

REGISTRATION REPORT

Part B **Section 6** **Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: HCV07

Product names: Vivendi 300 SL, Auksendy 300 SL, Cliophar Super

Chemical active substance:

Clopyralid-olamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 22/12/2021

MS Finalisation date: July 2023 (initial Core Assessment)

March 2024 (final Core Assessment)

Version history

| When | What |
|---------------|---|
| December 2021 | Article 43 submission for re-registration of HCV07 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191). |
| July 2023 | Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck-through and shaded for transparency. |
| March 2024 | Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period. |

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on HCV07*

| | |
|--|---|
| Product name and code | HCV07 |
| Formulation type | Soluble concentrate (SL) |
| Active substance(s) (incl. content) | Clopyralid-olamine, 395 g/l (300 g ae/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 | Yes (full list of approvals can be found in Part B, Section 0, point 0.1.4) |

* Information on the detailed composition of HCV07 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 HCV07 according to Regulation (EC) No 1272/2008

| | |
|--|---|
| Hazard class(es), categories | Chronic aquatic Cat 1 |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS09 |
| Signal word | Warning |
| Hazard statement(s) | H410 |
| Precautionary statement(s) | P391, P501 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for HCV07

| | Result | PPE / Risk mitigation measures |
|------------|------------|--------------------------------|
| Operators | Acceptable | Gloves during mixing/loading |
| Workers | Acceptable | None |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

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. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model] | Acceptability of exposure as- sessment | | | |
| | | | Method / Kind (incl. applica- tion technique *** | Max. number (min. interval between applications) a) per use b) per crop/ season | Max. applica- tion rate kg as/ha a) Clopyralid (kg.as/ha) | Water L/ha min / max | | | Operator | Worker | Residents | Bystander |
| 7 | Onion (BBCH 11-16) | F | Spraying, LCTM | 1 ; 1 | a) 0.158 kg as/ha (0.120 kg ae/ha†) | 100 - 400 | 42 | Critical GAP for workers, resident, bystander exposure [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

† Application rate is expressed as an acid equivalent (a.e.) within the risk assessment to align with the representation of the reference values.

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

Noticed data gaps are: **none**.

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substance and on EU endpoints and critical areas of concern identified during the EU review are given in

.






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

| | Clopyralid |
|--|--|
| Common Name | Clopyralid |
| CAS-No. | 1702-17-6 |
| Classification and proposed labelling | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | Hazard classes (s), categories: Eyes Cat 1 Chronic aquatic Cat 1 Code(s) for hazard pictogram(s): GHS05, GHS09 Signal word: Danger Hazard statement(s): H318: Causes serious eye damage. H410: Very toxic to aquatic life with long lasting effects. Precautionary statement(s): P273: Avoid release to the environment P280: Wear protective gloves/ protective clothing/ eye protection/ face protection. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P315: Get immediate medical attention. P501: Dispose of contents/container in accordance with applicable regulations. |
| Additional C&L proposal | EU specific statements: EUH401: To avoid risks to human health and the environment, comply with the instructions for use. |
| Agreed EU endpoints | |
| AOEL systemic | 0.15 mg/kg bw/d |
| AAOEL | 0.17 mg/kg bw/d |
| Reference | EFSA Conclusion (2018;16(6):5389) |
| Conditions to take into account/critical areas of concern with regard to toxicology | |
| According to Review Report/EFSA Conclusion for active substance | None |

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for HCV07 is given in the following tables. The studies provided are on the similar formulation EF-243. Both formulations contain 100 g/L clopyralid and are SL formulations. The data provided are therefore considered to be sufficient to support HCV07. 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 HCV07

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification (acc. to the criteria in Reg. 1272/2008) | Reference |
|---|-------------------|---------------|---|---|
| LD ₅₀ oral, rat (OECD 401) | (>) 5000 mg/kg bw | Yes | None |  |
| LD ₅₀ oral, rat (None) | (>) 5000 mg/kg bw | Yes | None |  |
| LD ₅₀ dermal, rat (OECD 402) | (>) 2000 mg/kg bw | Yes | None |  |
| LC ₅₀ inhalation, rat (OECD 403) | (>) 4.27 mg/L air | Yes | None |  |
| Skin irritation, model system | Non-irritant | Yes | None |  |

| | | | | |
|---|------------------------|-----|------|--|
| (OECD 404) | | | | |
| Eye irritation, model system (OECD 405) | Non-irritant | Yes | None | |
| Skin sensitisation, guinea pig/mouse (OECD 406) | Non-sensitising | Yes | None | |
| Supplementary studies for combinations of plant protection products | No data – not required | | | |

Table 6.3-2: Additional toxicological information relevant for classification/labelling of HCV07

| | Substance (concentration in product, % w/w) | Classification of the substance (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
|--|---|--|----------------|--|
| Toxicological properties of active substance(s) (relevant for classification of product) | Clopyralid 300 g/l | H410: Very toxic to aquatic life with long lasting effects. | Reg. 1272/2008 | H410: Very toxic to aquatic life with long lasting effects. |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | See part C | See part C | See part C | See part C |
| Further toxicological information | No data – not required | | | |

6.4 Toxicological Evaluation of Groundwater Metabolites

In accordance to EFSA conclusion (2018), there are no relevant groundwater metabolites from clopyralid, therefore no assessment is conducted.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance in HCV07 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substance in HCV07

| | Clopyralid | |
|-------------|------------|--|
| | Value | Reference |
| Concentrate | 10% | Guidance on dermal absorption (EFSA, 2017) |
| Dilution | 50% | Guidance on dermal absorption (EFSA, 2017) |

6.5.1 Justification for proposed values - Clopyralid

No data on dermal absorption for clopyralid in HCV07 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for clopyralid

| | Value | Justification for value | Acceptability of justification |
|-------------|-------|--|--------------------------------|
| Concentrate | 10% | EFSA default value for concentrated SL formulation (active substance concentration > 50 g/L) | Accepted |
| Dilution | 50% | EFSA default value for dilute SL formulation (active substance | Accepted |

| | Value | Justification for value | Acceptability of justification |
|--|-------|-------------------------|--------------------------------|
| | | concentration ≤ 50 g/L) | |

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 | HCV07 |
| Formulation type | SL |
| Category | Herbicide |
| Active substance(s) (incl. content) | Clopyralid 300 g/L |
| AOEL systemic | 0.15 mg/kg bw/d |
| AAOEL | 0.17 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption (EFSA Default values) | Concentrate: 10% Dilution: 50% |

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.

6.6.2 Operator exposure (KCP 7.2.1)

Estimated exposures (acute and longer term) from the proposed uses of HCV07 have been evaluated using the EFSA Calculator and do not present a risk for operators. Chronic operator exposure to clopyralid from application to onions was estimated to be 27% of the AOEL with standard work wear. Acute operator exposure to clopyralid from application to onions was estimated to be 46% of the AAOEL, based on standard work wear and gloves worn during mixing/loading.

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 HCV07 according to the critical use is presented in Table 6.6-2. The outcome of the estimation is presented in

Table 6.6-3 (acute exposure) and Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 1.

Table 6.6-2: Exposure models for intended uses

| | |
|--------------|---|
| Critical use | Onions (max. 0.4 L/ha); Min water volume = 100 L/ha |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 |

Table 6.6-3: Estimated operator exposure (acute exposure)

| Table 6.6-5: Estimated operator exposure (acute exposure) | | | |
|---|--------------|---------------------------------|---------------------|
| | | Clopyralid | |
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AAOEL |
| Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables | | | |

| | | | |
|--|--|--------|-----------|
| Application rate | 0.12 kg a.e./ha | | |
| Spray application (AOEM; 95 th percentile) Body weight: 60 kg | Work wear (arms, body and legs covered) M/L and A | 0.1965 | 116 |
| | Work wear (arms, body and legs covered) + Gloves for M/L | 0.0787 | 46 |

Table 6.6-4: Estimated operator exposure (longer term exposure)

| | | Clopyralid | |
|---|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables | | | |
| Application rate | 0.12 kg a.e./ha | | |
| Spray application (AOEM; 95 th percentile) Body weight: 60 kg | Work wear (arms, body and legs covered) M/L and A | 0.0407 | 27 |
| | Work wear (arms, body and legs covered) + Gloves for M/L | 0.0088 | 6 |

Operator exposure estimates have shown that the acceptable operator exposure level (6% of AOEL) and acute operator exposure level (46% of AAOEL) will not be exceeded under the conditions of intended use (application outdoors to low crops to target weeds in bulb vegetables and taking into account personal protective equipment (PPE): work wear (arms, body and legs covered) + Gloves for M/L.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

No unacceptable risk for workers from the supported uses of HCV07 was identified based on exposure estimates from the EFSA Model. The predicted worker exposure to clopyralid was 40% of the AOEL, based on normal work wear and no additional PPE.

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with HCV07 according to the critical use. The outcome of the estimation is presented Table 6.6-6 (longer term exposure). No acute exposure risk assessment is available for workers. Detailed calculations are in Appendix 1.

Table 6.6-5: Exposure models for intended uses

| | |
|--------------|---|
| Critical use | Bulb Vegetables (max. 0.40 L / kg product/ha); Min water volume = 100 L/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 6.6-6: Estimated worker exposure (longer term exposure)

| Estimated worker exposure (longer term exposure) | | | |
|--|--|------------------------------------|--------------------|
| | | Clopyralid | |
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 0.120 kg a.e./ha | |
| Body weight: 60 kg | Work wear (arms, body and legs covered) TC: 2500 cm²/person/h | 0.0600 | 40 |
| | Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h | 0.0139 | 9 |

Worker exposure estimates have shown that the operator exposure limit (9% of AOEL) will not be exceeded under the conditions of intended use (bulb vegetables -(reaching and picking).

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not applicable, generic value used.

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-7 shows the exposure model used for estimation of resident and bystander exposure to clopyralid. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure) and Table 6.6-9 (acute bystander exposure). Detailed calculations are in Appendix 1.

Table 6.6-7: Exposure models for intended uses

| | |
|--------------|--|
| Critical use | Onions (max. 0.40 L / kg product/ha); Min water volume = 100 L/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)

| | | Clopyralid | |
|--|-----------------------------------|---------------------------------------|--------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables <u>Buffer zone: 2-3 (m)</u> Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 0.120 kg a.e./ha (single application) | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.0161 | 11 |
| | Vapour (75 th perc.) | 0.0011 | 0.7 |
| | Deposits (75 th perc.) | 0.0010 | 0.7 |
| | Re-entry (75 th perc.) | 0.0101 | 7 |
| | Sum (mean) | 0.0187 | 12 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0039 | 3 |
| | Vapour (75 th perc.) | 0.0002 | 0.2 |
| | Deposits (75 th perc.) | 0.0004 | 0.3 |
| | Re-entry (75 th perc.) | 0.0056 | 4 |
| | Sum (mean) | 0.0068 | 5 |

Table 6.6-9: Estimated bystander exposure (acute exposure)

| | | Clopyralid | |
|--|-----------------------------------|------------------------------------|---------------------|
| Model data | | Total absorbed dose (mg/kg bw/day) | % of systemic AAOEL |
| Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables <u>Buffer zone: 2-3(m)</u> Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha | | | |
| Application rate | | 0.120 kg a.e./ha | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.0365 | 22 |
| | Vapour (95 th perc.) | 0.0011 | 0.6 |
| | Deposits (95 th perc.) | 0.0029 | 2 |
| | Re-entry (95 th perc.) | 0.0101 | 6 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.0099 | 6 |
| | Vapour (95 th perc.) | 0.0002 | 0.1 |
| | Deposits (95 th perc.) | 0.0012 | 0.7 |
| | Re-entry (95 th perc.) | 0.0056 | 3 |

Exposure estimates for occupants (adults and children) and/or bystanders have shown that the exposure limits (12% and 5% AOEL) and (6% and 3% AAOEL) for clopyralid will not be exceeded under the conditions of intended use according to the label. Therefore, the use of the product under assessment does not pose a threat to the health of these groups of people.

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) and AAOEL, respectively for clopyralid will not be exceeded under conditions of

intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| 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 7.1.1/1 | ██████ | 1990 | EF-243: Acute Oral Toxicity (Limit Test) in the Rat ████████████████████ GLP Unpublished | Y | Corteva Agriscience |
| KCP 7.1.1/2 | ██████ | 1981 | EF-243: Acute Oral Toxicity Study (LD ₅₀) in the Rat ████████████████████ GLP Unpublished | Y | Corteva Agriscience |
| KCP 7.1.2/1 | ██████ | 1990 | EF-243: Acute Dermal Toxicity (Limit Test) in the Rat ████████████████████ GLP Unpublished | Y | Corteva Agriscience |
| KCP 7.1.3/1 | ██████ | 1990 | EF-243: Acute Inhalation Toxicity Study Four-Hour Exposure (Nose-Only) in the Rat ████████████████████ GLP Unpublished | Y | Corteva Agriscience |
| KCP 7.1.4/1 | ██████ | 1990 | EF-243: Acute Dermal Irritation Test in the Rabbit ████████████████████ GLP Unpublished | Y | Corteva Agriscience |
| KCP 7.1.5/1 | ██████ | 1990 | EF-243: Acute Eye Irritation Test in the Rabbit ████████████████████ GLP Unpublished | Y | Corteva Agriscience |

| 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 7.1.6/1 | Guest, R. L. | 1990 | EF-243: Modified Nine-Induction Buehler Contact Sensitisation Study in the Guinea Pig [REDACTED] GLP Unpublished | Y | Corteva Agriscience |

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not applicable.

A 2.2 Acute oral toxicity (KCP 7.1.1)

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, the oral LD ₅₀ of EF-243 is higher than 5000 mg/kg bw in rats Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

A 2.2.1 Study 1

Reference KCP 7.1.1/1

Report EF-243: Acute Oral Toxicity (Limit Test) in the Rat, [REDACTED]

Guideline(s) OECD 401 (1981)

Deviations No

GLP Yes

Acceptability Yes

Duplication No
(if vertebrate study)

Materials and methods

| | |
|----------------------------------|----------------------------|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Rat, Sprague-Dawley |
| No. of animals (group size) | 5 rats/sex for LD50 study: |
| Dose(s) | 5000 mg/kg bw |
| Exposure | Once by gavage |
| Vehicle/Dilution | None |
| Post exposure observation period | 14 days |
| Remarks | None |

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of EF-243

| Dose (mg/kg bw) | Toxicological results * | Duration of signs | Time of death | LD ₅₀ (mg/kg bw) (14 days) |
|-----------------|-------------------------|-------------------|---------------|---------------------------------------|
| Male rats | | | | |
| 5000 | 0/0/5 | NA ^a | NA | > 5000 |
| Female rats | | | | |
| 5000 | 0/0/5 | NA | NA | > 5000 |

* Number of animals which died/number of animals with clinical signs/number of animals used

^a Not applicable

Table A 2: Summary of findings of acute oral toxicity study in rats of EF-243

| | |
|----------------|--|
| Mortality | No mortality occurred. |
| Clinical signs | No clinical signs of toxicity were observed. |

| | |
|--------------------------------|---|
| Body weight | Body weight gain was considered to be normal. |
| Macroscopic examination | The necropsies performed at the end of the study revealed no apparent findings. |

Conclusion

Under the experimental conditions, the oral LD₅₀ of EF-243 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, the oral LD₅₀ of EF-243 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

A 2.2.2 Study 2

| | |
|--------------------------------------|--|
| Reference | KCP 7.1.1/2 |
| Report | EF-243: Acute Oral Toxicity Study (LD ₅₀) in the Rat, [REDACTED] |
| Guideline(s) | None |
| Deviations | No |
| GLP | No. this study was conducted pre-GLP |
| Acceptability | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|---|---------------------|
| Test material (Lot/Batch No.) | EF-243 (EF-243) |
| Species | Rat, Sprague-Dawley |
| No. of animals (group size) | 5 rats/sex |
| Dose(s) | 5000 mg/kg bw |
| Exposure | Once by gavage |
| Vehicle/Dilution | None |
| Post exposure observation period | 14 days |
| Remarks | None |

Results and discussions

Table A 3: Results of acute oral toxicity study in rats of EF-243

| Dose (mg/kg bw) | Toxicological results * | Duration of signs | Time of death | LD ₅₀ (mg/kg bw) (14 days) |
|--------------------|-------------------------|-------------------|---------------|--|
| Male rats | | | | |
| 5000 | 0/0/5 | NA ^a | NA | > 5000 |
| Female rats | | | | |
| 5000 | 0/0/5 | NA | NA | > 5000 |

* Number of animals which died/number of animals with clinical signs/number of animals used

^a Not applicable

Table A 4: Summary of findings of acute oral toxicity study in rats of EF-243

| | |
|-----------------------|--|
| Mortality | No mortality occurred. |
| Clinical signs | No clinical signs of toxicity were observed. |

| | |
|--------------------------------|---|
| Body weight | Body weight gain was considered to be normal. |
| Macroscopic examination | The necropsies performed at the end of the study revealed no apparent findings. |

Conclusion

Under the experimental conditions, the oral LD₅₀ of EF-243 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, the dermal LD₅₀ of EF-243 is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

Reference KCP 7.1.2/1

Report EF-243: Acute Dermal Toxicity (Limit Test) in the Rat, [REDACTED]

Guideline(s) OECD 402 (1981)

Deviations No

GLP Yes

Acceptability Yes

Duplication No
(if vertebrate study)

Materials and methods

| | |
|---|------------------------------|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Rat, Sprague-Dawley |
| No. of animals (group size) | 5 rats/sex |
| Dose(s) | 2000 mg/kg bw |
| Exposure | 24 hours (dermal, occlusive) |
| Vehicle/Dilution | None |
| Post exposure observation period | 14 days |
| Remarks | None |

Results and discussions

Table A 5: Results of acute dermal toxicity study in rats of EF-243

| Dose (mg/kg bw) | Toxicological results * | Duration of signs | Time of death | LD ₅₀ (mg/kg bw) (14 days) |
|-----------------|-------------------------|-------------------|---------------|---------------------------------------|
| Male rats | | | | |
| 2000 | 0/0/5 | NA ^a | NA | > 2000 |
| Female rats | | | | |
| 2000 | 0/0/5 | NA | NA | > 2000 |

* Number of animals which died/number of animals with clinical signs/number of animals used

^a Not applicable

Table A 6: Summary of findings of acute dermal toxicity study in rats of EF-243

| | |
|--------------------------------|---|
| Mortality | No mortality occurred. |
| Clinical signs | No clinical signs of toxicity were observed. |
| Body weight | Body weight gain was considered to be normal. |
| Macroscopic examination | The necropsies performed at the end of the study revealed no apparent findings. |

Conclusion

Under the experimental conditions, the dermal LD₅₀ of EF-243 is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, the inhalation LC₅₀ of EF-243 is higher than 4.27 mg/L air in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

| | |
|--------------------------------------|---|
| Reference | KCP 7.1.3/1 |
| Report | EF-243: Acute Inhalation Toxicity Study Four-Hour Exposure (Nose-Only) in the Rat. [REDACTED] |
| Guideline(s) | OECD 403 (1981) |
| Deviations | No |
| GLP | Yes |
| Acceptability | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|---|-----------------------|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Rat, Sprague-Dawley |
| No. of animals (group size) | 5 rats/sex/dose |
| Concentration(s) | 4.27 mg/L air |
| Exposure | 4 hours (nose only) |
| Vehicle/Dilution | None |
| Post exposure observation period | 14 days |
| Remarks | None |

Results and discussions

Table A 7: Concentration(s) and exposure conditions

| Target conc. (mg/L air) | Actual conc. (mg/L air) | MMAD * (µm) | GSD ** (µm) |
|------------------------------------|------------------------------------|------------------------|------------------------|
| 5.0 | 4.27 | 2.5 | 0.46 |

* MMAD = Mass Median Aerodynamic Diameter

** GSD = Geometric Standard Deviation

Table A 8: Results of acute inhalation toxicity study in rats of EF-243

| Concentration (mg/L air) | Toxicological results * | Duration of signs | Time of death | LC ₅₀ (mg/L air) (14 days) |
|--------------------------|-------------------------|-------------------|-----------------|---------------------------------------|
| Male rats | | | | |
| 4.27 | 0/5/5 | One day | NA ^a | > 4.27 |
| Female rats | | | | |
| 4.27 | 0/5/5 | One day | NA | > 4.27 |

* Number of animals which died/number of animals with clinical signs/number of animals used

^a Not applicable

Table A 9: Summary of findings of acute inhalation toxicity study in rats of EF-243

| | |
|--------------------------------|--|
| Mortality | No mortality occurred. |
| Clinical signs | Yes. Hunched posture, piloerection, lethargy, and decreased respiratory rate were observed immediately on removal from the restraining tubes and one hour later. All animals continued to show hunched posture and piloerection one day after exposure but appeared normal two days after exposure and for the rest of the study period. |
| Body weight | Small loss in body weight was noted in all females and one male over the first week and in one female over the second week |
| Macroscopic examination | The necropsies performed at the end of the study revealed no apparent findings. |

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of EF-243 is higher than 4.27 mg/L air in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, EF-243 is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

| | |
|-----------------------------------|--|
| Reference | KCP 7.1.4/1 |
| Report | EF-243: Acute Dermal Irritation Test in the Rabbit, [REDACTED] |
| Guideline(s) | OECD 404 (1981) |
| Deviations | Yes. Test area only 2.5 cm ² , instead of 6 cm ² |
| GLP | Yes |
| Acceptability | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|---|----------------------------------|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Rabbit, New Zealand White |
| No. of animals (group size) | 2 females, 1 male |
| Initial test using one animal | No |
| Exposure | 0.5 mL (4 hours, semi-occlusive) |
| Vehicle/Dilution | None |
| Post exposure observation period | 72 hours |

| | |
|---------|------|
| Remarks | None |
|---------|------|

Results and discussions

Table A 10: Skin irritation of EF-243

| Animal No. | | Scores after treatment * | | | | Mean scores (24-72 h) | Reversible (day) |
|------------|----------|--------------------------|------|------|------|-----------------------|------------------|
| | | 1 h | 24 h | 48 h | 72 h | | |
| 76 Female | Erythema | 0 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 |
| 99 Female | Erythema | 1 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 |
| 111 Male | Erythema | 1 | 0 | 0 | 0 | 0 | 0 |
| | Oedema | 0 | 0 | 0 | 0 | 0 | 0 |

* scores in the range of 0 to 4

| | |
|-----------------|--|
| Clinical signs: | No clinical signs of toxicity were observed. |
|-----------------|--|

Conclusion

Under the experimental conditions, EF-243 is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, EF-243 is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

Reference KCP 7.1.5/1

Report EF-243: Acute Eye Irritation Test in the Rabbit, [REDACTED]

Guideline(s) OECD 405 (1987)

Deviations No

GLP Yes

Acceptability Yes

Duplication No
(if vertebrate study)

Materials and methods

| | |
|----------------------------------|---|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Rabbit, New Zealand White |
| No. of animals (group size) | 2 females, 1 male |
| Initial test using one animal | No |
| Exposure | 0.1 mL (single instillation in conjunctival sac of right eye) |
| Irrigation (time point) | No |
| Vehicle/Dilution | None |
| Post exposure observation period | 72 hours |
| Remarks | None |

Results and discussions

Table A 11: Eye irritation of EF-243

| Animal No. | | Scores after treatment * | | | | Reversible (day) |
|------------|------------------------|--------------------------|------|------|------|------------------|
| | | 1 h | 24 h | 48 h | 72 h | |
| 94 Female | Corneal opacity | 0 | 0 | 0 | 0 | 2 |
| | Iritis | 1 | 0 | 0 | 0 | |
| | Redness conjunctivae | 1 | 0 | 0 | 0 | |
| | Chemosis conjunctivae | 1 | 0 | 0 | 0 | |
| | Discharge conjunctivae | 2 | 0 | 0 | 0 | |
| 54 Female | Corneal opacity | 0 | 0 | 0 | 0 | 2 |
| | Iritis | 1 | 0 | 0 | 0 | |
| | Redness conjunctivae | 1 | 1 | 0 | 0 | |
| | Chemosis conjunctivae | 1 | 0 | 0 | 0 | |
| | Discharge conjunctivae | 1 | 0 | 0 | 0 | |
| 51 Male | Corneal opacity | 0 | 0 | 0 | 0 | 2 |
| | Iritis | 1 | 1 | 0 | 0 | |
| | Redness conjunctivae | 1 | 1 | 0 | 0 | |
| | Chemosis conjunctivae | 1 | 1 | 0 | 0 | |
| | Discharge conjunctivae | 2 | 0 | 0 | 0 | |

* Draiz scale scoring was conducted

| | |
|------------------------|---|
| Clinical signs: | No clinical signs of toxicity were observed. (If yes, describe kind of signs) |
|------------------------|---|

Conclusion

Under the experimental conditions, EF-243 is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

| | |
|-------------------|--|
| Comments of zRMS: | Under the experimental conditions, EF-243 is not a skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008. |
|-------------------|--|

| | |
|-----------------------------------|---|
| Reference | KCP 7.1.6/1 |
| Report | EF-243: Modified Nine-Induction Buehler Contact Sensitisation Study in the Guinea Pig, [REDACTED] |
| Guideline(s) | OECD 406 (1987) |
| Deviations | Yes. Only 12 animals treated, instead of 20. In the absence of a reaction in any of these animals together with the need for 15% of animals to have a positive response to trigger classification in the EU this study was considered to have adequately filled this data requirement |
| GLP | Yes |
| Acceptability | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|-------------------------------|---|
| Test material (Lot/Batch No.) | EF-243 (DB 940-89-40) |
| Species | Guinea pig, Dunkin-Hartley |
| No. of animals (group size) | Test substance group: 12 female guinea pigs Vehicle control group: 12 female guinea pigs |

| | |
|--|---|
| Range finding | Yes |
| Exposure (concentration(s), no. of applications) | Topical induction: 0.5 mL. Undiluted (9x / 6 hours) Challenge: 0.2 mL. Undiluted |
| Vehicle | None |
| Pretreatment prior to topical application | No |
| Reliability check | None |
| Remarks | None |

Results and discussions

Table A 12: Results of skin sensitisation study of EF-243

| | 24 hours | 48 hours | Total number of animals affected |
|----------------------------|-----------------|----------|----------------------------------|
| | After challenge | | |
| EF-243 | 0* | 0* | 0 |
| Test vehicle control group | 0* | 0* | 0 |

* Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

| | |
|------------------------|--|
| Clinical signs: | No clinical signs of toxicity were observed. |
|------------------------|--|

Conclusion

Under the experimental conditions, EF-243 is not a skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

No new or additional data submitted.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Safety data sheet for each co-formulant

Information regarding 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)

No new or additional data submitted.

A 2.11 Other/Special Studies

No new or additional data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for clopyralid

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

| | | | | | |
|-----------------------|---|--|----------------------------------|-------------------------------|--|
| Substance | Clopyralid | Formulation = Soluble concentrates, emulsifiable concentrate, etc. | Application rate-0.12 kg a.s./ha | Spray dilution = 1.2 g a.s./l | Vapour pressure = low volatile substances having a vapour pressure of <5*10 ⁻³ Pa |
| Scenario | Bulb vegetables / Outdoor / Downward spraying / Vehicle-mounted | | | Buffer = 2-3 | Number applications = 1, Application interval = 365 days |
| Percentage Absorption | Dermal for product = 10 | Dermal for in use dilution = 50 | Oral = 100 | Inhalation = 100 | |
| RVNAS | 0.15 mg/kg bw/day | | RVAAS | 0.17 mg/kg bw/day | |
| DFR | 3 µg a.s./cm ² per kg a.s./ha | | DT50 | 30 days | |

Table A 14: Estimation of acute and long-term operator exposure towards clopyralid according to EFSA guidance (without PPE)

| | | | | | |
|--------------------------|--|--|------------|-------------------|--|
| Operator Model | | Mixing, loading and application AOEM | | | |
| Potential exposure | Longer term systemic exposure mg/kg bw/day | 0.0655 | % of RVNAS | 43.69% | |
| | Acute systemic exposure mg/kg bw/day | 0.4181 | % of RVAAS | 245.95% | |
| Mixing and Loading | Gloves = No | Clothing = Work wear - arms, body and legs covered | RPE = None | Soluble bags = No | |
| Application | Gloves = No | Clothing = Work wear - arms, body and legs covered | RPE = None | Closed cabin = No | |
| Exposure (including PPE) | Longer term systemic exposure mg/kg bw/day | 0.0407 | % of RVNAS | 27.16% | |

| | | | | |
|----------------|--------------------------------------|--------|------------|---------|
| options above) | Acute systemic exposure mg/kg bw/day | 0.1965 | % of RVAAS | 115.56% |
|----------------|--------------------------------------|--------|------------|---------|

Table A 15: Estimation of acute and long-term operator exposure towards clopyralid according to EFSA guidance (with PPE)

| Operator Model | | Mixing, loading and application AOEM | | |
|--|--|--|------------|-------------------|
| Potential exposure | Longer term systemic exposure mg/kg bw/day | 0.0655 | % of RVNAS | 43.69% |
| | Acute systemic exposure mg/kg bw/day | 0.4181 | % of RVAAS | 245.95% |
| Mixing and Loading | Gloves = Yes | Clothing = Work wear - arms, body and legs covered | RPE = None | Soluble bags = No |
| Application | Gloves = No | Clothing = Work wear - arms, body and legs covered | RPE = None | Closed cabin = No |
| Exposure (including PPE options above) | Longer term systemic exposure mg/kg bw/day | 0.0088 | % of RVNAS | 5.85% |
| | Acute systemic exposure mg/kg bw/day | 0.0787 | % of RVAAS | 46.32% |

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for clopyralid

Table A 16: Input parameters considered for the estimation of worker exposure

| | |
|--|-------------------------------------|
| Crop type | Bulb vegetables |
| Indoor or outdoor | Outdoor |
| Application method | Downward spraying |
| Application equipment | Vehicle-mounted |
| Worker's task | Reaching, picking |
| Main body parts in contact with foliage | Hand and body |
| Application rate of active substance | 0.12 kg a.s./ha |
| Number of applications | 1 |
| Interval between multiple applications | 365 days |
| Half-life of active substance | 30 days |
| Multiple application factor | 1.0 |
| Dermal absorption of the product | 10.00% |
| Dermal absorption of the in-use dilution | 50.00% |
| Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$) | 0.36 µg a.s./cm ² |
| Working hours | 8 hr |
| Dermal transfer coefficient - Total potential exposure | 5800 cm ² /hr |
| Dermal transfer coefficient - arms, body and legs covered | 2500 cm ² /hr |
| Dermal transfer coefficient - hands, arms, body and legs covered | 580 cm ² /hr |
| Inhalation transfer coefficient for automated applications | NA ha/hr*10 ^{^(-3)} |
| Inhalation transfer coefficient for cutting ornamentals | NA ha/hr*10 ^{^(-3)} |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA ha/hr*10 ^{^(-3)} |

Table A 17: Estimation of longer-term worker exposure towards clopyralid according to EFSA guidance

| | | | | |
|---|--|--------|------------|--------|
| Worker - Reaching, pick- ing | Potential exposure mg/kg bw/day | 0.1392 | % of RVNAS | 92.80% |
| | Working clothing mg/kg bw/day | 0.0600 | % of RVNAS | 40.00% |
| | Working clothing and gloves mg/kg bw/day | 0.0139 | % of RVNAS | 9.28% |

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for clopyralid

Table A 18: Input parameters considered for the estimation of longer term resident exposure

| | | |
|---|--|--------------------------|
| Croptype | Bulb 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 | 0.12 | kg a.s./ha |
| Concentration of active substance (in-use dilution for liquid applications) | 1.2 | g a.s./l |
| Dermal absorption of product | 10.00% | |
| Dermal absorption of in-use dilution | 50.00% | |
| Oral absorption | 100.00% | |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 0.36 | µg a.s./cm ² |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10 ⁻³ Pa | |
| Concentration in air | 0.001 | mg/m ³ |
| Resident dermal spray drift exposure 75th percentile - adult | 0.47 | ml spray dilution/person |
| Resident dermal spray drift exposure 75th percentile - child | 0.327 | ml spray dilution/person |
| Resident inhal. spray drift exposure 75th percentile - adult | 0.00010 | ml spray dilution/person |
| Resident inhal. spray drift exposure 75th percentile - child | 0.00022 | ml spray dilution/person |
| Resident dermal spray drift exposure mean - adult | 0.22318 | ml spray dilution/person |
| Resident dermal spray drift exposure mean - child | 0.18 | ml spray dilution/person |
| Resident inhal. spray drift exposure mean - adult | 0.00009 | ml spray dilution/person |
| Resident inhal. spray drift exposure mean - child | 0.00017 | ml spray dilution/person |
| Exposure duration dermal | 2 | hours |
| Exposure duration inhalation | 24 | hours |

| | | |
|---|--------|------------------------|
| Exposure duration entry into treated crops | 0.25 | hours |
| Light clothing adjustment factor | 18.0% | |
| Breathing rate adult | 0.23 | m ³ /day/kg |
| Breathing rate child (1-3 year old) | 1.07 | m ³ /day/kg |
| Drift percentage on surface (75th percentile) | 5.60% | |
| Drift percentage on surface (mean) | 4.10% | |
| Turf transferable residues percentage | 5.00% | |
| Transfer coeff. of surface deposits-adult | 7300 | cm ² /hour |
| Transfer coeff. of surface deposits-child (1-3 year old) | 2600 | cm ² /hour |
| Saliva extraction percentage | 50.00% | |
| Surface area of hands mouthed | 20 | cm ² |
| Frequency of hand to mouth activity | 9.5 | events/hour |
| Ingestion rate for mouthing of grass per day | 25 | cm ² |
| Dislodgeable residues percentage transferability for object to mouth | 20.00% | |
| Transfer coefficient for entry into treated crops (75th percentile) - adult | 7500 | cm ² /h |
| Transfer coefficient for entry into treated crops (75th percentile) - child | 2250 | cm ² /h |
| Transfer coefficient for entry into treated crops (mean) - adult | 5980 | cm ² /h |
| Transfer coefficient for entry into treated crops (mean) - child | 1794 | cm ² /h |

Table A 19: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance

| | | | | |
|-------------------------|---|--------|------------|--------|
| Resident - child | Spray drift (75th percentile) mg/kg bw/day | 0.0161 | % of RVNAS | 10.74% |
| | Vapour (75th percentile) mg/kg bw/day | 0.0011 | % of RVNAS | 0.71% |
| | Surface deposits (75th percentile) mg/kg bw/day | 0.0010 | % of RVNAS | 0.65% |
| | Entry into treated crops (75th percentile) mg/kg bw/day | 0.0101 | % of RVNAS | 6.75% |
| | All pathways (mean) mg/kg bw/day | 0.0187 | % of RVNAS | 12.49% |

| | | | | |
|-------------------------|---|--------|------------|-------|
| Resident - adult | Spray drift (75th percentile) mg/kg bw/day | 0.0039 | % of RVNAS | 2.57% |
| | Vapour (75th percentile) mg/kg bw/day | 0.0002 | % of RVNAS | 0.15% |
| | Surface deposits (75th percentile) mg/kg bw/day | 0.0004 | % of RVNAS | 0.27% |
| | Entry into treated crops (75th percentile) mg/kg bw/day | 0.0056 | % of RVNAS | 3.75% |
| | All pathways (mean) mg/kg bw/day | 0.0068 | % of RVNAS | 4.56% |

Table A 20: Input parameters considered for the estimation of acute bystander exposure

| | | | |
|---|--|--------------------------|--------------------------|
| Croptype | Bulb vegetables | | |
| Application method | Downward spraying | | |
| Application equipment | Vehicle-mounted | | <i>i_AppEquip</i> |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | |
| Application rate of the product | 0.12 | kg a.s./ha | <i>i_AppRate</i> |
| Buffer strip | 2-3 | m | <i>i_Buffer</i> |
| Concentration of active substance (in-use dilution for liquid applications) | 1.2 | g a.s./l | <i>d_ConcAS</i> |
| Dermal absorption of product | 10.00% | | <i>i_AbsorpProduct</i> |
| Dermal absorption of in-use dilution | 50.00% | | <i>i_AbsorpInuse</i> |
| Oral absorption | 100.00% | | <i>i_AbsorpOralInuse</i> |
| Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$) | 0.36 | µg a.s./cm ² | <i>d_DFR</i> |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10⁻³Pa | | <i>i_Volat</i> |
| Concentration in air | 0.001 | mg/m ³ | <i>d_AirCon</i> |
| Bystander dermal spray drift exposure - adult | 1.21 | ml spray dilution/person | |
| Bystander dermal spray drift exposure - child | 0.74 | ml spray dilution/person | |
| Bystander inhal. spray drift exposure - adult | 0.00050 | ml spray dilution/person | |
| Bystander inhal. spray drift exposure - child | 0.00112 | ml spray dilution/person | |
| Exposure duration | 2 | hours | <i>d_ByExpDur</i> |
| Exposure duration entry into treated crops | 0.25 | hours | <i>d_ExpDurTreatCrop</i> |

| | | | |
|--|--------|---------------------------|---------------------|
| Light clothing adjustment factor | 18.0% | | <i>d_ClothAF</i> |
| Breathing rate adult | 0.23 | m ³ /kg bw/day | <i>d_BreathRAD</i> |
| Breathing rate child (1-3 year old) | 1.07 | m ³ /kg bw/day | <i>d_BreathRCh</i> |
| Drift percentage on surface (90th percentile) | 8.50% | | |
| Turf transferable residues percentage | 5.00% | | <i>d_Turf</i> |
| Transfer coeff. of surface deposits-adult | 14500 | cm ² /hour | <i>d_ByTCAd</i> |
| Transfer coeff. of surface deposits-child (1-3 year old) | 5200 | cm ² /hour | <i>d_ByTCCh</i> |
| Saliva extraction percentage | 50.00% | | <i>d_SalExt</i> |
| Surface area of hands mouthed | 20 | cm ² | <i>d_AreaHM</i> |
| Frequency of hand to mouth activity | 20 | events/hour | <i>d_ByFreqHM</i> |
| Ingestion rate for mouthing of grass per day | 25 | cm ² | <i>d_MouthGrass</i> |
| Dislodgeable residues percentage transferability for object to mouth | 20.00% | | <i>d_DRP</i> |
| Transfer coefficient for entry into treated crops - adult | 7500 | cm ² /h | <i>d_TcEntryAd</i> |
| Transfer coefficient for entry into treated crops - child | 2250 | cm ² /h | <i>d_TcEntryCh</i> |

Table A 21: Estimation of acute bystander exposure towards clopyralid according to EFSA guidance

| | | | | |
|--------------------------|---|--------|------------|--------|
| Bystander - child | Spray drift (95th percentile) mg/kg bw/day | 0.0365 | % of RVAAS | 21.50% |
| | Vapour (95th percentile) mg/kg bw/day | 0.0011 | % of RVAAS | 0.63% |
| | Surface deposits (95th percentile) mg/kg bw/day | 0.0029 | % of RVAAS | 1.71% |
| | Entry into treated crops (95th percentile) mg/kg bw/day | 0.0101 | % of RVAAS | 5.96% |
| Bystander - adult | Spray drift (95th percentile) mg/kg bw/day | 0.0099 | % of RVAAS | 5.84% |
| | Vapour (95th percentile) mg/kg bw/day | 0.0002 | % of RVAAS | 0.14% |
| | Surface deposits (95th percentile) mg/kg bw/day | 0.0012 | % of RVAAS | 0.73% |
| | Entry into treated crops (95th percentile) mg/kg bw/day | 0.0056 | % of RVAAS | 3.31% |

A 3.4 Combined exposure calculations for clopyralid

Not relevant.

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)

Not applicable. No higher tier studies were used.