

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: GLOB2013F

Product name(s): Observer

Chemical active substance:

Zoxamide, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2024

MS Finalisation date: 19/12/2024

Version history

When	What
January 2024	Initial dossier submission by applicant for approval of new product
February 2024	Submission to the Polish Ministry of Agriculture and Rural Development
April 2024	Submission to the evaluation unit
September 2024	RMS finalised evaluation
December 2024	zRMS finalised evaluation after commenting period
May 2025	Updated version of dRR
July 2025	Updated version of dRR

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9 Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by Globachem NV for approval of the formulation Observer (Product code: GLOB2013F) containing 450 g/L of zoxamide a suspension concentrate for use as a fungicide on: potato (seed potatoes, ware and starch potato) and table and wine grape.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the Applicant, all review comments, additions, and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

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: developmental 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. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CZ, HU, IE, PL, RO, SK	Seed, ware and starch potato (SOLTU)	F	<i>Phytophthora infestans</i> (PHYTIN)	Downward spraying	BBCH 21-79	a) 3 b) 3	7	a) 0.3 b) 0.9	a) 0.135 b) 0.405	150-300	7								
2	CZ, HU, IE, PL, RO, SK	Table and wine grape (VITVI)	F	<i>Plasmopara viticola</i> (PLASVI)	Air assisted	BBCH 13-52	a) 2 b) 2	8	a) 0.3 b) 0.6	a) 0.135 b) 0.270	100-1000	28								
3	CZ, HU, IE, PL, RO, SK	Table and wine grape (VITVI)	F	<i>Plasmopara viticola</i> (PLASVI)	Air assisted	BBCH 53-83	a) 2 b) 2	8	a) 0.368 b) 0.736	a) 0.166 b) 0.332	100-1000	28								
4	CZ, HU, IE, PL, RO, SK	Seed, ware and starch potato (SOLTU)	F	<i>Phytophthora infestans</i> (PHYTIN)	Downwards spraying	BBCH 21-79	a) 3 b) 3	7	a) 0.29 b) 0.87	a) 0.130 b) 0.390	150-300	7	Alternative GAP with a slightly lower dose rate in order to maintain a mitigation of maximum 10 m VFS only where necessary							

- * 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: | <p>(1) Numeration necessary to allow references</p> <p>(2) Use official codes/nomenclatures of EU</p> <p>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(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</p> <p>(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</p> <p>(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</p> | <p>(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</p> <p>(8) The maximum number of application possible under practical conditions of use must be provided</p> <p>(9) Minimum interval (in days) between applications of the same product.</p> <p>(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</p> <p>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>(13) PHI - minimum pre-harvest interval</p> <p>(14) Remarks may include: Extent of use/economic importance/restrictions</p> |
|-----------------------|---|--|

Review Comments:

GAP presented in the Table 9.1-1 of this document is revised with consideration of the outcome of the evaluation performed in area of ecotoxicology.

9.1.1 Overall conclusions

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)

The risk assessment for birds and mammals was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to birds and mammals from zoxamide and metabolites following application of GLOB2013F at the intended GAP. The TER_{lt} value for zoxamide and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2013F presents no unacceptable long-term risk to birds and mammals when applied according to the proposed GAP.

The risk assessment for secondary poisoning, required for zoxamide and its metabolites, showed that the risk for earthworm-eating and fish-eating birds and mammals is acceptable following use of GLOB2013F according to the proposed use pattern.

Furthermore, the risk assessment for exposure to zoxamide *via* drinking water also showed an acceptable risk.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

An acceptable risk for the formulation GLOB2013F in potato and grape is acceptable with the following mitigation measures:

For the countries that accept the EU agreed endpoints (see part B8) and for the countries that do not accept the EU agreed endpoints but where R3 is not relevant:

SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (late applications), to protect aquatic organisms use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: Alternatively, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

For the countries that do not accept the EU agreed endpoints and where R3 is relevant:

SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 15 m including a 15 m vegetated filter strip to surface water bodies. Alternatively, apply up to 0.29L/ha and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (late applications), to protect aquatic organisms use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.
OR in case VFSSMOD is accepted: Alternatively, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

For grape, for Poland specific scenarios:

SPe3: For grape use (early applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies (according to VFSSmode).

or

-respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.

SPe3: For grape use (late applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies (according to VFSSmode).

Or

-respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 75% drift reducing nozzles to surface water bodies.

~~-respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.~~

~~SPe3: For grape use (early applications), to protect aquatic organisms, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies.
Alternatively, respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.~~

~~SPe3: For grape use (late applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies.
Alternatively, use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.~~

Concerned Member States must decide on the consideration of mitigation measures guidance on National level.

9.1.1.3 Effects on bees (KCP 10.3.1)

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002 rev.2 (final). October 17. 2002).

The risk for bees is acceptable when using GLOB2013F according to the intended uses.

No risk mitigation measures are needed.

Concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on National level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

The risk for non-target arthropods is acceptable when using GLOB2013F according to the intended uses. No risk mitigation measures are needed.

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

The TER values indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2013F.

The EU review for zoxamide and the test on the formulation show that there are no effects on soil microbial activity at dose rates far higher than the corresponding PEC_{soil} of the intended use. Therefore, it is concluded that there is no unacceptable risk on soil microbial activity for GLOB2013F.

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

First tier risk assessment indicates that there is no unacceptable risk from GLOB2013F for non-target plants when applied according to the proposed use rates.

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

Tests on other non-target species are not required.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of GLOB2013F grouped according to application rate

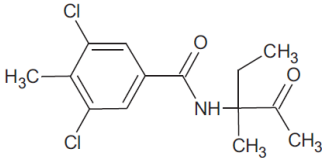
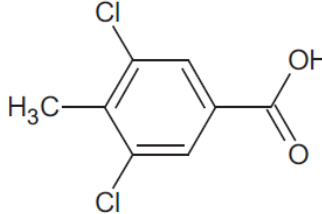
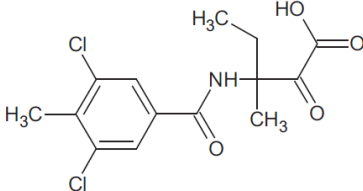
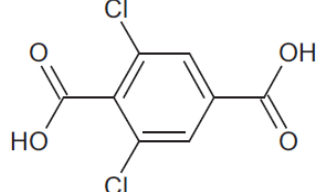
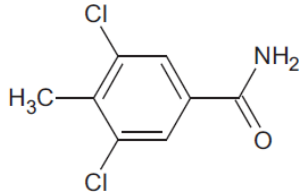
Grouping according to application rate			
Group	Intended uses	application rate	relevant parameter or value for sorting
1	1 (Potato) 4 (Potato)	3x135 g/ha 3 x 130 g/ha	application rate
2	2 (Grape, early) 3 (Grape, late)	2x135 g/ha 2x166 g/ha	Effective application rate: Use 2 covers use 3 on PECs and FOCUS STEP 1-2 where crop interception in earlier stages is much lower Application rate: Use 3 covers use 2 in cases where interception is not considered (ecotox).

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 GLOB2013F is indicated in the

table.

Table 9.1-3 Metabolites of zoxamide

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
RH-127450	302.15		Soil: 15.1% Water/Sediment: 39.3%	Yes, for soil and aquatic organisms
RH-24549	205		Soil: 33.8% Water/Sediment: 5%	Yes, for soil and aquatic organisms
RH-163353	332.15		Soil: 15% Water/Sediment: 20.6%	Yes, for soil and aquatic organisms
RH-141455	235.02		Soil: 8.4% Water/Sediment: 2.1%	Yes, for soil and aquatic organisms
RH-139432	204.06		Soil: 4.9% Water/Sediment: 42.4%	Yes, for aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with zoxamide. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. However, the provision of further data on the formulation is not considered essential, because the risk for birds from GLOB2013F can be adequately assessed from the risk assessment for the active substance. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Bobwhite quail (<i>Colinus virginianus</i>)	zoxamide	Acute	LD ₅₀ >2000 mg/kg bw	EFSA Journal 2017;15(9):4980
Bobwhite quail (<i>Colinus virginianus</i>)	zoxamide	Short-term	LD ₅₀ = 1889.3 mg/kg bw/d	EFSA Journal 2017;15(9):4980
Mallard duck (<i>Anas platyrhynchos</i>)	zoxamide	Short-term	LD ₅₀ = 1597.7 mg/kg bw/d	EFSA Journal 2017;15(9):4980
Mallard duck (<i>Anas platyrhynchos</i>)	zoxamide	Reproduction	NOEC = 122.8 g a.s./kg bw/d	EFSA Journal 2017;15(9):4980
Bobwhite quail (<i>Colinus virginianus</i>)	zoxamide	Reproduction	NOEC = 170.9 g a.s./kg bw/d	EFSA Journal 2017;15(9):4980

9.2.1.1 Justification for new endpoints

EU agreed endpoints were used in the risk assessment. No deviations were made.

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 **screening** ~~first-tier~~ risk assessments are summarised in the following tables.

Table 9.2-2: Screening ~~First-tier~~ assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2013F

Intended use		Potato				
Active substance/product		zoxamide				
Application rate (g/ha)		3 × 135 (covering use no. 4 with 130 g a.s)				
Acute toxicity (mg/kg bw)		>2000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.6	34.3	58.3	
Reprod. toxicity (mg/kg bw/d)		122.8				
TER criterion		5				

Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Screening step	Small omnivorous bird	64.8	2.0 × 0.53	9.27	13.2
Intended use	Grape				
Active substance/product	zoxamide				
Application rate (g/ha)	2 × 166 (covering use no. 2 with 135 g a.s)				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Screening step	Small omnivorous bird	95.3 158.8	1.4	15.82 26.36	126.42 54.2
Reprod. toxicity (mg/kg bw/d)	122.8				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Screening step	Small omnivorous bird	38.9 64.8	1.6 × 0.53	5.47 9.12	22.45 13.5

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.

9.2.2.2 Higher-tier risk assessment

Not required.

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 GLOB2013F 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 1207 mL/g, zoxamide belongs to the group of more sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 2 also covers the risk for mammals from all other intended uses (see 9.1.2).

For potato, to take into account the 3 applications, a MAF of 1.6 was used as a worst-case (effective

application rate = application rate x 1.6), which results in 216 g/ha.

For grape, to take into account the 2 applications, a MAF of 1.4 was used as a worst-case (effective application rate = application rate x 1.4), which results in 232.4 g/ha. This is considered as worst case to the assessment below.

Effective application rate (g/ha) =	232.4			
Acute toxicity (mg/kg bw) =	2000	quotient	=	0.1162
Reprod. toxicity (mg/kg bw/d) =	122.8	quotient	=	2.0603

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of zoxamide amounts to 3.76 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-127450 amounts to 3.5 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-24549 amounts to 3.83 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-163353 amounts to 1.43 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

The log P_{ow} of RH-141455 amounts to 1.94 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

The log P_{ow} of RH-139432 amounts to 2.7 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil.

Table 9.2-3: Assessment of the risk for earthworm-eating birds due to exposure to zoxamide via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	zoxamide	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0618	See dRR Part B8.
log P_{ow} / P_{ow}	3.76 / 5754.4	
Koc	1207	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	2.895	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.179	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.188	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	122.8	EFSA Journal 2017;15(9):4980
TER _{lt}	653.6	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-4: Assessment of the risk for earthworm-eating birds due to exposure to zoxamide via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	zoxamide	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0874	See dRR Part B8.
log P _{ow} / P _{ow}	5754.4	
Koc	1207	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	2.895	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.253	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.266	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	122.8	EFSA Journal 2017;15(9):4980
TER _{lt}	462.2	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-5: Assessment of the risk for earthworm-eating birds due to exposure to RH-127450 via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	RH-127450	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.014	See dRR Part B8.
log P _{ow} / P _{ow}	3.5 / 3162	
Koc	669	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	2.899	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.041	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.043	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	288.2	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-6: Assessment of the risk for earthworm-eating birds due to exposure to RH-127450 via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	RH-127450	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0132	See dRR Part B8.
log P _{ow} / P _{ow}	3162	

Parameter	RH-127450	comments
Koc	669	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	2.899	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.038	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.040	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	305.7	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to RH-24549 via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	RH-24549	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0133	See dRR Part B8.
log P _{ow} / P _{ow}	3.83 / 6761	
Koc	90.55	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	45.263	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.602	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.632	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	19.4	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-8: Assessment of the risk for earthworm-eating birds due to exposure to RH-24549 via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	RH-24549	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0134	See dRR Part B8.
log P _{ow} / P _{ow}	6761	
Koc	90.55	EFSA Journal 2017;15(9):4980
Foc	0.02	Default
BCF _{worm}	45.263	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.607	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$

Parameter	RH-24549	comments
Daily dietary dose (mg/kg bw/d)	0.637	DDD = $PEC_{\text{worm}} \times 1.05$
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	19.3	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 2 also covers the risk for birds from all other intended uses in group 2 (see 9.1.2).

Table 9.2-9: Assessment of the risk for fish-eating birds due to exposure to zoxamide via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	zoxamide	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0210821	See dRR Part B8.
BCF _{fish}	136	
BMF	/	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	2.867	$PEC_{\text{fish}} = PEC_{\text{water}} \times BCF_{\text{fish}}$
Daily dietary dose (mg/kg bw/d)	0.456	DDD = $PEC_{\text{fish}} \times 0.159$
NOEL (mg/kg bw/d)	122.8	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	269.4	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-10: Assessment of the risk for fish-eating birds due to exposure to zoxamide via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	zoxamide	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0140098	See dRR Part B8.
BCF _{fish}	136	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	1.905	$PEC_{\text{fish}} = PEC_{\text{water}} \times BCF_{\text{fish}}$
Daily dietary dose (mg/kg bw/d)	0.303	DDD = $PEC_{\text{fish}} \times 0.159$
NOEL (mg/kg bw/d)	122.8	EFSA Journal 2017;15(9):4980
TER _{lt}	405.4	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-11: Assessment of the risk for fish-eating birds due to exposure to RH-127450 via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	RH-127450	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0344781	See dRR Part B8.
BCF _{fish}	136	Parent value as a surrogate
BMF	/	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	4.6890	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.7456	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	16.471	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-12: Assessment of the risk for fish-eating birds due to exposure to RH-127450 via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	RH-127450	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0229755	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	3.125	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.497	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	24.7	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-13: Assessment of the risk for fish-eating birds due to exposure to RH-24549 via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	RH-24549	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0283548	See dRR Part B8.
BCF _{fish}	136	Parent value as a surrogate
BMF	/	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	3.8563	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.6131	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	20.028	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.2-14: Assessment of the risk for fish-eating birds due to exposure to RH-24549 via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	RH-24549	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0189018	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	2.571	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.409	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	12.28	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	30.0	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to birds from zoxamide and metabolites following application of GLOB2013F at the intended GAP. The TER_{lt} value for zoxamide and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2013F presents no unacceptable long-term risk to birds when applied according to the proposed GAP.

The risk assessment for secondary poisoning, required for zoxamide and its metabolites, showed that the risk for earthworm-eating and fish-eating birds is acceptable following use of GLOB2013F according to the proposed use pattern.

Furthermore, the risk assessment for exposure to zoxamide *via* drinking water also showed an acceptable risk.

Review comments:

The acute and long-term risk assessment for birds performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints. No formulation study was required.

According to the screening assessment for potato and grapes, the TER_a and TER_{lt} for zoxamide are greater than the Annex VI trigger of 5 and 10, respectively, indicating that the GLOB2013F presents an acceptable acute and long-term risk to birds according to the intended uses on potato and grapes.

There were also no negative effects regarding to drinking water exposure and of secondary poisoning (zoxamide and its metabolites RH-127450, RH-24549).

Overall, acceptable acute and reproductive risk to birds may be concluded for application of GLOB2013F in compliance with proposed GAP.

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

Effects on mammals of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. However, the provision of further data on the formulation GLOB2013F is not considered essential, because the risk for mammals from GLOB2013F can be adequately assessed from the risk assessment for the active substances.

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

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

Species	Substance	Exposure System	Results	Reference
Rat	zoxamide	Acute	LD ₅₀ > 5000 mg/kg bw	EFSA Journal 2017;15(9):4980
Rat	zoxamide	Long term (parental)	NOAEL = 360 mg/kg bw per day	EFSA Journal 2017;15(9):4980
Rat	zoxamide	Reproductive	NOAEL = 1474 mg/kg bw per day	EFSA Journal 2017;15(9):4980
Rat	zoxamide	Long term (offspring)	NOAEL = 360 mg/kg bw per day	EFSA Journal 2017;15(9):4980
Rabbit	zoxamide	Long term (development)	NOAEL = 1000 mg/kg bw per day	EFSA Journal 2017;15(9):4980
Rat	zoxamide	Long term (development)	NOAEL = 1000 mg/kg bw per day	EFSA Journal 2017;15(9):4980
Rat	zoxamide	* Value agreed in the Peer review meeting 160 by experts	71 * mg/kg bw/d	EFSA Journal 2017;15(9):4980
* Conservative endpoint, provided according to Experts' consultation; see Peer Review Report page 622. Values shown in bold used for risk assessment				

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 3 also covers the risk for **mammals** ~~birds~~ from all other intended uses in group 2 (see 9.1.2).

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2013F in potato

Intended use		Potato				
Active substance/product		zoxamide				
Application rate (g/ha)		3 × 135 (covering use no. 4 with 130 g a.s)				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	136.4 118.4	1.6	18.41 25.57	271.59 195.5	
Reprod. toxicity (mg/kg bw/d)		71				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening step	Small herbivorous mammal	72.3 48.3	2.0 × 0.53	9.76 6.91	7.27 10.27	

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

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2013F in grape

Intended use		Grape				
Active substance/product		zoxamide				
Application rate (g/ha)		2 × 166 (covering use no. 2 with 135 g a.s)				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	136.4 118.4	1.6 1.4	22.64 27.52	220.84 181.7	
Reprod. toxicity (mg/kg bw/d)		71				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening step	Small herbivorous mammal	72.3 48.3	1.6 × 0.53	10.17 6.80	6.98 10.44	

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

Not needed.

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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 1207 mL/g, zoxamide belongs to the group of more sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 2 also covers the risk for mammals from all other intended uses (see 9.1.2).

For potato, to take into account the 3 applications, a MAF of 1.6 was used as a worst-case (effective application rate = application rate x 1.6), which results in 216 g/ha.

For grape, to take into account the 2 applications, a MAF of 1.4 was used as a worst-case (effective application rate = application rate x 1.4), which results in 232.4 g/ha. This is considered as worst case to the assessment below.

Effective application rate (g/ha) =	232.4		
Acute toxicity (mg/kg bw) =	5000	quotient	= 0.046
Reprod. toxicity (mg/kg bw/d) =	71	quotient	= 3.277

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of zoxamide amounts to 3.76 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-127450 amounts to 3.5 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-24549 amounts to 3.83 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of RH-163353 amounts to 1.43 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

The log P_{ow} of RH-141455 amounts to 1.94 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

The log P_{ow} of RH-139432 amounts to 2.7 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 2 also covers the risk for mammals from all other intended uses in group 2 (see 9.1.2).

Table 9.3-4: Assessment of the risk for earthworm-eating mammals due to exposure to zoxamide via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	zoxamide	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0618	See dRR Part B8.
log P _{ow} / P _{ow}	5754.4	
Koc	1207	EFSA Journal 2017;15(9):4980
foc	0.02	Default
BCF _{worm}	2.895	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.179	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.229	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	71	EFSA Journal 2017;15(9):4980
TER _{lt}	310.0	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-5: Assessment of the risk for earthworm-eating mammals due to exposure to zoxamide via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	zoxamide	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0874	See dRR Part B8.
log P _{ow} / P _{ow}	5754.4	
Koc	1207	EFSA Journal 2017;15(9):4980
foc	0.02	Default
BCF _{worm}	2.895	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.253	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.324	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	71	EFSA Journal 2017;15(9):4980
TER _{lt}	219.2	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-6: Assessment of the risk for earthworm-eating mammals due to exposure to RH-127450 via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	RH-127450	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.014	See dRR Part B8.
log P _{ow} / P _{ow}	3162	
Koc	669	EFSA Journal 2017;15(9):4980
foc	0.02	Default
BCF _{worm}	2.899	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.041	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.052	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	136.7	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-7: Assessment of the risk for earthworm-eating mammals due to exposure to RH-127450 via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	RH-127450	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0132	See dRR Part B8.
log P _{ow} / P _{ow}	3162	
Koc	669	EFSA Journal 2017;15(9):4980
foc	0.02	Default
BCF _{worm}	2.899	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.038	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.049	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	145.0	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-8: Assessment of the risk for earthworm-eating mammals due to exposure to RH-24549 via bioaccumulation in earthworms (secondary poisoning) for the intended use in potato

Parameter	RH-24549	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0133	See dRR Part B8.
log P _{ow} / P _{ow}	6761	
Koc	90.55	EFSA Journal 2017;15(9):4980

Parameter	RH-24549	comments
foc	0.02	Default
BCF _{worm}	45.263	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.602	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.771	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	9.2	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-9: Assessment of the risk for earthworm-eating mammals due to exposure to RH-24549 via bioaccumulation in earthworms (secondary poisoning) for the intended use in grape

Parameter	RH-24549	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0134	See dRR Part B8.
log P _{ow} / P _{ow}	6761	
Koc	90.55	EFSA Journal 2017;15(9):4980
foc	0.02	Default
BCF _{worm}	45.263	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.607	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.776	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980, parent endpoint divided by 10
TER _{lt}	9.1	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 2 also covers the risk for mammals from all other intended uses in group 2 (see 9.1.2).

Table 9.3-10: Assessment of the risk for fish-eating mammals due to exposure to zoxamide via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	zoxamide	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.0210821	See dRR Part B8.
BCF _{fish}	136	
BMF	-	biomagnification factor (relevant for $BCF \geq 2000$)

PEC _{fish}	2.867	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.407	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	71	EFSA Journal 2017;15(9):4980
TER _{lt}	174.4	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-11: Assessment of the risk for fish-eating mammals due to exposure to zoxamide via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	zoxamide	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0140098	See dRR Part B8.
BCF _{fish}	136	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	1.905	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.271	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	71	EFSA Journal 2017;15(9):4980
TER _{lt}	262.4	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-12: Assessment of the risk for fish-eating mammals due to exposure to RH-127450 via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	RH-127450	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.0344781	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	4.689	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.666	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	10.7	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-13: Assessment of the risk for fish-eating mammals due to exposure to RH-127450 via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	RH-127450	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0229755	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	3.125	PEC _{fish} = PEC _{water} × BCF _{fish}

Daily dietary dose (mg/kg bw/d)	0.444	DDD = $PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	16.0	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-14: Assessment of the risk for fish-eating mammals due to exposure to RH-24549 via bioaccumulation in fish (secondary poisoning) for the intended use in potato

Parameter	RH-24549	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.0283548	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	3.856	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.548	DDD = $PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	13.0	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

Table 9.3-15: Assessment of the risk for fish-eating mammals due to exposure to RH-24549 via bioaccumulation in fish (secondary poisoning) for the intended use in grape

Parameter	RH-24549	comments
PEC _{sw} (twa = 21 d) (mg/L) Step 1	0.0189018	See dRR Part B8.
BCF _{fish}	136	Parent endpoint as a surrogate
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	2.571	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.365	DDD = $PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	7.1	EFSA Journal 2017;15(9):4980 (parent endpoint divided by 10)
TER _{lt}	19.5	TER criterion = ≥ 5 ; acceptable risk

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

The risk assessments for mammals indicated that the TER_a and TER_{lt} values are greater than the Annex VI trigger of 10 or 5 respectively, indicating that the use of GLOB2013F in potato and grape according to the proposed GAP poses a low acute and long-term risk to mammals.

Review comments:

The acute and long-term risk assessment for mammals performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints. No formulation study was required.

TER_A and TER_{LT} in the acute and long-term risk assessment indicated acceptable risk assessment for zoxamide already at screening step.

GLOB2013F presents no unacceptable risk to mammals resulting from exposure via drinking water. Presented secondary poisoning for zoxamide and its metabolites RH-127450, RH-24549 presents no unacceptable risk to mammals.

Overall, acceptable acute and reproductive risk to mammals may be concluded for application of GLOB2013F in compliance with proposed GAP.

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

Not required.

Review comments:

This issue is not assessed at the product level.

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 zoxamide and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
Fish				

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	zoxamide	Acute 96 hr (flow-through)	Mortality, LC ₅₀ 0.16 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Lepomis macrochirus</i>	zoxamide	Acute 96 hr (flow-through)	Mortality, LC ₅₀ >0.79 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Pimephales promelas</i>	zoxamide	Acute 96 hr (flow-through)	Mortality, LC ₅₀ >208 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Brachydanio rerio</i>	zoxamide	Acute 96 hr (flow-through)	Mortality, LC ₅₀ >0.73 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Cyprinodon variegatus</i>	zoxamide	Acute 96 hr (flow-through)	Mortality, LC ₅₀ >0.85 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Danio rerio</i>	Preparation	Acute 96 hr (static)	Mortality, LC ₅₀ 0.865 mg prep./L (0.184 mg a.s./L)	EFSA Journal 2017;15(9):4980
<i>Oncorhynchus mykiss</i>	RH-139432	Acute 96 hr (flow-through)	Mortality, LC ₅₀ 2 mg/L (mm)	EFSA Journal 2017;15(9):4980
<i>Oncorhynchus mykiss</i>	RH-24549	48h-semi static	Mortality, LC ₅₀ 23 mg/L (mm)	EFSA Journal 2017;15(9):4980
<i>Oncorhynchus mykiss</i>	RH-141455	Acute 96 hr	Mortality, LC ₅₀ >100 mg/L (mm)	xxxxxxx, 2020, 3202716 (xxxxxx, vertebrate study)
<i>Oncorhynchus mykiss</i>	RH-163353	Acute 96 hr	Mortality, LC ₅₀ >100 mg/L (mm)	xxxxxxx, 2020, 3202385 (xxxxxx, vertebrate study)
<i>Oncorhynchus mykiss</i>	RH-127450	Acute 96 hr	Mortality, LC ₅₀ 4.17 mg/L	xxxxxxx, 2020, 3202373 (xxxxxxx, vertebrate study)
<i>Oncorhynchus mykiss</i>	zoxamide	95 d (flow- through, ELS)	NOEC 0.00348 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Pimephales promelas</i>	zoxamide	202 d (flow- through, FLC)	NOEC 0.06 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Lepomis macrochirus</i>	zoxamide	28 day (flow-through, bioaccumulation)	BCF 95-136 mg a.s./L	EFSA Journal 2017;15(9):4980
<i>Danio rerio</i>	zoxamide	30 days - post- hatch under flow-through conditions, ELS	NOEC ≥0.12 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
Aquatic invertebrates				
<i>Daphnia magna</i>	zoxamide	48 h (flow- through)	Mortality, EC ₅₀ >0.78 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Mysidopsis bahia</i>	zoxamide	96h (flow- through)	Mortality, LC ₅₀ 0.076 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980

Species	Substance	Exposure System	Results	Reference
<i>Americamysis bahia</i>	RH-163353	96h, s	Mortality, LC ₅₀ > 24 mg a.s./L (nominal)	Shaw, A., 2023, 14365.6102
<i>Mysidopsis bahia</i>	RH-139432	96h, ss	Mortality, LC ₅₀ 7.343 mg/L (mm)	Mikulas, J., 2023, 25769-22
<i>Mysidopsis bahia</i>	RH-24549	96h, ss	Mortality, LC ₅₀ 35.766 mg/L (mm)	Doig, A., 2023, 25772-22
<i>Mysidopsis bahia</i>	RH-141455	96h, ss	Mortality, LC ₅₀ > 100 mg /L (nominal)	Mikulas, J., 2023, 25771-22
<i>Mysidopsis bahia</i>	RH-127450	96h, ss	Mortality, LC ₅₀ 0.364 mg/L (mm)	Mikulas, J., 2023, 25833-22
<i>Daphnia magna</i>	Preparation	48 h (static)	Mortality, EC ₅₀ >3.0 mg prep./L (>0.69 mg a.s./L)	EFSA Journal 2017;15(9):4980
<i>Daphnia magna</i>	zoxamide	21d (flow- through)	NOEC 0.039 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Chironomus riparius</i>	zoxamide	28d (flow- through)	NOEC 0.38 mg a.s./L (geomean) EC ₁₀ (development rate) 0.223mg a.s./L EC ₁₀ (emergence rate) 0.318 mg a.s./L	EFSA Journal 2017;15(9):4980
<i>Mysidopsis bahia</i>	zoxamide	27 d (flow- through)	NOEC 0.0072 mg a.s./L (mm)	EFSA Journal 2017;15(9):4980
<i>Daphnia magna</i>	RH-139432	48h (semi-static)	Mortality, EC ₅₀ 17 mg/L (mm)	EFSA Journal 2017;15(9):4980
<i>Daphnia magna</i>	RH-24549	48h - static	Mortality, EC ₅₀ 40 mg/L (mm)	EFSA Journal 2017;15(9):4980
Algae				
<i>Selenastrum capricornutum</i> **	Preparation	96h (static)	Growth rate: ErC50 (NOEC) 0.274 mg prep./L (0.0582 mg a.s./L) * Biomass: EbC50 (NOEC) 0.24 mg prep./L (0.0514 mg a.s./L) *	EFSA Journal 2017;15(9):4980

Species	Substance	Exposure System	Results	Reference
<i>Pseudokirchneriella subcapitata</i>	zoxamide	72h static	EC ₅₀ growth rate: 38.311 µg/L EC ₅₀ yield: 20.217 µg/L NOEC: 6.014 µg/L	Jarratt, N., 2023, FR/002786
<i>Desmodesmus subspicatus</i>	RH-24549	72h static	EbC50 >60 mg/L (nom) Growth rate: ErC50 >60 mg/L (nom)	EFSA Journal 2017;15(9):4980
<i>Pseudokirchneriella subcapitata</i>	RH-141455	72h static	EC ₅₀ >100 mg/L (nom) EC ₁₀ yield 96.3 mg/L (nom) EC ₁₀ growth rate >100 mg/L (nom)	EFSA Journal 2017;15(9):4980
<i>Raphidocelis subcapitata</i>	RH-163353	72h, s	EC ₅₀ yield > 100 mg/L (nom) EC ₅₀ growth rate >100 mg/L (nom)	Softcheck, K., 2023, 14365.6101
<i>Pseudokirchneriella subcapitata</i>	RH-127450	72h, s	EC ₅₀ yield > 1.32 mg/L (mm) EC ₅₀ growth rate > 1.32 mg/L (mm)	Mikulas, J., 2023 25834-22
<i>Pseudokirchneriella subcapitata</i>	RH-139432	72h, s	EC ₅₀ yield 6.498 mg/L (mm) EC ₅₀ growth rate > 9.987 mg/L (mm)	Mikulas, J., 2023, 25770-22
Aquatic plant				
<i>Lemna gibba</i>	zoxamide	14 d (static renewal)	7 d- EC ₅₀ >0.018 mg a.s./L(mm) 14 d- EC ₅₀ 0.017 mg a.s./L(mm) NOEC 0.009 mg a.s/L	EFSA Journal 2017;15(9):4980
Higher-tier studies (micro- or mesocosm studies)				
-				

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 – GLOB2013F

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	GLOB2013F	48 h, ss	EC ₅₀ > 7.88 mg formulation/L _{nom} (>1.99 mg a.s./L) _{mm}	Wilkins, S., 2023, FR/002721
<i>Pseudokirchneriella subcapitata</i>	GLOB2013F	72 h, s	ErC ₅₀ = 129 µg/L _{nom} (31.8 µg a.s./L) _{mm}	Wright, E., 2023, FR/002720

Species	Substance	Exposure System	Results	Reference
			$E_y C_{50} = 59.8 \mu\text{g/L}_{\text{nom}}$ ($26.4 \mu\text{g a.s./L}$) _{mm}	
Higher-tier studies (micro- or mesocosm studies)				
-				

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 from 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 zoxamide for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	EC ₁₀ (development rate)	NOEC
(µg/L)		160	3.48	76	7.2	58.2	223	9
AF		100	10	100	10	10	10	10
RAC (µg/L)		1.6	0.348	0.76	0.72	5.82	22.3	0.9
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	18.4873	11.5546	53.1244	24.3254	25.6768	3.1765	0.8290	20.5414
Step 2								
NEU Mar-May	1.4308	0.8943	4.1115	1.8826	1.9872	0.2458	0.0642	1.5898
NEU Jun-Sep	1.4308	0.8943	4.1115	1.8826	1.9872	0.2458	0.0642	1.5898
NEU Oct-Feb	2.9934	1.8709	8.6017	3.9387	4.1575	0.5143	0.1342	3.3260
SEU Mar-May	2.4726	1.5454	7.1052	3.2534	3.4342	0.4248	0.1109	2.7473
SEU Jun-Sep	1.9517	1.2198	5.6083	2.5680	2.7107	0.3353	0.0875	2.1686
SEU Oct-Feb	2.4726	1.5454	7.1052	3.2534	3.4342	0.4248	0.1109	2.7473
Step 3 (set 1, early)								
D3/ditch	0.7069	0.4418	2.0313	0.9301	0.9818	0.1215	0.0317	0.7854
D4/pond	0.02855	0.0178	0.0820	0.0376	0.0397	0.0049	0.0013	0.0317

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
D4/stream	0.5522	0.3451	1.5868	0.7266	0.7669	0.0949	0.0248	0.6136
D6/ditch	0.699	0.4369	2.0086	0.9197	0.9708	0.1201	0.0313	0.7767
R1/pond	0.6936	0.4335	1.9931	0.9126	0.9633	0.1192	0.0311	0.7707
R1/stream	0.05828	0.0364	0.1675	0.0767	0.0809	0.0100	0.0026	0.0648
R2/stream	0.5313	0.3321	1.5267	0.6991	0.7379	0.0913	0.0238	0.5903
R3/stream	0.6475	0.4047	1.8606	0.8520	0.8993	0.1113	0.0290	0.7194
Step 3 (set 1, late)								
D3/ditch	0.7072	0.4420	2.0322	0.9305	0.9822	0.1215	0.0317	0.7858
D4/pond	0.02854	0.0178	0.0820	0.0376	0.0396	0.0049	0.0013	0.0317
D4/stream	0.5315	0.3322	1.5273	0.6993	0.7382	0.0913	0.0238	0.5906
D6/ditch	0.7025	0.4391	2.0187	0.9243	0.9757	0.1207	0.0315	0.7806
R1/pond	0.7072	0.4420	2.0322	0.9305	0.9822	0.1215	0.0317	0.7858
R1/stream	0.05129	0.0321	0.1474	0.0675	0.0712	0.0088	0.0023	0.0570
R2/stream	0.6144	0.3840	1.7655	0.8084	0.8533	0.1056	0.0276	0.6827
R3/stream	0.6577	0.4111	1.8899	0.8654	0.9135	0.1130	0.0295	0.7308
Step 3 (set 2, early)								
D3/ditch	0.7069	0.4418	2.0313	0.9301	0.9818	0.1215	0.0317	0.7854
D4/pond	0.02855	0.0178	0.0820	0.0376	0.0397	0.0049	0.0013	0.0317
D4/stream	0.5522	0.3451	1.5868	0.7266	0.7669	0.0949	0.0248	0.6136
D6/ditch	0.699	0.4369	2.0086	0.9197	0.9708	0.1201	0.0313	0.7767
R1/pond	0.6936	0.4335	1.9931	0.9126	0.9633	0.1192	0.0311	0.7707
R1/stream	0.04746	0.0297	0.1364	0.0624	0.0659	0.0082	0.0021	0.0527
R2/stream	0.5308	0.3318	1.5253	0.6984	0.7372	0.0912	0.0238	0.5898
R3/stream	0.6475	0.4047	1.8606	0.8520	0.8993	0.1113	0.0290	0.7194

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
Step 3 (set 2, late)								
D3/ditch	0.7072	0.4420	2.0322	0.9305	0.9822	0.1215	0.0317	0.7858
D4/pond	0.02854	0.0178	0.0820	0.0376	0.0396	0.0049	0.0013	0.0317
D4/stream	0.5315	0.3322	1.5273	0.6993	0.7382	0.0913	0.0238	0.5906
D6/ditch	0.7025	0.4391	2.0187	0.9243	0.9757	0.1207	0.0315	0.7806
R1/pond	0.7072	0.4420	2.0322	0.9305	0.9822	0.1215	0.0317	0.7858
R1/stream	0.04261	0.0266	0.1224	0.0561	0.0592	0.0073	0.0019	0.0473
R2/stream	0.6137	0.3836	1.7635	0.8075	0.8524	0.1054	0.0275	0.6819
R3/stream	0.6577	0.4111	1.8899	0.8654	0.9135	0.1130	0.0295	0.7308

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 zoxamide for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	EC ₁₀ (development rate)	NOEC
(µg/L)		160	3.48	76	7.2	58.2	223	9
AF		100	10	100	10	10	10	10
RAC (µg/L)		1.6	0.348	0.76	0.72	5.82	22.3	0.9
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
	55.4620	34.6638	159.3736	72.9763	77.0306	9.5296	2.4871	61.6244
Step 2								
NEU Mar-May	2.1328	1.3330	6.1287	2.8063	2.9622	0.3665	0.0956	2.3698
NEU Jun-Sep	2.1328	1.3330	6.1287	2.8063	2.9622	0.3665	0.0956	2.3698
NEU Oct-Feb	4.6098	2.8811	13.2466	6.0655	6.4025	0.7921	0.2067	5.1220
SEU Mar-May	3.7841	2.3651	10.8739	4.9791	5.2557	0.6502	0.1697	4.2046
SEU Jun-Sep	2.9585	1.8491	8.5014	3.8928	4.1090	0.5083	0.1327	3.2872
SEU Oct-Feb	3.7841	2.3651	10.8739	4.9791	5.2557	0.6502	0.1697	4.2046
Step 3 (set 1, early)								
D3/ditch	0.5139	0.3212	1.4767	0.6762	0.7138	0.0883	0.0230	0.5710
D4/pond	0.05267	0.0329	0.1514	0.0693	0.0732	0.0090	0.0024	0.0585
D4/stream	0.4128	0.2580	1.1862	0.5432	0.5733	0.0709	0.0185	0.4587
D6/ditch	0.5119	0.3199	1.4710	0.6736	0.7110	0.0880	0.0230	0.5688
R1/pond	0.5079	0.3174	1.4595	0.6683	0.7054	0.0873	0.0228	0.5643
R1/stream	0.09206	0.0575	0.2645	0.1211	0.1279	0.0158	0.0041	0.1023
R2/stream	0.7032	0.4395	2.0207	0.9253	0.9767	0.1208	0.0315	0.7813
R3/stream	0.4759	0.2974	1.3675	0.6262	0.6610	0.0818	0.0213	0.5288
Step 3 (set 1, late)								
D3/ditch	0.5146	0.3216	1.4787	0.6771	0.7147	0.0884	0.0231	0.5718
D4/pond	0.05265	0.0329	0.1513	0.0693	0.0731	0.0090	0.0024	0.0585
D4/stream	0.4265	0.2666	1.2256	0.5612	0.5924	0.0733	0.0191	0.4739
D6/ditch	0.5118	0.3199	1.4707	0.6734	0.7108	0.0879	0.0230	0.5687
R1/pond	0.5141	0.3213	1.4773	0.6764	0.7140	0.0883	0.0231	0.5712
R1/stream	0.1558	0.0974	0.4477	0.2050	0.2164	0.0268	0.0070	0.1731

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
R2/stream	0.7277	0.4548	2.0911	0.9575	1.0107	0.1250	0.0326	0.8086
R3/stream	0.4758	0.2974	1.3672	0.6261	0.6608	0.0818	0.0213	0.5287
Step 3 (set 2, early)								
D3/ditch	0.5142	0.3214	1.4776	0.6766	0.7142	0.0884	0.0231	0.5713
D4/pond	0.03696	0.0231	0.1062	0.0486	0.0513	0.0064	0.0017	0.0411
D4/stream	0.4128	0.2580	1.1862	0.5432	0.5733	0.0709	0.0185	0.4587
D6/ditch	0.5119	0.3199	1.4710	0.6736	0.7110	0.0880	0.0230	0.5688
R1/pond	0.5079	0.3174	1.4595	0.6683	0.7054	0.0873	0.0228	0.5643
R1/stream	0.06533	0.0408	0.1877	0.0860	0.0907	0.0112	0.0029	0.0726
R2/stream	0.7026	0.4391	2.0190	0.9245	0.9758	0.1207	0.0315	0.7807
R3/stream	0.476	0.2975	1.3678	0.6263	0.6611	0.0818	0.0213	0.5289
Step 3 (set 2, late)								
D3/ditch	0.515	0.3219	1.4799	0.6776	0.7153	0.0885	0.0231	0.5722
D4/pond	0.03877	0.0242	0.1114	0.0510	0.0538	0.0067	0.0017	0.0431
D4/stream	0.4265	0.2666	1.2256	0.5612	0.5924	0.0733	0.0191	0.4739
D6/ditch	0.5118	0.3199	1.4707	0.6734	0.7108	0.0879	0.0230	0.5687
R1/pond	0.5145	0.3216	1.4784	0.6770	0.7146	0.0884	0.0231	0.5717
R1/stream	0.1152	0.0720	0.3310	0.1516	0.1600	0.0198	0.0052	0.1280
R2/stream	0.7269	0.4543	2.0888	0.9564	1.0096	0.1249	0.0326	0.8077
R3/stream	0.4758	0.2974	1.3672	0.6261	0.6608	0.0818	0.0213	0.5287

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 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-24549 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Desmodesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 23000	EC ₅₀ 35766	E _r C ₅₀ >60000
AF		100	100	10
RAC (µg/L)		230	357.66	6000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.5245	0.041	0.027	0.0016
Step 2				
NEU Mar-May	0.6033	0.003	0.002	0.0001
NEU Jun-Sep	0.6033	0.003	0.002	0.0001
NEU Oct-Feb	1.4559	0.006	0.004	0.0002
SEU Mar-May	1.1717	0.005	0.003	0.0002
SEU Jun-Sep	0.8875	0.004	0.002	0.0001
SEU Oct-Feb	1.1717	0.005	0.003	0.0002

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-24549 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Desmodesmus subspicatus</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		23000	35766	>60000
AF		100	100	10
RAC (µg/L)		230	357.66	6000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	28.5736	0.124	0.080	0.0048
Step 2				
NEU Mar-May	0.9714	0.004	0.003	0.0002
NEU Jun-Sep	0.9714	0.004	0.003	0.0002
NEU Oct-Feb	2.3139	0.010	0.006	0.0004
SEU Mar-May	1.8664	0.008	0.005	0.0003
SEU Jun-Sep	1.4189	0.006	0.004	0.0002
SEU Oct-Feb	1.8664	0.008	0.005	0.0003

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-127450 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		4170	364	1320
AF		100	100	10
RAC (µg/L)		41.7	3.64	132
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	12.0507	0.289	3.311	0.0913
Step 2				
NEU Mar-May	0.9674	0.023	0.266	0.0073
NEU Jun-Sep	0.9674	0.023	0.266	0.0073
NEU Oct-Feb	2.0112	0.048	0.553	0.0152
SEU Mar-May	1.6633	0.040	0.457	0.0126
SEU Jun-Sep	1.3153	0.032	0.361	0.0100
SEU Oct-Feb	1.6633	0.040	0.457	0.0126

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-127450 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		4170	364	1320
AF		100	100	10
RAC (µg/L)		41.7	3.64	132
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	36.1520	0.867	9.932	0.2739
Step 2				
NEU Mar-May	1.6815	0.040	0.462	0.0127
NEU Jun-Sep	1.6815	0.040	0.462	0.0127
NEU Oct-Feb	3.3256	0.080	0.914	0.0252
SEU Mar-May	2.7775	0.067	0.763	0.0210
SEU Jun-Sep	2.2295	0.053	0.613	0.0169
SEU Oct-Feb	2.7775	0.067	0.763	0.0210

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-139432 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		2000	7343	9987
AF		100	100	10
RAC (µg/L)		20	73.43	998.7
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	13.0512	0.653	0.1777	0.0131
Step 2				
NEU Mar-May	1.1363	0.057	0.0155	0.0011
NEU Jun-Sep	1.1363	0.057	0.0155	0.0011
NEU Oct-Feb	2.3677	0.118	0.0322	0.0024
SEU Mar-May	1.9573	0.098	0.0267	0.0020
SEU Jun-Sep	1.5468	0.077	0.0211	0.0015
SEU Oct-Feb	1.9573	0.098	0.0267	0.0020

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-139432 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		2000	7343	9987
AF		100	100	10
RAC (µg/L)		20	73.43	998.7
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	39.1536	1.958	0.5332	0.0392
Step 2				
NEU Mar-May	2.1763	0.109	0.0296	0.0022
NEU Jun-Sep	2.1763	0.109	0.0296	0.0022
NEU Oct-Feb	4.4046	0.220	0.0600	0.0044
SEU Mar-May	3.6618	0.183	0.0499	0.0037
SEU Jun-Sep	2.919	0.146	0.0398	0.0029
SEU Oct-Feb	3.6618	0.183	0.0499	0.0037

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-141455 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ >100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.3045	0.003	0.003	0.0003
Step 2				
NEU Mar-May	0.286	0.00029	0.00029	0.00003
NEU Jun-Sep	0.286	0.00029	0.00029	0.00003
NEU Oct-Feb	0.6879	0.00069	0.00069	0.00007
SEU Mar-May	0.554	0.00055	0.00055	0.00006
SEU Jun-Sep	0.42	0.00042	0.00042	0.00004
SEU Oct-Feb	0.554	0.00055	0.00055	0.00006

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-141455 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ >100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.9136	0.010	0.010	0.0010
Step 2				
NEU Mar-May	0.6481	0.00065	0.00065	0.00006
NEU Jun-Sep	0.6481	0.00065	0.00065	0.00006
NEU Oct-Feb	1.5608	0.00156	0.00156	0.00016
SEU Mar-May	1.2565	0.00126	0.00126	0.00013
SEU Jun-Sep	0.9523	0.00095	0.00095	0.00010
SEU Oct-Feb	1.2565	0.00126	0.00126	0.00013

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-163353 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Americamysis bahia</i>	<i>Raphidocelis subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ > 24000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	240	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	14.7443	0.015	0.061	0.0015
Step 2				
NEU Mar-May	1.2162	0.0012	0.0051	0.00012
NEU Jun-Sep	1.2162	0.0012	0.0051	0.00012
NEU Oct-Feb	2.6845	0.0027	0.0112	0.00027
SEU Mar-May	2.1951	0.0022	0.0091	0.00022
SEU Jun-Sep	1.7056	0.0017	0.0071	0.00017
SEU Oct-Feb	2.1951	0.0022	0.0091	0.00022

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-163353 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in potato (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Americamysis bahia</i>	<i>Raphidocelis subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ > 24000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	240	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	44.2328	0.044	0.184	0.0044
Step 2				
NEU Mar-May	2.2888	0.0023	0.0095	0.00023
NEU Jun-Sep	2.2888	0.0023	0.0095	0.00023
NEU Oct-Feb	4.9424	0.0049	0.0206	0.00049
SEU Mar-May	4.0578	0.0041	0.0169	0.00041
SEU Jun-Sep	3.1733	0.0032	0.0132	0.00032
SEU Oct-Feb	4.0578	0.0041	0.0169	0.00041

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for zoxamide for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants	
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>	
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	EC ₁₀ (development rate)	NOEC	
(µg/L)		160	3.48	76	7.2	58.2	223	9	
AF		100	10	100	10	10	10	10	
RAC (µg/L)		1.6	0.348	0.76	0.72	5.82	22.3	0.9	
FOCUS Scenario	PEC ^{gl-max} (µg/L)								
Step 1									
	18.4603	11.538	53.047	24.290	25.639	3.172	0.828	20.51	
Step 2									
NEU Mar-May	1.6307	1.019	4.686	2.146	2.265	0.280	0.073	1.132	
NEU Jun-Sep	1.6307	1.019	4.686	2.146	2.265	0.280	0.073	1.132	
NEU Oct-Feb	3.5058	2.191	10.074	4.613	4.869	0.602	0.157	2.434	
SEU Mar-May	2.8808	1.801	8.278	3.791	4.001	0.495	0.129	2.001	
SEU Jun-Sep	2.2558	1.410	6.482	2.968	3.133	0.388	0.101	1.567	
SEU Oct-Feb	2.8808	1.801	8.278	3.791	4.001	0.495	0.129	2.001	
Step 3 (set 1, BBCH13)									
D6 ditch	0.7537	0.471	2.166	0.992	1.047	0.130	0.034	0.837	
R1 pond	0.02601	0.016	0.075	0.034	0.036	0.004	0.001	0.029	
R1 stream	0.5556	0.347	1.597	0.731	0.772	0.095	0.025	0.617	

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
R2 stream	0.7381	0.461	2.121	0.971	1.025	0.127	0.033	0.820
R3 stream	0.786	0.491	2.259	1.034	1.092	0.135	0.035	0.873
R4 stream	0.5554	0.347	1.596	0.731	0.771	0.095	0.025	0.617
Step 3 (set 2, BBCH13)								
D6 ditch	0.7537	0.471	2.166	0.992	1.047	0.130	0.034	0.837
R1 pond	0.02601	0.016	0.075	0.034	0.036	0.004	0.001	0.029
R1 stream	0.5556	0.347	1.597	0.731	0.772	0.095	0.025	0.617
R2 stream	0.7381	0.461	2.121	0.971	1.025	0.127	0.033	0.820
R3 stream	0.786	0.491	2.259	1.034	1.092	0.135	0.035	0.873
R4 stream	0.5554	0.347	1.596	0.731	0.771	0.095	0.025	0.617
Step 3 (set 1, BBCH53)								
D6 ditch	2.835	1.772	8.147	3.730	3.938	0.487	0.127	3.150
R1 pond	0.1013	0.063	0.291	0.133	0.141	0.017	0.005	0.113
R1 stream	2.083	1.302	5.986	2.741	2.893	0.358	0.093	2.314
R2 stream	2.788	1.743	8.011	3.668	3.872	0.479	0.125	3.098
R3 stream	2.942	1.839	8.454	3.871	4.086	0.505	0.132	3.269
R4 stream	2.047	1.279	5.882	2.693	2.843	0.352	0.092	2.274
Step 3 (set 2, BBCH53)								
D6 ditch	2.835	1.772	8.147	3.730	3.938	0.487	0.127	3.150
R1 pond	0.1013	0.063	0.291	0.133	0.141	0.017	0.005	0.113
R1 stream	2.083	1.302	5.986	2.741	2.893	0.358	0.093	2.314
R2 stream	2.788	1.743	8.011	3.668	3.872	0.479	0.125	3.098

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
R3 stream	2.942	1.839	8.454	3.871	4.086	0.505	0.132	3.269
R4 stream	2.047	1.279	5.882	2.693	2.843	0.352	0.092	2.274
Step 3 (set 1, BBCH83)								
D6 ditch	2.846	1.779	8.178	3.745	3.953	0.489	0.128	3.162
R1 pond	0.1013	0.063	0.291	0.133	0.141	0.017	0.005	0.113
R1 stream	2.088	1.305	6.000	2.747	2.900	0.359	0.094	2.320
R2 stream	2.798	1.749	8.040	3.682	3.886	0.481	0.125	3.109
R3 stream	2.942	1.839	8.454	3.871	4.086	0.505	0.132	3.269
R4 stream	2.087	1.304	5.997	2.746	2.899	0.359	0.094	2.319
Step 3 (set 2, BBCH83)								
D6 ditch	2.846	1.779	8.178	3.745	3.953	0.489	0.128	3.162
R1 pond	0.1013	0.063	0.291	0.133	0.141	0.017	0.005	0.113
R1 stream	2.088	1.305	6.000	2.747	2.900	0.359	0.094	2.320
R2 stream	2.798	1.749	8.040	3.682	3.886	0.481	0.125	3.109
R3 stream	2.942	1.839	8.454	3.871	4.086	0.505	0.132	3.269
R4 stream	2.087	1.304	5.997	2.746	2.899	0.359	0.094	2.319

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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for zoxamide for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
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Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Mysidopsis bahia</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	EC ₁₀ (development rate)	NOEC
(µg/L)		160	3.48	76	7.2	58.2	223	9
AF		100	10	100	10	10	10	10
RAC (µg/L)	1.6	0.348	0.76	0.72	5.82	22.3	0.9	
FOCUS Scenario	PEC ^{gl-max} (µg/L)							
Step 1								
	36.9207	23.075	106.094	48.580	51.279	6.344	1.656	41.02
Step 2								
NEU Mar-May	2.2059	1.379	6.339	2.903	3.064	0.379	0.099	2.288
NEU Jun-Sep	2.2059	1.379	6.339	2.903	3.064	0.379	0.099	2.288
NEU Oct-Feb	4.7652	2.978	13.693	6.270	6.618	0.819	0.214	2.451
SEU Mar-May	3.9121	2.445	11.242	5.148	5.433	0.672	0.175	5.295
SEU Jun-Sep	3.0590	1.912	8.790	4.025	4.249	0.526	0.137	3.399
SEU Oct-Feb	3.9121	2.445	11.242	5.148	5.433	0.672	0.175	4.347
Step 3 (set 1, BBCH13)								
D6 ditch	0.698	0.436	2.006	0.918	0.969	0.120	0.031	0.776
R1 pond	0.03988	0.025	0.115	0.052	0.055	0.007	0.002	0.044
R1 stream	0.5033	0.315	1.446	0.662	0.699	0.086	0.023	0.559
R2 stream	0.6786	0.424	1.950	0.893	0.943	0.117	0.030	0.754
R3 stream	0.7151	0.447	2.055	0.941	0.993	0.123	0.032	0.795

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
R4 stream	0.5071	0.317	1.457	0.667	0.704	0.087	0.023	0.563
Step 3 (set 2, BBCH13)								
D6 ditch	0.6982	0.436	2.006	0.919	0.970	0.120	0.031	0.776
R1 pond	0.03272	0.020	0.094	0.043	0.045	0.006	0.001	0.044
R1 stream	0.5033	0.315	1.446	0.662	0.699	0.086	0.023	0.559
R2 stream	0.6786	0.424	1.950	0.893	0.943	0.117	0.030	0.754
R3 stream	0.7153	0.447	2.055	0.941	0.993	0.123	0.032	0.795
R4 stream	0.5071	0.317	1.457	0.667	0.704	0.087	0.023	0.563
Step 3 (set 1, BBCH53)								
D6 ditch	2.505	1.566	7.198	3.296	3.479	0.430	0.112	2.783
R1 pond	0.1582	0.099	0.455	0.208	0.220	0.027	0.007	0.176
R1 stream	1.837	1.148	5.279	2.417	2.551	0.316	0.082	2.041
R2 stream	2.46	1.538	7.069	3.237	3.417	0.423	0.110	2.733
R3 stream	2.596	1.623	7.460	3.416	3.606	0.446	0.116	2.884
R4 stream	1.806	1.129	5.190	2.376	2.508	0.310	0.081	2.007
Step 3 (set 2, BBCH53)								
D6 ditch	2.505	1.566	7.198	3.296	3.479	0.430	0.112	2.783
R1 pond	0.1208	0.076	0.347	0.159	0.168	0.021	0.005	0.176
R1 stream	1.837	1.148	5.279	2.417	2.551	0.316	0.082	2.041
R2 stream	2.46	1.538	7.069	3.237	3.417	0.423	0.110	2.733
R3 stream	2.596	1.623	7.460	3.416	3.606	0.446	0.116	2.884
R4 stream	1.806	1.129	5.190	2.376	2.508	0.310	0.081	2.007
Step 3 (set 1, BBCH83)								
D6 ditch	3.35	2.094	9.626	4.408	4.653	0.576	0.150	3.72

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. Prolonged	Algae	Sed. dwell. prolonged	Aquatic Plants
R1 pond	0.1435	0.090	0.412	0.189	0.199	0.025	0.006	0.159
R1 stream	1.842	1.151	5.293	2.424	2.558	0.316	0.083	2.047
R2 stream	2.469	1.543	7.095	3.249	3.429	0.424	0.111	2.743
R3 stream	2.596	1.623	7.460	3.416	3.606	0.446	0.116	2.884
R4 stream	1.841	1.151	5.290	2.422	2.557	0.316	0.083	2.046
Step 3 (set 2, BBCH83)								
D6 ditch	2.834	1.771	8.144	3.729	3.936	0.487	0.127	3.72
R1 pond	0.09871	0.062	0.284	0.130	0.137	0.017	0.004	0.159
R1 stream	1.842	1.151	5.293	2.424	2.558	0.316	0.083	2.047
R2 stream	2.469	1.543	7.095	3.249	3.429	0.424	0.111	2.743
R3 stream	2.596	1.623	7.460	3.416	3.606	0.446	0.116	2.884
R4 stream	1.841	1.151	5.290	2.422	2.557	0.316	0.083	2.046

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 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-24549 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Desmodesmus subspicatus</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		23000	35766	>60000
AF		100	100	10
RAC (µg/L)	230	357.66	6000	
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.5237	0.041	0.027	0.0016
Step 2				
NEU Mar-May	0.7162	0.0031	0.0020	0.00012
NEU Jun-Sep	0.7162	0.0031	0.0020	0.00012
NEU Oct-Feb	1.7393	0.0076	0.0049	0.00029
SEU Mar-May	1.3983	0.0061	0.0039	0.00023
SEU Jun-Sep	1.0573	0.0046	0.0030	0.00018
SEU Oct-Feb	1.3983	0.0061	0.0039	0.00023

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-24549 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Desmodesmus subspicatus</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		23000	35766	>60000
AF		100	100	10
RAC (µg/L)		230	357.66	6000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	19.0474	0.083	0.053	0.0032
Step 2				
NEU Mar-May	0.9899	0.0043	0.0028	0.00016
NEU Jun-Sep	0.9899	0.0043	0.0028	0.00016
NEU Oct-Feb	2.3803	0.0103	0.0067	0.00040
SEU Mar-May	1.9169	0.0083	0.0054	0.00032
SEU Jun-Sep	1.4534	0.0063	0.0041	0.00024
SEU Oct-Feb	1.9169	0.0083	0.0054	0.00032

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-127450 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		4170	364	1320
AF		100	100	10
RAC (µg/L)	41.7	3.64	132	
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	12.0411	0.289	3.308	0.0912
Step 2				
NEU Mar-May	1.1007	0.0264	0.3024	0.00834
NEU Jun-Sep	1.1007	0.0264	0.3024	0.00834
NEU Oct-Feb	2.3533	0.0564	0.6465	0.01783
SEU Mar-May	1.9357	0.0464	0.5318	0.01466
SEU Jun-Sep	1.5182	0.0364	0.4171	0.01150
SEU Oct-Feb	1.9357	0.0464	0.5318	0.01466

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-127450 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		4170	364	1320
AF		100	100	10
RAC (µg/L)		41.7	3.64	132
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	24.0823	0.578	6.616	0.1824
Step 2				
NEU Mar-May	1.6206	0.0389	0.4452	0.01228
NEU Jun-Sep	1.6206	0.0389	0.4452	0.01228
NEU Oct-Feb	3.3232	0.0797	0.9130	0.02518
SEU Mar-May	2.7556	0.0661	0.7570	0.02088
SEU Jun-Sep	2.1881	0.0525	0.6011	0.01658
SEU Oct-Feb	2.7556	0.0661	0.7570	0.02088

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-139432 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		2000	7343	9987
AF		100	100	10
RAC (µg/L)		20	73.43	998.7
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	13.0443	0.652	0.178	0.0131
Step 2				
NEU Mar-May	1.2937	0.0647	0.0176	0.00130
NEU Jun-Sep	1.2937	0.0647	0.0176	0.00130
NEU Oct-Feb	2.7714	0.1386	0.0377	0.00278
SEU Mar-May	2.2788	0.1139	0.0310	0.00228
SEU Jun-Sep	1.7862	0.0893	0.0243	0.00179
SEU Oct-Feb	2.2788	0.1139	0.0310	0.00228

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-139432 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		2000	7343	9987
AF		100	100	10
RAC (µg/L)	20	73.43	998.7	
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	26.0885	1.304	0.355	0.0261
Step 2				
NEU Mar-May	2.0130	0.1007	0.0274	0.00202
NEU Jun-Sep	2.0130	0.1007	0.0274	0.00202
NEU Oct-Feb	4.1789	0.2089	0.0569	0.00418
SEU Mar-May	3.4570	0.1729	0.0471	0.00346
SEU Jun-Sep	2.7350	0.1368	0.0372	0.00274
SEU Oct-Feb	3.4570	0.1729	0.0471	0.00346

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-141455 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ >100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.3041	0.003	0.003	0.0003
Step 2				
NEU Mar-May	0.3392	0.0003	0.0003	0.00003
NEU Jun-Sep	0.3392	0.0003	0.0003	0.00003
NEU Oct-Feb	0.8215	0.0008	0.0008	0.00008
SEU Mar-May	0.6607	0.0007	0.0007	0.00007
SEU Jun-Sep	0.5000	0.0005	0.0005	0.00005
SEU Oct-Feb	0.6607	0.0007	0.0007	0.00007

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-141455 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Mysidopsis bahia</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ >100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	6.6082	0.007	0.007	0.0007
Step 2				
NEU Mar-May	0.5780	0.0006	0.0006	0.00006
NEU Jun-Sep	0.5780	0.0006	0.0006	0.00006
NEU Oct-Feb	1.3959	0.0014	0.0014	0.00014
SEU Mar-May	1.1232	0.0011	0.0011	0.00011
SEU Jun-Sep	0.8506	0.0009	0.0009	0.00009
SEU Oct-Feb	1.1232	0.0011	0.0011	0.00011

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-163353 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (single application)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Americamysis bahia</i>	<i>Raphidocelis subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ > 24000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	240	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	14.7388	0.015	0.061	0.0015
Step 2				
NEU Mar-May	1.4068	0.0014	0.0059	0.00014
NEU Jun-Sep	1.4068	0.0014	0.0059	0.00014
NEU Oct-Feb	3.1688	0.0032	0.0132	0.00032
SEU Mar-May	2.5815	0.0026	0.0108	0.00026
SEU Jun-Sep	1.9942	0.0020	0.0083	0.00020
SEU Oct-Feb	2.5815	0.0026	0.0108	0.00026

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for RH-163353 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2013F in grape (multiple applications)

Group		Fish acute	Inverteb. Acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Americamysis bahia</i>	<i>Raphidocelis subcapitata</i>
Endpoint (µg/L)		LC ₅₀ >100000	EC ₅₀ > 24000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		1000	240	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	29.4776	0.029	0.123	0.0029
Step 2				
NEU Mar-May	2.1638	0.0022	0.0090	0.00022
NEU Jun-Sep	2.1638	0.0022	0.0090	0.00022
NEU Oct-Feb	4.7674	0.0048	0.0199	0.00048
SEU Mar-May	3.8995	0.0039	0.0162	0.00039
SEU Jun-Sep	3.0317	0.0030	0.0126	0.00030
SEU Oct-Feb	3.8995	0.0039	0.0162	0.00039

For the intended uses on potato and grape, calculated PEC/RAC ratios for zoxamide did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 3.48 µg/L 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 9.5-27: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (early, single application)

Intended use		Potato					
Active substance		zoxamide					
Application rate (g/ha)		3 ×135					
Nozzle reduction	No-spray buffer (m)	1	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	-	0.2317	0.1229	-	-	-
50 %		0.4274	0.1158	0.06143	-	-	-
75 %		0.2137	0.05791	0.03084	-	-	-
90 %		0.08547	0.02691	0.01668	-	-	-
None	D4 pond	-	0.02741	0.01979	-	-	-
50 %		0.02479	0.01509	0.01094	-	-	-
75 %		0.01413	0.008933	0.006508	-	-	-
90 %		0.007735	0.005239	0.003853	-	-	-
None	D4 stream	-	0.2332	0.1239	-	-	-
50 %		0.4297	0.117	0.06219	-	-	-
75 %		0.2153	0.05886	0.03137	-	-	-
90 %		0.08667	0.02398	0.01288	-	-	-
None	D6 ditch	-	0.2291	0.1215	-	-	-
50 %		0.4226	0.1145	0.06074	-	-	-
75 %		0.2113	0.05726	0.03037	-	-	-
90 %		0.08451	0.02291	0.0125	-	-	-
None	D6 ditch	-	0.2291	0.1215	-	-	-
50 %		0.4226	0.1145	0.06074	-	-	-
75 %		0.2113	0.05726	0.03037	-	-	-
90 %		0.08451	0.02291	0.0125	-	-	-
None	R1 pond	-	0.05812	0.05157	0.04447	0.03102	-
50 %		0.05586	0.04752	0.04396	0.03382	0.02334	-
75 %		0.0467	0.04223	0.04016	0.02851	0.01951	-
90 %		0.0412	0.03906	0.03788	0.02532	0.01721	-
None	R1 stream	-	0.5313	0.5313	0.3465	0.2415	-
50 %		0.5313	0.5313	0.5313	0.3465	0.2415	-
75 %		0.5313	0.5313	0.5313	0.3465	0.2415	-
90 %		0.5313	0.5313	0.5313	0.3465	0.2415	-
None	R2 stream	-	0.2743	0.1459	0.2743	0.1459	-

50 %		0.505	0.1454	0.1454	0.138	0.07357	-
75 %		0.2536	0.1454	0.1454	0.09378	0.06495	-
90 %		0.1454	0.1454	0.1454	0.09378	0.06495	-
None	R3 stream	-	0.2909	0.1544	0.2909	0.1544	-
50 %		0.5364	0.1457	0.1303	0.1457	0.07762	-
75 %		0.2684	0.1303	0.1303	0.08452	0.05888	-
90 %		0.1303	0.1303	0.1303	0.08452	0.05888	-
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D3 ditch	-	0.6658	0.3532	-	-	-
50 %		1.2282	0.3328	0.1765	-	-	-
75 %		0.6141	0.1664	0.0886	-	-	-
90 %		0.2456	0.0773	0.0479	-	-	-
None	D4 pond	-	0.0788	0.0569	-	-	-
50 %		0.0712	0.0434	0.0314	-	-	-
75 %		0.0406	0.0257	0.0187	-	-	-
90 %		0.0222	0.0151	0.0111	-	-	-
None	D4 stream	-	0.6701	0.3560	-	-	-
50 %		1.2348	0.3362	0.1787	-	-	-
75 %		0.6187	0.1691	0.0901	-	-	-
90 %		0.2491	0.0689	0.0370	-	-	-
None	D6 ditch	-	0.6583	0.3491	-	-	-
50 %		1.2144	0.3290	0.1745	-	-	-
75 %		0.6072	0.1645	0.0873	-	-	-
90 %		0.2428	0.0658	0.0359	-	-	-
None	D6 ditch	-	0.6583	0.3491	-	-	-
50 %		1.2144	0.3290	0.1745	-	-	-
75 %		0.6072	0.1645	0.0873	-	-	-
90 %		0.2428	0.0658	0.0359	-	-	-
None	R1 pond	-	0.1670	0.1482	0.1278	0.0891	-
50 %		0.1605	0.1366	0.1263	0.0972	0.0671	-
75 %		0.1342	0.1214	0.1154	0.0819	0.0561	-
90 %		0.1184	0.1122	0.1089	0.0728	0.0495	-
None	R1 stream	-	1.5267	1.5267	0.9957	0.6940	-
50 %		1.5267	1.5267	1.5267	0.9957	0.6940	-
75 %		1.5267	1.5267	1.5267	0.9957	0.6940	-
90 %		1.5267	1.5267	1.5267	0.9957	0.6940	-
None	R2 stream	-	0.7882	0.4193	0.7882	0.4193	-
50 %		1.4511	0.4178	0.4178	0.3966	0.2114	-

75 %	R3 stream	0.7287	0.4178	0.4178	0.2695	0.1866	-
90 %		0.4178	0.4178	0.4178	0.2695	0.1866	-
None		-	0.8359	0.4437	0.8359	0.4437	-
50 %		1.5414	0.4187	0.3744	0.4187	0.2230	-
75 %		0.7713	0.3744	0.3744	0.2429	0.1692	-
90 %		0.3744	0.3744	0.3744	0.2429	0.1692	-

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

Table 9.5-28: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (early, multiple applications)

Intended use		Potato					
Active substance		zoxamide					
Application rate (g/ha)		3 ×135					
Nozzle reduction	No-spray buffer (m)	1	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	-	0.165	0.08652	-	-	-
50 %		0.3118	0.08251	0.04326	-	-	-
75 %		0.1559	0.04157	0.02362	-	-	-
90 %		0.06236	0.02273	0.01504	-	-	-
None	D4 pond	-	0.05312	0.03817	-	-	-
50 %		0.04941	0.03021	0.02182	-	-	-
75 %		0.02927	0.01875	0.01365	-	-	-
90 %		0.01719	0.01189	0.008748	-	-	-
None	D4 stream	-	0.172	0.09037	-	-	-
50 %		0.3243	0.08645	0.04553	-	-	-
75 %		0.1628	0.04369	0.02312	-	-	-
90 %		0.06582	0.01803	0.009665	-	-	-
None	D6 ditch	-	0.1644	0.08617	-	-	-
50 %		0.3106	0.08218	0.04309	-	-	-
75 %		0.1553	0.04109	0.02204	-	-	-
90 %		0.06211	0.01937	0.01186	-	-	-
None	D6 ditch	-	0.1644	0.08617	-	-	-
50 %		0.3106	0.08218	0.04309	-	-	-
75 %		0.1553	0.04109	0.02204	-	-	-
90 %		0.06211	0.01937	0.01186	-	-	-
None	R1 pond	-	0.09177	0.07786	0.07505	0.05266	-

50 %		0.08831	0.07043	0.06262	0.05366	0.03737	-
75 %		0.06955	0.05977	0.05501	0.04297	0.02973	-
90 %		0.05831	0.05337	0.05118	0.03656	0.02515	-
None		-	0.7032	0.7032	0.4587	0.3197	0.148
50 %	R1 stream	0.7032	0.7032	0.7032	0.4587	0.3197	0.07495
75 %		0.7032	0.7032	0.7032	0.4587	0.3197	0.03864
90 %		0.7032	0.7032	0.7032	0.4587	0.3197	0.02072
None		-	0.4198	0.4198	0.2704	0.1871	-
50 %	R2 stream	0.4198	0.4198	0.4198	0.2704	0.1871	-
75 %		0.4198	0.4198	0.4198	0.2704	0.1871	-
90 %		0.4198	0.4198	0.4198	0.2704	0.1871	-
None		-	0.7574	0.7574	0.4938	0.3436	0.2075
50 %	R3 stream	0.7574	0.7574	0.7574	0.4938	0.3436	0.1043
75 %		0.7574	0.7574	0.7574	0.4938	0.3436	0.05345
90 %		0.7574	0.7574	0.7574	0.4938	0.3436	0.04508
RAC (µg/L)							
0.348		PEC/RAC ratio					
None		-	0.4741	0.2486	-	-	-
50 %	D3 ditch	0.8960	0.2371	0.1243	-	-	-
75 %		0.4480	0.1195	0.0679	-	-	-
90 %		0.1792	0.0653	0.0432	-	-	-
None		-	0.1526	0.1097	-	-	-
50 %	D4 pond	0.1420	0.0868	0.0627	-	-	-
75 %		0.0841	0.0539	0.0392	-	-	-
90 %		0.0494	0.0342	0.0251	-	-	-
None		-	0.4943	0.2597	-	-	-
50 %	D4 stream	0.9319	0.2484	0.1308	-	-	-
75 %		0.4678	0.1255	0.0664	-	-	-
90 %		0.1891	0.0518	0.0278	-	-	-
None		-	0.4724	0.2476	-	-	-
50 %	D6 ditch	0.8925	0.2361	0.1238	-	-	-
75 %		0.4463	0.1181	0.0633	-	-	-
90 %		0.1785	0.0557	0.0341	-	-	-
None		-	0.4724	0.2476	-	-	-
50 %	D6 ditch	0.8925	0.2361	0.1238	-	-	-
75 %		0.4463	0.1181	0.0633	-	-	-
90 %		0.1785	0.0557	0.0341	-	-	-
None		-	0.2637	0.2237	0.2157	0.1513	-
50 %	R1 pond	0.2538	0.2024	0.1799	0.1542	0.1074	-

75 %		0.1999	0.1718	0.1581	0.1235	0.0854	-
90 %		0.1676	0.1534	0.1471	0.1051	0.0723	-
None	R1 stream	-	2.0207	2.0207	1.3181	0.9187	0.4253
50 %		2.0207	2.0207	2.0207	1.3181	0.9187	0.2154
75 %		2.0207	2.0207	2.0207	1.3181	0.9187	0.1110
90 %		2.0207	2.0207	2.0207	1.3181	0.9187	0.0595
None	R2 stream	-	1.2063	1.2063	0.7770	0.5376	-
50 %		1.2063	1.2063	1.2063	0.7770	0.5376	-
75 %		1.2063	1.2063	1.2063	0.7770	0.5376	-
90 %		1.2063	1.2063	1.2063	0.7770	0.5376	-
None	R3 stream	-	2.1764	2.1764	1.4190	0.9874	0.5963
50 %		2.1764	2.1764	2.1764	1.4190	0.9874	0.2997
75 %		2.1764	2.1764	2.1764	1.4190	0.9874	0.1536
90 %		2.1764	2.1764	2.1764	1.4190	0.9874	0.1295

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

Table 9.5-29: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (late, single application)

Intended use		Potato					
Active substance		zoxamide					
Application rate (g/ha)		3 ×135					
Nozzle reduction	No-spray buffer (m)	1	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	-	0.2318	0.1229	-	-	-
50 %		0.4276	0.1159	0.06145	-	-	-
75 %		0.2138	0.05859	0.03388	-	-	-
90 %		0.08551	0.03242	0.02189	-	-	-
None	D4 pond	-	0.02853	0.02069	-	-	-
50 %		0.02626	0.01622	0.01185	-	-	-
75 %		0.01562	0.01008	0.007425	-	-	-
90 %		0.009229	0.00639	0.004774	-	-	-
None	D4 stream	-	0.2246	0.1193	-	-	-
50 %		0.4138	0.1127	0.05996	-	-	-
75 %		0.2074	0.05677	0.0303	-	-	-
90 %		0.08359	0.0232	0.0125	-	-	-
None	D6 ditch	-	0.2302	0.1221	-	-	-
50 %		0.4247	0.1151	0.06104	-	-	-

75 %	D6 ditch	0.2124	0.05755	0.03052	-	-	-
90 %		0.08494	0.02554	0.01545	-	-	-
None		-	0.2302	0.1221	-	-	-
50 %		0.4247	0.1151	0.06104	-	-	-
75 %		0.2124	0.05755	0.03052	-	-	-
90 %		0.08494	0.02554	0.01545	-	-	-
None	R1 pond	-	0.05216	0.04503	0.0418	0.02942	-
50 %		0.05009	0.04095	0.03698	0.03055	0.02133	-
75 %		0.0404	0.03536	0.03295	0.02494	0.01729	-
90 %		0.03458	0.032	0.03054	0.02157	0.01486	-
None	R1 stream	-	0.6144	0.6144	0.4003	0.2788	0.2065
50 %		0.6144	0.6144	0.6144	0.4003	0.2788	0.1046
75 %		0.6144	0.6144	0.6144	0.4003	0.2788	0.05364
90 %		0.6144	0.6144	0.6144	0.4003	0.2788	0.02307
None	R2 stream	-	0.2797	0.149	0.2797	0.149	-
50 %		0.5142	0.1412	0.0819	0.1412	0.07553	-
75 %		0.2589	0.0819	0.0819	0.072	0.03883	-
90 %		0.1056	0.0819	0.0819	0.05346	0.03729	-
None	R3 stream	-	0.4894	0.4894	0.3197	0.2232	-
50 %		0.5375	0.4894	0.4894	0.3197	0.2232	-
75 %		0.4894	0.4894	0.4894	0.3197	0.2232	-
90 %		0.4894	0.4894	0.4894	0.3197	0.2232	-
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D3 ditch	-	0.6661	0.3532	-	-	-
50 %		1.2287	0.3330	0.1766	-	-	-
75 %		0.6144	0.1684	0.0974	-	-	-
90 %		0.2457	0.0932	0.0629	-	-	-
None	D4 pond	-	0.0820	0.0595	-	-	-
50 %		0.0755	0.0466	0.0341	-	-	-
75 %		0.0449	0.0290	0.0213	-	-	-
90 %		0.0265	0.0184	0.0137	-	-	-
None	D4 stream	-	0.6454	0.3428	-	-	-
50 %		1.1891	0.3239	0.1723	-	-	-
75 %		0.5960	0.1631	0.0871	-	-	-
90 %		0.2402	0.0667	0.0359	-	-	-
None	D6 ditch	-	0.6615	0.3509	-	-	-
50 %		1.2204	0.3307	0.1754	-	-	-
75 %		0.6103	0.1654	0.0877	-	-	-

90 %		0.2441	0.0734	0.0444	-	-	-
None	D6 ditch	-	0.6615	0.3509	-	-	-
50 %		1.2204	0.3307	0.1754	-	-	-
75 %		0.6103	0.1654	0.0877	-	-	-
90 %		0.2441	0.0734	0.0444	-	-	-
None	R1 pond	-	0.1499	0.1294	0.1201	0.0845	-
50 %		0.1439	0.1177	0.1063	0.0878	0.0613	-
75 %		0.1161	0.1016	0.0947	0.0717	0.0497	-
90 %		0.0994	0.0920	0.0878	0.0620	0.0427	-
None	R1 stream	-	1.7655	1.7655	1.1503	0.8011	0.5934
50 %		1.7655	1.7655	1.7655	1.1503	0.8011	0.3006
75 %		1.7655	1.7655	1.7655	1.1503	0.8011	0.1541
90 %		1.7655	1.7655	1.7655	1.1503	0.8011	0.0663
None	R2 stream	-	0.8037	0.4282	0.8037	0.4282	-
50 %		1.4776	0.4057	0.2353	0.4057	0.2170	-
75 %		0.7440	0.2353	0.2353	0.2069	0.1116	-
90 %		0.3034	0.2353	0.2353	0.1536	0.1072	-
None	R3 stream	-	1.4063	1.4063	0.9187	0.6414	-
50 %		1.5445	1.4063	1.4063	0.9187	0.6414	-
75 %		1.4063	1.4063	1.4063	0.9187	0.6414	-
90 %		1.4063	1.4063	1.4063	0.9187	0.6414	-

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

Table 9.5-30: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (late, multiple applications)

Intended use		Potato					
Active substance		zoxamide					
Application rate (g/ha)		3 ×135					
Nozzle reduction	No-spray buffer (m)	1	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	-	0.1653	0.08665	-	-	-
50 %		0.3123	0.08263	0.04543	-	-	-
75 %		0.1561	0.04768	0.02976	-	-	-
90 %		0.06794	0.03159	0.02169	-	-	-
None	D4 pond	-	0.05632	0.04072	-	-	-
50 %		0.05351	0.03334	0.02432	-	-	-

75 %		0.03332	0.02186	0.01613	-	-	-
90 %		0.02121	0.01498	0.01122	-	-	-
None		-	0.1784	0.09392	-	-	-
50 %	D4 stream	0.336	0.09003	0.04759	-	-	-
75 %		0.1691	0.04585	0.02444	-	-	-
90 %		0.06891	0.01934	0.01464	-	-	-
None		-	0.1643	0.08617	-	-	-
50 %	D6 ditch	0.3106	0.08217	0.04308	-	-	-
75 %		0.1553	0.04198	0.0239	-	-	-
90 %		0.0621	0.02251	0.01484	-	-	-
None		-	0.1643	0.08617	-	-	-
50 %	D6 ditch	0.3106	0.08217	0.04308	-	-	-
75 %		0.1553	0.04198	0.0239	-	-	-
90 %		0.0621	0.02251	0.01484	-	-	-
None		-	0.1586	0.1494	0.1127	0.07818	-
50 %	R1 pond	0.157	0.1451	0.1397	0.09595	0.06552	-
75 %		0.145	0.1383	0.1349	0.08909	0.0606	-
90 %		0.1379	0.1342	0.132	0.08498	0.05765	-
None		-	0.7277	0.7277	0.474	0.3303	0.1488
50 %	R1 stream	0.7277	0.7277	0.7277	0.474	0.3303	0.1263
75 %		0.7277	0.7277	0.7277	0.474	0.3303	0.1263
90 %		0.7277	0.7277	0.7277	0.474	0.3303	0.1263
None		-	0.3092	0.3092	0.1999	0.1378	-
50 %	R2 stream	0.376	0.3092	0.3092	0.1992	0.1378	-
75 %		0.3092	0.3092	0.3092	0.1992	0.1378	-
90 %		0.3092	0.3092	0.3092	0.1992	0.1378	-
None		-	0.6643	0.6643	0.4341	0.3028	0.2079
50 %	R3 stream	0.6643	0.6643	0.6643	0.4341	0.3028	0.1056
75 %		0.6643	0.6643	0.6643	0.4341	0.3028	0.1044
90 %		0.6643	0.6643	0.6643	0.4341	0.3028	0.1044
RAC (µg/L)							
0.348		PEC/RAC ratio					
None		-	0.4750	0.2490	-	-	-
50 %	D3 ditch	0.8974	0.2374	0.1305	-	-	-
75 %		0.4486	0.1370	0.0855	-	-	-
90 %		0.1952	0.0908	0.0623	-	-	-
None		-	0.1618	0.1170	-	-	-
50 %	D4 pond	0.1538	0.0958	0.0699	-	-	-
75 %		0.0957	0.0628	0.0464	-	-	-

90 %		0.0609	0.0430	0.0322	-	-	-
None	D4 stream	-	0.5126	0.2699	-	-	-
50 %		0.9655	0.2587	0.1368	-	-	-
75 %		0.4859	0.1318	0.0702	-	-	-
90 %		0.1980	0.0556	0.0421	-	-	-
None	D6 ditch	-	0.4721	0.2476	-	-	-
50 %		0.8925	0.2361	0.1238	-	-	-
75 %		0.4463	0.1206	0.0687	-	-	-
90 %		0.1784	0.0647	0.0426	-	-	-
None	D6 ditch	-	0.4721	0.2476	-	-	-
50 %		0.8925	0.2361	0.1238	-	-	-
75 %		0.4463	0.1206	0.0687	-	-	-
90 %		0.1784	0.0647	0.0426	-	-	-
None	R1 pond	-	0.4557	0.4293	0.3239	0.2247	-
50 %		0.4511	0.4170	0.4014	0.2757	0.1883	-
75 %		0.4167	0.3974	0.3876	0.2560	0.1741	-
90 %		0.3963	0.3856	0.3793	0.2442	0.1657	-
None	R1 stream	-	2.0911	2.0911	1.3621	0.9491	0.4276
50 %		2.0911	2.0911	2.0911	1.3621	0.9491	0.3629
75 %		2.0911	2.0911	2.0911	1.3621	0.9491	0.3629
90 %		2.0911	2.0911	2.0911	1.3621	0.9491	0.3629
None	R2 stream	-	0.8885	0.8885	0.5744	0.3960	-
50 %		1.0805	0.8885	0.8885	0.5724	0.3960	-
75 %		0.8885	0.8885	0.8885	0.5724	0.3960	-
90 %		0.8885	0.8885	0.8885	0.5724	0.3960	-
None	R3 stream	-	1.9089	1.9089	1.2474	0.8701	0.5974
50 %		1.9089	1.9089	1.9089	1.2474	0.8701	0.3034
75 %		1.9089	1.9089	1.9089	1.2474	0.8701	0.3000
90 %		1.9089	1.9089	1.9089	1.2474	0.8701	0.3000

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

Table 9.5-31: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, single application)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5

	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	0.9375	0.4494	0.1582	-	-	-
50 %		0.4689	0.2247	0.07909	-	-	-
75 %		0.2344	0.1123	0.03954	-	-	-
90 %		0.09375	0.04494	0.01735	-	-	-
None	R1 pond	0.04959	0.03404	0.01931	0.03404	0.01931	0.03404
50 %		0.02739	0.01933	0.01139	0.01933	0.01139	0.01933
75 %		0.0163	0.01198	0.007432	0.01198	0.007432	0.01198
90 %		0.009646	0.007571	0.005057	0.007571	0.005057	0.007571
None	R1 stream	0.8393	0.4034	0.1431	0.4034	0.1431	0.4034
50 %		0.4208	0.203	0.123	0.203	0.07273	0.203
75 %		0.2121	0.123	0.123	0.1031	0.05199	0.1031
90 %		0.123	0.123	0.123	0.07654	0.05199	0.04314
None	R2 stream	1.115	0.536	0.1898	0.536	0.1898	0.536
50 %		0.5592	0.2694	0.09593	0.2694	0.09593	0.2694
75 %		0.2812	0.1361	0.04904	0.1361	0.04904	0.1361
90 %		0.1144	0.05613	0.02088	0.05613	0.02088	0.05613
None	R3 stream	1.185	0.7076	0.7076	0.5686	0.3189	0.5686
50 %		0.7076	0.7076	0.7076	0.459	0.3189	0.2848
75 %		0.7076	0.7076	0.7076	0.459	0.3189	0.1442
90 %		0.7076	0.7076	0.7076	0.459	0.3189	0.0605
None	R4 stream	0.8391	0.4032	0.143	0.4032	0.143	0.4032
50 %		0.4207	0.203	0.07271	0.203	0.07271	0.203
75 %		0.212	0.1031	0.04102	0.1031	0.03755	0.1031
90 %		0.08692	0.04314	0.04102	0.04314	0.01806	0.04314
RAC (µg/L) 0.348		PEC/RAC ratio					
None	D6 ditch	2.694	1.291	0.455	-	-	-
50 %		1.347	0.646	0.227	-	-	-
75 %		0.674	0.323	0.114	-	-	-
90 %		0.269	0.129	0.050	-	-	-
None	R1 pond	0.143	0.098	0.055	0.098	0.055	0.098
50 %		0.079	0.056	0.033	0.056	0.033	0.056
75 %		0.047	0.034	0.021	0.034	0.021	0.034
90 %		0.028	0.022	0.015	0.022	0.015	0.022
None	R1 stream	2.412	1.159	0.411	1.159	0.411	1.159
50 %		1.209	0.583	0.353	0.583	0.209	0.583
75 %		0.609	0.353	0.353	0.296	0.149	0.296

90 %		0.353	0.353	0.353	0.220	0.149	0.124
None	R2 stream	3.204	1.540	0.545	1.540	0.545	1.540
50 %		1.607	0.774	0.276	0.774	0.276	0.774
75 %		0.808	0.391	0.141	0.391	0.141	0.391
90 %		0.329	0.161	0.060	0.161	0.060	0.161
None	R3 stream	3.405	2.033	2.033	1.634	0.916	1.634
50 %		2.033	2.033	2.033	1.319	0.916	0.818
75 %		2.033	2.033	2.033	1.319	0.916	0.414
90 %		2.033	2.033	2.033	1.319	0.916	0.174
None	R4 stream	2.411	1.159	0.411	1.159	0.411	1.159
50 %		1.209	0.583	0.209	0.583	0.209	0.583
75 %		0.609	0.296	0.118	0.296	0.108	0.296
90 %		0.250	0.124	0.118	0.124	0.052	0.124

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

Table 9.5-32: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, multiple applications)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	0.8747	0.4094	0.1393	-	-	-
50 %		0.4372	0.2046	0.07718	-	-	-
75 %		0.2186	0.1106	0.04886	-	-	-
90 %		0.1019	0.06073	0.03205	-	-	-
None	R1 pond	0.07982	0.05408	0.03023	0.05408	0.03023	0.04721
50 %		0.04457	0.03117	0.01822	0.03117	0.01822	0.03117
75 %		0.02693	0.01973	0.01293	0.01973	0.01221	0.01973
90 %		0.01637	0.01339	0.01029	0.01286	0.008616	0.01286
None	R1 stream	0.7709	0.3726	0.3726	0.3618	0.1574	0.5054
50 %		0.3864	0.3726	0.3726	0.2319	0.1574	0.1823
75 %		0.3726	0.3726	0.3726	0.2319	0.1574	0.09274
90 %		0.3726	0.3726	0.3726	0.2319	0.1574	0.039
None	R2 stream	1.04	0.4883	0.1674	0.4883	0.1674	0.6819
50 %		0.5216	0.2457	0.0849	0.2457	0.0849	0.2457

75 %		0.2627	0.1244	0.04367	0.1244	0.04367	0.1244
90 %		0.1072	0.0517	0.03157	0.0517	0.0189	0.0517
None		1.091	0.7076	0.7076	0.5117	0.3189	0.713
50 %	R3 stream	0.7076	0.7076	0.7076	0.459	0.3189	0.2557
75 %		0.7076	0.7076	0.7076	0.459	0.3189	0.1297
90 %		0.7076	0.7076	0.7076	0.459	0.3189	0.05481
None		0.776	0.3647	0.3647	0.364	0.1621	0.5086
50 %	R4 stream	0.3889	0.3647	0.3647	0.2327	0.1621	0.1833
75 %		0.3647	0.3647	0.3647	0.2327	0.1621	0.09332
90 %		0.3647	0.3647	0.3647	0.2327	0.1621	0.03967
RAC (µg/L)							
0.348		PEC/RAC ratio					
None		2.514	1.176	0.400	-	-	-
50 %	D6 ditch	1.256	0.588	0.222	-	-	-
75 %		0.628	0.318	0.140	-	-	-
90 %		0.293	0.175	0.092	-	-	-
None		0.229	0.155	0.087	0.155	0.087	0.136
50 %	R1 pond	0.128	0.090	0.052	0.090	0.052	0.090
75 %		0.077	0.057	0.037	0.057	0.035	0.057
90 %		0.047	0.038	0.030	0.037	0.025	0.037
None		2.215	1.071	1.071	1.040	0.452	1.452
50 %	R1 stream	1.110	1.071	1.071	0.666	0.452	0.524
75 %		1.071	1.071	1.071	0.666	0.452	0.266
90 %		1.071	1.071	1.071	0.666	0.452	0.112
None		2.989	1.403	0.481	1.403	0.481	1.959
50 %	R2 stream	1.499	0.706	0.244	0.706	0.244	0.706
75 %		0.755	0.357	0.125	0.357	0.125	0.357
90 %		0.308	0.149	0.091	0.149	0.054	0.149
None		3.135	2.033	2.033	1.470	0.916	2.049
50 %	R3 stream	2.033	2.033	2.033	1.319	0.916	0.735
75 %		2.033	2.033	2.033	1.319	0.916	0.373
90 %		2.033	2.033	2.033	1.319	0.916	0.158
None		2.230	1.048	1.048	1.046	0.466	1.461
50 %	R4 stream	1.118	1.048	1.048	0.669	0.466	0.527
75 %		1.048	1.048	1.048	0.669	0.466	0.268
90 %		1.048	1.048	1.048	0.669	0.466	0.114

Table 9.5-33: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, single application)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.506	1.714	0.6209	-	-	-
50 %		1.752	0.8569	0.3104	-	-	-
75 %		0.8761	0.4285	0.1577	-	-	-
90 %		0.3506	0.18	0.08131	-	-	-
None	R1 pond	0.1766	0.1207	0.06789	0.1207	0.06789	0.1049
50 %		0.09214	0.06375	0.03813	0.06375	0.03655	0.06375
75 %		0.04988	0.03704	0.02454	0.03529	0.02088	0.03529
90 %		0.0277	0.02222	0.01639	0.01964	0.01251	0.01821
None	R1 stream	3.105	1.519	0.5511	1.519	0.5511	2.085
50 %		1.553	0.7606	0.5089	0.7606	0.2769	0.7606
75 %		0.7778	0.5089	0.5089	0.3822	0.2243	0.3822
90 %		0.5089	0.5089	0.5089	0.3253	0.2242	0.1554
None	R2 stream	4.159	2.036	0.7394	2.036	0.7394	2.793
50 %		2.082	1.02	0.3713	1.02	0.3713	1.02
75 %		1.044	0.5126	0.1875	0.5126	0.1875	0.5126
90 %		0.4206	0.2078	0.08472	0.2078	0.07717	0.2078
None	R3 stream	4.384	2.144	0.777	2.144	0.777	2.943
50 %		2.192	1.072	0.3885	1.072	0.3885	1.072
75 %		1.096	0.5366	0.1954	0.5366	0.1954	0.5366
90 %		0.439	0.2168	0.08088	0.2168	0.08088	0.2168
None	R4 stream	3.054	1.495	0.6988	1.495	0.543	2.051
50 %		1.529	0.7493	0.6988	0.7493	0.3145	0.7493
75 %		0.7664	0.6988	0.6988	0.4515	0.3145	0.3765
90 %		0.6988	0.6988	0.6988	0.4515	0.3145	0.153
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	10.075	4.925	1.784	-	-	-
50 %		5.034	2.462	0.892	-	-	-
75 %		2.518	1.231	0.453	-	-	-
90 %		1.007	0.517	0.234	-	-	-

None	R1 pond	0.507	0.347	0.195	0.347	0.195	0.301
50 %		0.265	0.183	0.110	0.183	0.105	0.183
75 %		0.143	0.106	0.071	0.101	0.060	0.101
90 %		0.080	0.064	0.047	0.056	0.036	0.052
None	R1 stream	8.922	4.365	1.584	4.365	1.584	5.991
50 %		4.463	2.186	1.462	2.186	0.796	2.186
75 %		2.235	1.462	1.462	1.098	0.645	1.098
90 %		1.462	1.462	1.462	0.935	0.644	0.447
None	R2 stream	11.951	5.851	2.125	5.851	2.125	8.026
50 %		5.983	2.931	1.067	2.931	1.067	2.931
75 %		3.000	1.473	0.539	1.473	0.539	1.473
90 %		1.209	0.597	0.243	0.597	0.222	0.597
None	R3 stream	12.598	6.161	2.233	6.161	2.233	8.457
50 %		6.299	3.080	1.116	3.080	1.116	3.080
75 %		3.149	1.542	0.561	1.542	0.561	1.542
90 %		1.261	0.623	0.232	0.623	0.232	0.623
None	R4 stream	8.776	4.296	2.008	4.296	1.560	5.894
50 %		4.394	2.153	2.008	2.153	0.904	2.153
75 %		2.202	2.008	2.008	1.297	0.904	1.082
90 %		2.008	2.008	2.008	1.297	0.904	0.440

Table 9.5-34: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, multiple applications)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.102	1.508	0.5417	-	-	-
50 %		1.551	0.754	0.2709	-	-	-
75 %		0.7754	0.377	0.1412	-	-	-
90 %		0.3102	0.1632	0.0749	-	-	-
None	R1 pond	0.2818	0.1919	0.1076	0.1919	0.1076	0.1667
50 %		0.1476	0.102	0.05902	0.102	0.05844	0.102
75 %		0.08064	0.05787	0.03775	0.05713	0.03388	0.05713
90 %		0.04346	0.03456	0.02501	0.0312	0.01995	0.03022

None	R1 stream	2.749	1.337	0.6644	1.337	0.481	1.839
50 %		1.375	0.6695	0.6644	0.6695	0.2928	0.6695
75 %		0.6887	0.6644	0.6644	0.4248	0.2928	0.3368
90 %		0.6644	0.6644	0.6644	0.4248	0.2928	0.1374
None	R2 stream	3.683	1.792	0.6455	1.792	0.6455	2.464
50 %		1.844	0.8983	0.3432	0.8983	0.3246	0.8983
75 %		0.9243	0.4517	0.3432	0.4517	0.1641	0.4517
90 %		0.373	0.3432	0.3432	0.2227	0.1546	0.1835
None	R3 stream	3.882	1.887	0.6779	1.887	0.6779	2.597
50 %		1.941	0.9437	0.3393	0.9437	0.3393	0.9437
75 %		0.9706	0.4723	0.1711	0.4723	0.1711	0.4723
90 %		0.3888	0.1914	0.07115	0.1914	0.07115	0.1914
None	R4 stream	2.705	1.316	0.6988	1.316	0.4741	1.81
50 %		1.354	0.6988	0.6988	0.6598	0.3145	0.6597
75 %		0.6988	0.6988	0.6988	0.4515	0.3145	0.3318
90 %		0.6988	0.6988	0.6988	0.4515	0.3145	0.1352
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	8.914	4.333	1.557	-	-	-
50 %		4.457	2.167	0.778	-	-	-
75 %		2.228	1.083	0.406	-	-	-
90 %		0.891	0.469	0.215	-	-	-
None	R1 pond	0.810	0.551	0.309	0.551	0.309	0.479
50 %		0.424	0.293	0.170	0.293	0.168	0.293
75 %		0.232	0.166	0.108	0.164	0.097	0.164
90 %		0.125	0.099	0.072	0.090	0.057	0.087
None	R1 stream	7.899	3.842	1.909	3.842	1.382	5.284
50 %		3.951	1.924	1.909	1.924	0.841	1.924
75 %		1.979	1.909	1.909	1.221	0.841	0.968
90 %		1.909	1.909	1.909	1.221	0.841	0.395
None	R2 stream	10.583	5.149	1.855	5.149	1.855	7.080
50 %		5.299	2.581	0.986	2.581	0.933	2.581
75 %		2.656	1.298	0.986	1.298	0.472	1.298
90 %		1.072	0.986	0.986	0.640	0.444	0.527
None	R3 stream	11.155	5.422	1.948	5.422	1.948	7.463
50 %		5.578	2.712	0.975	2.712	0.975	2.712
75 %		2.789	1.357	0.492	1.357	0.492	1.357
90 %		1.117	0.550	0.204	0.550	0.204	0.550
None	R4 stream	7.773	3.782	2.008	3.782	1.362	5.201

50 %		3.891	2.008	2.008	1.896	0.904	1.896
75 %		2.008	2.008	2.008	1.297	0.904	0.953
90 %		2.008	2.008	2.008	1.297	0.904	0.389

Table 9.5-35: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, single application)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.52	1.721	0.6234	-	-	-
50 %		1.759	0.8604	0.3254	-	-	-
75 %		0.8796	0.4468	0.1833	-	-	-
90 %		0.3814	0.2114	0.09808	-	-	-
None	R1 pond	0.1785	0.1224	0.06916	0.1224	0.06916	0.1066
50 %		0.09399	0.06548	0.03782	0.06548	0.03782	0.06548
75 %		0.05173	0.03703	0.02215	0.03703	0.02215	0.03703
90 %		0.02639	0.01995	0.01275	0.01995	0.01275	0.01995
None	R1 stream	3.112	1.523	0.5527	1.523	0.5527	2.09
50 %		1.557	0.7626	0.278	0.7626	0.278	0.7626
75 %		0.7801	0.3837	0.1416	0.3837	0.1416	0.3837
90 %		0.3156	0.1576	0.05984	0.1576	0.05984	0.1576
None	R2 stream	4.175	2.045	0.743	2.045	0.743	2.804
50 %		2.091	1.025	0.3736	1.025	0.3736	1.025
75 %		1.049	0.5158	0.1892	0.5158	0.1892	0.5158
90 %		0.4235	0.2099	0.07841	0.2099	0.07841	0.2099
None	R3 stream	4.384	2.145	0.7771	2.145	0.7771	2.943
50 %		2.193	1.072	0.3887	1.072	0.3887	1.072
75 %		1.097	0.5368	0.2619	0.5368	0.1965	0.5368
90 %		0.4393	0.2619	0.2619	0.2182	0.1191	0.2182
None	R4 stream	3.112	1.523	0.5526	1.523	0.5526	2.089
50 %		1.557	0.7624	0.278	0.7624	0.278	0.7624
75 %		0.78	0.3837	0.1416	0.3837	0.1416	0.3837
90 %		0.3155	0.1575	0.1382	0.1575	0.06185	0.1575
RAC (µg/L)							

0.348		PEC/RAC ratio					
None	D6 ditch	10.115	4.945	1.791	-	-	-
50 %		5.055	2.472	0.935	-	-	-
75 %		2.528	1.284	0.527	-	-	-
90 %		1.096	0.607	0.282	-	-	-
None	R1 pond	0.513	0.352	0.199	0.352	0.199	0.306
50 %		0.270	0.188	0.109	0.188	0.109	0.188
75 %		0.149	0.106	0.064	0.106	0.064	0.106
90 %		0.076	0.057	0.037	0.057	0.037	0.057
None	R1 stream	8.943	4.376	1.588	4.376	1.588	6.006
50 %		4.474	2.191	0.799	2.191	0.799	2.191
75 %		2.242	1.103	0.407	1.103	0.407	1.103
90 %		0.907	0.453	0.172	0.453	0.172	0.453
None	R2 stream	11.997	5.876	2.135	5.876	2.135	8.057
50 %		6.009	2.945	1.074	2.945	1.074	2.945
75 %		3.014	1.482	0.544	1.482	0.544	1.482
90 %		1.217	0.603	0.225	0.603	0.225	0.603
None	R3 stream	12.598	6.164	2.233	6.164	2.233	8.457
50 %		6.302	3.080	1.117	3.080	1.117	3.080
75 %		3.152	1.543	0.753	1.543	0.565	1.543
90 %		1.262	0.753	0.753	0.627	0.342	0.627
None	R4 stream	8.943	4.376	1.588	4.376	1.588	6.003
50 %		4.474	2.191	0.799	2.191	0.799	2.191
75 %		2.241	1.103	0.407	1.103	0.407	1.103
90 %		0.907	0.453	0.397	0.453	0.178	0.453

Table 9.5-36: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, multiple applications)

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	4.174	2.038	0.7397	-	-	-
50 %		2.097	1.029	0.3778	-	-	-
75 %		1.06	0.5248	0.2112	-	-	-

90 %		0.4405	0.2464	0.1166	-	-	-
None	R1 pond	0.2587	0.1769	0.09961	0.1769	0.09961	0.154
50 %		0.1369	0.09534	0.05506	0.09534	0.05506	0.09534
75 %		0.07615	0.05462	0.03279	0.05462	0.03279	0.05462
90 %		0.03973	0.03022	0.01945	0.03022	0.01945	0.03022
None	R1 stream	2.756	1.341	0.4826	1.341	0.4826	1.844
50 %		1.379	0.6716	0.2433	0.6716	0.2433	0.6716
75 %		0.6911	0.3383	0.1243	0.3383	0.1243	0.3383
90 %		0.2803	0.1395	0.05289	0.1395	0.05289	0.1395
None	R2 stream	3.697	1.8	0.6488	1.8	0.6488	2.475
50 %		1.852	0.9028	0.3267	0.9028	0.3267	0.9028
75 %		0.929	0.4546	0.1657	0.4546	0.1657	0.4546
90 %		0.3757	0.1854	0.06898	0.1854	0.06898	0.1854
None	R3 stream	3.882	1.887	0.6919	1.887	0.678	2.597
50 %		1.941	0.9438	0.6919	0.9438	0.3394	0.9438
75 %		0.9707	0.6919	0.6919	0.4725	0.3131	0.4725
90 %		0.6919	0.6919	0.6919	0.4501	0.3131	0.1929
None	R4 stream	2.755	1.34	0.7316	1.34	0.4825	1.844
50 %		1.379	0.7316	0.7316	0.6715	0.3273	0.6715
75 %		0.7316	0.7316	0.7316	0.4723	0.3273	0.3382
90 %		0.7316	0.7316	0.7316	0.4723	0.3273	0.1395
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	11.994	5.856	2.126	-	-	-
50 %		6.026	2.957	1.086	-	-	-
75 %		3.046	1.508	0.607	-	-	-
90 %		1.266	0.708	0.335	-	-	-
None	R1 pond	0.743	0.508	0.286	0.508	0.286	0.443
50 %		0.393	0.274	0.158	0.274	0.158	0.274
75 %		0.219	0.157	0.094	0.157	0.094	0.157
90 %		0.114	0.087	0.056	0.087	0.056	0.087
None	R1 stream	7.920	3.853	1.387	3.853	1.387	5.299
50 %		3.963	1.930	0.699	1.930	0.699	1.930
75 %		1.986	0.972	0.357	0.972	0.357	0.972
90 %		0.805	0.401	0.152	0.401	0.152	0.401
None	R2 stream	10.624	5.172	1.864	5.172	1.864	7.112
50 %		5.322	2.594	0.939	2.594	0.939	2.594
75 %		2.670	1.306	0.476	1.306	0.476	1.306
90 %		1.080	0.533	0.198	0.533	0.198	0.533

None	R3 stream	11.155	5.422	1.988	5.422	1.948	7.463
50 %		5.578	2.712	1.988	2.712	0.975	2.712
75 %		2.789	1.988	1.988	1.358	0.900	1.358
90 %		1.988	1.988	1.988	1.293	0.900	0.554
None	R4 stream	7.917	3.851	2.102	3.851	1.386	5.299
50 %		3.963	2.102	2.102	1.930	0.941	1.930
75 %		2.102	2.102	2.102	1.357	0.941	0.972
90 %		2.102	2.102	2.102	1.357	0.941	0.401

Additional aquatic risk assessment using geomean Koc

An additional aquatic risk assessment is provided here for zoxamide parent at step 4, using the geomean Koc (see part B8).

As the zoxamide metabolites are passing the risk assessment at step 1 at the vast majority, and only in a few cases in step 2 with such a wide margin that it would also cover a tenfold PEC_{sw}, it is not considered necessary to repeat the risk assessment with the recalculated PEC_{sw} with geomean Koc here.

For the same reason, no additional risk assessment has been provided in the cases of secondary poisoning in birds and mammals, as the margin is very wide.

Therefore, the risk assessment is provided here for zoxamide only at step 4.

Similar approach has been followed by implementing the PL specific grape scenarios in this section (see Part B8) in Tables 9.5-47 - 9.5-51.

Table 9.5-37: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (early, single application) - using geomean Koc

Intended use		Potato		
Active substance		zoxamide		
Application rate (g/ha)		3 × 135		
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.1229	-	0.2317
None	D4 pond	0.01979	-	0.02741
None	D4 stream	0.1239	-	0.2332
None	D6 ditch	0.1215	-	0.2291
None	D6 ditch	0.1206	-	0.2273
None	R1 pond	0.03134	-	0.02747
None	R1 stream	0.2467	-	0.2073
None	R2 stream	0.1459	-	0.2743
None	R3 stream	0.1544	-	0.2909

RAC (µg/L)		PEC/RAC ratio		
0.348				
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.353	-	0.666
None	D4 pond	0.057	-	0.079
None	D4 stream	0.356	-	0.670
None	D6 ditch	0.349	-	0.658
None	D6 ditch	0.347	-	0.653
None	R1 pond	0.090	-	0.079
None	R1 stream	0.709	-	0.596
None	R2 stream	0.419	-	0.788
None	R3 stream	0.444	-	0.836

Table 9.5-38: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (early, multiple applications) - using geomean Koc

Intended use		Potato			
Active substance		zoxamide			
Application rate (g/ha)		3 × 135			3 × 130*
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD	10
	No spray buffer (m)	10	15	5	10
None	D3 ditch	0.08652	0.05868	0.165	0.0833
None	D4 pond	0.03821	0.02959	0.05317	0.03698
None	D4 stream	0.09037	0.06129	0.172	0.08705
None	D6 ditch	0.08618	0.05844	0.1644	0.08297
None	D6 ditch	0.0855	0.05799	0.1631	0.08297
None	R1 pond	0.05307	0.04071	0.05084	0.05126
None	R1 stream	0.3264	0.2505	0.148	0.314
None	R2 stream	0.1912	0.1462	0.199	0.184
None	R3 stream	0.3512	0.2693	0.2075	0.3377
RAC (µg/L)		PEC/RAC ratio			
0.348					
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD	10
	No spray buffer (m)	10	15	5	10
None	D3 ditch	0.249	0.169	0.474	0.239

None	D4 pond	0.110	0.085	0.153	0.106
None	D4 stream	0.260	0.176	0.494	0.250
None	D6 ditch	0.248	0.168	0.472	0.238
None	D6 ditch	0.246	0.167	0.469	0.238
None	R1 pond	0.153	0.117	0.146	0.147
None	R1 stream	0.938	0.720	0.425	0.902
None	R2 stream	0.549	0.420	0.572	0.529
None	R3 stream	1.009	0.774	0.596	0.970

*additionally run in order to demonstrate a safe use at 10m VFS when R3 scenario is relevant

Table 9.5-39: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (late, single application) - using geomean Koc

Intended use		Potato		
Active substance		zoxamide		
Application rate (g/ha)		3 × 135		
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.1229	-	0.2318
None	D4 pond	0.02069	-	0.02853
None	D4 stream	0.1193	-	0.2246
None	D6 ditch	0.1221	-	0.2303
None	D6 ditch	0.1229	-	0.2318
None	R1 pond	0.02967	-	0.02862
None	R1 stream	0.2848	-	0.2065
None	R2 stream	0.149	-	0.2797
None	R3 stream	0.228	-	0.2915
RAC (µg/L)		PEC/RAC ratio		
0.348				
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.353	-	0.666
None	D4 pond	0.059	-	0.082
None	D4 stream	0.343	-	0.645
None	D6 ditch	0.351	-	0.662
None	D6 ditch	0.353	-	0.666
None	R1 pond	0.085	-	0.082

None	R1 stream	0.818	-	0.593
None	R2 stream	0.428	-	0.804
None	R3 stream	0.655	-	0.838

Table 9.5-40: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in potato (late, multiple applications) - using geomean Koc

Intended use		Potato		
Active substance		zoxamide		
Application rate (g/ha)		3 ×135		
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.08665	-	0.1653
None	D4 pond	0.04076	-	0.05637
None	D4 stream	0.09392	-	0.1784
None	D6 ditch	0.08617	-	0.1644
None	D6 ditch	0.1852	-	0.1852
None	R1 pond	0.0791	-	0.06745
None	R1 stream	0.3368	-	0.1488
None	R2 stream	0.1409	-	0.1999
None	R3 stream	0.3092	-	0.2079
RAC (µg/L)		PEC/RAC ratio		
0.348				
Nozzle reduction	Vegetative strip (m) (R scenarios only)	10	15	5 VFSSMOD
	No spray buffer (m)	10	15	5
None	D3 ditch	0.249	-	0.475
None	D4 pond	0.117	-	0.162
None	D4 stream	0.270	-	0.513
None	D6 ditch	0.248	-	0.472
None	D6 ditch	0.532	-	0.532
None	R1 pond	0.227	-	0.194
None	R1 stream	0.968	-	0.428
None	R2 stream	0.405	-	0.574
None	R3 stream	0.889	-	0.597

Table 9.5-41: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, single application) - using geomean Koc

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	0.9376	0.4494	0.1582	-	-	-
50 %		0.4689	0.2247	0.07909	-	-	-
75 %		0.2344	0.1123	0.03955	-	-	-
90 %		0.09375	0.04494	0.01735	-	-	-
None	R1 pond	0.04959	0.03404	0.01932	0.03404	0.01932	0.02982
50 %		0.02739	0.01934	0.01139	0.01934	0.01139	0.01934
75 %		0.01631	0.01198	0.007433	0.01198	0.007433	0.01198
90 %		0.009647	0.007572	0.005058	0.007572	0.005058	0.007572
None	R1 stream	0.8393	0.4034	0.1431	0.4034	0.1431	0.5576
50 %		0.4208	0.203	0.1252	0.203	0.07273	0.203
75 %		0.2121	0.1252	0.1252	0.1031	0.05293	0.1031
90 %		0.1252	0.1252	0.1252	0.07792	0.05293	0.04314
None	R2 stream	1.115	0.536	0.1898	0.536	0.1898	0.741
50 %		0.5592	0.2694	0.09594	0.2694	0.09594	0.2694
75 %		0.2812	0.1361	0.04904	0.1361	0.04904	0.1361
90 %		0.1144	0.05614	0.02088	0.05614	0.02088	0.05614
None	R3 stream	1.185	0.7218	0.7218	0.5686	0.3253	0.7868
50 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.2848
75 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.1442
90 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.0605
None	R4 stream	0.8391	0.4033	0.143	0.4033	0.143	0.5575
50 %		0.4207	0.203	0.07271	0.203	0.07271	0.203
75 %		0.212	0.1031	0.04145	0.1031	0.03755	0.1031
90 %		0.08692	0.04314	0.04145	0.04314	0.01813	0.04314
RAC (µg/L)		PEC/RAC ratio					
0.348							
None	D6 ditch	2.694	1.291	0.455	-	-	-
50 %		1.347	0.646	0.227	-	-	-
75 %		0.674	0.323	0.114	-	-	-
90 %		0.269	0.129	0.050	-	-	-

None	R1 pond	0.143	0.098	0.056	0.098	0.056	0.086
50 %		0.079	0.056	0.033	0.056	0.033	0.056
75 %		0.047	0.034	0.021	0.034	0.021	0.034
90 %		0.028	0.022	0.015	0.022	0.015	0.022
None	R1 stream	2.412	1.159	0.411	1.159	0.411	1.602
50 %		1.209	0.583	0.360	0.583	0.209	0.583
75 %		0.609	0.360	0.360	0.296	0.152	0.296
90 %		0.360	0.360	0.360	0.224	0.152	0.124
None	R2 stream	3.204	1.540	0.545	1.540	0.545	2.129
50 %		1.607	0.774	0.276	0.774	0.276	0.774
75 %		0.808	0.391	0.141	0.391	0.141	0.391
90 %		0.329	0.161	0.060	0.161	0.060	0.161
None	R3 stream	3.405	2.074	2.074	1.634	0.935	2.261
50 %		2.074	2.074	2.074	1.345	0.935	0.818
75 %		2.074	2.074	2.074	1.345	0.935	0.414
90 %		2.074	2.074	2.074	1.345	0.935	0.174
None	R4 stream	2.411	1.159	0.411	1.159	0.411	1.602
50 %		1.209	0.583	0.209	0.583	0.209	0.583
75 %		0.609	0.296	0.119	0.296	0.108	0.296
90 %		0.250	0.124	0.119	0.124	0.052	0.124

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

Table 9.5-42: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, multiple applications) - using geomean Koc

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	0.8747	0.4094	0.1393	┃	┃	┃
50 %		0.4372	0.2047	0.07721	┃	┃	┃
75 %		0.2187	0.1106	0.04888	┃	┃	┃
90 %		0.102	0.06075	0.03206	┃	┃	┃
None	R1 pond	0.07988	0.05412	0.03025	0.05412	0.03025	0.04725
50 %		0.0446	0.0312	0.01823	0.0312	0.01823	0.0312
75 %		0.02695	0.01974	0.01301	0.01974	0.01222	0.01974

90 %		0.01638	0.01348	0.01037	0.01287	0.008622	0.01287
None	R1 stream	0.7709	0.3797	0.3797	0.3618	0.1605	0.5054
50 %		0.3864	0.3797	0.3797	0.2362	0.1605	0.1823
75 %		0.3797	0.3797	0.3797	0.2362	0.1605	0.09274
90 %		0.3797	0.3797	0.3797	0.2362	0.1605	0.039
None	R2 stream	1.04	0.4883	0.1674	0.4883	0.1674	0.6819
50 %		0.5216	0.2457	0.08491	0.2457	0.08491	0.2457
75 %		0.2627	0.1244	0.04367	0.1244	0.04367	0.1244
90 %		0.1072	0.0517	0.03218	0.0517	0.0189	0.0517
None	R3 stream	1.091	0.7218	0.7218	0.5118	0.3253	0.713
50 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.2557
75 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.1297
90 %		0.7218	0.7218	0.7218	0.4682	0.3253	0.05481
None	R4 stream	0.776	0.3698	0.3698	0.364	0.1633	0.5086
50 %		0.3889	0.3698	0.3698	0.235	0.1633	0.1833
75 %		0.3698	0.3698	0.3698	0.235	0.1633	0.09333
90 %		0.3698	0.3698	0.3698	0.235	0.1633	0.03967
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	2.514	1.176	0.400	-	-	-
50 %		1.256	0.588	0.222	-	-	-
75 %		0.628	0.318	0.140	-	-	-
90 %		0.293	0.175	0.092	-	-	-
None	R1 pond	0.230	0.156	0.087	0.156	0.087	0.136
50 %		0.128	0.090	0.052	0.090	0.052	0.090
75 %		0.077	0.057	0.037	0.057	0.035	0.057
90 %		0.047	0.039	0.030	0.037	0.025	0.037
None	R1 stream	2.215	1.091	1.091	1.040	0.461	1.452
50 %		1.110	1.091	1.091	0.679	0.461	0.524
75 %		1.091	1.091	1.091	0.679	0.461	0.266
90 %		1.091	1.091	1.091	0.679	0.461	0.112
None	R2 stream	2.989	1.403	0.481	1.403	0.481	1.959
50 %		1.499	0.706	0.244	0.706	0.244	0.706
75 %		0.755	0.357	0.125	0.357	0.125	0.357
90 %		0.308	0.149	0.092	0.149	0.054	0.149
None	R3 stream	3.135	2.074	2.074	1.471	0.935	2.049
50 %		2.074	2.074	2.074	1.345	0.935	0.735
75 %		2.074	2.074	2.074	1.345	0.935	0.373
90 %		2.074	2.074	2.074	1.345	0.935	0.158

None	R4 stream	2.230	1.063	1.063	1.046	0.469	1.461
50 %		1.118	1.063	1.063	0.675	0.469	0.527
75 %		1.063	1.063	1.063	0.675	0.469	0.268
90 %		1.063	1.063	1.063	0.675	0.469	0.114

Table 9.5-43: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, single application) - using geomean Koc

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.506	1.714	0.6209	┃	┃	┃
50 %		1.752	0.857	0.3104	┃	┃	┃
75 %		0.8761	0.4285	0.1578	┃	┃	┃
90 %		0.3506	0.18	0.08134	┃	┃	┃
None	R1 pond	0.1767	0.1207	0.0679	0.1207	0.0679	0.1049
50 %		0.09215	0.06376	0.03831	0.06376	0.03655	0.06376
75 %		0.04989	0.03721	0.0247	0.0353	0.02088	0.0353
90 %		0.02786	0.02238	0.01654	0.01974	0.01258	0.01822
None	R1 stream	3.105	1.519	0.5512	1.519	0.5512	2.085
50 %		1.553	0.7606	0.5197	0.7606	0.2769	0.7606
75 %		0.7779	0.5197	0.5197	0.3822	0.229	0.3822
90 %		0.5197	0.5197	0.5197	0.3322	0.229	0.1554
None	R2 stream	4.159	2.036	0.7394	2.036	0.7394	2.793
50 %		2.082	1.02	0.3713	1.02	0.3713	1.02
75 %		1.044	0.5126	0.1875	0.5126	0.1875	0.5126
90 %		0.4206	0.2078	0.08652	0.2078	0.07717	0.2078
None	R3 stream	4.384	2.144	0.777	2.144	0.777	2.943
50 %		2.192	1.072	0.3886	1.072	0.3886	1.072
75 %		1.097	0.5367	0.1954	0.5367	0.1954	0.5367
90 %		0.439	0.2168	0.08088	0.2168	0.08088	0.2168
None	R4 stream	3.054	1.495	0.7096	1.495	0.543	2.051
50 %		1.529	0.7493	0.7096	0.7493	0.3174	0.7493
75 %		0.7665	0.7096	0.7096	0.4558	0.3174	0.3765
90 %		0.7096	0.7096	0.7096	0.4558	0.3174	0.153

RAC (µg/L)		PEC/RAC ratio					
0.348							
None	D6 ditch	10.075	4.925	1.784	-	-	-
50 %		5.034	2.463	0.892	-	-	-
75 %		2.518	1.231	0.453	-	-	-
90 %		1.007	0.517	0.234	-	-	-
None	R1 pond	0.508	0.347	0.195	0.347	0.195	0.301
50 %		0.265	0.183	0.110	0.183	0.105	0.183
75 %		0.143	0.107	0.071	0.101	0.060	0.101
90 %		0.080	0.064	0.048	0.057	0.036	0.052
None	R1 stream	8.922	4.365	1.584	4.365	1.584	5.991
50 %		4.463	2.186	1.493	2.186	0.796	2.186
75 %		2.235	1.493	1.493	1.098	0.658	1.098
90 %		1.493	1.493	1.493	0.955	0.658	0.447
None	R2 stream	11.951	5.851	2.125	5.851	2.125	8.026
50 %		5.983	2.931	1.067	2.931	1.067	2.931
75 %		3.000	1.473	0.539	1.473	0.539	1.473
90 %		1.209	0.597	0.249	0.597	0.222	0.597
None	R3 stream	12.598	6.161	2.233	6.161	2.233	8.457
50 %		6.299	3.080	1.117	3.080	1.117	3.080
75 %		3.152	1.542	0.561	1.542	0.561	1.542
90 %		1.261	0.623	0.232	0.623	0.232	0.623
None	R4 stream	8.776	4.296	2.039	4.296	1.560	5.894
50 %		4.394	2.153	2.039	2.153	0.912	2.153
75 %		2.203	2.039	2.039	1.310	0.912	1.082
90 %		2.039	2.039	2.039	1.310	0.912	0.440

Table 9.5-44: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, multiple applications) - using geomean Koc

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.103	1.508	0.5417	-	-	-
50 %		1.551	0.754	0.2709	-	-	-

75 %		0.7754	0.377	0.1412	-	-	-
90 %		0.3102	0.1633	0.07493	-	-	-
None		0.282	0.192	0.1076	0.192	0.1076	0.1668
50 %		0.1477	0.1021	0.05929	0.1021	0.05849	0.1021
75 %		0.0807	0.05814	0.03798	0.05717	0.03391	0.05717
90 %		0.0437	0.03479	0.02522	0.03135	0.02005	0.03024
None		2.749	1.337	0.6787	1.337	0.481	1.839
50 %		1.375	0.6787	0.6787	0.6695	0.2991	0.6695
75 %		0.6887	0.6787	0.6787	0.4338	0.2991	0.3368
90 %		0.6787	0.6787	0.6787	0.4338	0.2991	0.1374
None		3.683	1.792	0.6455	1.792	0.6455	2.465
50 %		1.844	0.8983	0.3506	0.8983	0.3246	0.8983
75 %		0.9243	0.4517	0.3506	0.4517	0.1641	0.4517
90 %		0.373	0.3506	0.3506	0.2275	0.158	0.1835
None		3.882	1.887	0.6779	1.887	0.6779	2.597
50 %		1.941	0.9437	0.3393	0.9437	0.3393	0.9437
75 %		0.9706	0.4723	0.1711	0.4723	0.1711	0.4723
90 %		0.3888	0.1915	0.07115	0.1915	0.07115	0.1915
None		2.705	1.316	0.7096	1.316	0.4741	1.81
50 %		1.354	0.7096	0.7096	0.6598	0.3174	0.6597
75 %		0.7096	0.7096	0.7096	0.4558	0.3174	0.3318
90 %		0.7096	0.7096	0.7096	0.4558	0.3174	0.1352
RAC (µg/L)							
0.348		PEC/RAC ratio					
None		8.917	4.333	1.557	-	-	-
50 %		4.457	2.167	0.778	-	-	-
75 %		2.228	1.083	0.406	-	-	-
90 %		0.891	0.469	0.215	-	-	-
None		0.810	0.552	0.309	0.552	0.309	0.479
50 %		0.424	0.293	0.170	0.293	0.168	0.293
75 %		0.232	0.167	0.109	0.164	0.097	0.164
90 %		0.126	0.100	0.072	0.090	0.058	0.087
None		7.899	3.842	1.950	3.842	1.382	5.284
50 %		3.951	1.950	1.950	1.924	0.859	1.924
75 %		1.979	1.950	1.950	1.247	0.859	0.968
90 %		1.950	1.950	1.950	1.247	0.859	0.395
None		10.583	5.149	1.855	5.149	1.855	7.083
50 %		5.299	2.581	1.007	2.581	0.933	2.581
75 %		2.656	1.298	1.007	1.298	0.472	1.298

90 %		1.072	1.007	1.007	0.654	0.454	0.527
None	R3 stream	11.155	5.422	1.948	5.422	1.948	7.463
50 %		5.578	2.712	0.975	2.712	0.975	2.712
75 %		2.789	1.357	0.492	1.357	0.492	1.357
90 %		1.117	0.550	0.204	0.550	0.204	0.550
None	R4 stream	7.773	3.782	2.039	3.782	1.362	5.201
50 %		3.891	2.039	2.039	1.896	0.912	1.896
75 %		2.039	2.039	2.039	1.310	0.912	0.953
90 %		2.039	2.039	2.039	1.310	0.912	0.389

Table 9.5-45: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, single application) - using geomean Koc

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	3.52	1.721	0.6234	1	1	1
50 %		1.759	0.8604	0.3255	1	1	1
75 %		0.8796	0.447	0.1834	1	1	1
90 %		0.3815	0.2115	0.09811	1	1	1
None	R1 pond	0.1785	0.1224	0.06917	0.1224	0.06917	0.1066
50 %		0.094	0.06549	0.03782	0.06549	0.03782	0.06549
75 %		0.05174	0.03703	0.02215	0.03703	0.02215	0.03703
90 %		0.02639	0.01995	0.01275	0.01995	0.01275	0.01995
None	R1 stream	3.112	1.523	0.5527	1.523	0.5527	2.09
50 %		1.557	0.7626	0.278	0.7626	0.278	0.7626
75 %		0.7801	0.3838	0.1416	0.3838	0.1416	0.3838
90 %		0.3156	0.1576	0.05984	0.1576	0.05984	0.1576
None	R2 stream	4.175	2.045	0.743	2.045	0.743	2.804
50 %		2.091	1.025	0.3736	1.025	0.3736	1.025
75 %		1.049	0.5158	0.1892	0.5158	0.1892	0.5158
90 %		0.4235	0.2099	0.07841	0.2099	0.07841	0.2099
None	R3 stream	4.384	2.145	0.7771	2.145	0.7771	2.943
50 %		2.193	1.073	0.3887	1.073	0.3887	1.073
75 %		1.097	0.5368	0.2664	0.5368	0.1965	0.5368

90 %		0.4393	0.2664	0.2664	0.2183	0.1211	0.2183
None	R4 stream	3.112	1.523	0.5526	1.523	0.5526	2.089
50 %		1.557	0.7625	0.278	0.7625	0.278	0.7625
75 %		0.78	0.3837	0.1416	0.3837	0.1416	0.3837
90 %		0.3155	0.1575	0.1406	0.1575	0.06294	0.1575
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	10.115	4.945	1.791	-	-	-
50 %		5.055	2.472	0.935	-	-	-
75 %		2.528	1.284	0.527	-	-	-
90 %		1.096	0.608	0.282	-	-	-
None	R1 pond	0.513	0.352	0.199	0.352	0.199	0.306
50 %		0.270	0.188	0.109	0.188	0.109	0.188
75 %		0.149	0.106	0.064	0.106	0.064	0.106
90 %		0.076	0.057	0.037	0.057	0.037	0.057
None	R1 stream	8.943	4.376	1.588	4.376	1.588	6.006
50 %		4.474	2.191	0.799	2.191	0.799	2.191
75 %		2.242	1.103	0.407	1.103	0.407	1.103
90 %		0.907	0.453	0.172	0.453	0.172	0.453
None	R2 stream	11.997	5.876	2.135	5.876	2.135	8.057
50 %		6.009	2.945	1.074	2.945	1.074	2.945
75 %		3.014	1.482	0.544	1.482	0.544	1.482
90 %		1.217	0.603	0.225	0.603	0.225	0.603
None	R3 stream	12.598	6.164	2.233	6.164	2.233	8.457
50 %		6.302	3.083	1.117	3.083	1.117	3.083
75 %		3.152	1.543	0.766	1.543	0.565	1.543
90 %		1.262	0.766	0.766	0.627	0.348	0.627
None	R4 stream	8.943	4.376	1.588	4.376	1.588	6.003
50 %		4.474	2.191	0.799	2.191	0.799	2.191
75 %		2.241	1.103	0.407	1.103	0.407	1.103
90 %		0.907	0.453	0.404	0.453	0.181	0.453

Table 9.5-46: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, multiple applications) - using geometric Koc

Intended use	Grape
Active substance	zoxamide
Application rate (g/ha)	2×166

Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D6 ditch	4.177	2.039	0.5659	-	-	-
50 %		2.099	1.03	0.3781	-	-	-
75 %		1.061	0.5253	0.2114	-	-	-
90 %		0.441	0.2467	0.1167	-	-	-
None	R1 pond	0.259	0.1771	0.08557	0.1771	0.09973	0.1542
50 %		0.1371	0.09545	0.05512	0.09545	0.05512	0.09545
75 %		0.07623	0.05469	0.03283	0.05469	0.03283	0.05469
90 %		0.03978	0.03025	0.01947	0.03025	0.01947	0.03025
None	R1 stream	2.756	1.341	0.3673	1.341	0.4826	1.844
50 %		1.379	0.6716	0.2433	0.6716	0.2433	0.6716
75 %		0.6911	0.3383	0.1243	0.3383	0.1243	0.3383
90 %		0.2804	0.1395	0.05289	0.1395	0.05289	0.1395
None	R2 stream	3.698	1.8	0.4937	1.8	0.6488	2.475
50 %		1.852	0.9029	0.3267	0.9029	0.3267	0.9029
75 %		0.929	0.4546	0.1657	0.4546	0.1657	0.4546
90 %		0.3757	0.1854	0.06899	0.1854	0.06899	0.1854
None	R3 stream	3.882	1.887	0.7064	1.887	0.678	2.597
50 %		1.941	0.9438	0.7064	0.9438	0.3394	0.9438
75 %		0.9708	0.7064	0.7064	0.4725	0.3197	0.4725
90 %		0.7064	0.7064	0.7064	0.4595	0.3197	0.1929
None	R4 stream	2.756	1.34	0.7454	1.34	0.4825	1.844
50 %		1.379	0.7454	0.7454	0.6715	0.3335	0.6715
75 %		0.7454	0.7454	0.7454	0.4815	0.3335	0.3382
90 %		0.7454	0.7454	0.7454	0.4815	0.3335	0.1395
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D6 ditch	12.003	5.859	1.626	-	-	-
50 %		6.032	2.960	1.086	-	-	-
75 %		3.049	1.509	0.607	-	-	-
90 %		1.267	0.709	0.335	-	-	-
None	R1 pond	0.744	0.509	0.246	0.509	0.287	0.443
50 %		0.394	0.274	0.158	0.274	0.158	0.274
75 %		0.219	0.157	0.094	0.157	0.094	0.157
90 %		0.114	0.087	0.056	0.087	0.056	0.087
None	R1 stream	7.920	3.853	1.055	3.853	1.387	5.299
50 %		3.963	1.930	0.699	1.930	0.699	1.930

75 %	R2 stream	1.986	0.972	0.357	0.972	0.357	0.972
90 %		0.806	0.401	0.152	0.401	0.152	0.401
None		10.626	5.172	1.419	5.172	1.864	7.112
50 %		5.322	2.595	0.939	2.595	0.939	2.595
75 %	R3 stream	2.670	1.306	0.476	1.306	0.476	1.306
90 %		1.080	0.533	0.198	0.533	0.198	0.533
None		11.155	5.422	2.030	5.422	1.948	7.463
50 %		5.578	2.712	2.030	2.712	0.975	2.712
75 %	R4 stream	2.790	2.030	2.030	1.358	0.919	1.358
90 %		2.030	2.030	2.030	1.320	0.919	0.554
None		7.920	3.851	2.142	3.851	1.386	5.299
50 %		3.963	2.142	2.142	1.930	0.958	1.930
75 %		2.142	2.142	2.142	1.384	0.958	0.972
90 %		2.142	2.142	2.142	1.384	0.958	0.401

Table 9.5-47: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, single application) using the PL specific scenarios

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	█	0.4546	0.1601	█	█	█
50 %		0.3756	0.2273	0.08004	█	█	█
75 %		0.1878	0.1137	0.043	█	█	█
90 %		0.07665	0.05127	0.02676	█	█	█
None	D4 pond	█	0.03407	0.0193	█	█	█
50 %		0.02741	0.01935	0.01139	█	█	█
75 %		0.01631	0.01199	0.007433	█	█	█
90 %		0.009653	0.007578	0.005059	█	█	█
None	D4 stream	█	0.487	0.1722	█	█	█
50 %		0.5081	0.2444	0.08683	█	█	█
75 %		0.2551	0.1232	0.04413	█	█	█
90 %		0.1033	0.05042	0.01852	█	█	█
None	R1 pond	█	0.03407	0.0193	0.03407	0.0193	0.03407
50 %		0.0274	0.01935	0.01139	0.01935	0.01139	0.01935

75 %		0.01631	0.01199	0.00743	0.01199	0.00743	0.01199
90 %		0.009648	0.007574	0.005056	0.007574	0.005056	0.007574
None		█	0.4038	0.1434	0.4038	0.1434	0.4038
50 %	R1 stream	0.4214	0.2034	0.0845	0.2034	0.07284	0.2034
75 %		0.2124	0.1032	0.0845	0.1032	0.03759	0.1032
90 %		0.08704	0.0845	0.0845	0.05192	0.03502	0.04316
RAC (µg/L)							
0.348		PEC/RAC ratio					
None		█	1.3063	0.4601	█	█	█
50 %	D3 ditch	1.0793	0.6532	0.2300	█	█	█
75 %		0.5397	0.3267	0.1236	█	█	█
90 %		0.2203	0.1473	0.0769	█	█	█
None		█	0.0979	0.0555	█	█	█
50 %	D4 pond	0.0788	0.0556	0.0327	█	█	█
75 %		0.0469	0.0345	0.0214	█	█	█
90 %		0.0277	0.0218	0.0145	█	█	█
None		█	1.3994	0.4948	█	█	█
50 %	D4 stream	1.4601	0.7023	0.2495	█	█	█
75 %		0.7330	0.3540	0.1268	█	█	█
90 %		0.2968	0.1449	0.0532	█	█	█
None		█	0.0979	0.0555	0.0979	0.0555	0.0979
50 %	R1 pond	0.0787	0.0556	0.0327	0.0556	0.0327	0.0556
75 %		0.0469	0.0345	0.0214	0.0345	0.0214	0.0345
90 %		0.0277	0.0218	0.0145	0.0218	0.0145	0.0218
None		█	1.1603	0.4121	1.1603	0.4121	1.1603
50 %	R1 stream	1.2109	0.5845	0.2428	0.5845	0.2093	0.5845
75 %		0.6103	0.2966	0.2428	0.2966	0.1080	0.2966
90 %		0.2501	0.2428	0.2428	0.1492	0.1006	0.1240

Table 9.5-48: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH13, multiple applications) using the PL specific scenarios

Intended use	Grape
Active substance	zoxamide

Application rate (g/ha)		2×135					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	█	0.4082	0.1389	█	█	█
50 %		0.436	0.2041	0.06946	█	█	█
75 %		0.218	0.1021	0.04011	█	█	█
90 %		0.08791	0.04957	0.02685	█	█	█
None	D4 pond	█	0.04978	0.02773	█	█	█
50 %		0.04098	0.02868	0.01671	█	█	█
75 %		0.02476	0.01814	0.01121	█	█	█
90 %		0.01504	0.01182	0.007907	█	█	█
None	D4 stream	█	0.4564	0.1561	█	█	█
50 %		0.4876	0.2292	0.07881	█	█	█
75 %		0.2449	0.1156	0.04046	█	█	█
90 %		0.09931	0.04792	0.01756	█	█	█
None	R1 pond	█	0.05423	0.03022	0.05423	0.03022	0.05423
50 %		0.04465	0.03126	0.01822	0.03126	0.01822	0.03126
75 %		0.02699	0.01978	0.01222	0.01978	0.01222	0.01978
90 %		0.0164	0.01289	0.009236	0.01289	0.008624	0.01289
None	R1 stream	█	0.3623	0.2522	0.3623	0.1245	0.3623
50 %		0.3871	0.2522	0.2522	0.1827	0.1045	0.1827
75 %		0.2522	0.2522	0.2522	0.1549	0.1045	0.09288
90 %		0.2522	0.2522	0.2522	0.1549	0.1045	0.03902
RAC (µg/L)		PEC/RAC ratio					
0.348							
None	D3 ditch	█	1.1730	0.3991	█	█	█
50 %		1.2529	0.5865	0.1996	█	█	█
75 %		0.6264	0.2934	0.1153	█	█	█
90 %		0.2526	0.1424	0.0772	█	█	█
None	D4 pond	█	0.1430	0.0797	█	█	█
50 %		0.1178	0.0824	0.0480	█	█	█
75 %		0.0711	0.0521	0.0322	█	█	█
90 %		0.0432	0.0340	0.0227	█	█	█
None	D4 stream	█	1.3115	0.4486	█	█	█
50 %		1.4011	0.6586	0.2265	█	█	█
75 %		0.7037	0.3322	0.1163	█	█	█
90 %		0.2854	0.1377	0.0505	█	█	█
None	R1 pond	█	0.1558	0.0868	0.1558	0.0868	0.1558

50 %		0.1283	0.0898	0.0524	0.0898	0.0524	0.0898
75 %		0.0776	0.0568	0.0351	0.0568	0.0351	0.0568
90 %		0.0471	0.0370	0.0265	0.0370	0.0248	0.0370
None		1	1.0411	0.7247	1.0411	0.3578	1.0411
50 %	R1 stream	1.1124	0.7247	0.7247	0.5250	0.3003	0.5250
75 %		0.7247	0.7247	0.7247	0.4451	0.3003	0.2669
90 %		0.7247	0.7247	0.7247	0.4451	0.3003	0.1121

Table 9.5-49: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, single application) using the PL specific scenarios

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None		1	1.712	0.6204	1	1	1
50 %		1.751	0.8562	0.3102	1	1	1
75 %		0.8754	0.4281	0.1551	1	1	1
90 %		0.3501	0.1712	0.0751	1	1	1
None		1	0.1886	0.06804	1	1	1
50 %		0.09227	0.0977	0.03663	1	1	1
75 %		0.04996	0.05226	0.02092	1	1	1
90 %		0.02457	0.02501	0.0115	1	1	1
None		1	1.919	0.6964	1	1	1
50 %		1.963	0.961	0.3492	1	1	1
75 %		0.9828	0.4818	0.1757	1	1	1
90 %		0.3949	0.1947	0.07235	1	1	1
None		1	0.1883	0.06794	0.1883	0.06794	0.1883
50 %		0.09213	0.09755	0.03657	0.09755	0.03657	0.09755
75 %		0.04988	0.05219	0.02138	0.05219	0.02089	0.05219
90 %		0.02454	0.02497	0.0132	0.02497	0.01148	0.02497
None		1	1.52	0.5516	1.52	0.5516	1.52
50 %		1.555	0.7611	0.4207	0.7611	0.2772	0.7611
75 %		0.7784	0.4207	0.4207	0.3823	0.1815	0.3823
90 %		0.4207	0.4207	0.4207	0.2654	0.1815	0.1557
RAC (µg/L)							

0.348		PEC/RAC ratio					
None	D3 ditch	█	4.9195	1.7828	█	█	█
50 %		5.0316	2.4603	0.8914	█	█	█
75 %		2.5155	1.2302	0.4457	█	█	█
90 %		1.0060	0.4920	0.2158	█	█	█
None	D4 pond	█	0.5420	0.1955	█	█	█
50 %		0.2651	0.2807	0.1053	█	█	█
75 %		0.1436	0.1502	0.0601	█	█	█
90 %		0.0706	0.0719	0.0330	█	█	█
None	D4 stream	█	5.5144	2.0011	█	█	█
50 %		5.6408	2.7615	1.0034	█	█	█
75 %		2.8241	1.3845	0.5049	█	█	█
90 %		1.1348	0.5595	0.2079	█	█	█
None	R1 pond	█	0.5411	0.1952	0.5411	0.1952	0.5411
50 %		0.2647	0.2803	0.1051	0.2803	0.1051	0.2803
75 %		0.1433	0.1500	0.0614	0.1500	0.0600	0.1500
90 %		0.0705	0.0718	0.0379	0.0718	0.0330	0.0718
None	R1 stream	█	4.3678	1.5851	4.3678	1.5851	4.3678
50 %		4.4684	2.1871	1.2089	2.1871	0.7966	2.1871
75 %		2.2368	1.2089	1.2089	1.0986	0.5216	1.0986
90 %		1.2089	1.2089	1.2089	0.7626	0.5216	0.4474

Table 9.5-50: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH53, multiple applications) using the PL specific scenarios

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	█	1.511	0.5428	█	█	█
50 %		1.554	0.7556	0.2714	█	█	█
75 %		0.7771	0.3779	0.1358	█	█	█
90 %		0.3109	0.1532	0.07033	█	█	█
None	D4 pond	█	0.1771	0.09924	█	█	█
50 %		0.1363	0.09412	0.05389	█	█	█
75 %		0.0744	0.05268	0.03124	█	█	█

90 %		0.03733	0.02785	0.01766	█	█	█
None	D4 stream	█	1.747	0.6275	█	█	█
50 %		1.797	0.8736	0.3139	█	█	█
75 %		0.8985	0.1628	0.1579	█	█	█
90 %		0.3597	0.1764	0.06467	█	█	█
None	R1 pond	█	0.1823	0.1033	0.1814	0.1018	0.1799
50 %		0.1409	0.09812	0.05726	0.09712	0.05576	0.09563
75 %		0.07809	0.05604	0.03426	0.05504	0.03275	0.05354
90 %		0.04045	0.03081	0.02047	0.02981	0.01896	0.02831
None	R1 stream	█	1.34	0.482	1.34	0.482	1.34
50 %		1.378	0.6709	0.4207	0.6709	0.2424	0.6709
75 %		0.6902	0.4207	0.4207	0.3372	0.1815	0.3372
90 %		0.4207	0.4207	0.4207	0.2654	0.1815	0.1381
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D3 ditch	█	4.3420	1.5598	█	█	█
50 %		4.4655	2.1713	0.7799	█	█	█
75 %		2.2330	1.0859	0.3902	█	█	█
90 %		0.8934	0.4402	0.2021	█	█	█
None	D4 pond	█	0.5089	0.2852	█	█	█
50 %		0.3917	0.2705	0.1549	█	█	█
75 %		0.2138	0.1514	0.0898	█	█	█
90 %		0.1073	0.0800	0.0507	█	█	█
None	D4 stream	█	5.0201	1.8032	█	█	█
50 %		5.1638	2.5103	0.9020	█	█	█
75 %		2.5819	0.4678	0.4537	█	█	█
90 %		1.0336	0.5069	0.1858	█	█	█
None	R1 pond	█	0.5239	0.2968	0.5213	0.2925	0.5170
50 %		0.4049	0.2820	0.1645	0.2791	0.1602	0.2748
75 %		0.2244	0.1610	0.0984	0.1582	0.0941	0.1539
90 %		0.1162	0.0885	0.0588	0.0857	0.0545	0.0814
None	R1 stream	█	3.8506	1.3851	3.8506	1.3851	3.8506
50 %		3.9598	1.9279	1.2089	1.9279	0.6966	1.9279
75 %		1.9833	1.2089	1.2089	0.9690	0.5216	0.9690
90 %		1.2089	1.2089	1.2089	0.7626	0.5216	0.3968

Table 9.5-51: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, single application) using the PL specific scenarios

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		1×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	1	1.72	0.623	1	1	1
50 %		1.758	0.8598	0.3115	1	1	1
75 %		0.879	0.4299	0.172	1	1	1
90 %		0.3573	0.1985	0.09268	1	1	1
None	D4 pond	1	0.1903	0.06932	1	1	1
50 %		0.09414	0.09944	0.0379	1	1	1
75 %		0.05182	0.05401	0.0222	1	1	1
90 %		0.02643	0.02675	0.01277	1	1	1
None	D4 stream	1	1.943	0.7049	1	1	1
50 %		1.987	0.9728	0.3536	1	1	1
75 %		0.9948	0.4877	0.1787	1	1	1
90 %		0.8181	0.1982	0.07385	1	1	1
None	R1 pond	1	0.19	0.06921	0.19	0.06921	0.19
50 %		0.09398	0.09928	0.03784	0.09928	0.03784	0.09928
75 %		0.05174	0.05392	0.02216	0.05392	0.02216	0.05392
90 %		0.02639	0.02671	0.01275	0.02671	0.01275	0.02671
None	R1 stream	1	1.523	0.5527	1.523	0.5527	1.523
50 %		1.557	0.7627	0.2781	0.7627	0.2781	0.7627
75 %		0.7802	0.3837	0.1417	0.3837	0.1417	0.3837
90 %		0.3156	0.1576	0.05985	0.1576	0.05985	0.1576
RAC (µg/L)		PEC/RAC ratio					
0.348							
None	D3 ditch	1	4.9425	1.7902	1	1	1
50 %		5.0517	2.4707	0.8951	1	1	1
75 %		2.5259	1.2353	0.4943	1	1	1
90 %		1.0267	0.5704	0.2663	1	1	1
None	D4 pond	1	0.5468	0.1992	1	1	1
50 %		0.2705	0.2857	0.1089	1	1	1
75 %		0.1489	0.1552	0.0638	1	1	1
90 %		0.0759	0.0769	0.0367	1	1	1

None	D4 stream	█	5.5833	2.0256	█	█	█
50 %		5.7098	2.7954	1.0161	█	█	█
75 %		2.8586	1.4014	0.5135	█	█	█
90 %		2.3509	0.5695	0.2122	█	█	█
None	R1 pond	█	0.5460	0.1989	0.5460	0.1989	0.5460
50 %		0.2701	0.2853	0.1087	0.2853	0.1087	0.2853
75 %		0.1487	0.1549	0.0637	0.1549	0.0637	0.1549
90 %		0.0758	0.0768	0.0366	0.0768	0.0366	0.0768
None	R1 stream	█	4.3764	1.5882	4.3764	1.5882	4.3764
50 %		4.4741	2.1917	0.7991	2.1917	0.7991	2.1917
75 %		2.2420	1.1026	0.4072	1.1026	0.4072	1.1026
90 %		0.9069	0.4529	0.1720	0.4529	0.1720	0.4529

Table 9.5-52: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for zoxamide based on FOCUS Step 4 calculations and toxicity data for fish with mitigation of spray drift and run-off for the use of GLOB2013F in grape (BBCH83, multiple applications) using the PL specific scenarios

Intended use		Grape					
Active substance		zoxamide					
Application rate (g/ha)		2×166					
Nozzle reduction	No-spray buffer (m)	3	5	10	5	10	5
	Vegetated filter strip (m)	None	None	None	5	10	5(VFSMOD)
None	D3 ditch	█	1.757	0.6351	█	█	█
50 %		1.808	0.8837	0.3216	█	█	█
75 %		0.9097	0.4472	0.1788	█	█	█
90 %		0.3723	0.2088	0.09924	█	█	█
None	D4 pond	█	0.1958	0.1103	█	█	█
50 %		0.1516	0.1056	0.06099	█	█	█
75 %		0.08435	0.06051	0.03633	█	█	█
90 %		0.04401	0.03347	0.02155	█	█	█
None	D4 stream	█	1.71	0.6152	█	█	█
50 %		1.759	0.8563	0.309	█	█	█
75 %		0.8808	0.4298	0.1564	█	█	█
90 %		0.3551	0.175	0.06493	█	█	█
None	R1 pond	█	0.1771	0.09974	0.1771	0.09974	0.1771
50 %		0.1371	0.09547	0.05512	0.09547	0.05512	0.09547
75 %		0.07626	0.05469	0.03283	0.05469	0.03283	0.05469
90 %		0.03978	0.03025	0.01947	0.03025	0.01947	0.03025

None	R1 stream	-	1.341	0.4827	1.341	0.4827	1.341
50 %		1.379	0.6717	0.2432	0.6717	0.2432	0.6717
75 %		0.6912	0.3382	0.1243	0.3382	0.1243	0.3382
90 %		0.2803	0.1395	0.05289	0.1395	0.05289	0.1395
RAC (µg/L)							
0.348		PEC/RAC ratio					
None	D3 ditch	-	5.0489	1.8250	-	-	-
50 %		5.1954	2.5394	0.9241	-	-	-
75 %		2.6141	1.2851	0.5138	-	-	-
90 %		1.0698	0.6000	0.2852	-	-	-
None	D4 pond	-	0.5626	0.3170	-	-	-
50 %		0.4356	0.3034	0.1753	-	-	-
75 %		0.2424	0.1739	0.1044	-	-	-
90 %		0.1265	0.0962	0.0619	-	-	-
None	D4 stream	-	4.9138	1.7678	-	-	-
50 %		5.0546	2.4606	0.8879	-	-	-
75 %		2.5310	1.2351	0.4494	-	-	-
90 %		1.0204	0.5029	0.1866	-	-	-
None	R1 pond	-	0.5089	0.2866	0.5089	0.2866	0.5089
50 %		0.3940	0.2743	0.1584	0.2743	0.1584	0.2743
75 %		0.2191	0.1572	0.0943	0.1572	0.0943	0.1572
90 %		0.1143	0.0869	0.0559	0.0869	0.0559	0.0869
None	R1 stream	-	3.8534	1.3871	3.8534	1.3871	3.8534
50 %		3.9626	1.9302	0.6989	1.9302	0.6989	1.9302
75 %		1.9862	0.9718	0.3572	0.9718	0.3572	0.9718
90 %		0.8055	0.4009	0.1520	0.4009	0.1520	0.4009

9.5.3 Overall conclusions

An acceptable risk for the formulation GLOB2013F in potato and grape is acceptable with the following mitigation measures:

For the countries that accept the EU agreed endpoints (see part B8) and for the countries that do not accept the EU agreed endpoints but where R3 is not relevant:

SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (late applications), to protect aquatic organisms use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.
OR in case VFSSMOD is accepted: Alternatively, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

For the countries that do not accept the EU agreed endpoints and where R3 is relevant:

SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 15 m including a 15 m vegetated filter strip to surface water bodies. Alternatively, apply up to 0.29 L/ha and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.

OR in case VFSSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

SPe3: For grape use (late applications), to protect aquatic organisms use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.
OR in case VFSSMOD is accepted: Alternatively, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.

For grape, for Poland specific scenarios:

SPe3: For grape use (early applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies (according to VFSSmode).

or

Alternatively, respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.

SPe3: For grape use (late applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies (according to VFSSmode).

or

respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 75% drift reducing nozzles to surface water bodies.

use 50% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies

Review comments:

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). An additional aquatic risk assessment is provided for zoxamide parent at step 4, using the geometric Koc (see part B8).

The PEC/RAC ratios for zoxamide and its metabolites are less than the trigger value of 1, indicating that the risk to aquatic organisms is acceptable following use of GLOB2013F according to the proposed use pattern when considering appropriate mitigation measures.

The acceptability of proposed risk mitigation measures used in refined risk assessment should be considered on National level.

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

Effects on bees of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	RH-117,281 2F	Acute, oral	Oral toxicity (LD ₅₀) >147 µg formulation/bee (corresponding to >33 µg a.s./bee)	EFSA Journal 2017;15(9):4980
<i>Apis mellifera</i>	zoxamide	Acute, contact	Contact toxicity (LD ₅₀) > 100 µg a.s./bee	EFSA Journal 2017;15(9):4980
<i>Apis mellifera</i>	RH-117,281 2F	Acute, contact	Contact toxicity (LD ₅₀) >200 µg formulation/bee (corresponding to >43.2 µg a.s./bee)	EFSA Journal 2017;15(9):4980
<i>Apis mellifera</i>	Zoxium 240 SC	Chronic	10 d- LC ₅₀ >5000 mg a.s./kg feed 174.8 µg a.s./bee/day	EFSA Journal 2017;15(9):4980
<i>Apis mellifera</i>	zoxamide	Larvae, chronic	NOEDD > 71.51 µg a.s./larva	Aguilar-Alberola, J., 2023
<i>Apis mellifera</i>	Zoxium 240 SC	Semi-field bee brood test	No effects on bee brood development up to 3.47 g Zoxium 240 SC/L feeding solution corresponding to 0.75 g a.s./L feeding solution	EFSA Journal 2017;15(9):4980
<i>Apis mellifera</i>	GLOB2013F	Acute, oral	Oral toxicity (LD ₅₀) >100 µg formulation/bee (corresponding to >45 µg a.s./bee)	Przychodzka, A., 2021
<i>Apis mellifera</i>	GLOB2013F	Acute, contact	Contact toxicity (LD ₅₀) >100 µg formulation/bee (corresponding to >45 µg a.s./bee)	Przychodzka, A., 2021
<i>Apis mellifera</i>	GLOB2013F	Adult, chronic	LDD ₅₀ > 99.75 µg formulation/bee (corresponding to >44.89 µg a.s./bee)	Konieczna, A., 2021
<i>Apis mellifera</i>	GLOB2013F	Larvae, chronic	NOEDD > 100 µg formulation/larva (corresponding to >45 µg a.s./larva)	Konieczna, A., 2021

Species	Substance	Exposure System	Results	Reference
<i>Bombus terrestris</i>	GLOB2013F	Acute, oral	Oral toxicity (LD ₅₀) >1000 µg formulation/bumblebee (corresponding to >450 µg a.s./bee)	Konieczna, A., 2021
<i>Bombus terrestris</i>	GLOB2013F	Acute, contact	Contact toxicity (LD ₅₀) >1000 µg formulation/bumblebee (corresponding to >450 µg a.s./bee)	Konieczna, A., 2021
Higher-tier studies (tunnel test, field studies)				
Not performed.				

9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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 (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 (grapes) also covers the risk for ~~bees~~ birds from all other intended uses in groups 1 and 2 (see 9.1.2).

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 GLOB2013F in grapes

Intended use	Grapes		
Active substance	zoxamide		
Application rate (g/ha)	2 × 166		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	> 33	166	< 5.03
Contact toxicity	> 100		< 1.3
Product	GLOB2013F		
Application rate (g/ha)	2 × 417.5*		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	> 100	417.5	< 4.18
Contact toxicity	> 100		< 4.18

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

*based on product density of 1.1346 g/mL

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

Not relevant.

Review Comments:

Since acceptable acute risk have been concluded for bees exposed to GLOB2013F at the Tier 1 level, a higher-tier risk assessment is not required for the proposed uses of GLOB2013F.

9.6.3 Effects on bumble bees

Table 9.6-3: First-tier assessment of the risk for bumble bees due to the use of GLOB2013F in grape

Intended use	Grape		
Product	GLOB2013F		
Application rate (g/ha)	2 × 417.5*		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)*	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 1000	417.5	< 0.418
Contact toxicity	> 1000		< 0.418

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

*based on product density of 1.1346

All the hazard quotients are below 50, indicating that the application of GLOB2013F poses a low acute risk to bumble bees.

Review Comments:

The evaluation of the risk for bumblebees 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 available toxicity data for GLOB2013F to bumblebees indicate lower toxicity than to honeybees. The submitted risk assessment, according to the guidance currently in force, has been accepted. It can therefore, be concluded that there will be negligible risk connected with the exposure of bumblebees to GLOB2013F.

9.6.4 Effects on solitary bees

No data/information available.

Review Comments:

According to SANCO/10329/2002 rev 2 final, the risk assessment for solitary bees is not required.

9.6.5 Effects on honey bee development and other honey bee life stages

Larval chronic risk assessment

A chronic larval study is available and the potential acceptable risk can be further demonstrated by carrying out a worst-case risk assessment through the calculation of a TER value as set out in the modified EPPO 2010 approach and according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028).

A worst-case of potential exposure via residues in pollen and nectar can be estimated based on the default worst-case residue of 1 mg a.s./kg plant material as proposed in the EPPO 2010 scheme (see Note 6 therein), based on a database of measured values from aerial plant parts, as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst-case data from Rortais et al., 2005¹, as proposed in the EPPO scheme, have been used to estimate the consumption by bee larvae:

Worker larvae consuming 59.4 mg sugar in 5 days. Assuming 30% sugar content of nectar, the worst-case consumption for worker larvae is:

$$59.4/0.30 = 198 \text{ mg nectar in 5 days.}$$

In addition worker larvae are considered to consume 2 mg pollen during their development phase (EFSA 2013).

Thus, considering the mean RUD values for nectar and pollen in EFSA 2013, exposure can be estimated for the whole development period. With an application rate of 166 g zoxamide/ha (corresponding with 417.5 g GLOB2013F/ha) this results into an exposure of nectar and pollen as follows:

Zoxamide

Nectar dose: $0.166 \times 2.9 \times 198/1000 = 0.168 \text{ } \mu\text{g a.s./larva}$

Pollen dose: $0.166 \times 6.1 \times 2/1000 = 0.002 \text{ } \mu\text{g a.s./larva}$

GLOB2013F

Nectar dose: $0.4175 \times 2.9 \times 198/1000 = 0.24 \text{ } \mu\text{g formulation/larva}$

Pollen dose: $0.4175 \times 6.1 \times 2/1000 = 0.0051 \text{ } \mu\text{g formulation/larva}$

Total exposure ETE = $0.17 \text{ } \mu\text{g zoxamide/larva}$ and $0.2451 \text{ } \mu\text{g GLOB2109F/larva}$.

This can be compared to the larval NOEDD of $45 \text{ } \mu\text{g zoxamide/larva}$ and $100 \text{ } \mu\text{g GLOB2013F/larva}$.

Adult chronic risk assessment

The adult chronic risk assessment is performed using the modified EPPO 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028).

This is based upon the method of EPPO 2010 risk assessment for systemic substances which is cited in the regulation as a current risk assessment scheme. It uses NOEDD values for the endpoint so avoids the

¹ Agnès RORTAIS, Gérard ARNOLD, Marie-Pierre HALM, Frédérique TOUFFET-BRIENS (2005). Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. *Apidologie* 36 (2005) 71–83

issues associated with the generation of LDD₅₀ values for substances of low toxicity, and calculates exposure in a similar way to EFSA 2013. The approach is also in line with other chronic risk assessments (e.g. birds and mammals). EPPO 2010 recommended the calculation of a TER using the following equation:

$$\text{TER} = \text{NOEDD}/\text{daily dose}$$

Where daily dose (DD) is based on the worst case a sugar need of 128 mg/bee/day (Rortais *et al.*, 2005) of a bee feeding exclusively from nectar containing 30% sugar using the following equation:

Zoxamide

$$\text{Daily dose } (\mu\text{g a.i./bee}) = \text{A.R.} \times [128 \text{ mg}/(1000 \times 0.3)] \times \text{RUD} = 0.166 \times [128/(1000 \times 0.3)] \times 2.9 = 0.205 \mu\text{g/bee}$$

A.R. = application rate in kg a.i./ha

RUD = residue per unit dose from the EFSA bee guidance.

Mean RUD_{nectar} = 2.9 mg a.i./kg (foliar sprays).

$$\text{TER} = \text{NOEDD}/\text{daily dose} = 44.89/0.205 = 218.98$$

GLOB2013F

$$\text{Daily dose } (\mu\text{g product/bee}) = \text{A.R.} \times [128 \text{ mg}/(1000 \times 0.3)] \times \text{RUD} = 0.4175 \times [128/(1000 \times 0.3)] \times 2.9 = 0.517 \mu\text{g/bee}$$

A.R. = application rate in kg product/ha

RUD = residue per unit dose from the EFSA bee guidance.

Mean RUD_{nectar} = 2.9 mg a.i./kg (foliar sprays).

$$\text{TER} = \text{NOEDD}/\text{daily dose} = 111.6/2.719 = 215.86$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the chronic risk to honey bees. It is clear that with a TER value of 218.98 for zoxamide and 215.86 for GLOB2013F, the proposed use of GLOB2013F pose an acceptable risk to adult bees.

Review comments:

The hazard quotients are below the trigger value of 1 considering the modified EPPO 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028) indicating that the active substances and formulation pose an acceptable chronic risk to honey bee larvae and adult honey bees.

Larval and adult chronic risk assessment according to EFSA, 2013

The chronic risk to bees has been also assessed according to the EFSA Guidance Document on bees (EFSA Journal 2013;11(7):3295, revision of 4 July 2014) considering an application rate of 0.3 L GLOB2013F /ha (corresponding with 0.340 g GLOB2013F/ha) for potato and 0.368 L GLOB2013F /ha (corresponding with 0.418 g GLOB2013F/ha) for grape.

BBCH stages < 10 and weed scenario have not been included as not relevant to GLOB2013F use on potato. BBCH stages < 10 have not been included as not relevant to GLOB2013F use on grape.

Non-relevance of weeds in potato fields has been further confirmed by the most recent EFSA guidance (EFSA Journal 2023;21(5):7989, 11 May 2023) that considers this scenario as not existing (see table 5 and 6 in the guidance, point 4.3.2 'Weeds in treated fields', page 26-27) for all potato growth stages,

based on available scientific evidence. Even if it is still an un-noted guidance, the regulatory consensus is that this scenario is not relevant for potato and therefore, risk assessment or other refinements on this particular scenario are not required.

Results of Tier 1 assessment are presented in the Table below.

Table 9.6-4: First-tier assessment of the chronic risk for bees due to the use of GLOB2013F on potato according to EFSA, 2013

category	scenario	BBCH	Honeybee	
			ETR	trigger
chronic	treated crop	10 - 39	0.00	0.03
chronic	treated crop	40 - 69	0.00	0.03
chronic	treated crop	≥ 70	0.00	0.03
chronic	field margin	10 - 39	0.00	0.03
chronic	field margin	40 - 69	0.00	0.03
chronic	field margin	≥ 70	0.00	0.03
chronic	adjacent crop	10 - 39	0.00	0.03
chronic	adjacent crop	40 - 69	0.00	0.03
chronic	adjacent crop	≥ 70	0.00	0.03
chronic	next crop	10 - 39	0.00	0.03
chronic	next crop	40 - 69	0.00	0.03
chronic	next crop	≥ 70	0.00	0.03
larva	treated crop	10 - 39	0.00	0.2
larva	treated crop	40 - 69	0.00	0.2
larva	treated crop	≥ 70	0.00	0.2
larva	field margin	10 - 39	0.00	0.2
larva	field margin	40 - 69	0.00	0.2
larva	field margin	≥ 70	0.00	0.2
larva	adjacent crop	10 - 39	0.00	0.2
larva	adjacent crop	40 - 69	0.00	0.2
larva	adjacent crop	≥ 70	0.00	0.2
larva	next crop	10 - 39	0.00	0.2
larva	next crop	40 - 69	0.00	0.2
larva	next crop	≥ 70	0.00	0.2

Table 9.6-5: First-tier assessment of the chronic risk for bees due to the use of GLOB2013F on grape according to EFSA, 2013

category	scenario	BBCH	Honeybee	
			ETR	trigger
chronic	treated crop	10 - 19	0.02	0.03
chronic	treated crop	20 - 39	0.02	0.03
chronic	treated crop	40 - 69	0.02	0.03
chronic	treated crop	≥ 70	0.00	0.03
chronic	weeds	10 - 19	0.01	0.03
chronic	weeds	20 - 39	0.00	0.03
chronic	weeds	40 - 69	0.00	0.03
chronic	weeds	≥ 70	0.00	0.03
chronic	field margin	10 - 19	0.00	0.03
chronic	field margin	20 - 39	0.00	0.03
chronic	field margin	40 - 69	0.00	0.03
chronic	field margin	≥ 70	0.00	0.03

chronic	adjacent crop	10 - 19	0.00	0.03
chronic	adjacent crop	20 - 39	0.00	0.03
chronic	adjacent crop	40 - 69	0.00	0.03
chronic	adjacent crop	≥ 70	0.00	0.03
chronic	next crop	10 - 19	0.00	0.03
chronic	next crop	20 - 39	0.00	0.03
chronic	next crop	40 - 69	0.00	0.03
chronic	next crop	≥ 70	0.00	0.03
larva	treated crop	10 - 19	0.02	0.2
larva	treated crop	20 - 39	0.02	0.2
larva	treated crop	40 - 69	0.02	0.2
larva	treated crop	≥ 70	0.00	0.2
larva	weeds	10 - 19	0.00	0.2
larva	weeds	20 - 39	0.00	0.2
larva	weeds	40 - 69	0.00	0.2
larva	weeds	≥ 70	0.00	0.2
larva	field margin	10 - 19	0.00	0.2
larva	field margin	20 - 39	0.00	0.2
larva	field margin	40 - 69	0.00	0.2
larva	field margin	≥ 70	0.00	0.2
larva	adjacent crop	10 - 19	0.00	0.2
larva	adjacent crop	20 - 39	0.00	0.2
larva	adjacent crop	40 - 69	0.00	0.2
larva	adjacent crop	≥ 70	0.00	0.2
larva	next crop	10 - 19	0.00	0.2
larva	next crop	20 - 39	0.00	0.2
larva	next crop	40 - 69	0.00	0.2
larva	next crop	≥ 70	0.00	0.2

Review comments:

Risk assessment according to EFSA, 2013 presented by the Applicant is considered acceptable. Concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on national level.

9.6.6 Overall conclusions

HQ values for oral and contact exposure are below the relevant trigger. Therefore, it can be assumed that the intended uses of GLOB2013F represent low risk exposure to honeybees.

The chronic TERs for honey bee adults and larvae are higher than the EPPO 2010 trigger of 1 and below the EFSA 2013 triggers of 0.03 for adult and 0.2 for larvae chronic risk respectively, indicating that the proposed use according to the intended GAP of GLOB2013F poses an acceptable chronic risk to honey bee larvae and adults.

Review comments:

The evaluation has been performed in line with SANCO/10329/2002 rev 2 final. The risk assessment performed for zoxamide and the formulated product GLOB2013F is agreed by the zRMS.

All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern GLOB2013F.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): Applicant provided chronic test on bees and evaluation of effects on honey bee development with formulated product. Nevertheless, such studies were deemed not necessary to finalize the risk assessment.

Concerned Member States must decide on the consideration of EPPO 2010 approach since there is no harmonized approach for the chronic risk assessment for bees.

Concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on national level.

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

Effects on non-target arthropods of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	GLOB2013F	Mortality, LR ₅₀ Reproduction, ER ₅₀	LR ₅₀ > 2760 mL/ha ER ₅₀ > 2760 mL/ha	Leopold, J., 2022
<i>Aphidius rhopalosiphi</i>	GLOB2013F	Mortality, LR ₅₀ Reproduction, ER ₅₀	LR ₅₀ > 2760 mL/ha ER ₅₀ > 2760 mL/ha	Leopold, J., 2022
Field or semi-field tests				
-				

9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 (potato) also covers the risk for non-target arthropods from all other intended uses in groups 2, 3 (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of GLOB2013F in potato

Intended use	Potato		
Product	GLOB2013F		
Application rate (mL formulation/ha)	3 × 300		
MAF	2.3		
Test species Tier I	LR₅₀ (lab.) (mL formulation/ha)	PER_{in-field} (mL/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 2760	690	< 0.25
<i>Aphidius rhopalosiphi</i>	> 2760		< 0.25

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 (potato) also covers the risk for non-target arthropods from all other intended uses in groups 2, 3 (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of GLOB2013F in potato

Intended use	Potato				
Active substance/product	GLOB2013F				
Application rate (mL/ha)	3 × 300				
MAF	2.3				
vdf	5*				
Test species Tier I	LR₅₀ (lab.) (mL/ha)	Drift rate	PER_{off-field} (mL/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 2760	0.0277	3.8226	10	0.014
<i>Aphidius rhopalosiphi</i>	> 2760				0.014

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.

* A vdf of 5 was used in accordance with the proposal made in the EFSA Recurring Issues in Ecotoxicology (EFSA Supporting publication 2019: EN-1673).

Review comments

Risk assessment presented by the Applicant is considered acceptable since it is worst case. However, for PL vdf of 10 is used, thus zRMS also calculated the off-field exposure with this parameter. Concerned MS should decide of use of vdf 5 or 10 on the National Level.

Intended use	potato				
Product	GLOB2013F				
Application rate (mL formulation/ha)	3 x 300				
MAF	2.3				
vdf	10 (2D exposure)				
Test species	Tier I				
	LR₅₀ (lab.) [mL formulation/ha]	Drift rate (%)	PER_{off-field} [L/ha]	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 2760	0.0277	1.91	10	0.007
<i>Aphidius rhopalosiphi</i>	> 2760				0.007

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 risk for non-target arthropods is acceptable when using GLOB2013F according to the intended uses.

No risk mitigation measures are needed.

Review comments:

Acceptable risk for non-target arthropods for in-field and off-field habitats may be concluded with no need for risk mitigation measures.

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 zoxamide and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Table 9.8-1: 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>	zoxamide	Overspray 56 d, chronic Artificial soil**	NOEC = 1 mg/kg dw NOEC _{corr} = 0.5 mg/kg dw*	Nienstedt, K. (1999), RAR of zoxamide, Volume 3 CA B9****
<i>Eisenia fetida</i>	zoxamide	Mixed into substrate 56 d, chronic Natural soil***	NOEC = 7 mg/kg dw NOEC _{corr} = 3.5 mg/kg dw*	Nienstedt, K. M. (2001), RAR of zoxamide, Volume 3 CA B9****
<i>Eisenia fetida</i>	RH-141455	56d – artificial soil	NOEC = 5 mg/kg dw	EFSA Journal 2017;15(9):4980
<i>Eisenia andrei</i>	GLOB2013F	Mixed into substrate 56 d, chronic Artificial soil	NOEC ≥ 10 mg/kg dw NOEC _{corr} = 5 mg/kg dw*	Straube, D., 2022
<i>Eisenia andrei</i>	RH-127450	Mixed into substrate 56 d, chronic Artificial soil	NOEC = 13.9 mg/kg dw NOEC _{corr} = 6.95 mg/kg dw*	Straube, D., 2023
<i>Eisenia andrei</i>	RH-24549	Mixed into substrate 56 d, chronic Artificial soil	NOEC = 13.9 mg/kg dw NOEC _{corr} = 6.95 mg/kg dw*	Straube, D., 2023
<i>Eisenia andrei</i>	RH-163353	Mixed into substrate 56 d, chronic Artificial soil	NOEC ≥ 25 mg/kg dw	Straube, D., 2023
<i>Folsomia candida</i>	GLOB2013F	28 d, chronic Artificial soil	NOEC ≥ 1000 mg formulation/kg dw NOEC _{corr} = 500 mg formulation/kg dw* equivalent to NOEC ≥ 448 mg/kg a.i. dw NOEC _{corr} = 224 mg zoxamide/kg dw*	Straube, D., 2022
<i>Hypoaspis aculeifer</i>	GLOB2013F	14 d, chronic Artificial soil	NOEC ≥ 1000 mg formulation/kg dw NOEC _{corr} = 500 mg formulation/kg dw* equivalent to NOEC ≥ 448 mg/kg a.i. dw NOEC _{corr} = 224 mg zoxamide/kg dw*	Straube, D., 2022
Field studies				

Species	Substance	Exposure System	Results	Reference
-				
Litter bag test				
-				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (for substances with log Pow > 2).

** Study with artificial soil

*** Study with natural soil LUFA 2.2 as refinement

**** SANTE/10052/2018 Rev 2 (23 March 2018): The two studies available for assessing the chronic risk to earthworms were considered not valid by EFSA. However, the validity threshold for the “coefficient of variation in control” (30%) is not exceeded when results are compared to solvent controls rather than untreated controls. The studies can therefore be considered as valid. The type of soil used in the natural soil study is a recognised standard agricultural soil and represents a worst case due to its low carbon content: it is therefore appropriate to use this study to assess the chronic risk to earthworms from zoxamide.

9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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 assessment 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 zoxamide.

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 GLOB2013F in potato

Intended use	Potato		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{It} (criterion TER ≥ 5)
zoxamide	0.5	0.1481	3.376
zoxamide	3.5	0.1481	23.633
GLOB2013F	5	0.1815 0.1755	27.54 28.490
RH-127450	6.95	0.0219	317.352
RH-24549	6.95	0.0279	249.104
RH-163353	25	0.0291	859.107
RH-141455	5	0.0120	416.667

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 _{It} (criterion TER ≥ 5)
GLOB2013F	500	0.1815 0.1755	2754.82 2849.003
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 _{It} (criterion TER ≥ 5)
GLOB2013F	500	0.1815 0.1755	2754.82 2849.003

TER values shown in bold fall below the relevant trigger.

*Parent endpoint divided by 10

* Endpoint obtained with artificial soil

** Refined endpoint obtained with natural soil LUFA 2.2

Table 9.8-3: 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 GLOB2013F in grape

Intended use	Grape		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{It} (criterion TER ≥ 5)
zoxamide	0.5*	0.1452	3.444
zoxamide	3.5**	0.1452	24.105
GLOB2013F	5	0.22692	22.034
RH-127450	6.95	0.0206	337.379
RH-24549	6.95	0.0281	247.331
RH-163353	25	0.0252	992.063
RH-141455	5	0.0102	490.196
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 _{It} (criterion TER ≥ 5)
GLOB2013F	500	0.22692	2203.420
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 _{It} (criterion TER ≥ 5)
GLOB2013F	500	0.22692	2203.420

TER values shown in bold fall below the relevant trigger.

* Endpoint obtained with artificial soil

** Refined endpoint obtained with natural soil LUFA 2.2

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The TER values indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2013F.

Review comments:

Based on the provided Risk Assessment zRMS notes that the TER_{LT} for the chronic effects on earthworms for zoxamide were less than the trigger of 5 indicating that chronic risk is unacceptable. Since first-tier assessment of chronic risk for earthworms due to the use of GLOB2013F in potato and grape is considered unacceptable further refinement should be provided.

Based on weight of evidence The Applicant presented and follow the approach of Nienstedt, K. M. (2001) provided in the RAR of zoxamide, accepted by SANTE/10052/2018 Rev 2 (23 March 2018). Reproductive effects were seen in a 56-day laboratory study of chronic toxicity conducted with an artificial soil and TER values were below the trigger value of 5. However, TERs calculated using the NOEC of 7 mg/kg taken from a long-term study conducted in natural soil are above the trigger value.

The Applicant generated a study on the formulation (Straube, D., 2023) using artificial soil where the risk for the formulation is acceptable.

Additionally, GLOB2013F is not expected to cause any significant effects on soil microbial populations when applied at label recommended doses. On the basis of the study results, it was concluded that GLOB2013F at the concentrations corresponding to the PEC: 1.36 mg of the test item/kg dry weight of soil and 5xPEC: 6.81 mg of the test item/kg dry weight of soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils (please, refer to commenting table in point 9.9-1).

Taking in to consideration that DT_{50s} of zoxamide and metabolites which is < 60 days, field studies are not necessary. Maximum DT_{50s} from laboratory studies of zoxamide is 13.6 days it means that in the field predicted values would be even lower.

Taking in to consideration available data the risk to soil non-target macro-organisms is considered to be acceptable.

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 zoxamide and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on soil microorganisms of GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	zoxamide	42 d, aerobic	<25% effect at 2 mg a.s./kg soil	EFSA Journal 2017;15(9):4980
C-mineralisation	zoxamide	14 d, aerobic	<25% effect at 2 mg a.s./kg soil	EFSA Journal 2017;15(9):4980
N-mineralisation	RH-141455	28 d, aerobic	<25% effect at 0.2-1 mg/kg soil	EFSA Journal 2017;15(9):4980
N-mineralisation	GLOB2013F	84 d, aerobic	<25% effect at 1.36-6.81 mg test item/kg soil dw, equivalent to 0.61-3.05 mg zoxamide/kg soil dw	Hammesfahr, U., 2022
N-mineralisation	RH-127450		<25% effect at 0.2 mg met./kg soil dw	Parent endpoint divided by 10
N-mineralisation	RH-24549		<25% effect at 0.2 mg met./kg soil dw	Parent endpoint divided by 10
N-mineralisation	RH-163353		<25% effect at 0.2 mg met./kg soil dw	Parent endpoint divided by 10

9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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 GLOB2013F in potato

Intended use	Potato		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
zoxamide	2 (at 48 d)	0.1481	Yes
zoxamide	3.05 (at 84 d)	0.1481	Yes

GLOB2013F	6.81 (at 84 d)	0.1815 0.1755	Yes
RH-127450	0.2	0.0219	Yes
RH-24549	0.2	0.0279	Yes
RH-163353	0.2	0.0291	Yes
RH-141455	1 (at 28d)	0.0120	Yes

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2013F in grape

Intended use	Grape		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
zoxamide	2 (at 48 d)	0.1452	Yes
zoxamide	3.05 (at 84 d)	0.1452	Yes
GLOB2013F	6.81 (at 84 d)	0.22692	Yes
RH-127450	0.2	0.0206	Yes
RH-24549	0.2	0.0281	Yes
RH-163353	0.2	0.0252	Yes
RH-141455	1 (at 28d)	0.0102	Yes

9.9.3 Overall conclusions

The EU review for zoxamide and the test on the formulation show that there are no effects on soil microbial activity at dose rates far higher than the corresponding PEC_{soil} of the intended use. Therefore, it is concluded that there is no unacceptable risk on soil microbial activity for GLOB2013F.

Review comments:

The risk assessment for soil micro-organisms exposed to GLOB2013F following the proposed uses of the formulation, was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002).

The risk assessment presented in Table 9.9-2 and 9.9-3 is agreed by the zRMS. The relevant PEC_{soil} for risk assessments is taken from Section 8 (Environmental Fate), for details please, refer to Section 8.

Based on the obtained results, soil nitrate formation rates were below the 25% trigger value. Thus, it is concluded that GLOB2013F had no significant impact on soil microorganisms when applied at test item concentrations up to 6.81 mg formulation/kg soil dry weight.

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 zoxamide 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 GLOB2013F were not evaluated as part of the EU assessment of zoxamide. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Vegetative vigour and seedling emergence studies have been conducted with GLOB2013F. New data submitted with this application are summarized in Appendix 2 - Effects on terrestrial non-target higher plants.

An overview of the endpoints and effects values of the formulation GLOB2013F is provided in Table 9.10-1 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>Avena sativa</i> (oats) _m <i>Allium cepa</i> (onion) _m <i>Zea mays</i> (corn) _m <i>Lolium perenne</i> (ryegrass) _m <i>Beta vulgaris</i> (sugar beet) _d <i>Helianthus annuus</i> (sunflower) _d <i>Glycine max</i> (soybean) _d <i>Solanum lycopersicum</i> (tomato) _d <i>Brassica napus</i> (oilseed rape) _d <i>Cucumis sativus</i> (cucumber) _d	GLOB2013F	21 d Seedling emergence	ER ₅₀ emergence > 1.2 L/ha ER ₅₀ percentage survival > 1.2 L/ha ER ₅₀ shoot fresh weight > 1.2 L/ha ER ₅₀ visual injury > 1.2 L/ha	Stead, A., 2023, STC/22/E1558
<i>Avena sativa</i> (oats) _m <i>Allium cepa</i> (onion) _m <i>Zea mays</i> (corn) _m <i>Lolium perenne</i> (ryegrass) _m <i>Beta vulgaris</i> (sugar beet) _d <i>Helianthus annuus</i> (sunflower) _d <i>Glycine max</i> (soybean) _d <i>Solanum lycopersicum</i> (tomato) _d <i>Brassica napus</i> (oilseed rape) _d <i>Cucumis sativus</i> (cucumber) _d	GLOB2013F	21 d Vegetative vigour	ER ₅₀ visual injury > 1.2 L/ha ER ₅₀ plant survival > 1.2 L/ha ER ₅₀ shoot fresh weight > 1.2 L/ha	Davies, C., 2023, STC/22/E1557

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation from 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”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is derived by the *BBA (2000)*² from the spray-drift predictions of *Ganzelmeier & Rautmann (2000)*³ as recommended by the “Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC, SANCO/10329/2002.

Consequently, the initial exposure assessment was based on air deposition following the application of GLOB2013F to areas adjacent to the field without and (if appropriate) with consideration of drift mitigation measures. Predicted exposure rates were calculated with the following formula:

$$PER_{\text{off-field}} = (\text{Appl. rate} \times \text{Spray drift})$$

where PER = Predicted Environmental Rate (kg/ha or L/ha)

Appl. rate = rate of a single application expressed in the same units as the PER

Spray drift = % of the applied rate deposited to the off-field area by spray drift

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 (grape) also covers the risk for non-target terrestrial plants from all other intended uses in groups 1 and 2 (see 9.1.2).

Table 9.10-2a: Assessment of the risk for non-target plants due to the use of GLOB2013F in grape (early application)

Intended use	Grape			
Active substance/product	GLOB2013F			
Application rate (L/ha)	0.3 L formulation/ ha 0.166			
Test species	ER₅₀ (L formulation/ha)	Drift rate	PER_{off-field} (L/ha)	TER criterion: TER ≥ 5
<i>Avena sativa</i> (oats) _m <i>Allium cepa</i> (onion) _m <i>Zea mays</i> (corn) _m <i>Lolium perenne</i> (ryegrass) _m <i>Beta vulgaris</i> (sugar beet) _d <i>Helianthus annuus</i> (sunflower) _d <i>Glycine max</i> (soybean) _d <i>Solanum lycopersicum</i> (tomato) _d <i>Brassica napus</i> (oilseed rape) _d <i>Cucumis sativus</i> (cucumber) _d	1.2	2.70 % 2.77%	0.0081 0.00046	148.15 2608.7

m: monocotyledonous; d: dicotyledonous

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

² BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

³ Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

Table 9.10-3b: Assessment of the risk for non-target plants due to the use of GLOB2013F in grape (late application)

Intended use	Grape			
Active substance/product	GLOB2013F			
Application rate (L/ha)	0.368 L formulation/ ha			
Test species	ER₅₀ (L formulation/ha)	Drift rate	PER_{off-field} (L/ha)	TER criterion: TER ≥ 5
<i>Avena sativa</i> (oats) _m <i>Allium cepa</i> (onion) _m <i>Zea mays</i> (corn) _m <i>Lolium perenne</i> (ryegrass) _m <i>Beta vulgaris</i> (sugar beet) _d <i>Helianthus annuus</i> (sunflower) _d <i>Glycine max</i> (soybean) _d <i>Solanum lycopersicum</i> (tomato) _d <i>Brassica napus</i> (oilseed rape) _d <i>Cucumis sativus</i> (cucumber) _d	1.2	8.02 %	0.029	41.38

m: monocotyledonous; d: dicotyledonous

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

Table 9.10-3: Assessment of the risk for non-target plants due to the use of GLOB2013F in potato

Intended use	Potato			
Product	GLOB2013F			
Application rate (L formulation/ha)	0.3 L formulation/ha			
Test species	ER₅₀ (formulation L/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Avena sativa</i> (oats) _m <i>Allium cepa</i> (onion) _m <i>Zea mays</i> (corn) _m <i>Lolium perenne</i> (ryegrass) _m <i>Beta vulgaris</i> (sugar beet) _d <i>Helianthus annuus</i> (sunflower) _d <i>Glycine max</i> (soybean) _d <i>Solanum lycopersicum</i> (tomato) _d <i>Brassica napus</i> (oilseed rape) _d <i>Cucumis sativus</i> (cucumber) _d	1.2	2.77%	0.0081	148.15

m: monocotyledonous; d: dicotyledonous

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

First tier risk assessment indicates that there is no unacceptable risk from GLOB2013F for non-target plants when applied according to the proposed use rates.

Review comments:

Risk assessment performed by the Applicant for non-target terrestrial plants was updated and accepted. Based on the predicted rates of GLOB2013F in off-field areas, the TER values describing the risk for non-target plants following exposure to formulation according to the GAP achieve the acceptability criteria $TER \geq 5$. No risk mitigation measures are needed.

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

Tests on other non-target species are not required.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

Implications for labelling resulting from ecotoxicological assessment (justification is provided in Part C):

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 9.13-1: Justified proposals for classification and labelling for GLOB2013F according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Aquatic Acute 1 Aquatic Chronic 1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS09
Signal word	Warning
Hazard statement(s)	H400 H410
Precautionary statement(s)	P273 P391 P501
Additional labelling phrases	<p>To avoid risks to man and the environment, comply with the instructions for use. [EUH401]</p> <p>For the countries that accept the EU agreed endpoints (see part B8) and for the countries that do not accept the EU agreed endpoints but where R3 is not relevant:</p> <p>SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.</p> <p><i>OR in case VFSSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.</i></p> <p>SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.</p> <p><i>OR in case VFSSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.</i></p> <p>SPe3: For grape use (late applications), to protect aquatic organisms use 75% drift reducing nozzles and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.</p> <p><i>OR in case VFSSMOD is accepted: Alternatively, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.</i></p> <p>For the countries that do not accept the EU agreed endpoints and where R3 is relevant:</p> <p>SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 15 m including a 15 m vegetated filter strip to surface water bodies. Alternatively, apply up to 0.29L/ha and respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.</p> <p><i>OR in case VFSSMOD is accepted: a 5 m no spray buffer zone including a 5 m vegetated filter strip.</i></p> <p>SPe3: For grape use (early applications), to protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip to surface water bodies.</p> <p><i>OR in case VFSSMOD is accepted: Alternatively, use 50% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip.</i></p> <p>For grape, for Poland specific scenarios:</p> <p>SPe3: For grape use (early applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5</p>

	<p>m vegetated filter strip to surface water bodies (according to VFSmode).</p> <p>Alternatively, or respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.</p> <p>SPE3: For grape use (late applications), to protect aquatic organisms, use 90% drift reducing nozzles and respect a 5 m no spray buffer zone including a 5 m vegetated filter strip to surface water bodies.</p> <p>or</p> <p>respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 75% drift reducing nozzles to surface water bodies.</p> <p>Alternatively, or respect an unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.</p>
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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1	Wilkins, S.	2023	GLOB2013F: <i>Daphnia magna</i> Acute Immobilisation Test, Fera Science Ltd, Report No.: FR/002721, GLP, Unpublished	N	Globachem NV
KCP 10.2.1	Wright, E.	2023	GLOB2013F: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002720, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.1	Przychodzka, A.	2021	Honeybees, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 213, Sorbolab Research Laboratory Llc, Report No.: 0064/0009/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.1	Konieczna, A.	2021	Bumblebee, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD 247 Guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0016/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.1	Przychodzka, A.	2021	Honeybees, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 214, Sorbolab Research Laboratory Llc, Report No.: 0064/0010/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.1	Konieczna, A.	2021	Bumblebee, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD 246 guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0013/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.2	Konieczna, A.	2021	Honey Bee, chronic oral toxicity test of the test item Zoxamide 450 SC according to OECD 245 Guideline, Sorbolab Research Laboratory Llc, Report No.: 0064/0015/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.1.3	Konieczna, A.	2021	Honey Bee Larval Toxicity Test following Repeated Exposure to the test item Zoxamide 450 SC according to OECD GD 239 ENV/JM/MONO(2016)34, Sorbolab Research Laboratory Llc, Report No.: 0064/0012/E, GLP, Unpublished	N	Globachem NV
KCP 10.3.2.1	Leopold, J.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates, Ibacon GmbH, Report No.: 169571063, GLP, Unpublished	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.1	Leopold, J.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates, Ibacon Gmbh, Report No.: 169571001, GLP, Unpublished	N	Globachem NV
KCP 10.4.1.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169571022, GLP, Unpublished	N	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil, Ibacon Gmbh, Report No.: 169571089, GLP, Unpublished	N	Globachem NV
KCP 10.4.2.1	Straube, D.	2022	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil, Ibacon Gmbh, Report No.: 169571016, GLP, Unpublished	N	Globachem NV
KCP 10.5	Hammesfahr, U.	2022	GLOB2013F: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Ibacon Gmbh, Report No.: 169571080, GLP, Unpublished	N	Globachem NV
KCP 10.6.2	Dewson, S.	2023	GLOB2013F: OECD Terrestrial Plant Test - Vegetative Vigour Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1557, GLP, Unpublished	N	Globachem NV
KCP 10.6.2	Stead, A.	2023	GLOB2013F: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1558, GLP, Unpublished	N	Globachem NV
KCA 8.2.1	xxxxxxx	2020	RH-163353: Fish, acute toxicity test - Amended final report 1,xxxxxxx, Report No.: 3202385, GLP, Unpublished	Y	Gowan*
KCA 8.2.1	xxxxxxx	2020	RH-141455: Fish, acute toxicity test, xxxxxx, Report No.: 3202716, GLP, Unpublished	Y	Gowan*
KCA 8.2.1	xxxxxxx	2020	RH-127450: Fish, acute toxicity test, xxxxxx, Report No.: 3202373, GLP, Unpublished	Y	Gowan*
KCA 8.2.4.2	Mikulas, J.	2023	RH-139432 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25769-22, GLP, Unpublished	N	Globachem NV
KCA 8.2.4.2	Doig, A.	2023	RH-24549 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25772-22, GLP, Unpublished	N	Globachem NV
KCA 8.2.4.2	Mikulas, J.	2023	RH-127450 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25833-22, GLP, Unpublished	N	Globachem NV

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
KCA 8.2.4.2	Mikulas, J.	2023	RH-141455 Mysid Shrimp (<i>Mysidopsis bahia</i>) 96-Hour Acute Toxicity Test, Stillmeadow Inc, Report No.: 25771-22, GLP, Unpublished	N	Globachem NV
KCA 8.2.4.2	Shaw, A.	2023	RH-163353 - Acute Toxicity to Mysids (<i>Americamysis bahia</i>) Under Static Conditions, Smithers Ers Ltd, Report No.: 14365.6102, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Jarratt, N.	2023	Zoxamide Technical: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Fera Science Ltd, Report No.: FR/002786, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Softcheck, K.	2023	RH-163353 - 72-Hour Toxicity Test with the Freshwater Green Alga, <i>Raphidocelis subcapitata</i> , Smithers Ers Ltd, Report No.: 14365.6101, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Mikulas, J.	2023	RH-139432 72-Hour Algal Inhibition Test with <i>Pseudokirchneriella subcapitata</i> , Stillmeadow Inc, Report No.: 25770-22, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Mikulas, J.	2023	RH-127450 72-Hour Algal Inhibition Test with <i>Pseudokirchneriella subcapitata</i> , Stillmeadow Inc, Report No.: 25834-22, GLP, Unpublished	N	Globachem NV
KCA 8.3.1.3	Aguilar-Alberola, J.	2023	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Eurofins Trialcamp S.L.U., Report No.: S23-106642, GLP, Unpublished	N	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-24549: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 166191022, GLP, Unpublished	N	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-127450: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 175161022, GLP, Unpublished	N	Globachem NV
KCA 8.4.1	Straube, D.	2023	RH-163353: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 175171022, GLP, Unpublished	N	Globachem NV

*Vertebrate data access is currently negotiated with the Notifier. The negotiation e-mail exchange was already sent to all MSs with the data matching package.

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

*Studies in the table below were generated to data match the AIR protected studies from the main notifier. The data matching package has been evaluated at EU level by the RMS Latvia and a copy was already sent to all MS.

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
KCA 8.2.4.1	Siche, O.	2022	RH-24549: Acute Toxicity to <i>Daphnia magna</i> in a Static 48-hour Immobilisation Test, Ibacon Gmbh, Report No.: 166191220, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Siche, O.	2023	(R)-Zoxamide: Toxicity to <i>Desmodesmus subspicatus</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 168331210, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Siche, O.	2023	(S)-Zoxamide: Toxicity to <i>Desmodesmus subspicatus</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 168321210, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Siche, O.	2022	Algae Growth Inhibition Study Green Algae (<i>Desmodesmus subspicatus</i>), Ibacon Gmbh, Report No.: 166191210, GLP, Unpublished	N	Globachem NV
KCA 8.2.6.1	Siche, O.	2022	RH-141455: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test, Ibacon Gmbh, Report No.: 166221210, GLP, Unpublished	N	Globachem NV
KCA 8.4.1	Straube, D.	2022	RH-141455: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Ibacon Gmbh, Report No.: 166221022, GLP, Unpublished	N	Globachem NV
KCA 8.5	Bauer, J.	2022	RH-141455: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Ibacon Gmbh, Report No.: 166221080, GLP, Unpublished	N	Globachem NV

List of data submitted by the applicant and not relied on

KCA 8.3.1.3	Aguilar-Alberola, J.	2023	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Eurofins Trialcamp S.L.U., Report No.: S23-106642, GLP, Unpublished	N	Globachem NV
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Appendix 2 Detailed evaluation of the new studies

Review Comment:

In order to provide sufficient detail, where appropriate, the following studies summaries have been adapted by the zRMS. Details were taken directly from the full studies reports provided in the dossier. zRMS text is highlighted in grey. The comments on individual studies are provided in grey comment boxes.

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

Summarised in Section 6 (Mammalian Toxicology)

A 2.1.1 KCP 10.1.1 Effects on birds

No data submitted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No data submitted.

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

No data submitted.

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 Aquatic invertebrates

Comments of zRMS:	<p>The study was conducted to OECD guideline 202 and according to the principles of GLP. No deviations were noted in the study. However, measured values should be provided in the study for the formulated product.</p> <p>In the definitive test the validity criteria were met as follows:</p> <ul style="list-style-type: none"> - The immobilization of <i>Daphnia magna</i> in the control was 0 % (criterion: not more than 10%), - The dissolved oxygen concentrations in the test vessels were within the range of 8.18– 8.49 mg/L (criterion: not less than 3 mg/L). <p>The analytical measurements demonstrated that the test item concentrations throughout the test was outside the range of 80-120% of nominal and for this reason endpoints are expressed as mean measured concentrations. The study is reliable and suitable for the risk assessment.</p> <p>EC₅₀/48 h is > 1.99 mg a.s/L</p>
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	NOEC/48 h value is 1.99 mg a.s/L
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Reference:	KCP 10.2.1
Report	GLOB2013F: <i>Daphnia magna</i> Acute Immobilisation Test, Wilkins, S., 2023, Fera Science Limited, Report No.: FR/002721
Guideline(s):	OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

<i>Test Item:</i>	GLOB2013F
<i>Test Species:</i>	<i>Daphnia magna</i> (Agrochemex Clone 5), an aquatic Cladoceran
<i>Source:</i>	CCSS (Centre for Chemical Stewardship and Safety), Fera
<i>Test Media:</i>	Elendt M4 medium
<i>Test System:</i>	<i>Daphnia magna</i> were exposed to a test concentration series of the test item diluted with Elendt M4 medium, compared with a negative control group (M4 medium only). The test was performed under semi-static conditions with renewal of the test media after 24 hours.
<i>Test Item Concentrations:</i>	Nominal concentrations of GLOB2013F were 0.49, 0.99, 1.97, 3.94, and 7.88 mg formulation/L with a negative control of untreated test media.
<i>Replicates:</i>	There were four replicates per treatment. Five test organisms were added to each treatment replicate.
<i>Observations:</i>	Immobility – Neonates that were unable to swim within 15 seconds after gentle agitation of the test vessel were recorded as immobile, even where the antennae were still moving.
<i>Test Endpoints:</i>	The test endpoint was the proportion of immobile and mobile test organisms at 24 hours (± 1 Hr) and 48 hours (± 2 Hr) after the start of the exposure.

Results and discussions

All samples were analysed by High Performance Liquid Chromatography with Diode Array Detection (HPLC-DAD). Triplicate samples were analysed from fresh media at the start of each 24-h renewal period (0 and 24-h) and from pooled replicate media at the end of each (24 and 48-h); a summary of the results are presented in **Table 1** below.

As the test item, GLOB2013F, is a formulation; and mixture of an active ingredient (zoxamide) and co-formulants, which was tested as a whole substance, results are reported using nominal concentrations of the test item (formulation). Values are also reported in terms of active substance (a.s.) based on mean analysed content.

Table 1: Summary of analytical measurement results of zoxamide in the test solutions

Nominal concentration of GLOB2013F (mg/L)	Nominal concentration of Zoxamide (mg/L) ^a	Mean measured concentration of Zoxamide (mg/L)				Geometric mean measured concentration of Zoxamide (mg/L)
		0-h (Fresh)	24-h (Aged)	24-h (Fresh)	48-h (Aged)	
Control	n/a	<30% of LOQ	<30% of LOQ	<30% of LOQ	<30% of LOQ	n/a
0.49	0.194	0.1875	0.1759	0.1936	0.1923	0.1872
0.99	0.389	0.3754	0.3339	0.3797	0.3412	0.3570
1.97	0.778	0.7286	0.5189	0.5469	0.5570	0.5826
3.94	1.56	1.505	0.9648	1.2931	1.0038	1.172
7.88	3.11	2.498	1.792	1.833	1.920	1.992

n/a = not applicable; LOQ = limit of quantification = 0.02 mg zoxamide/L

^a based on analysed content in COA provided by Sponsor.

No immobile daphnia were observed the negative control or GLOB2013F and only a single immobilised daphnia was observed at the 48-hr observation in the highest exposure rate.

No statistical analysis was performed due to lack of any observed dose related immobilization within any of the treatment groups at 24 or 48 hours. The EC₅₀ and NOEC are therefore defined as greater than the highest concentration tested.

Conclusion

On the basis of this test, it can be concluded that GLOB2013F is not acutely toxic to *Daphnia magna* exposed to between 0.49 and 7.88 mg formulation/L in a semi-static test. The EC₅₀ is determined to be greater than 7.88 mg formulation/L, the NOEC is also 7.88 mg formulation/L.

The EC₅₀ for immobilization was greater than 1.99 mg a.s. /L based on geomean dose rates calculated from mean measured concentration, and a NOEC of 1.99 mg a.s. /L.

The results for the active ingredient agree with the data provided by the Sponsor from the scientific literature.

EFSA (2017) requested in its Peer Review Conclusion; “Further data or refinement on aquatic invertebrates (*Mysidopsis bahia*) are needed to cover the risk for the metabolites RH-127450, RH-24549, RH-163353, RH-141455 and RH-139432. The Applicant provided the studies for mentioned metabolites.

Comments of zRMS:	The study on the mysid was conducted following the guideline OCSPP 850.1035 (2016), under GLP certification for RH-163353.		
	Validity criteria were met as follows:		
	Acceptability Criteria	Study Results	Criterion Met (Yes/No)
	Exposure vessels will be identical.	Exposure vessels were identical	yes
	Treatments will be indiscriminately assigned to individual exposure vessel locations and individual test organisms will be indiscriminately assigned to exposure vessels.	Treatments were indiscriminately assigned to individual exposure vessel locations and individual test organisms were indiscriminately assigned to each exposure vessel	yes
	A dilution water control, and solvent control, if necessary, will be included in the test	A dilution water control was included. No solvent was used during this exposure	yes
	No more than 10% of organisms in the control, or solvent control, if applicable, can show signs of disease, stress (e.g., discoloration, unusual behavior, immobilization), and/or death.	Mortality of 5% was observed in the control; no adverse effects were observed among control organisms	yes
	A surfactant or dispersant was not used in preparation of a stock or exposure solution	Neither a surfactant nor dispersant was used during preparation of solutions for this study	yes
	The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. All results refer to nominal concentrations.		

Reference: KCA 8.2.4.2
Report RH-163353 - Acute Toxicity to Mysids (*Americamysis bahia*) Under Static Conditions, Shaw, A., 2023, Smithers Ers Ltd, Report No.: 14365.6102
Guideline(s): OCSPP 850.1035
Deviations: No
GLP: Yes
Acceptability: **Yes** / No / Supplementary

Materials and methods

The purpose of this study was to estimate the 96-hour acute toxicity (LC_{50}) of RH-163353 to mysids (*Americamysis bahia*) under static conditions. The LC_{50} is defined as the concentration of the test substance in dilution water which causes mortality of 50% in the exposed test population after a fixed period of time. This value is often used as a relative indicator of potential acute hazards resulting from release of the test substance into aquatic environments. Results of this study are presented based on nominal concentrations of RH-163353.

Test Substance	
Name:	RH-163353
Synonym:	3-(3,5-dichloro-4-methylbenzamido)-3-methyl-2-oxopentanoic acid (RH-163353)
Batch No.:	GD-003454-03
CAS No.:	401520-47-6
Purity:	100%
Storage Conditions:	Stored at room temperature in a dark, ventilated cabinet in the original container
Expiry Date:	9 March 2024
Date Received:	16 March 2023
Received From:	Globachem Discovery Ltd., Macclesfield, United Kingdom
Test Concentrations	
Nominal Concentrations:	1.0, 2.3, 5.0, 11, and 24 mg/L
Mean Measured Concentrations:	0.99, 2.1, 4.7, 10, and 24 mg/L
Co-Solvent:	None
Co-Solvent Load:	Not applicable
Interval(s) of Analytical Verification:	0 and 96 hours

Results and discussions/Conclusion

The biological endpoint results are based on nominal concentrations. The nominal concentrations tested, the corresponding cumulative percent and number of mortalities, and the observations made during the definitive exposure are presented in Table 3.

Table 3. 96-Hour Static Exposure of Mysids (*Americamysis bahia*) to RH-163353 - Nominal Concentrations Tested, Corresponding Cumulative Percent and Number of Mortalities, and Observations

Nominal Concentration (mg/L)	Number of mysids added	Cumulative Percent Mortality ^a							
		24 Hour		48 Hour		72 Hour		96 Hour	
		Mortality	Sublethal	Mortality	Sublethal	Mortality	Sublethal	Mortality	Sublethal
Control	20	5 (1)	--	5 (1)	--	5 (1)	--	5 (1)	--
1.0	20	0 (0)	--	0 (0)	--	0 (0)	--	0 (0)	--
2.3	20	0 (0)	--	0 (0)	--	0 (0)	--	0 (0)	--
5.0	20	5 (1)	--	5 (1)	--	5 (1)	--	5 (1)	--
11	20	10 (2)	--	10 (2)	--	10 (2)	--	10 (2)	--
24	20	15 (3)	--	15 (3)	--	15 (3)	--	15 (3)	--

^a The actual number of mortalities is presented in parentheses and any sublethal effects are presented below.
^b '--' = no sublethal effects were observed

Materials and methods

This study was conducted to assess the toxicity of the test item, RH-139432, to the mysid shrimp, *Mysidopsis bahia*, in a 96-hour test with daily renewals.

Test concentrations were determined by a preliminary range-finding test. The test item concentrations of 1.5625 mg/L, 3.125 mg/L, 6.25 mg/L, 12.5 mg/L, and 25 mg/L were administered to the test system, *Mysidopsis bahia*, in synthetic seawater with daily renewals. Three replicates of ten organisms were treated with each concentration of the test item. Each of the three control containers contained 10 organisms in synthetic seawater and no test item. Dissolved oxygen, temperature, salinity and pH measurements were recorded at dosing and daily through study termination. Observations for mortality were made at 0, 24, 48, 72 and 96 hours after treatment. The test was terminated after 96 ± 2 hours of exposure.

Analytical measurements

Table 2. 96-Hour Static Exposure of Mysids (*Americamysis bahia*) to RH-163353 - Concentrations Measured in the Exposure Solutions

Nominal Concentration (mg/L)	Measured Concentration (mg/L)			Percent of Nominal ^a
	0-Hour	96-Hour	Mean ^a	
Control	<0.10 ^b	<0.10	NA ^c	NA
1.0	0.99	0.99	0.99	99
2.3	2.1	2.2	2.1	93
5.0	4.5	4.9	4.7	94
11	8.7	12	10	92
24	24	25	24	100
QC ^d #1 0.500	0.500 (99.9)	0.427 (85.4)		
QC#2 5.00	4.31 (86.1)	4.28 (85.7)		
QC#3 25.0	25.8 (103)	24.8 (99.4)		

^a Mean measured concentration and percent of nominal values were calculated using the actual analytical (unrounded) results and not the rounded values presented in this table.

^b Concentrations expressed as less than values were below the limit of detection (LOD). The LOD is dependent upon the lowest concentration calibration standard and the dilution factor of the controls (i.e., 0.0000300 mg/L × 3330 = 0.10 mg/L).

^c NA = Not Applicable

^d QC = Quality Control sample. Percent recovery for each QC sample is presented in parentheses.

Results and discussions/Conclusion

At 48 hours, the No Observed Effect Concentration (NOEC) of RH-139432 was determined to be 12.5 mg/L (5.04 mg/L), the 48-hour Median Lethal Concentration (LC₅₀) was > 25 mg/L (> 9.3 mg/L), and the 48-hour Lowest Observed Effect Concentration (LOEC) was 25 mg/L (9.3 mg/L).
At 96 hours, the (NOEC) of RH-139432 was determined to be 12.5 mg/L (5.04 mg/L), the 96-hour (LC₅₀) was > 19.203 mg/L (> 7.343 mg/L) with 95% confidence limits of 15.889 - 25.914 mg/L (6.2379 mg/L - 9.6840 mg/L), and the 96-hour (LOEC) was 25 mg/L (9.3 mg/L).
Parenthetical values are dose verified concentrations.

Results Based on Nominal Concentrations:	
96-Hour LC ₅₀ Value:	>24 mg/L
No-Observed-Effect Concentration (NOEC):	24 mg/L
Highest Concentration Producing 0% Toxicant-Related Mortality:	2.3 mg/L
Lowest Concentration Producing 100% Mortality:	>24 mg/L
Rationale for No Further Testing:	Although an LC ₅₀ value was not achieved, per discussion with the Study Sponsor, there is no need to test at higher concentrations.

Comments of zRMS:	The study on the mysid was conducted following the guideline OCSP 850.1035 (2016), under GLP certification for RH-139432.		
	Validity criteria were met as follows:		
	Acceptability Criteria	Study Results	Criterion Met (Yes/No)
	Exposure vessels will be identical.	Exposure vessels were identical	yes
	Treatments will be indiscriminately assigned to individual exposure vessel locations and individual test organisms will be indiscriminately assigned to exposure vessels.	Treatments were indiscriminately assigned to individual exposure vessel locations and individual test organisms were indiscriminately assigned to each exposure vessel	yes
	A dilution water control, and solvent control, if necessary, will be included in the test	A control solution was made using only dilution water	yes
	No more than 10% of organisms in the control, or solvent control, if applicable, can show signs of disease, stress (e.g., discoloration, unusual behavior, immobilization), and/or death.	Mortality of 3.33 % was observed in the control; no adverse effects were observed among control organisms	yes
	A surfactant or dispersant was not used in preparation of a stock or exposure solution	Neither a surfactant nor dispersant was used during preparation of solutions for this study	yes

Reference: KCA 8.2.4.2
Report RH-139432 Mysid Shrimp (*Mysidopsis bahia*) 96-Hour Acute Toxicity Test, Mikulas, J., 2023, Stillmeadow Inc, Report No.: 25769-22
Guideline(s): OCSP 850.1035

Deviations: No
GLP: Yes
Acceptability: Yes / No / Supplementary

TEST SYSTEM

Experimental Organism

Species: Mysid Shrimp, *Mysidopsis bahia*
Justification of Species: Specified in the regulatory guidelines
Source: Culture lab at STILLMEADOW, Inc.
Age: Juvenile (DOB: 31 Jul 23)
Quantity: 3 replicates of 10 organisms per test concentration and control

Organism Husbandry

Test Room: Environmentally controlled chamber B
Test Chambers: 600 mL glass beakers; filled with 400 mL of the appropriate solution
Test Medium: Synthetic seawater with a salinity of 22 ppt and a pH of 8.0
Loading: <30 mysids per liter
Acclimation: All organisms were held in water of the quality that was used in the test prior to testing. Changes in the water did not exceed 1°C and changes in the salinity did not exceed 5%. Background colors and light intensities were similar to those of the testing area.

Environmental Controls

Set to Maintain: Temperature Range of $25 \pm 2^{\circ}\text{C}$
14-hours light/10-hours dark cycle
Dissolved oxygen (DO) concentration of $\geq 60\%$ saturation
Actual Temperature: 23 - 25 °C
Actual DO: 68 - 99 %
Food: Mysids were fed daily with two drops of newly hatched *Artemia* nauplii *ad libitum*.

Animal husbandry and housing at STILLMEADOW, Inc. comply with standards outlined in the “Guide for the Care and Use of Laboratory Animals” (NRC Publication). No contaminants were expected to have been present in the feed or water that would have interfered with or affected the results of the study.

Aim

The objective of this study was to assess the toxicity of the test item, RH-139432, to *Mysidopsis bahia* in a 96-hour test with daily renewals.

Results

Definitive Test A 3.33% mortality was observed in control mysid and mysid treated with 1.5625 mg/L

and 6.25 mg/L of the test item. A mortality of 0.00% was observed in mysid treated with 3.125 mg/L of the test item. A mortality of 10.00% was observed in mysid treated with 12.5 mg/L and a mortality of 86.67% was observed in mysid treated with 25 mg/L of the test item. Observable abnormalities, besides mortality, included no bodies found, one mysid found on the bottom twitching and another twitching when prodded in the group treated with 25 mg/L while others were seen not swimming normally and seemed lethargic, and mysids in all groups treated with the test item appeared to not grow at the same rate as the control. Results presented are based on nominal concentrations and are presented in the following table.

Table 3 - Definitive Tests Mortality Results

Nominal Conc. (mg/L)	Replicate	Number of Surviving Organisms					Mortality
		0 Hours	24 Hours	48 Hours	72 Hours	96 Hours	
Control	A	10	10	10	10	10	3.33%
	B	10	9 ^A	9	9	9	
	C	10	10	10	10	10	
1.5625	A	10	10	9 ^C	9	9 ^F	3.33%
	B	10	10	10	10	10 ^F	
	C	10	10	10	10	10 ^F	
3.125	A	10	10	10	10	10 ^F	0.00%
	B	10	10	10	10	10 ^F	
	C	10	10	10	10	10 ^F	
6.25	A	10	10	10	10	10 ^F	3.33%
	B	10	10	10	10	10 ^F	
	C	10	10	10	9 ^A	9 ^F	
12.5	A	10	10	10	10	10 ^F	10.00%
	B	10	10	9 ^C	8 ^A	8 ^F	
	C	10	10	10	9 ^A	9 ^F	
25	A	10	10 ^B	8 ^D	6 ^E	4 ^G	86.67%
	B	10	10 ^B	9 ^D	5 ^E	0 ^G	
	C	10	10 ^B	5 ^D	0 ^E	-	

Note: All organisms had no observable abnormalities (NOA) unless otherwise indicated.

(-) - Not Applicable, all organisms dead; Conc. - Concentration

^A - One mysid missing; Rest NOA; Water NOA.

^B - Shrimp not swimming normal; Most moving lethargically; Water NOA

^C - One mysid dead; Other replicates NOA; Water NOA.

^D - Two mysid dead in replicate A; 5 dead in replicate C; Mysid lethargic and twitching on bottom; Water NOA.

^E - Two mysid dead in replicate A; 4 dead in replicate B, 1 twitching when prodded; 5 dead in replicate C; Surviving organisms swimming lethargically.

^F - Organisms appear not to have grown at same rate as control; Water NOA.

^G - Two mysid dead in replicate A; 5 dead in replicate B; Organisms appear not to have grown at same rate as control; Water NOA.

CONCLUSION

This study was conducted to assess the toxicity of the test item, RH-139432, to the mysid shrimp, *Mysidopsis bahia*, in a 96-hour test with daily renewals. A 3.33% mortality was observed in control mysid and mysid treated with 1.5625 mg/L and 6.25 mg/L of the test item. A mortality of 0.00% was observed in mysid treated with 3.125 mg/L of the test item. A mortality of 10.00% was observed in mysid treated with 12.5 mg/L and a mortality of 86.67% was observed in mysid treated with 25 mg/L of the test item. Observable abnormalities, besides mortality, included no bodies found, one mysid found on the bottom twitching and another twitching when prodded in the group treated with 25 mg/L while others were seen not swimming normally and seemed lethargic, and mysids in all groups treated with the test item appeared to not grow at the same rate as the control. At 48 hours, the No Observed Effect Concentration (NOEC) of RH-139432 was determined to be 12.5 mg/L (5.04 mg/L), the 48-hour Median Lethal Concentration (LC₅₀) was > 25 mg/L (> 9.3 mg/L), and the 48-hour Lowest Observed Effect Concentration (LOEC) was 25 mg/L (9.3 mg/L). At 96 hours, the (NOEC) of RH-139432 was determined to be 12.5 mg/L (5.04 mg/L), the 96-hour (LC₅₀) was 19.203 mg/L (7.343 mg/L) with 95% confidence limits of 15.889 - 25.914 mg/L (6.2379 mg/L - 9.6840 mg/L), and the 96-hour (LOEC) was 25 mg/L (9.3 mg/L). Parenthetical values are dose verified concentrations.

Comments of zRMS:	The study on the mysid was conducted following the guideline OCSP 850.1035 (2016), under GLP certification for RH-24549.		
	Validity criteria were met as follows:		
	Acceptability Criteria	Study Results	Criterion Met (Yes/No)
	Exposure vessels will be identical.	Exposure vessels were identical	yes
	Treatments will be indiscriminately assigned to individual exposure vessel locations and individual test organisms will be indiscriminately assigned to exposure vessels.	Treatments were indiscriminately assigned to individual exposure vessel locations and individual test organisms were indiscriminately assigned to each exposure vessel	yes
	A dilution water control, and solvent control, if necessary, will be included in the test	A control solution was made using only dilution water	yes
	No more than 10% of organisms in the control, or solvent control, if applicable, can show signs of disease, stress (e.g., discoloration, unusual behavior, immobilization), and/or death.	Mortality of 10.0 % was observed in the control; no adverse effects were observed among control organisms	yes
	A surfactant or dispersant was not used in preparation of a stock or exposure solution	Neither a surfactant nor dispersant was used during preparation of solutions for this study	yes

Reference: KCA 8.2.4.2

Report RH-24549 Mysid Shrimp (*Mysidopsis bahia*) 96-Hour Acute Toxicity Test, Doig, A., 2023, Stillmeadow Inc, Report No.: 25772-22

Guideline(s): OCSP 850.1035

Deviations: No

GLP: Yes

Acceptability: **Yes** / ~~No~~ / ~~Supportive~~

Materials and methods

This study was conducted to assess the toxicity of the test item, RH-24549, to the mysid shrimp, *Mysidopsis bahia*, in a 96-hour test with daily renewals.

Test concentrations were determined by a preliminary range-finding test. The test item concentrations of 6.25 mg/L, 12.5 mg/L, 25.0 mg/L, 50.0 mg/L, and 100 mg/L were administered to the test system, *Mysidopsis bahia*, in synthetic seawater with daily renewals. Three replicates of ten organisms were treated with each concentration of the test item. Each of the three control containers contained 10 organisms in synthetic seawater and no test item. Dissolved oxygen, temperature, salinity and pH measurements were recorded at dosing and daily through study termination. Observations for mortality

were made at 0, 24, 48, 72 and 96 hours after treatment. The test was terminated after 96 ± 1 hours of exposure.

Results and discussions/Conclusion

Definitive Test

A mortality of 10.00% was observed in the control group with 3 organisms missing from replica C at 72 hours. A 0.00% mortality was observed in mysid treated with 6.25 mg/L of the test item. A mortality of 3.33%, 16.66%, 13.33%, and 63.33% was observed in mysid treated with 12.5 mg/L, 25 mg/L, 50 mg/L 100 mg/L of the test item, respectively. There were no observable abnormalities, besides mortality, in all groups treated with the test item and the control. Results presented are based on nominal concentrations and are presented in the following table.

Table 3 - Definitive Test and Mortality Results

Nominal Conc. (mg/L)	Replicate	Number of Surviving Organisms					Mortality
		0 Hours	24 Hours	48 Hours	72 Hours	96 Hours	
Control	A	10	10	10	10	10	10.00%
	B	10	10	10	10	10	
	C	10	10	10	7 ^F	7	
6.25	A	10	10	10	10	10	0.00%
	B	10	10	10	10	10	
	C	10	10	10	10	10	
12.5	A	10	10	10	10	10	3.33%
	B	10	10	10	9 ^G	9	
	C	10	10	10	10	10	
25	A	10	10	10	9 ^G	8 ^H	16.66%
	B	10	10	10	10	10	
	C	10	10	10	10	7 ^F	
50	A	10	10	10	9 ^G	6 ^F	13.33%
	B	10	10	10	10	10	
	C	10	10	10	10	10	
100	A	10 ^A	10 ^A	7 ^{DE}	6 ^{BE}	2 ^I	63.33%
	B	10 ^A	10 ^A	8 ^{CE}	5 ^{DE}	4 ^H	
	C	10 ^A	10 ^A	9 ^{BE}	6 ^{DE}	5 ^H	

Note: All organisms had no observable abnormalities (NOA) unless otherwise indicated; Conc. - Concentration

^A - Water clear with some undissolved test material on top.

^B - One organism dead on bottom.

^C - Two organisms dead on bottom.

^D - Three organisms dead on bottom.

^E - Water clear with some undissolved test material stuck on sides of beakers and floating on top.

^F - Three organisms missing.

^G - One organism missing.

^H - One organism dead.

^I - Four organisms dead.

At 48 hours, the No Observed Effect Concentration (NOEC) of RH-24549 was determined to be 50 mg/L (22.12 mg/L). The 48-hour Median Lethal Concentration (LC₅₀) was determined to be > 100 mg/L (> 39.84 mg/L) and the 48-hour Lowest Observed Effect Concentration (LOEC) was 100 mg/L (39.84 mg/L). At 96 hours, the NOEC of RH-24549 was determined to be 50 mg/L (22.12 mg/L). The 96-hour LC₅₀ was determined to be 88.506 mg/L (35.766 mg/L) and the 96-hour LOEC was 100 mg/L (39.84 mg/L). Parenthetical values are dose verified concentrations.

Comments of zRMS:	The study on the mysid was conducted following the guideline OCSPP 850.1035 (2016), under GLP certification for RH-127450.		
	Validity criteria were met as follows:		
	Acceptability Criteria	Study Results	Criterion Met (Yes/No)
	Exposure vessels will be identical.	There was only one vessel	Comparison not possible
	Treatments will be indiscriminately assigned to individual exposure vessel locations and individual test organisms will be indiscriminately assigned to exposure vessels.	There was only one treatment	Yes
	A dilution water control, and solvent control, if necessary, will be included in the test	A dilution water control was included. No solvent was used during this exposure	yes
	No more than 10% of organisms in the control, or solvent control, if applicable, can show signs of disease, stress (e.g., discoloration, unusual behavior, immobilization), and/or death.	Mortality of 6.67 % was observed in the control; no adverse effects were observed among control organisms	yes
	A surfactant or dispersant was not used in preparation of a stock or exposure solution	Neither a surfactant nor dispersant was used during preparation of solutions for this study	yes
Final results are based on measured concentrations. The study is considered acceptable. NOEC 0.364 mg RH-127450 /L LC ₅₀ > 0.364 mg RH-127450 /L			

Reference: KCA 8.2.4.2

Report RH-127450 Mysid Shrimp (*Mysidopsis bahia*) 96-Hour Acute Toxicity Test, Mikulas, J., 2023, Stillmeadow Inc, Report No.: 25833-22

Guideline(s): OCSPP 850.1035

Deviations: No

GLP: Yes

Acceptability: **Yes** /No / Supportive

Materials and methods

This study was conducted to assess the toxicity of the test item, RH-127450, to the mysid shrimp, *Mysidopsis bahia*, in a 96-hour test with daily renewals.

Test concentrations were determined by a preliminary range-finding test. The test item concentration of 1.0 mg/L was administered to the test system, *Mysidopsis bahia*, in synthetic seawater with daily renewals. Three replicates of ten organisms were treated with each concentration of the test item. Each of the three control containers contained 10 organisms in synthetic seawater and no test item. Dissolved oxygen, temperature, salinity and pH measurements were recorded at dosing and daily through study termination. Observations for mortality were made at 0, 24, 48, 72 and 96 hours after treatment. The test was terminated after 96 ± 2 hours of exposure.

Results and discussions/Conclusion

Limit Test A 6.67% mortality was observed in control mysid and 3.33% mortality was observed in mysid treated with 1.0 mg/L of the test item. There were no observable abnormalities, besides mortality, in either the control or treated group. Results are presented in the following table.

Table 2 - Limit Test Mortality Results

Nominal Conc. (mg/L)	Replicate	Number of Surviving Organisms					Mortality
		0 Hours	24 Hours	48 Hours	72 Hours	96 Hours	
Control	A	10	10	10	10	10	6.67%
	B	10	10	8 ^A	8	8	
	C	10	10	10	10	10	
1.0	A	10	10	10	10	10	3.33%
	B	10	10	10	10	10	
	C	10	10	9 ^B	9	9	

Note: All organisms had no observable abnormalities (NOA) unless otherwise indicated; Conc. - Concentration

^A – Two organisms missing; Rest NOA.

^B – One organism dead on bottom; Rest NOA.

Evaluation of Results

At 48 and 96 hours, the No Observed Effect Concentration (NOEC) of RH-127450 was determined to be 1.0 mg/L (0.364 mg/L). The Median Lethal Concentration (LC₅₀) and the Lowest Observed Effect Concentration (LOEC) were > 1.0 mg/L (> 0.364 mg/L). Parenthetical values are dose verified concentrations.

Comments of zRMS:	The study on the mysid was conducted following the guideline OCSP 850.1035 (2016), under GLP certification for RH-141455.		
	Validity criteria were met as follows:		
	Acceptability Criteria	Study Results	Criterion Met (Yes/No)
	Exposure vessels will be identical.	Exposure vessels were identical	yes
	Treatments will be indiscriminately assigned to individual exposure vessel locations and individual test organisms will be indiscriminately assigned to exposure vessels.	Treatments were indiscriminately assigned to individual exposure vessel locations and individual test organisms were indiscriminately assigned to each exposure vessel	yes
	A dilution water control, and solvent control, if necessary, will be included in the test	A control solution was made using only dilution water	yes
	No more than 10% of organisms in the control, or solvent control, if applicable, can show signs of disease, stress (e.g., discoloration, unusual behavior, immobilization), and/or death.	No mortality was observed in the control; no adverse effects were observed among control organisms	yes
	A surfactant or dispersant was not used in preparation of a stock or exposure solution	Neither a surfactant nor dispersant was used during preparation of solutions for this study	yes
The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. All results refer to nominal concentrations.			

Reference: KCA 8.2.4.2

Report RH-141455 Mysid Shrimp (*Mysidopsis bahia*) 96-Hour Acute Toxicity Test, Mikulas, J., 2023, Stillmeadow Inc, Report No.: 25771-22

Guideline(s): OCSP 850.1035

Deviations: No

GLP: Yes

Acceptability: **Yes** / No / Supportive

Materials and methods

This study was conducted to assess the toxicity of the test item, RH-141455, to the mysid shrimp, *Mysidopsis bahia*, in a 96-hour test with daily renewals.

Test concentrations were determined by a preliminary range-finding test. The test item concentrations of 6.25 mg/L, 12.5 mg/L, 25.0 mg/L, 50.0 mg/L, and 100 mg/L were administered to the test system, *Mysidopsis bahia*, in synthetic seawater with daily renewals. Three replicates of ten organisms were

treated with each concentration of the test item. Each of the three control containers contained 10 organisms in synthetic seawater and no test item. Dissolved oxygen, temperature, salinity and pH measurements were recorded at dosing and daily through study termination. Observations for mortality were made at 0, 24, 48, 72 and 96 hours after treatment. The test was terminated after 96 ± 2 hours of exposure.

Table 3 - Definitive Test Mortality Results

Nominal Conc. (mg/L)	Replicate	Number of Surviving Organisms					Mortality
		0 Hours	24 Hours	48 Hours	72 Hours	96 Hours	
Control	A	10	10	10	10 ^A	10 ^A	0.00%
	B	10	10	10	10 ^A	10 ^A	
	C	10	10	10	10 ^A	10 ^A	
6.25	A	10	10	10	10 ^A	10 ^A	0.00%
	B	10	10	10	10 ^A	10 ^A	
	C	10	10	10	10 ^A	10 ^A	
12.5	A	10	10	10	10 ^A	10 ^A	0.00%
	B	10	10	10	10 ^A	10 ^A	
	C	10	10	10	10 ^A	10 ^A	
25	A	10	10	10	10 ^A	10 ^A	0.00%
	B	10	10	10	10 ^A	10 ^A	
	C	10	10	10	10 ^A	10 ^A	
50	A	10	10	10	10 ^A	10 ^A	0.00%
	B	10	10	10	10 ^A	10 ^A	
	C	10	10	10	10 ^A	10 ^A	
100	A	10	9 ^B	9	10 ^A ^C	10 ^A	6.67%
	B	10	8 ^B	8	8 ^A	8 ^A	
	C	10	10 ^B	10	10 ^A	10 ^A	

Note: All organisms had no observable abnormalities (NOA) unless otherwise indicated.

^A - Organisms look bigger in size compared to Day 1; Water NOA.

^B - One organism missing from replicate A and B; One organism eaten in replicate B; Rest NOA.

^C - Missing organism in replicate A found.

Results and discussions/Conclusion

At 48 and 96 hours, the No Observed Effect Concentration (NOEC) of RH-141455 was determined to be 100 mg/L (100.9 mg/L), the Median Lethal Concentration (LC₅₀) and the Lowest Observed Effect Concentration (LOEC) was > 100 mg/L (> 100.9 mg/L).

Parenthetical values are dose verified concentrations.

A 2.2.1.2 Algae

Comments of zRMS:	<p>The study was conducted according to OECD guideline 201 and principles of GLP. No deviations were noted.</p> <p>Validity criteria were met:</p> <ul style="list-style-type: none"> - the biomass in the control increased by a factor of 239.0 (1.825/day) 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 (exposure initiation – exposure termination) in the control culture was 0.8 % (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 9.1 % (criterion: it must not exceed 35%). <p>The analytical measurements demonstrated that the test item concentrations throughout the test was outside the range 80-120% of nominal and for this reason endpoints are expressed as geometric mean measured concentrations of zoxamide.</p>
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Reference:	KCP 10.2.1
Report	GLOB2013F: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Wright, E., 2023, Fera Science Limited, Report No.: FR/002720
Guideline(s):	OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	GLOB2013F
Test Species:	<i>Pseudokirchneriella subcapitata</i>
Source and Strain:	CCAP (Culture Collection of Algae and Protozoa), Oban, Scotland. Strain CCAP 278/4
Test Media:	OECD medium (OECD Test Guideline 201, 2011, Annex 3)
Test System:	The test system is defined as a test vessel (glass conical flask) containing approximately 100 mL of test medium and the test organisms (algal cells). The flasks were closed with a gas permeable plug during incubation.
Test Item Concentrations:	Nominal concentrations of GLOB2013F were 31.25, 62.5, 125, 250 and 500 µg/L, with a negative control of untreated test media.

<i>Reference Item:</i>	The performance of the test system was assessed using 3,5-dichlorophenol (3,5-DCP) as the reference item treatment. Nominal test concentration of 3,5-DCP was 2 mg/L, prepared with acetone as a solvent carrier to increase solubility.
<i>Replicates:</i>	There were six replicate control vessels and three for each test item treatment. The positive control had four replicate vessels.
<i>Toxic Endpoints:</i>	Two endpoints were calculated, the growth rate and yield; these are expressed as per cent inhibition relative to the control.

Results and discussions

All samples were analysed by liquid chromatography with mass spectroscopy (LC-MS). Triplicate samples were analysed from fresh media at the start of the test and from pooled media from replicates at the end of the test; a summary of the results for the active substance (a.s.) zoxamide are presented in Table S1.

Mean measured concentrations at 0 and 72 hours indicated that zoxamide was not at the required concentration over the 72-hour exposure period (i.e. some results differed from expected by greater than 20%; the mean recoveries per treatment rate at each time point, ranged between 71 and 120% of expected). The change in analysed concentration between the two time points indicate that zoxamide was not stable in solution over the test period (the majority of dose rates changed by >-10% between 0 and 72 hours) The % RSDs were, apart from one dose rate at one time point, all <10%, demonstrating that the test item was homogenous in solution. Therefore, analysis is reported as geometric mean measured concentrations of zoxamide.

As the test item, GLOB2013F, is a mixture of the active ingredient, zoxamide, and co-formulants which was tested as a whole substance, nominal concentrations of the test item were also used for data analysis and reporting.

Table S1: Nominal formulation concentrations and nominal & measured a.s. concentrations:

Nominal Concentration of GLOB2013F (µg/L)	Nominal Concentration of Zoxamide (µg/L)	Geometric Mean Measured Concentration zoxamide (µg/L)	GLOB2013F calculated based on Geometric Mean Measured zoxamide (µg/L)
31.25	12.3	12.32	31.20
62.50	24.7	26.26	66.51
125.0	49.4	34.76	88.03
250.0	98.7	95.61	242.1
500.0	197	188.8	478.2

The results of the definitive bioassay after 72-h of exposure indicated inhibition of growth (in terms of both yield and growth rate) at all dose rates tested. It was therefore not possible to estimate a NOEC. However, it was possible to estimate EC_{10, 20 & 50} values with 95% confidence intervals.

Statistical analysis for both growth rate and yield at 72-h were performed, with significant differences observed for both endpoints ($p = <0.05$).

The results for nominal concentrations of GLOB2013F (whole formulation) are shown in the following Table.

Test statistics, showing EC_x values with 95% Lower and Upper Confidence Limits based on nominal concentrations of GLOB2013F (µg/L) following a 72-h exposure

	EC _x with 95% Lower and Upper Confidence Limits (µg/L)			NOEC (µg/L)	LOEC (µg/L)
	EC ₁₀	EC ₂₀	EC ₅₀		
Growth Rate	31.5 (19.1 – 52.0)	51.0 (35.1 – 74.1)	129 (100 – 164)	< 31.25	≤ 31.25
Yield	31.9 (27.4 – 37.2)	39.6 (35.2 – 44.5)	59.8 (56.0 – 63.8)	< 31.25	≤ 31.25

The results of statistical analysis for the active ingredient – zoxamide as geometric mean measured concentration - are presented in the following Table.

Test statistics, showing EC values with 95% Lower and Upper Confidence Limits for the equivalent a.s. within the formulation based on geometric mean measured concentrations of zoxamide (µg/L) following a 72-hr exposure

	EC _x with 95% Lower and Upper Confidence Limits (µg/L)			NOEC (µg/L)	LOEC (µg/L)
	EC ₁₀	EC ₂₀	EC ₅₀		
Growth Rate	25.8 (25.3 – 26.3)	27.6 (27.2 – 28.0)	31.8 (31.3 – 32.4)	< 12.3	≤ 12.3
Yield	22.0 (19.6 – 24.6)	23.4 (21.6 – 25.3)	26.4 (25.7 – 27.1)	< 12.3	≤ 12.3

Test statistics, showing EC values with 95% Lower and Upper Confidence Limits for GLOB2013F (µg/L) based on geometric mean measured concentrations of zoxamide following a 72-hr exposure

	EC _x with 95% Lower and Upper Confidence Limits (µg/L)			NOEC (µg/L)	LOEC (µg/L)
	EC ₁₀	EC ₂₀	EC ₅₀		
Growth Rate	65.3 (64.1 – 66.6)	69.9 (68.9 – 70.9)	80.5 (79.3 – 82.1)	< 31.2	≤ 31.2
Yield	55.7 (49.6 – 62.3)	59.3 (54.7 – 64.1)	66.9 (65.1 – 68.6)	< 31.2	≤ 31.2

Conclusion

Pseudokirchneriella subcapitata was exposed to GLOB2013F, a suspension concentrate formulation with the active ingredient zoxamide, over a 72-hour period.

- Based on nominal concentrations of GLOB2013F, the 72-h EC₅₀ was 129 µg/L for growth rate and 59.8 µg/L for yield; the NOEC for both growth rate and yield was less than 31.25 µg/L.
- Based on geometric mean measured concentrations of zoxamide, the equivalent values for the a.s. within the formulation GLOB2013F are: 72-h EC₅₀ was 31.8 µg/L for growth rate and 26.4 µg/L for yield; the NOEC for both growth rate and yield was less than 12.3 µg/L.
- Based on geometric mean measured concentrations of zoxamide, the equivalent values for the formulation GLOB2013F are: 72-h EC₅₀ was 80.5 µg/L for growth rate and 66.9 µg/L for yield; the NOEC for both growth rate and yield was less than 31.2 µg/L.

Comments of zRMS:	<p>The study was conducted according to OECD guideline 201 and principles of GLP. No deviations were noted.</p> <p>Validity criteria were met:</p> <ul style="list-style-type: none"> - the biomass in the control increased by a factor of 234 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 (exposure initiation – exposure termination) in the control culture was 1.1 % (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 7.3 % (criterion: it must not exceed 35%). <p>The analytical measurements demonstrated that the test item concentrations throughout the test was outside the range 80-120% of nominal and for this reason endpoints are expressed as geometric mean measured concentrations of zoxamide.</p>
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Reference:	KCA 8.2.6.1
Report	Zoxamide Technical: <i>Pseudokirchneriella subcapitata</i> Growth Inhibition Test, Jarratt, N., Fera Science Ltd, Report No.: FR/002786
Guideline(s):	OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	Zoxamide Technical
Test Species:	<i>Pseudokirchneriella subcapitata</i>
Source and Strain:	CCAP (Culture Collection of Algae and Protozoa), Oban, Scotland. Strain CCAP 278/4
Test Media:	OECD medium (OECD Test Guideline 201, 2011, Annex 3)

<i>Test System:</i>	The test system is algal medium (to which test item is added); <i>Pseudokirchneriella subcapitata</i> in an exponential phase of growth was added to the algal medium.
<i>Test Item Concentrations:</i>	Nominal concentrations of Zoxamide Technical were 6.25, 12.5, 25, 50 and 100 µg/L, with a negative control of untreated test media and a solvent control of acetone and test media (0 mg/L).
<i>Reference Item:</i>	<p>The performance of the test system was assessed using 3,5-dichlorophenol (3,5-DCP) as the reference item treatment.</p> <p>Nominal test concentration of 3,5-DCP was 2 mg/L, prepared with acetone as a solvent carrier to increase solubility.</p>
<i>Replicates:</i>	There were six replicate vessels for each control and three for each test item treatment. The positive control had four replicate vessels.
<i>Toxic Endpoints:</i>	Two endpoints were calculated, the growth rate and yield following 72 hours of exposure; these are expressed as per cent inhibition relative to the control.

All samples were analysed by LC-MS. Triplicate samples were analysed from fresh media at the start of the test and from pooled media from replicates at the end of the test for the test item, zoxamide.

Results and discussions

Mean measured concentrations at 0 and 72 hours indicated that zoxamide was not stable over the exposure period (e.g. variation greater than 20%); the range was from 57 to 126%. Therefore, analysis is reported as geometric mean measured concentrations (i.e. geo mean concentration) of zoxamide.

The results of the definitive bioassay after 72-h of exposure indicated no effect on cell numbers at 6.01, 11.62 or 17.43 µg/L geometric mean measured concentration of zoxamide. Clear inhibition for algal cell number increase were observed in the 35.97 and 79.52 µg/L groups.

	EC _x with 95% Lower and Upper Confidence Limits (µg/L)			NOEC (µg/L)	LOEC (µg/L)
	EC ₅₀	EC ₂₀	EC ₁₀		
Growth Rate	38.311 (33 – 45)	20.714 (16 – 25)	15.020 (11 – 19)	6.014	11.62
Yield	20.217 (15 – 31)	12.003 (5.1 – 16)	9.140 (2.5 – 13)	6.014	11.62

Conclusion

Pseudokirchneriella subcapitata was exposed to zoxamide technical, a technical grade of the chemical zoxamide, over a 72-hour period. Based on geometric mean measured concentrations of zoxamide, the 72-h EC₅₀ was 38.311 µg/L for growth rate and 20.217 µg/L for yield; the NOEC for both growth rate and yield was 6.014 µg/L.

Comments of zRMS:	<p>The study was conducted according to OECD guideline 201 and principles of GLP. No deviations were noted.</p> <p>All the validity criteria were met:</p> <ul style="list-style-type: none"> - the biomass in the control increased by a factor of 104 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 (exposure initiation – exposure termination) in the control culture was 4.51 % (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 11.8 % (criterion: it must not exceed 35%). <p>The analytical measurements demonstrated that the test item concentrations throughout the test was in the range 80-120% of nominal. The results are expressed as nominal concentrations of RH-163353.</p>
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Reference:	KCA 8.2.6.1
Report	72-Hour Toxicity Test with the Freshwater Green Alga, <i>Raphidocelis subcapitata</i> , Softcheck, K. 2023, Smithers Ers Ltd, Report No.: 14365.6101
Guideline(s):	OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes /No / Supplementary

Materials and methods

The purpose of this study was to determine the effect of RH-163353 on the growth of the freshwater green alga, *Raphidocelis subcapitata*, under static conditions. The results of this study are presented based on mean measured concentrations of RH-163353 and are reported as the 72-hour EC₁₀, EC₂₀, and EC₅₀ values for average specific growth rate and yield, denoted as E_rC₁₀, E_rC₂₀, E_rC₅₀, and E_yC₁₀, E_yC₂₀, E_yC₅₀, respectively. If possible, the 72-hour No-Observed Effect Concentration (NOEC) and Lowest-Observed Effect Concentration (LOEC) values were also determined.

Test Substance	
Name:	RH-163353
Synonym:	3-(3,5-dichloro-4-methylbenzamido)-3-methyl-2-oxopentanoic acid (RH-163353)
Batch No.:	GD-003454-03
CAS No.:	401520-47-6
Purity:	100%
Storage Conditions:	Stored at room temperature in a dark, ventilated cabinet in the original container
Expiry Date:	9 March 2024

Date Received:	16 March 2023
Received From:	Globachem Discovery Ltd., Macclesfield, United Kingdom

Test Concentrations	
Nominal Concentrations:	3.1, 6.3, 13, 25, 50, and 100 mg/L
Mean Measured Concentrations	3.1, 5.9, 13, 26, 44, and 100 mg/L
Co-Solvent:	None
Co-Solvent Load:	Not Applicable
Interval(s) of Analytical Verification:	0 and 72 hours

Test Conditions	
Duration:	72-hours
Temperature:	24 to 25°C
Photoperiod:	None (continuous)
Photosynthetically-Active Radiation (PAR):	60 to 76 $\mu\text{E}/\text{m}^2/\text{S}$
Light Intensity:	4500 to 5200 lux
Agitation:	Continuous, 100 \pm 10 rpm on an orbital shaker, rate monitored & recorded daily

Analytical results

Table 3. 72-Hour Exposure of *Raphidocelis subcapitata* to RH-163353 - Concentrations Measured in the Exposure Solutions

Nominal Concentration (mg/L)	Measured Concentration (mg/L)		Mean Measured Concentrations (SD) ^a	Percent Decline from 0-Hour ^a	Percent of Nominal ^a
	0-Hour	72-Hour			
Control	<0.27 ^b	<0.91	NA ^c (NA)	NA	NA
3.1	2.9	3.4	3.1 (0.34)	-17	100
6.3	5.9	5.8	5.9 (0.020)	0	93
13	13	13/13 ^d	13 (0.033)	0	96
25	24	27	26 (2.5)	-15	100
50	45	44	44 (0.34)	1	89
100	94	110	100 (8.9)	-13	100
QC#1 1.50	1.28 (85.1)	1.37 (91.4)			
QC#2 25.0	24.1 (96.3)	21.9 (87.8)			
QC#3 100	98.7 (98.7)	109 (109)			

^a Mean measured concentration, standard deviation (SD), percent decline, and percent of nominal values were calculated using the actual analytical (unrounded) results and not the rounded values presented in this table.

^b Concentrations expressed as less than values were below the limit of detection (LOD). The LOD is dependent upon the lowest concentration calibration standard and the dilution factor of the controls. The LOD is higher at 72-hr because the low calibration standard could not be used in the calibration curve due to a preparation error.

^c NA = Not Applicable

^d Result of the additional sample without algae present to determine biological uptake/degradation, see [Section 2.7](#).

^e QC = Quality Control sample. Concentrations are presented as mg/L. Percent recovery for each QC sample is presented in parentheses.

Results and discussions/Conclusion

Biological Parameter	Results				
	Based on Mean Measured Concentrations (mg/L)				
	NOEC ^a	LOEC ^a	EC ₁₀ (95% CI) ^b	EC ₂₀ (95% CI)	EC ₅₀ (95% CI)
72-Hour Average Specific Growth Rate	100	>100	>100 (NA) ^c	>100 (NA)	>100 (NA)
72-Hour Yield	100	>100	>100 (NA)	>100 (NA)	>100 (NA)
^a Determined by Dunnett's Multiple Comparison Test.					
^b CI = Confidence Interval					
^c NA = Not Applicable; EC value was empirically estimated; therefore, a corresponding 95% confidence interval could not be determined.					

Rationale for no further testing: The highest concentration tested meets the maximum testing requirement in the OECD 201 guideline.

Comments of zRMS:	<p>The study was conducted according to OECD guideline 201 and principles of GLP. During the study each of the five concentrations only had four replicates. This deviation did not adversely affect the outcome of the study.</p> <p>All the validity criteria were met.</p> <p>The analytical measurements demonstrated that the test item concentrations throughout the test was outside the range 80-120% of nominal and for this reason endpoints are expressed as geometric mean measured concentrations of. RH-139432.</p>
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Reference: KCA 8.2.6.1

Report: 72-Hour Algal Inhibition Test with *Pseudokirchneriella subcapitata* (OECD 201) - Test Substance: RH-139432, Mikulas, J., Stillmeadow Inc, Report No.: 25770-22

Guideline(s): OECD 201

Deviations: No

GLP: Yes

Acceptability: **Yes** / No / Supplementary

Materials and methods

This study was conducted to determine the toxic effects of the test item, RH-139432, on the growth of the freshwater algae *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in a 72-hour static test.

Test concentrations were determined by a preliminary range-finding test. The test item concentrations chosen for the definitive test (1.25 mg/L, 2.5 mg/L, 5.0 mg/L, 10.0 mg/L and 20.0 mg/L) were administered to the test system, *Pseudokirchneriella subcapitata*, in OECD media. For each test concentration, four test flasks containing freshwater algae (10,000 cells/mL) were treated with the appropriate concentration of the test item. A control group consisted of six test flasks containing sterile medium and the test culture only. A positive control group consisted of three flasks treated with 20 mg/L zinc chloride. The cell density in each test and control container was measured at 24, 48 and 72 hours using a hemocytometer. Chamber temperature was measured daily with a calibrated thermometer. Daily maximum and minimum temperatures were also recorded. Light intensity was measured daily in at least 5 locations in the test areas at the height of the test solution in the test chambers. The pH of each test

solution was determined at test initiation. The pH of each test and control container was determined at test termination. The test was terminated after 72 ± 1 hours of exposure.

Analytical results

Table 2 - Dose Verification Results

Nominal Concentration (mg/L)	Calculated 3,5-Dichloro-4-methylbenzamide (mg/L)		
	0 Hour	72 Hour	Average
Control	0	0	0
1.25	0.683	0.629	0.655
2.5	1.226	1.268	1.247
5.0	3.568	4.536	4.023
10.0	5.245	6.845	5.992
20.0	10.572	9.434	9.987

The analytical measurements demonstrated that the test item concentrations throughout the test was outside the range 80-120% of nominal and for this reason endpoints are expressed as geometric mean measured concentrations of. RH-139432 (3,5-dichloro-4-methylbenzamide).

Results and discussions/Conclusion

Table 3 - Definitive Test Average Growth Rate Results

Test Conc. (mg/L)	Rep.	Cell Density x 10 ⁴ cells/mL			Avg. Growth Rate	Growth Rate Stats	Avg. Growth Curve Area	Growth Curve Area Stats	Init. pH	Term. pH
		24 Hours	48 Hours	72 Hours						
Cont.	A	33	121	471	2.052		9288			8.2
	B	18	103	460	2.044		8364			8.3
	C	40	98	461	2.044	Mean: 2.045	8784	Mean: 8706.00		8.2
	D	25	129	500	2.072	SD: 0.020	9396	SD: 773.63	8.0	8.4
	E	32	103	464	2.047	CV: 0.955	8748	CV: 8.9		8.2
	F	32	71	417	2.011		7416			8.2
		Mean 462.17								
1.25	A	37	101	340	1.943	Mean: 2.008	7332	Mean: 8358.00		7.9
	B	30	124	410	2.005		8556			8.2
	C	28	115	490	2.065	SD: 0.061	9252	SD: 972.025	7.7	8.2
	D	22	113	426	2.018	CV: 3.034	8292	CV: 11.630		8.3
			Mean 416.5							
		Percent Inhibition Yield: 9.88%				Percent Inhibition Growth Rate: 1.81%				
2.5	A	23	91	427	2.019	Mean: 2.021	7800	Mean: 7551.00		8.1
	B	26	103	414	2.009		8004			8.2
	C	34	41	461	2.044	SD: 0.018	7272	SD: 377.762	7.7	8.3
	D	21	69	419	2.013	CV: 0.913	7128	CV: 5.003		8.2
			Mean 430.25							
		Percent Inhibition Yield: 6.91%				Percent Inhibition Growth Rate: 1.16%				
5.0	A	10	10 ^B	14 ^A		Mean: 2.013		Mean: 8128.00		7.6
	B	26	123	422	2.015	SD: 0.004	8580	SD: 534.573	7.6	8.2
	C	25	96	415	2.009	CV: 0.196	7824	CV: 6.577		8.4
	D	20	104	422	2.015		7980			8.3
			Mean 419.67							
		Percent Inhibition Yield: 9.20%				Percent Inhibition Growth Rate: 1.55%				
10.0	A	24	83	272	1.869	Mean: 1.853	5772	Mean: 5400.00		8.0
	B	12	66	243	1.831		4728			7.9
	C	26	85	288	1.888	SD: 0.029	6060	SD: 700.845	7.7	8.2
	D	26	67	239	1.825	CV: 1.555	5040	CV: 12.979		8.1
			Mean 260.5							
		Percent Inhibition Yield: 43.64%				Percent Inhibition Growth Rate: 9.37%				
20.0 ^C	A	10	8	23	1.045	Mean: 1.106	648	Mean: 861.00		7.7
	B	7	20	24	1.059		876			7.7
	C	9	21	39	1.221	SD: 0.080	1128	SD: 201.365	7.7	7.7
	D	9	13	27	1.099	CV: 7.233	792	CV: 23.387		7.7
			Mean 28.25							
		Percent Inhibition Yield: 93.89%				Percent Inhibition Growth Rate: 45.91%				
C2 ^D 10 mg/L ZnCl ₂	A	3	4	4	0.462	Mean: 0.430	156	Mean: 120.00		7.3
	B	3	3	4	0.462		132			7.3
	C	2	2	3	0.366	SD: 0.055	72	SD: 43.267	6.9	7.4
			Mean 3.67			CV: 12.871		CV: 36.056		

Test Validity

The test was considered valid because the 72 hour terminal control increased by a factor of at least 16 times. The mean coefficient of variation was 16.304% at 72 hours.

At 72 hours, the test concentration of RH-139432 that resulted in cell density Median Effective Concentration (EC₅₀) was determined to be 11.267 mg/L (**6.4980** mg/L) with 95% confidence limits of 9.782 - 12.567 mg/L (5.8937 - 7.0100 mg/L).

At 72 hours, the test concentration of that resulted in cell density (EC₁₀) was determined to be 5.117 mg/L (4.0690 mg/L) with 95% confidence limits of 0.000 - 6.031 mg/L (0.0000 - 4.3524 mg/L).

At 72 hours, the cell density No Observed Effect Concentration (NOEC) was determined to be 5 mg/L (4.023 mg/L).

At 72 hours, the test concentration of RH-139432 that resulted in the growth rate Median Effective Concentration (EC₅₀) was determined to be > 20 mg/L (> **9.987** mg/L).

At 72 hours, the test concentration of that resulted in a growth rate (EC₁₀) was determined to be 10.172 mg/L (6.0606 mg/L) with 95% confidence limits of 9.222 - 10.744 mg/L (5.7225 - 6.3114 mg/L).

At 72 hours, the cell density No Observed Effect Concentration (NOEC) was determined to be 5 mg/L (4.023 mg/L). Parenthetical values are dose verified concentrations.

Comments of zRMS:	<p>The study was conducted according to OECD guideline 201 and principles of GLP.</p> <p>The design of the study was a limit test. The concentration needed for the limit test was determined by a preliminary range-finding test. The concentration chosen was 1.5 mg/L.</p> <p>The test was considered valid because the 72 hour terminal control increased by a factor of at least 16 times. The mean coefficient of variation was 15.453% at 72 hours.</p>
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Reference: KCA 8.2.6.1

Report 72-Hour Algal Inhibition Test with *Pseudokirchneriella subcapitata* (OECD 201) - Test Substance: RH-127450, Mikulas, J., Stillmeadow Inc, Report No.: 25834-22

Guideline(s): OECD 201

Deviations: No

GLP: Yes

Acceptability: **Yes** / No / Supplementary

Materials and methods

This study was conducted to determine the toxic effects of the test item, RH-127450, on the growth of the freshwater algae *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in a 72-hour static test.

The concentration needed for the limit test was determined by a preliminary range-finding test. The chosen concentration (1.5 mg/L) was administered to the test system, *Pseudokirchneriella subcapitata*, in OECD media. For the test concentration, six test flasks containing freshwater algae (10,000 cells/mL) were treated with 1.5 mg/L nominal concentration of the test item. A control group consisted of six test flasks containing sterile medium and the test culture only. A positive control group consisted of three flasks treated with 10 mg/L zinc chloride. The cell density in each test and control container was measured at 24, 48 and 72 hours using a hemocytometer. Chamber temperature was measured daily with a calibrated thermometer. Daily maximum and minimum temperatures were also recorded. Light intensity was measured daily in at least 5 locations in the test areas at the height of the test solution in the test

chambers. The pH of each test solution was determined at test initiation. The pH of each test and control container was determined at test termination. The test was terminated after 72 ± 1 hours of exposure.

Results and discussions/Conclusion

Analytical results

Table 2 - Dose Verification Results

Nominal Concentration (mg/L)	Calculated 3,5-dichloro-4-methyl-N-(3-methyl-2-oxopentan-3-yl)-benzamide		
	0 Hour	72 Hour	Geometric Mean
Control	0	0	0
1.5	0.648	2.689	1.320

Table 3 - Limit Test Average Growth Rate Results

Test Conc. (mg/L)	Rep.	Cell Density x 10 ⁴ cells/mL			Avg. Growth Rate	Growth Rate Stats	Avg. Growth Curve Area	Growth Curve Area Stats	Init. pH	Term. pH
		24 Hours	48 Hours	72 Hours						
Cont.	A	30	103	407	0.083		8016			8.9
	B	36	91	387	0.083		7632			9.0
	C	20	84	409	0.084	Mean: 0.083	7344	Mean: 7710.00		9.0
	D	15	102	421	0.084	SD: 0.001	7800	SD: 249.85	8.0	8.9
	E	25	121	373	0.082	CV: 1.065	7920	CV: 3.2		8.9
	F	29	110	356	0.082		7548			8.9
		Mean 392.2								
1.5*	A	25	97	386	0.083	Mean: 0.081	7500	Mean: 6771.00		8.9
	B	24	73	260	0.077	SD: 0.003	5388	SD: 993.678	7.8	8.0
	C	23	86	346	0.081	CV: 3.211	6708	CV: 14.675		8.9
	E	32	89	387	0.083		7488			8.5
		Mean 344.8								
		Percent Inhibition Yield: 12.09%				Percent Inhibition Growth Rate: 2.34%				
C2 10 mg/L ZnCl ₂	A	3	3	2	0.010					7.6
	B	5	3	3	0.015	Mean: 0.012				7.7
	C	2	2	2	0.010	SD: 0.003	NA	NA	7.4	7.7
		Mean 2.33				CV: 28.262				

Note: All organisms had no observable abnormalities unless otherwise indicated.

Conc - Concentration; Rep - Replicate; Avg - Average; Init - Initial; Term - Terminal; SD - Standard Deviation;

CV - Coefficient of Variation; Cont. - Control; C2 - Positive Control; NA - Not Applicable

*Replicates D and F considered outliers, removed from statistical analysis.

At 72 hours, the cell density and growth rate Median Effective Concentration (EC₅₀) and Lowest Observed Effect Concentration (LOEC) were determined to be > 1.5 mg/L (>1.32 mg/L) of the test item, RH-127450. At 72 hours, the growth rate EC₁₀ was > 1.5 mg/L (> 1.32 mg/L) and the cell density EC₁₀ was 1.2406 mg/L (1.0917 mg/L). At 72 hours, the cell density and growth rate No Observed Effect Concentration (NOEC) was determined to be 1.5 mg/L (1.32 mg/L). Parenthetical values are dose verified concentrations.

Test Validity

The test was considered valid because the 72 hour terminal control increased by a factor of at least 16 times. The mean coefficient of variation was 15.453% at 72 hours.

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

No data submitted.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No data submitted.

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

Comments of zRMS:	<p>The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted.</p> <p>The test was performed for one dose of 100 µg of the test item/bee (limit test), corresponding to 4065 mg of the test item/kg of food, and control. Dose and control consisted of three replicates of 10 bees. A reference test was performed parallel to the definitive test. It is in accordance with OECD 213 where in some cases (e.g. when a test substance is expected to be of low toxicity) a limit test may be performed, using 100 µg a.i./bee in order to demonstrate that the LD₅₀ is greater than this value.</p> <p>In the definitive test all the validity criteria were met as follows:</p> <ul style="list-style-type: none"> - The average mortality for the total number of controls was 3.3 % at the end of the experiment (criterion: it must not exceed 10%) - The 24-hour LD₅₀ of the reference item (dimethoate) was 0.18 µg/bee (criterion: 0.10 – 0.35 µg a.i./bee) <p>The study is reliable and suitable for the risk assessment.</p>
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Reference: KCP 10.3.1.1

Report Honeybees, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 213, Przychodzka, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0009/E

Guideline(s): OECD 213

Deviations: No

GLP: Yes

Acceptability: ☒ Yes ☐ No/Supplementary

Materials and methods

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: honeybees (*Apis mellifera carnica*)

Number of organisms: 10 bees/replicate; each dose and control in 3 replicates

Type of test: acute oral toxicity test (4 hours exposition and 48 hours from the moment of changing the solution with the test item to the sucrose solution)

Nominal tested doses (concentrations):

range-finding test:

- control
- 1 µg of the test item/bee (40.65 mg of the test item/kg of food)
- 10 µg of the test item/bee (406.5 mg of the test item/kg of food)
- 100 µg of the test item/bee (4065 mg of the test item/kg of food)

definitive test (limit test):

- control
- 100 µg of the test item/bee (4065 mg of the test item/kg of food).

Exposure route: test item was dissolved in 50% (m/v) sucrose solution and then diluted; solutions was administered in proper concentration in the volume of 200 µl/10 bees with glass micropipettes.

Test conditions: average temperature during range-finding test 25.05°C; average temperature during definitive test 24.428°C.

relative humidity: average humidity during range-finding test 69.063%; average humidity during definitive test 62.263%.

Results and discussions

Results of range-finding test:

During the range-finding test no mortality of bees was recorded.

Results of range-finding test calculated by ToxRat Professional			
Parameter	Time of observation		
	4 h	24 h	48 h
LD₁₀ [µg of the test item/bee]	n.d.** (nd. – nd.)*	n.d.** (nd. – nd.)*	n.d.** (n.d. – n.d.)*
LD₂₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₅₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD₁₀ test item dose causing mortality in 10% of individuals

LD₂₀ test item dose causing mortality in 20% of individuals

LD₅₀ test item dose causing mortality in 50% of individuals

*) the lower and upper 95% confidence limits are given in brackets

**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee

n.d. impossible to determine due to mathematical reasons

Final results

Table 9. Mortality of the bees and sings of intoxication – definitive test

Dose of test item [µg of the test item/bee]	Replicate	4 hours after the start of the exposure			24 hours from the end of the exposure			48 hours from the end of the exposure			Statistical significance
		Mortality		Symptoms of intoxication	Mortality		Symptoms of intoxication	Mortality		Symptoms of intoxication	
		[pcs.]	[%]		[pcs.]	[%]		[pcs.]	[%]		
Control	1	0	0.0	none	1	3.3	none	1	6.7	none	n .d.
	2	0		none	0		none	0		none	
	3	0		none	0		none	1		none	
100	1	0	0.0	none	0	0.0	4 a	0	0.0	none	-
	2	0		none	0		none	0		none	
	3	0		none	0		none	0		none	

- non-significant

n.d. not determined

a affected (bees still upright and attempting to walk, but showing signs of reduced coordination; hyperactivity; aggressiveness; increased self-cleaning behaviour; rotations; shivering)

Final results calculated by ToxRat Professional

Parameter	Time of observation	
	24 h	48 h
LD₁₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₂₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₅₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD₁₀ test item dose causing mortality in 10% of individuals

LD₂₀ test item dose causing mortality in 20% of individuals

LD₅₀ test item dose causing mortality in 50% of individuals

*) the lower and upper 95% confidence limits are given in brackets

**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee

n.d. impossible to determine due to mathematical reasons

Conclusion

The test item in the course of this experiment did not affect the survival of adult honey bee workers (*Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, used in the definitive test.

Based on the analysis of results, the LD₁₀ LD₂₀ and LD₅₀ values were defined as >100 µg of the test item/bee.

Comments of zRMS:	The study was conducted according OECD guideline 247 with the principles of GLP. No deviations were noted. In the definitive tests all the validity criteria were met. - bumblebee mortality in control after 48 h was 0.0% (required: ≤ 10%) - bumblebee mortality in reference test after 48 h was 76.7% (required: ≥50%)
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Reference: KCP 10.3.1.1

Report Bumblebee, Acute Oral Toxicity Test of the test item Zoxamide 450 SC according to OECD 247 Guideline, Konieczna, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0016/E

Guideline(s): OECD 247

Deviations: No
GLP: Yes
Acceptability: **Yes** ~~No/Supplementary~~

Material and Methods:

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: bumblebees (*Bombus terrestris*)

Number of organisms: 1 bumblebee per replicate; range-finding test 30 replicates; definitive test 50 replicates

Type of test: acute oral toxicity test (48 hours)

Nominal tested doses (concentrations):

range-finding test:

- 10 µg of the test item/bumblebee (203.252 mg of the test item/kg of food)
- 100 µg of the test item/bumblebee (2032.52 mg of the test item/kg of food)
- 1000 µg of the test item/bumblebee (20325.2 mg of the test item/kg of food)

definitive test (limit test):

- control – 50% (w/v) sucrose solution
- 1000 µg of the test item/bumblebee (20325.2 mg of the test item/kg of food.

Test item concentration during definitive test differed by no more than ±20% from nominal concentration.

Exposure route: test item was dissolved in 50% (m/v) sucrose solution and then diluted; solutions was administered in proper concentration in the volume of 40 µl/bumblebee with glass micropipettes.

Test conditions: average temperature during range-finding test 24.581°C; average temperature during definitive test 25.162°C.

relative humidity: average humidity during range-finding test 70.096%; average humidity during definitive test 62.585%.

Results of range-finding test

During the range-finding test no mortality of bumblebees was recorded.

Final results calculated by ToxRat Professional		
Parameter [µg of the test item/bumblebee]	Time of observation	
	24 h	48 h
LD₅₀	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
NOED	≥1000	≥1000
LOED	>1000	>1000

LD₅₀ test item dose causing mortality in 50% of individuals

NOED the highest test item dose not causing statistically significant differences in relations to the control

LOED the lowest dose of the test item inducing statistically significant differences compared to the control

* the lower and upper 95% confidence limits are given in brackets

** based on the analysis of the results, the value was defined as >1000 µg of the test item/bumblebee

n.d. impossible to determine due to mathematical reasons

Final results

In the course of the study, the test item did not shown apitoxic effects on adult bumblebee workers (*Bombus terrestris*). The test item is do not cause mortality at a dose of 1000 µg of the test item/bumblebee, used in the definitive test.

On the basis of data analysis, the values LD₅₀, LOED after 24 and 48 h were determined at the level of >1000 µg of test item/bumblebee and NOED value at the level of ≥1000 µg of test item/bumblebee.

Parameter [µg of the test item/bumblebee]	Time of observation	
	24 h	48 h
LD₅₀	>1000*	>1000*
NOED	≥1000*	≥1000*
LOED	>1000*	>1000*

LD₅₀ test item dose causing 50% mortality of individuals

NOED the highest test item dose not causing statistically significant differences in relations to the control

LOED the lowest dose of the test item inducing statistically significant differences compared to the control

* based on the analysis of the results

Conclusion

In the course of the study, the test item did not shown apitoxic effects on adult bumblebee workers (*Bombus terrestris*). The test item is do not cause mortality at a dose of 1000 µg of the test item/bumblebee, used in the definitive test.

On the basis of data analysis, the values LD₅₀, LOED after 24 and 48 h were determined at the level of >1000 µg of test item/bumblebee and NOED value at the level of ≥1000 µg of test item/bumblebee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	<p>The study was conducted to OECD guideline 214 and according to the principles of GLP.</p> <p>Following deviation were noted:</p> <p>The humidity during the definitive and reference test increased to maximum of 78.1%. These deviations had no effect on the results of the test since the test met the validity criteria.</p> <p>The test was performed for one dose of 100 µg of the test item/bee (limit test), corresponding to 4065 mg of the test item/kg of food, and control. Dose and control consisted of three replicates of 10 bees. A reference test was performed parallel to the definitive test. It is in accordance with OECD 213 where in some cases (e.g. when a test substance is expected to be of low toxicity) a limit test may be performed, using 100 µg a.i./bee in order to demonstrate that the LD₅₀ is greater than this value.</p> <ul style="list-style-type: none"> - The average mortality for the total number of controls was 3.3 % after 48h (criterion: it must not exceed 10%) - The 24-hour LD₅₀ of the reference item (dimethoate) was 0.213 µg/bee (criterion: 0.10 – 0.30 µg a.i./bee) <p>The study is reliable and suitable for the risk assessment.</p>
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Reference: KCP 10.3.1.1

Report Honeybees, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD Guideline 214, Przychodzka, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0010/E

Guideline(s): OECD 214

Deviations: No

GLP: Yes

Acceptability: Yes / No / Supplementary

Materials and methods

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: honeybees (*Apis mellifera carnica*)

Number of organisms: 10 bees/replicate; each dose and control in 3 replicates

Type of test: acute contact toxicity test (48 hours)

Nominal tested doses (concentrations):

range-finding test:

- control without wetting agent
- control with wetting agent
- 1 µg of the test item/bee (1 g of the test item/L)
- 10 µg of the test item/bee (10 g of the test item/L)
- 100 µg of the test item/bee (100 g of the test item/L)

definitive test (limit test):

- control without wetting agent
- control with wetting agent
- 100 µg of the test item/bee (100 g of the test item/L).

Exposure route: test item was dissolved in deionized water with 0.1% of wetting agent, Triton (R) X-100 and then diluted; solutions were topically applied in proper concentration on the thorax of honey bees using microapplicator delivering a 1 µL droplet.

Test conditions: average temperature during range-finding test 24.110°C; average temperature during definitive test 23.876°C. relative humidity: average humidity during range-finding test 66.932%; average humidity during definitive test 73.658%.

Results and discussions

Results of range-finding test

During the range-finding test no mortality of bees was recorded

Results of range-finding test calculated by ToxRat Professional		
Parameter	Time of observation	
	24 h	48 h
LD₁₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₂₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₅₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD₁₀ test item dose causing mortality in 10% of individuals

LD₂₀ test item dose causing mortality in 20% of individuals

LD₅₀ test item dose causing mortality in 50% of individuals

*) the lower and upper 95% confidence limits are given in brackets

**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee

n.d. impossible to determine due to mathematical reasons

Final results

Table 7. Mortality of the bees and sings of intoxication – definitive test

Dose of test item [µg of the test item/bee]	Replicate	4 hours		24 hours		48 hours		Statistical significance			
		Mortality		Signs of intoxication	Mortality		Signs of intoxication				
		[pcs.]	[%]		[pcs.]	[%]			[pcs.]	[%]	
Control without wetting agent	1	0	0.0	none	0	0.0	none	0	3.3	none	n.d.
	2	0		none	0		none	1		none	
	3	0		none	0		none	0		none	
Control with wetting agent	1	0	0.0	none	0	3.3	none	0	3.3	none	n.d.
	2	0		none	1		none	1		none	
	3	0		none	0		none	0		none	
100	1	0	0.0	none	0	0.0	none	0	3.3	none	-
	2	0		none	0		none	1		none	
	3	0		none	0		none	0		none	

- nonsignificant
n.d. not determined

Final results calculated by ToxRat Professional

Parameter	Time of observation	
	24 h	48 h
LD₁₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₂₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD₅₀ [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD₁₀ test item dose causing mortality in 10% of individuals

LD₂₀ test item dose causing mortality in 20% of individuals

LD₅₀ test item dose causing mortality in 50% of individuals

*) the lower and upper 95% confidence limits are given in brackets

**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee

n.d. impossible to determine due to mathematical reasons

Conclusion

The test item in the course of this experiment did not affect the survival of adult honey bee workers (*Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, corresponding to concentration 100 g of the test item/L.

Based on the analysis of results, the LD₁₀ LD₂₀ and LD₅₀ values were defined as >100 µg of the test item/bee.

Comments of zRMS:	<p>The study was conducted according OECD guideline 246 with the principles of GLP.</p> <p>The test was performed for one dose of 1000 µg/bumblebee (limit test) corresponding to the following concentration: 500 g of test item/L of solution and control. A reference test was performed parallel to the definitive test.</p> <p>It may be appropriate to conduct a limit test, using e.g. 100 µg a.i. or chemical / bumblebee in order to demonstrate that the LD₅₀ is greater than this value. The above described procedure should be used (including relevant controls, and</p>
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	<p>the use of the toxic reference substance), but instead of using 30 replicates per treatment group, 50 replicates are used, except for the toxic reference substance where at least 30 replicates are used. The study design of definitive test was carried out in accordance with OECD 246.</p> <p>In the definitive tests all the validity criteria were met as follows:</p> <ul style="list-style-type: none"> - bumblebee mortality in control after 48 h was 0.0% (required: $\leq 10\%$) - bumblebee mortality in reference test after 48 h was 66.7% (required: $\geq 50\%$)-
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Reference:	KCP 10.3.1.1
Report	Bumblebee, Acute Contact Toxicity Test of the test item Zoxamide 450 SC according to OECD 246 guideline, Konieczna, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0013/E
Guideline(s):	OECD 246
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Material and Methods

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: bumblebees (*Bombus terrestris*)

Number of organisms: 10 bumblebee per replicate; range-finding test 30 replicates; definitive test 50 replicates

Type of test: acute contact toxicity test (48 hours)

Nominal tested doses (concentrations):

range-finding test:

- control (deionized water containing a surfactant)
- 10 µg of the test item/bumblebee (5 g of the test item/L of solution)
- 100 µg of the test item/bumblebee (50 g of the test item/L of solution)
- 1000 µg of the test item/bumblebee (500 g of the test item/L of solution)

definitive test (limit test):

- control (deionized water containing a surfactant)
- 1000 µg of the test item/bumblebee (500 g of the test item/L of solution).

Test item concentration during definitive test differed by no more than $\pm 20\%$ from nominal concentration.

Exposure route: test item was dissolved in deionized water with 0.1% of wetting agent, Triton (R) X-100 and then diluted; solutions were topically applied in proper concentration on the thorax of bumblebee using microapplicator delivering a 2 µL droplet.

Test conditions: average temperature during range-finding test 24.581°C; average temperature during definitive test 24.222°C.

relative humidity: average humidity during range-finding test 70.096%; average humidity during definitive test 72.965%.

Results of range-finding test

During range-finding test, no bumblebee's mortality was observed.

Final results calculated by ToxRat Professional	
Parameter	Time of observation

[µg of the test item/bumblebee]	24 h	48 h
LD₅₀	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
NOED	≥1000	≥1000
LOED	>1000	>1000

LD₅₀ test item dose causing mortality in 50% of individuals

NOED the highest test item dose not causing statistically significant differences in relations to the control

LOED the lowest dose of the test item inducing statistically significant differences compared to the control

* the lower and upper 95% confidence limits are given in brackets

** **based on the analysis of the results, the value was defined as >1000 µg of the test item/bumblebee**

n.d. impossible to determine due to mathematical reasons

Final results

Parameter [µg of the test item/bumblebee]	Time of observation	
	24 h	48 h
LD₅₀	>1000*	>1000*
NOED	≥1000*	≥1000*
LOED	>1000*	>1000*

LD₅₀ test item dose causing 50% mortality of individuals

NOED the highest test item dose not causing statistically significant differences in relations to the control

LOED the lowest dose of the test item inducing statistically significant differences compared to the control

* **based on the analysis of the results**

Conclusion

In the course of the study, the test item did not shown apitoxic effects on adult bumblebee workers (*Bombus terrestris*). The test item is do not cause mortality at a dose of 1000 µg of the test item/bumblebee, used in the definitive test.

On the basis of data analysis, the values LD₅₀, LOED after 24 and 48 h were determined at the level of >1000 µg of test item/bumblebee and NOED value at the level of ≥1000 µg of test item/bumblebee.

A 2.3.1.2

KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	<p>The study was conducted to OECD guideline 245 and according to the principles of GLP. Following deviation were noted during the study:</p> <p>In the reference test control in 5 replicates was used, not 3 as planned. During the stability test changes in temperature and during the range-finding test changes in temperature and humidity took place. They resulted from everyday activities and observations and were recorded and corrected on an ongoing basis. These were short-term changes which did not affect the condition of the research system. The above deviations did not affect the test result. The study met the validity criteria.</p> <p>In the definitive test all the validity criteria were met as follows:</p> <p>After 10 days of continuous exposure, mortality in the control was 2.0 %% (required: ≤15%) Mortality in the reference treatment group was 70 % and thus above the threshold of 50 %.</p> <p>Overall, the study is considered acceptable.</p>
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Reference: KCP 10.3.1.2

Report Honey Bee, chronic oral toxicity test of the test item Zoxamide 450 SC

according to OECD 245 Guideline, Konieczna, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0015/E

Guideline(s): OECD 245
Deviations: No
GLP: Yes
Acceptability: **Yes** ~~No/Supplementary~~

Materials and methods

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: honeybees (*Apis mellifera carnica*)

Number of organisms: 10 bees per replicate; 3 replicates for range-finding test; 5 replicates for definitive test

Type of test: chronic oral toxicity test

Nominal tested concentrations:

stability test:

- control (0 mg of the test item/kg of food)
- 2500 mg of the test item/kg of food

range-finding test:

- control (0 mg of the test item/kg of food)
- 2.5 mg of the test item/kg of food
- 25 mg of the test item/kg of food
- 250 mg of the test item/kg of food
- 2500 mg of the test item/kg of food

definitive test (limit test):

- control (0 mg of the test item/kg of food)
- 2500 mg of the test item/kg of food (average test item intake dose: 99.75 µg/bee/day).

Test item concentration during definitive test differed by no more than $\pm 20\%$ from nominal concentration at the start and at the end of storage period. Solutions were prepared at the day 0, 4 and 8.

Exposure route: test item was dissolved in a 50% (w/v) aqueous sucrose solution, final concentrations of the test item were prepared with dilution method in 50% (w/v) sucrose solution. Solutions of the test item were administered to bees using syringes with removed tip)

Test conditions:

Temperature:

average temperature during stability test: for test conditions 32.851°C; for storage conditions 6.758°C; for storage (freezing) conditions -30.367°C;

average temperature during range-finding test 32.424°C

average temperature during definitive test 32.688°C

Relative humidity:

average humidity during stability test: for test conditions 63.001%

average humidity during range-finding test 65.529%

average temperature during definitive test 63.351%

Results and discussions

Results of stability test:

The stability of the test item under the conditions of the test and storage was confirmed on the basis of the results of chemical analysis.. Test item concentration differed by no more than $\pm 20\%$ from initial concentration.

Results of range finding-test

In the experiment, no statistically significant bee mortality was observed for all tested concentrations relative to the control. No signs of intoxication were observed.

Results of range-finding test calculated with ToxRat Professional	
Parameter	Concentration [mg of the test item/kg of food]
LC ₁₀	n.d. (n.d. – n.d.)*
LC ₂₀	n.d. (n.d. – n.d.)*
LC ₅₀	n.d. (n.d. – n.d.)*
LOEC	>2500.0
NOEC	≥2500.0

LC₁₀ concentration of test item causing mortality in 10% of individuals

LC₂₀ concentration of test item causing mortality in 20% of individuals

LC₅₀ concentration of the test item causing 50% mortality of individuals

NOEC the highest concentration of the tested item that did not cause statistically significant differences compared to the control

LOEC the lowest concentration of the tested item causing statistically significant differences from the control

n.d. impossible to determine for mathematical reasons

* lower and upper 95% confidence interval

Final results

Table 12. Final bee mortality results – definitive test

Test item nominal concentration [mg/kg of food]	Introduced individuals day 0 [pcs.]	Dead individuals day 10 [pcs.]	Mortality day 10 [%]	Statistical significance ^{*)}
control	50	1	2.0	not applicable
2500	50	1	2.0	-

- not statistically significant

*) values calculated by ToxRat Professional using Fisher's test at significance level $p > 0.05$

Final results calculated using ToxRat Professional			
Parameter	Concentration [mg of the test item/kg of food]	Parameter	Dose [µg of the test item/bee/day]
LC ₁₀	n.d.** (n.d. – n.d.)*	LDD ₁₀	n.d.*** (n.d. – n.d.)*

LC₂₀	n.d.** (n.d. – n.d.)*	LDD₂₀	n.d.*** (n.d. – n.d.)*
LC₅₀	n.d.** (n.d. – n.d.)*	LDD₅₀	n.d.*** (n.d. – n.d.)*
NOEC	n.d.**	NOEDD	n.d.***
LOEC	n.d.**	LOEDD	n.d.***

n.d. impossible to determine for mathematical reasons
LC₁₀ concentration of test item causing mortality in 10% of individuals
LC₂₀ concentration of test item causing mortality in 20% of individuals
LC₅₀ concentration of the test item causing 50% mortality of individuals
NOEC the highest concentration of the test item that did not cause statistically significant differences compared to the control
LOEC the lowest concentration of the test item causing statistically significant differences from the control
LDD₁₀ the daily dose of the test item causing mortality in 10% of individuals
LDD₂₀ the daily dose of the test item causing mortality in 20% of individuals
LDD₅₀ the daily dose of the test item causing mortality in 50% of individuals
NOEDD the highest daily dose of the test item, showing no statistically significant differences compared to the control
LOEDD the lowest daily dose of the test item inducing statistically significant differences compared to the control
* lower and upper 95% confidence interval
** based on the analysis of the results, the values were determined as >2500 mg of the test item/kg of food
*** based on the analysis of the results, the values were determined as >99.75 µg of the test item/bee/day

Conclusion

The test item in the course of this test did not show any apitoxic effect on the mortality of honey bees after 10 days of the experiment.

Based on the analysis of the results, the LC₁₀, LC₂₀, LC₅₀, LOEC and NOEC values were determined as >2500 mg of the test item/kg food, the LDD₁₀, LDD₂₀, LDD₅₀, LOEDD and NOEDD values were determined as >99.75 µg of the test item/bee/day.

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

Comments of zRMS:	<p>The study was conducted to guidance OECD 239 and according to the principles of GLP. No deviations to the guideline were noted in definitive test.</p> <p>All the validity criteria were met as follows:</p> <p>a) in the control plate(s) the cumulative larval mortality from D3 to D8 is ≤ 15% across all replicates (actual value 2.8 %);</p> <p>b) in the control plate(s) the adult emergence rate on D22 is ≥ 70% across all replicates (actual value 88.9%);</p> <p>c) in the reference item group (dimethoate) the larval mortality is ≥ 50% on D8 across all replicates (actual value 91.7%).</p> <p>Since all the validity criteria were met the study is considered to be reliable</p>
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Reference: KCP 10.3.1.3

Report Honey Bee Larval Toxicity Test following Repeated Exposure to the test item Zoxamide 450 SC according to OECD GD 239 ENV/JM/MONO(2016)34, Konieczna, A., 2021, SORBOLAB Research Laboratory LLC, Report No.: 0064/0012/E

Guideline(s): OECD GD 239 ENV/JM/MONO(2016)34
Deviations: No
GLP: Yes
Acceptability: Yes / No / Supportive

Materials and methods

Test item: Zoxamide 450 SC; 39.49% a.i.

Test species: honeybees (*Apis mellifera carnica*)

Number of organisms: 1 replicate per dose consist of 36 larvae (12 larvae from 3 colonies)

Type of test: larval toxicity test – repeated exposure

Nominal tested concentrations (doses):

stability test:

- control (0 g of test item/L of solution)
- 0.05 g of test item/L of solution, corresponding to 0.65 mg of test item/kg of food
- 50 g of test item/L of solution, corresponding to 650 mg of test item/kg of food

range-finding test:

- control (0 mg of test item/kg of food)
- 0.65 mg of test item/kg of food, corresponding to 0.1 µg of test item/larva
- 6.5 mg of test item/kg of food, corresponding to 1 µg of test item/larva
- 65 mg of test item/kg of food, corresponding to 10 µg of test item/larva
- 650 mg of test item/kg of food, corresponding to 100 µg of test item/larva

definitive test (limit test):

- control (0 mg of test item/kg of food)
- 650 mg of test item/kg of food, corresponding to 100 µg of test item/larva.

Test item concentration during definitive test differed by no more than $\pm 20\%$ from nominal concentration at the start and after 72 h.

Exposure route: test item was dissolved in deionized water. A series of dilutions of the test solutions were then prepared from the solution obtained. Final solutions of test item were prepared by adding given volume of solutions to following portions of food (larval diets). Fresh diets were prepared daily during exposition time.

Test conditions:

Temperature:

average temperature during stability test 5.899°C

average temperature during range-finding test for larval stage 34.856°C; for pre-pupal stage 34.716°C; for pupal/imago stage 34.670°C

average temperature during definitive test for larval stage 34.114°C; for pre-pupal stage 34.102°C; for pupal/imago stage 34.100°C

Relative humidity:

average humidity during range-finding test for larval stage 96.940%; for pre-pupal stage 81.729%; for pupal/imago stage 76.814%

average temperature during definitive test for larval stage 99.271%; for pre-pupal stage 78.524%; for pupal/imago stage 77.763%.

Results and discussions

Results of stability test

Test item stability in storage conditions was confirmed based on results solutions chemical analysis at the test beginning and after 24, 48 and 72 hours for all tested concentrations and control. Test item concentrations differed by no more than $\pm 20\%$ from initial concentrations for 72 hours.

Results of range finding-test

In course of the test, test item have shown no apitoxic effect for larval mortality at all tested concentrations.

Test item have shown no statistically significant apitoxic effect for pupal mortality at all tested concentrations.

Test item have shown no statistically significant apitoxic effect for adults emergence at all tested concentrations.

Results of range-finding test calculated by ToxRat Professional		
Stadium	Parameter	Value
Larval mortality (day 8)	LOEC	>650 mg of test item/kg of food
	NOEC	≥ 650 mg of test item/kg of food
Pupal mortality (day 22)	LOEC	>650 mg of test item/kg of food
	NOEC	≥ 650 mg of test item/kg of food
Emerged adults (day 22)	LOEC	>650 mg of test item/kg of food*
	NOEC	≥ 650 mg of test item/kg of food
	LOED	>100 μ g of test item/larva*
	NOED	≥ 100 μ g of test item/larva

* values determined based on the analysis of the results

Final results

Table 18. Pupal mortality – definitive test

Concentration [mg of test item/kg of food]	Time [day]			
	8	15		22
	Alive larvae [pcs.]	Dead pupae [pcs.]	Intoxication signs	Dead pupae* [pcs.]
Control	36	1	stunted development – 1	3
650	35	2	stunted development – 1	4

* cumulative amount from day 15 to day 22

Table 19. Final pupal mortality results – definitive test

Concentration [mg of test item/kg of food]	Time [day]					
	15		22			
	Mortality [%]	Statistical significance ^{*)}	Mortality [%]	Statistical significance ^{*)}	LOEC [mg of test item/kg of food]	NOEC [mg of test item/kg of food]
Control	2.8	not applicable	8.3	not applicable	>650	≥650
650	5.7	-	11.4	-		

- statistically insignificant

*) values calculated using ToxRat Professional using Fisher's with significance level p>0.05

Table 20. Number of emerged adults – definitive test

Concentration [mg of test item/kg of food]	Dose [µg of test item/ larva]	Time [day]					
		3	22				Statistical significance ^{*)}
		Introduced larvae [pcs.]	Emerged adults [pcs.]	Number of emerged adults [%]	Unemerged adults [pcs.]	Number of unemerged adults [%]	
Control	Control	36	33	91.7	3	8.3	not applicable
650	100	36	31	86.1	5	13.9	-

- statistically insignificant

*) values calculated using ToxRat Professional using Fisher's with significance level p>0.05

Table 21. Larval mortality – reference test

Concentration [mg of reference item/kg of food]	Time [day]					
	3	22				
	Introduced larvae [pcs.]	Emerged adults [pcs.]	Number of emerged adults [%]	Unemerged adults [pcs.]	Number of unemerged adults [%]	Statistical significance ^{*)}
Control with acetone	36	32	88.9	4	11.1	not applicable
0.32	36	3	8.3	33	91.7	+

+ statistically significant

*) values calculated using ToxRat Professional using Fisher Test with significance level p>0.05

Final results calculated using ToxRat Professional

Parameter	Concentration [mg of test item/kg of food]	Parameter	Dose [µg of test item/larva]
LC ₁₀	n.d.** (n.d.– n.d.)*	LD ₁₀	n.d.*** (n.d.– n.d.)*
LC ₂₀	n.d.** (n.d.– n.d.)*	LD ₂₀	n.d.*** (n.d.– n.d.)*
LC ₅₀	n.d.** (n.d.– n.d.)*	LD ₅₀	n.d.*** (n.d.– n.d.)*
NOEC	n.d.**	NOED	n.d.***
LOEC	n.d.**	LOED	n.d.***

*	upper and lower confidence limits (95%) given in the brackets
LC ₁₀	test item concentration causing mortality of 10% population
LC ₂₀	test item concentration causing mortality of 20% population
LC ₅₀	test item concentration causing mortality of 50% population
NOEC	the highest test item concentration not causing statistically significant differences in relations to the control
LOEC	the lowest test item concentration causing statistically significant differences in relations to the control
LD ₁₀	test item dose causing mortality of 10% population
LD ₂₀	test item dose causing mortality of 20% population
LD ₅₀	test item dose causing mortality of 50% population
NOED	the highest test item dose not causing statistically significant differences in relations to the control
LOED	the lowest test item dose causing statistically significant differences in relations to the control
n.d.	impossible to determine due to mathematical reasons
**	based on the analysis of the results, the value was determined to be >650 mg of the test item/kg of food
***	based on the analysis of the results, the value was determined to be >100 µg of the test item/larva

Conclusion

In course of the test, the test item has not shown apitoxic effect in mortality of following developmental stages of bees after 22 days of the test.

At the end of the study, the concentration and the dose causing 10%, 20% and 50% mortality of the population in the test (LC₁₀, LC₂₀, LC₅₀ and LD₁₀, LD₂₀, LD₅₀ values) were estimated, as well as NOEC and NOED values were estimated at 22 day.

Based on the analysis of the results, the LC₁₀, LC₂₀, LC₅₀ and NOEC values were determined as >650 mg of the test item/kg of food, the LD₁₀, LD₂₀, LD₅₀ and NOED values were determined as >100 µg of the test item/larva.

Comments of zRMS:	The study was not evaluated since it was not essential for finishing risk assessment to bees. Annex II data should be evaluated by RMS and end points agreed at the stage of Annex I renewal.
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Reference:	KCA 8.3.1.3
Report	Zoxamide technical: Honey Bee (<i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions, Aguilar Alberola, J., 2023, Eurofins Trialcamp S.L.U., Report No.: S23-106642
Guideline(s):	OECD 239
Deviations:	The reduction of the relative humidity conditions from $95 \pm 5\%$ to $80 \pm 5\%$ was done on day 7 (D7) of the test instead of on day 8 (D8). The reported deviation to the guidance has no impact on the outcome of the study since validity criteria for the control were met.
GLP:	Yes
Acceptability:	Yes / No /Supportive

Materials and methods

Test item:	Zoxamide technical; Batch code: L20210418Z; active substance (a.s.): zoxamide; content of a.s.: $98.86 \pm 0.29\%$ w/w (content of active substance according to Certificate of Analysis); analytical certificate date: 24 May 2022; estimated retest date: 13 May 2026.
Reference item:	BAS 152 I; Batch code: COD-002332; active substance (a.s.): dimethoate; content of

a.s. analysed: 100.55 % w/w (100 % w/w was considered); expiry date: 25 Jan 2024.

Test organisms: Honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae not older than 30 hours at grafting time.

Source: Commercial beehives from the in-house test facility stock, adequately fed, healthy and as far as possible disease free and queen right. The hives from which the larvae were obtained were not previously exposed to any chemical treatments within four weeks of test initiation.

Preparation of test organisms and larvae collection: On D-3, the queens from at least three colonies were isolated for one day within a queen excluder placed on a single frame with empty cells in their own hive, to provide known aged eggs and subsequent larvae.

On D-2, maximum 30 hours after isolation, the queens were released. Frames containing eggs were left in the excluder cages until hatching (D1). Three frames from different hives, containing the highest number of synchronized larvae, were selected for grafting in the laboratory.

Test design: Dose response test with duration of 21 days from grafting on day 1 to the final assessment on day 22. From day 3 until day 6 of the test, 5 different concentrations of Zoxamide technical were applied to the larvae of the test item groups and one single concentration of the reference item was applied to the larvae of the reference item group. Both, test and reference item, were supplied in diet B (day 3) and C (days 4, 5 and 6). The daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period. The cumulative feeding volume from day 3 until day 6 of 140 µL diet per larva was considered for the calculation of the cumulative doses per larva.

Two control groups (negative and solvent controls) were included in the test and exposed for the same period of time under identical exposure conditions to the treatments. Each treatment group consisted of 48 larvae; 16 from each of three different colonies (each colony representing one replicate). Larval mortality assessments were on days 4, 5, 6, 7, and 8. The presence of uneaten food was qualitatively recorded on day 8. Assessment of mortality during pupation phase was on day 15 and assessment of emergence on day 22 was recorded.

Test concentrations and doses: Controls: C1: Negative control (untreated diet).
C2: Solvent control (diet containing 1.5 % acetone).

Test item: 36.13, 72.25, 144.51, 289.01 and 578.02 mg test item/L diet (equivalent to 32.84, 65.68, 131.37, 262.74 and 525.47 mg test item/kg diet and 5.06, 10.12, 20.23, 40.46 and 80.92 µg test item/larva, respectively).

The equivalences in active substance are 35.71, 71.43, 142.86, 285.72 and 571.43 mg zoxamide/L diet (equivalent to 32.47, 64.94, 129.87, 259.74 and 519.48 mg zoxamide/kg diet and 5.00, 10.00, 20.00, 40.00 and 80.00 µg zoxamide/larva, respectively).

Reference item: R: 48.00 mg dimethoate/kg diet (equivalent to 7.39 µg dimethoate/larva).

Test conditions: Air Temperature: 33.7* 35.0 °C

Relative humidity: 34.5* 97.6 %

*Short term deviation (<2 hours).

Exposure to light: Constant darkness except during feeding and assessments.

Analytical verification: Samples of the highest and lowest concentrations of the test item treated larval diet were taken from D3 to D6, directly after preparation, and placed in the freezer at < 18 °C until shipment.

Analytical Phase was performed to verify the concentration of the samples taken. A method was validated and samples of diet were analysed for concentration determination of zoxamide.

Quantification was performed by liquid chromatography with tandem mass spectrometry (LC-MS/MS). The limit of quantification (LOQ) of the analytical method was 3.00 mg/test item/kg (2.97 mg zoxamide/kg) with a limit of detection (LOD) set at 0.619 mg zoxamide/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Statistics: Mortality on D22 showed no statistically significant differences between the control groups (Fisher's exact binomial test, $\alpha = 0.05$, two sided), therefore, data of the solvent control (C2) was used for the analysis of this parameter.

In order to determine the NOEC, the χ^2 -2x2 table test with Bonferroni correction (one-sided greater, $\alpha = 0.05$) was used.

EC_x/ED_x values could not be calculated since no statistically significant concentration/response was obtained. Because on D22 the corrected mortality obtained was below 50 % in all the treatment groups, the EC₅₀ was empirically estimated from the results.

Statistical calculations were made with MS Excel v.365 and the statistical program ToxRatPro® Version 3.3.0.

Results and discussions

The measured concentration in the samples from treatment T1 was within 20 % of nominal test concentration. The analysed concentrations of treatment T5 from D3 and D4 were lower than nominal (mean recovery values from A and R samples were 71.9 and 79.2 % of nominal, respectively), while the

recoveries from D5 and D6 were within 20 % of nominal test concentration. Although the weighted average recovery of the samples was calculated as 89.4 % of the nominal value, as worst case scenario, the treatment T5 values have been adjusted for the analysed concentration (corrected values: 510.78 mg zoxamide/L diet, 464.34 mg zoxamide/kg diet and 71.51 µg zoxamide/larva, these are the values shown in this section from now on).

On day 8, the cumulative larval mortality was 4.2 % for the negative control (C1) and 14.6 % for the solvent control (C2). On day 22, the adult emergence rate of the initial grafted larvae was 79.2 % for the negative control and 75.0 % for the solvent control. Therefore, the validity criteria for the control groups were met for both test periods: The D8 mortality was lower than 15 % and the D22 days emergence rate was greater than 70 %, across all replicates. Cumulative mortality in the Reference Item group also met the validity criteria (> 50 % at day 8, actual value 89.6 %).

Mean corrected cumulative larval mortality on day 8 (D8) of the test item treated groups relative to the solvent control (C2) was 4.9, 7.3, 2.4, 4.9 and 7.3 % in 32.47, 64.94, 129.87, 259.74 and 464.34 mg zoxamide/kg diet, respectively.

Mean corrected pupal mortality on day 15 (D15) of the test item treated groups relative to the solvent control (C2) was 17.9, 25.6, 20.5, 17.9 and 12.8 % in 32.47, 64.94, 129.87, 259.74 and 464.34 mg zoxamide/kg diet, respectively.

Mean corrected mortality at the end of the test (D22) of the test item treated groups relative to the solvent control (C2) was 16.7, 25.0, 16.7, 22.2 and 13.9 % in 32.47, 64.94, 129.87, 259.74 and 464.34 mg zoxamide/kg diet, respectively.

On day 8, one organism in treatment T4 (259.74 mg zoxamide/kg diet) and two organisms in treatment T5 (464.34 mg zoxamide/kg diet) were observed with uneaten food. All these organisms were recorded as dead from the D15 assessment. At the end of the test, in the final assessment of the emergence on day 22, no emerged bees were recorded as being affected (i.e. malformation).

Main results are shown in the table below:

Treatment Group [mg a.s./kg diet]	Cumulative Mortality [%]						
	D4	D5	D6	D7	D8	D15	D22
C1 []	0.0	2.1	2.1	2.1	4.2	20.8	20.8
C2 []	4.2	4.2	8.3	14.6	14.6	18.8	25.0
T1 [32.47]	2.1	6.3	6.3	10.4	10.4	33.3	37.5
T2 [64.94]	0.0	8.3	18.8	18.8	20.8	39.6	43.8
T3 [129.87]	2.1	2.1	6.3	12.5	12.5	35.4	37.5
T4 [259.74]	2.1	6.3	12.5	18.8	18.8	33.3	41.7
T5 [464.34]	4.2	4.2	6.3	8.3	8.3	29.2	35.4
R [48.00] ^a	39.6	54.2	72.9	85.4	89.6	100.0	100.0

a.s.: active substance (zoxamide);

^a mg dimethoate/kg diet.

Treatment Group [mg a.s./kg diet]	Corrected mortality [%] ^a						
	D4	D5	D6	D7	D8	D15	D22

C1	[1]	-4.3	-2.2	-6.8	-14.6	-12.2	2.6	-5.6
T1	[32.47]	-2.2	2.2	-2.3	-4.9	-4.9	17.9	16.7
T2	[64.94]	-4.3	4.3	11.4	4.9	7.3	25.6	25.0
T3	[129.87]	-2.2	-2.2	-2.3	-2.4	-2.4	20.5	16.7
T4	[259.74]	-2.2	2.2	4.5	4.9	4.9	17.9	22.2
T5	[464.34]	0.0	0.0	-2.3	-7.3	-7.3	12.8	13.9

a.s.: active substance (zoxamide);

^a Corrected for solvent control (C2) according to Abbott's formula (1925), modified by Schneider-Orelli (1947);

Conclusion

The repeated exposure of the test item 'Zoxamide technical' to honey bee (*Apis mellifera* L.) was tested under laboratory conditions over a 21-day period.

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

The test item concentrations of treatment T1 were analytically confirmed. Although the weighted average recovery of the samples was calculated as 89.4 % of the nominal value, as worst case scenario, the treatment T5 values have been adjusted for the analysed concentration. Therefore, endpoints are shown adjusted for the mean analysed concentration.

On day 8, one organism in treatment T4 (259.74 mg zoxamide/kg diet) and two organisms in treatment T5 (464.34 mg zoxamide/kg diet) were observed with uneaten food. All these organisms were recorded as dead from the D15 assessment. At the end of the test, in the final assessment of the emergence on day 22, no emerged bees were recorded as being affected (i.e. malformation).

Main endpoints of the study are shown in the following table.

Endpoints	Concentration		Dose
	[mg a.s./L diet]	[mg a.s./kg diet] ^a	[µg a.s./larva] ^b
NOEC/NOED	≥510.78	≥464.34	≥71.51
LOEC/LOED	≥510.78	≥464.34	≥71.51
EC ₁₀ /ED ₁₀	Not determined	Not determined	Not determined
[95 % c.l.]	Not determined	Not determined	Not determined
EC ₂₀ /ED ₂₀	Not determined	Not determined	Not determined
[95 % c.l.]	Not determined	Not determined	Not determined
EC ₅₀ /ED ₅₀	≥510.78	≥464.34	≥71.51
[95 % c.l.]	Not determined	Not determined	Not determined

a.s.: active substance (zoxamide; 98.86 ± 0.29 % w/w); c.l.: confidence limits;

^a Based on the diet density (1.1 g/mL);

^b Based on the cumulative application volume of 140 µL/larva.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No data submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No data submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No data submitted.

A 2.3.2 KCP 10.3.2 Effects on arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Using artificial substrates

Comments of zRMS:	The study follows the guideline specified by Mead Briggs M.A. et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met The study is reliable for Risk Assessment purposes.
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Reference: KCP 10.3.2.1

Report GLOB2013F (Zoxamide 450 g/L SC): Effects on the Parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates, Leopold, J., 2022, Ibacon GmbH, Report No.: 169571001

Guideline(s): Mead-Briggs et al. 2000 and Mead-Briggs et al. 2010

Deviations: No

GLP: Yes

Acceptability: **Yes** / No / Supplementary

Materials and methods

Test Item: GLOB2013F (Zoxamide 450 g/L SC); batch no.: CES 4648; analysed content of a.s.: 448.0 g/L zoxamide.

Test Species: Parasitoid (*Aphidius rhopalosiphi*), adults not older than 48 hours; source: Katz Biotech AG, Baruth, Germany.

Test Design: This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 4 replicates each containing 10 adult parasitoids. The parasitoids were exposed to dried residues on treated glass plates. Survival of the parasitoids was assessed after 2, 24 and 48 hours. After 48 hours, for treatment groups where the corrected mortality was ≤ 50 % the reproductive capacity was assessed by confining females individually over untreated barley plants infested with the host cereal aphids, *Rhopalosiphum padi*. The females were removed after 24 hours and the aphid-infested plants left for a further 11 - 12 days before the numbers of aphid mummies that had developed were assessed.

Endpoints: Mortality of exposed parasitoids; additionally, reproductive capacity for female survivors.

Validity Criteria:

- Control mortality should be ≤ 13 %.
- Reference item mortality should be ≥ 50 % corrected mortality.
- Mean reproduction rate of control treatment should be ≥ 5 mummies per

	female.
	– No more than 2 female parasitoids should produce zero values.
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L).
Test Rates:	Control, 173, 345, 690, 1380 and 2760 mL product/ha and reference item. The reference item was applied at an application rate of 0.3 mL Danadim Progress/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto glass plates <i>via</i> laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 20 - 22 °C; relative humidity: 73 - 80 % (acclimatisation and exposure period), 76 - 84 % (post-exposure period, within the test units); photoperiod: 16 h light : 8 h dark; light intensity: 730 - 1570 lux (acclimatisation, exposure and parasitisation period), 14790 - 17690 lux (post-parasitisation period).
Statistics:	Mortality: Bonferroni-Holm Fisher's Exact Binomial Test, Fisher's Exact Binomial Test (both one-sided greater, $\alpha = 0.05$). Reproduction: Dunnett's t-Test, (one-sided smaller, $\alpha = 0.05$).

Results and discussions

The mean mortality of *Aphidius rhopalosiphi* was 0.0 % in the control treatment and ranged from 0.0 to 2.5 % in the test item treatments. Mortality was not statistically significantly increased compared to the control up to and including the highest application rate of 2760 mL product/ha (Bonferroni-Holm Fisher's Exact Binomial Test, one-sided greater, $\alpha = 0.05$, see Table 2).

The reference item applied at a rate of 0.3 mL Danadim Progress/ha produced a statistically significant corrected mortality of 100.0 % after 48 hours (Fisher's Exact Binomial Test, one-sided greater, $\alpha = 0.05$).

No behavioural abnormalities (affected and/or moribund parasitoids) were observed at any test item application rate after 2, 24 or 48 hours.

Table 2. Mortality and parasitisation efficiency of the parasitoid wasp *Aphidius rhopalosiphi*

	Rate ¹⁾ [mL product/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	0	0.0	--	35.8	--
GLOB2013F	173	0.0 n.s.	0.0	37.7 n.s.	-5.2
GLOB2013F	345	0.0 n.s.	0.0	35.1 n.s.	1.9
GLOB2013F	690	0.0 n.s.	0.0	39.8 n.s.	-11.3
GLOB2013F	1380	0.0 n.s.	0.0	33.9 n.s.	5.4
GLOB2013F	2760	2.5 n.s.	2.5	42.3 n.s.	-18.1
Endpoints ⁶⁾					
	test item [mL product/ha]		zoxamide [g a.s./ha]		
Mortality: LR ₅₀ Value (95 % CL)	> 2760		> 1236		
NOER for Mortality	≥ 2760		≥ 1236		
LOER for Mortality	> 2760		> 1236		
Reproduction: ER ₅₀ Value	> 2760		> 1236		
NOER for Reproduction	≥ 2760		≥ 1236		
LOER for Reproduction	> 2760		> 1236		

1) Application rate in 200 L spray volume/ha

2) Mortality: after 48 hours of exposure to spray residues on glass plates,
(Bonferroni-Holm Fisher's Exact Test, one-sided greater, $\alpha = 0.05$; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli

4) Reproduction: mean number of parasitised aphids/female,
(Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

6) LR₅₀ and ER₅₀ values could not be calculated as no mortality or effects on reproduction above 50 % were noted.

Reproduction of *A. rhopalosiph*i was assessed in the control and all test item application rates. The mean reproduction rate was 35.8 mummies per female in the control and was between 33.9 and 42.3 mummies per female in the test item treatments, corresponding to a reduction of 5.4 to -18.1 % compared to the control. Reproduction was not statistically significantly reduced compared to the control up to and including the highest application rate of 2760 mL product/ha (Dunnett's t-test, one-sided smaller, $\alpha = 0.05$).

Validity criteria:

The reference item applied at a rate of 0.3 mL Danadim Progress/ha produced a statistically significant corrected mean mortality of 100.0 % after 48 hours (should be ≥ 50 % corrected mortality). The mean control mortality was 0.0 % after 48 hours of exposure (should not exceed 13 %). The mean control reproduction rate was 35.8 mummies per female (should be ≥ 5.0 mummies per female). One female parasitoid produced zero values in the control treatment (no more than 2 female parasitoids producing zero values). All validity criteria were met.

Conclusion

Under worst case laboratory conditions the LR₅₀ value of GLOB2013F (Zoxamide 450 g/L SC) for mortality is estimated to be greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha. The NOER (no observed effect rate) for mortality is equal to or greater than 2760 mL product/ha, equivalent to ≥ 1236 g a.s./ha, and the LOER (lowest observed effect rate) is greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha.

Reproduction of *Aphidius rhopalosiph*i was assessed in the control and at all test item application rates. Reproduction was not affected up to and including the highest application rate of 2760 mL product/ha. The ER₅₀ value of GLOB2013F (Zoxamide 450 g/L SC) for reproduction is estimated to be greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha. The NOER is equal to or greater

than 2760 mL product/ha, equivalent to ≥ 1236 g a.s./ha, and the LOER is greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha.
All validity criteria were met. The study is considered valid.

Comments of zRMS:	<p>The study follows the guideline specified by Blümel S. et al., 2000 and according to the principles of GLP. No deviations to the guideline were noted. All the validity criteria were met as follows:</p> <ul style="list-style-type: none"> - The control mortality was 10.0 % after 7 days (should not exceed 20 %). - The mean control reproduction rate was 7.8 eggs per female after 14 days (should be ≥ 4 eggs per female in the second week). - The reference item applied at a rate of 9.0 mL Danadim Progress/ha produced a statistically significant corrected mortality 100 % after 7 days (should be ≥ 50 % corrected mortality). <p>The study is reliable for Risk assessment purposes.</p>
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Reference:	KCP 10.3.2.1
Report	GLOB2013F (Zoxamide 450 g/L SC): Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates
Guideline(s):	Blümel <i>et al.</i> 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	GLOB2013F (Zoxamide 450 g/L SC); batch no.: CES 4648; analysed content of a.s.: 448.0 g/L zoxamide.
Test Species:	Predatory Mite (<i>Typhlodromus pyri</i>), protonymphs not older than 24 hours; source: Katz Biotech AG, Baruth, Germany.
Test Design:	This study comprised 7 treatment groups (5 application rates of the test item, control, reference item) with 3 replicates each containing 20 mites. The mites were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups where the corrected mortality was ≤ 50 % were sexed and the number of eggs per female was recorded at 3 assessment days within one week.
Endpoints:	Mortality after 7 days of exposure; additionally, reproduction capacity for survived mites.
Validity Criteria:	<ul style="list-style-type: none"> – Control mortality should not exceed 20 % on day 7 after exposure. – Reference item mortality should result in at least 50 % corrected mortality on day 7 after exposure. – Control reproductions (number of eggs per female) should be ≥ 4 eggs for the second week.
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L).
Test Rates:	Control, 173, 345, 690, 1380 and 2760 mL product/ha and reference item. The reference item was applied at an application rate of 9.0 mL Danadim Progress/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto glass plates via laboratory spraying

equipment, which were then air dried.

Test Conditions: Temperature: 24 - 26 °C; relative humidity: 67 - 70 %; photoperiod: 16 h light : 8 h dark; light intensity: 280 - 400 lux.

Statistics: Mortality: Chi² 2x2 Table Test with Bonferroni Correction, Fisher's Exact Binomial Test (one-sided greater, $\alpha = 0.05$).

Reproduction: Dunnett's t-Test, (one-sided smaller, $\alpha = 0.05$).

Results and discussions

The mean mortality of *Typhlodromus pyri* was 10.0 in the control treatment and ranged from 10.0 to 21.7 % in the test item treatments, corresponding to corrected mortalities of 0.0 to 13.0 %. Mortality was not statistically significantly increased compared to the control up to and including the highest application rate of 2760 mL product/ha (Chi² 2x2 Table Test with Bonferroni Correction, one-sided greater, $\alpha = 0.05$, see Table 3).

The reference item applied at a rate of 9.0 mL Danadim Progress/ha produced a statistically significant mortality of 100.0 % (corrected mortality 100.0 %) after 7 days (Fisher's Exact Binomial Test, one-sided greater, $\alpha = 0.05$).

Table 3. Mortality and reproduction of the mites

	Rate ¹⁾ [mL product/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female]	Effect on reproduction ⁵⁾ [%]
Control	0	10.0	-	7.8	-
GLOB2013F	173	15.0 n.s.	5.6	7.7 n.s.	0.7
GLOB2013F	345	10.0 n.s.	0.0	7.8 n.s.	0.0
GLOB2013F	690	21.7 n.s.	13.0	8.1 n.s.	-4.6
GLOB2013F	1380	15.0 n.s.	5.6	8.1 n.s.	-4.7
GLOB2013F	2760	13.3 n.s.	3.7	5.6 n.s.	28.5
Endpoints ⁶⁾					
	test item [mL product/ha]		zoxamide [g a.s./ha]		
Mortality: LR ₅₀ Value .	> 2760		> 1236		
NOER for Mortality	≥ 2760		≥ 1236		
LOER for Mortality	> 2760		> 1236		
Reproduction: ER ₅₀ Value.	> 2760		> 1236		
NOER for Reproduction	≥ 2760		≥ 1236		
LOER for Reproduction	> 2760		> 1236		

1) Application rate in 200 L spray volume/ha

2) Mortality: after 7 days of exposure to spray residues on glass plates

(Chi² 2x2 Table Test with Bonferroni Correction; one-sided greater; $\alpha = 0.05$; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli;

4) Reproduction: mean number of eggs/female,

(Dunnett's t-Test; one-sided smaller; $\alpha = 0.05$; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

6) LR₅₀ and ER₅₀ values could not be calculated as no mortality or effects on reproduction above 50 % were noted.

Reproduction of *T. pyri* was assessed in the control and at all test item application rates. The mean reproduction rate was 7.8 eggs per female in the control treatment. In the test item treatments, reproduction was between 5.6 and 8.1 eggs per female, corresponding to a reduction of -4.7 and 28.5 %. Reproduction was not statistically significantly reduced compared to the control up to and including the highest application rate of 2760 mL product/ha (Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$).

Validity criteria:

The reference item applied at a rate of 9.0 mL Danadim Progress/ha produced a statistically significant corrected mortality of 100.0 % after 7 days (should be ≥ 50 % corrected mortality). The control mortality was 10.0 % after 7 days (should not exceed 20 %). The mean control reproduction rate was 7.8 eggs per female after 14 days (should be ≥ 4 eggs per female in the second week). All validity criteria were met.

Conclusion

Under worst case laboratory conditions the LR_{50} value of GLOB2013F (Zoxamide 450 g/L SC) for mortality is estimated to be greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha. The NOER (no observed effect rate) for mortality is equal to or greater than 2760 mL product/ha, equivalent to ≥ 1236 g a.s./ha, and the LOER (lowest observed effect rate) is greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha.

Reproduction of *Typhlodromus pyri* was assessed in the control and at all test item application rates. Reproduction was not affected up to and including the highest application rate of 2760 mL product/ha. The ER_{50} value of GLOB2013F (Zoxamide 450 g/L SC) for reproduction is estimated to be greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha. The NOER is equal to or greater than 2760 mL product/ha, equivalent to ≥ 1236 g a.s./ha, and the LOER is greater than 2760 mL product/ha, equivalent to > 1236 g a.s./ha, in 200 L water/ha.

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

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory tests

No data submitted.

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

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	<p>The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study.</p> <p>In the definitive test all the validity criteria were met according to OECD 222:</p> <ul style="list-style-type: none"> - each replicate produced 47 to 121 juveniles (mean) at the end of the study (criterion: ≥ 30 juveniles by the end of the study), - the coefficient of variation of reproduction was 27.4 % (criterion: $\leq 30\%$), - adult mortality over the initial 4 weeks of the experiment was 0 % (criterion: $\leq 10\%$).
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Reference: KCP 10.4.1.1

Report GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction and Growth of Earthworms *Eisenia andrei* in Artificial Soil, Straube, D., 2022, Ibacon Gmbh, Report No.: 169571022

Guideline(s): OECD 222

Deviations: No

GLP: Yes

Acceptability: Yes / No / Supplementary

Materials and methods

Test Item:	GLOB2013F (Zoxamide 450 g/L SC); batch no.: CES 4648; content of a.i.: 448.0 g/L Zoxamide (authenticated)
Test Species:	Earthworm (<i>Eisenia andrei</i> , Bouché, 1972), adult earthworms (with clitellum and weight range 300 mg to 594 mg), approximately 7 to 8 months old, source: from an in-house culture.
Test Design:	56-day test in treated artificial soil prepared according to OECD 222; different concentrations of the test item were incorporated into the soil; 9 treatment groups (8 test item concentrations, control); 4 replicates for the test item treatments and 8 replicates for the control with 10 earthworms each. Assessment of adult earthworm mortality, behavioural effects and biomass development was carried out after 28 days exposure of adult earthworms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application).
Endpoints:	Mortality, weight change, feeding activity and reproduction rate were determined.
Reference Item:	Carbendazim (600 g/L nominal). The effects of the reference item were investigated in a separate GLP study.
Test Concentrations:	Control, 0.37, 0.60, 0.95, 1.53, 2.44, 3.91, 6.25 and 10.0 mg GLOB2013F (Zoxamide 450 g/L SC)/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 222; initial pH 5.8 to 6.0, pH at experimental end 6.3; water content 21.5% to 27.3% (43.0% to 54.5% of maximum water holding capacity, WHC) at experimental start and 26.3% to 30.1% (52.5% to 60.2% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux.
Statistics:	Standard procedures, Dunnett's t-test (body weight changes), Welsh t-test after Bonferroni-Holm and Logit Analysis (reproduction).

Results and discussions

All study validity criteria were met.

No mortality was observed in any treatment group.

The body weight changes of the earthworms after 28 days exposure to GLOB2013F (Zoxamide 450 g/L SC) were not statistically significantly different compared to the control up to and including the highest test concentration of 10.0 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, two-sided).

The reproduction rates were not statistically significantly different compared to the control up to and including the highest test concentration of 10.0 mg test item/kg soil dry weight (Welsh t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller).

No behavioural abnormalities were observed in any of the treatment groups.

The feeding activity in all the treated groups was comparable to the control (see Table 1).

Table 4. Effect of GLOB2013F (Zoxamide 450 g/L SC) on earthworms (*Eisenia andrei*) in a 56-day reproduction study

GLOB2013F (Zoxamide 450 g/L SC) [mg test item/kg soil dry weight]	Control	0.37	0.60	0.95	1.53	2.44	3.91	6.25	10.0
Mortality (day 28) [%]	0	0	0	0	0	0	0	0	0
Statistical Significance	-	-	-	-	-	-	-	-	-
Body weight change (day 28) [%]	38.5	36.6	37.1	41.1	38.3	41.4	34.0	44.3	42.3
Statistical Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	82	99	95	89	81	81	81	65	61
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Reproduction in [%] of control (day 56)	-	120	115	108	98	99	99	78	73
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg test item/kg soil dry weight]									
NOEC (day 28 mortality)	≥10.0								
LOEC (day 28 mortality)	>10.0								
LC ₅₀ ³⁾	>10.0								
NOEC (day 28 weight)	≥10.0								
LOEC (day 28 weight)	>10.0								
NOEC (day 56 reproduction)	≥10.0								
LOEC (day 56 reproduction)	>10.0								
EC ₁₀ ⁴⁾	n.d.								
EC ₂₀ ⁴⁾	n.d.								
EC ₅₀ ³⁾	>10.0								

The results represent rounded values calculated from the exact raw data.

- = not applicable

n.s. = not significantly different compared to the control

n.d. = not determined

¹⁾ Dunnett's t-test, $\alpha = 0.05$, two-sided

²⁾ Welch t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller

³⁾ estimated value

⁴⁾ At the two highest concentrations a reduction of reproduction of 22% and 27% was observed. This reduction is smaller than the acceptable CoV for the control replicates which determines the validity of the test. To obtain a realistic EC values calculation, effects of 50% reduction of reproduction or higher should have been detected.

Conclusion

In an earthworm reproduction and growth study with GLOB2013F (Zoxamide 450 g/L SC) the No Observed Effect Concentration (NOEC) for mortality, weight changes and reproduction of the earthworm *Eisenia andrei* was determined to be ≥10.0 mg test item/kg soil dry weight, *i.e.* the highest concentration tested. The Lowest Observed Effect Concentration (LOEC) for mortality, weight changes and reproduction was estimated to be >10.0 mg test item/kg soil dry weight. The LC₅₀ was estimated to be >10.0 mg test item/kg soil dry weight. No meaningful EC₁₀ and EC₂₀ could be determined as no adequate dose response was observed. The EC₅₀ was estimated to be >10.0 mg test item/kg soil dry weight.

Comments of zRMS:	<p>The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study.</p> <p>In the definitive test all the validity criteria were met according to OECD 222:</p> <ul style="list-style-type: none"> - each replicate produced 79 to 138 juveniles (mean) at the end of the study (criterion: ≥ 30 juveniles by the end of the study), - the coefficient of variation of reproduction was 17.6 % (criterion: ≤ 30%), - adult mortality over the initial 4 weeks of the experiment was 0 %
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	(criterion: $\leq 10\%$).
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Reference:	KCA 8.4.1
Report	RH-24549: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Straube, D., 2023, Ibacon GmbH, Report No.: 166191022
Guideline(s):	OECD 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	RH-24549; batch no.: C47360/1; purity: 97.9% by titration
Test Species:	Earthworm (<i>Eisenia andrei</i> , Bouché, 1972), adult earthworms (with clitellum and weight range 302 to 598 mg), approximately 8 to 9 months old, source: from an in-house culture.
Test Design:	56-day test in treated artificial soil prepared according to OECD 222; different concentrations of the test item were incorporated into the soil; 9 treatment groups (8 test item concentrations, control); 4 replicates for the test item treatments and 8 replicates for the control with 10 earthworms each. Assessment of adult earthworm mortality, behavioural effects and biomass development was carried out after 28 days exposure of adult earthworms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application).
Endpoints:	Mortality, weight change, feeding activity and reproduction rate were determined.
Reference Item:	Carbendazim (600 g/L nominal). The effects of the reference item were investigated in a separate GLP study.
Test Concentrations:	Control, 0.408, 0.735, 1.32, 2.38, 4.29, 7.72, 13.9 and 25.0 mg RH-24549/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 222; initial pH 5.9 to 6.1, pH at experimental end 6.1 to 6.3; water content 25.3% to 26.5% (50.6% to 53.0% of maximum water holding capacity, WHC) at experimental start and 24.4% to 26.3% (48.9% to 52.5% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux.
Statistics:	Standard procedures, Dunnett's t-test (body weight changes), Williams t-test (reproduction).

Results and discussions

All study validity criteria were met.

No mortality was observed in any treatment group.

The body weight changes of the earthworms after 28 days exposure to RH-24549 were not statistically significantly different compared to the control up to and including the highest test concentration of 25.0 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, two-sided).

The reproduction rates were not statistically significantly different compared to the control up to and including the test concentration of 13.9 mg test item/kg soil dry weight (Williams t-test, $\alpha = 0.05$, one-sided smaller). At the test concentration of 25.0 mg test item/kg soil dry weight reproduction was statistically significantly reduced compared to the control.

No behavioural abnormalities were observed in any of the treatment groups.
The feeding activity in all the treated groups was comparable to the control (see Table 1).

Table 5. Effect of RH-24549 on earthworms (*Eisenia andrei*) in a 56-day reproduction study

RH-24549 [mg test item/kg soil dry weight]	Control	0.408	0.735	1.32	2.38	4.29	7.72	13.9	25.0
Mortality (day 28) [%]	0	0	0	0	0	0	0	0	0
Statistical Significance	-	-	-	-	-	-	-	-	-
Body weight change (day 28) [%]	54.0	61.5	58.3	54.1	52.8	46.7	62.3	48.2	52.0
Statistical Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	102	110	94	82	91	93	96	92	75
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	*
Reproduction in [%] of control (day 56)	-	108	93	80	89	91	95	90	74
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg test item/kg soil dry weight]									
NOEC (day 28 mortality)	≥25.0								
LOEC (day 28 mortality)	>25.0								
LC ₅₀ ³⁾	>25.0								
NOEC (day 28 weight)	≥25.0								
LOEC (day 28 weight)	>25.0								
NOEC (day 56 reproduction)	13.9								
LOEC (day 56 reproduction)	25.0								
EC ₁₀	n.d.								
EC ₂₀	n.d.								
EC ₅₀ ³⁾	>25.0								

The results represent rounded values calculated from the exact raw data.

- = not applicable

n.s. = not significantly different compared to the control

n.d. = The EC₁₀ and EC₂₀ could not be statistically determined or estimated as no statistically significant concentration/response was found

* = significantly different compared to the control

¹⁾ Dunnett's t-test, $\alpha = 0.05$, two-sided

²⁾ Williams t-test, $\alpha = 0.05$, one-sided smaller

³⁾ estimated value

Conclusion

In an earthworm reproduction and growth study with RH-24549 the No Observed Effect Concentration (NOEC) for mortality and weight changes of the earthworm *Eisenia andrei* was determined to be ≥25.0 mg test item/kg soil dry weight, *i.e.* the highest concentration tested. The Lowest Observed Effect Concentration (LOEC) for mortality and weight changes was estimated to be >25.0 mg test item/kg soil dry weight. The LC₅₀ was estimated to be >25.0 mg test item/kg soil dry weight.

The NOEC for reproduction was determined to be 13.9 mg test item/kg soil dry weight. The LOEC for reproduction was determined to be 25.0 mg test item/kg soil dry weight. The EC₁₀ and EC₂₀ could not be statistically determined or estimated as no statistically significant concentration/response was found. The EC₅₀ was estimated to be >25.0 mg test item/kg soil dry weight.

Comments of zRMS:	<p>The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study.</p> <p>In the definitive test all the validity criteria were met according to OECD 222:</p> <ul style="list-style-type: none"> - each replicate produced 138 to 184 juveniles (mean) at the end of the study (criterion: ≥ 30 juveniles by the end of the study), - the coefficient of variation of reproduction was 10.3 % (criterion: $\leq 30\%$), - adult mortality over the initial 4 weeks of the experiment was 0 % (criterion: $\leq 10\%$).
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Reference:	KCA 8.4.1
Report	RH-127450: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Straube, D., 2023, Ibacon GmbH, Report No.: 175161022
Guideline(s):	OECD 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	RH-127450; batch no.: GD-003486-01; purity: 100%
Test Species:	Earthworm (<i>Eisenia andrei</i> , Bouché, 1972), adult earthworms (with clitellum and weight range 329 to 600 mg), approximately 10 months old, source: from an in-house culture.
Test Design:	56-day test in treated artificial soil prepared according to OECD 222; different concentrations of the test item were incorporated into the soil; 9 treatment groups (8 test item concentrations, control); 4 replicates for the test item treatments and 8 replicates for the control with 10 earthworms each. Assessment of adult earthworm mortality, behavioural effects and biomass development was carried out after 28 days exposure of adult earthworms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application).
Endpoints:	Mortality, weight change, feeding activity and reproduction rate were determined.
Reference Item:	Carbendazim (600 g/L nominal). The effects of the reference item were investigated in a separate GLP study.
Test Concentrations:	Control, 0.408, 0.735, 1.32, 2.38, 4.29, 7.72, 13.9 and 25.0 mg RH-127450/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 222; initial pH 6.0 to 6.2, pH at experimental end 5.9 to 6.1; water content 24.8% to 26.2% (49.6% to 52.4% of maximum water holding capacity, WHC) at experimental start and 25.5% to 27.1% (51.0% to 54.3% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h dark, light intensity: within the range of 400 lux to 800 lux.
Statistics:	Standard procedures, Fisher's Exact Test (mortality), Williams t-test (body weight changes), Dunnett's t-test (reproduction).

Results and discussions

All study validity criteria were met.

A slight mortality of 2.5% was found at the test concentration of 1.32 mg test item/kg soil dry weight, which was not statistically significantly different compared to the control, where 0% of the earthworms died (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

The body weight changes of the earthworms after 28 days exposure to RH-127450 were not statistically significantly different compared to the control up to and including the highest test concentration of 25.0 mg test item/kg soil dry weight (Williams t-test, $\alpha = 0.05$, one-sided smaller).

The reproduction rates were not statistically significantly different compared to the control up to and including the highest test concentration of 25.0 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, one-sided smaller). At the test concentration of 0.408 mg test item/kg soil dry weight an incidental reduction of reproduction of 25.2% was observed, which was statistically significantly reduced compared to the control, but determined to be not biological relevant as at the higher test concentrations (up to and including 13.9 mg test item/kg soil dry weight) no reduction of reproduction was observed.

No behavioural abnormalities were observed in any of the treatment groups.

The feeding activity in all the treated groups was comparable to the control (see Table 1).

Table 6. Effect of RH-127450 on earthworms (*Eisenia andrei*) in a 56-day reproduction study

RH-127450 [mg test item/kg soil dry weight]	Control	0.408	0.735	1.32	2.38	4.29	7.72	13.9	25.0
Mortality (day 28) [%]	0	0	0	2.5	0	0	0	0	0
Statistical Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Body weight change (day 28) [%]	19.6	22.2	22.0	16.1	26.5	25.5	27.0	30.2	26.4
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	156	117	156	176	134	133	124	124	115
Statistical Significance ³⁾	-	* ^a	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	*
Reproduction in [%] of control (day 56)	-	74.8	100	113	85.9	85.4	79.3	79.3	73.4
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg test item/kg soil dry weight]									
NOEC (day 28 mortality)	≥25.0								
LOEC (day 28 mortality)	>25.0								
LC ₅₀ ⁴⁾	>25.0								
NOEC (day 28 weight)	≥25.0								
LOEC (day 28 weight)	>25.0								
NOEC (day 56 reproduction)	13.9								
LOEC (day 56 reproduction)	25.0								
EC ₁₀	n.d.								
EC ₂₀	n.d.								
EC ₅₀ ⁴⁾	>25.0								

The results represent rounded values calculated from the exact raw data.

- = not applicable

^a = statistically significantly reduced compared to the control, but determined to be incidental and not biological relevant as at the higher test concentrations no statistically significant effect on reproduction was observed

n.s. = not significantly different compared to the control

n.d. = The EC₁₀ and EC₂₀ could not be statistically determined or estimated as no statistically significant concentration/response was found

* = significantly different compared to the control

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

²⁾ Williams t-test, $\alpha = 0.05$, one-sided smaller

³⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

⁴⁾ estimated value

Conclusion

In an earthworm reproduction and growth study with RH-127450 the No Observed Effect Concentration (NOEC) for mortality and weight changes of the earthworm *Eisenia andrei* was determined to be ≥25.0

mg test item/kg soil dry weight, *i.e.* the highest concentration tested. The Lowest Observed Effect Concentration (LOEC) was estimated to be >25.0 mg test item/kg soil dry weight. The LC₅₀ was estimated to be >25.0 mg test item/kg soil dry weight.

The NOEC for reproduction was determined to be 13.9 mg test item/kg soil dry weight. The LOEC for reproduction was determined to be 25.0 mg test item/kg soil dry weight.

The EC₁₀ and EC₂₀ could not be statistically determined or estimated as no statistically significant concentration/response was found. The EC₅₀ was estimated to be >25.0 mg test item/kg soil dry weight.

Comments of zRMS:	<p>The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation were noted during the study.</p> <p>In the definitive test all the validity criteria were met:</p> <ul style="list-style-type: none"> - each replicate produced 92 to 148 juveniles (mean) at the end of the study (criterion: ≥ 30 juveniles by the end of the study), - the coefficient of variation of reproduction was 20.1% (criterion: $\leq 30\%$), - adult mortality over the initial 4 weeks of the experiment was 0 % (criterion: $\leq 10\%$).
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Reference:	KCA 8.4.1
Report	RH-163353: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Straube, D., 2023, Ibacon GmbH, Report No.: 175171022
Guideline(s):	OECD 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

Test Item:	RH-163353; batch no.: GD-003454-02; Purity: 100%
Test Species:	Earthworm (<i>Eisenia andrei</i> , Bouché, 1972), adult earthworms (with clitellum and weight range 328 to 600 mg), approximately 9 months old, source: from an in-house culture.
Test Design:	56-day test in treated artificial soil prepared according to OECD; different concentrations of the test item were incorporated into the soil; 9 treatment groups (8 test item concentrations, control); 4 replicates for the test item treatments and 8 replicates for the control with 10 earthworms each. Assessment of adult earthworm mortality, behavioural effects and biomass development was carried out after 28 days exposure of adult earthworms in treated artificial soil. Reproduction rate (number of offspring) was assessed after additional 28 days (assessed 56 days after application).
Endpoints:	Mortality, weight change, feeding activity and reproduction rate were determined.
Reference Item:	Carbendazim (600 g/L nominal). The effects of the reference item were investigated in a separate GLP study.
Test Concentrations:	Control, 0.408, 0.735, 1.32, 2.38, 4.29, 7.72, 13.9 and 25.0 mg RH-163353/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 222; initial pH 5.9 to 6.2, pH at experimental end 6.2 to 6.3; water content 26.2% to 27.2% (53.5% to 55.4% of maximum water holding capacity, WHC) at experimental start and 25.3% to 27.0% (51.7% to 55.2% of the maximum WHC) at experimental end; temperature: within the range of 18 °C to 22 °C; photoperiod: 16 h light : 8 h

Statistics: dark, light intensity: within the range of 400 lux to 800 lux.
Standard procedures, Fisher's Exact Test (mortality), Dunnett's t-test (body weight changes and reproduction).

Results and discussions

All study validity criteria were met.

A slight mortality of 3% was found at the concentration of 7.72 mg test item/kg soil dry weight, respectively, which was not statistically significantly different compared to the control, where 0% of the earthworms died (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

The body weight changes of the earthworms after 28 days exposure to RH-163353 were not statistically significantly different compared to the control up to and including the highest test concentration of 25.0 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, two-sided).

The reproduction rates were not statistically significantly different compared to the control up to and including the highest test concentration of 25.0 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, one-sided smaller). No behavioural abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control (see Table 1).

Table 7. Effect of RH-163353 on earthworms (*Eisenia andrei*) in a 56-day reproduction study

RH-163353 [mg test item/kg soil dry weight]	Control	0.408	0.735	1.32	2.38	4.29	7.72	13.9	25.0
Mortality (day 28) [%]	0	0	0	0	0	0	3	0	0
Statistical Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Body weight change (day 28) [%]	21.2	20.8	26.1	21.3	28.5	29.4	22.9	26.0	26.6
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	114	111	138	120	129	102	92	107	116
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Reproduction in [%] of control (day 56)	-	98	121	106	113	89	81	94	102
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Endpoints [mg test item/kg soil dry weight]									
NOEC (day 28 mortality and weight)	≥25.0								
LOEC (day 28 mortality and weight)	>25.0								
LC ₅₀ ³⁾	>25.0								
NOEC (day 56 reproduction)	≥25.0								
LOEC (day 56 reproduction)	>25.0								
EC ₅₀ ³⁾	>25.0								

The results represent rounded values calculated from the exact raw data.

- = not applicable

n.s. = not significantly different compared to the control

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

²⁾ Dunnett's t-test, $\alpha = 0.05$, two-sided for weight changes and one-sided smaller for reproduction

³⁾ estimated value

Conclusion

In an earthworm reproduction and growth study with RH-163353 the No Observed Effect Concentration (NOEC) for mortality, weight changes and reproduction of the earthworm *Eisenia andrei* was determined to be ≥25.0 mg test item/kg soil dry weight, *i.e.* the highest concentration tested. The Lowest Observed Effect Concentration (LOEC) was estimated to be >25.0 mg test item/kg soil dry weight. The LC₅₀ and EC₅₀ were estimated to be >25.0 mg test item/kg soil dry weight.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No data submitted.

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

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	<p>The study was conducted to OECD guideline 232 and according to the principles of GLP. No deviations from the guideline occurred.</p> <p>The results are considered valid because the following criteria were satisfied in the controls:</p> <ul style="list-style-type: none"> - mean adult mortality: 8.0 % (criterion: $\leq 20\%$), - the mean number of juveniles per vessel at the end of the test: 1297 (criterion: ≥ 100 juveniles at the end of the test), - the coefficient of variation calculated for the number of juveniles: 21.8 % (criterion: $\leq 30\%$)
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Reference:	KCP 10.4.2.1
Report	GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil, Straube, D., 2022, Ibacon Gmbh, Report No.: 169571016 169571089
Guideline(s):	OECD 232
Deviations:	No
GLP:	Yes
Acceptability:	Yes/ No / Supplementary

Materials and methods

Test Item:	GLOB2013F (Zoxamide 450 g/L SC); batch no.: CES 4648; content of a.i.: 448.0 g/L Zoxamide (authenticated)
Test Species:	Collembola <i>Folsomia candida</i> , 10 - 12 days old, from cultures held at the laboratory.
Test Design:	28-day exposure in treated artificial soil. Different concentrations of the test item were mixed homogeneously into the soil which was placed into glass vessels before the Collembola were introduced on top of the soil; 8 concentrations and one control were tested; 4 replicates/concentration with 10 Collembola each (8 replicates for the control). Feeding of Collembola with approximately 2 mg dry yeast for each test vessel at the beginning of the test and on day 14. Assessment of adult mortality, behavioural effects and reproduction was performed after 28 days.
Endpoints:	Mortality of adult Collembola, behavioural effects, number of juveniles.
Reference Item:	Boric acid (the effects of the reference item were investigated in a separate GLP study).
Test Concentrations:	Control, 16.3, 29.4, 52.9, 95.3, 171, 309, 556 and 1000 mg GLOB2013F (Zoxamide 450 g/L SC)/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 232; pH at experimental start 6.0 to 6.1, pH

at experimental end 5.7 to 6.0; water content at experimental start 17.1% to 17.8% (50.4% to 52.4% of the maximum water holding capacity); water content at experimental end 15.0% to 16.3% (44.0% to 47.9% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark, light intensity within the range of 400 to 800 lux.

Statistics: Standard procedures, Fisher's Exact Test (mortality), Welsh t-test after Bonferroni-Holm (reproduction).

Results and discussions

A mortality of up to 18% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where 8% of the Collembola died (Fisher's Exact test, $\alpha = 0.05$, one-sided greater).

Table 3. Mortality of Adult Collembola after 28 days

Treatment Group	Number of Surviving Adults per Replicate								Mean Mortality [%]	Standard Deviation	Significance ¹
	1	2	3	4	5	6	7	8			
Control	10	8	7	10	10	9	10	10	8	± 12%	-
16.3	10	7	9	10	-	-	-	-	10	± 14%	n.s.
29.4	10	8	9	10	-	-	-	-	8	± 10%	n.s.
52.9	9	10	9	9	-	-	-	-	8	± 5%	n.s.
95.3	9	8	10	7	-	-	-	-	15	± 13%	n.s.
171	10	10	9	10	-	-	-	-	3	± 5%	n.s.
309	7	10	10	7	-	-	-	-	15	± 17%	n.s.
556	10	10	10	10	-	-	-	-	0	± 0%	n.s.
1000	6	10	9	8	-	-	-	-	18	± 17%	n.s.

The results represent rounded values calculated from the exact raw data

Test item dosages are given as mg test item/kg artificial soil dry weight

¹ Fisher's Exact Test, one-sided greater, $\alpha = 0.05$

- Not applicable

n.s. = Not statistically significantly different compared to the control

Reproduction of the Collembolan exposed to GLOB2013F (Zoxamide 450 g/L SC) was not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg test item/kg soil dry weight (Welsh t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller). No behavioural abnormalities were observed in any of the treatment groups.

Table 4. Reproduction of Collembola after 28 days

Treatment Group	Number of Juveniles per Replicate								Mean	Standard Deviation	% of Control	Significance ¹
	1	2	3	4	5	6	7	8				
Control	821	1487	1176	1687	1247	1132	1606	1219	1297	± 283	-	-
16.3	788	1123	1309	1273	-	-	-	-	1123	± 238	87	n.s.
29.4	1241	804	1591	1248	-	-	-	-	1221	± 322	94	n.s.
52.9	1453	1444	1462	1420	-	-	-	-	1445	± 18	111	n.s.
95.3	1456	730	1663	872	-	-	-	-	1180	± 450	91	n.s.
171	1612	1965	1031	1660	-	-	-	-	1567	± 390	121	n.s.
309	957	1459	1367	890	-	-	-	-	1168	± 286	90	n.s.
556	1309	1343	1322	1335	-	-	-	-	1327	± 15	102	n.s.
1000	824	1781	1585	909	-	-	-	-	1275	± 479	98	n.s.

The results represent rounded values calculated from the exact raw data

Test item dosages are given as mg test item/kg artificial soil dry weight

¹ Welsh t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller

- not applicable

n.s. = Not significantly different compared to the control

The results are shown in Table 8.

Table 8. Summary of the Effects of GLOB2013F (Zoxamide 450 g/L SC) on *Collembola (Folsomia candida)* in a 28-day Reproduction Study

GLOB2013F (Zoxamide 450 g/L SC) [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171	309	556	1000
Mean mortality (day 28) [%]	8	10	8	8	15	3	15	0	18
Significance 1)	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean no. of juveniles (day 28)	1297	1123	1221	1445	1180	1567	1168	1327	1275
Reproduction in [%] of control (day 28)	-	87	94	111	91	121	90	102	98
Statistical significance 2)	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥1000								
LOEC (mortality)	>1000								
LC50 (mortality) 3)	>1000								
NOEC (reproduction)	≥1000								
LOEC (reproduction)	>1000								
EC10 (reproduction) 3)	>1000								
EC20 (reproduction) 3)	>1000								
EC50 (reproduction) 3)	>1000								

n.s. = not significantly different compared to the control

1) Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

2) Welch t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller

3) estimated value

- not applicable

Conclusion

All validity criteria for the study were met.

GLOB2013F (Zoxamide 450 g/L SC) caused no statistically significant effects on mortality and reproduction of *Folsomia candida* up to and including the concentration of 1000 mg test item/kg soil dry weight. Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be ≥1000 mg test item/kg soil dry weight. The overall Lowest Observed Effect Concentration (LOEC) was estimated to be >1000 mg test item/kg soil dry weight. The LC₅₀ was estimated to be >1000 mg test item/kg soil dry weight. The EC₁₀, EC₂₀ and EC₅₀ values were estimated to be >1000 mg test item/kg soil dry weight.

Comments of zRMS:	<p>The study was conducted to OECD guideline 226 and according to the principles of GLP.</p> <p>The results are considered valid because the following criteria were satisfied in the control:</p> <ul style="list-style-type: none"> - mean adult mortality: 13 % (criterion: ≤ 20%), - the mean number of juveniles per vessel at the end of the test: 231 (criterion: ≥ 50 juveniles at the end of the test), - the coefficient of variation for the number of juveniles: 11.9 % (criterion: ≤ 30%).
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Reference: KCP 10.4.2.1

Report GLOB2013F (Zoxamide 450 g/L SC): Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil, Straube, D., 2022, Ibacon GmbH, Report No.: 169571089

Guideline(s):	OECD 226
Deviations:	No
GLP:	Yes
Acceptability:	Yes/ No / Supplementary

Materials and methods

Test Item:	GLOB2013F (Zoxamide 450 g/L SC); batch no.: CES 4648; content of a.i.: 448.0 g/L Zoxamide (authenticated)
Test Species:	Predatory mite <i>Hypoaspis aculeifer</i> , adult females, approximately 10 days after reaching the adult stage (31 days after placing adult females in clean rearing vessels and the start of the egg laying period in the synchronisation), cultured by ibacon.
Test Design:	14 days exposure in treated artificial soil. Different concentrations of the test item were mixed homogeneously into the soil, which was filled into glass vessels before the predatory mites were introduced on top of the soil; 8 concentrations and one control were tested; 4 replicates per test item concentration and 8 replicates for the control, with 10 female predatory mites in each replicate. Feeding of the mites with cheese mites (<i>Tyrophagus putrescentiae</i>) <i>ad libitum</i> at test start and on day 2, 4, 7, 9 and 11. Assessment of adult mortality and reproduction performed after 14 days.
Endpoints:	Adult mortality, number of juveniles.
Reference Item:	Dimethoate (the effects of the reference item were investigated in a separate GLP study).
Test Concentrations:	Control, 16.3, 29.4, 52.9, 95.3, 171, 309, 556 and 1000 mg GLOB2013F (Zoxamide 450 g/L SC)/kg soil dry weight.
Test Conditions:	Artificial soil based on OECD 226; initial pH 6.0 to 6.1, pH at experimental end 6.0 to 6.2; water content at experimental start 17.1% to 17.8% (50.4% to 52.4% of the maximum water holding capacity); at experimental end 16.2% to 17.1% (47.6% to 50.3% of the maximum water holding capacity); temperature: within the range of 18°C to 22°C; illumination: 16 h light : 8 h dark (within the range of 400 to 800 lux).
Statistics:	Standard procedures, Fisher's Exact Test (mortality), Dunnett's t-test (reproduction).

Results and discussions

There were no statistically significant effects on reproduction of *Hypoaspis aculeifer* up to and including the test concentration of 1000 mg test item/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, one-sided smaller). Therefore, the NOEC for reproduction was determined to be ≥ 1000 mg test item/kg soil dry weight and the LOEC for reproduction was estimated to be >1000 mg test item/kg soil dry weight.

Table 4. Reproduction of *Hypoaspis aculeifer* after 14 days

Treatment Group	Number of Juveniles per Replicate ¹								Mean	Standard Deviation	% of Control	Significance ²
	1	2	3	4	5	6	7	8				
Control	266	246	238	219	237	205	256	183	231	± 28	-	-
16.3	255	237	248	214	-	-	-	-	238	± 18	103	n.s.
29.4	244	235	212	255	-	-	-	-	236	± 18	102	n.s.
52.9	235	195	227	246	-	-	-	-	226	± 22	98	n.s.
95.3	195	200	254	230	-	-	-	-	219	± 28	95	n.s.
171	226	235	259	239	-	-	-	-	240	± 14	104	n.s.
309	216	215	230	213	-	-	-	-	219	± 8	95	n.s.
556	243	221	218	243	-	-	-	-	231	± 14	100	n.s.
1000	220	228	222	218	-	-	-	-	222	± 4	96	n.s.

The results represent rounded values calculated from the exact raw data

Test item dosages are given as mg test item/kg artificial soil dry weight

¹ Mean of two counts

² Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

- Not applicable

n.s. = Not significantly different compared to the control

All validity criteria for the study were met.

A mortality of up to 13% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where 1% of the adult mites died (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

Reproduction of the predatory mites exposed to GLOB2013F (Zoxamide 450 g/L SC) was not statistically significantly different compared to the control up to and including the highest test concentration of 1000 mg/kg soil dry weight (Dunnett's t-test, $\alpha = 0.05$, one-sided smaller).

No behavioural abnormalities were observed in any of the treatment groups. The results are shown in Table 9.

Table 9. Summary of the Effects of GLOB2013F (Zoxamide 450 g/L SC) on the Predatory Mite *Hypoaspis aculeifer* in a 14-day Reproduction Study

GLOB2013F (Zoxamide 450 g/L SC) [mg/kg soil dry weight]	Control	16.3	29.4	52.9	95.3	171	309	556	1000
Mortality (day 14) [%]	1	5	8	5	8	13	8	10	8
Statistical significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 14)	231	238	236	226	219	240	219	231	222
Reproduction in [%] of control (day 14)	-	103	102	98	95	104	95	100	96
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥1000								
LOEC (mortality)	>1000								
LC ₅₀ (mortality) ³⁾	>1000								
NOEC (reproduction)	≥1000								
LOEC (reproduction)	>1000								
EC ₁₀ (reproduction) ³⁾	>1000								
EC ₂₀ (reproduction) ³⁾	>1000								
EC ₅₀ (reproduction) ³⁾	>1000								

n.s. = not significantly different compared to the control

¹⁾ Fisher's Exact Test, $\alpha = 0.05$, one-sided greater

²⁾ Dunnett's t-test, $\alpha = 0.05$, one-sided smaller

³⁾ estimated value

- not applicable

Reference Item Test:

The reference item Dimethoate showed statistically significant treatment related effects on reproduction at a concentration of 2.23 mg a.i./kg soil dry weight and above. The EC₅₀ for reproduction was 2.95 mg a.i./kg soil dry weight.

Conclusion

GLOB2013F (Zoxamide 450 g/L SC) caused no statistically significant effects on mortality and reproduction of *Hypoaspis aculeifer* up to and including the concentration of 1000 mg test item/kg soil dry weight. Therefore, the overall No Observed Effect Concentration (NOEC) was determined to be ≥ 1000 mg test item/kg soil dry weight. The overall Lowest Observed Effect Concentration (LOEC) was estimated to be >1000 mg test item/kg soil dry weight. The LC₅₀ was estimated to be >1000 mg test item/kg soil dry weight. The EC₁₀, EC₂₀ and EC₅₀ values were estimated to be >1000 mg test item/kg soil dry weight.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study was carried out to the OECD Guideline 216 (2000) according to the principles of GLP.</p> <p>The test item is assumed to be uniformly distributed in the top 5 cm of soil (penetration depth 0.05 m) according to OECD 216 and EU Method C.21.</p> <p>According to OECD 216 the rate of nitrate formation in treated samples is compared with the rate in the controls, and the percent deviation of the treated from the control is calculated. At day 28 differences to the control of nitrate formation were 26.45% and 28.02% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively. For all further samplings till day 84, the deviations between test item treatments and control remained within the trigger range of 25% deviation.</p> <p>According to OECD 216 the test was continued until a difference equal to or less than 25 % is obtained, or for a maximum of 100 days</p> <p>At day 84, differences to the control were 4.00% and -0.66% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively.</p> <p>On the basis of the results, it was concluded that GLOB2013F at the concentrations corresponding to the PEC: 1.36 mg of the test item/kg dry weight of soil and 5 x PEC: 6.81 mg of the test item/kg dry weight of soil did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils..</p>
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Reference:	KCP 10.5
Report	GLOB2013F: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Hammesfahr, U., 2022, Ibacon GmbH, Report No.: 169571080
Guideline(s):	OECD 216
Deviations:	No

GLP: Yes
Acceptability: Yes/ No / Supplementary

Materials and methods

Test Item: GLOB2013F, Batch No. CES 4648
Test System: Biologically active agricultural soil: Loamy sand
Test Design: Determination of nitrogen-transformation in soil enriched with lucerne meal. Comparison of test item treated soil with a non-treated soil. Three replicates per treatment. NH_4^- , NO_2^- and NO_3^- -nitrogen formed in the nitrification process was determined by continuous flow analysis. Sampling scheme: 0, 7, 14, 28, 42, 56, 70, 84 and 98 days after treatment (samples of day 98 were not analysed as the study was finished after 84 days)
Test Rates: Control
1.36 mg GLOB2013F/kg soil dry weight
6.81 mg GLOB2013F/kg soil dry weight
Endpoints: Effects on NO_3^- -nitrogen production after 84 days exposure (soil nitrogen transformation).
Reference Item: Effects of sodium chloride were determined at a rate of 16 g/kg dry soil in a separate study (ibacon study code: 116526080) once a year.
Test Conditions: Moisture: 46% to 50% of maximum water holding capacity (WHC_{max}). Temperature: $20^\circ\text{C} \pm 2^\circ\text{C}$, in the dark.
Statistics: Calculation of mean values per treatment, standard deviation and coefficient of variation. Normality and homogeneity of variances were tested using the R/S-Test ($\alpha = 0.01$) and Levene's test ($\alpha = 0.01$), respectively and pair-wise comparisons of treated and control values according to Student t-test ($\alpha = 0.05$) were conducted.

Results and discussions

Nitrogen Transformation - Nitrate Content: Adverse effects of the test item on nitrate content in soil were observed at day 28. At day 28, differences to the control were 26.45% and 28.02% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively. For all further samplings till day 84, the deviations between test item treatments and control remained within the trigger range of 25% deviation. At day 84, differences to the control were 4.00% and -0.66% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively.

The results are summarized in Table 10.

Nitrogen Transformation - Mineral Nitrogen Content: Adverse effects of the test item on mineral nitrogen content in soil were observed at day 28. At day 28, differences to the control were 25.62% and 27.03% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively. For all further samplings till day 84, the deviations between test item treatments and control remained within the trigger range of 25% deviation. At day 84, differences to the control were 4.00% and -0.66% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively.

A summary of the results is shown in in Table 10.

Nitrogen Transformation - Nitrate Formation Rates: The cumulative soil nitrate formation rates did exceed the trigger range of $\pm 25\%$ set by OECD guideline 216 at the 0 - 28 day determination.

Differences to the control were 130.04% and 143.73% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively. In the intervals 0-70 days and 0-84 days, the deviations between test item treatments and control remained within the trigger range of 25% deviation. Differences to the control were 10.78% and 4.99% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively in the interval day 0-84.

The incremental soil nitrate formation rates did exceed the trigger range of $\pm 25\%$ set by OECD guideline 216 at the 14 - 28 day determination for the low test item treatment. Differences to the control were 32.37% and 11.76% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively. In the interval 28-42 days, the deviations between test item treatments and control remained within the trigger range of 25% deviation. Differences to the control were 0.80% and -4.67% in the 1.36 mg and 6.81 mg test item/kg soil dry weight treatment, respectively in the interval day 28-42. As the replicate variation was very high in the next intervals, the results have to be treated with care. This was a consequence of the fact, that the measured nitrate contents did not increase much in the control and treatments between sampling points day 56 and 84.

A summary of the results is shown in Table 10.

Validity Criteria:

The variation between the replicate control samples did not exceed the validity criterion of 15% throughout the study.

Table 10. Effects of the test item on Nitrogen Transformation in a Loamy Sand Soil

Nitrogen Transformation - NO ₃ – Nitrogen (mg / kg soil dry weight) Mean Values						
	Control		1.36 mg GLOB2013F/kg soil dw		6.81 mg GLOB2013F/kg soil dw	
Sampling	Nitrate-N Content	Replicate Variation ¹	Nitrate-N Content	Deviation ²	Nitrate-N Content	Deviation ²
Day 0	21.404	0.07	19.423	-9.26	18.855	-11.91
Day 7	11.733	11.28	16.401*	39.79	17.136*	46.05
Day 14	19.595	7.32	24.231	23.66	26.566*	35.58
Day 28	28.759	4.45	36.366*	26.45	36.817*	28.02
Day 42	46.165	8.21	53.913*	16.78	53.407*	15.69
Day 56	53.803	11.73	61.432*	14.18	61.934*	15.11
Day 70	63.532	3.27	69.751*	9.79	67.907	6.89
Day 84	63.488	5.42	66.030	4.00	63.070	-0.66
Nitrogen Transformation - Mineral Nitrogen ³ (mg / kg soil dry weight) Mean Values						
	Control		1.36 mg GLOB2013F/kg soil dw		6.81 mg GLOB2013F/kg soil dw	
Sampling	Mineral-N Content	Replicate Variation ¹	Mineral -N Content	Deviation ²	Mineral -N Content	Deviation ²
Day 0	29.832	0.44	27.125	-9.07	26.435	-11.39
Day 7	13.851	8.85	18.575*	34.11	19.139*	38.18
Day 14	20.583	6.85	25.156	22.22	27.456*	33.39
Day 28	29.454	4.38	37.001*	25.62	37.414*	27.03
Day 42	48.201	8.19	55.942*	16.06	55.540*	15.23
Day 56	55.888	11.04	63.454*	13.54	63.958*	14.44
Day 70	65.423	3.13	71.738*	9.65	69.908	6.86
Day 84	63.488	5.42	66.030	4.00	63.070	-0.66

Nitrogen Transformation - NO ₃ – Nitrogen Formation Rate (mg / kg soil dry weight per day) ⁴					
	Control	1.36 mg GLOB2013F/kg soil dw		6.81 mg GLOB2013F/kg soil dw	
Interval ⁴	Nitrate-N Formation	Nitrate-N Formation	Deviation ²	Nitrate-N Formation	Deviation ²
Day 0 - 7	-1.382	-0.432*	68.74	-0.245*	82.27
Day 0 - 14	-0.129	0.343*	365.89	0.551*	527.13
Day 0 - 28	0.263	0.605*	130.04	0.641*	143.73
Day 0 - 42	0.590	0.821*	39.15	0.823*	39.49
Day 0 - 56	0.578	0.750*	29.76	0.769*	33.04
Day 0 - 70	0.602	0.719*	19.44	0.701	16.45
Day 0 - 84	0.501	0.555	10.78	0.526	4.99
Nitrogen Transformation - NO ₃ – Nitrogen Formation Rate (mg / kg soil dry weight per day) ⁵					
	Control	1.36 mg GLOB2013F/kg soil dw		6.81 mg GLOB2013F/kg soil dw	
Interval ⁵	Nitrate-N Formation	Nitrate-N Formation	Deviation ²	Nitrate-N Formation	Deviation ²
Day 0 - 7	-1.382	-0.432*	68.74	-0.245*	82.27
Day 7 - 14	1.123	1.119	-0.36	1.347	19.95
Day 14 - 28	0.655	0.867	32.37	0.732	11.76
Day 28 - 42	1.243	1.253	0.80	1.185	-4.67
Day 42 - 56	0.546	0.537	-1.65	0.609	11.54
Day 56 - 70	0.695	0.594	-14.53	0.427	-38.56
Day 70 - 84	-0.003	-0.266	-8766.67	-0.346	-11433.33
¹ = % variation within control replicates (coefficient of variation, calculated as standard deviation / mean value x 100) ² = % deviation to control ³ = mineral nitrogen = sum of nitrite- nitrate- and ammonium-nitrogen ⁴ = related to test start ⁵ = related to successive intervals between samplings positive values = stimulatory effect; negative values = inhibitory effect dw = dry weight * statistically significantly different from control (Student t-test; α = 0.05)					

Conclusion

The test item had no long-term impact on nitrogen transformation (nitrate content, mineral nitrogen content and nitrate formation rates) of soil microorganisms when applied at 1.36 mg and 6.81 mg test item/kg soil dry weight treatment.

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

A 2.6.1 KCP 10.6.1 Summary of screening data

No data submitted.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The Vegetative vigour study was conducted to OECD guideline 227 and according to the principles of GLP. No deviations from OECD Guideline No. 227 were noted.
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	<p>In the definitive test all the validity criteria were met as follows:</p> <p>The percentage of seedling emergence of each seed lot is at least 70 %.</p> <ul style="list-style-type: none"> • Untreated control plants must not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformation). Plants exhibit only normal variation in growth and morphology for that particular species. • The mean survival of untreated control plants is at least 90 % for the duration of the study. • Environmental conditions for a particular species are identical and the growing media contain the same amount of soil matrix, support media or substrate from the same source. <p>The study is accepted and reliable for risk assessment purposes.</p>
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Reference:	KCP 10.6.2
Report	GLOB2013F: OECD Terrestrial Plant Test - Vegetative Vigour Test, Dewson, S., 2023, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1557
Guideline(s):	OECD 227
Deviations:	No
GLP:	Yes
Acceptability:	Yes / No / Supplementary

Materials and methods

A glasshouse study was conducted by Stockbridge Technology Centre Ltd to generate dose response data for GLOB2013F when applied post-emergence to four monocotyledon species and six dicotyledon species. The methodology for the study was based on OECD Guideline For The Testing of Chemicals, 227 Terrestrial Plant Test: Vegetative Vigour Test (July 2006). ER₁₀, ER₂₅, ER₅₀, NOEC and LOEC values based on percentage survival, shoot fresh weight reduction and percentage visual injury assessment at harvest were determined from the dose response data and used to assess the risk of GLOB2013F to terrestrial non-target plant species.

The test species consisted of four monocotyledon species (oats, onion, corn and ryegrass) and six dicotyledon species (sugar beet, sunflower, soybean, tomato, oilseed rape and cucumber). Species tested represented the plant families of Poaceae, Liliaceae, Chenopodiaceae, Asteraceae, Fabaceae, Solanaceae, Brassicaceae and Cucurbitaceae.

All species were treated with the test item on 8th June 2022. GLOB2013F was applied at five different rates to all species (0.075, 0.15, 0.3, 0.6 and 1.2 L product/ha) and compared with an untreated water only control. The water application rate was 200 L/ha. The Batch Number for the sample of GLOB2013F used in this study was A314F01-3. Applications were made post-emergence to all ten species at growth stage BBCH 12-14 (2 to 4 true leaves). No species displayed visual injury.

Results and discussions

NOEC and LOEC levels and ER₁₀, ER₂₅ and ER₅₀ values (with corresponding R-Sq values) for all species are summarized in the tables below.

Species	Visual injury at harvest
	L GLOB2013F/ha

	NOEC	LOEC	ER ₁₀	ER ₂₅	ER ₅₀	R-Sq
Oats	1.2	1.2	>1.2	>1.2	>1.2	N/A
Onion	1.2	1.2	>1.2	>1.2	>1.2	N/A
Corn	1.2	1.2	>1.2	>1.2	>1.2	N/A
Ryegrass	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sugar beet	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sunflower	1.2	1.2	>1.2	>1.2	>1.2	N/A
Soybean	1.2	1.2	>1.2	>1.2	>1.2	N/A
Tomato	1.2	1.2	>1.2	>1.2	>1.2	N/A
Oilseed rape	1.2	1.2	>1.2	>1.2	>1.2	N/A
Cucumber	1.2	1.2	>1.2	>1.2	>1.2	N/A

N/A = Not applicable as no effect at any treatment rate.

Species	Plant survival					
	L GLOB2013F/ha					
	NOEC	LOEC	ER ₁₀	ER ₂₅	ER ₅₀	R-Sq
Oats	1.2	1.2	>1.2	>1.2	>1.2	N/A
Onion	1.2	1.2	>1.2	>1.2	>1.2	N/A
Corn	1.2	1.2	>1.2	>1.2	>1.2	N/A
Ryegrass	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sugar beet	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sunflower	1.2	1.2	>1.2	>1.2	>1.2	N/A
Soybean	1.2	1.2	>1.2	>1.2	>1.2	N/A
Tomato	1.2	1.2	>1.2	>1.2	>1.2	N/A
Oilseed rape	1.2	1.2	>1.2	>1.2	>1.2	N/A
Cucumber	1.2	1.2	>1.2	>1.2	>1.2	N/A

N/A = Not applicable as no effect at any treatment rate.

Species	Shoot fresh weight at harvest					
	L GLOB2013F/ha					
	NOEC	LOEC	ER ₁₀	ER ₂₅	ER ₅₀	R-Sq
Oats	1.2	1.2	>1.2	>1.2	>1.2	N/A
Onion	1.2	1.2	>1.2	>1.2	>1.2	N/A
Corn	1.2	1.2	>1.2	>1.2	>1.2	N/A
Ryegrass	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sugar beet	1.2	1.2	>1.2	>1.2	>1.2	N/A
Sunflower	1.2	1.2	>1.2	>1.2	>1.2	N/A
Soybean	1.2	1.2	>1.2	>1.2	>1.2	N/A
Tomato	1.2	1.2	>1.2	>1.2	>1.2	N/A
Oilseed rape	1.2	1.2	>1.2	>1.2	>1.2	N/A
Cucumber	1.2	1.2	>1.2	>1.2	>1.2	N/A

N/A = Not applicable as no effect at any treatment rate.

Conclusion

Based on percentage visual injury assessment at harvest:

- The ER₁₀, ER₂₅ and ER₅₀ values for all species were >1.2 L GLOB2013F/ha.
- The NOEC and LOEC values for all species were 1.2 L GLOB2013F/ha.

Based on plant survival:

- The ER₁₀, ER₂₅ and ER₅₀ values for all species were >1.2 L GLOB2013F/ha.
- The NOEC and LOEC values for all species were 1.2 L GLOB2013F/ha.

Based on shoot fresh weight reduction at harvest:

- The ER₁₀, ER₂₅ and ER₅₀ values for all species were >1.2 L GLOB2013F/ha.
- The NOEC and LOEC values for all species were 1.2 L GLOB2013F/ha.

Comments of zRMS:	<p>The seedling emergence study was conducted to OECD guideline 208 and according to the principles of GLP. No deviations from OECD Guideline No. 208 were noted.</p> <p>In the definitive test all the validity criteria were met as follows:</p> <ul style="list-style-type: none"> - Emergence in the untreated control pots exceeded 70%. - Untreated control seedlings did not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformation). Untreated control seedlings only exhibited normal variation in growth and morphology for that particular species. - The mean survival of emerged untreated control seedlings was at least 90 % for the duration of the study. - Environmental conditions for a particular species were identical and the growing media contained the same amount of soil matrix, support media or substrate from the same source. <p>The study is acceptable and reliable for risk assessment purposes.</p>
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Reference:	KCP 10.6.2
Report	GLOB2013F: OECD Terrestrial Plant Test - Seedling Emergence and Seedling Growth Test, Stead, A., 2023, Stockbridge Technology Centre Ltd., Report No.: STC/22/E1558
Guideline(s):	OECD 208 ²²⁷
Deviations:	No
GLP:	Yes
Acceptability:	Yes/ No / Supplementary

Materials and methods

A glasshouse study was conducted by Stockbridge Technology Centre Ltd to generate dose response data for GLOB2013F when applied pre-emergence to ten species of non-target plants. The methodology for the study was based on OECD Guideline 208 (July 2006) Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. ER₁₀, ER₂₅, ER₅₀, NOEC and LOEC values based on seedling emergence, percentage survival, shoot fresh weight reduction and percentage visual injury at harvest were ascertained from the dose response data and will be used to assess the risk of GLOB2013F to terrestrial non-target plant species.

The test species consisted of four monocotyledon species (oats, onion, corn and ryegrass) and six dicotyledon species (sugar beet, sunflower, soybean, tomato, oilseed rape and cucumber). Species tested represented the plant families of Poaceae, Liliaceae, Chenopodiaceae, Asteraceae, Fabaceae, Solanaceae, Brassicaceae and Cucurbitaceae.

The Batch Number for the sample of GLOB2013F used in this study was A314F01-3.

Applications were made pre-emergence to all ten species.

All species were treated with the test item on 15th June 2022. GLOB2013F was applied to oats, onion, corn, ryegrass, sugar beet, sunflower, soybean, tomato, oilseed rape and cucumber at five different rates (0.075, 0.15, 0.3, 0.6 and 1.2 L product/ha) and compared with an untreated water only control. The water application rate was 200 L/ha.

Results and discussions

ER₁₀, ER₂₅ and ER₅₀ values (with corresponding R-Sq. values) and NOEC and LOEC values, based on seedling emergence are summarized below:

Species	ER ₁₀ # GLOB2013F (L/ha)	ER ₂₅ GLOB2013F (L/ha)	ER ₅₀ GLOB2013F (L/ha)	R-Sq.	NOEC GLOB2013F (L/ha)	LOEC GLOB2013F (L/ha)
Oats	>1.2	>1.2	>1.2	N/A	1.2	1.2
Onion	>1.2	>1.2	>1.2	N/A	1.2	1.2
Corn	>1.2	>1.2	>1.2	N/A	1.2	1.2
Ryegrass	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sugar beet	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sunflower	>1.2	>1.2	>1.2	N/A	1.2	1.2
Soybean	>1.2	>1.2	>1.2	N/A	1.2	1.2
Tomato	>1.2	>1.2	>1.2	N/A	1.2	1.2
Oilseed rape	>1.2	>1.2	>1.2	N/A	1.2	1.2
Cucumber	>1.2	>1.2	>1.2	N/A	1.2	1.2

ER₁₀ values should be treated with caution due to natural plant to plant variability.

N/A = not appropriate owing to tolerance of these species to GLOB2013F.

ER₁₀, ER₂₅ and ER₅₀ values (with corresponding R-Sq. values) and NOEC and LOEC values, based on percentage survival are summarized below:

Species	ER ₁₀ # GLOB2013F (L/ha)	ER ₂₅ GLOB2013F (L/ha)	ER ₅₀ GLOB2013F (L/ha)	R-Sq.	NOEC GLOB2013F (L/ha)	LOEC GLOB2013F (L/ha)
Oats	>1.2	>1.2	>1.2	N/A	1.2	1.2
Onion	>1.2	>1.2	>1.2	N/A	1.2	1.2
Corn	>1.2	>1.2	>1.2	N/A	1.2	1.2
Ryegrass	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sugar beet	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sunflower	>1.2	>1.2	>1.2	N/A	1.2	1.2
Soybean	>1.2	>1.2	>1.2	N/A	1.2	1.2
Tomato	>1.2	>1.2	>1.2	N/A	1.2	1.2
Oilseed rape	>1.2	>1.2	>1.2	N/A	1.2	1.2
Cucumber	>1.2	>1.2	>1.2	N/A	1.2	1.2

ER₁₀ values should be treated with caution due to natural plant to plant variability.

N/A = not appropriate owing to tolerance of these species to GLOB2013F.

ER₁₀, ER₂₅ and ER₅₀ values (with corresponding R-Sq. values) and NOEC and LOEC values, based on shoot fresh weight reduction are summarized below:

Species	ER ₁₀ # GLOB2013F (L/ha)	ER ₂₅ GLOB2013F (L/ha)	ER ₅₀ GLOB2013F (L/ha)	R-Sq.	NOEC GLOB2013F (L/ha)	LOEC GLOB2013F (L/ha)
Oats	>1.2	>1.2	>1.2	N/A	1.2	1.2
Onion	>1.2	>1.2	>1.2	N/A	1.2	1.2
Corn	>1.2	>1.2	>1.2	N/A	1.2	1.2
Ryegrass	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sugar beet	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sunflower	>1.2	>1.2	>1.2	N/A	1.2	1.2
Soybean	>1.2	>1.2	>1.2	N/A	1.2	1.2
Tomato	>1.2	>1.2	>1.2	N/A	1.2	1.2
Oilseed rape	>1.2	>1.2	>1.2	N/A	1.2	1.2
Cucumber	>1.2	>1.2	>1.2	N/A	1.2	1.2

ER₁₀ values should be treated with caution due to natural plant to plant variability.

N/A = not appropriate owing to tolerance of these species to GLOB2013F.

ER₁₀, ER₂₅ and ER₅₀ values (with corresponding R-Sq. values) and NOEC and LOEC values, based on percentage visual injury assessment at harvest are summarized below:

Species	ER ₁₀ # GLOB2013F (L/ha)	ER ₂₅ GLOB2013F (L/ha)	ER ₅₀ GLOB2013F (L/ha)	R-Sq.	NOEC GLOB2013F (L/ha)	LOEC GLOB2013F (L/ha)
Oats	>1.2	>1.2	>1.2	N/A	1.2	1.2
Onion	>1.2	>1.2	>1.2	N/A	1.2	1.2
Corn	>1.2	>1.2	>1.2	N/A	1.2	1.2
Ryegrass	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sugar beet	>1.2	>1.2	>1.2	N/A	1.2	1.2
Sunflower	>1.2	>1.2	>1.2	N/A	1.2	1.2
Soybean	>1.2	>1.2	>1.2	N/A	1.2	1.2
Tomato	>1.2	>1.2	>1.2	N/A	1.2	1.2
Oilseed rape	>1.2	>1.2	>1.2	N/A	1.2	1.2
Cucumber	>1.2	>1.2	>1.2	N/A	1.2	1.2

ER₁₀ values should be treated with caution due to natural plant to plant variability.

N/A = not appropriate owing to tolerance of these species to GLOB2013F.

Conclusion

Based on seedling emergence:

- All ten species had an ER₁₀, ER₂₅ and ER₅₀ value of >1.2 L product/ha and a NOEC and LOEC value of 1.2 L product/ha.

Based on percentage survival:

- All ten species had an ER₁₀, ER₂₅ and ER₅₀ value of >1.2 L product/ha and a NOEC and LOEC value of 1.2 L product/ha.

Based on shoot fresh weight reduction at harvest:

- All ten species had an ER₁₀, ER₂₅ and ER₅₀ value of >1.2 L product/ha and a NOEC and LOEC value of 1.2 L product/ha.

Based on percentage visual injury assessment at harvest:

- All ten species had an ER₁₀, ER₂₅ and ER₅₀ value of >1.2 L product/ha and a NOEC and LOEC value of 1.2 L product/ha.

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

No data submitted.

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

No data submitted.

A 2.8 KCP 10.8 Monitoring data

No data submitted.