REGISTRATION REPORT

Part A

Risk Management

Product code: COH 20WG

Product name(s): KUPPER 20 WG

Chemical active substance(s):

Copper hydroxide, 334 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SUMI AGRO France

Date: 15 July 2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company SUMI AGRO France has requested a marketing authorisation in France for the product KUPPER 20 WG (formulation code: COH 20 WG), containing 198.1 g/kg copper[1] (in the form of 334 g/kg copper hydroxide (CAS No 20427-59-2)) as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of SUMI AGRO France's application submitted on 31/08/2020 to market KUPPER 20 WG (COH 20 WG) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2020-2829) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of KUPPER 20 WG (COH 20 WG) has been made using endpoints agreed in the EU peer review of copper compound It also includes assessment of data and information related to KUPPER 20 WG (COH 20 WG) where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018[4,5], as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify risk for non-taget organisms for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

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1 COMMISSION IMPLEMENTING REGULATION (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 Peer review of the pesticide risk assessment of the active substance copper compounds Copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture, EFSA Journal 2018;16(1):515

5 Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture in light of confirmatory data. EFSA supporting publication 2018:EN-1486.

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018[6]). Based on an evaluation of the available data MRL have been proposed and a consumer risk assessment has been conducted. Some information required by the regulation has not been transmitted and a chronic risk for the consumers was identified. Therefore the consumer risk assessment is only tentative and some of the proposed MRL still require a decision by risk managers. Exposure reduction measures could also be investigated.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[7], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of KUPPER 20 WG (COH 20 WG).

1.2 Letters of Access

The applicant has provided a letter of access for active substance data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « *The tests and studies submitted in this registration dossier are required according to Regulation 284/2013 in order to support the intended uses for the product KUPPER 20 WG.* »

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of KUPPER 20 WG (COH 20 WG), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	COH 20 WG
Product name in MS	KUPPER 20 WG
Authorisation number	2250162
Kind of use	Professional use
Low risk product (article 47)	No

[6] REASONED OPINION ADOPTED: 1 March 2018. Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005 European Food Safety Authority (EFSA).

[7] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

Function	Fungicide
Applicant	SUMI AGRO FRANCE
Active substance(s) (incl. content)	Copper hydroxide 334 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	Paper/LDPE bag (5 kg, 10 kg, 25 kg) Paper/LDPE box (1 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for KUPPER 20 WG (COH 20 WG) resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin sensitisation, category 1 Serious eye damage, category 1 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS05 GHS07 GHS09
Signal word:	Danger
Hazard statement(s):	H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[8] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, the French Order of 12 April 2021[9] provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[10] is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021[11] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless

[8] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[9] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

[10] SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

[11] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

otherwise stated in the product authorisation, use on attractive crop[12] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 1	To protect soil macro-organisms, limit copper inputs to 4 kg/ha/year from all sources.
SPe 2	To protect aquatic organisms, do not discharge waste water from soil-less greenhouses directly into surface water.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres and a planted buffer strip of 20 metres to adjacent surface water bodies for uses on Flowers and Ornamentals, Cucurbits, Fresh legumes, Small fruits, Bulb vegetables, Potato, Tomato et Aubergine
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 50 metres and a planted buffer strip of 20 metres to adjacent surface water bodies for uses on Tree nuts.
SPe 8	May be harmful to pollinating insects. To protect pollinating insects, do not use in the presence of pollinators, do not apply during the flowering period of attractive crops, do not apply when weeds are in flower.
Precautionnary statement for permanent greenhouse	For applications under permanent greenhouse: “May affect pollinators and beneficial arthropods. Avoid unnecessary exposure”.
Other specific restrictions	
Re-entry period	48 hours
Storage	-

[12] List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

Risk mitigation measures	-
Agricultural recommendations	It should be mentioned on the label that the product can cause visual damage (spotting) on table grape berries and can impact the wine-making process. On ornamental crops, considering the diversity of crops, it is recommended, in case of doubts, to test the product selectivity on a small area. Moreover, it is also recommended to avoid applications during flowering, because of a risk of burnings on flowers. Specify measures to limit the transfer of copper into surface water through runoff, such as: • Grassing of field edges • Maintenance of the permeability of grassed areas at field edges (headlands, permanent vegetation cover) and within the field (between rows) • Limiting preferential water flow paths (working perpendicular to the slope, using ridges in hoed crops, using equipment that reduces wheel ruts) • O Using equipment that limits the amount of copper reaching the soil.
Bystander and resident protection	For uses on Tree nuts, respect an unsprayed zone of 10 meters from the last treated raw and : - areas where bystanders are present during treatment - areas where residents could be present For uses on Flowers and Ornamentals, Cucurbits, Fresh legumes, Small fruits, Bulb vegetables, Potato, Tomato et Aubergine, respect an unsprayed zone of 10 meters from the last treated raw and : - areas where bystanders are present during treatment - areas where residents could be present

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" , the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 15 July 2025

PPP (product name/code):	KUPPER 20 WG / COH20WG	Formulation type:	wg [a, b]
Active substance 1:	Copper hydroxide	Conc. of a.s. 1:	20% (200 g/kg) (expressed as Cu) [c]
Applicant:	SUMI AGRO France SAS	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide/bactéricide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Grape	F	*Plasmopara viticola* *Phomopsis viticola* *Guignardia bidwellii* *Pseudopezicula tracheiphila*	Broadcast spraying	Any time during the cycle Spring/Summer/Autumn/Winter	a) 6 b) 6	7	a) 2.00-2.80 (200-280 g/hL) b) 12.00-16.80	a) 0.40-0.56 b) 2.40-3.36	1000	21	**Not acceptable** (worker, efficacy (for *Phomopsis viticola and Pseudopezicula tracheiphila)*)
2a	FR	Pome fruits (apple, pear, quince)	F	*Venturia inaequalis* *Venturia pyrina* *Nectria galligena* *Botryosphaeria obtusa* *Monilia fructigena* *Mycosphaerella pyri*	Broadcast spraying	All leaves fallen/ Leaf and shoot development (BBCH 97-54) Autumn/Winter/Spring	a) 3 b) 3	7	a) 2.40-3.15 (200-210 g/hL) b) 7.20-9.45	a) 0.48-0.63 b) 1.44-1.89	1200-1500	F	**Not acceptable** (worker, efficacy (for *Mycosphaerella pyri)*)

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Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2b			F	*Erwynia amylovora*		Autumn/Winter/Spring	a) 4 b) 4	7	a) 0.72-1.05 (60-70 g/hL) b) 2.88-4.20	a) 0.14-0.21 b) 0.58-0.84	1200-1500	F	**Not acceptable** (worker, efficacy)
2c			F	*Phytophthora cactorum*	Localized collar spraying	All leaves fallen/Pre-flowering (BBCH 97-59) Autumn/Winter	a) 1 b) 1	-	a) 3.45 b) 3.45	1.2 g (600 pl.) 0.9 g (800 pl.) 0.7 g (1000 pl.)	10 L/plant	F	**Not acceptable** (worker)
									a) 3.45 b) 3.45	1.2 g (600 pl.) 0.9 g (800 pl.) 0.7 g (1000 pl.)	15 L/plant		**Not acceptable** (worker)
2d	FR	Medlar	F	*Venturia inaequalis*	Broadcast spraying	Sprouting/Bud development to leaf and shoot development (BBCH 00-51) Autumn/Winter	a) 4 b) 4	7	a) 2.20-3.36 (220-280 g/hL) b) 8.80-13.44	a) 0.44-0.67 b) 1.76-2.68	1000-1200	F	**Not acceptable** (worker)
3	FR	Stone fruits (peach, apricot, cherry, plum)	F	*Taphrina deformans* *Stigmina carpophila* *(Coryneum beijerinkii)* *Monilia laxa* *Monilia fructigena* *Venturia carpophila* *Blumeriella jaapii* *Taphrina cerasi* *Taphrina pruni* *Fusicoccum amygdali* *Tranzschelia pruni-spinosae* *Puccinia cerasi* Side effects on: *Xanthomonas campestris pv. pruni* *Pseudomonas syringae pv. persicae* *Pseudomonas syringae pv. syringae*	Broadcast spraying	Sprouting/Pre-flowering (BBCH 00-59) Autumn/Winter	a) 4 b) 4	7	a) 2.50-3.18 (250-265 g/hL) b) 10.00-12.72	a) 0.50-0.63 b) 2.00-2.54	1000-1200	F	**Not acceptable** (worker)

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Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
4	FR	Olive	F	*Spilocaea oleaginea – Cycloconium oleaginum* *Pseudomonas syringae* subsp. *savstanoi*	Broadcast spraying	Bud development to Fruit development (BBCH 00-79) Autumn/Winter/Spring	a) 3 b) 3	7	a) 2.30-3.30 (230-330 g/hL) b) 6.90-9.90	a) 0.46-0.66 b) 1.38-1.98	1000	14	**Not acceptable** (worker)
5	FR	Kiwi	F	*Pseudomonas syringar pv. actinidiae* *Phytophthora* spp. *Pseudomonas viridiflava*	Broadcast spraying	All leaves fallen Harvested product/Pre-flowering (BBCH 97-59) Autumn/Winter/Spring	a) 3 b) 3	7	a) 3.50 (350 g/hL) b) 10.50	a) 0.70 b) 2.10	1000	F	**Not acceptable** (worker)
6a	FR	Tree nuts (walnut, hazelnut, chestnut)	F	*Cytospora corylicola* *Mycosphaerella maculiformis* *Ophiognomonia leptostyla* Side effect on: *Xanthomonas campestris* pv. *juglandis* *Xanthomonas campestris* pv. *corylina* *Pseudomonas syringae* pv. *avellanae* Side effect on: Powdery mildew	Broadcast spraying	Sprouting/Inflo-rescence emergence (BBCH 00-54) Winter/Spring	a) 2 b) 2	7	a) 2.50-2.80 (250-280 g/hL) b) 5.00-5.60	a) 0.50-0.56 b) 1.00-1.12	1000	F	**acceptable**

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6b	FR	Almond tree	F	*Cytospora corylicola* *Mycosphaerella maculiformis* *Ophiognomonia leptostyla* Side effect on: *Xanthomonas campestris* pv. *juglandis* *Xanthomonas campestris* pv. *corylina* *Pseudomonas syringae* pv. *avellanae* Side effect on: Powdery mildew	Broadcast spraying	Sprouting/Inflo-rescence emer-gence (BBCH 00-54) Winter/Spring	a) 4 b) 4	7	a) 2.50-3.18 (250-265 g/hL) b) 10.00-12.72	a) 0.50-0.63 b) 2.00-2.54	1000-1200	F	**Not acceptable** (worker)
7	FR	Small fruits (currant, raspberry, gooseberry)	F	*Phomopsis cinerescens* *Phragmidium rubi-idaei* *Didymella applanata* *Phomopsis myrtilli*	Broadcast spraying	Sprouting/Bud and Leaf development (BBCH 00-51) Autumn/Winter/Spring	a) 2 b) 2	7	a) 2.00-2.60 (250-260 g/hL) b) 4.00-5.20	a) 0.40-0.52 b) 0.80-1.04	800-1000	F	**Not acceptable** (worker, efficacy (for *Phomopsis sp.)*)
8	FR	Tomato	F	*Phytophthora infestans* *Phytophthora nicotianae* var. *parasitica* *Pseudomonas syringae* pv. *tomato* *Xanthomonas campestris* pv. *vesicatoria* *Septoria lycopersici* *Alternaria alternata* *Pseudomonas corrugata* *Clavibacter michiganensis*	Broadcast spraying	Leaf development to Formation side shoots (BBCH 19-89). Autumn/Winter/ Spring	a) 4 b) 4	7	a) 2.45-2.80 (245-280 g/hL) b) 9.80-11.20	a) 0.49-0.56 b) 1.96-2.24	1000	3	**Acceptable**
9	FR	Aubergine	F	*Colletotrichum coccodes* *Didymella lycopersici*	Broadcast spraying	Leaf development to Harvest (BBCH 19-89) Autumn/Winter/Spring/Summer	a) 2 b) 2	7	a) 1.90-2.50 (190-250 g/hL) b) 2.80-5.00	a) 0.38-0.50 b) 0.76-1.00	1000	3	**Acceptable**
10a	FR	Cucurbits family (edible peel)	F	*Pseudoperonospora cubensis* *Colletotrichum lagenarium*	Broadcast spraying	Leaf development to Formation side	a) 2 b) 2	7	a) 1.52-2.50 (190-250 g/hL)	a) 0.30-0.50	800-1000	3	**Acceptable**

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Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
10b		Cucurbits family (inedible peel)		*Pseudomonas syringae pv. lachrymans*		shoots (BBCH 13-29) Autumn/Winter/Spring			b) 3.04-5.00	b) 0.60-1.00		7	**Accepbtale**
11	FR	Bulb vegetables (garlic, onion Spring onion, shallot)	F	*Peronospora schleideni* *Puccinia sp.* *Alternaria sp.* *Stemphylium sp.*	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 5 b) 5	7	a) 1.14-2.50 (190-250 g/hL) b) 5.70-12.5	a) 0.22-0.50 b) 1.14-2.50	600-1000	3	**Acceptable**
12	FR	Fresh legumes (*Pisum sativum* (PIBSX); Brad bean (VICFX) and Bean (PHSVX))	F	*Colletotrichum limdemuthianum* *Phytophthora phaseoli* *Peronospora pisi* *Ascochyta pisi* *Ascochyta fabae* *Uromyces fabae* *Peronospora viciae* *Uromyces appendiculatus* Side effects on: *Pseudomonas syringae pv. phaseolicola* *Xanthomonas campestris pv. phaseoli* *Pseudomonas syringae pv. pisi*	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 5 b) 5	7	a) 1.14-2.50 (190-250 g/hL) b) 5.70-12.50	a) 0.22-0.50 b) 1.14-2.50	600-1000	3	**Not acceptable** (MRL)
13	FR	Flowers and Ornamentals (rose, Carnation, Geranium, Chrysanthemum, Oleander, cherry laurel, etc.)	F	*Peronospora sparsa* *Marssonina rosae* *Alternaria dianthi* *Sphaeropsis malorum* *Phragmidium subcorticum* *Diplocarpon rosae* *Uromyces dianthi* *Puccinia horiana* *Phytophthora ramorum* Side effects on: Sooty mold (Fumaggini) Bacteriose	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 2 b) 2	7	a) 1.14-2.30 (190-230 g/hL) b) 2.28-4.60	a) 0.22-0.46 b) 0.45-0.92	600-1000	n.a.	**Accptable**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
14	FR	Forestry	F	*Foliage diseases: Seiridium (Coryneum) cardinale* *Sphaeropsis malorum* Sooty mold (Fumagine) Bacteriose	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 3 b) 3	7	a) 1.92-2.50 (240-250 g/hL) b) 5.76-7.50	a) 0.38-0.50 b) 1.15-1.50	800-1000	n.a.	**Not acceptable**
15	FR	Potato	F	*Phytophthora infestans* *Alternaria porri* f. sp. *solani* Side effects on: Bacteriose	Broadcast spraying	Leaf development to development of fruit (BBCH 12-81)	a) 4 b) 4	7	a) 2.20-2.60 (220-260 g/hL) b) 8.80-10.40	a) 0.44-0.52 b) 1.76-2.08	1000	14	**Acceptable**
16	FR	Tobacco	F	*Peronospora tabacina* *Phytophthora nicotianae*	Broadcast spraying	Leaf development (BBCH 11-19)	a) 2 b) 2	7	a) 2.00-2.50 (200-250 g/hL) b) 4.00-5.00	a) 0.40-0.50 b) 0.80-1.00	1000	n.a.	**Not acceptable** (worker)
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	FR	Tomato	G	*Phytophthora infestans* *Phytophthora nicotianae* var. *parasitica* *Pseudomonas syringae* pv. *tomato* *Xanthomonas campestris* pv. *vesicatoria* *Mycovellosiella fulva* (*Cladosporium*) *Septoria lycopersici* *Alternaria alternata* *Pseudomonas corrugata* *Clavibacter michiganensis*	Broadcast spraying	Leaf development to Harvest (BBCH 19-89) Autumn/Winter/ Spring/Summer	a) 4 b) 4	7	a) 2.45-2.80 (245-280 g/hL) b) 9.80-11.20	a) 0.49-0.56 b) 1.96-2.24	1000	3	**Acceptable**)
2	FR	Aubergine	G	*Colletotrichum coccodes* *Didymella lycopersici* *Erwinia carotovora*	Broadcast spraying	Leaf development to Harvest (BBCH 19-89) Autumn/Winter/ Spring	a) 2 b) 2	7	a) 1.90-2.50 (190-250 g/hL) b) 2.80-5.00	a) 0.38-0.50 b) 0.76-1.00	1000	3	**Acceptable**

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
3	FR	Cucurbits family (edible peel)	G	*Pseudoperonospora cubensis* *Colletotrichum lagenarium* *Pseudomonas syringae pv. lachrymans* *Erwinia carotovora*	Broadcast spraying	Leaf development to Formation side shoots (BBCH 13-29) Autumn/Winter/Spring	a) 2 b) 2	7	a) 1.52-2.50 (190-250 g/hL) b) 3.04-5.00	a) 0.30-0.50 b) 0.60-1.00	800-1000	3	**Accptable**
4	FR	Fresh legumes (beans, peas)	G	*Phytophthora phaseoli* *Uromyces appendiculatus*	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 5 b) 5	7	a) 1.14-2.50 (190-250 g/hL) b) 5.70-12.50	a) 0.22-0.50 b) 1.14-2.50	600-1000	3	**Not acceptable** (MRL)
5	FR	Flowers and Ornamentals: (rose, carnation, geranium, chrysanthemum, oleander, cherry laurel, etc.)	G	*Peronospora sparsa* *Marssonina rosae* *Alternaria dianthi* *Sphaeropsis malorum* *Phragmidium subcorticum* *Diplocarpon rosae* *Uromyces dianthi* *Puccinia horiana* *Phytophthora ramorum* Side effects on: Sooty mold (Fumaggini) Bacteriose	Broadcast spraying	Any time during cycle Autumn/Winter/Spring	a) 2 b) 2	7	a) 1.14-2.30 (190-230 g/hL) b) 2.28-4.60	a) 0.22-0.46 b) 0.45-0.92	600-1000	n.a.	**Acceptable**

Remarks table heading:

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

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

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

KUPPER 20 WG (COH 20 WG) is a wettable granule (WG). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the prod-uct is a green solid micro granules with mild odour. It is not explosive and has no oxidising proper-ties. The product is not flammable. It has a self- ignition temperature of 195.7°C. In aqueous solu-tion 1%, it has a pH value of 9.5 at 19°C. There is no effect of low and high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in paper/plastic bags or boxes. Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of KUPPER 20 WG (COH 20 WG) is considered as acceptable for most of the claimed uses, except on uses intended to control fire blight (*Erwinia amylovora*) on pome fruits for which the dose justification is considered insufficient; and for uses on dead-arm (*Phomopsis viticola)* and red fire *(Pseudopezicula tracheiphila)* on grapevine, ashy leaf spot (*Mycosphaerella pyri*) on pome fruits, canker and twig dieback *(Phomopsis sp.)* on small fruits, grey mould and sclerotinia (*Botrytis sp*. and *Sclerotinia sp*.) on aubergine for which the demonstration of the efficacy of the product is considered insufficient.
- The phytotoxicity level of KUPPER 20 WG (COH 20 WG) is considered as acceptable for all the claimed uses. On ornamental crops, considering the diversity of crops, it is recommended, in case of doubts, to test the product selectivity on a small area. Moreover, it is also recommended to avoid applications during flowering, because of a risk of burnings on flowers.
- The risks of negative impact on yield, cider making process, propagation, succeeding crops, adjacent crops are considered as negligible. Risks with copper such as spotting of table grape berries or on the wine-making process are known. However, these risks of negative impact are considered acceptable.
- There is a risk of resistance developing or appearing to copper for *Xanthomonas* bacteria requiring a monitoring on tomato and walnut and for *Pseudomonas* bacteria on kiwi.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of copper in the formulation are available and validated. However, this method is not specific to the variant copper hydroxide. A complementary method shall be provided to confirm the identity of the variant in the formulation.

Analytical methods for the determination of the relevant impurities are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of copper in plants (high water, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids.

According to EFSA conclusions, an ILV of the analytical methods for the determination of residues of copper in plants is required.

Analytical methods for the determination of residues of copper in food of animal origin are missing and are required. Moreover, the LOQ of the available methods for the determination of residues of copper in water is not in accordance with the European Directive 98/83/EC.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

KUPPER20WG containing 200 g/kg of copper hydroxyde has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin, is corrosive to the eye and is a skin sensitiser.

3.4.2 Operator exposure

The estimated operator exposure is presented in the table below :

Outdoor :

		Copper under the form of copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Critical use: Grapes			
Tractor mounted outdoor, upward applications			
Application rate		6*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1066	**133.20**
	Work wear (arms, body and legs covered) M/L and A	0.0328	**41.04**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0149	**18.59**
Critical use: Grapes			
Manual Hand-Held, upward applications			
Application rate		6*0.56 kg a.s./ha	
Spray application (AOEM**;**	Potential exposure	0.1171	**146.37**

75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0137	**17.11**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0054	**6.70**
Critical use: Grapes			
Manual Knapsack, upward applications			
Application rate		6*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0899	**112.33**
	Work wear (arms, body and legs covered) M/L and A	0.0071	**8.86**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0030	**3.77**
Critical use: Medlar Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Tractor mounted, upward applications			
Application rate		4*0.67 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1266	**158.24**
	Work wear (arms, body and legs covered) M/L and A	0.384	**48.03**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0174	**21.74**
Critical use: Medlar Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Manual Hand-Held, upward applications			
Application rate		4*0.67 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1220	**152.45**
	Work wear (arms, body and legs covered) M/L and A	0.0155	**19.41**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0059	**7.32**
Critical use: Medlar Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Manual Knapsack, upward applications			
Application rate		4*0.67 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0928	**116.01**
	Work wear (arms, body and legs covered) M/L and A	0.0076	**9.55**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0032	**3.95**
Critical use: Kiwi Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Tractor mounted, upward applications			

Application rate		3*0.7 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1320	**165.04**
	Work wear (arms, body and legs covered) M/L and A	0.0399	**49.91**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0181	**22.59**
Critical use: Kiwi Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Manual Hand-Held, upward applications			
Application rate		3*0.7 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1232	**154.01**
	Work wear (arms, body and legs covered) M/L and A	0.0160	**20.03**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0060	**7.49**
Critical use: Kiwi Covers : Stone fruits, pome fruits, Tree nuts, Olive			
Manual Knapsack, upward applications			
Application rate		3*0.7 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0936	**116.94**
	Work wear (arms, body and legs covered) M/L and A	0.0078	**9.73**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0032	**4.00**
Critical use: Tomato Covers : Aubergine, Cucurbits family, Bulb vegetables, Fresh legumes			
Tractor mounted, downward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0167	**20.83**
	Work wear (arms, body and legs covered) M/L and A	0.0112	**13.99**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0025	**3.16**
Critical use: Tomato Covers : Aubergine, Cucurbits family, Bulb vegetables, Fresh legumes			
Manual Hand-Held, downward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.2048	**255.95**
	Work wear (arms, body and legs covered) M/L and A	0.0253	**31.60**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0214	**26.79**

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Critical use: Tomato Covers : Aubergine, Cucurbits family, Bulb vegetables, Fresh legumes			
Manual Knapsack, downward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1382	**172.75**
	Work wear (arms, body and legs covered) M/L and A	0.0181	**22.66**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0142	**17.80**
Critical use: Small fruits			
Tractor mounted, downward applications			
Application rate		2*0.52 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.4700	**587.45**
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0595	**74.34%**
Critical use: Small fruits			
Manual Hand-Held, downward applications			
Application rate		2*0.52 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.3089	**143.98**
	Work wear (arms, body and legs covered) M/L and A	0.0130	**16.26**
Critical use: Small fruits			
Manual Knapsack, downward applications			
Application rate		2*0.52 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.2827	**110.86**
	Work wear (arms, body and legs covered) M/L and A	0.0069	**8.60**
Critical use: Forestry Covers Ornamentals			
Tractor mounted, downward applications			
Application rate		3*0.5 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0315	**39.41**
	Work wear (arms, body and legs covered) M/L and A	0.0144	**18.50**
Critical use: Forestry Covers Ornamentals			
Manual Hand-Held, downward applications			
Application rate		3*0.5 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1829	**228.63**
	Work wear (arms, body and legs covered) M/L and A	0.0226	**28.30**
Critical use: Forestry			

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Covers Ornamentals			
Manual Knapsack, downward applications			
Application rate		2*0.52 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1382	**172.75**
	Work wear (arms, body and legs covered) M/L and A	0.0181	**22.66**
Critical use: Potato			
Tractor mounted, downward applications			
Application rate		4*0.52 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0156	**19.56**
	Work wear (arms, body and legs covered) M/L and A	0.0105	**13.15**
Critical use: Potato			
Manual Hand-Held, downward applications			
Application rate		4*0.52 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1902	**237.73**
	Work wear (arms, body and legs covered) M/L and A	0.0235	**29.40**
Critical use: Potato			
Manual Knapsack, downward applications			
Application rate		4*0.52 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1382	**172.75**
	Work wear (arms, body and legs covered) M/L and A	0.0181	**22.66**
Critical use: Tobacco			
Tractor mounted, downward applications			
Application rate		2*0.5 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0151	**18.92**
	Work wear (arms, body and legs covered) M/L and A	0.0102	**12.73**
Critical use: Tobacco			
Manual Hand-Held, downward applications			
Application rate		2*0.5 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1829	**228.63**
	Work wear (arms, body and legs covered) M/L and A	0.0226	**28.30**
Critical use: Tobacco			
Manual Knapsack, downward applications			
Application rate		2*0.5 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1382	**172.75**
	Work wear (arms, body and	0.0181	**22.66**

	legs covered) M/L and A		

Indoor :

		Copper under the form of copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Critical use: Tomato			
Tractor mounted outdoor, upward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.5051	**631.35**
	Work wear (arms, body and legs covered) M/L and A	0.1377	**172.17**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.064	**79.66**
Manual Hand-Held, upward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1171	**146.37**
	Work wear (arms, body and legs covered) M/L and A	0.0137	**17.11**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Manual Knapsack, upward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0899	**112.33**
	Work wear (arms, body and legs covered) M/L and A	0.0071	**8.86**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Critical use: Fresh legumes Covers Aubergine, Cucurbits family			
Vehicle mounted, upward applications			
Application rate		5*0.50 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.4524	**565.47**
	Work wear (arms, body and legs covered) M/L and A	0.1243	**155.41**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0.0573	**71.67%**
Manual Hand-Held, upward applications			
Application rate		5*0.50 kg a.s./ha	

Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1142	**142.75**
	Work wear (arms, body and legs covered) M/L and A	0.0127	**15.82**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Manual Knapsack, upward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0881	**110.09**
	Work wear (arms, body and legs covered) M/L and A	0.0068	**8.47**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Critical use: Ornementals			
Vehicle mounted, upward applications			
Application rate		5*0.50 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0883	**110.32**
	Work wear (arms, body and legs covered) M/L and A	0.0277	**34.57**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Manual Hand-Held, upward applications			
Application rate		5*0.50 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1121	**140.18**
	Work wear (arms, body and legs covered) M/L and A	0.0120	**14.95**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-
Manual Knapsack, upward applications			
Application rate		4*0.56 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.0868	**108.49**
	Work wear (arms, body and legs covered) M/L and A	0.0066	**8.21**
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	-	-

Conclusion:

Indoor : The operator exposure is below the AOEL of copper for all uses and when adequate PPE are additionally worn for Tomato, Cucurbitis family and Fresh legumes and is therefore acceptable.

Outdoor : The operator exposure is below the AOEL of copper for all uses when adequate PPE were worn (small fruits with vehicle mounted)), this use is therefore unacceptable.

3.4.3 Worker exposure

The estimated worker exposure for professional use is presented in the table below :

Outdoor :

		Copper under the form of copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical Use: Grapes			
Hand harvesting Outdoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm²/kg a.s./ha Interval between applications: 7 days			
Application rate		6 x 0.56 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 30000 cm²/person/h	1.1907	1488.38
	Work wear (arms, body and legs covered) TC: 10100 cm²/person/h	0.4009	501.09
Critical Use: Medlar Covers Pome fruit, Stone fruit, Olive, Kiwi, Almond tree			
Hand harvesting Outdoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm²/kg a.s./ha Interval between applications: 7 days			
Number of applications and application rate		4 x 0.67 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 22500 cm²/person/h	1.01756	1271.95
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.20351	254.39
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/person/h	0.10175	127.20
Critical use: Tomato Covers Aubergine, cucurbits family, bulb vegetables, fresh legumes,			
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.56 kg.as/ha	
EFSA model 2014 (AOEM Excel	Potential TC: 22500 cm²/person/h	0.21924	274.05

calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.09450	118.13
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.02192	27.41
Critical use: Walnut, Hazelnut, Chestnut			
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.56 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.6804	850.50
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.1360	170.10
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0680	85.05
Critical use: Flowers and Ornamentals Covers Forestry			
Cutting, sorting, bundling, carrying Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 x 0.46 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.3478	434.70
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.1242	155.25
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0348	43.47
Critical use: Potato			
Inspection, Irrigation Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.52 kg.as/ha	
EFSA model 2014 (AOEM Excel	Potential TC: 12500 cm^2/person/h	0.1097	137.11

calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0123	15.36
Critical use:Tobacco			
Inspection, Irrigation Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 0.52 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 30000 cm^2/person/h	1.0530	1316.25
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.3545	443.14
	Work wear (arms, body and legs covered) + gloves TC: No TC available	NA	NA

Indoor :

		Copper under the form of copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Critical Use: Aubergines Covers cucurbits family,			
Reaching, picking Indoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm^2/kg a.s./ha Interval between applications: 7 days			
Application rate		2 x 0.50 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 5800 cm^2/person/h	0.1566	195.75
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.0675	84.38
	Work wear (arms, body and legs covered) + gloves TC: 580 cm^2/person/h	0.0157	19.58
Critical Use: Fresh legumes			
Reaching picking Indoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm^2/kg a.s./ha Interval between applications: 7 days			
Number of applications and application rate		5 x 0.5 kg.as/ha	

EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.2023	252.84
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0872	108.98
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0202	25.28
Critical Use: Flowers and Ornementals			
Reaching picking Indoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm^2/kg a.s./ha Interval between applications: 7 days			
Number of applications and application rate		2 x 0.46 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 14000 cm^2/person/h	0.3478	434.70
	Work wear (arms, body and legs covered) TC: 5000 cm^2/person/h	0.1242	155.25
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm^2/person/h	0.0348	43.47
Critical Use: Tomato			
Reaching picking Indoor Work rate: 8 hours/day DT_{50}: 7 days DFR: 3µg/cm^2/kg a.s./ha Interval between applications: 7 days			
Number of applications and application rate		4 x 0.56 kg.as/ha	
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 5800 cm^2/person/h	0.2192	274.05
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.0945	118.13
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0219	27.41

Conclusion:

Outdoor :

An unacceptable risk was identified for worker re-entering into Grapes, Medlar, Pome fruit, Stone fruit, Olive, Kiwi, Almond tree and Tobacco with COH20WG.

No unacceptable risk was identified for workers re-entering into tomato, Flowers and Ornamentals; Forestry, Walnut, Hazelnut and Chesnut when wearing work wear and gloves.

No unacceptable risk was identified for workers re-entering into Potato when wearing work wear.

Indoor :
No unacceptable risk was identified for workers re-entering for all uses when wearing work wear and gloves.

3.4.4 Bystander and resident exposure

Outdoor :
Residential exposure was assessed according to EFSA model using:
- the following dermal absorption values : 1% for the concentrate, 9% for the dilution
- the refined DT_{50} value of 7 days
- a buffer zone of 10 meters for high crops (grapes and orchards) or 2-3 meters for low crops (Tomato).

		Copper under the form of copper hydroxide	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapes			
AOEM calculator (EFSA Model) Tractor mounted, Manual Hand-Held, Manual Knapsack, upward application Buffer zone: 10 m Drift reduction technology: no DT_{50}: 7 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days Volume min: 1000 L/ha			
Number of applications and application rate		6 x 0.56 kg as/ha (as worst case)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0,0071	8,84%
	Vapour (75th perc.)	0,0011	1,34%
	Deposits (75th perc.)	0,0003	0,43%
	Re-entry (75th perc.)	0,0167	20,93%
	Sum (mean)	0,0193	24,18%
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,0039	4,87%
	Vapour (75th perc.)	0,0002	0,29%
	Deposits (75th perc.)	0,0001	0,15%
	Re-entry (75th perc.)	0,0093	11,63%
	Sum (mean)	0,0103	12,86%
Medlar Covers : Stone fruits, pome fruits, Tree nuts, Olive			
AOEM calculator (EFSA Model) Tractor mounted, Manual Hand-Held, Manual Knapsack upward application Buffer zone: 10 m Drift reduction technology: no DT_{50}: 7 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			

Volume min: 1000 L/ha			
Number of applications and application rate		4 x 0.67 kg.as/ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0,0085	10,58%
	Vapour (75th perc.)	0,0011	1,34%
	Deposits (75th perc.)	0,0034	4,31%
	Re-entry (75th perc.)	0,0191	23,85%
	Sum (mean)	0,0242	30,25%
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,0047	5,83%
	Vapour (75th perc.)	0,0002	0,29%
	Deposits (75th perc.)	0,0012	1,54%
	Re-entry (75th perc.)	0,0106	13,25%
	Sum (mean)	0,0126	15,71%
Kiwi			
AOEM calculator (EFSA Model) Tractor mounted, Manual Hand-Held, Manual Knapsack upward application Buffer zone: 10 m Drift reduction technology: no DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days Volume min: 1000 L/ha			
Number of applications and application rate		3 x 0.7 kg as/ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0,0088	11,05%
	Vapour (75th perc.)	0,0011	1,34%
	Deposits (75th perc.)	0,0034	4,21%
	Re-entry (75th perc.)	0,0186	23,26%
	Sum (mean)	0,0240	30,01%
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,0049	6,09%
	Vapour (75th perc.)	0,0002	0,29%
	Deposits (75th perc.)	0,0012	1,50%
	Re-entry (75th perc.)	0,0103	12,92%
	Sum (mean)	0,0125	15,59%
Tomato Covers ; Aubergine, cucurbits family, bulb vegetables, fresh legumes, Flowers And Ornamentals, Tobacco.			
AOEM calculator (EFSA Model) Tractor mounted, Manual Hand-Held, Manual Knapsack downward application Buffer zone: 2-3 m Drift reduction technology: no DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days Volume min: 1000 L/ha			
Number of applications and application rate		3 x 0.7 kg as/ha	
Resident child	Drift (75th perc.)	0,0014	1,70%

Body weight: 10 kg	Vapour (75th perc.)	0,0011	1,34%
	Deposits (75th perc.)	0,0018	2,25%
	Re-entry (75th perc.)	0,0159	19,93%
	Sum (mean)	0,0159	19,82%
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,0003	0,41%
	Vapour (75th perc.)	0,0002	0,29%
	Deposits (75th perc.)	0,0006	0,80%
	Re-entry (75th perc.)	0,0089	11,07%
	Sum (mean)	0,0079	9,90%
	Re-entry (75th perc.)	0,0089	11,07%
	Sum (mean)	0,0079	9,90%

Exposure of residents to copper hydroxide is lower than the AOEL for all intended uses.

Bystander exposure:
In the absence of the AAOEL determined for copper under the form of copper hydroxide, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, only resident exposure is provided since, ac-cording to EFSA Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): *"No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."*

Indoor :
Not relevant for greenhouse applications.

Conclusion :
Therefore, for all intended uses, exposure of residents is considered acceptable and exposure of bystander is covered by the resident.

3.4.5 Combined exposure

Not relevant. The product contains only one active substance.

3.5 Residues and consumer exposure (Part B, Section 7)

As flowers, ornamental plants and trees, forest and tobacco are non edible commodities, the respective intended uses were not assessed.

An exceedance of the current MRL for copper as laid down in Reg. (EC) 396/2005 of 50 mg/kg in grapes, 5 mg/kg in pome fruits (apple, pear, quince, medlar) for pre-flowering uses, 5 mg/kg in stone fruits (apricot, cherry, peach, plum) for pre-flowering uses, 30 mg/kg in tree nuts (almond, walnut, hazelnut, chestnut) for pre-flowering uses, 30 mg/kg in olive, 5.0 mg/kg in outdoor and indoor tomato and aubergine, 5.0 mg/kg

in outdoor and indoor edible peel cucurbits (cucumber, courgette and gherkin), 5.0 mg/kg in outdoor inedible peel cucurbits (melon, watermelon and pumpkin), 5.0 mg/kg in onion, garlic and shallot, 20 mg/kg in fresh beans with pods and fresh beans without pods, 20 mg/kg in kiwi for pre-flowering use, 5.0 mg/kg in potato and 5 mg/kg in small fruits (raspberry, currant, gooseberry) for pre-flowering use is not expected.

Due to insufficient residue trials, the uses on fresh peas without pods (outdoor), fresh lentils (outdoor), dry beans (outdoor)and fresh legumes (indoor) cannot be recommended.

The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for copper.

For chronic intake of copper residues, the calculation includes uncertainties linked to the methodology. Therefore, zRMS considers that the risk assessment for consumers cannot be finalised.

zRMS considers no firm conclusion can be reached for any of the intended uses of the product COH 20 WG.

Summary for Copper Hydroxide

Crop	PHI for COH20WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for COH20WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper		
OUTDOOR USES				
Grapes	21 days	Yes	21 days	
Pome fruits	F (BBCH 97-59)	Yes	F (BBCH 97-59)	
Stone fruits	F (BBCH 00-59)	Yes	F (BBCH 00-59)	
Olive	14 days	Yes	14 days	
Kiwi	F (BBCH 97-59)	Yes	F (BBCH 97-59)	
Nut fruits	F (BBCH 00-54)	Yes	F (BBCH 00-54)	
Small fruits	F (BBCH 00-51)	Yes	F (BBCH 00-51)	
Tomato	3 days	Yes	3 days	
Aubergine	3 days	Yes	3 days	
Cucurbits family (edible peel)	3 days	Yes	3 days	
Cucurbits family (inedible peel)	7 days	Yes	7 days	
Bulb vegetables (except spring onion)	3 days	Yes	3 days	
Fresh beans with pods	3 days	Yes	3 days	
Fresh beans	3 days	Yes	3 days	

Crop	PHI for COH20WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for COH20WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper		
without pod				
Fresh peas without pods and fresh lentils	3 days	No	-	Not recommended use
Potato	14 days	Yes	14 days	
Tobaco	NR		NR	Not assessed (non edible commodity)
Forestry	NR		NR	Not assessed (non edible commodity)
Ornamental plant and trees	NR		NR	Not assessed (non edible commodity)
INDOOR USES				
Tomato	3 days	Yes	3 days	
Aubergine	3 days	Yes	3 days	
Cucurbits family (edible peel)	3 days	Yes	3 days	
Fresh legumes	3 days	No	-	Not recommended use
Ornamental plant and trees	NR		NR	Not assessed (non edible commodity)

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of copper in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil can be used for the risk assessment for the non-target terrestrial organisms for all intended uses. In the absence of reliable PECsoil, accumulation for the active substance, the risk assessment for the non-target terrestrial organisms cannot be finalised for all intended uses.

For the uses (field and greenhouse uses) on vineyards, tomatoes, aubergine, cucumbers, PECgw for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE[13]. Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses.
For the uses on fresh legumes (field and greenhouses), flowers and ornamentals (field and greenhouses), Tobacco, Potato, Forestry, Bulb vegetables, Small fruits, Stone fruits, Almond tree, Tree nuts, kiwi, olive, medlar, pome fuits, , the risk to groundwater contamination cannot be finalised due to the absence of reliable FOCUS groundwater modelling.

Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bodies and FOCUS STEP 1-2 PECsw including mitigation measures) and the absence of results for all FOCUS scenarios, PECsw derived for the active substance cannot be used for the ecotoxicological risk assessment. As a consequence, the risk assessment cannot be finalised for the non-target aquatic organisms.

For application under permanent greenhouse with soil-less culture, no exposure assessment is considered needed.

Based on vapour pressure, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

An EFSA' Statement of the PPR panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products was recently

[13] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

published (2021). This document provides useful recommendations upon applicability of new methodologies in the context of transition metals and possible areas of development for assessing the risk from transition metals used in PPPs. However, it does not provide valid tools for exposure assessment in the environment and toxicity estimation upon non-target organisms. Furthermore, no clear specific risk assessment schemes for transition metals used as active substances in PPPs is provided. Therefore, the risk assessment and conclusion are based on the methodology agreed by the experts during the renewal approval of the active substance. The EU-agreed endpoints recommended in the EFSA journal (EFSA Journal 2018;16(1):5152) were considered for the Art. 43 dossiers for copper compounds.

Based on the guidance documents, the risks for soil non-target micro-organisms and non-target terrestrial plants are acceptable for the intended uses.

For aquatic organisms, as the toxicity reference value for copper proposed by the applicant was based on an approach rejected at European level, it could not be used. In addition, no reliable PECsw or PECsed were provided by the applicant for all uses. Therefore, the risk assessment for aquatic non-target species could not be finalised for uses in open field, in tunnels or in permanent greenhouses with soil-bound cultivation. For uses in permanent greenhouses with soil-less cultivation, the exposure of aquatic organisms to the active substance from the use of the product KUPPER 20 WG (COH 20 WG) is considered negligible.

For birds and mammals, the risk is not acceptable at Tier 1 for all intended uses. The arguments provided by the applicant to refine the risk assessment are identical to those that were considered insufficient at the European level. Therefore, without further data, the risk assessment for birds and mammals cannot be finalised except for applications under permanent greenhouse.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document[14].
For adult honey bees, the acute risk is not acceptable at Tier 1 for all intended uses. Higher-tier studies (cage and tunnel tests) are available and demonstrate that no adverse effects on adult honey bees are expected for all intended uses.
For honey bee larvae, the risks are not acceptable at Tier 1 for all intended uses except for tomato, aubergine, cucumber, melon, onion, beans, peas, flowers and ornamentals, roses, potatoes and tobacco in open-field or in walk-in tunnels. For all other uses in open-field or in walk-in tunnels, the higher-tier studies are not sufficient to demonstrate the absence of adverse effects of the product KUPPER 20 WG (COH 20 WG) on honey bee larvae. Therefore, the risk assessment for honey bee larvae cannot be finalised for applications in open-field or in walk-in tunnels except for tomato, aubergine, cucumber, melon, onion, beans, peas, flowers and ornamentals, roses, potatoes and tobacco.
For bumble bees, no acute risk assessment was provided by the applicant, although standard study protocols are available. Therefore, the risk assessment for bumble bees cannot be finalised for applications in open-field or in walk-in tunnels.
Overall, the risk for bees cannot be finalised for all requested uses except for applications under permanent greenhouse. For these structures, the following precautionary statement should be applied: “May affect pollinators. Avoid unnecessary exposure”.

For non-target arthropods, an acceptable risk could not be demonstrated with the available data for all intended uses. Therefore, the risk assessment for non-target arthropods cannot be finalised except for applications under permanent greenhouse. For these structures, the following precautionary statement should be applied: “May affect beneficial arthropods. Avoid unnecessary exposure”.

For soil organisms, since no reliable PEC soil are available, a Tier 1 risk assessment cannot be conducted.

[14] EFSA (2014) European Food Safety Authority, 2014. EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

For earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for appli-cations up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses.
For other soil meso- and macro-organisms, no higher-tier studies are available and extrapolating the results of the multiyear field study with earthworms to other soil meso- and macro-organisms was not supported by the experts at the Peer Review experts' meeting 169. Therefore, the risk for soil macro-organisms other than earthworms could not be finalised for all intended uses except for uses under permanent greenhouse with soil-less cultivation.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

KUPPER 20 WG (COH 20 WG) contains copper compounds, which is approved as a candidate to substitution because it fulfills PBT criteria (Persistant and Toxic);

Steps 1 and 2 (French guidance document 27 July 2015):

- **Taking into account the agronomic interest, especially in the context of organic farming**

In accordance with Article 50, paragraphs 1.b) 1.c) and 1.d) of Regulation (EC) N°1107/2009,

- considering the absence of plant protection products or non-chemical methods of prevention or control allowing to consider a substitution of the product without major practical or economic disadvantage, and specially in the frame of organic farming,
- considering also the need to guarantee a diversity of modes of action to reduce the emergence of resistance in target microorganisms,
- considering the need to take into account the minor uses of the product,

the substitution of the product will not be considered for all intended uses.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is "Not acceptable", please refer to relevant summary under point 3, "Background of authorisation decision and risk management".

5.1.1 Post-authorisation monitoring

The monitoring of resistance to copper should be put in place (one monitoring for all products based on copper) on *Xanthomonas sp.* on vegetable crops (e.g. tomato) and walnut, on *Pseudomonas sp*. on kiwi and the results should be provided at the time of the next renewal of the product's authorisation.

Set up field monitoring of impacts on birds and mammals, applying the recommendations of the EFSA 2023 guidance document. Provide the competent authorities with any new information likely to refine the risk assessment.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information regarding:

- Provide chronic toxicity studies to refine the assessment of chronic risks to birds and mammals.
- Provide laboratory and field toxicity tests on soil organisms other than earthworms.
- Provide data such as aged residues or a field study with the product to confirm the absence of risk to non-target arthropods.

Appendix 1 Copy of the product authorisation

KUPPER20WG_PAMM_2020-2829_D.pdf

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

KUPPER® 20 WG

FONGICIDE – Cuivre de l'hydroxyde de cuivre 200g/L soit 20%(m/m)
Granulé dispersable (WG)

KUPPER® 20WG - AMM n°: XXXXX

DANGER

H317 : Peut provoquer une allergie cutanée.
H318 : Provoque de graves lésions des yeux.
H410terme. : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long

EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.
P305+P351+P338 : EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P333+P313 : En cas d'irritation cutanée : Demander un avis médical/ Consulter un médecin.
P363 : Laver les vêtements contaminés avant réutilisation.
P391 : Recueillir le produit répandu.
P501 : Éliminer le contenu/récipient conformément à la réglementation locale/régionale/nationale/internationale.

EN CAS D'URGENCE : Composer le 15 ou le 112 ou contacter le centre antipoison le plus proche (Paris : 01 40 05 48 48). Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

Premiers soins

S'éloigner de la zone dangereuse.
En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.
En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.
En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.
En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison. Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité. En cas d'intoxication animale : contacter votre vétérinaire.

Fiche de sécurité disponibles sur www.quickfds.fr

Détenteur d'AMM et distributeur : SUMI AGRO France - 251 rue du faubourg SaintMartin 75010 Paris.
Fabricant : Phoenix-Del srl, Via Venezia 9, 35131 Padova, Italy

Logo Adivalor

Contenance : 5 Kg
N° de lot et date de fabrication : voir emballage

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL – RÉEMPLOI DE L'EMBALLAGE INTERDIT.

DESCRIPTIF DU PRODUIT
KUPPER® 20WG est un fongicide préventif qui agit par contact sur un grand nombre de cultures et de maladies.

USAGES ET DOSES AUTORISÉS

Cultures	Cible	Dose (kg/ha)	Nb. maxi. d'appli./an	Application	Intervalle entre appli. (Min)	Délai avant récolte (jours)
Vigne	Mildiou(s), Excoriose, Black rot, Rougeot parasitaire.	2.8	6	Tout au long du cycle (BBCH00-99)	7	21
Pommier, Poirier, …	Tavelure(s)., Chancre européen, Maladies du feuillage,moniliose	3.36	3	BBCH 97 à 54	7	F
	Feu bactérien	1.05	4	BBCH97 et 59	7	F
	Champignons (pythiacées)	3.45	1	Pulvérisation localisée de collier entre les stades (BBCH97 et 59)	-	F
Nèfles	Tavelure(s)	3.15	4	BBCH00 à 51	7	F

Pêcher, abricotier,..	Cloque(s), Coryneum et polystigma, Monilioses, Tavelure(s), Fusicoccum, Rouille(s)	3.18	4	BBCH00 à 59	7	F
Prunier, jujube	Cloque(s), Coryneum et polystigma, Monilioses, Tavelure,	3.18	4	BBCH00 à 59	7	F
Cerisier	Coryneum et polystigma, Monilioses, Taphrina	3.18	4	BBCH00 à 59	7	F
Olivier	Maladie de l'oeil de paon, Bactérioses	3.3	3	BBCH00 à 79	7	14
Kiwi	Phytophthora, bactérioses	3.5	3	BBCH97 à 59	7	F
Fruits à coque	Bactérioses	2.8	2	BBCH00 à 54	7	F
Noisetier	Dépérissement cryptogamique	2.8	2	BBCH00 à 54	7	F
Amandier	Chancres à champignons	3.18	4	BBCH00 à 54	7	F
Noyer	Anthracnose(s)	2.8	2	BBCH00 à 54	7	F
Châtaignier	Septoriose(s)	2.8	2	BBCH00 à 54	7	F
Cassissier	Dépérissement	2.6	2	BBCH00 à 51	7	F
Framboisier, mûres	Maladies du feuillage	2.6	2	BBCH00 à 51	7	F
Tomate (plein champ et sous abri)	Mildiou(s), Bactérioses, Maladies des taches brunes	2.8	4	BBCH19 à 89	7	3(frais) 10(industriel)
Aubergine (plein champ et sous abri)	Pourriture grise et sclérotinioses, Maladies des tâches brunes	2.5	2	BBCH19 à 89	7	3
Concombre, courgette, … (plein champ et sous abri)	Mildiou(s), Maladies des tâches brunes	2.5	2	BBCH13 à 29	7	3
Melon, pastèque…	Mildiou(s), Maladies des tâches brunes, Bactérioses	2.5	2	BBCH13 à 29	7	7
Oignon, ail…	Mildiou(s), Maladies des tâches brunes, Rouille(s)	2.5	5	BBCH00 à 99	7	3
Haricots	Maladies des tâches brunes, Rouille(s)	2.5	5	BBCH00 à 99	7	3
Haricots (sous abri)	Rouille(s)	2.5	5	BBCH00 à 99	7	3

Pois écossés frais, lentilles fraiches	Mildiou(s), Maladies des tâches brunes, Rouille(s)	2.5	5	BBCH00 à 99	7	3
Pois écossés frais, lentilles fraiches (sous abri)	Rouille(s)	2.5	5	BBCH00 à 99	7	3
Arbres et arbustes (plein champ et sous abri)	Mildiou(s), Brunissures et tavelures, Maladies des tâches foliaires, Chancres à champignons, Rouille(s)	2.3	2	BBCH00 à 99	7	N/A
Cultures florales et plantes vertes	Mildiou(s), Rouille(s)	2.3	2	BBCH00 à 99	7	N/A
Rosier (plein champ et sous abri)	Mildiou(s), Rouille(s)	2.3	2	BBCH00 à 99	7	N/A
Forêt	Maladies du feuillage	2.5	3	BBCH00 à 99	7	N/A
Pomme de terre	Mildiou(s), Maladies des tâches brunes	2.6	4	BBCH12 à 81	7	3
Tabac	Mildiou	2.5	2	BBCH11 à 19	7	3

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

PREPARATION / TRAITEMENT

Préparation de la bouillie : Remplir la cuve à moitié d'eau, mettre sous agitation. Verser la quantité de KUPPER®20WG nécessaire. Compléter le remplissage.
Veiller à une répartition homogène de la bouillie sur l'ensemble de la végétation à traiter. Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

Conditions d'application :
KUPPER® 20WG est un produit de contact à utiliser de façon préventive en fonction des risques de maladies. L'application de KUPPER® 20WG se fait par pulvérisation après dilution dans l'eau, sur l'ensemble des parties de la plante à traiter.
Pour protéger les organismes du sol, ne pas appliquer ce produit ou tout autre produit contenant du cuivre à une dose annuelle totale supérieure à 4 kg Cu/ha.
Seules les utilisations entraînant une application totale maximale de 28 kg de cuivre par hectare sur une période de sept ans sont autorisées.

Mélanges extemporanés et compatibilités : Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur. L'utilisateur est responsable du mélange et doit veiller à l'application des bonnes pratiques agricoles.

Prévention et gestion de la résistance : L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, Sumi Agro France décline toute responsabilité.

STOCKAGE DU PRODUIT : Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées. Ne pas stocker dans un local ou la température peut dépasser les 35°C.

MESURES DE PROTECTIONS DES INDIVIDUS :
Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.
Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Pour protéger l'opérateur, porter :
Pendant les phases de préparation, mélange, chargement du produit :

-LUNETTES ou ECRAN FACIAL certifiés EN 166 :2002 (CE, sigle 3)
-EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
-EPI partiel (blouse ou tablier à manches longues) de catégorie Ill et de type PB (3) à porter par-dessus la combinaison précitée.
-Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A).

Dans le cadre d'une application effectuée à l'aide d'une lance :

Pendant l'application : sans contact intense avec la végétation
Culture basse (< 50 cm)
-EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
- Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)
-Bottes certifiées EN 13 832-3:2006

Culture haute (> 50 cm)
-Combinaison de protection catégorie III type 4 certifiée EN 14605+A1:2009;
- Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)
-Bottes certifiées EN 13 832-3:2006

Pendant l'application : contact intense avec la végétation
- Combinaison de protection catégorie III type 3 certifiée EN 14605+A1:2009;
- Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur porté ou traîné à rampe, pneumatique ou atomiseur, pulvérisation vers le bas

En tracteur avec cabine fermée,

-EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
- Gants EN ISO 374-1/A1 et EN ISO 374-2 (types A,B ou C)

En tracteur sans cabine fermée avec une pulvérisation vers le bas

-EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
- Gants EN ISO 374-1/A1 et EN ISO 374-2 (types A,B ou C)

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur porté ou traîné à rampe, pneumatique ou atomiseur, pulvérisation vers le haut

En tracteur avec cabine fermée,

- EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
- Gants EN ISO 374-1/A1 et EN ISO 374-2 (types A,B ou C)

En tracteur sans cabine fermée avec une pulvérisation vers le haut

- Combinaison de protection catégorie III type 4 certifiée EN 14605+A1:2009;
- Gants EN ISO 374-1/A1 et EN ISO 374-2 (types A,B ou C)

Dans le cadre d'une application effectuée à l'aide d'un automate (usages sous abri) :
Sans contact intense avec la végétation
-Combinaison de protection catégorie III type 4 certifiée EN 14605+A1:2009;
-Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)
-Bottes certifiées EN 13 832-3:2006

Avec contact intense avec la végétation
-Combinaison de protection catégorie III type 3 certifiée EN 14605+A1:2009;
-Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)
-Bottes certifiées EN 13 832-3:2006

Pendant le nettoyage du matériel :
-LUNETTES ou ECRAN FACIAL certifiés EN 166 :2002 (CE, sigle 3)
-EPI vestimentaire couvrant bras et jambes de niveau C1 conforme à la norme NF EN ISO 27065.
-EPI partiel (blouse ou tablier à manches longues) de catégorie Ill et de type PB (3) à porter par-dessus la combinaison précitée ;
-Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A)

Pour le travailleur, porter
-Gants EN ISO 374-1/A1 et EN 16523-1+A1 (type A) en cas de contact avec la culture traitée.

Avertissement :

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases

la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces…
Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.