AE F147647	<0.00	. % <mark>0.002</mark> >	<0.004	₹0.001

Risk Assessment

Risk Assessment The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestria

Based on the endpoints are calculated using the following equations:

The risk is considered acceptable if

(2) all results from the laboratory studies are corrected by a factor 2 even when the organic Matter is less than 10 %.

for hone of the components logP_{OW} exceeds this trigger (refer to Section 2 of the MCA document (A 2.7), hence an additional assessment factor is not required.

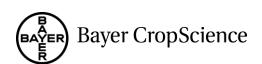
Table 10.6.1-3: TERLT calculations (formulated product) for earthworms

Crop / Compound	Species	Endp [mg/kş		PEC _{max} [mg/kg soil]	TER _{LT}	Trigger
Winter wheat, 1× 1.5	L prod./ha				Q.	
IMS + MSM + MPR OD 42	Eisenia fetida	NOEC	76	1.000	76	
Winter rye, 1× 0.6 L	prod./ha		Ö			
IMS + MSM + MPR OD 42	Eisenia fetida	NOEC	76	0300		

Table 10.6.1- 4: TER_{LT} calculations (<u>active substance mesosulfuror-methyl and metabolites</u>) for earthworms

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species	Endpoint (apg/kg soil)	PEC max/accy	TER _{LT}	Figger
Winter wheat, 1 × 15	g a.s./ha		0011	J. J.	Į
Mesosulfuron-methyl	Eisenia fetia a "	NOEC 325	90011	10,364	y
AE F154851	Eisenia f y ida	NOE® \$3.90°	Q0.002 O	¥46 9 \$ 0	
AE F160459	Eisenia fetid a	NOEC 90	L 0.00P	90,000	
AE F099095	Eis @ ia feti Q a	NOEC ≥ 100	0,002	≥≤50 000	5
AE F092944	Eisenia fe tida	NOES NOES 10 NO	< 0.00 f	3 10 000	3
AE F160460	Eisen lo fetida	NOEC & >100	$0^{\circ} < 0.0001$	°>≥ 100 000	
AE F140584	Eisknia feti d a	1 NOEC 117 2	₹0.001 @	≥ 117 000	
AE F147447	Bisenia fetida (NOSC 90	@ 0.001S	> 90 000	
Winter rye, 1 6 g as	/ha O	NOEC 90 S			
Mesosulfuron-methyl	Eisenia fet id a	ANOE OF 25	0.004	31 250	
AE F154831	Eisenia Etida ,	NOEC	∼ 0.001	≥ 93 900	
AE F160459	Eise ļija fetida,	NOEC 90	< 0.001	> 90 000	
AE F099095	Eįsenia fetida	NOEC Q 100	< 0.001	≥ 100 000	5
AE F092944	Bišenia Etida	NOEC V 10V	< 0.001	> 10 000	3
AE F16046Q	Eiseria fetjda/	NOEC > ≥ 100 №OEC > 2117	< 0.001	≥ 100 000	
AE F1405 <u>8</u> 4	Eisenia fettala	(MOEC) (2) 117	< 0.001	≥ 117 000	
AE F14 79 47	D isenia J etida	NOEC > 90	< 0.001	> 90 000	
AE F099095 AE F092944 AE F160460 AE F140584 AE F14047					



b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

		T				<u></u>
Crop / Compound	Species	Endpoint [mg/kg soil]	PECsoil,max/accu [mg/kg]	TER _{LT}	Exigger) Da
Winter wheat, 1×15	g a.s./ha					
Mesosulfuron-methyl	Eisenia fetida	NOEC 125	0.020	6 250		
AE F154851	Eisenia fetida	NOEC ≥ 93.9	0.004	≥ 23 475°		
AE F160459	Eisenia fetida	NOEC 900	0.002	45 000		. W
AE F099095	Eisenia fetida	NOEC ≥ 100	0.493	≥3 3 333		5
AE F092944	Eisenia fetida	NOEC © 10	\$0.001	10 000		
AE F160460	Eisenia fetida	NOEC 0 ≥ 100	0.00	<u> </u>		
AE F140584	Eisenia fetida	NOEC ≥ 117	50:901	≥ \$1 7 000 €		
AE F147447	Eisenia fetida	NOES V V 90 V	Ø.002 ~	3.3.00	4	
Winter rye, 1 × 6 g a.s	s <mark>./ha</mark>	A O	Q , (y 0 8		
Mesosulfuron-methyl	Eisenia fetida	NOEC 125)) 0.708	№ 625		
AE F154851	Eisenia fetida	NOKC 2 93.9	8.001	93 900	O	
AE F160459	Eisenia fetida	NOTEC ST 90	© <0.001	> 90,000		
AE F099095	Eisenia feti da	NOEC S) <u>po</u> 01	≥ 1000 000 √	/ 	
AE F092944	Eisenia f é ida «	NOEC FIO	0.001	10 000	<u> </u>	
AE F160460	Eisenia fetid a	NOEC 2 ≥ 100	√ <0:00 ×	≥ 100 000		
AE F140584	Eis ka ia feti k a	NOEC ≥ 117	20 7001	≥407 000		
AE F147447	Eisenia fe tida	NOTE V 90	<0.001 C	90 000		
	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	- W	@ ' (//	A .		

Conclusion: The SERLY Values meet the required trigger of 3, indigating at acceptable long-term risk to earthworms for the oriended uses.

acute earth from toxicity tests are no longer data Under the Regulation (EC) requirements.

	9	
Report	Ď	;2014;M-483205-01
Title:		Iodosulfuron methyl Sodium + mesosulfuron-methyl + mefenpyr-diethyl OD
*		42 (2410+36) G: Sublethal toxicity to the earthworm Eisenia fetida in
y	~ ~	artificial soil
Report No:	(° 4 °	\$\frac{1}{2}\tau 10.48^2 182 \$\tau^2\$
Document No		M-483205-01-1
Guidelines.		OECD 222 (2004), ISO 11268-2 (1998);none
GLP/GLP:		S

The purpose of this study was to determine the sublethal effects of formulation IMS + MSM + MPR OD 42 on reproduction, mortality and growth of the earthworm Eisenia fetida by dermal and alimentary uptake using an artificial soil in a laboratory test. The test was performed according to the



recommendations of the OECD Guideline 222 (2004) and the International Standard ISO 11268-2 (1998).

Material and Methods:

Test item: Iodosulfuron-methyl-sodium + mesosulfuron-methyl + mefenpyr-diethyl OD 42 (2+1 G, Short name: IMS+MSM+MPR OD 42 (2+10+30) G, BCS Codes: BCS-BB66887, BSC BCS-AF80757, Sample description: TOX10332-00, Specification No.: 202000008429, Material No. 06268129, Batch ID: EFKM002637, active ingredients (analysed concent): 0.218 % w/w £2.174 iodosulfuron-methyl-sodium (AE F115008); 1.04 % (10.33 gd) mesøsulfuron-methyl F130060), 2.98 % w/w (29.71 g/L) mefenpyr-dientyl (AE F107892), density (20°C). 0.966@/mL water solubility: dispersible.

Adult earthworms (Eisenia fetida, about 4 months old) were exposed to 10 - 17 - 28 = 46 - 46211 - 350 mg test item/kg dry weight (d/w.) of soil containing 68.5% quartz sand, 20% kaolin clay, 10% sphagnum peat, 1% food and 0.5% $CaCO_3$, at 18.0 – 21.7 °C and a photoperiod: light: dark = 16 h: 8 h (530 lx) and were fed with horse manure. Mortality and bromas change were determined after 4 weeks and reproduction was determined after 8 weeks.

OW/kg sont d.w.; control untreated, solvent control: Toxic standard: 5 and 10 mg Nutdazim 50 T none.

Dates of work:

Findings:

Effects on mortality, growth and reproduction of the earthworms Table 10.6.3- 1:

Test item Todos Information Indostribution Indostri	sodium + mesosulfuron-methy	rl + mefenpyr-diethyl
Test object	₹Ø D 42 Q +10+30) G	
Exposure	🛴 Elsenia fetida	
	O Artificial soil	
Exposure Mortality	Biomass change	Reproduction
	[mg test item/kg d.w.]	
NOEC DOEC DOEC DOEC DOEC DOEC DOEC DOEC D	≥ 350	76
LOEC () () () () () () () () () (> 350	127
LOEC EC_{10} $(95\% \text{ confidence limits})$ EC_{20} $(95\% \text{ confidence limits})$		
EC_{10}	-	60
(95%/confidence limits)		(52 - 69)
$ EC_{20} ^{1)}$	-	87
(95% confidence limits) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		(78 - 96)
EC ₁₀ , (95% confidence limits) EC ₂₀ (95% confidence limits) 1) based on Proofit analysis		



Observations:

Table 10.6.3-2: Effects on mortality, growth and reproduction of the earthworms

Ioo	Iodosulfuron-methyl-sodium + mesosulfuron-methyl + mefenpyr-diethyl OD (2+10+30) G [mg test item/kg d.w.]								
	Control	10	17	28	46	76	127	211	350
	Mortality of adult worms after 4 weeks								
Mortality	1.3	0.0	0.0	5.0	00	2.5	0.0	×2.5 ~	2.5
	Biomass c	hange (cha	nge in fresh	weight afte	er 4 weeks r	elative Q ii	nitial fresh	weight)	
Mean (mg)	139.6	149.9	141.0	127.7	145.0	140.4	137.6	13 4 QI	21.3 %
Mean (%)	33.9	36.5	34.1	31.1	35.3	9A.2 ⊘	° 33,4	\$ 2.8	293
		Number	of juveniles	per surqivi	ing adult w	orm after 8	weeks		~~
Mean	13.3	13.3	13.7	13,0	\$ 12.7 ڳ	1,14	₹ 8.5 €	5.7%	₹ <u>2</u> .6
		Ni	umber of ju	venites per	seplica te af	ter&week		4 6	A
Mean	131.8	132.5	136.5	123-80	12,7.0	110.8	853*	55.3*	2508*
	Reproduction compared to control (%)								
% to control	100	100.6	1036	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	9 6 9	\$4.1 \$	64.	3 1.9	19.5

No statistically significant differences between the control and test item were calculated for mortality and biomass (Fisher's Exact Binomial Test with Bonfersoni Correction, $\alpha = 0.05$, one sided greater)

Validity criteria:

- Adult mortality:

≤10 % Hobeing 1.3 % Ofter 4 weeks)

- Number of juveniles per replicate:

≥ 30 Deing \$26, 148, 111 \$265, 102, 151, 132 and 119

- Coefficient of variation of reproduction:

⊈30 %**⊕**being**⊕**6.4 %**Ø**

In a reference test, the number of juveniles was reduced by 39 and 100 % by the toxic standard Nutdazim 50 FLOW (Carbendazim, SC 500) at concentrations of 5 and 10 mg product/kg soil dws in comparison to the control. Therefore, the observed effects assure a high sensitivity of the test system.

Conclusion:

Formulation IMS + MSM + MPR OD 22 showed no statistically significantly adverse effects on mortality and biomass of the earthworm *Elsenia Toida* in artificial soil up to and including 350 mg test item go soil dry weight, i.e. the highest concentration tested. The test item showed statistically significantly adverse effects on reproduction at 127, 211 and 350 mg test item/kg soil d.w. Therefore, the overall No Observed Effect-Concentration (NOEC) was determined to be 76 mg test item/kg soil d.w., and the overall Lowest-Observed Effect-Concentration (LOEC) was determined to be 127 mg test item/kg soil d.w.

IIIA 10.6.4 Field tests

Considering the findings reported above no further studies are required.

^{*} statistically significantly different compared to control for reproduction (Williams-t-test, $\alpha = 0.05$, one-sided smaller)

IIIA 10.6.5 Residue content of earthworms

According to the "Guidance Document on Risk Assessment for Birds and Mammals under Councillation and C Directive 91/414/EEC", SANCO/4145/2000 (2002) a log $P_{ow} > 3$ is used to indicate that there wight be a potential for bioaccumulation. For information on the residue content of earthworms please references. to IIIA 10.1.9.

Effects on other non-target macro-organisms IIIA 10.6.6

Table 10.6.6-1: Endpoints of the <u>formulation</u> IMS

•	ioaccumulation. For	information on the resid	40%	
to IIIA 10.1.9.			4	ssessment
		ام		
			Ű	
IIIA 10.6.6 Ef	ffects on other non	ı-target macro-örgan	nisms 🖇 🛴	
		407		
Ecotoxicological e	endpoints used in ris	sk assessment		
Table 10 6 6_ 1 · Fn	dnoints of the formul	ation IMS TMSM + MP	> > OD Å∂∕used mærisk∻s	Secombut S
				4
Test substance	Test organism	Stud®type ©	Epdpoint &	Reference
			Qmg/kg dws]	0' 5'
		açro-organisms, chronic		
		reproduction, 4 d	ONOEC 316	$(20\overline{\mathbb{Q}})$
	Hypoaspis aculeif®	(5% yeat in test soil)	ONOEC 316	M -40 46 79-01-1
IMS + MSM +		tost item mixed into		\$KIII, % √10.6.6/01
MPR OD 42	- 4	reproduction 28 d		
		(5% peat in test soil)		2 011)
	Folsomia Candida	test item wrixed into	NOEC 17	M-407706-01-1
		Soil &		KIIIA 10.6.6/02
		W A N		

dws = dry weight soil

Table 10.6.6- 2: Endpoints 9 risk

Test substance	Test organism	Study type 0	Endpeint	References
Č			[mg/kg dws]	
Other non-target	macro-organisms, ch	ronic 💮 🧳		
		reproduction, 14 d ,	O'	(2012)
*	Hypoaspis aculeifer		NOEC ≥1000	M-429376-01-1
Mesosulfuron-		test item mixe Ointo soil		KCA 8.4.2.1/01
methyl	Formia Edndida	reproduction 28 d		(2012)
	FoDomia zandida 🤍	(5% peat in test son),	NOEC ≥1000	M-426538-01-1
~\psi		test item nixed into soil		KCA 8.4.2.1/02
		rreproduction, 28 d		(2013)
AE F154851	Folsomia Andida	(5% peat in test soil),	NOEC ≥ 100	M-462785-01-1
.// ·		test item mixed into soil		KCA 8.4.2.1/03
		Deproduction, 28 d		(2013)
AE F160459	Folsomia capadida $_{\mathbb{Q}}$	(5% peat in test soil),	NOEC ≥ 100	M-462786-01-1
		testQtem mixed into soil		KCA 8.4.2.1/04
Q"		pproduction, 14 d		2013)
	Hypocopis acaleifer *	$\mathbb{Q}5\%$ peat in test soil),	NOEC ≥ 100	M-454043-01-1
AE F09\$\frac{9}{44}		test item imaed into son		KCA 8.4.2.1/05
The residence of the second se	A	reproduction, 28 d		(2013)
	Folsomia candida	(5% peat in test soil),	NOEC ≥ 100	M-451142-01-1
		test item mixed into soil		KCA 8.4.2.1/06
U . U		reproduction, 28 d		(2013)
AE F 47447	Folsomia candida	(5% peat in test soil),	NOEC ≥ 100	M-462782-01-1
		test item mixed into soil		KCA 8.4.2.1/07

dws = dry weight soil

All above endpoints used in risk assessment are consistent with the *proposed* EU endpoints listed in Document N2 for mesosulfuron-methyl.

Predicted Environmental Concentrations used in risk assessment

Please refer to Point IIIA 10.6.1

Ecotoxicological endpoints and PEC_{soil} values used for TER carculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation.

TER = NOEC / PEC_{soil}

organisms are sumi	ndpoints and PEC _{soil} marised below. TER C _{soil} red acceptable if the RLT calculations (for earthworms)	t value were	alculated	using the qua	ation.	
TER = NOEC / PE	C _{soil}					
The risk is consider	red acceptable if the	TER is >5.7				Q J
ГаЫе 10.6.6- 3: ТЕ	Regregations (for	しょうしゃ しょうしゅう しゅうしゅう mulasted produc	et) for soil	macro-organisi	ns other Han	
	earthworms					
Crop / Compound	Species	Endpa [mg/kg	int S	PEC _{max}	TERLT	Trigge
Winter wheat, 1×1					'	1
IMS + MSM +	Hypolospis actheifer	NOEC X	316	1.00	316	5
MPR OD 42	Fobomia candida	NØEC J		1.00	17	
Winter rye, 1× 0.6	Loprod./ha	A NOR	216 0	6.400	790	
IMS + MSM + MPR 00042	Esterna sentas	NOEC O	13/	0.400	42.5	5
	Hypogrpis acheifer Formia candida Porod. Ha Eiseria fetida Foromia candida Foromia candida Foromia candida Foromia candida					

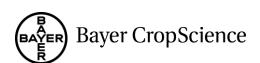


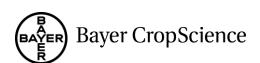
Table 10.6.6- 4: TER_{LT} calculations (<u>active substance mesosulfuron-methyl and metabolites</u>) for macro-organisms other than earthworms

a) risk assessment based on PEC values of originally submitted simulation

Crop / Compound	Species	Endpoint [mg/kg dws]	PECsoil,max/accu	TERLT	Trigger
Winter wheat, 1 × 1	15 g a.s./ha		× 1	» "O <u>,</u>	
Mesosulfuron-	Hypoaspis aculeifer	NOEC ≥ 100	0.01	≥ 90 909	
methyl	Folsomia candida	NOEC ≥ 100	0. @ Q1	≥ 9@909 5	
AE F154851	Folsomia candida	NOEC ó 10	0 6.002	©20 000 €	
AE F160459	Folsomia candida	NOEC ≥ 10		£ 100 6 00	
AE F092944	Hypoaspis aculeifer	NOEC ≥.10	0 0 < 0.001	S > 1500 000 €	
AE F092944	Folsomia candida	N ⊘ EC	0.001	3 00 000 "	<u>.</u>
AE F147447	Folsomia candida	NOEC > 10	0	> 1000000	
Winter rye, 1 × 6 g	a.s./ha				
Mesosulfuron-	Hypoaspis aculeifer	NOEC <>≥100	()	2 250 0 %	O
methyl	Folsomia candida	ØOEC~ ≥ 100	0.00	\$\sum_{2500000}\$\ \tag{5}\geq 25000000000000000000000000000000000000	Ŕ
AE F154851	Folsomia candida	NOE >10	0	> 1000 000	₹/
AE F160459	Folsomia zaddida	NOEC ∂≥10	0 0.001	\$100 g	5
AE F092944	Hypoaspis aculeifer	OEC ≥10	0.001	© > 100 000	
AE F092944	Folsoma candida	NOF ≥ 10	0 <0,001 ~	> 100 000	
AE F147447	Folsomia çandida	NGEC Z ≥ 10	© < 0.001	00 000	

b) risk assessment based on PEC values of alternative simulation using RMS requested parameters

Crop / Compound	Species O O	Endpoint mg/kg dws		Csoil,max/accu [mg/kg]	TERLT	Trigger
Winter wheat, 1 × 1	5 g assu/ha) '&' _		~ O		
Mesosyltaron-	Hopoaspio culeifer	NOEC O	≥ 1600		≥ 50 000	
methyl	Folsomia candida	ONOEC	\$1000 &	0.020	≥ 50 000	
AE F154851	Folsomia condida 🗢	NOEC	≥ 1000	0.004	\geq 25 000	
AE F160459	Folsomia Pandida	DOEC	≥ 1000	0.002	≥ 50 000	<mark>5</mark>
AE F092944	Hypogspis acuteifer	NOR	2 100	< 0.001	> 100 000	
AE F092944	Folsomia cardida &	NOEC . «	<u>≥ 100</u>	< 0.001	> 100 000	
AE F14 47	Folsomia candida	NOEGO	≥ 100	0.002	> 50 000	
Winter rye, 1 × 6 g	a.s./ha					
Mesosulfuron-	Hypoaspis aculeifer,	NOEC	≥ 1000	0.008	≥ 125 000	
methyl &	Folsomie Candida	OEC	≥ 1000	0.008	$\geq 125~000$	
AE F154854	Folsopia candida «	NOEC	≥ 100	0.001	$\geq 100~000$	
AE F160459		NOEC	≥ 100	< 0.001	> 100 000	<u>5</u>
A E E002044	Hypoaspys aculeifer	NOEC	≥ 100	< 0.001	> 100 000	
	Folsomia candida	NOEC	≥ 100	< 0.001	> 100 000	
AE F14747	Folsomia candida	NOEC	≥ 100	< 0.001	> 100 000	
Ű	·				·	



Conclusion: The TER_{LT} values meet the required trigger of 5, indicating an acceptable long-term risk for soil non-target macro-organisms other than earthworms, i.e. collembola and soil mites.

Effects on other soil non-target macro-organisms

or soil non-target macro-organisms other than earthworms, i.e. collembola and soil mites.				
Effects on other soi	acro-organisms other than earthworms, i.e. collembola and soil mites.			
Report:	b; ;201@M-404679-04\frac{1}{2}			
Title:	Iodosulfuron-methyl-sodium + mesosulfuron-methyl-sodium mefoppyr-diethyl			
	OD 42 (2+10+30) G: Influence on mortality and reproduction on the soil onte			
	species Hypoaspis aculeifer tested in artifical soil &			
Report No:	KRA-HR-48/11			
Document No:	M-404679-01-1 & & & & & & & & & & & & & & & & & &			
Guidelines:	OECD 226 from October 03,2008; OECD guideline for the Testing of			
	Chemicals - Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction			
	test in soil; none test in soil; none			
GLP/GEP:	yes O V V O V O V O V			

Objective:

The purpose of the study was to assess the effects of formulation MS + MSM + MPR QD 42 (2+10+30) G on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested during an exposure of 14 days in artificial soil comparing control and treatment. The test was performed according to the recommendations of the OE D Guldeline 26 (2008)

Material and methods:

Test item: Iodos Ifuro methyl-sodium + mesosulfiron methyl-sodium + mefenpyr-diethyl OD 42 (2+10+30) G; (Back) D: 2009-009105; Specification Nov. 102000008429 - 07; Sample description: TOX 08886-00; Master recipe 10: 0102735-001; content: 1,085 g iodosulfuron-methyl-sodium/L (0.198 % w/w); 10.55 c/mesos/furon/methyl-sodion/L (\$\infty\$05 \\ \w/w); 29.80 g mefenpyr-diethyl/L (2.97 %w/w); density. 1.002 g/mL

Ten adult, fertilized, female Hydraspis uculaiter per replicate (8 control replicates and 4 replicates for each test item concentration) were exposed to control and treatments. Concentrations of 100, 178, 316, 562 and 1000 mg test item Rg dry weight artificial soil were tested. In each test vessel 20 g dry weight artificial son were weighed in The Hypoaspic acule fer 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 brewer's yeast and with nomatodes bred on watered oat flakes. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lyx, 16 k 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% fine quartz sand, 5% Sphagnum peat, air dried and finely ground, 20 % Kaolin clay and proximately 0.17 % Calcium carbonate (CaCO₃).

After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20% eth lene glycol, 80% deionised water; 2 g detergent/L fixing solution were added). All Hypoaspis aculeifer were counted under a binocular.

Findings:

Table 10.6.6-5: Percent mortality and reproduction of adult, female Hypoaspis aculeifer after 14 days

Test item	Iodosulfuron-methyl-sodium + mesosulfuron methyl-sodium + mefenpyr-diethyl OD 42 (2+10+30) G Hypoaspis aculeifer					
Test object	+ mefenpyr-diethyl OD 42 (2+10+30) G					
Exposure		Hypoaspis aculeifer,				
		Artificial soil				
	% mortality (Adults)	M ean number o €″	Reproduction (% of @			
		juveniles per test sessel	control)			
		± standard dev.				
Control	2.5	345.3 ± 30.8 6°	\$ 4 - V			
100	17.5	300.0 ≠ 81.2 0	86.9% Q*			
178	0.0	° 385 ± 122				
316	0.0	© 292.7 ± 24.9	84.8			
562	35.0	♥ % 8.8 * \$ 12.6 ©	8.3			
1000	100 😂 🦠	0.0 = 0.0				
Reproduction Reproduction						
NOEC (mg test item/kg dr	y weight artif@al sojf		316			
LOEC (mg test item/kg dr	y weight artificial soit) 🔌		\$16 \$562\$			

^{*} statistical significance (Welch-t test®or inhomogeneous variances smaller, $\alpha = 0.05$)

Observations:

Validity of the study:

Validity criteria Recommended by the	Obtained in this study
Mean adult metality \(\text{O} \) \(\text{O} \) \(\text{V} \) \(\text{O} \) \(\text{S} \) \(\text{S} \) \(\text{S} \)	2.5%
Mean number of juveniles per replicate (with 10 as with females introduced)	345.3
Coefficient of variation calculated for the number of juvenile mites per repricate 30%	8.9%

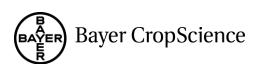
All validity criteria were

Mortality

In the control group 2.55% of the adul Hypothesis aculeifer died which is below the allowed maximum of ≤ 20 % mortality. The LG₅₀ was valculated to \mathbb{R}^2 609 mg test item/kg dry weight artificial soil. Confidence limits could not be carculated.

Reproduction

Concerning the number of juveniles stabstical analysis (Welch-t test for inhomogeneous variances with Bonterroni Holm adjustment, one-sided smaller, $\alpha = 0.05$) revealed no significant difference between control and all corcentrations up to 316 mg test item/kg dry weight artificial soil. Therefore the No-Observed-Effect Concentration (NOEC) for reproduction is 316 mg test item/kg dry weight artificial@oil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 562 mg test item/kg dry weight artificial soil. Probit analysis revealed an EC₅₀-value of 404 mg test item/kg dry



weight artificial soil with 95 % confidence limits of 317 and 646 mg test item/kg dry weight artificial soil.

Conclusions:

weight artificial soil	with 95 % confidence limits of 317 and 646 mg test item/kg dry weight artificial
soil.	
a	
Conclusions:	tem/kg dry weight artificial soil. tem/kg dry weight artificial soil. g; 2011;M-402706-01
NOEC: 316 mg test i	tem/kg dry weight artificial soil.
C	terriving dry weight artificial soft.
LOEC: 562 mg test 11	tem/kg dry weight artificial soil.
	tem/kg dry weight artificial soil.
Report:	g; ;2011;M-400,706-01
Title:	Iodosulfuron-methyl-sodium mesosulfaron-mediyl-sodium mefen yr-diethyl
	OD 42 (2+10+30) G: Influence on the reproduction of the contembolan species
	Folsomia candida tested in artificial soil
Report No:	FRM-COLL-113/113 & Q Q Q Q Q Q
Document No:	M-407706-01-1 💆 👸 🔊 🔊 🐧 👸 🛴
Guidelines:	OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing
	Chemicals - Collembolan Reproduction Lest in Soil; minor deviations
GLP/GEP:	yes & o' 'y' & & & & & & & & & & & & & & & & &

Objective:

The purpose of this study was to assess the effect of formulation IMS MSM + MPR OD 42 (2+10+30) G on survival and reproduction of the collembolar species Folsomia Condida during an exposure of 28 days in artificial soft comparing control and treatment. The test was performed according to the recommendations of the SECD viideline 232, (2009).

Material and wethods.

Material and wethods:

Iodosulfuron-methyl-sodjum + mesosulfuron-wethyl-sodjum + meterpyr-diethyl OD 42 (2+10+30) G (analytical findings: iodosulfaron-methyl-sodium 1985 g/C corresponding to 0.198 % w/w, mesosulfuron-methyl-sodium 10.55 g/L corresponding to 1.05 w/w, mefenpyr-diethyl 29.80 g/L corresponding to 257 % w/w, density: 1,002 g/mL, bach ID.: 2009-009105, master recipe ID: 0102735-001, specification no 102000008429-07 cample description: TOX08886-00. Since the first jest run on the lest item did not provide a final result, a second test run was performed studying lower test concentrations. 10 conlembolans (20-12 days old) per replicate (8 replicates for the control group and 4 replicates for the treatment group) were exposed to control (water treated), 100, 178, 316, 562 and 1000 mg test iten/kg antificial soil dry weight in the 1st test run and 10, 17, 30, 52 and 90 mg test item/kg and ficial soil dry weight in the 2nd test run at 20 ± 2 °C, 400 - 800 lux, 16h light: 8h dark. Daring the study, there were tod with granulated dry yeast.

The complete of the control of the c Mortality and reproduction were determined after 29 days (1st run) and 28 days (2nd run).

Findings

Table 10.6.6-7: Percent mortality and reproduction of adult *Folsomia candida* after 4 weeks treatment

Test item	Iodosulfuron-me	thyl-sodium + mesosulfuro	nmethyl-sodium,
Test object	+ mefenpyr-diethyl OD 42 (2+10+30) G		
Exposure		Folsomia candida 🚕	
		Artificial soil	
mg test item/kg soil dry	Adult mortality (%)	₩ean number o	Reproduction (% of Q'
weight		juveniles±S₽	control)
1 st test run			
Control	5	1432.4 ± 159.6 © °	
1000	100	0°≥∕0 ° ° °	
562	100 🐇		
316	100	$\mathbb{C} = 0 \pm 0$	0 *B
178	55	© 80.8 © 32.6	13 *B
100	7.5 🔊 🔊	11893 ± 68,04,	83 ***
2 nd test run			
Control	20 4	\$67 ±466 C	
90	2.5 ~ ~	⁷ √ 1295 ≠ 63 √ 7	\$ 83 *\\ \$ \\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
52	Q, 2.5 b	330±160	₽ 8 5 ***
30	Q 175 °	\$ \$69 ± \$9 \$	⊗7 *W
17	75 75 ₂₀	10 4498 2 48 6	96 n.s.
10		@ 1585 ± 73 ≥	© 101 n.s.
NOEC _{reproduction} (mg test ite	rhokg soil dry weight)		4 17
LOEC _{reproduction} (mg test ite	m/kg soil dry weight)		30

The calculations were performed with un-rounded values

Observations:

Validity of the study:

Validity Criteria for the untreated control of the study seconding OECD 232 from September 07, 2009.

Table 10.6.6-8 Validity criteria

Validity criteria	Recommended by the guideline	Obtaine stu	ed in this Idy
		1 st run	2 nd run
Mean-adult mortality	≤ 20%	5%	2.5%
Mean number of juveniles of replicate (with 100 collembolans in coduced)	≥ 100	1432	1567
Coefficient of variation calculated for the number of juveniles per replicate	≤ 30%	11.1%	10.6%

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

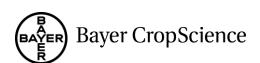
Mortality

In the control group 5 % (1st run) and 2.5 % (2nd run) of the adult *Folsomia candida* died which is below the allowed maximum of \leq 20 % mortality. The highest mortality rate of 100 % was observed in the treatment group from 316 up to 1000 mg test item/kg artificial soil dry weight.

^{*}B = statistically significant (Bonferroni-U tectone-sided-smaller, $\alpha = 0.05$)

^{*}W = statistically significant William's-t test one-sided-smaller, of 0.05)

n.s. = statistically pot significant (William's-t test one-side d-smaller, $\alpha = 0.05$)



Reproduction:

Concerning the number of juveniles statistical analysis (Bonferroni-U test, one-sided smaller, of 0.05) revealed statistically significant differences between the control and all treatment groups in the 1st test run. In the 2nd test run statistical analysis (William's-t Test, one sided smaller, $\alpha = 0.05$) revealed statistically significant differences from 30 up to 90 mg test item/kg artificial soo dry weight. Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 17 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 30 mg test item/kg artificial soil dry weight.

Conclusions:

NOEC reproduction: 17 mg test item/kg artificial soil dry weight.

LOEC reproduction: 30 mg test item/kg artificial soil dry weight.

HIA 10.6.7 Effects on organic matter breakdown

A study on the organic matter breakdown is not required based on the DT of value of the active substance and acceptable TER values for earthworms, soil macro-organisms and/or soil micro-organisms.

organisms.

IIIA 10.7

Ecotoxicological endpoints used in risk assessment

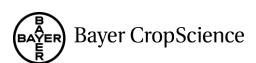
Endpoints of the formulation IMS + MSM + MPR OD 22 used in risk assessment Table 10.7- 🕼

Test item	Test design Ecotoxicological endpoint	Reference
* 7	N-transfer mation 7	
IMS + MSM +	no whereantable Q75 Porrod /ha	(2003)
MPR OD 42	effects ≥ 1.5 Gprod./kg dws	M-222656-01-1 KIIIA 10.7.1/01

dws = dry wei it soil

substance mesosulfuron-methyl and metabolites used in

Test item	Test design	Ecoroxico gical	endpoint	Reference	
N-transformatio	on,				
Mesosultiron- methyl AE F154851	228 d	no unacceptable effects	≥0.1 mg a.s./kg dws	(1998) M-143358-01-1 KCA 8.5/01	
AE F154851	28 d	no unacceptable effects	≥0.1 mg/kg dws	M-214090-01-1 KCA 8.5/02	(2002)
AE F160459	28 d	no unacceptable effects	≥0.1 mg/kg dws	(2002)	



				M-214086-01-1 KCA 8.5/03
AE F099095	28 d	no unacceptable effects	≥0.1 mg/kg dws	(2002) M214088-01-1 K&A 8.5/04
AE F092944	28 d	no unacceptable effects	≥0.137 mg/kg dws	M-453511-01-1
AE F147447	28 d	no unacceptable effects	0.057 mg/kg dws	(2013) M-460668-01-4 KC 8.5/10

dws = dry weight soil

All above endpoints used in risk assessment are consistent with the proposed Ewendpoints listed in Document N2 for mesosulfuron-methyl.

Predicted Environmental Concentrations used in risk assessmen

Please refer to Point IIIA 10.6.1

Risk assessment for soil nitrogen transformation

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

In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil microorganisms for the intended uses of formulation LMS + MSM + MPR OD 42.

IIIA 10.7.1 Laboratory testing

Report:	d; ;2003;M-222656-01
Title:	Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10 +
	2+30 (AE F115008 06 OD04 A104): Determination of effects on nitrogen
	transformation in soit
Report No:	C03#\$40 &
Document No(s):	M222656201-1 %
Guidelines: @	OECD: 216; Deviation not specified
GLP/GEP	Ayes & W

Objective v

The aim of the study was to determine the effects of formulation IMS + MSM + MPR OD 42 (Atlantis od), AE F115008 06 OD04 A104) on microbial nitrogen-turnover in soil. The study was designed to meet OECD criteria.

Material and Methods

A silty sand with 57 % sand content, 0.6 % organic carbon and a microbial biomass of 8.7 % of organic carbon was amended with 5 g lucerne meal per kg dry soil with a C/N ratio of 16/1. The soil was stored at 20 ± 1 °C. The pH before test start was 5.5. The following treatment levels were tested to be a start was 5.5. 1.5 and 7.5 L product/ha with addition of an untreated control. 3 replicates were used level.

Findings

Although deviations from the control were < 25% at day 28, the test day 42. pH varied between 5.5 and 5.7 during the lest. Percentual deviations from observed as follows:

Table 10.7.1-1: Rates of nitrogen transformation day: % difference between nitrateday of control and treated soiksamples

L product/ha	Day 0 - A	Ďay 7 - 14	Day 14 - 28 Day 28 - 42
1.5	+2 💝 🙇	\$ -7\$ B	-3
7.5	\$3 \times \tag{\psi}		Q +7

Conclusion

The formulation IMS MSM MPROD 40 (Atlantis OD) AE 115008 06 Q 1904 A104) has no estatis (see Point 10.7.) on further lab. impact on microbial progen turnover in will when applied at field rate and has no impact on

.) To further laboratory testing on soil non-target

IIIA 10.8 Effects on non-target plants

IIIA 10.8.1 Terrestrial plants

Ecotoxicological endpoints used in risk assessment

For herbicides and plant growth regulators, it is considered unprofitable to conduct tier 1 studies as it is inevitable that these will lead to tier 2 or dose response studies in order to generate data suitable for deterministic or probabilistic risk assessments, i.e. ER₅₀ values for 6-10 species, representing a broad range of plant species. The endpoints from the tier 2 studies on formulation IMS MSMQ MPR OD 42 are summarised in following table.

Table 10.8.1-1: Endpoints of the formulation IMS + MSM + MPR OD 12 used for risk assessment

			I
Number of species	Test method Test substance Application rate	Affects O	Reference
tested (species)	Test substance		0, %, %
	Application rate Tier 2 vegetative rigour IMS + MSM MPR QD 42		
Dicotyledoneae: 7	Tier 2 vegetative vigour VIMS + MSM MPR OD 42 VIMS + MSM MPR OD 42 VIMS And O (control) VIS, 0.7500.375, 0.188 and O (control) VIS (control) V	most sensitive	
(sugar beet, oilseed	IMS + MSM MPR QD 42 Q Q	species sunflower;	(2004) ₍₃₎
rape, radish,	0 (control), \$5, 0.75\(\tilde{0}.375\), \(\tilde{0}.188\) and	lowest ECse.	M-226821-01-1
cucumber, sunflower,	0.094 L prov./na togr cornagna oatso	0.027 L pcod./ha	KIIIA 10.8.1.2/01
soybean, tomato)	0 (contr@), 0.188, 0.094, 0.047, 6.023 and		%
Monocotyledoneae: 3	0.011 prod./ha for ogar beet, oilseed		O °
(onion, oat, corn)	rape, radish eucumber, sunflower, soybean,		
	tomato and onion with visual phytotoxicity		
	ratings and assessment of montality on		
**	Days 214 and 21, dry weight y		
Ž ^V	measurements on Day 21 3	0 ~	
Dicotyledoneae: 7.	Ther 2 seedling emergence	most sensorive	
(sugar beet, oilscod	MMS + MSM & MPR OF 42	species: onion;	(2004)
rape, radish,	0 (control), 15, 0.75, 0.375, 0.188 and	lowest EC50:	M-226820-01-1
cucumber, sunflower	0.094 L prod./ha for corn and oats	0.064 L prod./ha	KIIIA 10.8.1.3/01
soybean, tomato)	Q (control), 0.375 0.188 0.094, 0.047 and	~	
	0.0231 prod. And for sugar beet, oilseed	7	
(onion, oat, corn)	rape radish, cucumbor, suntlower, soybean,		
9	tornato and onion with daily assessments of		
	germination until 65% enfergence of		
	Contros seedlings, visinal phytoroxicity		
	ratings and assessments of number of plants		
4	on Pays Tand 14 and 19 Of after		
	emergence of 50% of control seeds;		
	assessments of mortality and measurement		
S	of day weight on Day 21		

Exposure situation considered for risk assessment

Effects on son-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000)⁷ from the spray-drift predictions of Ganzelmeier & Rautmann

⁷ BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.



(2000)⁸. For a single application to cereals, 2.77% of the application rate was assumed to reach areas at the edge of the crop (0 meter buffer zone; worst-case scenario). For a 5 m buffer zone a drift rate of 0.57% is assumed. For a 10 m buffer zone a drift rate of 0.29% is assumed.

According Table 10-1, the maximum label rate of IMS + MSM + MPR OD 42 1.5L product/ha for use in winter wheat, or 0.6 L product/ha for use in winter rye.

Risk assessment for Terrestrial Non-Target Higher Plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are a non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Deterministic Risk assessment

According to the Terrestrial Guidance Document, the risk to non-target plants is caluated by comparing the lowest ER₅₀ observed in the laboratory studies with the drift rates PER Field) inclosing a safety factor of 5. In addition, the usage of drift reducing nozzles is considered.

Table 10.8.1-2: Deterministic risk assessment for the formulation TMS MSM + MPROD 42 based on effects on seedling emergence

Distanc							
e	Drift	PEK 🗸	Endpoint Lowest		TER [tri	gger = 5]	
[m]	(%) &	product/nap	lowest FR ₅₀ [mL product/ha	No drift of reduction	39% drift Feduction	©5% drift Freduction	90% drift reduction
Winter w			oa, na	<u> </u>		Г	1
1	z ^e 2.77	4 <u>0</u> 55 8	od Ana	1.54	3.08	6.16	15.40
5 * *	0.57	8.55	1 .161 *	% 7/≪(/) .	1./1.3/1./7	29.94	74.85
10	0.29	4.35	© 64 ₂	24.71	29.43	58.85	147.13
Winter r	ye, 1× 60	0 ml prod.	pa g		Ä.		
1	2 Q7	016.620	% 4 ^	3.85	7.70	15.40	38.51
5	△ 0.57	3.42	\$ 64	\$ \$ 8.71, P	37.43	74.85	187.13
10	0.29	∘√974 4	64	36.78	73.56	147.13	367.82
Ganzeline				3.85 3.85 3.871 3.678			
Ganzalinha	ior U D	outmonn D (2000) Drift d	lrift raducing s	oravers and sorav	er testing Asn	eats of Applied

⁸ Ganzelineier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

⁹ Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under council directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

Table 10.8.1- 3: Deterministic risk assessment for the <u>formulation</u> IMS + MSM + MPR OD 42 based on effects on <u>vegetative vigour</u>

							4/2
Distance	Drift	PER	Endpoint		TER [trig	gger = 5	
		no drift	lowest				
[m]	(%)	reduction	ER_{50}	No drift	50% drift	√35% drift	90% doift
[111]	(70)	[mL	[mL	reduction	reduction	Treduction 🦠	reduction &
		product/ha]	product/ha]		Ö "Ä		
Winter w	heat, 1×	1500 mL pro	od./ha	e e			
1	2.77	41.55	27	0.65 🗳	1.30	2.60	Q 6.50°
5	0.57	8.55	27	3.16	6.32	12.63	31.58
10	0.29	4.35	27	, 6. 2 1 , ,	2 .41	24.83	° €62.07©
Winter ry	e, 1× 60	0 mL prod./l	na	Ŏ.Ű			, 4
1	2.77	16.62	27	1.62	3.25	6.50	16 .25 S
5	0.57	3.42	27	789	3 5.79	\$\infty 31.58\infty	78.9 5 %
10	0.29	1.74	27. © ″	(15.52) 15.52) The state of the state of	31.030	6267	155017

According to the results of the deterministic approach involving the most sensitive endpoint in the vegetative vigour study (shoot day weight of sonflower) the tollowing conclusions can be drawn:

- For one application of 1.50 product/has winter wheat, the tagger of 5 at J m distance is only exceeded if nozzles with at least 90% drift reduction and a 5 m buffer zone could be applied to mitigate the risk. Considering a distance of 10 m, no drift reducing nozzles are necessary.
- For one application of 0.6 Ioproduct ha to winter ye, the trigger of 5 at 1 m distance is only exceeded if nozzles with at least 75% drift reduction are used. Considering a distance of 5 m, no drift reducing nozzles are necessary.

The results of the deterministic risk assessment for vegetative vigour indicate the necessity of mitigation measures. However, as an alternative approach probabilistic risk assessment has been conducted.

Probabilistic Risk assessment

In addition to the deterministic risk assessment the Terrestrial Guidance Document recommends the use of the HC_5 (the concentration below which less than 5% of the species will be harmed above the EC_{50} level) which can be calculated from the data sets of ER_{50} growth inhibition levels. The EU guidance document for terrestrial ecotoxicology states: "If the ED_{50} for less than 5% of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable." Thus, the HC_5 itself (TER =1 Can be regarded to be protective.

The HC5 was Calculated according to

 $HC_5 = \mathbb{A} \mathcal{P} \exp(\text{avg-ks*std})$

With

avg = mean of log10 transformed EC_{50} values std = standard deviation of log10 transformed EC_{50} values ks = extrapolation factor

Although there is no common agreement whether to exclude "greater-than" figures from the HG5-calculation or to include them as "equal to"-figures, the exclusion of "greater than"-figures can be regarded as a very conservative approach. Moreover, it has to be decided, whether the HC5s calculated with EC50 for dry weight only (the lowest condpoint in most species) or with the lowest EC50.

Table 10.8.1-4: HCs-figures obtained from different calculation modes for seedling emergence and vegetative vigour. Lowest figures are printed in bold

HC ₅ Seeding	Vegetative
emer gence	
P T T T [Iproducth	
HC ₅ based on dry weight data from M species 0.079	∑ . 0 .021
HC ₅ based on dry weight data after exclusion of greater than-figures \$2.072.0	0.018
HC ₅ based on lowest endpoint from all species, $\sqrt{600} = 0.071$	0.021^{3}
HC ₅ based on lowest endpoint from all species after exclusion of greater-than-figures	0.0164)

With the exception of corn and oats EC₅₀ for survival) and Onion (EC₅₀ of emergence) same figures as for dry weight, since the dryweight-EC₅₀ was the lowest endpoint for all other species than corn, oats and onion

With the exception of corn and oats (EC 50 for survival) and officen (EC 50 of emergence) same figures as for dry weight, since the dryweight-EC 50 was the lowest endpoint for the other species than corn, oats and onion. As the EC 50 for and oats (EC 50 or survival) and soybean (EC 50 for shoot dry weight) are "greater than"-figures, these figures were excluded for alculation.

With the exception of oucumber (EC for survival) same figures as for dry weight, since the dryweight-EC was the lowest endpoint for all other species from cucumber.

With the exception of cucumber same figures as for dry weight, since the dryweight-EC₅₀ was the lowest endpoint for all other species than cucumber. As the EC₅₀ of cucumber (EC₅₀ for survival) and onion (EC₅₀ for shoot dry weight) are "greater than -figures, these figures were excluded for calculation.

Based on the valculations presented in Table 10-8.1- 4 the lowest HC₅-levels were taken as a most conservative approach. The following probabilistic risk assessment has been conducted with the vegetative vigour data only, since the HC₅ considerably lower than for seedling emergence. The TPR calculation is summarised in the following table; a trigger value of 1 is applied for acceptable risk in case of the HC₅.

Probabilistic risk assessment for the formulation IMS + MSM + MPR OD 42 based Table 10.8.1- 5: on effects on vegetative vigour

Distance	Drift	PER	Endpoint		TER [tri	gger = 1	
		no drift	HC5 based				, O b
[m]	(%)	reduction	on ER ₅₀	No drift	50% drift	7∕5‱ drift	90% dr##
[111]	(70)	[mL	[mL	reduction	reduction	reduction	reduction
		product/ha]	product/ha]		\$	\$\frac{1}{2} \frac{1}{2}	
Winter w	heat, 1×	1500 mL pro	od./ha	(' L	
1	2.77	41.55	16	0.39 🔏 "	0.77	1.54	3.85
5	0.57	8.55	16	1.87	3.76	7,49	× 18.71
10	0.29	4.35	16	3.68	7.36	49 .71 0	36.78 ×
Winter ry	e, 1× 60	0 mL prod./h	ıa			~ ~ ~	
1	2.77	16.62	16	O 0.96°	1.93	~ 3 ~3	9 .63
5	0.57	3.42	16	4.68	₽ 9 \$6 ₄	[Ø46.78
10	0.29	1.74	16	20	\$\tag{18.39}	_~ ©′36.7 % √	91.5

Based on the results of the probabilistic risk assessment involving the lowest endpoints of all species (after exclusion of all greater-than ligures) of the vegetative vizour test the following conclusions can be drawn:

- For one application of 1.5°L projuct/has winter wheat, the trigger of 1 at 1 m distance is exceeded if nozzlés with at least 75% drift eduction are used. Considering a distance of 5 m, no drift reducing nowles are necessary.
- For one application of 0.6 Leproduct has to winter rye, the trigger of 1 at 1 m distance is exceeded if rozzles with at Peast 50% drift reduction are used Considering a distance of 5 m, no drift reducing noz

Conclusion

Overall, it can be concloded that terrestrial non-target plants are not at risk when the product is applied in winter wheat and winter the at rates recommended according to good agricultural practice provided that a 5 m buffer zone is applied Alternatively 1 m distance is required when 75% drift reduced spray nozzles are used for the use in winter wheat and when 50% drift reduced spray nozzles are used for the use in winter rye

Please refer to Point III A 0.8. 53.

IIIA 10.8.1.2 Vegetative vigour

Report:	0;	;2004;M-226	821-01
Title:	Iodosulfuron-methyl-sodium + m		
	suspension concentrate; 2 + 30 +	10.44 g/l (Code: AE F1	5008 06 ODQ A1049
	Effects on vegetative vigour of ter	n species of non-target pla	ants y y
Report No:	C039372		
Document No:	M-226821-01-1	Ch L	
Guidelines:	OECD: 208 B, (draft 2000);Dev	ixtion not specified	
GLP/GEP:	yes		

Objective

The purpose of this specific study was to evaluate the effect of formulation MS MSM MPR OD 42 (Atlantis OD, AE F115008 06 OD04 A104), a formulation of odosulturon-methyl sodius. The mesosulfuron-methyl and mesosulfuron-methyl and mesosulfuron of the vegetative rigiour of ten point species representing a broad range of both dicotyledonous and monocotyledonous trant families.

Material and Methods

Plants from ten species; corn (Zea mays), cucumber (Cucunts satisfus), oats (Avona sativa), oilseed rape (Brassica napus), onion (Allium cepa), radisti, (Raphanus sativus), soybean (Glycine max), sugar beet (Beta vulgaris), sunflower (Helianthus annuus) and tomato (Lycopersicum esculentum) were sprayed with Atlantis OD (AFF115008 06 OD04 Af04) and the 24 leaf stage. Solutions of the product and serial dilutions were sprayed with doses of the product ranging from the maximum use rate of 1.5 L/ha down to 0.011 L/ha using a laboratory track sprayer. There were five dose rates that differed with each species. For oats and corn these were 1.5, 0.75, 0.375, 0.188 and 0.004 L/ha. For sunflower these were 0.375, 0.088, 0.094, 0.047 and 0.023 L/ha. For cucumber oilseed rape, onion, radish, soybean, sugar beet and tomato these were 0.188-0.094 0.047, 0.023 and 0.011 L/ha. Plants were grown and maintained under glasshouse conditions with a temperature 23 ±5°C during day, 18 ± 5°C at night. Assessments were made 21 days after application against the intreated controls. Statistical analysis of data was performed to obtain NOEC and EC of alues for survival and biomass (shoot dry weight), using probit analysis with maximum likelihood regression.

Findings A

All species showed the relevant phytotoxic symptoms for the product visible as chlorosis, stunting and necrosis.

Phytotoxicity due to Atlantis (D) (AE F115008 06 OD04 A104) resulted in a suppression of growth leading to a reduction in growth as measured by growth stage in all species, except for onion, where only marginal effects were seen at the highest dose tested. In all species except for cucumber, onion and soyban, the higher dose rates tested resulted in mortality.

Radish was the most sensitive species where Atlantis OD (AE F115008 06 OD04 A104) biomass measured as shoot dry weight was the most sensitive endpoint.

Biomass was also the most sensitive endpoint for all other species.

The table below summarises the NOEC, and where determined the EC_{25} and EC_{50} values for survival, the NOEC, and where determined the EC_{25} and EC_{50} for shoot dry weight.

Table 10.8.1.2-1: The effect of IMS + MSM + MPR OD 42 on ten species: survival and biomass dry weight)

		Survival			hoot dry weigh	nt & S	
		(L product/ha))	4	(L producting)		
	NOEC	EC25	EC ₅₀	NOEC 🗸	EC25 👟	∞ β C50 ✓	
Corn	0.375	0.472	0.77	0.18	0.23	30.38	
Cucumber	0.188	>0.188	>0,188	0.6	0,084	9 0. 23 1 _ (
Oats	0.188	0.280	₹ Ø .328	0.094		287 W	
Oilseed rape	0.047	0.106	0.138	0.023	Q,0.0325	0.056	
Onion	0.188	>0.188	>0.188	0 0,irss _4	>0>1 8 8 .	~ >0,7\ 8 8	
Radish	0.011	0.028	® .041 🔊	9 .011	0 011	0.038	
Soybean	0.188	>0.188	~>0.18 %	Q 0.047 [©]	0.0730	Ø0.13 6 √	
Sugar beet	0.094	0,153" ~	0.212	0.047	0.467	0.494	
Sunflower	0.047	Ø.080 & ~	₂ 0.099 ×	9.023 V	6 007	₾027	
Tomato	0.188	©×0.188/	\$\sqrt{0.188}	~ © 0.0235°	\$0.02 4	₾ 0.036	

Conclusion

Based on the results of this study in which formulation IMS + MSM + MPR QD 42 (Atlantis OD, AE F115008 06 OD04 A104) was tested under glasshouse conditions significant adverse effects were observed in all plant species tested, except onton. The most sensitive species was sunflower with the lowest EC_{50} of 0.027 product/ha for shoot dry weight.

IIIA 10.8.13 Seedling emergence

Report	h; ;2004;M-226820-01
Title:	Nodos Mfuron methy sodium + mefenpy diethyl + AE F130081; oil based
	suspension concentrate; 2 + 30 ⊕ 10.44 g/l (Code: AE F115008 06 OD04 A104):
Q	Frects on seeding emergence and growth in ten species of non-target plants
Report No: @	
Document No:	M226820201-1 0 0 0
Guidelines:	QECD: 208A, 2000); Deviation not specified
GLP/©EP:	yes Q D

Objective

The purpose of this specific study was to evaluate the effect of formulation IMS + MSM + MPR OD 42 (Atlantis OD, AFF1 5008 06 OD04 A104), a formulation of iodosulfuron-methyl-sodium, mesosulfuron-methyl and metarpyr-diethyl on the seedling emergence and seedling growth of ten plant species expresenting a proad range of both dicotyledonous and monocotyledonous plant families.

Material and Methods

Seeds of ten plant species corn (*Zea mays*), cucumber (*Cucumis sativus*), oats (*Avena sativa*), oilseed rape (*Brassica napus*), onion (*Allium cepa*), radish (*Raphanus sativus*) soybean (*Glycine max*), sugar

beet (*Beta vulgaris*), sunflower (*Helianthus annuus*) and tomato (*Lycopersicum esculentum*) were treated after sowing with Atlantis®OD (AE F115008 06 OD04 A104). Solutions of the product and serial dilutions were sprayed at doses ranging from the maximum use rate of 1.5 L/ha down to ©023 L/ha using a laboratory track sprayer. There were five dose rates that differed with each species. For oats and corn these were 1.5, 0.75, 0.375, 0.188 and 0.094 L/ha. For sugar beet, oilseed rape, radistry, cucumber, sunflower, soybean, tomato and onion these were 0.375, 0.188 0.094, 0.047 and 0.025 L/ha. Plants were grown and maintained under glasshous conditions with a temperature 23 5° C odday, 18 ± 5° C night.

Assessments were made 21 days after 50% emergence of control seedlings and evaluated against the cuntreated controls. Statistical analysis of data was performed to obtain SOEC and ECO values for emergence, survival and biomass (shoot dry weight), using profit analysis with maximum thelibood regression.

Findings

All species showed the relevant phytorixic symptoms for the product visible as chlorosis, stunting and necrosis.

Phytotoxicity due to Atlantis®OD (AE F115008 06 OD 04 AF04) resulted in a surpression of growth leading to a decrease in growth stage at the higher rates tested for oats, oilseed rape, on on, radish, sugar beet, sunflower and tomato. There were no reductions in growth for cour, cucumber and soybean.

Onion was the most sensitive species where Atlants OD (AE FJ) 500% 06 OD (A A104) also impacted emergence and surveyal with emergence being the most sensitive endpoint. In all other species biomass was the most sensitive endpoint. In corn, oats, oilseed rape onion radish, sugar beet, sunflower and omato CC₅₀ values for biomass were obtained that were within the dose range selected for these species. For the less sensitive cucumber and so bean the calculated EC₅₀ values were higher than their dose ranges.

The table below summarises the NOEC and where determined the EC₂₅ and EC₅₀ values for emergence and surgival, and the NOEC and where determined the EC₂₅ and EC₅₀ for shoot dry weight.

Table 10.8.1.2 : The effect of IMS + MSM + MPR OD 42 on ten species: seedling emergence, survival and biograss (shoot dry weight)

	Emergence (Laproduct/ha)			Survival		Shoot dry weight			
	(Laprodust ha)			(L product/ha)			(L product/ha)		
Plant species	NOE	E/C,25		NOEC	EC25	EC50	NOEC	EC25	EC50
Corn @	1.5	% 1.5 ≪	© >1. 5	0.375	>0.375	>0.375	0.188	0.256	0.631
Cucumber	√0,3 75 €	≫0.37 5	>0,375	0.375	>0.375	>0.375	0.188	0.174	0.327
Oats N	∜0.75©	>0%75	% 0.75	0.375	>0.375	>0.375	0.375	0.457	0.760
Oilse of rape	0.375	375	>0.375	0.375	>0.375	>0.375	0.094	0.122	0.229
Onion &		0.019	0.064	0.047	0.064	0.091	n.d.	0.117	0.133
Radish Ø	0.375	>0.375	>0.375	0.188	>0.375	>0.375	0.047	0.074	0.136
Soybean	0.375	>0.375	>0.375	0.375	>0.375	>0.375	0.094	0.259	>0.375
Sugar beet	0.375	>0.375	>0.375	0.375	>0.375	>0.375	0.047	0.083	0.155
Sunflower	0.375	>0.375	>0.375	0.375	>0.375	>0.375	0.047	0.044	0.098
Tomato	0.375	>0.375	>0.375	0.375	>0.375	>0.375	0.188	0.269	0.326

Conclusion

Based on the results of this study in which formulation IMS + MSM + MPR OD 42 (Atlantis[®] OD F115008 06 OD04 A104) was tested under glasshouse conditions adverse effects were observed in the plant species tested. The most sensitive species was onion with the lowest EC₅₀ of 0

F113008 06 OD04 A104) wa	is tested under glasshouse conditions adverse effects were observed in atr
plant species tested. The mos	est tested under glasshouse conditions adverse effects were observed in an extra sensitive species was onion with the lowest EC ₅₀ of 0.064 I cha for a sidered necessary. So the product as well as the single active substances towards aquatically a point 102. The risk assessment for Lemna, is presented under point
seedling emergence.	
IIIA 10 8 1 4 Field testin	
111/1 10.0.1.4 Ficia testin	
Further studies were not cons	sidered necessary.
IIIA 10.8.2 Aquatic pla	ants A. O. Q. Q. A. Q. O. Q.
The toxicological spectrum o	f the product as well as the single active substances towards aquate
plants is presented under the	Point 102. The risk assessment for <i>Jamus</i> presented under point with test
10.2.1.11.	
III 4 10 0 2 1 I	
IIIA 10.8.2.1 Lemna gro	win fest
Report:	ü; \$2060°;M-2233377-00°
Title: Influer	ge of mesosulfuron-methyl & iodosyffuron-methyl sodium & mefenpyr-
diethyl	OD 10 + 2 \$30 - influence on the growth of Lemma gibba G3 in a static test
Cofe:	AE 715008 06 QD04 AQ04 & & &
Report No: © 0377	13/ 4. 7/ 2/ 3/ 2/
	3377-0Pi &
	D. 224 · Deviation montaged
CT D (5. 24, 50 control of specifical

Objective

The aim of the study was to desermine the effects of formulation IMS + MSM + MPR OD 42 (Atlantis $^{\circ}$ OD AE For 5008 96 OD 4 A 1947) to the growth of Lemna gibba. The study was designed to meet OECD criteria.

Material and Methods

Lemna cultures with an initial frond number of 12 were cultivated in 20X AAP-medium for 7 days at 2.98, 9.53, 30 5, 97.73 313 and 1000 ag product/L under static conditions. In addition an untreated control was rested. 3 replicates were used per treatment level. The mean water temperature was 23.3 ± 0.1 °C. ph varied between 7.9 and 8.7. The light intensity during the test was 7579 lux (mean).

Analytical measurements for AE F130081 (mesosulfuron-methyl, sodium salt form) resulted in concentrations between 86% and 110% of nominal treatment levels in fresh water samples and

between 92% and 104% of nominal treatment levels in samples from aged water. Biological results are reported as nominal.

Inhibitory effects and intoxication symptoms are summarised in the following table.

Table 10.8.2.1-1: Frond counts, dry weights of plants and percent inhibition of their average growth rate

		((*)		
Nominal	7 days	7 days 💎	A days	O A days, V
(μg product/L)	frond #	dry weight (mg)	% Minhibition	% in Dibition (log , (
		, Č	(growth rate for ○	viomas)
			frænd#)	4
Untreated control	87	Q11.7		
2.98	91	(13.2° S	~ ~ 2.4 ° ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	* ~ -4.8~ *
9.53	99		2 - 70° 8'	-7 <u>4</u> 9
30.5	83	A 1.5 0	2.1	
97.7	29 🔏	7.5	, i €\56.0 obj	, 96.9
313	22	6.W . 4	69,47	₹ 20.8°
1000	20	() () () () () () () () () ()	₩ 7 6 1	21.6

Clustered fronds were observed as intoxication symptoms

Conclusion

The effect of formulation IMS + MSM MPROD 42 on the growth inhibition of Lemna gibba based on nominal figures areas follows:

7 day E_rC_{50} = 88.4 μ g product/L (95% confidence timits 30.5 - 94.7 μ g product/L)

7 day $E_{logb}C_{50}$ $000 \mu g$ product/L

7 day NOEC= 30.5 µg product/L

IIIA 10.8.2.2 Field tests

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2. Therefore, further studies are not considered necessary.

IIIA 10.9 Other non-target species (flora and fauna)

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2 to 10.8 of this dossier. Therefore, further data from biological primary screening of other preliminary tests are not considered relevant for the risk assessment.

IIIA 10.9. A vailable preliminary data on other non-target species (flora and fauna)

Not relevant. See statement provided under Point 10.9.

IIIA 10.9.2 Critical assessment of relevance of preliminary test data

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2 to 10.8 of this dossier. Therefore, further data from biological primary screening or other preliminary tests are not considered televant for the risk. The spectrum of the biological activity of the product is well represented by the results and the first assessments in Point 10.2 to 10.8 of this dessier. Therefore, further days from biological principly screening or other preliminary tests are not considered gelevant for the first assessment.

HIA 10.10.1 Laboratory studies

Not relevant. See statement provided under Point 10.10.

HIA 10.10.2 Field studies

Not relevant. See statement provided under Point 10.10.



Summary and evaluation of Points 9 and 10.1-10.10 IIIA 10.11

IIIA 10.11.1 Predicted distribution and fate in the environment and time courses involved

The distribution and fate of the active substance in the environment is found summarised in Document MCP, Section 9.

IIIA 10.11.2 Non-target species at risk and extent of potential exposure

A summary of the respective document chapters, conclusions given in the following text:

Terrestrial vertebrates

All toxicity-to-exposure-ratios (TER) for birds and maromals, preet the regulatory requirements in a risk assessment at screening level. Thus, no macceptable risk is for birds and mammals for the intended uses of the product

Aquatic organisms

TER values for fish, invertebrates and algae meet the regulatory trigger based on FOCUS Step 2 PPCsw values Phus, no unacceptable risk is to be expected for these aquatic organisms for the intended uses of the product.

For aquatic plant, a refined risk assessment is presented comparing PECsw at FOCUS Step 3 versus HC5 based on EC5 trata from 10 aquatic macrophyte pecies. The regulatory trigger is met for all scenario situations except D2. Since exposure in this scenario is definage, driven and cannot be reduced by the mitigation options implemented in FOCIS Step 4, no further refinement was made. In the MSs concerned with the DP scenario, a restriction of product use on drained fields during drainage season will be prop sed in the national dossiers somitted in the post Approval reregistration proces

Honey bees

A tier 1 risk assessment showed that the hazard protients (oral and contact) are below the EU-trigger value. Thus, no unacceptable risk is to be expected for the intended uses of the product.

Terrestrial non-target arthropods

A tier 1 risk assessment indicated no inacceptable adverse effects on non-target arthropods for the inor off-field habitats following the use of the product according to the proposed use pattern. No mitigation measures are needed

Earthworms and other soil non-target macro-organisms

A fier 1 risk assessment indicated no unacceptable chronic effects on earthworms. Tests with collembola and *Hypoaspis* also indicate no unacceptable risk for other soil non-target macroorganisms are from the intended uses of the product.

Non-target soil micro-organisms

No adverse effects on soil micro-organisms are to be expected for the intended uses of the product.

Terrestrial non-target plants

Based on a probabilistic risk assessment, the risk to non-target plants in the off-field environment is acceptable provided that a 5 m buffer zone is applied. Alternatively, 1 m distance is required when 75% drift reduced spray nozzles are used for the use in winter wheat and when 50% drift reduced spray nozzles are used for the use in winter rye.

IIIA 10.11.3 Short and long term risks for non-targets communities and processes

Please refer to point 10.11.2.

IIIA 10.11.4 Risk of fish kills and facalities in large vertebrates or terrestrial predators

According to the risk assessments presented, a large margin of safety applies for fish and terrestrial vertebrates, and there is no risk of bioaccumulation of the food chain. vertebrates, and there is no risk of bioaccumulation of the food chapt

