FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: MIEDZIAN 50 WP

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

Chemical active substance(s):

Copper as a copper oxychloride, 500 g/kg

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

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

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

Submission date: **07/2020**

MS Finalisation date: 03.2021; 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)

Table 8.1 GAP evaluated and approved under first evaluation (2013) and under extension to minor uses (2016) for the Miedzian 50 WP

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

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

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

Table 8.1-1: Critical use pattern of the formulated product

GAP rev. 2, date: 06.2020

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Apple, pear	Fpn	*Venturia inaequalis* *Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	14		
Minor uses according to Article 51 (zonal uses)														

2	PL	Quince	Fpn	*Venturia inaequalis Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	7		
3	PL	Medlar	Fpn	*Venturia inaequalis Erwinia amylovora*	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	7		
4	PL	Cherry, sweet cherry	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61 BBCH 65-73	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,5 kg Cu/ha b)1,5 kg Cu/ha a)0,75kg Cu/ha, b) 1,5 kg Cu/ha	500-750	14		
5	PL	Apricot	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a.		
6	PL	Plum	Fpn	*Pseudomonas syringae*	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a.		
7	PL	Peach	Fpn	*Taphrina deformans*	Spraying	BBCH 00-03	1	-	3,0	1,5 kg Cu/ha	700	n.a.		
8	PL	Walnut	Fpn	*Gnomonia leptostyla, Xantomonas campestris pv. Juglandis,*	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	n.a.		
9	PL	Hazelnut	Fpn	*Gnomonia leptostyla, Xanthomonas arborico-la pv. corylina*	Spraying	Before flowering	2	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	n.a.		
10	PL	Tomato (out-door)	Fpn	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7		
11	PL	Tomato (indoor)	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 56-88	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	1500-2000	3		
12	PL	Aubergines (outdoor)	Fpn	*Pseudomonas syringae, Phytophthora infestans*	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg	700	7		

										Cu/ha				
13	PL	Aubergines (indoor)	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	Spraying	BBCH 56-88	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	1500-2000	3		
14	PL	Cucumber (out-door)	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7		
15	PL	Cucumber (in-door)	I	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 10-89	4	7	a)1,6 b)6,4	a)0,8 kg Cu/ha b) 3,2 kg Cu/ha	500-1500	3		
16	PL	Gherkins	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7		
17	PL	Courgette	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7		
18	PL	Melon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b) 3,75 kg Cu/ha	500-1500	7		
19	PL	Pumpkins (in-door)	I	Pseudoperonospora cubensis *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	500-1500	7		
20	PL	Watermelon (indoor)	I	*Pseudoperonospora cubensis* *Alternaria spp Colleto-trichum orbiculare* *Bacterial diseases*	Spraying	BBCH 10-89	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	500-1500	7		
21	PL	French bean, beans with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum linde-muthianum,* *Botritis cinerea*	Spraying	BBCH 65-69	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600-800	7		

22	PL	Peas with pods	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum linde-muthianum, Botritis cinerea*	Spraying	BBCH 65-69	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600-800	7		
23	PL	Grape (table, wine)	Fpn	*Plasmopara viticola*	Spraying	BBCH 13-17, 71-73, 73-77	3	10-14	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	500-900	21		
24	PL	Currant	Fpn	*Drepanopeziza ribis, Mycosphaerella ribis* *Cronartium ribicola,*	Spraying	BBCH 59-65 BBCH 59 - 81	2	10	a)2.4 b)4.8	a)1,2kg Cu/ha b)2.4kg Cu/ha	700	7		

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.

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

Explanation for column 15 "Conclusion"

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

Table 8.1-2: Critical use pattern of MIEDZIAN 50 WP grouped according to intended uses

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

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.

8.2 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.

8.2.1 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)

8.2.1.1 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.

8.2.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No valid study.

8.3 Field studies (KCP 9.1.1.2)

8.3.1 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 8.3-1: 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 8.3-2: 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 8.3-3: 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~~
~~[1]Expressed as a percent of the 0-20 cm horizon result.~~

8.3.2 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 8.3-4: Soil accumulation and plateau concentration

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

~~No valid study.~~

8.4 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 8.4-5: 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				

8.4.1 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.

8.4.2 Lysimeter studies (KCP 9.1.2.2)

No valid study.

8.4.3 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.

8.5 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)

8.5.1 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 8.5-1: 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 sediment**	**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 8.5-2: 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 8.5-3: 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

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

8.6.1 Justification for new endpoints

8.6.2 Copper compound

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

Plant protection product	MIEDZIAN 50 WP
Use No.	1
Crop	Pome fruit (apple, pear)
Application rate (g/ha) /	4 x 1.5
Crop interception (%)	0 (worst case)
Number of applications/interval	4 / 7-10
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)

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

Plant protection product	MIEDZIAN 50 WP							
Use No.	1	2	3	4	5	6	7	8
Crop	Pome fruit	Stone fruit	Peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (g/ha) /	4 x 1.5	1 x 3.0	1 x 3.0	3 x 2.5	2 x 3.0	3 x 2.5	2 x 3.0	2 x 2.4
Crop interception (%)	0	0	0	0	0	0	0	0
Number of applications/interval	4 / 7-10	1 / -	1 / -	3 / 7-10	2 / 7	3 / 10-14	2 / 10-14	2 / 10
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)							

Table 8.6-3: Input parameter for active substance for 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

8.6.2.1 Copper compound

Calculations according to Article 43

Table 8.6-4: PEC_{soil} initial for copper compound on Orchards - pome fruits

PEC_{soil} (mg/kg) Application rate 4 x 0.75 kg/ha		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.0	1.0	4.0	4.0
Long term	100d	1.0	1.0	4.0	4.0
~~Plateau concentration after year 10~~		~~Not reached – Background level 39.95 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 79.81 mg/kg~~			

Calculations according to Article 51

Table 8.6-5: PEC_{soil} for copper compound on Orchards – pome fruits

PEC_{soil} (mg/kg) Application rate 4 x 0.75 kg/ha		Pome fruits			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.0	1.0	4.0	4.0
Long term	100d	1.0	1.0	4.0	4.0
~~Plateau concentration after year 10~~		~~Not reached – Background level 39.95~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 79.81~~			

Table 8.6-6: PEC_{soil} for copper compound on Orchards – stone fruit and peach

PEC_{soil} (mg/kg) Application rate 1.5 kg/ha		Stone fruits and peach	
		Single application	
		Actual	TWA
Initial		2.0	2.0
Long term	100d	2.0	2.0
~~Plateau concentration after year 10~~		~~Not reached – Background level 19.98 mg/kg~~	
~~Plateau concentration after year 20~~		~~Not reached – Background level 39.90 mg/kg~~	

Table 8.6-7: PEC$_{soil}$ for copper compound on fruiting vegetables and vine

PEC$_{soil}$ (mg/kg) Application rate 3 x 1.25 kg/ha		Fruiting vegetables and vine			
		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 8.6-8: PEC$_{soil}$ for copper compound on legumes and nuts

PEC$_{soil}$ (mg/kg) Application rate 2 x 1.5 kg/ha		Legumes and nuts			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		2.0	2.0	6.0	6.0
Long term	100d	2.0	2.0	6.0	6.0
~~Plateau concentration after year 10~~		~~Not reached – Background level 39.95 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 79.80 mg/kg~~			

Table 8.6-9: PEC$_{soil}$ for copper compound on currant

PEC$_{soil}$ (mg/kg) Application rate 2 x 1.2 kg/ha		Currant			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		1.6	1.6	3.2	3.2
Long term	100d	1.6	1.6	3.2	3.2
~~Plateau concentration after year 10~~		~~Not reached – Background level 31.96 mg/kg~~			
~~Plateau concentration after year 20~~		~~Not reached – Background level 63.84 mg/kg~~			

8.6.2.2 PEC$_{soil}$ of MIEDZIAN 50 WP

Table 8.6-10: PEC$_{soil}$ for MIEDZIAN 50 WP on fruiting vegetables and vine (worst case)

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 50 WP	3 x 2500	10.0	-	5	-

zRMS comments:
The PEC_S 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:

art.43

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 fruits	4 x 750	Not relevant	5	6	24	43.8	**71.8**
						58	**86**

^{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.

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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 fruits and peach	1 x 1500	Not relevant	5	6	12	43.8	**57.8**
						58	**72**
Fruiting vegetables and vine	3 x 1250	Not relevant	5	6	30	43.8	**48.8**
						58	**93**
Legumes and nuts	2 x 1500	Not relevant	5	6	36	7	**49**
						26	**68**
Currant	2 x 1200	Not relevant	5	6	19.2	7	**42.4**
						26	**48.4**

^{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.

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

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

8.7.1 Justification for new endpoints

8.7.2 Active substance (KCP 9.2.4.1)

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

Plant protection product	MIEDZIAN 50 WP
Use No.	1
Crop	Pome fruit (apple, pear)
Application rate (g/ha) /	4 x 1.5
Crop interception (%)	0 (worst case)
Number of applications/interval	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 8.7-2: Input parameters related to application for PEC_{gw} calculations, according to uses considering Article 51

Plant protection product	MIEDZIAN 50 WP							
Use No.	1	2	3	4	5	6	7	8
Crop	Pome fruit	Stone fruit	Peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (g/ha) /	4 x 1.5	1 x 3.0	1 x 3.0	3 x 2.5	2 x 3.0	3 x 2.5	2 x 3.0	2 x 2.4
Crop interception (%)	0	0	0	0	0	0	0	0
Number of applications/interval	4 / 7-10	1 / -	1 / -	3 / 7-10	2 / 7	3 / 10-14	2 / 10-14	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 8.7-3: PEC$_{gw}$ for copper on pome fruit (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	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

Calculations according to article 51

Table 8.7-4: 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.

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

8.8.1 Justification for new endpoints

Table 8.8-1: Input parameters related to application for PEC_{sw} calculations, according to uses considering Article 43

Plant protection product nvv	MIEDZIAN 50 WP
Use No.	1
Crop	Pome fruit (apple, pear)
Application rate (g/ha) /	4 x 1.5
Crop interception (%)	0 (worst case)
Number of applications/interval	4 / 7-10
Frequency of application	annual
Models used for calculation	FOCUS STEPS 1-2

Table 8.8-2: Input parameters related to application for PEC_{sw} calculations, according to uses considering Article 51

Plant protection product	MIEDZIAN 50 WP							
Use No.	1	2	3	4	5	6	7	8
Crop	Pome fruit	Stone fruit	Peach	Fruiting vegetables	Legumes	Vine	Nuts	Currant
Application rate (g/ha) /	4 x 1.5	1 x 3.0	1 x 3.0	3 x 2.5	2 x 3.0	3 x 2.5	2 x 3.0	2 x 2.4
Crop interception (%)	0	0	0	0	0	0	0	0
Number of applications/interval	4 / 7-10	1 / -	1 / -	3 / 7-10	2 / 7	3 / 10-14	2 / 10-14	2 / 10
Frequency of application	annual							
Models used for calculation	FOCUS STEPS 1-2							

8.8.1.1 Copper oxychloride and its metabolites

Table 8.8-3: Input parameters related to active substance copper for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	Copper	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	63.5	
Saturated vapour pressure (Pa)	0	N/Worst case
Water solubility (mg/L)	500	EFSA Journal 2018;16(1):5152
K_{foc} (mL/g)	33,918.3	EFSA Journal

Compound	Copper	Value in accordance to EU endpoint y/n/ Reference
		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

Table 8.8-4 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 compound	**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 8.8-5: Scheme of applications of MIEDZIAN 50 WP

Crop	Application of Cu [g/ha]	Application of Cu including factor of 3 [g/ha]
Pome fruits	4 x 750	4 x 250

Table 8.8-6: FOCUS Step 1,2 PEC_{sw} for copper following multiple applications of MIEDZIAN 50 WP 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	50m NSZ
Pome fruits	7.21	1.43	0.143	6.93	1.73	0.58	0.14

Crop	Sum of concentrations			
	VBZ 20 m + 10 m NSZ	VBZ 20 m + 20 NSZ	VBZ 20 m + 30 NSZ	VBZ 20 m + 50 NSZ
Pome fruits	7.073	1.873	0.723	**0.283**

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

Calculations according to Article 51

Table 8.8-7: 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 750	4 x 250
Stone fruits and peach	1 x 1500	1 x 500
Fruiting vegetables	3 x 1250	3 x 417
Legumes	2 x 1500	2 x 500
Vine	3 x 1250	3 x 417
Nuts	2 x 1500	2 x 500
Currant	2 x 1200	2 x 400

Table 8.8-8: 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	50m NSZ	60m NSZ	70m NSZ
Pome fruits	7.21	1.43	0.143	6.93	1.73	0.58	0.14	-	-
Stone fruits	3.61	0.72	0.072	18.98	4.34	1.66	0.49	0.32	0.22
Fruiting vegetables	9.02	1.79	0.179	0.27	0.14	0.094	0.057	-	-
Legumes	7.21	1.43	0.143	0.38	0.19	0.13	0.077	-	-
Vine	9.02	1.79	0.179	0.41	0.13	0.065	0.027	-	-
Nuts	7.21	1.43	0.143	15.4	3.99	1.37	0.35	0.22	-
Currant	5.77	1.15	0.115	0.3	0.15	0.1	0.06	-	-

Scenario	Sum of concentrations µg/L					
	VBZ 20 m + 10 m NSZ	VBZ 20 m + 20 NSZ	VBZ 20 m + 30 NSZ	VBZ 20 m + 50 NSZ	VBZ 20 m + 60 NSZ	VBZ 20 m + 70 NSZ
Pome fruits	7.073	1.873	0.723	**0.283**	-	-
Stone fruits	19.052	4.412	1.732	0.562	0.392	**0.292**
Fruiting vegetables	0.449	**0.319**	0.273	0.236	-	-
Legumes	0.523	**0.333**	0.273	0.22	-	-
Vine	0.589	**0.309**	0.244	0.206	-	-
Nuts	15.543	4.133	1.513	0.493	**0.363**	-
Currant	0.415	**0.265**	0.215	0.175	-	-

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

zRMS comments:

The 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 from drainage and runoff is in line with the EFSA conclusion (2018). Due to the fact that the PECsed calculation was not provided 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]	PECsed accumulation (7 years) [mg/kg]	PECsed accumulation (7 years) + background (17mg/kg) PEC_{sed} [mg/kg]
Re-authorization according Article 43, 1107/2009					
Pome fruit	4 x 1.5	4 x 0.750	Step1	9.47	26.470
			N-Europe Step 2	3.17	20.170
Minor uses according to Article 51, 1107/2009					
Pome fruit	4 x 1.5	4 x 0.750	Step1	9.47	26.470
			N-Europe Step 2	3.17	20.170
Stone fruit, peach	1 x 3.0	1 x 1.500	Step1	9.47	26.470
			N-Europe Step 2	3.17	20.170
Fruiting vegetables	3 x 2.5	3 x 1.250	Step1	9.47	26.420
			N-Europe Step 2	9.01	19.030
Legumes	2 x 3.0	2 x 1.500	Step1	7.53	24.530
			N-Europe Step 2	1.64	18.640
Vine	3 x 2.5	3 x 1.250	Step1	9.41	26.410
			N-Europe Step 2	3.05	20.050
Nuts	2 x 3.0	2 x 1.500	Step1	9.47	26.470
			N-Europe Step 2	3.32	20.320
Currant	2 x 2.4	2 x 1.200	Step1	6.02	23.020
			N-Europe Step 2	1.310	18.310

Additional PEC_{SW} calculations for greenhouse uses 11,13,15,18,19,20 (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
11	1250	0.1	0.417	0.139
13	1250		0.417	0.139
15	800		0.267	0.089
18	1250		0.417	0.139
19	1250		0.417	0.139
20	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).

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

Copper is not volatile at environmentally relevant temperatures and will therefore not be presented in air. Furthermore, copper cannot be transformed into related metabolites or degradation products and degradation processes likely to occur in air will have no action on copper.

zRMS comments:
Information on the fate and behaviour of copper hydroxide 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 50 WP 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	Disli, E.	2010	Batch and column experiments to support heavy metals (Cu,	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
9			Zn, and Mn) transport modeling in alluvial sediments between the Mogan Lake and the Eymir Lake, Goelbas, Ankara.		
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 Wenjiao/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 Mobility	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	-
KCP 9	Mohamad, Osama Abdalla; Hatab, Shaimaa Reda; Liu,	2012	Biosorption and Bioaccumulation of Cu2+ from Aqueous Solution Using Living M. amorphae Isolated from Mine Tailings	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
	Zhenshan; et al.				
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 agro-forestry catchment.	N	-
KCP 9	Ruello, Maria Letizia; Sani, Daniela; Sile-no, 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 gov-erning metal concentrations in a stream draining headwaters in NW Spain.	N	-
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, South-western 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 Ser-bia	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	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-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.	N	EUCuTF
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	-

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	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
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, G., & Matzner, E.	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
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	-
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., &	2010	Sorption and Selectivity Sequences of Cd, Cu, Ni, Pb, and Zn in Single- and Multi-Component Systems in a Cultivated Chilean Mollisol.	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
	Escudey, M.				
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	-
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.	N	EUCuTF

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			Not GLP, Unpublished.		
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, G., & Tack, F. M. G.	2009	Effect of Physicochemical Soil Characteristics on Copper and Lead Solubility in Polluted and Unpolluted Soils.	N	-
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., et. al.	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)