

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper Oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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## Version history

When	What
July.2020	Assessment by the expert
May 2021	Updated by applicant
August 2021	Updated by applicant
August 2021	Final version of RR after commenting

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on COBRANZA \***

Product name and code	SHA 9800 A/ COBRANZA
Formulation type	Water dispersible granules [Code: WG]
Active substance(s) (incl. content)	Copper oxychloride; 500 g/kg
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

\* Information on the detailed composition of COBRANZA can be found in the confidential dRR Part C.

### Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

**Table 6.1-2: Justified proposals for classification and labelling for COBRANZA according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	Acute Tox.(oral) 4; Acute Tox.(inhalation) 4
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H302, H332
Precautionary statement(s)	P261, P273, P280, P301+ P312, P304+P340, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for COBRANZA**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<del>Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L</del> Work wear (arms, body and legs covered) at M/L and A, Without RPE/PPE
Workers	Acceptable	Grapevine - Work wear (arms, body and legs covered) and gloves- time period of 8 days after application, Work wear (arms, body and legs covered) - time period of 15 days after application Potato - Work wear (arms, body and legs covered) Solanaceous fruits - Work wear (arms, body and legs covered) and gloves Pome fruits - Work wear (arms, body and legs covered) and gloves- time period of 7 days after application, Work wear (arms, body and legs covered) - time period of 14 days after

	Result	PPE / Risk mitigation measures
		application Grapevine - Work wear (arms, body and legs covered) and gloves Grapevine - Work wear (arms, body and legs covered) - time period of 17 days after application Potato, Solanaceous fruits - Potencial Pome fruits - Work wear (arms, body and legs covered)
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

**Table 6.1-4 Critical uses and overall conclusion of exposure assessment**

1	2	3	4	5	6	7	8	9	10				
Use- No.*	Crops and situa- tion (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks:  (e.g. safen- er/synergist (L/ha))  critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment				
			Method / Kind  (incl. applica- tion technique ***)	Max. number (min. interval between applications)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha	Water L/ha  min / max			Operator	Worker	Residents	Bystander	
1	Grapevine BBCH 15-85	F	Foliar Spray LCTM HCTM HCHH	4(10)	1.0	800-1000	21						
2	Potato BBCH 15-85	F	Foliar Spray LCTM	3(10)	1.2	500-1000	14						
3	Solanaceous fruits (Tomato, auber- gine) BBCH 15-85	F	Foliar Spray LCTM HCHH	3(10)	1.2	500-1000	3						
4	Pome fruit (apple, pear, quince) BBCH 15-85	F	Foliar Spray HCTM HCHH	3(10)	1.2	800-1000	21						

\* 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

\*\*\* e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

## 6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

**Table 6.2-1: Information on active substance(s)**

	Copper Oxychloride
Common Name	Copper Oxychloride
CAS-No.	1332-65-6 or 1332-40-7
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Acute Tox. 3, Acute Tox. 4 GHS06 H301, H332
Additional C&L proposal	-
AOEL systemic	0.08 mg/kg bw/d
Reference	SANTE/10506/2018 Rev. 5 27 November 2018
According to Review report for Copper Oxychloride (SANTE/10506/2018 Rev. 5 27 November 2018)	The review has identified acceptable exposure scenarios for operators, workers, residents, bystanders and groundwater which require however to be confirmed for each plant protection product.

## 6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of COBRANZA are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants, COBRANZA is predicted toxicity for in respect to acute oral and acute inhalation. The applicant has therefore proposed: COBRANZA is classified as irritating to acute tox with hazard statements H302, H332.

**Table 6.3-1: Additional toxicological information relevant for classification/labelling of COBRANZA**

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Copper Oxychloride (50% (w/w))	H302, H332	Reg. 1272/2008	H302, H332
Toxicological properties of non-active substance(s) (relevant for classification of product)				
Further toxicological information	No data – not required			

\* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

\*\* Material safety data sheet by the applicant

## 6.4 Toxicological Evaluation of Groundwater Metabolites

Not relevant. There is not metabolites.

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in COBRANZA are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in Copper Oxychloride 50% WG**

	Copper Oxychloride	
	Value	Reference
Concentrate	1% 0.1%	EFSA Journal 2018;16(1):5152 Position paper : ‘The fate of test item residues in the skin membranes in in vitro dermal absorption studies; impact on the risk assessment of inorganic copper salts’, 21 September 2020, xxxxx
Dilution	9% 1%	EFSA Journal 2018;16(1):5152 Position paper : ‘The fate of test item residues in the skin membranes in in vitro dermal absorption studies; impact on the risk assessment of inorganic copper salts’, 21 September 2020, xxxxx

### 6.5.1 Justification for proposed values – Oxychloride

The proposed dermal absorption rates for copper are based on dermal absorption studies on a formulation containing copper Oxychloride.

The study results are summarised in the following table. Full summaries of studies on the dermal absorption of copper that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

It has already been established during the EU peer review that, given the nature of the active substance ( $\text{Cu}^{2+}$ ), dermal penetration factors for both concentrate and in-use spray dilutions from these studies are justifiably relevant to all forms of copper (oxide, hydroxide, oxychloride, tribasic sulphate and Bordeaux Mixture) and all formulation types (WP, WG, and SC). Therefore, the results of the studies below are relevant for Copper oxychloride in COBRANZA

**Table 6.5-2: Summary of the results of submitted dermal absorption studies for copper**

Test	Concentrate	Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
<i>In vitro</i> (human)	0.4%	9% (0.3g Cu/L)	•DPX-GFJ52 (Copper hydroxide 53.8WG)	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product	xxxxx2017*
<i>In vitro</i> (human)	0.6% 0.1%	8.9% 3.5%	•Copper hydroxide 50 WP.	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can	xxxxx 2015*



Test	Concentrate	Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
			•Flowbrix			be used for current product.	
<i>In vitro</i> (human)	0.09%	5.68% (1.5 g/L)	<ul style="list-style-type: none"> <li>•Copper hydroxide 250 g Cu/L, SC.</li> <li>•Copper hydroxide 50 WP</li> <li>•H1B10 Copper hydroxide 25% WG</li> <li>•Copper Oxychloride 37.5 NC WG</li> <li>•Flowbrix</li> <li>•Bordeaux mixture 20% Cu WP</li> <li>•BBC/Bouillie Bordelaise</li> <li>•Nordox 75 WG</li> </ul>	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product .	xxxxx 2012*

Applicant update August 2021: Applicant is presenting an update on risk assessment based on refined dermal absorption values. During Art 43 evaluation of copper compounds in EU, EUCuTF has proposed a new approach on risk assessment and defended more realistic and less conservative dermal absorption values based on the transport mechanism of Cu through the skin which is fundamentally different to organic compounds (please refer to position paper). This approach has been already accepted by some CEU countries and applicant kindly request ZRMS Poland to take those values into account.

**ACCEPTABLE**

## 6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

**Table 6.6-1: Product information and toxicological reference values used for exposure assessment**

Product name and code	Copper Oxychloride 50% WG
Formulation type	WG
Category	Fungicide
Active substance(s) (incl. content)	<b>Copper Oxychloride</b> 500 g/kg
AOEL systemic	0.08 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100% 50%

Dermal absorption	Concentrate: 1 % 0.1% Dilution: 9 % 1%
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## 6.6.1 Selection of critical uses and justification

The critical GAPs used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the Southern EU zone is given in Part B, Section 0.

### Justification

All Intended uses of the GAP given in Part B, Section 0 are taken into account.

## 6.6.2 Operator exposure (KCP 7.2.1)

### 6.6.2.1 Estimation of operator exposure

A summary of the exposure model used for estimation of operator exposure to the active substances during application of COBRANZA according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6 3 (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-2: Exposure models for intended uses**

Critical uses	Grapevine (max. 2 L Kg product/ha) Potato (max. 2.4 L Kg product/ha) Solanaceous fruits (Tomato, aubergine) (max. 2.4 L Kg product/ha) Pome fruit (apple, pear, quince) (max. 2.4 L Kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

**Table 6.6-3: Estimated operator exposure (longer term exposure)**

Copper Oxychloride			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (grapevine)			
Application rate		1 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.3479802 0.0617029	435 77
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0436929 0.0277581	55 35
	Work wear (arms, body and legs covered) at M/L and A		
Manual-Hand held, upward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	

<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.1342792	168
	Work wear (arms, body and legs covered) at M/L and A	0.0207596	26
<b>Vehicle mounted, upward spraying outdoor to grapes</b>			
Application rate		1 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.1861868	233
	Work wear (arms, body and legs covered) at M/L and A	0.0547209	68
<b>Tractor mounted boom spray application outdoors to low crops (potato, solanaceous fruit)</b>			
Application rate		1.2 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.4844959 0.0322382	606 40
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0417526 0.0214360	52 27
	Work wear (arms, body and legs covered) at M/L and A		
<b>Manual-Hand held, downward spraying outdoor to solanaceous fruit</b>			
Application rate		1.2 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.4377706	547
	Work wear (arms, body and legs covered) at M/L and A	0.0533310	67
<b>Tractor mounted boom spray application outdoors to high crops (pome fruit)</b>			
Application rate		1.2 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.4005710 0.2220445	501 278
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0494012 0.0653506	62 80
	Work wear (arms, body and legs covered) at M/L and A		
<b>Manual-Hand held, upward spraying outdoor to pome fruit</b>			
Application rate		1.2 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.1406783	176
	Work wear (arms, body and legs covered) at M/L and A	0.0237704	30

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

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

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

**The following labelling is therefore required: None**

Applicant is presenting below refined risk assessment considering dermal absorption values given in position paper.

Copper Oxychloride			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (grapevine)			
Application rate		1 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0081773	10
	Work wear (arms, body and legs covered) at M/L and A	0.0044169	6
Manual-Hand held, upward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0424027	53
	Work wear (arms, body and legs covered) at M/L and A	0.0068092	9
Vehicle mounted, upward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0252322	32
	Work wear (arms, body and legs covered) at M/L and A	0.0106361	13
Tractor mounted boom spray application outdoors to low crops (potato, solanaceous fruit)			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0054742	7
	Work wear (arms, body and legs covered) at M/L and A	0.0043133	5
Manual-Hand held, downward spraying outdoor to solanaceous fruit			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0507410	63
	Work wear (arms, body and legs covered) at M/L and A	0.0080323	10
Tractor mounted boom spray application outdoors to high crops (pome fruit)			

Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0296508	37
	Work wear (arms, body and legs covered) at M/L and A	0.0121420	15
Manual-Hand held, upward spraying outdoor to pome fruit			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0208970	26
	Work wear (arms, body and legs covered) at M/L and A	0.0079140	10

Considering more realistic and less conservative dermal absorption values given in position paper conclusion on operator risk assessment is as follows:

According to the AOEM model, calculations, it can be concluded that the risk for the operator using COBRANZA is acceptable for grapes, vegetables and pome fruits without the use standard working clothing.

The following labelling is therefore required: None

ACCEPTABLE

## 6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

## 6.6.3 Worker exposure (KCP 7.2.3)

### 6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Oxychloride 50% WG according to the critical uses. Outcome of the estimation is presented in (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical uses	Grapevine (max. 4 x 2 L Kg product/ha) Potato (max. 3 x 2.4 L Kg product/ha) Solaceous fruits (Tomato, aubergine) (max. 3 x 2.4 L Kg product/ha) Pome fruit (apple, pear, quince) (max. 3 x 2.4 L Kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

**Table 6.6-5: Estimated worker exposure (longer term exposure)**

		<b>Copper oxychloride</b>	
<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg bw/day)</b>	<b>% of systemic AOEL</b>
<b>Grapevine</b> Hand harvesting/ Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days DFR: 1.9 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm <sup>2</sup> /person/h	1.0675740	1334
	Work wear (arms, body and legs covered) TC: 10100 cm <sup>2</sup> /person/h	0.3594166	449
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm <sup>2</sup> /person/h*	0.1729826	216

<b>Proposal of Re-entry period of 8 days</b> <b>Grapevine</b> Hand harvesting/ Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days <b>DFR: 0.84 µg/cm<sup>2</sup>/kg a.s./ha</b> Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm <sup>2</sup> /person/h	0.4719801	588
	Work wear (arms, body and legs covered) TC: 10100 cm <sup>2</sup> /person/h	0.1589000	199
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm <sup>2</sup> /person/h*	0.07833721	<b>98</b>
<b>Proposal of Re-entry period of 15 days</b> <b>Grapevine</b> Hand harvesting/ Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days <b>DFR: 0.42 µg/cm<sup>2</sup>/kg a.s./ha</b> Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm <sup>2</sup> /person/h	0.2359900	295
	Work wear (arms, body and legs covered) TC: 10100 cm <sup>2</sup> /person/h	0.0794500	<b>99</b>

\*In case of re-entry tasks in grapes the use of a lower than 10100 cm<sup>2</sup>/h TC value considering the use of gloves is considered acceptable. More specifically, as a Tier II the use of a refined TC of 4861 cm<sup>2</sup>/h is accepted considering the distribution of residues XXXXX (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);

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

		Copper oxychloride	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Potato</b> Inspection, irrigation / Outdoor Work rate: 2 hours/day, DT <sub>50</sub> : 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.235990	263
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0235990	<b>30</b>
<b>Solanaceous fruits (Tomato, aubergine)</b> Reaching, picking/Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.3782228	473
	Work wear (arms, body and legs covered) TC: 2500 cm <sup>2</sup> /person/h	0.1630271	204
	Work wear (arms, body and legs covered) and gloves TC: 580 cm <sup>2</sup> /person/h	0.0378223	<b>47</b>

#### **Potato**

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

#### **Solanaceous fruits (Tomato, aubergine)**

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

		<b>Copper oxychloride</b>	
<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg bw/day)</b>	<b>% of systemic AOEL</b>
<b>Pome fruit (apple, pear, quince)</b> Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	1.4672435	1834
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.2934487	367
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.1467243	184
<b>Proposal of Re-entry period of 7 days</b> Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days DFR: 1.51 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	0.7385126	923
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.1477025	185
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.0738513	<b>92</b>
<b>Proposal of Re-entry period of 14 days</b> Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 7 days DFR: 0.75 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	0.3668109	459
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.0733622	<b>92</b>
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.0366811	<b>46</b>

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



Applicant is presenting below refined risk assessment considering dermal absorption values given in position paper.

		Copper oxychloride	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Grapevine</b> Hand harvesting/ Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm <sup>2</sup> /person/h	0.3508393	439
	Work wear (arms, body and legs covered) TC: 10100 cm <sup>2</sup> /person/h	0.1181159	148
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm <sup>2</sup> /person/h*	0.0568477	71
<b>Proposal of Re-entry period of 17 days</b> <b>Grapevine</b> Hand harvesting/ Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 30 days DFR: 2.04 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm <sup>2</sup> /person/h	0.2385707	298
	Work wear (arms, body and legs covered) TC: 10100 cm <sup>2</sup> /person/h	0.0803188	100
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm <sup>2</sup> /person/h*	0.0383821	48

\*In case of re-entry tasks in grapes the use of a lower than 10100 cm<sup>2</sup>/h TC value considering the use of gloves is considered acceptable. More specifically, as a Tier II the use of a refined TC of 4861 cm<sup>2</sup>/h is accepted considering the distribution of residues - XXXXX (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);

		<b>Copper oxychloride</b>	
<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg bw/day)</b>	<b>% of systemic AOEL</b>
<b>Potato</b> Inspection, irrigation / Outdoor Work rate: 2 hours/day, DT <sub>50</sub> : 30 days, DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.0363549	45
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0040718	5
<b>Solanaceous fruits (Tomato, aubergine)</b> Reaching, picking/Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 30 days, DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.0674747	84
	Work wear (arms, body and legs covered) TC: 2500 cm <sup>2</sup> /person/h	0.0290839	36
	Work wear (arms, body and legs covered) and gloves TC: 580 cm <sup>2</sup> /person/h	0.0067475	8
<b>Pome fruit (apple, pear, quince)</b> Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT <sub>50</sub> : 30 days, DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	0.2617554	327
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.0523511	65
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.0261755	33

Considering more realistic and less conservative dermal absorption values given in position paper conclusion on operator risk assessment is as follows:

#### *Grapevine*

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapevine treated with COBRANZA or without gloves when a time period of 17 days after application is respected.

#### *Potato*

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

**Solanaceous fruits (Tomato, aubergine)**

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

**Pome fruit (apple, pear, quince)**

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated Pome fruit (apple, pear, quince) even without suitable protective clothing.

**ACCEPTABLE**

### 6.6.3.2 Refinement of generic DFR value (KCP 7.2)

A proposal to refine the DFR was made during the review of the information submitted by the EUCuTF for the renewal of approval of copper.

A study was conducted to compare two methods of spraying a 20% solution of copper sulphate onto vines (tractor mounted tunnel sprayer or pneumatic nebulizer) at 500 g/ha (xxxxx et al, 2013), see RAR Vol 3 (PPP) B.6.4.1/01. The average leaf deposits were between 3.1 and 9.6 µg/cm<sup>2</sup> equating to a DFR of between 0.6 and 1.9 µg/cm<sup>2</sup>/kg a.s applied.

For the refinement of the worker exposure, the upper value of this range of DFR values was taken, i.e. 1.9 µg/cm<sup>2</sup>/kg a.s. applied.

#### Refinement

##### Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period of 14 days. Therefore we propose to calculate DFR value at 8 and 15 days for grapevine, 7 and 14 for pome fruits.

Body weight 60 kg.

For this calculation DT<sub>50</sub> value of 7 days is considered according to “*RAR of Copper compounds Volume 1, - August 2018*”.

DFR<sub>t</sub> is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k, t}$$

Where:

DFR<sub>T</sub> Dislodgeable foliar residue at the time of re-entry (µg/cm<sup>2</sup>)

DFR<sub>0</sub> Dislodgeable foliar residue just after application (µg/cm<sup>2</sup>)

k Degradation constant (days<sup>-1</sup>), calculated from the half life time:

$$k = \ln(2)/DT_{50},$$

DT<sub>50</sub> Foliar half-life time (days)

t Re-entry interval (days)

Dislodgeable foliar residue just after application is calculated as:

$$DFR_0 = DFR_{def} \times MAF$$

Where:

DFR<sub>def</sub> default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm<sup>2</sup> per kg s.a/ha)

MAF<sub>m</sub> (multiple application factor for mean residue data for *n* application) is:

$$MAF = (1 - e^{-nki}) / (1 - e^{-ki})$$

where:

n is the number of applications

k is the rate constant for foliar dissipation  $k = \ln(2)/DT_{50}$ ,

i is the interval between applications (days)

DFR factor was calculated for every crop based on above formula and according to the EFSA Journal 2014;12(10):3874<sup>1</sup>, corresponding to a half-life <sub>foliar</sub> of 30 days.

**Grapevine:**

For grapevine, a number of 4 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 2.9. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 2.9 = 8.7 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 2.9 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 17 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 8.7 \mu\text{g}/\text{cm}^2 \times 0.680 = 5.92 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 5.92 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 2.04 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

**Grapevine:**

For grapevine, a number of 4 applications (n) and a 7 day interval (i) between applications is considered (worst case scenario) and MAF is 1.9. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.9 = 3.61 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 1.9 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 8 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 3.61 \mu\text{g}/\text{cm}^2 \times 0.371 = 1.34 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 1.34 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 0.84 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Therefore for 15 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 3.61 \mu\text{g}/\text{cm}^2 \times 0.186 = 0.67 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 0.67 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 0.42 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

**Pome fruits:**

For pome fruits, a number of 3 applications (n) and a 10 day interval (i) between applications is considered (worst case scenario) and MAF is 1.50. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.50 = 4.5 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 7 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.5 \mu\text{g}/\text{cm}^2 \times 0.502 = 2.26 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 2.26 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 1.51 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Therefore for 14 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.64 \mu\text{g}/\text{cm}^2 \times 0.200 = 1.13 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 1.13 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 0.75 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

### 6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

<sup>1</sup> Guidance of EFSA (EFSA Journal 2014;12(10):3874): “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products”

## 6.6.4 Resident and bystander exposure (KCP 7.2.2)

### 6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to Copper oxychloride. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in 0.

**Table 6.6-6: Exposure models for intended uses**

Critical uses	Grapevine (max. 4 x 2 L Kg product/ha) Potato (max. 3 x 2.4 L Kg product/ha) Solanaceous fruits (Tomato, aubergine) (max. 3 x 2.4 L Kg product/ha) Pome fruit (apple, pear, quince) (max. 3 x 2.4 L Kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

**Table 6.6-7: Estimated resident exposure (longer term exposure)**

		Copper oxychloride	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Grapevine/</b> Tractor mounted boom spray application outdoors to hight crops Buffer zone: 5 (m) Drift reduction technology: no DT50: 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0157865	19.73
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0021816	2.73
	Re-entry (75 <sup>th</sup> perc.)	0.0284766	35.60
	<b>Sum (mean)</b>	0.0358300	44.79
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0086999	10.87
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0006303	0.79

	Re-entry (75 <sup>th</sup> perc.)	0.0158203	19.78
	<b>Sum (mean)</b>	0.0190138	<b>23.77</b>
<b>Potato, Solanaceous fruits</b> Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT50: 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.00584462	7.31
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0044570	5.57
	Re-entry (75 <sup>th</sup> perc.)	0.0318938	39.87
	<b>Sum (mean)</b>	0.0329921	41.24
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0013914	1.74
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0012877	1.61
	Re-entry (75 <sup>th</sup> perc.)	0.0177188	22.15
	<b>Sum (mean)</b>	0.0159630	<b>19.95</b>
<b>Pome fruit</b> Tractor mounted boom spray application outdoors to high crops Buffer zone: 5(m) Drift reduction technology: no DT50: 7 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0189438	23.68
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0108402	13.55
	Re-entry (75 <sup>th</sup> perc.)	0.0275108	34.39
	<b>Sum (mean)</b>	0.0435180	54.40
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0104399	13.05
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0031319	3.91
	Re-entry (75 <sup>th</sup> perc.)	0.0152838	19.10
	<b>Sum (mean)</b>	0.0215671	<b>26.96</b>

**Estimation of resident/bystander accidental exposure to COBRANZA indicates no unacceptable risk when the product is used as intended.**

Applicant is presenting below refined risk assessment considering dermal absorption values given in position paper.

		Copper oxychloride	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Grapevine/</b> Tractor mounted boom spray application outdoors to hight crops Buffer zone: 5 (m) Drift reduction technology: no DT50: 30 days DFR: 3 µg/cm2/kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0019367	2.42
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0008841	1.11
	Re-entry (75 <sup>th</sup> perc.)	0.0049337	6.17
	Sum (mean)	0.0069760	8.72
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0010055	1.26
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0001092	0.14
	Re-entry (75 <sup>th</sup> perc.)	0.0027409	3.43
	Sum (mean)	0.0031620	3.95
<b>Potato, Solanaceous fruits</b> Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT50: 30 days DFR: 3 µg/cm2/kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0006963	0.87
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0016043	2.01
	Re-entry (75 <sup>th</sup> perc.)	0.0049079	6.13
	Sum (mean)	0.0065528	8.19
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0001582	0.20
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0001982	0.25
	Re-entry (75 <sup>th</sup> perc.)	0.0027266	3.41
	Sum (mean)	0.0026259	3.28
<b>Pome fruit</b> Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 (m) Drift reduction technology: no DT50: 30 days			

DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0023240	2.90
	Vapour (75 <sup>th</sup> perc.)	0.0010700	1.34
	Deposits (75 <sup>th</sup> perc.)	0.0045235	5.65
	Re-entry (75 <sup>th</sup> perc.)	0.0049079	6.13
	Sum (mean)	0.0008897	12.37
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0012067	1.51
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.29
	Deposits (75 <sup>th</sup> perc.)	0.0005587	0.70
	Re-entry (75 <sup>th</sup> perc.)	0.0027266	3.41
	Sum (mean)	0.0036146	4.52

Considering more realistic and less conservative dermal absorption values given in position paper conclusion on operator risk assessment is as follows:  
 No unacceptable risk for bystanders and residents was identified when the product is used as intended.

ACCEPTABLE

#### 6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Copper oxychloride will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

#### 6.6.5 Combined exposure

Not relevant. The product contains only one active substance.



## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

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

The following tables are to be completed by MS

### List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP	Y/N	Owner

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
			Published/Unpublished		

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

The classification of Copper oxychloride 50% WG was performed by calculation. The assessment of all acute toxicological properties of Copper oxychloride 50% WG are derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Copper oxychloride Technical	86.21	299 mg/kg	> 2000 mg/kg	2.83 mg/l	Not Irritating	Not Irritating	Not sensitising <sup>1)</sup>
co-formulant 1	xxx	3800 mg/kg <sup>1)</sup>	> 16000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
co-formulant 2	xxx	> 600 - < 1800 mg/kg	> 2000 mg/kg <sup>1)</sup>	1.09 mg/l	Not Irritating <sup>1)</sup>	Eye Dam.1, H318	Not sensitising <sup>1)</sup>
co-formulant 3	xx	> 4000 mg/kg <sup>1)</sup>	> 2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Eye Irrit.2, H319	Not sensitising <sup>1)</sup>
co-formulant 4	xxx	> 2000 mg/kg <sup>1)</sup>	> 2000 mg/kg <sup>1)</sup>	> 3 mg/l Not classified	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
co-formulant 5	xxx	> 2000 mg/kg <sup>1)</sup>	> 2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>

\* No Information / but in their MSDS are not classified acutely inhalation toxic

<sup>1)</sup> As co-formulant is not classified

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

$$\frac{100}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

where:

C<sub>i</sub> = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p><b>Calculation methodology is acceptable</b></p> <p><b>According to Regulation (EC) No 1272/2008 classification acute oral toxicity of Copper oxychloride 50% WG based on ingredients of the mixture is determined by calculation. ATE<sub>mix</sub> values was estimated to be 346 mg/kg.</b></p> <p><b>Therefore Copper Oxychloride 50% WG is classified as Acute Tox.4 / H302</b></p>
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The acute oral toxicity classification for Copper oxychloride 50% WG was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{86.21\%}{299} + \frac{xxx\%}{600}} = 346 \frac{mg}{kg}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Copper oxychloride 50% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

### Conclusion

The acute oral toxicity of Copper Oxychloride 50% WG was estimated to be 346 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is classified as Acute Toxicity Category 4 (oral) and H302 with pictogram GHS07 and signal word “Warning” is proposed.

### A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<b>Calculation methodology is acceptable</b> <b>According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified</b>
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There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is **not classified**. No signal word or hazard statement is required for this hazard.

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<b>Calculation methodology is acceptable</b> <b>According to Regulation (EC) No 1272/2008 classification acute inhalation toxicity of Copper oxychloride 50% WG based on ingredients of the mixture is determined by calculation. <math>ATE_{mix}</math> values was estimated to be 3.23 mg/l.</b> <b>Therefore Copper Oxychloride 50% WG is classified as Acute Tox.4 / H332</b>
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Acute inhalation toxicity classification for Copper Oxychloride 50% WG was calculated:

$$ATE_{mix} = \frac{100 - (\sum C_{unknown} if > 10\%)}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{86.21}{2.83} + \frac{xxx}{1.09}} = 3.23 \text{ mg/l}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Copper Oxychloride 50% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute inhalation toxicity of Copper Oxychloride 50% WG was estimated to be 3.23 mg/l. Therefore, according to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is classified as Acute Toxicity Category 4 (inhalation) and H332 with pictogram GHS07 and signal word “Warning” is proposed.

#### A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<b>Calculation methodology is acceptable</b> <b>According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified</b>
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There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as skin corrosion or irritation.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Copper Oxychloride 50% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is **not classified**. No signal word or hazard statement is required for this hazard.

#### A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<b>Calculation methodology is acceptable</b> <b>According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified</b>
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The product contains < 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is **not classified**. No signal word or hazard statement is required for this hazard.

#### A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<b>Calculation methodology is acceptable</b> <b>According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified</b>
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There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as skin sensitisation.

According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is **not classified**. No signal word or hazard statement is required for this hazard.

## A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

## A 2.9 Data on co-formulants (KCP 7.4)

### A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

### A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

## A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	<p><b>Acceptable</b> Copper dermal absorption values of 1% and 9% (rounded values), for the concentrate and the field dilution.</p> <p><b>Draft Renewal Assessment Report prepared according to the Commission Regulation (EC) N° 1107/2009 Copper compounds List of studies relied upon, essential for the Renewal and that can attract protection. February 2018</b></p>
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Based on studies from 2015 and 2017 supported by the first study from 2012, experts proposed copper dermal absorption values of 1% and 9% (rounded values), for the concentrate and the field dilution. These dermal absorption values cover all the formulations tested and thus can be applicable for all chemical form of copper and all type of copper formulations. (W.J.M. (2012xxxxx) In vitro dermal absorption OECD 428 , xxxxx, C. (2015) In vitro percutaneous absorption of copper, formulated as Copper hydroxide 50 WP or Copper oxychloride SC, through human and rat skin OECD 428 , xxxxx In vitro percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8 WG (35% as metallic copper), through human skin OECD 428 "Copper compounds RAR 2016" i "Copper RAR revised August 2018")

*For compounds such as copper, that are naturally present, it makes more sense to consider absolute numbers rather than % of applied dose in order to adequately judge the biological/toxicological relevance of the data. Nevertheless, based on a generally accepted triple-pack approach, a dermal absorption value of 0.1 % for the concentrate and 1 % for diluted products containing inorganic copper compounds, is considered adequately worst-case.*

*The fate of test item residues in the skin membranes in in vitro dermal absorption studies; impact on the risk assessment of inorganic copper salts', 21 September 2020, xxxxx MSc is acceptable*

## **A 2.11            Other/Special Studies**

No new additional other/special studies

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for Copper oxychloride

**Table A 1: Input parameters considered for the estimation of operator exposure for grapevine**

Formulation type	WG	Crop type	Grapevine
Application rate (AR)	1 kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	1 % (concentr.)	Indoor/outdoor	Outdoor
	9 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal/Dense
AOEL	0.08 mg/kg bw/d	Water soluble bag	No
AAOEL	0 mg/kg bw/d		

**Table A 2: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for grapevine**

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			gloves	
Specific exposure value	1422,1322987	µg/person	40,3459550	µg/person
Systemic exposure	23,7022050	mg/kg bw/d	0,6724326	mg/kg bw/d
Body			Work wear	
Specific exposure value	4178,7847391	µg/person	82,3720738	µg/person
Systemic exposure	69,6464123	mg/kg bw/d	1,3728679	mg/kg bw/d
Head			FP1, P1 and similar	
Specific exposure value	12,4729735	µg/person	9,9783788	µg/person
Systemic exposure	0,2078829	mg/kg bw/d	0,1663063	mg/kg bw/d
Inhalation			-	
Specific exposure value	4308,4395112	µg/person	1077,1098778	µg/person
Systemic exposure	71,8073252	mg/kg bw/d	17,9518313	mg/kg bw/d
Application				
Hands			gloves	
Specific exposure value	1749,8165081	µg/person	31,6666783	µg/person
Systemic exposure	5,6729128	mg/kg bw/d	0,5277780	mg/kg bw/d
Body			Work wear	
Specific exposure value	7930,5354254	µg/person	103,4695379	µg/person
Systemic exposure	132,1755904	mg/kg bw/d	1,7244923	mg/kg bw/d



<u>Head</u>			-	
Specific exposure value	1042,2034571	µg/person	1042,2034571	µg/person
<b>Systemic exposure</b>	<b>17,3700576</b>	<b>mg/kg bw/d</b>	<b>17,3700576</b>	<b>mg/kg bw/d</b>
<u>Inhalation</u>			-	
Specific exposure value	234,4282794	µg/person	234,4282794	µg/person
<b>Systemic exposure</b>	<b>3,9071380</b>	<b>mg/kg bw/d</b>	<b>3,9071380</b>	<b>mg/kg bw/d</b>
<b>Total</b>				
<b>Total systemic exposure</b>	<b>0,3479802</b>	<b>mg/kg bw/d</b>	<b>0,0436929</b>	<b>mg/kg bw/d</b>
<b>% of AAOEL</b>	<b>434.98</b>	<b>%</b>	<b>54.62</b>	<b>%</b>

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	11,1712103	3,2832569	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1861868	0,0547209	
% of RVNAS	232,73%	68,40%	

**Table A 3: Input parameters considered for the estimation of operator exposure for grapevine**

Substance	Copper oxychloride	Formulation = Wettable granules, soluble granules	Application rate-1 kg a.s. /ha	Spray dilution = 1,25 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes / Outdoor / Upward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 4, Application interval = 10 days
Percentage Absorption	Dermal for product = 1	Dermal for in use dilution = 9	Oral = 100	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	7 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,1343	% of RVNAS	167,85%
	Acute systemic exposure mg/kg bw/day		0,3302	% of RVAAS	412,80%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 4: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for grapevine**

<b>1. Total</b>			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8,0567515	1,2455770	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1342792	0,0207596	
% of RVNAS	167,85%	25,95%	

**Table A 5: Input parameters considered for the estimation of operator exposure for grapevine**

Substance	Copper oxychloride	Formulation = Wettable granules, soluble granules	Application rate-1 kg a.s. /ha	Spray dilution = 1,25 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Grapes / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 4, Application interval = 10 days
Percentage Absorption	Dermal for product = 1	Dermal for in use dilution = 9	Oral = 100	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	7 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0617	% of RVNAS	77,13%
	Acute systemic exposure mg/kg bw/day		0,0937	% of RVAAS	117,13%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 6: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for grapevine**

1. Total			
	Without RPE/PPE		With RPE/PPE
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,7021745		1,6654833
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0617029		0,0277581
% of RVNAS	77,13%		34,70%

**Table A 7: Input parameters considered for the estimation of operator exposure for potato and solanaceous fruit**

Formulation type	WP WG	Crop type	potato, solanaceous fruit
Application rate (AR)	1.2 kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	10 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	1 % (concentr.)	Indoor/outdoor	Outdoor
	9 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal/Dense
AOEL	0.08 mg/kg bw/d	Water soluble bag	No
AAOEL	0 mg/kg bw/d		

**Table A 8: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for potato and solanaceous fruit**

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			gloves	
Specific exposure value	5649,1639249	µg/person	129,5039711	µg/person
Systemic exposure	94,1527321	mg/kg bw/d	2,1583995	mg/kg bw/d
Body			Work wear	

Specific exposure value	14724,3407201	µg/person	403,1901594	µg/person
<b>Systemic exposure</b>	<b>245,4056787</b>	<b>mg/kg bw/d</b>	<b>6,7198360</b>	<b>mg/kg bw/d</b>
<u>Head</u>			FP1, P1 and similar	
Specific exposure value	74,8378411	µg/person	59,8702728	µg/person
<b>Systemic exposure</b>	<b>1,2472974</b>	<b>mg/kg bw/d</b>	<b>0,9978379</b>	<b>mg/kg bw/d</b>
<u>Inhalation</u>			-	
Specific exposure value	7343,4106009	µg/person	1835,8526502	µg/person
<b>Systemic exposure</b>	<b>122,3901767</b>	<b>mg/kg bw/d</b>	<b>30,5975442</b>	<b>mg/kg bw/d</b>
<b>Application</b>				
<u>Hands</u>			gloves	
Specific exposure value	800,9462515	µg/person	35,2352979	µg/person
<b>Systemic exposure</b>	<b>13,3491042</b>	<b>mg/kg bw/d</b>	<b>0,5872550</b>	<b>mg/kg bw/d</b>
<u>Body</u>			Work-wear	
Specific exposure value	447,8364254	µg/person	12,2849088	µg/person
<b>Systemic exposure</b>	<b>7,4639404</b>	<b>mg/kg bw/d</b>	<b>0,2047485</b>	<b>mg/kg bw/d</b>
<u>Head</u>			-	
Specific exposure value	21,1662837	µg/person	21,1662837	µg/person
<b>Systemic exposure</b>	<b>0,3527714</b>	<b>mg/kg bw/d</b>	<b>0,3527714</b>	<b>mg/kg bw/d</b>
<u>Inhalation</u>			-	
Specific exposure value	8,0546219	µg/person	8,0546219	µg/person
<b>Systemic exposure</b>	<b>0,1342437</b>	<b>mg/kg bw/d</b>	<b>0,1342437</b>	<b>mg/kg bw/d</b>
<b>Total</b>				
<b>Total systemic exposure</b>	<b>0,4844959</b>	<b>mg/kg bw/d</b>	<b>0,0417526</b>	<b>mg/kg bw/d</b>
<b>% of AAOEL</b>	<b>605.62</b>	<b>%</b>	<b>52.19</b>	<b>%</b>

<b>1. Total</b>			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,9342926	1,2861611	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0322382	0,0214360	
% of RVNAS	40,30%	26,80%	

**Table A 9: Input parameters considered for the estimation of operator exposure for potato and solanaceous fruit**

Substance	Copper oxychloride	Formulation = Wettable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 2,4 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Fruiting vegetables / Outdoor / Downward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 1	Dermal for in use dilution = 9	Oral = 100	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	7 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,4378	% of RVNAS	547,21%
	Acute systemic exposure mg/kg bw/day		0,6920	% of RVAAS	864,96%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 10: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for potato and solanaceous fruit**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	26,2662360	3,1998619	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,4377706	0,0533310	
% of RVNAS	547,21%	66,66%	

**Table A 11: Input parameters considered for the estimation of operator exposure for pome fruit**

Formulation type	WP <b>WG</b>	Crop type	Pome fruits
Application rate (AR)	1.2 kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	1 % (concentr.)	Indoor/outdoor	Outdoor
	9 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal/Dense
AOEL	0.08 mg/kg bw/d	Water soluble bag	No
AAOEL	0 mg/kg bw/d		

**Table A 12: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for pome fruit**

	Potential	With work wear + PPE/RPE
<b>Mixing and loading</b>		
Hands		gloves

Specific exposure value	1636,4249735	µg/person	45,4294511	µg/person
<b>Systemic exposure</b>	<b>27,2737496</b>	<b>mg/kg bw/d</b>	<b>0,7571575</b>	<b>mg/kg bw/d</b>
<u>Body</u>			Work wear	
Specific exposure value	4750,1669458	µg/person	96,8197331	µg/person
<b>Systemic exposure</b>	<b>79,1694491</b>	<b>mg/kg bw/d</b>	<b>1,6136622</b>	<b>mg/kg bw/d</b>
<u>Head</u>			FP1, P1 and similar	
Specific exposure value	14,9675682	µg/person	11,9740546	µg/person
<b>Systemic exposure</b>	<b>0,2494595</b>	<b>mg/kg bw/d</b>	<b>0,1995676</b>	<b>mg/kg bw/d</b>
<u>Inhalation</u>			-	
Specific exposure value	4548,6690400	µg/person	1137,1672600	µg/person
<b>Systemic exposure</b>	<b>75,8111507</b>	<b>mg/kg bw/d</b>	<b>18,9527877</b>	<b>mg/kg bw/d</b>
<b>Application</b>				
<u>Hands</u>			gloves	
Specific exposure value	2056,8757737	µg/person	38,0000139	µg/person
<b>Systemic exposure</b>	<b>34,2812629</b>	<b>mg/kg bw/d</b>	<b>0,6333336</b>	<b>mg/kg bw/d</b>
<u>Body</u>			Work wear	
Specific exposure value	9516,6425104	µg/person	124,1634455	µg/person
<b>Systemic exposure</b>	<b>158,6107085</b>	<b>mg/kg bw/d</b>	<b>2,0693908</b>	<b>mg/kg bw/d</b>
<u>Head</u>			-	
Specific exposure value	1250,6441485	µg/person	1250,6441485	µg/person
<b>Systemic exposure</b>	<b>20,8440691</b>	<b>mg/kg bw/d</b>	<b>20,8440691</b>	<b>mg/kg bw/d</b>
<u>Inhalation</u>			-	
Specific exposure value	259,8718758	µg/person	259,8718758	µg/person
<b>Systemic exposure</b>	<b>4,3311979</b>	<b>mg/kg bw/d</b>	<b>4,3311979</b>	<b>mg/kg bw/d</b>
<b>Total</b>				
<b>Total systemic exposure</b>	<b>0,4005710</b>	<b>mg/kg bw/d</b>	<b>0,0494012</b>	<b>mg/kg bw/d</b>
<b>% of AAOEL</b>	<b>500.71</b>	<b>%</b>	<b>61.75</b>	<b>%</b>

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	13,3226706	3,8610340	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2220445	0,0643506	
% of RVNAS	277,56%	80,44%	

**Table A 13: Input parameters considered for the estimation of operator exposure for pome fruit**

Substance	Copper oxychloride	Formulation = Wetable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 1,5 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 1	Dermal for in use dilution = 9	Oral = 100	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	7 days	
Operator Model					
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,1407	% of RVNAS	175,85%
	Acute systemic exposure mg/kg bw/day		0,3380	% of RVAAS	422,55%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 14: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for pome fruit**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8,4406962	1,4262257	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1406783	0,0237704	
% of RVNAS	175,85%	29,71%	

**Table A 15: Input parameters considered for the estimation of operator exposure Grapevine downward application**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1 kg a.s. /ha	Spray dilution = 1,25 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 4, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0082	% of RVNAS	10,22%
	Acute systemic exposure mg/kg bw/day		0,0166	% of RVAAS	20,74%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 16: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Grapevine downward application**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4906351	0,2650126	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0081773	0,0044169	
% of RVNAS	10,22%	5,52%	

**Table A 17: Input parameters considered for the estimation of operator exposure Grapevine manual- hand held application**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1 kg a.s. /ha	Spray dilution = 1,25 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes / Outdoor / Upward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use diluation = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0195	% of RVNAS	24,40%
	Acute systemic exposure mg/kg bw/day		0,0468	% of RVAAS	58,46%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 18: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Grapevine manual- hand held application**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,1713779	0,4149373	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0195230	0,0069156	
% of RVNAS	24,40%	8,64%	

**Table A 19: Input parameters considered for the estimation of operator exposure Grapevine upward application**



Substance	Copper oxychloride	Formulation = Wettable granules, soluble granules	Application rate-1 kg a.s. /ha	Spray dilution = 1,25 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0252	% of RVNAS	31,54%
	Acute systemic exposure mg/kg bw/day		0,1274	% of RVAAS	159,31%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 20: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Grapevine upward application**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,5139317	0,6381689	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0252322	0,0106361	
% of RVNAS	31,54%	13,30%	

**Table A 21: Input parameters considered for the estimation of operator exposure for Potato and solanaceous fruits**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 2,4 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Fruiting vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0055	% of RVNAS	6,84%
	Acute systemic exposure mg/kg bw/day		0,0208	% of RVAAS	26,04%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 22: Estimation of longer term operator exposure towards Copper oxychloride ac-**

### According to EFSA guidance for Potato and solanaceous fruits

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3284497	0,2587971	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0054742	0,0043133	
% of RVNAS	6,84%	5,39%	

**Table A 23: Input parameters considered for the estimation of operator exposure for Solanaceous fruits manual-hand held applications**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 2,4 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Fruiting vegetables / Outdoor / Downward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0507	% of RVNAS	63,43%
	Acute systemic exposure mg/kg bw/day		0,0820	% of RVAAS	102,53%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 24: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Solanaceous fruits manual-hand held applications**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,0444610	0,4819356	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0507410	0,0080323	
% of RVNAS	63,43%	10,04%	

**Table A 25: Input parameters considered for the estimation of operator exposure for Pome fruits upward applications**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 1,5 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0297	% of RVNAS	37,06%
	Acute systemic exposure mg/kg bw/day		0,1519	% of RVAAS	189,92%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 26: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Pome fruits upward applications**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,7790464	0,7285218	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0296508	0,0121420	
% of RVNAS	37,06%	15,18%	

**Table A 27: Input parameters considered for the estimation of operator exposure for Pome fruits manual hand-held applications**

Substance	Copper oxychloride	Formulation = Wetttable granules, soluble granules	Application rate-1,2 kg a.s. /ha	Spray dilution = 1,5 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Manual-Hand held			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 0,1	Dermal for in use dilution = 1	Oral = 50	Inhalation = 100	
RVNAS	0,08 mg/kg bw/day		RVAAS	0,08 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0209	% of RVNAS	26,12%
	Acute systemic exposure mg/kg bw/day		0,0484	% of RVAAS	60,44%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 28: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for Pome fruits manual hand-held applications**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,2538185	0,4748379	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0208970	0,0079140	
% of RVNAS	26,12%	9,89%	

## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for Copper oxychloride e with EFSA model

**Table A 29: Input parameters considered for the estimation of worker exposure for grapevine**

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	1.9	µg/cm²/kg a.s./ha
Application rate (AR)	1	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	4		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	30000	cm²/h
Multiple application factor (MAF)	1.6		TC dermal (work wear)	10100	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	4861	cm²/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

**Table A 30: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine**

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	1,0675740	mg/kg bw/d	0,3594166	mg/kg bw/d	0,172982576	mg/kg bw/d
AOEL	1334,47	%	449.27	%	216	%

**Table A 31: Input parameters considered for the estimation of worker exposure for re-entry period of 8 days**

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	0.84	µg/cm²/kg a.s./ha
Application rate (AR)	1	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	4		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	30000	cm²/h
Multiple application factor (MAF)	1.6		TC dermal (work wear)	10100	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	4861	cm²/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>

**Table A 32: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 8 days**

**Table A 32: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 8 days**

**Table A 33: Input parameters considered for the estimation of worker exposure for re-entry period of 15 days**

**Table A 33: Input parameters considered for the estimation of worker exposure for re-entry period of 15 days**

**Table A 34: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days**

**Table A 34: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days**

**Table A 35: Input parameters considered for the estimation of worker exposure for potato**

**Table A 35: Input parameters considered for the estimation of worker exposure for potato**

**Table A 36: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for potato**

**Table A 36: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for potato**

	Potential	With work wear	With work wear and gloves
Worker (re-entry): Dermal exposure after application			
(DFR x TC x WR x AR x MAF x DA) / BW			

	Potential		With work wear		With work wear and gloves	
Systemic exposure	0,2107054	mg/kg bw/d	0,0235990	mg/kg bw/d	-	mg/kg bw/d
AOEL	263.38	%	29.50	%	-	%

**Table A 37: Input parameters considered for the estimation of worker exposure for solanaceous fruits**

Intended use(s)	solanaceous fruits		Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	1.2	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	5800	cm <sup>2</sup> /h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	2500	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm <sup>2</sup> /h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

**Table A 38: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for solanaceous fruits**

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0,3782228	mg/kg bw/d	0,1630271	mg/kg bw/d	0,0378223	mg/kg bw/d
AOEL	472.78	%	203.78	%	47.28	%

**Table A 39: Input parameters considered for the estimation of worker exposure for pome fruit**

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	1.2	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	22500	cm <sup>2</sup> /h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	4500	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm <sup>2</sup> /h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

**Table A 40: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for pome fruit**

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	1,4672435	mg/kg bw/d	0,2934487	mg/kg bw/d	0,1467243	mg/kg bw/d
AOEL	1834.05	%	366.81	%	183.41	%

**Table A 41: Input parameters considered for the estimation of worker exposure for re-entry period of 7 days**

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	1.51	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	1.2	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	22500	cm <sup>2</sup> /h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	4500	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm <sup>2</sup> /h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

**Table A 42: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 7 days**

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0,7385126	mg/kg bw/d	0,1477025	mg/kg bw/d	0,0738513	mg/kg bw/d
AOEL	923.14	%	184.63	%	92.31	%

**Table A 43: Input parameters considered for the estimation of worker exposure for re-entry period of 15 days**

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	0.75	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	1.2	kg a.s./ha	Dermal absorption (DA)	9	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	22500	cm <sup>2</sup> /h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	4500	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm <sup>2</sup> /h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

**Table A 44: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days**

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0,3668109	mg/kg bw/d	0,0733622	mg/kg bw/d	0,0366811	mg/kg bw/d
AOEL	458.51	%	91.70	%	45.85	%

**Table A 45: Input parameters considered for the estimation of worker exposure for grapevine**

Worker exposure from residues on foliage for	
Crop type	Grapes
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Hand harvesting
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1 kg a.s./ha
Number of applications	4
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,9
Dermal absorption of the product	0,10%
Dermal absorption of the in-use dilution	1,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	30000 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	10100 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	4861 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 46: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	21,0503596	7,0869544	3,4108599
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3508393	0,1181159	0,0568477
% of RVNAS	438,55%	147,64%	71,06%

**Table A 47: Input parameters considered for the estimation of worker exposure for grapevine re-entry period of 17 days**

Worker exposure from residues on foliage for	
Crop type	Grapes
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Hand harvesting
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1 kg a.s./ha
Number of applications	4
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,9
Dermal absorption of the product	0,10%
Dermal absorption of the in-use dilution	1,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	2,04 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	30000 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	10100 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 48: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine re-entry period of 17 days**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	14,3142445	4,8191290	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2385707	0,0803188	
% of RVNAS	298,21%	100,40%	



**Table A 49: Input parameters considered for the estimation of worker exposure for potato**

Worker exposure from residues on foliage for	
Crop type	Root and tuber vegetables
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Inspection, irrigation
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1,2 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	0,10%
Dermal absorption of the in-use dilution	1,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6 µg a.s./cm <sup>2</sup>
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 50: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for potato**

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	2,1812949	0,2443050	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0363549	0,0040718	
% of RVNAS	45,44%	5,09%	

**Table A 51: Input parameters considered for the estimation of worker exposure for solanaceous fruits**

Worker exposure from residues on foliage for	
Crop type	Fruiting vegetables
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1,2 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	0,10%
Dermal absorption of the in-use dilution	1,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 52: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for solanaceous fruits**

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	4,0484834	1,7450360	0,4048483
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0674747	0,0290839	0,0067475
% of RVNAS	84,34%	36,35%	8,43%

**Table A 53: Input parameters considered for the estimation of worker exposure for pome fruits**

Worker exposure from residues on foliage for	
Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1,2 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	0,10%
Dermal absorption of the in-use dilution	1,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 54: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for pome fruits**

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	15,7053236	3,1410647	1,5705324
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2617554	0,0523511	0,0261755
% of RVNAS	327,19%	65,44%	32,72%

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Copper oxychloride

**Table A 55: Input parameters considered for the estimation of longer term resident exposure for grapevine**

Intended use(s)	grapevine		Drift reduction (DR)		%
Application rate (AR)	1	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm <sup>2</sup> /h (adult)
				2600	cm <sup>2</sup> /h (child)
Minimum water volume	800	L/ha	Drift on surface (D) - 75 <sup>th</sup> perc.	3.07	%

(V)					
Buffer strip	5	m	Drift on surface (D) - mean	2.32	%
Number of applications (NA)	4		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H <sub>D</sub> )	2	h
Half-life of active substance	7	days	Exposure duration inhal. (H <sub>I</sub> )	24	h
Multiple application factor (MAF)	1.88		Exposure duration entry into treated crops (H <sub>E</sub> )	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m <sup>3</sup>
	10	kg/person (children)			
Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.08	mg/kg bw/d	Surface Area of Hands (SA)	20	cm <sup>2</sup>
Spray drift dermal (SD) - 75 <sup>th</sup> perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	9.5	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 <sup>th</sup> perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR <sub>OM</sub> )	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm <sup>2</sup> /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 <sup>th</sup> perc.	7500	cm <sup>2</sup> /h (adult)
	0.00133	mL spray dilution (child)		2250	cm <sup>2</sup> /h (child)
Inhalation rate (IR)	0.23	m <sup>3</sup> /d (adult)	TC entry into treated crops - mean:	5980	cm <sup>2</sup> /h (adult)
	1.07	m <sup>3</sup> /d (child)		1794	cm <sup>2</sup> /h (child)

**Table A 56: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for grapevine**

Child			Adult		
Spray drift (75 <sup>th</sup> perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0,0157865	mg/kg bw/d	Systemic exposure	0.00234303	mg/kg bw/d
% of AOEL:	19.73	%	% of AOEL:	10.87	%
Vapour (75 <sup>th</sup> perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0,0010700	mg/kg bw/d	Systemic exposure	0,0002300	mg/kg bw/d
% of AOEL:	1.34	%	% of AOEL:	0.29	%
Surface deposits (75 <sup>th</sup> perc.)					

<b>Dermal</b>					
AR x MAF x D x TTR x TC x H <sub>D</sub> x DA / BW					
Systemic exposure	0,0013470	mg/kg bw/d	Systemic exposure	0,0006303	mg/kg bw/d
<b>Hand to mouth</b>					
AR x MAF x D x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
	0,0005468		Systemic exposure		mg/kg bw/d
<b>Object to mouth</b>					
AR x MAF x D x DR <sub>OM</sub> x IgR x OA / BW					
	0,0002878		Systemic exposure		mg/kg bw/d
<b>Total</b>					
Systemic exposure	0,0021816	mg/kg bw/d	Systemic exposure	0,0006303	mg/kg bw/d
% of AOEL:	2.73	%	% of AOEL:	0.79	%
Entry into treated crops (75 <sup>th</sup> perc.)					
<b>Dermal</b>					
AR x MAF x TC x H <sub>D</sub> x DFR x DA / BW					
Systemic exposure	0,0284766	mg/kg bw/d	Systemic exposure	0,0158203	mg/kg bw/d
<b>Hand to mouth</b>					
AR x MAF x 100% x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
			Systemic exposure		mg/kg bw/d
<b>Object to mouth</b>					
AR x MAF x 100% x DR <sub>OM</sub> x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<b>Total</b>					
Systemic exposure	0,0284766	mg/kg bw/d	Systemic exposure	0,0158203	mg/kg bw/d
% of AOEL:	35.60	%	% of AOEL:	19.78	%
All pathways (mean)					
Systemic exposure	0,0358300	mg/kg bw/d	Systemic exposure	0,0190138	mg/kg bw/d
% of AOEL:	44.79	%	% of AOEL:	23.77	%

**Table A 57: Input parameters considered for the estimation of longer term resident exposure for potato and solanaceous fruits**

Intended use(s)	potato and solanaceous fruits		Drift reduction (DR)		%
Application rate (AR)	1.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm <sup>2</sup> /h (adult)
				2600	cm <sup>2</sup> /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 <sup>th</sup> perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H <sub>D</sub> )	2	h
Half-life of active substance	7	days	Exposure duration inhal. (H <sub>I</sub> )	24	h
Multiple application factor (MAF)	1.8		Exposure duration entry into treated crops (H <sub>E</sub> )	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m <sup>3</sup>
	10	kg/person (children)			

Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.08	mg/kg bw/d	Surface Area of Hands (SA)	20	cm <sup>2</sup>
Spray drift dermal (SD) - 75 <sup>th</sup> perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	9.5	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 <sup>th</sup> perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR <sub>OM</sub> )	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm <sup>2</sup> /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 <sup>th</sup> perc.	7500	cm <sup>2</sup> /h (adult)
	0.00017	mL spray dilution (child)		2250	cm <sup>2</sup> /h (child)
Inhalation rate (IR)	0.23	m <sup>3</sup> /d (adult)	TC entry into treated crops - mean:	5980	cm <sup>2</sup> /h (adult)
	1.07	m <sup>3</sup> /d (child)		1794	cm <sup>2</sup> /h (child)

**Table A 58: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for potato and solanaceous fruits**

Child		Adult			
Spray drift (75 <sup>th</sup> perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0,0058446	mg/kg bw/d	Systemic exposure	0,0013914	mg/kg bw/d
% of AOEL:	7.31	%	% of AOEL:	1.74	%
Vapour (75 <sup>th</sup> perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0,0010700	mg/kg bw/d	Systemic exposure	0,0002300	mg/kg bw/d
% of AOEL:	1.34	%	% of AOEL:	0.29	%
Surface deposits (75 <sup>th</sup> perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H <sub>D</sub> x DA / BW					
Systemic exposure	0,0027518	mg/kg bw/d	Systemic exposure	0,0012877	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
	0,0011172		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR <sub>OM</sub> x IgR x OA / BW					
	0,0005880		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0,0044570	mg/kg bw/d	Systemic exposure	0,0012877	mg/kg bw/d
% of AOEL:	5.57	%	% of AOEL:	1.61	%

Entry into treated crops (75 <sup>th</sup> perc.)					
<b>Dermal</b>					
AR x MAF x TC x H <sub>D</sub> x DFR x DA / BW					
Systemic exposure	0,0318938	mg/kg bw/d	Systemic exposure	0,0177188	mg/kg bw/d
<b>Hand to mouth</b>					
AR x MAF x 100% x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
			Systemic exposure		mg/kg bw/d
<b>Object to mouth</b>					
AR x MAF x 100% x DR <sub>OM</sub> x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<b>Total</b>					
Systemic exposure	0,0318938	mg/kg bw/d	Systemic exposure	0,0177188	mg/kg bw/d
% of AOEL:	39.87	%	% of AOEL:	22.15	%
<b>All pathways (mean)</b>					
Systemic exposure	0,0329921	mg/kg bw/d	Systemic exposure	0,0159630	mg/kg bw/d
% of AOEL:	41.24	%	% of AOEL:	19.95	%

**Table A 59: Input parameters considered for the estimation of longer term resident exposure for pome fruit**

Intended use(s)	Ppme fruits		Drift reduction (DR)		%
Application rate (AR)	1.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm <sup>2</sup> /h (adult)
				2600	cm <sup>2</sup> /h (child)
Minimum water volume (V)	800	L/ha	Drift on surface (D) - 75 <sup>th</sup> perc.	15.79	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H <sub>D</sub> )	2	h
Half-life of active substance	7	days	Exposure duration inhal. (H <sub>I</sub> )	24	h
Multiple application factor (MAF)	1.50		Exposure duration entry into treated crops (H <sub>E</sub> )	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m <sup>3</sup>
	10	kg/person (children)			
Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.08	mg/kg bw/d	Surface Area of Hands (SA)	20	cm <sup>2</sup>
Spray drift dermal (SD) - 75 <sup>th</sup> perc.	5..3	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	9.5	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 <sup>th</sup> perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR <sub>OM</sub> )	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm <sup>2</sup> /d
	1.11	mL spray dilution (child)			

Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 <sup>th</sup> perc.	7500	cm <sup>2</sup> /h (adult)
	0.00133	mL spray dilution (child)		2250	cm <sup>2</sup> /h (child)
Inhalation rate (IR)	0.23	m <sup>3</sup> /d (adult)	TC entry into treated crops - mean:	5980	cm <sup>2</sup> /h (adult)
	1.07	m <sup>3</sup> /d (child)		1794	cm <sup>2</sup> /h (child)

**Table A 60: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for pome fruit**

Child		Adult			
Spray drift (75 <sup>th</sup> perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0,0189438	mg/kg bw/d	Systemic exposure	0,0104399	mg/kg bw/d
% of AOEL:	23.68	%	% of AOEL:	13.05	%
Vapour (75 <sup>th</sup> perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0,0010700	mg/kg bw/d	Systemic exposure	0,0002300	mg/kg bw/d
% of AOEL:	1.34	%	% of AOEL:	0.29	%
Surface deposits (75 <sup>th</sup> perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H <sub>D</sub> x DA / BW					
Systemic exposure	0,0066929	mg/kg bw/d	Systemic exposure	0,0023187	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
	0,0027172		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR <sub>OM</sub> x IgR x OA / BW					
	0,0014301		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0,0108402	mg/kg bw/d	Systemic exposure	0,0031319	mg/kg bw/d
% of AOEL:	13.55	%	% of AOEL:	3.91	%
Entry into treated crops (75 <sup>th</sup> perc.)					
<u>Dermal</u>					
AR x MAF x TC x H <sub>D</sub> x DFR x DA / BW					
Systemic exposure	0,0275108	mg/kg bw/d	Systemic exposure	0,0121863	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR <sub>OM</sub> x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0,0275108	mg/kg bw/d	Systemic exposure	0,0152838	mg/kg bw/d
% of AOEL:	34.39	%	% of AOEL:	19.10	%

All pathways (mean)					
Systemic exposure	0,0435180		mg/kg bw/d	Systemic exposure	0,0215671
% of AOEL:	54.40	%	% of AOEL:	26.96	%

**Table A 61: Input parameters considered for the estimation of longer term resident exposure for grapevine**

Resident exposure for	
Croptype	Grapes
Application method	Upward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	5 m
Application rate of the product	1 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,25 g a.s./l
Dermal absorption of product	0,10%
Dermal absorption of in-use dilution	1,00%
Oral absorption	50,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	3 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa Pa
Concentration in air	0,001 mg/m <sup>3</sup>
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0,25 hours
Light clothing adjustment factor	18,0%
Breathing rate adult	0,23 m <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg
Drift percentage on surface (75th percentile)	3,07%
Drift percentage on surface (mean)	2,32%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h



**Table A 62: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for grapevine**

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0193666	0,0107000	0,0088410	0,0493368	0,0697596
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019367	0,0010700	0,0008841	0,0049337	0,0069760
% of RVNAS	2,42%	1,34%	1,11%	6,17%	8,72%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0603325	0,0138000	0,0065522	0,1644559	0,1897227
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0010055	0,0002300	0,0001092	0,0027409	0,0031620
% of RVNAS	1,26%	0,29%	0,14%	3,43%	3,95%

**Table A 63: Input parameters considered for the estimation of longer term resident exposure for potato, solanaceous fruits**

Resident exposure for			
Croptype	Fruiting vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Formulation type	Wettable granules, soluble granules		
Buffer strip	2-3 m		
Application rate of the product	1,2 kg a.s./ha		
Concentration of active substance (in-use dilution for liquid applications)	2,4 g a.s./l		
Dermal absorption of product	0,10%		
Dermal absorption of in-use dilution	1,00%		
Oral absorption	50,00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6 µg a.s./cm <sup>2</sup>		
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa		
Concentration in air	0,001 mg/m <sup>3</sup>		
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person		
Exposure duration dermal	2 hours		
Exposure duration inhalation	24 hours		
Exposure duration entry into treated crops	0,25 hours		
Light clothing adjustment factor	18,0%		
Breathing rate adult	0,23 m <sup>3</sup> /day/kg		
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg		
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour		
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour		
Saliva extraction percentage	50,00%		
Surface area of hands mouthed	20 cm <sup>2</sup>		
Frequency of hand to mouth activity	9,5 events/hour		
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>		
Dislodgeable residues percentage transferability for object to mouth	20,00%		
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h		
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h		
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h		
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h		

**Table A 64: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for potato, solanaceous fruits**

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0069634	0,0107000	0,0160427	0,0490791	0,0655284
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006963	0,0010700	0,0016043	0,0049079	0,0065528
% of RVNAS	0,87%	1,34%	2,01%	6,13%	8,19%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0094896	0,0138000	0,0118895	0,1635971	0,1575544
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0001582	0,0002300	0,0001982	0,0027266	0,0026259
% of RVNAS	0,20%	0,29%	0,25%	3,41%	3,28%

**Table A 65: Input parameters considered for the estimation of longer term resident exposure for pome fruits**

Resident exposure for	
Croptype	Pome fruit
Application method	Upward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	5 m
Application rate of the product	1,2 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,5 g a.s./l
Dermal absorption of product	0,10%
Dermal absorption of in-use dilution	1,00%
Oral absorption	50,00%
Dislodgeable foliar residue (I_AppRate*I_DFR)	3,6 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Concentration in air	0,001 mg/m <sup>3</sup>
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0,25 hours
Light clothing adjustment factor	18,0%
Breathing rate adult	0,23 m <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg
Drift percentage on surface (75th percentile)	15,79%
Drift percentage on surface (mean)	11,69%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 66: Estimation of longer term resident exposure towards Copper oxychloride according to EFSA guidance for pome fruits**

<b>1.1 1-3 year old child</b>					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0232399	0,0107000	0,0452347	0,0490791	0,0989702
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0023240	0,0010700	0,0045235	0,0049079	0,0098970
% of RVNAS	2,90%	1,34%	5,65%	6,13%	12,37%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0723990	0,0138000	0,0335242	0,1635971	0,2168748
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0012067	0,0002300	0,0005587	0,0027266	0,0036146
% of RVNAS	1,51%	0,29%	0,70%	3,41%	4,52%

#### Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)