FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 9100 A

Product name: HYCOP

Chemical active substance:

Copper hydroxide, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2019

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Version history

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

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on HYCOP *

Product name and code	SHA 9100 A / HYCOP
Formulation type	Wettable powder [Code: WP]
Active substance(s) (incl. content)	Copper hydroxide; 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 HYCOP 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 HYCOP according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4; Eye Dam. 1, Acute Tox. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS05, GHS06
Signal word	Danger
Hazard statement(s)	H302, H318, H330
Precautionary statement(s)	P260, P273, P280, P284,P301+P312, P304+P340, P305+P351+P338, P310, P391, P403+P233, 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 HYCOP

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L - upward spraying to grapevine, pome fruits and manual-Hand held Solanaceous fruits Work wear (arms, body and legs covered) at M/L and A + gloves M/L - manual-Hand held (grapevine) Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A - downward spraying to grapevine and manual-Hand held pome fruits

	Result	PPE / Risk mitigation measures
		Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A - upward spraying to grapevine Work wear (arms, body and legs covered) at M/L and A - manual-Hand held (grapevine, Solanaceous fruits and pome fruits), downward spraying to grapevine Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L - upward spraying to pome fruits, potato and solanaceous fruits
Workers	Acceptable	Grapevine - Work wear (arms, body and legs covered) and gloves- time period of 10 days after application Work wear (arms, body and legs covered) - time period of 17 days after application Potato - Work wear (arms, body and legs covered) Solanaceous fruits - Work wear (arms, body and legs covered) and gloves Pome fruits - Work wear (arms, body and legs covered) and gloves- time period of 7 days after application Work wear (arms, body and legs covered) - time period of 14 days after application Grapevine - Work wear (arms, body and legs covered) and gloves Grapevine - Work wear (arms, body and legs covered) - time period of 21 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 situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique ***)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application 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(7)	1	800-1000	21					
2	Potato BBCH 15-85	F	Foliar Spray LCTM	3(7)	1.2	500-1000	14					
3	Solanaceous fruits (Tomato, aubergine) BBCH 15-85	F	Foliar Spray LCTM HCHH	3(7)	1.2	500-1000	3					

1	2	3	4	5	6	7	8	9	10
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 hydroxide
Common Name	Copper hydroxide
CAS-No.	20427-59-2
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	
Additional C&L proposal	-
AOEL systemic	0.08 mg/kg bw/d
Reference	SANTE/10506/2018 Rev. 5 27 November 2018 Efsa Journal .2018,16 (1): 5152
According to Review report for Copper hydroxide (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 HYCOP are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants, HYCOP is predicted toxicity for in respect to acute oral, acute inhalation and eye damage. The applicant has therefore proposed: HYCOP is classified as irritating to acute tox with hazard statements H302, H330 and eyes with hazard statement H318.

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

	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 hydroxide (50% (w/w))	H302, H318, H330***	Reg. 1272/2008	H302, H318, H330
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
*** **Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009**

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 HYCOP are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Copper hydroxide 50% WP

	Copper hydroxide	
	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, Wilfred XXX, MSc.
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, Wilfred XXX, MSc.

6.5.1 Justification for proposed values - Copper hydroxide

The proposed dermal absorption rates for copper are based on dermal absorption studies on a formulation containing copper hydroxide.
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 (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 hydroxide in HYCOP

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*
In vitro (human)	0.4%	9% (0.3g Cu/L)	• DPX-GFJ52 (Copper hydroxide 53.8WG)	Yes	Yes (see Appendix A 2.9)	Justification accepted. Endpoint can be used for current product	XXX, 2017*
In vitro (human)	0.6% 0.1%	8.9% 3.5%	• Copper hydroxide 50 WP. • Flowbrix	Yes	Yes (see Appendix A 2.9)	Justification accepted. Endpoint can be used for current product	XXX, 2015*
In vitro (human)	0.09%	5.68% (1.5 g/L)	• Copper hydroxide 250 g Cu/L, SC. • Copper hydroxide 50 WP • H1B10 Copper hydroxide 25% WG • Copper Oxychloride 37.5 NC WG • Flowbrix • Bordeaux mixture 20% Cu WP • BBC/Bouillie Bordelaise	Yes	Yes (see Appendix A 2.9)	Justification accepted. Endpoint can be used for current product.	XXX, 2012*

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*
			• Nordox 75 WG				

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 hydroxide 50% WP
Formulation type	WP
Category	Fungicide
Active substance(s) (incl. content)	**Copper hydroxide** 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%

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 HYCOP 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 hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
~~Tractor mounted boom spray application outdoors to low crops~~ **~~(grapevine)~~** Vehicle mounted, upward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.3479802	435
	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	**55**
Manual-Hand held, upward spraying outdoor to **grapes**			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.2351874	294
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L	0.0749013	**94**
Vehicle mounted, downward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.2234963	**279**
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and	0.0750719	**94**

	similar M/L		
Tractor mounted boom spray application outdoors to low crops **(potato, solanaceous fruit)**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.4844959	606
	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	**52**
Manual-Hand held, downward spraying outdoor to **solanaceous fruit**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.5482851	685
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0598452	**75**
Tractor mounted boom spray application outdoors to high crops **(pome fruit)**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.4005710	501
	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	**62**
Manual-Hand held, upward spraying outdoor to **pome fruit**			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.2511927	314
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A	0.0659990	**83**

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

According to the AOEM model for manual application, it can be concluded that the risk for the operator using HYCOP is acceptable for solanaceous fruit with the use 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

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

		Copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Vehicle mounted, upward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.1049267	131
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A	0.0781200	**98**
Manual-Hand held, upward spraying outdoor to **grapes**			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.0779698	97
	Work wear (arms, body and legs covered) at M/L and A	0.0618195	**77**
Vehicle mounted, downward spraying outdoor to grapes			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.0878718	110
	Work wear (arms, body and legs covered) at M/L and A	0.0773855	**97**
Tractor mounted boom spray application outdoors to low crops **(potato, solanaceous fruit)**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.1589567	199
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0318466	**40**
Manual-Hand held, downward spraying outdoor to **solanaceous fruit**			
Application rate		1.2 kg a.s./ha	
Spray application	Without RPE/PPE	0.1128447	141

(AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) at M/L and A	0.0661108	**83**
Tractor mounted boom spray application outdoors to high crops **(pome fruit)**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.1145601	143
	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L	0.0261573	**33**
Manual-Hand held, upward spraying outdoor to **pome fruit**			
Application rate		1.2 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Without RPE/PPE	0.0830007	104
	Work wear (arms, body and legs covered) at M/L and A	0.0659925	**82**

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 HYCOP is acceptable for grapes with the use standard working clothing (long sleeved shirt and trousers) during mixing/loading and application.
According to the AOEM model, calculations, it can be concluded that the risk for the operator using HYCOP is acceptable for vegetables and pome fruits with the use standard working clothing (long sleeved shirt and trousers) during mixing/loading and application and with the use FP1, P1 or similar mixing/loading.
According to the AOEM model for manual application, it can be concluded that the risk for the operator using HYCOP is acceptable for grapes, solanaceous fruit 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:
P280: Wear protective gloves, face protection

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 men-tioned 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 Copper hydroxide 50% WP according to the critical uses. Outcome of the estimation is presented in (longer term exposure). Detailed calculations are in 0.

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

		Copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 1.9 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	1.2825000	1603
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.4317750	540
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm2/person/h*	0.2078078	260
Proposal of Re-entry period of 10 days **Grapevine** Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 0.69 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	0.4657500	582
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.1568025	196
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm2/person/h*	0.0772003	**97**

Proposal of Re-entry period of 17 days **Grapevine** Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 0.35 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	0.2262500	295
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.0795375	**99**

*In case of re-entry tasks in grapes the use of a lower than 10100 cm2/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 cm2/h is accepted considering the distribution of residues - Baugher (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 HYCOP a time period of 10 days after application is respected or without gloves when a time period of 17 days after application is respected.

		Copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Potato Inspection, irrigation / Outdoor Work rate: 2 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.2362500	295
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0264600	**33**
Solanaceous fruits (Tomato, aubergine) Reaching, picking/Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm^2/person/h	0.4384800	548
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.1890000	236
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0438480	**55**

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).

		Copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Pome fruit (apple, pear, quince) Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 3 µg/cm^2/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^2/person/h	1.4672435	1834
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.2934487	367
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.1467243	184
Proposal of Re-entry period of 7 days Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 1.51 µg/cm^2/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^2/person/h	0.7385126	923
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.1477025	185
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0738513	**92**

Proposal of Re-entry period of 14 days Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 7 days DFR: 0.75 µg/cm^2/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^2/person/h	0.3668109	459
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0733622	**92**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0366811	**46**

Pome fruit (apple, pear, quince)
It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-

entering pome fruits treated with HYCOP 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 hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm²/person/h	0.3827849	478
	Work wear (arms, body and legs covered) TC: 10100 cm²/person/h	0.1288709	161
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm2/person/h*	0.0620239	**78**

Proposal of Re-entry period of 21 days **Grapevine** Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 1.84 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm²/person/h	0.2347747	293
	Work wear (arms, body and legs covered) TC: 10100 cm²/person/h	0.0790408	**99**

*In case of re-entry tasks in grapes the use of a lower than 10100 cm2/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 cm2/h is accepted considering the distribution of residues - Baugher (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);

		Copper hydroxide	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Potato Inspection, irrigation / Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0386145	**48**
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0043248	**5**
Solanaceous fruits (Tomato, aubergine) Reaching, picking/Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0716686	**88**
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0308916	**39**
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	0.0071669	**9**

Pome fruit (apple, pear, quince) Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 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	
Body weight: 60 kg	Potential TC: 22500 cm²/person/h	0.2617554	327
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.0523511	**65**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/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 HYCOP or without gloves when a time period of 21 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.

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 (Mescalchin 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/cm² equating to a DFR of between 0.6 and 1.9 µg/cm²/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/cm²/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 10 and 17 days for grapevine, 7 and 14 for pome fruits.

Body weight 60 kg.

For this calculation DT_{50} value of 7 days is considered according to "*RAR of Copper compounds Volume 1, - August 2018*".

DFR_t is calculated according the following formula:

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

Where:

DFR_T	Dislodgeable foliar residue at the time of re-entry (µg/cm^2)
DFR_0	Dislodgeable foliar residue just after application (µg/cm^2)
k	Degradation constant (days $^{-1}$), calculated from the half life time: $k = ln(2)/DT_{50}$,
DT_{50}	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_{def} 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/cm² per kg s.a/ha)

MAF_m (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[1], corresponding to a half-life $_{foliar}$ of 30 days.

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 3.2. The following DFR value is calculated:

$DFR_0 = DFR_{def} \times 3.2 = 9.6$ µg/cm² (where $DFR_{def} = 3.2$ µg/cm² per kg s.a/ha)

Therefore for 21 days of re-entry interval:

$DFR_T = DFR_0 \times e^{-k,t} = 9.6$ µg/cm² × 0.614 = 5.89 µg/cm²

Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 5.89$ µg/cm² the $DFR_{def\,ref} = 1.84$ µg/cm² 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:

$DFR_0 = DFR_{def} \times 1.9 = 3.61$ µg/cm² (where $DFR_{def} = 1.9$ µg/cm² per kg s.a/ha)

Therefore for 10 days of re-entry interval:

$DFR_T = DFR_0 \times e^{-k,t} = 3.61$ µg/cm² × 0.366 = 1.32 µg/cm²

Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 1.32$ µg/cm² the $DFR_{def\,ref} = 0.69$ µg/cm² per kg s.a/ha

Therefore for 17 days of re-entry interval:

$DFR_T = DFR_0 \times e^{-k,t} = 3.61$ µg/cm² × 0.183 = 0.66 µg/cm²

Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 0.66$ µg/cm² the $DFR_{def\,ref} = 0.35$ µg/cm² 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:

$DFR_0 = DFR_{def} \times 1.50 = 4.5$ µg/cm² (where $DFR_{def} = 3$ µg/cm² per kg s.a/ha)

Therefore for 7 days of re-entry interval:

$DFR_T = DFR_0 \times e^{-k,t} = 4.5$ µg/cm² × 0.502 = 2.26 µg/cm²

Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 2.26$ µg/cm² the $DFR_{def\,ref} = 1.51$ µg/cm² per kg s.a/ha

Therefore for 14 days of re-entry interval:

$DFR_T = DFR_0 \times e^{-k,t} = 5.64$ µg/cm² × 0.200 = 1.13 µg/cm²

Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 1.13$ µg/cm² the $DFR_{def\,ref} = 0.75$ µg/cm² per kg s.a/ha

[1] 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"

6.6.3.3 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.

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 hydroxide. 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 hydroxide	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine/ Tractor mounted boom spray application outdoors to hight crops Buffer zone: 5 (m) Drift reduction technology: no DT50: 7 days DFR: 3 µg/cm2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0157865	19.73
	Vapour (75th perc.)	0.0010700	1.34

	Deposits (75th perc.)	0.0021816	2.73
	Re-entry (75th perc.)	0.0284766	35.60
	Sum (mean)	0.0358300	44.79
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0086999	10.87
	Vapour (75th perc.)	0.0002300	0.29
	Deposits (75th perc.)	0.0006303	0.79
	Re-entry (75th perc.)	0.0158203	19.78
	Sum (mean)	0.0190138	23.77
Potato, Solanaceous fruits Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT50: 7 days DFR: 3 µg/cm2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.00584462	7.31
	Vapour (75th perc.)	0.0010700	1.34
	Deposits (75th perc.)	0.0044570	5.57
	Re-entry (75th perc.)	0.0318938	39.87
	Sum (mean)	0.0329921	41.24
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0013914	1.74
	Vapour (75th perc.)	0.0002300	0.29
	Deposits (75th perc.)	0.0012877	1.61
	Re-entry (75th perc.)	0.0177188	22.15
	Sum (mean)	0.0159630	19.95
Pome fruit Tractor mounted boom spray application outdoors to high crops Buffer zone: 5(m) Drift reduction technology: no DT50: 7 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 (75th perc.)	0.0189438	23.68
	Vapour (75th perc.)	0.0010700	1.34
	Deposits (75th perc.)	0.0108402	13.55
	Re-entry (75th perc.)	0.0275108	34.39
	Sum (mean)	0.0435180	54.40
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0104399	13.05
	Vapour (75th perc.)	0.0002300	0.29

	Deposits (75th perc.)	0.0031319	3.91
	Re-entry (75th perc.)	0.0152838	19.10
	Sum (mean)	0.0215671	26.96

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

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

		Copper hydroxide	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Grapevine/ 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: 7 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0019367	2.43
	Vapour (75th perc.)	0.0010700	1.34
	Deposits (75th perc.)	0.0009646	1.21
	Re-entry (75th perc.)	0.005329	6.73
	Sum (mean)	0.0073950	9.24
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0010055	1.26
	Vapour (75th perc.)	0.0002300	0.29
	Deposits (75th perc.)	0.0001191	0.15
	Re-entry (75th perc.)	0.0029905	3.74
	Sum (mean)	0.0033686	4.21
Potato, Solanaceous fruits 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: 7 days			
Number of applications and application rate		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0006963	0.87
	Vapour (75th perc.)	0.0010700	1.34
	Deposits (75th perc.)	0.0017040	2.13
	Re-entry (75th perc.)	0.0052130	6.52
	Sum (mean)	0.0068691	8.59

Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0001582	0.20
	Vapour (75th perc.)	0.0002300	0.29
	Deposits (75th perc.)	0.0002105	0.26
	Re-entry (75th perc.)	0.0028961	3.62
	Sum (mean)	0.0027700	3.46
Pome fruit Tractor mounted boom spray application outdoors to high 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		3 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0023240	2.90
	Vapour (75th perc.)	0.0010700	1.34
	Deposits (75th perc.)	0.0045235	5.65
	Re-entry (75th perc.)	0.0049079	6.13
	Sum (mean)	0.0098970	12.37
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0012067	1.51
	Vapour (75th perc.)	0.0002300	0.29
	Deposits (75th perc.)	0.0005587	0.70
	Re-entry (75th 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.

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 hydroxide 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**	Verte-brate 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**	Verte-brate study Y/N	Owner
KCP XX	Author	YYYY	Title	Y/N	Owner

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The classification of Copper Hydroxide 50% WP was performed by calculation. The assessment of all acute toxicological properties of Copper Hydroxide 50% WP 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 hydroxide Technical	**82.58**	500 mg/kg	> 2000 mg/kg	0.05 mg/l [3)]	Not Irritating[1)]	Eye Dam. 1 H318	Not sensitising[1)]
co-formulant 1	**XXX**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
co-formulant 2	**XXX**	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]
co-formulant 3	**XXX**	500 mg/kg	> 2000 mg/kg[1)]	*Not classified	Skin Irrit. 2 H315	Eye Dam. 1 H318	Not sensitising[1]
co-formulant 4	**XXX**	> 2000 mg/kg	> 2000 mg/kg	*Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1]

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

[1)] As co-formulant is not classified

[2)] According to the Regulation (EC) n°1272/2008, ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4; H302.

[3)] According to the Regulation (EC) n°1272/2008, ATE = 0.05 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4; H330.

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_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients

A 2.1 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**Method of calculation is acceptable** **Acute oral toxicity calculation for Copper Hydroxide 50% WP is 602mg/kg (< 2000 mg/kg)** **According to the Regulation EC No. 1272/2008, using worse results from calculations, Copper Hydroxide 50% WP should be classified for oral toxicity H302/Acute Tox.4**

The acute oral toxicity classification for Copper Hydroxide 50% WP: was calculated:

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

$$ATE_{mix} = \frac{100\%}{\frac{82.58\%}{500} + \frac{\text{xxx}\%}{500}} = 602\frac{mg}{kg}$$

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

Conclusion
The acute oral toxicity calculation for Copper Hydroxide 50% WP was estimated to be < 2000 mg/kg, Copper Hydroxide 50% WP therefore should be classified as harmful by swallow.

According to the Regulation EC No. 1272/2008, using worse results from calculations, Copper Hydroxide 50% WP should be classified for oral toxicity. Therefore the Signal Word "**Warning**" and the Hazard Statement "**H302: Harmful by swallow**" are proposed.

A 2.2 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	**Method of calculation is acceptable** **Acute dermal toxicity calculation for Copper Hydroxide 50% WP is not classfied according to the Regulation EC No. 1272/2008**

There is no co-formulant in the Copper Hydroxide 50% WP recipe classified as danger through dermal toxicity. The MSDS of the co-formulants do not specify a hazard in relation to this endpoint and online literature has not indicated any additional concerns. Copper Hydroxide 50% WP is considered of low concern via dermal.

According to the Regulation EC No. 1272/2008, Copper Hydroxide 50% WP is not classified. No signal word or hazard statement is required.

A 2.3 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**Method of calculation is acceptable** **Using the calculation method, the acute inhalation toxicity of Copper Hydroxide 50% WP was estimated to be 0.06 mg/l** **According to the Regulation EC No. 1272/2008, using worse results from calculations, Copper Hydroxide 50% WP should be classified for inhalation toxicity H330/Acute Tox.2**

Acute inhalation toxicity classification for Copper Hydroxide 50% WP was calculated:

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

$$\boldsymbol{ATE_{mix} = \frac{100\%}{\frac{xx\%}{0.05}} = 0.06 \frac{mg}{l}}$$

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

Using the calculation method, the acute inhalation toxicity of Copper Hydroxide 50% WP was estimated to be 0.06 mg/l. Thus, classification is required according to Regulation (EC) No. 1272/2008. The product is classified as category 2. The signal word “Danger” and the hazard statement “H330: Fatal if inhaled” is required.

A 2.4 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**Method of calculation is acceptable** **Using the calculation method, Copper Hydroxide 50% WP is not skin irritation** **According to the Regulation EC No. 1272/2008, using worse results from calculations, Copper Hydroxide 50% WP is not classified**

The product contains < 10% of formulants considered as dermal irritants (classified as: Skin Irrit. 2; H315: Causes Skin Irritation). Under the GHS classification system these components are below the additive trigger value of value of 10% for formulants/co-formulants for the “H315: Causes skin irritation” the classification according to Regulation (EC) no. 1272/2008.

Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Copper Hydroxide 50% WP 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 Hydroxide 50% WP is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**Method of calculation is acceptable** **Using the calculation method, Copper Hydroxide 50% WP is eye damage** **According to the Regulation EC No. 1272/2008, , Copper Hydroxide 50% WP is classified H318/ Eye Dam.1**

The product contains 82.58% of the active substance Copper hydroxide Technical, and it is classified as eye damage, category 1 (H318). Under the GHS classification system, this component gets the additive trigger value of 3% for ingredients for the "H318: Causes serious eye damage".

According to the Regulation EC No. 1272/2008, Copper Hydroxide 50% WP, is classified in Eye Dam. (Cat. 1). Signal word "**Danger**" with the hazard statement "**H318: Causes serious eye damage**"

A 2.6 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**Method of calculation is acceptable** **Using the calculation method, Copper Hydroxide 50% WP is not sensitizer** **According to the Regulation EC No. 1272/2008, , Copper Hydroxide 50% WP is not classified**

There is no co-formulant in the Copper Hydroxide 50% WP recipe classified as danger through Skin Sensitizer. The MSDS of the co-formulants do not specify a hazard in relation to this endpoint and online literature has not indicated any additional concerns. Copper Hydroxide 50% WP is considered of low concern via sensitising.

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

A 2.7 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 2.8 Data on co-formulants (KCP 7.4)

A 2.8.1 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 2.8.2 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 2.9 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	**Acceptable** **Ccopper dermal absorption values of 1% and 9% (rounded values), for the concentrate and the field dilution** **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**

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.(*XXX, W.J.M. (2012),* In vitro dermal absorption OECD 428 *, W.J.M. and Kunne, 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 *, (XXX 2017)* In vitro percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8 WG (35% as metallic copper), through human skin OECD 428 *, XXX, W.J.M. and Kunne, C. (2015), (XXX 2017) z "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, Wilfred XXX, MSc is acceptable**

A 2.10 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 hydroxide

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

Formulation type	WP		Crop type	Grapevine
Application rate (AR)	1	kg a.s./ha	Application method	~~Upward spraying~~ 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 2: Estimation of longer term operator exposure towards Copper hydroxide 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**
Head			-	
Specific exposure value	1042,2034571	µg/person	1042,2034571	µg/person
Systemic exposure	**17,3700576**	**mg/kg bw/d**	**17,3700576**	**mg/kg bw/d**
Inhalation			-	
Specific exposure value	234,4282794	µg/person	234,4282794	µg/person
Systemic exposure	**3,9071380**	**mg/kg bw/d**	**3,9071380**	**mg/kg bw/d**
Total				
Total systemic exposure	**0,3479802**	**mg/kg bw/d**	**0,0436929**	**mg/kg bw/d**
% of AAOEL	**434.98**	**%**	**54.62**	**%**

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**13,4097774**	**4,5043147**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,2234963**	**0,0750719**	
% of RVNAS	**279,37%**	**93,84%**	

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

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 1	Dermal for in use diluation = 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		0,2352	% of RVNAS	293,98%
	Acute systemic exposure mg/kg bw/day		0,5177	% of RVAAS	647,07%
Mixing and Loading		Gloves = Yes	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 hydroxide according to EFSA guidance for grapevine for manual application

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**14,1112435**	**4,4940797**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,2351874**	**0,0749013**	
% of RVNAS	**293,98%**	**93,63%**	

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

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 1	Dermal for in use diluation = 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		0,3480	% of RVNAS	434,98%
	Acute systemic exposure mg/kg bw/day		1,2532	% of RVAAS	1566,48%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = FP1, P1 and similar	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 6: Estimation of longer term operator exposure towards Copper hydroxide according to EFSA guidance for grapevine for upward spraying

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**20,8788132**	**2,6215742**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,3479802**	**0,0436929**	
% of RVNAS	**434,98%**	**54,62%**	

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

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

Table A 9: Input parameters considered for the estimation of operator exposure solanaceous fruit for manual application

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 1	Dermal for in use diluation = 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		0,4845	% of RVNAS	605,62%
	Acute systemic exposure mg/kg bw/day		0,7149	% of RVAAS	893,59%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = FP1, P1 and similar	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 10: Estimation of longer term operator exposure towards Copper hydroxide according to EFSA guidance and solanaceous fruit for manual application

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**29,0697567**	**2,5051582**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,4844959**	**0,0417526**	
% of RVNAS	**605,62%**	**52,19%**	

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

Formulation type	WP		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 hydroxide according to EFSA guidance for pome fruit

	Potential	**With work wear + PPE/RPE**

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

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

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 1	Dermal for in use diluation = 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		0,2512	% of RVNAS	313,99%
	Acute systemic exposure mg/kg bw/day		0,5356	% of RVAAS	669,54%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 14: Estimation of longer term operator exposure towards Copper hydroxide according to EFSA guidance for pome fruit for manual application

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**15,0715642**	**3,9599396**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,2511927**	**0,0659990**	
% of RVNAS	**313,99%**	**82,50%**	

Table A 15: Input parameters considered for the estimation of operator for upward application to grapes

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 4, Application interval = 7 days
Percentage Absoprtion	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		0,1049	% of RVNAS	131,16%
	Acute systemic exposure mg/kg bw/day		0,2260	% of RVAAS	282,49%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 16: Estimation of longer term operator exposure towards Copper hydroxide according to EFSA guidance for upward application to grapes

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**6,2956018**	**4,6872024**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,1049267**	**0,0781200**	
% of RVNAS	**131,16%**	**97,65%**	

Table A 17: Input parameters considered for the estimation of operator for manual-hand held upward application to grapes

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 7 days
Percentage Absoprtion	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		0,0780	% of RVNAS	97,46%
	Acute systemic exposure mg/kg bw/day		0,1373	% of RVAAS	171,62%
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 hydroxide according to EFSA guidance for manual-hand held upward application to grapes

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**4,6781879**	**3,7091676**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0779698**	**0,0618195**	
% of RVNAS	**97,46%**	**77,27%**	

Table A 19: Input parameters considered for the estimation of operator for downward application to grapes

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 7 days
Percentage Absoprtion	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		0,0879	% of RVNAS	109,84%
	Acute systemic exposure mg/kg bw/day		0,1151	% of RVAAS	143,93%
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 hydroxide according to EFSA guidance for downward application to grapes

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**5,2723052**	**4,6431302**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0878718**	**0,0773855**	
% of RVNAS	**109,84%**	**96,73%**	

Table A 21: Input parameters considered for the estimation of operator for potato and solanaceous fruits

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 7 days
Percentage Absoprtion	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		0,1590	% of RVNAS	198,70%
	Acute systemic exposure mg/kg bw/day		0,1540	% of RVAAS	192,52%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = FP1, P1 and similar	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 22: Estimation of longer term operator exposure towards Copper hydroxide 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)	**9,5374049**	**1,9107955**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,1589567**	**0,0318466**	
% of RVNAS	**198,70%**	**39,81%**	

Table A 23: Input parameters considered for the estimation of operator for manual -hand held to potato and solanaceous fruits

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 = 7 days
Percentage Absoprtion	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		0,1128	% of RVNAS	141,06%
	Acute systemic exposure mg/kg bw/day		0,1739	% of RVAAS	217,35%
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 hydroxide according to EFSA guidance for manual -hand held to 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)	**6,7706824**	**3,9666493**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,1128447**	**0,0661108**	
% of RVNAS	**141,06%**	**82,64%**	

Table A 25: Input parameters considered for the estimation of operator for upward application to pome fruits

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 Absoprtion	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		0,1146	% of RVNAS	143,20%
	Acute systemic exposure mg/kg bw/day		0,2526	% of RVAAS	315,72%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = FP1, P1 and similar	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 26: Estimation of longer term operator exposure towards Copper hydroxide according to EFSA guidance for upward application to pome fruits

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**6,8736038**	**1,5694401**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,1145601**	**0,0261573**	
% of RVNAS	**143,20%**	**32,70%**	

Table A 27: Input parameters considered for the estimation of operator for manual – hand held application to pome fruits

Substance	Copper hydroxide	Formulation = Wettable powder, soluble powder	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 Absoprtion	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		0,0830	% of RVNAS	103,75%
	Acute systemic exposure mg/kg bw/day		0,1402	% of RVAAS	175,26%
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 hydroxide according to EFSA guidance for manual – hand held application to pome fruits

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4,9800398	3,9595516	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0830007	0,0659925	
% of RVNAS	103,75%	82,49%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Copper hydroxide 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	7	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)	1.9		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^{-3}
AAOEL		mg/kg bw/d			

Table A 30: Estimation of longer term worker exposure towards Copper hydroxide 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	1.2825000	**mg/kg bw/d**	**0,4317750**	**mg/kg bw/d**	**0.20780775**	**mg/kg bw/d**
AOEL	1603.13	**%**	**539.72**	**%**	**260**	**%**

Table A 31: Input parameters considered for the estimation of worker exposure for re-entry period of 10 days

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	0.69	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	7	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)	1.9		TC dermal (work wear)	10100	cm²/h

Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	4861	cm^2/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 32: Estimation of worker exposure towards Copper hydroxide according to EFSA guidance for re-entry period of 10 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	0,4657500	**mg/kg bw/d**	**0,1568025**	**mg/kg bw/d**	**0.07720028**	**mg/kg bw/d**
AOEL	582.19	**%**	**196**	**%**	**97**	**%**

Table A 33: Input parameters considered for the estimation of worker exposure for re-entry period of 27 days

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	0.35	$\mu g/cm^2$/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	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	30000	cm^2/h
Multiple application factor (MAF)	1.9		TC dermal (work wear)	10100	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm^2/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 34: Estimation of worker exposure towards Copper hydroxide according to EFSA guidance for re-entry period of 27 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	0,2362500	**mg/kg bw/d**	**0,0795375**	**mg/kg bw/d**	-	**mg/kg bw/d**
AOEL	295.31	**%**	**99.42**	**%**	-	**%**

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

Intended use(s)	Potato		Dislodgeable foliar residue (DFR)	3	$\mu g/cm^2$/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	7	days	Work rate per day (WR)	2	h/d
Half-life of active substance	7	days	TC dermal (potential)	12500	cm^2/h
Multiple application factor (MAF)	1.80		TC dermal (work wear)	1400	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm^2/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 36: Estimation of longer term worker exposure towards Copper hydroxide 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						
Systemic exposure	0,2362500	**mg/kg bw/d**	**0,0264600**	**mg/kg bw/d**	-	**mg/kg bw/d**
AOEL	295.31	**%**	**33.08**	**%**	-	**%**

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/cm²/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	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	5800	cm²/h
Multiple application factor (MAF)	1.80		TC dermal (work wear)	2500	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm²/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 38: Estimation of longer term worker exposure towards Copper hydroxide 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	0,4384800	**mg/kg bw/d**	**0,1890000**	**mg/kg bw/d**	**0,0438480**	**mg/kg bw/d**
AOEL	548.10	**%**	**236.25**	**%**	**54.81**	**%**

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/cm²/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	cm²/h
Multiple application factor (MAF)	1.88		TC dermal (work wear)	4500	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm²/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

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

	Potential	**With work wear**	**With work wear and gloves**
Worker (re-entry): Dermal exposure after application			

	Potential		**With work wear**		**With work wear and gloves**	
(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/cm²/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^2/h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	4500	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm^2/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 42: Estimation of worker exposure towards Copper hydroxide 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/cm²/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^2/h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	4500	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm^2/h
AOEL	0.08	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10^{-3}
AAOEL		mg/kg bw/d			

Table A 44: Estimation of worker exposure towards Copper hydroxide 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			

	Potential		With work wear		With work wear and gloves	
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	7	days
Half-life of active substance	30	days
Multiple application factor	3,2	
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^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	4861	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 46: Estimation of worker exposure towards Copper hydroxide 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)	22,9670927	7,7322545	3,7214346
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3827849	0,1288709	0,0620239
% of RVNAS	478,48%	161,09%	77,53%

Table A 47: Input parameters considered for the estimation of worker exposure for grapevine with re-entry period of 21 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	7	days
Half-life of active substance	30	days
Multiple application factor	3,2	
Dermal absorption of the product	0,10%	
Dermal absorption of the in-use dilution	1,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,84	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	30000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	10100	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 48: Estimation of worker exposure towards Copper hydroxide according to EFSA guidance for grapevine with re-entry period of 21 days

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	14,0864835	4,7424495	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2347747	0,0790408	
% of RVNAS	293,47%	98,80%	

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	7	days
Half-life of active substance	30	days
Multiple application factor	2,6	
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^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 50: Estimation of worker exposure towards Copper hydroxide 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)	2,3168716	0,2594896	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0386145	0,0043248	
% of RVNAS	48,27%	5,41%	

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	7	days
Half-life of active substance	30	days
Multiple application factor	2,6	
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^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 52: Estimation of worker exposure towards Copper hydroxide 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)	4,3001137	1,8534973	0,4300114
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0716686	0,0308916	0,0071669
% of RVNAS	89,59%	38,61%	8,96%

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^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 54: Estimation of worker exposure towards Copper hydroxide 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 hydroxide

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	7300	cm^2/h (adult)

			deposits (TC)	2600	cm^2/h (child)
Minimum water volume (V)	800	L/ha	Drift on surface (D) - 75th perc.	3.07	%
Buffer strip	5	m	Drift on surface (D) - mean	2.32	%
Number of applications (NA)	4		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H_D)	2	h
Half-life of active substance	7	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.88		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m^3
	10	kg/person (children)			
Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	$\mu g/cm^2/kg$ 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^2
Spray drift dermal (SD) - 75th 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) - 75th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	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^2/d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00133	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	0.23	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	1.07	m^3/d (child)		1794	cm^2/h (child)

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

Child			**Adult**		
Spray drift (75th 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 (75th 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 (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0,0013470**	**mg/kg bw/d**	**Systemic exposure**	**0,0006303**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
	0,0005468		**Systemic exposure**		**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
	0,0002878		**Systemic exposure**		**mg/kg bw/d**
Total					
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 (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0,0284766**	**mg/kg bw/d**	**Systemic exposure**	**0,0158203**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					
AR x MAF x 100% x DR_{OM} x IgR x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Total					
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^2/h (adult)
				2600	cm^2/h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75th 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	7	days	Exposure duration dermal (H_D)	2	h

Half-life of active substance	7	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.8		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m^3
	10	kg/person (children)			
Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm^2/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^2
Spray drift dermal (SD) - 75th 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) - 75th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	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^2/d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00017	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	0.23	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	1.07	m^3/d (child)		1794	cm^2/h (child)

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

Child		**Adult**			
Spray drift (75th 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 (75th 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 (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0,0027518**	**mg/kg bw/d**	**Systemic exposure**	**0,0012877**	**mg/kg bw/d**
Hand to mouth					

AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
	0,0011172		**Systemic exposure**		**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
	0,0005880		**Systemic exposure**		**mg/kg bw/d**
Total					
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 (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0,0318938**	**mg/kg bw/d**	**Systemic exposure**	**0,0177188**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					
AR x MAF x 100% x DR_{OM} x IgR x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Total					
Systemic exposure	**0,0318938**	**mg/kg bw/d**	**Systemic exposure**	**0,0177188**	**mg/kg bw/d**
% of AOEL:	**39.87**	**%**	**% of AOEL:**	**22.15**	**%**
All pathways (mean)					
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^2/h (adult)
				2600	cm^2/h (child)
Minimum water volume (V)	800	L/ha	Drift on surface (D) - 75th 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_D)	2	h
Half-life of active substance	7	days	Exposure duration inhal. (H_I)	24	h
Multiple application factor (MAF)	1.50		Exposure duration entry into treated crops (H_E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m^3
	10	kg/person (children)			
Dermal absorption (DA)	9	% ('worst case')	Dislodgeable foliar residue (DFR)	3	$\mu g/cm^2/kg$ 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^2
Spray drift dermal (SD) - 75th 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) - 75th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR_{OM})	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^2/d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75th perc.	7500	cm^2/h (adult)
	0.00133	mL spray dilution (child)		2250	cm^2/h (child)
Inhalation rate (IR)	0.23	m^3/d (adult)	TC entry into treated crops - mean:	5980	cm^2/h (adult)
	1.07	m^3/d (child)		1794	cm^2/h (child)

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

Child		**Adult**			
Spray drift (75th 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 (75th 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 (75th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H_D x DA / BW					
Systemic exposure	**0,0066929**	**mg/kg bw/d**	**Systemic exposure**	**0,0023187**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H_D x OA / BW					
	0,0027172		**Systemic exposure**		**mg/kg bw/d**
Object to mouth					
AR x MAF x D x DR_{OM} x IgR x OA / BW					
	0,0014301		**Systemic exposure**		**mg/kg bw/d**
Total					
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 (75th perc.)					
Dermal					
AR x MAF x TC x H_D x DFR x DA / BW					
Systemic exposure	**0,0275108**	**mg/kg bw/d**	**Systemic exposure**	**0,0121863**	**mg/kg bw/d**
Hand to mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H_D x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Object to mouth					
AR x MAF x 100% x DR_{OM} x IgR x OA / BW					
			Systemic exposure		**mg/kg bw/d**
Total					
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**	**mg/kg bw/d**
% 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 powder, soluble powder	
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^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
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^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/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^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 62: Estimation of longer term resident exposure towards Copper hydroxide 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	0,0096460	0,0538291	0,0739498
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019367	0,0010700	0,0009646	0,0053829	0,0073950
% of RVNAS	2,42%	1,34%	1,21%	6,73%	9,24%

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	0,0071488	0,1794304	0,2021132
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0010055	0,0002300	0,0001191	0,0029905	0,0033686
% of RVNAS	1,26%	0,29%	0,15%	3,74%	4,21%

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

Resident exposure for		
Croptype	Fruiting vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Wettable powder, soluble powder	
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^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
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^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/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^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 64: Estimation of longer term resident exposure towards Copper hydroxide according to EFSA guidance for potato and 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	0,0170398	0,0521296	0,0686907
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0006963	0,0010700	0,0017040	0,0052130	0,0068691
% of RVNAS	0,87%	1,34%	2,13%	6,52%	8,59%
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	0,0126285	0,1737654	0,1662030
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0001582	0,0002300	0,0002105	0,0028961	0,0027700
% of RVNAS	0,20%	0,29%	0,26%	3,62%	3,46%

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 powder, soluble powder	
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^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
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^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/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^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 66: Estimation of longer term resident exposure towards Copper hydroxide according to EFSA guidance for pome 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)	0,0232399	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%

1.2 Adult	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)