

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB1913H

Product name: Roxy XL

Chemical active substances:

Prosulfocarb, 900 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: September 2022

MS Finalisation date: 04/08/2023

After commenting period: 21/11/2023

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Version history

| When | What |
|----------------|------------------------------------------------------------------|
| September 2022 | Initial submission by the applicant for approval of new product. |
| August 2023 | zRMS assessment |
| November 2023 | After commenting period |
| | |
| | |

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on GLOB1913H *

| | |
|--------------------------------------------------------------------------------------------------------------|-------------------------------|
| Product name and code | GLOB1913H |
| Formulation type | Emulsifiable concentrate [EC] |
| Active substance(s) (incl. content) | Prosulfocarb: 900 g/L |
| Function | Herbicide |
| 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 GLOB1913H 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 GLOB1913H according to Regulation (EC) No 1272/2008

| | |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Hazard class(es), categories | Eye Irrit. 2, Skin Sens. 1 |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS07 |
| Signal word | Warning |
| Hazard statement(s) | H317, H319 |
| Precautionary statement(s) | P261, P272, P280, P302+P352, P305+P351+P338, P321, P337+P313, P333+P313, P363 P362+P364, P501 P391 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains: prosulfocarb |

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB1913H

| | Result | PPE / Risk mitigation measures |
|------------|------------|----------------------------------------------|
| Operators | Acceptable | Gloves during mixing/loading and application |
| Workers | Acceptable | None |
| Residents | Acceptable | 5 m + 50% DRT |
| Bystanders | Acceptable | 5 m + 50% DRT |

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No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

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

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

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
|--------------|----------------------------------------------------|-------------------------------|----------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-----------------------------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------|-----------|-----------|
| Use- No.* | Crops and situation (e.g. growth stage of crop) | F, Fn, Fpn G, Gn, Gpn or I ** | Application | | Application rate | | PHI (d) | Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model] | Acceptability of exposure assessment | | | |
| | | | Method / Kind (incl. application technique ***) | Max. number (min. interval between applications) a) per use b) per crop/season | Max. application rate kg as/ha a) a.s. 1 b) a.s. 2 | Water L/ha min / max | | | Operator | Worker | Residents | Bystander |
| 5 | Potatoes | F | Spraying, LCTM | a) 1 b) 1 | a)Prosulfocarb: 3.96 | 155 - 300 | NR | 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 | | | | |

* 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 |

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

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.

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

| | Prosulfocarb |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Common Name | Prosulfocarb |
| CAS-No. | 52888-80-9 |
| Classification and proposed labelling | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | Hazard classes, categories: Acute Tox 4, Skin Sens. 1 Code for hazard pictogram: GHS07 Signal word: Warning Hazard statements: H302, H317 Precautionary statements: P261, P264, P270, P272, P273, P280, P301+P312, P330, P302+P352, P321, P333+P313, P363 |
| Additional C&L proposal | None |
| Agreed EU endpoints | |
| AOEL systemic | 0.007 mg/kg bw/d (corrected for 72% oral absorption) |
| Reference | EFSA Conclusion EFSA Scientific Report (2007) 111, 1-81 |
| Conditions to take into account/critical areas of concern with regard to toxicology | |
| According to Review Report/EFSA Conclusion for active substance | Operator safety |

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB1913H is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB1913H

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification (acc. to the criteria in Reg. 1272/2008) | Reference |
|-------------------------------------------------|----------------------|------------------------|---------------------------------------------------------|---------------------------------------|
| LD ₅₀ oral | Study not necessary. | Yes /No/ Supplementary | None | Theoretical calculations (see Part C) |
| LD ₅₀ dermal | Study not necessary. | Yes /No/ Supplementary | None | Theoretical calculations (see Part C) |
| LC ₅₀ inhalation | Study not necessary. | Yes /No/ Supplementary | None | Theoretical calculations |

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| | | | | |
|---------------------------------------------------------------------|------------------------|---------------------------|--------------------|---------------------------------------|
| | | | | (see Part C) |
| Skin irritation | Non-irritant | Yes /No/ Supplementary | None | Theoretical calculations (see Part C) |
| Eye irritation | Irritant | Yes /No/ Supplementary | Eye Irrit. 2; H319 | Theoretical calculations (see Part C) |
| Skin sensitisation | Sensitising | Yes /No/ Supplementary | Skin Sens. 1; H317 | Theoretical calculations (see Part C) |
| Supplementary studies for combinations of plant protection products | No data – not required | | | |

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB1913H

| | 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) |
|-----------------------------------|---------------------------------------------|--------------------------------------------------------------------------|-----------|--------------------------------------------------------------------|
| 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

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in GLOB1913H (Emulsifiable concentrate [EC]) are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GLOB1913H

| | Prosulfocarb | |
|-----------------|--------------|----------------------------------|
| | Value | Reference |
| Concentrate | 0.24 % | New study reported in Appendix 2 |
| Dilution (1:86) | 3 % | New study reported in Appendix 2 |

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6.5.1 Justification for proposed values – Prosulfocarb

Proposed dermal absorption rates for prosulfocarb are based on dermal absorption studies on a formulation identical to GLOB1913H. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of prosulfocarb/GLOB1913H that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

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

| Test | Concentrate | Spray dilution (1:133 1:86) | Formulation in study | Acceptability of study | Justification provided on representativity of study formulation for current product | Acceptability of justification | Reference* |
|------------------|-------------|-----------------------------------|----------------------|--------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| In vitro (human) | 0.24% | 3% | GLOB1913H | Yes / No / Supplementary | Not required | Justification accepted. Endpoint can be used for current product / Justification not accepted. Endpoint cannot be used for current product. | Hassler S., 2020 |

* indicates that a study was reviewed at EU level

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 | GLOB1913H |
| Formulation type | EC |
| Category | Herbicide |
| Container size(s), short description | 0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L, HDPE, HDPE-F, HDPE-EVOH, HDPE/PA, 42-63 mm |
| Active substance(s) (incl. content) | Prosulfocarb 900 g/L |
| AOEL systemic | 0.007 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 72 % |

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| | |
|-------------------|------------------------------------------------------------------------------------------|
| Dermal absorption | Concentrate: 0.24% Dilution: 3% (Dilution rate: 1:86) (Based on product GLOB1913H) |
|-------------------|------------------------------------------------------------------------------------------|

6.6.1 Selection of critical use(s) and justification

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

Justification

The use in potatoes has the highest dose rate and is covering all other uses.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance during application of GLOB1913H according to the critical use(s) 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 use(s) | Potato (max. 4.4 L product/ha) |
| Model(s) | 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)

| Prosulfocarb | | | |
|-----------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 3.96 kg a.s./ha | |
| Spray application (AOEM; 75 th percentile) Body weight: 60 kg | Work wear (arms, body and legs covered) M/L and A | 0.0277416 | 396.31 |
| | Work wear (arms, body and legs covered) M/L and A + Gloves M/L and A | 0.0020866 | 29.81 |

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.

| | |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study comment 6.6.2: | The applicant presented calculations for the application of Roxy XL (GLOB1913H) on potato: max dose 4.4 L/ha (Field). It is the worst case and the operator exposure assessment which was performed also covers intended uses on cereals within the Central Zone as were given in Part B, Section 0 of this registration documentation. The calculations were done correctly. |
| Agreed endpoint 6.6.2: | According to EFSA AOEM calculations, it can be concluded that the risk of operator exposure during mixing & loading and application using the tractor-mounted on field on potato is acceptable under conditions of intended use when gloves are used during mixing/loading and application and the work wear (long sleeved shirt, long trousers) is worn during loading, mixing and application. Due to the fact that the product is classified as Eye Irrit. 2 H319 and Skin Sens. 1 H317, the operator should wear protective goggles or face protection during mixing/loading and application operations. Thus, the operator using Roxy XL (GLOB1913H) will be safe as long as he wears work wear, gloves and protective goggles or face protection. |

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(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB1913H according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

| | |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Critical use(s) | Potato (max. 1 x 4.4 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 |

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

| | | Prosulfocarb | |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | |
| Number of applications and application rate | | 1 x 3.96 kg a.s./ha | |
| Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.1485000 | 2121.43 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.0166320 | 237.60 |

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

The AOEM model predicts exposure to prosulfocarb above the acceptable limits for a worker assuming arms, body and legs covered (workwear; bare hands). To refine the risk, the generic Dislodgeable Foliar Residues (DFR) were refined (0.62 µg/cm²/kg a.s./ha) and the transfer coefficient (TC) recalculated based on the refined DFR for the use of prosulfocarb as determined in the study of Perny, A. (2016) summarized under section 6.6.3.3 below.

Table 6.6-6: Estimated worker exposure (longer term exposure) - refined

| | | Prosulfocarb | |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 0.62 µg/cm ² /kg a.s./ha | | | |
| Number of applications and application rate | | 1 x 3.96 kg a.s./ha | |
| Body weight: 60 kg | Work wear (arms, body and legs covered) TC: 601 cm ² /person/h | 0.001476 | 21.08 |

6.6.3.3 Measurement of worker exposure

Since worker exposure estimations carried out for prosulfocarb indicated that the acceptable operator exposure level (AOEL) was exceeded under conditions of intended uses, a field study measuring the worker exposure has been provided. A summary of the study is presented below. For the detailed evaluation of new studies please refer to Appendix 4. No detailed summaries are provided if the study was already assessed and accepted at EU level.

A worker exposure study was performed using an 800 g/L EC formulation of prosulfocarb in 2015, in Northern France. Based on this study, the generic Dislodgeable Foliar Residues were refined and the transfer coefficient was recalculated. The study is summarized below.

| | |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Report: | Perny, A (2016). Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe, 2015. ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France Laboratory Report No. RB424, issue date 29 December 2015. Unpublished. Syngenta File No. A8545G_10414 |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

The purpose of the study was the determination of dermal and inhalation exposure of re-entry workers during typical tasks related to crop scouting activities following a tractor boom application of A8545G (emulsifiable concentrate formulation of 800 g/L prosulfocarb) on cereal crops at BBCH stage 25-26. The study was conducted under field conditions.

Twelve operators were recruited and monitored. The dermal and inhalation exposure of these subjects to the test substance was monitored at three locations in Northern France (4 workers per site) for a duration of 2 hours for each worker, which is considered a representative duration for crop inspection activities according to the EFSA guidance¹ on non-dietary exposure assessment.

¹ EFSA 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 [55 pp.]

Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted of a long-sleeved T-shirt, leggings and cotton socks, covering arms, legs, feet and torso. Head exposure was measured by face/neck wipes. Nitrile dosimeter gloves were used for the determination of potential hand exposure. Actual dermal exposure of the hands beneath protective gloves was determined by the hand wash procedure. Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator's breathing zone.

The test substance was applied at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. Applications were made to crops 1-2 hours before the workers re-entered the field in order to allow the spray to dry.

Samples of each dosimeter matrix were fortified in the field to assess potential degradation of prosulfocarb due to exposure to environmental conditions, handling, packaging, shipping, and storage.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, actual hand exposure for protected hands beneath gloves and (potential) inhalation exposure were calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken. These DFR measurements enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops.

Based on this study, the generic Dislodgeable Foliar Residues were refined to 0.62 µg a.i./cm² and the transfer coefficient was recalculated to 601 cm²/h.

Based on the data in this study also transfer coefficient specific for residents was calculated taking into account the outer dosimeters (lower arm and lower leg, i.e. excluding upper arm and leg and torso, which are considered to be clothed), inner dosimeters (lower arm, upper arm, lower leg, upper leg, front torso, rear torso, socks) and hands (hand wash and protective gloves). The transfer coefficients to be used for the resident are the mean of 661.10 cm²/h and the 75th parametric percentile of 849.62 cm²/h for adults, and the mean of 198.33 cm²/h and the 75th parametric percentile of 254.89 cm²/h for children.

| | |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study comment 6.6.3: | <p>The evaluator agrees with estimation of worker exposure after entry into a previously treated area or handling a crop treated with Roxy XL (GLOB1913H) according to the critical use on potato. The worker exposure assessment which was performed also covers intended uses on cereals within the Central Zone as were given in Part B, Section 0 of this registration documentation.</p> <p>The calculations were done correctly.</p> <p>The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of potatoes treated with a product Roxy XL (GLOB1913H), at maximal dose of 4.4 L product/ha calculated with the EFSA AOEM, assuming standard DFR and TC amounted 237,60% of respective AOEL for prosulfocarb. However when empirical</p> |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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| | DFR of 0.62 µg/cm ² /kg a.s./ha and TC of 601 cm ² /person/h were taken into account in calculation the worker exposure amounted to 21.8 % of AOEL for prosulfocarb, thus not causing an unacceptable risk. |
| Agreed endpoint 6.6.3: | According to the calculations, it can be concluded that the risk of worker exposure during re-entry activities is acceptable. The risk for worker exposure during re-entry activities on field of potatoes treated with Roxy XL (GLOB1913H) is acceptable without the PPE but worker should be wearing the adequate work clothing (arms, body and legs covered) for its intended use within good agricultural practice. |

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 6.6-7 shows the exposure model(s) used for estimation of resident and bystander exposure to prosulfocarb. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

| | |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Critical use(s) | Potato (max.1 x 4.4 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 |

Table 6.6-8: Estimated resident exposure (longer term exposure)

| | | Prosulfocarb | |
|----------------------------------------------------------------------------------------------------------------------|--|------------------------------------|--------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 m Drift reduction technology: no | | | |

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| | | | |
|---------------------------------------------------------------------|-----------------------------------|---------------------|--------|
| DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | |
| Number of applications and application rate | | 1 x 3.96 kg a.s./ha | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0327262 | 467.52 |
| | Vapour (75 th perc.) | 0.0010700 | 15.29 |
| | Deposits (75 th perc.) | 0.0040449 | 57.78 |
| | Re-entry (75 th perc.) | 0.0200475 | 286.39 |
| | Sum (mean) | 0.0382241 | 546.06 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0076969 | 109.96 |
| | Vapour (75 th perc.) | 0.0002300 | 3.29 |
| | Deposits (75 th perc.) | 0.0008094 | 11.56 |
| | Re-entry (75 th perc.) | 0.0111375 | 159.11 |
| | Sum (mean) | 0.0133859 | 191.23 |

The AOEM model predicts exposure to Prosulfocarb above the acceptable limits for residents living near fields treated with GLOB1913H. To refine the risk, the generic Dislodgeable Foliar Residues (DFR) were refined and the transfer coefficient (TC) recalculated based on the refined DFR for the use of Prosulfocarb. Reference is made to section 6.6.3.3 for the study summary in which the DFR measurements were performed. Refined calculations for the resident exposure are shown below.

Table 6.6-9: Estimated resident exposure (longer term exposure)

| | | Prosulfocarb | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------|--------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes – 50% DT ₅₀ : 30 days DFR: 0.62 µg/cm ² /kg a.s./ha TC adult: 601-849.62 cm ² /h | | | |
| Number of applications and application rate | | 1 x 3.96 kg a.s./ha | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0063 | 86.85 |
| | Vapour (75 th perc.) | 0.00107 | 15.29 |
| | Deposits (75 th perc.) | 0.0016613 | 23.73 |
| | Re-entry (75 th perc.) | 0.00033 | 6.70 |
| | Sum (mean) | 0.006968 | 98.06 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0013 | 18.50 |
| | Vapour (75 th perc.) | 0.00023 | 3.29 |
| | Deposits (75 th perc.) | 0.0003324 | 4.75 |
| | Re-entry (75 th perc.) | 0.00018 | 3.72 |

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| | | | |
|--|------------|----------|-------|
| | Sum (mean) | 0.001374 | 19.57 |
|--|------------|----------|-------|

Using the refined DRF and TC values, the risk for residents is acceptable when using a buffer zone of 5 m, 50% drift reducing techniques and a minimal water volume of 155 L/ha.

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for prosulfocarb 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.

| | |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study comment 6.6.4: | <p>The evaluator agrees with estimation of resident exposure after application of Roxy XL (GLOB1913H) on potato. The resident (child and adult) exposure assessment which was performed also covers intended uses on cereals within the Central Zone as were given in Part B, Section 0 of this registration documentation.</p> <p>The exposure estimation of resident (adult and child) to prosulfocarb, applied on a field of potatoes at maximal dose of 4.4 L product/ha, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted 546.06 % to 191.23% of respective AOEL. However when empirical DFR of 0.62 µg/cm²/kg a.s./ha and TC of 601 849.62 cm²/person/h and drift reduction technology (50%) and 5 m buffer strip were taken into account in calculation the exposure amounted to 98.06 % of AOEL for child resident and 19.57 % of AOEL for adult resident, thus not causing an unacceptable risk.</p> <p>The calculations were done correctly. The exposure assessment for residents also covers bystander exposure.</p> |
| Agreed endpoint 6.6.4: | <p>According to calculations, it can be concluded that there is no unacceptable risk to any resident (child and adult) and bystander after application product Roxy XL (GLOB1913H) to potatoes at maximal dose of 4.4 L product/ha when drift reduction technology (50%) and 5 m buffer strip are used.</p> |

6.6.5 Combined exposure

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------|------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------------------------|
| KCP 7.2 | Perny A. | 2016 | Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe RB424 Anadiag GLP Unpublished | N | Syngenta <i>Globachem access</i> |
| KCP 7.3 | Hassler S. | 2020 | Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as Prosulfocarb 900 EC through human skin membranes 20200051 Innovative Environmental Services (IES) Ltd. GLP Unpublished | N | Globachem NV |

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

| 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 |
|------------|-----------|------|---------------------------------------------------------------------------------------------------------------|-------------------------|-------|
| None | | | | | |

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 |
| | | | | | |

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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 Published/Unpublished | Y/N | Owner |
| | | | | | |

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Bridging was not performed.

A 2.2 Acute oral toxicity (KCP 7.1.1)

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.5 Skin irritation (KCP 7.1.4)

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.6 Eye irritation (KCP 7.1.5)

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.7 Skin sensitisation (KCP 7.1.6)

No tests were performed on GLOB1913H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

None.

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)

A 2.10.1 Study 1 – Prosulfocarb in GLOB1913H

| | |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Comments of zRMS: | <p>The study performed according to international guidelines and in GLP conditions is acceptable.</p> <p>The results of the study were used in line with recommendations of the EU Dermal absorption guidelines (EFSA Journal 2017;15(6):4873) to derive the following dermal absorption values through human skin for assessment of dermal exposure:</p> <ul style="list-style-type: none"> - 0.24 % for the concentrated product and - 3 % for the diluted product (1:86) |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| | |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference | KCP 7.3 |
| Report | Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1913H through human skin membranes, Hassler S., 2020, 20200051 |
| Guideline(s) | Yes, OECD 428, Council Regulation (EC) No 440/2008, Method B45 |
| Deviations | No |
| GLP | Yes |
| Acceptability | Yes /No/Supplementary |
| Duplication (if vertebrate study) | No |

Materials and methods

| | | |
|---------------|----------------------|------------|
| Test material | Name (Lot/Batch No.) | XXV/43/A/1 |
|---------------|----------------------|------------|

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| | | |
|---------------|----------------------|---------------------|
| Product | Test preparation | Spiking |
| | Specific activity | 7161 kBq/mg |
| | Radiochemical purity | 96.81% |
| | Name (Lot/Batch No.) | PC38-07022019.01 |
| | Company code | Prosulfocarb 900 EC |
| | Concentration a.s. | 900 g/L |
| Blank product | Formulation type | EC |
| | Name (Lot/Batch No.) | - |
| | Concentration a.s. | - |

| | | |
|--------------------|-------------------------------|---------------------------------------------|
| Test system | | |
| Diffusion cell | Cell type | dynamic |
| | (if dynamic) Flow rate | 3 ml/h |
| | Exposed skin area | 1 cm ² |
| | Cover | unoccluded |
| Membrane | Skin type | dermatomed |
| | Skin thickness range | 400 µm |
| | Skin donors age | 39-67 |
| | Skin donors sex | m+f |
| | Location | abdomen |
| | Source | ex vivo |
| | Integrity test | Y |
| Receptor | Receptor medium | Phosphate buffered saline with 5% Volpo N20 |
| | Solubility in receptor medium | Y |
| Sample Time | Exposure time | 6 h |
| | Observation time | 24 h |
| Sampling | Sample intervals | 1-2 h |
| Washing | | post exposure + post observation |
| Final Procedure | Tape stripping | y |
| | TS1-2 analysed separately | Y |
| Remarks: | | |

| Tested doses | Concentrate | Spray dilution 1 |
|---------------------------------|-------------|------------------|
| Target concentration [mg/ml] | 900 | 10.5 |
| Area dose [µg/cm ²] | 9000 | 105 |
| Total dose [µg/cell] | 9000 | 105 |
| Specific activity [kBq/ml] | 1508 | 713 |
| No. of donors | 5 | 4 |
| No of cells used/valid cells | 10/10 | 10/10 |

Results and discussions

Table A 1: In-vitro dermal penetration of active substance 1 formulated as product code/name GLOB1913H/Roxy XL through human skin - Recovery data

| Dose group | High dose | Low dose |
|------------------------------------------------|---------------------------|-----------------------|
| | (Formulation concentrate) | (Spray dilution 1:86) |
| Target concentration [mg/mL] | 900 | 10.5 |
| Target dose [µg/cm ²] | 9000 | 105 |
| Mean actual applied dose [µg/cm ²] | 9036 | 105.7 |
| | Recovery [%] | Recovery [%] |

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| | Mean | S.D. | Mean | S.D. |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------|-----------------------|------|
| Dislodgeable dose | | | | |
| Skin washing after 6 + 24 h | 98.15 | 2.46 | 85.86 | 5.32 |
| Donor chamber wash | 0.10 | 0.08 | 0.71 | 0.37 |
| Dose associated to skin | | | | |
| Tape strips: 1 st sample, strips 1 + 2 | 0.28 | 0.24 | 7.18 | 4.39 |
| Tape strips: 2 nd sample; strips 3 – 10 | 0.10 | 0.03 | 0.20 | 0.10 |
| Skin preparation | 0.05 | 0.05 | 0.69 | 0.21 |
| Absorbed dose | | | | |
| Receptor fluid | 0.03 | 0.01 | 1.52 | 0.57 |
| Receptor chamber wash | 0.01 | 0.00 | 0.07 | 0.03 |
| Total recovery¹ | | | | |
| Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}] | No [29.67% ± 8.16] | | No [36.41% ± 8.41] | |
| If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ² | 0.19 | 0.07 | 2.48 | 0.76 |
| If yes: Absorption estimates = absorbed dose + skin preparation | N/A | N/A | N/A | N/A |
| Absorption estimate normalised ³ | | | | |
| Relevant absorption estimate ⁴ | 0.238 | | 3.030 | |
| Absorption estimates used for risk assessment⁵ | 0.24 | | 3 | |

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, the standard deviation corrected for the number of replicates was added to the mean% dermal penetration.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint:

The dermal penetration of prosulfocarb formulated as GLOB1913H through human dermatomed skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 0.19 ± 0.07% (mean ± standard deviation) and 2.48 ± 0.76% for the formulation concentrate and the 1:86 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 0.24% and 3% for the formulation concentrate and the 1:86 spray dilution based on the EFSA guidance criteria.

A 2.11 Other/Special Studies

/

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Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Prosulfocarb

Table A 2: Estimation of longer term operator exposure towards prosulfocarb according to EFSA guidance, including input parameters

| Operator exposure for GLOB1913H outdoor spray applications | | | | | |
|------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------|--------------------------|--------------------|------------------------------|
| Application rate of active substance | 3.96 | kg a.s./ha | L.AppRate | | |
| Assumed area treated | 50 | ha/day | L.AreaTreated | | |
| Amount of active substance applied | 198 | kg a.s./day | L.AmountAS | | |
| Dermal absorption of the product | 0.24% | | L.AbsorpProduct | | |
| Dermal absorption of in-use dilution | 3.00% | | L.AbsorInUse | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | | | |
| Indoor or Outdoor application | Outdoor | | | | |
| Application method | Downward spraying | | | | |
| Application equipment | Vehicle-mounted | | | | |
| Season | not relevant | | | | |
| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 284709 | 1093069 | AOEM | |
| | Body | 146800 | 334746 | AOEM | |
| | Head | 10273 | 56342 | AOEM | |
| | Protected hands (gloves) | 1076 | 39217 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 2580 | 28958 | AOEM | |
| | Protected head (hood and face shield) | 165 | 3190 | AOEM | |
| | Inhalation | 18 | 33 | AOEM | |
| | Protective Equipment | Select for inclusion | | Penetration factor | Inhalation Protection factor |
| | Gloves | No | | | |
| | Clothing | work wear - arms, body and legs covered | | cl. in AOEM model | |
| | Head and respiratory PPE | None | | 1 | 1 |
| | Water soluble bag | No | | 1 | |
| Application | Exposure values | µg exposure/day applied | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 29368 | 110223 | AOEM | |
| | Body | 16421 | 84648 | AOEM | |
| | Head | 776 | 2340 | AOEM | |
| | Protected hands (gloves) | 749 | 6175 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 450 | 1105 | AOEM | |
| | Inhalation | 15 | 61 | AOEM | |
| | Protective Equipment | Select for inclusion | | Penetration factor | Inhalation Protection factor |
| | Gloves | No | | | |
| | Clothing | work wear - arms, body and legs covered | | cl. in AOEM model | |
| | Head and respiratory PPE | None | | 1 | 1 |
| | Closed cab | No | | vehicle mounted | |

1. Total

| | Without RPE/PPE | With RPE/PPE |
|------------------------------------------------------------------------------------------------|------------------|------------------|
| Longer term | | |
| Total systemic exposure from mixing, loading and application (mg a.s./day) | 2.4897301 | 1.6644974 |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | 0.0414955 | 0.0277416 |
| % of RfNAS | 592.79% | 396.31% |

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Table A 3: Estimation of longer term operator exposure towards prosulfocarb according to EFSA guidance, including input parameters – gloves M/L and A

| Operator exposure for GLOB1913H outdoor spray applications | | | | | |
|------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------|--------------------------|--------------------|------------------------------|
| Application rate of active substance | 3.96 | kg a.s./ha | L.AppRate | | |
| Assumed area treated | 50 | ha/day | L.AreaTreated | | |
| Amount of active substance applied | 198 | kg a.s./day | L.AmountAS | | |
| Dermal absorption of the product | 0.24% | | L.AbsorpProduct | | |
| Dermal absorption of in-use dilution | 3.00% | | L.AbsorbUse | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | | | |
| Indoor or Outdoor application | Outdoor | | | | |
| Application method | Downward spraying | | | | |
| Application equipment | Vehicle-mounted | | | | |
| Season | not relevant | | | | |
| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 284709 | 1093069 | AOEM | |
| | Body | 146800 | 334746 | AOEM | |
| | Head | 10273 | 56342 | AOEM | |
| | Protected hands (gloves) | 1076 | 39217 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 2580 | 28958 | AOEM | |
| | Protected head (hood and face shield) | 165 | 3190 | AOEM | |
| | Inhalation | 18 | 33 | AOEM | |
| | Protective Equipment | Select for inclusion | | Penetration factor | Inhalation Protection factor |
| | Gloves | Yes | | cl. in AOEM model | |
| | Clothing | work wear - arms, body and legs covered | | cl. in AOEM model | |
| | Head and respiratory PPE | None | | 1 | 1 |
| Application | Water soluble bag | No | | 1 | |
| | Exposure values | µg exposure/day applied | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 29368 | 110223 | AOEM | |
| | Body | 16421 | 84648 | AOEM | |
| | Head | 776 | 2340 | AOEM | |
| | Protected hands (gloves) | 749 | 6175 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 450 | 1105 | AOEM | |
| | Inhalation | 15 | 61 | AOEM | |
| | Protective Equipment | Select for inclusion | | Penetration factor | Inhalation Protection factor |
| | Gloves | Yes | | cl. in AOEM model | |
| | Clothing | work wear - arms, body and legs covered | | cl. in AOEM model | |
| | Head and respiratory PPE | None | | 1 | 1 |
| | Closed cab | No | | vehicle mounted | |

1. Total

| | Without RPE/PPE | With RPE/PPE |
|------------------------------------------------------------------------------------------------|------------------|------------------|
| Longer term | | |
| Total systemic exposure from mixing, loading and application (mg a.s./day) | 2.4897301 | 0.1251974 |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | 0.0414955 | 0.0020866 |
| % of RYNAS | 592.79% | 29.81% |

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Prosulfocarb

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Table A 4: Estimation of longer term worker exposure towards prosulfocarb according to EFSA guidance, including input parameters

| Worker exposure from residues on foliage for GLOB1913H | | | | |
|--------------------------------------------------------------------|-------------------------------------|-----------------------------------------|-------------------------------------|-----------------|
| 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 | 3.96 | kg a.s./ha | | i_AppRate |
| Number of applications | 1 | | | i_AppNo |
| Interval between multiple applications | 365 | days | | i_AppInt |
| Half-life of active substance | 30 | days | | d_HalfLifeAS |
| Multiple application factor | 1.0 | | | d_MAF |
| Dermal absorption of the product | 0.24% | | | i_AbsorpProduct |
| Dermal absorption of the in-use dilution | 3.00% | | | i_Absorpinuse |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 11.88 | µg a.s./cm ² | | d_DFR |
| Working hours | 2 | hr | | d_WorkHr |
| Dermal transfer coefficient - Total potential exposure | 12500 | cm ² /hr | | d_DermTcUCV |
| Dermal transfer coefficient - arms, body and legs covered | 1400 | cm ² /hr | | d_DermTcCV1 |
| 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)} | | d_InhalTcAut |
| Inhalation transfer coefficient for cutting ornamentals | NA | ha/hr*10 ^{^(-3)} | | d_InhalTcCut |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA | ha/hr*10 ^{^(-3)} | | d_InhalTcSort |
| 1. Total | | | | |
| | Potential exposure | Work wear - arms, body and legs covered | Working wear and gloves | Comments |
| Total systemic exposure (mg a.s./day) | 8.9100000 | 0.9979200 | no TC available for this assessment | |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 0.1485000 | 0.0166320 | | |
| % of RVNAS | 2121.43% | 237.60% | | |

Table A 5: Estimation of longer term worker exposure towards prosulfocarb according to EFSA guidance, including input parameters – refined DFR and TC

| Worker exposure | |
|----------------------------------|----------|
| DFR | 0.62 |
| TC | 601 |
| T | 2 |
| Dosis | 3.96 |
| Dermal absorption (%) | 3 |
| PDE (mg a.s./d) | 2.951 |
| Systemic exposure (mg a.s./d) | 0.088535 |
| Worker exposure (mg a.s./kg bw x | 0.001476 |
| AOEL | 0.007 |
| % AOEL | 21.08 |

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Prosulfocarb

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Table A 6: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters

| Resident exposure for GLOB1913H | | | | | |
|-----------------------------------------------------------------------------|------------------------------------------------------|--------------------------|--|------------------------------------|--|
| Croptype | Root and tuber vegetables | | | | |
| Application method | Downward spraying | | | | |
| Application equipment | Vehicle-mounted | | | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | | | |
| Buffer strip | 2-3 m | | | | |
| Application rate of the product | 3.96 kg a.s./ha | | | | |
| Concentration of active substance (in-use dilution for liquid applications) | 39.6 g a.s./l | | | | |
| Dermal absorption of product | 0.24% | | | | |
| Dermal absorption of in-use dilution | 3.00% | | | | |
| Oral absorption | 72.00% | | | | |
| Dislodgeable foliar residue (L_AppRate*_DFR) | 11.88 µg a.s./cm² | | | | |
| low volatile substances | | | | | |
| Vapour pressure of in-use dilution | having a vapour pressure of Pa | | | | |
| Concentration in air | 0.001 mg/m³ | | | | |
| 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 m³/day/kg | | | | |
| Breathing rate child (1-3 year old) | 1.07 m³/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 cm²/hour | | | | |
| Transfer coeff. of surface deposits-child (1-3 year old) | 2600 cm²/hour | | | | |
| Saliva extraction percentage | 50.00% | | | | |
| Surface area of hands mouthed | 20 cm² | | | | |
| Frequency of hand to mouth activity | 9.5 events/hour | | | | |
| Ingestion rate for mouthing of grass per day | 25 cm² | | | | |
| Dislodgeable residues percentage transferability for object to mouth | 20.00% | | | | |
| Transfer coefficient for entry into treated crops (75th percentil | 7500 cm²/h | | | | |
| Transfer coefficient for entry into treated crops (75th percentil | 2250 cm²/h | | | | |
| Transfer coefficient for entry into treated crops (mean) - adult | 5980 cm²/h | | | | |
| Transfer coefficient for entry into treated crops (mean) - child | 1794 cm²/h | | | | |
| 1. Total | | | | | |
| 1.1 1-3 year old child | | | | | |
| Spray drift (75th percentile) | | Vapour (75th percentile) | | Surface deposits (75th percentile) | |
| Total systemic exposure (mg a.s./day) | | 0.3272623 | | 0.0107000 | |
| Total systemic exposure per kg body weight (mg a.s./kg bw/day) | | 0.0327262 | | 0.0010700 | |
| % of RYNAS | | 467.52% | | 15.29% | |
| 1.2 Adult | | | | | |
| Spray drift | | Vapour | | Surface deposits | |
| Total systemic exposure (mg a.s./day) | | 0.4618152 | | 0.0138000 | |
| Total systemic exposure per kg body weight (mg a.s./kg bw/day) | | 0.0076969 | | 0.0002300 | |
| % of RYNAS | | 109.96% | | 3.29% | |

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Table A 7: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters - refined

| | |
|----------------------------------------------------------------------------|-----------|
| Resident adult exposure 75th percentile | |
| Formulation (liquid = 1, solid = 2) | 1 |
| Dose rate a.i. (g/ha) | 3360 |
| Water volume (L/ha) | 155 |
| Concentration (mg a.i./mL) | 25.548387 |
| MAF | 1 |
| Drift reduction (0.5 or 1) | 0.5 |
| Dermal absorption (%) | 3 |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Vapour pressure (Pa) | 0.00079 |
| Oral absorption (%) | 72 |
| AOEL (mg a.i./kg bw \times d) | 0.007 |
| Spray drift 75th percentile | |
| Dermal exposure (mL/person) (see table) | 0.24 |
| Light clothing adjustment factor (%) | 18 |
| Inhalation exposure (mL/person) (see table) | 0.00009 |
| Systemic dermal exposure (mg a.i./person) | 0.0754 |
| Systemic inhalation exposure (mg a.i./pers) | 0.0023 |
| Total systemic exposure (mg a.i./person) | 0.0777 |
| Total systemic exposure (mg a.i./kg bw) | 0.0013 |
| % AOEL | 18.50 |
| Vapour | |
| Vapour concentration ($\mu\text{g}/\text{m}^3$) | 1 |
| Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$) | 0.23 |
| Systemic exposure via inhalation (mg/d) | 0.0138 |
| Systemic exposure via inhalation (mg/d \times kg) | 0.00023 |
| % AOEL | 3.29 |
| Surface deposits | |
| Application rate (mg/cm^2) | 0.0396 |
| Drift percentage (%) (see table) | 2.3 |
| Turf transferable residues (%) | 5 |
| Transfer coefficient (cm^2/h) | 7300 |
| Duration of exposure (h) | 2 |
| Dermal absorption (%) | 0.03 |
| Systemic exposure (mg/d) | 0.0199465 |
| Systemic exposure (mg/kg bw \times d) | 0.0003324 |
| % AOEL | 4.75 |
| Entry into treated crops 75th percentile | |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Transfer coefficient (cm^2/h) | 849.62 |
| Timing exposure (hours) | 0.25 |
| Dose rate (kg a.i./ha) | 3.96 |
| Dermal absorption (%) | 3 |
| Systemic exposure (mg a.s./d) | 0.016 |
| Systemic exposure (mg a.s./kg bw \times d) | 0.00026 |
| % AOEL | 3.72 |

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| | |
|----------------------------------------------------------------------------|------------|
| Resident adult exposure mean | |
| Formulation (liquid = 1, solid = 2) | 1 |
| Dose rate a.i. (g/ha) | 3960 |
| Water volume (L/ha) | 155 |
| Concentration (mg a.i./mL) | 25.5483871 |
| MAF | 1 |
| Drift reduction (0.5 or 1) | 0.5 |
| Dermal absorption (%) | 3 |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Vapour pressure (Pa) | 0.00079 |
| Oral absorption (%) | 72 |
| AOEL (mg a.i./kg bw x d) | 0.007 |
| Spray drift mean | |
| Dermal exposure (mL/person) (see table) | 0.12278 |
| Light clothing adjustment factor (%) | 18 |
| Inhalation exposure (mL/person) (see table) | 0.00008 |
| Systemic dermal exposure (mg a.i./person) | 0.0386 |
| Systemic inhalation exposure (mg a.i./pers) | 0.0020 |
| Total systemic exposure (mg a.i./person) | 0.0406269 |
| Total systemic exposure (mg a.i./kg bw) | 0.0006771 |
| % AOEL | 9.67 |
| Vapour | |
| Vapour concentration ($\mu\text{g}/\text{m}^3$) | 1 |
| Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$) | 0.23 |
| Systemic exposure via inhalation (mg/d) | 0.0138 |
| Systemic exposure via inhalation (mg/d x kg) | 0.00023 |
| % AOEL | 3.29 |
| Surface deposits | |
| Application rate (mg/cm ²) | 0.0396 |
| Drift percentage (%) (see table) | 1.8 |
| Turf transferable residues (%) | 5 |
| Transfer coefficient (cm ² /h) | 7300 |
| Duration of exposure (h) | 2 |
| Dermal absorption (%) | 0.03 |
| Systemic exposure (mg/d) | 0.0156103 |
| Systemic exposure (mg/kg bw x d) | 0.0002602 |
| % AOEL | 3.72 |
| Entry into treated crops | |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Transfer coefficient (cm ² /h) | 661.1 |
| Timing exposure (hours) | 0.25 |
| Dose rate (kg a.i./ha) | 3.96 |
| Dermal absorption (%) | 3 |
| Systemic exposure (mg a.s./d) | 0.012 |
| Systemic exposure (mg a.s./kg bw x d) | 0.000 |
| % AOEL | 2.90 |
| All pathways | |
| Total systemic exposure (mg a.s./d) | 0.082211 |
| Total systemic exposure (mg a.s./kg bw x d) | 0.001370 |
| % AOEL | 19.57 |

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| | |
|---------------------------------------------------------------------------|-----------|
| Resident child exposure 75th percentile | |
| Formulation (liquid = 1, solid = 2) | 1 |
| Dose rate a.i. (g/ha) | 3360 |
| Water volume (L/ha) | 155 |
| Concentration (mg a.i./mL) | 25.548387 |
| MAF | 1 |
| Drift reduction (0.5 or 1) | 0.5 |
| Dermal absorption (%) | 3 |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{h})$) | 0.62 |
| Vapour pressure (Pa) | 0.00079 |
| Oral absorption (%) | 72 |
| AOEL (mg a.i./kg bw x d) | 0.007 |
| Spray drift 75th percentile | |
| Dermal exposure (mL/person) (see table) | 0.17365 |
| Light clothing adjustment factor (%) | 18 |
| Inhalation exposure (mL/person) (see table) | 0.00017 |
| Systemic dermal exposure (mg a.i./person) | 0.0565 |
| Systemic inhalation exposure (mg a.i./person) | 0.0043 |
| Total systemic exposure (mg a.i./person) | 0.0608 |
| Total systemic exposure (mg a.i./kg bw) | 0.0061 |
| % AOEL | 86.85 |
| Vapour | |
| Vapour concentration ($\mu\text{g}/\text{m}^3$) | 1 |
| Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$) | 1.07 |
| Systemic exposure via inhalation (mg/d) | 0.0107 |
| Systemic exposure via inhalation (mg/d x kg) | 0.00107 |
| % AOEL | 15.23 |
| Surface deposits | |
| <i>Dermal exposure</i> | |
| Application rate (mg/cm ²) | 0.0336 |
| Drift percentage (%) (see table) | 2.3 |
| Turf transferable residues (%) | 5 |
| Transfer coefficient (cm ² /h) | 2600 |
| Duration of exposure (h) | 2 |
| Dermal absorption (%) | 0.03 |
| Systemic exposure (mg/d) | 0.0071042 |
| Systemic exposure (mg/kg bw x d) | 0.0007104 |
| % AOEL | 10.15 |
| <i>Hand to mouth exposure</i> | |
| Saliva extraction factor (%) | 50.00 |
| Surface area of hands (cm ²) | 20.00 |
| Frequency of hand to mouth (events/h) | 3.50 |
| Systemic exposure (mg/d) | 0.006230 |
| Systemic exposure (mg/kg bw x d) | 0.0006230 |
| % AOEL | 8.90 |
| <i>Children's object to mouth</i> | |
| Drift percentage (%) (see table) | 2.30 |
| Dislodgeable residues percentage (%) | 20 |
| Ingestion rate for mouthing grass/day (cm ²) | 25 |
| Systemic exposure (mg/d) | 0.0032783 |
| Systemic exposure (mg/kg bw x d) | 0.0003279 |
| % AOEL | 4.68 |
| <i>Total surface deposit exposure</i> | |
| Total systemic exposure (mg a.s./d) | 0.0166130 |
| Total systemic exposure (mg a.s./kg bw x d) | 0.0016613 |
| % AOEL | 23.73 |
| Entry into treated crops 75th percentile | |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{h})$) | 0.62 |
| Transfer coefficient | 254.89 |
| Timing exposure (hours) | 0.25 |
| Dose rate (kg a.i./ha) | 3.36 |
| Dermal absorption (%) | 3 |
| Systemic exposure (mg a.s./d) | 0.00469 |
| Systemic exposure (mg a.s./kg bw x d) | 0.00047 |
| % AOEL | 6.70 |

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| | |
|----------------------------------------------------------------------------|------------|
| Resident child exposure mean | |
| Formulation (liquid = 1, solid = 2) | 1 |
| Dose rate a.i. (g/ha) | 3960 |
| Water volume (L/ha) | 155 |
| Concentration (mg a.i./mL) | 25.5483871 |
| MAF | 1 |
| Drift reduction (0.5 or 1) | 0.5 |
| Dermal absorption (%) | 3 |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Vapour pressure (Pa) | 0.00079 |
| Oral absorption (%) | 72 |
| AOEL (mg a.i./kg bw x d) | 0.007 |
| Spray drift mean | |
| Dermal exposure (mL/person) (see table) | 0.12 |
| Light clothing adjustment factor (%) | 18 |
| Inhalation exposure (mL/person) (see table) | 0.00014 |
| Systemic dermal exposure (mg a.i./pers) | 0.0377 |
| Systemic inhalation exposure (mg a.i./pe) | 0.0036 |
| Total systemic exposure (mg a.i./person) | 0.0412862 |
| Total systemic exposure (mg a.i./kg bw) | 0.0041286 |
| % AOEL | 58.98 |
| Vapour | |
| Vapour concentration ($\mu\text{g}/\text{m}^3$) | 1 |
| Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$) | 1.07 |
| Systemic exposure via inhalation (mg/d) | 0.0107 |
| Systemic exposure via inhalation (mg/d) | 0.00107 |
| % AOEL | 15.29 |
| Surface deposits | |
| <i>Dermal exposure</i> | |
| Application rate (mg/cm^2) | 0.0396 |
| Drift percentage (%) (see table) | 1.8 |
| Turf transferable residues (%) | 5 |
| Transfer coefficient (cm^2/h) | 2600 |
| Duration of exposure (h) | 2 |
| Dermal absorption (%) | 0.03 |
| Systemic exposure (mg/d) | 0.0055538 |
| Systemic exposure (mg/kg bw x d) | 0.0005560 |
| % AOEL | 7.94 |
| <i>Hand to mouth exposure</i> | |
| Saliva extraction factor (%) | 50.00 |
| Surface area of hands (cm^2) | 20.00 |
| Frequency of hand to mouth (events/h) | 9.50 |
| Systemic exposure (mg/d) | 0.004876 |
| Systemic exposure (mg/kg bw x d) | 0.0004876 |
| % AOEL | 6.97 |
| <i>Children's object to mouth</i> | |
| Drift percentage (%) (see table) | 1.80 |
| Dislodgeable residues percentage (%) | 20 |
| Ingestion rate for mouthing grass/day (c) | 25 |
| Systemic exposure (mg/d) | 0.00256608 |
| Systemic exposure (mg/kg bw x d) | 0.00025661 |
| % AOEL | 3.67 |
| <i>Total surface deposit exposure</i> | |
| Total systemic exposure (mg a.s./d) | 0.0130015 |
| Total systemic exposure (mg a.s./kg bw) | 0.0013001 |
| % AOEL | 18.57 |
| Entry into treated crops | |
| DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$) | 0.62 |
| Transfer coefficient (cm^2/h) | 198.33 |
| Timing exposure (hours) | 0.25 |
| Dose rate (kg a.i./ha) | 3.96 |
| Dermal absorption (%) | 3 |
| Systemic exposure (mg a.s./d) | 0.004 |
| Systemic exposure (mg a.s./kg bw x d) | 0.00037 |
| % AOEL | 5.22 |
| All pathways | |
| Total systemic exposure (mg a.s./d) | 0.068640 |
| Total systemic exposure (mg a.s./kg bw) | 0.006864 |
| % AOEL | 98.06 |

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)

A worker exposure study was performed using an 800 g/L EC formulation of prosulfocarb in 2015, in Northern France. Based on this study, the generic Dislodgeable Foliar Residues were refined and the transfer coefficient was recalculated.

| | |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Report: | Perny. A (2016). Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe, 2015. ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France Laboratory Report No. RB424, issue date 29 December 2015. Unpublished. Syngenta File No. A8545G_10414 |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Guidelines

This study was done according to OECD Series on Testing and Assessment No. 9 “Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application”, Paris 1997. OCDE/GD(97)148.

Deviations: None

GLP: Yes. Signed and dated GLP and Quality Assurance statements were provided.

Executive Summary

The purpose of the study was the determination of dermal and inhalation exposure of re-entry workers during typical tasks related to crop scouting activities following a tractor boom application of A8545G (emulsifiable concentrate formulation of 800 g/L prosulfocarb) on cereal crops at BBCH stage 25-26. The study was conducted under field conditions.

Twelve operators were recruited and monitored. The dermal and inhalation exposure of these subjects to the test substance was monitored at three locations in Northern France (4 workers per site) for a duration of 2 hours for each worker, which is considered a representative duration for crop inspection activities according to the EFSA guidance² on non-dietary exposure assessment.

Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted of a long-sleeved T-shirt, leggings and cotton socks, covering arms, legs, feet and torso. Head exposure was measured by face/neck wipes. Nitrile dosimeter gloves were used for the determination of potential hand exposure. Actual dermal exposure of the hands beneath protective gloves was determined by the hand wash procedure. Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator's breathing zone.

² EFSA 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 [55 pp.]

The test substance was applied at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. Applications were made to crops 1-2 hours before the workers re-entered the field in order to allow the spray to dry.

Samples of each dosimeter matrix were fortified in the field to assess potential degradation of prosulfocarb due to exposure to environmental conditions, handling, packaging, shipping, and storage.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, actual hand exposure for protected hands beneath gloves and (potential) inhalation exposure were calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken. These DFR measurements enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops.

Materials

| | |
|------------------------------------|--------------------------------------------|
| Test Material: | DEFI, A8545G |
| Description: | Formulation type, Emulsifiable concentrate |
| Lot/Batch #: | BSN4DO220 |
| Stability of test compound: | Stable when stored in cool dry conditions. |

Study Design and Methods

| | |
|----------------------------|---------------------------------------------------------------------|
| Field phase dates: | Start: 13 th March 2015 End: 19 th March 2015 |
| Experimental dates: | 5 th March 2015 to 16 th September 2015 |

Study Description:

Twelve workers (9 male and 3 female) were recruited and monitored for the study. These subjects all had experience in the tasks they were required to perform. All subjects were required to give their informed consent to participate in the study, which was conducted at three sites in Northern France.

The test substance was applied to winter wheat at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. The applications were made using field crop boom sprayers owned by the spray applicators. These applications were made before the workers re-entered the field.

Each of the three trial sites was sub-divided into four individual 1 ha blocks, one per worker. Workers entered the field 1-2 hours after the spray application had been made and performed a typical scouting activity. This activity involved passing through the crop on a row to row basis, periodically bending to touch the plants to inspect them. The frequency of the hand to crop contact varied between workers. The monitoring period for the scouting task was 2 hours, which is considered a representative timescale for this type of activity according to the EFSA guidance on non-dietary exposure assessment.

The dermal and inhalation exposure of the workers to the test substance was monitored during the re-entry activity. Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted

of a long-sleeved cotton T-shirt, cotton leggings and cotton socks, covering arms, legs, feet and torso. This was worn over the operator's regular underwear and directly under the outer dosimeter.

Head exposure was measured by face/neck wipes taken at the end of the working day. Two wipes (10 cm × 10 cm) were moistened with 4 mL diluted soap solution (5 mL pH neutral liquid soap: 1000 mL de-ionised water); one was used to wipe the face and the other was used to wipe the neck. Both wipes were taken as one sample, collected in a polyethylene bag and put into a freezer at the end of each day and stored until transport to the analytical facility.

Nitrile gloves were worn by workers throughout the monitored task. After the end of the task gloves were removed by the study personnel, put in a plastic bag and stored in a freezer at the end of the day until transport to the analytical facility.

Actual dermal exposure of the hands beneath protective gloves was determined using a hand wash procedure carried out once at the end of the monitoring period with 2 portions of 500 mL of diluted soap solution (5 mL pH neutral liquid soap: 1000 mL de-ionised water). Solutions were combined and collected in HDPE bottles, put into a freezer at the end of each day and stored until transport to the analytical facility.

Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator's breathing zone. The pump was operated for the duration of the exposure-monitoring period, and the duration time was recorded. The pump was calibrated to a sample flow rate of approximately 1.5 L/min. The air flow rate was measured before and after use and the average airflow rate was calculated. The pumps were checked periodically, throughout the monitoring period, to ensure that they were running. At the conclusion of the exposure monitoring period the sampling device was disconnected and the XAD-2/OVS tube was sealed. The samples were put in a freezer at the end of each day until transport to the analytical facility.

Study details are given in the table below:

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Table A 8: Summary of study parameters for re-entry workers performing crop inspection in early post-emergence cereals

| Study type | | | Passive dosimetry: Matrices were: cotton/polyester coverall, underwear with long sleeves and long legs; Nitrile gloves, hand wash, face wipes, OVS air filters | | | | |
|----------------------|----------|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|----------------------------------|---------------|
| Crop | | | Cereals, early post emergent | | | | |
| Number of replicates | | | 12 | | | | |
| Spraying equipment | | | Vehicle mounted boom sprayers | | | | |
| Protective clothing | | | Cotton/polyester coverall and nitrile rubber gloves. | | | | |
| Site | Operator | Total time scouting[min] | Area of treated plot (ha) | Crop / Growth stage | kg a.s. /ha | Frequency of scouting activities | |
| | | | | | | Touching plants (n) | Crouching (n) |
| 1 | 1 | 120 | 5.66 | Winter wheat / 25-26 | 3.912 | 100+ | 81 |
| | 2 | 120 | | | | 37 | 37 |
| | 3 | 120 | | | | 18 | 5 |
| | 4 | 122 | | | | 9 | 8 |
| 2 | 5 | 123 | 5.5 | Winter wheat / 25-26 | 3.784 | 26 | 19 |
| | 6 | 120 | | | | 54 | 54 |
| | 7 | 120 | | | | 57 | 37 |
| | 8 | 120 | | | | 147 | 43 |
| 3 | 9 | 121 | 6 | Winter wheat /26 | 4 | 42 | 36 |
| | 10 | 120 | | | | 23 | 19 |
| | 11 | 120 | | | | 40 | 20 |
| | 12 | 120 | | | | 106 | 21 |

The dosimeters acted as collection media for the test substance and were removed at the end, with the assistance of a member of the monitoring team. At the end of the monitoring period, the inner and outer dosimeters were sectioned into six samples (front torso, back torso, lower arms, upper arms, lower legs, upper legs), and each sample was wrapped in aluminium foil, labelled and put into a plastic bag. The samples were put into a freezer at the end of each day and stored until transport to the analytical facility.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, hand exposure for protected hands beneath gloves and (potential) inhalation exposure was calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken to enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops. These samples were collected from a smaller area of 60 m² which was located within each worker's 1 ha work zone. The re-entry worker had no access to this sub-plot. Before application of prosulfocarb was made to the crop the leaf weight to surface area ratio was determined (for each site). From this analysis the minimum number of wheat leaves required to represent a total leaf area (both sides) of a minimum 400 cm² was determined prior to sample collection. Three replicates of treated leaves were collected from each of the trial sub-plots. Leaf samples were collected in glass bottles and stored in cool conditions prior to sample analysis. 400 mL of 0.01% Aerosol OT-100 detergent solution was used for the dislodging procedure. Once added to the leaf samples the jars were shaken for 10 minutes. Dislodging solution was then removed, replaced with new 400 mL solution and the jars shaken for a further 10 minutes. Finally, the dislodging solutions from both sessions were pooled and

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retained in plastic bottles. All DFR samples were extracted with dislodging solution within 4 hours of sampling.

Results

With the exception of the recoveries for the Site 3, inner dosimeter, low level field fortification samples, field fortifications for all dosimeters were in the range of 70% to 110% and no corrections to the dosimeter samples were necessary. Recoveries for the Site 3, inner dosimeter, low level field fortification samples were < 70% and ambient samples with low levels of analyte detected were corrected to 100%. These included the samples for the lower and upper arm, front and rear torso and upper leg. However, the lower leg samples were not corrected, as the workers exposure samples were above the high level fortification level where acceptable field recovery had been achieved.

A summary of the worker exposure results is presented in the table below. For the calculation of potential inhalation exposure an inhalation rate of 21 L/min was assumed.

Table A 9: Individual Dermal and Inhalation exposures for re-entry workers performing crop inspection in early post-emergence cereals

| | Residue (prosulfocarb) | | | | | |
|------------------------------------------|------------------------|--------|---------|--------|---------|---------|
| Operator | 1 | 2 | 3 | 4 | 5 | 6 |
| Outer dosimeter (µg/sample) | 1588.22 | 537.17 | 1102.67 | 287.5 | 972.22 | 1042.2 |
| Inner dosimeter (µg/sample) | 602.63 | 136.61 | 610.17 | 470.02 | 326.49 | 608.24 |
| Socks (µg/sample) | 44.28 | 0.28 | 0.38 | 76.54 | 3.33 | 0.57 |
| Face/neck wipes (µg/sample) | 1.28 | 2.27 | 0.32 | 0.22 | 1.4 | 8.05 |
| Nitrile Gloves (µg/sample) | 2769.97 | 118.59 | 305.62 | 84.28 | 2309.24 | 4111.7 |
| Hand wash (µg/L) | 0.28 | 0.22 | 4.46 | 0.15 | 0.52 | 0.36 |
| PDE (mg) | 5.007 | 0.795 | 2.024 | 0.919 | 3.613 | 5.771 |
| ADE (mg) - no gloves | 3.418 | 0.258 | 0.921 | 0.631 | 2.641 | 4.729 |
| ADE (mg) – with gloves | 0.648 | 0.139 | 0.615 | 0.547 | 0.332 | 0.617 |
| PIE (mg) | 0.016 | 0.012 | 0.009 | 0.003 | 0.012 | 0.024 |
| DFR (µg/cm ²) – Mean value | 0.903 | 1.793 | 1.540 | 1.329 | 3.358 | 2.337 |
| DFR (µg/cm ² /kg a.s./ha) | 0.231 | 0.458 | 0.394 | 0.340 | 0.887 | 0.618 |
| TC (cm ² /h) Actual no gloves | 1892.82 | 71.95 | 298.95 | 233.64 | 383.65 | 1011.75 |

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| | Residue (prosulfocarb) | | | | | |
|------------------------------------------|------------------------|---------|--------|---------|---------|---------|
| Operator | 1 | 2 | 3 | 4 | 5 | 6 |
| | Residue (prosulfocarb) | | | | | |
| Operator | 7 | 8 | 9 | 10 | 11 | 12 |
| Outer dosimeter (µg/sample) | 2817.27 | 1769.59 | 848.38 | 1985.77 | 1118.43 | 1132.53 |
| Inner dosimeter (µg/sample) | 461.181 | 388.3 | 305.46 | 286.94 | 316.68 | 448.61 |
| Socks (µg/sample) | 46.98 | 25.41 | 0.12 | 0.46 | 0.11 | 0.31 |
| Face/neck wipes (µg/sample) | 2.82 | 3.39 | 3.9 | 4.45 | 2.87 | 4.09 |
| Nitrile Gloves (µg/sample) | 1270.18 | 1569.7 | 593.42 | 2053.19 | 1338.22 | 762.42 |
| Hand wash (µg/L) | 0.37 | 18.74 | 0.34 | 0.46 | 0.51 | 0.42 |
| PDE (mg) | 4.599 | 3.775 | 1.752 | 4.331 | 2.777 | 2.348 |
| ADE (mg) - no gloves | 1.782 | 2.006 | 0.903 | 2.345 | 1.658 | 1.216 |
| ADE (mg) – with gloves | 0.511 | 0.436 | 0.310 | 0.292 | 0.320 | 0.453 |
| PIE (mg) | 0.035 | 0.031 | 0.023 | 0.018 | 0.014 | 0.013 |
| DFR (µg/cm ²) – Mean value | 2.803 | 2.977 | 3.108 | 2.757 | 2.575 | 3.488 |
| DFR (µg/cm ² /kg a.s./ha) | 0.741 | 0.787 | 0.777 | 0.689 | 0.644 | 0.872 |
| TC (cm ² /h) Actual no gloves | 317.75 | 336.88 | 144.09 | 425.32 | 322.02 | 174.29 |

PDE = the sum of residues of outer dosimeter, inner dosimeter, nitrile gloves, hand-wash and face/neck wipes.

ADE (no protective gloves) = the sum of residues of inner dosimeter, nitrile gloves, hand-wash and face/neck wipes.

Potential Inhalation exposure = Residues measured in the breathing zone extrapolated to an inhalation rate of 21 L/min.

Calculation of TC value for workers

In order to calculate TC values for each replicate, each worker in the study has an associated DFR value. According to the EFSA guidance, TC values are calculated as follows:

$$TC (cm^2/h) = DE (\mu g/h) / DFR (\mu g/cm^2)$$

The table below shows the geometric mean and empirical and parametric 75th percentiles calculated for total systemic exposure, both with and without gloves. The transfer coefficient calculated for this work task is also given.

Table A 10: Summary statistics calculated from the exposure study

| | Geometric mean | Empirical 75 th percentile | Parametric 75 th percentile |
|--------------------------------------------------------|----------------|---------------------------------------|----------------------------------------|
| Total systemic exposure – no gloves (mg/kg bw/day) | 0.0006 | 0.0011* | 0.0010 |
| Total systemic exposure – with gloves (mg/kg bw/day) | 0.0003 | 0.0005* | 0.0004 |
| Transfer coefficient – No gloves (cm ² /hr) | 324.4 | 394.1 | 601.0* |

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| | | | |
|----------------------------------------------------------|------|-------|-------|
| Transfer coefficient – With gloves (cm ² /hr) | 89.2 | 149.0 | 148.2 |
|----------------------------------------------------------|------|-------|-------|

*Values given in bold are the higher of the empirical and parametric estimate and are used for the exposure assessment.

Calculation of TC values for residents and bystanders

The EFSA guidance derives TC values for residents and bystanders entering treated crops by calculating the appropriate percentiles from the datasets for crop inspection for individuals with lower legs and lower arms uncovered. It is possible to derive similar values from this study as the upper and lower arms and legs were analysed and reported separately.

Consequently, the appropriate dosimeters to calculate dermal exposure for residents and bystanders are considered to be:

Outer dosimeter: lower arm, lower leg (i.e. excluding upper arm and leg and torso, which are considered to be clothed)

Inner dosimeter: lower arm, upper arm, lower leg, upper leg, front torso, rear torso, socks

Hands: hand wash and protective gloves. It should be noted that workers in the study were engaged in activities which involved a considerable amount of contact between the hands and treated foliage. Hand exposure as measured on gloves and hand wash was the highest contributor to overall exposure. As such, the TC values are protective of members of the public who are walking through treated fields.

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Table A 11: Dermal exposure and DFR results for re-entry workers performing crop inspection in early growth stage arable crops

| SITE | | 1 | | | | 2 | | | | 3 | | | |
|----------------------------------------------------------------|-----------------|----------------|---------------|----------------|--------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| WORKER | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Bodyweight (kg) | | 78 | 76 | 94 | 94 | 60 | 80 | 66 | 85 | 54 | 76 | 90 | 86 |
| Outer do- simeter (µg/sample) | Lower arm | 361.95 | 72.99 | 17.61 | 8.76 | 54.99 | 126.37 | 101.2 | 119.57 | 96.43 | 36.44 | 28.49 | 28.977 |
| | Upper arm | 28.13 | 42.36 | 10.73 | 4.48 | 20.2 | 28.21 | 89.7 | 163.63 | 39.49 | 37.45 | 49.22 | 37.92 |
| | Front torso | 88.82 | 27.54 | 26.77 | 42.88 | 39.13 | 58.53 | 231.88 | 237.54 | 183.5 | 312.78 | 206.75 | 214.02 |
| | Rear torso | 104.75 | 48.56 | 66.23 | 40.03 | 50.34 | 74.59 | 300.3 | 192.43 | 66.77 | 174.19 | 117.36 | 108.31 |
| | Lower leg | 817.54 | 233.2 | 911.7 | 167.63 | 763.24 | 653.12 | 1529.85 | 754.75 | 346.48 | 1193.3 | 489.08 | 648.34 |
| | Upper leg | 187.03 | 112.52 | 69.63 | 23.72 | 44.32 | 101.38 | 564.34 | 301.67 | 115.71 | 231.61 | 227.53 | 94.97 |
| Inner do- simeter (µg/sample) | Lower arm | 0.33 | 0.58 | 0.42 | 0.52 | 0.06 | 2.48 | 2.804 | 5.62 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Upper arm | 0.12 | 0.08 | 0.54 | 0.3 | 0.04 | 0.06 | 0.06 | 0.24 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Front torso | 0.07 | 1.33 | 2.65 | 0.04 | 0.16 | 3.6 | 3.6 | 3.33 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Rear torso | 0.03 | 0.74 | 1.99 | 0.42 | 0.15 | 4.25 | 4.25 | 5.1 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Lower leg | 524.03 | 128.3 | 543.01 | 441.22 | 280.31 | 455.6 | 301.06 | 323.16 | 230.24 | 189.06 | 212.26 | 386.77 |
| | Upper leg | 78.05 | 5.58 | 61.56 | 27.52 | 45.77 | 142.25 | 146.32 | 50.85 | 0.00 | 0.00 | 0.00 | 0.00 |
| (µg/sample) | Socks | 44.28 | 0.28 | 0.38 | 76.54 | 3.33 | 0.57 | 46.98 | 25.41 | 0.12 | 0.46 | 0.11 | 0.31 |
| (µg/L) | Hand wash | 0.28 | 0.22 | 4.46 | 0.15 | 0.52 | 0.36 | 0.37 | 18.74 | 0.34 | 0.46 | 0.51 | 0.42 |
| (µg/sample) | Nitrile gloves | 2769.97 | 118.59 | 305.62 | 84.28 | 2309.24 | 4111.7 | 1270.18 | 1569.7 | 593.42 | 2053.19 | 1338.22 | 762.42 |
| (µg/sample) | Face/neck wipes | 1.28 | 2.27 | 0.32 | 0.22 | 1.4 | 8.05 | 2.82 | 3.39 | 3.9 | 4.45 | 2.87 | 4.09 |
| Total dermal exposure for resi- dent/bystander (µg) | | 4597.93 | 564.16 | 1850.26 | 807.6 | 3459.21 | 5508.41 | 3412.58 | 2879.86 | 1346.15 | 3575.24 | 2175.96 | 1893.16 |
| Application rate (kg a.i./ha) | | 3.912 | | | | 3.784 | | | | 4.00 | | | |
| DFR (µg/cm ²) | Sample 1 | 0.993 | 1.889 | 1.554 | 1.231 | 3.377 | 2.133 | 2.494 | 2.399 | 3.075 | 2.459 | 2.047 | 2.372 |
| | Sample 2 | 0.883 | 1.836 | 1.51 | 1.539 | 3.522 | 2.5 | 3.453 | 2.855 | 2.885 | 2.482 | 3.068 | 3.221 |
| | Sample 2 | 0.833 | 1.653 | 1.557 | 1.216 | 3.175 | 2.378 | 2.463 | 3.676 | 3.365 | 3.331 | 2.61 | 4.871 |
| | Mean | 0.903 | 1.793 | 1.540 | 1.329 | 3.358 | 2.337 | 2.803 | 2.977 | 3.108 | 2.757 | 2.575 | 3.488 |

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| | Mean/kg a.i./ha | 0.231 | 0.458 | 0.394 | 0.340 | 0.887 | 0.618 | 0.741 | 0.787 | 0.777 | 0.689 | 0.644 | 0.872 |
|-------------------|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Exposure time (h) | | 2 | 2 | 2 | 2.033 | 2.050 | 2 | 2 | 2 | 2.017 | 2 | 2 | 2 |

*values in grey indicate dosimeters which were not included in the calculation of dermal exposure for the resident or bystanders, such that an individual with exposed lower arms and lower legs is represented.

In order to calculate TC values for each replicate, each worker in the study has an associated DFR value. According to the EFSA guidance, TC values are calculated as follows:

$$TC \text{ (cm}^2\text{/h)} = DE \text{ (}\mu\text{g/h)} / DFR \text{ (}\mu\text{g/cm}^2\text{)}$$

This calculation can be carried out for the resident and bystander in the same way using the total dermal exposure values calculated above expressed as $\mu\text{g/h}$, taking into account the specific exposure duration recorded. The table below shows the calculated TC values for each individual as well as the mean and empirical and 75th and 95th percentile values. Corresponding TC values for the child resident and bystander are also calculated taking into account the correction factor of 0.3 as identified from the EFSA guidance.

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Table A 12: Calculation of TC values for resident and bystander

| Replicate | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|------------------------|---------|--------|---------|--------|---------|---------|---------|---------|---------|---------|---------|---------|
| Dermal exposure (µg) | 4597.93 | 564.16 | 1850.26 | 807.60 | 3459.21 | 5508.41 | 3412.58 | 2879.86 | 1346.15 | 3575.24 | 2175.96 | 1893.16 |
| Exposure time (h) | 2 | 2 | 2 | 2.033 | 2.05 | 2 | 2 | 2 | 2.017 | 2 | 2 | 2 |
| Dermal exposure (µg/h) | 2298.97 | 282.08 | 925.13 | 397.18 | 1687.42 | 2754.21 | 1706.29 | 1439.93 | 667.51 | 1787.62 | 1087.98 | 946.58 |
| DFR (µg/cm²) | 0.90 | 1.79 | 1.54 | 1.33 | 3.36 | 2.34 | 2.80 | 2.98 | 3.11 | 2.76 | 2.58 | 3.49 |
| TC adult (cm²/h) | 2545.92 | 157.35 | 600.60 | 298.93 | 502.51 | 1178.52 | 608.66 | 483.74 | 214.75 | 648.31 | 422.52 | 271.38 |
| TC child (cm²/h) | 763.78 | 47.21 | 180.18 | 89.68 | 150.75 | 353.56 | 182.60 | 145.12 | 64.42 | 194.49 | 126.76 | 81.41 |

| Parameter | Log normality | Mean | Empirical 75 th | Parametric 75 th | Empirical 95 th | Parametric 95 th |
|------------------|---------------|--------|----------------------------|-----------------------------|----------------------------|-----------------------------|
| TC adult (cm²/h) | Yes | 661.10 | 618.58 | 849.62 | 1793.85 | 2009.89 |
| TC child (cm²/h) | Yes | 198.33 | 185.57 | 254.89 | 538.16 | 602.97 |

For small datasets, the higher of the appropriate empirical and parametric percentiles should be used in risk assessment. Accordingly, from this evaluation, the parametric 75th TC values for both adult and child resident should be used to calculate exposure during entry into treated crops. The corresponding parametric 95th percentiles could be used to calculate bystander exposure. However, it should be noted that at this point, no guidance is available for setting an appropriate endpoint for this acute exposure scenario. For the resident, the mean values should be used to calculate exposure during re-entry into treated crops when considering the sum of the 4 relevant pathways. The study is considered to be robust and the derivation of the TC values in accordance with the EFSA guidance and as such provides a valid refinement to the EFSA calculator.

| | |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| zRMS comment: | The study performed according to relevant OECD guidelines and in GLP conditions is acceptable and results can be used in estimation of exposure of workers and resident (adult and child). The mean empirical dislodgeable foliar residue (DFR) of prosulfocarb was found to be 0.62 µg/cm ² /kg a.s./ha. Transfer coefficient was found to be 601 cm ² /hour with bare hands and 149 cm ² /hr if protective gloves are worn. |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|