FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: **ORKAN 350 SL**

Product name(s): **ORKAN 350 SL / SPRINTER 350 SL**

Chemical active substances:

Glyphosate, 260 g/L

MCPA, 90 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 26/10/2021

Version history

When	What
November 2018	Submission to the Polish Ministry of Agriculture and Rural Development
May 2020	Submission to the Polish Ministry of Agriculture and Rural Development, updated version of dRR
June 2020	Submission to the evaluation unit Merit Mark
January 2021	Addition of new studies (KCP 10.3.2 and KCP 10.4), new calculations for aquatic species (KCP 10.2)
January 2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

Table of Contents

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental 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. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	Poland	Apple	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* ~~**susceptible weeds in dose 8,0 l/ha:**~~ ~~*Taraxacum officinale*~~ ~~*Epilobium ciliatum*~~ ~~*Lamium purpureum*~~ ~~*Elymus repens*~~ ~~*Equisetum arvense*~~	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7.0 L ~~8,0~~ L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-~~8L~~/ha: 0,63~~-0,72~~ kg/ha (MCPA) 1,82~~-2,08~~ kg/ha (glyphosate)	300 L/ha	n.a.									

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Minor uses according to Article 51 (field uses)																				
2	Poland	Cherry	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Poa annua* *Vicia cracca* *Chenopodium album* ***susceptible weeds in dose 7,0 l/ha:*** *Taraxacum officinale* *Epilobium ciliatum*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7 L/ha: 0,63 kg/ha (MCPA) 1,82 kg/ha (glyphosate)	300 L/ha	n.a.								
3	Poland	Pear, quince, medlar	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* ~~**susceptible weeds in dose 8,0 l/ha:**~~ ~~*Taraxacum officinale*~~ ~~*Epilobium ciliatum*~~ ~~*Lamium purpureum*~~ ~~*Elymus repens*~~ ~~*Equisetum arvense*~~	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7.0 ~~8,0~~ L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-~~8~~L/ha: 0,63-~~0,72~~ kg/ha (MCPA) 1,82-~~2,08~~ kg/ha (glyphosate)	300 L/ha	n.a.								
4	Poland	Sweet cherry, plum, peach, apricot, nectarine	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Poa annua* *Vicia cracca* *Chenopodium album* ***susceptible weeds in***	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to	1	-	5,0- 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7 L/ha:	300 L/ha	n.a.								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				dose 7,0 l/ha: *Taraxacum officinale* *Epilobium ciliatum*		destruction occurring species weeds				0,63 kg/ha (MCPA) 1,82 kg/ha (glyphosate)										
5	Poland	Hazelnuts, Walnuts	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* ~~**susceptible weeds in dose 8,0 l/ha:**~~ ~~*Taraxacum officinale*~~ ~~*Epilobium ciliatum*~~ ~~*Lamium purpureum*~~ ~~*Elymus repens*~~ ~~*Equisetum arvense*~~	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7.0 ~~8,0~~ L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-~~8~~L/ha: 0,63~~-0,72~~ kg/ha (MCPA) 1,82~~-2,08~~ kg/ha (glyphosate)	300 L/ha	n.a.								

* 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 heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. 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 and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Review Comments:

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

9.1.1 Overall conclusions

This application was submitted by Synthos Agro Sp. z o.o. for renewal of authorisation of plant protection product ORKAN 350 SL in Poland according to art. 43 of Regulation 1107/2009. Report has been provided by the Applicant and contains the new information for glyphosate.

ORKAN 350 SL / SPRINTER 350 SL (formulation type: Soluble liquid concentrate) containing 260 g/L glyphosate and 90 g/L MCPA for use as herbicide in orchards (pome fruits: apple, pear, quince, medlar, loquat; stone fruits: cherries, sweet cherries, peaches, nectarines, plums; tree nuts: hazelnuts, walnuts)

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

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

9.1.1.1 Effects on birds (KCP 10.1.1)

An estimation of risk indicate low risk for birds of each range of assessed issues. Calculations conducted due to the influence ORKAN 350 SL due to the acute and long-term toxicity and reproductive did not indicate any hazardous properties and danger for birds. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

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

~~An estimation of risk indicate low risk for mammals of each range of assessed issues. Calculations conducted due to the influence ORKAN 350 SL due to the acute and long-term toxicity and reproductive did not indicate any hazardous properties and danger for mammals which was confirmed by high risk assessment.~~

Acceptable acute risk was assumed for all proposed application rates of glyphosate (2080, 1820, 1300 g glyphosate/ha) and MCPA (720, 630 and 450 g MCPA/ha) due to the use of ORKAN 350 SL in orchards and assumption of intra-row application.
Acceptable long-term risk was not achieved for both active substances since the trigger value of 5 was not met in TIER 1 for mammals for all proposed application rates. Therefore, higher risk assessment was performed.
For all application rates of MCPA acceptable risk was assumed based on the refined EU agreed fTWA of 0.16. and assumption of intra-row application.
For application 7L/ha and 5L/ha rates of glyphosate acceptable risk was assumed based on the refined EU agreed fTWA of 0.19 and refined FIR/bw, PD value (from Rinke) and assumption of intra-row application.

Since for the application rate 8L/ha TERlt for glyphosate for vole was 4.72 after higher refinement, the risk was unacceptable. And authorization can not be granted for 8L product/ha.

There were also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

Performed acute mixture toxicity for mammals considered acceptable risk. For mammals mixture toxicity was acceptable for dose up to 7 L formulation/ha.

Concerned Member States must decide on the applicability of risk refinement, provided by the zRMS, at the product authorization.

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

Not relevant

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Taking into consideration risk mitigation calculations for ORKAN 400 SL – use in Orchards, following risk mitigation measures should be applied:
- 10 m unsprayed buffer zone with 10 m vegetated filter strip.

9.1.1.5 Effects on bees (KCP 10.3.1)

The evaluation of the risk for bees has been performed in line with SANCO/10329/2002 rev 2 final.
The HQ values are lower than the trigger of 50, indicating low risk for bees from glyphosate and MCPA following application of ORKAN 350 SL. Calculation conducted for ORKAN 350 SL regarding to the oral and contact toxicity also confirm no risk for bees due to the use that formulation: achieved values are lower than 50.
Therefore, a low risk to bees is expected from the application of ORKAN 350 SL following application according to the proposed GAP.
No chronic and larvae data was provided with the formulation. Nevertheless, such studies were deemed not necessary to finalize the risk assessment, so they were not specifically required. According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): the Applicant should provide chronic test on bees and evaluation of effects on honey bee development with formulated. These deficiencies need to be fulfilled by 31.12.2021.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

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.
Since for *Typhlodromus pyri* HQ in-field value is over 1 ~~2~~ (2.96) what indicates risk for NTA, additional studies for one more species (*Chrysoperla carnea*) were performed to prove low risk for arthropods. Moreover Aged residue study~~ies~~ for *Typhlodromus pyri* was performed to show possibility of recolonization of treated area. Results for additional species (*Chrysoperla carnea*) show that proposed dose of product ORKAN 350 SL do not pose a risk for less vulnerable organisms - HQin-field and off-filed were below the trigger value. During aged residue studies, it was shown that after application of product, reduction of reproduction for *T.pyri* is less than 50%, what indicate acceptable risk.
Higher tier study and studies for additional species prove that application of ORKAN 350 SL using dose proposed in GAP do not indicate unacceptable risk for arthropods.

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

The calculated chronic TER for ORKAN 350 SL and metabolite of glyphosate are above the trigger value of 5 indicating acceptable chronic risk to earthworms from the proposed uses of ORKAN 350 SL.
~~Since possible risk for *T.pyri* was shown during studies,~~ Additional studies for *Folsomia candida* and *Hypoaspis aculifer* were performed. For both tested species, low risk after application of ORKAN 350 SL using dose of 8 L/ha was noted.

9.1.1.8 Effects on soil microbial activity (KCP 10.5)

On the basis of results, it was assessed that ORKAN 350 SL in considered applications does not pose unacceptable risk to soil microorganisms.
The risk to soil micro-organisms is considered to be low for all representative uses.

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

Taking into consideration risk mitigation calculations for ORKAN 350 SL – use in Orchards, following risk mitigation measures should be applied:
- an unsprayed buffer zone of 5 m to non-agricultural land or 1 m with 50% drift reducing technology
~~- 3 m buffer zone with vegetated filter strip and 75 % drift reduction nozzle,~~
~~- 10 m buffer zone with vegetated filter strip and 50 % drift reduction nozzle or,~~
~~- 15 m buffer zone with vegetated filter strip~~

Using the above-mentioned precautions, formulation ORKAN 350 SL can be used and will not have a negative impact on non-target terrestrial plants.

Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization.

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

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

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

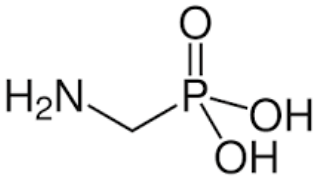
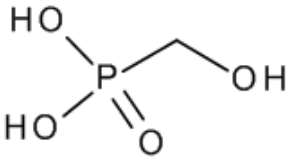
Table 9.1-2: Critical use pattern of ORKAN 350 SL grouped according to crop

Grouping according to crop			
Group	**Intended uses**	**Crop**	**Dose**
1	Orchards (pome fruit and nuts)	Apple, pear, quince, medlar, loquat, hazelnuts, walnuts	5 – 8 L/ha
2	Orchards (stone fruit)	Sweet cherry, cherry, plum, peach, apricot, nectarine	5 – 7 L/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 ORKAN 350 SL is indicated in the table.

Table 9.1-3 Metabolites of glyphosate and MCPA

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AMPA (aminomethyl-phosphonic acid)	111.04		Soil 53.8% Water/Sediment: 27.1%	Soil Groundwater Surface water
HMPA 2-Hydroxy-3-methylpentanoic acid	112.02		Surface Water 10%	Surface water

There are no relevant metabolites of MCPA.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with glyphosate and MCPA. Full details of these studies are provided in the respective EU DAR and related documents.
However, the provision of further data on the ORKAN 350 SL is not considered essential, because of low risk of glyphosate and MCPA to birds provided in previous studies.

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

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Glyphosate acid	Acute	LD_{50} > 4334 (extrapolated with factor 2.167) mg/kg bw	EFSA Journal 2015;13(11):4302
Bobwhite quail	Glyphosate acid	Long-term	LD_{50} >96.3 mg/kg bw	EFSA Journal 2015;13(11):4302
Bobwhite quail	MCPA	Acute	LD_{50} = 270 mg/kg bw	MCPA SANCO/4062/2001-final 11 July 20081
Bobwhite quail	MCPA	Reproductive	NOEC = 93.2 mgas/kg bw/d	MCPA SANCO/4062/2001-final 11 July 20081

9.2.1.1 Justification for new endpoints

Selection of the endpoint used for acute risk assessment:

To justify the use of the EU agreed endpoints, the assessment of combined toxicity was performed.

Theoretical toxicity approach
The theoretical toxicity of the product was calculated using the formula given below and compared with the empirical value

$$LD_{50}(mix) = (\sum \frac{x(a.s._i)}{LD_{50}(a.s._i)})^{-1}$$

where:
X (a.s.i) = fraction of the active substance [i] in the mixture (the sum Σ X(a.s.i) must be 1).
LD_{50} (a.s.i) = acute toxicity for the active substance [i]

Compound in ORKAN 350 SL	**Content (%)**	**Proportion**	**LD_{50} (mg as/kg)**	**Fraction a.s./ LD50 a.s.**	**Theoretical LD_{50} of the formulation (mg tot as/kg)**	**Tox per fraction (a.s.)**	**Deviation tox per fraction (a.s.) to tox per fraction (mix) [%]**
MCPA	9	0.25	270	0.00092	917.43	1080	16.26
Glyphosate	26	0.75	4334	0.00017		5778.7	486.13
Sum	35	1	-	0.00109		-	-

Performed evaluation indicates that based on the assumption of dose additivity. surrogate LD_{50} = 917.43 mg/kg bw/d. A combined acute risk assessment is required if for one active substance the deviation between 'tox per fraction (a.s.)' and 'tox per fraction (mix)' is ≥ 10 %. In this case the mix-tox risk would be not covered by the assessment for the active substances. Further evaluation for combined active substances is required.

Theoretical toxicity approach
Additionally, empirical toxicity was compared with the predicted mixture toxicity assuming dose additivity, according to the formula:
where:
$X(a.s._i)$ = fraction of active substance [i] in the mixture (here: formulation)
$LD_{50}(a.s._i)$ = acute toxicity value for active substance [i]
LD_{50}(mix) = measured acute toxicity value for the mixture (here: formulation)

$$\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} = \frac{1}{LD_{50}(mix)}$$

A greater value on the left side of the equation indicates that the formulation is not more toxic than predicted from the toxicity of the individual components.
Here, the value on the left side is 0.00092, and on the right side is 0.00011 (MCPA) and 0.0001 to 0.001 (glyphosate)
Conclusion: Toxicity of the active substances do not increase when formulated and the use of the EU-greed endpoints in the risk assessment is justified.

9.2.2 Risk assessment for spray applications

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

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

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

Screening and First-tier assessment

Table 9.2-2: Screening and First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards**				
Active substance/product	Glyphosate				
Application rate (kg/ha)	1 × 2.080				
Acute toxicity (mg/kg bw)	4334				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small insectivorous bird	46.8	1	97.3	44.5
Reprod. toxicity (mg/kg bw/d)	96.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous bird	18.2	0.53	20.06	**4.8**
TIER 1					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Orchards not crop directed all season	small insectivorous/ worm feeding species “thrush’’	2.7	0.53	2.97	32.4
Orchards not crop directed all season	Small granivorous ‘’finch’’	12.6	0.53	13.8	6.97

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.

For glyphosate the resulting TER_A values are over the trigger value of 10 for acute toxicity and below 5 for long term toxicity as defined in the EFSA Journal 2009; 7(12):1438. Since the obtained result 4.8 for TER_{lt} ~~represents the worst case with unrealistic conditions and~~ is ~~just~~ below the trigger value of 5, ~~no further justifications~~ TIER 1 was performed.

Table 9.2-3: Screening and First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards**				
Active substance/product	MCPA				
Application rate (kg/ha)	1 × 0.72				
Acute toxicity (mg/kg bw)	270				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small insectivorous bird	46.8	1	33.7	**8.01**
TIER 1					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards not crop directed all season	small insectivorous/ worm feeding species "thrush''	7.4	1	5.32	50.75
Orchards not crop directed all season	Small granivorous ''finch''	27.4	1	19.72	13.69
Reprod. toxicity (mg/kg bw/d)	93.2				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous bird	18.2	0.53	6.95	13.4

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.

For MCPA ~~glyphosate~~ the resulting TER_A values are below the trigger value of 10 for acute toxicity and over 5 for long term toxicity as defined in the EFSA Journal 2009; 7(12):1438. However, the obtained result 8.01 for TER_a represents the worst case. When using appropriate shortcut value 7.4 for focal species - small insectivorous/ worm feeding species "thrush" – DDD_{90} value is 5.33 and TER_a is 50.7, and small granivorous ''finch'' DDD_{90} value is 19.72 and TER_a is 13.69. which show low risk for birds, and no further justifications are needed.

It was noted that the combined reproductive risk assessment was not presented by the Applicant. Therefore, respective calculations were performed by the zRMS and are presented below. As at present the dose additivity approach is not considered acceptable for the long-term combitox assessment, the simplified approach has been used.

Table 9.2-4 Mixture toxicity – acute

Product	ORKAN 350 SL				
Application rate (g/ha)	1 x (2.08 + 0.72)				
Acute toxicity (mg/kg bw)	917.43				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening assesment	Small insectivorous birds	46.8	1.00	131.04	**7.00**

Tier 1					
Orchards not crop directed all season	small insectivorous/ worm feeding species "thrush''	7.4	1	20.72	44.27
Orchards not crop directed all season	Small granivorous ''finch''	27.4	1	76.72	11.95

Performed acute mixture toxicity show low risk for birds for use of ORKAN 350 SL according to critical GAP.

The combined TER value is calculated according to the following formula:

$TER_{LTcombi}$ = trigger/((trigger/$TER_{substance\ 1}$)+(trigger/$TER_{substance\ 2}$))

An acceptable risk is expected when $TER_{LTcombi}$> trigger.

Table 9.2-5 Mixture toxicity - long term

Crop	TER_{LT} 1)		Trigger/TER glyphosate	Trigger/TER MCPA	$TER_{LTcombi}$	Trigger
	glyphosate	MCPA				
Orchards	44.5	8.01	0.11	0.62	6.84	5

1) For both substance TER_{LT} values calculated at the screening step are taken for combitox evaluation

The calculated long-term TER_{mix} is above the trigger of 5 indicating acceptable long-term risk to birds exposed to the mixture of active substances in ORKAN 350 SL.

9.2.2.2 Higher-tier risk assessment

Not relevant.

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since ORKAN 350 SL is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 15844, glyphosate belongs to the group of more sorptive substances.

With a K(f)oc of 80.25 and 38.4 (depending on pH of soil), MCPA belongs to the group of less sorptive substances.

Table 9.2-4: Ratio of effective application rate to relevant endpoint for birds in drinking water exposure due to the use of glyphosate and MCPA

Effective application rate (g/ha) =		2080 g of glyphosate	quotient =	720g of MCPA	quotient =
Acute toxicity (mg/kg bw)	=	4334	2.1	270 mg	2.7
Reprod. toxicity (mg/kg bw/d)	=	96.3	21.6	93.2 mg	7.7

Since 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 MCPA and 3000 in the case of glyphosate no more calculations are needed.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} values of glyphosate and MCPA are below 3 and thus do not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

An estimation of risk indicates low risk for birds of each range of assessed issues. Calculations conducted due to the influence ORKAN 350 SL due to the acute and long-term toxicity and reproductive did not indicate any hazardous properties and danger for birds. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

Review comments:

The acute and long-term risk assessment for birds performed by the Applicant is agreed by the zRMS. It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints. No formulation study was required.
The Toxicity Exposure Ratios (TER_A and TER_{LT}) in the acute and long-term risk assessment - were calculated for both active substances for relevant species.
Additionally, zRMS provided acute and long-term risk assessment for the mixture.
All TER values were calculated for the highest application rate 8L/ha (corresponding to 0.72 kg/ha MCPA and 2.08 kg/ha glyphosate).

All TER_A and TER_{LT} values are above a trigger value of 5 or 10 respectively (Screening step or TIER 1 or TER_{mix} calculations).
Overall, acceptable acute and reproductive risk to birds may be concluded for application of ORKAN 350 SL in compliance with proposed GAP.
ORKAN 350 SL presents no unacceptable risk to birds resulting from exposure via drinking water. Since the log Pow value of glyphosate its relevant metabolite AMPA and MCPA are all below the trigger of 3, the evaluation of the risk of secondary poisoning is not triggered.

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

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with glyphosate and MCPA ~~2,4 D~~ and relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

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

Species	Substance	Exposure System	Results	Reference
Rat Wistar	glyphosate	Oral 1 d Acute	LD_{50} > 2000 mg/kg bw	EFSA Journal 2015;13(11):4302
Rat, sprague dawley	AMPA	Oral 1 d Acute	LD_{50} > 5000 mg/kg bw	EFSA Journal 2015;13(11):4302
Rat SD	AMPA	Oral toxicity reproductive test	NOAEL = 400 mg/kg bw	EFSA Journal 2015;13(11):4302
Rat	glyphosate	Dietary Reproductive test	NOEL = 197 mg/kg bw/d	EFSA Journal 2015;13(11):4302
Rabbit	Glyphosate acid	Reproductive toxicity (long-term)	**NOAEL = 50 mg/kg bw/day (Tier I)**	EFSA Journal 2015;13(11):4302
Rat	MCPA	Acute	LD_{50} = 962mg/kg bw	MCPA SANCO/4062/2001-final 11 July 20081
Rat	MCPA	Short-term	NOEL = 37.8 mg/kg bw/d	MCPA SANCO/4062/2001-final 11 July 20081

9.3.1.1 Justification for new endpoints

Selection of the endpoint used for acute risk assessment:

To justify the use of the EU agreed endpoints, the assessment of combined toxicity was performed.

Theoretical toxicity approach
The theoretical toxicity of the product was calculated using the formula given below and compared with the empirical value

$$LD_{50}(mix) = \left(\sum \frac{x(a.s._i)}{LD_{50}(a.s._i)}\right)^{-1}$$

where:
X (a.s.i) = fraction of the active substance [i] in the mixture (the sum Σ X(a.s.i) must be 1).
LD_{50} (a.s.i) = acute toxicity for the active substance [i]

Compound in ORKAN 350 SL	**Content (%)**	**Proportion**	**LD_{50} (mg as/kg)**	**Fraction a.s./ LD50 a.s.**	**Theoretical LD_{50} of the formulation (mg tot as/kg)**	**Tox per fraction (a.s.)**	**Deviation tox per fraction (a.s.) to tox per fraction (mix) [%]**
MCPA	9	0.25	962	0.00026	1587.3	3848	2.41
Glyphosate	26	0.75	2000	0.00037		2667	1.68
Sum	35	1	-	0.00063		-	-

Performed evaluation indicates that based on the assumption of dose additivity. surrogate LD_{50} = 1587.3 mg/kg bw/d. A combined acute risk assessment is required if for one active substance the deviation between 'tox per fraction (a.s.)' and 'tox per fraction (mix)' is ≥ 10 %. In this case the mix-tox risk would be covered by the assessment for the active substances. Further evaluation for combined active substances is not required.

Theoretical toxicity approach
Additionally, empirical toxicity was compared with the predicted mixture toxicity assuming dose additivity, according to the formula:
where:
$X(a.s._i)$ = fraction of active substance [i] in the mixture (here: formulation)
$LD_{50}(a.s._i)$ = acute toxicity value for active substance [i]
LD_{50}(mix) = measured acute toxicity value for the mixture (here: formulation)

$$\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} = \frac{1}{LD_{50}(mix)}$$

A greater value on the left side of the equation indicates that the formulation is not more toxic than predicted from the toxicity of the individual components.
Here, the value on the left side is 0.00026, and on the right side is 0.00063 (MCPA) and 0.00037 to 0.00063 (glyphosate).
Conclusion: Toxicity of the active substances do not increase when formulated and the use of the EU-greed endpoints in the risk assessment is justified.

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of ORKAN 350 SL in orchards

Intended use	Orchards				
Active substance/product	Glyphosate				
Application rate (g/ha)	1 × 2080				
Acute toxicity (mg/kg bw)	2000 (EU agreed endpoint) ~~3.228~~				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small herbivorous mammal	136.4	1	284	**7.04** ~~11.4~~
TIER 1					
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90}	**DDD_{90}** (mg/kg bw/d)	TER_a
Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew"	5.4	1	11.23	178.09
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole	136.4	1	284	**7.04**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	35.1	1	73	27.39
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	17.2	1	36	55.5
Reprod. toxicity (mg/kg bw/d)	50 (EU agreed endpoint) ~~197~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small herbivorous mammal	72.3	0.53	79.7	**0.62** ~~2.5~~
TIER 1					
Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew"	1.9	0.53	2.09	24
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole	72.3	0.53	79.7	**0.62**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	14.3	0.53	15.76	**3.32**

Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	7.8	0.53	8.59	5.82

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.

As the trigger values of 10 was not met for small herbivorous mammals and trigger of 5 for small herbivorous mammals and large herbivorous mammal "lagomorph" for the application of ORKAN 350 SL in orchards considering the highest application rate 8L product/ha, further assessment should be performed.

For the exposure assessment in orchards, it was assumed that due to the specific type of application (directed intra-row spray), only 50% of the crop surface will be treated. This approach was agreed during the EU renewal of glyphosate.
Screening assessment of the acute and long-term/reproductive risk for mammals exposed to the active substance glyphosate due to the use of ORKAN 350 SL in orchards

Table 9.3-3 TIER 2 assessment of the acute and long-term/reproductive risk for mammals exposed to the active substance glyphosate due to the use of ORKAN 350 SL

Active substance	Glyphosate (intra row)				
Application rate (g/ha)	1 x 2080*				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal	136.4	1.00	141.65	14.12
Reprod. toxicity (mg/kg bw/d)	50				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal	72.3	0.53	39.85	**1.25**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	14.3	0.53	7.88	6.34

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

For glyphosate, the trigger value of 5 for chronic exposure is not met at TIER 2 level for the use in orchards at an application rate of 2080 g a.s./ha. Thus, further risk assessment is required for long-term exposure of mammals to glyphosate.

Review comments:

It was noted that the Applicant did not used proper endpoints accepted at the EU level. It should be noted that selection of the correct endpoints was already discussed during the Toxicological and

Ecotoxicological Praper Meeting (October 2015) and the RMS in the RAR. Acute risk assessment should be based on the lowest limit LD_{50} of >2000 mg/kg bw/d. Reproductive toxicity eendpoint to be used in the mammalian risk assessment for glyphosate should be based on the NOAEL of 50.0 mg a.s./kg bw/d. Thus, zRMS corrected these values in the table above.

Table 9.3-3: Screening and First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of ORKAN 350 SL in orchards

Intended use	Orchards				
Active substance/product	MCPA				
Application rate (g/ha)	1 × 720				
Acute toxicity (mg/kg bw)	962				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small herbivorous mammal	136.4	1	98	**9.8**
TIER 1					
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90}	**DDD_{90}** (mg/kg bw/d)	TER_a
Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew"	5.4	1	3.8	253
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole	136.4	1	98	**9.81**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	35.1	1	9.45	101
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	17.2	1	12.38	77
Reprod. toxicity (mg/kg bw/d)	37.8 ~~197~~				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small herbivorous mammal	72.3	0.53	28	**1.35** ~~7.0~~
TIER 1					
Orchards Application crop directed BBCH < 10 or not crop directed	Small insectivorous mammal "shrew"	1.9	0.53	0.72	52.5
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole	72.3	0.53	28	**1.35**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	57.8	0.53	21.96	**1.72**
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	43.4	0.53	16.49	**2.29**

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.

In TIER 2 the same approach that was agreed during the EU renewal and used above for glyphosate was used for MCPA. For the exposure assessment in orchards, it was assumed that due to the specific type of application (directed intra-row spray), only 50% of the crop surface will be actually treated.

Table TIER 2 assessment of the acute and long-term/reproductive risk for mammals exposed to the active substance MCPA due to the use of ORKAN 350 SL in orchards

Intended use	Orchards – intra row				
Active substance/product	MCPA				
Application rate (g/ha)	1 × 720*				
Acute toxicity (mg/kg bw)	962				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal	136.4	1	49	19.63
Reprod. toxicity (mg/kg bw/d)	37.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
TIER 2					
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal "vole	72.3	0.53	13.79	**2.74**
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal "lagomorph"	57.8	0.53	11.02	**3.43**
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	43.4	0.53	8.28	**4.56**

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

As the trigger values of 5 was not met for small herbivorous mammals (vole, mouse) and large herbivorous (lagomorph) for the application of ORKAN 350 SL in orchards considering the highest application rate, additionally a Tier 2 assessment is performed

For MCPA the resulting TER_a and TERlt value are above ~~is below~~ the trigger value of 10 and 5 as defined in the EFSA Journal 2009; 7(12):1438. ~~However calculations represent the worst case with unrealistic conditions and the results is just below the trigger value. Therefore it can be concluded that the risk for mammal is low.~~

Acceptable acute risk was assumed for all sensitive species for all the application rates for glyphosate (2080, 1820, 1300 g glyphosate/ha) and MCPA (720, 630 and 450 g MCPA/ha) assuming intra row approach.

Taking the consideration obtained results in previous screening and Tier 1, Tier 2 steps a higher tier risk assessment has to be performed for glyphosate and MCPA for:

- Chronic exposure for small herbivorous mammal vole (glyphosate and MCPA) and
- Chronic exposure for mouse and lagomorph (MCPA)

Long- term refinement for glyphosate

Default foliar 10 days used in Tier 1 and Tier 2 risk assessment would be refined on the basis of residue decline performed on grass in glyphosate RAR Vol.3 (2015).

Refinement of TWA based on glyphosate residue decline on grass

Default foliar 10 days values for glyphosate were refined based on measured residues in grass.
The methodology used to calculate the TWA for glyphosate in grass foliage for the long-term risk assessment follows the procedure described in the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). According to the approach outlined in the Guidance Document on Terrestrial Ecotoxicology, the dissipation of glyphosate in grass was estimated using the standard first-order dissipation model:

$$Ct = Ci \times e^{-kt}$$

k = first order rate constant
Ci = initial residue concentration
Ct = residue concentration at time t

The decline of glyphosate residue in grass was characterized using data from 22 residue trials each of which had a day 0 value. Based on this data, the k value for grass foliage was calculated to be 0.2476 $days^{-1}$ (Renewal Assessment Report for glyphosate of 29 January 2015, Volume 3, Annex B.9, B.9.13**)**.
The average DT_{50} for grass foliage was 2.8 days.
The 21-day time weighted average (TWA) for glyphosate in grass foliage has been calculated according to the following formula:

$$TWA = \frac{\left(1 - e^{-kt} \right)}{kt}$$

The fTWA agreed during the EU renewal of glyphosate is calculated to be 0.19 for the active substance glyphosate acid and grass foliage and will be used in the long-term risk assessment for mammals feeding on foliage for ORKAN 350 SL.

Table: Tier 3 assessment of the long-term/reproductive risk for mammals exposed to the active substance glyphosate due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards (intra row)**				
Active substance	Glyphosate				
Application rate (g/ha)	1 x 2080*				
Reprod. toxicity (mg/kg bw/d)	50				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal "vole	72.3	1 x 0.19	14.32	**3.52**

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

Table: Tier 3 assessment of the long-term/reproductive risk for mammals exposed to the active substance glyphosate due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards (intra row)**				
Active substance	Glyphosate				
Application rate (g/ha)	1 x 1820*				
Reprod. toxicity (mg/kg bw/d)	50				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal "vole	72.3	1 x 0.19	12.50	**4**

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

Table: Tier 3 assessment of the long-term/reproductive risk for mammals exposed to the active substance glyphosate due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards (intra row)**				
Active substance	Glyphosate				
Application rate (g/ha)	1 x 1300*				
Reprod. toxicity (mg/kg bw/d)	50				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal "vole	72.3	1 x 0.19	8.92	5.6

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

For the lowest application rate of glyphosate 1300 g g a.s/ha the acceptable risk was assumed based on the refined EU agreed TWA of 0.19 and assumption of intra-row application

Long- term refinement for MCPA

Default foliar 10 days used in Tier 1 and Tier 2 risk assessment would be refined on the basis of residue decline performed in MCPA Addendum Vol.3 (2004).

Below zRMS presented the detailed results directly from MCPA Addendum:

Residues in Feed

Data from 26 residue studies in cereals and pasture were used for the calculation. Treatment in the Southern European zone was at a lower rate than the maximum GAP of 1.8 kg/ha, but since this represents normal agronomic practice (maximum label rates in the range 800 – 1200g/ha in cereals and up to 1600g/ha in pasture) it is more realistic to use the initial residue figures from these data unaltered. Using the Southern data has the benefit of greatly increasing the number of data points used and therefore increases the confidence in the results.

	Crop	*Individual day 0 residues (mg/kg)*		*Arithmetic Mean Day 0 Residue*
		1999	*2000*	*(mg/kg)*
Northern	*Cereals*	*53, 89, 31, 66*	*69, 113, 46, 57*	***67.2***
Europe	*Pasture*	*80, 98*	*128, 85, 59, 10*	
Southern	*Cereals**	*20, 37, 25, 24*	*61, 19, 45, 19*	
Europe	*Pasture***	*138, 31*	*135, 208*	

** Trials treated at 1.2 kg/ha*
*** Trials treated at 1.6 kg/ha*
Northern European crops treated at 1.8 kg/ha

The mean initial residue value of 67.2 ppm is appropriate for the estimation of long term risk to mammals. The decline of residues is discussed below

Estimated Residue Decline

As the object is to review the long term risk to mammals the fact that the residue declines must be taken into account. The estimated worst case scenario is the application to long grass/pasture (where the crop cover means that little will be lost to bare ground). The estimate below is based on grassland data from 4 trials:

	Residue at day					***Est DT50****
	0	***7***	***14***	***28***	***56***	***days***
N Eurpe Grassland 1	*80*	*6.7*	*5.6*	*1.4*	*0.2*	***2.32***
N Eurpe Grassland 2	*98*	*4.9*	*1.1*	*0.76*	*0.38*	
S Eurpe Grassland 1	*138*	*19*	*11*	*7.5*	*3*	
S Eurpe Grassland 2	*31*	*7.4*	*6.6*	*3*	*0.66*	

**Based on 1st order kinetics between days 0 and 56 days*
N Europe Grassland trial IR 18196/R9117
S Europe Grassland Trial IR18200/R9119

The above data does not conform strictly to 1st or 2nd order kinetics (probably because it is influenced by the multiple factors of metabolism, growth dilution and wash off). Initial decay is rapid, but decay is slower later. However, an exponential plot of the decay (see Appendix 1) gives a mean ***DT_{50} of 2.32 days****.*
Detailed calculation of half-life time is presented in table and figure below.

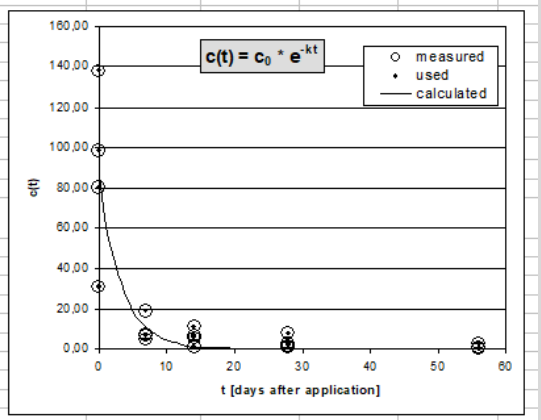
Appendix 1

Calculation of the half-life time of a substance from experimental data

assuming single-exponential first-order kinetics

Substance:	MCPA	**Operator:**	A L Bond
Study type:	Residue Decline	**Date:**	05.11.2002
Study no.:	Wild Mammal Risk Assessment		
Test system:	Pasture		
initial concentr.:	86,75	(mean of the 4 residue curves)	
degradation rate:	0,2990	d^{-1}	

data point	for optimisation	sampling time (DAA)	measured values	calculated values	squared difference
1	1	0	80,000	86,750	45,563
2	1	7	6,700	10,696	15,972
3	1	14	5,600	1,319	18,328
4	1	28	1,400	0,020	1,904
5	1	56	0,200	0,000	0,040
6	1	0	98,000	86,750	126,563
7	1	7	4,900	10,696	33,599
8	1	14	1,100	1,319	0,048
9	1	28	0,760	0,020	0,548
10	1	56	0,380	0,000	0,144
11	1	0	138,000	86,750	2626,563
12	1	7	19,000	10,696	68,949
13	1	14	11,000	1,319	93,724
14	1	28	7,500	0,020	55,950
15	1	56	3,000	0,000	9,000
16	1	0	31,000	86,750	3108,063
17	1	7	7,400	10,696	10,867
18	1	14	6,600	1,319	27,890
19	1	28	3,000	0,020	8,880
20	1	56	0,660	0,000	0,436
			sum of squared differences:		6253,027



DT-50:	**2,32**	days
DT-90:	**7,70**	days
B:	**0,8299**	

In conclusion taking to consideration calculated DT_{50}=2.32 new fTWA value for MCPA is 0.16 and it would be used in the higher tier refinement.

Table: Tier 3 assessment of the long-term/reproductive risk for mammals exposed to the active substance MCPA due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards (intra row)**				
Active substance	MCPA				
Application rate (g/ha)	1 × 720*				
Reprod. toxicity (mg/kg bw/d)	37.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal "vole	72.3	1 x 0.16	4.16	9.08
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph”	57.8	1 x 0.16	3.32	11.38
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse”	43.4	1 x 0.16	2.49	15.18

*Because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per ‘unit of treated surface area’; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

For all application rates of MCPA acceptable risk was assumed based on the refined EU agreed fTWA of 0.16. and assumption of intra-row application

In the higher tier TER calculations, further refinement was considered for glyphosate:

PD and FIR/bw values of the diet according to Rinke (1991)

A PD of 25% non-grass herbs and 75% grass and cereals is considered relevant for purposes of evaluation of the risk to vole in orchards following application of ORKAN 350 SL
It should be noted that this approach has been already taken by the MS-PL in the course of evaluation of several plant protection products at the national level. As the study by Rinke (1991) is publicly available, there are no restrictions regarding use of this results in the risk assessment.

Calculations of new short cut value based on data from EFSA B&M guidance (i.e. bw and RUDs).

Indicator/generic focal species	Typ of food	FIR/bw	RUD_{mean}	PD	SV_m
Small herbivorous mammal "vole"	Monocotyledons	1.57	54.2	0.25	21.3
	Dicotyledonos	1.57	28.7	0.75	32.4
SUM				1.0	53.7

The risk assessment based on the refined parameters is presented in table below.

Higher tier reproductive risk to small herbivorous mammal "vole" for glyphosate

Rate (kg a.s./ha)	Shortcut value*	DF	TWA	DDD (mg a.s./kg bw/d)	Toxicity (mg a.s./kg bw/d)	TER
2.08* Orchards Application crop directed BBCH < 10 or not crop directed	53.7	1.0	0.19	10.61	50	**4.72**
1.82* Orchards Application crop directed BBCH < 10 or not crop directed	53.7	1.0	0.19	9.28	50	5.38
1.30* Orchards Application crop directed BBCH < 10 or not crop directed	53.7	1.0	0.19	6.63	50	7.54

* maximum safe application rate, because applications are made to the intra-rows (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area'; the actual application rate per ha orchard will only be 50% of the reported rate. Exposure estimations considered the 50 % of the total application rate.

It was noted that the combined reproductive risk assessment was not presented by the Applicant. Therefore, respective calculations were performed by the zRMS and are presented below.

Calculations were provided for safe doses of the active substances.

The combined TER value is calculated according to the following formula:

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

where:

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

Mixture toxicity – acute

Mixture toxicity - acute

Crop scenario		TER_A 1)		$TER_{LTcombi}$	Trigger
		glyphosate	MCPA		
Orchards	Small herbivorous mammal (vole)	14.12	19.63	17.88	10

1) For both substance TIER 2 values (TER for glyphosate for 7 L/ha and TER for MCPA for 8 L/ha) are taken for combitox evaluation

The calculated acute TER_{mix} is above the trigger of 10 indicating acceptable risk to mammals exposed to the mixture of active substances in ORKAN 350 SL at the application dose up to 7L/ha.

Mixture toxicity – chronic

Performed acute mixture toxicity show low risk for birds for use of ORKAN 350 at application dose 7 and 5 L/ha.

Mixture toxicity - long term

Crop scenario		TER_{LT} 1)		$TER_{LTcombi}$	Trigger
		glyphosate	MCPA		
Orchards	Small herbivorous mammal (vole)	5.38	10.55	6.25	5

1) For both substance TIER 3 values (TER for glyphosate for 7 L/ha and TER for MCPA for 8 L/ha) are taken for combitox evaluation

The calculated long-term TER_{mix} is above the trigger of 5 indicating acceptable risk to mammals exposed to the mixture of active substances in ORKAN 350 SL at the application dose up to 7L/ha.

Overall conclusion

Based on higher tier assessment step, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to ORKAN 350 SL use according to the GAP does achieve the acceptability criteria for the following intended uses:

- 7 L/ha ORKAN 350 SL
- 5 L/ha ORKAN 350 SL

Refinement should be considered at the National Level.

9.3.2.2 Drinking water exposure

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

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 15844, glyphosate belongs to the group of more sorptive substances.

With a K(f)oc of 80.25 and 38.4 (depending on pH of soil), MCPA belongs to the group of less sorptive substances.

Table 9.3-4: Ratio of effective application rate to relevant endpoint for mammals in drinking water exposure due to the use of glyphosate and MCPA

Effective application rate (g/ha) =	2080 g of glyphosate	quotient =	720g of MCPA	quotient =
Acute toxicity (mg/kg bw) =	2000	1.04	962 ~~270~~ mg	0.74 ~~2.7~~
Reprod. toxicity (mg/kg bw/d) =	50 ~~197~~	41.6 ~~10.6~~	37.8 ~~93.2~~ mg	19.04 ~~7.7~~

Since 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 MCPA and 3000 in the case of glyphosate no more calculations are needed.

9.3.2.3 Effects of secondary poisoning

The log P_{ow} values of glyphosate and MCPA are below 3 and thus do not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.4 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

An estimation of risk indicate low risk for mammals of each range of assessed issues. Calculations conducted due to the influence ORKAN 350 SL due to the acute and long-term toxicity and reproductive did not indicate any hazardous properties and danger for mammals which was confirmed by high risk assessment. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

Review comments:

The acute and long-term risk assessment for mammals performed by the Applicant is not agreed by the zRMS. Not EU accepted endpoints was used for the evaluation. Also TIER 1 and refinement were not performed.
Thus, zRMS performed risk assessment for mammals in line with recommendations of the EFSA (2009) with assumption of EU agreed endpoints.
For glyphosate following refinement options were used: fTWA, PD and assumption of intra-row application. For MCPA following refinement options were used: fTWA and assumption of intra-row application.
Performed mixture toxicity showed acceptable risk for the application rates 5-7L formulation/ha.
ORKAN 350 SL presents acceptable risk to mammals resulting from exposure via drinking water. Since the log Pow value of glyphosate, its relevant metabolite AMPA and MCPA are all below the trigger of 3, the evaluation of the risk of secondary poisoning is not triggered.

ORKAN 350 SL presents no unacceptable acute and long-term risk for mammals at 7L product/ha and 5 L product/ha. For the highest dose 8L product/ha long-term risk is not accepted.

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

Not relevant.

Review comments:

This issue is not assessed at the product level.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with glyphosate and MCPA. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of ORKAN 350 SL were not evaluated as part of the EU assessment of glyphosate and MCPA. 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 – glyphosate, MCPA and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Pimephales promelas	Glyphosate acid	Chronic, 255 d	NOEC = 25.7 mg a.s./L $_{nom}$	EFSA Journal 2015;13(11):4302
Oncorhynchus mykiss	Glyphosate acid	96 h, s	LC_{50} = 38 mg a.s./L $_{nom}$	EFSA Journal 2015;13(11):4302
Brachydanio rerio	Glyphosate acid	Chronic, 168 h	NOEC = 1[1] mg/L	EFSA Journal 2015;13(11):4302

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	AMPA	96 h, s	LC_{50} = 520 mg a.s./L mm	EFSA Journal 2015;13(11):4302
Pimpephales promelas	AMPA	33 d, f	NOEC = 12 mg a.s./L mm	EFSA Journal 2015;13(11):4302
Daphnia magna	Glyphosate acid	48 h, s	EC_{50} = 40 mg a.s./L mm	EFSA Journal 2015;13(11):4302
Daphnia magna	Glyphosate acid	21 d, ss	NOEC = 12.5 mg a.s./L mm	EFSA Journal 2015;13(11):4302
Daphnia magna	AMPA	48 h, s	EC_{50} > 690 ~~100 mg a.s./L mm~~	Renewal Assessment Report for glyphosate (Germany 2013)
Daphnia magna	AMPA	21 d, ss	NOEC = 15 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Daphnia magna	HMPA	48 h, s	EC_{50} > 100 mg a.s./L mm	Renewal Assessment Report for glyphosate (Germany 2013)
Anabaena flos-aquae	Glyphosate acid	72 h, s	E_bC_{50} = 8.5 nom E_rC_{50} = 22 nom	EFSA Journal 2015;13(11):4302
Skeletonema costatum	Glyphosate acid	72 h, s	**E_rC_{50} = 18** mg a.s./L nom E_yC_{50} = 11 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Pseudokirchneriella subcapitata	Glyphosate acid	72 h, s	E_rC_{50} = 19 mg a.s./L nom E_yC_{50} = 18 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Pseudokirchneriella subcapitata	AMPA	72 h, s	E_rC_{50} = 200 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Desmodesmus subcapitatus	AMPA	72 h, s	E_rC_{50} = 452 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Pseudokirchneriella subcapitata	HMPA	72 h, s	E_rC_{50} > 115 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Lemna gibba	Glyphosate acid	14 d, ss	E_rC_{50} (fron count) = 12 mg a.s./L nom ~~E_rC_{50} (dry weight) = 20 mg a.s./L nom~~ NOEC (fron count) = 1.5 mg a.s./L nom	EFSA Journal 2015;13(11):4302
Lemna gibba	HMPA	7 d, ss	E_rC_{50} > 123 mg a.s./L	EFSA Journal 2015;13(11):4302
Myriophyllum aquaticum	MON 52276	14 d, s	4.44 $a.e.^{-2}$ (mm.) < 0.3 $a.e.^2$ (mm.)	EFSA Journal 2015;13(11):4302
Oncorhynchus mykiss	MCPA	96 h, f	LC_{50} = 50 mg a.s./L	MCPA

Species	Substance	Exposure System	Results	Reference
				SANCO/4062/2001-final 11 July 20081
Pimephales promelas	MCPA	28 d, f	NOEC = 15 mg a.s./L	MCPA SANCO/4062/2001-final 11 July 20081
Daphnia magna	MCPA	48 h, s	EC_{50} > 190 mg a.s./L	MCPA SANCO/4062/2001-final 11 July 20081
Daphnia magna	MCPA	21 d, f	NOEC = 50 mg a.s./L	MCPA SANCO/4062/2001-final 11 July 20081
Selenastrum capricornutum	MCPA	120 h, s	EC_{50} = 79.8 mg a.s./L (cell density) E_rC_{50} > 392 ~~398~~ mg a.s./L	MCPA SANCO/4062/2001-final 11 July 20081
Navicula pelliculosa	MCPA	120 h, s	E_rC_{50} = 117 mg a.s./L (growth rate) EC_{50} = 32.9 mg a.s./L (cell density)	MCPA SANCO/4062/2001-final 11 July 20081
Lemna gibba	MCPA	14 d	E_rC_{50} = 0.152 mg a.s./L	MCPA SANCO/4062/2001-final 11 July 20081

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
[1] See justification for new endpoints.
[2] [2] a.e.: acid equivalents

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – ORKAN 350 SL

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	ORKAN 350 SL	96 h, s	LC_{50} = 6.71 mg/L $_{nom}$	Registration report, IOŚ-PIB, 2011 Żmijowski G., 2009a, W/60/09
Daphnia magna	ORKAN 350 SL	48 h, s	EC_{50} = 11.4 mg/L $_{nom}$	Registration report, IOŚ-PIB, 2011 Żmijowski G., 2009b, W/59/09
Pseudokirchneriella subcapitata	ORKAN 350 SL	72 h, s	E_rC_{50} = 0.73 mg/L $_{nom}$ E_yC_{50} = 0.18 mg/L $_{nom}$	Registration report, IOŚ-PIB, 2011 Żmijowski G., 2009c, W/58/09
Lemna minor	ORKAN 350 SL	7 d, ss	ErC_{50} = 14.71 mg/L E_yC_{50} = 4.77 mg/L $_{nom}$	Registration report, IOŚ-PIB, 2011 Żmijowski G., 2009d, W/61/09

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

Review comments:
Studies on toxicity of the product ORKAN 350 SL to aquatic organisms were already agreed by the Institute of Environmental Protection – National Research Institute (IOŚ-PIB) in the course of the first authorisation of the product in Poland. These studies are still considered valid.

9.5.1.1 Justification for new endpoints

Since the most endangered groups of aquatic organism are higher plants (*Lemna gibba)*, what is confirmed by studies in SANCO/4062/2001-final 11 July 20081, and EC_{50} for different species of algae are quite similar (no more than 10 times more toxic for one species), no additional studies for second algae species were performed.

Glyphosate acid - Chronic fish endpoint
The risk assessment for the active substances should be based on peer-reviewed and EU accepted endpoints. NOEC value for fish of 1.0 mg a.s./L was agreed during the renewal of glyphosate and considered relevant for the chronic risk assessment. Since NOEC of 1.0 mg a.s./L is the lowest available endpoint also should be used in the chronic risk assessment for fish as a worst-case scenario. The calculations presented in Table 9.5-3 have been amended accordingly.

9.5.2 Risk assessment

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

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

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for glyphosate for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of ORKAN 350 SL in orchards

Group		**Fish acute**	**Fish prolonged**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Macrophytes**	
Test species		***Oncorhynchus mykiss***	***Brachydanio rerio***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***A. flosaquae*** ~~***Pseudokirchn. subcapitata***~~	***Myriophyllum aquaticum***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	NOEC	EC_{50}	NOEC	$Eb_{y}C_{50}$	$Eb_{r}C_{50}$	$E_{r}C_{50}$
(µg/L)		38000 ~~6710~~	1000	25700	40000 ~~11400~~	12500	8500 ~~730~~	4400~~18000~~	12000~~4770~~
AF		100	10	10	100	10	10	10	10
RAC (µg/L)		380 ~~67~~	100	2570	400 ~~114~~	1250	850 ~~73~~	440 ~~1800~~	1200 ~~477~~
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**								
Step 1	51.35	0.13 ~~0.766~~	0.51	0.020	0.13 ~~0.450~~	0.041	0.06 ~~0.703~~	0.12 ~~0.029~~	0.043 ~~0.108~~

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

~~For the intended uses in orchards, calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive group of aquatic organisms (RAC for *Oncorhynchus mykiss* = 67 µg/L) in several FOCUS Steps 3 scenarios. Therefore, no further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW}.~~

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AMPA for each organism group based on FOCUS Steps 1 calculations for the use of ORKAN 350 SL in orchards

Group		**Fish acute**	**Fish chronic**	**Inverteb. acute**	**Inverteb. chronic**	**Algae**		**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***		***Pseudokirchn. Subcapittata***	***Desmodesmus subcapitata***	***M. aquaticum***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	Eb_rC_{50}	E_bC_{50}
(µg/L)		520000	12000	100000	15000	200000	89900 ~~452000~~	31100
AF		100	10	100	10	10	10	10
RAC (µg/L)		5200	1200	1000	1500	20000	8990 ~~45200~~	3110
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	29.42	0.006	0.025	0.029	0.020	0.001	0.0032 ~~0.001~~	0.0094

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

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMPA for each organism group based on FOCUS Steps 1 calculations for the use of ORKAN 350 SL in orchards

Group		**Inverteb. acute**	**Algae**	**Macrophytes**
Test species		***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemna gibba***
Endpoint		EC_{50}	Eb_rC_{50}	Eb_rC_{50}
(µg/L)		>100000	>115000	>123000
AF		100	10	10
RAC (µg/L)		1000	11500	12300
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1 orchards				
	20.96	0.02	0.002	0.002

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

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for MCPA pH<7 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of ORKAN 350 SL in orchards

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum*** ~~***Pseudokirchn. subcapitata***~~	***Navicula pelliculosa***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	ErC_{50}	E_rC_{50}
(µg/L)		50 000 ~~6710~~	15000	190 000~~11400~~	50000	392000 ~~730~~	117000	152
AF		100	10	100	10	10	10	10
RAC (µg/L)		500~~67.1~~	1500	1 900 ~~114~~	5000	39200 ~~73~~	11700	15.2
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	223.42	**3.330**	0.149	1.9**60**	0.045	**3.061**	0.019	**14.699**
Step 2								
Mar. – May / June – Sep.	37.06 ~~43.67~~	0.09 ~~0.651~~	0.004 ~~0.029~~	0.05 ~~0.383~~	0.0012 ~~0.009~~	0.08 ~~0.598~~	0.005 ~~0.004~~	**2.43** **2.873**
Step 3								
D3 ditch	4.547	~~0.068~~	~~0.003~~	~~0.040~~	~~0.001~~	~~0.062~~	~~0.000~~	0.299
D4 pond	0.1594	~~0.002~~	~~0.000~~	~~0.001~~	~~0.000~~	~~0.002~~	~~0.000~~	0.010
D4 stream	3.607	~~0.054~~	~~0.002~~	~~0.032~~	~~0.001~~	~~0.049~~	~~0.000~~	0.237
R1 pond	0.5756	~~0.009~~	~~0.000~~	~~0.005~~	~~0.000~~	~~0.008~~	~~0.000~~	0.038
R1 stream	20.96	~~0.312~~	~~0.014~~	~~0.184~~	~~0.004~~	~~0.287~~	~~0.002~~	**1.379**

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

For the intended uses in orchards, calculated PEC/RAC ratios do not indicate an acceptable risk for the most sensitive group of aquatic organisms (RAC for *Lemna gibba* = 15.2 µg/L) in one of the FOCUS Steps 3 scenario (R1 stream). Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies. based on FOCUS Step 4 PEC_{SW}.

FOCUS Step 4

Table 9.5-7: Global maximum PEC_{sw} values for MCPA pH <7, following single application of ORKAN 350 SL to orchards, according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 - MCPA	
Nozzle reduction	Vegetative strip (m)	0	10
	No spray buffer (m)	10	10
None	D3 ditch	**0.6537**	**0.6537**
50 %		**0.3268**	---
None	D4 pond	**1.260**	**0.09991**
50 %		**0.09333**	---
None	D 4 stream	**0.6996**	**0.6996**
50 %		**0.3502**	---
None	R1 pond	**0.5350**	**0.09786**
50 %		**0.5018**	---
None	R1 stream	20.96	**0.5843**
50 %		20.96	---

RAC: Regulatory acceptable concentration
PEC/RAC ratios below the relevant trigger of 1 are shown in bold

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for MCPA pH>7 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of ORKAN 350 SL in orchards

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Macrophytes**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Selenastrum capricornutum*** ~~***Pseudokirchn. subcapitata***~~	***Navicula pelliculosa***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	E_rC_{50}	E_rC_{50}
(µg/L)		50 000 ~~6710~~	15000	190 000~~11400~~	50000	392000~~730~~	117000	152
AF		100	10	100	10	10	10	10
RAC (µg/L)		500~~67.1~~	1500	1 900 ~~114~~	5000	39200 ~~73~~	11700	15.2
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1								
	223.42 ~~234.93~~	0.45 ~~**3.501**~~	0.157	**0.12** ~~**2.061**~~	0.047	0.006~~**3.218**~~	0.020	**14.7** ~~**15.456**~~
Step 2								
Mar. – May / June – Sep.	38.92 ~~40.90~~	0.08 ~~0.610~~	0.026 ~~0.027~~	0.02 ~~0.359~~	0.008	0.001 ~~0.560~~	0.003	**2.64** ~~**2.691**~~
Step 3								
D3 ditch	~~4.547~~	~~0.068~~	~~0.003~~	~~0.040~~	~~0.001~~	~~0.062~~	~~0.000~~	0.299
D4 pond	~~0.1584~~	~~0.002~~	~~0.000~~	~~0.001~~	~~0.000~~	~~0.002~~	~~0.000~~	0.010
D4 stream	~~3.607~~	~~0.054~~	~~0.002~~	~~0.032~~	~~0.001~~	~~0.049~~	~~0.000~~	0.237
R1 pond	~~0.4770~~	~~0.007~~	~~0.000~~	~~0.004~~	~~0.000~~	~~0.007~~	~~0.000~~	0.031
R1 stream	~~16.53~~	~~0.246~~	~~0.011~~	~~0.145~~	~~0.003~~	~~0.226~~	~~0.001~~	**1.088**

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

For the intended uses in orchards, calculated PEC/RAC ratios do not indicate an acceptable risk for the most sensitive group of aquatic organisms (RAC for *Lemna gibba* = 15.2 µg/L) in one of the FOCUS Steps 3 scenario (R1 stream). Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies. based on FOCUS Step 4 PEC_{SW}.

FOCUS Step 4

Table 9.5-9: Global maximum PEC_{sw} values for MCPA pH>7, following single application of ORKAN 350 SL to orchards, according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 MCPA	
Nozzle reduction	Vegetative strip (m)	0	10
	No spray buffer (m)	10	10
None	D3 ditch	**0.6537**	**0.6537**
50 %		**0.3268**	---
None	D4 pond	**0.09892**	**0.09892**
50 %		**0.08892**	---
None	D 4 stream	**0.6992**	**0.6992**
50 %		**0.3499**	---
None	R1 pond	**0.4361**	**0.09787**
[illegible]		[illegible]	[illegible]
None	R1 stream	16.53	**0.5843**
50 %		16.53	---

RAC: Regulatory acceptable concentration
PEC/RAC ratios below the relevant trigger of 1 are shown in bold

Review Comments:

The Step 4 PECsw values as presented above were updated by the expert in area of environmental fate and behaviour (for more details, see Core Assessment, RR Part B, Section 8).

Consideration of mixture toxicity

ORKAN 350 SL containing two active ingredients (glyphosate and MCPA). Studies with the product have been conducted for: fish (acute), daphnia (acute), algae and aquatic plants.

According to the decision scheme of the EFSA, the plausibility of the measured formulation toxicity (EC_{50} for product) against the calculated mixture toxicity EC50mix-CA (based on the percentage of the a.s. in the formulation) should be checked. This is done by means of the model deviation ratio (MDR = EC_{50}mix-CA/EC_{50} for product).

Table: The surrogate EC_{50} for the mixture of active substances with known toxicity assuming dose additivity

Aquatic organism	**EC_{50}/LC_{50}/NOEC for the mixture**	**Endpoint derived from the studies with ORKAN 350 SL**
Algae ErC_{50} Glyphosate > 18 mg/L MCPA > 392 mg/L	ErC_{50}(mix)=23.852 mg a.s./L	ErC_{50} = 0.73 mg/L nom Corresponding to 0.17 mg glyphosate/L+0.06 mg MCPA/L*
Lemna minor ErC_{50} Glyphosate > 12 mg/L MCPA = 0.152 mg/L	ErC_{50}(mix)= 0.570 mg a.s./L	ErC_{50} = 14.72 mg/L Corresponding to 3.35 mg glyphosate/L + 1.16 mg MCPA/L*

* in calculation density of the formulation was taken to consideration

Decision scheme for mixture toxcitiy risk assessment for ORKAN 350 SL

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

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

Answer: Measured toxicity data for the formulation and the a.s. are available for fish, daphnia, algae and lemna. As **alga and lemna** are the most sensitive aquatic organisms, it is justified to conduct the mixture toxicity risk assessment only for these two organism groups. → Go to 2

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

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

Equation 13:

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

Equation 15:

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

Calculation of the acute mixture toxicity of the formulation

Table: Composition of the product

Composition		**Fraction considering density [%]**	**$p_{i\ mix}$ = Fraction of active substance i in the mixture with $\sum p_{i\ mix} = 100$ [%]**
Name/code of the product	**ORKAN 350 SL**		
Name of the active substance A	**glyphosate**		
Name of the active substance B	**MCPA**		
Density [g product/cm^3]	**1.143**		
	Nominal [g a.s./kg or L product]		
Concentrations of the active substance A in the product	260	22.7%	74%
Concentrations of the active substance B in the product	90	7.9%	26%

Endpoint/Test species	**Toxicity of the product [mg product/L]**	**Toxicity of the product (a.s. based) ($EC_{x\ PPP}$) [mg a.s./L]**	**Toxicity of the a.s. glyphosate ($EC_{x\ A}$) [mg a.s./L]**	**Toxicity of the a.s. MCPA ($EC_{x\ B}$) [mg a.s./L]**	**Triggers (from EFSA Journal 2013;11(7):3290)**
E_rC_{50} algae	0.73	0.224	18	> 392	0.1
E_rC_{50} lemna	14.72	4.507	12	> 0.152	0.1

Table: Calculation of toxicity exposure in ORKAN 350 SL

Toxicity per fraction of the glyphosate($1/TU_A$) [mg a.s./L]	**Toxicity per fraction of the MCPA ($1/TU_B$) [mg a.s./L]**	**Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA} = 1/\sum (TU_i)$) [mg a.s./L]**	**Model deviation ratio (MDR = $EC_{x\ mix\text{-}CA}/EC_{x\ PPP}$)**	**$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PEC_{mix}) (at lower exposure tier)**
24.23	1524.44	23.852	106.702	0.874
16.15	0.59	0.570	0.390	1.368

Answer:
MDR for algae is above 5 go to step 10
MDR for Lemna is between 0.2 -5. Therefore, go to Step 3.

Step 10

Carefully recheck the apparent synergism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of heterogeneous input data (a.s.) and of co-formulants ignored in the CA calculation. Does the apparent synergism remain?

Yes:	Go to 3
If measured data are not available or if the assessment in point 3 indicates that the mixtures are not similar (use modified ETR trigger values, see section 10.3.4):	Go to 8
No:	Go to 3

Answer:Yes. → Go to step 3

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

Table 3. Results of compareECmix-CA(a.s. in PPP) to ECmix-CA (a.s. in PECmix)

		Triggers	
Endpoint/Test species	**ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix)**	**0.8-1.2**	**<0.8 or >1.2**
ErC_{50} algae	0.874	**yes**	
ErC_{50} *lemna*	1.368		**yes**

Answer: Calculated factors for:

- *lemna* give results outside the range of 0.8 -1.2. Therefore, go to step 5.

STEP 5. Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. (TUi)?

Table: Results of toxicity driver's calculation

		glyphosate		MCPA		Triggers	
Endpoint/Test species	Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA}$) [mg a.s./L]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}$-TU_i) [%]	Toxicity per fraction ($1/TU_i$) [mg a.s./L]	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}$-TU_i) [%]	>=90% for one a.s.	>=90% for no a.s.
ErC_{50} algae	23.852	24.231	98.4%	1524.444	1,6%	Yes	
ErC_{50} lemna	0.570	16.154	3.5%	0.591	96,5%	Yes	

Equation 14:

$$\sum_{i=1}^{n} TU_i = \sum_{i=1}^{n} \frac{c_i}{EC_{x_i}}$$

Answer: The toxicity drivers were found for algae and lemna. Therefore, got to Step 6.. Conduct a RA based on single-substance toxicity data (ECx a.s.) for the identified 'driver' of mixture toxicity, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured ECx a.s. and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.

9.5.3 Overall conclusions

Taking into consideration risk mitigation calculations for ORKAN 400 SL – use in Orchards, following risk mitigation measures should be applied:
- 10 m no spray buffer zone with 10 m vegetated filter strip.

Review comments:

The evaluation of the risk for aquatic was performed in accordance with 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(EFSA Journal 2013;11(7):3290).

Calculated PEC/RAC values for glyphosate and its relevant metabolites are below the trigger value of 1 at step 1, indicating that active substance poses a low risk to aquatic organisms.

For MCPA most of PEC/RAC values were below the trigger 1 with the exception of *Lemna gibba* for which the PEC/RAC value was above the trigger value of 1 (D3 ditch, D4 pond, D4 stream, R1 pond, R1 stream scenarios) indicating that MCPA poses a potential risk to higher plants.

Based on the results of the higher tier risk assessment (FOCUS Step 4 values in combination with lowest toxicity endpoint for *Lemna gibba*) following buffer zones with vegetative strips (Section 8) are required for use of ORKAN 350 SL in ORCHARDS according to critical GAP:

Orchards at application rate 1x 8L/ha of ORKAN 350 SL

- 10 m vegetative strip with 10 m no spray buffer zone

Based on mix-tox calculations the toxicity drivers were found for algae and lemna. Thus, no further assessment were need since active substances would cover risk for mixture.

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

Effects on bees of ORKAN 350 SL were not evaluated as part of the EU assessment of MCPA and glyphosate. New data submitted with this application are listed in Appendix 2 ~~Annex 1 **Błąd! Nie można odnaleźć źródła odwołania.**~~

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Glyphosate	Oral	LD_{50} = 100 µg/bee	EFSA Journal 2015;13(11):4302
Apis mellifera	Glyphosate	Contact	LD_{50} > 100 µg/bee	EFSA Journal 2015;13(11):4302
Apis mellifera	MCPA	Oral	LD_{50} > 200 µg/bee	MCPA SANCO/4062/2001-final 11 July 20081

Species	Substance	Exposure System	Results	Reference
Apis mellifera	MCPA	Contact	LD_{50} > 200 µg/bee	MCPA SANCO/4062/2001-final 11 July 20081
Apis mellifera	ORKAN 350 SL	Oral	LD_{50} > 200 µg/bee	Czarnecka M., 2017, B/228/16
Apis mellifera	ORKAN 350 SL	Contact	LD_{50} > 200 µg/bee	Czarnecka M., 2017, B/229/16 ~~B/228/16~~

9.6.1.1 Justification for new endpoints

Not relevant.

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).

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 ORKAN 350 SL in orchard

Intended use	Orchards		
Active substance	glyphosate		
Application rate (g/ha)	1 × 2080		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	100	2080	20.8
Contact toxicity	> 100		20.8
Active substance	MCPA		
Application rate (g/ha)	1 × 720		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 200	720	3.6
Contact toxicity	> 200		3.6
Product	ORKAN 350 SL		
Application rate (g/ha)	1 × 9144		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 200	9144	45.72
Contact toxicity	> 200		45.72

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

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

Not relevant.

Review Comments:

Since acceptable acute risk have been concluded for bees exposed to ORKAN 350 SL at the Tier 1, a higher-tier risk assessment is not required for the proposed uses of ORKAN 350 SL.

9.6.3 Effects on bumble bees

Not relevant.

Review Comments:

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

9.6.4 Effects on solitary bees

Not relevant.

Review Comments:

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

9.6.5 Overall conclusions

The HQ values are lower than the trigger of 50, indicating low risk for bees from glyphosate and MCPA following application of ORKAN 350 SL. Calculation conducted for ORKAN 350 SL regarding to the oral and contact toxicity also confirm no risk for bees due to the use that formulation: achieved values are lower than 50. Therefore, a low risk to bees is expected from the application of ORKAN 350 SL following application according to the proposed GAP.

Review Comments:

The evaluation has been performed in line with SANCO/10329/2002 rev 2 final.
The risk assessment performed for active substances glyphosate and MCPA and the formulated product ORKAN 350 SL is agreed by the zRMS. All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern of ORKAN 350 SL.
All calculated HQ values based on a single maximum application rate of 2.08 g glyphosate + 0.72 g MCPA also covering lower doses of ORKAN 350 SL to orchards
According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): Applicant should provide chronic test on bees and evaluation of effects on honey bee development with formulated product. The chronic studies were not performed, therefore, for Poland, the deficiencies need to be fill by 31.12.2021. Concerned Member States must decide on the consideration of data requirements on national level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with MCPA, glyphosate and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target arthropods of ORKAN 350 SL were not evaluated as part of the EU assessment of MCPA and glyphosate. New data submitted with this application are listed in Appendix 1.

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	ORKAN 350 SL	Extended laboratory test blackberry leaves (2D)	LR_{50} = 2.7 L product /ha ER_{50} > 2.0 L product /ha	Czarnecka M., 2017, B/231/16
Aphidius rhopalosiphi (adults)	ORKAN 350 SL	Extended laboratory test barley plants (2D)	LR_{50} > 8.0 L product/ha Corresponding to (709.6 g MCPA/ha + 2032.0 g glyphosate/ha) ER_{50} > 8.0 L product/ha Corresponding to (709.6 g MCPA/ha + 2032.0 g glyphosate/ha)	Czarnecka M., 2017, B/230/16
Chrysoperla carnea	ORKAN 350 SL	Extended laboratory test bean plants (2D)	LR_{50} > 8 L/ha Corresponding to (709.6 g MCPA/ha + 2032.0 g glyphosate/ha) ER_{50} > 8 L/ha Corresponding to (709.6 g MCPA/ha + 2032.0 g glyphosate/ha)	Šklíba J., 2020, 20/254
Typhlodromus pyri	ORKAN 350 SL	Aged residue extended laboratory test (2D)	ER_{50} > 8 L/ha after 0, 7 and 14 day after treatment Corresponding to (709.6 g MCPA/ha + 2032.0 g glyphosate/ha)	Zelová J., 2020, 20/256

9.7.1.1 Justification for new endpoints

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

Risk assessment was performed for the highest dose of the product ORKAN 350 SL used in orchards which represents worst-case scenario.
~~To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target arthropods from all other intended uses in groups xxx (see 9.1.2).~~

Table 9.7-2: The Tier II based on extended laboratory studies ~~First- and higher-tier~~ assessment of the in-field risk for non-target arthropods due to the use of ORKAN 350 SL in orchards

Intended use	**Orchards**		
Active substance/product	**ORKAN 350 SL**		
Application rate (g product /ha)	**1 × 8000**		
MAF	**1**		
Test species Tier II	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 1 ~~2~~**
Typhlodromus pyri	2700	8000	**2.96**
Aphidius rhopalosiphi	8000		1
Chrysoperla carnea	8000		1

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

Since the Tier II risk assessment indicates that ORKAN 350 SL pose an unacceptable risk to *Typhlodromus pyri*, further assessment is necessary.

On the basis of the risk assessment results also with additional species *Chrysoperla carnea* it is clear that the most sensitive species was T.pyri. That is why additional age residue study on T. pyri was performed and presented below (Zelová J., 2020, 20/256).

In the study all validity criteria were met. However, application of ORKAN 350 SL increased T. *pyri* mortality in all aged treatments compared to negative control, although not in a predictable way.
The highest and significantly different (P <0.05) mortality compared to negative control was recorded in the longest ageing interval (14A), whilst the lowest mortality was recorded for the shortest ageing interval (0A). The result could be explained by the different physical condition of aged leaves (14A and 7A) at the test initiation compared to fresh leaves of 0A treatment and negative control. These leaves – already dried after the treatment of glyphosate-based test item (ORKAN 350 SL), could affect the surviving of T. *pyri*.

Results:
After exposure to ORKAN 350 SL at rates of 8.0 L/ha, the percentages of *T.pyri* corrected mortality were 18.5, 21.0 and 27.2%, for samples applied 0, 7 and 14 days before introduction organisms on treated plants, respectively and reduction of reproduction was -18.2, 48.6 and 46.4, respectively.

Table 4. Mortality of *T. pyri* in individual aged treatments (14A, 7A and 0A), negative control (UTC) and toxic reference control.

Treatment ID	% Mortality mean ± SD	Corrected % mortality after Abbott (1925)	Statistical significance
UTC	19 ± 10.2	0.0	
14A	41 ± 16.4	27.2	*
7A	36 ± 10.2	21.0	
0A	34 ± 12.6	18.5	
Tox. Ref.	98 ± 2.7	97.5	n/a

* mortality significantly higher than in the untreated control (Dunnett's test: P<0.05, following One-way ANOVA)

Table 5. Fecundity of *T. pyri* females surviving the mortality phase in negative control (UTC) and aged treatments (14A, 7A and 0A).

Treatment ID	Mean ± SD reproductive output per female	% Mean decrease of reproductive output	Statistical significance
UTC	4.57 ± 0.59	0.0	
14A	2.45 ± 1.56	46.4	
7A	2.35 ± 1.26	48.6	*
0A	5.40 ± 1.55	-18.2	

* reproductive output significantly lower than in the negative control (Dunnett's test: P<0.05, following One-way ANOVA)

Conclusions:

Overall, the effects of ORKAN 350 SL applied with an application rate of 8L/ha on survival and reproduction were less than the ESCORT 2 trigger of 50 % after 0 and 7 days of aging. In conclusion, the in-field HQ values indicate that ORKAN 350 SL poses no undue risk to in-field non-target arthropods following application according to the proposed use patterns.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: TIER II ~~First- and higher-~~tier assessment of the off-field risk for non-target arthropods due to the use of ORKAN 350 SL in orchards

Intended use	Orchards
Active substance/product	ORKAN 350 SL
Application rate (g product/ha)	1 × 8000
MAF	1
vdf	10 ~~(Tier 1)~~

Test species Tier II	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1 ~~2~~**
Typhlodromus pyri	2700	2.77	22.16	5 ~~10~~	0.04 ~~0.08~~
Aphidius rhopalosiphi	8000				0.014 ~~0.03~~
Chrysoperla carnea	8000				0.014 ~~0.03~~

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF:

Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

According to calculations, risk for *T.pyri* in-field after application cannot be excluded – $HQ_{in\text{-}field}$ >2 (2.96). Therefore calculations for one another species had to be performed. Calculations for *C.carnea* show no risk from using of ORKAN 350 SL.

9.7.2.3 Additional higher-tier risk assessment

Since, using of ORKAN 350 SL according to calculations may indicate risk for Typhlodromus pyri, aged-residue study was performed to estimate appropriate time of recolonization.
According to results of higher-tier aged-residue study, low risk for Typhlodromus pyri is predicted just after application. Study shows that ER_{50} value is higher than 8.0 L/ha, what is proposed dose for ORKAN 350 SL.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Since for *Typhlodromus pyri* HQ in-field value is over 1 ~~2~~ (2.96) what indicates risk for NTA, additional studies for one more species (*Chrysoperla carnea*) were performed to prove low risk for arthropods. Moreover Aged residue studies for *Typhlodromus pyri* was performed to show possibility of recolonization of treated area. Results for additional species (*Chrysoperla carnea*) show that proposed dose of product ORKAN 350 SL do not pose a risk for less vulnerable organisms - HQin-field and off-filed were below the trigger value. During aged residue studies, it was shown that after application of product, reduction of reproduction for *T.pyri* is less than 50%, what indicate acceptable risk.
Higher tier study and studies for additional species prove that application of ORKAN 350 SL using dose proposed in GAP do not indicate unacceptable risk for arthropods.

Review comments:

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the guidance document ESCORT 2.

Acceptable in-field risk was indicated for *Aphidius rhopalosiphi* at TIER 2 but the risk was not acceptable for *Typhlodromus pyri.* Additional study for Chrysoperla carnea was performed indicated low risk for arthropods. For Tyhlodromus TIER 3 risk was performed on the basis of age residues studies. During aged residue studies, it was shown that after application of product, reduction of reproduction for T.pyri is less than 50%, what indicate acceptable risk. Moreover there is a potential of recovery from the off-field areas. As noted in the mammal risk assessment, the DT_{50} of glyphosate on grass foliage is 2.8 days. As glyphosate is the main constituent of the product this supports the assumption that recovery will be possible within a few days.
The HQ for recommended species: *Typhlodromus pyri* and *Aphidius rhopalosiphi* is below the ESCORT 2 trigger value of 1 indicating acceptable off-field risk to non-target arthropods at tier II level.
On this basis acceptable risk for in-field and off-field habitats may be concluded with no need for risk mitigation measures.

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

9.8.1 Toxicity data

Effects on earthworms of ORKAN 350 SL were not evaluated as part of the EU assessment of glyphosate and MCPA. 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

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	MON 0139 (63.81% w/w Glyphosate IPA salt)	56 d Chronic toxicity	NOEC > 1000 mg /kg dry soil equivalent to NOEC > 473 mg a.e. /kg dry soil.	EFSA Journal 2015;13(11):4302
Eisenia fetida	AMPA	56 d Chronic toxicity	NOEC= 131.9 mg a.s./kg dw soil	Renewal Assessment Report 18.12.2013 for Glyphosate
Eisenia fetida	ORKAN 350 SL	Mixed into substrate / 56 d, chronic 10% peat content	NOEC = 320 mg product/kg dw	Wróbel, A. 2009, G/16/09 ~~G/15/09~~
Folsomia candida	ORKAN 350 SL	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 308.64 (reproduction) formulation/kg dry weight of soil)	Meler A., 2020, 0030/0013/E
Hypoaspis aculeifer	ORKAN 350 SL	Mixed into substrate 14 d, chronic 5 % peat content	NOEC= 95.26 mg/kg dw	Woźniak A., 2020, 0030/0012/E

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

zRMS comments:

Currently endpoints for soil organisms must be corrected by a factor of 2 for substances with log Pow > 3 regardless of the peat content in the study, log Pow of glyphosate and MCPA are < 2 so endpoints were not divided by 2.

9.8.1.1 Justification for new endpoints

Not relevant.

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 is considered for AMPA.~~

Table 9.8-2: First-tier assessment of the chronic risk for earthworms due to the use of ORKAN 350 SL in orchards

Intended use			
Chronic effects on earthworms			
Product/active substance/ metabolite	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Glyphosate provided as: MON 0139 (63.81% w/w Glyphosate IPA salt)	473	1.664	284.2
AMPA	131.9	1.784	74
ORKAN 350 SL	320	7.315 ~~6.4~~	43.74 ~~50~~
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC** (mg/kg dw)	**PEC_{soil}** (mg/kg dw)	**TER_{lt}** (criterion TER ≥ 5)
ORKAN 350 SL	308.64 (*Folsomia candida*)	7.315 ~~6.4~~	42.19 48.23
ORKAN 350 SL	95.26 (*Hypoaspis aculeifer*)	7.315 ~~6.4~~	13.02 ~~14.88~~

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The calculated chronic TER for ORKAN 350 SL and metabolite of glyphosate are above the trigger value of 5 indicating acceptable acute risk to earthworms and other soil micro- and mesofauna from the proposed uses of ORKAN 350 SL.

Review Comments:

The risk assessment for soil macro- and meso-fauna presented in Table 9.8-2 has been corrected with consideration of the new PECsoil values for the formulation agreed in Section 8. Calculated TERlt values indicated acceptable long-term risk to soil meso- and macro-organisms for ORKAN 350 SL in orchards. No further assessment is deemed necessary.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Effects on soil microorganisms of ORKAN 350 SL were not evaluated as part of the EU assessment of MCPA and glyphosate. New data submitted with this application are listed in Appendix 1.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	ORKAN 350 SL	28 d, aerobic soil type	Effect lower than 25 % at 61 mg /kg soil	Dec W., 2017, G/111/16

9.9.1.1 Justification for new endpoints

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-6 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of ORKAN 350 SL in orchards

Intended use			
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
ORKAN 350 SL	61 (at 28 d)	7.315 ~~6.4~~	yes

9.9.3 Overall conclusions

On the basis of results it was assessed that ORKAN 350 SL in considered applications does not pose unacceptable risk to soil microorganisms.
The risk to soil micro-organisms is considered to be low for all representative uses.

Review comments:

The risk assessment for soil micro-organisms exposed to ORKAN 350 SL, following the proposed uses of the formulation, was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002).

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

Based on the obtained results, soil nitrate formation rates were below the 25% trigger value. Thus, it is concluded that ORKAN 350 SL had no significant impact on soil microorganisms when applied at test item concentrations up to 61 mg formulation/kg soil dry weight.

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

9.10.1 Toxicity data

Effects on non-target terrestrial plants of ORKAN 350 SL were not evaluated as part of the EU assessment of glyphosate or MCPA. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Brassica napus d *Lolium perenne* m *Allium cepa* m *Avena sativa* m *Helianthus annus* d *Cucumis sativus* d	ORKAN 350 SL	21 d Seedling emergence	1) ~~LOEC emergence = 0.099 L/ha*~~ 2) ER_{50} plant weight = 1.395 L/ha 3) ER_{50} plant height = 1.733 L/ha	Kaźmierczuk M., 2018, 23B-04-16
Brassica napus d *Lolium perenne* m *Allium cepa* m *Avena sativa* m *Helianthus annus* d *Cucumis sativus* d	ORKAN 350 SL	21 d Vegetative vigour	1) ER_{50} plant weight = 0.797 L/ha 2) ER_{50} plant height = 1.489 g/ha	Kaźmierczuk M., 2018, 24B-04-16

m: monocotyledonous; d: dicotyledonous

~~* Since the EC_{50} value was obtained, basing on statistically not-significant dose-response curve, LOEC value is used~~

9.10.1.1 Justification for new endpoints

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

Table 9.10-2: Assessment of the risk for non-target plants due to the use of ORKAN 350 SL in orchards

Intended use	Orchards
Active substance/product	ORKAN 350 SL
Application rate (L/ha)	1 × 8.0
MAF	1

Test species	**ER_{50} (L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Oilseed rape ~~*Allium cepa*~~	1.395 ~~0.099~~	2.77	0.22	6.31 ~~**0.45**~~

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

Table 9.10-3: Assessment of the risk for non-target plants due to the use of ORKAN 350 SL in orchards

Intended use	Orchards
Active substance/product	ORKAN 350 SL
Application rate (L/ha)	1 × 8.0
MAF	1

Test species	**ER_{50} (L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Lulium perenne	0.797	2.77	0.22	**3.62**

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

~~**Table 9.10-4: Risk assessment for non-target terrestrial plants due to the use of ORKAN 350 SL in orchards considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**~~

~~**Intended use**~~	~~Orchards~~
~~**Active substance/product**~~	~~ORKAN 350 SL~~
~~**Application rate (L/ha)**~~	~~1 × 8.000~~
~~**MAF**~~	~~1~~

~~**Buffer strip (m)**~~	~~**Drift rate (%)**~~	~~**$PER_{off\text{-}field}$ (g/ha)**~~	~~**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**~~	~~**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**~~	~~**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**~~
~~1~~	~~2.77~~	~~0.22~~	~~0.11~~	~~0.055~~	~~0.022~~
~~3~~	~~0.95~~	~~0.075~~	~~0.038~~	~~0.019~~	~~0.008~~

10	0.29	0.023	0.012	0.006	0.002
15	0.20	0.016	0.0079	0.0040	0.0016
Toxicity value ER_{50} = 0.099 L/ha		**TER** **criterion: TER ≥ 5**			
1		0.45	0.9	1.8	4.5
3		1.3	2.6	**5.2**	**13**
10		4.3	**8.6**	**17**	**43**
15		**6.2**	**12**	**25**	**62**

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

Table 9.10-5: Risk assessment for non-target terrestrial plants due to the use of ORKAN 350 SL in orchards considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Orchards			
Active substance/product		ORKAN 350 SL			
Application rate (L/ha)		1 × 8.000			
MAF		1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	0.22	0.11	0.055	0.022
3	0.95	0.075	0.038	0.019	0.008
5	0.57	0.045	0.0228	0.0114	0.004
Toxicity value ER_{50} = 0.797 L/ha		**TER** **criterion: TER ≥ 5**			
1		3.6	**7.2**	**14**	**36**
3		**11**	**21**	**42**	**106**
5		**17.71**	**34.95**	**69.91**	**199.25**

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

9.10.3 Overall conclusions

Taking into consideration risk mitigation calculations for ORKAN 350 SL – use in Orchards, following risk mitigation measures should be applied:

- 5m unsprayed buffer zone to non-agricultural land or
-1 m unsprayed buffer zone with 50 % drift reduction nozzle

~~- 3 m buffer zone with vegetated filter strip and 75 % drift reduction nozzle,~~
~~- 10 m buffer zone with vegetated filter strip and 50 % drift reduction nozzle or,~~
~~- 15 m buffer zone with vegetated filter strip to non-agricultural land~~

Using the above-mentioned precautions, formulation ORKAN 350 SL can be used and will not have a

negative impact on non-target terrestrial plants.

Review comments:

Risk assessment performed by the Applicant for non-target terrestrial plants was updated and accepted. Based on the predicted rates of ORKAN 350 SL in off-field areas, the TER values describing the risk for non-target plants following exposure to formulation according to the GAP achieve the acceptability criteria TER ≥ 5. with applying for orchards:
an unsprayed buffer zone of 1 m with 50% drift reducing technology or an unsprayed buffer zone of 5 m without drift reduction technology to non-agricultural land.

Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization.

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

ORKAN 350 SL was classified and labeled according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

For classification of ORKAN 350 SL was based on formulation studies (algae E_rC_{50} < 1 mg product/L) and mixtures classification method was used.

~~**Acute Category 1** (concentration of compounds is higher than 25%)~~
~~**Chronic Category 1** (concentration of MCPA is lower than 25%).~~
~~**Chronic Category 2** (concentration of glyphosate and MCPA is higher than 25%).~~

CLASSIFICATION	
Hazard classes, categories:	Acuatic Acute 1 Aquatic Chronic 2
LABELLING	
Hazard pictograms:	 GHS09

Signal word:	Warning
Hazard statements:	H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements:	~~P273 – Avoid release to the environment.~~ P391 - Collect spillage. P501 - Dispose of contents/container to an approved waste disposal plant.
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic species respect a: - 10 m non sprayed buffer zone with 10 m vegetated filter strip. To protect non target terrestrial plants respect a: - an unsprayed buffer zone of 5 m to non-agricultural land or 1 m with 50% drift reducing technology ~~**- 3 m buffer zone with vegetated filter strip and 75 % drift reduction nozzle,**~~ ~~**- 10 m buffer zone with vegetated filter strip and 50 % drift reduction nozzle,**~~ ~~**- 15 m buffer zone with vegetated filter strip.**~~

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	[redacted]	2009a	Orkan 350 SL – Badanie toksyczności ostrej dla pstrąga tęczowego; xxxxxxxxxxxxxxxx Study code: WB/60/09 GLP; Unpublished	Y	Synthos Agro Sp. z o.o.
	Żmijowski, G et al	2009b	Orkan 350 SL – Rozwielitka ostry test unieruchomienia; Institute of Industrial Organic Chemistry (Pszczyna) Study code: WB/59/09 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
	Żmijowski, G et al	2009c	Orkan 350 SL – Badanie hamowania wzrostu Pseudokirchneriella subcapitata SAG.61.81; Institute of Industrial Organic Chemistry (Pszczyna) Study code: WB/58/09 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
	Żmijowski, G et al	2009d	Orkan 350 SL – Badanie hamowania wzrostu Lemna minor UTCC 490; Institute of Industrial Organic Chemistry (Pszczyna) Study code: WB/61/09 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Czarnecka Małgorzata	2017	ORKAN 350 SL. Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/228/16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.

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
	Czarnecka Małgorzata	2017	ORKAN 350 SL. Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/229/16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
KCP 10.3.2	Czarnecka Małgorzata	2017	An extended laboratory test for evaluating the effects of ORKAN 350 SL on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/230/16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
	Czarnecka Małgorzata	2017	An extended laboratory test for evaluating the effects of ORKAN 350 SL on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/231/16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
	Šklíba Jan	2020	GLP rate-response extended laboratory study to determine effects of a plant protection product ORKAN 350 SL on the green lacewing, *Chrysoperla carnea* (Neuroptera: Chrysopidae) i2L Research Europe s.r.o. Study code: 20/254 GLP, Unpublished	N	Synthos Agro Sp. z o.o.
	Zelová Jitka	2020	An aged-residue extended GLP laboratory study to determine effects of a plant protection product ORKAN 350 SL on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) i2L Research Europe s.r.o. Study code: 20/256 GLP, Unpublished	N	Synthos Agro Sp. z o.o.
KCP 10.4	Meler Agnieszka	2020	Badanie rozmnażania skoczogonków *Folsomia candida* według wytycznej OECD 232 Laboratorium Badawcze SORBOLAB Sp. z o.o. Study code: 0030/0013/E GLP, Unpublished	N	Synthos Agro Sp. z o.o.
	Woźniak Agnieszka	2020	Badanie rozmnażania roztoczy *Hypoaspis aculeifer* według wytycznej	N	Synthos

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
			OECD 226 Laboratorium Badawcze SORBOLAB Sp. z o.o. Study code: 0030/0012/E GLP, Unpublished		Agro Sp. z o.o.
	A. Wróbel	2009	Orkan 350 SL – Badanie wpływu narozmnażanie się dżdżownic (Eisenia fetida Sav.) Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/16/09 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
KCP 10.5	Dec Weronika	2017	ORKAN 350 SL . Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/111/16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
KCP 10.6	Marcin Kaźmierczuk	2018	Ocena fitotoksyczności preparatu ORKAN 350 SL – test wigoru wegetatywnego. Institute of Environmental Protection – National Research Institute Study code: 24B-04-16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.
	Marcin Kaźmierczuk	2018	Ocena toksyczności preparatu ORKAN 350 SL w stosunku do kiełkowania i wzrostu siewek. Institute of Environmental Protection – National Research Institute Study code: 23B-04-16 GLP; Unpublished	N	Synthos Agro Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1	---	1978	One-generation Reproduction Study – Bobwhite Quail; Glyphosate technical. Doc ID 2310921/139-141 GLP	Y	---
	---	1997	Glyphosate acid. Acute oral toxicity (LD_{50}) to bobwhite quail BVL no 2310906 GLP	Y	---
	xxxxx	1994	MCPA Acid: A One Generation Reproduction Study with the Northern Bobwhite (Colinus virginianus) MCPA xxxxxxxxxxx GLP, unpublished	Y	---
KCP 10.1.2	xxxxxxxxx	1992	The effect of Dietary Administration of Glyphosate on Reproductive Function of Two Generations in Rat TOX9552389	Y	---
	---	2007	Glyphosate Technical (NUP05068) Acute oral toxicity study in rats. ASB2012-11390	Y	NUFARM
KCP 10.2	---	1993	96-Hour Acute Toxicity Study in Rainbow trout with (Aminomethyl)Phosphonic Acid (Static)	Y	---
	---	2000	Chronic Toxicity of Glifosate Tecnico Nufarm to zebra fish larvae (Brachydanio rerio) BVL no 2310938 GLP, Not Published	Y	NUFARM
	---	2002	Review Report for the active substance Glyphosate (SANCO/6511/VI/99-final)	Y	---
	---	2011	AMPA (Aminomethylphosphonic acid). An early lifestage toxicity test with the fathead minnow (*Pimpephales promelas*)	Y	---
	xxxxxxxxxxx	1990a	MCPA (as DMA-salt): 96-hour acute toxicity study (LC50) in the rainbow trout (flow through) MCPA xxxxxxxxxxxxxxxxxxxx, unpublished	Y	
	Bogers, M.	1998	Freshwater Algal Growth Inhibition Test with (Aminomethyl)-phosphonic Acid BVL no 2310985 GLP	N	---

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**
	Bogers, M.	1998	Acute toxicity Study in Daphnia magna with (Aminomethyl) Phosphonic Acid (Static) GLP	N	---
	Brown D	2001	MCPA: Toxicity to the Freshwater Algae Selenastrum capricornutum – (A Review of data) MCPA DPWG Unpublished	N	
	Dengler,	1994	IFU93006/01-Ss	N	---
	xxxxxxxx	1997a	MCPA DMAS: An Early Life Stage Toxicity Study With the Fathead Minnow MCPA xxxxxxxxxxxxxxxxxxxxGLP, unpublished	Y	
	Drottar K E	1997b	A Flow Through Life Cycle Toxicity Test With The Cladoceran (Daphnia magna) MCPA DPWG Wildlife Internatonal USA 364A-101 GLP, unpublished	N	
	Drottar K R	1999	MCPA DMAS: A 14-Day Toxicity Test with Duckweed (Lemna gibba G3) MCPA DPWG Wildlife International USA 364A-103 GLP, unpublished	N	
	Handley et al.,	1995	Glyphosate, *Daphnia magna*, acute toxicity test. Published	N	---
	Hoberg J R	1994	MCPA DMA Salt: Toxicity to Duckweed, Lemna gibba MCPA DPWG Springborn laboratories USA 93-11-5046 GLP, unpublished	N	
	xxxxxxxxxxx	1992	Acute toxicity to common carp, Cyprinus carpio, under flow-through test conditions TO-91-295 GLP, Not Published	Y	SYNGENTA
	Mattock S D	1998	MCPA: Toxicity to Lemna minor MCPA DPWG Covance Laboratories UK 785/19-D2145 GLP, unpublished	N	
	Magor, S.E., Shillabeer, N	1999	Glyphosate acid: Chronic toxicity to *Daphnia magna*. BL6535/B SYN GLP, Not Published	N	SYNGENTA
	Mayer P; Oldersma	2000	Determination of the Effect of MCPA DMAS on the Growth of the Freshwater Green Algae	N	

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**
	H; Hansveit A O		Selenastrum capricornutum MCPA DPWG TNO report V2317/01 GLP, unpublished		
	Minderhout, T.	2011	AMPA (Aminomethylphosphonic acid): A semi-static life cycle toxicity test with Cladoceran (*Dapnia magna*) GLP	N	---
	Moore K W, Hutchings M J	2000b	MCPA: Toxicity to duckweed Lemna gibba (final report) Brixham Environmental Laboratory MCPA DPWG AstraZeneca UK Ltd / BL688837/B GLP, unpublished	N	
	Palmer S J, Kendall T Z, Krueger H O	1999a	MCPA DMAS: A 5-Day Toxicity Test with the Freshwater Alga (Selenastrum capricornutum), MCPA DPWG Wildlife International Limited USA 364A104 GLP, unpublished	N	
	Palmer S J, Kendall T Z, Krueger H O	1999b	MCPA DMAS: A 5 Day Toxicity Test with the Marine Diatom (Skeletonema costatum) MCPA DPWG Wildlife International Limited USA 364A107 GLP, unpublished	N	
	Palmer S J, Kendall T Z, Krueger H O	1999c	MCPA DMAS: A 5 Day Toxicity Test with the Freshwater Alga (Anabaena flosaquae) MCPA DPWG Wildlife International Limited USA 364A105B GLP, unpublished	N	
	Palmer S J, Kendall T Z, Krueger H O	1999d	MCPA DMAS: A 5 Day Toxicity Test with the Freshwater Diatom (Navicula pelliculosa) MCPA DPWG Wildlife International Limited USA 364A106A GLP, unpublished	N	
	Palmer, S.J., et al.	2011	HMPA (Hydroxymethylphosphonic acid): A 48-hour static acute toxicity test with the cladoceran (*Daphnia magna*)	N	---
	Porch, J.R., et al.	2011	HMPA (hydroxymethylphosphonic acid): A 7-day static renewal toxicity test with Duckweed (*Lemna gibba* G3) GLP 2310999/139A-3987	N	---
	Smyth, D.V. Kent, S.J.,	1995	Glyphosate acid: Toxicity to green alga Selenastrum capricornutum BL5550/B SYN	N	SYNGENTA

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**
	Morris, D.S., Morgan, D.J., Wallece, S.J.		GLP, Not Published		
	Smyth, D.V., Shillabeer, N., Morris, D.S., Wallece, S.j.	1996	Glyphosate acid: Toxicity to blue-green alga Anabaena flos-aquae BL5698/B SYN GLP, Not Published	N	SYNGENTA
	Smyth, D.V. Kent, S.J., Morris, D.S., Shearing, J.M., Shillabeer, N.,	1996	Glyphosate acid: Toxicity to marine alga Skeletonema costatum BL5684/B SYN GLP, Not Published	N	SYNGENTA
	Wenzel, A	2012	Effect of AMPA (Aminomethylphosphonic acid) on the Growth of *Myriophyllum aquaticum* in the presence of sediment, with subsequent recovery period GLP	N	---
KCP 10.3.1	Fraser and Jenkins	1972	The Acute Contact and Oral Toxicities of CP 67573 and MON 2139 to Worker Honey Bees. HU85X094	N	Monsanto
	Harwood R W J, Allan J	2001	MCPA A Laboratory Evaluation of the Acute Toxicity of MCPA to the Honey Bee (Apis Mellifera): 48-hour Contact and Oral LD50 MCPA DPWG Inveresk Research UK 19393A GLP, unpublished	N	
KCP.10.3.2	Adelberger I	1999	MCPA DMA: Toxicity to the Predatory Mite, Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) in the Laboratory MCPA DPWG GAB Biotechnologie, Germany 99038/01-NTLp GLP, unpublished	N	
	Kemmeter F	1999a	MCPA DMA: Toxicity to the Green Lacewing, Chrysoperla carnea Steph (Neuroptera, Chrysopidae) in the Laboratory MCPA DPWG GAB Biotechnologie, Germany 99038/02-NLCc GLP, unpublished	N	

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**
	Kemmeter F	1999b	MCPA DMA: Toxicity to the Wolf Spider, Pardosa spp (Araneae Lycosidae) in the Laboratory MCPA DPWG GAB Biotechnologie, Germany 99038/01- NLPa GLP, unpublished	N	
	Schuld M	1999a	MCPA DMA: Toxicity to the Aphid Parasitoid Aphidius rhopalosiphi (Hymenoptera, Braconidae) DeStefaniPerez in the Laboratory MCPA DPWG GAB Biotechnologie, Germany 99038/01- NLAp GLP, unpublished	N	
	Schuld M	1999b	MCPA DMA: Toxicity to the Aphid Parasitoid Aphidius rhopalosiphi (Hymenoptera, Braconidae) Using an Extended Laboratory Test MCPA DPWG GAB Biotechnologie, Germany 99038/01- NEAp GLP, unpublished	N	
KCP 10.4	Mallet, M.J.	2002	Sinon Glyphosate Technical: The acute Toxicity to the Earthworm *Eisenia foetida* GLP,	N	---
	Moser, T., Rombke, J.	2000	Acute toxicity of AMPA technical material to the earthworm *Eisenia fetida* in an artificial soil test. GLP	N	---
	Servajean, E.	2003	Laboratory determination of the side-effects of aminomethyl phosphonic acid (AMPA) on the reproductive performance of earthworm (*Eisenia fetida*) using artificial soil substrate.) GLP,	N	---
KCP 10.5	Schulz, L.	2010	AMPA – Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests). Doc ID: 2311050/10 10 48 010 C/N GLP	N	---

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new studies

Review Comment:

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

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Summarised in Section 6 (Mammalian Toxicology)

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

Study 1.

Comments of zRMS:	The ORKAN 350 SL- acute toxicity for Rainbow trout, has been already evaluated and accepted during first authorization of ORKAN 350 SL containing 260 g/L glyphosate and 90 g/L MCPA. One deviation to the guideline was noted: -length of the fishes (6.4 cm) was above the recommended length (3-6 cm). However, since all validity criteria were met deviation did not influenced the study results. Already evaluated studies are available only in Polish. Thus, zRMS presented below summaries of these studies in English. Only key issues are pointed out as an executive summary. The study was conducted to OECD guideline 203 (1992) and according to the principles of GLP. Since there is the new version of OECD 203 adopted on 18 June 2019, zRMS evaluated the study according to the recent guideline. In the definitive test all validity criteria were met. - The mortality of fish in the control was 0%. - The dissolved oxygen concentration was in the range of 90.8-103.2 % of air saturation value. - Samples of each test item concentration and the control collected at exposure initiation and termination were chemically analysed. The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. Following endpoint was considered as relevant for risk assessment purposes: LC_{50}= 6.71

Reference:	KCP 10.2
Report	Orkan 350 SL – Badanie toksyczności ostrej dla pstrąga tęczowego; xxxxxxxxxxxxxxx Study code: B/60/09 GLP; 2009a, Unpublished
Guideline(s):	According to OECD Guideline No 203 (1992)
Deviations:	Yes, minor
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods:

Test item: ORKAN 350 SL
Test organism: Rainbow trout (Oncorhynchus mykiss.)
age: not specified
average weight: 3.31 g
average body length: 6.4 cm
supplier: Hodowla Ryb Łososiowatych w Zawoi
Test design: static 96 h of exposure
Concentration of test material: 1,0; 1,8; 3,2; 5,6 i 10 mg/l.
Test conditions: temperature of water: 13.0 – 13.9 °C
pH of the control: 7.13 – 7.55
dissolved oxygen concentration in the test item concentrations and the control: 90.8 – 103.2%
lighting daily cycle: 16 h light : 8 h dark, no feeding; constant aeration.
Endpoint values: LC_{50}, LC_0, LC_{100}

Table Analytical measurements MCPA

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie MCPA [mg/l]	Średnie stężenie MCPA (n = 3) oznaczone w czasie [mg/l]			
		t0	% stężenia nominalnego	t96	% stężenia nominalnego
Kontrola	0,000	<LOQ	--	<LOQ	--
1,0	0,079	0,076	96,20	0,078	98,73
1,8	0,143	0,143	100,00	0,141	98,60
3,2	0,254	0,252	99,21	0,248	97,64
5,6	0,445	0,411	92,36	0,431	96,85
10	0,795	0,790	99,37	0,790	99,73

Table Analytical measurements glyphosate

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie glifosatu [mg/l]	Średnie stężenie glifosatu (n = 3) oznaczone w czasie [mg/l]			
		t0	% stężenia nominalnego	t96	% stężenia nominalnego
Kontrola	0,000	<LOQ	--	<LOQ	--
1,0	0,228	<LOQ	--	<LOQ	--
1,8	0,411	<LOQ	--	<LOQ	--
3,2	0,731	<LOQ	--	<LOQ	--
5,6	1,280	1,313	102,58	1,150	89,84
10	2,285	2,424	106,08	2,379	98,14

Table: Definitive test summary of toxic signs and mortality

Nominal concentration	Control	**Treatment (mg/L test item)**				
		1.0	1.8	3.2	5.6	10
Mortality (%)	0	0	0	12.5	0	100
Symptoms	none	none	none	none	unusual swimming behavior	none

Endpoints

Table: Summary of the test endpoints

Endpoint values [mg/L]	**Time of exposure**
	96h
Endpoint values based on the nominal concentrations of product	
LC_{50}	6.71
LC_0	1.80
LC_{100}	10.00

Study 2

Comments of zRMS:	The ORKAN 350 SL: Daphnia magna, Acute immobilization test has been already evaluated and accepted during first authorization of ORKAN 350 SL containing 260 g/L glyphosate and 90 g/L MCPA. conducted to OECD guideline 202 and according to the principles of GLP. One deviation to the guideline was noted: -differences between temperature measurements were higher than recommended $\pm 2^0$C. However, since all validity criteria were met deviation did not influenced the study results. Already evaluated studies are available only in Polish. Thus, zRMS presented below summaries of these studies in English. Only key issues are pointed out as an executive summary. In the definitive test the validity criteria were met: - The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%), - The dissolved oxygen concentrations in the test vessels were within the range of 6.68– 9.0 mg/L (criterion: not less than 3 mg/L). The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.2
Report	Orkan 350 SL – Rozwielitka ostry test unieruchomienia; Institute of Industrial Organic Chemistry (Pszczyna), Żmijowski, G et al Study code: W/59/09, 2009b GLP; Unpublished
Guideline(s):	Yes, OECD guideline for the testing of chemicals No. 202 and the EU method C.2
Deviations:	Yes, minor
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods:
Test item: ORKAN 350 SL
Test organism: *Daphnia magna* Straus
Test design: static 48 h of exposure
Concentration of test material: 3.2, 5.6, 10, 18, 32 (mg/L)
Endpoint values: EC_{50}, EC_0, EC_{100}, NOEC

Table Analytical measurements MCPA

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie MCPA [mg/l]	Średnie stężenie MCPA (n = 3) oznaczone w czasie [mg/l]			
		t0	% stężenia nominalnego	t48	% stężenia nominalnego
Kontrola	0,000	<LOQ	--	<LOQ	--
3,2	0,254	0,25	98,43	0,26	102,36
5,6	0,445	0,41	92,13	0,45	101,12
10	0,795	0,75	94,34	0,75	94,34
18	1,431	1,33	92,94	1,51	105,52
32	2,544	2,48	97,48	2,61	102,59

Table Analytical measurements glyphosate

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie glifosatu [mg/l]	Średnie stężenie glifosatu (n = 3) oznaczone w czasie [mg/l]			
		t0	% stężenia nominalnego	t48	% stężenia nominalnego
Kontrola	0,000	<LOQ	--	<LOQ	--
3,2	0,731	0,74	101,23	0,75	102,60
5,6	1,280	1,26	98,44	1,24	96,88
10	2,285	2,17	94,97	2,07	90,59
18	4,110	4,03	98,05	4,07	99,03
32	7,310	7,06	96,58	6,80	93,02

Table: Definitive test

Nominal concentration	Control	**Treatment (mg/L test item)**				
		3.2	5.6	10	18	32
Immobilization (%)	0	0	15	25	85	100

Endpoints

Table: Summary of the test endpoints

Endpoint values [mg/L]	**Time of exposure**
	48h
Endpoint values based on the nominal concentrations of product	
EC_{50}	11.4
EC_0	3.2
EC_{100}	32
NOEC	10

Study 3

Comments of zRMS:	ORKAN 350 SL *Pseudokirchneriella subcapitata*, Growth inhibition study has been already evaluated and accepted during first authorization of ORKAN 350 SL containing 260 g/L glyphosate and 90 g/L MCPA. conducted to OECD guideline 201 and according to the principles of GLP. In the definitive test the validity criteria were met: - The biomass in the control increased by a factor of 152.0 within the 72-hour test period (criterion: at least a 16-fold growth), - The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 2.8 % (criterion: it must not exceed 7%), - The mean coefficient of variation for the section-by-section growth rate in the control culture was 6.6% (criterion: it must not exceed 35%). The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. Following endpoints are relevant for risk assessment purposes: The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata:* ErC_{50}/72 h= 0.73 mg/L nom The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata:* EyC_{50}/72 h =0.18 mg/L nom

Reference:	KCP 10.2
Report	Orkan 350 SL – Badanie hamowania wzrostu *Pseudokirchneriella subcapitata* SAG.61.81; Institute of Industrial Organic Chemistry (Pszczyna), Żmijowski, G et al., Study code: W/58/09, 2009c, GLP; Unpublished
Guideline(s):	Yes, OECD guideline for the testing of chemicals No. 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods

Test item: Orkan 350 SL
Test organism: *Pseudokirchneriella subcapitata: (Reinsch)* Korshikov (poprzednio Selenastrum capricornutum Prinz), specyfikacja SAG. 61.81.
Supplier: Kolekcja Glonów Uniwersytetu w Getyndze, Niemcy
Test design: static 72h

Nominal test item concentrations: 0,056; 0,10; 0,18; 0,32; 0,56 i 1,0 mg/l.

Analytical measurements

Due to the limitations of the analytical methods, no determination of the content was performed glyphosate (LOQ = 1.0 mg / l) and determination of MCPA content (LOQ = 0.02 mg / l) in concentrations 0.056 and 0.10 mg / L. At the start of the experiment, the MCPA content was in the range of 86.1 - 96.6%
nominal content, and on the end of the experiment it was in the range of 83.9 - 90.9% of the nominal content. On the day of starting the experiment, the content of the tested material in the solutions was checked

working values (10 and 100 mg / l) used to prepare the test concentrations. Content of MCPA was at the level of 102.3 and 97.5% of the nominal content, respectively, and for glyphosate 102.0% and 86.1% of the nominal content, respectively. Based on the results of the chemical analysis, it is stated that the tested concentrations were prepared correctly, and the tested material is stable in aqueous solutions under the conditions of the experiment for 72 h. Due to above, the final values were calculated based on the nominal concentrations of the test material.

Table Results of the Growth inhibition study

Stężenie [mg/L]	Powt.	Średnia liczba komórek (10E+04 kom./ml)			Średnie specyficzne tempo wzrostu			Przyrost biomasy (10E+04 kom./ml)
		24 h	48 h	72 h	0-24 h	0-48 h	0-72 h	0-72 h
1,0	1	3	3,9	10,5	1,099	0,680	0,784	9,5
	2	2,4	3	7,1	0,875	0,549	0,653	6,1
	3	1,7	1,7	4,2	0,531	0,265	0,478	3,2
	Średnia	**2,4**	**2,9**	**7,3**	**0,835**	**0,498**	**0,639**	**6,3**
	SD	**0,7**	**1,1**	**3,2**	**0,286**	**0,212**	**0,153**	**3,2**
	CV (%)	**27,5**	**38,6**	**43,4**	**34,274**	**42,583**	**24,002**	**50,3**

Results

The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata:*
ErC_{50}/72 h= 0.73 mg product /L (95% confidence interval: 0.65-0.84)
The EyC_{50} is 0.18 mg product/L (48h, nom, static), corresponding to 0

Table: Endpoints based on the growth rate

E_rC_x [mg/L]	Czas ekspozycji [h]		
	24	48	72
E_rC_{10}	0,209 (0,080 – 0,312)	0,137 (0,089 – 0,182)	**0,142 (0,107 – 0,175)**
E_rC_{20}	0,386 (0,233 – 0,510)	0,229 (0,171 – 0,280)	**0,249 (0,207 – 0,288)**
E_rC_{50}	1,248 (0,893 – 2,633)	0,609 (0,522 – 0,734)	**0,727 (0,646 – 0,836)**
NOEC	≥ 1,0	0,10	**0,056**
LOEC	> 1,0	0,18	**0,10**

Table: Endpoints based on the biomass

E_yC_x [mg/L]	Czas ekspozycji [h]		
	24	48	72
E_yC_{10}	0,109 (0,040 – 0,175)	0,061 (0,036 – 0,084)	**0,052 (0,040 – 0,063)**
E_yC_{20}	0,205 (0,109 – 0,287)	0,096 (0,065 – 0,123)	**0,079 (0,065 – 0,092)**
E_yC_{50}	0,688 (0,515 – 1,083)	0,230 (0,190 – 0,279)	**0,176 (0,158 – 0,196)**
NOEC	0,10	0,10	**0,056**
LOEC	0,18	0,18	**0,10**

Study 4

Comments of zRMS:	ORKAN 350 SL *Lemna minor* UTCC 490 Growth inhibition test study has been already evaluated and accepted during first authorization of ORKAN 350 SL containing 260 g/L glyphosate and 90 g/L MCPA. conducted to OECD guideline 221 and according to the principles of GLP. Some deviations were noted: - Differences between temperature during the study were > $\pm 2^0$C - Differences in pH should not be more than 1.5 unit, and was 1.69 between day 2-4 and 1.58 between day 4-7 The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment. In the definitive test the validity criteria were met: - The doubling time of frond number in the control was 1.5 days, criterion: less than 2.5 days - The average specific growth rate in the control between day 0 and day 7 was 0.442 d^{-1} (minimum requirement: higher than 0.275 d^{-1}). The study is considered to be reliable and suitable for the risk assessment. All results refer to nominal concentrations. The study is considered reliable and suitable for the risk assessment. Following endpoints were accepted for risk assessment purposes: EyC_{50} = 4.77 mg/L nom ErC_{50} = 14.72 mg/L

Reference:	KCP 10.2.1-4
Report	Orkan 350 SL – Badanie hamowania wzrostu *Lemna minor* UTCC 490; Institute of Industrial Organic Chemistry (Pszczyna), Żmijowski, G et al , Study code: W/61/09, GLP; Unpublished
Guideline(s):	Yes, OECD guideline for the testing of chemicals No. 221
Deviations:	Yes, minor
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods

Test item:	Orkan 350 SL ; the content of active ingredient:.
Test organism:	The freshwater aquatic plant, *Lemna minor* UTCC 490, Kolekcji Kultur Uniwersytetu w Toronto, Kanada.
Test design:	Semi-static system with 2 renewals; 7 days of exposure; three replicates for each test item concentration and six replicates for control.
Nominal test item concentrations:	Control, 0.32; 1.0; 3.2; 10 and 32 mg/l.
Test conditions:	SIS medium, pH of the control: 6.53 – 8.52, glass crystallizers containing 150 mL of a given test item concentration or control; initial frond number: 9, temperature:

	23.7 – 26.2ºC, light: 9440 lx,
Chemical determinations:	
Statistics:	Probit analysis (using linear regression), and Analyses by Shapiro-Wilk's Test on Normal Distribution, Cochran's Test Procedure on Variance Homogenity, Welch t-test for inhomogeneous variances with Bonferroni Adjustment, Williams Multiple Sequential t-test Procedure,
Endpoint values:	ErC_{50}, EyC_{50}, ErC_{20}, EyC_{20}, ErC_{10}, EyC_{10} and NOEC i LOEC, based on frond number and based on dry weight.

Summary

The growth of *Lemna minor* exposed to the test item, Orkan 350 SL was investigated in a 7-day semi-static test with 2 renewals.

Analytical results

Due to the limitations of the analytical method, no glyphosate content was detected (LOQ = 1.0 mg / l) at nominal concentrations of 0.32 and 1.0 mg / L. On the day of starting the experiment, the MCPA content was in the range of 84.0 - 100.9% at nominal content on day 2 in 48-hour solutions in the range of 97.5 - 110.4% of the content and on the day of the end of the experiment it was found in 72-hour solutions in the range of 89.7 - 106.7% of the nominal content. At the start of the experiment, the glyphosate content was in the range 92.3 - 110.8 % of the nominal content on day 2 in 48-hour solutions in the range 100.2 - 104.0% content, and on the day of the end of the experiment it was found in 72-hour solutions in the range of 98.0 - 101.2% of the nominal content. Based on the the chemical results, it is concluded that the tested concentrations were prepared correctly, and the tested material is stable in aqueous solutions under the conditions of the experiment in within 72 h. Therefore, the end values were calculated from the concentrations nominal test material.

Table Analytical results MCPA

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie MCPA [mg/l]	Średnie stężenie (n = 3) MCPA oznaczone w czasie [mg/l]					
		Dzień 1, Świeże roztwory	% stężenia nominalnego	Dzień 2, roztwory 48-godzinne	% stężenia nominalnego	Dzień 7, roztwory 72-godzinne	% stężenia nominalnego
Kontrola	0,000	n.d.*	-	n.d.*	-	n.d.*	-
0,32	0,025	0,021	84,0	0,025	100,0	0,026	104,0
1,0	0,079	0,068	86,1	0,077	97,5	0,076	96,2
3,2	0,254	0,252	99,2	0,249	98,0	0,241	94,9
10	0,795	0,751	94,5	0,793	99,7	0,713	89,7
32	2,544	2,567	100,9	2,808	110,4	2,714	106,7

Table Analytical results glyphosate

Nominalne stężenie badanego materiału [mg/l]	Nominalne stężenie glifosatu [mg/l]	Średnie stężenie (n = 3) glifosatu oznaczone w czasie [mg/l]					
		Dzień 1, Świeże roztwory	% stężenia nominalnego	Dzień 2, roztwory 48-godzinne	% stężenia nominalnego	Dzień 7, roztwory 72-godzinne	% stężenia nominalnego
Kontrola	0,000	n.d.*	-	n.d.*	-	n.d.*	-
0,32	0,073	n.d.*	-	n.d.*	-	n.d.*	-
1,0	0,228	n.d.*	-	n.d.*	-	n.d.*	-
3,2	0,731	0,81	110,8	0,76	104,0	0,74	101,2
10	2,285	2,11	92,3	2,29	100,2	2,24	98,0
32	7,310	7,56	103,4	7,33	100,3	6,75	92,3

Phytotoxic observation

After 7 days of the experiment changes in plant morphology were observed at the following concentrations: 3.2; 10 and 32 mg / l. They were reduction of frond number, shortening or loss of roots, deformation and disintegration of the colony and folding of the members. The intensity of the changes increased with increasing concentration.

Table Summary of the toxicity for *Lemna minor* after 7 days of exposure

Na podstawie liczby członów	Stężenia nominalne [mg/L]	0,32	1,0	3,2	10	32
	Inhibicja przyrostu biomasy [%]	6,25	0,00	42,74	70,67	94,81
	Inhibicja specyficznego tempa wzrostu [%]	1,87	0,00	16,07	34,52	71,61
	Wartości EC [mg/L] z 95% przedziałem ufności (na podstawie nominalnych stężeń badanego materiału)					
	E_yC_{50} (7 d)	4,77 (2,54 – 8,93)				
	E_yC_{20} (7 d)	1,81 (0,32 – 3,16)				
	E_yC_{10} (7 d)	1,09 (0,09 – 2,18)				
	E_rC_{50} (7 d)	14,72 (11,04 – 20,30)				
	E_rC_{20} (7 d)	4,96 (2,65 – 7,07)				
	E_rC_{10} (7 d)	2,81 (1,14 – 4,49)				
Na podstawie suchsi masy	Inhibicja przyrostu biomasy [%]	1,93	0,00	28,15	62,57	94,36
	Inhibicja specyficznego tempa wzrostu [%]	0,51	0,00	8,69	25,43	68,48
	Wartości EC [mg/L] z 95% przedziałem ufności (na podstawie nominalnych stężeń badanego materiału)					
	E_yC_{50} (7 d)	6,62 (5,18 – 8,45)				
	E_yC_{20} (7 d)	2,65 (1,63 – 3,57)				
	E_yC_{10} (7 d)	1,64 (0,84 – 2,41)				
	E_rC_{50} (7 d)	19,35 (16,28 – 23,36)				
	E_rC_{20} (7 d)	7,61 (5,42 – 9,55)				
	E_rC_{10} (7 d)	4,67 (2,88 – 6,34)				

Conclusions

In a 7-day semi-static experiment, impact ORKAN 350 SL on the growth inhibition of Lemna minor was tested. The EyC50 value was 4.77 mg / l (95% confidence interval 2.54 - 8.93) and an ErC50 value of 14.72 mg / l (95% confidence interval 11.04 - 20.30) per based on the frond number and an EyC50 value of 6.62 mg / l (95% confidence interval 5.18 - 8.45) and an ErC50 value of 19.35 mg / L (95% confidence interval 16.28 - 23.36) on a dry basis mass.

Values of LOEC and NOEC after 7 days based on the number of fronds for the biomass and specific increment growth rates were not computed for mathematical reasons.

7-day LOEC and NOEC values based on dry weight for biomass and specific increase the growth rates are 3.2 and 1.0 mg / l, respectively.

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

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met as follows: - The average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%) - The 24-hour LD_{50} of the reference item (dimethoate) was 0.13 µg/bee (criterion: 0.10 – 0.35 µg a.i./bee) The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} >200.0 µg/honeybee, corresponding to >44 µg glyphosate/honeybee +15.5 µg MCPA/honeybee

Report	ORKAN 350 SL: Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, Czarnecka M., 2017, Study code: B/228/16 ~~288/16~~
Guideline(s):	OECD 213 / EU Method C.16.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study
The aims of the study were to use a laboratory method to determine the acute oral toxicity of the test item, Orkan 350 SL to adult worker honeybees and to estimate the median lethal dose, i.e. the oral LD_{50} value, if possible.

Study design
Four doses of the test item were used. These included: 25.0, 50.0, 100.0, and 200.0 mg/honeybee (1.9 mg MCPA/honeybee + 5.6 mg glyphosate/honeybee; 3.9 mg MCPA/honeybee + 11.1 mg glyphosate/honeybee; 7.8 mg MCPA/honeybee + 22.2 mg glyphosate/honeybee; 15.5 mg MCPA/honeybee + 44.4 mg glyphosate/honeybee). The final number and the range of doses was selected on the basis of the preliminary test results.
Each group of bees (3 replicates/group; 10 bees/replicate) was fed with 100 mL of a 50% sucrose solution containing the test item using a micropipette. During the entire experiment, the insects were
caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the bees and the precision of the test procedure. After the administration, the insects were observed for mortality and signs of toxicity of the test item (behavioural abnormalities). These observations were made after 4, 24, and 48 hours. The acute oral toxicity test finished after the 48 hours.

Material and methods
Test item: Orkan 350 SL; content: 88.7 g MCPA/L (CAS no.: 94-74-6) and 254.0 g glyphosate/L (CAS no.: 1071-83-6) as active ingredients; batch no.: 02/2016; production date: June 02, 2016; expiry date: June, 2018.
Biological test system : the honeybee, *Apis mellifera* L.; strain: carnica; source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/14];
age: approximately 3 weeks.
Test design: - test item: exposure time: 48 hours; number of doses: 4 doses and a control; number of replicates: 3 replicates containing 10 bees each;
- reference item: exposure time: 24 hours; number of doses: 3 doses;

number of replicates: 3 replicates containing 10 bees each.
Test item doses: 0.0 (control), 25.0, 50.0, 100.0, and 200.0 µg/bee (7.5, 15.0, 30.0, 60.0 mg s.a./honeybee) and control.
Reference item doses: 0.03, 0.06 and 0.12 µg a.i./bee.
Test conditions: temperature: 25ºC, relative air humidity: 63-68%, place: a dark room.
Endpoints:
Statistical method:
- honeybee mortality 48 hours after the administration,
- the oral 24-h LD50 value for the reference item (dimethoate).
probit analysis using linear max. likelihood regression.

Results:
The acute oral toxicity study results of the test item ORKAN 350 SL on honeybees (*Apis mellifera* L.) in the laboratory test after 48 hours, are summarized below.

Table Results of the acute oral toxicity study of Orkan 350 SL on honeybees (*Apis mellifera* L.)

Dose		**Mortality after 48 h**	**LD_{50} after 48 h**	
ORKAN 350 SL [µg/bee]	**MCPA + glyphosate [µg/bee]**	**[%]** *	**ORKAN 350 SL [µg/bee]**	**Active substance [µg/bee]**
0.0 (control)		0.0	above 200.0 (corresponding to >60 a.i/bee)	above 44.4 µg of glyphosate + 15.5 µg of MCPA
25.0	**1.9 + 5.6**	3.3		
50.0	**3.9 + 11.1**	0.0		
100.0	**7.8 + 22.2**	3.3		
200.0	**15.5 + 44.4**	3.3		

After 48 hours of exposure, mortality of the control group and at the doses was 0.0% and for the treated groups' mortality percentages at the doses 25.0, 50.0, 100.0 and 200.0 µg t.i./honeybee, were 3.3, 0.0, 3.3 and 3.3%, respectively.
During the definitive test no abnormal behavioural effects were observed after 48 hours of exposition.

Conclusions:
The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than to 200 µg t.i./honeybee (60.0 mg a.i./honeybee).With respect to the test results, it can be concluded that the test item, Orkan 350 SL had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met as follows: - The average mortality for the total number of controls was 0.0% after 48h (criterion: it must not exceed 10%) - The 24-hour LD_{50} of the reference item (dimethoate) was 0.25 µg/bee (criterion: 0.10 – 0.30 µg a.i./bee) The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: 48 h LD_{50} >200.0 µg/honeybee, corresponding to >44 µg glyphosate/honeybee +15.5 µg MCPA/honeybee

Report	ORKAN 350 SL: Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, Czarnecka M., 2017, Study code: BW/229/16
Guideline(s):	OECD 214 / EU Method C.17.
Deviations:	No

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

Aim of the study
The aims of the study were to use a laboratory method to determine the acute contact toxicity of the test item, Orkan 350 SL to adult worker honeybees and to estimate the median lethal dose, i.e. the contact LD_{50} value, if possible.
Study design
The acute contact toxicity study of the test item, Orkan 350 SL was conducted to estimate the contact LD_{50} values to honeybees (*Apis mellifera* L.). Four doses of the test item were used. These included: 25.0, 50.0, 100.0, and 200.0 mg/honeybee (1.9 mg MCPA/honeybee + 5.6 mg glyphosate/honeybee; 3.9 mg MCPA/honeybee + 11.1 mg glyphosate/honeybee; 7.8 mg MCPA/honeybee + 22.2 mg glyphosate/honeybee; 15.5 mg MCPA/honeybee + 44.4 mg glyphosate/honeybee). The final number and the range of doses was selected on the basis of the preliminary test results.
A microapplicator was used to apply the test item. The volume was 1 mL/bee. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure. After the application, the insects were observed for mortality and signs of toxicity of the test item (behavioural abnormalities). These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.
Materials and methods
Test item: Orkan 350 SL; content: 88.7 g MCPA/L (CAS no.: 94-74-6) and 254.0 g glifosatu/L (CAS no.: 1071-83-6) as active ingredients; batch no.: 02/2016; production date: June 02, 2016; expiry date: June, 2018.
Biological test system: the honeybee, *Apis mellifera* L.; strain: carnica, source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/14]; age: approximately 3 weeks.
Test design: - the test item: exposure duration: 48 hours; number of doses: 4 doses and a control; number of replicates: 3; number of bees: 10 bees/replicate,
- the reference item: exposure duration: 24 hours; number of doses: 3; number of replicates: 3; number of bees: 10 bees/replicate.
Test item doses: 0.0 (control), 25.0, 50.0, 100.0, and 200.0 µg/bee (7.5, 15.0, 30.0, 60.0 mg s.a./honeybee) and control.
Reference item doses: 0.1, 0.2, 0.4 µg a.i./bee.
Test conditions: temperature: 25ºC; relative air humidity: 63-66%; place: a dark room.
Endpoints:
Statistical method:
- honeybee mortality after 48 hours of the exposure,
- the 24 h contact LD50 of the reference item (dimethoate).
probit analysis using linear max. likelihood regression.

Results:
The median lethal doses of ORKAN 350 SL (LD_{50} contact) after 24 and 48 h are higher than the highest used dose, i.e. 200 µg/honeybee. Results are summarized below.

Table 1. Results of the acute contact toxicity study of Orkan 350 SL on honeybees (*Apis mellifera* L.)

Dose		**Mortality after 48 h**	**LD_{50} after 48 h**	
ORKAN 350 SL [µg/bee]	**MCPA + glyphosate [µg/bee]**	**[%] ***	**ORKAN 350 SL [µg/bee]**	**Active substance [µg/bee]**
0.0 (control)		0.0	above 200.0 (corresponding to >60	above 44.4 µg of glyphosate + 15.5 µg of MCPA
25.0	**1.9 + 5.6**	0.0		
50.0	**3.9 + 11.1**	3.3		

100.0	**7.8 + 22.2**	0.0	a.i/bee)	
200.0	**15.5 + 44.4**	3.3		

After 48 hours of exposure, mortality of the control group and at the doses was 0.0% and for the treated groups' mortality percentages at the doses 25.0, 50.0, 100.0 and 200.0 µg t.i./honeybee, were 0.0, 3.3, 0.0 and 3.3 %, respectively.

The median lethal doses LD_{50}/24 h LD_{50}/48 h are higher than the maximum dose, i.e. 200.0 µg t.i./honeybee, used in the study.
During the definitive test no abnormal behavioural effects were observed in doses 25.0, 50.0, 100.0 and 200.0 µg t.i./honeybee.

Conclusions:
The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than 200.0 µg t.i./honeybee (corresponding to 60.0 mg a.i./honeybee). With respect to the test results, it can be concluded that the test item, ORKAN 350 SL, has no adverse effect on mortality of honeybees (*Apis mellifera* L.).

A 2.4 KCP 10.3.2 Effects on arthropods other than bees

Study 1

Comments of zRMS:	The study follows the guideline specified by Mead Briggs M.A. et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met according to Mead Briggs et al.: – after 48 hours, mortality of the control group was 10.0% (criterion: a maximum of 10.0%), – after 48 hours of the exposure to the reference item at the rate of 5.0 mL/ha, mortality, corrected using the formula of Abbott was 66.7% (criterion: a minimum of 50%), – all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), – the mean number of mummies per female in the control group was 30.1 (criterion: a minimum of 5.0 mummies/female), – all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring). Considering the current test guideline (Mead Briggs M.A. et al, 2000) the study is considered valid.

Report	An extended laboratory test for evaluating the effects of ORKAN 350 SL on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez), Czarnecka M., 2017, Study code: B/230/16
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000, Mead-Briggs M.A. et al., 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim and design of the study

The extended laboratory test involved the evaluation of the effects of the test item, Orkan 350 SL on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi.* On the basis of the results of the non-GLP preliminary test, the definitive test was performed as a single-rate limit test. The maximum recommended field rate of 8.0 L Orkan 350 SL/ha (709.6 g MCPA/ha + 2032.0 g glyphosate/ha) was used.

Adult female wasps were exposed to the test item applied to barley plants. Observations of settling behaviour were made during the initial 3 hours of exposure. The aims were to determine repellence of insects from the plants treated with the test item, Orkan 350 SL and to check if the test insects had contact with barley plants sprayed with the test item. Settling behaviour of females from each replicate was observed five times. Mortality was determined 2, 24, and 48 hours after the introduction of the wasps to the test arenas. Females which survived the 48-hour exposure to the test item, Orkan 350 SL and the ones from the control group were subjected to fecundity assessments. Fifteen female wasps from the group treated with the test item, Orkan 350 SL and the control were individually introduced into the fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which the wasp pupae were developing) was recorded. Mortality after 48 hours of exposure and the percentage of fecundity reduction (Pr) 12 days after the oviposition were the endpoints. To verify the sensitivity of the biological test system and the precision of the test procedure, Bi 58 Nowy 400 EC (400 g dimethoate/L), which is an insecticide, was used as a reference item. The rate of the reference item was 5.0 mL/ha (2.0 g dimethoate/ha). The control group was treated with distilled water.

Materials and methods:

Test item: Orkan 350 SL, content: 88.7 g MCPA/L (CAS no.: 94-74-6) and 254.0 g glyphosate/L (CAS no.: 1071-83-6) as active ingredients, batch no.: 02/2016; production date: June 02, 2016; expiry date: June, 2018.

Biological test system: the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez), Hymenoptera: Braconidae, Aphiidinae

– age: adult females (24 - 48 hours after emerging from mummies)

– source: a laboratory-bred culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)

Experimental design: 3 test groups:

– a control group (0.0 L/ha)

– Orkan 350 SL at the rate of 8.0 L/ha (709.6 g MCPA/ha + 2032.0 g glyphosate/ha)

– Bi 58 Nowy 400 EC at the rate of 5.0 mL/ha (2.0 g a.i./ha).

6 replicates/group; 5 females/replicate

Test conditions:

– temperature: 18-20.5°C

– relative air humidity: 68-85%

– photoperiod: 16 hours light (mortality assessment and oviposition: 2345 lx; fecundity assessment: 5195 lx) : 8 hours dark

Statistical analyses: Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, one-way analysis of variance (ANOVA), Chi-square test, Chi-square test with Yate's Correction, Yule's correlation coefficient (Φ), two-sample t-test

Endpoints: – wasp mortality after 48 hours of exposure

– reduction in fecundity (Pr) of the surviving female wasps exposed to the test item, Orkan 350 SL 12 days after the oviposition period

Results:

After 48 hours of exposure ORKAN 350 SL at the rate of 8.0 L/ha percentages of mortality of *A. rhopalosiphi* were 6.7%.

Based on the obtained mortality results LR_{50} could not be estimated. It can be assumed that the LR_{50} is higher than 8.0 L/ha of ORKAN 350 SL.

The fecundity assessment showed that the mean number of mummies per female in the control group was 30.1. As for the wasps treated with ORKAN 350 SL at the rate 8.0 L/ha the mean number of mummies per female was 23.9. Fecundity reduction (Pr) in the group treated with the test item was 6.7%.

Based on the obtained mortality results ER_{50} could not be estimated. It can be assumed that the ER_{50} is higher than 8.0 L/ha of ORKAN 350 SL.

Table 5. Mortality of *A. rhopalosiphi* after 48 hours - definitive test.

Study group [application rate]		Tested wasps [no.]	Mortality								
			Dead wasps [no.]						Total		Corrected[f]
[L/ha][a]	[g a.i.ha][b]		Replicates								
	[g/ha][c]		I	II	III	IV	V	VI	[no.]	[%]	[%]
Control [0.0]		30	0	1	1	0	1	0	3	10.0	-
Orkan 350 SL											
8.0	2741.6 709.6+2032.0	30	0	0	1	0	1	0	2	6.7	(-3.7)[g]
[mL/ha][d]	[g/ha][e]	Bi 58 Nowy 400 EC									
5.0	2.0	30	4	2	4	4	4	3	21	70.0[h]	66.7

The definitive test was performed from between 28.11.2016 – 13.12.2016.

[a]: [L test item/ha]
[b]: [g total active ingredients of the test item/ha]
[c]: [g MCPA/ha + g glyphosate/ha]
[d]: [mL reference item/ha]
[e]: [g active ingredient of the reference item/ha]
[f]: mortality corrected using Abbott's formula [1]
[g]: negative value indicates a lower mortality of the wasps in the group treated with the test item compared to the control
[h]: statistically significant difference compared to the control group (Chi-square test, $p<0.05$, $\Phi=0.6$)

Table 9. Fecundity of *A. rhopalosiphi* - definitive test.

Replicates (isolator number)	Mummies per female 12 days after oviposition [no.]	
	Control	Orkan 350 SL
	Application rate	
	0.0	8.0[a] 2741.6[b] 709.6+2032.0[c]
I	33	31
II	32	27
III	31	24
IV	41	24
V	23	17
VI	41	12
VII	26	28
VIII	14	23
IX	39	22
X	23	24
XI	34	30
XII	28	39
XIII	25	23
XIV	34	21
XV	27	14
Mean number mummies per female ± SD	**30.1 ± 7.4**	**23.9 ± 6.8**
Fecundity reduction relative to the control (Pr) [%]	**-**	**20.4***

SD: standard deviation
[a]: [L test item/ha]
[b]: [g total active ingredients of the test item/ha]
[c]: [g MCPA/ha + g glyphosate/ha]
*statistically significant difference compared to the control group (two-sample t-test, $p<0.05$)

Conclusions:
On the basis of the obtained results it can be concluded that ORKAN 350 SL at the rate of 8.0 L/ha has no adverse effect on the mortality of the wasps. ER_{50} based on fecundity of parasitic wasp is higher than 8.0 L/ha of ORKAN 350 SL.

		~~Mortality~~		~~Fecundity~~			
~~ORKAN 350 SL [µg/bee]~~	~~MCPA + glyphosate [µg/bee]~~	~~Total [%]~~	~~LR_{50} [L/ha]~~	~~ORKAN 350 SL [µg/bee]~~	~~MCPA + glyphosate [µg/bee]~~	~~Total [%]~~	~~ER50 [kg/ha]~~
~~Control~~		~~0.0~~	~~> 8.0~~	~~Control~~	~~Control~~	~~0.0~~	~~> 8.0~~
~~8.0~~	~~709.6+2032~~	~~6.7~~		~~8.0~~	~~709.6+2032~~	~~23.9~~	

The effects of the test item, Orkan 350 SL on mortality and fecundity of *Aphidius rhopalosiphi* in the extended laboratory test are summarized below.

Study group [application rate]			Parameter (endpoint)			
			Mortality after 48 h of the exposure		Fecundity	
Test item			Total	Corre-cted[f]	Mean no. of mummies/ female	Fecundity reduction Pr [%]
[L/ha][a]	[g a.i./ha][b]	[g/ha][c]	[%]	[%]		
Control (0.0)			10.0	–	30.1	–
8.0	**2741.6**	**709.6+2032.0**	6.7	**(-3.7)[g]**	23.9	**20.4[h]**
LR_{50}			above 8.0 L/ha (>2741.6 g a.i./ha)			
Reference item			-			
[mL/ha][d]	[g/ha][e]	-				
5.0	**2.0**		70.0[i]	**66.7**	not assessed	

[a]: [L test item/ha]
[b]: [g total active ingredients of the test item/ha]
[c]: [g MCPA/ha + g glyphosate/ha]
[d]: [mL reference item/ha]
[e]: [g active ingredient of the reference item/ha]
[f]: mortality corrected using the Abbott's formula [1]
[g]: negative value indicates a lower mortality of the wasps in the group treated with the test item compared to the control
[h]: statistically significant difference compared to the control group (two-sample t-test, $p<0.05$)
[i]: statistically significant difference compared to the control group (Chi-square test, $p<0.05$, $\Phi=0.6$)

Study 2

Comments of zRMS:	The study follows the guideline specified by Blümel et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met as follows: - mortality of the control group was 1.7% on day 7 of exposure (criterion: a maximum of 20%), - corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 91.5% on day 7 of exposure (criterion: a minimum of 50%), - the mean number of eggs per female in the control group was 5.6 (required: ≥ 4 eggs per female). Considering the current test guideline (Blümel et al., 2000) the study is considered

	valid.

Report	An extended laboratory test for evaluating the effects of ORKAN 350 SL on the predatory mite, *Typhlodromus pyri* (Sch.) Czarnecka M., 2017, Study code: B/231/16
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim and study design

The aim of the extended laboratory test was to evaluate the effects of the test item, Orkan 350 SL on mortality and reproduction of the predatory mite, *T. pyri* (Sch.). On the basis of a non-GLP preliminary test results, a control and four application rates of the test item were used. The rates were 0.5, 1.0, 2.0, and 4.0 L/ha (44.4 g MCPA/ha + 127.0 g glyphosate/ha, 88.7 g MCPA/ha + 254.0 g glyphosate/ha, 177.4 g MCPA/ha + 508.0 g glyphosate/ha, and 354.8 g MCPA/ha + 1016.0 g glyphosate/ha).

The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to blackberry leaf discs. They were fed with pine pollen (*Pinus sp.*) and the two-spotted spider mite, *Tetranychus urticae* (Carl Ludwig Koch). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and the groups treated with the test item at the rates of 0.5, 1.0, and 2.0 L/ha (44.4 g MCPA/ha + 127.0 g glyphosate/ha, 88.7 g MCPA/ha + 254.0 g glyphosate/ha, and 177.4 g MCPA/ha + 508.0 g glyphosate/ha) were made after 8, 11, and 14 days of the treatment.

Mortality of *T. pyri* after 7 days of the treatment (determination of the LR50 and NOERmortality values) and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, i.e. Bi 58 Nowy 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.

Materials and methods: Test item:	Orkan 350 SL, content: 88.7 g MCPA/L (CAS no.: 94-74-6) and 254.0 g glyphosate/L (CAS no.: 1071-83-6) as active ingredients, batch no.: 02/2016; production date: June 02, 2016; expiry date: June, 2018.
Biological test system:	the predatory mite, *T. pyri* Sch. (Acari: *Phytoseiidae*)
– age:	24-hour-old protonymphs
– source:	a laboratory culture at the Institute of Industrial Organic Chemistry; the culture was obtained from the Research Institute of Horticulture, Skierniewice, Poland
Experimental design:	6 test groups: – a control group (0.0 L/ha) – Orkan 350 SL at the rate of 0.5 L/ha (44.4 g MCPA/ha + 127.0 g glyphosate/ha) – Orkan 350 SL at the rate of 1.0 L/ha (88.7 g MCPA/ha + 254.0 g glyphosate/ha) – Orkan 350 SL at the rate of 2.0 L/ha (177.4 g MCPA/ha + 508.0 g glyphosate/ha) – Orkan 350 SL at the rate of 4.0 L/ha (354.8 g MCPA/ha + 1016.0 g glyphosate/ha) – Bi 58 Nowy 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha) 3 replicates/group; 20 larvae of T.pyri/replicate
Test conditions:	
– temperature:	24-26°C
– relative air humidity:	60-88%
– photoperiod:	16 h day (655 lux) : 8 h night
Statistical analyses:	Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, one-way analysis of variance (ANOVA), Chi-square test, Yule's correlation coefficient (Φ), Step-down Cochran-Armitage test, probit analysis: linear max. likelihood regression, and Williams Multiple Sequential t-test
Endpoints:	– mite mortality after 7 days of the treatment (determination of the LR50 and NOERmortality values), – reproduction reduction (Pr) after 14 days of the treatment.

Results:

In the definitive test, mortality of the control group after 7 days of exposure was 1.7%. After 7 days of exposure to ORKAN 350 SL at rates of 0.5, 1.0, 2.0 and 4.0 L/ha, the percentages of *T. pyri*, mortality were 1.7, 10.0, 33.3 and 73.3%, respectively. There were statistically significant differences in mortality between groups treated with the test item at rates of 1.0, 2.0 and 4.0 L/ha and the control group (Step-down Cochran-Armitage test procedure, $p>0.05$). On the basis of the obtained mortality results, the LR_{50} is 2.7 L/ha of ORKAN 350 SL. The NOERmortality is 0.5 L/ha of ORKAN 350 SL. The mean reproduction rate (Rr) in the control group was 5.6 eggs/female. The mean Rr after 14 days of exposure to ORKAN 350 SL at rates 0.5, 1.0 and 2.0 L/ha were 4.2, 4.3 and 4.5 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.5, 1.0 and 2.0 L/ha were 25.5, 23.3 and 21.0%, respectively.

At the significance level of $\alpha \leq 0.05$, there was no statistically significant difference between the groups treated with the test item and the control group (William multiple sequential t-test procedure).
On the basis of the obtained results the endpoints regarding reproduction could not be determined. It may be assumed that it is higher than the highest rate used in the reproduction assessment. The $NOER_{reproduction}$ could not be determinated.

Table Summary of test results

Concentration of the formulation	**total active ingredients and g MCPA/ha + g glyphosate/ha**	**Mortality**		**Reproduction**			
ORKAN 350 SL ~~[µg/bee]~~ (L/ha)	**[g a.i./ha]**	**Total [%]**	**LR_{50} [L/ha]**	**ORKAN 350 SL ~~[µg/bee]~~**	**Mean number of eggs/ female (Rr)[no.]**	**Reproduction Pr [%]**	**ER_{50} [L/ha]**
Control (0.0)	-	1.7	2.7	Control (0.0)	5.6	-	-
0.5	171.4 44.4+127.0	1.7		0.15	4.2	25.5	
1.0+	342.7 88.7+254.0	10.0		0.96	4.3	23.3	
2.0+	685.4 177.4+508.0	33.3		2.4+	4.5	21.0	
4.0+	1370.8 354.8+1016.0	72.9		-	-	n.a	
$NOER_{mortality}$	**0.5 [L product/ha] 171.4 g a.i./ha g- total 44.4+127.0 g/ha- g MCPA/ha + g glypho-sate/ha**			**$NOER_{reproduction}$ - n.d [L/ha]**			

n.a- not assessed
n.d- not determined

Reproduction of the group treated with the test item at the rate of 4.0 L/ha (1370.8 g a.i./ha) was not assessed, because mite mortality was high, i.e. > 50%.

Conclusions:
Based on the results it can be stated that ORKAN 350 SL, at the rates of 1.0, 2.0 and 4.0 L/ha has significant adverse effect on mortality of the mites. The rates of 0.5, 1.0 and 2.0 L/ha of ORKAN 350 SL have no significant effect on the reproduction of the tested organisms.

On the basis of the obtained mortality results, the LR50 value (the application rate at which the test item is observed to cause 50% mortality of the biological test system), i.e. 2.7 L Orkan 350 SL/ha (925.3 g a.i./ha) and NOERmortality value (the highest rate at which the test item is observed to have no statistically significant effects on mortality), i.e. 0.5 L Orkan 350 SL/ha (171.4 g a.i./ha) were estimated.

statistically significant effects on mortality), i.e. 0.5 L Orkan 350 SL/ha (171.4 g a.i./ha) were estimated. After 7 days of exposure to Bi 58 Nowy 400 EC at the rate of 9.0 mL/ha, mortality of the mites, corrected using the formula of Abbott [1], was 91.5% (Table 2). The relationship between Bi 58 Nowy 400 EC and mite mortality was statistically significant (Chi-square test, $p<0.05$) and almost complete ($\Phi=0.9$). The results showed that the test system was sensitive to dimethoate.

Study 3

Comments of zRMS:	The study follows the guideline specified by Vogt et al. and according to the principles of GLP. Following deviations to the guideline were noted: Temperature: was outside the recommended rate 23 - 28 °C during several short periods of time One decrease of relative humidity: below 60%. However, these deviations did not influence the final results and all the validity criteria were met. In the definitive test all the validity criteria were met as follows: - mortality in the untreated control was 20 %. For the test to be considered valid, it should not exceed 20%. - mortality in the toxic reference treatment was 66.7 %. For the test to be considered valid it should exceed 50%. - fecundity in the untreated control (mean number of eggs per female per day) was 23.7 For the test to be considered valid, the minimum number is 15. - hatching rate (fertility) in the untreated control was 78 %. For the test to considered valid, a minimum mean hatching rate should be 70% The study is considered valid.

Report	GLP rate-response extended laboratory study to determine effects of a plant protection product ORKAN 350 SL on the green lacewing, *Chrysoperla carnea* (Neuroptera: Chrysopidae) Šklíba J., 2020, Study code: 20/254
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt *et al*. (2000)
Deviations:	Yes (did not have any impact on the results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study

A GLP extended laboratory study was conducted to assess the effects of ORKAN 350 SL on mortality and reproductive performance of lacewing Chrysoperla carnea (Neuroptera: Chrysopidae). Mortality and reproductive performance of Chrysoperla carnea was determined after their exposure to fresh dry residues of the test product on bean leaf discs (Phaseolus vulgaris var. Dalmatin)

Material and methods

Test system

- species: Chrysoperla carnea (Neuroptera: Chrysopidae).
- age: 2-3 days old Chrysoperla carnea larvae were used for the trial.
- source: Synchronized Chrysoperla carnea eggs were obtained from a laboratory culture (Katz Biotech AG)

Product tested: The product sample (ORKAN 350 SL, Batch No. A2004002) was provided by the Sponsor 11.8. 2020 and kept under ambient room temperature (i2L chemical store)

Test rates: 5 rates

T1: 24 L/ha: 24L product /ha at 300 L/ha is equal to 40 mL in 500 mL that is 45.68 g (40*1.142) of product in 500 ml of solution 45.68 g of the product fill up to 500 g with demineralized water
T2: 8 L/ha 166.67 g of T1 fill up to 500 g with demineralized water
T3: 2.7 L/ha 166.67 g of T2 fill up to 500 g with demineralized water
T4: 0.9 L/ha 166.67 g of T3 fill up to 500 g with demineralized water
T5: 0.3 L/ha 166.67 g of T4 fill up to 500 g with demineralized water

Number of replicates: 30 test units were made for each treatment (5) and control (2).

Experimental design Product application: Treatments were applied on discs/segments of bean leaves (Phaseolus vulgaris var. Dalmatin) distributed on a 25x35cm glass sitting on a tarred balance. The treatment application was conducted using a powered sprayer (Libertis 5L, Tecnoma, France) with a fine hollow cone nozzle (Berthoud 8/10). The application volume was 300 L/ha ± 5%

- photoperiod: Optimal light conditions (≥1000 lx). The illuminance at the level of the test units was 2000 lx during the light phase of the 16L:8D cycle.
Mortality phase: Survival of the larvae was checked 3 times a week. Pupation and hatching was recorded together with any abnormalities in behaviour and development. Individuals who escaped or were killed by manipulation were subtracted from the initial number of larvae. Mortality was calculated on the basis of the number of healthy adults emerged in the respective treatments.

Fecundity phase: Adults were kept in transparent breeding boxes (approximately 2L) with gauze on the top and water and food provided. The food was prepared of 15 ml condensed milk, 1 egg, 1 egg yolk, 30 g honey, 20 g fructose, 30 g dried brewer's yeast, 50 g wheat germ and approximately 45 ml deionised water and was replaced every 2–3 days. The reproductive test started one week after first egg laying was detested in each breeding box. Before the test, the adults in each box were sexed and the boxes were cleaned from any eggs. Two egg samples covering an egg laying period of 24 hours were taken within one week. Eggs laid on the walls of the reproduction boxes were also counted. The eggs of each sample attached to the gauze were incubated for hatching in containers to determine their fertility. Food was added before the larvae hatch to avoid cannibalism. Hatched larvae were counted and removed from the breeding boxes once a day. When no further hatching of larvae was observed all unhatched eggs on the gauze were counted and the percentage of the hatched eggs was determined.

Statistical analyses were performed with ToxRat 3.3.0.

Results:
After exposure to ORKAN 350 SL at rates of 0.3, 0.9, 2.7, 8.0 and 24 L/ha, the percentages of *C.carnea* corrected mortality were 0.9, 0.0, -7.1, -4.2 and 5.2%, respectively and reduction of reproduction was not observed in any of used rate.

- There were no statistically significant differences in mortality between any group treated with the test item and the control group (Chi² 2x2 Table Test with Bonferroni Correction, p>0.05).

Table 4. Mortality of *C. carnea* females in individual treatments

Treatment ID	Test substance	Application rate (L product /ha)	% mortality	Abbott-corrected % mortality
UTC	water only	-	20.0	0.0
T5	ORKAN 350 SL	0.3	20.7	0.9
T4		0.9	20.0	0.0
T3		2.7	14.3	-7.1
T2		8	16.7	-4.2
T1		24	24.1	5.2
Ref	Dimethoate	40 g a.i./Ha	66.7	58.3

Table 5. Fecundity and egg fertility of *C. carnea* in individual treatments

Treatment ID	Test substance	Application rate (L product /ha)	Fecundity		Fertility
			No eggs per female and day	% decrease	% of hatched eggs
UTC	water only	-	23.8	0	78.0
T5	ORKAN 350 SL	0.3	18.3	23	75.8
T4		0.9	22.4	6	76.0
T3		2.7	17.9	25	79.5
T2		8	29.4	-24	85.7
T1		24	22.0	7	79.5
Ref	Dimethoate	40 g a.i./Ha	n/a	n/a	n/a

On the basis of the obtained mortality results, the LR_{50} is over 24 L/ha of ORKAN 350 SL. The $NOER_{mortality}$ is higher than or equal to 24 L/ha ORKAN 350 SL.
On the basis of the obtained reproduction results, the ER_{50} is over 24 L/ha L/ha of ORKAN 350 SL.

Conclusions:
Based on the results it can be stated that for ORKAN 350 SL the LR_{50} and ER_{50} is over 24 L/ha of ORKAN 350 SL, what indicate safe use of product.

Study 4

Comments of zRMS:	The study follows the guideline specified by Blumel S. et al., 2000 and according to the principles of GLP. Following deviations to the guideline were noted: Four irregularities occurred during the course of the study that considered protocol deviations. *The test item (ORKAN 350 SL) application increased T. pyri mortality in all aged treatments compared to negative control, although not in a predictable way.* *The highest and significantly different (P <0.05) mortality compared to negative control was recorded in the longest ageing interval (14A), whilst the lowest mortality was recorded for the shortest ageing interval (0A). The result could be explained by the different physical condition of aged leaves (14A and 7A) at the test initiation compared to fresh leaves of 0A treatment and negative control. These leaves – already dried after the treatment of glyphosate-based test item (ORKAN 350 SL), could affect the surviving of T. pyri.* All mortality and reproduction tests were considered to be valid as: - mean mortality in the negative control was 19 %. For the test to be considered valid the mean mortality (dead plus escaped individuals) in the negative control should not exceed 20 % on the 7th day of mite exposure. - the cumulative mean number of eggs per female in the control (from the 7th to 14th day following mite exposure) was 4.6 For the test to be considered valid it should be ≥ 4 eggs/female. - the cumulative mean mortality (control corrected) of mites exposed to the fresh toxic reference treatment was 98%. For the test to be considered valid it should range between 50 to 100%. The study is considered valid.

Report	An aged-residue extended GLP laboratory study to determine effects of a plant protection product ORKAN 350 SL on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), Zelová J., 2020, Study code: 20/256
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (2000) (Blumel S. et al., 2000)
Deviations:	Yes (did not have any impact on the results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study

A GLP laboratory study was conducted to assess the side effect of aged residues of ORKAN 350 SL to a non-target arthropod Typhlodromus pyri. Mortality and fecundity of Typhlodromus pyri was determined after their release on leave discs originated from potted bean plants (Phaseolus vulgaris var. DALMATIN) following maximal application (8 L/ha) of three different ageing intervals (14, 7 and 0 days), negative and positive control, all in five replicates per treatment.

Materials and methods
Test system - species: Typhlodromus pyri, Phytoseiidae, Acari
- age: 24 hours old T. pyri protonymphs were used for the trial.
- source: T. pyri eggs were obtained from a laboratory culture of a commercial supplier (Katz Biotech AG).
- rearing: The eggs were delivered 24.09.2020 and kept in an incubator under recommended conditions (18°C) to achieve the exact date of hatching (28 - 29.09.2020),
Test item
Test item tested : ORKAN 350 SL

Test rates
The test item was diluted in demineralized water shortly prior to application and the solution was thoroughly agitated to ensure homogeneity. The application volume for all aged treatments was 300 L/ha. The test item was tested at one maximal application rate specified by the sponsor (Table 2) at three ageing intervals (14, 7 and 0 days).

Product application
The treatment application was conducted using a powered sprayer (Libertis 5L, Tecnoma, France) with a fine hollow cone nozzle (Berthoud 8/10; spray pressure of 3 bars). The pots Study code: 20/256 Page 10 of 39 with mature bean plants were sprayed while placed on 0.25 m2 polystyrene square laying on a tared balance. To achieve the application amount as close to the target value as possible the whole area of the square was sprayed homogeneously until an amount of spray as close to 7.5 g as possible was achieved (for the actual application amounts see Table 3). All final depositions were within ± 10% of the target deposition rate according to i2L SOP/248 (Appendix VII). For the 14 and 7 ageing intervals (14A, 7A), treated leaves were left to dry and then removed from the plants. Dry leaves were cut into the disc shape, placed on a dry cotton patch in a Petri dish with the treated surface facing upwards and left to age in the laboratory for the required time (see Protocol deviation no. 1 in Appendix VI). The bean leaves for 0 ageing interval (0A), negative (water only) and positive (toxic reference) controls were treated, left to dry and used to prepare test units shortly before the trial initiation – release of mites on leaf discs.

Test units
After the spraying the bean plants, mature leaves were removed from these plants [this took place 15.09. 2020 for 14 ageing interval (14A), 22.09.2020 for 7 ageing interval (7A), 29.09.2020 for 0 ageing interval (0A) and controls]. From these leaves approximately 11-14 cm2 segments were cut. The leaf segments with their treated surface facing upwards were laid on a piece of acetate sheet laying on water-saturated cotton wool in plastic Petri-dishes 8.5 cm in diameter. To provide a water source for the mites, a strip of filter paper (approximately 10 Study code: 20/256 Page 11 of 39 mm wide) was laid over the leaf segment in a way it extended approximately 10 mm onto its surface with a remaining approximately 20 mm section on the cotton wool. To prevent the mites from escaping, a barrier was formed around the edge of the leaf segment using nondrying glue (Raupenleim grün, F. Schacht GmbH & Co KG, Bültenweg 48, D-38106 Braunschweig). For an example of the test units see Fig. 1.

Number of replicates
Five replicates were made for each ageing interval and for the toxic reference and untreated control (25 test units in total).

Mite exposure and mortality phase
Cohorts of 20 T. pyri protonymphs were transferred into each test unit using a fine artist brush. To avoid contamination, a new brush was used for each treatment. During the whole Study code: 20/256 Page 12 of 39 experiment, apple pollen was supplied every 2-3 days and the water level in the dishes was topped up every day. The mites were exposed to the test arenas for 7 days before continuing to the fecundity phase. Mortality assessment For the mortality assessment, the condition of the mites was assessed under a binocular microscope after 4 and 7 days. The number of dead (motionless even after touching them with a

fine artist brush), surviving and escaped mites per test unit were counted. Mortality was calculated by adding the number of predatory mites which had escaped to the number of those which had died. This number was compared with the number of mites present at the beginning of the trial. Escapees were those which were not found in the test units.

Fecundity phase

Fecundity assessments were carried out using mites surviving the mortality phase. Sex ratio was assessed on the 7th day of the mite exposure (i.e. at the mortality assessment). The sex ratio did not fall below 5 females: 1 male in any of the test units, no adjustment of the sex ratio was therefore necessary. Any eggs and larvae present on the 7th day of mite exposure were removed from the test units and discarded. In addition, a small shelter, constructed from a strip of clear acetate sheet folded into W-shape, was added close to the centre of each leaf segment. Folds of the acetate sheet are places where females prefer to lay their eggs. Fresh pollen and water were added periodically as in the mortality phase.

Statistical analyses

Statistical analyses were performed following the requirements outlined in Blümel et al. 2000
with Minitab 16 (Minitab Inc.)

Deviations

Protocol deviation no. 1 describes the change in ageing of bean leaves treated by the glyphosate-based test item (ORKAN 350 SL) causing leave necrosis soon after the treatment.

Title: An aged-residue extended GLP laboratory study to determine effects of a plant protection product ORKAN 350 SL on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae)

Description of deviation	The test item ORKAN 350 SL is a glyphosate-based herbicide that caused dying of leaves shortly after the treatment application onto potted *Phaseolus* plants. Therefore, the treated leaves were removed from the plants after the treatment application had dried, they were cut into the disc shape and placed on a dry cotton patch in a Petri dish with the treated surface facing upwards. The leaf discs were left in the laboratory for the ageing intervals 14 and 7 days.
Reason for deviation	ORKAN 350 SL contains glyphosate - a broad-spectrum systemic herbicide that caused dying of *Phaseolus* plants (leaves) that were needed for the tests in 14 and 7 days following the treatment.
Impact on study	No impact. The test item residues at two ageing intervals (14 and 7 days) were tested on dried leaf discs.

Protocol deviation no. 2 describes short temperature deviations outside of the required temperature range.

Protocol deviation no. 3 describes the reason for keeping the supplied T. pyri eggs below 20°C prior to the start of the test.

Protocol deviation no. 4 describes adding of a strip of clear acetate sheet folded into W-shape, close to the centre of each leaf segment in fecundity phase.

Results:

After exposure to ORKAN 350 SL at rates of 8.0 L/ha, the percentages of *T.pyri* corrected mortality were 18.5, 21.0 and 27.2%, for samples applied 0, 7 and 14 days before introduction organisms on treated plants, respectively and reduction of reproduction was -18.2, 48.6 and 46.4, respectively.

Table 4. Mortality of *T. pyri* in individual aged treatments (14A, 7A and 0A), negative control (UTC) and toxic reference control.

Treatment ID	% Mortality mean ± SD	Corrected % mortality after Abbott (1925)	Statistical significance
UTC	19 ± 10.2	0.0	
14A	41 ± 16.4	27.2	*
7A	36 ± 10.2	21.0	
0A	34 ± 12.6	18.5	
Tox. Ref.	98 ± 2.7	97.5	n/a

* mortality significantly higher than in the untreated control (Dunnett's test: P<0.05, following One-way ANOVA)

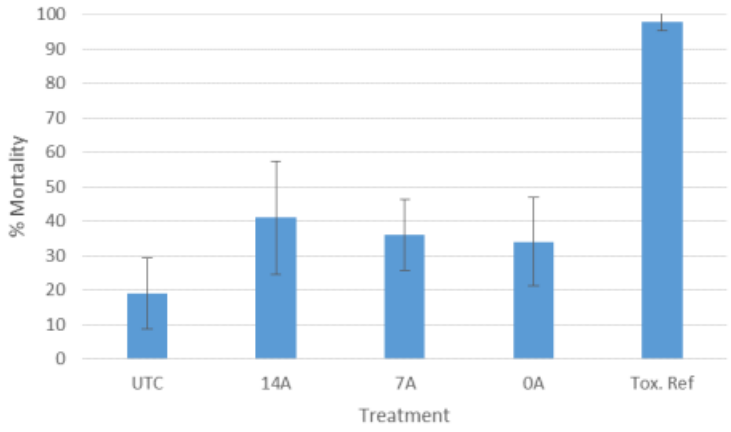


Figure 2. Mean ± SD % mortality in individual aged treatments (14A, 7A, 0A), negative control (UTC) and toxic refference control (Tox. Ref.).

Table 5. Fecundity of *T. pyri* females surviving the mortality phase in negative control (UTC) and aged treatments (14A, 7A and 0A).

Treatment ID	Mean ± SD reproductive output per female	% Mean decrease of reproductive output	Statistical significance
UTC	4.57 ± 0.59	0.0	
14A	2.45 ± 1.56	46.4	
7A	2.35 ± 1.26	48.6	*
0A	5.40 ± 1.55	-18.2	

* reproductive output significantly lower than in the negative control (Dunnett's test: P<0.05, following One-way ANOVA)

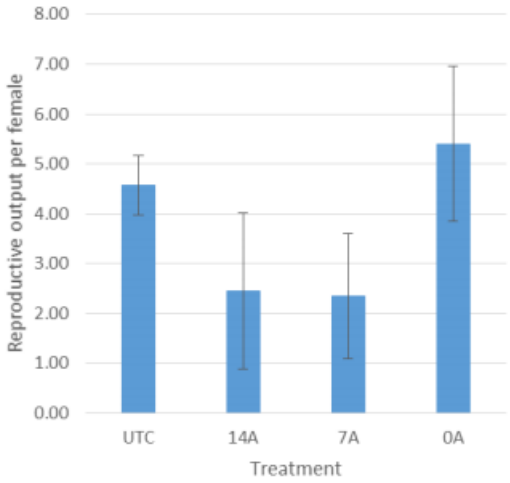


Figure 3. Mean ± SD reproductive output per *T. pyri* females in individual aged treatments (14A, 7A, 0A) and negative control (UTC)

On the basis of the obtained mortality and reproduction results, the LR50 and ER50 are over 8.0 L/ha of ORKAN 350 SL.
Result show low risk for organisms and short time of possible recolonization after treatment.

Conclusions:
Based on the results it can be stated that for ORKAN 350 SL the LR50 and ER50 is over 8.0 L/ha of ORKAN 350 SL, what indicate safe use of product.
The highest and significantly different (P <0.05) mortality compared to negative control was recorded in the longest ageing interval (14A), whilst the lowest mortality was recorded for the shortest ageing interval (0A). The result could be explained by the different physical condition of aged leaves (14A and 7A) at the test initiation compared to fresh leaves of 0A treatment and negative control. These leaves – already dried after the treatment of glyphosate-based test item (ORKAN 350 SL), could affect the surviving of T. pyri.

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

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The ORKAN 350 SL- Earthworm Reproduction Test (*Eisenia fetida*), has been already evaluated and accepted during first authorization of ORKAN 350 SL containing 260 g/L glyphosate and 90 g/L MCPA. The study was conducted to OECD guideline 222 and according to the principles of GLP. No deviation has been noted in the study. In the definitive test all the validity criteria were met: - each replicate produced 156 juveniles (mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment), - the coefficient of variation of reproduction was 11.1 % (criterion: ≤ 30%), - adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%). The study is reliable and suitable for the risk assessment. Overall, the study is considered acceptable with following endpoints: NOEC = 320 mg product/kg dw

Reference:	KCP 10.4
Report	A. Wróbel, 2009 Orkan 350 SL – Badanie wpływu na rozmnażanie się dżdżownic (Eisenia fetida Sav.), Institute of Industrial Organic Chemistry (Pszczyna), Study code: G/16/09, GLP; Unpublished
Guideline(s):	Yes, OECD guideline for the testing of chemicals No. 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary
The aims of the study were to assess the impact of ORKAN 350 SL on reproduction of the earthworm, *Eisenia fetida* and to determine the EC_{10}, EC_{20}, EC_{50}, and NOEC.

Materials and methods
Test item: ORKAN 350 SL
Test organism: the earthworm, Eisenia fetida
Artificial soil: 10% sphagnum peat, 20% kaolin clay, 70% industrial sand
Test design: number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate control, 8, 32, 56, 100, 180, 320, 560 i 1000mg/kg dry soil

Behaviour
The research showed that the ORKAN 350 SL preparation used in concentrations: 18 - 1000 mg / kg dry soil of the artificial substrate did not cause changes in behaviour earthworms and no pathological or physical changes were found in the subjected individuals. There was also no decrease in food consumption by earthworms during the experiment.

Results

After 4 weeks of the experiment, it was concluded that ORKAN 250 SL: - did not cause mortality of adult

earthworm at used concentrations of the test item.

Table1 : Mortality of the adult earthworms (*Eisenia fetida*) after 4 weeks of the experiment

Stężenie [mg/kg s.m. podłoża]	*Powtórzenie*	*Liczba badanych osobników*	*Osobniki martwe*	*Sumaryczna śmiertelność*	
				Szt.	*%*
0,0 (kontrola)	*1*	*10*	*0*		
	2	*10*	*0*	*0*	*0*
	3	*10*	*0*		
	4	*10*	*0*		
	5	*10*	*0*	*0*	*0*
	6	*10*	*0*		
	7	*10*	*0*		
	8	*10*	*0*		
18	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
32	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
56	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
100	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
180	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
320	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
560	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		
1000	*1*	*10*	*0*		
	2	*10*	*0*		
	3	*10*	*0*	*0*	*0*
	4	*10*	*0*		

Table 2: Results of the observation of the adult earthworms (*Eisenia fetida*) after 4 weeks of the experiment for changes in behaviour and in morphology

Stężenie [mg/kg s.m. podłoża]	*Powtórzenie*	*Liczba badanych osobników*	*Zmiany patologiczne i w zachowaniu dorosłych dżdżownic*
0,0 (kontrola)	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
	5	*10*	*10 bz*
	6	*10*	*10 bz*
	7	*10*	*10 bz*
	8	*10*	*10 bz*
18	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
32	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
56	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
100	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
180	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
320	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
560	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*
1000	*1*	*10*	*10 bz*
	2	*10*	*10 bz*
	3	*10*	*10 bz*
	4	*10*	*10 bz*

bz – bez zmian,

bz- no changes

Table 3: Body weight increase in the adult earthworms (*Eisenia fetida)* after 4 weeks of the experiment

Stężenie [mg/kg s.m podłoża]	powtórzenie	Na początku doświadczenia		Po 4 tygodniach doświadczenia		Przyrost masy		Średni przyrost	
		Liczba dżdżownic	Średnia masa 1 dżdżownicy [mg]	Liczba dżdżownic	Średnia masa 1 dżdżownicy [mg]	mg	%	mg	%
0,0 (kontrola)	1	10	537	10	534	-3	-0,5	-1,3	-0,3
	2	10	531	10	584	53	10,0		
	3	10	510	10	516	6	1,2		
	4	10	489	10	462	-27	-5,5		
	5	10	532	10	487	-45	-8,5		
	6	10	541	10	538	-3	-0,6		
	7	10	483	10	496	13	2,7		
	8	10	532	10	528	-4	-0,8		
18	1	10	503	10	513	10	2,0	3,8	0,2
	2	10	500	10	505	5	1,0		
	3	10	486	10	480	-6	-1,2		
	4	10	503	10	509	6	1,2		
32	1	10	507	10	471	-36	-7,1	-20,8	-4,1
	2	10	520	10	506	-14	-2,7		
	3	10	544	10	539	-6	-1,1		
	4	10	497	10	470	-27	-5,4		
56	1	10	506	10	485	-21	-4,2	-7,0	-1,4
	2	10	488	10	482	-6	-1,2		
	3	10	512	10	515	3	0,6		
	4	10	501	10	497	-4	-0,8		
100	1	10	536	10	489	-47	-8,8	2,8	0,8
	2	10	495	10	512	17	3,4		
	3	10	490	10	540	50	10,2		
	4	10	511	10	502	-9	-1,8		
180	1	10	492	10	496	4	0,8	5,3	1,1
	2	10	488	10	471	-17	-3,5		
	3	10	487	10	519	32	6,6		
	4	10	498	10	500	2	0,4		
320	1	10	558	10	495	-63	-11,3	-12,8	-2,1
	2	10	537	10	510	-27	-5,0		
	3	10	498	10	526	28	5,6		
	4	10	502	10	513	11	2,2		
560	1	10	494	10	487	-7	-1,4	-15,5	-3,1
	2	10	534	10	519	-15	-2,8		
	3	10	490	10	464	-26	-5,3		
	4	10	500	10	486	-14	-2,8		
1000	1	10	536	10	487	-49	-9,1	8,0	1,8
	2	10	498	10	520	22	4,4		
	3	10	499	10	529	30	6,0		
	4	10	488	10	517	29	5,9		

Table 4 : Number of juvenile earthworms (*Eisenia fetida*) after 4 weeks of the experiment

Stężenie [mg/kg s.m podłoża]	*Powtórzenie*	*Liczba młodych dżdżownic*	*Średnia ±SD*	*CV [%]*
0,0 (kontrola)	*1*	*166*	*156,4 ± 17,4*	*11,1*
	2	*145*		
	3	*156*		
	4	*145*		
	5	*126*		
	6	*171*		
	7	*161*		
	8	*181*		
18	*1*	*158*	*144,5± 13,4*	*9,3*
	2	*126*		
	3	*148*		
	4	*146*		
32	*1*	*125*	*132,0± 26,2*	*19,8*
	2	*104*		
	3	*132*		
	4	*167*		
56	*1*	*138*	*144,0± 9,9*	*6,9*
	2	*134*		
	3	*156*		
	4	*148*		
100	*1*	*160*	*142,0± 14,6*	*10,3*
	2	*138*		
	3	*145*		
	4	*125*		
180	*1*	*163*	*155,0± 14,5*	*9,3*
	2	*157*		
	3	*166*		
	4	*134*		
320	*1*	*117*	*142,5± 19,4*	*13,6*
	2	*163*		
	3	*150*		
	4	*140*		
560	*1*	*127*	*117,8± 7,6*	*6,5*
	2	*111*		
	3	*112*		
	4	*121*		
1000	*1*	*83*	*71,8± 7,7*	*10,7*
	2	*66*		
	3	*68*		
	4	*70*		

Conclusion

Table 5 : Endpoint values determined during the earthworm (*Eisenia fetida*) reproduction test

EC_{50}	*NOEC*	*LOEC*
Stężenie mg/kg suchej masy podłoża		
931,6 (683,4 – 2868,2)	*320*	*560*

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

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

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 226 and according to the principles of GLP. No deviations from the Guideline were found. The validity criteria for the control group were met: – Mean mortality of adult females: ≤ 20% (observed: 10 %) - Mean number of juvenile per replicate: ≥ 50 (calculated: 56.5) – Coefficient of variation (mean number of juveniles per replicate): ≤ 30 % (calculated: 3.8 %) The study is reliable and suitable for the risk assessment.

Aim of the study
A study to evaluate the effect of the tested item ORKAN 350 SL on the reproduction of predatory mites *Hypoaspis aculeifer* was carried out on the basis of the OECD guideline 226. During the test, the influence of the tested item on the number of offspring and survival of parent animals was determined in comparison to the control group.

Tested species
The research system composed of females of Hypoaspis aculeifer in the age of 7-14 days after reaching maturity, i.e. 28-35 days after beginning of synchronization (eggs laying).

Report	Predatory mite Hypoaspis aculeifer reproduction test according to guideline ~~Badanie rozmnażania roztoczy *Hypoaspis aculeifer* według wytycznej~~ OECD 226, Woźniak Agnieszka., 2020, Study code: 0030/0012/E
Guideline(s):	OECD No. 226
Deviations:	Yes (did not have any impact on the results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test organism	*Hypoaspis aculeifer*
Test design	14 days of exposure
Nominal test item concentrations	16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, 1000 mg/L Tested concentrations were prepared in four replicates, whereas control in eight replicates.

Tested concentrations definitive test:	
mg of the test item/kg dry weight of soil)	the sum of the geometric mean of the determined concentrations of active substances during the definitive test

	control (0 mg of the test item/kg dry weight of soil)	control (0 sum mg of the active substances/kg of dry weight of soil)
	16.33	3.110
	29.40	6.377
	52.92	11.383
	95.26	18.035
	171.47	34.004
	308.64	70.556
	555.56	104.335
	1000.0	195.508
Test conditions	definitive test: -average temperature 20.241°C (minimal temperature 18.70°C; maximal temperature 21.10°C) -photoperiod 16 h day/8 h night with light intensity 625-670 lux	
Environmental conditions	duration time: 14 days. -Test vessels and density: experiment was conducted using plastic containers of diameter approximately 4 cm. In one test vessel were 10 adult female mites. The animals in groups of 10 were distributed into the test vessels - Feeding: during the test, mites were fed with young Folsomia candida individuals in ad libidum amount. pH: pH value in test vessels was maintained at level of 6.20-6.36 at the beginning of the test and 6.20–6.41 at the end of the test (required in OECD 226: pH 6.0±0.5). - Water content: soil moisture was maintained through test vessels weight measurements during the test and addition of proper deionized water amount. Water content at the beginning of the test was 17.48-18.88% (which corresponds to 48.55-52.43% WHC) and 17.30–19.03% at the end of the test (which corresponds to 48.06-52.85% WHC). Water content difference before and after the test was from -8,34 to 7,40 % (required in OECD 226: 40-60% maximal water holding capacity, maximal water content difference 10%). - Lighting: lighting in daily cycle 16 hours light of light intensity 625-660 lux (required in OECD 226: 400-800 lux) and 8 hours of darkness. - Temperature: test was conducted at average temperature 20.469°C; minimal temperature 18.60°C; maximal 22.0°C (required according to OECD 226: 20±2°C).	
Statistical data analysis	Based on obtained data, statistical analysis was performed in accordance with OECD 226 Guideline using ToxRat Professional statistical software.	

Results:

Table 16. Adult individuals mortality – definitive test

Nominal concentration [mg of the test item/kg dry weight of soil]	Introduced adult individuals [pcs.]	Survived adult individuals [%]	Dead adult individuals [pcs.]	Mortality [%]	Statistical significance*)
Control	80	90.00	8	10.00	not applicable
16.33	40	87.50	5	12.50	-
29.40	40	87.50	5	12.50	-
52.92	40	95.00	2	5.00	-
95.26	40	92.50	3	7.50	-
171.47	40	87.50	5	12.50	-
308.64	40	97.50	1	2.50	-
555.56	40	87.50	5	12.50	-
1000.0	40	90.0	4	10.00	-

- statistically insignificant
*) values calculated by ToxRat Professional using Chi2x2 Test after Bonferroni correction at significance level p>0.05

Table 17. Offspring number – definitive test

Nominal concentration [mg of the test item/kg dry weight of soil]	Average offspring number [pcs.]	Reduction [%]	Statistical significance *)
Control	112.9	not applicable	not applicable
16.33	103.8	8.084	-
29.40	104.0	7.863	-
52.92	107.8	4.540	-
95.26	104.5	7.420	-
171.47	94.5	16.279	+
308.64	91.0	19.380	+
555.56	85.3	24.474	+
1000.0	84.8	24.917	+

- statistically insignificant
+ statistically significant
*) values calculated by ToxRat Professional using t-Welsh test after Bonferroni-Holm test at significance level p≤0,05

Analytical measurements

Table 35. Calculation of the differences in nominal concentrations from those determined for the active substance glyphosate – definitive test

Date [day]	Determined concentration of the active substance - glyphosate [mg active substance/kg dry weight of soil]	Difference to nominal concentration [%]
Nominal concentration of the active substance - glyphosate 3.73414 mg active substance/kg dry weight of soil		
0	3.21644	-13.80
7	2.35209	-36.96
14	1.70564	-54.29
Nominal concentration of the active substance - glyphosate 6.71790 mg active substance/kg dry weight of soil		
0	5.58729	-16.83
7	5.01658	-25.33
14	3.93497	-41.43
Nominal concentration of the active substance - glyphosate 12.09222 mg active substance/kg dry weight of soil		
0	10.13773	-16.16
7	8.28373	-31.50
14	7.03412	-41.83
Nominal concentration of the active substance - glyphosate 21.76691 mg active substance/kg dry weight of soil		
0	18.40240	-15.46
7	13.70794	-37.02
14	9.65135	-55.66
Nominal concentration of the active substance - glyphosate 39.18090 mg active substance/kg dry weight of soil		
0	33.61910	-14.20
7	27.05871	-30.94
14	18.06535	-53.89
Nominal concentration of the active substance - glyphosate 70.52424 mg active substance/kg dry weight of soil		
0	66.23590	-6.08
7	52.43017	-25.66
14	42.44491	-39.82
Nominal concentration of the active substance - glyphosate 126.94546 mg active substance/kg dry weight of soil		
0	112.67676	-11.24
7	86.74445	-31.67
14	49.68849	-60.86
Nominal concentration of the active substance - glyphosate 228.50000 mg active substance/kg dry weight of soil		
0	202.51360	-11.37
7	165.70989	-27.48
14	93.42557	-59.11

Table 36. Calculation of the differences in nominal concentrations from those determined for the active substance MCPA – definitive test

Date [day]	Determined concentration of the active substance – MCPA [mg active substance/kg dry weight of soil]	Difference to nominal concentration [%]
Nominal concentration of active substance – MCPA 1.29824 mg of active substance/kg of dry weight of soil		
0	1,17457	-9,53
7	0,81968	-36,86
14	0,46490	-64,19
Nominal concentration of active substance – MCPA 2.33730 mg of active substance/kg of dry weight of soil		
0	1,93298	-17,30
7	1,71313	-26,70
14	1,19442	-48,90
Nominal concentration of active substance – MCPA 4.20714 mg active substance/kg dry weight of soil		
0	3,93845	-6,39
7	2,84874	-32,29
14	2,38748	-43,25
Nominal concentration of active substance – MCPA 7.57317 mg of active substance/kg of dry weight of soil		
0	6,33354	-16,37
7	5,13404	-32,21
14	2,95798	-60,94
Nominal concentration of active substance – MCPA 13.63187 mg of active substance/kg of dry weight of soil		
0	11,41032	-16,30
7	10,22391	-25,00
14	5,41381	-60,29
Nominal concentration of active substance – MCPA 24.53688 mg of active substance/kg of dry weight of soil		
0	21,21943	-13,52
7	19,61589	-20,06
14	13,39444	-45,41
Nominal concentration of active substance - MCPA 44.16702 mg of active substance/kg of dry weight of soil		
0	37,20308	-15,77
7	29,81136	-32,50
14	15,36038	-65,22
Nominal concentration of active substance – MCPA 79.50000 mg of active substance/kg of dry weight of soil		
0	69,45504	-12,64
7	56,78249	-28,58
14	30,10258	-62,14

Table 38. The sum of the geometric mean of the determined concentrations of active substances – definitive test

Nominal concentration [mg of the test item/kg dry weight of soil]	Nominal sum of active substance [sum of mg active substances/kg dry weight of soil]	The sum of the geometric mean of the determined concentrations of active substances [sum of mg active substances/kg dry weight of soil]
16.33000	5.02964	3.11046
29.40000	9.05520	6.37714
52.92000	16.29936	11.38266
95.26000	29.34008	18.03454
171.47000	52.81276	34.00386
308.64000	95.06112	70.55617
555.56000	171.11248	104.33473
1000.00000	308.00000	195.50830

Table 1. Final results

Final results calculated using ToxRat Professional based on geometric mean of active substances					
Parameter	**Sum of mg active substances/kg dry weight of soil**				
	EC_{10}	**EC_{20}**	**EC_{50}**	**NOEC**	**LOEC**
Offspring number	16.163 (4.882– 53.512)*	85.844 (22.710 – 342.320)*	nd. (n.d. – n.d.)*	18.035	34.004
Parameter	**LC_{10}**	**LC_{20}**	**LC_{50}**	**NOEC**	**LOEC**
Adult survival	n.d.**) (n.d. – n.d.)*	n.d. **) (n.d. – n.d.)*	n.d. **) (n.d. – n.d.)*	≥195.508	>195,508

EC_{10} determined sum of the active substance concentration causing reduction by 10%
EC_{20} determined sum of the active substance concentration causing reduction by 20%
EC_{50} determined sum of the active substance concentration causing reduction by 50%
LC_{10} determined sum of the active substance concentration causing mortality in 10% of individuals
LC_{20} determined sum of the active substance concentration causing mortality in 20% of individuals
LC_{50} determined sum of the active substance concentration mortality in 50% of individuals
LOEC the lowest determined sum of the active substance concentration causing statistically significant differences in comparison to the control
NOEC the highest non observe effective determined sum of the active substance concentration causing no statistically significant differences in comparison to the control
nd. impossible due to the mathematical reasons
*) in the brackets is given lower and upper 95% confidence interval
) **based on the analysis of the results, the value was determined as> 195.508 sum of mg active substances/kg soil dry weight

On the basis of the results, it was concluded that after 14 days, at the control group the mortality of adult mites was 10%. At concentrations ranging from 16.33 to 1000 mg of the test item/kg dry weight of artificial soil, after 14 days of exposure to the test item, mortality of the adult mites was ranging from 2.5 to 12.5%. According to calculations, there were no statistically significant differences between the test item concentrations and the control.
The concentration of the test item causing 50% mortality of the adult mites (LC_{50}) is higher than 1000 mg/kg dry weight of artificial soil.
After 14 days of the experiment, it was concluded that ORKAN 350 SL had no statistically significant impact on reproduction of the mites at the concentrations up to 95.26 mg/kg dry weight of artificial soil.

Conclusions

	ORKAN 350 SL [mg/kg dry weight of artificial soil]
NOEC (reproduction)	**95.26**
LOEC (reproduction)	**171.47**
LC_{50}	**Not determined (>1000)**
NOEC (survival)	**≥1000**
LOEC (survival)	**>1000**

Study 2

Comments of zRMS:

The study was conducted to OECD guideline 232 and according to the principles of GLP.

Following deviations were noted:
The temperature during the range-finding test and definitive test the temperature exceeded the temperature recommended by the OECD guideline 232. Range-finding test: minimal temperature 17.9°C, maximal temperature 22.2°C; definitive test: minimal temperature 17.9°C (required in accordance with OECD 232: 20±2°C). Temperature fluctuations were not affected on the condition of the test system. Due to the lack of availability of the dye Kentmere recommended by OECD guideline 232, dark non-toxic food dye was used in the extraction of organisms. These deviations had no effect on the course of the study since all the validity criteria of the study were met.

The test met all the Validity criteria in accordance with OECD 232:

Validity criterion	Recommended	Obtained
Mean adult mortality at the end of the test in the untreated controls	should not exceed 20%	1.3%
The mean number of juveniles per vessel at the end of the test; in the untreated controls	at least 100	342.875
The coefficient of variation calculated for the number of juveniles at the end of the definitive test in the untreated controls	less than 30%	11.8%
the efficiency of the method used to extract the springtails in test	should be > 95%.	99.31
mean number of juveniles in the toxic reference treatment	at least 50% lower than in the control treatment	97.751% reduction

The study is reliable and suitable for the risk assessment.

Report	Collembolan *Folsomia candida* reproduction test according to guideline ~~Badanie rozmnażania skoczogonków *Folsomia candida* według wytycznej~~ OECD 232, Meler Agnieszka, 2020, Study code: 0030/0013/E
Guideline(s):	OECD No. 232
Deviations:	Yes (did not have any impact on the results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

The aim of the study
The conducted study was aimed at determine the impact of the test item on reproduction of soil invertebrates, collembolans Folsomia candida. During the study, the impact of the test item on the offspring number and the survival of the parental individuals were determined. The effect of the test item was compared with a control group.

Materials and methods

<table>
<tr><td>Test organism</td><td>Folsomia candida</td></tr>
<tr><td>Test design</td><td>28 days of exposure
tested concentrations in four replicates and control in eight replicates
(10 individuals per replicate), random arrangement of test vessels</td></tr>
<tr><td>Nominal test item concentrations</td><td>16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, 1000 mg test item /L

<table>
<tr><td colspan="2">Tested concentrations definitive test:</td></tr>
<tr><td>mg of the test item/kg dry weight of soil)</td><td>the sum of the geometric mean of the determined concentrations of active substances during the definitive test</td></tr>
<tr><td>control (0 mg of the test item/kg dry weight of soil)</td><td>control (0 sum mg of the active substances/kg of dry weight of soil)</td></tr>
<tr><td>16.33</td><td>2.736</td></tr>
<tr><td>29.40</td><td>5.038</td></tr>
<tr><td>52.92</td><td>8.267</td></tr>
<tr><td>95.26</td><td>14.278</td></tr>
<tr><td>171.47</td><td>24.665</td></tr>
<tr><td>308.64 (NOEC)</td><td>43.080</td></tr>
<tr><td>555.56</td><td>76.582</td></tr>
<tr><td>1000.0</td><td>135.698</td></tr>
</table></td></tr>
<tr><td>Experimental conditions:</td><td>definitive test mean temperature 19.896°C (minimal temperature 17.9°C, maximal temperature 21.0°C); photoperiod 16 h day/8 h night with light intensity 668-690 lux

- Feeding: collembolans were fed at the beginning for the test, and after two weeks with lyophilized
bakers’ yeast.
Amount and frequency of feeding are presented in Table 17.
- Soil moisture: soil moisture was maintained by measurement of test containers mass during the test
and addition of proper amount of the deionized water. The weight of test containers did not differ
by more than 2% (required in accordance OECD 232: <2%). Soil moisture was 16.20-17.13%
at the beginning of the test, which corresponds to 52.43-55.44% of maximal water holding capacity
and 15.00-15.80% at the end of the test, which corresponds to 48.54-51.13% WHC (required
in accordance with 232: 40-60% WHC).
Results of soil moisture are shown in Table 19, and water capacity in Table 20.
- pH of the soil: pH value in the test containers were maintained at the level of 6.145-6.365
at the beginning of the test and 6.075-6.30 at the end of the test.
Results of the pH measurements are shown in Table 18.
- Light intensity: fluorescent lighting in the diel cycle of 16 hours of light of the intensity 668-690 lux</td></tr>
</table>

	(required in accordance with OECD 232: 400-800 lux) and 8 hours of darkness. Results of light intensity measurement are presented in Table 21. - Temperature: the experiment was conducted in the average temperature of 19.896°C; minimal temperature 17.9°C, maximal temperature 21.0°C (required in accordance with OECD 232: 20±2°C).
Statistical analysis	On the basis of the obtained data, a statistical analysis was performed using the ToxRat Professional statistical program

Results:
On the basis of the results, it was concluded that after 28 days, at the control group the mortality of adult collembolans was 1.3%. At concentrations ranging from 16.33 to 1000 mg of the test item/kg dry weight of artificial soil, after 28 days of exposure to the test item, mortality of the adult collembolans was ranging from 0.0 to 25.0%.

Final results

Analytical measurements

Table 25. Calculation of the differences in nominal concentrations from those determined for the active substance glyphosate – definitive test

Date [day]	Determined concentration of the active substance - glyphosate [mg active substance/kg dry weight of soil]	Difference to nominal concentration [%]
Nominal concentration of the active substance - glyphosate 3.73414 mg active substance/kg dry weight of soil		
0	3.52504	-5.53
14	1.72148	-53.87
28	1.50256	-59.73
Nominal concentration of the active substance - glyphosate 6.71790 mg active substance/kg dry weight of soil		
0	6.02961	-10.25
14	3.93904	-41.37
28	2.43121	-63.81
Nominal concentration of the active substance - glyphosate 12.09222 mg active substance/kg dry weight of soil		
0	11.13763	-7.89
14	7.13901	-40.96
28	3.16427	-73.83
Nominal concentration of the active substance - glyphosate 21.76691 mg active substance/kg dry weight of soil		
0	19.64528	-9.75
14	9.65075	-55.66
28	7.55541	-65.29
Nominal concentration of the active substance - glyphosate 39.18090 mg active substance/kg dry weight of soil		
0	32.83215	-16.20
14	17.90860	-54.29
28	11.51443	-70.61
Nominal concentration of the active substance - glyphosate 70.52424 mg active substance/kg dry weight of soil		
0	65.86044	-6.61
14	33.86549	-51.98
28	15.45565	-78.08
Nominal concentration of the active substance - glyphosate 126.94546 mg active substance/kg dry weight of soil		
0	107.65331	-15.20
14	49.84877	-60.73
28	37.31754	-70.60
Nominal concentration of the active substance - glyphosate 228.50000 mg active substance/kg dry weight of soil		
0	193.61453	-15.27
14	92.80244	-59.39
28	63.87946	-72.04

The tested item has a statistically significant effect on the number of mite offspring at the nominal concentration of 555.56 mg of the test item/kg dry weight of soil, 1000.0 mg of the test item/kg dry weight of soil, which correspond to the geometric mean of the sum of active substances determined during the test 76.582 sum mg of active substances/kg of soil dry weight, 135.698 sum mg of active substances/kg dry weight of soil. The tested item has a statistically significant effect on the survival of adults at the nominal concentration of 171.47 mg of the test item/kg dry weight of soil, 308.64 mg of the test item/kg dry weight of soil, 555.56 mg of the test item/kg dry weight of soil, 1000.0 mg of the test item/kg dry weight of soil correspond to the geometric mean of the sum of active substances determined during the test 24.665 sum mg of active substances/kg of soil dry weight to 135.698 sum mg of active substances/kg of soil dry weight. Final results are shown in Table below.

Table 1. Final results

Final results calculated using ToxRat Professional based on geometric mean of active substances			
Parameter	**Number of juvenile**	**Parameter**	**Adult individuals survival**
EC_{10} [sum of mg active substances/kg dry weight of soil]	44.647 (24.240-82.236)*	**LC_{10} [sum of mg active substances/kg dry weight of soil]**	29.318 (16.913-44.994)*
EC_{20} [sum of mg active substances/kg dry weight of soil]	78.210 (40.482-154.473)*	**LC_{20} [sum of mg active substances/kg dry weight of soil]**	73.963 (48.032-143.237)*
EC_{50} [sum of mg active substances/kg dry weight of soil]	228.579 (75.320-662.442)*	**LC_{50} [sum of mg active substances/kg dry weight of soil]**	n.d.** (n.d.-n.d.)*
LOEC [sum of mg active substances/kg dry weight of soil]	76.582	**LOEC [sum of mg active substances/kg dry weight of soil]**	24.665
NOEC [sum of mg active substances/kg dry weight of soil]	43.080	**NOEC [sum of mg active substances/kg dry weight of soil]**	14.278

EC_{10} determined sum of the active substance concentration causing reduction by 10%
EC_{20} determined sum of the active substance concentration causing reduction by 20%
EC_{50} determined sum of the active substance concentration causing reduction by 50%
LC_{10} determined sum of the active substance concentration causing mortality in 10% of individuals
LC_{20} determined sum of the active substance concentration causing mortality in 20% of individuals
LC_{50} determined sum of the active substance concentration mortality in 50% of individuals
LOEC the lowest determined sum of the active substance concentration causing statistically significant differences in comparison to the control
NOEC the highest non observe effective determined sum of the active substance concentration causing no statistically significant differences in comparison to the control
nd. impossible due to the mathematical reasons
*) in the brackets is given lower and upper 95% confidence interval
) **based on the analysis of the results, the value was determined as> 135.698 sum of mg active substances/kg soil dry weight

The concentration of the test item causing 50% mortality of the adult collembolans (LC_{50}) is not determined (over 1000 mg/kg dry weight of artificial soil).
After 28 days of the experiment, it was concluded that ORKAN 350 SL had statistically significant impact on reproduction of the collembolans at the concentrations 555.56 and 1000 mg/kg dry weight of artificial soil.

Conclusions

	ORKAN 350 SL [mg/kg dry weight of artificial soil]
NOEC (reproduction)	**308.64**
LOEC (reproduction)	**555.56**
LC_{50}	**Not determined (>1000)**
NOEC (survival)	**95.26**
LOEC (survival)	**171.47**

A 2.5.2.1 KCP 10.4.2.1 Species level testing

A 2.5.2.2 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil microbal activity

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. No deviations were noted. In the definitive test all the validity criteria were met as follows: - The coefficients of variation (CV) in the control were 9.3; 6.7; 10.6; 10.2 % and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%. The soil nitrate formation rates were below the 25% trigger value given by the OECD 216 guideline. On the basis of the results, it was concluded that ORKAN 350 SL at the concentrations of 12.2 mg/kg of the soil and 61 mg/kg of the soil, did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Report	ORKAN 350 SL: Soil Microorganisms: Nitrogen Transformation Test, Dec W., 2017, Study code: G/111/16
Guideline(s):	OECD 216 / EU Method C.21.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study

The aim of the study was to detect long-term adverse effects of ORKAN 350 SL on the processes of nitrogen transformation in aerobic surface soils.

Study design

Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm.
The concentrations of the test item were 12.2 mg/kg (PEC)1 and 61 mg/kg (5xPEC) of the soil. The treated and the control soils were divided into three replicates.
On the basis of nitrate ion concentration measured in a given volume of soil extract samples, concentration of nitrate ions in soil samples on 0, 7, 14 and 28 day of experiment was calculated. The values were expressed as mg of nitrate ions / kg dry weight of soil.
The method involves a measurement of the nitrate ion concentration in a soil extract obtained by using distilled water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used.
On the basis of nitrate ions concentration obtained after 0, 7, 14 and 28 days of experiment, the mean nitrate formation rates [mg / kg dry weight of soil / day] for selected time intervals i.e. 0-7, 0–14 and 0–28

were calculated. The percentage deviation from the control was calculated using the nitrate formation rate [mg/kg dry weight of soil/day] in selected time intervals, i.e. 0 – 7, 0 – 14 and 0 – 28.
The coefficient of variation (CV) for the control groups was calculated on the basis of nitrate ions concentration [mg/kg dry weight of soil] after 0, 7, 14 and 28 days of the experiment.

Material and methods

Test item:	**ORKAN 350 SL**
Soil:	Agricultural soil, taken from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna
Test design:	three portions of soil (3 x 1500 g), i.e. control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.
Concentrations of the test material:	control; 12.2 mg/kg of the soil (PEC) and 61 mg/kg of the soil (5xPEC).
Test conditions:	Temperature: 18 – 20°C, soil moisture: 46.4% – 54.9% of the maximum water holding capacity, incubation in darkness.
Endpoints:	The concentration of nitrate ions [mg/kg dry weight of soil] after 0, 7, 14 and 28 days of incubation. The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14 and 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14 and 0– 28 days.

Statistical analysis:
- Shapiro-Wilk's test on Normal Distribution
- Levene's Test on Variance Homogenity (with Residuals)
- Williams Multiple Sequential t-test Procedure
- Student-t test for Homogenous Variances

Results:
The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 12.2 mg test item/kg dry weight soil and 5 x PEC: 61 mg the test item/kg dry soil did not exceed 25% on 28 day of analysis. Detailed results are presented in tables below.

Table 8. Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC 12.2 mg of the soil				5 x PEC 61mg of the soil			
	Replicate I	Replicate II	Replicate III	mean ± SD	Replicate I	Replicate II	Replicate III	mean ± SD	Replicate I	Replicate II	Replicate III	mean ± SD
0 - 7	4.018	2.982	2.104	3.035 ± 0.96	3.882	4.775	4.975	4.544+ ± 0.58	1.451	1.108	2.108	1.556+ ± 0.51
0 - 14	4.260	3.588	2.363	3.404 ± 0.96	5.795	5.895	5.767	5.819+ ± 0.07	5.401	4.923	5.030	5.118+ ± 0.25
0 - 28	5.814	7.659	7.414	6.962 ± 1.0	8.393	7.559	7.189	7.714 ± 0.62	8.156	6.797	6.881	7.278 ± 0.76

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

+ - statistically significant differences

Table 9. Deviations from the control based on nitrogen ion formation rate for selected time intervals [%].

Time interval [d]	PEC (12.2 mg/kg of the soil)	5xPEC (61 mg/kg of the soil)
0 - 7	49.74	-48.72
0 - 14	70.97	50.37
0 - 28	10.79	4.54

"-" values of nitrate formation rate lower than the one obtained for the control

Conclusions:

On the basis of the results, it was concluded that ORKAN 350 SL at the concentration corresponding to the PEC: 12.2 mg test item/kg dry weight soil and 5 x PEC: 61 mg the test item/kg dry did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	Since Carbon Transformation Test is no longer data requirement, thus the study was not evaluated by zRMS

~~Study 2~~

~~Report~~	~~ORKAN 350 SL: Soil Microorganisms: Carbon Transformation Test, Dec W., 2017, Study code: G/112/16~~
~~Guideline(s):~~	~~OECD 216 / EU Method C.21.~~
~~Deviations:~~	~~No~~

~~GLP:~~ ~~Yes~~

~~Acceptability:~~ ~~Yes~~

~~Duplication (if vertebrate study)~~ ~~No~~

~~**Results:**~~

~~The difference in the carbon transformation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 12.2 mg test item/kg dry weight soil and 5 x PEC: 61 mg the test item/kg dry soil did not exceed 25% on 28 day of analysis.~~

~~**Conclusions:**~~

~~On the basis of the results, it was concluded that ORKAN 350 SL at the concentration corresponding to the PEC: 12.2 mg test item/kg dry weight soil and 5 x PEC: 61 mg the test item/kg dry did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.~~

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

A 2.7.1 KCP 10.6.2 Testing on non-target plants

Study 1

Comments of zRMS:	The study has only polish title, thus for clarity reasons the title was translated by zRMS: Evaluation the impact of ORKAN 350 SL on Seedling Emergence and Seedling Growth Test according to the OECD Guideline No. 208 The Applicant performed the study only in polish; thus the English summary is presented only as executive summary. The seedling emergence study was conducted to OECD guideline 208 and according to the principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met as follows: Validity criteria in the study: • The control seedling emergence should be ≥ 70 % (observed: 70.8 to 100%). • No visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) were observed on the control seedlings of each species and normal variation in growth and morphology of control plants was observed. • The mean survival of emerged control seedlings should be ≥ 90 % (observed: 100 %). • The environmental conditions for each particular species were identical and growing media contained the same amount of soil matrix, support media, or substrate from the same source. The study is considered acceptable for the risk assessment purposes.

Report	Evaluation the impact of ORKAN 350 SL on Seedling Emergence and Seedling Growth Test according to the OECD Guideline No. 208 Ocena toksyczności preparatu ORKAN 350 SL w stosunku do kiełkowania i wzrostu siewek zgodnie z metodyką OECD 208, 23B-04-16, Kaźmierczuk

	M., 2018.
Guideline(s):	OECD 208
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test organism	*Brassica napus, Lolium, perenne, Alium cepa, Avena sativa, Helianthus annuus, Cucumis sativus*
Test design	21d of exposure
Nominal test item concentrations	8.0, 2.667, 0.889, 0.296, 0.099, 0.033 mg/L
Temperature:	20.3-28.4^{0}C
Photoperiod:	16 h light: 8 h dark
Relative humidity:	60-73%
Time of the exposure	21 days

Results:

Test item in the concentrations of 8.0 and 2.667 L/ha delay germination of Brassica napus and Helianthus annuus. Each used test item concentrations inhibit the germination of Allium cepa, test item concentrations of 8.0 and 2.667 L/ha inhibit germination of Cucumis sativus and test item concentration of 8.0 L/ha inhibit germination of Lolium perenne and Avena sativa.

The test item cause mortality of the seedlings of Allium cepa in the test item concentrations of 0.889 – 8.0 L/ha.

No phytotoxic effects were observed for Lolium perenne and Allium cepa. For Brassica napus, deformed plants and wilting were observed in the test item concentrations of 8.0 and 2.667 L/ha and chlorosis int the concentration of 2.667 L/ha. For Helianthus annuus, wilting was observed in the test item concentrations of 0.889 and 2.667 L/ha, deformed plants were observed in the concentrations in the range of 0.889 - 8.0 L/ha, chlorosis in the concentrations in the range of 0.296 - 8.0 L/ha. For Cucumis sativus deformed plants were observed in the concentrations in the range of 0.296 - 8.0 L/ha and chlorosis int the concentrations of 0.889 and 2.667 L/ha.

No inhibitions of yield of biomass and length of Lolium perenne and length of Avena sativa were observed. For Brassica napus and Helianthus annuus, yield inhibition of biomass and length were observed in four and two highest test item concentrations, respectively. Yield inhibition of biomass for Allium cepa was observed in the concentrations in the range of 0.296 - 8.0 L/ha and yield inhibition of length was observed in the highest concentration. For Avena sativa yield inhibition of biomass was observed in the highest test item concentration. For Cucumis sativus yield inhibition of biomass for three highest concentrations and yield of length for the highest concentration were observed.

Table: Impact of ORKAN 350 SL on biomass of plants

Roślina	Wartości średnie	Średnia masa pędów [g] dla poszczególnych dawek [l/ha] preparatu ORKAN 350 SL						
		Kontrola	8,0	2,667	0,889	0,296	0,099	0,033
Rzepak (*Brassica napus*)	Średnia masa pędu [g]	0,54	0,06	0,26	0.34	0,42	0,53	0,57
	Średnia masa pędu w porównaniu do kontroli [%]	100	11	48	63	78	98	106
Życica trwała (*Lolium perenne*)	Średnia masa pędu [g]	0,16	0,12	0,15	0,16	0,16	0,17	0,18
	Średnia masa pędu w porównaniu do kontroli [%]	100	75	94	100	100	106	113
Cebula (*Alium cepa*)	Średnia masa pędu [g]	0,13	0,02	0,08	0,08	0,09	0,12	0,13
	Średnia masa pędu w porównaniu do kontroli [%]	100	15	62	62	69	92	100
Owies zwyczajny (*Avena sativa*)	Średnia masa pędu [g]	0,36	0,23	0,36	0,36	0,35	0,37	0,37
	Średnia masa pędu w porównaniu do kontroli [%]	100	64	100	100	97	103	103
Słonecznik (*Helianthus annuus*)	Średnia masa pędu [g]	1,86	1,00	1,56	1,74	1,86	1,86	1,91
	Średnia masa pędu w porównaniu do kontroli [%]	100	54	84	94	100	100	103
Ogórek (*Cucumis sativa*)	Średnia masa pędu [g]	1,96	1,35	1,46	1,68	1,85	1,85	1,86
	Średnia masa pędu w porównaniu do kontroli [%]	100	69	74	86	94	94	95

Table: Impact of ORKAN 350 SL on Shoot Dry Weight of plants

Roślina	Wartości średnie	Średnia długość pędów [cm] dla poszczególnych dawek [l/ha] preparatu ORKAN 350 SL						
		Kontrola	8,0	2,667	0,889	0,296	0,099	0,033
Rzepak (*Brassica napus*)	Średnia długość pędu [cm]	11,60	1,4	5,8	8.3	8,4	11,5	11,6
	Średnia długość pędu w porównaniu do kontroli [%]	100	12	50	72	72	99	100
Życica trwała (*Lolium perenne*)	Średnia długość pędu [cm]	23,4	18,9	21,7	22,0	22,2	24,4	22,1
	Średnia długość pędu w porównaniu do kontroli [%]	100	81	93	94	95	104	94
Cebula (*Alium cepa*)	Średnia długość pędu [cm]	12,1	3,0	8,9	12,0	11,0	11,5	11,6
	Średnia długość pędu w porównaniu do kontroli [%]	100	25	74	99	91	95	96
Owies zwyczajny (*Avena sativa*)	Średnia długość pędu [cm]	26,7	25,8	26,4	26,2	26,5	26,4	26,4
	Średnia długość pędu w porównaniu do kontroli [%]	100	97	99	98	99	99	99
Słonecznik (*Helianthus annuus*)	Średnia długość pędu [cm]	26,5	12,3	19,9	23,3	25,3	24,5	25,4
	Średnia długość pędu w porównaniu do kontroli [%]	100	46	75	88	95	92	96
Ogórek (*Cucumis sativa*)	Średnia długość pędu [cm]	4,7	3,7	4,4	4,3	4,4	4,0	4,2
	Średnia długość pędu w porównaniu do kontroli [%]	100	79	94	91	94	85	89

Conclusions:

Tabela 19. Wyniki obliczonych wartości EC25-21 d, LC/EC50-21d, NOEC, LOEC (95 % przedział ufności) dla ORKAN 350 SL.

Roślina	NOEC [l/ha]	LOEC [l/ha]	EC(LC)25 [l/ha]	EC(LC)50 [l/ha]
Wschody – 14d				
Rzepak	≥8,000	>8,000	4,184 (0,457-38,292)	>8,000
Życica trwała	≥8,000	>8,000	n.d.	>8,000
Cebula	0,033	0,099	n.d.	0,011* (0,000-0,575)
Owies zwyczajny	≥8,000	>8,000	2,313	>8,000
Słonecznik	≥8,000	>8,000	6,000	>8,000
Ogórek	nd	nd	nd	0,335*
Przeżywalność – 21d				
Rzepak	nd	nd	>8,000	>8,000
Życica trwała	nd	nd	>8,000	>8,000
Cebula	nd	nd	1,533 (0,699-3,360)	3,646 (1,545-8,603)
Owies zwyczajny	nd	nd	>8,000	>8,000
Słonecznik	nd	nd	>8,000	>8,000
Ogórek	nd	nd	>8,000	>8,000
Biomasa – 21d				
Rzepak	0,099	0,296	0,422 (0,203-0,880)	1,395 (0,627-3,229)
Życica trwała	≥8,000	>8,000	15,588	>8,000
Cebula	0,296	0,889	0,261 (0,051-0,905)	3,310 (1,111-46,456)
Owies zwyczajny	nd	nd	7,755	8,279
Słonecznik	2,667	8,000	2,659 (1,573-6,347)	9,734 (4,987-110,962)
Ogórek	0,889	2,667	3,986	>8,000
Długość pędów -21d				
Rzepak	0,099	0,296	0,522 (0,261-1,041)	1,733 (0,812-3,838)
Życica trwała	2,667	8,000	>8,000	>8,000
Cebula	0,889	2,667	2,654 (1,137-27,044)	4,780 (3,082-3874,897)
Owies zwyczajny	≥8,000	>8,000	>8,000	>8,000
Słonecznik	0,296	0,889	1,983 (1,316-3,410)	7,708 (4,361-23,153)
Ogórek	2,667	8,000	>8,000	>8,000

On the basis of the results, it was concluded that ORKAN 350 SL ~~may affects the seedling of non-target plants. and risk mitigation options have to be considered.~~ The lowest ERC_{50} is 1.395 L formulation /ha for oilseed rape.

Study 2

Comments of zRMS:	The study has only polish title, thus for clarity reasons the title was translated by zRMS: ORKAN 350 SL: Terrestrial Plant Test: Vegetative Vigour Test The Applicant performed the study only in polish; thus the English summary is presented only as executive summary. The Vegetative vigour study was conducted to OECD guideline 227 and according to the principles of GLP. No deviations were noted during the study. In the definitive test all the validity criteria were met as follows: - the seedling emergence (validity criterion: at least 70%) was as follows: 100% *brassica napus* 70.8% *lolium perenne* 75% *alium cepa* 87.5% *avena sativa* 95.8% *helianthus annuus* 75% *cucumis sativus* - the mean survival of the emerged control seedlings was 100% in case of all species (validity criterion: at least 90%), - the control seedlings did not exhibit any visible phytotoxic symptoms, - environmental conditions for all plants belonging to the same species were identical. The study is considered acceptable for the risk assessment purposes.

Report	ORKAN 350 SL: Terrestrial Plant Test: Vegetative Vigour Test Ocena fitotoksyczności preparatu ORKAN 350 SL – test wigoru wegetatywnego zgodnie z metodyką OECD 227, 24B-04-16, Kaźmierczuk M., 2018.
Guideline(s):	OECD 227
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test organism	*Brassica napus, Lolium, perenne, Alium cepa, Avena sativa, Helianthus annuus, Cucumis sativus*
Test design	21d of exposure
Nominal test item concentrations	8.0, 2.667, 0.889, 0.296, 0.099, 0.033 mg/L

Aim of the study

The study aimed at evaluating the impact of ORKAN 350 SL on vegetative vigour of terrestrial plants.

Results:

Lethal effects were observed for Helianthus annuus, Lolium perenne and Brassica napus in the concentrations of 2.667 and 8.0 L/ha and for Avena sativa and Cucumis sativus in the concentration of

8.0 L/ha. No lethal effects were observed for Alium cepa. Chlorosis and deformations were observed for Alium cepa exposed to each concentration. Deformations were observed for Helianthus annuus in the concentrations higher than 0.296 L/ha . Deformation of Cucumis sativus was observed in the concentration of 8.0 L/ha. Phytotoxic effects were not observed for Lolium perenne.
Yield inhibition of biomass and plant length of Avena sativa were observed in the concentration of 8.0 L/ha. The same effects were observed for Helianthus annuus in the concentrations in the range of 0.296 – 8.0 L/ha and for Cucumis sativus in the concentrations of 8.0, 2.667 L/ha.
Yield inhibition of biomass of Brassica napus was observed for test item concentrations in the range of 0.889 – 8.0 L/ha. Yield inhibition of biomass of Lolium perenne was observed for each test item concentration and shoots length inhibition was observed for concentrations of 8.0, 2.667 L/ha..
Stimulation of growth of shoots was observed for Allium cepa.

Table: Endpoints obtained in the end of the study

Roślina	NOEC [l/ha]	LOEC [l/ha]	LC25 [l/ha]	LC50 [l/ha]
mortality21d	Przeżywalność-21d			
brassica napus	0,889	2,667	1,384 (0,229- 8,364)	2,724 (0,506-14,650)
lolium perenne	0,889	2,667	2,501 (2,279-2,744)	2,790 (2,536-3,069)
alium cepa	>8,000	>8,000	>8,000	>8,000
avena sativa	2,667	8,000	2,507 (0,222-28,266)	3,959 (0,452-34,659)
helianthus annuus	0,889	2,667	1,567 (1,175-2,088)	2,085 (1,675-2,596)
cucumis sativus	2,667	8,000	6,286	7,117
Roślina	NOEC [l/ha]	LOEC [l/ha]	EC25 [l/ha]	EC50 [l/ha]
biomass-21d	Biomasa-21d			
brassica napus	n.d.	n.d.	0,499 (0,143-1,742)	1,332 (0,545-3,255)
lolium perenne	n.d.	n.d.	0,154 (0,025-0,944)	0,797 (0,233-2,723)
alium cepa	n.d.	n.d.	>8,000	>8,000
avena sativa	n.d.	n.d.	1,855 (0,343-10,032)	3,863 (1,020-14,630)
helianthus annuus	n.d.	n.d.	0,530 (0,299-0,940)	1,176 (0,779-1,774)
cucumis sativus	n.d.	n.d.	2,024 (1,535-2,6700)	3,399 (2,761-4,185)
shoots lenght-21d	Długość pędów-21d			
brassica napus	n.d.	n.d.	5,158 (2,097-12,6890)	>8.000
lolium perenne	n.d.	n.d.	2,390 (1,742-3,280)	3,233 (2,280-4,587)
alium cepa	n.d.	n.d.	>8,000	>8,000
avena sativa	n.d.	n.d.	5,710 (2,663-12,242)	7,569 (6,198-9,241)
helianthus annuus	n.d.	n.d.	0,430 (0,145-1,275)	1,489 (0,685-3,237)
cucumis sativus	n.d.	n.d.	2,257 (1,325-3,844)	4,306 (2,914-6,362)

n.d: nie określono ze względów matematycznych

Conclusions:

The test item, **ORKAN 350 SL** applied at rates ranging from 0.033 mg/L-8 mg/L had impact on vegetative vigour of tested species
The test item cause mortality of Helianthus annuus, Lolium perenne and Brassica napus in the concentrations of 2.667 and 8.0 L/ha and for Avena sativa and Cucumis sativus in the concentration of 8.0 L/ha. No lethal effects were observed for Alium cepa.
On the basis of the results, it was concluded that ORKAN 350 may affects the growth of non-target plants. ~~and risk mitigation options have to be considered.~~ The lowest obtained ERC_{50} is 0.797 L/formulation/ha for *lolium parenne*.

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

No additional data.

A 2.9 KCP 10.8 Monitoring data

No additional data.