

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: ADM.00150.I.2.A

Product name: LEAXO

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(Authorisation acc. to Art. 33)

Sponsor: ADAMA Makhtesheim Ltd.

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: August 2023

MS Finalisation date: January 2024 (initial Core Assessment)

November 2024 (final Core Assessment)

Version history

| When | What |
|---------------|---|
| August 2023 | Applicant version v 1.0 |
| January 2023 | <p>Initial zRMS assessment</p> <p>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.</p> |
| November 2024 | <p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.</p> |

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Reviewer comment:

This report has been completed by the applicant. Changes or deleted information in the text of the report and the reviewer comments are highlighted in grey or have been put in grey table.

This part of dossier summarizes data related to the toxicity and NDE assessment for the plant protection product LEAXO 200 SL (product code ADM.00150.I.2.A containing the active substance acetamiprid (200 g/L). Dossier has been submitted to support registration according art. 33 of 1107/2009 in Poland also for zonal registration for which PL was designated zRMS. Intended use of PPP is as an insecticide.

To assess the acute toxicity properties and hazard classification (CLP) of ADM.00150.I.2.A outcome of an *in vitro* studies and calculation method according to Regulation (EC) No 1272/2008 has been applied. For these calculation data of all individual ingredients including active substances, safener, emulsifier, stabilizer and solvent were considered. Details of the calculation can be found in the confidential dossier of this submission (Registration Report - Part C).

zRMS PL in accordance with the EC recommendations to avoid tests on animals, for the purposes of hazard classification use the data obtained using the calculation method (ATEmix/additivity formula) and do not request for new *in vivo* data. The calculation of the endpoints indicated to have a low dermal and inhalation toxicity does not induce dermal sensitization. It has an oral toxicity 795 mg/kg bw and showed a eye irritating effect.

According to amendments (ATP18) in Regulation (EC) No 1272/2008 to be enforced from 23 November 2023, Acetamiprid needs to be classified as Repr. 2. Since the Acetamiprid concentration in the product Acetamiprid 200 SL is $\geq 3.0\%$, the product needs to be classified as Repr. 2 as well.

NDE assessment for operator, workers and B&R has been calculated using the AOEM model (EFSA calculator, version March 2015) and considering the worst-case exposure scenario to cover all the intended uses (highest application rate per application as well as the highest application rate per year with the shorter interval between each application). All NDE calculations provided for operator, workers and B&R resulting from use of PPP, considering all tasks according to the critical use(s), identify safe use of the product LEAXO 200 SL (ADM.00150.I.2.A).

Reviewer additional discussion reflecting cMS comments (November 2024): Due to the lack of data in the OPEX model, calculating operator exposure for manual application techniques in low ornamentals is not feasible. Therefore, it is assumed that manual application techniques for low ornamentals are adequately represented by those used for high ornamentals.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on ADM.00150.I.2.A/Acetamiprid 200 SL*

| | |
|--|------------------------------------|
| Product name and code | ADM.00150.I.2.A/Acetamiprid 200 SL |
| Formulation type | formulation type [SL] |
| Active substance(s) (incl. content) | Acetamiprid; 200 g/L |
| Function | Insecticide |
| Product already evaluated as the 'representative formulation' during the approval of the active substance(s) | Yes |
| Product previously evaluated in another MS according to Uniform Principles | Yes (please refer to B0) |

* Information on the detailed composition of ADM.00150.I.2.A/Acetamiprid 200 SL can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

~~According to the current harmonised classification, Acetamiprid is classified as oral acute tox 4 with acute toxicity range from >300 and ≤ 200 mg/kg bw (acute toxicity point estimate 500 mg/kg bw). The applicant, however, has used acute toxicity point estimate of 301 (lower limit of the specified range) for classification of product toxicity since acute oral toxicity study with the product itself results in similar classification.~~

Table 6.1-2: Justified proposals for classification and labelling for ADM.00150.I.2.A /Acetamiprid 200 SL (Carnadine / Kestrel)* according to Regulation (EC) No 1272/2008

| | |
|--|---|
| Hazard class(es), categories | Oral acute Tox 4 (Current harmonized C&L) |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS07 |
| Signal word | Warning |
| Hazard statement(s) | H302 |
| Precautionary statement(s) | P264, P270, P280, P301 + P312, P330, P501, P305 + P351 + P338, P337 + P313 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
| | One ingredient with 22.01 and another one with 16.73% of the mixture consist of ingredients of unknown inhalation toxicity. |

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:

ATP18; Commission Delegated Regulation (EU) 2022/692 of 16 February 2022

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 23 November 2023.

The product toxicity is also calculated with the proposed classification of Acetamiprid as oral acute tox 3 (acute toxicity point estimate of 140 mg/kg bw) and repr. 2 (Table 6.1-3).

Table 6.1-3: Justified proposals for classification and labelling for ADM.00150.I.2.A /Acetamiprid 200 SL (Carnadine / Kestrel)* according to Regulation (EC) No 1272/2008. The information which is determined for the label is formatted bold:

| | |
|---|---|
| Hazard class, categories: | Oral acute Tox 4, Repr 2, Eye irrit 2 |
| Hazard pictograms or Code(s) for hazard pictogram(s): | GHS07, GHS08 |
| Signal word: | Warning |
| Hazard statement(s): | H302, H361d, H319 |
| Precautionary statement(s): | P264 , P270, P301 + P312 , P330, P501 P201 , P202, P281 P280 , P308 + P313 , P405, P501 P337 + P313 |
| Additional labelling phrases: | To avoid risks to human health and the environment, comply with the instructions for use. [EUH401] |
| | 16.73 and 22.01% of the mixture consist of ingredients of unknown inhalation toxicity. All ingredients of the mixture are of unknown respiratory sensitization. |

Table 6.1-4: Summary of risk assessment for operators, workers, residents and bystanders for ADM.00150.I.2.A/Acetamiprid 200 SL – New online AOEM

| | Result | PPE / Risk mitigation measures |
|------------|------------|--|
| Operators | Acceptable | Potato, cereals (except corn), flower bulbs and flower tubers: Gloves during mixing/loading Corn, floriculture, tree nursery & perennial nursery crops, oilseeds, sugar beet: Gloves during mixing/loading/application Apple: Gloves during mixing/loading/application and hood during application Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers New online EFSA Model, manual-hand held M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar |
| Workers | Acceptable | Cereals including corn, potatoes, oilseeds: Without PPE Apple, Flower bulbs and flower tuber, floriculture, tree nursery & perennial nursery crops, sugar beets: Gloves |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

Reviewer comment:

Due to the classification of the product with hazard category Eye irrit 2 (H319), operators should wear additionally eye protection during all activities

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 6.1-4 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 6.1-5 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 | F, Fn, Fpn | Application | | Application rate | | PHI (d) | Remarks: (e.g. | Acceptability of exposure assessment |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
|-----|---|--------------------|--|--|---|-----------------------------|------------------|--|----------|--------|-----------|-----------|
| | stage of crop) | G, Gn, Gpn or I ** | 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 g as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model] | Operator | Worker | Residents | Bystander |
| I | Corn | F | Foliar spraying, overall | a) 1 b) 1 | a) 60 b) 60 | 300 - 500 | 56 | Umbrella GAP | # | # | | |
| IIa | Apple | F | Foliar spraying, overall | a) 1 b) 1 | a) 80 b) 80 | 500 - 1000 | 14 | Umbrella GAP | # | # | | |
| IIb | Apple | F | Foliar spraying, overall | a) 1-2 (8) b) 1-2 (8) | a) 25 b) 50 | 500 - 1000 | 14 | Umbrella GAP | # | # | | |
| III | Potato | F | Foliar spraying, overall | a) 1 b) 1 | a) 36 b) 36 | 100 - 500 | 7 | Umbrella GAP | # | # | | |
| IVa | Spring wheat Spring barley Spring oats Spring Durum wheat Spring tritiale | F | Foliar spraying, overall | a) 1-2 (10) b) 1-2 (10) | a) 35 b) 70 | 100 - 400 | follow crop BBCH | Umbrella GAP | # | # | | |
| IVb | Spring wheat Spring barley Spring oats Spring Durum wheat Spring tritiale | F | Foliar spraying, overall | a) 1 (30) b) 1-2 (30) | a) 35 b) 70 | 100 - 400 | follow crop BBCH | Umbrella GAP | # | # | | |
| Va | Winter wheat, Winter barley, Winter rye, Winter tritiale | F | Foliar spraying, overall | a) 1-2 (10) b) 1-2 (10) | a) 36 b) 72 | 100- 400 | follow crop BBCH | Umbrella GAP | # | # | | |
| Vb | Winter wheat, Winter barley, Winter rye, Winter tritiale | F | Foliar spraying, overall | a) 1 b) 1 | a) 30 b) 30 | 100- 400 | follow crop BBCH | Umbrella GAP | # | # | | |
| VIa | Winter OSR | F | Foliar spraying, overall | a) 1-2 (7) b) 1-2 (7) | a) 60 b) 120 | 100- 400 | 28 | Umbrella GAP | # | # | | |
| VIb | Winter OSR | F | Foliar spraying, overall | a) 1 b) 1 | a) 60 b) 120 | 100- 200 | 28 | Umbrella GAP | # | # | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
|------|--|---|--------------------------|----------------------|-----------------|----------|------|--------------|----|---|--|--|
| VIII | Sugar beet | F | Foliar spraying, overall | a) 2 (7) b) 2 (7) | a) 50 b) 100 | 200-400 | 35 | Umbrella GAP | # | # | | |
| IXa | Flower bulbs and flower tubers | F | Foliar spraying, overall | a) 1 b) 1 | a) 46 b) 46 | 200-400 | n.a. | Umbrella GAP | # | # | | |
| IXb | Flower bulbs and flower tubers | F | Foliar spraying, overall | a) 2 (7) b) 2 (7) | a) 34 b) 68 | 200-400 | n.a. | Umbrella GAP | # | # | | |
| Xa | Floriculture, Tree nursery & Perennial nursery crops | F | Foliar spraying, overall | a) 1 b) 1 | a) 46 b) 46 | 200-1000 | n.a. | Umbrella GAP | # | # | | |
| Xb | Floriculture, Tree nursery & Perennial nursery crops | F | Foliar spraying, overall | a) 2 (7) b) 2 (7) | a) 34 b) 68 | 200-1000 | n.a. | Umbrella GAP | # | # | | |

* 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

taking into account NDE (acute exposure/AAOEL) for acetamiprid relevant PPE/RMM has been accepted; refer table Table 6.1

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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

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

Table 6.2-1: Information on active substance

| | Acetamiprid |
|--|---|
| Common Name | Acetamiprid |
| CAS-No. | 135410-20-7 |
| Classification and proposed labelling | |
| With regard to toxicological endpoints (according to the current harmonized classification and criteria in Reg. 1272/2008, as amended) | <p>Hazard classes (s), categories: Acute oral Cat. 4 Codes for hazard pictogram: GHS07 Signal word: Warning Hazard statement(s): H302 (Harmful if swallowed) Precautionary statements: P264, P270, P301 + P312, P330, P501</p> <p><u>Summary of Classification and Labelling for acetamiprid</u> ATP18 Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 <u>Entry into force and application</u> This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 23 November 2023.</p> <p>Classification: <u>Hazard Class and Category Code(s)</u> Repr. 2; Acute Tox. 3 <u>Hazard statement Code(s)</u> H361d Suspected of damaging the unborn child H301 Toxic if swallowed Labelling: <u>Pictogram, Signal Word Code(s)</u></p> <div style="display: flex; align-items: center; justify-content: center;">  <div style="margin: 0 10px;">GHS08</div>  <div style="margin: 0 10px;">GHS06</div> </div> <p><u>Hazard statement Code(s)</u> H361d H301 Precautionary statement(s): Prevention: P201; P202; P280; P264; P270 Response: P308+P313; P301+P310; P321</p> |
| Proposed classification after renewal (amendments to Regulation (EC) No 1272/2008 to be enforced from 23 November 2023) | Hazard classes (s), categories: Acute oral toxicity 3, Repr. 2 Code(s) for hazard pictogram(s): GHS06, GHS08 Signal word: Danger Hazard statement(s): H301 Toxic if swallowed; H361d Suspected of damaging the unborn child Precautionary statement(s): P264, P270, P301+P310, P321, P330, P405, P501 |
| Additional C&L proposal | - |
| Agreed EU endpoints | |
| AOEL systemic | 0.025 mg/kg bw/d (based on rat, developmental neurotoxicity study; not corrected for oral absorption, calculated with uncertainty factor of 100) |
| AAOEL systemic | 0.025 mg/kg bw/d (based on rat, developmental neurotoxicity study; not corrected for oral absorption, calculated with uncertainty factor of 100) |
| Reference | EFSA Conclusion, 2016 |
| Conditions to take into account/critical areas of concern with regard to toxicology | |
| COMMISSION IMPLEMENTING REGULATION (EU) No 2018/113 | In this overall assessment Member States — should pay particular attention to operator exposure. Risk mitigation measures should be applied where appropriate. |

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for ADM.00150.I.2.A/Acetamiprid 200 LSL 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. In addition, calculation of product toxicity is provided based on toxicity of the active substance and the respective co-formulants. All details on calculation are provided in Part C.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ADM.00150.I.2.A/Acetamiprid 200 SL

zRMS comment: Table has been redrafted to reflects CMS comments

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification (acc. to the criteria in Reg. 1272/2008) | Reference |
|--|------------------------|---------------|--|--|
| LD ₅₀ oral, calculation (current harmonized classification) | 1710 mg/kg bw* | | Category 4 (H302) | Calculations are provided in Part C |
| LD ₅₀ oral, calculation (amendments to Regulation (EC) No 1272/2008 to be enforced from 23 November 2023) | 795 mg/kg bw* | Yes | Category 4 (H302) | Calculations are provided in Part C |
| LD ₅₀ dermal, calculation | >2000 mg/kg bw* | Yes | Not classified | Calculations are provided in Part C |
| LC ₅₀ inhalation, calculation | Not classified | Yes | Not classified | Calculations are provided in Part C |
| Skin irritation, calculation | Non-Irritant* | Yes | None | Calculations are provided in Part C |
| Eye irritation, calculation | Eye Irritant* | Yes | Eye Irritant 2 | Calculations are provided in Part C |
| Skin sensitisation, calculation | Non-sensitising* | Yes | None | Calculations are provided in Part C |
| LC ₅₀ inhalation, rat (OECD 403) | >5.16 mg/L air | Yes | None | KCP 7.1.3/01 ■■■■■**, Report No. 12/445-004P |
| Skin irritation, human epidermis (OECD 439) | Non-irritant* | No | None | KCP 7.1.4/01 Kiss, I. (2013), Report No. 12/445-006N |
| Eye irritation, isolated chicken eyes (OECD 438) | Slight irritant* | Yes | According to the guideline OECD 438, the product does not require a classification as a severe eye irritant. | KCP 7.1.5/01 Kiss, I. (2013), Report No. 12/445-038CS |
| Supplementary studies for combinations of plant protection products | No data – not required | - | - | - |

* *In vivo* studies were performed to satisfy the regulatory requirements of countries outside the EU. The results of these studies were in line with the results from the alternative approach taking the available data on the ingredients as the basis. Therefore, these studies have not been presented as part of this application in the EU, although the study reports are available upon request.

** Acute inhalation – This *in vivo* study was not performed with the intention for use within the EU. It was however performed to satisfy the regulatory requirements of countries outside of the EU. However, due to the high percentage of co-formulants with an unknown inhalation toxicity, the calculation method might not give a correct result. For this reason, the study is included as part of this application.

Table 6.3-2: Additional toxicological information relevant for classification/labelling of ADM.00150.I.2.A/Acetamiprid

| | 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) according to current harmonized classification) | active substance (Acetamiprid 17.61% (w/w)) | None | N.a. | N.a. |
| Toxicological properties of active substance(s) (relevant for classification of product according to amendments in Regulation (EC) No 1272/2008 to be enforced from 23 November 2023 | Acetamiprid 17.61% (w/w) | Repr. 2 ($\geq 3.0\%$) | N.a. | Repr. 2 |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | No data – not required | | | |
| 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 $0.1 \mu\text{g/L}$ – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in ADM.00150.I.2.A / Acetamiprid 200 SL are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in ADM.00150.I.2.A / Acetamiprid 200 SL

| Acetamiprid 200 SL | | | |
|--|--------------|--|--|
| | Experimental | | EU agreed endpoint (EFSA Conclusion (2016)) |
| Concentrate 200 g/L | 4% | Recalculated dermal absorption values (according to EFSA Journal 2017;15(6):4873) of study reported in Appendix 2 | Not applicable. The product was not the representative formulation. |
| Dilution 0.035 g/L (Dilution rate 5714) | 31% | Recalculated dermal absorption values (according to EFSA Journal 2017;15(6):4873) of study reported in Appendix 2 | Not applicable. The product was not the representative formulation. |

6.5.1 Justification for proposed values - Acetamiprid

Proposed dermal absorption rates for acetamiprid are based on dermal absorption studies on a formulation identical to ADM.00150.I.2.A/Acetamiprid 200 SL. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of ADM.00150.I.2.A/Acetamiprid 200 SL 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 acetamiprid

| Test | Concentrate | Spray dilution (5714 dilution factor) | Formulation in study | Acceptability of study | Justification provided on representativity of study formulation for current product | Acceptability of justification | Reference* |
|----------------------------|-------------|--|-------------------------|---------------------------|--|--|---|
| <i>In vitro</i> (rat) | 11.9 ± 1.7% | 42.7 ± 5.6% | Acetamiprid 200 SL | Yes | Yes (see Appendix A 2.10) | Justification accepted. Endpoint can be used for current product | KCP 7.3/01 Rheus, A.A., 2013 |
| <i>In vitro</i> (human) | 3.4 ± 0.6% | 25.1 ± 5.9% | Acetamiprid 200 SL | Yes | Yes (see Appendix A 2.10) | Justification accepted. Endpoint can be used for current product | KCP 7.3/01 Rheus, A.A., 2013 |
| <i>In vitro</i> (human) | 4.03% | 30.51% | Acetamiprid 200 SL | Yes | Yes (see Appendix A 2.10) | Justification accepted. Endpoint can be used for current product | KCP 7.3/01 Rheus, A.A., 2013 Recalculated based on EFSA 2017 |

* 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 | ADM.00150.I.2.A / Acetamiprid 200 SL |
| Formulation type | SL |
| Category | Insecticide |
| Container size(s), short description | Not applicable* |
| Active substance(s) (incl. content) | Acetamiprid (200 g/L) |
| AOEL systemic | 0.025 mg/kg bw/d |
| AAOEL systemic | 0.025 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | Concentrate: 4% ** Spra dilution ≥ 0.035 g/L: 31% Spray dilution of 0.034 g a.s./ha was pro rata corrected to 32% Spray dilution of 0.025 g a.s./ha was pro rata corrected to 43% |

* Information about containers is not needed anymore since exposure calculations are conducted only with the EFSA model.

** The dermal absorption value for the concentrate with 200 g/L was not pro rata corrected.

*** The dermal absorption value for spray dilutions higher than 0.035 g/L was not pro rata corrected.

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 6.1-5. A list of all intended uses within the Central zone is given in Part B, Section 0.

Justification

For the sake of completeness, all umbrella GAPs were presented.

Table 6.6-2: Uses covered by cGAPs for operator, worker, resident and bystander exposure to ADM.00150.I.2.A/Acetamiprid 200 SL

| Scenarios | Uses covered by cGAPs for: | | |
|---|----------------------------|-----------------|-----------------------------|
| | Operator exposure | Worker exposure | Bystander/resident exposure |
| For sake of completeness, all umbrella GAPs were presented. | | | |

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 substances during application of ADM.00150.I.2.A/Acetamiprid 200 SL, according to the critical use(s) is presented in Table 6.6-3. The outcome of the estimation is presented in ^{*}. Due to missing data within the OPEX model for manual downward applications at application rates below 1.5 kg a.s./ha, it is not feasible to calculate the correct %AOEL for this use. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1.

^{*} The DA value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-35. Detailed calculations are in Appendix 3.

A summary of the exposure models used for estimation of operator exposure to the active substances during application of ADM.00150.I.2.A/Acetamiprid 200 SL, according to the critical use(s) is presented in Table 6.6-3. The outcome of the estimation is presented in Table 6.6-4 - Table 6.6-39. Detailed calculations are in Appendix 3.

The assessment of operator exposure during the application of plant protection products in low ornamentals (Flower bulbs and flower tubers at 1x 46 g a.s./ha and 2x 34 g a.s./ha) has revealed results exceeding 100%. This discrepancy arises primarily from the limitations of data within the EFSA model concerning manual downward application techniques: The EFSA model lacks specific data for downward manual hand held and knapsack application rates lower than 1.5 kg active substance (a.s.) per hectare (ha). As a result, when assessing exposure for manual downward application rates below this threshold, the model defaults to the exposure estimates for the application rate of 1.5 kg a.s./ha which is much higher (at a magnitude of ca. 30) than the relevant uses of the intended GAP (1x 46 g a.s./ha and 2x 34 g a.s./ha). This is visible for example that there is effectively no difference in the outcome results of exposure (total absorbed dose) between applying two doses of 0.034 kg a.s./ha (as presented in Table 6.6-25 and Table 6.6-26) and a single application of 0.046 kg a.s./ha. Therefore, the applicant believes that accurately calculating operator exposure during manual downward spraying for the intended ornamental uses is not feasible. This issue is particularly relevant for manual application methods in low ornamentals, where operators apply rates below 1.5 kg a.s./ha. In contrast, the model provides sufficient data for manual upward spraying of high ornamentals, allowing for calculations based on appropriate input parameters. In general, it is assumed that upward spraying is expected to yield higher operator exposure compared to lower applications.

Therefore, manual downward spraying uses in ornamentals are additionally calculated for upward spraying techniques. The results for manual upward applications to ornamentals are acceptable (%AOEL is below 100%). This suggests that if manual upward spraying to ornamentals is deemed acceptable, then the associated risks of manual downward spraying to ornamentals should also be considered acceptable.

Table 6.6-3: Exposure models for intended uses

| | |
|-----------------|--|
| Critical use(s) | Cereals (corn) (max. 1x 0.3 L product/ha); 1x 60 g a.s./ha Apples (max. 1x 0.4 L product/ha); 1x 80 g a.s./ha Apples (max. 2x 0.125 L product/ha); 2x 25 g a.s./ha Potatoes (max. 1x 0.18 L product/ha); 1x 36 g a.s./ha Cereals (max. 2x 0.175 L product/ha); 2x 35 g a.s./ha Cereals (max. 2x 0.18 L product/ha); 2x 36 g a.s./ha Cereals (max. 1x 0.15 L product/ha); 1x 30 g a.s./ha Sugar beet (max 2x 0.25 L product/ha); 2x 50 g a.s./ha Flower bulbs and flower tubers (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Flower bulbs and flower tubers (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha |
|-----------------|--|

| | |
|--------|---|
| Models | <p>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</p> <p>New AOEM online model as provided by EU based on EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022;20(1):7032</p> |
|--------|---|

* Due to missing data within the OPEX model for manual downward applications at application rates below 1.5 kg a.s./ha, it is not feasible to calculate the correct %AOEL for this use. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1.

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

| | | Acetamiprid | |
|---|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.06 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.01 | 54.6 |

Table 6.6-5: Estimated operator exposure (acute exposure) – Cereals (corn)

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.06 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 91.9 |

Table 6.6-6: Estimated operator exposure (longer term exposure) - Apples

| | | Acetamiprid | |
|---|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.08 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | Work wear (arms, body and legs covered) M/L and A | 0.02 | 86.5 |
| Application rate | | 2 × 0.025 kg a.s./ha* | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.01 | 41.4 |

* The DA-value for the spray dilution of 0.025 g a.s./ha was pro rata corrected from 31% to 43%.

Table 6.6-7: Estimated operator exposure (acute exposure) - Apples

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.08 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + Faceshield App: Workwear + Protected hands + Hood | 0.02 | 86.2 |
| Application rate | | 2 × 0.025 kg a.s./ha* | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 63.4 |

* The DA-value for the spray dilution of 0.025 g a.s./ha was pro rata corrected from 31% to 43%

Table 6.6-8: Estimated operator exposure (longer term exposure) - Potatoes

| | | Acetamiprid | |
|---|--------------------------------|---------------------------------|--------------------|
| 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 | | 1 × 0.036 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 38.2 |

Table 6.6-9: Estimated operator exposure (acute exposure) - Potatoes

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.036 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 82.4 |

Table 6.6-10: Estimated operator exposure (longer term exposure) - Cereals

| | | Acetamiprid | |
|---|--------------------------------|---------------------------------|--------------------|
| 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 | | 2 × 0.035 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.009 | 37.4 |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.036 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 38.2 |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.03 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.008 | 33.6 |

Table 6.6-11: Estimated operator exposure (acute exposure) - Cereals

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 2x 0.035 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 80.7 |
| Application rate | | 2x 0.036 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 82.4 |
| Application rate | | 1 × 0.03 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 72.2 |

Table 6.6-12: Estimated operator exposure (longer term exposure) – Oilseed rape

| | | Acetamiprid | |
|---|--------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |

| | | | |
|---|--------------------------------|---------------------|------|
| Application rate | | 2 × 0.06 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 54.6 |

Table 6.6-13: Estimated operator exposure (acute exposure) -- Oilseed rape

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.06 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 91.9 |

Table 6.6-14: Estimated operator exposure (longer term exposure) – Sugar beet

| | | Acetamiprid | |
|---|--------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.05 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 48.00 |

Table 6.6-15: Estimated operator exposure (acute exposure) – Sugar beet

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.05 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 88.5 |

Table 6.6-16: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Tractor mounted

| | | Acetamiprid | |
|---|--------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) | M/L: Workwear App: Workwear | 0.01 | 45.3 |

| | | | |
|--------------------|--|--|--|
| Body weight: 60 kg | | | |
|--------------------|--|--|--|

Table 6.6-17: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Tractor mounted

| | | Acetamiprid | |
|--|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 98.4 |

Table 6.6-18: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Manual-hand held

| | | Acetamiprid | |
|--|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | 185* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct %AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-19: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Manual-hand held

| | | Acetamiprid | |
|--|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | 1298* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct %AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-20: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Manual knapsack

| | | Acetamiprid | |
|--|--|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | 185* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct % AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-21: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Manual knapsack

| | | Acetamiprid | |
|--|--|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | 1297* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct % AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-22: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Tractor mounted

| | | Acetamiprid | |
|--|--------------------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.009 | 36.7 |

Table 6.6-23: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Tractor mounted

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to low crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 79.00 |

Table 6.6-24: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Manual-hand held

| | | Acetamiprid | |
|---|--|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual hand held spray application outdoors to low ornamentals | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | 185* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct %AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1.

Table 6.6-25: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Manual-hand held

| | | Acetamiprid | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual hand held spray application outdoors to low ornamentals | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | 1387* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct %AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-26: Estimated operator exposure (longer term exposure) - Flower bulbs and flower tubers – Calculated as low ornamentals – Manual knapsack

| | | Acetamiprid | |
|---|--------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual knapsack application outdoors to low ornamentals | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |

| | | | |
|---|--|------|------|
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | 185* |
|---|--|------|------|

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct % AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-27: Estimated operator exposure (acute exposure) - Flower bulbs and flower tubers - Calculated as low ornamentals – Manual knapsack

| Acetamiprid | | | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual knapsack application outdoors to low ornamentals | | | |
| Application rate | | 2 × 0.034 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | 1388* |

* Due to missing data within the OPEX model for manual downward applications, this does not represent the correct % AOEL. Instead, it is assumed, that this use is covered by the manual upward spraying to high ornamentals. Expert statement is given in 6.6.2.1

Table 6.6-28: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Tractor mounted

| Acetamiprid | | | |
|---|--------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 54.3 |

Table 6.6-29: Estimated operator exposure (acute exposure) - Floriculture, tree nursery & perennial nursery crops – Tractor mounted

| Acetamiprid | | | |
|---|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 84.3 |

Table 6.6-30: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Manual-hand held

| | | Acetamiprid | |
|--|--------------------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual-hand held spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 45.2 |

Table 6.6-31: Estimated operator exposure (acute exposure) - Floriculture, tree nursery & perennial nursery crops – Manual-hand held

| | | Acetamiprid | |
|--|--|------------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual-hand held spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.01 | 55.9 |

Table 6.6-32: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Manual knapsack

| | | Acetamiprid | |
|--|--------------------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual knapsack spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 75 th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 54.7 |

Table 6.6-33: Estimated operator exposure (acute exposure) - Floriculture, tree nursery & perennial nursery crops – Manual knapsack

| | | Acetamiprid | |
|--|---|------------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual knapsack spray application outdoors to high crops | | | |
| Application rate | | 1 × 0.046 kg a.s./ha | |
| Spray application (new online AOEM; 95 th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 67.3 |

Table 6.6-34: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Tractor mounted

| | | Acetamiprid | |
|--|--------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 75th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 43.1 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-35: Estimated operator exposure (acute exposure) – Floriculture, tree nursery & perennial nursery crops – Tractor mounted

| | | Acetamiprid | |
|--|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Tractor mounted spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 95th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 64.4 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-36: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Manual-hand held

| | | | |
|--|--------------------------------|------------------------------------|--------------------|
| Nursery crops | | Manual hand held | |
| | | Acetamiprid | |
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual-hand held spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 75th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 41.4 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-37: Estimated operator exposure (acute exposure) – Floriculture, tree nursery & perennial nursery crops – Manual-hand held

| | | Acetamiprid | |
|--|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual-hand held spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 95th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 94.8 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-38: Estimated operator exposure (longer term exposure) - Floriculture, tree nursery & perennial nursery crops – Manual knapsack

| | | Acetamiprid | |
|--|--------------------------------|---------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AOEL |
| Manual knapsack spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 75th percentile) Body weight: 60 kg | M/L: Workwear App: Workwear | 0.01 | 54.3 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

Table 6.6-39: Estimated operator exposure (acute exposure) – Floriculture, tree nursery & perennial nursery crops – Manual knapsack

| | | Acetamiprid | |
|--|--|---------------------------------|---------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg/day] | % of systemic AAOEL |
| Manual knapsack spray application outdoors to high crops | | | |
| Application rate | | 2 × 0.034 kg a.s./ha* | |
| Spray application (new online AOEM; 95th percentile) Body weight: 60 kg | M/L: Workwear + Protected hands App: Workwear | 0.02 | 64.7 |

* The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6- shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with ADM.00150.I.2.A/Acetamiprid 200 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6- to Table 6.6-. Detailed calculations are in Appendix 3.

Table 6.6-40: Exposure models for intended uses

| | |
|-----------------|--|
| Critical use(s) | Cereals (corn) (max. 0.3 L product/ha); 1x 60 g a.s./ha Apples (max. 0.4 L product/ha); 1x 80 g a.s./ha Apples (max. 2x 0.125 L product/ha); 2x 25 g a.s./ha Potatoes (max. 0.18 L product/ha); 1x 36 g a.s./ha Cereals (max. 2x 0.175 L product/ha); 2x 35 g a.s./ha – 10 days min. interval Cereals (max. 2x 0.175 L product/ha); 2x 35 g a.s./ha – 30 days min. interval Cereals (max. 2x 0.18 L product/ha); 2x 36 g a.s./ha Cereals (max. 1x 0.15 L product/ha); 1x 30 g a.s./ha Oilseed (max. 2x 0.3 L product/ha); 2x 60 g a.s./ha Oilseed (max. 1x 0.3 L product/ha); 1x 60 g a.s./ha Sugar beet (max 2x 0.25 L product/ha); 2x 50 g a.s./ha Flower bulbs and flower tubers (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Flower bulbs and flower tubers (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha |
| Models | 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 New AOEM online model as provided by EU based on EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022;20(1):7032 |

Table 6.6-41: Estimated worker exposure – Cereals (corn) 1x 60 g a.s./ha

| | | Acetamiprid | | |
|---|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.06 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 93 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 10.4 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 9.3 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-42: Estimated worker exposure – Apples – 1x 80 g a.s./ha

| | | Acetamiprid | | |
|--|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.08 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 22500 cm ² /person/h | 0.2 | 893 | 95 |
| | Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h | 0.04 | 179 | 26 |
| | Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h | 0.02 | 89.3 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: n.a. | | | | |
| Application rate | | 1x 0.08 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.03 | 124 | 10 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 13.9 | 0 |
| | Work wear (arms, body and legs | 0.003 | 12.4 | 0 |

| | | | | |
|---|---|--------------------|------|---------------------------------|
| | covered) and gloves TC: 1250 cm ² /person/h | | | |
| Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.08 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.1 | 496 | 70 |
| | Work wear (arms, body and legs covered) TC: 3500 cm ² /person/h | 0.03 | 139 | 15 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.01 | 49.6 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-43: Estimated worker exposure – Apples – 2x 25 g a.s./ha

| | | Acetamiprid | | |
|--|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 8 days DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 2x 0.025 kg a.s./ha** | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 22500 cm²/person/h | 0.2 | 715 | 86 |
| | Work wear (arms, body and legs covered) TC: 4500 cm²/person/h | 0.04 | 143 | 16 |
| | Work wear (arms, body and legs covered) and gloves TC: 2250 cm²/person/h | 0.02 | 71.5 | 0 |
| Inspection, irrigation / Outdoor Work rate: 8 hours/day Interval: 8 days DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 2x 0.025 kg a.s./ha** | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm²/person/h | 0.02 | 99.3 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.003 | 11.1 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h | 0.002 | 9.9 | 0 |

| | | | | |
|---|--|-----------------------|------|------------------------------|
| Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 8 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.025 kg a.s./ha** | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.1 | 397 | 60 |
| | Work wear (arms, body and legs covered) TC: 3500 cm ² /person/h | 0.03 | 111 | 5 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.01 | 39.7 | 0 |

* Re-entry period to reach an AOEL of <100%

** The DA-value for the spray dilution of 0.025 g a.s./ha was pro rata corrected from 31% to 43%.

Table 6.6-44: Estimated worker exposure – Potatoes 1x 36 g a.s./ha

| | | Acetamiprid | | |
|---|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 1x 0.036 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 5800 cm²/person/h | 0.03 | 104 | 2 |
| | Work wear (arms, body and legs covered) TC: 2500 cm²/person/h | 0.01 | 44.6 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h | 0.003 | 10.4 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 1x 0.036 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm²/person/h | 0.01 | 55.8 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.002 | 6.2 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h | 0.001 | 5.6 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-45: Estimated worker exposure – Cereals – 2x 35 g a.s./ha - 10 days min. interval

| | | Acetamiprid | | |
|--|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 10 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.035 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 97.1 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 10.9 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 9.7 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-46: Estimated worker exposure – Cereals – 2x 35 g a.s./ha - 30 days min. interval

| | | Acetamiprid | | |
|--|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 30 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.035 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 81.4 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.002 | 9.1 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 8.1 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-47: Estimated worker exposure – Cereals – 2x 36 g a.s./ha

| | | Acetamiprid | |
|--|--------------|------------------------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 10 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | |
| Application rate | | 2x 0.036 kg a.s./ha | Re-entry restriction [days]* |

| | | | | |
|---------------------------------------|--|-------|------|---|
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 99.9 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 11.2 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 10 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-48: Estimated worker exposure – Cereals – 1x 30 g a.s./ha

| | | Acetamiprid | | |
|--|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 1x 0.03 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm²/person/h | 0.01 | 46.5 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.001 | 5.2 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h | 0.001 | 4.7 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-40: Estimated worker exposure – Oilseed – 2x 60 g a.s./ha

| | | Acetamiprid | | |
|--|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 2x 0.06 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm²/person/h | 0.04 | 172 | 24 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.005 | 19.3 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h | 0.004 | 17.2 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-50: Estimated worker exposure – Oilseed – 1x 60 g a.s./ha

| | | Acetamiprid | | |
|---|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.06 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 93 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 10.4 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 9.3 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-51: Estimated worker exposure – Sugar beet – 2x 50 g a.s./ha

| | | Acetamiprid | | |
|--|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.05 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 5800 cm ² /person/h | 0.07 | 266 | 43 |
| | Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h | 0.03 | 115 | 6 |
| | Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h | 0.007 | 26.6 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.05 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.04 | 143 | 16 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.004 | 16.1 | 0 |
| | Work wear (arms, body and legs covered) and gloves | 0.004 | 14.3 | 0 |

| | | | | |
|---|---|--------------------|------|------------------------------|
| | TC: 1250 cm ² /person/h | | | |
| Removing bolting sugar beets / Outdoor Work rate: 8 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.05 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 18600 cm ² /person/h | 0.2 | 853 | 93 |
| | Work wear (arms, body and legs covered) TC: 4400 cm ² /person/h | 0.05 | 202 | 31 |
| | Work wear (arms, body and legs covered) and gloves TC: 430 cm ² /person/h | 0.005 | 19.7 | 0 |
| | Hands covered (gloves), no workwear TC 14300 cm ² /person/h | 0.2 | 656 | 82 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-52: Estimated worker exposure – Flower bulbs and flower tubers – 1x 46 g a.s./ha

| Estimated worker exposure – Flower bulbs and flower tubers – 1x 40 g a.s./ha | | | | |
|--|--|------------------------------------|---------------------|------------------------------|
| | | Acetamiprid | | |
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/ cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.046 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 14000 cm ² /person/h | 0.08 | 319 | 51 |
| | Work wear (arms, body and legs covered) TC: 5000 cm ² /person/h | 0.03 | 114 | 6 |
| | Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h | 0.008 | 31.9 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.046 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 71.3 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.002 | 8 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 7.1 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-53: Estimated worker exposure – Flower bulbs and flower tubers – 2x 34 g a.s./ha

| | | Acetamiprid | | |
|---|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.034 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 14000 cm ² /person/h | 0.1 | 437 | 64 |
| | Work wear (arms, body and legs covered) TC: 5000 cm ² /person/h | 0.04 | 156 | 20 |
| | Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h | 0.01 | 43.7 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 2x 0.034 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 97.5 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.003 | 10.9 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 9.7 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-54: Estimated worker exposure – Floriculture, tree nursery & perennial nursery crops – 1x 46 g a.s./ha

| | | Acetamiprid | | |
|--|--|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 1x 0.046 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 14000 cm²/person/h | 0.08 | 319 | 51 |
| | Work wear (arms, body and legs covered) TC: 5000 cm²/person/h | 0.03 | 114 | 6 |
| | Work wear (arms, body and legs | 0.008 | 31.9 | 0 |

| | | | | |
|---|---|---------------------|------|---------------------------------|
| | covered) and gloves TC: 1400 cm ² /person/h | | | |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | |
| Application rate | | 1x 0.046 kg a.s./ha | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.02 | 71.3 | 0 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.002 | 8 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.002 | 7.1 | 0 |

* Re-entry period to reach an AOEL of <100%

Table 6.6-55: Estimated worker exposure – Floriculture, tree nursery & perennial nursery crops – 2x 34 g a.s./ha

| | | Acetamiprid | | |
|--|---|------------------------------------|---------------------|------------------------------|
| Model data | Level of PPE | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL | |
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 2x 0.034 kg a.s./ha** | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 14000 cm²/person/h | 0.1 | 450 | 66 |
| | Work wear (arms, body and legs covered) TC: 5000 cm²/person/h | 0.04 | 161 | 21 |
| | Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h | 0.01 | 45 | 0 |
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha | | | | |
| Application rate | | 2x 0.034 kg a.s./ha** | | Re-entry restriction [days]* |
| New online AOEM Body weight: 60 kg | Potential TC: 12500 cm²/person/h | 0.03 | 100.4 | 1 |
| | Work wear (arms, body and legs covered) TC: 1400 cm²/person/h | 0.003 | 11.2 | 0 |
| | Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h | 0.003 | 10 | 0 |

* Re-entry period to reach an AOEL of <100%

** The DA-value for the spray dilution of 0.034 g a.s./ha was pro rata corrected from 31% to 32%.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

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

Table 6.6- shows the exposure model(s) used for estimation of resident and bystander exposure to Acetamiprid. The outcome of the estimation is presented in Table 6.6- to Table 6.6-41. Detailed calculations are in Appendix 3.

Table 6.6-56: Exposure models for intended uses

| | |
|-----------------|---|
| Critical use(s) | Cereals (corn) (max. 0.3 L product/ha); 1x 60 g a.s./ha Apples (max. 0.4 L product/ha); 1x 80 g a.s./ha Apples (max. 2x 0.125 L product/ha); 2x 25 g a.s./ha Potatoes (max. 0.18 L product/ha); 1x 36 g a.s./ha Cereals (max. 2x 0.175 L product/ha); 2x 35 g a.s./ha – 10 days min. interval Cereals (max. 2x 0.175 L product/ha); 2x 35 g a.s./ha – 30 days min. interval Cereals (max. 2x 0.18 L product/ha); 2x 36 g a.s./ha Cereals (max. 1x 0.15 L product/ha); 1x 30 g a.s./ha Cereals (max. 2x 0.3 L product/ha); 2x 60 g a.s./ha Sugar beet (max 2x 0.25 L product/ha); 2x 50 g a.s./ha Flower bulbs and flower tubers (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Flower bulbs and flower tubers (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 1x 0.23 L product/ha); 1x 46 g a.s./ha Floriculture, tree nursery & perennial nursery crops (max. 2x 0.17 L product/ha); 2x 34 g a.s./ha |
| Models | 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 New AOEM online model as provided by EU based on EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022;20(1):7032 |

Table 6.6-57: Estimated resident exposure (longer term exposure) – Cereals (corn) – 1x 60 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 300 L | | | |
| Number of applications and application rate | | 1x 0.06 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.002 | 6.7 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0003 | 1.3 |
| | Re-entry (75 th perc.) | 0.003 | 12.6 |

| | | | |
|--------------------------------------|-----------------------------------|--------|------|
| | Sum (mean) | 0.004 | 17.8 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0004 | 1.6 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.5 |
| | Re-entry (75 th perc.) | 0.002 | 7 |
| | Sum (mean) | 0.002 | 7.8 |

Table 6.6-58: Estimated bystander exposure (acute exposure) – Cereals (corn) – 1x 60 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 300 L | | | |
| Number of applications and application rate | | 1x 0.06 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.004 | 15.2 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0009 | 3.8 |
| | Re-entry (95 th perc.) | 0.003 | 12.6 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.001 | 4.1 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0004 | 1.5 |
| | Re-entry (95 th perc.) | 0.002 | 7 |

Table 6.6-59: Estimated resident exposure (longer term exposure) – Apples – 1x 80 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.08 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.007 | 27.5 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.001 | 4.8 |
| | Re-entry (75 th perc.) | 0.004 | 16.7 |
| | Sum (mean) | 0.01 | 38.2 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.004 | 15.3 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0005 | 1.9 |
| | Re-entry (75 th perc.) | 0.002 | 9.3 |
| | Sum (mean) | 0.005 | 19.9 |
| New AOEM online model Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.08 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.007 | 27.5 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0005 | 1.8 |
| | Re-entry (75 th perc.) | 0.004 | 16.7 |
| | Sum (mean) | 0.009 | 35.8 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.004 | 15.3 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0002 | 0.7 |
| | Re-entry (75 th perc.) | 0.002 | 9.3 |
| | Sum (mean) | 0.005 | 18.9 |

Table 6.6-60: Estimated bystander exposure (acute exposure) – Apples – 1x 80 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.08 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.02 | 63.2 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.003 | 11.9 |
| | Re-entry (95 th perc.) | 0.004 | 16.7 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.009 | 35 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.001 | 4.8 |
| | Re-entry (95 th perc.) | 0.002 | 9.3 |
| New AOEM online model Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.08 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.02 | 63.2 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 5 |
| | Re-entry (95 th perc.) | 0.004 | 16.7 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.009 | 35 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0005 | 2 |
| | Re-entry (95 th perc.) | 0.002 | 9.3 |

Table 6.6-61: Estimated resident exposure (longer term exposure) – Apples – 2x 25 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 2x 0.025 kg a.s./ha Dermal absorption: 43% DFR: 3 µg/cm² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 12 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0009 | 3.7 |
| | Re-entry (75 th perc.) | 0.003 | 13.4 |
| | Sum (mean) | 0.006 | 24.5 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.002 | 6.7 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0004 | 1.5 |
| | Re-entry (75 th perc.) | 0.002 | 7.4 |
| | Sum (mean) | 0.003 | 12.5 |
| New AOEM online model Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 2x 0.025 kg a.s./ha Dermal absorption: 43% DFR: 3 µg/cm² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 12 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0004 | 1.4 |
| | Re-entry (75 th perc.) | 0.003 | 13.4 |
| | Sum (mean) | 0.006 | 22.7 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.002 | 6.7 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.6 |
| | Re-entry (75 th perc.) | 0.002 | 7.4 |
| | Sum (mean) | 0.003 | 11.7 |

Table 6.6-62: Estimated bystander exposure (acute exposure) – Apples – 2x 25 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.025 kg a.s./ha Dermal absorption: 43% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 27.6 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.002 | 9.1 |
| | Re-entry (95 th perc.) | 0.003 | 13.4 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.004 | 15.3 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.001 | 3.8 |
| | Re-entry (95 th perc.) | 0.002 | 7.4 |
| New AOEM online model Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 L | | | |
| Number of applications and application rate | | 1x 0.025 kg a.s./ha Dermal absorption: 43% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 27.6 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 3.9 |
| | Re-entry (95 th perc.) | 0.003 | 13.4 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.004 | 15.3 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0004 | 1.6 |
| | Re-entry (95 th perc.) | 0.002 | 7.4 |

Table 6.6-63: Estimated resident exposure (longer term exposure) – Potatoes – 1x 36 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 1x 0.036 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 12.1 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0002 | 0.8 |
| | Re-entry (75 th perc.) | 0.002 | 7.5 |
| | Sum (mean) | 0.004 | 16.4 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0007 | 2.9 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 8e-05 | 0.3 |
| | Re-entry (75 th perc.) | 0.001 | 4.2 |
| | Sum (mean) | 0.001 | 6 |

Table 6.6-64: Estimated bystander exposure (acute exposure) – Potatoes – 1x 36 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 1x 0.036 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 27.3 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0006 | 2.3 |
| | Re-entry (95 th perc.) | 0.002 | 7.5 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.002 | 7.4 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0002 | 0.9 |
| | Re-entry (95 th perc.) | 0.001 | 4.2 |

Table 6.6-65: Estimated resident exposure (longer term exposure) – Cereals – 2x 35 g a.s./ha 10 days min. interval

| | | Acetamiprid | |
|--|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.035 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 11.8 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0003 | 1.3 |
| | Re-entry (75 th perc.) | 0.003 | 13.1 |
| | Sum (mean) | 0.005 | 21.1 |

| | | | |
|--------------------------------------|-----------------------------------|--------|-----|
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0007 | 2.8 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.5 |
| | Re-entry (75 th perc.) | 0.002 | 7.3 |
| | Sum (mean) | 0.002 | 8.6 |

Table 6.6-66: Estimated bystander exposure (acute exposure) – Cereals – 2x 35 g a.s./ha – 10 days min. interval

| Model data | Acetamiprid | | |
|--|-----------------------------------|---|---------------------|
| | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.035 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 26.5 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 4 |
| | Re-entry (95 th perc.) | 0.003 | 13.1 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.002 | 7.2 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0004 | 1.6 |
| | Re-entry (95 th perc.) | 0.002 | 7.3 |

Table 6.6-67: Estimated resident exposure (longer term exposure) – Cereals – 2x 35 g a.s./ha - 30 days min. interval

| | | Acetamiprid | |
|--|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 30 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.035 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 11.8 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0003 | 1.1 |
| | Re-entry (75 th perc.) | 0.003 | 11 |
| | Sum (mean) | 0.005 | 19.2 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0007 | 2.8 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.4 |
| | Re-entry (75 th perc.) | 0.002 | 6.1 |
| | Sum (mean) | 0.002 | 7.6 |

Table 6.6-68: Estimated bystander exposure (acute exposure) – Cereals – 2x 35 g a.s./ha – 30 days min. interval

| | | Acetamiprid | |
|--|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 30 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.035 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 26.5 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0008 | 3.3 |
| | Re-entry (95 th perc.) | 0.003 | 11 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.002 | 7.2 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0003 | 1.3 |
| | Re-entry (95 th perc.) | 0.002 | 6.1 |

Table 6.6-69: Estimated resident exposure (longer term exposure) – Cereals – 2x 36 g a.s./ha

| | | Acetamiprid | |
|--|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.036 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 12.1 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0003 | 1.4 |
| | Re-entry (75 th perc.) | 0.003 | 13.5 |
| | Sum (mean) | 0.005 | 21.6 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0007 | 2.9 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.5 |
| | Re-entry (75 th perc.) | 0.002 | 7.5 |
| | Sum (mean) | 0.002 | 8.8 |

Table 6.6-70: Estimated bystander exposure (acute exposure) – Cereals – 2x 36 g a.s./ha

| | | Acetamiprid | |
|--|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.036 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.007 | 27.3 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 4.1 |
| | Re-entry (95 th perc.) | 0.003 | 13.5 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.002 | 7.4 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0004 | 1.6 |
| | Re-entry (95 th perc.) | 0.002 | 7.5 |

Table 6.6-71: Estimated resident exposure (longer term exposure) – Cereals 1x 30 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 1x 0.03 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.003 | 10.1 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0002 | 0.6 |
| | Re-entry (75 th perc.) | 0.002 | 6.3 |
| | Sum (mean) | 0.004 | 14.2 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0006 | 2.4 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 6e-05 | 0.3 |
| | Re-entry (75 th perc.) | 0.0009 | 3.5 |
| | Sum (mean) | 0.001 | 5.2 |

Table 6.6-72: Estimated bystander exposure (acute exposure) – Cereals – 1x 30 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Early season Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 1x 0.03 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.006 | 22.7 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0005 | 1.9 |
| | Re-entry (95 th perc.) | 0.002 | 6.3 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.002 | 6.2 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0002 | 0.8 |
| | Re-entry (95 th perc.) | 0.0009 | 3.5 |

Table 6.6-73: Estimated resident exposure (longer term exposure) – Cereals – 2x 60 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.06 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.005 | 20.2 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0006 | 2.4 |
| | Re-entry (75 th perc.) | 0.006 | 23.2 |
| | Sum (mean) | 0.009 | 34.5 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.001 | 4.8 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0002 | 0.9 |
| | Re-entry (75 th perc.) | 0.003 | 12.9 |
| | Sum (mean) | 0.004 | 14.3 |

Table 6.6-74: Estimated bystander exposure (acute exposure) – Cereals – 2x 60 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 L | | | |
| Number of applications and application rate | | 2x 0.06 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.01 | 45.5 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.002 | 7 |
| | Re-entry (95 th perc.) | 0.006 | 23.2 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.003 | 12.3 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0007 | 2.8 |
| | Re-entry (95 th perc.) | 0.003 | 12.9 |

Table 6.6-75: Estimated resident exposure (longer term exposure) – Sugar beet – 2x 50 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.05 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.002 | 8.4 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0005 | 2 |
| | Re-entry (75 th perc.) | 0.005 | 19.4 |
| | Sum (mean) | 0.006 | 24.7 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0005 | 2 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0002 | 0.8 |
| | Re-entry (75 th perc.) | 0.003 | 10.8 |
| | Sum (mean) | 0.003 | 11.2 |

Table 6.6-76: Estimated bystander exposure (acute exposure) - Sugar beet – 2x 50 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.05 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.005 | 18.9 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 5.9 |
| | Re-entry (95 th perc.) | 0.005 | 19.4 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.001 | 5.1 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0006 | 2.4 |
| | Re-entry (95 th perc.) | 0.003 | 10.8 |

Table 6.6-77: Estimated resident exposure (longer term exposure) – Flower bulbs and flower tubers – 1x 46 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 1x 0.046 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.002 | 7.7 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0002 | 1 |
| | Re-entry (75 th perc.) | 0.002 | 9.6 |
| | Sum (mean) | 0.004 | 15.8 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0005 | 1.8 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.4 |
| | Re-entry (75 th perc.) | 0.001 | 5.3 |
| | Sum (mean) | 0.002 | 6.5 |

Table 6.6-78: Estimated bystander exposure (acute exposure) - Flower bulbs and flower tubers – 1x 46 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 1x 0.046 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.004 | 17.4 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0007 | 2.9 |
| | Re-entry (95 th perc.) | 0.002 | 9.6 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.001 | 4.7 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0003 | 1.2 |
| | Re-entry (95 th perc.) | 0.001 | 5.3 |

Table 6.6-79: Estimated resident exposure (longer term exposure) – Flower bulbs and flower tubers – 2x 34 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.034 kg a.s./ha Dermal absorption: 32% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.001 | 5.7 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0003 | 1.3 |
| | Re-entry (75 th perc.) | 0.003 | 13.2 |
| | Sum (mean) | 0.004 | 17.8 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.0003 | 1.4 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 0.0001 | 0.5 |
| | Re-entry (75 th perc.) | 0.002 | 7.3 |
| | Sum (mean) | 0.002 | 7.9 |

Table 6.6-80 Estimated bystander exposure (acute exposure) - Flower bulbs and flower tubers – 2x 34 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.034 kg a.s./ha Dermal absorption: 32% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.003 | 12.9 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.001 | 4 |
| | Re-entry (95 th perc.) | 0.003 | 13.2 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.0009 | 3.5 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0004 | 1.6 |
| | Re-entry (95 th perc.) | 0.002 | 7.3 |

Table 6.6-81: Estimated resident exposure (longer term exposure) - Floriculture, Tree nursery – 1x 46 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 1x 0.046 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.01 | 39.6 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0001 | 0.5 |
| | Re-entry (75 th perc.) | 0.002 | 9.6 |
| | Sum (mean) | 0.009 | 37.3 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.005 | 22 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 5e-05 | 0.2 |
| | Re-entry (75 th perc.) | 0.001 | 5.3 |
| | Sum (mean) | 0.005 | 19.9 |

Table 6.6-41: Estimated bystander exposure (acute exposure) – Floriculture, Tree nursery – 1x 46 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 1x 0.046 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.02 | 90.8 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0003 | 1.2 |
| | Re-entry (95 th perc.) | 0.002 | 9.6 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.01 | 50.3 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0001 | 0.5 |
| | Re-entry (95 th perc.) | 0.001 | 5.3 |

Table 6.6-42: Estimated bystander exposure (acute exposure) - Floriculture, Tree nursery - 1x 46 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------|---|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 1x 0.046 kg a.s./ha Dermal absorption: 31% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.02 | 90.8 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0003 | 1.2 |
| | Re-entry (95th perc.) | 0.002 | 9.6 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.01 | 50.3 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0001 | 0.5 |
| | Re-entry (95th perc.) | 0.001 | 5.3 |

Table 6.6-43: Estimated resident exposure (longer term exposure) - Floriculture, Tree nursery – 2x 34 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|---|--------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.034 kg a.s./ha Dermal absorption: 32% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Resident child Body weight: 10 kg | Drift (75 th perc.) | 0.008 | 30.1 |
| | Vapour (75 th perc.) | 0.0008 | 3.2 |
| | Deposits (75 th perc.) | 0.0002 | 0.8 |
| | Re-entry (75 th perc.) | 0.003 | 13.5 |
| | Sum (mean) | 0.009 | 34.4 |
| Resident adult Body weight: 60 kg | Drift (75 th perc.) | 0.004 | 16.7 |
| | Vapour (75 th perc.) | 0.0003 | 1.1 |
| | Deposits (75 th perc.) | 7e-05 | 0.3 |
| | Re-entry (75 th perc.) | 0.002 | 7.5 |
| | Sum (mean) | 0.005 | 18.2 |

Table 6.6-44: Estimated bystander exposure (acute exposure) - Floriculture, Tree nursery - 2x 34 g a.s./ha

| | | Acetamiprid | |
|---|-----------------------------------|--|---------------------|
| Model data | | Total absorbed dose [mg/kg bw/day] | % of systemic AAOEL |
| New AOEM online model Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 L | | | |
| Number of applications and application rate | | 2x 0.0346 kg a.s./ha Dermal absorption: 32% DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days | |
| Bystander child Body weight: 10 kg | Drift (95 th perc.) | 0.02 | 69.1 |
| | Vapour (95 th perc.) | 0.0008 | 3.2 |
| | Deposits (95 th perc.) | 0.0004 | 1.7 |
| | Re-entry (95 th perc.) | 0.003 | 13.5 |
| Bystander adult Body weight: 60 kg | Drift (95 th perc.) | 0.01 | 38.3 |
| | Vapour (95 th perc.) | 0.0003 | 1.1 |
| | Deposits (95 th perc.) | 0.0002 | 0.7 |
| | Re-entry (95 th perc.) | 0.002 | 7.5 |

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 acetamiprid 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 7.1.3/01 | ██████████. | 2013 | Acetamiprid 200 SL: Acute inhalation toxicity study (Nose-only) in the rat 12/445-004P ██████████ GLP Unpublished | Y | Adama |
| KCP 7.1.4/01 | Kiss I. | 2013 | Acetamiprid 200 SL: <i>In vitro</i> skin irritation test in the EPISKIN model 12/445-043B Source CiToxLAB Hungary Ltd GLP Unpublished | N | Adama |
| KCP 7.1.5/01 | Kiss I. | 2013 | Acetamiprid 200 SL: <i>In vitro</i> eye irritation test in isolated chicken eyes 12/445-038CS Source CiToxLAB Hungary Ltd GLP Unpublished | N | Adama |
| KCP 7.3/01 | Rheus, A.A. | 2013 | <i>In vitro</i> percutaneous absorption of Acetamiprid, formulated as Acetamiprid 200 SL, through human and rat skin V20330/08 Source TNO Triskelion GLP Unpublished | N | Adama |

| 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 7.3/02 | Di Donato | 2023 | Acetamiprid - <i>In vitro</i> percutaneous penetration of [¹⁴ C]Acetamiprid formulated as Acetamiprid 200 SL (ADM.00150.I.2.A) through Human Skin Membranes - This study is ongoing. 20220544 Source: Innovative Environmental Services (IES) GLP Unpublished | N | Adama |

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 |
|------------|-----------|------|--|-------------------------|-------------|
| CA 5.7.1 | ████ | 2008 | An oral developmental neurotoxicity study of actamiprid in rats ████ Source: █████ GLP Unpublished | Y | Nippon Soda |

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

The acute toxicity endpoints were calculated according to the Commission Regulation (EC) No. 1272/2008, based on the classification of the active substance and the formulants of Acetamiprid 200 SL. The product is formerly known under the product code MCW-2222. The two products are identical. The summary of the acute inhalation toxicity study is presented, since Acetamiprid 200 SL contains two ingredients with unknown inhalation toxicity.

A 2.1 Statement on bridging possibilities

| | |
|-------------------|-----------------------------|
| Comments of zRMS: | Bridging is not applicable. |
|-------------------|-----------------------------|

A 2.2 Acute oral toxicity (KCP 7.1.1)

| | |
|-------------------|---|
| Comments of zRMS: | Accepted, product toxicity has been calculated with the proposed classification of Acetamiprid as oral acute tox 3 (acute toxicity point estimate of 140 mg/kg bw) and Repr. 2. For more detailed information please refer Part C (1.3.2 Available toxicological data for each formulant; Tables 1.3-3 and 1.3-4 (KCP 7.4). |
|-------------------|---|

No vertebrate study is submitted. Classification for acute oral toxicity is based on the classification of the active substance and the formulants of Acetamiprid 200 SL. According to the Commission Regulation (EC) No. 1272/2008, the calculated ATE is 1710 mg/kg bw (current harmonized classification) and 795 mg/kg bw (amendments to Regulation (EC) No 1272/2008 to be enforced from 23 November 2023). Therefore, Acetamiprid 200 SL needs to be labelled as Category 4 (H302). For more detailed information reference is made to Part C (KCP 7.4).

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

| | |
|-------------------|---|
| Comments of zRMS: | Hazard assessment and proposed classification of the product has been based on content ingredients of the mixture (Additivity formula) (for details see Part C (KCP 7.4). Calculation accepted. |
|-------------------|---|

No vertebrate study is submitted. Classification for acute dermal toxicity is based on the classification of the active substance and the formulants of Acetamiprid 200 SL. According to the Commission Regulation (EC) No. 1272/2008, the calculated ATE is over 2000 mg/kg bw. Therefore, Acetamiprid 200 SL does not need to be labelled. For more detailed information reference is made to Part C (KCP 7.4).

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

| | |
|-------------------|--|
| Comments of zRMS: | <p>In an acute inhalation toxicity study [REDACTED], 2013 Wistar Crl:WI rats were exposed to a test atmosphere of ACETAMIPRID 200 SL. The test item was administered undiluted. The study was performed in two steps. A sighting exposure was performed first, where a test atmosphere at a target concentration of 5 mg/L was tested on single animals of both sexes (Group 0.1). No lethality was observed at this concentration, therefore the main study was performed at a target concentration of 5 mg/L as Group1. Five male and five female rats were used in this group.</p> <p>In both study phases, the animals were exposed to the test atmosphere for 4 hours using a nose-only exposure system. Aerosol concentrations were measured gravimetrically 17 times during each 4-hour exposure and the particle size distributions of the test aerosols were determined 3 times. A 14-day observation period followed the exposures.</p> <p>Clinical observations were performed for all animals during exposure at hourly intervals, following removal from restraint, approximately 1 hour following the end of the exposure, and daily for 14 days thereafter. Bodyweight was measured on Days 0 (before the exposure), 1, 3, 7 and 14. Gross necropsy was performed on all animals sacrificed on Day 14. The quality of the test atmosphere fully complied with criteria documented in the respective guidelines: OECD 403, EPA OPPTS 870.1300 and Council Regulation (EC) No 440/2008. The mean achieved atmosphere concentrations were 5.00 and 5.16 in Group 0.1 and Group 1, respectively. The mass median aerodynamic diameter (MMAD) was 2.30 µm and 2.22 µm with geometric standard deviation (GSD) 2.07 and 2.06 in the sighting group and the main group, respectively. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted</p> |
|-------------------|--|

A 2.4.1 Study 1

| | |
|--------------------------------------|--|
| Reference | 7.1.3/01 |
| Report | Acetamiprid 200 SL acute inhalation toxicity study (nose-only) in the rat., [REDACTED], 2013, Report No.: 12/445-004P |
| Guideline(s) | OECD 403 (2009) |
| Deviations | Major deviations: None Minor deviations: None Exposure duration for rats was only 4 h instead of 6 h. |
| GLP | Yes |
| Acceptability | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|----------------------------------|---|
| Test material (Lot/Batch No.) | Acetamiprid 200 SL (Lot/Batch No. 577-271212-02) |
| Species | Rat, Crl:WI |
| No. of animals (group size) | 5 rats/sex/dose (main group), 1 rat (sighting exposure group 0.1) |
| Concentration(s) | 5 mg/L air |
| Exposure | 4 hours (nose only) |
| Vehicle/Dilution | None |
| Post exposure observation period | 14 days |
| Remarks | None |

Results and discussions

Table A 1: Concentration(s) and exposure conditions

| Part of Study | Target conc. [mg/L air] | Actual conc. [mg/L air] | MMAD * [µm] | GSD ** [µm] | Nominal conc. [mg/L air] |
|------------------------------|----------------------------|----------------------------|----------------|----------------|-----------------------------|
| Sighting exposure: Group 0.1 | 5 | 5.00 | 2.30 | 2.07 | 20.09 |
| Main study: Group 1 | 5 | 5.16 | 2.22 | 2.06 | 19.88 |

* MMAD = Mass Median Aerodynamic Diameter

** GSD = Geometric Standard Deviation

Table A 2: Results of acute inhalation toxicity study in rats of ADM.00150.I.2.A/Acetamiprid

| Concentration [mg/L air] | Toxicological results * | Duration of signs | Time of death | LC ₅₀ [mg/L air] (14 days) |
|-----------------------------|-------------------------|-------------------|---------------|--|
| Male rats | | | | |
| 5.00 | 0/1/1 | 2 days | n.a. | > 5.00 |
| Female rats | | | | |
| 5.00 | 0/1/1 | 2 days | n.a. | > 5.00 |
| Male rats | | | | |
| 5.16 | 0/5/5 | 1 day | n.a. | > 5.16 |
| Female rats | | | | |
| 5.16 | 0/5/5 | 1 day | n.a. | > 5.16 |

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

n.a. Not applicable

Table A 3: Summary of findings of acute inhalation toxicity study in rats of ADM.00150.I.2.A/Acetamiprid

| | |
|--------------------------------|--|
| Mortality | No mortality occurred. |
| Clinical signs | Yes (In group 0.1: Laboured respiration (slight to moderate) in both animals on Day 0-2. Hunched back in both male and female during the period of Day 0-2. In the male animal, continuous tremor and decreased activity were seen on Day 0 and Day 0-1, respectively. Wet fur, ruffled fur and red-brown staining were observed in both animals on Day 0-1, but the red-brown staining persisted to Day 5 in male and Day 14 in female animal. These observations were considered not to be toxicologically significant. In group 1: Laboured respiration (slight to moderate) in all rats, continuous tremor in a single female on Day 0. Wet fur and/or ruffled fur and/or red-brown staining in all animals on Day 0-1 but were considered not to be toxicologically significant.) |
| Body weight | Reduced (Slight to moderate bodyweight loss (6.3-11.1%) in both animals on Day 1-3 in Group 0.1. The animals gained back their initial bodyweight values between Day 3 and Day 7. In Group 1, slight bodyweight loss (2.0-8.9%) was noted in all animals on Day 1-3. Both males and females returned to their initial bodyweight values by up to Day 7.) |
| Macroscopic examination | The necropsies performed at the end of the study revealed no apparent findings. |

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of ADM.00150.I.2.A/Acetamiprid 200 SL is higher than 5.16 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: | Hazard assessment and proposed classification of the product has been based on content ingredients of the mixture (Additivity formula) (for details see Part C (KCP 7.4). Calculation accepted. |
|-------------------|---|

No vertebrate study is submitted. Classification for skin irritation is based on the classification of the active substance and the formulants of Acetamiprid 200 SL. According to the Commission Regulation (EC) No. 1272/2008, the calculated as being not irritating to the skin. Therefore, Acetamiprid 200 SL does not need to be labelled. For more detailed information reference is made to Part C (KCP 7.4).

A 2.5.1 Study 1

| | |
|-------------------|--|
| Comments of zRMS: | Regarding an <i>in vitro</i> study Kiss, I., 2013, (<i>Acetamiprid 200 SL: In vitro skin irritation test in the EPISKIN model</i>) zRMS reviewer draws attention to the following information available in GD OECD 439 revision 14 June 2021 INITIAL CONSIDERATIONS AND LIMITATIONS Subsection 8: p.2 (..) <u>data indicates a lack of applicability of the RhE based <i>in vitro</i> skin irritation test for agrochemical formulations (47).</u> (..). See also: Kolle S.N, van Ravenzwaay B. and Landsiedel R. (2017). Regulatory accepted but out of domain: <i>In vitro</i> skin irritation tests for agrochemical formulations. Regul. Toxicol. Pharmacol 89, 125-130. Thus, taking into account mentioned above information zRMS decided to conclude assessment in this hazard category for the ADM.00150.I.2.A based on content ingredients of the mixture (Additivity formula) (for details see Part C (KCP 7.4). |
|-------------------|--|

| | |
|--------------------------------------|---|
| Reference | 7.1.4/01 |
| Report | Acetamiprid 200 SL: <i>In vitro</i> skin irritation test in the EPISKIN model., Kiss, I., 2013, Report No.: 12/445-043B |
| Guideline(s) | OECD 439 (2010) |
| Deviations | Major deviations: None Minor deviations: Calibration information for measuring device is not given. Reference to historical data of the model are not given. |
| GLP | Yes |
| Acceptability | Yes No |
| Duplication (if vertebrate study) | Not applicable |

Materials and methods

| | |
|-------------------------------|--|
| Test material (Lot/Batch No.) | Acetamiprid 200 SL (Lot/Batch No. 577-271212-02) |
| Test system | MTT (Thiazolyl blue) cell viability assay, on the EPISKIN reconstituted human epidermis. |
| No. of replicates / well | 3 for the test item and 3 negative controls + 3 positive controls |
| Cultivation conditions | 37 °C, 5% CO2 |
| Exposure | 42 h |
| Vehicle/Dilution | None |
| Remarks | None |

Results and discussions

Table A 4: In vitro skin irritation of ADM.00150.I.2.A/Acetamiprid 200 LS- Results of optical density measured at 540 nm

| Substance | Mean optical density* [TOD] | Mean viability ± SD [% RV] |
|------------------------|--------------------------------|-------------------------------|
| Negative control (PBS) | 0.670 | 100 ± 7 |
| Positive control (SDS) | 0.072 | 11 ± 3.41 |
| Test item (MCW-2222) | 0.659 | 98 ± 3.79 |

* For the test item, the material had a residual colour which was expected to cause an OD of 0.034 in the final solutions. This was subtracted from the measured OD values.

Conclusion

Under the experimental conditions, ADM.00150.I.2.A/Acetamiprid 200 LS 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: | Hazard assessment and proposed classification of the product has been based on content ingredients of the mixture (Additivity formula) (for details see Part C (KCP 7.4). Calculation accepted. |
|-------------------|---|

No vertebrate study is submitted. Classification for eye irritation is based on the classification of the active substance and the formulants of Acetamiprid 200 SL. According to the Commission Regulation (EC) No. 1272/2008, the calculated as being irritating to the eye. Therefore, Acetamiprid 200 SL needs to be labelled as Eye irritant 2. For more detailed information reference is made to Part C (KCP 7.4).

A 2.6.1 Study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>An in vitro eye irritation study of the test item ACETAMIPRID 200 SL was performed in isolated chicken's eyes. The irritation effects of the test item were evaluated according to the OECD No.: 438 (07th September 2009).</p> <p>After the zero reference measurements, the eye was held in horizontal position and 30 µL of ACETAMIPRID 200 SL was applied onto the centre of the cornea such that the entire surface of the cornea was covered. After 10 seconds, the surface was rinsed with saline. The positive control eyes were treated in a similar way with 30 µL Trichloroacetic acid 30 (w/v) %. The negative control eye was treated with 30 µL of physiological saline. Corneal thickness, corneal opacity and fluorescein retention were measured.</p> <p>In this in vitro eye irritation study in the Isolated Chicken Eyes model with ACETAMIPRID 200 SL, <u>the results suggest that the test item is slightly irritating.</u></p> <p>Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.</p> <p>According to the guideline OECD 438, ACETAMIPRID 200 SL does not require a classification as a severe eye irritant, an <i>in vivo</i> study is required for classification but <u>available assessment based on content ingredients of the mixture confirmed that ACETAMIPRID 200 SL has irritating properties and needs to be labelled as Eye irritant 2.</u></p> |
|-------------------|---|

| | |
|---------------|---|
| Reference: | KCP 7.1.5/01 |
| Report | Acetamiprid 200 SL: <i>In vitro</i> eye irritation test in isolated chicken eyes. Kiss I., 2013, Report No.: 12/445-038CS |
| Guideline(s): | OECD 438 |
| Deviations: | None |
| GLP: | Yes |

Acceptability: Yes
Duplication No
(if vertebrate study)

Materials and methods

| | |
|---|---|
| Test material (Lot/Batch No.) | Acetamidrid 200 SL (577-271212-02) |
| Species | Chicken, Ross 308 |
| No. of animals (group size) | 3 isolated eyes per treatment |
| Initial test using one animal | No, study involves <i>in vitro</i> testing |
| Exposure | 30 µL test item (single instillation in cornea, 10 sec, after exposure washed with 20 mL isotonic saline) |
| Irritation (time point) | Slightly irritating (75 minutes) |
| Vehicle/Dilution | None |
| Post exposure observation period | 30, 75, 120, 180, 240 minutes |
| Remarks | None |

Results and discussions

Table A5: Eye irritation of MCW-2222/Acetamidrid 200

| Observation | Test item (MCW-2222) | | Positive control (Trichloroacetic acid 30% (w/v)) | | Negative control (Sodium chloride 0.9%) | |
|--|-------------------------|-------------|--|-------------|--|-------------|
| | Value | ICE Class * | Value | ICE Class * | Value | ICE Class * |
| Mean maximum corneal swelling at up to 75 min | 0% | I | -2% | I | 0% | I |
| Mean maximum corneal swelling at up to 240 min | -2% | I | -12% | II | 0% | I |
| Mean maximum corneal opacity | 1 | II | 3.67 | IV | 0.00 | I |
| Mean fluorescein retention | 2.33 | III | 2.83 | IV | 0.00 | I |
| Other Observations | None | | Immediate cornea opacity score 4. | | None | |
| Overall ICE Class * | 1xI 1xII 1xIII | | 1xII 2xIV | | 3xI | |

Conclusion

Under the experimental conditions, MCW-2222/Acetamidrid 200 is slightly irritating. According to the guideline OECD 438, Acetamidrid 200 SL does not require a classification as a severe eye irritant, an *in vivo* study is required for classification.

A 2.7 Skin sensitisation (KCP 7.1.6)

| | |
|-------------------|---|
| Comments of zRMS: | Hazard assessment and proposed classification of the product has been based on content ingredients of the mixture (Additivity formula) (for details see Part C (KCP 7.4). Calculation accepted. |
|-------------------|---|

No vertebrate study is submitted. Classification for skin sensitisation is based on the classification of the active substance and the formulants of Acetamidrid 200 SL. According to the Commission Regulation (EC) No. 1272/2008, the calculated as being not sensitising to the skin. Therefore, Acetamidrid 200 SL does not need to be labelled. For more detailed information reference is made to Part C (KCP 7.4).

| | |
|-------------------|---|
| Comments of zRMS: | Information provided in points A 2.8 – A.2.9.1 are sufficient and acceptable. |
|-------------------|---|

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

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 – Active substance 1 in ADM.00150.I.2.A/Acetamiprid

Comparative dermal absorption, in vitro using rat and human skin

| | |
|-------------------|--|
| Comments of zRMS: | <p><i>In vitro</i> percutaneous absorption of acetamiprid, formulated as Acetamiprid 200 SL, has been measured through human and rat skin membranes. The test substance was tested at two target concentrations: 200 g.L⁻¹ (concentrate) and 0.035 g.L⁻¹ (field dilution). The concentrate represents the maximal concentration possible when handling the undiluted formulation, while 0.035 g.L⁻¹ reflects the concentration recommended for use in the field. The objective of the study was to elucidate the extent of percutaneous absorption of the compound-related radioactivity. The contact time was 8 hours, i.e. a normal working day, and the post exposure time was 16 hours. In addition to the amount of [¹⁴C]Acetamiprid in the receptor fluid, the residues remaining in/on the skin membranes and in the stratum corneum (16 h post exposure) were determined. The study was performed in flow-through diffusion cells.</p> <p>Dermal absorption values found in the study conducted by Reus, 2013 were recalculated according to the new EFSA Dermal absorption guidance of 2017 (EFSA Journal 2017;15(6):4873). For more details, please refer to Table A 12 to Table A13.</p> <p>Results of the study and conclusions are adequate for NDE assessment. Study accepted.</p> |
|-------------------|--|

A 1.1.1 Study 1

| | |
|--------------------------------------|---|
| Reference: | KCP 7.3/01 |
| Report | <i>In vitro</i> percutaneous absorption of Acetamiprid, formulated as Acetamiprid 200 SL, through human and rat skin, Rheus, A. A., 2013, Report No.: V20330/08 |
| Guideline(s): | OECD 428, April 2004. EU Method B.45 (Reg. No. 440/2008) |
| Deviations: | No deviation which affected the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication (if vertebrate study) | No |

Materials and methods

| | |
|--|--|
| Test materials (Lot/Batch No.) | <u>Acetamiprid 200 SL (577-271212-02)</u> <u>Blank formulation: MCW 2222 blank (301212)</u> <u>Radiolabelled material: [methylene-14C]-Acetamiprid (239-141-0321-A-20121206-DRE, 98.3% radiochemical purity)</u> |
| Vehicle | [¹⁴ C] acetamiprid dissolved in methanol The solvent was evaporated under N ₂ gas until complete dryness. |
| Skin preparations | <u>Human skin</u> , 4 donors (born from 1955-1969, breast and abdomen samples, 2 skin membranes from 3 donors and 1 skin membrane from one donor in each test group) <u>Rat skin</u> , 1 donor (male rat (Wistar WU, Charles River, Germany), ca. 8 weeks old) <u>Preparation</u> : The full thickness skin samples (human and rat) were dermatomed to slices which contained epidermis and some dermis and which were 200 – 400 µm thick. |
| Test system | <u>Diffusion cell</u> : PermeGear Inc. flow-through diffusion cell (Temp. approx. 32±1°C, 1.6 mL/h flow-rate) <u>Receptor fluid</u> : |

| | |
|--|---|
| | saline (0.9% sodium chloride (w/v) containing 0.01% sodium azide, (w/v)), supplemented 5% bovine serum albumin (BSA, w/v). |
| Membrane integrity and membrane selection | The <u>integrity</u> of the selected skin samples was tested with tritiated water ($^3\text{H}_2\text{O}$). The membranes were exposed to 200 μL over 3 hours. <u>Selection:</u> Skin membranes with a Kp value below the cut-off value of $2.5 \times 10^{-3} \text{ cm/h}$ (human) or $3.5 \times 10^{-3} \text{ cm/h}$ (rat) were selected for the study. |
| Application on skin | <u>Volume applied per skin:</u> 6.4 μL of dose preparations applied topically on 0.64 cm^2 skin membrane <u>Concentrate human (A):</u> n=7, 202.3 g/L total concentration, $2053 \pm 36 \mu\text{g/cm}^2$ mean dose a.s. applied <u>Dilution human (B):</u> n=7, 0.036 g/L total concentration, $0.37 \pm 0.00 \mu\text{g/cm}^2$ mean dose a.s. applied <u>Concentrate rat (C):</u> n=6, 202.3 g/L total concentration, $2077 \pm 12 \mu\text{g/cm}^2$ mean dose a.s. applied <u>Dilution rat (D):</u> n=6, 0.036 g/L total concentration, $0.37 \pm 0.00 \mu\text{g/cm}^2$ mean dose a.s. applied <u>Exposure time:</u> 8 h |
| Sampling | <u>Receptor fluid</u> samples were collected during the following intervals: 0-1 h, 1-2 h, followed by 2-h intervals until 24 hours after application. <u>Skin wash:</u> After an exposure period of 8 h, the unabsorbed test substance was removed from the application site using a mild soap solution (i.e. 3% Teepol in water), water and cotton swabs. After 24 h of exposure, the diffusion cell was dismantled. <u>Receptor and donor compartments</u> were washed twice with 1.0 mL ethanol. <u>Each skin membrane was tape stripped 15 times</u> using D-Squame® Skin Sampling Discs (CuDerm Corporation) and a D-Squame pressure device. Tape strips were stored individually for further analysis. <u>Skin membranes</u> were digested in a 1.5 M KOH solution with 20% aqueous ethanol for at least 24 h. |
| Analysis of radioactivity | The radioactivity in the samples was determined using a Canberra Packard Tricarb 3100 TR scintillation counter. Ultima Gold™ scintillation liquid (Packard) was added to samples of the receptor fluid (10 mL per sample), the diffusion cell washes (10 mL per sample), the cotton swab extracts (10 mL to a 0.5 mL aliquot of each sample), the tape strips (4 mL per sample), and to samples of the mock dosing samples (10 mL per sample). For the determination of radioactivity in digested skin preparations, 15 mL Hionic Fluor™ scintillation liquid (Packard) was added to each digested skin membrane. Radioactivity was determined in all collected samples. |
| HPLC | HPLC with radiodetection was carried out using an Inertsil ODS-2 (250 x 4.6 mm, 5 μm) column with demineralised water + 0.1% trifluoroacetic acid (TFA) and acetonitrile + 0.1% TFA as mobile phases and an UV detector wavelength of 247 nm. |
| Remarks | None |

Results and discussions

Integrity of skin membranes

Skin membranes with a Kp value below the cut-off value of $2.5 \times 10^{-3} \text{ cm/h}$ (human) or $3.5 \times 10^{-3} \text{ cm/h}$ (rat) were selected for the study, except two human skin membranes with a Kp value slightly higher than 2.5 (i.e. a Kp value of 2.52) were included in the study (one skin membrane in group A and one skin membrane in group B), due to an insufficient number of skin membranes of donor 2 that met the acceptance criteria.

Receptor fluid solubility

The solubility of acetamiprid in water was reported to be ca 2.95 mg/mL. Considering the maximum absorption of acetamiprid into the receptor fluid of 116.3 μg (i.e. $181.7 \mu\text{g/cm}^2$ in 38.4 mL over 24 h, i.e. 3.0 $\mu\text{g/mL}$ (replicate C-3), the solubility of the test substance in the receptor fluid was considered sufficient. Furthermore, in the flow-through cells used, the volume of the receptor fluid in the receptor chamber beneath the skin is ca. 0.2 mL, which at a flow rate of ca. 1.6 mL/h, was replenished continuously (8 times per hour). Thus, it was assured that the rate of diffusion into the receptor fluid did not become a rate-limiting

step.

Analytical check of dose preparations

The homogeneity of [¹⁴C]acetamiprid in the dose preparations was checked; the coefficients of variation (CV) of the dose preparations were 0.5% (A/C) and 0.2% (B/D), and therefore considered sufficient. The radiochemical purity of [¹⁴C]acetamiprid in the dose preparations was found to be >97% for both dose preparations.

Table A6: Distribution of radioactivity following the application of [¹⁴C]Acetamiprid to human and rat skin *in vitro*

| Dose level Skin type | High | | Low | |
|--|-------------|-------------|-----------------|-----------------|
| | Human | Rat | Human | Rat |
| Skin surface (Skin swabs) [%] | 96.1 ± 2.6 | 87.5 ± 3.2 | 72.5 ± 7.4 | 55.0 ± 5.8 |
| Skin surface (2 surface tape strips) [%] | 0.10 ± 0.03 | 0.03 ± 0.03 | 0.79 ± 0.36 | 0.68 ± 0.21 |
| Remaining on cell (Donor chamber) [%] | 0.13 ± 0.21 | 0.06 ± 0.02 | 0.47 ± 0.65 | 0.23 ± 0.12 |
| Total [%] | 96.33 | 87.59 | 73.76 | 55.91 |
| 75% absorbed in RF in first half of study | No | Yes | No | Yes |
| Receptor fluid [%] | 2.75 ± 0.69 | 8.15 ± 0.27 | 14.24 ± 7.34 | 11.75 ± 5.22 |
| Skin [%] | 0.36 ± 0.14 | 3.42 ± 1.19 | 8.73 ± 3.62 | 23.6 ± 6.0 |
| Remaining on cell [%] | 0.01 ± 0.01 | 0.01 ± 0.01 | 0.16 ± 0.04 | 0.06 ± 0.02 |
| Total [%] | 3.1 ± 0.6 | 11.6 ± 1.4 | 23.1 ± 6.6 | 35.4 ± 8.7 |
| Stratum Corneum (Tape strips 3-15) [%] | 0.31 ± 0.09 | 0.29 ± 0.38 | 1.92 ± 1.00 | 7.31 ± 5.20 |
| Total absorbable [%] | 3.4 ± 0.6 | 11.9 ± 1.7 | 25.1 ± 5.9 | 42.7 ± 5.6 |
| Total recovery [%] | 99.7 ± 2.5 | 99.5 ± 2.0 | 98.8 ± 4.8 | 98.6 ± 2.6 |
| Absorption rate (µg equiv./cm ² /h) | 6.38 ± 3.12 | 32.8 ± 2.3 | 0.0041 ± 0.0034 | 0.0073 ± 0.0046 |

Conclusion

The total absorbable dose was found to be 3.4% and 25.1% in human skin for the high and low dose levels, respectively and 11.9% (high dose) and 42.7% (low dose) in rat skin.

Based on the potentially absorbed dose, for the concentrate formulation human skin was 3.5 times less permeable for acetamiprid compared to rat skin (11.9 / 3.4), while for the field dilution, human skin was 1.7 times less permeable for acetamiprid compared to rat skin (42.7 / 25.1).

Recalculation according to EFSA 2017¹

Dermal absorption values found in the study conducted by Reus, 2013 were recalculated according to the new EFSA Dermal absorption guidance of 2017 (EFSA Journal 2017;15(6):4873). For more details, please refer to Table A 12 to Table A13.

¹ EFSA Journal 2017;15(6):4873

[illegible]

Table A8: Recalculation of dermal absorption values for dilution 1 (0.035 g/L) - human.

[illegible]

Table A8: Results for recalculation of dermal absorption values

Results and discussion

| | Concentrate | | Dilution 1 | |
|--|-------------|-------|------------|-------|
| | | | (1:xxx) | |
| Target concentration [mg/mL] | 202.3 | | 0.036 | |
| Target dose [$\mu\text{g}/\text{cm}^2$] | 2053 | | 0.37 | |
| Mean actual applied dose [$\mu\text{g}/\text{cm}^2$] | | | | |
| Recovery [%] | Mean | SD | Mean | SD |
| Dislodgeable dose | | | | |
| Skin wash after x hours | 96.09 | 2.62 | 72.49 | 7.38 |
| Donor chamber wash | 0.13 | 0.21 | 0.47 | 0.65 |
| Skin associated dose | | | | |
| Tape strips 1-2 | 0.11 | 0.04 | 0.79 | 0.36 |
| Tape strips 3-x | 0.31 | 0.09 | 1.91 | 1.00 |
| Skin preparation | 0.36 | 0.14 | 8.73 | 3.62 |
| Absorbed dose | | | | |
| Receptor fluid | 2.75 | 0.69 | 14.24 | 7.34 |
| Receptor chamber wash | 0.01 | 0.01 | 0.16 | 0.04 |
| Total recovery | 99.76 | 2.49 | 98.79 | 4.77 |
| LLC of t _{0.5} absorption | 58.44 | 13.31 | 48.71 | 12.09 |
| Absorption complete? | No | | No | |
| Measured absorption, if LLC of t _{0.5} ≤ 75% | 3.43 | 0.65 | 25.04 | 5.94 |
| Measured absorption, if LLC of t _{0.5} > 75% | N/A | N/A | N/A | N/A |
| Measured absorption corrected | 3.43 | 0.65 | 25.04 | 5.94 |
| Relevant absorption estimate | 4.031 | | 30.508 | |
| Final estimate (rounded) | 4 | | 31 | |

Table A9: Recalculation of dermal absorption values for the concentrate (200 g/L) - *in vitro* - human.

| Replicate | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|--------------------------|------------|------------|------------|------------|------------|------------|------------|
| T0.5 <= 75 % | | | | | | | |
| Absorbed dose | 2.62 | 2.72 | 3.86 | 2.65 | 3.43 | 2.26 | 1.83 |
| Tape strips 3-x | 0.28 | 0.21 | 0.25 | 0.23 | 0.43 | 0.44 | 0.31 |
| Skin preparation | 0.19 | 0.2 | 0.3 | 0.41 | 0.43 | 0.4 | 0.59 |
| Sum | 3.09 | 3.13 | 4.41 | 3.29 | 4.29 | 3.1 | 2.73 |
| Relevant data normalised | 3.09 | 3.13 | 4.41 | 3.29 | 4.29 | 3.1 | 2.73 |
| Relevant data added | 3.09 | 3.13 | 4.41 | 3.29 | 4.29 | 3.1 | 2.73 |
| Relevant data | 3.09 | 3.13 | 4.41 | 3.29 | 4.29 | 3.1 | 2.73 |
| T0.5 > 75 % | | | | | | | |
| Absorbed dose | 2.62 | 2.72 | 3.86 | 2.65 | 3.43 | 2.26 | 1.83 |
| Skin preparation | 0.19 | 0.2 | 0.3 | 0.41 | 0.43 | 0.4 | 0.59 |
| Sum | 2.81 | 2.92 | 4.16 | 3.06 | 3.86 | 2.66 | 2.42 |
| Relevant data normalised | 2.81 | 2.92 | 4.16 | 3.06 | 3.86 | 2.66 | 2.42 |
| Relevant data added | 2.81 | 2.92 | 4.16 | 3.06 | 3.86 | 2.66 | 2.42 |
| Relevant data | 2.81 | 2.92 | 4.16 | 3.06 | 3.86 | 2.66 | 2.42 |
| Non-absorbed dose | 95.77 | 99.54 | 95.83 | 91.54 | 97.16 | 97.4 | 97.02 |
| Total Recovery | 98.86 | 102.67 | 100.24 | 94.83 | 101.45 | 100.5 | 99.75 |
| T0.5 | 75.1879699 | 84.5045045 | 88.2352941 | 69.2585895 | 79.5518207 | 56.2363239 | 49.3297587 |

| | Replicate | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|-----------------------|-------------------------------|------|------|------|------|------|------|------|
| [%] | Donor ID | | | | | | | |
| | | | | | | | | |
| Receptor fluid | Receptor fluid | 2.61 | 2.71 | 3.85 | 2.64 | 3.42 | 2.24 | 1.8 |
| Receptor chamber wash | Receptor compartment wash | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.02 | 0.03 |
| Donor chamber wash | Donor compartment wash | 0.03 | 0.04 | 0.13 | 0.59 | 0.05 | 0.04 | 0.03 |
| | Tape strips | | | | | | | |
| Tape strips 1+2 | 1 | 0.14 | 0.1 | 0.1 | 0.05 | 0.11 | 0.16 | 0.09 |
| Tape strips 1+2 | 2 | | | | | | | |
| Tape strips 3-x | 3 | 0.05 | 0.03 | 0.03 | 0.02 | 0.03 | 0.03 | 0.03 |
| Tape strips 3-x | 4 | 0.04 | 0.02 | 0.02 | 0.02 | 0.03 | 0.05 | 0.05 |
| Tape strips 3-x | 5 | 0.03 | 0.02 | 0.03 | 0.02 | 0.02 | 0.03 | 0.03 |
| Tape strips 3-x | 6 | 0.03 | 0.01 | 0.02 | 0.02 | 0.03 | 0.03 | 0.02 |
| Tape strips 3-x | 7 | 0.02 | 0.02 | 0.02 | 0.03 | 0.03 | 0.04 | 0.03 |
| Tape strips 3-x | 8 | 0.01 | 0.02 | 0.01 | 0.01 | 0.02 | 0.03 | 0.02 |
| Tape strips 3-x | 9 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.04 | 0.02 |
| Tape strips 3-x | 10 | 0.01 | 0.01 | 0.02 | 0.02 | 0.03 | 0.03 | 0.01 |
| Tape strips 3-x | 11 | 0.01 | 0.02 | 0.02 | 0.03 | 0.04 | 0.03 | 0.02 |
| Tape strips 3-x | 12 | 0.01 | 0.02 | 0.01 | 0.01 | 0.03 | 0.03 | 0.02 |
| Tape strips 3-x | 13 | 0.02 | 0.01 | 0.02 | 0.02 | 0.04 | 0.03 | 0.02 |
| Tape strips 3-x | 14 | 0.02 | 0.01 | 0.02 | 0.01 | 0.07 | 0.03 | 0.02 |
| Tape strips 3-x | 15 | 0.02 | 0.01 | 0.02 | 0.01 | 0.05 | 0.04 | 0.02 |
| Skin wash | Skin wash | 95.6 | 99.4 | 95.6 | 90.9 | 97 | 97.2 | 96.9 |
| Skin preparation | Stripped skin | 0.19 | 0.2 | 0.3 | 0.41 | 0.43 | 0.4 | 0.59 |
| | | | | | | | | |
| T0.5 Receptor fluid | Receptor fluid after 12 hours | 40 | 46.9 | 67.5 | 38.3 | 56.8 | 25.7 | 18.4 |
| T1 Receptor fluid | Receptor fluid after 24 hours | 53.2 | 55.5 | 76.5 | 55.3 | 71.4 | 45.7 | 37.3 |

Table A10: Recalculation of dermal absorption values for dilution 1 (0.035 g/L) - human

| Replicate | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|--------------------------|------------|-------|------------|------------|------------|------------|------------|
| T0.5 <= 75 % | | | | | | | |
| Absorbed dose | 17.46 | 13.88 | 11.68 | 13.32 | 28.55 | 11.27 | 4.64 |
| Tape strips 3-x | 1.86 | 2.42 | 0.67 | 1.52 | 0.85 | 2.55 | 3.49 |
| Skin preparation | 5.85 | 5.06 | 12.08 | 9.74 | 5.84 | 14.69 | 7.88 |
| Sum | 25.17 | 21.36 | 24.43 | 24.58 | 35.24 | 28.51 | 16.01 |
| Relevant data normalised | 25.17 | 21.36 | 24.43 | 24.58 | 35.24 | 28.51 | 16.01 |
| Relevant data added | 25.17 | 21.36 | 24.43 | 24.58 | 35.24 | 28.51 | 16.01 |
| Relevant data | 25.17 | 21.36 | 24.43 | 24.58 | 35.24 | 28.51 | 16.01 |
| T0.5 > 75 % | | | | | | | |
| Absorbed dose | 17.46 | 13.88 | 11.68 | 13.32 | 28.55 | 11.27 | 4.64 |
| Skin preparation | 5.85 | 5.06 | 12.08 | 9.74 | 5.84 | 14.69 | 7.88 |
| Sum | 23.31 | 18.94 | 23.76 | 23.06 | 34.39 | 25.96 | 12.52 |
| Relevant data normalised | 23.31 | 18.94 | 23.76 | 23.06 | 34.39 | 25.96 | 12.52 |
| Relevant data added | 23.31 | 18.94 | 23.76 | 23.06 | 34.39 | 25.96 | 12.52 |
| Relevant data | 23.31 | 18.94 | 23.76 | 23.06 | 34.39 | 25.96 | 12.52 |
| Non-absorbed dose | 73.52 | 77.67 | 65.42 | 76.57 | 62.53 | 77.32 | 83.19 |
| Total Recovery | 98.69 | 99.03 | 89.85 | 101.15 | 97.77 | 105.83 | 99.2 |
| T0.5 | 68.2539683 | 66 | 65.1162791 | 53.0612245 | 80.7692308 | 51.2195122 | 41.1764706 |

| | Replicate | | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|-----------------------|-------------------------------|----|-------|-------|-------|-------|-------|-------|-------|
| [%] | Donor ID | | | | | | | | |
| | | | | | | | | | |
| Receptor fluid | Receptor fluid | | 17.26 | 13.74 | 11.53 | 13.14 | 28.41 | 11.04 | 4.54 |
| Receptor chamber wash | Receptor compartment wash | | 0.2 | 0.14 | 0.15 | 0.18 | 0.14 | 0.23 | 0.1 |
| Donor chamber wash | Donor compartment wash | | 0.19 | 0.16 | 1.94 | 0.18 | 0.38 | 0.22 | 0.24 |
| | Tape strips | | | | | | | | |
| Tape strips 1+2 | | 1 | 0.83 | 0.81 | 0.38 | 1.09 | 0.35 | 0.7 | 1.35 |
| Tape strips 1+2 | | 2 | | | | | | | |
| Tape strips 3-x | | 3 | 0.17 | 0.22 | 0.05 | 0.07 | 0.08 | 0.23 | 0.23 |
| Tape strips 3-x | | 4 | 0.18 | 0.16 | 0.09 | 0.11 | 0.1 | 0.17 | 0.21 |
| Tape strips 3-x | | 5 | 0.14 | 0.3 | 0.07 | 0.18 | 0.11 | 0.4 | 0.29 |
| Tape strips 3-x | | 6 | 0.17 | 0.26 | 0.05 | 0.13 | 0.05 | 0.11 | 0.25 |
| Tape strips 3-x | | 7 | 0.3 | 0.14 | 0.05 | 0.37 | 0.06 | 0.15 | 0.39 |
| Tape strips 3-x | | 8 | 0.18 | 0.23 | 0.05 | 0.1 | 0.1 | 0.15 | 0.21 |
| Tape strips 3-x | | 9 | 0.11 | 0.37 | 0.05 | 0.06 | 0.07 | 0.13 | 0.25 |
| Tape strips 3-x | | 10 | 0.12 | 0.15 | 0.03 | 0.08 | 0.09 | 0.14 | 0.37 |
| Tape strips 3-x | | 11 | 0.16 | 0.14 | 0.14 | 0.07 | 0.04 | 0.17 | 0.23 |
| Tape strips 3-x | | 12 | 0.1 | 0.1 | 0.02 | 0.1 | 0.03 | 0.38 | 0.4 |
| Tape strips 3-x | | 13 | 0.08 | 0.1 | 0.01 | 0.08 | 0.04 | 0.16 | 0.34 |
| Tape strips 3-x | | 14 | 0.09 | 0.16 | 0.04 | 0.09 | 0.04 | 0.25 | 0.19 |
| Tape strips 3-x | | 15 | 0.06 | 0.09 | 0.02 | 0.08 | 0.04 | 0.11 | 0.13 |
| Skin wash | Skin wash | | 72.5 | 76.7 | 63.1 | 75.3 | 61.8 | 76.4 | 81.6 |
| Skin preparation | Stripped skin | | 5.85 | 5.06 | 12.08 | 9.74 | 5.84 | 14.69 | 7.88 |
| | | | | | | | | | |
| T0.5 Receptor fluid | Receptor fluid after 12 hours | | 0.043 | 0.033 | 0.028 | 0.026 | 0.084 | 0.021 | 0.007 |
| T1 Receptor fluid | Receptor fluid after 24 hours | | 0.063 | 0.05 | 0.043 | 0.049 | 0.104 | 0.041 | 0.017 |

A 2.11 **Other/Special Studies**

Not applicable.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for acetamiprid

Table A 9: Estimation of operator exposure towards acetamiprid for the application on cereals (corn) – 1x 60 g a.s./ha - New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1x 0.06 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.01 | 54.6 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1x 0.06 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 91.9 |

Table A 10: Estimation of operator exposure towards acetamiprid for the application on apples – 1x 80 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--|--|--------------------|
| Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1x 0.08 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.02 | 86.5 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|-----------------------------------|------------------------|
| Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1x 0.08 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands + Faceshield App: Workwear + Protected hands + Hood | 0.02 | 86.2 |

Table A 11: Estimation of operator exposure towards acetamiprid for the application on apples –1x 25 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--------------------------------|---|-----------------------|
| Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2x 0.025 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 43.4 % | | | |
| Acetamiprid | M/L: Workwear App: Workwear | 0.01 | 41.4 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|---|--|-----------------------------------|------------------------|
| Orchards/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2x 0.025 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 43.4 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 63.4 |

Table A 12: Estimation of operator exposure towards acetamiprid for the application on potatoes 1x 36 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--------------------------------|--|--------------------|
| Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1x 0.036 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear App: Workwear | 0.01 | 38.2 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|---|--|--------------------------------|---------------------|
| Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1x 0.036 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear | 0.02 | 82.4 |

Table A 13: Estimation of operator exposure towards acetamiprid for the application on cereals – 2x 35 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--------------------------------|--|--------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2x 0.035 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear App: Workwear | 0.009 | 37.4 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|---|--------------------------------|---------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 2x 0.035 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear | 0.02 | 80.7 |

Table A 14: Estimation of operator exposure towards acetamiprid for the application on cereals – 2x 36 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|---|--|--------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 2x 0.036 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.01 | 38.2 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|---|--------------------------------|---------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 2x 0.036 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear | 0.02 | 82.4 |

Table A 15: Estimation of operator exposure towards acetamiprid for the application on cereals – 1x 30 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1x 0.03 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.008 | 33.6 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1x 0.03 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear | 0.02 | 72.2 |

Table A 16: Estimation of operator exposure towards acetamiprid for the application on oilseed rape – 2x 60 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 2x 0.06 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.01 | 54.6 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2x 0.06 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 91.9 |

Table A 17: Estimation of operator exposure towards acetamiprid for the application on sugar beet – 2x 50 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--------------------------------|--|--------------------|
| Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.05 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear App: Workwear | 0.01 | 48 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|---|--|--------------------------------|---------------------|
| Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.05 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 88.5 |

Table A 18: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers – 1x 46 g a.s./ha – New online EFSA Model, vehicle mounted

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.01 | 45.3 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear | 0.02 | 98.4 |

Table A 19: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers – 2x 34 g a.s./ha – New online EFSA Model, vehicle mounted

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.009 | 36.7 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear | 0.02 | 79 |

Table A 20: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers — 1x 46 g a.s./ha – New online EFSA Model, manual-hand held

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | No safe use! |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | No safe use! |

Table A 21: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers — 1x 46 g a.s./ha – New online EFSA Model, manual knapsack

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | No safe use! |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | No safe use! |

Table A 22: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers — 2 x 0.034 kg a.s./ha – New online EFSA Model, manual-hand held

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | No safe use! |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | No safe use! |

Table A 23: Estimation of operator exposure towards acetamiprid for the application on flower bulbs and flower tubers — 2 x 0.034 kg a.s./ha – New online EFSA Model, manual knapsack

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--|--|--------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.05 | No safe use! |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| Low ornamentals/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | | |
| Acetamipride | M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar | 0.3 | No safe use! |

Table A 24: Estimation of operator exposure towards acetamiprid for the application on floriculture, tree nursery & perennial nursery crops – 1x 46 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--|--|--------------------|
| High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear App: Workwear | 0.01 | 54.3 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|---|--|--------------------------------|---------------------|
| High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Acetamiprid | Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31 % | | |
| | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 84.3 |

Table A 25: Estimation of operator exposure towards acetamiprid for the application on floriculture, tree nursery & perennial nursery crops – 2x 34 g a.s./ha – New online EFSA Model

Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|--------------------------------|--|--------------------|
| High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31.9117647058824 % | | | |
| Acetamiprid | M/L: Workwear App: Workwear | 0.01 | 43.1 |

Acute exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw] | % of systemic AAOEL |
|--|--|--------------------------------|---------------------|
| High ornamentals/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption (concentrate): 4 % Dermal absorption (in-use dilution): 31.9117647058824 % | | | |
| Acetamiprid | M/L: Workwear + Protected hands App: Workwear + Protected hands | 0.02 | 64.4 |

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for acetamiprid

Table A 26: Estimation of worker exposure towards acetamiprid for the application on corn – 1x 60 g a.s./ha - New online EFSA-Model

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 93 | 0 |
| Workwear | 0.003 | 10.4 | 0 |
| Workwear and gloves | 0.002 | 9.3 | 0 |
| Hands covered, no workwear | | | |

Table A 27: Estimation of worker exposure towards acetamiprid for the application on apples – 1x 80 g a.s./ha - New online EFSA-Model

Maintenance/thinning / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: NA Body weight: 60 kg TC (potential): 22500 cm ² /h TC (workwear (arms, body and legs covered)): 4500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 2250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.2 | 893 | 95 |
| Workwear | 0.04 | 179 | 26 |
| Workwear and gloves | 0.02 | 89.3 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.03 | 124 | 10 |
| Workwear | 0.003 | 13.9 | 0 |
| Workwear and gloves | 0.003 | 12.4 | 0 |
| Hands covered, no workwear | | | |

Searching, reaching, picking / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 3500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.1 | 496 | 70 |
| Workwear | 0.03 | 139 | 15 |
| Workwear and gloves | 0.01 | 49.6 | 0 |
| Hands covered, no workwear | | | |

Table A 28: Estimation of worker exposure towards acetamiprid for the application on apples – 2x 25 g a.s./ha - New online EFSA-Model

Maintenance/thinning / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Maintenance/thinning / Outdoor Work rate: 8 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 22500 cm ² /h TC (workwear (arms, body and legs covered)): 4500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 2250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.2 | 715 | 86 |
| Workwear | 0.04 | 143 | 16 |
| Workwear and gloves | 0.02 | 71.5 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 99.3 | 0 |
| Workwear | 0.003 | 11.1 | 0 |
| Workwear and gloves | 0.002 | 9.9 | 0 |
| Hands covered, no workwear | | | |

Searching, reaching, picking / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Searching, reaching, picking / Outdoor Work rate: 8 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 3500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.1 | 397 | 60 |
| Workwear | 0.03 | 111 | 5 |
| Workwear and gloves | 0.01 | 39.7 | 0 |
| Hands covered, no workwear | | | |

Table A 29: Estimation of worker exposure towards acetamiprid for the application on potatoes – 1x 36 g a.s./ha - New online EFSA-Model

Reaching, picking (all except Brassica) / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.03 | 104 | 2 |
| Workwear | 0.01 | 44.6 | 0 |
| Workwear and gloves | 0.003 | 10.4 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|--------------------|-----------------------------|
| Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.01 | 55.8 | 0 |
| Workwear | 0.002 | 6.2 | 0 |
| Workwear and gloves | 0.001 | 5.6 | 0 |
| Hands covered, no workwear | | | |

Table A 30: Estimation of worker exposure towards acetamiprid for the application on cereals – 2x 35 g a.s./ha - New online EFSA-Model - 10 days min. interval

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 97.1 | 0 |
| Workwear | 0.003 | 10.9 | 0 |
| Workwear and gloves | 0.002 | 9.7 | 0 |
| Hands covered, no workwear | | | |

Table A 31: Estimation of worker exposure towards acetamiprid for the application on cereals – 2x 35 g a.s./ha - New online EFSA-Model - 30 days min. interval

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 30 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 81.4 | 0 |
| Workwear | 0.002 | 9.1 | 0 |
| Workwear and gloves | 0.002 | 8.1 | 0 |
| Hands covered, no workwear | | | |

Table A 32: Estimation of worker exposure towards acetamiprid for the application on cereals – 2x 36 g a.s./ha - New online EFSA-Model

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 10 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 99.9 | 0 |
| Workwear | 0.003 | 11.2 | 0 |
| Workwear and gloves | 0.002 | 10 | 0 |
| Hands covered, no workwear | | | |

Table A 33: Estimation of worker exposure towards acetamiprid for the application on cereals – 1x 30 g a.s./ha - New online EFSA-Model

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.03 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.01 | 46.5 | 0 |
| Workwear | 0.001 | 5.2 | 0 |
| Workwear and gloves | 0.001 | 4.7 | 0 |
| Hands covered, no workwear | | | |

Table A 34: Estimation of worker exposure towards acetamiprid for the application on oilseeds – 2x 60 g a.s./ha - New online EFSA-Model

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.04 | 172 | 24 |
| Workwear | 0.005 | 19.3 | 0 |
| Workwear and gloves | 0.004 | 17.2 | 0 |
| Hands covered, no workwear | | | |

Table A 35: Estimation of worker exposure towards acetamiprid for the application on oilseeds – 1x 60 g a.s./ha - New online EFSA-Model

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 93 | 0 |
| Workwear | 0.003 | 10.4 | 0 |
| Workwear and gloves | 0.002 | 9.3 | 0 |
| Hands covered, no workwear | | | |

Table A 36: Estimation of worker exposure towards acetamiprid for the application on sugar beets – 2x 50 g a.s./ha - New online EFSA-Model

Reaching, picking (all except Brassica) / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|--------------------|-----------------------------|
| Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.05 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.07 | 266 | 43 |
| Workwear | 0.03 | 115 | 6 |
| Workwear and gloves | 0.007 | 26.6 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.05 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.04 | 143 | 16 |
| Workwear | 0.004 | 16.1 | 0 |
| Workwear and gloves | 0.004 | 14.3 | 0 |
| Hands covered, no workwear | | | |

Removing bolting sugar beets / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| removing bolting sugar beets / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 18600 cm ² /h TC (workwear (arms, body and legs covered)): 4400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 430 cm ² /h TC (gloves): 14300 cm ² /h | | | |
| Number of applications & application rate: 2 x 0.05 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.2 | 853 | 93 |
| Workwear | 0.05 | 202 | 31 |
| Workwear and gloves | 0.005 | 19.7 | 0 |
| Hands covered, no workwear | 0.2 | 656 | 82 |

Table A 37: Estimation of worker exposure towards acetamiprid for the application on flower bulbs and flower tubers – 1x 46 g a.s./ha - New online EFSA-Model

Cutting, sorting, bundling, carrying / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 14000 cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1400 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.08 | 319 | 51 |
| Workwear | 0.03 | 114 | 6 |
| Workwear and gloves | 0.008 | 31.9 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 71.3 | 0 |
| Workwear | 0.002 | 8 | 0 |
| Workwear and gloves | 0.002 | 7.1 | 0 |
| Hands covered, no workwear | | | |

Table A 38: Estimation of worker exposure towards acetamiprid for the application on flower bulbs and flower tubers – 2x 34 g a.s./ha - New online EFSA-Model

Cutting, sorting, bundling, carrying / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 14000 cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1400 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.1 | 437 | 64 |
| Workwear | 0.04 | 156 | 20 |
| Workwear and gloves | 0.01 | 43.7 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Number of applications & application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 97.5 | 0 |
| Workwear | 0.003 | 10.9 | 0 |
| Workwear and gloves | 0.002 | 9.7 | 0 |
| Hands covered, no workwear | | | |

Table A 39: Estimation of worker exposure towards acetamiprid for the application on flower bulbs and flower tubers – 1x 46 g a.s./ha - New online EFSA-Model

Cutting, sorting, bundling, carrying / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: NA Body weight: 60 kg TC (potential): 14000 cm ² /h TC (workwear (arms, body and legs covered)): 5000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1400 cm ² /h TC (gloves): NA cm ² /h | | | |
| Acetamiprid Number of applications & application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.08 | 319 | 51 |
| Workwear | 0.03 | 114 | 6 |
| Workwear and gloves | 0.008 | 31.9 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h | | | |
| Acetamiprid Number of applications & application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.02 | 71.3 | 0 |
| Workwear | 0.002 | 8 | 0 |
| Workwear and gloves | 0.002 | 7.1 | 0 |
| Hands covered, no workwear | | | |

Table A 40: Estimation of worker exposure towards acetamiprid for the application on floriculture, tree nursery & perennial nursery crops – 2x 34 g a.s./ha - New online EFSA-Model

Cutting, sorting, bundling, carrying / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Cutting, sorting, bundling, carrying / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 14000 cm²/h TC (workwear (arms, body and legs covered)): 5000 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1400 cm²/h TC (gloves): NA cm²/h | | | |
| Number of applications & application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31.9117647058824 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.1 | 450 | 66 |
| Workwear | 0.04 | 161 | 21 |
| Workwear and gloves | 0.01 | 45 | 0 |
| Hands covered, no workwear | | | |

Inspection, irrigation / Outdoor

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h | | | |
| Number of applications & application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31.9117647058824 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 0.03 | 100.4 | 1 |
| Workwear | 0.003 | 11.2 | 0 |
| Workwear and gloves | 0.003 | 10 | 0 |
| Hands covered, no workwear | | | |

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for acetamiprid

Table A 41: Estimation of longer-term resident exposure towards acetamiprid on cereals – 1x 60 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 300 l | | | |
| Number of applications and application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.002 | 6.7 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0003 | 1.3 |
| | Re-entry (75th perc.) | 0.003 | 12.6 |
| | Sum (mean) | 0.004 | 17.8 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0004 | 1.6 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.5 |
| | Re-entry (75th perc.) | 0.002 | 7 |
| | Sum (mean) | 0.002 | 7.8 |

Table A 42: Estimated bystander exposure (acute exposure) – Cereals (corn) – 1x 60 g a.s./ha - New online EFSA-Model

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 300 l | | | |
| Number of applications and application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.004 | 15.2 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0009 | 3.8 |
| | Re-entry (95th perc.) | 0.003 | 12.6 |

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|---|------------------------|
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.001 | 4.1 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0004 | 1.5 |
| | Re-entry (95th perc.) | 0.002 | 7 |

Table A 43: Estimation of longer-term resident exposure towards acetamiprid on apples - 80 g a.s./ha – New online EFSA-Model

Early season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|---|-----------------------|
| Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.007 | 27.5 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.001 | 4.8 |
| | Re-entry (75th perc.) | 0.004 | 16.7 |
| | Sum (mean) | 0.01 | 38.2 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.004 | 15.3 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0005 | 1.9 |
| | Re-entry (75th perc.) | 0.002 | 9.3 |
| | Sum (mean) | 0.005 | 19.9 |

Late season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|--|--------------------|
| Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.007 | 27.5 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0005 | 1.8 |
| | Re-entry (75th perc.) | 0.004 | 16.7 |
| | Sum (mean) | 0.009 | 35.8 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.004 | 15.3 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0002 | 0.7 |
| | Re-entry (75th perc.) | 0.002 | 9.3 |
| | Sum (mean) | 0.005 | 18.9 |

Table A 44: Estimated bystander exposure (acute exposure) – apples – 1x 80 g a.s./ha - New online EFSA-Model

Early season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.02 | 63.2 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.003 | 11.9 |
| | Re-entry (95th perc.) | 0.004 | 16.7 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.009 | 35 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.001 | 4.8 |
| | Re-entry (95th perc.) | 0.002 | 9.3 |

Late season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 1 x 0.08 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.02 | 63.2 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 5 |
| | Re-entry (95th perc.) | 0.004 | 16.7 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.009 | 35 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0005 | 2 |
| | Re-entry (95th perc.) | 0.002 | 9.3 |

Table A 45: Estimation of longer-term resident exposure towards acetamiprid on apples - 2x 25 g a.s./ha – New online EFSA-Model

Early season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 12 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0009 | 3.7 |
| | Re-entry (75th perc.) | 0.003 | 13.4 |
| | Sum (mean) | 0.006 | 24.5 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.002 | 6.7 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0004 | 1.5 |
| | Re-entry (75th perc.) | 0.002 | 7.4 |
| | Sum (mean) | 0.003 | 12.5 |

Late season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 12 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0004 | 1.4 |
| | Re-entry (75th perc.) | 0.003 | 13.4 |
| | Sum (mean) | 0.006 | 22.7 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.002 | 6.7 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.6 |
| | Re-entry (75th perc.) | 0.002 | 7.4 |
| | Sum (mean) | 0.003 | 11.7 |

Table A 46: Estimated bystander exposure (acute exposure) – Apples – 2x 25 g a.s./ha - New online EFSA-Model

Early season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOL |
|---|-----------------------|--|--------------------|
| Season: Early season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.007 | 27.6 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.002 | 9.1 |
| | Re-entry (95th perc.) | 0.003 | 13.4 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.004 | 15.3 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.001 | 3.8 |
| | Re-entry (95th perc.) | 0.002 | 7.4 |

Late season

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---|-----------------------|--|---------------------|
| Season: Late season Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 500 l | | | |
| Number of applications and application rate: 2 x 0.025 kg a.s./ha Dermal absorption: 43.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.007 | 27.6 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 3.9 |
| | Re-entry (95th perc.) | 0.003 | 13.4 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.004 | 15.3 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0004 | 1.6 |
| | Re-entry (95th perc.) | 0.002 | 7.4 |

Table A 47: Estimation of longer-term resident exposure towards acetamiprid on potatoes - 1x 36 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 1 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 12.1 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0002 | 0.8 |
| | Re-entry (75th perc.) | 0.002 | 7.5 |
| | Sum (mean) | 0.004 | 16.4 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0007 | 2.9 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 8e-05 | 0.3 |
| | Re-entry (75th perc.) | 0.001 | 4.2 |
| | Sum (mean) | 0.001 | 6 |

Table A 48: Estimated bystander exposure (acute exposure) – Potatoes – 1x 36 g a.s./ha -

New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---|--|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 1 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | Drift (95th perc.) | 0.007 | 27.3 |
| | Bystander child Vapour (95th perc.) | 0.0008 | 3.2 |
| | Body weight: 10 kg Deposits (95th perc.) | 0.0006 | 2.3 |
| | Re-entry (95th perc.) | 0.002 | 7.5 |
| Bystander adult | Drift (95th perc.) | 0.002 | 7.4 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Body weight: 60 kg Deposits (95th perc.) | 0.0002 | 0.9 |
| | Re-entry (95th perc.) | 0.001 | 4.2 |

Table A 49: Estimation of longer-term resident exposure towards acetamiprid on cereals - 2x 35 g a.s./ha - 10 days min. interval – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|--|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | Drift (75th perc.) | 0.003 | 11.8 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Resident child Deposits (75th perc.) | 0.0003 | 1.3 |
| | Body weight: 10 kg Re-entry (75th perc.) | 0.003 | 13.1 |
| | Sum (mean) | 0.005 | 21.1 |
| Resident adult | Drift (75th perc.) | 0.0007 | 2.8 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Body weight: 60 kg Deposits (75th perc.) | 0.0001 | 0.5 |
| | Re-entry (75th perc.) | 0.002 | 7.3 |
| | Sum (mean) | 0.002 | 8.6 |

Table A 50: Estimated bystander exposure (acute exposure) – Cereals – 2x 35 g a.s./ha – 10 days min. interval - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.007 | 26.5 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 4 |
| | Re-entry (95th perc.) | 0.003 | 13.1 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.002 | 7.2 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0004 | 1.6 |
| | Re-entry (95th perc.) | 0.002 | 7.3 |

Table A 51: Estimation of longer-term resident exposure towards acetamiprid on cereals - 2x 35 g a.s./ha - 30 days min. interval – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 30 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 11.8 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0003 | 1.1 |
| | Re-entry (75th perc.) | 0.003 | 11 |
| | Sum (mean) | 0.005 | 19.2 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0007 | 2.8 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.4 |
| | Re-entry (75th perc.) | 0.002 | 6.1 |
| | Sum (mean) | 0.002 | 7.6 |

Table A 52: Estimated bystander exposure (acute exposure) – Cereals (corn) – 2x 35 g a.s./ha - 30 days min. interval - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 30 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.035 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.007 | 26.5 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0008 | 3.3 |
| | Re-entry (95th perc.) | 0.003 | 11 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.002 | 7.2 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0003 | 1.3 |
| | Re-entry (95th perc.) | 0.002 | 6.1 |

Table A 53: Estimation of longer-term resident exposure towards acetamiprid on cereals - 2x 36 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 12.1 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0003 | 1.4 |
| | Re-entry (75th perc.) | 0.003 | 13.5 |
| | Sum (mean) | 0.005 | 21.6 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0007 | 2.9 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.5 |
| | Re-entry (75th perc.) | 0.002 | 7.5 |
| | Sum (mean) | 0.002 | 8.8 |

Table A 54: Estimated bystander exposure (acute exposure) – Cereals – 2x 36 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 10 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.036 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.007 | 27.3 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 4.1 |
| | Re-entry (95th perc.) | 0.003 | 13.5 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.002 | 7.4 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0004 | 1.6 |
| | Re-entry (95th perc.) | 0.002 | 7.5 |

Table A 55: Estimation of longer-term resident exposure towards acetamiprid on cereals - 1x 30 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 1 x 0.03 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.003 | 10.1 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0002 | 0.6 |
| | Re-entry (75th perc.) | 0.002 | 6.3 |
| | Sum (mean) | 0.004 | 14.2 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0006 | 2.4 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 6e-05 | 0.3 |
| | Re-entry (75th perc.) | 0.0009 | 3.5 |
| | Sum (mean) | 0.001 | 5.2 |

Table A 56: Estimated bystander exposure (acute exposure) – Cereals – 1x 30 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 1 x 0.03 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.006 | 22.7 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0005 | 1.9 |
| | Re-entry (95th perc.) | 0.002 | 6.3 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.002 | 6.2 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0002 | 0.8 |
| | Re-entry (95th perc.) | 0.0009 | 3.5 |

Table A 57: Estimation of longer-term resident exposure towards acetamiprid on cereals - 2x 60 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.005 | 20.2 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0006 | 2.4 |
| | Re-entry (75th perc.) | 0.006 | 23.2 |
| | Sum (mean) | 0.009 | 34.5 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.001 | 4.8 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0002 | 0.9 |
| | Re-entry (75th perc.) | 0.003 | 12.9 |
| | Sum (mean) | 0.004 | 14.3 |

Table A 58: Estimated bystander exposure (acute exposure) – Cereals – 2x 60 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l | | | |
| Number of applications and application rate: 2 x 0.06 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.01 | 45.5 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.002 | 7 |
| | Re-entry (95th perc.) | 0.006 | 23.2 |

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---------------------------------------|-----------------------|--|---------------------|
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.003 | 12.3 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0007 | 2.8 |
| | Re-entry (95th perc.) | 0.003 | 12.9 |

Table A 59: Estimation of longer-term resident exposure towards acetamiprid on sugar beets - 2x 50 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 2 x 0.05 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.002 | 8.4 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0005 | 2 |
| | Re-entry (75th perc.) | 0.005 | 19.4 |
| | Sum (mean) | 0.006 | 24.7 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0005 | 2 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0002 | 0.8 |
| | Re-entry (75th perc.) | 0.003 | 10.8 |
| | Sum (mean) | 0.003 | 11.2 |

Table A 60: Estimated bystander exposure (acute exposure) – Sugar beets – 2x 50 g a.s./ha
- New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|--|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 2 x 0.05 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.005 | 18.9 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 5.9 |
| | Re-entry (95th perc.) | 0.005 | 19.4 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.001 | 5.1 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0006 | 2.4 |
| | Re-entry (95th perc.) | 0.003 | 10.8 |

Table A 61: Estimation of longer-term resident exposure towards acetamiprid on flower bulbs and flower tubers – 1x 46 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.002 | 7.7 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0002 | 1 |
| | Re-entry (75th perc.) | 0.002 | 9.6 |
| | Sum (mean) | 0.004 | 15.8 |

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--------------------------------------|-----------------------|--|--------------------|
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0005 | 1.8 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.4 |
| | Re-entry (75th perc.) | 0.001 | 5.3 |
| | Sum (mean) | 0.002 | 6.5 |

Table A 62: Estimated bystander exposure (acute exposure) – Flower bulbs and flower tubers – 1x 46 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.004 | 17.4 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0007 | 2.9 |
| | Re-entry (95th perc.) | 0.002 | 9.6 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.001 | 4.7 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0003 | 1.2 |
| | Re-entry (95th perc.) | 0.001 | 5.3 |

Table A 63: Estimation of longer-term resident exposure towards acetamiprid on flower bulbs and flower tubers - 2x 34 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.001 | 5.7 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0003 | 1.3 |
| | Re-entry (75th perc.) | 0.003 | 13.2 |
| | Sum (mean) | 0.004 | 17.8 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.0003 | 1.4 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 0.0001 | 0.5 |
| | Re-entry (75th perc.) | 0.002 | 7.3 |
| | Sum (mean) | 0.002 | 7.9 |

Table A 64: Estimated bystander exposure (acute exposure) – Flower bulbs and flower tubers - 2x 34 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAoEL |
|---|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 2 x 0.034 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.003 | 12.9 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.001 | 4 |
| | Re-entry (95th perc.) | 0.003 | 13.2 |

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---------------------------------------|-----------------------|--|---------------------|
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.0009 | 3.5 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0004 | 1.6 |
| | Re-entry (95th perc.) | 0.002 | 7.3 |

Table A 65: Estimation of longer-term resident exposure towards acetamiprid on floriculture, tree nursery - 1x 46 g a.s./ha – New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|---|-----------------------|--|--------------------|
| Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Acetamiprid | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.01 | 39.6 |
| | Vapour (75th perc.) | 0.0008 | 3.2 |
| | Deposits (75th perc.) | 0.0001 | 0.5 |
| | Re-entry (75th perc.) | 0.002 | 9.6 |
| | Sum (mean) | 0.009 | 37.3 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.005 | 22 |
| | Vapour (75th perc.) | 0.0003 | 1.1 |
| | Deposits (75th perc.) | 5e-05 | 0.2 |
| | Re-entry (75th perc.) | 0.001 | 5.3 |
| | Sum (mean) | 0.005 | 19.9 |

Table A 66: Estimated bystander exposure (acute exposure) – Floriculture, tree nursery - 1x 46 g a.s./ha - New online EFSA-Model

Season: Not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AAOEL |
|---|-----------------------|--|---------------------|
| Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 200 l | | | |
| Number of applications and application rate: 1 x 0.046 kg a.s./ha Dermal absorption: 31 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Bystander child Body weight: 10 kg | Drift (95th perc.) | 0.02 | 90.8 |
| | Vapour (95th perc.) | 0.0008 | 3.2 |
| | Deposits (95th perc.) | 0.0003 | 1.2 |
| | Re-entry (95th perc.) | 0.002 | 9.6 |
| Bystander adult Body weight: 60 kg | Drift (95th perc.) | 0.01 | 50.3 |
| | Vapour (95th perc.) | 0.0003 | 1.1 |
| | Deposits (95th perc.) | 0.0001 | 0.5 |
| | Re-entry (95th perc.) | 0.001 | 5.3 |

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.