FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: MIEDZIAN EXTRA 350 SC

Product names: **MIEDZIAN EXTRA 350 SC, COBRESAL EXTRA 350 SC, KARES 350 SC**

Chemical active substance:

Copper as a copper oxychloride, 350 g/l

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(re-authorization according art. 43, 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. and KCP 10.4)
03/2021	Recalculation of risk for animals according to new EU endpoint
05/2021	Finalisation of the assessment ppp Miedziam Extra 350 SC by zRMS.
08/2022	Final report after commenting period.

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9 Ecotoxicology (KCP 10)

9.1.1. The currently valid GAP for the product Miedzian Extra 350 SC

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Apple	Fpn	*Venturia inaequalis*	spraying	BBCH 00-07	a)1 b)2	7-10	a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	n.a.	
2	PL	Pear	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	7	
3	PL	Cherry, sweet cherry	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	7	
4	PL	Peach	Fpn	*Taphrina deformans*	Spraying	BBCH 00-03	1	-	7,0	2,45 kg Cu/ha	700	n.a.	
5	PL	Tomato (outdoor)	Fpn	*Pseudomonas syringae pv. Tomato,* *Phytophthora infestans*	Spraying	BBCH 51-85	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	
6	PL	Tomato (indoor)	I	*Pseudomonas syringae pv. Tomato,* *Phytophthora infestans*	Spraying	BBCH 56-88	3	7	a)3,0 b)9,0	a)1.05 kg Cu/ha b)3.15 kg Cu/ha	1200	7	
7	PL	Cucumber (outdoor)	Fpn	*Pseudomonas syringae pv. Lachrymans,* *Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	
8	PL	French bean, bean with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola,* *Colletotrichum lindemuthi-anum,* *Botritis cinerea*	Spraying	BBCH 65-69	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Minor uses according to Article 51 (zonal uses)													
9	PL	Grape (table, wine)	Fpn	*Plasmopara viticola*	Spraying	BBCH 13-17, 71-73, 73-77	3	10	a)3,0 b)9,0	a)1,05kg Cu/ha b)3,15 kg Cu/ha	500-900	7	
10	PL	Currant	Fpn	*Drepanopeziza ribis, Mycosphaerella ribis Cronartium ribicola,*	Spraying	BBCH 59-81	3	10	a)3,0 b)9,0	a)1,05kg Cu/ha b)3,15kg Cu/ha	700	7	
11	PL	*Goniolimon tatari-cum*	F	*Peronospora statices*	spraying	Rosettes with 15-18 leaves	3	7	a) 2,0 b)6,0	a)0,7 kg Cu/ha B)2,1 kg Cu/ha	1000	n.a.	
12	PL	Walnut	Fpn	*Gnomonia leptostyla, Xantomonas campestris pv. Juglandis,*	Spraying	Before flow-ering	2	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800-1000	n.a.	
13	PL	Hazelnut	Fpn	*Gnomonia leptostyla, Xanthomonas arboricola pv. corylina*	Spraying	Before flow-ering	2	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800-1000	n.a.	

9.1.2. Intended uses (only NATIONAL GAP) - re-authorization according art. 43, Reg. 1107/2009

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/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Apple	Fpn	*Venturia inaequalis*	spraying	BBCH 00-07	a)1 b)2	7-10	a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	n.a.								
2	PL	Pear	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	7								
Minor uses according to Article 51 (field uses)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
3	PL	Quince	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	7								
4	PL	Medlar	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	7								
5	PL	Cherry, sweet cherry	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	14								
6	PL	Apricot	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500-750	14								
7	PL	Plum	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha	500-750	14								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
										b) 1,05 kg Cu/ha										
8	PL	Peach	Fpn	*Taphrina deformans*	Spraying	BBCH 00-03	1	-	3,0	1,05 kg Cu/ha	700	n.a.								
9	PL	Walnut	Fpn	*Gnomonia leptostyla, Xantomonas campestris pv. Juglandis,*	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800-1000	n.a.								
10	PL	Hazelnut	Fpn	*Gnomonia leptostyla, Xanthomonas arboricola pv. corylina*	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800-1000	n.a.								
11	PL	Tomato (outdoor)	Fpn	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 51-85	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7								
12	PL	Tomato (indoor)	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 56-88	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200-1000	3								
13	PL	Aubergines (outdoor)	Fpn	*Pseudomonas syringae, Phytophthora infestans*	Spraying	BBCH 51-85	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7								
14	PL	Aubergines (indoor)	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 56-88	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200-1000	3								
15	PL	Cucumber (outdoor)	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	3								
16	PL	Cucumber (indoor)	I	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 10-89	4	7	a) 2.3 b) 9.2	a) 0.800kg Cu/ha b)3,20 kg Cu/ha	200-1500	3								
17	PL	Gherkins	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora*	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg	700	7								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				cubensis						Cu/ha										
18	PL	Courgette	Fpn	*Pseudomonas syringae pv. Lachrymans*, *Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7									
19	PL	Melon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200-1500	7									
20	PL	Pumpkins (in-door)	I	Pseudoperonospora cubensis *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200-1500	7									
21	PL	Watermelon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200-1500	7									
22	PL	French bean, bean with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola*, *Colletotrichum linde-muthianum*, *Botritis cinerea*	Spraying	BBCH 65-69	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7									
23	PL	Peas with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola*, *Colletotrichum linde-muthianum*, *Botritis cinerea*	Spraying	BBCH 65-69	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7									
24	PL	Grape (table, wine)	Fpn	*Plasmopara viticola*	Spraying	BBCH 13-17, 71-73, 73-77	3	10	a)3,0 b)9,0	a)1,05kg Cu/ha b)3,15 kg Cu/ha	500-900	21									
25	PL	Currant	Fpn	*Drepanopeziza ribis*, *Mycosphaerella ribis* *Cronartium ribicola*,	Spraying	BBCH 59-65 BBCH 65 - 81	2	10	a)3,0 b)6,0	a)1,05kg Cu/ha b)2,1kg Cu/ha	700	7									

Remarks table heading:

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

Remarks columns:

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

Proposed uses no: 3, 4, 6, 7, 13, 14, 16, 17, 18, 19, 20, 21, 23 are new and they were not previously evaluated.

Explanation for column 15 “Conclusion”

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

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 EXTRA 350 SC due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for birds.~~

The risk assessment based on the WoE approach indicate low risk for birds of each type of proposed uses up to 4 kg a.s./ha for Poland. However, at MSs level the risk assessment should be considered further, if necessary.

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 EXTRA 350 SC 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.~~

The risk assessment based on the WoE approach indicate low risk for mammals of each type of proposed uses up to 4 kg a.s./ha. However , at MSs level the risk assessment should be considered further, if necessary.

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.An estimation of risk indicate low risk for mammals of each range of assessed issues. Calculations conducted due to the influence MIEDZIAN EXTRA 350 SC 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.

9.1.1.3 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)

To protect aquatic organisms – respect an unsprayed buffer zone of (distance to be specified) to surface water bodies.
When using in pome fruit:
- 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables and vine:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in currant and legumes:
- ~~10 m buffer zone with~~ 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Using the above-mentioned precautions, formulation MIEDZIAN EXTRA 350 SC can be used and will not have a negative impact on aquatic species.

9.1.1.5 Article 43

9.1.1.6

9.1.1.7 Taking into consideration risk mitigation calculations for MIEDZIAN EXTRA 350 SC –following risk mitigation measures should be applied:

When using in orchards (apples and pears):
- 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Article 51

Taking into consideration risk mitigation calculations for MIEDZIAN EXTRA 350 SC –following risk mitigation measures should be applied:
When using in pome fruit:
- 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables and vine:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

When using in currant and legumes:
- 10 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Using the above-mentioned precautions, formulation MIEDZIAN EXTRA 350 SC 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 end-point 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_{sedacc} values to determine protective measures, similar to PECsw 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 Extra 350 SC for Poland until relevant modeling for non-organic compounds will be available.

Greenhouse uses

Additional PEC_{SW} calculations for greenhouse uses (indoor crops; spray drift only, without mitigation) were performed by RMS 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**		
	Max. PEC_{sw} (µg/L)					
Use 12	0.139	0.11	0.375	0.059		
Use 14	0.139	0.11	0.375	0.058		

Use 16	0.089	0.071	0.24	0.037
Use 19	0.139	0.11	0.375	0.059
Use 20	0.139	0.11	0.375	0.059
Use 21	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

9.1.1.8 Effects on bees (KCP 10.3.1)

The HQ value for contact toxicity is lower than the trigger of 50, indicating low risk to bees from MIEDZIAN EXTRA 350 SC following application. The HQ value for oral toxicity is over the trigger of 50, indicating high risk for bees. However higher tier studies was agreed at EU level for bees.
Based on the all available information evaluated at EU level the application of MIEDZIAN EXTRA 350 SC with the proposed GAP (up to 1.25 kg a.s./ha) needs the following risk restriction:
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.

9.1.1.9 Effects on arthropods other than bees (KCP 10.3.2)

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 EXTRA 350 SC.

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

On the basis of results it was assessed that MIEDZIAN EXTRA 350 SC in considered applications does not pose unacceptable risk to earthworms.
The risk to earthworms is considered to be low for all representative uses up to 4 kg Cu/ha.
At MSs level the risk assessment should be considered further, if necessary.

9.1.1.11 Effects on soil microbial activity (KCP 10.5)

On the basis of results it was assessed that MIEDZIAN EXTRA 350 SC 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.

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

Since MIEDZIAN EXTRA 350 SC is fungicidal plant protection product and has no impact on non-target terrestrial plants, no risk for terrestrial plant are considered.

9.1.1.13 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 0-1: Critical use pattern of MIEDZIAN EXTRA 350 SC 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]**	**Interception**
1	Pome fruits (apple)	2 x 1.5	2 x 0.525	2 x 50%,
	Pome fruits (pear)	4 x 1.5	4 x 0.525	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 0.525	2 x 50%, 2 x 60%
3	Stone fruits (cherry, sweet cherry, apricot, plum)	1 x 3.0	1 x 1.05	60%
4	Peach	1 x 3.0	1 x 1.05	50%
5	Fruiting vegetables (tomatoes, cucumbers, aubergines, gherkins, courgette, melon, pumpkin, watermelon)	3 x 3.6	3 x 1.25	80%
6	Legumes (French bean, bean with pods, peas with pods)	3 x 2.5	3 x 0.875	70%
7	Vine	3 x 3.0	3 x 1.05	1 x 50% / 2x 75%
8	Nuts (Walnut, Hazelnut)	2 x 3.0	2 x 1.05	2 x 50%
9	Currant	2 x 3.0	2 x 1.05	2 x 60 %

9.1.3 Consideration of metabolites

Copper in form of an oxychloride, which is main and only active substance in MIEDZIAN EXTRA 350 SC, 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 EXTRA 350 SC 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,	NOAEL = 5.05	EFSA Journal

Species	Substance	Exposure System	Results	Reference
		Long-term	mg/kg bw/d	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 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)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.
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 EXTRA 350 SC in orchards

Intended use	**Pome fruits**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	2 × 0.525 (apple) 4 × 0.525 (pear)				
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 (apple)	Small insectivorous bird	46.8	1.4	34.4	**5.03**
Orchards (pear)	Small insectivorous bird	46.8	1.8	44.2	**3.91**
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 (apple)	Small insectivorous bird	18.2	0.74	7.09	**0.71**
Orchards (pear)	Small insectivorous bird	18.2	0.95	9.08	**0.56**

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 EXTRA 350 SC in orchards

Intended use	**Pome fruits**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	2 × 0.525 (apple) 4 × 0.525 (pear)				
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 (apple)	Small insectivorous bird "tit"	46.8	1.4	34.4	**5.03**
Spring, summer (pear)	Small insectivorous bird "tit"	46.8	1.8	44.2	**3.91**
BBCH ≥ 40 (pear)	Small insectivorous/wor m feeding species "thrush"	2.2	1.4*	1.62	107
BBCH ≥ 40 (pear)	Small granivorous bird "finch"	8.2	1.4*	6.03	29
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 (apple)	Small insectivorous bird "tit"	18.2	0.74	7.07	**0.71**
Spring, summer (pear)	Small insectivorous bird "tit"	18.2	0.95	9.08	**0.56**
BBCH ≥ 40 (pear)	Small insectivorous/wor m feeding species "thrush"	0.8	0.74*	0.31	16.3
BBCH ≥ 40 (pear)	Small granivorous bird "finch"	3.8	0.74*	1.48	**3.41**

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 EXTRA 350 SC in minor uses

Intended use	**Minor uses**
Active substance/product	Copper oxychloride
Application rate (g/ha)	2 x 1.05 (bush) 4x 0.525 (pome fruits) 1 x 1.05 (stone fruits) 2 x 1.05 (nuts) 3 x 1.05 (vine) 3 × 1.25 (fruiting vegetables) 3 x 0.875 (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	68.06	**2.54**
Orchards (pome fruits)	Small insectivorous bird	46.8	1.8	44.23	**3.91**
Orchards (stone fruits)	Small insectivorous bird	46.8	1	49.14	**3.52**
Orchards (nuts)	Small insectivorous bird	46.8	1.4	68.80	**2.51**
Vineyard	Small omnivorous bird	95.3	1.6	160.10	**1.08**
Fruiting vegetables,	Small omnivorous bird	158.8	1.6	317.60	**0.54**
Legumes,	Small omnivorous bird	158.8	1.6	222.32	**0.78**
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	17.92	**0.28**
Orchards (pome fruits)	Small insectivorous bird	18.2	0.95	9.12	**0.55**
Orchards (stone fruits)	Small insectivorous bird	18.2	0.53	10.13	**0.50**
Orchards (nuts)	Small insectivorous bird	18.2	0.74	14.18	**0.36**
Vineyard	Small omnivorous bird	38.9	0.85	34.64	**0.15**
Fruiting vegetables, legumes,	Small omnivorous bird	64.8	0.85	68.69	**0.07**
Legumes,	Small omnivorous bird	64.8	0.85	48.08	**0.11**

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 EXTRA 350 SC in minor uses

Intended use	**Minor uses**				
Active substance/product	Copper oxychloride				
Application rate (g/ha)	2 x 1.05 (bush) 4x 0.525 (pome fruits) 1 x 1.05 (stone fruits) 2 x 1.05 (nuts) 3 x 1.05 (vine) 3 × 1.25 (fruiting vegetables) 3 x 0.875 (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	1.4	68.06	**2.54**
Bush BBCH 00 - 79	Small insectivorous bird	52.2	1.4	76.73	**2.25**

	"warbler"				
Vineyard BBCH 10 - 19	Small insectivorous species "Redstart"	27.4	1.6	46.03	**3.76**
Vineyard BBCH > 20	Small insectivorous species "Redstart"	25.7	1.6	43.18	**4.01**
Vineyard BBCH 10 - 19	Small granivorous bird "Finch"	14.8	1.6	24.86	**6.96**
Vineyard BBCH > 40	Small granivorous bird "Finch"	7.4	1.6	12.43	13.92
Vineyard BBCH 10 - 19	Small omnivorous bird "lark"	14.4	1.6	24.19	**7.15**
Vineyard BBCH > 40	Small omnivorous bird "lark"	7.2	1.6	12.10	14.30
Legumes BBCH > 50	Small granivorous bird "finch"	7.4	1.6	10.36	16.70
Legumes BBCH > 50	Small omnivorous bird "lark"	7.2	1.6	10.08	17.16
Legumes BBCH > 20	Small insectivorous bird "wagtail"	25.2	1.6	35.28	**4.90**
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 (pome fruits)	Small insectivorous bird "tit"	46.8	1.8	44.23	**3.91**
Orchards, Spring, summer (stone fruits)	Small insectivorous bird "tit"	46.8	1	49.14	**3.52**
Orchards, BBCH ≥ 40 (stone fruits)	Small insectivorous/wor m feeding species "thrush"	2.2	1	2.31	74.89
Orchards, BBCH ≥ 40 (stone fruits)	Small granivorous bird "finch"	8.2	1	8.61	20.09
Orchards, Spring, summer (nuts)	Small insectivorous bird "tit"	46.8	1.4	68.80	**2.51**
Orchards, BBCH 10-19 (nuts)	Small insectivorous/ worm feeding species "thrush	5.9	1.4	8.67	19.95
Orchards, BBCH 20-39 (nuts)	Small insectivorous/ worm feeding species "thrush	4.4	1.4	6.47	26.75
Orchards, BBCH ≥ 40	Small insectivorous/ worm feeding species "thrush"	2.2	1.4	3.23	53.49
Orchards, BBCH 10-19 (nuts)	Small granivorous bird "finch"	21.9	1.4	32.19	**5.37**
Orchards, BBCH 20-39 (nuts)	Small granivorous bird "finch"	16.4	1.4	24.11	**7.18**
Orchards, BBCH ≥ 40	Small granivorous bird "finch"	8.2	1.4	12.05	14.35

Reprod. toxicity (mg/kg bw/d)	5.05				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**$MAF_m \times TWA$**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bush BBCH 71 - 79	Frugivorous bird “blackcap”	23.0	0.74	17.92	**0.28**
Bush BBCH 00 - 79	Small insectivorous bird “warbler”	20.3	0.74	15.82	**0.32**
Vineyard BBCH 10 - 19	Small insectivorous species “Redstart”	11.5	0.85	10.24	**0.49**
Vineyard BBCH > 20	Small insectivorous species “Redstart”	9.9	0.85	8.81	**0.57**
Vineyard BBCH 10 - 19	Small granivorous bird “Finch”	6.9	0.85	6.14	**0.82**
Vineyard BBCH > 40	Small granivorous bird “Finch”	3.4	0.85	3.03	**1.67**
Vineyard BBCH 10 - 19	Small omnivorous bird “lark”	6.5	0.85	5.79	**0.87**
Vineyard BBCH > 40	Small omnivorous bird “lark”	3.3	0.85	2.94	**1.72**
Legumes BBCH > 50	Small granivorous bird “finch”	3.4	0.85	2.52	**2.00**
Legumes BBCH > 50	Small omnivorous bird “lark”	3.3	0.85	2.45	**2.06**
Legumes BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.85	7.20	**0.70**
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 (pome fruits)	Small insectivorous bird “tit”	18.2	0.95	9.12	**0.55**
Orchards, Spring, summer	Small insectivorous bird “tit”	18.2	0.53	10.13	**0.50**
Orchards, BBCH ≥ 40 (stone fruits)	Small insectivorous/wor m feeding species “thrush”	0.8	0.53	0.45	11.34
Orchards, BBCH ≥ 40 (stone fruits)	Small granivorous bird "finch"	3.8	0.53	2.11	**2.39**
Orchards, Spring, summer (nuts)	Small insectivorous bird “tit”	46.8	0.74	36.46	**0.14**
Orchards, BBCH 10-19 (nuts)	Small insectivorous/ worm feeding species “thrush	2.1	0.74	1.64	**3.09**
Orchards, BBCH 20-39 (nuts)	Small insectivorous/ worm feeding species “thrush	1.6	0.74	1.25	**4.05**
Orchards, BBCH ≥ 40 (nuts)	Small insectivorous/ worm feeding species “thrush”	0.8	0.74	0.62	8.10

Orchards, BBCH 10-19 (nuts)	Small granivorous bird "finch"	10.1	0.74	7.87	**0.64**
Orchards, BBCH 20-39 (nuts)	Small granivorous bird "finch"	7.6	0.74	5.92	**0.85**
Orchards, BBCH ≥ 40 (nuuts)	Small granivorous bird "finch"	3.8	0.74	2.96	**1.71**

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.

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) until the existence of an accepted guidance document.

The final decision should be considered at MSs level.

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 kg Cu/ha/**year**~~ **4 kg a.s./ha,** for birds, therefore no more justification is needed.

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 EXTRA 350 SC 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)	=	1250		
Acute toxicity (mg/kg bw)	=	173	quotient	= 7.2
Reprod. toxicity (mg/kg bw/d)	=	5.05	quotient	= 248

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 EXTRA 350 SC 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 EXTRA 350 SC 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 fruiting vegetables also covers the risk for birds 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 EXTRA 350 SC in orchards

Intended use	Pome fruit				
Active substance/product	Copper oxychloride				
Application rate (kg/ha)	2 × 0.525 (apple) 4 × 0.525 (pear)				
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 (apple)	Small herbivorous mammal	136.4	1.4	100.3	**1.62**
Orchards (pear)	Small herbivorous mammal	136.4	1.8	128.9	**1.26**
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 (apple)	Small herbivorous mammal	72.3	0.74	28.1	**0.57**
Orchards (pear)	Small herbivorous mammal	72.3	0.95	36.1	**0.44**

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 EXTRA 350 SC in orchards

Intended use	Pome fruit
Active substance/product	Copper oxychloride
Application rate (kg/ha)	2 × 0.525 (apple)

	4 × 0.525 (pear)				
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 (apple)	Small insectivorous mammal "shrew"	5.4	1.4	3.97	40.97
BBCH <10 (apple)	Small herbivorous mammal "vole	136.4	1.4	100.25	**1.62**
BBCH <10 (apple)	Large herbivorous mammal "lagomorph"	35.1	1.4	25.80	**6.30**
BBCH < 10 (apple)	Small omnivorous mammal "mouse"	17.2	1.4	12.64	12.86
BBCH <10 (pear)	Small insectivorous mammal "shrew"	5.4	1.8	5.10	31.86
BBCH <10 (pear)	Small herbivorous mammal "vole	136.4	1.8	128.90	**1.26**
BBCH ≥ 40 (pear)	Small herbivorous mammal "vole	40.9	1.8	38.65	**4.21**
BBCH <10 (pear)	Large herbivorous mammal "lagomorph"	35.1	1.8	33.17	**4.90**
BBCH ≥ 40 (pear)	Large herbivorous mammal "lagomorph"	10.5	1.8	9.92	16.39
BBCH < 10 (pear)	Small omnivorous mammal "mouse"	17.2	1.8	16.25	10.00
BBCH ≥ 40 (pear)	Small omnivorous mammal "mouse"	5.2	1.8	4.91	33.09
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}**
BBCH <10 (apple)	Small insectivorous mammal "shrew"	1.9	0.74	0.74	21.68
BBCH <10 (apple)	Small herbivorous mammal "vole	72.3	0.74	28.09	**0.57**
BBCH <10 (apple)	Large herbivorous mammal "lagomorph"	14.3	0.74	5.56	**2.88**
BBCH < 10 (apple)	Small omnivorous mammal "mouse"	7.8	0.74	3.03	5.28
BBCH <10 (pear)	Small insectivorous mammal "shrew"	1.9	0.95	0.95	16.88
BBCH <10 (pear)	Small herbivorous mammal "vole	72.3	0.95	36.06	**0.44**
BBCH ≥ 40 (pear)	Small herbivorous mammal "vole	21.7	0.95	10.82	**1.48**
BBCH <10 (pear)	Large herbivorous mammal	14.3	0.95	7.13	**2.24**

	"lagomorph"				
BBCH ≥ 40 (pear)	Large herbivorous mammal "lagomorph"	4.3	0.95	2.14	7.46
BBCH < 10 (pear)	Small omnivorous mammal "mouse"	7.8	0.95	3.89	**4.11**
BBCH ≥ 40 (pear)	Small omnivorous mammal "mouse"	2.4	0.95	1.20	13.37

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 EXTRA 350 SC in minor uses

Intended use	Minor uses
Active substance/product	Copper oxychloride
Application rate (g/ha)	2 x 1.05 (bush) 4x 0.525 (pome fruits) 1 x 1.05 (stone fruits) 2 x 1.05 (nuts) 3 x 1.05 (vine) 3 × 1.25 (fruiting vegetables) 3 x 0.875 (legumes)
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	Small herbivorous mammal	81.9	1.4	120.39	**1.35**
Orchards (pome fruits)	Small herbivorous mammal	136.4	1.8	128.90	**1.26**
Orchards (stone fruits)	Small herbivorous mammal	136.4	1	143.22	**1.14**
Orchards (nuts)	Small herbivorous mammal	136.4	1.4	200.51	**0.81**
legumes	Small herbivorous mammal	136.4	1.6	229.15	**0.71**
Vines	Small herbivorous mammal	136.4	1.6	272.80	**0.60**
Fruiting vegetables	Small herbivorous mammal	136.4	1.6	190.96	**0.85**

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	Small herbivorous mammal	43.4	0.74	33.81	**0.47**
Orchards (pome fruits)	Small herbivorous mammal	72.3	0.95	36.21	**0.44**
Orchards (stone fruits)	Small herbivorous mammal	72.3	0.53	40.23	**0.40**
Orchards (nuts)	Small herbivorous mammal	72.3	0.74	56.33	**0.28**
legumes	Small herbivorous mammal	72.3	0.85	64.38	**0.25**
Vines	Small herbivorous mammal	72.3	0.85	76.64	**0.21**

Fruiting vegetables	Small herbivorous mammal	72.3	0.85	53.65	**0.30**

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 EXTRA 350 SC in minor uses

Intended use	Minor uses
Active substance/product	Copper oxychloride
Application rate (g/ha)	2 x 1.05 (bush) 4x 0.525 (pome fruits) 1 x 1.05 (stone fruits) 2 x 1.05 (nuts) 3 x 1.05 (vine) 3 × 1.25 (fruiting vegetables) 3 x 0.875 (legumes)
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	60.12	**2.70**
Bush BBCH 71-79	Frugivorous mammal "dormouse"	19.4	1.4	28.52	**5.70**
Bush BBCH >40	Small omnivorous mammal "mouse"	5.2	1.4	7.64	21.27
Vineyard BBCH 10 - 19	Large herbivorous mammal "lagomorph"	16.3	1.6	27.38	**5.94**
Vineyard BBCH > 40	Large herbivorous mammal "lagomorph"	8.1	1.6	13.61	11.95
Vineyard BBCH 10 - 19	Small insectivorous mammal "shrew"	7.6	1.6	12.77	12.73
Vineyard BBCH 10 - 19	Small herbivorous mammal "vole"	81.9	1.6	137.59	**1.18**
Vineyard BBCH > 40	Small herbivorous mammal "vole"	40.9	1.6	68.71	**2.37**
Vineyard BBCH 10 - 19	Small omnivorous mammal "mouse"	10.3	1.6	17.30	**9.40**
Vineyard BBCH > 40	Small omnivorous mammal "mouse"	5.2	1.6	8.74	18.61
Legume BBCH > 50	Small herbivorous mammal "vole	40.9	1.6	57.26	**2.84**
Legume BBCH > 50	Small omnivorous mammal "mouse"	5.2	1.6	7.28	22.34
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal "shrew"	7.6	1.6	15.20	10.70
Fruiting vegetables	Small insectivorous mammal	5.4	1.6	10.80	15.06

BBCH > 20	"shrew"				
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole"	136.4	1.6	272.80	**0.60**
Fruiting vegetables BBCH > 50	Small herbivorous mammal "vole"	40.9	1.6	81.80	**1.99**
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 (pome fruit)	Small insectivorous mammal "shrew"	5.4	1.8	5.10	31.86
Orchards BBCH <10 (pome fruit)	Small herbivorous mammal "vole	136.4	1.8	128.90	**1.26**
Orchards BBCH <10 (pome fruit)	Large herbivorous mammal "lagomorph"	35.1	1.8	33.17	**4.90**
Orchards BBCH < 10 (pome fruit)	Small omnivorous mammal "mouse"	17.2	1.8	16.25	10.00
Orchards BBCH <10 (stone fruits)	Small insectivorous mammal "shrew"	5.4	1.0	5.67	28.68
Orchards BBCH <10 (stone fruits)	Small herbivorous mammal "vole	136.4	1.0	143.22	**1.14**
Orchards BBCH ≥ 40 (stone fruits)	Small herbivorous mammal "vole	40.9	1.0	42.95	**3.79**
Orchards BBCH <10 (stone fruits)	Large herbivorous mammal "lagomorph"	35.1	1.0	36.86	**4.41**
Orchards BBCH ≥ 40 (stone fruits)	Large herbivorous mammal "lagomorph"	10.5	1.0	11.03	14.75
Orchards BBCH < 10 (stone fruits)	Small omnivorous mammal "mouse"	17.2	1.0	18.06	**9.00**
Orchards BBCH ≥ 40 (stone fruits)	Small omnivorous mammal "mouse"	5.2	1.0	5.46	29.78
Orchards BBCH <10 (nuts)	Small insectivorous mammal "shrew"	5.4	1.4	7.94	20.48
Orchards BBCH <10 (nuts)	Small herbivorous mammal "vole	136.4	1.4	200.51	**0.81**
Orchards BBCH ≥ 40 (nuts)	Small herbivorous mammal "vole	40.9	1.4	60.12	**2.70**
Orchards BBCH <10 (nuts)	Large herbivorous mammal "lagomorph"	35.1	1.4	51.60	**3.15**
Orchards BBCH ≥ 40 (nuts)	Large herbivorous mammal "lagomorph"	10.5	1.4	15.44	10.53
Orchards BBCH < 10 (nuts)	Small omnivorous mammal "mouse"	17.2	1.4	25.28	**6.43**
Orchards BBCH ≥ 40 (nuts)	Small omnivorous mammal "mouse"	5.2	1.4	7.64	21.27
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	16.91	**0.95**
Bush BBCH 71-79	Frugivorous mammal “dormouse”	9.7	0.74	7.56	**2.12**
Bush BBCH >40	Small omnivorous mammal “mouse”	2.3	0.74	1.79	8.93
Vineyard BBCH 10 - 19	Large herbivorous mammal “lagomorph”	6.7	0.85	5.97	**2.68**
Vineyard BBCH > 40	Large herbivorous mammal “lagomorph”	3.3	0.85	2.94	5.45
Vineyard BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.85	3.74	**4.28**
Vineyard BBCH 10 - 19	Small herbivorous mammal “vole”	43.4	0.85	38.64	**0.41**
Vineyard BBCH > 40	Small herbivorous mammal “vole”	21.7	0.85	19.32	**0.83**
Vineyard BBCH 10 - 19	Small omnivorous mammal “mouse”	4.7	0.85	4.18	**3.82**
Vineyard BBCH > 40	Small omnivorous mammal “mouse”	2.3	0.85	2.05	7.81
Legume BBCH > 50	Small herbivorous mammal “vole	21.7	0.85	16.10	**0.99**
Legume BBCH > 50	Small omnivorous mammal “mouse”	2.3	0.85	1.71	9.38
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 (pome fruit)	Small insectivorous mammal “shrew”	1.9	0.95	0.95	16.81
Orchards BBCH <10 (pome fruit)	Small herbivorous mammal “vole	72.3	0.95	36.21	**0.44**
Orchards BBCH <10 (pome fruit)	Large herbivorous mammal “lagomorph”	14.3	0.95	7.16	**2.23**
Orchards BBCH < 10 (pome fruit)	Small omnivorous mammal “mouse”	7.8	0.95	3.91	**4.10**

Orchards BBCH <10 (stone fruits)	Small insectivorous mammal "shrew"	1.9	0.53	1.06	15.13
Orchards BBCH <10 (stone fruits)	Small herbivorous mammal "vole	72.3	0.53	40.23	**0.40**
Orchards BBCH ≥ 40 (stone fruits)	Small herbivorous mammal "vole	21.7	0.53	12.08	**1.32**
Orchards BBCH <10 (stone fruits)	Large herbivorous mammal "lagomorph"	14.3	0.53	7.96	**2.01**
Orchards BBCH ≥ 40 (stone fruits)	Large herbivorous mammal "lagomorph"	4.3	0.53	2.39	6.69
Orchards BBCH < 10 (stone fruits)	Small omnivorous mammal "mouse"	7.8	0.53	4.34	**3.69**
Orchards BBCH ≥ 40 (stone fruits)	Small omnivorous mammal "mouse"	2.4	0.53	1.34	11.98
Orchards BBCH <10 (nuts)	Small insectivorous mammal "shrew"	1.9	0.74	1.48	10.81
Orchards BBCH <10 (nuts)	Small herbivorous mammal "vole	72.3	0.74	56.33	**0.28**
Orchards BBCH ≥ 40 (nuts)	Small herbivorous mammal "vole	21.7	0.74	16.91	**0.95**
Orchards BBCH <10 (nuts)	Large herbivorous mammal "lagomorph"	14.3	0.74	11.14	**1.44**
Orchards BBCH ≥ 40 (nuts)	Large herbivorous mammal "lagomorph"	4.3	0.74	3.35	**4.78**
Orchards BBCH < 10 (nuts)	Small omnivorous mammal "mouse"	7.8	0.74	6.08	**2.63**
Orchards BBCH ≥ 40 (nuts)	Small omnivorous mammal "mouse"	2.4	0.74	1.87	8.56

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 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.

9.3.2.2 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.

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 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.

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.

9.3.2.3 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.

Effective application rate (g/ha)	=	1250		
Acute toxicity (mg/kg bw)	=	162.6	quotient	= 7.7
Reprod. toxicity (mg/kg bw/d)	=	16	quotient	= 78

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 EXTRA 350 SC due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for mammals which was confirmed by ap-

propriate 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 EXTRA 350 SC were not evaluated as part of the EU assessment copper compound. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2

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

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 magna	copper hydroxide	48 h, s	LC50 = 0.0266 mg dissolved Cu/L	2.4 µg/L#	EFSA Journal 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 EXTRA 350 SC

Species	Substance	Exposure System	Results	Reference
Daphnia magna	MIEDZIAN EXTRA 350 SC	48 h, s	EC_{50} = 1.169 mg a.s./L $_{nom}$	Woźniak A./2020/ 0030/0003/E
Pseudokirchneriella subcapitata	MIEDZIAN EXTRA 350 SC	72 h, s	E_rC_{50} = 1.428 mg/L $_{nom}$ E_yC_{50} = 0.367 mg/L $_{nom}$	Meler, A./2020/ 0030/0004/E

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

Since, toxicity for algae is more than 10 times higher than for fish, toxicity studies for fish, as a less sensitive species, was not performed.
Since, the results for formulation shows lower toxicity than active substance, those result are not suitable for risk calculations, according to EFSA Journal 2013;11(7):3290.

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 each organism group based on FOCUS Steps 1 and 2 calculations for the use of MIEDZIAN EXTRA 350 SC in major uses – (apple, pear)

Crop	Calculations via run-off/drainage only			Calculations with drift mitigation				
	Step 1	Step 2	Step 2 with 90% mitigation (20 m VBZ)	10m NSZ	20m NSZ	30m NSZ	40m NSZ	50m NSZ
Apple	2.52	0.5	0.05	5.39	1.4	0.48	0.22	0.12
Pear	5.05	1.0	0.1	4.85	1.21	0.4	0.18	0.1

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 + 40 NSZ
Apple	5.44	1.45	0.53	**0.27**
Pear	4.95	1.31	0.50	**0.28**

Values below the RAC are bold
NSZ: No-spray buffer zone
VBZ: Vegetative buffer zone

Calculations according to Article 51

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper for each organism group based on FOCUS Steps 1 and 2 calculations for the use of MIEDZIAN EXTRA 350 SC in minor uses

Crop	Calculations via run-off/drainage only			Calculations with drift mitigation					
	Step 1	Step 2	Step 2 with 90% mitigation (20 m VBZ)	10m NSZ	20m NSZ	30m NSZ	40m NSZ	50m NSZ	60m NSZ
Pome fruits	5.05	1.0	0.1	4.85	1.21	0.40	0.18	0.1	-
Stone fruits	2.52	0.5	0.05	13.29	3.04	1.16	0.59	0.34	0.22
Fruiting vegetables	9.02	1.79	0.18	0.27	0.14	0.09	-	-	-
Legumes	6.32	1.25	0.13	0.19	0.10	-	-	-	-
Vine	7.57	1.5	0.15	0.34	0.11	0.05	-	-	-
Nuts	5.05	1.0	0.1	10.78	2.79	0.96	0.45	0.25	0.15
Currant	5.05	1.0	0.1	0.26	0.13	-	-	-	-

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 + 40 NSZ	VBZ 20 m + 50 NSZ	VBZ 20 m + 60 NSZ
Pome fruits	4.95	1.31	0.40	**0.28**	**0.20**	-
Stone fruits	13.34	3.09	1.21	0.64	0.39	**0.27**
Fruiting vegetables	0.45	**0.32**	**0.27**	-	-	-
Legumes	**0.32**	**0.33**	-	-	-	-
Vine	0.49	**0.26**	**0.20**	-	-	-
Nuts	10.88	2.89	1.06	0.55	**0.35**	**0.25**
Currant	**0.36**	**0.23**	-	-	-	-

Values below the RAC are bold

NSZ: No-spray buffer zone

VBZ: Vegetative buffer zone

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 Extra 350 SC in pome fruits (Apple).

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		36.59	**17.68**	**304.92**	**137.56**	**48.14**	**16.42**	0.73	18.11	**5.61**
Step 2										
N-Europe	March-May	15.37	**7.43**	**128.08**	**57.78**	**20.22**	**6.90**	0.31	~~17.387~~ 17.39	**5.38**
~~S-Europe~~	~~March-May~~	~~15.27~~	~~7.43~~	~~128.08~~	~~57.78~~	~~20.22~~	~~6.91~~	~~0.31~~	~~17.558~~	~~5.44~~

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 9.5.2-2 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 Extra 350 SC in pome fruits (Pear).

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		73.17	**35.35**	**609.75**	**275.08**	**96.28**	**32.83**	**1.46**	19.21	**5.95**
Step 2										
N-Europe	March-May	15.09	**7.29**	**125.75**	**56.73**	**19.86**	**6.77**	0.30	~~17.739~~ 17.74	**5.49**
~~S-Europe~~	~~March-May~~	~~15.09~~	~~7.29~~	~~125.75~~	~~56.73~~	~~19.86~~	~~6.77~~	~~0.30~~	~~18.08~~	~~5.60~~

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 9.5.2-3 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 Extra 350 SC 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		73.17	**35.35**	**609.75**	**275.08**	**96.28**	**32.83**	**1.46**	19.21	**5.95**
Step 2										
N-Europe	March-May	15.09	**7.29**	**125.75**	**56.73**	**19.86**	**6.77**	0.30	~~17.739~~ 17.74	**5.49**
~~S-Europe~~	~~March-May~~	~~15.09~~	~~7.29~~	~~125.75~~	~~56.73~~	~~19.86~~	~~6.77~~	~~0.30~~	~~18.06~~	~~5.60~~

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 Extra 350 SC 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		36.59	**17.68**	**304.92**	**137.56**	**48.14**	**16.42**	0.73	18.11	**5.61**
Step 2										
N-Europe	March-May	34.06	**16.45**	**283.83**	**128.05**	**44.82**	**15.28**	0.68	~~17.419~~ 17.42	**5.39**
~~S-Europe~~	~~March-May~~	~~24.08~~	~~16.45~~	~~283.83~~	~~128.05~~	~~44.82~~	~~15.28~~	~~0.68~~	~~17.503~~	~~5.45~~

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 Extra 350 SC (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		20.53	**9.92**	**171.08**	**77.18**	**27.01**	**9.21**	0.41	20.14	**6.24**
Step 2										
N-Europe	March-May	2.99	**1.44**	**24.92**	**11.24**	**3.93**	**1.34**	0.06	~~17.668~~ 17.67	**5.47**
~~S-Europe~~	~~March-May~~	~~2.93~~	~~1.82~~	~~32.33~~	~~14.59~~	~~5.11~~	~~1.74~~	~~0.08~~	~~18.28~~	~~5.66~~

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 Extra 350 SC in legume.

Group			**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sediment dwelling**		**Sediment dwell-ing**
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		14.37	**6.94**	**119.75**	**54.02**	**18.91**	**6.45**	0.29	19.21	**5.94**
Step 2										
N-Europe	March-May	2.10	**1.01**	**17.50**	**7.89**	**2.76**	0.94	0.04	~~17.468~~ 17.77	~~**5.41**~~ **5.50**
S-Europe	March-May	2.72	1.31	22.67	10.23	3.58	1.22	0.05	17.698	5.54

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 Extra 350 SC 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		17.02	**8.22**	**141.83**	**63.98**	**22.39**	**7.64**	0.34	19.64	**6.08**
Step 2										
N-Europe	March-May	3.16	**1.53**	**26.33**	**11.88**	**4.16**	**1.42**	0.06	17.573	**5.44**
S-Europe		2.22	1.60	27.67	12.48	4.37	1.49	0.07	18.08	5.60

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 Extra 350 SC 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		73.17	**35.35**	**609.75**	**275.08**	**96.28**	**32.83**	**1.46**	19.21	**5.95**
Step 2										
N-Europe	March-May	30.74	**14.85**	**256.17**	**115.56**	**40.45**	**13.79**	0.61	17.774	**5.50**
S-Europe		30.74	14.85	256.17	115.56	40.45	13.79	0.61	18.11	5.61

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 9.5.2-9: 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 Extra 350 SC in currant.

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		11.35	**5.48**	**94.58**	**42.67**	**14.93**	**5.09**	0.23	18.76	**5.81**
Step 2										
N-Europe	March-May	3.0	**1.45**	**25.00**	**11.28**	**3.95**	**1.35**	0.06	17.383	**5.38**
S-Europe		3.0	1.45	25.00	11.28	3.95	1.35	0.06	17.763	5.0

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 water) 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.

Calculations according to Article 43

Table 9.5.2-10:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in in pome fruits (Apple).

Group		**Fish acute (higher tier)**	**Fish prolonged (higher tier)**	**Inverteb. Acute (higher tier)**	**Inverteb. prolonged (higher tier)**	**Algae (higher tier)**
Test species		**7 fish species**		**Indoor microcosm study**		
Endpoint (µg/L)		$SSD\text{-}HC_5$ 3.73	$SSD\text{-}HC_5$ 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Dissolved copper	**Max. PEC_{sw} (µg/L)**	**PEC/RAC**				
STEP 2 (N-Europe and S-Europe)	15.37	**12.40**	**41.54**	**6.40**		
STEP 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	5.44	**4.39**	**14.70**	**2.27**		
20 m VFS + 20 m NSZ	1.45	**1.17**	**3.92**	0.60		
20 m VFS + 30 m NSZ	0.48	0.39	**1.30**	0.20		
20 m VFS + 40 m NSZ	0.27	0.22	0.73	0.11		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip; NSZ = no-spray zone; DRT = drift reducing technology; SE = South Europe, N-North Europe

Table 9.5.2-11:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in pome fruits (Pear).

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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2	15.09	**12.17**	**40.78**	**6.29**		
STEP 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	4.95	**3.99**	**13.38**	**2.06**		
20 m VFS + 20 m NSZ	1.31	**1.06**	**3.54**	0.55		
20 m VFS + 30 m NSZ	0.50	0.40	**1.35**	0.21		
20 m VFS + 40 m NSZ	0.28	0.23	0.76	0.12		

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

Calculation according to article 51

Table 9.5.2-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in pome fruits.

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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2	15.09	**12.17**	**40.78**	**6.29**		
STEP 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	4.95	**3.99**	**13.38**	**2.06**		
20 m VFS + 20 m NSZ	1.31	**1.06**	**3.54**	0.55		
20 m VFS + 30 m NSZ	0.50	0.40	**1.35**	0.21		
20 m VFS + 40 m NSZ	0.28	0.23	0.76	0.12		

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

Table 9.5.2-13:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in stone fruits.

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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2	34.06	**27.47**	**92.05**	**14.19**		
STEP 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	13.34	**10.76**	**36.05**	**5.56**		
20 m VFS + 20 m NSZ	3.09	**2.49**	**8.35**	**1.29**		
20 m VFS + 30 m NSZ	1.21	0.98	**3.27**	0.50		
20 m VFS + 40 m NSZ	0.64	0.52	**1.73**	0.27		
20 m VFS + 50 m NSZ	0.39	0.31	**1.05**	0.16		
20 m VFS + 60 m NSZ	0.27	0.22	0.73	0.11		

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

Table 9.5.2-14:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in fruiting vegetables.

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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2 (N-Europe)	2.99	**2.41**	**8.08**	**1.25**		
STEP 2 (S-Europe)	3.88	**3.13**	**10.49**	**1.62**		
STEP 2 + Mitigation (90%)						
20 m VFS + 10 m NSZ	0.45	0.36	**1.22**	0.19		
20 m VFS + 20 m NSZ	0.32	0.26	0.86	0.13		

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

Table 9.5.2-15:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in legume.

Group		**Fish acute (higher tier)**	**Fish pro-longed (high-er tier)**	**Inverteb. Acute (high-er 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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2 (N-Europe)	2.10	**1.69**	**5.68**	0.88		
STEP 2 (S-Europe)	2.72	**2.19**	**7.35**	**1.13**		
STEP 2 + Mitigation (90%)						
20 m VFS + 10 m NSZ	0.32	0.26	0.86	0.13		

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

Table 9.5.2-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group based on maximum PECsw of dissolved copper (PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in vines.

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		
Dissolved copper	**Max.PEC_{sw} (µg/L)**					
STEP 2 (N-Europe)	3.16	**2.55**	**8.54**	**1.32**		
STEP 2 (S-Europe)	3.32	**2.68**	**8.97**	**1.38**		
Step 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	0.49	0.40	**1.32**	0.20		
20 m VFS + 20 m NSZ	0.26	0.21	0.70	0.11		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip; NSZ = no-spray zone;

Table 9.5.2-17:Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds for each organism group PECsw of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in nuts

Group		**Fish acute (higher tier)**	**Fish pro-longed (high-er tier)**	**Inverteb. Acute (high-er 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		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2 (N-Europe)	30.74	**24.79**	**83.08**	**12.81**		
STEP 2 (S-Europe)	30.74	**24.79**	**83.08**	**12.81**		
STEP 2 + Mitigations (90%)						
20 m VFS + 10 m NSZ	10.88	**8.77**	**29.41**	**4.53**		
20 m VFS + 20 m NSZ	2.89	**2.33**	**7.81**	**1.20**		
20 m VFS + 30 m NSZ	1.06	0.85	**2.86**	0.44		
20 m VFS + 40 m NSZ	0.55	0.44	**1.49**	0.23		
20 m VFS + 50 m NSZ	0.35	0.28	0.95	0.15		

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

Table 9.5.2-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for copper compounds based on maximum PEC_{sw} of dissolved copper (tier 1b PECsw) considering different mitigation options for the use of Miedzian Extra 350 SC in currant.

Group		**Fish acute (higher tier)**	**Fish prolonged (higher tier)**	**Inverteb. Acute (higher tier)**	**Inverteb. prolonged (higher tier)**	**Algae (higher tier)**
Test species		**7 fish species**		**Indoor microcosm study**		
Endpoint (µg/L)		$SSD\text{-}HC_5$ 3.73	$SSD\text{-}HC_5$ 1.11	ETO-RAC = 4.8		
AF		3	3	2		
RAC (µg/L)		1.24	0.37	2.4		
Dissolved copper	**Max. PEC_{sw} (µg/L)**					
STEP 2 (N-Europe)	3.0	**2.42**	**8.11**	**1.25**		
STEP 2 (S-Europe)	3.0	**2.42**	**8.11**	**1.25**		
STEP 2 + Mitigation (90%)						
20 m VFS + 10 m NSZ	0.36	0.29	0.97	0.15		

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; VFS = vegetated filter strip; ; DRT = drift reducing technology; SE = South Europe, N=North Europe

9.5.3 Overall conclusions

Article 43

Taking into consideration risk mitigation calculations for MIEDZIAN EXTRA 350 SC –following risk mitigation measures should be applied:
When using in orchards (apples and pears):
- 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Article 51

Taking into consideration risk mitigation calculations for MIEDZIAN EXTRA 350 SC –following risk mitigation measures should be applied:
When using in pome fruit:
- 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in fruiting vegetables and vine:
- 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

When using in currant and legumes:
- 10 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in stone fruits
- 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,
When using in orchards - nuts
- 50 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle,

Using the above-mentioned precautions, formulation MIEDZIAN EXTRA 350 SC 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 end-point 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_{sedacc} values to determine protective measures, similar to PECsw 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 Extra 350 SC for Poland until relevant modeling for non-organic compounds will be available.

Greenhouse uses

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

Use Nº (Crop)	Application of Cu g/ha	Drift rate (ditch) %	PECsw 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 prolonged (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**		
	Max. PEC_{sw} (µg/L)					
Use 12	0.139	0.11	0.375	0.059		
Use 14	0.139	0.11	0.375	0.058		
Use 16	0.089	0.071	0.24	0.037		
Use 19	0.139	0.11	0.375	0.059		
Use 20	0.139	0.11	0.375	0.059		
Use 21	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 EXTRA 350 SC were not evaluated as part of the EU assessment of copper compound. Data submitted with this application are listed in Appendix 1.

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
Apis mellifera	Copper oxychloride	Contact	LD_{50} = 44.3 µg/bee	EFSA Journal 2013;11(6):3235
Apis mellifera	MIEDZIAN EXTRA 350 SC	Oral	LD_{50} = 51.51 µg/bee	Irzyk, M./2006/ B/35/06
Apis mellifera	MIEDZIAN EXTRA 350 SC	Contact	LD_{50} > 200 µg/bee	Irzyk, M./2006/ B/36/06
Higher-tier studies (field studies)				
~~Apis mellifera~~	~~MIEDZIAN EXTRA 350 SC~~	~~Prevention time~~	~~Prevention time = 1 h~~	~~Londzin, W./2006/ B/76/06~~

9.6.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.6.2 Risk assessment

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

9.6.2.1 Hazard quotients for bees

Calculations according to Article 43:

Table 9.6-2: First-tier assessment of the risk for bees due to the use of MIEDZIAN EXTRA 350 SC in pome fruit

Intended use	Pome fruit
Active substance	Copper oxychloride
Single application rate (g/ha)	Apple – 525 g s.a. /1500 g product Pear –525 g s.a. /1500 g product

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	525	43.4
Contact toxicity	44.3		11.9
Product	MIEDZIAN EXTRA 350 SC		
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	51.51	1500	29.1
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

Table 9.6-3: First-tier assessment of the risk for bees due to the use of MIEDZIAN EXTRA 350 SC ~~in fruiting vegetables~~ for minor crops

Intended use	Minor uses				
Active substance	Copper oxychloride				
Single application rate (g/ha)	Pome fruits – 525 s.a. /1500 product Stone fruits / nuts / vine / currant – 1050 s.a. / 3000 product Fruiting vegetables - 1250 s.a. / 3600 product Legumes – 875 s.a. / 2500 product				
Test design	**LD_{50} (lab.) (µg a.s. /bee)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**			
		Pome fruits	**Stone fruits / nuts/vine/currant**	**Fruiting vegetables**	**Legumes**
Oral toxicity	12.1	43.4	**86.8**	**103.3**	**72.3**
Contact toxicity	44.3	11.9	23.7	28.2	19.8
Product	Fruiting vegetables				
Application rate (g/ha)	Copper oxychloride				
Test design	**LD_{50} (lab.) (µg product /bee)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**			
		Pome fruits	**Stone fruits / nuts/vine/currant**	**Fruiting vegetables**	**Legumes**
Oral toxicity	51.51	29.1	**58.2**	**69.9**	48.5
Contact toxicity	> 200	7.5	15	18	12.5

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

Q_{HO} value breach the relevant trigger when using in stone fruits, nuts, vine, currants, and fruiting vegetables what indicate risk for bees. Higher tier test is required.

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

In field studies, prevention time for bees was determined. According to result, MIEDZIAN EXTRA 350 SC is safe for bees when used in ratio 15 L/ha (dose higher than proposed in GAP) one hour before bees

activities.

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 is only slight below 50 for acute oral exposure to bees.
Therefore to confirmed the safe use a semi-field study and a cage test which were evaluated during the renewal of the active substance was considered by zRMS. The results indicated that no significant effects 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 applica-tion of 2.5 kg a.s./ha a statistically significant reduction was observed on flight intensity at t rate of 2.5 kg a.s/ha.
Taking into account that the application rate of Miedzian Extra 350 SC the risk is considered acceptable to bees with the following risk restriction:
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.

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 EXTRA 350 SC following application in minor uses. 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 EXTRA 350 SC following application according to the proposed GAP. However, application should be performed in time of no bees activities.

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 EXTRA 350 SC were not evaluated as part of the EU assessment of copper compound.

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 EXTRA 350 SC	Laboratory test glass plates (2D)	LR_{50} > 8.28 L/ha	Knapik, M. 2020, B-94-20
Aphidius rhopalosiphi (adults)	MIEDZIAN EXTRA 350 SC	Laboratory test glass plates (2D)	LR_{50} > 8.28 L/ha	Knapik, M. 2020, B-95-20

9.7.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

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 EXTRA 350 SC in pome fruit

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the pears also covers the risk for non-target arthropods from uses in apples (see 9.1.2).

Intended use	Orchards (pome fruit)		
Active substance/product	MIEDZIAN EXTRA 350 SC		
Application rate (g/ha)	4 × 1500		
MAF	2.7[#] (foliar)		
Test species Tier I	**LR_{50} (lab.) (kg/ha)**	**$PER_{in\text{-}field}$ (kg/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>8.28	4.05	0.49
Aphidius rhopalosiphi	>8.28		0.49
Intended use	Orchards (pome fruit)		
Active substance/product	MIEDZIAN EXTRA 350 SC		
Application rate (g/ha)	4 × 1500		
MAF	1 soil		

Test species Tier I	LR_{50} (lab.) (kg/ha)	$PER_{in\text{-}field}$ (kg/ha)	$HQ_{in\text{-}field}$ criterion: HQ ≤ 2
Typhlodromus pyri	>8.28	6	0.72
Aphidius rhopalosiphi	>8.28	6	0.72

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 EXTRA 350 SC in pome fruits

Intended use	Orchrds (pome fruits)
Active substance/product	MIEDZIAN EXTRA 350 SC
Application rate (g L/ha)	4 × 1500 (1.5 L/ha)
MAF	2.7
Vdf	10 (Tier 1), **5*(Tier 1)**

Test species Tier I	LR_{50} (lab.) (~~kg~~ L/ha)	Drift rate #	$PER_{off\text{-}field}$ (~~kg~~ L/ha)	CF	$HQ_{off\text{-}field}$ criterion: HQ ≤ 2
Typhlodromus pyri	>8.28	23.61	0.096 0.191	10	0.12 0.23
Aphidius rhopalosiphi	>8.28				0.12 0.23

Intended use	Orchards (pome fruits)
Active sub-stance/product	**MIEDZIAN EXTRA 350 SC**
Application rate (g L/ha)	4 × 1.5 L (max 6 L/ha)
MAF	1 (soil)

Test species Tier I	LR_{50} (lab.) (L/ha)	Drift rate #	$PER_{off\text{-}field}$ (L/ha)	CF	$HQ_{off\text{-}field}$ criterion: HQ ≤ 2
Typhlodromus pyri	>8.28	23.61	0.146 0.28	10	0.17 0.34
Aphidius rhopalosiphi	>8.28				0.17 0.34

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 the Harmonisation Meeting in Central Zone.

Calculations according to Article 51

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group fruiting vegetables also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of MIEDZIAN EXTRA 350 SC in fruiting vegetables

Intended use	Fruiting vegetables		
Active substance/product	MIEDZIAN EXTRA 350 SC		
Application rate (L/ha)	3 × 3.6		
MAF	2.3		
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**$PER_{in\text{-}field}$ (L/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 8.280	8.280	1
Aphidius rhopalosiphi	> 8.280		1
Intended use	**Fruiting vegetables**		
Active substance/product	MIEDZIAN EXTRA 350 SC		
Application rate (L/ha)	3 × 3.6 (10.2 total)		
MAF	1		
Typhlodromus pyri	> 8.280	10.8	1.24
Aphidius rhopalosiphi	> 8.280		1.24

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

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

9.7.2.3 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group fruiting vegetables also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of MIEDZIAN EXTRA 350 SC in fruiting vegetables

Intended use	Fruiting vegetables				
Active substance/product	MIEDZIAN EXTRA 350 SC				
Application rate (L/ha)	3 × 3.6				
MAF	2.3				
vdf	10 (Tier 1), **5*(Tier 1)**				
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (l/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**

Typhlodromus pyri	> 8.280	2.01	0.01664 0.03328	10	0.02 0.04
Aphidius rhopalosiphi	> 8.280				0.02 0.04
Intended use **Active sub-stance/product** **Application rate (L/ha)** **vdf**	Fruiting vegetables MIEDZIAN EXTRA 350 SC 3 × 3.6 (10.8 L/ha) 10 (Tier 1), **5*(Tier 1)**				
Typhlodromus pyri	> 8.280	2.01	0.022 0.043	10	0.026 0.052
Aphidius rhopalosiphi	> 8.280				0.026 0.052

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

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

in blue added by zRMS-PL

*according to recommendation given during the 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 Extra 350 SC.**

9.7.2.4 Additional higher-tier risk assessment

Not relevant.

9.7.2.5 Risk mitigation measures

No risk mitigation needed.

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 EXTRA 350 SC.

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

9.8.1 Toxicity data

Studies on the toxicity to earthworms (macrofauna) have been carried out with copper. Full details of these studies are provided in the respective EU DAR and related documents.

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.6.2, Table 8.6-11.

However, the provision of further data on the MIEDZIAN EXTRA 350 SC is not considered essential, because established RAC for copper is over predicted concentration obtained in soil after 20 years of use of MIEDZIAN EXTRA 350 SC. Therefore low risk for earthworm is assumed after using of MIEDZIAN EXTRA 350 SC. Necessary justifications are shown in points below.

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
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

Species	Substance	Exposure System	Results	Reference
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
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

Species	Substance	Exposure System	Results	Reference
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
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	MIEDZIAN EXTRA 350 SC	Mixed into substrate / 56 d, chronic	$NOEC_{reproduction}$ = 41.43 mg/kg soil dw = 10.2 mg Cu	Woźniak, A., 2020, 0030/0005/E
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

Species	Substance	Exposure System	Results	Reference
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
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

Species	Substance	Exposure System	Results	Reference
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
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

~~**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~~
~~*Eisenia fetida*~~	~~Copper oxychloride~~	~~Mixed into substrate / 56 d, chronic~~	~~NOEC = 15 mg Cu/kg soil 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)~~
Eisenia fetida	MIEDZIAN EXTRA 350 SC	Mixed into substrate / 56 d, chronic	$NOEC_{reproduction}$ = 41.43 mg/kg soil dw = 10.2 mg Cu EC_{10} =19.905 mg product/kg dws	Woźniak, A., 2020, 0030/0005/E

9.8.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.6.2.1, Table 8.6-11. 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 EXTRA 350 SC in orchard (pome fruit)

Since uses in pears represents the worst case for application, only this calculation is performed.

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	1.4	10.7
Product/active substance	**RAC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**criterion RAC ≥ PEC**
Copper	42.67	27.97	Yes

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

Calculations according to Article 51

Since uses in fruiting vegetables represents the worst case for application, only this calculation is performed.

Table 9.8-4: First-tier assessment of the chronic risk for earthworms and due to the use of MIEDZIAN EXTRA 350 SC in fruiting vegetables

Intended use	Fruiting vegetables		
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 EXTRA 350 SC 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: 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 350 SC.

Intended use	**0rchards (apple/ pear) Art. 43.**		
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	53.6[1]/63.4 [1]	**0.15/0.13**
Copper oxychloride	8.4	67.8[2]/77.6 [2]	**0.12/0.10**
Miedzaian Extra 350 SC	10.5	53.6[1]/63.4 [1]	**0.15/0.13**
		67.8[2]/77.6 [2]	**0.15/0.13**
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	53.6[1]/63.4 [1]	**0.57/0.49**
Copper oxychloride	31	67.8[2]/77.6 [2]	**0.46/0.40**
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	53.6[1]/63.4 [1]	**3.4/2.82**
Copper oxychloride	179	67.8[2]/77.6 [2]	**2.64/2.30**

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: 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 350 SC.

Intended use	**0rchards (Pome fruits, Stone fruits and Peach)**
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	63.4 [1]/53.6 [1]	**0.132/0.16**
Copper oxychloride	8.4	77.6 [2]/67.8 [2]	**0.10/0.12**
Miedzaian Extra 350 SC	10.5	63.4 [1]/53.6 [1]	**0.16/019**
		77.6 [2]/67.8 [2]	**0.13/0.15**
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	63.4 [1]/53.6 [1]	**0.49/0.57**
Copper oxychloride	31	77.6 [2]/67.8 [2]	**0.40/0.46**
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	63.4 [1]/53.6 [1]	**2.82/3.34**
Copper oxychloride	179	77.6 [2]/67.8 [2]	**2.30/2.64**
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	42 [1]	**0.2**
Copper oxychloride	8.4	61 [2]	**0.14**
Miedzaian Extra 350 SC	10.5	42 [1]	**0.25**
		61 [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 [1]	**0.73**
Copper oxychloride	31	61 [2]	**0.50**
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 [1]	**4.26**
Copper oxychloride	179	61 [2]	**2.93**
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	31.5 [1]	**0.26**
Copper oxychloride	8.4	37.9 [2]	**0.22**
Miedzaian Extra 350 SC	10.5	31.5 [1]	**0.33**

		37.9 [2]	**0.27**
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	31.5 [1]	**0.98**
Copper oxychloride	31	37.9 [2]	**0.81**
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	31.5[1]	5.70
Copper oxychloride	179	37.9 [2]	**4.72**
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	67.9 [1]	**0.12**
Copper oxychloride	8.4	77.6 [2]	**0.10**
Miedzaian Extra 350 SC	10.5	67.9 [1]	**0.15**
		77.6 [2]	**0.13**
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	67.9 [1]	**0.45**
Copper oxychloride	31	77.6 [2]	**0.40**
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	67.9 [1]	**2.63**
Copper oxychloride	179	77.6 [2]	**2.30**
Intended use	**Vines**		
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	57.4	**0.14**
Copper oxychloride	8.4	189.4	**0.044**
Miedzaian Extra 350 SC	10.5	57.4	**0.19**
		189.4	**0.055**
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	57.4	**0.54**

Copper oxychloride	31	189.4	**0.16**
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	57.4	**3.11**
Copper oxychloride	179	189.4	**0.94**

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 macroorganism should be decided at MS level.

9.8.3 Overall conclusions

On the basis of results of higher tier studies for earthworms evaluated at EU level it was assessed that MIEDZIAN EXTRA 350 SC in considered applications up to 4 kg Cu./ha does not pose unacceptable risk to earthworms and other soil-macroorganism.
The risk to earthworms is considered to be low for all representative uses.

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

Effects on soil microorganisms of MIEDZIAN EXTRA 350 SC were not evaluated as part of the EU assessment of copper. New data submitted with this application are listed in Appendix 1 and described 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 kg/ha, 24.3 mg Cu/kg soil dw < 25 %	EFSA Journal 2013;11(6):3235
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
N-mineralisation	MIEDZIAN EXTRA 350 SC	28 d, aerobic soil type	Nitrate formation rate 57.6 mg/kg soil dw < 25 %	Wołany M./ 2020/ G/48/19

9.9.1.1 Justification for new endpoints

No deviation from EU agreed endpoints.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.6.2, 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:

Since uses in pears represents the worst case for application, only this calculation is performed.

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of MIEDZIAN EXTRA 350 SC 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)	27.97	no
MIEDZIAN EXTRA 350 SC	57.6 (at 28 d)	8.0	yes
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 EXTRA 350 SC in fruiting vegetables

Intended use	Fruiting vegetables

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 EXTRA 350 SC	57.6 (at 28 d)	14.4	yes
Copper hydroxide (WP)	64	49.94	yes

~~Based on calculations for MIEDZIAN EXTRA 350 SC, 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 EXTRA 350 SC.~~

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).

To achieve a concise risk assessment, the risk envelope approach is applied.

For the copper oxychloride the risk is not acceptable. 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 Extra 350 SC according to the proposed GAP as the <25% effects were observed for 57.6 mg product/kg dws.

Finally the risk is considered acceptable for Miedzian Extra 350 SC.

9.9.3 Overall conclusions

On the basis of results it was assessed that MIEDZIAN EXTRA 350 SC 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 MIEDZIAN EXTRA 350 SC is not considered essential, because active substance, copper in the form of copper oxychloride are fungicide and have no impact on the terrestrial plants.

zRMS comments:

The study for non-target plats from exposure the MIEDZIAN EXTRA 350 SC was not available.

However, the phytotoxicity assessment was provided in Section Efficacy (see point 3.4.5.) and was carried out with the use of different cultivars (commercially grown varieties), which is compliant with PP 1/135 Phytotoxicity assessment. In all assessment no phytotoxicity was shown.

No phytotoxicity symptom caused by Miedzian Extra 350 SC at the highest dose rate of 5 l/ha was recorded in all trials.

Tested fungicide Miedzian Extra 350 SC did not affect negatively quality and the yield of apple cv. 'Ligol', 'Jonagored' and 'Jonagored Decosta'. During visual observations no influence of tested product on organisms, which were not the subject of control, was noted.

The use of Miedzian Extra 350 SC had a significant impact on the increase in the quantity and quality of tomato and cucumber yield as compared to the control combination. The application of the tested dose of the product statistically significantly increased the amount and quality of commercial yield in comparison. In addition the toxicity assessment to non-target terrestrial plants with copper compounds was evaluated at EU level. The copper in the form of copper oxychloride had no impact on the terrestrial plants.

In zRMS opinion the risk for non –target plants is considered acceptable.

9.10.1.1 Justification for new endpoints

Not relevant.

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

No risk mitigation needed.

9.10.3 Overall conclusions

Since MIEDZIAN EXTRA 350 SC is fungicidal plant protection product and has no impact on non-target terrestrial plants, no risk for terrestrial plant are considered.

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 EXTRA 350 SC 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 EXTRA 350 SC 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 an unsprayed buffer zone of (~~distance to be specified)~~ to surface water bodies. When using in pome fruit: - 40 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle, When using in fruiting vegetables and vine: - 20 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle, When using in currant and legumes: - 10 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle, When using in stone fruits - 60 m buffer zone with 20m vegetated filter strip and 90 % drift reduction nozzle, When using in orchards - nuts - 50 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 Extra 350 SC 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
SPe8	Dangerous to bees. Do not use where bees are actively foraging. **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.**

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	Meler, A.	2020	Freshwater algae growth inhibition test according to OECD 201, SORBOLAB Research Laboratory LLC, Report number 0030/0003/E, GLP	N	Synthos Agro Sp. z o.o.
KCP 10.2	Woźniak, A.	2020	Daphnia acute immobilization test according to OECD 202, SORBOLAB Research Laboratory LLC, Report number 0030/0003/E, GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Irzyk, M.	2006	MIEDZIAN EXTRA 350 SC; Honeybees (*Apis melifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code B/35/06, GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Irzyk, M.	2006	MIEDZIAN EXTRA 350 SC; Honeybees (*Apis melifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code B/36/06, GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.1	Londzin, W.	2006	MIEDZIAN EXTRA 350 SC; Determination of prevention time for Honey-bee (*Apis melifera L.*), Study code: B/78/06, GLP	N	Synthos Agro Sp. z o.o.
KCP 10.3.2	Knapik, M.	2020	A laboratory test for evaluating the effects of MIEDZIAN EXTRA 350 SC on the predatory mite, *Typhlodromus pyri* (Sch.). Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code B-94-20 GLP	N	Synthos Agro Sp. z o.o.
10.3.2.	Knapik, M.	2020	A laboratory test for evaluating the effects of MIEDZIAN EXTRA 350 SC 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-95-20 GLP	N	Synthos Agro Sp. z o.o.
KCP 10.4	Woźniak, A.	2020	Earthworm reproduction test according to OECD 222 SORBOLAB Research Laboratory LLC,	N	Synthos Agro

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
			Report number 0030/0005/E, GLP		Sp. z o.o.
KCP 10.5	Wołany, M.	2020	MIEDZIAN EXTRA 350 SC, Soil Microorganism: Nitrogen Transformation Test Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Archives, Doświadczalna 27, 43 – 200 Pszczyna, Study code G/48/19 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

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 10.1.1	-	2000	Copper oxychloride 50% WP, acute oral toxicity (LD50) to Japanese quail. Report No.: 12953/00, GLP	Y	-
KCP 10.1.2	xxx	2002a	Tribasic copper sulphate: acute oral toxicity in the rat - acute toxic class method, GLP, Published	Y	-
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
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

zRMS comments:

The study is considered valid. All validity criteria were met.
-In the control the number of immobilized daphnia at the end of the test was 0% (required: ≤10%)

-The lowest oxygen concentration at the end of the test in the control and the tested concentrations was 7.24 mg/L (required: ≥3 mg/L)

Agreed endpoints:
48h LC_{50}= 15.546 mg product/L correspond to 1.169 mg a.s./L

Study 2

Report	Daphnia acute immobilization test according to OECD 202. Woźniak, A., Study code 0030/0004/E
Guideline(s):	OECD No. 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:
The aim of the study was the evaluation of the test item effect on the daphnia *Daphnia magna* immobilization. The study was conducted in accordance with OECD Guideline 202. The impact of the test item was compared to the control group. Based on the results obtained, EC_{10}, EC_{50}, EC_{95} NOEC and LOEC values were estimated.

Materials and methods

Test design	stability test: tested concentrations and control in one repetition range finding test: tested concentrations and control in one repetition definitive test: tested concentrations and control in four repetitions
Type of exposure	static test
Test vessels	glass beakers of 100 mL volume; volume of solution 80 mL
Medium	ISO
Time of exposure	48 h
Tested concentrations	stability test control (0 mg/L); 1.0 mg/L; 100 mg/L range finding test: control (0 mg/L); 1.0 mg/L; 10 mg/L; 100 mg/L definitive test: control (0 mg/L); 0.43 mg/L; 0.94 mg/L; 2.1 mg/L; 4.5 mg/L; 10 mg/L
Test conditions	stability test: average temperature 20.173°C (minimal temperature 20.00°C, maximal temperature 20.70°C) photoperiod 16 h day/8 h night with a light intensity of 1100 – 1140 lux range finding test: average temperature 20.383°C (minimal temperature 20.20°C, maximal temperature 20.80°C) photoperiod 16 h day/8h night with a light intensity of 1100 – 1150 lux definitive test: average temperature 20.646°C (minimal temperature 20.20°C, maximal temperature 21.30°C)

photoperiod 16 h day/8 h night with a light intensity of 1100 – 1120 lux

Validity criteria:

The test met the criteria of validity according to OECD Guideline 202:

- in the control the number of immobilized daphnia at the end of the test was 0% (required: ≤10%)
- the lowest oxygen concentration at the end of the test in the control and the tested concentrations was 7.24 mg/L (required: ≥3 mg/L).

Chemical determination:

Table 21. Results of the characteristics of the analytical method

Parameter	The required criterion	The obtained result		
Selectivity	In copper standard sample, test item and copper oxychloride samples there is a copper peak at 327.395 nm. Samples of ISO medium and dilution solution (blank) do not have peaks interfering with copper under given analysis conditions.	In copper standard sample, test item and copper oxychloride samples there is a copper peak at 327.395 nm. Samples of ISO medium and dilution solution (blank) do not have peaks interfering with copper under given analysis conditions		
Linearity	r ≥ 0.99	r = 0.999 (calibration curve: 0.012 mg/L – 0.4 mg/L)		
Accuracy [%]	70-110	level I	95.7	98
		level II	99.5	
Precision (RSD) [%]	≤ 20	level I	2.21	
		level II	0.39	
Limit of detection [mg/L]	-	0.00619		
Limit of quantification [mg/L]	-	0.01858		

Table 23. Results of analytical determinations – definitive test

Date of analysis	Description of the sample by the Laboratory of Ecotoxicology	Description of the sample by the Laboratory of Physical and Analytical Chemistry	Determined concentration of copper [mg/L]	Dilution factor	Concentration of copper in specimen after correction of concentration in control [mg/L]**)	Concentration of test item [mg/L]	The average concentration of test item [mg/L]
01.06.2020	control 0 h	62/2020 1	<LOQ*)	1	not applicable	not applicable	not applicable
		62/2020 2	<LOQ*)	1	not applicable	not applicable	
	0.43 mg/L 0h	63/2020 1	0.07598	1	0.07598	0.37108	0.37
		63/2020 2	0.07687	1	0.07687	0.37543	
	10 mg/L 0 h	64/2020 1	0.19620	10	0.19620	9.58242	9.59
		64/2020 2	0.19665	10	0.19665	9.60449	
03.06.2020	control 48 h	72/2020 1	<LOQ*)	1	not applicable	not applicable	not applicable
		72/2020 2	<LOQ*)	1	not applicable	not applicable	
	0.43 mg/l 48 h	73/2020 1	0.07787	1	0.07787	0.38033	0.37
		73/2020 2	0.07556	1	0.07556	0.36905	
	10 mg/L 48 h	74/2020 1	0.19397	10	0.19397	9.47341	9.48
		74/2020 2	0.19424	10	0.19424	9.48684	

*) LOQ (limit of quantification) = 0.00380 mg/L (copper)

**) If the copper concentration in the control> LOQ then the determined copper concentration from the control should be subtracted from the determined copper concentration

Final results:
The tested item statistically significant affects the immobilization of daphnia after 24 h in concentrations 2.1 mg/L, 4.5 mg/L, 10.0 mg/L and after 48 h of exposure in the concentrations 0.94 mg/L, 2.1 mg/L, 4.5 mg/L, 10.0 mg/L.

Table 1. Final results **Final results calculated by ToxRat Professional**

	Parameter 24 h	**Time of measurement 48 h**
EC10 [mg/L]	1.237 (0.230 – 2.323)*	0.311 (0.127 – 0.503)*
EC50 [mg/L]	15.546 (7.197 – 192.802)*	1.169 (0.805 – 1.602)*
EC95 [mg/L]	n.d. (n.d. – n.d.)*	6.399 (3.996 – 15.348)*
LOEC [mg/L]	2.1	0.94
NOEC [mg/L]	0.94	0.43

Conclusion
The endpoint values determined on the basis of the nominal test item concentrations are given below:
The EC_{50}/96 h values is 1.169 mg/L (95% confidence interval: 0.805 – 1.602).

Study 3

zRMS comments:

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

- Yield in control during 72 hours of test increased exponentially 193.2 times (OECD 201: ≥16)
- The coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 1.1% (requirements according to OECD 201: <7%)
- The average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 25.1% (requirements according to OECD 201: <35%)

Agreed endpoints:

Final results calculated by ToxRat Professional			
Parameter	**Yield**	**Average specific growth rate**	**Sectional growth rate**
EC_{10} - 72 h [mg/L]	0.356 (0.000 – n.d.)*	0.101 (0.038 – 0.268)*	0.140 (0.074 – 0.265)*
EC_{20} - 72 h [mg/L]	0.360 (n.d. – n.d.)*	0.251 (0.101 – 0.633)*	0.206 (0.114 – 0.376)*
EC_{50} - 72 h [mg/L]	0.367 (n.d. – n.d.)*	1.428 (0.466 – 4.325)*	0.428 (0.207 – 0.889)*
LOEC - 72 h [mg/L]	0.370	0.370	0.370
NOEC - 72 h [mg/L]	0.120	0.120	0.120

EC_{10} effective concentration of test item for 10% reduction
EC_{20} effective concentration of test item for 20% reduction
EC_{50} effective concentration of test item for 50% reduction
LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control
*) the lower and upper 95% confidence limits are given in brackets
n.d. not determined due to mathematical reasons

Report	Freshwater algae growth inhibition test according to OECD 201, Meler, A., Study code: 0030/0003/E
Guideline(s):	OECD No. 201
Deviations:	Yes, but have no influence on the results of the test
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:
The aim of the study was to determine the effect of test item Miedzian Extra 350 SC on the growth of algae *Pseudokirchneriella subcapitata* expressed in yield, average specific growth rate, sectional growth rate based on OECD 201. The end points of the test are the EC_{10}, EC_{20} and EC_{50} values for these parameters determined on the basis of measurements of the algae cell count. The NOEC and LOEC values were also statistically determined.

Materials and methods

Test design	stability test: tested concentration and control in two repetitions (test item solutions and test item solutions inocululated with algae) range-finding test: tested concentrations in two repetitions and control in four repetitions definitive test: tested concentration in three repetitions and control in six repetitions
Type of exposure	static test
Time of exposure	72 h
Test vessels	250 mL conical glass flasks, volume solution 50 mL
Medium	AAP
Shaking	continuous on orbital shakers with a frequency of 90 rpm
Tested concentrations	stability test: control (0 mg/L); 1.0 mg/L; 100 mg/L range-finding test: control (0 mg/L); 0.1 mg/L; 1.0 mg/L; 10 mg/L; 100 mg/L definitve test control (0 mg/L); 0.12 mg/L; 0.37 mg/L; 1.11 mg/L; 3.33 mg/L; 10.0 mg/L
Test conditions	stability test: average temperature 23.486°C (minimal temperature 22.3°C, maximal temperature 24.0°C) continuous fluorescent lighting: 8290 – 8500 lux range-finding test average temperature 21.511°C (minimal temperature 20.9°C, maximal temperature 23.5°C) continuous fluorescent lighting 8480 - 8580 lux definitive test: average temperature 22.789 °C (minimal temperature 22.2 °C, maximal

temperature 23.1°C)
continuous fluorescent lighting 8200 - 8680 lux

Validity criteria:
The test met all the validity criteria in accordance with the OECD Guideline 201:
- yield in control during 72 hours of test increased exponentially 193.2 times (requirements according to OECD 201: ≥16)

- the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 1.1% (requirements according to OECD 201: <7%)

- the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 25.1% (requirements according to OECD 201: <35%).

Analytical measurements:

Table 26. Results of analytical determinations - definitive test

Date of analysis	Description of the sample by the Laboratory of Ecotoxicology	Description of the sample by the Laboratory of Physical and Analytical Chemistry	Determined concentration of copper [mg/L]	Dilution factor	Concentration of copper in specimen after correction of concentration in control [mg/L]**	Concentration of test item [mg/L]	The average concentration of test item [mg/L]
01.06.2020	kontrola 0 h	58/2020 1	<LOQ*	1	not applicable	not applicable	not applicable
		58/2020 2	<LOQ*	1	not applicable	not applicable	
	0,12 mg/l 0 h	59/2020 1	0.02497	1	0.02497	0.12193	0.12
		59/2020 2	0.02443	1	0.02443	0.11931	
	1,11 mg/L 0 h	60/2020 1	0.21398	1	0.21398	1.04508	1.05
		60/2020 2	0.21572	1	0.21572	1.05358	
	10 mg/L 0 h	61/2020 1	0.19579	10	0.19579	9.56244	9.47
		61/2020 2	0.19215	10	0.19215	9.38452	
04.06.2020	kontrola 72 h	81/2020 1	0.01298***	1	not applicable	not applicable	not applicable
		81/2020 2	0.01155***	1	not applicable	not applicable	
	0,12 mg/l 72 h	82/2020 1	0.03937	1	0.02710	0.13238	0.13
		82/2020 2	0.03887	1	0.02660	0.12991	
	1,11 mg/L 72 h	83/2020 1	0.24053	1	0.22826	1.11480	1.12
		83/2020 2	0.24308	1	0.23081	1.12725	
	10 mg/L 72 h	84/2020 1	0.24003	10	0.22776	11.12366	11.10
		84/2020 2	0.23925	10	0.22698	11.08552	

* LOQ (limit of quantification) = 0.00231 mg/L (copper)
** If the copper concentration in the control> LOQ. then the determined copper concentration from the control should be subtracted from the determined copper concentration.
*** The average concentration of copper in control specimen = 0.01227

Final results:
In the course of the study the test item showed statistically significant effects on yield, average specific growth rate and sectional growth rate of algae *Pseudokirchneriella subcapitata* after 72 h exposure in concentrations: 0.37mg/L; 1.11 mg/L; 3.33 mg/L and 10.0 mg/L.

Final results calculated by ToxRat Professional			
Parameter	**Yield**	**Average specific growth rate**	**Sectional growth rate**
EC_{10} - 72 h [mg/L]	0.356 (0.000 – n.d.)*	0.101 (0.038 – 0.268)*	0.140 (0.074 – 0.265)*
EC_{20} - 72 h [mg/L]	0.360 (n.d. – n.d.)*	0.251 (0.101 – 0.633)*	0.206 (0.114 – 0.376)*
EC_{50} - 72 h [mg/L]	0.367 (n.d. – n.d.)*	1.428 (0.466 – 4.325)*	0.428 (0.207 – 0.889)*
LOEC - 72 h [mg/L]	0.370	0.370	0.370
NOEC - 72 h [mg/L]	0.120	0.120	0.120

EC_{10} effective concentration of test item for 10% reduction
EC_{20} effective concentration of test item for 20% reduction
EC_{50} effective concentration of test item for 50% reduction
LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control
*) the lower and upper 95% confidence limits are given in brackets
n.d. not determined due to mathematical reasons

Conclusion
The endpoint values based on the nominal test item concentrations:
The concentration causing a 50% inhibition of the growth rate of *Pseudokirchneriella subcapitata*, i.e. the ErC50/72 h value is 1.428 mg/L (95% confidence interval: 0.466 – 4.325).
The concentration causing a 50% inhibition of yield of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 0.367 mg/L (95% confidence interval: not determined).
The concentration causing a 50% inhibition of sectional growth rate of *Pseudokirchneriella subcapitata*, i.e. the EyC50/72 h value is 0.428 mg/L (95% confidence interval: 0.207 – 0.889).

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**
A 2.3.1.1.2	**KCP 10.3.1.1.2**	**Acute contact toxicity to bees**
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**

Study 1

zRMS comments:

The study is considered valid. 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} >8.28 L product/ha
ER_{50}>8.28 L product/ha

Report	A laboratory test for evaluating the effects of MIEDZIAN EXTRA 350 SC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez), Knapik M., 2020, Study code: B-95-20
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 EXTRA 350 SC 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 EXTRA 350 SC active substance: 346.0 g/L of copper batch number: A2091132 manufacturing date: 01.05.2020 expiry date: 01.05.2022
Biological test system:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae
– age:	adult females (24 – 48 hours after emerging from mummies)
– source:	the culture was obtained from a commercial breeder (BiasLabs Ltd., London, UK)
Experimental design:	5 study groups: − a control group (0.0 L/ha) − MIEDZIAN EXTRA 350 SC at the rates: • 2.07 L/ha • 4.14 L/ha • 8.28 L/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 – 74%
– photoperiod:	16 h light : 8 h dark
– light intensity:	mortality assessment and oviposition: 2652 lx; fecundity assessment: 4822 lx
Statistical analysis:	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

Validity criteria
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:
In the definitive test, mortality of the control group after 48 hours of exposure was 0.0%. After 48 hours of exposure to MIEDZIAN EXTRA 350 SC at the rates of 2.07, 4.14 and 8.28 L/ha percentages of mortality of *A. rhopalosiphi*, were 0.0%.
Based on the obtained mortality results the LR_{50} value could not be estimated. However, it could be assumed that the LR_{50} is higher than 8.28 L/ha of the test item. The $NOER_{mortality}$ is higher than or equal to 8.28 L/ha of the test item.
Mortality of the wasps exposed to Bi 58 Top 400 EC at the rate of 0.12 mL/ha was 85.0% after 24 hours. Therefore, the validity criterion specified in the Method description was met. The results showed that the test organisms were sensitive to dimethoate.

	Mortality	
MIEDZIAN EXTRA 350 SC [L/ha]	Total [%]	LR_{50} [L/ha]
Control	0.0	> 8.28
2.07	0.0	
4.14	0.0	
8.28	0.0	

Conclusions:
On the basis of the obtained results it can be concluded that MIEDZIAN EXTRA 350 SC at the rate of 8.28 L/ha has no adverse effect on the mortality of the wasps.

Study 2

zRMS comments:

The study is considered valid. 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 88.3% on day 7 of exposure (criterion: from 50 to 100%)

− The mean number of eggs per female in the control group was 8.9 (required: ≥ 4 eggs per female).

Agreed endpoints:

LR_{50} >8.28 L product/ha
ER_{50}>8.28 L product/ha

Report	A laboratory test for evaluating the effects of MIEDZIAN EXTRA 350 SC on the predatory mite, *Typhlodromus pyri* (Sch.) Knapik M., 2020, Study code: B-94-20
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 study was to determine the impact of MIEDZIAN EXTRA 350 SC on mortality and reproduction of the predatory mite, *Typhlodromus pyri*. The endpoints of this test were mortality of the mites after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment.

Materials and methods:

Test item:	Name: MIEDZIAN EXTRA 350 SC
Active substance:	346 g/L of copper
Batch number:	A2091132
Manufacture date:	01.05.2020
Expiry date:	01.05.2022
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 L/ha) − 1.33 L/ha − 3.32 L/ha − 8.28 L/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 – 25°C
– relative air humidity:	63 – 77%
– photoperiod:	16 h light : 8 h dark
– light intensity:	892 lux
Statistical analysis:	Probit analysis using max. likelihood regression, Tarone's Test Procedure, Step-down Cochran-Armitage Test Procedure, 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

Validity criteria
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 88.3% on day 7 of exposure (criterion: from 50 to 100%),

− the mean number of eggs per female in the control group was 8.9 (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 EXTRA 350 SC at rates of 1.33, 3.32 and 8.28 L/ha, the percentages of *T. pyri*, mortality were 3.3, 5.0 and 11.7%, respectively.

There were statistically significant differences in mortality between group treated with the test item at rate of 3.32 and 8.28 L/ha and the control group (Step-down Cochran-Armitage Test Procedure, p(trend)>α).
On the basis of the obtained mortality results, the LR_{50} is over 8.28 L/ha of MIEDZIAN EXTRA 350 SC.
The NOERmortality is 1.33 L/ha of MIEDZIAN EXTRA 350 SC.
The mean reproduction rate (Rr) in the control group was 8.9 eggs/female. The mean Rr after 14 days of exposure to MIEDZIAN EXTRA 350 SC at rates 1.33, 3.32 and 8.28 L/ha were 8.4, 6.8 and 5.9 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 1.33, 3.32 and 8.28 L/ha were 6.0, 23.1 and 34.3%, respectively.
At the significance level of $\alpha \leq 0.05$, there was statistically significant difference between rates 3.32 and 8.28 L/ha 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 8.28 L/ha. The $NOER_{reproduction}$ is 1.33 L/ha.

	Mortality		Reproduction			
MIEDZIAN EXTRA 350 SC [L/ha]	Total [%]	LR_{50} [L/ha]	MIEDZIAN EXTRA 350 SC [L/ha]	Mean number of eggs/ female (Rr)[no.]	Reproduction Pr [%]	ER50 [L/ha]
Control	0.0	>8.28	Control	8.9	-	>8.28
1.33	3.3		1.33	8.4	6.0	
3.32	5.0		3.32	6.8	23.1	
8.28	11.7		8.28	5.9	34.3	
$NOER_{mortality}$ 1.33 [L/ha]			$NOER_{reproduction}$ 1.33 [L/ha]			

Conclusions:
Based on the results it can be stated that MIEDZIAN EXTRA 350 SC, at the rates of 3.32 and 8.28 L/ha has significant adverse effect on mortality of the mites. The rates of 3.32 and 8.28 L/ha of MIEDZIAN EXTRA 350 SC 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

zRMS comments:

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

- The average number of offspring in the control was 79.8 (requirements: >30 individuals)
- The coefficient of variation in reproduction was 14.4% (requirements: ≤30%)
- Adult mortality after 28 days of the test was 1.3% (requirements: ≤10%)

Agreed endpoints:

NOER=41.43 mg product/kg dws

EC_{10} =19.905 mg product/kg dws

Report	Earthworm Reproduction Test according to OECD 222, Woźniak A., 2020, Study code: 0030/0005/E
Guideline(s):	OECD No. 222
Deviations:	Yes (deviations had no impact on study and results)
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Aim of the study:

The aim of the study was to evaluate the effect of the test item on the *Eisenia fetida* earthworms reproduction based on guideline OECD 222. During the test, the impact of the test item on the number of offspring, weight and survival of the parental individuals was determined. The effect of the test item was compared to the control group. On the basis of the obtained results, ECx, NOEC and LOEC values were estimated.

Materials and methods

Test design	range finding test: control and tested concentrations: 1 replicate, 10 earthworms definitive test: control: 8 replicate, 10 earthworms for each replicate tested concentrations: 4 replicates, 10 earthworms for each replicate
Test vessels	glass aquarium, size about 14.5 × 14.5 × 14.5 cm and cross-section area about 210 cm2
Time of exposition	range finding test: 14 days definitive test: 56 days
Tested concentrations	range finding test: 1,0; 10,0; 100,0; 500,0; 1000,0 mg/kg dry weight of soil definitive test: nominal concentrations 24.37; 41.43; 70.73; 119.73; 203.54; 346.02; 588.24; 1000.0 mg/kg dry weight of soil
Test conditions	range finding test: average temperature 19.399°C (minimal temperature 18.40°C; maximal temperature 20.10°C) photoperiod: 16 h day/8 h night with light intensity of 610-660 lux definitive test: average temperature 20.099°C (minimal temperature 18.80°C; maximal temperature 21.50°C); photoperiod 16 h day/8 h night with light intensity of 600-650 lux

Validity criteria:

The study met the validation criteria in accordance with OECD Guideline 222 (Appendix 4 and Appendix 5):
- The average number of offspring in the control was 79.8 (requirements: >30 individuals).
- The coefficient of variation in reproduction was 14.4% (requirements: ≤30%).
- Adult mortality after 28 days of the test was 1.3% (requirements: ≤10%).

Analytical determinations:

Table 26. Results of the characteristics of the analytical method

Parameter	Required criterium	Obtained result		
Selectivity	In the samples of copper standard , the tested item and the copper oxychloride standard there is a peak derived from copper at a wavelength of 327.395 nm. There are no peaks in the dilution solution (blank) that interfere with the copper under the given analysis conditions. Where there is copper in soil samples (control sample). the value of the copper concentration in the control will be subtracted from samples of the tested item in the soil.	In the samples of copper standard, the tested item and the copper oxychloride standard there is a derived peak from copper at a wavelength of 327.395 nm. In dilution solution (blank) there are no interfering peaks with copper under the given analysis conditions. Copper is present in the control samples. thus the value of the copper concentration in the control sample it is subtracted from samples of the tested item in the soil.		
Linearity	r ≥ 0.99	r = 0.999 (in the concentration range: 0.1 mg/L – 1.6 mg/L)		
Accuracy [%]	70-110	level I	89.4	90.0
		level II	90.4	
Precision [% RSDr]	≤ 20	level I	3.76	
		level II	1.02	
Limit of detection [mg/kg]	-	0.95252		
Limit of quantification [mg/kg]	-	2.85755		

Table 27. Results of analytical determinations – definitive test

Date of the anaylsis	Sample ID by the Laboratory of Ecotoxicology	Sample ID by the Laboratory of Physicochemistry	Determined concentration of copper [mg/L] **)	Dilution factor	Concentration of copper in the sample after dilution [mg/L]	Copper concentration after correction of the copper concentration in the control sample [mg/L] *)	The soil weight taken for mineralization [g]	Test item concentration [mg/kg]	Average test item concentration [mg/kg]
18.06.2020	Control day 0	192/2020	0.020253	1	0.020253	-	1.02413	-	-
		192/2020	0.021864	1	0.021864	-	1.04251	-	
	24.37 mg/kg day 0	193/2020	0.146352	1	0.146352	0.125294	1.09621	23.26	23.58
		193/2020	0.145120	1	0.145120	0.124062	1.05620	23.90	
	41.43 mg/kg day 0	194/2020	0.213494	1	0.213494	0.192436	1.01642	38.53	38.29
		194/2020	0.212018	1	0.212018	0.190960	1.02136	38.05	
	70.73 mg/kg day 0	195/2020	0.345673	1	0.345673	0.324615	1.01538	65.06	65.57
		195/2020	0.350258	1	0.350258	0.329200	1.01381	66.08	
	119.73 mg/kg day 0	196/2020	0.572290	1	0.572290	0.551232	1.06562	105.27	105.30
		196/2020	0.581699	1	0.581699	0.560641	1.08312	105.34	
	203.54 mg/kg day 0	197/2020	0.976177	1	0.976177	0.955119	1.01761	191.00	191.18
		197/2020	0.988799	1	0.988799	0.967741	1.02919	191.35	
	346.02 mg/kg day 0	198/2020	0.340957	5	1.704785	1.683727	1.04075	329.22	324.25
		198/2020	0.337555	5	1.687775	1.666717	1.06236	319.27	
	588.24 mg/kg day 0	199/2020	0.297166	10	2.971660	2.950602	1.09713	547.29	561.95
		199/2020	0.304757	10	3.047570	3.026512	1.06814	576.61	
	1000.0 mg/kg day 0	200/2020	0.491743	10	4.917430	4.896372	1.06289	937.46	947.27
		200/2020	0.495698	10	4.956980	4.935922	1.04951	957.08	

*) If the concentration of copper in the control > LOQ (0.01404 mg/L) the determined copper concentration of the control should be subtracted from the determined copper concentration.
**) Average concentration of copper in the control sample = 0.0210585 mg/L

Date of the anaylsis	Sample ID by the Laboratory of Ecotoxicology	Sample ID by the Laboratory of Physicochemistry	Determined concentration of copper [mg/L] **)	Dilution factor	Concentration of copper in the sample after dilution [mg/L]	Copper concentration after correction of the copper concentration in the control sample*) [mg/L]	The soil weight taken for mineralization [g]	Test item concentration [mg/kg]	Average test item concentration [mg/kg]
16.07.2020	Control day 28	331/2020	0.021838	1.00	0.021838	-	1.02180	-	-
		331/2020	0.022098	1.00	0.022098	-	1.08510	-	
	24.37 mg/kg day 28	332/2020	0.126143	1.00	0.126143	0.104175	0.99410	21.33	21.32
		332/2020	0.127644	1.00	0.127644	0.105676	1.00850	21.32	
	41.43 mg/kg day 28	333/2020	0.207043	1.00	0.207043	0.185075	1.02643	36.69	36.83
		333/2020	0.208072	1.00	0.208072	0.186104	1.02470	36.96	
	70.73 mg/kg day 28	334/2020	0.330832	1.00	0.330832	0.308864	1.06981	58.75	59.81
		334/2020	0.332317	1.00	0.332317	0.310349	1.03752	60.87	
	119.73 mg/kg day 28	335/2020	0.522100	1.00	0.522100	0.500132	1.06214	95.82	98.48
		335/2020	0.523193	1.00	0.523193	0.501225	1.00851	101.14	
	203.54 mg/kg day 28	336/2020	0.875672	1.00	0.875672	0.853704	0.98240	176.84	174.06
		336/2020	0.868611	1.00	0.868611	0.846643	1.00587	171.29	
	346.02 mg/kg day 28	337/2020	0.270343	5.00	1.351715	1.329747	0.98930	273.53	269.77
		337/2020	0.266079	5.00	1.330395	1.308427	1.00098	266.00	
	588.24 mg/kg day 28	338/2020	0.251096	10.00	2.510960	2.488992	1.03527	489.25	491.83
		338/2020	0.246214	10.00	2.462140	2.440172	1.00439	494.41	
	1000.0 mg/kg day 28	339/2020	0.436117	10.00	4.361170	4.339202	1.00741	876.53	863.24
		339/2020	0.427050	10.00	4.270500	4.248532	1.01721	849.95	

*) If the concentration of copper in the control > LOQ (0.01404 mg/L) the determined copper concentration of the control should be subtracted from the determined copper concentration.
**) Average concentration of copper in the control sample = 0.0210585 mg/L

Date of the anaylsis	Sample ID by the Laboratory of Ecotoxicology	Sample ID by the Laboratory of Physicochemistry	Determined concentration of copper [mg/L] **)	Dilution factor	Concentration of copper in the sample after dilution [mg/L]	Copper concentration after correction of the copper concentration in the control sample*) [mg/L]	The soil weight taken for mineralization [g]	Test item concentration [mg/kg]	Average test item concentration [mg/kg]
13.08.2020	Control day 56	532/2020	0.018416	1.00	0.018416	-	0.98430	-	-
		532/2020	0.017403	1.00	0.017403	-	1.00390	-	
	24.37 mg/kg day 56	533/2020	0.122493	1.00	0.122493	0.104584	1.02391	20.79	20.72
		533/2020	0.123364	1.00	0.123364	0.105455	1.03913	20.65	
	41.43 mg/kg day 56	534/2020	0.204925	1.00	0.204126	0.186216	1.07542	35.24	35.66
		534/2020	0.202054	1.00	0.202054	0.184145	1.03871	36.08	
	70.73 mg/kg day 56	535/2020	0.313604	1.00	0.312067	0.294158	1.02651	58.32	57.70
		535/2020	0.317427	1.00	0.317427	0.299518	1.06784	57.08	
	119.73 mg/kg day 56	536/2020	0.511174	1.00	0.511174	0.493265	1.08532	92.49	93.36
		536/2020	0.512815	1.00	0.512815	0.494906	1.06892	94.22	
	203.54 mg/kg day 56	537/2020	0.868603	1.00	0.868603	0.850694	1.04060	166.36	169.08
		537/2020	0.862602	1.00	0.862602	0.844693	1.00061	171.79	
	346.02 mg/kg day 56	538/2020	0.263206	5.00	1.316030	1.298121	1.03201	255.98	255.96
		538/2020	0.260711	5.00	1.303555	1.285646	1.02220	255.95	
	588.24 mg/kg day 56	539/2020	0.223610	10.00	2.236100	2.218191	0.98650	457.58	453.94
		539/2020	0.223773	10.00	2.237730	2.219821	1.00321	450.29	
	1000.0 mg/kg day 56	540/2020	0.395259	10.00	3.952590	3.934681	0.98451	813.31	810.24
		540/2020	0.394547	10.00	3.945470	3.927561	0.99020	807.17	

*) If the concentration of copper in the control > LOQ (0.01404 mg/L) the determined copper concentration of the control should be subtracted from the determined copper concentration.
**) Average concentration of copper in the control sample = 0.0210585 mg/L

Results:

On the basis of the results, it was concluded that after 4 weeks, at the control group there was 1.2% of mortality of adult earthworm. At concentrations ranging from 24.37 to 1000 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 0.0 to 7.5%.

The concentration of the test item causing 50% mortality of the adult earthworms (LC_{50}) is higher than 1000 mg/kg dry weight of artificial soil. No changes in the appearance (morphology) and behaviour of the earthworms were noticed.

After the application of the test item at the concentrations ranging from 24.37 to 1000 mg/kg dry weight of artificial soil, the body weight decrease when compared to control was between 7.6 to 31.8%.

After 8 weeks of the experiment, the obtained results led to the following conclusions:

After the application of the test item at the concentrations ranging from 24.37 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 29.5 – 69.5 per replicate. The mean number of juveniles in the control group was equal to 79.8 per replicate.

After 8 weeks of the experiment, it was concluded that MIEDZIAN EXTRA 350 SC had statistically significant impact on reproduction of the earthworms at the concentrations between 70.43 - 1000 mg/kg dry weight of artificial soil.

Conclusions

	MIEDZIAN EXTRA 350 SC [mg/kg dry weight of artrificial soil]
EC_{10}	**19.905 (6.606 – 54.100)**
EC_{20}	**56.813 (19.733 – 164.296)**
EC_{50}	**466.287**

	(116.170 – 1761.784)
NOEC (reproduction)	**41.43**
LOEC (reproduction)	**70.73**
LC_{50}	**>1000**
NOEC (survival)	**≥1000**
LOEC (survival)	**>1000**

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

zRMS comments:

- The coefficients of variation (CV) in the control group were 5.5, 6.5, 9.4 and 5.5%, after 0, 7, 14 and 28 days of incubation (the variation between replicate control samples should be is less than ± 15%)

Agreed endpoints:
On the basis of the results, it was concluded that MIEDZIAN EXTRA 350 SC at the concentration corresponding to the PEC: 17.28 mg of the test item / kg dry weight of soil (4.15 mg of copper / kg dry weight of soil), and upper PEC: 57.6 mg of the test item / kg dry weight of soil (13.84 mg of copper /kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Report	MIEDZIAN EXTRA 350 SC: Soil microorganisms: Nitrogen transformation test, Wołany, M., Study code: G/48/19
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 216 (2000) and EU Method C.21
Deviations:	Yes (deviation had no impact on test 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 EXTRA 350 SC** on the process of nitrogen transformation in aerobic surface soils.

Materials and methods

Test material:	**MIEDZIAN EXTRA 350 SC** batch no.: 05052018
Active substance:	copper: 346.0 g/L (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: 17.28 mg of the test item / kg dry weight of soil (4.15 mg of copper / kg dry weight of soil) upper PEC: 57.6 mg of the test item / kg dry weight of soil (13.84 mg of copper /kg dry weight of soil).
Test conditions:	temperature: 20.4 – 22.0°C, soil moisture: 54.9% – 59.8% 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 criteria
The coefficients of variation (CV) in the control group were 5.5, 6.5, 9.4 and 5.5%, 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: 17.28 mg of the test item / kg dry weight of soil (4.15 mg

of copper / kg dry weight of soil), and upper PEC: 57.6 mg of the test item / kg dry weight of soil (13.84 mg of copper /kg dry weight of soil) did not exceed 25% on 28 day of analysis.

Conclusion

On the basis of the results, it was concluded that MIEDZIAN EXTRA 350 SC at the concentration corresponding to the PEC: 17.28 mg of the test item / kg dry weight of soil (4.15 mg of copper / kg dry weight of soil), and upper PEC: 57.6 mg of the test item / kg dry weight of soil (13.84 mg of copper /kg dry weight of soil) 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