

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 9800 A

Product name: COBRANZA

Chemical active substance:

Copper Oxychloride, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

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

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|-------------------|--|-----------|

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on COBRANZA *

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

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

Justified proposals for classification and labelling

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

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

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

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

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

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

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

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

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

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

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

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

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

Explanation for column 10 “Acceptability of exposure assessment”

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

6.2 Toxicological Information on Active Substance(s)

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

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

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

6.3 Toxicological Evaluation of Plant Protection Product

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

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

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

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

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Not relevant. There is not metabolites.

6.5 Dermal Absorption (KCP 7.3)

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

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

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

6.5.1 Justification for proposed values – Oxychloride

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

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

It has already been established during the EU peer review that, given the nature of the active substance (Cu²⁺), dermal penetration factors for both concentrate and in-use spray dilutions from these studies are justifiably relevant to all forms of copper (oxide, hydroxide, oxychloride, tribasic sulphate and Bordeaux Mixture) and all formulation types (WP, WG, and SC). Therefore, the results of the studies below are relevant for Copper oxychloride in COBRANZA

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

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

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

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

ACCEPTABLE

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

| | |
|-------------------------------------|--------------------------------------|
| Product name and code | Copper Oxchloride 50% WG |
| Formulation type | WG |
| Category | Fungicide |
| Active substance(s) (incl. content) | Copper Oxchloride 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 COBRANZA according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6 3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

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

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

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

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

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

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

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

The following labelling is therefore required: None

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

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

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

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

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

The following labelling is therefore required: None

ACCEPTABLE

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

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

Table 6.6-4: Exposure models for intended uses

| | |
|---------------|---|
| Critical uses | Grapevine (max. 4 x 2 L Kg product/ha) Potato (max. 3 x 2.4 L Kg product/ha) 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 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 cm ² /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/cm²/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 cm ² /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/cm²/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 XXXXX (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);

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

| | | Copper oxychloride | |
|---|---|---|---------------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| 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/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 |

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

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

| | | Copper oxychloride | |
|--|--|---|---------------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Grapevine Hand harvesting/ Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 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 | 0.3508393 | 439 |
| | Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h | 0.1181159 | 148 |
| | Work wear (arms, body and legs covered) and gloves TC: 4861 cm ² /person/h* | 0.0568477 | 71 |
| Proposal of Re-entry period of 17 days Grapevine Hand harvesting/ Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 2.04 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 | 0.2385707 | 298 |
| | Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h | 0.0803188 | 100 |
| | Work wear (arms, body and legs covered) and gloves TC: 4861 cm ² /person/h* | 0.0383821 | 48 |

*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 - XXXXX (2005) - and the assumptions presented in detail in BROWSE WorkerDeliverable 2.4 (2014);

| | | 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 : 30 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 cm²/person/h | 0.0363549 | 45 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.0040718 | 5 |
| Solanaceous fruits (Tomato, aubergine) Reaching, picking/Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 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 cm²/person/h | 0.0674747 | 84 |
| | Work wear (arms, body and legs covered) TC: 2500 cm²/person/h | 0.0290839 | 36 |
| | Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h | 0.0067475 | 8 |
| Pome fruit (apple, pear, quince) Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 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 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 COBRANZA or without gloves when a time period of 17 days after application is respected.

Potato

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

Solanaceous fruits (Tomato, aubergine)

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

Pome fruit (apple, pear, quince)

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

ACCEPTABLE

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

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

A study was conducted to compare two methods of spraying a 20% solution of copper sulphate onto vines (tractor mounted tunnel sprayer or pneumatic nebulizer) at 500 g/ha (xxxxx et al, 2013), see RAR Vol 3 (PPP) B.6.4.1/01. The average leaf deposits were between 3.1 and 9.6 µg/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 DT₅₀ 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)

DFR₀ Dislodgeable foliar residue just after application (µg/cm²)

k Degradation constant (days⁻¹), calculated from the half life time:

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

DT₅₀ 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:

$$MAF = (1 - e^{-nk}) / (1 - e^{-k})$$

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):3874¹, corresponding to a half-life _{foliar} of 30 days.

Grapevine:

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

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

Therefore for 17 days of re-entry interval:

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

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

Grapevine:

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

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

Therefore for 8 days of re-entry interval:

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

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

Therefore for 15 days of re-entry interval:

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

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

Pome fruits:

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

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

Therefore for 7 days of re-entry interval:

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

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

Therefore for 14 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.5 \mu\text{g}/\text{cm}^2 \times 0.200 = 1.13 \mu\text{g}/\text{cm}^2$$

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

6.6.3.3 Measurement of worker exposure

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

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”

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

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

Table 6.6-6: Exposure models for intended uses

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

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

| | | Copper oxychloride | |
|---|-----------------------------------|------------------------------------|--------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Grapevine/ Tractor mounted boom spray application outdoors to hight crops Buffer zone: 5 (m) Drift reduction technology: no DT50: 7 days DFR: 3 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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0157865 | 19.73 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0021816 | 2.73 |
| | Re-entry (75 th perc.) | 0.0284766 | 35.60 |
| | Sum (mean) | 0.0358300 | 44.79 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0086999 | 10.87 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0006303 | 0.79 |

| | | | |
|---|-----------------------------------|--------------------|--------------|
| | Re-entry (75 th 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/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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.00584462 | 7.31 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0044570 | 5.57 |
| | Re-entry (75 th perc.) | 0.0318938 | 39.87 |
| | Sum (mean) | 0.0329921 | 41.24 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0013914 | 1.74 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0012877 | 1.61 |
| | Re-entry (75 th 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/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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0189438 | 23.68 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0108402 | 13.55 |
| | Re-entry (75 th perc.) | 0.0275108 | 34.39 |
| | Sum (mean) | 0.0435180 | 54.40 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0104399 | 13.05 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0031319 | 3.91 |
| | Re-entry (75 th 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.

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

| | | Copper oxychloride | |
|---|-----------------------------------|---|---------------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Grapevine/ Tractor mounted boom spray application outdoors to high crops | | | |
| Buffer zone: 5 (m) | | | |
| Drift reduction technology: no | | | |
| DT50: 30 days | | | |
| DFR: 3 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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0019367 | 2.42 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0008841 | 1.11 |
| | Re-entry (75 th perc.) | 0.0049337 | 6.17 |
| | Sum (mean) | 0.0069760 | 8.72 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0010055 | 1.26 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0001092 | 0.14 |
| | Re-entry (75 th perc.) | 0.0027409 | 3.43 |
| | Sum (mean) | 0.0031620 | 3.95 |
| 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/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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0006963 | 0.87 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0016043 | 2.01 |
| | Re-entry (75 th perc.) | 0.0049079 | 6.13 |
| | Sum (mean) | 0.0065528 | 8.19 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0001582 | 0.20 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0001982 | 0.25 |
| | Re-entry (75 th perc.) | 0.0027266 | 3.41 |
| | Sum (mean) | 0.0026259 | 3.28 |
| 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/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 | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0023240 | 2.90 |
| | Vapour (75 th perc.) | 0.0010700 | 1.34 |
| | Deposits (75 th perc.) | 0.0045235 | 5.65 |
| | Re-entry (75 th perc.) | 0.0049079 | 6.13 |
| | Sum (mean) | 0.0008897 | 12.37 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0012067 | 1.51 |
| | Vapour (75 th perc.) | 0.0002300 | 0.29 |
| | Deposits (75 th perc.) | 0.0005587 | 0.70 |
| | Re-entry (75 th perc.) | 0.0027266 | 3.41 |
| | Sum (mean) | 0.0036146 | 4.52 |

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

ACCEPTABLE

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

| 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 Irritating ¹⁾ | 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: | <p>Calculation methodology is acceptable</p> <p>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.</p> <p>Therefore Copper Oxychloride 50% WG is classified as Acute Tox.4 / H302</p> |
|-------------------|---|

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

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

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

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

Conclusion

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

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

| | |
|-------------------|--|
| Comments of zRMS: | 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:

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

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

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

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

A 2.5 Skin irritation (KCP 7.1.4)

| | |
|-------------------|--|
| Comments of zRMS: | 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) In vitro dermal absorption OECD 428, 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, In vitro percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8 WG (35% as metallic copper), through human skin OECD 428 "Copper compounds RAR 2016" i "Copper RAR revised August 2018")

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

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

A 2.11 Other/Special Studies

No new additional other/special studies

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Copper oxychloride

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

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

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

| | Potential | | With work wear + PPE/RPE | |
|---------------------------|--------------------|-------------------|--------------------------|-------------------|
| Mixing and loading | | | | |
| <u>Hands</u> | | | 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 |
| <u>Body</u> | | | 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 |
| <u>Head</u> | | | 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 |
| <u>Inhalation</u> | | | - | |
| 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 | | | | |
| <u>Hands</u> | | | 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 |
| <u>Body</u> | | | Work wear | |
| Specific exposure value | 7930,5354254 | µg/person | 103,4695379 | µg/person |
| Systemic exposure | 132,1755904 | mg/kg bw/d | 1,7244923 | mg/kg bw/d |

| | | | | |
|--------------------------------|-------------------|-------------------|-------------------|-------------------|
| <u>Head</u> | | | - | |
| Specific exposure value | 1042,2034571 | µg/person | 1042,2034571 | µg/person |
| Systemic exposure | 17,3700576 | mg/kg bw/d | 17,3700576 | mg/kg bw/d |
| <u>Inhalation</u> | | | - | |
| 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 | % |

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

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

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

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

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

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

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

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

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

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

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

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

| | Potential | With work wear + PPE/RPE |
|---------------------------|------------------------|--------------------------|
| Mixing and loading | | |
| <u>Hands</u> | | 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 |
| <u>Body</u> | | 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 |
| <u>Head</u> | | | 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 |
| <u>Inhalation</u> | | | - | |
| 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 | | | | |
| <u>Hands</u> | | | 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 |
| <u>Body</u> | | | 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 |
| <u>Head</u> | | | - | |
| 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 |
| <u>Inhalation</u> | | | - | |
| 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 | % |

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

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

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

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

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

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

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

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

| | Potential | With work wear + PPE/RPE |
|---------------------------|-----------|--------------------------|
| 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 |
| <u>Body</u> | | | 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 |
| <u>Head</u> | | | 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 |
| <u>Inhalation</u> | | | - | |
| 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 | | | | |
| <u>Hands</u> | | | 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 |
| <u>Body</u> | | | 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 |
| <u>Head</u> | | | - | |
| 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 |
| <u>Inhalation</u> | | | - | |
| 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 | % |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ording to EFSA guidance for Potato and solanaceous fruits

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

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

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

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

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

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

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

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

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

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

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

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

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

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Copper oxychloride e with EFSA model

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

| Intended use(s) | Grapevine | | Dislodgeable foliar residue (DFR) | 1.9 | $\mu\text{g}/\text{cm}^2/\text{kg a.s./ha}$ |
|-----------------------------------|-----------|------------|-----------------------------------|-------|---|
| 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 | - | $\text{ha}/\text{h} \times 10^{-3}$ |
| AAOEL | | mg/kg bw/d | | | |

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

| | Potential | | With work wear | | With work wear and gloves | |
|--|-----------|------------|----------------|------------|---------------------------|------------|
| Worker (re-entry): Dermal exposure after application | | | | | | |
| $(\text{DFR} \times \text{TC} \times \text{WR} \times \text{AR} \times \text{MAF} \times \text{DA}) / \text{BW}$ | | | | | | |
| Systemic exposure | 1,0675740 | mg/kg bw/d | 0,3594166 | mg/kg bw/d | 0,172982576 | mg/kg bw/d |
| AOEL | 1334,47 | % | 449,27 | % | 216 | % |

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

| Intended use(s) | Grapevine | | Dislodgeable foliar residue (DFR) | 0.84 | $\mu\text{g}/\text{cm}^2/\text{kg a.s./ha}$ |
|-----------------------------------|-----------|------------|-----------------------------------|-------|---|
| 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 | - | $\text{ha}/\text{h} \times 10^{-3}$ |

| | | | | | |
|-------|--|------------|--|--|--|
| AAOEL | | mg/kg bw/d | | | |
|-------|--|------------|--|--|--|

Table A 32: 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 33: 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 | 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) | - | 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 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 35: Input parameters considered for the estimation of worker exposure for potato

| | | | | | |
|-----------------------------------|--------|------------|-----------------------------------|-------|--------------------------------|
| Intended use(s) | Potato | | 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) | 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 oxychloride according to EFSA guidance for potato

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

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

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

| | | | | | |
|-----------------------------------|--------------------|------------|-----------------------------------|------|--------------------------------|
| Intended use(s) | solanaceous fruits | | Dislodgeable foliar residue (DFR) | 3 | µg/cm 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 38: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for solanaceous fruits

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

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

| | | | | | |
|-----------------------------------|-------------|------------|-----------------------------------|-------|--------------------------------|
| Intended use(s) | Pome fruits | | Dislodgeable foliar residue (DFR) | 3 | µg/cm 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 40: Estimation of longer term worker exposure towards Copper oxychloride according to EFSA guidance for pome fruit

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

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

| | | | | | |
|-----------------------------------|-------------|------------|-----------------------------------|-------|--------------------------------|
| Intended use(s) | Pome fruits | | Dislodgeable foliar residue (DFR) | 1.51 | µg/cm 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 42: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 7 days

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

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

| | | | | | |
|-----------------------------------|-------------|------------|-----------------------------------|-------|--------------------------------|
| Intended use(s) | Pome fruits | | Dislodgeable foliar residue (DFR) | 0.75 | µg/cm 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 44: Estimation of worker exposure towards Copper oxychloride according to EFSA guidance for re-entry period of 15 days

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

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

| Worker exposure from residues on foliage for | |
|--|----------------------------|
| Crop type | Grapes |
| Indoor or outdoor | Outdoor |
| Application method | Upward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Hand harvesting |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 1 kg a.s./ha |
| Number of applications | 4 |
| Interval between multiple applications | 10 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 2,9 |
| Dermal absorption of the product | 0,10% |
| Dermal absorption of the in-use dilution | 1,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 3 µg a.s./cm 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 longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine

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

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

| Worker exposure from residues on foliage for | |
|--|---|
| Crop type | Grapes |
| Indoor or outdoor | Outdoor |
| Application method | Upward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Hand harvesting |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 1 kg a.s./ha |
| Number of applications | 4 |
| Interval between multiple applications | 10 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 2,9 |
| Dermal absorption of the product | 0,10% |
| Dermal absorption of the in-use dilution | 1,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 2,04 µg a.s./cm 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 longer term worker exposure towards Copper oxychloride according to EFSA guidance for grapevine re-entry period of 17 days

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

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

| Worker exposure from residues on foliage for | |
|--|-------------------------------------|
| Crop type | Root and tuber vegetables |
| Indoor or outdoor | Outdoor |
| Application method | Downward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Inspection, irrigation |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 1,2 kg a.s./ha |
| Number of applications | 3 |
| Interval between multiple applications | 10 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 2,4 |
| Dermal absorption of the product | 0,10% |
| Dermal absorption of the in-use dilution | 1,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 3,6 µg a.s./cm 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 |
| 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 longer term worker exposure towards Copper oxychloride according to EFSA guidance for potato

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

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

| Worker exposure from residues on foliage for | |
|--|-----------------------------|
| Crop type | Fruiting vegetables |
| Indoor or outdoor | Outdoor |
| Application method | Downward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Reaching, picking |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 1,2 kg a.s./ha |
| Number of applications | 3 |
| Interval between multiple applications | 10 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 2,4 |
| Dermal absorption of the product | 0,10% |
| Dermal absorption of the in-use dilution | 1,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 3,6 µg a.s./cm 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 longer term worker exposure towards Copper oxychloride according to EFSA guidance for solanaceous fruits

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

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

| Worker exposure from residues on foliage for | |
|--|------------------------------|
| Crop type | Pome fruit |
| Indoor or outdoor | Outdoor |
| Application method | Upward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Searching, reaching, picking |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 1,2 kg a.s./ha |
| Number of applications | 3 |
| Interval between multiple applications | 10 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 2,4 |
| Dermal absorption of the product | 0,10% |
| Dermal absorption of the in-use dilution | 1,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 3,6 µg a.s./cm 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 longer term worker exposure towards Copper oxychloride according to EFSA guidance for pome fruits

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

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Copper oxychloride

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

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

| | | | | | |
|--|---------|---------------------------|--|-------|-----------------------------|
| (V) | | | | | |
| Buffer strip | 5 | m | Drift on surface (D) - mean | 2.32 | % |
| Number of applications (NA) | 4 | | Turf Transferable Residues (TTR) | 5 | % |
| Interval between applications | 10 | days | Exposure duration dermal (H _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 | 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) - 75 th perc. | 5.63 | mL spray dilution (adult) | Frequency of Hand to Mouth (Freq) | 9.5 | events/h |
| | 1.689 | mL spray dilution (child) | | | |
| Spray drift inhal. (SI) - 75 th 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 - 75 th 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 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 (75 th 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) - 75 th perc. | 5.60 | % |
| Buffer strip | 2-3 | m | Drift on surface (D) - mean | 4.10 | % |
| Number of applications (NA) | 3 | | Turf Transferable Residues (TTR) | 5 | % |
| Interval between applications | 10 | days | Exposure duration dermal (H _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) - 75 th perc. | 0.47 | mL spray dilution (adult) | Frequency of Hand to Mouth (Freq) | 9.5 | events/h |
| | 0.327 | mL spray dilution (child) | | | |
| Spray drift inhal. (SI) - 75 th 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 - 75 th 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 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 |
| <u>Object to mouth</u> | | | | | |
| AR x MAF x D x DR _{OM} x IgR x OA / BW | | | | | |
| | 0,0005880 | | Systemic exposure | | mg/kg bw/d |
| <u>Total</u> | | | | | |
| Systemic exposure | 0,0044570 | mg/kg bw/d | Systemic exposure | 0,0012877 | mg/kg bw/d |
| % of AOEL: | 5.57 | % | % of AOEL: | 1.61 | % |

| Entry into treated crops (75 th 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) - 75 th 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) - 75 th perc. | 5..3 | mL spray dilution (adult) | Frequency of Hand to Mouth (Freq) | 9.5 | events/h |
| | 1.689 | mL spray dilution (child) | | | |
| Spray drift inhal. (SI) - 75 th 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 - 75 th 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 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.) | | | | | |
| <u>Dermal</u> | | | | | |
| 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 |
| <u>Hand to mouth</u> | | | | | |
| AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW | | | | | |
| | 0,0027172 | | Systemic exposure | | mg/kg bw/d |
| <u>Object to mouth</u> | | | | | |
| 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.) | | | | | |
| <u>Dermal</u> | | | | | |
| 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 |
| <u>Hand to mouth</u> | | | | | |
| 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 |
| <u>Object to mouth</u> | | | | | |
| 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 | |
| % of AOEL: | 54.40 | % | % of AOEL: | 26.96 | % | |

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

| Resident exposure for | |
|---|---|
| Croptype | Grapes |
| Application method | Upward spraying |
| Application equipment | Vehicle-mounted |
| Formulation type | Wettable granules, soluble granules |
| Buffer strip | 5 m |
| Application rate of the product | 1 kg a.s./ha |
| Concentration of active substance (in-use dilution for liquid applications) | 1,25 g a.s./l |
| Dermal absorption of product | 0,10% |
| Dermal absorption of in-use dilution | 1,00% |
| Oral absorption | 50,00% |
| Dislodgeable foliar residue (I_AppRate*I_DFR) | 3 µg a.s./cm ² |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10 ⁻³ Pa 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 oxychloride according to EFSA guidance for grapevine

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

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

| Resident exposure for | |
|---|--|
| Croptype | Fruiting vegetables |
| Application method | Downward spraying |
| Application equipment | Vehicle-mounted |
| Formulation type | Wettable granules, soluble granules |
| Buffer strip | 2-3 m |
| Application rate of the product | 1,2 kg a.s./ha |
| Concentration of active substance (in-use dilution for liquid applications) | 2,4 g a.s./l |
| Dermal absorption of product | 0,10% |
| Dermal absorption of in-use dilution | 1,00% |
| Oral absorption | 50,00% |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 3,6 µg a.s./cm ² |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10 ⁻³ 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 oxychloride according to EFSA guidance for potato, solanaceous fruits

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

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

| Resident exposure for | |
|---|--|
| Croptype | Pome fruit |
| Application method | Upward spraying |
| Application equipment | Vehicle-mounted |
| Formulation type | Wettable granules, soluble granules |
| Buffer strip | 5 m |
| Application rate of the product | 1,2 kg a.s./ha |
| Concentration of active substance (in-use dilution for liquid applications) | 1,5 g a.s./l |
| Dermal absorption of product | 0,10% |
| Dermal absorption of in-use dilution | 1,00% |
| Oral absorption | 50,00% |
| Dislodgeable foliar residue (I_AppRate*I_DFR) | 3,6 µg a.s./cm ² |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10 ⁻³ 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 oxychloride 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 a.s./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 a.s./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)