FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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: 04.2021; 08/2022

Version history

When	What
07/2020	Renewal of registration of plant protection product according art. 43, Reg. 1107/2009
03/2021	Recalculation of risk (PEC_{soil}, PEC_{gw}, PEC_{sw}) according to new EU endpoint
03/2021	Evaluated by RMS
04.2021	The new calculation was assessed by RMS
08/2022	The Final RR

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8 Fate and behaviour in the environment (KCP 9)

8.1.1. 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 safen-er/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 lindemuthianum, 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.	

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

GAP rev.2, date: 07.2020

PPP (product name/code):	MIEDZIAN EXTRA 350 SC	Formulation type:	Suspension Concentrate (SC)
Active substance 1:	Copper oxychloride	Conc. of as 1:	23,77% (350 g Cu/l)
Applicant:	Synthos Agro Sp. z.o.o.	Professional use:	☒
Zone(s):	Central	Non professional use:	☒
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	**Conclusion** Groundwater
					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	15
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)	**Conclusion** Groundwater
					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		
Minor uses according to Article 51 (zonal uses)														
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	1	7-10	a) 3	a) 1,05 kg Cu/ha	500-	14		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	**Conclusion** Groundwater
					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			
						BBCH 60	2		b)3 a)1,5 b)3	b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	750			
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		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	**Conclusion** Groundwater
					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			
17	PL	Gherkins	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		
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 Colletotrichum 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 (indoor)	I	Pseudoperonospora cubensis *Alternaria spp Colletotrichum 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 Colletotrichum 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 lindemuthianum, 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 lindemuthianum,*	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	15
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)	**Conclusion** Groundwater
					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			
				Botritis cinerea										A
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		A
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		A

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

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%,
2	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				
3	Pome fruits (quince, medlar)	4 x 1.5	4 x 0.525	2 x 50%, 2 x 60%
4	Stone fruits (cherry, sweet cherry, apricot, plum)	1 x 3.0	1 x 1.05	60%
5	Peach	1 x 3.0	1 x 1.05	50%
6	Fruiting vegetables (tomatoes, cucumbers, aubergines, gherkins, courgette, melon, pumpkin, watermelon)	3 x 3.6	3 x 1.25	80%
7	Legumes (French bean, bean with pods, peas with pods)	3 x 2.5	3 x 0.875	70%
8	Vine	3 x 3.0	3 x 1.05	1 x 50% / 2x 75%
9	Nuts (Walnut, Hazelnut)	2 x 3.0	2 x 1.05	2 x 50%
10	Currant	2 x 3.0	2 x 1.05	---

zRMS comments:

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. New data submitted by applicant are presented on yellow. Not agreed or not relevant information is struck through and shaded for transparency.

8.1 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.1.1 Aerobic degradation in soil (KCP 9.1.1.1)

Reference to:

- ~~Peer review of the pesticide risk assessment of the active substance copper (EFSA Journal EFSA Journal 2013;11(6):3235);~~
- Peer review of the pesticide risk assessment of the active substance copper compound (EFSA Journal 2018;16(1):5152)

8.1.1.1 Copper compound

No degradation is expected. Transformation of the free soluble ion in different complexed species is expected according available published literature. However, no quantitative estimation of the rate of these processes is available. Ecotoxicological significance of availability of the different possible species is not known.

8.1.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No valid study.

8.2 Field studies (KCP 9.1.1.2)

8.2.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Reference to:

- Peer review of the pesticide risk assessment of the active substance copper (EFSA Journal EFSA Journal 2013;11(6):3235);
- Peer review of the pesticide risk assessment of the active substance copper compound (EFSA Journal 2018;16(1):5152)

~~Table 8.2-1: Mean copper levels detected in soil horizons of Italian vineyard soils~~

~~Soil type~~	~~Location~~	~~pH (mean)~~	~~Depth (cm)~~	~~Mobile copper by DTPA extraction (5)~~	~~Mobile copper by $CaCl_2$ extraction (%)~~
~~Vineyard~~	~~Italy~~	~~7.11~~	~~0-10~~	~~37.4~~	~~0.1~~
			~~10-20~~	~~38.2~~	~~0.1~~

			~~20-40~~	~~37.0~~	~~0.1~~
			~~46-60~~	~~32.8~~	~~0.1~~
			~~60-100~~	~~29.4~~	~~0.1~~

~~Table 8.2-2: Concentrations of copper in Portuguese vineyard soil~~

~~Region~~	~~Depth (cm)~~	~~Description~~	~~Total copper (mg/kg)~~	~~Extractable copper (mg/kg)~~
~~Plain~~	~~0-20~~	~~Not ploughed~~	~~130.2~~	~~72.3~~
	~~0-20~~	~~Ploughed, not fertilized~~	~~102.4~~	~~56.0~~
	~~0-20~~	~~Ploughed, not fertilized~~	~~120.8~~	~~66.8~~
	~~20-50~~	~~-~~	~~106.9~~	~~55.3~~
	~~50-100~~	~~-~~	~~74.4~~	~~32.6~~
	~~100-135~~	~~-~~	~~23.4~~	~~2.6~~
~~Terrace~~	~~0-25~~	~~-~~	~~58.4~~	~~24.5~~
	~~25-45/50~~	~~With roots, friable~~	~~45.2~~	~~16.3~~
	~~25-45/50~~	~~No roots, firm~~	~~30.5~~	~~6.2~~
	~~45/50-100~~	~~With roots, friable~~	~~38.7~~	~~9.4~~
	~~45/50-100~~	~~No roots, firm~~	~~38.0~~	~~10.1~~

~~Table 8.2-3: Copper content in the soil profile of established German vineyards~~

~~Soil type~~	~~Location~~	~~pH~~	~~Depth (cm)~~	~~Mean copper content (mg/kg)~~	~~%1~~
~~Vineyard~~	~~Germany~~	~~n.d.~~	~~0-20~~	~~317~~	~~-~~
			~~20-40~~	~~159~~	~~50~~
			~~46-60~~	~~95~~	~~30~~
			~~60-80~~	~~59~~	~~19~~
			~~80-100~~	~~54~~	~~17~~
			~~100-120~~	~~45~~	~~14~~
			~~120-140~~	~~34~~	~~11~~
			~~140-160~~	~~15~~	~~5~~
~~n.d. – not determined~~ ~~1Expressed as a percent of the 0-20 cm horizon result.~~					

8.2.2 Soil accumulation testing (KCP 9.1.1.2.2)

Plateau concentration calculations are reported related to the intended uses (see below). A review of European monitoring programs was used to identify levels of copper present in soil from natural or anthropogenic sources other than the regulated use for the soil exposure assessments. The values suitable for use in soil exposure assessments are summarised below.

Table 8.2-4: Soil accumulation and plateau concentration

~~Soil~~	~~Soil concentration (mg Cu/kg soil DM)~~	
~~Background level~~	~~11.5~~	~~Overall median value~~
~~Vineyards~~	~~28~~ ~~66.4~~ ~~160~~ ~~77.5~~	~~Overall median 10th percentile value *~~ ~~Overall median value~~ ~~Overall median 90th percentile value*~~ ~~Overall mean value~~
~~Arable fields~~	~~32~~ ~~7~~ ~~13.4~~ ~~26~~ ~~15.9~~	~~Overall median 10th percentile value#~~ ~~Overall median value~~ ~~Overall median 90th percentile value#~~ ~~Overall mean value~~
~~Orchards~~	~~-~~ ~~48.3~~ ~~58~~ ~~22.5~~	~~Overall median 10th percentile value *~~ ~~Overall median value~~ ~~Overall median 90th percentile value*~~ ~~Overall mean value~~

~~*Values for overall median 10th and 90th percentile values from dataset considered in EFSA, 2018 # Values for overall median 10th and 90th percentile values, from data set considered in EFSA 201~~

A review of European monitoring programs was used to identify levels of copper present in soil from natural or anthropogenic sources other than the regulated use for the soil exposure assessments. The values suitable for use in soil exposure assessments are summarised below.

Summary of measured background values of total copper contents in different agriculatural soils in the EU from European monitoring data (EU-LoEP 2018)

Soil	Soil concentration (mg Cu/kg soil DM)	
Vineyards	28 72 160 67	Overall 10th percentile value Overall median value Overall 90th percentile value Overall mean value
Arable fields	32 7 13 26 15	EFSA (2013) Overall 10th percentile value Overall median value Overall 90th percentile value Overall mean value
Orchards	- 48.3 58 22	Overall 10th percentile value Overall median value Overall 90th percentile value Overall mean value

(see EU-LoEP in Appendix A, EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152

8.3 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Reference to:
- Peer review of the pesticide risk assessment of the active substance copper (EFSA Journal EFSA

Journal 2013;11(6):3235);

- Peer review of the pesticide risk assessment of the active substance copper compound (EFSA Journal 2018;16(1):5152)

Table 8.3-5: Soil adsorption of copper

Parent							
Soil Type	OC %	Soil pH (as $CaCl_2$)	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
494 topsoil samples from arable land and grass land across Europe	0.5-48.0	3.28-4.00	-	2300.0-35202.4	-	-	-
	0.6-49.0	4.02-4.99	-	908.7-337000	-	-	-
	0.7-36.0	5.08-5.48	-	1727.8-505444.4	-	-	-
	0.5-42.0	5.53-6.50	-	350.0-430400.0	-	-	-
	0.5-22.0	6.51-7.98	-	5163.3-1062833.3	-	-	-
Median value (if not pH dependent)			-		-	-	-
Geometric mean (if not pH dependent)			-	pH 4-5: 19509.9 pH 5.5-6.5: 33918.3	-	-	-
Arithmetic mean (if not pH dependent)			-				-
pH dependence, Yes or No			Yes				

8.3.1 Column leaching (KCP 9.1.2.1)

Eluation (mm): 300 mm
Time period (d): 2d

Leachate: 1% active substance in leachate ≈ 99% total residues retained in top 6 cm

Eluation (mm): 370 - 380 mm
Time period (d): 2d

Copper was applied to soil columns containing Speyer 2.1, 2.2 and 2.3 standard soils at a rate equivalent to 1 kg/ha. Levels of copper detected in the leachate, after correction for the amounts present in control samples, did not exceed 0.01 mg/L.

8.3.2 Lysimeter studies (KCP 9.1.2.2)

No valid study.

8.3.3 Field leaching studies (KCP 9.1.2.3)

~~No valid study.~~
A review of the existing monitoring programmes and published literature on copper levels in groundwater has been conducted. Generally natural levels of copper in groundwater were low, with background concentrations ranging from < 0.1 to 18 µg/L which is within the range of natural background levels. Copper concentrations never approach the legal limit of 2 mg/L set by the European Drinking Water Directive

(98/83/EC7) for groundwater.

8.4 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Refer to:

- Peer review of the pesticide risk assessment of the active substance copper (EFSA Journal EFSA Journal 2013;11(6):3235);
- Peer review of the pesticide risk assessment of the active substance copper compound (EFSA Journal 2018;16(1):5152)

8.4.1 Copper compound

Hydrolytic degradation of the active substance and metabolites below 10%.
Photolytic degradation of active substance and metabolites below 10%.
Substance is not ready biodegradable

Table 8.4-1: Summary of degradation in water/sediment of copper

Copper hydroxide WP Distribution (max. in water 60% after 4 d. /max. in sediment 50 % after 375 days)										
Water/sediment system	**pH water phase**	**pH sed-iment**	**t. °C**	**DegT50 whole syst. (d)**	**St. (r^2)**	**DissT50 water (d)**	**St. (r^2)**	**DissT50 sed. (d)**	**St. (r^2)**	**Method of calculation**
Microcosm	7-10	nd	5-25	> 400 d	-	Max 30.5	-	> 400 d	-	Model Maker v.4/

Table 8.4-2: Summary of degradation in water/sediment of copper, Water / sediment study

Total copper										
Water / sediment system	pH water phase	pH sed [a)]	t. °C	$DissT_{50}$ /$DissT_{90}$ whole sys.	St. (χ^2)	$DissT_{50}$ /$DissT_{90}$ Water Total copper	St. (χ^2)	$DissT_{50}$ /$DissT_{90}$ sed	St. (χ^2)	Method of calculation
Microcosm 2.5 µg total Cu/L	-	-	-	-	-	-	-	-	-	-
Microcosm 12 µg total Cu/L	-	-	-	-	-	-	-	-	-	-
Microcosm 24 µg total Cu/L	-	-	-	-	-	5-22 d Geomean: 9.9 d (n=6)	-	-	-	SFO

Microcosm 120 µg total Cu/L	-	-	-	-	-	7-30.5 d Geomean: 11.4 d (n=6)	-	-	-	SFO
Microcosm 240 µg total Cu/L	-	-	-	-	-	4-18 d Geomean: 6.1 d (n=6)	-	-	-	SFO
Geometric mean at 20°C b)				-		8.8 d		-		SFO

Table 8.4-3: Summary of degradation in water/sediment of copper, Water / sediment study

Dissolved copper										
Water / sediment system	pH water phase	pH sed a)	t. °C	$DissT_{50}$ /$DissT_{90}$ whole sys.	St. (χ^2)	$DissT_{50}$ /$DissT_{90}$ Water	St. (χ^2)	$DissT_{50}$ /$DissT_{90}$ sed	St. (χ^2)	Method of calculation
Microcosm 2.5 µg total Cu/L	-	-	-	-	-	5.48-8.87	4.15-25.2	-	-	SFO
Microcosm 12 µg total Cu/L	-	-	-	-	-	7.2-119	3.1-14.0	-	-	SFO
Microcosm 24 µg total Cu/L	-	-	-	-	-	3.32-22.3	4.83-19.5	-	-	SFO/FOMC
Microcosm 120 µg total Cu/L	-	-	-	-	-	3.42-26.8	2.93-23.8	-	-	SFO
Microcosm 240 µg total Cu/L	-	-	-	-	-	3.1-7.77	3.98-28.3	-	-	SFO
Geometric mean at 20°C b)				-		8.08(=27)		-		SFO

8.5 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.5.1 Justification for new endpoints

8.5.2 Copper compound

Table 8.5-1: Input parameters related to application for PEC_{soil} calculations, according to uses considering Article 43

Plant protection product	MIEDZIAN EXTRA 350 SC	
Use No.	1	2
Crop	Pome fruit (apple)	Pome fruit (pear)

Application rate (g as/ha)	2 x 0.525	4 x 0.525
Number of applications/interval	4 / 7-10	4 / 7-10
Crop interception (%)	0 (worst case)	
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)	

Table 8.5-2: Input parameters related to application for PEC_{soil} calculations, according to uses considering Article 51

Use No.	1	2	3	4	5	6	7
Crop	Pome fruit	Stone fruit and peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (g as/ha) /	4 x 0.525	1 x 1.05	3 x 1.25	3 x 0.875	3 x 1.05	2 x 1.05	2 x 1.05
Number of applications/interval	2 / 7-10	1 / -	3 / 7-10	3 / 7	3 / 10	2 / 10	2 / 10
Crop interception (%)	0 (worst case)						
Depth of soil layer (relevant for plateau concentration) (cm)	5						

Table 8.5-3: Input parameter for active substancefor PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Copper	63.5	-	1 000 000	EFSA Journal 2018;16(1):5152

Calculations according to Article 43

Table 8.5-4: PEC$_{soil}$ for copper compound on Orchards - pome fruits - apple

PEC$_{soil}$ (mg/kg) Application rate 2x0.525 kg/ha		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.7	0.7	1.4	1.4
Long term	100 d	0.7	0.7	1.4	1.4
~~Plateau concentration after year 10~~		~~Not reached – Background level 13.98 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 27.93 mg/kg~~			

Table 8.5-5: PEC$_{soil}$ for copper compound on Orchards - pome fruits - pear

PEC$_{soil}$ (mg/kg) Application rate 4x0.525 kg/ha		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.7	0.7	2.8	2.8
Long term	100 d	0.7	0.7	2.8	2.8
~~Plateau concentration after year 10~~		~~Not reached – Background level 27.97 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 55.86 mg/kg~~			

Calculations according to Article 51

Table 8.5-6: PEC$_{soil}$ for copper compound on Orchards – pome fruits

PEC$_{soil}$ (mg/kg) Application rate 4x0.525 kg/ha		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.7	0.7	2.8	2.8
Long term	100 d	0.7	0.7	2.8	2.8
~~Plateau concentration after year 10~~		~~Not reached – Background level 27.97 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 55.86 mg/kg~~			

Table 8.5-7: PEC$_{soil}$ for copper compound on Orchards – stone fruit and peach

PEC$_{soil}$ (mg/kg) Application rate 1 x 1.05 kg/ha		Stone fruits and peach	
		Single application	
		Actual	TWA
Initial		1.4	1.4
Long term	100d	1.4	1.4
~~Plateau concentration after year 10~~		~~Not reached – Background level 13.98 mg/kg~~	
~~Plateau concentration after year 20~~		~~Not reached – Background level 27.93 mg/kg~~	

Table 8.5-8: PEC$_{soil}$ for copper compound on fruiting vegetables

PEC$_{soil}$ (mg/kg) Application rate 3 x 1.25 kg/ha		Fruiting vegetables			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.67	1.67	5.0	5.0
Long term	100d	1.67	1.67	5.0	5.0
~~Plateau concentration after year 10~~		~~Not reached – Background level 49.94 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 99.76 mg/kg~~			

Table 8.5-9: PEC$_{soil}$ for copper compound on legumes

PEC$_{soil}$ (mg/kg) Application rate 3 x 0.875 kg/ha		Legumes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.17	1.17	3.5	3.5
Long term	100d	1.17	1.17	3.5	3.5
~~Plateau concentration after year 10~~		~~Not reached – Background level 34.96 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 69.83 mg/kg~~			

Table 8.5-10: PEC$_{soil}$ for copper compound on vine

PEC$_{soil}$ (mg/kg) Application rate 3 x 1.05 kg/ha		Vine			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.4	1.4	4.2	4.2
Long term	100d	1.4	1.4	4.2	4.2
~~Plateau concentration after year 10~~		~~Not reached – Background level 41.95 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 83.80 mg/kg~~			

Table 8.5-11: PEC$_{soil}$ for copper compound on nuts and currants

PEC$_{soil}$ (mg/kg) Application rate 2 x 1.05 kg/ha		Nuts and currants			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.4	1.4	~~4.2~~ 2.8	~~4.2~~ 2.8
Long term	100d	1.4	1.4	~~4.2~~ 2.8	~~4.~~2 2.8
~~Plateau concentration after year 10~~		~~Not reached – Background level 27.97 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 55.86 mg/kg~~			

8.5.2.1 PEC_{soil} of MIEDZIAN EXTRA 350 SC

Table 8.5-12: Maximal PEC_{soil} for MIEDZIAN EXTRA 350 SC on fruiting vegetables

Active substance/ reparation	**Application rate (g/ha)**	**PEC_{act} (mg/kg)**	**PEC_{twa}21 d (mg/kg)**	**Tillage depth (cm)**	**$PEC_{soil,plateau}$ (mg/kg)**
Copper	3 x 1250	5.0	5.0	5	Not reached - Background level after 10 years = 49.94 mg/kg
MIEDZIAN EXTRA 350 SC	3 x 3600	14.4	-	5	-

zRMS comments:

The PEC_{S}ini have been calculated supposing a standard soil density of 1.5 g/cm^3 and no interception. The modelling is considered to be correct.
The calculations cover proposed uses in GAP.
Background values of copper were added by RMS. The 7 years' period was considered and additionally, the natural copper background ($PEC_{Soil,\ accumulation}$ values which consider different values of the soil background level (e.g. 90th percentile value, median value, 10th percentile value) was accepted.
Calculations performed by RMS are included below:

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Individual Crop	Rate per Season	DT_{50} [A]	$PEC_{soil\ accumulation}$ calculation			Background Monitoring Value [B]	Overall $PEC_{soil,\ accumulation}$ [C]
			Soil depth	No. of years	C_{low} [D]		
	[g a.s. /ha]		[cm]		[mg/kg]	[mg/kg]	[mg/kg]
Orchards - (apple)	2 x 525	Not relevant	5	6	8.4	43.8*	**53.6**
						58	**67.8**

Individual Crop	Rate per Season	DT_{50} [A]	$PEC_{soil\ accumulation}$ calculation			Background Monitoring Value [B]	Overall $PEC_{soil,\ accumulation}$ [C]
			Soil depth	No. of years	C_{low} [D]		
	[g a.s. /ha]		[cm]		[mg/kg]	[mg/kg]	[mg/kg]
Orchards (pear)	4 x 525	Not relevant	5	6	16.8	43.8*	**63.4**
						58	**77.6**

[A] Copper is an element so DT_{50} value is not relevant
[B] 10th percentile value, median value and 90th percentile value in European arable and vineyard soils
[C] Overall $PEC_{soil,\ accumulation}$ = Background monitoring value + C_{low} + $PEC_{soil,\ initial}$ over 7 years
[D] C_{low} = Max PECsoil after 6 years considering a maximum application rate per year and no degradation.
* Overall median value for orchards

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Individual Crop	Rate per Season	DT_{50} [A]	$PEC_{soil\ accumulation}$ calculation			Background Monitoring Value [B]	Overall $PEC_{soil,\ accumulation}$ [C]
			Soil depth	No. of years	C_{low} [D]		
	[g a.s. /ha]		[cm]		[mg/kg]	[mg/kg]	[mg/kg]
Orchards pome fruit	4 x 525	Not relevant	5	6	16.8	43.8*	**63.4**
						58	**77.6**

Individual Crop	Rate per Season	DT_{50} [A]	$PEC_{soil\ accumulation}$ calculation			Background Monitoring Value [B]	Overall $PEC_{soil,\ accumulation}$ [C]
			Soil depth	No. of years	C_{low} [D]		
	[g a.s. /ha]		[cm]		[mg/kg]	[mg/kg]	[mg/kg]
Orchards – stone fruits and peach	1 x 1050	Not relevant	5	6	8.4	43.8*	**53.6**
						58	**67.8**
Fruiting vegetables	3 x 1250	Not relevant	5	6	30	7	**42**
						26	**61**
Legumines	3x875	Not relevant	5	6	21	7	**31.5**
						13.4	**37.9**
Currant, Nuts	2 x 1050	Not relevant	5	6	16.8	48.3*	**67.9**
						58	**77.6**
Vine	3 x 1050	Not relevant	5	6	25.2	28	**57.4**
						160	**189.4**

[A] Copper is an element so DT_{50} value is not relevant
[B] 10th percentile value, median value and 90th percentile value in European arable and vineyard soils
[C] Overall $PEC_{soil,\ accumulation}$ = Background monitoring value + C_{low} + $PEC_{soil,\ initial}$ over 7 years
[D] C_{low} = Max PECsoil after 6 years considering a maximum application rate per year and no degradation.
* Overall median value for orchards

The $PEC_{S,\ accum}$ reported above can be used for the risk assessment to the soil organisms (see section B-9)

8.6 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.6.1 Justification for new endpoints

8.6.2 Copper (KCP 9.2.4.1)

Table 8.6-1: Input parameters related to application for PEC_{gw} calculations, according to uses considering Article 43

Plant protection product	MIEDZIAN EXTRA 350 SC	
Use No.	1	2
Crop	Pome fruit (apple)	Pome fruit (pear)
Application rate (g/ha) /	2 x 1.5	4 x 1.5
Crop interception (%)	0 (worst case)	
Number of applications/interval	2 / 7-10	4 / 7-10
Frequency of application	Annual	
Water solubility (mg/L)	500 at pH 7 and 20°C	
parent DT50	1,000,000 days (No degradation is expected in soil).	
Koc / Kom (mL/g),	19509.9 / 11315.7	
mean 1/n	1	
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	

Table 8.6-2: Input parameters related to application for PEC_{gw} calculations, according to uses considering Article 51

Plant protection product	MIEDZIAN EXTRA 350 SC						
Use No.	1	2	3	4	5	6	7
Crop	Pome fruit	Stone fruit and peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (kg a.s/ha) /	4 x 0.525	1 x 1.05	3 x 1.25	3 x 0.875	3 x 1.05	2 x 1.05	2 x 1.05
Crop interception (%)	0	0	0	0	0	0	0
Number of applications/interval	2 / 7-10	1 / -	3 / 7-10	3 / 7	3 / 10	2 / 10	2 / 10
Frequency of application	annual						
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,						

Calculations according to Article 43

Table 8.6-3: PEC$_{gw}$ for copper on pome fruits (pear) (with FOCUS PEARL 4.4.4./PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Pome fruit (pear)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Since for the pear as the worst case, the obtained value, in each scenario, is below 0.001 µg/L, no additional calculations were performed.

Calculations according to article 51

Table 8.6-4: PEC$_{gw}$ for copper on fruiting vegetables (with FOCUS PEARL 4.4.4./PELMO 5.5.3),

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		PEARL	PELMO
Fruiting vegetables	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Since for the fruiting vegetables as a worst case, the obtained value, in each scenario, is below 0.001 µg/L, no additional calculations were performed.

zRMS comments:

The submitted PECgw assessment was accepted for proposed pattern use. The calculations cover proposed uses in GAP. The used endpoints are consistent with LoEP (EFSA 2018) and the worst case was considered. The predicted

concentrations for copper on application proposed in GAP lower than to the regulatory threshold 0.1 µg/L in groundwater at 1 m depth in all scenario with PELMO model and PEARL
In concordance with the EFSA conclusion on Copper, these predicted groundwater concentrations are far below the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC) for groundwater.

8.7 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.7.1 Justification for new endpoints

8.7.1.1 $PEC_{sw/sed}$ of MIEDZIAN EXTRA 350 SC

Table 8.7-1: Input parameters related to application for PEC_{sw} calculations, according to uses considering Article 43

Plant protection product	MIEDZIAN EXTRA 350 SC	
Use No.	1	2
Crop	Pome fruit (apple)	Pome fruit (pear)
Application rate (kg a.s/ha)	2 x 0.525	4 x 0.525
Crop interception (%)	0 (worst case)	
Number of applications/interval	2 / 7-10	4 / 7-10
Frequency of application	annual	
Models used for calculation	FOCUS STEPS 1-2	

Table 8.7-2: Input parameters related to application for PEC_{sw} calculations, according to uses considering Article 51

Plant protection product	MIEDZIAN EXTRA 350 SC						
Use No.	1	2	3	4	5	6	7
Crop	Pome fruit	Stone fruit and peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (kg a.s/ha) /	4 x 0.525	1 x 1.05	3 x 1.25	3 x 0.875	3 x 1.05	2 x 1.05	2 x 1.05
Crop interception (%)	0	0	0	0	0	0	0
Number of applications/interval	2 / 7-10	1 / -	3 / 7-10	3 / 7	3 / 10	2 / 10	2 / 10
Frequency of application	annual						
Models used for calculation	FOCUS STEPS 1-2						

Table 8.7-3: Input parameters related to copper for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	Copper	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	63.5	Y/EFSA Journal 2013;11(6):323
Saturated vapour pressure (Pa)	0	Worst case
Water solubility (mg/L)	500	EFSA Journal 2018;16(1):5152
K_{foc} (mL/g)	33,918.3	EFSA Journal 2018;16(1):5152
Freundlich Exponent 1/n	1	EFSA Journal 2018;16(1):5152
$DT_{50,soil}$ (d)	1 000	EFSA Journal 2018;16(1):5152
$DT_{50,water}$ (d)	1 000	EFSA Journal 2018;16(1):5152
$DT_{50,sed}$ (d)	1 000	EFSA Journal 2018;16(1):5152
$DT_{50,whole\ system}$ (d)	1 000	EFSA Journal 2018;16(1):5152
Water solubility (mg/L)	500	EFSA Journal 2018;16(1):5152
K_{foc} (mL/g)	33,918.3	EFSA Journal 2018;16(1):5152
Freundlich Exponent 1/n	1	EFSA Journal 2018;16(1):5152
$DT_{50,soil}$ (d)	1 000	EFSA Journal 2018;16(1):5152

Table 8.7-4 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Copper oxychloride	**0.37 µg/L**

According to study Blust and Joosen (2016) high rate of copper concentration decline was demonstrated in a realistic water/sediment scenario . Authors proposed factor of 10 to recalculated concentration of dissolved copper on base of total copper concentration. In followed calculations more rigoristic factor of 3 was used due to high risk for aquatic organism relay on copper toxicity.

$PEC_{sw/sed}$

Calculations according to Article 43

Table 8.7-5: Scheme of applications of MIEDZIAN EXTRA 350 SC

Crop	Application of Cu [g/ha]	Application of Cu including factor of 3 [g/ha]
Apple	2 x 525	2 x 175
Pear	4 x 525	4 x 175

Table 8.7-6: FOCUS Step 1,2 PEC_{sw} for copper following multiple applications of MIEDZIAN EXTRA 350 SC to pome fruits

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 8.7-7: Scheme of applications of MIEDZIAN 50 WP to different types of crops (minor uses)

Crop	Application of Cu [g/ha]	Application of Cu including factor of 3 [g/ha]
Pome fruits	4 x 525	4 x 175
Stone fruits and peach	1 x 1050	1 x 350
Fruiting vegetables	3 x 1250	3 x 417
Legumes	3 x 875	3 x 292
Vine	3 x 1050	3 x 350
Nuts	2 x 1050	2 x 350
Currant	2 x 1050	2 x 350

Table 8.7-8: FOCUS Step 1,2 PEC_{sw} for copper following multiple applications of MIEDZIAN 50 WP to 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

zRMS comments:

The calculations with step 1 & 2 models of PECsw and PECsed for Copper has been accepted. The endpoints used for surface water exposure assessment are consistent with list of end-points EFSA Journal 2018; 16(1):5152,119 for Copper. Application rate used in the calculations was determined assuming the GAP.
The opinion of the RMS the model used by the Applicant to determine the PECsw/sed from drainage and runoff is in line with the EFSA conclusion (2018).
Due to the fact that the PECsed calculation was not included by the Applicant these calculations were performed by the zRMS.

The PECsed results are presented in the table below:

Crop	Application [kg /ha]	Application rate [kg Cu/ha]	PEC_{sed} [mg/kg]	PEC_{sed} accumulation (7 years) [mg/kg]	PEC_{sed} accumulation (7 years) + background (17mg/kg) PEC_{sed} [mg/kg]
Re-authorization according Article 43, 1107/2009					
Pome fruit	2 x 1.5	2 x 525	Step1	1.11	18.11
			N-Europe Step 2	0.39	17.39
Pome fruit	4 x 1.5	4 x 525	Step1	2.21	19.21
			N-Europe Step 2	0.74	17.74
Minor uses according to Article 51, 1107/2009					
Pome fruit	4 x 1.5	4 x 525	Step1	2.21	19.21
			N-Europe Step 2	0.74	17.74
Stone fruit, peach	1 x 3.0	1 x 1050	Step1	1.11	18.11
			N-Europe Step 2	0.42	17.42
Fruiting vegetables	3 x 3.6	3 x 1250	Step1	3.14	20.14
			N-Europe Step 2	0.67	17.67
Legumes	3 x 2.5	3 x 875	Step1	2.20	19.20
			N-Europe Step 2	0.47	17.47
Vine	3 x 3.0	3 x 1050	Step1	2.64	19.64
			N-Europe Step 2	0.57	17.57
Nuts	2 x 3.0	2 x 1050	Step1	2.21	19.21
			N-Europe Step 2	0.77	17.77
Currant	2 x 3.0	2 x 1050	Step1	1.76	18.76
			N-Europe Step 2	0.38	17.38

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

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).

8.8 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Copper as a metal is not volatile, no data considering photolysis and photochemical degradation in air are available.

ZRMS comments:
Information on the fate and behaviour of copper oxychloride in the air provided by the Applicant is in line with the EU agreed data reported in EFSA Journal 2018; 16(1):5152,119.
Due to its properties copper hydroxide is not expected to pose an unacceptable risk to the atmosphere following application of Miedzian Extra 350 SC according to the intended use pattern.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9	Bam, Edward K. P.; et al.	2011	Major ions and trace elements partitioning in unsaturated zone profile of the Densu river basin, Ghana and the implications for groundwater	N	-
KCP 9	Bhupander Kumar; et al.	2010	Distribution, partitioning, bioaccumulation of trace elements in water, sediment and fish from sewage fed fish ponds in eastern Kolkata, India	N	-
KCP 9	Birsan, Elena; Diacu, Elena	2012	Copper speciation assessment in aquatic ecosystem affected by historical mining activities	N	-
KCP 9	Disli, E.	2010	Batch and column experiments to support heavy metals (Cu, Zn, and Mn) transport modeling in alluvial sediments between the Mogan Lake and the Eymir Lake, Goelbas, Ankara.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9	Du, Jianjun; et al	2014	Optical Reading of Contaminants in Aqueous Media Based on Gold Nanoparticles	N	-
KCP 9	El-Zokm, G. M.; et al	2012	Studies of some heavy metals in water and sediment in El-Max fish farm, Egypt.	N	-
KCP 9	Ferronato, C.; et al	2013	Chemical and microbiological parameters in fresh water and sediments to evaluate the pollution risk in the Reno river watershed (north Italy).	N	-
KCP 9	Gupta, S.; et al	2012	Major ion chemistry and metal distribution in coal mine pit lake contaminated with industrial effluents: constraints of weathering and anthropogenic inputs	N	-
KCP 9	Halim, M. A.; et al	2013	Mobility and impact of trace metals in Barapukuria coal mining area, Northwest Bangladesh	N	-
KCP 9	Hayzoun, H.; et al	2015	Organic carbon, and major and trace element dynamic and fate in a large river subjected to poorly-regulated urban and industrial pressures (Sebou River, Morocco).	N	-
KCP 9	Huang DeKun; et al	2011	Particle dynamics of 7Be, 210Pb and the implications of sedimentation of heavy metals in the Wen-jiao/Wenchang and Wanquan River estuaries, Hainan, China.	N	-
KCP 9	Huang, Jian Zhi; et al.	2012	Remobilization of heavy metals during the resuspension of Liangshui River sediments using an annular flume	N	-
KCP 9	Huo ShouLiang; et al.	2013	Application of equilibrium partitioning approach to derive sediment quality criteria for heavy metals in a shallow eutrophic lake, Lake Chaohu, China.	N	-
KCP 9	Khadhar Samia; et al	2013	Transport of heavy metal pollution from the Wadi El Bey basin toward the Tunisian Gulf	N	-
KCP 9	Liu Fei; et al	2013	Risk evaluation of heavy metals in the surface sediments of Lake Chaohu in China.	N	-
KCP 9	Lourino-Cabana, B.; et al	2010	Impacts of Metal Contamination in Calcareous Waters of Deûle River (France): Water Quality and Thermodynamic Studies on Metallic Mo-bility	N	-
KCP 9	McKenzie, Erica R.; Young, Thomas M.	2013	A novel fractionation approach for water constituents-distribution of storm event metals	N	-
KCP 9	Michalopoulos, et al.	2014	Effects of an intensive hog farming operation on groundwater in east Mediterranean (II): a study on K , Na , Cl , PO43 -P, Ca2 , Mg2 , Fe3 /Fe2 , Mn2 , Cu2 , Zn2 and Ni2.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9	Mohamad, Osama Abdalla; Hatab, Shaimaa Reda; Liu, Zhenshan; et al.	2012	Biosorption and Bioaccumulation of Cu2+ from Aqueous Solution Using Living M. amorphae Isolated from Mine Tailings	N	-
KCP 9	Nayek, S.; Gupta, S.; Saha, R. N.	2013	Heavy metal distribution and chemical fractionation in water, suspended solids and bed sediments of industrial discharge channel: an implication to ecological risk	N	-
KCP 9	Ollivier, P.; et al.	2011	Major and trace element partition and fluxes in the Rhone River	N	-
KCP 9	Ololade, I. A.; et al.	2011	Metal partitioning in sediment pore water from the Ondo coastal region, Nigeria.	N	-
KCP 9	Oursel, B.; et al.	2014	Mood inputs in a Mediterranean coastal zone impacted by a large urban area: Dynamic and fate of trace metals.	N	-
KCP 9	Palleiro, L.; et al.	2014	Baseflow and runoff event metal concentrations, partition and its relation with physicochemical variables in an agroforestry catchment.	N	-
KCP 9	Ruello, Maria Letizia; Sani, Daniela; Sileno, Miriam; Fava, Gabriele	2011	Persistence of heavy metals in river sediments	N	-
KCP 9	Salbu B.; et al.	2013	Environmental impact assessment of radionuclides and trace elements at the Kurday U mining site, Kazakhstan	N	-
KCP 9	Sheppard, S. C.; Long, J. M.; Sanipelli, B.	2010	Measured elemental transfer factors for boreal hunter/gatherer scenarios: fish, game and berries	N	-
KCP 9	Skipperud, L.; et al.	2013	Environmental impact assessment of radionuclide and metal contamination at the former U sites Taboshar and Digmai, Tajikistan.	N	-
KCP 9	Soto-Varela, F.; et al.	2014	Identifying environmental and geochemical variables governing metal concentrations in a stream draining headwaters in NW Spain.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9	Sultana, M. S.; et al.	2012	Toxic metal contamination on the river near industrial area of Dhaka.	N	-
KCP 9	Tijani, M. N.; Onodera, S.	2009	Hydrogeochemical assessment of metals contamination in an urban drainage system: a case study of Osogbo Township, SW-Nigeria.	N	-
KCP 9	Tijani, M. N.; Okunlola, O. A.; Ikpe, E. U.	2010	A geochemical assessment of water and bottom sediments contamination of Eleyele Lake catchment, Ibadan, Southwestern Nigeria	N	-
KCP 9	Trinh Anh Duc; Vu Duc Loi; Ta Thi Thao	2013	Partition of heavy metals in a tropical river system impacted by municipal waste.	N	-
KCP 9	Vukovic, et al.	2011	Heavy metal and bacterial pollution of the Sava river in Serbia	N	-
KCP 9	Vukovic, et al.	2011	Distribution and accumulation of heavy metals in the water and sediments of the River Sava	N	-
KCP 9	Vukovic, et al.	2012	A new approach to the analysis of the accumulation and enrichment of heavy metals in the Danube River sediment along the Iron Gate reservoir in Serbia	N	-
KCP 9	Wennrich, et al.	2012	Behavior of metalloids and metals from highly polluted soil samples when mobilized by water - Evaluation of static versus dynamic leaching	N	-
KCP 9	Zhang DaWen; et al.	2012	Distribution of heavy metals in water, suspended particulate matter and sediment of Poyang Lake, China.	N	-
KCP 9	Zheng, Shasha; Wang, Peifang; Wang, Chao; Hou, Jun; Qian, Jin	2013	Distribution of metals in water and suspended particulate matter during the resuspension processes in Taihu Lake sediment, China	N	-
KCP 9.1	Alberti, G., Cristini, A., Loi, A., Melis, P., Pilo, G.	1997	Copper and lead sorption by different fractions of two Sardinian soils. Proceedings of the 3rd International Conference on the Biogeochemistry of Trace Elements, INRA. Paris. Not GLP, Published.	N	Public
KCP 9.1	Antic, T.	1992	Part A: Leaching test for the following preparations: URA-08740-F-0-WP – URA-06180-F-0-SC. Experimental part of study. Establishment of leaching water for the validation of the method of analysis. Spiess-	N	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Urania Agrochem GmbH, Report No. C91VSF01 GLP, Unpublished. Part B: Final report. Analysis by residue U91AWF01. Determination of copper in leaching water, Report No. U91AWF01. Spiess-Urania Agrochem GmbH. GLP. Unpublished.		
KCP 9.1	Blust R and Joosen S	2016	Kinetics and speciation of copper in copper based fungicide formulations used in crop protection (Update February 2016) F-Cu 2015-7 Department of Biology, University of Antwerp, Belgium No GLP Not Published	N	EUCuTF
KCP 9.1	Bolan. N, Adriano, D., Mani, S., Khan, A.	2003	Adsorption, complexation and phytoavailability of copper as influenced by organic manure. Environmental toxicology and chemistry, Vol. 22, No. 2, pp-450-456. Not GLP, Published.	N	Public
KCP 9.1	Bansal, O. P.	2009	Competitive adsorption of heavy metals by soils of Aligarh district.	N	-
KCP 9.1	Braz, A. M. D., et al.	2013	Distribution coefficients of potentially toxic elements in soils from the eastern Amazon.	N	-
KCP 9.1	Braz, A. M. D., et al.	2013	Prediction of the distribution coefficients of metals in Amazonian soils.	N	-
KCP 9.1	Cerqueira, B., et al.	2011	Retention and Mobility of Copper and Lead in Soils as Influenced by Soil Horizon Properties.	N	-
KCP 9.1	Cetoil, A. et al	2003	Soil copper mobility and bioavailability – a review, Section 1 and 2. ENSA.M-INRA-UMR Rhizosphère & Symbiose. Not GLP, Unpublished.	N	EUCuTF
KCP 9.1	Cetois, A., Quesnoit, M., Hinsinger, P.	2003	Soil copper mobility and bioavailability – a review, Section 3. ENSA.M-INRA-UMR Rhizosphère & Symbiose. Not GLP, Unpublished.	N	EUCuTF
KCP 9.1	Chlopecka, A.	1993	Forms of trace metals from inorganic sources in soils and amounts found in spring barley, Water, Air and Soil Pollution, Vol. 40, pp 127-134. Not GLP, Published.	N	Public

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 9.1	Chorom, M., et al..	2013	Monometal and competitive adsorption of Cd, Ni, and Zn in soil treated with different contents of cow manure.	N	-
KCP 9.1	Christiansen, K. S, et al.	2014	Experimental determinations of soil copper toxicity to lettuce (*Lactuca sativa*) growth in highly different copper spiked and aged soils.	N	-
KCP 9.1	Degryse, F., Smolders, E., & Parker, D. R.	2009	Partitioning of metals (Cd, Co, Cu, Ni, Pb, Zn) in soils: concepts, methodologies, prediction and applications - a review	N	-
KCP 9.1	Deluisa, A., et al	1996	Copper pollution in Italian vineyard soils. Commun. Soil Sci. Plant Anal., Vol. 27, pp. 1537-1548. Not GLP, Published.	N	Public
KCP 9.1	Díaz-Barrientos, E., *et al.*	2003	Copper and zinc retention by an organically amended soil. Chemosphere, Vol. 50, pp. 911-917. Not GLP, Published.	N	Public
KCP 9.1	Disli, E.	2010	Batch and Column Experiments to Support Heavy Metals (Cu, Zn, and Mn) Transport Modeling in Alluvial Sediments Between the Mogan Lake	N	-
KCP 9.1	Ferrier, F.		Fate and behaviour of copper in soil. Elf Atochem Agri S.A. Not GLP, Unpublished.	N	EUCuTF
KCP 9.1	Flores-Velez, L.M., Ducaroir, J., Jaunet, A.M., Robert, M.A.	1996	Study of the distribution of copper in an acid sandy vineyard soil by three different methods. European Journal of Soil Science, Vol. 47, pp. 523-532. Not GLP. Published.	N	Public
KCP 9.1	Garrett, R. G., Hall, G. E. M., Vaive, J. E., & Pelchat, P.	2009	A water-leach procedure for estimating bioaccessibility of elements in soils from transects across the United States and Canada.	N	-
KCP 9.1	Grathwohl, P., & Susset, B.	2009	Comparison of percolation to batch and sequential leaching tests: Theory and data.	N	-
KCP 9.1	Huang, J. H., Ilgen,	2011	Fluxes and budgets of Cd, Zn, Cu, Cr and Ni in a remote forested catchment in Germany	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	G., & Matzner, E.				
KCP 9.1	Jalali, M., & Jalili, A.	2011	Competitive adsorption of trace elements in calcareous soils as affected by sewage sludge, poultry manure, and municipal waste compost	N	-
KCP 9.1	Jalali, M., & Moradi, F.	2013	Competitive sorption of Cd, Cu, Mn, Ni, Pb and Zn in polluted and unpolluted calcareous soils.	N	-
KCP 9.1	Jalali, M., & Zinli, N. A. M.	2013	Effect of common ions on copper sorption behavior in dryland calcareous soils in Iran.	N	-
KCP 9.1	Janik, L. J., et al.	2015	GEMAS: Prediction of solid-solution partitioning coefficients (Kd) for cationic metals in soils using mid-infrared diffuse reflectance spectroscopy.	N	-
KCP 9.1	Jordao, C. P., et al.	2011	Adsorption from Brazilian soils of Cu(II) and Cd(II) using cattle manure vermicompost	N	-
KCP 9.1	Jungic, D.; Coric, R.	2013	Heavy metals in anthropogenic soil and percolated water in an apple orchard in lower Meimurje area	N	-
KCP 9.1	Kang, S. M., Ra, J. B., & Kim, S. K.	2009	Changes of distribution coefficients of Cu, Cr, and As in different soil matrix in a laboratory scale.	N	-
KCP 9.1	Kang, J., Zhang, Z. Q., & Wang, J. J.	2011	Influence of humic substances on bioavailability of Cu and Zn during sewage sludge composting.	N	-
KCP 9.1	Lamb, D. T., et al.	2009	Heavy metal (Cu, Zn, Cd and Pb) partitioning and bioaccessibility in uncontaminated and long-term contaminated soils.	N	-
KCP 9.1	Lemnitzer, B.	2000	Soil leaching study with URA-08740-F-0-WP. Spiess-Urania Chemicals GmbH, Report No. 00 10 35 901. GLP, Unpublished.	N	EUCuTF
KCP 9.1	Lock, K., Janssen, R.	2003	Influence of ageing on metal availability in soils. Reviews of environmental contamination and toxicology, Vol. 178: pp 1-21. Not GLP. Published.	N	Public
KCP 9.1	Lu, S. G., & Xu, Q. F.	2009	Competitive adsorption of Cd, Cu, Pb and Zn by different soils of Eastern China.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1	Magalhães, M.J., Sequeira, E.M., Lucas, M.D.	1985	Copper and zinc in vineyards of central Portugal. Water, Air and Soil Pollution, Vol. 26, pp. 1-17. Not GLP, Published.	N	Public
KCP 9.1	Mathur, S.P., Sanderson, R.B.	1984	The effect of copper applications on the movement of copper and other elements in organic soils. Water, Air and Soil Pollution, Vol. 22, pp. 277-288. Not GLP, Published.	N	Public
KCP 9.1	McLaren, R.G., Crawford D.V	1973	Studies on soil copper II. The specific adsorption of copper by soils. Journal of Soil Science, Vol. 24, No. 4, pp. 443-452. Not GLP, Published.	N	Public
KCP 9.1	Molina, M., Manquian-Cerda, K., & Escudey, M.	2010	Sorption and Selectivity Sequences of Cd, Cu, Ni, Pb, and Zn in Single- and Multi-Component Systems in a Cultivated Chilean Mollisol.	N	-
KCP 9.1	Okonokhua, B. O.	2014	Bioavailability of Cu in freshly spiked, leached and field-contaminated soils.	N	-
KCP 9.1	Ololade, I. A., Lajide, L., Ololade, O. O., & Adeyemi, O.	2011	Metal partitioning in sediment pore water from the Ondo coastal region, Nigeria.	N	-
KCP 9.1	Osunbitan, J. A.; Adekalu, K. O.; Aina, P. O.	2014	Intermittent leaching of copper from copper based fungicide through a saturated soil profile	N	-
KCP 9.1	Pang, C. F., et al.	2013	Bioaccumulation, toxicokinetics, and effects of copper from sediment spiked with aqueous Cu, nano-CuO, or micro-CuO in the deposit-feeding snail, *Potamopyrgus antipodarum*.	N	-
KCP 9.1	Rodriguez-Oroz, D., et al.	2012	Heavy Metals Mobility in Experimental Disturbed and Undisturbed Acid Soil Columns in Spanish Pyrenees.	N	-
KCP 9.1	Römkens, P.F., Salomons, W.	1993	The non-applicability of the simple Kd - approach in modelling trace metal behaviour; a field study. Heavy metals in the environment, International conference, Vol. 2, pp 496-499. Not GLP, Published	N	Public
KCP 9.1	Saha, P. K., Badruzzaman, A. B. M.	2014	An experimental investigation of sorption of copper on sandy soil by laboratory batch and column experiments.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1	SALAM D.; EL-FADEL M.	2008	Mobility and Availability of Copper in Agricultural Soils Irrigated from Water Treated with Copper Sulfate Algaecide	N	-
KCP 9.1	Scholl, W., Enkelmann, R.	1984	The copper content of vineyard soils. Landwirtsch. Forschung, Vol. 37 (3-4), pp. 286-297. Not GLP, Published.	N	Public
KCP 9.1	Shaheen, S. M., Tsadilas, C. D., Mitsibonas, T., & Tzouvalekas, M.	2009	Distribution Coefficient of Copper in Different Soils from Egypt and Greece.	N	-
KCP 9.1	Shaheen, S. M., Tsadilas, C. D., & Rinklebe, J.	2013	A review of the distribution coefficients of trace elements in soils: influence of sorption system, element characteristics, and soil colloidal properties.	N	-
KCP 9.1	Sheppard, S. C.	2011	Robust Prediction of Kd from Soil Properties for Environmental Assessment.	N	-
KCP 9.1	Strumpf, Th., Traulsen, B.D., Pestemer, W.	2000a	Final report on the study: Availability of copper in soils used for agriculture. BBA Institute of Ecological Chemistry, Berlin. Not GLP. Unpublished.	N	EUCuTF
KCP 9.1	Strumpf, Th., Traulsen, B.D., Pestemer, W.	2000b	Quantification of copper by compact lysimeters test after Funguran application in highly copper-contaminated farmland soil. BBA Institute for Ecological Chemistry, Berlin. Not GLP, Unpublished.	N	EUCuTF
KCP 9.1	Turan, M., Ata, S., Gunes, A., Ataoglu, N., Esringu, A., Uzun, O., Ozgul, M., Canbolat, M. Y., & Bogdan, I.	2010	Determination of Competitive Adsorption and Desorption of Heavy Metals by Isotherm and Sequential Extraction Methods in Different Soil Orders in Erzurum Plain.	N	-
KCP 9.1	Unamuno, V. I. R., Meers, E., Du Laing,	2009	Effect of Physicochemical Soil Characteristics on Copper and Lead Solubility in Polluted and Unpolluted Soils.	N	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	G., & Tack, F. M. G.				
KCP 9.1	Vidal, M., Santos, M. J., Abrao, T., Rodriguez, J., & Rigol, A.	2009	Modeling competitive metal sorption in a mineral soil.	N	-
KCP 9.1	Williams, J. R., & Pillay, A. E.	2014	Development of distribution coefficients for extracted metals from environmental samples in aqueous acidic media.	N	-
KCP 9.1	Zhang, D. W., Wei, Y. H., Zhang, L., Luo, L. G., Chen, Y. W., & Tu, T. H.	2012	Distribution of Heavy Metals in Water, Suspended Particulate Matter and Sediment of Poyang Lake, China	N	-
KCP 9.2	Masuda, K., Boyd, C.E.	1993	Comparative evaluation of the solubility and algal toxicity of copper sulphate and chelated copper. Aquaculture, Vol. 117, pp. 287-302. Not GLP, Published.	N	Public
KCP 9.2	Schäfers, C.	2000	Community level study with copper hydroxide 50% WP in aquatic microcosms. Fraunhofer-Institut for Molecular Biology and Applied Ecology, Report No. URA-001/4-50. GLP, Unpublished.	N	EUCuTF
KCP 9.2	Wagemann, R., Barica, J.	1979	Speciation and rate of loss of copper from lakewater with implications to toxicity. Water Research, Vol. 13, pp. 515-523. Not GLP. Published.	N	Public

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 Annex II studies

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)