

REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: GLOB2011I

Product name(s): SANKARI

Chemical active substance:

Pelargonic acid, 650 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situa- tion (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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 arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
4 (cover- ing use 1)	PL, CZ, IE and FR	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW], winter tritcale [TTLWI])	F	Aphids / Rhopalosiphum padi [RHOPPA], Sitobion avenae [MACASV]	downward spraying	At first infestation / BBCH 10- 29 (au- tumn: end of Septem- ber to end of Decem- ber)	a) 2 (14) b) 2 (14)	14 days	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA								
5 (cover- ing use 2)	PL, CZ, IE and FR	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW],	F	Aphids / Rhopalosiphum padi [RHOPPA], Sitobion avenae [MACASV]	downward spraying	At first infestation / BBCH 21- 49 (spring: March to May)	a) 2 (14) b) 2 (14)	14 days	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		winter triticale [TTLWI])																		
6 (covering use 3)	PL, CZ, IE and FR	Cereals (winter and spring wheat [TRZAW & TRZAS], winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring triticale [TTLWI & TTLSO])	F	Aphids / Rhopalosiphum padi [RHOPPA], Sitobion avenae [MACASV]	downward spraying	BBCH 51-77 (spring: May to beginning of July)	a) 2 (14) b) 2 (14)	14 days	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA								
8 (covering use 7)	PL, CZ, IE and FR	Oilseed rape (winter) [BRSNW]	F	Flea beetle / <i>Phyllotreta</i> sp. [PHYESP]	downward spraying	At first infestation / BBCH 10-16 (summer-autumn: late August to end of October)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA								
10 (covering use 9)	PL, CZ, IE and FR	Oilseed rape (winter and spring) [BRSNW and BRSNS]	F	Cabbage seed - pod weevil / <i>Ceutorhynchus obstrictus</i> [CEUTAS]	downward spraying	At first infestation / BBCH 50-65 (spring: April to July)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA	The treatment against pollen beetle also fights the cabbage seed/pod weevil <i>Ceutorhynchus obstrictus</i> (CEUTAS)							
11	PL, CZ, IE and FR	Potato [SOLTU]	F	Colorado beetle / <i>Leptinotarsa decemlineata</i> [LPTNDE]	downward spraying	At first infestation / BBCH 35-85 (spring-summer: May to	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
						August)														
13 (covering use 12)	PL, CZ, IE and FR	Maize [ZEAMX]	F	Corn borer / <i>Ostrinia nubilalis</i> [PYRUNU]	downward spraying	At first infestation / BBCH 51-71 (summer: June to July)	a) 2 (14) b) 2 (14)	14	a) 3.0 b) 6.0	a) 1950 b) 3900	200-600	NA								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (field uses)																				
Minor uses according to Article 51 (interzonal uses)																				

* 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:	<ul style="list-style-type: none">(1) Numeration necessary to allow references(2) Use official codes/nomenclatures of EU(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated	<ul style="list-style-type: none">(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application(8) The maximum number of application possible under practical conditions of use must be provided(9) Minimum interval (in days) between applications of the same product.(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".(13) PHI - minimum pre-harvest interval(14) Remarks may include: Extent of use/economic importance/restrictions
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9.1.1 Overall conclusions

zRMS comments:

The risk assessment was performed on the basis of EU agreed endpoints in accordance with EFSA Journal 2013;11(1):3023.

According to Commission Implementing Regulation (EU) 2023/1446:

As regards the approval of the active substances fatty acids C7-C20 (in particular, pelargonic acid) and plant oils/rape seed oil, the Commission has presented the renewal report and a draft Regulation renewing their approval to the Standing Committee on Plants, Animals, Food and Feed. Pending the delivery of an opinion of this Committee on the draft Regulations, additional time is needed to adopt the ensuing risk management decision and

*As the delivery of an opinion of the Standing Committee on Plants, Animals, Food and Feed is pending, the duration of the extension for the active substances aluminium ammonium sulphate, aluminium silicate, fat distillation residues, **fatty acids C7-C20** and plant oils/rape seed oil should be set at fifteen months and a half.*

However the *Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid)* (EFSA Journal 2021;19(8):6813) was published in 2021. Therefore, the new agreed endpoints could be used for the risk assessment. Risk assessment with new agreed endpoints was performed by zRMS for **information for the sake of** completeness in each section.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), In EFSA Journal 2013;11(1):3023, a waiver was concluded for all representative formulations on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals:

“The available toxicity data indicated low acute and short-term (for birds only) toxicity to birds and mammals. Acute and short-term (for birds only) first tier risk assessments for birds and mammals indicated a high risk as the resulting TER values were less than the trigger value. However, given that fatty acids are an essential component of the diet of birds and mammals a low risk was concluded. No reproductive toxicity data were available. However, on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals a low reproductive risk was identified.”

This conclusion can be extrapolated to GLOB2011I especially since doses proposed in this evaluation are far below the doses evaluated for the representative formulations in the EU Review of pelargonic acid.

Review Comments 9.3	<p>The EU dossier determined an acceptable acute and chronic risk to mammals by considering the weight of evidence, taking into account the localized use, the ubiquitous nature of fatty acids in the environment, and their easy degradability. Consequently, the acceptable risk to mammals is established based on the overall evidence. As a result, there is no need for additional evaluation of the risk to birds and mammals for uses aligned with those assessed in the EU review.</p> <p>Nevertheless, the evaluator provided a risk assessment based on endpoint from EFSA Conclusion (2013) for the proposed uses as follows:</p>
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Endpoints and effect values relevant for the risk assessment for mammals				
Species	Substance	Exposure System	Results	Reference
Rat	(C9:0)	Acute	LD50 > 2000 mg a.s./kg bw	EFSA Conclusion Fatty acids C7 to C18 (2013)
<p>For risk assessment worst case based on endpoint from EFSA Conclusion (2013) is presented.</p> <p>For Pelargonic acid, there are no available long term studies and therefore the LD50/10 (> 200 mg a.s./kg bw/day) can be used for the long term risk assessment (as a worst case).</p>				
First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2011I in Cereals				
Intended use	Cereals			
Active substance/product	Pelargonic acid			
Application rate (g/ha)	2 × 1300			
Acute toxicity (mg/kg bw)	2000			
TER criterion	≥10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	TER _a
Cereals	Small herbivorous mammal	118.4	1.2	10.8
Reprod. toxicity (mg/kg bw/d)	200			
TER criterion	≥5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	TER _{it}
Cereals	Small herbivorous mammal	48.3	1.4x0.53	4.29
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9		109.1
Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7		9.6
Cereals BBCH ≥ 40	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25%	2.3		90.1

		weeds 50% weed seeds 25% ground arthropods			
	Cereals BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2		49.4
	Cereals BBCH 10-29	Small omnivorous mammal “mouse” Com- bination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8		26.6
	Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Com- bination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9		53.2
	Cereals Early (shoots)	Large herbivorous mammal “lagomorph” Grass + cereals 100% cereal shoots	22.3		9.3
SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.					
First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Oilseed rape / Potatoes					
Intended use		Oilseed rape / Potatoes			
Active sub- stance/product		Pelargonic acid			
Application rate (g/ha)		2 × 0.975			
Acute toxicity (mg/kg bw)		2000			
TER criterion		≥10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	TER_a	
Oilseed rape / Potatoes	Small herbivorous mammal	118.4	1.2	14.4	
Reprod. toxicity (mg/kg bw/d)		200			
TER criterion		≥5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	TER_{lt}	
Oilseed rape / Potatoes	Small herbivorous mammal	48.3	1.4x0.53	5.72	
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.					

	First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Maize				
	Intended use		Maize		
	Active sub-stance/product		Pelargonic acid		
	Application rate (g/ha)		2 × 1.950		
	Acute toxicity (mg/kg bw)		2000		
	TER criterion		≥10		
	Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	TER _a
	Maize	Small herbivorous mam-mal	118.4	1.2	7.2
	Maize BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4		158.3
	Maize BBCH ≥ 40	Small herbivorous mam-mal "vole Grass + cereals All maize shoots + later grass	34.1		25.1
	Maize BBCH ≥ 40	Small omnivorous mam-mal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	4.3		198.8
	Reprod. toxicity (mg/kg bw/d)		200		
	TER criterion		≥5		
	Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	TER _{lt}
	Maize	Small herbivorous mam-mal	48.3	1.4x0.53	2.86
	Maize BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9		72.8
	Maize BBCH ≥ 40	Small herbivorous mam-mal "vole Grass + cereals All maize shoots + later grass	18.1		7.6
	Maize BBCH ≥ 40	Small omnivorous mam-mal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground	1.9		72.8

	arthropods			
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.				
The values of TER _A and TER _{LT} are respectively higher than the trigger of 10 and 5 for GLOB2011I.				
In the EU dossier an acceptable acute risk to mammals was concluded based on the weight of evidence even though TER _A are below the relevant triggers indicating a potential unacceptable risk. It is concluded in the DAR that taking into account low toxicity (no toxicity noted at the highest concentrations tested neither in the acute toxicity studies nor in the short-term toxicity studies) and the ready biodegradability of fatty acids, their ubiquitous nature, and limited use in the environment no special risk mitigation measures are required for mammals.				
Additionally in the EFSA conclusion (6813) risk assessment of July 2021 is stated that no risk is expected for prolonged exposure to pelargonic acid in birds and mammals as is already present in nature.				
Therefore, the risk to mammals is considered acceptable.				
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} ≥ 500 L/kg).				
Effective application rate [g/ha]= 1950				
Acute toxicity [mg/kg bw] = > 2000 quotient = 0.975				
Reprod. toxicity [mg/kg bw/d] = > 200 quotient = 9.75				
With a K(f) _{oc} of 137, Pelargonic acid belongs to the group of less sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50, a quantitative risk assessment (calculation of TER values) is not necessary.				
At environmental pH, the log Pow of Pelargonic acid is lower than 3 (pH 7.0: log Pow=2.4). Therefore, no risk assessment for secondary poisoning is required.				
The risk from secondary poisoning is considered to be acceptable by zRMS.				

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

No risk to birds and mammals is identified following the use of GLOB2011I according to proposed GAPs.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

No risk to aquatic organisms is identified following the use of GLOB2011I according to proposed GAPs.

9.1.1.4 Effects on bees (KCP 10.3.1)

No risk to bees is identified following the use of GLOB2011I according to proposed GAPs when evaluated according to SANCO 2002 and EPPO 2010.

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

No risk to arthropods (other than bees) is identified following the use of GLOB2011I according to proposed GAPs.

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

No risk to soil organisms is identified following the use of GLOB2011I according to proposed GAPs.

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

No risk to non-target plants is identified following the use of GLOB2011I according to proposed GAPs.

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

No risk to other terrestrial organisms is identified following the use of GLOB2011I according to proposed GAPs.

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 GLOB2011I grouped according to application rate and criterion

Grouping according to application rate			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
Birds (9.2)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate and general waiver	2 x 3L/Ha (2 x 1950 g a.s./Ha)
Effects on terrestrial vertebrates other than birds (9.3)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate and general waiver	2 x 3L/Ha (2 x 1950 g a.s./Ha)
Effects on aquatic organisms (9.5)			
002	Use 4: Cereals (covering use 1)	Application rate, timing of application and crop type	2 x 2L/Ha (2 x 1300 g a.s./Ha), BBCH 10-29, winter cereals
003	Use 5: Cereals (covering use 2)	Application rate, timing of	2 x 2L/Ha (2 x 1300 g a.s./Ha),

Grouping according to application rate			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
		application and crop type	BBCH 21-49, winter cereals
004	Use 6: Cereals (covering use 3)	Application rate, timing of application and crop type	2 x 2L/Ha (2 x 1300 g a.s./Ha), BBCH 51-77, winter & spring cereals
005	Uses 8: Winter oilseed rape (covering use 7)	Application rate, timing of application and crop type	2 x 1.5L/Ha (2 x 975 g a.s./Ha), BBCH 10-16, winter oilseed rape
006	Uses 10: Winter oilseed rape (covering use 9)	Application rate, timing of application and crop type	2 x 1.5L/Ha (2 x 975 g a.s./Ha), BBCH 50-65, winter and spring oilseed rape
007	Use 11: Potato	Application rate and crop type	2 x 1.5L/Ha (2 x 975 g a.s./Ha), Potato
008	Use 13: Maize (covering use 12:)	Application rate and crop type	2 x 2L/Ha (2 x 1950 g a.s./Ha), maize
Effects on bees (9.6)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate	2 x 3L/Ha (2 x 1300 g a.s./Ha)
Effects on arthropods other than bees (9.7)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate	2 x 3L/Ha (2 x 1950 g a.s./Ha)
Effects on non-target soil meso- and macrofauna (9.8)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate	2 x 3L/Ha (2 x 1950 g a.s./Ha)
Effects on soil microbial activity (9.9)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate	2 x 3L/Ha (2 x 1950 g a.s./Ha)
Effects on non-target terrestrial plants (9.10)			
001	Use 13: Maize (covering uses 1-12: cereals, oilseed rape, potato, maize)	Application rate	2 x 3L/Ha (2 x 1950 g a.s./Ha)

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 GLOB2011I is indicated in the table.

No major metabolites are identified for pelargonic acid.

Table 9.1-3 Metabolites of pelargonic acid

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
None identified	-	-	-	Not relevant

9.2 Effects on birds (KCP 10.1.1)

In EFSA Journal 2013;11(1):3023, a waiver was concluded for all representative formulations on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals:

“The available toxicity data indicated low acute and short-term (for birds only) toxicity to birds and mammals. Acute and short-term (for birds only) first tier risk assessments for birds and mammals indicated a high risk as the resulting TER values were less than the trigger value. However, given that fatty acids are an essential component of the diet of birds and mammals a low risk was concluded. No reproductive toxicity data were available. However, on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals a low reproductive risk was identified.”

This conclusion can be extrapolated to GLOB2011I especially since doses proposed in this evaluation are far below the doses evaluated for the representative formulations in the EU Review of pelargonic acid.

Review Com-
ments 9.2.

The EU dossier determined an acceptable acute and chronic risk to birds by considering the weight of evidence, taking into account the localized use, the ubiquitous nature of fatty acids in the environment, and their easy degradability. Consequently, the acceptable risk to birds is established based on the overall evidence. As a result, there is no need for additional evaluation of the risk to birds and mammals for uses aligned with those assessed in the EU review.

Nevertheless, the evaluator provided a risk assessment based on endpoint from EFSA Conclusion (2013) for the proposed uses as follows:

Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
<i>Anas platyrhynchos</i>	Safer’s Insecticidal Soap H4 (SL), containing 50.5% Potassium salts of fatty acids	Oral 1 d Acute	LD ₅₀ > 1268 mg a.s./kg b.w. (extrapolated to LD ₅₀ = 2394 mg a.s./kg b.w.) ^a	EFSA Conclusion (2013) ¹
Birds	fatty acids	Oral 1 d Acute	LD50 (geomean) (mg a.s./kg bw) > 2949 ^b	EFSA Conclusion (2021) ²

The endpoints used in the risk assessment are marked **in bold**.

^a All acute studies in mammals testing the active substance or the formulation COM 508 16 H EW resulted in an LD₅₀ above the maximum possible tested rate, thus it is considered feasible to use the highest identified LD₅₀ of > 2000 mg a.s./kg bw.

¹ EFSA Conclusion - European Food Safety Authority (2013), Conclusion on pesticide peer review of the active substance Fatty acids C7 to C18, EFSA Journal;11(1):3023

² Conclusion on the peer review of the pesticide risk assessment of the active substance pelargonic acid. EFSA Journal 2021;19(8):6813

^b Since there are no acute studies available with Pelargonic acid the endpoints based on products with fatty acids can be used for the acute risk assessment. In all acute studies there were no mortality and therefore the resulting endpoints could be extrapolated according to Paragraph 2.1.2 of the Birds and Mammals guidance document. RMS proposes that the endpoint of 2949 mg as/kg bw can be used as acute endpoint

For Pelargonic acid, there are no available long term studies and therefore the LD50/10 (> 239.4 mg a.s./kg bw/day) can be used for the long term risk assessment.

First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Cereals

Intended use	Cereals			
Active sub-stance/product	Pelargonic acid			
Application rate (g/ha)	2 × 1300			
Acute toxicity (mg/kg bw)	2394			
TER criterion	≥10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	TERa
Cereals	Small omnivorous bird	158.8	1.2	9.7
Cereals BBCH 10 - 29	Small omnivorous bird "lark" Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24	1.2	63.9
Cereals BBCH 10 - 29	Small omnivorous bird "lark" Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	24	1.2	63.9
Cereals BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	7.2	1.2	213.1
Cereals BBCH 30 -39	Small omnivorous bird "lark" Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	12	1.2	127.9
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	30.5	1.2	50.3
Cereals Late post-emergence (May-June) BBCH 71-89	Small insectivorous bird "passerine" Foliar insects 100% foliar insects	57.6	1.2	26.6
Reprod. toxicity		239.4		

	(mg/kg bw/d)		≥5		
	TER criterion				
	Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	TER _{It}
	Cereals	Small omnivorous bird	64.8	1.4x0.53	3.8
	Cereals BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9		22.8
	Cereals BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9		22.8
	Cereals BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3		75.2
	Cereals BBCH 30 -39	Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4		46.0
	Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2		15.3
	Cereals Late post-emergence (May-June) BBCH 71-89	Small insectivorous bird "passerine" Foliar insects 100% foliar insects	22.4		11.1
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.					
First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Oilseed rape / Potatoes					
Intended use		Oilseed rape / Potatoes			
Active substance/product		Pelargonic acid			
Application rate (g/ha)		2 × 0.975			
Acute toxicity (mg/kg bw)		2394			
TER criterion		≥10			
Crop scenario	Indicator/generic focal	SV ₉₀	MAF ₉₀	TER _a	

	Growth stage	species			
	Oilseed rape / Potatoes	Small omnivorous bird	158.8	1.2	12.9
	Reprod. toxicity (mg/kg bw/d)	239.4			
	TER criterion	≥5			
	Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	TER_{It}
	Growth stage				
	Oilseed rape / Potatoes	Small omnivorous bird	64.8	1.4x0.53	5.1
	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.				
	First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Maize				
	Intended use	Maize			
	Active sub-stance/product	Pelargonic acid			
	Application rate (g/ha)	2 × 1.950			
	Acute toxicity (mg/kg bw)	2394			
	TER criterion	≥10			
	Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	TER_a
	Growth stage				
	Maize	Small omnivorous bird	158.8	1.2	6.4
	Maize BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods. 50% foliar arthropods	12.6		81.2
	Maize BBCH ≥ 40	Medium granivorous bird "gamebird" Small seeds 100% seed	1.6		639.4
	Maize BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	13.9		73.6
	Maize BBCH ≥ 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.0		170.5
	Reprod. toxicity (mg/kg bw/d)	239.4			
	TER criterion	≥5			
	Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	TER_{It}
	Growth stage				
	Maize	Small omnivorous bird	64.8	1.4x0.53	5.1

	Maize BBCH \geq 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods. 50% foliar arthropods	4.8		34.5
	Maize BBCH \geq 40	Medium granivorous bird "gamebird" Small seeds 100% seed	0.8		206.8
	Maize BBCH \geq 40	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves	5.7		29.0
	Maize BBCH \geq 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7		61.3

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

The values of TER_A and TER_{LT} are respectively higher than the trigger of 10 and 5 for GLOB2011I.

In the EU dossier an acceptable acute risk to birds was concluded based on the weight of evidence even though TER_A are below the relevant triggers indicating a potential unacceptable risk. It is concluded in the DAR that taking into account low toxicity (no toxicity noted at the highest concentrations tested neither in the acute toxicity studies nor in the short-term toxicity studies) and the ready biodegradability of fatty acids, their ubiquitous nature, and limited use in the environment no special risk mitigation measures are required for birds.

Additionally in the EFSA conclusion (6813) risk assessment of July 2021 is stated that no risk is expected for prolonged exposure to pelargonic acid in birds and mammals as is already present in nature.

Therefore, the risk to birds is considered acceptable.

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).

Effective application rate [g/ha] =	1950		
Acute toxicity [mg/kg bw] =	> 2394	quotient	= 0.81
Reprod. toxicity [mg/kg bw/d] =	> 239.4	quotient	= 8.14

With a $K(f)_{oc}$ of 137, Pelargonic acid belongs to the group of less sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50, a quantitative risk assessment (calculation of TER values) is not necessary.

At environmental pH, the log Pow of Pelargonic acid is lower than 3 (pH 7.0: log

	Pow=2.4). Therefore, no risk assessment for secondary poisoning is required.
	The risk from secondary poisoning is considered to be acceptable by zRMS.

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

In EFSA Journal 2013;11(1):3023, a waiver was concluded for all representative formulations on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals:

“The available toxicity data indicated low acute and short-term (for birds only) toxicity to birds and mammals. Acute and short-term (for birds only) first tier risk assessments for birds and mammals indicated a high risk as the resulting TER values were less than the trigger value. However, given that fatty acids are an essential component of the diet of birds and mammals a low risk was concluded. No reproductive toxicity data were available. However, on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals a low reproductive risk was identified.”

This conclusion can be extrapolated to GLOB2011I especially since doses proposed in this evaluation are far below the doses evaluated for the representative formulations in the EU Review of pelargonic acid.

Review Comments 9.3	<p>The EU dossier determined an acceptable acute and chronic risk to mammals by considering the weight of evidence, taking into account the localized use, the ubiquitous nature of fatty acids in the environment, and their easy degradability. Consequently, the acceptable risk to mammals is established based on the overall evidence. As a result, there is no need for additional evaluation of the risk to birds and mammals for uses aligned with those assessed in the EU review.</p> <p>Nevertheless, the evaluator provided a risk assessment based on endpoint from EFSA Conclusion (2013) for the proposed uses as follows:</p> <p>Endpoints and effect values relevant for the risk assessment for mammals</p> <table><tr><th>Species</th><th>Substance</th><th>Exposure System</th><th>Results</th><th>Reference</th></tr><tr><td>Rat</td><td>(C9:0)</td><td>Acute</td><td>LD50 > 2000 mg a.s./kg bw</td><td>EFSA Conclusion Fatty acids C7 to C18 (2013)</td></tr></table> <p>For risk assessment worst case based on endpoint from EFSA Conclusion (2013) is presented.</p> <p>For Pelargonic acid, there are no available long term studies and therefore the LD50/10 (> 200 mg a.s./kg bw/day) can be used for the long term risk assessment (as a worst case).</p> <p>First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2011I in Cereals</p> <table><tr><th>Intended use</th><th>Cereals</th></tr><tr><td>Active sub-</td><td>Pelargonic acid</td></tr></table>	Species	Substance	Exposure System	Results	Reference	Rat	(C9:0)	Acute	LD50 > 2000 mg a.s./kg bw	EFSA Conclusion Fatty acids C7 to C18 (2013)	Intended use	Cereals	Active sub-	Pelargonic acid
	Species	Substance	Exposure System	Results	Reference										
	Rat	(C9:0)	Acute	LD50 > 2000 mg a.s./kg bw	EFSA Conclusion Fatty acids C7 to C18 (2013)										
	Intended use	Cereals													
	Active sub-	Pelargonic acid													

	stance/product				
	Application rate (g/ha)				
	Acute toxicity (mg/kg bw)				
	TER criterion				
			2 × 1300		
			2000		
			≥10		
	Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	TER _a
	Cereals	Small herbivorous mammal	118.4	1.2	10.8
	Reprod. toxicity (mg/kg bw/d)		200		
	TER criterion				
			≥5		
	Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	TER _{lt}
	Cereals	Small herbivorous mammal	48.3	1.4x0.53	4.29
	Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9		109.1
	Cereals BBCH ≥ 40	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7		9.6
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	90.1		
Cereals BBCH 10 - 19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	49.4		
Cereals BBCH 10-29	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	26.6		
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	53.2		
Cereals Early (shoots)	Large herbivorous mammal “lagomorph” Grass + cereals 100% cereal shoots	22.3	9.3		

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

First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Oilseed rape / Potatoes

Intended use	Oilseed rape / Potatoes			
Active sub-stance/product	Pelargonic acid			
Application rate (g/ha)	2 × 0.975			
Acute toxicity (mg/kg bw)	2000			
TER criterion	≥10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	TER _a
Oilseed rape / Potatoes	Small herbivorous mammal	118.4	1.2	14.4
Reprod. toxicity (mg/kg bw/d)	200			
TER criterion	≥5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	TER _{lt}
Oilseed rape / Potatoes	Small herbivorous mammal	48.3	1.4x0.53	5.72

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.

First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB2011I in Maize

Intended use	Maize			
Active sub-stance/product	Pelargonic acid			
Application rate (g/ha)	2 × 1.950			
Acute toxicity (mg/kg bw)	2000			
TER criterion	≥10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	TER _a
Maize	Small herbivorous mammal	118.4	1.2	7.2
Maize BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	5.4		158.3
Maize BBCH ≥	Small herbivorous mam-	34.1		25.1

	40	mal "vole Grass + cereals All maize shoots + later grass			
	Maize BBCH ≥ 40	Small omnivorous mam- mal “mouse” Combination (invertebrates with inter- ception) 25% weeds 50% weed seeds 25% ground arthropods	4.3		198.8
	Reprod. toxicity (mg/kg bw/d)		200		
	TER criterion		≥5		
	Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	TER_{lt}
	Maize	Small herbivorous mam- mal	48.3	1.4x0.53	2.86
	Maize BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9		72.8
	Maize BBCH ≥ 40	Small herbivorous mam- mal "vole Grass + cereals All maize shoots + later grass	18.1		7.6
	Maize BBCH ≥ 40	Small omnivorous mam- mal “mouse” Combination (invertebrates with inter- ception) 25% weeds 50% weed seeds 25% ground arthropods	1.9		72.8
	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.				
The values of TER _A and TER _{LT} are respectively higher than the trigger of 10 and 5 for GLOB2011I.					
In the EU dossier an acceptable acute risk to mammals was concluded based on the weight of evidence even though TER _A are below the relevant triggers indicating a potential unacceptable risk. It is concluded in the DAR that taking into account low toxicity (no toxicity noted at the highest concentrations tested neither in the acute toxicity studies nor in the short-term toxicity studies) and the ready biodegradability of fatty acids, their ubiquitous nature, and limited use in the environment no special risk mitigation measures are required for mammals. Additionally in the EFSA conclusion (6813) risk assessment of July 2021 is stated that no risk is expected for prolonged exposure to perlagonic acid in birds and mam- mals as is already present in nature.					
Therefore, the risk to mammals is considered acceptable.					
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					

	<p>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).</p> <p>Effective application rate [g/ha] = 1950 Acute toxicity [mg/kg bw] = > 2000 quotient = 0.975 Reprod. toxicity [mg/kg bw/d] = > 200 quotient = 9.75</p> <p>With a $K(f)_{oc}$ of 137, Pelargonic acid belongs to the group of less sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 50, a quantitative risk assessment (calculation of TER values) is not necessary.</p> <p>At environmental pH, the log P_{ow} of Pelargonic acid is lower than 3 (pH 7.0: log P_{ow}=2.4). Therefore, no risk assessment for secondary poisoning is required. The risk from secondary poisoning is considered to be acceptable by zRMS.</p>
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9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available. Not required.

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 pelargonic acid. Full details of these studies are provided in the respective EU Review and related documents.

Effects on aquatic organisms of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Salmo gairdnerii</i>	„Insecticidal Soap #4“ (approximately 50.5% Potassium salt)	96 h, s	LC50 = 8.79 mg a.s./L (nom)	EFSA 2013
<i>Oncorhynchus mykiss</i>	Neudosan-Wirkstoff (Potassium salt)	21 days, ss	Growth NOEC = 5.0 mg a.s./L	EFSA 2013
<i>Danio rerio</i>	lauric acid (dodecanoic acid)	21 days, f	Mortality NOEC = 2.0 mg as/L (nom) Growth NOEC = 6.4 mg a.s./L (nom)	EFSA 2013

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	„Safer“s Herbicide H2“ (30% nonanoic & 30% decanoic acid)	48 h, s	EC50 = 10.2 mg a.s./L (nom.)	EFSA 2013
<i>Daphnia magna</i>	Neudosan-Wirkstoff (Potassium salt)	21 d, ss	Reproduction, NOEC = 0.5 mg a.s./L (m.m.)	EFSA 2013
<i>Sediment dweller</i>	-	-	No data available	EFSA 2013
<i>Scenedesmus subspicatus</i>	„Ecoinsect“ (50.5% Potassium salt)	72 h, s	ErC50 = 3.8 mg a.s./L (nom.) EbC50 = 1.2 mg a.s./L (nom.)	EFSA 2013
<i>Lemna gibba</i>	-	-	No data available	EFSA 2013
Higher-tier studies (micro- or mesocosm studies)				
None				

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 9.5-2-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – pelargonic acid according to EFSA Journal 2021;19(8):6813

Species	Substance	Exposure System	Results	Reference
Acute fish				
<i>Oncorhynchus mykiss</i>	Pelargonic acid (Emery 1202)	96 h, s-r	LC50 = 129 mg a.s./L mm	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
Chronic fish				
<i>Oncorhynchus mykiss</i>	Pelargonic acid (Emery 1202)	87 d (ELS), f	NOEC = 1.62 mg a.s./L	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
Acute aquatic invertebrates				
<i>Daphnia magna</i>	Pelargonic acid (Emery 1202)	48 h, ss	EC50 = 50.05 mg a.s./L nom	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
Long-term aquatic invertebrates				
<i>Daphnia magna</i>	Pelargonic acid (Emery 1202)	21d, ss	NOEC = 0.76 mg a.s./L mm	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
Algae				
<i>Pseudokirchneriella subcapitata</i>	Pelargonic acid (Emery 1202)	72 h, s	ErC50 = 21.9 mg a.s./L nom ErC20 = 7.80 mg a.s./L nom EbC10 = 4.55 mg a.s./L nom NOEC = 1.0 mg a.s./L nom	EFSA Conclusion (EFSA Journal 2021;19(8):6813)

Species	Substance	Exposure System	Results	Reference
<i>Lemna gibba</i>	Pelargonic acid (Emery 1202)	7 d, ss	ErC ₅₀ = 101.5 mg a.s./L _{mm}	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Myriophyllum spicatum</i>	Pelargonic acid (Emery 1202)	14 d, ss	ErC ₅₀ = 31.78 mg a.s./L_{mm} NOErC=0.77 mg a.s./L _{mm}	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
Higher-tier studies (micro- or mesocosm studies)				
n.a.				

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – GLOB2011I

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Not required, fish is not the most sensitive aquatic specie and it is possible to extrapolate data from results obtained with the active substance.			
Daphnia magna	GLOB2011I	48 h, s	EC ₅₀ = 12.5 mg/L_{nom} EC ₂₀ = 5.38 mg/L _{nom} EC ₁₀ = 3.46 mg/L _{nom} NOEC = 10.3 mg/L _{nom}	Börschig C., 2023a, Study no. 167841220
Pseudokirchneriella subcapitata	GLOB2011I	72 h, s	ErC ₅₀ = 11.7 mg PPP/L_{nom} ErC ₂₀ = 2.68 mg PPP/L _{nom} ErC ₁₀ = 1.24 mg PPP/L _{nom} NOErC < 9.87 mg/L _{nom}	Börschig C., 2023b, Study no. 167841210
Myriophyllum spicatum	GLOB2011I	14 d, ss	ErC ₅₀ = 204 mg PPP/L_{nom} ErC ₂₀ = 67.0 mg PPP/L _{nom} ErC ₁₀ = 37.5 mg PPP/L _{nom} NOErC = 19.4 mg PPP/L _{nom}	Börschig C., 2023c, Study no. 167841215
Higher-tier studies (micro- or mesocosm studies)				
None				

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

9.5.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints is proposed.

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use groups 2,3,4,5,6,7,8 also covers the risk for aquatic organisms from all other intended uses (i.e. uses 1, 2 and 3) (see 9.1.2).

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 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2011I in winter cereals at BBCH 10-29 (use 4/use group 2)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i> */ <i>Oncorhynchus mykiss</i> **	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	629.37 419.58*	7.16 4.77	3.15 2.10	6.17 4.11	12.59 8.39	1.66 1.10
Step 2						
N-Europe March-May	18.96 37.81*	0.22 0.43	0.09 0.19	0.19 0.37	0.38 0.76	0.05 0.10
N-Europe June-Sept Oct-Feb	18.96 88.25*	0.22 1.00	0.09 0.44	0.19 0.87	0.38 1.77	0.05 0.23
Step 3 (Multiple application, start of the window)						
D3/ditch	7.18	0.08	0.04	0.07	0.14	0.02
D4/pond	2.54	0.03	0.01	0.02	0.05	0.01
D4/stream	6.16	0.07	0.03	0.06	0.12	0.02

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
D5/pond	3.37	0.04	0.02	0.03	0.07	0.01
D5/stream	23.26	0.26	0.12	0.23	0.47	0.06
R1/pond	0.56	0.01	0.00	0.01	0.01	0.00
R1/stream	30.04	0.34	0.15	0.29	0.60	0.08
R3/stream	64.36	0.73	0.32	0.63	1.29	0.17
R4/stream	11.43	0.13	0.06	0.11	0.23	0.03
Step 3 (Multiple application, end of the window)						
D3/ditch	7.18	0.08	0.04	0.07	0.14	0.02
D4/pond	12.22	0.14	0.06	0.12	0.24	0.03
D4/stream	24.93	0.28	0.12	0.24	0.50	0.07
D5/pond	3.37	0.04	0.02	0.03	0.07	0.01
D5/stream	23.26	0.26	0.12	0.23	0.47	0.06
R1/pond	0.64	0.01	0.00	0.01	0.01	0.00
R1/stream	11.56	0.13	0.06	0.11	0.23	0.03
R3/stream	56.17	0.64	0.28	0.55	1.12	0.15
R4/stream	4.65	0.05	0.02	0.05	0.09	0.01
Step 3 (Single application, start of the window)						
D3/ditch	8.21	0.09	0.04	0.08	0.16	0.02
D4/pond	0.28	0.00	0.00	0.00	0.01	0.00
D4/stream	7.13	0.08	0.04	0.07	0.14	0.02
D5/pond	0.36	0.00	0.00	0.00	0.01	0.00
D5/stream	7.69	0.09	0.04	0.08	0.15	0.02
R1/pond	0.44	0.01	0.00	0.00	0.01	0.00
R1/stream	30.04	0.34	0.15	0.29	0.60	0.08

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
R3/stream	64.36	0.73	0.32	0.63	1.29	0.17
R4/stream	11.44	0.13	0.06	0.11	0.23	0.03
Step 3 (Single application, end of the window)						
D3/ditch	8.21	0.09	0.04	0.08	0.16	0.02
D4/pond	2.39	0.03	0.01	0.02	0.05	0.01
D4/stream	6.76	0.08	0.03	0.07	0.14	0.02
D5/pond	0.36	0.00	0.00	0.00	0.01	0.00
D5/stream	7.69	0.09	0.04	0.08	0.15	0.02
R1/pond	0.28	0.00	0.00	0.00	0.01	0.00
R1/stream	6.84	0.08	0.03	0.07	0.14	0.02
R3/stream	56.17	0.64	0.28	0.55	1.12	0.15
R4/stream	5.37	0.06	0.03	0.05	0.11	0.01

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

* Corrected according to Part B8

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter cereals at BBCH 21-49 (use 5/use group 3)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	419.58	4.77	2.10	4.11	8.39	1.10
Step 2						
N-Europe March-May	37.81	0.43	0.19	0.37	0.76	0.10

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 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter cereals at BBCH 51-77 (use 6/use group 4)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	419.58	4.77	2.10	4.11	8.39	1.10
Step 2						
N-Europe March-May	31.08	0.35	0.16	0.30	0.62	0.08
N-Europe June-Sept	31.08	0.35	0.16	0.30	0.62	0.08

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in spring cereals at BBCH 51-77 (use 6/use group 4)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	419.58	4.77	2.10	4.11	8.39	1.10
Step 2						
N-Europe March-May	31.08	0.35	0.16	0.30	0.62	0.08
N-Europe June-Sept	31.08	0.35	0.16	0.30	0.62	0.08

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

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter oilseed rape at BBCH 10-16 (use 8/use group 5)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	314.69	3.58	1.57	3.09	6.29	0.83
Step 2						
N-Europe Oct-Feb	40.97	0.47	0.20	0.40	0.82	0.11
N-Europe June-Sept	18.27	0.21	0.09	0.18	0.37	0.05

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

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter oilseed rape at BBCH 50-65 (use 10/use group 6)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	314.69	3.58	1.57	3.09	6.29	0.83
Step 2						
N-Europe March-May	18.27	0.21	0.09	0.18	0.37	0.05
N-Europe June-Sept	18.27	0.21	0.09	0.18	0.37	0.05

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

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in spring oilseed rape at BBCH 50-65 (use 10/use group 6)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	314.69	3.58	1.57	3.09	6.29	0.83
Step 2						
N-Europe March-May	18.27	0.21	0.09	0.18	0.37	0.05
N-Europe June-Sept	18.27	0.21	0.09	0.18	0.37	0.05

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

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in potatoes at BBCH 35-85 (use 11/use group 7)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	314.69	3.58	1.57	3.09	6.29	0.83
Step 2						
N-Europe March-May	15.75	0.18	0.08	0.15	0.32	0.04
N-Europe June-Sept	15.75	0.18	0.08	0.15	0.32	0.04

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

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in maize at BBCH 51-71 (use 13/use group 8)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
Test species		<i>Salmo gairdnerii</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Scenedesmus subspicatus</i>
Endpoint (µg/L)		LC ₅₀ 8790	NOEC 2000	EC ₅₀ 10200	NOEC 500	ErC ₅₀ /EyC ₅₀ 3800
AF		100	10	100	10	10
RAC (µg/L)		87.9	200	102	50	380
FOCUS Scenario	PEC _{gl-max} (µg/L)					
Step 1						
	629.37	7.16	3.15	6.17	12.59	1.66
Step 2						
N-Europe March-May	18.96	0.22	0.09	0.19	0.38	0.05
N-Europe June-Sept	18.96	0.22	0.09	0.19	0.38	0.05

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

For intended uses 5-6-8-10-11-13 (covering uses 2-3-7-9-12), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrate as characterised by a NOEC for *Daphnia magna* of 500 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 2 scenarios. Therefore, no further assessment is necessary.

For intended use 4 (covering use 1), calculated PEC/RAC ratios did indicate a potential risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrate as characterised by a NOEC for *Daphnia magna* of 500 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 2 winter scenarios. Therefore, further assessment through step 3 is necessary.

For intended use 4 (covering use 1), calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic invertebrate as characterised by a NOEC for *Daphnia magna* of 500 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 3 winter scenarios (with exception of R3 scenario which is only applicable for Austria and Hungary thus not applicable for this submission). Therefore, no further assessment through step 4 is necessary.

Risk for formulation GLOB2011I

The worst-case RAC derived from data obtained with GLOB2011I on *Pseudokirchneriella subcapitata* is 1170 µg/L (ErC50 of 11700 µg/L divided by the assessment factor of 10). This value is far above the worst case PEC_{sw} calculated for GLOB2011I (i.e. 21.1 µg GLOB2011I/L for the use 13/use group 1). No risk is expected following the use of GLOB2011I according to proposed GAPs.

9.5.3 Overall conclusions

No unacceptable risk is present for aquatic organisms after the use of GLOB2011I according to the intended GAPs. No risk mitigation measure is necessary.

Review Comments 9.5	zRMS comments:					
	Pelargonic acid					
	The risk assessment was performed based on the EU agreed endpoints in accordance with EFSA Journal 2013;11(1):3023.					
	Approval of renewal pelargonic acid is ongoing but the Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid) (EFSA Journal 2021;19(8):6813) was published in 2021. Therefore, the comparison of agreed endpoints for 2013 and 2021 was performed below.					
	Comparison of agreed endpoints for active substance for 2013 and 2021					
	Species	Fish		Daphnia		Algae
						Aquatic plants
		LC50 [mg a.s./L]	NOEC [mg a.s./L]	EC50 [mg a.s./L]	NOEC*/EC10** [mg a.s./L]	ErC50 [mg a.s./L]
	Results EFSA 2013	8.79	2.0	10.2	0.5*a	1.2
	Results EFSA 2021	129	1.62	50.05	0.76 **	21.9
	a the worst-case endpoint is in bold					
	The aquatic risk assessment of pelargonic acid is driven by aquatic invertebrates (NOEC = 0.5 mg as./l					

(EFSA 2013) and EC10 = 0.76 mg as./l (EFSA 2021)).
The NOEC of 0.5 mg as/l (EFSA 2013) is the worst case and the risk assessment based on the endpoint presented in the EFSA Journal 2013;11(1):3023 covers the new agreed endpoint.
Additionally, in EFSA Journal 2021;19(8):6813 new endpoint for aquatic macrophytes (*Myriophyllum spicatum*) has been established.

For completeness, the PEC/RAC calculations with new agreed endpoints were presented below.

Table 9.5 3-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2011I in winter cereals at BBCH 10-29 (use 4/use group 2)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
AF		129000	1620	50050	760	21900	
RAC (µg/L)		100	10	100	10	10	31780
		1290	162	500.5	76	2190	3178
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	419.58	0.33	2.59	0.84	5.52	0.19	0.13
Step 2							
N-Europe March-May	37.81	0.03	0.23	0.08	0.50	0.02	0.01
N-Europe Oct-Feb	88.25	0.07	0.54	0.18	1.16	0.04	0.03
Step 3 (Multiple application, start of the window)							
D3/ditch	7.18	-	-	-	0.09	-	-
D4/pond	2.54	-	-	-	0.03	-	-
D4/stream	6.16	-	-	-	0.08	-	-
D5/pond	3.37	-	-	-	0.04	-	-
D5/stream	23.26	-	-	-	0.31	-	-
R1/pond	0.56	-	-	-	0.01	-	-
R1/stream	30.04	-	-	-	0.40	-	-
R3/stream	64.36	-	-	-	0.85	-	-
R4/stream	11.43	-	-	-	0.15	-	-
Step 3 (Multiple application, end of the window)							
D3/ditch	7.18				0.09		
D4/pond	12.22				0.16		
D4/stream	24.93				0.33		

	D5/pond	3.37				0.04			
	D5/stream	23.26				0.31			
	R1/pond	0.64				0.01			
	R1/stream	11.56				0.15			
	R3/stream	56.17				0.74			
	R4/stream	4.65	-	-	-	0.06	-	-	
	Step 3 (Single application, start of the window)								
	D3/ditch	8.21	-	-	-	0.11	-	-	
	D4/pond	0.28	-	-	-	0.004	-	-	
	D4/stream	7.13	-	-	-	0.10	-	-	
	D5/pond	0.36	-	-	-	0.0004	-	-	
	D5/stream	7.69	-	-	-	0.10	-	-	
	R1/pond	0.44	-	-	-	0.01	-	-	
	R1/stream	30.04	-	-	-	0.40	-	-	
	R3/stream	64.36	-	-	-	0.85	-	-	
	R4/stream	11.44	-	-	-	0.15	-	-	
	Step 3 (Single application, end of the window)								
	D3/ditch	8.21	-	-	-	0.11	-	-	
	D4/pond	2.39	-	-	-	0.03	-	-	
	D4/stream	6.76	-	-	-	0.09	-	-	
	D5/pond	0.36	-	-	-	0.005	-	-	
	D5/stream	7.69	-	-	-	0.10	-	-	
	R1/pond	0.28	-	-	-	0.004	-	-	
	R1/stream	6.84	-	-	-	0.09	-	-	
	R3/stream	56.17	-	-	-	0.74	-	-	
	R4/stream	5.37	-	-	-	0.07	-	-	
	Table 9.5 4-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter cereals at BBCH 21-49 (use 5/use group 3)								
	Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte	
	Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum	
	Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50	
			129000	1620	50050	760	21900		
	AF		100	10	100	10	10	31780	
	RAC (µg/L)		1290	162	500.5	76	2190	3178	
FOCUS Scenario	PEC gl-max (µg/L)								

Step 1							
	419.58	0.33	2.59	0.84	5.52	0.19	0.13
Step 2							
N-Europe March-May	37.81	0.03	0.23	0.08	0.50	0.02	0.01
Table 9.5 5-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter cereals at BBCH 51-77 (use 6/use group 4)							
Group		Fish acute	Fish longed pro-	Inverteb. acute	Inverteb. pro-longed	Algae	Aquatic macro-phyte
Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
Endpoint		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
(µg/L)		129000	1620	50050	760	21900	
AF		100	10	100	10	10	31780
RAC (µg/L)		1290	162	500.5	76	2190	3178
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	419.58	0.33	2.59	0.84	5.52	0.19	0.13
Step 2							
N-Europe March-May	31.08	0.02	0.19	0.06	0.41	0.01	0.01
N-Europe- June-Sept	31.08	0.02	0.19	0.06	0.41	0.01	0.01
Table 9.5 6-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in spring cereals at BBCH 51-77 (use 6/use group 4)							
Group		Fish acute	Fish longed pro-	Inverteb. acute	Inverteb. pro-longed	Algae	Aquatic macro-phyte
Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
Endpoint		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
(µg/L)		129000	1620	50050	760	21900	
AF		100	10	100	10	10	31780
RAC (µg/L)		1290	162	500.5	76	2190	3178

	FOCUS Scenario	PEC gl-max (µg/L)						
	Step 1							
		419.58	0.33	2.59	0.84	5.52	0.19	0.13
	Step 2							
	N-Europe March-May	31.08	0.02	0.19	0.06	0.41	0.01	0.01
	N-Europe June-Sept	31.08	0.02	0.19	0.06	0.41	0.01	0.01
Table 9.5 7-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter oilseed rape at BBCH 10-16 (use 8/use group 5)								
	Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
	Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
	Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
	AF		129000	1620	50050	760	21900	
	RAC (µg/L)		100	10	100	10	10	31780
			1290	162	500.5	76	2190	3178
	FOCUS Scenario	PEC gl-max (µg/L)						
	Step 1							
		314.69	0.32	1.94	0.63	4.14	0.14	0.10
	Step 2							
	N-Europe Oct-Feb	40.97	0.03	0.25	0.08	0.54	0.02	0.01
	N-Europe June-Sept	18.27	0.01	0.1	0.04	0.24	0.01	0.01
Table 9.5 8-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in winter oilseed rape at BBCH 50-65 (use 10/use group 6)								
	Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
	Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
	Endpoint		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50

Table 9.5 9-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in spring oilseed rape at BBCH 50-65 (use 10/use group 6)	(µg/L)		129000	1620	50050	760	21900	
	AF		100	10	100	10	10	31780
	RAC (µg/L)		1290	162	500.5	76	2190	3178
	FOCUS Scenario	PEC gl-max (µg/L)						
	Step 1							
		314.69	0.32	1.94	0.63	4.14	0.14	0.10
	Step 2							
	N-Europe March-May	18.27	0.01	0.1	0.04	0.24	0.01	0.01
	N-Europe June-Sept	18.27	0.01	0.1	0.04	0.24	0.01	0.01

Table 9.5 10-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in spring oilseed rape at BBCH 50-65 (use 10/use group 6)	Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
	Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
	Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
	AF		129000	1620	50050	760	21900	
	RAC (µg/L)		100	10	100	10	10	31780
	FOCUS Scenario	PEC gl-max (µg/L)	1290	162	500.5	76	2190	3178
	Step 1							
		314.69	0.32	1.94	0.63	4.14	0.14	0.10
	Step 2							
	N-Europe March-May	18.27	0.01	0.1	0.04	0.24	0.01	0.01
	N-Europe June-Sept	18.27	0.01	0.1	0.04	0.24	0.01	0.01

organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in potatoes at BBCH 35-85 (use 11/use group 7)							
Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
		129000	1620	50050	760	21900	
AF		100	10	100	10	10	31780
RAC (µg/L)		1290	162	500.5	76	2190	3178
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	314.69	0.32	1.94	0.63	4.14	0.14	0.10
Step 2							
N-Europe March-May	15.75	0.01	0.1	0.03	0.21	0.01	0.005
N-Europe June-Sept	15.75	0.01	0.1	0.03	0.21	0.01	0.005

Table 9.5 11-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for pelargonic acid for each organism group based on FOCUS Steps 1 and 2 calculations for the use of GLOB2011I in maize at BBCH 51-71 (use 13/use group 8)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophyte
Test species		Oncorhynchus mykiss	Oncorhynchus mykiss	Daphnia magna	Daphnia magna	Scenedesmus subspicatus	M. spicatum
Endpoint (µg/L)		LC50	NOEC	EC50	EC10	ErC50/EyC50	ErC50
		129000	1620	50050	760	21900	
AF		100	10	100	10	10	31780
RAC (µg/L)		1290	162	500.5	76	2190	3178
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	629.37	0.49	3.89	1.26	8.28	0.29	0.20
Step 2							

	N-Europe March-May	18.88	0.01	0.12	0.04	0.25	0.01	0.01
	N-Europe June-Sept	18.88	0.01	0.12	0.04	0.25	0.01	0.01
<p>The first tier risk assessment for pelargonic acid was performed by Applicant based on the EU agreed endpoints (EFSA Journal 2013;11(1):3023) and FOCUS Step 1 to 3 PECsw values. All PEC/RAC ratios are below trigger value of 1 except R3/stream scenario in winter cereals. According to the applicant's comment this scenario is not applicable for this submission.</p> <p>Additionally for completeness, the first tier risk assessment for pelargonic acid was performed by zRMS based on the EU agreed endpoints (EFSA Journal 2021;19(8):6813) and FOCUS Step 1 to 3 PECsw values. Taking into account the new agreed endpoints all PEC/RAC ratios for all intended uses are below trigger value of 1.</p> <p>For GLOB2011I/Sankari For GLOB2011I/Sankari tests on invertebrates <i>Daphnia magna</i>, on algae <i>Pseudokirchneriella subcapitata</i>, and on aquatic plants <i>Myriophyllum spicatum</i> were provided by Applicant, but no tests are reported for fish. Based on the aquatic acute data for active substance fish is not the most sensitive aquatic species and is not expected that the formulation to be more sensitive to fish than invertebrates, algae and macrophytes. It is possible to predict acute toxicity of the formulation on the basis of data for active substance therefore no acute fish study with the formulation is considered necessary.</p> <p>The PECsw values of formulation GLOB2011I were assessed and accepted in Part B8.</p>								
Cropping scenario	FOCUS scenario	1 m						
		% drift	Max. PECsw (µg/L)					
Winter cereals	Ditch	1.9274	11.7044					
	Pond	0.3282	0.5979					
	Stream	1.9274	11.7044					
		-	14.04528*					
Spring cereals	Ditch	1.9274	11.7044					
	Pond	0.3282	0.5979					
	Stream	1.9274	11.7044					
		-	14.04528*					
Winter oilseed rape	Ditch	1.9274	8.7783					
	Pond	0.3282	0.4484					
	Stream	1.9274	8.7783					
		-	10.53396*					
Spring oilseed rape	Ditch	1.9274	8.7783					
	Pond	0.3282	0.4484					
	Stream	1.9274	8.7783					
		-	10.53396*					
Potato	Ditch	1.6838	8.7783					
	Pond	0.2743	0.4484					
	Stream	1.6838	8.7783					
		-	10.53396*					
Maize	Ditch	1.9274	17.5566					
	Pond	0.3282	0.8969					

		Stream	1.9274	17.5566
			-	21.06792*
<p>Pseudokirchneriella subcapitata is the most sensitive aquatic organisms with ErC50 11.7 mg formulation/L. Taking into account the worst case PECsw value at 21.1 µg formulation/L (for the use in maize) PEC/RAC ratio value is below trigger value of 1.</p> <p>PEC/RAC = 21.1/1170 = 0.02</p> <p>Conclusion According to the performed risk assessment there is no potential of risk for aquatic organisms resulting from acute and long-term exposure to active substances following use of GLOB2011I/Sankari in compliance with proposed GAP without the risk mitigation measures.</p> <p>In case of intended use in winter cereals, relevance of R3/stream scenario should be considered at the national level.</p>				

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 pelargonic acid. Full details of these studies are provided in the respective EU Review and related documents. There is no new study submitted.

Effects on bees of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Neudosan Neu (515 g/L potassium salts of natural fatty acids)	Oral	LD ₅₀ > 96.04 µg a.s./bee*	EFSA, 2013
Apis mellifera	Neudosan Neu (515 g/L potassium salts of natural fatty acids)	Contact	LD ₅₀ > 100 µg a.s./bee*	EFSA, 2013
Apis mellifera	Pelargonic acid	10 d chronic adult feeding study	No data	EFSA, 2013
Apis mellifera	Pelargonic acid	22 d repeated exposure larval toxicity study	No data	EFSA, 2013
Apis mellifera	GLOB2011I (Pelargonic acid 650 g/L EC)	Oral	LD ₅₀ > 364 µg a.s./bee	Schabio, S., 2023, study # 163761035
Apis mellifera	GLOB2011I (Pelargonic acid 650 g/L EC)	Contact	LD ₅₀ = 293.4 µg a.s./bee	Schabio, S., 2023, study # 163761035

Species	Substance	Exposure System	Results	Reference
<i>Bombus terrestris</i>	GLOB2011I	Oral, acute, 48h	LD50 > 218.8 µg a.s./bee	Schabio, S., 2022a, study # 163761105
<i>Bombus terrestris</i>	GLOB2011I	Contact, acute, 48h	LD50 > 530.4 µg a.s./bee	Schabio, S., 2022a, study # 163761105
<i>Apis mellifera</i>	GLOB2011I	Adult, chronic	LDD50 = 34.3 µg a.s./bee/day NOEDD = 19.1 µg a.s./bee/day	Schabio, S., 2022b, study # 163761136
<i>Apis mellifera</i>	GLOB2011I	Larvae, chronic, 22 d	ED50 = 406.37 µg a.s./larva NOED = 44.75 µg a.s./larva ED10 = 67.00 µg a.s./larva	Colli, M., 2022, study # BT256/21
Higher-tier studies (tunnel test, field studies)				
-				

*No data available on technical material in EFSA 2013 but on the representative formulation. Risk assessment done for illustrative purposes only. Data on GLOB2011 is to be used for risk assessment.

9.6.1.1 Justification for new endpoints

As GLOB2011I is not identical to the reference formulation used during the EU Review of fatty acids, toxicity to bees from the formulation was also tested and used in the risk assessment.

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 001 also covers the risk for honeybees from all other intended uses in group 002 to 008 (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 GLOB2011I in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)			
Active substance	Pelargonic acid			
Application rate (g/ha)	2 × 1950			
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50	

Oral toxicity	> 96.04*	1950	< 20.3
Contact toxicity	> 100*		< 19.5
Product	GLOB2011I		
Application rate (g/ha)	2 × 1950		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity (48h)	> 364	1950	< 5.36
Contact toxicity (48h)	293.4		6.65

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

*No data available on technical material in EFSA 2013 but on the representative formulation. Risk assessment done for illustrative purposes only. Data on GLOB2011 is to be used for risk assessment.

9.6.3 Chronic risk assessment (KCP 10.3.1.2)

The chronic risk assessments were only performed using the endpoints of the studies with the formulated product, since there were no chronic endpoints listed in EFSA 2013.

9.6.3.1 Larval chronic risk assessment

The endpoints used in the risk assessment are:

- for the active substance: no EU agreed endpoint (EFSA 2013).
- for the PPP: the NOED of 44.75 µg a.s./larva (endpoint obtained with GLOB2011I)

ASSESSMENT ACCORDING TO SANCO 2002 AND EPPO 2010

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 SANCO 2002 and the modified EPPO 2010 approach 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 proposed in the EPPO 2010 scheme (see Note 6), 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., 2005*³, 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 with 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).

³ 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

Thus, considering the mean RUD values for nectar and pollen in EFSA 2013 exposure can be estimated for the whole development period.

Using PPP endpoints:

Nectar dose: $2.7201 \times 2.9 \times 198/1000 = 1.56188 \mu\text{g GLOB2011I/larva}$

Pollen dose: $2.7201 \times 6.1 \times 2/1000 = 0.03319 \mu\text{g GLOB 2011I/larva}$

For nectar for larvae, dose/developmental period ($\mu\text{g a.s./larvae/d.p.}$)

$= \text{A.R.} \times (0.0594 \text{ g}/(1000 \times 0.3)) \times \text{RUD} \times 1000 = 1.95 \text{ kg a.s./ha} \times (0.0594 \text{ g}/(1000 \times 0.3)) \times 2.9 \text{ mg a.s./kg} \times 1000 = 1.1197 \mu\text{g a.s./larvae/d.p.}$

For pollen for larvae, dose/developmental period ($\mu\text{g a.s./larvae/d.p.}$)

$= \text{A.R.} \times \text{RUD} \times 2 \text{ mg/5 days i.e. d.p.} = 1.95 \text{ kg a.s./ha} \times 6.1 \text{ mg a.s./kg} \times 2 \text{ mg/5 days i.e. d.p} = 0.02379 \mu\text{g a.s./larvae/d.p.}$

Total exposure ETE = $1.59507 \mu\text{g GLOB2011I/larvae}$ (as a default worst-case residue at $2.7201 \text{ kg GLOB2011I/ha}$)

Total exposure ETE = $1.143 \text{ a.s./larvae / d.p.}$

This can be compared to the larval NOED of $62.50 \text{ } 44.75 \mu\text{g GLOB2011I/larva}$.

$\text{TER} = \text{NOEDD} (\mu\text{g/larva}) / \text{ETE} (\mu\text{g/larva}) = 62.50 \text{ } 44.75 / 1.59507 = 28.06 \text{ } 39.18$

This can be compared to the larval NOED of $44.75 \mu\text{g a.s./larva} \mu\text{g GLOB2011I/larva}$.

$\text{TER} = \text{NOEDD} (\mu\text{g/larva}) / \text{ETE} (\mu\text{g/larva}) = 44.75 / 1.143 = 39.13$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the chronic risk to honeybees. It is clear that with a TER value of 28.06, the proposed uses of GLOB2011I pose an acceptable risk to bee larval development.

The risk assessment was also conducted according to the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)” (EFSA Journal 2013;11(7):3295).

9.6.3.2 Adult chronic risk assessment

The endpoints used in the risk assessment are:

- for the active substance: no EU agreed endpoint (EFSA 2013).
- For the PPP: the LDD50 of $34.3 \mu\text{g a.s./bee/day}$ and NOEDD of $19.1 \mu\text{g a.s./bee/day}$ (endpoints obtained with GLOB2011I)

ASSESSMENT ACCORDING TO SANCO 2002 AND EPPO 2010

The adult chronic risk assessment is performed using SANCO 2002 and 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 issues associated with the generation of LDD₅₀ values for substances of low toxicity and calculates expo-

sure 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:

$$\text{Daily dose } (\mu\text{g a.i./bee}) = \text{A.R.} \times [128 \text{ mg}/(1000 \times 0.3)] \times \text{RUD} = 1.95 \times [128/(1000 \times 0.3)] \times 2.9 = 2.4128 \mu\text{g/bee}$$

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).

Using PPP endpoint:

$$\text{TER} = \text{NOEDD}/\text{daily dose} = 19.1/2.4128 = 7.92$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the chronic risk to honeybees. It is clear that with a TER value of 3.77 (AS endpoint) or 7.92 (PPP endpoint), the proposed uses of GLOB2011I pose an acceptable chronic risk to adult bees.

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

Not relevant.

9.6.4 Effects on bumble bees

The evaluation of the risk for bumble bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 001 also covers the risk for bumble bees from all other intended uses in group 002 to 008 (see 9.1.2).

Table 9.6-3: First-tier assessment of the risk for bumble bees due to the use of GLOB2011I in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)		
Product	GLOB2011I		
Application rate (L/ha)	2 × 3		
Test design	LD₅₀ (lab.) (μg/bee)	Single application rate (g a.s./ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity (48h)	> 218.8	1950	< 8.91
Contact toxicity (48h)	> 530.4		< 3.68

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

No risk to bumble bees is identified as Q_{HO} and Q_{HC} are below the trigger value of 50.

9.6.5 Effects on solitary bees

Not required.

9.6.6 Overall conclusions

GLOB2011I does not pose unacceptable risk to bees when applied according to the intended uses.

zRMS Comments:	<p>The submitted risk assessment is based on SANCO guidance (2002) and new EU guidance (2013). The EU agreed endpoints for active substance were used in risk assessment. New studies for acute and chronic toxicity were submitted and accepted.</p> <p>The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.</p> <p>The chronic risk assessment performed in accordance with modified EPPO scheme (2010) approach according to ECPA proposal of 9 June 2017 was submitted and accepted. Its relevance will be decided at the Member State level.</p> <p>The hazard quotients are below the trigger value, indicating that the active substance and formulation pose an acceptable acute and chronic risk to bees. Therefore, an acceptable risk to bees is expected from the application of GLOB2011I in accordance with proposed use pattern.</p>
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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 pelargonic acid. Full details of these studies are provided in the respective EU Review and related documents.

Effects on non-target arthropods of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (protonymphs)	GLOB2011I	Laboratory test glass plates (2D)	Extended lab tests performed directly as	-

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosiphi</i> (adults)	GLOB2011I	Laboratory test glass plates (2D)	endpoints available in the EFSA Conclusions would have lead to a potential risk to non target arthropods.	-
<i>Typhlodromus pyri</i> (protonymphs)	GLOB2011I	Extended lab test, natural substrate (vine leaves), 2D	LR50 = 1376 g a.s./ha (2109 ml GLOB2011I/ha) ER50 > 710 g a.s./ha (> 1088 ml GLOB2011I/ha)	Leopold, J. (2022a), study # 167841062
<i>Aphidius rhopalosiphi</i> (adults)	GLOB2011I	Extended lab test, natural substrate (barley plants), 3D	LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha) ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)	Leopold, J. (2022c), study # 167841002
<i>Chrysoperla carnea</i>	GLOB2011I	Extended lab test, natural substrate (vine leaves), 2D	LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha) ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)	Leopold, J. (2022d), study # 167841047
<i>Orius laevigatus</i>	GLOB2011I	Extended lab test, natural substrate (vine leaves), 2D	LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha) ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)	Leopold, J. (2022e), study # 167841052
<i>Typhlodromus pyri</i> (protonymphs)	GLOB2011I	Extended lab test – aged residue test, natural substrate (potted vine plants), 3D	After application of 6800 ml GLOB2011I/ha (4436 g a.s./ha), mortality was < 50% [31.1% (Day 0), 11.8% (Day 7) and -4.8% (Day 14)] and effect on reproduction was < 50% [33.3% (Day 0-7), 0.00% (Day 7-14) and -29.4% (Day 14-21)]	Leopold, J. (2022b), study # 167841060
Field or semi-field tests				
-				

9.7.1.1 Justification for new endpoints

GLOB2011I was not evaluated during EU renewal of pelargonic acid. EU agreed endpoints are based on various PPP studies not performed with pelargonic acid technical. As a consequence, endpoints related to GLOB2011I are more relevant and used in the risk assessment.

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 001 (maize) also covers the risk for non-target arthropods from all other intended uses in groups 002 to 008 (cereals, oilseed rape, potatoes and maize) (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 GLOB2011I in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)		
Active substance/product	Pelargonic acid / GLOB2011I		
Application rate (g/ha)	2 × 3L		
MAF	1.7		
Test species Tier I	LR₅₀ (lab.) (g/ha)	PER_{in-field} (g/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	-	-	-
<i>Aphidius rhopalosiphi</i>	-		-
Test species Higher-tier	LR₅₀ (lab.) (L/ha)	PER_{in-field} (L/ha)	HQ_{in-field} criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	2.109	5.1	2.42
<i>Aphidius rhopalosiphi</i>	> 6.8	5.1	0.75
<i>Chrysoperla carnea</i>	> 6.8	5.1	0.75
<i>Orius laevigatus</i>	> 6.8	5.1	0.75
Test species Higher-tier	Rate with ≤ 50 % effect (L/ha) at 0 DALT	PER_{in-field} (L/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	6.8	5.1	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

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

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 001 (maize) also covers the risk for non-target arthropods from all other intended uses in groups 002 to 008 (cereals, oilseed rape, potatoes and maize) (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 GLOB2011I in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)				
Active substance/product	Pelargonic acid / GLOB2011I				
Application rate (L/ha)	2 × 3L				
MAF	1.7				
vdf	10 5 (Higher-tier)				
Test species Tier I	LR₅₀ (lab.) (g/ha)	Drift rate	PER_{off-field} (g/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	-	-	-	10	-
<i>Aphidius rhopalosiphi</i>	-				-
Test species Higher-tier	LR₅₀ (extended) (L/ha)	Drift rate	PER_{off-field} (L/ha) vdf = 10 vdf = 5	CF	HQ_{off-field} criterion: HQ ≤ 1
<i>Typhlodromus pyri</i>	2.109	0.0277	0.014127 0.028254	5	0.034 0.013
<i>Aphidius rhopalosiphi</i>	> 6.8				< 0.01 < 004
<i>Chrysoperla carnea</i>	> 6.8				< 0.01 < 004
<i>Orius laevigatus</i>	> 6.8				< 0.01 < 004

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

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

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The risk assessment indicates that the risk for non-target arthropods is acceptable for the intended uses of GLOB2011I. No mitigation measures are needed.

zRMS Comments:	The submitted risk assessment based on the “Guidance Document on Terrestrial Ecotoxicology” (2002) was accepted.
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	<p>New studies for formulation were submitted. The laboratory studies 2D and 3D were evaluated and accepted for the risk assessment.</p> <p>In field risk. The hazard quotients are below the trigger value ($HQ \leq 1$) for most species. Only for <i>Typhlodromus pyri</i> the $HQ > 1$. Considering an extended aged residue study performed on <i>Typhlodromus pyri</i>, where values 50% of lethal and sub-lethal effects are below PER, the active substance poses an acceptable risk to arthropods other than bees.</p> <p>Off-field risk. The hazard quotients are below the trigger value ($HQ \leq 1$) for all species indicating that the active substance poses an acceptable risk to arthropods other than bees.</p> <p>Conclusion The risk to arthropods other than bees is acceptable if the GLOB2011I is applied in accordance with proposed use pattern.</p>
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9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

No chronic toxicity studies to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with pelargonic acid or with representative formulations. Nevertheless, data can be extrapolated from studies performed with GLOB2011I.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	„NEU 1107 H“ 21% Pelargonic acid	Acute 14 days	LC50 > 210 mg a.s./kg dws LC50 corr > 105 mg a.s./kg dws*	EFSA Conclusions 2013
<i>Eisenia fetida</i>	Pelargonic acid	Long-term (8 weeks)	No data submitted	EFSA Conclusions 2013
<i>Folsomia candida</i>	Pelargonic acid	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	No data submitted	EFSA Conclusions 2013
<i>Hypoaspis aculeifer</i>	Pelargonic acid	Mixed into substrate 14 d, chronic 5 % peat content	No data submitted	EFSA Conclusions 2013
<i>Eisenia fetida</i>	GLOB2011I (Pelargonic acid 650 g/L EC)	Mixed into substrate / Overspray 28 d, acute 5/10 % peat content	NOEC \geq 179.2 mg PPP/kg dws NOEC \geq 128.3 mg a.s./kg dws	Hübner S./2022a/ Study 167841022

Species	Substance	Exposure System	Results	Reference
			NOEC _{corr.} ≥ 64.2 mg a.s./kg dws	
<i>Folsomia candida</i>	GLOB2011I (Pelargonic acid 650 g/L EC)	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	<u>Reproduction:</u> NOEC = 47.5 mg PPP/kg dws NOEC = 34.01 mg a.s./kg dws NOEC _{Corr} = 17.0 mg a.s./kg dws	Hübner S./2022b/ Study 167841016
<i>Hypoaspis aculeifer</i>	GLOB2011I (Pelargonic acid 650 g/L EC)	Mixed into substrate 14 d, chronic 5 % peat content	<u>Reproduction:</u> NOEC = 278 mg PPP/kg dws NOEC = 199.1 mg a.s./kg dws NOEC _{Corr.} = 99.5 mg a.s./kg dws	Hübner S./2022c/ Study 167841089
Field studies				
-				
Litter bag test				
-				

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

** Worst case endpoint out of representative PPPs as surrogate value for endpoint of technical pelargonic acid (no study performed on technical pelargonic acid)

Table 9.8-2-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) for pelargonic acid according to EFSA Journal 2021;19(8):6813

Species	Substance	Exposure System	Results	Lowest end-point /organism	Reference
<i>Eisenia andrei</i>	COM 508 16 H EW (Pelargonic acid 23.157%)	Long-term (8 weeks) Mixed into soil	NOEC = 500 mg a.s./kg dry soil NOEC _{corr.} = 250 mg a.s./kg dws EC ₁₀ = 579 mg a.s./kg dws EC _{10corr.} = 289.5 mg a.s./kg dws	NOEC_{corr} = 21.95 mg a.s./kg soil d.w.	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Eisenia fetida</i>	NEU 1170 H (Pelargonic acid 180.8 g/L)	Long-term (8 weeks) Mixed into soil	NOEC = 1536.9 mg a.s./kg dry soil NOEC _{corr} = 768.45 mg a.s./kg dry soil		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Eisenia andrei</i>	VVH-86086 / BCP 1004D (Pelargonic acid 71.96 % w/w nom.)	Long-term (8 weeks) Mixed into	NOEC = 387 mg a.s/kg soil dw		EFSA Conclusion (EFSA Journal 2021;19(8):6813)

Species	Substance	Exposure System	Results	Lowest end-point /organism	Reference
		soil	NOEC _{corr} =193.5 mg a.s./kg dws		
<i>Eisenia andrei</i>	MON 74134 (Pelargonic acid 1.82 w/v)	Long-term (8 weeks) Mixed into soil	NOEC = 43.9 mg a.s./kg dws NOEC _{corr} =21.95 mg a.s./kg dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Eisenia andrei</i>	Emery 1202 Pelargonic acid	Chronic toxicity	NOEC = 61.7 mg a.s./kg soil d.w. NOEC _{corr} =30.85 mg a.s./kg dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Folsomia candida</i>	VVH-86086 / BCP 1004D (Pelargonic acid 71.96 % w/w nom.)	28 days	NOEC = 36.69 mg a.s./kg soil d.w. NOEC _{corr} =18.34 mg a.s./kg soil d.w.	NOEC_{corr}=14.7 mg a.s./kg soil	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	COM 508 16 H EW (Pelargonic acid 23.157%)		NOEC = 180 mg a.s./kg soil dw NOEC _{corr} = 90 mg a.s./kg soil dw		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	NEU 1170 H (Pelargonic acid 180.8 g/L)		NOEC = 55.6 mg a.s./kg soil d.w. NOEC _{corr} =27.8 mg a.s./kg soil d.w.		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	MON 74134 (Pelargonic acid 18.3 gr/L)		NOEC=29.4 mg a.s./kg dws NOEC _{corr} =14.7 mg a.s./kg soil.		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	ABP-811 (Pelargonic acid 61.07 % w/w)		NOEC= 104.735 mg a.s./kg d.w. NOEC _{corr} =52.33 mg a.s./kg dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
<i>Hypoaspis aculeifer</i>	VVH-86086 / BCP 1004D (Pelargonic acid 71.96 % (w/w) nom.)	14 days	NOEC = 286.14 mg a.s./kg soil d.w. NOEC _{corr} = 143.07 mg a.s./kg soil d.w.	NOEC_{corr} = 14.7 mg a.s./kg soil d.w.	EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	COM 508 16 H EW (Pelargonic acid 23.157%)		NOEC = 300 mg a.s./kg soil d.w. NOEC _{corr} = 150 mg a.s./kg soil d.w.		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	NEU 1170 H (Pelargonic acid 180.8 g/L)		NOEC = 282.4 mg a.s./kg soil dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)

Species	Substance	Exposure System	Results	Lowest end-point /organism	Reference
			NOEC _{corr.} = 141.2 mg a.s./kg dws		
	MON 74134 (Pelargonic acid 18.3 gr/L)		NOEC=309 mg a.s./kg dws NOEC _{corr.} 154.5 mg a.s./kg dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)
	ABP-811 (Pelargonic acid 61.07 % w/w)		NOEC= 610.7 mg a.s./kg d.w. NOEC _{corr.} =305.35 mg a.s./kg dws		EFSA Conclusion (EFSA Journal 2021;19(8):6813)

9.8.1.1 Justification for new endpoints

Not applicable for active substance endpoints. No chronic studies were available for earthworm, *Folsomia candida* or *Hypoaspis aculeifer*.

For the PPP endpoints, GLOB2011I was not evaluated during EU renewal of pelargonic acid. As a consequence, endpoints related to GLOB2011I are provided and used in the risk assessment.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 13/group 001 (maize) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (uses 1-12) in groups 002-008 (cereals, oilseed rape, potatoes, maize) (see 9.1.2).

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 GLOB2011I in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)		
Chronic effects on earthworms			
Product/active substance	NOEC _{corr} (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)

Pelargonic acid*	-	1.802	-
GLOB2011I (Pelargonic acid 650 g/L EC)	≥ 64.2 ≥ 89.6	2.429	≤ 26.4 ≥ 36.9
Chronic effects on other soil macro- and mesofauna			
Folsomia candida			
Product/active substance	NOEC_{corr} (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Pelargonic acid*	-	1.802	-
GLOB2011I (Pelargonic acid 650 g/L EC)	17.0 23.75	2.429	7.00 9.8
Hypoaspis aculeifer			
Product/active substance	NOEC_{corr} (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Pelargonic acid*	-	1.802	-
GLOB2011I (Pelargonic acid 650 g/L EC)	99.5 139	2.429	41.0 57.2

TER values shown in bold fall below the relevant trigger.

* No endpoint set in EFSA 2013 but data can be extrapolated from data obtained with GLOB2011I

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

There is no unacceptable risk to soil meso- and macrofauna when applying GLOB2011I according to the intended use.

zRMS Comments:	zRMS comments:	
	<p>Pelargonic acid</p> <p>The predicted environmental concentrations in soil for the use in maize, as a worst-case, was used for the risk assessment.</p> <p>The risk assessment carried out by Applicant was performed based on endpoints related to GLOB2011I as in EFSA Journal 2013;11(1):3023 no chronic data were available for earthworm, <i>Folsomia candida</i> or <i>Hypoaspis aculeifer</i>.</p> <p>Renewal of pelargonic acid is ongoing but the <i>Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid)</i> (EFSA Journal 2021;19(8):6813) was published in 2021. Therefore, the risk assessment can be performed on the basis of EU agreed endpoints from EFSA Journal 2021;19(8):6813. TERs calculations are presented below:</p>	
	Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)
Chronic effects on earthworms		

Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Pelargonic acid	21.95	1.802	12.2
Chronic effects on other soil macro- and mesofauna			
Folsomia candida			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Pelargonic acid	14.7	1.802	8.2
Hypoaspis aculeifer			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Pelargonic acid	141.20	1.802	78.4
All TER _{LT} values are above trigger value of 5.			
Conclusion: According to the performed risk assessment there is low chronic risk to earthworms and other non-target organisms resulting from long-term exposure to active substances following use of GLOB2011I / Sankari in compliance with proposed GAP.			

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 pelargonic acid. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on soil microorganisms of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Pelargonic acid	28 d, aerobic loamy sand	No data submitted*	EFSA Conclusions 2013
N-mineralisation	GLOB2011I	28 d, aerobic soil type	<25% effect at 0-42 or 28-42 days at both 4.86 and 48.58 mg GLOB2011I/kg dws	Bauer J./2022/ Study 167841080

* No endpoint set in EFSA 2013 but data can be extrapolated from data obtained with GLOB2011I

9.9.1.1 Justification for new endpoints

Not applicable for the active substance.

For the PPP, GLOB2011I was not evaluated during EU renewal of pelargonic acid so relevant endpoints are proposed.

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use 13/group 001 (maize) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (uses 1-12) in groups 002-008 (cereals, oilseed rape, potatoes, maize) (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2011I in cereals (use 3/use group 001) also covering uses in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pelargonic acid*	-	1.802	-
GLOB2011I	48.58 (at 42 d)	2.429	Yes

* No endpoint set in EFSA 2013 but data can be extrapolated from data obtained with GLOB2011I

9.9.3 Overall conclusions

An acceptable risk is indicated for soil micro-organisms for the intended uses of GLOB2011I.

zRMS Comments:	zRMS comments:	
	<p>The risk assessment carried out by Applicant was performed based on endpoints related to GLOB2011I as in EFSA Journal 2013;11(1):3023 no chronic data were available for N-mineralization.</p> <p>Renewal of pelargonic acid is ongoing but the <i>Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid)</i> (EFSA Journal 2021;19(8):6813) was published in 2021. Therefore, the risk assessment can be performed on the basis of EU agreed endpoints from EFSA Journal 2021;19(8):6813 and is presented below:</p>	
	Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)

N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg a.s./kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pelargonic acid	103	1.802	Yes
<p>The predicted environmental concentrations in soil for the use in maize, as a worst-case, was used for the risk assessment.</p> <p>For the assessment of risk to micro-organisms for formulation the endpoints from studies presented in Appendix 2 were used.</p> <p>Conclusion: Since no effects (> 25%) were seen at application rates far higher than the values of PEC_{soil} for active substance and formulation it can be concluded that application of GLOB2011I / Sankari, according to the GAP, will not cause any detrimental effect to soil microorganisms</p>			

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 pelargonic acid's representative's formulations. Full details of these studies are provided in the respective EU Review and related documents.

Effects on non-target terrestrial plants of GLOB2011I were not evaluated as part of the EU assessment of pelargonic acid. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
<i>Brassica napus</i> _d ¹⁾ <i>Pisum sativum</i> _d ²⁾ <i>Cucumis sativus</i> _d ³⁾ <i>Solanum lycopersicum</i> _d ⁴⁾ <i>Allium cepa</i> _m ⁵⁾ <i>Avena sativa</i> _m ⁶⁾	GLOB2011I	21 d Seedling emergence	1,2,3,4,5,6) ER ₅₀ emergence > 8000 ml PPP/ha 1,2,3,4,5,6) ER ₅₀ plant fresh weight > 8000 ml PPP/ha	Bützler, R./2022/ Study # 167841086
<i>Brassica napus</i> _d ¹⁾ <i>Pisum sativum</i> _d ²⁾	GLOB2011I	21 d Vegetative vigour	1,2,3,4,5,6) ER ₅₀ plant fresh weight > 8000	Bützler, R./2022/ Study # 167841087

Species	Substance	Exposure System	Results	Reference
<i>Cucumis sativus</i> _d ³⁾ <i>Solanum lycopersicum</i> _d ⁴⁾ <i>Allium cepa</i> _m ⁵⁾ <i>Avena sativa</i> _m ⁶⁾			ml PPP/ha ¹⁾ ER ₅₀ plant phytotoxicity 8872 ml PPP/ha ^{2,3,4,5,6)} ER ₅₀ plant phytotoxicity > 8000 ml PPP/ha	

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not applicable for the active substance.

For the PPP, GLOB2011I was not evaluated during EU renewal of pelargonic acid so relevant endpoints are proposed.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 001 (maize) also covers the risk for non-target terrestrial plants from all other intended uses in groups 002-008 (cereals, oilseed rape, potatoes and maize) (see 9.1.2).

Table 9.10-2: Assessment of the risk for non-target plants due to the use of GLOB2011I in maize (use 11/use group 005) also covering uses in maize (use 13/use group 001) covering uses in cereals, oilseed rape, potatoes and maize (uses 1-12/use groups 002 to 008)

Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)			
Active substance/product	Pelargonic acid / GLOB2011I			
Application rate (g a.s./ha)	2 × 1950			
MAF	1.7			
Test species	ER ₅₀ (g a.s./ha)	Drift rate	PER _{off-field} (g a.s./ha)	TER criterion: TER ≥ 5

<i>Brassica napus</i> <i>Pisum sativum</i> <i>Cucumis sativus</i> <i>Solanum lycopersicum</i> <i>Allium cepa</i> <i>Avena sativa</i>	> 5200 (8000 ml PPP)/ha (worst case value for all species)	2.38% (1m, 82 nd percentile for 2 applications)	210.4	> 24.7
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MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

There is no unacceptable risk for non-target plants from the intended uses of GLOB2011I. No mitigation measures are needed.

zRMS Comments:	zRMS comments: Basic drift values for two applications (82nd percentiles) and multiple application factor MAF were used for a risk assessment. In the current guidance document (European Commission, 2002b) only single application is considered and according to the <i>Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology</i> (EFSA Supporting publication 2015:EN-924): no MAF values should be used by default, until a guidance document is developed. Therefore the risk assessment was corrected below. The risk assessment was performed based on the endpoint for formulation GLOB2011I / Sankari for the maximum application rate in maize as a worst-case scenario.				
	Intended use	Maize (use 13/use group 001) (covering uses 1-12/use groups 002 to 008: cereals, oilseed rape, potatoes, maize)			
	Active sub-stance/product	Pelargonic acid / GLOB2011I			
	Application rate (g a.s./ha)	2 × 3 L/ha			
	MAF	1			
	Test species	ER₅₀ (mL a.s./ha)	Drift rate	PER_{off-field} (mL a.s./ha)	TER criterion: TER ≥ 5

	<i>Brassica napus</i> <i>Pisum sativum</i> <i>Cucumis sativus</i> <i>Solanum lycopersicum</i> <i>Allium cepa</i> <i>Avena sativa</i>	> 8000 ml PPP/ha (worst case value for all species)	2.77% (1m)	83.1	> 96.2
<p>The TER value is above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.</p> <p>Conclusion No unacceptable risk to non-target terrestrial plants is expected following the application of GLOB2011I / Sankari according to the proposed use pattern.</p>					

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

The ecotoxicological classification of GLOB2011I was based on theoretical calculations according to Regulation 1272/2008 or based on own available data on the formulation.

Acute toxicity:

There is acute toxicity data available for the mixture GLOB2011I on *Daphnia magna* (see Table 9.5-2). Since the ErC₅₀ is > 1 mg/L, GLOB2011I **should not be classified for Aquatic Acute Tox.**

Also, data available on pelargonic and co-formulants for fish (see Part C) confirm that GLOB2011I **should not be classified for Aquatic Acute Tox.**

Chronic toxicity:

There is chronic toxicity data available for the mixture GLOB2011I on *Pseudokirchneriella subcapitata* and *Myriophyllum spicatum* (see Table 9.5-2). Since the active substance is readily biodegradable and any representative value ErC₅₀/NOEC is > 1 mg/L, GLOB2011I **should not be classified for Aquatic Chronic Tox.**

Also, data available on pelargonic and co-formulants for fish (see Part C) confirm that GLOB2011I **should not be classified for Aquatic Acute Tox.**

Pictogram: -

Signal word: -

H-statements

-

P-statements

-

Other safety/precautionary phrases:

-

zRMS cooments

Endpoints and effect values for aquatic organisms – GLOB2011I

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	Not required, fish is not the most sensitive aquatic specie and it is possible to extrapolate data from results obtained with the active substance.			
<i>Daphnia magna</i>	GLOB2011I	48 h, s	EC ₅₀ = 12.5 mg/L_{nom} EC ₂₀ = 5.38 mg/L _{nom} EC ₁₀ = 3.46 mg/L _{nom} NOEC = 10.3 mg/L _{nom}	Börschig C., 2023a, Study no. 167841220
<i>Pseudokirchneriella subcapitata</i>	GLOB2011I	72 h, s	E _r C ₅₀ = 11.7 mg PPP/L_{nom} E _r C ₂₀ = 2.68 mg PPP/L _{nom} E _r C ₁₀ = 1.24 mg PPP/L _{nom} NOE _r C < 9.87 mg/L _{nom}	Börschig C., 2023b, Study no. 167841210
<i>Myriophyllum spicatum</i>	GLOB2011I	14 d, ss	E _r C ₅₀ = 204 mg PPP/L_{nom} E _r C ₂₀ = 67.0 mg PPP/L _{nom} E _r C ₁₀ = 37.5 mg PPP/L _{nom} NOE _r C = 19.4 mg PPP/L _{nom}	Börschig C., 2023c, Study no. 167841215

For formulation GLOB2011I the toxicity data are available for *Daphnia magna*, *Pseudokirchneriella subcapitata* and *Myriophyllum spicatum*. No data are available for fish.

According to the Guidance on the Application of the CLP Criteria, Version 5.0, July 2017: *Where a classification is made based on the test data, valid data should be normally be available on each of fish, crustacea and algae or other aquatic plants, unless a decision to classify in the most stringent category(ies) (Acute 1 and Chronic 1) can be made without a full dataset.*

Because of based on the available data the formulation cannot be classified in the most stringent categories this approach cannot be used in classification.

According to the Guidance on the Application of the CLP Criteria, Version 5.0, July 2017: *When infor-*

mation on the classification of the components and test data on the mixture as a whole are available for some, but not all three trophic levels: classification based on the summation method.

The active substance pelargonic acid has the harmonised classification and labelling and is classified as Aquatic Chronic 3 H412 in accordance with a Commission Regulation (EU) 2015/1221 of 24 July 2015 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, for the purposes of its adaptation to technical and scientific progress (ATP 07). The concentration of pelargonic acid in Sankari (GLOB2011I) is equal 71.36% it means that it is more than 25%. Thus the classification Aquatic Chronic 3 H412 (Harmful to aquatic life with long lasting effects) according to criteria of Regulation EC 1272/2008 (CLP) is required for the product Sankari (GLOB2011I).

Conclusion:

The classification for aquatic hazard of the product Sankari (GLOB2011I):

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1	Börschig, C.	2023a	GLOB2011I: Acute Toxicity to Daphnia magna in a Semi-Static 48-hour Immobilisation Test Study No. 167841220 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.2.1	Börschig, C.	2023b	GLOB2011I: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test Study No. 167841210 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.2.1	Börschig, C.	2023c	GLOB2011I: Toxicity to the Aquatic Plant Myriophyllum spicatum in a Semi-Static Growth Inhibition Test with a Prior Rooting Phase Study No. 167841215 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.1.1	Schabio, S.	2023	GLOB2011I: Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory Study No. 163761035 ibacon GmbH 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 10.3.1.1	Schabio, S.	2022a	GLOB2011I: Effects (Acute Contact and Oral) on Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory Study No. 163761105 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.1.2	Schabio, S.	2022b	GLOB2011I: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory Study No. 163761136 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.1.3	Colli, M.	2022	Effects of GLOB2011I on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Study No. BT256/21 BioTecnologie BT S.r.l. GLP Unpublished	N	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022a	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Dose Response Test Study No. 167841062 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022b	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Aged Residue Test Study No. 167841060 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022c	GLOB2011I: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenop-tera, Braconidae), Extended Laboratory Study - Dose Response Test	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
			Study No. 167841002 ibacon GmbH GLP Unpublished		
KCP 10.3.2.2	Leopold, J.	2022d	GLOB2011I: Effects on the Lacewing Chrysoperla carnea (Neuroptera: Chrysopidae), Extended Laboratory Study - Dose Response Test Study No. 167841047 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022e	GLOB2011I: Effects on the Predatory Bug Orius laevigatus (Heteroptera, Anthocoridae), Extended Laboratory Study - Dose Response Test Study No. 167841052 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.4.1.1	Hübner, S.	2022a	GLOB2011I: Effects on Reproduction and Growth of Earthworms Eisenia andrei in Artificial Soil Study No. 167841022 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.4.2.1	Hübner, S.	2022b	GLOB2011I: Effects on Reproduction of Collembola (Folsomia candida) in Artificial Soil Study No. 167841016 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.4.2.1	Hübner, S.	2022c	GLOB2011I: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil Study No. 167841089 ibacon GmbH GLP	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
			Unpublished		
KCP 10.5	Bauer, J.	2022	GLOB2011I: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study No. 167841080 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.6.2	Bützler, R.	2022a	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Study No. 167841086 ibacon GmbH GLP Unpublished	N	Globachem nv
KCP 10.6.2	Bützler, R.	2022b	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Study No. 167841087 ibacon GmbH GLP Unpublished	N	Globachem nv

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
None					

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

No new study submitted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No new study submitted.

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

No new study 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

Reference:	KCP 10.2.1
Report	GLOB2011I: Acute Toxicity to <i>Daphnia magna</i> in a Semi-Static 48-hour Immobilisation Test, Börschig C., 2023a, Study No. 167841220
Guideline(s):	OECD 202 and SANTE/2020/12830 Rev.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.i. (pelargonic acid): 652.3 g/L (analytical, pre storage).
Test Species:	<i>Daphnia magna</i> , clone 5; 6.75 to 21.50 hours old. Source: The daphnids introduced in the test were taken from ibacon's in-house laboratory culture.
Test Design:	This study encompassed 7 treatment groups (5 dose rates of the test item), a surfactant control and a control) each containing 20 individuals. The mobility of the daphnids was determined in a semi-static 48-hour test by visual observation after 24 and 48 hours.
Endpoints:	Number of immobile organisms after 24 and 48 hours
Test Concentrations:	50, 22.7, 10.3, 4.7 and 2.1 mg test item/L (spacing factor 2.2) (each with 100 µL Tween 80/L), a surfactant control (100 µL Tween 80/L)

Test Conditions:

and a control.

Water temperature: 19.8 to 21.7 °C (target: 18 °C – 22 °C; ± 1 °C within this range);

pH value: 7.5 to 8.5 (target: 6 - 9);

dissolved oxygen concentration: 6.3 to 8.5 mg/L (target: ≥ 3 mg/L);

photoperiod: 16 h light : 8 h dark;

light intensity: 660 to 820 lux (target: ≤ 1500 lux);

Thus, test conditions were within the ranges requested by guideline OECD 202

Results

Validity Criteria:

Control immobilisation rate:

Achieved: 0 % (target: ≤ 10 %),

Dissolved oxygen concentration at test end:

Achieved: ≥ 8.3 mg O₂/L (target: ≥ 3 mg O₂/L)

Thus, the validity criteria were met

Biological Test Results:

After 48 hours of exposure no immobilisation of the test daphnids was observed in the control. In the surfactant control one animal was immobile. Three, two and four daphnids were immobile in the concentrations of 2.1, 4.7 and 10.3 mg test item/L, respectively. At the concentration of 22.7 mg test item/L, 18 daphnids were immobile and all daphnids were immobile at the concentration of 50 mg test item/L. Sublethal effects on the daphnids were observed in each test item treatment and the surfactant control after 48 hours.

Table 30.2.1-1. Summary of Biological Results

Nominal concentration [mg test item/L]	% of immobilised daphnids after	
	24 hours	48 hours
Control	0	0
Surfactant Control	0	5
2.1	5	15
4.7	5	10
10.3	0	20
22.7	35*	90*
50	75*	100*
EC ₅₀ [mg test item/L]:	40.9	12.5
95 % CI [mg test item/L]:	4.57 - > 50	4.24 - 36.8
EC ₂₀ [mg test item/L]:	9.88	5.38
95 % CI [mg test item/L]:	2.57 - 37.9	1.64 - 17.6
EC ₁₀ [mg test item/L]:	4.7	3.46
95 % CI [mg test item/L]:	0.933 - 23.7	0.829 - 14.4
NOEC [mg test item/L]:	10.3	10.3
LOEC [mg test item/L]:	22.7	22.7

Values refer to nominal test concentrations

CI: Confidence interval, *: statistically different to the surfactant control

Analytical Results:

The quantification of the active ingredient pelargonic acid of the test item GLOB2011I in the test samples was performed using liquid chromatography with MS detection.

In the freshly prepared test media at the start of the test and at the re-

newal of the test media 87 % of the nominal test concentrations were found (average of all test concentrations). In the aged test media after each 24 hour renewal period 88 % of the nominal value was determined (average of all test concentrations).

Conclusion:

The study was valid since all required validity criteria were met.

The toxic effect of the test item GLOB2011I to *Daphnia magna* was assessed in a semi-static concentration-response test. The 48-hour NOEC was determined to be 10.3 mg test item/L (equivalent to 7.38 mg a.s./L). The 48-hour LOEC was determined to be 22.7 mg test item/L (equivalent to 16.3 mg a.s./L) and the 48-hour EC₅₀ value was calculated to be 12.5 mg test item/L (equivalent to 8.95 mg a.s./L).

The initial concentrations and the maintenance of the exposure concentrations during the test were determined in the analytical part. All reported results refer to nominal values since the concentrations of the test item were within $\pm 20\%$ of the nominal concentrations during the test.

Finally, it can be concluded that GLOB2011I is harmful to daphnia with a 48h-EC₅₀ of 12.5 mg PPP/L (equivalent to 8.95 mg a.s./L).

Comments of zRMS:	<p>The study was performed according to OECD TG 202 and principles of GLP. The validity criteria are met. The immobility in the control group is below 10% (observed 0%) The measured, lowest value of oxygen concentration at the end of the test is ≥ 8.3 mg/L (required ≥ 3 mg/L).</p> <p>The study is considered acceptable and suitable for the risk assessment. All results refer to nominal concentrations since the measured concentrations were within 80 to 120% of nominal.</p> <p>48h-EC₅₀ of 12.5 mg PPP/L (equivalent to 8.95 mg a.s./L).</p>
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Reference:	KCP 10.2.1
Report	GLOB2011I: Toxicity to <i>Pseudokirchneriella subcapitata</i> in an Algal Growth Inhibition Test, Börschig C., 2023b, Study No. 167841210
Guideline(s):	OECD 201, OECD 23 and SANTE/2020/12830 Rev.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; Batch No.: GLOB2011I09H15M21SANK; content of a.i. (perlagonic acid): 652.3 g/L.
Test Species:	<i>Pseudokirchneriella subcapitata</i> , Strain No. 61.81 SAG formerly known as <i>Selenastrum capricornutum</i> , and recently renamed as <i>Raphidocelis subcapitata</i> (KORSHIKOV). Cultivated in the laboratories of ibacon; original source: "Culture Collection of Algae at Goettingen University (SAG)", 37073 Göttingen, Germany.
Test Design:	This study encompassed 6 treatment groups (5 concentrations of the test item and a control) with three replicates per test concentration and six replicates for the control. At test start 50 mL of the test media were inoculated with nominal 5000 algal cells per mL test medium and de-

Endpoints: Yield and growth rate of the algae
Test Concentrations: 250, 114, 52, 23 and 11 mg test item/L (spacing factor 2.2) and a control, corresponding to following geometric mean measured concentrations of the test item: 225, 100, 44.2, 19.1, 9.87 mg test item/L.
Test Conditions: Water temperature: observed: 22.3 to 22.8 °C (target: 21 – 24 °C, controlled at ± 2 °C);
pH value in the control at test start: 8.2,
pH value in the control at test end: 7.8;
pH values in the test item treatments at test start: 8.0 to 8.1,
pH values in the test item treatments at test end: 7.7 to 7.8;
(target pH: 8.1 ± 0.1 at test start in untreated test water)
continuous illumination:
observed mean light intensity: 8105 lux (7740 to 8450 lux)
(target: 4440 – 8880 lux, ± 15 % of mean value)

Sample Description	fresh (0h)			aged (24h)			aged (48h)			aged (72h)			Geometric Mean _{2,3}	
[mg test item/L]	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	% of nominal ¹	RSD [%]	n	[%]	[mg test item/L]
Control	n.a.	n.a.	2	n.a.	n.a.	2	n.a.	n.a.	2	n.a.	n.a.	2	n.a.	n.a.
11	90	2	2	91	1	2	89	1	2	89	15	2	90	9.87
23	90	1	2	87	5	2	85	6	2	67	12	2	83	19.1
52	88	3	2	91	2	2	86	1	2	69	22	2	85	44.2
114	77	23	2	90	2	2	91	2	2	89	2	2	88	100
250	96	2	2	90	0	2	89	2	2	87	1	2	90	225

Results

Biological Results

Validity Criteria:

Cell density in the control:

Achieved: 62.3-fold increase (criterion: ≥ 16) within 72 hours;

Coefficient of Variation (CV) of sectional (daily) growth rate of the control:

Achieved: 10.7 % (criterion: $\leq 35\%$);

CV of average growth of control replicates:

Achieved: 5.3 % (criterion: $\leq 7\%$);

and thus, the validity criteria were met.

Overview of Inhibition of Yield and Growth Rate

Nominal concentration [mg test item/L]	11	23	52	114	250
% Inhibition yield 72h	86.8*	94.0*	96.7*	99.0*	100.0*
Inhibition growth rate 72h	46.5*	62.6*	73.4*	89.1*	100.0*

Negative values in '% inhibition' indicate an increase in growth relative to that of the control

Table 40.2.1-2. Biological Results

Parameter	Yield [mg test item/L]	Growth rate [mg test item/L]
72-hour EC ₅₀	< 11 (< 9.87)	13.5 (11.7)
95 % conf. interval	n.d.	11.0 – 16.6 (9.58 - 14.4)
72-hour EC ₂₀	< 11 (< 9.87)	3.05 (2.68)
95 % conf. interval	n.d.	2.22 – 4.19 (1.96 – 3.67)
72-hour EC ₁₀	< 11 (< 9.87)	1.40 (1.24)
95 % conf. interval	n.d.	0.913 – 2.15 (0.814 – 1.90)
72-hour NOEC	< 11 (< 9.87)	< 11 (< 9.87)
72-hour LOEC	≤ 11 (≤ 9.87)	≤ 11 (≤ 9.87)

n.d. = not determinable, Values below 11 mg/L for nominal results and below 9.87 mg/L for geometric mean measured results are extrapolated.

Values without brackets refer to nominal test concentrations; values in brackets refer to geometric mean measured test concentrations

Analytical Results:

The quantification of the active ingredient pelargonic acid of the test item GLOB2011I in the test samples was performed using liquid chromatography with MS detection.

At the start of the test 88 % of the nominal test concentrations were found (average of all test concentrations). After 72 hours test duration, 80 % of the nominal value was determined (average of all test concentrations).

Conclusion:

The study is valid since all required validity criteria were fulfilled.

The influence of GLOB2011I on the growth of the freshwater green algae *Pseudokirchneriella subcapitata* was assessed in a static concentration-response test.

Endpoints based on nominal test concentration:

The 72-hour EyC₅₀ was determined to be < 11 mg test item/L, and the 72-hour ErC₅₀ value was calculated to be 13.5 mg test item/L (equivalent to 9.67 mg a.s./L). The 72-hour NOEyC was determined to be < 11 mg test item/L and the associated 72-hour LOEyC was ≤ 11 mg test item/L. The 72-hour NOErC was determined to be < 11 mg test item/L and the associated 72-hour LOErC was ≤ 11 mg test item/L.

Endpoints based on geometric mean measured concentration:

The 72-hour EyC₅₀ was determined to be < 9.87 mg test item/L, and the 72-hour ErC₅₀ value was calculated to be 11.7 mg test item/L (equivalent to 8.38 mg a.s./L). The 72-hour NOEyC was determined to be < 9.87 mg test item/L and the associated 72-hour LOEyC was ≤ 9.87 mg test item/L. The 72-hour NOErC was determined to be < 9.87 mg test item/L and the associated 72-hour LOErC was ≤ 9.87 mg test item/L. The initial concentrations and the maintenance of the exposure concentrations during the test were determined in the analytical part. All reported results refer to nominal and geometric mean values.

Finally, it can be concluded that GLOB2011I is harmful to algae with a 72h-ErC₅₀ of 11.7 mg PPP/L (equivalent to 8.38 mg a.s./L).

Comments of zRMS:	The study was performed according to OECD TG 201 and principles of GLP. The validity criteria are met. The biomass in the control cultures increased exponentially by a factor of 62.3 within the 72 hours test period (factor 16 after 72 hours is required according to guideline OECD Guideline 201 (2011)). The mean coefficient of variation for section-by-section specific growth rates in the control cultures was 10.7% (not exceeding 35%). The co-efficient of variation of average
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	<p>specific growth rates during the whole test period in replicate control cultures was 5.3% and did not exceed 7%. No deviations to the study plan were noted.</p> <p>The study is considered acceptable and suitable for the risk assessment. The results for test item refer to geometric mean measured test concentrations.</p> <p>72h-ErC50 of 11.7 mg PPP/L (equivalent to 8.38 mg a.s./L).</p>
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Reference: KCP 10.2.1

Report GLOB2011I:
Toxicity to the Aquatic Plant *Myriophyllum spicatum* in a Semi-Static Growth Inhibition Test with a Prior Rooting Phase, Börschig C., 2023c, Study No. 167841215

Guideline(s): OECD 239 and SANTE/2020/12830 Rev.1

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Material and methods

Test Item: GLOB2011I; Batch No.: GLOB2011I09H15M21SANK; Content of a.i.: Pelargonic acid: 650 g/L (nominal) and 652.3 g/L (analytical)

Test Species: *Myriophyllum spicatum*

Test Design: This study encompassed 6 treatment groups (5 dose rates of the test item and a control) with five replicates per test concentration and ten replicates for the control.

After a pre-rooting phase of 7 days, 1 plant per replicate was incubated for 14 days under semi-static conditions. The shoot length was determined at test start and day 14. Sublethal parameters were assessed at test start, once during the test (e.g. day 7) and at test end. At test end fresh and dry weight of each replicate was determined. The samples of fresh and aged test media collected at test start, test end and water renewals were analysed.

Endpoints: Inhibition of growth expressed in terms of yield and growth rate, based on total shoot length, fresh and dry weight

Test Concentrations: Nominal: 250, 78.1, 24.4, 7.6 and 2.4 mg test item/L (spacing factor 3.2) and a control; Corresponding to time weighted average concentrations of 228, 67.9, 19.4, 3.75 and 0.781 mg test item/L.

Test Conditions: Water temperature: observed: 20.4 - 22.4 °C (target: 20 ± 2 °C);
light regime: 16 h light : 8 h dark; observed mean light intensity: 8806 lux (8070 - 9780 lux) (target: 8000-10000 lux);
oxygen concentrations in the freshly prepared test media: 7.4 - 8.9 mg/L, in the aged test media: 0.7 - 12.6 mg/L.
pH values at pre-rooting phase: 7.9,
pH values of the control in the freshly prepared test media: 7.6 - 8.0, in the aged test media: 8.0 - 9.9*;
pH values of test item treatments in the freshly prepared test media: 7.6 - 8.0, in the aged test media: 7.1 – 9.6;
* According to the OECD guideline 239 the increase of pH of >1.5 does not invalidate the study.
The pH increases because HCO₃⁻ from the medium is metabolised by growing plants. They need the CO₂ for their cell growth and release OH⁻, which in

consequence increases the pH of the test medium. This is a natural reaction called biogenic decalcification.

Results

Validity Criteria:

Control plants did not show any sign of sublethal effects and were visibly free from contamination by other organisms such as algae and/or bacterial film.

The total shoot length increased by a factor of 4.5 after 14 days of exposure (criteria: factor of ≥ 2).

The fresh weight increased by a factor of 3.7 after 14 days of exposure (criteria: factor of ≥ 2).

The coefficient of variation of yield fresh weight was 16.1 % (criteria: $\leq 35\%$).

Thus, all validity criteria were met.

Biological Results:

Observed effects followed a concentration-response-relationship. Phytotoxic symptoms were observed at 3.75, 19.4, 67.9 and 228 mg test item/L and number and extent of the symptoms increased with increasing test concentration. Symptoms observed were shortened shoot tips (3.75, 19.4, 67.9 and 228 mg test item/L), chlorosis, and bacterial contamination (19.4, 67.9 and 228 mg test item/L) and shortened and fewer roots (67.9 and 228 mg test item/L).

Table 50.2.1-3. Summary of Biological Results

Parameter	Yield (total shoot length) [mg test item/L]	Growth rate (total shoot length) [mg test item/L]	Yield (fresh weight) [mg test item/L]	Growth rate (fresh weight) [mg test item/L]	Yield (dry weight) [mg test item/L]	Growth rate (dry weight) [mg test item/L]
EC ₅₀ (14-day)	215	316*	131	204	205	358*
95 % conf. limits	165 - 280*	221 - 452*	82.6 - 207	139 - 299*	100 - 418*	130 - 987*
EC ₂₀ (14-day)	105	139	48.5	67.0	60.8	74.9
95 % conf. limits	67.9 - 163	73.0 - 260*	22.9 - 102	33.6 - 131	16.8 - 211	14.0 - 392*
EC ₁₀ (14-day)	72.7	90.8	28.9	37.5	32.2	33.1
95 % conf. limits	39.8 - 132	37.3 - 216	10.3 - 80.1	14.5 - 94.4	5.50 - 180	3.30 - 321*
14-day NOEC	67.9	67.9	19.4	19.4	67.9	≥ 228
14-day LOEC	228	228	67.9	67.9	228	> 228

Values refer to time weighted average concentration *extrapolated by 3-param. normal CDF

Analytical Results:

The quantification of the active ingredient pelargonic acid of the test item GLOB2011I in the test samples was performed using liquid chromatography with MS detection.

At the start of the test and in the freshly prepared test medium at the renewal periods (day 2, 5, 7, 9, and 12), 91% of the nominal test concentrations was quantified in the overlying test media (average of all test concentrations). In the aged test medium at the end of each renewal period and at test end (day 2, 5, 7, 9, 12, and 14), 57% of the nominal test concentrations was quantified (average of all test concentrations). However, the concentration changes were dependant on the

treatment level, with the lowest test item concentration regularly degrading below the Limit of Quantification (<LOQ), and the highest test item concentration remaining within nominal levels. The intermediate treatment levels showed degradation patterns within this spectrum, ranging between <LOQ and nominal.

Conclusion:

The study is valid since all required validity criteria were fulfilled.

The influence of GLOB2011I on the growth of the dicotyledonous freshwater plant *Myriophyllum spicatum* was assessed in a semi-static concentration-response test with five water renewals.

The 14-day NOEC and the LOEC were determined to be 67.9 and 228 mg test item/L for total shoot length and 19.4 and 67.9 mg test item/L for fresh weight and 67.9 mg test item/L and 228 mg test item/L for dry weight, respectively.

The 14-day NOEC and the LOEC were determined to be 67.9 and 228 mg test item/L for total shoot length and 19.4 and 67.9 mg test item/L for fresh weight and ≥ 228 and > 228 for dry weight, respectively.

The 14-day EC50 was calculated to be 215, 131 and 205 mg test item/L for total shoot length, fresh weight and dry weight, respectively.

The 14-day ErC50 was calculated to be 316, 204 and 358 mg test item/L for shoot length, fresh weight and dry weight, respectively.

The correct application of the test item and the maintenance of the exposure concentrations during the test were determined in the analytical part. All reported results refer to time weighted average concentrations, since the test item concentrations were not within $\pm 20\%$ of the nominal concentrations during the test.

Finally, it can be concluded that GLOB2011I is not toxic to aquatic plant with a 14d-ErC50 of 204 mg PPP/L (equivalent to 146 mg a.s./L).

Comments of zRMS:	<p>The study was performed according to OECD TG 239 and principles of GLP. The validity criteria are met. The mean coefficient of variation for yield in the control does not exceed 35% between replicates (coefficient of yield fresh weight was 16.1%). The mean total shoot length and mean total shoot fresh weight in control should be doubled during the test (actual: shoot length increased by a factor of 4.5 after 14 days of exposure and fresh weight increased by a factor of 3.7 after 14 days of exposure). During the test the visual observations of the test organisms was performed. Control plants did not show any sign of sublethal effects and were visibly free from contamination by other organisms such as algae and/or bacterial film. pH Values of test item treatments in the freshly prepared test media: 7.6 - 8.0, in the aged test media: 7.1 – 9.6. According to OECD TG 239 deviation of more than 1.5 units would not invalidate the test. All reported results refer to time weighted average concentrations, since the test item concentrations were not within $\pm 20\%$ of the nominal concentrations during the test.</p> <p>The study is considered acceptable and suitable for the risk assessment.</p> <p>14d-ErC₅₀ of 204 mg PPP/L (equivalent to 146 mg a.s./L).</p>
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A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No new study submitted.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

No new study 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

A 2.3.1.1.2 Study 1

Comments of zRMS:	<p>The contact and oral tests are considered valid as the control mortality in each case was < 10 % and the LD50 values obtained with the reference item (dimethoate) were within the required ranges.</p> <p>Study limitations: In a contact test a 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item; ibacon experience has proven that higher volumes are suitable and no adverse effects on the outcome of the study are to be expected (Schmitzer et al. 2002).</p> <p>Study is acceptable.</p>
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Reference:	KCP 10.3.1.1.1; KCP 10.3.1.1.2
Report	GLOB2011I: Effects (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory, Schabio S., 2023, Study No 163761035
Guideline(s):	YES (OECD (1998), Test No. 213: Honeybees, Acute Oral Toxicity Test, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris; OECD (1998), Test No. 214: Honeybees, Acute Contact Toxicity Test, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

Test Item: GLOB2011I, Batch No.: GLOB2011I06H10M21SANK,
content: Pelargonic acid: 650 g/L (nominal), according to Sponsor Mail,

	644.4 g/L according to GLP CoA. The doses were calculated taking into account the nominal content of the active substance in the test item (650 g/L).
Test Species:	Honey bee (<i>Apis mellifera</i> L.); female worker bees; obtained from a healthy and queen-right colony, bred by ibacon, collected in the morning of use.
Test Design:	Acute contact and oral LD ₅₀ test; duration 72 hours; 3 replicates for the contact and oral test, each consisting of 10 bees per cage per treatment; assessment of mortality after 4, 24 and 48 hours and 72 hours, because of increasing mortality between 24 and 48 hours; reference item: dimethoate 408 g/L (analytical).
Test Concentrations:	<u>Contact test:</u> 424.3, 212.1, 106.1, 53.0 and 26.5 µg a.i./bee <u>Oral test (target):</u> 424.3, 212.1, 106.1, 53.0 and 26.5 µg a.i./bee <u>Oral test (measured):</u> 386.1, 217.1, 117.4, 58.1 and 30.0 µg a.i./bee The concentrations were calculated taking into account the nominal content of the a.i. (650 g/L and a relative density of 0.963) and recalculated taking into account the analysed concentration 644.4 g/L and a density of 0.900 g/mL from the GLP CoA
Test Conditions:	Temperature: 24 - 26 °C; relative humidity: 60 - 65 %; photoperiod: 24 h darkness.

Results and discussions

Contact Test:

The contact test was prolonged for a further 24 hours up to 72 hours due to increasing mortality between 24 and 48 hours. 424.3, 212.1, 106.1, 53.0 and 26.5 µg a.i./bee led to mortality of 83.3, 20.0, 20.0, 16.7 and 16.7 % at test termination (72 hours). There was 6.7 % mortality in the water control group (water + 0.5 % Adhäsit).

During the first 24 hours behavioural impairments such as apathy, discoordinated movements (= affected) and moribund bees were observed in the 424.3 and 212.1 µg a.i./bee dose groups. In the 53.0 µg a.i./bee dose group a single moribund bee could be observed. After 48 hours one moribund bee was found in the 424.3 g a.i./bee treatment group.

Oral Test:

The contact test was prolonged for a further 24 hours up to 72 hours due to increasing mortality between 24 and 48 hours. The maximum target dose levels of the test item 424.3 µg a.i./bee could not be achieved, because the bees did not ingest the full volume of treated sugar solution even when offered over a period of six hours. Actual oral consumed doses of 386.1, 217.1, 117.4, 58.1 and 30.0 µg a.i./bee led to mortality of 46.7, 10.0, 0.0, 0.0 and 3.3 % at test termination (72 hours). No mortality occurred in the water control (50 % w/v sucrose solution = 500 g sucrose/L tap water).

In the oral test during the first 24 hours moribund and affected bees were observed in the 386.1 µg a.i./bee dose group. In the 217.1 µg a.i./bee dose group a single moribund bee could be observed. After 72 hours one affected bee was found in the highest rate.

Table 60.3.1.1-1. Toxicity of GLOB2011I to honey bees; laboratory test

Test Item	GLOB2011I	
Test Species	<i>Apis mellifera</i> L.	
Exposure	contact (Adhäsit (0.5 %)/water)	oral (50 % w/v sucrose solution)
Application rate [µg a.i./bee]	424.3, 212.1, 106.1, 53.0 and 26.5	Target: 424.3, 212.1, 106.1, 53.0 and 26.5 Consumed: 386.1, 217.1, 117.4, 58.1 and 30.0
LD ₅₀ [µg a.i./bee]	24 hours: 369.4 48 hours: 243.7 72 hours: 202.5	24 hours: >386.1 48 hours: >386.1 72 hours: >386.1
NOED [µg a.i./bee]	24 hours: 106.1 48 hours: 106.1 72 hours: 212.1	24 hours: 217.1 48 hours: 217.1 72 hours: 117.4

LD₅₀: Contact Test: according to Trimmed Spearman-Kärber ($\alpha = 0.05$, one-sided greater).

NOED Contact: Step Down Rao-Scott-Cochran-Armitage test ($\alpha = 0.05$, one-sided greater)
NOED Oral: Chi² 2x2 with bonferroni correction and Step down Cochran-Armitage test ($\alpha = 0.05$, one-sided greater)

The contact and oral LD₅₀ (24 h) values for the reference item (dimethoate) were calculated to be 0.20 and 0.16 µg a.i./bee, respectively.

Conclusion

The acute toxicity of GLOB2011I on adult honeybees (*Apis mellifera* L.) was investigated in an acute contact and an acute oral, dose-response study under laboratory conditions.

The contact LD₅₀ values (24 h, 48 h and 72 h) of GLOB2011I were determined to be 369.4, 243.7 and 202.5 µg a.i./bee, respectively.

The contact NOED values (24 h, 48 h and 72 h) were 106.1, 106.1 and 212.1 µg a.i./bee and from the oral test 217.1, 217.1 and 117.4 µg a.i./bee.

The oral LD₅₀ values (24 h, 48 h and 72 h) were determined to be > 386.1 µg a.i./bee.

Comments of zRMS:	<p>The contact and oral tests are considered valid as the control mortality in each case was < 10 % and the mortality due to the reference item (dimethoate) was ≥ 50 % at test end.</p> <p>Study limitations: In a contact test a 5 µL droplet was chosen in deviation to the guideline recommendation of a 2 µL droplet, since a higher volume ensured a more reliable dispersion of the test item; ibacon experience has proven that higher volumes are suitable and no adverse effects on the outcome of the study are to be expected (Schmitzer et al. 2002).</p> <p>Study is acceptable.</p>
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Reference: KCP 10.3.1.1.1; KCP 10.3.1.1.2

Report GLOB2011I: Effects (Acute Contact and Oral) on Bumblebees (*Bombus terrestris* L.) in the Laboratory, Schabio S., 2022a, Study No 163761105

Guideline(s): YES (OECD No. 246, OECD No. 247 and SANTE/2020/12830 Rev.1

Deviations: No

GLP: Yes
Acceptability: Yes/No/Supplementary
Duplication (if vertebrate study) No

Test Item: GLOB2011I, Lot No.: GLOB2011I06H10M21SANK, content: Pelargonic acid: 644.4 g/L (analysed) (pre storage equivalent to 99.15 % of the declared content) (according to the GLP-CoA from December 01, 2021). The doses were calculated taking into account the nominal content of the active substance in the test item (650 g/L) and the density (963 g/L). After the GLP certificate of analysis was provided by the sponsor the dose rates were recalculated taking into account the reanalysed content of the a.s. 644.4 g/L and the density (900 g/L) (analysed).

Test Species: Bumblebee (*Bombus terrestris* L.); female worker bumblebees; obtained from a commercial bumblebee breeding company (Koppert Deutschland GmbH, Zeppelinstr. 32, D-47638 Straelen, Germany).

Test Design: Acute Contact Dose Response Test:
Duration: 48 h; replicates: 30 per each dose of the test item treatment (five doses), water control, solvent control and the reference item treatment group, each consisting of 1 bumblebee per cage per treatment; assessment of mortality and behavioural abnormalities: after 4 (\pm 0.5); 24 (\pm 2) and 48 (\pm 2) hours; reference item: dimethoate 417 g/L (analysed).
Analytical verification of the concentration of the active ingredient GLOB2011I in the contact application solutions of the highest and lowest dose.
Acute Oral Dose Response Test:
Duration: 48 h; replicates: 35 per each (five) dose of the test item treatment group, water control, solvent control and the reference item treatment group, each consisting of 1 bumblebee per cage per treatment (individual bumblebees which did not take up at least 80 % of the mean food uptake per treatment group were excluded from the evaluation; see section 6.9 Result Evaluation); assessment of mortality and behavioural abnormalities: after 4 (\pm 0.5); 24 (\pm 2) and 48 (\pm 2) hours; reference item: dimethoate 408 g/L (analysed).
Analytical verification of the concentration of the active ingredient GLOB2011I in the oral feeding solutions of the highest and lowest dose.

Materials and methods

Test Item Dose Levels:	<u>Contact Dose Response Test (nominal):</u> 530.4, 265.2, 132.6, 66.30 and 33.15 µg a.s./bumblebee <u>Oral Dose Response Test (target):</u> 530.4, 265.2, 132.6, 66.30 and 33.15 µg a.s./bumblebee <u>Oral Dose Response Test (mean consumption):</u> 97.71, 218.8, 140.7, 72.33 and 37.82 µg a.s./bumblebee The nominal dose levels according to the study plan were 500, 250, 125, 62.5, and 31.25 µg a.s./bumblebee for the contact test and oral test. After the GLP certificate of analysis was provided by the sponsor the dose rates were recalculated taking into account the reanalysed content of the a.s. (644.4 g/L) and the density (900 g/L) (analytical).		
Analytical Results of the Contact Test:	contact test (530.4 µg a.s./bumblebee)	80	%
	contact test (33.15 µg a.s./bumblebee)	88	%
Analytical Results of the Oral Test:	oral test (530.4 µg a.s./bumblebee)	93	%
	oral test (33.15 µg a.s./bumblebee)	105	%
Test Conditions:			
<u>Contact Test:</u>	Acclimatisation:	Temperature: 25-26°C Relative Humidity: 59 – 62 %	
	Exposure:	Temperature: 24–26°C Relative Humidity: 58 – 62 %	
<u>Oral Test:</u>	Acclimatisation:	Temperature: 24-25°C Relative Humidity: 63 – 64 %	
	Exposure:	Temperature:24- 25 °C Relative Humidity: 62 – 64 %	
Photoperiod:	Photoperiod:	24 h darkness (except handling procedures, including treatment and observations).	
Study Validity:	This study met the OECD 246 (2017) and OECD 247 (2017) validity criteria as the control mortality in both the oral and contact test was ≤ 10 % and the mortality due to the reference item (dimethoate) was > 50 % at test end.		

Results and discussions

Contact Test:

In the contact test a droplet of 5 µL⁴ containing the targeted dose levels of 530.4, 265.2, 132.6, 66.30 and 33.15 µg a.s./bumblebee was applied on the dorsal thorax of each exposed bumblebee. At the end of the contact toxicity test (48 hours after application) 13.3, 0.0, 10.0, 0.0 and 6.7 % mortality occurred in the 530.4, 265.2, 132.6, 66.30 and 33.15 µg a.s./bumblebee test item treatment groups, respectively. No mortality occurred in the water control (tap water containing 0.1 % v/v Triton X-100) and solvent control (acetone) treatment groups.

During the 4 hours assessment, affected and/or moribund bumblebees were observed in the 530.4 and 33.15 µg a.s./bumblebee dose level groups. No test item induced behavioural effects were observed at any time in the other test item treated groups in the contact test.

⁴ Adjustment to the guidance: a 5 µL droplet was chosen instead of 2 µL since a higher volume allows a higher application dose.

The contact target dose level of the reference item of 10 µg dimethoate/bumblebee was applied on the dorsal thorax of each exposed bumblebee. The mortality in the reference item treatment group was 76.7 % (at 48 hours after application).

The contact test is considered valid as the water control (tap water containing 0.1 % v/v Triton X-100) and solvent control (acetone) mortality was ≤ 10 % and the reference item (dimethoate) mortality was ≥ 50 %.

Oral Test:

In the oral test the targeted dose levels of 530.4, 265.2, 132.6, 66.30 and 33.15 µg a.s./bumblebee would have been achieved if an exact amount of 40 mg treated feeding solution had been consumed by each exposed bumblebee. This was not the case and the actual food uptake per bumblebee in the different treatment groups varied between 3 and 57 mg. Values for 80 % of the mean food uptake were calculated considering all 35 replicates for each test item treatment group, the water control, solvent control and the reference item treatment group. Bumblebees which did not consume at least 80 % of the mean food uptake per treatment group were excluded from the derivation of the end points, as well as from the calculation of the actual mean oral doses in the test and reference item treatment groups. This was done to avoid potentially overestimating the final endpoints.

The actual mean consumed oral doses of the test item were 97.71, 218.8, 140.7, 72.33 and 37.82 µg a.s./bumblebee. After 48 hours there was 25 % mortality in the 218.8 µg a.s./bumblebee test item treatment group. No mortality occurred in the other test item treatment groups or in the water control (50 % w/v sucrose solution). In the solvent control (50 % w/v sucrose solution containing 1 % v/v Tween80 + 0.1 % Xanthan) group a mortality of 3.7 % occurs. For the 97.71, 218.8, 140.7, 72.33 and 37.82 µg a.s./bumblebee test item treatment groups, 19, 8, 20, 25 and 30 bumblebees respectively were considered for the evaluation (≥ 80 % of the mean food uptake). For the water control (50 % w/v sucrose solution) and solvent control (50 % w/v sucrose solution containing 1 % v/v Tween80 + 0.1 % Xanthan) treatment groups, 34 and 26 bumblebees respectively were considered for the evaluation.

No test item related behavioural effects were observed at any time in the oral test.

The reference item targeted dose level of 4.0 µg dimethoate/bumblebee would have been achieved if exactly 40 mg treated feeding solution had been consumed by each bumblebee. Considering bumblebees with a food uptake of at least 80 % of the mean food uptake, the mean consumption corresponded to an actual mean oral dose of 4.1 µg dimethoate/bumblebee. For the reference item treatment group, 20 bumblebees were considered for the evaluation. The mortality in the reference item treatment group was 100.0 % at 48 hours after application.

The oral test is considered valid as the water control (50 % w/v sucrose solution) and solvent control (50 % w/v sucrose solution containing 1 % v/v Tween80 + 0.1 % Xanthan) mortality was ≤ 10 % and the reference item (dimethoate) mortality was ≥ 50 %.

Table 70.3.1.1-2. Toxicity to Bumblebees; Laboratory Tests

Test Item	GLOB2011II	
Test Species	<i>Bombus terrestris</i> L.	
Exposure	Contact (acetone)	Oral ¹ (50 % w/v sucrose solution containing 1 % v/v Tween80 + 0.1 % Xanthan)
Target dose rates [µg a.s./bumblebee]	530.4, 265.2, 132.6, 66.30 and 33.15	530.4, 265.2, 132.6, 66.30 and 33.15

Actual dose rates [µg a.s./bumblebee]	n.a.		97.71, 218.8, 140.7, 72.33 and 37.82	
Test Duration:	24 h	48 h	24 h	48 h
LD ₅₀ [µg a.s./bumblebee] ^{2,3}	> 530.4	> 530.4	> 218.8	> 218.8
LD ₂₀ [µg a.s./bumblebee] ^{2,3}	> 530.4	> 530.4	n.d.	n.d.
LD ₁₀ [µg a.s./bumblebee] ^{2,3}	n.d.	n.d.	n.d.	n.d.
NOED [µg a.s./bumblebee] ^{2,4}	≥ 530.4	≥ 530.4	≥ 218.8	140.7

¹ For the 97.71, 218.8, 140.7, 72.33 and 37.82 µg a.s./bumblebee test item treatment groups, 19, 8, 20, 25 and 30 bumblebees respectively were considered for the evaluation. After the GLP certificate of analysis was provided by the sponsor the dose rates were recalculated taking into account the reanalysed analytical content of the a.s. (644.4 g/L) and the density (900 g/L) (analytical).

² Results obtained from test item treated groups were compared to those obtained from the pooled controls.

³ As the test item treatment groups in the contact test did not show mortality ≥ 20.0 %, no statistical evaluation of the LD₅₀ and LD₂₀ values was carried out. The contact LD₁₀ could not be determined by the statistical program. The contact LD₅₀ and LD₂₀ values were considered to be higher than the highest dose rates tested. As the test item treatment groups in the oral test did not show mortality > 50.0 %, no statistical evaluation of the LD₅₀ value was carried out. The contact LD₂₀ and LD₁₀ could not be determined by the statistical program. The contact LD₅₀ value was considered to be higher than the highest dose rate tested.

⁴ The contact NOED of the test item was estimated using the multiple sequentially rejective Fisher Test after Bonferroni-Holm (pairwise comparison, one-sided greater, α = 0.05), which is a distribution-free test and does not require testing for normality or homogeneity prior to analysis. For the oral NOED Chi² 2x2 with Bonferroni Correction was used.

n.a.= not applicable

n.d. = not determined

Analytical Results:

The analytical recovery rates of the active substance Pelargonic Acid (Nonanoic Acid) were as follows:

Concentration/bumblebee	Nominal concentration of Pelargonic Acid (Nonanoic Acid) in the solution	Recovery of the nominal value of Pelargonic Acid (Nonanoic Acid) in the solution
<u>Contact Test:</u> Application solution (530.4 µg a.s./bumblebee*)	106 g a.s./L application solution	88 %
<u>Contact Test:</u> Application solution (33.15 µg a.s./bumblebee*)	6.63 g a.s./L application solution	80 %

Oral Test: Feeding solution (530.4 µg a.s./ bumblebee*)	13.3 g a.s./kg feeding solution	93 %
Oral Test: Feeding solution (33.15 µg a.s./ bumblebee*)	0.829 g a.s./kg feeding solution	105 %

* The dose levels according to the study plan were 500, 250, 125, 62.5, and 31.25 µg a.s./bumblebee for the contact test and oral test. After the GLP certificate of analysis was provided by the sponsor the dose rates were recalculated taking into account the reanalysed content of the a.s. 644.4 g/L and the density (900 g/L) (analysed).

Conclusion

The toxicity of GLOB2011I was tested in an acute contact and oral toxicity test using bumblebees. As the test item treatment groups in the contact test showed a maximum mortality of 13.3 % %, no statistical evaluation of the LD50 and LD20 values was carried out. The contact LD10 could not be determined by the statistical program. The contact LD50 and LD20 values were considered to be higher than the highest dose rates tested > 530.4 µg a.s./bumblebee. The contact NOED (48 h) value was calculated to be ≥ 530.4 µg a.s./bumblebee.

As the test item treatment groups in the oral test showed a maximum mortality of 25.0 %, no statistical evaluation of the LD50 value was carried out. The contact LD20 and LD10 could not be determined by the statistical program. The contact LD50 value was considered to be higher than the highest dose rate tested > 218.8 µg a.s./bumblebee. The oral NOED (48 h) value was calculated to be 140.7 µg a.s./bumblebee.

The recovery rates of the GLOB2011I in all test item concentrations were within ± 20 % of the nominal concentrations.

A 2.3.1.1.3 KCP 10.3.1.1.2 Acute contact toxicity to bees

Please refer to combined oral and contact toxicity studies summarized in the point KCP 10.3.1.1.1 above.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	<p>All validity criteria were met.</p> <p>Study is acceptable.</p> <p>There was a deviation from the study plan in section related to the analysis of test item concentrations. The original plan scheduled the analysis of feeding solutions on Day 0, but a deviation occurred, and the analysis were prepared on Day 2 instead. The reason cited for the deviation was a human mistake. Despite the deviation, it is presumed that the study was not adversely affected, as the samples were analyzed.</p>
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Reference: KCP 10.3.1.2

Report GLOB2011I: Chronic Oral Toxicity Test on the Honey Bee (Apis mellifera)

	L.) in the Laboratory, Schabio S., 2022b, Study # 163761136
Guideline(s):	Yes, OECD 245 (2017) and SANTE/2020/12830 Rev.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

Test Item:	GLOB2011I Lot No.: GLOB2011I06H10M21SANK content: Pelargonic acid: 650 g/L (nominal), according to Sponsor Mail, 644.4 g/L according to GLP CoA. The doses were recalculated taking into account the active content of substance in the test item (see 6.6 Application of the Test Item, the Control and the Reference Item)
Test Species:	Honey bee (<i>Apis mellifera</i> L.); freshly emerged young female worker bees; obtained from a healthy and queen-right colony, bred by ibacon. After hatch, the bees were collected and thereafter acclimatized under test conditions for one day.
Age of the Honey Bees:	Two days old worker bees.
Test Design:	10 days chronic oral feeding test in the laboratory (dose response test). Young honey bees were provided with 5 concentrations of the test item treated sugar solutions <i>ad libitum</i> over a period of 10 days. An untreated control, a Xanthan control and a reference item (Danadim; 408 g/L dimethoate) were included in this study. 3 replicates per treatment, each consisting of 10 bees per test cage.
Endpoints:	Daily assessment of mortality and behavioural abnormalities up to day 10. Endpoints: LC ₅₀ , LC ₂₀ , LC ₁₀ , LDD ₅₀ , LDD ₂₀ , LDD ₁₀ , NOEC, NOEDD.
Test Concentrations:	Test item: 5303.9, 2652.0, 1326.0, 663.0 and 331.5 ppm (mg a.i./kg feeding solution)*** Reference item: 1 ppm dimethoate (1 mg dimethoate/kg feeding solution)
Target Dose Level:	Test item: 106.1, 53.0, 26.5, 13.3 and 6.6 µg a.i./bee per day* Reference item: 0.02 µg a.i./bee per day* * taking into account a mean uptake of feeding solution of 20 mg/bee/day; the exact dose per bee per day was calculated after determination of the definitive food uptake of the bees at test end (see “Actual Mean Dose Level”).
Actual Mean Dose Level:	Test item: 53.3, 34.9, 19.1, 10.1 and 6.1 µg a.i./bee/day** Reference item: 0.013 µg a.i./bee/day** ** based on daily actual intake taking into consideration loss by evaporation *** recalculated concentration of the feeding solution based on the density of 0.900 g/mL and a amount of 644.4 g/L pelargonic Acid.
Evaporation:	In order to adjust for possible evaporation of test solutions from the feeders, evaporation figure was subtracted from the calculated uptake to give the real uptake accounting the loss by evaporation.

Test Conditions: Temperature: 32 - 33 °C; relative humidity: 55 - 61 %; photoperiod: 24 h darkness (except during observation).

Study Validity: This study met the OECD 245 (2017) validity criteria as the control mortality was < 10 % and the mortality of the reference item (dimethoate) was ≥ 50 % at test end.

Results and discussions

The test item was daily administered to the bees in sugar solution at the following recalculated concentrations: 5303.9, 2652.0, 1326.0, 663.0 and 331.5 mg a.i./kg feeding solution. These concentrations led to a daily mean dose of 53.3, 34.9, 19.1, 10.1 and 6.1 µg a.i./bee/day (based on daily actual intake adjusted for evaporation) after 10 days.

Mortality occurred in all test item treated dose levels ranging from 3.3 to 93.3 % at test end (10 days following the start of chronic exposure). There was 3.3 % mortality in the control (50 % w/v sucrose solution) and in the Xanthan control.

No behavioural impairments were observed at any time in any of the test item treatments.

Table 80.3.1.2-1. 10 days Chronic Oral Toxicity of GLOB2011I to young honey bees; laboratory test

Test Organism		<i>Apis mellifera</i> L.	
Exposure		Oral 10 days chronic exposure	
Treatment Group	Concentration ³ [mg a.i./kg]	Dose Level ¹ [µg a.i./bee/day]	Mortality at day 10 ² [% Mean]
GLOB2011I	5303.9	53.3	93.3 (*)
	2652.0	34.9	60.0 (*)
	1326.0	19.1	6.7 (n.s.)
	663.0	10.1	6.7 (n.s.)
	331.5	6.1	3.3 (n.s.)
Untreated control	0.0	0.0	3.3
Xanthan Control	0.0	0.0	3.3
Reference Item	1.0	0.013	100.0
Endpoint at test termination (day 10)			
LC ₅₀	LDD ₅₀	NOEC	NOEDD
2775.9 mg a.i./kg	34.3 µg a.i./bee/day	1326.0 mg a.i./kg	19.1 µg a.i./bee/day
LC ₂₀	LDD ₂₀	LC ₁₀	LDD ₁₀
1705.5 mg a.i./kg	24.2 µg a.i./bee/day	1235.3 mg a.i./kg	19.2 µg a.i./bee/day

1) mean dose per bee per day; dose measured based on consumed feeding solution adjusted for evaporation

2) Mortality at study termination 10 days after start of first feeding

Statistics:

LC_{50/20/10}/LDD_{50/20/10}: according to Weibull Analysis.

NOEC/NOEDD: was determined using Step-down Cochran-Armitage (pairwise comparison, one-sided greater, α = 0.05).

n.s. = no statistically significant difference compared to the control, * = statistically significant difference compared to the control

3) recalculated concentration of the feeding solution based on the density of 0.900 g/mL and a purity of 644.4 g/L pelargonic Acid.

The analytical recovery rates of the active ingredient GLOB2011I in the feeding solutions were as follows:

	Recovery rate [%] ¹
Concentration ²	Day 2 ³
5303.9	102
331.5	106

¹ recovery rate of the a.i. in feeding solution [ppm]

² recalculated nominal concentration of the a.i. in the feeding solution [ppm]

³ Day 0 = freshly prepared feeding solution

Conclusion

The chronic oral toxicity of GLOB2011I on young adult worker honey bees (*Apis mellifera* L.) was investigated in a 10-day chronic, dose-response feeding study under laboratory conditions.

All validity criteria for the study were met. After 10 days of continuous exposure, mortality in the control and Xanthan control was 3.3 % and thus below the threshold of 15%. Mortality in the reference treatment group was 100 % and thus above the threshold of 50 %.

The recovery rates of Pelargonic acid in the highest and lowest test item concentration of Day 1 was within ± 20 % of the nominal concentrations.

The LDD50, LDD20 and LDD10 were determined to be 34.3, 24.2 and 19.2 μg a.i./bee/day, respectively. This corresponds to a LC50, LC20 and LC10 of 2775.9, 1705.5 and 1235.3 mg a.i./kg feeding solution, respectively.

The NOEDD was determined to be 19.1 μg a.i./bee/day and the NOEC was 1326.0 mg a.i./kg food.

No behavioural impairments were observed at any time in any of the test item treatments.

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>All validity criteria were met.</p> <p>Study is acceptable.</p> <p>ED50 = 567.56 μg test item/larva (406.37 μg a.s./larva)</p> <p>NOED = 62.50 μg test item/larva (44.75 μg a.s./larva)</p> <p>NOEC= 405.84 mg test item/kg diet /8(290.58 mg a.s./kg diet)</p>
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Reference: KCP 10.3.1.3

Report Effects of GLOB2011I on honeybees (*Apis mellifera* L.) 22-day larval toxicity test with repeated exposure, Colli M., 2022, Study # BT256/21

Guideline(s): Yes, OECD 245 (2017) and SANTE/2020/12830 Rev.1

Deviations: Mortality assessment done on Day 8

GLP: Yes

Acceptability: Yes/No/Supplementary
Duplication No
(if vertebrate study)

Materials and methods

Test Item: GLOB2011I
Lot No.: GLOB2011I06H10M21SANK
content: Pelargonic acid: 650 g/L (nominal), 644.4 g/L (measured concentration) (density 0.9 g/mL)

Test Species: *Apis mellifera ligustica* from healthy colony maintained at BioTecnologie BT S.r.l.

Age of the Honey Bees: 3 day old bee larvae (D3)

Test Design: The 22-day larval toxicity test with repeated exposure in the laboratory was performed as a dose-response test: the test item was diluted in the larval food (aqueous sugar solution mixed with royal jelly) and administered daily to the larvae from day 3 (D3) to 6 (D6) of the test.
The stock solutions in ultrapure water and the treated diet were prepared fresh each day of administration.
For the untreated control 3 replicates and 14 larvae per replicate were set up (more subjects were allocated to the control group than the treatment groups in order to optimize power to detect the effects, according to OECD Document 54 on the Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application, 2006).
For each test item treatment group and the reference item treatment group, 3 replicates and 12 larvae per replicate were set up.

Endpoints: Daily assessment of mortality and behavioural abnormalities up to day 8. Effect on adult emergence up to day 22.
Endpoints: LC₅₀, LC₂₀, LC₁₀, LDD₅₀, LDD₂₀, LDD₁₀, NOEC, NOEDD.

Test Concentrations: The doses expressed as concentrations are shown below.

Table 10.3.1.3-1 Trial layout – treatments expressed as concentrations

Groups	Concentrations	
	[mg test item/kg diet]	[mg a.s./kg diet]
Water control	0	0
Test item (T1)	202.92	145.29
Test item (T2)	405.84	290.58
Test item (T3)	811.69	581.17
Test item (T4)	1623.38	1162.34
Test item (T5)	3246.75	2324.68

Target Dose Level: The doses of the test item are shown below.
The reference item Dimethoate was tested at a cumulative dose of 7.39 µg/larva (48 mg/kg diet).
An untreated control was run in parallel with the royal jelly-based diet.
Chemical analysis by HPLC-MS/MS was performed to verify correct application of the test item.

Table 90.3.1.3-2 Trial layout – treatments expressed as doses

Groups	Cumulative doses	
	[µg test item/larva]	[µg a.s./larva]
Water control	0	0
Test item (T1)	31.25	22.38
Test item (T2)	62.50	44.75
Test item (T3)	125.00	89.50
Test item (T4)	250.00	179.00
Test item (T5)	500.00	358.00

Test Conditions: Temperature: 32.9-34.9 °C; relative humidity: 84.0-96.2% (D1 to D8), 82.4-86.7% (D8 to D15), 40.8-73.8% (D15-D22); photoperiod: 24 h darkness (except during observation).

Study Validity: According to the OECD Guidance Document No. 239 (Jul- 2016 and updated on Jul-2021) the test was considered valid because:

- a) in the control group the cumulative larval mortality from D3 to D8 was 4.76% (average value across all replicates);
- b) in the control plates the adult emergence rate on D22 was 88.10% (average value across all replicates);
- c) in the reference item group (Dimethoate) larval mortality at D8 was 100%

Results and discussions

The results are presented here after:

Table 10.3.1.3-3 Mortality and Corrected Mortality (CM) of larvae (on D8)

Treatment	Cumulative dose [µg test item/larva]	Concentration [mg test item/kg diet]	Larvae mortality on D8		
			Mean%	CM - Mean %	Sign.
Water control	0	0	4.76	n.a.	n.a.
Test item (T1)	31.25	202.92	11.11	6.67	-
Test item (T2)	62.50	405.84	2.78	-2.08	-
Test item (T3)	125.00	811.69	8.33	3.75	-
Test item (T4)	250.00	1623.38	2.78	-2.08	-
Test item (T5)	500.00	3246.75	5.56	0.83	-

n.a. = not applicable

+ : significant; - : non-significant (Chi² 2x2 Table Test with Bonferroni Correction - α = 0.05, one-sided greater).

Table 10.3.1.3-4 Pupal Mortality

Treatment	Cumulative dose [µg test item/larva]	Concentration [mg test item/kg diet]	Pupal mortality from D8 to D15*	Pupal mortality from D8 to D22**
			Mean %	Mean %
Water control	0	0	2.56	7.51
Test item (T1)	31.25	202.92	3.03	3.03
Test item (T2)	62.50	405.84	0.00	11.36

Test item (T3)	125.00	811.69	8.59	23.84
Test item (T4)	250.00	1623.38	11.36	31.31
Test item (T5)	500.00	3246.75	11.11	50.00

*calculated as a percentage comparing the number of dead pupae from D8 to D15 with the number of alive pupae on D8

**calculated as a percentage comparing the number of dead pupae from D8 to D22 with the number of alive pupae on D8

Table 10.3.1.3-5 Total mortality and corrected mortality (CM) from D3 to D22 and emergence on D22

Treatment	Cumulative dose [µg test item/larva]	Concentration [mg test item/ kg diet]	Mortality (larvae + pupae) on D22		Adult emergence on D22	
			Mean%	CM - Mean %	Mean %	Sign.
Water control	0	0	11.90	n.a.	88.10	n.a.
Test item (T1)	31.25	202.92	13.89	2.25	86.11	-
Test item (T2)	62.50	405.84	13.89	2.25	86.11	-
Test item (T3)	125.00	811.69	30.56	21.17	69.44	+
Test item (T4)	250.00	1623.38	33.33	24.32	66.67	+
Test item (T5)	500.00	3246.75	52.78	46.40	47.22	+

n.a. = not applicable

+ : significant; - : non-significant (Step-down Cochran-Armitage test - $\alpha = 0.05$, one-sided greater).

Table 10.3.1.3-6 Reference item - mean mortality

Treatment	Dose [µg a.s./larva]	Concentration [mg a.s./kg diet]	Mortality on D8 Mean %
Reference item	7.39	48.00	100.00

Analytical results demonstrate that the active substance Pelargonic acid content in the stock solutions (at highest and lowest concentration) prepared on D3, was in the range of $\pm 20\%$ of nominal concentrations. Therefore, results are based on nominal doses.

No contaminations were found in the untreated control solution.

Conclusion

The effects of the test item GLOB2011I on the larval development and subsequent adult emergence of honeybees (*Apis mellifera* L.) were tested in a GLP compliant laboratory study.

The validity criteria of OECD Guidance Document No. 239 (Jul-2016 updated on Jul-2021) with regards to control larval mortality on D8, control adults' emergence on D22 and toxicity of the reference item were met. Thus, the study is valid.

Regarding the effects on larvae on D8 (developmental period), the test item GLOB2011I caused no statistically significant mortality at the tested doses. Therefore, the NOED value for larvae on D8 was determined to be higher than or equal to 500.00 µg test item/larva (equivalent to 358.00 µg a.s./larva). The NOEC value was determined to be ≥ 3246.75 mg test item/kg diet (equivalent to 2324.68 mg a.s./kg diet).

Regarding the effects on adult emergence on D22, the test item GLOB2011I caused statistically significant reduction in emergence rate compared to the control starting from the T3 tested dose. Therefore, the

NOED and the NOEC values for adult emergence were 62.50 µg test item/larva (equivalent to 44.75 µg a.s./larva) and 405.84 mg test item/kg diet (equivalent to 290.58 mg a.s./kg diet), respectively.

The D22 data allowed the extrapolation of the EC₁₀, EC₂₀ and EC₅₀.

Reliability of ED_x (and consequently of EC_x) values was evaluated according to the Appendix E of EFSA Technical report 2019: EN-1673 (Outcome of pesticides peer review meeting on general recurring issues in ecotoxicology): ED₁₀ and ED₂₀ were classified as Fair, ED₅₀ was classified as Poor.

Table 10.3.1.3-7 Summary results for all endpoints

Critical dose	Larvae Mortality D8 [µg test item/larva]	Adult Emergence D22 [µg test item/larva]
LD/ED ₁₀	n.d.	93.57 (c.l. 95%: 49.61 – 134.41)
LD/ED ₂₀	n.d.	173.73 (c.l. 95%: 118.02 – 242.95)
LD/ED ₅₀	n.d.	567.56 (c.l. 95%: 377.07 – 1238.48)
NOED	500.00	62.50
Critical concentration	Larvae Mortality D8 [mg test item/kg diet]	Adult Emergence D22 [mg test item/kg diet]
LC/EC ₁₀	n.d.	607.61 (c.l. 95%: 322.14 – 872.81)
LC/EC ₂₀	n.d.	1128.14 (c.l. 95%: 766.35 – 1577.58)
LC/EC ₅₀	n.d.	3685.46 (c.l. 95%: 2448.51 – 8041.99)
NOEC	3246.75	405.84

ED/EC_x evaluated by Probit analysis.

n.d.: not determined due to a poor robustness of data

c.l.: confidence limits

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No new study was submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No new study was submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No new study was 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

No new studies were submitted.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory tests

Study 1

Comments of zRMS:	The study was performed according to Blümel et al. (2000), Oomen (1988) and principles of GLP. The validity criteria are met. LR50 = 1376 g a.s./ha (2109 ml GLOB2011I/ha) ER50 > 710 g a.s./ha (> 1088 ml GLOB2011I/ha)
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Reference:	KCP 10.3.2.2
Report	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Dose Response Test, Leopold J., 2022a, Study No. 167841062
Guideline(s):	Yes, Blümel et al. (2000), Oomen (1988)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.s. (pre storage): 652.3 g/L pelargonic acid (C9), equivalent to 100.4 % of the declared content.
Test Species:	Predatory mite (<i>Typhlodromus pyri</i>), protonymphs less than 24 hours old; 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 6 replicates each containing 10 mites. The mites were exposed to dried residues on treated leaf surfaces (vine leaves). 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 females was recorded on 3 assessment days within one week.
Endpoints:	Mortality after 7 days of exposure; additionally, reproduction capacity for all variants with less than 50 % corrected mortality.
Validity Criteria:	<ul style="list-style-type: none"> - Control mortality should not exceed 20 % at day 7 after exposure. - Reference Item mortality should result in at least 50 % corrected mortality at day 7 after exposure. - Control reproduction should be ≥ 4 eggs per female for the second week.
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L).
Test Rates:	Control, 174, 435, 1088, 2720 and 6800 mL product/ha and reference item. The reference item was applied at an application rate of 40 mL DANADIM PROGRESS/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto leaves via laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 23 - 25 °C; relative humidity: 67 - 71 %; photoperiod: 16 h light : 8 h dark; light intensity: 280 - 370 lux.
Statistics:	Standard procedures, mortality: Step-down Rao-Scott-Cochran-Armitage Test, Fisher Exact Binomial Test (both one-sided greater, $\alpha = 0.05$), LR ₅₀ calculation by Weibull Analysis, reproduction: Dunnett's t-Test (one-sided smaller, $\alpha = 0.05$).

Results

The mean mortality of *Typhlodromus pyri* was 11.7 % in the control treatment. In the test item treatments, it ranged from 13.3 to 91.7 % (corresponding to 1.9 to 90.6 % corrected mortality). There was no statistically significant increase of mortality compared to the control up to and including the application rate of 1088 mL product/ha (Step-down Rao-Scott-Cochran-Armitage Test, one-sided greater, $\alpha = 0.05$, see Table 100.3.2.2-1).

The reference item applied at a rate of 40.0 mL Danadim Progress/ha produced a statistically significant mortality of 100.0 % (corrected mortality 100.0 %) after 7 days.

Reproduction of *T. pyri* was assessed in the control and at 174, 435 and 1088 mL product/ha. In the control treatment, the mean reproduction was 5.3 eggs per female. In the test item treatments, 4.1 to 4.3 eggs per female were recorded, corresponding to a reduction of reproduction of 19.3 to 21.5 %. Reproduction was not statistically significantly reduced compared to the control up to and including the application rate of 1088 mL product/ha (Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$).

Table 100.3.2.2-1. Mortality and reproduction of *Typhlodromus pyri*

	Rate ¹⁾ [mL product/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female]	Effect on reproduction ⁵⁾ [%]
Control		11.7	--	5.3	--
GLOB2011I	174	16.7 n.s.	5.7	4.2 n.s.	21.2
GLOB2011I	435	13.3 n.s.	1.9	4.3 n.s.	19.3
GLOB2011I	1088	23.3 n.s.	13.2	4.1 n.s.	21.5
GLOB2011I	2720	86.7 *	84.9	--	--
GLOB2011I	6800	91.7 *	90.6	--	--
Endpoints ⁶⁾					
		[mL product/ha]		[g a.s./ha]	
Mortality: LR ₅₀ Value (95% CL):		2109 (907 – 4903)		1376 (592 – 3198)	
NOER for Mortality:		1088		710	
LOER for Mortality:		2720		1774	
Reproduction: ER ₅₀ Value:		> 1088		> 710	
NOER for Reproduction:		≥ 1088		≥ 710	
LOER for Reproduction:		> 1088		> 710	

1) Application rate in 200 L spray volume/ha

2) Mortality: after 7 days of exposure to spray residues on leaf surfaces

(Step-down Rao-Scott-Cochran-Armitage Test,; one-sided greater; $\alpha = 0.05$; n.s. = not significant; * = significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli; negative values indicate better survivorship compared to control

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 was calculated with Weibull Analysis; ER₅₀ could not be calculated as no effects above 50% were noted; 95% CL = 95% confidence limits

Validity criteria:

The reference item applied at a rate of 40 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 11.7 % after 7 days (should not exceed 20 %). The mean control reproduction rate was 5.3 eggs per female after 14 days (should be ≥ 4 eggs per female in the second week). All validity criteria were met.

Conclusions

Under extended laboratory conditions the LR₅₀ of GLOB2011I is 2109 mL product/ha (equivalent to 1376 g a.s./ha) in 200 L water/ha (95 % confidence limits: 907 – 4903 mL product, equivalent to 592 – 3198 g a.s./ha). The NOER (no observed effect rate) for mortality effects was 1088 mL product/ha (equivalent to 710 g a.s./ha) and the LOER (lowest observed effect rate) for mortality effects was 2720 mL product/ha (equivalent to 1774 g a.s./ha) in 200 L water/ha.

Reproduction of *Typhlodromus pyri* was assessed in the control and at 174, 435 and 1088 mL product/ha. There were no effects on reproduction up to and including 1088 mL product/ha. Therefore, the ER₅₀ was estimated to be greater than 1088 mL product/ha (equivalent to > 710 g a.s./ha) in 200 L water/ha. The NOER for reproduction effects was equal to or greater than 1088 mL product/ha (equivalent to ≥ 710 g a.s./ha) and the LOER for reproduction effects was greater than 1088 mL product/ha (equivalent to > 710 g a.s./ha) in 200 L water/ha.

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

Study 2

Comments of zRMS:	The study was performed according to Blümel et al. (2000), Oomen (1988) and principles of GLP. The validity criteria are met.
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Reference:	KCP 10.3.2.2
Report	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Aged Residue Test, Leopold J., 2022b, Study No. 167841060
Guideline(s):	Yes, Blümel et al. (2000), Oomen (1988)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.s. (pre storage): 652.3 g/L pelargonic acid (C9), equivalent to 100.4 % of the declared content.
Test Species:	Predatory mite (<i>Typhlodromus pyri</i> Scheuten), protonymphs, not older than 24 hours; egg source: Katz Biotech AG, Baruth, Germany.
Test Design:	Three bioassays were performed in this aged residue study. The first bioassay was started on the day of application, the second and third bioassays were started 7 and 14 days after the application, respectively. The study encompassed 3 treatment groups (1 test item dose rate, control, reference item) in the first bioassay and 2 treatment groups (1 test item dose rate, control) in the second and third bioassay with 10 replicates each containing 10 mites. The mites were exposed to freshly dried and aged residues on leaves from field treated potted vine plants. Assessment of the number of living, escaped and dead mites were made 3 and 7 days after the start of each bioassay. For the reproduction assessment surviving mites from the control and the test item treatment group where the corrected mortality was ≤ 50 % were sexed and the number of eggs per females was recorded at 3 further assessment days within one week.

Validity Criteria:	<ul style="list-style-type: none">- The mean control mortality should not exceed 20 %.- Mean reference item mortality should be ≥ 50 % corrected mortality.- The mean control reproduction rate should be ≥ 4 eggs per female for the second week.
Endpoints:	Mortality of exposed mites. Additionally, reproduction capacity for all treatments with ≤ 50 % corrected mortality.
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L)
Test Rates:	Control, 6800 mL product/ha and reference item. The reference item was applied at an application rate of 50 mL Danadim Progress/ha. All items were applied in 400 L spray volume/ha. The items were sprayed onto potted vine plants grown in the field <i>via</i> field spraying equipment and air dried afterwards outdoors under natural conditions.
Test Conditions during Bioassays:	Temperature: 23 - 25 °C; relative humidity: 60 - 71 %; photoperiod: 16 h light; 8 h dark; light intensity: 380 - 510 lux.
Climatic Conditions during Test Item Application and Aging of Residues:	Test item application: air temperature 17 – 18 °C; air humidity 55 – 58 %; wind velocity 0.0 - 0.1 m/s Aging of spray residues: air temperature 13 – 31 °C; relative air humidity 24 - 100 %

Results

First bioassay on day of test item application:

The mortality of *T. pyri* was 10.0 % in the control and 38.0 % in the test item treatment and statistically significantly increased in the test item treatment group compared to the control (Chi² 2x2 Table Test; one-sided greater; $\alpha = 0.05$).

In the reference item, mortality was 99.0 % (corrected mortality 98.9 %) and statistically significantly increased compared to the control (Chi² 2x2 Table Test; one-sided greater; $\alpha = 0.05$).

Reproduction of *T. pyri* was assessed in the control and in the test item treatment. It was 6.1 eggs per female in the control and 8.1 eggs per female in the test item treatment, corresponding to an increase of 33.3 % compared to the control treatment. Reproduction was not statistically significantly reduced compared to the control (Student t-Test, one-sided smaller, $\alpha = 0.05$).

Second bioassay 7 days after test item application:

The mortality of *T. pyri* was 7.0 % in the control and 18.0 % in the test item treatment (corrected mortality 11.8 %) and was statistically significantly increased in the test item treatment group compared to the control (Chi² 2x2 Table Test; one-sided greater; $\alpha = 0.05$).

Reproduction of *T. pyri* was assessed in the control and in the test item treatment. It was 5.6 eggs per female both in the control and test item treatment. Reproduction was not statistically significantly reduced compared to the control (Student t-Test, one-sided smaller, $\alpha = 0.05$).

Third bioassay 14 days after test item application:

The mortality of *T. pyri* was 17.0 % in the control and 13.0 % in the test item treatment (corrected mortality – 4.8 %) and was not statistically significantly increased in the test item treatment group compared to the control (Chi² 2x2 Table Test; one-sided greater; $\alpha = 0.05$).

Reproduction of *T. pyri* was assessed in the control and in the test item treatment. It was 4.3 eggs per female in the control and 5.6 eggs per female in the test item treatment, corresponding to an increase of 29.4 % compared to the control treatment. Reproduction was not statistically significantly reduced compared to the control (Student t-Test, one-sided smaller, $\alpha = 0.05$).

Table 110.3.2.2-2. Mortality and reproduction of *Typhlodromus pyri* on day 0, 7 and 14 after test item application

Bioassays	Rate ¹⁾ [mL product/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female]	Effect on re- production ⁵⁾ [%]
1 st bioassay (day 0)					
Control	--	10.0	--	--	--
GLOB2011I	6800	38.0 *	31.1	6.1 n.s.	-33.3
reference item (Danadim Progress)	50.0	99.0 *	98.9	8.1	--
2 nd bioassay (day 7)					
Control	--	7.0	--	5.6	--
GLOB2011I	6800	18.0 *	11.8	5.6 n.s.	0.0
3 rd bioassay (day 14)					
Control	--	17.0	--	4.3	--
GLOB2011I	6800	13.0 n.s.	-4.8	5.6 n.s.	-29.4

1) Application rate in 400 L spray volume/ha; application was done in the field under outdoor conditions

2) Mortality: after 7 days of exposure to fresh and aged spray residues on treated leaf surfaces

(test item/reference item: Chi² 2x2 Table Test, $\alpha = 0.05$, one-sided greater; * = significant; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli; negative value means better survivorship compared to the control

4) Reproduction: mean number of eggs/female,

(Student t-Test, $\alpha = 0.05$, one-sided smaller; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control.

Validity criteria:

The reference item applied at a rate of 50.0 mL Danadim Progress/ha produced a statistically significant corrected mortality of 98.9 % after 7 days (should be ≥ 50 % corrected mortality). The control mortality was between 7.0 and 17.0 % after 7 days of exposure in all bioassays (should not exceed 20 %). The mean control reproduction rate ranged from 4.3 to 6.1 eggs per female for the second week (should be ≥ 4 eggs per female). All validity criteria were met.

Conclusions

The duration and the extent of effects of fresh dried and aged residues of GLOB2011I applied with an application rate of 6800 mL product/ha on potted vine plants on the predatory mite *Typhlodromus pyri* were evaluated under extended laboratory conditions.

The mortality of *Typhlodromus pyri* was statistically significantly reduced compared to the control by exposure to freshly dried residues on the day of application of GLOB2011I, but the corrected mortality was below the trigger value of 50 % (31.1 %).

In the second bioassay, mortality of *T. pyri* was statistically significantly reduced compared to the control by exposure to aged residues 7 days after application of GLOB2011I. The corrected mortality was 11.8 % and below the trigger value of 50 %.

In the third bioassay, mortality of *T. pyri* was not statistically significantly reduced compared to the control by exposure to aged residues 14 days after application of GLOB2011I. The corrected mortality was -4.8 % and below the trigger value of 50 %.

The reproductive capacity of adult *T. pyri* was assessed in all three bioassays. Reproduction was not statistically significantly reduced compared to the control and the effect on reproduction was below the trigger value of 50 % in all bioassays with an increase of 33.3, 0.0 and 29.4 % compared to the control, respectively.

Overall, a single application of 6800 mL GLOB2011I/ha in 400 L tap water/ha did not cause unacceptable effects on mortality and reproduction of *T. pyri* either on the day of application or after aging periods of 7 and 14 days under natural conditions with rain protection. Both effects were always below the ESCORT 2 trigger value of 50 %.

All validity criteria were met at all bioassays. The study is considered valid.

Study 3

Comments of zRMS:	The study was performed according to Mead-Briggs et al. (2010) and principles of GLP. The validity criteria are met. The study is considered acceptable and suitable for the risk assessment. LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha) ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)
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Reference:	KCP 10.3.2.2
Report	GLOB2011I: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae), Extended Laboratory Study - Dose Response Test, Leopold J., 2022c, Study No. 167841002
Guideline(s):	Yes, Mead-Briggs et al. (2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.s. (pre storage): 652.3 g/L pelargonic acid (C9), equivalent to 100.4 % of the declared content.
Test Species:	Parasitoid (<i>Aphidius rhopalosiphi</i>), 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 6 replicates each containing 5 female parasitoids. The parasitoids were exposed to dried residues on treated plant surfaces (barley plants). Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups with ≤ 50 % corrected mortality survived females were removed and their reproductive capacity was assessed by confining them individually over untreated barley plants infested with the host cereal aphids, <i>Rhopalosiphum padi</i> . The adult parasitoids were removed after 24 hours and the aphid-infested plants left for 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 was assessed.
Validity Criteria:	<ul style="list-style-type: none"> - Control mortality should be ≤ 10 %. - Reference item mortality should be > 50 % corrected mortality. - Mean reproduction rate of control treatment should be ≥ 5 mummies per surviving female. - No more than 2 surviving female parasitoids should be producing zero values in the control treatment.
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L).
Test Rates:	Control, 84.0, 252, 756, 2267 and 6800 mL product/ha and reference item. The reference item was applied at an application rate of 10.0 mL Danadim Progress/ha. All treatments were applied in 400 L spray volume/ha. The spraying solutions were sprayed onto barley plants <i>via</i> laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 20 - 21 °C; relative humidity: 73 - 82 % (acclimatisation and exposure period), 75 - 78 % (post-exposure period, within the test units); photoperiod: 16 h light : 8 h dark; light intensity: 510 - 650 lux (acclimatisa-

Statistics: tion and exposure period), 1650 - 1670 lux (parasitisation period), 15250 - 18220 lux (post-parasitisation period).
Mortality: Fisher's Exact Binomial Test with Bonferroni-Holm Correction, Fisher's Exact Binomial Test (both one-sided greater, $\alpha = 0.05$).
Settling of parasitoids: Williams t-Test, Dunnett's t-Test, Student t-Test, Welch t-Test (all one-sided smaller, $\alpha = 0.05$)
Reproduction: Dunnett's t-Test (one-sided smaller, $\alpha = 0.05$).

Results

The results are summarized in Table 120.3.2.2-3.

Table 120.3.2.2-3. Mortality and parasitisation efficiency of *Aphidius rhopalosiphi*

	Rate ¹⁾ [mL prod- uct/ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [mummies/female]	Effect on reproduction ⁵⁾ [%]
Control	-	0.0	--	44.1	--
GLOB2011I	84.0	0.0 n.s.	0.0	58.7 n.s.	-33.0
GLOB2011I	252	0.0 n.s.	0.0	53.6 n.s.	-21.5
GLOB2011I	756	0.0 n.s.	0.0	51.6 n.s.	-17.0
GLOB2011I	2267	0.0 n.s.	0.0	55.6 n.s.	-26.0
GLOB2011I	6800	13.3 n.s.	13.3	37.7 n.s.	14.6
Endpoints ⁶⁾					
	[mL product/ha]		[g a.s./ha]		
Mortality: LR ₅₀ Value	> 6800		> 4436		
NOER for Mortality	≥ 6800		≥ 4436		
LOER for Mortality	> 6800		> 4436		
Reproduction: ER ₅₀ Value	> 6800		> 4436		
NOER for Reproduction	≥ 6800		≥ 4436		
LOER for Reproduction	> 6800		> 4436		

1) Application rate in 400 L spray volume/ha

2) Mortality: after 48 hours of exposure to spray residues on plant surfaces

(Fisher's Exact Binomial Test with Bonferroni-Holm 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 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 could not be calculated since no mortalities or effects on reproduction above 50% were noted.

The mean mortality of *Aphidius rhopalosiphi* was 0.0 % in the control treatment and was between 0.0 and 13.3 % in the test item treatments. Mortality was not statistically significantly increased compared to the control up to and including the highest test item application rate of 6800 mL product/ha (Fisher's Exact Binomial Test with Bonferroni-Holm Correction, one-sided greater, $\alpha = 0.05$).

One moribund parasitoid was observed at 6800 mL product/ha after 48 hours. No further behavioural abnormalities were recorded at any assessment or test item application rate.

During the initial 2.5 hours, the settling rate of the parasitoids on the plants was between 27.3 and 91.3 % in the test item treatments and was statistically significantly reduced compared to the control at all test item rates with exception of the lowest rate of 84.0 mL product/ha (Williams t-Test, one-sided smaller, α

= 0.05). At 6800 mL product/ha, the settling rate remained under the 30 % threshold. At the control and reference item treatment, it was 92.0 and 70.7 %, respectively and for the reference item it was statistically significantly reduced compared to the control (Student t-Test, one-sided smaller, $\alpha = 0.05$). As the settling rate was below the threshold value of 30% for repellent effects at 6800 mL product/ha, further assessments of the settling behaviour were carried out after 24 and 48 hours.

After 24 hours, the settling rate was 73.3 % in the control treatment and ranged from 68.3 to 86.7 % in the test item treatments. No statistically significant reduction compared to the control was noted (Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$).

After 48 hours, the settling rate was 73.3 % in the control treatment and was between 69.4 and 86.7 % in the test item treatments. No statistically significant reduction compared to the control was observed (Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$).

In the reference item treatment, the settling rate was 66.7% after 24 hours and 0.0 % after 48 hours, but not meaningful due to increasing mortality (83.3 % after 24 hours, 100.0 % after 48 hours).

The mean reproduction of *A. rhopalosiphii* was 44.1 mummies per female in the control and ranged from 37.7 to 58.7 mummies per female in the test item treatments. Reproduction was assessed in the control and at all test item application rates. Reproduction was not statistically significantly reduced compared to the control up to and including the highest test item application rate of 6800 mL product/ha (Dunnett's t-Test, one-sided smaller, $\alpha = 0.05$).

The reference item applied at a rate of 10.0 mL Danadim Progress/ha produced a statistically significant corrected mortality of 100.0 % after 48 hours (Fisher's Exact Binomial Test; one-sided greater, $\alpha = 0.05$).

Validity criteria:

The reference item applied at a rate of 10.0 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 10 %). The mean control reproduction rate was 44.1 mummies per female (should be ≥ 5.0 mummies per surviving female). One female parasitoid produced zero values in the control treatment (no more than 2 surviving female parasitoids producing zero values). All validity criteria were met.

Conclusions

Under extended laboratory conditions the LR50 value of GLOB2011I is estimated to be greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 400 L water/ha. For mortality effects, the NOER (No Observed Effect Rate) is equal to or higher than 6800 mL product/ha (equivalent to ≥ 4436 g a.s./ha) and the LOER (Lowest Observed Effect Rate) is higher than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 400 L water/ha.

Since the settling rate of the parasitoids on the plants was < 30 % at the highest test item application rate of 6800 mL product/ha during the initial 2.5 hours, it has to be concluded that this behaviour was caused by a repellent treatment effect. However, this impairment was only short-term and no longer observed at the following assessments indicating that the parasitoids were sufficiently exposed to the spray deposits also at the highest rate.

Reproduction of *A. rhopalosiphii* was assessed in the control and at all test item application rates. There was no statistically significant effect on reproduction compared to the control up to and including the highest test item application rate of 6800 mL product/ha. Therefore, the ER50 value for reproduction is estimated to be greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 400 L water/ha. For reproduction effects, the NOER is equal to or greater than 6800 mL product/ha (equivalent to ≥ 4436 g a.s./ha) and the LOER is greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 400 L water/ha.

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

Study 4

Comments of zRMS:	The study was performed according to Vogt et al. (2000) (modified for exposure of <i>C. carnea</i> on natural substrate) and principles of GLP. The validity criteria are met. The study is considered acceptable and suitable for the risk assessment. LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)
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	ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)
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Reference:	KCP 10.3.2.2
Report	GLOB2011I: Effects on the Lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae), Extended Laboratory Study - Dose Response Test, Leopold J., 2022d, Study No. 167841047
Guideline(s):	Yes, Vogt et al. (2000) (this guideline was modified for exposure of <i>C. carnea</i> on natural substrate).
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; analysed content of a.s. (pre storage): 652.3 g/L pelargonic acid (C9), equivalent to 100.4 % of the declared content.
Test Species:	Lacewing (<i>Chrysoperla carnea</i>), 2 - 3 days old larvae; 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 40 replicates each containing 1 larva. The larvae were exposed to dried residues on treated leaf surfaces (vine leaves). Exposure lasted until pupae were transferred to the reproduction units for development of adults. Mortality checks were carried out regularly until hatching of adult lacewings. In addition, for the control and the test item treatment groups where the corrected mortality was ≤ 50 %, the reproduction performance, <i>i.e.</i> egg deposition and larval hatching rate, was determined (2 checks/week, 24 hours period each check).
Endpoints:	Larval and pupal mortality. Additionally, reproductive capacity of female survivors for treatment groups with ≤ 50 % corrected mortality.
Validity Criteria:	<ul style="list-style-type: none"> - Pre-imaginal control mortality should not exceed 20 %. - Pre-imaginal mortality of the reference item group should result in at least 50 % (preferably < 100 %) corrected mortality. - Mean fecundity in the control group should be at least 15 eggs per female per day. <p>Mean larval hatching rate of the control group should be at least 70 %.</p>
Reference Item:	Danadim Progress (nominal: 400 g dimethoate/L).
Test Rates:	Control, 84.0, 252, 756, 2267 and 6800 mL product/ha (equivalent to 54.8, 164, 493, 1479 and 4436 g a.s./ha based on the active substance content of 652.3 g/L) and reference item. The reference item was applied at an application rate of 170 mL Danadim Progress/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto leaves <i>via</i> laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 24 - 27 °C; relative humidity: 62 - 72 %; photoperiod: 16 h light; 8 h dark; light intensity: 1010 - 1280 lux.
Statistics:	<p>Mortality: χ^2 2x2 Table Test with Bonferroni Correction, Fisher's Exact Binomial Test (both one-sided greater, $\alpha = 0.05$).</p> <p>Reproduction: In agreement with the guideline, no statistical evaluation was performed.</p>

Results

The results are summarized in Table 120.3.2.2-4.

Table 130.3.2.2-4. Pre-imaginal mortality and reproduction of *Chrysoperla carnea*

	Rate ¹⁾ [mL product/ha]/ [g a.s./ha]	Mortality ²⁾ [%]	Mortality corr. ³⁾ [%]	Reproduction ⁴⁾ [eggs/female/day]	Effect on Reproduc- tion ⁵⁾ [%]	Larval hatching rate ⁶⁾ [%]
Control	--	17.5	--	25.8	--	94.5
GLOB2011I	84.0 / 54.8	32.5 n.s.	18.2	21.5	16.8	95.2
GLOB2011I	252 / 164	27.5 n.s.	12.1	24.4	5.5	95.8
GLOB2011I	756 / 493	27.5 n.s.	12.1	25.3	2.0	94.5
GLOB2011I	2267 / 1479	15.0 n.s.	-3.0	35.7	-38.0	96.1
GLOB2011I	6800 / 4436	22.5 n.s.	6.1	28.0	-8.2	93.9
Endpoints ⁷⁾						
	[mL product/ha]			[g a.s./ha]		
Mortality: LR ₅₀ value	> 6800			> 4436		
NOER for mortality	≥ 6800			≥ 4436		
LOER for mortality	>6800			>4436		
Reproduction: ER ₅₀ value	> 6800			> 4436		

1) Application rate in 200 L spray volume/ha

2) Pre-imaginal mortality after exposure to spray residues on leaf surfaces

(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; negative values indicate a better survivorship compared to the control treatment

4) Reproduction: mean number of eggs per female per day;

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

6) For the determination of the hatching rate only eggs were considered which were laid on the gauze of the oviposition cages due to technical reasons.

7) The LR₅₀ value could not be calculated as no mortalities above 50 % and no clear dose-relationship were observed; the ER₅₀ value for reproduction was determined by expert judgement.

The mean mortality of *Chrysoperla carnea* was 17.5 % in the control treatment and was between 15.0 and 32.5 % in the test item treatments, corresponding to corrected mortalities of -3.0 to 18.2 %. Mortality was not statistically significantly increased compared to the control up to and including the highest application rate of 6800 mL product/ha (Chi² 2x2 Table Test with Bonferroni Correction, one-sided greater, α = 0.05).

The reference item applied at a rate of 170 mL Danadim Progress/ha produced a statistically significant mortality of 85.0 % (81.8 % corrected mortality; Fisher's Exact Binomial Test, one-sided greater, α = 0.05).

Reproduction of *C. carnea* was assessed in the control and in all test item application rates. The mean number of eggs per female and day was 25.8 in the control treatment. In the test item treatments, it ranged from 21.5 eggs per female and day (84.0 mL product/ha) to 35.7 eggs per female and day (2267 mL product/ha), corresponding to a reduction of 16.8 % to -38.0 %. Reproduction was > 15 eggs per female and day in all test item rates. No clear dose-response relationship was recognizable.

The mean hatching rate was higher than 70 % in the control and in all test item application rates. In the control treatment, the hatching rate was 94.5 % and ranged from 93.9 % (6800 mL product/ha) to 96.1 % (2267 mL product/ha) in the test item treatments.

Validity criteria

The reference item applied at a rate of 170 mL Danadim Progress/ha produced a statistically significant corrected mean mortality of 81.8 % after 25 days (should be \geq 50 % corrected mortality). The pre-imaginal control mortality was 17.5 % (should not exceed 20 %). The mean control fecundity was 25.8 eggs per female per day (should be \geq 15 eggs per female per day). Mean larval hatching rate of the control group was 94.5 % (should be at least 70 %). All validity criteria were met.

Conclusions

Under extended laboratory conditions the LR50 of GLOB2011I is estimated to be greater than 6800 mL product/ha, equivalent to > 4436 g a.s./ha, in 200 L water/ha. The NOER (no observed effect rate) for mortality effects is equal to or greater than 6800 mL product/ha, equivalent to \geq 4436 g a.s./ha, and the LOER (lowest observed effect rate) is greater than 6800 mL product/ha, equivalent to > 4436 g a.s./ha, in 200 L water/ha.

The reproductive capacity of *C. carnea* was tested in all test item application rates. The mean hatching rate was comparable to the control in all test item application rates and was always > 70 %. Reproduction was > 15 eggs per female per day in all test item application rates and in the control. This indicates that there was no negative effect of the test item on reproductive performance of *C. carnea* up to and including the highest application rate of 6800 mL product/ha. The ER50 value for effects on reproduction is estimated to be greater than 6800 mL product/ha, equivalent to > 4436 g a.s./ha, in 200 L water/ha.

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

Study 5

Comments of zRMS:	<p>The study was performed according to Bakker et al., (2000) and principles of GLP. The validity criteria are met.</p> <p>The study is considered acceptable and suitable for the risk assessment.</p> <p>LR50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)</p> <p>ER50 > 4436 g a.s./ha (> 6800 ml GLOB2011I/ha)</p>
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Reference: KCP 10.3.2.2

Report GLOB2011I: Effects on the Predatory Bug *Orius laevigatus* (Heteroptera, Anthocoridae), Extended Laboratory Study - Dose Response Test, Leopold J., 2022e, Study No. 167841052

Guideline(s): Yes, Bakker et al., (2000)

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

Material and methods

Test item: GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.s. (pre storage): 652.3 g/L pelargonic acid (C9), equivalent to 100.4 % of the declared content.

Test Species: Predatory bug (*Orius laevisgatus*), nymphs (4 - 5 days old, second instar); source: Katz Biotech AG, Baruth, Germany.

Test Design: This study encompassed 7 treatment groups (5 application rates of the test item, control, reference item) with 50 replicates each containing 1 nymph. The nymphs were exposed to dried residues on treated leaf surfaces (vine leaves). Exposure time lasted 9 - 11 days when adults were transferred to the pre-oviposition units. Mortality checks were carried out at least 2 times a week after treatment. In addition, for the control and the test item treatment group the reproduction performance, *i.e.* egg deposition (fecundity) and nymphal hatching rate (fertility) was determined (2 checks, each lasting 2 days, nymphal hatching rate from the first check).

Endpoints: Nymphal mortality and LR₅₀: lethal rate producing 50 % mortality after exposure. Additionally, the reproductive capacity was assessed.

Validity Criteria:

- Control mortality should not exceed 25 % (dead and escaped individuals).
- Reference item mortality should result in at least 40 % corrected mortality (if possible < 100 %).
- Fecundity in the control group should be ≥ 2 eggs per female per day (mean value).
- No more than 5 bugs of the control group should produce zero values.

At least 70 % of the eggs produced in the control group should hatch successfully.

Reference Item: Danadim Progress (nominal: 400 g dimethoate/L).

Test Rates: Control, 84.0, 252, 756, 2267 and 6800 mL product/ha. The reference item was applied at an application rate of 11.0 mL Danadim Progress/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto leaves *via* laboratory spraying equipment, which were then air dried.

Test Conditions: Temperature: 23 - 25 °C; relative humidity: 66 - 71 %; photoperiod: 16 h light: 8 h dark; light intensity: 420 - 660 lux.

Statistics: Mortality: Chi² 2x2 Table Test with Bonferroni Correction, Fisher Exact Binomial Test (both one-sided greater, $\alpha = 0.05$).
Fecundity: Dunnett's t-Test (one-sided smaller; $\alpha = 0.05$); fertility: Chi² 2x2 Table Test with Bonferroni Correction (one-sided greater; $\alpha = 0.05$).

Results

The results are summarized in Table 120.3.2.2-5.

Table 140.3.2.2-5. Effects of GLOB2011I on mortality and reproduction of the predatory bug, *Orius laevisgatus*, exposed to fresh dried residue on leaves in the laboratory

	Rate ¹⁾	Mortality ²⁾	Mortality corr. ³⁾	Fecundity ⁴⁾	Reduction of Fecundity ⁵⁾	Fertility (hatching rate) ⁶⁾	Reduction of Fertility ⁵⁾
	[mL prod./ha]	[%]	[%]	[eggs/female/day]	[%]	[%]	[%]

Table 140.3.2.2-5. Effects of GLOB2011I on mortality and reproduction of the predatory bug, *Orius laevigatus*, exposed to fresh dried residue on leaves in the laboratory

Control	--	20.0	--	6.2	--	76.8	--
GLOB2011I	84.0	6.0 n.s.	-17.5	8.2 n.s.	-32.6	81.1 n.s.	-5.7
GLOB2011I	252	12.0 n.s.	-10.0	6.5 n.s.	-4.6	84.9 n.s.	-10.5
GLOB2011I	756	18.0 n.s.	-2.5	7.6 n.s.	-23.5	87.9 n.s.	-14.5
GLOB2011I	2267	18.0 n.s.	-2.5	6.7 n.s.	-7.8	77.9 n.s.	-1.4
GLOB2011I	6800	16.0 n.s.	-5.0	7.1 n.s.	-15.4	76.9 n.s.	-0.2
Endpoints ⁷⁾							
		[mL product/ha]		[g a.s./ha]			
Mortality: LR₅₀ Value:		> 6800		> 4436			
NOER for Mortality:		≥ 6800		≥ 4436			
LOER for Mortality:		> 6800		> 4436			
Fecundity: ER₅₀ Value:		> 6800		> 4436			
NOER for Fecundity:		≥ 6800		≥ 4436			
LOER for Fecundity:		> 6800		> 4436			
Fertility: ER₅₀ Value:		> 6800		> 4436			
NOER for Fertility:		≥ 6800		≥ 4436			
LOER for Fertility:		> 6800		> 4436			

1) Application rate in 200 L spray volume/ha; prod. = product

2) Mortality: after exposure to spray residues on leaves

(Chi² 2x2 Table Test with Bonferroni Correction, $\alpha = 0.05$; one-sided greater; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli; negative values indicates a better survivorship compared to the control

4) Fecundity: mean number of eggs/female/day (Dunnett's t-Test; one-sided smaller; $\alpha = 0.05$; n.s. = not significant)

5) Calculated in the exact raw data; negative value indicates a better performance compared to the control

6) Fertility: mean larval hatching rate (Chi² 2x2 Table Test with Bonferroni Correction, $\alpha = 0.05$; one-sided greater; n.s. = not significant)

7) LR₅₀ and ER₅₀ could not be calculated as no mortality and effects on reproduction above 50% were noted.

The mean nymphal mortality of *Orius laevigatus* was 20.0 % in the control and was between 6.0 and 18.0 % in the test item treatments, corresponding to corrected mortalities of -17.5 to -2.5%. Mortality was not statistically significantly increased compared to the control up to and including the highest application rate of 6800 mL product/ha (Chi² 2x2 Table Test with Bonferroni Correction, one-sided greater, $\alpha = 0.05$).

The reference item applied at a rate of 11.0 mL Danadim Progress/ha produced a statistically significant mortality of 78.0 % (72.5 % corrected mortality; Fisher's Exact Binomial Test; one-sided greater; $\alpha = 0.05$).

The reproductive capacity of *O. laevigatus* was tested at all application rates. Fecundity was 6.2 eggs per female per day in the control treatment and ranged from 6.5 to 8.2 eggs per female per day in the test item

treatments, corresponding to -32.6 to -4.6 % reduction compared to the control. There was no statistically significant effect on fecundity up to and including the highest application rate of 6800 mL product/ha in 200 L water/ha (Dunnett's t-Test; one-sided smaller; $\alpha = 0.05$).

The fertility (mean nymphal hatching rate) was 76.8 % in the control. In the test item treatments, fertility was between 76.9 and 87.9 %. There was no statistically significant effect on fertility up to and including the highest application rate of 6800 mL product/ha (Chi² 2x2 Table Test with Bonferroni Correction; one-sided smaller; $\alpha = 0.05$).

Validity criteria:

The reference item applied at a rate of 11.0 mL Danadim Progress/ha produced a statistically significant corrected mean mortality of 72.5 % after 10 days (should be ≥ 40 % corrected mortality). The mean control mortality was 20.0 % (should not exceed 25 %). The mean control reproduction rate was 6.2 eggs per female per day (should be ≥ 2.0 eggs per female per day). No bugs produced zero values in the control treatment (no more than 5 bugs of the control group should produce zero values). The mean hatching rate of the control treatment was 76.8 % (at least 70 % of the eggs produced in the control group should hatch successfully). All validity criteria were met.

Conclusions

Under extended laboratory conditions the LR50 value of GLOB2011I is estimated to be greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha. The NOER (No Observed Effect Rate) for mortality effects was equal to or greater than 6800 mL product/ha (equivalent to ≥ 4436 g a.s./ha) and the LOER (Lowest Observed Effect Rate) for mortality effects was greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha.

The reproductive capacity of *Orius laevigatus* was tested at all application rates. There was no test item related effect on fecundity (eggs produced per female per day) up to and including the highest application rate of 6800 mL product/ha in 200 L water/ha. There was no statistically significant effect on fertility of *O. laevigatus* (nymphal hatching rate) up to and including the highest application rate 6800 mL product/ha.

The NOER (no observed effect rate) for fecundity effects was equal to or greater than 6800 mL product/ha (equivalent to ≥ 4436 g a.s./ha) and the LOER (lowest observed effect rate) was greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha. The ER50 value for fecundity is estimated to be greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha.

The NOER (no observed effect rate) for fertility effects was 6800 mL product/ha (equivalent to ≥ 4436 g a.s./ha) and the LOER (lowest observed effect rate) was 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha. The ER50 value for fecundity is estimated to be greater than 6800 mL product/ha (equivalent to > 4436 g a.s./ha) in 200 L water/ha.

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

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 performed according to OECD TG 222 and principles of GLP. The validity criteria are met. For the control group:</p> <ul style="list-style-type: none"> - Adult mortality: ≤ 10 % (being 0.0 %) - Number of juveniles per replicate: ≥ 30 (being 90 to 143) - Coefficient of variation of reproduction: ≤ 30 % (being 16.02 %). <p>There were no deviations to the study plan.</p>
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	The study is considered acceptable and suitable for the risk assessment.
	NOEC \geq 179.2 mg test item/kg soil dry weight (equivalent to 128.3 mg a.i./kg dws)

Reference:	KCP 10.4.1.1
Report	GLOB2011I: Effects on Reproduction and Growth of Earthworms <i>Eisenia andrei</i> in Artificial Soil, Hübner S., 2022a, Study No. 167841022
Guideline(s):	Yes, OECD 222 (2016) and ISO 11268-2 (2012)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Material and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content of a.i.: Pelar-gonic Acid (Nonanoic Acid) 652.3 g/L (authenticated), 650 g/L (declared)
Test Species:	Earthworm (<i>Eisenia andrei</i> , Bouché, 1972), adult earthworms (with clitellum and weight range 304 to 598 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; 10 treatment groups (9 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 deter-mined.
Reference Item:	Carbendazim (600 g/L nominal). The effects of the reference item were inves-tigated in a separate GLP study.
Test Concentrations:	Control, 1.63, 2.93, 5.27, 9.48, 17.1, 30.7, 55.3, 99.6 and 179.2 mg GLOB2011I/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 222; initial pH 5.5 to 5.9, pH at experi-mental end 6.1; water content 25.1% to 26.8% (50.2% to 53.6% of maximum water holding capacity, WHC) at experimental start and 25.4% to 27.1% (50.8% to 54.2% 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, Fisher's Exact Test (mortality), Dunnett's t-test (body weight changes and reproduction)

Results and Discussion:

All study validity criteria were met.

A mortality of up to 5% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where a mortality of 0% was observed (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

The body weight changes of the earthworms after 28 days exposure to GLOB2011I were not statistically significantly different compared to the control up to and including the highest test concentration of 179.2 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 179.2 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 10.4.1.1-1).

Table 150.4.1.1-1. Effect of GLOB2011I on earthworms (*Eisenia andrei*) in a 56-day reproduction study

GLOB2011I [mg test item/kg soil dry weight]	Con- trol	1.63	2.93	5.27	9.48	17.1	30.7	55.3	99.6	179.2
Mortality (day 28) [%]	0	0	0	0	0	5	0	0	3	0
Statistical Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Body weight change (day 28) [%]	20.1	16.1	23.4	15.7	13.5	21.9	19.2	19.9	16.7	18.7
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Mean No. of juveniles (day 56)	119	127	109	117	134	115	108	131	119	103
Statistical Significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Reproduction in [%] of con- trol (day 56)	-	107	92	99	113	97	91	111	100	87
Food consumption [g]	25.0	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)	≥ 179.2									
LOEC (day 28 mortality)	> 179.2									
LC ₅₀ ³⁾	> 179.2									
NOEC (day 28 weight)	≥ 179.2									
LOEC (day 28 weight)	> 179.2									
NOEC (day 56 reproduction)	≥ 179.2									
LOEC (day 56 reproduction)	> 179.2									
EC ₅₀ ³⁾	> 179.2									

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 GLOB2011I the No Observed Effect Concentration (NOEC) for mortality, weight changes and reproduction of the earthworm *Eisenia andrei* was determined to be ≥ 179.2 mg test item/kg soil dry weight (equivalent to 128.3 mg a.i./kg dws), i.e. the highest concentration tested. The Lowest Observed Effect Concentration (LOEC) was estimated to be > 179.2 mg test item/kg soil dry weight (equivalent to 128.3 mg a.i./kg dws). The LC50 and EC50 were estimated to be > 179.2 mg test item/kg soil dry weight (equivalent to 128.3 mg a.i./kg dws).

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No new study was 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 performed according to OECD TG 232 and principles of GLP. The validity criteria were met. For the control group:</p> <ul style="list-style-type: none"> - Mean adult mortality: $\leq 20\%$ (observed: 6%) - Mean number of juveniles per test vessel: ≥ 100 (observed: 831 to 1067 per replicate) - Coefficient of variation for the mean number of juveniles: $< 30\%$ (observed: 9.4%) <p>There were no deviations to the study plan.</p> <p>The study is considered acceptable and suitable for the risk assessment.</p> <p>$NOEC_{repr.} = 47.5$ mg test item/kg soil dry weight (equivalent to 34.0 mg a.s./kg dws).</p>
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Reference:	KCP 10.4.2.1
Report	GLOB2011I: Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil, Hübner S., 2022b, Study No. 167841016
Guideline(s):	Yes, OECD 232 (2016) and SIO 11267 (2014)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Materials and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content: Pelargonic Acid (Nonanoic Acid) 650 g/L (declared), 652.3 g/L (authenticated).
Test Species:	Collembola <i>Folsomia candida</i> , 9 - 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 test item 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, 2.52, 4.53, 8.15, 14.7, 26.4, 47.5, 85.6 and 154 mg GLOB2011I/kg soil dry weight.
Test Conditions:	Artificial soil according to OECD 232; pH at experimental start 6.0 to 6.2, pH at experimental end 5.7 to 5.8; water content at experimental start 17.3% to 17.9% (50.9% to 52.7% of the maximum water holding capacity); water content at experimental end 15.2% to 16.6% (44.8% to 48.7% 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, Step-down Cochran-Armitage Test (mortality), Trimmed Spearman-Kärber procedure (LC_{50}), Williams t-test (reproduction), 3-param. Normal CDF (EC values).

Results and discussions

All validity criteria for the study were met.

A mortality of up to 25% was observed in the test item treated groups up to and including the test concentration of 85.6 mg test item/kg soil dry weight, which was not statistically significantly different compared to the control, where 6% of the *Collembola* died (Step-down Cochran-Armitage Test, $\alpha = 0.05$, one-sided greater). At the highest test concentration of 154 mg test item/kg soil dry weight, a mortality of 75% was observed, which was statistically significantly increased compared to the control.

Reproduction of the *Collembolan* exposed to GLOB2011I was not statistically significantly different compared to the control up to and including the test concentration of 47.5 mg test item/kg soil dry weight (Williams t-test, $\alpha = 0.05$, one-sided smaller). At the test concentration of 85.6 mg test item/kg soil dry weight and above, reproduction was statistically significantly decreased compared to the control.

No behavioural abnormalities were observed in any of the treatment groups. The results are shown in Table 160.4.2.1-1.

Table 160.4.2.1-1. Summary of the Effects of GLOB2011I on Collembola (*Folsomia candida*) in a 28-day Reproduction Study

GLOB2011I [mg/kg soil dry weight]	Control	2.52	4.53	8.15	14.7	26.4	47.5	85.6	154
Mean mortality (day 28) [%]	6	10	5	25	5	15	8	13	75
Significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	*
Mean no. of juveniles (day 28)	960	1040	958	918	954	866	957	788	197
Reproduction in [%] of control (day 28)	-	108	100	96	99	90	100	82	21
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	*	*
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	85.6								
LOEC (mortality)	154								
LC ₅₀ (mortality) ³⁾	105.3 (95% confidence limits 91.4 – 121.3)								
NOEC (reproduction)	47.5								
LOEC (reproduction)	85.6								
EC Values (reproduction) ⁴⁾	EC ₁₀ : 75.9			EC ₂₀ : 88.0			EC ₅₀ : 116.8		
95% confidence limits	67.4 – 85.5			77.8 – 99.4			98.3 – 137.5		

n.s. = not significantly different compared to the control

* = significantly different compared to the control

¹⁾ Step-down Cochran-Armitage Test, $\alpha = 0.05$, one-sided greater

²⁾ Williams t-test, $\alpha = 0.05$, one-sided smaller

³⁾ Trimmed Spearman-Kärber procedure

⁴⁾ 3-param. Normal CDF

- not applicable

Conclusion

The No Observed Effect Concentration (NOEC) of GLOB2011I for mortality of *Folsomia candida* was determined to be 85.6 mg test item/kg soil dry weight (equivalent to 61.3 mg a.s./kg dws). The Lowest Observed Effect Concentration (LOEC) for mortality was determined to be 154 mg test item/kg soil dry weight. The LC₅₀ was determined to be 105.3 mg test item/kg soil dry weight (equivalent to 75.4 mg a.s./kg dws).

The NOEC of GLOB2011I for reproduction of *Folsomia candida* was determined to be 47.5 mg test item/kg soil dry weight (equivalent to 34.0 mg a.s./kg dws). The LOEC for reproduction was determined to be 85.6 mg test item/kg soil dry weight (equivalent to 61.3 mg a.s./kg dws).

The EC₁₀ for *Folsomia candida* in artificial soil was determined to be 75.9 mg test item/kg soil dry weight, EC₂₀ was determined to be 88.0 mg test item/kg soil dry weight (equivalent to 63.0 mg a.s./kg dws) and the EC₅₀ was determined to be 116.8 mg test item/kg soil dry weight (equivalent to 83.6 mg a.s./kg dws).

Comments of zRMS:	<p>The study was performed according to OECD TG 226 and principles of GLP. The validity criteria were met. For the control group:</p> <ul style="list-style-type: none"> - Mean mortality of adult females: ≤ 20 % (observed: 0.0 %) - Mean number of juveniles per replicate: ≥ 50 (observed: 306.4) - Coefficient of variation (mean number of juveniles per replicate): ≤ 30 % (observed: 6.0 %) <p>The study is considered acceptable and suitable for the risk assessment.</p> <p>NOEC_{repr.} = 278 mg test item/kg soil dry weight (equivalent to = 199.1 mg a.s./kg dws).</p>
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Reference:	KCP 10.4.2.1
Report	GLOB2011I: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil, Hübner S., 2022c, Study No. 167841089
Guideline(s):	Yes, OECD 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Materials and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content: Pelargonic Acid (Nonanoic Acid): Declared content 650 g/L, authenticated content 652.3 g/L (according to GLP CoA)
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, 8.17, 14.7, 26.5, 47.6, 85.7, 154, 278 and 500 mg GLOB2011I/kg soil dry weight.
Test Conditions:	Artificial soil based on OECD 226; initial pH 5.8 to 5.9, pH at experimental end 5.8 to 6.0; water content at experimental start 17.0% to 17.5% (50.0% to 51.4% of the maximum water holding capacity); at experimental end 15.6% to 17.3% (46.0% to 50.9% 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), Williams t-test (reproduction), 3-param. normal CDF (EC values).

Results and discussions

All validity criteria for the study were met.

A mortality of up to 10% was observed in the test item treated groups, which was not statistically significantly different compared to the control, where 3% of the adult mites died (Fisher's Exact Test, $\alpha = 0.05$, one-sided greater).

Reproduction of the predatory mites exposed to GLOB2011I was not statistically significantly different compared to the control up to and including the test concentration of 278 mg test item/kg soil dry weight (Williams t-test, $\alpha = 0.05$, one-sided smaller). At the test concentration of 500 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 results are shown in Table 170.4.2.1-2.

Table 170.4.2.1-2. Summary of the Effects of GLOB2011I on the Predatory Mite *Hypoaspis aculeifer* in a 14-day Reproduction Study

GLOB2011I [mg/kg soil dry weight]	Con- trol	8.17	14.7	26.5	47.6	85.7	154	278	500
Mortality (day 14) [%]	3	8	5	8	0	0	10	0	3
Statistical significance ¹⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
No. of juveniles (day 14)	219	213	235	208	247	214	219	201	192
Reproduction in [%] of control (day 14)	-	97	108	95	113	98	100	92	88
Statistical significance ²⁾	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	*
Endpoints [mg/kg soil dry weight]									
NOEC (mortality)	≥500								
LOEC (mortality)	>500								
LC ₅₀ (mortality) ³⁾	>500								
NOEC (reproduction)	278								
LOEC (reproduction)	500								
EC Values (reproduction) ⁴⁾	EC ₁₀ = 477.1		EC ₂₀ = 799.1			EC ₅₀ = >500			
95% confidence limits	289.2 – 787.0		392.7 - 1574.4			-			

n.s. = not significantly different compared to the control

* = 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⁾ estimated value

⁴⁾ 3-param. normal CDF

- not applicable

Results and discussions

GLOB2011I caused no statistically significant effects on mortality of *Hypoaspis aculeifer* up to and including the highest test concentration of 500 mg test item/kg soil dry weight (equivalent to >358.1 mg a.s./kg dws). Therefore, the No Observed Effect Concentration (NOEC) for mortality was determined to be ≥500 mg test item/kg soil dry weight. The Lowest Observed Effect Concentration (LOEC) for mortality was estimated to be >500 mg test item/kg soil dry weight (equivalent to >358.1 mg a.s./kg dws). The LC₅₀ was estimated to be >500 mg test item/kg soil dry weight (equivalent to >358.1 mg a.s./kg dws). The NOEC of GLOB2011I for reproduction of *Hypoaspis aculeifer* was determined to be 278 mg test item/kg soil dry weight. The LOEC for reproduction was estimated to be 500 mg test item/kg soil dry weight (equivalent to >358.1 mg a.s./kg dws).

The EC₁₀ was determined to be 477.1 mg test item/kg soil dry weight (equivalent to >341.7 mg a.s./kg dws). The EC₂₀ was determined to be 799.1 mg test item/kg soil dry weight (equivalent to >572.2 mg a.s./kg dws). The EC₅₀ was estimated to be >500 mg test item/kg soil dry weight (equivalent to >358.1 mg a.s./kg dws).

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No new study was submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. All the validity criterion were met.
	The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.5
Report	GLOB2011I: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation), Bauer J., 2022, Study No. 167841080
Guideline(s):	Yes, OECD 226 216 (2000), EPPO PP 3/7(2) chapter, EPPO Bulletin 33:200-202 (2003) and SETAC (1995)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Materials and methods

Test Item:	GLOB2011I, Lot No. GLOB2011I09H15M21SANK
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 and 42 days after treatment
Test Rates:	Control 4.86 mg GLOB2011I/kg soil dry weight 48.58 mg GLOB2011I/kg soil dry weight
Endpoints:	Effects on NO ₃ -nitrogen production after 42 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: 48% to 50% of maximum water holding capacity (WHC _{max}). Temperature: 20°C ± 2°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:	No adverse effects of the test item on nitrate content in soil were observed at day 42. At day 42 differences to the control were -0.05% and -7.49% in the 4.86 mg and 48.58 mg test item/kg soil dry weight treatment, respectively. The results are summarized in Table 180.5-1.
Nitrogen Transformation - Mineral Nitrogen Content:	The mineral nitrogen contents in soil were within the trigger range of ± 25% set by EPPO and SETAC guidelines at day 42. At day 42 differences to the control were -0.05% and -7.49% in the 4.86 mg and 48.58 mg test item/kg soil dry weight treatment, respectively. A summary of the results is shown in in Table 180.5-1.
Nitrogen Transformation - Nitrate Formation Rates:	The cumulative soil nitrate formation rates did not exceed the trigger range of ± 25% set by OECD guideline 216 at the 0 - 42 day determination. Differences to the control were -1.40% and -12.04% in the 4.86 mg and 48.58 mg test item/kg soil dry weight treatment, respectively. The incremental soil nitrate formation rates did not exceed the trigger

range of $\pm 25\%$ set by OECD guideline 216 at the 28 - 42 day determination. Differences to the control were 20.82% and 4.31% in the 4.86 mg and 48.58 mg test item/kg soil dry weight treatment, respectively. A summary of the results is shown in Table 180.5-1.

Validity Criteria: The variation between the replicate control samples did not exceed the validity criterion of 15% throughout the study.

Table 180.5-1. 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		4.86 mg GLOB2011I/kg soil dw		48.58 mg GLOB2011I/kg soil dw	
Sampling	Nitrate-N Content	Replicate Variation ¹	Nitrate-N Content	Deviation ²	Nitrate-N Content	Deviation ²
Day 0	26.567	0.49	27.253	2.58	26.862	1.11
Day 7	32.070	0.96	27.628*	-13.85	26.899*	-16.12
Day 14	42.692	2.05	38.134*	-10.68	36.701*	-14.03
Day 28	55.124	7.60	52.365	-5.01	50.823	-7.80
Day 42	77.504	3.74	77.468	-0.05	71.696*	-7.49
Nitrogen Transformation - Mineral Nitrogen ³ (mg / kg soil dry weight) Mean Values						
	Control		4.86 mg GLOB2011I/kg soil dw		48.58 mg GLOB2011I/kg soil dw	
Sampling	Mineral-N Content	Replicate Variation ¹	Mineral -N Content	Deviation ²	Mineral -N Content	Deviation ²
Day 0	36.013	0.44	35.825	-0.52	34.789*	-3.40
Day 7	32.070	0.96	27.628*	-13.85	26.899*	-16.12
Day 14	43.931	2.14	39.743*	-9.53	38.283*	-12.86
Day 28	48.449	27.85	53.522	10.47	51.977	7.28
Day 42	77.504	3.74	77.468	-0.05	71.696*	-7.49
Nitrogen Transformation - NO ₃ – Nitrogen Formation Rate (mg / kg soil dry weight per day) ⁴						
	Control		4.86 mg GLOB2011I/kg soil dw		48.58 mg GLOB2011I/kg soil dw	
Interval ⁴	Nitrate-N Formation		Nitrate-N Formation	Deviation ²	Nitrate-N Formation	Deviation ²
Day 0 - 7	0.786		0.054*	-93.13	0.005*	-99.36
Day 0 - 14	1.152		0.766*	-33.51	0.703*	-38.98
Day 0 - 28	1.023		0.897	-12.32	0.857	-16.23
Day 0 - 42	1.213		1.196	-1.40	1.067*	-12.04
Nitrogen Transformation - NO ₃ – Nitrogen Formation Rate (mg / kg soil dry weight per day) ⁵						
	Control		4.86 mg GLOB2011I/kg soil dw		48.58 mg GLOB2011I/kg soil dw	
Interval ⁵	Nitrate-N Formation		Nitrate-N Formation	Deviation ²	Nitrate-N Formation	Deviation ²
Day 0 - 7	0.786		0.054*	-93.13	0.005*	-99.36
Day 7 - 14	1.517		1.555	2.50	1.400	-7.71
Day 14 - 28	0.907		1.065	17.42	1.008	11.14
Day 28 - 42	1.484		1.793	20.82	1.548	4.31

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; $\alpha = 0.05$)

Conclusion

GLOB2011I had no impact on nitrogen transformation (nitrate content, mineral nitrogen content and nitrate formation rates) of soil microorganisms when applied at 4.86 mg and 48.58 mg test item/kg soil dry weight treatment (equivalent to 3.48 and 34.79 mg a.s./kg dws).

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

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	<p>The study was conducted to OECD guideline 208 and according to the principles of GLP. All the validity criterion are met.</p> <ul style="list-style-type: none"> - the seedling emergence is at least 70%; (actually 75-100%), - the seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species (actually: are met); - the mean survival of emerged control seedlings is at least 90% for the duration of the study (actually 100%) - environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source (actually: are met); <p>The study is considered to be reliable and suitable for the risk assessment.</p> <p>ER₅₀ = 8000 mL test item/ha</p>
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Reference:	KCP 10.6.2
Report	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test, Bützler R., Horstmann C., 2022a, study # 167841086
Guideline(s):	Yes, OECD 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test" (adopted July 19, 2006)
Deviations:	No
GLP:	Yes

Acceptability: Yes/No/Supplementary

Duplication (if vertebrate study) Not applicable

Materials and methods

Test Item: GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content: (Pelargonic acid): 650 g/L (nominal), 652.3 g/L (analytical).

Test Species: Six plant species from six different plant families were tested: *Brassica napus*, *Pisum sativum*, *Cucumis sativus*, *Solanum lycopersicum*, *Allium cepa* and *Avena sativa*.

Test rates: Following rates beside a control with deionised water were tested: 500, 1000, 2000, 4000 and 8000 mL product/ha.

Test Design: On the day after sowing different rates of the test item were sprayed in 200 L/ha of deionised water onto the soil. At least 20 seeds were tested per rate and species. The exposure time was 14 or 21 days after 50% emergence in the respective control depending on the growth of the seedlings. The concentration of the active ingredient in the stock solution was verified analytically.

Endpoints: ER10, ER20, ER50 and NOER and LOER based on plant fresh weight and emergence; ER10, ER20, ER50 based on phytotoxicity; Observation of mortality.

Test Conditions: The study was performed in a growth chamber. Exposure conditions were as follows: mean temperature was 20.6 °C (15.8 °C to 23.4 °C). Mean humidity was 58% (45% to 69%). Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 340 µE/m²/s (300 to 400 µE/m²/s).

Results and discussions

The results based on fresh weight and emergence are summarized in Table 10.6.2-1 and Table 10.6.2-2, respectively.

Table 10.6.2-1. Summary of effect rates (based on fresh weight)

	NOER [mL test item/ha]	LOER [mL test item/ha]	Statistical Analysis	ER ₁₀ [mL test item/ha]	ER ₂₀ [mL test item/ha]	ER ₅₀ [mL test item/ha]
<i>Brassica napus</i>	≥ 8000 [#]	> 8000 [#]	¹	n.d.	> 8000 [§]	> 8000 [§]
<i>Pisum sativum</i>	≥ 8000	> 8000	²	n.d.	> 8000 [§]	> 8000 [§]
<i>Cucumis sativus</i>	≥ 8000	> 8000	²	> 8000 [§]	> 8000 [§]	> 8000 [§]
<i>Solanum lycopersicum</i>	≥ 8000	> 8000	²	n.d.	> 8000 [§]	> 8000 [§]
<i>Solanum lycopersicum</i> per plant	≥ 8000	> 8000	²	n.d.	> 8000 [§]	> 8000 [§]
<i>Allium cepa</i>	4000 [#]	8000 [#]	²	n.d.	n.d.	> 8000 [§]
<i>Allium cepa</i> per plant	4000	8000	³	n.d.	n.d.	> 8000 [§]
<i>Avena sativa</i>	≥ 8000	> 8000	²	> 8000 [§]	> 8000 [§]	> 8000 [§]

n.d. not determined due to mathematical reasons

§ estimated value

expert judgement

¹ multiple comparison, Bonferroni-Holm U-test, $\alpha = 0.05$

² multiple comparison, Dunnett's t-test, $\alpha = 0.05$

³ multiple comparison, Williams t-test, $\alpha = 0.05$

Table 10.6.2-2. Summary of effect rates (based on emergence)

	NOER [mL test item/ha]	LOER [mL test item/ha]	Statistical Analysis	ER ₁₀ [mL test item/ha]	ER ₂₀ [mL test item/ha]	ER ₅₀ [mL test item/ha]
<i>Brassica napus</i>	≥ 8000	> 8000	¹	> 8000 [§]	> 8000 [§]	> 8000 [§]
<i>Pisum sativum</i>	≥ 8000	> 8000	¹	n.d.	> 8000 [§]	> 8000 [§]
<i>Cucumis sativus</i>	≥ 8000	> 8000	¹	> 8000 [§]	> 8000 [§]	> 8000 [§]
<i>Solanum lycopersicum</i>	≥ 8000	> 8000	¹	n.d.	n.d.	> 8000 [§]
<i>Allium cepa</i>	≥ 8000	> 8000	¹	n.d.	n.d.	> 8000 [§]
<i>Avena sativa</i>	≥ 8000	> 8000	¹	> 8000 [§]	> 8000 [§]	> 8000 [§]

n.d. not determined due to mathematical reasons

[§] estimated value

¹ two sample comparison Fisher's Exact Binomial Test with Bonferroni Correction, $\alpha = 0.05$

Conclusion

GLOB2011I was tested for effects on seedling emergence and seedling growth of six plant species out of six different plant families.

The analytical recovery rate of the active ingredient pelargonic acid in the stock solution was 92% of the nominal value.

The most sensitive species in terms of fresh weight was *Allium cepa*. The fresh weight was statistically significantly reduced at 1000, 2000 and 8000 mL GLOB2011I/ha, but not in a dose dependent manner. For 1000 and 2000 mL GLOB2011I/ha this was mainly due to a lower emergence rate, which was not statistically significantly reduced. Therefore, the fresh weight per plant of the test item treatment groups was compared to the control. The fresh weight per plant was statistically significantly reduced at 8000 mL GLOB2011I/ha (-39.6%). Thus, *Allium cepa* showed a NOER of 4000 mL GLOB2011I/ha and a LOER of 8000 mL GLOB2011I/ha.

For all other tested plants the fresh weight was not statistically significantly reduced at 8000 mL GLOB2011I/ha. Thus, these species showed a NOER of ≥ 8000 mL GLOB2011I/ha and a LOER of > 8000 mL GLOB2011I/ha.

The emergence rate was not statistically significantly reduced for any plant species tested.

No mortality was observed for any species tested.

The only phytotoxic effects observed at the final check were a slight chlorosis and necrosis for some replicates for *Brassica napus* and a slight necrosis for some replicates for *Avena sativa* at 8000 mL GLOB2011I/ha.

Comments of zRMS:	<p>The study was conducted to OECD guideline 227 and according to the principles of GLP. All the validity criterion are met.</p> <ul style="list-style-type: none"> Seedling emergence: ≥ 70 % (actual 75 - 100 %). For control group: mean plant survival for the duration of the study: ≥ 90 % (actual 100 %), plants do not exhibit visible phytotoxic effects in the control and the plants exhibit only normal variation in growth and morphology for that particular species, environmental conditions for a particular species are identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source. <p>The study is considered to be reliable and suitable for the risk assessment.</p> <p>ER₅₀ > 8000 mL test item/ha</p>
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Reference: KCP 10.6

Report GLOB2011I:
Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test, Bützler R., Horstmann C., 2022b, study # 167841087

Guideline(s):	Yes, OECD 227 "Terrestrial Plant Test: Vegetative Vigour Test" (adopted July 19, 2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test Item:	GLOB2011I; batch no.: GLOB2011I09H15M21SANK; content: (Pelargonic acid): 650 g/L (nominal), 652.3 g/L (analytical).
Test Species:	Six plant species from six different plant families were tested: Brassica napus, Pisum sativum, Cucumis sativus, Solanum lycopersicum, Allium cepa and Avena sativa.
Test rates:	Following rates beside a control with deionised water were tested: 500, 1000, 2000, 4000 and 8000 mL product/ha.
Test Design:	The plants were grown until they had reached the 2 to 4 true leaf stage prior to dosing. Test rates were calculated for a water amount of 200 L/ha and were administered onto the plants using laboratory spraying equipment. At least 20 plants were tested per rate and species. The concentration of the active ingredient in the stock solution was verified analytically. The exposure time was 21 days.
Endpoints:	ER10, ER20, ER50 and NOER and LOER based on plant fresh weight; ER10, ER20, ER50 based on phytotoxicity; Observation of mortality.
Test Conditions:	The study was performed in a growth chamber. Pre-application conditions were as follows: mean temperature was 20.1 °C (16.4 °C to 23.0 °C). Mean humidity was 58% (46% to 79%). Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 333 µE/m ² /s (300 to 400 µE/m ² /s). Exposure conditions were as follows: mean temperature was 20.0 °C (16.5 °C to 22.8 °C). Mean humidity was 60% (46% to 80%). Photoperiod: 16 hours light / 8 hours dark. Mean light intensity during the day was 364 µE/m ² /s (300 to 400 µE/m ² /s).

Results and discussions

The results of effect rates based on fresh weight are summarized in Table 10.6.2-3.

Table 10.6.2-3. Summary of effect rates (based on fresh weight)

	NOER [mL test item/ha]	LOER [mL test item/ha]	Statistical Analysis	ER ₁₀ [mL test item/ha]	ER ₂₀ [mL test item/ha]	ER ₅₀ [mL test item/ha]	Statistical Analysis
<i>Brassica napus</i>	4000	8000	¹	1630 [#]	5247 [#]	> 8000 [§]	⁴
				lower 95%-cl 1002	3711		
				upper 95%-cl 2283	8882		
				r ² = 0.504			

<i>Pisum sativum</i>	≥ 8000	> 8000	¹	n.d.	> 8000 [§]	> 8000 [§]
<i>Cucumis sativus</i>	≥ 8000	> 8000	¹	> 8000 [§]	≥ 8000 [§]	> 8000 [§]
<i>Solanum lycopersicum</i>	≥ 8000	> 8000	²	n.d.	n.d.	> 8000 [§]
<i>Allium cepa</i>	≥ 8000	> 8000	²	n.d.	> 8000 [§]	> 8000 [§]
<i>Avena sativa</i>	4000	8000	³	1753	5283	> 8000 [§] ⁴
				lower 95%-cl	593	3045
				upper 95%-cl	3041	17584
				r ² =0.906		

results represent rounded values based on exact data

n.d. not determined due to mathematical reasons

the ER_x-values are calculated on each replicate per rate

§ estimated value

¹ multiple comparison, Williams t-test, $\alpha = 0.05$

² multiple comparison, Dunnett's t-test, $\alpha = 0.05$

³ multiple comparison, Bonferroni-Welch t-test, $\alpha = 0.05$

⁴ Weibull Analysis, cl = confidence limits

Conclusion

GLOB2011I was tested for effects on the vegetative vigour using six plant species out of six different plant families.

The analytical recovery rate of the active ingredient pelargonic acid in the stock solution was 96% of the nominal value. In the control solution no active ingredient was detected.

The most sensitive species in terms of fresh weight were *Brassica napus* and *Avena sativa*, where the fresh weight was statistically significantly reduced at 8000 mL GLOB2011I/ha (-35.2% and -23.8%, respectively). Thus, *Brassica napus* and *Avena sativa* showed a NOER of 4000 mL GLOB2011I/ha and a LOER of 8000 mL GLOB2011I/ha.

For all other tested plants the fresh weight was not statistically significantly reduced at 8000 mL GLOB2011I/ha. Thus, these species showed a NOER ≥ 8000 mL GLOB2011I/ha and a LOER > 8000 mL GLOB2011I/ha.

All plant species showed ER₅₀ values of >8000 mL GLOB2011I/ha.

No mortality was observed for any species tested.

Some phytotoxic effects were observed during the course of the study. The effects were dose related and tend to recover with time. 21 days after application, some chlorosis and necrosis were still observed at the two higher rates (all species except *Allium cepa*). Additionally *Brassica napus* showed deformation of plants at the higher rates.

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

No new study was submitted.

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

No new study was submitted.

A 2.8 KCP 10.8 Monitoring data

No new study was submitted.