FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 0724 A

Product name: COREY

Chemical active substances:

Rimsulfuron, 150 g/kg

Nicosulfuron, 300 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

MS Finalisation date: December 2020, July 2021, January 2022, September 2022

Version history

When	What
December 2020	**Finalisation of the assessement of the product SHA 0724A/ COREY**
February 2021	Applicant update
July 2021	ZRMS finalisation of the assessment
January 2022	Applicant update
January 2022	Final vesrion after Commenting Period process
September 2022	Final version after Second Commenting period process

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9 Ecotoxicology (KCP 10)

zRMS comments:

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. Not agreed or not relevant information is struck through and shadow for transparency. In addition in blue corrected values or information were added by zRMS, if relevant.

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: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-l	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	**Maize**	F	Broadleaved and grass weeds	Foliar spray	BBCH 12-18	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 0.015 rimsulfuron + 0.03 nicosulfuron b) 0.015 rimsulfuron + 0.03 nicosulfuron	200-400	-	-							

* 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 “Conclusions”

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

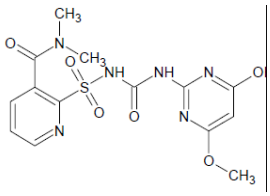
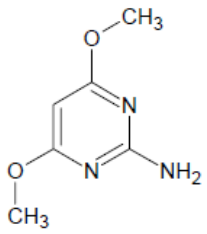
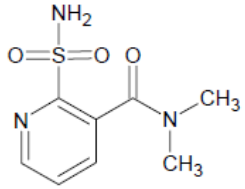
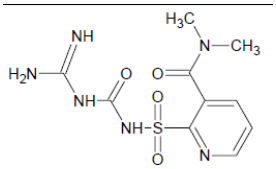
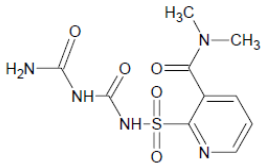
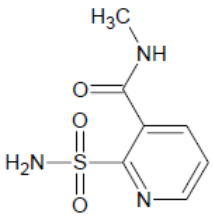
Remarks table:

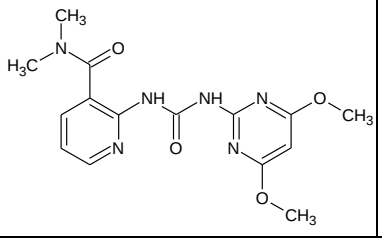
(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) F: professional field use, Fn: non-professional field 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

9.1.1 Overall conclusions

9.1.1.1

9.1.1.2 Table 9.1-3 Metabolites of Nicosulfuron

9.1.1.3 Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
HMUD (2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-N-dimethylpyridine-3-carboxamide)	396.4 g/mol		Soil:14.4% Water: 14.1% Sediment: 5.7% Water/sediment: 19.3%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
ADMP (4,6-dimethoxypyrimidin-2-amine)	155.2 g/mol		Soil: 9.8% Water: 23.1%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
ASDM (N,N-dimethyl-2-sulfamoylpyridine-3-carboxmide)	229.2 g/mol		Soil: 63.4% Water: 61% Sediment: 4.4% Water/sediment: 61%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
AUSN (2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	314.3 g/mol		Soil: 26.8% Water: 9.1% Sediment: 2.4% Water/sediment: 11.1%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
UCSN (2-[(carbamoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	315.3 g/mol		Soil: 11% Water: 5.4% Sediment: 1.4% Water/sediment: 6.5%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
MU-466 (N-methyl-2-sulfamoylpyridine-3-carboxamide)	215.2 g/mol			-

9.1.1.3 Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
DUDN 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-N,N-dimethylpyridine-3-carboxamide	346.3 g/mol		Soil: 1 x 10^{-10}% Water: 22.3%*	Aquatic organisms

9.1.1.4 Effects on birds (KCP 10.1.1), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

- Birds:

All the TER_a and TER_{lt} values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to birds according to the intended uses, as well as for drinking water exposure and secondary poisoning.

- Mammals:

All the TER_a and TER_{lt} values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to mammals according to the intended uses, as well as for drinking water exposure and secondary poisoning.

9.1.1.5 Effects on aquatic organisms (KCP 10.2)

Rimsulfuron

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 4.6 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

- R3 stream and R4 stream scenarios: A 5 m no spray buffer zone and a 5 m vegetative buffer strip are required.

For IN-70941, IN-70942 and IN-E9260 metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

Nicosulfuron

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 1.7 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

- D3 ditch scenario: A 5 m no spray buffer zone is required.
- R1 stream scenario: A 10 m no spray buffer zone and a 10 m vegetative buffer strip are required.
- R2 stream, R3 stream and R4 stream: A 20 m no spray buffer zone and a 20 m vegetative buffer strip are reduction are not enough for acceptable risk. After the refinement with the results of the recovery phase of the study on *Lemna* conducted with nicosulfuron (RAC equal to 0.74 µg nicosulfuron/L), the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.

For ASDM, AUSN, HMUD, ADMP and UCSN metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.- nicosulfuron and its metabolites could be concluded already for Step 1 PEC_{sw} values.

For aquatic macrophytes – Lemna sp. two approaches in the risk assessment for the a.s.- **nicosulfuron** were considered by the Applicant:

- PEC/RAC calculated on the basis of the lowest E_yC_{50} with 1.7 µg a.s./L
- PEC/RAC calculated on the basis on RAC≤ 0.74 µg s.a/L

At the zonal level the standard approach in line with EFSA AGD (2013) is required.

When the risk assessment is based **on EyC_{50}** value, unacceptable risk is identified for D3, R1 (stream), R2 (stream) and R3 (stream) and R4 (stream) scenarios.

FOCUS Step 4 modelling PEC_{sw} values assuming a 5 meter no spray buffer zone for the remaining surface water resulted in an acceptable PEC/RAC values for scenarios D3 (ditch). In addition, a 10 meter no spray buffer zone including 10 m vegetative buffer strip, resulted in an acceptable PEC/RAC values for the remaining surface water scenario R1 stream.

However, unacceptable PEC/RAC values were obtained for R2, R3 and R4 stream scenarios even with a 20 meter no spray buffer zone including 20 m vegetative buffer strip.

However, as consideration of E_yC_{50} value is not in line with recommendations of EFSA (2013), further evaluation was not performed at the zonal level and is deemed necessary in concerned Member States that prefer to use this approach in the aquatic risk assessment.

For this reason PEC/RAC calculations based on E_rC_{50} of 2.7 µg s.a/L (**RAC-0.27 µg s.a./L)** for aquatic macrophytes, agreed at EU level was provided additionally by zRMS in the Table 9.5-9.

It should be noted that zRMS did not accept the risk assessment based on RAC of 0.74 µg s.a./L value proposed by the applicant.

In zRMS opinion this value is not appropriate to replace the agreed E_rC_{50} **of 2.7 µg s.a./L** value included in the LoEP for nicosulfuron.

On the basis of the standard risk assessment performed in line with EFSA aquatic guidance (2013) following conclusions could be derived:

- Acceptable risk to aquatic macrophytes with no need for risk mitigation measures was demonstrated in scenarios D3, D4, D5, D6, R1 (pond)
- Acceptable risk to aquatic macrophytes with consideration of 5 meter no spray buffer zone in-

cluding 5 m vegetative buffer strip R1 stream scenario

• Acceptable risk to aquatic macrophytes with consideration 20 meter no spray buffer zone including 20 m vegetative buffer strip for R2 scenario

An unacceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R3 and R4.

Therefore, further refinement is required for these scenarios.

COREY

For the endpoints from formulated product COREY, 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk

However, the combined risk assessment for aquatic organism is considered not acceptable as the applicant used not appropriate value for Nicosulfuron (RAC of 0.74 microgram/L). Therefore, further refinement of mixture toxicity assessment for R streams scenarios should be considered at national level.
The final risk mitigation measures should be decided at MSs level.

Conclusion

~~***Maize – SPe 3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies.*~~

zRMS's comment to updated risk assessment provided by the applicant (February 2021) for R scenarios OPTION 1:

Based on the results of refinement risk assessment for nicosulfuron the acceptable PEC/RAC values were obtained for R1, R2, R3 and R4 stream scenarios **with a 5 meter no spray buffer zone including 5 m vegetative buffer strip when VFSMOD is considered.**

COREY

For the endpoints from formulated product COREY, 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk.

In addition, for the combined exposure the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.
Conclusion
Maize – SPe 3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies.*
The final risk mitigation measures for aquatic organism should be considered at MSs level.

9.1.1.6 Effects on bees (KCP 10.3.1)

First-tier assessments indicate that no unacceptable risk for bees exposed to COREY is expected according to the proposed intended uses.
In the case of chronic data for formulation COREY further consideration should be decided at MSs level the chronic test for adult bees and larvae should be submitted for ppp Corey and according to EU Reg. 284/2009.

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field

risk after the application of COREY.

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

The acute and chronic TER values for earthworms and other soil macro- and mesofauna for COREY were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance Rimsulfuron and Nicosulfuron do not pose acute and chronic risk to earthworms and other soil macro- and mesofauna.

Risk assessments conducted with relevant PEC_{soil} for the active substances Rimsulfuron and Nicosulfuron indicate a low risk to soil microorganisms when applied according to the proposed use rates. The use of COREY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Rimsulfuron and Nicosulfuron shows that the Annex VI trigger value of 5 is not reached. Therefore, mitigation measures are needed. When there is 75% nozzle reduction OR 5m buffer zone, COREY poses a low risk to non-target plants when applied according to the proposed use rates.

Maize – SPe 3: *To protect non-target plants use 75% drift reducing nozzles OR respect an unsprayed buffer zone of 5m to non-agricultural land. The final risk mitigation measures should be considered at MSs level.*

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

Rimsulfuron:
Data from a test with activated sludge are available and indicate that the risk to biological methods of sewage treatment plants is low.

Nicosulfuron:
Effects on biological methods for sewage treatment

Test type/organism	**Endpoint**
Activated sludge	--
Pseudomonas putida	Nicosulfuron EC_{50} > 250 mg as/L (no reported effects) ASDM, AUSN, UCSN, MU-466, HMUD > 100 mg metabolite/L (no significant inhibition)

9.1.2 Grouping of intended uses for risk assessment

Not relevant.

9.1.3 Consideration of metabolites

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

Table 9.1-2 Metabolites of Rimsulfuron

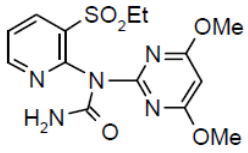
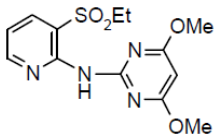
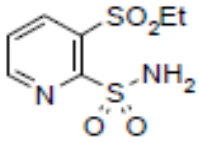
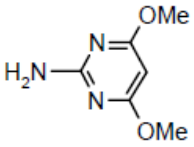
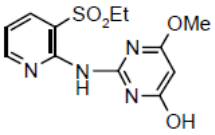
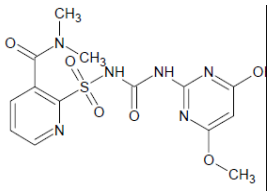
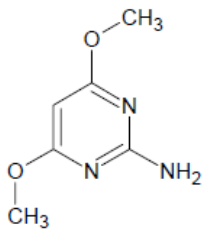
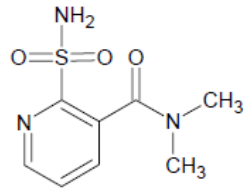
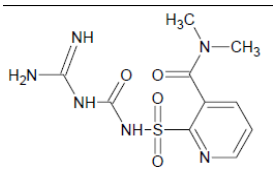
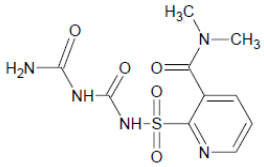
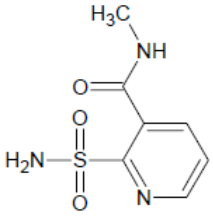
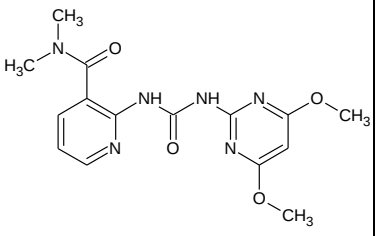
Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
IN-70941 (N-(4.6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsuflonyl)-2-pyridinyl] urea)	367.4 g/mol		Soil: 54.5% Total system: 87.2%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
IN-70942 (N-[3-(ethylsulfuronyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimiinamine)	324.36 g/mol		Soil: 23.5% Total system: 83.8%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
IN-E9260 (3-(ethylsulfuonyl)-2-pyridinesulfonamide)	250.30 g/mol		Soil: 18.9% Total system: 16.2%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
IN-J0290 (4,6-dimethoxy-2-pyrimidinamine) a.k.a ADMP	155.20 g/mol		Soil: 12.7% Total system: 19.1%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
IN-JF999 (2-[[3-ethylsulfonyl)-2-pyridinyl]amino]-6-methoxy-4(1H)-pyrimidinone)	310.33 g/mol		Soil: 1 x 10^{-10}% Total system: 24.5%	Aquatic organisms

Table 9.1-3 Metabolites of Nicosulfuron

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
HMUD (2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-N-N-dimethylpyridine-3-carboxamide)	396.4 g/mol		Soil:14.4% Water: 14.1% Sediment: 5.7% Water/sediment: 19.3%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
ADMP (4,6-dimethoxypyrimidin-2-amine)	155.2 g/mol		Soil: 9.8% Water: 23.1%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
ASDM (N,N-dimethyl-2-sulfamoylpyridine-3-carboxmide)	229.2 g/mol		Soil: 63.4% Water: 61% Sediment: 4.4% Water/sediment: 61%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
AUSN (2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	314.3 g/mol		Soil: 26.8% Water: 9.1% Sediment: 2.4% Water/sediment: 11.1%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
UCSN (2-[(carbamoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide	315.3 g/mol		Soil: 11% Water: 5.4% Sediment: 1.4% Water/sediment: 6.5%	Aquatic organisms Erthworms and other soil meso- and marco-fauna Microbial activity
MU-466 (N-methyl-2-sulfamoylpyridine-3-carboxamide)	215.2 g/mol			-
DUDN 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-N,N-dimethylpyridine-3-carboxamide	346.3 g/mol		Soil: 1 x 10^{-10}% Water: 22.3%*	Aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Rimsulfuron, Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of COREY (Rimsulfuron 15% + Nicosulfuron 30% WG) were not evaluated as part of the EU assessment of Rimsulfuron and Nicosulfuron. However, the provision of further data on the formulation COREY is not considered essential, because risk to mammals may be sufficiently assessed using the EU agreed endpoints and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

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

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

Species	Substance	Exposure System	Results	Reference
Mallard duck *Anas platyrhynchos*	Rimsulfuron	Acute	**LD_{50} > 2250** mg a.s./kg bw/day**	EFSA Scientific Report 2005; 45; 1-61
Bobwhite quail *Colinus viriginianus*	Rimsulfuron	Acute	LD_{50} > 2250** mg a.s./kg bw/day	
Mallard duck *Anas platyrhynchos*	Rimsulfuron	Dietary toxicity (short-term)	LC_{50} > 5620 mg as/kg food NOEC = 5620 mg as/kg food LD_{50} > 1610 mg a.s./kg bw/day	
Bobwhite quail *Colinus viriginianus*	Rimsulfuron	Dietary toxicity (short-term)	LC_{50} > 5620 mg as/kg food NOEC = 5620 mg as/kg food	
Mallard duck *Anas platyrhynchos*	Rimsulfuron	Reproductive toxicity (long-term)	NOAEL = 1250 mg as/kg food	
Bobwhite quail *Colinus viriginianus*	Rimsulfuron	Reproductive toxicity (long-term)	NOAEL = 1250 mg as/kg food **NOAED = 142 mg a.s./kg bw/day**	
Bobwhite quail *Colinus viriginianus*	Nicosulfuron tech.	Acute	**LD_{50} > 2000* mg a.s./kg bw/day** NOEL = 2000 mg a.s./kg bw/day	EFSA Scientific Report 2007; 120; 1-91
Mallard duck *Anas platyrhynchos*	Nicosulfuron tech.	Acute	LD_{50} > 2000* mg a.s./kg bw/day NOEL = 2000 mg a.s./kg bw/day	
Bobwhite quail *Colinus viriginianus*	SL-950 4% SC	Acute	LD_{50} > 2000 mg a.s./kg bw/day NOEL = 2000 mg a.s./kg bw/day	
Mallard duck *Anas platyrhynchos*	SL-950 4% SC	Acute	LD_{50} > 2000 mg a.s./kg bw/day NOEL = 2000 mg a.s./kg bw/day	
Mallard duck *Anas platyrhynchos*	Nicosulfuron	Dietary 5 d	LD_{50} > 5000 mg/kg food NOEL = 5000 mg/kg food LD_{50} > 911 mg a.s./kg bw/day NOEL = 911 mg a.s./kg bw/day	
Bobwhite quail *Colinus viriginianus*	Nicosulfuron	Dietary 5 d	LD_{50} > 5000 mg/kg food NOEL = 5000 mg/kg food LD_{50} > 1603 mg a.s./kg bw/day NOEL = 1603 mg a.s./kg bw/day	
Japanese quail *Coturnix japonica*	Nicosulfuron	Reproductive toxicity (long-term)	NOEC = 1000 mg a.s./kg food **NOEC = 171 mg a.s./kg bw/day**	

* Nicosulfuron dietary LDD_{50} of >911 mg as/kg bw/d is formally lower than acute LD_{50} of >2000 mg as/kg bw, however under test conditions it corresponds to the maximum tested dose of 5000 mg as/kg feed, and this concentrations was determined as the NOEL. Therefore, it is justified to assess acute risk with the acute LD_{50} of >2000 mg as/kg bw

** Rimsulfuron dietary LDD_{50} of >1610 mg as/kg bw/d is formally lower than acute LD_{50} of >2250 mg as/kg bw, however under test conditions it corresponds to the maximum tested dose of 5620 mg as/kg feed, and this concentrations was determined as the NOEL. Therefore, it is justified to assess acute risk with the acute LD_{50} of >2250 mg as/kg bw

zRMS comments:

Avian toxicity data presented in Table 9.2-1 are in general in line with EU agreed endpoints reported in EFSA Scientific Report 2005; 45; 1-61 for rimsulfuron and EFSA Scientific Report 2007; 120; 1-91 for nicosulfuron. It is noted that the acute toxicity study for SHA 0724 A / COREY birds is not provided. However, the vertebrate toxicity testing must be performed only when crucial for the evaluation.

Therefore, the provision of further data on the formulation SHA 0724 A / COREY is not considered essential, because risk to mammals may be sufficiently assessed using the EU agreed endpoints for both active substances and no new studies should not be conducted in regards of animal welfare.

9.2.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones.

9.2.2 Risk assessment for spray applications

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

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

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

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds regarding Rimsulfuron due to the use of COREY in maize

Intended use	**Maize**				
Active substance/product	Rimsulfuron				
Application rate (g/ha)	1 x 15				
Acute toxicity (mg/kg bw)	2250				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Indicator species for screening	158.8	1.0	2.38	944.6
Reprod. toxicity (mg/kg bw/d)	142				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Indicator species for screening	64.8	1.0 x 0.53	0.52	275.6

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds regarding Nicosulfuron due to the use of COREY in maize

Intended use	**Maize**				
Active substance/product	Nicosulfuron				
Application rate (g/ha)	1 x 30				
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**
Maize	Indicator species for screening	158.8	1.0	4.76	419.8
Reprod. toxicity (mg/kg bw/d)	171				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Indicator species for screening	64.8	1.0 x 0.53	1.03	166.0

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[1], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

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

With:

$X(\text{a.s.}_i)$ = fraction of each a.s. in the mixture

$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation COREY addressed in this dossier is Rimsulfuron 15% + Nicosulfuron 30% WG, making up a total of 450 g a.s./Kg product. According to GAP, the maximum application rate is 0.1 kg product/ha, therefore, an application rate of 45 g a.s./ha was considered in the assessment.

Below table shows the calculation of the predicted LD_{50} (mix) of Rimsulfuron and Nicosulfuron when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

[1] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.2-4: Avian LD_{50} (mix) for Rimsulfuron and Nicosulfuron when combined as COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron
Content in the formulation COREY	15%	30%
Fraction in the a.s. mixture	0.333	0.666
LD_{50} of a.s. [mg/kg bw]	> 2250	>2000
Fraction / LD_{50}	0.00015	0.00033
Sum	0.00048	
1/ sum = predicted LD_{50} (mix)	2076.92 mg mix/kg bw	

Table 9.2-5: Avian "tox per fraction" for the COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron	"mix"
Content in the formulation COREY	15%	30%	45%
Fraction in mixture	0.333	0.666	1.0
LD_{50} (mg/kg bw)	> 2250	>2000	2076.92
Tox per fraction	6750	3000	2076.92
Contribution to predicted toxicity	30.8%	69.2%	

Rimsulfuron contributes to 30.8% to mixture toxicity and nicosulfuron have an impact on the predicted risk of 69.2%, therefore, surrogate LD_{50} was used in the acute risk assessment.

Table 9.2-6: Screening step assessment of the acute risk for birds due to the use of COREY in all crops

Intended use	Maize				
Active substance/product	COREY				
Application rate (g/ha)	1 x 45				
LD_{50} (mix) (mg/kg bw)	2076.92				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	158.8	1.0	7.15	290.6

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.

According to reults, no unacceptable acute risk due to combined exposure are obtained in acording to the proposed GAP.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes. Hence, in the case of an unacceptable TER_{mix}, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

Despite all of this, the reproductive risk from combined exposure has been performed by the Applicant:

Reproductive risks from combined exposure

Table 9.2-7: Avian NOEL (mix) for Rimsulfuron and Nicosulfuron when combined as COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron
Content in the formulation COREY	15%	30%
Fraction in the a.s. mixture	0.333	0.666
NOEL of a.s. [mg/kg bw]	142	171
Fraction / NOEL	0.00235	0.00390
Sum	0.00625	
1/ sum = predicted NOEL (mix)	160.10 mg mix/kg bw	

Table 9.2-8: Avian "tox per fraction" for the COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron	"mix"
Content in the formulation COREY	15%	30%	45%
Fraction in mixture	0.333	0.666	1.0
NOEL (mg/kg bw)	142	171	160.10
Tox per fraction	426.00	256.50	160.10
Contribution to predicted toxicity	37.58%	62.42%	

Rimsulfuron contributes to 37.58% to mixture toxicity, while the nicosulfuron have an impact on the predicted risk of 62.42%, therefore, surrogate NOEL was used in the long-term risk assessment.

Table 9.2-9: Screening step assessment of the long-term risk for birds due to the use of COREY in maize

Intended use	Maize				
Active substance/product	COREY				
Application rate (g/ha)	1 x 45				
NOEL (mix) (mg/kg bw)	160.10				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening	Indicator species for screening	64.8	1.0 x 0.53	1.55	103.6

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

zRMS comments:

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). The presented above birds risk assessment is agreed by the zRMS.

All TER values exceed the relevant triggers indicating that SHA 0724 A /COREY does not pose an unacceptable risk to birds following applications according to recommended use pattern.

On the basis of performed calculations, acceptable acute and long-term risk to birds may be concluded from proposed uses of SHA 0724 A / CORE.

9.2.2.2 Higher-tier risk assessment

Not necessary.

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 COREY is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorp-

tive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 42.4 (geometric mean, n = 4 (EFSA Scientific Report (2005) 45, 1-61)), Rimsulfuron belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	15		
Acute toxicity (mg/kg bw)	=	2250	quotient	=	< 0.01
Reprod. toxicity (mg/kg bw/d)	=	142	quotient	=	0.11

As the ratios of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) do not exceed the value of 50 for Rimsulfuron, it is not necessary to conduct a drinking water risk assessment for birds.

With a K(f)oc of 20.7 (EFSA Scientific Report (2007) 120, 1-91), Nicosulfuron belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	30		
Acute toxicity (mg/kg bw)	=	2000	quotient	=	0.02
Reprod. toxicity (mg/kg bw/d)	=	171	quotient	=	0.18

As the ratios of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) do not exceed the value of 50 for Nicosulfuron, it is not necessary to conduct a drinking water risk assessment for birds.

zRMS comments:

Screening evaluation of the risk resulting from exposure to rimsulfuron and nicosulfuron via drinking water is agreed by the zRMS. It is not necessary to conduct a drinking water risk assessment for birds.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Rimsulfuron amounts to -1.46 at pH 7 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of Nicosulfuron amounts to 0.61 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

zRMS comments:

The evaluation of the risk of secondary poisoning for earthworm-eating birds for rimsulfuron and nicosulfuron is not triggered due to log Pow being <3.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

zRMS comments:

The evaluation of the risk of secondary poisoning for fish-eating birds for rimsulfuron and nicosulfuron is not triggered due to log Pow being <3.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

All the TER_a and TER_{lt} values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to birds according to the intended uses, as well as for drinking water exposure and secondary poisoning.

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 Rimsulfuron, Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of COREY were not evaluated as part of the EU assessment of Rimsulfuron and Nicosulfuron. However, the provision of further data on the formulation COREY is not considered essential, because risk may be reliably assessed using the EU-agreed endpoints only and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

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

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

Species	Substance	Exposure System	Results	Reference
Rat	Rimsulfuron	Oral 1 d Acute	**LD_{50} = 5000 mg/kg bw**	EFSA Scientific Report (2005) 45, 1-61
Rat	Rimsulfuron	Chronic, multigeneration	NOAEL = 3000 mg a.s./kg diet **NOAED = 11.8 mg a.s./kg bw/day**	

Species	Substance	Exposure System	Results	Reference
Rat	Nicosulfuron	Oral 1 d Acute	**LD_{50} > 5000 mg/kg bw**	EFSA Scientific Report (2007) 120, 1-91
Mouse	Nicosulfuron	Oral 1 d Acute	**LD_{50} > 5000 mg/kg bw**	
Rat	ASDM	Oral 1 d Acute	LD_{50} > 5000 mg/kg bw	
Rat	AUSN	Oral 1 d Acute	LD_{50} > 2000 mg/kg bw	
Rat	Nicosulfuron	Long-term	**NOAEL = 3861 (male)*** & 4404 (female)* **mg/kg bw/d**	

* Based on highest treatment dose – no significant adverse effects in study

9.3.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones.

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals regarding Rimsulfuron due to the use of COREY in maize

Intended use	Maize				
Active substance/product	Rimsulfuron				
Application rate (g/ha)	1 x 15				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Small omnivorous mammal	136.4	1.0	2.05	2443.8
Reprod. toxicity (mg/kg bw/d)	11.8				
TER criterion	5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m ×**	**DDD_m**	**TER_{lt}**

Growth stage			**TWA**	**(mg/kg bw/d)**	
Maize	Small omnivorous mammal	72.3	1.0 x 0.53	0.57	20.5

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals regarding Nicosulfuron due to the use of COREY in maize

Intended use	**Maize**				
Active substance/product	Nicosulfuron				
Application rate (g/ha)	1 x 30				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Small omnivorous mammal	136.4	1.0	4.09	1221.9
Reprod. toxicity (mg/kg bw/d)	3861				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Small omnivorous mammal	72.3	1.0 x 0.53	1.15	3358.7

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[2], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

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

With:

$X(\text{a.s.}_i)$ = fraction of each a.s. in the mixture

$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation COREY addressed in this dossier is Rimsulfuron 15% + Nicosulfuron 30% WG, making up a total of 450 g a.s./Kg product. According to GAP, the maximum application rate is 0.1 kg product/ha, therefore, an application rate of 45 g a.s./ha was considered in the assessment.

Below table shows the calculation of the predicted LD_{50} (mix) of Rimsulfuron and Nicosulfuron when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

Table 9.3-4: Mammalian LD_{50} (mix) for Rimsulfuron and Nicosulfuron when combined as COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron
Content in the formulation COREY	15%	30%
Fraction in the a.s. mixture	0.333	0.666
LD_{50} of a.s. [mg/kg bw]	>5000	>5000
Fraction / LD_{50}	0.000066	0.00013
Sum	0.0002	
1/ sum = predicted LD_{50} (mix)	5000 mg mix/kg bw	

[2] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.3-5: Mammalian "tox per fraction" for the COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron	"mix"
Content in the formulation COREY	15%	30%	45%
Fraction in mixture	0.333	0.666	1.0
LD_{50} (mg/kg bw)	>5000	>5000	5000
Tox per fraction	15000	7500	5000
Contribution to predicted toxicity	33.3%	66.7%	

Rimsulfuron contributes to 33.3% to mixture toxicity and nicosulfuron have an impact on the predicted risk of 66.7%, therefore, surrogate LD_{50} was used in the acute risk assessment.

Table 9.3-6: Screening step assessment of the acute risk for mammals due to the use of COREY in all crops

Intended use	Maize				
Active substance/product	COREY				
Application rate (g/ha)	1 x 45				
LD_{50} (mix) (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	136.4	1.0	6.14	814.6

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.

According to reults, no unacceptable acute risk is obtained for combined exposure acording to the proposed GAP.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TERmix value can only be used for illustrating purposes. Hence, in the case of an unacceptable TERmix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

Despite all of this, the reproductive risk from combined exposure has been performed by the Applicant:

Reproductive risks from combined exposure

Table 9.3-7: Mammalian NOEL (mix) for Rimsulfuron and Nicosulfuron when combined as COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron
Content in the formulation COREY	15%	30%
Fraction in the a.s. mixture	0.333	0.666
NOEL of a.s. [mg/kg bw]	11.8	3861
Fraction / NOEL	0.0282	0.0002
Sum	0.028421254	
1/ sum = predicted NOEL (mix)	35.18 mg mix/kg bw	

Table 9.3-8: Mammalian "tox per fraction" for the COREY (step 1 in EFSA GD 2009, Appendix B)

	Rimsulfuron	Nicosulfuron	"mix"
Content in the formulation COREY	15%	30%	45%
Fraction in mixture	0.333	0.666	1.0
NOEL (mg/kg bw)	11.8	3861	35.18
Tox per fraction	35.4	5791.5	35.18
Contribution to predicted toxicity	99.39%	0.61%	

The tox per fraction is 35.4 for Rimsulfuron and 5791.5 for Nicosulfuron. The NOEL for Rimsulfuron and surrogate NOEL are very similar this indicates that this active substance will contribute to ≥ 90 % to mixture toxicity, while the other components of the mixture will only have a marginal impact on the predicted risk. Consequently, the risk assessment will be driven by rimsulfuron, and hence the risk from combined exposure is covered by this active substance.

zRMS comments:

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).

The presented above mammals risk assessment is agreed by the zRMS. All TER_A and TER_{LT} values exceed the relevant triggers indicating that does not pose an unacceptable acute and long term risk to mammals following applications according to recommended use pattern.

Regarding, the calculation of acute combined toxicity no unacceptable acute risk is obtained for combined exposure acording to the proposed GAP.

Regarding the calculation of long combined toxicity the NOEL for rimsulfuron and surrogate NOEL are very similar this indicates that this active substance will contribute to ≥ 90% to mixture toxicity.

Therefore, the risk from combined exposure is covered by this active substance - rimsulfuron.

9.3.2.2 Higher-tier risk assessment

Not relevant.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 42.4 (geometric mean, n = 4 (EFSA Scientific Report (2005) 45, 1-61)), Rimsulfuron belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	15		
Acute toxicity (mg/kg bw)	=	5000	quotient	= < 0.01
Reprod. toxicity (mg/kg bw/d)	=	11.8	quotient	= 1.27

As the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) do not exceed the value of 50 for Rimsulfuron, it is not necessary to conduct a drinking water risk assessment for mammals.

With a K(f)oc of 20.7 (EFSA Scientific Report (2007) 120, 1-91), Nicosulfuron belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	30		
Acute toxicity (mg/kg bw)	=	> 5000	quotient	= < 0.01
Reprod. toxicity (mg/kg bw/d)	=	3861	quotient	= < 0.01

As the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) do not exceed the value of 50 for Nicosulfuron, it is not necessary to conduct a drinking water risk assessment for mammals.

zRMS comments:

Screening evaluation of the risk resulting from exposure to rimsulfuron and nicosulfuron via drinking water is agreed by the zRMS. It is not necessary to conduct a drinking water risk assessment for mammals.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Rimsulfuron amounts to -1.46 at pH7 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of Nicosulfuron amounts to 0.61 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

zRMS comments:

The evaluation of the risk of secondary poisoning for earthworm-eating mammals for rimsulfuron and nicosulfuron is not triggered due to log Pow being <3.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

zRMS comments:

The evaluation of the risk of secondary poisoning for fish-eating-mammals for rimsulfuron and nicosulfuron is not triggered due to log Pow being <3.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

All the TER_a and TER_{lt} values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to mammals according to the intended uses, as well as for drinking water exposure and secondary poisoning.

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

No data available.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Rimsulfuron, Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

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

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

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

Species	Substance	Exposure System	Results	Reference
Fish				EFSA Scientific Report (2005) 45, 1-61
L. macrochirus	Rimsulfuron	96 h	LC_{50} > 390 mg a.s./L_{mm}	
O. mykiss	Rimsulfuron	96 h	**LC_{50} > 390 mg a.s./L_{mm}**	
O. mykiss	Rimsulfuron	90 d	NOEC = 125 mg a.s./L_{nom}	
O. mykiss	Rimsulfuron	21 d	**NOEC = 125 mg a.s./L_{nom}**	
O. mykiss	IN-70941	96 h	**LC_{50} > 110 mg/L_{nom}**	
O. mykiss	IN-70942	96 h	**LC_{50} = 180 mg/L_{nmm}**	
O. mykiss	IN-E9260	96 h	**LC_{50} > 314 mg/L_{mm}**	
Aquatic invertebrates				
D. magna	Rimsulfuron	48 h	**EC_{50} > 360 mg a.s./L_{mm}**	
D. magna	Rimsulfuron	21 d	**NOEC = 1 mg a.s./L_{nom}**	
D. magna	IN-70941	48 h	**EC_{50} = 95 mg/L_{nom}**	
D. magna	IN-70942	48 h	**EC_{50} = 178 mg/L_{mm}**	
D. magna	IN-E9260	48 h	**EC_{50} = 184 mg/L_{nom}**	
Sediment-dwelling organisms				
C. riparius	IN-70942	28 d	NOEC ≥ 0.2 mg/kg sed_{nom}	
Algae				
P. subcapitata	Rimsulfuron	72 h, s	E_bC_{50} = 1.2 mg/L_{mm}	
P. subcapitata	IN-70941	72 h, s	E_bC_{50} > 8.9 mg/L_{mm}	
P. subcapitata	IN-70942	72 h, s	E_bC_{50} > 10 mg/L_{nom}	
S. subspicatus	IN-E9260	72 h, s	E_bC_{50} > 100 mg/L_{nom}	
Higher plant				
L. minor	Rimsulfuron	14 d	Frond count: **E_rC_{50} = 0.0046 mg/L_{mm}**	
L. gibba	IN-70942	14 d, s	Frond count: E_rC_{50} > 0.02 mg/L_{nom}	
L. gibba	Rimsulfuron 25 WG	14 d, s	Frond count: E_rC_{50} = 0.03 mg/L	
L. gibba	Rimsulfuron 25 WG + IN-KG691	14 d, s	Frond count: E_rC_{50} = 0.16 mg/L	
Higher-tier studies (micro- or mesocosm studies)				
Not relevant.				

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

Species	Substance	Exposure System	Results	Reference
Fish				
O. mykiss	Nicosulfuron	96 h	LC_{50} = 65.7 mg a.s./L	EFSA Scientific Report (2007) 120, 1-91
O. mykiss	Nicosulfuron	28 d	NOEC = 10 mg a.s./L	
O. mykiss	SL-950 4% SC	96 h	LC_{50} = 2.2 – 4.0 mg a.s./L	
L. macrochirus	ASDM###	96 h	LC_{50} > 100 mg/L	
B. rerio (zebra fish)	AUSN	96 h	LC_{50} > 100 mg/L	
O. mykiss	MU-466	96h	LC_{50} > 100 mg/L	
O. mykiss	HMUD	96h	LC_{50} > 100 mg/L	
O. mykiss	ADMP	96h	LC_{50} > 100 mg/L	
Aquatic invertebrate				
D. magna	Nicosulfuron	48 h	EC_{50} = 90 mg a.s./L	EFSA Scientific Report (2007) 120, 1-91
D. magna	Nicosulfuron	21 d	NOEC = 5.2 mg a.s./L	
D. magna	SL-950 4% SC	48 h	EC_{50} = 3.3 mg a.s./L	
D. magna	ASDM###	48 h	EC_{50} > 954 mg/L	
D. magna	AUSN	48 h	EC_{50} > 100 mg/L	
D. magna	MU-466	48 h	EC_{50} > 100 mg/L	
D. magna	HMUD	48 h	EC_{50} > 100 mg/L	
D. magna	UCSN	48 h	EC_{50} > 100 mg/L	
D. magna	ADMP	48 h	EC_{50} > 100 mg/L	
Algae				
A. flos-aquae	Nicosulfuron	72 h	E_bC_{50} = 7.8 mg a.s./L	EFSA Scientific Report (2007) 120, 1-91
S. subspicatus	SL-950 4% SC	72 h	E_rC_{50} > 4.0 mg a.s./L	
P. subcapitata	ASDM###	72 h	E_rC_{50} > 336 mg/L E_bC_{50} > 54 mg/L	
S. subspicatus	AUSN	72 h	E_rC_{50} & E_bC_{50} > 100 mg/L	
S. subspicatus	MU-466	72 h	E_rC_{50} > 100 mg/L E_bC_{50} = 84.4 mg/L	
S. subspicatus	HMUD	72 h	E_rC_{50} & E_bC_{50} > 100 mg/L	
S. subspicatus	UCSN	72 h	E_rC_{50} & E_bC_{50} > 100 mg/L	
S. subspicatus	ADMP	72 h	E_rC_{50} & E_bC_{50} > 100 mg/L	
Higher plant				
L. gibba	Nicosulfuron	7 d front count Growth rate	EC_{50} = 0.0017 mg/L E_rC_{50} = 0.0027 mg/L	EFSA Scientific Report (2007) 120, 1-91
L. gibba	SL-950 4% SC	7 day frond count Spec. growth rate Biomass (dry wt.)	EC_{50} = 0.0024 mg a.s./L E_rC_{50} = 0.0042 mg a.s./L E_bC_{50} > 0.0092 mg a.s./L	

Species	Substance	Exposure System	Results	Reference
L. gibba	ASDM###	7 d front count, growth rate & biomass	EC_{50}, E_rC_{50} & E_bC_{50} > 100 mg/L	
L. gibba	AUSN	7 d front count, growth rate & biomass	EC_{50}, E_rC_{50} & E_bC_{50} > 100 mg/L	
L. gibba	HMUD	7 d front count, growth rate & biomass	EC_{50}, E_rC_{50} & E_bC_{50} > 1 mg/L	
L. gibba	UCSN	7 d front count, growth rate & biomass	EC_{50}, E_rC_{50} & E_bC_{50} > 100 mg/L	
~~Higher~~ Tier 1 studies ~~(micro- or mesocosm studies)~~				
L. gibba	Nicosulfuron tech.	7 d, s	7-day E_yC_{50} = 1.2 µg a.s/L (frond number) 7-day E_rC_{50} = 2.1 µg a.s/L (frond number) NOEC = 0.28 µg a.s/L LOEC = 0.74 µg a.s/L	KCP 10.2.1-05 Bätscher, R. 2008 B75341
Myriophyllum spicatum	Nicosulfuron tech.	14 d, s	E_rC_{50}/14d = 0.30 mg/L E_yC_{50}/14d = 0.12 mg/L (fresh weight) E_rC_{50}/14d = 9.75 mg/L E_yC_{50}/14d = 1.69 mg/L (dry weight) E_rC_{50}/14d = 0.13 mg/L E_yC_{50}/14d = 0.08 mg/L (shot length)	KCP 10.2.1-06 Brzozowska, K. 2017 W/21/16*

###: ASDM is code named 'DAM 520' in some of the submitted toxicity reports

*the study should be considered at MSs level, if nesessary

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

Species	Substance	Exposure System	Results	Reference
O. mykiss	COREY	96 h, s	LC_{50} = 300.95 mg/L $_{nom}$	KCP 10.2.1-01 xxxx, 2019 W/208/17
P. subcapitata	COREY	72 h, s	E_rC_{50} = 6.634 mg/L $_{nom}$ E_yC_{50} = 0.980 mg/L $_{nom}$	KCP 10.2.1-02 Bak, P., 2018 W/209/17
D. magna	COREY	48 h, ss	EC_{50} > 100 mg/L $_{nom}$	KCP 10.2.1-03 Bak, P., 2018 W/210/17
L. gibba	COREY	7 d, ss	Frond: E_rC_{50} = 0.00748 mg/L_{nom} E_yC_{50} = 0.00258 mg/L_{nom} Dry weight: E_rC_{50} > 100 mg/L_{nom} E_yC_{50} = 0.10079 mg/L_{nom}	KCP 10.2.1-04 Bak, P., 2018 W/211/17
Higher-tier studies (micro- or mesocosm studies)				
No data submitted				

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

zRMS comments:

Aquatic toxicity data presented in Tables 9.5-1 and 9.5-3 are in general in line with EU agreed endpoints reported in EFSA Scientific Report 2005; 45; 1-61 for rimsulfuron and EFSA Scientific Report 2007; 120; 1-91 for nicosulfuron.

In the course of the EU review for nicosulfuron it was concluded that sufficient data are available for *Lemna gibba* and no data gap in this area was identified in EFSA Journal 2007; 120; 1-91.

~~It should be noted that the risk assessment for nicosulfuron in EFSA Conclusion 2007 was not based on growth rate.~~

According to the EFSA Scientific Report (2007) 120, 1-91 for nicosulfuron, it is shown that risk assessment for aquatic plants (*Lemna gibba*) was based also on growth rate.

For this reason, zRMS decided provided the risk based on the E_rC_{50} of 0.0027 mg a.s./L value agreed at EU level and according to recommend given in EFSA AGD 2009.

In support of this submission the applicant provided one additional static- renewal study with recovery phase on toxicity of nicosulfuron to *Lemna gibba* (KCP 10.2.1-05, Bätscher, R. 2008, B75341).

In this study after the 7-day exposure of the plants - Lemna gibba to the test item, the recovery of growth of the affected plants was monitored during two weeks. Some plants of the test concentrations of 0.74, 2.1 and 7.1 µg/L (nominal 1.0, 3.2 and 10 µg/L, respectively) were transferred to test water free of test item.

The growth of the treated plants was compared to parallel running control cultures.

From this exposure time period the following endpoints were determined:

7 day- E_yC_{50} = 1.2 µg a.s./L (frond number)

7-day E_rC_{50} = 2.1 µg a.s./L (frond number)

NOEC= 0.28 µg a.s./L

LOEC=0.74 µg a.s./L

After, the 7 day exposure period, the recovery of growth of the affected plants was monitored during two weeks. During the first week of recovery (Day 7-14 day of the study), the growth at the concentration 0.74 µg a.s/L was not significantly inhibited and no symptoms of toxicity were indicated at the end of the week.

The growth rate of the plants exposed to 0.74 µg a.s./L was recovered after one week.

In the second week recovery of the plants exposed to 0.74 µg a.s./L was confirmed in the second week.

In zRMS opinion the **RAC of 0.74 µg a.s./L** value obtained from this kind of the study with recovery phase should be not used in the risk assessment for the active substance nicosulfuron.

It should be noted the in the field situation the recovery depend on a lot of parameters and ecology of the species. It is acknowledged that although this species recovers quickly this may not be the case for less sensitive aquatic macrophyte test species.

The options of the refinement of the risk assessment for aquatic macrophytes is presented in details in AGD 2013.

One of the option of the refinement is provided the Tier 2C $RAC_{sw;ch}$ derivation on the basis of refined exposure laboratory tests, and their use in the RA.

According to AGD 2013 the refined exposure tests should simulate a realistic worst-case exposure relative to that predicted for the edge-of-field, and they should be long enough to allow the expression of the maximum effects.
RACs derived from refined exposure toxicity tests should always be expressed in terms of peak exposure concentration in these tests, and that these RACs should always be compared with the $PEC_{sw;max}$.
In zRMS opinion the 7 day E_rC_{50} of 2.1 µg a.s./L value from the new study seems to be more appropriate value for use in the risk assessment.
However, taking into consideration the 7 d E_rC_{50} of 2.7 µg a.s./L agreed EU value which is close to 7 d E_rC_{50} of 2.1 µg a.s./L value zRMS proposed to use in the risk assessment the EU agreed endpoint of 2.7 µg a.s/L giving RAC of 0.27 µg a.s./L.
The slight lower value of RAC-0.21 µg a.s./L (KCP 10.2.1-05, Bätscher, R. 2008, B75341) has no significant impact for ratio PEC/RAC and the final conclusion from the risk assessment for aquatic macrophytes.

9.5.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to COREY formulation.

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.

Rimsulfuron

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Rimsulfuron for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher-tier information**
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***S. capricornutum***	***L. gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	E_rC_{50}

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher-tier information**
(µg/L)		390000	125000	360000	1000	1200	4.6
AF		100	10	100	10	10	10
RAC (µg/L)		3900	12500	3600	100	120	0.46
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**						
Step 1							
	4.87	0.001	<0.001	0.001	0.049	0.041	**10.587**
Step 2							
S-Europe	1.32	<0.001	<0.001	<0.001	0.013	0.011	**2.870**
N-Europe	0.71	<0.001	<0.001	<0.001	0.007	0.006	**1.543**
Step 3							
D3/ditch	0.083	<0.001	<0.001	<0.001	0.001	0.001	0.180
D4/pond	0.013	<0.001	<0.001	<0.001	<0.001	<0.001	0.028
D4/stream	0.070	<0.001	<0.001	<0.001	0.001	0.001	0.152
D5/pond	0.006	<0.001	<0.001	<0.001	<0.001	<0.001	0.013
D5/stream	0.072	<0.001	<0.001	<0.001	0.001	0.001	0.157
D6/ditch	0.079	<0.001	<0.001	<0.001	0.001	0.001	0.172
R1/pond	0.007	<0.001	<0.001	<0.001	<0.001	<0.001	0.015
R1/stream	0.174	<0.001	<0.001	<0.001	0.002	0.001	0.378
R2/stream	0.417	<0.001	<0.001	<0.001	0.004	0.003	0.907
R3/stream	0.619	<0.001	<0.001	<0.001	0.006	0.005	**1.346**
R4/stream	0.625	<0.001	<0.001	<0.001	0.006	0.005	**1.359**

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

Metabolites of Rimsulfuron

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-70941 for each organism group based on FOCUS Steps 1, 2 ~~and 3~~ calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***S. subcapitata***
Endpoint		LC_{50}	EC_{50}	EC_{50}
(µg/L)		110000	95000	8900
AF		100	100	10
RAC (µg/L)		1100	950	890
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	5.63	0.005	0.006	0.006
Step 2				
S-Europe	1.59	0.001	0.002	0.002
N-Europe	0.84	0.001	0.001	0.001

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

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-70942 for each organism group based on FOCUS Steps 1, 2 ~~and 3~~ calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Higher-tier information**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***	***S.capricornutum***	***L. gibba***		***C. riparius***
Endpoint		LC_{50}	EC_{50}	EC_{50}	EC_{50}		NOEC
(µg/L)		180000	178000	10000	20		200
AF		100	100	10	10		10
RAC (µg/L)		1800	1780	1000	2		20
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**					**PEC_{sed} (µg/L)**	
Step 1							
	3.30	0.002	0.002	0.003	**1.650**	6.25	0.313
Step 2							
S-Europe	0.92	0.001	0.001	0.001	0.460	1.76	0.088
N-Europe	0.50	<0.001	<0.001	0.001	0.250	0.94	0.047

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IN-E9260 for each organism group based on FOCUS Steps 1, 2 ~~and 3~~ calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***P. subcapitata***
Endpoint (µg/L)		LC_{50} 314000	EC_{50} 184000	EC_{50} 100000
AF		100	100	10
RAC (µg/L)		3140	1840	10000
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**			
Step 1				
	1.00	<0.001	0.001	<0.001
Step 2				
S-Europe	0.29	<0.001	<0.001	<0.001
N-Europe	0.15	<0.001	<0.001	<0.001

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

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 4.6 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Rimsulfuron based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of COREY in maize

Intended use		**Maize**	
Active substance		Rimsulfuron	
Application rate (g/ha)		1 x 15	
Nozzle reduction	**Vegetated filter strip (m)**	5	10
	No-spray buffer (m)	5	10
None	R3 stream	0.402	0.280
	R4 stream	0.408	0.284
RAC (µg/L) 0.46		**PEC/RAC ratio**	
None	R3 stream	0.874	0.609
	R4 stream	0.887	0.617

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

zRMS comments:

The risk assessment presented in Tables 9.5-4 to 9.5-8 above is agreed by the zRMS.

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.-rimsulfuron and its metabolites could be concluded already for Step 1 PECsw values.

For aquatic macrophytes acceptable risk for a.s.- rimsulfuron could be concluded for STEP 3 for ll scenarios except R3 and R4 and for its metabolites for STEP 1-2.

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies .Ttaking into account **5 meter vegetative buffer for R3 and R4 scenarios the risk is considered acceptable.**

Nicosulfuron

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Nicosulfuron for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	~~**Higher tier information**~~	
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***A. flos-aquae***	***L. gibba***	***L. gibba***
Endpoint (µg/L)		LC_{50} 2200	NOEC 10000	EC_{50} 3300	NOEC 5200	E_bC_{50} >4000	EC_{50} 1.7	E_rC_{50} 2.7*
AF		100	10	100	10	10	10	10
RAC (µg/L)		22	1000	33	520	400	0.17	0.27
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	10.07	0.458	0.010	0.305	0.019	0.025	**59.235**	**37.29**
Step 2								
S-Europe	2.74	0.125	0.003	0.083	0.005	0.007	**16.118**	**10.14**
N-Europe	1.50	0.068	0.002	0.045	0.003	0.004	**8.824**	**5.55**
Step 3								
D3/ditch	0.170	0.008	<0.001	0.005	<0.001	<0.001	**1.000**	0.630
D4/pond	0.033	0.002	<0.001	0.001	<0.001	<0.001	0.194	0.122
D4/stream	0.143	0.007	<0.001	0.004	<0.001	<0.001	0.841	0.530
D5/pond	0.014	0.001	<0.001	<0.001	<0.001	<0.001	0.082	0.052
D5/stream	0.144	0.007	<0.001	0.004	<0.001	<0.001	0.847	0.533
D6/ditch	0.158	0.007	<0.001	0.005	<0.001	<0.001	0.929	0.585
R1/pond	0.011	0.001	<0.001	<0.001	<0.001	<0.001	0.065	0.041

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**~~Higher tier information~~**	
R1/stream	0.334	0.015	<0.001	0.010	0.001	0.001	**1.965**	**1.237**
R2/stream	1.015	0.046	0.001	0.031	0.002	0.003	**5.971**	**3.759**
R3/stream	1.215	0.055	0.001	0.037	0.002	0.003	**7.147**	**4.500**
R4/stream	1.296	0.059	0.001	0.039	0.002	0.003	**7.624**	**4.800**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*the value agreed at EU level, added by zRMS

Metabolites of Nicosulfuron

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for ASDM for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Higher-tier information**
Test species		***L. macrochirus***	***D. magna***	***P. subcapitata***	***L. gibba***
Endpoint		LC_{50}	EC_{50}	E_bC_{50}	EC_{50}
(µg/L)		100000	954000	336000	100000
AF		100	100	10	10
RAC (µg/L)		1000	9540	33600	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1					
	7.00	0.007	0.001	<0.001	0.001
Step 2					
S-Europe	1.98	0.002	<0.001	<0.001	<0.001
N-Europe	1.04	0.001	<0.001	<0.001	<0.001

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

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AUSN for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Higher-tier information**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Scenedesmus subspicatus***	***Lemna gibba***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}	EC_{50}
(µg/L)		100000	100000	100000	100000
AF		100	100	10	10
RAC (µg/L)		1000	1000	10000	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1					
	2.83	0.003	0.003	<0.001	<0.001
Step 2					
S-Europe	0.81	0.001	0.001	<0.001	<0.001
N-Europe	0.42	<0.001	<0.001	<0.001	<0.001

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

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for HMUD for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***O. mykiss***	***D. magna***	***S. subcapitata***	***L. gibba***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}	EC_{50}
(µg/L)		100000	100000	100000	1000
AF		100	100	10	10
RAC (µg/L)		1000	1000	10000	100
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1					
	3.29	0.003	0.003	<0.001	0.033
Step 2					
S-Europe	0.89	0.001	0.001	<0.001	0.009
N-Europe	0.47	<0.001	<0.001	<0.001	0.005

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

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for ADMP for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***S. subspicatus***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		100000	100000	100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	1.19	0.001	0.001	<0.001
Step 2				
S-Europe	0.29	<0.001	<0.001	<0.001
N-Europe	0.15	<0.001	<0.001	<0.001

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

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for UCSN for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of COREY in maize

Group		**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species		***Daphnia magna***	***S. subspicatus***	***L. gibba***
Endpoint		EC_{50}	E_rC_{50}	EC_{50}
(µg/L)		100000	100000	100000
AF		100	10	10
RAC (µg/L)		1000	10000	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	1.35	0.001	<0.001	<0.001
Step 2				
S-Europe	0.39	<0.001	<0.001	<0.001
N-Europe	0.20	<0.001	<0.001	<0.001

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

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 1.7 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Table 9.5-15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Nicosulfuron based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of COREY in maize

Intended use		**Maize**				
Active substance		Nicosulfuron				
Application rate (g/ha)		1 x 30				
Nozzle reduction	**Vegetated filter strip (m)**	None	5	10	15	20
	No-spray buffer (m)	5	5	10	15	20
None	D3 ditch	0.065	-	-	-	-
	R1 stream	-	0.204	0.137	-	-
	R2 stream	-	0.649	0.448	0.342	0.232
	R3 stream	-	0.789	0.550	0.421	0.287
	R4 stream	-	0.846	0.589	0.452	0.309
RAC (µg/L)		**PEC/RAC ratio**				
0.17						
	D3 ditch	0.382	-	-	-	-

	R1 stream	-	**1.200**	0.806	-	-
	R2 stream	-	**3.818**	**2.635**	**2.012**	**1.365**
	R3 stream	-	**4.641**	**3.235**	**2.476**	**1.688**
	R4 stream	-	**4.976**	**3.465**	**2.659**	**1.818**
RAC (µg/L) 0.27*		**PEC/RAC ratio**				
	D3 ditch	-	-	-	-	-
	R1 stream	-	0.756	0.507	-	-
	R2 stream	-	**2.404**	**1.659**	**1.267**	0.859
	R3 stream	-	**2.922**	**2.037**	**1.559**	**1.063**
	R4 stream	-	**3.133**	**2.181**	**1.674**	**1.144**

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*value based on 7 d E_rC_{50} of 2.7 µg/L, agreed at EU level.

FOCUS Step 4 modelling PEC_{sw} values assuming a 5 meter no spray buffer zone for the remaining surface water resulted in an acceptable PEC/RAC values for scenarios D3 ditch. In addition, a 10 meter no spray buffer zone including 10 m vegetative buffer strip, resulted in an acceptable PEC/RAC values for the remaining surface water scenario R1 stream. However, unacceptable PEC/RAC values were obtained for R2, R3 and R4 stream scenarios even with a 20 meter no spray buffer zone including 20 m vegetative buffer strip.

A refinement was performed considering the results of recovery from a new study submitted with this application.

Based on the results of the recovery phase of the study on *Lemna* conducted with nicosulfuron (new report KCP 10.2.1-05 submitted with this application are listed in Appendix 1 and summarised in Appendix 2) the effects of nicosulfuron on it are expected to be reversible at concentrations lower than or equal to 0.74 µg nicosulfuron/L. This value is above initial PEC_{sw} for all scenarios, therefore the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.

Table 9.5-16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Nicosulfuron based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of COREY in maize – refined endpoint

Intended use		**Maize**				
Active substance		Nicosulfuron				
Application rate (g/ha)		1 x ~~39.6~~ 30				
Nozzle reduction	**Vegetated filter strip (m)**	None	5	10	15	20
	No-spray buffer (m)	5	5	10	15	20
None	D3 ditch	0.065	-	-	-	-
	R1 stream	-	0.204	0.137	-	-
	R2 stream	-	0.649	0.448	0.342	0.232

	R3 stream	-	0.789	0.550	0.421	0.287
	R4 stream	-	0.846	0.589	0.452	0.309
RAC (µg/L) 0.74		**PEC/RAC ratio**				
None	D3 ditch	0.088	-	-	-	-
	R1 stream	-	0.276	0.185	-	-
	R2 stream	-	0.877	0.605	0.462	0.314
	R3 stream	-	**1.066**	0.743	0.569	0.388
	R4 stream	-	**1.143**	0.796	0.611	0.418

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

zRMS comments:

Nicosulfuron:

The risk assessment presented in Tables 9.5-4 to 9.5-15 above is agreed by the zRMS.

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.- nicosulfuron and its metabolites could be concluded already for Step 1 PEC_{sw} values.

For aquatic macrophytes – Lemna sp. two approaches in the risk assessment for the a.s.- **nicosulfuron** were considered by the Applicant:

- PEC/RAC calculated on the basis of the lowest E_yC_{50} with 1.7 µg a.s./L
- PEC/RAC calculated on the basis on RAC≤ 0.74 µg s.a/L

At the zonal level the standard approach in line with EFSA AGD (2013) is required.

When the risk assessment is based on EyC_{50} value, unacceptable risk is identified for D3, R1 (stream), R2 (stream) and R3 (stream), R 4 (stream) scenarios.

FOCUS Step 4 modelling PEC_{sw} values assuming a 5 meter no spray buffer zone for the remaining surface water resulted in an acceptable PEC/RAC values for scenarios D3 (ditch).

In addition, a 10 meter no spray buffer zone including 10 m vegetative buffer strip, resulted in an acceptable PEC/RAC values for the remaining surface water scenario R1 stream.

However, unacceptable PEC/RAC values were obtained for R2, R3 and R4 stream scenarios even with a 20 meter no spray buffer zone including 20 m vegetative buffer strip.

However, as consideration of E_yC_{50} value is not in line with recommendations of EFSA (2013), further evaluation was not performed at the zonal level and is deemed necessary in concerned Member States that prefer to use this approach in the aquatic risk assessment.

For this reason PEC/RAC calculations based on E_rC_{50} of 2.7 µg s.a/L (RAC-0.27 µg s.a./L) for aquatic macrophytes, agreed at EU level was provided additionally by zRMS in the Table 9.5-9.

It should be noted that zRMS did not accept the risk assessment based on RAC of 0.74 µg s.a./L value proposed by the applicant.

In zRMS opinion this value is not appropriate to replace the agreed E_rC_{50} of 2.7 µg s.a./L value included

in the LoEP for nicosulfuron.

On the basis of the standard risk assessment performed in line with EFSA aquatic guidance (2013) following conclusions could be derived:

- Acceptable risk to aquatic macrophytes with no need for risk mitigation measures was demonstrated in scenarios D3, D4, D5, D6, R1 (pond)
- Acceptable risk to aquatic macrophytes with consideration of 5 meter no spray buffer zone including 5 m vegetative buffer strip R1 stream scenario
- Acceptable risk to aquatic macrophytes with consideration 20 meter no spray buffer zone including 20 m vegetative buffer strip for R2 scenario

An unacceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R3 and R4.

Therefore, further refinement is required for these scenarios.

Updated according to ZRMS request

OPTION 1: VFSMOD approach

Further refinement was done for those scenarios at which unacceptable risk is obtained considering the proposed endpoint E_rC_{50} of 2.7 µg s.a./L. VFSMOD calculations have been done for all R scenarios, except for R1 pond. The PEC/RAC calculations are given below:

Table 9.5-17: Aquatic organisms: VFSMOD Global maximum PECsw calculation and acceptability of risk (PEC/RAC < 1) for Nicosulfuron based on FOCUS Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of COREY in maize

Intended use **Active substance** **Application rate (g/ha)**		**Maize** Nicosulfuron 1 x 30	
Nozzle reduction	**Vegetated filter strip (m)**	5	10
	No-spray buffer (m)	5	10
None	R1 stream	0.045	0.024
50%		0.023	-
None	R2 stream	0.061	0.033
50%		0.031	-
None	R3 stream	0.064	0.034
50%		0.032	-
None	R4 stream	0.046	0.024
50%		0.023	-
RAC (µg/L) 0.27		**PEC/RAC ratio**	
None	R1 stream	0.167	0.089

50%		0.085	-
None	R2 stream	0.226	0.122
50%		0.115	-
None	R3 stream	0.237	0.126
50%		0.119	-
None	R4 stream	0.170	0.089
50%		0.085	-

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

Based on the results, acceptable PEC/RAC values were obtained for R stream scenarios with a 5 meter no spray buffer zone including 5 m vegetative buffer strip when VFSMOD is considered.

zRMS comment to updated risk assessment provided by the applicant (February 2021) for R scenarios OPTION 1:

We agree with the refinement using the VFSmod PEC calculations.

Based on the results, acceptable PEC/RAC values were obtained for R1, R2, R3 and R4 stream scenarios with a 5 meter no spray buffer zone including 5 m vegetative buffer strip when VFSMOD is considered.

OPTION 2: New study and recovery

Furthermore, the applicant wishes to refer to a new macrophyte study performed with nicosulfuron technical on *Myriophyllum spicatum* (KCP 10.2.1-06; Study code: W/21/16)). This study concludes an E_rC_{50} (shoot length) equal to 130 µg/L (related RAC = 13 µg/L), which is far above the E_rC_{50} calculated for *Lemna gibba* (study without recovery), which was equal to 2.7 µg/L. The worst-case PECsw for nicosulfuron is equal to 1.296 µg/L (Step 3 – R4 stream). Therefore, the effects of nicosulfuron to *Myriophyllum* can be considered as acceptable. With new study provided, applicant tries to demostrate that nicosulfuron technical exposure can be considered as safe even on other macrophytes and therefore the risk to other species could be covered using this endpoint in the risk assessment

To support the above mentioned recovery, application patterns for scenarios R3 and R4 at 20m with non spray buffer plus 20m of vegetative buffer have been calculated by EPAT v1.1.1 in order to clarify that only one peak is greater than the RAC value (0.27 µg/L) from *Lemna* during a whole year observation period see below.

As can be observed from the figures the maximum peak is produced in the internally SWASH choosen days 84 and 58 for R3 and R4 respectively and has a duration of less than one day (0.334 and 0.666 days for R3 and R4 respectively) the EPAT program only considers that the other peaks are not an event. Futhermore, the concentration of the other peaks is at least one order of magnitude lower than the maximun. Hence, the species that show recovery like *L. gibba* could recover since the there is only one peak on the year and therefore enough biologically period of time. Beside, the toxicity endpoint for *Myriophyllum spicatum* is well above the maximum PEC_{sw} at Step 3. Therefore, no significant persistent effects are to be expected from the exposure of macrophytes to nicosulfuron following the application of COREY according to the intended GAP.

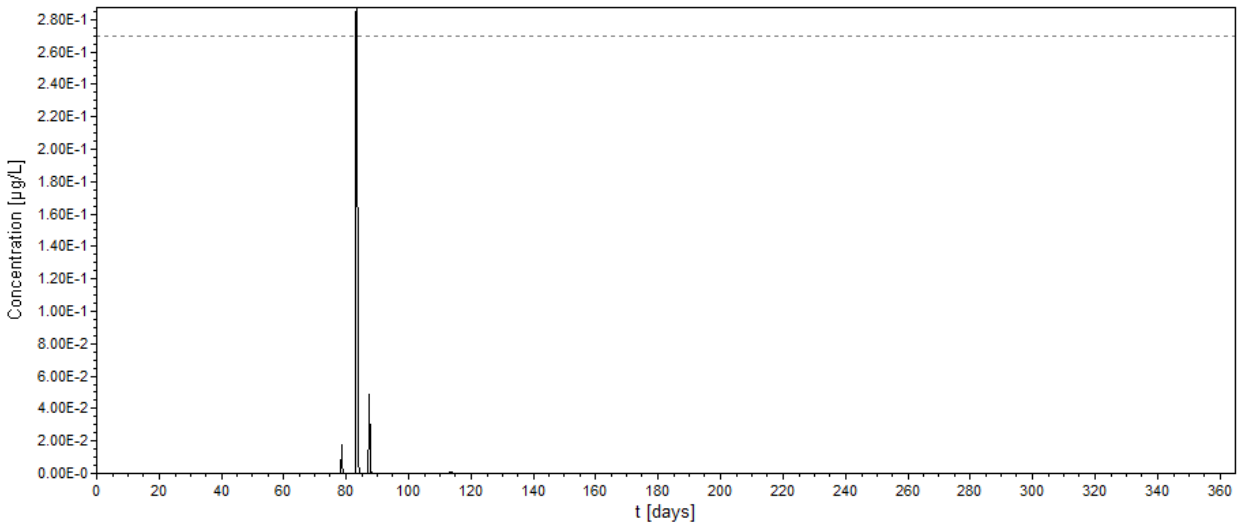


Figure 1: R3 stream application pattern at 20m of non spray buffer, plus 20 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

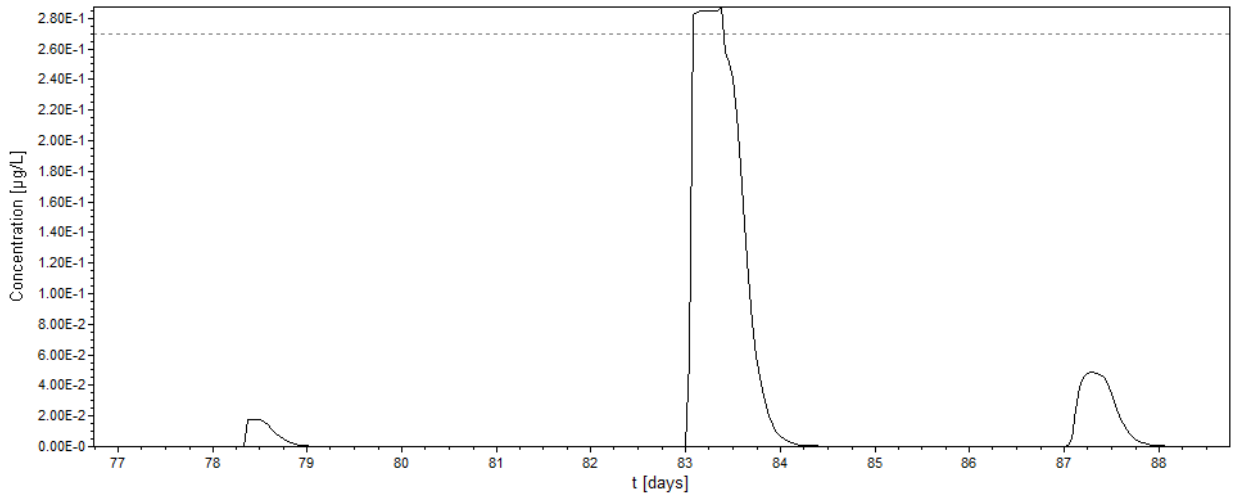


Figure 2: Detailed R3 stream application pattern at 20m of non spray buffer, plus 20 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

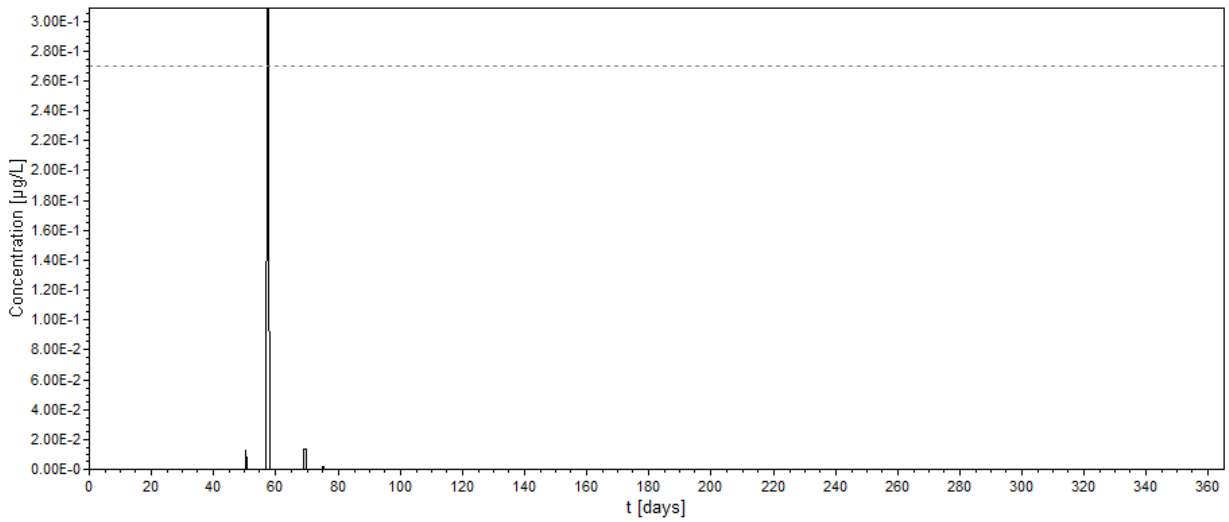


Figure 3: R4 stream application pattern at 20m of non spray buffer, plus 20m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

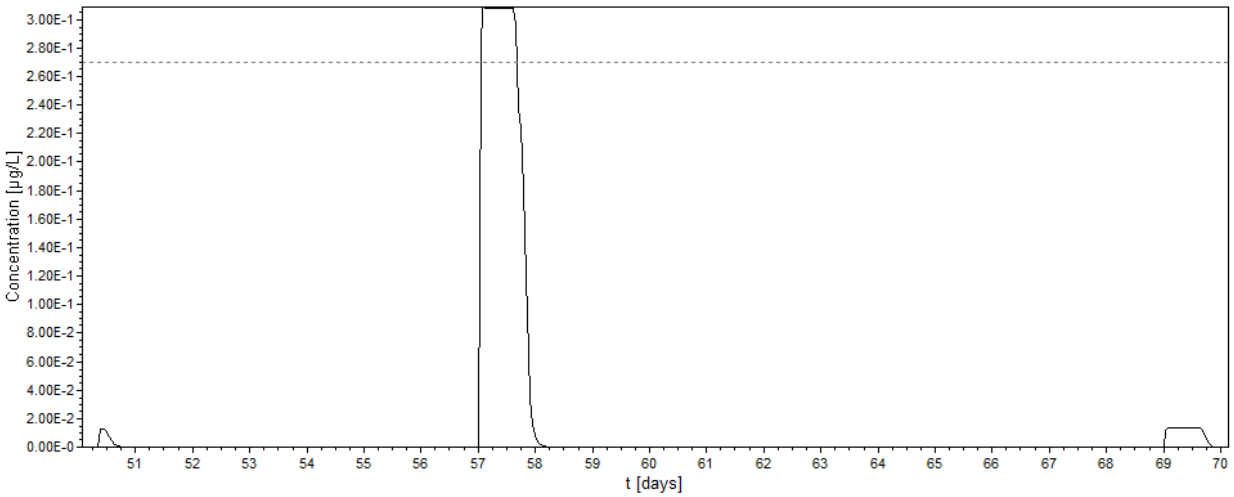


Figure 4: Detailed R4 stream application pattern at 20m of non spray buffer, plus 2 m of vegetative strip. Dotted line is the RAC value of 0.27 µg/L.

Hence, the very sensitive species *L. gibba* can recover from an exposure to 0.74 µg/L within a biologically acceptable period of time. Furthermore, the toxicity endpoint for *Myriophyllum spicatum* is well above the maximum PECsw at Step 3. Therefore, no significant persistent effects is to be expected from the exposure of macrophytes to nicosulfuron following the application of COREY according to the intended GAP.

zRMS commmets to updated risk assessment provided by the applicant (February 2021)
OPTION 2:

The second option of the refinement should be considered at MS level.

zRMS preferred Option 1 to refine the risk assessment which based on VFSmod PECcalculations, according to recommendation given in Harmonisation Meeting for authorazation of ppp in Central Zone in Dessau 2019.

COREY

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for COREY for each organism group for the use of COREY in maize

Group			**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic plants**
Test species			***O. mykiss***	***D. magna***	***P. subcapitata***	***L. gibba***
Endpoint			LC_{50}	EC_{50}	E_rC_{50}	E_rC_{50}
(µg/L)			300950	100000	6634	7.48
AF			100	100	10	10
RAC (µg/L)			3009.5	1000	663.4	0.748
Distance	**%Nozzles**	**PEC $_{gl\text{-}max}$ (µg/L)**				
1m	None	0.923	<0.001	0.001	0.001	**1.234**
	50%	0.462	<0.001	<0.001	0.001	0.617
	75%	0.231	<0.001	<0.001	<0.001	0.308

Group			Fish acute	Inverteb. acute	Algae	Aquatic plants
	90%	0.092	<0.001	<0.001	<0.001	0.123
5m	None	0.190	<0.001	<0.001	<0.001	0.254
	50%	0.095	<0.001	<0.001	<0.001	0.127
	75%	0.048	<0.001	<0.001	<0.001	0.064
	90%	0.019	<0.001	<0.001	<0.001	0.025

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

Risk assessment for the combinations of a.s. in the formulation

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. In addition, as demonstrated in the short-term studies here above there are no indications for interactions of the active substances (no synergisms or additional toxicity occurs due to the co-formulants) given that the formulation does not cause an (unexpected) increased toxicity compared to the active substances. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute/short-term assessment. The long-term risk was assessed considering data for the active substances in the formulation and no chronic combined risk assessment has been performed.

According to the new EFSA Scientific Opinion (EFSA, 2013) measured and calculated mixture tox-icity should be compared to determine synergistic, additive or antagonistic effects of the formula-tion. In the following the concentration addition (CA) model is used as proposed by EFSA.

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity ($LC_{50}/_{EC50\ mix\text{-}CA}$) by the measured mix-ture toxicity ($LC_{50}/EC_{50\ COREY}$). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, i.e. if the MDR is between 0.2 and 5 the observed and calculated mix-ture toxicities are considered in agreement.

The calculated MDR values are between 0.2 and 5 for each organism (see Table 9.5-12), indicating that the formulation does not cause an (unexpected) increased toxicity compared to the active sub-stances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants.

Active susbtance / species	Test system	Endpoint (mg a.s./L)
Rimsulfuron		
Oncorhynchus mykiss	LC_{50} 96h	390
Daphnia magna	EC_{50} 48h	360
S. capricornutum	EC_{50} 72h	1.2
L. minor	E_rC_{50} 14d	0.0046
Nicosulfuron		
Oncorhynchus mykiss	LC_{50} 96h	2.2
Daphnia magna	EC_{50} 48h	3.3
A. flos-aquae	E_bC_{50} 72h	4
L. gibba	EC_{50} 7d	0.0017

Table 9.5-19: Summary of results obtained in the studies with the formulated product COREY and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]			
		Measured toxicity of COREY ($LC_{50\ COREY}$ or $EC_{50\ COREY}$) (mg/L)	Measured toxicity of COREY (converted to be a.i. based) ($LC_{50\ COREY}$ or $EC_{50\ COREY}$) (mg a.s./L)	Calculated mixture toxicity[a] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Model deviation ratio (MDR = $EC_{50\ mix\text{-}CA}$ / $EC_{50\ COREY}$)
O. mykiss	LC_{50}, acute, 96 h	300.95	100.216	7.231	0.072
D. magna	EC_{50}, acute, 48 h	100	33.300	10.759	0.323
P. subcapitata	E_rC_{50}, 72 h	6.634	2.209	1.519	0.688
L. gibba	E_rC_{50}, 7d	0.00748	0.002	0.003	1.221

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Table 9.5-20: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in COREY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated mixture toxicity (a.s. in PEC_{mix})[b] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$ at lower exposure tier	Factors ($EC_{50\ mix\text{-}CA}$ (a.s. in COREY)/$EC_{50\ mix\text{-}CA}$ (a.s. in PEC_{mix})) at lower exposure tier
O. mykiss	LC_{50}, acute, 96 h	7.231	3.233	2.237
D. magna	EC_{50}, acute, 48 h	10.759	4.841	2.223
P. subcapitata	E_rC_{50}, static, 72 h	1.519	2.286	0.665
L. gibba	E_rC_{50}, semi static 7d	0.003	0.002	1.427

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

[b] The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Rimsulfuron (0.000710 mg/L at Step 2 for NEU scenario) and Nicosulfuron (0.001500 mg/L at Step 2 for NEU scenario).

Table 9.5-21: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in COREY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated toxicity per fraction of COREY (based on each a.s.) ($1/TU_i$)[a]	Deviation from mixture toxicity ($1\text{-}EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}$ - TU_i)) [%]
O. mykiss	LC_{50}, acute, 96 h	7.231	Rimsulfuron: 557.4 Nicosulfuron: 7.326	Rimsulfuron: 1.30% Nicosulfuron: 98.70%
D. magna	EC_{50}, acute, 48 h	10.759	Rimsulfuron: 514.5 Nicosulfuron: 10.989	Rimsulfuron: 2.09% Nicosulfuron: 97.91%
P. subcapitata	E_rC_{50}, static, 72 h	1.519	Rimsulfuron: 1.715 Nicosulfuron: 13.32	Rimsulfuron: 88.60% Nicosulfuron: 11.40%
L. gibba	E_rC_{50}, semi static 7d	0.003	Rimsulfuron: 0.007 Nicosulfuron: 0.006	Rimsulfuron: 45.63% Nicosulfuron: 54.37%

[a] TUi is defined as the concentration of the i^{th} a.s. at the $EC_{50\ COREY}$ (re-caculated to the sum of a.s.) divided by the respective single-substance toxicity ($EC_{50\ a.s.}$). This is calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Regarding COREY, nicosulfuron clearly drives the acute risk for fish and aquatic invertebrates, but not for algae and aquatic plants. For these two last species, the studies performed with the formulated product COREY do not reflect the toxicity of one particular active substance, as the formulation toxicity – end-point recalculated to each active substance concentrations – does not come for 90 % (of more) from the toxicity per fraction of a single a.s. (TUi) (see Table 9.5-20).

Table 9.5-22: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for fish

Exposure	Lower exposure tier		Higher exposure tier	
	Rimsulfuron	**Nicosulfuron**	**Rimsulfuron**	**Nicosulfuron**
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	~~Step 2 (NEU)~~ SEU	~~Step 2 (NEU)~~ SEU
PECsw [mg a.s./L]	0.000710	0.001500	~~0.001320~~	~~0.002740~~
Relative proportions of the individual mixture components in the environment (pi PEC)	~~0.321~~ 0.33	~~0.679~~ 0.67	~~0.325~~	~~0.675~~
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		~~0.004060~~	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	3.233		~~3.251~~	
ETRmix = PECmix/ECx PPP	0.0007		~~0.0012~~	
Trigger	0.01			

No unacceptable risk to fish is expected from the exposure to the combined active substances following proposed uses of the product.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC_{xCOREY}) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC_{xCOREY}) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_{xCOREY}) by means of the model deviation ratio (MDR = ECxmix-CA/EC_{xCOREY}).	MDR = < 0.2	Please refer to table 9.5-18	Go to 9

9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data ($EC_{x\ COREY}$) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible)		Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity ($EC_{x\ COREY}$) 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 $EC_{x\ COREY}$ 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 $EC_{x\ mix\text{-}CA}$ (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).	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PECmix) = 2.237 (<0.8 or >1.2)	Please refer to table 9.5-19	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity ($EC_{x\ COREY}$), 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)?	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TUi) = 98.70% (Nicosulfuron) (>=90% for one a.s.)	Please refer to table 9.5-20	Go to 6
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.	Covered by active substance assessment.		**Low risk**

Table 9.5-23: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for aquatic invertebrates

Exposure	Lower exposure tier		Higher exposure tier	
	Rimsulfuron	**Nicosulfuron**	**Rimsulfuron**	**Nicosulfuron**
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	Step 2 ~~(NEU)~~ SEU	Step 2 (SEU)
PECsw [mg a.s./L]	0.000710	0.001500	~~0.001320~~	~~0.002740~~
Relative proportions of the individual mixture components in the environment (pi PEC)	~~0.321~~ 0.33	~~0.679~~ 0.67	~~0.325~~	~~0.675~~
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		~~0.004060~~	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	4.841		~~4.868~~	
ETRmix = PECmix/ECx PPP	0.0005		~~0.0008~~	
Trigger	0.01			

No unacceptable risk to aquatic invertebrates is expected from the exposure to the combined active substances following proposed uses of the product.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for aquatic invertebrates.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC_{xCOREY}) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC_{xCOREY}) against the calculated mixture toxicity $EC_{xmix\text{-}CA}$ (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_{xCOREY}) by means of the model deviation ratio (MDR = $EC_{xmix\text{-}CA}/EC_{xCOREY}$).	MDR = 0.2-5	Please refer to table 9.5-18	Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (EC_{xCOREY}) 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 EC_{xCOREY} 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 $EC_{xmix\text{-}CA}$ (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).	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PECmix) is <0.8 or >1.2	Please refer to table 9.5-19	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity ($EC_{x\ COREY}$), 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)?	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TUi) = 98.70% (Nicosulfuron) (>=90% for one a.s.)	Please refer to table 9.5-20	Go to 6
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.	Covered by active substance assessment.		**Low risk**

Table 9.5-24: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for algae

Exposure	Lower exposure tier		Higher exposure tier	
	Rimsulfuron	**Nicosulfuron**	**Rimsulfuron**	**Nicosulfuron**
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	Step 2 (~~NEU~~) SEU	Step 2 (SEU)
PECsw [mg a.s./L]	0.000710	0.001500	~~0.001320~~	~~0.002740~~
Relative proportions of the individual mixture components in the environment (pi PEC)	~~0.321~~ 0.33	~~0.679~~ 0.67	~~0.325~~	~~0.675~~
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		~~0.004060~~	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	2.286		~~2.275~~	
ETRmix = PECmix/ECx PPP	0.001		~~0.002~~	
Trigger	0.1			

No unacceptable risk to algae is expected from the exposure to the combined active substances following proposed uses of the product.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for aquatic invertebrates.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC_{xCOREY}) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC_{xCOREY}) against the calculated mixture toxicity $EC_{xmix\text{-}CA}$ (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_{xCOREY}) by means of the model deviation ratio (MDR = $EC_{xmix\text{-}CA}/EC_{xCOREY}$).	MDR = 0.2-5	Please refer to table 9.5-18	Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (EC_{xCOREY}) 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 EC_{xCOREY} 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 $EC_{xmix\text{-}CA}$ (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).	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PECmix) is <0.8 or >1.2	Please refer to table 9.5-19	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity ($EC_{x\ COREY}$), 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)?	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TUi) >=90% for no a.s.	Please refer to table 9.5-20	Go to 8
8	Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8	If $ETR_{mix\text{-}}$ < 0.10 for aquatic invertebrates: Low risk	Please refer to table 9.5-23	**Low risk**

Table 9.5-25: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for aquatic plants

Exposure	**Lower exposure tier**		**Higher exposure tier**	
	Rimsulfuron	**Nicosulfuron**	~~**Rimsulfuron**~~	~~**Nicosulfuron**~~
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	~~Step 2 (NEU)~~	~~Step 2 (SEU)~~
PECsw [mg a.s./L]	0.000710	0.001500	~~0.001320~~	~~0.002740~~
Relative proportions of the individual mixture components in the environment (pi PEC)	~~0.321~~ 0.33	~~0.679~~ 0.67	~~0.325~~	~~0.675~~
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		~~0.004060~~	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	0.002		~~0.002~~	
ETRmix = PECmix/ECx PPP	~~1.105~~ **0.704**		~~2.03~~	
Trigger	0.1			

An unacceptable risk to aquatic plants cannot be assumed after exposure to the combined active substances following proposed uses of the product.

A refinement was performed considering the results of recovery from a new study submitted with this application.
Based on the results of the recovery phase of the study on *Lemna* conducted with nicosulfuron (new report KCP 10.2.1-05 submitted with this application are listed in Appendix 1 and summarised in Appendix 2) the effects of nicosulfuron on it are expected to be reversible at concentrations lower than or equal to 0.74 µg nicosulfuron/L. Hence, the trigger considered after applying this new endpoint, would be 1, instead of 0.1.

Active susbtance / species	**Test system**	**Endpoint (mg a.s./L)**
Rimsulfuron		
Oncorhynchus mykiss	LC_{50} 96h	390
Daphnia magna	EC_{50} 48h	360
S. capricornutum	EC_{50} 72h	1.2
L. minor	E_rC_{50} 14d	0.0046
Nicosulfuron		
Oncorhynchus mykiss	LC_{50} 96h	2.2
Daphnia magna	EC_{50} 48h	3.3
A. flos aquae	E_bC_{50} 72h	4
L. gibba	EC_{50} 7d	0.00074

Table 9.5-26: Summary of results obtained in the studies with the formulated product COREY and comparison of calculated and measured mixture toxicity – *Lemna* endpoint refinement

Test species	**Endpoint & Test system**	**LC_{50} / EC_{50} [mg/L]**			
		Measured toxicity of COREY (LC_{50} COREY or EC_{50} COREY) (mg/L)	**Measured toxicity of COREY (converted to be a.i. based) (LC_{50} COREY or EC_{50} COREY) (mg a.s./L)**	**Calculated mixture toxicity[a] LC_{50} mix-CA or EC_{50} mix-CA**	**Model deviation ratio (MDR = EC_{50} mix-CA / EC_{50} COREY)**
L. gibba	LOEC, 7d	0.00748	0.002	0.002	0.720

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Table 9.5-27: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix} – *Lemna* endpoint refinement

Test species	**Endpoint & Test system**	**LC_{50} / EC_{50} [mg/L]**		
		Calculated mixture toxicity (a.s. in COREY) LC_{50} mix-CA or EC_{50} mix-CA	**Calculated mixture toxicity (a.s. in PEC_{mix})[b] LC_{50} mix-CA or EC_{50} mix-CA at lower exposure tier**	**Factors (EC_{50} mix-CA (a.s. in COREY)/EC_{50} mix-CA (a.s. in PEC_{mix})) at lower exposure tier**
L. gibba	LOEC, static 7d	0.002	0.001	1.769

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

[b] The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Rimsulfuron (0.000710 mg/L at Step 2 for NEU scenario) and Nicosulfuron (0.001500 mg/L at Step 2 for NEU scenario).

Table 9.5-28: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s. *Lemna* endpoint refinement

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in COREY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated toxicity per fraction of COREY (based on each a.s.) $(1/TU_i)$[a]	Deviation from mixture toxicity $(1\text{-}EC_{x\ mix\text{-}CA} \times (1/EC_{x\ mix\text{-}CA} - TU_i))$ [%]
L. gibba	LOEC, static 7d	0.002	Rimsulfuron: 0.007 Nicosulfuron: 0.002	Rimsulfuron: 27.3% Nicosulfuron: 72.7%

[a] TUi is defined as the concentration of the i^{th} a.s. at the $EC_{50\ COREY}$ (re-caculated to the sum of a.s.) divided by the respective single-substance toxicity ($EC_{50\ a.s.}$). This is calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Table 9.5-29: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for aquatic plants *Lemna* endpoint refinement

Exposure	Lower exposure tier		Higher exposure tier (refinement)	
	Rimsulfuron	Nicosulfuron	Rimsulfuron	Nicosulfuron
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	Step 3 (R4 stream)	Step 4 (10 m VBZ, R4 stream)
PECsw [mg a.s./L]	0.000710	0.001500	0.000625	0.000589
Relative proportions of the individual mixture components in the environment (pi PEC)	0.321	0.679	0.515	0.485
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		0.001214	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	0.0010		0.0013	
ETRmix = PECmix/ECx PPP	2.21		0.934	
Trigger	1			

The refinement is conducted by taking into account FOCUS PEC_{sw} values for Rimsulfuron (Step 3) and Nicosulfuron (Step 4; 10 m vegetative buffer strip) (see Table 9.5-28). No unacceptable risk to aquatic plants is expected from the exposure to the combined active substances following proposed uses of the product.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for aquatic plants.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC_{xCOREY}) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2

2	Check the plausibility of the measured formulation toxicity (EC_{xCOREY}) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_{xCOREY}) by means of the model deviation ratio (MDR = ECxmix-CA/EC_{xCOREY}).	MDR = 0.2-5	Please refer to table 9.5-25	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity ($EC_{x\ COREY}$) 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 $EC_{x\ COREY}$ 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 $EC_{x\ mix\text{-}CA}$ (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).	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PECmix) = 2.237 (<0.8 or >1.2)	Please refer to table 9.5-26	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity ($EC_{x\ COREY}$), 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)?	Deviation from mixture toxicity = 1-$EC_{x\ mix\text{-}CA}$ x (1/$EC_{x\ mix\text{-}CA}$-TUi) >= 90% for no a.s.	Please refer to table 9.5-27	Go to 8
8	Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8	If $ETR_{mix\text{-}}$ < 1 for aquatic plants: Low risk	Please refer to table 9.5-28	**Low risk**

zRMS comments:

The proposed endpoint for nicosulfuron RAC of 0.74 µg/L to refine the risk for Lemna sp. has not been accepted by zRMS.

The mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD using the calculator presented during Harmoniztion meeting in Central Zone in Brno was used by zRMS.

The mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for aquatic plants– *Lemna* endpoint ErC_{50}= 2.7 microgram/L with STEP3 calculations.

Macrophytes- Lemna sp. 7 d E_rC_{50}=0.0027 mg a.s./L	
ETRmix-PPP	
Step 1	**4.758074866**
Step 2	
N-Europe	**0.703838384**
S-Europe	**1.293024361**
Step 3	

D1/ ditch	
D1/ stream	
D2/ ditch	
D2/ stream	
D3/ ditch	0.080575163
D4/ pond	0.01465003
D4/ stream	0.067836007
D5/ pond	0.006369578
D5/ stream	0.068791444
D6/ ditch	
R1/ pond	0.00573262
R1/ stream	**0.161787285**
R2/ stream	**0.456061794**
R3/ stream	**0.584090315**
R4/ stream	**0.61179798**
Trigger value	**0.1**

With consideration density of the product=1.072 g/cm3

Final CONCLUSION	low risk
	high risk

Based on the above results of the combine risk assessment the refinment is still needed for all R streams scenarios.

Therefore, further refinment for relevant R stream scenarios should be consideded with FOCUS STEP 4 PEC_{sw} calculations at MSs level.

Updated according to ZRMS request

As an alternative to the nicosulfuron RAC of 0.74 µg/L, a different approach following new provided PECsw for nicosulfuron (Table 9.5-17) was followed using *Lemna* endpoint (E_rC_{50} = 2.7 µg/L).

Active susbtance / species	**Test system**	**Endpoint (mg a.s./L)**
Rimsulfuron		
Oncorhynchus mykiss	LC_{50} 96h	390
Daphnia magna	EC_{50} 48h	360
S. capricornutum	EC_{50} 72h	1.2
L. minor	E_rC_{50} 14d	0.0046
Nicosulfuron		
Oncorhynchus mykiss	LC_{50} 96h	2.2
Daphnia magna	EC_{50} 48h	3.3
A. flos-aquae	E_bC_{50} 72h	4
L. gibba	EC_{50} 7d	0.0027

Table 9.5-30: Summary of results obtained in the studies with the formulated product COREY and comparison of calculated and measured mixture toxicity – *Lemna* updated

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]			
		Measured toxicity of COREY ($LC_{50\ COREY}$ or $EC_{50\ COREY}$) (mg/L)	Measured toxicity of COREY (converted to be a.i. based) ($LC_{50\ COREY}$ or $EC_{50\ COREY}$) (mg a.s./L)	Calculated mixture toxicity[a] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Model deviation ratio (MDR = $EC_{50\ mix\text{-}CA}$ / $EC_{50\ COREY}$)
L. gibba	LOEC, 7d	0.00748	0.003	0.003	0.930

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Table 9.5-31: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix} – *Lemna* updated

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in COREY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated mixture toxicity (a.s. in PEC_{mix})[b] $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$ at lower exposure tier	Factors ($EC_{50\ mix\text{-}CA}$ (a.s. in COREY)/$EC_{50\ mix\text{-}CA}$ (a.s. in PEC_{mix})) at lower exposure tier
L. gibba	LOEC, static 7d	0.003	0.003	1.006

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

[b] The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Rimsulfuron (0.000710 mg/L at Step 2 for NEU scenario) and Nicosulfuron (0.001500 mg/L at Step 2 for NEU scenario).

Table 9.5-32: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s. – *Lemna* updated

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in COREY) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	Calculated toxicity per fraction of COREY (based on each a.s.) ($1/TU_i$)[a]	Deviation from mixture toxicity ($1\text{-}EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}$ - TU_i)) [%]
L. gibba	LOEC, static 7d	0.003	Rimsulfuron: 0.014 Nicosulfuron: 0.004	Rimsulfuron: 22.7% Nicosulfuron: 77.3%

[a] TUi is defined as the concentration of the i^{th} a.s. at the $EC_{50\ COREY}$ (re-caculated to the sum of a.s.) divided by the respective single-substance toxicity ($EC_{50\ a.s.}$). This is calculated based on the nominal contents of Rimsulfuron (150 g/kg) and Nicosulfuron (300 g/kg) within the formulation.

Table 9.5-33: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in maize for aquatic plants– *Lemna* updated

Exposure	Lower exposure tier		Higher exposure tier	
	Rimsulfuron	Nicosulfuron	Rimsulfuron	Nicosulfuron
Exposure tier (FOCUS step)	Step 2 (NEU)	Step 2 (NEU)	Step 4 (10 m VBZ, R4 stream)	Step 4 (10 m VBZ, R3 stream)
PECsw [mg a.s./L]	0.000710	0.001500	0.000284	0.000034
Relative proportions of the individual mixture components in the environment (pi PEC)	0.321	0.679	0.893	0.107
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.002210		0.000318	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = ∑ (pi PEC/ECx i)) [mg a.s./L]	0.003		0.003	
ETRmix = PECmix/ECx PPP	**0.737**		0.094	
Trigger	0.1			

The refinement is conducted by taking into account PEC_{sw} values for Rimsulfuron (Step 4; 10 m VBZ) and Nicosulfuron (Step 4; 10 m VBZ) (see Table 9.5-33). No unacceptable risk to aquatic plants is expected from the exposure to the combined active substances following proposed uses of the product.

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for aquatic plants.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC_{xCOREY}) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC_{xCOREY}) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC_{xCOREY}) by means of the model deviation ratio (MDR = ECxmix-CA/EC_{xCOREY}).	MDR = 0.2-5	Please refer to table 9.5-30	Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity ($EC_{x\ COREY}$) 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 $EC_{x\ COREY}$ 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 $EC_{x\ mix\text{-}CA}$ (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).	$EC_{x\ mix\text{-}CA}$ (a.s. in product)/$EC_{x\ mix\text{-}CA}$ (a.s. in PECmix) = 1.006 (0.8 - 1.2)	Please refer to table 9.5-31	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETRmix) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If $ETR_{mix\text{-}}$ < 0.1 for aquatic plants: Low risk	Please refer to table 9.5-33	**Low risk**

zRMS comments to upaded risk assessment for R scenarios (February 2021)

The mixture toxicity assessment for R4 and R3 scenarios provided by the applicant (February 2021) is considered acceptable by zRMS. This assessment covers also risk for R1 (stream) scenario.

The combined exposure the risk is considered acceptable with

- an unsprayed vegetated buffer zone of 10 m.

  The final decision of the risk mitigation masures should be decided at MSs level.

9.5.3 Overall conclusions

Rimsulfuron

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 4.6 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

- R3 stream and R4 stream scenarios: A 5 m no spray buffer zone and a 5 m vegetative buffer strip are required.

For IN-70941, IN-70942 and IN-E9260 metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

Nicosulfuron

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 1.7 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

- D3 ditch scenario: A 5 m no spray buffer zone is required.
- R1 stream scenario: A 10 m no spray buffer zone and a 10 m vegetative buffer strip are required.
- R2 stream, R3 stream and R4 stream: A 20 m no spray buffer zone and a 20 m vegetative buffer strip are reduction are not enough for acceptable risk. After the refinement with the results of the recovery phase of the study on *Lemna* conducted with nicosulfuron (RAC equal to 0.74 µg nicosulfuron/L), the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.

For ASDM, AUSN, HMUD, ADMP and UCSN metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

COREY

For the endpoints from formulated product COREY, 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk.~~–In addition, for the combined exposure the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.~~ However, based on the results of mixture toxicity assessment, further refinement for R streams scenarios should be considered at national level.
The final risk mititgatin measures for Corey should be decided at MSs level.

zRMS comments:

On the basis of the standard risk assessment performed in line with EFSA aquatic guidance (2013) following conclusions could be derived:

Rimsulfuron:

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.-rimsulfuron and its metabolites could be concluded already for Step 1 PECsw values.

For aquatic macrophytes acceptable risk for a.s.- rimsulfuron could be concluded for STEP 3 for all scenarios excpet R3 and R4, and for its metabolites for STEP 1-2.

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Taking into account **5 meter vegetative buffer for R2 and R3 scenarios the risk is considered acceptable.**

Nicosulfuron:

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.- nicosulfuron and its metabolites could be concluded already for Step 1 PEC_{sw} values.

- Acceptable risk to aquatic macrophytes with no need for risk mitigation measures based on Step 3 calculations was demonstrated in scenarios D3, D4, D5, D6, R1 (pond)
- Acceptable risk to aquatic macrophytes with consideration of 5 m vegetated filter strip was demonstrated in scenarios R1 stream scenario
- Acceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R2 stream scenario

An unacceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R3 and R4. Therefore, further refinement is required for these scenarios.

Further refinement is required for also for mixture toxicity risk assessment for R scenarios at national level.

The proposed endpoint for nicosulfuron RAC of 0.74 µg/L has not been accepted by zRMS.

The final risk mitigation for COREY including mixture toxicity for aquatic organism should be consideded at MSs level.

Updated according to ZRMS request

According to previously inserted changes, the conclusions related to nicosulfuron and combined exposure were changed as below:

Nicosulfuron

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 2.7 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. As R3 and R4 scenarios showed an unacceptable risk, an alternative approach was followed using VFSMOD Global maximum PECsw values. Furthermore, the nicosulfuron concentration pattern was studied to support the recovery observed in the *Lemna* study and a new study with a different macrophyte (*Myriophyllum spicatum*; EC_{50} = 130 µg/L) was submitted to compare the sensitivity of higher plants to nicosulfuron.

Hence, based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

- R1 stream, R2 stream, R3 stream and R4 stream: A 5 m no spray buffer zone and a 5 m vegetative buffer strip are required.

For ASDM, AUSN, HMUD, ADMP and UCSN metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

COREY

For the endpoints from formulated product COREY, 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk. In addition, for the combined exposure the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.

Conclusion

Maize – SPe 3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies.*

zRMS comment to updated risk assessment provided by the applicant (April 2021):

We agree with updated risk assessment provided by the applicant with consideration Option 1 and calculations of the mixture toxicity assessment for R scenarios .

The following risk mitigation measures are required:

COREY

For the endpoints from formulated product COREY, 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk.

In addition, for the combined exposure the risk is considered acceptable with an unsprayed vegetated buffer zone of 10 m.

Conclusion

Maize – SPe 3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies.*

The final risk mitigation measures for aquatic organism should be considered at MSs level.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Rimsulfuron and Nicosulfuron. Full details of these studies are provided in the respective EU DAR and related documents.

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

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

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	DPX-E9636 (rimsulfuron)	Oral (acute)	LD_{50} > 100 µg a.s./bee	EFSA Scientific Report (2005) 45, 1-61
Apis mellifera	DPX-E9636 (rimsulfuron)	Contact (acute)	Contact (24-96 h) – not available	
Apis mellifera	DPX-E9636 plus IN-KG691 (rimsulfuron)	Oral (acute)	**LD_{50} = 41.1 µg a.s./bee**	
Apis mellifera	DPX-E9636 plus IN-KG691 (rimsulfuron)	Contact (acute)	**LD_{50} = 27.9 µg a.s./bee**	

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Rimsulfuron technical	Chronic, 10 d	LDD_{50} > 18.51 µg a.s./bee/day **NOEDD ≥ 18.51 µg a.s./bee/day**	KCP 10.3.1.2.1 Ansaloni, T., 2018, TRC16-193BA
Apis mellifera	Rimsulfuron technical	Larval, repeated exposure	**NOED ≥ 100.00 µg as/larva** EC_{10} Not determined	KCP 10.3.1.3.1 Aguilar-Alberola, J.A. & Marín Víllora, M. 2018, TRC16-162BA
Apis mellifera	Technical nicosulfuron	Oral (acute)	Study details did not allow calculation of oral LD_{50} in terms of µg a.s./bee [LC_{50} > 1000 mg a.s./litre in diet]	EFSA Scientific Report (2007) 120, 1-91
Apis mellifera	Technical nicosulfuron	Contact (acute)	**LD_{50} = 76 µg a.s./bee**	
Apis mellifera	Formulation: 'SL-950 4% SC'	Oral (acute)	LD_{50} >131 µg product/bee – **equivalent to 5.24 µg a.s./bee**	
Apis mellifera	Formulation: 'SL-950 4% SC'	Contact (acute)	Contact (24-96 h) – not available	
Apis mellifera	Nicosulfuron technical	Chronic, 10 d	LDD_{50} > 7.93 µg a.s./bee/day **NOEDD 7.93 µg a.s./bee/day**	KCP 10.3.1.2.2 Ansaloni, T., 2018, TRC16-049BA
Apis mellifera	COREY	Oral	**LD_{50} > 400 µg f.p./bee**	KCP 10.3.1.1.1 Stalmach, M. 2019, B/176/16
Apis mellifera	COREY	Contact	**LD_{50} > 400 µg f.p./bee**	KCP 10.3.1.1.2 Stalmach, M. 2019, B/177/16
Higher-tier studies (tunnel test, field studies)				
Rimsulfuron: Rimsulfuron had no impact on honeybee mortality, flight intesity, behaviour, colony condition or brood development following application to flowering *Phacelia tanacetifolia* in a cage test (80 g Rimsulfuron 25 WG or Rimsulfuron 25 WG + IN-KG 691 surfactant). Nicosulfuron: No bee field studies were conducted and non are required.				

9.6.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to COREY formulation.

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 COREY in maize

Intended use	**Maize**		
Active substance	Rimsulfuron		
Application rate (g/ha)	1 x 15		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	41.1	15	0.36
Contact toxicity	27.9		0.54
Active substance	Nicosulfuron		
Application rate (g/ha)	1 x 30		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	5.24	30	5.73
Contact toxicity	76		0.39
Product	COREY		
Application rate (g/ha)	1 x 100 g f.p./ha		
Test design	**LD_{50} (lab.) (µg f.p./bee)**	**Single application rate (g f.p./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>400	100	0.25
Contact toxicity	>400		0.25

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

Due to the results of laboratory tests rimsulfuron, nicosulfuron and the formulation COREY are considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field.

The EPPO Standard PP 3/10(3) propose define a **bee brood-feeding test**. Effects on brood may be assessed qualitatively or quantitatively depending on the test that is performed. A larvae bees study has been performed by the Applicant and effects were assessed quantitatively. According to EPPO Standard PP 3/10(3), a calculation of the ratio (TER) between the no observed effect level (NOEL) and exposure should be performed. Exposure is assessed by estimating the amount of residues that may be ingested by a bee in 1 day. Since residues in plant material are not available, a generic worst-case value of 1 mg a.s./kg plant matrix was proposed. This value is deduced from a compilation of the data generated in various plant species treated with systemic insecticides.

The oral NOED is measured in µg active substance per bee and residues in plant parts are expressed in mg/kg. Therefore, a conversion of residue data is necessary to express exposure as an amount of residue ingested. This conversion may be done by multiplying the residue concentration (mg a.s./kg plant part) by the daily food ingestion that reflects the dietary need in sugar for a larvae bee. The maximum food ingestion may be estimated from Rortais et al., 2005 at 59.4 mg sugar/larvae for five days for workers. The data set provided by Rortais et al. (2005) is considered to satisfyingly represent food consumption estimates of the different categories of bees. Considering the maximum amount of sugar a worker larvae bee consumes per day (11.88 mg/larva/day) and the amount of sugar in nectar of 15% (worst-case sugar content based on the available scientific literature (Maccagnani et al., 2003; Monzon et al., 2004; Nicolson, 2009)), adults consume an amount of nectar of 79.2 mg/larva/day (thus will be exposed to 0.0792 µg a.s./larva/day). The relevant calculations are presented below.

- 1 kg (=1000000 mg) of plant matrix contains 1 mg of a.s. (=1000 µg a.s.) → 1 mg plant matrix (=nectar) contain 0.001 µg a.s.
- Consumption of 11.88 mg sugar/larva/day and 15% sugar content in nectar → 79.2 mg nectar/larva/day → 79.2*0.001 µg a.s. = 0.0792 µg a.s.

In addition, according to Rortais et al. (2005) a worker larvae might consume up to 5.4 mg of pollen in 5 days which corresponds to 1.08 mg pollen/larva/day.

Tier-1 calculations based on consumption of both nectar and pollen are presented below:

Table 9.6-3: Risk assessment of the risk for larvae bees due to the use of rimsulfuron

Test design	NOED (lab.) (µg a.s./larva)	Consumption (µg a.s./larva)		TER criterion: TER≥ 1
		Nectar	Pollen	
Larvae	100 (Rimsulfuron)	0.0792	0.00108	1245.64

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

Applicability of such approach is justified following the risk assessment scheme for Identification of potential risks to larvae according to *EPPO Standard PP 3/10(3)*.

Question	EPPO Standard PP 3/10 provisions	Option	Justification	Outcome
4	Can effects on growth or development of bees be excluded (risk assessment for bee brood triggered)?	No		Go to 5
5	Conduct a bee brood-feeding test (see Note 8). Effects on brood may be assessed qualitatively or quantitatively depending on the test that is performed. In the case where effects are assessed quantitatively, calculate the ratio (TER) between the no observed effect level (NOEL) and exposure. Exposure is assessed by estimating the amount of residues that may be ingested by a bee in 1 day.	Ratio≥1		Go to 11
11	Categorize as low risk to bees	No		Low risk demonstrated

The EPPO 2010 scheme does not recommend a **chronic assessment for adults** for foliar spray applications. However, as an approach is proposed as an assessment refinement for seed coatings/soil treatments (point 7, on the scheme), this approach can be adapted to provide a worst-case assessment for foliar sprays.

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

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from Rortais et al., 2005, as proposed in the EPPO 2010 scheme, have been used to

estimate the consumption by bee foragers: 898.8 mg sugar/bee for seven days (worst case for nectar foragers). Considering the maximum amount of sugar a nectar foragers bee consumes per day (128.4 mg/bee/day) and the amount of sugar in nectar of 15% (worst-case sugar content based on the available scientific literature (Maccagnani et al., 2003; Monzon et al., 2004; Nicolson, 2009)), adults consume an amount of nectar of 856 mg/bee/day (thus will be exposed to 0.856 µg a.s./bee/day). The relevant calculations are presented below.

- 1 kg (=1000000 mg) of plant matrix contains 1 mg of a.s. (=1000 µg a.s.) → 1 mg plant matrix (=nectar) contain 0.001 µg a.s.
- Consumption of 128.4 mg sugar/bee/day and 15% sugar content in nectar → 856 mg nectar/bee/day → 856*0.001 µg a.s. = 0.856 µg a.s.

In addition, according to Rortais et al. (2005) honeybees might consume several milligrams of pollen per day. Then as a worst case scenario, the nurses pollen consumption was considered, which might be up to 65 mg of pollen in 10 days, which corresponds to 6.5 mg pollen/bee/day.

Tier-1 calculations based on consumption of both nectar and pollen are presented below:

Table 9.6-4: Risk assessment of the risk for adult bees due to the use of rimsulfuron and nicosulfuron

Test design	**NOED (lab.) (µg a.s./bee)**	**Consumption (µg a.s./bee)**		**TER criterion: TER≥ 1**
		Nectar	**Pollen**	
Foraging bees (nectar foragers)	≥18.51 (Rimsulfuron)	0.856	0.0065	21.46
	7.93 (Nicosulfuron)			9.19

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

According to the trigger proposed by the EPPO 2010 scheme it is clear that with above TER values there is a wide safety margin, indicating that the proposed uses of rimsulfuron and nicosulfuron pose an acceptable chronic risk to adult bees.

zRMS comments:

The risk assessment for adult bees based on the laboratory tests with rimsulfuron, nicosulfuron and the formulation COREY are considered acceptable.

All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field.

According to the trigger proposed by the EPPO 2010 scheme the TER values have a wide safety margin, indicating that the proposed uses of rimsulfuron, nicosulfuron pose an acceptable chronic risk to adult bees.

According to EU Reg. 284 /2009, the chronic toxicity test for adult bees, the chronic test for larvae should be provided for authorisation of plant protection product.

Taking into account the GD for bees, 2013 (which is still not implemented at EU level) generally, a study with the active substance will be sufficient; however, if there is an indication from the acute oral study that the formulation is more toxic than the active substance, then the formulation should be tested.

In determining whether there is a difference then the endpoints should be expressed in terms of active substance and if the formulation endpoint is more than a factor of 5 or greater then it can be assumed that

the formulation is of greater toxicity and hence testing should be carried out using the formulation. If the formulation is less than a factor of 5 more toxic then the adult chronic toxicity and larval study should be carried out on the active substance.

After compare the acute toxicity of the formulation in terms of a.s. LD_{50} > 6.08 µg rimsulfuron/bee, LD_{50} > 12.4 µg nicosulfuron/ bee with the endpoint from LoEP: LD_{50} = 41.1 µg rimsulfuron/bee, LD_{50} =5.24 µg nicosulfuron/ bee, the ratio is higher than 5 in case of rimsulfuron.

It should be noted that for rimsulfuron no impact on honeybee mortality, flight intesity, behaviour, colony condition or brood development following application to flowering *Phacelia tanacetifolia* in a cage test (80 g Rimsulfuron 25 WG or Rimsulfuron 25 WG + IN-KG 691 surfactant) was noted according to information provided in LoEP.

In addition, the applicant provided the chronic risk assessment according to EPPO2010 scheme.

According to the trigger proposed by the EPPO 2010 scheme TER values there is a wide safety margin, indicating that the proposed uses of rimsulfuron and nicosulfuron pose an acceptable chronic risk to adult bees.

Therefore, for the of chronic data for formulation COREY further consideration should be decided at MSs level and the chronic test for adult bees and larvae should be submitted for ppp Corey according to EU Reg. 284/2009.

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

Not relevant.

9.6.3 Effects on bumble bees

Not required.

9.6.4 Effects on solitary bees

Not required.

9.6.5 Overall conclusions

First-tier assessments indicate that no unacceptable risk for bees exposed to COREY is expected according to the proposed intended uses.

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

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

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

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (Protonymph)	DPX-E9636 25 WG + IN KG691* (Rimsulfuron)	Laboratory test, glass plates, 14 d	Mortality/ Fecundity (14d, protonymph to adult, glass plate): 9/0% at 1,1 g as/ha, 8/0% at 27,5 g as/ha, 3/0% at 1,1 g as/ha + 0,4*, 11/0% at 27,5 g as/ha + 0,4*, 2/0% at 0.016*, 11/10% at 0.4* LR_{50}>27,5 g as/ha	EFSA Scientific Report (2005), 45, 1-61
Aphidius Rhopalosiphi (adult)	DPX-E9636 25 WG (Rimsulfuron)	Laboratory test, glass plates, 48 h	Mortality/ parasitisation capacity (48h, adult, glass plate): 14/1% at 37,5 g as/ha LR_{50}>37,5 g as/ha	
Chrysoperla carnea	DPX-E9636 25 WG (Rimsulfuron)	Laboratory test, glass plates	Mortality/fertility (exposure till hatching, adult, glass plate): 4/22% at 37,5 g as/ha	
Aleochara bilineata (adult)	DPX-E9636 25 WG (Rimsulfuron)	Extended laboratory, 28 d	Mortality/parasitation capacity (28d, adult, sand): 0/5% at 1,1 g as/ha, 0/22% at 27,5 g as/ha	
Aphidius rhopalosiphi	Nicosulfuron formulation 'SL-950 4% SC'	Laboratory test, glass plates, 48 h	<u>% mortality</u> Water ctrl: 0% 60 g a.s./ha: 15% (n.s.) <u>Parasitism (no. aphid mummies /female)</u> Water ctrl: 33.3% 60 g a.s./ha: 16.6 – red. of 50% (sig. at P=0.05)	EFSA Scientific report (2007) 120, 1-91

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi	Nicosulfuron formulation 'SL-950 4% SC'	48 h exposure to deposit on freshly sprayed barley seedlings)	% mortality Water ctrl: 0% 60 g a.s./ha: 5% (n.s.) Parasitism (nº aphid mummies /female) Water ctrl: 21.1 60 g a.s./ha: 17.6% (n.s.)	
Typhlodromus pyri	Nicosulfuron formulation 'SL-950 4% SC'	Proto-nymph through to adult stage (14 day exposure to glass plate residue)	% mortality (after 7 days exposure) Water ctrl: 17% 1.5 L prod./ha: 41% - ctrl corr. 29% (n.s.) Fecundity (nº of eggs per female during days 7-14) Control: 9.0 1.5 L prod./ha: 9.1 (n.s.)	
Poecilus cupreus	Nicosulfuron formulation 'SL-950 4% SC'	Adult (28 day exposure to initial spray & residues in moist sand substrate)	% mortality (after 28 day exposure) Water ctrl: 33% 1.5 L prod./ha: 40% -control corr. 10% (n.s.) Mean prey consumption per beetle over study period: Water ctrl: 8.6 1.5 L prod./ha: 8.4 (n.s.)	
Coccinella septempunctata	Nicosulfuron formulation 'SL-950 4% SC'	3 day old larvae through to pupae stage (15-20 day exposure to glass plate residue)	% mortality during exposure phase (based on nº of emerging adults): Water ctrl: 18% 1.5 L prod./ha: 16% -ctrl corr. - 6% (n.s.) 3.0 L prod./ha: 40% -ctrl corr. 19% (n.s.) Fecundity (nº of eggs per female during 8-9 week post-exposure phase) & % hatch Control: 137.7 & 60.4% hatch 1.5 L prod./ha: 91.5 & 84.6% hatch (n.s.) 3.0 L prod./ha: 123.4 & 91.2% hatch (n.s.)	
Aleochara bilineata	Nicosulfuron formulation 'SL-950 4% SC'	Adult plus developing F1 beetles present in treated substrate (28 day exposure to residues in moist sand substrate)	% mortality (after 28 day exposure) Water ctrl: 0% 1.5 L prod./ha: 0% Parasitism rate (mean nº per treatment group of F1 beetles emerging from Delia pupae) Water ctrl.: 356 1.5 L prod./ha: 284 – equivalent to 20% red. (n.s.)	

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi	COREY	Laboratory test (2D)	LR_{50} > 500 g/ha	KCP 10.3.2.1-01 Stalmach, M. 2018, B/178/16
Typhlodromus pyri	COREY	Laboratory test (2D)	LR_{50} > 500 g/ha	KCP 10.3.2.1-02 Stalmach, M. 2019, B/179/16
Field or semi-field tests				
Rimsulfuron: Not required. Nicosulfuron: No non-target arthropods studies were conducted and none are required.				

(n.s.): not significant

9.7.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to COREY formulation.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods regarding rimsulfuron due to the use of COREY in maize

Intended use	**Maize**		
Active substance	Rimsulfuron		
Application rate (g/ha)	1 x 15		
MAF	1		
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	27.5	15	0.55
A. rhopalosiphi	37.5		0.40
C. carnea	37.5		0.40
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
A. bilineata	27.5	15	yes

Table 9.7-3: First- and higher-tier assessment of the in-field risk for non-target arthropods regarding nicosulfuron due to the use of COREY in maize

Intended use	**Maize**
Active substance	Nicosulfuron
Application rate (g/ha)	1 x 30
MAF	1

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	60	30	0.50
A. rhopalosiphi	60		0.50
P. cupreus	60		0.50
C. septempunctata	120		0.25
A. bilineata	60		0.50
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
A. rhopalosiphi	60	30	yes

Table 9.7-4: First-tier assessment of the in-field risk for non-target arthropods due to the use of COREY in maize

Intended use	**Maize**		
Product	COREY		
Application rate (g/ha)	1 x 100		
MAF	1		
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	>500	100	0.20
A. rhopalosiphi	>500		0.20

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.

The resulting in-field HQ values for *T. pyri* and *A. rhopalosiphi* is well below the trigger of 2, showing no unacceptable in-field risk to non-target arthropods after application of COREY.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods regarding rimsulfuron due to the use of COREY in maize

Intended use	**Maize**				
Active substance	Rimsulfuron				
Application rate (g/ha)	1 x 15				
MAF	1				
vdf	10 (2D) 1 (3D)				
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	27.5	0.0277	0.042	10	0.015
A. rhopalosiphi	37.5				0.011
C. carnea	37.5				0.011
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
A. bilineata	27.5	0.0277	0.416	5	yes

Table 9.7-6: First- and higher-tier assessment of the off-field risk for non-target arthropods regarding nicosulfuron due to the use of COREY in maize

Intended use	**Maize**
Active substance	Nicosulfuron
Application rate (g/ha)	1 x 30
MAF	1
vdf	10 (2D) / 1 (3D)

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	60	0.0277	0.083	10	0.014
A. rhopalosiphi	60				0.014
P. cupreus	60				0.014
C. septempunctata	120				0.007
A. bilineata	60				0.014
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
A. rhopalosiphi	60	0.0277	0.831	5	yes

Table 9.7-7: First-tier assessment of the off-field risk for non-target arthropods due to the use of COREY in maize

Intended use	**Maize**
Product	COREY
Application rate (g/ha)	1 x 100
MAF	1
vdf	10 (2D), 5(D)*/ 1 (3D)

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
T. pyri	>500	0.0277	0.277 0.554*	10	0.006 0.0118*
A. rhopalosiphi	>500				0.006 0.0118*

*According to recommendation given by Harmonization Meeting in Central Zone

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

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

zRMS comments:

The 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. There are the laboratory tests for SHA 0724 A/COREY on Typh-

lodromus pyri and the other one on Aphidius rhopalosiphi were submitted to support this application. Based on the results of these studies and HQ <2 values in-field and off-field risk after the application of COREY is considered acceptable.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

Not relevant.

9.7.3 Overall conclusions

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of COREY.

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

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Rimsulfuron and Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

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

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

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

Species	Substance	Exposure System	Results	Reference
~~*Eisenia fetida*~~	~~Technical rimsulfuron~~	~~Acute~~	~~LC_{50} > 1000 mg as./kg~~	EFSA Scientific Report (2005), 45, 1-61
~~*Eisenia fetida*~~	~~Rimsulfuron 25% WG~~	~~Acute~~	~~LC_{50} > 1000 mg Prod./kg~~ ~~LC_{50} > 250 mg as./kg~~	
~~*Eisenia fetida*~~	~~Rimsulfuron 25% WG + Exell~~	~~Acute~~	~~LC_{50} > 1000 mg Prod./kg~~ ~~LC_{50} > 22.5 mg as./kg~~	

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	IN-70941	Chronic	NOEC 0.18 mg/kg	
Eisenia fetida	IN-70942	Chronic	NOEC 0.18 mg/kg	
Eisenia fetida	IN-E9260	Chronic	NOEC 0.18 mg/kg	
Folsomia candida	IN-70941	Chronic	NOEC ≥ 0.183 mg/kg	
Folsomia candida	IN-70942	Chronic	NOEC ≥ 0.183 mg/kg	
Folsomia candida	IN-E9260	Chronic	NOEC ≥ 0.183 mg/kg	
~~*Eisenia fetida*~~	~~Technical nicosulfuron~~	~~Acute, 14 d~~	~~LC_{50} > 1000 mg a.s. /kg d.w. soil (highest test dose, no affects reported)~~	
Eisenia fetida	ASDM	Acute, 14 d	LC_{50} > 1000 mg ASDM /kg d.w. soil (highest test dose, no affects reported)	
Eisenia fetida	ADMP, AUSN, HMUD, MU-466 & UCSN	Acute, 14 d	LC_{50} > 1250 mg metabolite /kg d.w. soil (highest test dose, no affects reported)	
Eisenia fetida	'SL-950 4% SC'	Acute, 14 d	LC_{50} > 1000 mg formulation /kg d.w. soil (highest test dose, no affects reported)	EFSA Scientific Report (2007) 120, 1-91
Eisenia fetida	AUSN	Chronic (8 weeks) (reproductive toxicity study)	NOEC 0.100 mg AUSN /kg d.w. soil (highest test dose)	
Eisenia fetida	UCSN	Chronic (8 weeks) (reproductive toxicity study)	NOEC 0.050 mg UCSN /kg d.w. soil (highest test dose)	
Eisenia fetida	ASDM	Chronic (8 weeks) (reproductive toxicity study)	NOEC 0.350 mg ASDM /kg d.w. soil (highest test dose)	
Folsomia candida	AUSN	Chronic (28 days) (reproductive toxicity study)	NOEC 0.100 mg AUSN /kg d.w. soil (highest test dose)	
Folsomia candida	UCSN	Chronic (28 days) (reproductive toxicity study)	NOEC 0.050 mg UCSN /kg d.w. soil (highest test dose)	
Folsomia candida	ASDM	Chronic (28 days) (reproductive toxicity study)	NOEC 0.100 mg ASDM /kg d.w. soil (highest test dose)	
Eisenia fetida	COREY	Mixed into substrate 56 d, chronic 10 % peat content	NOEC = 320 mg/kg dw EC_{10}=179.5 mg/kg dw	KCP 10.4.1.1 Pieczka, P., 2019 G/272/17

Species	Substance	Exposure System	Results	Reference
Folsomia candida	COREY	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 320 mg/kg dw EC_{10}= 311.2 mg/kg dw	KCP 10.4.2.1-01 Pieczka, P., 2019 G/273/17
Field studies				
Not required.				
Litter bag test				
Not required.				

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

9.8.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to COREY formulation.

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, tables from 8.7-3 to 8.7-19. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Rimsulfuron and Nicosulfuron.

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

Intended use	**Maize**		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
~~Rimsulfuron~~	~~> 1000~~	~~0.015~~	~~66666.7~~
~~Nicosulfuron~~	~~> 1000~~	~~0.030~~	~~33333.3~~
ASDM	> 1000	0.013*	76923.1
ADMP	> 1250	0.001	1250000
AUSN	> 1250	0.007*	178571.4
HMUD	> 1250	0.004	312500
UCSN	> 1250	0.003*	416666.7
Chronic effects on earthworms			

Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
IN-70941	0.18	0.010*	18
IN-70942	0.18	0.003*	60
IN-E9260	0.18	0.003*	60
AUSN	0.100	0.007*	14.3
UCSN	0.050	0.003*	16.7
ASDM	0.350	0.013*	26.9
COREY	~~320~~ 179.5	0.100	~~3200~~ 1795
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)**
IN-70941 (*Folsomia candida*)	> 0.183	0.010*	18.3
IN-70942 (*Folsomia candida*)	> 0.183	0.003*	61
IN-E9260 (*Folsomia candida*)	> 0.183	0.003*	61
AUSN (*Folsomia candida*)	0.100	0.007*	14.3
UCSN (*Folsomia candida*)	0.050	0.003*	16.7
ASDM (*Folsomia candida*)	0.100	0.013*	7.7
COREY (*Folsomia candida*)	~~320~~ 311.7	0.100	~~3200~~ 3117

TER values shown in bold fall below the relevant trigger.
* $PEC_{accumulation}$

Chronic studies with COREY on earthworms and collembolan were submitted by the Applicant and no unacceptable risk was obtained after the risk assessment. Moreover, the risk assessment for NTA was acceptable with endpoints for tested indicator species including the ground dwelling arthropod *Aleochara bilineata* after exposure to both active substances in the mixture. Therefore, according to SANCO/10329/2002 rev 2 final, the Applicant considers that an acceptable risk to *Hypoaspis aculeifer* for formulation COREY can be concluded based on low risks to earthworms and other soil macro-organisms and ground dwelling arthropod *Aleochara bilineata*.
Therefore, it is expected that chronic toxicity on *Hypoaspis* will result from prolonged exposure and the formulation is not expected to remain intact in the environment.

zRMS comments:

The risk assessment for soil macro- and meso-fauna in agreed by the zRMS with following corrections:

1. Acute risk assessment for earthworms is no longer required so it was struck through in Table 9.8-2 above.
2. The chronic risk assessment for earthworms for SHA 0724 A/COREY based on NOEC value derived has been struck through as EC_{10} value was lower and thus more relevant for the risk assessment.
3. The risk assessment for *F. candida* for SHA 0724 A/COREY based on NOEC values has been struck through as EC_{10} values were lower and thus more relevant for the risk assessment.

All these corrections has no impact on the outcome of the calculations and acceptable risk from intended

uses of SHA 0724 A/COREY may be concluded for all soil macro-organisms.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The acute and chronic TER values for earthworms and other soil macro- and mesofauna for COREY were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance Rimsulfuron and Nicosulfuron do not pose acute and chronic risk to earthworms and other soil macro- and mesofauna.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Rimsulfuron, Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

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

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

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Rimsulfuron 25 WG + EXELL	28 d, aerobic	< 25% effect up to 0.25 kg prep/ha + 2.5 L Exell	EFSA Scientific Report (2005) 45, 1-61
N-mineralisation	Rimsulfuron 25 WG	28 d, aerobic	< 25% effect up to 0.6 kg prep/ha (0.2 mg/kg dw soil)*	
N-mineralisation	IN-70941	28 d, aerobic	< 25% effect at day 28 at 0.150 kg/ha (0.2 mg/kg dw soil)	
N-mineralisation	IN-E9260	28 d, aerobic	< 25% effect at day 28 at 0.150 kg/ha (0.2 mg/kg dw soil)	
~~C-mineralisation~~	~~Rimsulfuron 25 WG + EXELL~~	~~28 d, aerobic~~	~~< 25% effect up to 0.25 kg prep/ha + 2.5 L Exell~~	

Endpoint	Substance	Exposure System	Results	Reference
~~C-mineralisation~~	~~Rimsulfuron 25 WG~~	~~28 d, aerobic~~	~~< 25% effect up to 0.6 kg prep/ha (0.150 kg a.s./ha)~~	
~~C-mineralisation~~	~~IN-70941~~	~~28 d, aerobic~~	~~< 25% effect at day 28 at 0.150 kg/ha (0.2 mg/kg dw soil)~~	
~~C-mineralisation~~	~~IN-E9260~~	~~28 d, aerobic~~	~~< 25% effect at day 28 at 0.150 kg/ha (0.2 mg/kg dw soil)~~	
N-mineralisation	Nicosulfuron	29 d, aerobic	At 0.08 & 0.8 mg as/kg soil dw < 25% deviation from control by study end (day 28)	EFSA Scientific Report (2007) 120, 1-91
N-mineralisation	SL-950 4% SC	28 day study	At doses equivalent to 0.08 & 0.8 mg a.s. /kg soil d.wt. < 25% deviation from control by study end (day 29)	
N-mineralisation	AUSN	29 d, aerobic	0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)	
N-mineralisation	UCSN	28 day study	0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)	
N-mineralisation	ASMD	28 day study	0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)	
~~C-mineralisation~~	~~Nicosulfuron~~	~~29 d, aerobic~~	~~At 0.08 & 0.8 mg as/kg soil dw < 25% deviation from control by study end (day 28)~~	
~~C-mineralisation~~	~~SL-950 4% SC~~	~~28 day study~~	~~At doses equivalent to 0.08 & 0.8 mg a.s. /kg soil d.wt. < 25% deviation from control by study end (day 29)~~	
~~C-mineralisation~~	~~AUSN~~	~~29 d, aerobic~~	~~0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)~~	
~~C-mineralisation~~	~~UCSN~~	~~28 day study~~	~~0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)~~	
~~C-mineralisation~~	~~ASMD~~	~~28 day study~~	~~0.082 mg AUSN + 0.034 mg UCSN + 0.191 mg ASDM/kg dry soil: < 25% deviation from control by study end (day 28)~~	
N-mineralisation	COREY	28 d, aerobic soil type	No effects >25% on nitrogen transformation at 0.27 and 1.35 mg test item/kg dry soil weight.	KCP 10.5-01 Pieczka, P., 2018 G/271/17

Endpoint	Substance	Exposure System	Results	Reference
~~C-mineralisation~~	~~COREY~~	~~28 d, aerobic soil type~~	~~No effects >25% on carbon transformation at 0.27 and 1.35 mg test item/kg dry soil weight.~~	~~KCP 10.5.02 Pieczka, P., 2019 C/270/17~~

* Conversion of endpoint (g/ha) in endpoint (mg a.s./kg soil)
Endpoint 2 = 150 / (100 x Soil depth (cm) x Soil dry bulk density (g/cm^3))
= 150 / 750
= 0.2 mg a.s./kg soil

9.9.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to COREY formulation

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, tables from 8.7-3 to 8.7-19 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 COREY in maize

Intended use	**Maize**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Rimsulfuron 25 WG (Rimsulfuron)	0.2 (at 28 d)	0.015	yes
IN-70941	0.2 (at 28 d)	0.010*	yes
IN-E9260	0.2 (at 28 d)	0.003*	yes
Nicosulfuron	0.8 (at 28 d)	0.030	yes
AUSN	0.082 (at 29 d)	0.007*	yes
UCSN	0.034 (at 28 d)	0.003*	yes
ASDM	0.191 (at 28 d)	0.013*	yes
COREY	1.35 (at 28 d)	0.100	yes
~~**C-mineralisation**~~			
~~**Product/active substance**~~	~~**Max. conc. with effects ≤ 25 % (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**Risk acceptable?**~~
~~Rimsulfuron 25 WG (Rimsulfuron)~~	~~0.2 (at 28 d)~~	~~0.015~~	~~yes~~
~~IN-70941~~	~~0.2 (at 28 d)~~	~~0.010*~~	~~yes~~
~~IN-E9260~~	~~0.2 (at 28 d)~~	~~0.003*~~	~~yes~~
~~Nicosulfuron~~	~~0.8 (at 28 d)~~	~~0.030~~	~~yes~~

~~AUSN~~	~~0.082 (at 29 d)~~	~~0.007*~~	~~yes~~
~~UCSN~~	~~0.034 (at 28 d)~~	~~0.003*~~	~~yes~~
~~ASDM~~	~~0.191 (at 28 d)~~	~~0.013*~~	~~yes~~
~~COREY~~	~~1.35 (at 28 d)~~	~~0.100~~	~~yes~~

* $PEC_{accumulation}$

zRMS comments:

The risk assessment presented in Table 9.9-2 is agreed by the zRMS.

Maximum PEC_{soil} values are considerably lower than concentrations at which effects were < 25%.

On this basis acceptable risk to soil micro-organisms may be concluded from intended uses of SHA 0724 A/COREY. Risk assessment for effects on carbon transformation has been struck through as being no longer a data requirement.

9.9.3 Overall conclusions

Risk assessments conducted with relevant PEC_{soil} for the active substances Rimsulfuron and Nicosulfuron indicate a low risk to soil microorganisms when applied according to the proposed use rates. The use of COREY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Rimsulfuron, Nicosulfuron and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of COREY were not evaluated as part of the EU assessment of Rimsulfuron and Nicosulfuron.

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

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

Species	Substance	Exposure System	Results	Reference
Sorghum bicolor	Rimsulfuron	Green House Test	ED_{50} technical rimsulfuron 0.17 g as/ha ED_{50} 25 WG formulation 4.89 g product/ha (equal to 1.22 g as/ha)	EFSA Scientific Report (2005), 45, 1-61
Rice	SL-950 4% SC (Nicosulfuron)	Post-emergence (vegetative vigour)	ER_{50} = 0.47 g as/ha (based on % of plants showing visible adverse effects in glasshouse test)	EFSA Scientific Report (2007) 120, 1-91
Most sensitive species not ascertained (equivalent endpoint for six tested dicot / monocot crop species	SL-950 4% SC (Nicosulfuron)	Pre-emergence (emergence)	$ER_{50\ emergence}$ > 20 g a.s./ha (no adverse effects at 20 g a.s./ha)	
Onion (*Allium cepa*)	COREY	Seedling Emergence	ER_{50} (shoot length) = 8.7 g f.p./ha	KCP 10.6.2-01 Pieczka, P., 2019 G/275/17
Carrot (*Daucus carota*)	COREY	Vegetative Vigour Test	ER_{50} (Plant dry weight) = 3.7 g f.p./ha	KCP 10.6.2-02 Pieczka, P., 2019 G/276/17

9.10.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones.

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 COREY in maize

Intended use	**Maize**			
Active substance	COREY			
Application rate (g/ha)	1 x 100			
MAF	1			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Onion (*Allium cepa*)	8.7 (Seedling emergence)	0.0277	2.77	**3.14**
Carrot (*Daucus carota*)	3.7 (Vegetative vigour test)			**1.34**

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

zRMS comments:

Deterministic risk assessment for presented in Tables 9.10-2 above is agreed by the zRMS.

Acceptable risk could be not concluded with E_rC_{50} of 3.7 g/ha value from vegetative vigour test with E_rC_{50} of 8.7 g product/ha value from seedling emergence test for the max. application rate of 100 g product/ha ($PER_{in\text{-}field}$).

Therefore, further refinement was needed to concluded the acceptable risk to non target plants.

For this reason the applicant provided the risk mitigation measures in the Table 9.10-3 below.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

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

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of COREY in maize considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use	**Maize**
Active substance	COREY
Application rate (g/ha)	1 x 100
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	0.0277	2.77	1.385	0.6925	0.277
5	0.0057	0.57	0.285	0.1425	0.057
10	0.0029	0.29	0.145	0.0725	0.029
Toxicity value ER_{50} = 3.7 g a.s./ha		**TER** **criterion: TER ≥ 5**			
1		**1.34**	**2.67**	5.34	13.36
5		6.49	12.98	-	-
10		12.76	-	-	-

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

ZRMS comments:

Based on the lowest toxicity endpoint E_rC_{50} of 3.7 g product/ha value form vegetative vigour test the risk is acceptable when following risk mitigation measures are applied to non - agricultural land.

- 75% drift reducing nozzles OR respect an unsprayed buffer zone of 5m to non-agricultural land.

The final risk mitigation measures should be considered at MSs level.

9.10.3 Overall conclusions

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Rimsulfuron and Nicosulfuron shows that the Annex VI trigger value of 5 is not reached. Therefore, mitigation measures are needed. When there is 75% nozzle reduction OR 5m buffer zone, COREY poses a low risk to non-target plants when applied according to the proposed use rates.

Maize – SPe 3: *To protect non-target plants use 75% drift reducing nozzles OR respect an unsprayed buffer zone of 5m to non-agricultural land.*

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

Rimsulfuron:
Data from a test with activated sludge are available and indicate that the risk to biological methods of sewage treatment plants is low.

Nicosulfuron:
Effects on biological methods for sewage treatment

Test type/organism	**End point**
Activated sludge	--
Pseudomonas putida	Nicosulfuron EC_{50} > 250 mg as/L (no reported effects) ASDM, AUSN, UCSN, MU-466, HMUD > 100 mg metabolite/L (no significant inhibition)

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	Rimsulfuron 15% + Nicosulfuron 30% WG
Common Name	COREY
Classification ad proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria Reg. 1272/2008, as amended)	Hazards classe(s), categories: Aquatic Acute Category 1 Aquatic Chronic Category 1 Code(s) for hazard pictogram(s): GHS09 Signal word: Warning Hazard statement(s): H400, H410 Precautionary statement: P273, P391, P501

zRMS comments:

zRMS agrres with classification and labelling:

Hazard statement(s): H400, H410

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-01	xxxx	2019	Rimsulfuron 15% + Nicosulfuron 30% WG. Rainbow trout, Acute toxicity test xxxxx report No. W/208/17 GLP, unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1-02	Bak, P.	2018	Rimsulfuron 15% + Nicosulfuron 30% WG. *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) SAG 61.81 Growth inhibition test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/209/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Bak, P.	2018	Rimsulfuron 15% + Nicosulfuron 30% WG. *Daphnia magna*, acute immobilisation test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/210/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-04	Bak, P.	2018	Rimsulfuron 15% + Nicosulfuron 30% WG. *Lemna gibba* CPCC 310, Growth inhibition test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/211/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-05	Bätscher, R.	2008	Toxicity of Nicosulfuron technical to the Aquatic Higher Plant *Lemna gibba* in a 7-Day Growth Inhibition Test, Supplemented With Testing for Recovery of Growth B75341. GLP, unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-06	Brzozowska, K.	2017	Nicosulfuron technical. Water-sediment *Myriophyllum spicatum* toxicity test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/21/16 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.1	Stalmach, M.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/176/16 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Stalmach, M.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/177/16 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2.1	Ansaloni, T.	2018	Rimsulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* Trialcamp S.L.U. TRC16-193BA GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2.2	Ansaloni, T.	2018	Nicosulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L. Trialcamp S.L.U. TRC16-049BA GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.3.1	Aguilar-Alberola, J.A. & Marín Víllora, M.	2018	Toxicity of Rimsulfuron Technical on honeybee larvae (*Apis mellifera* L.) after repeated exposure under laboratory conditions Trialcamp S.L.U. TRC16-162BA GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-01	Stalmach, M.	2018	A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/178/16 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-02	Stalmach, M.	2019	A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WDG on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/179/16 GLP, unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4.1.1	Pieczka, P.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Earthworm Reproduction Test (*Eisenia andrei*) Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/272/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Pieczka, P.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Collembolan (*Folsomia candida*) Reproduction Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/273/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.5-01	Pieczka, P.	2018	Rimsulfuron 15% + Nicosulfuron 30% WDG. Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/271/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-01	Pieczka, P.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/275/17 GLP, unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Pieczka, P.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/276/17 GLP, unpublished	N	Sharda Cropchem Limited

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

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

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
KCP 10.5-02	Pieczka, P.	2019	Rimsulfuron 15% + Nicosulfuron 30% WDG. Soil Microorganisms: Carbon Transformation Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/270/17 GLP, unpublished	N	Sharda Cropchem Limited

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

A 2.2 KCP 10.2 Effects on aquatic organisms

zRMS comment:

The E_rC_{50} endpoints. "*The endpoint ErC50 is selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary.*

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

A 2.2.1.1.1 Study 1

Comments of zRMS:	The study was considered valid. All validity criteria were met.

	• the biomass in the control increased by a factor of 102.0 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 2.5% (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 13.6% (criterion: it must not exceed 35%). At exposure initiation, the determined concentration of rimsulfuron was in the range of 80.1 – 89.9% of nominal concentration and the deter-mined concentration of nicosulfuron was in the range of 94.3 – 104.0% of nominal concentration. The results confirm that the test item concentrations were prepared correctly. At expo-sure termination, the deter-mined concentration of rimsulfuron was in the range of 81.3 – 87.9% of nominal concentration and the determined concentration of nico-sulfu-ron was in the range of 96.6 – 105.9% of nominal concentration. Therefore, the concentrations of rimsulfuron and nicosulfuron were stable under test conditions. **Agreed endpoints**: The endpoint values determined on the basis of the nominal test item concentra-tions and mortality of fish are given below: **The LC_{50} /96 h = 300.95 mg/L** **(95% confidence intervals: 237.33 –** 386.02) The LOEC/96 h =455 mg/L. The NOEC/96 h = 207 mg/L. The endpoint values determined on the basis of the nominal concentrations of rimsulfuron and mortality of fish: The LC_{50} /96 h = 45.74 mg/L (95% confidence intervals: 36.07 – 58.67) The LOEC/96 h =69.16 mg/L. The NOEC/96 h =31.46 mg/L. The endpoint values determined on the basis of the nominal concentrations of nicosulfuron and mortality of fish: The LC_{50} /96 h =90.59 mg/L (95% confidence intervals: 71.44 – 116.19) The LOEC/96 h =136.96 mg/L. The NOEC/96 h = 62.31 mg/L.

Reference: KCP 10.2.1 - 01

Report "Rimsulfuron 15% + Nicosulfuron 30% WG: Rainbow Trout, Acute Toxici-ty Test".
xxxx, 2019, W/208/17. xxxxx

Guideline(s): Yes, OECD Guideline No. 203 (1992)

Deviations: One deviation from the study plan regarding date of study completion. The date of study completion in the Study plan was November 2018 but due to necessity of Sponsor's acceptance the date was postponed.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Yes

Experimental period: 96h

Materials and methods

Test item:

Description:	Rimsulfuron 15% + Nicosulfuron 30% WG
Production batch:	SCL - 65843
A.i. content:	rimsulfuron: 15.2% (w/w); nicosulfuron: 30.1% (w/w)

Test system:

Species:	Rainbow trout (*Oncorhynchus mykiss*)
Strain:	Walb.
Age:	5.5 months
Average weight:	0.89 g ± 0.16 g
Average length:	4.65 cm ± 0.35 cm
Source:	'The Culture of Salmonidae Fish in Zawoja', Poland.
Acclimation period:	7-day quarantine, 12-day acclimatization. Fish mortality during the quarantine period was lower than 5%.
Diet:	During the adaptation the fish were fed with standard granulated fish food. Feeding of the fish was terminated 24 h before exposure initiation.

Experimental conditions:

Temperature:	14.7 – 15.0°C (continuously recorded)
Dissolved O_2:	92 – 100% ASV
Hardness:	39.5 mg/L $CaCO_3$
pH:	7.71 – 7.89 (measured in all test item concentrations and the control at exposure initiation and at exposure termination)
Light and photoperiod:	16h light and 8h dark
Loading:	Seven fish in each aquarium, the ratio of fish weight per volume (10 L) was 0.62 g/L.
Test procedure:	The test was performed in temperature-controlled aquaria and incubated in a temperature-controlled room.

Test design and treatment

Static system (96 h of exposure).
According to the preliminary test results, the main final test included the test item concentrations of 1000, 455, 207, 94, 43, 19, 8.8 mg/L plus the control.. The fish were observed for intoxication symptoms and mortality 3, 6, 24, 48, 72 and 96 h of exposure.
The concentrations of rimsulfuron and nicosulfuron were chemically determined using a validated high performance liquid chromatographic method with DAD detection. The validated analytical method was performed according to SANCO/3029/99 rev.4. At exposure initiation, the determined

concentration of rimsulfuron was in the range of 80.1 – 89.9% of nominal concentration and the determined concentration of nicosulfuron was in the range of 94.3 – 104.0% of nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentration of rimsulfuron was in the range of 81.3 – 87.9% of nominal concentration and the determined concentration of nicosulfuron was in the range of 96.6 – 105.9% of nominal concentration. Therefore, the concentrations of rimsulfuron and nicosulfuron were stable under test conditions.

Concentration and stability of rimsulfuron – definitive test

Nominal test item concentration (mg/L)	Nominal concentration of rimsulfuron [mg/L]	Average concentration (n=3) of rimsulfuron measured in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	-	<LoD	-	<LoD	-
8.8	1.34	1.205	89.9	1.125	84.0
19	2.89	2.423	83.8	2.450	84.8
43	6.54	5.287	80.8	5.349	81.8
94	14.29	11.44	80.1	11.85	82.9
207	31.46	26.22	83.3	26.68	84.8
455	69.16	56.96	82.4	60.77	87.9
1000	152.00	124.69	82.0	123.55	81.3

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Concentration and stability of nicosulfuron – definitive test

Nominal test item concentration (mg/L)	Nominal concentration of rimsulfuron [mg/L]	Average concentration (n=3) of rimsulfuron measured in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	-	<LoD	-	<LoD	-
8.8	2.65	2.499	94.3	2.561	96.6
19	5.72	5.828	101.9	5.927	103.6
43	12.94	12.37	95.6	12.85	99.3
94	28.29	28.11	99.4	28.64	101.2
207	62.31	63.75	102.3	63.75	102.3
455	136.96	139.12	101.6	145.10	105.9
1000	301.00	313.08	104.0	312.66	103.9

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Results

Mortality of fish in test item concentrations – definitive test

Dose (mg/L)	Mortality of fish at 24h			Mortality of fish at 96h		
	Number of dead fish	Number of alive fish	Total mortality of fish (%)	Number of dead fish	Number of alive fish	Total mortality of fish (%)
Control	0	7	0	0	7	0
8.8	0	7	0	0	7	0
19	0	7	0	0	7	0
43	0	7	0	0	7	0
94	0	7	0	0	7	0
207	0	7	0	0	7	0

455	4	3	57.1	7	0	100
1000	7	0	100	7	0	100

The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:
The LC_{50} /96 h value is 300.95 mg/L (95% confidence intervals: 237.33 – 386.02)
The LOEC/96 h value is 455 mg/L.
The NOEC/96 h value is 207 mg/L.

The endpoint values determined on the basis of the nominal concentrations of rimsulfuron and mortality of fish:
The LC_{50} /96 h value is 45.74 mg/L (95% confidence intervals: 36.07 – 58.67)
The LOEC/96 h value is 69.16 mg/L.
The NOEC/96 h value is 31.46 mg/L.
The endpoint values determined on the basis of the nominal concentrations of nicosulfuron and mortality of fish:
The LC_{50} /96 h value is 90.59 mg/L (95% confidence intervals: 71.44 – 116.19)
The LOEC/96 h value is 136.96 mg/L.
The NOEC/96 h value is 62.31 mg/L.

Conclusion
The LC_{50} value after 96 h of exposure is 300.95 mg/L (nominal test item concentration).

A 2.2.1.1.2 Study 2

Comments of zRMS:

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

- the biomass in the control increased by a factor of 102.0 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 2.5% (criterion: it must not exceed 7%),
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 13.6% (criterion: it must not exceed 35%).

Agreed endpoints:

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	0.696 (0.505 – 0.901)	0.107 (0.078 – 0.139)	0.215 (0.156 – 0.279)	0.0708 (0.0488 – 0.0957)
ErC_{20}	1.509 (1.197 – 1.829)	0.232 (0.184 – 0.281)	0.467 (0.370 – 0.566)	0.1683 (0.1284 – 0.2105)
ErC_{50}	**6.634** (5.805 – 7.604)	1.010 (0.884 – 1.156)	2.056 (1.798 – 2.357)	0.8815 (0.7589 – 1.0250)
LOEC	0.977	0.15	0.300	0.082
NOEC	0.305	0.046	0.095	0.029

	Yield				
EyC_{10}	0.173 (0.152 – 0.193)	0.026 (0.023 – 0.029)	0.053 (0.047 – 0.060)	0.0134 (0.0117 – 0.0151)
EyC_{20}	0.313 (0.286 – 0.341)	0.047 (0.043 – 0.052)	0.097 (0.088 – 0.105)	0.0263 (0.0238 – 0.0288)
EyC_{50}	0.980 (0.926 – 1.037)	0.150 (0.141 – 0.158)	0.303 (0.286 – 0.320)	0.0961 (0.0900 – 0.1026)
LOEC	0.305	0.046	0.095	0.029
NOEC	0.095	0.014	0.029	0.0084

Reference:	KCP 10.2.1-02
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WG *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) SAG 61.81 Growth inhibition test*"*. Bąk P., W/209/17, 2018. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD Guideline No. 201 (2006)
Deviations:	Yes The study plan stated that the study completion date is June 2018. The draft report was sent in June 2018. However, the final report is July 2018.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The influence of Rimsulfuron 15% + Nicosulfuron 30% WG on the growth of the green algal species *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) SAG 61.81 was investigated in a 72-hour test. The algae were exposed on six test item concentrations: 32, 10, 3.125, 0.977, 0.305, 0.095 mg/L. For exposure, three replicates were used for each test item concentration, whereas six replicates for control. The number of algal cells was determined with an indirect method, which involves a spectrophotometric measurement of the absorbance of algal suspension at 670 nm and converting its value into the number of cells using a standard curve. The absorbance for each replicate of each test item concentration and the control was measured after 24, 48, and 72 h of exposure. Morphology observations of the algae cells were performed at exposure termination.

Material and methods

Test item: Name: Rimsulfuron 15% + Nicosulfuron 30% WG
Batch number: SCL-44986
Manufacturing date: 25th May 2016
Expiry date: 24th May 2018

Test organism: The unicellular freshwater green algae, *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) SAG 61.81. The algae were obtained from the Culture Collection of Algae at Göttingen University, Germany.

Test duration: 72 hours

Test water: The AAP medium (U.S. EPA) recommended by OECD Guideline No. 201 (2006)

Test conditions: Temperature: 21.9 – 22.5ºC (continuously measured using a sensor submerged in an additional test vessel containing 100 mL of the AAP medium)
pH of the control: 7.53 – 8.55 (measured in all test item concentrations and the control at exposure initiation before the splitting up into replicates and at exposure termination in pooled replicates)
Lighting: continuous illumination
Light intensity: 7198 – 7510 lux

Test concentrations: 32, 10, 3.125, 0.977, 0.305, 0.095 mg/L plus the control.

Statistical analysis: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm, Stepdown Jonckheere-Terpsta Test Procedure.

Validity criteria: - the biomass in the control increased by a factor of 102.0 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 2.5% (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 13.6% (criterion: it must not exceed 35%).

Concentrations of rimsulfuron and nicosulfuron, definitive test

Time of analysis	Nominal concentration of the tet item (mg/L)	Average determined concentration of rimsulfuron (mg/L)	% of the nominal concentration	Average determined concentration of nicosulfuron (mg/L)	% of the nominal concentration
Exposure initiation	**Control**	< LoD	-	< LoD	-
	0.095	0.013	92.9	0.0268	92.4
	0.305	0.042	90.8	0.0956	100.6
	0.977	0.121	81.5	0.302	99.7
	3.125	0.404	85.1	0.986	101.8
	10	1.728	113.7	3.230	104.2
	32	5.491	112.9	10.308	103.9
24 h of exposure	**Control**	< LoD	-	< LoD	-
	0.095	0.0085	60.7	0.0281	96.9
	0.305	0.0291	62.8	0.0888	93.5
	0.977	0.076	51.2	0.282	93.1
	3.125	0.425	89.5	1.044	107.7
	10	1.431	94.1	2.926	94.4
	32	4.370	89.8	9.248	93.2
48 h of exposure	**Control**	< LoD	-	< LoD	-
	0.095	0.0069	49.3	0.0264	91.0
	0.305	0.0253	54.6	0.0877	92.3
	0.977	0.074	49.8	0.281	92.7
	3.125	0.416	87.6	1.037	107.0
	10	1.426	93.8	2.917	94.1
	32	4.353	89.5	9.240	93.1

Exposure termination	**Control**	< LoD	-	< LoD	-
	0.095	0.0076	54.3	0.0282	97.2
	0.305	0.0253	54.6	0.0878	92.4
	0.977	0.078	52.5	0.280	92.4
	3.125	0.399	84.0	1.103	113.8
	10	1.338	88.0	2.965	95.6
	32	4.210	86.6	9.490	95.7

--- - not calculated; LoQ = 0.001 mg/L; LoD = 0.0003 mg/L

Results

Inhibition of growth rate and yield, definitive test

Nominal test item concentration (mg/L)	% inhibition after 72h of exposure (growth rate)	% inhibition after 72h of exposure (yield)
Control	0.0	0.0
0.095	-1.0*	-4.5*
0.305	4.5	19.7
0.977	15.4	52.1
3.125	32.4	78.9
10	58.1	94.3
32	83.0	98.6

*Inhibition is lower than 0.0%, which means that the algal cell density at exposure termination was higher than in the control.

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	0.696 (0.505 – 0.901)	0.107 (0.078 – 0.139)	0.215 (0.156 – 0.279)	0.0708 (0.0488 – 0.0957)
ErC_{20}	1.509 (1.197 – 1.829)	0.232 (0.184 – 0.281)	0.467 (0.370 – 0.566)	0.1683 (0.1284 – 0.2105)
ErC_{50}	6.634 (5.805 – 7.604)	1.010 (0.884 – 1.156)	2.056 (1.798 – 2.357)	0.8815 (0.7589 – 1.0250)
LOEC	0.977	0.15	0.300	0.082
NOEC	0.305	0.046	0.095	0.029
Yield				
EyC_{10}	0.173 (0.152 – 0.193)	0.026 (0.023 – 0.029)	0.053 (0.047 – 0.060)	0.0134 (0.0117 – 0.0151)
EyC_{20}	0.313 (0.286 – 0.341)	0.047 (0.043 – 0.052)	0.097 (0.088 – 0.105)	0.0263 (0.0238 – 0.0288)
EyC_{50}	0.980 (0.926 – 1.037)	0.150 (0.141 – 0.158)	0.303 (0.286 – 0.320)	0.0961 (0.0900 – 0.1026)
LOEC	0.305	0.046	0.095	0.029
NOEC	0.095	0.014	0.029	0.0084

A 2.2.1.1.3 Study 3

Comments of zRMS:	The study was considered valid. All validity criteria were met. • the percentage of 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 8.5 – 9.1 mg/L (criterion: not less than 3 mg/L). **Agreed endpoints:** The endpoint values determined based on the nominal test item concentrations: **EC_{50}/48 h > 100 mg/L.** The endpoint values determined based on the nominal concentrations of rimsulfuron in the test item: EC_{50}/48 h >15.2 mg/L. The endpoint values determined based on the nominal concentrations of nicosulfuron in the test item: EC_{50}/48 h > 31.0 mg/L.

Reference:	KCP 10.2.1-03
Report	"Rimsulfuron 15% + Nicosulfuron 30% WG: *Daphnia magna*, Acute immobilization test", Paweł Bąk (2018) Report No. W/210/17. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

Immobilisation of Daphnia magna exposed to the test item Rimsulfuron 15% + Nicosulfuron 30% WG was investigated during a 48-hours semi-static test with a renewal after 24 h of exposure. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. Single test item concentration of 100 mg/L plus the control were used, as a limit test.

Test conditions: Temperature: 18.3 – 20.1ºC (continuously recorded using an electronic device with a sensor in an additional test vessel containing the test medium); pH of the control: 7.62 – 7.76; dissolved oxygen concentration in the control: 8.5 – 9.1 mg/L (measured in all test item concentrations and the control at exposure initiation at renewal before splitting up into replicates and at renewal and at exposure termination in pooled replicates); daily cycle: 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration; medium: Elendt M7.

The Daphnia magna were observed for immobilisation after 24 and 48 h of exposure. The Daphnia magna were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel.

In the control and in the test item concentration of 100 mg/L, no immobilisation of Daphnia magna was observed during exposure.

The concentrations of rimsulfuron and nicosulfuron were determined using a validated liquid chromatographic method. Samples of fresh test item concentration and the control collected at exposure initiation and at renewal, and spent test item concentration and the control collected at renewal and at exposure termination were chemically determined.

In fresh samples, the determined concentrations of rimsulfuron were 106.3 and 99.8% of the nominal concentration and the determined concentrations of nicosulfuron were 99.8 and 106.8% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.

In spent samples, the determined concentrations of rimsulfuron were 87.6 and 89.2% of the nominal concentration and the determined concentrations of nicosulfuron were 98.9 and 96.1% of the nominal concentration. Therefore, the concentrations of rimsulfuron and nicosulfuron were stable under test conditions.
The endpoint values were determined based on the nominal test item concentration, nominal concentrations of rimsulfuron in the test item and nominal concentrations of nicosulfuron in the test item.

Concentration and stability of the rimsulfuron and nicosulfuron – definitive test

Nominal concentration	Control	Rimsulfuron 15.2 mg/L	Nicosulfuron 31 mg/L	Day of sampling
Average determined concentration (n=3) in samples collected (mg/L)	< LoD	16.154	30.946	at exposure initiation (fresh)
% of the nominal concentration	-	106.3	99.8	
Average determined concentration (n=3) in samples collected (mg/L)	< LoD	13.313	30.674	after 24 h of exposure (spent, 24h old)
% of the nominal concentration	-	87.6	98.9	
Average determined concentration (n=3) in samples collected (mg/L)	< LoD	15.169	33.101	after 24 h of exposure (fresh)
% of the nominal concentration	-	99.8	106.8	
Average determined concentration (n=3) in samples collected (mg/L)	< LoD	13.552	29.803	exposure termination (spent, 24h old)
% of the nominal concentration	-	89.2	96.1	

LoQ = 0.001 mg/L
LoD = 0.0003

Results

Preliminary test

In the preliminary test, the recorded temperature was in the range of 19.0 – 22.1ºC. The pH values measured at exposure initiation were in the range of 7.20 – 7.76. At renewal, the pH values measured in spent test item concentrations and the control were in the range of 7.50 – 7.66 and in the range of 7.12 – 7.67 in fresh test item concentrations and the control. The pH values at exposure termination were in the range of 7.70 – 7.75. The dissolved oxygen concentrations measured at exposure initiation were 8.8 mg/L. At renewal, the dissolved oxygen concentrations measured in spent test item concentrations and the control were 8.7 mg/L and in the range of 8.9 – 9.0 mg/L in fresh test item concentrations and the control. The dissolved oxygen concentrations measured at exposure termination were in the range of 8.4 – 8.6 mg/L.
In the preliminary test, no immobilisation of Daphnia magna was observed during exposure neither in the control nor in the test item concentrations.
In the preliminary test, the concentrations of rimsulfuron and nicosulfuron were determined in solubility test using a validated chromatographic method [SOP/C/499]. At the test initiation, concentration of nicosulfuron was 95.5% of nominal and concentration of rimsulfuron was 104.4% of nominal, what confirm correct preparation of the test item concentration and its appropriate solubility.
Since the concentration of rimsulfuron was not stable after 2 days of the test initiation, the definitive test was planned to be performed in a semi-static design with renewal after 24 h of exposure.

Definitive test

In the definitive test, the recorded temperature during exposure was in the range of 18.3 – 20.1ºC and constant within ±1.0ºC. The pH values measured at exposure initiation were in the range of 7.30 – 7.76. At renewal, the pH values measured in spent test item concentrations and the control were in the range of 7.56 – 7.66 and in the range of 7.28 – 7.71 in fresh test item concentrations and the control. The pH values at exposure termination were in the range of 7.43 – 7.62. The dissolved oxygen concentrations measured at exposure initiation were in the range of 8.7 – 8.9 mg/L. At renewal, the dissolved oxygen concentrations measured in spent test item concentrations and the control were in the range of 8.6 – 8.7 mg/L and in the range of 8.9 – 9.1 mg/L in fresh test item concentrations and the control. The dissolved oxygen concentrations measured at exposure termination were in the range of 8.5 – 8.6 mg/L.
In the control and in the test item concentration of 100 mg/L, no immobilisation of Daphnia magna was observed during exposure.
In fresh samples, the determined concentration of rimsulfuron was in the range of 99.8 – 106.3% and the determined concentration of nicosulfuron was in the range of 99.8 – 106.8% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. In spent samples the determined concentration of rimsulfuron was in the range of 87.6 – 89.2% and the determined concentration of nicosulfuron was in the range of 96.1 – 98.9% of the nominal concentration. Therefore, the concentrations of rimsulfuron and nicosulfuron were stable under test conditions.

Table 10.2.1-02-01 Immobilization of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	**Number of *Daphnia magna***	**Number of immobilized *Daphnia magna***								**Total of immobilized *Daphnia magna* [%]**	
		24 h				**48 h**					
		Replicates									
		A	B	C	D	A	B	C	D	**24 h**	**48 h**
Control	20	0	0	0	0	0	0	0	0	0	0
100.00	20	0	0	0	0	0	0	0	0	0	0

Validity criteria

In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004):

- the percentage of 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 8.5 – 9.1 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values determined based on the nominal test item concentrations:
The median concentrations causing 50% immobilisation of Daphnia magna after 24 and 48 h of exposure, i.e. the EC_{50}/24 h and EC_{50}/48 h value are higher than 100 mg/L.
The endpoint values determined based on the nominal concentrations of rimsulfuron in the test item:
The median concentrations causing 50% immobilisation of Daphnia magna after 24 and 48 h of exposure, i.e. the EC_{50}/24 h and EC_{50}/48 h value are higher than 15.2 mg/L.
The endpoint values determined based on the nominal concentrations of nicosulfuron in the test item:
The median concentrations causing 50% immobilisation of Daphnia magna after 24 and 48 h of exposure, i.e. the EC_{50}/24 h and EC_{50}/48 h value are higher than 31.0 mg/L.

A 2.2.1.1.4 Study 4

Comments of zRMS:

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

- the study was considered valid. All validity criteria were met.
- the doubling time of frond number in the control was 2.3 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 8.6).
  the average specific growth rate in the control between day 0 and day 7 was 0.305 d-1 (minimum requirement: higher than 0.275 d-1).

Agreed endpoints:

Frond number

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	n.d.	n.d.	n.d.	n.d.
ErC_{20}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
ErC_{50}	**0.00748** (0.00693 – 0.00807)	0.00115 (0.00107 – 0.00124)	0.00236 (0.00218 – 0.00254)	0.00085 (0.00079 – 0.00090)
LOEC	≤ 0.0015	≤ 0.00023	≤ 0.00047	≤ 0.0003
NOEC	< 0.0015	< 0.00023	< 0.00047	<0.0003
Yield				
EyC_{10}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
EyC_{20}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
EyC_{50}	0.00258 (0.00247 – 0.00269)	0.00040 (0.00038 – 0.00041)	0.00081 (0.00078 – 0.00085)	0.00037 (0.00036 – 0.00037)
LOEC	≤ 0.0015	≤ 0.00023	≤ 0.00047	≤ 0.0003
NOEC	< 0.0015	< 0.00023	< 0.00047	< 0.0003

Dry weight

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	< 0.0015	< 0.00023	< 0.00047	n.d.
ErC_{20}	0.03987 (0.01763 – 0.07665)	0.00612 (0.00271 – 0.01175)	0.01241 (0.00549 – 0.02384)	0.00428 (0.00191 – 0.00815)
ErC_{50}	> 100	> 15.2	> 31.0	> 9.854
LOEC	0.006	0.00093	0.0019	0.0005
NOEC	0.0015	0.00023	0.00047	0.0003
Yield				
EyC_{10}	n.d.	n.d.	n.d.	n.d.
EyC_{20}	< 0.0015	< 0.00023	< 0.00047	n.d.
EyC_{50}	0.10079 (0.07535 – 0.13335)	0.01544 (0.01155 – 0.02042)	0.03136 (0.02346 – 0.04146)	0.01084 (0.00811 – 0.01434)
LOEC	0.006	0.00093	0.0019	0.0005
NOEC	0.0015	0.00023	0.00047	0.0003

***** n.d. – not determined

Reference:	KCP 10.2.1-04
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WG *Lemna gibba* CPCC 310, Growth inhibition test". Bąk P., W/211/17, 2018. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD Guideline No. 221 (2006) Adopted 23 rd March, 2006
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The growth of Lemna gibba exposed to the test item, Rimsulfuron 15% + Nicosulfuron 30% WG, was investigated in a 7 day semi-static test with daily renewals. The initial frond number in each test item concentration and in the control was nine. The following test item concentrations were used: 100, 25, 6.25, 1.56, 0.39, 0.098, 0.024, 0.006 and 0.0015 mg/L plus the control. The total number of fronds in each test vessel was counted twice during exposure (day 2 and 5) and at exposure termination. The observations of plant development, i.e. size of fronds, necrosis, chlorosis, colony break-up, gibbosity, changes in the appearance of roots were performed at the same time. After 7 days of exposure, in none of the test item concentrations distinctive changes from the normal development of plants in the control were observed. The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of rimsulfuron, nominal concentrations of nicosulfuron and geometric mean of determined concentrations of rimsulfuron.

Material and methods

Test item:	Name: Rimsulfuron 15% + Nicosulfuron 30% WG Batch number: SCL-44986 Production date: 25 May 2016 Expiry date: 24 May 2018
Test organisms:	The freshwater aquatic plant, *Lemna gibba* L. CPCC 310 cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology; the plants were obtained from the Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada.
Test design:	Semi-static system with daily renewals; 7 days of exposure; three replicates for each test item concentration and six replicates for control.
Test medium:	20X AAP nutrient solution
Nominal test item concentrations:	100, 25, 6.25, 1.56, 0.39, 0.098, 0.024, 0.006 and 0.0015 mg/L plus the control.
Test conditions:	pH of the control: 7.31 – 8.86 (measured in fresh test item concentrations and the control before splitting up into replicates at exposure initiation and at each renewal and in spent test item concentrations and the control at each renewal and at exposure termination in pooled replicates).

Mean light intensity: 7740 - 7972 lux, constant illumination (measured at exposure initiation, twice during exposure (on day 2 and 4 in the preliminary test and on day 2 and 5 in the definitive test) and at exposure termination)
Glass crystallizers containing 150 mL of a given test item concentration or control
Initial frond number: 9, i.e. 3 plants per 3 fronds;
Temperature: 24.1 – 25.1ºC (continuously recorded in an additional test vessel with 20X AAP medium)

Chemical determinations: The concentrations of rimsulfuron and nicosulfuron were determined with validated liquid chromatographic method with DAD detection.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Step-down Jonckheere-Terpstra Test Procedure.

Validity criteria: - the doubling time of frond number in the control was 2.3 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 8.6).
- the average specific growth rate in the control between day 0 and day 7 was 0.305 d-1 (minimum requirement: higher than 0.275 d-1).

Concentration and stability of rimsulfuron, definitive test

Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00101	0.00390	0.01315	0.04780	0.258	1.009	4.007	15.744	day 3 fresh
% of the nominal concentration	---	112.2	108.3	87.7	81.0	107.5	106.2	105.4	103.6	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00115	0.00525	0.01916	0.113	0.491	1.111	5.575	day 4 spent
% of the nominal concentration	---	---	31.9	35.0	32.5	47.1	51.7	29.2	36.7	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00351	0.01419	0.04839	0.249	0.977	3.063	15.854	day 4 fresh
% of the nominal concentration	---	---	97.5	94.6	82.0	103.8	102.8	80.6	104.3	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	<LoD	0.00119	0.00616	0.01435	0.124	0.474	0.715	4.899	day 5 spent
% of the nominal concentration	---	---	33.1	41.1	24.3	51.7	49.9	18.8	32.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00345	0.01255	0.04816	0.236	0.972	3.982	15.835	day 5 fresh
% of the nominal concentration	---	---	95.8	83.7	81.6	98.3	102.3	104.8	104.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00222	0.00637	0.02337	0.160	0.678	0.973	4.671	day 6 spent
% of the nominal concentration	---	---	61.7	42.5	39.6	66.7	71.4	25.6	30.7	

Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00343	0.01370	0.04949	0.256	0.978	3.894	13.054	day 6 fresh
% of the nominal concentration	---	---	95.3	91.3	83.9	106.7	102.9	102.5	85.9	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	< LoQ	0.00118	0.00648	0.01334	0.138	0.407	1.543	7.600	day 7 spent
% of the nominal concentration	---	---	32.8	43.2	22.6	57.5	42.8	40.6	50.0	

--- - not calculated
LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Concentration and stability of nicosulfuron, definitive test

Nominal test item concentration [mg/L]	Control	0.006	0.024	0.098	0.39	1.56	6.25	25	100	Day of sampling
Nominal concentration of nicosulfuron [mg/L]	Control	0.0019	0.0076	0.03	0.12	0.48	1.94	7.75	31.0	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00190	0.00783	0.03282	0.11025	0.436	1.752	7.243	28.802	day 0 fresh
% of the nominal concentration	---	102.2	105.2	109.4	91.9	90.8	90.3	93.5	92.9	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00163	0.00606	0.02471	0.09802	0.449	1.855	7.369	29.292	day 1 spent
% of the nominal concentration	---	87.6	81.5	82.4	81.7	93.5	95.6	95.1	94.5	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00153	0.00699	0.02806	0.11059	0.433	1.745	6.937	27.657	day 1 fresh
% of the nominal concentration	---	82.3	94.0	93.5	92.2	90.2	89.9	89.5	89.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00181	0.00860	0.03346	0.09944	0.451	1.825	6.897	27.343	day 2 spent
% of the nominal concentration	---	97.3	115.6	111.5	82.9	94.0	94.1	89.0	88.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00167	0.00714	0.03186	0.10138	0.434	1.759	7.164	28.287	day 2 fresh
% of the nominal concentration	---	89.8	96.0	106.2	84.5	90.4	90.7	92.4	91.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00193	0.00674	0.03370	0.09737	0.460	1.793	6.375	25.333	day 3 spent
% of the nominal concentration	---	103.8	90.6	112.3	81.1	95.8	92.4	82.3	81.7	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00154	0.00741	0.02947	0.10720	0.433	1.753	7.139	28.221	day 3 fresh
% of the nominal concentration	---	82.8	99.6	98.2	89.3	90.2	90.4	92.1	91.0	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00200	0.00729	0.03133	0.10622	0.443	1.801	6.797	26.584	day 4 spent
% of the nominal concentration	---	107.5	98.0	104.4	88.5	92.3	92.8	87.7	85.8	

Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00217	0.00784	0.03220	0.10517	0.424	1.725	6.789	28.162	day 4 fresh
% of the nominal concentration	---	116.7	105.4	107.3	87.6	88.3	88.9	87.6	90.8	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00209	0.00690	0.03047	0.10083	0.432	1.745	6.735	27.208	day 5 spent
% of the nominal concentration	---	112.4	92.7	101.6	84.0	90.0	89.9	86.9	87.8	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00168	0.00816	0.03181	0.09631	0.436	1.780	7.112	28.155	day 5 fresh
% of the nominal concentration	---	90.3	109.7	106.0	80.3	90.8	91.8	91.8	90.8	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00195	0.00846	0.03215	0.11728	0.447	1.817	6.975	27.960	day 6 spent
% of the nominal concentration	---	104.8	113.7	107.2	97.7	93.1	93.7	90.0	90.2	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00168	0.00742	0.03194	0.09832	0.426	1.764	7.168	26.006	day 6 fresh
% of the nominal concentration	---	90.3	99.7	106.5	81.9	88.8	90.9	92.5	83.9	
Average determined concentration (n=3) in samples collected [mg/L]	<LoD	0.00201	0.00648	0.03243	0.09610	0.453	1.780	6.368	25.890	day 7 spent
% of the nominal concentration	---	108.1	87.1	108.1	80.1	94.4	91.8	82.2	83.5	

--- - not calculated
LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Findings

Inhibition of growth rate and yield, definitive test

Nominal test item concentration [mg/L]	Based on frond number		Based on dry weight	
	% Inhibition at exposure termination (growth rate)	% Inhibition at exposure termination (yield)	% Inhibition at exposure termination (growth rate)	% Inhibition at exposure termination (yield)
Control	0.0	0.0	0.0	0.0
0.0015	16.0	33.8	-1.0*	-3.0*
0.006	50.1	74.7	11.9	32.6
0.024	80.5	93.2	26.3	59.0
0.098	80.5	93.2	26.7	58.4
0.39	85.5	95.1	30.5	64.3
1.56	86.5	95.6	33.7	67.8
6.25	87.9	96.1	39.0	73.9
25	89.2	96.6	34.4	68.9
100	93.6	98.1	45.1	79.1

* inhibition below 0% means that dry weight at exposure termination were higher than dry weight in the control at exposure termination.

Frond number

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	n.d.	n.d.	n.d.	n.d.
ErC_{20}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
ErC_{50}	0.00748 (0.00693 – 0.00807)	0.00115 (0.00107 – 0.00124)	0.00236 (0.00218 – 0.00254)	0.00085 (0.00079 – 0.00090)
LOEC	≤ 0.0015	≤ 0.00023	≤ 0.00047	≤ 0.0003
NOEC	< 0.0015	< 0.00023	< 0.00047	<0.0003
Yield				
EyC_{10}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
EyC_{20}	< 0.0015	< 0.00023	< 0.00047	< 0.0003
EyC_{50}	0.00258 (0.00247 – 0.00269)	0.00040 (0.00038 – 0.00041)	0.00081 (0.00078 – 0.00085)	0.00037 (0.00036 – 0.00037)
LOEC	≤ 0.0015	≤ 0.00023	≤ 0.00047	≤ 0.0003
NOEC	< 0.0015	< 0.00023	< 0.00047	< 0.0003

Dry weight

Endpoint values [mg/L]	Nominal concentrations			Mean measured
	Test Item	Rimsulfuron	Nicosulfuron	Rimsulfuron
	[mg f.p./L]	[mg a.s./L]	[mg a.s./L]	[mg a.s./L]
Growth rate				
ErC_{10}	< 0.0015	< 0.00023	< 0.00047	n.d.
ErC_{20}	0.03987 (0.01763 – 0.07665)	0.00612 (0.00271 – 0.01175)	0.01241 (0.00549 – 0.02384)	0.00428 (0.00191 – 0.00815)
ErC_{50}	> 100	> 15.2	> 31.0	> 9.854
LOEC	0.006	0.00093	0.0019	0.0005
NOEC	0.0015	0.00023	0.00047	0.0003
Yield				
EyC_{10}	n.d.	n.d.	n.d.	n.d.
EyC_{20}	< 0.0015	< 0.00023	< 0.00047	n.d.
EyC_{50}	0.10079 (0.07535 – 0.13335)	0.01544 (0.01155 – 0.02042)	0.03136 (0.02346 – 0.04146)	0.01084 (0.00811 – 0.01434)
LOEC	0.006	0.00093	0.0019	0.0005
NOEC	0.0015	0.00023	0.00047	0.0003

***** n.d. – not determined

A 2.2.1.1.5 Study 5

Comments of zRMS:	The study is considered valid. All validity criteria were met. • The doubling time (Td) of frond number in the control calculated for each week was between 1.6 and 2.1 days (Td = ln 2 / μ) during the study(according to the test guideline, the validity criterion for the study (Td < 2.5 days corresponding to an average growth rate of 0.275 day-1)). **Agreed endpoints:** **<u>Exposure 7 day period:</u>**

	7-day E_yC_{50} = 1.2 µg a.s/L (frond number) **7-day E_rC_{50} = 2.1 µg a.s/L (frond number)** NOEC= 0.28 µg a.s/L **LOEC=0.74 µg a.s/L** **<u>Recovery period</u>:** Complete recovery of *Lemna gibba* after 7-day exposure to Nicosulfuron technical was demonstrated for the exposure concentration of 0.74 µg/L after 7 and 14 days in test medium free of test item. The plants of the exposure concentrations of 2.1 and 7.1 µg/L were still affected after the recovery period of 14 days.

Reference: KCP 10.2.1-05

Report "Toxicity of Nicosulfuron technical to the Aquatic Higher Plant *Lemna gibba* in a 7-Day Growth Inhibition Test, Supplemented With Testing for Recovery of Growth". Bätscher, R, 2008, B75341

Guideline(s): Yes (OECD 221). This study was supplemented with an additional experimental part in which the recovery of plant growth was monitored.

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods
Materials

Test item:

Description: Nicosulfuron technical
Batch number: SI-01
A.i. content: 93.1% min

Test system:

Species: *Lemna gibba* G3 (family Lemnaceae, Macrophyta.
Strain: -
Age: -
Source: Bayer CropScience AG, 40789 Monheim, Germany in 2007.
Medium: 20X AAP

Experimental conditions:

Temperature: 22.0 – 23.0 °C
pH values: 8.6 – 8.8
Mean light intensity: 6500-8500 lux, illumination constant
Test vessels: glass dishes containing 250 mL of each treatment
Initial frond number: 12

Experimental period: 7 days Static-Renewal conditions

Test design:

The test design included three replicates per test concentration and control. Each replicate consisted of a 250-mL glass dish (diameter of 9.5 cm) filled with 150 mL of test medium, resulting in a water depth of approximately 21 mm. The test vessels were covered with glass dishes. The test vessels were labelled with the study number and all necessary additional information to ensure unique identification.
The test plants were exposed for seven days to the following concentrations of Nicosulfuron technical: 0.10, 0.32, 1.0, 3.2, 10 and 32 µg/L. Additionally, a control (test water without addition of the test item) was run in parallel.
A stock solution of the nominal concentration of 20 mg/L was freshly prepared before the test medium renewals. For the preparation of the stock solutions on Days 0, 2 and 5, the amount of 20.0, 20.1 and 20.2 mg of test item, respectively, was mixed into 1000 mL of test water using ultrasonic treatment (15 minutes) and intense stirring (30 minutes at room temperature). The stock solutions were diluted with test water to prepare the test media of the test concentrations mentioned above.
For the determination of the actual test item concentrations, quadruplicate samples were taken from each treatment at the start and end of each renewal period.
The selection of the test concentrations was based on the results of a range-finding test (non-GLP).
After the 7-day exposure of the plants to the test item, the recovery of growth of the affected plants was monitored during two weeks. Some plants of the test concentrations of 0.74, 2.1 and 7.1 µg/L (nominal 1.0, 3.2 and 10 µg/L, respectively) were transferred to test water free of test item. The growth of the treated plants was compared to parallel running control cultures.

Determination of the Growth Inhibition and Calculation of Results:

During the first week of the study, the *Lemna* colonies were inspected in each test vessel for changes in frond and colony number and appearance (discoloration, sinking, root length, or other visible abnormalities) on Days 2, 5 and 7.

The dry weight of a sample of fronds equivalent to that used to inoculate the test vessels was determined at the start of the test. At Day 7, the dry weight of the plants of each test vessel (minus the plants used to start the recovery period at the nominal concentration of 1.0 µg/L) was determined.

The plants were dried at about 60 °C in a laboratory vacuum oven for 48 hours (sufficient to reach a constant weight).

During the two weeks of recovery, the fronds and colonies were counted twice a week (on Days 12, 14, 19 and 21). The dry weight of the plants was determined after the first and the second week of recovery (Days 14 and 21 of the study; minus the plants used to continue the recovery period).
As on Day 7, 14 and 21 some plants were used to start the following week of the recovery phase, the determined dry weights were corrected for these plants (based on the calculated dry weight per frond). These corrected weights are given in the tables and used for calculation of the growth rates and yield.
The dry weight determinations on Day 7 and 14 were further used to calculate the dry weight of the plants in each replicate at the start of each week of recovery.

Inhibition of *Lemna* growth after 7 days was determined by:
a) Average specific growth rates (µ)

b) Yield (Y)

For the exposure period (Day 0-7), the EC10, EC20 and EC50 values for the inhibition of the average growth rate and yield based on frond numbers and dry weight and their 95% confidence limits were calculated as far as possible by Probit Analysis . The 7-day NOEC and LOEC were determined by testing the parameters at the test concentrations on statistically significant differences to the control values by multiple Dunnett's tests.
The assessment of recovery of growth of the test plants was based on the section-by-section growth rates based on frond numbers and on the weekly average growth rates based on frond numbers and dry weight of the plants. The growth rates were compared with the control by Williams' tests.The Williams' test was used as the Dunnett's test could not be applied due to the low number of degrees of freedom of the data.
Based on these statistical results, the NOEAC (No Observed Ecologically Adverse Concentration) for the growth of *Lemna gibba* was determined.

Analyses of the Test Item Concentrations

During the exposure period, quadruplicate samples were taken from the test media of all test concentrations and from the control at the start (Day 0, 2 and 5) and at the end (Day 2, 5 and 7) of each test medium renewal period. For the sampling of the aged media, the test media of the three replicates per test concentration were pooled. After the exposure period, no further samples were taken.
Immediately after sampling, acetonitrile (2.5 mL) and ammonium hydroxide 24.5% (47 µL) were added to each sample (10 mL) to stabilize the latter during the storage period. The samples were stored in a refrigerator until analysis.
The concentrations of the test item were analytically measured in two of the quadruplicate samples from the test concentrations of 0.32 to 32 µg/L.
From the control, one sample was analyzed from each sampling time. The samples from the lowest test concentration of 0.10 µg/L were not analyzed as this concentration was below the 7-day NOEC

Analytical results:

In the test media of the nominal concentrations of 0.32 to 32 µg/L, the measured concentrations of the test item at the start of the test medium renewal periods (Day 0, 2 and 5) were between 50 and 130% of the nominal values.
At the end of these periods (Day 2, 5 and 7), 50 to 109% of the nominal concentrations were found. The mean measured concentrations of the test item (calculated as time-weighted means) were between 65 and 89% of the nominal values.

The reported biological results were based on the mean measured concentrations of the test item which were 0.28 µg/L (nominal 0.32 µg/L), 0.74 µg/L (nominal 1.0 µg/L), 2.1 µg/L (nominal 3.2 µg/L), 7.1 µg/L (nominal 10 µg/L) and 24 µg/L (nominal 32 µg/L).

The concentration of 0.74 µg/L was determined to be the 7-day LOEC (lowest concentration tested showing effects) as at this concentration the average growth rate and the yield based on frond numbers and dry weight after the exposure period of 7 days **were statistically significantly lower than in the control.**

At the 7-day NOEC (highest concentration tested without toxic effects) corresponding to the next lower concentration of 0.28 µg/L and up to this concentration, the growth of the plants was not inhibited and no abnormalities in growth and appearance of the plants was determined after the exposure period of 7 days.

The EC10, EC20 and EC50 for inhibition of the average growth rates and yield based on frond numbers and dry weight after 7 days of exposure were calculated as far as possible by Probit Analysis.
No abnormalities in appearance of the test plants were recorded during the 7-days test period in the control and at the nominal test concentrations of 0.10 µg/L (not determined analytically) and the mean measured concentration of 0.28 µg/L (nominal 0.32 µg/L).

At the mean measured concentrations of 0.74 to 7.1 µg/L (nominal 1.0 to 10 µg/L), the newly formed fronds were stunted.
At the mean measured concentration of 24 µg/L (nominal 32 µg/L), some plants showed chlorosis.

Results:

Results based on 7 days exposure phase

7-day E_yC_{50} = 1.2 µg a.s/L (frond number)
7-day E_rC_{50} = 2.1 µg a.s/L (frond number)
NOEC= 0.28 µg a.s/L
LOEC=0.74 µg a.s/L

Recovery phase

Complete recovery of *Lemna gibba* after 7-day exposure to Nicosulfuron technical was demonstrated for the exposure concentration of 0.74 µg/L after 7 and 14 days in test medium free of test item. The plants of the exposure concentrations of 2.1 and 7.1 µg/L were still affected after the recovery period of 14 days.

Results of the first week recovery period

Section-by-Section Growth Rates Based on Frond Numbers during the First Week of Recovery

Nominal test item concentration# (µg/L)	Section-by-section growth rates µ (day^{-1}) and inhibition of µ (I_r)			
	Days 7–12		Days 12–14	
	µ	I_r (%)	µ	I_r (%)
Control	0.484	0.0	0.317	0.0
1.0	0.465	4.0	0.332	-4.7
3.2	0.213*	56.1	0.254*	19.8
10	0.110*	77.3	0.175*	44.9

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to Williams' tests, one-sided, α = 0.05)

Average Growth Rates Based on Frond Numbers during the First Week of Recovery

Nominal test item concentration# (µg/L)	Average Growth rate µ (day^{-1}) and inhibition of µ (I_r)	
	Days 7–14	
	µ	I_r (%)
Control	0.437	0.0
1.0	0.427	2.2
3.2	0.224*	48.6
10	0.129*	70.5

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to Williams' tests, one-sided, α = 0.05)

Average Growth Rates Based on Dry Weights during the First Week of Recovery

Nominal test item concentration# (µg/L)	Average Growth rate µ (day^{-1}) and inhibition of µ (I_r)	
	Days 7–14	
	µ	I_r (%)
Control	0.420	0.0
1.0	0.403	4.0
3.2	0.117*	72.1
10	0.047*	88.9

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to a Williams' test, one-sided, α = 0.05)

Results of the second week recovery period

Section-by-Section Growth Rates Based on Frond Numbers during the Second Week of Recovery

Nominal test item concentration# (µg/L)	Section-by-section growth rates µ (day^{-1}) and inhibition of µ (I_r)			
	Days 14–19		Days 19–21	
	µ	I_r (%)	µ	I_r (%)
Control	0.378	0.0	0.356	0.0
1.0	0.363	4.1	0.383	-7.5
3.2	0.335*	11.4	0.304	14.4
10	0.279*	26.4	0.241*	32.2

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to Williams' test, one-sided, α = 0.05)

Average Growth Rates Based on Frond Numbers during the Second Week of Recovery

Nominal test item concentration# (µg/L)	Average growth rates µ (day^{-1}) and inhibition of µ (I_r)	
	Days 14–21	
	µ	I_r (%)
Control	0.372	0.0
1.0	0.368	0.9
3.2	0.327*	12.2
10	0.268*	28.0

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to a Williams' test, one-sided, α = 0.05)

Average Growth Rates Based on Dry Weights during the Second Week of Recovery

Nominal test item concentration# (µg/L)	Average Growth rate µ (day^{-1}) and inhibition of µ (I_r)	
	Days 14–21	
	µ	I_r (%)
Control	0.395	0.0
1.0	0.397	-0.6
3.2	0.319*	19.3
10	0.176*	55.3

#: concentration of the test item during the seven days of exposure
*: mean value significantly lower than in the control
(according to a Williams' test, one-sided, α = 0.05)

Conclusion

7-day EyC50	1.2 µg a.s/L
7-day ErC50	2.1 µg a.s/L
NOEC	0.28 µg a.s/L
LOEC	0.74 µg a.s/L

A 2.2.1.1.6 Study 6

Comments of zRMS:	The study is considered valid. All validity criteria were met. The study was not taken into account in the current dossier and can be considered at MSs level, if relevant. **Agreed endpoints:** The endpoint value based on fresh weight: The E_rC_{50}/14d = 0.30 mg/L (95% confidence limits: 0.23 – 0.39). The E_yC_{50}/14d = 0.12 mg/L (95% confidence limits: 0.10 – 0.15). The endpoint value based on dry weight: The E_rC_{50}/14d =9.75 mg/L (95% confidence limits: 5.01 – 29.00). The E_yC_{50}/14d =1.69 mg/L (95% confidence limits: 0.97 – 3.43). The endpoint value based on total shot length: The E_rC_{50}/14d = 0.13 mg/L (95% confidence limits: 0.12 – 0.15). The E_yC_{50}/14d = 0.08 mg/L (95% confidence limits: 0.07 – 0.09).

Reference:	KCP 10.2.1-06
Report:	"Nicosulfuron technical. Water-sediment *Myriophyllum spicatum* toxicity test". Katarzyna Brzozowska, W/21/16, 2017. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD Guideline No. 239 (2014)
Deviations:	Yes: In the definitive test, the temperature during exposure phase was in the range of 17.7 – 22.8ºC (i.e. not within the range of 20 ± 2ºC). Therefore, range and fluctuations of the temperature were greater than stated in the study plan, OECD Guideline and SOP/W87. However, the growth of plants in the control was sufficient and the validity criteria were met. Therefore, the impact of the temperature fluctuations on the generated results is assumed not significant (negligible).
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The growth of watermilfoil *Myriophyllum spicatum* exposed to the test item, Nicosulfuron tech. for 14 days was studied in water-sediment system, in static test design, in conditions required for the vegetative growth.

The toxicity test consisted of a rooting phase (7 days) and an exposure phase (14 days).
The plants (representative group) of the mean total shoot length 8.2 cm and of the mean fresh weight 184 mg were exposed in a set of nominal test item concentrations: 10, 3.1, 0.98, 0.31, 0.095, 0.03 mg/L plus control. Three plants rooted in a pot with sediment were placed in a beaker and overlaid with test medium. The test item was applied into aqueous phase of water-sediment system. For each nominal test item concentration four replicates (i.e. 12 plants) and for the control six replicates (i.e. 18 plants) were used.

Mean total shoot length in the control in comparison to the mean total shoot length at exposure initiation increased 2.2-fold. Mean fresh weight in the control in comparison to the mean fresh weight for representative group at exposure initiation increased 3.2-fold.

The impact of the test item on the plants growth was assessed based on total shoot length (i.e. sum of each side shoot length and main shoot length), fresh weight and dry weight of plants. In the tested range of the test item concentrations the inhibition of growth rate for total shoot length ranged 14.6 – 78.4%, for fresh weight ranged 13.9 – 89.4%, for dry weight ranged 16.3 – 56.2% in comparison with plants in the control. The inhibition of yield for total shoot length ranged 20.0 – 84.5%, for fresh weight ranged 21.9 – 93.2%, for dry weight ranged 27.1 - 73.1% in comparison with plants in the control.

In the test item concentrations of 0.03 and 0.095 mg/L no changes in comparison to the plants in the control were observed. In the test item concentration of 0.31 mg/L distorted apical tips and shortened roots were reported. In the test item concentrations of 0.98 and 3.1 mg/L distorted apical tips and few short roots were observed. In the test item concentration of 10 mg/L distorted apical tips and few short roots or no roots were observed.

The test item contents in aqueous phase (overlying medium) was determined in the collected samples of water-sediment system using a validated liquid chromatography method.

In samples collected at exposure initiation the determined test item concentrations in aqueous phase was in the range of 94.0 – 106.5% of nominal concentration. The results confirm that the test item concentrations were prepared correctly.

In samples collected at exposure termination, the determined test item concentration in aqueous phase was in the range of 87.7 – 93.3% of nominal concentration. Therefore, the test item concentrations in aqueous phase were stable under test conditions.

Endpoint values were determined based on the nominal test item concentrations.

Concentration and stability of test item, definitive test

Nominal test item concentration [mg/L]	Mean determined test item concentration in aqueous phase [mg/L]			
	at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	< LoD	-	< LoD	-
0.03	0.0316	105.4	0.028	93.3
0.095	0.1012	106.5	0.086	90.5
0.31	0.310	100.0	0.285	91.9
0.98	0.975	99.5	0.859	87.7
3.1	3.084	99.5	2.847	91.8
10	9.397	94.0	8.832	88.3

LoQ = 0.001 mg/L
LoD = 0.0005 mg/L

Material and methods

Test item:	Name: Nicosulfuron technical Batch number: SCL-70201 Production date: December 15, 2015 Expiry date: December 14, 2017

Test organisms:	Watermilfoil *Myriophyllum spicatum* Linné, dicotyledonous freshwater submerged plant, macrophyte, maintained in culture at the Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology.
Test design:	Rooting phase of 7 days; during rooting five plants per replicate. Exposure phase of 14 days; exposure with application of the test item into aqueous phase of water-sediment system, exposure in a static design; three plants per replicate; four replicates for each test item concentration and six replicates for the control.
Nominal test item concentrations:	10, 3.1, 0.98, 0.31, 0.095, 0.03 mg/L plus control.
Test conditions:	
Chemical determinations:	The test item concentrations were chemically determined with a validated liquid chromatographic method with DAD detection.
Statistics:	Calculations by probit method and statistical analysis: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity (with Residuals), Williams Multiple Sequential t-test Procedure, Multiple Sequentially-rejective U-test after Bonferroni-Holm.
Validity criteria:	
	- the mean total shoot length in the control in comparison with the mean total shoot length at exposure initiation increased 2.2-fold. The criterion of at least doubling the total shoot length was met.
	- the mean fresh weight in the control in comparison with the mean fresh weight for representative group at exposure initiation increased 3.2-fold. The criterion of at least doubling the fresh weight was met.
	- the plants in the control were without visual symptoms of chlorosis and during the exposure phase no contamination with algae, fungi or bacteria on the plants, on the sediment surface or in the test medium was observed.
	- the mean coefficient of variation for yield based on fresh weight in replicates of the control in a period from exposure initiation to termination was 17.1%; did not exceed 35%
Test conditions:	pH of the control: 7.37 – 8.86 (measured in aqueous phase, overlaid over the plants, in each replicate, at exposure initiation, on day 7 and also at exposure termination. Measurements were done at the same time of the day, within 2 hours from daylight onset (dawn) in a daily cycle of irradiation).
	Mean light intensity: 10.07 – 10.264 klux in a daily cycle of 16 h day and 8 h night
	Glass aquaria with aerated test medium Smart and Barko and a conditioned sediment.

Temperature: 17.7 – 22.8ºC (continuously recorded using electronic data logger with a sensor submerged in test medium in an additional 2 L beaker

Findings

Inhibition of growth rate, definitive test

Nominal test item concentration [mg/L]	Inhibition of growth rate [%]		
	Total shoot length	Fresh weight	Dry weight
Control	0.0	0.0	0.0
0.03	14.6	13.9	16.9
0.095	58.4	40.9	16.3
0.31	72.0	50.1	21.3
0.98	73.9	67.1	20.4
3.1	78.3	77.6	38.6
10	78.4	89.4	56.2

Inhibition of yield, definitive test

Nominal test item concentration [mg/L]	Inhibition of growth rate [%]		
	Total shoot length	Fresh weight	Dry weight
Control	0.0	0.0	0.0
0.03	20.0	21.9	27.1
0.095	67.3	55.1	27.6
0.31	79.3	63.9	34.6
0.98	80.7	78.5	33.4
3.1	84.5	85.6	54.8
10	84.2	93.2	73.1

Endpoint values for growth rate based on nominal test item concentrations [mg/L], definitive test

Endpoint value	Total shoot length		Fresh weight	Dry weight
	day 7	day 14	day 14	day 14
E_rC_{50}	0.08 (0.05 – 0.10)	0.13 (0.12 – 0.15)	0.30 (0.23 – 0.39)	9.75 (5.01 – 29.00)
E_rC_{20}	<0.03	<0.03	0.03 (0.02 – 0.04)	0.24 (0.08 – 0.45)
E_rC_{10}	<0.03	<0.03	<0.03	0.03 (0.01 – 0.09)
LOEC	≤0.03	≤0.03	≤0.03	≤0.03
NOEC	<0.03	<0.03	<0.03	<0.03

Endpoint values for yield based on nominal test item concentrations [mg/L], definitive test

Endpoint value	Total shoot length		Fresh weight	Dry weight
	day 7	day 14	day 14	day 14
E_yC_{50}	0.05 (0.04 – 0.07)	0.08 (0.07 – 0.09)	0.12 (0.10 – 0.15)	1.69 (0.97 – 3.43)
E_yC_{20}	<0.03	<0.03	<0.03	0.03 (0.01 – 0.08)
E_yC_{10}	<0.03	<0.03	<0.03	<0.03
LOEC	≤0.03	≤0.03	≤0.03	≤0.03
NOEC	<0.03	<0.03	<0.03	<0.03

Conclusions

The endpoint values determined based on nominal test item concentrations are the following:

The endpoint value based on fresh weight:
The E_rC_{50}/14d is 0.30 mg/L (95% confidence limits: 0.23 – 0.39).

The E_yC_{50}/14d is 0.12 mg/L (95% confidence limits: 0.10 – 0.15).
The endpoint value based on dry weight:
The E_rC_{50}/14d is 9.75 mg/L (95% confidence limits: 5.01 – 29.00).
The E_yC_{50}/14d is 1.69 mg/L (95% confidence limits: 0.97 – 3.43).
The endpoint value based on total shot length:
The E_rC_{50}/14d is 0.13 mg/L (95% confidence limits: 0.12 – 0.15).
The E_yC_{50}/14d is 0.08 mg/L (95% confidence limits: 0.07 – 0.09).

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 considered valid. All validity criteria were met. • the average mortality for the total number of controls was 3.3% at the end of the experiment (criterion: it must not exceed 10%), • the LD_{50}/24h of the reference item (dimethoate) was 0.11 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee). **Agreed endpoint:** **48 h LD_{50} oral >400 µg product /bee**

Reference:	KCP 10.3.1.1.1
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WDG Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test" Stalmach M., 2019, B/176/16. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998)
Deviations:	Yes The study should be completed in December, but it was completed in February 2019.
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study):	No

Summary

The acute oral toxicity study of Rimsulfuron 15% + Nicosulfuron 30% WDG was conducted to determine the LD50 values for honeybees. Five doses of the test item were used, i.e.: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee. The range of these doses was selected on the basis of the preliminary test results. Each group was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses mentioned above, using a micropipette. During the entire experiment, the insects were caged in groups of 10. The general condition of the test honeybees and the reliability of the tests conducted on them were controlled using the recommended reference item - dimethoate. After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Material and methods

Test item:	Name: Rimsulfuron 15% + Nicosulfuron 30% WDG Batch number: SCL-65843 Content: rimsulfuron 15.2% (w/w) + nicosulfuron 30.1% (w/w) Manufacturing date: 08.03.2018 Expiry date: 07.03.2020
Test organisms:	The honeybee, *Apis mellifera* L Source: Institute of Industrial Organic Chemistry, Branch Pszczyna Age: approximately 3 weeks
Test design:	- exposure time: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test item doses:	25.0, 50.0, 100.0, 200.0 and 400.0 µg test item/bee and a control (0.0 µg/bee)
Test medium:	50% w/v sucrose in water
Endpoints:	- honeybee mortality after 24 and 48 hours of the exposure, - the oral LD_{50} of the test item after 24 and 48 hours of the exposure, - the LD_{50}/24h of the reference item (dimethoate)
Test conditions:	Temperature: 25°C Relative air humidity: 53– 55%
Statistical analysis:	regression analysis using the log-probit method
Validity criteria:	- the average mortality for the total number of controls was 3.3% at the end of the experiment (criterion: it must not exceed 10%), - the LD_{50}/24h of the reference item (dimethoate) was 0.11 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee).

Findings

Test item dose		**No. of honeybees**	**24 hours**		**48 hours**	
µg/bee	**µg a.i./bee**		**Total mortal-**	**LD_{50}**	**Total mortali-**	**LD_{50}**

		tested	ity			ty			
			[no.]	[%]	Test item [µg/bee]	[no.]	[%]	Test item [µg/bee]	Active ingre-dient [µg/bee]
0.0 (Control)		30	1	3.3	> 400.0	1	3.3	> 400.0	> 6.08[a] + 12.04[b]
25.0	0.38[a] + 0.75[b]	30	2	3.4*		2	3.4*		
50.0	0.76[a] + 1.51[b]	30	2	3.4*		2	3.4*		
100.0	1.52[a] + 3.01[b]	30	2	3.4*		2	3.4*		
200.0	3.04[a] + 6.02[b]	30	2	3.4*		3	6.9*		
400.0	6.08[a] + 12.04[b]	30	3	6.9*		5	13.8*		

[a]: rimsulfuron
[b]: nicosulfuron
*: the control response of 3.3% was compensed using Abbott's formula

Endpoints	
LD_{50} - 48 h	>400 µg f.p./bee

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study was considered valid. All validity criteria were met. • the average mortality for the total number of controls was 3.3% after 48 h (criterion: it must not exceed 10%), • the 24 hour LD_{50} of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee). **Agreed endpoint:** **48 h LD_{50} contact >400 µg product /bee**

Reference:	KCP 10.3.1.1.2
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WDG Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test". Stalmach M., 2019, B/177/16. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 214 (1998)
Deviations:	Yes The study should be completed in December, but it was completed in February 2019.
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study):	No

Summary

The acute contact toxicity study of Rimsulfuron 15% + Nicosulfuron 30% WDG was conducted to determine the LD_{50}. Five doses of the test item were used: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee. The recommended reference item, dimethoate (Danadim 400 EC) 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. 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.

Material and methods

Test item:	Name: Rimsulfuron 15% + Nicosulfuron 30% WDG Batch number: SCL-65843 Content: rimsulfuron 15.2% (w/w) + nicosulfuron 30.1% (w/w) Manufacturing date: 08.03.2018 Expiry date: 07.03.2020
Test organisms:	The honeybee, *Apis mellifera* L Source: Institute of Industrial Organic Chemistry, Branch Pszczyna Age: approximately 3 weeks
Test design:	Test item: - exposure time: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test design (reference item):	- exposure time: 24 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test item doses:	25.0, 50.0, 100.0, 200.0 and 400.0 µg test item/bee and a control (0.0 µg/bee)
Reference test Item doses:	0.03, 0.06, and 0.12 µg a.i./bee
Endpoints:	- honeybee mortality after 24 and 48 hours of exposure - the contact LD_{50} of the test item after 24 and 48 hours of the exposure, - the contact LD_{50}/24 h of the reference item (dimethoate).
Test conditions:	Temperature: 24 – 25°C Relative air humidity: 53 – 54 %
Statistical analysis:	regression analysis using the log-probit method

Validity criteria: -the average mortality for the total number of controls was 3.3% after 48 h (criterion: it must not exceed 10%),
-the 24 hour LD_{50} of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

Findings

During the definitive test no abnormal behavioural effects were observed in all doses used in the study. The amount of the sucrose solution consumed by the insects shows a reduction during 24 and 48 h ranged from -12.0 to 22.9% as compared to the control.

After 24 hours of exposure, mortality of the bees treated with the reference item at rates 0.03, 0.06 and 0.12 µg a.i./honeybee corrected according Abbott's equation, were 17.2, 31.0 and 55.2%, respectively. The median lethal dose of dimethoate (LD_{50} oral) after 24 hours determined with the log-probit method, with 95% confidence limits, is 0.11 µg a.i./bee (confidence limits: 0.07 – 0.3 µg dimethoate/bee). In the group treated with the test item no abnormal behavioural effects were observed.

Test item dose		**No. of honeybees tested**	**24 hours**			**48 hours**			
			Total mortality		**LD_{50}**	**Total mortality**		**LD_{50}**	
µg/bee	**µg a.i./bee**		**[no.]**	**[%]**	**Test item [µg/bee]**	**[no.]**	**[%]**	**Test item [µg/bee]**	**Active ingredient [µg/bee]**
0.0 (Control)		30	1	3.3	> 400.0	1	3.3	> 400.0	> 6.08[a] + 12.04[b]
25.0	0.38[a] + 0.75[b]	30	0	0.0		0	0.0		
50.0	0.76[a] + 1.51[b]	30	0	0.0		0	0.0		
100.0	1.52[a] + 3.01[b]	30	0	0.0		2	6.7		
200.0	3.04[a] + 6.02[b]	30	2	6.7		2	6.7		
400.0	6.08[a] + 12.04[b]	30	1	3.3		2	6.7		

[a]: rimsulfuron
[b]: nicosulfuron

Endpoints	
LD_{50} - 48 h	>400 µg f.p./bee

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

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

- the mean mortality in the control was ≤ 15% at the end of the test.
- the mean mortality in the reference item group was ≥50 % at the end of the test

Agreed endpoints:

Test item: Rimsulfuron Technical	
LDD_{50}	**> 18.51 [µg a.i./bee/day]**
LC_{50} / LDD_{50}	**> 840.34 [mg a.i./Kg]**
NOEDD	**≥ 18.51 [µg a.i./bee/day]**
NOEC	**≥ 840.34 [mg a.i./Kg]**

Reference	KCP 10.3.1.2.1
Report:	Ansaloni, T., 2018 Rimsulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L. Study code: TRC16-193BA
Source:	Trialcamp S.L.U. Poligon Industrial l'Alter. Avda. Antic Regne de Valencia, 25, 46290 Alcasser (Valencia). Spain. Unpublished report No.: TRC16-193BA. Issued: 2018.
Guidelines:	CEB (2012) method, adaptions of OECD Guidelines nº 213 (1998), publications of Decourty et al. (2005) and Suchail et al (2001), recommendations of the German ring test group (2013) and EPPO 170
Deviations to Guidelines:	None.
GLP:	Yes (certified laboratory).
Study Objective:	To determine the effects of Rimsulfuron Technical on the honey bee *Apis mellifera* L. from chronic feeding exposure. To determine the median lethal daily dose / Concentration (LDD_{50} / LC_{50}) and the no observed effect daily dose / concentration (NOEDD / NOEC) values, where possible.
Test item:	Rimsulfuron technical; Batch code: SCL-30188; active substance: Rimsulfuron; content of a.s. determined by certificate of analysis: 98% (w/w); expiry date: 21 Feb 2017.
Reference product:	BAS 152 11 I; Batch number FRE-001226; active ingredient: Dimethoate; content of a.i. analysed: 420.3 g/L density: 1.072 g/cm^3.
Test organisms:	**Test species:** *Apis mellifera* L. (Hymenoptera, Apidae) **Life Stage:** Young adult worker bees (newly hatched; 1 to 2 days old). **Source:** Queen-right, healthy colony from a comercial apiary.

Preparation of test organism: Two days before the beginning of the test, frames with capped cells are transferred from the hive to an incubator, transported to Trialcamp facilities and ubicated on a bioclimatic chamber. One day prior to test start, the bees will be randomly collected directly from the frames, introduced into the test units and kept under test conditions until start of the test. Acclimatisation period lasted since bee collection to the start of the test. During this period bees were fed *ad libitum* with a 50 % w/v sucrose solution.

Test design: Limit test; duration 10 days, one control group, one concentration of the test item, one concentration of the reference item; 5 replicates of 10 bees each per treatment group. Daily assessment of mortality and behavioural abnormalities over the 10 day test period.

Five additional test units without bees but with full food syringes containing pure 50 % (w/v) aqueous sucrose solution for evaluation of the evaporation.

Test concentrations / doses:
Control: C (50 % (w/v) aqueous sucrose solution)
Test Item: 100 µg rimsulfuron/bee/day
Reference Item: R: 0.107 µg Dimethoate/bee/day.

Test conditions:
Temperature: 32.17 – 34.11 °C
Relative humidity: 37.40* – 69.98 %

* Short term deviation (<2 h).

Exposure to light: Constant darkness, except during application and assessments.

Sampling: Two duplicate samples, one shipment and one retain, of Treated Solution from the last day of application will be stored in a freezer at ≤ -18 ºC until shipment and delivery to the analytical laboratory for analytical determination of the actual concentration of the test chemical.

Analytical verification: Analytical data were required to demonstrate the concentration of the active ingredient Rimsulfuron (representative sample) and its solubility in the solvent. Quantification was performed by HPLC. The limit of quantification (LOQ) of the analytical method was 10.76 µg/mL, with a limit of detection (LOD) set at 3.23 µg/mL (30 % of the LOQ).

Analytical study was performed to verify the concentration of the samples taken. For the analytical concentration verification, Rimsulfuron residues were determined.

The measured concentration in the samples was within 20 % of nominal test concentration used, thus the concentrations of the test item were confirmed and the endpoints are based on nominal concentrations.

Analytical recoveries for Rimsulfuron

Sample code	Timing	Matrix	Replicate	Nominal Concentration [µg/g*]	Analysed Concentration [µg/g*]	% of Nominal
TRC16-118BA 2S	D9	50 % (w/v) aqueous sucrose solution	1	840.34	762.1610	90.70
			2	840.34	762.6404	90.75

* Considering a density of the 50% (w/v) sucrose solution of 1.19 g/mL

Statistics: Statistical calculations were made by using the statistical program TOXRAT PROFESSIONAL V. 3.2.1

Parametric pair wise test (Student t-test, one sided smaller; $\alpha = 0.05$) was used to evaluate whether there were significant differences between daily consumption of the control and the test item treatment and to determine the NOEDD / NOEC. No statistical analysis was performed on mortality data.

Findings: Results are shown in the tables below.

In the control C (untreated 50 % (w/v) aqueous sucrose solution) the validity criteria was met (mortality < 15% after 10 days of exposure). There was 8.00% of mortality after 10 days of continuous feeding. In the reference item group the mortality continuously increased during the test period and reached 100.00 % (corrected mortality 100.00 %) after 10 days. Consequently, validity criteria for both control and reference item mortality were met and the test was considered valid.

The overall mean daily consumption of feeding solution over the entire test period of the control group (untreated 50 % (w/v) aqueous sucrose solution) was 19.28 µL/bee/day. The overall mean daily consumption of feeding solution at the test item applied dose of 100.0 µg a.i./bee/day was 18.50 µL/bee/day. In the reference item treatment group, the overall mean daily consumption of feeding solution was 18.03 µL/bee/day.

In the test item group, at the consumed dose of 18.50 µg a.i./bee/day, a cumulative mortality of 4.00% was observed at the final assessment after 10 days.

Overall, three individual bees in the treatment group and one individual in the control group were observed with symptoms of intoxication throughout the study. The symptom observed was lack of coordination. By the end of the study (day 10) at the consumed dose of 18.50 µg a.i./bee/day, the percentage of affected bees based on the surviving individuals was 0.00%.

After 10 days of continuous exposure the accumulated mean uptake of product at the treatment level of 100 µg a.i./bee/day was 185.04 µg a.i./bee.

Treatment	10 day cumulative mortality	Corrected mortality[1]	Overall mean consumption of feeding solution	Daily dietary dose	Accumulated mean uptake
Control:					
	[%]		**[µL/bee/day]**	-	-
C	8.00	-	19.28	-	-
Reference item: BAS 152 11 I [µg a.i./bee/day]					
	[%]		**[µL/bee/day]**	**[µg a.i./bee/day]**	**[µg a.i./bee]**
R (0.107)	100.00	100.00	18.03	0.0193	0.135
Test item: Rimsulfuron Technical [µg a.i./bee/day]					
	[%]		**[µL/bee/day]**	**[µg a.s.bee/day]**	**[µg a.s./bee]**
T (100.0)	4.00	-4.35	18.50	18.50	185.04

[1] mortality corrected with the corresponding control mortality according to SCHNEIDER-ORELLI, O. (1947)

Conclusion: All validity criteria were met and the study was deemed valid. The endpoints determined are shown in the table below.
No statistically significant differences were observed in mean daily consumption between any of the test item treatments and the control group.

Overall, three individual bees in the treatment group and one individual in the control group were observed with symptoms of intoxication throughout the study. The symptom observed was lack of coordination. By the end of the study (day 10) at the consumed dose of 18.50 µg a.i./bee/day, the percentage of affected bees based on the surviving individuals was 0.00%.

The results obtained with the toxic reference substance confirmed the sensitivity of the bees under the conditions of the oral test.

Test item: Rimsulfuron Technical	
LDD_{50}	> 18.51 [µg a.i./bee/day]
LC_{50} / LDD_{50}	> 840.34 [mg a.i./Kg]
NOEDD	≥ 18.51 [µg a.i./bee/day]
NOEC	≥ 840.34 [mg a.i./Kg]

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

- the mortality observed in control treatment was equal or less than 15% for the duration of the test (final cumulated mortality = 0.00% for both the negative and the solvent control).
- the mean mortality in the reference product concentration was ≥ 50% at the end of the test (final cumulated mortality = 100.00%).

Agreed endpoints:

Test item: Nicosulfuron Technical	
LC_{50}	> 336.13 mg a.i./kg food
LDD_{50}	> 7.93 µg a.i./bee/day
NOEC	336.13 mg a.i./kg food
NOEDD	**7.93 µg a.i./bee/day**

Reference: KCP 10.3.1.2.2
Report: Ansaloni, T., 2018 Nicosulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L.
Source: Trialcamp S.L.U. Poligon Industrial l'Alter. Avda. Antic Regne de Valencia, 25, 46290 Alcasser (Valencia). Spain.
Unpublished report No.: TRC16-049BA. Issued: 2018.
Guidelines: CEB (2012) method, adaptions of OECD Guidelines nº 213 (1998), publications of Decourty et al. (2005) and Suchail et al (2001), recommendations of the german ring test group (2013) and EPPO 170

Deviations to Guidelines:	None.	
GLP:	Yes (certified laboratory).	
Study Objective:	To determine the chronic oral toxicity of the test item Nicosulfuron technical to *Apis mellifera* L under laboratory conditions.	
Test item:	Nicosulfuron technical, batch SCL-70201, purity for Nicosulfuron 99%, expiry December 14h, 2017.	
Reference product:	BAS 152 11 I; Batch number FRE-001226; active ingredient: Dimethoate; content of a.i. analysed: 420.3 g/L density: 1.072 g/cm^3.	
Test organisms:	**Test species:**	*Apis mellifera* L. (Hymenoptera, Apidae)
	Life Stage:	Young adult worker bees (≤ 24h old).
	Source:	Queen-right, healthy colony from a comercial apiary.
	Preparation of test organism:	Two days before the beginning of the test, frames with capped cells are transferred from the hive to an incubator, transported to Trialcamp facilities and ubicated on a bioclimatic chamber. One day prior to test start, the bees will be randomly collected directly from the frames, introduced into the test units and kept under test conditions until start of the test. Acclimatisation period lasted since bee collection to the start of the test. During this period bees were fed *ad libitum* with a 50 % w/v sucrose solution.
Test design:	A single dose of 40 µg Nicosulfuron/bee/day was assessed.; duration 10 days, two control groups, one with untreated sucrose solution 50% w/v and one with sucrose solution mixed with acetone, and the reference product Dimethoate 40% EC at a daily dose of 0.107 µg a.i./bee/day were concurrently tested. Five replicates per treatment each enclosing at least ten bees, were group fed with one feeder per cage containing 1000 µl of test solution, thus providing 100 µl of test solution per bee per day. Five additional test units without bees but with full food syringes containing pure 50 % (w/v) aqueous sucrose solution for evaluation of the evaporation.	
Test concentrations / doses:	Control 1:	C (50 % (w/v) aqueous sucrose solution)
	Control 2:	Sucrose solution + 5% Acetone
	Test Item:	40.00 µg nicosulfuron/bee/day
	Reference Item:	R: 0.107 µg Dimethoate/bee/day.
Test conditions:	Temperature:	33 ± 2 ºC
	Relative humidity:	48.99 – 74.39%
	* Short term deviation (<2 h).	
	Exposure to light:	Constant darkness, except during application and assessments.
Sampling:	Duplicate samples, one shipment and one retain, of Stock solution and Treated Solution from the last day of application will be stored in a freezer at ≤ -18 ºC until shipment and delivery to the analytical laboratory for analytical determination of the actual concentration of the test chemical.	

Analytical verification:

Analytical data were required to demonstrate the concentration of the active ingredient Nicosulfuron (representative sample) and its solubility in the solvent. Quantification was performed by HPLC. The limit of quantification (LOQ) of the analytical method was 9.91 µg/mL, with a limit of detection (LOD) set at 2.97 µg/mL (30 % of the LOQ).

Analytical study was performed to verify the concentration of the samples taken. For the analytical concentration verification, Nicosulfuron residues were determined.

The measured concentration in the samples was within 20 % of nominal test concentration used, thus the concentrations of the test item were confirmed and the endpoints are based on nominal concentrations.

Analytical recoveries for Nicosulfuron

Sample code	Timing	Matrix	Replicate	Nominal Concentration [µg/g*]		Analysed Concentration [µg/g*]		% of Nominal
				(mg/kg)	mg/L*	(mg/kg)	mg/L*	
TRC16-048BA 3S	D9	50 % (w/v) aqueous sucrose solution	1	336.14	400.00	311.66	370.88	92.72
			2	336.14	400.00	311.76	370.99	92.75

* Considering a density of the 50% (w/v) sucrose solution of 1.19 g/mL

Statistics:

Statistical calculations were made by using the statistical program SPSS 19.0; SPSS©Onc, 1989-2010

Mean daily consumptions of the controls and of the test item were compared amongst them by means of a parametric pair wise test (t- test; $\alpha = 0.05$).

The average mortality given by the test item in all the replicates of each concentration at day 10 was first corrected for the control mortality using the Abbott's formula (1925) modified by Shneider – Orelli (1947).

No statistical analysis was performed on mortality data

Findings:

Consumed Diet

Mean daily consumptions in the water control and the solvent control groups were 18.64 and 19.35 µl/bee of the offered diet, respectively.

Mean daily consumption of the bees exposed to the test item was 19.82 µl/bee of the offered diet.

Mean cumulative consumption (consumption over the ten days dosing period) was 79.27 µg Nicosulfuron/bee. No statistical significant difference in mean daily diet consumption was observed between the control groups and between the treatment group and each of the controls.

Daily mean consumption of the reference product bees was 15.04 µl/bee of the offered diet, which corresponds to a daily consumption of 1.42E-02 µg Dimethoate/bee. Cumulative consumption of the reference bees corresponded to a dose of 0.099 µg Dimethoate/bee.

Mortality

Mean cumulative mortality both in the blank control and in the solvent control after the ten days of exposure was 0.00%. Mean cumulative mortality of the hon-

eybees dosed orally with the test item for ten consecutive days was 0.00%. Mean cumulative mortality of the reference product at ten days was 100.00%.

Treatment	10 day cumulative mortality	Abbotts' transformed mortality (%)	Accumulated mean uptake [1]
Sugar solution:			
	[%]		-
U1	0.00	-	-
Sugar solution + 5% acetone			
	[%]		-
U2	0.00	0.00	-
Test item (40 µg Nicosulfuron/bee/day)			
	[%]		**[µg a.s./bee]**
T	0.00	0.00	79.27
Reference product (0.273 µg/bee/day)			
	[%]		**[µg a.s./bee]**
R	100.00	100.00	0.104(°)

1 Nicosulfuron for the test item
(°) Cumulative over 7 days of application

Conclusion: All validity criteria were met and the study was deemed valid. The endpoints determined are shown in the table below.

The consumed chronic LDD_{50}-value for Nicosulfuron technical was higher than the mean consumed dose of 7.93 µg Nicosulfuron/bee/day.

Based on the mortality data, the NOEDD (No Observed Effect Dietary Dose) was determined to correspond to a daily consumed dose of 7.93 µg Nicosulfuron/bee/day.

No symptoms of intoxication were observed throughout the test for any of the controls bees and for the bees exposed to the test item.

Test item: Nicosulfuron Technical	
LC_{50}	> 336.13 mg a.i./kg food
LDD_{50}	> 7.93 µg a.i./bee/day
NOEC	336.13 mg a.i./kg food
NOEDD	7.93 µg a.i./bee/day

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

Comments of zRMS:

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

- the cumulative larval mortality from day 3 (D3) until day 8 (D8) was ≤ 15 % across all replicates (actual 14.58 %).
- on day 22 (D22) the adult emergence rate is ≥ 70% across all replicates (actual 77.08 %).
- reference Item Mortality: The cumulative larval mortality was ≥ 50 % across all replicates on Day 8 (D8) (actual 64.58 %).

Agreed endpoints:
Endpoints for D22

Endpoint	Active ingredient	Test item
LC_{50} (95 % Confidence limits)	> 649.091 mg rimsulfuron/kg diet (Not determined)	> 661.056 mg test item/kg diet (Not determined)
LD_{50} (95 % Confidence limits)	> 100.000 µg rimsulfuron/larva (Not determined)	> 101.843 µg test item/larva (Not determined)
LC_{10}	Not determined	Not determined
LD10	Not determined	Not determined
NOEC	≥ 649.091 mg rimsulfuron/kg diet	≥ 661.056 mg test item/kg diet
NOED	≥ 100.000 µg rimsulfuron/larva	≥ 101.843 µg test item/larva

Reference	KCP 10.3.1.3.1
Report:	Aguilar-Alberola, J.A. & Marín Víllora, M. 2018. Toxicity of Rimsulfuron Technical on honeybee larvae (*Apis mellifera* L.) after repeated exposure under laboratory conditions
Test facility:	Trialcamp S.L.U. Unpublished report No.: TRC16-162BA. Issued: 2018.
Guidelines:	OECD Guidance Document No. 239 (2016)
Deviations to Guidance:	None.
GLP:	Yes (certified laboratory).
Study Objective:	To determine the effects of the test item Rimsulfuron Technical on the honeybee larvae (*Apis mellifera* L.), after a repeated exposure in a 22 day in vitro test and to determine the No Observed Effect Dose/Concentration (NOED/NOEC) and the median Lethal Dose/Concentration (LD_{50}/LC_{50}), where possible.
Test item:	Rimsulfuron Technical; Batch number: SCL-30188; active ingredient: Rimsulfuron; content of a.i. determined by certificate of analysis: 98.19 % w/w.
Reference item:	Dimethoate Technical; Batch number 305015A161; active ingredient: Dimethoate; content of a.i. analysed: 99.9 % w/w.
Test organisms:	Honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae not older than 30 hours at grafting time.

Source: Commercial beehives from the in-house test facility stock, adequately fed, healthy and as far as possible disease-free and queen-right.

Preparation of test organisms and larvae collection: At D-3, the queens of at least three colonies were confined in their own hive containing a comb with empty cells.
At D-2, maximum 30 hours after encaging, the queens were released. Combs containing eggs were left in the excluder cages until hatching (D1). Three combs from different hives, containing the highest number of synchronized larvae, were selected for grafting in the laboratory.

Test design: Dose response test with duration of 22 days from grafting on day 1 to the final assessment on day 22. From day 3 until day 6 of the test, five different concentrations of Rimsulfuron Technical were applied to the larvae of the test item groups, and one single concentration of the reference item was applied to the larvae of the reference item group. Both, test and reference items, were supplied with diet B or C. The analyzed content of rimsulfuron was considered for calculation of the test item doses and dimethoate for the reference item dose. The daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period. The cumulative feeding volume from day 3 until day 6 of 140 µL diet per larva and the density of the diet (1.1 g/cm3) were considered for the calculation of the cumulative doses per larva. A control group was included in the test and exposed for the same period of time under identical exposure conditions to the untreated artificial diet. Each treatment group consisted of 48 larvae from three different colonies (each colony representing a replicate). Mortality assessments were on days 4, 5, 6, 7, and 8. The presence of uneaten food was qualitatively recorded on day 8. Assessment of mortality during pupation phase on day 15 and assessment of emergence on day 22.

Test concentrations and doses: Control: One control group (U).
Test Item: Five test item groups (T1 – T5) with 27.775, 62.032, 137.026, 300.901 and 661.056 mg test item/kg diet, equivalent to the cumulative doses of 4.269, 9.391, 20.661, 45.455 and 100.000 µg rimsulfuron/larva.
Reference item: One reference item group (R) with a cumulative dose of 7.39 µg dimethoate/larva.

Endpoints: NOEC/NOED and LC_{50}/LD_{50} on day 22.

Test conditions: Air Temperature: Min / Max: 33.7 °C* / 36.6 °C**
Relative humidity: Min / Max: 0.0 %RH / 100.0 % RH
(Data recorded during period D15-D22 seems not reliable)
Exposure to light: Constant darkness except during feeding and assessments
*Short term deviation (<2 hours), ** Deviation (>2 hours).

Sampling: The sampling was performed on every application day. Samples of each stock solution were collected and located in the freezer at < -18 ºC until shipment.

Analytical verification: A method was validated and specimens of aqueous solution were analysed for concentration determination of rimsulfuron. Quantification was performed by HPLC.
The limit of quantification (LOQ) of the analytical method was 10.76 µg/mL with a limit of detection (LOD) set at 3.23 µg/mL (30 % of the LOQ).

Sample description	Nominal concentration of Rimsulfuron [µg/g]	Analysed concentration of Rimsulfuron [µg/g]	Recovery [%]
Stock solution at D3	7138.41	6741.6	94.4
Stock solution at D4	7138.41	6212.8	87.0
Stock solution at D5	7138.41	6131.8	85.9
Stock solution at D6	7138.41	6725.6	94.2

Statistics: Since in all test item groups the mortality was below 50 % at 22D, the LC_{50}/LD_{50} values could not be calculated.
It was decided not to calculate or estimate the endpoints LC_{10} and LD_{10} due to the lack of statistically significant dose/response.
In order to determine the NOED, a Chi2 2x2 Test with Bonferroni correction (one-sided greater, $\alpha = 0.05$) was used.
Statistical calculations were made with the statistical program ToxRatPro Version 3.2.1.

Findings: In the control group, the cumulative larval mortality from day 3 (D3) until day 8 (D8) was 14.58 %. On day 22 (D22), the adult emergence rate in the control group was 77.08 % of the initial grafted larvae. Therefore the validity criteria for control group was met for both test periods; the D8 mortality was under 15.00 % and the D22 emergence rate was greater than 70.00 %, across all replicates.

In the test item doses of 4.269, 9.391, 20.661, 45.455 and 100.000 µg rimsulfuron/larva the cumulative mean mortality at 22 days (D22) after grafting was 31.25, 18.75, 29.17, 18.75 and 33.33 % respectively, equivalent to the mean emergence rate of 68.75, 81.25, 70.83, 81.25 and 66.67 %. No statistically significant differences in the adult emergence at D22 were determined at any of the test item concentrations compared to the control group.

At day 8 there were no affected larvae. Larvae with presence of uneaten food were recorded at treatment levels T1 and T3 (4.269 and 20.661 µg rimsulfuron/larva, respectively). This behavioural effect represented a 6.52 %, and 2.33 % of alive larvae at T1 and T3 treatments, respectively. At the end of the test, in the final assessment of the emergence on day 22 there was not recorded any affected emerged bee (i.e. malformation).

Cumulative mortality in the Reference Item group was 64.58 % at day 8 and 89.58 % at day 22 across all replicates.

Mortality Results of all Treatment Groups at D22

Treatment Group	Dose [µg a. i./larva] [a]	Cumulative Mortality [%]	Corrected Mortality [%]
Control	-	22.92	-
Test Item Rimsulfuron Technical	4.269	31.25	10.81
	9.391	18.75	-5.41
	20.661	29.17	8.11
	45.455	18.75	-5.41
	100.00	33.33	13.51
Reference Item (dimethoate)	7.39	89.58	86.49

[a] Based on the analysed content of active ingredient (rimsulfuron for the test item, dimethoate for the toxic reference item).

Conclusions: In a repeated exposure larval toxicity test with Rimsulfuron Technical and a duration of 22 days, cumulative mortality in the Control group was 14.58 % on D8 and 22.92 % on D22. In the Reference Item group was 64.58 % on D8 and 89.58 % on D22 across all replicates. The study was deemed valid since all validity criteria were met.

The 22-Day adult emergence No Observed Effect Dose (NOED) was determined to be greater than or equal to 100.000 µg rimsulfuron/larva, equivalent to 101.843 µg test item/larva. Based on the NOED value, the corresponding No Observed Effect Concentration (NOEC) was empirically estimated to be greater than or equal to 649.091 mg rimsulfuron/kg diet, equivalent to 661.056 mg test item/kg diet.

The 22-Day adult emergence-LD_{50} was empirically estimated to be greater than 100.000 µg rimsulfuron/larva, equivalents to 101.843 µg test item/larva. With regard LC_{50} value, was estimated to be greater than 649.091 mg rimsulfuron/kg diet, equivalent to 661.056 mg test item/kg diet.

Endpoints for D22

Endpoint	Active ingredient	Test item
LC_{50} **(95 % Confidence limits)**	> 649.091 mg rimsulfuron/kg diet (Not determined)	> 661.056 mg test item/kg diet (Not determined)
LD_{50} **(95 % Confidence limits)**	> 100.000 µg rimsulfuron/larva (Not determined)	> 101.843 µg test item/larva (Not determined)
LC_{10}	Not determined	Not determined
LD10	Not determined	Not determined
NOEC	≥ 649.091 mg rimsulfuron/kg diet	≥ 661.056 mg test item/kg diet
NOED	≥ 100.000 µg rimsulfuron/larva	≥ 101.843 µg test item/larva

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

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

- after 48 hours mortality of the control groups (without and with 0.1% adjuvant) were 0.0% (criterion: a maximum of 10.0%),
- after 24 hours mortality of the group treated with the reference item at the rate of 0.1 mL/ha was 77.5% (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 without adjuvant was 19.3 and in the control group with 0.1% adjuvant was 23.4 (criterion: a minimum of 5.0 mummies/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Agreed endpoints

Mortality and fecundity of *Aphidius rhopalosiphi* in the laboratory test

Mortality	Fecundity
LR_{50} [g/ha] >500	**ER_{50} [g/ha] 52.7**
$NOER_{mortality} \geq 500$ g/ha	**$NOER_{fecundity} < 125$ g/ha**

Reference:	KCP 10.3.2.1-01
Report	"A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)". Monika Stalmach, 2018, B/178/16. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The laboratory test involved the evaluation of the effects of the test item Rimsulfuron 15% + Nicosulfuron 30% WG (batch number: SCL-44986) on mortality and fecundity of the parasitic wasp, *Aphidius*

rhopalosiphi (adult females (24 - 48 hours after emerging from mummies). The wasps were reared on the barley, *Hordeum vulgare* L. infested with the bird cherry-oat aphid, *Rhopalosiphum padi*. Cages were covered with nylon mesh. Honey drops applied to the nylon mesh served as supplementary food for the wasps.

Three application rates of the test item and a water control and control with 0.1% adjuvant (Trend 90 EC) were used. The rates were 125, 250 and 500 g/ha (with 0.1% adjuvant). Plastic plates were prepared and sprayed using the Potter laboratory spray tower. The application rate of 200 ± 20 L spray fluid/ha was used to calibrate the spray tower. The mean rates of the spray fluid was 2.0 mg/cm^2 (min: 1.9 – max: 2.1 mg/cm^2) in the preliminary test and 2.0 mg/cm^2 (min: 1.9 – max: 2.1 mg/cm^2) in the definitive test. After calibration, the plates were sprayed with distilled water (the control group without adjuvant), distilled water with 0.1% Trend 90 EC (control with adjuvant), suspensions of Rimsulfuron 15% + Nicosulfuron 30% WG (the treated groups), and a water emulsion of Danadim 400 EC at the rate of 0.1 mL/ha (the reference item group). The range of rates was selected on the basis of the non-GLP preliminary test results and suggestions of the Sponsor.

Adult female wasps were exposed to the test item applied to plastic plates. They were confined for 48 hours, and their condition was assessed after 2, 24, and 48 hours. Test conditions: temperature: 19 – 22°C; relative air humidity: 70 – 76%; photoperiod: 16 hours light (mortality assessment and oviposition: 1667 lx; fecundity assessment: 6058 lx): 8 hours dark).

Then, all females which survived 48-hour exposure to Rimsulfuron 15% + Nicosulfuron 30% WG and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, fifteen female wasps from the groups treated with the test item at the rates, i.e. 125, 250 and 500 g/ha (with 0.1% adjuvant) and the control group were individually introduced into 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 wasp pupae were developing) was recorded.

Mortality of the wasps 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 test system and the precision of the test procedure, an insecticide, i.e. Danadim 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 0.1 mL/ha (0.04 g dimethoate/ha). The control group was treated with distilled water.

Statistical analyses: Chi2 2x2 Table test with Bonferroni Correction, probit analysis (non-linear regression); Student-t test, one-way analysis of variances (ANOVA), Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Williams Multiple Sequential t-test procedure.

Results

Mortality and fecundity of *Aphidius rhopalosiphi* in the laboratory test

Parameter (endpoints)								
Mortality				**Fecundity**				
Test item [application rate]		**Total [%]**	**LR_{50}**	**Test item [application rate]**		**mean no. of mummies/ female**	**Fecundity reduction Pr [%]**	**ER_{50}**
Test item [g/ha] with 0.1% adjuvant	**Active ingredients [g/ha]**		**[g/ha]**	**Test item [g/ha] with 0.1% adjuvant**	**Active ingredients [g/ha]**			**[g/ha]**
Control without adjuvant		0.0	>500	**Control without adjuvant**		19.3	--	~~52.7~~ >500*
Control with 0.1% adjuvant		0.0		**Control with 0.1% adjuvant**		23.4	--	
125	19.0[a] + 38.8[b]	0.0		125[+]		14.1	39.6	
250	38.0[a] + 77.5[b]	0.0		250[+]		13.3	43.3	
500	76.0[a] + 155.0[b]	2.5		500[+]		12.9	44.7	
$NOER_{mortality} \geq 500$ g/ha				**$NOER_{fecundity} < 125$ g/ha**				
Reference item: Danadim 400 EC								
Reference item [mL/ha]				0.1				
Active ingredient [g/ha]				0.04				
Mortality								
Total [%]				77.5				

a: Rimsulfuron
b: Nicosulfuron
*: statistically significant differences between control without adjuvant and control with 0.1% adjuvant
+ statistically significant differences between control with 0.1% adjuvant and groups exposed to test item; ToxRat Professional 3.2.1. software [12], [SOP/B/67]
*estimated visualy by zRMS

Findings

- The control without adjuvant group and control with 0.1% adjuvant survived the 48-hour mortality assessment. After 48 hours of exposure to Rimsulfuron 15% + Nicosulfuron 30% WG at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) percentages of mortality of *A. rhopalosiphi* were 0.0, 0.0 and 2.5%, respectively.
- Based on the obtained mortality results it can be assumed that the LR50 is higher than 500 g/ha of Rimsulfuron 15% + Nicosulfuron 30% WG with 0.1% adjuvant. It can be also assumed that the $NOER_{mortality}$ is higher or equal than 500 g/ha of test item with 0.1% adjuvant.
- Mortality of the wasps exposed to Danadim 400 EC at the rate of 0.1 mL/ha was 77.5% after 24 hours. Therefore, the validity criterion specified in the Method description was met [6]. The results showed that the test organisms were sensitive to dimethoate.
- The fecundity assessment showed that the mean number of mummies per female in the control group was 19.3. The mean number of the mummies in control without adjuvant was 19.3 and in the control with 0.1% adjuvant was 23.4.
- At the significance level of 0.05 there were statistically significant differences in fecundity between the control without adjuvant and control with adjuvant. The control with adjuvant was accepted as the reference group.
- As for the wasps treated with Rimsulfuron 15% + Nicosulfuron 30% WG at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) the mean number of mummies per female were 14.1, 13.3 and 12.9, respectively.
- Fecundity reduction (Pr) in the group treated with the test item at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) were 39.6, 43.3 and 44.4%, respectively. At the significance level of 0.05, there were statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) and the control group (Williams Multiple Sequential t-test procedure, $|t| > |t^*|$).
- On the basis of the obtained fecundity results, the ER50 is 52.7 g/ha of Rimsulfuron 15% + Nicosulfuron 30% WG with 0.1% adjuvant. The $NOER_{fecundity}$ is lover than 125 g/ha of the test item (with 0.1% adjuvant).

Validity criteria

The following validity criteria were met during the study:

- after 48 hours mortality of the control groups (without and with 0.1% adjuvant) were 0.0% (criterion: a maximum of 10.0%),
- after 24 hours mortality of the group treated with the reference item at the rate of 0.1 mL/ha was 77.5% (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 without adjuvant was 19.3 and in the control group with 0.1% adjuvant was 23.4 (criterion: a minimum of 5.0 mummies/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Conclusion

On the basis of the obtained results it can be concluded that Rimsulfuron 15% + Nicosulfuron 30% WG at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) has no adverse effect on mortality of the wasps. Test item at the rates of 125, 250, 500 g/ha (with 0.1% adjuvant) has an adverse effect on fecundity of the wasps.

Comments of zRMS:

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

- mortality of the control group without 0.1% adjuvant was 0.0% and in the control group with 0.1% adjuvant 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 96.7% on day 7 of exposure (criterion: a minimum of 50%),
- the mean number of eggs per female in the control group without 0.1% adjuvant was 4.1 and in the control group with 0.1% adjuvant was 5.1 (required: ≥ 4 eggs per female).

Agreed endpoints:

Mortality	**Reproduction**
LR_{50}[g/ha] >500	**ER_{50}[g/ha] > 500**
$NOER_{mortality}$≥ 500 [g/ha]	**$NOER_{reproduction}$ ≥ 500 [g/ha]**

Reference: KCP 10.3.2.1-02

Report: "A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WDG on the predatory mite, *Typhlodromus pyri* (Sch.)". Monika Stalmach, 2019, Study Code B/179/16. Institute of Industrial Organic Chemistry Branch Pszczyna

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: According to the Amendment No. 1 to the Study Plan B/179/16, study should be completed in November 2018, but it was completed in January 2019, which had no impact on the results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): Not relevant

Materials and methods

The aim of the extended laboratory test was to evaluate the effects of the test item, Rimsulfuron 15% + Nicosulfuron 30% WDG (batch number: SCL-65843) on mortality and reproduction of the predatory mite, *T. pyri* (Sch.). The mites are reared on the bean, *Phaseolus vulgaris* L. (Fabaceae) infested with the two-spotted spider mite, *Tetranychus urticae* Koch.
On the basis of the non-GLP preliminary test results it was decided to use three rates of the test item in the definitive test. These were: 125.0, 250.0 and 500.0 g/ha (with 0.1% adjuvant). The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to plastic discs. The mites were fed with pine pollen (*Pinus* sp.).
All spray fluids were prepared on the application day. The volumes corresponded to 200 L spray fluid/ha. Plastic discs were prepared and sprayed using the Potter laboratory spray tower. The mean rates of the spray fluid was 2.0 mg/cm^2 (min: 1.9 – max: 2.1 mg/cm^2) in the preliminary test and 2.0 mg/cm^2 (min: 1.9 – max: 2.0 mg/cm^2) in the definitive test. After calibration, the plastic discs were sprayed with distilled water (the control group without 0.1% adjuvant), water with 0.1% adjuvant (control with 0.1% adjuvant) suspensions of Rimsulfuron 15% + Nicosulfuron 30% WDG (the treated groups with 0.1% adjuvant), and a water emulsion of Danadim 400 EC at the rate of 9.0 mL/ha (the reference item group).

Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and all groups treated with the test item were made after 8, 11, and 14 days of the treatment. Test conditions: temperature: 24 – 27°C; relative air humidity: 68 – 89%; photoperiod: 16 h light : 8 h dark; light intensity: 886 lux.

Mortality of *T.pyri* after 7 days of the treatment 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, Danadim 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.
Statistical analysis: regression analysis using the log-probit method, Chi2 2x2 Table Test with Bonferroni Correction, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Williams Multiple Sequential t-test Procedure.

Results
The effects of Rimsulfuron 15% + Nicosulfuron 30% WDG on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Parameter (endpoints)							
Mortality				**Reproduction**			
Study group [application rate]		**Total [%]**	**LR_{50}**	**Study group [application rate]**	**M ean number of eggs/ female (Rr) [no.]**	**Reproduction reduction Pr [%]**	**ER_{50}**
Test item [g/ha] with 0.1% adjuvant	**Active ingredients [g/kg]**		**[g/ha]**	**Test item [g/ha] with 0.1% adjuvant**			**[g/ha]**
Control without 0.1% adjuvant*		--	Above 500	Control without 0.1% adjuvant*	4.1	--	Above 500
Control with 0.1% adjuvant		1.7		Control with 0.1% adjuvant	5.1	--	
125	19.0a + 38.8b	1.7		125	4.0	2.9	
250	38.0a + 77.5a	5.0		250	3.8	8.6	
500	76.0a + 155.0b	1.7		500	3.9	5.0	
$NOER_{mortality} \geq$ 500 [g/ha]				**$NOER_{reproduction} \geq$ 500 [g/ha]**			
Reference item: Danadim 400 EC							
Reference item [mL/ha]			9.0				

Active ingredient [g/ha]	3.6
Mortality	
Total [%]	96.7

[a]: Rimsulfuron
[b]: Nicosulfuron
*: control without 0.1% adjuvant was accepted as the reference group

Findings

- In the definitive test were used two control groups: without 0.1% adjuvant and without 0.1% adjuvant. Mortality of the control group without 0.1% adjuvant and with 0.1% adjuvant after 7 days of exposure were 0.0 and 1.7%, respectively. At the significance level of 0.1, there were no statistically significant differences in mortality between the control group without 0.1% adjuvant and with 0.1% adjuvant. For this reason control without 0.1% adjuvant was accepted as the reference group.
- The percentages of mortality of T. pyri after 7 days of exposure was 1.7, 5.0 and 1.7% at the rates 125, 250 and 500 g/ha (with 0.1% adjuvant), respectively.
- On the basis of the obtained mortality results, the LR50 could not be estimated. Based on mortality results it can be assumed that LR50 is higher than 500 g/ha of Rimsulfuron 15% + Nicosulfuron 30% WG (with 0.1% adjuvant). The NOERmortality is higher than or equal to 500 g/ha (with 0.1% adjuvant) of test item.
- At the significance level of 0.1, there were no statistically significant differences in mortality between the group treated with the test item at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) and the control group (Chi2 2x2 table test with Bonferroni Correction p(z) > alpha*).
- After 7 days of exposure to Danadim 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha), mortality of the mites was 96.7%. Therefore, the validity criterion specified in the Method description was met.
- The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.
- The mean reproduction rate (Rr) in the control group without 0.1% adjuvant was 4.1 eggs/female. The mean reproduction rate (Rr) in the control group with 0.1% adjuvant was 5.1 eggs/female. At the significance of ≤ 0.1, there were no statistically significant differences in mortality between the control group without 0.1% adjuvant and with 0.1% adjuvant. For this reason control without 0.1% adjuvant was accepted as the reference group.
- The mean reproduction rates after 14 days of exposure to Rimsulfuron 15% + Nicosulfuron 30% WDG at the rates 125, 250 and 500 g/ha (with 0.1% adjuvant) were 4.0, 3.8 and 3.9 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 125, 250 and 500 g/ha were 2.9, 8.6, and 5.0%, respectively.
- At the significance level of ≤ 0.1, there were no statistically significant differences at rates 125, 250 and 500 g/ha (with 0.1% adjuvant) (Williams Multiple Sequential t-test procedure; $|t| > |t^*|$)
- On the basis of the obtained results it could be assumed that the ER50 is above 500 g/ha (with 0.1% adjuvant) of Rimsulfuron 15% + Nicosulfuron 30% WDG. the NOERreproduction is higher than or equal to 500 g/ha (with 0.1% adjuvant) of test item.

Conclusions

On the basis of the obtained results it can be concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG at the rates of 125, 250 and 500 g/ha (with 0.1% adjuvant) has no adverse effect on mortality. The test item at all tested rates has no adverse effect on reproduction of the mites.

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

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:

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

- each replicate produced 104.4 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 23.3% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 3.8% (criterion: ≤ 10%).

Agreed endpoints:

EC_{10}, EC_{20}, EC_{50}, LC_{50}, NOEC and LOEC values

Endpoint	Value [mg test item /kg dry weight of artificial soil]	Value [mg rimsulfuron/kg dry weight of the artificial soil]	Value [mg nicosulfu-ron/kg dry weight of the artificial soil]
EC_{10}	179.5	27.3	54
EC_{20}	458.2	69.6	137.9
EC_{50}	> 1000	> 152	> 301
NOEC (reproduction)	320	48.6	96.3
LOEC (reproduction)	560	85.1	168.6
LC_{50}	> 1000	> 152	> 301
NOEC (survival)	> 1000	> 152	> 301
LOEC (survival)	> 1000	> 152	> 301

Reference:	KCP 10.4.1.1
Report	"Rimsulfuron 15% + Nicosulfuron 30% WDG. Earthworm Reproduction Test (*Eisenia andrei*)". Paweł Pieczka, 2019, G/272/17, Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 222 (2016)
Deviations:	Contrary to what had been planned, the study finished in February 2019, and not in November/December 2018.. These deviations did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Rimsulfuron 15% + Nicosulfuron 30% WDG; Batch Number SCL- 65843; active substance: rimsulfuron: 15.2 % (w/w); nicosulfuron: 30.1% (w/w)
Test species:	*Eisenia andrei* obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology.
Soil:	10% sphagnum peat, 20% kaolin clay, 70% air-dried quartz sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of earthworms: 10 earthworms/replicate Test duration: 8 weeks
Application rates:	Control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560, and 1000 mg/kg dry weight of the artificial soil. The test item in the form of an aqueous suspensions was mixed with a suitable amounts of the artificial soil. The treated and the untreated soils were placed in plastic containers. A volume of water used to prepare the aqueous suspension was suitable enough to obtain about 50% (between 40% – 60%) of the maximum water holding capacity at the beginning of the experiment.
Test conditions:	temperature: 18.0 – 22.0°C; pH at the beginning of the experiment: 6.00 – 6.10; pH at the end of the experiment: 5.89 – 5.96 (additional containers with the artificial soil (1 for the control and 1 for each concentration) were prepared to determine the pH and the soil moisture content at the beginning and at the end of the experiment); soil moisture content at the beginning of the experiment: 19.2 – 20.3% (43.5 – 46.0% of the maximum water holding capacity); soil moisture content at the end of the experiment: 20.1 – 22.1% (45.5 – 50.0% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 544 – 602 lux light intensity at the end of the experiment: 586 – 615 lux
Statistical analysis:	EC_{10}, EC_{20}, EC_{50}, LC_{50} – probit or logit analysis using linear max. likelihood regression NOEC (reproduction, survival) –Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure LOEC: a value suggested by the ToxRat Professional 2.10 statistical computer software
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC LC_{50}, NOEC, LOEC

Results and Conclusions

On the basis of the results, it was concluded that after 4 weeks, at the control group there was mortality of adult earthworm noticed and it was equal to 3.8%. At concentrations ranging from 5.6 to 1000 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 0.0 to 12.5%.
The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is higher than 1000 mg/kg dry weight of artificial soil (152 mg of rimsulfuron + 301 mg of nicosulfuron/kg dry weight of artificial soil).
No changes in the appearance (morphology) and behaviour of the living earthworms were noticed.
After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of artificial soil, the body weight increase was between -8.9 to 5.1%. As for the control group, the body weight increase was equal to 2.8%.
After 8 weeks of the experiment, the obtained results led to the following conclusions:
After the application of the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 70.5 – 134.3 per replicate. The mean number of juveniles in the control group was equal to 104.4 per replicate.

After 8 weeks of the experiment, it was concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG had statistically significant impact on reproduction of the earthworms at the concentrations between 560 – 1000 mg/kg dry weight of artificial soil.

Summary of results (mortality, body weight change and number of juveniles)

Concentration (mg/kg dry weight of the artificial soil)	Total mortality (4 weeks)		Mean body weight increase (4 weeks)		Number of juvenile earthworms after 8 weeks of the experiment		
	No.	%	mg	%	Mean±SD	Comparison to the control [%]	CV* [%]
0 (Control)	3	3.8	11.6	2.8	104.4 ± 24.3	-	23.3
5.6	0	0.0	-36.3	-8.9	113.8 ± 28.8	109.0	25.4
10	0	0.0	3.3	0.7	77.3 ± 29.1	74.0	37.6
18	0	0.0	2.5	0.6	123.3 ± 26.3	118.1	21.4
32	0	0.0	-26.0	-6.4	87.8 ± 12.1	84.1	13.8
56	0	0.0	-22.0	-5.3	134.3 ± 35.1	128.6	26.1
100	0	0.0	-10.0	-2.4	114.8 ± 29.2	109.9	25.5
180	5	12.5	-9.8	-2.4	100.5 ± 26.8	96.3	26.6
320	0	0.0	-17.3	-4.2	91.8 ± 13.9	87.9	15.1
560	1	2.5	-20.9	-4.8	70.5^{+} ± 8.1	67.5	11.5
1000	0	0.0	22.8	5.1	74.0^{+} ± 14.1	70.9	19.0

* - coefficient of variation
+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

Reference substance – carbendazim. Number of juvenile earthworms

Concentration (mg/kg dry weight of the artificial soil)	**Number of juvenile earthworms after 8 weeks of the experiment**		
	Mean±SD	**Comparison to the control [%]**	**CV [%]**
0.0 (control with acetone)	123.1 ± 20.8	-	16.9
0.0 (control)	131.1 ± 14.7	106.5	11.2
1.0	99.3 ± 14.2	80.6	14.4
1.5	119.0^{+} ± 31.4	96.6	26.4
2.25	80.5^{+} ± 15.7	65.4	19.5
3.37	72.3^{+} ± 8.7	58.7	12.1
5.0	51.3^{+} ± 9.7	41.6	18.9
NOEC	1.50		
LOEC	2.25		

+- statistically significant differences between the control and the treatment groups (Alpha = 0.05, one-sided smaller)

The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

EC_{10}, EC_{20}, EC_{50}, LC_{50}, NOEC and LOEC values

Endpoint	**Value [mg test item /kg dry weight of artificial soil]**	**Value [mg rimsulfuron/kg dry weight of the artificial soil]**	**Value [mg nicosulfuron/kg dry weight of the artificial soil]**
EC_{10}	179.5	27.3	54
EC_{20}	458.2	69.6	137.9
EC_{50}	> 1000	> 152	> 301
NOEC (reproduction)	320	48.6	96.3
LOEC (reproduction)	560	85.1	168.6
LC_{50}	> 1000	> 152	> 301
NOEC (survival)	> 1000	> 152	> 301
LOEC (survival)	> 1000	> 152	> 301

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

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

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:

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

- mean adult mortality: 8.8% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 1214.0 (criterion: ≥ 100 juveniles at the end of the test),
- the coefficient of variation calculated for the number of juveniles: 14.0(criterion: ≤ 30%).

Agreed endpoints:

Impact of the Rimsulfuron 15% + Nicosulfuron 30% WDG on survival of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]	
		rimsulfuron	nicosulfuron
LC_{10}	>1000	>152	>301
LC_{20}	>1000	>152	>301
LC_{50}	>1000	>152	>301
NOEC	>1000	>152	>301
LOEC	>1000	>152	>301

Impact of the Rimsulfuron 15% + Nicosulfuron 30% WDG on reproduction of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]	
		rimsulfuron	nicosulfuron
EC_{10}	**311.7** (46.4 – 474.7)	**47.4** (7.1 – 72.2)	**93.8** (14.0 – 142.9)
EC_{20}	**532.7** (236.4 – 749.0)	**81.0** (35.9 – 113.8)	**160.3** (71.2 – 225.4)
EC_{50}	**>1000*** (977.6 – >1000*)	**>152*** (148.6 – >152*)	**>301*** (294.3 – >301*)
NOEC	**320**	**48.6**	**96.3**
LOEC	**560**	**85.1**	**168.6**

* values obtained above the tested concentration range

Reference:	KCP 10.4.2.1-01
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WDG Collembolan (*Folsomia candida*) Reproduction Test". Pieczka P., 2019, G/273/17. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD No. 232 (2016)
Deviations:	Yes At the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016).

	Physiological or pathological symptoms or distinct changes in behavior were not described. The study was finished in January 2019 and not in November/December 2018 as it had been planned.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aims of the study were to assess the impact of Rimsulfuron 15% + Nicosulfuron 30% WDG on reproduction of the collembolans, *Folsomia candida* and to determine the EC_{10}, EC_{20}, EC_{50}, and NOEC.
Nine concentrations of the test item were used. These included: 5.6; 10; 18, 32; 56; 100; 180; 320; 560; 1000 mg of the test item/kg dry weight of the artificial soil. The test item in form of aqueous suspension was mixed with the artificial soil. Each concentration was divided into four replicates. There were also a concurrent control group divided into eight replicates. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Material and methods

Test item:	Name: Rimsulfuron 15% + Nicosulfuron 30% WDG Batch number: SCL-65843 Content: rimsulfuron 15.2% (w/w) + nicosulfuron 30.1% (w/w) Manufacturing date: 08.03.2018 Expiry date: 07.03.2020
Test organism:	The collembolan, *Folsomia candida* obtained from a standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. The collembolans used in the study were 9 – 12 days old.
Test design:	Test duration: 28 days Number of replicates: 4 replicates / concentration + 8 replicates / control; Number of collembolans: 10 / replicate
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Endpoints:	EC_{10}, EC_{20}, EC_{50}, LC_{10}, LC_{20}, LC_{50}, LOEC and NOEC
Test conditions:	Temperature: 19 – 21°C pH at the beginning of the test: 5.67 – 5.75 pH at the end of the test: 5.90 – 6.07 Soil moisture content at the beginning of the test: 12.7 – 14.6% Soil moisture content at the end of the test: 12.3 – 14.0% In order to maintain proper moisture content, the containers with the artificial soil were weighed at the beginning and after 2 weeks of the experiment. Water loss did not exceed 2%, so no water was added Lighting: 16 h light and 8 h dark; Light intensity at the beginning of the test: 637 - 652 lux Light intensity at the end of the test: 615 - 636 lux
Concentrations of the test item:	control, 5.6; 10; 18, 32; 56; 100; 180; 320; 560; 1000 mg of the test item/kg of dry weight of the artificial soil. Glass containers with a capacity of 100 mL, with covers were used.

Statistical analysis:	EC_{10}, EC_{20}, EC_{50}, LC_{10}, LC_{20} and LC_{50} – a probit analysis or Weibull analysis NOEC (number of juveniles): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure, NOEC (survival): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Multiple Sequentially-rejective U-test After Bonferroni-Holm LOEC – a value suggested by the program
Validity criteria:	- mean adult mortality: 8.8% (criterion: ≤ 20%), - the mean number of juveniles per vessel at the end of the test: 1214.0 (criterion: ≥ 100 juveniles at the end of the test), - the coefficient of variation calculated for the number of juveniles: 14.0(criterion: ≤ 30%). the coefficient of variation calculated for the number of juveniles was 12.7% (criterion: ≤ 30%)

Findings

Summary of results (mortality and number of juveniles)

Concentration (mg/kg dw soil)	Total mortality (28d)		Number of juvenile earthworms after 28 d of the experiment		
	No.	%	Mean±SD	Comparison to the control [%]	CV* [%]
0 (Control)	7	8.8	1214.0 ± 169.71	-	14.0
5.6	6	15.0	1103.0 ± 162.81	90.9	14.8
10	5	12.5	1095.8 ± 148.02	90.3	13.5
18	1	2.5	1326.8 ± 199.12	109.3	15.0
32	5	12.5	1091.8 ± 131.37	89.9	12.0
56	3	7.5	1284.8 ± 110.96	105.8	8.6
100	4	10.0	1328.3 ± 218.14	109.4	16.4
180	6	15.0	1113.3 ± 125.16	91.7	11.2
320	5	12.5	1101.0 ± 278.54	90.7	25.3
560	6	15.0	985.5^{+} ± 229.65	81.2	23.3
1000	5	12.5	744.5^{+} ± 120.02	61.3	16.1

*CV – coefficient of variation
+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

Reference substance – boric acid. Number of juvenile collembolans

Concentration (mg/kg dw soil)	Number of juvenile earthworms after 28 d of the experiment		
	Mean±SD	Comparison to the control [%]	CV* [%]
0 (Control)	709.0 ± 66.5	100.0	9.4
15	787.5 ± 51.6	111.1	6.6
22	692.0 ± 80.6	97.6	11.6
32	614.5 ± 27.6	86.7	4.5
46	620.5 ± 142.1	87.5	22.9
68	498.0^{+} ± 100.4	70.2	20.2
100	311.0^{+} ± 18.4	43.9	5.9
150	333.5^{+} ± 7.8	47.0	2.3
220	270.0^{+} ± 59.4	38.1	22.0
320	99.0^{+} ± 14.1	14.0	14.3
460	29.0^{+} ± 11.3	4.1	39.0
680	0.0	0.0	-
1000	0.0	0.0	-
EC_{50}	**118.5 (99.9 – 140.7)**		

+ - statistically significant difference between the control and the treatment group (Alpha = 0.05, one-sided smaller)

Impact of the Rimsulfuron 15% + Nicosulfuron 30% WDG on survival of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]	
		rimsulfuron	nicosulfuron
LC_{10}	>1000	>152	>301
LC_{20}	>1000	>152	>301
LC_{50}	>1000	>152	>301
NOEC	>1000	>152	>301
LOEC	>1000	>152	>301

Impact of the Rimsulfuron 15% + Nicosulfuron 30% WDG on reproduction of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]	
		rimsulfuron	nicosulfuron
EC_{10}	**311.7**	**47.4**	**93.8**

	(46.4 – 474.7)	(7.1 – 72.2)	(14.0 – 142.9)
EC_{20}	**532.7** (236.4 – 749.0)	**81.0** (35.9 – 113.8)	**160.3** (71.2 – 225.4)
EC_{50}	**>1000*** (977.6 – >1000*)	**>152*** (148.6 – >152*)	**>301*** (294.3 – >301*)
NOEC	**320**	**48.6**	**96.3**
LOEC	**560**	**85.1**	**168.6**

* values obtained above the tested concentration range

After 28 days of the experiment mortality of the adult collembolans at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil were observed from 2.5 to 15.0%.
The mean number of juveniles after exposure of adult collembolans was between 744.5 – 1328.3 per replicate. In the control the mean values of juveniles was 1214.0 per replicate.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil carbon and nitrogen transformation

Comments of zRMS:	The study is considered valid. All validity criteria were met. • the coefficient of variation in the control group was as follows: 13.0, 9.2, 2.3 and 12.0% on 0, the 7th, 14th and 28th day of soil incubation, respectively. The criterion of validity: the variation between replicate samples in the control should be less than ± 15%. **Agreed endpoint:** On the basis of the results, it was concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG at the concentration corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference	**KCP 10.5-01**
Report	"Rimsulfuron 15% + Nicosulfuron 30% WDG: Soil Microorganisms: Nitrogen Transformation Test". Paweł Pieczka, 2018. STUDY CODE: G/271/17. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s)	OECD Guideline No. 216 (2000) / EU Method C.21
Deviations	The study finished in October 2018 and not in September 2018 as it had been planned. According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer (chapter 3.4.4.4.). The predicted environmental concentration (PEC) was calculated assuming 2.5

	cm of the soil depth according to the German conditions for the substances with the mobility in soil KFoc < 500 mL/g. Thus, the applied soil depth is a deviation from OECD Guideline No. 216 (2000), EU Method C.21 and SOP/G/32, where the PEC is calculated by using 5 cm of the soil depth. (chapter 3.3.). According to OECD Guideline No. 216 and EU Method C.21, the substrate chosen for the test (the powdered Lucerne meal) should have a favourable carbon to nitrogen ratio (usually between 12/1 and 16/1). In this study a C/N ratio is lower than the one mentioned in OECD Guideline No. 216 and EU Method C.21. However, it is not a validity criterion and a critical point in the study and it has no influence on the obtained results during the test (3.4.1.). These deviations did not affect the results of the study.
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Material and methods

Test material	Rimsulfuron 15% + Nicosulfuron 30% WDG batch no.: SCL-65843)
Soil	Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna
Test design	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.
Concentrations of the test material	control, PEC: 0.27 mg test item/kg dry soil (i.e. 0.04 mg rimsulfuron/kg dry soil + 0.08 mg of nicosulfuron/kg dry soil), 5 x PEC: 1.35 mg test item/kg dry soil (i.e. 0.21 mg rimsulfuron/kg dry soil + 0.41 mg of nicosulfuron/kg dry soil).
Test conditions	Temperature: 19.0 – 22.0°C, soil moisture: 46.5% – 50.3% of the maximum water holding capacity, incubation in darkness.
Endpoints	The concentration of nitrate [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14, 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14, 0 – 28 days.
Statistical analysis	- Shapiro-Wilk's test on Normal Distribution, - Levene's Test on Variance Homogeneity (with Residuals) - Dunnett's Multiple t-test Procedure

Study design

The aim of the study was to detect long-term adverse effects of Rimsulfuron 15% + Nicosulfuron 30% WDG on the processes of nitrogen transformation in aerobic surface soils.
Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm.
The concentrations of the test item were 0.27 mg test item/kg dry soil (i.e. 0.04 mg rimsulfuron/kg dry soil + 0.08 mg of nicosulfuron/kg dry soil), and 1.35 mg test item/kg dry soil (i.e. 0.21 mg rimsulfuron/kg dry soil + 0.41 mg of nicosulfuron/kg dry soil). The first concentration is the maximum predicted environmental concentration (PEC). The upper tested concentration is the single application rate multiplied by five (5 x PEC).
The treated and the control soils were divided into three replicates.
On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrate.

The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using 0.1 M KCl. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used.
The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

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: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil) did not exceed 25% on 28 day of analysis.

Deviations from the control based on nitrate formation rate for selected time intervals [%]

Time interval [d]	**PEC** 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil)	**5 x PEC** 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil)
0 – 7	11.7	11.3
0 – 14	6.3	1.6
0 – 28	10.2	8.9

Conclusions
On the basis of the results, it was concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG at the concentration corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	The study is considered valid. All validity criteria were met. • The coefficients of variation (CV) in the control group were 0.5, 0.5, 4.0 and 2.0%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%. **Agreed endpoint:** On the basis of the results, it was concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG at the concentrations corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

Reference: KCP 10.5-02

Report "Rimsulfuron 15% + Nicosulfuron 30% WDG. Soil Microorganisms: Carbon Transformation Test", Paweł Pieczka, 2019, G/270/17. Institute of Industrial Organic Chemistry Branch Pszczyna.

Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22
Deviations:	The predicted environmental concentration (PEC) is calculated assuming 2.5 cm of the soil depth according to the German conditions for the active substances with the mobility in soil KFoc < 500 mL/g. Thus, the applied soil depth is a deviation from OECD Guideline No. 217 (2000), the EU Method C.22, and SOP/G/33 (chapter 3.3.). The study finished in February 2019 and not in September 2018 as it had been planned. This deviations did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:	
Description:	Rimsulfuron 15% + Nicosulfuron 30% WDG
Production batch:	SCL-65843
Active ingredients content:	rimsulfuron – 15.2% (w/w); nicosulfuron – 30.1% (w/w)
Vehicle and control:	Distilled water
Test system:	
Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	19.0 – 22.0°C
Humidity:	48.1 – 51.2% of MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Experimental period:	17/07/2018 – 15/08/2018
Test design and treatment:	3 portions of soil weighing 1500 g each: one control group and two groups containing the test item. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days. Concentrations of the test material: control, PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron/kg dry weight of soil) and 5xPEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron/kg dry weight of soil). The mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation.

Statistics: In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity, and the Williams Multiple Sequential t-test were used.

Results After 0, 7, 14 and 28 days of incubation, no statistically significant differences in respiration intensity between the control soil and the soil treated with the test item at the concentration corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil) were observed.

The percentage deviations between the control soil and the soil treated with the test item at the concentrations corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil) did not exceed 25% on 28 day of analysis.

When the difference in respiration rates between the lower treatment and a control is equal to or less than 25% at any sampling day after 28, a given test item can be perceived as having no long-term influence on carbon transformations in soil.

Mean Oxygen (O_2) consumption - deviations from the control [%]:

Day	Control	PEC		5 x PEC	
		Consumption [mg/kg dry weight soil/hour]	Deviation [%]	Consumption [mg/kg dry weight soil/hour]	Deviation [%]
0	26.4 ± 3.44	36.2 ± 8.52	23.5	30.2 ± 0.75	2.5
7	36.5 ± 3.36	35.8 ± 3.80	10.6	30.0 ± 6.85	22.8
14	34.6 ± 0.81	32.8 ± 3.45	10.5	34.6 ± 0.84	2.4
28	29.7 ± 3.57	28.7 ± 3.11	10.8	27.1 ± 0.44	1.6

Oxygen (O_2) consumption - deviations from the control [%]

Day	PEC 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil)	5 x PEC 1.35 mg of test item/kg of dry weight soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil)
0	-37.1	-14.1
7	2.0	17.9
14	5.4	0.2
28	3.4	8.8

"-" – values of oxygen consumption higher than the one obtained for the control group
Values obtained using ToxRat 2.10. computer software

Conclusion

On the basis of the results, it was concluded that Rimsulfuron 15% + Nicosulfuron 30% WDG at the concentrations corresponding to the PEC: 0.27 mg of test item/kg of dry weight soil (i.e. 0.04 mg of rimsulfuron + 0.08 mg of nicosulfuron / kg dry weight of soil) and 5 x PEC: 1.35 mg of test item/kg of dry weight

soil (i.e. 0.21 mg of rimsulfuron + 0.41 mg of nicosulfuron / kg dry weight of soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

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

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:

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

- The seedling emergence in the control (validity criterion: at least 70%) was as follows:

81.0% - sunflower,

100.0 % - cabbage,

85.7% - pea,

100.0% – carrot,

75.0% – onion, 95.0% – oats,

- The mean survival of the emerged control seedlings was 100% for all tested sp cies (validity criterion: at least 90%);;
- The control seedlings did not exhibit any visible phytotoxic effects;
- The environmental conditions for all plants of the same species were identical

Agreed endpints:

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g test item/ha).

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 100	> 100	53.8	> 100	88.7 (56.5 - >100)	> 100
NOER	≥ 100	3.7	33.3	≥ 100	≥ 100	≥ 100
Shoot length (plants without roots)						
ER_{50}	27.1	12.8	13.8 (7.9 – 24.2	62.0	8.7	70.7 (65.5 – 76.4)
NOER	11.1	3.7	3.7	3.7	0.14	33.3
Plant dry weight (plants without roots)						
ER_{50}	29.0 (23.6 – 35.9)	18.0 (10.5 – 31.3)	20.0 (10.0 – 41.5)	56.7 (34.2 - >100)	>100 (82.3 - >100)	44.9 (27.0 – 77.7)
NOER	11.1	3.7	3.7	11.1	033.3	33.3

Reference:	KCP 10.6.2-01
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WDG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test". Pieczka P., G/275/17, 2019. Łukasiewicz Research Network Institute Of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD No. 208 (2006)
Deviations:	Yes According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50 µE/m2/s. In experiment the light intensity was between 116.7 – 154.8. The study finished in August 2019, and not in November/December 2018.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Rimsulfuron 15% + Nicosulfuron 30% WDG on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species: sunflower, cabbage, pea, carrot, onion and oats. Five application rates were sprayed onto the soil surface. The experiment was conducted in a plant growth chamber. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence and visual phytotoxicity. The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed. The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, NOER.

Material and methods

Test item: Name: Rimsulfuron 15% + Nicosulfuron 30% WDG
Batch number: SCL-65843
Content: rimsulfuron 15.2% (w/w) + nicosulfuron 30.1% (w/w)
Manufacturing date: 08.03.2018
Expiry date: 07.03.2020

Test species:: sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*)

Test design: Number of rates: 8 application rates + control,
Number of replicates:
sunflower: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
cabbage: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
pea: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
carrot: 5 plants/pot – 20 plants/concentration (4 pots/concentration);
onion - 5 plants/pot – 20 seeds/concentration (4 pots/concentration);
oats - 5 plants/pot – 20 plants/concentration (4 pots/concentration).
Total number of plants per application rate – 20 or 21
The test item was sprayed onto the soil surface with calibrated spraying equipment. The pots were placed on trays. To prevent bias, random assignment of the test and the control pots is recommended. They were rearranged once a week.

Termination: 14 days after the emergence of 50% of the control seedlings

Application rates: control, 0.05; 0.14; 0.4; 1.2; 3.7; 11.1; 33.3; 100.0 g of the test item/ha

The test item was sprayed onto the soil using a suitable spraying chamber. The spraying chamber works as a pressure sprayer which makes it possible to apply traditional nozzles used in plant protection. Before the test item was applied, the spraying equipment had been calibrated using deionised water in order to select a suitable nozzle providing the most appropriate way of application under the conditions of specified pressure and working quickness.

Soil: sandy loam . Collected from the place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna, where no plant protection products or organic and inorganic fertilizers had been used. The soil was collected from a depth of 20 cm and sieved to 2 mm particle size. The soil was distributed to plastic pots. Each pot contained about 717 g of the soil (i.e. 600 g dry weight).

Test conditions:
Temperature: 18.0 – 26.4°C (constantly monitored)
Humidity: 45.3 – 93.6% (constantly monitored)
Photoperiod: 16 hours light / 8 hours darkness
Light intensity: 116.7 – 154.8 µE/m2/s (measured at the beginning and at the end of the experiment)
Carbon dioxide concentration: 347 – 391 ppm

Appropriate soil nutrients were supplemented once a week to maintain good plant vigour. Top watering was used during the exposure period.

Statistical analysis: ER_{10}, ER_{25}, ER_{50} – probit analysis, logit analysis, Weibull analysis, Moving average computation after Thompson, Nonlinear regression using the 4parameter logistic.
NOER – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity, Williams Multiple Sequential t-test Procedure or
Fisher's Exact Binomial Test with Bonferroni Correction.

Validity criteria: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:
81.0% - sunflower,
100.0 % - cabbage,
85.7% - pea,
100.0% – carrot,
75.0% – onion, 95.0% – oats,
- the mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%);;
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical

Findings

Compared effect to the control (%)

Appl. Rate (g/ha)	Sunflower			Cabbage			Pea		
	Plant nº	Shoot lenght	Plant weight	Plant nº	Shoot lenght	Plant weight	Plant nº	Shoot lenght	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
0.05	94.1	108.3	112.2	85.7	97.0	118.1	94.4	91.8	104.9

0.14	94.1	92.9	109.7	100.0	97.3	119.3	105.6	108.7	138.2
0.4	70.6	99.1	104.1	85.7	104.0	127.6	100.0	110.2	121.2
1.2	88.2	98.2	112.6	95.2	95.3	132.1	111.1	102.5	125.4
3.7	88.2	90.0	89.3	95.2	91.6	107.5	88.9	102.6	132.1
11.1	70.6	82.5	76.0	61.9	52.7	51.5	100.0	44.0	49.2
33.3	70.6	42.2	40.9	81.0	40.1	32.1	77.8	30.7	47.8
100.0	64.7	31.9	25.7	66.7	29.8	20.6	16.7	4.7	9.4
Appl. Rate (g/ha)	**Carrot**			**Onion**			**Oats**		
	Plant n°	**Shoot lenght**	**Plant weight**	**Plant n°**	**Shoot lenght**	**Plant weight**	**Plant n°**	**Shoot lenght**	**Plant weight**
Ctrl	-	-	-	-	-	-	-	-	-
0.05	100.0	107.3	118.2	106.7	92.2	111.6	94.7	118.5	112.6
0.14	80.0	95.5	113.4	120.0	83.3	89.7	100.0	113.6	105.0
0.4	100.0	100.2	113.0	120.0	77.1	97.5	89.5	125.2	134.3
1.2	70.0	90.5	97.8	106.7	67.7	108.1	100.0	110.5	116.1
3.7	70.0	89.9	97.8	120.0	65.7	93.7	100.0	109.8	115.2
11.1	85.0	80.6	92.6	93.3	47.2	78.3	100.0	97.2	91.9
33.3	90.0	52.6	49.0	80.0	29.6	67.3	100.0	86.6	100.1
100.0	85.0	48.1	43.7	46.7	35.3	60.4	84.2	31.5	22.4

Phytotoxicity and plant damage

Sunflower (*Helianthus annuus*): After the application of the test item at the application rates ranging from 11.1 – 100 g of the test item/ha, the plant damage as stunted growth and spots were observed.

Cabbage (*Brassica oleracea* var. *capitata*): After the application of the test item at the rate of 1.2 and ranging from 11.1 – 100 g of the test item/ha, stunted growth was observed. Chlorosis and necrosis were also observed from 11.1 – 100 g of the test item/ha. Dead plants were observed at 0.05 and 11.1 g of the test item/ha.

Pea (*Pisum sativum*): After the application of the test item at the rates ranging from 11.1 – 100 g of the test item/ha, stunted growth and deformations were observed. Dead plants were observed at 0.05 and 33.3 g of the test item/ha.

Carrot (*Daucus carota*): After the application of the test item at rates between 11.1 - 100 g of the test item/ha, the plant damage as stunted growth and chlorosis were observed. Dead plants were observed at 1.2 g of the test item/ha.

Onion (*Allium cepa*): After the application of the test item at rates between 0.4 - 100 g of the test item/ha, the plant damage as stunted growth was observed. Wilting was observed at rates between 33.3 and 100.0 g of the test item/ha. Dead plants were observed at 0.14, 3.7, 33.3 and 100.0 g of the test item/ha.

Oats (*Avena sativa*): After the application of the test item at the rates ranging from 33.3 - 100 g of the test item/ha, the plant damage as stunted growth was observed.

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g test item/ha).

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 100	> 100	53.8	> 100	88.7 (56.5 - >100)	> 100
NOER	≥ 100	3.7	33.3	≥ 100	≥ 100	≥ 100
Shoot length (plants without roots)						
ER_{50}	27.1	12.8	13.8 (7.9 – 24.2	62.0	8.7	70.7 (65.5 – 76.4)
NOER	11.1	3.7	3.7	3.7	0.14	33.3
Plant dry weight (plants without roots)						
ER_{50}	29.0 (23.6 – 35.9)	18.0 (10.5 – 31.3)	20.0 (10.0 – 41.5)	56.7 (34.2 - >100)	>100 (82.3 - >100)	44.9 (27.0 – 77.7)
NOER	11.1	3.7	3.7	11.1	033.3	33.3

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g rimsulfuron/ha).

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 15.2	15.2	8.2	> 15.2	13.5 (8.6 - >15.2)	> 15.2
NOER	≥ 15.2	0.6	5.1	≥ 15.2	≥ 15.2	≥ 15.2
Shoot length (plants without roots)						
ER_{50}	4.1	1.9	2.1 (1.2 – 3.7)	9.4	1.3	10.7 (10.0 – 11.6)
NOER	1.7	0.6	0.6	0.6	0.02	5.1
Plant dry weight (plants without roots)						
ER_{50}	4.4 (3.6 – 5.5)	2.7 (1.6 – 4.8)	3.0 (1.5 – 6.3)	8.6 (5.2 - >15.2)	>15.2	6.8 (4.1 – 11.8)
NOER	1.7	0.6	0.6	1.7	5.1	5.1

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g nicosulfuron/ha).

	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	>30.1	30.1	16.2	>30.1	26.7 (17.0 - >30.1)	>30.1
NOER	≥ 30.1	1.1	10	≥ 30.1	≥ 30.1	≥ 30.1
Shoot length (plants without roots)						
ER_{50}	8.2	3.9	4.2 (2.4 – 7.3)	18.7	2.6	21.3 (19.7 – 23.0)
NOER	3.3	1.1	1.1	1.1	0.04	10.0
Plant dry weight (plants without roots)						
ER_{50}	8.7 (7.1 – 10.8)	5.4 (3.2 – 9.4)	6.0 (3.0 – 12.5)	17.1 (10.3 - >30.1)	>30.1 (24.8 - >30.1	13.5 (8.1 – 23.4)
NOER	3.3	1.1	1.1	3.3	10.0	10.0

The following order of the test plant sensitivity was noticed:

cabbage, pea > onion > carrot, sunflower > oats

Comments of zRMS:

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

- The seedling emergence (validity criterion: at least 70%) was as follows:

90.5 – 97.6% – pea,
92.9 – 97.6% – sunflower,
88.1 – 92.9% – cabbage,
90 - 100% – carrot,
92.5 - 100% – oats,
90 - 100% – onion,

- The mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- The control seedlings did not exhibit any visible phytotoxic symptoms,
- Theenvironmental conditions for all plants belonging to the same species were identical.

Agreed endpints:

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g test item/ha).

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 100	38.7 (26.3 – 62.6)	> 100	> 100	> 100	> 100
NOER	> 100	11.1	> 100	≥ 100	> 100	≥ 100
Shoot length (plants without roots)						
ER_{50}	48.0 (32.8 - 77.4)	40.1 (27.5 – 64.0)	> 100	8.0 (4.5 – 14.7)	63.1 (47.4 – 91.4)	68.4 (47.5 – >100)
NOER	3.7	3.7	1.2	1.2	3.7	0.4
Plant dry weight (plants without roots)						
ER_{50}	>100.0	20.0 (13.6 – 29.5)	94.0 (67.2 – >100)	3.7 (1.3 – 9.8)	61.0 (35.7 – >100)	61.4 (47.5 – 85.0)
NOER	33.3	3.7	11.1	1.2	11.1	11.1

Reference:	KCP 10.6.2-02
Report:	"Rimsulfuron 15% + Nicosulfuron 30% WDG Terrestrial Plant Test: Vegetative Vigour Test". Pieczka P., G/276/17, 2019. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD No. 227 (2006)
Deviations:	Yes According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. In experiment light intensity was between 99.8 – 134.2 µE/m2/s. The study was finished in March 2019 and not in November/December 2018.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Rimsulfuron 15% + Nicosulfuron 30% WDG on vegetative vigour of six terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species: sun-

flower, cabbage, pea, carrot, onion and oats. The plants were grown to the 2- to 4- true leaf stage. The test item was sprayed onto the plants. Eight rates of the test item were used in the experiment. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity. The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed. The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER10, ER25, ER50, and NOER.

Material and methods

Test item:
Name: Rimsulfuron 15% + Nicosulfuron 30% WDG
Batch number: SCL-65843
Content: rimsulfuron 15.2% (w/w) + nicosulfuron 30.1% (w/w)
Manufacturing date: 08.03.2018
Expiry date: 07.03.2020

Test species::
sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*)

Test design:
Number of rates: 8 application rates + control
Number of replicates: 4 or 7 replicates/rate
sunflower: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
cabbage: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
pea: 3 plants/pot – 21 plants/concentration (7 pots/concentration);
carrot: 5 plants/pot – 20 plants/concentration (4 pots/concentration);
onion - 5 plants/pot – 20 seeds/concentration (4 pots/concentration);
oats - 5 plants/pot – 20 plants/concentration (4 pots/concentration).
The total number of plants per application rate: 20 or 21
The test item was sprayed onto the plants with calibrated spraying equipment. The pots were placed on trays. To prevent bias, random assignment of the test and the control pots is recommended. They were rearranged once a week.
Test termination: 21 days after the spraying

Application rates:
control, 0.05; 0.14; 0.4; 1.2; 3.7; 11.1; 33.3; 100.0 g of the test item/ha
The test item was sprayed onto the plants using a suitable spraying chamber. The spraying chamber works as a pressure sprayer which makes it possible to apply traditional nozzles used in plant protection. Before the test item was applied, the spraying equipment had been calibrated using deionised water in order to select a suitable nozzle providing the most appropriate way of application under the conditions of specified pressure and working quickness.

Soil:
sandy loam. The soil was taken from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna. The site chosen for soil collection had not been treated with any plant protection products or organic and inorganic fertilisers. The soil was collected from a depth of 20 cm. It was sieved to 2 mm particle size to homogenize it and remove coarse particles.

Test conditions:
Temperature: 18.0 – 26.4°C (constantly monitored)
Humidity: 45.3 – 93.6% (constantly monitored)
Controlled light – dark cycles (16h:8h),
Light intensity: 99.8 – 134.2 µE/m2/s (measured at the beginning and at the end of the experiment)
Carbon dioxide concentration: 321 – 384 ppm.

Appropriate soil nutrients were supplemented once a week to maintain good plant vigour. Top watering was used during the exposure period.

Statistical analysis: ER10, ER25, ER50 – probit or logit analysis
NOER - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment or Fisher's Exact Binomial Test with Bonferroni Correction.

Validity criteria: - the seedling emergence (validity criterion: at least 70%) was as follows:
90.5 – 97.6% – pea,
92.9 – 97.6% – sunflower,
88.1 – 92.9% – cabbage,
90 - 100% – carrot,
92.5 - 100% – oats,
90 - 100% – onion,
- the mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Findings

Compared effect to the control (%)

Appl. Rate (g/ha)	Pea			Sunflower			Cabbage		
	Plant n°	Shoot lenght	Plant weight	Plant n°	Shoot lenght	Plant weight	Plant n°	Shoot lenght	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
0.05	100.0	95.0	112.8	100.0	105.7	103.0	100.0	100.1	103.7
0.14	100.0	90.4	99.9	100.0	114.7	111.2	100.0	100.2	88.5
0.4	100.0	105.1	135.8	100.0	114.8	110.5	100.0	103.7	95.8
1.2	100.0	107.0	124.7	100.0	107.2	86.5	100.0	104.1	111.5
3.7	100.0	102.8	149.4	100.0	112.2	106.4	100.0	92.2	122.2
11.1	100.0	88.6	126.9	85.7	68.9	70.6	100.0	87.8	128.0
33.3	100.0	52.5	91.7	42.9	51.2	27.7	100.0	82.7	77.4
100.0	100.0	35.2	60.9	28.6	35.2	15.4	100.0	79.8	48.9
Appl. Rate (g/ha)	**Carrot**			**Onion**			**Oats**		
	Plant n°	Shoot lenght	Plant weight	Plant n°	Shoot lenght	Plant weight	Plant n°	Shoot lenght	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
0.05	100.0	94.8	118.0	100.0	106.0	112.1	100.0	95.0	99.4
0.14	100.0	94.3	77.7	100.0	100.9	83.9	100.0	114.3	127.9
0.4	100.0	91.0	92.3	100.0	102.4	112.1	100.0	97.4	105.6
1.2	100.0	87.9	97.2	100.0	106.0	130.3	100.0	94.3	108.0
3.7	100.0	60.7	43.1	100.0	88.2	102.9	100.0	92.9	95.1
11.1	100.0	35.6	17.5	100.0	72.4	93.9	100.0	75.8	91.0
33.3	100.0	24.2	7.1	100.0	64.2	59.1	80.0	56.6	58.2
100.0	90.0	25.8	9.3	100.0	41.7	40.1	80.0	47.1	41.3

Phytotoxicity and plant damage

Pea (*Pisum sativum*): After the application of the test item at the rates ranging from 0.05 to 100 g of the test item/ha, the plant damage as chlorosis was observed. Stunted growth was also observed from 0.14 to 1.2 and 11.1 to 100 g of the test item/ha. Wilting was observed from 0.4 to 100 g of the test item/ha. And deformations were observed from 33.3 to 100 g of the test item/ha.

Sunflower (*Helianthus annuus*): After the application of the test item at the rates ranging from 3.7 to 100 g of the test item/ha, the plant damage as chlorosis was observed. Dead plants, stunted growth and necrosis was observed from 11.1 to 100 g of the test item/ha. Spots and wilting were observed from 33.3 and 100 g of the test item/ha.

Cabbage (*Brassica oleracea* var. *capitata*): After the application of the test item at the rates ranging from 11.1 to 100 g of the test item/ha, the plant damage as stunted growth was observed. Chlorosis and wilting was also observed from 33.3 to 100 g of the test item/ha. Deformations were observed at 100 g of the test item/ha.

Carrot (*Daucus carota*): After the application of the test item at the rates ranging from 0.4 to 100 g of the test item/ha, the plant damage as stunted growth was observed. Chlorosis, wilting and deformations were observed from 3.7 to 100 g of the test item/ha. Dead plants were also observed at 100 g of the test item/ha.

Onion (*Allium cepa*): After the application of the test item at the rates ranging from 11.1 to 100 g of the test item/ha the plant damage as stunted growth, wilting, chlorosis were observed.

Oats (*Avena sativa*): After the application of the test item at the rates ranging from 11.1 to 100 g of the test item/ha, the plant damage as stunted growth, chlorosis and necrosis was observed. Wilting and dead plants were observed from 33.3 to 100 g of the test item/ha.

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g test item/ha).

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 100	38.7 (26.3 – 62.6)	> 100	> 100	> 100	> 100
NOER	> 100	11.1	> 100	≥ 100	> 100	≥ 100
Shoot length (plants without roots)						
ER_{50}	48.0 (32.8 - 77.4)	40.1 (27.5 – 64.0)	> 100	8.0 (4.5 – 14.7)	63.1 (47.4 – 91.4)	68.4 (47.5 – >100)
NOER	3.7	3.7	1.2	1.2	3.7	0.4
Plant dry weight (plants without roots)						
ER_{50}	>100.0	20.0 (13.6 – 29.5)	94.0 (67.2 – >100)	3.7 (1.3 – 9.8)	61.0 (35.7 – >100)	61.4 (47.5 – 85.0)
NOER	33.3	3.7	11.1	1.2	11.1	11.1

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g rimsulfuron/ha).

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 15.2	5.9 (4.0 – 9.5)	>15.2	>15.2	>15.2	15.2
NOER	≥ 15.2	1.7	>15.2	≥ 15.2	>15.2	≥ 15.2
Shoot length (plants without roots)						
ER_{50}	7.3 (5.0 – 11.8)	6.1 (4.2 – 9.7)	> 15.2	1.2 (0.7 – 2.2)	9.6 (7.2 – 14.2)	10.4 (7.2 – >15.2)
NOER	0.6	0.6	0.2	0.2	0.6	0.6
Plant dry weight (plants without roots)						
ER_{50}	>15.2	3.0 (2.1 – 4.5)	14.3 (10.2 – >15.2)	0.6 (0.2 – 1.5)	9.3 (5.4 – >15.2)	9.3 (7.2 – 12.9)
NOER	5.1	0.6	1.7	0.2	1.7	1.7

Rimsulfuron 15% + Nicosulfuron 30% WDG: the ER_{50}, NOER values (g nicosulfuron/ha).

	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	>30.1	11.6 (7.9 – 18.8)	>30.1	>30.1	>30.1	30.1
NOER	>30.1	3.3	>30.1	>30.1	>30.1	>30.1
Shoot length (plants without roots)						
ER_{50}	14.4 (9.9 – 23.3)	12.1 (8.3 – 19.3)	> 30.1	2.4 (1.4 – 4.4)	19.0 (14.3 – 28.1)	20.6 (14.6 – >30.1)
NOER	1.1	1.1	0.4	0.4	1.1	0.12
Plant dry weight (plants without roots)						
ER_{50}	>30.1	6.0 (4.1 – 8.9)	28.3 (20.2– >30.1)	1.1 (0.4 – 2.9)	18.4 (10.7 – >30.1)	18.5 (14.3 – 25.6)
NOER	10.0	1.1	3.3	0.4	3.3	3.3

The following order of the test plant sensitivity was noticed:
cabbage > pea, onion > oats > carrot >sunflower.

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

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

A 2.8 KCP 10.8 Monitoring data