FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: MIEDZIAN 50 WP

Product name(s): **MIEDZIAN 50 WP,**

~~**COBRESAL 50 WP, DALION 50 WP, SPATOR 50 WP**~~

Chemical active substance:

Copper as a copper oxychloride, 500 g/kg

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(re-authorization according art. 43 and art. 51, Reg. 1107/2009)

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

Submission date: **07/2020**

MS Finalisation date: 05/2021, 08/2022

Version history

When	What
07/2020	Renewal of registration of plant protection product according art. 43, Reg. 1107/2009
12/2020	Addition of new studies (KCP 10.3.2.)
03/2021	Recalculation of risk for animals according to new EU endpoint
05/2021	Finalisation of the assessment of the product Miedzian 50 WP by zRMS-PL.
08/2022	Final version after commenting period

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9 Ecotoxicology (KCP 10)

Table 9.1 GAP evaluated and approved under first evaluation (2013) and under extension to minor uses (2016) for the Miedzian 50 WP

1	2	3	4	5	6	7		8				9			10	11
Use-No. [e]	**Crop and/ or situation** **	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: development stages of the pest or pest group)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:**
						Type	**Conc. of as**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg as/hL min max**	**Water L/ha min / max**	**kg as/ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Apple, pear	PL	Miedzian 50 WP	F	*Venturia inaequalis, Venturia pirina*	WP	500 g/kg	spraying	BBCH 00-07	1-2	7-10 days	-	500-750	0,75	7	
2	Apple, pear	PL	Miedzian 50 WP	F	*Ervinia amylovora*	WP	500 g/kg	spraying	BBCH 60-71	1-2	7-10 days	-	500-750	0,375-0,75	7	
3	Cherry, sweet cherry	PL	Miedzian 50 WP	F	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61 BBCH 65-71 BBCH 72-73	1-3	7-10 dni	-	500-750	0,75 -1,5	7	
4	Peach	PL	Miedzian 50 WP	F	*Taphrina deformans*	WP	500 g/kg	spraying	BBCH 00-03	1	-	-	700	3,5	Not applicable	
~~5~~	~~Sugar beet~~	PL	Miedzian 50 WP	~~F~~	~~*Cercospora beticola*~~	WP	500 g/kg	~~spraying~~	~~BBCH 39~~	~~1-3~~	~~7-14~~	-	~~200-400~~	~~2,5~~	~~7~~	**The crop was deleted in 2014 due to lack of residue trials**
6	Cucumber	PL	Miedzian 50 WP	F	*Pseudomonas syringa Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 62-78	2-3	7-10 days	-	700	1,5	7	
7	Tomato (field)	PL	Miedzian 50 WP	F	*Phytophtora infestans Pseudomonas syrin-*	WP	500 g/kg	spraying	BBCH 51-85	3	7-10 days	-	700	1,5	7	

1	2	3	4	5	6	7		8				9			10	11
Use-No. [e]	**Crop and/ or situation** **	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: development stages of the pest or pest group)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:**
						Type	**Conc. of as**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg as/hL min max**	**Water L/ha min / max**	**kg as/ha** min max		
					gae											
8	Tomato (indoor)	PL	Miedzian 50 WP	I	*Phytophtora infestans* *Pseudomonas phaseolicola*	WP	500 g/kg	spraying	BBCH 56-88	3	7-10 days	-	1500-2000	3,0	7	
9	French bean	PL		F	*Botrytis cinerea* *Colletotrichum lindemuthianum*	WP	500 g/kg	spraying	BBCH 65-69	2	7 days	-	600-800	1,5	7	
Minor uses according to Article 51 (zonal uses)																
10	Grape	PL		F	*Plasmopara viticola*	WP	500 g/kg	spraying	I. BBCH 13-17 II. BBCH 71-73 III. BBCH 73-77	3	10 days	-	500-900	1,25	7	
11	Black currant	PL		F	*Drepanopeziza ribis* *Cronartium ribicola* *Mycosphaerella ribis*	WP	500 g/kg	spraying	BBCH 59 - 81	3	10 days	-	700	1,5	7	
12	Walnut	PL		F	*Gnomonia leptostyla*, *Xantomonas campestris pv. Juglandis*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
13	Huzelnut	PL		F	*Monilia coryli*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
14	*Goniolimon tataricum*	PL		F	*Peronospora statices*	WP	500 g/kg	spraying	Rosettes with 15-18 leaves	3	7 days	-	1000	1,0	Not applicable	

9.1 Critical GAP and overall conclusions re-authorization according art. 43, Reg. 1107/2009

Table 9.1-1: Table of critical GAPs

GAP rev. 2, date: 06.2020

PPP (product name/code):	MIEDZIAN 50 WP	Formulation type:	Wettable powder (WP)
Active substance 1:	copper oxychloride	Conc. of as 1:	50% (500g Cu/kg)
Applicant:	Synthos Agro Sp. z o.o.	Professional use:	☒
Zone(s):	central	Non professional use:	☒
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ syner-gist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Apple, pear	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	14								
Minor uses according to Article 51 (zonal uses)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
2	PL	Quince	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	7								
3	PL	Medlar	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	7								
4	PL	Cherry, sweet cherry	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61 BBCH 65-73	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,5 kg Cu/ha b)1,5 kg Cu/ha a)0,75kg Cu/ha, b) 1,5 kg Cu/ha	500-750	14								
5	PL	Apricot	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a.								
6	PL	Plum	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a.								
7	PL	Peach	Fpn	*Taphrina deformans*	Spraying	BBCH 00-03	1	-	3,0	1,5 kg Cu/ha	700	n.a.								
8	PL	Walnut	Fpn	*Gnomonia leptostyla*, *Xantomonas campestris pv. Juglandis*,	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	n.a.								
9	PL	Hazelnut	Fpn	*Gnomonia leptostyla*, *Xanthomonas arboricola pv. corylina*	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	n.a.								
10	PL	Tomato (outdoor)	Fpn	*Pseudomonas syringae pv. Tomato*, *Phytophthora infestans*	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7								
11	PL	Tomato (indoor)	I	*Pseudomonas syrin-*	Spraying	BBCH 56-	3	7-10	a)2,5	a)1,25kg	1500-2000	3								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				gae pv. Tomato, Phytophthora infestans		88			b)7,5	Cu/ha b)3,75 kg Cu/ha										
12	PL	Aubergines (outdoor)	Fpn	*Pseudomonas syringae, Phytophthora infestans*	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7								
13	PL	Aubergines (indoor)	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 56-88	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	1500-2000	3								
14	PL	Cucumber (outdoor)	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7								
15	PL	Cucumber (indoor)	I	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 10-89	4	7	a)1,6 b)6,4	a)0,8 kg Cu/ha b) 3,2 kg Cu/ha	500-1500	3								
16	PL	Gherkins	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7								
17	PL	Courgette	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7								
18	PL	Melon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colletotrichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b) 3,75 kg Cu/ha	500-1500	7								
19	PL	Pumpkins (indoor)	I	Pseudoperonospora cubensis *Alternaria spp Colletotrichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	500-1500	7								
20	PL	Watermelon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colle-*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg	500-1500	7								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				totrichum orbiculare Bacterial diseases						Cu/ha										
21	PL	French bean, beans with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum lindemuthianum, Botritis cinerea*	Spraying	BBCH 65-69	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600-800	7									
22	PL	Peas with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum lindemuthianum, Botritis cinerea*	Spraying	BBCH 65-69	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600-800	7									
23	PL	Grape (table, wine)	Fpn	*Plasmopara viticola*	Spraying	BBCH 13-17, 71-73, 73-77	3	10-14	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	500-900	21									
24	PL	Currant	Fpn	*Drepanopeziza ribis, Mycosphaerella ribis* *Cronartium ribicola,*	Spraying	BBCH 59-65 BBCH 59 - 81	2	10	a)2.4 b)4.8	a)1,2kg Cu/ha b)2.4kg Cu/ha	700	7									

* 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

Proposed uses no: 2, 3, 5, 6, 12, 13, 15, 16, 17, 18, 19, 20 and 22 are new and they were not previously evaluated.

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

9.1.1 Overall conclusions

ZRMS comments:

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

9.1.1.1 Effects on birds (KCP 10.1.1),

~~An estimation of risk indicate low risk for birds of each range of assessed issues. Calculations conducted due to the influence of MIEDZIAN 50 WP due to the acute, long term and reproductive toxicity did not indicate any hazardous properties and danger for birds.~~

Based on WoE approach the risk is considered acceptable up to 4 kg Cu/ha. The risk for birds should be considered at MSs level.

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

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

~~An estimation of risk indicate low risk for mammals of each range of assessed issues. Calculations conducted due to the influence MIEDZIAN 50 WP due to the acute, long term and reproductive toxicity did not indicate any hazardous properties and danger for mammals which was confirmed by appropriate studies.~~

Based on WoE approach the risk is considered acceptable up to 4 kg Cu/ha. The risk for mammals should be considered at MSs level.

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

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

Not relevant.

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Taking into consideration risk mitigation calculations for MIEDZIAN 50 WP –following risk mitigation measures should be applied:
When using in pome fruit:
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables, vine, currant and legumes:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits
- 70 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

For greenhouse uses as defined in Regulation 1107/2009; high and low technical greenhouses no risk mitigation measures are required for aquatic organism.
In case of the same application method with any type of open structure it is considered that the risk assessment should be carried out as "field" uses (protected structures such as: low mini tunnel, plastic shelter, walk-in tunnel, net shelter and shade house) the risk mitigation measures for aquatic organism should be applied
Therefore, when using Miedzian 50 WP in these protected structures in fruiting vegetables to protect aquatic organisms – respect
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle to surface water bodies

Using the above-mentioned precautions, formulation MIEDZIAN 50 WP can be used and will not have a negative impact on aquatic species.

9.1.1.5 Effects on aquatic organisms (KCP 10.2)

The HQ value for contact toxicity is lower than the trigger of 50, indicating low risk to bees from MIEDZIAN 50 WP following application. The HQ value for oral toxicity is over the trigger of 50, indicating high risk for bees. ~~However higher tier studies proved low risk for bees.~~
~~Therefore a low risk to bees is expected from the application of MIEDZIAN 50 WP following application according to the proposed GAP. However, application should be performed in time of no bees activities.~~
Taking into account that the application rate is between 0.75 kg CU up to 1.5 kg Cu/ha kg Cu/ha the following risk mitigation measures should be applied:
SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.
According to new requirements of Reg. No. 284/2013, data on chronic effects on development of bees and chronic test for adult bees for present formulation Miedzian 50 WP should have been submitted by applicant as exposure of bees to the formulation Miedzian 50 WP cannot be excluded.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

~~$HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for *A. rhopalosiphi* and *T.pyri* are below the ESCORT 2 trigger of 2.~~ The calculations present an acceptable risk to non-target arthropods, after spray application of MIEDZIAN 50 WP.

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

The calculated chronic (reproduction) effect on earthworms is predicted to be low after annual application of MIEDZIAN 50 WP, indicating acceptable chronic risk from the proposed uses of MIEDZIAN 50 WP up to 4 kg Cu/ha.

9.1.1.8 Effects on soil microbial activity (KCP 10.5)

On the basis of results it was assessed that MIEDZIAN 50 WP in considered applications does not pose unacceptable risk to soil microorganisms.
The risk to soil micro-organisms is considered to be low for all representative uses.

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

Since the copper oxychloride is a fungicide no risk for non-target terrestrial plants is predicted.

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

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of MIEDZIAN 50 WP grouped according to intended uses

Grouping according to criterion				
Re-authorization according Article 43, 1107/2009				
Group	**Intended uses**	**Application rate [kg /ha]**	**Application rate [kg Cu/ha]**	**Worst case interception**
1	Pome fruits (apple, pear)	4 x 1.5	4 x 0.75	2 x 50%, 2 x 60%
Minor uses according to Article 51, 1107/2009				
2	Pome fruits (quince, medlar)	4 x 1.5	4 x 0.75	2 x 50%, 2 x 60%
3	Stone fruits (cherry, sweet cherry, apricot, plum)	1 x 3.0	1 x 1.5	60%
4	Peach	1 x 3.0	1 x 1.5	50%
5	Fruiting vegetables (tomatoes, cucumbers, aubergines, gherkins, courgette, melon, pumpkin, watermelon)	3 x 2.5	3 x 1.25	80%
6	Legumes (French bean, bean with pods, peas with pods)	2 x 3.0	2 x 1.5	70%
7	Vine	3 x 2.5	3 x 1.25	1 x 50% / 2x 75%
8	Nuts (Walnut, Hazelnut)	2 x 3.0	2 x 1.5	2 x 50%
9	Currant	2 x 2.4	2 x 1.2	2 x 60 %

9.1.3 Consideration of metabolites

Copper in form of an oxychloride, which is main and only active substance in MIEDZIAN 50 WP, has no relevant metabolites.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with copper compounds. Full details of these studies are provided in the respective EU DAR and related documents.
The provision of further data on the MIEDZIAN 50 WP is not considered essential, because the risk for birds could be estimated based on the active substances toxicity.

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

Species	**Substance**	**Exposure System**	**Results**	**Reference**
Coturnix coturnix japonica	Copper oxychloride WP	Oral, Acute	LD_{50} = 173 mg/kg bw	EFSA Journal 2013;11(6):323
Colinus virginianus	Copper hydroxide	Dietary, 24 weeks, Long-term	NOAEL = 5.05 mg/kg bw/d	EFSA Journal 2013;11(6):323

9.2.1.1 Justification for new endpoints

No deviation from 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 in nuts and fruiting vegetables also covers the risk for birds from all other intended uses (see 9.1.2).

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

Calculations according to Article 43

Table 9.2-2: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of MIEDZIAN 50 WP in orchards

Intended use	**Pome fruits**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	4 × 0.75 (pome fruits)				
Acute toxicity (mg/kg bw)	173				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small insectivorous bird	46.8	1.8	63.18	**2.74**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous bird	18.2	0.95	12.97	**0.39**

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: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of MIEDZIAN 50 WP in orchards

Intended use	**Pome fruits**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	4 × 0.75 (pome fruits)				
Acute toxicity (mg/kg bw)	173				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Spring, summer	Small insectivorous bird “tit”	46.8	1.8	63.18	**2.74**

BBCH ≥ 40	Small insectivorous/wor m feeding species "thrush"	2.2	1.4*	2.31	75
BBCH ≥ 40	Small granivorous bird "finch"	8.2	1.4*	8.61	20
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Spring, summer	Small insectivorous bird "tit"	18.2	0.95	12.97	**0.39**
BBCH ≥ 40	Small insectivorous/wor m feeding species "thrush"	0.8	0.74*	0.44	11.5
BBCH ≥ 40	Small granivorous bird "finch"	3.8	0.74*	2.11	**2.39**

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.
* Since only two application can be performed for BBCH >40, MAF 1.4 is used.

The results of calculations for major uses (orchards), show unacceptable risk for birds. However, a literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for birds Therefore, no further calculations is needed.

Calculations according to Article 51

Table 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of MIEDZIAN 50 WP in minor uses

Intended use	**Minor uses**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	2 x 1.2 (bush) 2 x 1.5 (orchards) 3 x 1.25 (vine) 3 × 1.25 (fruiting vegetables, legumes)				
Acute toxicity (mg/kg bw)	173				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bush	Small frugivorous bird	46.3	1.4	77.8	**2.22**
Orchards	Small insectivorous bird	46.8	1.4	98.3	**1.76**
Vineyard	Small omnivorous bird	95.3	1.8	214.4	**0.81**
Fruiting vegetables, legumes,	Small omnivorous bird	158.8	1.8	357.3	**0.48**
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bush	Small frugivorous bird	23.0	0.74	20.4	**0.25**
Orchards	Small insectivorous bird	18.2	0.74	20.2	**0.25**
Vineyard	Small omnivorous bird	38.9	0.95	46.2	**0.11**

Fruiting vegetables, legumes,	Small omnivorous bird	64.8	0.95	76.95	**0.07**

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 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of MIEDZIAN 50 WP in minor uses

Intended use	**Minor uses**
Active substance/product	Copper oxychloride
Application rate (g/ha)	2 x 1.2 (bush) 2 x 1.5 (orchards) 3 x 1.25 (vine) 3 × 1.25 (fruiting vegetables, legumes)
Acute toxicity (mg/kg bw)	173
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bush BBCH 71 - 79	Frugivorous bird “blackcap”	46.3	1.8	100.01	**1.73**
Bush BBCH 00 - 79	Small insectivorous bird “warbler”	52.2	1.8	112.75	**1.53**
Vineyard BBCH 10 - 19	Small insectivorous species “Redstart”	27.4	1.6	54.80	**3.16**
Vineyard BBCH > 20	Small insectivorous species “Redstart”	25.7	1.6	51.40	**3.37**
Vineyard BBCH 10 - 19	Small granivorous bird “Finch”	14.8	1.6	29.60	**5.84**
Vineyard BBCH > 40	Small granivorous bird “Finch”	7.4	1.6	14.80	11.69
Vineyard BBCH 10 - 19	Small omnivorous bird “lark”	14.4	1.6	28.80	**6.01**
Vineyard BBCH > 40	Small omnivorous bird “lark”	7.2	1.6	14.40	12.01
Legumes BBCH > 50	Small granivorous bird “finch”	7.4	1.8	19.98	**8.66**
Legumes BBCH > 50	Small omnivorous bird “lark”	7.2	1.8	19.44	**8.90**
Legumes BBCH > 20	Small insectivorous bird “wagtail”	25.2	1.8	68.04	**2.54**
Fruiting vegetables BBCH 71 - 89	Frugivorous bird “crow”	57.4	1.6	114.80	**1.51**
Fruiting vegetables BBCH > 50	Small omnivorous bird “lark”	7.2	1.6	14.40	12.01
Fruiting vegetables BBCH 71 - 89	Frugivorous bird “Starling”	49.4	1.6	98.80	**1.75**
Fruiting vegetables BBCH > 20	Small insectivorous bird “wagtail”	25.2	1.6	50.40	**3.43**
Orchards, Spring, summer	Small insectivorous bird “tit”	46.8	1.8	63.18	**2.74**
Orchards, BBCH ≥ 40	Small insectivorous/wor m feeding species “thrush”	2.2	1.8	2.97	58.25

Orchards, BBCH ≥ 40	Small granivorous bird "finch"	8.2	1.8	11.07	15.63
Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bush BBCH 71 - 79	Frugivorous bird “blackcap”	23.0	0.95	26.33	**0.19**
Bush BBCH 00 - 79	Small insectivorous bird “warbler”	20.3	0.95	23.24	**0.22**
Vineyard BBCH 10 - 19	Small insectivorous species “Redstart”	11.5	0.85	12.19	**0.41**
Vineyard BBCH > 20	Small insectivorous species “Redstart”	9.9	0.85	10.49	**0.48**
Vineyard BBCH 10 - 19	Small granivorous bird “Finch”	6.9	0.85	7.31	**0.69**
Vineyard BBCH > 40	Small granivorous bird “Finch”	3.4	0.85	3.60	**1.40**
Vineyard BBCH 10 - 19	Small omnivorous bird “lark”	6.5	0.85	6.89	**0.73**
Vineyard BBCH > 40	Small omnivorous bird “lark”	3.3	0.85	3.50	**1.44**
Legumes BBCH > 50	Small granivorous bird “finch”	3.4	0.95	4.87	**1.04**
Legumes BBCH > 50	Small omnivorous bird “lark”	3.3	0.95	4.72	**1.07**
Legumes BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.95	13.88	**0.36**
Fruiting vegetables BBCH 71 - 89	Frugivorous bird “crow”	32.0	0.85	33.92	**0.15**
Fruiting vegetables BBCH > 50	Small omnivorous bird “lark”	3.3	0.85	3.50	**1.44**
Fruiting vegetables BBCH 71 - 89	Frugivorous bird “Starling”	20.7	0.85	21.94	**0.23**
Fruiting vegetables BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.85	10.28	**0.49**
Orchards, Spring, summer	Small insectivorous bird “tit”	18.2	0.95	13.02	**0.39**
Orchards, BBCH ≥ 40	Small insectivorous/wor m feeding species “thrush”	0.8	0.95	0.57	8.82
Orchards, BBCH ≥ 40	Small granivorous bird "finch"	3.8	0.95	2.72	**1.86**

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 results of calculations for minor uses, show unacceptable risk for birds. However, a literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for birds Therefore, no further calculations is needed.

9.2.2.2 Higher-tier risk assessment

A literature review provides a weight of evidence approach concluding to acceptable risks to birds for

doses of ~~5~~ **4 kg Cu/ha/year**, for birds, therefore no more justification is needed.

zRMS comments:

For copper oxychloride endpoints in line with EFSA Journal 2018;16(1):5152 were considered.

The Tier I acute and long-term risk assessment to birds was indicated as high for all the representative uses.

Following approach proposed in the Peer Review Expert Meeting 169 (2017) the risk assessment shall be conducted using the MAF and TWA = 1 and one maximum cumulative annual application rate.

The applicant provided the calculation based on the default values of MAF and the application rates given in the GAP which are not in line with recommendation given in EFSA Conclusion, 2018 by the EFSA experts.

Finally the applicant referred to WoE approach and concluded that 5 kg a.s./ha should be considered acceptable for risk to birds from copper.

It should be noted that the WoE was discussed at the Pesticides Peer Review Meeting 169; the experts considered the evidence provided as not satisfactory to exclude the acute risk to birds and mammals.

Furthermore, the experts concluded that the data from the wildlife reports which were part of the evidence provided along with information of bird population (e.g. abundance and density), may be indicative of the absence of incidents but not sufficient to address the acute risk identified.

The experts concluded that the WoE could be considered acceptable for addressing the long-term risk to birds and mammals for application rate up to 5 kg a.s./ha for granivorous and insectivorus birds; however, further data were considered necessary to draw a conclusion covering all the feeding guild categories, i.e. **omnivorous and frugivorous birds and large herbivorous and frugivorous mammals (data gap).**

By generating further data, the experts considered it useful to focus on, e.g. further investigation of the avoidance and further data on residue in food items.

Therefore, based on this conclusion further refinement is required at MSs level for omnivorous and frugivorous birds for all proposed uses for cooper hydroxide depended on own indicator focal species.

zRMS-PL is of the same opinion as RMS in RAR revised and, taking into account all the available data and due to the absence of an adapted guide to evaluate elements such as copper and that the conclusions were based on more than a realistic worst case scenario, this WoE approach could be used to conclude acceptable risk for Poland at dose requested (maximum annual application rate of 4 kg Cu/ha).

The final decision should be considered at MSs level.

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 MIEDZIAN 50 WP is not a product not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a K(f)oc of 50000, copper belongs to the group of more sorptive substances.

Effective application rate (g/ha)	=	1500		
Acute toxicity (mg/kg bw)	=	173	quotient	= 8.7
Reprod. toxicity (mg/kg bw/d)	=	5.05	quotient	= 297

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 3000 in the case of copper oxychloride no more calculations are needed.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} values of copper is below 3 and thus a risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

ZRMS comments:

According to EFSA conclusion (EFSA Journal 2018;16(1):5152), a literature review provides evidence of lack of bioaccumulation in aquatic food chain.

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

Not relevant.

9.2.4 Overall conclusions

An estimation of risk indicate low risk for birds of each range of assessed issues. Calculations conducted due to the influence of MIEDZIAN 50 WP due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for birds. There were also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

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

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with copper. Full details of these studies are provided in the respective EU DAR and related documents.
The provision of further data on the MIEDZIAN 50 WP is not considered essential, because of using data for active substance to estimate the risk for mammals from formulation.

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

Species	Substance	Exposure System	Results	Reference
Mouse	Copper oxychloride	Oral, Acute	LD_{50} = 1180 mg Cu/kg bw	EFSA Journal 2013;11(6):3235
Rat	Tribasic copper sulfate	Oral, Acute	LD_{50} = 162.6 mg Cu/kg bw	EFSA Journal 2018;16(1):5152
Rat	Copper sulfate	Long-term, 90 d	NOEL = 16 mg Cu/kg bw/d	EFSA Journal 2013;11(6):3235

9.3.1.1 Justification for new endpoints

No deviation from 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 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 in nuts and fruiting vegetables also covers the risk for mammals from all other intended uses (see 9.1.2).

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.

Calculations according to Article 43

Table 9.3-2: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of MIEDZIAN 50 WP in orchards

Intended use	Pome fruit				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	4 × 750				
Acute toxicity (mg/kg bw)	162.6				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}***	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small herbivorous mammal	136.4	1.8	184.14	**0.88**
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m* × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous mammal	72.3	0.95	51.73	**0.31**

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

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of MIEDZIAN 50 WP in orchards

Intended use	Pome fruit				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	4 × 750				
Acute toxicity (mg/kg bw)	162.6				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}***	**DDD_{90} (mg/kg bw/d)**	**TER_a**
BBCH <10	Small insectivorous mammal "shrew"	5.4	1.8	7.29	22.3
BBCH <10	Small herbivorous mammal "vole	136.4	1.8	184.1	**0.88**
BBCH ≥ 40	Small herbivorous mammal "vole	40.9	1.8	55.2	**2.94**
BBCH <10	Large herbivorous mammal "lagomorph"	35.1	1.8	47.4	**3.43**
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	10.5	1.8	14.2	11.5
BBCH < 10	Small omnivorous mammal "mouse"	17.2	1.8	23.2	**7.00**

BBCH ≥ 40	Small omnivorous mammal "mouse"	5.2	1.8	7.02	23.2
Reprod. toxicity (mg/kg bw/d) **TER criterion**	16 5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m^* × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
BBCH <10	Small insectivorous mammal "shrew"	1.9	0.95	1.36	11.8
BBCH <10	Small herbivorous mammal "vole	72.3	0.95	51.7	**0.31**
BBCH ≥ 40	Small herbivorous mammal "vole	21.7	0.95	15.5	**1.03**
BBCH <10	Large herbivorous mammal "lagomorph"	14.3	0.95	10.2	**1.56**
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	4.3	0.95	3.08	5.20
BBCH < 10	Small omnivorous mammal "mouse"	7.8	0.95	5.58	**2.87**
BBCH ≥ 40	Small omnivorous mammal "mouse"	2.4	0.95	1.72	9.32

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.

Calculations according to Article 51

Table 9.3-4: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of MIEDZIAN 50 WP in minor uses

Intended use **Active substance/product** **Application rate (g/ha)**	Minor uses Copper oxychloride 2 x 1.2 (bush) 2 x 1.5 (orchards / legumes) 3 x 1.25 (fruiting vegetables, vine)				
Acute toxicity (mg/kg bw) **TER criterion**	162.6 10				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bush	Small herbivorous mammal	81.9	1.4	137.6	**1.18**
Orchards / legumes	Small herbivorous mammal	136.4	1.4	286.4	**0.57**
Vines / Fruiting vegetables	Small herbivorous mammal	136.4	1.6	272.8	**0.60**
Reprod. toxicity (mg/kg bw/d) **TER criterion**	16 5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m^* × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bush	Small herbivorous mammal	43.4	0.74	38.5	**0.42**
Orchards / legumes	Small herbivorous mammal	72.3	0.74	80.3	**0.062**

Vines / Fruiting vegetables	Small herbivorous mammal	72.3	0.85	76.8	**0.21**

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.
* Since copper is highly persistence, worst case (number of application) was used for calculations instead of MAF

Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of MIEDZIAN 50 WP in minor uses

Intended use	Minor uses
Active substance/product	Copper oxychloride
Application rate (g/ha)	2 x 1.2 (bush) 2 x 1.5 (orchards / legumes) 3 x 1.25 (fruiting vegetables, vine)
Acute toxicity (mg/kg bw)	162.6
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bush BBCH >40	Small herbivorous mammal "vole"	40.9	1.4	68.71	**2.37**
Bush BBCH 71-79	Frugivorous mammal "dormouse"	19.4	1.4	32.59	**4.99**
Bush BBCH >40	Small omnivorous mammal "mouse"	5.2	1.4	8.74	18.61
Vineyard BBCH 10 - 19	Large herbivorous mammal "lagomorph"	16.3	1.6	32.60	**4.99**
Vineyard BBCH > 40	Large herbivorous mammal "lagomorph"	8.1	1.6	16.20	10.04
Vineyard BBCH 10 - 19	Small insectivorous mammal "shrew"	7.6	1.6	15.20	10.70
Vineyard BBCH 10 - 19	Small herbivorous mammal "vole"	81.9	1.6	163.80	**0.99**
Vineyard BBCH > 40	Small herbivorous mammal "vole"	40.9	1.6	81.80	**1.99**
Vineyard BBCH 10 - 19	Small omnivorous mammal "mouse"	10.3	1.6	20.60	**7.89**
Vineyard BBCH > 40	Small omnivorous mammal "mouse"	5.2	1.6	10.40	15.63
Legume BBCH > 50	Small herbivorous mammal "vole	40.9	1.4	85.89	**1.89**
Legume BBCH > 50	Small omnivorous mammal "mouse"	5.2	1.4	10.92	14.89
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal "shrew"	7.6	1.6	15.20	10.70
Fruiting vegetables BBCH > 20	Small insectivorous mammal "shrew"	5.4	1.6	10.80	15.06
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole"	136.4	1.6	272.80	**0.60**
Fruiting vegetables	Small herbivorous mammal	40.9	1.6	81.80	**1.99**

BBCH > 50	"vole"				
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal "mouse"	17.2	1.6	34.40	**4.73**
Fruiting vegetables BBCH > 50	Small omnivorous mammal "mouse"	5.2	1.6	10.40	15.63
Orchards BBCH <10	Small insectivorous mammal "shrew"	5.4	1.4	11.34	14.34
Orchards BBCH <10	Small herbivorous mammal "vole	136.4	1.4	286.44	**0.57**
Orchards BBCH ≥ 40	Small herbivorous mammal "vole	40.9	1.4	85.89	**1.89**
Orchards BBCH <10	Large herbivorous mammal "lagomorph"	35.1	1.4	73.71	**2.21**
Orchards BBCH ≥ 40	Large herbivorous mammal "lagomorph"	10.5	1.4	22.05	**7.37**
Orchards BBCH < 10	Small omnivorous mammal "mouse"	17.2	1.4	36.12	**4.50**
Orchards BBCH ≥ 40	Small omnivorous mammal "mouse"	5.2	1.4	10.92	14.89
Reprod. toxicity (mg/kg bw/d)	16				
TER criterion	5				
Crop scenario	**Indicator/generic focal species**	**SV_m**	**MAF_m^* × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bush BBCH >40	Small herbivorous mammal "vole"	21.7	0.74	19.32	**0.83**
Bush BBCH 71-79	Frugivorous mammal "dormouse"	9.7	0.74	8.64	**1.85**
Bush BBCH >40	Small omnivorous mammal "mouse"	2.3	0.74	2.05	7.81
Vineyard BBCH 10 - 19	Large herbivorous mammal "lagomorph"	6.7	0.85	7.10	**2.25**
Vineyard BBCH > 40	Large herbivorous mammal "lagomorph"	3.3	0.85	3.50	**4.57**
Vineyard BBCH 10 - 19	Small insectivorous mammal "shrew"	4.2	0.85	4.45	**3.59**
Vineyard BBCH 10 - 19	Small herbivorous mammal "vole"	43.4	0.85	46.00	**0.35**
Vineyard BBCH > 40	Small herbivorous mammal "vole"	21.7	0.85	23.00	**0.70**
Vineyard BBCH 10 - 19	Small omnivorous mammal "mouse"	4.7	0.85	4.98	**3.21**
Vineyard BBCH > 40	Small omnivorous mammal "mouse"	2.3	0.85	2.44	6.56
Legume BBCH > 50	Small herbivorous mammal "vole	21.7	0.74	24.15	**0.66**
Legume BBCH > 50	Small omnivorous mammal "mouse"	2.3	0.74	2.56	6.25

Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal "shrew"	4.2	0.85	4.45	**3.59**
Fruiting vegetables BBCH > 20	Small insectivorous mammal "shrew"	1.9	0.85	2.01	7.94
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole"	72.3	0.85	76.64	**0.21**
Fruiting vegetables BBCH > 50	Small herbivorous mammal "vole"	21.7	0.85	23.00	**0.70**
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal "mouse"	7.8	0.85	8.27	**1.94**
Fruiting vegetables BBCH > 50	Small omnivorous mammal "mouse"	2.3	0.85	2.44	6.56
Orchards BBCH <10	Small insectivorous mammal "shrew"	1.9	0.74	2.11	7.57
Orchards BBCH <10	Small herbivorous mammal "vole	72.3	0.74	80.47	**0.20**
Orchards BBCH ≥ 40	Small herbivorous mammal "vole	21.7	0.74	24.15	**0.66**
Orchards BBCH <10	Large herbivorous mammal "lagomorph"	14.3	0.74	15.92	**1.01**
Orchards BBCH ≥ 40	Large herbivorous mammal "lagomorph"	4.3	0.74	4.79	**3.34**
Orchards BBCH < 10	Small omnivorous mammal "mouse"	7.8	0.74	8.68	**1.84**
Orchards BBCH ≥ 40	Small omnivorous mammal "mouse"	2.4	0.74	2.67	5.99

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.
* Since copper is highly persistence, worst case (number of application) was used for calculations instead of MAF

The results of calculations show unacceptable risk for mammals. However, due to information obtained from peer review for copper compounds (EFSA Journal 2013;11(6):3235) "A literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence.
Therefore no further risk assessment is necessary.

ZRMS comments:

Copper oxychloride

The acute and long-term TER values for copper are below the relevant trigger values at screening step and at Tier 1 for most of the scenarios, according to the use pattern of the product Copper oxychloride.

Following approach proposed in the Peer Review Expert Meeting 169 (2017) the risk assessment shall be conducted using the MAF and TWA = 1 and one maximum cumulative annual application rate.

The applicant provided the calculation based on the defult values of MAF and the application rates given in the GAP **which are not in line with recommendation given in EFSA Conclusion, 2018 by the EFSA experts.**

Further, finally the applicant referred to WoE approach and concluded that 5 kg a.s./ha should be considered acceptable for risk to mammals from copper.

The weight of evidence (WoE) approach is available in the RAR for copper compounds.

During the renewal of copper hydroxide the RMS -France concluded the following: "*A weight-of-evidence based approach to refine the mammals risk assessments is submitted. Together with the studies of Schabacker, J. and Rastall, A. 2009 a & b the effects of copper exposure on wild life is studied. The RMS considers that the literature review provided by the notifier (EUCuTF) gives evidence of homeostatic mechanisms for mammals. Theoretical acute and long-term dietary exposure of shrew and vole observed in the papers performed by Hunter et al. (1987a, b; 1989) is much higher than the one calculated for a standard application rate of copper in vineyard and tomato crops. Thus, the acute and the long-term risk to mammals due to copper exposure can be considered acceptable for the small herbivorous mammal "vole" and the small insectivorous mammal "shrew".*"

Further, according to EFSA Conclusion 2018, literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence except for large herbivorous mammal.

Therefore, based on this conclusion further refinement is required at MSs level for all proposed uses for large herbivorous mammals.

zRMS-PL is of the same opinion as RMS in RAR revised, and taking into account all the available data and due to the absence of an adapted guide to evaluate elements such as copper and that the conclusions were based on *more than a realistic worst case scenario*, the WoE approach could be used to conclude acceptable risk for Poland at the dose rate requested until the existence of an accepted guidance document.

The final decision should be considered at MSs level.

9.3.2.2 Higher-tier risk assessment

The results of calculations show unacceptable risk for mammals. However, due to information obtained from peer review for copper compounds (EFSA Journal 2013;11(6):3235) "A literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence.
Therefore no further risk assessment is necessary.

9.3.2.3 Drinking water exposure

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

Puddle scenario

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

With a K(f)oc of 50000, copper belongs to the group of more sorptive substances.

Table 9.3-6: Ratio of effective application rate to relevant endpoint for mammals in drinking water exposure due to the use of MIEDZIAN 50 WP

Effective application rate (g/ha) =	1500 g of copper oxychloride	quotient =
Acute toxicity (mg/kg bw) =	162.6	9.2
Reprod. toxicity (mg/kg bw/d) =	16	94

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 3000 in the case of copper oxychloride no more calculations are needed.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} values of copper, is below 3 and thus a risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

zRMS comments:

According to EFSA conclusion (EFSA Journal 2018;16(1):5152), a literature review provides evidence of lack of bioaccumulation in aquatic food chain.

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

Not relevant.

9.3.4 Overall conclusions

An estimation of risk indicate low risk for mammals of each range of assessed issues. Calculations conducted due to the influence MIEDZIAN 50 WP due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for mammals which was confirmed by appropriate studies. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

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

Not relevant.

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

Effects on aquatic organisms of MIEDZIAN 50 WP were not evaluated as part of the EU assessment copper compound. There is no new data submitted with this application. Previous studies are listed in Appendix 1.

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

Species	Substance	Exposure System	Results	RAC	Reference
Oncorhynchus mykiss	Copper oxide	96 h, f	LC_{50} = 0.0344 mg dissolved Cu/L	1.24 µg/L *	EFSA Journal 2018;16(1):5152
Acipenser transmontanus	Copper sulfate	53d, f	EC10 = 0.00112 mg dissolved Cu/L	0.37 µg/L **	EFSA Journal 2018;16(1):5152
Daphnia	copper	48 h, s	LC50 =	2.4 µg/L#	EFSA Journal

Species	Substance	Exposure System	Results	RAC	Reference
magna	hydroxide		0.0266 mg dissolved Cu/L		2018;16(1):5152
Daphnia magna	copper oxychloride	21 d, ss	NOEC = 0.0076 mg a.s./L	2.4 µg/L#	EFSA Journal 2013;11(6):3235
Chironomus riparius	Tribasic copper sulfate	28 d (static) water spiked test	NOEC = 0.5 mg a.s./L (nom)	50 µg/L	EFSA Journal 2018;16(1):5152
Tubifex tubifex	Copper chloride	28 d (semi-static, spiked sediment)	NOEC = 16.17 mg/kg dry weight normalized to 2.5% OC	3.23 µg/L	EFSA Journal 2018;16(1):5152
S. capricornutum	Copper hydroxide WP	72 h, s	ErC50 = 0.02229 mg a.s./L nom	2.4 µg/L#	EFSA Journal 2018;16(1):5152
Indoor microcosm study	Copper hydroxide WP	6 applications at 10- d interval followed by 250 days of monitoring	NOEC = 0.0048 mg dissolved Cu/L	2.4 µg/L#	EFSA Journal 2018;16(1):5152

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

* Fish, acute, data from 7 fish species available from the literature were used. Therefore, this allows to derived a SSD-HC_5 values of 3.73 µg/L, an AF of 3 is applied.

**Fish, chronic (based on SSD analysis SSD-HC_5 = 0.00111 mg/L AF = 3

RAC based on the results of indoor microcosm study with AF = 2.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – MIEDZIAN 50 WP

Species	Substance	Exposure System	Results	Reference*
Salvelinus fontinalis	MIEDZIAN 50 WP	96 h	LC_{50} = 14.35mg/L $_{nom}$	xxx / 1997
Cyprinus carpio L.	MIEDZIAN 50 WP	96 h	LC_{50} = 63.8 mg/L $_{nom}$	xxx 1997
Daphnia magna	MIEDZIAN 50 WP	48 h	EC_{50} = 9.9 mg/L $_{nom}$	xxx 1997
Scenedesmus quadricauda	MIEDZIAN 50 WP	72 h	E_rC_{50} = 17.8 mg/L $_{nom}$	xxx 1997

nom: based on nominal concentrations; mm: based on mean measured concentrations
*the study previously evaluated by zRMS in IEP-NRI (2013)

Since, the results for MIEDZIAN 50 WP shows lower toxicity than active substance and formulated active substance, those result are not suitable for risk calculations and results for active substance is used for calculations, according to EFSA Journal 2013;11(7):3290.
Since concentration of active substance of copper oxychloride is 87.5% in product MIEDZIAN 50WP, it is comparable to other formulated products containing copper oxychloride. Therefore, risk assessment for aquatic species is performed based on available and accepted results from other studies.

9.5.1.1 Justification for new endpoints

No deviation from 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 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.
Since copper is inorganic active substance, FOCUS step 3 and 4 cannot be used. Therefore risk mitigations are based only on run-off/drainage mitigation and spray-drift mitigations for STEP 2.
All calculations considering predicted environmental concentration in surface water are precisely described in dRR Part B Section B8, Chapter 8.8).

Since RAC for chronic assessment for fish represents the worst case for surface water toxicity, risk mitigations are based on this RAC.

~~Calculations according to article 43~~

~~Table 9.5.3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper for fish (chronic exposure) based on FOCUS Steps 1, 2 calculations for the use of MIEDZIAN 50 WP in pome fruiting~~

~~Crop~~	~~Calculations via run-off/drainage only~~			~~Calculations via drift mitigation~~			
	~~Step 1~~	~~Step 2~~	~~Step 2 with 90% mitigation (20 m VBZ)~~	~~10m NSZ~~	~~20m NSZ~~	~~30m NSZ~~	~~50m NSZ~~
~~Pome-fruits~~	~~7.21~~	~~1.43~~	~~0.143~~	~~5.93~~	~~1.72~~	~~0.58~~	~~0.34~~

~~Crop~~	~~Sum of concentrations µg/L~~			
	~~VBZ 20 m + 10 m NSZ~~	~~VBZ 20 m + 20 NSZ~~	~~VBZ 20 m + 30 NSZ~~	~~VBZ 20 m + 50 NSZ~~
~~Pome-fruits~~	~~7.072~~	~~1.872~~	~~0.722~~	~~0.282~~

~~Values below the RAC are bold~~
~~NSZ- No spray buffer zone~~
~~VBZ- Vegetative buffer zone~~
~~PEC- Predicted environmental concentration; RAC- Regulatory acceptable concentration~~

~~Calculations for minor uses according to Article 51~~

~~Table 9.5.4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper for fish (chronic exposure) based on FOCUS Steps 1, 2 calculations for the use of MIEDZIAN 50 WP in minor uses~~

~~Crop~~	~~Calculations via run-off/drainage only~~			~~Calculations via drift mitigation~~					
	~~Step 1~~	~~Step 2~~	~~Step 2 with 90% mitigation (20 m VBZ)~~	~~10m NSZ~~	~~20m NSZ~~	~~30m NSZ~~	~~50m NSZ~~	~~60m NSZ~~	~~70m NSZ~~
~~Pome fruits~~	~~7.21~~	~~1.43~~	~~0.143~~	~~5.93~~	~~1.72~~	~~0.58~~	~~0.34~~	~~!~~	~~!~~

Stone fruits	3.61	0.72	0.072	18.98	4.34	1.66	0.49	0.22	0.22
Fruiting vegetables	9.02	1.79	0.179	0.27	0.14	0.094	0.057	-	-
Legumes	7.21	1.43	0.143	0.38	0.19	0.13	0.077	-	-
Vine	9.02	1.79	0.179	0.41	0.15	0.095	0.022	-	-
Nuts	7.21	1.43	0.143	15.4	3.98	1.37	0.25	0.22	-
Currant	5.77	1.15	0.115	0.2	0.15	0.1	0.06	-	-

Scenario	Sum of concentrations µg/l					
	VBZ 20 m + 10 m NSZ	VBZ 20 m + 20 NSZ	VBZ 20 m + 30 NSZ	VBZ 20 m + 50 NSZ	VBZ 20 m + 60 NSZ	VBZ 20 m + 70 NSZ
Pome-fruits	7.072	1.872	0.722	0.282	-	-
Stone-fruits	19.052	4.412	1.732	0.562	0.392	0.292
Fruiting vegetables	0.449	0.319	0.279	0.236	-	-
Legumes	0.522	0.333	0.279	0.22	-	-
Vine	0.589	0.309	0.244	0.206	-	-
Nuts	15.548	4.132	1.512	0.492	0.262	-
Currant	0.415	0.265	0.215	0.175	-	-

~~Values below the RAC are bold~~
~~NSZ: No spray buffer zone~~
~~VBZ: Vegetative buffer zone~~
~~PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration~~

~~Since, the final endpoint of 3.23 ug/kg of sediment for invertebrates living in sediment is not finalised and fully accepted on the level of EU, this endpoint is not considered during calculations of risk mitigation. Therefore only calculations for water living animals are considered relevant, and on their base, the mitigation measures are calculated.~~

Calculations according to article 43

Table 9.5.2-1 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in pome fruits.

Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw. max (µg/L)**	**PEC/RAC ratios**						**PEC sed max (mg/kg)**	**PEC/RAC ratios**
Step 1		313.6	**151.498**	**2613.333**	**1178.947**	**412.632**	**140.691**	**6.272**	26.470	**8.195**
Step 2										
N-Europe	March-May	64.66	**31.237**	**538.833**	**243.083**	**85.079**	**29.009**	**1.293**	20.170	**6.245**
~~S-Europe~~	~~March-May~~	~~64.66~~	~~31.237~~	~~538.833~~	~~243.083~~	~~85.079~~	~~29.009~~	~~1.293~~	~~21.620~~	~~6.693~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Calculation according to article 51

Table 9.5.2-2 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in pome fruits.

Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-max (µg/L)**	**PEC/RAC ratios**						**PEC sed max (mg/k)**	**PEC/RAC ratios**
Step 1		313.6	**151.498**	**2613.333**	**1178.947**	**412.632**	**140.691**	**6.272**	26.470	**8.195**
Step 2										
N-Europe	Mar - May	64.66	**31.237**	**538.833**	**243.083**	**85.079**	**29.009**	**1.293**	20.170	**6.245**
~~S-Europe~~	~~Mar—May~~	~~64.66~~	~~31.237~~	~~538.833~~	~~243.083~~	~~85.079~~	~~29.009~~	~~1.293~~	~~24.624~~	~~6.693~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-3 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in stone fruits.

Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-$_{max}$ (µg/L)**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/k)**	**PEC/RAC ratios**
Step 1		156.8	**75.749**	**1306.667**	**589.474**	**206.316**	**70.345**	**3.136**	21.740	**6.731**
Step 2										
N-Europe	March-May	145.99	**70.527**	**1216.583**	**548.835**	**192.092**	**65.496**	**2.920**	18.800	**5.820**
~~S-Europe~~	~~March-May~~	~~145.99~~	~~70.527~~	~~1216.583~~	~~548.835~~	~~192.092~~	~~65.496~~	~~2.920~~	~~19.520~~	~~6.046~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in fruiting vegetables.

Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-$_{max}$ (µg/L)**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/kg)**	**PEC/RAC ratios**
Step 1		61.53	**29.725**	**512.750**	**231.316**	**80.961**	**27.604**	**1.231**	26.420	**8.180**
Step 2										
N-Europe	March-May	8.97	**4.333**	**74.750**	**33.722**	**11.803**	**4.024**	0.179	19.030	**5.892**
~~S-Europe~~	~~March-May~~	~~11.63~~	~~5.618~~	~~96.917~~	~~43.722~~	~~15.302~~	~~5.218~~	~~0.232~~	~~20.820~~	~~6.445~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;
PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in legume.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC $_{sw-max}$ (µg/L**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/kg)**	**PEC/RAC ratios**
Step 1		49.22	**23.778**	**410.167**	**185.038**	**64.763**	**22.082**	0.984	24.530	**7.594**
Step 2										
N-Europe	March-May	12.58	**6.077**	**104.833**	**47.293**	**16.553**	**5.644**	0.252	18.640	**5.771**
~~S-Europe~~	~~March-May~~	~~12.58~~	~~6.077~~	~~104.833~~	~~47.293~~	~~16.553~~	~~5.644~~	~~0.252~~	~~20.400~~	~~6.222~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold *according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in vines.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubifex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-$_{max}$ (µg/L)**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/kg)**	**PEC/ RAC ratios**
Step 1		60.78	**29.362**	**506.500**	**228.496**	**79.974**	**27.268**	**1.216**	26.410	**8.176**
Step 2										
N-Europe	March-May	11.29	**5.454**	**94.083**	**42.444**	**14.855**	**5.065**	0.226	19.050	**5.898**
~~S.Europe~~		~~11.86~~	~~5.729~~	~~98.833~~	~~44.596~~	~~15.605~~	~~5.321~~	~~0.237~~	~~20.870~~	~~6.461~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in nuts.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubi-fex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-$_{max}$ (µg/L)**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/kg)**	**PEC/ RAC ratios**
Step 1		313.6	**151.498**	**2613.333**	**1178.947**	**412.632**	**140.691**	**6.272**	26.470	**8.176**
Step 2										
N-Europe	March-May	131.73	**63.638**	**1097.750**	**495.226**	**173.329**	**59.098**	**2.635**	20.320	**5.898**
S-Europe		131.73	63.638	1097.750	495.226	173.329	59.098	2.635	21.780	6.461

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Table 9.5.2-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for cooper for each organism group based on FOCUS Steps 1-2 calculations for the use of Miedzian 50 WP in currant.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwelling**
Test species			***Oncorhynchus mykiss***	***Acipenser transmontanus***	***Daphnia magna***	***Daphnia magna***	***Selenasrtum capricornutum***	***Chironomus ripatius***		***Tubifex tubi-fex***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	NOEC		NOEC
(µg/L)			207	1.12	26.6	7.6	22.29	500		16.17 mg/kg
AF			100	10	100	10	10	10		5*
RAC (µg/L)			2.07	0.12	0.266	0.76	2.229	50		3.23
Region	**Season of application**	**PEC sw-$_{max}$ (µg/L)**	**PEC/RAC ratios**						**PEC sed $_{max}$ (mg/kg)**	**PEC/ RAC ratios**
Step 1		38.90	**18.792**	**324.167**	**146.241**	**51.184**	**17.452**	0.778	23.020	**7.127**
Step 2										
N-Europe	March-May	10.30	**4.976**	**85.833**	**38.722**	**13.553**	**4.621**	0.206	18.310	**5.669**
~~S-Europe~~	March-May	~~10.30~~	~~4.976~~	~~85.833~~	~~38.722~~	~~13.553~~	~~4.621~~	~~0.206~~	~~19.480~~	~~6.031~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to the EFSA Journal 2018;16(1):5152

Based on the results performed in the Tables above, the PEC/RAC ratio is above trigger of 1 for fish, aquatic invertebrates and algae. In case of sediment dwelling organism for species *Chironmus riparius* (spiked in sediment) the an unacceptable risk is identified .
In addition, since according to EFSA Journal 2018;16(1):5152 the background level of copper in sediment of 17 mg/kg is considered, the calculatitons are not fully relevant and the risk for sediment dwelling organim (spiked in sediment) needs further consideration.
Since, the final endpoint of 3.23 mg/kg of sediment for invertebrates living in sediment is not finalised and fully accepted on the level of EU, this endpoint is not considered during calculations of risk mitigation. Therefore only calculations for water living animals are considered relevant, and on their base, the mitigation measures are calculated/
Refined endpoints based on species sensitivity distribution (SSD) were available for both the acute and chronic risk assessment for fish and were discussed and agreed on in the Pesticide Peer Review meeting. The respective endpoints are reported in the EFSA conclusion (EFSA Journal 2018;16(1):5152) and considered for the higher tier risk assessment below. It was agreed that total or dissolved copper might be considered as equivalent; and that the SSD could be built using data expressed both as total and dissolved copper, depending on how the studies had been designed and reported.

With respect to algae and aquatic invertebrates, a microcosm study was available. The experts at the Pesticide Peer Review meeting agreed to use the end point derived from this study (ETO-RAC) together with an assessment factor of 2.

9.5.3 Overall conclusions

Article 43

Taking into consideration risk mitigation calculations for MIEDZIAN 50 WP –following risk mitigation measures should be applied:
When using in pome fruit:
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Article 51

Taking into consideration risk mitigation calculations for MIEDZIAN 50 WP –following risk mitigation measures should be applied:
When using in pome fruit:
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables, vine, currant and legumes:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits
- 70 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Using the above-mentioned precautions, formulation MIEDZIAN 50 WP can be used and will not have a negative impact on aquatic species.

zRMS comments:

We agree with the risk assessment for aquatic organism.
The calculations for water living animals are considered relevant, and on their base - on the lowest endpoint for fish with RAC =0.37 microgram/L, the mitigation measures are calculated.
In case of sediment dwelling organism with the lowest endpoint of 3.23 microgram/L the risk assessment at EU level is not finalised for the active substance.
However, there is no approved guideline for calculating PEC_{sed} values to determine protective measures, similar to PEC_{sw} value approach. Therefore, a high risk to sediment dwellers (exposure via sediment) was still concluded for proposed uses. The MS should apply their own mitigation measure at national level.
zRMS-PL proposes to apply existing default mitigation measure for product – Miedzian 50 WP for Poland:

Article 43

Taking into consideration risk mitigation calculations for MIEDZIAN 50 WP – following risk mitigation measures should be applied:
When using in pome fruit at rate 0.75 kg a.s./ha:
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Article 51

Taking into consideration risk mitigation calculations for MIEDZIAN 50 WP –following risk mitigation measures should be applied:
When using in pome fruit for application dose at rate 1.5 kg a.s./ha
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables, vine, currant and legumes:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits at rate 1.5 kg a.s./ha
- 70 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Greenhouse uses

Additional PEC_{SW} calculations for greenhouse uses (indoor crops; spray drift only, without mitigation) were performed by zRMS calculations in Section 8.

Use Nº (Crop)	Application of Cu g/ha	Drift rate (ditch) %	PEC_{SW} µg/L	PECsw including factor of 3 µg/L
12	1250	0.1	0.417	0.139
14	1250		0.417	0.139
16	800		0.267	0.089
19	1250		0.417	0.139
20	1250		0.417	0.139
21	1250		0.417	0.139

The intended uses in greenhouse are considered to be covered by the calculations provided (greenhouse as defined in Regulation 1107/2009; high and low technical greenhouses).
In case of the same application method with any type of open structure it is considered that the risk assessment should be carried out as "field" uses (protected structures such as: low mini tunnel, plastic shelter, walk-in tunnel, net shelter and shade house).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds based on dissolved maximum PEC_{sw}.

Group		Fish acute (higher tier)	Fish pro-longed (higher tier)	Inverteb. Acute (higher tier)	Inverteb. prolonged (higher tier)	Algae (higher tier)
Test species		**7 fish species**		**Indoor microcosm study**		
Endpoint (µg/L)		**SSD-HC_5 3.73**	**SSD-HC_5 1.11**	**ETO-RAC = 4.8**		
AF		3	3	2		
RAC (µg/L)		**1.24**	**0.37**	**2.4**		
Use Nº (Crop)	**Max. PEC_{sw} (µg/L)**					
11	0.139	0.11	0.375	0.059		
13	0.139	0.11	0.375	0.058		
15	0.089	0.071	0.24	0.037		
18	0.139	0.11	0.375	0.059		
19	0.139	0.11	0.375	0.059		
20	0.139	0.11	0.375	0.059		

The risk assessment for greenhouse as defined in Regulation 1107/2009; high and low technical greenhouses is considered acceptable as the PEC/RAC value is above 1.
In case of the same application method with any type of open structure it is considered that the risk assessment should be carried out as "field" uses (protected structures such as: low mini tunnel, plastic shelter, walk-in tunnel, net shelter and shade house).
Therefore, the risk mitigation measures for aquatic organism should be applied when using in these protected structures **in fruiting vegetables (indoor uses):**
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle to surface water bodies

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

Effects on bees of MIEDZIAN 50 WP were not evaluated as part of the EU assessment of copper compound. 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	Copper oxychloride	Oral	LD_{50} = 12.1 µg/bee	EFSA Journal 2013;11(6):3235

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Copper oxychloride	Contact	LD_{50} = 44.3 µg/bee	EFSA Journal 2013;11(6):3235
Apis mellifera	MIEDZIAN 50 WP	Oral	LD_{50} = 14.24 µg/bee	Grzesica M., 2019, Study code: B/23/19
Apis mellifera	MIEDZIAN 50 WP	Contact	LD_{50} > 200 µg/bee	Grzesica M., 2019, Study code: B/24/19

9.6.1.1 Justification for new 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

Calculations according to Article 43:

Table 9.6-2: First-tier assessment of the risk for bees due to the use of MIEDZIAN 50 WP in pome fruit

Intended use	Pome fruit		
Active substance	Copper oxychloride		
Application rate (g/ha)	4 x 750 (for copper)		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	12.1	750	**61.9**
Contact toxicity	44.3		16.9
Product	MIEDZIAN 50 WP		
Application rate (g/ha)	4 × 1500		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	14.24	1500	**105**
Contact toxicity	> 200		7.5

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

Calculations performed for minor uses according to Article 51

Since using in orchards (nuts) represents the worst case for minor uses it is used for calculations

Table 9.6-3: First-tier assessment of the risk for bees due to the use of MIEDZIAN 50 WP in nuts

Intended use	Orchards

Active substance **Application rate (g/ha)**	Copper oxychloride 2 × 1500		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	12.1	1500	**124**
Contact toxicity	44.3		34
Product **Application rate (g/ha)**	MIEDZIAN 50 WP 2 × 3000		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	14.24	3000	**211**
Contact toxicity	> 200		15

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

9.6.2.2 Higher-tier risk assessment for bees

In additional studies, prevention time for bees was determined. One hour is predicted as a period of time, after which MIEDZIAN 50 WP is safe for bees (Londzin, W. et al. 2007).
In tunnel test low risk for bees was proved when using with Copper Oxychloride 50 % WP with dose of 2500 g a.s./ha (Kleinhenz, M. 2011)

zRMS comments:

The risk assessment for acute oral and contact exposure for bees has been accepted by ZRMS-PL.

Based on the result above the trigger value below 50 for acute oral exposure to bees.

During the renewal of the active substance – copper a semi-field study and- cage tests with Copper oxychloride WP and Bordeaux Mixture were performed. The results indicated that no significant effects were found on the numbers of dead bees or on their behaviour or brood development up to concentrations of 1.25 kg Cu/ha. However, in tunnel test performed with Copper Oxychloride WP on phacelia with single application of 2.5 kg Cu./ha a statistically significant reduction was observed on flight intensity at t rate of 2.5 kg Cu/ha.

Therefore, the following risk mitigation measures should be applied:

SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.

According to new requirements of Reg. No. 284/2013, data on chronic effects on development of bees and chronic test for adult bees for present formulation Miedzian 50 WP should have been submitted by applicant as exposure of bees to the formulation Miedzian 50 WP cannot be excluded.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

The HQ value for contact toxicity is lower than the trigger of 50, indicating low risk to bees from MIEDZIAN 50 WP following application. The HQ value for oral toxicity is over the trigger of 50, indicating high risk for bees. ~~However higher tier studies proved low risk for bees.~~
~~Therefore a low risk to bees is expected from the application of MIEDZIAN 50 WP following application according to the proposed GAP. However, application should be performed in time of no bees activities.~~
Therefore, we propose to following risk mitigation measures to bees:

- **Dangerous to bees.**

To protect bees and other pollinating insects do not apply to crop plants when in flower

- Do not use where bees are actively foraging.

-Do not apply when flowering weeds are present.

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

Effects on non-target arthropods of MIEDZIAN 50 WP were not evaluated as part of the EU assessment of copper compound. 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)	MIEDZIAN 50 WP	Laboratory test	LR_{50} > 5.75 kg/ha	Holewik P., 2020, Study code: B-92-20
Aphidius rhopalosiphi (adults)	MIEDZIAN 50 WP	Laboratory test	LR_{50} > 5.75 kg/ha	Holewik P., 2020, Study code: B-93-20

9.7.1.1 Justification for new endpoints

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

Calculations according to Article 43

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of MIEDZIAN 50 WP in pome fruit

Intended use	Orchards (pome fruit)		
Active substance/product	MIEDZIAN 50 WP		
Application rate (g/ha)	4 × 1500		
MAF	2.7#		
Test species Tier I	**LR_{50} (lab.) (kg/ha)**	**$PER_{in-field}$ (kg/ha)**	**$HQ_{in-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>5.75	4.05	0.7
Aphidius rhopalosiphi	>5.75		0.7
Intended use	**Orchards (pome fruit)**		
Active substance/product	**MIEDZIAN 50 WP**		
Application rate (g/ha)	**4 × 1500**		
MAF	1 (soil)		
Typhlodromus pyri	>5.75	6.0	1.043
Aphidius rhopalosiphi	>5.75		1.043

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

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- tier assessment of the off-field risk for non-target arthropods due to the use of MIEDZIAN 50 WP in pome fruits

Intended use	Orchards (pome fruits)				
Active substance/product	MIEDZIAN 50 WP				
Application rate (g/ha)	4 × 1500				
MAF	2.7				
Vdf	10 (Tier 1), 5 (Tier 1)*				
Test species Tier I	**LR_{50} (lab.) (kg/ha)**	**Drift rate #**	**$PER_{off-field}$ (kg/ha)**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>5.75	23.61	0.096 0.191	10	0.17 0.33
Aphidius rhopalosiphi	>5.75				0.17 0.33
Intended use	**Orchards (pome fruits)**				
Active substance/product	**MIEDZIAN 50 WP**				
Application rate (g/ha)	**4 × 1500 (6000)**				
MAF	**1 (soil)**				
Vdf	**10 (tier1),** 5 (Tier 1)*				

Typhlodromus pyri	>5.75	23.61	0.141 0.28	10	0.246 0.49
Aphidius rhopalosiphi	>5.75				

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.
Drift rate value for fruit (four application) was used
* according to recommendation given during Harmonisation meeting in Central Zone

Calculations according to Article 51

Fruiting vegetables as a worst case for calculations were used

Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of MIEDZIAN 50 WP in fruiting vegetables

Intended use	Fruiting vegetables		
Active substance/product	MIEDZIAN 50 WP		
Application rate (g/ha)	3 × 2500		
MAF	2.3#		
Test species Tier I	**LR_{50} (lab.) (kg/ha)**	**$PER_{in\text{-}field}$ (kg/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>5.75	5.75	1.0
Aphidius rhopalosiphi	>5.75		1.0
Intended use	**Fruiting vegetables**		
Active substance/product	**MIEDZIAN 50 WP**		
Application rate (g/ha)	**3 × 2500 (7500)**		
MAF	**1 (soil)**		
Typhlodromus pyri	>5.75	7.5	1.3
Aphidius rhopalosiphi	>5.75		

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

9.7.2.3 Risk assessment for off-field exposure

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of MIEDZIAN 50 WP in fruiting vegetables

Intended use	Fruiting vegetables				
Active substance/product	MIEDZIAN 50 WP				
Application rate (g/ha)	3 × 2500				
MAF	2.3				
Vdf	10 (Tier 1), 5 (Tier 1)*				
Test species Tier I	**LR_{50} (lab.) (kg/ha)**	**Drift rate #**	**$PER_{off\text{-}field}$ (kg/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>5.75	6.90	0.040 0.08	10	0.07 0.14
Aphidius rhopalosiphi	>5.75				0.07 0.14

Intended use	**Fruiting vegetables**				
Active sub-stance/product	**MIEDZIAN 50 WP**				
Application rate (g/ha)	**3 × 2500 (7500)**				
MAF	**1**				
Vdf	10 (Tier 1), 5 (Tier 1)*				
Typhlodromus pyri	>5.75	6.90	0.045 0.10	10	0.08 0.18
Aphidius rhopalosiphi	>5.75				

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.
Drift rate value for veegetables (three application) was used
* according to recommendation given during Harmonisation meeting in Central Zone

zRMS comments:

The in-field and off field risk to non-target arthropods is considered as low for all the representative uses when foliar MAF was considered.

However, during the Ecotox Expert Meeting 169 it was suggested that for soil the total amount applied in the season should be used since it cannot be ensured that dissipation occur between applications.

The experts agreed to use the total amount applied in the year in the risk assessment for soil NTA for application <20 BBCH.

Based on calculated PER_{soil} in-field and PER_{soil} off -field the risk to non-target arthropods is considered as low for all the representative uses of **Miedzian 50 WP.**

9.7.2.4 Additional higher-tier risk assessment

Not relevant.

9.7.2.5 Risk mitigation measures

9.7.3 Overall conclusions

A. rhopalosiphi and *T. pyri* are organisms used to designation the initial assessment.
$HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for *A. rhopalosiphi* and *T.pyri* are below the ESCORT 2 trigger of 2. The calculations present an acceptable risk to non-target arthropods, after spray application of MIEDZIAN 50 WP.

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 copper oxychloride. Full details of these studies are provided in the respective EU

DAR and related documents.
Since previous studies present safe concentration of copper in the soil, what indicate low risk for soil organism, and predicted concentration is not reach after application of MIEDZIAN 50 WP, no further study was performed.

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

~~Species~~	~~Substance~~	~~Exposure System~~	~~Results~~	~~Reference~~
~~*Eisenia fetida*~~	~~Copper oxychloride~~	~~Mixed into substrate / 56 d, chronic~~	~~NOEC = 15 mg Cu/kg dw~~	~~Peer review EFSA Journal 2013;11(6):3235~~
~~*Eisenia fetida*~~	~~Copper~~	~~Field studies~~	~~RAC = 42.67 mg Cu/kg soil dw~~	~~Renewal Assessment Report for Copper compounds (France)~~

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

Table 9.8-2: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna).

Species	Substance	Exposure System	Results	Reference
Earthworms				
Eisenia fetida	Copper oxychloride	Chronic, 56 d OECD soil	$NOEC_{r(cp)}$ <40.5 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d LUFA: 3.9% OECD: 10%	**$NOEC_{r(cp)}$ = 8.4 mg Cu/kg soil (LUFA 2.2 soil)** $NOEC_{r(cp)}$ = 103.2 mg Cu/kg soil (OECD soil) $NOEC_{r(jp)}$ = 103.2 mg Cu/kg soil (OECD soil)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 13.2 mg Cu/kg soil (OECD soil) $NOEC_{r(jp)}$ = 35.2 mg Cu/kg soil (OECD soil) and 37.2 mg Cu/kg soil (LUFA 2.2 soil)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 21 d OM: 4.7%	$NOEC_g$ = 715 mg Cu/kg soil $NOEC_r$ = 115 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Cu oxychloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 83.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	$Cu(NO_3)_2.3H_2O$	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 28.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper nitrate	Chronic, 56 d OM: 10%	LC_{50} = 555 mg Cu/kg soil $NOEC_m$ = 202.4 mg Cu/kg soil EC_{50} (cocoons) = 53.3 mg Cu/kg soil $NOEC_{r(cp)}$ = 12.4 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Copper nitrate	Chronic, 21 d OM: 10%	$NOEC_{r(cp)}$ = 32.3 mg Cu/kg soil $NOEC_g$ = 728.2 mg Cu/kg soil $NOEC_m$ = 296.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	Cu acetate	Chronic, 28 d	LC_{50} = 82.8 – 3717 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida	$CuCl_2$	Chronic, 21 d	NOEC=300 mg Cu/kg soil (mortality and growth)	EFSA Journal 2018;16(1):5152
Eisenia fetida	Copper chloride	Chronic, 28 d	$EC_{10,r}$ = 54 – 324 mg Cu/kg soil (17 values for different soil types)	EFSA Journal 2018;16(1):5152
Eisenia andrei	Unknown	Chronic, 28 d OM: 3.7%	$EC_{10,r}$ = 159 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d OM: 0.5%	$NOEC_m$ = 192 mg Cu/kg soil $NOEC_r$ = 192 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper salt	Chronic, 84 d OM: 10%	$NOEC_g$ = 59.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{r(cp)}$ = 123.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia andrei	Copper chloride	Chronic, 84 d OM: 10%	EC50 > 100 mg Cu/kg soil $NOEC_g$ = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 84 d	$NOEC_m$ = 162 mg Cu/kg soi	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 42 d OM: 3.4-5.7%	$NOEC_r$ = 54 mg Cu/kg soil $NOEC_{lb}$ = 54 mg Cu/kg soil $NOEC_g$ = 131 mg Cu/kg soil $NOEC_m$ = 131 mg Cu/kg soil $NOEC_{lb}$ = 63 mg Cu/kg soil $NOEC_m$ = 136 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 294 d OM: 9.8%	$NOEC_g$ = 154 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Lumbricus rubellus	Copper chloride	Chronic, 110 d OM: 0.5%	$NOEC_g$ = 76 mg Cu/kg soil $NOEC_m$ = 153 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Allobophora calliginosa (=*Aporrectodea caliginosa*)	Copper sulfate	Chronic, 14 d	$NOEC_m$ = 511 mg Cu/kg soil $NOEC_{r(cp)}$ = 60.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Aporrectodea caliginosa	Copper sulfate	Chronic, 42 d and 56 d OM: 21.6%	$NOEC_g$ = 35.7 mg Cu/kg soil $NOEC_{r(cp)}$ = 80.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Dendrobaena rubida	Copper nitrate	Chronic, 90 d OM: 7.7-11.7%	$NOEC_{r(cp)}$ = 100 (pH 5.5) and 101.3 mg Cu/kg soil (pH 6.5)	EFSA Journal 2018;16(1):5152
Dendrobaena rubida	Copper nitrate	Chronic, 120 d OM: 7.7-11.7%	4 month-NOEC (cocoon reduction) = 100 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Octalasium cyaneum	Copper sulfate	Chronic, 14 d and 30 d OM: 5.4-72%	30 d – $NOEC_m$ =153 mg Cu/kg soil 14 d – $NOEC_m$ =1214 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Eisenia fetida		Mixed into substrate / 56 d, chronic	$NOEC_{reproduction}$ =	
Other soil macroorganisms				
Enchytraeidae (Oligochaeta, Annelida)				
Cognettia sphagnetorum	Copper chloride	Chronic, 70 d OM: 66%	35-day $EC_{10, g}$ = 73.7 mg Cu/kg soil 63-day $EC_{10, g}$ = 451.7 mg Cu/kg soil 42-day $EC_{10, g}$ = 322.7 mg Cu/kg soil 70-day $EC_{10, f}$ = 465.7 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. albidus	Copper chloride	Chronic, 42 d OM: 5.5%	$EC_{10, m}$ = 347 mg Cu/kg soil $EC_{10, r}$ = 71 mg Cu/kg soil $EC_{10, a}$ = 362 mg Cu/kg soil $NOEC_m$ = 430 mg Cu/kg soil $NOEC_r$ = 230 mg Cu/kg soil $NOEC_a$ = 230 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. albidus	Copper chloride	Chronic, 42 d OM: 3.6%	$EC_{10, r}$ (soil 1) = 355 mg Cu/kg soil $EC_{10, r}$ (soil 2) = 107 mg Cu/kg soil $EC_{10, r}$ (soil 3) = 72 mg Cu/kg soil $EC_{10, r}$ (soil 4) = 119 mg Cu/kg soil $EC_{10, r}$ (soil 5) = 399 mg Cu/kg soil $EC_{10, r}$ (soil 6) = 241 mg Cu/kg soil NOEC in field transects: 418 to ≥ 689 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
E. crypticus	Copper chloride	Chronic, 56 d OM: 3.9%	EC_{50} (reprod., 11°C) ≈ 70 mg Cu/kg soil EC_{50} (reprod., 18°C) ≈ 160 mg Cu/kg soil EC_{50} (reprod., 25°C) ≈ 180 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	Chronic, 21 d OM: 4.6%	$EC_{10, r}$ = 126.5 mg Cu/kg soil $NOEC_r$ = 135 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	Chronic, 63 d OM: 3.9%	21-day $EC_{10, r}$ = 180.2 mg Cu/kg soil 63-day $EC_{10, r}$ = 90.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
E. crypticus	Copper chloride	OM: 3.9%	$EC_{10, r}$ = 55 mg Cu/kg soil $EC_{10, m}$ = 62 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Collembola (Hexapoda, Arthropoda)				
Folsomia candida	Copper chloride	Chronic, 28 d OM: 1.4-37%	**$EC_{10, r}$ = 31** – 1460 mg Cu/kg soil (21 values for different soil types)	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper nitrate	Chronic, 28 d	$EC_{50, r}$ (pH 6.0)= 703.2 mg Cu/kg soil $NOEC_r$ (pH 6.0)= 203.2 mg Cu/kg soil $NOEC_m$ (pH 6.0)= ≥3003.2 mg Cu/kg soil $EC_{50, r}$ (pH 5.0) = 713.2 mg Cu/kg soil $NOEC_r$ (pH 5.0) = 203.2 mg Cu/kg soil $NOEC_m$ (pH 5.0) = 43.2 mg Cu/kg soil $EC_{50, r}$ (pH 4.5) = 1483.2 mg Cu/kg soil $NOEC_r$ (pH 4.5) = 1003.2 mg Cu/kg soil $NOEC_m$ (pH 4.5) = ≥3003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 42 d OM: 10%	$NOEC_r$ = 203.2 mg Cu/kg soil $NOEC_m$ = 1003.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 28 d OM: 10%	$NOEC_{ri}$ = 803.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152
Folsomia candida	Copper chloride	Chronic, 21 or 56 d	21-day $NOEC_g$ (LUFA 2.2) = 205.2 mg Cu/kg soil 21-day $NOEC_r$ (LUFA 2.2) = 405.2 mg Cu/kg soil 56-day $NOEC_g$ (OECD) = 803.2 mg Cu/kg soil 56-day $NOEC_r$ (OECD) = 403.2 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

Species	Substance	Exposure System	Results	Reference
Folsomia candida	Copper chloride	OM: 3%	$EC_{10, r}$ = 212 mg Cu/kg soil NOEC = 320 mg Cu/kg soil	EFSA Journal 2018;16(1):5152

9.8.1.1 Justification for new endpoints

9.8.2 Risk assessment

The evaluation of the risk for earthworms 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). Since concentration of active substance of copper oxychloride is 87.5% in product MIEDZIAN 50WP, risk assessment for earthworms is performed based on available and accepted results from other higher tier studies.

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 8.6.2.1, Table 8.6-12. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for copper oxychloride.

Calculations According to Article 43

Table 9.8-3: First-tier assessment of the chronic risk for earthworms due to the use of MIEDZIAN 50 WP in orchard (pome fruit)

Intended use	Orchard (pome fruits)		
Chronic effects on earthworms (reproduction)			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw) after one year**	**criterion TER ≥5**
Copper	15	1.000	15
Product/active substance	**RAC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**criterion RAC ≥ PEC**
Copper	42.67	39.95	Yes

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

Calculations for minor uses according to Article 51

Since use in vine represents the worst case for application, only this calculation is performed.

Table 9.8-4: 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 MIEDZIAN 50 WP in vine

Intended use	vine
Chronic effects on earthworms (reproduction)	

Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw) after one year**	**criterion TER ≥5**
Copper	15	5.0	**3**
Product/active substance	**RAC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**criterion RAC ≥ PEC**
Copper	42.67	49.94	**No**

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

9.8.2.2 Higher-tier risk assessment

According to field studies, during annual application of copper in a dose of 4 kg/ha, no negative influence on reproduction of earthworms was observed. Since the highest proposed dose for MIEDZIAN 50 WP is 3.75 kg/ha/year no risk for earthworm should be considered.

zRMS comments:

zRMS doesn't agree with the risk assessment provided by the applicant. The risk assessment with considered PECs for the - a.s. agreed in Section 8 and with endpoints included in EFSA Conclusion 2018 is presented in the Tables below.

Table 9.8-5_{corr}: 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 Miedzian 50 WP.

Intended use	0rchards		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	8.4	71.8 [1]	**0.11**
Copper oxychloride	8.4	86 [2]	**0.08**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	31	71.8 [1]	**0.43**
Copper oxychloride	31	86 [2]	**0.36**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	179	71.8 [1]	**2.50**
Copper oxychloride	179	86 [2]	**2.08**

TER values shown in bold fall below the relevant trigger.
[1] Overall $PEC_{soil, accumulation}$ at 90th percentile.
[2] Overall $PEC_{soil, accumulation}$ at 10th percentile.

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Table 9.8-6$_{corr}$: 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 Miedzian 50 WP.

Intended use	**0rchards**		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	8.4	57.8 [1]	**0.14**
Copper oxychloride	8.4	72 [2]	**0.11**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC$_{10}$ (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	31	57.8 [1]	**0.53**
Copper oxychloride	31	72 [2]	**2.32**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC$_{10}$ (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	179	57.8 [1]	**3.10**
Copper oxychloride	179	72 [2]	**2.48**
Intended use	**Fruiting vegetables**		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	8.4	48.8 [1]	**0.17**
Copper oxychloride	8.4	93 [2]	**0.09**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC$_{10}$ (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	31	48.8 [1]	**0.63**
Copper oxychloride	31	93 [2]	**0.33**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC$_{10}$ (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	179	48.8 [1]	**3.66**
Copper oxychloride	179	93 [2]	**1.92**
Intended use	**Legumines**		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC$_{soil}$ (mg/kg dw)**	**TER$_{lt}$ (criterion TER ≥ 5)**
Copper oxychloride	8.4	49 [1]	**0.17**
Copper oxychloride	8.4	68 [2]	**0.12**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			

Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	31	49 [1]	**0.63**
Copper oxychloride	31	68 [2]	**0.45**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	179	49 [1]	**3.65**
Copper oxychloride	179	68 [2]	**2.63**
Intended use	**Currant, nuts**		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	8.4	42.4 [1]	**0.19**
Copper oxychloride	8.4	48.4 [2]	**0.17**
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	31	42.4 [1]	**0.73**
Copper oxychloride	31	48.4 [2]	**0.64**
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	**EC_{10} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Copper oxychloride	179	42.4 [1]	**4.22**
Copper oxychloride	179	48.4 [2]	**3.7**

TER values shown in bold fall below the relevant trigger.
[1] Overall $PEC_{soil, accumulation}$ at 90th percentile.
[2] Overall $PEC_{soil, accumulation}$ at 10th percentile.

The long-term TER values for Copper are below the trigger value of 5, indicating a risk to earthworms and other non-target soil organisms (meso- and macrofauna).

Therefore, further refinement was needed for higher tier risk assessment.

Several studies were assessed during the RAR, it was concluded an acceptable risk to earthworms at the maximum dose rate of 4 kg Cu /ha per year. During expert meeting (Report from Pesticides Peer Review Meeting 169, 09-10 October 2017, Copper compounds) it was concluded that earthworms seem to be the most sensitive group.

In the same time the risk for soil – macro-organism was not able to be ruled out still (TER_{lt} below 5).

Considering all the available information, zRMS-PL is of the same opinion as RMS in RAR, and considers that the long-term risk of copper compounds would be acceptable for an annual dose rate not higher than 4 kg Cu/ha per year for all soil macro-organism.

Spe 1: To protect soil organisms do not apply this or any other product containing copper for an annual dose rate higher than 4 kg Cu/ha per year.

The risk for soil macro-organism should be considered at MSs level.

9.8.3 Overall conclusions

The calculated chronic (reproduction) effect on earthworms is predicted to be low after annual application of MIEDZIAN 50 WP, indicating acceptable chronic risk from the proposed uses of MIEDZIAN 50 WP.

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

Effects on soil microorganisms of MIEDZIAN 50 WP were not evaluated as part of the EU assessment of copper oxychloride WP. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Copper oxychloride (WP)	28 d, aerobic soil type	Nitrate formation rate 18.1 mg Cu/kg soil dw < 25 %	Peer review EFSA Journal 2013;11(6):3235
N-mineralisation	MIEDZIAN 50 WP	28 d, aerobic soil type	Nitrate formation rate 16.1 mg Cu/kg soil dw < 25 %	Holewik P, 2020, G/46/19
N-mineralisation	Copper hydroxide (WP)	1 year, field studies	Nitrate formation rate 48 kg/ha, 64 mg Cu/kg soil dw < 25 %	EFSA Journal 2013;11(6):3235

9.9.1.1 Justification for new endpoints

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), 8.6.2.1, Table 8.6-11 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Calculations according to Article 43:

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of MIEDZIAN 50 WP in orchards (pome fruits)

Intended use	Orchard (pome fruits)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Copper oxychloride	18.1 (at 28 d)	39.95	no
MIEDZIAN 50 WP	16.1 (at 28 d)	39.95	no
Copper hydroxide (WP)	64	39.95	yes

Calculations for minor uses according to Article 51

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of MIEDZIAN 50 WP in vine

Intended use	Vine		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Copper oxychloride	18.1 (at 28 d)	49.94	no
MIEDZIAN 50 WP	16.1 (at 28 d)	49.94	no
Copper hydroxide (WP)	64	49.94	yes

Since using in vine represents the worst case, PEC obtained for this crop is used for calculations.

Based on calculations for MIEDZIAN 50 WP, risk for microorganisms is not acceptable. However there was no evidence of significant effects on evolved CO2 and nitrogen nitrification after a 28-day incubation in the presence of ground vine leaves, based on soils contaminated with Copper Hydroxide WP at 48 kg Cu/ha, which dose is relevant to 64 mg Cu/kg soil, what is concentration over predicted concentration in soil after 10 years of using MIEDZIAN 50 WP.

ZRMS comments:

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 assessment covering the proposed use pattern are taken from Section 8 (Environmental Fate). The risk assessment was not acceptable for Copper oxychloride.However the field study evaluated at EU level is available for copper compounds.

This muti-field site study was carried out in three sites in France. Up to four months after treatment with Copper Hydroxide WP (8 x 2 kg Cu/ha and 48 kg Cu/ha) there were no effects on the CO_2 evolution and nitrogen mineralization.

There was no either evidence of significant effects on evolved CO2 and nitrogen nitrification after a 28-day incubation in the presence of ground vine leaves, based on soils contaminated with Copper Hydroxide WP at 16 kg and 48 kg Cu/ha.

In addition, no risk for soil micro-organisms is expected after the application Miedzian 50 WP according to the proposed GAP as the <25% effects were observed for 16.1 mg product/kg dws.

9.9.3 Overall conclusions

On the basis of results it was assessed that MIEDZIAN 50 WP in considered applications does not pose unacceptable risk to soil microorganisms.
The risk to soil micro-organisms is considered to be low for all representative uses.

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

However, the provision of further data on the formulation is not considered essential, because active substance copper oxychloride is a fungicide and as proved in studies presented in DAR (France, 2007) has no aversive effects to terrestrial plants.

zRMS comments:

The study for non-target plants from exposure the MIEDZIAN EXTRA 350 SC was not available.
However, the phytotoxicity assessment was provided in Section Efficacy (see point 3.4.5.)
Phytotoxicity was visual only in two trials on apple flowers of the Idared variety. In all others trial no phytotoxicity was shown. No phytotoxicity symptom caused by Miedzian 50 WP at the highest dose rate of 6 kg/ha was recorded in all trials.
Based on the result above the risk for non- target plants is considered acceptable.

9.10.1.1 Justification for new endpoints

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

Not relevant.

9.10.2.3 Higher-tier risk assessment

Not relevant.

-

9.10.2.4 Risk mitigation measures

9.10.3 Overall conclusions

Since the copper oxychloride is a fungicide no risk for non-target terrestrial plants is predicted.

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

No additional data.

9.13 Classification and Labelling

MIEDZIAN 50 WP was classified and labeled according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

For classification of MIEDZIAN 50 WP mixtures classification method was used.

Acute Category 1 (concentration of copper oxychloride is higher than 25%).
Chronic Category 1 (concentration of copper oxychloride is higher than 25%).

CLASSIFICATION	
Hazard classes, categories:	Aquatic Acute 1, Aquatic Chronic 1,
LABELLING	
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statements:	H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements:	~~P273 – Avoid release to the environment.~~ P391 - Collect spillage.

	P501 - Dispose of contents/container to an approved waste disposal plant.

Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect a: When using in pome fruit: **- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,** When using in fruiting vegetables, vine, currant and legumes: **- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,** When using in stone fruits **- 70 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,** When using in orchards - nuts **- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,** For greenhouse uses as defined in Regulation 1107/2009; high and low technical greenhouses no risk mitigation measures are required for aquatic organism. In case of the same application method with any type of open structure it is considered that the risk assessment should be carried out as "field" uses (protected structures such as: low mini tunnel, plastic shelter, walk-in tunnel, net shelter and shade house) the risk mitigation measures for aquatic organism should be applied Therefore, when using Miedzian 50 WP in these protected structures in fruiting vegetables to protect aquatic organisms – respect - 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle to surface water bodies ~~Application should be performed in time of no bees and other pollinators activities~~ ***SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.***

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2	xxx	1997	Ocena toksycznego działania preparatu MIEDZIAN 50 WP na organizmy wodne xxx Non-GLP	Y	Synthos Agro Sp. z o.o.
KCP 10.3.1	Grzesica, M.	2019	Honeybees (*Apis melifera* L.), Acute Oral Toxicity Test Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code G/23/19 GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Grzesica, M.	2019	Honeybees (*Apis melifera* L.), Acute Contact Toxicity Test Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code G/24/19 GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Londzin, W.	2007	Technical copper oxychloride; Determination of prevention time for Honey-bee (*Apis melifera L.*), Study code: B/05/07 GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.2	Holewik, P.	2020	A laboratory test for evaluating the effects of MIEDZIAN 50 WP on the predatory mite, *Typhlodromus pyri* (Sch.). Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna,	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study code B-92-20 GLP		
KCP 10.3.2	Holewik, P.	2020	A laboratory test for evaluating the effects of MIEDZIAN 50 WP on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefan-Perez) Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code B-93-20 GLP	N	Synthos Agro Sp. z o.o.
KCP 10.5	Holewik, P.	2020	MIEDZIAN 50 WP, Soil Microorganism: Nitrogen Transformation Test Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code G/46/19 GLP	N	Synthos Agro Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1	-	2000	Copper oxychloride 50% WP, acute oral toxicity (LD50) to Japanese quail. Report No.: 12953/00, GLP	Y	-
KCP 10.1.1	-	1990a	The effects of dietary inclusion of copper hydroxide on reproduction in the bobwhite quail. Report No.: CSF 4/89767, GLP	Y	-
KCP 10.1.2	xxx	2002a	Tribasic copper sulphate: acute oral toxicity in the rat - acute toxic class method, GLP,	Y	-

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
			Published		
KCP 10.2	-	2000a	Early life stage toxicity of Funguran-OH (URA-08740-F-O-WP) to rainbow trout *(Oncorhynchus mykiss)* Report No.: URA-001/4-18, GLP	N	-
KCP 10.2	-	2002a	Acute toxicity of copper (I) oxide technical to rainbow trout (Oncorhynchus mykiss) Report No. ECT-004/4-13. GLP Not published	Y	EUCuTF
KCP 10.2	Bellmann, W.	1993	21 d *Daphnia* reproduction test according to OECD Guideline 202, Part II, test article Funguran Report No.: 40095.315-202-II-05, GLP	N	-
KCP 10.2	Hargreaves, Paterson	2003	*S. capricornatum* 72-hour toxicity test	N	-
KCP 10.2	xxx	2014	(Acipenser transmontanus) and Rainbow Trout (Oncorhynchus mykiss) to Cadmium, Copper, Lead, or Zinc in Laboratory Water-Only Exposures Not GLP Published	Y	Public
KCP 10.2	xxx	1997a	Copper oxychloride technical, acute toxicity for rainbow trout (*Oncorhynchus mykiss)* Report No. CRO 12/973592, GLP, Unpublished	Y	Agri-Estrella Erachem, Isagro, IQV, Manica, Montanwerke Brixlegg, Spiess-Ukraina
KCP 10.2	Mallett, M.J.	2002	The acute toxicity of copper hydroxide technical to Daphnia magna CEMAS Report No. CEMR-1621 GLP Not published	N	EUCuTF

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	Noack, M.	2000a	Copper oxychloride: Acute immobilisation test (48 h) to *Daphnia magna* STRAUS Report No.: DAI73981, GLP	N	-
KCP 10.2	Schäfers, C.	2000b	Community level study with copper hydroxide 50% WP in aquatic microcosms Report number: URA-001/4-50 GLP Not published	N	EUCuTF
KCP 10.2	Stäbler, D.	2002	Assessment of Side effects of tribasic copper sulphate 15% SC on the larvae of the midge, Chironomus riparius with the laboratory test method. Report No. 20011426/01-ASCr GLP Not published	N	EUCuTF
KCP 10.3.1	Bruhnke, C.	2001	Acute effects on the honeybee *Apis melifera* (Hymenoptera, Apidae) URA-13900-F-O-WP GLP	N	-
KCP 10.3.1	Kleinhenz, M.	2011	Determination of side-effects of Copper on honebees (*Apis melifera* L.) after aplication of Copper Oxychloride 50% WP in *Phacelia tanacetifolia* in Germany 2011\ Reportn number S11-02236 GLP	N	-
KCP 10.4	Helling, B., et al.	2000	Effect of the fungicide copper oxychloride on the growth and reproduction of Eisenia fetida (Oligochaeta). Non GLP	N	-
KCP 10.4	Klein, O.	2015	A field study to evaluate the effects of copper on the earthworm fauna in Central Europe Report No. 20031343/G1-NFEw GLP Not published	N	EUCuTF
KCP 10.5	Scheerbaum, D.	2002	Copper oxychloride (WP) – Effects on soil micro-organisms Unpublished report no. 010704 UK GLP	N	-

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

A 2.2 KCP 10.2 Effects on aquatic organisms

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

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

zRMS comments:

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

- 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 exposure of the reference item (dimethoate) was 0.20 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee)

Agreed endpoints:

48 h LD_{50}/96 h = 14.24 µg product /honeybee.

Report	MIEDZIAN 50 WP: Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test, Grzesica M., 2019, Study code: B/23/19
Guideline(s):	OECD 213 / EU Method C.16.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:
The aims of the study were to use a laboratory method to determine the acute oral toxicity of Miedzian 50 WP to adult worker honeybees and the LD50 values.

Materials and methods:

Test item:	name: Miedzian 50 WP active substance: Cu in the form of copper oxychloride: 482 g/kg batch number: 283744/04 manufacturing date: 10.2018 expiry date: 10.2021
Biological test system:	the honeybee. *Apis mellifera* L. strain: carnica source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies age: approximately 3 weeks
Test design:	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:	3.125, 6.25, 12.5, 25.0 and 50.0 µg test item/bee and a control (0.0 µg/bee)

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 LD50/24 h exposure of the reference item (dimethoate) was 0.20 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee).

Results:
The acute oral toxicity study results of the test item MIEDZIAN 50 WP on honeybees (*Apis mellifera* L.) in the laboratory test after 96 hours, are summarized below.

After 96 hours of exposure, mortality of the control group was 0.0% and for the treated groups' mortality percentages after Abbott's correction at the doses of 3.125, 6.25, 12.5, 25 and 50 µg t.i./honeybee, were 13.3, 16.7, 50.0, 66.7 and 86.7%, respectively.
During the definitive test abnormal behavioural effects were observed after 4 hours of exposition.

Results of mortality:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 96 h		LD_{50} after 96 h [µg/bee]
		Total		
		[no.]	[%]	
0.0 (Control)	30	0	**0.0**	**14.24*** *(10.85 – 18.98)*
3.125	30	4	**13.3**	
6.25	30	5	**16.7**	
12.5	30	15	**50.0**	
25.0	30	20	**66.7**	
50.0	30	26	**86.7**	

*: the LD_{50} (with 95% confidence limits) was calculated with the log-probit method (ToxRat Proffesional 3.3.0 software[9], [SOP/B/67]).

Conclusions:
The median lethal dose and LD_{50}/96 h is 14.24 µg t.i./honeybee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

zRMS comments:

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

- 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 exposure of the reference item (dimethoate) was 0.20 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee)

Agreed endpoints:

LD_{50}/48 h > 200.0 µg product ./honeybee

	Grzesica M., 2019, Study code: B/24/19
Guideline(s):	OECD 214 / EU Method C.17.
Deviations:	Yes, regarding the number of tested doses.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study: The aims of the study were to use a laboratory method to determine the acute contact toxicity of Miedzian 50 WP to adult worker honeybees and to demonstrate that the LD50 values are higher than the highest dose used in the test.

Materials and methods:

Test item:	name: Miedzian 50 WP active substance: Cu in the form of copper oxychloride: 482 g/kg batch number: 283744/04 manufacturing date: 10.2018 expiry date: 10.2021
Biological test system:	the honeybee, *Apis mellifera* L., strain: carnica source: an apiary at the Institute of Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicological Studies age: approximately 3 weeks
Test design:	- the test item: exposure duration: 48 hours number of doses: 4 doses and a control number of replicates: 3 replicates number of bees: 10 bees/replicate - the reference item: exposure duration: 24 hours number of doses: 3 doses number of replicates: 3 replicates number of bees: 10 bees/replicate
Test item doses:	25.0, 50.0, 100.0 and 200.0 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 – 26ºC, relative air humidity: 62 – 67% place: a dark room
Endpoints:	- honeybee mortality after 24 and 48 hours of exposure - LD50/24 h and LD50/48 h of the test item - LD50/24 h of the reference item (dimethoate)
Statistical method:	regression analysis using the log-probit method

The following validity criteria were met during the test:
- the average mortality for the control was 3.3% after 48 h (criterion: it must not exceed 10%),
- the LD50/24 h of the reference item (dimethoate) was 0.23 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

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

After 24 and 48 hours of exposure, mortality of the control group and each treated group was 0.0%
The median lethal doses LD_{50}/24 h LD_{50}/48 h are higher than the maximum dose, i.e. 200.0 µg t.i./honeybee, used in the study.
During the definitive test no abnormal behavioural effects were observed in doses 25.0, 50.0, 100.0 and 200.0 µg t.i./honeybee.

Result for mortality:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD_{50} [µg/bee]
		Total			
		[no.]	[%]	[%][c]	
0.0 (Control)	30	1	3.3	–	> 200.0
25.0	30	1	3.3	0.0	
50.0	30	3	10.0	6.9	
100.0	30	2	6.7	3.5	
200.0	30	2	6.7	3.5	

[c]: mortality corrected using the formula of Abbott [10]

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

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

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

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 2.4 KCP 10.3.2 Effects on arthropods other than bees

zRMS comments:

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

– after 48 hours mortality of the control group were 0.0% (criterion: a maximum of 13.0%),

– after 24 hours mortality of the group treated with the reference item at the rate of 0.12 mL/ha was

85.0% (criterion: from 75 to 100%),

– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),

– the mean number of mummies per female in the control group was 16.4 (criterion: a minimum of 5.0 mummies/female),

– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Agreed endpoints:

LR_{50}>5.75 kg product/ha
ER_{50}>5.75 kg product/ha

Study 1

Report	A laboratory test for evaluating the effects of MIEDZIAN 50 WP on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez), Holewik P., 2020, Study code: B-93-20
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000,)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

AIM OF THE STUDY
The aim of the study was to determine the effect of MIEDZIAN 50 WP on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. The endpoints of this test were mortality of the wasps after 48 hours of exposure and fecundity reduction (Pr) 12 days after the oviposition phase.

Materials and methods:

Test item:	name: MIEDZIAN 50 WP active substance: copper: 491.8 g/kg batch number: A2091007 manufacturing date: 28.04.2020 expiry date: 28.04.2023
Biological test system:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: *Braconidae, Aphiidi-nae*
– age:	adult females (24 – 48 hours after emerging from mummies)
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Experimental design:	5 study groups: □ a control group (0.0 mL/ha) MIEDZIAN 50 WP at the rates: 5.75 kg/ha 2.30 kg/ha 0.92 kg/ha reference item: Bi 58 Top 400 EC at the rate of 0.12 mL/ha

	number of replicates: 4 number of wasps in each replicate: 10
Test conditions:	
– temperature:	18 – 21°C
– relative air humidity:	63 – 73%
– photoperiod:	16 h light : 8 h dark
– light intensity:	mortality assessment and oviposition: 2652 lx; fecundity assessment: 4822 lx
Statistical analysis:	Probit analysis using max. likelihood regression, Estimated parameters of the 3-param. normal CDF, Shapiro Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity (with Residuals), Williams Multiple Sequential 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 to test item, recorded 12 days after the oviposition period – determination of the ER50 and the NOERfecundity

The following validity criteria were met during the study:
– after 48 hours mortality of the control group were 0.0% (criterion: a maximum of 13.0%),
– after 24 hours mortality of the group treated with the reference item at the rate of 0.12 mL/ha was 85.0% (criterion: from 75 to 100%),
– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
– the mean number of mummies per female in the control group was 16.4 (criterion: a minimum of 5.0 mummies/female),
– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Results:
After 48 hours of exposure MIEDZIAN 50 WP at the control and at the rates of 0.92, 2.30 and 5.75 kg/ha percentages of mortality of *A. rhopalosiphi* were 0.0, 5.0, 0.0 and 0.0%, respectively.
Based on the obtained mortality results LR_{50} could not be estimated. It can be assumed that the LR_{50} is higher than 5.75 kg/ha of MIEDZIAN 50 WP.
The fecundity assessment showed that the mean number of mummies per female in the control group was 16.4. As for the wasps treated with MIEDZIAN 50 WP at the rates of 0.92, 2.30 and 5.75 kg/ha the mean number of mummies per female were 14.3, 13.3 and 10.7, respectively. Fecundity reduction (Pr) in the groups treated with the test item were 13.0, 18.7 and 34.6%, respectively.
Based on the obtained mortality results ER_{50} could not be estimated. It can be assumed that the ER_{50} is higher than 5.75 kg/ha of MIEDZIAN 50 WP.

	Mortality		Fecundity		
MIEDZIAN 50 WP [kg/ha]	Total [%]	LR_{50} [kg/ha]	MIEDZIAN 50 WP [kg/ha]	Total[%]	ER50 [kg/ha]
Control	0.0	> 5.75	Control	0.0	> 5.75
0.92	5.0		0.92	13.0	
2.30	0.0		2.30	18.7	
5.75	0.0		5.75	34.6	

Conclusions:
On the basis of the obtained results it can be concluded that MIEDZIAN 50 WP at the rate of 5.75 kg/ha has no adverse effect on the mortality of the wasps.
MIEDZIAN 50 WP at the rate 5.75 kg/ha has an effect on fecundity of the wasps lower than 50%.

Study 2

zRMS comments:

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

- Mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),

- Mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 95.0% on day 7 of exposure (criterion: from 50 to 100%),

- The mean number of eggs per female in the control group was 6.0 (required: ≥ 4 eggs per female)

Agreed endpoints:

LR_{50}>5.75 kg product/ha

ER_{50}>5.75 kg product/ha

Report	A laboratory test for evaluating the effects of MIEDZIAN 50 WP on the predatory mite, *Typhlodromus pyri* (Sch.) Holewik P., 2020, Study code: B-92-20
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	Yes (deviation did not influence the study course and results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:
The aim of the laboratory test was to evaluate the effects of the test item, MIEDZIAN 50 WP on mortality and re-production of the predatory mite, *T. pyri* (Sch.).

Materials and methods:

Test item:	name: MIEDZIAN 50 WP active substance: copper: 491.8 g/kg batch number: A2091007 production date: 28.04.2020 expiry date: 28.04.2023
Biological test system:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseiidae)*
– age:	24-hour-old protonymphs
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Experimental design:	5 study groups: a control group (0.0 mL/ha) MIEDZIAN 50 WP at the rates: 5.75 kg/ha 2.30 kg/ha 0.92 kg/ha reference item: Bi 58 Top 400 EC at the rate of 9.0 mL/ha number of replicates: 3 number of mites in each replicate: 20

Test conditions:
– temperature: 23.0 – 25.0°C
– relative air humidity: 60.0 – 77.0%
– photoperiod: 16 h light : 8 h dark
– light intensity: 652 lux
Statistical analysis: Probit analysis using max. likelihood regression, Chi2 2x2 Table Test with Bonferroni Correction, Shapiro Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity (with Residuals), Williams Multiple Sequential t-test Procedure

Endpoints:

– mite mortality after 7 days of the treatment
– LR50 and NOERmortality
– reproduction reduction (Pr) after 14 days of the treatment
– ER50 and NOERreproduction

The following validity criteria were met during the study [3]:
- mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),

- mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 95.0% on day 7 of exposure (criterion: from 50 to 100%),

- the mean number of eggs per female in the control group was 6.0 (required: ≥ 4 eggs per female).

Results:
In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to MIEDZIAN 50 WP at rates of 0.92, 2.30 and 5.75 kg/ha, the percentages of *T. pyri*, mortality were 0.0, 3.3 and 6.7%, respectively.
There were statistically significant differences in mortality between group treated with the test item at rate of 5.75 kg/ha and the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > Alpha*).
On the basis of the obtained mortality results, the LR_{50} is over 5.75 kg/ha of MIEDZIAN 50 WP. The NOER-mortality is 2.30 kg/ha of MIEDZIAN 50 WP.
The mean reproduction rate (Rr) in the control group was 6.0 eggs/female. The mean Rr after 14 days of exposure to MIEDZIAN 50 WP at rates 0.92, 2.30 and 5.75 kg/ha were 4.0, 3.8 and 4.1 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.92, 2.30 and 5.75 kg/ha were 32.8, 34.9 and 31.7%, respectively.
At the significance level of $\alpha \leq 0.05$, there was statistically significant difference between each group treated with the test item and the control group (Williams Multiple Sequential t-test Procedure,|t|>|t*|).
On the basis of the obtained results the endpoints regarding reproduction is higher than 5.75 kg/ha. The $NOER_{reproduction}$ is lower than 0.92 kg/ha.

	Mortality		Reproduction			
MIEDZIAN 50 WP [kg/ha]	Total [%]	LR_{50} [kg/ha]	MIEDZIAN 50 WP [kg/ha]	Mean number of eggs/ female (Rr)[no.]	Reproduction Pr [%]	ER50 [kg/ha]
Control	0.0	>5.7.5	Control	6.0	-	>5.7.5
0.92	0.0		0.92	4.0	32.8	
2.30	3.3		2.30	3.9	34.9	
5.75	6.7		5.75	4.1	31.7	
$NOER_{mortality}$ 2.3 [kg/ha]			$NOER_{reproduction}$ < 0.92 [kg/ha]			

Conclusions:
Based on the results it can be stated that MIEDZIAN 50 WP, at the rates of 5.75 kg/ha has significant adverse effect on mortality of the mites. The rates of 0.92, 2.30 and 5.75 kg/ha of MIEDZIAN 50 WP have significant effect on the reproduction of the tested organisms.

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

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

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

A 2.5.2.1 KCP 10.4.2.1 Species level testing

A 2.5.2.2 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil nitrogen transformation

Study 1

zRMS comments:

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

The coefficients of variation (CV) in the control group were 11.5, 2.3, 6.7 and 5.1%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Agreed endpoints:

On the basis of the results, it was concluded that MIEDZIAN 50 WP at the concentration corresponding to the PEC: 10.0 mg test item/kg dry weight soil and upper PEC: 33.3 mg the test item/kg dry weight did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Report	MIEDZIAN 50 WP: Soil Microorganisms: Nitrogen Transformation Test, Holewik P., 2020, Study code: G/46/19
Guideline(s):	OECD 216 / EU Method C.21.
Deviations:	Yes, However, they did not affect the results
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:

The aim of this study was to detect long-term adverse effects of **MIEDZIAN 50 WP** on the process of nitrogen transformation in aerobic surface soils.

Materials and methods:

Test material:	**MIEDZIAN 50 WP** batch no.: 283744/04
Active substance:	copper: 482 g/kg (Appendix No. 1)
Soil:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna.
Test design:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.
Concentrations of the test item:	control, PEC: 10.00 mg of the test item / kg dry weight of soil (4.82 mg of the copper/kg dry weight of soil), upper PEC: 33.30 mg of the test item / kg dry weight of soil (16.10 mg of the copper/kg dry weight of soil)
Test conditions:	temperature: 20.4 – 22.0°C, soil moisture: 52.3% – 58.0% of the maximum water holding capacity, incubation in darkness
Endpoints:	The concentration of nitrate [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 – 7, 0 – 14, 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 – 7, 0 – 14, 0 – 28 days.
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogeneity (with Residuals) - Williams Multiple Sequential t-test Procedure

Validity criterion:

The coefficients of variation (CV) in the control group were 11.5, 2.3, 6.7 and 5.1%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Results:

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 10.0 mg test item/kg dry weight soil and upper PEC: 33.3 mg the test item/kg dry soil did not exceed 25% on 28 day of analysis.

Conclusions:

On the basis of the results, it was concluded that MIEDZIAN 50 WP at the concentration corresponding to the PEC: 10.0 mg test item/kg dry weight soil and upper PEC: 33.3 mg the test item/kg dry weight did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

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

A 2.7.1 KCP 10.6.1 Summary of screening data

A 2.7.2 KCP 10.6.2 Testing on non-target plants

A 2.7.3 KCP 10.6.3 Extended laboratory studies on non-target plants

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

A 2.9 KCP 10.8 Monitoring data