FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

MS Finalisation date: 02/2021; 10/2021; 11/2021, April 2022, May 2022

Version history

When	What
July 2019	Dossier submitted by Sharda
February 2021	Evaluated by RMS
October 2021	Final version of the RR after commenting
November 2021	Labeling supplement
April 2022	Additional evaluation on area of Efficacy and Fate and behaviour and Ecotox Sections for early application for orchards for PL registration of the product.
May 2022	Correction on area of Ecotox for risk mitigation to aquatic organism for vines

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Sharda Cropchem España S.L.

The application is for approval of COBRANZA, a water dispersible granules formulation containing 500 g/kg of copper oxychloride (expressed as Cu), as a fungicide on grapevine, potato, solanaceous fruit (tomato, aubergine) and pome fruit (apple, pear and quince).

zRMS: Poland

1.2 Letters of Access

A letter of access to protected data for copper compound allowing the renewal of approval is submitted by applicant to support the application for COBRANZA.

1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation COBRANZA as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No.1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 9800 A
Product name in MS	COBRANZA
Authorization number	First registration
Function	Fungicide
Applicant	Sharda Cropchem España S.L
Active substance(s) (incl. content)	Copper oxychloride, 500 g/kg

Formulation type	Water dispersible granules [Code: WG]
Packaging	20-50 g, 100 g, 200 g, 250 g, 500 g, 750 g, 1 kg, 4 kg, 5 kg, 10 kg, 20 kg, 25 kg PE (multilayer)
Coformulants of concern for national authorizations	-
Restrictions related to identiy	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for COBRANZA resulted in the decision to grant the authorization.

Efficacy section:
All uses are accepted. Aubergine, pear and quince can be register only on the basis on article 51. Apple can be accepted only for dose 1,15 kg/ha with 3 applications per season; potato only for dose 2,0 kg/ha with 4 application per season and tomato with dose 1,5 kg/ha use by 3 application per season.

Residues section:
All uses applied for were authorised except for use(s) on field Solanaceous fruits (Tomato, aubergine) due to lack of the field trials.
Pome fruit (apple, pear, quince): There is no agreement on the proposed use because the provided new studies are not in line with it. It is possible to accept the application in line with the GAP of the provided new trials. GAP corrections were made in accordance with the GAP of provided field new trials.

Ecotoxicology Section:
For potato no acceptable risk for non-target arthropods is identified for rate 4 x 1000 g Cu/ha.
For potato an acceptable risk for non-target arthropods is identified for rate 3 x 1200 g Cu/ha.
~~No safe use was identified for early application in orchards.~~
Mammalian toxicology
Classification and labeling are acceptable. The assessment of the operator, worker, resident / bystander in relation to COBRANZA indicates that there is no unacceptable risk when the product is
used in accordance with the specified PPE for the purpose and label

2.3 Substances of concern for national monitoring

Not relevant.

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:	Acute Tox. 4 (oral) Acute Tox. 4 (inhalation) Aquatic Acute 1 Aquatic Chronic 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	**GHS07, GHS09**
Signal word:	**Warning**
Hazard statement(s):	**H302, H332,** H400, **H410**
Precautionary statement(s):	**P261, ~~P273~~, P280, P301+P312, P304+P340, P391, P501**
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

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).
SPe3	Spe3: To protect aquatic organisms respect • 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzles for application rate in potatoes, tomato, aubergine (Solanceous fruit) • 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzles for early and late application in apples • 20 meter vegetative buffer strip and 90% drift reduction nozzles for application in vines
SPe8	**SPe 8**: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.

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

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L
Worker protection:	
P280	Grapevine - Work wear (arms, body and legs covered) and gloves- time period of 15 days after application Work wear (arms, body and legs covered) - time period of 22 days after application Potato - Work wear (arms, body and legs covered) Solanaceous fruits - Work wear (arms, body and legs covered) and gloves Pome fruits - Work wear (arms, body and legs covered) and gloves- time period of 7 days after application Work wear (arms, body and legs covered) - time period of 14 days after application
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
	Spe3: To protect aquatic organisms respect • 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzles for application rate in potatoes, tomato, aubergine (Solanceous fruit) • 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzles for early and late application in apples • 20 meter vegetative buffer strip and 90% drift reduction nozzles for application in vines **SPe 8**: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.
Other specific restrictions	
respective code if available	are there any other national requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

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):

Integrated pest management (IPM)/sustainable use:	Relevant for use no.

-	-	-
Environmental protection:		Relevant for use no.
SPe3	Spe3: To protect aquatic organisms respect • 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzles for application rate in potatoes, tomato, aubergine (Solanceous fruit) • 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzles for early and late application in apples • 20 meter vegetative buffer strip and 90% drift reduction nozzles for application in vines	-
SPe8	**SPe 8**: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.	

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: 2016-June-23th

PPP (product name/code):	COBRANZA / SHA 9800 A	Formulation type:	WG (Water dispersible granules)
Active substance 1:	Copper oxychloride	Conc. of as 1:	500 g/Kg (expressed as Cu)
Active substance 2:	-	Conc. of as 2:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem España S.L.	Professional use:	☒
Zone(s):	CENTRAL	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	CEU	**Grapevine**	F	Downy mildew *(Plasmopara viticola)*	Foliar Spray	BBCH 15-85	a) 4 b) 4	10-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800-1000	21	* Expressed as Cu ~~**Ecotoxicology Section:** The risk is not finalised for aquatic organism.~~

2	CEU	**Potato**	F	Late blight *(Phytophthora infestans)*	Foliar Spray	BBCH 15-85	a) 4 b) 4	10-12	a) 2.0-2.4 b) 7.2-8.0	a) 1.0-1.2* b) 3.6-4.0*	500-1000	14	* Expressed as Cu 4 applications for the dose of 2.0 kg/ha **Ecotoxicology Section:** The risk is not finalised for aquatic organism. The risk for non-target arthropods is identified for rate 4 x 2 kg/ha The risk for non-target arthropods is identified for rate 4 x 2 kg/ha. Acceptable risk is for rate 3x 1200 g Cu/ha
3	CEU	**Solanaceous fruits (Tomato, aubergine)**	F	Late blight *(Phytophthora infestans)*	Foliar Spray	BBCH 15-85	a) 3 b) 3	10-12	a) 1.5-2.4 b) 4.5-7.2	a) 0.75-1.2* b) 2.25-3.6*	500-1000	3	* Expressed as Cu **Ecotoxicology Section:** The risk is not finalised for aquatic organism. **Residues section:** use not accepted
4	CEU	**Pome fruit (apple, pear, quince)**	F	Scab (*Venturia spp*.)	Foliar Spray	BBCH 15-85	a) 5 3 b) 5 3	10-12	a) 1.15-2.4 b) 5.75-7.2	a) 0.575-1.2* b) 2.875-3.6*	800-1000	14-21	* Expressed as Cu 3 applications for the dose –of 1.15 kg/ha **Ecotoxicology Section:** The risk is not finalised for aquatic organism. No safe use for aquatic organism for early application

Ecotoxicology Section: The risk for aquatic organism should be updated by the applicant with consideration of the PECsw values with further mitigation measures.

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

Remarks columns:

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

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of navy blue solid, with slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable and does not have a relative self-ignition temperature. In aqueous solution, it has a pH value around 6.08 at 20 °C. There is no effect of 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 year at ambient temperature. Its technical characteristics are acceptable for a water dispersible granules (WG) formulation.
The intended concentration of use is 0.115% to 0.48% w/v.

3.2 Efficacy (Part B, Section 3)

COBRANZA is a "Water-dispersible Granular" (WG) formulation containing 500 grams per Kilogram (g/kg) copper oxychloride (expressed as Cu) for the control of downy mildew (*Plasmopara viticola*) of grapevine, late blight (*Phytophthora infestans*) of potato and solanaceous crops as well as scab (*Venturia* spp.) of pome fruits. In compliance with the GAP, the following dose rates are applied for registration:

- Up to four applications per season (BBCH 15-85) to control *Plasmopara viticola* in grapevine, target rate: 2.0 kg/ha
- Up to four applications per season (BBCH 15-85) to control *Phytophthora infestans* in potato, target rate: 2.0 kg/ha
- Up to three applications per season (BBCH 15-85) to control *Phytophthora infestans* in solanaceous fruits, target rate: 1.5 kg/ha
- Up to three applications per season (BBCH 15-85) to control *Venturia spp.* in pom fruits, target rate: 1.15 kg/ha

This document serves the registration of COBRANZA (Copper oxychloride 50% WG) in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the fungicidal efficacy and crop safety of Copper oxychloride 50% WG in the GAP claimed crops.

To support the registration of Copper oxychloride 50% WG in the GAP claimed crops, trials have been set up in grapevine and pome fruit orchards as well as tomato and potato field crops. In all trials, the copper oxychloride formulation prepared by Sharda Cropchem España – Copper oxychloride 50% WG – was compared against a reference copper formulation currently on the market in Europe from The trials were conducted in 2016 and 2017 in a range of countries in the Maritime EPPO zone (i.e. N-France, Czech Republic and United Kingdom), the North-east EPPO zone (i.e. Poland), the South-east EPPO zone (i.e. Hungary) and the Mediterranean EPPO zone (i.e. S-France, Spain, Italy and Greece).

3.2.1 Efficacy data

Preliminary tests

The activity of copper oxychloride is well known. Copper oxychloride has been marketed by e.g. United Phosphorous as well as BASF for the use in fruits, vegetables and other crops to control a wide range of fungal, bacterial and other pests for a number of years, i.e. copper oxychloride has been used since its introduction in 1990. Based on the knowledge about the active substance (+28 years) and the experiences with the active in the label claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

Field trials were established to determine the minimum effective dose for the control of the targets claimed in this dossier. In the following, summaries of the performance of Copper oxychloride 50% WG on the key diseases in grapevine, potato, tomato and pome fruits are presented.

Copper oxychloride 50% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Copper oxychloride 50% WG applied at 0.75 kg/ha, 1.5 kg/ha and 2.0 kg/ha was evaluated in 13 grapevine trials for the control of *Plasmopara viticola* or as in efficacy trials conducted in potato (19), tomato (13) and apple (17) where the proposed dose rates in the different countries as well as at two reduced dose rates were tested for the control of *Phytophthora infestans*, *Phytophthora infestans* and *Venturia inaequalis*, respectively. The dose rates tested reflects approx. 31-52% and 62-83% and 100% of the recommended rate of Copper oxychloride 50% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. N-France, England and Czech Republic), the North-east EPPO zone (i.e. Poland), the South-east EPPO zone (i.e. Hungary) and the Mediterranean EPPO zone (i.e. Greece, Spain, Italy and S-France).

In summary, reducing the application rate of Copper oxychloride 50% WG from the proposed dose rates resulted in decreased efficacy against the causal agents of downy mildew (*Plasmopara viticola*) of grapevine, late blight (*Phytophthora infestans*) of potato and solanaceous crops as well as scab (*Venturia spp.*) of pome fruits.

According to the presented results, the proposed dose rate in the different countries and different crops provided the optimal overall control and should be considered as effective against the diseases, for which activity of Copper oxychloride 50% WG is claimed. As diseases often occur as complexes of several pathogens throughout a season, the proposed number of applications of Copper oxychloride 50% WG at the proposed rate in the different crops should be applied to efficiently control all pathogens claimed on the label.

The same pathogens are controlled by copper oxychloride in the GAP claimed crops. When applied protectively or at early stages of infestation, under the recommended conditions, the same level of control would be expected in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one use, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on other uses.

Efficacy tests and conclusions regarding authorization of intended uses

Details of experiment are presented above by Applicant. All used methodology is in accordance to GEP rules, in exception of EPPO 1/181 (4). Applicant carried out studies during only one growing season, which is not in line with EPPO 1/181 (4). However, clarifications regarding the limitation of the study to only one growing season presented by Applicant have been accepted by ZRMs. Only apple against VENTIN and potato against PHYTIN were studied during two growing seasons (2016 and 2017) in Poland (N-E EPPO zone).

Applicant submitted in total 62 field trials showing the results in research into product efficacy carried out in grapevines (13 trials), potatoes (19 trials), tomatoes (13 trials) and apples (17 trials). Those efficacy trials were performed in North-East EPPO (PL), Maritime (N-FR, CZ, UK), MED (SP, S-FR, IT, GR) and S-E (HU).

The following efficacy scale was used:
- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should been representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest).

The number of trials is not sufficient in some cases and do not fulfil EPPO requirements:

- **grapevines** (minor crop) – Maritime: 4 trials (FR-2, CZ-2); MED: 8 trials (FR-2, SP-2, IT-2, GR-2), S-E – 1 trial (HU), N-E- lack of trials.

Only for Maritime and MED EPPO zone Applicant submitted enough number of trials. cMS from S-E should decide if only 1 valid trial is acceptable, in view of the importance of PLASVI, and any national extrapolations. For Poland (N-E) we can consider results from neighboring countries, so 2 valid trials carried out in CZ should be acceptable in the opinion of Evaluator.

COBRANZA (product code: SHA 9800 A) applied at the recommended dose rate of up to 2.0 kg/ha in grapevines provided an acceptable to high level of control against the key disease claimed (PLASVI).

Regarding number of applications, trials where conducted with 4-8 applications to cover the hole season to avoid applications of other formulations in the crop. 8 application were studied in N-FR (2 trials), CZ (1 trial) and S-FR (2 trials), 6 applications: CZ (1 trial), GR (2 trials) and HU (1 trial); 5 applications: ES (2 trails), 4 applications: IT (2 trials). This is common practice in trials to avoid treatments with other actives to assure efficacy obtained is from the formulation tested. Applicant can confirm that results presented summary tables were obtained from assessments after the 3rd and 4th application to assure maximum reliability with the GAP.

- **potato** (major crop) – Maritime: 5 trials (FR-1, CZ-2, UK-2); MED: 7 trials (FR-1, SP-2, IT-2, GR-2); S-E: 1 trial (HU); N-E: 6 trials (PL).

Only for MED and N-E EPPO zone Applicant submitted enough number of trials (at least 6 are required). cMS from Maritime and S-E should decide if limited number of trials is acceptable, in view of the importance of PHYTIN, and any national extrapolations.

COBRANZA (product code: 9800 A) applied at the recommended dose rate of up to 2.4 kg/ha (Maritime, S-E and MED EPPO zone) and 2,0 kg/ha in N-E (PL) in potato provided an acceptable to high level of control against the key diseases claimed (PHYTIN). From Polish label we should excluded proposed dose 2,4 kg/ha – it was studied only during 2 trials carried out in CZ. Also, results carried out in Poland (N-E) showed that dose 2,0 kg/ha is effective, so it makes no sense to propose a higher dose in this case for Poland.

Regarding number of applications, trials where conducted with 3-8 applications to cover the hole season to avoid applications of other formulations in the crop. 4 applications were studied in CZ (1 trial), UK (1 trial); 3 applications in IT (2 trials) and GR (2 trials), 5 applications in UK (1 trial), 6 applications in CZ (1 trial), PL (6 trials) and HU (1 trial); 8 applications in N-FR (2 trials) and S-FR (2 trials). This is common practice in trials to avoid treatments with other actives to assure efficacy obtained is from the formulation tested. Applicant can confirm that results presented summary tables were obtained from assessments after the 3rd and 4th application to assure maximum reliability with the GAP.

- **tomato** (minor crop) – Maritime: 3 trials (CZ-1, UK-2); MED: 7 trials (FR-1, SP-2, IT-2, GR-2); S-E: 1 trial (HU); N-E: 2 trials (PL).

For Maritime, MED and N-E EPPO zone Applicant submitted enough number of trials. cMS from S-E EPPO zone should decide if only 1 valid trial can be accepted, in view of the importance of PHYTIN, and any national extrapolations. Lack of trials carried out on aubergine – only registration on the basis on 51

Article is possible without any efficacy trials.

COBRANZA (product code: 9800 A) applied at the recommended dose rate of up to 2.4 kg/ha (Maritime, S-E and MED EPPO zone) and 1,5 kg/ha in N-E (PL) in tomato provided an acceptable to high level of control against the key diseases claimed (PHYTIN). From Polish label we should excluded proposed dose 2,4 kg/ha – it was studied only during 1 trial carried out in CZ. Also, results carried out in Poland (N-E) showed that dose 1,5 kg/ha is effective, so it makes no sense to propose a higher dose in this case for Poland.

Regarding number of applications, trials where conducted with 3-8 applications to cover the hole season to avoid applications of other formulations in the crop. 3 applications were studied in IT (2 trials) and PL (1 trial); 4 applications – UK (1 trial) and PL (1 trial); 5 applications – CZ (2 trials) and HU (1 trial); 6 applications: GR (2 trials) and 8 applications in ES (2 trials) and S-FR (1 valid trial). This is common practice in trials to avoid treatments with other actives to assure efficacy obtained is from the formulation tested. Applicant can confirm that results presented in summary tables were obtained from assessments after the 3rd application to assure maximum reliability with the GAP.

- **Apple** (major crop) – Maritime: 4 trials (CZ-2, UK-2); MED: 6 trials (SP-2, IT-2, GR-2); S-E: 1 trial (HU); N-E: 6 trials (PL).

Only for MED and N-E EPPO zone Applicant submitted enough number of trials. cMS from Maritime and S-E EPPO zone should decide if limited number of trials is accepted, in view of the importance of VENTIN, and any national extrapolations. Lack of efficacy trials for pear and quince - only registration on the basis on 51 Article is possible without any efficacy trials.

COBRANZA (product code: 9800 A) applied at the recommended dose rate of up to 2.4 kg/ha (Maritime, S-E and MED EPPO zone) and 1,15 kg/ha in N-E (PL) in apple provided an acceptable to high level of control against the key diseases claimed (VENTIN). From Polish label we should excluded proposed dose 2,4 kg/ha – it was studied only during 2 trials carried out in CZ. Also, results carried out in Poland (N-E) showed that dose 1,15 kg/ha is effective, so it makes no sense to propose a higher dose in this case for Poland.

Regarding number of applications, trials where conducted with 3-8 applications to cover the hole season to avoid applications of other formulations in the crop. 3 applications were studied in PL (4 trials); 4 applications – GR (2 trials) and IT (1 trial), IT (2 trials); 5 applications – HU (1 trial), ES (2 trials), IT (1 trial) and PL (2 trials); 6 applications: UK (1 trial) and 8 applications: CZ (1 trial). This is common practice in trials to avoid treatments with other actives to assure efficacy obtained is from the formulation tested. Applicant can confirm that results presented in summary tables were obtained from assessments after the 3rd application to assure maximum reliability with the GAP.

As the residue section can only accept a maximum of 3 applications on apple per season, we are of the opinion that the label should accept a maximum of 3 applications per season at a rate of 1.15 kg/ha for apple trees. Assessment after 3 applications were made in 4 Polish trials also in 2 trials from Czech Republic assessment of efficacy was done after 3rd treatment (dose 0,75 kg/ha and 1,5 kg/ha were studied). Dose 1,5 kg/ha was characterized by comparable efficacy to dose 1,15 kg/ha from Polish trials. For the other two Polish studies, efficacy evaluations were made after the 4th and 5th treatments (> BBCH 77). However, based on the 4 efficacy with recommended dose 1,15 kg/ha and 2 trials with studied dose 0.75 and 1.5 kg/ha that demonstrated application efficacy after the 3rd season, we believe that the documentation is sufficient to obtain registration for application at 1.15 kg/ha max 3 times per season. Due to the fact that the Applicant should present at least 6 studies in which the dose of 1,15 kg/ha would be evaluated after 3 applications, we apply for conditional registration of application on apple trees in Poland. Condition - submit at least 2 efficacy studies carried out in Poland or neighboring country within one-two years from the date of registration, confirm the effectiveness of 1.15 kg/ha in max 3 applications per season.

As diseases often occur as a complex of several diseases with different susceptibility towards copper oxychloride, up to three applications per season of Copper oxychloride 50% WG at the recommended dose concentration should be used to efficiently control the diseases claimed on the label.

Compared to the copper oxychloride reference products tested, the efficacy obtained with Copper oxychloride 50% WG is comparable against the key diseases tested.

Compared to the other copper compound reference products tested, the efficacy obtained with Copper oxychloride 50% WG is comparable against the key diseases tested.

The trial results are considered valid for all intended Central zone countries.

Copper oxychloride 50% WG is suitable for the control of downy mildew (*Plasmopara viticola*) of grapevine, late blight (*Phytophthora infestans*) of potato and solanaceous crops as well as scab (*Venturia inaequalis*) of pome fruits.

The same pathogens are controlled by copper oxychloride in the GAP claimed crops. When applied protectively or at early stages of infestation, under the recommended conditions, the same level of control would be expected in all GAP claimed crops and this has been seen in the trials.

EFFECTIVENESS ACCORDING TO LWA APPROACH:

According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the test product should be presented and interpreted according to LWA by the applicant. From efficacy`s point of view, the reference to ha ground area is not sufficient any more (EPPO PP 1/239). Therefore, the Evaluator calculated the LWA for COBRANZA, using the treated canopy height as well as the row distance between the rows from the single trial reports (where these parameters were available).

Conversion of the application dose in kg/ha LWA
According to the EPPO guideline PP 1/239(2) “great efforts are being made to obtain optimum efficacy from the applied product and to avoid unnecessary emission of products into the environment and residues in feed and food” and “the best watt to achieves this is to adapt dose rate to the area where the treatment is needed (e.g. crop canopy) and its structure.
An easy way to establish correct application dose in three-dimensional crops is to use dose per treated leaf area unit (LWA).

To calculate LWA is needed to know distance between rows and treated foliage height.

Calculation of LWA:

$$\text{Leaf Wall Area (LWA)} = \frac{2 \times \text{tree height [m]}}{\text{Distance between rows [m]}} \times 10\,000\ m^2/ha$$

APPLE (VENTIN)

Below LWA is calculated for each report:

Trial report	Tree height [m]	Spacing within row [m]	Row spacing [m]	LWA (m^2)
SHA005-16-EFF003-001 (UK)	2,2-2,5	No data	No data	No data
SHA005-16-EFF003-002 (UK)	1,8-3,0	No data	No data	No data
SWEPL-CZE16-OXHT-MABSD-PPT17 (CZ)	3,3-3,8	1,2	3,5	18857-21714
SWEPL-CZE16-OXHT-MABSD-PPT18 (CZ)	2,8-3,7	3,0	5,0	11200-14800
375-01-F17-334 (PL)	3,2	1,2	3,5	18286
375-02-F17-335 (PL)	2,2	1,5	3,8	11579
375-03-F17-336 (PL)	4,0	2,5	4,0	20000
375-04-F17-337 (PL)	3,4	1,2	3,8	17895
PL 16 079 PL1 (PL)	2,6-2,8	2,0	4,0	13000-14000
PL 16 079 PL2 (PL)	2,8-3,0	2,0	4,0	14000-15000
F-14/2/2016	No data	1,0	4,0	No data
16E063/1 (GR)	3,0	1,0	3,6	16667
16E063/2 (GR)	3,0	1,2	3,8	15789
E46AG16-01 (IT)	No data	4,0	4,0	No data

E45AG16-02 (IT)	No data	2,5	4,0	No data
033E16S (ES)	2,1-2,3	3,5	4,5	9333-10222
034E16S (ES)	1,85-2,0	2,0	4,0	9250-10000

For determining the dose per ha ground for every m canopy height we should dose per ha LWA * conversion factor (the conversion factor is calculated by dividing the leaf wall area by 10 000) *canopy height (m) = ‘dose per ha ground per m canopy height).

- **Maritime EPPO zone:** range of LWA vary between 11200 and 21714 what indicates that the ratio to calculate application per LWA should be between 1,11 and 2,14 kg/ha LWA. The conversion factor is 1,12 and 2,17. If we consider the average of LWA's (16643) noted in all trials then the proposed dose should be: 1,44 kg/ha LWA (on the basis the average LWA and dose 2,4 kg/ha per ground).

- **South-East EPPO zone:** in the trial lack of height of canopy. No pos-sibility of calculating the dose of LWA. The final decision to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc.

- **North-East EPPO zone:** LWA vary between 11579 and 20000 what in-dicates that the ratio to calculate application per LWA should be 0,99 and 1,15 kg/ha LWA. The conversion factor is 1,16 and 2,00. If we consider the average of LWA's (15470) noted in all trials then the proposed dose should be: 0,74 kg/ha LWA (on the basis the average LWA and dose 1,15 kg/ha per ground).

- **MED EPPO zone:** LWA vary between 9250 and 10222 what indicates that the ratio to calculate application per LWA should be 2,34 and 3,84 kg/ha LWA. The conversion factor is 0,925 and 1,15. If we consider the average of LWA's (11876) noted in all trials then the proposed dose should be: 2,02 kg/ha LWA (on the basis the average LWA and dose 2,4 kg/ha per ground).

The final decision to accept this approach and to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc. The field tests presented by the Applicant are characterized by very different testing conditions, e.g. large differences in the number of crops, height or row spacing which directly translates into the proposed dose of LWA. Therefore, as ZRMs we present only the obtained results, and we expect their detailed interpretation by each cMS, accordingly to agro-climatic conditions and average LWA of apple trees crops.

GRAPEVINES (PLASVI)

Below LWA is calculated for each report:

Trial report	Tree height [m]	Spacing within row [m]	Row spacing [m]	LWA (m^2)
S-16-00494-03 (FR)	2,0-2,4	1,15	2,7	14815-17778
S-16-00494-04 (FR)	0,8-1,5	0,90	1,35	11852-22222
SWEPL-CZE16-OXHT-VITVI-PPT19 (CZ)	1,5-2,0	1,0	3,0	10000-13333
SWEPL-CZE16-OXHT-VITVI-PPT20 (CZ)	1,9-2,4	1,0	3,0	12667--16000
F-13/1/2016 (HU)	Lack o data	1,0	3,0	Lack of data
16E60/1 (GR)	1,6	1,3	2,1	15238
16E60/2 (GR)	1,6	1,4	2,0	16000
E43AG16-01 (IT)	Lack of data	1,2	1,3	Lack of data
E43AG16-02 (IT)	Lack of data	0,8	1,5	Lack of data
027E16S (ES)	Lack of data	1,5	3,0	Lack of data
028E16S (ES)	Lack of data	1,5	3,0	Lack of data
S-16-00494-01 (FR)	1,25-1,5	1,0	2,5	10000-12000
S-16-00494-02 (FR)	0,9-1,6	1,0	2,0	9000-16000

• Maritime EPPO zone: range of LWA vary between 10000 and 17778 what indicates that the ratio to calculate application per LWA should be between 0,50 and 0,89 kg/ha LWA. **If we consider the average of LWA's (14833) noted in all trials then the proposed dose should be: 1,35 kg/ ha LWA.**

- Mediterranean EPPO zone: range of LWA vary between 9000 and 16000 what indicates that the ratio to calculate application per LWA should be between 0,45 and 0,80 kg/ha LWA. **If we consider the average of LWA's (13040) noted in all trials then the proposed dose should be: 1,53 kg/ ha LWA.**
- South-East EPPO zone: in the trial lack of height of canopy. No possibility of calculating the dose of LWA. The final decision to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc.
- North-East EPPO zone: lack of trials. We can take into consideration 2 trials from neighbouring countries (CZ). Range of LWA vary between 10000 and 16000 what indicates that the ratio to calculate application per LWA should be between 0,50 and 0,80 kg/ha LWA. **If we consider the average of LWA's (13000) noted in all trials then the proposed dose should be: 1,54 kg/ ha LWA.**

The final decision to accept this approach and to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

The active substance copper oxychloride belongs to the chemical class of inorganic copper compounds in the group of multi-site contact fungicides and is classified in Group M1 by FRAC (FRAC MOA Code: Multi-site, Group code M1).

Copper oxychloride is a protective fungicide used to control bacterial and fungal diseases of fruit, vegetable, nut, and field crops. These diseases include mildew, leaf spots, blights and apple scab. It is used as a protective fungicide (Bordeaux mixture) for leaf application and seed treatment. It is also used as an algacide and herbicide, and to kill slugs and snails in irrigation and municipal water treatment systems. It has been used to control Dutch elm disease.

Copper fungicides have been used by fruit and vegetable growers for many years as protectant treatments to prevent spore germination on plant tissue. Fungicides based on copper provide cost effective disease control but also have an additional benefit over non-copper fungicides which is their activity against bacterial pathogens.

Plant surfaces need to have a complete coverage of copper fungicide to defend the plant against infection. Copper fungicides work by preventing spore germination and can act at several stages in the fungus development. Any plant surface left untreated remains a potential disease infection site.

The Registration of COBRANZA (Copper oxychloride 50% WG) is endorsed.

The agronomic risk for the COBRANZA (product code: SHA 9800 A) which include copper oxychloride is estimated as low.

The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided.

Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk

of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.

3.2.3 Adverse effects on treated crops

Phytotoxicity to host crop

As Copper oxychloride 50% WG is a fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Copper oxychloride 50% WG at the recommended rates in grapevine, potato, solanaceous crops and pome fruits was evaluated in 63 efficacy trials. In grapevine trials, Copper oxychloride 50% WG was applied at dose rates ranging from 0.75 kg/ha to 2.0 kg/ha and in potato, tomato and apple trials, Copper oxychloride 50% WG was applied at 0.75 kg/ha to 2.4 kg/ha. This is equivalent to up to 1000 g copper oxychloride/ha or 1200 g copper oxychloride/ha. In two English potato trials, Copper oxychloride 50% WG was furthermore applied at 5.0 kg/ha and in two English tomato trials, Copper oxychloride 50% WG was furthermore applied at 3.0 kg/ha. In the Polish trials, Copper oxychloride 50% WG was applied at 1.0 to 2.0 kg/ha in potato, 0.75 to 1.5 kg/ha in tomato and 0.6 to 1.15 kg/ha in apple. Furthermore, to give additional evidence to the safe use of Copper oxychloride 50% WG in the GAP claimed crops, the results obtained in four grapevine field trials conducted in support of the vinification study are reported. In the vinification trials, Copper oxychloride 50% WG was applied at 2.0 kg/ha, in an application scheme where Chaoline (fosetyl-Al 47.1% + metiram 28.9% WG) was applied at the first three applications, followed by three applications of Copper oxychloride 50% WG at 2.0 kg/ha and finally, three or four applications of Dithane Neotec (mancozeb 75% WG) were applied.

Effects on yield and quality

To evaluate the effect of Copper oxychloride 50% WG on the yield of grapevine, potato, solanaceous crops and pome fruits, the results obtained in 24 efficacy trials conducted in 2016 and 2017 have been included to support the registration of Copper oxychloride 50% WG in the label claimed crops.

The 24 trials were conducted on grapevine (4), potato (12), tomato (4) and apple (4). Copper oxychloride 50% WG was applied at four (3), five (3), six (12) or eight (6) applications at growth stages relevant to the proposed GAP. All trials presented in this section of the Review Report were located within the Maritime, the North-east or the Mediterranean EPPO zone as defined by EPPO Standard PP1/241(1).

Copper oxychloride 50% WG applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, in grapevine, potato, tomato and apple did not affect crop yield significantly in any of the 24 trials harvested. Furthermore, the data obtained in trials harvested demonstrate that Copper oxychloride 50% WG is as safe to the crop as the reference products used in the trials (copper oxychloride, tribasic copper sulphate and captan).

Grapevine, potato, solanaceous crops and pome fruits are claimed on the label. For crops and recommendations claimed on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in grapevine, potato, tomato and apple where harvest data demonstrated the safe use following application of Copper oxychloride 50% WG as recommended. Furthermore, the data presented in this Review Report also clearly demonstrates that the efficacy and crop safety of Copper oxychloride 50% WG is equivalent to the standard copper oxychloride reference products as well as the other copper compound reference products to which it was compared in the trials.

Effect on transformation processes

Processing can include physical processing such as cooking of potatoes. It has already been shown in previous section that the application of Copper oxychloride 50% WG at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed.

Other processes depend on biological activity and are referred to as 'transformation'. These include e.g. wine-making and are potentially sensitive to plant protection products. Fungicides are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) *Effects of plant protection products on transformation processes*). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 4) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, copper oxychloride-containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, the active is part of many products which have been used for a long time as fungicide in e.g. vegetables, grapevine and pome fruits. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

To give additional support to these arguments, the applicant wishes to refer to the DAR on copper compounds, Section B 7.8.3. (Monograph (2007), Vol. III, p. 641-705) where results obtained with a number of residue trials are presented.

According to the DAR on copper compounds, available residue data on copper in processing commodities on grape were considered sufficient and acceptable. For further information please refer to Registration Report Part B Section 7 (Metabolism and Residues).

However, to demonstrate that no adverse effects on transformation processes is to be expected, vinification tests conducted on grapes have been carried out. These show no effect from Sharda Copper oxychloride 50% WG formulation or the reference product on the vinification process of treated grapes.

Impact on treated plants or plant products to be used for propagations

Copper oxychloride 50% WG is composed of oxychloride copper, which has been widely used for several years on e.g. vegetables and fruits, without identifying any issues in regards to seeds of treated plants to germinate as well as the ability of treated plant part to be used for propagating purposes.

Thus, negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products.

3.2.4 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

In orchards and other perennial crops, the impact on succeeding crops is not relevant.

As per the DAR for copper compounds (Volume 3, Annex B, part 5/D, B9, pp. 73 (2007)), the following argumentation was given in favour of copper oxychloride not having an adverse effect on non-target plants:

Copper is an essential element to all plants and must exist in soil for growth, development and reproduction. Copper may also be toxic in excessive soil concentrations to plants. Plants have developed homeostatic mechanisms to deal with low and high levels of copper in soil. Predicting whether certain plants will be susceptible to copper in soil is made complex by the bioavailability of copper, related to soil pH, organic carbon, soil structure and -texture, associated micro-organisms and so on.

Copper is toxic to plants at concentrations from 0.02 mg Cu/L (ICA, 1999) when tested in nutrient media without the interference of soil binding. However, some grasses are able to grow in soils with levels of 11,000 mg Cu/kg (xxxxx., 1987) and some tree species are intolerant to soil copper concentrations of 12.5 mg Cu/kg (xxxxx, 1995). Therefore, the concentrations of copper in soils that are toxic to plants vary greatly amongst species.

The risk to non-target flora following use of copper salts are considered to be very low. Copper is not taken up by the foliage of plants and only selectively absorbed by roots. The annual input of copper of 5.3 mg Cu/kg d.w. (based on cumulative application of 4000 g Cu/ha per season in e.g. vineyards) is relatively low and not expected to elicit toxicity, based on the weight of evidence from studies on individual species and plant communities. Over longer periods, the ageing of copper in soils will reduce bioavailability and thus reduce risk significantly. Furthermore, copper is recommended for use on a wide range of plants, grown under a wide range of agronomic conditions, indicating that higher plants can tolerate relatively high amounts of copper.

Based on this, the risk to non-target plants is considered as acceptable for proposed uses.

Impact on other plants including adjacent crops

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, it was demonstrated that Copper oxychloride 50% WG is not phytotoxic to the crops claimed in the GAP.

When applied with foliar application, the maximum individual proposed rate of Copper oxychloride 50% WG is 2.4 kg/ha (equivalent to 1200 g copper oxychloride/ha) in e.g. pome fruit orchards and the maximum cumulative application rate per season is 8.0 kg/ha (4 x 2.0 kg/ha, equivalent to 4000 g copper oxychloride applied per hectare throughout the season) in e.g. vineyards.

As a fungicide, copper oxychloride would not be expected to pose a high risk to non-crop plants, based on the argumentation given in the previous section). Furthermore, according to the revised Ganzelmeier drift values, the PEC for copper oxychloride would be only 8.02% of the maximum individual applied dose at a drift distance of 3 m (i.e. 96.24 g ai/ha) following a late application in e.g. pome fruit orchards. Throughout the season, the cumulative PEC for copper oxychloride would be only 11.01% of the total applied dose at a drift distance of 3 m (i.e. 396.36 g ai/ha) in the worst-case scenario (3 x 2.4 kg/ha in pome fruit crops). Given the magnitude of this difference, the data are considered sufficient to demonstrate that in normal use, copper oxychloride should not pose an unacceptable risk to non-target flora.

Finally, copper oxychloride has been used for decades on several crops, including annuals and perennials, without problems.

Conclusion

Based on this, the risk to non-target plants from copper oxychloride is considered low.

For further information and guidance on the agronomic risk following a foliar application of copper oxychloride at a field rate of up to 1200 g copper oxychloride/ha per application, please refer to Registration Report Part B Section 9: Ecotoxicological studies.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trial conducted.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for Copper oxychloride in food and feed of plant origin, water, air, soil, tissues and in the formulation Copper oxychloride 50% WG are available.

3.3.1 Analytical method for the formulation

3.3.1.1 Determination of the active substances in the plant protection product

An analytical method for the determination of Copper oxychloride in the formulation COBRANZA (Copper Oxychloride 50% WG) has been developed and sufficiently validated. The determination of the active ingredient is performed by potentiometric titration with platinum electrode method.
According to the SANCO/3030/99 rev.4 guidance document, the analytical method for the determination of Copper oxychloride in Copper Oxychloride 50% WG was validated.

	Copper oxychloride
Author(s), year	Xxxxxxxxxxx, 2016
Principle of method	Potentiometric titration with platinum electrode method
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Range of copper oxychloride from 0.0826 g to 0.1797 g (corresponds to the concentration range of 67% to 134 % of copper content in the preparation) $R^2 = 1$
Precision – Repeatability Mean n = 6 (%RSD)	RSD = 0.08% Acceptable relative standard deviation for main ingredient (~ 50%) is RSDr $\leq$ 1.48%.
Accuracy n = 12 (% Recovery)	Average recovery : 99.36 %
Interference/ Specificity	No interference, the method is specific
Comment	None

3.3.1.2 Determination of relevant impurities

An analytical methods for the determination of relevant impurities (Sb, Pb, Cr, Co, As, Cd, Ni, Hg) in the formulation COBRANZA (Copper Oxychloride 50% WG) have been developed and sufficiently validated. The determination of the As, Cd, Ni, Pb, Co, Cr and Sb has been determined simultaneously in a sample of test item by ICP-OES method and the determination of Hg by the Direct Mercury Analyzer.
According to the SANCO/3030/99 rev.5 guidance document, the analytical methods for the determination of relevant impurities in Copper Oxychloride 50% WG were validated.

	Sb	Pb	Cr	Co	As	Cd	Ni	Hg
Author(s), year	xxxxx, 2020							
Principle of method	ICP-OES							Direct Mercury Analyzer
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	9 points 0.02-4.0 mg/L y=222.22821x + 9.191954921 R = 1.00000	9 points 0.02-4.0 mg/L y=54.33365x – 0.035113311 R = 0.99998	10 points 0.005-2.0 mg/L y=1558.92325x - 1.546766698 R = 0.99996	10 points 0.005-2.0 mg/L for level 0.006 mgCo/L: y=3017.12398x + 9.374008671 R = 0.99999 for level 0.5 mgCo/L: y=2974.15212x + 2.060145133 R = 0.99998	9 points 0.02-4.0 mg/L y=147.11832x + 4.127608487 R = 0.99999	9 points 0.005-2.0 mg/L y=8259.45793x + 7.261907727 R = 0.99999	9 points 0.02-4.0 mg/L y=709.51012 + 18.47835109 R = 0.99998	8 points 0.005 – 2.5 mg/kg (FP) y=0.93424x + 0.43993524 R = 0.99989
Precision – Repeatability Mean n = 5 (%RSD)	0.02 mg/L %RSD = 4% 0.5 mg/L %RSD = 3%	0.1 mg/L %RSD = 5% 0.5 mg/L %RSD = 2%	0.01 mg/L %RSD = 2% 0.5 mg/L %RSD = 1%	0.006 mg/L %RSD = 3% 0.5 mg/L %RSD = 1%	0.1 mg/L %RSD = 2% 0.5 mg/L %RSD = 1%	0.1 mg/L %RSD = 1% 0.5 mg/L %RSD = 1%	0.1 mg/L %RSD = 1% 0.5 mg/L %RSD = 2%	0.01 mg/kg (FP) %RSD = 6% 0.2 mg/kg (FP) %RSD = 1%
Accuracy n = 10 (% Recovery)	Global mean recovery: 81 ± 18%	Global mean recovery: 85 ± 6%	Global mean recovery: 116 ± 10%	Global mean recovery: 81 ± 2%	Global mean recovery: 94 ± 3%	Global mean recovery: 79 ± 1%	Global mean recovery: 87 ± 5%	Global mean recovery: 101 ± 5%
Interference/ Specificity	No interference							
LOQ	LOQ = 1 mg/kg (FP)	LOQ = 5 mg/kg (FP)	LOQ = 0.5 mg/kg (FP)	LOQ = 0.3 mg/kg (FP)	LOQ = 5.0 mg/kg (FP)	LOQ = 5.0 mg/kg (FP)	LOQ = 5.0 mg/kg (FP)	LOQ = 0.01 mg/kg (FP)

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3.3.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are:

- none

A letter of access to protected data for copper compound allowing the renewal of approval is submitted by applicant to support the application for COBRANZA.

Commodity/crop	**Supported/ Not supported**
Berries and small fruits (Grapevine)	Supported
Root and tuber vegetables (Potato)	Supported
Solanaceous fruits (Tomato, aubergine)	Supported
Pome fruit (apple, pear, quince)	Supported

3.4 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for COBRANZA (Oxychloride 50% WG) were not evaluated as part of the EU review of Copper oxychloride. Therefore, all relevant data were provided and are considered adequate.
The assessment of all acute toxicological properties of Copper Oxychloride 50% WG was derived from the calculation method based on the classification of the active compound and co-formulants.

Classification: H302 Harmful if swallowed.
H332 Fatal if inhaled.

3.4.1 Operator exposure

Operator exposure to COBRANZA was not evaluated as part of the EU review of Copper Oxychloride for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.
Estimations of potential operator exposure have been undertaken for Copper Oxychloride using the AOEM.

Conclusion:
According to the AOEM model, calculations, it can be concluded that the risk for the operator using COBRANZA is acceptable for grapes vegetables and pome fruits with the use of gloves and standard working clothing (long sleeved shirt and trousers) during mixing/loading and application and with the use FP1, P1 or similar mixing/loading.

The following labelling is therefore required:
P280: Wear protective gloves, face protection

3.4.2 Worker exposure

Worker exposure to COBRANZA was not evaluated as part of the EU review of Copper Oxychloride for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.
Estimations of potential worker exposure have been undertaken for COBRANZA using the AOEM.

Conclusion:
Grapevine

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapevine treated with COBRANZA a time period of 8 days after application is respected or without gloves when a time period of 15 days after application is respected.

Potato

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated Potato even without suitable protective clothing.

Solanaceous fruits (Tomato, aubergine)

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves).

Pome fruit (apple, pear, quince)

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering pome fruits treated with COBRANZA a time period of 7 days after application is respected or without gloves when a time period of 14 days after application is respected

3.4.3 Bystander and resident exposure

Bystander and resident exposures to COBRANZA was not evaluated as part of the EU review of Copper Oxychloride. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM.

It can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to COBRANZA.

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

A letter of access to protected data for copper compound allowing the renewal of approval is submitted by applicant to support the application for COBRANZA.
Storage stability
No new data are submitted in the framework of this application.
Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of copper in crop commodities will be stable and copper is not expected to metabolize or to form degradation products.
Metabolism in plant and animal
The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance.
The data evaluated is sufficient to support the proposed uses.
The residue definitions agreed for monitoring and risk assessment:
Copper compounds (copper)
No further data are required.
Magnitude of residues in plants
Grapevine
Proposed GAP: BBCH 15-85, 4 applications, interval between applications: 10-12 days, 1.0 kg (as copper), PHI: 21 days
GAP on which MRL/EU a.s. assessment is based: 4 x 2 kg as/ha, BBCH: 15-91, PHI 21d (wine grape, *EFSA Journal 2018;16(3):5212*)
Representative uses: 3 x 1.25 kg as/ha, BBCH: 12-89, PHI 21d (*SANTE/10506/2018Rev. 5, 27November 2018*)
The number of trials is sufficient as to support the use of Copper hydroxide in grapevines according to the proposed GAP in Central Zone (see DAR; trials also reported in RAR).
The residues arising from the proposed use will not exceed the MRLs for wine grape set at 50 mg/kg (Reg. (EU) 149/2008). Extrapolation to table grapes is possible (SANCO 7525/VI/95_rev 10.3).
Pome fruit (apple, pear, quince)
Proposed GAP: BBCH 15-85, 5 applications, interval between applications: 10-14 days, 0.575-1.2 kg (as copper), PHI: 14 days
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.
Trials GAP: 3 x 1.2 kg as/ha, interval – 10 days, BBCH 83, PHI 21 days
Four trials were conducted in Hungary in 2019. Two harvest trials and two decline curve trials were set up on apples in Poland in 2019.

Results: 4 x <1.0 (LOQ), 1.2, 1.4, 1.5, 2,9 mg/kg.
GAP of trials is different than proposed. The residues arising from the trials are below MRL.
There is no agreement on the proposed use because the studies are not in line with it.
It is possible to accept the application in line with the provided new trials. GAP corrections were made in accordance with the GAP of this field new trials.
Extrapolation to pear and quince is possible (SANCO 7525/VI/95_rev 10.3).
Potato
Proposed GAP: BBCH 15-85, 4 applications, interval between applications: 10-12 days, 1.0-1.2 kg (as copper), PHI: 14 days
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Four trials were conducted in Hungary in 2019. Two harvest trials and two decline curve trials were set up on potatoes in Poland in 2019.
Trials GAP: 4 x 1.2 kg as/ha, interval – 7 days, BBCH 85
Results: 8 x < 3.7 (LOQ)
The number of trials is sufficient as to support the use of Copper hydroxide in potato according to the proposed GAP in Central Zone.
The residues arising from the proposed use will not exceed the MRLs for potatoes set at 5.0 mg/kg (Reg. (EU) 149/2008).
Solanaceous fruits (Tomato, aubergine)
Proposed GAP: BBCH 15-85, 3 applications, interval between applications: 10-12 days, 0.75-1.2 kg (as copper), PHI: 14 days
The EU data (EFSA, 2008; EFSA Journal 2018;16(1):5152) are sufficient to cover proposed uses in SEU and protected uses in NEU and SEU. There is no sufficient data to cover proposed uses in outdoor NEU.
Uses are not accepted.

Magnitude of residues in livestock

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

Industrial Processing and/or Household Preparation

No supplementary studies on the effects of industrial processing and/or household preparations on residue levels have been conducted or are required

Magnitude of residues in representative succeeding crops

EFSA Journal 2018;16(1):5152: *Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops).*
No additional studies are required.

3.5.1 Consumer exposure

The TMDI estimates for the various diets were found 92.6% of ADI. The highest TMDI was calculated for the NL Toddler. For this diet, maize and wheat were the highest contributors to the residue intake, representing 11% of ADI, respectively. It should be noted that the biggest contributors (cereal) are not supported uses for copper compounds. It is therefore determined that the exceedance of the ADI of copper to be unlikely.
The proposed uses of copper in the formulation COBRANZA do not represent unacceptable acute and chronic risks for the consumer.

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

Concentrations of Copper oxychloride in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

Intended use pattern of COBRANZA

Crop	Application rate (kg ai/ha)	Application method	Max. number of applica-tions	Minimum application interval (days)	Application timing
Grapevine	1	Foliar spray	4	10	BBCH 15-85
Potato	1	Foliar spray	4	10	BBCH 15-85
Solanaceous fruits (Tomato, aubergine)	1.2	Foliar spray	3	10	BBCH 15-85
Pome fruit (apple, pear, quince)	1.2	Foliar spray	3	10	BBCH 15-85

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Copper oxychloride using the EU agreed endpoints (EFSA Journal 2018;16(1):5152).

Maximum PEC_{soil} value was 165.33 mg Cu/kg for Copper oxychloride following the highest application rate of 4 x 1000 g Cu/ha.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} calculations have been conducted with Copper hydroxide using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and EU agreed endpoints (EFSA Journal 2018;16(1):5152).

PECgw values were all below 0.001 µg/L.
In accordance with national law – Regulation of Minister of Health, 20th April, 2010 amending the regulation on the quality of water intended for human consumption (Journal of Laws 2010 No. 72, item. 466) – the highest acceptable copper concentration in drinking water is 2.0 mg/l. The assessed PECgw value is below trigger value of 0.1 µg/L and also below 2.0 mg/L (legal limit set by the European Drinking Water Directive (98/83/EC) for groundwater)

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

The $PEC_{sw/sed}$ of Copper oxychloride have been assessed the models FOCUS STEP 1, 2 using EU agreed endpoints (EFSA Journal 2018;16(1):5152), combined with several mitigation measures.

The PECsw have been calculated taking into account the protection zones WBZ and NSZ and the use of appropriate anti-drift techniques. Details of the calculations are included in B8.

The PECsw and PECsed values may be used in the aquatic risk assessment.

In addition, calculations of PECsw were performed to refine the exposure for “early” application using 60% interception.

PECsw and PECsed values for active substance copper following a single application to all proposed crop in GAP

Crop	Calculations with drift and run off mitigation and 90% mitigation nozzle reduction							
	Exposure by runoff and drainage		Exposure by drift					
	PECsw (runoff and drainage) STEP2 unmitigated µg/L)	PECsw with 90% reduction runoff (20 m VBZ) µg/L)	PECsw (drift) STEP2 unmitigated µg/L)	PECsw (90% reduction drift) µg/L)	10m NSZ µg/L)	20m NSZ µg/L)	30m NSZ µg/L)	50m NSZ µg/L)
Apple, pear, quince early 1x1200g Cu/ha	2.32	0.23	46.40	4.64	0.46	0.16	0.04	0.01

Sum PECsw (drift and runoff) values for active substance copper following a single application to all proposed crop in GAP after risk mitigation measure

Crop	Sum of concentrations µg/L of copper and 90% mitigation nozzle reduction			
	20 m VBZ 10 m NSZ	20 m VBZ 20 m NSZ	20 m VBZ 30 m NSZ	20 m VBZ 50 m NSZ
Apple, pear, quince early 1x1200g Cu/ha	**0.69**	**0.39**	**0.27**	**0.24**

3.6.4 Predicted environmental concentrations in air (PEC_{air})

Copper oxychloride is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the Copper hydroxide due to volatilization with subsequent deposition should not be considered.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

❖ Brids

According to screening and tier I assessments for different intended crops uses, TERa and TERlt values are below the Annex VI triggers, indicating that Cobranza presents an unacceptable acute and long-term risk to birds according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment was necessary. Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for birds exposed to applications of Cobranza at the proposed label rate.
The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

❖ Mammals

According to screening and tier I assessments for different intended crops uses, TERa and TER_{lt} values are below the Annex VI triggers, indicating that Cobranza presents an unacceptable acute and long-term risk to mammals according to the intended uses. Therefore, an acute and long-term higher-tier risk assessment was necessary. Therefore, a WoE is applied. In this context, it can be conclude that the risk is low for mammals exposed to applications of Cobranza at the proposed label rate.

The risk for drinking water exposure is acceptable and the effect of secondary poisoning is not expected.

3.7.2 Effects on aquatic species

The ratios between predicted environmental concentrations in surface water bodies (PECsw) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended uses in the GAP.
To achieve a concise risk assessment for aquatic dwelling organisms, an ETO-RACsw; ch value of 0.37 µg/L was used as this value was protective of all acute and chronic risks to all relevant aquatic species.
Based on the lowest value RAC of 0.37 microgram/L for fish the PECsw/RAC ratio is below 1, when following risk mitigation measures are applied:

- 20 meter buffer zone with 10 meter vegetative buffer strip and 90% drift reduction nozzels for application rate in potatoes, tomato, aubergine (Solanceous fruit)
- 30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzels for application rate late apples
- 20 meter vegetative buffer strip and 90% drift reduction nozzles for application in vines

It should be indicated that no safe risk is identified for apple, pear and quince early application when 50 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzles.
For the lower dose proposed in the GAP the applicant should provide additional calculations in NA for Poland.

Therefore, further refinement was provided for PL registration of the product Cobranza taking into account the updated PECsw calculations provided by e-fate expert **for early application** in orchards presented in the Table below:

Sum PECsw (drift and runoff) values for active substance copper following a single application to all proposed crop in GAP after risk mitigation measure

Crop	Sum of concentrations µg/L of copper and 90% mitigation nozzle reduction
	20 m VBZ 30 m NSZ
Apple, pear, quince **early** 1x1200g Cu/ha	0.27

Taking into account the **RAC of 0.37 microgram/L for fish** the PEC_{sw}/RAC ratio is below 1 (0.27/0.37=0.73), when following risk mitigation measures are applied:

- **30 meter buffer zone with 20 meter vegetative buffer strip and 90% drift reduction nozzles for early application in orchards**

Sediment dwelling organism
According to the calculations of PEC/RAC ratio in Core Dossier , the risk from the use of active substance for early and late applications in vines, apples and potatoes is not acceptable for sediment dwelling organisms considering the active substance-copper.
However, there is no approved guideline for calculating PECsedacc values to determine protective measures for non-organic compounds. The existing default mitigation measure for PECsw for copper for aquatic organism was considered to reduce to exposure for sediment dwelling organism for Poland until relevant modelling will be available.

3.7.3 Effects on bees

The risk assessment for bees has been done. The Q_{HC} values are below 50, indicating a low risk to bees following the application of COBRANZA at the proposed label rate. However, Q_{HO} was higher than trigger and risk was detected. After a higher-tier risk assessment based on semi-field study which was conducted with copper oxychloride WP on *Phacalia*, no significant effects were detected at maximum application rate according to GAP. However, the chronic test for adult bees and larvae should be submitted by the applicant according to REg.284/2009. Based on all available information the following risk mitigation measures to bees should be applied.
SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.

3.7.4 Effects on other arthropod species other than bees

No in-field risk assessment is expected after application of Cobranza in vines and orchards and potato and fruiting vegetables at rate 3 x 1200 g Cu/ha/
An unacceptable risk in field was concluded for potatoes, for max proposed doses 4 x 1000 g Cu./ha
No off-field risk to non-target arthropods is expected after the application of Cobranza according to the proposed GAP.

3.7.5 Effects on non-target soil meso- and macrofauna

The risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) has been done. A risk to earthworms and other non-target soil organisms following the application of Corbanza at the proposed label rate can be excluded up to rate of 4 kg Cu./ha.

3.7.6 Effects on soil organisms

No risk for soil micro-organisms is expected after the application COBRANZA according to the proposed GAP.

3.7.7 Effects on non-target terrestrial plants

The calculated TER values are above the Annex VI trigger of 5 based on ER50 values from vegetative vigour and seedling emergence tests and PERoff -field for all intended uses

3.7.8 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

Copper is an element and therefore the formation of metabolites or breakdown products is not possible.

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

COBRANZA contains copper oxychloride which is approved as a candidate for substitution because two of PBT criteria. However, the applicant disagrees with this classification and is challenging the application of the 'P' criteria to inorganic substances under Reg 1107/2009 since it is not applied to such substances under Regs. (EU) 528/2012 or 1278/2008.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja skuteczności:
nie akceptuje dawki 2,4 kg/ha dla jabłoni, gruszy, pigwy aplikowanej 3 razy w sezonie; dawki 2,4 kg/ha aplikowanej 4 razy w sezonie na ziemniaku oraz dawki 2,4 kg/ha aplikowanej 3 razy w sezonie na pomidorze, z uwagi na niewystarczającą liczbę badań. Miedź może powodować uszkodzenia kwiatów i liści w owocach ziarnkowych, gdy jest stosowana później niż BBCH 53. W związku z tym, w opinii oceniającego, na etykiecie powinno być umieszczone ostrzeżenie o możliwości wystąpienia fitotoksycznych uszkodzeń owoców ziarnkowych. Jest to informacja, którą zawarto w etykiecie produktu w środkach ostrożności. Wynika z praktyki stosowania fungicydów miedziowych. W badaniach przedstawionych przez Aplikanta wykazano tylko, iż niektóre odmiany mogą być bardziej wrażliwe na miedź. Jednak nie stwierdzono działania fitotoksycznego środka. Dlatego zaakceptowano pełne okienko aplikacyjne produktu.

Sekcja pozostałości:
Brak zgody na zastosowanie w ochronie pomidora i bakłażana
Jabłoń, grusza, pigwa: zgoda na maksymalną liczbę zabiegów w sezonie: 3; okres karencji: 21 dni; odstęp miedzy zabiegami: 10 dni
Ziemniak, winorośl: odstęp miedzy zabiegami: 10 - 12 dni
Sekcja Ekotoksykologii:
Brak zgody na zastosowanie w ochronie ziemniak w dawce 4 x 2000 g /ha. Zgoda na zastosowanie 3 x 2.4 kg/ha.
~~Brak zgody na zastosowanie wczesne w sadach.~~

Załącznik do zezwolenia MRiRW nr R- / z dnia ……. r.

Posiadacz zezwolenia:
Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcja, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel. (22) 886 9328 lub (17) 240 13 07, e-mail: eu.sales@shardaintl.com

COBRANZA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
miedź w postaci tlenochlorku miedzi **– 84.49% (500g/kg)**

Zezwolenie MRiRW nr R- ……. z dnia ……. r.

Uwaga

H302 - Działa szkodliwie po połknięciu
H332- Działa szkodliwie w następstwie wdychania.

~~H302+H332 - Działa szkodliwie po połknięciu lub w następstwie wdychania~~.
H410 - Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH 401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P261 - Unikać wdychania pyłu, mgły.
~~P273 - Unikać uwolnienia do środowiska.~~
P280 - Stosować odzież ochronną, rękawice ochronne, ochronę twarzy, ochronę oczu.
~~P312 - W przypadku złego samopoczucia skontaktować się z lekarzem, z OŚRODKIEM ZATRUĆ~~.
P301+ P312 – W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem
P304+P340- W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania**.**
P391 - Zebrać wyciek.
P501 - Zawartość/pojemnik usuwać do specjalny punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi.

OPIS DZIAŁANIA
COBRANZA jest środkiem grzybobójczym w formie granul do sporządzania zawiesiny wodnej (WG) o działaniu powierzchniowym do stosowania zapobiegawczego w ochronie winorośli, ~~ziemniaka, pomidora, bakłażan~~, jabłoni, ~~gruszy oraz pigwy~~ przed chorobami grzybowymi i bakteryjnymi.
Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych, sadowniczych i ręcznych.
STOSOWANIE ŚRODKA

Winorośl
Mączniak rzekomy
Termin stosowania: : Środek stosować zapobiegawczo, od fazy 5 liści do fazy mięknięcia jagód w gronach (BBCH 15-85).
Maksymalna dawka dla jednorazowego zastosowania: 2,0 kg/ha (1,54 kg / 10 000m^2 LWA – powierzchnie ściany owoconośnej)
Zalecana dawka do jednorazowego stosowania: 2,0 kg/ha. (1,54 kg / 10 000m^2 LWA – powierzchnie ściany owoconośnej)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4.
Odstęp między zabiegami: ~~co najmniej 7~~ 10-12 dni.

Zalecana ilość wody: **800-1000 l/ha**.
Zalecane opryskiwanie: **średniokropliste.**

~~**Ziemniak**~~
~~*Zaraza ziemniaka*~~
~~Termin stosowania: Środek stosować od fazy 5 liści do wstępnej fazy dojrzewania jagód - jagody na pierwszym owocostanie zmieniają barwę z zielonej na brązową (BBCH 85). (BBCH 15-85).~~
~~**Maksymalna dawka dla jednorazowego zastosowania: 2,4 kg/ha.**~~
~~**Zalecana dawka do jednorazowego stosowania: 2,4 kg/ha.**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.**~~
~~**Odstęp między zabiegami: co najmniej 7 dni.**~~

~~lub~~

~~**Maksymalna dawka dla jednorazowego zastosowania: 2,0 kg/ha.**~~
~~**Zalecana dawka do jednorazowego stosowania: 2,0 kg/ha.**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4.**~~
~~**Odstęp między zabiegami: co najmniej 7 dni.**~~

~~Zalecana ilość wody: **500-1000 l/ha**.~~
~~Zalecane opryskiwanie: **średniokropliste.**~~

~~**Pomidor, bakłażan**~~
~~*Zaraza ziemniaka*~~
~~Termin stosowania: środek stosować od fazy 5 liści do końca fazy gdy 50% owoców uzyskuje typową barwę (BBCH 15-85).~~
~~**Maksymalna dawka dla jednorazowego zastosowania: 2,4 kg/ha 1,5 kg/ha.**~~
~~**Zalecana dawka do jednorazowego stosowania: 1,5 – 2,4 kg/ha.**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.**~~
~~**Odstęp między zabiegami: co najmniej 7 dni.**~~

~~Zalecana ilość wody: **500-1000 l/ha**.~~
~~Zalecane opryskiwanie: **średniokropliste.**~~

~~**Jabłoń, grusza, pigwa**~~
parch
Termin stosowania: środek stosować zapobiegawczo lub interwencyjnie od fazy rozwoju liści do fazy zaawansowanego dojrzewania (BBCH 15-85).
~~**Maksymalna dawka dla jednorazowego zastosowania: 2,4 kg/ha.**~~
~~**Zalecana dawka do jednorazowego stosowania: 2,4 kg/ha.**~~

~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.**~~
~~**Odstęp między zabiegami: co najmniej 7 dni.**~~

~~lub~~

Maksymalna dawka dla jednorazowego zastosowania: 1,15 kg/ha (0,74 kg/ 10000m^2 LWA – powierzchni ściany owoconośnej).
Zalecana dawka do jednorazowego stosowania: 1,15 kg/ha (0,74 kg/ 10000m^2 LWA – powierzchni ściany owoconośnej).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~5~~ 3.
Odstęp między zabiegami: co najmniej ~~7~~ 10 dni.

Zalecana ilość wody: **800-1000 l/ha**.
Zalecane opryskiwanie: **średniokropliste.**

~~Środek nie może być stosowany~~ **~~we wczesnych fazach wzrostu w uprawie jabłoni~~**

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ
1. Niektóre odmiany jabłoni (np. Idared, Jonagored) mogą okazać się wrażliwe na działanie środka. Zaleca się wykonanie testu kontrolnego na 10 – 14 dni przed zastosowaniem środka w celu sprawdzenia czy opisane symptomy występują.
2. Miedź może powodować uszkodzenia kwiatów i liści w owocach ziarnkowych po zastosowaniu jej później niż BBCH 53.

SPORZĄDZANIE CIECZY UŻYTKOWEJ Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić jej ilość. Odważoną ilość środka wymieszać w osobnym naczyniu z małą ilością wody, następnie wlać przez sito do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz mechaniczne wymieszać. Po pracy trzykrotnie aparaturę dokładnie wymyć.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY
Z resztkami cieczy użytkowej po zabiegu oraz z wodą użyta do mycia aparatury należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:
- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA
Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:
Nie jeść, nie pić, ani nie palić podczas używania produktu.
W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
~~Stosować ochronę oczu/ ochronę twarzy/ rękawice ochronne/ odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.~~
Stosować odzież roboczą (zakryte ramiona, ciało i nogi) oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych

Środki ostrożności związane z ochroną środowiska naturalnego:
Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.
Zebrać rozsypany produkt.

W celu ochrony organizmów wodnych należy zastosować

- 20 metrową strefę w tym 10 metrową zadarnioną wraz z użyciem końcówek redukujących znoszenie o 90% w uprawie pomidora, bakłażana
- 30 metrową strefę w tym 20 metrową zadarnioną wraz z użyciem końcówek redukujących znoszenie o 90% we wczesnym i późnym zastosowaniu w uprawie jabłoni, ~~gruszy, pigwy~~

~~Środek nie może być stosowany we wczesnych fazach wzrostu w uprawie jabłoni, gruszy pigwy~~

- 20 metrową strefę zadarnioną wraz z użyciem końcówek redukujących znoszenie o 90%

Niebezpieczne dla pszczół
W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia:
Nie używać w miejscach gdzie pszczoły mają pożytek
Nie stosować kiedy występują kwitnące chwasty
Usuwać chwasty przed kwitnieniem

OKRES OD ZASTOSOWANIA ŚRODKA DO DNIA, W KTÓRYM NA OBSZAR, NA KTÓRYM ZASTOSOWANO ŚRODEK MOGĄ WEJŚĆ LUDZIE ORAZ ZOSTAĆ WPROWADZONE ZWIERZĘTA:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA DO DNIA ZBIORU ROŚLINY UPRAWNEJ (okres karencji):

Winorośl – 21 dni
~~Ziemniak – 14 dni~~
~~Pomidor, bakłażan – 3 dni~~
Jabłoń, ~~grusza, pigwa~~ – ~~14~~ 21 dni

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY DO DNIA, W KTÓRYM MOŻNA SIAĆ LUB SADZIĆ ROŚLINY UPRAWIANE NASTĘPCZO:

Nie dotyczy.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY PRZEZNACZONE NA PASZĘ DO DNIA, W KTÓRYM ZWIERZĘTA MOGĄ BYĆ KARMIONE TYMI ROŚLINAMI (okres karencji dla pasz):

Nie dotyczy.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN
I OPAKOWANIA
Chronić przed dziećmi

Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0^0C-30^0C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC
Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę

Okres ważności – 2 lata.
Data produkcji -
Zawartość netto -
Nr partii -

Letter of Access

A letter of access to protected data for copper compound allowing the renewal of approval was submitted by Applicant to the Polish Ministry of Agriculture and Rural Development in August 2020.

Appendix 3 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.1.3	xxxxx	2021	Determination of Co, Cr, Sb, and Hg in Copper Oxychlo-ride xxxxxx xxxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 2.1 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1	xxxxx	2016	Copper oxychloride 50% Wg. Part I: Evaluation of physicochemical properties of the initial preparation and after accelerated storage. xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 2.2.1	xxx	2016	Copper oxychloride 50% WG. Determination of explosive properties. xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	xxxxx	2016	Copper oxychloride 50% WG. Determination of flammability, relative self-ignition temperature and oxidizing properties. xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 2.7.1 KCP 2.7.5	xxxxx	2016	Copper oxychloride 50% WG. Method development and validation for determination of the content of active substance in the formulation. xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 5.1.1	xxxxx	2016	Copper Oxychloride 50 % WG: Method development and validation for determination of the content of active substance in the formulation. xxxxx GLP/Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 5.2.1/01	xxxxx	2018	Determination of residues of 10% tribasic copper, 4% dimethomorph and 25% fosetyl aluminium in courgettes, melons and potatoes. xxxxx GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Limited
KCP 5.2.1/02	xxxxx	2017	Method Validation for the determination of copper in/on dry and oily matrices and Matrix Effect evaluation on dry, oily, high water and acid matrices xxxxx Published	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.2.5/01	xxxxx	2018	Validation of the Analytical Method for the determination of Copper residues in Air xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Copper oxychloride 50% WG (500 g/kg copper oxychloride WG) – EU Cental zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.1.1.2	xxxxx	2018	Copper 50% (as Oxychloride) WG Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.2.2-01	xxxxx	2019	An extended laboratory test for evaluating the effects of Copper 50% (as Oxychloride) WG on the predatory mite, *Typhlodromus pyri* (Sch.) xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd.
KCP 10.3.2.2-02	xxxxx	2019	An extended laboratory test for evaluating the effects of Copper hydroxide 50% WP on the parasitic wasp, *Aphidius rhopalosiphi* xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd.
KCP 10.4.2.1-01	xxxxx	2019	Copper 50% (as Oxychloride) WG Collembolan (*Folsomia candida*) Reproduction Test xxxxx Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd.

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2 and KCP 5.2	xxxxx	2002a	Analytical method validation for the determination of copper in/on grapes and their processed fractions xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2 and KCP 5.2	xxxxx	2002b	Analytical method validation for the determination of copper in/on tomatoes, their processed fractions and leaves. xxxxx GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2 and KCP 5.2	xxxxx	2010	Method validation for the reduction of the Limit of Quantification for copper in representative matrices of plant origin. xxxxx GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2008a	Magnitude of residues of copper in field melons (cucurbits-inedible peel) following applications of metallic copper (as copper oxychloride)/Cymoxanil (DPX-KK807) 44WP (9.5:1)-southern Europe, season 2007 xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	Hansford, R.J.	2008b	Magnitude of residues of copper in protected melons (curcurbits – inedible peel) following applications of metallic copper (as copper oxychloride) / cymoxanil (DPX-KK807) 44WP (9.5:1) – Southern Europe, season 2007 xxxxx GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	xxxxx	2006b	Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, season 2005 xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2006c	Magnitude of residues of copper and cymoxanil in protected melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates – southern europe, 2004 xxxxx GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2006a	Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, 2004 xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2005	Residue determination of copper in melon after 6 applications of ATOFAP02 (WG 20%) or ATOFAP17NC (WG 40%) xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2006	Residue determination of copper in melon after 6 applications of ATOFAP02 (Copper - 20% WG) or ATOFAP17NC (Copper - 40% WG) xxxxx Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	xxxxx	2015	A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe Company Report No: 20031343/G1-NFEw Eurofins GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.1.2	Blust R., Steven Joosen S	2015	Kinetics and speciation of copper in copper based fungi-cide formulations used in crop protection (Update Febru-ary 2016) F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium Non-GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2000	Community level study with Copper hydroxide 50% WP in aquatic microcosms Company Report No: URA-001/4-50 xxxxx GLP: Yes Publised: No	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2015	In vitro percutaneous absorption of copper, formulated as Copper hydroxide 50 WP or Copper oxychloride SC, through human and rat skin Company Report No: V20600/19 + Amendment 01 xxxxx GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	xxxxx	2016	Validation of the determination of 65Cu in receptor fluid, stripped skin, tape strips, receptor/donor wash solution and skin wash used in the 'In vitro percutaneous absorption test of copper through human and rat skin', using a double-focusing high resolution inductively coupled plasma mass spectrometer (HR-ICP-MS) Company Report No: V20801 xxxxx GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.1.2	xxxxx	2016	In vitro dermal absorption of copper (Cu) from 8 formula-tions through human skin Company Report No: V9062 + Amendment 01 xxxxx GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.2	Riccelli S.	2016	Method Validation for the determination of copper in/on tomato juice and melon (pulp and peel) Company Report No: RA.16.08 Isagro GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	European Union Copper Task Force
KCP 5.2	Anon.	2014	Foodstuffs – Determination of trace elements – Pressure digestion Report No.: DIN EN 13805 Deutsches Institut für Normung Non-GLP Publised:	N	N	-	Public

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Anon.	2003	Foodstuffs – Determination of trace elements – Determination of lead, cadmium, zinc, copper, iron and chromium by atomic absorption spectrometry (AAS) after dry ashing Report No.: EN 14082 European committee for standardization Non-GLP Published	N	N	-	Public
KCP 5.2	Kiefer, R.	2003	Validation of an analytical method for the determination of bioavailable copper in soil samples Company Report No: 20031084/02-UVX GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH GLP Unpublised	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.2	Carey, D. O.	1989	Method validation report for terrestrial outdoor field dissipation study with copper-containing pesticides Company Report No: 88-003 Biospherics Inc. GLP Unpublised	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.2	Kiefer, R.	2004	Validation of an analytical method for the determination of total copper in soil samples Company Report No: 20031084/01-UVX GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH GLP Unpublised	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	xxxxx	2001	Assessment of side effects of URA-13900-F-0-WP on the larvae of the midge, *Chironomous riparius* with the laboratory test method. Company Report No: 99520/01-ASCr xxxxx GLP Unpublised	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.2	xxxxx.	2000	Assessment of side effects of URA-08740-F-0-WP on the larvae of the midge, *Chironomous riparius* with the laboratory test method Company Report No: 99507/01-ASCr xxxxx GmbH GLP Unpublised	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.2	Martinez M. P.	2016	Validation of the analytical method for the determination of copper in surface water Company Report No.: CH-157/2016 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 5.2	Anon.	1991	German standard methods for the examination of water, waste water and sludge; Cations (group E); Determination of copper by atomic absorption spectrometry (AAS) (E 7) Report No.: DIN 38406 Part 7, September 1991 Deutsches Institut für Normung Non-GLP Publised	N	N	-	Public

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Anon.	2004	Water quality. Determination of trace elements using atomic absorption spectrometry with graphite furnace Report No.: DIN EN ISO 15586 Deutsches Institut für Normung Non-GLP Publised	N	N	-	Public
KCP 5.2	Anon.	1999	Determination of suspended matter in ambient air. Measurement of the concentration by mass of As, Be, Cd, Co, Cr, Cu, Mn, Ni, Pb, Sb, Tl, Zn by atomic absorption spectrometry (AAS) after sampling on filters and digestion in an oxidising acid mixture. Report No.: VDI 2267, Part 1 Verein Deutscher Ingenieure Non-GLP Published	N	N	-	Public
KCP 5.2	Anon.	1999	Determination of suspended matter in ambient air. Measurement of the concentration by mass of As, Be, Cd, Co, Cr, Cu, Mn, Ni, Pb, Sb, Tl, Zn by atomic absorption spectrometry (AAS) after sampling on filters and digestion in an oxidising acid mixture. Report No.: VDI 2267, Part 1 Verein Deutscher Ingenieure Non-GLP Published	N	N	-	Public
KCP 5.2	xxxxx	2004	Five copper substances: Absorption, distribution, and excretion in male rats. Company Report No: DuPont-11784 xxxxx GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.1-01	Coulomb, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of copper, cymoxanil and folpet. 9801AGT Viti R&D, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.1-02	Brereton, R.	2003a	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.1-03	Martin, C.	2003a	Copper: Residue levels in wine grapes from trials conducted in southern France, Italy and southern Spain during 2002., AF/6891/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.1-04	Brereton, R.	2003b	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Germany during 2001 AF/5991/CU. Agrisearch GLP, Unpublished.	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
K-CA 6.3.1-05	Martin, C.	2003b	Copper: Residue levels in wine grapes from trials conducted in Northern France and Germany during 2002 AF/6890/CU Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
K-CA 6.3.1-06	Brereton, R.	2003c	Copper: Residue levels in wine grapes from a single trial con-ducted in northern France during 2002. AF/6842/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force
K-CA 6.3.1-07	Collina, A	1998a	Determinazione dei residui di rame in uva a seguito di trattamenti per la difes della vite con I formulate pasta caffaro e cuprocaffaro 255 CER/RES (11/98) Industrie Chimiche Caffaro Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force
K-CA 6.3.1-08	Malet & Allard	1999a	Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur vigne. Ministère de l'agriculture et de la pêche, RVVIXX198/43 Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force
K-CA 6.3.1-09	Collina, A	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98) Industrie Chimiche Caffaro, Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force
CA 6.3.1-10	Brereton, R	2003d	Copper: Residue levels in table grape and processed fractions from trials conducted in Spain and Italy during 2001. AF/5990/CU Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force
CA 6.3.1-11	Brereton, R	2003e	Copper: Residue levels in table grape from a single trial con-ducted in Spain during 2002. AF/6550/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Un-ion Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.2-01	Martin, C	2003c	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.2-02	Malet, J C & Allard, L	1999b	n.b. This reference is comprised of three separate reports in one pdf document… 1. Mesure du niveau de résidus de cuivre sur tomate. RLTOXX197/30 Ministère de l'agriculture et de la pêche Y N 2. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX198/42 Ministère de l'agriculture et de la pêche Y N 3. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX199/43 Ministère de l'agriculture et de la pêche Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.2-03	Brereton, R	2003f	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001. AF/5987/CU. Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.2-04	Martin, C.	2003d	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.2-05	Brereton, R.	2003g	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2001. AF/5986/CU. Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.2-06	Martin, C.	2003e	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.3-01	Brereton, R.	2002	Copper: Residue levels in tomato (protected) from trials conducted in France, Spain and Italy during 2001. AF/5988/CU. Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.3-02	Martin, C.	2003f	Copper: Residue levels in tomato (protected) from trials conducted in France, Spain and Italy during 2002. AF/6549/CU. Agrisearch, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.4-01	Kreke, N.	2009a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2009 C 48132 Harlan laboratories Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.4-02	Kreke, N.	2010a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2010 C 91095 Harlan laboratories Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.4-03	Kreke, N.	2011	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern Europe in 2011 D35555 Harlan laboratories Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.5-01	Kreke, N.	2009b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in northern and southern Europe in 2009 C48121 Harlan laboratories Yes No	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.5-02	Kreke, N.	2010b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in greenhouse in northern and southern Europe in 2010 C91084 Harlan laboratories Yes No	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.6-01	Foster, A.C.	2006a	Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, 2004 DuPont-14542, Revision No. 1 Charles River Laboratories (UK) Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.6-02	Foster, A.C.	2006b	Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, season 2005 DuPont-16970 Charles River Laboratories (UK) Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.6-03	Hansford, R.J.	2008a	Magnitude of residues of copper in field melons (cucurbits-inedible peel) following applications of metallic copper (as copper oxychloride)/Cymoxanil (DPX-KK807) 44WP (9.5:1)-southern Europe, season 2007 DuPont-22565 Charles River Laboratories (UK) Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.6-04	Goebel, O	2005	Residue determination of copper in melon after 6 applications of ATOFAP02 (WG 20%) or ATOFAP17NC (WG 40%) B_05RFLME01 Staphyt Yes No	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.3.6-05	Goebel, O	2006	Residue determination of copper in melon after 6 applications of ATOFAP02 (Copper - 20% WG) or ATOFAP17NC (Copper - 40% WG) B_06RFLME01 Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.7-01	Foster, AC	2006c	Magnitude of residues of copper and cymoxanil in protected melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates – southern europe, 2004 DuPont 14536 DuPont Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.3.7-02	Hansford, R.J.	2008b	Magnitude of residues of copper in protected melons (curcurbits – inedible peel) following applications of metallic copper (as copper oxychloride) / cymoxanil (DPX-KK807) 44WP (9.5:1) – Southern Europe, season 2007 DuPont 22564 DuPont Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/01:	Brereton, R.	2003h	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001 AF/5987/CU Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 6.5.3/02:	Martin, C.	2003g	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU Agrisearch Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/03	Coulomb, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of copper, cymoxanil and folpet 9801AGT, Processing phase 9801ATV. Viti R&D Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/03	Saint-Joly, C.	1999a	Analyses de résidus de cuivre sur raisin, vin, marc et mout. 981218 Lara Laboratoire Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/03	Saint-Joly, C.	2003a	Analyses de résidus de cuivre et cymoxanil sur raisin, vin. 981219. Lara Laboratoire Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/03	Saint-Joly, C.	2003b	Analyses de résidus de cuivre, cymoxanil et folpel sur raisin et vin. 981220. Lara Laboratoire Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/03	Saint-Joly, C.	1999b	Analyses de résidus de cuivre sur raisin. Lara Laboratoire, 990723. Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

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CA 6.5.3/04:	Collina, A.	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98) Industrie Chimiche Caffaro, Y N	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/05:	Perny, A.	1999	Determination of copper residues in grape raw agricultural commodity, and in must and wine following treatments with the preparation Bouillie Bordelaise RSR under field conditions in France in 1998. R 8031	N	Y	Data/study report never submitted before to Poland	UPL
CA 6.5.3/06:	Brereton, R..	2003i	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/09	Anon	1992	Cuprasol (49.9% copper as copper oxychloride) SPI 12827	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/10	Anon	1992	Wacker 83 v (24.8% copper as copper oxychloride) SPI 12828	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
CA 6.5.3/11	Anon	1992	Fitoran grün (42.8% copper as copper oxychloride) SPI 12828	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.1.2-01	xxxxx	2019	Addendum to Final Report: A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe: Statistical Analysis of a long term earthworm field study xxxxx Addendum 1 to Final Report 20031343/G1-NFEw Non GLP Unpublished	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force
KCP 10.4.1.2-02	xxxxx	2018	Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology. Paper: April 2018, Volume 27, Issue 3, pp 300–312 GLP Published	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data pro-tection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.1.2-03	Caetano et al.,	2015	Copper toxicity in a natural reference soil: ecotoxicological data for the derivation of preliminary soil screening values Ecotoxicology. Paper: January 2016, Volume 25, Issue 1, pp 163–177 | Cite as GLP Published	N	Y	Data/study report never submitted before to Poland	European Union Copper Task Force