FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: TOTO 75 SG

Product name(s): TOTO 75 SG/TYTAN 75 SG/HERKULES 75 SG

Chemical active substance:

Thifensulfuron-methyl, 682 g/kg

Metsulfuron-methyl, 68 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: Innvigo Sp z o.o..

Submission date: 01.2019

MS Finalisation date: 07/2021; 10/2022

Version history

When	What
July 2021	Finalisation of the assessment by zRMS
October 2022	Final Registration Report

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

PPP (product name/code):	TOTO 75 SG	Formulation type:	75 SG [a, b]
Active substance 1:	Thifensulfuron-methyl	Conc. of as 1:	682g/kg [c]
Active substance.3:	Metsulfuron-methyl	Conc. of as ….:	68 g/kg [c]
Safener:	n/a	Conc. of safener:	conc. [c]
Synergist:	n/a	Conc. of synergist:	conc. [c]
Applicant:	Innvigp Sp. z o.o.	Professional use:	☒
Zone(s):	northern/central/southern/interzonal [d]	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: herbicidec

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha
1													
2													
3													
4													
Field uses													
1	PL, SK	Winter wheat	F	weeds	spray medium	PL: BBCH 21-29 SK: BBCH 22-29	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensulfuron methyl 47.7 g	200-300	N/A	PL: plus adiuvant ASYSTENT+90 EC in dose 0,1l/ha

										+ metsulfuron methyl 4.8 g			
2	PL, SK	Winter wheat	F	weeds	spray medium	PL: BBCH 30-31 SK: BBCH 30-31	1	N/A	c) 0,09 d) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g	200-300	N/A	PL: plus adiuvant ASYSTENT+90 EC in dose 0,1l/ha
3	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 21 -29	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is currently pending
4	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 30 -31	1	N/A	c) 0,09 d) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is currently pending
5	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 21 -29	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g b) thifensulfuron methyl 47.7 g + metsulfuron methyl 4.8 g			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is currently pending
6	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 30 -31	1	N/A	c) 0,09 d) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron			PL: plus adiuvant PARTNER+ in dose 0,5 l/ha

										methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g			SK – extention of registration is currently pending
7	PL, SK	Winter rye	F	Weeds	spray medium	BBCH 21 -31	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g b) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g			SK – extention of registration is currently pending: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha PL: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha + adiuvant Partner+ in dose 0,5 l/ha
8	PL, SK	Winter triticale	F	Weeds	spray medium	BBCH 21 -31	1	N/A	a) 0,07 b) 0,07	a) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g b) thifensulfuron methyl 47,7 g + metsulfuron methyl 4,8 g			SK – extention of registration is currently pending: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha PL: Tank Mix with Galaper (fluroksypyr) 250 EC in dose 0,25 l of product /ha + adiuvant Partner+ in dose 0,5 l/ha
EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3	-	-	-	-	-	-	-	-	-	-	-	-	-

4	-	-	-	-	-	-	-	-	-	-	-	-	-
Minor uses according to article 51													
5	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
\(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

9.1.1 Overall conclusion

ZRMS comment:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. The changes are introduced directly as text in blue. Not agreed or not relevant information is struck through for transparency.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

TOTO 75 SG poses no unacceptable risk to birds and mammals used according to the label.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

TOTO 75 SG poses no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone.
To protect aquatic organism following risk mitigation measures is required:
-20 meters vegetative buffer zone and 30 meters no-spray buffer zone

9.1.1.3 Effects on bees (KCP 10.3.1)

TOTO 75 SG poses no unacceptable risk to bees according to the label. According to Reg. 284/2009 the chronic study for adult bees and chronic study for larvae should be submitted by the applicant.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

TOTO 75 SG poses no unacceptable risk to NTA according to the label

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

TOTO 75 SG poses no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

TOTO 75 SG poses no unacceptable risk to non-target terrestrial plants according to the label with appropriate buffer zone and drift reducing techniques.

To protect NTP the following risk mitigation measures are required to non-crop land:
-10 meters buffer zone or 5 meters buffer zone and 90%, 75% or-50% nozzles reduction, or 1 meter buffer zone and 90% nozzles reduction

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

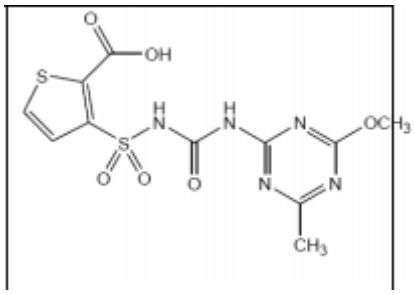
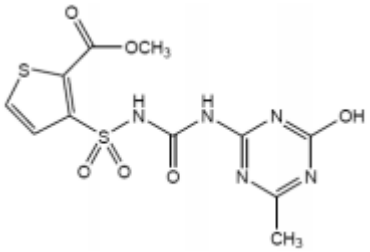
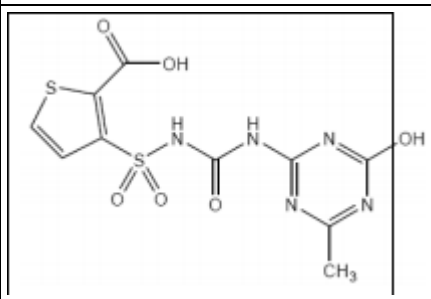
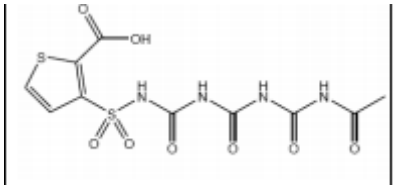
Table 9.1-2: Critical use pattern of TOTO 75 SG grouped according to crop, application rate, number of applications, timing, etc.

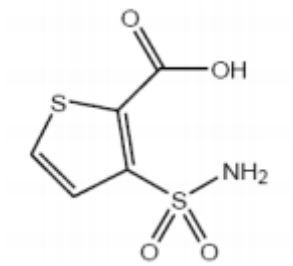
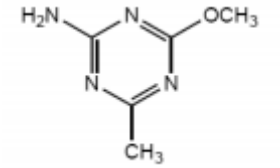
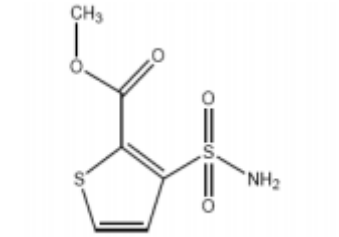
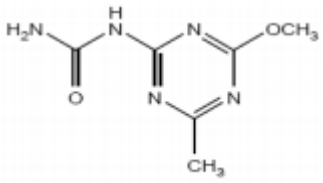
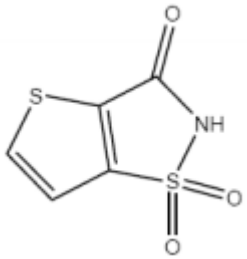
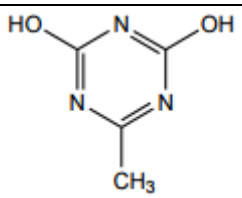
Grouping according to crop, application rate, number of applications, timing criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
	Winter cereals BBCH 21-31 70 g [prod]/ha	crop	crop
	Winter cereals BBCH 30-31 90 g[prod]/ha	crop	crop

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of TOTO 75 SG is indicated in the table.

Table 9.1-3 Metabolites of Thifensulfuron-methyl

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Risk assessment required?
IN-L9225	373.4 g/mol		Soil (lab): 49.13- 93.52% at 14d; max 94%) Hydrolytic degradation: pH 9 70.05% AR (30□C) (30d); 79.8% AR (25ºC) (30d) Maximum occurrence in water/sediment (%AR):55/7 %	Yes
IN-L9226	373.4		Soil (Lab): max 18.5% Hydrolytic degradation: pH 4 13.6% AR (25ºC) (3d) Maximum occurrence in water/sediment (%AR):7.8/7.2 %	Yes
IN-JZ789	359.3		Soil: 0.5- 9.73% at 61d; max 10% Maximum occurrence in water/sediment (%AR):21/4 %	Yes
2-Acid-3-triuret	378.3		Soil: 3.13-16.95% at 61d; max 17%	Yes

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Risk assessment required?
IN-L9223	207.2		Soil: 0.15-19.3% at 29d; max 19% Maximum occurrence in water/sediment (%AR):39/8 %	Yes
IN-A4098	140.1		Soil: 2.47-17.97% at 29d; max 18% Soil photolysis: 32.3% at 30 d, triazine label Hydrolytic degradation: pH 4 26.1% AR (25ºC) (14d) pH 7 5.9% AR (25ºC) (30d). pH 9 12.4% AR (25ºC) (30d) Maximum occurrence in water/sediment (%AR):20/7%	Yes
IN-A5546	221.2		Soil: max 10.5% at 2d Soil photolysis: max 27.7% at 15d, thiophene label Hydrolytic degradation: pH 4 64.2% AR (25ºC) (30d) pH 7 7.6% AR (25ºC) (30d) Photolytic degradation water: 10.3% AR	Yes
IN-V7160	183.2		Soil: 0% - 9.6% at 15d, from photolysis study$; Max 9.6% Photolytic degradation water: 23.8 % AR Maximum occurrence in water/sediment (%AR):25/6%	Yes
IN-W8268	189.2		Soil: max 29.6% at 4d	Yes
IN-F5475	142		Hydrolytic degradation: pH 4, 33.2% AR (25ºC) (30d)	Yes

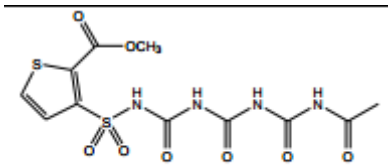
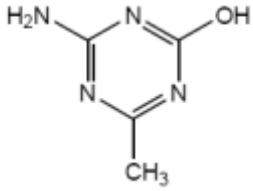
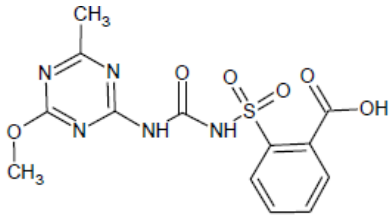
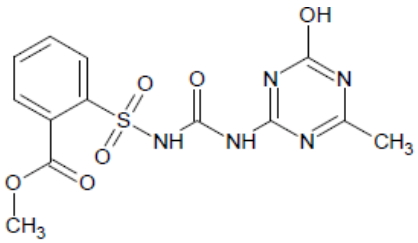
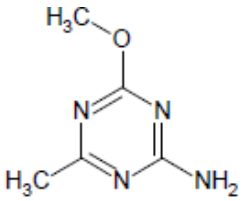
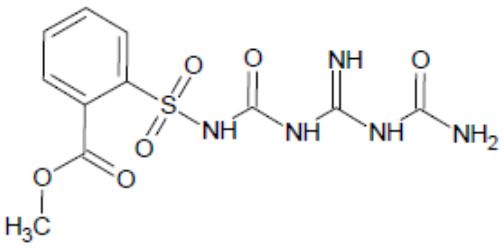
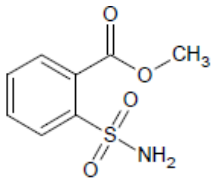
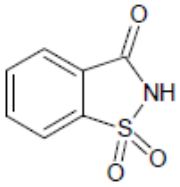
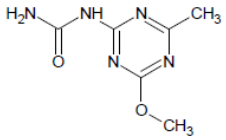
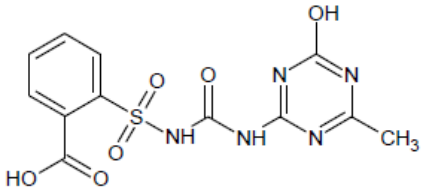
Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Risk assessment required?
IN-RDF00	392.4		Hydrolytic degradation: pH 4, 33.95% AR (25^{0}C) (30d)	Yes
IN-B5528	126.1		Soil anaerobic: maximum of 8.1% at 121 d Hydrolytic degradation: pH 4, 25.3% AR (20^{0}C) (30d)	Yes

Table 9.1-4: Metabolites of Metsulfuron-methyl

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
IN-F5438	367.34		Soil (lab): Phenyl label: max. observed: 15.6 % (30 d) Triazine label: max. observed: 14.6 % (30 d) Water/sediment: >10%	PECsoil PECgw PEC sw
IN-B5067	364.24		Soil (lab): Phenyl label: max. observed: 16.2 % (90 d) Triazine label: max. observed: 14.0 % (90 d) Water/sediment: 21.7 %;	PECsoil PECgw PEC sw
IN-A4098	140.1		Soil (lab): Triazine label: IN-A4098, max. observed: 42,3 % and arising (120 d) Water/sediment: 21.7 %;	PECsoil PECgw PEC sw

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
IN-NC148	343.32		Soil (lab): Phenyl label: max. observed: 23 % (90 d) Triazine label: max. observed: 20.7 % (90 d) Water/sediment: <0.1 %;	PECsoil PECgw PEC sw
IN-D5803	215.22		Phenyl label: max. observed: 48.7 % (28 d) Water/sediment: 39.9 %;	PECsoil PECgw PEC sw
IN-00581	183.07		Soil (lab): Phenyl label: max. observed: 8.7 % (21 d) Water/sediment: <0.1 %;	PECsoil PECgw PEC sw
IN-V7160	183.07		Soil (lab): max. observed: 12.8 % (30 d) Water/sediment: <0.1 %;	PECsoil PECgw PEC sw
IN-JX909	353.3		Soil: N/D Water/sediment: >10%	PEC sw

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Thifensulfuron-methyl and metsulfuron-methyl. Full details of these studies are provided in the respective EU DAR and related documents Effects on birds of TOTO 75 SG were not evaluated as part of the EU assessment of thifensulfuron-methyl.

However, the provision of further data on the TOTO 75 SG is not considered essential, because studies from Annex I inclusion can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Mallard duck (*Anas platyrhynchos*)	Thifensulfuron-methyl	Oral Acute	LD_{50} >2510 mg a.s./kg bw	EFSA Journal 2015;13(7):4201
Bobwhite quail (*Colinus virginianus*)	Thifensulfuron-methyl	Dietary Short-term	LDD_{50} >1524 (mg/kg bw per day)	EFSA Journal 2015;13(7):4201
Mallard duck (*Anas platyrhynchos)*	Thifensulfuron-methyl	Dietary Short-term	LDD_{50} >1306 mg/kg bw/day	EFSA Journal 2015;13(7):4201
Bobwhite quail (Colinus virginianus)	Thifensulfuron-methyl	Dietary Reproductive toxicity	NOAEL = 23 mg/kg bw/day	EFSA Journal 2015;13(7):4201
Mallard duck (Anas platyrhynchos)	Thifensulfuron-methyl	Dietary Reproductive toxicity	NOAEL = 172 mg/kg bw/day	EFSA Journal 2015;13(7):4201
Mallard (A. platyrhynchus)	Metsulfuron-methyl	Oral 1 d Acute	LD50 >2510 mg a.s./kg bw	EFSA Journal 2015;13(1):3936
Mallard (A. platyrhynchus)	Metsulfuron-methyl	Dietary Reproductive toxicity	NOAEL= 100 mg a.s./kg bw per day	EFSA Journal 2015;13(1):3936

zRMS comments:

We agree with the endpoints presented in the Table 9.2-1 above.

Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.1.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening first-tier risk assessments are summarised in the following tables.

Table 9.2-2: Screening First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of TOTO 75 SG in winter cereals

Intended use	**Winter cereals**				
Active substance/product	Thifensulfuron methyl				
Application rate (g/ha)	1 x 61.4 g as/ha				
Acute toxicity (mg/kg bw)	2510				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	9.75	257.3

Reprod. toxicity (mg/kg bw/d)	23				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	1.0 x 0.53	2.11	10.9

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of TOTO 75 SG in cereals winter for the Metsulfuron-methyl.

Intended use	**Cereals winter**				
Active substance/product	Metsulfuron-methyl				
Application rate (g/ha)	1 X 6.1 g a.s/ha				
Acute toxicity (mg/kg bw)	2510				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small omnivorous bird	158.8	1.0	0.97	2591.2
Reprod. toxicity (mg/kg bw/d)	100				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small omnivorous bird	64.8	0.53	0.21	477.3

Combined risk assessment for TOTO 75 SG mixture

A TER_{mix} was calculated with the following formula:

$$TER(mix) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

TER_A Thifensulfuron-methyl	**TER_A Metsulfuron-methyl**	**$TER_{mix\ birds\ acute}$**	**Trigger value**
257.3	2591.2	~~280.18~~ 233.32	10
TER_{LT} Thifensulfuron-methyl	**TER_{LT} Metsulfuron-methyl**	**$TER_{mix\ birds\ chronic}$**	**Trigger value**

10.9	477.3	~~11.96~~ 10.67	5

Conclusion
The calculated TERmix and TER for individual active substance value is higher than the trigger value of 10 for acute risk assessment and higher than the trigger value of 5 for chronic risk assessment , indicating TOTO 75 SG does not posses unacceptable acute and long-term risk for birds.
No further risk refinement is needed.

zRMS comments:

The risk assessment at screening and Tier 1 is considered acceptable. The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Safe use of active substances for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively , indicating the acute and long-term risk is acceptable.

The combined risk assessment of two active substances for birds was also considered acceptable.

9.2.1.2 Higher-tier risk assessment

Since for Thifensulfuron-methyl and mestsulfuron-methyl acute TER is above 10 and TER long term is above 5, no higher-tier risk assessment is required.

9.2.1.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since TOTO 75 SG is a product not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 1 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in 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 exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 9 thifensulfuron-methyl belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals.

Effective application rate (g/ha)	=	61.4		
Acute toxicity (mg/kg bw)	=	2510	quotient =	0.025
Reprod. toxicity (mg/kg bw/d)	=	23	quotient =	2.67

With a K(f)oc of 12, Metsulfuron-methyl belongs to the group of less sorptive substances. To achieve a

concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on cereals winter/spring:

Effective application rate (g/ha)	=	6.1		
Acute toxicity (mg/kg bw)	=	2510	quotient =	0.0024
Reprod. toxicity (mg/kg bw/d)	=	100	quotient =	0.061

Hazard quotient for Puddle scenario for thifensulfuron-methyl and metsulfuron-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

zRMS comments:

We agree that hazard quotient for Puddle scenario for thifensulfuron-methyl and metsulfuron-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

9.2.1.4 Effects of secondary poisoning

The log P_{ow} of Thifensulfuron-methyl and Metsulfuron-methyl is below 3 and thusdo not exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required required.

zRMS comments:

As both active substances have log Pow of less than 3, neither active substance is expected to bioaccumulate in the environment. It is therefore considered that secondary poisoning is not expected to occur from the proposed use of Toto 75 SG.

9.2.1.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.2 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.3 Overall conclusions

In conclusion, the acute, short term risk and long term to birds from the proposed uses of Thifensulfuron-methyl and metsulfuron-methyl was found acceptable. With regards to the risk to earthworm-eating birds an acceptable risk was identified for the proposed uses of Thifensulfuron-methyl and metsfulfuron-methyl an acceptable risk could be identified for fish-eating birds for the proposed uses. TOTO 75 SG poses no unacceptable risk to birds with according to the label.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Thifensulfuron-methyl, metsulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU documents

However, the provision of further data on the formulation TOTO 75 SG is not considered essential, because the selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Thifensulfuron methyl	Acute	LD_{50} >5000 mg/kg bw	EFSA Journal 2015;13(7):4201
Rat	Thifensulfuron-methyl	Long-term	NOAEL=1.3 mg/kg bw day #	EFSA Journal 2015;13(7):4201
Rat	Thifensulfuron-methyl	Long-term*	NOAEL=43 mg/kg bw day #	EFSA Journal 2015;13(7):4201
#The NOAEL of 1.3 mg/kg b.w per day was used in the screening step assessment as it was used in the human risk assessment to set the ADI. This NOAEL was further refined at first tier to 43 mg/kg b.w per day. Should a higher tier assessment be required in the future then the ecological relevance of this NOAEL should be considered further.				
Rat	Metsulfuron-methyl	Acute	LD50>5000 mg/kg bw	EFSA Journal 2015;13(1):3936
Rat	Metsulfuron-methyl	Long term	NOAEL=25 mg/kg bw	EFSA Journal 2015;13(1):3936

zRMS comments3

We agree with the endpoints presented in the Table 9.2-1 above.

Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals.

9.3.1.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening and first-tier risk assessments are summarised in the following tables.

Table 9.3-2: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of TOTO 75 SG in winter cereals

Intended use	Winter cereals				
Active substance/product	Thifensulfuron methyl				
Application rate (g/ha)	1 x 61.4 g as/ha				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	7.27	687.5
Reprod. toxicity (mg/kg bw/d)	1.3				
TER criterion	5				

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_{90} (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	1.0 x 0.53	1.57	**0.83**
First Tier Risk Assessment					
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	5.4	0.53		21.0
Cereals BBCH 10-29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	34.1	0.53		5.1
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	4.3	0.53		10.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Since in first tier TER long term values are below trigger 5, the risk refinement is necessary.

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to Metsulfuron-methyl the use of TOTO 75 SG in cereals winter

Intended use	cereals winter				
Active substance/product	Metsulfuron-methyl				
Application rate (g/ha)	1 × 6.1				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening step	Small herbivorous mammal	118.4	1.0	0.72	6922.9
Reprod. toxicity (mg/kg bw/d)	25				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	0.16	160.10

Combined risk assessment for TOTO 75 SG mixture

A TER_{mix} was calculated with the following formula:

$$TER(mix) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

TER_A Thifensulfuron-methyl	**TER_A Metsulfuron-methyl**	**$TER_{mix\ mammals\ acute}$**	**Trigger value**
687.5	5992.9	~~748.71~~ 641.025	10
TER_{LT} Thifensulfuron-methyl	**TER_{LT} Metsulfuron-methyl**	**$TER_{mix\ mammals\ chronic}$**	**Trigger value**
5.1	160.1	~~5.59~~ **4.95***	5

***acceptable by zRMS**

zRMS comments:

The risk assessment at screening and Tier 1 is considered acceptable. The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Safe use of active substances for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable.

The combined risk assessment of two active substances for mammals is closed to value of 5 (being 4.95) and was considered acceptable by zRMS.

9.3.1.2 Higher-tier risk assessment

Not required

9.3.1.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in 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 exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 9, thifensulfuron-methyl belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals.

Effective application rate (g/ha) = 61.4			

Acute toxicity (mg/kg bw)	= 5000		quotient	=	0.01228
Reprod. toxicity (mg/kg bw/d)	= 1.3		quotient	=	47.23

With a K(f)oc of 12, Metsulfuron-methyl belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on cereals winter/spring

Effective application rate (g/ha) =6.1
Acute toxicity (mg/kg bw) =5000 quotient = 0.00122
Reprod. toxicity (mg/kg bw/d) = 25 quotient = 0.244

Hazard quotient for Puddle scenario for thifensulfuron-methyl and metsulfuron-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

zRMS comments:

We agree that hazard quotient for Puddle scenario for thifensulfuron-methyl and metsulfuron-methyl are below trigger value 50, so no specific calculations of exposure and TER are necessary.

9.3.1.4 Effects of secondary poisoning

The log Pow of Thifensulfuron-methyl, Metsulfuron-methyl are below 3 and thusdo not exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required required.

zRMS comments:

As both active substances have log Pow of less than 3, neither active substance is expected to bioaccumulate in the environment. It is therefore considered that secondary poisoning is not expected to occur from the proposed use of Toto 75 SG.

9.3.1.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.2 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.3 Overall conclusions

In conclusion, the acute, short term risk and and long-term risk to mammals from the proposed uses of Thifensulfuron-methyl was found acceptable. With regards to the risk to earthworm-eating mammals an acceptable risk was identified for the proposed uses of thifensulfuron-methyl and metsulfuron-methyl. An acceptable risk could be identified for fish-eating mammals for the proposed uses. TOTO 75 SG pose no unacceptable to mammals with according to the label.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

N/A

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with thifensulfuron-methyl, metsulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU documents..

Effects on aquatic organisms of TOTO 75 SG were not evaluated as part of the EU assessment of Thifensulfuron-methyl and metsulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Thifensulfuron-methyl

Species	Substance	Exposure System	Results mg/L	Reference
Midge fly larvae* (*Chironomous riparius)*	Thifensulfuron-methyl	48 h (static)	LC_{50} >100 (nom)	EFSA Journal 2015;13(7):4201
Vallisneria americana	Thifensulfuron-methyl acid	14 d (static)	ErC_{50}= 0.00023 (mm)	EFSA Journal 2015;13(7):4201
Additional information				
No suitable data demonstrating the toxicity of thifensulfuron-methyl to fish, aquatic invertebrates and algae were available. Toxicity data were available for the formulated products 'Thifensulfuron-methyl 50 SG', 'CHA 8730' and 'FH-009'. It was discussed at the expert meeting whether toxicity data for the formulated products could be used to perform a risk assessment for the active substance. The experts raised a concern that the composition of the formulation can influence the toxicity and therefore it was not considered appropriate. Therefore, no assessment of the risk to fish, aquatic invertebrates and algae could be performed and a data gap was identified. The experts also agreed that neither of the available toxicity studies on Lemna spp. were reliable for risk assessment. Suitable toxicity data were available for other aquatic plants species, but it was agreed that the endpoints derived (EC50 values) did not account for the phytotoxic effects observed in the studies. It was therefore agreed to perform a risk assessment using the NOEC for the most sensitive species (*Vallisneria americana).* It was noted that the available data did indicate that Lemna spp. were more sensitive to thifensulfuron-methyl in relation to the additional aquatic plant species tested and therefore the experts considered that this assessment was only illustrative and should not be used to conclude on the risk to aquatic plants.				

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-L9225

Species	Substance	Exposure System	Results mg/L	Reference
Rainbow trout (*Oncorhynchus mykiss)*	IN-L9225	96 hr (Static)	LC_{50} >120 (mm)	EFSA Journal 2015;13(7):4201
Water flea (*Daphnia magna)*	IN-L9225	48 h (static)	EC50>130(mm)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-L9225	72 h (static)	EbC_{50} 33.4 cell density (nom) ErC_{50}	EFSA Journal 2015;13(7):4201

Species	Substance	Exposure System	Results mg/L	Reference
			36.5 (nom) (DuPont)	
Duckweed (Lemna gibba)	IN-L9225	14 d (static)	EC_{50}= 36.76 (mm) ErC_{50} (frond count)= 82.2 (mm)	EFSA Journal 2015;13(7):4201

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-JZ789

Species	Substance	Exposure System	Results mg/L	Reference
Rainbow trout (Oncorhynchus mykiss)	IN-JZ789	96 hr (Static)	LC_{50} >0.94 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-JZ789	48 h (static)	EC50> >1.1 (mm)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-JZ789	72 h (static)	EC50 >1.28 (mm)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-JZ789	14 d (static)	EC50 (frond count and biomass) ErC50 (frond count) >100 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-4: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-V7160

Species	Substance	Exposure System	Results mg/L	Reference
Rainbow trout (Oncorhynchus mykiss)	IN-V7160	96 hr (Static)	LC_{50} >1.0 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-V7160	48 h (static)	EC50>1.3 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-V7160	21 d (semi-static)	Adult body length NOEC=11 (mm)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-V7160	72 h (static)	EC50 >11 (mm)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-V7160	14 d (static)	EC50 (frond count and biomass) ErC50 (frond count) >100 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-5: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-A4098

Species	Substance	Exposure System	Results mg/L	Reference
Rainbow trout	IN-A4098	96 hr (Static)	LC_{50} >0.93 (mm)	EFSA Journal

Species	Substance	Exposure System	Results mg/L	Reference
(Oncorhynchus mykiss)			(DuPont)	2015;13(7):4201
Water flea (Daphnia magna)	IN-A4098	48 h (static)	EC50 >99 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-A4098	21 d (semi-static)	Reproduction, NOEC=32 (nom)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-A4098	72 h (static)	EbC50 >10 (nom) ErC50 >10 (nom)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-A4098	14 d (static)	EC_{50} (frond count and biomass) ErC_{50} (frond count) >10 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-6: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-W8268

Species	Substance	Exposure System	Results mg/L	Reference
Rainbow trout (Oncorhynchus mykiss)	IN-W8268	96 hr (Static)	LC_{50} >115 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-W8268	48 h (static)	EC_{50} >125 (mm)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-W8268	72 h (static)	EbC50 >100 (nom) EyC50 >100 (nom) ErC50 >100 (nom)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-W8268	7 d (static)	EyC50 30.3 (nom) ErC50 >100 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-7: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-L9223

Species	Substance	Exposure System	Results mg/L	Reference
Water flea (Daphnia magna)	IN-L9223	48 h (static)	EC50 >1.2 (mm)	EFSA Journal 2015;13(7):4201
Water flea (Daphnia magna)	IN-L9223	21 d (semi-static)	Reproduction, NOEC=13 (mm)	EFSA Journal 2015;13(7):4201
Pseudokirchneriella subcapitata	IN-L9223	72 h (static)	EC50>1.3 (mm)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-L9223	7 d (static)	EC_{50} (frond count and biomass) >172.1 (nom) ErC50 (frond count) >172.1 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-8: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-L9225

Species	Substance	Exposure System	Results mg/L	Reference
Pseudokirchneriella subcapitata	IN-L9226	72 h (static)	ECr_{50} >89 (nom) EyC_{50} >89 (nom) EbC_{50} >89 (nom)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-L9226	14 d (static)	EC_{50} >37.5 (mm)	EFSA Journal 2015;13(7):4201

Table 9.5-9: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-A5546

Species	Substance	Exposure System	Results mg/L	Reference
Pseudokirchneriella subcapitata	IN-A5546	72 h (static)	E_bC_{50}> 48 (mm) (nom) ErC_{50} >110 (DuPont)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	IN-A5546	7 d (static)	EC_{50} (yield, biomass and growth rate) >40.4 (mm)	EFSA Journal 2015;13(7):4201

Table 9.5-10: Endpoints and effect values relevant for the risk assessment for aquatic organisms – 2-acid-3-triuret

Species	Substance	Exposure System	Results mg/L	Reference
Pseudokirchneriella subcapitata	2-acid-3-triuret	72 h (static)	EyC_{50} >100 (nom) ErC_{50} >100 (nom)	EFSA Journal 2015;13(7):4201
Duckweed (Lemna gibba)	2-acid-3-triuret	7 d (static)	EyC_{50} >100 (nom) ErC_{50} >100 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-11: Endpoints and effect values relevant for the risk assessment for aquatic organisms – IN-B5528

Species	Substance	Exposure System	Results mg/L	Reference
Duckweed (Lemna gibba)	IN-B5528	7 d (static)	EyC_{50} >119.52 (nom) ErC_{50} >119.52 (nom)	EFSA Journal 2015;13(7):4201

Table 9.5-12: **Endpoints and effect values relevant for the risk assessment for aquatic organisms – Metsulfuron-methyl and relevant metabolites**

Species	Substance	Exposure System	Results mg/L	Reference
Oncorhynchus mykiss	Metsulfuron-methyl	96-hr (static)	Mortality, EC50 >113 (mm)	EFSA Journal 2015;13(1):3936
Poecilia reticulata	Metsulfuron-methyl	Mortality, EC50	Mortality, EC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Salmo gairdneri	Metsulfuron-methyl	Growth NOEC	28 d NOEC = 68 mg/L	EFSA Journal 2015;13(1):3936
Daphnia magna	Metsulfuron-methyl	48-h (static)	Mortality, EC50= 43.1 (nom)	EFSA Journal 2015;13(1):3936
Daphnia magna	Metsulfuron-methyl	21-d (semi-static)	Reproduction, NOEC= 3.13 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	Metsulfuron-methyl	72-h (static)	Growth, ErC50=0.875 Growth, EbC50=0.157	EFSA Journal 2015;13(1):3936
Anabaena flos-aquae	Metsulfuron-methyl	72-h (static)	Growth, ErC50=0.1134 (nom) Growth, EbC50=0.0582 (nom)	EFSA Journal 2015;13(1):3936
Lemna minor	Metsulfuron-methyl	7-d (static- renewal)	Frond count, 7-d ErC50=0.00036	EFSA Journal 2015;13(1):3936
Lemna gibba	Metsulfuron-methyl	7-d (static)	Frond count, ErC50=0.000570 (nom) NOErC(Biomass)= 0.00025 (nom) NOEbC=0.000365 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	Metsulfuron-methyl	16-d (static), 7-d exposure during dormancy	Frond count, ErC50=0.0022 EbC50= 0.0022	EFSA Journal 2015;13(1):3936
Lemna gibba	Metsulfuron-methyl	Variable exposure duration toxicity test (static)	Frond count, 12-h ErC50= 0.0314 (nom) 24-h ErC50= 0.0104 (nom) 48-h ErC50= 0.0017 (nom) 96-h ErC50= 0.0013 (nom) Biomass, 12-h ErC50 >0.206 (nom) 24-h ErC50 >0.0617 (nom) 48-h ErC50 >0.0185 (nom) 96-h ErC50 >0.0056 (nom)	EFSA Journal 2015;13(1):3936
Myriophyllum	Metsulfuron-methyl	14-d (static)	Shoot dry weight,	EFSA Journal

Species	Substance	Exposure System	Results mg/L	Reference
aquaticum			EbC50 >98 (mm)	2015;13(1):3936
Vallisneria americana	Metsulfuron-methyl	14-d (static)	Shoot dry weight, EbC50>92 (mm)	EFSA Journal 2015;13(1):3936
Ceratophyllum demersum	Metsulfuron-methyl	14-d (static)	Shoot dry weight, EbC50>96 (mm)	EFSA Journal 2015;13(1):3936
Elodea canadensis	Metsulfuron-methyl	14-d (static)	Shoot dry weight, EbC50= 2.9 (mm)	EFSA Journal 2015;13(1):3936
Myriophyllum spicatum	Metsulfuron-methyl	14-d (static)	Shoot dry weight, EbC50>24 (mm) Shoot lenght, ErC50<24 (mm)	EFSA Journal 2015;13(1):3936
Oncorhynchus mykiss	IN-JX909	96-hr (static)	Mortality, EC50=543 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-JX909	48-h (static)	Mortality, EC50=134 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-JX909	96-h (static)	Growth, ErC50=73 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-JX909	14-d (static)	Frond count, ErC50=30 (mm)	EFSA Journal 2015;13(1):3936
Oncorhynchus mykiss	IN-00581	96-hr (static)	Mortality, EC50>124 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-00581	48-h (static)	Mortality, EC50>118 (mm)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-00581	72-h (static)	Growth, ErC50>10 (nom) Growth, EbC50>10 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-00581	14-d (static)	Frond count, ErC50>5.48 nom	EFSA Journal 2015;13(1):3936
Oncorhynchus mykiss	IN-A4098	96-hr (static)	Mortality, EC50>126 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-A4098	48-h (static)	Mortality, EC50 >99 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-A4098	21-d (semi-static)	Reproduction, NOEC= 32 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-A4098	72-h (static)	Growth, ErC50 >100 (nom) Growth, EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-A4098	14-d (static)	Frond count, ErC50 >10 (nom) Dry weight, EbC50 >10 (nom)	EFSA Journal 2015;13(1):3936
Oncorhynchus mykiss	IN-F5438	96-hr (static)	Mortality, EC50 >9.2 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-F5438	48-h (static)	Mortality, EC50	EFSA Journal

Species	Substance	Exposure System	Results mg/L	Reference
			>9.3 (mm)	2015;13(1):3936
P. subcapitata	IN-F5438	72-h (static)	Growth, ErC50>10 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-F5438	7d (static)	Dry weight EbC50=0.082 (nom)	EFSA Journal 2015;13(1):3936
Oncorhynchus mykiss	IN-V7160	96-hr (static)	Mortality, EC50 >1.0 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-V7160	48-h (static)	Mortality, EC50 >1.3 (mm)	EFSA Journal 2015;13(1):3936
Daphnia magna	IN-V7160	21-d (semi-static)	Reproduction, NOEC 11 (mm)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-V7160	72-h (static)	Growth, ErC50 >100 (nom) Growth, EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-V7160	14-d (static)	Frond count, ErC50 >10 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-B5067	72-h (static)	Growth, ErC50 >100 (nom) Growth, EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-B5067	7-d (static)	Frond count, ErC50= 0.258 (nom) Dry weight, EbC50= 0.147 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-NC148	72-h (static)	Growth, ErC50 >100 (nom) Growth, EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-NC148	7-d (static)	Frond count, ErC50 >100 (nom) Dry weight EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
P. subcapitata	IN-D5803	72-h (static)	Growth, ErC50 >3.46 (nom) Growth, EbC50 >3.46 (nom)	EFSA Journal 2015;13(1):3936
Lemna gibba	IN-D5803	7-d (static)	Frond count, ErC50 >100 (nom) Dry weight EbC50 >100 (nom)	EFSA Journal 2015;13(1):3936
Higher-tier studies (micro- or mesocosm studies)				
No further tests submitted				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-13: Endpoints and effect values relevant for the risk assessment for aquatic organisms – TOTO 75 SG

Species	Substance	Exposure System	Results	Reference
Cyprinus carpio	TOTO 75 SG	96h	LC50 > 100 mg/L	xxx, Study code: W/52/08
Oncorhynchus mykiss	TOTO 75 SG	96h	LC50 > 100 mg/L	xxx, Study code: W/51/08
Daphnia magna	TOTO 75 SG	48 h, static	The EC_{50}/48 h > 100 mg/L	xxx, Study code: W/53/08
Pseudokirchneriella subcapitata	TOTO 75 SG	72 h, static	E_rC_{50}/72 h= 6.80mg/L E_yC_{50}/72 h=0.78 mg/L	xxx, Study code: W/55/08
Anabaena flos-aquae	TOTO 75 SG	72 h, static	E_rC_{50}/72 h =2.08 mg E_yC_{50}/72 h= 0.80 mg/L	xxx, Study code: W/54/08
Lemna Gibba	TOTO 75 SG	7d, static	ErC_{50}/7 d (frond number) = 1.49 µg/L EyC_{50}/7(frond number)= 0.975 µg/L ErC_{50}/7 d (dry weight) = 18.9 µg/L EyC_{50}/7(dry weight)= 1.56 µg/L	xxx., Study code:94401240
Higher-tier studies (micro- or mesocosm studies)				
Not required				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

No new data for active substances is presented with this application.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thifensulfuron methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Inverteb. acute**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Vallisneria americana***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	LC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	100 000	0.23
AF		-	-	-	-	-	100	10
RAC (µg/L)		-	-	-	-	-	1000	0.023
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	16.15	-	-	-	-	-	0.016	702.17
Step 2								
N-Europe	0.81	-	-	-	-	-	0.001	35.22
Step 3								
D3/ditch	0.3019	-	-	-	-	-	0.0003	**13.126**
D4/pond	0.01048	-	-	-	-	-	0.0000	0.456
D4/stream	0.2235	-	-	-	-	-	0.0002	**9.717**
D5/pond	0.01048	-	-	-	-	-	0.0000	0.456
D5/stream	0.2389	-	-	-	-	-	0.0002	**10.387**
R1/pond	0.01048	-	-	-	-	-	0.0000	0.456
R1/stream	0.2270	-	-	-	-	-	0.0002	**9.870**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Inverteb. acute	Aquatic plants
R3/stream	0.2984	-	-	-	-	-	0.0003	**12.974**
R4/stream	0.1973	-	-	-	-	-	0.0002	**8.578**
Step 4 – 20 meters vegetative and 20 meters no-spray buffer zone								
D3/ditch	0.02267	-	-	-	-	-	0.00002	0.986
D4/pond	0.004291	-	-	-	-	-	0.00000	0.187
D4/stream	0.02238	-	-	-	-	-	0.00002	0.973
D5/pond	0.004292	-	-	-	-	-	0.00000	0.187
D5/stream	0.02392	-	-	-	-	-	0.00002	**1.040**
R1/pond	0.004292	-	-	-	-	-	0.00000	0.187
R1/stream	0.04720	-	-	-	-	-	0.00005	**2.052**
R3/stream	0.07032	-	-	-	-	-	0.00007	**3.057**
R4/stream	0.01976	-	-	-	-	-	0.00002	0.859
Step 4 – 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode								
D3/ditch	0.01544	-	-	-	-	-	0.00002	0.671
D4/pond	0.003293	-	-	-	-	-	0.00000	0.143
D4/stream	0.01529	-	-	-	-	-	0.00002	0.665
D5/pond	0.003294	-	-	-	-	-	0.00000	0.143
D5/stream	0.01634	-	-	-	-	-	0.00002	0.710
R1/pond	0.003294	-	-	-	-	-	0.00000	0.143
R1/stream	0.01362	-	-	-	-	-	0.00001	0.592
R3/stream	0.01914	-	-	-	-	-	0.00002	0.832

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Inverteb. acute	Aquatic plants
R4/stream	0.01349	-	-	-	-	-	0.00001	0.587

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

In the EFSA conclusion for thifensulfuron-methyl (EFSA Journal 2015) it was concluded that no suitable data demonstrating the toxicity of thifensulfuron-methyl to fish, aquatic invertebrates and algae are available. Therefore, no assessment of the risk to fish, aquatic invertebrates and algae could be performed and a data gap was identified. With regard to aquatic plants it was also agreed that the available studies with *Lemna sp*. were not considered reliable for the risk assessment.

A study with an additional aquatic plant species *Vallisneria americana* was considered to be acceptable, however the it was noted that the available data indicated that *Lemna sp*. was the more sensitive and so the EU review considered that risk assessments conducted with the *Vallisneria americana* endpoint were illustrative only and should not be used to conclude the risk to aquatic plants.

Therefore, the risk assessment for aquatic macrophyte - *Vallisneria americana* for thifensulfuron-methyl presented above is considered as illustrative only.

Based on this assessment with consideration PEC_{sw} STEP 4 vfs mod the following risk mitigation measures are required.

- 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode, for scenarios: D5 (stream), R1 (stream) and R3 (stream)
- 20 meters vegetative and 20 meters no-spray buffer zone for scenarios: D3 (ditch), D4 (stream), R4 (stream)

The risk for Chironmus sp. is considered acceptable as the RAC/PEC ratio is below w trigger of 1.

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9225 for each organism based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	EbC50	EC_{50}

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
(µg/L)		120 000	-	130 000	-	-	33 400	36 760
AF		100	-	100	-	-	10	10
RAC (µg/L)		1200	-	1300	-	-	3340	3676
Exposure	PEC $_{gl-max}$ (µg/L)							
Step 1								
	32.24	0.02687	-	0.02480	-	-	0.00965	0.0088
Step 2								
	4.04	0.00337	-	0.00311	-	#-!	0.00121	0.0011

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-JZ789 for each organism based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	E_bC_{50}	ErC_{50}
(µg/L)		940	-	1100	-	-	1280	100 000
AF		100	-	100	-	-	10	10
RAC (µg/L)		9.4	-	11	-	-	128	10000
Exposure	PEC $_{gl-max}$ (µg/L)							
Step 1								
	32.24	3.42979	-	2.93091	-	-	0.25188	0.0032
Step 2								

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
	4.04	0.42979	-	0.36727	-	-	0.03156	0.0004

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-V7160 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC50	ErC_{50}
(µg/L)		1000	-	1300	11000	-	11 000	100 000
AF		100	-	100	10	-	10	10
RAC (µg/L)		10	-	13	1100	-	1100	10000
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	32.24	3.22400	-	2.48000	0.02931	-	0.02931	0.0032
Step 2								
	4.04	0.40400	-	0.31077	0.00367	-	0.00367	0.0004

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-A4098 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		930	-	99 000	32000	-	10 000	100 00
AF		100	-	100	10	-	10	10
RAC (µg/L)		9.3	-	990	3200	-	1000	1000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	32.24	3.46667	-	0.03257	0.01008	-	0.03224	0.0322
Step 2								
	4.04	0.43441	-	0.00408	0.00126	-	0.00404	0.0040

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-W8268 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		115 000	-	125 000	-	-	10 0000	30 300
AF		100	-	100	-	-	10	10
RAC (µg/L)		1150	-	1250	-	-	10000	3030
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Step 1								
	32.24	0.02803	-	0.02579	-	-	0.00322	0.0106
Step 2								
	4.04	0.00351	-	0.00323	-	-	0.00040	0.0013

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9223 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	EC_{50}	ErC_{50}
(µg/L)		-	-	1200	13000	-	1300	172 100
AF		-	-	100	10	-	10	10
RAC (µg/L)		-	-	12	1300	-	130	17210
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	32.24	-	-	2.68667	0.02480	-	0.24800	0.0019
Step 2								
	4.04	-	-	0.33667	0.00311	-	0.03108	0.0002

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9226 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	EC_{50}
(µg/L)		-	-	-	-	-	89 000	37500
AF		-	-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	-	8900	3750
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	32.24	-	-	-	-		0.00362	0.0086
Step 2								
	4.04	-	-	-	-	-	0.00045	0.0011

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-A5546 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50} >110 000 E_bC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	48 000	40400
AF		-	-	-	-	-	10	10

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
RAC (µg/L)		-	-	-	-	-	4800	4040
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	32.24	-	-	-	-		0.00672	0.0080
Step 2								
	4.04	-	-	-	-	-	0.00084	0.0010

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite 2-acid-3-triuret for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	100 000	100 000
AF		-	-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	-	10 000	10 000
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	32.24	-	-	-	-		0.00322	0.0032
Step 2								
	4.04	-	-	-	-	-	0.00040	0.0004

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-B5528 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 21

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint (µg/L)		LC_{50} -	NOEC -	EC_{50} -	NOEC -	LC_{50} -	EC_{50} -	ErC_{50} 119 520
AF		-	-	-	-	-	-	10
RAC (µg/L)		-	-	-	-	-	-	11952
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	32.24	-	-	-	-		-	0.0027
Step 2								
	4.04	-	-	-	-	-	-	0.0003

zRMS comments:

The evaluation of the risk for aquatic organisms for metabolites of Thifensulfuron-methlyl was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios < 1 presented in the Tables above for all tested metabolites of Thifensulfuron-methlyl, indicated an acceptable risk for aquatic organism.

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for thifensulfuron methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Inverteb. acute**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Vallisneria americana***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	LC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	100 000	0.23
AF		-	-	-	-	-	100	10
RAC (µg/L)		-	-	-	-	-	1000	0.023
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	20.79	-	-	-	-	-	0.02079	903.913
Step 2								
N-Europe	0.94	-	-	-	-	-	0.00094	40.870
Step 3								
D3/ditch	0.3890	-	-	-	-	-	0.00039	**16.913**
D4/pond	0.01347	-	-	-	-	-	0.00001	0.586
D4/stream	0.2877	-	-	-	-	-	0.00029	**12.509**
D5/pond	0.01347	-	-	-	-	-	0.00001	0.586
D5/stream	0.3107	-	-	-	-	-	0.00031	**13.509**
R1/pond	0.01347	-	-	-	-	-	0.00001	0.586
R1/stream	0.2926	-	-	-	-	-	0.00029	**12.722**
R3/stream	0.3602	-	-	-	-	-	0.00036	**15.661**
R4/stream	0.2575	-	-	-	-	-	0.00026	**11.196**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Inverteb. acute	Aquatic plants
Step 4 – 20 meters vegetative and 20 meters no-spray buffer zone								
D3/ditch	0.02893	-	-	-	-	-	0.00003	**1.258**
D4/pond	0.005588	-	-	-	-	-	0.00001	0.243
D4/stream	0.02893	-	-	-	-	-	0.00003	**1.258**
D5/pond	0.005589	-	-	-	-	-	0.00001	0.243
D5/stream	0.03125	-	-	-	-	-	0.00003	**1.359**
R1/pond	0.005589	-	-	-	-	-	0.00001	0.243
R1/stream	0.06083	-	-	-	-	-	0.00006	**2.645**
R3/stream	0.03622	-	-	-	-	-	0.00004	**1.575**
R4/stream	0.02590	-	-	-	-	-	0.00003	**1.126**
Step 4 – 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode								
D3/ditch	0.01973	-	-	-	-	-	0.00002	0.858
D4/pond	0.004291	-	-	-	-	-	0.00000	0.187
D4/stream	0.01965	-	-	-	-	-	0.00002	0.854
D5/pond	0.004292	-	-	-	-	-	0.00000	0.187
D5/stream	0.02122	-	-	-	-	-	0.00002	0.923
R1/pond	0.004292	-	-	-	-	-	0.00000	0.187
R1/stream	0.01752	-	-	-	-	-	0.00002	0.762
R3/stream	0.02460	-	-	-	-	-	0.00002	1.070
R4/stream	0.01759	-	-	-	-	-	0.00002	0.765

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

In the EFSA conclusion for thifensulfuron-methyl (EFSA Journal 2015) it was concluded that no suitable data demonstrating the toxicity of thifensulfuron-methyl to fish, aquatic invertebrates and algae are available. Therefore, no assessment of the risk to fish, aquatic invertebrates and algae could be performed and a data gap was identified. With regard to aquatic plants it was also agreed that the available studies with *Lemna sp*. were not considered reliable for the risk assessment.

A study with an additional aquatic plant species *Vallisneria americana* was considered to be acceptable, however the it was noted that the available data indicated that *Lemna sp*. was the more sensitive and so the EU review considered that risk assessments conducted with the *Vallisneria americana* endpoint were illustrative only and should not be used to conclude the risk to aquatic plants.

Therefore, the risk assessment for aquatic macrophyte - *Vallisneria americana* for thifensulfuron-methyl presented above is considered as illustrative only.

Based on this assessment with consideration PEC_{sw} STEP 4 vfs mod the following risk mitigation measures are required.

- 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode, for scenarios D3 (ditch): D4 (stream), D5 (stream), R1 (stream) and R3 (stream) and R4 (stream)

The risk for Chironmus sp. is considered acceptable as the RAC/PEC ratio is below w trigger of 1.

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9225 for each organism based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint (µg/L)		LC_{50} 120 000	NOEC -	EC_{50} 130 000	NOEC -	LC_{50} -	EbC50 33 400	EC_{50} 36 760
AF		100	-	100	-	-	10	10
RAC (µg/L)		1200	-	1300	-	-	3340	3676

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	41.5	0.03458	-	0.03192	-	-	0.01243	0.0113
Step 2								
	4.27	0.00356	-	0.00328	-	-	0.00128	0.0012

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-JZ789 for each organism based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint (µg/L)		LC_{50} 940	NOEC -	EC_{50} 1100	NOEC -	LC_{50} -	E_bC_{50} 1280	ErC_{50} 100 000
AF		100	-	100	-	-	10	10
RAC (µg/L)		9.4	-	11	-	-	128	10000
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	41.5	4.41489	-	3.77273	-	-	0.32422	0.0042
Step 2								
	4.27	0.45426	-	0.38818	-	-	0.03336	0.0004

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-V7160 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC50	ErC_{50}
(µg/L)		1000	-	1300	11000	-	11 000	100 000
AF		100	-	100	10	-	10	10
RAC (µg/L)		10	-	13	1100	-	1100	10000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	41.5	4.15000	-	3.19231	0.03773	-	0.03773	0.0042
Step 2								
	4.27	0.42700	-	0.32846	0.00388	-	0.00388	0.0004

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-A4098 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		930	-	99 000	32000	-	10 000	100 00
AF		100	-	100	10	-	10	10
RAC (µg/L)		9.3	-	990	3200	-	1000	1000

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Exposure	PEC gl-max (µg/L)							
Step 1								
	41.5	4.46237	-	0.04192	0.01297	-	0.04150	0.0415
Step 2								
	4.27	0.45914	-	0.00431	0.00133	-	0.00427	0.0043

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-W8268 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		115 000	-	125 000	-	-	10 0000	30 300
AF		100	-	100	-	-	10	10
RAC (µg/L)		1150	-	1250	-	-	10000	3030
Exposure	PEC gl-max (µg/L)							
Step 1								
	41.5	0.03609	-	0.03320	-	-	0.00415	0.0137
Step 2								
	4.27	0.00371	-	0.00342	-	-	0.00043	0.0014

Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9223 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint (µg/L)		LC_{50} -	NOEC -	EC_{50} 1200	NOEC 13000	LC_{50} -	EC_{50} 1300	ErC_{50} 172 100
AF		-	-	100	10	-	10	10
RAC (µg/L)		-	-	12	1300	-	130	17210
Exposure	PEC $_{gl\text{-}max}$ (µg/L)							
Step 1								
	41.5	-	-	3.45833	0.03192	-	0.31923	0.0024
Step 2								
	4.27	-	-	0.35583	0.00328	-	0.03285	0.0002

Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-L9226 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint (µg/L)		LC_{50} -	NOEC -	EC_{50} -	NOEC -	LC_{50} -	ErC_{50} 89 000	EC_{50} 37500
AF		-	-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	-	8900	3750

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Exposure	PEC gl-max (µg/L)							
Step 1								
	41.5	-	-	-	-	-	0.00466	0.0111
Step 2								
	4.27	-	-	-	-	-	0.00048	0.0011

Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-A5546 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Chironomous riparius*	*Pseudokirchneriella subcapitata*	*Duckweed Lemna gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50} >110 000 E_bC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	48 000	40400
AF		-	-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	-	4800	4040
Exposure	PEC gl-max (µg/L)							
Step 1								
	41.5	-	-	-	-	-	0.00865	0.0103
Step 2								
	4.27	-	-	-	-	-	0.00089	0.0011

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite 2-acid-3-triuret for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	ErC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	100 000	100 000
AF		-	-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	-	10 000	10 000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	41.5	-	-	-	-		0.00415	0.0042
Step 2								
	4.27	-	-	-	-	-	0.00043	0.0004

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite IN-B5528 for each organism based on FOCUS Step 1 s 2 calculations for the use of TOTO 75 SG in winter cereals at BBCH 30

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Chironomous riparius***	***Pseudokirchneriella subcapitata***	***Duckweed Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	LC_{50}	EC_{50}	ErC_{50}
(µg/L)		-	-	-	-	-	-	119 520
AF		-	-	-	-	-	-	10
RAC (µg/L)		-	-	-	-	-	-	11952

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Inverteb. acute	Algae	Aquatic plants
Exposure	PEC gl-max (µg/L)							
Step 1								
	41.5	-	-	-	-		-	0.0035
Step 2								
	4.27	-	-	-	-	-	-	0.0004

zRMS comments:

The evaluation of the risk for aquatic organisms for metabolites of Thifensulfuron-methyl was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios < 1 presented in the Tables above for all tested metabolites of Thifensulfuron-methyl, indicated an acceptable risk for aquatic organism.

Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Metsulfuron-methyl for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of TOTO 75 SG in cereals winter at BBCH 21

Group		**Fish acute**	Fish prolonged	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	Aquatic plants	Aquatic plants
Test species		***Poecilia reticulata***	Salmo gairdneri	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna Gibba***	*Lemna Gibba*	*Lemna Gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	~~E~~~~b~~rC50	ErbC50	E_bC_{50}	E_rC_{50}
(µg/L)		100000	68000	43100	3130	58.2	0.36	0.36	0.57
AF		100	10	100	10	10	10	5	10
RAC (µg/L)		1000	6800	431	313	5.82	0.036	0.072	0.057
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	1.62	0.0016	0.0002	0.0038	0.0052	0.2784	45.00	22.500	28.421
Step 2									
PEC/RAC	0.32	0.0003	0.0000	0.0007	0.0010	0.0550	8.89	4.444	5.614

Group		**Fish acute**	Fish prolonged	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	Aquatic plants	Aquatic plants
Exposure Winter cereals	Step 3								
D3/ditch	0.04096	0.0000	0.0000	0.0001	0.0001	0.0070	**1.14**	0.569	0.719
D4/pond	0.02401	0.0000	0.0000	0.0001	0.0001	0.0041	0.67	0.333	0.421
D4/stream	0.03146	0.0000	0.0000	0.0001	0.0001	0.0054	0.8739	0.437	0.552
D5/pond	0.005069	0.0000	0.0000	0.0000	0.0000	0.0009	0.1408	0.070	0.089
D5/stream	0.02549	0.0000	0.0000	0.0001	0.0001	0.0044	0.7081	0.354	0.447
D6/ditch	0.001361	0.0000	0.0000	0.0000	0.0000	0.0002	0.0378	0.019	0.024
R1/pond	0.04461	0.0000	0.0000	0.0001	0.0001	0.0077	**1.2392**	0.620	0.783
R1/stream	0.04386	0.0000	0.0000	0.0001	0.0001	0.0075	**1.2183**	0.609	0.769
R3/stream	0.01976	0.0000	0.0000	0.0000	0.0001	0.0034	0.5489	0.274	0.347
R4/stream	0.04096	0.0000	0.0000	0.0001	0.0001	0.0070	**1.1378**	0.569	0.719
Exposure Winter cereals	Step 4 – 20 meters vegetative and 20 meters no-spray buffer zone								
D3/ditch	0.01303	0.0000	0.0000	0.0000	0.0000	0.0022	0.36	-	-
D4/pond	0.02396	0.0000	0.0000	0.0001	0.0001	0.0041	0.67	-	-
D4/stream	0.01252	0.0000	0.0000	0.0000	0.0000	0.0022	0.3478		-
D5/pond	0.004371	0.0000	0.0000	0.0000	0.0000	0.0008	0.1214	-	-
D5/stream	0.003896	0.0000	0.0000	0.0000	0.0000	0.0007	0.1082	-	-
D6/ditch	0.000418	0.0000	0.0000	0.0000	0.0000	0.0001	0.0116	-	-
R1/pond	0.009276	0.0000	0.0000	0.0000	0.0000	0.0016	0.2577	-	-
R1/stream	0.01034	0.0000	0.0000	0.0000	0.0000	0.0018	0.2872	-	-
R3/stream	0.001928	0.0000	0.0000	0.0000	0.0000	0.0003	0.0536	-	-

Group		**Fish acute**	Fish prolonged	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	Aquatic plants	Aquatic plants
R4/stream	0.01303	0.0000	0.0000	0.0000	0.0000	0.0022	0.3619		
Exposure Winter cereals	Step 4 – 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode								
D3/ditch	0.01237	0.0000	0.0000	0.0000	0.0000	0.0021	0.34	-	-
D4/pond	0.02395	0.0000	0.0000	0.0001	0.0001	0.0041	0.67	-	-
D4/stream	0.01252	0.0000	0.0000	0.0000	0.0000	0.0022	0.3478	-	-
D5/pond	0.004271	0.0000	0.0000	0.0000	0.0000	0.0007	0.1186	-	-
D5/stream	0.003313	0.0000	0.0000	0.0000	0.0000	0.0006	0.0920	-	-
D6/ditch	0.000299	0.0000	0.0000	0.0000	0.0000	0.0001	0.0083	-	-
R1/pond	0.001460	0.0000	0.0000	0.0000	0.0000	0.0003	0.0406	-	-
R1/stream	0.002050	0.0000	0.0000	0.0000	0.0000	0.0004	0.0569	-	-
R3/stream	0.001446	0.0000	0.0000	0.0000	0.0000	0.0002	0.0402	-	-
R4/stream	0.01237	0.0000	0.0000	0.0000	0.0000	0.0021	0.3436	-	-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

For metsulfuron-methyl during Pesticides Peer Review Meeting 115 the experts agreed to use AF 5 only in combination with the Lemna E_bC_{50} endpoint of 0.365 µg/L. Therefore, for Lemna sp. the endpoint E_rC_{50} of 0.57 µg/L with AF of 10 should be used. Therefore, zRMS added in the Table above with relevant values. However, the risk provided by the applicant is the worst case scenario and the calculation are considered acceptable.

The acceptable risk was obtained in FOCUS STEP 4for D3 and R1, R4 scenarios when the following risk mitigation are applied to surfacewater bodies:

– 20 meters vegetative and 20 meters no-spray buffer zone or

– 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode

Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-A4098 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 21

		IN-A4098							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	ErC50	-	EC50
(µg/L)		126000	-	99000	-	32000	100000		10000
AF		100	-	100	-	10	10	-	10
RAC (µg/L)		1260	-	990	-	3200	10000	-	1000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.66	0.0005	-	0.0007	-	0.0002	0.0001	-	0.0007

Table 9.5-38: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-00581 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Lemna gibba***
Endpoint		LC_{50}		EC_{50}	-	EC50	EC50
(µg/L)		124000	-	118000		10000	5480
AF		100	-	100	-	10	10
RAC (µg/L)		1240	-	1180	-	1000	548
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**						
Step 1							
PEC/RAC	0.07	0.0001	#ARG!	0.0001	#ARG!	0.0001	0.0001

Table 9.5-39:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-D5803 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Lemna gibba***
Endpoint		-		-	-	EC_{50}	EC_{50}
(µg/L)		-	-	-		3480	100000
AF		-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	348	10000
Exposure	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
PEC/RAC	0.45	-	-	-	-	0.0013	0.0000

Table 9.5-40:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-NC148 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

	IN-NC148								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	E~~b~~rC50	-	EC50
(µg/L)		-	-	-	-	-	100000	-	100000
AF		-	-	-	-	-	10	-	10
RAC (µg/L)		-	-	-	-	-	10000	-	10000

	IN-NC148								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.31	-	-	-	-	-	<0.0001	-	<0.0001

Table 9.5-41:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-F5438 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

	IN-F5438								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	ErC50	-	EC50
(µg/L)		9200	-	9300	-	-	10000	-	82
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		92	-	93	-	-	1000	-	8.2
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.53	0.0058	-	0.0057	-	-	0.0005	-	0.0646

Table 9.5-42:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-V7160 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

		IN-V7160							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	~~E~~b~~r~~C50	-	EC50
(µg/L)		1000	-	1300	-	11000	100000	-	10000
AF		100	-	100	-	10	10	-	10
RAC (µg/L)		10	-	13	-	1100	10000	-	1000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.09	0.0090	-	0.0069	-	0.0001	0.0000	-	0.0001

Table 9.5-43:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-JX909 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 21**

		IN-JX909							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	-	~~E~~b~~r~~C50	-	EC50
(µg/L)		543000	-	134000	-	-	73000	-	30000
AF		100	-	100	-	-	10	-	10

	IN-JX909								
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
RAC (µg/L)		5430	-	1340	-	-	7300	-	3000
Exposure	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
PEC/RAC	0.17	0.0000	-	0.0001	-	-	0.0000	-	0.0001

zRMS comments:

The evaluation of the risk for aquatic organisms for metabolites of Metsulfuron -methlyl was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1 PECSW for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios < 1 presented in the Tables above for all tested metabolites of Metsulfuron-methlyl, indicated an acceptable risk for aquatic organism.

Table 9.5-44: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Metsulfuron-methyl for each organism based on FOCUS Steps 1, 2 and 3 calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

Group		**Fish acute**	Fish prolonged	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	Aquatic plants	Aquatic plants
Test species		***Poecilia reticulata***	Salmo gairdneri	***Daphnia magna***	***Daphnia magna***	***Anabaena flos-aquae***	***Lemna Gibba***	*Lemna Gibba*	*Lemna Gibba*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	~~Ebr~~C50	ErC50	ErC50	ErC50
(µg/L)		100000	68000	43100	3130	58.2	0.36	0.36	0.57
AF		100	10	100	10	10	10	5	10
RAC (µg/L)		1000	6800	431	313	5.82	0.036	0.072	0.057
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	2.06	0.0021	0.0003	0.0048	0.0066	0.3540	57.2222	28.611	36,140
Step 2									
PEC/RAC	0.34	0.0003	0.0001	0.0008	0.0011	0.0584	9.4444	4.722	5.965
Exposure Winter cereals	Step 3								
D3/ditch	0.05363	0.0001	0.0000	0.0001	0.0002	0.0092	**1.4897**	0.745	0.941
D4/pond	0.03088	0.0000	0.0000	0.0001	0.0001	0.0053	0.86	0.429	0.542
D4/stream	0.04048	0.0000	0.0000	0.0001	0.0001	0.0070	**1.1244**	0.562	0.710
D5/pond	0.006265	0.0000	0.0000	0.0000	0.0000	0.0011	0.1740	0.087	0.110
D5/stream	0.03278	0.0000	0.0000	0.0001	0.0001	0.0056	0.9106	0.455	0.575
D6/ditch	0.001652	0.0000	0.0000	0.0000	0.0000	0.0003	0.0459	0.023	0.029
R1/pond	0.05670	0.0001	0.0000	0.0001	0.0002	0.0097	**1.5750**	0.788	0.995

Group		**Fish acute**	Fish prolonged	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	Aquatic plants	Aquatic plants
R1/stream	0.03588	0.0000	0.0000	0.0001	0.0001	0.0062	**0.9967**	0.498	0.629
R3/stream	0.02566	0.0000	0.0000	0.0001	0.0001	0.0044	0.7128	0.356	0.450
R4/stream	0.05363	0.0001	0.0000	0.0001	0.0002	0.0092	**1.4897**	0.745	0.941
Exposure Winter cereals	Step 4 – 20 meters vegetative and 20 meters no-spray buffer zone								
D3/ditch	0.01780	0.0000	0.0000	0.0000	0.0001	0.0031	0.4944		
D4/pond	0.03083	0.0000	0.0000	0.0001	0.0001	0.0053	0.86		
D4/stream	0.01604	0.0000	0.0000	0.0000	0.0001	0.0028	0.4456		
D5/pond	0.005566	0.0000	0.0000	0.0000	0.0000	0.0010	0.1546		
D5/stream	0.005068	0.0000	0.0000	0.0000	0.0000	0.0009	0.1408		
D6/ditch	0.000603	0.0000	0.0000	0.0000	0.0000	0.0001	0.0168		
R1/pond	0.01179	0.0000	0.0000	0.0000	0.0000	0.0020	0.3275		
R1/stream	0.007958	0.0000	0.0000	0.0000	0.0000	0.0014	0.2211		
R3/stream	0.002688	0.0000	0.0000	0.0000	0.0000	0.0005	0.0747		
R4/stream	0.01780	0.0000	0.0000	0.0000	0.0001	0.0031	0.4944		
Exposure Winter cereals	Step 4 – 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode								
D3/ditch	0.01681	0.0000	0.0000	0.0000	0.0001	0.0029	0.4669		
D4/pond	0.03082	0.0000	0.0000	0.0001	0.0001	0.0053	0.86		
D4/stream	0.01604	0.0000	0.0000	0.0000	0.0001	0.0028	0.4456		
D5/pond	0.005695	0.0000	0.0000	0.0000	0.0000	0.0010	0.1582		
D5/stream	0.003889	0.0000	0.0000	0.0000	0.0000	0.0007	0.1080		
D6/ditch	0.000399	0.0000	0.0000	0.0000	0.0000	0.0001	0.0111		

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Aquatic plants	Aquatic plants
R1/pond	0.001703	0.0000	0.0000	0.0000	0.0000	0.0003	0.0473		
R1/stream	0.002392	0.0000	0.0000	0.0000	0.0000	0.0004	0.0664		
R3/stream	0.001710	0.0000	0.0000	0.0000	0.0000	0.0003	0.0475		
R4/stream	0.01681	0.0000	0.0000	0.0000	0.0001	0.0029	0.4669		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

For metsulfuron-methyl during Pesticides Peer Review Meeting 115 the experts agreed to use AF 5 only in combination with the Lemna E_bC_{50} endpoint of 0.365 µg/L. Therefore, for Lemna sp. the endpoint E_rC_{50} of 0.57 µg/L with AF of 10 should be used. Therefore, zRMS added in the Table above with relevant values. However, the risk provided by the applicant is the worst case scenario and the calculation are considered acceptable.

The acceptable risk was obtained in FOCUS STEP 4 for D3, D4 (stream) and R1, R4 scenarios when the following risk mitigation are applied to surfacewater bodies:

– 20 meters vegetative and 20 meters no-spray buffer zone or

– 20 meters vegetative and 30 meters no-spray buffer zone – vfs mode

Table 9.5-45: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-A4098 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

		IN-A4098							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	ErC50	-	EC50
(µg/L)		126000	-	99000	-	32000	100000		10000
AF		100	-	100	-	10	10	-	10
RAC (µg/L)		1260	-	990	-	3200	10000	-	1000
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	0.84	0.0007	-	0.0008	-	0.0003	0.0001	-	0.0008

Table 9.5-46:: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-00581 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Lemna gibba***
Endpoint		LC_{50}		EC_{50}	-	EC50	EC50
(µg/L)		124000	-	118000		10000	5480
AF		100	-	100	-	10	10
RAC (µg/L)		1240	-	1180	-	1000	548
Exposure	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
PEC/RAC	0.08	0.0001	#ARG!	0.0001	#ARG!	0.0001	0.0001

Table 9.5-47: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-D5803 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1 calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Lemna gibba***
Endpoint (µg/L)		- -	-	- -	-	EC_{50} 3480	EC_{50} 100000
AF		-	-	-	-	10	10
RAC (µg/L)		-	-	-	-	348	10000
Exposure	**PEC $_{gl-max}$ (µg/L)**						
Step 1							
PEC/RAC	0.57	-	-	-	-	0.0016	0.0000

Table 9.5-48: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-NC148 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

	IN-NC148								
Group		**Fish acute**	**Fish prolonged**	**Inverte b. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint (µg/L)		LC_{50} -	-	EC_{50} -	- -	NOEC -	E~~b~~rC50 100000	- -	EC50 100000
AF		-	-	-	-	-	10	-	10
RAC (µg/L)		-	-	-	-	-	10000	-	10000
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	0.39	-	-	-	-	-	<0.0001	-	<0.0001

Table 9.5-49: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-F5438 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

		IN-F5438							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	ErC50	-	EC50
(µg/L)		9200	-	9300	-	-	10000	-	82
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		92	-	93	-	-	1000	-	8.2
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	0.68	0.0074	-	0.0073	-	-	0.0007	-	0.0829

Table 9.5-50: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-V7160 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

		IN-V7160							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	NOEC	ErC50	-	EC50
(µg/L)		1000	-	1300	-	11000	100000	-	10000
AF		100	-	100	-	10	10	-	10
RAC (µg/L)		10	-	13	-	1100	10000	-	1000
Exposure	**PEC $_{gl-max}$ (µg/L)**								
Step 1									
PEC/RAC	0.11	0.0110	-	0.0085	-	0.0001	0.0000	-	0.0001

Table 9.5-51: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites IN-JX909 of Metsulfuron-methyl for each organism group based on FOCUS Steps 1, calculations for the use of TOTO 75 SG in cereals winter at BBCH 30**

		IN-JX909							
Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inver-teb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	-	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna Gibba***
Endpoint		LC_{50}		EC_{50}	-	-	~~E~~b~~r~~C50	-	EC50
(µg/L)		543000	-	134000	-	-	73000	-	30000
AF		100	-	100	-	-	10	-	10
RAC (µg/L)		5430	-	1340	-	-	7300	-	3000
Exposure	**PEC gl-max (µg/L)**								
Step 1									
PEC/RAC	0.21	0.0000	-	0.0002	-	-	0.0000	-	0.0001

zRMS comments:

The evaluation of the risk for aquatic organisms for metabolites of Metsulfuron-methlyl was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios < 1 presented in the Tables above for all tested metabolites of Metsulfuron-methyl indicated an acceptable risk for aquatic organism.

9.5.2.1 Risk assessment for formulation to aquatic organisms

Table 9.5-52: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TOTO 75 SG for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of TOTO 75 SG in winter cereals.**

Intended use	Winter cereals
Formulation	TOTO 75 SG
Application rate (g[prod]/ha)	1 x 90
Entry into surface water via spray drift (Drift Calculator from SWASH)	
Buffer zone (m)	**PECsw [µg prod/L]**
1	0.5782
~~6~~ 5	0.1330
Entry into surface water via spraydrift (Drift Calculator from SWASH)	
Buffer zone (m)	**RAC/PEC ratio** **O. mykiss =EC_{50} > 100 mg/L** **RAC=1 000** µg/L **(AF=100)**
1	0.0005782
Buffer zone (m)	**RAC/PEC ratio** ***Daphnia magna* = *EC50= 100 mg/L*** **RAC=1000 (AF=10)**
1	0.0005782
Buffer zone (m)	**RAC/PEC ratio** ***Pseudokirchmeirella subcapitata* E_rC_{50} =6.80 mg/L** **RAC=680 (AF=10)**
1	0.00085
Buffer zone (m)	**RAC/PEC ratio** **Anabaena flos-aque =EC_{50} 2 800 µg/L** **RAC=280 (AF=10)**
1	0.0021
Buffer zone (m)	**RAC/PEC ratio** **Lemna Gibba =EC50 1.49 µg/L** **RAC=0.149 (AF=10)**
1	3.64
5	0.89

Based on the calculated concentrations of the formulation TOTO 75 SG (spray drift) respectively its active ingredients Thifensulfuron-methyl and metsulfuron-methyl (run-off and drainage) in surface water (PEC_{SW} according to FOCUS STEP 1-2, STEP 3 and Step 4), the calculated RAC/PEC values for the risk

resulting from an exposure of aquatic organisms to TOTO 75 SG according to the GAP of the formulation are below the trigger value <1 for run-off exposure and drainage.

zRMS comments:

Studies were conducted to assess the effect of the product on quatic organisms; green algae Pseudokirchneriella subcapitata and the aquatic plant, Lemna gibba. An additional study with a second species of algae - Anabaena flos-aquae has also been considered.

Based on the calculated concentrations of the formulation TOTO 75 SG (spray drift) for the lowest endpoint – Lemna gibba the **5 meter drift buffer zone should be applied to surface water bodies**.

Decision scheme for mixture toxcitiy risk assessment for TOTO 75 SG

Step 1. Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?

Only for the a.s. (ECxa.s.): Go to 7
For both formulation (ECxPPP) and a.s. (ECxa.s.): Go to 2

Answer: Measured toxicity data for the formulation and the a.s. are available for ~~invertebrate~~AQUATIC MACROPHYTE~~.~~ As these are the most sensitive aquatic organisms, it is justified to conduct the mixture toxicity risk assessment only for this organism groups → Go to 2

STEP 2. Check the plausibility of the measured formulation toxicity (EC_xPPP) against the calculated mixture toxicity EC_{xmix}-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_xPPP) by means of the model deviation ratio (MDR = EC_{xmix}-CA/EC_xPPP).

If MDR = 0.2–5 (CA approximately holds for the mixture)
If MDR > 5 (mixture more toxic than CA)
If MDR < 0.2 (mixture less toxic than CA)

Equation 13:

$$EC_{X_{mix-CA}} = \left(\sum_{i=1}^{n} \frac{p_i}{EC_{X_i}} \right)^{-1}$$

Equation 15:

$$MDR = \frac{EC_{X_{mix-CA}}\ (calculated\ mixture\ toxicity)}{EC_{X_{PPP}}\ (measured\ mixture\ toxicity)}$$

Calculation of the acute mixture toxicity of the formulation

Table 1. Composition of TOTO 75 SG

Name/code of the product	TOTO 75 SG		
Name of the active substance A	Thifensulfuron-methyl		
Name of the active substance B	Metsulfuron-methyl		
Density [g product/cm^3]	1.0		
	Nominal [g a.s./kg or L product]	Fraction considering density [%]	$p_{i\ mix}$ = Fraction of active substance i in the mixture with $\sum p_{i\ mix} = 100$ [%]
Concentrations of the active substance Thifensulfuron-methyl in the product	682	68.2%	90.9%
Concentrations of the active substance Metsulfuron-methyl in the product	68	6.8%	9.1%

Endpoint/Test species	Toxicity of the product [mg product/L]	Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]	Toxicity of the a.s. Thifensulfuron-methyl ($EC_{x\ A}$) [mg a.s./L]	Toxicity of the a.s. Metsulfuron-methyl ($EC_{x\ B}$) [mg a.s./L]	Triggers (from EFSA Journal 2013;11(7):3290)
ErC50 higher plant	0.00149	0.001	0.00023	0.00036	0.1

Table 3. Calculation of toxicity exposure in TOTO 75 SG

Toxicity per fraction of the Thifensulfuron-methyl ($1/TU_A$) [mg a.s./L]	Toxicity per fraction of the Metsulfuron-methyl ($1/TU_B$) [mg a.s./L]	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA} = 1/\sum(TU_i)$) [mg a.s./L]	Model deviation ratio ($MDR = EC_{x\ mix\text{-}CA}/EC_{x\ PPP}$)	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PEC_{mix}) (at lower exposure tier)
0.000252933	0.003970588	0.000	0.213	0.935

Answer: MDRs only for higher plant could calculate and its value is between triggers value 0.2-5. Go to step 3.

Step 3. Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).

Answer: ECx mix-CA is between triggers value 0.8-1.2. Go to step 4

Step 4. Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETRmix) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.

Exposure		**(lower exposure tier)**	**(higher exposure tier)**								
Exposure tier (FOCUS step)		STEP 2	Step 4 (20m veg bz and 30m ns bz (vfs), D3 ditch)	Step 4 (20m veg bz and 30m ns bz (vfs), D4 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), D4 stream)	Step 4 (20m veg bz and 30m ns bz (vfs), D5 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), D5 stream)	Step 4 (20m veg bz and 30m ns bz (vfs), R1 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), R1 stream)	Step 3 (20m veg bz and 30m ns bz (vfs), R3 stream)	Step 3 (20m veg bz and 30m ns bz (vfs), R4 stream)
PECsw [mg a.s./L]		0.000940	0.000020	0.000004	0.000020	0.000004	0.000021	0.000004	0.000018	0.000025	0.000018

Exposure tier (FOCUS step)		STEP 2	Step 4 (20m veg bz and 30m ns bz (vfs), D3 ditch)	Step 4 (20m veg bz and 30m ns bz (vfs), D4 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), D4 stream)	Step 4 (20m veg bz and 30m ns bz (vfs), D5 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), D5 stream)	Step 4 (20m veg bz and 30m ns bz (vfs), R1 pond)	Step 4 (20m veg bz and 30m ns bz (vfs), R1 stream)	Step 3 (20m veg bz and 30m ns bz (vfs), R3 stream)	Step 3 (20m veg bz and 30m ns bz (vfs), R4 stream)
PECsw [mg a.s./L]		0.000340	0.000017	0.000031	0.000016	0.000006	0.000004	0.000000	0.000002	0.000002	0.000002

Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.001280	0.000037	0.000035	0.000036	0.000010	0.000025	0.000005	0.000019	0.000027	0.000019

Endpoint/Test species ErC50 higher plant		**$ETR_{mix} = PEC_{mix}/EC_{x\ PPP}$**									**Triggers**
0.0011	1.145	0.033	0.031	0.032	0.009	0.022	0.004	0.017	0.024	0.017	0.10

Answer: Results are acceptable according to the label with using 20 meters vegetative and 30 meter no-spray buffer zone.

For Plant Protection product TOTO 75 SG, for the most sensitive species is required buffer zone of 20 meters vegetative buffer zone and 30 meters no-spray buffer zone.

zRMS comments:

The mixture toxicity calculations provided by the applicant was based on E_bC_{50} value for metsulfuron - methyl with 0.36 microgram/L It was considered acceptable as it is lower value than ErC50 of 0.57 microgram/L. The calculations provided by zRMS based on E_rC_{50} value of 0.57 microgram/L have not significant impact for the results of mixture toxicity assessment.

STEP 1

Endpoint/Test species	**Toxicity of the product [mg product/L]**	**Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]**	**Toxicity of the a.s. Thifensulfuron-methyl ($EC_{x\ A}$) [mg a.s./L]**	**Toxicity of the a.s. Metsulfuron-methyl ($EC_{x\ B}$) [mg a.s./L]**	**Triggers (from EFSA Journal 2013;11(7):3290)**
ErC_{50} higher plant	0.00149	0.0011	0.00023	0.00057	0.1

STEP 2

Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA} = 1/\sum (TU_i)$) [mg a.s./L]	**Model deviation ratio ($MDR = EC_{x\ mix\text{-}CA}/EC_{x\ PPP}$)**
0.00011175	0.22

*****based on STEP 2-lower Tier

MDR for aquatic plants is between 0.2-5.

STEP 3

ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) (at lower exposure tier)	0.879

ECx mix-CA is between triggers value 0.8-1.2.
STEP 4 : The ETR_{mix} calculations provided by the applicant with EbC50 value was considered acceptable**.**

For Plant Protection product TOTO 75 SG, for the most sensitive species is required buffer zone of 20 meters vegetative buffer zone and 30 meters no-spray buffer zone**.**

The final risk mitigatiom measures shoul be decided at MSs level.

9.5.3 Overall conclusions

The risk for the entry routes run-off and drainage is also not acceptable without buffer zones for the intended use of TOTO 75 SG .

Therefore, using buffer zone of 20 meters vegetative buffer zone and 30 meters no-spray buffer zone, the use TOTO 75 SG according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1).

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out active substance thifensulfuron-methyl and metsulfuron-methyl. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of TOTO 75 SG were not evaluated as part of the EU assessment of thifensulfuron-methyl and metsulfuron-methyl. New data submitted with this application are listed and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Thifensulfuron-methyl	Acute Oral	LD_{50} >7.1 µg /bee	EFSA Journal 2015;13(7):4201
Apis mellifera	Thifensulfuron-methyl	Acute Contact	LD_{50} >100 µg /bee	EFSA Journal 2015;13(7):4201
Apis mellifera	Metsulfuron-methyl	Oral	LD_{50} >44.3 µg a.s/bee	EFSA Journal 2015;13(1):3936
Apis mellifera	Metsulfuron-methyl	Contact	LD_{50} > 50 µg a.s/bee	EFSA Journal 2015;13(1):3936
Apis mellifera	TOTO 75 SG	Acute Oral	LD_{50} > 200 µg/bee	xxx, Study code: B/33/08
Apis mellifera	TOTO 75 SG	Acute Contact	LD50 > 200 µg/bee	xxx, Study code: B/34/08
Higher-tier studies (tunnel test, field studies)				
Not required				

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and EFSA Journal 2013;11(7):3295 EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*)

9.6.2.1 Hazard quotients for bee

Table 9.6-2: First-tier assessment of the risk for bees due to the use of TOTO 75 SG in winter cereals

Intended use	Winter cereals		
Active substance	Thifensulfuron methyl		
Application rate (g/ha)	1 x 61.4 g a.s/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**

Oral toxicity	7.1	61.4	8.65
Contact toxicity	100		0.614
Intended use **Active substance** **Application rate (g/ha)**	Cereals winter Metsulfuron-methyl 1 × 6.1g as/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	44.3	6.1	0.14
Contact toxicity	50		0.122
Product **Application rate (g/ha)**	TOTO 75 SG 1 x 90 g product/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 200	90	<0.45
Contact toxicity	> 200		<0.45

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

zRMS comments:

The Q_{HO} and Q_{HC} values for metsulfuron-methyl, thifensulfuron-methyl and the formulation are all below the trigger of 50 and so indicate acceptable acute risk to bees based on the maximum intended use of TOTO 75 SG. According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by tha applicant.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant

9.6.4 Effects on solitary bees

Not relevant

9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than trigger values for honey bees, indicating that TOTO 75 SG applied at the maximum use rate in winter cereals poses low risk to bees.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Thifensulfuron-methyl and

metsulfuron-methyl. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of TOTO 75 SG were not evaluated as part of the EU assessment of any active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	TOTO 75 SG	Laboratory test glass plates (2D)	LR50 > 90 g prod/ha	xxx, Study code: 128611063
Aphidius rhopalosiphi (adults)	TOTO 75 SG	Laboratory test glass plates (2D)	LR50 > 90 g prod/ha	xxx, Study code: 128611001
Field or semi-field tests				
Not required				

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals covers the risk for non-target arthropods from all other intended uses.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of TOTO 75 SG in winter cereals

Calculations PER in-field values according to ESCORT 2 as:
Application rate × MAF.

Intended use	Winter cereals
Active substance/product	TOTO 75 SG
Application rate (g/ha)	1 × 90 g prod/ha
MAF	1.0

Test species Tier I	**LR_{50} (lab.) (g [a.s.]/ha)**	**$PER_{in\text{-}field}$ (g [a.s.]/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 90	90	1
Aphidius rhopalosiphi	> 90		1

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

zRMS comments:

The risk to non-target arthropods is considered to be from exposure to the formulation Toto 75 SG.

The risk from the formulation Toto 75 SG based on the results from laboratory studies for indicator species T.pyri and Aphidius rhopalosiphi indicating an acceptable in–field as the HQ-in field values were <2.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on winter cereals covers the risk for non-target arthropods from all intended uses.
Calculate PERoff-field values according to ESCORT 2 as:
Application rate × MAF × (drift factor/vegetation distribution factor)
Calculate the corrected PERoff-field values according to ESCORT 2 as:
corr. PERoff-field = PERoff-field * correction factor

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of TOTO 75 SG in winter cereals

Intended use	Winter cereals
Active substance/product	TOTO 75 SG
Application rate (g/ha)	1 × 90 g a.s/ha
MAF	1.0
vdf	10 – 2 D, 3D -

Test species Tier I	**LR_{50} (lab.) (g [a.s.]/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Aphidius rhopalosiphi	> 90	2.77	0.2493	10	0.0277
Typhlodromus pyri	> 90	2.77	0.2493	10	0.0277

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

zRMS comments:

The risk from the formulation Toto 75 SG based on the results from laboratory studies for two indicator species indicating an acceptable off–field risk as the $HQ_{off\text{-}field}$ values are <2.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

All hazard quotients (HQ) are considerably less than 2, indicating that TOTO 75 SG applied at the maximum use rate in winter cereals poses no risk to non-target arthropods. No risk mitigation needed.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with two active substances thifensulfuron-methyl and metsulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of TOTO 75 SG were not evaluated as part of the EU assessment of any of active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results mg/kg	Reference
Eisenia fetida	TSM Thifensulfuron-methyl (CHA 8730)	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 4.617 $NOEC_{corr}$ = 2.31*	EFSA conclusion 2015
Eisenia fetida	IN-A4098	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 0.2 NOEC=8.0	EFSA Journal 2015;13(7):4201
Eisenia fetida	IN-L9223	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 10	EFSA Journal 2015;13(7):4201
Eisenia fetida	IN-L9225	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 0.4	EFSA Journal 2015;13(7):4201
Eisenia fetida	IN-W8268	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 8.0	EFSA Journal 2015;13(7):4201
Collembola (F.candida)	IN-A4098	Chronic 28 days	NOEC = 0.045 NOEC = 31.7	EFSA Journal 2015;13(7):4201
Predatory mite (H.aculeifer)	IN-A4098	Chronic 14 days	NOEC = 100	EFSA Journal 2015;13(7):4201
Collembola (F.candida)	IN-L9223	Chronic 28 days	NOEC = 100	EFSA Journal 2015;13(7):4201
Collembola (F.candida)	IN-L9225	Chronic 28 days	NOEC = 10	EFSA Journal 2015;13(7):4201
Predatory mite (H.aculeifer)	IN-L9225	Chronic 14 days	NOEC = 100	EFSA Journal 2015;13(7):4201
Collembola (F.candida)	IN-W8268	Chronic 28 days	NOEC = 100	EFSA Journal 2015;13(7):4201
Predatory mite	IN-W8268	Chronic 14 days	NOEC = 50	EFSA Journal

Species	Substance	Exposure System	Results mg/kg	Reference
(H.aculeifer)				2015;13(7):4201
Folsomia candida	Metsulfuron-methyl	Mixed into substrate 28 d, chronic	28-d NOEC ≥250 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-00581 (saccharin)	Mixed into substrate 28 d, chronic	28-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Hypoaspis aculeifer	IN-00581 (saccharin)	Mixed into substrate 14 d, chronic	14-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-A4098	Mixed into substrate 28 d, chronic	28-d NOEC ≥0.225 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Hypoaspis aculeifer	IN-A4098	Mixed into substrate 14 d, chronic	14-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-D5803	Mixed into substrate 28 d, chronic	28-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-F5438	Mixed into substrate 28 d, chronic	28-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Hypoaspis aculeifer	IN-F5438	Mixed into substrate 14 d, chronic	14-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-NC148	Mixed into substrate 28 d, chronic	28-d NOEC = 0.277 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Folsomia candida	IN-V7160	Mixed into substrate 28 d, chronic	28-d NOEC = 50 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Hypoaspis aculeifer	IN-V7160	Mixed into substrate 14 d, chronic	14-d NOEC ≥100 mg/kg soil dw	EFSA Journal 2015;13(1):3936
Eisenia fetida	TOTO 75 SG	Mixed into substrate 56 d, chronic 10 % peat content	NOECreproduction ≥ 100 mg product/kg dry weight of artificial soil	xxx, Study code: G/60/16
Folsomia candida	TOTO 75 SG	Mixed into substrate 28d, chronic 5 % peat content	NOEC = 1000 mg product/kg dry weight of artificial soil	xxx, Study code: CHR-19-6
Hypoaspis (Geolaelaps) aculeifer	TOTO 75 SG	Mixed into substrate 14d, chronic 5 % peat content	NOEC = 1000 mg/kg dry weight of artificial soil	xxx, Study code:CHR-19-5

Species	Substance	Exposure System	Results mg/kg	Reference
Folsomia candida	IN-A4098	Mixed into substrate 28d, chronic 5 % peat content	NOEC ≥ 0.72 mg/kg dry weight of artificial soil	xxx, Study code: 128571016. **Chemirol study**

* according to SANCO/10329/2002 a correction of the endpoints is required, if K_{OC} > 2. The following values are listed in the EFSA conclusions: Koc TSM = 19.9

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for thifensulfuron methyl and metsulfuron-methyl.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of TOTO 75 SG in winter cereals

Intended use	Winter cereals		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required.			
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl		0.0684	
IN-A4098	0.2	0.0367*	5.44
IN-L9223	10	0.0684**	126.20
IN-L9225	0.4	0.0684**	5.85
IN-W8268	8.0	0.0684**	116.96
Metsulfuron-methyl	-	~~0.0065~~	-
IN-00581	0.050	0.0003	7.69
IN-A4098	0.20	0.0367*	5.44
~~IN-B5067~~	-	~~0.0005~~	-
IN-NC148	0.05	0.0015	33.33
IN-F5438	0.202	0.0005	134.67
IN-V7160	100	0.0001	100 000

Intended use	Winter cereals		
IN-D5803	100	0.0003	33 333
TOTO 75 SG	100	0.096	1 041.67
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl	-	0.0684	-
IN-A4098	0.045	0.0085***	5.30
IN-L9223	100	0.0684**	1 462
IN-L9225	10	0.0684**	146
IN-W8268	100	0.0684**	1 462
Metsulfuron-methyl	250	0.0065	38 461
IN-00581	100	0.0003	333 333
IN-A4098	0.225	0.0085***	26.47
~~IN-B5067~~	-	~~0.0005~~	-
IN-NC148	0.277	0.0015	185
IN-F5438	100	0.0005	200 000
IN-V7160	50	0.0001	500 000
IN-D5803	100	0.0003	333 333
TOTO 75 SG	1000	0.096	10 417
IN-A4098 (Chemirol study)	0.72	0.0367***	19.62
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl	-	~~0.0684~~	-
IN-A4098	100	0.0367*	2 725
IN-L9225	100	0.0684**	1 462
IN-W8268	50	0.0684**	731
Metsulfuron-methyl	-	0.0065	-
IN-00581	100	0.0003	333 333
IN-A4098	100	0.0367*	2 725
~~IN-B5067~~	-	~~0.0005~~	-
IN-NC148	-	0.0015	-
IN-F5438	100	0.0005	200 000
IN-V7160	100	0.0001	1 000 000
IN-D5803	-	0.0003	-
TOTO 75 SG	1000	0.096	10 417

TER values shown in bold fall below the relevant trigger.

*Sum of PECacc of metabolite from calculation of PECs's two active substance
**PECacc from parent used like as worst case scenario for thifensulfuron's metabolites excep IN-A4098
*** For calculation exposure of IN-A4098 on Folsomia candida used sum of IN-A4098's PECs initial (Refined PECsoil for metabolite IN-A4098, considering peak occurrence and molecular weight). Additionally provided the calculation using sum of IN-A4098's PECs accumulation and Chemirol's study of exposure IN-A4098 on Folsomia candid (xxx, Study code: 128571016).

zRMS comments:

The risk assessment for earthworms and other soil macro-organism was verified by zRMS.

The risk assessment provided by the zRMS considered PECs agreed at Section 8 by e-fate expert.

All TER_{LT} values for both active substances and their metabolites and also for the product Toto 75SG are above trigger of 5, indicting acceptable long-term risk assessment.

It has to be noted that no studies to assess chronic toxicity on earthworms and macro-organisms in the case of the thifensulfuron-methyl metabolites IN-JZ798 and 2-acid-3triuret are available.

On the assumption that metabolites IN-JZ798 and 2-acid-3triuret are 10 times more toxic than thifensulfuron-methyl (as unrealistic worst case) the estimated NOEC is 0.231 mg a.s./kg dws.

Therefore, taking into account the PEC_s values for these metabolites from Section 8 and estimated NOEC, TER_{LT} values were calculated by zRMS.

Table 9.8-3corr: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of TOTO 75 SG in winter cereals.

Intended use	Winter cereals		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Not required.			
Chronic effects on earthworms			
Product/active substance	**NOEC/EC10 (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl	2.31	0.0684	33.77
IN-A4098	8	0.08	1000
IN-L9223	10	0.007	1428.57
IN-L9225	0.4	0.059	6.77
IN-W8268	8.0	0.009	888.88
JZ789	0.231	0.006	38.5
2-acid-3-triuret	0.231	0.011	21
Metsulfuron-methyl	-		-
IN-00581	0.050	0.0003	7.69
IN-A4098	0.20	0.0015	133.33

IN-NC148	0.05	0.0015	33.33
IN-F5438	0.202	0.0005	134.67
IN-V7160	100	0.0001	100 000
IN-D5803	100	0.0003	33 333
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl	-	-	-
IN-A4098	31.7	0,08	396.25
IN-L9223	100	0.007	14285.71
IN-L9225	10	0.059	169.5
IN-W8268	100	0.009	11111.11
Metsulfuron-methyl	250	0.0065	38 461
IN-00581	100	0.0003	333 333
IN-A4098	0.225	0.0015	150
IN-NC148	0.277	0.0015	185
IN-F5438	100	0.0005	200 000
IN-V7160	50	0.0001	500 000
IN-D5803	100	0.0003	333 333
IN-A4098 (Chemirol study)	0.72	0.0015	480
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Thifensulfuron-methyl	**-**		-
IN-A4098	100	0.08	1250
IN-L9225	100	0.059	1694.91
IN-W8268	50	0.009	5555.55
Metsulfuron-methyl	-		-
IN-00581	100	0.0003	333 333
IN-A4098	100	0.0015	66666.66
IN-NC148	-	0.0015	-
IN-F5438	100	0.0005	200 000
IN-V7160	100	0.0001	1 000 000

The TER_{Lt} values are above the trigger of 5 for both active substance and their metabolites and ppp Toto 75 SG indicating an acceptable risk.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The acute and long-term risk to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed as low for TOTO 75 SG in a first-tier risk assessment.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with three active substances Thifensulfuron methyl, metsulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU documents.

Effects on soil microorganisms of TOTO 75 SG were not evaluated as part of the EU assessment of thifensulfuron-methyl and metsulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation C-mineralisation	Thifensulfuron -methyl	28 d/28d, aerobic soil type	Rate at which there was less than 25% deviation from the control = 0.53 g/ha	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-A4098	28 days	Rate at which there was less than 25% deviation from the control = 0.125	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.125	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-A5546	28 days	Rate at which there was less than 25% deviation from the control = 0.827	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.827	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-JZ789	28 days	51.6% deviation from the control at 0.1 mg/kg soil 48.8% deviation at 1.0 mg/kg soil (study not extended)	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the	EFSA Journal 2015;13(7):4201

Endpoint	Substance	Exposure System	Results	Reference
			control = 1.0	
N-mineralisation	IN-L9223	28 days	Rate at which there was less than 25% deviation from the control = 1.0	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 1.0	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-L9225	28 days	Rate at which there was less than 25% deviation from the control = 0.42	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.42	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-L9226	28 days	Rate at which there was less than 25% deviation from the control = 0.39	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.39	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-V7160	28 days	Rate at which there was less than 25% deviation from the control = 0.843	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.843	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-W8268	28 days	Rate at which there was less than 25% deviation from the control = 0.20	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 0.20	EFSA Journal 2015;13(7):4201
N-mineralisation	2-acid-3-triuret	28 days	Rate at which there was less than 25% deviation from the control = 1.0	EFSA Journal 2015;13(7):4201
C-mineralisation		28 days	Rate at which there was less than 25% deviation from the control = 1.0	EFSA Journal 2015;13(7):4201
N-mineralisation	TOTO 75 SG	56 d, aerobic	0.3 mg/kg: No effect	xxx, Study code:

Endpoint	Substance	Exposure System	Results	Reference
				G/27/08
N-mineralisation	IN-L5296	28 d, aerobic soil type	< 25% effect (IN-L5296)	EFSA Scientific Report (2004) 15, 1-52
N-mineralisation	IN-00581 (saccharin)	28 d, aerobic soil type	28-d NOAEC = 0.20	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-A4098	42 d, aerobic soil type	42-d NOAEC = 0.204	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-B5067	42 d, aerobic soil type	42-d NOAEC = 0.102	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-D5803	28 d, aerobic soil type	28-d NOAEC = 0.0597	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-F5438	28 d, aerobic soil type	28-d NOAEC = 1.0	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-V7160	28 d, aerobic soil type	28-d NOAEC = 0.8427	EFSA Journal 2015;13(1):3936
N-mineralisation	IN-NC148	28 d, aerobic soil type	28-d NOAEC = 0.0981	EFSA Journal 2015;13(1):3936

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 0).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of TOTO 75 SG in winter cereals

Intended use	winter cereals		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Thifensulfuron-methyl	Rate at which there was less than 25% deviation from the control = 0.53	0.0684	YES
IN-A4098	Rate at which there was less than 25% deviation from the control = 0.125	~~0.0367~~ 0.08	YES
IN-A5546	Rate at which there was less than 25% deviation from the control = 0.827	~~0.0684~~ 0.012	YES
IN-JZ789	51.6% deviation from the control at 0.1 mg/kg soil 48.8% deviation at 1.0 mg/kg soil (study not extended	~~0.0684~~ 0.006	YES

IN-L9223	Rate at which there was less than 25% deviation from the control = 1.0	~~0.0684~~ 0.007	YES
IN-L9225	Rate at which there was less than 25% deviation from the control = 0.42	~~0.0684~~ 0.059	YES
IN-L9226	Rate at which there was less than 25% deviation from the control = 0.39	~~0.0684~~ 0.012	YES
IN-V7160	Rate at which there was less than 25% deviation from the control = 0.843	0.0684 0.030	YES
IN-W8268	Rate at which there was less than 25% deviation from the control = 0.20	~~0.0684~~ 0.009	YES
2-acid-3-triuret	Rate at which there was less than 25% deviation from the control = 1.0	~~0.0684~~ 0.011	YES
IN-00581 (saccharin)	28-d NOAEC = 0.20	0.0003	YES
IN-A4098	42-d NOAEC = 0.204	~~0.0367~~ 0.0015	YES
IN-B5067	42-d NOAEC = 0.102	0.0005	YES
IN-D5803	28-d NOAEC = 0.0597	0.0003	YES
IN-F5438	28-d NOAEC = 1.0	0.0005	YES
IN-V7160	28-d NOAEC = 0.8427	0.0001	YES
IN-NC148	28-d NOAEC = 0.0981	0.0015	YES
TOTO 75 SG	0.3 mg/kg: No effect	0.096	YES

ZRMS comments:

The risk assessment for soil micro-organism after exposure of both active substances and their metabolites was verified by the zRMS with considertation PECs values agreed by e-fate experts in Section 8. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs soil for the maximum application rate of active substances and the product Toto 75 SG.

9.9.3 Overall conclusions

The Predicted Environmental Concentrations of the formulation TOTO 75 SG and its active substance Thifensulfuron-methyl and metsulfuron-methyl in soil are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days or more of exposure, indicating that the proposed use of TOTO 75 SG poses an acceptable risk to soil microorganisms.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Thifensulfuron-methyl and metsulfuron-methyl. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of TOTO 75 SG were not evaluated as part of the EU assessment of thifensulfuron methyl and metsulfuron-methyl. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results ER_{50} g/ha	Reference
Brassica napus	TOTO 75 SG	14 d Seedling emergence	6.19	xxx, Study code: 97831086
Pisum sativum			1.58	
Solanum lycopersicum			4.89	
Beta vulgaris			2.45	
Daucus carota			7.22	
Lactuca sativa			10.6	
Lolium perenne			16.4	
Allium cepa			6.76	
Brassica napus		21 d Vegetative vigour	48.2	xxx, Study code: 97831087
Pisum sativum			90	
Solanum lycopersicum			90	
Beta vulgaris			13.3	
Daucus carota			3.53	
Lactuca sativa			4.99	
Lolium perenne			97.1	
Allium cepa			8.69	

m: monocotyledonous; d: dicotyledonous

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of TOTO 75 SG in winter cereals

Intended use	Winter cereals				
Active substance/product	TOTO 75 SG				
Application rate (g/ha)	1 x 90 g formulation/ha				
MAF	1				
Test species	**ER_{50} (g formulation /ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**	
Brassica napus	6.19	0.0277	2.49	2.49	14 d Seedling emergence
Pisum sativum	1.58	0.0277	2.49	0.64	
Solanum lycopersicum	4.89	0.0277	2.49	1.96	
Beta vulgaris	2.45	0.0277	2.49	0.98	
Daucus carota	7.22	0.0277	2.49	2.90	
Lactuca sativa	10.6	0.0277	2.49	4.26	
Lolium perenne	16.4	0.0277	2.49	**6.59**	
Allium cepa	6.76	0.0277	2.49	**2.71**	
Brassica napus	48.2	0.0277	2.49	19.36	21 d Vegetative vigour
Pisum sativum	90	0.0277	2.49	**36.14**	
Solanum lycopersicum	90	0.0277	2.49	36.14	
Beta vulgaris	13.3	0.0277	2.49	5.34	
Daucus carota	3.53	0.0277	2.49	1.41	
Lactuca sativa	4.99	0.0277	2.49	2.00	
Lolium perenne	97.1	0.0277	2.49	38.99	
Allium cepa	8.69	0.0277	2.49	3.49	

9.10.2.3 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of TOTO 75 SG in winter cereals considering risk mitigation

Intended use	Winter cereals				
Active substance/product	TOTO 75 SG				
Application rate (g/ha)	1 x 90 g formulation/ha				
MAF	1				
Buffer strip (m)	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**

1	0.0277	2.49	1.25	0.63	0.25
5	0.0057	0.513	0.26	0.13	0.05
10	0.0029	0.26	0.13	0.065	0.026
Toxicity value ER_{50} = 1.58 g formulation /ha		**TER** **criterion: TER ≥ 5**			
1		**0.64**	1.26	2.51	6.32
5		3.08	6.08	12.15	31.6
10		6.08	12.16	24.31	60.77

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

zRMS comments:

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the ER_{50} of1.58 g formulation/L and PER_{off}- field values, the risk is considered acceptable when following risk mitigation measures will be applied to non-crop land:

- 10 meters buffer zone,

or

-5 meters buffer zone and 90%, 75%

or

-50% nozzles reduction, or1 meter buffer zone and 90% nozzles reduction

9.10.3 Overall conclusions

Based on the predicted rates of TOTO 75 SG in off-field areas, the TER values describing the risk for non-target plants following exposure to TOTO 75 SG according to the GAP of the formulation TOTO 75 SG achieve the acceptability criteria TER ≥ 5, with applying buffer zone:

- 10 meters buffer zone, or
- 5 meters buffer zone and 90%, 75% or 50% nozzles reduction, or
- 1 meter buffer zone and 90% nozzles reduction

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant

9.12 Monitoring data (KCP 10.8)

Please refer to the point 9.5 (KCP 10.2)

9.13 Classification and Labelling

Pictogram: GHS09

Warning

Classification:
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long-lasting effects.

Precautionary statement(s): P391 – Collect spillage.
P501: Dispose of contents/container in accordance with local regulation

Additional labelling phrases: EUH401- To avoid risks to man and the environment, comply with the instructions for use.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1/01	xxx	2021	Toto 75 SG Calculations For Terrestial Verterbrates No-GLP Unpublished	N	Chemirol
KCP 10.1/02	xxx	2021	Toto 75 SG Calculations For Terrestial Verterbrates No-GLP Unpublished	N	Chemirol
KCP 10.2/01	xxx	**2008**	TOTO 75 WG - acute toxicity to carp xxx, Poland, Study Code W/52/08 GLP Unpublished	Y	Chemirol
KCP 10.2/02	xxx	**2008**	TOTO 75 WG - acute toxicity to rainbow trout xxx, xxx, Poland, Study Code W/51/08 GLP Unpublished	Y	Chemirol
KCP 10.2/03	xxx	**2008**	TOTO 75 – Dahnia magna acute immobilization test xxx, Poland, Study Code W/53/08 GLP Unpublished	Y	Chemirol
KCP 10.2/04	xxx	**2008**	TOTO 75 WG – *Pseudokirchneriella subcapitata* growth inhibition test xxx, Poland, Study Code W/55/08 GLP Unpublished	Y	Chemirol
KCP 10.2/05	xxx	**2008**	TOTO 75 WG – *Anabaena flos-aquae* growth inhibition test xxx, Poland, Study Code W/54/08 GLP Unpublished	Y	Chemirol
KCP 10.2/06	xxx	**2016**	Toxicity of TOTO 75 SG to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test xxx GLP Unpublished	Y	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3/01	xxx	**2008**	TOTO 75 WG - acute oral toxicity to honeybee xxx, Poland, Study Code B/29/08 GLP Unpublished Dossier Documents K-III and L-III	Y	Chemirol
KCP 10.3/02	xxx	**2008**	TOTO 75 WG - acute contact toxicity to honeybee xxx, Poland Study Code B/30/08 GLP Unpublished Dossier Documents K-III and L-III	Y	Chemirol
KCP 10.3/04	**xxx**	**2017**	TOTO 75 SG: Effects on the Predatory Mite Typhlodromus pyri in the Laboratory - Dose Response Test - (GLP compliant study based on xxx., 2000) Study No. 128611063 GLP Unpublished	Y	Chemirol
KCP 10.3/05	xxx	**2017**	TOTO 75 SG: Effects on the Parasitoid Aphidius rhopalosiphi in the Laboratory - Dose Response Test – xxx **Study No. 128611001** GLP Unpublished	Y	Chemirol
KCP 10.4/01	xxx	2016	TOTO 75 SG Earthworm Reproduction Test (Eisenia fetida) xxx, Poland xxx STUDY CODE: G/60/16 GLP Unpublished	Y	Chemirol
KCP 10.4/02	xxx	2019	TOTO 75 SG – A laboratory test to determine the effects of fresh residues on the predatory soil mite Hypoaspis aculeifer (Acari, Laelapidae) in an artificial soil substrate Study code: CHR-19-5 xxx GLP Unpublished	N	Chemirol
KCP	xxx	2019	TOTO 75 SG – A laboratory test to determine the effects of fresh	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.4/02			residues on the springtail Folsomia candida (Collembola, Isotomidae) in an artificial soil substrate Study code: CHR-19-6 xxx GLP Unpublished		
KCP 10.4/03	xxx	2017	IN-A4098: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil Study code: 128571016 xxx GLP Unpublished	N	Chemirol
KCP 10.5/01	xxx	**2008**	TOTO 75- Soil Microorganisms: Nitrogen transformation test xxx, Poland, Study Code G/27/08 GLP Unpublished Dossier Documents K-III and L-III	Y	Chemirol
KCP 10.6/01	xxx	**2015**	TOTO 75 SG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test xxx Germany Project 97831086 GLP Unpublished	Y	Chemirol
KCP 10.6/02	xxx	**2015**	TOTO 75 SG: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test xxx Germany Project 97831087 GLP Unpublished	Y	Chemirol

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1/01	-	1984	An acute oral toxicity study in the mallard with H# 15,172 125-84 Submitted in 1995 EU Dossier Published: No	Y	DuPont
KCP 10.1.1/02	-	1994 b	H-19,811 (M6316): A onegeneration reproduction study with the northern bobwhite (Colinus virginianus) 411-94 Submitted in 1995 EU Dossier Published: No	Y	DuPont
KCP 10.2/01	-	1983	96-hour LC50 to bluegill sunfish 509-83 Submitted in 1995 EU Dossier Published: No	Y	DuPont
KCP 10.2/02	-	1988	Report on the test for acute toxicity of CGA 150829 to rainbow trout """""""""""""""""" """""" """""""" 87 13 26 (Study No. 19) GLP: No Published: No	Y	DuPont
KCP 10.2/03	-	2000	N-W8268: Static, acute, 96-hour, limit test to rainbow trout, Oncorhynchus mykiss """""""""""""" """""""""""" """""""""""""""""""" """""""""""- 4683 GLP: Yes Published: No	Y	DuPont
KCP 10.2/04	-	2001	IN-L9225: Static, acute, 96-hour limit test to rainbow trout, Oncorhynchus mykiss """""""""""" """""""""""" """""""""""""""""""" """""""""""- 5622 GLP: Yes	Y	DuPont
KCP 10.2/05	-	1999 b	IN-L9223: Static, acute, 96-hour, limit test to rainbow trout, Oncorhynchus mykiss """""""""""""" """""""""""""" """""""""""""""""""" """""""""""""""3217 Submitted in ECCO rounds in the 1995 Annex I review Published: No	Y	DuPont
KCP 10.2/06	-	1999 c	N-V7160: Static, acute, 96-hour, limit test to rainbow trout, Oncorhynchus mykiss """""""""""" """""""""""" """""""""""""""""""" """""""""""""""3561 Submitted in ECCO rounds in the 1995 Annex I revi	Y	DuPont
KCP 10.2/07	-	1999	IN-JZ789: Static-renewal, acute, 96-hour, limit test to rainbow trout, Oncorhynchus mykiss """""""""""""" """""""""""" """""""""""""""""""" """""""""""""""1655 Submitted in ECCO rounds in the 1995 Annex I review Published: No	Y	DuPont
KCP 10.2/08	Wetzel, J.W.	1986	Daphnia magna static acute 24 and 48-hour EC50 of INM-6316-20 DuPont Haskell Laboratory HLR 258-86 Submitted in 1995 EU Dossier Published: No	N	DuPont
KCP 10.2/09	Samel, A.	1999 b	IN-L9223: Static, acute, 48-hour limit test to Daphnia magna DuPont Haskell Laboratory DuPont-3216 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.2/10	Samel, A.	2001	IN-L9225: Static, acute, 48-hour toxicity test to Daphnia magna DuPont Haskell Laboratory DuPont-5621 GLP: Yes Published: No	N	DuPont
KCP 10.2/11	Hoke, R.A.	1999	IN-JZ789: Static, acute, 48-hour limit test to Daphnia magna DuPont Haskell Laboratory DuPont-1654 Submitted in ECCO rounds in the 1995 Annex I review	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Published: Yes		
KCP 10.2/12	Samel, A	1999 c	IN-V7160: Static, acute, 48-hour, limit test to Daphnia magna DuPont Haskell Laboratory DuPont-3560 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.2/13	Samel, A.	2000	IN-W8268: Static, acute, 48-hour EC50 to Daphnia magna DuPont Haskell Laboratory DuPont-4682 GLP: Yes Published: No	N	DuPont
KCP 10.2/14	Samel, A.	2000	N-L9223: 21-day chronic, staticrenewal toxicity to Daphnia magna DuPont Haskell Laboratory DuPont-4487 GLP: Yes Published: No	N	DuPont
KCP 10.2/15	Hoke, R.A.	2001	IN-V7160: 21-day chronic toxicity to Daphnia magna DuPont Haskell Laboratory DuPont-4507 GLP: Yes Published: No	N	DuPont
KCP 10.2/16	Samel, A.	1999	IN-A4098: 21-day chronic toxicity to Daphnia magna DuPont Haskell Laboratory DuPont-3344 GLP: Yes Published: No	N	DuPont
KCP 10.2/17	Hicks, S.L.	1995	hifensulfuron methyl (DPXM6316): Influence on growth and reproduction of four select algal species ABC Laboratories, Inc. and DuPont Haskell Laboratory AMR 2890-93 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.2/18	Falk, S.	2012	TIM 2-acid-3-triuret – Testing of Toxic Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata. Eurofins Agroscience Services Cheminova A/S Report No.: 306 TIM Amdt 1 GLP, Unpublished	N	DuPont
KCP 10.2/19	Sloman, T.L.	1999 b	IN-JZ789: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont Haskell Laboratory DuPont-2850 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.2/20	Sloman, T.L.	2001	N-L9225: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont Haskell Laboratory DuPont-5620 GLP: Yes Published: No	N	DuPont
KCP 10.2/21	Sloman, T.L.	1999 d	IN-V7160: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont Haskell Laboratory DuPont-3190 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.2/22	Juckeland , D	2012	Acute toxicity of thifensulfuronmethyl technical to Chironomus riparius in a 48-hour static test Biochem agrar Cheminova A/S Report No.: 296 TIM GLP, Unpublished	N	Taskforce
KCP 10.2/23	Vinken, R., Wydra, V.	2011 a	Toxicity of Hydroxy-TM (DM-TH) to the Aquatic Plant Lemna gibba in a Semi-Static Growth Inhibition Test IBACON GmbH Cheminova A/S Study No.: 32582240 Cheminova A/S Report No.: 54 TIM GLP, Unpublished	N	Taskforce
KCP 10.2/24	Weber, K.,	2012	TIM 2-acid-3-triuret - Assessment of Toxic Effects on the Duckweed Lemna gibba in a Semi-Static Test Eurofins Agroscience Services Cheminova A/S Report No.: 307 TIM GLP, Unpublished	N	Taskforce
KCP 10.2/25	Pawlowsk i, S., Wydra, V	2006 b	Toxicity of 2-amino-4-methoxy-6- methyl-1,3,5-triazine (MM-TA) to the aquatic plant Lemna gibba in a static growth inhibition test IBACON GmbH Cheminova A/S Report No.: 203 MEM GLP, Unpublished	N	Taskforce

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/26	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2001	IN-L9225-6: Influence on growth rate of the duckweed, Lemna gibba T.R. Wilbury Laboratories, Inc. DuPont-4654 GLP: Yes Published: No	N	DuPont
KCP 10.2/27	Sloman, T.L., Leva, S .E.	1998	IN-A4098: Influence on growth and reproduction of Lemna gibba G3 DuPont Haskell Laboratory DuPont-1223 GLP: Yes Published: No	N	DuPont
KCP 10.2/28	Sloman, T.L.	2001 a	IN-JZ789: Influence on growth and reproduction of Lemna gibba G3 DuPont Haskell Laboratory DuPont-5617 GLP: Yes Published: No	N	DuPont
KCP 10.2/29	Sloman, T.L.	2001 b	IN-L9223: Influence on growth and reproduction of Lemna gibba G3 DuPont Haskell Laboratory DuPont-5618 GLP: Yes Published: No	N	DuPont
KCP 10.2/30	Sloman, T.L.	2001 c	N-V7160: Influence on growth and reproduction of Lemna gibba G3 DuPont Haskell Laboratory DuPont-5619 GLP: Yes Published: No	N	DuPont
KCP 10.2/31	Sloman T.L.	2004	N-L9226: Influence on growth and reproduction of Lemna gibba G3 DuPont Haskell Laboratory DuPont-14480 GLP: Yes Published: No	N	DuPont
KCP 10.2/32	Sloman T.L	2006	IN-A5546: Static, 7-day growth inhibition limit test to Lemna gibba G3 DuPont Haskell Laboratory DuPont-19856 GLP: Yes Published: No	N	DuPont
KCP 10.3.1/01	Vinall, S.	1998	Thifensulfuron methyl technical: Acute oral and contact toxicity to the honeybee, Apis mellifera L. University of Southampton, Agrochemical Evaluation Unit (AEU) AMR 5091-98 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.3.1/02	Vinall, S.	1998	Thifensulfuron methyl technical: Acute oral and contact toxicity to the honeybee, Apis mellifera L. University of Southampton, Agrochemical Evaluation Unit (AEU) AMR 5091-98 Submitted in ECCO rounds in the 1995 Annex I review Published: No	N	DuPont
KCP 10.4/01	Klug, T.	2010	IN-A4098: Effect on reproduction of the predatory mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil eurofins-GAB GmbH DuPont-29930 GLP: Yes Published: No	N	DuPont
KCP 10.4/02	Lührs, U.	2010 a	IN-W8268: Effects on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat IBACON DuPont-29924 GLP: Yes Published: No	N	DuPont
KCP 10.4/03	Lührs, U	2010 b	IN-L9225: Effects of reproduction on the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat IBACON DuPont-29923 GLP: Yes Published: No	N	DuPont
KCP 10.4/04	Höhn, P.	2011	IN-L9225: A laboratory test to study the effects on reproduction of the springtail Folsomia candida Willem (Collembola, Isotomidae) Eurofins Agroscience Services GmbH DuPont-29936, Revision No. 1 GLP: Yes Published: No	N	DuPont
KCP 10.4/05	Luhrs, U.	2004 a	IN-A4098: Effects on the Collembola, Folsomia candida in artificial soil IBACON DuPont-13995 GLP: Yes Published: No	N	DuPont
KCP 10.4/06	Luhrs, U.	2004 b	IN-W8268: Effects on the Collembola, Folsomia candida in artificial soil IBACON DuPont-14478 GLP: Yes Published: No	N	DuPont
KCP 10.4/07	Lührs, U.	2007 b	Acute Toxicity (14 Days) of Hydroxy-TM (DM-TH) to the Earthworm Eisenia fetida in Artificial Soil IBACON GmbH	N	TaskForce

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Cheminova A/S Study No.: 32583021 Cheminova A/S Report No.: 26 TIM GLP, Unpublished		
KCP 10.4/08	Lührs, U.	2001	IN-L9225: Acute toxicity to the earthworm, Eisenia fetida (Savigny) in artificial soil IBACON DuPont-5510 GLP: Yes Published: No	N	DuPont
KCP 10.4/09	Lührs, U.	2007 a	IN-L9223: Acute toxicity to earthworm, Eisenia fetida in artificial soil IBACON DuPont-21529 GLP: Yes Published: No	N	DuPont
KCP 10.4/10	Lührs, U.	2005	Acute toxicity (14 Days) of 2- amino-4-methoxy-6-methyl-1,3,5- triazine (MM-TA) to the earthworm Eisenia fetida in artificial soil IBACON GmbH Cheminova A/S Report No.: 159 MEM GLP, Unpublished	N	DuPont
KCP 10.4/11	Wachter, S.	1999	IN-L9226: Acute toxicity to earthworm, Eisenia foetida Michaelsen GAB Biotechnologie GmbH DuPont-3031 GLP: Yes Published: No	N	DuPont
KCP 10.4/12	Noack, M.	2001 a	IN-L9225: Effects on reproduction and growth of the earthworm, Eisenia fetida (Savigny, 1826) in artificial soil Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-3890 GLP: Yes Published: No		
KCP 10.4/13	Lührs, U.	2007 e	Effects of Thifensulfuron Acid (THA) on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil IBACON GmbH Cheminova A/S Study No.: 32592022 Cheminova A/S Report No.: 48 TIM GLP, Unpublished	N	TaskForce
KCP 10.4/14	Noack, M.	2001 b	IN-A4098: Effects on reproduction and growth of the earthworm, Eisenia fetida (Savigny, 1826) in artificial soil Dr. U. Noack-Laboratorium for Angewandte Biologie DuPont-4270 GLP: Yes Published: No	N	DuPont
KCP 10.4/15	Lührs, U.	2007 f	Effects of 2-amino-4-methoxy-6- methyl-1,3,5-triazine (MM-TA) on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil IBACON GmbH Cheminova A/S Study No.: 32601022 Cheminova A/S Report No.: 20 TBM GLP, Unpublished	N	DuPont
KCP 10.4/16	Ganssma nn, M.		Effects of 4-methoxy-6-methyl- 1,3,5-triazin-2-amine on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat IBACON GmbH Rotam Agrochem International Co. Ltd, Unpublished report No.: 69422022 GLP, Unpublished	N	Rotam
KCP 10.5/01	Nienstedt, K.M.	1999	FOE 5043-Sulfonic acid Na-salt: A 14-day acute toxicity test with the earthworm (Eisenia fetida) Source: Springborn Laboratories, Horn, Switzerland Generated by: Bayer AG, Submitted by: Bayer AG, Bayer file No.: 99-005-1022 Date: July 15, 1999 GLP not published	N	DuPont
KCP 10.5/01	Helweg, A., Elmholt, S.	1986 a	Influence of DPX M 6316-30 on ammonification and nitrification in sandy clay and in coarse sandy soil. Danish Research Service for Plant and Soil Science 6316/ME 5 Submitted in 1995 EU Dossier Published: No	N	DuPont
KCP 10.5/02	Reis, K.- H.	2007 a	Effects of Thiophene Sulfonimide (TP-SI) on the Activity of the Soil Microflora in the Laboratory IBACON GmbH Cheminova A/S Study No.: 32575080 Cheminova A/S Report	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			No.: 46 TIM GLP, Unpublished		
KCP 10.5/03	Kölzer, U	2004	IN-L9225: Assessment of the effects on soil microflora GAB Biotechnologie GmbH DuPont-14479 GLP: Yes Published: No	N	DuPont
KCP 10.5/04	Reis, K-H	2001	N-W8268: Effects on soil nontarget microorganisms IBACON DuPont-5500 GLP: Yes Published: No	N	DuPont
KCP 10.5/05	Reis, K-H	2003	N-A4098: Assessment of the effects on soil microflora IBACON DuPont-12117 GLP: Yes Published: No	N	DuPont
KCP 10.5/06	Reis, K-H.	2006	IN-A5546: Assessment of the effects on soil microflora IBACON DuPont-19855 GLP: Yes Published: No	N	DuPont
KCP 10.5/07	Reis, K-H.	2007 a	IN-L9226: Assessment of the effects on soil microflora IBACON DuPont-21525 GLP: Yes Published: No	N	DuPont
KCP 10.5/08	Reis, K-H.	2007 b	IN-V7160: Assessment of the effects on soil microflora IBACON DuPont-21526 GLP: Yes Published: No	N	DuPont
KCP 10.5/09	Reis, K-H	2007 c	IN-L9223: Assessment of the effects on soil microflora IBACON DuPont-21527 GLP: Yes Published: No	N	DuPont
KCP 10.5/10	Kölzer, U	2004	IN-L9225: Assessment of the effects on soil microflora GAB Biotechnologie GmbH DuPont-14479 GLP: Yes Published: No	N	DuPont
KCP 10.1.1/01	-	1981	Acute oral LD50 - mallard duck – H-14,028 - final report HLO 359-81 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/02	-	1981	Eight-day dietary LC50 - bobwhite quail - H-14,028 - final report HLO 460-81 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/03	-	1981	Eight-day dietary LC50 - mallard duck - H-14,028 - final report HLO 455-81 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/04	-	1996	DPX-T6376-141 (metsulfuron methyl): A reproduction study with the northern bobwhite (Colinus virginianus) AMR 3412-95 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/05	-	1996	DPX-T6376-141 (metsulfuron methyl): A reproduction study with the mallard (Anas platyrhynchos) AMR 3413-95 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/06	-	1982	96-hour LC50 to rainbow trout HLR 515-82 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/07	-	1999	IN-JX909: A 96-hour static acute toxicity test with the rainbow trout (Oncorhynchus mykiss) DuPont-1273 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/08	-	1982	96-hour LC50 to bluegill sunfish HLR 154-8	Y	DPF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP No Unpublished		
KCP 10.1.1/09	-	1988	Flow-through acute 21-day LC50 and NOEC of DPX-T6376-74 to rainbow trout (Salmo gairdneri) HLR 759-88 GLP Yes Unpublished	Y	DPF
KCP 10.1.1/11	-	1984	Residue studies with [14C] metsulfuron methyl in bluegill sunfish (revision 1) AMR 81-82, Revision No. 1 GLP No Unpublished	Y	DPF
KCP 10.1.1/12	Phillips, F.X., Hall, C.L.	1982	48-hour LC50 to Daphnia magna HLR 157-82 DuPont Haskell Laboratory GLP No Unpublished	N	DPF
KCP 10.1.1/13	Palmer, S.J., Krueger, H.O.	1999	IN-JX909: A 48-hour static acute toxicity test with the cladoceran (Daphnia magna) DuPont-1274 Wildlife International Ltd. (USA) GLP Yes Unpublished	N	DPF
KCP 10.1.1/14	Hutton, D.G.	1989	Chronic toxicity of DPX-T6376-74 to Daphnia magna HLR 833-88 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPF
KCP 10.1.1/15	Handley, J.W., Douglas, M.T.	1988	The algistatic activity of DPX-T6376 (revision 1). DPT 171(a)/871368/2, Revision No. 1 Huntingdon Research Centre GLP Yes Unpublished	N	DPF
KCP 10.1.1/16	Frobis, A.D.	1987	Acute toxicity screen of metsulfuron methyl to Selenastrum capricornutum HLR 844-87 ABC Laboratories, Inc. (Missouri) GLP Yes Unpublished	N	DPF
KCP 10.1.1/17	Hicks, S.L.	1997	DPX-T6376: Influence on growth and reproduction of Anabaena flos-aquae AMR 3838-96 ABC Laboratories, Inc. GLP Yes Unpublished	N	DPF
KCP 10.1.1/18	Hicks, S.L.	1997	DPX-T6376: Influence on growth and reproduction of Skeletonema costatum AMR 3840-96 ABC Laboratories, Inc. GLP Yes Unpublished	N	DPF
KCP 10.1.1/19	Palmer, S.J., Krueger, H.O.	1999	IN-JX909: Influence on growth and growth rate of the green alga Selenastrum capricornutum. DuPont-1271	N	DPF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Wildlife International Ltd. (USA) GLP Yes Unpublished		
KCP 10.2/01	Douglas, M.T., Handley, J.W.	1988	An assessment of the inhibitory effect of DPX-T6376 technical on the growth of duckweed (Lemna minor) DPT 186(b)/881173 Huntingdon Research Centre GLP Yes Unpublished	N	DPF
KCP 10.2/02	Sloman, T.L., Leva, S.E.	1998	IN-A4098:Influence on growth and reproduction of Lemna gibba G3 DuPont-1223 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPF
KCP 10.2/03	Palmer, S.J., Krueger, H.O.	1999	IN-JX909: Influence on growth and reproduction of Lemna gibba G3 DuPont-1272 Wildlife International Ltd. (USA) GLP Yes Unpublished	N	DPF
KCP 10.2/04	Nengel, S.	1998	Metsulfuron methyl technical (DPX-T6376): Acute oral and contact toxicity to the honey bee, Apis mellifera L AMR 5182-98 GAB Biotechnologie GLP Yes Unpublished	N	DPF
KCP 10.2/05	Meade, A.B.	1984	Acute contact LD50 study in honey bees (Apis mellifera L.) with INT6376 - Final report ABM 84-4 DuPont Experimental Station GLP No Unpublished	N	DPF
KCP 10.2/06	Nengel, S.	1998	Metsulfuron methyl technical (DPX-T6376): acute oral and contact toxicity to the honey bee, Apis mellifera L. AMR 5182-98 GAB Biotechnologie, GLP Yes Unpublished	N	DPF
KCP 10.2/07	Austin, H.M.	1999	Metsulfuron methyl (DPX-T6376) 20 WG: A laboratory study to evaluate the effects on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera: Braconidae) DuPont-1082 Ecotox Ltd. GLP Yes Unpublished	N	DPF
KCP 10.2/08	Tessier, C.	1999	Metsulfuron methyl (DPX-T6376) 20-WG: A laboratory study to evaluate the effects on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) DuPont-1083 Ecotox Ltd. GLP Yes Unpublished	N	DPF
KCP 10.2/09	Sankanu, A.	1999	Metsulfuron methyl (DPX-T6376) 20-WG: A laboratory study to evaluate the effects on the ground beetle, Poecilus cupreus L.	N	DPF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			(Coleoptera: Carabidae) DuPont-1084 Ecotox Ltd. GLP Yes Unpublished		
KCP 10.2/10	Austin, H.M.	1999	Metsulfuron methyl (DPX-T6376) 20 WG: A laboratory study to evaluate the effects on the green lacewing, Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) (Bigler, 1988) DuPont-1081 Ecotox Ltd. GLP Yes Unpublished	N	DPF
KCP 10.2/11	Coulson, J.M., Edwards, P.J., Hill, R.W.	1985	HD 116/85-269: Determination of the toxicity to the earthworm (Eisenia foetida) BLB2841 Zeneca, Brixham Laboratories GLP Yes Unpublished	N	DPF
KCP 10.2/12	Gossmann, A.		IN-A4089 a degradate of metsulfuron methyl: Acute toxicity to the earthworm, Eisenia fetida (Savigny) in artificial soil AMR 5167-98 Institut fur Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DPF
KCP 10.2/13	Gossmann, A.	1999	IN-00581: Acute Toxicity to the earthworm Eisenia fetida (Savigny) in Artificial soil DuPont-2004, Revision No. 1 Institut fur Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DPF
KCP 10.2/14	Gossmann, A.	1999	IN-B5067: Acute toxicity to the earthworm Eisenia fetida (Savigny) in artificial soil DuPont-2005 Institut fur Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	DPF
KCP 10.2/15	Gossmann, A.	1999	IN-NC148: acute toxicity to the earthworm Eisenia fetida (savigny) in artificial soil DuPont-2007 IBACON GLP Yes Unpublished	N	DPF
KCP 10.2/16	Helwig, A.	1985	Influence of DPX 6376 on ammonification and nitrification in soil 6376/ME 3 National Research Center for Plant Protection GLP No Unpublished	N	DPF
KCP 10.2/17	Helwig, A.	1985	Influence of DPX 6376 on respiration in soil 6376/ME 2 National Research Center for Plant Protection GLP No Unpublished	N	DPF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/18	-	1998	DPX-T6376: A 96-hour static acute toxicity test with the rainbow trout (Oncorhynchus mykiss) AMR 5023-98 GLP Yes Unpublished	Y	DPR
KCP 10.2/19	-	2000	IN-00581: Static, acute, 96-hour, LC50 to rainbow trout, Oncorhynchus mykiss DuPont-4039 GLP Yes Unpublished	Y	DPR
KCP 10.2/20	-	2000	IN-D5119: Static, acute, 96-hour LC50 to rainbow trout, Oncorhynchus mykiss DuPont-4041 GLP Yes Unpublished	Y	DPR
KCP 10.2/21	-	1999	IN-F5438: Static, acute, 96-hour limit test to rainbow trout, Oncorhynchus mykiss DuPont-3227 GLP Yes Unpublished	Y	DPR
KCP 10.2/22	-	1988	Report on the test for acute toxicity of CGA 150829 to rainbow trout Ciba 87 13 26 (Study No. 19) GLP No Unpublished	Y	Syngenta
KCP 10.2/23	-	1999	IN-V7160: Static, acute, 96-hour, limit test to rainbow trout, Oncorhynchus mykiss DuPont-3561 GLP Yes Unpublished	Y	DPR
KCP 10.2/24	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2000	IN-D5119: Static, acute, 48-hour EC50 to Daphnia magna DuPont-4040 T.R. Wilbury Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/25	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2000	IN-00581: Acute, 48 hour, limit test with Daphnia magna DuPont-4038 T.R. Wilbury Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/26	Heusel, R., Weller, O., Gosch, H.	1998	AE F059411 Substance, technical. Metabolite of AEF115008. Code: AE F059411 00 1C99 0001. Acute toxicity to Daphnia magna (waterflea) AgrEvo CE98/088 (M-181330-01-1) Hoechst Schering AgrEvo GmbH GLP Yes Unpublished	N	Bayer
KCP 10.2/27	Hoke, R.A.	1999	IN-F5438: static, acute, 48-hour limit test to Daphnia magna DuPont-3228 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/28	Samel, A.	1999	IN-A4098: Static, acute, 48-hour EC50 to Daphnia magna DuPont-3247	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DuPont Haskell Laboratory GLP Yes Unpublished		
KCP 10.2/29	Samel, A.	1999	IN-V7160: Static, acute, 48-hour limit test to Daphnia magna DuPont-3560 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/30	Samel, A.	2001	Metsulfuron methyl (DPX-T6376) technical: Static, acute, 48-hour toxicity test to Daphnia magna DuPont-6023 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/31	Drotter; K.R., Krueger; H.O.	1998	DPX-T6376: A semi-static life-cycle toxicity test with the cladoceran (Daphnia magna) AMR 5025-98 Wildlife International Ltd. (USA) GLP Yes Unpublished	N	DPR
KCP 10.2/32	Hoke, R.A.	2001	IN-V7160: 21-day chronic toxicity to Daphnia magna DuPont-4507 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/33	Samel, A	1999	IN-A4098: 21-day chronic toxicity to Daphnia magna DuPont-3344 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/34	Heusel, R., Weller, O., Gosch, H.	1998	AEF059411 Substance, technical Metabolite of AEF115008 Code: AE F059411 00 1C99 0001 Algal growth inhibition - Pseudokirchneriella subcapitata AgrEvo CE98/087 (M-181379-01-1) Hoechst Schering AgrEvo GmbH GLP Yes Unpublished	N	Bayer
KCP 10.2/35	Rufli, H.	1987	Report on the alga, growth inhibition test with CGA 150829 Ciba 871325 (Study No. 17) Ciba-Geigy Ltd GLP No Unpublished	N	Syngenta
KCP 10.2/36	Sloman, T.L.	1999	IN-F5438: Influence on growth and growth rate of the blue-green alga Selenastrum capricornutum DuPont-3156 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/37	Sloman, T.L.	1999	IN-V7160: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont-3190 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/38	Sloman, T.L.	2000	Metsulfuron methyl technical: influence on growth and growth rate of the blue-green alga Anabaena flos-aquae DuPont-3774 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/39	Sloman, T.L.	2000	IN-D5119: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont-3961 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/40	Sloman, T.L.	2000	IN-00581: Influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont-3962 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/41	Sloman, T.L., Leva, S.E.	1999	Metsulfuron methyl technical: influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont-1224 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/42	Chandrasehar, G.	2010	IN-B5528: Effect on growth and growth rate to the duck weed, Lemna gibba DuPont-29481 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.2/43	Ferrell, B.D.	2004	IN-B5067: Influence on growth and reproduction of Lemna gibba G3 DuPont-12740 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/44	Ferrell, B.D.	2010	IN-B5685: Static-renewal, 7-day growth inhibition toxicity test with Lemna gibba DuPont-29891 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/45	Grade, R.	2001	Acute toxicity test of CGA 150829 (metabolite of CGA 131036) to the duckweed Lemna gibba G3 under static conditions SYN 2001882 (Study No. 16) Syngenta Crop Protection-Ecological Sciences GLP Yes Unpublished	N	Syngenta
KCP 10.2/46	Hoberg, J.R.	2011	Metsulfuron methyl (DPX-T6376) technical - growth inhibition of the aquatic macrophyte Myriophyllum spicatum DuPont-30620 Springborn Smithers Laboratories GLP Yes Unpublished	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/47	Hoberg, J.R.	2011	Metsulfuron methyl (DPX-T6376) technical - growth inhibition of the aquatic macrophyte Elodea canadensis DuPont-30618 Springborn Smithers Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/48	Hoberg, J.R.	2011	Metsulfuron methyl (DPX-T6376) technical - growth inhibition of the aquatic macrophyte Ceratophyllum demersum DuPont-30619 Springborn Smithers Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/49	Hoberg, J.R.	2011	Metsulfuron methyl (DPX-T6376) technical - Growth inhibition of the aquatic macrophyte Vallisneria americana DuPont-30617 Springborn Smithers Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/50	Hoberg, J.R.	2011	Metsulfuron methyl (DPX-T6376) technical- growth inhibition of the aquatic macrophyte Myriophyllum aquaticum DuPont-30621 Smithers Viscient GLP Yes Unpublished	N	DPR
KCP 10.2/51	Porch, J.R., Kendall, T.Z., Krueger, H.O.	2011	Metsulfuron methyl (DPX-T6376) technical: A 7-day, variable exposure duration toxicity test with duckweed (Lemna gibba G3) DuPont-30622 Wildlife International Ltd (USA) GLP Yes Unpublished	N	DPR
KCP 10.2/52	Porch, J.R., Kendall, T.Z., Krueger, H.O.	2011	Metsulfuron methyl (DPX-T6376) technical: A 16-day toxicity test on duckweed (Lemna gibba G3) with exposure during dormancy DuPont-30623 Wildlife International Ltd (USA) GLP Yes Unpublished	N	DPR
KCP 10.2/53	Rebstock, M.	2011	IN-NC148: 7-day growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DuPont-30881 ABC Laboratories, Inc. (Missouri) GLP Yes Unpublished	N	DPR
KCP 10.2/54	Sloman, T.L.	1999	IN-V7160: Influence on growth and reproduction of Lemna gibba G3 DuPont-3189 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/55	Sloman, T.L.	1999	IN-F5438: Iinfluence on growth and reproduction of Lemna gibba G3 DuPont-3252 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/56	Sloman, T.L.	2000	IN-D5119: Influence on growth and reproduction of Lemna gibba G3 DuPont-3550 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/57	Sloman, T.L.	2000	IN-00581: Influence on growth and reproduction of Lemna gibba G3 DuPont-3551 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/58	Sloman, T.L.	2001	IN-V7160: Iinfluence on growth and reproduction of Lemna gibba G3 DuPont-5619 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.2/59	Sowig, P.	2002	Duckweed (Lemna gibba G3) growth inhibition test AE F059411; substance, pure (metabolite of AE F115008) Aventis CE01/072 (M-203638-01-1) Aventis CropScience GmbH GLP Yes Unpublished	N	Bayer
KCP 10.2/60	Ward, T.J., Boeri, R.L., Wyskiel, D.C.	2004	IN-D5803: Influence on growth rate of the duckweed, Lemna gibba DuPont-14234 T.R. Wilbury Laboratories GLP Yes Unpublished	N	DPR
KCP 10.2/61	Moll, M.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): A rate-response laboratory test to assess the effects on the parasitoid, Aphidius rhopalosiphi DuPont-9857 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.2/62	Moll, M.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: An extended laboratory test to evaluate the effetcs on the parastoid, Aphidius rhopalosiphi (Hymenoptera, Braconidae)	N	DPR
KCP 10.2/63	Gehrig, M.	2010	IN-NC148: Effect on reproduction of the predatory mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil DuPont-30880 Eurofins Agroscience Services GmbH GLP Yes Unpublished	N	DPR
KCP 10.2/64	Klug, T.	2010	IN-A4098: Effect on reproduction of the predatory mite Hypoaspis (Geolaelaps) aculeifer Canestrini (Acari: Laelapidae) in artificial soil DuPont-29930 eurofins-GAB GmbH GLP Yes Unpublished	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/65	Lührs, U.	2010	IN-00581: Effects on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DuPont-29484 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/66	Lührs, U.	2010	IN-F5438: Effects on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DuPont-30184 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/67	Lührs, U.	2010	IN-V7160: Effects on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DuPont-30276 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/68	Moll, M.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: An extended laboratory test to evaluate the effects on the predatory mite, Typhlodromus pyri (Acari, Phytoseiidae) DuPont-30730 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/69	Schwiening, S.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): a laboratory rate-response test to assess the effects on the predatory mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) DuPont-9858 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.2/70	Schmitzer, S.	2002	Metsulfuron methyl (DPX-T6376) 20SG (water soluble paste extruded granule): A laboratory study to evaluate the effects on the ground beetle, Poecilus cupreus L. DuPont-9860 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.2/71	Moll, M.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): Effects on the lacewing, Chrysoperla carnea, in the laboratory DuPont-9859 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.2/72	Moll, M.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: An extended laboratory test to evaluate the effects on the lacewing, Chrysoperla carnea (Neuroptera: Chrysopidae) DuPont-30731	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished		
KCP 10.2/73	Lührs, U.	2004	IN-A4098: Effects on the Collembola, Folsomia candida in artificial soil DuPont-13995 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/74	Lührs, U.	2004	IN-00581: Effects on the Collembola, Folsomia candida in artificial soil DuPont-14346 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/75	Lührs, U.	2004	IN-NC148: Effects on the Collembola, Folsomia candida in artificial soil DuPont-14231 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/76	Lührs, U.	2006	IN-D5119: Effects on the Collembola, Folsomia candida in artificial soil DuPont-17569 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/77	Lührs, U.	2010	IN-D5803: Effects on the collembola Folsomia candida in artificial soil with 5% peat DuPont-29480 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/78	Lührs, U.	2010	IN-F5438: Effects on the Collembola Folsomia candida in artificial soil with 5% peat DuPont-30183, Revision No. 1 IBACON GLP Yes Unpublished	N	DPR
KCP 10.2/79	Lührs, U.	2010	IN-V7160: Effects on the collembola Folsomia candida in artificial soil with 5% peat DuPont-30216 IBACON GLP Yes Unpublished	N	DPR
KCP 10.3.1/01	Candolfi, M., Grimm, C.	1998	Acute toxicity test of CGA 150829 to the earthworm (Eisenia fetida) SYN 981743 Syngenta Crop Protection-Ecological Sciences GLP Yes Unpublished	N	Syngenta
KCP 10.3.1/02	Gossmann, A.	1998	IN-A4089 a degradate of metsulfuron methyl: Acute toxicity to the earthworm, Eisenia fetida (Savigny) in artificial soil AMR 5167-98	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Institut fur Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished		
KCP 10.3.1/03	Gossmann, A.	1999	IN-F5438: Acute toxicity to the earthworm Eisenia fetida (Savigny) in artificial soil DuPont-2006 IBACON GLP Yes Unpublished	N	DPR
KCP 10.3.1/04	Lührs, U.	2001	IN-D5119: Acute toxicity to the earthworm, Eisenia fetida (Savigny) in artificial soil DuPont-5972 IBACON GLP Yes Unpublished	N	DPR
KCP 10.3.1/05	Lührs, U.	2007	IN-V7160: Acute toxicity to the earthworm, Eisenia fetida in artificial soil DuPont-21530 IBACON GLP Yes Unpublished	N	DPR
KCP 10.3.1/06	Shanmugasundaram, R.	2010	IN-B5528: Acute toxicity to the earthworm, Eisenia fetida in artificial soil with 5% peat DuPont-29482 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/01	Shanmugasundaram, R.	2010	IN-B5685: Acute toxicity to the earthworm, Eisenia fetida in artificial soil with 5% peat DuPont-29892 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/02	Shanmugasundaram, R.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil with 5% peat DuPont-30728 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/03	Sowig, P.	1998	AE F059411 Substance, technical Metabolite of AEF115008 Code: AE F059411 00 1C99 0001 Acute toxicity to earthworms (Eisenia fetida) AgrEvo CE98/086 (M-181872-01-1) Hoechst Schering AgrEvo GmbH GLP Yes Unpublished	N	Bayer
KCP 10.4/04	Harwood, R.W.J., Allan, J.	2001	IN-00581: Effects on reproduction and growth of the earthworm, Eisenia fetida (Savigny, 1826), in artificial soil DuPont-3895, Amendment No. 4 Inveresk Research	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Yes Unpublished		
KCP 10.4/05	Jeyalakshmi, T.	2010	IN-V7160: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil with 5% peat DuPont-30215 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/06	Lührs, U.	2006	IN-D5119: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil DuPont-17571 IBACON GLP Yes Unpublished	N	DPR
KCP 10.4/07	Lührs, U.	2010	IN-D5803: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil with 5% peat DuPont-29479 IBACON GLP Yes Unpublished	N	DPR
KCP 10.4/08	MacIsaac, E., Knight, B.	2001	IN-NC148: Effects on reproduction and growth of the earthworm, Eisenia fetida (Savigny, 1826), in artificial soil DuPont-3896 Inveresk Research GLP Yes Unpublished	N	DPR
KCP 10.4/09	Noack, M.	2001	IN-A4098: Effects on reproduction and growth of the earthworm, Eisenia fetida (Savigny, 1826) in artificial soil DuPont-4270 Dr. U. Noack-Laboratorium for Angewandte Biologie GLP Yes Unpublished	N	DPR
KCP 10.4/10	Shanmugasundaram, R.	2010	IN-F5438: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil with 5% peat DuPont-30182 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/11	Shanmugasundaram, R.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: Effects on reproduction and growth of the earthworm, Eisenia fetida, in artificial soil with 5% peat DuPont-30728 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/12	-	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble Paste Extruded Granule): Static, acute, 96-hour limit test to rainbow trout, Oncorhynchus mykiss -DuPont-10058 GLP Yes Unpublished	Y	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/13	Bergfield, A.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: 48-hour static, acute toxicity test with the cladoceran, Daphnia magna DuPont-30727 ABC Laboratories, Inc. (Missouri) GLP Yes Unpublished	N	DPR
KCP 10.4/14	Samel, A.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): Static, acute, 48-hour toxicity test to Daphnia magna DuPont-10057 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.4/15	Bergfield, A.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: 72-hour growth inhibition test with the freshwater green alga, Pseudokirchneriella subcapitata DuPont-30725 ABC Laboratories, Inc. (Missouri) GLP Yes Unpublished	N	DPR
KCP 10.4/16	Sloman, T.L.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): influence on growth and growth rate of the green alga Selenastrum capricornutum DuPont-10241 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.4/17	Schmitzer, S.	2002	Metsulfuron methyl (DPX-T6376) 20SG (water soluble paste extruded granule): acute oral and contact toxicity to the honeybee, Apis mellifera L. (Hymenoptera, Apidae) DuPont-9861 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.4/18	Shanmugasundaram, R.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: Acute oral and contact toxicity to the honey bee, Apis mellifera, L. DuPont-30732 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished	N	DPR
KCP 10.4/19	Schmitzer, S.	2002	Metsulfuron methyl (DPX-T6376) 20SG (water soluble paste extruded granule): acute oral and contact toxicity to the honeybee, Apis mellifera L. (Hymenoptera, Apidae) DuPont-9861 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.4/20	Shanmugasundaram, R.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: Acute oral and contact toxicity to the honey bee, Apis mellifera, L.	N	DPR

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DuPont-30732 International Institute of Biotechnology and Toxicology (IIBAT) GLP Yes Unpublished		
KCP 10.4/21	Lührs, U.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): acute toxicity to the earthworm, Eisenia fetida, in artificial soil DuPont-9865 Institüt für Biologische Analytik und Consulting GmbH (IBACON) GLP Yes Unpublished	N	DPR
KCP 10.4/22	Green, J.W.	2012	Aquatic plant species sensitivity distributions for metsulfuron methyl DuPont-35398 EU Not applicable - position paper GLP No Unpublished	N	DPR
KCP 10.5/01	Bergfield, A.	2011	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule) plus DPX-KG691 surfactant: 7-day growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DuPont-30726 ABC Laboratories, Inc. (Missouri) GLP Yes Unpublished	N	DPR
KCP 10.5/02	Sloman, T.L.	2002	Metsulfuron methyl (DPX-T6376) 20SG (soluble paste extruded granule): Influence on growth and reproduction of Lemna gibba G3 DuPont-10242 DuPont Haskell Laboratory GLP Yes Unpublished	N	DPR
KCP 10.5/03	Grade, R., Wydra, V.		Acute toxicity of metsulfuron-methyl technical to Daphnia magna in a 48-Hour immobilization test Cheminova A/S Study No.: 24674220 Cheminova A/S Report No.: 197 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/04	Grade, R., Wydra, V., Moll, M.	2006	Influence of metsulfuron-methyl technical to Daphnia magna in a semi static reproduction test Cheminova A/S Study No.: 24675221 Cheminova A/S Report No.: 200 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/05	Grade, R., Wydra, V., Moll, M.	2006	Influence of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) to Daphnia magna in a semi static reproduction test Cheminova A/S Study No.: 24703221 Cheminova A/S Report No.: 168 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP	Pawlowski, S.,	2006	Toxicity of metsulfuron-methyl technical to	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.5/06	Wydra, V.		Pseudokirchneriella subcapitata in an algal growth inhibition test Cheminova A/S Study No.: 24673210 Cheminova A/S Report No.: 217 MEM IBACON GmbH GLP Yes Unpublished		
KCP 10.5/07	Pawlowski, S., Wydra, V.	2006	Toxicity of metsulfuron-methyl technical to Anabaena flos-aquae in an algal growth inhibition test Cheminova A/S Study No.: 24672210 Cheminova A/S Report No.: 216 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/08	Pawlowski, S., Wydra, V.	2006	Toxicity of saccharin to Pseudokirchneriella subcapitata in an algal growth inhibition test Cheminova A/S Study No.: 24721210 Cheminova A/S Report No.: 204 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/09	Pawlowski, S., Wydra, V.	2006	Toxicity of hydroxy-MM (BDM-MM) to Pseudokirchneriella subcapitata in an algal growth Cheminova A/S Study No.: 24711210 Cheminova A/S Report No.: 208 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/10	Pawlowski, S., Wydra, V.		Toxicity of metsulfuron-methyl acid (MM-A) to Pseudokirchneriella subcapitata in an algal growth inhibition test Cheminova A/S Study No.: 24691210 Cheminova A/S Report No.: 206 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/11	Falk, S.	2012	Carbamoyl Guanidine - Testing of Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata Cheminova A/S Study No.: S11-03006 Cheminova A/S Report No.: 302 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.5/12	Falk, S.	2012	Methylsaccharin - Testing of Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata Cheminova A/S Study No.: S11-03010 Cheminova A/S Report No.: 305 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/01	Pawlowski, S., Wydra, V.	2006	Toxicity of methylsaccharin (M-AS-BA) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24743240 Cheminova A/S Report No.: 207 MEM IBACON GmbH GLP Yes	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.1.1/02	Pawlowski, S., Wydra, V.	2006	Toxicity of saccharin to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24722240 Cheminova A/S Report No.: 205 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/03	Pawlowski, S., Wydra, V.	2006	Toxicity of hydroxy-MM (BDM-MM) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24712240 Cheminova A/S Report No.: 202 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/04	Pawlowski, S., Wydra, V.	2006	Toxicity of hydroxy-MM (BDM-MM) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24712240 amdt 1 Cheminova A/S Report No.: 202 MEM amdt 1 IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/05	Pawlowski, S., Wydra, V.	2006	Toxicity of metsulfuron-methyl acid (MM-A) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24692240 Cheminova A/S Report No.: 201 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/06	Pawlowski, S., Wydra, V.	2006	Toxicity of metsulfuron-methyl acid (MM-A) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24692240 amdt 1 Cheminova A/S Report No.: 201 MEM amdt 1 IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/07	Pawlowski, S., Wydra, V.	2006	Toxicity of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) to the aquatic plant Lemna gibba in a static growth inhibition test Cheminova A/S Study No.: 24702240 Cheminova A/S Report No.: 203 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/08	Weber, K.	2012	Carbamoyl Guanidine - Assessment of Toxic Effects on the Duckweed Lemna gibba in a Semi-Static Test Cheminova A/S Study No.: S11-03007 Cheminova A/S Report No.: 303 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/09	Schmitzer, S.	2006	Effects of metsulfuron-methyl technical (acute contact and oral) on Honey Bees (Apis mellifera L.) in the laboratory Cheminova A/S Study No.: 24671035 Cheminova A/S Report No.: 196 MEM IBACON GmbH	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Yes Unpublished		
KCP 10.1.1/11	Schmitzer, S.	2006	Effects of metsulfuron-methyl technical (acute contact and oral) on Honey Bees (Apis mellifera L.) in the laboratory Cheminova A/S Study No.: 24671035 Cheminova A/S Report No.: 196 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/12	Moll, M.	2005	Effects of metsulfuron-methyl 200 g/kg WG on the parasitoid Aphidius rhopalosiphi in the laboratory – dose response test Cheminova A/S Study No.: 24686001 Cheminova A/S Report No.: 166 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/13	Rosenkranz, B.	2005	Effects of metsulfuron-methyl 200 g/kg WG on the predatory mite Typhlodromus pyri in the laboratory – dose response test Cheminova A/S Study No.: 24687063 Cheminova A/S Report No.: 167 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/14	Lührs, U.	2005	Acute toxicity (14 days) of methylsaccharin (M-AS-BA) to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24741021 Cheminova A/S Report No.: 163 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/15	Lührs, U.	2005	Acute toxicity (14 days) of saccharin to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24723021 Cheminova A/S Report No.: 161 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/16	Lührs, U.	2005	Acute toxicity (14 days) of hydroxy-MM (BDM-MM) to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24713021 Cheminova A/S Report No.: 160 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/17	Lührs, U.	2005	Acute toxicity (14 days) of carbamoyl guanidine (M-AS-BA-CG) to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24731021 Cheminova A/S Report No.: 162 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.1.1/18	Lührs, U.	2005	Acute toxicity (14 days) of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24704021 Cheminova A/S Report No.: 159 MEM	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			IBACON GmbH GLP Yes Unpublished		
KCP 10.1.1/19	Schöbinger, U.	2012	Acute Toxicity of Metsulfuron (free acid) on Earthworms, Eisenia fetida Using an Artificial Soil Test Cheminova A/S Study No.: S11-03004 Cheminova A/S Report No.: 300 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/01	Vinall, S.	2010	A laboratory test to determine the effects of fresh residues of technical-grade metsulfuron-methyl on the springtail, Folsomia candida (Collembola, Isotomidae) Cheminova A/S Study No.: CVA-10-5 Cheminova A/S Report No.: 249 MEM Mambo-Tox Ltd. GLP Yes Unpublished	N	CHE
KCP 10.2/02	Lührs, U.	2007	Effects of Saccharin on reproduction and growth of earthworms Eisenia fetida in artificial soil IBACON GmbH Study No.: 32621022 Cheminova A/S Report No.: 231 MEM GLP Yes Unpublished	N	CHE
KCP 10.2/03	Lührs, U.	2007	Effects of Saccharin on the reproduction of the Collembola Folsomia candida in artifical soil IBACON GmbH Study No.: 32622016 Cheminova A/S Report No.: 233 MEM GLP Yes Unpublished	N	CHE
KCP 10.2/04	Schöbinger, U.	2012	Sublethal toxicity of carbamoyl guanidine to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: S11-03008 Cheminova A/S Report No.: 304 MEM Agroscience Services EcoChem Eurofins GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/05	Höhn, P.	2012	Carbamoyl guanidine: Effects on the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomida) using an artificial soil test with 5% peat content Cheminova A/S Study No.: S11-03009 Cheminova A/S Report No.: 296 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/06	Lührs, U.	2007	Effects of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) on reproduction and growth of earthworms Eisenia fetida in artificial soil Cheminova A/S Study No.: 32601022 Cheminova A/S Report No.: 20 TBM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/07	Höhn, P.	2011	Aminotriazin: Effects on the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomida) using an artificial soil test with 5% peat content Cheminova A/S Study No.: S11-03011	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Cheminova A/S Report No.: 306 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished		
KCP 10.2/08	Reis, K.-H.	2006	Effects of methylsaccharin (M-AS-BA) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24742080 Cheminova A/S Report No.: 195 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/09	Reis, K.-H.	2006	Effects of saccharin on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24724080 Cheminova A/S Report No.: 193 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/10	Reis, K.-H.	2006	Effects of hydroxy-MM (BDM-MM) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24714080 Cheminova A/S Report No.: 107 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/11	Reis, K.-H.	2006	Effects of carbamoyl guanidine (M-AS-BA-CG) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24732080 Cheminova A/S Report No.: 198 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/12	Reis, K.-H.	2006	Effects of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) on the activity of the Soil microflora in the laboratory Cheminova A/S Study No.: 24705080 Cheminova A/S Report No.: 194 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/13	Schöbinger, U.	2012	Effects of metsulfuron (free acid) on the activity of the soil microflora Cheminova A/S Study No.: S11-03005 Cheminova A/S Report No.: 301 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/14	Lührs, U.	2007	Effects of Saccharin on reproduction and growth of earthworms Eisenia fetida in artificial soil Study No.: 32621022 Cheminova A/S Report No.: 231 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/15	Lührs, U.	2007	Effects of Saccharin on the reproduction of the Collembola Folsomia candida in artifical soil	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study No.: 32622016 Cheminova A/S Report No.: 233 MEM IBACON GmbH GLP Yes Unpublished		
KCP 10.2/16	Schöbinger, U.	2012	Sublethal toxicity of carbamoyl guanidine to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: S11-03008 Cheminova A/S Report No.: 304 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/17	Höhn, P.	2012	Carbamoyl guanidine: Effects on the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomida) using an artificial soil test with 5% peat content Cheminova A/S Study No.: S11-03009 Cheminova A/S Report No.: 296 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/18	Lührs, U.	2007	Effects of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) on reproduction and growth of earthworms Eisenia fetida in artificial soil Cheminova A/S Study No.: 32601022 Cheminova A/S Report No.: 20 TBM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/19	Höhn, P.	2011	Aminotriazin: Effects on the reproductive output of the springtail Folsomia candida Willem (Collembola, Isotomida) using an artificial soil test with 5% peat content Cheminova A/S Study No.: S11-03011 Cheminova A/S Report No.: 306 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/20	Reis, K.-H.	2006	Effects of methylsaccharin (M-AS-BA) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24742080 Cheminova A/S Report No.: 195 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/21	Reis, K.-H.	2006	Effects of saccharin on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24724080 Cheminova A/S Report No.: 193 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/22	Reis, K.-H.	2006	Effects of hydroxy-MM (BDM-MM) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24714080 Cheminova A/S Report No.: 107 MEM IBACON GmbH GLP Yes	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/23	Reis, K.-H.	2006	Effects of carbamoyl guanidine (M-AS-BA-CG) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24732080 Cheminova A/S Report No.: 198 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/24	Reis, K.-H.	2006	Effects of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) on the activity of the Soil microflora in the laboratory Cheminova A/S Study No.: 24705080 Cheminova A/S Report No.: 194 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/25	Schöbinger, U.	2012	Effects of metsulfuron (free acid) on the activity of the soil microflora Cheminova A/S Study No.: S11-03005 Cheminova A/S Report No.: 301 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/26	Reis, K.-H.	2006	Effects of methylsaccharin (M-AS-BA) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24742080 Cheminova A/S Report No.: 195 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/27	Reis, K.-H.	2006	Effects of saccharin on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24724080 Cheminova A/S Report No.: 193 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/28	Reis, K.-H.	2006	Effects of hydroxy-MM (BDM-MM) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24714080 Cheminova A/S Report No.: 107 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/29	Reis, K.-H.	2006	Effects of carbamoyl guanidine (M-AS-BA-CG) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24732080 Cheminova A/S Report No.: 198 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/30	Reis, K.-H.	2006	Effects of 2-amino-4-methoxy-6-methyl-1,3,5-triazine (MM-TA) on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24705080 Cheminova A/S Report No.: 194 MEM IBACON GmbH GLP Yes	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/31	Schöbinger, U.	2012	Effects of metsulfuron (free acid) on the activity of the soil microflora Eurofins Agroscience Services EcoChem GmbH Cheminova A/S Study No.: S11-03005 Cheminova A/S Report No.: 301 MEM GLP Yes Unpublished	N	CHE
KCP 10.2/32	Reis, K.-H.	2005	Toxicity of metsulfuron-methyl technical to activated sludge in a respiration inhibition test Cheminova A/S Study No.: 24677171 Cheminova A/S Report No.: 157 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/33	-	2005	Acute toxicity of metsulfuron-methyl 200 g/kg WG to rainbow trout (Oncorhynchus mykiss) in a 96-Hour Static Test xxx Study No.: 24683230 xxx Report No.: 156 MEM GLP Yes Unpublished	Y	CHE
KCP 10.2/34	Grade, R., Wydra, V.	2005	Acute toxicity of metsulfuron-methyl 200 g/kg WG to Daphnia magna in a 48-hour immobilization test Cheminova A/S Study No.: 24682220 Cheminova A/S Report No.: 155 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/35	Pawlowski, S., Wydra, V.	2005	Toxicity of metsulfuron-methyl 200 g/kg WG to Pseudokirchneriella subcapitata in an algal growth inhibition test Cheminova A/S Study No.: 24681210 Cheminova A/S Report No.: 154 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/36	Schmitzer, S.	2005	Effects of metsulfuron-methyl 200 g/kg WG (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Cheminova A/S Study No.: 24685035 Cheminova A/S Report No.: 175 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/37	Schmitzer, S.	2005	Effects of metsulfuron-methyl 200 g/kg WG (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Cheminova A/S Study No.: 24685035 Cheminova A/S Report No.: 175 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/38	Moll, M.	2005	Effects of metsulfuron-methyl 200 g/kg WG on the parasitoid Aphidius rhopalosiphi in the laboratory, dose response test Cheminova A/S Study No.: 24686001 Cheminova A/S Report No.: 166 MEM IBACON GmbH GLP Yes	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/39	Rosenkranz, B.	2005	Effects of metsulfuron-methyl 200 g/kg WG on the predatory mite Typhlodromus pyri in the laboratory, dose response test Cheminova A/S Study No.: 24687063 Cheminova A/S Report No.: 167 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/40	Lührs, U.	2005	Acute toxicity (14 days) of metsulfuron-methyl 200 g/kg WG to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: 24688021 Cheminova A/S Report No.: 158 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/41	Schöbinger, U.	2012	Sublethal toxicity of Metsulfuron-methyl 200 g/kg WG to the earthworm Eisenia fetida in artificial soil Cheminova A/S Study No.: S11-03003 Cheminova A/S Report No.: 299 MEM Eurofins Agroscience Services EcoChem GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/42	Reis, K.-H.	2005	Effects of metsulfuron-methyl 200 g/kg WG on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24689080 Cheminova A/S Report No.: 176 MEM IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/43	Reis, K.-H.	2006	Effects of metsulfuron-methyl 200 g/kg WG on the activity of the soil microflora in the laboratory Cheminova A/S Study No.: 24689080 Cheminova A/S Report No.: 176 MEM amdt1 IBACON GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/44	Siemoneit, S.	2005	Effect of metsulfuron-methyl 200 g/kg WG on vegetative vigour of terrestrial plants Cheminova A/S, Study No.: AS6 Cheminova A/S Report No.: 177 MEM Rheinland-Pfalz (RLP) AgroScience GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/45	Siemoneit, S.	2005	Effects of metsulfuron-methyl 200 g/kg WG on seedling emergence of terrestrial plants Cheminova A/S, Study No.: AS5 Cheminova A/S Report No.: 174 MEM Rheinland-Pfalz (RLP) AgroScience GmbH GLP Yes Unpublished	N	CHE
KCP 10.2/46	Pawlowski, S.	2006	Toxicity of metsulfuron-methyl 200 g/kg WG to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test Cheminova A/S Study No.: 24684240 Cheminova A/S Report No.: 219 MEM IBACON GmbH GLP Yes	N	CHE

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/51	Deshmukh N.S.	2001	Acute immobilisation test of metsulfuron-methyl technical in Daphnia magna (24 hour EC50) Intox report No. 01.835 Intox PVT Ltd GLP Yes Unpublished	N	Rotam
KCP 10.2/52	Migchielsen M.H.J.	2001	Acute toxicity study in Daphnia magna with Bis-desmethyl Metsulfuron-methyl (static) Project No. 309195 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/53	Bogers M.	2003	Skeletonema costatum, marine algal growth inhibition test with Metsulfuron-methyl Project No. 385583 NOTOX B.V. GLP Yes unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/54	Bogers M.	2004	Anabaena flos-aquae, fresh water cyanobacteria growth inhibition test with Metsulfuron-methyl technical Project No. 385572 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/55	Migchielsen M.H.J.	2001	Fresh water algal growth inhibition test with Bis-desmethyl Metsulfuron-methyl Project No. 309206 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/56	Kuhl, R., Wydra, V.	2009	Toxicity of metsulfuron-methyl to the aquatic plant Lemna gibba in a Static Growth Inhibition Test. Report: 45531240 IBACON GmbH & Co. KG GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/57	Bogers M.	2002	A 7-day aquatic plant toxicity test using Lemna minor with Bis-desmethyl Metsulfuron-methyl + report amendment number 1 and 2 Project No. 309217 NOTOX B.V. GLP Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/58	Junker, T and Witte, A.	2012	O-desmethyl metsulfuron (IN-B5067) A Study with the Freshwater Aquatic Plant Lemna gibba - Toxicity and Growth Inhibition Study Number (ECT): 12AV15WA CIP – Chemisches Institut Pforzheim GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/59	Bogers M.	2001	A 7-day aquatic plant toxicity test with Triazine Amine Project No. 309149 NOTOX B.V. GLP	N	EU AIR2 MSM TF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.2/60	Junker, T and Witte, A.	2012	Carbamoyl guanidine (IN-NC148) A Study with the Freshwater Aquatic Plant Lemna gibba - Toxicity and Growth Inhibition Study Number (ECT): 12AV16WA CIP – Chemisches Institut Pforzheim GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/61	Junker, T and Witte, A.	2012	Phenyl urea (IN-B5685): A Study with the Freshwater Aquatic Plant Lemna gibba - Toxicity and Growth Inhibition Study Number (ECT): 12AV17WA CIP – Chemisches Institut Pforzheim GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/62	Hoffmann, K and Wydra, V.	2012	Toxicity of Metsulfuron acid (IN-F5438) to the Aquatic Plant Lemna gibba in a Semi-Static Growth Inhibition Test Institut für Biologische Analytik und Consulting Project 61204240 IBACON GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/63	Van Sikkelerus B.P.C.	2003	Acute contact and oral toxicity study in the honeybee with Metsulfuron-methyl (laboratory test) Project No. 385267 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/64	Geuijen W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and reproduction of the parasitic wasp Aphidius rhopalosiphi (laboratory test) NOTOX B.V. Project No. 309037 NOTOX B.V. GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/65	Geuijen W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on the survival and reproduction of the phytoseiid mite Typhlodromus pyri Scheuten (laboratory test) NOTOX B.V. Project No. 309048 NOTOX B.V. GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/66	Geuijen W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and food consumption of the carabid beetle Poecilus cupreus (laboratory test) NOTOX B.V. Project No. 309059 NOTOX B.V. GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/67	Geuijen W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and reproduction of the green lacewing Chrysoperla carnea (laboratory test) NOTOX B.V. Project No. 309026 NOTOX B.V. GLP Yes Unpublished	N	EU AIR2 MSM TF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2/68	Deshmukh N.S. and Naik	2001	Earthworm, acute toxicity test with metsulfuron-methyl technical Intox report No. 01.836 Intox PVT. LTD GLP Yes Unpublished	N	Rotam
KCP 10.2/69	van Erp Y.H.M.	2001	Acute toxicity study in the earthworm Eisenia fetida fetida with Saccharin (combined range-finding and limit test) + 1 report amendment NOTOX B.V. Project No. 309138 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/70	van Erp Y.H.M.	2001	Acute toxicity study in the earthworm Eisenia fetida fetida with Triazine Amine (combined range-finding and limit test) + 1 report amendment NOTOX B.V. Project No. 309162 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/71	Geuijen W.H.C.	2002	Acute toxicity study in the earthworm Eisenia foetida foetida with Metsulfuron-methyl Carbamoyl Guanidine (combined range-finding and limit test) + 1 report amendment NOTOX B.V.Project No. 309173 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/72	van Erp Y.H.M.	2001	Acute toxicity study in the earthworm Eisenia fetida fetida with O-desmethyl Metsulfuron-methyl (combined range-finding and limit test) + 1 report amendment NOTOX B.V. Project No. 309184 NOTOX B.V. GLP Yes Unpublished	N	AgriChem B.V. and Nufarm
KCP 10.2/73	Ganßmann, M.	2012	Acute Toxicity (14 Days) of Methyl 2-(aminosulfonyl)benzoate to the Earthworm Eisenia fetida in Artificial Soil with 5% Peat Project 72322021 Institut für Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/74	Moser, Th.	2012	Acid Sulphonamide: Acute toxicity to the earthworm Eisenia fetida in an artificial soil with 5% peat Study Number: 12AV5RA ECT Oekotoxikologie GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/75	Moser, Th.	2012	Phenyl urea: Acute toxicity to the earthworm Eisenia fetida in an artificial soil with 5% peat Study Number: 12AV4RA ECT Oekotoxikologie GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/76	Moser, Th.	2012	Metsulfuron Acid (IN-F5438): Acute toxicity to the earthworm Eisenia fetida in an artificial soil with 5% peat Study Number: 12AV6RA	N	EU AIR2 MSM TF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			ECT Oekotoxikologie GmbH GLP Yes Unpublished		
KCP 10.2/77	Ganßmann, M.	2012	Effects of Carbamoyl Guanidine on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat Project 69371022 Institut für Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.2/78	Juan D.	2009	Earthworm reproduction test with IN-NC148 (Carbomyl guanidine) and Saccharin, on Eisenia fetida - Laboratory study with artificial soil Enigma report No. EPA-BQD-01-09 GLP Yes Unpublished	N	Rotam
KCP 10.2/79	Juan D.	2009	Earthworm reproduction test with IN-NC148 (Carbomyl guanidine) and Saccharin, on Eisenia fetida - Laboratory study with artificial soil Enigma report No. EPA-BQD-01-09 GLP Yes Unpublished	N	Rotam
KCP 10.3.1/01	Ganßmann, M.	2012	Effects of 4-Methoxy-6-methyl-1,3,5-triazin-2-amine on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat. Project 69422022 Institut für Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.3.1/02	Ganßmann, M.	2012	Effects of metsulfuron acid on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 5% Peat Project 69422022 Institut für Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.3.1/03	Moser, Th., and A. Scheffcyzk	2012	Triazine amine: acute and reproduction toxicity to the collembolan species Folsomia candida in artificial soil Study Number: 12AV1CR ECT Oekotoxikologie GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.3.1/04	Moser, Th., and A. Scheffcyzk	2012	Carbamoyl guanidine: acute and reproduction toxicity to the collembolan species Folsomia candida in artificial soil Study Number: 12AV2CR ECT Oekotoxikologie GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.3.1/05	Förster, B.	2012	Triazine Amine: Effects on Soil Microorganisms ECT Study Number: 12AV9BB ECT Oekotoxikologie GmbH GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP	Porch J.R.	2009	Metsulfuron-methyl 20% Wg: A toxicity test to determine the	N	AgriChem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
10.3.1/06	Krueger H.O. Martin K.H.		effects of the test substance on vegetative vigour of six species of plants Project no. 525-121 Wildlife International, Ltd. GLP Yes Unpublished		B.V.
KCP 10.4/01	Porch J.R. Krueger H.O. Kendall, T.Z.	2011	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of four species of plants Project no. 525-138 Wildlife International, Ltd. GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/02	Porch J.R. Krueger H.O. Martin K.H.	2011	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of six species of plants Project no. 525-141 Wildlife International, Ltd. GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/03	Fiebig, S.	2007	Pike (CA2204) Terrestrial Plant Test, Vegetative Vigour Test Report: TNW116541 Dr. U Noack-Laboratorien GLP Yes Unpublished	N	Nufarm
KCP 10.4/04	Büche, C	2006	Terrestrial (non-target) plant test with metsulfuron-methyl 200WG: Seedling emergence and seedling growth & vegetative vigour test RCC Study Number: A 16154 RCC Ltd, Environmental chemistry and Pharmanalytics GLP Yes Unpublished	N	Rotam
KCP 10.4/05	Porch J.R. Krueger H.O. Martin K.H.	2009	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on seedling emergence of six species of plants Project no. 525-120 Wildlife International, Ltd GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/06	Fiebig, S.	2007	Pike (CA2204) Terrestrial Plant Test, Seedling Emergence and Growth Test Report: TNK116541 Dr. U Noack-Laboratorien GLP Yes Unpublished	N	Nufarm
KCP 10.4/07	Büche, C	2006	Terrestrial (non-target) plant test with metsulfuron-methyl 200WG: Seedling emergence and seedling growth & vegetative vigour test RCC Study Number: A 16154 RCC Ltd, Environmental chemistry and Pharmanalytics GLP Yes Unpublished	N	Rotam
KCP 10.4/08	Feil-Klein, N	2012	Toxicity of Metsulfuron-Methyl Technical Grade to Activated Sludge in a Respiration Inhibition Test Project 69431171 Institut für Biologische Analytik und Consulting IBACON	N	EU AIR2 MSM TF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GmbH GLP Yes Unpublished		
KCP 10.4/09		2004	Acute oral toxicity study of metsulfuron methyl 200g/kg WDG in Japanese quail GLP Yes Unpublished	N	Rotam
KCP 10.4/10		2002	96-hour acute toxicity study in rainbow trout with Metsulfuron-methyl 20% WG (static) Project No. 346512 GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/11		2003	Metsulfuron-methyl 20% WDG: Acute toxicity to rainbow trout (Oncorhynchus mykiss) Report no.: 950/049 GLP Unpublished	N	Nufarm
KCP 10.4/12		2004	Toxicity of Metsulfuron-methyl 200g/kg WDG to fish - Cyprinus capio (common carp) in a static acute test Report 04.1286 GLP Yes Unpublished	N	Rotam
KCP 10.4/13	Migchielsen, M.H.J.	2002	Acute toxicity study in Daphnia magna with Metsulfuron-methyl 20% WG (static) Project No. 346523 NOTOX GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/14	Wetton, P.M. and McKenzie, J.	2003	Metsulfuron-methyl 20% WDG: Acute toxicity to Daphnia Magna Project no.: 950/050 Safepharm Laboratories Ltd. GLP Yes Unpublished	N	Nufarm
KCP 10.4/15	Mead, C. and McKenzie, J.	2003	Metsulfuron-methyl 20% WDG: Algal inhibition test Project no.: 950/051 Safepharm Laboratories Ltd. GLP Yes Unpublished	N	Nufarm
KCP 10.4/16	Meller M., Junker, Th. and Seck, C	2005	Metsulfuron-methyl (200g/kg WG): A study on the toxicity to the Blue-green Algae Anabaena flos-aquae Report AL1AB ECT, Germany and Battelle, Switzerland ECT Oekotoxikologie GLP Yes Unpublished	N	Rotam
KCP 10.4/17		2002	Assessment of acute oral toxicity with Metsulfuron-methyl 20% WG in the rat (acute toxic class method) Report no.: 346466 GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.4/18		2002	Metsulfuron-methyl 20% WDG: Acute oral toxicity in the rat Report no.: 950/044 GLP Yes Unpublished	N	Nufarm

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/19		2005	Metsulfuron methyl 200 g/kg WG, Acute oral toxicity (UDP) in rats Report no.: 8771-04 GLP Yes Unpublished	N	Rotam
KCP 10.4/20	Pore, M.P. and Naik, P.Y.	2004	Acute contact toxicity test of metsulfuron methyl 200g/kg WDG in honeybees (Apis mellifera) Intox PVT. Report 04.1288 GLP Yes Unpublished	N	Rotam
KCP 10.4/21	Geuijen, W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and reproduction of the parasitic wasp Aphidius rhopalosiphi (laboratory test) Notox B.V. Project 309037 GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.4/22	Geuijen, W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and reproduction of the phytoseiid mite Typhlodromus pyri Scheuten (laboratory test) Notox B.V. Project No. 309048 GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.5/01	Geuijen, W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and food consumption of the carabid beetle Poecilus cupreus (laboratory test) Project No. 309059 Notox B.V. GLP Yes Not published	N	EU AIR2 MSM TF
KCP 10.5/02	Geuijen, W.H.C.	2001	Effects of Metsulfuron-methyl 20% WG on survival and reproduction of the green lacewing Chrysoperla carnea (laboratory test) Project No. 309026 Notox B.V. GLP Yes Unpublished	N	EU AIR2 MSM TF
KCP 10.5/03	Pore, M.P. and Naik, P.Y.	2004	Earthworm, acute toxicity test with metsulfuron methyl 200g/kg WDG Intox PVT. Report 04.1287 GLP Yes Unpublished	N	Rotam
KCP 10.5/04	Porch J.R. Krueger H.O. Martin K.H.	2009	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of six species of plants Wildlife International, Ltd. Project no. 525-121 GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.5/05	Porch J.R. Krueger H.O. Kendall, T.Z.	2011	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of four species of plants Project no. 525-138 Wildlife International, Ltd. GLP Yes	N	AgriChem B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.5/06	Porch J.R. Krueger H.O. Martin K.H.	2011	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of six species of plants Project no. 525-141 Wildlife International, Ltd. GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.5/07	Fiebig, S.	2007	Pike (CA2204) Terrestrial Plant Test, Vegetative Vigour Test. Report: TNW116541 Dr. U.Noack-Laboratorien GLP Yes Unpublished	N	Nufarm
KCP 10.5/08	Büche, C.	2006	Terrestrial (non-target) plant test with metsulfuron methyl 200 WG: Seedling emergence and seedling growth & vegetative vigour test RCC Report A16154 GLP Yes Unpublished	N	Rotam
KCP 10.5/09	Porch J.R. Krueger H.O. Martin K.H.	2009	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on seedling emergence of six species of plants Project no. 525-120 Wildlife International, Ltd. GLP Yes Unpublished	N	AgriChem B.V.
KCP 10.5/10	Fiebig, S.	2007	Pike (CA2204) Terrestrial Plant Test, Seedling Emergence and Growth Test. Report: TNK116541 Dr. U.Noack-Laboratorien GLP Unpublished	N	Nufarm
KCP 10.5/11	Büche, C.	2006	Terrestrial (non-target) plant test with metsulfuron methyl 200 WG: Seedling emergence and seedling growth & vegetative vigour test RCC Report A16154 GLP Yes Unpublished	N	Rotam

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

No additional studies were performed.

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No additional studies were performed.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No additional studies were performed.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No additional studies were performed.

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No additional studies were performed.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No additional studies were performed.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies were performed.

A 2.2 KCP 10.2 Effects on aquatic organisms

Study 1

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.2/01, xxxx, 2008
Title:	TOTO 75 – Acute toxicity to carp
Document No:	xxxx, Poland, Study Code W/52/08
Guidelines:	OECD Guideline No 203/ method EU C.1.
GLP	Yes

Materials and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuron methyl, according to the Certificate of Analysis Issued by xxx, Oct. 08, 2007. Content of thifensulfuron methyl and metsulfuron methyl confirmed by Certificate of Analysis No 125/BA/10 issued by xxx, Warsaw, Poland, 14.10.2010, Cross reference K-III

- ✓ carp (*Cyprinus carpio)* 8 fish per test concentration (mean body length 5.28 cm, mean body weight 1.81 g) for 96 h under semi-static conditions

- ✓ stability of a.s. under the test conditions was validated.

Summary

Test substance	TOTO 75 (750 g as/kg)
Test object	carp
Exposure	96h, semi-static
LC_{50} mg/L	>100 mg/L
LC_0 mg/L	>100 mg/L
LC_{100} mg/L	>100 mg/L

Conclusion: TOTO 75 poses no risk to carp (not classifiable)

Study 2

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.2/02, xxx, 2008
Title:	TOTO 75 – Acute toxicity to rainbow trout
Document No:	xxx, Poland, Study Code W/51/08
Guidelines:	OECD Guideline No 203/ method EU C.1.
GLP	Yes

Materials and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed by Certificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III

- ✓ trount (*Onchoryncus mykiss)* 7 fish per test concentration (mean body length 5.04 cm, mean body weight 1.25 g) for 96 h under static conditions

- ✓ stability of a.s. under the test conditions was validated.

Summary

Test substance	TOTO 75 (750 g as/kg)
Test object	Rainbow trout
Exposure	96h, semi-static
LC_{50} mg/L	>100 mg/L
LC_0 mg/L	>100 mg/L
LC_{100} mg/L	>100 mg/L

Conclusion: TOTO 75 poses no risk to trout (not classifiable)

Study 3

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.2/03, xxx
Title:	TOTO 75 – Daphnia magna acute immobolization test
Document No:	xxx, Poland, Study Code W/53/08
Guidelines:	OECD Guideline No 202/ method C2.
GLP	Yes

Materials and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed byCertificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III

- ✓ first instar *Daphnia magna* (< 24 h old) in a static test system were exposed for 48 h to nominal concentration of 100 mg formulation./L.

Findings:

Test substance	TOTO 75 (750 g as/kg)
Test object	*Daphnia magna*
Exposure	48h, static
EC_{50} mg/L	>100 mg/L
EC_0 mg/L	>100 mg/L
EC_{100} mg/L	>100 mg/L

Conclusion: TOTO 75 poses no risk to *Daphnia magna*. (not classifiable)

Study 4

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.2/04, xxx
Title:	TOTO 75 – Growth inhibition test against *Pseudokirchneriella subcapitata* SAG 61.81
Document No:	xxx, Poland, Study Code W/55/08
Guidelines:	OECD Guideline No 201/ method C3.
GLP	Yes

Materials and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed byCertificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III
- ✓ Algae culture of *Pseudokirchneriella subcapitata* 61.81 SAG (formerly *Selenastrum capricornutum)*
- ✓ Growth medium was prepared using sterile distilled water (filter Barnstead EASYPure RF, USA) with reagent-grade chemicals (Sigma and Aldrich) [9].
- ✓ The assay was performed according to the OECD Guideline No 201 [1], method C.3 [2] and SOP/W/20 [11] with the objective of determining the EC_{50} for average growth rate inhibition (E_yC_{50}) and yield inhibition (E_rC_{50}), as well as NOEC and LOEC values for growth and yield.

Findings:

Test Substance	TOTO 75 (750 g as/kg)
Test Object	*Pseudokirchneriella subcapitata*
Exposure	72h, static
ErC_{50}/72h (growth rate) mg/L	6.90
E_yC_{50}/72h (yield inhibition) mg/L	0.78
NOEC mg/L (growth)	0.10
LOEC mg/L (growth)	0.32
NOEC mg/L (yield)	0.10
LOEC mg/L (yield)	0.32

Study 5

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.2/05, xxx
Title:	TOTO 75 – Growth inhibition test against *Anabaena* flos-aquae UTEX 1444
Document No:	xxx, xxx, Poland, Study Code W/54/08
Guidelines:	OECD Guideline No 201/ method C3.
GLP	Yes

Materials and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed byCertificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III

- ✓ A suspension of cyanobacterium culture *Anabaena flos-aquae* UTEX 1444 was obtained from the Culture Collection of Algea, University of Texas, Austin, USA

- ✓ Growth medium was prepared using sterile distilled water (filter Barnstead EASYPure RF, USA) with reagent-grade chemicals (Sigma and Aldrich) [9].

- ✓ The assay was performed according to the OECD Guideline No 201 [1], method C.3 [2] and SOP/W/20 [11] with the objective of determining the EC_{50} for average growth rate inhibition (E_yC_{50}) and yield inhibition (E_rC_{50}), as well as NOEC and LOEC values for growth and yield.

Findings:

Test Substance	TOTO 75
Test Object	*Anabaena flos-aquae*
Exposure	72h, static
ErC_{50}/72h (growth rate) mg/L	2.08
E_yC_{50}/72h (yield inhibition) mg/L	0.90
NOEC mg/L (growth)	3.2
LOEC mg/L (growth)	10.0
NOEC mg/L (yield)	0.10
LOEC mg/L (yield)	0.32

Study 6

zRMS comments:

The study is considered valid. All validity criteria were met.

Agreed endpoints:

ErC_{50}/7d (growth rate) µg/L	1.59
E_yC_{50}/7d (yield inhibition) µg/L	0.975
NOEC µg/L (growth)	0.5
LOEC µg/L (growth)	1.58
NOEC µg/L (yield)	0.5
LOEC µg/L (yield)	1.58

Report:	KCP 10.2/06, xxx
Title:	Toxicity of TOTO 75 SG to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test
Document No:	xxx Germany
Guidelines:	OECD Guideline No 201/ method C3.
GLP	Yes

Materials and methods:

Test Item: TOTO 75 SG; Batch No.: 1004/13; content of a.i. (analytical): Thifensulfuron: 69.4 %; Metsulfuron: 7.19 %, according to certificate of analysis.
Test Species: *Lemna gibba* G 3
Test Design: This study encompassed 6 treatment groups (5 dose rates of the test item and a control) with three replicates per test concentration and control.
At test start 12 fronds were introduced in each replicate and incubated for 7 days under static conditions. The frond numbers were determined on day 3, 5 and 7. The dry weight of each replicate from test end was determined.
Endpoints: Yield and growth rate based on frond number and dry weight.

Findings:

Test Substance	TOTO 75
Test Object	*Lemna Gibba*
Exposure	7d, static
ErC_{50}/7d (growth rate) µg/L	1.59
E_yC_{50}/7d (yield inhibition) µg/L	0.975
NOEC µg/L (growth)	0.5
LOEC µg/L (growth)	1.58
NOEC µg/L (yield)	0.5
LOEC µg/L (yield)	1.58

Conclusion

The influence of TOTO 75 SG on the growth of the freshwater plant Lemna gibba was assessed in a static dose-response test.

The 7-day EyC50 was calculated to be 0.975 and 1.56 µg test item/L for frond number and dry weight, respectively. The 7-day ErC50 was calculated to be 1.59 and 18.9 µg test item/L for frond number and dry weight, respectively.

The 7-day NOEyC and the LOEyC were determined to be 0.5 and 1.58 µg test item/L for frond number and dry weight, respectively. The 7-day NOErC and the LOErC were determined to be 0.5 and 1.58 µg test item/L for frond number and dry weight, respectively.

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No additional studies were performed.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No additional studies were performed.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

The following bee acute oral study performed on TOTO 75 is provided in support of the assessment.

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KIIIA1 10.3/01, xxx, 2008
Title:	TOTO 75 - acute oral toxicity to honeybee (*Apis mellifera* L.)
Document No:	xxx, Study Code B/33/08
Guidelines:	OECD No 213 method C.16
GLP	Yes

Material and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed byCertificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III
- ✓ The test material was dissolved in sugar and the so obtained syrup fed individually to test animals (3 replicates x 10 animals) via syringe (10 µg /bee) in the following dosage: 25, 50, 100, 200 µg /bee of TOTO 75 and the results used to determine LD50 values. After application, observations were made concerning mortality and any other signs of toxicity beginning at the fourth hour after treatment and then every 24 hours. Observations ended after 96 hours from the time of exposure.

Findings:

Test substance	TOTO 75
Test object	Bees (oral)
Oral LD_{50} (48 h)	.200 µg /bee

Conclusion: No mortality or abnormalities were observed in any treatments

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.3/02, xxx, 2008
Title:	TOTO 75 - acute dorsal contact toxicity to honeybee (*Apis mellifera* L.)
Document No:	xxx, Poland, Study Code B/34/08
Guidelines:	OECD No 214 method C.17
GLP	Yes

Material and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed byCertificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III
- ✓ A water suspension of the test material (1 µl /bee) was dorsally applied in 3 replicates x 10 animals, via micro-applicator in the following dosage: 25, 50, 100, 200 µg /bee and the results used to determine LD50 values.
- ✓ After application, observations were made concerning mortality and any other signs of toxicity beginning at the fourth hour after treatment and then every 24 hours. Observations ended after 96 hours from the time of exposure.

Findings:

Test substance	TOTO 75
Test object	Bees (contact)
Contact LD_{50} (48 h)	.200 µg /bee

Conclusion: No mortality or abnormalities were observed in all treatments

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

No additional studies were performed.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies were performed.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional studies were performed.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies were performed.

A 2.3.1.7 KCP 10.3.1.7 Non target arthropods studies

Study 1

zRMS comments:

The study is considered acceptable. All validity criteria were met.

– mortality of the control group was 11.7% on day 7 of exposure (criterion: a maximum of 20%),
– corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 81.1% on day 7 of exposure (criterion: a minimum of 50%),
– the mean number of eggs per female in the control group was 4.3 (required: ≥ 4 eggs per female).

Agreed endpoints:
LR_{50}>90 g product/ha

Report:	KCP 10.3/03, xxx
Title:	TOTO 75 SG: Effects on the Predatory Mite Typhlodromus pyri in the Laboratory - Dose Response Test -
Document No:	xxx, Study No. 128611063
Guidelines:	SETAC Guidance Documents: ESCORT I (xxx., 1994); ESCORT II (xxx., 2001); IOBC, BART, EPPO Guideli nes (xxx et al., 2000)
GLP	Yes

Summary

	were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups where the corrected mortality was < 50 % were sexed and the number of eggs per female was recorded at 3 assessment days within one week.
Endpoints:	Mortality after 7 days of exposure; LR_{50}: lethal rate producing 50 % mortality after exposure over 7 days, additionally reproduction capacity for survived mites.
Reference Item:	Perfekthion (nominal: 400 g dimethoate/L).
Test Rates:	Control, 1.11, 3.33, 10.0, 30.0 and 90.0 g product/ha and reference item. The reference item was applied at an application rate of 8.0 mL Perfekthion/ha. All treatments were applied in 200 L water/ha. The spraying dilutions were sprayed onto glass plates via laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 24 - 26 °C; relative humidity: 67 - 70 %; photoperiod: 16 h light : 8 h dark; light intensity: 230 - 570 lux.

~~**Material and Methods:**~~

~~Test Item: TOTO 75 SG; batch no.: 1905/15; content of a.s.: 65.71 ± 1.45 [%] Thifensulfuron methyl and 6.94 ± 0.96 [%] Metsulfuron methyl.~~

~~Test Species: Predatory Mite (Typhlodromus pyri), protonymphs less than 24 hours old; source: xxx.~~

~~Test Design: This study comprised 7 treatment groups (5 dose rates of the test item, control, reference item) with 3 replicates each containing 20 mites. The mites were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups where the corrected mortality was < 50 % were sexed and the number of eggs per female was recorded at 3 assessment days within one week.~~

Findings:

Test substance	TOTO 75
Test object	Phytoseiid mite *Typhlodromus pyri Sch.*
LR_{50} (7 d) Tier I exposure scenario	>90 g/ha

Validity Criteria of the Study

Control Mortality:	20.0 %, validity criterion was met
Reference Item Mortality:	93.8 % corrected mortality, validity criterion was met
Control Reproduction:	7.8 eggs per female, validity criterion was met

Conclusion: TOTO 75 poses no undue risk to phytoseiid mite

Study 2

The study is considered acceptable. All validity criteria were met.

Control Mortality:	0.0 %, validity criterion was met
Reference Item Mortality:	100.0 % corrected mortality, validity criterion was met
Control Reproduction Rate:	– 29.9 mummies per female (mean value), validity criterion was met; – There was one parasitoid producing zero values, validity criterion was met

Agreed endpoints:

LR_{50}>90 g ppp/ha

Report:	KCP 10.3/04, xxx
Title:	TOTO 75 SG: Effects on the Parasitoid Aphidius rhopalosiphi in the Laboratory - Dose Response Test-
Document No:	xxx, Study No. 128611001
Guidelines:	SETAC Guidance Documents: ESCORT I (xxx., 1994); ESCORT II (xxx., 2001); IOBC, BART, EPPO Guidelines (xxx., 2000)
GLP	Yes

Material and methods:

Test Item: TOTO 75 SG; batch no.: 1905/15; content of a.s.: 65.71 ± 1.45 [%] Thifensulfuron methyl and 6.94 ± 0.96 [%] Metsulfuron methyl.

Test Species: Parasitoid (Aphidius rhopalosiphi), adults not older than 48 hours; source: xxx, Germany.

Test Design: This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 4 replicates each containing 10 adult parasitoids. The parasitoids were exposed to dried residues on treated glass plates. Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups where the corrected mortality was < 50 % the reproductive capacity was assessed by confining females individually over untreated barley plants infested with the host cereal aphids, Rhopalosiphum padi. The females were removed after 24 hours and the aphid-infested plants left for a further 12 days before the numbers of aphid mummies that had developed were assessed.

Findings:

Test substance	TOTO 75
Test object	*Parasitoids* *Aphidius rhopalosiphi.*
LR_{50} (48 h) Tier I exposure scenario	>90 g/ha

Validity Criteria of the Study

Control Mortality: Should not exceed 13 % (se
Reference Item Mortality: Should result in at least 50
Control Reproduction Rate:

– ≥ 5 mummies per female
– There should be no more
7.1).

Conclusion: TOTO 75 poses no undue risk to parasitoids.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Study 1

zRMS comments:

The study is considered acceptable. All validity criteria were met.
The results are considered valid because the following criteria were satisfied in the controls:
• each replicate produced 108 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
• the coefficient of variation of reproduction was 12.5% (criterion: ≤ 30%),
• adult mortality over the initial 4 weeks of the experiment was 0% (criterion: ≤ 10%).

Agreed enpoints:
NOEC=100 mg ppp/kg dws
EC_{10}=62.7 mg ppp/kg dws

Report:	KCP 10.4/01. 2016, xxx
Title:	**TOTO 75 SG Earthworm Reproduction Test *(Eisenia fetida)***
Document No:	xxx, Poland xxx STUDY CODE: G/60/16
Guidelines:	OECD Guideline 222 (1984) method C.8
GLP	Yes

The aims of the study were to assess the impact of **TOTO 75 SG** on reproduction of the earthworm, *Eisenia fetida* and to determine the EC_{10}, EC_{25}, EC_{50}, and NOEC.

The test item (an aqueous suspension) was mixed with the artificial soil. The concentrations of the test item were 5.6; 10; 18; 32; 56; 100; 180; 320; 560 and 1000 mg/kg dry soil. Each of them was divided into four replicates. There was also an untreated control group divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all adult worms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined.

The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Materials and methods:

Test item:	**TOTO 75 SG** batch number: 1609/14, active substance: thifensulfuron – methyl – 75.25% ± 1.42% metsulfuron – methyl – 7.15% ± 0.27%
Artificial soil:	10% sphagnum peat, 20% kaolin clay, 70% industrial sand
Test organism:	the earthworm, *Eisenia fetida* obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology [SOP/G/34]
Test design:	test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Concentrations of the test item:	a control; 5.6; 10; 18; 32; 56; 100; 180; 320; 560 and 1000 mg/kg dry soil
Test conditions:	temperature: 17.0 – 22.0°C; pH at the beginning of the experiment: 5.90 – 6.09; pH at the end of the experiment: 6.12 – 6.41; soil moisture content at the beginning of the experiment: 22.38 – 24.37% (47.58 – 51.81% of the maximum water holding capacity); soil moisture content at the end of the experiment: 22.47 – 23.68% (47.78 – 50.35% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity: 485– 580 lux

Results:

After 4 weeks, **TOTO 75 SG** at the concentrations used in the experiment did not cause mortality of the adult earthworms.

No changes in the appearance (morphology) and behaviour of the earthworms were noticed.

After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry soil, the body weight increase was between 30.4 – 50.4%. As for the control group, it was equal to 35.6%.

After 8 weeks of the experiment, it was concluded that **TOTO 75 SG** at the concentrations ranging from 180 to 1000 mg/kg dry soil had an adverse significant impact on reproduction.

The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period **(EC_{10})** is **equal to 62.7 mg/kg dry soil**.

The concentration of the test item causing a 25% reduction in the number of juveniles produced within the exposure period **(EC_{25})** is **equal to 141.3 mg/kg dry soil**.

The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period **(EC_{50})** is **equal to 348.5 mg/kg dry soil**.

The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction **(LOEC)** is equal to **180 mg/kg dry soil**.

The highest concentration at which the test item is observed to have no statistically significant effects on reproduction **(NOEC)** is equal to **100 mg/kg dry soil**.

The concentration of the test item causing 50% mortality of the adult earthworms **(LC_{50})** is **above 1000 mg/kg dry soil**.

~~**Materials and methods**~~

- ~~On the basis of the range – finding test, eight concentrations of the test item were chosen to be used in the experiment. These included: 18; 32; 56; 100; 180; 320; 560 and 1000 mg/kg dry soil. The concentrations were arranged in a geometric series with a separation factor of 1.8 [2]. There were four replicates of each test concentration. At the same time, an untreated control group (eight replicates) was introduced to the soil without the test item.~~

- ~~Name:~~ ~~TOTO 75 SG~~

~~Batch No.:~~ ~~1609/14,~~

~~Active Ingredient / Content:~~ ~~thifensulfuron – methyl – 75.25% ± 1.42%~~
~~metsulfuron – methyl – 7.15% ± 0.27%~~

~~Date of Production:~~ ~~October 2014~~

~~Certificate of Analysis Ref Code:~~ ~~No. 055/BA/15 of April 09, 2015 (Appendix No. 1)~~

~~Type of Formulation:~~ ~~SG~~
~~Type:~~ ~~Herbicide~~

Findings:

Test substance	TOTO 75 SG
Test object	Eisenia fetida
NOEC mg a.i. /kg dry soil	The obtained results made it possible to conclude that TOTO 75 SG at the concentrations ranging from 180 to 1000 mg/kg dry soil had an adverse statistical significant impact on reproduction of the earthworms. It was 52.7% to 29.7% in comparison to control group. TOTO 75 SG at the concentrations ranging from 5.6 to 100 mg/kg dry soil had no statistical significant impact on reproduction of the earthworms. NOEC-100 mg/kg

Validity Criteria

The results are considered valid because the following criteria were satisfied in the controls:
 each replicate produced 108 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),

 the coefficient of variation of reproduction was 12.5% (criterion: ≤ 30%),

 adult mortality over the initial 4 weeks of the experiment was 0% (criterion: ≤ 10%).

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No additional studies were performed.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Study 1

zRMS comments:

The study is considered acceptable. All validity criteria were met.

- control treatment mortality should not exceed 20% at the end of the test (actual value of control in test = 6%).
- the mean number of juveniles recorded in the control treatment should be at least 50 per replicate at the end of the test (actual value of control in test = 272).
- the coefficient of variation of reproduction in the control should not exceed 30% (actual value of control in test = 8.5%).
- the efficiency of the method used to extract the mites in this test should be > 90%. In a separate test, carried out by the Test Facility, this was determined to be 98.0% (98% for the adult female mites and 98% for the juvenile mites) (Geary, 2018).

Agreed endpoints:
LC_{50} > 1000 mg test item/kg soil dry weight
$NOEC_{survival\ and\ reproduction}$ = 1000 mg test item/kg soil dry weight

Report:	KCP 10.4/02. 2016, xxx
Title:	**TOTO 75 SG – A laboratory test to determine the effects of fresh residues on the predatory soil mite Hypoaspis aculeifer (Acari, Laelapidae) in an artificial soil substrate)**
Document No:	xxx Study code: CHR-19-5
Guidelines:	OECD (2016). OECD Guidelines for the testing of chemicals, No. 226 Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil.
GLP	Yes

Materials and methods

- Following a preliminary range-finding test, TOTO 75 SG was evaluated in a definitive test at a single treatment concentration, equivalent to 1000 mg test item/kg soil dry weight. This concentration was compared to an untreated (water only) control.

- Treatments were incorporated into an artificial soil substrate (containing 5% w/w peat), aliquots of which were then transferred into small, ventilated, glass jars (n = 8 for control and test-item treatment concentrations). Ten female soil mites (approximately 7-14 days after becoming adult) were then introduced into each arena. Cheese mites (Tyrophagus putrescentiae (Schrank)) were provided as food for the predatory soil mites and were replenished ad libitum. At 14 days after treatment (DAT), both the numbers of surviving adult predatory soil mites and of their offspring were recorded.

- Statistical analysis was used to determine the no-observed-effect concentration (NOEC) with respect to both mite survival and reproduction. The median lethal concentration (LC50) for the mites originally introduced was estimated, as was the median effect concentration (EC50) for reproduction.

Test item = TOTO 75 SG
Formulation type = water soluble granule (SG)
Batch number = 0603/18Z
Active substances = a) thifensulfuron methyl b) metsulfuron methyl
.
Nominal content of a.s. = a) 682 g/kg (68.2 % m/m) b) 68 g/kg (6.8 % m/m)

Measured content of a.s. = a) 68.96 ± 0.75% m/m (equivalent to 689.6 ± 7.5 g/kg)
b) 7.09 ± 0.16% m/m (equivalent to 70.9 ± 1.6 g/kg)
Expiration date = March 2020
Appearance = off-white granules
Storage at Test Facility = ambient laboratory conditions, < 30°C

Results

The results are summarised in Table A. Based on the number of offspring produced, the 14-day EC_{50} was estimated to be > 1000 mg test item/kg soil dry weight, the highest concentration tested. The LC_{50} was also estimated to be > 1000 mg test item/kg soil dry weight. The overall NOEC with respect to both mite survival and reproduction was 1000 mg test item/kg soil dry weight.

Table A. The effects of TOTO 75 SG on the survival and reproduction of the soil mite *Hypoaspis aculeifer*

Treatment	Test item concentration (mg test item/ kg soil dry wt.)	% mortality at 14 DAT [a)]	Corrected % mortality at 14 DAT [b)]	Mean no. progeny per replicate [c)]	% change in numbers of progeny, relative to control [d)]
Control	-	6	-	272	-
TOTO 75 SG	1000	5	-1	295	-8

a) Treatments were compared with the control using Fisher's Exact Binomial test ($\alpha = 0.05$, one-sided, > control), but there were no significant differences.

b) Derived using Abbott's formula. A negative value represents an increase in mite survival, relative to the control.

c) The treatments were compared to the control by Student's t-test ($\alpha = 0.05$, one-sided, < control), but there were no significant differences.

d) A negative value indicates an increase in reproduction, relative to the control.

A laboratory test was carried out to determine the effects of TOTO 75 SG on the predatory soil mite *Hypoaspis aculeifer*, when applied to an artificial soil substrate containing 5% peat. The 14-day EC_{50} for effects on reproduction was estimated to be > 1000 mg test item/kg soil dry weight. The LC_{50} value for the adult mites originally introduced was estimated to be > 1000 mg test item/kg soil dry weight. The NOEC for both survival and reproduction was 1000 mg test item/kg soil dry weight.

Validity Criteria

According to the Study Plan and OECD Guideline 226 (OECD, 2016), for the test to be deemed valid:
- control treatment mortality should not exceed 20% at the end of the test (actual value of control in test = 6%).
- the mean number of juveniles recorded in the control treatment should be at least 50 per replicate at the end of the test (actual value of control in test = 272).
- the coefficient of variation of reproduction in the control should not exceed 30% (actual value of control in test = 8.5%).
- the efficiency of the method used to extract the mites in this test should be > 90%. In a separate test, carried out by the Test Facility, this was determined to be 98.0% (98% for the adult female mites and 98% for the juvenile mites) (Geary, 2018).
All of these criteria were therefore met in the test.

Study 2

zRMS comments:

The study is considered acceptable. All validity criteria were met.

- control treatment mortality should not exceed 20% at the end of the test (actual value of control = 11%).
- the mean number of juveniles recorded in the control treatment should be at least 100 per replicate at the end of the test (actual value of control in test = 631).
- the coefficient of variation of reproduction in the control should not exceed 30% (actual value in control = 19%).

- the efficiency of the method used to extract the springtails in this test should be > 95%. In a separate test, reported by the Test Facility in April 2019, this was determined to be 100% for the adult springtails and 99.3% for the juvenile springtails (Cooper, 2019).

Agreed endpoints:
The 28-day $EC_{50rep.}$ > 1000 mg test item/kg soil dry weight.
The 28-day LC_{50} > 1000 mg test item/kg soil dry weight.

Report:	KCP 10.4/03. xxx
Title:	**TOTO 75 SG – A laboratory test to determine the effects of fresh residues on the springtail Folsomia candida (Collembola, Isotomidae) in an artificial soil substrate.**
Document No:	xxx UK xxx-Tox Study/Report No. CHR-19-6
Guidelines:	OECD Guidelines For Testing Chemicals. Collembolan reproduction test in soil (OECD 232, 2016)
GLP	Yes

Materials and methods

- Following a preliminary range-finding bioassay, TOTO 75 SG was evaluated in a definitive bioassay at a single treatment concentration, equivalent to 1000 mg test item/kg soil dry weight, which was compared to a control treatment of purified water.

- The test item treatment was incorporated into a standard artificial soil substrate (containing 5% peat), aliquots of which were then transferred to small lidded jars (n = 8 per treatment). Ten juvenile F. candida (12 days old) were introduced into each jar. Dry granulated yeast was provided on the soil surface as food and this was replenished after 14 days. At 28 days, the numbers of the original springtails still surviving and the numbers of any offspring they had produced were recorded.

- The results were used to determine the no-observed-effect concentration (NOEC) for the test item with respect to the assessments of both mortality and reproduction. In addition, a value for the median lethal concentration (LC50) and the median effect concentration (EC50) with respect to reproduction were derived by extrapolation from the results.

- Test item = TOTO 75 SG
- Formulation type = water soluble granule (SG)
- Lot number = 0603/18Z
- Active substance = a) thifensulfuron methyl b) metsulfuron methyl
- Nominal content of a.s. = a) 682 g/kg (68.2 % m/m) b) 68 g/kg (6.8 % m/m)
- Measured content of a.s. = a) 68.96 ± 0.75% m/m (equivalent to 689.6 ± 7.5 g/kg)
- b) 7.09 ± 0.16% m/m (equivalent to 70.9 ± 1.6 g/kg)
- Expiration date = March 2020
- Appearance = Off-white granules
- Storage at Test Facility = ambient laboratory conditions

Results

The results of assessments are summarised in Table A. Springtail survival was unusually low in replicate 6 of the test item treatment, which subsequently resulted in lower offspring numbers. It was considered that this was an anomaly and so this replicate has been excluded from statistical analyses.
Based on statistical analyses, the overall NOEC with respect to both springtail survival and reproduction was 1000 mg test item/kg soil dry weight. Based on the numbers of offspring produced, the 28-day EC50 value for the test item was > 1000 mg test item/kg soil dry weight. The LC50 was also > 1000 mg test item/kg soil dry weight.

Table A. The effects of TOTO 75 SG on the survival and reproduction of the springtail Folsomia candida.

Treatment	Test item conc. [mg test item/ kg soil dry wt.]	% mortality at 28 DAT [a)]	% corrected mortality [b)]	Mean no. progeny per replicate [c)]	% change in no. progeny, relative to control [d)]
Control	-	11	-	631	-
TOTO 75 SG	1000	7	-5	547	13

a) Treatments were compared using Fisher's Exact Binomial Test (one-sided, > control, $\alpha = 0.05$), but there was no significant difference.

b) Calculated using Abbott's formula. A negative value represents an increase in springtail survival relative to the control.

c) Numbers of F_1 progeny in each treatment were compared by two sample t-test procedure (one-sided, < control, $\alpha = 0.05$), but there was no significant difference.

d) A positive value indicates a decrease in reproduction, relative to the control.

Conclusions
In a laboratory test with TOTO 75 SG and the springtail *Folsomia candida*, the NOEC with respect to assessments of both adult springtail survival and reproduction was 1000 mg test item/kg soil dry weight. The 28-day EC_{50} value for reproduction was > 1000 mg test item/kg soil dry weight. The 28-day LC_{50} value was also > 1000 mg test item/kg soil dry weight.

Validity Criteria

According to OECD Guideline 232 (2016), for the test to be deemed valid:
- control treatment mortality should not exceed 20% at the end of the test (actual value of control = 11%).
- the mean number of juveniles recorded in the control treatment should be at least 100 per replicate at the end of the test (actual value of control in test = 631).
- the coefficient of variation of reproduction in the control should not exceed 30% (actual value in control = 19%).
- the efficiency of the method used to extract the springtails in this test should be > 95%. In a separate test, reported by the Test Facility in April 2019, this was determined to be 100% for the adult springtails and 99.3% for the juvenile springtails (Cooper, 2019).
Thus, all of these criteria were met.

Study 3

zRMS comments:

The study is considered acceptable. All validity criteria were met.

Agreed endpoints:

$NOEC_{mortality\ and\ reproduction} \geq$ 0.72 mg test item/kg soil

EC_{10} and EC_{20} > 0.72 mg test item/kg soil

Report:	KCP 10.4/04. xxx
Title:	IN-A4098: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil
Document No:	xxx Study No. 128571016
Guidelines:	GLP compliant study based on OECD 232, 2016 and ISO 11267, 2014
GLP	Yes

Material and Methods:

Test Item:	IN-A4098, chemical name: 2-Amino-4-methoxy-6-methyl-1,3,5-triazine; batch no.: MKBT2543V; purity: 99.9% (HPLC)
Test Species:	Collembola *Folsomia candida*, 9-12 days old, from cultures held at the laboratory.
Test Design:	28-d exposure in treated artificial soil. Different concentrations of the test item were mixed homogeneously into the soil which was placed into glass vessels before the Collembola were introduced on top of the soil; 5 concentrations and one control; 4 replicates/concentration with 10 Collembola each (8 replicates for the control). Feeding of Collembola with approximately 2 mg dry yeast for each test vessel at the beginning of the test and on day 14. Assessment of adult mortality, behavioural effects and reproduction was performed after 28 d.
Endpoints:	Mortality of adult Collembola, behavioural effects, number of juveniles.
Reference Item:	Boric acid (The effects of the reference item were investigated in a separate study.)
Test Concentrations:	Control, 0.045, 0.09, 0.18, 0.36 and 0.72 mg IN-A4098/kg soil1.
Test Conditions:	Artificial soil according to OECD 232; pH at experimental start 5.8, pH at experimental end 5.7 to 5.8; water content at experimental start 20.2% to 20.6% (51.9% to 52.8% of the maximum water holding capacity); at experimental end 19.9% to 21.2% (51.0% to 54.3% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark, light intensity within the range of 400 to 800 lux.
Statistics:	Standard procedures, Fisher's Exact Test (mortality), Dunnett's t-test (reproduction).

Results and Discussion:

All validity criteria for the study were met.
A mortality of up to 13% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where 8% of the Collembola died (Fisher's Exact test, α = 0.05, one-sided greater).
Reproduction of the Collembolan exposed to IN-A4098 was not statistically significantly different compared to the control up to and including the highest test concentration of 0.72 mg/kg soil (Dunnett's t-test, α = 0.05, one-sided smaller).
No behavioural abnormalities were observed in any of the treatment groups. The results are shown in Table 1.

Table 1. Effect of IN-A4098 on Collembola (*Folsomia candida)* in a 28-day reproduction study

IN-A4098 [mg/kg soil dry weight]	Control	0.045	0.09	0.18	0.36	0.72
Mortality (day 28) [%]	8	5	5	13	10	5
Significance [1)]	-	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 28)	523	523	489	521	523	577
Significance [2)]	-	n.s.	n.s.	n.s.	n.s.	n.s.
Reproduction in [%] of control (day 28)	-	100	93.5	100	100	110
Endpoints [mg test item/kg soil dry weight]						
NOEC (mortality)	≥0.72					
LOEC (mortality)	>0.72					
NOEC (reproduction)	≥0.72					
LOEC (reproduction)	>0.72					

n.s. = not significantly different compared to the control
[1)] Fisher's Exact Test, α = 0.05, one-sided greater
[2)] Dunnett's t-test, α = 0.05, one-sided smaller
- not applicable

Conclusion:
The No Observed Effect Concentration (NOEC) for mortality and reproduction was determined to be ≥0.72 mg test item/kg soil. The Lowest Observed Effect Concentration (LOEC) for mortality and reproduction was estimated to be >0.72 mg test item/kg soil.
As the obtained results did not follow a concentration-response relationship EC_x values (e.g. EC_{10}, EC_{20}) could not be determined mathematically. The EC_{10} and EC_{20} are estimated to be >0.72 mg test item/kg soil.

A 2.5 KCP 10.6 Effects on soil microbial activity

Study 1

zRMS comments:

The study was accepted in th previous evaluation of the product.

Report:	KCP 10.5/01, xxx, 2008
Title:	TOTO 75- Soil Microorganisms: NItrogen transformation test
Document No:	xxx, Poland, Study Code G/27/08
Guidelines:	OECD Guideline 216, EU method C.21
GLP	Yes

Material and methods:

- ✓ TOTO 75, production date Sept. 10, 2007; Batch No: H20070910-1; storage conditions: dry room with temperature 0-20 ºC; stability: up tp Sept 9, 2009, containing 68.2% (682 g/kg) thifensulfuron-methyl and 6.8% (68 g/kg) metsulfuronmethyl, according to the Certificate of Analysis Issued by xxx Co. Ltd, Oct. 08, 2007. Content of metsulfuron-methyl and thifensulfuron-methyl confirmed by Certificate of Analysis No 125/BA/10 issued by xxx, Poland, 14.10.2010, Cross reference K-III

- ✓ The soil was taken from place (49º59', 780N and 018º55', 190E) adjoining tht Institute of Organic Industry, Branch Pszczyna. The site of soil collection was covered by grass. Moreover, the sampling place has not been used for agricultural purposes during the past five years, no plant protection products, as well as

organic and inorganic fertilisers have been used. Soil samples were taken from a depth of 0 down to 20 cm. Test material was applied to soil adjusted for moisture at 0.02 mg/kg dry soil and at a rate 5 times higher, 0.1 mg/kg dry soil.

- ✓ Predicted environmental concentration $PEC_{(1)}$ after single application was calculated according to the following formula:

$$\mathbf{PEC_{(1)} = A \times (1 - f_{int}) / 100 \times d \times bd\ [mg/kg\ of\ soil]}$$

Where

A is application rate [g ha^{-1}] = 0.090 kg/ha

f_{int} is fraction intercepted by crop canopy = 0.5

d is mixing depth [cm] = 5 cm

bd is dry soil bulk density [g cm^{-3}] = 1.5 g/cm^3

- ✓ The principle of method was based on the spectrophotometric measurement of the nitrate ions concentration in soil extract of the 1 % potassium sulphate (VI) solution. Analysis was based on the measurement of the intensity of yellow colour, generated in the reaction with phenyldisulphonic at 410 nm.
- ✓

Findings:

No significant differences in nitrate concentration between control and soil treated with the test material were observed over a period of 28 days. The obtained percent deviations from the control were less than ± 25%.

Overall Conclusions:

TOTO 75 had no effect on soil biomass or mineral nitrogen level at either the recommended field rate or the five-fold field application rate.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Not available.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Study 1

zRMS comments:

The study is considered acceptable. All validity criteria were met.

Germination Rate of the Control Seeds:	87% -100%, validity criterion was met.
Mean Survival of Emerged Control Seedlings:	100%, validity criterion was met.
Growth and Morphology of the Control Seedlings:	The control seedlings exhibited no visible phytotoxic effects and the plants exhibited only normal variation in growth and morphology for that particular species; validity criterion was met.

Agreed endpoints:

ER50 (g product/ha)
ER50 Brassica napus-6.19
ER50 Pisum sativum – 1.58
ER50 Solanum lycopersicum- 4.89
ER50 Beta vulgaris -2.45
ER50 Daucus carota -7.22
ER50 Lactuca sativa -10.6
ER50 Avena sativa – n.d.
ER50 Lolium perenne -16.4
ER50 Zea mays –n.a.
ER50 Allium cepa-6.76

The least sensitive species were the monocotyledonous plant species Avena sativa, Zea mays for which no ERx values could be calculated, but a NOER value of ≥ 90.00 g a.s./ha could be determined.

Report:	KCP 10.6/01/ 2016, xxx
Title:	TOTO 75 SG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test
Document No:	xxx Germany Project 97831086
Guidelines:	OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test" (adopted July 19, 2006)
GLP	Yes

Materials and methods

Name:	TOTO 75 SG
Batch-No.:	0704/14
Active Ingredient(s) / Content:	Thifensulfuron-methyl: 63.53% ± 1.46% w/w (analytical) Metsulfuron-methyl: 7.31% ± 0.36%
Certificate of Analysis Ref. Code / Date:	According to certificate of analysis No 292/BA/15 November 06, 2015
Type:	Herbicide
Type of Formulation:	SG
Species Selection:	Ten species, six dicotyledonous and four monocotyledonous species were tested, representing e

Findings:

Test substance	TOTO 75 SG
Test object	*Brassica napus,* *Pisum sativum* *Solanum lycopersicum* *Beta vulgaris* *Daucus carota* *Lactuca sativa* *Avena sativa* *Lolium perenne* *Zea mays* *Allium cepa*
ER50 (g product/ha)	*Brassica napus-6.19* ***Pisum sativum – 1.58*** *Solanum lycopersicum- 4.89* *Beta vulgaris -2.45* *Daucus carota -7.22* *Lactuca sativa -10.6* *Avena sativa -* *Lolium perenne -16.4* *Zea mays --* *Allium cepa-6.76* The least sensitive species were the monocotyledonous plant species Avena sativa, Zea mays for which no ER_x values could be calculated, but a NOER value of ≥ 90.00 g a.s./ha could be determined.

Validity Criteria

Germination Rate of the Control Seeds:	87% -100%, validity criterion was met.
Mean Survival of Emerged Control Seedlings:	100%, validity criterion was met.
Growth and Morphology of the Control Seedlings:	The control seedlings exhibited no visible phytotoxic effects and the plants exhibited only normal variation in growth and morphology for that particular species; validity criterion was met.

Study 2

zRMS comments:

The study is considered acceptable. All validity criteria were met.

- Germination Rate of the Seeds: 81 - 100%, validity criterion was met.
- Mean Survival of Control Plants: 100%, validity criterion was met.
- Growth and Morphology of the Control Plants: The control plants exhibited no visible phytotoxic effects and the plants exhibited only normal variation in growth and

Agreed endpoints:

ER50 (g product/ha)

ER50 Brassica napus- 48.2
ER50 Pisum sativum >90

ER50 Solanum lycopersicum >90
ER50 Beta vulgaris - 13.3
ER50 Daucus carota -3.53
ER50 Lactuca sativa -4.99
ER50Avena sativa -
ER50 Lolium perenne -97.1
ER50 Zea mays –n.d.
ER50 Allium cepa -8.69
The least sensitive species were the monocotyledonous plant species Avena sativa, Zea mays for which no ERx values could be calculated, but a NOER value of ≥ 90.00 g a.s./ha could be determined.

Report:	KCP 10.6/02 2016, xxx
Title:	TOTO 75 SG:Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test
Document No:	xxx Germany Project 97831087
Guidelines:	OECD 227
GLP	Yes

Materials and methods

Name:	TOTO 75 SG
Batch-No.:	0704/14
Active Ingredient(s) / Content:	Thifensulfuron-methyl: 63.53% ± 1.46% w/w (analytical) Metsulfuron-methyl: 7.31% ± 0.36% w/w (analytical)
Certificate of Analysis Ref. Code / Date:	No 292/BA/15 November 06, 2015
Type:	Herbicide
Type of Formulation:	SG
Species Selection:	Ten species were tested, six dicotyledonous and four monocotyledonous species, representing eight plant families

Findings:

Test substance	TOTO 75 SG
Test object	*Brassica napus* *Pisum sativum* *Solanum lycopersicum* *Beta vulgaris* *Daucus carota* *Lactuca sativa* *Avena sativa* *Lolium perenne* *Zea mays* *Allium cepa*
ER50 (g a.s./ha)	*Brassica napus- 48.2* *Pisum sativum >90* *Solanum lycopersicum >90* *Beta vulgaris - 13.3* *Daucus carota -3.53* *Lactuca sativa -4.99* *Avena sativa -* *Lolium perenne -97.1* *Zea mays -* *Allium cepa -8.69* The least sensitive species were the monocotyledonous plant species Avena sativa, Zea mays for which no ER_x values could be calculated, but a NOER value of ≥ 90.00 g a.s./ha could be determined.

Validity Criteria

Germination Rate of the Seeds:	81 - 100%, validity criterion was met. For details see Table 9.
Mean Survival of Control Plants:	100%, validity criterion was met.
Growth and Morphology of the Control Plants:	The control plants exhibited no visible phytotoxic effects and the plants exhibited only normal variation in growth and

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

No additional studies were performed.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No additional studies were performed.

A 2.8 KCP 10.8 Monitoring data

No additional studies were performed.