

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 4100 A

Product name: HIFEN

Chemical active substance:

Thifensulfuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem Ltd.

Submission date: September 2023

MS Finalisation date: March 2024; February 2025, March 2025

Version history

When	What
September 2023	Submission by Applicant
March 2024	First assessment by zRMS
July 2024	Applicant update
February 2025	The final Registration Report.
March 2025	Corrected of final Registration Report.

Table of Contents

9	Ecotoxicology (KCP 10).....	6
9.1	Critical GAP and overall conclusions.....	7
9.1.1	Overall conclusions.....	9
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)	9
9.1.1.2	Effects on aquatic organisms (KCP 10.2).....	9
9.1.1.3	Effects on bees (KCP 10.3.1).....	10
9.1.1.4	Effects on arthropods other than bees (KCP 10.3.2)	10
9.1.1.5	Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)	10
9.1.1.6	Effects on non-target terrestrial plants (KCP 10.6)	10
9.1.1.7	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	10
9.1.2	Grouping of intended uses for risk assessment.....	9
9.1.3	Consideration of metabolites	11
9.2	Effects on birds (KCP 10.1.1).....	12
9.2.1	Toxicity data	12
9.2.1.1	Justification for new endpoints	13
9.2.2	Risk assessment for spray applications.....	13
9.2.2.1	First-tier assessment (screening/generic focal species)	13
9.2.2.2	Higher-tier risk assessment	14
9.2.2.3	Drinking water exposure.....	14
9.2.2.4	Effects of secondary poisoning.....	15
9.2.2.5	Biomagnification in terrestrial food chains.....	15
9.2.3	Risk assessment for baits, pellets, granules, pills or treated seed	15
9.2.4	Overall conclusions.....	15
9.3	Effects on terrestrial vertebrates other than birds (KCP 10.1.2).....	16
9.3.1	Toxicity data	16
9.3.1.1	Justification for new endpoints	17
9.3.2	Risk assessment for spray applications.....	17
9.3.2.1	First-tier assessment (screening/generic focal species)	17
9.3.2.2	Higher-tier risk assessment	18
9.3.2.3	Drinking water exposure.....	18
9.3.2.4	Effects of secondary poisoning.....	19
9.3.2.5	Biomagnification in terrestrial food chains.....	19
9.3.3	Risk assessment for baits, pellets, granules, pills or treated seed	19
9.3.4	Overall conclusions.....	19
9.4	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	20
9.5	Effects on aquatic organisms (KCP 10.2).....	20
9.5.1	Toxicity data	20
9.5.1.1	Justification for new endpoints	23
9.5.2	Risk assessment	23
9.5.3	Overall conclusions.....	36
9.6	Effects on bees (KCP 10.3.1).....	37
9.6.1	Toxicity data	37
9.6.1.1	Justification for new endpoints	38

9.6.2	Risk assessment	38
9.6.2.1	Hazard quotients for bees.....	38
9.6.2.2	Higher-tier risk assessment for bees (tunnel test, field studies).....	40
9.6.3	Effects on bumble bees	40
9.6.4	Effects on solitary bees	40
9.6.5	Overall conclusions.....	40
9.7	Effects on arthropods other than bees (KCP 10.3.2)	41
9.7.1	Toxicity data	41
9.7.1.1	Justification for new endpoints	42
9.7.2	Risk assessment	42
9.7.2.1	Risk assessment for in-field exposure.....	42
9.7.2.2	Risk assessment for off-field exposure	42
9.7.2.3	Additional higher-tier risk assessment.....	43
9.7.2.4	Risk mitigation measures	43
9.7.3	Overall conclusions.....	43
9.8	Effects on non-target soil meso- and macrofauna (KCP 10.4)	43
9.8.1	Toxicity data	43
9.8.1.1	Justification for new endpoints	45
9.8.2	Risk assessment	45
9.8.2.1	First-tier risk assessment.....	45
9.8.2.2	Higher-tier risk assessment.....	46
9.8.3	Overall conclusions.....	46
9.9	Effects on soil microbial activity (KCP 10.5).....	48
9.9.1	Toxicity data	48
9.9.1.1	Justification for new endpoints	49
9.9.2	Risk assessment	49
9.9.3	Overall conclusions.....	50
9.10	Effects on non-target terrestrial plants (KCP 10.6)	50
9.10.1	Toxicity data	50
9.10.1.1	Justification for new endpoints	51
9.10.2	Risk assessment	51
9.10.2.1	Tier-1 risk assessment (based screening data)	51
9.10.2.2	Tier-2 risk assessment (based on dose-response data).....	51
9.10.2.3	Higher-tier risk assessment	52
9.10.2.4	Risk mitigation measures	52
9.10.3	Overall conclusions.....	52
9.11	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	52
9.12	Monitoring data (KCP 10.8)	53
9.13	Classification and Labelling	53
Appendix 1	Lists of data considered in support of the evaluation	54
Appendix 2	Detailed evaluation of the new studies	58
A 2.1	KCP 10.1 Effects on birds and other terrestrial vertebrates.....	58
A 2.1.1	KCP 10.1.1 Effects on birds	58
A 2.1.2	KCP 10.1.2 Effects on terrestrial vertebrates other than birds	58
A 2.1.3	KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians).....	58
A 2.2	KCP 10.2 Effects on aquatic organisms	58

A 2.2.1	KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	58
A 2.2.2	KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms.....	71
A 2.2.3	KCP 10.2.3 Further testing on aquatic organisms	71
A 2.3	KCP 10.3 Effects on arthropods	71
A 2.3.1	KCP 10.3.1 Effects on bees	71
A 2.4	KCP 10.3 Effects on arthropods other than bees	82
A 2.5	KCP 10.4 Effects on non-target soil meso- and macrofauna.....	88
A 2.5.1	KCP 10.4.1 Earthworms	88
A 2.5.2	KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)	90
A 2.6	KCP 10.5 Effects on soil nitrogen transformation.....	94
A 2.7	KCP 10.6 Effects on terrestrial non-target higher plants.....	96
A 2.7.1	KCP 10.6.1 Summary of screening data	96
A 2.7.2	KCP 10.6.2 Testing on non-target plants.....	96
A 2.7.3	KCP 10.6.3 Extended laboratory studies on non-target plants	101
A 2.8	KCP 10.7 Effects on other terrestrial organisms (flora and fauna).....	101
A 2.9	KCP 10.8 Monitoring data.....	101

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Winter cereals (wheat, barley, rye, oats, tritica- le)	F	Broadleaved weeds	Foliar Spray	BBCH 13-39 (Spring)	a) 1 b) 1	N.A	a) 0.04 b) 0.04	a) 0.03 b) 0.03	200-400	-		A	A	R	A	A	A	R

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:	(1) Numeration necessary to allow references (2) Use official codes/nomenclatures of EU (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure) (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application (5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated	(7) Growth stage at first and 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 (8) The maximum number of application possible under practical conditions of use must be provided (9) Minimum interval (in days) between applications of the same product. (10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". (13) PHI - minimum pre-harvest interval (14) Remarks may include: Extent of use/economic importance/restrictions
-----------------------	--	--

9.1.1 Overall conclusions

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.

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)

- **Birds:**

According to the screening assessments for winter cereals, all the TERa and TERlt values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A/ HIFEN presents no unacceptable acute and long-term risk to birds according to the intended uses on winter cereals.

- **Mammals:**

According to the screening, first-tier and higher-tier assessment for winter cereals, all the TERa and TERlt values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A/ HIFEN presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Based on this assessment with consideration PECsw STEP 4 the following risk mitigation measures are required to surface water bodies.

- for D3 (ditch), D4 (stream), D5 (stream), D6 (ditch) scenarios: 5 meter buffer zone + 50 % drift reduction nozzles or 10 meter buffer zone
- for R1 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip
- for R3 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip +50% drift reduction nozzles or 10 m drift buffer zone + 10 meter vegetative buffer strip
- for R4 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies (the worst case for R3 scenario)

PL

D3, D4, R1 scenario are relevant.

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies

The risk assessment for aquatic organisms with risk mitigation measured should be considered by MSs.

9.1.1.3 Effects on bees (KCP 10.3.1)

The QHO and QHC values for, 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 HIFEN. According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by the applicant. The chronic risk assessment based on chronic studies for bees (adult and larvae) should be performed in line with the EFSA 2013 guideline during the transition period. **The Applicant should provide the chronic risk assessment based on chronic studies for bees (adult and larvae) performed in line with the EFSA 2013 guideline.**

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

The in-field and off-field HQ values calculated for the product SHA 4100 A / HIFEN for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use pattern. In addition, the PER in- and off-field values are below rate with ≤ 50 % effect for two species *Chrysoperla carnea* and *Orius laevigatus* indicating an acceptable risk in-field and off-field for these species.

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

- **Non-target soil meso- and macrofauna:**

The acute and chronic TER for Thifensulfuron-methyl were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance does not pose an acute and long-term risk to earthworms and other soil-macro- and mesofauna when applied according to the proposed uses rates

- **Soil microbial activity:**

Risk assessments conducted with relevant PECsoil for active substance Thifensulfuron-methyl and its relevant metabolites and in SHA 4100 A/ HIFEN formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

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

The risk to non-target plants for SHA 4100 A/ HIFEN is considered to be acceptable when applied according to the proposed use rates.

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

The result from the activated sludge studies indicate that microbial activity in such systems is at low risk from Thifensulfuron-methyl. Contamination of sewage treatment systems via agricultural use of Thifensulfuron-methyl in the representative formulations is considered to be low.

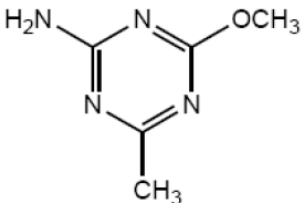
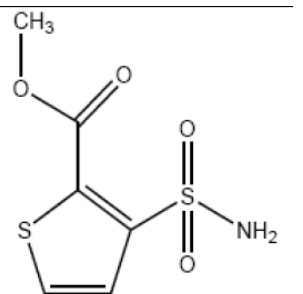
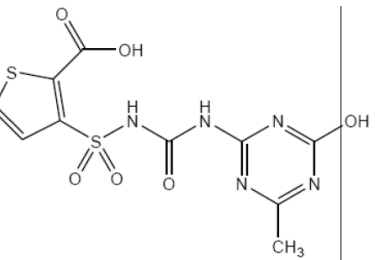
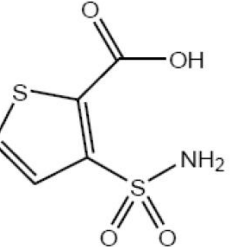
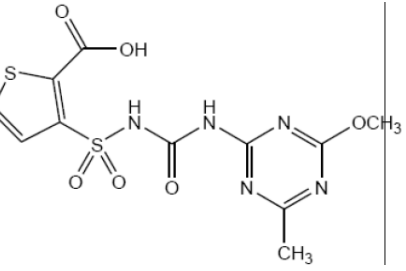
9.1.2 Grouping of intended uses for risk assessment

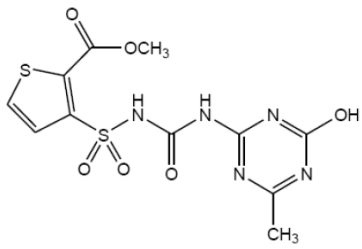
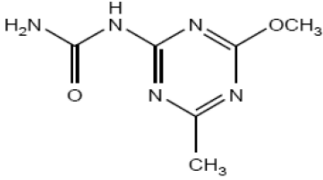
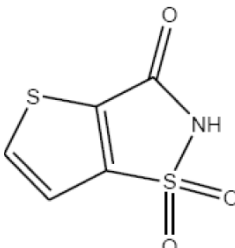
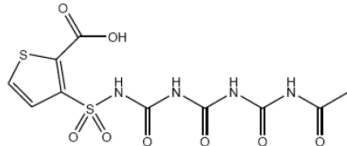
Not relevant

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 SHA 4100 A / HIFEN is indicated in the table.

Table 9.1-2 Metabolites of Thifensulfuron-methyl

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IN-A4098		140.1	Soil: 18% Water: 20% Sediment: 7% ^a	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-A5546		221.2	Soil: 27.7% Whole system: 93.1%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-JZ789		359.3	Soil: 10% Water: 21% Sediment: 4%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-L9223		207.2	Soil: 19% Water: 39% Sediment: 8% ^a	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-L9225		373.4	Soil: 94% Water: 55% Sediment: 7% ^a	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IN-L9226		373.4	Soil: 18.5% Water: 78% Sediment: 7.2%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-V7160		183.2	Soil: 9.6% Water: 25% Sediment: 6%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
IN-W8268		189.2	Soil: 29.6%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms
2-acid-3-triuret		378.3	Soil: 17%	Yes, for aquatic organisms, soil meso- and macrofauna and soil microorganisms

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 its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of Thifensulfuron 75 % WG were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the SHA 4100 A / HIFEN is not considered essential, because active substance toxicity data 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 <i>Anas platyrhynchos</i>	Thifensulfuron-methyl	Oral 1 d	LD ₅₀ > 2510 (4739)* mg a.s./kg bw	EFSA Journal 2015;13(7):4201

Species	Substance	Exposure System	Results	Reference
		Acute		
Bobwhite quail <i>Colinus virginianus</i>	Thifensulfuron-methyl	Dietary 8 d Short-term	LDD ₅₀ > 1524 mg/kg bw/d	
Mallard duck <i>Anas platyrhynchos</i>	Thifensulfuron-methyl	Dietary 8 d Short-term	LDD₅₀ > 1306 mg/kg bw/d	
Bobwhite quail <i>Colinus virginianus</i>	Thifensulfuron-methyl	Dietary Reproductive toxicity	NOEL = 23 mg/kg bw/d	
Mallard duck <i>Anas platyrhynchos</i>	Thifensulfuron-methyl	Dietary Reproductive toxicity	NOEL = 172 mg/kg bw/d	
*extrapolated endpoint based on no mortality in the acute bird study in accordance with EFSA (2009)				

zRMS comments:

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

9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

According to EFSA guidance (2009), where the dietary LC₅₀ is lower than the acute LD₅₀, the dietary LC₅₀ should be used. Therefore, the LC₅₀ > 1306 mg a.s./kg bw/d will be used in the acute risk assessment for Thifensulfuron-methyl.

9.2.2 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).

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

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

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SHA 4100 A / HIFEN in winter cereals

Intended use	Winter cereals
Active substance/product	Thifensulfuron-methyl

Application rate (g/ha)		1 x 30				
Acute toxicity (mg/kg bw)		> 1306				
TER criterion						
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Cereals - screening	Small omnivorous bird	158.8	1.0	4.76	274.14	
Reprod. toxicity (mg/kg bw/d)		23				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Cereals - screening	Small omnivorous bird	64.8	1.0 x 0.53	1.03	22.32	

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.

zRMS comment: Agreed.

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 substance 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.

9.2.2.2 Higher-tier risk assessment

Not relevant.

9.2.2.3 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 SHA 4100 A / HIFEN is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 13.3, Thifensulfuron-methyl belongs to the group of less sorptive substances.

Effective application rate (g/ha)=	30		
Acute toxicity (mg/kg bw) =	> 1306	quotient =	0.02

Reprod. toxicity (mg/kg bw/d) =	23	quotient =	1.30
---------------------------------	----	------------	------

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is not necessary.

zRMS comments:

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

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Thifensulfuron-methyl amounts to 0.0253 at pH 5, -1.65 at pH 7 and -2.10 at pH 9; thus, does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

zRMS comments:

As the active substance has log P_{ow} 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 **HIFEN**.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.2.4 Overall conclusions

According to the screening assessments for winter cereals, all the TER_a and TER_{lt} values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A / HIFEN presents no unacceptable acute and long-term risk to birds according to the intended uses on winter cereals.

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 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

Effects on mammals of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the formulation SHA 4100 A / HIFEN is not considered essential, because active substance toxicity data 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 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Thifensulfuron-methyl	Oral 1 d Acute	LD ₅₀ > 5000 mg a.s./kg bw	EFSA Journal 2015;13(7):4201
Rat	IN-L9225	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	
Rat	IN-A4098	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw (males) LD ₅₀ = 1000 mg/kg bw (females)	
Rat	IN-W8268	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	
Rat	Thifensulfuron-methyl	Dietary Reproductive toxicity Two-generation study	NOAEL = 1.3 mg/kg bw/d #	
Rat	Thifensulfuron-methyl	Dietary Reproductive toxicity Two-generation study	NOAEL = 43 mg/kg bw/d #	

#: The NOAEL of 1.3 mg/kg bw/d 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 bw/d. Should a higher tier assessment be required in the future then the ecological relevance of this NOAEL should be considered further.

zRMS comments:

We agree with the endpoints presented in the Table 9.3-1 above. The NOAEL =43 mg a.s./kg bw is recommended value to use in refined risk assessment.

zRMS comments:

We agree with the endpoints presented in the Table 9.3-1 above. The NOAEL =43 mg a.s./kg bw is recommended value to use in refined risk assessment.

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.3.2 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).

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SHA 4100 A / HIFEN in winter cereals

Intended use		Winter cereals				
Active substance/product		Thifensulfuron-methyl				
Application rate (g/ha)		1 x 30				
Acute toxicity (mg/kg bw)		> 1000 (to cover metabolite IN-A4098)				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Cereals - screening	Small herbivorous mammal	118.4	1.0	3.55	281.7	
Reprod. toxicity (mg/kg bw/d)		1.3				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.0 x 0.53	0.03	43.3	
Cereals BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.0 x 0.53	0.07	19.4	
Cereals BBCH 10-29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.0 x 0.53	0.12	10.5	
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	1.0 x 0.53	0.06	21.0	
Cereals Early	Large herbivorous mammal “lag-	22.3	1.0 x 0.53	0.36	3.7	

(shoots)	omorph” Grass + cereals 100% cereal shoots				
----------	---	--	--	--	--

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.

9.3.2.2 Higher-tier risk assessment

According to EFSA bird and mammal guidance (2009), it is stated that if the lowest relevant endpoint from the developmental study is lower than the lowest endpoint from the 2-generation rat study, then the developmental study endpoint should be used in the risk assessment. Otherwise the endpoint from the 2-generation rat study should be used. The lowest endpoint is a parental NOAEL of 43 mg/kg bw/day from the 2-generation rat study. This NOAEL will therefore be used in the higher-tier assessment.

Table 9.3-3: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 4100 A / HIFEN in winter cereals – refined NOAEL

Intended use		Winter cereals				
Active substance/product		Thifensulfuron-methyl				
Application rate (g/ha)		1 x 30				
Reprod. toxicity (mg/kg bw/d)		43				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Cereals Early (shoots)	Large herbivorous mammal “lag-omorph” Grass + cereals 100% cereal shoots	22.3	1.0 x 0.53	0.36	121.3	

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.

zRMS comments:

We agree with higher risk assessment for Large herbivorous mammal “lagomorph” Grass + cereals 100% cereal shoots with consideration of NOAEL=43 mg a.s./kg w agreed at EU level.
The TER_{LT} value is above trigger for all species and the risk is considered an acceptable.

9.3.2.3 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 13.3, Thifensulfuron-methyl belongs to the group of less sorptive substances.

Effective application rate (g/ha) =	30		
Acute toxicity (mg/kg bw) =	> 5000	quotient	= 0.01

Reprod. toxicity (mg/kg bw/d) =	1.3	quotient =	23.08
---------------------------------	-----	------------	-------

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50 for at least one-use scenario, a quantitative risk assessment (calculation of TER values) is not necessary.

zRMS comments:

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

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Thifensulfuron-methyl amounts to 0.0253 at pH 5, -1.65 at pH 7 and -2.10 at pH 9; thus, does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

zRMS comments: Agreed.

As the active substance has log P_{ow} 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 **HIFEN**.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.3.4 Overall conclusions

According to the screening, first-tier and higher-tier assessment for winter cereals, all the TER_a and TER_{lt} values for Thifensulfuron-methyl are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 4100 A / HIFEN presents no unacceptable acute and long-term risk to mammals according to the intended uses on winter cereals.

zRMS comments: Agreed.

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

Not data available.

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 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

However, the provision of further data on the formulation 1 is not considered essential, because active substance toxicity data 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 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Thifensulfuron-methyl and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish – laboratory tests				
<i>Oncorhynchus mykiss</i>	IN-L9225	96 h, s	LC ₅₀ > 120 mg/L _{mm}	EFSA Journal 2015;13(7):4201
<i>Oncorhynchus mykiss</i>	IN-JZ789	96 h, s	LC ₅₀ > 0.94 mg/L _{mm}	
<i>Oncorhynchus mykiss</i>	IN-V7160	96 h, s	LC ₅₀ > 1.0 mg/L _{mm}	
<i>Oncorhynchus mykiss</i>	IN-A4098	96 h, s	LC ₅₀ > 200 mg/L _{nom}	
<i>Oncorhynchus mykiss</i>	IN-A4098	96 h, s	LC ₅₀ > 0.93 mg/L _{mm}	
<i>Oncorhynchus mykiss</i>	IN-W8268	96 h, s	LC ₅₀ > 115 mg/L _{mm}	
Aquatic invertebrates – laboratory tests				
<i>Chironomus riparius</i> *	Thifensulfuron-methyl	48 h, s	EC ₅₀ > 100 mg a.s./L _{nom}	EFSA Journal 2015;13(7):4201
<i>Daphnia magna</i>	IN-L9225	48 h, s	EC ₅₀ > 130 mg/L _{mm}	
<i>Daphnia magna</i>	IN-L9223	48 h, s	EC ₅₀ > 1.2 mg/L _{mm}	
<i>Daphnia magna</i>	IN-JZ789	48 h, s	EC ₅₀ > 1.1 mg/L _{mm}	
<i>Daphnia magna</i>	IN-V7160	48 h, s	EC ₅₀ > 1.3 mg/L _{mm}	
<i>Daphnia magna</i>	IN-A4098	48 h, s	EC ₅₀ > 100 mg/L _{nom}	
<i>Daphnia magna</i>	IN-A4098	48 h, s	EC ₅₀ > 99 mg/L _{mm}	
<i>Daphnia magna</i>	IN-W8268	48 h, s	EC ₅₀ > 125 mg/L _{mm}	
<i>Daphnia magna</i>	IN-L9223	21 d, ss	NOEC = 13 mg/L _{mm}	

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	IN-L9223	21 d, ss	NOEC = 31 mg/L _{nom}	
<i>Daphnia magna</i>	IN-V7160	21 d, ss	NOEC = 11 mg/L _{mm}	
<i>Daphnia magna</i>	IN-V7160	21 d, ss	NOEC = 31 mg/L _{nom}	
<i>Daphnia magna</i>	IN-A4098	21 d, ss	NOEC = 32 mg/L _{nom}	
<i>Daphnia magna</i>	IN-A4098	21 d, ss	NOEC = 97 mg/L _{mm}	
Algae – laboratory tests#				
<i>P. subcapitata</i>	IN-L9225	72 h, s	E _b C ₅₀ = 33.4 cell density mg/L _{nom} E _r C ₅₀ = 36.5 mg/L _{nom}	EFSA Journal 2015;13(7):4201
<i>P. subcapitata</i>	IN-L9223	72 h, s	EC ₅₀ > 1.3 mg/L _{mm}	
<i>P. subcapitata</i>	IN-JZ789	72 h, s	EC ₅₀ > 1.28 mg/L _{mm}	
<i>P. subcapitata</i>	IN-V7160	72 h, s	EC ₅₀ > 11 mg/L _{mm}	
<i>S. subspicatus</i>	IN-A4098	72 h, s	E _b C ₅₀ > 90 mg/L _{nom} E _r C ₅₀ > 90 mg/L _{nom}	
<i>P. subcapitata</i>	IN-A4098	72 h, s	E _b C ₅₀ > 100 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>P. subcapitata</i>	IN-A4098	72 h, s	E _b C ₅₀ > 100 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>P. subcapitata</i>	IN-A4098	72 h, s	E _b C ₅₀ > 10 mg/L _{nom} E _r C ₅₀ > 10 mg/L _{nom}	
<i>P. subcapitata</i>	IN-W8268	72 h, s	E _b C ₅₀ = 29.9 cell density 100 mg/L _{nom} E _r C ₅₀ = 31.6 mg/L _{nom}	
<i>P. subcapitata</i>	IN-W8268	72 h, s	E _b C ₅₀ > 100 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>P. subcapitata</i>	IN-L9226	72 h, s	EC ₅₀ (yield, biomass and growth rate) > 89 mg/L _{nom}	
<i>P. subcapitata</i>	IN-A5546	72 h, s	E _b C ₅₀ = 48 mg/L _{mm} E _r C ₅₀ > 110 mg/L _{mm}	
<i>P. subcapitata</i>	2-acid-3-triuret	72 h, s	E _b C ₅₀ > 100 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
Higher plant – laboratory test#				
<i>C. demersum</i>	Thifensulfuron-methyl	14 d, s**	E _r C ₅₀ = 32.15 mg a.s./L _{mm}	EFSA Journal 2015;13(7):4201
<i>E. canadensis</i>	Thifensulfuron-methyl	14 d, s**	E _r C ₅₀ = 0.0217 mg a.s./L _{mm}	
<i>M. aquaticum</i>	Thifensulfuron-methyl	14 d, s**	E _r C ₅₀ = 0.1871 mg a.s./L _{mm}	
<i>V. americana</i>	Thifensulfuron-methyl	14 d, s	E _r C ₅₀ = 0.00023 mg a.s./L _{mm} NOEC = 0.00011 mg a.s./L _{mm}	
<i>Lemna gibba</i>	IN-L9225	14 d, s	EC ₅₀ = 36.76 mg/L _{mm} E _r C ₅₀ (frond count) = 82.2 mg/L _{mm}	

Species	Substance	Exposure System	Results	Reference
<i>Lemna gibba</i>	IN-L9223	14 d, s	EC ₅₀ (frond count and biomass) > 172.1 mg/L _{nom} E _r C ₅₀ (frond count) 172.1 mg/L _{nom}	
<i>Lemna gibba</i>	IN-JZ789	14 d, s	EC ₅₀ (frond count and biomass) > 100 mg/L _{nom} E _r C ₅₀ (frond count) > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-V7160	14 d, s	EC ₅₀ (frond count and biomass) > 100 mg/L _{nom} E _r C ₅₀ (frond count) 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-A4098	14 d, s	EC ₅₀ (frond count and biomass) > 10 mg/L _{nom} E _r C ₅₀ (frond count) 10 mg/L _{nom}	
<i>Lemna gibba</i>	IN-A4098	7 d, s	EC ₅₀ > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-A4098	7 d, s	E _r C ₅₀ , E _b C ₅₀ > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-W8268	7 d, s	E _y C ₅₀ = 30.3 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-W8268	14 d, s	E _b C ₅₀ > 100 mg/L _{nom} EC ₅₀ = 39.5 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-L9226	7 d, s	E _y C ₅₀ = 0.17 mg/L _{mm} E _r C ₅₀ = 0.31 mg/L _{mm}	
<i>Lemna gibba</i>	IN-L9226	14 d, s	EC ₅₀ > 37.5 mg/L _{mm}	
<i>Lemna gibba</i>	IN-A5546	7 d, s	EC ₅₀ (yield, biomass and growth rate) > 40.4 mg/L _{mm}	
<i>Lemna gibba</i>	2-acid-3-triuret	7 d, s	E _y C ₅₀ > 100 mg/L _{nom} E _r C ₅₀ > 100 mg/L _{nom}	
<i>Lemna gibba</i>	IN-B5528	7 d, s	E _y C ₅₀ > 119.52 mg/L _{nom} E _r C ₅₀ > 119.52 mg/L _{nom} E _b C ₅₀ > 119.52 mg/L _{nom}	
Higher tier studies				
<i>Lemna gibba</i>	Thifensulfuron-methyl	7 d variable exposure duration ***	E _y C ₅₀ (12 h exposure) = 0.149 mg a.s./L _{nom} E _r C ₅₀ (12 h exposure) = 0.632 mg a.s./L _{nom} E _y C ₅₀ (24 h exposure) = 0.0149 mg a.s./L _{nom} E _r C ₅₀ (24 h exposure) > 0.198 mg a.s./L _{nom} E _y C ₅₀ (48 h exposure) = 0.0035 mg a.s./L _{nom} E _r C ₅₀ (48 h exposure) > 0.0593 mg a.s./L _{nom} E _y C ₅₀ (96 h exposure) =	EFSA Journal 2015;13(7):4201

Species	Substance	Exposure System	Results	Reference
			0.00045 mg a.s./L _{nom} E _r C ₅₀ (96 h exposure) = 0.0032 mg a.s./L _{nom}	
<i>Lemna gibba</i>	Thifensulfuron-methyl	16 d (9 d period at lower temperature) ***	E _y C ₅₀ = 0.068 mg a.s./L _{mm} E _r C ₅₀ > 0.447 mg a.s./L _{mm}	
Microsom or mesocosm tests				
Not submitted				

* This study was considered to be valid however it can not be considered suitable for use in a refined risk assessment.

** Endpoints from these studies were not deemed to be appropriate for use in a higher tier risk assessment but were used in a qualitative way together with the E_rC₅₀ proposed by the RMS for *Vallisneria spiralis*.

*** These studies were considered to be valid however, they were not considered suitable for use in refined risk assessment.

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 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – SHA 4100 A / HIFEN

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	SHA 4100 A / HIFEN	96 h, s	LC ₅₀ = 78.30 mg/L _{nom}	
<i>Daphnia magna</i>	SHA 4100 A / HIFEN	48 h, s	EC ₅₀ = 142.49 mg/L _{nom}	E. Nierzedzka, 2016, report No. W/165/16
<i>Pseudokirchneriella subcapitata</i>	SHA 4100 A / HIFEN	72 h, s	E _r C ₅₀ = 10.69 mg/L _{nom} E _y C ₅₀ = 1.14 mg/L _{nom}	E. Nierzedzka, 2016, report No. W/164/16
Higher-tier studies (micro- or mesocosm studies)				
Not submitted.				

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

Not relevant as there is no deviation to the EU agreed endpoints.

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 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for the product SHA 4100 A/ HIFEN for each organism group for the use in winter cereals

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀	EC ₅₀	E _r C ₅₀
AF		78300	142490	10690
RAC (µg/L)		100	100	10
PEC _{gl-max} (µg/L)		783	1424.9	1069
	0.369	0.0005	0.0003	0.0003

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

Table 9.5-4: 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 SHA 4100 A / HIFEN in winter cereals

Group		Inverteb. acute	Higher-tier information
Test species		<i>C. riparius</i>	<i>V. americana</i>
Endpoint (µg/L)		EC ₅₀	E _r C ₅₀
AF		100 000	0.23
RAC (µg/L)		100	10
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 1			
	10.10	0.01	439.1
Step 2			
N-Europe Oct-Feb	0.91	0.001	39.6
S-Europe Oct-Feb	0.78	0.001	33.9
Step 3			
D1/ditch	0.205	0.00021	8.91
D1/stream	0.171	0.00017	7.43
D2/ditch	1.625	0.00163	70.65
D2/stream	1.027	0.00103	44.65
D3/ditch	0.190	0.00019	8.26
D4/pond	0.007	0.00001	0.30
D4/stream	0.145	0.00015	6.30
D5/pond	0.007	0.00001	0.30
D5/stream	0.150	0.00015	6.52
D6/ditch	0.189	0.00019	8.22
R1/pond	0.007	0.00001	0.30
R1/stream	0.138	0.00014	6.00

Group		Inverteb. acute	Higher-tier information
R3/stream	0.303	0.00030	13.17
R4/stream	0.199	0.00020	8.65

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

For the intended uses on winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an E_rC_{50} for *V. americana* of 0.23 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for Thifensulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of SHA 4100 A / HIFEN in winter cereals

Intended use		Winter cereals							
Active substance		Thifensulfuron-methyl							
Application rate (g/ha)		1 x 30							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	-	-	-	-	5	10	15	20
None	D1 ditch	0.160	0.160	-	-	-	-	-	-
50 %		0.160	-	-	-	-	-	-	-
None	D1 stream	0.152	0.152	-	-	-	-	-	-
50 %		0.152	-	-	-	-	-	-	-
None	D2 ditch	1.625	1.625	-	-	-	-	-	-
50 %		1.625	-	-	-	-	-	-	-
None	D2 stream	1.027	1.027	-	-	-	-	-	-
50 %		1.027	-	-	-	-	-	-	-
None	D3 ditch	0.051	0.027	-	-	-	-	-	-
50 %		0.026	-	-	-	-	-	-	-
None	D4 stream	0.053	0.028	-	-	-	-	-	-
50 %		0.027	-	-	-	-	-	-	-
None	D5 stream	0.055	0.029	-	-	-	-	-	-
50 %		0.027	-	-	-	-	-	-	-
None	D6 ditch	0.051	0.028	-	-	-	-	-	-
50 %		0.026	-	-	-	-	-	-	-
None	R1 stream	0.138	0.138	-	-	0.084	0.057	0.043	-

50 %		0.138	-	-	-	0.084	0.057	-	-
None	R3 stream	0.303	0.303	-	-	0.194	0.134	0.102	0.069
50 %		0.303	-	-	-	0.194	0.134	0.102	-
None	R4 stream	0.199	0.199	-	-	0.130	0.090	0.069	0.047
50 %		0.199	-	-	-	0.130	0.090	0.069	-
RAC (µg/L)		PEC/RAC ratio							
0.023									
None	D1 ditch	6.957	6.957	-	-	-	-	-	-
50 %		6.957	-	-	-	-	-	-	-
None	D1 stream	6.609	6.609	-	-	-	-	-	-
50 %		6.609	-	-	-	-	-	-	-
None	D2 ditch	70.652	70.652	-	-	-	-	-	-
50 %		70.652	-	-	-	-	-	-	-
None	D2 stream	44.652	44.652	-	-	-	-	-	-
50 %		44.652	-	-	-	-	-	-	-
None	D3 ditch	2.217	1.174	-	-	-	-	-	-
50 %		1.13	-	-	-	-	-	-	-
None	D4 stream	2.304	1.217	-	-	-	-	-	-
50 %		1.174	-	-	-	-	-	-	-
None	D5 stream	2.391	1.261	-	-	-	-	-	-
50 %		1.174	-	-	-	-	-	-	-
None	D6 ditch	2.217	1.217	-	-	-	-	-	-
50 %		1.13	-	-	-	-	-	-	-
None	R1 stream	6.00	6.00	-	-	3.652	2.478	1.87	-
50 %		6.00	-	-	-	3.652	2.478	-	-
None	R3 stream	13.174	13.174	-	-	8.435	5.826	4.435	3.00
50 %		13.174	-	-	-	8.435	5.826	4.435	-
None	R4 stream	8.652	8.652	-	-	5.652	3.913	3.00	2.043
50 %		8.652	-	-	-	5.652	3.913	3.00	-

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

Table 9.5-6: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Thifensulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of SHA 4100 A / HIFEN in winter cereals (VFSSMOD Step 4)

Intended use		Winter cereals	
Active substance		Thifensulfuron-methyl	
Application rate (g/ha)		1 x 30	
Nozzle reduction	No-spray buffer (m)	5	10
	Vegetated filter strip (m)	5	10
None	R1 stream	0.046	-
50 %		-	-
None	R3 stream	0.065	0.034
50 %		0.032	-
None	R4 stream	0.046	-
50 %		-	-
RAC (µg/L) 0.023	PEC/RAC ratio		
None	R1 stream	2.00	-
50 %		-	-
None	R3 stream	2.826	1.478
50 %		1.391	-
None	R4 stream	2.00	-
50 %		-	-

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

Unacceptable risk was identified for R1 and R3 that are relevant scenarios in Poland for aquatic plants RAC = 0.023 µg/L, further risk assessment will be conducted based refinement accepted in Thifensulfuron-methyl Renewal Assessment Report. New RAC for aquatic plants was set as based on available Thifensulfuron methyl data for aquatic macrophytes. Geomean approach was used for most sensitive monocotyledons endpoints. Resulting new RAC for aquatic plants to be 0.05 µg a.s./L for use in a tier 2A assessment.

Updated STEP 3 and step 4 calculations are presented below.

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Thifensulfuron-methyl for aquatic plants on FOCUS Steps 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Aquatic plants
Test species		<i>Most sensitive monocotyledons</i>
Endpoint		E _r C ₅₀

Group		Aquatic plants
(µg/L)		0.5
AF		10
RAC (µg/L)		0.05
FOCUS Scenario	PEC _{gl-max} (µg/L)	
Step 3		
D1/ditch	0.205	4.10
D1/stream	0.171	3.42
D2/ditch	1.625	32.50
D2/stream	1.027	20.54
D3/ditch	0.190	3.80
D4/pond	0.007	0.14
D4/stream	0.145	2.90
D5/pond	0.007	0.14
D5/stream	0.150	3.00
D6/ditch	0.189	3.78
R1/pond	0.007	0.14
R1/stream	0.138	2.76
R3/stream	0.303	6.06
R4/stream	0.199	3.98

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

For D4 pond, D5 pond, R1 pond FOCUS scenarios acceptable risk was identified. Further calculations are shown for Step 4 assuming reduced emission to water bodies due to use of buffer strips.

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Thifensulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of SHA 4100 A / HIFEN in winter cereals

Intended use		Winter cereals							
Active substance		Thifensulfuron-methyl							
Application rate (g/ha)		1 x 30							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	-	-	-	-	5	10	15	20
None	D1 ditch	0.160	0.160	-	-	-	-	-	-

50 %		0.160	-	-	-	-	-	-	-
None	D1 stream	0.152	0.152	-	-	-	-	-	-
50 %		0.152	-	-	-	-	-	-	-
None	D2 ditch	1.625	1.625	-	-	-	-	-	-
50 %		1.625	-	-	-	-	-	-	-
None	D2 stream	1.027	1.027	-	-	-	-	-	-
50 %		1.027	-	-	-	-	-	-	-
None	D3 ditch	0.051	0.027	-	-	-	-	-	-
50 %		0.026	-	-	-	-	-	-	-
None	D4 stream	0.053	0.028	-	-	-	-	-	-
50 %		0.027	-	-	-	-	-	-	-
None	D5 stream	0.055	0.029	-	-	-	-	-	-
50 %		0.027	-	-	-	-	-	-	-
None	D6 ditch	0.051	0.028	-	-	-	-	-	-
50 %		0.026	-	-	-	-	-	-	-
None	R1 stream	0.138	0.138	-	-	0.084	0.057	0.043	-
50 %		0.138	-	-	-	0.084	0.057	-	-
None	R3 stream	0.303	0.303	-	-	0.194	0.134	0.102	0.069
50 %		0.303	-	-	-	0.194	0.134	0.102	-
None	R4 stream	0.199	0.199	-	-	0.130	0.090	0.069	0.047
50 %		0.199	-	-	-	0.130	0.090	0.069	-
RAC (µg/L)									
0.05		PEC/RAC ratio							
None	D1 ditch	3.2	3.2	-	-	-	-	-	-
50 %		3.2	-	-	-	-	-	-	-
None	D1 stream	3.04	3.04	-	-	-	-	-	-
50 %		3.04	-	-	-	-	-	-	-
None	D2 ditch	32.5	32.5	-	-	-	-	-	-
50 %		32.5	-	-	-	-	-	-	-
None	D2 stream	20.54	20.54	-	-	-	-	-	-
50 %		20.54	-	-	-	-	-	-	-
None	D3 ditch	1.02	0.54	-	-	-	-	-	-
50 %		0.52	-	-	-	-	-	-	-
None	D4 stream	1.06	0.56	-	-	-	-	-	-
50 %		0.54	-	-	-	-	-	-	-
None	D5 stream	1.1	0.58	-	-	-	-	-	-

50 %		0.54	-	-	-	-	-	-	-
None	D6 ditch	1.02	0.56	-	-	-	-	-	-
50 %		0.52	-	-	-	-	-	-	-
None	R1 stream	2.76	2.76	-	-	1.68	1.14	0.86	-
50 %		2.76	-	-	-	1.68	1.14	-	-
None	R3 stream	6.06	6.06	-	-	3.88	2.68	2.04	1.38
50 %		6.06	-	-	-	3.88	2.68	2.04	-
None	R4 stream	3.98	3.98	-	-	2.6	1.8	1.38	0.94
50 %		3.98	-	-	-	2.6	1.8	1.38	-

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

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Thifensulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of SHA 4100 A / HIFEN in winter cereals (VFSSMOD Step 4)

Intended use		Winter cereals	
Active substance		Thifensulfuron-methyl	
Application rate (g/ha)		1 x 30	
Nozzle reduction	No-spray buffer (m)	5	10
	Vegetated filter strip (m)	5	10
None	R1 stream	0.046	-
50 %		-	-
None	R3 stream	0.065	0.034
50 %		0.032	-
None	R4 stream	0.046	-
50 %		-	-
RAC (µg/L) 0.05	PEC/RAC ratio		
None	R1 stream	0.92	-
50 %		-	-
None	R3 stream	1.3	0.68
50 %		0.64	-
None	R4 stream	0.92	-
50 %		-	-

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

Metabolites of Thifensulfuron-methyl

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-L9225 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Fish acute	Inverteb. acute	Algae	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		LC ₅₀ 120000	EC ₅₀ 130000	E _r C ₅₀ /E _y C ₅₀ 33400	EC ₅₀ 36760
AF		100	100	10	10
RAC (µg/L)		1200	1300	3340	3676
FOCUS Scenario	PEC _{gl-max} (µg/L)				
Step 1					
	20.28	0.02	0.02	0.01	0.01
Step 2					
N-Europe Oct-Feb	5.94	0.005	0.005	0.002	0.002
S-Europe Oct-Feb	4.81	0.004	0.004	0.001	0.001

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-L9223 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information
Test species		<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		EC ₅₀ 1200	NOEC 13000	E _r C ₅₀ /E _y C ₅₀ 1300	EC ₅₀ 172100
AF		100	10	10	10
RAC (µg/L)		12	1300	130	17210
FOCUS Scenario	PEC _{gl-max} (µg/L)				
Step 1					
	20.28	1.69	0.02	0.16	0.001
Step 2					

Group		Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information
N-Europe Oct-Feb	5.94	0.50	0.005	0.05	0.0003
S-Europe Oct-Feb	4.81	0.40	0.004	0.04	0.0003

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

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-JZ789 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Fish acute	Inverteb. acute	Algae	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		LC ₅₀ 940	EC ₅₀ 1100	E _r C ₅₀ /E _y C ₅₀ 1280	EC ₅₀ 100000
AF		100	100	10	10
RAC (µg/L)		9.4	11	128	10000
FOCUS Scenario	PEC _{max} gl- (µg/L)				
Step 1					
	20.28	2.16	1.84	0.16	0.002
Step 2					
N-Europe Oct-Feb	5.94	0.63	0.54	0.05	0.0006
S-Europe Oct-Feb	4.81	0.51	0.44	0.04	0.0005

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

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-V7160 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Fish acute	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		LC ₅₀ 1000	EC ₅₀ 1300	NOEC 11000	E _r C ₅₀ /E _y C ₅₀ 11000	EC ₅₀ 100000
AF		100	100	10	10	10
RAC (µg/L)		10	13	1100	1100	10000

Group		Fish acute	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	20.28	2.03	1.56	0.02	0.02	0.002
Step 2						
N-Europe Oct-Feb	5.94	0.59	0.46	0.005	0.005	0.0006
S-Europe Oct-Feb	4.81	0.48	0.37	0.004	0.004	0.0005

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

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-A4098 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Fish acute	Inverteb. acute	Inverteb. prolonged	Algae	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		LC ₅₀	EC ₅₀	NOEC	ErC ₅₀ /EyC ₅₀	EC ₅₀
AF		930	99000	32000	10000	10000
RAC (µg/L)		100	100	10	10	10
FOCUS Scenario	PEC _{gl-max} (µg/L)	9.3	990	3200	1000	1000
Step 1						
	20.28	2.18	0.02	0.01	0.02	0.02
Step 2						
N-Europe Oct-Feb	5.94	0.64	0.006	0.002	0.006	0.006
S-Europe Oct-Feb	4.81	0.52	0.005	0.002	0.005	0.005

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

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-W8268 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Fish acute	Inverteb. acute	Algae	Higher-tier information
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint		LC ₅₀	EC ₅₀	ErC ₅₀ /EyC ₅₀	EC ₅₀

Group		Fish acute	Inverteb. acute	Algae	Higher-tier information
(µg/L)		115000	125000	29900	30300
AF		100	100	10	10
RAC (µg/L)		1150	1250	2990	3030
FOCUS Scenario	PEC _{gl-max} (µg/L)				
Step 1					
	20.28	0.02	0.02	0.01	0.01
Step 2					
N-Europe Oct-Feb	5.94	0.005	0.005	0.002	0.002
S-Europe Oct-Feb	4.81	0.004	0.004	0.002	0.002

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

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-L9226 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Algae	Higher-tier information
Test species		<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		E _r C ₅₀ /E _y C ₅₀	EC ₅₀
AF		89000	170
RAC (µg/L)		10	10
FOCUS Scenario	PEC _{gl-max} (µg/L)	8900	17
Step 1			
	20.28	0.002	1.19
Step 2			
N-Europe Oct-Feb	5.94	0.0007	0.35
S-Europe Oct-Feb	4.81	0.0005	0.28

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

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-A5546 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Algae	Higher-tier information
Test species		<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		E _r C ₅₀ /E _y C ₅₀	EC ₅₀
AF		48000	40400
RAC (µg/L)		10	10
		4800	4040

Group		Algae	Higher-tier information
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 1			
	20.8	0.004	0.005
Step 2			
N-Europe Oct-Feb	5.94	0.001	0.001
S-Europe Oct-Feb	4.81	0.001	0.001

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

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2-acid-3-triuret for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Algae	Higher-tier information
Test species		<i>Pseudokirchn. subcapitata</i>	<i>L. gibba</i>
Endpoint (µg/L)		E _r C ₅₀ /E _y C ₅₀ 100000	EC ₅₀ 100000
AF		10	10
RAC (µg/L)		10000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 1			
	20.28	0.002	0.002
Step 2			
N-Europe Oct-Feb	5.94	0.0006	0.0006
S-Europe Oct-Feb	4.81	0.0005	0.0005

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

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-B5528 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 4100 A / HIFEN in winter cereals

Group		Higher-tier information
Test species		<i>L. gibba</i>
Endpoint (µg/L)		EC ₅₀ 119520
AF		10
RAC (µg/L)		11952
FOCUS Scenario	PEC _{gl-max} (µg/L)	
Step 1		
	20.28	0.002
Step 2		
N-Europe Oct-Feb	5.94	0.0005

Group		Higher-tier information
S-Europe Oct-Feb	4.81	0.0004

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

9.5.3 Overall conclusions

For the intended uses on winter cereals, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant) in few FOCUS Steps 1-3 scenarios (D4/pond, D5/pond, R1/pond). Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} for the other scenario considering reduced exposure of surface water bodies.

However, for all the other scenarios, the calculations did not indicate an acceptable risk for aquatic organisms. Further risk assessment was conducted based on refinement accepted in Thifensulfuron-methyl Renewal Assessment Report. New RAC for aquatic plants was set as based on available Thifensulfuron-methyl data for aquatic macrophytes. Geomean approach was used for most sensitive monocotyledons endpoints. Resulting new RAC for aquatic plants to be 0.05 µg a.s./L for use in a tier 2A assessment. Based on this assessment with consideration PEC_{sw} STEP 4 the following risk mitigation measures are required to surface water bodies.

- for D3 (ditch), D4 (stream), D5 (stream), D6 (ditch) scenarios: 5 meter buffer zone + 50 % drift reduction nozzles or 10 meter buffer zone
- for R1 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip
- for R3 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip +50% drift reduction nozzles or 10 m drift buffer zone + 10 meter vegetative buffer strip
- for R4 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip

SPE3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies

Metabolite of Thifensulfuron-methyl: For all the intended uses on winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

zRMS comment: The evaluation of the risk for aquatic 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” (EFSA Journal 2013;11(7):3290). Acute toxicity studies of **HIFEN** to fish, invertebrates, algae were submitted in this dossier. Evaluator agrees with modelling carried out by Applicant. Predicted environmental concentrations of active substance in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated using the simulation models FOCUS. Applicant used endpoints in accordance EFSA endpoints (Journal 2015; 13(7):4201)

In the RAR of Thifensulfuron-methyl (RAR 11_Vol3_B9-confirmatory data post commenting), a proposal to obtain a geometric mean value from the available studies on aquatic macrophytes was present-ed. The final conclusion by the RMS was the proposal to use a geometric mean ErC50 value of 0.00050 mg a.s./L (equivalent to 0.5 µg a.s./L) in the risk assessment. According to what is indicated in the RAR, this is also the most conservative geometric mean of those that can be derived based on the available data. The ErC50 value of 0.00050 mg a.s./L is obtained from the most sensitive endpoints for monocotyledons species:

- ErC₅₀ = 0.0011 mg a.s./L (frond count, *Lemna gibba*)
- ErC₅₀ = 0.00023 mg a.s./L (shoot height, *Vallisneria americana*)

Both endpoints for *Vallisneria americana* and *Lemna gibba* are included in the update of the List of Endpoints following confirmatory data evaluation

By applying the default assessment factor of 10 to the geomean E_rC_{50} value of 0.5 µg a.s./L, the RAC is 0.05 µg a.s./L which was used in the tier 2A assessment.

Based on RAC of 0.05 µg a.s./L the risk mitigation measures is required for R1 and R3 scenarios. Refined risk based on geomean approach for aquatic macrophytes and VFSmod PEC calculations was also provided and accepted for PL. The refinement risk assessment for aquatic organisms should be considered by MSs level.

Metabolite of Thifensulfuron-methyl:

For all the intended uses on winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Conclusion:

Based on this assessment with consideration PEC_{sw} STEP 4 the following risk mitigation measures are required to surface water bodies.

- for D3 (ditch), D4 (stream), D5 (stream), D6 (ditch) scenarios: 5 meter buffer zone + 50 % drift reduction nozzles or 10 meter buffer zone
- for R1 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip
- for R3 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip +50% drift reduction nozzles or 10 m drift buffer zone + 10 meter vegetative buffer strip
- for R4 (stream) scenario: 5 m drift buffer zone + 5 meter vegetative buffer strip

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies (the worst case for R3 scenario)

PL

D3, D4, R1 scenario are relevant.

SPe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies or an unsprayed buffer zone of 5 m to surface water bodies with 50% of nozzles reduction or an unsprayed buffer zone of 10 m to surface water bodies

The risk assessment for aquatic organisms with risk mitigation measured should be considered by MSs.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Thifensulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the formulation is not considered essential, because active substance toxicity data 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 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Thifensulfuron-methyl	Oral	LD ₅₀ > 7.1 µg a.s./bee	EFSA Journal 2015;13(7):4201
<i>Apis mellifera</i>	Thifensulfuron-methyl	Contact	LD ₅₀ > 100 µg a.s./bee	
<i>Apis mellifera</i>	SHA 4100 A / HIFEN	Oral	LD ₅₀ > 200 µg/bee (equivalent to 150.6 µg a.s./bee)	P. Parma, 2016, report No. B/140/15
<i>Apis mellifera</i>	SHA 4100 A / HIFEN	Contact	LD ₅₀ > 200 µg/bee (equivalent to 150.6 µg a.s./bee)	P. Parma, 2016, report No. B/141/15
<i>Apis mellifera</i>	HIFEN	Chronic adult 10 d	LDD ₅₀ = 10.72 µg/bee (equivalent to 8.06 µg of Thifensulfuron-methyl/bee) NOEDD = 2.6 µg/bee (equivalent to 1.95 µg of Thifensulfuron-methyl/bee)	KCP 10.3.1.2 Mohanraj, M., 2024 Report No. 14183/2023
<i>Apis mellifera</i>	HIFEN	Larval, repeated exposure 22 d	NOED = 1.60 µg/larva (equivalent to 1.20 µg Thifensulfuron-methyl/larva)	KCP 10.3.1.3 Mohanraj, M., 2024 Report No. 14184/2023
Higher-tier studies (tunnel test, field studies)				
Not required.				

9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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 (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of SHA 4100 A / HIF-EN in winter cereals

Intended use	Winter cereals
Active substance	Thifensulfuron-methyl

Application rate (g/ha)		1 x 30	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 7.1	30	4.23
Contact toxicity	> 100		0.30
Product		SHA 4100 A / HIFEN	
Application rate (g/ha)		1 x 40	
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 200	40	0.20
Contact toxicity	> 200		0.20

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

Chronic risk assessment – EFSA 2013

Table 9.6-3 Screening assessment of the acute and chronic risk for bees due to the use of HIFEN in cereals (EFSA Journal 2013; 11(7): 3295)

Intended use	Cereals			
Active substance	Thifensulfuron-methyl			
Application rate (g/ha)	1 x 30			
Contact route of exposure				
	"calculation factor" (linked with dust)	HQ	Trigger	Risk indicator
Honey bee	1	0.2	42	OK
Oral route of exposure (pollen and nectar)				
	"calculation factor" (Ef x SV)	ETR	Trigger	Risk indicator
Honey bee acute	7.6	0.00	0.2	OK
Honey bee chronic	7.6	0.028	0.03	OK
Honey bee larvae	4.4	0.11	0.2	OK
Accumulative effects				
Has the substance a potential for accumulative toxicity (see section 8.1.1.3 and pertinent part of Appendix O in the GD)?			No	

Exposure to contaminated water				
Guttation				
According to the planned implementation, this assessment is not to be used for applications submitted after 31 st January 2018. Also, for application submitted after that date it was noted that “the assessment scheme as such is considered to be acceptable but more information is needed on which crops and under what circumstances guttation droplets are produced and to what extent guttation droplets are used as a water source. It should also be clarified if it is useful to provide water to honeybees as a possible risk mitigation measures”.				
Surface water				
	water consumption (µL)	ETR	Trigger	Risk indicator
acute	11.4	0.00	0.2	OK
chronic	11.4	0.000	0.03	OK
larvae	111	0.00	0.2	OK

Puddle water				
	water consumption (µL)	ETR	Trigger	Risk indicator
acute	11.4	0.00	0.2	OK
chronic	11.4	0.001	0.03	OK
larvae	111	0.09	0.2	OK

The trigger value for adult and larvae toxicity is not exceeded, therefore further refinement is not necessary and acceptable risk for chronic exposure is obtained.

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

Not relevant.

9.6.3 Effects on bumble bees

No data available.

9.6.4 Effects on solitary bees

No data available.

9.6.5 Overall conclusions

First-tier assessments indicate that no unacceptable risk for bees exposed to SHA 4100 A / HIFEN is expected according to the proposed intended uses.

zRMS comment:

The QHO and QHC values for, 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 HIFEN. According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by the applicant. The chronic risk assessment based on chronic studies for bees (adult and larvae) should be performed in line with the EFSA 2013 guideline during the transition period. **The Applicant should provide the chronic risk assessment based on chronic studies for bees (adult and larvae) performed in line with the EFSA 2013 guideline.**

Updated March 2025

The chronic tests for adult bee and larvae were submitted by Applicant.

The screening step risk assessment in line with EFSA (2013) has been performed by the Applicant, using endpoints from submitted studies.

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 its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the SHA 4100 A / HIFEN is not considered essential, because active substance toxicity data can be used.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (protonymphs)	Thifensulfuron methyl 50 SG	Laboratory test glass plates (2D)	LR ₅₀ > 450 g product/ha (equivalent to 227 g a.s./ha)	EFSA Journal 2015;13(7):4201
<i>Aphidius rhopalosiphi</i> (adults)	Thifensulfuron methyl 50 SG	Laboratory test glass plates (2D)	LR ₅₀ > 450 g product/ha (equivalent to 227 g a.s./ha)	
<i>Chrysoperla carnea</i> (larvae)	Thifensulfuron methyl 50 SG	Extended laboratory test	At 450 g product/ha (equivalent to 227 g a.s./ha): Mortality: 18.6% Reproduction: 43%	
<i>Orius laevigatus</i> (nymphs – 2 nd instar)	Thifensulfuron methyl 50 SG	Extended laboratory test	At 450 g product/ha (equivalent to 227 g a.s./ha): Mortality: 5% Reproduction: -2%	
<i>Typhlodromus pyri</i> (protonymphs)	SHA 4100 A / HIF-EN	Laboratory test glass plates (2D)	LR ₅₀ > 80 g product/ha (equivalent to 60.2 g a.s./ha)	P. Parma, 2018, report No. B/138/15
<i>Aphidius rhopalosiphi</i> (adults)	SHA 4100 A / HIF-EN	Laboratory test glass plates (2D)	LR ₅₀ = 23.17 ml product/ha (equivalent to 17.40 g a.s./ha) ER ₅₀ = 21.12 ml product/ha (equivalent to 15.68 g a.s./ha)	Angayarkanni V., 2021 8250/2021
Field or semi-field tests				
Not required.				

9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of SHA 4100 A / HIFEN in winter cereals

Intended use	Winter cereals		
Active substance/product	Thifensulfuron-methyl		
Application rate (g/ha)	1 x 30		
MAF	1.0		
Test species Tier I	LR₅₀ (lab.) (g/ha)	PER_{in-field} (g/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	60.2	30	0.50
<i>Aphidius rhopalosiphi</i>	17.4		1.72
Test species Higher Tier	Rate with ≤ 50 % effect* (g/ha)	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Chrysoperla carnea</i>	227	30	Yes
<i>Orius laevisgatus</i>	227		Yes

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 LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of SHA 4100 A / HIFEN in winter cereals

Intended use	Winter cereals				
Active substance/product	Thifensulfuron-methyl				
Application rate (g/ha)	1 x 30				
MAF	1.0				
vdf	10 (Tier 1)				
Test species Tier I	LR₅₀ (lab.) (g/ha)	Drift rate	PER_{off-field} (g/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	60.2	2.77	0.08	10	0.013
<i>Aphidius rhopalosiphi</i>	17.4				0.005

Test species Higher Tier	Rate with $\leq 50\%$ effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	PER _{off-field} below rate with $\leq 50\%$ effect?
<i>Chrysoperla carnea</i>	227	2.77	0.08	5	Yes
<i>Orius laevigatus</i>	227				Yes

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 LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with $\leq 50\%$ effect.

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

The in-field and off-field HQ values calculated for the product SHA 4100 A / HIFEN for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use pattern. In addition, the PER in- and off-field values are below rate with $\leq 50\%$ effect for two species *Chrysoperla carnea* and *Orius laevigatus* indicating an acceptable risk in-field and off-field for these species.

zRMS comments: Agreed.

The risk to non-target arthropods is considered to be from exposure to the formulation **HIFEN**. The risk from the formulation **HIFEN** based on the results from laboratory studies for indicator species *T.pyri* and *A.rhopalosiphi* indicating an acceptable in-field risk as the HQ-in field values were <2 . The off-field risk for this species are considered an acceptable as the HQ-off field values were <2 . In addition, the PER in- and PER off-field values are below rate with $\leq 50\%$ effect for two additional species such as *Chrysoperla carnea* and *Orius laevigatus* indicating an acceptable risk in-field and off-field.

No refinement risk assessment is required. The risk assessment for non-target arthropods other than bees should be considered by MSs level.

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 Thifensulfuron-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 SHA 4100 A /

HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the SHA 4100 A / HIFEN is not considered essential, because active substance toxicity data 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 9.8-1: 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	Reference
<i>Eisenia fetida</i>	IN-A4098	56 d, chronic	NOEC = 0.2 mg/kg dw	EFSA Journal 2015;13(7):4201
<i>Eisenia fetida</i>	IN-A4098	56 d, chronic	NOEC = 0.202 mg/kg dw	
<i>Eisenia fetida</i>	IN-A4098	56 d, chronic	NOEC = 8.0 mg/kg dw	
<i>Eisenia fetida</i>	IN-L9223	56 d, chronic	NOEC = 10 mg/kg dw	
<i>Eisenia fetida</i>	IN-L9225	56 d, chronic	NOEC = 0.4 mg/kg dw	
<i>Eisenia fetida</i>	IN-L9225	56 d, chronic	NOEC = 8.0 mg/kg dw	
<i>Eisenia fetida</i>	IN-W8268	56 d, chronic	NOEC = 80 mg/kg dw	
<i>Eisenia fetida</i>	IN-W8268	56 d, chronic	NOEC = 8.0 mg/kg dw	
<i>E. fetida</i>	SHA 4100 A / HIFEN	8 weeks	NOEC = 18 mg/kg dw EC ₁₀ = 82.5 mg/kg dw	M. Knapik, 2016, report No. G/257/15
Other soil macro-organisms				
<i>F. candida</i>	IN-A4098	28 d, chronic	NOEC = 0.045 mg/kg dw	EFSA Journal 2015;13(7):4201
<i>H. aculeifer</i>	IN-A4098	14 d, chronic	NOEC = 31.7 mg/kg dw	
<i>F. candida</i>	IN-L9223	28 d, chronic	NOEC = 100 mg/kg dw	
<i>F. candida</i>	IN-L9225	28 d, chronic	NOEC = 100 mg/kg dw	
<i>H. aculeifer</i>	IN-L9225	14 d, chronic	NOEC = 10 mg/kg dw NOEC = 100 mg/kg dw	
<i>F. candida</i>	IN-W8268	28 d, chronic	NOEC = 100 mg/kg dw	
<i>H. aculeifer</i>	IN-W8268	14 d, chronic	NOEC = 50 mg/kg dw	
<i>F. candida</i>	SHA 4100 A / HIFEN	28 d, chronic	NOEC = 32 mg/kg dw EC₁₀ = 16.5 mg/kg dw	M. Knapik, 2016, report No. G/258/15
<i>H. aculeifer</i>	SHA 4100 A / HIFEN	14 d, chronic	EC₁₀ = 558.24 mg/kg dw NOEC = 751 mg/kg dw	Angayarkanni V, 2021 Study code: 8249/2021
Field studies				
Not required.				
Litter bag test				
Not required.				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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.

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 SHA 4100 A / HIFEN in winter cereals

Intended use	Winter cereals		
Chronic effects on earthworms			
Product/active substance	NOEC/ EC ₁₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IN-A4098	0.2	0.011	18
IN-L9223	10	0.008	1250
IN-L9225	0.4	0.038	11
IN-W8268	8.0	0.002	4000
SHA 4100 A / HIFEN	18	0.053	340
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC/ EC ₁₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IN-A4098 (<i>F. candida</i>)	0.045	0.0013*	35
IN-L9223 (<i>F. candida</i>)	100	0.008	12500
IN-L9225 (<i>F.candida</i>)	100	0.038	2632
IN-W8268 (<i>F.candida</i>)	100	0.002	50000
IN-A4098 (<i>H.aculeifer</i>)	31.7	0.011	2882
IN-L9225 (<i>H.aculeifer</i>)	10	0.038	263
IN-W8268 (<i>H.aculeifer</i>)	50	0.002	25000
SHA 4100 A / HIFEN (<i>F. candida</i>)	16.5	0.053	311
SHA 4100 A / HIFEN (<i>H.aculeifer</i>)	558.24	0.053	10533

TER values shown in bold fall below the relevant trigger.

* refined PEC_{soil} for metabolite IN-A4098, considering peak occurrence (32.3%) and molecular weight.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The acute and chronic TER for Thifensulfuron-methyl were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance does not pose an acute and long-term risk to earthworms and other soil-macro- and mesofauna when applied according to the proposed uses rates.

zRMS comment:

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance, their metabolites and for product **HIFEN** are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product **HIFEN**.

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 and toxicity endpoints agreed in EFSA Conclusion 2015.

All TER_{LT} values for active substance and its metabolites and also for the product **HIFEN** are above trigger of 5, indicating 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-3-triuret are available.

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

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

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 HIFEN 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	0.040	57.75
JZ789	0.231	0.007	33
2-acid-3-triuret	0.231	0.007	33
Chronic effects on other soil macro- and mesofauna <i>Folsomia candida</i>			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IN-W8268 (<i>F. candida</i>)	100	0.002	50 000
Chronic effects on other soil macro- and mesofauna <i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
IN-A4098	100	0.0013	76923.08
IN-L9225	100	0.038	2631.58
SHA 4100 A / HIFEN (<i>H.aculeifer</i>)	558.24	0.053	10532.83

**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: K_{OC} TSM = 19.9

TER_{LT} values are above the trigger of 5 for both active substance and its metabolites and ppp HIF-EN indicating an acceptable risk.

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 Thifensulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Thifensulfuron-methyl	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 400 g/ha	EFSA Journal 2015;13(7):4201
N-mineralisation	IN-A4098	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.125 mg/kg dw	
N-mineralisation	IN-A4098	42 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.204 mg/kg dw	
N-mineralisation	IN-A5546	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.827 mg/kg dw	
N-mineralisation	IN-JZ789	28 d, aerobic	51.6% deviation from the control at 0.1 mg/kg soil 48.8% deviation at 1.0 mg/kg soil (study not extended)	
N-mineralisation	IN-L9223	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 1.0 mg/kg dw	
N-mineralisation	IN-L9223	42 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.849 mg/kg dw	
N-mineralisation	IN-L9225	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.42 mg/kg dw	
N-mineralisation	IN-L9225	42 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.413 mg/kg dw	
N-mineralisation	IN-L9226	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.39 mg/kg dw	

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	IN-L9226	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.827 mg/kg dw	
N-mineralisation	IN-V7160	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.843 mg/kg dw	
N-mineralisation	IN-W8268	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 0.20 mg/kg dw	
N-mineralisation	IN-W8268	56 d, chronic	Rate at which there was less than 25% deviation from the control = 0.8 mg/kg dw	
N-mineralisation	2-acid-3-triuret	28 d, aerobic	Rate at which there was less than 25% deviation from the control = 1.0 mg/kg dw	
N-mineralisation	SHA 4100 A / HIFEN	28 d, aerobic	No adverse effect at 0.053 and 0.27 mg/kg dw	M. Knapik, 2016, report No. G/256/15

9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of SHA 4100 A / HIFEN 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	400 g/ha (at 28 d)	0.040	yes
IN-A4098	0.125 (at 28 d)	0.011	yes
IN-A5546	0.827 (at 42 d)	0.006	yes
IN-JZ789	1.0 (at 28 d)	0.007	yes
IN-L9223	0.849 (at 42 d)	0.008	yes
IN-L9225	0.413 (at 42 d)	0.038	yes
IN-L9226	0.39 (at 28 d)	0.007	yes
IN-V7160	0.843 (at 28 d)	0.006	yes
IN-W8268	0.2 (at 28 d)	0.002	yes
2-acid-3-triuret	1.0 (at 28 d)	0.007	yes
SHA 4100 A / HIFEN	0.27 (at 28 d)	0.053	yes

9.9.3 Overall conclusions

Risk assessments conducted with relevant PEC_{soil} for active substance Thifensulfuron-methyl and its relevant metabolites and in SHA 4100 A / HIFEN formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

zRMS comments:

Agreed. The risk assessment for soil micro-organism after exposure of both active substances and their metabolites was accepted by the zRMS with consideration 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 substance and the product HEIFEN.

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 its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of SHA 4100 A / HIFEN were not evaluated as part of the EU assessment of Thifensulfuron-methyl.

However, the provision of further data on the formulation is not considered essential, because active substance toxicity data 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 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
<i>Beta vulgaris</i>	Thifensulfuron methyl 50 SG	Seedling emergence	ER ₅₀ emergence = 0.606 g a.s./ha	EFSA Journal 2015;13(7):4201
<i>Beta vulgaris</i>	Thifensulfuron methyl 50 SG	Vegetative vigour	ER ₅₀ vegetative vigour = 0.613 g a.s./ha*	
<i>Sunflower</i> <i>Corn</i> <i>Pea*</i> <i>Oilseed rape</i> <i>Oats</i> <i>Tomatto</i>	SHA 4100 A / HIFEN	Seedling emergence	ER ₅₀ = 6.10 g/ha (4.58 g a.s./ha)	KCP 10.6.2-01 Radha S., 2021
<i>Sunflower</i> <i>Corn</i> <i>Pea</i> <i>Oilseed rape</i> <i>Oats</i> <i>Tomatto</i>	SHA 4100 A / HIFEN	Vegetative vigour	ER ₅₀ = 6.04 g/ha (4.54 g a.s./ha)	KCP 10.6.2-02 Radha S., 2021

m: monocotyledonous; d: dicotyledonous

*: endpoint from testing with the a.s.

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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”, (SAN-CO/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 SHA 4100 A / HIFEN in winter cereals

Intended use	Winter cereals
Active substance/product	Thifensulfuron-methyl

Application rate (g/ha)		1 x 30		
MAF		1.0		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Pea</i> SE	4.58	0.0277	0.831	~~6.41~~ 5.51
<i>Oats</i> VV	4.54	0.0277	0.831	~~6.36~~ 5.46

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The risk to non-target plants for HIFEN is considered to be acceptable when applied according to the proposed use rates.

zRMS comment:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/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 ER₅₀ = 4.54 g a.s./ha value as a toxicity endpoint proposed by the Applicant from vegetative vigour test and PER_{off-field}, indicated no needs for further refinement. The risk mitigation measures are not necessary. The risk assessment for non-target plants should be considered by MSs level.

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

Test type/organism	Total respiration (mg a.s./L)	Heterotrophic respiration (mg a.s./L)	Nitrification respiration (mg a.s./L)
Activated sludge	> 1000	-	-
Activated sludge	871.3	849.1	494.8

The result from the activated sludge studies indicate that microbial activity in such systems is at low risk from Thifensulfuron-methyl. Contamination of sewage treatment systems via agricultural use of Thifensulfuron-methyl in the representative formulations is considered to be low.

zRMS comments:

Agreed.

9.12 Monitoring data (KCP 10.8)

No data available.

9.13 Classification and Labelling

	SHA 4100 A / HIFEN
Common Name	SHA 4100 A / HIFEN
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	H410 with pictogram GHS09 is proposed.

zRMS comments:

Agreed..

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 10.2.1-01	■	2016	Thifensulfuron 75% WDG rainbow trout, acute toxicity tests ■	N	SHARDA Cropchem Limited
KCP 10.2.1-02	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Daphnia magna, acute immobilization test Institute of Industrial Organic Chrmistry, Branch Pszczyna report No.W/165/16 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.2.1-03	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Pseudokirchneriella subcapitata SAG 61.81 growth inhibition tests Institute of Industrial Organic Chrmistry, Branch Pszczyna report No.W/164/16 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.2.1-04	Ewa Nierzedzka	2016	Thifensulfuron 75% WDG Lemna gibba CPCC 310, growth inhibition tests Institute of Industrial Organic Chrmistry, Branch Pszczyna report No.W/166/16 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Pawel Parma	2016	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute oral toxicity test Institute of Industrial Organic Chrmistry, Branch Pszczyna report No.B/140/15 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Pawel Parma	2016	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute contact toxicity test Institute of Industrial Organic Chrmistry, Branch Pszczyna report No.B/141/15 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP	Mohanraj, M.	2024	Chronic Oral Toxicity Study of Thifensulfuron-methyl 75% WDG on adult honey bee (<i>Apis mellifera</i>)	N	SHARDA

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
10.3.1.2			Bioscience Research Foundation. Report No.: 14183/2023 GLP/Unpublished		Cropchem Limited
KCP 10.3.1.3	Mohanraj, M.	2024	Effect of Thifensulfuron-methyl 75% DWG on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure Bioscience Research Foundation. Report No.: 14184/2023 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.3-01	Pawel Parma	2018	A laboratory test for evaluating the effects of Thifensulfuron 75% WDG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Institute of Industrial Organic Chemistry, Branch Pszczyna report No.B/138/15 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.3.2.1-02	Angayarkanni V.	2021	A laboratory test for evaluating the effects of Thifensulfuron-methyl 75% WDG on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani - Perez) Study code: 8250/2021 Bioscience Research Foundation GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.4.1.1	Marta Knapik	2016	Thifensulfuron-methyl 75% WDG, earthworm reproduction test (<i>Eisenia fetida</i>) Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/257/15 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Marta Knapik	2016	Thifensulfuron-methyl 75% WDG, Collembolan (<i>Folsomia candida</i>) Reproduction test Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/258/15 GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.4.2.1-02	Angayarkanni V.	2021	Effects of Thifensulfuron-methyl 75% WDG on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil Study code: 8249/2021 Bioscience Research Foundation GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.5	Weronika Dec	2016	Thifensulfuron-methyl 75% WDG Soil microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry, Branch Pszczyna report No. G/256/15 GLP/Unpublished	N	SHARDA Cropchem Limited

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 10.6.2-01	Radha S.	2021	Effect of Thifensulfuron-methyl 75% WDG on vegetative vigour of terrestrial plants Study code: 8248/2020 Bioscience Research Foundation GLP/Unpublished	N	SHARDA Cropchem Limited
KCP 10.6.2-02	Radha S.	2021	Effect of Thifensulfuron-methyl 75% WDG on seedling emergence and seedling growth of terrestrial plants Study code: 8247/2020 Bioscience Research Foundation GLP/Unpublished	N	SHARDA Cropchem Limited

The following tables are to be completed by MS

List of data submitted by the applicant and not 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

List of data relied on not submitted by the applicant but necessary for evaluation

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

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

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

A 2.2.1.1.1 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. - the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used); - dissolved oxygen concentrations were within the range of 91 – 99% of air saturation value (obligatory above 60% of air saturation value). Agreed endpoints: The LC₅₀/96 h = 78.30 mg/L (with 95% confidence limits: 50.37 – 121.92) The LOEC/96 h = 206.61 g/L The NOEC/96 h = 93.91 mg/L The LC₅₀/96 h = 58.93 mg a.s./L (with 95% confidence limits: 37.90 – 91.78) The LOEC/96 h = 155.60 mg a.s./L The NOEC/96 h = 70.70 mg a.s./L
-------------------	---

Reference:	KCP 10.2.1-01
Report	Thifensulfuron 75% WDG rainbow trout, acute toxicity tests, Ewa Nierzedzka, 2016, report No. W/109/16
Guidelines	Yes, OECD guideline No. 203
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The acute toxicity study of the test item, Thifensulfuron 75% WDG on the rainbow trout, *Oncorhynchus mykiss* Walb. was conducted as a static test. Approximately 3 months old rainbow trout were exposed to a test item concentrations of 1000, 454.54, 206.61, 93.91, 42.69, 19.40 mg/L plus control. The test vessels were glass aquaria with a capacity of 10 L. There was one replicate of each test item concentration and the control. Seven fish were introduced into each aquarium. The fish were observed for mortality and intoxication symptoms after 3, 6, 24, 48, 72 and 96 h of exposure.

Test item:	Thifensulfuron 75% WDG; batch number: SWEPL - 13205; purity: 75.3% m/m; manufacturing date: June 25, 2015; expiry date: June 24, 2017.
Test organism:	Rainbow trout (<i>Oncorhynchus mykiss</i>), age: approximately 3 months, average weight: 1.28 g $\pm$ 0.21 g, average body length: 4.64 cm $\pm$ 0.28 cm, supplier: Hodowla Ryb Łososiowatych, Zawoja, Poland.
Test design:	Static system (96 hours), one replicate of seven fish for each test item concentration and the control, fish loading: 0.90 g/L.
Nominal test item concentrations:	1000, 454.54, 206.61, 93.91, 42.69, 19.40 mg/L plus the control.
Nominal concentration of Thifensulfuron-methyl in the test item:	753.0, 342.3, 155.6, 70.7, 32.1, 14.6 mg/L plus the control.
Test conditions:	Temperature: 14.3 – 15.2 °C; pH of the control: 7.04 – 7.28; oxygen concentration in the control: 92 – 97% of the air saturation value; daily cycle: 16 h day : 8 h night, no feeding, constant aeration.

Chemical determinations: The concentrations of the test item were chemically determined with a validated liquid chromatographic method with DAD detection.

Endpoint values: LC₅₀, LOEC, and NOEC

Results and conclusion

Chemical results:

Nominal test item concentration [mg/L]	Nominal concentration of thifensulfuron methyl [mg/L]	Mean concentration (n=3) of the test item measured in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	0.000	<LoD	--	<LoD	--
19.40	14.6	19.570	100.88	19.330	99.64
42.69	32.1	41.884	98.11	41.419	97.02
93.91	70.7	95.304	101.48	95.178	101.35
206.61	155.6	211.482	102.36	215.772	104.43
454.54	342.3	452.952	99.65	443.528	97.58
1000	753.0	989.737	98.97	995.247	99.52

LOQ = 0.002 mg/L

LOD = 0.001 mg/L

Intoxicant test

Nominal test item concentration [mg/L]	Symptoms	Time of exposure					
		3 h	6 h	24 h	48 h	72 h	96 h
Control	UR	7 NN	7 NN	7 NN	7 NN	7 NN	7 NN
	SP	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
	FO	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
	U	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
19.40	UR	7 NN	7 NN	7 NN	7 NN	7 NN	7 NN
	SP	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
	FO	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
	U	7 NR	7 NR	7 NR	7 NR	7 NR	7 NR
42.69	UR	7 NN	7 NN	7 NN	6 NN	6 NN	6 NN
	SP	7 NR	7 NR	7 NR	6 NR	6 NR	6 NR
	FO	7 NR	7 NR	7 NR	6 NR	6 NR	6 NR
	U	7 NR	7 NR	7 NR	6 NR	6 NR	6 NR
93.91	UR	7 NN	7 NN	7 NN	4 NN	4 NN	3 NN
	SP	7 NR	7 NR	1 U 6 NR	4 NR	4 NR	3 NR
	FO	7 NR	7 NR	5 F 2 NR	4 F	4 F	3 F
	U	7 NR	7 NR	7 NR	4 NR	4 NR	3 NR
206.61	UR	7 NN	1 T 4 NN	--	--	--	--
	SP	7 NR	5 U	--	--	--	--
	FO	7 F	5 F	--	--	--	--
	U	7 NR	5 NR	--	--	--	--
454.54	UR	--	--	--	--	--	--
	SP	--	--	--	--	--	--
	FO	--	--	--	--	--	--
	U	--	--	--	--	--	--
1000	UR	--	--	--	--	--	--
	SP	--	--	--	--	--	--
	FO	--	--	--	--	--	--
	U	--	--	--	--	--	--
Symptoms:		UR – loss of equilibrium					
		SP – swimming behaviour					
		FO – respiratory functions					
		U – pigmentation					
		NN – no, T – yes					
		NR – normal, U – unbalanced					
		NR – normal, F – faulty, problems					
		NR – normal, NT – untypical					

Mortality;

Nominal test item concentration [mg/L]	Number of fish	Number of dead fish						Total mortality [%]
		3 h	6 h	24 h	48 h	72 h	96 h	
Control	7	0	0	0	0	0	0	0
19.40	7	0	0	0	0	0	0	0
42.69	7	0	0	0	1	1	1	14.3
93.91	7	0	0	0	3	3	4	57.1
206.61	7	0	2	7	7	7	7	100
454.54	7	7	7	7	7	7	7	100
1000	7	7	7	7	7	7	7	100

Time of exposure: 12.09.2016 – 16.09.2016.

The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:

The LC₅₀/96 h is 78.30 mg/L (with 95% confidence limits: 50.37 – 121.92)

The LOEC/96 h is 206.61 mg/L.

The NOEC/96 h is 93.91 mg/L.

The endpoint values determined on the basis of the nominal concentration of Thifensulfuron-methyl in the test item and mortality of fish are given below:

The LC₅₀/96 h is 58.93 mg/L (with 95% confidence limits: 37.90 – 91.78).

The LOEC/96 h is 155.60 mg/L.

The NOEC/96 h is 70.70 mg/L.

A 2.2.1.1.2 Study 2

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	- the percentage of immobilization of <i>Daphnia magna</i> in the control was 0% (criterion: not more than 10%), - the concentrations of oxygen in the test vessels were within the range of 8.3 – 8.6 mg/L (criterion: not less than 3 mg/L). Agreed endpoints: The EC₅₀/48 h =142.49 mg/L The LOEC/48 h =145.45 mg/L The NOEC/48 h =66.12 mg/L The EC₅₀/48 h = 107.37 mg a.s./L The LOEC/48 h =109.52 mg a.s./L The NOEC/48 h =49.79 mg a.s. /L

Reference:	KCP 10.2.1-02
Report	Thifensulfuron 75% WDG <i>Daphnia magna</i> , acute immobilization test, Ewa Nierzedzka, 2016, report No. W/165/16
Guidelines:	Yes, OECD guidelines No. 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

Immobilization of *Daphnia magna* exposed to the test item Thifensulfuron 75% WDG was investigated during a 48-hour static test. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of each treatment per replicate. Nine nominal test item concentrations, i.e.: 320, 145.45, 66.12, 30.05, 13.66, 6.21, 2.82, 1.28, and 0.58 mg/L and the control were used. Four replicates of the test item concentration and the control with five *Daphnia magna* per replicate were used.

Test item:	Thifensulfuron 75% WDG; batch number: SWEPL - 13205; purity: 75.3% m/m; manufacturing date: June 25, 2015; expiry date: June 24, 2017.
Test organism:	<i>Daphnia magna</i> Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from the laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.
Test design:	Static test (48 hours); four replicates per treatment, five <i>Daphnia magna</i> in each replicate.
Nominal test item concentrations:	320, 145.45, 66.12, 30.05, 13.66, 6.21, 2.82, 1.28, and 0.58 mg/L plus the control.
Nominal concentration of Thifensulfuron-methyl:	240.96, 109.52, 49.79, 22.63, 10.29, 4.68, 2.12, 0.96, and 0.44 mg/L plus the control.
Test conditions:	Temperature: 20.1 – 21.3°C; pH of the control: 7.18 – 7.45; oxygen concentration: 8.3 – 8.6 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration.
Chemical determinations:	The concentrations of the test item were chemically determined with a validated liquid chromatographic method with DAD.
Statistical analysis:	Fisher Exact Binomial Test with Bonferroni Correction
Endpoint values:	EC ₅₀ , NOEC, and LOEC.

Results and conclusion

Immobilisation:

Nominal test item concentration [mg/L]	Number of tested organisms	Number of immobilized <i>Daphnia magna</i>								Total immobilization [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
0.58	20	0	0	0	0	0	0	0	0	0	0
1.28	20	0	0	0	0	0	0	0	0	0	0
2.82	20	0	0	0	0	0	0	0	0	0	0
6.21	20	0	0	0	0	0	0	0	0	0	0
13.66	20	0	0	0	0	0	0	0	0	0	0
30.05	20	0	0	0	0	0	0	0	0	0	0
66.12	20	0	0	0	0	0	0	0	0	0	0
145.45	20	0	0	0	1	4	3	2	2	5	55
320	20	5	4	4	3	5	5	5	5	80	100

Time of exposure: 12.10.2016 – 14.10.2016

Concentration of the test item during the test.

Nominal test item concentration [mg/L]	Nominal concentration of tifensulfuron methyl [mg/L]	Mean concentration (n=3) of the test item measured in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	0.000	0.000	--	0.000	--
0.58	0.44	0.556	95.9	0.582	100.3
1.28	0.96	1.311	102.4	1.322	103.3
2.82	2.12	2.955	104.8	2.969	105.3
6.21	4.68	6.572	105.8	6.494	104.6
13.66	10.29	14.157	103.6	14.124	103.4
30.05	22.63	30.591	101.8	30.770	102.4
66.12	49.79	67.540	102.1	66.249	100.2
145.45	109.52	147.187	101.2	149.773	103.0
320	240.96	338.487	105.8	320.839	100.3

LoQ = 0.002 mg/L
LoD = 0.001 mg/L

The endpoint values determined based on the nominal test item concentration after 48 h of exposure are given below:

The EC₅₀/48 h is 142.49 mg/L.

The LOEC/48 h is 145.45 mg/L.

The NOEC/48 h is 66.12 mg/L.

The endpoint values determined based on the nominal concentration of Thifensulfuron-methyl in the test item after 48 h of exposure are given below:

The EC₅₀/48 h is 107.37 mg/L.

The LOEC/48 h is 109.52 mg/L.

The NOEC/48 h is 49.79 mg/L.

A 2.2.1.1.3 Study 3

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	- the biomass in the control increased by a factor of 111.0 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (the exposure initiation – the exposure termination) in the control culture was 1.4% (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 23.9% (criterion: it must not exceed 35%).
	Agreed endpoints: The endpoint values determined on the basis of the nominal test item concentra-

	tions are given below: The concentration causing a 50% inhibition of the growth rate of <i>Pseudokirchneriella subcapitata</i>, i.e. the $E_rC_{50}/72$ h value is 10.69 mg/L (95% confidence limits: 9.42 - 12.16) $E_rC_{20}/72$ h value is 1.55 mg/L (95% confidence limits: 1.25 – 1.86), $E_rC_{10}/72$ h value is 0.56 (95% confidence limits: 0.42 – 0.72). The LOEC/72 h value for the growth rate is 0.03 mg/L. The NOEC/72 h value for the growth rate is 0.01 mg/L. The concentration causing a 50% inhibition of yield of <i>Pseudokirchneriella subcapitata</i>, i.e. the $E_yC_{50}/72$ h value is 1.14 mg/L (95% confidence limits: 0.91 – 1.43) $E_yC_{20}/72$ h value is 0.31 mg/L (95% confidence limits: 0.20 – 0.41), $E_yC_{10}/72$ h value is 0.15 mg/L (95% confidence limits: 0.09 – 0.23). The LOEC/72 h value for the yield is 0.95 mg/L. The NOEC/72 h value for the yield is 0.30 mg/L. <u>The endpoint values determined on the basis of the nominal concentration of Thifensulfuron-methyl in the test item are given below:</u> The concentration causing a 50% inhibition of the growth rate of <i>Pseudokirchneriella subcapitata</i>, i.e. the $E_rC_{50}/72$ h value is 8.06 mg/L (95% confidence limits: 7.10 - 9.17) $E_rC_{20}/72$ h value is 1.17 mg/L (95% confidence limits: 0.95 – 1.41), $E_rC_{10}/72$ h value is 0.43 (95% confidence limits: 0.32 – 0.55). The LOEC/72 h value for the growth rate is 0.02 mg/L. The NOEC/72 h value for the growth rate is 0.01 mg/L. The concentration causing a 50% inhibition of yield of <i>Pseudokirchneriella subcapitata</i>, i.e. the $E_yC_{50}/72$ h value is 0.87 mg/L (95% confidence limits: 0.69 – 1.09) $E_yC_{20}/72$ h value is 0.24 mg/L (95% confidence limits: 0.16 – 0.32), $E_yC_{10}/72$ h value is 0.12 mg/L (95% confidence limits: 0.07 – 0.18). The LOEC/72 h value for the yield is 0.72 mg/L. The NOEC/72 h value for the yield is 0.23 mg/L.
--	---

Reference:	KCP 10.2.1-03
Report	Thifensulfuron 75% WDG <i>Pseudokirchneriella subcapitata</i> SAG 61.81 growth inhibition tests, Ewa Nierzedzka, 2016, report No. W/164/16
Guidelines:	Yes, OECD guidelines No. 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The growth of the green algae *Pseudokirchneriella subcapitata* exposed to the test item, Thifensulfuron 75% WDG was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL. Each of them contained 100 mL of a given test item concentration and the control. The initial density of the algae was 1×10^4 cells/mL. Nine test item concentrations: 100, 31.25, 9.77, 3.05, 0.95, 0.30, 0.10, 0.03 and 0.01 mg/L plus the control were used (with the spacing factor of 3.2).

- Test item: Thifensulfuron 75% WDG;
batch number: SWEPL - 13205;
purity: 75.3% m/m;
manufacturing date: June 25, 2015;
expiry date: June 24, 2017.
- Test organism: The unicellular freshwater green algae, *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. *Raphidocelis subcapitata*, *Selenastrum capricornutum* Prinz) SAG 61.81 cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology. The algae were obtained from the Culture Collection of Algae at Göttingen University, Germany.
- Test design: 72 hours of the exposure;
three replicates of each test item concentration
six replicates of the control;
a background for the control and each test item concentration;
initial algal cell density: 1×10^4 cells/mL.
- Nominal test item concentrations: 100, 31.25, 9.77, 3.05, 0.95, 0.30, 0.10, 0.03, and 0.01 mg/L plus the control.
- Nominal Thifensulfuron-methyl concentrations: 75.3, 23.53, 7.36, 2.30, 0.72, 0.23, 0.08, 0.02 mg/L and 0.01 mg/L plus the control.
- Test conditions: Temperature: 21.8 – 22.3°C;
pH of the control: 7.32 – 7.48;
average light intensity: 7124 – 7426 lx;
constant illumination and shaking; the AAP medium.
- Chemical determinations: The test item concentrations were determined with a liquid chromatographic method with DAD detection.
- Statistical analyses: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure.
- Endpoint values: E_rC_{50} , E_yC_{50} , LOEC, and NOEC.

Results and conclusion

The concentration of test item during the test.

Nominal test item concentration [mg/L]	Nominal concentration of thifensulfuron methyl [mg/L]	Mean concentration(n = 3) of the test item in samples [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of initial concentration
Control	0.00	< LoD	--	< LoD	--
0.01	0.01	0.0099	99.00	0.0091	91.91
0.03	0.02	0.0275	91.67	0.0245	89.09
0.10	0.08	0.103	103.00	0.092	89.32
0.30	0.23	0.289	96.33	0.264	91.35
0.95	0.72	0.857	90.21	0.815	95.10
3.05	2.30	3.012	98.75	2.948	97.88
9.77	7.36	9.208	94.25	9.493	103.10
31.25	23.53	28.897	92.47	29.414	101.79
100	75.3	94.312	94.31	95.913	101.70

LoQ = 0.002 mg/L

LoD = 0.001 mg/L

The endpoint values determined on the basis of the nominal test item concentrations are given below:

The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the $E_rC_{50}/72$ h value is 10.69 mg/L (95% confidence limits: 9.42 - 12.16)

$E_rC_{20}/72$ h value is 1.55 mg/L (95% confidence limits: 1.25 – 1.86),

$E_rC_{10}/72$ h value is 0.56 (95% confidence limits: 0.42 – 0.72).

The LOEC/72 h value for the growth rate is 0.03 mg/L.

The NOEC/72 h value for the growth rate is 0.01 mg/L.

The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the $E_yC_{50}/72$ h value is 1.14 mg/L (95% confidence limits: 0.91 – 1.43)

$E_yC_{20}/72$ h value is 0.31 mg/L (95% confidence limits: 0.20 – 0.41),

$E_yC_{10}/72$ h value is 0.15 mg/L (95% confidence limits: 0.09 – 0.23).

The LOEC/72 h value for the yield is 0.95 mg/L.

The NOEC/72 h value for the yield is 0.30 mg/L.

The endpoint values determined on the basis of the nominal concentration of Thifensulfuron-methyl in the test item are given below:

The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the $E_rC_{50}/72$ h value is 8.06 mg/L (95% confidence limits: 7.10 - 9.17)

$E_rC_{20}/72$ h value is 1.17 mg/L (95% confidence limits: 0.95 – 1.41),

$E_rC_{10}/72$ h value is 0.43 (95% confidence limits: 0.32 – 0.55).

The LOEC/72 h value for the growth rate is 0.02 mg/L.

The NOEC/72 h value for the growth rate is 0.01 mg/L.

The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the $E_yC_{50}/72$ h value is 0.87 mg/L (95% confidence limits: 0.69 – 1.09)

$E_yC_{20}/72$ h value is 0.24 mg/L (95% confidence limits: 0.16 – 0.32),

$E_yC_{10}/72$ h value is 0.12 mg/L (95% confidence limits: 0.07 – 0.18).

The LOEC/72 h value for the yield is 0.72 mg/L.

The NOEC/72 h value for the yield is 0.23 mg/L.

A 2.2.1.1.4 Study 4

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	- The doubling time of frond number in the control was 1.6 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 21.4). - The average specific growth rate in the control between day 0 and day 7 was 0.437 d⁻¹ (minimum requirement: higher than 0.275 d⁻¹). Agreed endpoints: The endpoint values determined on the basis of the nominal test item concentrations are given below: Endpoint values calculated on the basis of the frond number: The E_rC₅₀/7 d value is 0.0033 mg/L (with 95% confidence limits: 0.0024 – 0.0046), The E_yC₅₀/7 d value is 0.0011 mg/L (with 95% confidence limits: 0.0008 – 0.0016), The LOEC/7 d value for growth rate and yield is 0.0003 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L. Endpoint values calculated on the basis of the dry weight: The E_rC₅₀/7 d value is higher than 0.10 mg/L. The E_yC₅₀/7 d value is 0.0067 mg/L (with 95% confidence limits: 0.0031 – 0.0159), The LOEC/7 d value for growth rate and yield is 0.0003 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L. The endpoint values determined on the basis of the nominal concentrations of Thifensulfuron-methyl in the test item are given below: Endpoint values calculated on the basis of the frond number: The E_rC₅₀/7 d value is higher than 0.0026 mg/L (with 95% confidence limits: 0.0018 – 0.0036), The E_yC₅₀/7 d value is higher than 0.0009 mg/L (with 95% confidence limits: 0.0006 – 0.0013), The LOEC/7 d value for growth rate and yield is 0.0002 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L. Endpoint values calculated on the basis of the dry weight: The E_rC₅₀/7 d value is higher than 0.0753 mg/L, The E_yC₅₀/7 d value is 0.0051 mg/L (95% confidence limit: 0.0023 – 0.0125), The LOEC/7 d value for growth rate and yield is 0.0002 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L.

Reference:	KCP 10.2.1-04
Report	Thifensulfuron 75% WDG Lemna gibba CPCC 310, growth inhibition tests, Ewa Nierzedzka, 2016, report No. W/166/16
Guidelines:	Yes, OECD guideline No. W/166/16
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication	No

(if vertebrate study)

Materials and methods

The growth of *Lemna gibba* CPCC 310 exposed to the test item, Thifensulfuron 75% WDG was investigated during a 7-day semi-static test with three renewals. The test was performed in glass crystallizers containing 150 mL of each treatment per replicate. The initial frond number in each test item concentration and in the control was nine. In the test, the test item concentrations of 0.1, 0.032, 0.010, 0.003, 0.001, 0.0003, 0.0001 mg/L plus the control were used.

Test item: Thifensulfuron 75% WDG;
batch number: SWEPL - 13205;
purity: 75.3% m/m;
manufacturing date: June 25, 2015;
expiry date: June 24, 2017.

Test organism: The freshwater aquatic plant, *Lemna gibba* L. CPCC 310 cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology; the plants were obtained from the Canadian Phycological Culture Centre, Department of Biology, University of Waterloo, Ontario, Canada.

Test design: Semi-static system with three renewals;
7 days of exposure;
three replicates of each test item concentration;
six replicates of the control.

Nominal test item concentrations: 0.1, 0.032, 0.010, 0.003, 0.001, 0.0003, 0.0001 mg/L plus the control.

Nominal concentration of Thifensulfuron-methyl in the test item: 0.075, 0.024, 0.008, 0.002, 0.0008, 0.0002, 0.0001 mg/L plus the control.

Test conditions: Medium: 20X AAP;
pH of the control: 7.23 – 9.47;
average light intensity: 7333 – 8018 lux;
constant illumination; g
lass crystallizers containing 150 mL of a given test item concentration or control;
initial frond number: 9, i.e. 3 plants per 3 fronds; temperature measured in an additional test vessel was in the range of 24.7 – 25.4°C.

Chemical determinations: The concentrations of the test item were chemically determined with validated liquid chromatographic method with DAD detection.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, Williams Multiple Sequential t-test Procedure.

Endpoint values: E_rC_x , E_yC_x , LOEC, and NOEC.

Results and conclusion

The concentration of the test item

Nominal test item concentration [mg/L]	Control	0.003	0.010	0.032	0.100	Day of sampling
Nominal concentration of thifensulfuron methyl in the test item [mg/L]	---	0.0023	0.0075	0.0241	0.0753	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00312	0.0095	0.0312	0.0972	Day 0, fresh
% of nominal concentration	---	104.0	95.0	97.5	97.2	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00268	0.0082	0.0263	0.0816	Day 2, old
% of nominal concentration	---	89.3	82.0	82.2	81.6	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00320	0.0101	0.0314	0.0999	Day 2, fresh
% of nominal concentration	---	106.7	101.0	98.1	99.9	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00250	0.0081	0.0262	0.0839	Day 4, old
% of nominal concentration	---	83.3	81.0	81.9	83.9	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00296	0.0097	0.0308	0.0926	Day 4, fresh
% of nominal concentration	---	98.7	97.0	96.3	92.6	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00260	0.0083	0.0261	0.0841	Day 6, old
% of nominal concentration	---	86.7	83.0	81.6	84.1	

Nominal test item concentration [mg/L]	Control	0.003	0.010	0.032	0.100	Day of sampling
Nominal concentration of thifensulfuron methyl in the test item [mg/L]	---	0.0023	0.0075	0.0241	0.0753	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00286	0.0097	0.0312	0.0990	Day 6, fresh
% of nominal concentration	---	95.3	97.0	97.5	99.0	
Mean measured test item concentration (n = 3) [mg/L]	<LoD	0.00261	0.0088	0.0297	0.0919	Day 7, old
% of nominal concentration	---	87.0	88.0	92.8	91.9	

LoQ = 0.002 mg/L
LoD = 0.001 mg/L

The endpoint values determined on the basis of the nominal test item concentrations are given below:

Endpoint values calculated on the basis of the frond number:

The $E_rC_{50/7}$ d value is 0.0033 mg/L (with 95% confidence limits: 0.0024 – 0.0046),

The $E_yC_{50/7}$ d value is 0.0011 mg/L (with 95% confidence limits: 0.0008 – 0.0016),

The LOEC/7 d value for growth rate and yield is 0.0003 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L.

Endpoint values calculated on the basis of the dry weight:

The $E_rC_{50/7}$ d value is higher than 0.10 mg/L.

The $E_yC_{50/7}$ d value is 0.0067 mg/L (with 95% confidence limits: 0.0031 – 0.0159),

The LOEC/7 d value for growth rate and yield is 0.0003 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L.

The endpoint values determined on the basis of the nominal concentrations of Thifensulfuron-methyl in the test item are given below:

Endpoint values calculated on the basis of the frond number:

The $E_rC_{50/7}$ d value is higher than 0.0026 mg/L (with 95% confidence limits: 0.0018 – 0.0036),

The $E_yC_{50}/7$ d value is higher than 0.0009 mg/L (with 95% confidence limits: 0.0006 – 0.0013),
The LOEC/7 d value for growth rate and yield is 0.0002 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L.

Endpoint values calculated on the basis of the dry weight:

The $E_rC_{50}/7$ d value is higher than 0.0753 mg/L,

The $E_yC_{50}/7$ d value is 0.0051 mg/L (95% confidence limit: 0.0023 – 0.0125),

The LOEC/7 d value for growth rate and yield is 0.0002 mg/L and the NOEC/7 d value for growth rate and yield is 0.0001 mg/L.

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

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

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

A 2.3.1.1.2 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	- the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), - the 24-hour LD_{50} of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee).
	Agreed endpoint: LD_{50} 48 h >200.0 mg/honeybee (150.6 mg a.i./honeybee).

Reference:	KCP 10.3.1.1.1
Report	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute oral toxicity test, Pawel Parma, 2016, report No. B/140/15
Guideline	Yes, OECD guideline No. 213 and EU Method C.16
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The acute oral toxicity study of Thifensulfuron 75% WDG described in this Report was conducted to determine the LD₅₀ values for honeybees. Five different doses (12.5, 25.0, 50.0, 100.0 and 200.0 mg/honeybee) were used. The range of doses was selected on the basis of the preliminary test results.

Test item: name: Thifensulfuron 75% WDG; content: thifensulfuron: 75.3% (m/m) as active ingredient; batch number: SWEPL - 13205; date of production: June 25, 2015; expire date: June 24, 2017.

Biological test system: the honeybee, *Apis mellifera* L.; strain: carnica; source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna; age: approximately 3 weeks.

Test design: - test item: exposure time: 48 hours; number of doses: 5 doses and a control; number of replicates: 3 replicates containing 10 bees each;
- reference item: exposure time: 24 hours; number of doses: 3 doses; number of replicates: 3 replicates containing 10 bees each.

Test item doses: 0.0 (control), 12.5, 25.0, 50.0, 100.0 and 200.0 µg/bee;

Reference item doses: 0.0 (control), 0.03, 0.06 and 0.12 µg a.i./bee.

Test conditions: temperature: 24.5 - 26°C; relative air humidity: 61 - 62%; place: a dark room.

Endpoints: LD₅₀

Statistical method: regression analysis using the log-probit method.

Results and discussions

Table: Honeybee mortality at the LD₅₀ after 48 hours of exposure – definitive experiments

Dose		Number of tested bees [no.]	Mortality					LD ₅₀ [µg/bee]
			Number of dead bees [no.]			Total		
			replicates					
[µg test item/bee]	[µg a.i./bee]		I	II	III	[no.]	[%]	
0.0 (control)		30	0	0	0	0	0.00	Above 200
12.5	9.4	30	0	0	0	0	0.00	
25.0	18.8	30	0	0	0	0	0.00	
50.0	37.7	30	1	0	0	1	3.33	
100.0	75.3	30	0	0	0	0	0.00	
200.0	150.6	30	0	0	0	0	0.00	

Conclusion

The median lethal doses (LD₅₀ 24 h and LD₅₀ 48 h per os) are higher than the highest dose used in the test, i.e. 200.0 mg/honeybee (150.6 mg a.i./honeybee).

A 2.3.1.1.3 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.1.4 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
-------------------	---

	- the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), - the 24-hour LD₅₀ of the reference item (dimethoate) was 0.27 µg/bee (criterion: 0.10 - 0.30 µg a.i./bee).
	Agreed endpoint: 48 hours LD₅₀ > 200 mg/honeybee (150.6 mg a.i./honeybee).

Reference:	KCP 10.3.1.1.2
Report	Thifensulfuron 75% WDG, Honeybees (<i>Apis mellifera</i> L.), acute contact toxicity test, Pawel Parma, 2016, report No. B/141/15
Guideline	Yes, OECD guidelines No. 214 and EU Method C.17
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The acute contact toxicity study of Thifensulfuron 75% WDG described in this Report was conducted to determine the effects on honeybees. Five different doses i.e. 12.5, 25.0, 50.0, 100.0 and 200.0 mg/honeybee, were used to determine the LD₅₀ values. The range of doses was selected on the basis of the preliminary test results.

Test item: name: Thifensulfuron 75% WDG; content: thifensulfuron: 75.3% (m/m) as active ingredient; batch number: SWEPL - 13205; date of production: June 25, 2015; expire date: June 24, 2017.

Biological test system: the honeybee, *Apis mellifera* L.; strain: carnica; source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/14]; age: approximately 3 weeks.

Test design: - test item: exposure time: 48 hours; number of doses: 5 doses and a control; number of replicates: 3 replicates containing 10 bees each;
- reference item: exposure time: 24 hours; number of doses: 3 doses; number of replicates: 3 replicates containing 10 bees each.

Test item doses: 0.0 (control), 12.5, 25.0, 50.0, 100.0 and 200.0 µg/bee;

Reference item doses: 0.0 (control), 0.1, 0.2 and 0.4 µg a.i./bee.

Test conditions: temperature: 24.5 - 26°C; relative air humidity: 61 - 62%; place: a dark room.

Endpoints: LD₅₀

Statistical method: regression analysis using the log-probit method.

Results and discussions

Table: Honeybee mortality and the LD₅₀ after 48 hours of exposure – definitive experiment

Dose		Number of tested bees [no.]	Mortality					LD ₅₀ [µg/bee]
			Number of dead bees [no.]			Total		
			replicates					
[µg test item/bee]	[µg a.i./bee]		I	II	III	[no.]	[%]	
0.0 (control)		30	0	0	0	0	0.00	Above 200.0
12.5	9.4	30	0	0	0	0	0.00	
25.0	18.8	30	0	0	0	0	0.00	
50.0	37.7	30	0	0	0	1	0.00	
100.0	75.3	30	0	0	0	0	0.00	
200.0	150.6	30	0	0	0	0	0.00	

Conclusion

The median lethal doses (LD₅₀ contact) after 24 and 48 hours are above the highest used dose, i.e. 200 mg/honeybee (150.6 mg a.i./honeybee).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	
	Updated March 2025
	The chronic tests for adult bee was submitted by Applicant.

Reference:	KCP 10.3.1.2
Report	“Chronic Oral Toxicity Study of Thifensulfuron-methyl 75% WDG on adult honey bee (<i>Apis mellifera</i>)” Mohanraj, M., 2024. Study No.: 14183/2023. Bioscience Research Foundation.
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 245 (2017).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

This study was carried out to evaluate the chronic oral toxicity of **Thifensulfuron-methyl 75% WDG** sponsored by Sharda Cropchem Limited in honey bees (*Apis mellifera*) at Bioscience Research Foundation, India. The study was conducted as per the OECD guideline No. 245.

Honeybees were acclimatized for 24 hours. The bees were orally treated with control, 2.6, 6.4, 16.0, 40.0 and 100 µg/bee concentrations in 50% w/v sucrose solution. A concurrent control group with 50% w/v sucrose solution was also maintained. After 24 h treatment, the treated diet was withdrawn from the respective treatment groups, feeder tube was weighed and replaced with freshly prepared treated diet.

Dose (µg/bee)	Dose (µg Thifensulfuron methyl ^a /bee)
Control	-
2.6	1.92
6.4	4.81
16.0	12.02
40.0	30.06
100	75.15

a: based on the content of Thifensulfuron-methyl i.e., 75.15% given by the sponsor

The Corresponding concentrations of the above-mentioned doses are 128, 320, 800, 2000 and 5000 mg/Kg respectively.

Concentration (mg/Kg)	Concentration (mg Thifensulfuron methyl ^a /Kg)
Control	-
128	96.19
320	240.48
800	601.20
2000	1503.00
5000	3757.50

a: based on the content of Thifensulfuron-methyl i.e., 75.15% given by the sponsor

At the end of the study period, Control group appeared normal and 0% mortality was observed throughout the experimental period. The cumulative mortality observed at the end study period (10 days of exposure) was 6.67, 43.33, 63.33, 80.00 and 100.00 % in bees exposed to 2.6, 6.4, 16.0, 40 and 100 µg/bee doses respectively.

A toxic reference standard group exposed to 0.8 mg a.i./kg dimethoate/bee in sucrose solution (50% w/v) was also maintained. The mortality of 0.8 mg a.i./kg reference standard was 60.00%, which was within the range at 10 days following the test substance exposure.

The test met the validity criteria, as mortality in the control did not exceed 15% as described in Guidance Documents - OECD Guideline No. 245, Chronic Oral Toxicity – Honeybee.

Materials and methods

Test item:

Thifensulfuron-methyl 75%WDG

CAS No.: 79277-27-3

IUPAC Name: methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate

CAS Name: methyl3-((((4-methoxy-6- methyl-1,3,5-triazin-2-yl)amino)carbonyl)amino) sulfonyl)-2-thiophenecarboxylate

Batch No.: SCL- 73021

Active ingredient content (w/w): 75.15%

Production date: 12th June 2023

Expiry date: 11th June 2025

Appearance: Off white Granular columnar

Formulation type: Water Dispersible Granules

Storage conditions: Ambient temperature (+15 to + 25°C)

Test organism: **Species:** *Apis mellifera* (L) strain carnica
Source: Bee hive maintained at BRF test facility.
Stage: 2 days old young adult bee

Test design: **Test duration:** 10 days
Number of replicates: Reference standard - 3 replicates/concentration,
Dose response test - 3 replicates/concentration
Number of adult bees: 10 bees / replicate

Test concentrations: **Untreated control**
Test item: 5 concentrations of 128, 320, 800, 2000 and 5000 mg/Kg food corresponding to daily doses of 2.6, 6.4, 16, 40 and 100 µg/bee/day (nominal, assuming daily uptake of 1 mL feeding solution/ bee/day).

Test conditions: **Temperature:** 24.2– 25.9°C
Relative humidity: 51 - 69%
Photoperiod: Complete darkness except during the observations

Results

The bees were orally treated with control, 2.6, 6.4, 16, 40 and 100 µg/bee doses in 50% w/v sucrose solution. A concurrent control group with 50% w/v sucrose solution was also maintained. The average feed consumption recorded for 10 days of treatment with test substance was 2.6, 6.5, 16, 39.8 and 100 µg/bee corresponding to the nominal dose 2.6, 6.4, 16, 40 and 100 µg/bee respectively.

At the end of every 24 (10 days exposure) hour observation bees treated with control group appeared normal and no toxic sign was observed.

- On day 1, no toxicity signs was observed in bees exposed control, 2.6 and 6.4 µg/bee appeared normal and toxicity signs (affected) was observed in bees exposed to 16, 40 and 100 µg/bee.
- On day 2 , toxicity signs affected and mortality was observed in bees exposed to 16, 40 and 100 µg/bee. whereas bees exposed to control, 2.6 and 6.4 µg/bee appeared normal.
- On day 3 , toxicity signs affected and mortality was observed in bees exposed to 16, 40 and 100 µg/bee µg/bee. toxicity signs affected whereas bees exposed to control, 2.6 and 6.4 µg/bee appeared normal.
- On day 4, toxicity signs affected and mortality was observed in bees exposed to 40 and 100 µg/bee. toxicity signs affected was observed in bees exposed to 6.4 and 16.0 µg/bee whereas bees exposed to control and 2.6 µg/bee appeared normal.
- On day 5 toxicity signs affected and mortality was observed in bees exposed to 6.4, 16, 40 and 100 µg/bee. whereas bees exposed to control and 2.6 µg/bee appeared normal.

- On day 6 toxicity signs affected and mortality was observed in bees exposed to 6.4, 40 and 100 µg/bee. toxicity signs affected was observed in bees exposed to 16 µg/bee. whereas bees exposed to control and 2.6 µg/bee appeared normal.
- On day 7, toxicity signs affected and mortality was observed in bees exposed to 6.4, 16, 40 and 100 µg/bee. whereas bees exposed to control and 2.6 µg/bee appeared normal
- On day 8, toxicity signs affected and mortality was observed in bees exposed to 6.4, 16 and 40 µg/bee. toxicity signs mortality was observed in bees exposed to 100 µg/bee whereas bees exposed to control appeared normal
- On day 9, toxicity signs affected and mortality was observed in bees exposed to 6.4, 16 and 40 µg/bee. toxicity signs affected was observed in bees exposed to 2.6 µg/bee whereas bees exposed to control appeared normal.
- On day 10, toxicity signs affected and mortality was observed in bees exposed to 2.6, 6.4, 16 and 40 µg/bee. whereas bees exposed to control appeared normal.

Table 1. Dose Response test – summary of mortality and test item intake

Initial		Consumed		No. of tested bees	Mortality		LC ₅₀	LDD ₅₀
Concentration [mg/kg of food]	Dose [µg/20mg/ bee/day]	Concentration [mg/kg of food]	Dose [µg/bee/ day]		total	No. of bees [%]		
Thifensulfuron-methyl 75% WDG								
Control				30	0	0.00	532.6 (489.1 – 576.1)	10.72 (9.9– 11.6)
128.0	2.6	128.0	2.6	30	2	6.67		
320.0	6.4	320.0	6.5	30	13	43.33		
800.0	16.0	800.0	16.0	30	19	63.33		
2000.0	40.0	2000.0	39.8	30	24	80.00		
5000.0	100.0	5000.0	100.0	30	30	100.00		
Dimethoate								
0.8 mg a.i./kg	0.016 µg a.i./bee	0.8 mg a.i./kg	0.01 µg a.i./bee	30	18	60.00	Not determined	
Thifensulfuron- methyl 75% WDG	NOEC [mg/kg]				128			
	NOEDD [µg/bee/ day]				2.6			

Table 2. Summary of feed consumption data – Dose Response Test

Initial		Consumed		Consumption of A 50% Sucrose Solution* [mg/bee/day]			Average consumption [mg/bee/day]
Concentration [mg/kg of food]	Dose [µg/20mg/bee/day]	Concentration [mg/kg of food]	Dose [µg/bee/day]	replicates			
				I	II	III	

Thifensulfuron-methyl 75% WDG							
Control				20.76	20.93	19.95	20.55
128.0	2.6	128.0	2.6	20.42	19.69	20.24	20.12
320.0	6.4	320.0	6.5	20.21	20.23	20.72	20.39
800.0	16.0	800.0	16.0	20.81	19.48	19.65	19.98
2000.0	40.0	2000.0	39.8	19.36	20.49	19.87	19.91
5000.0	100.0	5000.0	100.0	20.12	19.93	19.95	20.00
0.8mg a.i./kg	0.016 µg a.i./bee	0.8 mg a.i./kg	0.01 µg a.i./bee	19.37	19.82	19.10	19.43

20.16

Validity of the test

- There was no mortality in control group.
- The average mortality in the reference substance treated group is 60.00 % at the end of the test (Test Guideline criteria: $\geq 50\%$).

Conclusions

Based on feed consumption (test item intake) LDD₅₀ was calculated to be 10.72 (lower limit 9.9 – upper limit 11.6) µg/bee i.e., 8.06 (lower limit 7.41 – upper limit 8.72) µg Thifensulfuron-methyl /bee.

LC₅₀ was determined as 532.6 (lower limit 489.1 – upper limit 576.1) mg/kg food i.e., 400.24 (lower limit 367.55 - upper limit 432.94) mg Thifensulfuron-methyl /kg food.

The NOEC was determined as 128 mg /kg i.e., 96.19 mg Thifensulfuron-methyl /kg food.

NOEDD was determined as 2.6 µg/bee i.e., 1.95 µg Thifensulfuron-methyl /bee.

Reference substance study: The mortality of reference substance 0.8 mg a.i./kg was found to be 60.00% between the stipulated range of 0.5 – 1.0 mg a.i./kg for 10 days exposure on *Apis mellifera*.

Table 3. Endpoints based on feed consumption

Endpoint	Value [µg/bee/day]	Value Based on Thifensulfuron-methyl ^a content [µg a.s./bee/day]
LDD ₅₀	10.72 (9.9 – 11.6)	8.06 (7.41 – 8.72)
NOEDD	2.6	1.95

a: based on the content of Thifensulfuron-methyl i.e., 75.15% given by the sponsor

Table 4. Endpoints for chronic oral toxicity on honey bee

Endpoint	Value (mg/kg)	Value Based on Thifensulfuron-methyl ^a content (mg a.s./kg)
LC ₅₀	532.6	400.24

	(489.1 – 576.1)	(367.55 – 432.94)
NOEC	128	96.19

a: based on the content of Thifensulfuron-methyl i.e., 75.15% given by the sponsor

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

Comments of zRMS:	Updated March 2025
	The chronic tests for larvae with repeated exposure were submitted by Applicant.

Reference:	KCP 10.3.1.3
Report	Effect of Thifensulfuron-methyl 75% WDG on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Mohanraj M., 2024, Study No.: 14184/2023. Bioscience Research Foundation.
Guideline(s):	Yes, OECD guideline No. 239 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No

The repeated exposure effect of Thifensulfuron-methyl 75 % WDG on larvae of honey bees (*Apis mellifera*) (L.) was conducted for Sharda Cropchem Ltd, India at Bioscience Research Foundation. The study was conducted as per the OECD guidance document No. 239. The test was carried out under laboratory conditions on honeybee larvae (*Apis mellifera* L.) by repeatedly exposed to Thifensulfuron-methyl 75% WDG. The doses were selected for main study based on the sponsor recommendations and the following doses 1.6, 3.1, 6.3, 12.5 and 25 µg/larva were used for the study.

Dose (µg/larva)	Dose (µg Thifensulfuron- methyl ^a / larva)
Control	-
1.6	1.17
3.1	2.35
6.3	4.70
12.5	9.39
25	18.79

^a: based on the content of Thifensulfuron-methyl i.e., 75.15% w/w

The concentrations of test item in the diet were 10.2, 20.3, 40.6, 81.3 and 162.5 mg/kg food. Additionally, honeybee larvae were treated with Dimethoate as reference item at a dose of 7.39 µg a.i.dimethoate/larva (test concentration 48 mg a.i./kg) of diet and with an untreated diet as control.

Concentration (mg/kg)	Concentration (mg Thifensulfuron-methyl ^a /kg)
Control	-
10.2	7.63

20.3	15.26
40.6	30.53
81.3	61.06
162.5	122.12

#: based on the content of Thifensulfuron-methyl i.e., 75.15% w/w

Materials and methods

Test item:

Thifensulfuron-methyl 75% WDG
IUPAC Name: methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoylsulfamoyl thiophene-2-carboxylate
CAS No: 79277-27-3
CAS Name: methyl 3-((((4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino)carbonyl)amino)sulfonyl)-2-thiophenecarboxylate
batch number: SCL-73021
appearance: Off white Granular columnar
manufacture date: 12th June 2023
expiry date: 11th June 2025
storage conditions: Ambient temperature (+15 to +25°C)

Test system:

Honey bee -*Apis mellifera* (L.); Hymenoptera, *Apoidea* (strain: carnica)
Stage: First instar larvae (L 1, one day old) during grafting of queen-right colonies in good health condition.
Source: Bee hive maintained at BRF test facility.
Test duration: 22 days

Concentrations/replicates:

Main study: Control, 1.6, 3.1, 6.3, 12.5 and 25 µg /larvae
Reference study: 7.39 µg a.i./larva
Number of larvae/Replication: 12
Replications: 3

Test conditions:

temperature: (D1-D8): 34.2 - 34.7° C, (D8-D15): 34.3 - 34.6° C, (D15-D22): 34.2 - 34.9° C
relative air humidity: (D1-D8): 90- 95%, (D8-D15): 72 - 80% (D15-D22): 63-75%
photoperiod: Complete darkness except during observations.

Statistical analysis:

The NOED and NOEC was determined by one-way ANOVA test using Graph Pad Prism 8.2. The ED₁₀, ED₂₀ and ED₅₀ of adult emergence (D22) was determined by probit analysis using NCSS-2000.

Results

One day old honeybee larvae (D1) of *Apis mellifera* L (first instar) were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates before start of the treatment (3 days). On 4 successive days (D3 to D6) the larvae were repeatedly exposed to Thifensulfuron-methyl 75% WDG diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications no additional feedings provided to the larvae.

The test carried out with 7 treatment groups were as: 5 dose of the test item, 1 untreated control group and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate.

Assessments of cumulative larval mortality were done on days (D4, D5, D6, D7 and D8). Additionally, other observations were reported on D8 such as small body size and large quantities of remaining food. Pupal mortality was assessed at D15, and emergence of adults was evaluated at D22 respectively.

The concentration of the active substance in the test item solution and control was determined by analytical verification.

Table 1. Toxicity of Thifensulfuron-methyl 75% WDG to larvae of *Apis mellifera* L.

Treatment group	Test solution (ID)	Dose [μg a.i./larval]	Conc. [mg a.i./kg food]	On D8			On D15		On D22		
				Larval mortality D3 to D8		Mean OO	Pupae stage D8 to D15		Total mortality D3-D22		Adult emergence rate %
				Mor.(%)	Corr.(%)	(%)	Mor.(%)	Corr.(%)	Mor.(%)	Corr.(%)	(%)
Control	A1	-	-	2.78	-	0	2.78	0	5.56	0	94.44
Test item	T1	1.6	10.2	5.56	2.86	0	2.78	0.00	8.33	2.94	91.67
	T2	3.1	20.3	8.33	5.71	0	11.11	8.57	36.11	32.35	63.89
	T3	6.3	40.6	19.44	17.14	0	16.67	14.29	61.11	58.82	38.89
	T4	12.5	81.3	36.11	34.29	0	27.78	25.71	77.78	76.47	22.22
	T5	25	162.5	55.56	54.29	0	19.44	17.14	100.00	100.00	0.00
Ref. Item	R1	7.39 μg a.i./larva	48 mg a.i./larva	61.11	60.00	0	8.33	5.71	88.89	88.24	11.11

Note: D-Day, Mor- Mortality, corr.-Corrected Mortality, OO-Other observation Results are averages based on 3 replicates, containing 12 larvae each;

corr.: corrected mortality (according to SCHNEIDER-ORELLI 1947): reference item and test item was corrected by A1 negative values are set to "0"; calculations are performed with non-rounded values; CL: confidence limit

OO: Other observations (e.g. remaining food)

1 Average % of pupal mortality was calculated according to the following formula: Sum of dead between D8 and D22 / Sum of living larvae on D8 x 100%

2 Adult emergence [%] = 100 [%] - Mortality of D22 [%]

Test validity criteria

- Larval mortality in the control: $\leq 15\%$ for larvae across all control replicates (between D3 and D8)
- Adult emergence rate: $\geq 70\%$ for bees across all control replicates (between D3 and D22)
- Larval mortality in the reference item: $\geq 50\%$ for larvae exposed to 7.39 μg a.i./larva across all reference replicates (between D3 and D8)

Conclusions

Test item doses	Up to D22		
	Endpoint with 95% CL	Value based on Confidence Dose (μg as/larva)	Value based on Thifensulfuron-methyl content (μg as/larva)
	ED ₁₀	1.91 (1.72 - 2.09)	1.43 (1.29 - 1.57)
	ED ₂₀	2.74	2.06

Test item concentrations		(2.52 -2.95)	(1.90 -2.22)
	ED ₅₀	5.45 (5.14 -5.77)	4.10 (3.86 -4.34)
	NOED	1.60	1.20
	Endpoint with 95% CL	Value based on Confidence concentrations (mg as/kg food)	Value based on Thifensulfuron-methyl ^a content (mg as/ kg food)
	EC ₁₀	12.34 (11.14 -13.55)	9.28 (8.37-10.19)
	EC ₂₀	17.71 (16.33-19.10)	13.32 (12.28 -14.36)
	EC ₅₀	35.33 (33.30- 37.37)	26.57 (25.04-28.10)
	NOEC	10.20	7.67

^a: based on the content of Thifensulfuron-methyl i.e., 75.15% w/w

In a repeated exposure larval toxicity study with Thifensulfuron-methyl 75% WDG, the ED₅₀ (successful adult emergence up to D22) was calculated to be 5.45 µg/larva (i.e., 4.10 µg Thifensulfuron-methyl/larva) which is equivalent to an EC₅₀ of 35.33 mg/kg (i.e., 26.57 mg Thifensulfuron-methyl /kg).

The ED₁₀ (successful adult emergence up to D22) was calculated to be 1.91 µg/larva (i.e., 1.43 µg Thifensulfuron-methyl /larva) which is equivalent to an EC₁₀ of 12.34 mg/kg (i.e., 9.28 mg Thifensulfuron-methyl /kg food).

The ED₂₀ (successful adult emergence up to D22) was calculated to be 2.74 µg/larva (i.e., 2.06 µg Thifensulfuron-methyl /larva) which is equivalent to an EC₂₀ of 17.71 mg/kg (i.e., 13.32 mg Thifensulfuron-methyl /kg food).

The NOED was 1.60 µg/larva (i.e., 1.20 µg Thifensulfuron-methyl /larva) and the corresponding NOEC was 10.20 mg/kg food (i.e., 7.67 mg Thifensulfuron-methyl /kg food).

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.3 Effects on arthropods other than bees

A 2.4.1.1.1 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
-------------------	---

– mortality of the control group was 1.7% 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 86.4% on day 7 of exposure (criterion: from 50 to 100%),

– the mean number of eggs per female in the control group was 4.1 (required: ≥ 4 eggs per female).

Agreed endpoints:

Effect of Thifensulfuron 75% WDG on mortality and reproduction of *T. pyri*

Study group [app. rate]		Parameter (endpoint)							
Test item		Mortality				Reproduction			
[g/ha]	[g ai/ha]	Total [%]	Corrected*	LR ₅₀		Mean no. eggs/female [no.]	Reproduction reduction [%]	ER ₅₀	
				[g/ha]	[g ai/ha]			[g/ha]	[g ai/ha]
Control (0.0)		1.7	-	-		4.1	-	-	
10.0	7.5	10.0	8.5	> 80.0	> 60.2	4.3	(-4.8)	> 80.0	> 60.2
20.0	15.1	3.3	1.7			3.2	22.1 ⁺		
40.0	30.1	21.7	20.3 ⁺			3.0	27.0 ⁺		
80.0	60.2	13.3	11.9 ⁺			2.7	33.9 ⁺		
NOER _{mortality}				20.0	15.1	NOER _{reproduction}		10.0	7.5
Reference item									
[mL/ha]	[g ai/ha]	--							
9.0	3.6	86.7	86.4	Not determined		Not assessed			

*: mortality corrected using the formula Abbott

+: statistically significant difference

Reference: KCP 10.3-01

Report A laboratory test for evaluating the effects of Thifensulfuron 75% WDG on the predatory mite, *Typhlodromus pyri* (Sch.), Pawel Parma, 2018, report No. B/138/15

Guidelines Yes, according to ESCORT 1 and the ESCORT 2 and the guidelines developed by the IOBC, BART and EPPO Joint initiative

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication (if vertebrate study) No

Materials and methods

The aim of the laboratory test was to evaluate the effects of the test item, Thifensulfuron 75% WDG on mortality and reproduction of the predatory mite, *T. pyri* (Sch.).

On the basis of the preliminary test results, it was decided to use four rates of the test item in the definitive test. These were 10.0, 20.0, 40.0 and 80.0 g/ha (i.e. 7.5, 15.1, 30.1 and 60.2 g a.i./ha).

The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to discs. The mites were fed with pine pollen (*Pinus sp.*). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and all groups treated with the test item were made after 8, 11, and 14 days of the treatment.

Test item: name: Thifensulfuron 75% WDG; content: 75.3% (m/m) of Thifensulfuron as an active ingredient; batch number: SWEPL - 13205; manufacturing date: 25th June 2015; expiry date: 24th June 2017

Biological test system: the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: Phytoseiidae)

- age: 24-hour-old protonymphs
– source: a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from the Research Institute of Pomology and Floriculture, Skierniewice, Poland and renewed from commercial supplier, Katz Biotech

Experimental design: 6 study groups:
– a control group (0.0 g/ha)
– Thifensulfuron 75% WDG at the rate of 10.0 g/ha (7.5 g a.i./ha)
– Thifensulfuron 75% WDG at the rate of 20.0 g/ha (15.1 g a.i./ha)
– Thifensulfuron 75% WDG at the rate of 40.0 g/ha (30.1 g a.i./ha)
– Thifensulfuron 75% WDG at the rate of 80.0 g/ha (60.2 g a.i./ha)
– Danadim 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha)
number of replicates: 3; number of mites in each replicate: 20

Test conditions: temperature: 23.5 – 26°C
relative air humidity: 65 – 90%
photoperiod: 16 h light (919 lux) : 8 h dark

Statistical analysis: Probit analysis using linear max. likelihood regression, non-linear regression, chi2 2x2 table test with Bonferroni correction, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Williams multiple sequential t-test procedure.

Endpoints: – mite mortality after 7 days of the treatment (LR₅₀ and NOER_{mortality})
– reproduction reduction (Pr) after 14 days of the treatment (ER₅₀ and NOER_{reproduction})

Results and discussions

Table: Effect of Thifensulfuron 75% WDG on mortality and reproduction of *T. pyri*

Study group [app. rate]		Parameter (endpoint)							
		Mortality				Reproduction			
Test item		Total [%]	Corrected*	LR ₅₀		Mean no. eggs/female [no.]	Reproduction reduction [%]	ER ₅₀	
[g/ha]	[g ai/ha]			[g/ha]	[g ai/ha]			[g/ha]	[g ai/ha]
Control (0.0)		1.7	-	-		4.1	-	-	
10.0	7.5	10.0	8.5	> 80.0	> 60.2	4.3	(-4.8)	> 80.0	> 60.2
20.0	15.1	3.3	1.7			3.2	22.1 ⁺		
40.0	30.1	21.7	20.3 ⁺			3.0	27.0 ⁺		
80.0	60.2	13.3	11.9 ⁺			2.7	33.9 ⁺		
NOER _{mortality}				20.0	15.1	NOER _{reproduction}		10.0	7.5
Reference item		--							
[mL/ha]	[g ai/ha]								
9.0	3.6	86.7	86.4	Not determined		Not assessed			

*: mortality corrected using the formula Abbott

+: statistically significant difference

Conclusion

On the basis of the obtained results it can be concluded that Thifensulfuron 75% WDG at the rates of 10.0 and 20.0 g/ha (i.e. 7.5 and 15.1 g a.i./ha) has no adverse effect on mortality of the mites. The test item at the rate of 10.0 g/ha (i.e. 7.5 g a.i./ha) has no adverse effect on reproduction of the mites.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
-------------------	---

– After 48 hours, mortality in the control group was 0.0% (criterion: a maximum of 10.0%), – After 48 hours, mortality in the group treated with the reference item at a rate of 5.0 g/ha was 85.0% (criterion: minimum of 50%) – The mean number of mummies per female in the control was 32.4 (criterion: a minimum of 5.0 mummies/female) – All wasps in the control group gave offspring)criterion: a maximum of 2 females giving no offspring) –All wasps survived at 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity) Agreed endpoints:						
	Study group (application rate) (mL test item/ha)	Parameter (endpoint)				
		Mortality after 48 h			Fecundity	
		Total (%)	LR₅₀	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER₅₀
			[g test item/ha] [g a.i./ha]			[g test item/ha] [g a.i./ha]
	Control	0.0		32.4	-	
	Thifensulfuron-methyl 75% WDG					
	8.06	2.5	23.17 mL/ha (17.40^a g a.i./ha)	29.9	7.8	21.12 mL/ha (15.86^a g a.i./ha)
	12.90	12.5		22.7	29.9 ⁺	
	20.64	45.0 ⁺		17.4	46.3 ⁺	
	33.02	65.0 ⁺		-*	-*	
	52.84	100.0 ⁺		-*	-*	
	NOER_{mortality}		8.06 mL/ha (6.05^a g a.i./ha)	NOER_{fecundity}		8.06 mL/ha (6.05^a g a.i./ha)
	TAFGOR		Mortality after 24 h			
0.4 mL/ha		85.0%				
-* - the fecundity was not determined due to the mortality higher than 50% in comparison with the control group						
+: statistically significant differences at $p < 0.05$						
a: Thifensulfuron-methyl						

Reference: KCP 10.3.2.1-02

Report: “A laboratory test for evaluating the effects of Thifensulfuron-methyl 75% WDG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez)”. Dr. V. Angayarkanni, 2021, 8250/2021. Bioscience Research Foundation

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

SUMMARY

The laboratory test involved the evaluation of the effects of the test item, Thifensulfuron-methyl 75% WDG on mortality and fecundity of the parasitic wasp, *A. rhopalosiphi*. Five rates of the test item were used. These were 8.06, 12.90, 20.64, 33.02 and 52.84 mL/ha (6.05, 9.69, 15.50, 24.79 and 39.68 g Thifensulfuron-methyl/ha).

Adult wasps were exposed to the test item applied to bean leafs. The parasitoids were confined for 48 h and their condition was assessed after 2, 24, and 48 hours. Then, females which survived the 48-hour exposure to the test item and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, 15 female wasps from the groups treated with the test item and the ones from the control group were individually introduced into the fecundity units containing the barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which the wasp pupae were developing) was recorded.

Mortality of the wasps after 48 hours of the exposure and the percentage of fecundity reduction (Pr) relative to the control group recorded 12 days after the oviposition were the endpoints.

To assess the susceptibility of the test system and the sensitivity of the test method, an insecticide, TAFGOR (30% dimethoate EC) was used as a reference item. The rate of the reference item was 0.4 mL/ha (0.12 g dimethoate/ha). The control group was comprised of wasps having contact with glass plates sprayed with distilled water.

Materials and methods:

Test item:	Name: Thifensulfuron-methyl 75% WDG; content: 75.1% w/w of Thifensulfuron-methyl (CAS no.: 79277-27-3) as an active ingredient; batch no.: SCL-77990; manufacturing date: September 15, 2019; expiry date: September 14, 2021.
Biological test system:	the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez); Hymenoptera: <i>Braconidae</i>
– age:	Larvae (24 - 48 hours after emerging from mummies)
– source:	BRF Insectary
Experimental design:	7 test groups: – a control group (0.0 mL/ha) – Thifensulfuron-methyl 75% WDG at the rate of 8.06 mL/ha (6.05 g Thifensulfuron-methyl/ha) – Thifensulfuron-methyl 75% WDG at the rate of 12.90 mL/ha (9.69 g Thifensulfuron-methyl/ha) – Thifensulfuron-methyl 75% WDG at the rate of 20.64 mL/ha (15.50 g Thifensulfuron-methyl/ha) – Thifensulfuron-methyl 75% WDG at the rate of 33.02 mL/ha (24.79 g Thifensulfuron-methyl/ha) – Thifensulfuron-methyl 75% WDG at the rate of 52.84 mL/ha (39.68 g Thifensulfuron-methyl/ha) – TAFGOR at the rate of 0.4 mL/ha (0.12 g a.i./ha) 4 replicates/group 10 wasps/replicate
Test conditions:	
– temperature:	19.4 – 21.3°C
– relative air humidity:	68 – 80%
– photoperiod:	16 hours light (460 – 625 mortality and oviposition), (4550 – 5110 fecundity) : 8 hours dark
Statistical analyses:	Endpoints values for mortality and reproduction were determined by using Probit analysis in the NCSS (Number Cruncher Statistical System)

and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel Sheets

Endpoints:

- LR₅₀ and ER₅₀ value
- NOER mortality and fecundity

RESULTS AND DISCUSSION:

Study group (application rate) (mL test item/ha)	Parameter (endpoint)				
	Mortality after 48 h		Fecundity		
	Total (%)	LR ₅₀	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER ₅₀
[g test item/ha] [g a.i./ha]		[g test item/ha] [g a.i./ha]			
Control	0.0		32.4	-	
Thifensulfuron-methyl 75% WDG					
8.06	2.5	23.17 mL/ha (17.40 ^a g a.i./ha)	29.9	7.8	21.12 mL/ha (15.86 ^a g a.i./ha)
12.90	12.5		22.7	29.9 ⁺	
20.64	45.0 ⁺		17.4	46.3 ⁺	
33.02	65.0 ⁺		-*	-*	
52.84	100.0 ⁺		-*	-*	
NOER _{mortality}		8.06 mL/ha (6.05 ^a g a.i./ha)	NOER _{fecundity}		8.06 mL/ha (6.05 ^a g a.i./ha)
TAFGOR	Mortality after 24 h				
0.4 mL/ha	85.0%				

-* - the fecundity was not determined due to the mortality higher than 50% in comparison with the control group

+ : statistically significant differences at $p < 0.05$

a: Thifensulfuron-methyl

Mortality of wasps after 48 hours of exposure to Thifensulfuron-methyl 75% WDG at rates of 8.06, 12.90, 20.64, 33.02 and 52.84 mL/ha was 2.5, 10, 47.5, 70 and 100%, respectively.

There were no statistically significant differences in mortality between the group treated with the test item at the rate of 8.06 mL/ha and the control group.

On the basis of the mortality results, the LR₅₀ is 23.17 mL test item/ha (17.40g Thifensulfuron-methyl/ha). The NOER_{mortality} value is 8.06 mL Test item/ha (6.05 g Thifensulfuron-methyl/ha)

The fecundity assessment showed that the mean number of mummies per female in the group treated with Thifensulfuron-methyl 75% WDG at rates of 8.06, 12.90 and 20.64 mL/ha was 29.9, 22.7 and 17.4 respectively.

Fecundity reduction (Pr) in the group treated with the test item at rates of 8.06, 12.90 and 20.64 mL/ha was 7.8, 29.9 and 46.3% respectively.

There were no statistically significant differences in fecundity between the group treated with the test item at the rates of 8.06 mL/ha and the control group.

On the basis of the obtained fecundity results, the ER₅₀ value is 21.12 mL test item/ha (15.86 g Thifensulfuron-methyl/ha). The NOER_{reproduction} value is 8.06 mL test item/ha (6.05 g Thifensulfuron-methyl/ha)

On the basis of the obtained results, it can be concluded that Thifensulfuron-methyl 75% WDG had no adverse effects on mortality of the wasps at rates of 8.06 mL/ha and fecundity of *Aphidius rhopalosiphi* at rates of 8.06 mL/ha.

TEST VALIDITY CRITERIA

The following validity criteria were met during the study:

- After 48 hours, mortality in the control group was 0.0% (criterion: a maximum of 10.0%),
- After 48 hours, mortality in the group treated with the reference item at a rate of 5.0 g/ha was 85.0% (criterion: minimum of 50%)
- The mean number of mummies per female in the control was 32.4 (criterion: a minimum of 5.0 mummies/female)
- All wasps in the control group gave offspring)criterion: a maximum of 2 females giving no offspring)
- All wasps survived at 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity)

A 2.5 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.5.1.1.1 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • each replicate produced 137.8 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment), • the coefficient of variation of reproduction was 5.7% (criterion: $\leq 30\%$), • adult mortality over the initial 4 weeks of the experiment was 1.3% (criterion: $\leq 10\%$). Agreed endpoints: EC₁₀ = 82.5 mg/kg dry soil. EC₂₀ =111.2 mg/kg dry soil. EC₅₀=197.1 mg/kg dry soil. NOEC =18 mg/kg dry soil. LOEC =32 mg/kg dry soil.
-------------------	--

Reference:	KCP 10.4.1.1
Report	Thifensulfuron-methyl 75% WDG, earthworm reproduction test (<i>Eisenia fetida</i>), Marta Knapik, 2016, report No. G/257/15
Guidelines	Yes, OECD guideline No. 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The aims of the study were to assess the impact of Thifensulfuron – methyl 75% WDG on reproduction of the earthworm, *Eisenia fetida* and to determine the EC₁₀, EC₂₀, EC₅₀, and NOEC.

The test item in the form of a water suspension was mixed with the artificial soil. The concentrations of the test item were 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.

Test item: Thifensulfuron – methyl 75% WDG
batch number: SWEPL - 13205,
active substance: thifensulfuron – methyl – 75.3%

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

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; 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: 5.82 – 5.88; pH at the end of the experiment: 5.94 – 6.15; soil moisture content at the beginning of the experiment: 23.9 – 24.4% (50.38– 51.43% of the maximum water holding capacity); soil moisture content at the end of the experiment: 25.3 – 26.6% (53.33 – 56.07% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity: 553– 715 lux

Statistical analysis: EC₁₀, EC₂₀, EC₅₀ – the probit method NOEC, LOEC – the Shapiro-Wilk's Test on Normal Distribution, the Bartlett's Test Procedure on Variance Homogeneity, the Williams Multiple Sequential t-test Procedure, Fisher's Exact Binomial Test with Bonferroni Correction and Levene's Test on Variance Homogeneity (with Residuals)

Endpoints: EC₁₀, EC₂₀, EC₅₀, NOEC

Results and discussions

After 4 weeks, in control group and the concentrations: 32; 320 and 1000 mg/kg dry soil mortality of the adult earthworms were observed.

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 10 to 1000 mg/kg dry soil, the body weight increase was between 4.6 – 27.8%. As for the control group, it was equal to 27.4%.

After 8 weeks of the experiment, it was concluded that Thifensulfuron – methyl 75% WDG had impact on reproduction of the earthworms in concentrations ranging from 10 to 1000 mg/kg dry soil.

Conclusion

The concentration of the test item causing a 10% reduction in the number of juveniles produced within

the exposure period (EC₁₀) is 82.5 mg/kg dry soil.

The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period (EC₂₀) is 111.2 mg/kg dry soil.

The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period (EC₅₀) is 197.1 mg/kg dry soil.

The highest concentration at which the test item is observed to have no statistically significant effects on reproduction (NOEC) is 18 mg/kg dry soil.

The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction (LOEC) is 32 mg/kg dry soil.

The concentration of the test item causing 50% mortality of the adult earthworms (LC₅₀) is above 1000 mg/kg dry soil.

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.5.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.5.2.1.1 Study 1

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
-------------------	---

Reference: KCP 10.4.2

Report Thifensulfuron-methyl 75% WDG, Collembolan (*Folsomia candida*) Reproduction test, Marta Knapik, 2016, report No. G/258/15

Guidelines Yes, OECD guideline No. 232

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication No
(if vertebrate study)

Materials and methods

The aims of the study were to assess the impact of Thifensulfuron-methyl 75% WDG on reproduction of the collembolans, *Folsomia candida* and to determine the EC₁₀, EC₂₀, EC₅₀, and NOEC.

Ten concentrations of the test item were used. These included: 1.8, 3.2, 5.6, 10, 18, 32, 56, 100, 180 and 320 mg/kg dry soil. The test item in the form of suspension was mixed with the artificial soil. Each concentration was divided into four replicates. There were also a concurrent control group divided into eight replicates. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Test item: Thifensulfuron – methyl 75% WDG
batch no.: SWEPL-13205
active substance: Thifensulfuron – methyl – 75.3%

Artificial soil: 5% peat, 20% clay, and 75% sand

Test organism: the collembolan, *Folsomia candida* obtained from a standard laboratory culture at the

Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology

Test design: test duration: 28 days

Concentrations of the test item: control, 1.8, 3.2, 5.6, 10, 18, 32, 56, 100, 180 and 320 mg/kg dry soil

Test conditions: temperature: 18 – 23°C;
pH at the beginning of the test: 5.90 – 6.10;
pH at the end of the test: 6.05 – 6.15;
soil moisture content at the beginning of the test: 12.2 – 12.6% (50.1-51.7% of the maximum water holding capacity);
soil moisture content at the end of the test: 12.1 – 12.6% (49.7– 51.7% of the maximum water holding capacity);
lighting: 12 h light and 12 h dark; light intensity: 572 – 711 lux

Statistical analysis: EC₁₀, EC₂₀, and EC₅₀ – a probit method
NOEC – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) and Multiple Sequentially rejective U-test After Bonferroni-Holm

Endpoints: EC₁₀, EC₂₀, EC₅₀, and NOEC

Results and conclusion

After 28 days of the experiment mortality of the adult collembolans were observed. Mortality (depending on the concentration of the test item) ranged from 7.5 to 20%.

The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below

Endpoint	Value [mg of test item/kg dry soil]	Value [mg Thifensulfuron-methyl/kg dry soil]
LC ₁₀	> 320	> 240.96
LC ₂₀	> 320	> 240.96
LC ₅₀	> 320	> 240.96
NOEC	320	240.96
LOEC	> 320	> 240.96

After the exposure of the adult collembolans to the test item at the concentrations ranging from 1.8 to 320.0 mg/kg dry soil, the mean number of juveniles was between 150.5 ÷ 320.8 per replicate.

The mean number of juveniles in the control was 298.3 per replicate.

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg Thifensulfuron-methyl/kg dry soil]
EC ₁₀	16.5 (6.04-28.5)	12.4
EC ₂₀	44.9 (25.1-65.1)	33.8
EC ₅₀	304.4 (202.6-598.6)	229.2
NOEC	32.0	24.1

LOEC	56.0	42.2
-------------	-------------	-------------

A 2.5.2.2 KCP 10.4.2.1 Species level testing

Com-ments of zRMS:	The study is considered acceptable. All validity criteria were met.		
	- each replicate produced 137.8 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment), - the coefficient of variation of reproduction was 5.7% (criterion: $\leq 30\%$), - adult mortality over the initial 4 weeks of the experiment was 1.3% (criterion: $\leq 10\%$).		
	Agreed endpoints:		
	a – Thifensulfuron-methyl		
	Endpoints	[mg t.i./kg sdw]	[mg Thifensulfuron-methyl/kg sdw]
	NOEC reproductive output	555.56	417.23
	LOEC reproductive output	1000	751.00
	EC ₁₀	743.33 (551.04 – 935.62)	558.24 ^a (413.83 – 702.65)
	EC ₂₀	>1000 (n.d)	>751.00 ^a (n.d)
	EC ₅₀	>1000 (n.d)	>751.00 ^a (n.d)
	n.d. – not determined		

Reference: KCP 10.4.2.1

Report	“Thifensulfuron-methyl 75% WDG on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil”. Dr. V. Angayarkanni. 2021. Study code: 8249/2021. BIOSCIENCE RESEARCH FOUNDATION
Guideline(s):	OECD Guideline No. 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item: Thifensulfuron-methyl 75% WDG
batch no.: SCL-77990
active substance content: Thifensulfuron-methyl, 75.1% (w/w)

Artificial soil 5% sphagnum peat (a particle size of 2 ± 1 mm); 20% kaolin clay; 75% air-dried industrial sand (with more than 50 % of the particles between 50 and 200 microns)

Biological test system : *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari, Laelapidae), from their-house culture, adult mites (33 days after starting of the egg-laying for synchronisation).

Test design: Adult females were exposed to the test substance in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of juveniles per test unit and additionally the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A Dose-response test with 10 different test substance concentrations and 4 replicates each as well as a water control (without test substance) with 8 replicates; 10 adult females were exposed per replicate.

Test doses: 0 (control), 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test substance/kg soil dry weight. Equivalent to 3.79, 6.81, 12.26, 22.26, 39.74, 71.54, 128.77, 231.79, 417.23 and 751.0 mg Thifensulfuron-methyl/kg soil dry weight.

Test conditions: Temperature during exposure: 20.5 °C to 21.2 °C
pH at the beginning of the test: 6.22 to 6.49
pH at the end of the test: 5.82 to 6.31
Soil moisture content at the beginning of the test: 20.02 % to 21.30 % (corresponding to 51.33 – 52.46 % of the WHC_{max})
Soil moisture content at the end of the test: 19.15 % to 21.20 % (corresponding to 50.68 – 52.44 % of the WHC_{max})
Lighting: 16 h light and 8 h dark (long day conditions); light intensity: 590 lux to 635 lux

Endpoints: LOEC and NOEC for mortality and reproductive output; EC_{10, 20, 50} for reproductive output and LC_{10, 20, 50} for mortality output where possible.

Results and discussions

Mortality after 14 days of experiment at the concentrations of the test item ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, mortality was between 0.00 and 30%. As for the control group, it was 0.00%.

No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in the control group and in any of the test substance groups.

After the application of the test item at the concentration ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 104.25 and 128.00 per replicate. As for the control group, the number of juveniles was equal to 128.13 per replicate.

The toxic reference item (a.i. dimethoate) was conducted between 03.06.2020 and 26.06.2020. The EC₅₀ for reproductive output was determined to be 4.02 mg/kg soil dry weight. This is within the target range of 3.0 to 7.0 mg dimethoate/kg soil dry weight given by the OECD guideline 226 (2016) and hence acceptable sensitivity of the test system was assured.

Mortality and reproductive output of *H. aculeifer* after exposure to artificial soil treated with test item

a – Thifensulfuron-methyl

Treatment group	Test substance Concentration [mg t.s./kg sdw]	Mean Mortality [%]	Mean n° of juveniles per replicate	Coefficient of Variation [%]	Reduction in reproductive output [%] ^a
Control	0	0.0	128.13 ± 2.53	1.98	-
Thifensulfuron-methyl 75% WDG	5.04	0.0	128.00 ± 0.82	0.64	0.10
	9.07	0.0	127.75 ± 2.06	1.61	0.29
	16.33	0.0	127.50 ± 1.73	1.36	0.49
	29.40	2.5	127.00 ± 2.16	1.70	0.88
	52.92	0.0	126.50 ± 1.73	1.37	1.17
	95.26	2 ± 5	126.25 ± 3.30	2.62	1.46
	171.47	2 ± 5	126.00 ± 1.83	1.45	1.66
	308.64	2 ± 5	124.25 ± 3.30	2.66	3.02
	555.56	3 ± 7.5	123.25 ± 4.27	3.47	3.80
	1000	30 ± 8.2	104.25 ± 2.22	2.13	18.63 ⁺

Endpoints	[mg t.i./kg sdw]	[mg Thifensulfuron-methyl/kg sdw]
NOEC _{mortality}	555.56	417.23
LOEC _{mortality}	1000	751.00
LC ₁₀	340.42 (281.05 – 399.79)	255.66 ^a (211.07 – 300.24)
LC ₂₀	976.01 (734.56 - >1000)	732.98 ^a (551.65 - >751.00)
LC ₅₀	>1000 (n.d)	>751.00 ^a (n.d)
NOEC _{reproductive output}	555.56	417.23
LOEC _{reproductive output}	1000	751.00
EC ₁₀	743.33 (551.04 – 935.62)	558.24 ^a (413.83 – 702.65)
EC ₂₀	>1000 (n.d)	>751.00 ^a (n.d)
EC ₅₀	>1000 (n.d)	>751.00 ^a (n.d)

n.d. – not determined

Conclusion

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

A 2.5.2.3 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil nitrogen transformation

A 2.6.1.1.1 Study 1

Comments of zRMS:

The study is considered acceptable. All validity criteria were met:
The coefficients of variation (CV) in the control group were 5.4, 10.5, 9.1, and 4.0%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples should be less than ± 15%.
Deviations from the OECD Guideline No. 216 (2000) and EU Method C.21:
1. The content of the flask was shaken for 24 hours. According to OECD Guideline 216 the probes should be shaken for 60 minutes. This deviation had no influence on the obtained results, because the correlation between the nitrate ions concentration extracted from the control soil and treated soil was always the same independently of the shaking time.

Deviations from the OECD Guideline No. 216 (2000), EU Method C.21, Study Plan and SOP/G/32:
1. The temperature increased to 23°C during incubation. However, these were short-term deviations which had no impact on the results of the experiment.

The agreed toxicity endpoints:

Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC 0.053 mg/kg soil				5 x PEC 0.27 mg/kg soil			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 - 7	4.175	6.104	6.168	5.483 ± 1.13	6.464	4.664	9.049	6.725 ± 2.20	3.061	4.754	9.597	5.804 ± 3.39
0 - 14	-0.212	0.256	0.167	0.070 ± 0.25	-0.154	0.0	0.193	0.013 ± 0.17	0.963	0.552	-0.112	0.468 ± 0.54
0 - 28	4.761	4.584	4.295	4.546 ± 0.24	4.488	5.190	4.656	4.778 ± 0.37	4.691	5.166	4.902	4.920 ± 0.24

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mean of mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14, 28 day

Reference:	KCP 10.5-02
Report	Thifensulfuron-methyl 75% WDG Soil microorganisms: Nitrogen Transformation Test, Weronika Dec, 2017, report No. G/256/15
Guidelines	Yes, OECD guideline No. 216 and EU Method C.21
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The aim of the study was to detect long-term adverse effects of Thifensulfuron – methyl 75% WDG on the processes of nitrogen transformation in aerobic surface soils.
Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm. The concentrations of the test item were 0.053 (PEC) and 0.27 mg/kg dry soil (5xPEC) (0.0399 and 0.203 mg of thifensulfuron - methyl/kg of soil, respectively). The treated and the control soils were divided into three replicates.

On days 0, 7, 14, and 28 of incubation, soil samples were collected to determine the quantities of nitrates.

Test material: Thifensulfuron-methyl 75% WDG

Soil: Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

Test design: Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.

Concentrations of the test material:

- Control;
- PEC: 0.053 mg/kg dry soil (0.0399 mg of Thifensulfuron-methyl/kg of soil);
- 5 x PEC: 0.27 mg/kg dry soil (0.203 mg of thifensulfuron - methyl/kg of soil)

Test conditions: Temperature: 18 – 23°C,
soil moisture: 49.1% – 50.7% of the maximum water holding capacity, incubation in darkness.

Endpoints: The concentration of nitrate ions [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation
The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14, 0 – 28 days.
Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14, 0 – 28 days.

Statistical analysis:

- Shapiro-Wilk's test on Normal Distribution
- Levene's Test on Variance Homogeneity
- Student-t test for Homogeneous Variances with Bonferroni – Holm Adjustment
- Williams Multiple Sequential t-test Procedure

Results and discussions

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC (0.053 mg/kg dry soil) and 5 x PEC (0.27 mg/kg dry soil) did not exceed 25% on 28 day of analysis

Conclusion

On the basis of the results, it was concluded that Thifensulfuron-methyl 75% WDG at the concentrations corresponding to the PEC (0.053 mg/kg dry soil) and 5 x PEC (0.27 mg/kg dry soil) (0.0399 and 0.203 mg of Thifensulfuron-methyl/kg of soil, respectively), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils

A 2.7 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.7.1 KCP 10.6.1 Summary of screening data

A 2.7.2 KCP 10.6.2 Testing on non-target plants

Comments of	The study is considered acceptable. All validity criteria were met.
-------------	---

[illegible]

Tomato (<i>Solanum lycopersicon</i>) ER ₅₀ > 24 g formulation/ha (34% effect)	
Reference:	KCP 10.6.2-01
Report	“Thifensulfuron-methyl 75% WDG on vegetative vigour of terrestrial plants. Dr. S. Radha. 2021. Study code: 8248/2020. Bioscience Research Foundation.
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Thifensulfuron-methyl 75% WDG; Batch Number: SCL-77990; active substance content: Thifensulfuron-methyl, 75.1% (w/w)
Test species:	Sunflower (<i>helianthus annuus</i>), Corn (<i>Zea mays</i>), oats (<i>Avena sativa</i>), Pea (<i>Pisum sativum</i>), tomato (<i>Solanum lycopersicon</i>) and oilseed rape (<i>brassica napus</i>).
Soil:	Sandy loam soil, 1.2% organic carbon, 2 mm particle size
Study design:	Number of rates: 5 application rates + control; number of replicates: 7 replicates/rate. The total number of plants per application rate – 21. Test termination: 21 days after the spraying.
Application rates:	Control, 1.5, 3, 6, 12 and 24 g test item/ha (1.13, 2.25, 4.51, 9.01 and 18.02 g Thifensulfuron-methyl/ha).
Volume of distilled water used to prepare the highest rate:	300 L water/ha.
Test conditions:	Temperature: 21.2 – 22.3°C, humidity: 57.2 – 68.3%, controlled light – dark cycles (16h:8h), light intensity: 334 – 400 $\mu\text{E}/\text{m}^2/\text{s}$, carbon dioxide concentration: 324 – 345 ppm.
Statistical analysis:	ER ₁₀ , ER ₂₅ , ER ₅₀ and NOER values were determined by using a Probit analysis in the NCSS and one-way ANOVA using Graph Pad Prism 8.0
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER

Results and Conclusions

The test item Thifensulfuron-methyl 75% WDG applied at rates ranging from 1.5 to 24 g test item/ha had a varied impact on vegetative vigour of all plant species.

There was mortality observed for all the plant species at rates ranging from 1.5 to 24 g test item/ha. The phytotoxic symptoms for all the plant species tested were observed at the rates of 3 to 24 g/ha. The following symptoms were not observed on 21 days after the test item application: Chlorosis, necrosis, wilting, leaf deformation, stem deformation or death.

Table 3 - Endpoint values – Vegetative vigour

Endpoint Value (L/ha ^a)		Sunflower (<i>Helianthus annuus</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	Oilseed rape (<i>Brassica napus</i>)	Oats (<i>Avena sativa</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number at the end of the experiment							
ER₁₀	g/ha ^a	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
	g/ha ^b	<1.13	<1.13	<1.13	<1.13	<1.13	<1.13
ER₂₅	g/ha ^a	1.94	2.60	2.79	2.72	2.71	2.49

	g/ha ^b	2.21	1.95	2.10	2.04	2.04	1.87
ER₅₀	g/ha ^a	8.05	6.74	6.96	6.42	6.76	6.73
	g/ha ^b	6.05	5.06	5.23	4.82	5.08	5.05
NOER	g/ha ^a	1.5	1.5	1.5	1.5	1.5	1.5
	g/ha ^b	1.13	1.13	1.13	1.13	1.13	1.13
Shoot length (plants without roots)							
ER₁₀	g/ha ^a	<1.5	1.54	1.52	1.92	1.56	<1.5
	g/ha ^b	<1.13	1.16	1.14	1.44	1.17	<1.13
ER₂₅	g/ha ^a	2.88	3.11	3.16	3.88	2.96	3.00
	g/ha ^b	2.16	2.34	2.37	2.91	2.22	2.25
ER₅₀	g/ha ^a	6.11	6.78	7.13	8.43	6.04	7.37
	g/ha ^b	4.59	5.09	5.35	6.33	4.54	5.53
NOER	g/ha ^a	1.5	1.5	1.5	1.5	1.5	1.5
	g/ha ^b	1.13	1.13	1.13	1.13	1.13	1.13
Plant dry weight (plants without roots)							
ER₁₀	g/ha ^a	<1.5	1.81	2.10	1.81	2.08	2.11
	g/ha ^b	<1.13	1.36	1.58	1.36	1.56	1.58
ER₂₅	g/ha ^a	3.05	3.82	4.04	3.71	4.15	4.25
	g/ha ^b	2.29	2.87	3.03	2.79	3.12	3.19
ER₅₀	g/ha ^a	7.47	8.72	8.39	8.25	8.95	9.23
	g/ha ^b	5.61	6.55	6.30	6.20	6.72	6.93
NOER	g/ha ^a	1.5	1.5	1.5	1.5	1.5	1.5
	g/ha ^b	1.13	1.13	1.13	1.13	1.13	1.13

a: value for the test item i.e. Thifensulfuron-methyl 75% WDG expressed as g/ha

b: Value for the active substance, i.e Thifensulfuron-methyl expressed as g/ha

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. The following validity criteria were met:					
	- The seedling emergence in the control (validity criterion: at least 70%) was as follows: 100% - sunflower, 100% - corn, 100% - pea, 100% - oilseed rape, 100% - oats, 100% - tomato, - The mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%), - The control seedlings did not exhibit any visible phytotoxic symptoms, - Environmental conditions for all plants belonging to the same species were identical.					
	Agreed endpoints:					
	Endpoint Value (L/ha^a)	Sunflower (<i>Helianthus annuus</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	Oilseed rape (<i>Brassica napus</i>)	Tomato (<i>Solanum lycopersicon</i>)
	Plant number at the end of the experiment					
	ER₁₀	1.25	1.46	1.11	1.02	1.26
	ER₂₅	2.72	3.12	2.6	2.55	2.79
	ER₅₀	6.42	7.28	6.71	7.06	6.76
	NOER	1.5	1.5	1.5	1.5	1.5
	Shoot length (plants without roots)					
	ER₁₀	1.41	1.56	1.43	1.43	1.49
	ER₂₅	3.08	3.25	2.88	2.91	3.05
	ER₅₀	7.38	7.36	6.26	6.40	6.75
	NOER	1.5	1.5	1.5	1.5	1.5

Plant dry weight (plants without roots)							
ER ₁₀	1.79	1.47	1.50	1.44	1.44	1.46	
ER ₂₅	3.34	2.98	2.91	2.88	2.94	2.39	
ER ₅₀	6.70	6.49	6.10	6.24	6.51	6.18	
NOER	1.5	1.5	1.5	1.5	1.5	1.5	
a: value for the test item. Expressed as g/ha							
Phytotoxicity parameter: The phytotoxicity parameter was assessment by RMS based on data in the study: Sunflower (<i>Helianthus annuus</i>) ER ₅₀ > 24 g formulation/ha (26% effect) Corn (<i>Zea mays</i>) ER ₅₀ > 24 g formulation/ha (23% effect) Pea (<i>Pisum sativum</i>) ER ₅₀ > 24 g formulation/ha (25% effect) Oilseed rape (<i>Brassica napus</i>) ER ₅₀ > 24 g formulation/ha (23% effect) Oats (<i>Avena sativa</i>) ER ₅₀ > 24 g formulation/ha (25% effect) Tomato (<i>Solanum lycopersicon</i>) ER ₅₀ > 24 g formulation/ha (23.33% effect)							

Reference:	KCP 10.6.2-02
Report	“Effect of Thifensulfuron-methyl 75% WDG on seedling emergence and seedling growth of terrestrial plants”. Dr. S. Radha, 2021. Study code: 8247/2020. Bioscience Research Foundation
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Thifensulfuron-methyl 75% WDG; Batch Number SCL - 77990; active substance content: Thifensulfuron-methyl, 75.1% (w/w)
Test species:	Sunflower (<i>Helianthus annuus</i>), tomato (<i>Solanum lycopersicon</i>), Oilseed rape (<i>Brassica napus</i>), pea (<i>Pisum sativum</i>), corn (<i>Zea mays</i>) and Oats (<i>Avena sativa</i>).
Soil:	Sandy loam soil, 1.2% organic carbon, 2 mm particle size
Study design:	Number of concentrations: 5 application rates + a control Number of replicates: 7 replicates of each application rate and the control Number of seeds: 3 seeds/replicate Test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	Control, 1.5, 3, 6, 12 and 24 g test item/ha (1.13, 2.25, 4.51, 9.01 and 18.02 g Thifensulfuron-methyl/ha). Volume of distilled water used to prepare the highest rate: 300 L water/ha.
Test conditions:	Temperature: 21.2– 22.3 °C; humidity: 57.2 – 68.3%; lighting: 16 h light : 8 h dark; light intensity: 334 – 400 µE/m ² /s; carbon dioxide concentration: 324 – 345 ppm
Statistical analysis:	ER ₁₀ , ER ₂₅ , ER ₅₀ and NOER – Probit in the NCSS and one-way ANOVA using GraphPad Prism 8.0, respectively
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER

Results and Conclusions

The application of the test item at the rates ranging from 1.5 to 24 g/ha had a varied impact on seedling emergence and seedling growth of all the plant species tested.

After the application of the test item 3 to 24 g/ha, seedling emergence was delayed for all the species. However all the plant species emerged after the application of the test item at rates ranging from 1.5 to 24 g/ha. The phytotoxic symptoms were observed for all the plant species at all the rates. The following symptoms were observed:

- Sunflower, pea, oats and tomato, chlorosis, wilting, leaf deformation or stem deformation.
- Corn and oilseed rape: chlorosis, necrosis, leaf deformation or stem deformation.

Table 4 - Endpoint values

Endpoint Value (L/ha ^a)	Sunflower (<i>Helianthus annuus</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	Oilseed rape (<i>Brassica napus</i>)	Oats (<i>Avena sativa</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number at the end of the experiment						
ER₁₀	1.25	1.46	1.11	1.02	1.26	1.23
ER₂₅	2.72	3.12	2.6	2.55	2.79	2.87
ER₅₀	6.42	7.28	6.71	7.06	6.76	7.37
NOER	1.5	1.5	1.5	1.5	1.5	1.5
Shoot length (plants without roots)						
ER₁₀	1.41	1.56	1.43	1.43	1.49	1.44
ER₂₅	3.08	3.25	2.88	2.91	3.05	2.91
ER₅₀	7.38	7.36	6.26	6.40	6.75	6.31
NOER	1.5	1.5	1.5	1.5	1.5	1.5
Plant dry weight (plants without roots)						
ER₁₀	1.79	1.47	1.50	1.44	1.44	1.46
ER₂₅	3.34	2.98	2.91	2.88	2.94	2.39
ER₅₀	6.70	6.49	6.10	6.24	6.51	6.18
NOER	1.5	1.5	1.5	1.5	1.5	1.5

a: value for the test item. Expressed as g/ha

A 2.7.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.8 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.9 KCP 10.8 Monitoring data