Appendix to:

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance copper compounds. EFSA Journal 2018;16(1):5152, 119 pp. doi:10.2903/j.efsa.2018.5152

Appendix A - List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Copper(I), copper(II) and variants (Not an ISO common name)
Function (*e.g.* fungicide)	Fungicide and bactericide
Rapporteur Member State	France
Co-rapporteur Member State	Germany

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Copper hydroxide

Chemical name (IUPAC)	copper(II) hydroxide or cupric hydroxide
Chemical name (CA)	copper hydroxide
CIPAC No	44.305
CAS No	20427-59-2
EC No (EINECS or ELINCS)	243-815-9
FAO Specification (including year of publication)	FAO specification AGP:CP/362 (1998)
Minimum purity of the active substance as manufactured	Expressed as total copper content Albaugh 609 g/kg Kocide 618 g/kg Cinkarna 616 g/kg Nufarm 609 g/kg IQV 625 g/kg Saldeco 584 g/kg Isagro 593 g/kg Spiess-Urania 583 g/kg

Total Cu content (min. % (w/w))	Max. heavy metals content (expressed in g/g Cu)		
	Lead	Cadmium	Arsenic
57.3	0.0005	0.0001	0.0001

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic max. 0.1 mg/g Cu Cadmium max. 0.1 mg/g Cu Lead max. 0.3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg
Molecular formula	CuH_2O_2
Molar mass	97.6 g/mol
Structural formula	$Cu(OH)_2$

Copper oxychloride

Chemical name (IUPAC)	dicopper(II) chloride trihydroxide
Chemical name (CA)	copper chloride hydroxide or copper chloride oxide hydrate
CIPAC No	44.602
CAS No	1332-65-6 or 1332-40-7
EC No (EINECS or ELINCS)	215-572-9 or 603-724-0
FAO Specification (including year of publication)	FAO specification AGP: CP/251 (1991) (44.2Oxch/TC/S, 1989)

Total Cu content (min. % (w/w))	Max. heavy metals content (expressed in g/g Cu)				Water (%)
	Lead	Cadmium	Arsenic	Water copper soluble	
55.0	0.0005	0.0001	0.0001	0.010	2.0

Minimum purity of the active substance as manufactured	Expressed as total copper content Albaugh 571 g/kg Montanwerke 569 g/kg Cinkarna 577 g/kg Prince Erachem 573 g/kg IQV 575 g/kg Saldeco 581 g/kg Isagro 570 g/kg Spiess-Urania 579 g/kg Manica 577 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic max. 0.1 mg/g Cu Cadmium max. 0.1 mg/g Cu Lead max. 0.3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg
Molecular formula	$[Cu_2H_3O_3Cl]_n$
Molar mass	213.6 n g/mol where n =1 or 2
Structural formula	$[Cu_2Cl(OH)_3]_n$

Bordeaux Mixture

Chemical name (IUPAC)	traditional mixture of copper(II) sulfate and calcium hydroxide
Chemical name (CA)	Bordeaux mixture
CIPAC No	44.604
CAS No	8011-63-0
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	No specification for Bordeaux mixture FAO specification for copper sulfate AGP:CP/251 (1991) (44.2s/TC/S, 1989)

Total Cu content (min. % (w/w))	Max. heavy metals content (expressed in g/g Cu)				
	Lead	Cadmium	Arsenic		
25.0	0.0005	0.0001	0.0001		

Minimum purity of the active substance as manufactured	Expressed as total copper content IQV 263 g/kg Saldeco 276 g/kg Isagro 263 g/kg UPL 257 g/kg Manica 270 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic max. 0.1 mg/g Cu Cadmium max. 0.1 mg/g Cu Lead max. 0.3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg
Molecular formula	$Ca_3Cu_4H_6O_{22}S_4.nH_2O$
Molar mass	860 + 18n g/mol where n = 1 to 6
Structural formula	$Cu_4(OH)_6SO_4.3CaSO_4.nH_2O$

Tribasic copper sulfate

Chemical name (IUPAC)	copper(II) hydroxide sulfate
Chemical name (CA)	tribasic copper sulfate
CIPAC No	44.306
CAS No	12527-76-3 or 1333-22-8
EC No (EINECS or ELINCS)	215-582-3
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured	Expressed as total copper content Albaugh 518 g/kg Nufarm 543 g/kg (dry weight) Cinkarna 540 g/kg UPL 490 g/kg

	Manica 530 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic max. 0.1 mg/g Cu Cadmium max. 0.1 mg/g Cu Lead max. 0.3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg
Molecular formula	$Cu_4H_6O_{10}S.nH_2O$
Molar mass	452.3 + 18n g/mol where n = 0 or 0.5
Structural formula	$Cu_4(OH)_6SO_4.\ nH_2O$

Copper (I) oxide

Chemical name (IUPAC)	copper(I) oxide or cuprous oxide
Chemical name (CA)	Cuprous oxide
CIPAC No	44.603
CAS No	1317-39-1
EC No (EINECS or ELINCS)	215-270-7
FAO Specification (including year of publication)	FAO specification AGP:CP/251 (1991) (44.lox/TC/S, 1989)

Total Cu min % (w/w)	Max. heavy metals content (expressed in g/g Cu)					CuO (%)	Water (%)
	Pb	Cd	As	Water copper soluble	Metallic copper		
82.0	0.0005	0.0001	0.0001	0.025	0.05	0.10	1.5

Minimum purity of the active substance as manufactured	Expressed as total copper content 858 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic max. 0.1 mg/g Cu Cadmium max. 0.1 mg/g Cu Lead max. 0.3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg
Molecular formula	Cu_2O
Molar mass	143.14 g/mol
Structural formula	Cu_2O

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	Copper hydroxide	Decomposes before melting (60.1% Cu)
	Copper oxychloride	Decomposes before melting (57.39% Cu)
	Bordeaux mixture	Greater than 400 °C (not measured above) (26.70% Cu)
	Tribasic copper sulfate	Greater than 360 °C (not measured above) (54.2% Cu)
	Copper(I) oxide	Greater than 400 °C (not measured above) (97%)
Boiling point (state purity)	Copper hydroxide	Decomposes before boiling (60.1% Cu)
	Copper oxychloride	Decomposes before boiling (57.39% Cu)
	Bordeaux mixture	Greater than 400 °C (not measured above) (26.70% Cu)
	Tribasic copper sulfate	Greater than 360 °C (not measured above) (54.2%)
	Copperm (I) oxide	Greater than 400 °C (not measured above) (97%)
Temperature of decomposition (state purity)	Copper hydroxide	Decomposes at 229 °C (60.1% Cu)
	Copper oxychloride	Decomposes from approximatively 240 °C (57.39% Cu)
	Bordeaux mixture	Greater than 400 °C (not measured above) (26.70% Cu)
	Tribasic copper sulfate	Greater than 360 °C (not measured above) (54.2% Cu)
	Copper(I) oxide	Sometimes an exothermic event occurred, corresponding to the oxidation from copper (I) to copper (II), at least at 332°C
Appearance (state purity)	Copper hydroxide	Blue powder (60.1% Cu)
	Copper oxychloride	Light green, very fine, non-free flowing powder (57.39% Cu)
	Bordeaux mixture	Light green, very fine, not free-flowing powder (26.70% Cu)
	Tribasic copper sulfate	Lumpy blueish-green powder (54.2% Cu)
	Copper(I) oxide	Opaque, orange, fine and easily compactable powder (97%)

Vapour pressure (state temperature, state purity)	Not applicable as expected to be negligible (all copper variants)
Henry's law constant (state temperature)	Not applicable as expected to be negligible (all copper variants)

Solubility in water (state temperature, state purity and pH)

Copper hydroxide	At 20 °C (60.1% Cu) 0.506 mg/L at pH 6.4-6.6 39.8 g/L at pH 4-6 0.25 mg/L at pH 10
Copper oxychloride	At 20 °C (57.39% Cu) 1.19 mg/L at pH 6.5-6.6 101 g/L at pH 3.1 0.525 mg/L at pH 10.1
Bordeaux mixture	At 20°C (26.70% Cu) 2.20*10-3 g/L at pH 6.8 129 g/L at pH 2.9 1.10*10-3 g/L at pH 9.8
Tribasic copper sulfate	At 20 °C (54.2% Cu) < 3.42*10-3 g/L at neutral pH 0.5 g/L at pH 4-6 < 2.55*10-4 g/L at pH 10.1
Copper(I) oxide	At 20°C (Purity: 97%) 6.39*10-4 g/L at pH 6.8 28.6 g/L at pH 2.9 5.39*10-4 g/L at pH 9.8

Solubility in organic solvents (state temperature, state purity)

Copper oxychloride

Organic solvent	Solubility at 20°C (g/L) (Purity: 57.39% Cu)
toluene	<1.1*10-2
dichloromethane	<1.0*10-2
hexane	<9.8*10-3
ethyl acetate	<1.1*10-2
methanol	<8.2*10-3
acetone	<8.4*10-3

Copper hydroxide

Organic solvent	Solubility at 30°C (copper concentration ppb) (Purity: 60.1% Cu)
heptane	7.01
xylene	15.7
1,2-dichloroethane	61.0
isopropyl alcohol	1.64
acetone	5.0
ethyl acetate	2.57

Tribasic copper sulfate

Organic solvent	Solubility at 20°C (g/L) (Purity: 54.2% Cu)
heptane	<0.1
p-xylene	<0.1
1,2-dichloroethane	<0.1
1-octanol	<0.1
acetone	<0.1
ethyl-acetate	<0.1

Bordeaux mixture

Organic solvent	Solubility at 20°C (g/L) (Purity: 26.70% Cu)
toluene	<9.6*10-3
dichloromethane	<8.8*10-3
hexane	<9.8*10-3
ethyl acetate	<8.4*10-3
methanol	<9.0*10-3
acetone	<8.8*10-3

Copper (I) oxide

Organic solvent	Solubility at 20°C (g/L) (Purity: 97%)
toluene	<1.4*10-2
dichloromethane	<1*10-2
hexane	<1.2*10-2
ethyl acetate	<1.2*10-2
methanol	<9.8*10-3
acetone	<1.3*10-2

Surface tension
(state concentration and temperature, state purity)

Copper hydroxide	Not applicable (solubility is too low)
Copper oxychloride	72.2 mN/m (1.10*10-3 g/L, 20°C, 57.39% Cu)
Bordeaux mixture	68.9 mN/m (1.43*10-3 g/L, 20°C, 26.7% Cu)
Tribasic copper sulfate	72.2 mN/m (2.90*10-3 g/L, 20°C, 54.2% Cu)
Copper(I) oxide	Not applicable (solubility is too low)

Partition coefficient
(state temperature, pH and purity)

Not applicable for all copper variants. Calculated to be 2.78 as the ratio between solubility in n-octanol over solubility in water for coppper hydroxide.

Dissociation constant (state purity)

Not appropriate

UV/VIS absorption (max.) incl. ε
(state purity, pH)

Copper oxychloride

λmax	ε molar absorption coefficient (L/mol/cm)		
(purity: 57.9% Cu)	Neutral (pH ≈6)	Acid (pH <2)	Basic (pH >10)
205	Not applicable	2850	Not applicable
250	Not applicable	1461	Not applicable
800	Not applicable	38	Not applicable
290	Not applicable	260	Not applicable
295	Not applicable	195	Not applicable

Copper hydroxide

λmax (purity: 60.1% Cu)	ε molar absorption coefficient (L/mol/cm)		
	Neutral (pH ≈6)	Acid (pH <2)	Basic (pH >10)
205	Not applicable	3605	Not applicable
250	Not applicable	185	Not applicable
800	Not applicable	13	Not applicable
290	Not applicable	32	Not applicable
295	Not applicable	24	Not applicable

Tribasic copper sulfate

Due to low solubility at basic and neutral pH, spectrum is obtained in acidic solutions only (pH @20°C =1.92-1.95).

Two absorbance maxima:

-798 nm; ε = 47.8 $L.mol^{-1}.cm^{-1}$

-<200 nm; ε = 7093 $L.mol^{-1}.cm^{-1}$

In fact, tribasic copper sulfate is not stable in acidic solution. The spectrum obtained is the spectrum of copper sulfate.

Bordeaux mixture

λmax (purity: 26.7 % Cu)	ε molar absorption coefficient (L/mol/cm)		
	Neutral (pH ≈6)	Acid (pH <2)	Basic (pH >10)
205	Not applicable	5923	Not applicable
250	Not applicable	3119	Not applicable
800	Not applicable	70	Not applicable
290	Not applicable	520	Not applicable
295	Not applicable	398	Not applicable

Copper(I) oxide

λmax (Purity: >99%)	ε molar absorption coefficient (L/mol/cm)		
	Neutral (pH ≈6)	Acid (pH <2)	Basic (pH >10)
205	Not applicable	2978	Not applicable
250	Not applicable	1425	Not applicable
800	Not applicable	40	Not applicable
290*	Not applicable	265	Not applicable
295*	Not applicable	198	Not applicable

Flammability (state purity)	Theoretical assessment for copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, and Bordeaux mixture. Not highly flammable
Explosive properties (state purity)	Theoretical assessment for copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, and Bordeaux mixture Not explosive

Oxidising properties (state purity)	Theoretical assessment for copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, and Bordeaux mixture Not oxidising

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State	Product Name	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Grape	C/S	Funguran-OH	F	*Bacterial necrosis Elsinoë ampelina*	WP	500	Airblast sprayer	BBCH 91 - 11	a) 3 b) 3	21 days	n.a.	400-1000	a) 1.25 b) 3.75	90	
Grape	C/S	Funguran-OH	F	*Plasmopara viticola, Elsinoë ampelina*	WP	500	Airblast sprayer Knapsack Sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100-1200	a) 1.25 b) 6.0	21	Annual application must not exceed 5 kg/ha during the bird breeding season
Tomato	C/S	Funguran-OH	F	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WP	500	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200-1000	a) 0.85 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season RMS remarks: No Northern trials were available.
Tomato	C/S	Funguran-OH	G	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WP	500	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200–1000	a) 1.25 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season
Cucurbits	C/S	Funguran-OH	F	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WP	500	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 0.85 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Cucurbits	C/S	Funguran-OH	G	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WP	500	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 1.25 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Grape	C/S	Funguran-OH	F	*Plasmopara viticola,*	WP	500	Airblast sprayer	BBCH 12 - 89	a) 8	7 days	n.a.	100–1200	a) 1.25	21	Flexible dosing regimen Total applied must not

				Elsinoë ampelina					b) 8				b) See Column Remarks		exceed 30 kg/ha in any rolling 5 year period and 8 kg/ha/yr in any single year. Annual application must not exceed 5 kg/ha during the bird breeding season

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Grape	C/S	Curenox 50	F	*Bacterial necrosis Elsinoë ampelina*	WG	500	Airblast sprayer	BBCH 91 - 11	a) 3 b) 3	21 days	n.a.	400-1000	a) 1.25 b) 3.75	90	
Grape	C/S	Curenox 50	F	*Plasmopara viticola, Elsinoë ampelina*	WG	500	Airblast sprayer Knapsack Sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100-1200	a) 1.25 b) 6.0	21	Annual application must not exceed 5 kg/ha during the bird breeding season
Tomato	C/S	Curenox 50	F	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	500	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200-1000	a) 0.85 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season RMS remarks: No Northern trials were available.
Tomato	C/S	Curenox 50	G	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	500	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200–1000	a) 1.25 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season
Cucurbits	C/S	Curenox 50	F	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	500	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 0.85 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Cucurbits	C/S	Curenox 50	G	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	500	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 1.25 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Grape	C/S	Curenox 50	F	*Plasmopara viticola, Elsinoë ampelina*	WG	500	Airblast sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100–1200	a) 1.25 b) See Column Remarks	21	Flexible dosing regimen Total applied must not exceed 30 kg/ha in any rolling 5 year period and 8 kg/ha/yr in any single year.

															Annual application must not exceed 5 kg/ha during the bird breeding season

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Crop and/or situation (a)	Member State	Product Name	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Grape	C/S	Poltiglia Caffaro 20 DF New	F	*Bacterial necrosis Elsinoë ampelina*	WG	200	Airblast sprayer	BBCH 91 - 11	a) 3 b) 3	21 days	n.a.	400-1000	a) 1.25 b) 3.75	90	
Grape	C/S	Poltiglia Caffaro 20 DF New	F	*Plasmopara viticola, Elsinoë ampelina*	WG	200	Airblast sprayer Knapsack Sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100-1200	a) 1.25 b) 6.0	21	Annual application must not exceed 5 kg/ha during the bird breeding season
Tomato	C/S	Poltiglia Caffaro 20 DF New	F	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	200	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200-1000	a) 0.85 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season RMS remarks: No Northern trials were available.
Tomato	C/S	Poltiglia Caffaro 20 DF New	G	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	200	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200–1000	a) 1.25 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season
Cucurbits	C/S	Poltiglia Caffaro 20 DF New	F	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	200	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 0.85 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Cucurbits	C/S	Poltiglia Caffaro 20 DF New	G	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	200	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 1.25 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Grape	C/S	Poltiglia Caffaro 20 DF New	F	*Plasmopara viticola, Elsinoë ampelina*	WG	200	Airblast sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100–1200	a) 1.25 b) See Column Remarks	21	Flexible dosing regimen Total applied must not exceed 30 kg/ha in any rolling 5 year period and 8 kg/ha/yr in any single year.

															Annual application must not exceed 5 kg/ha during the bird breeding season

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Grape	C/S	Cuproxat SC	F	*Bacterial necrosis Elsinoë ampelina*	SC	190	Airblast sprayer	BBCH 91 - 11	a) 3 b) 3	21 days	n.a.	400-1000	a) 1.25 b) 3.75	90	
Grape	C/S	Cuproxat SC	F	*Plasmopara viticola, Elsinoë ampelina*	SC	190	Airblast sprayer Knapsack Sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100-1200	a) 1.25 b) 6.0	21	Annual application must not exceed 5 kg/ha during the bird breeding season
Tomato	C/S	Cuproxat SC	F	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	SC	190	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200-1000	a) 0.85 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season RMS remarks: No Northern trials were available.
Tomato	C/S	Cuproxat SC	G	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	SC	190	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200–1000	a) 1.25 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season
Cucurbits	C/S	Cuproxat SC	F	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	SC	190	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 0.85 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Cucurbits	C/S	Cuproxat SC	G	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	SC	190	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 1.25 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Grape	C/S	Cuproxat SC	F	*Plasmopara viticola, Elsinoë ampelina*	SC	190	Airblast sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100–1200	a) 1.25 b) See Column Remarks	21	Flexible dosing regimen Total applied must not exceed 30 kg/ha in any rolling 5 year period and 8 kg/ha/yr in any single

															year. Annual application must not exceed 5 kg/ha during the bird breeding season

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Grape	C/S	Nordox 75	F	*Bacterial necrosis Elsinoë ampelina*	WG	750	Airblast sprayer	BBCH 91 - 11	a) 3 b) 3	21 days	n.a.	400-1000	a) 1.25 b) 3.75	90	
Grape	C/S	Nordox 75	F	*Plasmopara viticola, Elsinoë ampelina*	WG	750	Airblast sprayer Knapsack Sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100-1200	a) 1.25 b) 6.0	21	Annual application must not exceed 5 kg/ha during the bird breeding season
Tomato	C/S	Nordox 75	F	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	750	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200-1000	a) 0.85 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season RMS remarks: No Northern trials were available.
Tomato	C/S	Nordox 75	G	*Phytophthora spp Alternaria, Colletotrichum, Pseudomonas, Xanthomonas*	WG	750	Foliar spray	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	200–1000	a) 1.25 b) 6.0	3	Annual application must not exceed 5 kg/ha during the bird breeding season
Cucurbits	C/S	Nordox 75	F	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	750	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 0.85 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Cucurbits	C/S	Nordox 75	G	*Peronospora cubensis; Alternaria spp Colletotrichum spp Bacterial diseases*	WG	750	Foliar spray	BBCH 10 - 89	a) 8 b) 8	7 days	n.a.	200–1500	a) 1.25 b) 6.0	See Column Remarks	Annual application must not exceed 5 kg/ha during the bird breeding season PHI: 3 d (Cucumber, zucchini), 7 d (Melon, watermelon
Grape	C/S	Nordox 75	F	*Plasmopara viticola, Elsinoë ampelina*	WG	750	Airblast sprayer	BBCH 12 - 89	a) 8 b) 8	7 days	n.a.	100–1200	a) 1.25 b) See Column Remarks	21	Flexible dosing regimen Total applied must not exceed 30 kg/ha in any rolling 5 year period and 8 kg/ha/yr in any single

															year. Annual application must not exceed 5 kg/ha during the bird breeding season

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
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(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
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(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Not applicable															

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Copper based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

Copper based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Copper based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism	Not required

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Electrolysis method (CIPAC 44/TC/M3.1) Titration method (CIPAC 44/TC/M3.2)
Impurities in technical a.s. (analytical technique)	Heavy metals: ICP/MS or ICP-OES Soluble copper in water: CIPAC MT 98.2 Water: CIPAC MT 17.4
Plant protection product (analytical technique)	CIPAC method 44/WP/M CIPAC method 44/DP/M Titration method (CIPAC 44/TC/M3.2) complexometric titration with sodium EDTA

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Total copper
Food of animal origin		Total copper
Soil		Total copper
Sediment		Total copper
Water	surface	Dissolved copper
	drinking/ground	Dissolved copper
Air		Total copper
Body fluids and tissues		Total copper

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	AAS method validated for total copper with LOQ = 0.2 mg/kg in plants with high water and high acid content. A method is required for plants with high oil content and dry crops. ILV for plants: open point
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	not needed for the representative uses
Soil (analytical technique and LOQ)	ICP-AES validated for total copper with LOQ = 5 mg/kg in soil
Water (analytical technique and LOQ)	ICP-MS validated for dissolved copper with LOQ = 0.3 µg/L in surface/drinking water. ILV in drinking water: open point ~~required~~. A method is required with LOQ ≤ 0.1 µg/L in groundwater.

Air (analytical technique and LOQ)	ICP-OES: LOQ = 0.3 ng/m^3 GF-AAS A new validation in air is on-going.
Body fluids and tissues (analytical technique and LOQ)	ICP-AES validated for total copper with LOQ = 3.0 mg/kg in plasma, LOQ = 359 mg/kg in liver

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Copper
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	Not explosive, not oxidizing, not flammable
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	Not explosive, not oxidizing, not flammable

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	50 % copper oral absorption from a mixed diet in human[3] (based on faecal excretion considering endogenous losses of copper) Similar absorption in rats
Toxicokinetics	Cmax = 10.2 ±1.0 µg Cu/g liver Tmax = 12 hours (liver)
Distribution	Widely distributed, the liver being the regulation organ. Copper is bound to ceruloplasmin.
Potential for bioaccumulation	No potential for accumulation, except in cases of genetic disease or chronic administration of high dose (60 mg/person per day), where copper accumulates in the liver
Rate and extent of excretion	Rapidly excreted (> 90%) within 48 hours. Terminal half/life in rat of 10.1 hours. Excretion via the bile. No entero-hepatic circulation occurs. Excretion mainly bound to metallothioneins of the intestinal brush border and lost in faeces. Minor amounts in urine and from skin and hair.
Metabolism in animals	Does not occur; copper is a monoatomic ion and cannot be metabolized
In vitro metabolism	Not required as no metabolism occurs
Toxicologically relevant compounds (animals and plants)	Copper
Toxicologically relevant compounds (environment)	Copper

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	Copper hydroxide:	489 mg/kg bw	**H302**
	Copper oxychloride:	299 mg/kg bw	**H301**
	Bordeaux Mixture:	>2000 mg/kg bw	
	Tribasic copper sulphate:	300-500 mg/kg bw	**H302**
	Copper (I) oxide:	300-500 mg/kg bw	**H302**
Rat LD_{50} dermal	Copper hydroxide:	>2000 mg/kg bw	
	Copper oxychloride:	>2000 mg/kg bw	
	Bordeaux Mixture:	>2000 mg/kg bw	
	Tribasic copper sulphate:	>2000 mg/kg bw	
	Copper (I) oxide:	>2000 mg/kg bw	
Rat LC_{50} inhalation	Copper hydroxide:	0.45 mg/L air (WB)	**H330**

[3] based on DRAFT SCIENTIFIC OPINION on Dietary Reference Values for copper; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), July 2015

(per 4 h) *(WB = whole body, NO = nose only)*	Copper oxychloride: Bordeaux Mixture: Tribasic copper sulphate: Copper (I) oxide:	2.83 mg/L air (NO) 1.97 mg/L air (WB) Not feasible 2.92 mg/L air (NO)	**H332** **H332** **H332**
Skin irritation	Copper hydroxide: Copper oxychloride: Bordeaux Mixture: Tribasic copper sulphate: Copper (I) oxide:	Not irritating Not irritating Not irritating Not irritating Not irritating	
Eye irritation	Copper hydroxide: Copper oxychloride: Bordeaux Mixture: Tribasic copper sulphate: Copper (I) oxide:	Irritating Cat. 1 Not irritating Irritating Cat. 1 Not irritating Irritating Cat. 1	**H318** **H318** **H318**
Skin sensitisation *(M = M&K)*	Copper hydroxide: Copper oxychloride: Bordeaux Mixture: Tribasic copper sulphate: Copper (I) oxide:	Not sensitising (M) Not sensitising (M) Not sensitising (M) Not sensitising (M) Not sensitising (M)	
Phototoxicity	Not required		

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Copper sulphate: Rat: liver (inflammation), kidney (protein droplets in tubule epithelial cells), stomach (hyperplasia/hyperkeratosis of limiting ridge), some haematological changes Mouse: stomach (hyperplasia/hyperkeratosis of limiting ridge) Dog: increase in copper level in the kidney, liver and spleen, and elevated levels of serum GPT (ALT)	
Relevant oral NOAEL	90-day rat: 16 mg/kg bw per day 90-day mouse: 97 mg/kg bw per day 1-year dog: 15 mg/kg bw per day (test substance: copper gluconate)	
Relevant dermal NOAEL	28-day, rabbit: 500 mg/kg bw per day	
Relevant inhalation NOAEL	28-day, rat: 2 mg/m^3 (systemic NOAEC – highest concentration tested) 0.2 mg/m^3 (local NOAEC) based on a pattern of responses observed in the lung and lung-draining lymph nodes typical from inhalation of poorly soluble aerosol particles: histiocytosis, perivascular mononuclear cell infiltrates and acute inflammation of the lungs, and lymphoid hyperplasia (test	

	substance: cuprous oxide)	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	Copper sulphate: Negative (Ames) Copper oxychloride: Negative (Ames) Bordeaux Mixture: Negative (Ames) Copper oxide: Negative (Ames)	
In vivo studies	Enteral administration: Copper sulphate: Negative (UDS, bone marrow MN tests) Parenteral administration (e.g. IP): Copper sulphate: Equivocal results (Bone marrow CA and MN assays)	
Photomutagenicity	Not required	
Potential for genotoxicity	Copper compounds are unlikely to be genotoxic in normal, correct use. Possibility of oxidative damage to DNA only if the robust homeostatic mechanisms are overwhelmed	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: liver (hypertrophied hyperchromatic parenchymal cells, necrosis and marked inflammatory reaction), kidneys (changes on the proximal convoluted tubule)	
Relevant long-term NOAEL	2-year, rat: 27 mg/kg bw per day (administered as potassium sodium copper chlorophyllin). Study suffering of insufficiencies. Mouse study not available but not required	
Carcinogenicity (target organ, tumour type)	No carcinogenic potential in rats. No evidence of carcinogenic potential in humans after oral ingestion.	
Relevant NOAEL for carcinogenicity	Adequate NOAEL/LOAEL not derived Weight of evidence indicates no carcinogenic hazard at realistic levels of exposure	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Rats (copper sulphate): Parental toxicity: Slightly reduced spleen weight with no histopathological correlate Reproductive toxicity: No adverse effect in 2-generation study	

	Offspring toxicity: Slightly reduced spleen weight with no histopathological correlate	
Relevant parental NOAEL	15 mg/kg bw per day	
Relevant reproductive NOAEL	24 mg/kg bw per day	
Relevant offspring NOAEL	15 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Mouse (copper sulphate): Maternal toxicity: No data given Developmental toxicity: Decreased foetal weight, increased foetal mortality and incidence of abnormalities Rabbit (copper hydroxide): Maternal toxicity: Inappetance, initial body weight loss and lower mean weight gain (31-72%), gastrointestinal disturbance Developmental toxicity: Increased incidence of supernumerary ribs	
Relevant maternal NOAEL	Mouse: Not determined Rabbit: 6 mg Cu/kg per day*	
Relevant developmental NOAEL	Mouse: 100 mg Cu/kg per day Rabbit: 6 mg Cu/kg per day*	

* Note: it must be considered that the received dose cannot be adequately quantified, owing to the refection (coprophagy) in rabbits and results in a second enteral exposure to that proportion of the administered copper that is excreted in faeces.

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No data available	
Repeated neurotoxicity	A study in rat showed a reduction of exploratory activity after 90-day gavage administration of 25 mg Cu/kg bw per day as copper sulphate. A study in rats showed pro-oxidative effects in plasma and brain, modified brain lipids, increases in markers of programmed cell death in brain after a 30-day dietary administration of low level of copper.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Delayed neurotoxicity assessment not required	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Immunotoxicity: no evidence of immunotoxicity of copper at realistic levels of exposure. Humans (dietary, 5 months): minor changes in immune function (reduced IL2R, increased IL6, reduced response to influenza vaccine) at 7- 8 mg Cu per day. NOAEL not investigated Mice (drinking water, 3-10 weeks): copper can cause an inhibition of the immune response probably through an indirect mechanism involving zinc deficiency caused by excess copper. Alzheimer's disease (AD): a possible causative link between disturbed copper homeostasis and AD pathology in humans remains unclear. Animal studies suggest that low level of copper in drinking water associated with a high-fat diet might disrupt amyloid-β homeostasis in the brain, with consequent relevance to AD Clinical trial in patients with mild AD: copper supplementation of 8 mg Cu daily for 12 months does not induce changes in cognitive abilities or any enhancement of the progression of AD. Neurotoxicity: A mechanistic study using fish DNA has demonstrated a possible pathway by which oxidative damage to neurons might be caused, with catecholamines being oxidized to reactive oxygen species (ROS) in the presence of transition metals, including copper. Allergy to copper: Humans (patch testing): NOAEL 5% Cu in petrolatum. LOAEL not established
	No published evidence for ED potential. Evidence *in vitro* that copper is not estrogenic and that its presence in water between 10^{-4} and 10^{-7} M can mitigate the oestrogenic potential of some EDCs
Studies performed on metabolites or impurities	Metabolites not relevant; no studies performed

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

The evidence shows that European diets contain copper at between 1 and 2 mg Cu/person per day. Copper has been used as a plant protection product for over 100 years. Data on humans show that repeated long-term intakes greater than 30 mg/day are toxic, intakes between 10 and 30 mg/day are without ill-effect, and that intakes of up to 10 mg/day do not even challenge the homeostatic mechanisms.

From more than 30 years of use the few adverse effects observed were clearly related to well known potential for slight to severe eye irritation.

In case of physiological (genetic) dysfunction in human, two diseases could occur in man namely Wilson's disease, and Menkes' disease which are well documented in the medical literature. For both diseases the copper accumulation causes different effects including neurological ones (e.g. degeneration basal ganglia, mental retardation, seizures)

WHO 1996: proposal of upper limits to the safe range of population mean intakes:

For Adults: 10-12 mg Cu/day corresponding to 0.2 mg Cu/kg bw per day

For Children: 0.15 mg Cu/kg bw per day

Summary[4] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg Cu/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.15	based on human data (WHO value of 0.15 mg Cu/kg bw/day for children)	No SF for human data
Acute Reference Dose (ARfD)	Not allocated – not necessary		
Acceptable Operator Exposure Level (AOEL)	0.08	based on human data (WHO value of 0.15 mg Cu/kg bw/day for children)	No SF for human data *
Acute Acceptable Operator Exposure Level (AAOEL)	Not allocated – not necessary		

* Including correction for limited oral absorption/bioavailability (50%).

Previously agreed reference values approved for the first inclusion:
ADI: same value
AOEL: 0.072 mg/kg bw/d (based on WHO value 0.2 mg Cu/kg bw/d for adults supported by 1-year dog study and 90-day rat studies) corrected by 36% oral absorption and applying an UF of 100.
ARfD: not necessary

[4] If available include also reference values for metabolites

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulations: Five copper forms: hydroxide copper, oxychloride copper, Bordeaux mixture and copper (I) oxide, tribasic copper sulphate as WP, WG or SC formulations.	Concentrate: 1 % Spray dilution (0.33g Cu/L): 9% Based on *in vitro* through human skin studies performed with representative formulations.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

NORDOX 75 WG

Operators

Use: tomato, cucurbit (outdoor), tractor mounted equipment, application rate 0,85 kg a.s./ha	
Exposure estimates (model):	% of AOEL
UK POEM	
Without PPE:	419
PPE (gloves):	89
German model	
Without PPE:	64
EFSA model:	
Coverall	20
Use: grapes, broadcast air-assisted equipment, application rate 1,25 kg a.s./ha	
Exposure estimates (model):	% of AOEL
UK POEM	
Without PPE:	1811
PPE (gloves):	1155
German model	
Without PPE:	194
PPE (gloves and coverall):	31
EFSA model:	
Coverall	83
Use: tomato, cucurbits (indoor), handheld equipment, application rate 1.25 kg a.s./ha	
Exposure estimates (model):	% of AOEL
German model:	
Without PPE:	93
PPE (gloves):	19
ECPA greenhouse model	
Without PPE:	102
PPE (gloves and coverall):	51
EFSA model:	
Coverall	31

Workers	Use: grapes (1.25 kg Cu/ha, refined DT_{50} (7 days)) Exposure estimates — % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1130 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 624 **EFSA model** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1125 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 650
	Use: tomato, cucurbits (1.25 kg as/ha, indoor, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65 **EFSA model:** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65
Bystanders and residents	Use: grapes (worst case scenario):1.25 kg Cu/ha, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II :** Bystander (*adults*) 9.7 **Martin *et al.* (2008):** Bystander *Adults* 8.5 *Child* 6.7 Resident *(worst case: 8 applications, 7 days interval)* *Adults* 1.6 *Child* 3.2 **EFSA model:** *Bystander* *not necessary* Resident (sum) : *8 applications, 7 days interval* *Child* 171 *Adult* 93 *3 applications, 21 days interval* *Child* 154 *Adult* 84

Use: tomato, cucurbits (0.85 kg as/ha,outdoor, refined DT_{50} of 7 days)	
EFSA model:	
Bystander	*not necessary*
Resident (sum)	
8 applications, 7 days interval	
Child	33
Adult	16

FUNGURAN OH

Operators

Use: tomato, curcubit (outdoor), tractor mounted equipment, application rate 0.85 kg a.s./ha	
Exposure estimates (model):	% of AOEL
UK POEM	
Without PPE:	642
PPE (gloves):	244
German model	
Without PPE:	95
PPE (gloves):	67
EFSA model:	
Coverall	248
Coverall + Gloves	149
Coverall + gloves + RPE (mask M/L)	45

Use: grapes, broadcast air-assisted equipment, application rate 1,25 kg a.s./ha	
Exposure estimates (model):	% of AOEL
UK POEM	
Without PPE:	1900
PPE (gloves):	1221
German model	
Without PPE:	211
PPE (gloves and coverall):	43
EFSA model:	
Coverall	213
Gloves + Coverall	135
Coverall + gloves + RPE (mask M/L)	63

	Use: tomato, curcubits (indoor), handheld equipment, application rate 1.25 kg a.s./ha Exposure estimates (model): % of AOEL German model: Without PPE: 117 PPE (gloves): 85 ECPA greenhouse model Without PPE: 114 PPE (gloves and coverall): 56 EFSA model: Coverall 120 Coverall + gloves 84
Workers	Use: grapes (1.25 kg Cu/ha, refined DT_{50} (7 days)) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1130 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 624 **EFSA model** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1125 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 650
	Use: tomato, cucurbits (1.25 kg as/ha, indoor, refined DT_{50} of 7 days) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65 **EFSA model:** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65

Bystanders and residents	Use: grapes (worst case scenario):1.25 kg Cu/ha, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II :** Bystander (*adults*) — 9.7 **Martin *et al.* (2008):** Bystander *Adults* — 8.5 *Child* — 6.7 Resident *(worst case: 8 applications, 7 days interval)* *Adults* — 1.6 *Child* — 3.2 **EFSA model:** *Bystander* — *not necessary* Resident (sum) : *8 applications, 7 days interval* *Child* — 171 *Adult* — 93 *3 applications, 21 days interval* *Child* — 154 *Adult* — 84
	Use: tomato, cucurbits (0.85 kg as/ha,outdoor, refined DT_{50} of 7 days) **EFSA model:** *Bystander* — *not necessary* Resident (sum) *8 applications, 7 days interval* *Child* — 33 *Adult* — 16

POLTIGLIA CAFFARO 20DF

Operators	Use: tomato, curcubit (outdoor), tractor mounted equipment, application rate 0,85 kg a.s./ha Exposure estimates (model): — % of AOEL UK POEM Without PPE: — 419 PPE (gloves): — 89 German model Without PPE: — 64.5 EFSA model: Coverall — 20

	Use: grapes, broadcast air-assisted equipment, application rate 1,25 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 1811 PPE (gloves): 1155 German model Without PPE: 194 PPE (gloves and coverall): 31 EFSA model: Coverall 83
	Use: tomato, curcubits (indoor), handheld equipment, application rate 1.25 kg a.s./ha Exposure estimates (model): % of AOEL German model: Without PPE: 93 PPE (gloves): 19.5 ECPA greenhouse model Without PPE: 102 PPE (gloves and coverall): 51 EFSA model: Coverall 31
Workers	Use: grapes (1.25 kg Cu/ha, refined DT_{50} (7 days)) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1130 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 624 **EFSA model** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1125 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 650
	Use: tomato, cucurbits (1.25 kg as/ha, indoor, refined DT_{50} of 7 days) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65 **EFSA model:** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65

Bystanders and residents	Use: grapes (worst case scenario):1.25 kg Cu/ha, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II :** Bystander (*adults*) — 9.7 **Martin *et al.* (2008):** Bystander *Adults* — 8.5 *Child* — 6.7 Resident *(worst case: 8 applications, 7 days interval)* *Adults* — 1.6 *Child* — 3.2 **EFSA model:** *Bystander* — *not necessary* Resident (sum) : *8 applications, 7 days interval* *Child* — 171 *Adult* — 93 *3 applications, 21 days interval* *Child* — 154 *Adult* — 84
	Use: tomato, cucurbits (0.85 kg as/ha,outdoor, refined DT_{50} of 7 days) EFSA model: *Bystander* — *not necessary* Resident (sum) *8 applications, 7 days interval* *Child* — 33 *Adult* — 16

CUPROXAT SC

Operators	Use: tomato, curcubit (outdoor), tractor mounted equipment, application rate 0,85 kg a.s./ha Exposure estimates (model): — % of AOEL UK POEM Without PPE: — 354 PPE (gloves): — 57 German model Without PPE: — 64 EFSA model: Coverall — 31

	Use: grapes, broadcast air-assisted equipment, application rate 1,25 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 1775 PPE (gloves): 1137 German model Without PPE: 192 PPE (gloves and coverall): 30 EFSA model: Coverall 87
	Use: tomato, curcubits (indoor), handheld equipment, application rate 1.25 kg a.s./ha Exposure estimates (model): % of AOEL German model: Without PPE: 135 PPE (gloves): 20 ECPA greenhouse model Without PPE: 102 PPE (gloves and coverall): 51 EFSA model: Coverall 31
Workers	Use: grapes (1.25 kg Cu/ha, refined DT_{50} (7 days)) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1130 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 624 **EFSA model** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1125 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 650
	Use: tomato, cucurbits (1.25 kg as/ha, indoor, refined DT_{50} of 7 days) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65 **EFSA model:** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65

Bystanders and residents	Use: grapes (worst case scenario):1.25 kg Cu/ha, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II :** Bystander (*adults*) 9.7 **Martin *et al.* (2008):** Bystander *Adults* 8.5 *Child* 6.7 Resident *(worst case: 8 applications, 7 days interval)* *Adults* 1.6 *Child* 3.2 **EFSA model:** *Bystander* *not necessary* Resident (sum) : *8 applications, 7 days interval* *Child* 171 *Adult* 93 *3 applications, 21 days interval* *Child* 154 *Adult* 84
	Use: tomato, cucurbits (0.85 kg as/ha,outdoor, refined DT_{50} of 7 days) **EFSA model:** *Bystander* *not necessary* Resident (sum) *8 applications, 7 days interval* *Child* 33 *Adult* 16

CURENOX 50WG

Operators	Use: tomato, curcubit (outdoor), tractor mounted equipment, application rate 0,85 kg a.s./ha Exposure estimates (model): — % of AOEL UK POEM Without PPE: 419 PPE (gloves): 89 German model Without PPE: 64 EFSA model: Coverall 20

	Use: grapes, broadcast air-assisted equipment, application rate 1,25 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 1811 PPE (gloves): 1152 German model Without PPE: 192 PPE (gloves and coverall): 31 EFSA model: Coverall 83
	Use: tomato, curcubits (indoor), handheld equipment, application rate 1.25 kg a.s./ha Exposure estimates (model): % of AOEL German model: Without PPE: 93 PPE (gloves): 19 ECPA greenhouse model Without PPE: 102 PPE (gloves and coverall): 51 EFSA model: Coverall 31
Workers	Use: grapes (1.25 kg Cu/ha, refined DT_{50} (7 days)) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1130 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 624 **EFSA model** *8 applications, interval between application of 7 days:* Without PPE (work wear, bare hands) 1125 *3 applications, interval between application of 21 days:* Without PPE (work wear, bare hands) 650
	Use: tomato, cucurbits (1.25 kg as/ha, indoor, refined DT_{50} of 7 days) Exposure estimates % of AOEL **EUROPOEM II** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65 **EFSA model:** *8 applications, interval between application of 7 days:* Without PPE (workwear, bare hands) 280 With PPE (workwear + gloves) 65

Bystanders and residents	Use: grapes (worst case scenario):1.25 kg Cu/ha, refined DT_{50} of 7 days) Exposure estimates — % of AOEL **EUROPOEM II :** Bystander (*adults*) 9.7 **Martin *et al.* (2008):** Bystander *Adults* 8.5 *Child* 6.7 Resident *(worst case: 8 applications, 7 days interval)* *Adults* 1.6 *Child* 3.2 **EFSA model:** *Bystander* *not necessary* Resident (sum) : *8 applications, 7 days interval* *Child* 171 *Adult* 93 *3 applications, 21 days interval* *Child* 154 *Adult* 84
	Use: tomato, cucurbits (0.85 kg as/ha,outdoor, refined DT_{50} of 7 days) **EFSA model:** *Bystander* *not necessary* Resident (sum) *8 applications, 7 days interval* *Child* 33 *Adult* 16

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :	Copper hydroxide
Harmonised classification according to Regulation (EC) No 1272/2008[5] and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][6] :	Acute oral Cat. 4; H302: Harmful if swallowed Acute inhalation Cat. 2; H330: Fatal if inhaled Eye irritation Cat. 1; H318: Causes serious eye damage

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[6]. Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 195, 20.7.2016, 11-25.

Peer review proposal [7] for harmonised classification according to Regulation (EC) No 1272/2008:	Agree with above

Substance :	Copper oxychloride
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] :	Acute oral Cat. 3; H301: Toxic if swallowed Acute inhalation Cat. 4; H332: Harmful if inhaled
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	Agree with above

Substance :	Bordeaux mixture
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] :	Acute inhalation Cat. 4; H332: Harmful if inhaled Eye irritation Cat. 1; H318: Causes serious eye damage
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	Agree with above

Substance :	Tribasic copper sulphate
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] :	Acute oral Cat. 4; H302: Harmful if swallowed
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	Agree with above

Substance :	Copper oxide
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] :	Acute oral Cat. 4; H302: Harmful if swallowed Acute inhalation Cat. 4; H332: Harmful if inhaled Eye irritation Cat. 1; H318: Causes serious eye damage
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	Agree with above

[7] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products.			
Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	-	-	-	Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products.
Rotational crop and primary crop metabolism similar?	Yes			
Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**			
	20 min, 90°C, pH 4	-	-	-
	60 min, 100°C, pH 5	-	-	-
	20 min, 120°C, pH 6	-	-	-
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products.			

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	total copper
Plant residue definition for risk assessment (RD-RA)	total copper
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

Copper is a monoatomic element and inherently stable. Therefore, it is not expected to metabolise or to form degradation products.

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	No study available and not required.
Field rotational crop study **OECD Guideline 504**	No study available and not required. As copper is an essential micronutrient for plants and it is assumed that copper uptake is succeeding crop is auto regulated by the crops. Therefore, the survey on the endogenous copper levels in all plant commodities was considered as a surrogate to rotational crops studies. These data could allow deriving risk assessment values for all plant commodities.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Since copper cannot degrade and since the analytical techniques measure total copper content, storage stability studies are not required.

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Grapes (wine and table)	NEU	0.40; 0.79; 0.83; 0.94; 0.97; 1.1; 1.15; 3x 1.2; 1.27; 3x 1.5	MRL derived from endogenous levels (to support the "vegetative growth stage" GAP). Residue trials are required to support the "no residue situation".	2	1.5	1.15
	NEU	-	No trials compliant with GAPs for post-flowering application.	-	-	-
	SEU	0.40; 0.79; 0.83; 0.94; 0.97; 1.1; 1.15; 3x 1.2; 1.27; 3x 1.5	MRL derived from endogenous levels (to support the "vegetative growth stage" GAP). Residue trials are required to support the "no residue situation".	2	1.5	1.15
	SEU	-	No trials compliant with GAPs for post-flowering application.	-	-	-
Tomatoes	NEU	-	No trials compliant with GAP.	-	-	-
	SEU	-	No trials compliant with GAP.	-	-	-
	Indoor	-	No trials compliant with GAP.	-	-	-
Cucurbits with edible peel	NEU	-	No trials compliant with GAP.	-	-	-
	SEU	-	No trials compliant with GAP.	-	-	-
	Indoor	-	No trials compliant with GAP.	-	-	-
Cucurbits with inedible peel	NEU	-	No trials compliant with GAP.	-	-	-
	SEU	-	No trials compliant with GAP.	-	-	-
	Indoor	<1.97; 2x <2.0; 2x <2.1; 5.0	6 trials compliant with GAP. 2 trials in are still required in post-approval. $MRL_{OECD} = 8$	8	5.0	2.05
MRL application						
Not relevant.						

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Not provided and not requested.						
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Still required.						

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Not relevant	-	-	-	-
MRL application				
Not relevant	-	-	-	-

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

Not relevant

Conversion Factors (CF) for monitoring to risk assessment

Not relevant.

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Representative uses				
Cucurbit, inedible peel: distribution between peel-pulp	5	0.14; 0.28; 0.42; 0.46; 0.92	0.42	/
Tomatoes, washed fruit	2	<0.74; <1	<0.87	/
Tomatoes, juice	3	<4.44; <5.71; <6	- [c]	/
Tomatoes, canned fruit	3	<0.74; <0.95; <1	<0.95	/
Wine grape, must	14	0.4; 2x 0.6; 2x 0.7; <0.8; 0.8; 0.9; 1.5; 1.8; 1.9; 2.5; 2.9; 4.7	0.85	/
Wine grape, juice	9	0.10; <0.15; 0.17; <0.21; <0.39; 0.42; 0.54; 0.65; 0.70	0.39	/
Wine grape, wine*	19	5x <0.01; 0.02; 2x 0.03; <0.03; <0.04; <0.07; 0.20; <0.33; <0.46; <0.55; 2x <0.6; <0.76; <0.78	0.04	/
Wine grape, wet pomace	6	0.8; 1.0; 2x 1.2; 6.1; 6.8	1.2	/
Table grape, raisins	3	2.6; 2.6; 2.9	2.6	/
Cucumber, washed	4	0.40; 0.71; 0.82; 0.83	0.76	/
MRL application				
Not relevant	-	-	-	-

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring
[c]: A processing factor should not be derived for this commodity because the reported values are artificially high due to the high LOQ of the analytical method used for processed commodities.
* Referred to as wine or bottle wine in reports; does not include young wine.

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Consumer risk assessment limited to the representative uses

ADI	0.15 mg/kg bw per day
TMDI (% ADI), according to EFSA PRIMo	Highest TMDI: 9.4 % ADI (WHO Cluster diet B)
NTMDI (% ADI), according to (to be specified)	Not provided, not required.
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: 3.5 % ADI (FR all population)
NEDI (% ADI), according to (to be specified)	0.15 mg/kg bw per day
Factors included in the calculations	Peeling factor of 0.42 for cucurbits with inedible peel.
ARfD	Not relevant.
IESTI (% ARfD, according to EFSA PRIMo)	Not applicable.
NESTI (% ARfD, according to (to be specified)	Not applicable.
Factors included in IESTI and NESTI	Not applicable.

Consumer risk assessment including endogenous levels of copper, representative uses and

exposure via water.

ADI	0.15 mg/kg bw per day
TMDI (% ADI), according to EFSA PRIMo	Not relevant.
NTMDI (% ADI), according to (to be specified)	Not provided, not required.
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI (considering commodities of plant and animal origin): 72.3 % ADI (WHO Cluster diet B) IEDI (considering tap water – median and average occurrence data): 0.62-15.1% ADI IEDI (considering water and water-based products – average occurrence data): 5.4% ADI
NEDI (% ADI), according to (to be specified)	Not provided, not required.
Factors included in the calculations	Peeling factor of 0.42 for cucurbits with inedible peel.
ARfD	Not relevant.
IESTI (% ARfD, according to EFSA PRIMo)	Not applicable.
NESTI (% ARfD, according to (to be specified)	Not applicable.
Factors included in IESTI and NESTI	Not applicable.

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[(a)]	Commodity/Group	MRL/Import tolerance[(b)] (mg/kg) and Comments	
Plant commodities			
Representative uses			
0151000	Table and wine-grapes	2	Based on endogenous levels. Trials are required to confirm the "no residue situation.
0233000	Cucurbits with inedible peel	8	Provisional/tentative MRL: 2 trials are missing.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days Non-extractable residues after 100 days Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not applicable to inorganic salts.

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days Non-extractable residues after 100 days Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to inorganic salts.

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) Mineralisation at study end Non-extractable residues at study end	Not applicable to inorganic salts.

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions						
Soil type	*X*[8]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
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] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	*X*[9]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	Method of calculation
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.									

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not applicable to inorganic salts.
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	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.

[13] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

[13] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.[14] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

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

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions						
Soil type	*X*[10]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
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.							

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis					
Soil type	*X*[11]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at ??°N	St. (χ^2)	Method of calculation
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.						

[13] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.[14]
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
nt and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 195, 20.7.2016, 11-25.

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	OC %	Soil pH[a)]	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	4.01-4.99	-	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				

a) Measured in $CaCL_2$

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Elution (mm): 300 mm Time period (d): 2 d Copper was applied to soil columns containing Speyer 2.2, 2.3 and 3L and Leipzig standard soils at a rate equivalent to ca 18 kg copper/ha. Leachate: 1 % total residues/radioactivity in leachate ≈ 99 % total residues retained in top 6 cm
	Elution (mm): 370-380 Time period (d): 2 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.
Aged residues leaching	No study submitted

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	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 <0.63 to 25 µg/L, with the exception of volcanic aquifers. In the upper soil layers, typical copper concentrations in soil water and leachate from field leaching and lysimeter studies ranged from 1 to 90 µg/L, with a peak concentration of 164.2 µg/L detected at a depth of 25 cm. A review of copper levels in groundwater aquifers with possible anthropogenic inputs detected a range of concentrations from <LOD to 39 µg/L, with a peak concentration of 90 µg/L. Typical concentrations in ranged 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.

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	Not relevant

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)Photolytic degradation of active substance and metabolites above 10 %	Not relevant
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not relevant

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	No data submitted, substance considered not readily biodegradable

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	t. °C	$DissT_{50}$ /$DissT_{90}$ whole sys. (suspended sediment test)		St. (χ^2)	$DissT_{50}$ /$DissT_{90}$ Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C		At study temp	Normalised to x °C		
Not studied. No degradation is expected.										

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

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

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

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

Cu^{2+} ions										
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
Dissipation in water of Cu^{2+} ions is very fast.										

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
No degradation is expected.					

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested

Photochemical oxidative degradation in air	-
Volatilisation	from plant surfaces (BBA guideline): Not studied - no data requested
	from soil surfaces (BBA guideline): Not studied - no data requested

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Total copper Surface water: Total copper, Dissolved copper Sediment: Total copper Ground water: Total copper Air: none

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	A small soil survey of 38 Belgium field sites was conducted between August and October 2013. The median soil concentration measured in treated plots was 52 mg total Cu/kg (range 9 to 159 mg Cu/kg). In soil from adjacent untreated areas, the median soil concentration was 16 mg total Cu/kg (range 5 to 87 mg Cu/kg), which is within the normal background range.
	A large soil monitoring programme was conducted in Austria to establish the amounts of copper in agricultural soils. No significant differences were found in the total copper concentrations measured in soil samples from organically and conventionally managed fields. The Austrian soil data showed highest copper loads in locations with a long-term history of viticulture. Soil copper levels were significantly lower in orchards with evidence of accumulation of copper was found in only ca. 5% of locations. In the majority of arable soils, copper concentrations were at the natural background level of up to 30 mg/kg. Only occasionally samples with higher copper contents were reported where vineyards had been converted to arable land.
	A total of 85 vineyards were surveyed in Germany between 2009 and 2010 to determine copper contents of soils. The mean copper concentrations in the top 5 cm depth of soil was 121 mg/kg and 102 mg/kg in the top 20 cm. The levels of copper in vineyard soil varied greatly in different German viticulture regions. Historical records indicated high copper fungicide application rates of up to 50 kg Cu/ha from 1890 up to the 1940s have been applied in German vineyards, which was concluded

	to be the cause of the current high copper levels found in very long established vineyards. In vineyards cultivated over the last 25 years, total copper concentrations were less than 40 mg Cu/kg soil (DM).
	A review of the existing monitoring programmes and published literature on copper levels in European agricultural soils has been conducted, with the aim of identifying a concentration suitable for use in soil exposure assessments for various crops. The natural background level of copper proposed by EFSA of 32 mg/kg was found to be highly conservative, at more than double the median value of 11 mg/kg measured across Europe. No convincing evidence for accumulation of copper in arable fields was found, but elevated copper levels were observed in a proportion of vineyard soils and to a much lesser extent in some orchard soils.
Surface water (indicate location and type of study)	The European geological mapping project (FOREGS Geochemical Atlas of Europe) was used to obtain monitoring data for surface water and sediments. Dissolved copper concentrations in stream water range over two orders of magnitude, from 0.08 to 14.6 µg/L, with a median value of 0.88 µg/L. The median total copper concentration in stream sediments was 17 mg/kg, with a range from 1.0 to 877 mg/kg and in floodplain sediment varied from 2 to 495 mg/kg, with a median value of 17 mg/kg (according to analysis by XRF).
Ground water (indicate location and type of study)	A review of the existing monitoring programmes and published literature on copper levels in groundwater has been conducted. Copper concentrations never approach the legal limit of 2 mg/L set by the European Drinking Water Directive (98/83/EC7) for groundwater.
Air (indicate location and type of study)	Not applicable for copper

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

FUNUGURAN-OH, CURENOX 50, POTIGLIA CAFFARO DF New, CUPROXAT SC, NORDOX 75

The different background values used for PECsoil calculations are reported in section 'Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)'.

Parent Method of calculation	DT_{50} (d): No degradation is expected. Kinetics: - Field or Lab: -

Application data	Crop: Grape Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: no crop interception Number of applications: 1 Interval (d): - Annual Application rate(s): 6000 g a.s./ha* or 8000 g a.s./ha** in any single year

* Total must not exceed 6 kg/ha/yr
** Total must not exceed 30 kg/ha any rolling 5 year period

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-		8.0 (for 6000 g a.s./ha/yr) 10.67 (for 8000 g a.s./ha/yr*)	
Short term	24h	-	-	-	-
	2d	-	-	-	-
	4d	-	-	-	-
Long term	7d	-	-	-	-
	28d	-	-	-	-
	50d	-	-	-	-
	100d	-	-	-	-
Plateau concentration **		Not reached Background level 10th centile: 108 mg/kg after 10 yr Background level 90th centile: 240 mg/kg after 10 yr			

Parent Method of calculation	DT$_{50}$ (d): No degradation is expected. Kinetics: - Field or Lab: -
Application data	Crop: Cucurbits, Tomato Depth of soil layer: 5cm and 20cm Soil bulk density: 1.5g/cm^3 % plant interception: no crop interception Number of applications: 1 Interval (d): - Annual Application rate(s): 6000 g a.s./ha*

* Total must not exceed 6 kg/ha/yr
** These PECsoil are representative for added copper for a time period of 10 years considering a range of different background values through two values derived for vineyard soils (10th percentile, median and 90th percentile values).

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-		8.0 (for 6000 g a.s./ha/yr)	
Short term	24h	-	-	-	-
	2d	-	-	-	-
	4d	-	-	-	-
Long term	7d	-	-	-	-
	28d	-	-	-	-
	50d	-	-	-	-
	100d	-	-	-	-
Plateau concentration *		Not reached Background level 10th centile: 35 mg/kg after 10 yr Background level 90th centile: 54 mg/kg after 10 yr			

* These PECsoil are representative for added copper for a time period of 10 years considering a range of different background values through two values derived for European arable soils (10th percentile, median and 90th percentile values).

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

FUNUGURAN-OH, CURENOX 50, POTIGLIA CAFFARO DF New, CUPROXAT SC, NORDOX 75

The different background values used for PECgroundwater calculations are reported in section 'Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)'.

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO v5.5.3, FOCUS PEARL v4.4.4 Crop: Grape Crop uptake factor: 0 Water solubility (mg/L): 500 at pH 7 and 20°C Vapour pressure: 0 Pa at 20°C parent DT50: 1,000,000 days (No degradation is expected in soil). Kdoc parent, geomean: 19509.9 mL/goc, Kdom parent, geomean: 11315.7 mL/gom, mean 1/n= 1. Metabolites: -
Application rate	Gross application rate: 6000 g Total copper/ha. Crop growth stage: BBCH 11-91 Canopy interception %: 0 Application rate net of interception: 6000 g/ha. No. of applications: 1 Time of application (absolute application dates): 21 January Vines: Background level considered in modelling: 160 mg Cu/kg

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			Met I	*Met II*	*Met III*
FOCUS PELMO 5.5.3 / Grape	Chateaudun	< 0.001	-	-	-
	Hamburg	< 0.001	-	-	-
	Jokioinen	-	-	-	-
	Kremsmunster	< 0.001	-	-	-
	Okehampton	-	-	-	-
	Piacenza	< 0.001	-	-	-
	Porto	<-0.001	-	-	-
	Sevilla	< 0.001	-	-	-
	Thiva	< 0.001	-	-	-

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			Met I	*Met II*	*Met III*
FOCUS PEARL 4.4.4 / Grape	Chateaudun	< 0.001	-	-	-
	Hamburg	< 0.001	-	-	-
	Jokioinen	-	-	-	-
	Kremsmunster	< 0.001	-	-	-
	Okehampton	-	-	-	-
	Piacenza	< 0.001	-	-	-
	Porto	< 0.001	-	-	-
	Sevilla	< 0.001	-	-	-
	Thiva	< 0.001	-	-	-

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO v5.5.3, FOCUS PEARL v4.4.4 Crop: Tomato, Cucurbits Crop uptake factor: 0 Water solubility (mg/L): 500 at pH 7 and 20°C Vapour pressure: 0 Pa at 20°C parent DT50: 1,000,000 days (No degradation is expected in soil). Kdoc parent, geomean: 19509.9 mL/goc, Kdom parent, geomean: 11315.7 mL/gom, mean 1/n= 1. Metabolites: -
Application rate	Gross application rate: 6000 g Total copper/ha. Crop growth stage: Canopy interception %: 0 Application rate net of interception: 6000 g/ha. No. of applications: 1 Time of application (absolute application dates): 0 days post emergence Tomatoes/Curcumbers: Background level considered in modelling: 26 mg Cu/kg

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			Met I	*Met II*	*Met III*
FOCUS PELMO 5.5.3 / Tomato, Cucurbits	Chateaudun	< 0.001	-	-	-
	Hamburg	-	-	-	-
	Jokioinen	-	-	-	-
	Kremsmunster	-	-	-	-
	Okehampton	-	-	-	-
	Piacenza	< 0.001	-	-	-
	Porto	-	-	-	-
	Sevilla	< 0.001	-	-	-
	Thiva	< 0.001	-	-	-

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			Met I	*Met II*	*Met III*
FOCUS PELMO 5.5.3 / Tomato, Cucurbits	Chateaudun	< 0.001	-	-	-
	Hamburg	-	-	-	-
	Jokioinen	-	-	-	-
	Kremsmunster	-	-	-	-
	Okehampton	-	-	-	-
	Piacenza	< 0.001	-	-	-
	Porto	-	-	-	-
	Sevilla	< 0.001	-	-	-
	Thiva	< 0.001	-	-	-

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For field and lysimeter studies Location: *UK, N. Yorkshire* Study type (e.g. lysimeter, field): *lysimeter* Soil properties: pH = , OC= , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: *x* years, *x* applications year Duration. Average annual rainfall (mm): *x* mm Average annual leachate volume (mm): *x* mm

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

FUNUGURAN-OH, CURENOX 50, POTIGLIA CAFFARO DF New, CUPROXAT SC, NORDOX 75

PECsw results

A.) via Spray drift/runoff/drainage without mitigation (field crops)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEP 1-2 (v3.2) Water solubility (mg/L): 500 at pH 7 and 20°C Kdoc parent, geomean: 33,918.3 mL/goc DT50 soil (d): 1,000 DT50 water (d): 1,000 DT50 sediment (d): 1,000 Crop interception (%): no
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Crop and growth stage: Vines; all BBCH stages Tomatoes: BBCH 12-89 Cucumbers: BBCH 10-89 Number of applications: See following table Interval (d): See following table Application rate(s): See following table Application window: See following table

Uses	Application pattern	Season of application	Region	Step 1		Step 2	
				PECsw (µg/L)	PECsed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Tomatoes, Cucumbers	1 x 850 g/ha	Mar.-May	N	13.95	-	7.82	-
			S			7.82	-
	7 x 850 g/ha (7 days)		N	97.63	-	9.47	-
			S			17.9	-
Vines, late applns.	1 x 1,250 g/ha	Oct.-Feb.	N	42.46	-	33.45	-
			S			33.45	-
	3 x 1,250 g/ha (7 days)		N	127.39	-	30.55	-
			S			30.55	-
	4 x 1,250 g/ha (21 days)		N	169.86	-	30.27	-
			S			30.27	-
Vines, early applns.	1 x 1,250 g/ha	Mar.-May	N	20.26	-	11.25	-
			S			11.25	-
	6*1,250 (7 days)		N	121.56	-	12.61	-
			S			23.27	-

B.) via run-off/drainage only with runoff mitigation (Field crops)

Application rate	Version control no. of FOCUS calculator: FOCUS STEP 1-2 (v3.2) Option: No spray drift

	Water solubility (mg/L): 500 at pH 7 and 20°C Kdoc parent, geomean: 33,918.3 mL/goc DT50 soil (d): 1,000 DT50 water (d): 1,000 DT50 sediment (d): 1,000 Crop interception (%): no Mitigation measures: 90% reduction on runoff
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Crop and growth stage: Vines; all BBCH stages Tomatoes: BBCH 12-89 Cucumbers: BBCH 10-89 Number of applications: See following table Interval (d): See following table Application rate(s): See following table Application window: See following table

Uses	Application pattern	Season of application	Region	Step 1		Step 2		
				PECsw (µg/L)	PECsed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)	PECsw with 90% mitigation (µg/L)
Tomatoes, Cucumbers	1 x 850 g/ha	Mar.-May	N	6.13	-	1.22	-	0.122
			S			2.45	-	0.245
	7 x 850 g/ha (7 days)		N	42.91	-	8.43	-	0.843
			S			16.87	-	1.687
Vines, late applns.	1 x 1,250 g/ha	Oct.-Feb.	N	9.01	-	4.49	-	0.449
			S			3.6	-	0.36
	3 x 1,250 g/ha (7 days)		N	27.04	-	13.29	-	1.329
			S			10.63	-	1.063
	4 x 1,250 g/ha (21 days)		N	36.06	-	17.85	-	1.785
			S			14.28	-	1.428
Vines, early applns.	1 x 1,250 g/ha	Mar.-May	N	9.01	-	1.8	-	0.18
			S			3.6	-	0.36
	6*1,250 (7 days)		N	54.08	-	10.66	-	1.066
			S			21.31	-	2.13
Tomatoes, Cucumbers	1 x 6,000 g/ha	Mar.-May	N	43.27	-	8.63	-	0.863
			S			17.26	-	1.726
Vines	1 x 6,000 g/ha	Oct.-Feb.	N	43.27	-	21.57	-	2.157
			S			17.26	-	1.726
	1 x 8,000 g/ha		N	57.69	-	28.76	-	2.876
			S			23.01	-	2.301

C.) via Spray drift only with spray drift mitigation (Field crops)

Application rate	Version control no. of FOCUS calculator: FOCUS STEP 1-2 (v3.2)

	Option: No Drainage/Runoff Water solubility (mg/L): 500 at pH 7 and 20°C Kdoc parent, geomean: 33,918.3 mL/goc DT50 soil (d): 1,000 DT50 water (d): 1,000 DT50 sediment (d): 1,000 Crop interception (%): no Mitigation measures: Drift values for different distances derived from Drift calculator v1.1
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Crop and growth stage: Vines; all BBCH stages Tomatoes: BBCH 12-89 Cucumbers: BBCH 10-89 Number of applications: See following table Interval (d): See following table Application rate(s): See following table Application window: See following table

Uses	Application pattern	Season of application	Region	Step 1	
				PECsw (µg/L)	PECsed (µg/kg)
Tomatoes, Cucumbers	1 x 850 g/ha	Mar.-May	N	13.95	-
			S		
	7 x 850 g/ha (7 days)		N	97.63	-
			S		
Vines, late applns.	1 x 1,250 g/ha	Oct.-Feb.	N	42.46	-
			S		
	3 x 1,250 g/ha (7 days)		N	127.39	-
			S		
	4 x 1,250 g/ha (21 days)		N	169.86	-
			S		
Vines, early applns.	1 x 1,250 g/ha	Mar.-May	N	20.26	-
			S		
	6*1,250 (7 days)		N	60.78	-
			S		

Uses	Application pattern	Season of application	Region	Step 2					
				PECsw (µg/L)	PECsed (µg/kg)	including a NSZ of 10 m	including a NSZ of 20 m	including a NSZ of 30 m	including a NSZ of 50 m
Tomatoes, Cucumbers	1 x 850 g/ha	Mar.-May	N	7.82	-	0.82 (89)	0.42 (95)	--	--
			S						
	7 x 850 g/ha (7 days)		N	5.32	-	0.56 (90)	0.28 (95)	--	--
			S						
Vines, late applns.	1 x 1,250 g/ha	Oct.-Feb.	N	33.45	-	5.09 (85)	1.72 (95)	--	--
			S						

	3 x 1,250 g/ha (7 days)		N	30.55	-	4.54 (85)	1.51 (95)	--	--
			S						
	4 x 1,250 g/ha (21 days)		N	30.27	-	4.55 (85)	1.53 (95)	--	--
			S						
Vines, early applns.	1 x 1,250 g/ha	Mar.-May	N	11.25	-	1.21 (89)	0.53 (95)	--	--
			S						
	6*1,250 (7 days)		N	11.29	-	1.46 (87)	--	--	--
			S						

NSZ: No-spray buffer zone

-- Values going beyond 95% mitigation

In brackets, % reduction in exposure

PECsw from calculations reported in points b) and c) were summed in order to derive the final PEC results from all entry routes to water bodies that introduced the maximum mitigation agreed in FOCUS Landscape and mitigation (FOCUS, 2007) guidance.

Uses	Application pattern	Season of application	Scenario	PECsw Step 2, Runoff/Drainage	PECsw Step 2, Drift	Total
				Including 90% reduction	Including NSZ 20 m	VBZ 20 m + NSZ 20m
Tomatoes, Cucumbers	1 x 850 g/ha	Mar.-May	N	0.122	0.42	0.54
			S	0.245	0.42	0.66
	7 x 850 g/ha (7 days)		N	0.843	0.28	1.12
			S	1.687	0.28	1.97
Vines, late appl.	1 x 1250 g/ha	Oct.-Feb	N	0.449	1.72	2.17
			S	0.36	1.72	2.08
	3 x 1250 g/ha (7 days)		N	1.329	1.51	2.84
			S	1.063	1.51	2.58
	4 x 1250 g/ha (21 days)		N	1.785	1.53	3.31
			S	1.428	1.53	2.95
Vines, early appl.	1 x 1250 g/ha	Mar.-May	N	0.18	0.53	0.71
			S	0.36	0.53	0.89
	6 x 1250 (7 days)		N	1.066	-	-
			S	2.131	-	-
Tomatoes, Cucumbers	1 x 6000 g/ha	Mar.-May	N	0.863	0.42	1.28
			S	1.726	0.42	2.14
Vines	1 x 6000 g/ha	Oct.-Feb	N	2.157	1.72	3.88
			S	1.726	1.72	3.45
	1 x 8000 g/ha		N	2.876	1.72	4.60
			S	2.301	1.72	4.02

D.) via Spray drift only without mitigation (Indoor crops)

Parent Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): not needed Kdoc parent, geomean: not needed DT50 soil (d): not needed DT50 water (d): not needed

	DT50 sediment (d): not needed Crop interception (%): no
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Crop and growth stage: Tomatoes/Cucumbers; BBCH 10-89 Number of applications: 1-8 Interval (d): 7 Application rate(s): 1,250-6,000 g/ha Application window: - Drift value: 0.1%

Crop	Maximum Application Rate [g a.s. /ha]	Buffer [m]	Drift Rate [%]	PEC_{sw} [µg/L]
Tomatoes Cucumbers	1 x 1,250	-	0.1	0.42
Tomatoes Cucumbers	1 x 6,000	-	0.1	2.00

PECsed results

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEP 1-2 v3.2 Water solubility (mg/L): 500 at pH 7 and 20°C Kdoc parent, geomean: 10,000 mL/goc DT50 soil (d): 1,000 DT50 water (d): 1,000 DT50 sediment (d): 1,000 Crop interception (%): no
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Crop and growth stage: Grape; all BBCH stages Tomatoes: BBCH 12-89 Cucumbers: BBCH 10-89 Number of applications: See following table Interval (d): See following table Application rate(s): See following table Application window: See following table Mitigation measures: 80-90% reduction on runoff Background level of copper in sediment considered: 17 mg/kg (median value)

	Scenario	Step 2 *via* run-off/drainage		
		$PEC_{sed,\ accumulation}$ Total copper (10 years accumulation) + background level (mg/kg)	$PEC_{sed,\ accumulation}$ Total copper (10 years accumulation) background level (mg/kg) Mitigation applied: 80%	$PEC_{sed,\ accumulation}$ Total copper (10 years accumulation) background level (mg/kg) Mitigation applied: 90%
Outdoor uses no interception, 1 * 850 g/ha; early application; march-may	N	21.0	17.8	17.4
	S	24.9	18.6	17.8
Outdoor uses no interception, 1 * 850 g/ha; late application; June-Sep	N	21.0	17.8	17.4
	S	22.9	18.2	17.6
Outdoor uses no interception, 1 * 1250 g/ha; early application; Octo-Feb	N	31.6	19.9	18.5
	S	28.7	19.3	18.2
Outdoor uses no interception, 1 * 1250 g/ha; late application; June-Sept	N	22.8	18.2	17.6
	S	25.7	18.7	17.9
Outdoor uses no interception, 1 * 6000 g/ha; early application; Octo-Feb	N	86.9	31.0	24.0
	S	72.9	28.2	22.6
Outdoor uses no interception, 1 * 6000 g/ha; late application; June-Sept	N	45.0	22.6	19.8
	S	59.0	25.4	21.2

Crop	Maximum Application Rate [g a.s. /ha]	Buffer [m]	$PEC_{sed,\ accumulation}$ Total copper (10 years accumulation) + background level (mg/kg)
Tomatoes Cucumbers	1 x 850	Step 3	19.1
		5 m	17.6
		10 m	17.3
		20 m	17.1
		50 m	--
Tomatoes Cucumbers	1 x 6,000	Step 3	25.3
		5 m	19.2
		10 m	18.2
		20 m	17.6
		50 m	--
Vines, late applns.	1 x 1,250	Step 3	25.1
		5 m	21.9
		10 m	18.8
		20 m	17.6
		50 m	--
Vines, late applns.	1 x 6,000	Step 3	49.0

Crop	Maximum Application Rate [g a.s. /ha]	Buffer [m]	$PEC_{sed,\ accumulation}$ Total copper (10 years accumulation) + background level (mg/kg)
		5 m	36.3
		10 m	23.9
		20 m	19.4
		50 m	--
Vines, early applns.	1 x 1,250	Step 3	19.7
		5 m	18.6
		10 m	17.6
		20 m	17.2
		50 m	--
Vines, early applns.	1 x 6,000	Step 3	28.8
		5 m	23.8
		10 m	19.2
		20 m	17.7
		50 m	--

-- Values going beyond 95% mitigation on calculated PECsw

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	Not relevant.

PEC

Maximum concentration	-

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Birds ‡				
Species	Test substance	Time scale	LD50 (mg Cu/kg bw)	
Colinus virginianus	Copper hydroxide	Acute	223	
Coturnix coturnix japonica	Copper hydroxide	Acute	556	
Colinus virginianus	Copper hydroxide WP	Acute	357	
Colinus virginianus	Copper oxychloride	Acute	511	
Coturnix coturnix japonica	**Copper oxychloride WP**	**Acute**	**173** [a]	
Colinus virginianus	Bordeaux mixture	Acute	> 616	
Colinus virginianus	Bordeaux mixture WP	Acute	> 439.9	
Colinus virginianus	Tribasic copper sulfate	Acute	616	
Colinus virginianus	Tribasic copper sulfate SC	Acute	> 72.4	
Coturnix coturnix japonica	Tribasic copper sulfate SC	Acute	221	
Coturnix coturnix japonica	Copper oxide	Acute	1 183	
Coturnix coturnix japonica	Copper oxide WG	Acute	650	
Species	Test substance	Time scale	LC50 (mg Cu/kg bw/day)	LD50 (mg Cu/kg feed)
Colinus virginianus	Copper oxychloride	Short-term	1939	333
Colinus virginianus	Bordeaux mixture	Short-term	> 1369	> 334.1
Species	Test substance	Time scale	NOEL (mg Cu/kg bw/day)	NOEC (mg Cu/kg feed)
Colinus virginianus	Copper hydroxide	Short-term	123.6 [b]	883 [c]
Anas platyrhynchos	Copper hydroxide	Short-term	215.6 [b]	1 053 [c]
Colinus virginianus	Copper hydroxide	Short-term	135.2 [b]	963 [c]
Anas platyrhynchos	Copper hydroxide	Short-term	190.6 [b]	963 [c]
Colinus virginianus	Tribasic copper sulfate	Short-term	89 [b]	246 [c]
Anas platyrhynchos	Tribasic copper sulfate	Short-term	176.3 [b]	530 [c]
Colinus virginianus	Copper oxide	Short-term	32 [b]	136 [c]
Colinus virginianus	Copper hydroxide	Long-term	**5.05** [a]	57.5 [a]

Anas platyrhynchos	Copper hydroxide	Long-term	42.34	288
Colinus virginianus	Copper hydroxide	Long-term	25.41	288
Anas platyrhynchos	Copper hydroxide	Long-term	50.3	288
Endocrine disrupting properties (Annex Part A, points 8.1.5) No information highlights any ED property of copper				
Additional higher tier studies (Annex Part A, points 10.1.1.2): A literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for granivorous and insectivorous birds.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): There have been 14 potentially relevant publications identified. A range of median lethal or effective concentrations for amphibians was found to be from 19.5 to 180 µg Cu/L while the lowest value that caused significant effects to an amphibian (toad) was 4.25 µg/L (measured concentrations). A NOAL value of 283.3 mg/kg soil (mean measured concentrations) was identified. Concerning the risk for amphibians and reptiles, no guidance document is available; however, based on the data retrieved form the literature, those organisms are considered less sensitive than fish or birds. Therefore, the risk assessment peformed for birds and aquatic organisms are considered to cover that of amphibians and reptiles.				

a: data retained for the risk assessment
b: LD_{50} was not relevant because of food avoidance
c: LC_{50} was not relevant because of food avoidance

Mammals ‡			
Species	Test substance	Time scale	LD_{50} (mg Cu/kg bw)
Rat	**Tribasic copper sulfate**	**Acute**	**162.6** [a] to 271
Species	Test substance	Time scale	NOEL (mg Cu/kg bw)
Rat	**Copper sulfate**	**Long-term (90 days)**	**16** [a] (males) 17 (females)
Additional higher tier studies ‡			

a: data retained for the risk assessment.

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Vineyard s at 1250 g a.s./ha [8 applications]

The risk assessment provided below was realized assuming a MAF and TWA = 1 and one maximal application at 8 kg/ha for vineyard.

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	762.4	**0.2**	10
All	Small omnivorous bird	Long-term	311.2	**0.016**	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Birds)					
BBCH 10-19	Small insectivorous bird "redstart"	Acute	219.2	**0.8**	10
BBCH >20	Small insectivorous bird "redstart"	Acute	205.6	**0.8**	10
BBCH 10-19	Small granivorous bird “finch”	Acute	118.4	**1.5**	10
BBCH 20-39	Small granivorous bird “finch”	Acute	99.2	**1.7**	10
BBCH >40	Small granivorous bird “finch”	Acute	59.2	**2.9**	10
Ripening	Frugivorous burd “Thrush/Starling”	Acute	231.2	**0.7**	10
BBCH 10-19	Small omnivorous bird "lark"	Acute	115.2	**1.5**	10
BBCH 20-39	Small omnivorous bird "lark"	Acute	96	**1.8**	10
BBCH >40	Small omnivorous bird "lark"	Acute	57.6	**3.0**	10
BBCH 10-19	Small insectivorous bird "redstart"	Long-term	92	**0.05**	5
BBCH >20	Small insectivorous bird "redstart"	Long-term	79.2	**0.06**	5
BBCH 10-19	Small granivorous bird “finch”	Long-term	55.2	**0.09**	5
BBCH 20-39	Small granivorous bird “finch”	Long-term	45.6	**0.11**	5
BBCH >40	Small granivorous bird “finch”	Long-term	27.2	**0.18**	5
Ripening	Frugivorous burd “Thrush/Starling”	Long-term	115.2	**0.04**	5
BBCH 10-19	Small omnivorous bird "lark"	Long-term	52	**0.1**	5
BBCH 20-39	Small omnivorous bird "lark"	Long-term	43.2	**0.12**	5
BBCH >40	Small omnivorous bird "lark"	Long-term	26.4	**0.19**	5
Higher tier (birds): A literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for granivorous and insectivorous birds.					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1091.2	**0.15**	10
All	Small herbivorous mammal	Long-term	578.4	**0.03**	5
Tier 1 (Mammals)					
Application ground directed	Large herbivorous mammal “lagomorph”	Acute	217.6	**0.75**	10
BBCH 10-19	Large herbivorous mammal “lagomorph”	Acute	130.4	**1.25**	10
BBCH 20-39	Large herbivorous mammal “lagomorph”	Acute	108.8	**1.50**	10
BBCH >40	Large herbivorous mammal “lagomorph”	Acute	64.8	**2.51**	10

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH 10-19	Small insectivorous mammal "shrew"	Acute	60.8	**2.67**	10
BBCH >20	Small insectivorous mammal "shrew"	Acute	43.2	**3.76**	10
Application ground directed	Small herbivorous mammal "vole"	Acute	1091.2	**0.15**	10
Application crop directed BBCH 10-19	Small herbivorous mammal "vole"	Acute	655.2	**0.25**	10
Application crop directed BBCH 20-39	Small herbivorous mammal "vole"	Acute	545.6	**0.30**	10
Application crop directed BBCH >40	Small herbivorous mammal "vole"	Acute	327.2	**0.50**	10
Application ground directed	Small omnivorous mammal "mouse"	Acute	137.6	**1.18**	10
Application crop directed BBCH 10-19	Small omnivorous mammal "mouse"	Acute	82.4	**1.97**	10
Application crop directed BBCH 20-39	Small omnivorous mammal "mouse"	Acute	68.8	**2.36**	10
Application crop directed BBCH >40	Small omnivorous mammal "mouse"	Acute	41.6	**3.91**	10
Application ground directed	Large herbivorous mammal "lagomorph"	Long-term	88.8	**0.18**	5
BBCH 10-19	Large herbivorous mammal "lagomorph"	Long-term	53.6	**0.30**	5
BBCH 20-39	Large herbivorous mammal "lagomorph"	Long-term	44	**0.36**	5
BBCH >40	Large herbivorous mammal "lagomorph"	Long-term	26.4	**0.61**	5
BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	33.6	**0.48**	5
BBCH >20	Small insectivorous mammal "shrew"	Long-term	15.2	1.05	5
Application ground directed	Small herbivorous mammal "vole"	Long-term	578.4	**0.03**	5
Application crop directed BBCH 10-19	Small herbivorous mammal "vole"	Long-term	347.2	**0.05**	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Application crop directed BBCH 20-39	Small herbivorous mammal "vole"	Long-term	288.8	**0.05**	5
Application crop directed BBCH >40	Small herbivorous mammal "vole"	Long-term	173.6	**0.09**	5
Application ground directed	Small omnivorous mammal "mouse"	Long-term	62.4	**0.26**	5
Application crop directed BBCH 10-19	Small omnivorous mammal "mouse"	Long-term	37.6	**0.42**	5
Application crop directed BBCH 20-39	Small omnivorous mammal "mouse"	Long-term	31.2	**0.51**	5
Application crop directed BBCH >40	Small omnivorous mammal "mouse"	Long-term	18.4	**0.87**	5

Higher tier (Mammals): A literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence except for large herbivorous.

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

A literature review provides evidence of lack of bioaccumulation in aquatic food chain.

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	Not required		5

Puddle scenario, Screening step

1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for birds and mammals

2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed for birds and mammals

Fruiting vegetables 850 g a.s./ha, [8 applications]

The risk assessment provided below was realized assuming a MAF and TWA = 1 and one maximal application at 6 kg/ha for fruiting vegetables.

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	952.8	**0.18**	10
All	Small omnivorous bird	Long-term	388.80	**0.013**	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Birds)					
BBCH 71-89	Frugivorous bird "crow"	Acute	344.4	**0.50**	10
BBCH 10-49	Small granivorous bird “finch”	Acute	148.2	**1.17**	10
BBCH >50	Small granivorous bird “finch”	Acute	~~12.0~~ 44.4	3.90	10
BBCH 10-49	Small omnivorous bird "lark"	Acute	144	**1.21**	10
BBCH >50	Small omnivorous bird "lark"	Acute	43.2	4.00	10
BBCH 71-89	Frugivorous bird "starling""	Acute	296.6	**0.58**	10
BBCH 10-19	Small insectivorous bird "wagtail"	Acute	160.8	**1.07**	10
BBCH >20	Small insectivorous bird "wagtail"	Acute	151.2	**1.14**	10
BBCH 71-89	Frugivorous bird "crow"	Long-term	192	**0.03**	5
BBCH 10-49	Small granivorous bird “finch”	Long-term	68.4	**0.07**	5
BBCH >50	Small granivorous bird “finch”	Long-term	20.4	**0.24**	5
BBCH 10-49	Small omnivorous bird "lark"	Long-term	65.4	**0.08**	5
BBCH >50	Small omnivorous bird "lark"	Long-term	19.8	**0.25**	5
BBCH 71-89	Frugivorous bird "starling""	Long-term	124.2	**0.04**	5
BBCH 10-19	Small insectivorous bird "wagtail"	Long-term	67.8	**0.07**	5
BBCH >20	Small insectivorous bird "wagtail"	Long-term	58.2	**0.09**	5
Higher tier (birds): A literature review provides a weight of evidence approach concluding to acceptable risks to birds for doses of 5 kg Cu/ha/year, for granivorous and insectivorous birds.					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	818.4	**0.2**	10
All	Small herbivorous mammal	Long-term	433.8	**0.04**	5
Tier 1 (Mammals)					
BBCH 71-89	Frugivorous mammal “rat”	Acute	271.2	**0.60**	10
BBCH 10-19	Small insectivorous mammal “shrew”	Acute	45.6	**3.67**	10
BBCH >20	Small insectivorous mammal “shrew”	Acute	32.4	**5.02**	10
BBCH 10-49	Small herbivorous mammal “vole”	Acute	818.4	**0.20**	10
BBCH >50	Small herbivorous mammal “vole”	Acute	243.6	**0.67**	10

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH 10-49	Small omnivorous mammal "mouse"	Acute	103.2	**1.57**	10
BBCH >50	Small omnivorous mammal "mouse"	Acute	31.2	**5.21**	10
BBCH 71-89	Frugivorous mammal "rat"	Long-term	151.2	**0.11**	5
BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	25.2	**0.63**	5
BBCH >20	Small insectivorous mammal "shrew"	Long-term	11.4	**1.40**	5
BBCH 10-49	Small herbivorous mammal "vole"	Long-term	433.4	**0.04**	5
BBCH >50	Small herbivorous mammal "vole"	Long-term	130.2	**0.12**	5
BBCH 10-49	Small omnivorous mammal "mouse"	Long-term	46.8	**0.34**	5
BBCH >50	Small omnivorous mammal "mouse"	Long-term	13.8	**1.16**	5

Higher tier (Mammals): A literature review provides evidence of homeostatic mechanisms, and allows concluding to acceptable long-term risks based on weight of evidence except for large herbivorous.

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

A literature review provides evidence of lack of bioaccumulation in aquatic food chain.

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	Not required		5

Puddle scenario, Screening step

1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
Laboratory tests ‡				
Fish				

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
O. mykiss	Copper hydroxide WP	96 hr (flow-through)	Mortality, LC_{50}	0.0165 total (mm) 0.0080 dissolved (mm)
O. mykiss	Copper oxychloride	96 hr (flow-through)	Mortality, LC_{50}	> 43.8 total (mm) > 0.106 dissolved (mm)
O. mykiss	Copper oxychloride	96 hr (semi-static)	Mortality, LC_{50}	0.047 dissolved (mm)
O. mykiss	Copper oxychloride WP	96 hr (flow-through)	Mortality, LC_{50}	0.78 total (mm) 0.0109 dissolved (mm)
O. mykiss	Bordeaux mixture	96 hr (semi-static)	Mortality, LC_{50}	> 21.39 total (mm) > 0.125 dissolved (mm)
O. mykiss	Bordeaux mixture	96 hr (semi-static)	Mortality, LC_{50}	0.082 total (mm)
O. mykiss	Bordeaux mixture WP	96 hr (semi-static)	Mortality, LC_{50}	0.052 total (mm)
O. mykiss	Tribasic copper sulfate SC	96 hr (static)	Mortality, LC_{50}	13.18 total (mm)
C. carpio	Tribasic copper sulfate SC	96 hr (flow-through)	Mortality, LC_{50}	> 19.3 total (mm)
O. mykiss	**Copper oxide**	**96 hr (flow-through)**	**Mortality, LC_{50}**	**0.207 total (mm) 0.0344 dissolved (mm)**
O. mykiss	Copper oxide WP	96 hr (flow-through)	Mortality, LC_{50}	0.047 total (mm) 0.0106 dissolved (mm)
C. carpio	Copper oxide WG	96 hr (semi-static)	Mortality, LC_{50}	4.37 total (nom)
O. mykiss	Copper hydroxide WP	ELS – 92 d	Growth NOEC	0.0155 total (mm) 0.0017 dissolved (mm)
O. mykiss	Tribasic copper sulfate SC	21 d(flow-through)	Growth NOEC	0.97 total (nom)

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
O. mykiss	*Copper Hydroxide WP (with sediment)*	48 hr (static)	Mortality, LC_{50}	0.54 total (mm) 0.18 dissolved (mm)
D. rerio (embryo)[12]	Copper hydroxide	48 hr (static)	Mortality, NOEC	≤ 3.2 total (nom)
	Copper oxychloride	48 hr (static)	Mortality, NOEC	18.0 total (nom)
	Bordeaux mixture	48 hr (static)	Mortality, NOEC	22.5 total (nom)
	Tribasic copper sulfate	48 hr (static)	Mortality, NOEC	76.8 total (nom)
	Copper oxide	48 hr (static)	Mortality, NOEC	1.06 total (nom)

labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
Pimephales promelas	Copper sulfate	270 d (flow-through)	NOEC (number of eggs/spawn)	0.066 mg/L (dissolved Cu)
Perca fluviatilis	Copper sulfate	30 d (flow-through)	NOEC (mortality)	0.188 mg/L (total Cu)
Perca fluviatilis	Copper sulfate	18 d (flow-through)	NOEC (growth rate)	0.022 mg/L (total Cu)
Pimephales notatus	Copper sulfate	60 d (flow-through)	NOEC (growth rate) NOEC (growth rate, mortality) NOEC (reproduction)	0.0441 mg/L (total Cu) 0.0718 mg/L (total Cu) 0.0043 mg/L (total Cu)
Oncorhynchus mykiss	Copper chloride	60 d (flow-through)	NOEC = (growth) (total Cu)	0.0022 mg/L (total Cu)
Salvelinus fontinalis	Copper sulfate	189 & 244 d (flow-through)	244-d NOEC (growth rate, number of eggs/spawn) 189-d NOEC (growth rate, mortality)	0.0174 mg/L (growth rate, number of eggs/spawn) (total Cu) 0.0095 mg/L (growth rate, mortality) (total Cu)
Pimephales promelas	Copper sulfate	330-d (flow-through)	NOEC (growth rate, mortality) NOEC (reproduction)	0.033 mg/L (total Cu) 0.0145 mg/L (total Cu)
Pimephales promelas	Copper sulfate	327-d (flow-through)	NOEC (growth rate, mortality, reproduction)	0.0106 mg/L (total Cu)
Oncorhynchus kisutch	Cu^{2+} (copper salt not reported)	61-d (flow-through)	NOEC (growth rate) NOEC (mortality)	0.021 mg/L (dissolved Cu) 0.018 mg/L (dissolved Cu)
Oncorhynchus mykiss		61-d (flow-through) 270 d (flow-through)	NOEC (growth rate) NOEC (mortality)	0.045 mg/L (dissolved Cu) 0.024 mg/L (dissolved Cu)

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
Pimephales promelas	Copper sulfate	7; 97 and 187-d (flow-through)	NOEC (growth rate) NOEC (eggs/female) NOEC (eggs/female) NOEC (eggs/female)	0.0595 mg/L (total Cu) 0.0165 mg/L (total Cu) 0.023 mg/L (total Cu) 0.016 mg/L (total Cu)
Ictalurus punctatus	Copper sulfate	60-d (flow-through)	NOEC (growth rate, mortality)	0.013 mg/L (total Cu)
Salvelinus fontinalis			30-d NOEC (growth rate - soft water) 30-d NOEC (growth rate, mortality - hard water) 30-d NOEC (reproduction) 60-d NOEC (mortality) 60-d NOEC (reproduction)	0.007 mg/L (total Cu) 0.021 mg/L (total Cu) 0.049 mg/L (total Cu) 0.013 mg/L (total Cu) 0.007 mg/L (total Cu)
Pimephales promelas	Copper sulfate	28-d (flow-through)	NOEC (mortality)	0.061 mg/L (total Cu)
Neomacheilus barbatulus	Copper sulfate	64-d (flow-through)	NOEC (survival)	0.120 mg/L (total Cu)
Pimephales promelas	Copper nitrate	32-d (flow-through)	NOEC (mortality, growth)	0.0048 mg/L (total Cu)
Salvenus fontinalis	Copper sulfate	45-d (flow-through)	NOEC (mortality, growth)	0.0114 mg/L (total Cu)
Oncorhynchus mykiss		40-d (flow-through)	NOEC (mortality, growth)	0.0129 mg/L (total Cu)
Catostomus commersoni		35-d (flow-through)	NOEC (mortality, growth)	0.0349 mg/L (total Cu)
Esox lucius		60-d (flow-through)	NOEC (mortality, growth)	0.0223 mg/L (total Cu)

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
Oncorhynchus mykiss	Copper sulfate	30-d (flow-though)	LC_{10} (mortality – pH 5.1) LC_{10} (mortality – pH 6.2) LC_{10} (mortality – pH 7.1) LC_{10} (mortality – pH 7.9) LC_{10} (mortality – pH 8.6)	0.0038 mg/L (dissolved Cu) 0.0047 mg/L (dissolved Cu) 0.0039 mg/L (dissolved Cu) 0.0076 mg/L (dissolved Cu) 0.0161 mg/L (dissolved Cu)
Acipenser transmontanus	Copper sulfate	66-d (flow-though)	NOEC (mortality)	0.0059 mg/L (dissolved Cu)
Acipenser transmontanus	**Copper sulfate**	**14-d; 28-d; 53-d (flow-through)**	14-d LC_{10} (mortality) **53-d EC_{10} (growth)** 28-d LC_{10} (mortality) 28-d EC_{10} (growth) 28-d EC_{10} (growth)	0.00183 mg/L (dissolved Cu) **0.00112 mg/L (dissolved Cu)** 0.00372 mg/L (dissolved Cu) 0.00196 mg/L (dissolved Cu) 0.00203 mg/L (dissolved Cu)
Oncorhynchus mykiss		14-d; 28-d; 53-d (flow-through)	21-d LC_{10} (mortality) 52-d LC_{10} (mortality) 21-d EC_{10} (biomass) 28-d LC_{10} (mortality) 28-d EC_{10} (growth) 28-d EC_{10} (biomass)	0.037 mg/L (dissolved Cu) 0.034 mg/L (dissolved Cu) 0.031 mg/L (dissolved Cu) 0.034 mg/L (dissolved Cu) 0.013 mg/L (dissolved Cu) 0.025 mg/L (dissolved Cu)
Aquatic invertebrate				
D. magna	**Copper hydroxide**	**48 h (static)**	**Mortality, LC_{50}**	0.0308 total (mm) **0.0266 dissolved (mm)**
D. magna	Copper oxychloride	48 h (static)	Mortality, LC_{50}	0.29 total (nom)*
D. magna	Bordeaux mixture	48 h (static)	Mortality, LC_{50}	1.87 total (mm)*
D. magna	Copper oxide	48 h (static)	Mortality, LC_{50}	0.45 total (nom)*

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
D. magna	**Copper oxychloride**	**21 d (semi-static)**	**Reproduction, NOEC**	**0.0076 total (geometric mean measured)#**
D. magna	Copper oxychloride	21 d (semi-static)	Reproduction, NOEC	0.059 total (nom)
D. magna	Tribasic copper sulfate SC	21 d (semi-static)	Reproduction, NOEC	0.057 total (mm)
D. magna (21-d studies with sediment)**	Copper hydroxide WP	21 d (semi-static)	Mortality, LC_{50}	0.024 total (mm)
			Reproduction, NOEC	0.0299 total (mm)
	Copper hydroxide SC	21 d (semi-static)	Mortality, LC_{50}	0.0109 total (mm)
			Reproduction, NOEC	0.027 total (mm)
	Copper oxychloride WP	21 d (semi-static)	Mortality, LC_{50}	0.0298 total (mm)
			Reproduction, NOEC	0.0461 total (mm)
	Bordeaux mixture WP	21 d (semi-static)	Mortality, LC_{50}	0.0198 total (mm)
			Reproduction, NOEC	0.0378 total (mm)
	Tribasic copper sulfate SC	21 d (semi-static)	Mortality, LC_{50}	0.0167 total (mm)
			Reproduction, NOEC	0.0334 total (mm)
	Copper oxide WP	21 d (semi-static)	Mortality, LC_{50}	0.0113 total (mm)
			Reproduction, NOEC	0.0122 total (mm)
Sediment dwelling organisms				
Chironomus riparius	**Tribasic copper sulfate**	**28 d (static)**	**NOEC**	**0.50 total (nom) water spiked test**
Chironomus riparius	Copper chloride	28 d (semi-static, spiked sediment)	NOEC (survival)	NOEC = 64.27 mg/kg dry weight normalized to 2.5% OC
Tubifex tubifex	Copper sulfate	28 d (static, spiked sediment)	NOEC (reproduction)	NOEC = 152.04 mg/kg dry weight normalized to 2.5% OC
	Copper chloride	**28 d (semi-static, spiked sediment)**	**NOEC (reproduction, growth)**	**NOEC = 16.17 mg/kg dry weight normalized to 2.5% OC**

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
	Copper chloride	28 d (static, spiked sediment)	NOEC (reproduction, growth)	NOEC = 639 mg/kg dry weight normalized to 2.5% OC
	Copper sulfate	28 d (static, spiked sediment)	NOEC (Survival, autotomy, reproduction and total growth rate)	NOEC = 243.97 mg/kg dry weight normalized to 2.5% OC
Hyalella azteca	Copper chloride	28 d (semi-static, spiked sediment)	NOEC (growth)	NOEC = 25.70 mg/kg dry weight normalized to 2.5% OC
Lumbriculus variegatus	Copper chloride	28 d (semi-static, spiked sediment)	NOEC (biomass)	NOEC = 76.82 mg/kg dry weight normalized to 2.5% OC
Gammarus pulex	Copper chloride	35 d (semi-static, spiked sediment)	NOEC (survival)	NOEC = 27.04 mg/kg dry weight normalized to 2.5% OC
Hyalella azteca	Copper chloride	28 d (semi-static, spiked sediment)	NOEC (growth)	NOEC = 50.77 mg/kg dry weight normalized to 2.5% OC
Hexagenia spp.	Copper chloride	21 d (semi-static, spiked sediment)	NOEC (growth)	NOEC = 116.99 mg/kg dry weight normalized to 2.5% OC
Bellamya aeruginosa	Copper sulfate	21 d (continuous renewal, spiked sediment)	NOEC (fecundity)	NOEC = 48.34 mg/kg dry weight normalized to 2.5% OC
Algae				
S. capricornutum	**Copper hydroxide WP**	**72 h (static)**	Biomass: E_bC_{50} **Growth rate: E_rC_{50}**	0.00939 total (nom) **0.02229 total (nom)**
S. subspicatus	Copper oxychloride	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	49.81 total (mm) > 165.9 total (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity [a] (mg/L)
D. subspicatus	Bordeaux mixture WP	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{10} Growth rate: E_rC_{10}	0.64 mg /L total (nom) 11.55 mg /L total (nom) 0.07 mg /L total (nom) 5.54 mg /L total (nom)
P. subcapitata	Copper oxide WP	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.147 total (mm) 0.299 total (mm) 0.045 dissolved (mm) 0.133 dissolved (mm)
Microcosm or mesocosm tests				
Indoor microcosm study	**Copper hydroxide WP**	**6 applications at 10-d interval followed by 250 days of monitoring**	**NOEC**	0.012 total (nom) **0.0048 dissolved (mm)[b] (AF = 2 applied)**
Outdoor mesocosm study including fish	Copper sulfate	18 months (flow-through)	NOEC community	5 µg/L (total Cu) 4 µg/L (dissolved Cu)

Further testing on aquatic organisms

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

Fish, chronic (based on SSD analysis SSD-HC_5 = 0.00111 mg/L (AF = 43

Sediment dwelling organisms (based on toxicity dataset and due considerations of sediment properties) lowest available endpoint = 16.17 mg/kg normalized for 2.5% OC. Considering that data for 5 additionnal species are available (besides the tier 1 *Chrinomus riparius* and *Hyallela Azteca* species) an AF = 5 has been set.

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

No information highlights any ED property of copper.

[a] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

according to the study summary, this study was performed following the guideline OECD 202 and not according to the OECD 211. The full compliance to one of the validity criteria of the OECD 211 could not be confirmed from the information available in the RAR; it is reported that the cumulative number of offspring per female was >40 on day 21, according to the validity criteria the mean number of living offspring produced per parent animal surviving at the end of the test should be > 60. It is noted that in the study summary it is mentioned that this validity criteria cannot be accurately estimated with the test method that was followed.

* The dilution medium used in this study is the Elendt M4 medium which contains EDTA. This chelating agent is known to have an outcome on the biological resulst as it chelates metals such as copper. Therefore, the results from this study should not be used for the purpose of risk assessment.

** Study done in presence of sediment. According to the EFSA aquatic guidance in order to use thi study in the risk assessment a comparison with the predicted exposure scenaris should be performed to demonstrate that the exposure cover the worst case, a full comparison was not done, however, this estudy was not used in the risk assessment.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance
$logP_{O/W}$	-
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	A literature review provides evidence of lack of bioaccumulation
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-
Annex VI Trigger for the bioconcentration factor	-
Clearance time (days) (CT_{50})	-
(CT_{90})	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-
Higher tier study	
-	

* based on total ^{14}C or on specific compounds

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

NSZ: No-spray buffer zone

VBZ: Vegetative buffer zone

First and second-tier **$RAC_{sw;ac}$** value for **fish** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered);

Uses	Application pattern	Season of application	Region	Step 1 PECsw (µg/L)	RACsw; ac (= 0.34 µg/L) PEC>RAC	Step 2 PECsw (µg/L)	RACsw; ac (= 0.34 µg/L) PEC>RAC	SSD-RACsw; ac (= 1.24 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	Mar.-May	N	13.95	Yes	7.82	Yes	Yes
			S			7.82		
	7 x 850 g/ha (7 days)		N	97.63	Yes	9.47		
			S			17.9		
Vines, late applns.	1 x 1250 g/ha	Oct.-Feb.	N	42.46	Yes	33.45		
			S			33.45		
	3 x 1250 g/ha (7 days)		N	127.39	Yes	30.55		
			S			30.55		
	4 x 1250 g/ha (21 days)		N	169.86	Yes	30.27		
			S			30.27		
Vines, early applns.	1 x 1250 g/ha	Mar.-May	N	20.26	Yes	11.25		
			S			11.25		
	6*1250 (7 days)		N	121.56	Yes	12.61		
			S			23.27		

Greenhouse uses

Uses	**Growth Stage**	**Number of**	**Maximum**	**Buffer**	**Drift Rate From**	**PEC_{sw}**	**RACsw; ac (= 0.34 µg/L)**	**SSD-RACsw; ac (= 1.24 µg/L)**

		Applications	Application Rate		FOCUS ditch	[µg/L]	PEC>RAC	PEC>RAC
	BBCH	[-]	[g a.s. /ha]	[m]	[%]			
Tomatoes & Cucumbers	oct-89	1	1250	-	0.1	0.42	Yes	**No**
Tomatoes & Cucumbers	oct-89	1	6,000	-	0.1	2	Yes	Yes

* Values going beyond 95% mitigation are not included, also true for NSZ above 20 m

RMS underlines that it is not possible to consider unsprayed buffer zones higher than 20 m since such mitigations can exceed the trigger value of 95% mitigation.

First and second-tier **$RAC_{sw;ac}$** value for **fish** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered and the highest acceptable mitigation measure);

Uses	Application pattern	Scenario	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	RACsw; ac (= 0.34 µg/L) PEC>RAC	SSD-RACsw; ac (= 1.24 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	N	0.122	0.42	0.54	Yes	**No**
		S	0.245	0.42	0.66	Yes	**No**
	7 x 850 g/ha (7 days)	N	0.843	0.28	1.12	Yes	**No**
		S	1.687	0.28	1.97	Yes	Yes
Vines, late appl.	1 x 1250 g/ha	N	0.449	1.72	2.17	Yes	Yes
		S	0.36	1.72	2.08	Yes	Yes
	3 x 1250 g/ha (7 days)	N	1.329	1.51	2.84	Yes	Yes
		S	1.063	1.51	2.58	Yes	Yes
	4 x 1250 g/ha (21 days)	N	1.785	1.53	3.31	Yes	Yes
		S	1.428	1.53	2.95	Yes	Yes
Vines, early appli	1 x 1250	N	0.18	0.53	0.71	Yes	**No**

	g/ha	S	0.36	0.53	0.89	Yes	**No**
	6*1250	N	1.066	-*	-	-	-
	(7 days)	S	2.131	-*	-	-	-

* no reliable PECsw available since values going beyond 95% mitigation for drift exposure

Uses	Application pattern	Season of application	Region	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	RACsw; ac (= 0.34 µg/L) PEC>RAC	SSD-RACsw; ac (= 1.24 µg/L) PEC>RAC
Leafy vegetables	1 x 6000 g/ha	Mar.-May	N	0.863	0.42	1.28	Yes	Yes
			S	1.726	0.42	2.14	Yes	Yes
Vines	1 x 6000 g/ha	Oct.-Feb.	N	2.157	1.72	3.88	Yes	Yes
			S	1.726	1.72	3.45	Yes	Yes
	1 x 8000 g/ha		N	2.876	1.72	4.6	Yes	Yes
			S	2.301	1.72	4.02	Yes	Yes

First and second-tier **$RAC_{sw;ch}$** value for **fish** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered);

Uses	Application pattern	Season of application	Region	Step 1 PECsw (µg/L)	RACsw; ~~ac~~ech (= 0.112 µg/L) PEC>RAC SSD-RACsw; ac (= 0.37 µg/L) PEC>RAC	Step 2 PECsw (µg/L)	RACsw; ~~ac~~ech (= 0.112 µg/L) PEC>RAC	SSD-RACsw; ~~ac~~ech (= 0.37 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	Mar.-May	N	13.95	Yes	7.82	Yes	Yes
			S			7.82		

	7 x 850 g/ha (7 days)		N	97.63	Yes	9.47		
			S			17.9		
Vines, late applns.	1 x 1250 g/ha	Oct.-Feb.	N	42.46	Yes	33.45		
			S			33.45		
	3 x 1250 g/ha (7 days)		N	127.39	Yes	30.55		
			S			30.55		
	4 x 1250 g/ha (21 days)		N	169.86	Yes	30.27		
			S			30.27		
Vines, early applns.	1 x 1250 g/ha	Mar.-May	N	20.26	Yes	11.25		
			S			11.25		
	6*1250 (7 days)		N	121.56	Yes	12.61		
			S			23.27		

Greenhouse uses

Uses	**Growth Stage**	**Number of Applications**	**Maximum Application Rate**	**Buffer**	**Drift Rate From FOCUS ditch**	**PEC_{sw} [µg/L]**	**RACsw; ch (= 0.112 µg/L) PEC>RAC**	**SSD-RACsw; ch (= 0.37 µg/L) PEC>RAC**
	BBCH	**[-]**	**[g a.s. /ha]**	**[m]**	**[%]**			
Tomatoes & Cucumbers	oct-89	1	1250	-	0.1	0.42	Yes	Yes
Tomatoes & Cucumbers	oct-89	1	6,000	-	0.1	2	Yes	Yes

* Values going beyond 95% mitigation are not included, also true for NSZ above 20 m

RMS underlines that it is not possible to consider unsprayed buffer zones higher than 20 m since such mitigations can exceed the trigger value of 95% mitigation.

First and second-tier **$RAC_{sw;ch}$** value for **fish** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered and the highest acceptable mitigation measure);

Uses	Application	Scenario	PECsw Step 2,	PECsw	Total	RACsw;	SSD-

	pattern		Runoff/Drainage Including 90% reduction	Step 2, Drift Including NSZ 20 m	VBZ 20 m + NSZ 20m	ch (= 0.112 µg/L) PEC>RAC	RACsw; ch (= 0.37 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	N	0.122	0.42	0.54	Yes	Yes
		S	0.245	0.42	0.66	Yes	Yes
	7 x 850 g/ha (7 days)	N	0.843	0.28	1.12	Yes	Yes
		S	1.687	0.28	1.97	Yes	Yes
Vines, late appl.	1 x 1250 g/ha	N	0.449	1.72	2.17	Yes	Yes
		S	0.36	1.72	2.08	Yes	Yes
	3 x 1250 g/ha (7 days)	N	1.329	1.51	2.84	Yes	Yes
		S	1.063	1.51	2.58	Yes	Yes
	4 x 1250 g/ha (21 days)	N	1.785	1.53	3.31	Yes	Yes
		S	1.428	1.53	2.95	Yes	Yes
Vines, early appli	1 x 1250 g/ha	N	0.18	0.53	0.71	Yes	Yes
		S	0.36	0.53	0.89	Yes	Yes
	6*1250 (7 days)	N	1.066	-*	-	-	-
		S	2.131	-*	-	-	-

* no reliable PECsw available since values going beyond 95% mitigation for drift exposure

Uses	Application pattern	Season of application	Region	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	RACsw; ch (= 0.112 µg/L) PEC>RAC	SSD-RACsw; ch (= 0.37 µg/L) PEC>RAC
Leafy vegetables	1 x 6000 g/ha	Mar.-May	N	0.863	0.42	1.28	Yes	Yes
			S	1.726	0.42	2.14	Yes	Yes
Vines	1 x 6000 g/ha	Oct.-Feb.	N	2.157	1.72	3.88	Yes	Yes
			S	1.726	1.72	3.45	Yes	Yes

	1 x 8000 g/ha		N	2.876	1.72	4.6	Yes	Yes
			S	2.301	1.72	4.02	Yes	Yes

Refined **ETO-RAC$_{sw;ch}$** value for **aquatic invertebrates** and **algae** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered);

Uses	Application pattern	Season of application	Region	Step 1 PECsw (µg/L)	ETO-RACsw; ch (= 2.4 µg/L) PEC>RAC	Step 2 PECsw (µg/L)	ETO-RACsw; ch (= 2.4 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	Mar.-May	N	13.95	Yes	7.82	Yes
			S			7.82	
	7 x 850 g/ha (7 days)		N	97.63	Yes	9.47	
			S			17.9	
Vines, late applns.	1 x 1250 g/ha	Oct.-Feb.	N	42.46	Yes	33.45	
			S			33.45	
	3 x 1250 g/ha (7 days)		N	127.39	Yes	30.55	
			S			30.55	
	4 x 1250 g/ha (21 days)		N	169.86	Yes	30.27	
			S			30.27	
Vines, early applns.	1 x 1250 g/ha	Mar.-May	N	20.26	Yes	11.25	
			S			11.25	
	6*1250 (7 days)		N	121.56	Yes	12.61	
			S			23.27	

Greenhouse uses

Uses	**Growth Stage**	**Number of Applications**	**Maximum Application Rate**	**Buffer**	**Drift Rate From FOCUS ditch**	**PEC$_{sw}$ [µg/L]**	**ETO-RACsw ; ch (= 2.4 µg/L) PEC>RAC**

	BBCH	[-]	[g a.s. /ha]	[m]	[%]		
Tomatoes & Cucumbers	oct-89	1	1250	-	0.1	0.42	**No**
Tomatoes & Cucumbers	oct-89	1	6,000	-	0.1	2	**No**

Uses	Application pattern	Scenario	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	ETO-RACsw ; ch (= 2.4 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	N	0.122	0.42	0.54	**No**
		S	0.245	0.42	0.66	**No**
	7 x 850 g/ha (7 days)	N	0.843	0.28	1.12	**No**
		S	1.687	0.28	1.97	**No**
Vines, late appl.	1 x 1250 g/ha	N	0.449	1.72	2.17	**No**
		S	0.36	1.72	2.08	**No**
	3 x 1250 g/ha (7 days)	N	1.329	1.51	2.84	Yes
		S	1.063	1.51	2.58	Yes
	4 x 1250 g/ha (21 days)	N	1.785	1.53	3.31	Yes
		S	1.428	1.53	2.95	Yes
Vines, early appli	1 x 1250 g/ha	N	0.18	0.53	0.71	**No**
		S	0.36	0.53	0.89	**No**
	6*1250 (7 days)	N	1.066	-*	-	-
		S	2.131	-*	-	-

* no reliable PECsw available since values going beyond 95% mitigation for drift exposure

Uses	Application pattern	Season of application	Region	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	ETO-RACsw ; ch (= 2.4 µg/L) PEC>RAC
Leafy vegetables	1 x 6000 g/ha	Mar.-May	N	0.863	0.42	1.28	**No**
			S	1.726	0.42	2.14	**No**
Vines	1 x 6000 g/ha	Oct.-Feb.	N	2.157	1.72	3.88	Yes
			S	1.726	1.72	3.45	Yes
	1 x 8000 g/ha		N	2.876	1.72	4.6	Yes
			S	2.301	1.72	4.02	Yes

First-tier **$RAC_{sed;ch}$** value **sediment-dwelling organisms** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered);

Uses	Application pattern	Season of application	Region	Step 1 PECsw (µg/L)	RACsed ; ch (=50 µg/L) PEC>RAC	Step 2 PECsw (µg/L)	RACsed ; ch (=50 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	Mar.-May	N	13.95	**No**	-	**No**
			S			-	
	7 x 850 g/ha (7 days)		N	97.63	Yes	9.47	
			S			17.9	
Vines, late applns.	1 x 1250 g/ha	Oct.-Feb.	N	42.46	**No**	-	
			S			-	
	3 x 1250 g/ha (7 days)		N	127.39	Yes	30.55	
			S			30.55	
	4 x 1250 g/ha (21 days)		N	169.86	Yes	30.27	
			S			30.27	
Vines, early applns.	1 x 1250 g/ha	Mar.-May	N	20.26	**No**	-	
			S			-	

	6*1250 (7 days)		N	121.56	Yes	12.61	
			S			23.27	

Greenhouse uses

Uses	**Growth Stage**	**Number of Applications**	**Maximum Application Rate**	**Buffer**	**Drift Rate From FOCUS ditch**	**PEC_{sw} [µg/L]**	RACsed ; ch (=50 µg/L) PEC>RAC
	BBCH	**[-]**	**[g a.s. /ha]**	**[m]**	**[%]**		
Tomatoes & Cucumbers	oct-89	1	1250	-	0.1	0.42	**No**
Tomatoes & Cucumbers	oct-89	1	6,000	-	0.1	2	**No**

* Values going beyond 95% mitigation are not included, also true for NSZ above 20 m

RMS underlines that it is not possible to consider unsprayed buffer zones higher than 20 m since such mitigations can exceed the trigger value of 95% mitigation.

First-tier **$RAC_{sed;ch}$** value **sediment-dwelling organisms** for copper compared to relevant maximum PECsw values for Copper at Step 1 and Step 2 (All entry routes to water bodies considered and the highest acceptable mitigation measure);

Uses	Application pattern	Scenario	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	RACsed ; ch (=50 µg/L) PEC>RAC
Leafy vegetables	1 x 850 g/ha	N	0.122	0.42	0.54	**No**
		S	0.245	0.42	0.66	**No**
	7 x 850 g/ha (7 days)	N	0.843	0.28	1.12	**No**
		S	1.687	0.28	1.97	**No**
Vines, late appl.	1 x 1250	N	0.449	1.72	2.17	**No**

	g/ha	S	0.36	1.72	2.08	**No**
	3 x 1250 g/ha (7 days)	N	1.329	1.51	2.84	**No**
		S	1.063	1.51	2.58	**No**
	4 x 1250 g/ha (21 days)	N	1.785	1.53	3.31	**No**
		S	1.428	1.53	2.95	**No**
Vines, early appli	1 x 1250 g/ha	N	0.18	0.53	0.71	**No**
		S	0.36	0.53	0.89	**No**
	6*1250 (7 days)	N	1.066	-*	-	-
		S	2.131	-*	-	-

* no reliable PECsw available since values going beyond 95% mitigation for drift exposure

Uses	Application pattern	Season of application	Region	PECsw Step 2, Runoff/Drainage Including 90% reduction	PECsw Step 2, Drift Including NSZ 20 m	Total VBZ 20 m + NSZ 20m	RACsed ; ch (=50 µg/L) PEC>RAC
Leafy vegetables	1 x 6000 g/ha	Mar.-May	N	0.863	0.42	1.28	**No**
			S	1.726	0.42	2.14	**No**
Vines	1 x 6000 g/ha	Oct.-Feb.	N	2.157	1.72	3.88	**No**
			S	1.726	1.72	3.45	**No**
	1 x 8000 g/ha		N	2.876	1.72	4.6	**No**
			S	2.301	1.72	4.02	**No**

First-tier and refined **$RAC_{sed;ch}$** value **sediment-dwelling organisms** for copper compared to relevant PEC_{sed} values via drift exposure, with copper background level

Crop	**Growth Stage** **BBCH**	**Maximum Application Rate** **[g a.s. /ha]**	**Buffer** **[m]**	**$PEC_{sed,\ accumulation\ Total\ copper}$** (10 years accumulation) + background level **[mg/kg]**	RACsed ; ch (= 1.62 mg/kg) Total copper; PEC>RAC	RACsed ; ch (= 3.23 mg/kg) Total copper; PEC>RAC
Tomatoes & Cucumbers Outdoor uses	oct-89	850	Step 3	19.1	Yes	Yes
			5 m	17.6	Yes	Yes
			10 m	17.3	Yes	Yes
			20 m	17.1	Yes	Yes
			50 m	17.1	Yes	Yes
Tomatoes & Cucumbers Outdoor uses	oct-89	6000 *	Step 3	25.3	Yes	Yes
			5 m	19.2	Yes	Yes
			10 m	18.2	Yes	Yes
			20 m	17.6	Yes	Yes
			50 m	17.3	Yes	Yes
Tomatoes & Cucumbers Indoor uses	oct-89	1250	-	17.2	Yes	Yes
Tomatoes & Cucumbers Indoor uses	oct-89	6000 *	-	17.8	Yes	Yes
Vines (Late)		1250	Step 3	25.1	Yes	Yes

			5 m	21.9	Yes	Yes
			10 m	18.8	Yes	Yes
			20 m	17.6	Yes	Yes
			50 m	17.2	Yes	Yes
Vines (Late)		6000	Step 3	49.0	Yes	Yes
			5 m	36.3	Yes	Yes
			10 m	23.9	Yes	Yes
			20 m	19.4	Yes	Yes
			50 m	17.6	Yes	Yes
Vines (Early)		1250	Step 3	19.7	Yes	Yes
			5 m	18.6	Yes	Yes
			10 m	17.6	Yes	Yes
			20 m	17.2	Yes	Yes
			50 m	17.0	Yes	Yes
Vines (Early)		6000	Step 3	28.8	Yes	Yes
			5 m	23.8	Yes	Yes
			10 m	19.2	Yes	Yes
			20 m	17.7	Yes	Yes
			50 m	17.1	Yes	Yes

* Conservative approach; no dissipation considered between applications

First-tier and refined **$RAC_{sed;ch}$** value **sediment-dwelling organisms** for copper compared to relevant $PEC_{sed,\ accumulation}$ values for run-off/drainage exposure (Step 2, Koc = 10000 mL/g), with copper background level.

	Scenario	**Step 2**				
		Total copper (10 years background level)	**Mitigation applied: 80%**	**Mitigation applied: 90%**	RACsed ; ch (= 1.62 mg/kg) Total copper; PEC>RAC	RACsed ; ch (= 3.23 mg/kg) Total copper; PEC>RAC

		PECsed, accu (mg/kg)				
Outdoor uses no interception, 1 * 850 g/ha; early application; march-may	N	21.0	17.8	17.4	Yes	Yes
	S	24.9	18.6	17.8	Yes	Yes
Outdoor uses no interception, 1 * 850 g/ha; late application; June-Sep	N	21.0	17.8	17.4	Yes	Yes
	S	22.9	18.2	17.6	Yes	Yes
Outdoor uses no interception, 1 * 1250 g/ha; early application; Octo-Feb	N	31.6	19.9	18.5	Yes	Yes
	S	28.7	19.3	18.2	Yes	Yes
Outdoor uses no interception, 1 * 1250 g/ha; late application; June-Sept	N	22.8	18.2	17.6	Yes	Yes
	S	25.7	18.7	17.9	Yes	Yes
Outdoor uses no interception, 1 * 6000 g/ha; early application; Octo-Feb	N	86.9	31.0	24.0	Yes	Yes
	S	72.9	28.2	22.6	Yes	Yes
Outdoor uses no interception, 1 * 6000 g/ha; late application; June-Sept	N	45.0	22.6	19.8	Yes	Yes
	S	59.0	25.4	21.2	Yes	Yes

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	Copper hydroxide technical	Acute	Contact toxicity (LD_{50})	**44.46 µg/bee**
Apis mellifera	Copper hydroxide WP	Acute	Oral toxicity (LD_{50}) Contact toxicity (LD_{50})	**49.0 µg/bee** >57 µg/bee
Apis mellifera	Copper oxychloride	Acute	Oral toxicity (LD_{50}) Contact toxicity (LD_{50})	**12.1 µg/bee** **44.3 µg/bee**
Apis mellifera	Bordeaux mixture WP	Acute	Oral toxicity (LD_{50}) Contact toxicity (LD_{50})	**23.3 µg/bee** **>25.2 µg/bee**
Apis mellifera	Tribasic copper sulfate SC	Acute	Oral toxicity (LD_{50}) Contact toxicity (LD_{50})	**40 µg/bee** **>23.5 µg/bee**
Apis mellifera	Copper oxide technical	Acute	Contact toxicity (LD_{50})	>22.0 µg/bee
Apis mellifera	Copper oxide WG	Acute	Oral toxicity (LD_{50})	**>116.0 µg/bee**
Apis mellifera	Copper oxide WG	Acute	Contact toxicity (LD_{50})	**>82.5 µg/bee**
Field or semi-field tests: Two outdoor cages were performed with Copper Oxychloride WP and Bordeaux mixture WP. No significant effects at rates up to 1.25 kg a.s/ha Tunnel test performed with Copper Oxychloride WP on phacelia– single application of 2.5 kg a.s./ha. a Statistically significant reduction is observed on flight intensity at t rate of 2.5 kg a.s/ha.				

Risk assessment for vineyards at 1250 g a.s./ha [1 application] (worst-case scenario)

Species	Test substance	Risk quotient	HQ	Trigger
Apis mellifera	Copper hydroxide	Oral	26	50

Species	Test substance	Risk quotient	HQ	Trigger
Apis mellifera	Copper oxychloride	Oral	**103**	50
Apis mellifera	Bordeaux mixture	Oral	**54**	50
Apis mellifera	Tribasic copper sulfate	Oral	31	50
Apis mellifera	Copper oxide	Oral	< 11	50
Apis mellifera	Copper hydroxide	Contact	28	50
Apis mellifera	Copper oxychloride	Contact	28	50
Apis mellifera	Bordeaux mixture	Contact	**< 50**	50
Apis mellifera	Tribasic copper sulfate	Contact	**< 53**	50
Apis mellifera	Copper oxide	Contact	< 15	50

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity (LR_{50} kgCu/ha)
Aphidius rhopalosiphi	Copper hydroxide WP	Mortality	**0.05**
	Bordeaux Mixture	Mortality	> **14.7**
	Tribasic copper sulfate	Mortality	> **0.1344**
	Copper oxide	Mortality	**39.2**
Typhlodromus pyri	Copper hydroxide	Mortality	> **14.88**
	Copper oxychloride	Mortality	> **14.89**
	Bordeaux Mixture	Mortality	> **13.2**
	Tribasic copper sulfate	Mortality	> **0.08**
	Copper oxide	Mortality	> **26.1**

First tier risk assessment based on laboratory tests

Test substance	Species	Effect (LR_{50} kgCu/ha)	HQ in-field	HQ off-field[1]	Trigger
Copper hydroxide					
Using a MAF foliar					
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*A. rhopalosiphi*	0.05	**87.5**	**5.77**	2
	T. pyri	>14.88	< 0.29	< 0.02	2
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*A. rhopalosiphi*	0.05	**87.5**	-	2
	T. pyri	>14.88	< 0.29	-	2
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	0.05	**59.5**	**3.72**	2
	T. pyri	>14.88	< 0.20	< 0.01	2
Using a MAFsoil (MAFsoil = 1)*					
Vines (downy mildew) –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	0.05	**80**	**6.42**	2
	T. pyri	>14.88	<0.27	<0.02	2
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*A. rhopalosiphi*	0.05	**120**	-	2
	T. pyri	>14.88	<0.40	-	2
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	0.05	**120**	**9.62**	2
	T. pyri	>14.88	<0.40	<0.03	2
Copper oxychloride					
Using a MAF foliar					
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*T. pyri*	>14.89	< 0.29	< 0.02	2
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*T. pyri*	>14.89	< 0.29	-	2
Tomatoes/cucurbits – 0.85 kgCu/ha (glasshouse), 8 applications	*T. pyri*	>14.89	< 0.20	< 0.01	2
Using a MAFsoil (MAFsoil = 1)*					
Vines (downy mildew) –8 kg Cu/ha, 1 application.	*T. pyri*	>14.89	<0.27	<0.02	2
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*T. pyri*	>14.89	<0.534	-	2
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*T. pyri*	14.89	<0.40	<0.03	2
Bordeaux Mixture					
Using a MAFfoliar					

Test substance	Species	Effect (LR_{50} kgCu/ha)	HQ in-field	HQ off-field[1]	Trigger
Vines (downy mildew) – 1.25 kgCu/ha, , 8 applications	*A. rhopalosiphi*	>14.7	< 0.29	< 0.02	2
	T. pyri	>13.2	< 0.33	< 0.02	2
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), , 8 applications	*A. rhopalosiphi*	>14.7	< 0.29	-	2
	T. pyri	>13.2	< 0.33	-	2
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	>14.7	< 0.20	< 0.01	2
	T. pyri	>13.2	< 0.22	< 0.01	2
Using a MAFsoil (MAFsoil = 1)*					
Vines (downy mildew) –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>14.7	< 0.27	<0.02	2
	T. pyri	>13.2	<0.30	< 0.02	2
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>14.7	<0.54	-	2
	T. pyri	>13.2	<0.61	-	2
Tomatoes/cucurbits – 8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>14.7	<0.41	<0.03	2
	T. pyri	>13.2	<0.45	<0.04	2
Tribasic copper sulfate					
Using a MAFfoliar					
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*A. rhopalosiphi*	>0.1344	**< 32.55**	**< 2.04**	2
	T. pyri	>0.08	**< 54.68**	**< 3.425**	2
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*A. rhopalosiphi*	>0.1344	**< 32.55**	-	2
	T. pyri	>0.08	**< 54.68**	-	2
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	>0.1344	**< 22.14**	< 1.38	2
	T. pyri	>0.08	**< 37.19**	**< 2.32**	2
Using a MAFsoil (MAFsoil = 1)*					
Vines (downy mildew) –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>0.1344	**< 29.76**	**<2.39**	2
	T. pyri	>0.08	**<50**	**<4.01**	2
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>0.1344	**<59.52**	-	2
	T. pyri	>0.08	**<100**	-	2
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>0.1344	**<44.64**	**<3.58**	2
	T. pyri	>0.08	**<75**	**<6.02**	2
Copper oxide					
Using a MAFfoliar					
Vines (downy	*A. rhopalosiphi*	>39.2	< 0.11	< 0.01	2

Test substance	Species	Effect (LR_{50} kgCu/ha)	HQ in-field	HQ off-field[1]	Trigger
mildew) – 1.25 kgCu/ha, 8 applications	*T. pyri*	>26.1	< 0.17	< 0.01	2
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*A. rhopalosiphi*	>39.2	< 0.11	-	2
	T. pyri	>26.1	< 0.17	-	2
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	>39.2	< 0.07	< 0.01	2
	T. pyri	>26.1	< 0.11	< 0.01	2
Using a MAFsoil (MAFsoil = 1)*					
Vines (downy mildew) –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>39.2	<0.10	<0.01	2
	T. pyri	>26.1	<0.15	<0.01	2
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>39.2	<0.20	-	2
	T. pyri	>26.1	<0.31	-	2
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	>39.2	<0.15	< 0.01	2
	T. pyri	>26.1	<0.23	<0.02	2

[1] distance assumed to calculate the drift rate: 3 m

* During the ecotox expert meeting it was suggested that for soil the total amount applied in the season should be used since it cannot be ensured that dissipation occur between applications. The experts agreed to use the total amount applied in the year in the risk assessment for soil NTA.

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (kg Cu/ha)	End point	% effect[2]	Trigger value
T. cacoeciae	adults	Copper hydroxide WP	0.59	parasitisation	6.4	50 %
T. cacoeciae	adults	Copper oxychloride WP	2.02	parasitisation	- 42.9	50 %
D. rapae	adults	Copper hydroxide WP	0.59	mortality parasitisation	14.8 52.5	50 %
P. cupreus	adults	Copper hydroxide WP	0.59	mortality predation	0 8.0	50 %
P. amentata	adults	Tribasic copper sulfate SC	0.0202 0.2688	mortality predation	2.9 4.39	50 %
C. carnea	larvae	Copper hydroxide WP	0.56	mortality fecundity	55.6 71.1	50 %
C. 7-punctata	larvae	Copper oxychloride WP	0.58	mortality fecundity	17.5 - 149	50 %
C. 7-punctata	larvae	Tribasic copper sulfate SC	0.0067 0.1344	mortality fecundity	20.88 43.8	50 %
A. rhopalosiphi	adults	Copper hydroxide WP	**3.213**	Mortality fecundity	10 -7.4	50 %

Species	Life stage	Test substance, substrate and duration	Dose (kg Cu/ha)	End point	% effect[2]	Trigger value
A. rhopalosiphi	adults	Copper oxychloride WP (3D study)	1.0 **3.97** 1.0 **3.97**	mortality parasitisation	0 0 - 22.38 10.89	50 %
A. rhopalosiphi	adults	Tribasic copper sulfate	0.00154 0.00768 0.0384 0.192 **0.960** 0.00154 0.00768 0.0384 0.192 **0.960**	mortality parasitisation	0.0 2.5 2.5 5.0 2.5 - 29.8 - 72.6 - 40.4 - 13.8 30.5	50 %
T. pyri	protonymphs	Copper hydroxide WP	**3.213**	mortality fecundity	-7.4 16.9	50 %
T. pyri	protonymphs	Tribasic copper sulfate SC	0.015 0.06 0.25 1.01 **4.032** 0.015 0.06 0.25 1.01 **4.032**	mortality fecundity	1.8 3.5 13.9 3.5 0.0 - 7.3 - 17.1 - 11.0 12.2 31.7	50 %
C. carnea	larvae	Copper hydroxyde WP	**1.922**	Mortality fecundity	12.5 0	50 %
C. carnea	larvae	Copper oxychloride WP	0.5 1 2 4 **8** 0.5 1 2 4 **8**	mortality fecundity	4.8 21.4 11.9 23.8 40.5 1.7 16.7 7.9 15.3 6.7	50 %

[2] positive percentages relate to adverse effects

Risk assessment for – [representative use] at [application rate] g a.s./ha [x number of applications] based on extended lab test

Test substance and GAP	Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Copper hydroxyde				
Using a MAFfoliar				

Test substance and GAP	Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*A. rhopalosiphi*	3.268	2.1875	0.068
	T. pyri	3.268	2.1875	0.068
	Chrysoperla carnea	1.9224	**2.1875**	0.068
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*A. rhopalosiphi*	3.268	**4.375**	-
	T. pyri	3.268	**4.375**	-
	Chrysoperla carnea	1.9224	**4.375**	-
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	3.268	2.975	0.093
	T. pyri	3.268	2.975	0.093
	Chrysoperla carnea	1.9224	**2.975**	0.093
Using a MAFsoil (MAFsoil = 1)*				
Vines (downy mildew) –4 kg Cu/ha, 1 application.	*A. rhopalosiphi*	3.268	**4**	0.321
	T. pyri	3.268	**4**	0.321
	Chrysoperla carnea	1.9224	**4**	0.321
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*A. rhopalosiphi*	3.268	**6**	-
	T. pyri	3.268	**6**	-
	Chrysoperla carnea	1.9224	**6**	-
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*A. rhopalosiphi*	3.268	**8**	0.481
	T. pyri	3.268	**8**	0.481
	Chrysoperla carnea	1.9224	**8**	0.481
Copper oxychloride				
Using a MAF foliar				
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*A. rhopalosiphi*	3.97	2.1875	0.068
	Chrysoperla carnea	8	2.1875	0.068
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*A. rhopalosiphi*	3.97	**4.375**	-
	Chrysoperla carnea	8	4.375	-

Test substance and GAP	Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*A. rhopalosiphi*	3.97	2.975	0.093
	Chrysoperla carnea	8	2.975	0.093
Using a MAFsoil (MAFsoil = 1)*				
Vines (downy mildew) 4 kg Cu/ha, 1 application.	*A. rhopalosiphi (3D)*	3.97	**4**	0.321
	Chrysoperla carnea	8	4	0.321
Tomatoes/cucurbits – 6 kg Cu/ha, 1 application.	*A. rhopalosiphi (3D)*	3.97	**6**	-
	Chrysoperla carnea	8	6	-
Tomatoes/cucurbits –8 kg Cu/ha, 1 application.	*A. rhopalosiphi (3D)*	3.97	**8**	~~0.117~~ 0.481
	Chrysoperla carnea	8	**8**	~~0.117~~ 0.481
Tribasic copper sulfate				
Using a MAF foliar				
Vines (downy mildew) – 1.25 kgCu/ha, 8 applications	*Typhlodromus pyri*	4.032	2.1875	0.068
	Aphidius rhopalosiphi	0.96	**2.1875**	0.068
Tomatoes/cucurbits – 1.25 kgCu/ha (glasshouse), 8 applications	*Typhlodromus pyri*	4.032	**4.375**	-
	Aphidius rhopalosiphi	0.96	**4.375**	-
Tomatoes/cucurbits – 0.85 kgCu/ha, 8 applications	*Typhlodromus pyri*	4.032	**2.975**	0.093
	Aphidius rhopalosiphi	0.96	**2.975**	0.093
Using a MAFsoil (MAFsoil = 1)*				
Vines (downy mildew) –4 kg Cu/ha, 1 application.	*Typhlodromus pyri*	4.032	**4**	0.321
	Aphidius rhopalosiphi	0.96	4	0.321
Tomatoes/cucurbits –6 kg Cu/ha, 1 application.	*Typhlodromus pyri*	4.032	**6**	-
	Aphidius rhopalosiphi	0.96	**6**	-
Tomatoes/cucurbits 8 kg Cu/ha, 1 application.	*Typhlodromus pyri*	4.032	**8**	0.481
	Aphidius rhopalosiphi	0.96	**8**	0.481

[1]indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field or field tests
Not required

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity (mg Cu/kg soil) [1]
Earthworms					
Eisenia fetida	Copper oxychloride	OECD soil	Chronic 56 days	Reproduction	$NOEC_{r(cp)}$ < 40.5
Eisenia andrei	Copper chloride	LUFA: 3.9% OECD: 10%	Chronic 28 days	Reproduction	**$NOEC_{r(cp)}$ = 8.4 (LUFA 2.2 soil)** $NOEC_{r(cp)}$ = 103.2 (OECD soil) $NOEC_{r(jp)}$ = 103.2 (OECD soil)
Eisenia fetida	Copper chloride	10%	Chronic 28 days	Reproduction	$NOEC_{r(cp)}$ = 13.2 (OECD soil) $NOEC_{r(jp)}$ = 35.2 (OECD soil) and 37.2 (LUFA 2.2 soil)
Eisenia fetida	Copper chloride	4.7%	Chronic 21 days	Reproduction, growth	$NOEC_g$ = 715 $NOEC_r$ = 115
Eisenia fetida	Cu oxychloride	10%	Chronic 28 days	Reproduction	$NOEC_{r(cp)}$ = 83.2
Eisenia fetida	$Cu(NO_3)_2.3H_2O$	10%	Chronic 28 days	Reproduction	$NOEC_{r(cp)}$ = 28.2
Eisenia fetida	Copper nitrate	10%	Chronic 56 days	Mortality, reproduction	LC_{50} = 555 $NOEC_m$ = 202.4 EC_{50} (cocoons) = 53.3 $NOEC_{r(cp)}$ = 12.4
Eisenia fetida	Copper nitrate	10%	Chronic 21 days	Growth, reproduction, mortality	$NOEC_{r(cp)}$ = 32.3 $NOEC_g$ = 728.2 $NOEC_m$ = 296.2
Eisenia fetida	Cu acetate		Chronic 28 days	Mortality	LC_{50} = 82.8 – 3717
Eisenia fetida	$CuCl_2$	-	Chronic 21 days	Growth, mortality	NOEC=300 (mortality and growth)
Eisenia fetida	Copper chloride	-	Chronic 28 days	Reproduction	$EC_{10,r}$ = 54 – 324 (17 values for different soil types)
Eisenia andrei	Unknown	3.7%	Chronic 28 days	Reproduction	$EC_{10,r}$ = 159
Eisenia andrei	Copper chloride	0.5%	Chronic 28 days	Reproduction, mortality	$NOEC_m$ = 192 $NOEC_r$ = 192

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity (mg Cu/kg soil) [1]
Eisenia andrei	Copper salt	10%	Chronic 84 days	Growth	$NOEC_g$ = 59.2
Eisenia andrei	Copper chloride	10%	Chronic 28 days	Reproduction	$NOEC_{r(cp)}$ = 123.2
Eisenia andrei	Copper chloride	10%	Chronic 84 days	Growth	EC_{50} > 100 $NOEC_g$ = 62
Lumbricus rubellus	Copper chloride	-	Chronic 84 days	Mortality	$NOEC_m$ = 162
Lumbricus rubellus	Copper chloride	3.4-5.7%	Chronic 42 days	Growth, reproduction, mortality	$NOEC_r$ = 54 $NOEC_{lb}$ = 54 $NOEC_g$ = 131 $NOEC_m$ = 131 $NOEC_{lb}$ = 63 $NOEC_m$ = 136
Lumbricus rubellus	Copper chloride	9.8%	Chronic 294 days	Growth	$NOEC_g$ = 154
Lumbricus rubellus	Copper chloride	0.5%	Chronic 110 days	Growth, mortality	$NOEC_g$ = 76 $NOEC_m$ = 153
Allobophora calliginosa (=*Aporrectodea caliginosa*)	Copper sulfate	-	Chronic 14 days	Mortality, reproduction	$NOEC_m$ = 511 $NOEC_{r(cp)}$ = 60.7
Aporrectodea caliginosa	Copper sulfate	21.6%	Chronic 42 and 56 days	Growth, reproduction	$NOEC_g$ = 35.7 $NOEC_{r(cp)}$ = 80.7
Dendrobaena rubida	Copper nitrate	7.7-11.7%	Chronic 90 days	Reproduction	$NOEC_{r(cp)}$ = 100 (pH 5.5) and 101.3 (pH 6.5)
Dendrobaena rubida	Copper nitrate	7.7-11.7%	Chronic 120 days	Reproduction	4 month-NOEC (cocoon reduction) = 100
Octalasium cyaneum	Copper sulfate	5.4-72%	Chronic 14 and 30 days	Mortality	30 d – $NOEC_m$ =153 14 d – $NOEC_m$ =1214
Other soil macroorganisms					

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity (mg Cu/kg soil) [1]
Enchytraeidae (Oligochaeta, Annelida)					
Cognettia sphagnetorum	Copper chloride	66%	70 days	Growth	35-day $EC_{10, g}$ = 73.7 63-day $EC_{10, g}$ = 451.7 42-day $EC_{10, g}$ = 322.7 70-day $EC_{10, f}$ = 465.7
E. albidus	Copper chloride	5.5%	42 days	Mortality, growth, reproduction	$EC_{10, m}$ = 347 $EC_{10, r}$ = 71 $EC_{10, a}$ = 362 $NOEC_m$ = 430 $NOEC_r$ = 230 $NOEC_a$ = 230
E. albidus	Copper chloride	3.6%	42 days	Mortality, growth, reproduction	$EC_{10, r}$ (soil 1) = 355 $EC_{10, r}$ (soil 2) = 107 $EC_{10, r}$ (soil 3) = 72 $EC_{10, r}$ (soil 4) = 119 $EC_{10, r}$ (soil 5) = 399 $EC_{10, r}$ (soil 6) = 241 NOEC in field transects: 418 to ≥ 689
E. crypticus	Copper chloride	3.9%	56 days	Reproduction	EC_{50} (reprod., 11°C) ≈ 70 EC_{50} (reprod., 18°C) ≈ 160 EC_{50} (reprod., 25°C) ≈ 180
E. crypticus	Copper chloride	4.6%	21 days	Reproduction	$EC_{10, r}$ = 126.5 $NOEC_r$ = 135
E. crypticus	Copper chloride	3.9%	63 days	Reproduction	21-day $EC_{10, r}$ = 180.2 63-day $EC_{10, r}$ = 90.2
E. crypticus	Copper chloride	3%	Not reported	Reproduction, mortality	$EC_{10, r}$ = 55 $EC_{10, m}$ = 62
Collembola (Hexapoda, Arthropoda)					

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity (mg Cu/kg soil) [1]
Folsomia candida	Copper chloride	1.4-37%	28 days	Reproduction	**$EC_{10, r}$ = 31** – 1460 (21 values for different soil types)
Folsomia candida	Copper nitrate	-	28 days	Reproduction, mortality	$EC_{50, r}$ (pH 6.0)= 703.2 $NOEC_r$ (pH 6.0)= 203.2 $NOEC_m$ (pH 6.0)= ≥3003.2 $EC_{50, r}$ (pH 5.0) = 713.2 $NOEC_r$ (pH 5.0) = 203.2 $NOEC_m$ (pH 5.0) = 43.2 $EC_{50, r}$ (pH 4.5) = 1483.2 $NOEC_r$ (pH 4.5) = 1003.2 $NOEC_m$ (pH 4.5) = ≥3003.2
Folsomia candida	Copper chloride	10%	42 days	Reproduction, mortality	$NOEC_r$ = 203.2 $NOEC_m$ = 1003.2
Folsomia candida	Copper chloride	10%	28 days		$NOEC_{ri}$ = 803.2
Folsomia candida	Copper chloride	-	21 or 56 days	Growth, reproduction	21-day $NOEC_g$ (LUFA 2.2) = 205.2 21-day $NOEC_r$ (LUFA 2.2) = 405.2 56-day $NOEC_g$ (OECD) = 803.2 56-day $NOEC_r$ (OECD) = 403.2
Folsomia candida	Copper chloride	3%	Not reported	Reproduction	$EC_{10, r}$ = 212 NOEC = 320
Folsomia fimetaria	Copper chloride	3.9%	21 days	Growth, reproduction, mortality	14-day $EC_{10, r}$ = 43* 21-day $EC_{10, r}$ = 61* 21-day $EC_{10, g}$ (male) = 850 21-day $EC_{10, g}$ (female) = 547 21-day $EC_{10, g}$ (juvenile) = 532 21-day $NOEC_m$ (male and female) ≥ 1005 21-day $EC_{10, m}$ (juvenile) = 883

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity (mg Cu/kg soil) [1]
Folsomia fimetaria	Copper chloride	4.7%	21 days	Growth, reproduction, mortality	$EC_{10, m}$ (overall) = 828 $EC_{10, m}$ (female) = 519 $EC_{10, m}$ (male) = 771 $EC_{10, g}$ (overall) = 1090 $EC_{10, g}$ (overall) = 997 $EC_{10, g}$ (overall) = 1242 $EC_{10, r}$ = 352 EC_{10} > 2911 (high background - historical Cu contaminated site)
Folsomia fimetaria	Copper sulfate	4.5%	21 days	Reproduction	$EC_{10, r}$ = 141
Folsomia fimetaria	Copper sulfate	4.5%	21 days	Reproduction	$EC_{10, r}$ = 667
Isotoma viridis	Copper chloride	3.9%	56 days	Growth	$NOEC_g$ (LUFA 2.2) = 55.2 $NOEC_g$ (OECD) = 403
Isopoda (Crustacea, Arthropoda)					
Porcellio scaber	Copper chloride	-	4 and 8 weeks	Growth	8-week LC_{50} = 2880 4-week $EC_{10, g}$ (body mass gain) = 349
Acari (Arachnica, Arthropoda)					
Platynothrus peltifer	Copper nitrate	3.9	90 days	Growth, Mortality and reproduction	$NOEC_m \geq 1498$ $NOEC_g$ = 598 $NOEC_r$ = 168
Platynothrus peltifer	Copper chloride	3.9	70 days	Reproduction	$NOEC_r$ = 68.2
Hypoaspis aculeifer	Copper chloride	3.9	21 days	Reproduction	**EC_{10} = 179**
Hypoaspis aculeifer	Copper chloride	3.0	Not reported	Reproduction	$EC_{10, r}$ = 2* $NOEC_r$ = 320
Nematoda (Nematoda)					
Plectus acuminatus	Copper chloride	-	21 days	Reproduction	$EC_{50, r(jp)}$ = 165.2 $NOEC_{r(jp)}$ = 35.2

* EC_{10} below lowest dose tested and therefore not considered reliable (OECD, 2006[13])

[1] $NOEC_{r(cp)=}$NOEC reproduction based on cocoons production; $NOEC_{r(jp)=}$ NOEC reproduction based on juveniles production; $NOEC_{g=}$ NOEC based on growth; $NOEC_{m=}$ NOEC based on mortality; $NOEC_{lb=}$ NOEC based on litter breakdown; $EC_{10, f=}$ EC10 based on fragmentation; $EC_{10, a=}$ EC10 based on avoidance

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Higher tier testing (e.g. modelling or field studies)
Earthworms Field study - A field study on earthworm populations has been conducted over 10 years on grassland, with copper applications every year. After 10 years of treatment with copper the NOAEC of the study is the dose rate 4 kg copper/ha/year.

Soil micro-organisms

Nitrogen transformation	Copper hydroxide WP	no effect at day 62 at 12.5 kg Cu/ha
	Copper oxychloride WP	no effect at day 28 at 12.4 kg Cu/ha
	Copper oxychloride WP	no effect at day 28 at 18.1 kg Cu/ha
	Bordeaux mixture WP	no effect at day 28 at 20.0 kg Cu/ha
	Tribasic copper sulfate SC	no effect at day 28 at 11.6 kg Cu/ha
	Copper oxide WP	no effect at day 28 at 15.0 kg Cu/ha
Field studies		
A multi-field site study was carried out in three sites in France. Up to four months after treatment with Copper Hydroxide WP (8 x 2 kg Cu/ha and 48 kg Cu/ha) there were no effects on the CO_2 evolution and nitrogen mineralization. There was no either evidence of significant effects on evolved CO_2 and nitrogen nitrification after a 28-day incubation in the presence of ground vine leaves, based on soils contaminated with Copper Hydroxide WP at 16 kg and 48 kg Cu/ha.		

Toxicity/exposure ratios for soil organisms

[Representative use] at [application rate] g a.s./ha [x number of applications]

Test organism	Crop and application rate	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia andrei	Vineyards	Chronic	240	**0.035**	5
Eisenia andrei	Tomatoes/Cucurbits	Chronic	54	**0.156**	5
Other soil macroorganisms					
Folsomia candida	Vineyards	Chronic	240	**0.13**	5
Folsomia candida	Tomatoes/Cucurbits	Chronic	54	**0.57**	5
Hypoaspis aculeifer	Vineyards	Chronic	240	**0.75**	5
Hypoaspis aculeifer	Tomatoes/Cucurbits	Chronic	54	**3.31**	5

[1]PEC accumulation. These PECsoil are representative for added copper for a time period of 10 years considering a range of different background values through two values derived for European arable soils (90th percentile values).

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER_{50} tests should be provided

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
6 specie	5 different copper-based test item	**>2 000**	-	-Vineyard: 100.25 g a.s./ha (3 m distance, late application (8.02%)) -Tomatoes/cucurbits: 34.625 g a.s./ha (1m distance (2.77%)	>19.9 >57.8	5
Extended laboratory studies :- Semi-field and field test:-						

[1] exposure has been estimated with Ganzelmeier drift data
[2] dose is expressed in units of a.s.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	EC_{50} = 43 mg Cu/L (Copper hydroxide)
Activated sludge	EC_{50} = 269 mg Cu/L (Copper oxychloride)
Activated sludge	EC_{50} = 337 mg Cu/L (Bordeaux Mixture)
Activated sludge	EC_{50} > 15.5 mg Cu/L (Tribasic copper sulfate)
Activated sludge	EC_{50} = 157 mg Cu/L (Copper oxide)
Pseudomonas sp	No study submitted

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.

Earthworm's field studies were submitted. Those studies give indication of an effect of copper content in soil on earthworm species abundance and diversity especially for endogeic earthworm's specie, such as *Aporrectodea caliginosa* for soils with total copper content > 100 mg Cu/kg d.w.

Available monitoring data concerning effect of the PPP.

None

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Total copper
water	Total and dissolved copper
sediment	Total copper
groundwater	Dissolved copper

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Copper hydroxyde
Harmonised classification according to Regulation (EC) No 1272/2008[14] and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] [15]:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 10) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 10)
Peer review proposal[16] for harmonised classification according to Regulation (EC) No 1272/2008:	

Substance	Copper oxychloride
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 10) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 10)
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	

Substance	Bordeaux mixture
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 10) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 10)
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	

Substance	Tribasic copper sulfate
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 1) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 10)
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	

Substance	Copper (I) oxide

[14] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[15]. Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 195, 20.7.2016, 11-25.

[16] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 100) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 100)
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:	