FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: **T-75WG-OR2C**

Product name(s): **TOSCANA TOP 75 WG**

Chemical active substance:

Tribenuron methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT (Poland)

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2020

MS Finalisation date: 15/10/2021

Version history

When	What
December 2020	First submission of product authorization.
December 2020	Submission to the Polish Ministry of Agriculture and Rural Development, updated version of dRR
February 2021	Submission to the evaluation unit Merit Mark
August 2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

New data have been highlights in yellow.

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9 Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by CIECH Sarzyna S.A. for approval of the formulation T-75WG-OR2-C / TOSCANA TOP 75WG containing 750 g/kg tribenuron methyl, for use as herbicide in cereals, miscanthus and grasses grown for seeds.

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

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

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**zRMS Conclusion** ~~(efficacy)~~						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-							
2	PL	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	-							

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**zRMS Conclusion** ~~(efficacy)~~						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
3	PL	Spring soft wheat (TRZAS), Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-							
4	DE	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
5	DE	Winter soft wheat (TRZAW) Winter rye (SECCW), Winter triticale (TTLWI) Winter barley (HORVW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
6	DE	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**zRMS Conclusion** ~~(efficacy)~~						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
7	HU	Winter soft wheat (TRZAW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
8	HU	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
9	RO	Winter soft wheat (TRZAW)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,025 kg/ha; b) 0,025 kg/ha	a) 18,75 g as/ha b) 18,75 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
10	RO	Spring barley (HORVS)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	To be submitted further via mutual recognition procedure							
Minor uses according to Article 51 (zonal uses)																				
11	PL	Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Autumn BBCH 13 – 29	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-							
12	PL	Durum wheat (TRZDU),	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring	a) 1 b) 1	n.a.	a) 0,025 kg/ha;	a) 18,75 g as/ha	200 / 400	n.a.	-							

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**zRMS Conclusion** ~~(efficacy)~~						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
		Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)				BBCH 13 – 39			b) 0,025 kg/ha	b) 18,75 g as/ha										
13	PL	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02 kg/ha; b) 0,02 kg/ha	a) 15 g as/ha b) 15 g as/ha	200 / 400	n.a.	-							
14	PL	Miscanthus sp. (MISSS)	F	Annual dicotyledonous weeds	Broadcast - foliar	BBCH 12 -14	a) 1 b) 1	n.a.	a) 0,02~~5~~ kg/ha; b) 0,02~~5~~ kg/ha	a) 15.00 ~~18,75~~ g as/ha b) 15.00 ~~18,75~~ g as/ha	200 / 400	n.a.	-							
15	PL	Grasses grown for seeds	F	Annual dicotyledonous weeds	Broadcast - foliar	Spring BBCH 13 – 39	a) 1 b) 1	n.a.	a) 0,02~~5~~ kg/ha; b) 0,02~~5~~ kg/ha	a) 15.00 ~~18,75~~ g as/ha b) 15.00 ~~18,75~~ g as/ha	200 / 400	n.a.	-							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 "Conclusion"

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

Remarks table:

(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

Review Comments:

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

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The risk to Birds and mammals from the proposed uses of TOSCANA TOP 75 WG was assessed according to EFSA guidance (EFSA Journal 2009; 7(12):1438).

Effect on birds

The risk assessment performed for birds ~~and mammals~~ indicate acceptable acute and long-term risk to birds ~~and mammals~~ exposed to tribenuron methyl following application of TOSCANA TOP 75 WG acc. to intended GAP.

The TER_a and TER_{lt} values for a plant metabolite IN-B5685 of tribenuron-methyl were calculated for the highest proposed application rate of 8.6 g metabolite/ha and the risk for metabolite was accepted according to intended GAP.

Effects on terrestrial vertebrates other than birds

The risk assessment performed for mammals indicate acceptable acute and long-term risk exposed to tribenuron methyl and the relevant plant metabolite following application of TOSCANA TOP 75 WG for intended use in cereals.

Acute risk assessment performed for mammals indicate acceptable acute risk exposed to tribenuron methyl and the relevant plant metabolite following application of TOSCANA TOP 75 WG for intended use in grassland.

Acceptable long-term risk was not achieved for active substance and plant metabolite since the trigger value of 5 was not met for vole for the proposed application rate at TIER 1. Therefore, higher refinement was performed. PT refinement for vole presented by the Applicant was not agreed by zRMS.

zRMS performed the risk assessment based on the refined diet for vole, however for the proposed dose 18.75 g a.s/ha the risk was not acceptable. Thus, zRMS used the maximum safe application rate 15.00 g a.s/ha.

In conclusion, aacceptable risk for the tribenuron methyl and acceptable risk for its plant metabolite was assumed based on the refined proportions of feed item in the diet (PD) with maximum safe application rate to 15g a.s/ha.

Taking to consideration that at the higher tier acceptable long-term risk was assumed for tribenuron methyl in use of grasses the authorisation can be granted for grasses at the application dose 15 g a.s/ha (uses 14, 15).

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

As the active substance Tribenuron-methyl has a log Pow value of < 3 it was not necessary to consider the risk to birds and mammals from secondary poisoning.

No risk to birds or mammals via drinking water was identified, as the ratio of the effective application rate to relevant endpoints was < 50 (threshold relevant to the Koc of tribenuron-methyl).

Regarding effects on other terrestrial vertebrate wildlife (reptiles and amphibians) no data/information available.

9.1.1.2 9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Based on PEC/RAC calculations performed in all scenarios, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for TOSCANA TOP 75 WG provided that following risk mitigation measures are taken into account:

- a vegetative buffer strip of 20 m to surface water bodies is required.

Based on the results of the higher tier risk assessment (FOCUS Step 4 values in combination with lowest toxicity endpoint for *Lemna gibba* following buffer zones with vegetative strips according are required as follows:

Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Winter cereals spring application at rate 15 g a.s./ha, pH < 7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Winter cereals spring application at rate 15 g a.s./ha, pH > 7
- 20 m vegetative strips with 20 m non- sprayed buffer zone to surface water bodies

Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Grasses – spring application, 18.75 g a. s./ha
- no mitigation measures required

For TOSCANA TOP 75 WG – use in cereals, following risk mitigation measures should be applied taking to consideration VFSmode:

Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Winter cereals autumn application at rate 15 g a.s./ha, pH < 7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Winter cereals autumn application at rate 15 g a.s./ha, pH > 7
- 3 m vegetative strips with 3 m non- sprayed buffer zone to surface water bodies

Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Grasses – spring application, 18.75 g a. s./ha
- no mitigation measures required

For scenarios relevant for Poland: D3, D4, R1 no mitigation measures are required.
However, as for Poland the relevant scenarios are D3, D4 and R1 only, no unacceptable risk is indicated following the TOSCANA TOP 75 WG application. Thus, none mitigation measures are required on the label.

Concerned Member States must decide on the consideration of risk mitigation measures

9.1.1.3 Effects on bees (KCP 10.3.1)

The evaluation of the risk for bees has been performed in line with SANCO/10329/2002 rev 2 final.

Based on results obtained ~~for~~ in oral and contact studies on honeybees all calculated hazard quotients are considerably less than trigger values, indicating that the formulation poses a low risk to bees. Therefore, a low risk to bees is expected from the application TOSCANA TOP 75 WG according to the proposed GAP and no mitigation measures are required.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): the Applicant provided the chronic test on bees and chronic test for larvae for formulated product.

It should be noted that The Applicant presented Larval Toxicity Test with single exposure while larval toxicity test with repeated exposure should be provided to cover not only acute but also chronic exposure to larva.

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

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Based on results obtained for TOSCANA TOP 75 WG in laboratory studies on *T. pyri* and *A. rhopalosiphi* the corresponding 'in-field' and "off-field" hazard quotients are below the trigger value of 2 indicating an acceptable 'in-field' and "off-field" risk to non-target arthropods, following application of TOSCANA TOP 75 WG according to the proposed GAP.

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

Risk to earthworms arising from the application of TOSKANA TOP 75 WG according to the intended GAP uses can be excluded as the trigger values of 5 for long-term risk were exceeded by far.
Effects on other soil ~~other soil~~ macroorganisms were not investigated since there are no risks associated with the use of TOSCANA TOP 75 WG to earthworms ~~arthropods other than bees.~~

The risk to soil microorganisms is acceptable since effects on the nitrogen transformations are acceptable at concentration which is higher than the maximum relevant PEC soil for the maximum application rate of active substance Tribenuron methyl and its relevant metabolite.

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

The risk for non-target plants in the off-crop area is indicated to be acceptable ~~when applying either 75% drift reduction or a 5 m buffer strip~~. following risk mitigation measures

Winter cereals and minor uses at the application rate 25 g product/ha
- 1 m and use of 75% drift reducing technology or,
- 5 m buffer zone with no drift reducing technology to non-agricultural land

Spring and winter cereals and minor uses at the application rate 20 g product/ha
- 1 m and use of 50% drift reducing technology or,
- 5 m buffer zone with no drift reducing technology to non-agricultural land

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

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

Additional tests on other non-target species are not required.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of TOSCANA TOP 75 WG grouped according to application time and rate

Grouping according to time of application time and rate			
Group (According to critical GAP)	**Intended uses**	**relevant use parameters for grouping**	**Risk assessment** Relevant parameter or value for sorting
Effects on birds and mammals (9.2 and 9.3)			
1-13	Cereals	Crop scenario: cereals	Crop, application rate, number of applications, timing.
14, 15	Grasses	Crop scenario: grasses	
Aquatic organisms (9.5)			
1, 5, 7, 9, 12	Winter cereals (spring application) - 0.025 kg product/ha BBCH 13-39	Grouping according to Section 8 - Environmental Fate	-highest PECsw for tribenuron methyl and relevant metabolites -pH<7or pH>7
2, 6, 8, 10, 13	Spring cereals (spring application) - 0.02 kg product/ha BBCH 13 – 39		
3, 4, 11	Winter cereals (autumn application) - 0.02 kg product/ha BBCH:13-29		
14, 15	Grassland, (spring application), 0.025 kg product/ha		
Bees (9.6)			
1-15	Generic risk envelope covering all product uses	Risk assessments are based on the maximum single application rate of 1 x 0.025 kg product/ha (corresponding to18,75 g as/ha kg a.s./ha) in cereals	Maximum single application rate
Effects on arthropods other than bees (9.7)			
1-15	According to GAP In-field	In-field and off-field risk assessments are based on the maximum application rate	Maximum single application rate
1-15	According to GAP Off-field		Maximum single application rate
Effects on non-target soil macrofauna (9.8)			

Grouping according to time of application time and rate			
Group (According to critical GAP)	**Intended uses**	**relevant use parameters for grouping**	**Risk assessment** Relevant parameter or value for sorting
1-15	Generic risk envelope covering all product uses		Worst case PECsoil value taken from Section 8 (Environmental Fate)
Effects on non-target soil meso- and macrofauna for metabolites (9.8)			
1-15	Generic risk envelope covering all product uses		Worst case PECsoil value taken from Section 8 (Environmental Fate)
Effects on non-target terrestrial plants (9.10)			
1-15	According to GAP	Risk assessments are based on the maximum single application rate for each type of crops	Application rate and drift rate
~~1~~	~~Winter cereals (spring application) – 0.025 kg /ha~~	~~- highest PECsw for tribenuron methyl and relevant metabolites~~ ~~- the highest exposure scenario~~ ~~- highest PEC soil for tribenuron methyl and relevant metabolites~~ ~~- the highest shortcut values~~	~~- risk assessment for aquatic organisms,~~ ~~- risk assessment for bees, arthropods other than bees, non-target plants~~ ~~- risk assessment for soil organisms (covers the other intended uses)~~ ~~- screening assessment of the acute and long-term/reproductive risk for birds and mammals~~
~~2,~~	~~Spring cereals (spring application) - 0.02 kg /ha~~	~~- highest PECsw for tribenuron methyl and relevant metabolites~~	~~- risk assessment for aquatic organisms~~
~~3~~	~~Winter cereals (autumn application) – 0.02 kg /ha~~	~~- highest PECsw for tribenuron methyl and relevant metabolites~~	~~risk assessment for aquatic organisms~~
~~4~~	~~Grasses (spring application) - 0.025 kg/ha~~	~~highest PECsw for tribenuron methyl and relevant metabolites~~	~~risk assessment for aquatic organisms~~

Review comments:

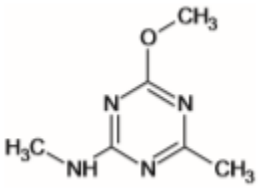
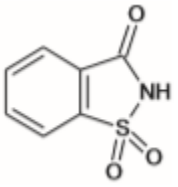
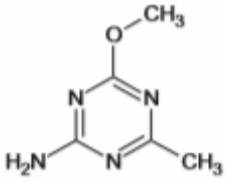
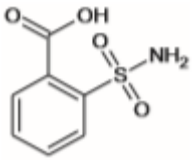
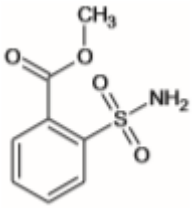
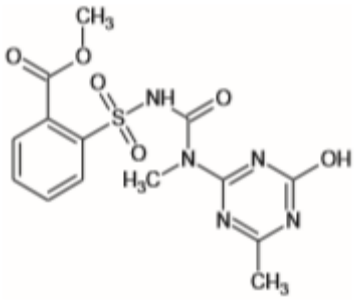
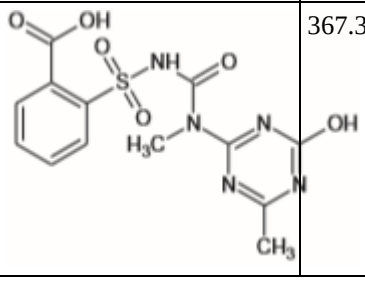
The grouping of the intended uses of TOSCANA TOP 75WG provided by the Applicant in Table 9.1-2 was very general, therefore for clarity of the assessment zRMS updated critical GAP.

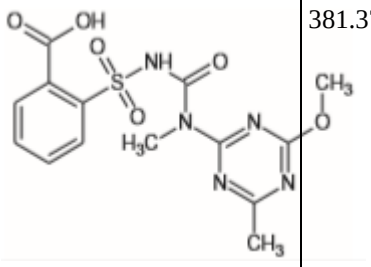
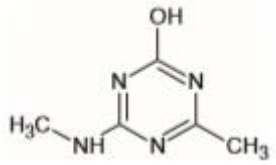
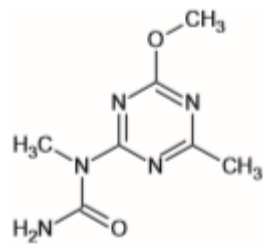
9.1.3 Consideration of metabolites

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 TOSCANA TOP 75 WG is indicat-

ed in the table.

Table 9.1-3 Metabolites of tribenuron methyl

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IN-L5296		154.17	Soil :85.7% Water/sediment: up to 88.9% (total system, 56 d), max 42% in water (14 d), max 86% in sediment (56 d)	Yes, aquatics and soil organisms
IN-00581 saccharin		183.19	Soil :33.9% Water/sediment: up to 38.4% (total system, 14 d), max 32% in water (14 d), max 6.4% in sediment (14 d)	Yes, aquatics and soil organisms
IN-A4098		140.4 ~~10.14~~	Soil :12.6% Water/sediment: 0.0001% , 0.0001 % in water, 0.0001% in sediment	Yes, aquatics and soil organisms
IN-D5119		201.20	Soil : 6.1% Water/sediment: up to 26.5% (total system, 56 d), max 19% in water (56 d), max 7.5% in sediment (56 d)	Yes, aquatics
IN-D5803		215.22	Soil :46.6% Water/sediment: 0.0001% , 0.0001 % in water, 0.0001% in sediment	Yes, aquatics
IN-GK521		381.37	Soil :32.1% Water/sediment: 0.0001% , 0.0001 % in water, 0.0001% in sediment	Yes, aquatics and soil organisms
IN-GN815		367.34	Soil : 6.8% Water/sediment: up to 13% (total system, 29 d), max 5.7% in water (42 d), max 9.2% in sediment (29 d)	Yes, aquatics

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
IN-R9803		381.37	Soil:9.1%	-
IN-R9805		140.15	Soil :7.6 % Water/sediment: up to 14.7% (total system, 71 d), max 9% in water (71 d), max 5.7% in sediment (71 d)	Yes, aquatics and soil organisms
M2		197.19	Soil :16.2 % Water/sediment: 0.0001% , 0.0001 % in water, 0.0001% in sediment	Yes, aquatics and soil organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Effects on birds for TOSCANA TOP 75WG were not evaluated as part of the EU review of Tribenuron-methyl. However further data on TOSCANA TOP 75WG is not relevant as active substance data on toxicity to birds is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for TOSCANA TOP 75WG with the proposed use pattern are provided here.

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

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Tribenuron-methyl	Acute oral	LD_{50}>2250mg/kg bw per day	EFSA Journal 2017;15(7):4912
Bobwhite quail	Tribenuron-methyl	Reproduction, 23 weeks	NOEL = 22 ♂, 21 ♀mg/kg bw per day	EFSA Journal 2017;15(7):4912
Mallard duck	Tribenuron-methyl	Reproduction, 21 weeks	NOEL = 21 ♂, 23 ♀mg/kg bw per day (reproduction 21 weeks)	EFSA Journal 2017;15(7):4912

The lowest short and long-term relevant endpoints values were used in the risk assessment in order to provide a worst-case scenario.

9.2.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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).
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group ~~winter~~ cereals (application rate: 0.025kg product/ha) also covers cereals at the application dose 0.020 kg product/ha.
The risk assessment for the use group grasses at application rate 0.025 kg product/ha covers uses 14, 15 according to critical GAP. ~~the risk for birds from all other intended uses~~ (see 9.1.2).

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: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of TOSCANA TOP 75WG in cereals

Intended use	Cereals ~~Winter~~				
Active substance/product	Tribenuron methyl~~t~~				
Application rate (g a.s/ha)	1× 18.75				
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**
Cereals	Small omnivorous bird	158.8	1	2.98	>755
Reprod. toxicity (mg/kg bw/d)	21				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small omnivorous bird	64.8	1*0.53	0.64	32.8

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

Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of TOSCANA TOP 75WG in grassland

Intended use	Grassland				
Active substance/product	Tribenuron methyl~~t~~				
Application rate (g a.s/ha)	1× 18.75				
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**
Grassland ~~Cereals~~	Large herbivorous ~~Small omnivorous~~ bird	30.5	1	0.57	3947
Reprod. toxicity (mg/kg bw/d)	21				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Grassland ~~Cereals~~	Large herbivorous bird ~~Small omnivorous~~	16.2	1*0.53	0.16	131.25

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.

Plant metabolites

The overall highest maximum observed occurrence of metabolites in crops was 46% TRR in hay for the triazine amine metabolites and 44.6% TRR in grain for the sulphonamide-related compounds (EFSA Journal 2017;15(7):4912).

Since no experimental avian toxicity data were available for any of the metabolites of tribenuron-methyl, the risk assessment was performed for a "worst case hypothetical plant metabolite" which was assumed to be 10 times more toxic than the active substance and occur at 46% TRR. The resulting DDDs and TERs for acute and long-term exposure are presented in the tables below.

Table 9.2-3a: Screening assessment of the acute and long-term/reproductive risk for birds due to ~~metabolites of Tribenuron-methyl after~~ the use of TOSCANA TOP 75WG for sulfonamide urea (IN-B5685) in cereals (worst-case hypothetical metabolite)

Intended use		**Cereals ~~Winter~~**			
Metabolite/product		IN-B5685 Worst case metabolite / TOSCANA TOP 75WG			
Application rate (g metabolite/ha)		1 x 18.75 x Max. obs. =1 x 18.75 x 46*%=8.6			
Acute toxicity (mg/kg bw/d)		>225**			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals	Small omnivorous bird	158.8	1	1.37	164.2
Reprod. toxicity (mg/kg bw/d)		2.1**			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals	Small omnivorous bird	64.8	1*0.53	0.3	7

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.
* Maximum occurrence of plant metabolite is 46%
** metabolites 10 times more toxic than active substance

Daily dietary doses (DDD) were calculated for the avian indicator species based on the shortcut values presented above together with the application rates according to the critical GAP, considering also the maximum observed occurrence of the metabolites.

The TER_A values for the "worst case hypothetical plant metabolite" exceed the Annex VI trigger value of 10, indicating that metabolites may be as much as 100 times more acutely toxic to birds than the active substance, without raising any concerns. Therefore, the acute risk to birds can be considered as acceptable and without need for further consideration.
The TER_{LT} values for the "worst case hypothetical plant metabolite" are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to birds in winter cereals. Therefore, no further consideration is required.

9.2.2.2 Higher-tier risk assessment

The TER_A value calculated in the screening level risk assessment for birds exceed the Annex VI trigger value of 10 for all evaluated scenarios. The acute risk to birds can be considered as acceptable and without need for further consideration.
In addition, the TER_{LT} values for all evaluated scenarios are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to birds in winter cereals. Therefore no further consideration is required.

9.2.2.3 Drinking water exposure

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

Leaf scenario

Since TOSCANA TOP 75WG is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a K(f)oc <500 L/kg (with a K(f)oc of 38.9 (pH <7) and 8.6 (pH >7), Tribenuron-methyl belongs to the group of less sorptive substances. Thus, the trigger of 50 cannot be exceeded.

Effective application rate (g/ha)	=	18.75		
Acute toxicity (mg/kg bw)	=	2250	quotient =	0.0083
Reprod. toxicity (mg/kg bw/d)	=	21	quotient =	0.89

IN-B5685				
Estimated rate (g a.s./ha)** =		8.6		
Acute toxicity (mg a.s./kg bw)* =		225	quotient =	0.038
Reprod. toxicity (mg a.s./kg bw/d)* =		2.1	quotient =	4.09

The ratio is below the trigger value indicating an acceptable risk and no further consideration for tribenuron-methyl and its metabolite is needed

9.2.2.4 Effects of secondary poisoning

According to the EC Guidance Document on Risk Assessment for Birds and Mammals, substances with a log P_{OW} greater than 3 have potential for bioaccumulation and should be assessed for the risk of biomagnification in terrestrial food chains.

Tribenuron-methyl has a log P_{OW} value < 3.0 (EFSA Journal 2017;15(7):4912). It was therefore not necessary to consider the risk from secondary poisoning further. Tribenuron-methyl products, when used according to the GAP, do not present a risk to birds as a result of acute, sub-chronic or chronic exposure or through secondary poisoning, and no further work is necessary.

In addition, the risk of secondary poisoning from soil and surface water metabolites was not considered as part of the EU review of the active substance and has therefore not been considered in this assessment. A low risk in concluded.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

The TER_A value calculated in the screening level risk assessment for birds exceed the Annex VI trigger value of 10 for all evaluated scenarios. The acute risk to birds can be considered as acceptable and without need for further consideration.

In addition, the TER_{LT} values for all evaluated scenarios are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to birds in cereals and grassland. Therefore, no further consideration is required.

No unacceptable risk to birds is expected from the use of TOSCANA TOP 75WG when it is applied according to the proposed use pattern.

Review comments:

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

However, since in the screening assessment of the acute and long-term/reproductive risk for birds due to the use of TOSCANA TOP 75WG in grassland not correct indicator species were used, zRMS updated table 9.2 3.
The TER_A and TER_{LT} values for tribenuron-methyl and its plant metabolite IN-B5685 were calculated for the highest proposed application rate of 18.75 g a.s./ha. and 8.6 g metabolite/ha respectively.
Based on screening step the acceptable acute and reproductive risk to birds was concluded for application of TOSCANA TOP 75WG in winter and spring cereals and grasses according to the intended uses.

TOSCANA TOP 75WG presents no unacceptable risk to birds resulting from exposure via drinking water. Since the log Pow value of tribenuron-methyl and its relevant soil and aquatic metabolites are all below the trigger of 3, the evaluation of the risk of secondary poisoning is not triggered.

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

The effects on terrestrial vertebrates other than birds for TOSCANA TOP 75WG were not evaluated as part of the EU review of Tribenuron-methyl. However further data on TOSCANA TOP 75WG is not relevant as active substance data on toxicity to terrestrial vertebrates other than birds is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for TOSCANA TOP 75WG with the proposed use pattern are provided here.

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Tribenuron-methyl and its relevant metabolites. Effects on mammals of TOSCANA TOP 75WG were not evaluated as part of the EU assessment of Tribenuron-methyl.

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

Species	Substance	Exposure System	Results (mg/kg bw per day)	Reference
Rat	Tribenuron-methyl	Acute oral	LD_{50}>5000	EFSA Journal 2017;15(7):4912
Rat	Tribenuron-methyl	Reproductive toxicity Two-generation study	NOAEL = 2	EFSA Journal 2017;15(7):4912
Rat	Triazine amine (IN-L5296)	Acute oral	LD_{50}=394	EFSA Journal 2017;15(7):4912
Rat	Triazine amine (IN-L5296)	4-week, repeated dose gavage	NOAEL= 8	EFSA Journal 2017;15(7):4912
Rat	Sulfonamide urea (IN-B5685)	Acute oral	LD_{50}>11000	EFSA Journal 2017;15(7):4912
Rat	Sulfonamide urea (IN-B5685)	10 days, repeated dose gavage	NOAEL ≥ 220 [a]	EFSA Journal 2017;15(7):4912
Rat	Sulfonamide (IN-D5803)	Acute oral	LD_{50}>7500[b]	EFSA Journal 2017;15(7):4912

[a] The study was considered of limited reliability but supportive
[b] Data from EFSA Conclusions for metsulfuron-methyl (EFSA, 2015a) and ethmetsulfuron (EFSA, 2014a)

9.3.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints

9.3.2 Risk assessment for spray applications

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

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

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

Table 9.3-2: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of TOSCANA TOP 75WG in cereals

Intended use	Cereals ~~Winter~~				
Active substance/product	Tribenuron methyl~~u~~				
Application rate (g a.s/ha)	1× 18.75				
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**
cereals	Small herbivorous mammal	118.4	1	2.22	2252
Reprod. toxicity (mg/kg bw/d)	2				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
cereals	Small herbivorous mammal	48.3	1*0.53	0.48	**4.2**

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

Table 9.3-3: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of TOSCANA TOP 75WG in grassland

Intended use	Grassland				
Active substance/product	Tribenuron methyl~~u~~				
Application rate (g a.s/ha)	1× 18.75				
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**
Grassland ~~cereals~~	Small herbivorous mammal	136.4	1	2.56	1953
Reprod. toxicity (mg/kg bw/d)	2				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Grassland ~~cereals~~	Small herbivorous mammal	72.3	1*0.53	0.72	**2.8**

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

The TER_{LT} value for Tribenuron-methyl is lower than the Annex VI trigger value of 5, indicating Tribenuron-methyl poses an unacceptable long-term risk to mammals following application of TOSCANA

TOP 75WG at the proposed use rates. Tier 1 assessment is required.

Table 9.3-4: First-tier assessment of the long-term/reproductive risk for mammals due to the use of TOSCANA TOP 75WG in cereals

Intended use	Cereals ~~Winter~~				
Active substance/product	Tribenuron methyl/ TOSCANA TOP 75WG				
Application rate (g a.s/ha)	1 × 18.75				
Reprod. toxicity (mg/kg bw/d)	2				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 10 - 19	Smal insectivorous mammal ‘’shrew’’	4.2	0.53	0.04	50
Cereals BBCH >20	Smal insectivorous mammal ‘’shrew’’	1.9	0.53	0.02	100
Cereals (Early shoots)	Large herbivorous mammals “lagomorph”	22.3	0.53	0.22	9.1
Cereals BBCH 10 - 29	Small omnivorous mammal “mouse”	7.8	0.53	0.08	25
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse”	3.9	0.53	0.04	50

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

Table 9.3-5: First-tier ~~Tier 1~~ assessment of the long-term/reproductive risk for mammals due to the use of TOSCANA TOP 75WG in grassland

Intended use	Grassland				
Active substance/product	Tribenuron methyl~~a~~				
Application rate (g a.s/ha)	1× 18.75				
Reprod. toxicity (mg/kg bw/d)	2				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Grassland All season	Large herbivorous mammals “lagomorph”	17.3	0.53	0.17	11.76
Grassland Late	Smal insectivorous mammal ‘’shrew’’	1.9	0.53	0.02	100
Grassland All season	Small herbivorous mammal ‘’vole’’	72.3	0.53	0.71	**2.82**
Grassland Late season (seed heads)	All season Small herbivorous mammal ‘’mouse’’	6.6	0.53	0.06	33.33
Grassland New sown grass seeds	All season Small herbivorous mammal ‘’mouse’’	6.6	0.53	0.06	33.33
~~Grassland~~	~~Large herbivorous bird~~	~~16.2~~	~~1*0.53~~	~~0.16~~	~~12.5~~

~~'Growing shoots'~~	~~"goose"~~				

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.

Review comments:

As the trigger value of 5 was not met at TIER 1 for small herbivorous mammals for the application of TOSCANA TOP 75WG in grasslands for application rate 0.025 kg product/ha, higher assessment should be performed.

Plant metabolites

The overall highest maximum observed occurrence of metabolites in crops was 46% TRR in hay for the triazine amine metabolites and 44.6% TRR in grain for the sulphonamide-related compounds (EFSA Journal 2017;15(7):4912).

Since experimental mammal toxicity data are available for the metabolites of tribenuron-methyl, the risk assessment was performed for the worst case plant metabolite (lowest toxicity endpoints and highest occurrence) which is Triazine amine (IN-L5296) and occurs at 46% TRR. The resulting DDDs and TERs for acute and long term exposure are presented in the tables below.

Table 9.3-4a: Screening assessment of the acute and long-term/reproductive risk for mammals due to metabolites of Tribenuron-methyl after the use of TOSCANA TOP 75WG in cereals

Intended use		**Cereals ~~Winter~~**			
Metabolite/product		Triazine amine (IN-L5296)			
Application rate (g metabolite/ha)		1 x 18.75 x Max. obs. =1 x 18.75 x 46%*=8.6			
Acute toxicity (mg/kg bw/d)		394**			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
~~Winter~~ cereals ~~BBCH 20- 29~~	Small herbivorous mammal	118.4	1	1.02	386
Reprod. toxicity (mg/kg bw/d)		8**			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
~~Winter~~ cereals ~~BBCH20- 29~~	Small herbivorous mammal	48.3	1*0.53	0.22	36

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.

* Maximum occurrence of plant metabolite is 26%

** Endpoints are from the acute oral and 4-week, repeated dose gavage studies performed for mammals (EFSA Journal 2017;15(7):4912)

Table 9.3-4b: Screening assessment of the acute and long-term/reproductive risk for mammals due to metabolites of Tribenuron-methyl due to the use of TOSCANA TOP 75WG in grassland

Intended use	**Grassland**				
Metabolite	Triazine amine (IN-L5296)				
Application rate (g metabolite/ha)	1 x 18.75 x Max. obs. =1 x 18.75 x 46%*=8.6				
Acute toxicity (mg/kg bw/d)	394**				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Grassland	Small herbivorous mammal	136.4	1	1.17	336.75
Reprod. toxicity (mg/kg bw/d)	8**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Grassland	Small herbivorous mammal	72.3	1*0.53	0.33	24.24

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.

* Maximum occurrence of plant metabolite is 26%

** Endpoints are from the acute oral and 4-week, repeated dose gavage studies performed for mammals (EFSA Journal 2017;15(7):4912)

Acute risk assessment for IN-B5685, IN-GN815 (covering: IN-37739 and IN-QHP91) metabolites is not required since for active substance the wide margin of safety was confirmed (TERa for the tribenuron methyl is 2252)

Nevertheless, a long-term screening assessment has been conducted for sulfonamide urea (IN-B5685) for which actual measured NOAEL value is available.

Table 9.3-5a: Screening assessment of the long-term/reproductive risk for mammals due to the use of CHR/H/1TR for sulfonamide urea (IN-B5685) in cereals

Intended use	**Cereals**				
Metabolite	IN-B5685				
Application rate (g metabolite /ha)	8.6 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw/d)	220**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	0.22	1000

* Maximum occurrence of plant metabolite is 46%

**Endpoint is from the 10 days, repeated dose gavage study performed for mammals (EFSA Journal 2017;15(7):4912)

Table 9.3-5b: Screening assessment of the long-term/reproductive risk for mammals due to the use of CHR/H/1TR for sulfonamide urea (IN-B5685) in grassland

Intended use	**Grassland**				
Metabolite	IN-B5685				
Application rate (g metabolite /ha)	8.6 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw/d)	220**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	72.3	0.53	0.33	666.7

* Maximum occurrence of plant metabolite is 46%
**Endpoint is from the 10 days, repeated dose gavage study performed for mammals (EFSA Journal 2017;15(7):4912)

The following plant metabolites are not considered to be covered by any other risk assessment performed above:

– α-hydroxy-triazine amine (IN-37739); 15% occurrence in wheat
– 4-methoxy-6-(methylamino)-1,3,5-triazine-2-methanol (IN-QHP91); 12% occurrence in wheat
– O-demethyl-tribenuron free acid (IN-GN815); 17% occurrence in wheat

To cover these metabolites, the zRMS performed an additional assessment based on assumption that metabolite IN-GN815 is 10 times more toxic than the active substance and occur at 17% in plant parts.

Table 9.3-6a: Long-term screening for IN-GN815

Intended use	**Cereals**				
Metabolite	IN-GN815				
Application rate (g metabolite /ha)	1 x 18.75 x Max. obs. =1 x 18.75 x 17%*= 3.2 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw/d)	0.2**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening step	Small herbivorous mammal	48.3	0.53	0.08	**2.5**

* Maximum occurrence of plant metabolite is 17%
** metabolite 10 times more toxic than active substance

Table 9.3-6b: Long-term screening for IN-GN815

Intended use	**Grassland**				
Metabolite	IN-GN815				
Application rate (g metabolite /ha)	1 x 18.75 x Max. obs. =1 x 18.75 x 17%*= 3.2 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw/d)	0.2**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Screening step	Small herbivorous mammal	72.3	0.53	0.12	**1.66**

* Maximum occurrence of plant metabolite is 17%
** metabolite 10 times more toxic than active substance

Since TERlt was lower than 5, unacceptable risk to mammals was indicated in the long-term screening assessment. Thus, further assessment is presented in tables below.

Table B.9.3-7a: Long-term Tier 1 assessment for mammals exposed to IN-GN815

Intended use	**Cereals**				
Metabolite	IN-GN815				
Application rate (g/ha)	3.2 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw)	0.2**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TERlt**
First Tier Risk Assessment					
Cereals BBCH 10 - 19	Smal insectivorous mammal ‘’shrew’’	4.2	0.53	0.0071	28.16
Cereals BBCH >20	Smal insectivorous mammal ‘’shrew’’	1.9	0.53	0.0032	62.5
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	0.53	0.0034	58.82
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	0.53	0.014	14.28
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse”	3.9	0.53	0.007	28.57

* Maximum occurrence of plant metabolite is 17%
** metabolite 10 times more toxic than active substance

Table B.9.3-7b: Long-term Tier 1 assessment for mammals exposed to IN-GN815

Intended use	**Grasslands**				
Metabolite	IN-GN815				
Application rate (g/ha)	3.2 (application rate x max. obs. % of metabolite*)				
Reprod. toxicity (mg/kg bw)	0.2**				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TERlt**
First Tier Risk Assessment					
Grassland All season	Large herbivorous mammals “lagomorph”	17.3	0.53	0.03	6.66
Grassland Late	Smal insectivorous mammal ‘’shrew’’	1.9	0.53	0.0032	62.5
Grassland All season	Small herbivorous mammal ‘’vole’’	72.3	0.53	0.12	**1.66**
Grassland	All season	6.6	0.53	0.01	20

Late season (seed heads)	Small herbivorous mammal ‘’mouse’’				
Grassland New sown grass seeds	All season Small herbivorous mammal ‘’mouse’’	6.6	0.53	0.01	20

* Maximum occurrence of plant metabolite is 17%
** metabolite 10 times more toxic than active substance

Risk assessment provided for IN-GN815 covers risk assessment for IN-37739 and IN-QHP91 metabolites.

Based on performed assessment, an acceptable risk to mammals exposed to major plant metabolites can be concluded for proposed uses of TOSCANA TOP 75WG in winter and spring cereals.

However, as the trigger value of 5 was not met at TIER 1 for small herbivorous mammals for the application of TOSCANA TOP 75WG in grasslands for metabolite IN-GN815, higher assessment should be performed.

Daily dietary doses (DDD) were calculated for the mammal indicator species based on the shortcut values presented above together with the application rates according to the critical GAP, considering also the maximum observed occurrence of the metabolite.
The TER_A values for the worst-case plant metabolite exceed the Annex VI trigger value of 10, indicating that the acute risk to mammals can be considered as acceptable and without need for further consideration.
In addition, the TER_{LT} values for the worst-case plant metabolite are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to birds in winter cereals. Therefore, no further consideration is required.

9.3.2.2 Higher-tier risk assessment

The TER_A value calculated in the screening level risk assessment for mammals exceed the Annex VI trigger value of 10 for all evaluated scenarios. The acute risk to mammals can be considered as acceptable and without need for further consideration.

~~In addition, the TER_{LT} values for all evaluated scenarios are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to mammals in winter cereals. Therefore, no further consideration is required.~~

Higher-tier risk assessment

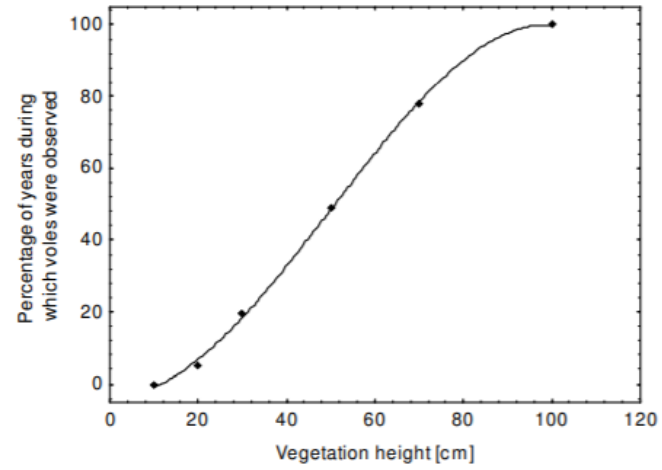
Refinements are required for the grassland application scenario (small herbivorous mammal ‘vole’), Where for Tribenuron methyl TER_{LT} = 2.82 ~~2.78~~ and for metabolite IN-GN815 TERlt=1.66.

Refinement of PT value

The usage of grasslands, which will be kept mown short, would be expected to be very minimal as voles require good vegetation cover to avoid predation (Xxxxxx, 1981[1]). This requirement for ground cover has been demonstrated by Xxxxxx and Xxxxxx (1979[2]). They analysed the occurrence of common voles (Microtus arvalis) and related occurrence and vegetation height.

[1] xxxxx, R. 1981: Spatial structure of rodent populations co-occurring in different crop fields. Pol. Ecol. Stud. 7: 213-227.
2 xxxxxxxx. 1979 Habitat and interspecific displacement of small mammals in the Netherlands. Netherlands Journal of Zoology 29(2): 177-214.

Figure 1. Correlation of vegetation height and the probability of occurrence of common voles (calculated from Xxxxxx and Xxxxxx 1979).



Above figure clearly shows that at the low vegetation heights expected for grasslands(<10cms) the occurrence of common voles will be virtually nil. This suggests that small herbivorous voles are not a relevant focal species in grasslands since their occurrence in this situation will be minimal and hence the risk to mammals will be acceptable. This is especially true in areas where the common vole (Microtus arvalis) does not occur and instead bank voles (Clethrionomys glareolus) and field voles (Microtus agrestis) occur, since these species tend to be even more restricted to good cover and less likely to venture into open areas than the common vole. This species is clearly known to prefer woodland areas (Harris & Xxxxxx, 2000[3]) and would not spend any significant time on open grassland.
These observations indicate that greens and tees are not relevant habitats for small mammals, probably due to the lack of cover (as indicated by the papers described above) and probably also low food availability. In light of these considerations, it is reasonable to assume that herbivorous mammals will spend minimal time foraging for food on tees, greens or fairways and that the PT value would be much less than one. The proportion of time spent feeding in the treated area could be as high as 75 % to demonstrate an acceptable risk to small herbivorous mammals, as presented in the risk refinement.

Proportions of feed item in the diet (PD)

As stated above, for the representative small herbivore as relevant for Tier 1 assessments, the vole conservatively is assumed solely to feed on grasses, the feed item reported to contain the highest residue levels (default mean RUD = 54.2 mg/kg) together with the lowest assimilation efficiency and low food energy.
Studies have demonstrated that common voles (*Microtus arvalis*) prefer to consume dicotyledons rather than monocotyledonous grasses. A study of the diet of the common vole in grassland in Germany examined the diet of 363 individuals caught by snap-trapping through analysis of stomach contents (Xxxxxx (1990[4]; 1991[5]). The results showed that dicotyledons, such as Taraxacum officinale and Trifolium pratense, were preferred and were eaten at a higher frequency than would be expected from their relative occurrence in the grassland habitat in question. Overall, it was reported that dicotyledons comprised a mean volume percentage of 63.5% of stomach contents of common vole. Therefore, the risk assessment can be refined by considering a common vole consuming a diet comprising 60% dicotyledons (non-grass herbs) and 40% grasses.

[3] Xxxxxx & Xxxxxx (2000) Mammals of the British Isles: handbook, 4th edition. The Mammal Society.
[4] Xxxxxx, T. 1990. Zur Nahrungsökologie von Microtus arvalis (Pallas, 1778) auf Dauergrünland. I. Allgemeine Nahrungspräferenzen. Zeitschrift für Säugetierkunde 55: 106-114
[5] Xxxxxx, T. (1991). Percentage of volume versus number of species: availability and intake of grasses and forbs in Microtus arvalis. Folia Zoologica 40 (2): 143 – 151.

Feed item			**Food energy** FE_i	**Assimilation efficiency** AE_i	**Moisture content** MC_i	**Food energy** FE_i fresh	**Food energy** $FE_{i,total}$ fresh	**Daily energy expenditure** DEE	**Fresh Food intake rate** $FIR_{i,total}$ fresh	**Body weight** bw	**FIR/bw**
Category	[%] (fraction)	PD_i (fraction)	[kJ/g dry]	[%]	[%]	[kJ/g fresh]		[kJ/d]	[g fresh weight/d]	[g]	
Small herbivorous scenario – common vole (Approach 2)											
Monocotyledons	40	0.40	17.6	47	76.4	0.78	1.75	65.09	38.29	25	1.49
Dicotyledonos	60	0.60	17.8	76	88.1	0.97					
Sum	100										

Intended use	Grassland
Active substance	Tribenuron methyl~~u~~
Application rate [g a.s./ha]	1 × 18.75 g a.s./ha
Reprod. toxicity [mg/kg bw/d]	2
TER criterion	5

Focal species	Food category, % in diet	RUDm × DF [mg/kg food]	FIR/bw	MAFm × TWA	PT	DDDm [mg/kg bw/d]	TERlt
"herbivorous" Microtus arvalis (Common vole)	Monocotyledons 25%	54.2 × 1	1.49	1 × 0.53	0.7	0.4	**5.0**
	Dicotyledonos 75%	28.7 × 1		1 × 0.53			

Also the relevance of the 'vole' scenarios for regulatory approvals of PPPs in crops is questionable because of the special biological characteristics of voles, particularly concerning population dynamics and resilience to stressors. Some of those key characteristics are:

- Arable crops cannot be regarded as primary habitats for common voles;
- High fecundity and population recuperation of the vole; Common vole populations naturally display cyclical changes, and a strong ability to recover from decimation due to their high reproductive potential;
- Common voles are considered pests in many agricultural areas, since their high biomass consumption can lead to severe crop damage.
- Other agricultural techniques being also means of population control
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached

Due to all uncertainties and discrepancies around the relevance of voles, the risk to small herbivorous mammals should be covered by the assessment of risk to another rodent, i.e. the omnivorous wood mouse (Apodemus sylvaticus). . Therefore, the risk assessment for small herbivorous mammals can be

concluded to be acceptable (even with TER lower than the trigger value) if it is acceptable for other small omnivorous mammal (wood mouse) which is considered as a relevant focal species.
Taking this considerations into account, all TER_{LT} values for mammals in grassland is above the trigger value of 5, indicating that the potential long-term risk to mammals can be excluded.

Review comments:

As the trigger value of 5 was not met at TIER 1 for small herbivorous mammals for the application of TOSCANA TOP 75WG in grasslands for application rate 0.025 kg product/ha, higher assessment should be performed for active substance and metabolite IN-GN815.

1. Considerations on the relevance of voles in agricultural landscapes and for the environmental risk assessment

It is noted that relevance of the vole scenario is currently extensively discussed at the EU level. Nevertheless, until respective information is available in the updated EFSA birds and mammal's guidance, this species is considered relevant for grasslands and the risk has to be addressed. Taking this into account, the information presented above by the Applicant is not agreed by the zRMS.

2. PD and FIR/bw values of the diet according to Xxxxxx (1991)

Studies by Rinke[1] and Lüthi et all[2] are commonly used for purposes of the refinement of the risk at National and Zonal level.

In the study by Rinke[1] were investigates vole feeding preferences (mono versus dicot) via stomach content analysis. No exact percentages of each per animal were determined, instead, animals were categorized into 5 potential categories of dicot consumption (20% intervals). Overall, despite the fact that more monocots were available in the surrounding areas (70%), voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing >80% dicot material in stomach contents. For the chronic risk assessment, in spring and summer, the diet can be set on 25% monocots and 75% dicots.
Additionally, in Lüthi et all[2] also an extensive study on the diet of the common vole in monocot and dicot dominated fields was performed. The study is very detailed (considering that it is public literature) and a large number of samples/voles were considered.

A PD of 25% non-grass herbs and 75% grass and cereals is considered relevant for purposes of evaluation of the risk to vole in grasslands following application of Toscana Top 75 WG.

It should be noted that this approach has been already taken by the zRMS in the course of evaluation of several plant protection products at the national level. As the studies by Xxxxxx (1991) and Lüthi et al. (2010) are publicly available, there are no restrictions regarding use of their results in the risk assessment.

zRMS performed the risk assessment based on the refined diet below for the maximum safe application rate 15.00 g a.s/ha

Intended use	grassland
Active substance	Tribenuron methyl
Application rate [g a.s./ha]	1 × 15 g a.s./ha
Reprod. toxicity [mg/kg bw/d]	2
TER criterion	5

Focal species	Food category, % in diet	RUDm × DF [mg/kg food]	FIR/bw	MAFm × TWA	PT	DDDm [mg/kg bw/d]	TERlt

"herbivorous" Microtus arvalis (Common vole)	Monocotyledons 25%	54.2 × 1	1.49	1 × 0.53	1	∑=0.5	5
	Dicotyledonos 75%	28.7 × 1		1 × 0.53			

PT refinement for vole presented by the Applicant was not agreed by zRMS.

As presented above zRMS performed the risk assessment based on the refined diet for vole. However for the proposed dose 18.75 g a.s/ha the risk was not acceptable. Thus, zRMS used the maximum safe application rate 15.00 g a.s/ha in grassland. The refinement of the risk demonstrated acceptable risk for small herbivores exposed to tribenuron-methyl after application of TOSCANA TOP 75WG (at rate 15.00 g a.s/ha).

Intended use	grassland
Metabolite	metabolite IN-GN815
Application rate [g a.s./ha]	1 × 3.2 g metabolite/ha
Reprod. toxicity [mg/kg bw/d]	2
TER criterion	5

Focal species	Food category, % in diet	RUDm × DF [mg/kg food]	FIR/bw	MAFm × TWA	PT	DDDm [mg/kg bw/d]	TERlt
"herbivorous" Microtus arvalis (Common vole)	Monocotyledons 25%	54.2 × 1	1.49	1 × 0.53	1	0.03	25
	Dicotyledonos 75%	28.7 × 1		1 × 0.53		0.05	
						∑=0.08	

Refinement of the risk demonstrate acceptable risk for small herbivores exposed to IN-GN815 after application of TOSCANA TOP 75WG at the maximum intended application rate in grassland.

In conclusion, acceptable risk for the tribenuron methyl and acceptable risk for its plant metabolite was assumed based on the refined proportions of feed item in the diet (PD) with maximum safe application rate to 15 g a.s/ha.

[xxxx] (1991) "Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtus arvalis. Folia zoologica 40 (2): 143- 151" And on Lüthi, M. et all. Nutritional ecology of Microtus arvalis (Pallas, 1779) in sown wild flower fields and quasi-natural habitats. Revue suisse de Zoologie 117 (4): 811-828; December 2010

[xxxx] et all. 2010 (Nutritional ecology of Microtus arvalis (Pallas, 1779) in sown wild flower fields and quasi-natural habitats. Revue suisse de Zoologie 117 (4): 811-828; dec. 2010)

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 <500 L/kg (with a K(f)oc of 38.9 (pH <7) and 8.6 (pH >7), Tribenuron-methyl belongs to the group of less sorptive substances. Thus, the trigger of 50 cannot be exceeded.

Effective application rate (g/ha)	=	18.75		
Acute toxicity (mg/kg bw)	=	5000	quotient =	0.004
Reprod. toxicity (mg/kg bw/d)	=	2	quotient =	9.4

The ratio is below the trigger value indicating an acceptable risk and no further consideration is needed.

IN-L5296 is a metabolite which the highest content in comparison to other metabolites in water/sediment 88.9%. This metabolite also has the lowest acute toxicity (IN-L5296 LD_{50} = 394 mg/kg bw per day). That toxicity is lower than the toxicity of the active substance thus this metabolite need to be considered in the risk assessment. The other metabolites are considered covered under the risk envelope by the risk assessment conducted with that acute toxicity endpoint.

Effective application rate (g/ha)	=	18.75 x 88.9 % = 16.66 (application rate x max. obs. % of metabolite		
Acute toxicity (mg/kg bw)	=	394	quotient =	0.04
Reprod. toxicity (mg/kg bw/d)	=	8	quotient =	2.08

9.3.2.4 Effects of secondary poisoning

Tribenuron-methyl would be expected to have negligible potential to bioaccumulate in animal tissues, as indicated by a log p_{ow}< 3. Consequently, the risk of secondary poisoning for mammals arising from Tribenuron-methyl applications is also considered to be negligible and has not been considered further in this risk assessment.
The risk of secondary poisoning from the metabolites in soil and surface water was not considered as part of the EU review of the active substance and has therefore not been considered in this assessment. A low risk is concluded.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

The TER_A value calculated in the screening level risk assessment for mammals exceed the Annex VI trigger value of 10 for all evaluated scenarios. The acute risk to mammals can be considered as acceptable and without need for further consideration.

In addition, the TER_{LT} values for all evaluated scenarios are greater than the Annex VI trigger of 5, indicating TOSCANA TOP 75WG presents acceptable long-term risk to mammals in cereals. Therefore, no further consideration is required.

No unacceptable risk to mammals is expected from the use of TOSCANA TOP 75WG when it is applied according to the proposed use pattern.

Review comments:

The acute and long-term risk assessment for mammals performed by the Applicant is generally agreed by the zRMS. With the exception of first-tier assessment of the long-term risk for mammals due to the use of TOSCANA TOP 75WG in grassland. zRMS updated TIER 1 with correct indicator species.
It was performed in line with recommendations of the EFSA (2009) with assumption of EU agreed end-points. No formulation study was required.
Acceptable long-term risk was assumed for tribenuron methyl in use of cereals at the maximum application dose 18.75 g a.s/ha.

Acceptable risk assessment based on the refined diet for vole, for the proposed dose 18.75 g a.s/ha the risk was not acceptable. Thus, zRMS used the maximum safe application rate 15.00 g a.s/ha in the refinement for use in grasses.

In conclusion, aacceptable risk for the tribenuron methyl and acceptable risk for its plant metabolite was assumed based on the refined proportions of feed item in the diet (PD) with maximum safe application rate to 15g a.s/ha for use in grasses.

TOSCANA TOP 75WG presents acceptable risk resulting from exposure via drinking water. Since the log Pow value of tribenuron-methyl and its relevant soil and aquatic metabolites are all below the trigger of 3, the evaluation of the risk of secondary poisoning is not triggered.

Overall, acceptable acute and reproductive risk to mammals may be concluded for application of TOSCANA TOP 75WG in winter and spring cereals and grasses according to the intended uses.

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

Not available.

Review comments:

This issue is not assessed at the product level.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Tribenuron-methyl and its metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on aquatic organisms of TOSCANA TOP 75WG were not evaluated as part of the EU assessment of Tribenuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Fish				
Oncorhynchus mykiss Rainbow trout	Tribenuronmethyl	96h (static)	LC_{50} = 738 mg a.s./L $_{mm}$	EFSA Journal 2017;15(7):4912
Oncorhynchus mykiss Rainbow trout	IN-00581 = saccharin	96h (static)	LC_{50}>124 mg /L $_{mm}$	EFSA Journal 2017;15(7):4912
Oncorhynchus mykiss Rainbow trout	IN-A4098 = Ndemethyl triazine amine (AE F059411, CG A150829)	96h (static)	LC_{50}=200 mg /L $_{mm}$	EFSA Journal 2017;15(7):4912
Oncorhynchus mykiss Rainbow trout	IN-D5119 Acid sulfonamide	96h (static)	LC_{50}>115 mg /L $_{mm}$	EFSA Journal 2017;15(7):4912
Oncorhynchus mykiss Rainbow trout	IN-L5296 Methyl triazine amine	96h (static)	LC_{50} =172 mg /L $_{mm}$	EFSA Journal 2017;15(7):4912
Cyprinodon variegatus Sheepshead minnow	Tribenuron methyl	28d (flowthrough) Early lifestage (ELS)	NOEC =11.9 mg /L $_{mm}$	EFSA Journal 2017;15(7):4912
Aquatic invertebrates				
Daphnia magna Water flea	Tribenuronmethyl	48h (static)	EC_{50}>894 mg a.s./L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-00581 = saccharin	48h (static)	EC_{50}>118 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-A4098 = Ndemethyl triazine amine (AE F059411, CG A150829)	48h (static)	EC_{50}>99 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-D5119 Acid sulfonamide	48h (static)	EC_{50}>120 mg/ L (nom)	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-L5296 Methyl triazine amine	48h (static)	EC_{50}>1020 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	Tribenuronmethyl	21d (staticrenewal)	EC_{10}=52 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	Tribenuronmethyl	21d (staticrenewal)	Mortality, reproduction, NOEC - 41 (nom)	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-A4098 = Ndemethyl triazine amine (AE F059411, CG A150829)	21d (static)	NOEC=97 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Daphnia magna Water flea	IN-L5296 Methyl triazine amine	21d (static)	NOEC=49 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Algae				
Pseudokirchneriella subcapitata Green algae	Tribenuronmethyl	72h (static)	ErC_{50}=0.068 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata Green algae	IN-00581 = saccharin	72h (static)	ErC_{50}>10 mg/ L (nom)	EFSA Journal 2017;15(7):4912
Scenedesmus subspicatus Green algae	IN-A4098 = Ndemethyl triazine amine (AE F059411, CG A150829)	72h (static)	EbC_{50}>90 mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-R9805 Odemethyl triazine amine	72h (static)	ErC_{50}=142mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-GN815	72h (static)	ErC_{50}>120mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-GK521	72h (static)	ErC_{50}=12.9mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-D5803 Sulfonamide, methylsaccharin	72h (static)	ErC_{50}>19.7mg/ L (geometric mean of measured initial and measured at highest test concentration after 72h)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	M2 Triazine urea	72h (static)	ErC_{50}>100mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-D5119 Acid sulfonamide	72h (static)	ErC_{50}>10mg/ L (nom)	EFSA Journal 2017;15(7):4912
Pseudokirchneriella subcapitata Green algae	IN-L5296 Methyl triazine amine	72h (static)	ErC_{50}>10mg/ L (nom)	EFSA Journal 2017;15(7):4912
Anabaena flosaquae Cyanobacteria	Tribenuronmethyl	72h (static)	ErC_{50}>100mg/ L (nom)	EFSA Journal 2017;15(7):4912
Higher plants				
Lemna gibba Duck weed	Tribenuronmethyl	7d (static)	ErC_{50}= 0.0047mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	Tribenuronmethyl	16d low temperature (12°C), (static)	ErC_{50}= 0.0062mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-00581 = saccharin	7d (static)	$ErCr_{50}$>11 mg/ L $_{mm}$	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-A4098 = Ndemethyl triazine amine (AE F059411, CG A150829)	7d (static)	ErC_{50}>100mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-D5119 Acid sulfonamide	7d (static)	ErC_{50}>11mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-L5296 Methyl triazine amine	14d (static)	ErC_{50}>10mg/ L (nom)	EFSA Journal 2017;15(7):4912

Species	Substance	Exposure System	Results	Reference
Lemna gibba Duck weed	IN-R9805 Odemethyl triazine amine	7d (static)	ErC_{50}>100mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-GN815	7d (static)	ErC_{50}>120mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-GK521	7d (static)	ErC_{50}=0.29mg/ L (nom)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	IN-D5803 Sulfonamide, methylsaccharin	7d (static)	ErC_{20}=10mg/ L (nominal degradation product saccharine)	EFSA Journal 2017;15(7):4912
Lemna gibba Duck weed	M2 Triazine urea	7d (static)	ErC_{50}>100mg/ L (nom)	EFSA Journal 2017;15(7):4912

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

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – TOSCANA TOP 75WG

Species	Substance	Exposure System	Results	Reference
Daphnia magna	TOSCANA TOP 75WG	48 h, s	LC_{50} > 135.5 mg formulation/L $_{nom}$ (>100.04 mg as/L)	E. Xxxxxx 2017, W/265/17
Pseudokirchneriella subcapitata	TOSCANA TOP 75WG	72 h, s	E_rC_{50} = 0.230 mg formulation/L $_{nom}$ (0.17 mg as/L) E_yC_{50} = 0.020 mg formulation/L $_{nom}$	E. Xxxxxx 2018, W/266/17
Naviculla pelliculosa	TOSCANA TOP 75WG	72 h, s	E_rC_{50} = 144.42 mg formulation/L $_{nom}$ (106.63 mg as/L) E_yC_{50} = 29.44 mg formulation/L $_{nom}$ (21.74 mg as/L)	E. Xxxxxx 2018, W/267/17
Lemna gibba	TOSCANA TOP 75WG	7d, ss	E_rC_{50} = 0.031 mg formulation/L $_{nom}$ ErC_{50} =0.018 mg as/L based on the geometric means of determined concentrations of tribenuron methyl E_yC_{50} = 0.0085 mg formulation/L $_{nom}$ EyC_{50}=0.0051 mg as/L based on the geometric means of determined concentrations of tribenuron methyl Endpoints based on the frond number	E. Xxxxxx 2018, W/268/17

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

Review comments:

In the study on toxicity of the formulation TOSCANA TOP 75WG on on *Lemna gibba* the analytical measurements demonstrated that the test item concentrations throughout the test were outside the recommended range 80-120% of nominal. For this reason, endpoints are expressed as mean measured concentrations of tribenuron methyl. The study is reliable and suitable for the risk assessment with following endpoints:
ErC_{50}= 0.018 mg a.s/L (mm)
EyC_{50}= 0.051 mg a.s/L (mm)

For risk assessment purposes toxicity endpoint from the formulation TOSCANA TOP 75WG studies are expressed as active substance based on assumption that formulation contains 75% w/w tribenuron-methyl.

9.5.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints

9.5.2 Risk assessment

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

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

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Tribenuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOSCANA TOP 75WG in and winter cereals (pH<7, pH>7) – spring application, 18.75 g as/ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**		**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Cyprinodon variagatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchinella subcapitata***	***Anabaena flosaque***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	E_rC_{50}	ErC_{50}
(µg/L)		738000	11900	>894000	41000 ~~52000~~	68	>100000	4.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		7380	1190	8940	4100 ~~5200~~	6.8	10000	0.47
FOCUS Scenario	PEC_{gl-max} (µg/L) pH <7/pH >7							
Step 1								
	6.11/6.35	0.00/0.00	0.01/0.001	0.00/0.00	0.00/0.00	0.90/0.93	0.00/0.00	**13 / 13.5**
Step 2								
N-Europe	0.85/1.19	-	-	-	-	-	-	**1.81 / 2.53**
Step 3								
winter cereals, spring application (18.75 g as/ha)								
D3/ditch	0.1187 / 0.1374	-	-	-	-	-	-	0.25 / 0.29
D4/pond	0.004107 / 0.03550	-	-	-	-	-	-	0.009 / 0.08
D4/stream	0.09913 / 0.1117	-	-	-	-	-	-	0.21 / 0.24

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Aquatic plants
D5/pond	0.004102 / 0.007685	-	-	-	-	-	-	0.009 / 0.016
D5/stream	0.09484 / 0.09692	-	-	-	-	-	-	0.20 / 0.21
R1/pond	0.004100 / 0.004100	-	-	-	-	-	-	0.009 / 0.009
R1/stream	0.1888 / 0.2928	-	-	-	-	-	-	0.41 / 0.62
R3/stream	0.1205 / 0.1408	-	-	-	-	-	-	0.26 / 0.30
R4/stream	0.5895 / 0.9560	-	-	-	-	-	-	**1.25 / 2.03**

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

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Tribenuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOSCANA TOP 75WG in and spring cereals (pH<7, pH>7) – spring application, 15 g a/ha

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Cyprinodon variagatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchinella subcapitata***	***Anabaena flosaque***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	E_rC_{50}	ErC_{50}
(µg/L)		738000	11900	>894000	41000 ~~52000~~	68	>100000	4.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		7380	1190	8940	4100 ~~5200~~	6.8	10000	0.47

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**		**Aquatic plants**
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L) pH <7/ pH >7							
Step 1								
	4.89 / 5.08	0.00 / 0.00	0.00 / 0.00	0.00 / 0.00	0.00 /	0.72 / 0.75	0.00 / 0.00	**10.40 / 10.81**
Step 2								
N-Europe	0. 68 / 0.96	-	-	-	-	-	-	**1.45 / 2.04**
Step 3								
spring cereals, spring application (15 g as/ha)								
D3/ditch	0.0951 / 0.1145	-	-	-	-	-	-	0.20 / 0.24
D4/pond	0.003287 / 0.02886	-	-	-	-	-	-	0.01 / 0.06
D4/stream	0.07778 /0.08899	-	-	-	-	-	-	0.17 / 0.19
D5/pond	0.003297 / 0.005828	-	-	-	-	-	-	0.01 / 0.01
D5/stream	0.08299 / 0.08454	-	-	-	-	-	-	0.18 / 0.18
R4/stream	0.4781 /0.7697	-	-	-	-	-	-	**1.02 / 1.64**

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Tribenuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOSCANA TOP 75WG in and winter cereals (pH<7, pH>7) –autumn application 15 g a.s/ha

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**		**Aquatic plants**
Test species		***Oncorhynchus mykiss***	***Cyprinodon variagatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchinella subcapitata***	***Anabaena flosaque***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	E_rC_{50}	ErC_{50}
(µg/L)		738000	11900	>894000	41000 ~~52000~~	68	>100000	4.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		7380	1190	8940	4100 ~~5200~~	6.8	10000	0.47
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L) pH <7/ pH >7							
Step 1								
	4.89 / 5.08	0.00 / 0.00	0.00 / 0.00	0.00 / 0.00	0.00 /	0.72 / 0.75	0.00 / 0.00	**10.40 / 10.81**
Step 2								
N-Europe	1.52 / 2.21	-	-	-	-	-	-	**3.23 / 4.7**
Step 3								
winter cereals, autumn application (15 g as/ha)								
D3/ditch	0.09475 / 0.1621	-	-	-	-	-	-	0.20 / 0.34
D4/pond	0.02370 / 0.3806	-	-	-	-	-	-	0.05 / 0.81
D4/stream	0.08223 / 0.3119	-	-	-	-	-	-	0.17 / 0.66
D5/pond	0.03949 / 0.3940	-	-	-	-	-	-	0.08 / 0.84
D5/stream	0.08871 / 0.2668	-	-	-	-	-	-	0.19 / 0.57
R1/pond	0.003280/0.003280	-	-	-	-	-	-	0.01 / 0.01

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Aquatic plants
R1/stream	0.09029 / 0.09197	-	-	-	-	-	-	0.19 / 0.20
R3/stream	0.9270 / 1.181	-	-	-	-	-	-	**1.97 / 2.51**
R4/stream	0.2127 / 0.1606	-	-	-	-	-	-	0.45 / 0.34

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 Tribenuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of TOSCANA TOP 75WG in grassland (pH<7, pH>7) – spring application, 18.75 g a. s./ha

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Aquatic plants
Test species		***Oncorhynchus mykiss***	***Cyprinodon variagatus***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchinella subcapitata***	***Anabaena flosaque***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	E_rC_{50}	ErC_{50}
(µg/L)		738000	11900	>894000	41000 ~~52000~~	68	>100000	4.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		7380	1190	8940	4100 ~~5200~~	6.8	10000	0.47
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L) pH <7/pH >7							
Step 1								
	6.1143/6.3516	0.00 / 0.00	0.00 / 0.00	0.00 / 0.00	0.00 /	0.90 / 0.93	0.00 / 0.00	**13.009 / 13.51**
Step 2								
N-Europe	0.4280/0.5658	-	-	-	-	-	-	0.91 / **1.2**
Step 3								
grass, spring application (18.75 g as/ha)								

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Aquatic plants
D3/ditch	0.1190/0.1347	-	-	-	-	-	-	0.25 / 0.29
D4/pond	0.0041/0.0064	-	-	-	-	-	-	0.01 / 0.01
D4/stream	0.0909/0.0947	-	-	-	-	-	-	0.19 / 0.20

Table 9.5-7: The risk assessment for aquatic species (most sensitive species of each group) for Tribenuron-methyl metabolites (winter and spring cereals – dose of 15 g as/L).

Use pattern	Organism	Test substance	Toxicity endpoint mg/L	FOCUS Step 1 PEC_{sw} µg/L	RAC	PEC/RAC	PEC/RAC <1
Crop: Winter	Fish *Oncorhynchus mykiss*	IN-00581	96 h LC50 >124	1.69	1240	0.0014	YES
		IN-A4098	96 h LC50 = 0.93	0.21	9.3	0.023	
		IN - D5119	96 h LC50 >115	0.84	1150	0.0007	
		IN-L5296	96 h LC50 = 172	3.11	1720	0.0018	
	Invertebrate *Daphnia magna*	IN-0581	48 h EC_{50} >118	1.69	1180	0.0014	YES
		IN-A4098	48 h EC_{50} >99	0.21	990	0.0002	
		IN-D5119	48 h EC_{50} >120	0.84	1200	0.0007	
		IN-L5296	48 h EC_{50} >1020	3.11	10200	0.0003	
	Algae *Pseudokirchneriella subcapitata*	IN-00581	72 h E_rC_{50} >10	1.69	1000	0.0017	YES
		IN-A4098	72 h E_bC_{50} >90	0.21	9000	0.000022	
		IN-R9805	72 h E_rC_{50} = 142	0.35	14200	0.000025	
		IN-GN815	72 h E_rC_{50} >120	0.92	12000	0.000077	
		IN-GK521	72 h E_rC_{50} = 12.9	1.51	1290	0.001	
		IN-D5803	72 h E_rC_{50} >19.7	1.24	1970	0.00063	
		M2	72 h E_rC_{50} >100	0.37	10000	0.00004	
		IN-D5119	72 h E_rC_{50} >10	0.84	1000	0.0008	
		IN-L5296	72 h E_rC_{50} >10	3.11	1000	0.003	
	Aquatic plants *Lemna sp.*	IN-00581	7 d E_rC_{50} > 11	1.69	1100	0.0015	YES
		IN-A4098	7 d E_rC_{50} > 100	0.21	10000	0.00002	
		IN-R9805	7 d E_rC_{50} > 100	0.35	10000	0.000035	
		IN-GN815	7 d E_rC_{50} > 120	0.92	12000	0.00008	

		IN-GK521	7 d E_rC_{50} = 0.29	1.51	29	0.052	
		IN-D5803	7 d E_rC_{20} =10	1.24	1000	0.0012	
		M2	7 d E_rC_{50} > 100	0.37	10000	0.00004	
		IN-D5119	7 d E_rC_{50} > 11	0.84	1100	0.0008	
		IN-L5296	7 d E_rC_{50} > 10	3.11	1000	0.003	

Table 9.5-8: The risk assessment for aquatic species (most sensitive species of each group) for Tribenuron-methyl metabolites (winter cereals – dose of 18.75 g as/L).

Use pattern	Organism	Test sub-stance	Toxicity endpoint mg/L	FOCUS Step 1 PEC_{sw} µg/L	RAC	PEC/RAC	PEC/RAC <1
Crop: Winter cereals	Fish (acute) *Oncorhynchus mykiss*	IN-00581	96 h LC50 >124	2.1	1240	0.002	YES
		IN-A4098	96 h LC50 >200 ~~96 h LC50 = 0.93~~	0.26	2000 ~~9.3~~	0.00013 ~~0.03~~	
		IN - D5119	96 h LC50 >115	1.06	1150	0.001	
		IN-L5296	96 h LC50 = 172	3.89	1720	0.0023	
	Invertebrate (acute) *Daphnia magna*	IN-00581	48 h EC_{50} >118	2.1	1180	0.002	YES
		IN-A4098	48 h EC_{50} >99	0.26	990	0.0003	
		IN-D5119	48 h EC_{50} >120	1.06	1200	0.001	
		IN-L5296	48 h EC_{50}= 115 ~~48 h EC_{50} >1020~~	3.89	10200	0.0004	
	Algae *Pseudokirchneriella subcapitata*	IN-00581	72 h E_rC_{50} >10	2.1	1000	0.0021	YES
		IN-A4098	72 h E_bC_{50} >90	0.26	9000	0.00003	
		IN-R9805	72 h E_rC_{50} = 100 ~~142~~	0.44	10000 ~~14200~~	0.000044 ~~0.00003~~	
		IN-GN815	72 h E_rC_{50} >100 ~~120~~	1.15	10000 ~~12000~~	0.0001	
		IN-GK521	72 h E_rC_{50} = 12.9	1.89	1290	0.002	
		IN-D5803	72 h E_rC_{50} >19.7	1.53	1970	0.00078	
		M2	72 h E_rC_{50} >100	0.46	10000	0.0001	
		IN-D5119	72 h E_rC_{50} >10	1.06	1000	0.0001	
		IN-L5296	72 h E_rC_{50} >10	3.89	1000	0.004	
	Aquatic plants *Lemna sp.*	IN-00581	7 d E_rC_{50} > 11	2.1	1100	0.002	YES
		IN-A4098	7 d E_rC_{50} > 100	0.26	10000	0.00003	
		IN-R9805	7 d E_rC_{50} > 100	0.44	10000	0.00004	
		IN-GN815	7 d E_rC_{50} > 100 ~~120~~	1.15	10000 ~~12000~~	0.0001	
		IN-GK521	7 d E_rC_{50} = 0.29	1.89	29	0.066	
		IN-D5803	7 d E_rC_{20} =10	1.53	1000	0.002	

		M2	7 d E_rC_{50} > 100	0.46	10000	0.0001	
		IN-D5119	7 d E_rC_{50} > 11	1.06	1100	0.001	
		IN-L5296	7 d E_rC_{50} > 10	3.89	1000	0.004	

For the intended uses cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for aquatic plants as characterised by ErC50 for *Lemna gibba* of 0.47 µg a.s./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. The calculated PEC/RAC ratios indicate the risk for trubenuron methyl of pH>7 covers the risk of tribenuron methyl of pH < 7.

At Step 4 run off mitigation of the pesticide was calculated for 1 and 3 m via vegetated filter strip efficiency using the VFSmod model. Additionally, the run off mitigation was considered with a vegetative buffer of 10-12 m and 18-20 m. To see more details please refer to Section 8 (Environmental Fate), Chapter 8.9.2.2.

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for tribenuron-methyl based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of TOSCANA TOP 75 WG in winter and spring cereals (spring application) and winter cereals (autumn application).

Intended use **Active substance** **Application rate (g/ha)**		Spring/Winter cereals Tribenuron methyl pH >7 1 × 15 (spring cereals/spring application and winter cereals/autumn application) 1 x 18.75 (winter cereals / spring application)			
Nozzle reduction	**No-spray buffer (m)**	**1**	**3**	**10**	**20**
	Vegetated filter strip (m) – VFSmod	**1**	**3**	**-**	**-**
	Vegetative buffer (m)	**-**	**-**	**10 - 12**	**18 - 20**
None	spring cereals, spring application, 15 g as/ha				
None	**R4/stream**	0.2212	0.03589	0.3474	0.1814
None	winter cereals, spring application, 18.75 g as/ha				
None	**R4/stream**	0.2769	0.04474	0.4316	0.2253
None	winter cereals, autumn application, 15 g as/ha				
None	**R3/stream**	0.4886	0.3831	0.5312	0.2774
RAC (µg/L) **0.47**		**PEC/RAC ratio**			
None	spring cereals, spring application 15 g as/ha				
None	**R4/stream**	0.47	-	-	-
None	winter cereals, spring application, 18.75 g as/ha				
None	**R4/stream**	0.47	-	-	-
None	winter cereals, autumn application, 15 g as/ha				

	R3/stream	**1.04**	0.82	**1.13**	0.59

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

Risk assessment for formulation to aquatic organisms

In addition, in order to assess the risk of the formulation according to the endpoints derived with the formulation studies, the formulation endpoint to the most sensitive organism (*Lemna gibba)* was considered. For this assessment the ratio between predicted environmental concentrations in surface water bodies for the formulation (PEC_{SW} formulation) and the regulatory acceptable concentration (RAC= 3.1 µg formulation./L) for aquatic organisms, was calculated.

The PEC values of the formulation TOSCANA TOP 75 WG in surface water have been assessed with the FOCUS SWASH model. The PEC_{SW} were calculated for single application and for the highest application rate recommended for use in winter cereals and spring cereals (for details please refer to Section 8).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for TOSCANA TOP 75 WG for each organism group based on Drift Calculator SWASH MODEL ver 5.3 calculations for the use of TOSCANA TOP 75 WG in cereals

Intended use **Formulation** **Application rate (g[prod]/ha)**	Cereals TOSCANA TOP 75 WG 1 x 25 g	
RAC	ErC50 =0.031 mg formulation/L for *Lemna gibba* AF=10 RAC=3.1 µg formulation./L	
winter cereals 1 x 25 g product/ha, spring spraying, ditch -worst case		
PECsw (µg prod/L)	Buffer zone 1 m	0.1606
PEC/RAC	Buffer zone 1 m	0.05
spring cereals 1 x 20 g product/ha, spring spraying winter cereals 1 x 20 g product/ha, autumn spraying, ditch worst-case		
PECsw (µg prod/L)	Buffer zone 1 m	0.1285
PEC/RAC	Buffer zone 1 m	0.04

*The lowest toxicity endpoint from the formulation TOSCANA TOP 75WG studies

Review comments:

To take to consideration exposure of aquatic organisms to the formulation by spray drift, zRMS performed appropriate calculations presented it in tables above. The drift exposure was assessed by Fate and Behaviour Evaluator (Section 8) using the Drift Calculator in SWASH model. All the ratios PEC/RAC were below 1 for all aquatic organisms.
In addition, zRMS performed calculation for the lowest endpoint (expressed as a.s.) from the available formulation studies and worst-case PEC value from Step 2.
Thus, for the formulated product, no potential risks are identified for aquatic organisms following application of TOSCANA TOP 75WG to winter and spring cereals and grasses. An acceptable risk was concluded without the need for mitigation.

9.5.3 Overall conclusions

Based on PEC/RAC calculations performed in all scenarios, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for TOSCANA TOP 75 WG provided that following risk mitigation measures are taken into account:

- a vegetative buffer strip of 20 m to surface water bodies is required.

According to "Working Document of the Central Zone in the Authorization of Plant Protection Products - Part B section 8 - Environmental fate and behavior, Version 1 rev. 1 – June 2018" it should be checked with individual MS wheather VFSmod approach is acceptable or not. Therefore, a vegetative filter strip of 3 m (VFSmod) should be also considered if required.

However, for Poland the relevant scenarios are D3, D4 and R1. Thus, no unacceptable risk is indicated following the TOSCANA TOP 75 WG application. None mitigation measures are required.

Review Comments:

The evaluation of the risk for aquatic was performed in accordance with Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009(EFSA Journal 2013;11(7):3290).

For the active substance tribenuron-methyl calculated PEC/RAC ratios for winter and spring cereals and spring grasslands did indicate an acceptable risk in almost all FOCUS Steps 1-3 scenarios with the exception of Scenario: R3stream and R4stream

To refine the risk to aquatic organisms for scenario R3stream and R4stream appropriate risk mitigation measures are required:

- a vegetative buffer strip of 20 m to surface water bodies is required.

The run-off reduction was considered with a vegetative buffer strip of 10 m and 20 m according to SWAN model. with RAC = 0.47 µg a.s/L

SWAN model

Crop	Application rate g a.s./ha	Tribenuron-methyl pH < 7	Tribenuron-methyl pH > 7
Winter cereals spring application	18.75	0.2661 (R4 stream) 10 m VBS* + 10 m NSS	0.4316 (R4 stream) 10 m VBS* + 10 m NSS
Winter cereals autumn application	15.00	0.4170 (R3 stream) 10 m VBS* + 10 m NSS	0.2774 (R3 stream) 20 m VBS* + 20 m NSS
Spring cereals	15.00	0.2158 (R4 stream) 10 m VBS* + 10 m NSS	0.3474 (R4 stream) 10 m VBS* + 10 m NSS

*** vegetated buffer strip**

Additionally, the run-off reduction was considered with 1 and 3 m buffer using VFS mode:

VFSmod

Crop	Application rate g a.s./ha	Tribenuron-methyl pH < 7	Tribenuron-methyl pH > 7
Winter cereals spring application	18.75	0.1451 (R4 stream) 1 m VFS + 1 m NSS	0.2769 (R4 stream) 1 m VFS + 1 m NSS
Winter cereals autumn application	15.00	0.3439 (R3 stream) 1 m VFS + 1 m NSS	0.3831 (R3 stream) 3 m VFS + 3 m NSS
Spring cereals	15.00	0.1165 (R4 stream) 1 m VFS + 1 m NSS	0.2212 (R4 stream) 1 m VFS + 1 m NSS

For all tribenuron-methyl metabolites, calculated PEC/RAC ratios for winter and spring cereals and grasses indicate an acceptable risk already at FOCUS Steps 1.

For the formulated product, no potential risks are identified for aquatic organisms following application of TOSCANA TOP 75 WG to winter and spring cereals and grasslands.

Based on the results of the higher tier risk assessment (FOCUS Step 4 values in combination with lowest toxicity endpoint for *Lemna gibba* following buffer zones with vegetative strips according are required as follows:

Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Winter cereals spring application at rate 15 g a.s./ha, pH < 7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Winter cereals spring application at rate 15 g a.s./ha, pH > 7
- 20 m vegetative strips with 20 m non- sprayed buffer zone to surface water bodies

Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7
- 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies

Grasses – spring application, 18.75 g a. s./ha
- no mitigation measures required

For TOSCANA TOP 75 WG – use in cereals, following risk mitigation measures should be applied taking to consideration VFSmode:

Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Winter cereals autumn application at rate 15 g a.s./ha, pH < 7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Winter cereals autumn application at rate 15 g a.s./ha, pH > 7
- 3 m vegetative strips with 3 m non- sprayed buffer zone to surface water bodies

Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7
- 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

Grasses – spring application, 18.75 g a. s./ha
- no mitigation measures required

For scenarios relevant for Poland: D3, D4, R1 no mitigation measures are required.

Concerned Member States must decide on the consideration of risk mitigation measures

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

Effects on bees of TOSCANA TOP 75WG were not evaluated as part of the EU assessment of tribenuron methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results		Reference
Apis mellifera	Tribenuron methyl technical	Oral	LD_{50} >9.1µg a.s./bee		EFSA Journal 2017;15(7):4912
		Contact	LD_{50} >98.4µg a.s./bee		
Apis mellifera	Tribenuron methyl 75WG	Contact	LD_{50}>100 µg a.s./bee		EFSA Journal 2017;15(7):4912
		Oral	LD_{50} >186 µg a.s./bee		
Apis mellifera	Tribenuron methyl 50SG	Contact	LD_{50}>100 µg a.s./bee		EFSA Journal 2017;15(7):4912
		Oral	LD_{50} >77.1 µg a.s./bee		
Apis mellifera	Tribenuron methyl 50SG + DPX-KG691 surfactant	Contact	LD_{50}>200 µg a.s./bee		EFSA Journal 2017;15(7):4912
		Oral	LD_{50} =33.7 µg a.s./bee		
Apis mellifera	Tribenuron methyl 750 g/kg WG	Contact	LD_{50}>100 µg a.s./bee		EFSA Journal 2017;15(7):4912
		Oral	LD_{50} >108.8 µg a.s./bee		
Apis mellifera	Tribenuron-methyl technical	10 days Chronic	Oral LD_{50} > 74.3 µg a.s./bee/day Oral $NOEL_{mortality}$=74.3 µg a.s./bee/day		EFSA Journal 2017;15(7):4912
Apis mellifera	Tribenuron-methyl 75 WG	10 days Chronic	Oral LD_{50} > 147.5 µg a.s./bee/day Oral $NOEL_{hpg}$ =147.5 µg a.s./bee/day Oral $NOEL_{mortality}$=124.7 µg a.s./bee/day		EFSA Journal 2017;15(7):4912
Apis mellifera	TOSCANA TOP 75 WG (Formulation Tribenuron methyl 75 WG)	Oral	LD_{50} >200 µg/bee (>147.7 µg a.s./bee)		E.Xxxxxx B/05/17, 2017
Apis mellifera	TOSCANA TOP 75 WG (Formulation Tribenuron methyl 75 WG)	Contact	LD_{50} >200 µg/bee (>147.7 µg a.s./bee)		E.Xxxxxx B/06/17, 2017
Apis mellifera	PP-108 H (Formulation Tribenuron	10 days Chronic	LDD_{50}	> 26.20 µg product/bee/day	T. Xxxxxx, STUDY TRC15-250BA,
				> 19.81 µg a.s./bee/day	

Species	Substance	Exposure System	Results		Reference
	methyl 75 WG)		NOEDD	> 26.20 µg product /bee/day	2017
				> 19.81 µg a.s./bee/day	
Apis mellifera (honey bee larvae)	PP-108 H (Formulation Tribenuron methyl 75 WG)	120 h single ~~Repeated~~ exposure	LD_{50}(120hr)	235.53 µg product/larvae/developmental period D3 to D8	T. Xxxxxx, STUDY TRC15-249BA, 2017
				176.06 µg a.i./larvae/developmental period D3 to D8	
			NOED	155.91 µg product/ /larva/developmental period D3 to D8	
				117.87 µg a.i./ larva/developmental period D3 to D8)	
Higher-tier studies (tunnel test, field studies)					
Not available					

9.6.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.6.2 Risk assessment

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

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 TOSCANA TOP 75 WG in cereals and also in minor uses mentioned in the GAP table

Intended use	Cereals		
Active substance	Tribenuron-methyl		
Application rate (g a.s/ha)	1× 18.75		
Test design	**LD_{50} (lab.) (µg a.s/bee)**	**Single application rate (g a.s/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	9.1	18.75	2.06
Contact toxicity	98.4		0.19
Product	TOSCANA TOP 75WG		
Application rate (g product/ha)	1 × 25		

Test design	**LD_{50} (lab.) (µg product/bee)**	**Single application rate (g product/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	200	25	0.125
Contact toxicity	200		0.125

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

The risk assessment for bees presented in this draft registration report includes also exposure resulting from the use of TOSCANA TOP 75 WG in protection of the requested minor crops (the maximum single application rate for all of requested crops is the same as in group of cereals presented in the GAP).

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

Not relevant.

Review Comments:

Since acceptable acute risk have been concluded for bees exposed to TOSCANA TOP 75WG at the Tier 1 level, a higher-tier risk assessment is not required for the proposed uses of TOSCANA TOP 75WG.

9.6.3 Effects on bumble bees

No data/information available

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

9.6.4 Effects on solitary bees

No data/information available

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

9.6.5 Overall conclusions

The oral median lethal dose (48-hour LD_{50}) in the honeybee, *Apis mellifera* is greater than 200 µg /bee. The contact median lethal dose (48-hour LD_{50}) in the honeybee is also greater than 200 µg /bee.

All calculated hazard quotients are considerably less than trigger values, indicating that the active substances pose a low risk to bees. Therefore, a low risk to bees is expected from the application of TOSCANA TOP 75 WG according to the proposed GAP.

Review Comments:

The evaluation has been performed in line with SANCO/10329/2002 rev 2 final.
The risk assessment performed for active substance tribenuron-methyl and the formulated product is agreed by the zRMS.
Risk assessments are based on the maximum single application rate of 1 x 0.025 kg product/ha (corresponding to 18,75 g a.s/ha kg a.s./ha) in cereals. All calculated hazard quotients are lower than 50, indicating that the acute oral and contact risk to bees is acceptable following the use according to the proposed use pattern of TOSCANA TOP 75WG.

The Applicant provided chronic test on bees and evaluation of effects on honey bee development with formulated product. The chronic studies for TOSCANA TOP 75WG were evaluated and accepted by zRMS but not taken to consideration in risk assessment since the evaluation was done according to SANCO/10329/2002 rev 2 final.

Concerned Member States must decide on the consideration of data requirements on national level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Tribenuron methyl. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of TOSCANA TOP 75 WG were not evaluated as part of the EU assessment of Tribenuron methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	TOSCANA TOP 75 WG	Laboratory test glass plates (2D)	LR_{50} = 25 g/ product ha (>18.5 g a.s/ha) ER_{50} = 25g product /ha (>18.5 g a.s/ha)	E.Xxxxxx, B/08/17, 2017
Aphidius rhopalosiphi (adults)	TOSCANA TOP 75 WG	Laboratory test glass plates (2D)	LR_{50} = 25 g product /ha (>18.5 g a.s/ha) ER_{50} = 25g product /ha (>18.5 g a.s/ha)	E.Xxxxxx, B/07/17, 2018

9.7.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-2: First- ~~and higher~~ tier assessment of the in-field risk for non-target arthropods due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Cereals		
Active substance/product	Tribenuron-methyl/ TOSCANA TOP 75 WG		
Application rate (g a.s/ha)	1× 18.75		
MAF	1		
Test species Tier I	**LR_{50} (lab.) (g a.s/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>18.5	18.75	< 1.01
Aphidius rhopalosiphi	>18.5		< 1.01

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

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- ~~and higher~~ tier assessment of the off-field risk for non-target arthropods due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Cereals				
Active substance/product	Tribenuron-methyl/ TOSCANA TOP 75 WG				
Application rate (g a.s/ha)	1× 18.75				
MAF	1				
vdf	10 (Tier 1) ~~5~~ [a)]				
Test species Tier I	**LR_{50} (lab.) (g a.s/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>18.5	0.0277	0.052 ~~0.10~~	10	< 0.028 ~~0.05~~
Aphidius rhopalosiphi	>18.5				< 0.028 ~~0.05~~

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

~~a) In accordance with EFSA (2019). Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673.~~

The risk assessment for minor crops presented in the GAP is covered by a risk assessment performed for the product TOSCANA TOP 75 WG. The growth stage of presented minor uses, number~~s~~ of ~~and intervals between~~ applications and doses are the same as the main intended uses in cereals.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

For *A. rhopalosiphi* and *T. pyri* the corresponding 'in-field' and "off-field" hazard quotients are below the trigger value of 2 indicating an acceptable 'in-field' and "off-field" risk to non-target arthropods, following application of TOSCANA TOP 75 WG according to the proposed GAP.

Review Comments:

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

For the zonal evaluations in the Risk assessment for off-field exposure default factor VDF of 10 was used by zRMS. VDF of 5 should be considered at for National authorisations.

The HQ for recommended species: *Typhlodromus pyri* and *Aphidius rhopalosiphi* is below the ESCORT 2 trigger value of 2, indicating acceptable in-field and off-field risk to non-target arthropods already at tier I level. All calculated HQ values based on a single maximum application rate of 18.75 g also covering lower dose 15 g a.s/ha of TOSCANA TOP 75 WG to cereals and minor crops according to the GAP.

On this basis acceptable risk for in-field and off-field habitats may be concluded with no need for risk mitigation measures.

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

9.8.1 Toxicity data

Studies on the toxicity to earthworms ~~and other non-target soil organisms (meso- and macrofauna)~~ have been carried out with Tribenuron methyl and its 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 TOSCANA TOP 75 WG were not evaluated as part of the EU assessment of Tribenuron methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	End point	Results	Reference
Earthworms					
TOSCANA TOP 75 WG					
Eisenia andrei	TRIBENURON METYL 75 WG	Test item incorporated into the soil / 10% peat Chronic, 56 days	EC_{10} NOEC	104.7 mg/kg dry soil Which corresponds to 77.3 mg a.s/kg dry weight soil 180 ~~100~~ mg formulation/kg dry soil Which corresponds to 132.9 mg a.s/kg dry weight soil	Anna Xxxxxx, 2018, Study code G/154/17
	Tribenuron-methyl, relevant degradation products and related formulated products from EU review				
Eisenia fetida	Tribenuron-methyl technical	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	**3.2 mg a.s./kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	Tribenuron methyl 50SG + DPX-KG691 surfactant	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC EC_{10} repro	61.75 mg a.s./kg dry soil 70.5 mg a.s./kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-00581 (saccharin)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	0.05 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-00581 (saccharin)	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	**100 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-00581 (saccharin)	This metabolite was also evaluated for metsulfuron-methyl, ethametsulfuron-methyl and propoxycarbazone-sodium (EFSA, 2014a, 2015a, 2016b). The lowest reported NOECs were lower than 100 mg/kg dry soil, it is noted that this endpoints were set at the highest concentration tested. There was only a NOEC = 0.04 mg/kg dry soil not set at the highest concentration tested, however, concerns were raised during the peer review on this endpoint and it was not used in the risk assessment.			EFSA Journal 2017;15(7):4912

Species	Substance	Exposure System	End point	Results	Reference
Eisenia fetida	IN-A4098 (N-demethyl-triazine amine)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	0.2 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-A4098 (N-demethyl-triazine amine)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	**8.0 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-A4098 (N-demethyl-triazine amine)	This metabolite was also evaluated for chlorsulfuron, iodosulfuron-methyl-sodium, thifensulfuron-methyl, metsulfuron-methyl, prosulfuron and triasulfuron (EFSA, 2008; 2014b; 2015a,b,c; 2016a). The lowest reported NOECs were 0.2 and 0.202 mg/lg dry soil The use of these endpoints in the risk assessment would not change the outcome, therefore, the risk assessment was not updated.			EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-D5119 (acid sulfonamide)***	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	1000 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-D5119 (acid sulfonamide)***	This metabolite was also evaluated for ethametsulfuron-methyl (EFSA, 2014a). The reported NOEC was 1000 mg/kg dry soil.			EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-D5803 (sulfonamide) ***	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	**100 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-D5803 (sulfonamide) ***	This metabolite was also evaluated for metsulfuron-methyl and ethametsulfuron-methyl (EFSA, 2014a, 2015a). The lowest reported NOEC was 100 mg/kg dry soil.			EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-GK521 (O-demethyl-tribenuron methyl)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	**100 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-GK521 (O-demethyl-tribenuron methyl)	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	1.52 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-GN815 (O-demethyl-tribenuron free	Test item incorpo-rated into the soil /	NOEC [a]	100 mg/kg dry soil	EFSA Journal 2017;15(7):4912

Species	Substance	Exposure System	End point	Results	Reference
	acid) ***	10% peat Chronic, 56 days			
Eisenia fetida	IN-GN815 (O-demethyl-tribenuron free acid) ***	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	3.2 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-L5296 (triazine amine)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	**0.2 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-R9803 (tribenuron free acid) ***	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	**6.0 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-R9805 (O-demethyl-triazine amine)	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	100 mg/kg dry soil	EFSA Journal 2017;15(7):4912
Eisenia fetida	IN-R9805 (O-demethyl-triazine amine)	Test item incorpo-rated into the soil / 10% peat Chronic, 56 days	NOEC [a]	**1000 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Eisenia fetida	M2 (triazine urea)	Test item incorpo-rated into the soil / 5% peat Chronic, 56 days	NOEC [a]	**5.0 mg/kg dry soil**	EFSA Journal 2017;15(7):4912
Other soil macroorganisms					
Not relevant					
Field studies					
Not relevant					
Litter bag test					
Not relevant					

* In the study from Schöbinger 2013, a 26% increase in reproduction was observed. It is uncertain whether such effect could be considered as adverse at population level. In addition it is noted that the standard deviation in the control was 18.2% and a higher mortality in the control than in the treatment was observed (13% against 0%). This adds uncertainties on the biological significance of this finding. In light of the above the endpoint was set at 493 mg a.s./kg soil.
** An increase in the reproduction was observed at this concentration. It is uncertain whether such effect could be considered as adverse at population level

*** Endpoints for metabolite IN-D5119, IN-GN815, IN-D5803, IN-9803 are presented, however these metabolites were not included in the risk assessment presented below. IN-D5119, IN-GN815 are not included in the residue definition for soil Moreover according to experts' consultation (PPR TC 139, March 2017) it was agreed not to consider metabolite IN-R9803 and IN-D5803in the risk assessment.
a All values = the highest tested concentrations.

9.8.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for tribenuron methyl but needs to be considered for some relevant metabolites of tribenuron methyl (IN-00581, IN-A4098, IN-L5296, IN-R9805). Initial PEC_{soil} is considered for the formulated product.
To achieve a concise risk assessment, the risk envelope approach is applied. The assessment presented below covers application in spring cereals (spring spraying) and winter cereals (autumn and spring spraying) and minor crops presented in the GAP table (see 9.1.2).

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 TOSCANA TOP 75 WG in cereals

Intended use	Winter cereals 1× 25 g PPP/ha		
Chronic effects on earthworms			
Product/active substance	**NOEC/EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 5)**
TRIBENURON METYL 75 WG	104.7 ~~100~~	0.0333	3144 ~~3003~~
Tribenuron -methyl	3.2	0.025	128
IN-00581	100	0.0045*	22222
IN-A4098	8.0	0.0013*	6154
IN-L5296	0.2	0.0116*	17
IN-GK521	100	0.0077	12987
IN-R9805	1000	0.0009*	1111111
M2	5.0	0.0020	2500

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

Table 9.8-3: First-tier assessment of the chronic risk for other non-target soil organisms (meso- and macrofauna) for relevant metabolites due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Cereals		
Chronic effects on other soil macro- and mesofauna *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Tribenuron-methyl	-	-	-
IN-00581	100	0.0045*	22222
IN-A4098	0.255	0.0013*	196
IN-GK521	100	0.0077	12987
IN-L5296	0.116	0.0116*	10
IN-R9805	100	0.0009*	111111
M2	3*	0.0020	1500
CHR/H/1TR 50 SG	-	-	-
Chronic effects on other soil macro- and mesofauna *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Tribenuron-methyl	-	-	-
IN-00581	100	0.0045*	22222
IN-A4098	100	0.0013*	76923
IN-GK521	25	0.0077	3246
IN-L5296	100	0.0116*	8620
IN-R9805	50	0.0009*	55555
M2	No data available	-	-
CHR/H/1TR 50 SG	-	-	-

TER values shown in bold fall below the relevant trigger.

Review comments:

According to the urrent requirement, effects on soil organisms (other than earthworms) shall be investigated. In the EU peer reviewed dossier, no chronic endpoints are available for the active substance on *Folsomia candida* and *Hypoaspis aculeifer*. Also no toxicity studies on the formulation was submitted by the applicant to *Folsomia candida and Hypoaspis aculeifer.*

However, it should be noted that for formulation applied as a foliar spray, data on the relevant two non-target arthropod species (*Aphidius rhopalosiph* and *Typhlodromus pyri*) might be taken into account for a preliminary risk assessment. If effects do not occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* may not be required according to the new requirement.

The risk assessment for the formulation Tribenuron methyl 75 WG on the relevant two non-target arthropod species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*), is acceptable at Tier 1. Consequently, for the current dossier studies with formulation on *Hypoaspis aculeifer* and *Folsomia candida* are considered not required by zRMS, as indicated in the Reg. UE n°283/2013 & 284/2013.

Non-target soil organisms may be exposed to the metabolites: IN-00581, IN-A4098, IN-GK521, IN-L5296, IN-R9805, M2. So the risk assessment due to the relevant metabolites to non-target soil

organisms should be assessed.

zRMS presented risk assessment for relevant metabolites for *Folsomia and Hypoaspis* with the use of endpoints from LOEP, available in the EFSA Conclusion (2017) in table 9.8-3.

9.8.2.2 Higher-tier risk assessment

Not relevant.

Review comments:

A higher tier assessment is not required based on the low risk indicated in the chronic assessment on earthworms, collembolan, and soil mite.

9.8.3 Overall conclusions

Risk to earthworms arising from the application of TOSCANA TOP 75 WG according to the intended GAP uses can be excluded as the trigger values of 5 for long-term risk were exceeded by far.
Effects on other soil other soil macro - organism were not investigated since in Tier 1 there are no risks associated with the use of TOSCANA TOP 75 WG for earthworms and arthropods other than bees.

Review Comments:

The risk assessment for earthworms exposed to tribenuron-methyl, its relevant metabolites and formulation following application of TOSCANA TOP 75 WG according to critical GAP was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002) and was accepted by the zRMS.

Additionally, zRMS provided risk assessment for relevant metabolites for *Folsomia and Hypoaspis.*

TERlt values calculated for all considered compounds and TOSCANA TOP 75 WG were above the triggers indicating acceptable long-term risk to earthworms. No further evaluation is deemed necessary.

Overall, acceptable risk could be concluded for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of TOSCANA TOP 75 WG in cereals and minor crops according to GAP.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

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

Effects on soil microorganisms of TOSCANA TOP 75 WG were not evaluated as part of the EU assessment of tribenuron methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Endpoint	Substance	Exposure System	No effects (< 25 % difference to control) up to	Reference
N-mineralisation	TRIBENURON METYL 75 WG	28 days	0.165 mg formulation/kg of soil	Anna Xxxxxx, 2018, Study code G/155/17
	IN-00581 (saccharine)	28 days	0.20 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-00581 (saccharine)	28 days	0.0511 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-00581 (saccharine)	42 days	0.204 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-00581 (saccharine)	This metabolite was also evaluated for metsulfuron-methyl, ethametsulfuron-methyl and propoxycarbazone-sodium (EFSA, 2014a, 2015a, 2016b). No adverse data were identified.		EFSA Journal 2017;15(7):4912
	IN-A4098 (N-demethyl-triazine amine)	28 days	0.0397 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-A4098 (N-demethyl-triazine amine)	This metabolite was also evaluated for chlorsulfuron, iodosulfuronmethyl-sodium, thifensulfuron-methyl, metsulfuron-methyl, prosulfuron and triasulfuron (EFSA, 2008, 2014b, 2015a,b,c, 2016a). No adverse data were identified.		EFSA Journal 2017;15(7):4912
	IN-D5119 (acid sulfonamide) *	28 days	0.0533 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-D5119 (acid sulfonamide) *	This metabolite was also evaluated for ethametsulfuron-methyl (EFSA, 2014a). No adverse data were identified.		EFSA Journal 2017;15(7):4912
	IN-D5803 (sulfonamide) *	42 days	0.0597 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-D5803 (sulfonamide) *	This metabolite was also evaluated for metsulfuron-methyl and ethametsulfuron-methyl (EFSA, 2014a, 2015a). No adverse data were identified		EFSA Journal 2017;15(7):4912
	IN-GK521 (O-demethyl tribenuron methyl)	28 days	1.62 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-GK521 (O-demethyl tribenuron methyl)	28 days	0.2 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-L5296 (triazine amine)	No data	0.02 mg/kg dry soil, estimated as 10 times more toxic than the active substance	EFSA Journal 2017;15(7):4912
	IN-GN815 (O-demethyl-tribenuron	28 days	1.41 mg/kg dry soil	EFSA Journal 2017;15(7):4912

Endpoint	Substance	Exposure System	No effects (< 25 % difference to control) up to	Reference
	free acid) *			
	IN-GN815 (O-demethyl-tribenuron free acid) *	28 days	0.2 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-R9805 (O-demethyl-triazine amine)	28 days	200 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-R9803 (tribenuron free acid)*	28 days	1.17 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	IN-R9803 (tribenuron free acid)*	28 days	0.4 mg/kg dry soil	EFSA Journal 2017;15(7):4912
	M2 (triazine urea)	28 days	0.2 mg/kg dry soil	EFSA Journal 2017;15(7):4912

*** Endpoints for metabolite IN-D5119, IN-GN815, IN-D5803, IN-9803 are presented, however these metabolites were not included in the risk assessment presented below. IN-D5119, IN-GN815 are not included in the residue definition for soil Moreover according to experts' consultation (PPR TC 139, March 2017) it was agreed not to consider metabolite IN-R9803 and IN-D5803in the risk assessment.

9.9.1.1 Justification for new endpoints

No deviation from EU agreed endpoints

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).
To achieve a concise risk assessment, the risk envelope approach is applied. The assessment presented below covers application in spring cereals (spring spraying), winter cereals (autumn and spring spraying) and minor crops (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Winter cereals 1·x 25 g PPP/ha		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
TRIBENURON METYL 75 WG	0.165	0.0333	yes
IN-00581 (saccharine)	0.204	0.0045*	yes
IN-A4098 (N-demethyl-triazine	0.0397	0.0013*	yes
IN-GK521 (O-demethyl tribenuron methyl)	1.62	0.0077	yes

IN-L5296 (triazine amine)	0.02	0.0116*	yes
IN-R9805 (O-demethyl-triazine amine)	200	0.0009*	yes
M2 (triazine urea)	0.2	0.002	yes

*$PEC_{accumulation}$ was considered

9.9.3 Overall conclusions

The risk to soil microorganisms is acceptable since effects on the nitrogen transformations are acceptable at concentration which is higher than the maximum relevant PEC soil for the maximum application rate of active substance Tribenuron methyl and its relevant metabolites.

Review comments:

The risk assessment for soil micro-organisms exposed to TOSCANA TOP 75 WG, following the proposed uses of the formulation, was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology" (SANCO/10329/2002).

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

It is concluded that TOSCANA TOP 75 WG had no significant impact on soil microorganisms when applied at test item concentrations up to 0.165 mg formulation/kg soil dry weight which is higher than maximum PECs 0.0333 mg formulation/kg dw following worst-case application for cereals.

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

Effects on non-target terrestrial plants of TOSCANA TOP 75 WG were not evaluated as part of the EU assessment of Tribenuron methyl. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Daucus carota$_d$ *Helianthus annuus*$_d$ *Brassica olerace var. capitata*$_d$ *Pisum sativum*$_d$ *Phaseolus vulgaris*$_d$ *Solanum lycopersicon*$_d$ *Allium cepa*$_m$ *Lolium perenne*$_m$	TRIBENURON METYL 75 WG	21 d Seedling emergence	ER_{50} emergence > 25 g formulation/ha *(all species)* ER_{50} plant weight > 25 g formulation/ha *(all species)* ER_{50} plant height = > 25 g formulation/ha	Anna Xxxxxx, 2018, Study code G/156/17

Species	Substance	Exposure System	Results	Reference
Avena sativa$_m$ *Triticum aestivum*$_m$			*(all species)*	
Daucus carota$_d$ *Helianthus annuus*$_d$ *Brassica olerace var. capitata*$_d$ *Pisum sativum*$_d$ *Phaseolus vulgaris*$_d$ *Solanum lycopersicon*$_d$ *Allium cepa*$_m$ *Lolium perenne*$_m$ *Avena sativa*$_m$ *Triticum aestivum*$_m$	TRIBENURON METYL 75 WG	21 d Vegetative vigour	[1)] ER_{50} mortality > 25 g formulation/ha *(all species)* ER_{50} plant weight = **1.6 g formulation /ha** *(Daucus carota)* ER_{50} plant height = 2.5 g formulation/ha *(Daucus carota)*	Anna Xxxxxx, 2018, Study code G/157/17

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

No deviations from EU end-points.

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.
To achieve a concise risk assessment, the risk envelope approach is applied. The assessment presented below covers application in spring cereals (spring spraying), winter cereals (autumn and spring spraying) and minor crops (see 9.1.2).

Table 9.10-2a: Assessment of the risk for non-target plants due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Cereals and minor crops as presented in the GAP table			
Active substance/product	TOSCANA TOP 75 WG			
Application rate (g formulation /ha)	1 × 25 g/ha			
MAF	1			
Test species	**ER_{50} (g formulation/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Daucus carota	1.6	2.77%	0.6925	2.31

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

fall below the relevant trigger.

Table 9.10-3b: Assessment of the risk for non-target plants due to the use of TOSCANA TOP 75 WG in cereals

Intended use	Cereals and minor crops as presented in the GAP table			
Active substance/product	TOSCANA TOP 75 WG			
Application rate (g/ha)	1 × 20 g/ha			
MAF	1			
Test species	**ER_{50} (g formulation/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Daucus carota	1.6	2.77%	0.554	2.89

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 9.10-4a: Risk assessment for non-target terrestrial plants due to the use of TOSCANA TOP 75 WG in cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Cereals and minor crops as presented in the GAP table			
Active substance/product		TOSCANA TOP 75 WG			
Application rate (g/ha)		1 × 25g/ha			
MAF		1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
1	2.77	0.6925	0.3463	0.1731	0.0693
5	0.57	0.1425	0.07125	0.0356	0.0143
Toxicity value ER_{50} = 1.6 g/ha		**TER criterion: TER ≥ 5**			
1		**2.31**	**4.62**	9.24	-
5		11.23	-	-	-

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

Table 9.10-5b: Risk assessment for non-target terrestrial plants due to the use of TOSCANA TOP 75 WG in cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Cereals and minor crops as presented in the GAP table			
Active substance/product		TOSCANA TOP 75 WG			
Application rate (g/ha)		**1 × 20g/ha**			
MAF		1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	0.554	0.277	0.138	0.0554
5	0.57	0.114	0.057	0.0285	0.0114
Toxicity value		**TER**			
ER_{50} = 1.6 g/ha		**criterion: TER ≥ 5**			
1		**2.89**	5.78	11.59	28.88
5		14.03	28.07	56.14	140.35

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

9.10.3 Overall conclusions

The risk for non-target plants in the off-crop area is indicated to be acceptable when applying either 75% drift reduction or a 5 m buffer strip.

Review comments:

Risk assessment performed by the Applicant for non-target terrestrial plants was accepted. Since the Applicant did not provide risk assessment for the lower application rate 20 g product/ha the assessment was performed by zRMS.

Acceptable risk for non-target terrestrial plants could be concluded for CHR/H/1TR 50 SG when following risk mitigation measures are applied:

Winter cereals and minor uses at the application rate 25 g product/ha
- 1 m and use of 75% drift reducing technology or,
- 5 m buffer zone with no drift reducing technology to non-agricultural land

Spring and winter cereals and minor uses at the application rate 20 g product/ha
- 1 m and use of 50% drift reducing technology or,
- 5 m buffer zone with no drift reducing technology to non-agricultural land

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

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

Additional tests on other non-target species are not required.

9.11 Monitoring data (KCP 10.8)

Not required.

9.12 Classification and Labelling

TOSCANA TOP 75WG was classified and labeled according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Ingredient classified as hazardous to the aquatic environment are:
- active substance tribenuron methyl in a concentration of 75 % classified as “Aquatic Acute 1” and “Aquatic Chronic 1”.

Multiplying factor of M =10 according to Table 4.1.3 was chosen and used in classification for tribenuron (based on ErC_{50} for *Lemna sp*.: 0.031 mg/L).

According to above information and Table 4.1.1 it was assumed that TOSCANA TOP 75WG is classified as Aquatic Acute Category 1 (concentration of active substance mulitiplied by its corresponding M-factor of 10 is equal 750% thus is higher value than 25 %).
According to above information and Table 4.1.2 it was assumed that TOSCANA TOP 75WG is classified as Aquatic Chronic Category 1 (concentration of active substance mulitiplied by its corresponding M-factor of 10 is equal 750 % thus is higher value than 25 %).

CLASSIFICATION	
Hazard class(es), categories:	Aquatic Acute 1 (H400) , Aquatic Chronic 1 (H410)
LABELLING	
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H410 – Very toxic to aquatic life with long lasting effects.

Precautionary statement(s):	~~P273 – Avoid release to the environment.~~ P391 – Collect spillage
Additional phrase(s):	EUH401 - To avoid risks to human health and the environment, comply with the instructions for use. P501: Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste

Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	The mitigation measures proposed by the Applicant at Step 4 of tribenuron methyl run-off mitigation via vegetated filter strip efficiency was calculated for 1 and 3 m buffer using the VFS model following mitigation measures are required - a vegetative buffer strip of 20 m to surface water bodies is required or Based on the results of the higher tier risk assessment (FOCUS Step 4 values in combination with lowest toxicity endpoint for *Lemna gibba* following buffer zones with vegetative strips according are required as follows: Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7 - 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies Winter cereals spring application at rate 15 g a.s./ha, pH < 7 - 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies Winter cereals spring application at rate 15 g a.s./ha, pH > 7 - 20 m vegetative strips with 20 m non- sprayed buffer zone to surface water bodies Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7 - 10 m vegetative strips with 10 m non- sprayed buffer zone to surface water bodies Grasses – spring application, 18.75 g a. s./ha - no mitigation measures required For TOSCANA TOP 75 WG – use in cereals, following risk mitigation measures should be applied taking to consideration VFSmode: Winter cereals spring application at rate 18.75 g a.s./ha, pH < 7 and pH >7 - 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies Winter cereals autumn application at rate 15 g a.s./ha, pH < 7 - 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies Winter cereals autumn application at rate 15 g a.s./ha, pH > 7 - 3 m vegetative strips with 3 m non- sprayed buffer zone to surface water bodies Spring cereals application at rate 15 g a.s./ha, pH < 7 and pH >7 - 1 m vegetative strips with 1 m non- sprayed buffer zone to surface water bodies

	Grasses – spring application, 18.75 g a. s./ha - no mitigation measures required Concerned Member States must decide on the consideration of risk mitigation measures
SPe3	**Winter cereals and minor uses at the application rate 25 g product/ha** - 1 m and use of 75% drift reducing technology or, - 5 m buffer zone with no drift reducing technology to non-agricultural land **Spring and winter cereals and minor uses at the application rate 20 g product/ha** - 1 m and use of 50% drift reducing technology or, - 5 m buffer zone with no drift reducing technology to non-agricultural land Concerned Member States must decide on the applicability of indicated risk mitigation measures at the product authorization. ~~To protect non-target plants respect an unsprayed buffer zone of 5 m or 1m with 75% drift reduction to non-agricultural land.~~

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 10.2.1/01	Ewa Xxxxxx	2017	Tribenuron methyl 75 WG, *Daphnia magna*, Acute Immobilization Test Institute of Industrial Organic Chemistry W/265/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.1/02	Ewa Xxxxxx	2018	Tribenuron methyl 75 WG , *Pseudokirchneriella subcapitata* SAG 61.81 Growth Inhibition Test Institute of Industrial Organic Chemistry W/266/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.1/03	Ewa Xxxxxx	2018	Tribenuron methyl 75 WG, *Lemna gibba* CPCC 310 Growth inhibition test Institute of Industrial Organic Chemistry W/268/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.2.1/04	Ewa Xxxxxx	2018	Tribenuron methyl 75 WG, *Navicula pelliculosa* SAG 1050-3 Growth Inhibition Test Institute of Industrial Organic Chemistry W/267/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.1/01	E.Xxxxxx	2017	Tribenuron metyl 75 WG, Honeybees (*Apis mellifera L.*), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry B/05/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP	E.Xxxxxx	2017	Tribenuron metyl 75 WG, Honeybees (*Apis mellifera L.*), Acute Contact Toxicity Test	N	CIECH

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
10.3.1/02			Institute of Industrial Organic Chemistry B/06/17 GLP Unpublished		Sarzyna S.A.
KCP 10.3.1/03	T. Xxxxxx	2017	Chronic toxicity of PP-108 H (Tribenuron methyl 75 WG) on honeybees (Apis mellifera L.) STUDY TRC15-250BA GLP Unpublished	N	TF PROPLAN-CHEMIROL-SARABIA
KCP 10.3.1/04	T. Xxxxxx	2017	Toxicity of PP-108 H (Tribenuron methyl 75 WG) on honey bee larvae (Apis mellifera L.) after repeated exposure under laboratory conditions STUDY TRC15-249BA GLP Unpublished	N	TF PROPLAN-CHEMIROL-SARABIA
KCP 10.3.2/01	E.Xxxxxx	2018	A laboratory test for evaluating the effects of Tribenuron metyl 75 WG on the parasitic wasp, *Aphidius rhopalosiphi* (Xxxxxx) Institute of Industrial Organic Chemistry B/07/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.3.2/02	E.Xxxxxx	2017	A laboratory test for evaluating the effects of Tribenuron metyl 75 WG on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry B/08/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.4.1.1	A.Xxxxxx	2018	TRIBENURON METYL 75 WG Earthworm Reproduction Test *(Eisenia andrei)* Institute of Industrial Organic Chemistry G/154/17 GLP Unpublished	N	CIECH Sarzyna S.A.

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	A.Xxxxxx	2018	TRIBENURON - METYL 75 WG Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry G/155/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.6.2/01	A.Xxxxxx	2018	TRIBENURON METYL 75 WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry G/156/17 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 10.6.2/02	A.Xxxxxx	2018	Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry G/157/17 GLP Unpublished	N	CIECH Sarzyna S.A.

Appendix 2 Detailed evaluation of the new studies

Review Comment:

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

All the studies were performed on the formulation Tribenuron methyl 75 WG which is the same formulation as T-75WG-OR2-C / TOSCANA TOP 75WG which was confirmed by the Applicant.

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Summarised in Section 6 (Mammalian Toxicology)

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

Study 1

Comments of zRMS:	Acute immobilization test was conducted to OECD guideline 202 and according to the principles of GLP. No deviation to the guideline was noted during the study. In the definitive test the validity criteria were met: - The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%), - The dissolved oxygen concentrations in the test vessels were within the range of 8.3– 8.8 mg/L (criterion: not less than 3 mg/L). The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.2.1
Report	Tribenuron methyl 75 WG, Daphnia magna, Acute Immobilization Test, Ewa Xxxxxx, MSc Eng, 2017, STUDY CODE: W/265/17, Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Aim of the study

The aim of the study was to demonstrate that the EC_{50} value after 48 hours of exposure of Daphnia magna is higher than the test item concentration used for exposure, i.e. 135.5 mg/L (100 mg/L of tribenuron methyl) (limit test).

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.
Biological test system:	*Daphnia magna Straus* (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Culturing of *Daphnia magna*	Daphnia magna was cultured in glass beakers with a capacity of 150 mL (one parent per vessel) at room temperature with daily cycle 16 h light : 8 h dark. The Daphnia magna were fed daily with a suspension of the algae,

	mixture of two species Pseudokirchneriella subcapitata : Desmodesmus subspicatus (in a ratio 2 : 1). Group B vitamins and micronutrients necessary for proper growth were supplied with a lyophilized suspension of Spirulina sp.
Culture medium	The Elendt M7 medium recommended by the OECD Guideline No. 202 (2004) and EU Method C.2. was used to culture the test organism and as a diluent/solvent of the test item
Test conditions	The preliminary and definitive tests were conducted in a static design with exposure for 48 h. The tests were conducted with daily cycle 16 h light : 8 h dark. The temperature was continuously recorded using a sensor submerged in an additional test vessel containing the test medium. pH values and the dissolved oxygen concentrations were measured at exposure initiation in the test item concentrations and the control before splitting into replicates. The pH values and the dissolved oxygen concentrations were also measured at exposure termination in the test item concentrations and the control in pooled replicates.
Preparing the test item concentrations	**Preliminary tests (non-GLP)** The first preliminary test was performed using following test item concentrations: 100, 10, 1.0 and 0.1 mg/L plus the control. The second preliminary test was performed using following test item concentrations: 320, 100, and 32 mg/L. **Definitive test** **The definitive test** was performed using a single test item concentration of 135.5 mg/L (i.e. 100 mg/L of tribenuron methyl) plus the control.
Test with the reference material	The test with reference material was performed with potassium dichromate. During exposure, the temperature was in the range of 20.8 – 22.2°C, and the dissolved oxygen concentration was higher than 3 mg/L. Five concentrations of the reference material of 0.32, 0.56, 1.0, 1.8, and 3.2 mg/L and a control were used. There were four replicates of every concentration and the control.

Summary

Immobilization of young Daphnia magna exposed to the test item, Tribenuron methyl 75 WG was investigated during a 48-hour static test. A single test item concentration of 135.5 mg/l and a control were used (limit test). Four replicates of test item concentration and the control with five Daphnia magna per replicate were used. Daphnia magna were observed for immobilization after 24 and 48 h of exposure.

Analytical measurement

The samples of the test item concentration and the control at exposure initiation and at exposure termination were chemically determined. The determined concentration of tribenuron methyl in sample collected at exposure initiation was 100.8% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. The determined concentration of tribenuron methyl in sample at exposure termination was 88.9% of the nominal concentration. Therefore, it can be concluded that the concentration of tribenuron methyl was stable during exposure under test conditions. The results are presented in Table below.

Table 1. Concentration and stability of tribenuron methyl, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of tribenuron methyl [mg/L]	Average determined concentration of tribenuron methyl in samples collected			
		at exposure initiation [mg/L]	% of the nominal concentration	at exposure termination [mg/L]	% of the nominal concentration
Control	---	<LoD	---	<LoD	---
135.5	100.04	101.217	100.81	89.263	88.91

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

Results of chemical determinations

Table 2. pH values and dissolved oxygen concentrations in definitive test

Nominal test item concentration [mg/L]	pH values		Dissolved oxygen concentrations [mg/L]	
	at exposure initiation #	at exposure termination *	at exposure initiation #	at exposure termination *
Control	7.99	7.99	8.8	8.3
135.5	7.05	7.82	8.8	8.4

#- pH values and dissolved oxygen concentrations measured in samples before split up into replicates
*- pH values and dissolved oxygen concentrations measured in samples of pooled replicates

Results and discussions

In the control and in the test item concentration of 135 mg/l no immobilization was observed during exposure. The endpoints were determined on the basis of nominal test item concentration. In the test item concentration of 135.5 mg/l and in the control no immobilization of Daphnia magna was observed during exposure. Therefore, no statistical analysis was needed. The EC_{50} value after 48h of exposure is higher than 135.5 mg/l. The LOEC/48h value is higher than 100mg/l. The NOEC/48h value is higher than or equal to 100 mg/l.

Table 3. 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
135.5	20	0	0	0	0	0	0	0	0	0	0

Time of exposure: 31.10.2017 – 02.11.2017

Conclusion

<u>The endpoint values based on nominal test item concentrations are given below.</u>
The EC_{50}/48 h value is higher than 135.5 mg/L (limit test).

Study 2

Comments of zRMS:	The study was conducted to OECD guideline 201 and according to the principles of GLP. No deviation from the guideline occurred. In the definitive test all the validity criteria were met - The biomass in the control increased by a factor of 177.0 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 1.1 % (criterion: it must not exceed 7%), - The mean coefficient of variation for the section-by-section growth rate in the control culture was 17.4% (criterion: it must not exceed 35%). The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.2.1
Report	Tribenuron methyl 75 WG , *Pseudokirchneriella subcapitata* SAG 61.81 Growth Inhibition Test, Ewa Xxxxxx, MSc Eng, 2018, STUDY CODE: W/266/17, Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline No. 201 (2006) / EU Method C.3
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.
Biological test system:	Unicellular freshwater green algae *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. Selenastrum capricornutum Prinz, Raphidocelis subcapitata Korshikov), specification SAG 61.81, cultured in the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology, stock from the Culture Collection of Algae at Gottingen University, Germany.
Test organism:	Unicellular freshwater green algae Pseudokirchneriella subcapitata (Reinsch) Korshikov (syn. Selenastrum capricornutum Prinz, Raphidocelis subcapitata Korshikov), specification SAG 61.81, cultured in the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology, stock from the Culture Collection of Algae at Göttin-

	gen University, Germany.
Test design:	72 hours of exposure; three replicates per each test item concentration; six replicates per the control; a background for the control and each test item concentration; initial algal cell density: 1 x 10^4 cells/mL.
Nominal test item concentrations:	10, 3.13, 0.98, 0.31, 0.095, 0.030, 0.0093 mg/L plus the control
Test conditions:	Temperature: 21.8 – 22.6°C; pH of the control: 7.57 – 8.43; mean light intensity: 6700 – 7152 lux; constant illumination and shaking; the AAP medium
Chemical determinations:	he concentrations of tribenuron methyl were determined with a validated chromatographic method with UV-Vis detection.
Statistical tests	Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, Multiple Sequentially-rejective U-test after Bonferroni-Holm.

Summary

The growth of the green algae *Pseudokirchneriella subcapitata* exposed to the test item, Tribenuron methyl 75 WG was investigated during 72-hour test. The test was performed in glass flasks with a capacity of 250 ml. Each of them contained 100 ml of a given test item concentration and the control. The initial density of the algae was 1x10^4 cells/ml. The following test item concentrations were used: 10, 3.13, 0.98, 0.31, 0.095, 0.030, 0.0093 mg/l (three replicates per each test item concentrations) plus the control (six replicates per control).
Density of algae cells was determined in each replicate after 24, 48 and 72h of exposure. Morphology observations of the algae cells were performed at exposure termination**.**

Analytical measurements

The concentrations of tribenuron methyl were chemically determined using a validated chromatographic method. Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. The determined concentrations of tribenuron methyl in samples collected at exposure initiation were in the range of 92.22 – 103.59% of the nominal concentration. The results confirm correct preparation of the test item concentrations. The determined concentrations of tribenuron methyl in samples collected at exposure termination were in the range of 80.03 – 86.96% of the nominal concentration. Therefore, concentrations of tribenuron methyl were stable under the test conditions.

Table 1. Concentration and stability of tribenuron methyl, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of tribenuron methyl [mg/L]	Average determined concentration of tribenuron methyl (n = 3)			
		exposure initiation [mg/L]	% of the nominal concentration	exposure termination [mg/L]	% of the nominal concentration
Control	---	< LoD	---	< LoD	---
0.0093	0.0069	0.0069	100.00	0.0060	86.96
0.030	0.0221	0.0212	95.93	0.0179	81.00
0.095	0.0701	0.0662	94.44	0.0574	81.88
0.31	0.2289	0.2315	101.14	0.1832	80.03
0.98	0.7235	0.6672	92.22	0.6104	84.37
3.13	2.3109	2.2558	97.62	1.9726	85.36
10	7.3830	7.6477	103.59	6.3606	86.15

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

Results and discussions

The endpoint values were determined on the basis of the nominal test item concentrations. The E_rC_x and the E_yC_x values were calculated with the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were determined on the basis of the results of statistical analyses. To conduct statistical analyses, the ToxRat Professional commercial software was used. Results are shown in Tables below.
In all test item concentrations, no differences of algae cells were reported as compared to the algae cells in the control.

Table 2. Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.00	0.00
0.0093	3.28	15.73
0.030	24.05	71.61
0.095	46.21	91.36
0.31	56.64	95.20
0.98	70.07	97.87
3.13	74.58	98.37
10	94.34	99.41

Table 31. Growth rate endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	6.027 (n.d.)	0.372 (0.209 – 0.672)	0.230 (0.161 – 0.327)
E_rC_{20}	n.d.	0.017 (0.004 – 0.038)	0.019 (0.010 – 0.033)
E_rC_{10}	n.d.	< 0.0093	< 0.0093
LOEC	n.d.	0.030	n.d.
NOEC	n.d.	0.0093	n.d.

(-) – 95% confidence interval
n.d.- not determined
Calculations were made according to [9], [SOP/W/68]

Table 42. Yield endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	0.745 (n.d.)	0.024 (0.017 – 0.033)	0.020 (0.018 – 0.022)
E_yC_{20}	n.d.	< 0.0093	0.010 (0.009 – 0.011)
E_yC_{10}	n.d.	n.d.	< 0.0093
LOEC	0.095	≤ 0.0093	≤ 0.0093
NOEC	0.030	< 0.0093	< 0.0093

Calculations were made according to [9], [SOP/W/68]
(-) – 95% confidence interval
n.d.- not determined

Conclusion

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

The E_rC_{50}/72 h value is 0.230 mg/L (95% confidence interval: 0.161 – 0.327).

The LOEC/72 h and NOEC/72 h values for growth rate were not determined on the basis of obtained results.

The E_yC_{50}/72 h value is 0.020 mg/L (95% confidence interval: 0.018 – 0.022).

The LOEC/72 h value for yield is lower than or equal to 0.0093 mg/L.

The NOEC/72 h value for yield is lower than 0.0093 mg/L.

Study 3

Comments of zRMS:	Growth inhibition test study was conducted to OECD guideline 221 and according to the principles of GLP. No deviations were noted during the study. It should be noted that the NOEC/7 d (= 0.00015 mg/L) is below LoD value The analytical measurements demonstrated that the test item concentrations at exposure initiation was within 80-120% of nominal, but in the end of the test item concentration in comparison was outside this range (44.8 – 70.2% of the nominal concentration) For this reason, endpoints are expressed mean measured concentrations. In the definitive test the validity criteria were met: - The doubling time of frond number in the control was < 2.5 days, criterion: less than 2.5 days - The average specific growth rate in the control between day 0 and day 7 was 0.277 d^{-1} (minimum requirement: higher than 0.275 d^{-1}). The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.2.1
Report	Tribenuron methyl 75 WG, *Lemna gibba* CPCC 310 Growth inhibition test, Ewa Xxxxxx, MSc Eng, 2018, Study code: W/268/17, Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline No. 221 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Summary

The growth of *Lemna gibba* exposed to the test item, Tribenuron metyl 75 WG was investigated in a 7 day semi-static test with two renewals. The test was performed in glass crystallizers containing 150 mL of each treatment per replicate. The initial frond number in each test item concentration and in the control was nine. The following test item concentrations: 10, 2.5, 0.63, 0.16, 0.039, 0.0098, 0.0024, 0.00061, 0.00015 mg/L plus the control were used for exposure. The total number of fronds in each test vessel was counted twice during exposure (day 3 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.

Materials and methods

Test item: Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.

Biological test system:	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 two renewals; 7 days of exposure; three replicates for each test item concentration and six replicates for control.
Nominal test item concentrations:	10, 2.5, 0.63, 0.16, 0.039, 0.0098, 0.0024, 0.00061, 0.00015 mg/L plus the control.
Nominal concentrations of tribenuron methyl in the test item:	7.38, 1.85, 0.47, 0.12, 0.029, 0.0072, 0.0018, 0.00045, 0.00011 mg/L plus the control.
Geometric mean of determined concentrations of tribenuron methyl in the test item:	5.3710, 1.1819, 0.3578, 0.0897, 0.0228, 0.0059, 0.0012, 0.0004, 0.0003 mg/L plus the control.
Test conditions:	20X AAP nutrient solution, pH of the control: 7.44 – 10.13, mean light intensity: 7264 – 8128 lux, constant illumination, 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: 22.9 – 24.7ºC.
Chemical determinations:	The concentration of tribenuron methyl was determined with validated liquid chromatographic method with UV-Vis detection.
Statistics	Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Bartlett Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure, Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment
Endpoint values:	ErC50, ErC20, ErC10, EyC50, EyC20, EyC10, LOEC and NOEC, based on frond number and dry weight.

Analytical measurements

The concentrations of tribenuron methyl were chemically determined using a validated chromatographic method. Samples of each test item concentration and the control were collected at exposure initiation and at exposure termination. **The test item concentrations of 0.00061 and 0.00015 mg/L were below LoQ value and the test item concentration of 0.00015 mg/L was below LoD value.**

At exposure initiation the determined concentration of tribenuron methyl was in the range of 85.6 – 98.9% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination the determined concentration of tribenuron methyl was in the range of 44.8 – 70.2% of the nominal concentration. Therefore, the concentrations of tribenuron methyl was unstable under test conditions between renewals. The endpoint values were determined based on the nominal test item concentrations and geometric mean of determined concentrations of tribenuron methyl in the test item.

Table 1. Concentration and stability of tribenuron methyl, definitive test

Nominal test item concentration [mg/L]	control	0.00015	0.00061	0.0024	0.0098	0.039	0.16	0.63	2.5	10	Day of sampling
Nominal concentration of tribenuron methyl [mg/L]	---	0.00011	0.00045	0.0018	0.0072	0.029	0.12	0.47	1.85	7.38	
Geometric means of determined concentrations of tribenuron methyl* [mg/L]	---	0.0003	0.0004	0.0012	0.0059	0.0228	0.0897	0.3578	1.1819	5.3710	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	< LoD	< LoQ	0.00169	0.00700	0.0273	0.110	0.431	1.685	7.060	day 0 fresh
% of the nominal concentration	---	---	---	93.9	97.2	94.1	91.7	91.7	91.1	95.7	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	<LoD	< LoD	0.000889	0.00491	0.0190	0.0732	0.297	0.829	4.086	day 3 spent
% of the nominal concentration	---	---	---	49.4	68.2	65.5	61.0	63.2	44.8	55.4	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	---	---	0.00178	---	---	---	---	---	6.748	day 3 fresh
% of the nominal concentration	--	---	---	98.9	---	---	---	---	---	91.4	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	---	---	0.00082	---	---	---	---	---	5.179	day 5 spent
% of the nominal concentration	---	---	---	45.6	---	---	---	---	---	70.2	

Nominal test item concentration [mg/L]	control	0.00015	0.00061	0.0024	0.0098	0.039	0.16	0.63	2.5	10	Day of sampling
Nominal concentration of tribenuron methyl [mg/L]	---	0.00011	0.00045	0.0018	0.0072	0.029	0.12	0.47	1.85	7.38	
Geometric means of determined concentrations of tribenuron methyl* [mg/L]	---	0.0003	0.0004	0.0012	0.0059	0.0228	0.0897	0.3578	1.1819	5.3710	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	---	---	0.00154	---	---	---	---	---	6.453	day 5 fresh
% of the nominal concentration	---	---	---	85.6	---	---	---	---	---	87.4	
Mean concentration (n=3) of tribenuron methyl [mg/L]	<LoD	---	---	0.00089	---	---	---	---	---	4.354	day 7 old
% of the nominal concentration	---	---	---	49.4	---	---	---	---	---	59.0	

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

Results and discussions

The endpoint values were determined on the basis of the nominal test item concentrations and the geometric means if determined concentrations of tribenuron methyl. The EC_x values were calculated using the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were determined on the basis of the results of statistical analyses. The ToxRat Professional commercial software was used. The endpoint values are given in Tables below.

Table 2. Section-by-section growth rate, growth rate and yield based on frond number, definitive test

Nominal test item concentration [mg/L]	Section-by-section growth rate *			Mean growth rate	Yield**		
	0 – 3 d	3 – 5 d	5 – 7 d	0 – 7 d	3 d	5 d	7 d
Control	0.390	0.241	0.122	0.271	20	38	51
	0.366	0.209	0.119	0.251	18	32	43
	0.423	0.252	0.180	0.305	23	44	67
	0.366	0.197	0.211	0.273	18	31	52
	0.390	0.161	0.243	0.282	20	31	56
	0.412	0.186	0.184	0.282	22	36	56
mean	**0.391**	**0.208**	**0.176**	**0.277**	**20.2**	**35.3**	**54.2**
standard deviation	*0.023*	*0.034*	*0.049*	*0.018*	*2.04*	*5.13*	*7.88*
0.00015	0.390	0.208	0.102	0.256	20	35	45
	0.366	0.233	0.141	0.264	18	34	48
	0.378	0.259	0.114	0.269	19	38	50
mean	**0.378**	**0.233**	**0.119**	**0.263**	**19.0**	**35.7**	**47.7**
standard deviation	*0.012*	*0.025*	*0.020*	*0.006*	*1.00*	*2.08*	*2.52*
0.00061	0.378	0.191	0.109	0.248	19	32	42
	0.378	0.226	0.129	0.264	19	35	48
	0.366	0.221	0.107	0.251	18	33	43
mean	**0.374**	**0.213**	**0.115**	**0.254**	**18.7**	**33.3**	**44.3**
standard deviation	*0.007*	*0.019*	*0.013*	*0.009*	*0.58*	*1.53*	*3.21*
0.0024	0.313	0.238	0.098	0.230	14	28	36
	0.366	0.184	0.104	0.239	18	30	39
	0.390	0.173	0.119	0.251	20	32	43
mean	**0.356**	**0.198**	**0.107**	**0.240**	**17.3**	**30.0**	**39.3**
standard deviation	*0.040*	*0.035*	*0.011*	*0.010*	*3.06*	*2.00*	*3.51*
0.0098	0.266	0.203	0.131	0.209	11	21	30
	0.282	0.161	0.197	0.223	12	20	34
	0.249	0.176	0.115	0.190	10	18	25
mean	**0.266**	**0.180**	**0.148**	**0.208**	**11.0**	**19.7**	**29.7**
standard deviation	*0.017*	*0.021*	*0.043*	*0.017*	*1.00*	*1.53*	*4.51*
0.039	0.096	0.203	0.077	0.121	3	9	12
	0.096	0.077	0.226	0.128	3	5	13
	0.096	0.174	0.106	0.121	3	8	12
mean	**0.096**	**0.151**	**0.136**	**0.123**	**3.0**	**7.3**	**12.3**
standard deviation	*0.000*	*0.066*	*0.079*	*0.004*	*0.00*	*2.08*	*0.58*

Nominal test item concentration [mg/L]	Section-by-section growth rate *			Mean growth rate	Yield**		
	0 – 3 d	3 – 5 d	5 – 7 d	0 – 7 d	3 d	5 d	7 d
0.16	0.096	0.000	0.040	0.053	3.0	3	4
	0.000	0.144	0.000	0.041	0.0	3	3
	0.096	0.000	0.040	0.053	3.0	3	4
mean	**0.064**	**0.048**	**0.027**	**0.049**	**2.0**	**3.0**	**3.7**
standard deviation	*0.055*	*0.083*	*0.023*	*0.007*	*1.73*	*0.00*	*0.58*
0.63	0.000	0.100	0.000	0.029	0	2	2
	0.035	0.048	0.044	0.041	1	2	3
	0.067	0.044	0.000	0.041	2	3	3
mean	**0.034**	**0.064**	**0.015**	**0.037**	**1.0**	**2.3**	**2.7**
standard deviation	*0.033*	*0.032*	*0.025*	*0.007*	*1.00*	*0.58*	*0.58*
2.5	0.035	0.000	0.091	0.041	1	1	3
	0.035	0.000	0.000	0.015	1	1	1
	0.035	0.000	0.048	0.029	1	1	2
mean	**0.035**	**0.000**	**0.046**	**0.028**	**1.0**	**1.0**	**2.0**
standard deviation	*0.000*	*0.000*	*0.046*	*0.013*	*0.00*	*0.00*	*1.00*
10	0.000	0.000	0.100	0.029	0.0	0	2
	0.035	0.000	n.d.	0.000	1.0	1	0
	0.000	0.053	0.048	0.029	0.0	1	2
mean	**0.012**	**0.018**	**n.d.**	**0.019**	**0.3**	**0.7**	**1.3**
standard deviation	*0.020*	*0.030*	*n.d.*	*0.017*	*0.58*	*0.58*	*1.15*

Example calculations:
*growth rate = ln (frond number on day 3) - ln (frond number on day 0) / 3 days
** yield = (frond number on day 3) – (frond number on day 0)

Table 3 ~~1~~. Growth rate endpoint values based on the nominal test item concentrations [mg/L], definitive test.

Endpoint values	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E_yC_{50}	0.019	0.028	0.031	> 10
E_yC_{20}	0.003 (0.002 – 0.005)	0.003 (0.002 – 0.004)	0.0011 (0.0005 – 0.0019)	0.0075 (0.0005 – 0.0295)
E_yC_{10}	0.0016 (0.0006 – 0.0026)	0.0014 (0.0009 – 0.0021)	0.00036 (0.00012 – 0.00074)	0.00095 (0.00002 – 0.00594)
LOEC	0.0024	0.0098	≤ 0.00015	0.0390
NOEC	0.00061	0.0024	< 0.00015	0.0098

Calculations according to [4], [SOP/W/68]
(-) the 95% confidence interval

Endpoint values	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E_yC_{50}	0.006 (0.005 – 0.008)	0.007 (0.006 – 0.009)	0.0051 (0.0037 – 0.0072)	0.2181 (0.0736 – 0.8592)
E_yC_{20}	0.002 (0.001 – 0.002)	0.002 (0.001 – 0.002)	0.0007 (0.0004 – 0.0011)	0.0048 (0.0004 – 0.0179)
E_yC_{10}	0.0008 (0.0004 – 0.0013)	0.0008 (0.0005 – 0.0012)	0.00025 (0.00012 – 0.00043)	0.00066 (0.00002 – 0.00379)
LOEC	0.0012	0.0059	≤ 0.0003	0.0228
NOEC	0.0004	0.0012	< 0.0003	0.0059

Table 5 3. Endpoint values of growth rate based on the geometric means of determined concentrations of tribenuron methyl in the test item – definitive test.

Endpoint values	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E_rC_{50}	0.011 (0.007 – 0.017)	0.016 (0.011 – 0.024)	0.018 (0.012 – 0.028)	> 5.371
E_rC_{20}	0.002 (0.001 – 0.004)	0.003 (0.001 – 0.005)	0.0025 (0.0011 – 0.0043)	0.094 (0.021 – 0.254)
E_rC_{10}	0.0011 (0.0003 – 0.0022)	0.0013 (0.0005 – 0.0024)	0.0009 (0.0003 – 0.0018)	0.0062 (0.0003 – 0.0263)
LOEC	0.0059	0.0059	0.0004	0.0059
NOEC	0.0012	0.0012	0.0003	0.0012

Table 6 4. Endpoint values of yield based on the geometric means of determined concentrations of tribenuron methyl in the test item – definitive test.

Endpoint values	Frond number			Dry weight
	0-3 d	0-5 d	0-7 d	0-7 d
E_yC_{50}	0.006 (0.005 – 0.008)	0.007 (0.006 – 0.009)	0.0051 (0.0037 – 0.0072)	0.2181 (0.0736 – 0.8592)
E_yC_{20}	0.002 (0.001 – 0.002)	0.002 (0.001 – 0.002)	0.0007 (0.0004 – 0.0011)	0.0048 (0.0004 – 0.0179)
E_yC_{10}	0.0008 (0.0004 – 0.0013)	0.0008 (0.0005 – 0.0012)	0.00025 (0.00012 – 0.00043)	0.00066 (0.00002 – 0.00379)
LOEC	0.0012	0.0059	≤ 0.0003	0.0228
NOEC	0.0004	0.0012	< 0.0003	0.0059

Conclusion

At exposure initiation the determined concentration of tribenuron methyl was in the range of 85.6 –98.9% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination the determined concentration of tribenuron methyl was in the range of 44.8 – 70.2% of the nominal concentration. The concentrations of tribenuron methyl were unstable under test conditions between renewals. Therefore, the endpoint values were determined based on the nominal test item concentrations and geometric mean of determined concentrations of tribenuron methyl in the test item.

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

Endpoints based on the frond number:

The E_rC_{50}/7 d value is 0.031 mg/L (95% confidence interval 0.020 – 0.050).

The E_rC_{20}/7 d value is 0.0042 mg/L (95% confidence interval 0.0017 – 0.0076).

The E_rC_{10}/7 d value is 0.0015 mg/L (95% confidence interval 0.0004 – 0.0031).

For growth rate, the LOEC/7 d value is 0.00061 mg/L, whereas NOEC/7 d value is 0.00015 mg/L.

The E_yC_{50}/7 d value is 0.0085 mg/L (95% confidence interval 0.0056 – 0.0131).

The E_yC_{20}/7 d value is 0.0011 mg/L (95% confidence interval 0.0005 – 0.0019).

The E_yC_{10}/7 d value is 0.00036 mg/L (95% confidence interval 0.00012 – 0.00074).

For yield the LOEC/7 d value is lower than or equal to 0.00015 mg/L, whereas the NOEC/7 d value is lower than 0.00015 mg/L.

Endpoints based on the dry weight:

The E_rC_{50}/7 d value is higher than 5.371 mg/L.

The E_rC_{20}/7 d value is 0.094 mg/L (95% confidence interval 0.021 – 0.254).

The E_rC_{10}/7 d value is 0.0062 mg/L (95% confidence interval 0.0003 – 0.0263).

For growth rate LOEC/7 d value is 0.0059 mg/L, whereas the NOEC/7 d value is 0.0012 mg/L.

The E_yC_{50}/7 d value is 0.2181 mg/L (95% confidence interval 0.0736 – 0.8592).

The E_yC_{20}/7 d value is 0.0048 mg/L (95% confidence interval 0.0004 – 0.0179).

The E_yC_{10}/7 d value is 0.00066 mg/L (95% confidence interval 0.00002 – 0.00379).

For yield the LOEC/7 d value is 0.0228 mg/L, whereas the NOEC/7 d value is 0.0059 mg/L.

The endpoint values based on the geometric means of determined concentrations of tribenuron methyl in the test item:

Endpoints based on the frond number:

The E_rC_{50}/7 d value is 0.018 mg/L (95% confidence interval 0.012 – 0.028).

The E_rC_{20}/7 d value is 0.0025 mg/L (95% confidence interval 0.0011 – 0.0043).

The E_rC_{10}/7 d value is 0.0009 mg/L (95% confidence interval 0.0003 – 0.0018).

For growth rate LOEC/7 d value is 0.0004 mg/L, whereas the NOEC/7 d value is 0.0003 mg/L.

The E_yC_{50}/7 d value is 0.0051 mg/L (95% confidence interval 0.0037 – 0.0072).

The E_yC_{20}/7 d value is 0.0007 mg/L (95% confidence interval 0.0004 – 0.0011).

The E_yC_{10}/7 d value is 0.00025 mg/L (95% confidence interval 0.00012 – 0.00043).

For yield the LOEC/7 d value is lower than or equal to 0.0003 mg/L, whereas the NOEC/7 d value is lower than 0.0003 mg/L.

Endpoints based on the dry weight:

The E_rC_{50}/7 d value is higher than 5.371 mg/L.

The E_rC_{20}/7 d value is 0.094 mg/L (95% confidence interval 0.021 – 0.254).

The E_rC_{10}/7 d value is 0.0062 mg/L (95% confidence interval 0.0003 – 0.0263).

For growth rate LOEC/7 d value is 0.0059 mg/L, whereas the NOEC/7 d value is 0.0012 mg/L.

The E_yC_{50}/7 d value is 0.2181 mg/L (95% confidence interval 0.0736 – 0.8592).

The E_yC_{20}/7 d value is 0.0048 mg/L (95% confidence interval 0.0004 – 0.0179).

The E_yC_{10}/7 d value is 0.00066 mg/L (95% confidence interval 0.00002 – 0.00379).

For yield the LOEC/7 d value is 0.0228 mg/L, whereas the NOEC/7 d value is 0.0059 mg/L.

Study 4

Comments of zRMS:	The study was conducted to OECD guideline 201 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met. - the biomass in the control increased by a factor of 82.8 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 2.1% (criterion: it must not exceed 10%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 28.6% (criterion: it must not exceed 35%). The analytical measurements demonstrated that the test item concentrations throughout the test was within 80-120% of nominal and for this reason endpoints are expressed as nominal concentrations. The study is considered reliable and suitable for the risk assessment

Reference:	KCP 10.2.1
Report	Tribenuron methyl 75 WG, *Navicula pelliculosa* SAG 1050-3 Growth Inhibition Test, Ewa Xxxxxx, MSc Eng,, 2018, STUDY CODE: W/267/17, Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline No. 201 (2006) / EU Method C.3
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.
Biological test system:	The freshwater diatoms *Navicula pelliculosa* (Bréb.) Hilse specification SAG 1050 – 3, cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Aquatic Toxicology. The diatoms were obtained from the Culture Collection of Algae at Göttingen University, Germany.
Test design:	72 hours of exposure; three replicates of each test item concentration and six replicates of the control; initial diatoms cell density: 1 x 10^4 cells/mL.
Nominal test item concentrations:	320, 100, 32, 10, 3.2, 1.0 mg/L plus the control
Test conditions:	Temperature: 22.4 – 23.4°C; pH of the control: 7.66 – 7.75; mean light intensity: 5492 – 5746 lux; constant illumination and shaking; the AAP-Si medium
Chemical determinations:	The concentrations of tribenuron methyl were determined with a validated chromatographic method with UV-Vis detection
Statistics:	Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Welch-t test for Inhomogeneous Variances with BonferroniHolm Adjustment.
Endpoint values:	ErC50, EyC50, NOEC, LOEC.

Summary

The growth of the green algae *Navicula pelliculosa* exposed to the test item, Tribenuron methyl 75 WG was investigated during 72-hour test. The test was performed in glass flasks with a capacity of 250 ml. Each of them contained 100 ml of a given test item concentration and the control. The initial density of the algae was 1x10^4 cells/ml. The following test item concentrations were used: 320, 100, 32, 10, 3.2, 1.0 mg/l (three replicates) plus the control (six replicates).
Density of algae cells was determined in each replicate after 24, 48 and 72h of exposure. Morphology observations of the algae cells were performed at exposure termination.

Analytical measurements

The concentrations of tribenuron methyl were chemically determined using a validated chromatographic method. Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. The determined concentrations of tribenuron methyl in samples collected at exposure initiation were in the range of 89.6 – 95.3% of the nominal concentration. The results confirm correct preparation of the test item concentrations. The determined concentrations of tribenuron methyl in samples collected at exposure termination were in the range of 81.7 – 93.1% of the nominal concentration. Therefore, concentrations of tribenuron methyl were stable under the test conditions.

Concentration and stability of tribenuron methyl, definitive test is presented below.

Nominal test item concentration [mg/L]	Nominal concentration of tribenuron methyl [mg/L]	Average determined concentration of tribenuron methyl (n = 3)			
		exposure initiation [mg/L]	% of the nominal concentration	exposure termination [mg/L]	% of the nominal concentration
Control	---	< LoD	---	< LoD	---
1.0	0.74	0.663	89.6	0.689	93.1
3.2	2.36	2.249	95.3	2.182	92.5
10	7.38	6.888	93.3	6.760	91.6
32	23.63	22.328	94.5	21.724	91.9
100	73.83	67.200	91.0	60.303	81.7
320	236.26	222.282	94.1	195.246	82.6

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

Results and discussions

The endpoint values were determined on the basis of the nominal test item concentrations and nominal concentrations of tribenuron methyl in the test item. The E_rC_x and the E_yC_x values were calculated with the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were determined on the basis of the results of statistical analyses. Results are shown in Tables below.
In all test item concentrations no differences of algae cells were reported as compared to the algae cells in the control.

Table 1. Growth rate endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	19.81 (n.d.)	130.64 (92.20 – 193.28)	144.42 (122.94 – 171.33)
E_rC_{20}	0.84 (n.d.)	41.79 (18.86– 63.21)	48.45 (35.88 – 60.37)
E_rC_{10}	n.d.	23.03 (7.32 – 39.64)	27.37 (17.92 – 36.80)
LOEC	10.00	> 320.00	32.00
NOEC	3.20	≥ 320.00	10.00

(-) – 95% confidence interval

Table 2. Yield endpoint values based on the nominal test item concentrations, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	7.51 (n.d.)	34.04 (21.44 – 55.63)	29.44 (23.56 – 36.81)
E_yC_{20}	n.d.	4.51 (1.69 – 8.20)	7.75 (5.16 – 10.44)
E_yC_{10}	n.d.	1.57 (0.39 – 3.47)	3.85 (2.21 – 5.69)
LOEC	10.00	10.00	32.00
NOEC	3.20	3.20	10.00

Table 3. Growth rate endpoint values based on the nominal concentrations of tribenuron methyl in the test item, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_rC_{50}	14.63 (n.d.)	96.46 (68.08 – 142.70)	106.63 (90.77 – 126.50)
E_rC_{20}	0.62 (n.d.)	30.87 (13.93 – 46.69)	35.77 (26.49 – 44.57)
E_rC_{10}	n.d.	17.01 (5.41 – 29.28)	20.21 (13.23 – 27.18)
LOEC	7.38	> 236.26	23.63
NOEC	2.36	≥ 236.26	7.38

(-) – 95% confidence interval
n.d.- not determined

Table 4. Yield endpoint values based on the nominal concentrations of tribenuron methyl in the test item, definitive test

Endpoint value [mg/L]	Time of exposure:		
	24 h	48 h	72 h
E_yC_{50}	5.54 (n.d.)	25.13 (15.83 – 41.08)	21.74 (17.39 – 27.18)
E_yC_{20}	n.d.	3.33 (1.25 – 6.05)	5.72 (3.81 – 7.71)
E_yC_{10}	n.d.	1.16 (0.29 – 2.56)	2.84 (1.63 – 4.20)
LOEC	7.38	7.38	23.63
NOEC	2.36	2.36	7.38

Conclusion

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

The E_rC_{50}/72 h value is 144.42 mg/L (95% confidence interval: 122.94 – 171.33).

The E_yC_{50}/72 h value is 29.44 mg/L (95% confidence interval: 23.56 – 36.81).

The LOEC/72 h value for growth rate and yield is 32 mg/L.

The NOEC/72 h value for growth rate and yield is 10 mg/L.

The endpoint values determined based on the nominal concentrations of tribenuron methyl in the test item are given below:

The E_rC_{50}/72 h value is 106.63 mg/L (95% confidence interval: 90.77 – 126.50).

The E_yC_{50}/72 h value is 21.74 mg/L (95% confidence interval: 17.39 – 27.18).

The LOEC/72 h value for growth rate and yield is 23.63 mg/L.

The NOEC/72 h value for growth rate and yield is 7.38 mg/L.

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

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.3.1/01
Report	Tribenuron metyl 75 WG, Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, E. Xxxxxx, 2017, B/05/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes (OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.
Biological test system:	the honeybee, *Apis mellifera* L. strain: carnica source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna, age: approximately 3 weeks
Test design:	- test item: exposure time: 96 hours; number of doses: 5 doses and a control; number of replicates: 3 replicates; number of bees: 10 bees/replicate; - 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:	12.5, 25, 50, 100 and 200 µg/bee and control (0.0 µg/bee).
Reference item doses:	0.03, 0.06 and 0.12 µg a.i./bee.
Test conditions:	temperature: 22 – 25ºC; relative air humidity: 52 - 64%; place: a dark room
Endpoints:	- honeybee mortality after 96 hours of the exposure (LD_{50}), - LD_{50}/24 h value of the reference item (dimethoate)
Statistical method:	regression analysis using the log-probit method.

Summary

Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses enumerated 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 test 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 96-hour exposure.

Results and discussions

The median lethal doses (LD_{50}) after 24, 48, 72 and 96 hours of exposure are higher than the maximum used dose, i.e. 200 µg test item/honeybee (> 147.7 µg a.i./honeybee).

Dose		Number of tested bees [no.]	Mortality after 96 h		LD_{50} after 96 h	
			Total			
[µg test item/bee]	[µg a.i./bee]		[no.]	[%]	[µg test item/bee]	[µg a.i./bee]
0.0 (Control)		30	0	0.0	above 200.0	above 147.7
12.5	9.2	30	0	0.0		
25.0	18.5	30	0	0.0		
50.0	36.9	30	0	0.0		
100.0	73.8	30	1	3.3		
200.0	147.7	30	4	13.3		

Mortality of the control group after 96 h was 0.0%. Mortality in the groups exposed to the test item at the doses 12.5, 25, 50, 100 and 200 µg/bee (9.2, 18.5, 36.9, 73.8, 147.7 µg a.i./bee) after 96 h were 0.0, 0.0, 0.0, 3.3 and 13.3%. Signs of toxicity (behavioural abnormalities) such as paralysis of 3 bees were observed at the dose of 200 µg/bee after 24 hour of exposure.
After 48, 72 and 96 h of exposure no abnormal behavioural effects were observed.

The following validity criteria were met during the test:
- the average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%),
- the LD_{50}/24 h of the reference item (dimethoate) was 0.12 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee).

Conclusion

The median lethal doses (LD_{50}/24 h, LD_{50}/48, LD_{50}/72 and LD_{50}/96 h) are higher than the maximum dose used in the test, i.e. 200.0 µg test item/bee (147.7 µg a.i./bee).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the principles of GLP. Following deviation to the guideline were noted: This deviation concerned replacing anaesthesia with mechanical immobilization. Considering 0.0% mortality in the control group this deviation had no impact on the study results. In the definitive test all the validity criteria were met. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.3.1/02
Report	Tribenuron metyl 75 WG, Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, E. Xxxxxx, 2017, B/06/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes (OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008))
Deviations:	Yes ~~No~~
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG; content: 738.3 g/kg of tribenuron methyl; batch number: 12/16; production date: October 27, 2016; expiry date: October 27, 2018.
Biological test system:	the honeybee, *Apis mellifera* L. strain: carnica source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna, age: approximately 3 weeks
Test design:	- test item: exposure time: 48 hours; number of doses: 5 doses and a control; number of replicates: 3 replicates; number of bees: 10 bees/replicate - 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:	12.5, 25, 50, 100, and 200 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2, and 0.4 µg a.i./bee
Test conditions:	temperature: 24.5 – 25ºC relative air humidity: 61 – 64% place: a dark room
Endpoints:	- honeybee mortality after 48 hours of exposure (LD50) - the 24-h LD_{50} of the reference item (dimethoate)
Statistical method:	regression analysis using the log-probit method

Summary

The acute contact toxicity study of Tribenuron methyl 75 WG was conducted to determine the LD_{50}. Five doses of the test item were used. These included: 12.5, 25.0, 50.0, 100.0, and 200.0 µg/honeybee (9.2, 18.5, 36.9, 73.8, 147.7 µg a.i./honeybee). The range of doses was selected based on the preliminary test results. A micro applicator was used to apply the test item. The volume was 1 µl/bee. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e., dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure. After the application, the insects were observed for mortality and other 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.

Results and discussions

The median lethal doses (LD_{50}-24h and LD_{50}-48h) are higher than the maximum used dose, i.e. 200.0 µg test item/honeybee (> 147.7 µg a.i./honeybee).

Dose		Number of tested bees [no.]	Mortality after 48 h		LD_{50} after 48 h	
			Total			
[µg test item/bee]	[µg a.i./bee]		[no.]	[%]	[µg test item/bee]	[µg a.i./bee]
0.0 (Control)		30	0	0.0	above 200.0	above 147.7
12.5	9.2	30	0	0.0		
25.0	18.5	30	0	0.0		
50.0	36.9	30	0	0.0		
100.0	73.8	30	0	0.0		
200.0	147.7	30	2	6.7		

Mortality of the control group after 48 hours of exposure was 0.0%. Mortality of the bees in the control group and in all groups exposed to the test item at the doses of 12.5, 25.0, 50.0, 100.0 and 200.0 µg/bee (9.2, 18.5, 36.9, 73.8, 147.7 µg a.i./bee) after 48 h were 0.0, 0.0, 0.0, 0.0 and 6.7%. No signs of toxicity (behavioural abnormalities) such as excitement (uncoordinated movement, increased activity, or intensive cleaning) or paralysis were observed during the 48-hour exposure.

The following validity criteria were met during the test:
- the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%),
- the LD_{50}/24 of the reference item (dimethoate) was 0.23 µg/bee (criterion: 0.10 - 0.30 µg a.i./bee)

Conclusion

The median lethal doses (LD50/24 h and LD50/48 h) are higher than the maximum dose used in the test, i.e. 200.0 µg test item/bee (> 147.7 µg a.i./bee).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Study 1

Comments of zRMS:	The study was performed in 2016 according to OECD 213 (1998) and EPPO method 170 (2010). However, since there is the new guideline OECD 245 chronic oral toxicity test (10 day feeding test) (2017) adopted on 22 September 2017, zRMS evaluated the study according to the recent guideline and according to the principles of GLP. The test was considered valid as the results obtained met the set validity criterion: - Mortality observed in control treatment was equal or less than 15% for the duration of the test (final cumulated mortality = 2.00%). - Mean mortality in the reference product concentration was ≥ 50% at the end of the test (final cumulated mortality = 100.00%). No deviations were noted during the study all validity criteria were met. The study is considered acceptable.

Reference:	KCP 10.3.1/03
Report	Chronic toxicity of PP-108H (Tribenuron methyl 75 WG) test on honeybee (*Apis mellifera L*), Xxxxxx T, 2017, TRC15-250BA, TRIALCAMP S.L.U., Spain
Guideline(s):	Yes (CEB (2012), OECD 213, EPPO 170)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

I. MATERIALS AND METHODS

Test Material:	PP-108H (Tribenuron methyl 75WG)
Description:	Light beige solid
Lot/Batch #:	20150728-1
Purity:	Tribenuron methyl 75.6% w/w (analysed)
Stability of test compound:	Stable
Positive control:	Positive control: Perfekthion BASF 152111 (400g/L dimethoate)
Test species	
Species:	Honey bee (*Apis mellifera*)
Age:	Bees from a healthy colony were one day old The colony was queen-right.
Source:	176-V-026 (15km from test site)
Acclimation period:	1 day
Feeding:	50% (w/v) sucrose solution.
Water	Deionised water.
Housing:	10 bees per test cage.

Test duration: 10 days

Environmental conditions -

Temperature: 33 °C

Humidity: 50 to 70%

Photoperiod: Dark

B. STUDY DESIGN AND METHODS:

1. In life dates: 19-10-2016 to 29-10-2016

2.Animal assignment and treatment:

The bees were taken from a healthy queen-right colon that was disease free. The emerging worker bees were collected from sealed combs using a hatching box supplied with pollen for the newly emerged worker bees. After 24 hours the newly emerged worker bees were transferred to the experimental unit and acclimatised for one day to provide bees for the study that were two days old. All bees were active and healthy at the commencement of the study.

The ventilated stainless steel test units each containing one replicate of 10 bees were kept in an incubator at a temperature of 33C, a relative humidity of 59 to 70% in darkness. The bees were exposed continuously to the treatments which were made up in a 50% sucrose solution and administered by a syringe feeder. The syringe feeder was replaced daily and the quantity of sucrose solution taken by the test animals was recorded. All treatments were replicated five times.

Feeding solutions containing the test item and the positive control were prepared daily. The concentration of the test item was 840.34 mg ai/kg food equivalent to 132.8µg/bee/day of the product (100 µg/bee/day of tribenuron methyl). The dimethoate concentration was 0.9 mg ai/kg food equivalent to 0.273 µg/bee/day of the formulation (0.107 µg/bee/day of dimethoate ai). All treatments were dosed at 100µL solution/bee. The untreated control consisted of sucrose solution only. The test item rates were determined in a preliminary non-GLP study.

3. Observations:

Mortality - assessed daily.

Sublethal effects - assessed daily including whether or not bees were moribund or displaying abnormal behaviour (apathy, reduced coordination, vomiting, stationary for long periods of time, poor reaction to stimulus eg light).

Food consumption - total food consumption and consumption per individual bee (by calculation)

In order to adjust for possible evaporation of feeding solutions the loss in weight from syringe feeders in cages without bees were used to determine the evaporation constant which in turn was used to correct the food consumption data.

Analysis of feed solutions to determine concentrations of test items

4. Statistics:

LC_{50}/LDD_{50}: according to Trimmed Spearman-Karber procedure.
NOEC/NOEDD: was estimated by comparing mortality observed in the treatments with the test product with mortality of the control. Comparison was carried out with a non parametric pair-wise test (Mann-Whitney exact test).
All statistics was performed using the software SPSS 19

II. RESULTS AND DISCUSSION

A. MORTALITY

Mean cumulative mortality of the honeybees dosed orally with the test product for ten consecutive days was 6.00± 2.45%.

Cumulative mortality in the control after the ten days of exposure was 2.00 ± 2.00% .

Mean cumulative mortality of the reference product at ten days was 100.00%.

Estimated LDD_{50} at 10 days was higher than the mean consumed dose of 19.81µg Tribenuron-methyl per bee per day equal to 26.20 µg consumed formulated product/bee/day.

Based on the mortality data, the NOEDD at 10 days was determined to be 19.81 µg Tribenuron-methyl per beeper day, corresponding to 26.20 µg consumed formulated product/bee/day.

Consumed Diet

Daily mean consumption in the control group was 18.41 µl/bee of the offered diet. Mean daily consumption of the bees exposed to the test product was 19.81 µl/bee. Mean cumulative consumption (consumption over the ten days dosing period) was 198.10 µg Tribenuron methyl/bee. Daily consumption (in µl solution/bee/day) observed for the assayed test product concentration was not statistically significantly different than daily consumption of the control group. Daily mean consumption of the reference product bees was 17.25 µl/bee of the offered diet, which corresponds to a daily consumption of $1.85E^{-02}$ µg Dimethoate/bee. Cumulative consumption of the reference bees corresponded to a dose of 0.129 µg Dimethoate/bee.

Table A2.3.1.2-1: Food consumption over the test period

Treatment	Nominal Dose (µg a.i./bee/day)	Consumed solution (µl/bee/day)	Average consumed dose (µg a.i./bee)	
			Daily	Cumulative (10 days)
Sugar solution	--	18.41	--	--
Test product	100.00	19.81	19.81	198.10
Reference product	0.107	17.25	0.0185	0.129 (*)

(*) Cumulative over 7 days of application

Table A 2.3.1.2-2: Mean mortality after 10 days exposure

Treatment	Total number of bees dosed	Mean Consumed Dosage (µg a.i./bee/day)	Final Mortality (cumulative %)	SE	Abbotts' transformed mortality (%)
Sugar solution	50	--	2.00	2.00	--
Test product	50	19.81	6.00	2.45	4.08
Reference product	50	0.0185	100.00	--	100.00

Table A 2.3.1.2-3: Study endpoints

	LDD_{50}		NOEDD	
	formulated product	Tribenuron-methyl*	formulated product	Tribenuron-methyl*
Endpoints	> 26.20 µg	> 19.81 µg	26.20 µg	19.81 µg

*** Analytical content**

B. OTHER EFFECTS (BEHAVIOURAL OBSERVATION)

One affected bee of those exposed to the test product was observed both on Day 5 and Day 8 after the first application. No symptoms of intoxication were observed for the control bees throughout the study.

C VALIDITY CRITERIA

Control mortality <15% (final cumulated mortality = 2.00%).
Mean mortality in the reference product concentration was ≥ 50% at the end of the test (final cumulated mortality = 100.00%).

D ANALYTICAL DATA

The analysis of the treated solution was performed by CAMBIUM, S.L under the study number E16128 (Determination of Tribenuron-methyl in samples from ecotoxicological studies). The analytical study shows that recovery from test samples was 89.14%.
For further information please refer to the Core Assessment Part B Section 5 Analytical methods.

II. CONCLUSIONS

Treated diet with PP-108 H (Tribenuron methyl 75 WG) did not result in a statistically significantly difference in food consumption when compared to the untreated control.

Virtually no sub-lethal effects were observed throughout the study.

The estimated consumed chronic LDD_{50}-value for PP-108 H (Tribenuron methyl 75 WG) was higher than the mean consumed dose of 19.81 µg Tribenuron methyl/bee/day, equal to 26.20 µg consumed formulated product/bee/day.Based on the mortality data, the NOEDD at 10 days was determined to be 19.81 µg Tribenuron methyl/bee/day, corresponding to 26.20 µg consumed formulated product/bee/day.

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

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages (= larval toxicity)

Study 1

Comments of zRMS:	The Applicant presented single exposure study on larval Toxicity of Tribenuron methyl 75 WG. The study was conducted to OECD guideline 237 and according to the principles of GLP. In the definitive test no deviation was noted. The following validity criteria were met: - Average mortality of the control group treated with distilled water was 11.1% at the end of the experiment. Criterion: ≤ 15% - Mortality of the larvae treated with the reference item (dimethoate) was 56.3% (corrected using Abbott's formula Criterion: ≥ 50% on D7. The Applicant presented Larval Toxicity Test with single exposure while larval toxicity test with repeated exposure should be provided to cover not only acute but also chronic exposure to larva. However, zRMS is of the opinion that the study can be used in risk assessment because the formulation Tribenuron methyl 75 WG is an herbicide (insecticidal action is not expected) used only once during the season in cereals and grasses. Also, it should be noted that for other non-target arthropods other than bees low risk for in-field and off-field habitats was concluded. Overall, the study is considered acceptable. Nevertheless, concerned Member States must decide on the consideration of data requirements of the EFSA Bee guidance (2013) on national level.

Reference:	KCP 10.3.1 /04
Report	Xxxxxx T 2017, Toxicity of PP-108H (Tribenuron methyl 75 WG) test on honeybee (*Apis mellifera L*) after repeated exposure under laboratory conditions. TRC15-249BA, TRIALCAMP S.L.U., Spain
Guideline(s):	OECD 237, EPPO 170
Deviations:	No
GLP:	Yes
Acceptability:	Yes/Consideration on MS level
Duplication (if vertebrate study)	No

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material:	PP-108H (Tribenuron methyl 75WG)
Description:	Light beige solid
Lot/Batch #:	20150728-1
Purity:	Tribenuron methyl 75.6% w/w (analysed)
Stability of test compound:	Stable
Positive control:	Positive control: Perfekthion BASF 152111 (400g/L dimethoate)
2. Test species -	
Species:	Honey bee (*Apis mellifera*)
Age:	Synchronized first instar (L1) larvae originating from three adequately fed, healthy, as far as possible parasite-free and queen-right colonies.
Source:	Trialcamp S.L.U., Poligono Industrial l'Alter, Avda. Antic Regne de Valencia, 25 46290 Alcasser (Valencia), Spain
Acclimation period:	No acclimatisation period. However please refer to animal assignment in treatment below as the three days in the study prior to treatment could be considered an acclimatisation period.

Feeding:

The larval Diet A was prepared freshly at D1 of the test; Diet B and C were prepared freshly prior to use. Each larva was fed once a day (except on day 2 (D2)) with a standardised amount of artificial diet until day 6. (D6).

Diet A (D1, volume administered: 20 µL/larva): 44.25% w/w of fresh royal jelly + 44.25% weight of an aqueous solution containing 0.9% w/w of yeast extract, 5.3% w/w of glucose and 5.3% w/w of fructose.

Diet B (D3, volume administered: 20 µL/larva): 42.956% w/w of fresh royal jelly + 42.94% w/w of an aqueous solution containing 1.3% w/w of yeast extract, 6.4% w/w of glucose and 6.4% w/w of fructose.

Diet C (D4 to D6): 50% w/w of fresh royal jelly + 30% w/w of an aqueous solution containing 2.0% w/w of yeast extract, 9.0% w/w of glucose and 9.0% w/w of fructose.
The following volumes of diet were administered on days D4 to D6: D4 = 30 µL, D5 = 40 µL, D6 = 50 µL. Care was taken to avoid damaging the larval during the feeding process.

Housing:

Larvae were transferred into crystal polystyrene grafting cells having a diameter of 9 mm. Each cell was placed into a well of a sterile 48-well cellular culture plate. Open plates of the control group, all test item groups and the reference item group were individually placed into hermetically sealed Plexiglas desiccators in order to maintain a water saturated atmosphere from day 1 to day 8.

Test duration: 8 days

3. Environmental conditions -

Temperature: 34 - 35°C

Humidity: 58.81 to 100%

Photoperiod: Dark

B. STUDY DESIGN AND METHODS:

1. In life dates: 19-09-2016 to 26-09-2016

2.Animal assignment and treatment:

The hives used for honey bee larvae collection were adequately fed, healthy, as far as possible parasite-free and queen-right. Four days prior to grafting of larvae (D-3) in order to synchronize the age of larvae used in the test the queens of at least three colonies were confined in their own colony in an excluder cage containing a comb with empty cells. Three days prior to grafting (D-2), and a maximum 30 hours after encaging, the queens were released from the cages. The combs containing eggs were left in the excluder cages during the incubation stage until hatching on day 1 (D1). In the laboratory 48 larvae (16 larvae/ hive) were selected for grafting. Before the first application of the test item on day 3 (D3), a check was conducted to ensure all larvae used were of similar size and alive. On day 1 (D1) 20 µL of diet A were dropped into each grafting cell of the well plate. Using a grafting tool one larva was transferred from the comb to each cell on the surface of the diet. Larvae were grafted in excess to replace non-suitable larvae with individuals from the reserve plates on day 3 (D3). When a plate was completed it was placed into a hermetically sealed Plexiglas desiccator.

The study was conducted as a dose response test with a duration of 8 days from grafting on day 1 (D1) to the final assessment on day 8 (D8). Five concentrations of the test item in the diet (0.633, 0.842, 1.20, 1.489 and 1.981 µg test item/µL equivalent to cumulative doses of 88.62, 117.87, 156.76, 208.5 and 277.3µg/larvae) a positive control (Dimethoate 40 mg in the diet equivalent to 0.9 - 2.2µg/larvae equivalent to a cumulative dose of 6.2µg/larvae) and an untreated control. For each treatment group 48 larvae from three different hives were tested over 8 days. Each hive equates to one replicate and 16 larvae from each replicate were used.

3. Observations:

Mortality: assessments were conducted before feeding on day 4 (D4), 5 (D5), day 6 (D6), day 7 (D7) and day 8 (D8).

Larval appearance: size and general health.

Food consumption: the presence of an uneaten food was recorded.

4. Statistics:

For mortality data of the test itema non-parametric pair-wise test (Fisher'sexact test) was employed. For the estimation of the No Observed Effect Dose a standard probit analysis (Finney 1971) was performed for the calculation of the LD_{50}-value at D8. All statistics were performed using the statistical software SPSS 19; SPSS©Onc, 1989-2010

II. RESULTS AND DISCUSSION

A. MORTALITY

In the untreated control group cumulative larval mortality on day 8 (D8) was 0 %. Cumulative mortality in the dimethoate treatment group was 100 %

On day 8 the test item doses of 88.62, 117.87, 156.76, 208.5 and 277.3µg/larvae cumulative mean mortality was 4.17, 8.33, 45.83, 64.85 and 97.92% respectively.

On D8 in the control group and at the lowest test item treatment one individual of the surviving larvae had unconsumed diet. In the 117.87 and 156.76 test item treatments two individuals of the surviving larvae had unconsumed diet. In the 208.5 test item treatment five larvae had unconsumed diet.

Table A 2.3.1.2-1: Mean mortality of tribenuron methyl to honeybee larvae

Treatment and		***Apis mellifera larvae***				
Exposure		**Cumulative mortality (%)**				
Treatment group	Concentration (µg/larvae)	D4	D5	D6	D7	D8
Tribenuron methyl	88.62	2.08	2.08	2.08	4.17	4.17
	117.87	0.00	0.00	4.17	6.25	8.33
	156.76	0.00	4.17	18.75	41.67	45.83
	208.50	0.00	18.75	47.92	60.42	64.58
	277.30	0.00	18.75	77.08	89.58	97.92
Untreated control	--	0.00	0.00	0.00	0.00	0.00
Dimethoate	6.20	35.42	79.17	97.92	100.00	100.00

Table A 2.3.1.2-4: Study endpoints

	LD_{50}(120hr) µg a.i./larvae		**NOED (µg/larva/developmental period D3 to D8)**	
	formulated product	**Tribenuron-methyl***	**formulated product**	**Tribenuron-methyl***
Endpoints	235.53	176.06	155.91	117.87

B. OTHER EFFECTS (BEHAVIOURAL OBSERVATION)

No behavioral impairments other than failure to consume food resulting in under development were observed.

C. VALIDITY CRITERIA

All validity criteria were met

D ANALYTICAL DATA

Please refer to the Core Assessment Part B Section 5 Analytical methods

III. CONCLUSIONS

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

The estimated LD_{50}120 hours value for PP-108 H (Tribenuron methyl 75 WG) corresponded to a cumulative dose of 178.06 µg Tribenuron-methyl/larva equivalent to 235.53 µg formulated product/larva., The NOED is 117.87 µg Tribenuron-methyl/larva equivalent to 155.91 µg formulated product/larva.

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

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 arthropods other than bees

A 2.3.2.1 Study 1

Comments of zRMS:	The study follows the guideline specified by Mead Briggs M.A. et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met. The study is considered acceptable.

Reference:	KCP 10.3.2
Report	A laboratory test for evaluating the effects of Tribenuron metyl 75 WG on the parasitic wasp, *Aphidius rhopalosiphi* (Xxxxxx) E. Xxxxxx, 2018, B/07/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes (ESCORT 1 (Xxxxxx K.L. et al., 1994), ESCORT 2 (Xxxxxx M.P. et al., 2001) IOBC, BART and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	Name: Tribenuron metyl 75 WG, content: tribenuron methyl 738.3 g/kg, batch number: 12/16, production date: October 27, 2016; expiry date: October 27, 2018
Biological test system:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae – age: adult females (24 - 48 hours after emerging from mummies) – source: a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)

Test unit:	The test unit for mortality assessment (exposure unit) consisted of two glass plates (12 x 12 cm) fitted with rubbers to a stainless-steel frame. On the side walls, there were ten holes covered with fine-gauge mesh providing ventilation for the insects and two holes to introduce the wasps to the test units. Later these holes were sealed with cotton bungs soaked with a 1:3 v/v solution of honey in water used as a source of food. For fecundity assessment, the test unit consisted of a transparent PMMA cylinder (isolator) with a diameter of 11 cm and a height of 20 cm put on a plastic pot with a diameter of 12 cm. The pots contained 20 untreated seedlings of 7-day-old barley infested with the bird cherry-oat aphid, Rhopalosiphum padi (more than 100 aphids per pot). To provide good ventilation, the apex of each cylinder and two longitudinal openings on its two sides were covered with metal netting. There was a hole in the cylinder enabling introduction of the wasps to the test unit. The hole was filled with a cotton bung soaked with a 1:3 v/v solution of honey in water.
Experimental design:	5 test groups: – a control group (0.0 g/ha) – Tribenuron metyl 75 WG at the rate of 6.25 g/ha (4.6 g a.i./ha) – Tribenuron metyl 75 WG at the rate of 12.5 g/ha (9.3 g a.i./ha) – Tribenuron metyl 75 WG at the rate of 25.0 g/ha (18.5 g a.i./ha) – Danadim 400 EC at the rate of 0.1 mL/ha (0.04 g a.i./ha) number of replicates: 4 replicates/group number of wasps: 10 wasps/replicate
Test conditions:	**Temperature:** 19.0 – 21.0°C **Humidity:** 68-73% **Photoperiod:** 16 h light/8h dark
Statistical analyses:	Probit analysis, Chi2 2x2 Table test with Bonferroni Correction, ShapiroWilk's test on normal distribution, Levene's test on variance homogeneity, Dunnett's Multiple t-test procedure.
Endpoints:	– wasp mortality after 48 hours of exposure – determination of the LR50 and the NOERmortality – reduction in fecundity (Pr) of surviving female wasps exposed Tribenuron metyl 75 WG, recorded 12 days after the oviposition period – determination of the ER50 and the NOERfecundity

The laboratory test involved the evaluation of the effects of the test item, Tribenuron metyl 75 WG on mortality and fecundity of the parasitic wasp, Aphidius rhopalosiphi. On the basis of the results of the non-GLP preliminary test and consultations with the Sponsor, the definitive test was performed on three rates of the test item. These were: 6.25, 12.5, and 25.0 g/ha (i.e. 4.6, 9.3, and 18.5 g a.i./ha).
Adult wasps were exposed to the test item applied to glass plates. Mortality assessments were made 2, 24, and 48 hours after the introduction of the wasps to the test arenas.
Then, females which survived 48-hour exposure to Tribenuron metyl 75 WG at all tested rates i.e. 6.25, 12.5, and 25.0 g/ha (i.e. 4.6, 9.3, and 18.5 g a.i./ha) and the ones from the control group were subjected to fecundity assessment. To allow the oviposition, fifteen female wasps from the groups treated with Tribenuron metyl 75 WG at the rates of 6.25, 12.5, and 25.0 g/ha 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.

Results and discussions

The effects of Tribenuron metyl 75 WG on mortality and fecundity of *Aphidius rhopalosiphi* in the laboratory test are summarized below.

Study group [application rate]		Parameter (endpoint)							
		Mortality after 48 h				Fecundity			
Test item		Total [%]	Corrected [d] [%]	LR_{50}		mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50}	
[g/ha][a]	[g a.i./ha][b]			[g/ha] [a]	[g a.i./ha] [b]			[g/ha] [a]	[g a.i./ha] [b]
Control (0.0)		5.0	-	-		14.9	-	-	
6.25	**4.6**	12.5	**7.9**			15.9	(-6.3)		
12.5	**9.3**	12.5	**7.9**	**> 25.0**	> 18.5	14.7	1.8	**> 25.0**	> 18.5
25.0	**18.5**	15.0	**10.5**			14.3	4.0		
$NOER_{mortality}$				**≥ 25.0**	≥ 18.5	$NOER_{fecundity}$		**≥ 25.0**	≥ 18.5
Reference item		Mortality after 24 h				—			
[mL/ha][c]	[g a.i./ha] [b]								
0.1	**0.04**	80.0	**79.5**	not determined		not assessed			

[a]: [g test item/ha]
[b]: [g active ingredient/ha]
[c]: [mL reference item/ha]
[d]: mortality corrected using the formula of Abbott [1]
*: The negative value indicates higher mean number mummies per female in the group treated with the test item than in the control group.

After 48 hours mortality of the control wasps was 5.0%. After 48 hours of exposure to Tribenuron metyl 75 WG at the rates of 6.25, 12.5 and 25.0 g/ha (i.e. 4.6, 9.3, and 18.5 g a.i./ha) the percentages of mortality corrected using the formula of Abbott, were 7.9, 7.9 and 10.5%, respectively.
Mortality of the wasps exposed to Danadim 400 EC at the rate of 0.1 mL/ha, corrected using the formula of Abbott was 79.5% after 24 hours. Therefore, the validity criterion specified in the Method description was met. 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 14.9. As for the wasps treated with Tribenuron metyl 75 WG at the rates of 6.25, 12.5 and 25.0 g/ha (i.e. 4.6, 9.3, and 18.5 g a.i./ha), the mean numbers of mummies/female were 15.9, 14.7 and 14.3, respectively.

The following validity criteria were met during the study:
– after 48 hours mortality of the control group was 5.0% (criterion: a maximum of 13.0%),
– after 24 hours the Abbott corrected mortality of the group treated with the reference item at the rate of 0.1 mL/ha was 79.5% (criterion: from 75 to 100%),

– the mean number of mummies per female in the control group was 14.9 (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).

Conclusions:

On the basis of the obtained results it can be concluded that Tribenuron metyl 75 WG at all the rates i.e.

6.25, 12.5 and 25.0 g/ha (4.6, 9.3, and 18.5 g a.i./ha) has no adverse effect on mortality and fecundity of the wasps.
On the basis of the obtained mortality results, the LR_{50} and the $NOER_{mortality}$ values could not be estimated. It can only be concluded that the LR_{50} value is higher than the highest tested rate, i.e. > 25.0 g/ha (> 18.5 g a.i./ha) and $NOER_{mortality}$ is higher than or equal to the highest tested rate, i.e. 25.0 g/ha (≥ 18.5 g a.i./ha).

A 2.3.2.2 Study 2

Comments of zRMS:	The study follows the guideline specified by Xxxxxx et al. (2000) and according to the principles of GLP. No deviations to the guideline were noted. In the definitive test all the validity criteria were met as follows: The study is considered acceptable.

Reference:	KCP 10.3.2
Report	A laboratory test for evaluating the effects of Tribenuron metyl 75 WG on the predatory mite, *Typhlodromus pyri* (Sch.), E. Xxxxxx, 2017, B/08/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes (ESCORT 1 (Xxxxxx K.L. et al., 1994), ESCORT 2 (Xxxxxx M.P. et al., 2001) IOBC, BART and EPPO Joint Initiative (Xxxxxx S. et al., 2000))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	name: Tribenuron metyl 75 WG, content: tribenuron methyl 738.3 g/kg, batch number: 12/16, production date: October 27, 2016; expiry date: October 27, 2018
Biological test system:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: Phytoseiidae) – age: 24-hour-old protonymphs, – source: a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna [SOP/B/33]; the culture was obtained from the Research Institute of Pomology and Floriculture, Skierniewice, Poland the mites are reared on the bean, Phaseolus vulgaris L. (Fabaceae) infested with the two-spotted spider mite, Tetranychus urticae Koch.,
Test unit	Each test set consisted of a glass tray filled with water and a glass bench containing 5 test units. Plastic discs (ϕ 45 mm) were floating on the water surface in glass Petri dishes ('island dishes', ϕ 54 mm) with central holes at the bottom (ϕ 6 mm). Water in the test units prevented the mites from escaping.
Experimental design:	– 6 study groups: – a control group (0.0 g/ha) – Tribenuron metyl

	75 WG at the rate of 3.13 g/ha (i.e. 2.3 g a.i./ha) – Tribenuron metyl 75 WG at the rate of 6.25 g/ha (i.e. 4.6 g a.i./ha) – Tribenuron metyl 75 WG at the rate of 12.5 g/ha (i.e. 9.2 g a.i./ha) – Tribenuron metyl 75 WG at the rate of 25.0 g/ha (i.e. 18.5 g a.i./ha) – Danadim 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha) number of replicates: 3; number of mites in each replicate: 20
Test conditions:	**Temperature:** 24.0 – 26.0°C **Humidity:** 60-90% **Photoperiod:** 16 h light/8h dark
Statistical analysis:	regression analysis using the log-probit method, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, ch^{i2} 2x2 table test with Bonferroni correction, Dunnett's Multiple t-test Procedure
Endpoints:	– mite mortality after 7 days of the treatment (LR50 and NOER-mortality) – reproduction reduction (Pr) after 14 days of the treatment (ER_{50} and NOERreproduction)

Summary

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

On the basis of the non-GLP preliminary test results it was decided to use four rates of the test item in the definitive test. These were: 3.13, 6.25, 12.5, and 25.0 g/ha (2.3, 4.6, 9.2, and 18.5 g a.i./ha). 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.) and T. urticae eggs. 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 10, 12, and 14 days of the treatment.

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.

Results and discussions

The effects of Tribenuron metyl 75 WG on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Study group [application rate]		Parameter (endpoint)						
		Mortality			Reproduction			
Test item			LR_{50}		Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]	ER_{50}	
[g/ha] [a]	[g a.i./ha] [c]	[%] [d]	[g/ha] [a]	[g a.i./ha] [c]			[g/ha] [a]	[g a.i./ha] [c]
Control (0.0)		-	-		7.1	-	-	
3.13	**2.3**	(-3.9) *	> 25	> 18.5	7.7	**(-9.0)** **	> 25	> 18.5
6.25	**4.6**	0.0			7.7	**(-8.4)** **		
12.5	**9.2**	3.9			7.6	**(-6.7)** **		
25.0	**18.5**	5.8			6.4	**9.9**		
$NOER_{mortality}$			≥ 25	≥ 18.5	$NOER_{reproduction}$		≥ 25.0	≥ 18.5
Reference item		-						
[mL/ha] [b]	[g a.i./ha] [c]							
9.0	**3.6**	92.3	not determined		not assessed			

[a]: [g test item/ha]
[b]: [mL reference item/ha]
[c]: [g active ingredient/ha]
[d]: mortality corrected using the formula of Abbott [1]
*: the negative value indicates lower mortality in the treated group than in the control group
**: the negative values indicate higher mean reproduction value in the treated group than in the control group

In the definitive test, mortality of the control group after 7 days of exposure was 13.3%. After 7 days of exposure to Tribenuron metyl 75 WG at the rates of 3.13, 6.25, 12.5 and 25.0 g/ha the percentages of mortality of *T. pyri*, corrected using the formula of Abbott, were (-3.9), 0.0, 3.9 and 5.8%, respectively. The mean reproduction rate (Rr) in the control group was 7.1 eggs/female. The mean reproduction rates after 14 days of exposure to Tribenuron metyl 75 WG at the rates 3.13, 6.25, 12.5 and 25.0 g/ha were 7.7, 7.7, 7.6, and 6.4 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by Tribenuron metyl 75 WG at the rates of 3.13, 6.25, 12.5 and 25.0 g/ha were (-9.0), (-8.4), (-6.7), and 9.9%, respectively. The negative values indicate higher mean reproduction value in the treated group than in the control group.
On the basis of the obtained mortality results, the LR_{50} and the $NOER_{mortality}$ values could not be estimated. It can only be concluded that the LR_{50} value is higher than 25.0 g/ha (> 18.5 g a.i./ha) and the $NOER_{mortality}$ is higher than or equal to 25.0 g/ha (≥ 18.5 g a.i./ha).

The following validity criteria were met during the study:
– mortality of the control group was 13.3% 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 92.3% on day 7 of exposure (criterion: a minimum of 50%),
– the mean number of eggs per female in the control group was 7.1 (required: ≥ 4 eggs per female).

Conclusions:

On the basis of the obtained results it can be concluded that Tribenuron metyl 75 WG at the rates of 3.13, 6.25, 12.5 and 25.0 g/ha (2.3, 4.6, 9.2, and 18.5 g a.i./ha) has no adverse effect on mortality and 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 was conducted to OECD guideline 222 and according to the principles of GLP. It was noted that in table with summary results the NOEC for reproduction is reported as 100 while it should be 180 mg/kg dry weight of the artificial soil provided. Correct table from the study was directly copied by zRMS in the study summary. Temperature was shortly outside the recommended by guideline range, this deviation did not influence results of the study. All the validity criteria were met according to OECD Guideline No. 222. The study is reliable and suitable for the risk assessment.

Reference:	KCP 10.4.1.1
Report	TRIBENURON METYL 75 WG Earthworm Reproduction Test *(Eisenia andrei)*, Anna Xxxxxx, 2018, Study code G/154/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 222 (2016)
Deviations:	The temperature during the experiment was between 18 – 22.5 °C, it should have been between 18.0 – 22.0°C. However, it was a short-term deviation which did not affect the course of the experiment or the results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

1. Test material: TRIBENURON METYL 75 WG
   Batch number: 12/16
   Concentration of the concentration of the Tribenuron-methyl 738.3 g/kg

2. Test organism: adult (about 2 months old) the earthworms, *Eisenia andrei* (body weight between 341 – 434 mg) *obtained* from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology

3. Test design: test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate

4. Concentrations of the test item: control, 18, 32, 56, 100, 180, 320, 560, and 1000 mg/kg dry soil

5. Composition of artificial soil: 10% sphagnum peat, 20% kaolin clay, 70% industrial sand

6. Test Conditions: temperature: 19 – 22°C; pH at the beginning of the test: 5.50 – 5.84;

pH at the end of the test: 5.67 – 6.12; soil moisture content at the beginning of the test: 15.1 – 16.0% (47.0 – 49.6% of the maximum water holding ca-pacity); soil moisture content at the end of the test: 14.3 – 14.8% (44.3 – 45.9% of the maximum water holding capacity); lighting: 16 h light and 8h dark; light intensity: 576 - 661 lux

The aims of the study were to assess the impact of TRIBENURON METYL 75 WG on reproduction of the earthworm, *Eisenia andrei* and to determine the EC_{10}, EC_{20}, EC_{50}, and NOEC. The test item in the form of an aqueous solution was mixed with a suitable amount of the artificial soil. The concentrations of the test item were 18, 32, 56, 100, 180, 320, 560, and 1000 mg/kg dry soil. Each of them was divided into four replicates. There were also untreated control group (with deionized water and without test item) divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all adult earthworms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Results and discussions

On the basis of the results, it was concluded that after 4 weeks, at the control group there was no mortality of adult earthworms noticed. At concentrations ranging from 18 to 1000.0 mg/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 5.0%.

Mortality of the Adult Earthworms

Concentration [mg/kg dry soil]	Replicate	Number of tested earthworms [no.]	Number of dead earthworms [no.]	Total mortality	
				no.	%
0 (control)	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
	5	10	0		
	6	10	0		
	7	10	0		
	8	10	0		
18	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
32	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
56	1	8	2	2	5.0
	2	10	0		
	3	10	0		
	4	10	0		
100	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
180	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
320	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
560	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		
1000	1	10	0	0	0
	2	10	0		
	3	10	0		
	4	10	0		

No changes in the appearance (morphology) and behaviour of the earthworms were noticed.

Concentration [mg/kg dry soil]	Replicate	Number of tested earthworms [no.]	Changes in behaviour and in morphology*
0 (control)	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
	5	10	10 nc
	6	10	10 nc
	7	10	10 nc
	8	10	10 nc
18	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
32	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
56	1	10	2 d, 8 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
100	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
180	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
320	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
560	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc
1000	1	10	10 nc
	2	10	10 nc
	3	10	10 nc
	4	10	10 nc

* nc – no changes, d - dead

Body Weights of the Adult Earthworms

After the application of the test item at the concentrations ranging from 18 to 1000.0 mg/kg dry soil, the body weight increase was between 12.8 to 30.5%. As for the control group, it was equal to 29.7%.

Concentration [mg/kg dry soil]	Replicate	At the beginning of the experiment		After 4 weeks of the experiment		Body weight increase/decrease		Mean body weight increase	
		Number of earthworms [no.]	Mean weight of 1 earthworm [mg]	Number of earthworms [no.]	Mean weight of 1 earthworm [mg]	mg	%	mg	%
0 (control)	1	10	434	10	488	54	12.4	111.9	29.7
	2	10	375	10	485	110	29.3		
	3	10	413	10	527	114	27.6		
	4	10	386	10	475	89	23.1		
	5	10	351	10	507	156	44.4		
	6	10	386	10	503	117	30.3		
	7	10	386	10	485	99	25.6		
	8	10	347	10	503	156	45.0		
18	1	10	383	10	483	100	26.1	112.5	30.5
	2	10	365	10	466	101	27.7		
	3	10	368	10	510	142	38.6		
	4	10	359	10	466	107	29.8		
32	1	10	380	10	462	82	21.6	106.5	28.4
	2	10	341	10	475	134	39.3		
	3	10	393	10	489	96	24.4		
	4	10	403	10	517	114	28.3		
56	1	10	373	8	566	193	51.8	110.8	29.0
	2	10	410	10	471	61	14.9		
	3	10	400	10	485	85	21.3		
	4	10	368	10	472	104	28.3		
100	1	10	392	10	418	26	6.6	87.8	24.7
	2	10	377	10	468	91	24.1		
	3	10	347	10	443	96	27.7		
	4	10	342	10	480	138	40.4		
180	1	10	362	10	454	92	25.4	98.8	27.1
	2	10	354	10	451	97	27.4		
	3	10	374	10	501	127	34.0		
	4	10	365	10	444	79	21.6		
320	1	10	394	10	451	57	14.5	56.0	14.4
	2	10	391	10	452	61	15.6		
	3	10	395	10	446	51	12.9		
	4	10	372	10	427	55	14.8		
560	1	10	412	10	498	86	20.9	49.8	12.8
	2	10	385	10	443	58	15.1		
	3	10	414	10	411	-3	-0.7		
	4	10	362	10	420	58	16.0		
1000	1	10	360	10	457	97	26.9	66.5	17.1
	2	10	418	10	488	70	16.7		
	3	10	415	10	475	60	14.5		
	4	10	381	10	420	39	10.2		

Reproductive Assessment

After 8 weeks of the experiment, it was concluded that **TRIBENURON METYL 75 WG** had an impact on reproduction of the earthworms in concentrations ranging from 320 to 1000 mg/kg dry weight of the artificial soil.

Concentration [mg/kg dry soil]	Replicate	Number of juveniles [no.]	Mean ±SD	Comparison to the control [%]	CV** [%]
0 (control)	1	182	204.5 ± 33.0	100.0	16.1
	2	196			
	3	182			
	4	202			
	5	198			
	6	167			
	7	248			
	8	261			
18	1	178	195.0 ± 39.6	95.4	20.3
	2	151			
	3	208			
	4	243			
32	1	192	202.5 ± 31.4	99.0	15.5
	2	223			
	3	232			
	4	163			
56	1	211	191.0 ± 17.4	93.4	9.1
	2	169			
	3	195			
	4	189			
100	1	205	176.8 ± 24.7	86.4	14.0
	2	162			
	3	189			
	4	151			
180	1	150	173.0 ± 40.7	84.6	23.6
	2	186			
	3	224			
	4	132			
320	1	160	161.5* ± 9.5	79.0	5.9
	2	174			
	3	151			
	4	161			
560	1	132	115.8* ± 21.4	56.6	18.5
	2	108			
	3	89			
	4	134			
1000	1	81	94.5* ± 21.3	46.2	22.5
	2	126			
	3	89			
	4	82			

* - statistically significant difference between the control group and the group treated with the test item (Williams Multiple Sequential t-test Procedure, alpha = 0.05); ** CV – coefficient of variation

ECx values for the number of offspring, survival of adult earthworms as well as the NOEC and LOEC values were calculated using the ToxRat Professional statistical program and are presented below:

Endpoint values determined during the earthworm reproduction test (*Eisenia andrei*).

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg active ingredient/kg dry soil]
EC_{10}	**104.7** (56.2 – 151.8)	**77.3** (41.5 – 112.1)
EC_{20}	**216.2** (148.3 – 278.6)	**159.6** (109.5 – 205.7)
EC_{50}	**866.6** (675.2 – 1251.8)	**639.8** (485.2 – 924.2)
NOEC	**180**	**132.9**
LOEC	**320**	**236.3**
LC_{50}	**> 1000**	**> 738.3**

Parameter	Value [mg/kg dry weight of artificial soil]	Value [mg active ingredient/kg dry soil]
EC_{10}	104.7 (56.2 – 151.8)	77.3 (41.5 – 112.1)
EC_{20}	216.2 (148.3 – 278.6)	159.6 (109.5 – 205.7)
EC_{50}	866.6 (675.2 – 1251.8)	639.8 (485.2 – 924.2)
NOEC	100	132.9
LOEC	320	236.3
LC_{50}	> 1000	> 738.3

The results are considered valid because the following **criteria** were satisfied in the controls:

- each replicate produced 204.5 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 16.1% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%).

Conclusion:
In the course of this experiment and the statistical calculations performed, it was shown that test material does not affect the survival and growth (expressed in mass change) of adults in 4 weeks of experiment. But it affects reproduction expressed in the number of young earthworms under the end of the study in the concentration range 320 to 1000 mg/kg dry weight of the artificial soil. The NOEC for reproduction was determined as 180 ~~100~~ mg/kg dry weight of the artificial soil.

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

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. Deviations of soil extraction and temperature were noted. A blank sample was prepared in the same way as the soil extract. Method of extraction in control group and two treated groups was the same, thus the comparison of the results is reliable, and these changes did not influence results of the study. In the definitive test all the validity criteria were met. On the basis of the results, it was concluded that TRIBENURON - METYL 75 WG at the concentrations of 0.033 mg test item/kg of soil (i.e. 0.025 mg a.s/kg soil) and 5xPEC: 0.165 mg the test item/kg of soil (i.e. 0.125 mg a.s/kg soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference:	KCP 10.5
Report	TRIBENURON - METYL 75 WG Soil Microorganisms: Nitrogen Transformation Test, Anna Xxxxxx, 2018, Study code G/155/17, Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 216 (2000) / EU Method C.21.
Deviations:	Deviations from the OECD Guideline No. 21~~2~~6 (2000): 1. According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction will be 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. The deviation did not affect the results of the study. 2. The test room temperature during the experiment should be from 18.0 to 20.0˚C but it ranged from 17.0 to 22.0˚C. The temperature changes were short – lived and they did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

1. Test material: TRIBENURON METYL 75 WG
   Batch number: 12/16
   Concentration of Tribenuron-methyl 738.3 g/kg

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

3. Test design: test duration: 28 days; 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.

The aim of the study was to detect long-term adverse effects of TRIBENURON METYL 75 WG on the processes of nitrogen transformation in aerobic surface soils. Experiment was performed on freshly collected, agricultural soil. The soil was manually cleared of large objects and sieved to a particle size of 2 mm. The test item in form of aqueous oil suspension was mixed with soil. The concentrations of the test item were 0.033 mg test item/kg of soil (i.e. 0.025 mg a.s/kg soil) and 5xPEC: 0.165 mg the test item/kg of soil (i.e. 0.125 mg a.s/kg soil). The treated and the control soils were divided into three replicates. On days 0, 7, 14 28 of incubation, soil samples were collected to determine the quantities of nitrates. The method involves a measurement of the nitrate ion concentration in a soil extract obtained by using deionized water. 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 and discussions

There were no statistically significant differences between the control and the group treated with test item at both concentrations. i.e. PEC and 5×PEC in nitrate formation rates at time intervals 0 - 14 days. For the time interval 0 – 7, there was a statistically significant difference between the control group and the group treated with the test item only at the higher concentration of the test item, i.e. 0.165 mg of the test item/kg soil. There were statistically significant differences between the control and the group treated with test item at both concentrations. i.e. PEC and 5×PEC in nitrate formation rates at time intervals 0 - 28 days.

Time interval [d]	Control				PEC 0.033 mg/kg soil				5 x PEC 0.165 mg/kg soil			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 - 7	21.54	12.75	8.46	14.25 ± 6.66	0.631	17.6	-8.30	3.22 ± 13.17	-3.89	-5.75	-3.18	-4.27* ± 1.33
0 - 14	28.41	19.31	20.16	22.63 ± 5.03	23.46	24.64	28.85	25.65 ± 2.84	22.99	17.38	23.99	21.45 ± 3.56
0 - 28	48.26	44.72	48.53	47.16 ± 2.12	38.19	38.00	42.82	39.67* ± 2.73	35.44	38.28	34.53	36.08* ± 1.96

* statistically significant difference between the control and the treated group (Williams Multiple Sequential t-test Procedure, $\alpha = 0.05$)

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

The percent deviation from the control calculated on the basis of the nitrate formation rate of the soil treated with the test item at both concentrations (PEC and 5 x PEC) did not exceed 25% on 42 day of the analysis.

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

Time interval [d]	PEC 0.033 mg/kg soil	5 x PEC 0.165 mg/kg soil
0 - 7	76.7	130.0
0 - 14	-13.4	5.2
0 - 28	15.9	23.5

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

Validity criteria:
The coefficients of variation (CV) in the control group were 3.7, 4.1, 5.2 and 2.5% after 0, 7, 14, 28 of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Conclusion:
As regards to the obtained results, it was concluded that TRIBENURON METYL 75 WG at the concentrations corresponding to the 0.033 mg test item/kg of soil (i.e. 0.025 mg a.s/kg soil) and 5xPEC: 0.165 mg the test item/kg of soil (i.e. 0.125 mg a.s/kg soil) can be perceived as having no long-term influence on nitrogen transformations in soil.

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 seedling emergence study was conducted to OECD guideline 208 and according to the principles of GLP. Since in the definitive test all the validity criteria were met the study is considered acceptable for the risk assessment purposes.

Reference:	KCP 10.6.2/01
Report	TRIBENURON METYL 75 WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, Anna Xxxxxx, 2018, Study code G/156/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test"
Deviations:	• The number of seeds per pot was a deviation from the OECD Guideline No. 208. Nevertheless, the increased number of seeds per replicate significantly decreased the variability between replicates. Therefore, this deviation from the guideline recommendation ensures an optimal and more reliable statistical analysis with higher discriminatory power. The deviation did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

1. Test material: TRIBENURON METYL 75 WG
   Batch number: 12/16
   Concentration of Tribenuron-methyl 738.3 g/kg

2. Test organism: Ten plant species were used. These were carrot *(Daucus carota)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica olerace var. capitata)*, pea *(Pisum sativum)*, bean *(Phaseolus vulgaris)*, tomato *(Solanum lycopersicon)*, onion *(Allium cepa)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*, wheat *(Triticum aestivum).*

3. Test design:

Five or seven application rates of the test item were used in the experiment. They were determined on the basis of the non-GLP range – finding test results. In cultivation of carrot, bean, perennial ryegrass, tomato and wheat five application rates will be used i.e. 0.64, 1.6, 4.0, 10.0 and 25 g test item/ha.

In cultivation of sunflower, cabbage, pea, onion and oats seven application rates will be used i.e. 0.10, 0.26, 0.64, 1.6, 4.0, 10.0 and 25 g test item/ha. The volume of deionized water used to prepare the test item at the highest rate corresponded to 300 L/ha. One untreated control group was used for each species. Four replicates were used, both for control and treated groups. The test system was the same for all test species. There were 5 seeds in each pot. A pot was defined as the replicate. There were four replicates/rate. The total number of seeds/rates was twenty.

The concentration of tribenuron methyl in water was determined with a validated analytical method. The test item was sprayed onto the soil using a suitable spraying chamber. The experiment finished 14 days after the emergence of 50% of the control seedlings. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual phytotoxicity (7 and 14 days after the emergence of 50% of the control seedlings). At the end of the experiment, the plants were counted, cut down, measured, dried to a constant weight at 60°C, and weighed.

Results and discussions:
The test item i.e. TRIBENURON METYL 75 WG had no impact on the growth and seedling emergence of sunflower, pea, perennial ryegrass and wheat. The test item impacted the growth of cabbage, bean, carrot, tomato, onion and oats.
After the application of the test item at the rates ranging from 0.64 to 25.0 g/ha test plant species such as carrot, bean, perennial ryegrass, tomato and wheat emerged.
After the application of the test item at the rates ranging from 0.10 to 25.0 g/ha test plant species such as sunflower, cabbage, pea, onion and oats also emerged.
After the application of the test item at the highest application rate equal to 25.0 g /ha, onion emergence was delayed by one day in comparison to the control. After the application of the test item at rates 4.0 and 25.0 g/ha, bean emergence was also delayed by one day when compared to the control. Carrot emergence was delayed by one day after application of the test item at rates ranging from 4.0 to 25.0 g/ha.
For the other species used in the experiment, the emergence of plants was not delayed in comparison to the control group, i.e. perennial ryegrass, tomato, wheat, sunflower, cabbage, pea and oats.
The death of one onion plant was noticed at application rates equal to 0.1, 0.26, 0.64 and 1.6 g/ha. At the higher application rates, i.e. 10.0 and 25.0 g/ha the death of plants was not observed.
Only one phytotoxic symptom such as stunted growth of carrot, cabbage and tomato was observed during the experiment.
On the basis of NOER, ER25 and ER50 values determined from the shoot length, it was proved that the test item did not inhibit the process of growth of sunflower, pea, onion, perennial, ryegrass and wheat. The shoot length was inhibited for carrot, cabbage, bean, tomato and oats.
On the basis of NOER,ER_{25} and ER_{50} values determined from the shoot dry weight, it was proved that the test item did not inhibit the process of growth of sunflower, pea, bean perennial ryegrass, oats and wheat. The shoot dry weight of carrot, cabbage, tomato and onion was inhibited.

	Carrot *Daucus carota*	Sunflower *Helianthus annuus*	Cabbage *Brassica olreacea var. capitata*	Pea *Pisum sativum*	Bean *Phaseolus vulgaris*	Tomato *Solanum lycopersicon*
Plant number at the end of the experiment						
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0
NOER	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0
Shoot length (plants without roots)						
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0
NOER	10.0	≥ 25.0	0.26	≥ 25.0	0.64	10.0
Plant dry weight (plants without roots)						
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0
NOER	10.0	≥ 25.0	1.6	≥ 25.0	≥ 25.0	10.0

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*	Wheat *Triticum aestivum*
Plant number at the end of the experiment				
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0
NOER	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0
Shoot length (plants without roots)				
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0
NOER	≥ 25.0	≥ 25.0	10.0	≥ 25.0
Plant dry weight (plants without roots)				
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0
NOER	10.0	≥ 25.0	≥ 25.0	≥ 25.0

Only one phytotoxic symptom such as stunted growth of carrot, cabbage and tomato was observed during the experiment.

Validity of the test:

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Conclusion:

The lowest ER_{50} was above the highest dose of the test item that is 25 g test item /ha for all treated plants.
The following order of the test plant sensitivity was noticed:
cabbage > bean > carrot, tomato > onion > oats > sunflower, pea, perennial ryegrass, wheat

Comments of zRMS:	The Vegetative vigour study was conducted to OECD guideline 227 and according to the principles of GLP. Some, ER_{50} endpoints derived for the test item were not reliable since they were determined as out of the range of the tested application rates. The endpoints were estimated as higher than highest analysed application dose. These values would be treated as $ER_{50=} >$ 25.0 g test item/ha. Some deviations were noted during the study which are described in table below. And did not affect the final reslt of the study. In the definitive test all the validity criteria were met. The study is considered acceptable for the risk assessment purposes.

Reference:	KCP 10.6.2/02
Report	TRIBENURON METYL 75 WG, Terrestrial Plant Test: Vegetative Vigour Test, Anna Xxxxxx, 2018, Study code G/157/17, Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Guideline(s):	Yes. According to the OECD Guideline for the Testing of Chemicals No. 227 "Terrestrial Plant Test: Vegetative Vigour Test".
Deviations:	1.According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 117.2 – 150.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. 2.The number of seeds per pot is a deviation from the OECD Guideline No. 227. Nevertheless, in the course of statistical evaluation of the results the increased number of seeds per replicate significantly decreased the variability between replicates. There were 10 seeds in each pot. The replicate is defined as a pot. The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, there were 5 plants/pot.Therefore, this deviation from the guideline recommendation ensures an optimal and more reliable statistical analysis with a high discriminatory power.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

1. Test material: TRIBENURON METYL 75 WG
   Batch number: 12/16
   Concentration of Tribenuron-methyl 738.3 g/kg

2. Test organism: Ten plant species were used. These were carrot *(Daucus carota)*, sunflower *(Heli-*

anthus annuus), cabbage *(Brassica olerace var. capitata)*, pea *(Pisum sativum)*, bean *(Phaseolus vulgaris)*, tomato *(Solanum lycopersicon)*, onion *(Allium cepa)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*, wheat *(Triticum aestivum).*

3. Test design:

Six or seven rates of the test item were used in the experiment. They were determined on the basis of the non-GLP range - finding test results. In cultivation of cabbage, pea, onion, perennial ryegrass, wheat and oats six application rates were used i.e. 0.26, 0.64, 1.6, 4.0, 10.0 and 25 g test item/ha. In cultivation of carrot, sunflower, tomato and bean seven application rates were used i.e. 0.10, 0.26, 0.64, 1.6, 4.0, 10.0 and 25 g test item/ha. In case of each species, there were one untreated control group. A separation factor was 2.5. No rates higher than the maximum recommended rate, i.e. 25.0 g/ha were used. The volume of deionized water used to prepare the test item at the highest rate corresponded to 300 L/ha. One untreated control group was used for each species. Four replicates were used, both for control and treated groups. The test system was the same for all test species.
Seeds of the test plant species were sown in plastic pots (pot's diameter – 15 cm, pot's surface area – about 177 cm2) containing the test soil. There were 10 seeds in each pot. The replicate is defined as a pot. The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, there were 5 plants/pot. The total number of plants per application rate was twenty. Next, 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. The concentration of tribenuron metyl in water was determined with a validated analytical method.

Results and discussions:

The test item, i.e. Tribenuron methyl 75 WG applied at rates ranging from 0.1 to 25 g/ha had a varied impact on vegetative vigour of the test plant species. The impact depended on the rate and species. Mortality of single plants after application of the test item at the rate of 25 g/ha was observed in case of carrot, bean and tomato. In cultivation of pea, sunflower, cabbage, onion, perennial ryegrass, oats and wheat plants mortality was not observed. On the basis of NOER, ER25 and ER50 values determined from the shoot length and shoot dry
weight, it was observed that the test item caused growth inhibition of carrot, pea, sunflower, tomato, cabbage, onion and perennial ryegrass. Growth of wheat was slightly inhibited (NOER from dry weight was 4.0 g/ha). Growth inhibition of oats was not observed. Some phototoxic symptoms were observed after 21 days of the exposure:
- stunted growth (carrot, sunflower, cabbage, pea, bean, tomato, onion, perennial ryegrass);
- wilting (tomato);
- chlorosis (carrot, sunflower, cabbage, pea, bean, tomato, onion);
- deformations (sunflower, cabbage, pea, bean, tomato, perennial ryegrass);
- necrosis (carrot, sunflower, bean, tomato, onion);
- mortality of single plants at the rate of 25 g/ha (carrot, bean and tomato).

In case of wheat and oats no phytotoxic symptoms were observed.

The following order of the test plant sensitivity was noticed:
carrot > sunflower > tomato > onion > perennial ryegrass > cabbage > bean >pea > wheat >
oats

The ER_{50} and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of test item / ha for all test species are given below:

	Carrot *Daucus carota*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Bean** *Phaseolus vulgaris*	**Tomato** *Solanum lycopersicon*
Plant number at the end of the experiment						
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0	> 25.0
NOER	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0
Shoot length (plants without roots)						
ER_{50}	2.5 (0.9 – 8.4)	3.6 (2.0 – 6.7)	> 25.0	> 25.0	> 25.0	5.4 (3.3 – 9.8)
NOER	0.26	0.64	4.0	10.0	10.0	0.26
Plant dry weight (plants without roots)						
ER_{50}	1.6 (0.5 – 4.8)	2.4 (0.9 – 6.7)	38.9* (17.6 – 295.3*)	> 25.0	> 25.0	2.4 (1.6 – 3.5)
NOER	0.26	0.26	1.6	≥ 25.0	4.0	0.26

* Value determined out of the range of the tested application rates
The ER25, ER50 and NOER values were calculated using the ToxRat Professional 3.2.1. computer software.

	Onion *Allium cepa*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*	Wheat *Triticum aestivum*
Plant number at the end of the experiment				
ER_{50}	> 25.0	> 25.0	> 25.0	> 25.0
NOER	≥ 25.0	≥ 25.0	≥ 25.0	≥ 25.0
Shoot length (plants without roots)				
ER_{50}	19.1 (13.9 – 30.4*)	22.1 (15.9 – 39.8*)	> 25.0	> 25.0
NOER	0.64	4.0	≥ 25.0	≥ 25.0
Plant dry weight (plants without roots)				
ER_{50}	15.4 (11.2 – 24.3)	17.6 (9.8 – 58.8*)	> 25.0	> 25.0
NOER	1.6	0.64	≥ 25.0	4.0

* Value determined out of the range of the tested application rates
The ER25, ER50 and NOER values were calculated using the ToxRat Professional 3.2.1. computer software

Validity of the test:

- Seedling emergence in the control was at least 70%
- In none of the control replications of any plants species there were any signs of intoxications visible
- Mean survival of plants in control was 100% for every species (required at least 90%)
- Environmental conditions and soil were identical for all used in the experiment plants species

Conclusion:

The lowest ER_{50} value determined on the basis of plant dry weight was equal to 1.6 g/ha and it was for Carrot.
The following order of the test plant sensitivity was noticed:
carrot > sunflower > tomato > onion > perennial ryegrass > cabbage > bean >pea > wheat > oats

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

Not needed.

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

A 2.8 KCP 10.8 Monitoring data