FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 9800 A

Product name(s): 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: June 2019

MS Finalisation date: 28/01/2021; 08/2021

Version history

When	What
May 2020	Applicant updated document
January 2021	ZRMs evaluated version of dRR.
August 2021	ZRMs added some information's after commenting period.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). In yellow, ZRMs added some information's after commenting period.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This document summarises the information related to the efficacy data of the plant protection product **Copper oxychloride 50% WG (COBRANZA; Product code: SHA 9800 A)** containing the active substance copper oxychloride, which was included into Annex I of Council Directive 91/414/EEC and renewed the approval in accordance with Regulation (EC) No 1107/2009 under Commission Implementing Regulation (EU) 2018/1981.

Final Renewal report for the active substances copper compounds (SANTE/10506/2018 Rev. 5 – 27 November 2018) is considered to provide the relevant review information or a reference to where such information can be found.

Copper oxychloride 50% WG 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.

This dossier demonstrates the broad efficacy spectrum of Copper oxychloride 50% WG against the key pathogen in grapevine, solanaceous crops and pome fruits and demonstrates that the formulation is safe to the GAP claimed crops. To prove the fungicidal efficacy and crop safety of Copper oxychloride 50% WG, trials were set up in grapevine and pome fruit orchards as well as tomato and potato field crops. 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).

According to the CEU GAP, the maximum proposed application rate of Copper oxychloride 50% WG in Potato and Solanaceous crops is 2.4 kilograms per hectare (kg/ha), with up to three applications per season for the control of Late blight (*Phytophthora infestans* – PHYTIN). For the control of Scab (*Venturia spp.* – VENTSP) in pome fruits, the maximum proposed application rate of Copper oxychloride 50% WG is also 2.4 kg/ha, with up to three applications per season. When targeting Downy mildew (*Plasmopara viticola* – PLASVI) in Grapevine, the maximum proposed application rate is 2.0 kg/ha, with up to four applications per season. This will deliver max. 1000 g or 1200 g copper oxychloride per hectare, depending on the crop and pest to control. In CEU, the lowest proposed application rate of Copper oxychloride 50% WG is 2.0 kg/ha, with up to four applications per season in Potato against Late blight (*Phytophthora infestans* – PHYTIN), 1.5 kg/ha, with up to three applications per season in Tomato against Late blight (*Phytophthora infestans* – PHYTIN) and 1.15 kg/ha, with up to five applications per season in pome fruits against Scab (*Venturia inaequalis* – VENTIN). This will deliver min. 575 g to 1000 g copper oxy-

chloride per hectare, depending on the crop and pest to control. In the current document, results obtained in field trials with Copper oxychloride 50% WG applied at 0.60 kg/ha to 5.0 kg/ha will be presented where these have been tested against similar dose rates of copper-containing reference products and/or national reference products currently marketed in the countries where the trials were conducted.

The data presented in this document fully support the label claim for Copper oxychloride 50% WG for the control of downy mildew (*Plasmopara viticola*) of grapevine, late blight (*Phytophthora infestans*) of solanaceous crops as well as scab (*Venturia spp.*) of pome fruits.

The claims of crop safety on grapevine, potato, solanaceous crops and pome fruits are supported with a total of 67 trials conducted in France, Czech Republic, UK, Poland, Hungary, Spain, Italy and Greece in 2016 and 2017 in grapevine, potato, tomato and apple. In all trials, Copper oxychloride 50% WG proved to be crop safe and did not significantly affect the crop adversely when applied as recommended. The same was observed in the treatments where Copper oxychloride 50% WG was applied at dose rates higher than the recommended rate, representative of sprayer overlap.

Overall, Copper oxychloride 50% WG is an effective, selective fungicide for control of downy mildew of grapevine, late blight of potato and solanaceous crops as well as scab of pome fruits. Copper oxychloride is an effective component in the solution for sustainable resistance strategies.

The Registration of Copper oxychloride 50% WG in the GAP claimed crops is endorsed.

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Grapevine**	F	Downy mildew *(Plasmo-para 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	To be con-firmed by cMS
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 3 applications for the dose of 2.4 kg/ha, 4 applica-tions for the dose of 2.0 kg/ha	To be con-firmed by cMS
3	CEU	**Solanaceous fruits (Tomato, auber-gine)**	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	To be con-firmed by cMS
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	* Expressed as Cu 3 applications for the dose of 2.4 kg/ha, ~~5~~ 3 appli-cations for the dose of 1.15 kg/ha	To be con-firmed by cMS

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Copper oxychloride 50% WG** containing the active substance copper oxychloride, which was included into Annex I of Council Directive 91/414/EEC and renewed the approval in accordance with Regulation (EC) No 1107/2009 under Commission Implementing Regulation (EU) 2018/1981.

Final Renewal report for the active substances copper compounds (SANTE/10506/2018 Rev. 5 – 27 November 2018) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on copper oxychloride as well as other copper compounds, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27rd November 2018 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of copper oxychloride relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	**KCP 6.0/001 Biological Assessment Dossier Copper oxychloride 50% WG, Central**

Description of the plant protection product

Copper oxychloride 50% WG is a "Water-dispersible Granular" (WG) formulation containing 500 grams per Kilogram (g/kg) copper oxychloride 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.

Overall, Copper oxychloride 50% WG is an effective, selective fungicide for the control of downy mildew of grapevine, late blight of solanaceous crops as well as scab of pome fruits. Copper oxychloride is an effective component in the solution for sustainable resistance strategies.

According to the CEU GAP, the maximum proposed application rate of Copper oxychloride 50% WG in Potato and Solanaceous crops is 2.4 kilograms per hectare (kg/ha), with up to three applications per season for the control of Late blight (*Phytophthora infestans* – PHYTIN). For the control of Scab (*Venturia spp.* – VENTSP) in pome fruits, the maximum proposed application rate of Copper oxychloride 50% WG is also 2.4 kg/ha, with up to three applications per season. When targeting Downy mildew (*Plasmopara viticola* – PLASVI) in Grapevine, the maximum proposed application rate is 2.0 kg/ha, with up to four applications per season. This will deliver max. 1000 g or 1200 g copper oxychloride per hectare, depending on the crop and pest to control. In CEU, the lowest proposed application rate of Copper oxychloride 50% WG is 2.0 kg/ha, with up to four applications per season in Potato against Late blight (*Phytophthora infestans* – PHYTIN), 1.5 kg/ha, with up to three applications per season in Tomato against Late blight (*Phytophthora infestans* – PHYTIN) and 1.15 kg/ha, with up to five applications per season in pome fruits against Scab (*Venturia inaequalis* – VENTIN). This will deliver min. 575 g to 1000 g copper oxychloride per hectare, depending on the crop and pest to control. In the current document, results obtained in field trials with Copper oxychloride 50% WG applied at 0.60 kg/ha to 5.0 kg/ha will be presented where these have been tested against similar dose rates of copper-containing reference products and/or national reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for Copper oxychloride 50% WG for the control of downy mildew (*Plasmopara viticola*) of grapevine, late blight (*Phytophthora infestans*) of solanaceous crops as well as scab (*Venturia spp.*) of pome fruits, as listed in the table below.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Max. requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Grapevine	PLASVI	CEU	4 x 2.0 kg/ha	BBCH 15-85
Potato	PHYTIN	CEU CEU	3 x 2.4 kg/ha 4 x 2.0 kg/ha	BBCH 15-85 BBCH 15-85
Solanaceous fruits	PHYTIN	CEU CEU	3 x 2.4 kg/ha 3 x 1.5 kg/ha	BBCH 15-85 BBCH 15-85
Pome fruit	VENTIN	CEU CEU	3 x 2.4 kg/ha 5 x 1.15 kg/ha	BBCH 15-85 BBCH 15-85

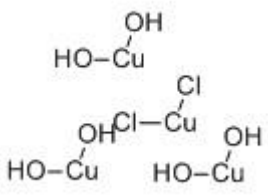
Further details are in the table "All intended uses" in Part B - Section 0.

Description of active substance copper oxychloride

The active substance copper oxychloride belongs to the chemical class of inorganic copper compounds. Copper oxychloride is a protective fungicide used to control bacterial and fungal diseases of fruit, vegetable, nut, and field crops.

Today, copper oxychloride is registered and commercialised in several formulations, as straight product as well as in mixtures, around the world.

Table 3.2-2: Identity of copper oxychloride

Common name	Copper oxychloride
IUPAC name	dicopper chloride trioxide
CA name	copper chloride hydroxide
CIPAC No	44.602
CAS Registry No.	1332-40-7
EEC No	215-572-9
Molecular formula	$(ClCu_2H_3O_3)_2$
Molecular mass	427.14 g/mol
Minimum purity	> 569 g/kg total copper
Structural formula[1]	

[1] Source: Chemical Book. Internet, Wednesday February 6th, 2019. URL: https://www.chemicalbook.com/ChemicalProductProperty_EN_CB9781274.htm

Mode of action, copper oxychloride

Copper oxychloride is a 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 algaecide 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.
FRAC (Fungicide Resistance Action Committee) presents copper fungicides as an inorganic compound in the group of multi-site contact fungicides. Due to its primary target site and its chemical family, in the FRAC mode of action classification, it is classified as group M01 Fungicide.

Information on similar formulations and current approvals

Data presented in this dossier is generated using this formulation in comparison with reference products containing copper compounds. Copper oxychloride is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-3: Current approvals of copper oxychloride-containing products in the EU Central Zone as well as connected EPPO zones where trials were conducted. Reference products used in trials are also included.

Country	Product	Active ingredient	Approval number
Austria	Badge WG	Copper hydroxide 244 g/kg + Copper oxychloride 245 g/kg WG	3966-0
Czech Rep.	Cuprocaffaro Micro	Copper oxychloride 657.9 g/kg WG	4624-0
France	Styrocuive DF	Copper oxychloride 50% w/w WG	9400346
	Cuproxat SC	Tribasic copper sulphate 19% SC	2090119
	Bouillie Bordelaise RSR Disperss NC	Copper 20% w/w WG	9800474
Germany	Funguran	Copper ~~oxychloride~~ hydroxid 756 g/kg WP	050723-00
Greece	e.g. Check 50 WG Cuproxat 19 SC	Copper oxychloride 50% w/w WG Tribasic copper sulphate 19% w/w SC	60081 6790
Hungary	Cuprosan 50 WP	Copper oxychloride 50% w/w WP	04.2/3215-2/2016
Ireland	Curenox 50 WP	Copper oxychloride 87.8% WP	05829
Italy	e.g. Copper Pro 50 WDG Cuproxat S.D.I.	Copper oxychloride 50% w/w WG Tribasic copper sulphate 19% w/w SC	009014 011569
Poland	e.g. Neoram 37.5 WG Cuproxat 345 SC	Copper oxychloride 375 g/kg WG Tribasic copper sulphate 19% w/w SC	R-203/2015 R-1/2009
Portugal	e.g. Cuprocaffaro WG Cuproxat	Copper oxychloride 37.5% w/w WG Tribasic copper sulphate 19% w/w SC	3791 3913
Spain	e.g. Sanagricola 500 WG Cuproxat 34.5	Copper oxychloride 50% w/w WG Tribasic copper sulphate 19% w/w SC	18406 19425
UK	Cuprokylt Captan 80 WDG	Copper oxychloride 87.8% w/w WP Captan 800 g/kg WG	17079 16293

Description of the target pests

All the key target diseases (*Plasmopara viticola*, *Phytophthora infestans* and *Venturia* spp.) are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product are described in detail in the Biological Assessment dossier.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
ALTESO	*Alternaria solani*	Early blight
PHYTIN	*Phytophthora infestans*	Late blight of tomato
PLASVI	*Plasmopara viticola*	Downy mildew of grapevine
VENTIN	*Venturia inaequalis*	Scab

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Grapevine	CEU	CEU	*Plasmopara viticola*	CEU	-
Potato	CEU	-	*Phytophthora infestans*	CEU	-
Tomato and aubergine	CEU	CEU	*Phytophthora infestans*	CEU	-
Apple, pear and quince	CEU	CEU	*Venturia inaequalis*	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in France, Czech Republic, England, Poland, Hungary, Spain, Italy and Greece in 2016 and 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (6.2 Testing effectiveness)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Copper oxychloride 50% WG, 63 efficacy trials were conducted in the Maritime (16), the North-east (14), the South-east (4) and the Mediterranean (29) EPPO zones. In these, the level of control obtained by Copper oxychloride 50% WG at the recommended dose rate applied in grapevine (13), potato (19), tomato (14) and apple (17) was assessed on the key diseases present in the trials. Due to low pest severity and -incidence, one of these trials was excluded from the efficacy evaluation. However, selectivity data from this S-French tomato trial were included to demonstrate the safe use of Copper oxychloride 50% WG in the GAP claimed crops.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Target(s)*	Crop(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
PLASVI	Grapevine	France	2016	MED + E + S	2 (2)	2 (2)	-	-	GEP	
		Czech Rep.	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Hungary	2016	MED + E + S	-	-	1 (1)	-	GEP	
		Spain	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Greece	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Total, PLASVI			**4 (4)**	**8 (8)**	**1 (1)**	**-**		
PHYTIN	Potato	France	2016	MED + E + S	1 (1)	1 (1)	-	-	GEP	
		Czech Rep.	2016	MED + E + S	2 (2)	-	-	-	GEP	
		England	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Poland	2016	MED + E + S	-	-	-	2 (2)	GEP	
		Poland	2017	MED + E + S	-	-	-	4 (4)	GEP	
		Hungary	2016	MED + E + S	-	-	1 (1)	-	GEP	
		Spain	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Greece	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Total, PHYTIN (potato)			**5 (5)**	**7 (7)**	**1 (1)**	**6 (6)**		
PHYTIN	Tomato	France	2016	MED + E + S	-	2 (1)	-	-	GEP	
		Czech Rep.	2016	MED + E + S	1 (1)	-	-	-	GEP	
		England	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Poland	2016	MED + E + S	-	-	-	2 (2)	GEP	
		Hungary	2016	MED + E + S	-	-	1 (1)	-	GEP	
		Spain	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Greece	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Total, PHYTIN (tomato)			**3 (3)**	**8 (7)**	**1 (1)**	**2 (2)**		
VENTIN	Pome fruits (apple)	Czech Rep.	2016	MED + E + S	2 (2)	-	-	-	GEP	
		England	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Poland	2016	MED + E + S	-	-	-	2 (2)	GEP	
		Poland	2017	MED + E + S	-	-	-	4 (4)	GEP	
		Hungary	2016	MED + E + S	-	-	1 (1)	-	GEP	
		Spain	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Greece	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Total, VENTIN (apple)			**4 (4)**	**6 (6)**	**1 (1)**	**6 (6)**		
		Total, all crops			**16 (16)**	**29 (28)**	**4 (4)**	**14 (14)**		

In the trials used to assess the level of control obtained with Copper oxychloride 50% WG, a different number of assessments were conducted during the course of the trials. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the level of pest severity (PESSEV) is minimum 1% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either the assessment timing before the 3rd or 4th application or the first assessment timing available thereafter. Alternatively, the assessment timing most commonly used is presented in the summary tables.

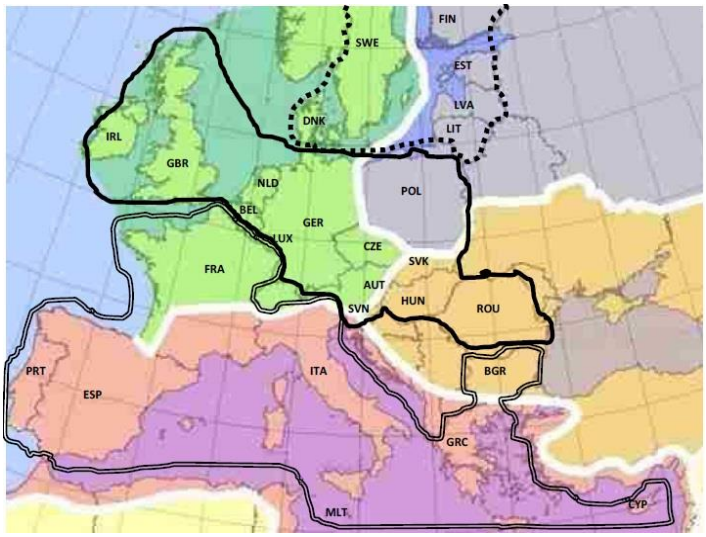
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country[2].

N-France, Czech Republic and England are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; Hungary is located in the South-east EPPO zone and Spain, Italy, Greece and S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This document is prepared to support the registration of Copper oxychloride 50% WG throughout the Central Registration zone, therefore data from the Maritime, the North-east and the South-east EPPO zone are included. Data obtained in Mediterranean EPPO zone has also been added as supporting information, however, the data from each climatic zone is summarised separately.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the Central and Southern EU, but common is that *Plasmopara viticola* attack vines, *Phytophthora infestans* attacks potatoes and Solanaceous crops and *Venturia* spp. attacks pome fruits from the South to the North, from East to West when the weather conditions are favourable for the pests to infest the crops.

[2] Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, xxxxx, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

The same copper oxychloride containing fungicides are already registered and used in all countries for the same uses. Please refer to Table 3.2-3 for the registration numbers in the different countries. In Central- and South zone countries, copper oxychloride fungicides are used as a protective fungicide, which should be applied during the growing season, before or shortly after outbreaks of the diseases claimed on the label are foreseen.

(i) *Pest physiology*

The physiology of the target diseases (*Plasmopara viticola*, *Phytophthora infestans* and *Venturia spp.*) is similar throughout the Central- and Southern part of Europe. Although trials were performed in different countries, sites were selected to exert maximum disease pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different regions in which the trials were conducted.

(ii) *Site selection*

Where the trials were conducted, the sites were carefully selected to ensure that for the fungal disease, the level of control was assessed on a range of populations, when treated at the recommended application timings. To exert maximum control pressure and to exacerbate treatment differences in each country, this included some trials which contained high infestation levels. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for cultivating grapes, potatoes, solanaceous fruits and pome fruits are similar throughout the Central zone as well as in connected EPPO zones were supporting trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Copper oxychloride 50% WG has been tested on a wide range of varieties in the efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for the specific crop production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that a foliar applied fungicide will be affected in any way by soil type and so this factor can be ignored for the purposes of this document.

On the basis that the above factors do not influence the overall performance of Copper oxychloride 50% WG, it is the applicant’s contention that data from the Czech Republic, the United Kingdom, Poland and Hungary is equally valid in demonstrating the products performance throughout the Central EU zone and the data from France, Spain, Greece and Italy is valid as supporting data.

Efficacy trials were carried out with Copper oxychloride 50% WG in comparison to a commercially available reference copper formulation currently on the market in Europe from e.g. Certis Europe B.V. (Cuprokylt = copper oxychloride), Industrias Quimicas del Valles (Styrocuivre DF = copper oxychloride), Nufarm (Cuproxat 19% SC = tribasic copper sulphate) or UPL Europe (Bouillie Bordelaise RSR Disperss NC = copper sulphate). The trials were carried out on field- and orchard crops.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials (Valid eff. trials)
Tribasic copper sulphate					
Cuproxat 19% SC	SC	190 g/L tribasic copper sulphate	2.17 L/ha 2.25 L/ha 2.5 L/ha 2.92 L/ha 3.0 L/ha 3.47 L/ha 3.94 L/ha 4.0 L/ha 5.0 L/ha 5.3 L/ha 6.3 L/ha	CZ ES FR GR HU IT PL	7 (7) 8 (8) 5 (5) 8 (8) 4 (4) 8 (8) 14 (14)
Copper sulphate					
Bouillie Bordelaise RSR Disperss NC	WG	20% w/w copper sulphate	6.25 kg/ha	FR	3 (2)
Copper oxychloride					
Cyprokylt	WP	50% w/w copper oxychloride	2.4 kg/ha 3.0 kg/ha 5.0 kg/ha	UK	6 (6)
Styrocuivre DF	WP	50% w/w copper oxychloride	10 kg/ha	FR	3 (2)
National reference product					
Captan	WG	800 g/kg captan	2.0 kg/ha	UK	2 (2)

Comments of zRMS:	This document was prepared by Applicant for registration the COBRANZA (product code: SHA 9800 A) containing copper oxychloride, 500 g/kg (as Cu). The formulation of this product is a water dispersible granules (WG). All necessary information's about tested plant protection products, active substances, studied pests, reference products, etc. are correctly presented in this drr by Applicant. Copper oxychloride 50% WG is an effective, selective fungicide for the control of downy mildew of grapevine, late blight of solanaceous crops as well as scab of pome fruits. Copper oxychloride is an effective component in the solution for sustainable resistance strategies. In Poland 33 plant protection products containing copper are already registered. The product – COBRANZA (product code: SHA 9800 A) containing copper oxychloride by Sharda Cropchem España S.L. has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs.

3.2.1 Preliminary tests (KCP 6.1)

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 glass-houses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Comments of zRMS:	Statement accepted. Products containing Copper compounds, including copper oxychloride, have been registered for many years (over 28) and the efficacy of the active ingredient has been widely researched and is well known. Therefore, no preliminary screening tests are required in the opinion of Evaluator.

3.2.2 Minimum effective dose tests (KCP 6.2)

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).

Control of *Plasmopara viticola* in grapevine at proposed rate (2.0 kg/ha)

To prove and to support the proposed dose rate of 2.0 kg/ha Copper oxychloride 50% WG [1000 g copper oxychloride per hectare] for the control of Downy mildew of grapevine (caused by *Plasmopara viticola* (PLASVI)), the assessment results from thirteen efficacy trials performed in the Maritime EPPO zone (4), the South-east EPPO zone (1) and the Mediterranean EPPO zone (8) are reported. The trials were conducted in N-France (2), Czech Republic (2), Hungary (1), Italy (2), S-France (2), Greece (2) and Spain (2) in 2016. In the trials, Copper oxychloride 50% WG was included at 2.0 kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (0.75 kg/ha [375 g copper oxychloride per hectare, per application] and 1.5 kg/ha [750 g copper oxychloride per hectare, per application]). In the trials, specifically targeted for this pathogen, four, five, six or eight applications were applied in the late spring/summer (May-August) at growth stages ranging between BBCH 53 and BBCH 85.

The results obtained with Copper oxychloride 50% WG applied for the control of *Plasmopara viticola* in grapevine are presented in Table 3.2-8, Table 3.2-9 and Table 3.2-10 for results obtained in the Maritime EPPO zone (four trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (eight trials).

Table 3.2-8: Minimum effective dose – Maritime zone: Minimum effective dose of Copper oxychloride 50% WG against PLASVI in grapevine.

		Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.0 kg/ha	
Target: PLASVI	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Grapevine								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 5-12 DALT (trt. 4 & 5)	4	13.2 (1.2-36.9)	**58.1**	31.6-70.7	**65.2**	27.0-95.8	**75.8**	45.4-100
Mean % control, one observation on **BUNCHES** per trial, **PESSEV** at 5-12 DALT (4, 5 & 7)	4	11.6 (1.2-27.1)	**56.3**	37.7-80.7	**76.2**	36.7-92.7	**76.3**	17.8-100
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 5-12 DALT (trt. 4 & 5)	4	55.4 (20.8-92.0)	**48.4**	33.3-64.9	**56.3**	35.1-96.2	**63.7**	43.2-100
Mean % control, one observation on **BUNCHES** per trial, **PESINC** at 5-12 DALT (trt. 4 & 5)	4	40.8 (12.0-77.6)	**45.2**	33.5-62.8	**67.8**	44.4-88.4	**77.8**	49.1-100

Table 3.2-9: Minimum effective dose – South-east zone: Minimum effective dose of Copper oxychloride 50% WG against PLASVI in grapevine.

		Mean % Control from one trial in the South-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.0 kg/ha	
Target: PLASVI	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Grapevine								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 13 DAT6	1	96.0	**50.0**	-	**77.1**	-	**68.8**	-
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 13 DAT6	1	50.4	**84.7**	-	**91.3**	-	**85.9**	-

Table 3.2-10: Minimum effective dose – Mediterranean zone: Minimum effective dose of Copper oxychloride 50% WG against PLASVI in grapevine.

		Mean % Control from 8 trials in the Mediterranean EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.0 kg/ha	
Target: PLASVI	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Grapevine								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 3-52 DALT (trt. 4, 5, 6 & 8)	8	11.9 (2.6-39.6)	**77.5**	66.5-82.3	**81.8**	72.1-90.7	**84.4**	68.8-94.8

Mean % control, one observation on **BUNCHES** per trial, **PESSEV** at 6-31 DALT (trt. 4, 5 & 7)	5	6.6 (2.8-12.0)	**74.6**	65.9-80.7	**80.0**	68.2-86.6	**87.0**	80.4-91.4
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 3-14 DALT (trt. 3, 4, 5 & 6)	8	40.9 (6.7-90.3)	**62.9**	51.9-80.4	**72.1**	52.2-98.2	**76.0**	58.3-100
Mean % control, one observation on **BUNCHES** per trial, **PESINC** at 3-52 DALT (trt. 4, 5, 6 & 8)	6	29.6 (7.0-75.3)	**61.9**	41.6-84.0	**66.8**	45.3-86.6	**73.5**	50.4-89.5

The data from the 13 trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Plasmopara viticola* in grapevine is 2.0 kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Phytophthora infestans* in potato at maximum proposed dose rate (2.4 kg/ha)

To prove and to support the maximum proposed dose rate of 2.4 kg/ha Copper oxychloride 50% WG [1200 g copper oxychloride per hectare] for the control of Late blight of potato (caused by *Phytophthora infestans* - PHYTIN), the assessment results from thirteen efficacy trials performed in the Maritime EPPO zone (5), the South-east EPPO zone (1) and the Mediterranean EPPO zone (7) are reported. The trials were conducted in N-France (1), Czech Republic (2), England (2), Hungary (1), Italy (2), S-France (1), Greece (2) and Spain (2) in 2016. In most trials, Copper oxychloride 50% WG was included at 2.4 kg/ha to demonstrate the maximum recommended dose rate as well as at two lower dose rates (0.75 kg/ha [375 g copper oxychloride per hectare, per application] and 1.5 kg/ha [750 g copper oxychloride per hectare, per application]). In two English trials, Copper oxychloride 50% WG was not tested at 0.75 kg/ha, but only at the 63% dose rate (1.5 kg/ha) as well as the recommended dose rate (2.4 kg/ha). In the trials, specifically targeted for this pathogen, three, four, five, six or eight applications were applied in the late spring/summer (May-August) at growth stages ranging between BBCH 16 and BBCH 79.

The results obtained with Copper oxychloride 50% WG applied for the control of *Phytophthora infestans* at the maximum proposed dose rate in potato are presented in Table 3.2-11, Table 3.2-12 and Table 3.2-13 for results obtained in the Maritime EPPO zone (five trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (seven trials).

Table 3.2-11: Minimum effective dose – Maritime zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in potato.

		Mean % Control from 5 trials in the Maritime EPPO Zone at a range of doses of Copper oxychloride 50% WG				
		Untreated	**1.5 kg/ha**		**2.4 kg/ha**	
Target: PHYTIN	**No. of trials**	**Mean % (range)**	**Mean**	**Range**	**Mean**	**Range**
Potato		**PESSEV**				
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 6-14 DALT (trt. 3-4)	5	32.7 (4.4-80.0)	**62.7**	23.4-99.9	**64.8**	25.0-100
Mean % control, one observation on **TUBERS at harvest** per trial, **PESSEV** at 48 DAT6	1	0.7	**0**	-	**0**	-
Mean % control, one observation on **TUBERS after storage** per trial, **PESSEV** at 76-111 DALT (trt. 4-6)	3	1.2 (0.5-2.5)	**22.7**	0-68	**26.7**	0-80

Table 3.2-12: Minimum effective dose – South-east zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in potato.

Target: PHYTIN	No. of trials	Mean % Control from one trial in the South-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 14 DAT6	1	100	**37.6**	-	**58.0**	-	**65.8**	-
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 14 DAT6	1	100	**0**	-	**0**	-	**0**	-

The data from the 13 trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Phytophthora infestans* in potato is 2.4 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2-13: Minimum effective dose – Mediterranean zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in potato.

Target: PHYTIN	No. of trials	Mean % Control from 7 trials in the Mediterranean EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 6-7 DALT (trt. 3 & 7)	7	41.5 (13.1-69.0)	**71.9**	60.6-79.7	**75.1**	60.7-81.3	**79.2**	61.2-87.8
Mean % control, one observation on **TUBERS** per trial, **PESSEV / WEIDIS** at 7-36 DAT6	2	2871.0 (470-5272)	**59.2**	44.5-73.8	**67.3**	57.0-77.6	**75.7**	68.1-83.3
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 6-7 DAT3	2	89.0 (80.0-98.0)	**60.4**	57.7-63.1	**63.8**	63.7-63.8	**65.8**	64.8-66.8
Mean % control, one observation on **TUBERS** per trial, **PESINC** at 36-67 DAT6	2	5.4 (4.4-6.3)	**59.6**	47.1-72.0	**67.7**	54.3-81.0	**71.1**	57.1-85.0

Control of *Phytophthora infestans* in potato at lowest proposed dose rate (2.0 kg/ha)

To prove and to support the lowest proposed dose rate of 2.0 kg/ha Copper oxychloride 50% WG [1000 g copper oxychloride per hectare] for the control of Late blight of potato (caused by *Phytophthora infestans* - PHYTIN), the assessment results from six efficacy trials performed in the North-east EPPO zone are re-

ported. The trials were conducted in Poland in 2016 and 2017. In the Polish trials, Copper oxychloride 50% WG was included at 2.0 kg/ha to demonstrate the lowest recommended dose rate as well as at two lower dose rates (1.0 kg/ha [500 g copper oxychloride per hectare, per application] and 1.5 kg/ha [750 g copper oxychloride per hectare, per application]). In the trials, specifically targeted for this pathogen, six applications were applied during the summer (June-August) at growth stages ranging between BBCH 51 and BBCH 89.

The results obtained with Copper oxychloride 50% WG applied for the control of *Phytophthora infestans* in potato are presented in Table 3.2-14 for results obtained in the North-east EPPO zone (six trials).

Table 3.2-14: Minimum effective dose – North-east zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in potato.

		Mean % Control from 6 trials in Poland / the North-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	**1.0 kg/ha**		**1.5 kg/ha**		**2.0 kg/ha**	
Target: PHYTIN	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Potato								
Mean % control, one observation on **LEAVES/PLANTS** per trial, **PESSEV** at 7-10 DAT4	6	51.9 (10.0-75.0)	**58.1**	45.2-75.4	**69.2**	50.8-83.3	**78.0**	67.0-86.7
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **TUBERS after storage** per trial, **PESINC** at 91-127 DAT6	2	4.3 (0.5-8.0)	**82.8**	65.6-100	**81.3**	62.5-100	**82.8**	65.6-100

The data from the six trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Phytophthora infestans* in potato is 2.0 kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Phytophthora infestans* in tomato at maximum proposed dose rate (2.4 kg/ha)

To prove and to support the maximum proposed dose rate of 2.4 kg/ha Copper oxychloride 50% WG [1200 g copper oxychloride per hectare] for the control of Late blight in Solanaceae (caused by *Phytophthora infestans* (PHYTIN)), the assessment results from eleven efficacy trials performed in the Maritime EPPO zone (3), the South-east EPPO zone (1) and the Mediterranean EPPO zone (7) are reported. The trials were conducted in Czech Republic (1), England (2), Hungary (1), Italy (2), S-France (1), Greece (2) and Spain (2) in 2016. In most trials, Copper oxychloride 50% WG was included at 2.4 kg/ha to demonstrate the maximum recommended dose rate as well as at two lower dose rates (0.75 kg/ha [375 g copper oxychloride per hectare, per application] and 1.5 kg/ha [750 g copper oxychloride per hectare, per application]). In two English trials, Copper oxychloride 50% WG was not tested at 0.75 kg/ha, but only at the 63% dose rate (1.5 kg/ha) as well as the recommended dose rate (2.4 kg/ha). In the trials, specifically targeted for this pathogen, three, four, five, six or eight applications were applied in the late spring/summer (May-August) at growth stages ranging between BBCH 15 and BBCH 89.

The results obtained with Copper oxychloride 50% WG applied for the control of *Phytophthora infestans* at the maximum proposed dose rate in tomato are presented in Table 3.2-15, Table 3.2-16 and Table 3.2-17 for results obtained in the Maritime EPPO zone (three trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (seven trials).

Table 3.2-15: Minimum effective dose – Maritime zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in tomato.

Target: PHYTIN	No. of trials	Mean % Control from 3 trials in the Maritime EPPO Zone at a range of doses of Copper oxychloride 50% WG				
		Untreated	1.5 kg/ha		2.4 kg/ha	
		Mean % (range)	Mean	Range	Mean	Range
Tomato		**PESSEV**				
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 11-16 DAT3	3	18.4 (4.5-30.1)	**46.3**	28.8-60.2	**55.6**	32.5-75.9
Mean % control, one observation on **FRUITS** per trial, **PESSEV** at 13 DAT3	1	2.0	**87.8**	-	**94.6**	-
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 13 DAT3	1	7.9	**39.7**	-	**44.9**	-

Table 3.2-16: Minimum effective dose – South-east zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in tomato.

Target: PHYTIN	No. of trials	Mean % Control from one trial in the South-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 13 DAT5	1	57.8	**77.5**	-	**82.9**	-	**80.7**	-
		Mean % Control from one trial in the South-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	**0.75 kg/ha**		**1.5 kg/ha**		**2.4 kg/ha**	
Target: PHYTIN	**No. of trials**	**Mean % PESINC (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 11 DAT4	1	97.5	**7.7**	-	**12.8**	-	**15.4**	-

Table 3.2-17: Minimum effective dose – Mediterranean zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in tomato.

Target: PHYTIN	No. of trials	Mean % Control from 7 trials in the Mediterranean EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 5-10 DALT (trt. 3 & 6)	7	38.9 (13.3-74.6)	**67.1**	38.0-83.4	**74.0**	36.5-89.1	**81.4**	59.3-94.3

		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 7-14 DALT (trt. 3 & 6)	7	61.1 (20.6-100)	**46.7**	27.5-57.4	**58.9**	32.1-69.6	**67.4**	48.9-81.5
Mean % control, one observation on **FRUITS** per trial, **PESINC** at 10 DAT8	1	8.5	**56.8**	-	**79.3**	-	**83.0**	-

The data from the 11 trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Phytophthora infestans* in tomato and other solanaceous crops is 2.4 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Phytophthora infestans* in tomato at lowest proposed dose rate (1.5 kg/ha)

To prove and to support the lowest proposed dose rate of 1.5 kg/ha Copper oxychloride 50% WG [750 g copper oxychloride per hectare] for the control of Late blight in Solanaceae (caused by *Phytophthora infestans* (PHYTIN)), the assessment results from two efficacy trials performed in the North-east EPPO zone are reported. The trials were conducted in Poland in 2016. In the Polish trials, Copper oxychloride 50% WG was included at 1.5 kg/ha to demonstrate the lowest recommended dose rate as well as at two lower dose rates (0.75 kg/ha [375 g copper oxychloride per hectare, per application] and 1.15 kg/ha [575 g copper oxychloride per hectare, per application]). In the trials, specifically targeted for this pathogen, three or four applications were applied during the summer (June-July) at growth stages ranging between BBCH 62 and BBCH 82.

The results obtained with Copper oxychloride 50% WG applied for the control of *Phytophthora infestans* at the lowest proposed dose rate in tomato are presented in Table 3.2-18 for results obtained in the North-east EPPO zone (two trials).

The data from the two trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Phytophthora infestans* in tomato is 1.5 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2-18: Minimum effective dose – North-east zone: Minimum effective dose of Copper oxychloride 50% WG against PHYTIN in tomato.

		Mean % Control from 2 trials in Poland / the North-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.15 kg/ha		1.5 kg/ha	
Target: PHYTIN	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Tomato								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 8-10 DALT (trt. 2 & 4)	2	10.6 (6.3-15.0)	**63.2**	56.3-70.0	**59.4**	47.5-71.3	**87.7**	80.4-95.0

Control of *Venturia inaequalis* in apple at maximum proposed dose rate (2.4 kg/ha)

To prove and to support the requested dose rate of 2.4 kg/ha Copper oxychloride 50% WG [1200 g copper oxychloride per hectare] for the control of Scab in Pome fruits (caused by *Venturia inaequalis* (VENTIN)), the assessment results from eleven efficacy trials performed in the Maritime EPPO zone (4), the South-east EPPO zone (1) and the Mediterranean EPPO zone (6) are reported. The trials were conducted in Czech Republic (2), England (2), Hungary (1), Italy (2), Greece (2) and Spain (2) in 2016. In the trials, Copper oxychloride 50% WG was included at 2.4 kg/ha to demonstrate the recommended dose rate as

well as at two lower dose rates (0.75 kg/ha [375 g copper oxychloride per hectare, per application] and 1.5 kg/ha [750 g copper oxychloride per hectare, per application]). In the trials, specifically targeted for this pathogen, four, five, six or eight applications were applied at growth stages ranging between BBCH 40 and BBCH 81.

The results obtained with Copper oxychloride 50% WG applied for the control of *Venturia inaequalis* in apple are presented in Table 3.2-19, Table 3.2-20 and Table 3.2-21 for results obtained in the Maritime EPPO zone (four trials), the South-east EPPO zone (one trial) and the Mediterranean EPPO zone (six trials).

Table 3.2-19: Minimum effective dose – Maritime zone: Minimum effective dose of Copper oxychloride 50% WG against VENTIN in apple.

		Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
Target: VENTIN	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Apple								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 3-4 DAT4	2	10.8 (2.0-19.5)	**45.2**	43.4-47.1	**59.0**	52.8-65.3	**66.1**	58.1-74.1
Mean % control, one observation on **FRUITS** per trial, **THOHEU** at 62-63 DAT8	2	20.7 (20-21.4)	**49.4**	29.3-69.6	**72.7**	68.2-77.2	**86.2**	83.0-89.5
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 3-13 DALT (trt. 3 & 4)	4	46.5 (32.5-62.0)	**28.8**	0-47.6	**27.6**	0-60.7	**36.9**	0-69.3
Mean % control, one observation on **FRUITS** per trial, **PESINC** at 50 DAT6	1	10.5	**0**	-	**0**	-	**0**	-

Table 3.2-20: Minimum effective dose – South-east zone: Minimum effective dose of Copper oxychloride 50% WG against VENTIN in apple.

		Mean % Control from one trial in the South-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
Target: VENTIN	**No. of trials**	**Mean % PESSEV (range)**	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Apple								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 22 DAT5	1	3.3	**59.8**	-	**78.0**	-	**84.8**	-
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 22 DAT5	1	28.3	**47.8**	-	**61.9**	-	**75.2**	-

Table 3.2-21: Minimum effective dose – Mediterranean zone: Minimum effective dose of Copper oxychloride 50% WG against VENTIN in apple.

Target: VENTIN	No. of trials	Mean % Control from 6 trials in the Mediterranean EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.75 kg/ha		1.5 kg/ha		2.4 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Apple								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 11-14 DALT (trt. 3 & 5)	4	19.2 (3.4-36.8)	**79.7**	74.3-82.8	**85.3**	80.6-90.6	**89.3**	87.0-92.2
Mean % control, one observation on **FRUITS** per trial, **PESSEV** at 14-68 DALT (trt. 5)	3	1.5 (1.2-1.6)	**62.5**	57.6-67.4	**74.0**	67.0-77.8	**79.3**	77.2-81.8
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **BARK** per trial, **COUINF** at 12-57 DALT (trt. 3 & 5)	2	67.4 (66.3-68.5)	**77.9**	75.7-80.0	**81.9**	77.2-86.5	**84.5**	78.2-90.7
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 11-14 DALT (trt. 2, 3 & 5)	6	42.6 (14.3-78.8)	**68.9**	54.5-80.1	**75.2**	65.6-86.6	**79.6**	65.6-91.3
Mean % control, one observation on **FRUITS** per trial, **PESINC** at 7 DAT5	1	7.5	**51.8**	-	**57.1**	-	**77.0**	-

The data from the 11 trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Venturia inaequalis* in apple and other pome fruits is 2.4 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Venturia inaequalis* in apple at lowest proposed dose rate (1.15 kg/ha)

To prove and to support the requested dose rate of 1.15 kg/ha Copper oxychloride 50% WG [575 g copper oxychloride per hectare] for the control of Scab in Pome fruits (caused by *Venturia inaequalis* (VENTIN)), the assessment results from six efficacy trials performed in the North-east EPPO zone are reported. The trials were conducted in Poland in 2016 and 2017. In the Polish trials, Copper oxychloride 50% WG was included at 1.15 kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (0.60 kg/ha [300 g copper oxychloride per hectare, per application] and 0.95 kg/ha [475 g copper oxychloride per hectare, per application]). In the trials, specifically targeted for this pathogen, three or five applications were applied during the spring/early summer (April-June) at growth stages ranging between BBCH 01 and BBCH 74.

The results obtained with Copper oxychloride 50% WG applied for the control of *Venturia inaequalis* at the lowest proposed dose rate in pome fruits are presented in Table 3.2-22 for results obtained in the North-east EPPO zone (six trials).

Table 3.2-22: Minimum effective dose – North-east zone: Minimum effective dose of Copper oxychloride 50% WG against VENTIN in Apple.

Target: VENTIN	No. of trials	Mean % Control from 6 trials in Poland / the North-east EPPO Zone at a range of doses of Copper oxychloride 50% WG						
		Untreated	0.60 kg/ha		0.95 kg/ha		1.15 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range

Apple								
Mean % control, one observation on **LEAVES** per trial, **PESSEV** at 62-63 DAT5	2	3.1 (2.8-3.3)	**44.2**	28.2-60.1	**68.8**	66.1-71.5	**70.5**	61.7-79.2
Mean % control, one observation on **FRUITS** per trial, **THOHEU** at 58-69 DALT (trt. 3 & 5)	6	9.9 (5.4-20.0)	**64.6**	37.7-86.1	**73.3**	51.7-92.6	**80.1**	68.1-97.2
		Mean % PESINC	**Mean**	**Range**	**Mean**	**Range**	**Mean**	**Range**
Mean % control, one observation on **LEAVES** per trial, **PESINC** at 18-69 DALT (trt. 3 & 5)	5	11.4 (5.4-20.0)	**43.9**	32.8-57.4	**59.1**	43.8-76.0	**66.1**	49.2-87.7
Mean % control, one observation on **FRUITS** per trial, **PESINC** at 58-69DAT3	4	15.9 (9.0-27.8)	**56.3**	36.6-84.3	**66.1**	55.3-91.3	**77.2**	65.8-97.9

The data from the six trials proves that the minimum effective dose rate of Copper oxychloride 50% WG to control *Venturia inaequalis* in pome fruits is 1.15 kg/ha, with up to five applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Summary and conclusions on the minimum effective dose

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.

This Review Report also clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and cropsafetyness of Copper oxychloride 50% WG is equivalent to the efficacy and cropsafetyness of the standard copper-component reference products, hereunder also copper oxychloride containing reference products, against which Copper oxychloride 50% WG was compared. The applicant therefore wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2). During field tests Applicant used different doses of fungicide COBRANZA (product code: SHA 9800 A) containing copper oxychloride. So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

	What is more, fungicides products containing active ingredient – copper oxychloride have been allowed to use for many years. Also, in the literature of crop protection vast amounts of information can be found on efficacy of the plant protection products containing copper oxychloride. 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: • grapevines: 0,75 kg/ha (0,38N); 1,5 kg/ha (0,75N), 2,0 kg/ha (N) at Maritime, MED and S-E; recommended minimum effective dose is 2,0 kg/ha for all EPPO zones. • potato: 1,5 kg/ha (0,63 N) and 2,4 kg/ha (N) at Maritime EPPO zone, 0,75 kg/ha (0,31N), 1,5 kg/ha (0,63N) and 2,4 kg/ha (N) at S-E and MED; 1,0 kg/ha (0,5N), 1,5 kg/ha (0,75N) and 2,0 kg/ha (N) at N-E EPPO zone; recommended minimum effective dose for Maritime, MED and S- E is 2,4 kg/ha and for N-E (PL) id 2,0 kg/ha. • tomato: 1,5 kg/ha (0,63N) and 2,4 kg/ha (N) at Maritime EPPO zone; 0,75 kg/ha (0,31N), 1,5 kg/ha (0,63N) and 2,4 kg/ha (N) at S-E and MED; 0,75 kg/ha (0,5N), 1,15 kg/ha (0,77N) and 1,5 kg/ha (N) at N-E EPPO zone; recommended minimum effective dose for Maritime, MED and S-E is 2,4 kg/ha and for N-E (PL) is 1,5 kg/ha. • apple: 0,75 kg/ha (0,31N), 1,5 kg/ha (0,63N) and 2,4 kg/ha at Maritime, S-E and MED EPPO zone; 0,60 kg/ha (0,52N), 0,95 kg/ha (0,83N) and 1,15 kg/ha (N) at N-E EPPO zone; recommended minimum effective dose for Maritime, MED and S-E EPPO zone is 2,4 kg/ha and for N-E (PL) is 1,15 kg/ha. 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 applicant wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported. However, such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar copper oxychloride products.

3.2.3 Efficacy tests (KCP 6.2)

Efficacy data are presented from sixty-two efficacy trials where the disease pressure was sufficient high for the trial to be claimed valid. Results from these trials have been included in this document to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The trials were carried out in 2016 and 2017 in France, Czech Republic, England, Poland, Hungary, Greece, Spain and Italy. Efficacy was assessed on *Plasmopara viticola* (PLASVI), *Phytophthora infestans* (PHYTIN) and *Venturia inaequalis* (VENTIN).

In the trials used to assess the level of control obtained with Copper oxychloride 50% WG, a different number of assessments were conducted during the course of the trials. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the

data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the level of pest severity (PESSEV) is minimum 1% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either the assessment timing before the 3rd or 4th application or the first assessment timing available thereafter. Alternatively, the assessment timing most commonly used is presented in the summary tables.

Efficacy trials were carried out with Copper oxychloride 50% WG in comparison to a commercially available reference copper formulation currently on the market in Europe from e.g. Certis Europe B.V. (Cuprokylt = copper oxychloride), Industrias Quimicas del Valles (Styrocuivre DF = copper oxychloride), Nufarm (Cuproxat 19% SC = tribasic copper sulphate) or UPL Europe (Bouillie Bordelaise RSR Disperss NC = copper sulphate). The trials were carried out on field- and orchard crops.

Table 3.2-23: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(4), PP 1/181(4), PP 1/135(4)
	Specific guidelines	Grapevine: EPPO PP 1/31(3) Potato: EPPO PP 1/002(4) Tomato: EPPO PP 1/065(3), PP 1/263(1), PP 1/002(4) Apple: EPPO PP 1/05(3)
Experimental design	Plot design	RCBD (63, hereof one excl. from efficacy summary)
	Plot size	4-96 m²
	Number of replications	4 (63, hereof one excl. from efficacy summary)
Crop	Trials per crop	Grapevine (13) Potato (19) Tomato (14, hereof one excl. from efficacy summary) Apple (17)
	Varieties per crop	Grapevine: Cabernet sauvignon, Chardonnay, Cinsaut, Grenache, Insolia, Malvasia, Nerello mascalese, Pinot auxerrois, Tempranillo, Ugri blanc, Zweigeltrebe blau Potato: Adela, Agria, Bintje, Bisestile, Charlotte, Duke of York, Eurogrande, King Edward, Musica, Sante, Universal, Vineta, Vivaldi Tomato: Alliance, Bobcat, Hector, Krakus, Matina, Missouri, Optima, Perfectpeel, Rio, Toro F1, UG 124 Apple: Bramley, Cox, Fuji, Gala, Granny Smith, Idared, Jonagold, Jonagored, Mutsu, Red delicious, Royal gala, Rubinstar, Scarlet spur, Spartan
	Sowing period / plantation age	Grapevine: 1 year to 30 years Potato: February 3rd to September 29th Tomato: April 22nd to August 19th Apple: 3 to 36 years
Application	Crop stage (BBCH)* at application	Grapevine: BBCH 53-73 (1st appl.) and BBCH 72-85 (last appl.) Potato: BBCH 16-71 (1st appl.) and BBCH 34-89 (last appl.) Tomato: BBCH 14-81 (1st appl.) and BBCH 71-89 (last appl.) Apple: BBCH 01-74 (1st appl.) and BBCH 39-81 (last appl.)
	Timing Pest stage at appl. (1)	Pre-infection (38, hereof one excl. from efficacy summary) Post-infection (25)
	Number of appl. Intervals between appl.	3 (12), 4 (9), 5 (11), 6 (18) or 8 (13, hereof one excl. from efficacy sumary) 5-35 days
	Spray volumes	200-1200 L/ha

Assessment	Assessment types	- Visual estimation of Pest incidence, compared to 'untreated' ('untreated' = 0 % control; total control = 100 % control) – based on the number of attacked fruits as percentage of total harvested fruits per plot or on a sample of a defined number of fruits per plot, as compared to the untreated check. - Visual estimation of Pest severity, compared to 'untreated' ('untreated' = 0 % control; total control = 100 % control) – based on the assessment of attacked fruit area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	1 to 111 DALT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial innoculation…	Natural
	Field / Greenhouse...	Field

Control of *Plasmopara viticola* in Grapevine

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Grapevine Preventive or at first disease symptoms
Use rate Use frequency Application timing	2.0 kg/ha Copper oxychloride 50% WG Up to 4x Preventative or at first signs of infection
Target disease	Downy mildew of grapevine (*Plasmopara viticola*)

The effectiveness of applying Copper oxychloride 50% WG against *Plasmopara viticola* was evaluated in thirteen grapevine trials, assessed for pest severity and pest incidence on leaves and/or bunches. These trials were carried out in 2016 in the Maritime EPPO zone (4; i.e. N-France (2) and the Czech Republic (2)), the South-east EPPO zone (1; i.e. Hungary) and the Mediterranean EPPO zone (8; i.e. Spain (2), Greece (2), S-France (2) and Italy (2)). The objective was to confirm the performance of Copper oxychloride 50% WG at the proposed dose rate of 2.0 kg/ha (i.e. 1000 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, four, five, six or eight applications were applied at growth stages ranging between BBCH 53 and BBCH 85.

In the trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper sulphate 19% SC formulation, i.e. Cuproxat 19% SC.

Maritime zone

In the Maritime trials, *Plasmopara viticola* was assessed at 35 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-24 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-24: Maritime zone: Efficacy of 2.0 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.0 kg/ha [1000 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 5.3 L/ha [1007 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.0 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 5.3 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	5-12 DALT (trt. 4 & 5)	4	13.2 (1.2-36.9)	75.8 (45.4-100)	74.1 (26.9-98.5)	1	2	1	=
Bunches	5-12 DALT (trt. 4, 5 & 7)	4	11.6 (1.2-27.1)	76.3 (17.8-100)	76.2 (14.3-98.1))	0	3	1	=
Pest incidence			**PESINC**						
Leaves	5-12 DALT (trt. 4 & 5)	4	55.4 (20.8-92.0)	63.7 (43.2-100)	64.0 (31.1-96.2)	1	2	1	=
Bunches	5-12 DALT (trt. 4 & 5)	4	40.8 (12.0-77.6)	77.8 (49.1-100)	76.1 (35.1-94.9)	2	1	1	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Plasmopara viticola*, equivalent to that achieved by the reference product. At one of the 16 assessments included in the summary table, Copper oxychloride 50% WG performed significantly better than the tribasic copper sulphate reference product at comparable dose rates. At the remaining 15 assessments, no significant differences were observed between the two tested products.

South-east zone

In the South-east trials, *Plasmopara viticola* was assessed at four assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-25 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-25: South-east zone: Efficacy of 2.0 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.0 kg/ha [1000 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 5.3 L/ha [1007 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.0 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 5.3 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	12 DAT5	1	49.4	87.0	86.0	0	1	0	=
Pest incidence			**PESINC**						
Leaves	12 DAT5	1	92.0	70.7	75.0	0	1	0	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Plasmopara viticola*, equivalent to that achieved by the reference product. No statistical evaluation was reported in the Hungarian trial.

Mediterranean zone

In the Mediterranean trials, *Plasmopara viticola* was assessed at 125 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-26 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-26: Mediterranean zone: Efficacy of 2.0 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.0 kg/ha [1000 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at Mean (min-max) 5.3 L/ha [1007 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.0 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 5.3 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	7-52 DALT (trt. 4-5, 8)	8	16.9 (2.6-45.3)	84.2 (68.8-94.8)	84.2 (73.5-95.5)	0	7	1	=
Bunches	3-31 DALT (trt. 5, 6)	5	9.6 (2.8-15.7)	85.5 (80.4-89.8)	85.7 (79.0-91.1))	0	5	0	=
Pest incidence			**PESINC**						
Leaves	3-14 DALT (trt. 4, 5 & 6)	8	44.7 (6.7-90.3)	71.7 (58.3-89.1)	67.1 (48.3-89.9)	3	5	0	=
Bunches	3-52 DALT (trt. 4-6, 8)	6	29.9 (7.0-75.3)	73.3 (50.4-89.5)	67.6 (48.5-89.9)	2	4	0	>

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Plasmopara viticola*, equivalent to that achieved by the reference product. At two of the 27 assessments included in the summary tables, Copper oxychloride 50% WG performed significantly better than the tribasic copper sulphate reference product at comparable dose rates. At the remaining 25 assessments, no significant differences were observed between the two tested products.

Control of *Phytophthora infestans* in Potato with 2.4 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Potato Preventive or at first disease symptoms
Use rate Use frequency Application timing	2.4 kg/ha Copper oxychloride 50% WG Up to 3x Preventative or at first signs of infection
Target disease	Late blight of potato (*Phytophthora infestans*)

The effectiveness of applying Copper oxychloride 50% WG at 2.4 kg/ha against *Phytophthora infestans* in potato field crops was evaluated in thirteen potato trials, assessed for pest severity and pest incidence on leaves and/or tubers. These trials were carried out in 2016 in the Maritime EPPO zone (5; i.e. N-France (1), the Czech Republic (2) and England (2)), the South-east EPPO zone (1; i.e. Hungary) and the Mediterranean EPPO zone (7; i.e. Spain (2), Greece (2), S-France (1) and Italy (2)). The objective was to confirm the performance of Copper oxychloride 50% WG at the highest proposed dose rate (2.4 kg/ha, i.e. 1200 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, three, four, five, six or eight applications were applied at growth stages ranging between BBCH 16 and BBCH 79.

In Spanish, Italian, Greek, Hungarian, Czech as well as one French trial, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC. In two

English trials as well as one French trial, Copper oxychloride 50% WG was tested alongside an EU approved copper oxychloride formulation, i.e. Cuprokylt (UK) or Styrocuivre DF (S-FR). In the S-French trial, Copper oxychloride 50% WG was furthermore compared against an EU approved copper sulphate formulation, i.e. Bouillie Bordelaise RSR Disperss NC.

Maritime zone

In the Maritime trials, *Phytophthora infestans* was assessed at 32 assessments, which were considered valid (i.e. PESSEV > 1%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-27 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-27: Maritime zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in potato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	2-67 DALT (trt. 2-5)	5	51.7 (4.8-96.0)	70.1 (25.0-96.2)	69.5 (18.8-93.3)	1	3	1	=
Tubers, at harvest	48 DAT6	1	0.7	0	0	0	1	0	=
Tubers, after storage	76-111 DALT (trt. 4-6)	3	1.2 (0.5-2.5)	26.7 (0-80)	22.7 (0-68)	1	2	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 1N = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	2-10 DALT (trt. 2,4 & 5)	3	57.9 (10.0-96.0)	85.7 (70.8-96.2)	83.3 (66.7-93.3)	0	3	0	=
Tubers, at harvest	48 DAT6	1	0.7	0	0	0	1	0	=
Tubers, after storage	76-109 DALT (trt. 4 & 6)	2	1.5 (0.5-2.5)	40.0 (0-80)	34.0 (0-68)	1	1	0	>

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper oxychloride 50% WP ref. prod. at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper oxychloride 50% WP ref. product at 2.4 kg/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	14-67 DALT (trt. 3 & 4)	2	42.4 (4.8-80.0)	46.7 (25.0-68.4)	48.8 (18.8-78.9)	1	0	1	=
Tubers, after storage	111 DAT5	1	0.5	0	0	0	1	0	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. At all assessments (9), Copper oxychloride 50% WG performed statistically equivalent to the different copper reference product included in the trials.

South-east zone

In the South-east trials, *Phytophthora infestans* was assessed at six assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-28 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-28: South-east zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in potato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at Mean (min-max) 6.3 L/ha [1197 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	14 DAT6	1	100	65.8	75.0	0	0	1	<
Pest incidence			**PESINC**						
Leaves	14 DAT6	1	100	0	0	0	1	0	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. No statistical evaluation was reported in the Hungarian trial.

Mediterranean zone

In the Mediterranean trials, *Phytophthora infestans* was assessed at 40 assessments, which were considered valid (i.e. WEIDIS, PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-29 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-29: Mediterranean zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in potato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha	Efficacy obtained with: Copper ref. prod. at Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	4-10 DALT (trt. 2-3, 7)	7	30.7 (13.1-42.7)	81.8 (61.2-93.3)	86.1 (78.2-96.7)	0	5	2	=
Tubers [WEIDIS]	7-36 DAT6	2	2871.0 (470-5272)	75.7 (68.1-83.3)	62.8 (61.3-64.3))	2	0	0	>

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Part assessed	Days after	No.	Mean	Efficacy obtained with		No. of trials where Copper oxychloride			
Pest incidence			**PESINC**						
Leaves	4-7 DAT2	2	73.8 (61.0-86.5)	77.8 (72.0-83.6)	81.9 (73.8-89.9)	0	1	1	=
Tuber	36-67 DAT6	2	5.4 (4.4-6.3)	71.1 (57.1-85.0)	81.6 (77.1-86.0)	0	1	1	<

	Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Copper oxychloride 50% WG at:	Tribasic copper sulphate 190 g/L SC ref. prod. at	50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control			Overall
				Mean (min-max)					
				2.4 kg/ha [1200 g ai/ha]	6.3 L/ha [1197 g ai/ha]	>	=	<	
Pest severity			**PESSEV**						
Leaves	4-10 DALT (trt. 2 & 3)	6	33.7 (20.5-42.7)	85.3 (75.4-95.3)	87.3 (78.2-96.7)	0	5	1	=
Tubers [WEIDIS]	7-36 DAT6	2	2871.0 (470-5272)	75.7 (68.1-83.3)	62.8 (61.3-64.3))	2	0	0	>
Pest incidence			**PESINC**						
Leaves	4-7 DAT2	2	73.8 (61.0-86.5)	77.8 (72.0-83.6)	81.9 (73.8-89.9)	0	1	1	=
Tuber	36-67 DAT6	2	5.4 (4.4-6.3)	71.1 (57.1-85.0)	81.6 (77.1-86.0)	0	1	1	<

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at:	Efficacy obtained with: Copper oxychloride 50% WP ref. prod. at	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper oxychloride 50% WP ref. product at 10.0 kg/ha = : ± 5% control			Overall
				Mean (min-max)					
				2.4 kg/ha	10 kg/ha	>	=	<	
Pest severity			**PESSEV**						
Leaves	7 DAT7	1	13.1	61.2	78.5	0	0	1	<

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at:	Efficacy obtained with: Copper sulphate 20% WG ref. prod. at	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper sulphate 20% WG ref. product at 6.25 kg/ha = : ± 5% control			Overall
				Mean (min-max)					
				2.4 kg/ha [1200 g ai/ha]	6.25 kg/ha [1250 g ai/ha]	>	=	<	
Pest severity			**PESSEV**						
Leaves	7 DAT7	1	13.1	61.2	78.5	0	0	1	<

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference products. At all assessments (14) included in the summary tables, Copper oxychloride 50% WG performed statistically equivalent to the different copper reference products included in the trials.

Control of *Phytophthora infestans* in Potato with 2.0 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Potato Preventive or at first disease symptoms
Use rate Use frequency Application timing	2.0 kg/ha Copper oxychloride 50% WG Up to 4x Preventative or at first signs of infection
Target disease	Late blight of potato (*Phytophthora infestans*)

The effectiveness of applying Copper oxychloride 50% WG at 2.0 kg/ha against *Phytophthora infestans* in potato field crops was evaluated in six potato trials, assessed for pest severity and pest incidence on leaves, plants in general and/or tubers. These trials were carried out in 2016 and 2017 in the North-east EPPO zone (i.e. Poland). The objective was to confirm the performance of Copper oxychloride 50% WG at the lowest proposed dose rate (2.0 kg/ha, i.e. 1000 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, six applications were applied at growth stages ranging between BBCH 51 and BBCH 89.

In the Polish trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC.

North-east zone

In the North-east trials, *Phytophthora infestans* was assessed at 35 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-30 therefore only contains one assessment per plant part from the Polish trials assessed repeatedly.

Table 3.2-30: North-east zone: Efficacy of 2.0 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in potato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.0 kg/ha [1000 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 5.0 L/ha [950 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.0 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC ref. product at 5.0 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves/plants	7-10 DALT (trt. 2-4)	6	33.7 (10.0-69.0)	81.6 (69.6-91.6)	78.2 (41.0-93.6)	1	4	1	=
Tubers, at harvest	*46-82 DAT6*	*6*	*0.0*	-	-	*0*	*6*	*0*	=
Tubers, after storage	91-127 DAT6	2	4.3 (0.5-8.0)	82.8 (65.6-100)	78.1 (56.3-100)	1	1	0	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. At all assessments (14), Copper oxychloride 50% WG performed statistically equivalent to the tribasic copper sulphate reference product included in the trials.

Control of *Phytophthora infestans* in Tomato with 2.4 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Tomato Preventive or at first disease symptoms
Use rate Use frequency Application timing	2.4 kg/ha Copper oxychloride 50% WG Up to 3x Preventative or at first signs of infection
Target disease	Late blight of tomato (*Phytophthora infestans*)

The effectiveness of applying Copper oxychloride 50% WG at 2.4 kg/ha against *Phytophthora infestans* in tomato crops was evaluated in eleven tomato trials, assessed for pest severity and pest incidence on leaves and/or fruits. These trials were carried out in 2016 in the Maritime EPPO zone (3; i.e. the Czech Republic (1) and England (2)), the South-east EPPO zone (1; i.e. Hungary) and the Mediterranean EPPO zone (7; i.e. Spain (2), Greece (2), S-France (1) and Italy (2)). The objective was to confirm the performance of Copper oxychloride 50% WG at the maximum proposed dose rate (2.4 kg/ha, i.e. 1200 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, three, four, five, six or eight applications were applied at growth stages ranging between BBCH 15 and BBCH 89.

In Spanish, Italian, Greek, Hungarian as well as Czech trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC. In two English trials as well as one French trial, Copper oxychloride 50% WG was tested alongside an EU approved copper oxychloride formulation, i.e. Cuprokylt (UK) or Styrocuivre DF (S-FR). In the S-French trial, Copper oxychloride 50% WG was furthermore compared against an EU approved copper sulphate formulation, i.e. Bouillie Bordelaise RSR Disperss NC.

Maritime zone

In the Maritime trials, *P. infestans* was assessed at 16 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-31 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. At all assessments (5), Copper oxychloride 50% WG performed statistically equivalent to the different copper reference product included in the trials.

Table 3.2-31: Maritime zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in tomato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	11-16 DALT (trt. 3 & 5)	3	25.0 (4.5-49.8)	58.6 (41.6-75.9)	43.7 (16.7-91.0)	2	0	1	>
Fruit	13 DAT3	1	2.0	94.6	97.6	0	1	0	=

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Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control >	=	<	Overall
Pest incidence			**PESINC**						
Leaves	13 DAT3	1	7.9	44.9	45.0	0	1	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 1.5 kg/ha [750 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 3.47 L/ha [660 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 1.5 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 3.47 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	13 DAT3	1	49.8	31.6	23.6	1	0	0	>
Fruit	13 DAT3	1	2.0	87.8	97.6	0	0	1	<
Pest incidence			**PESINC**						
Leaves	13 DAT3	1	7.9	39.7	45.0	0	0	1	<

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha	Efficacy obtained with: Copper oxychloride 50% WP ref. prod. at: Mean (min-max) 2.4 kg/ha	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper oxychloride 50% WP ref. product at 2.4 kg/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Plants	11-16 DAT3	2	12.6 (4.5-20.8)	67.1 (58.3-75.9)	53.8 (16.7-91.0)	1	0	1	>

South-east zone

In the South-east trials, *Phytophthora infestans* was assessed at six assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-32 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-32: South-east zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in tomato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 6.3 L/ha [1197 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	13 DAT5	1	57.8	80.7	78.8	0	1	0	=
Pest incidence			**PESINC**						
Leaves	13 DAT5	1	100	30.0	15.0	1	0	0	>

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. No statistical evaluation was reported in the Hungarian trial.

Mediterranean zone

In the Mediterranean trials, *Phytophthora infestans* was assessed at 79 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-33 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference products. At all assessments (18), Copper oxychloride 50% WG performed statistically equivalent to the different copper reference product included in the trials.

Table 3.2-33: Mediterranean zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in tomato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	5-9 DALT (trt. 2-6)	7	42.8 (31.7-59.8)	83.5 (59.3-96.1)	82.3 (65.1-94.9)	0	6	1	=
Pest incidence			**PESINC**						
Leaves	7-9 DALT (trt. 2, 3, 6)	7	52.6 (20.6-92.0)	70.8 (48.9-81.5)	72.2 (58.7-81.8)	2	3	2	=
Fruit	10 DAT8	1	8.5	83.0	82.1	0	1	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 6.3 L/ha [1197 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	5-8 DALT (trt. 2-5)	6	44.6 (34.4-59.8)	87.5 (74.9-96.1)	85.2 (71.6-94.9)	0	6	0	=
Pest incidence			**PESINC**						
Leaves	7-9 DALT (trt. 2-3)	6	54.1 (20.6-92.0)	74.5 (69.7-81.5)	74.4 (65.1-81.8)	2	3	1	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper oxychloride 50% WP ref. prod. at: Mean (min-max) 10 kg/ha [5000 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper oxychloride 50% WP ref. product at 10.0 kg/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	9 DAT6	1	31.7	59.3	48.0	1	0	0	>
Pest incidence			**PESINC**						
Leaves	9 DAT6	1	43.8	48.9	34.2	1	0	0	>
Fruit	10 DAT8	1	8.5	83.0	83.8	0	1	0	=

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Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper sulphate 20% WG ref. prod. at Mean (min-max) 6.25 kg/ha [1250 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper sulphate 20% WG ref. product at 6.25 kg/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	9 DAT6	1	31.7	59.3	65.1	0	0	1	<
Pest incidence			**PESINC**						
Leaves	9 DAT6	1	43.8	48.9	58.7	0	0	1	<
Fruit	10 DAT8	1	8.5	83.0	82.1	0	1	0	=

Control of *Phytophthora infestans* in Tomato with 1.5 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Tomato Preventive or at first disease symptoms
Use rate Use frequency Application timing	1.5 kg/ha Copper oxychloride 50% WG Up to 3x Preventative or at first signs of infection
Target disease	Late blight of tomato (*Phytophthora infestans*)

The effectiveness of applying Copper oxychloride 50% WG at 1.5 kg/ha against *Phytophthora infestans* in tomato crops was evaluated in two tomato trials, assessed for pest severity on leaves. These trials were carried out in 2016 in the North-east EPPO zone (i.e. Poland). The objective was to confirm the performance of Copper oxychloride 50% WG at the lowest proposed dose rate (1.5 kg/ha, i.e. 750 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, three or four applications were applied at growth stages ranging between BBCH 62 and BBCH 82.

In the Polish trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC.

North-east zone

In the North-east trials, *Phytophthora infestans* was assessed at five assessments, which were considered valid (i.e. PESSEV > 1%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-34 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-34: North-east zone: Efficacy of 1.5 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Phytophthora infestans* in tomato in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 1.5 kg/ha [750 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at Mean (min-max) 4.0 L/ha [760 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 1.5 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 4.0 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	8-10 DALT (trt. 2 & 4)	2	10.6 (6.3-15.0)	87.7 (80.4-95.0)	77.3 (75.0-79.6)	1	1	0	>

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the reference product. At both assessments, Copper oxychloride 50% WG performed statistically equivalent to the tribasic copper sulphate reference product included in the trials.

Control of *Venturia spp.* in Pome fruits with 2.4 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Pome fruits (Apple, Pear, Quince) Preventive or at first disease symptoms
Use rate Use frequency Application timing	2.4 kg/ha Copper oxychloride 50% WG Up to 3x Preventative or at first signs of infection
Target disease	Scab (*Venturia spp.*)

The effectiveness of applying Copper oxychloride 50% WG at 2.4 kg/ha against *Venturia spp.* was evaluated in eleven apple trials, assessed for pest severity and pest incidence on leaves and/or fruits. These trials were carried out in 2016 in the Maritime EPPO zone (4; i.e. the Czech Republic (2) and England (2)), the South-east EPPO zone (1; i.e. Hungary) and the Mediterranean EPPO zone (6; i.e. Spain (2), Greece (2) and Italy (2)). The objective was to confirm the performance of Copper oxychloride 50% WG at the maximum proposed dose rate (2.4 kg/ha, i.e. 1200 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, four, five, six or eight applications were applied at growth stages ranging between BBCH 40 and BBCH 81.

In all trials, conducted in apple, the Scab was identified as *Venturia inaequalis* (VENTIN).

In Spanish, Italian, Greek, Hungarian as well as Czech trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC. In two English trials, Copper oxychloride 50% WG was tested alongside an EU approved copper oxychloride formulation, i.e. Cuprokylt (UK) as well as an EU approved captan 80% WG formulation, i.e. Captan.

Maritime zone

In the Maritime trials, *Venturia inaequalis* was assessed at 23 assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-35 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-35: Maritime zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Venturia inaequalis* in apple in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	30-62 DAT8	2	20.8 (2.6-39.0)	75.2 (74.2-76.1)	75.8 (62.4-89.2)	1	0	1	=
Fruit [THOHEU]	62-63 DAT8	2	20.7 (20.0-21.4)	86.2 (83.0-89.5)	72.1 (59.1-85.1)	1	1	0	>

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Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper ref. prod. at: Mean (min-max) 1N	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper Ref. product at 1N = : ± 5% control >	=	<	Overall
Pest incidence			**PESINC**						
Leaves	3-13 DALT (trt. 3-4)	4	46.5 (32.8-62.0)	36.9 (0-69.3)	36.1 (0-66.5)	1	2	1	=
Fruit	50 DAT6	1	10.5	0	0	0	1	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Copper oxy-chloride 50% WP ref. prod. at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the copper oxychloride 50% WP ref. product at 2.4 kg/ha = : ± 5% control >	=	<	Overall
Pest incidence			**PESINC**						
Leaves	13 DAT3	2	37.1 (32.5-41.8)	10.8 (0-21.6)	0.0 (-)	1	1	0	=
Fruit	50 DAT6	1	10.5	0	0	0	1	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Captan 80% WG ref. prod. At: Mean (min-max) 2.0 kg/ha [1600 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the captan 80% WG ref. product at 2.0 kg/ha = : ± 5% control >	=	<	Overall
Pest incidence			**PESINC**						
Leaves	13 DAT3	2	37.1 (32.5-41.8)	10.8 (0-21.6)	12.9 (0-25.7)	0	2	0	=
Fruit	50 DAT6	1	10.5	0	0	0	1	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 1.5 kg/ha [750 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 3.47 L/ha [659 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 1.5 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 3.47 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	30-62 DAT8	2	20.8 (2.6-39.0)	72.9 (72.1-73.7)	75.8 (62.4-89.2)	1	0	1	=
Fruit [THOHEU]	62-63 DAT8	2	20.7 (20.0-21.4)	72.7 (68.2-77.2)	72.1 (59.1-85.1)	1	0	1	=
Pest incidence			**PESINC**						
Leaves	3-4 DAT4	2	55.8 (49.6-62.0)	55.1 (49.5-60.7)	59.4 (52.4-66.5)	1	0	1	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Venturia inaequalis*, equivalent to that achieved by the reference product. At all three assessment where Copper oxychloride 50% WG at 2.4 kg/ha was compared against the copper oxychloride 50% WG reference product, no significant differences were observed between the two tested products. At one of three assessments, the Captan 80% WG reference product at 2.0 kg/ha performed significantly better than Copper oxychloride 50% WG at 2.4 kg/ha. At the remaining two assessments, no significant differences were observed between the two tested products. At one of 6 assessments, Copper oxychloride 50% WG at 1.5 kg/ha performed significantly better than the tribasic copper sulphate reference product at 3.47 L/ha and at another assessment, the tribasic copper sulphate reference product at 3.47 L/ha performed significantly better than Copper oxychloride 50% WG at 1.5 kg/ha. At the remaining four assessments, no significant differences were observed between the two tested products.

South-east zone

In the South-east trials, *Venturia inaequalis* was assessed at four assessments, which were considered valid (i.e. PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-36 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-36: South-east zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Venturia inaequalis* in apple in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 6.3 L/ha [1197 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	22 DAT5	1	3.3	84.8	83.3	0	1	0	=
Pest incidence			**PESINC**						
Leaves	22 DAT5	1	28.3	75.2	76.1	0	1	0	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Venturia inaequalis*, equivalent to that achieved by the reference product. No statistical evaluation was reported in the Hungarian trial.

Mediterranean zone

In the Mediterranean trials, *Venturia inaequalis* was assessed at 37 assessments, which were considered valid (i.e. THOHEU, PESSEV > 1% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-37 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-37: Mediterranean zone: Efficacy of 2.4 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Venturia inaequalis* in apple in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 2.4 kg/ha [1200 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at: Mean (min-max) 6.3 L/ha [1197 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 2.4 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 6.3 L/ha = : ± 5% control: >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	7-14 DAT3	4	18.5 (2.4-36.8)	88.5 (83.8-92.2)	90.6 (81.3-94.6)	0	3	1	=
Fruit	14-68 DALT (trt. 5)	3	1.5 (1.2-1.6)	79.3 (77.2-81.8)	79.2 (73.5-87.0)	1	1	1	=
Pest incidence			**PESINC**						
Bark	12-57 DALT (trt. 3 & 5)	2	67.4 (66.3-68.5)	84.5 (78.2-90.7)	84.7 (81.1-88.2)	0	2	0	=
Leaves	7-14 DALT (trt. 2-5)	6	42.6 (14.3-78.8)	79.6 (65.6-91.3)	81.7 (69.9-88.3)	0	4	2	=
Fruit	7 DAT5	1	7.5	77	83	0	0	1	<

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Venturia inaequalis*, equivalent to that achieved by the reference products. At one of the sixteen assessments, Copper oxychloride 50% WG at 2.4 kg/ha performed significantly better than the tribasic copper sulphate reference product at 6.3 L/ha. At the remaining fifteen assessments, no significant differences were observed between Copper oxychloride 50% WG and the different copper reference products included in the trials.

Control of *Venturia spp.* in Pome fruits with 1.15 kg/ha

The efficacy trials were conducted to prove the following label claims:

Crop, stage	Pome fruits (Apple, Pear, Quince) Preventive or at first disease symptoms
Use rate Use frequency Application timing	1.15 kg/ha Copper oxychloride 50% WG Up to 5x Preventative or at first signs of infection
Target disease	Scab (*Venturia spp.*)

The effectiveness of applying Copper oxychloride 50% WG at 1.15 kg/ha against *Venturia spp.* was evaluated in six apple trials, assessed for pest severity and pest incidence on leaves and fruits. These trials were carried out in 2016 and 2017 in the North-east EPPO zone (i.e. Poland). The objective was to confirm the performance of Copper oxychloride 50% WG at the lowest proposed dose rate (1.15 kg/ha, i.e. 575 g copper oxychloride per hectare) and demonstrate comparability to the reference product. In the trials specifically targeted for this pathogen, three or five applications were applied at growth stages ranging between BBCH 39 and BBCH 74.

In the Polish trials, Copper oxychloride 50% WG was tested alongside an EU approved tribasic copper 19% SC formulation, i.e. Cuproxat 19% SC.

<u>North-east zone</u>

In the North-east trials, *Venturia inaequalis* was assessed at 34 assessments, which were considered valid (i.e. PESSEV ≥ 1%, THOHEU or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-38 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-38: North-east zone: Efficacy of 1.15 kg/ha Copper oxychloride 50% WG and reference product at equivalent dose rate applied against *Venturia inaequalis* in apple in the efficacy tests.

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with: Copper oxychloride 50% WG at: Mean (min-max) 1.15 kg/ha [575 g ai/ha]	Efficacy obtained with: Tribasic copper sulphate 190 g/L SC ref. prod. at Mean (min-max) 3.0 L/ha [570 g ai/ha]	No. of trials where Copper oxychloride 50% WG at 1.15 kg/ha is >, < or =, compared to the tribasic copper sulphate 190 g/L SC Ref. product at 3.0 L/ha = : ± 5% control >	=	<	Overall
Pest severity			**PESSEV**						
Leaves	62-63 DAT5	2	3.1 (2.8-3.3)	70.5 (61.7-79.2)	70.6 (63.8-77.4)	0	2	0	=
Fruit (THOHEU)	18-19 DALT (trt. 3 & 5)	6	8.3 (2.4-20.0)	83.2 (68.1-97.2)	86.0 (67.3-100)	0	4	2	=
Pest incidence			**PESINC**						
Leaves	18-43 DALT (trt. 3 & 5)	5	11.4 (5.4-20.0)	66.1 (49.2-87.7)	62.3 (49.4-81.5)	2	3	0	=
Fruit	58-69 DAT3	4	15.9 (9.0-27.8)	77.2 (65.8-97.9)	79.2 (61.5-100)	0	3	1	=

The individual trial results show that Copper oxychloride 50% WG gave good to excellent control of *Venturia inaequalis*, equivalent to that achieved by the reference product. Statistical evaluation was possible at 11 of 17 assessments and at all of these (11), Copper oxychloride 50% WG performed statistically equivalent to the tribasic copper sulphate 19% SC reference product included in the trials.

Summary and conclusion

Based on the results of sixty-two efficacy trials carried out in 2016 and 2017, the following can be concluded for the intended use of Copper oxychloride 50% WG applied at GAP recommended dose rates in Grapevine, Potato, Solanaceae and Pome fruits:

- Copper oxychloride 50% WG 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). As diseases in grapevine often occur as a complex of several diseases with different susceptibility towards copper oxychloride, up to four applications per season of Copper oxychloride 50% WG at the recommended dose rate per application should be used to efficiently control the diseases claimed on the label.
- Copper oxychloride 50% WG applied at the recommended dose rate of up to 2.4 kg/ha in potato, tomato and apples provided an acceptable to high level of control against the key diseases claimed (i.e. PHYTIN and VENTIN). 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.
- The lowest recommended dose rates of Copper oxychloride 50% WG in potato is 2.0 kg/ha, 1.5 kg/ha in tomato and 1.15 kg/ha in apple. When applied at the lowest recommended dose rates in potato, tomato and apple, Copper oxychloride 50% WG provided an acceptable to high level of control against the key diseases claimed (i.e. PHYTIN and VENTIN). As diseases often occur as a complex of several diseases with different susceptibility towards copper oxychloride, up to four (potato), three (tomato) or five (apple) applications per season of Copper oxychloride 50% WG at the lowest recommended dose rate 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. 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. This Review Report also clearly demonstrates that the efficacy and cropsafetyness of Copper oxychloride 50% WG is equivalent to the efficacy and cropsafetyness of the standard copper-component reference products, hereunder also copper oxychloride containing reference products, against which Copper oxychloride 50% WG was compared. The applicant therefore wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required " particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought". It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented "where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops". Copper formulations have been registered in Central zone and in countries where trials were conducted for various years like Cuproxat 345 SC (reg nr R-1/2009) registered in Poland in 2009, Neoram 37.5 WG (reg nr R-203/2015) registered in Poland in 2015, Cuproxat SC (reg nr 3910-0) registered in the Czech Republic in 2008, Funguran progress (reg nr 006896-00) registered in Germany in 2011, Cuprokylt (reg nr 17079) registered in the United Kingdom in 2015, Cuproxat SC (reg nr 2090119) registered in France in 2009 or Styrocuivre DF (reg nr 9400346) registered in France in 1994. According to this formulation has been widely proved in Central zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	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. Control of *Phythophthora infestans*: For a major crop and pest, five efficacy trials from just one year are not in accordance with EPPO standards PP 1/214 (Principle of acceptable efficacy) and PP 1/226 (Number of efficacy trials) and not sufficient for an evaluation, in the opinion of cMS from Germany. So, an authorization in Germany is unacceptable. 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 applica-

	tions: 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 in Poland and 2,4 kg/ha for cMS. 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 efficacies 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. **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 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: LWA vary between 11579 and 20000 what indicates 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.**

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(4) *Resistance risk analysis* in particular point 6. *Registration requirements* and Appendix I of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed, and the rare fungicide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low, and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term resistance be limited to situations where the conditions in both (a) and (b) below are met:

(a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and

(b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

3.3.1 Mode of action

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 M01 by FRAC (FRAC MOA Code: Multi-site, Group code M01).

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.

3.3.2 Mechanism of resistance

As mentioned, copper oxychloride has multi-site mode of action and therefore resistance rarely develop. In a study conducted by Barak and Edgington (1984), thiol compounds in the fungal cells could be involved in such resistance to a multi-site fungicide like copper oxychloride.

3.3.3 Evidence of resistance

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to copper fungicides across Europe. According to the FRAC, copper fungicides have never been known to encounter practical resistance, even after many years of use.

The risk for resistance for inorganic copper is according to Fungicide Resistance Action Committee (FRAC) low.

Even though resistance appears not to be a problem in the EU according to FRAC, it is of course not a guarantee that it does not exists somewhere in Europe and caution should be taken when using Copper oxychloride 50% WG in the recommended crops at the recommend dose rates.

3.3.4 Cross-resistance

No cross-resistance has been reported between group members M01 to M12, to which copper oxychloride belongs (FRAC, 2012).

3.3.5 Sensitivity data

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Copper fungicides have been tested and used worldwide for +300 years and it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years, and Sharda will work closely together with FRAC to assist with this work.

3.3.6 Use pattern

Copper oxychloride 50% WG is composed of copper oxychloride which is an inorganic contact fungicide which prevents spore germination. In the EU Central zone, the formulation is proposed for control of downy mildew in grapevine (*Plasmopara viticola*), late blight, caused by *Phytophthora infestans*, in solanaceous crops and potato as well as Scab, caused by *Venturia inaequalis*, in pome fruits. In the CEU, the maximum proposed dose rate is 2.4 kg/ha, with up to three applications per season in Solanaceous crops and Potato against Late blight (*Phytophthora infestans* – PHYTIN) as well as against Scab (*Venturia inaequalis* – VENTIN) in Pome fruits. When targeting Downy mildew (*Plasmopara viticola* – PLASVI) in Grapevine, the maximum proposed application rate is 2.0 kg/ha, with up to four applications per season. In the CEU, the lowest proposed application rate of Copper oxychloride 50% WG is 2.0 kg/ha, with up to four applications per season in Potato against Late blight (*Phytophthora infestans* – PHYTIN), 1.5 kg/ha, with up to three applications per season in Tomato against Late blight (*Phytophthora infestans* – PHYTIN) and 1.15 kg/ha, with up to five applications per season in pome fruits against Scab (*Venturia inaequalis* – VENTIN).

The application may be employed when the climatically conditions are favourable for infestation or when warnings have been released in the different regions. Dependent on the crop and the pest to be controlled, this will deliver 575 g/ha to 1200 g/ha copper oxychloride per application.

Copper oxychloride has been used as straight product as well as in mixtures for many years.

3.3.7 Resistance risk assessment of unrestricted use pattern

The active substances

FRAC regards the resistance risk of the Group M01 (copper (different salts), hereunder copper oxychloride) as low.

The disease

Some of the target pathogens for the use of Copper oxychloride 50% WG have developed resistance to a range of fungicide groups, but today, despite a long use, fungal pathogens rarely develop resistance towards copper fungicides. The resistance risk associated with any individual disease is dependent on a number of factors related to the disease epidemiology, these include:

- Life cycle; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build-up of resistance.
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection and the faster the spread of resistant strains.
- Isolation of pathogen populations; the more isolated the crop, through geography, or protected crops, the less chance of ingress of sensitive forms or loss of resistant forms.
- Occurrence of a sexual stage in the life cycle; this may (e.g. *Septoria* spp.) or may not increase resistance risk (*Blumeria graminis* f. sp. *tritici*).

The intended disease targets for Copper oxychloride 50% WG vary in terms of their intrinsic resistance risk. The resistance risk of target pathogens of Copper oxychloride 50% WG is available at www.frac.info.

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended disease target for Copper oxychloride 50% WG may be low to high in annual crops like solanaceous crops and potato (depending on whether a successful crop rotation system is applied or mono-cropping is carried out in the crop) and high in orchard-grown crops like grapevine and pome fruits due to the continuous cropping.

Cultural control measures that can be adopted to reduce selection pressure are e.g. crop rotations, resistant crop varieties, cultural measure like adjusting planting date and soil cultivation (e.g. ploughing) as well as good crop hygiene.

The plant protection product

For optimum disease control, Copper oxychloride 50% WG is applied at the rates recommended in the GAP. These have been shown to be the minimum effective dose for the key target pathogens (Section 3.2.2).

3.3.8 Test methods

There are several monitoring methods approved by FRAC (available on www.frac.info).

3.3.9 Acceptability of the resistance risk

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.), the unrestricted use pattern for Copper oxychloride 50% WG would be season long usage with an unrestricted number of applications.

Overall, it is clear that the unrestricted use of Copper oxychloride 50% WG presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.10 Resistance management strategy

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations made by FRAC.

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be at an early stage of development (e.g. at the first signs of disease or as soon as disease symptoms appear) or as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

3.3.11 Implementation of the Management Strategy

Information on the management of resistance and the specific Resistance Management Strategy for Copper oxychloride 50% WG is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts for general information or to address a particular issue in a specific geographical area were it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- FRAC publications including the web site www.frac.info
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to FRAC and local Fungicide Resistance working groups for information and advice

3.3.12 Monitoring, reporting and reaction to the change in performance

Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 3.2.3) and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by FRAC.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance can be confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season
- Reduction in number of applications
- Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	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.

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

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.

The trials were conducted in the Maritime zone (16; i.e. N-France (3), Czech Republic (7) and England (6)), the North-east zone (14; i.e. Poland), the South-east zone (4; i.e. Hungary) and the Mediterranean zone (33; i.e. Spain (8), Italy (8), Greece (8) and S-France (5 eff. + 4 vinification)) in 2016 and 2017 to evaluate the crop safetyness of Copper oxychloride 50% WG in the GAP claimed crops.

3.4.1.1 Grapevine (VITVI)

Crop phytotoxicity was evaluated in thirteen efficacy trials where Copper oxychloride 50% WG was applied at four, five, six or eight applications when the grapevine crop was at growth stages ranging between BBCH 53 and BBCH 85, at the rate of 0.75, 1.5 and 2.0 kg/ha. The 2.0 kg/ha dose rate corresponds to 100% of the proposed dose rate. Furthermore, the crop phytotoxicity was evaluated in four vinification trials where Copper oxychloride 50% WG was applied at 2.0 kg/ha at three applications. Crop phytotoxicity was assessed in the trials at various intervals from application and up to termination of the trial.

Phytotoxicity in grapevine trials, Maritime EPPO zone

Four efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in grapevine. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the four efficacy trials conducted in the Maritime EPPO zone. Furthermore, harvest results from two Czech grapevine trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in grapevine trials, South-east EPPO zone

One efficacy trial was conducted in the South-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in grapevine. The trial was conducted on the commercially available variety Chardonnay.

No adverse effects in regard to phytotoxicity were observed in the Hungarian efficacy trial conducted in grapevine. No South-east trials were taken to harvest.

Phytotoxicity in grapevine trials, Mediterranean EPPO zone

A total of eight efficacy trials and four vinification trials were conducted in vineyards in the Mediterranean EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in grapevine. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the eight efficacy trials as well as no adverse effects were observed in any of the four vinification trials conducted in the Mediterranean EPPO zone. Furthermore, harvest results from six grapevine trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

3.4.1.2 Potato (SOLTU)

Crop phytotoxicity was evaluated in nineteen efficacy trials where Copper oxychloride 50% WG was applied at three, four, five, six or eight applications when the potato crop was at growth stages ranging between BBCH 16 and BBCH 89, at the rate of 0.75 kg/ha to 5.0 kg/ha. The 5.0 kg/ha dose rate corresponds to 208% of the maximum proposed dose rate. Crop phytotoxicity was assessed in the trials at various intervals from application and up to termination of the trial.

Phytotoxicity in potato trials, Maritime EPPO zone

Five efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in potato. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the five efficacy trials conducted in the Maritime EPPO zone. Furthermore, harvest results from three potato trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in potato trials, North-east EPPO zone

Six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in potato. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the six efficacy trials conducted in the North-east EPPO zone. Furthermore, harvest results from six potato trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in potato trials, South-east EPPO zone

One efficacy trial was conducted in the South-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in potato. The trial was conducted on the commercially available variety Musica.

No adverse effects in regard to phytotoxicity were observed in the Hungarian efficacy trial conducted in potato. No South-east trials were taken to harvest.

Phytotoxicity in potato trials, Mediterranean EPPO zone

Seven efficacy trials were conducted in potato field crops in the Mediterranean EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the seven efficacy trials conducted in the Mediterranean EPPO zone. Furthermore, harvest results from two Spanish potato trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

3.4.1.3 Tomato (LYPES)

Crop phytotoxicity was evaluated in fourteen efficacy trials where Copper oxychloride 50% WG was applied at three, four, five, six or eight applications when the tomato crop was at growth stages ranging between BBCH 14 and BBCH 89, at the rate of 0.75 kg/ha to 3.0 kg/ha. The 3.0 kg/ha dose rate corresponds to 125% of the maximum proposed dose rate. Crop phytotoxicity was assessed in the trials at various intervals from application and up to termination of the trial.

Phytotoxicity in tomato trials, Maritime EPPO zone

Three efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in tomato and other solanaceous crops. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the three efficacy trials conducted in the Maritime EPPO zone. Furthermore, harvest results from two Maritime tomato trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in tomato trials, North-east EPPO zone

Two efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in tomato. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in either of the two efficacy trials conducted in the North-east EPPO zone. No North-east tomato trials were taken to harvest.

Phytotoxicity in tomato trials, South-east EPPO zone

One efficacy trial was conducted in the South-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in tomato and other solanaceous crops. The trial was conducted on the commercially available variety UG 124.

No adverse effects in regard to phytotoxicity were observed in the Hungarian efficacy trial conducted in tomato. No South-east trials were taken to harvest.

Phytotoxicity in tomato trials, Mediterranean EPPO zone

Eight efficacy trials were conducted in tomato field crops in the Mediterranean EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in tomato and other solanaceous crops. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the eight efficacy trials conducted in the Mediterranean EPPO zone. Furthermore, harvest results from two Spanish tomato trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

3.4.1.4 Apple (MABSD)

Crop phytotoxicity was evaluated in seventeen efficacy trials where Copper oxychloride 50% WG was applied at three, four, five, six or eight applications when the apple crop was at growth stages ranging between BBCH 01 and BBCH 81, at the rate of 0.60 kg/ha to 2.4 kg/ha. The 2.4 kg/ha dose rate corresponds to 100% of the maximum proposed dose rate and 209% of the lowest proposed dose rate. Crop phytotoxicity was assessed in the trials at various intervals from application and up to termination of the trial.

Phytotoxicity in apple trials, Maritime EPPO zone

Four efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in apple and other pome fruit crops. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the four efficacy trials conducted in the Maritime EPPO zone. Furthermore, harvest results from three Maritime apple trials harvested demonstrated that the applied treatments did not have any significant detrimental effects on yield or quality of yield either.

Phytotoxicity in apple trials, North-east EPPO zone

Six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in apple. The trials were conducted on the commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the six efficacy trials conducted in the North-east EPPO zone.

In two efficacy trials, conducted in Poland in 2016 on the varieties Idared and Jonagored, adverse effects were observed as slightly increased russeting at the last assessment. In both trials, the tribasic copper sulphate reference product caused similar levels of russeting on the apples.

The russetting observed in the Polish efficacy trials are presented in Table 3.4-1.

Table 3.4-1: Visual crop phytotoxicity of Copper oxychloride 50% WG and reference products in apple after split application in efficacy trials (maximum crop phytotoxicity observed)

Trial number	Crop	Variety	Ass. date DAT	UTC	%-relative to Untreated				Type of phytotoxicity
					Copper oxychloride 50% WG		Copper sulphate Ref. Prod.		
				-	0.95 kg/ha [475 g/ha]	1.15 kg/ha [575 g/ha]	2.5 L/ha [475 g/ha]	3.0 L/ha [570 g/ha]	Symptom
PL 16 079 PL1	MABSD	Idared	111 (5)	1.0	116	120	122	118	Russeting (1-5, index)
PL 16 079 PL2	MABSD	Jonagored	109 (5)	1.1	114	128	115	126	Russeting (1-5, index)

Phytotoxicity in apple trials, South-east EPPO zone

One efficacy trial was conducted in the South-east EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in apple and other pome fruit crops. The trial was conducted on the commercially available variety Gala.

No adverse effects in regard to phytotoxicity were observed in the Hungarian efficacy trial conducted in apple. No South-east trials were taken to harvest.

Phytotoxicity in apple trials, Mediterranean EPPO zone

Six efficacy trials were conducted in apple orchards in the Mediterranean EPPO zone to assess the crop safety of Copper oxychloride 50% WG when applied as recommended in apple and other pome fruit crops. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the six efficacy trials conducted in the Mediterranean EPPO zone.

3.4.1.5 Overall conclusion

Copper oxychloride 50% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on grapevine, potato, tomato and apple when applied as recommended. The same was observed in the treatments where Copper oxychloride 50% WG was applied at dose rates higher than the recommended rate, representative of sprayer overlap.

As the data on grapevine, potato, tomato and apple show, the crop safety and efficacy of Copper oxychloride 50% WG is equivalent to that of the straight copper oxychloride reference products as well as the other copper compound reference products tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Table 3.4-2: Phytotoxicity of product

Number of trials with…		Efficacy trials (63 trials)				Vinification trials (4 trials)	
		Test product		Reference product		Test product	Reference product
		Up to 2.0 kg/ha	Up to 2.4 kg/ha	0.625N	1.0N	2.0 kg/ha	1N
Maximum of phytotoxicity recorded during the	0% to 5%	13	50	49	49	4	4
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0

Number of trials with…		Efficacy trials (63 trials)				Vinification trials (4 trials)	
		Test product		Reference product		Test product	Reference product
		Up to 2.0 kg/ha	Up to 2.4 kg/ha	0.625N	1.0N	2.0 kg/ha	1N
trials	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	13	50	49	49	4	4
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Comments of zRMS:	The phytotoxicity assessments were carried out during efficacy trials about tested plant protection product and have been carried out in accordance with EPPO-Guidelines. The conduct of the field work is principally compliant with "Good Agricultural Practice" and in accordance with EPPO Guidelines PP 1/135. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in some trials. Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. N dose, lower and even higher in some trials than recommended doses were studied during trials, which is accepted for fungicides. EPPO 1/135 (3) – Phytotoxicity assessment states: 'EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent'. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3). Phytotoxicity was assessed during efficacy trials. Detailed information's are presented by Applicant. Copper oxychloride 50% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on grapevine, potato, tomato and apple when applied as recommended. Copper is reported to cause damage to flowers and leaves in pome fruit in practice when applied later than BBCH 53. With regard to this, a warning of the possibility of phytotoxic damages to the pome fruit should be put on the label, in the opinion of Evaluator. Only in two trials from N-E EPPO zone carried out on apple in 2016 on the varieties: Idared and Jonagored, adverse effects were observed as slightly increased russeting at the last assessment. In both trials, the tribasic copper sulphate reference product caused similar levels of russeting on the apples. In the opinion of Evaluator, in the label should be put an entry about sensitivity of this two varieties of apple (Idared and Jonagored) on the copper ant risk of increased russeting. Lack of trials for pear, quince and aubergine. Without any trials this crops as minor can be registered only on the basis on Article 51. However, final decision is left to each cMS.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

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).

Materials and Methods:

Plot yields, as fresh weight plant material, were measured at harvest and, in most cases, converted to t/ha. The data of the treated plots are presented as relative values in relation to the fresh weight harvested from the untreated plots. For further information on materials and methods please refer to section 3.2.3 *Efficacy tests* as the harvested trials were efficacy trials.

3.4.2.1 Summary and evaluation of the field trials conducted in grapevine, potato, tomato and apple, treated with 4-8 applications

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Table 3.4-3 for trials conducted in grapevine, potato, tomato and apple.

Grapevine

A total of four efficacy trials conducted in grapevine were harvested. The trials were conducted in the Czech Republic (2) and Spain (2) in 2016. In the efficacy trials, Copper oxychloride 50% WG was applied five (2), six (1) or eight (1) times at 0.75, 1.5 and 2.0 kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 53 and BBCH 81. In Table 3.4-3, the results obtained in the efficacy trials when treated with 1.5 kg/ha and 2.0 kg/ha are presented.

Neither Copper oxychloride 50% WG nor the tribasic copper sulphate reference product (Cuproxat 19% SC) significantly affected the yield when applied at the proposed dose rate (2.0 kg/ha) in any of the four trials. The results obtained in the trials supports the label claim that Copper oxychloride 50% WG is safe to be applied at the recommended dose rate to grapevines at the recommended number of applications.

Potato

A total of twelve efficacy trials conducted in potato field crops were harvested. The trials were conducted in England (1), the Czech Republic (2), N-France (1), Poland (6) and Spain (2) in 2016 and 2017. In the efficacy trials, Copper oxychloride 50% WG was applied four (2), six (9) or eight (1) times at 0.75, 1.5 and 2.4 kg/ha in the majority of the trials, whereas in the Polish trials, Copper oxychloride 50% WG was applied at 1.0, 1.5 and 2.0 kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 24 and BBCH 89. In Table 3.4-3, the results obtained in the efficacy trials when treated with the 0.63N or 0.80N (1.5 kg/ha) dose rate and 1N (2.0 kg/ha or 2.4 kg/ha) dose rates are presented. In the lower part of the summary table, the results obtained with the test product is presented against the specific reference product at comparable rates.

Neither Copper oxychloride 50% WG, the copper oxychloride 50% WP reference product (Cuprokylt) nor the tribasic copper sulphate reference product (Cuproxat 19% SC) significantly affected the yield when applied at the proposed dose rates (2.0 kg/ha or 2.4 kg/ha) in any of the twelve trials. The results obtained in the trials supports the label claim that Copper oxychloride 50% WG is safe to be applied at the recommended dose rate to potato at the recommended number of applications.

Table 3.4-3: Maritime, North-east and Mediterranean zone – Crop yield (t/ha or kg/plot) of grapes, potato tubers, tomatoes and apples treated with Copper oxychloride 50% WG, 4-8 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Tribasic copper sulphate ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg/t per plot/ha	1.5 kg/ha [750 g ai/ha]	2.0 kg/ha [1000 g ai/ha]	3.94-4.0 L/ha [748.6-760 g ai/ha]	5.0-5.3 L/ha [950-1007 g ai/ha]
Grapevine - Efficacy trials						
Maritime zone	2	4.1 (1.9-6.3)	105 (103-107)	104 (103-106)	103 (102-103)	104 (103-105)
Mediterranean zone	2	11.0 (10.8-11.1)	104 (102-105)	108 (105-111)	100 (99-101)	105 (104-106)
Potato - Efficacy trials						
North-east zone	6	36.3 (33.0-42.5)	113 (104-142)	116 (103-156)	117 (108-134)	120 (96-167)
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Copper ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg/t per plot/ha	1.5 kg/ha [750 g ai/ha]	2.4 kg/ha [1200 g ai/ha]	0.625N	1N
Potato - Efficacy trials						
Maritime zone	4	18.9 (6.9-26.2)	124 (114-142)	120 (104-133)	125 (120-132)	129 (120-137)
Mediterranean zone	2	4.9 (4.6-5.2)	111 (110-113)	118 (113-122)	79 (78-79)	115 (108-122)
Tomato - Efficacy trials						
Maritime zone	2	21.4 (3.2-39.6)	124 (104-144)	119 (105-132)	127 (108-147)	119 (102-136)
Mediterranean zone	2	37.8 (32.9-42.8)	105 (104-106)	110 (109-111)	111 (109-112)	108 (107-109)
Apple – Efficacy trials						
Maritime zone	3	46.9 (1.4-119.9)	93 (78-104)	88 (62-104)	91 (69-105)	102 (101-104)
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Tribasic copper sulphate ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg/t per plot/ha	1.5 kg/ha [750 g ai/ha]	2.4 kg/ha [1200 g ai/ha]	3.94 L/ha [748.6 g ai/ha]	6.3 L/ha [1197 g ai/ha]
Potato - Efficacy trials						
Maritime zone	3	16.5 (6.9-25.9)	127 (116-142)	120 (104-133)	127 (120-132)	132 (126-137)
Mediterranean zone	2	4.9 (4.6-5.2)	111 (110-113)	118 (113-122)	79 (78-79)	115 (108-122)
Tomato - Efficacy trials						
Maritime zone	1	39.5	104	105	108	102
Mediterranean zone	2	37.8 (32.9-42.8)	105 (104-106)	110 (109-111)	111 (109-112)	108 (107-109)
Apple – Efficacy trials						
Maritime zone	2	10.5 (1.4-19.5)	101 (99-104)	101 (98-104)	102 (99-105)	102 (99-104)
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Copper oxychloride ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg per 100 fr/plot	2.4 kg/ha	3.0 kg/ha	2.4 kg/ha	3.0 kg/ha
Tomato - Efficacy trials						
Maritime zone	1	3.2	132	153	147	136
Apple – Efficacy trials						
Maritime zone	1	119.9	62	-	69	-
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Copper oxychloride ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg/t per plot/ha	2.4 kg/ha	5.0 kg/ha	2.4 kg/ha	5.0 kg/ha
Potato - Efficacy trials						
Maritime zone	1	26.2	120	123	120	120
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:		Captan ref. prod. at:	
		Mean (min-max)	% relative, compared to untreated (min-max)			
		Kg/t per plot/ha	1.5 kg/ha [750 g ai/ha]	2.4 kg/ha [1200 g ai/ha]	-	2.0 kg/ha [1600 g ai/ha]
Apple – Efficacy trials						
Maritime zone	1	119.9	78	62	-	101

Tomato

A total of four efficacy trials conducted in tomato field crops were harvested. The trials were conducted in England (1), the Czech Republic (1) and Spain (2) in 2016. In the efficacy trials, Copper oxychloride 50% WG was applied four (1), five (1) or eight (2) times at 0.75, 1.5 and 2.4 kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 55 and BBCH 89. In Table 3.4-3, the results obtained in

the efficacy trials when treated with 1.5 kg/ha and 2.4 kg/ha are presented. In the lower part of the summary table, the results obtained with the test product is presented against the specific reference product at comparable rates.

Neither Copper oxychloride 50% WG, the copper oxychloride 50% WP reference product (Cuprokylt) nor the tribasic copper sulphate reference product (Cuproxat 19% SC) significantly affected the yield when applied at the maximum proposed dose rate (2.4 kg/ha) in any of the four trials. The results obtained in the trials supports the label claim that Copper oxychloride 50% WG is safe to be applied at the recommended dose rate to tomato at the recommended number of applications.

Apple

A total of four efficacy trials conducted in apples were harvested. The trials were conducted in England (2) and the Czech Republic (2) in 2016. In the efficacy trials, Copper oxychloride 50% WG was applied six (2) or eight (2) times at 0.75, 1.5 and 2.4 kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 40 and BBCH 81. In Table 3.4-3, the results obtained in the efficacy trials when treated with 1.5 kg/ha and 2.4 kg/ha are presented. In the lower part of the summary table, the results obtained with the test product is presented against the specific reference product at comparable rates.

Neither Copper oxychloride 50% WG, the copper oxychloride 50% WP reference product (Cuprokylt), the tribasic copper sulphate reference product (Cuproxat 19% SC) nor the captan 80% WG reference product (Captan) significantly affected the yield when applied at the maximum proposed dose rate (2.4 kg/ha) in any of the four trials. The results obtained in the trials supports the label claim that Copper oxychloride 50% WG is safe to be applied at the recommended dose rate to apple at the recommended number of applications.

Conclusion

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. The applicant therefore wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

3.4.2.2 Relationship between phytotoxicity and yield

No adverse effects were observed in any of the 63 efficacy trials as well as four vinification trials. In the 24 trials harvested, no significant reductions in crop yield were recorded in any of the plots treated with Copper oxychloride 50% WG at the recommended dose rate.

Comments of zRMS:	ZRMs agree with Applicant. COBRANZA (product code: SHA 9800 A) containing copper oxychloride applied at the recommended rate did not significantly affect the crop yield. The data obtained in trials harvested demonstrate that COBRANZA (product code: SHA 9800 A) containing copper oxychloride is as safe to the crop as the reference products used in the trials

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Twenty-four efficacy trials treated with Copper oxychloride 50% WG were harvested and yields and/or quality of yield recorded. In these, assessments were conducted on the potential impact of treatment on sales quality of potatoes, tomatoes and apples, fruit colour of apples as well as sugar- and acid content of grapes and apples.

Quality of grapes

The results obtained from assessments on the quality of the harvested vine grapes from two efficacy trials conducted in the Czech Republic are presented in Table 3.4-4.

Table 3.4-4: Maritime zone – Quality of harvested vine grapes – crop treated with Copper oxychloride 50% WG, 6-8 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Tribasic copper sulphate ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	0.75 kg/ha	1.5 kg/ha	2.4 kg/ha	2.17 L/ha	2.92 L/ha
Efficacy trials, Maritime EPPO zone							
Acid content (g/L)	2	7.4 (6.4-8.4)	99 (99-99)	99 (99-99)	99 (98-100)	99 (98-99)	99 (99-99)
Sugar content (ºBrix)	2	21.5 (21.1-22.0)	101 (101-101)	100 (100-100)	100 (100-101)	89 (76-101)	100 (100-100)

In the trials evaluated, Copper oxychloride 50% WG had no detrimental effect on the quality parameters assessed on the harvested vine grapes. When comparing the results obtained with Copper oxychloride 50% WG against the results obtained with the tribasic copper sulphate reference product at applied dose rates, both products performed statistically similar on all quality parameters assessed.

Quality of potato tubers

The results obtained from assessments on the quality of the harvested potato tubers are presented in Table 3.4-5.

In the trials evaluated, Copper oxychloride 50% WG had no detrimental effect on the quality parameters assessed on the harvested potato tubers. When comparing the results obtained with Copper oxychloride 50% WG against the results obtained with the copper oxychloride reference product at comparable dose rates or the tribasic copper sulphate reference product at comparable rates, both products performed statistically similar on all quality parameters assessed.

Table 3.4-5: Maritime, North-east and Mediterranean zone – Quality of harvested potato tubers – crop treated with Copper oxychloride 50% WG, 4-8 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Copper oxychloride 50% WP ref. Prod. At:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	1.5 kg/ha	2.4 kg/ha	5.0 kg/ha	2.4 kg/ha	5.0 kg/ha
Efficacy trials, Maritime EPPO zone							
Tubers, class 1 (kg/plot)	1	0.0	0.0	0.0	0.0	0.0	0.0
Tubers, class 2 (kg/plot)	1	0.9	143	124	137	192	164
Tubers, class 3 (kg/plot)	1	6.6	98	99	95	130	109
Tubers, class 4 (kg/plot)	1	7.7	166	180	182	128	158
Tubers, class 5 (kg/plot)	1	10.9	85	91	96	103	96
Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Tribasic copper sulphate ref. Prod. At:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	0.75 kg/ha	1.5 kg/ha	2.4 kg/ha	2.17 L/ha	3.47 L/ha

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Tribasic copper sulphate ref. Prod. At:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	1.0 kg/ha	1.5 kg/ha	2.0 kg/ha	4.0 L/ha	5.0 L/ha
Efficacy trials, Maritime EPPO zone (cont.)							
Tubers, large (t/ha)	2	0.3 (0.1-0.5)	103 (86-120)	163 (86-240)	177 (114-240)	277 (114-440)	351 (343-360)
Tubers, medium (t/ha)	2	4.4 (0.2-8.5)	112 (100-124)	167 (134-200)	218 (136-300)	236 (121-350)	288 (126-450)
Tubers, small (t/ha)	2	18.2 (3.3-33.2)	89 (70-108)	86 (62-110)	101 (84-117)	93 (78-108)	87 (65-108)
Efficacy trials, North-east EPPO zone							
Tubers, small (kg/plot)	6	1.9 (0.1-3.0)	90 (70-100)	95 (57-117)	72 (38-117)	98 (26-123)	80 (15-117)
Tubers, medium (kg/plot)	6	26.5 (18.1-37.2)	97 (88-106)	102 (96-111)	102 (94-109)	100 (96-105)	100 (87-115)
Tubers, large (kg/plot)	6	14.5 (5.4-22.5)	124 (99-146)	133 (113-183)	146 (122-216)	145 (131-173)	158 (106-259)
Tubers, unmarket. (kg/plot)	4	2.0 (1.8-2.5)	101 (76-117)	112 (99-127)	98 (81-106)	101 (99-103)	100 (79-111)
Efficacy trials, Mediterranean EPPO zone							
Tubers, class 1 (kg/plot)	2	13.4 (10.3-16.6)	126 (116-136)	70 (63-77)	114 (106-122)	65 (64-67)	120 (120-121)
Tubers, class 2 (kg/plot)	2	5.4 (2.5-8.3)	155 (144-167)	93 (79-107)	136 (132-139)	86 (81-91)	151 (149-152)
Tubers, discarded (kg/plot)	2	5.9 (5.9-5.9)	113 (113-113)	63 (63-63)	100 (100-100)	27 (27-27)	67 (67-67)

Quality of tomato fruits

The results obtained from assessments on the quality of the harvested tomatoes from one efficacy trial conducted in the UK are presented in Table 3.4-6.

Table 3.4-6: Maritime zone – Quality of harvested tomatoes – crop treated with Copper oxychloride 50% WG, 4 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Copper oxychloride 50% WP ref. Prod. At:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	1.5 kg/ha	2.4 kg/ha	3.0 kg/ha	2.4 kg/ha	3.0 kg/ha
Efficacy trials, Maritime EPPO zone							
Fruits, Grade 1 (kg/100 fr.)	1	0.5	178	122	170	159	138
Fruits, Grade 2 (kg/100 fr.)	1	0.4	118	133	132	114	131
Fruits, Grade 3 (kg/100 fr.)	1	2.3	144	137	153	149	137

In the trial evaluated, Copper oxychloride 50% WG had no detrimental effect on the quality parameters assessed on the harvested tomato fruits. When comparing the results obtained with Copper oxychloride 50% WG against the results obtained with the copper oxychloride reference product at registered rates, both products performed statistically similar on all quality parameters assessed.

Quality of apple fruits

The results obtained from assessments on the quality of the harvested apple fruits are presented in Table 3.4-7.

Table 3.4-7: Maritime zone – Quality of harvested apples – crop treated with Copper oxychloride 50% WG, 6-8 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Copper oxychloride ref. prod. at:	Captan ref. prod. at:
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	0.75 kg/ha	1.5 kg/ha	2.4 kg/ha	2.4 kg/ha	2.0 kg/ha
Efficacy trials, Maritime EPPO zone							
Fruits, colour grade (1-4)	1	1.0	100	100	100	100	100
Fruits, Grade 1 (no/100 fr.)	1	92.0	101	100	100	107	103
Fruits, Grade 2 (no/100 fr.)	1	8.0	88	100	100	25	63
Fruits, marketable (kg/plot)	1	22.9	81	66	63	55	54
Fruits, unmarket. (kg/plot)	1	97.0	85	81	62	73	112

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Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:			Tribasic copper sulphate ref. Prod. At:	
			% relative, compared to untreated (min-max, no. of trials)				
		Mean (min-max)	0.75 kg/ha	1.5 kg/ha	2.4 kg/ha	2.17 L/ha	3.47 L/ha
Efficacy trials, Maritime EPPO zone (cont.)							
Acid content (g/L)	2	2.7 (0.5-5.0)	96 (93-100)	98 (95-101)	96 (90-102)	98 (92-103)	97 (94-101)
Sugar content (ºBrix)	2	13.0 (12.8-13.3)	100 (99-102)	99 (98-101)	99 (98-101)	101 (99-104)	100 (99-100)

In the trials evaluated, Copper oxychloride 50% WG had no detrimental effect on the quality parameters assessed on the harvested apples. When comparing the results obtained with Copper oxychloride 50% WG against the results obtained with the tribasic copper sulphate reference product at comparable dose rates or the reference products included in the English trials (copper oxychloride reference product as well as captan at registered rates), all three products performed statistically similar on all quality parameters assessed.

Conclusion

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 the quality of the crop yield significantly in any of the 18 trials where the quality of the harvested crop was assessed. 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. The applicant therefore wishes to cite the original registrant's data on copper oxychloride now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	ZRMs agree with Applicant. COBRANZA (product code: SHA 9800 A) containing copper oxychloride applied at the recommended rate did not significantly affect the crop yield. The data obtained in trials harvested demonstrate that COBRANZA (product code: SHA 9800 A) containing copper oxychloride is as safe to the crop as the reference products used in the trials

3.4.4 Effects on transformation processes (KCP 6.4.4)

Processing can include physical processing such as cooking of potatoes. It has already been shown in section 3.4.3 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 in 3.4.3.

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.

3.4.4.1 Vinification test

Four field tests were conducted in S-France by SARL Cotesia who carried out the field part whereas the wine making process tests were carried out by Biotek Agriculture. The objective of the studies was to investigate the potential effect of copper oxychloride on the vinification process.

Materials and Methods:

Three plot replicated trials were carried out to generate specimens of grapes for vinification and wine taint testing. The treatments applied in the field trials are summarised in Table 3.4-8. In all trials, the test product was tested in a scenario where first Chaoline (fosetyl-Al 47.1% + metiram 28.9% WG, reg.no.: 9600368) 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, reg.no. 9900242) were applied. In the treatment with the refence product (Cuproxat SC), the same scenario was repeated, i.e. first three applications with Chaoline, followed by three applications of the reference products which then were followed by three or four applications of Dithane Neotec.

Table 3.4-8: Vinification studies

Trial no.	Country	Year	Crop	Variety	No of appl.	Growth stage at 1st / last appl.	Time between appl.
Mediterranean EPPO zone							
F16CP02UEN01	FR	2016	VITVI	Tanat	9	53 / 81-83	12-16
F16CP02UEN02	FR	2016	VITVI	Ugni blanc	9	53 / 81-83	10-17
F16CP02UEN03	FR	2016	VITVI	Cabernet sauvignon	9	53 / 83-85	12-15
F16CP02UEN04	FR	2016	VITVI	Petit manseng	10	53 / 79-81	11-15

Results:

At harvest, assessments were conducted on alcohol content, acidity content, pH and weight of 200 grapes. These yield quality parameters obtained in these trials are presented in Table 3.4-9. According to the results of these analyses, there are no differences between the tested and the reference treatment at harvest.

Table 3.4-9: Quality of harvested grapevine berries – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
		Mean (min-max)	2.0 kg/ha	5.3 L/ha
Alcohol content - berries				

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
		Mean (min-max)	2.0 kg/ha	5.3 L/ha
Mediterranean zone	4	-	12.6 (10.9-15.6)	12.2 (10.6-15.6)
Acidity content (g H_2SO_4/L) - berries				
Mediterranean zone	4	-	4.1 (2.6-5.2)	4.2 (2.8-5.4)
pH - berries				
Mediterranean zone	4	-	3.6 (3.4-3.8)	3.6 (3.4-3.8)
Weight (g) - berries				
Mediterranean zone	4	-	334.5 (236.5-460.7)	331.6 (238.6-499.7)

After washing, the grapes were crushed and left for fermentation. Different parameters were assessed on the fresh must, as presented in Table 3.4-10. There were no significant differences between the samples.

Table 3.4-10: Quality of fresh grapevine must – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
		Mean (min-max)	2.0 kg/ha	5.3 L/ha
Density – must				
Mediterranean zone	4	-	1101.8 (1085-1118)	1101.3 (1084-1119)
pH – must				
Mediterranean zone	4	-	3.5 (3.2-3.8)	3.5 (3.2-3.8)
Acidity content (g H_2SO_4/L) – must				
Mediterranean zone	4	-	4.6 (3.2-6.2)	4.6 (3.2-6.0)
Alcohol content (%) – must				
Mediterranean zone	4	-	13.8 (11.2-16.9)	13.7 (11.1-17.1)
K content (g/L) – must				
Mediterranean zone	4	-	1.3 (0.6-2.5)	1.4 (0.6-2.6)

During fermentation, time was recorded for latent time and alcoholic fermentation duration, as presented in Table 3.4-11. There was no difference between the samples for the alcoholic fermentation period.

Table 3.4-11: Alcoholic fermentation – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
		Mean (min-max)	2.0 kg/ha	5.3 L/ha
Latent time (days)				
Mediterranean zone	4	-	1.0 (1.0-1.0)	1.3 (1.0-2.0)
Alcoholic fermentation duration (days)				
Mediterranean zone	4	-	16.3 (14-21)	16.3 (14-21)

Red wines were subjected to malolactic fermentation (MLF) and during MLF, time was recorded for latent time and alcoholic fermentation duration, as presented in Table 3.4-12. Before malolactic fermentation, different quality parameters were assessed on the fermented product, as also presented in Table 3.4-12. Copper oxychloride 50% WG did not impact the malolactic fermentation in any way.

Table 3.4-12: Malolactic fermentation of red wines – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

Crop, trial type	No. of trials	Favourable Conditions	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
			2.0 kg/ha	5.3 L/ha
Alcohol content (% vol.)				
Mediterranean zone	2	<13	13.5 (12.1-14.8)	12.9 (11.8-13.9)
pH				
Mediterranean zone	2	≥ 3.4	3.7 (-)	3.7 (3.6-3.8)
Free SO2				

Crop, trial type	No. of trials	Favourable Conditions	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
			2.0 kg/ha	5.3 L/ha
Mediterranean zone	2	< 8	<8-9	<8-9
Total SO2				
Mediterranean zone	2	< 30	30-<30	30-<30
Temperature (ºC)				
Mediterranean zone	2	18 to 22	21.0 (-)	21.0 (-)
Latent time of induced MLF (days)				
Mediterranean zone	2	-	5.5 (5-6)	5.5 (5-6)
Duration of induced MLF (days)				
Mediterranean zone	2	-	23.5 (13-34)	23.5 (13-34)

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Latent time of spontaneous MLF (days)				
Mediterranean zone	2	-	5.5 (5-6)	5.5 (5-6)
Duration of spontaneous MLF (days)				
Mediterranean zone	2	-	40.0 (25-55)	36.5 (25-48)

After fermentation, different quality parameters were assessed on the fermented product, as presented in Table 3.4-13.

Table 3.4-13: Quality of bottled wine – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

Crop, trial type	No. of trials	Untreated	Copper oxychloride 50% WG at:	Cuproxat SC at:
			Mean (min-max)	
		Mean (min-max)	2.0 kg/ha	5.3 L/ha
Sugar residue (g/l)				
Mediterranean zone	4	-	1.9 (1.2-2.8)	2.2 (1.3-3.6)
Alcohol content				
Mediterranean zone	4	-	14.0 (11.9-17.0)	13.7 (11.8-17.1)
pH				
Mediterranean zone	4	-	3.6 (3.1-4.3)	3.6 (3.1-4.2)
Total acidity				
Mediterranean zone	4	-	4.6 (4.2-5.4)	4.7 (4.1-5.3)
Volatile acidity				
Mediterranean zone	4	-	0.5 (0.1-0.9)	0.6 (0.2-0.9)
FML				
Mediterranean zone	4	-	1.0 (0-2)	1.0 (0-2)
Free SO2				
Mediterranean zone	4	-	21.3 (20-23)	20.5 (11-25)
Total SO2				
Mediterranean zone	4	-	82.0 (62-116)	89.3 (71-120)
DO 420				
Mediterranean zone	4	-	0.4 (0.1-0.8)	0.4 (0.2-0.7)
DO 520				
Mediterranean zone	2	-	0.7 (-)	0.8 (0.7-1.0)
DO 620				
Mediterranean zone	2	-	0.2 (0.2-0.2)	0.2 (0.2-0.3)
DO 280				
Mediterranean zone	2	-	61.6 (50.9-72.2)	62.9 (55.9-69.8)
Colour intensity				
Mediterranean zone	2	-	1.6 (1.4-1.7)	1.7 (1.6-1.8)

The fresh wine was subjected to a triangular taint test after bottling and in all four trials, no significant difference was found between the two treatments, which conclude on a non-perceptible difference between the 2 samples. At the same taint test, the tasters were asked to note the wines according to 14 criteria of tasting estimated according to a scale from 0 to 9, indicating the level of perception of the taster, nil to strong. The results based on these fourteen criteria of tasting was that there is no significant difference between the profiles of the wines.

Table 3.4-14: Taint test, after bottling – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

	Trial no. 1 – Tanat		Trial no. 2 – Ugni blanc	
Ref.: Cuproxat SC	**Right response**	**Wrong response**	**Right response**	**Wrong response**
Copper oxychloride 50% WG	1	9	4	6
Significant level	7	7	7	7
Result	No difference		No difference	

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	Trial no. 3 – Cabernet sauvignon		Trial no. 4 – Petit manseng	
Ref.: Cuproxat SC	**Right response**	**Wrong response**	**Right response**	**Wrong response**
Copper oxychloride 50% WG	5	5	1	9
Significant level	7	7	7	7
Result	No difference		No difference	

One year after bottling, the stored wine was subjected to another triangular taint test and again the tasters were asked to note the wines according to 14 criteria of tasting estimated according to a scale from 0 to 9, indicating the level of perception of the taster, nil to strong. The results based on these fourteen criteria of tasting was that there is no significant difference between the profiles of the wines in any of the four studies.

Table 3.4-15: Taint test, one year after bottling – Crop treated with Copper oxychloride 50% WG with three applications in vinification studies

	Trial no. 1 – Tanat		Trial no. 2 – Ugni blanc	
Ref.: Cuproxat SC	**Right response**	**Wrong response**	**Right response**	**Wrong response**
Copper oxychloride 50% WG	6	4	6	4
Significant level	7	7	7	7
Result	No difference		No difference	

	Trial no. 3 – Cabernet sauvignon		Trial no. 4 – Petit manseng	
Ref.: Cuproxat SC	**Right response**	**Wrong response**	**Right response**	**Wrong response**
Copper oxychloride 50% WG	5	5	3	7
Significant level	7	7	7	7
Result	No difference		No difference	

Comments of zRMS:	Transformation processes that may be sensitive to treatment with plant protection products are considered to be those that depend on biological activity, for example the activity of yeasts in bread-making, baking, vinification and brewing, according to guidance provided in EPPO standard PP1/243(2); Effects of plant protection products on transformation processes. Four field tests were conducted in S-France by SARL Cotesia who carried out the field part whereas the wine making process tests were carried out by Biotek Agriculture. The objective of the studies was to investigate the potential effect of copper oxychloride on the vinification process. At harvest, assessments were conducted on alcohol content, acidity content, pH and weight of 200 grapes. According to the results of these analyses, there are no differences between the samples for the alcoholic fermentation period, acidity content, pH or weight. An assessment of the risk of taint after crop processing was submitted (EPPO standard 242: Taint tests). This is relevant for orchard fruits, nuts, and vines. The results based on fourteen criteria of tasting was that there is no significant difference between the profiles of the wines and no significant difference between the profiles of the wines in any of the four studies.

	Other Copper fungicides have not been shown to present a risk of occurrence of taint or odour nor to have an adverse influence on the quality. There are no indications that the use of the product could have an influence on the processing procedure and other products based on the same active ingredient have not been shown to have an adverse influence on these processes. In conclusion, no negative influence of the product COBRANZA (product code: SHA 9800 A) on the yield of treated plants and plant products is to be expected when applied at the intended dose rate and used according to the label recommendations.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Copper oxychloride 50% WG is a fungicide based on copper oxychloride which is without herbicidal activity. According to EPPO PP 1/135(4), no data are normally required for fungicides such as Copper oxychloride 50% WG. Furthermore, copper oxychloride has been used for several years on e.g. ornamentals, beet crops, grapes and solanaceous crop, without identifying any issues in regard 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.

Currently, there are no label restrictions regarding the use of copper oxychloride on crops destined for propagation and there seems no reason to suppose that Copper oxychloride 50% WG will perform any differently to those products in this respect.

The product complies with the Uniform Principles.

Comments of zRMS:	Based on the absence of negative effects on parts of plant used for propagating purposes from practice, it can be concluded, that a negative effect of COBRANZA (product code: SHA 9800 A) on parts of plant used for propagating purposes is not expected in the opinion of Evaluator.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

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 (Hunter *et al.*, 1987) and some tree species are intolerant to soil copper concentrations of 12.5 mg Cu/kg (Powell and Lyons, 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.

Comments of zRMS:	Based on this, it is reasonable to conclude that COBRANZA (product code: SHA 9800 A) has no adverse effects on replacement or succeeding crops sown or planted following its application as per label recommendations. Therefore, no label restrictions on the sowing or planting of succeeding or replacement crops following the application of COBRANZA (product code: 9800 A) is necessary in the opinion of Evaluator.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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 (3.5.1). 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.

Comments of zRMS:	Without any herbicide effect COBRANZA (product code: SHA 9800 A) poses an acceptable risk to succeeding crops and other plants including adjacent crops following the proposed uses.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Copper oxychloride 50% WG in 2016 and 2017, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

The product complies with the Uniform Principles.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	Statement accepted. All detailed information's are presented in dRR part B section 9.

3.6 Other/special studies

No other studies were conducted.

Comments of zRMS:	Statement accepted.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type			
			2016			2017
			Efficacy Field	Vinification Field	Vinification Laboratory	Efficacy Field
Grapevine						
Agrolab	MED	GR	2			
Agrigeos	MED	IT	2			
GMW Bioscience	MED	ES	2			
Eurofins	MED	FR	2			
Eurofins	MAR	FR	2			
SARL Cotesia	MED	FR		4		
Biotek Agriculture	MED	FR			1	
PP Trial	MAR	CZ	2			
Gov. Office of Györ-Moson-Sopron County	S-E	HU	1			
Potato						
Agrolab	MED	GR	2			
Agrigeos	MED	IT	2			
GMW Bioscience	MED	ES	2			
Eurofins	MED	FR	1			
CentrExpé	MAR	FR	1			
Z.z.s. Kujavy	MAR	CZ	1			
Zemservis	MAR	CZ	1			
SGS Group	MAR	UK	2			
Anadiag	N-E	PL	2			
Fertico Sp. Z.o.o.	N-E	PL				4
Gov. Office of Nógrad County	S-E	HU	1			
Tomato						
Agrolab	MED	GR	2			
Agrigeos	MED	IT	2			
GMW Bioscience	MED	ES	2			
Eurofins	MED	FR	2			
V.u. Pícninářský	MAR	CZ	1			
SGS Group	MAR	UK	2			
Anadiag	N-E	PL	2			
Gov. Office of Békés County	S-E	HU	1			
Apple						
Agrolab	MED	GR	2			
Agrigeos	MED	IT	2			
GMW Bioscience	MED	ES	2			
PP Trial	MAR	CZ	2			
SGS Group	MAR	UK	2			
Anadiag	N-E	PL	2			
Fertico Sp. Z.o.o.	N-E	PL				4
Gov. Office of Szabolcs-Szatmar-Bereg County	S-E	HU	1			
Total, All crops			**59**	**4**	**1**	**8**

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Copper oxychloride 50% WG (500 g/kg copper oxychloride WG) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA