DRAFT REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper Oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

MS Finalisation date: 06/2020

Version history

When	What
July.2020	Assessment by the expert

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on COBRANZA *

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

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

Justified proposals for classification and labelling

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

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

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

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

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) at M/L and A + gloves M/L and A + FP1,P1 and similar M/L
Workers	Acceptable	Grapevine - Work wear (arms, body and legs covered) and gloves- time period of 8 days after application Work wear (arms, body and legs covered) - time period of 15 days after application Potato - Work wear (arms, body and legs covered) Solanaceous fruits - Work wear (arms, body and legs covered) and gloves Pome fruits - Work wear (arms, body and legs covered) and gloves- time period of 7 days after application

	Result	PPE / Risk mitigation measures
		Work wear (arms, body and legs covered) - time period of 14 days after application
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	4(10)	1.0	800-1000	21					
2	Potato BBCH 15-85	F	Foliar Spray LCTM	3(10)	1.2	500-1000	14					
3	Solanaceous fruits (Tomato, aubergine) BBCH 15-85	F	Foliar Spray LCTM	3(10)	1.2	500-1000	3					
4	Pome fruit (apple, pear, quince) BBCH 15-85	F	Foliar Spray HCTM	3(10)	1.2	800-1000	21					

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

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

6.2 Toxicological Information on Active Substance(s)

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

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

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

6.3 Toxicological Evaluation of Plant Protection Product

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

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

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

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Not relevant. There is not metabolites.

6.5 Dermal Absorption (KCP 7.3)

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

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

	Copper Oxychloride	
	Value	**Reference**
Concentrate	1%	EFSA Journal 2018;16(1):5152
Dilution	9%	EFSA Journal 2018;16(1):5152

6.5.1 Justification for proposed values – Oxychloride

The proposed dermal absorption rates for copper are based on dermal absorption studies on a formulation containing copper Oxychloride.
The study results are summarised in the following table. Full summaries of studies on the dermal absorption of copper that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.
It has already been established during the EU peer review that, given the nature of the active substance (Cu^{2+}), dermal penetration factors for both concentrate and in-use spray dilutions from these studies are justifiably relevant to all forms of copper (oxide, hydroxide, oxychloride, tribasic sulphate and Bordeaux Mixture) and all formulation types (WP, WG, and SC).Therefore, the results of the studies below are relevant for Copper oxychloride in COBRANZA

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

Test	Concentrate	Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.4%	9% (0.3g Cu/L)	• DPX-GFJ52 (Copper hydroxide 53.8WG)	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product	xxxxx, 2017*
In vitro (human)	0.6% 0.1%	8.9% 3.5%	• Copper hydroxide 50 WP. • Flowbrix	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product.	xxxxx, 2015*
In vitro (human)	0.09%	5.68% (1.5 g/L)	• Copper hydroxide 250 g Cu/L, SC. • Copper hydroxide 50 WP • H1B10 Cop-	Yes	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product .	Xxxxx 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*
			per hydroxide 25% WG • Copper Oxychloride 37.5 NC WG • Flowbrix • Bordeaux mixture 20% Cu WP • BBC/Bouillie Bordelaise • Nordox 75 WG				

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	Copper Oxychloride 50% WG
Formulation type	WG
Category	Fungicide
Active substance(s) (incl. content)	**Copper Oxychloride** 500 g/kg
AOEL systemic	0.08 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 1 % Dilution: 9 %

6.6.1 Selection of critical uses and justification

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

Justification

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

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

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

Table 6.6-2: Exposure models for intended uses

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

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

		Copper Oxychloride	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops **(grapevine)**			
Application rate		1 kg a.s./ha	
Spray application (AOEM**;** 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**
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**
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**

According to the AOEM model, calculations, it can be concluded that the risk for the operator us-

ing COBRANZA is acceptable for grapes vegetables and pome fruits with the use of gloves and standard working clothing (long sleeved shirt and trousers) during mixing/loading and application and with the use FP1, P1 or similar mixing/loading.
The following labelling is therefore required:
P280: Wear protective gloves, face protection

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Oxychloride 50% WG according to the critical uses. Outcome of the estimation is presented in *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 COBRANZA a time period of 8 days after application is respected or without gloves when a time period of 15 days after application is respected. (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 product/ha) Potato (max. 3 x 2.4 L product/ha) Solanaceous fruits (Tomato, aubergine) (max. 3 x 2.4 L product/ha) Pome fruit (apple, pear, quince) (max. 3 x 2.4 L 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 oxychloride	
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: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	1.0675740	1334
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.3594166	449
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm2/person/h*	0.1729826	216
Proposal of Re-entry period of 8 days **Grapevine** Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 7 days **DFR: 0.84 µg/cm^2/kg a.s./ha** Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	0.4719801	588
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.1589000	199
	Work wear (arms, body and legs covered) and gloves TC: 4861 cm2/person/h*	0.07833721	**98**

Proposal of Re-entry period of 15 days **Grapevine** Hand harvesting/ Outdoor Work rate: 8 hours/day, DT_{50}: 7 days **DFR: 0.42 µg/cm^2/kg a.s./ha** Interval between treatments: 10 days			
Number of applications and application rate		4 x 1 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000cm^2/person/h	0.2359900	295
	Work wear (arms, body and legs covered) TC: 10100 cm^2/person/h	0.0794500	**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 COBRANZA a time period of 8 days after application is respected or without gloves when a time period of 15 days after application is respected.

		Copper oxychloride	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
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: 10 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	0.235990	263
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0235990	**30**
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: 10 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	0.3782228	473
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.1630271	204
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0378223	**47**

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 oxychloride	
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/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	1.4672435	1834
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.2934487	367
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/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/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	0.7385126	923
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.1477025	185
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/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/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	0.3668109	459
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.0733622	**92**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/person/h	0.0366811	**46**

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

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 8 and 15 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/cm²)

DFR_0 Dislodgeable foliar residue just after application (µg/cm²)

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.

<u>Grapevine</u>:

[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"

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 8 days of re-entry interval:
$DFR_T = DFR_0 \times e^{-k,t} = 3.61$ µg/cm² × 0.371 = 1.34 µg/cm²
Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 1.34$ µg/cm² the $DFR_{def\,ref} = 0.84$ µg/cm² per kg s.a/ha

Therefore for 15 days of re-entry interval:
$DFR_T = DFR_0 \times e^{-k,t} = 3.61$ µg/cm² × 0.186 = 0.67 µg/cm²
Therefore for $DFR_T = DFR_{def\,ref} \times MAF = 0.67$ µg/cm² the $DFR_{def\,ref} = 0.42$ 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

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 oxychloride. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in 0.

Table 6.6-6: Exposure models for intended uses

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

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

		Copper oxychloride	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
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: 10 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: 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.)	0.00584462	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	Drift (75th perc.)	0.0013914	1.74

Body weight: 60 kg	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**

Estimation of resident/bystander accidental exposure to COBRANZA indicates no unacceptable risk 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 oxychloride will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

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

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Copper oxychloride Technical	86.21	299 mg/kg	> 2000 mg/kg	2.83 mg/l	Not Irritating	Not Irritating	Not sensitising[1)]
co-formulant 1	xxx	3800 mg/ kg[1)]	> 16000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
co-formulant 2	xxx	> 600 - < 1800 mg/kg	> 2000 mg/kg[1)]	1.09 mg/l	Not Irritating[1)]	Eye Dam.1, H318	Not sensitising[1)]
co-formulant 3	xx	> 4000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Eye Irrit.2, H319	Not sensitising[1)]
co-formulant 4	xxx	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	> 3 mg/l Not classified	Not Irritating[1)]	Not Irritating[1)]	Not sensitising[1)]
co-formulant 5	xxx	> 2000 mg/kg[1)]	> 2000 mg/kg[1)]	*	Not Irritating[1)]	Not Irritating1)	Not sensitising[1)]

* No Information / but in their MSDS are not classified acutely inhalation toxic
[1)] As co-formulant is not classified

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

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

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

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

A 2.2 Acute oral toxicity (KCP 7.1.1)

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

The acute oral toxicity classification for Copper oxychloride 50% WG was calculated:

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

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

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

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

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

Comments of zRMS:	**Calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified**

There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as danger through dermal contact.
According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

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

Acute inhalation toxicity classification for Copper Oxychloride 50% WG was calculated:

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

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

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

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

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**Calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified**

There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as skin corrosion or irritation.
Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of Copper Oxychloride 50% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

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

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**Calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified**

The product contains < 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

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

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**Calculation methodology is acceptable** **According to the Regulation EC No. 1272/2008, Copper Oxychloride 50% WG is not classified**

There is no co-formulant in the Copper Oxychloride 50% WG recipe classified as skin sensitisation.

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

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

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	**Acceptable** **Copper 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. (*W.J.M. (2012), Maas* In vitro dermal absorption OECD 428 , xxxxx, xxxxx. *(2015)* In vitro percutaneous absorption of copper, formulated as Copper hydroxide 50 WP or Copper oxychloride SC, through human and rat skin OECD 428 xxxxx In vitro percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8 WG (35% as metallic copper), through human skin OECD 428 *"Copper compounds RAR 2016" i "Copper RAR revised August 2018")*

A 2.11 Other/Special Studies

No new additional other/special studies

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Copper oxychloride

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

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

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

	Potential		**With work wear + PPE/RPE**	
Mixing and loading				
Hands			gloves	
Specific exposure value	1422,1322987	µg/person	40,3459550	µg/person
Systemic exposure	**23,7022050**	**mg/kg bw/d**	**0,6724326**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	4178,7847391	µg/person	82,3720738	µg/person
Systemic exposure	**69,6464123**	**mg/kg bw/d**	**1,3728679**	**mg/kg bw/d**
Head			FP1, P1 and similar	
Specific exposure value	12,4729735	µg/person	9,9783788	µg/person
Systemic exposure	**0,2078829**	**mg/kg bw/d**	**0,1663063**	**mg/kg bw/d**
Inhalation			-	
Specific exposure value	4308,4395112	µg/person	1077,1098778	µg/person
Systemic exposure	**71,8073252**	**mg/kg bw/d**	**17,9518313**	**mg/kg bw/d**
Application				
Hands			gloves	
Specific exposure value	1749,8165081	µg/person	31,6666783	µg/person
Systemic exposure	**5.6729128**	**mg/kg bw/d**	**0,5277780**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	7930,5354254	µg/person	103,4695379	µg/person
Systemic exposure	**132,1755904**	**mg/kg bw/d**	**1,7244923**	**mg/kg bw/d**

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**	**%**

Table A 3: 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 4: Estimation of longer term operator exposure towards Copper oxychloride according to EFSA guidance for potato and solanaceous fruit

	Potential		**With work wear + PPE/RPE**	
Mixing and loading				
Hands			gloves	
Specific exposure value	5649,1639249	µg/person	129,5039711	µg/person
Systemic exposure	**94,1527321**	**mg/kg bw/d**	**2,1583995**	**mg/kg bw/d**
Body			Work wear	
Specific exposure value	14724,3407201	µg/person	403,1901594	µg/person
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 5: 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 6: Estimation of longer term operator exposure towards Copper oxychloride 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**	**%**

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Copper oxychloride e with EFSA model

Table A 7: Input parameters considered for the estimation of worker exposure for grapevine

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	1.9	µg/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	10	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)	1.6		TC dermal (work wear)	10100	cm^2/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 8: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine

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

Table A 9: Input parameters considered for the estimation of worker exposure for re-entry period of 8 days

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	0.84	µg/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	10	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)	1.6		TC dermal (work wear)	10100	cm^2/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 10: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 8 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	0,4719801	**mg/kg bw/d**	**0,1589000**	**mg/kg bw/d**	**0,078337206**	**mg/kg bw/d**
AOEL	589.98	**%**	**198,62**	**%**	**98**	**%**

Table A 11: Input parameters considered for the estimation of worker exposure for re-entry period of 15 days

Intended use(s)	Grapevine		Dislodgeable foliar residue (DFR)	0.42	$\mu g/cm^2/kg$ 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	10	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)	1.6		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 12: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0,2359900	**mg/kg bw/d**	**0,0794500**	**mg/kg bw/d**	-	**mg/kg bw/d**
AOEL	249.99	**%**	**99.31**	**%**	-	**%**

Table A 13: 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	10	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 14: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for potato

	Potential		**With work wear**		**With work wear and gloves**	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0,2107054	**mg/kg bw/d**	**0,0235990**	**mg/kg bw/d**	-	**mg/kg bw/d**
AOEL	263.38	**%**	**29.50**	**%**	-	**%**

Table A 15: Input parameters considered for the estimation of worker exposure for solanaceous fruits

Intended use(s)	solanaceous fruits		Dislodgeable foliar residue (DFR)	3	µg/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	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	7	days	TC dermal (potential)	5800	cm^2/h
Multiple application factor (MAF)	1.5		TC dermal (work wear)	2500	cm^2/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	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 16: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for solanaceous fruits

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

Table A 17: Input parameters considered for the estimation of worker exposure for pome fruit

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	3	µg/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	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 18: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for pome fruit

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

	Potential		With work wear		With work wear and gloves	
AOEL	1834.05	**%**	**366.81**	**%**	**183.41**	**%**

Table A 19: Input parameters considered for the estimation of worker exposure for re-entry period of 7 days

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	1.51	µg/cm^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	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 20: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 7 days

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

Table A 21: Input parameters considered for the estimation of worker exposure for re-entry period of 15 days

Intended use(s)	Pome fruits		Dislodgeable foliar residue (DFR)	0.75	µg/cm^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	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 22: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days

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

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Copper oxychloride

Table A 23: Input parameters considered for the estimation of longer term resident exposure for grapevine

Intended use(s)	grapevine		Drift reduction (DR)		%
Application rate (AR)	1	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm^2/h (adult)
				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	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)	1.88		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 24: Estimation of longer term resident exposure towards Copper oxychloride 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 25: 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	3		Turf Transferable Residues	5	%

(NA)			(TTR)		
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)	1.8		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 26: Estimation of longer term resident exposure towards Copper oxychloride 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.)					
<u>Dermal</u>					
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**
<u>Hand to mouth</u>					

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 27: 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	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.	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 28: Estimation of longer term resident exposure towards Copper oxychloride 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**	**%**

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)