

Appendix to:

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 91 pp. doi:10.2903/j.efsa.2016.4610

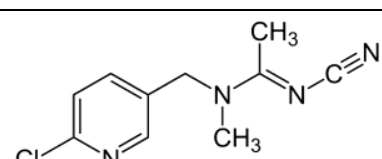
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Appendix A – List of end points for the active substance and the representative formulation

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

| | |
|------------------------------------|-----------------|
| Active substance (ISO Common Name) | Acetamiprid |
| Function (e.g. fungicide) | Insecticide |
| Rapporteur Member State | The Netherlands |
| Co-rapporteur Member State | Spain |

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

| | |
|---|--|
| Chemical name (IUPAC) | (<i>E</i>)- <i>N</i> ¹ -[(6-Chloro-3-pyridyl)methyl]- <i>N</i> ² -cyano- <i>N</i> ¹ -methylethanamide |
| Chemical name (CA) | (<i>E</i>)- <i>N</i> [(6-Chloro-3-pyridinyl)methyl]- <i>N</i> -cyano- <i>N</i> -methylethanamide |
| CIPAC No | 649 |
| CAS No | 135410-20-7 |
| EC No (EINECS or ELINCS) | Not allocated |
| FAO Specification (including year of publication) | None |
| Minimum purity of the active substance as manufactured | 990 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None |
| Molecular formula | C ₁₀ H ₁₁ ClN ₄ |
| Molar mass | 222.68 g/mol |
| Structural formula |  |

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| | |
|---|---|
| Melting point (state purity) | 98.9 °C (99.7%, tech) |
| Boiling point (state purity) | No boiling point observed before decomposition (≥99.9%) |
| Temperature of decomposition (state purity) | > 200 °C (≥99.9%) |
| Appearance (state purity) | Fine white powder (≥99.9%, pure) Very pale yellow fine powder (99.9%, tech) |
| Vapour pressure (state temperature, state purity) | 1.73 x 10 ⁻⁷ Pa at 50 °C (≥99%) The vapour pressure is expected to be less than 1 x 10 ⁻⁶ Pa at 25 °C. Acetamiprid is non-volatile |
| Henry's law constant (state temperature) | < 5.3 x 10 ⁻⁸ Pa m ³ mol ⁻¹ (25 °C) |
| Solubility in water (state temperature, state purity and pH) | Distilled water: 4.25 g/L at 25 °C 3.48 g/L at 25 °C (pH 5) (>99%) 2.95 g/L at 25 °C (pH 7) (>99%) 3.96 g/L at 25 °C (pH 9) (>99%) |
| Solubility in organic solvents (state temperature, state purity) | At 25 °C (>99%) hexane: 6.54 ppm xylene: 4.01 g/100 g benzene: 2.44 g/100 g dichloromethane: >20 g/100 g chloroform: >20 g/100 g methanol: >20 g/100 g ethanol: >20 g/100 g acetone: >20 g/100 g acetonitrile: >20 g/100 g tetrahydrofuran: >20 g/100 g carbon disulphide: 507 ppm The solubilities are expressed as weight of a.s. per weight of solvent. At 20 °C (>99%) Ethyl acetate 37.8 g/L |
| Surface tension (state concentration and temperature, state purity) | 70.9 mN/m at 19.5 °C (1 g/L solution) (99.9%, tech) |
| Partition coefficient (state temperature, pH and purity) | log P _{OW} = 0.80 at 25 °C (neutral pH) (>99%) |
| Dissociation constant (state purity) | pKa = 0.7 at 25 °C (>99%) |

UV/VIS absorption (max.) incl. ϵ
(state purity, pH)

Neutral solution (CH₃OH/H₂O):
 λ_{\max} (nm); ϵ (L mol⁻¹ cm⁻¹)
247 1.97 x 10⁴
217 1.21 x 10⁴

Acidic solution (CH₃OH/HCl):
 λ_{\max} (nm); ϵ (L mol⁻¹ cm⁻¹)
248 1.96 x 10⁴
215 1.22 x 10⁴

Alkaline solution (CH₃OH/NaOH):
 λ_{\max} (nm); ϵ (L mol⁻¹ cm⁻¹)
246 1.91 x 10⁴

Flammability (state purity)

Not classified as highly flammable (99.9%, tech)
No self-ignition temperature was determined up to 450°C

Explosive properties (state purity)

No explosive properties (99.9%, tech)

Oxidising properties (state purity)

No oxidising properties (expert statement)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)

(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| Acetamiprid 20 SG | | Critical Uses – justification and GAP tables | |
|-------------------------|----------------------|--|-------------------------------------|
| PPP (product name/code) | ACETAMIRPID 20 SG | Formulation type: | SG |
| active substance 1 | Acetamiprid | Conc. of as 1: | 200 g/kg |
| active substance 2 | Not applicable | Conc. of as 2: | Not applicable |
| active substance 3 | Not applicable | Conc. of as: | Not applicable |
| safener | None | Conc. of safener: | Not applicable |
| synergist | None | Conc. of synergist: | Not applicable |
| Applicant: | Nippon Soda Co., Ltd | professional use | <input checked="" type="checkbox"/> |
| Zone(s): | EU | non professional use | <input type="checkbox"/> |
| Verified by MS: | Y | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 |
|-------------|--------------------|--|-------------------|--|------------------|--|---|---|--|-----------------------------------|---------------|--|
| Use- No. | Member state(s) | Crop and/ or situation (crop destination / purpose of crop) | F G or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | Max. number (min. interval between applications) a) per use b) per crop/ season | Application rate | | Water L/ha min / max | PHI (days) | Remarks: e.g. safener/syner gist per ha e.g. recommended or mandatory tank mixtures |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | | kg product / ha a) max. rate per appl. b) max. total rate per crop/season | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | | | |
| 1 | EU | Tomato | G | Aphids | Foliar | BBCH 61 – 89 (January- December) | a) 2 (7) b) 2 (7) | a) 0.5 b) 1.0 | a) 0.100 b) 0.200 | 300 – 1500 | 3 | Use in greenhouse is in permanent structure |
| 2 | EU | Pome fruit | F | Aphids | Foliar | BBCH 77 – 87 (June - September) | a) 2 (14) b) 2 (14) | a) 0.375 b) 0.750 | a) 0.075 b) 0.150 | 300 – 1000 | 14 | |
| 3 | EU | Potato | F | Colorado potato beetle / aphids | Foliar | BBCH 45 – 93 (May-October) | a) 3 (7) b) 3 (7) | a) 0.250 b) 0.750 | a) 0.05 b) 0.150 | 400 – 600 | 7 | |

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | | Application | | | | Application rate per treatment | | | PHI (days) (m) | Remarks |
|---|-------------------------|--------------|--------------|--|-------------|----------------|-------------------|-------------------------------------|--------------------|------------------------------------|--------------------------------|--------------------|------------------------|----------------|---------|
| | | | | | Type (d-f) | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

It is considered that it has been established for or several representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The representative GAP is supported. No adverse effects are known from current registrations of the product.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The representative GAP is supported. No undesirable or unintended effects are expected based on existing registrations.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

IM-1-5

Information not available. Not required whilst this metabolite is considered toxicologically relevant based on the proposed classification Acute Tox 3 for IM-1-5; and on the proposed classification Carc cat 2 for acetamiprid.

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

| | |
|---|--|
| Technical a.s. (analytical technique) | HPLC-UV (255 nm) using methyl 4-hydroxybenzoate as internal standard |
| Impurities in technical a.s. (analytical technique) | HPLC-UV HSGC-FID |
| Plant protection product (analytical technique) | HPLC-UV (250 nm) |

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

| | |
|-------------------------|--|
| Food of plant origin | Acetamiprid |
| Food of animal origin | <i>N</i> -desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid |
| Soil | Acetamiprid |
| Sediment | No residue definition provided |
| Water surface | Acetamiprid |
| drinking/ground | Acetamiprid, IM-1-5 |
| Air | Acetamiprid |
| Body fluids and tissues | No residue definition provided, IM-2-1 and 6-chloronicotinic acid (IC-0) were the main residues identified in rat urine. |

Monitoring/Enforcement methods

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Multiresidue method (QuEChERS) HPLC-MS/MS (LOQ 0.01 mg/kg for apple, potato, whole orange, maize grain, sunflower seed and honey) |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Multiresidue method (QuEChERS) HPLC-MS/MS (LOQ 0.01 mg/kg for IM-2-1, all matrices). (The same method was also validated with the same LOQ for acetamiprid, but it was not included in the monitoring residue definition) |
| Soil (analytical technique and LOQ) | HPLC-MS/MS (LOQ 0.002 mg/kg for acetamiprid and IM-1-5) |

Water (analytical technique and LOQ)

Acetamiprid: HPLC-MS/MS (LOQ 0.1 µg/L in drinking, ground and surface water)

IM-1-5: HPLC-MS/MS (LOQ 0.05 µg/L in drinking, ground and surface water).

Air (analytical technique and LOQ)

HPLC-MS/MS (LOQ 0.002 µg/m³) for acetamiprid

Body fluids and tissues (analytical technique and LOQ)

HPLC-MS/MS (LOQ 0.05 mg/L in blood) for acetamiprid

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance

Acetamiprid

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹:

No classification proposed based on physical and chemical data

Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008:

No classification proposed based on physical and chemical data

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Section 2 Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

| | |
|---|---|
| Rate and extent of oral absorption/systemic bioavailability | Rapid and almost complete (> 96% at 24 h after single oral administration). |
| Toxicokinetics | <p><u>Single administration</u></p> <p>C_{max}: 1 ppm (low dose), 40.5 ppm (high dose)</p> <p>T_{max}: 0.5 – 2 h (low dose), 3 - 7 h (high dose)</p> <p>T_{1/2}: 5.8 - 7.1 h (low dose), 8 – 15 h (high dose)</p> <p><u>Repeated administration</u></p> <p>C_{max}: 0.8 µg/ml</p> <p>T_{max}: 2.8 h</p> <p>T_{1/2}: 4.4 – 5.6 h</p> |
| Distribution | Highest concentration after single administration in adrenal glands, thyroid, liver and kidney; after repeated administration in the GI tract, liver and kidney |
| Potential for bioaccumulation | Low potential for accumulation |
| Rate and extent of excretion | Rapid and higher than 90% at 96 h, mainly via urine, after single and repeated oral administrations, regardless of the dose level. |
| Metabolism in animals | <p>Approximately > 90% metabolised.</p> <p>Main metabolites for the ring-labelled compound (rats): nicotinic acid derivative IC-0 and demethylated compound IM-2-1 (approx.. 50%)</p> <p>Main metabolites for the CN-labelled compound (rats): IM-2-1, IS-1-1 and IS-2-1 (approx. 70%)</p> <p>Metabolite IM-1-5 (4.5%) is detected in rat metabolism only by HPLC analysis of fresh urine samples.</p> |
| <i>In vitro</i> metabolism | Data gap |
| Toxicologically relevant compounds (animals and plants) | Acetamiprid and IM-1-5 |
| Toxicologically relevant compounds (environment) | Acetamiprid and IM-1-5 |

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

| | | |
|---------------------------------|---|-------------------|
| Rat LD ₅₀ oral | In water: 217 mg/kg bw (male) and 146 mg/kg bw (female) In corn oil: 195 mg/kg bw (male) and 140-200 mg/kg bw (female) | Acute Tox. 3 H301 |
| Rat LD ₅₀ dermal | > 2000 mg/kg bw | |
| Rat LC ₅₀ inhalation | > 1.15 mg/L air /4h (highest attainable concentration, snout-only exposure) | |
| Skin irritation | Non-irritant | |
| Eye irritation | Non-irritant | |
| Skin sensitisation | Not sensitising (M&K) | |
| Phototoxicity | Not required | |

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

| | | |
|--------------------------------|--|--|
| Target organ / critical effect | Rat and mouse: liver (increased liver weight, hepatocellular hypertrophy) Rat, mouse, dog: body weight decrease | |
| Relevant oral NOAEL | 90-day rat: 12.4 mg/kg bw per day 90-day mouse: 106.1 mg/kg bw per day 90-day dog: 13 mg/kg bw per day 1-year dog: 20 mg/kg bw per day Overall short-term dog: 13 mg/kg bw per day | |
| Relevant dermal NOAEL | 21-day, rabbit: 1000 mg/kg bw per day | |
| Relevant inhalation NOAEL | No data - not required | |

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

| | | |
|----------------------------|---|--|
| <i>In vitro</i> studies | Acetamiprid did not induce gene mutation in the Ames test and in the mammalian cell study (CHO/HPRT), and was inactive to induce DNA damage in the unscheduled DNA synthesis (UDS) test with rat liver cells. Acetamiprid was positive in a chromosomal aberration assay in CHO cells, with and without metabolic activation. | |
| <i>In vivo</i> studies | Acetamiprid did not induce DNA damage in the unscheduled DNA synthesis (UDS) test with rat liver cells <i>in vivo</i> , and did not induce any significant increase of chromosome aberrations in bone marrow of rats and was not mutagenic in the mouse bone marrow micronucleus test. | |
| Photomutagenicity | Not required | |
| Potential for genotoxicity | Acetamiprid is unlikely to be genotoxic <i>in vivo</i> | |

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

| | | |
|--|---|-------------|
| Long-term effects (target organ/critical effect) | Decreased body weight and liver effects (vacuolation and centrilobular hypertrophy) (rats and mice) Amyloidosis in adrenal cortex and increased spleen weight (mice) | |
| Relevant long-term NOAEL | 2-year, rat: 7.1 mg/kg bw per day 18-month, mouse: 20.3 mg/kg bw per day | |
| Carcinogenicity (target organ, tumour type) | Rat: increased incidence of adenocarcinoma in mammary gland Mouse: no tumours | Carc 2 H351 |
| Relevant NOAEL for carcinogenicity | 2-year, rat: 7.14 mg/kg bw per day; 18-month, mouse: 186.3 mg/kg bw per day | |

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

| | | |
|---------------------------------------|---|--|
| Reproduction target / critical effect | <u>Rat 2-generation study:</u> Parental toxicity: reduced body weight Reproductive toxicity: no adverse effect Offspring's toxicity: reduced postnatal survival F2, decreased pup weight | |
| Relevant parental NOAEL | 17.9 mg/kg bw per day | |
| Relevant reproductive NOAEL | 51 mg/kg bw per day, highest tested dose | |
| Relevant offspring NOAEL | 17.9 mg/kg bw per day | |

Developmental toxicity

| | | |
|--|---|--|
| Developmental target / critical effect | Maternal toxicity: reduced bodyweight gain, decreased food consumption (rat and rabbit); increased liver weight (rat) Developmental toxicity: shortening of the 13 th rib (rat); no adverse effect (rabbit) | |
| Relevant maternal NOAEL | Rat: 16 mg/kg bw per day Rabbit: 15 mg/kg bw per day | |
| Relevant developmental NOAEL | Rat: 16 mg/kg bw per day Rabbit: 30 mg/kg bw per day | |

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

| | | |
|---------------------|---|--|
| Acute neurotoxicity | Rat NOAEL = 10 mg/kg bw, based on behavioural changes and reduced locomotor activity. | |
|---------------------|---|--|

| | | |
|--|---|--|
| Repeated neurotoxicity | 13-week neurotoxicity study, rat: NOAEL (systemic toxicity) = 14.8 mg/kg bw per day, based on decreased food consumption and body weight. NOAEL (neurotoxicity) = 118 mg/kg bw per day (highest dose tested), no evidence of neurotoxicity. | |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | Acute delayed neurotoxicity study (hens): No delayed neurotoxic potential in hens treated at the determined LD ₅₀ value of 129 mg/kg bw. Developmental neurotoxicity study (rat): NOAEL = 2.5 mg/kg bw per day, based on reduced auditory startle response and uncertainties and methodological drawbacks in the study. | |

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

| | |
|--|---|
| Supplementary studies on the active substance | No immunotoxic potential in rats and mice (in 4-week studies): NOAEL 62.9 mg/kg bw per day in rats, and 128 mg/kg bw per day in mice |
| Endocrine disrupting properties | Unlikely to be endocrine disruptor |
| Studies performed on metabolites or impurities | <p>IM-I-0 (IM-0): acute oral LD₅₀ 1483 mg/kg bw (rat); Ames negative; 90-day NOAEL 48.9 mg/kg bw per day, 90-d rat study)</p> <p>IM-1-3: acute oral LD₅₀ 900 mg/kg bw (rat); Ames negative</p> <p>IM-1-4: acute oral LD₅₀ 926.84 mg/kg bw (rat); acute dermal LD₅₀ > 2000 mg/kg bw (rat); not mutagenic (Ames, CHO/HGPRT) and not clastogenic (<i>in vivo</i> mouse micronucleus); 90-day NOAEL 112.2 mg/kg bw per day (rat study)</p> <p>IM-2-1: acute oral LD₅₀ 1762 mg/kg bw (rat); Ames negative</p> <p>IM-2-3: acute oral LD₅₀ 900 mg/kg bw (rat); Ames negative</p> <p>IM-1-2: acute oral LD₅₀ > 5000 mg/kg bw (rat); Ames negative</p> <p>IS-1-1: acute oral LD₅₀ 2420 mg/kg bw (rat); Ames negative</p> <p>IS-2-1: acute oral LD₅₀ > 5000 mg/kg bw (rat); Ames negative</p> <p>IC-0: acute oral LD₅₀ > 5000 mg/kg bw (rat); Ames negative</p> <p>IB-1-1: acute oral LD₅₀ > 2000 mg/kg bw (rat); Ames negative</p> <p>IM-1-5: acute oral LD₅₀ 141 mg/kg bw in males and 132 mg/kg bw in females (rat, administered in corn oil) ; not mutagenic (2 Ames, MLA)</p> |

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)**Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)**

Acceptable Daily Intake (ADI)

Acute Reference Dose (ARfD)

Acceptable Operator Exposure Level (AOEL)

Acute Acceptable Operator Exposure Level (AAOEL)

Medical surveillance on manufacturing personnel did not reveal any adverse effects related to acetamiprid exposure

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|----------------------------------|--|-----------------------|
| 0.025* | rat, developmental neurotoxicity study | 100 |
| 0.025* | rat, developmental neurotoxicity study | 100 |
| 0.025* | rat, developmental neurotoxicity study | 100 |
| 0.025** | rat, developmental neurotoxicity study | 100 |

* During the first review, the ADI and AOEL values were 0.07 mg/kg bw per day based on 2-year and multigeneration rat studies (UF 100) and the ARfD was 0.1 mg/kg bw based on the rat acute neurotoxicity study (UF 100)

** This value has been agreed by the experts but not used for non-dietary risk assessment

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation
(Acetamiprid 20 SG, 200 g/kg)

0.6% and 8% for the concentrate and dilution of formulation EXP-60707B, respectively (chemically identical to Acetamiprid 20 SG) in an *in vitro* dermal penetration study in human skin

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Use: potatoes, tractor mounted equipment,
application rate 0.05 kg a.s./ha

Exposure estimates (model): % of AOEL

UK POEM

Without PPE 40

German model

Without PPE 11

Use: pome fruit, tractor mounted air-assisted,
application rate 0.075 kg a.s./ha

Exposure estimates (model): % of AOEL

UK POEM

Without PPE 172

With PPE (gloves, RPE) 119

German model

Without PPE 33

AOEM

³ If available include also reference values for metabolites

Workers

| | |
|---|------------------|
| Without PPE | 22 |
| <u>Use:</u> tomato, greenhouse | |
| <u>Exposure estimates</u> (model): | <u>% of AOEL</u> |
| <u>ECPA Southern greenhouse</u> | |
| Without PPE | 161 |
| With PPE (gloves, impervious clothing) | 9 |
| <u>Dutch greenhouse model</u> | |
| Without PPE | 97 |
| <u>Outdoor crops</u> | |
| The estimated exposure is less than the AOEL for the worker wearing adequate work clothing but no PPE and assuming no dissipation of DFR between or following applications. | |
| Hand harvesting activities (pome fruit): 86% of AOEL (EUROPOEM II) or 74% (EFSA model). | |
| <u>Indoor (protected) crops</u> | |
| The estimated exposure is less than the AOEL for the worker wearing adequate work clothing but no PPE and assuming no dissipation of DFR between or following applications. | |
| Hand harvesting activities (tomato): 64% of AOEL (EUROPOEM II) or 55% (EFSA model). | |
| <u>Field uses:</u> 5 % of AOEL for adult bystander (EUROPOEM II). 6% for the bystander and 4% for the resident (German model, based on Martin et al. 2008). | |
| <u>Greenhouse use:</u> 6% adult bystander (EUROPOEM II); 4% for the bystander and resident (German model). | |

Bystanders and residents

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance:

Acetamiprid

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴:

Acute Tox. 4; H302 Harmful if swallowed

Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

Acute Tox. 3; H301 Toxic if swallowed
Carc. 2; H351 Suspected of causing cancer

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Section 3 Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops (Plant groups covered) | Crop groups | Crops | Application(s) | DAT (days) |
|--|--|--|----------------------------------|--|
| | Fruit | Eggplant | 1x 9 g/hl (dotting to surface) | 7, 14 |
| | | Apple | 1x 208 g/h (dotting to surface) | 0, 7, 14, 28, 90 |
| | | | 1x 104 g/ha (dotting to surface) | 0, 14, 28, 62 |
| | Root | Carrot | 2x 100 g/ha (foliar treatment) | 14 |
| | Leafy | Cabbage | 1x 302 g/ha (foliar treatment) | 0, 14, 28, 63 |
| | | | 1x 5940 g/ha (soil application) | 7, 14 and 28 |
| | | | 1x 299 g/ha (foliar treatment) | 0, 7, 14, 28, 63 |
| | Cereals/grass | - | | |
| | Pulses/Oilseeds | Cotton | 4x 127 & 1230 g/ha (foliar) | 14 and 28 |
| | Miscellaneous | - | | |
| Acetamiprid main component of residues (almost 50 to 99 % TRR), except in cabbage head and cotton seeds after foliar application where metabolite IC-0 (6-chloronicotinic acid) was detected as major (<i>ca.</i> 46 and 24 % TRR respectively). IC-0 was also present in carrot root at 26% TRR but in this case parent was the major residue. | | | | |
| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
| Rotational crop and primary crop metabolism similar? | Root/tuber | Turnip | 0 | Since acetamiprid DT ₅₀ values in soil range between 0.8-7.9 days, study was conducted with metabolite IM-1-5 the most persistent soil metabolite (DT ₅₀ 319 to 663 days). |
| | Leafy | Spinach | 0 | |
| | Cereal | Wheat | 0 | |
| | Other | - | | |
| | The only [¹⁴ C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity. | | | |
| Processed commodities (standard hydrolysis study) | Conditions | Acetamiprid (0.1 mg/kg) (% Applied Radioactivity) | | Acetamiprid (1.0 mg/kg) (% Applied Radioactivity) |
| Residue pattern in processed and raw commodities similar? | 20 min, 90°C, pH 4 | 95.6 | | 93.3 |
| | 60 min, 100°C, pH 5 | 95.1 | | 95.6 |
| | 20 min, 120°C, pH 6 | 98.1 | | 97.6 |
| | Acetamiprid stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites. | | | |
| | Plant residue definition for monitoring (RD-Mo) | | Acetamiprid | |
| Plant residue definition risk assessment (RD-RA) | | Acetamiprid | | |
| Conversion factor (monitoring to risk assessment) | | not applicable | | |

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

| Animals covered | Animal | Dose (mg/kg feed/d) | Duration (days) | N rate/comment |
|--|---|------------------------|--------------------|----------------|
| | Laying hen | 1 and 10 | 14 | |
| | Goat/Cow | 1 and 10 | 7 | |
| | Pig | | | Not required |
| | Fish | | | Not required |
| | Extensive elimination in the excreta (more than 95% of administered radioactivity) was observed for the two species. Acetamiprid extensively metabolised and only detected in milk. In all matrices residues identified as IM-2-1, except in goat muscle, where IM-2-2 was predominant, but at low levels (0.03 mg eq/kg) | | | |
| Time needed to reach a plateau concentration in milk and eggs (days) | 4-8 days to reach a steady state in eggs 1-3 days to reach a steady state in milk | | | |
| Animal residue definition for monitoring (RD-Mo) | Metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid | | | |
| Animal residue definition for risk assessment (RD-RA) | Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid | | | |
| Conversion factor (monitoring to risk assessment) | Milk: 1.3 Other mammalian products: 1.1 Poultry matrices: not required | | | |
| Metabolism in rat and ruminant similar (Yes/No) | Yes | | | |
| Fat soluble residues (Yes/No) | No | | | |

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)
Confined rotational crop study
(Quantitative aspect)

TRR in the range of 0.096 to 0.531 mg eq/kg in feed and of 0.004-0.100 mg eq/kg in food commodities. 77% to 94% of TRR extractable (acetonitrile:water), with IM-1-5 as the sole metabolite identified (0.09 to 0.41 mg eq/kg in feed and 0.01-0.09 mg eq/kg in food commodities).

Field rotational crop study

Field studies in NEU and SEU conducted at ca. 300 g/ha on bare soil. Acetamiprid, IM-1-4 and IM-1-5 residues:
 -<0.01 mg/kg in spinach (all PBIs and growth stages).
 -<0.01 mg/kg in turnip (all PBIs and growth stages when harvested at maturity).
 -0.04/0.15/0.03 mg/kg for acetamiprid/IM-1-4/IM-1-5 in immature whole plant at 360 day PBI.
 -<0.01 mg/kg in wheat, except forage at 30 d PBI in NEU with IM-1-4 at 0.013 mg/kg.
 Storage stability not available for IM-1-4 and IM-1-5.
 Since most of the samples were analysed for IM-1-5 within 36 days and since IM-1-5 was not included for the purpose of risk assessment, storage stability data are not required. Data on IM-1-4 are considered informative only.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

| Plant products (Category) | Commodity | T (°C) | Stability (Months) | | |
|------------------------------|--|-----------|--------------------|--|--|
| | | | Acetamiprid | | |
| High water | Cabbage, cucumber | -18 | 12 | | |
| | Apple, tomato, | -18 | ≤13 | | |
| | lettuce | -18 | 15 | | |
| High oil | Cotton seed, cotton oil, orange oil | -18 | 12 | | |
| High protein | Fodder peas | -18 | 12 | | |
| High starch | Potato tuber | -18 | 8 | | |
| High acid | Orange, orange juice | -18 | 12 | | |
| Processed commodities | Apple juice/wet pomace Cotton gin trash/hulls/meal Orange dried pulp | -18 | 12 | | |

For high water- content matrices acetamiprid residues are concluded to be stable for up to 15 months

| Animal | Animal commodity | T (°C) | Stability (Month/Year) | | | |
|--------|------------------|-----------|------------------------|--|--|--|
| | | | | | | |
| - | Muscle | | | | | |
| - | Liver | | | | | |
| - | Kidney | | | | | |
| - | Milk | | | | | |
| - | Egg | | | | | |
| | | | | | | |

Samples of the livestock feeding studies were stored for less than 1 month under freezer conditions. Storage stability studies are therefore not required.

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

| Crop (GAP) | Region/ Indoor (a) | Residue levels (mg/kg) in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|---|--------------------------|--|--|-----------------------------|----------------------|------------------------|
| Representative uses | | | | | | |
| Apple and pear (2x 75 g/ha, PHI 14 days) | NEU | 0.010; 2x 0.020; 0.025; 0.026; 2x 0.030; 2x 0.031; 0.034; 0.040; 2x 0.056; 0.071 | Trials not conducted according to the proposed GAP, since performed with intervals between applications of 28 to 49 days in NEU and of 45 to 49 days in SEU (instead of 14 days). MRL not proposed. | no proposal | | |
| | SEU | <0.010; 0.015; 2x 0.017; 0.020; 2x 0.028; 0.031; 0.034; 0.044; 0.056 | | | | |
| Potato (3x 50 g/ha, PHI 7 days) | NEU | 4x <0.01 | | 0.01* | 0.01 | 0.01 |
| | SEU | 4x <0.01 | | | | |
| Tomato (3x 50 g/ha, PHI 7 days) | Indoor | <0.01; 0.015; 0.06; 0.08; 0.081; 0.12; 0.13; 0.15; 0.21; 0.28 <u>underlined values</u> : Normal tomato (Other; cherry tomato) | Trials not conducted according to the proposed GAP, since performed with intervals between applications of 29 to 33 days (instead of 7 days). MRL not proposed. | no proposal | | |
| Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1) | | | | | | |
| Residues studies in honey and pollen are not required. | | | | | | |

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR_{Mo}).

Inputs for animal burden calculations⁽¹⁾

| Feed commodity | Median dietary burden | | Maximum dietary burden | |
|---------------------------|-----------------------|-------------------|------------------------|---------------------|
| | (mg/kg) | Comment | (mg/kg) | Comment |
| Representative use | | | | |
| Potato, culls | 0.01 | STMR | 0.01 | Highest residue |
| Potato, process waste | 0.01 | STMR extrapolated | 0.01 | STMR (extrapolated) |
| Potato, dried pulp | 0.01 | STMR extrapolated | 0.01 | STMR (extrapolated) |

N/A= Not applicable (HR not relevant for by products, only STMR-p considered for calculations)

⁽¹⁾: Provisional calculation considering the identified data gap for the submission of residue trials on pome fruits.

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4) ⁽¹⁾

| MRL calculations | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|--|-----------------------------------|-------------------------|-----------------------------------|-------------------------|-----------------------------------|-------------------------|-----------------------------------|-------------------------|-----------------------------------|-------------------------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) Intake >0.004 mg/kg bw Feeding study submitted | Beef cattle | 0.001 | Ram/Ewe | 0.002 | Breeding | 0.001 | Broiler | 0.001 | Carp | Not required |
| | Dairy cattle | 0.002 | Lamb | 0.001 | Finishing | 0.001 | Layer | 0.000 | Trout | Not required |
| | | | | | | | Turkey | 0.001 | Fish intake >0.1 mg/kg DM | |
| | No | | No | | No | | No | | N/A | |
| | Yes, Lactating cow, 28-day | | | | | | Yes, Laying hens, 28-day | | N/A | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: N Dairy: N | Level | Lamb: N Ewe: N | Level | N rate Breed/Finish | Level | B or T: N Layer: N | Level | N rate Carp/Trout |
| | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals |
| Muscle | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Fat | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Meat ^(b) | N/A | | N/A | | N/A | | N/A | | | |
| Liver | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |
| Kidney | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |
| Milk ^(a) | N/A | N/A | N/A | N/A | | | | | | |
| Eggs | | | | | | | N/A | N/A | | |
| Method of calculation ^(c) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |

^(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).

^(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

| STMR calculations | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|
| Median expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle | 0.001 | Ram/Ewe | 0.002 | Breeding | 0.001 | Broiler | 0.001 | Carp | Not required |
| | Dairy cattle | 0.002 | Lamb | 0.001 | Finishing | 0.001 | Layer | 0.000 | Trout | Not required |
| | | | | | | | Turkey | 0.001 | | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: N Dairy: N | Level | Lamb : N Ewe: N | Level | N rate Breed/Finish | Level | B or T: N Layer: N | Level | N rate Carp/Trout |
| | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N |
| Muscle | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Fat | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Meat ^(a) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |
| Liver | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |
| Kidney | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | | |
| Milk | N/A | N/A | N/A | N/A | | | | | | |
| Eggs | | | | | | | N/A | N/A | | |
| Method of calculation ^(c) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

^(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

^(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

| Crop (RAC)/Processed product | Number of studies ^(a) | Processing Factor (PF) | | Conversion Factor (CF _p) for RA ^(b) |
|------------------------------|----------------------------------|------------------------|-----------|--|
| | | Individual values | Median PF | |
| Apple, juice | 2 | 0.73; 0.87 | 0.80 | |
| Apple, wet pomace | 2 | 1.23; 1.39 | 1.30 | |

^(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

^(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9) Including all uses (representative uses and uses related to an MRL application)**ADI**

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

ARfD

IESTI (% ARfD), according to EFSA PRIMo

NESTI (% ARfD), according to EFSA PRIMo

Factors included in IESTI and NESTI

ADI

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

Factors included in the calculations

ARfD

IESTI (% ARfD), according to EFSA PRIMo rev.2

NESTI (% ARfD), according to EFSA PRIMo

Factors included in IESTI and NESTI

Representative uses (potato only, data gaps for residue trials on tomatoes and pome fruits)

0.025 mg/kg bw per day

Highest TMDI: <1% ADI (DE, child)

0.025 mg/kg bw

Highest IESTI: 6 % ARfD (UK infant)

Existing uses

Uses identified under Article 12 MRL review (EFSA, 2011b) and additional uses assessed in (EFSA, 2014, 2015, 2016)

0.025 mg/kg bw per day

Highest TMDI: 20% ADI (DE, child)

0.025 mg/kg bw

Exceedance of the ARfD (% ARfD): scarole (262%), apple (251%), spinach (233%), pear (233%), lettuce (204%), kale (197%), celery (143%), beet leaves (133%), peach (133%), purslane (115%), Chinese cabbage (108%) and head cabbage (105%)

Other food commodities: <100% ARfD

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

| Code ^(a) | Commodity/Group | MRL/Import tolerance ^(b) (mg/kg) and Comments | |
|---------------------|-----------------|---|---|
| Plant commodities | | | |
| 0130000 | Pome fruits | no proposal | NEU and SEU trials conducted according to the supported GAP are requested (data gap) |
| 0211000 | Potatoes | 0.01* | NEU and SEU |
| 0231010 | Tomatoes | no proposal | Indoor trials conducted according to the supported GAP are requested (data gap) |
| Animal commodities | | | |
| | | | No MRLs required considering the representative use on potato only (estimated burden <0.004 mg/kg bw/d) |

^(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

^(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Section 4 Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

| | |
|--|---|
| Mineralisation after 100 days | 9.6 -61.4 % after 112 - 120 d, [pyridine ring ¹⁴ C-labelled acetamiprid] (n ⁶ = 4) |
| Non-extractable residues after 100 days | 17.5 - 32.3 % after 112-120 d, [pyridine ring ¹⁴ C-labelled acetamiprid] (n = 4) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | IM-1-2 55 % at 1 d (n= 5) IM-1-4 72 % at 14 d (n= 8) IC-0 11.3 % at 2 d (n= 8) IM-1-5 20 % at 13 d (n= 4) (only in calcareous soils) [pyridine ring ¹⁴ C-labelled acetamiprid] |

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

| | |
|---|--|
| Mineralisation after 100 days | 0.25 % after 182 d, [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |
| Non-extractable residues after 100 days | 12.13 % after 14 d, [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | IM-1-4 46.7 % at 119 d (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| | |
|---|--|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | IM-1-4 46.5 % at 30 d irradiated samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) IM-1-4 65.3 % at 30 d dark control samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |
| Mineralisation at study end | 0.22 % at 30 d irradiated samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) 0.24 % at 30 d dark control samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |
| Non-extractable residues at study end | 13.41 % at 30 d irradiated samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) 12.8 % at 30 d dark control samples (n= 1), [pyridine ring ¹⁴ C-labelled acetamiprid] (n= 1) |

⁶ n corresponds to the number of soils.

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Trigger endpoint

| Parent | Dark aerobic conditions | | | | | | |
|--|-------------------------|------------------|----------------|---|-------------------------------------|-----------------------|-----------------------|
| Soil type | X ⁷ | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | Parameters bi-phasic models | St. (X ²) | Method of calculation |
| Collombey loamy sand, Morgenroth, 1997 | | 7.6 | 20/50% pF2.5 | 1.4 / 4.7 | | 7.7 | SFO |
| Clay loam Burr, 1997 | | 7.4 | 20/45% MWHC | 5.4 / 54.5 | k1:0.00806 k2:0.1628 g: 0.155 | 6.9 | DFOP |
| Clay loam 10°C Burr, 1997 | | 7.4 | 10/45% MWHC | 7.9 / 49.3 | k1:0.1057 k2:0.0065 g: 0.8686 | 3.7 | DFOP |
| Sandy loam, Burr 1997 | | 5.6 | 20/45% MWHC | 2.5 / 14.3 | α:1.744 β:5.212 | 4.6 | FOMC |
| Silty Clay loam Burr, 1997 | | 7.9-8.5 | 20/45% MWHC | 0.8 / 2.8 | | 9.5 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.1 / 5.2 | α:2.278 β:3.000 | 8.4 | FOMC |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 1.1 / 3.8 | | 9.3 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1 / 3.3 | | 8.4 | SFO |

^{a)} Measured in water

Modelling endpoints

| Parent | Dark aerobic conditions | | | | | | |
|--|-------------------------|------------------|----------------|---|--|-----------------------|-----------------------|
| Soil type | X ⁸ | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | DT ₅₀ (d) 20 °C pF2/10kPa ^{b)} | St. (X ²) | Method of calculation |
| Collombey loamy sand, Morgenroth, 1997 | | 7.6 | 20/50% pF2.5 | 1.4 / 4.7 | 1.2 | 7.7 | SFO |
| Clay loam Burr, 1997 | | 7.4 | 20/45% MWHC | 4.7 / 15.8 | 4.7 | 11.8 | SFO |
| Sandy loam, Burr 1997 | | 5.6 | 20/45% MWHC | 2.5 / 8.3 | 2.5 | 8.8 | SFO |
| Silty Clay loam Burr, 1997 | | 7.9-8.5 | 20/45% MWHC | 0.8 / 2.8 | 0.8 | 9.5 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.1 / 3.7 | 1.1 | 9.9 | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 1.1 / 3.8 | 1.1 | 9.7 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1 / 3.2 | 1 | 8.6 | SFO |
| Geometric mean (if not pH dependent) | | | | | 1.45 | | |
| pH dependence, <i>No</i> | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

⁷ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Trigger endpoint

| IM-1-2 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid | | | | | |
|--------------------------|----------------|---|----------------|---|-----------------------------|-----------------------|-----------------------|
| Soil type | X ² | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | Parameters bi-phasic models | St. (X ²) | Method of calculation |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.9 / 6.3 | | 9.6 | SFO ^{b)} |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 1.9 / 6.3 | | 13.0 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1.6 / 5.3 | | 12.3 | SFO |


^{a)} Measured in water

^{b)} Parent fitted with FOMC model

| IM-1-4 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-2 | | | | | |
|--|----------------|--|----------------|---|-----------------------------|-----------------------|-----------------------|
| Soil type | X ² | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | Parameters bi-phasic models | St. (X ²) | Method of calculation |
| Collombey loamy sand, Morgenroth, 1997 | | 7.6 | 20/50% pF2.5 | 46.2 / 154 | | 22.8 | SFO |
| Clay loam Burr, 1997 | | 7.4 | 20/45% MWHC | 142 / 473 | | 8.7 | SFO ^{a)} |
| Clay loam 10°C Burr, 1997 | | 7.4 | 10/45% MWHC | 171 / 569 | | 5.3 | SFO ^{a)} |
| Sandy loam, Burr 1997 | | 5.6 | 20/45% MWHC | 146 / 483 | | 6.2 | SFO ^{b)} |
| Silty Clay loam Burr, 1997 | | 7.9-8.5 | 20/45% MWHC | 3.7 / 12.3 | | 9.1 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 4.2 / 14 | | 22 | SFO ^{b)} |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 2.3 / 7.8 | | 18.1 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 3 / 10 | | 14.9 | SFO |


^{a)} Parent kinetics DFOP

^{b)} Parent kinetics FOMC

| IC-0 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-4 | | | | | |
|---------------------------------|---|---|---------------------------|---|--|--------------------------------------|----------------------------------|
| Soil type |  | pH^{a)} | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | Parameters bi-phasic models | St. (χ^2) | Method of calculation |
| Silty Clay loam Burr, 1997 | | 7.9- 8.5 | 20/45% MWHC | 3.6 / 11.8 | | 32.6 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.2 / 4.1 | | 4.3 | SFO ^{b)} |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 2.7 / 8.9 | | 11.6 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1.8 / 6.0 | | 10.0 | SFO |
| Sandy loam Lowden, 1997 | | 6.7 | 20/45% MWHC | 3.1 / 10.1 | | 10 | SFO |
| Silty Clay loam Lowden, 1997 | | 7.8 | 20/45% MWHC | 2.4 / 8.0 | | 9.1 | SFO |
| Clay loam Lowden, 1997 | | 7.2 | 20/45% MWHC | 5.6 / 18.5 | | 9.8 | SFO |

^{a)} Measured in water

^{b)} Parent kinetics FOMC

| IM-1-5 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid | | | | | |
|--------------------------------|--|--|---------------------------|---|--|--------------------------------------|----------------------------------|
| Soil type |  | pH^{a)} | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | Parameters bi-phasic models | St. (χ^2) | Method of calculation |
| Silty Clay loam Burr, 1997 | | 7.9- 8.5 | 20/45% MWHC | 319 / 1059 | | 5.1 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | - | | - | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | - | | - | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 486 / 1614 | | 10.3 | SFO |
| Loam (France) Jewkes 2014 | | 7.5 | 78.4% pF2 moisture | 663/2203 | | 4.7 | SFO |
| Loam (Hungary) Jewkes 2014 | | 7.8 | 60.7% pF2 moisture | 420/1395 | | 3.5 | SFO |
| Sandy Clay Loam Jewkes 2014 | | 7.6 | 66.4% pF2 moisture | 378/1254 | | 2.8 | SFO |

^{a)} Measured in water

Modelling endpoint

| IM-1-2 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid | | | | | | |
|--------------------------------------|----------------------|--|---------------------------|---|---|---|--------------------------------|----------------------------------|
| Soil type | X² | pH^{a)} | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | f. f. k_f / k_{dp} | DT₅₀ (d) 20 °C pF2/10kPa b) | St. (X²) | Method of calculation |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.6 / 5.3 | 0.97 | 1.6 | 12.3 | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 1.9 / 6.3 | 0.68 | 1.9 | 13.0 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1.6 / 5.3 | 0.66 | 1.6 | 12.3 | SFO |
| Geometric mean (if not pH dependent) | | | | | | 1.7 | | |
| Arithmetic mean | | | | | 0.77 | | | |
| pH dependence, <i>No</i> | | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

| IM-1-4 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-2 | | | | | | |
|--|----------------------|---|---------------------------|---|---|---|--------------------------------|----------------------------------|
| Soil type | X² | pH^{a)} | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | f. f. k_f / k_{dp} | DT₅₀ (d) 20 °C pF2/10kPa b) | St. (X²) | Method of calculation |
| Collombey loamy sand, Morgenroth, 1997 | | 7.6 | 20/50% pF2.5 | 46.2 / 154 | 0.56 | 40.0 | 22.8 | SFO |
| Clay loam Burr, 1997 | | 7.4 | 20/45% MWHC | 169 / 560 | 0.61 | 169 | 10.5 | SFO |
| Sandy loam, Burr 1997 | | 5.6 | 20/45% MWHC | 166 / 552.8 | 0.75 | 166 | 6.7 | SFO |
| Silty Clay loam Burr, 1997 | | 7.9- 8.5 | 20/45% MWHC | 3.7 / 12.3 | 1 | 3.7 | 9.1 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 4.8 / 16.1 | 0.44 | 4.8 | 22.3 | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 2.3 / 7.8 | 0.97 | 2.3 | 18.1 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 3 / 10 | 0.71 | 3.0 | 14.9 | SFO |
| Geometric mean (if not pH dependent) | | | | | | 14.6 | | |
| Arithmetic mean | | | | | 0.72 | | | |
| pH dependence, <i>No</i> | | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

| IC-0 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-4 | | | | | | |
|--------------------------------------|----------|--|-------------------|--|--|--|---------------------|--------------------------|
| Soil type | χ^2 | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | f. f. k _f / k _{dp} | DT ₅₀ (d) 20 °C pF2/10kPa b) | St. (χ^2) | Method of calculation |
| Silty Clay loam Burr, 1997 | | 7.9- 8.5 | 20/45% MWHC | 3.6 / 11.8 | 0.3 | 3.6 | 32.6 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | 1.4 / 4.6 | 1 | 1.4 | 5.1 | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | 2.7 / 8.9 | 0.39 | 2.7 | 11.6 | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 1.8 / 6.0 | 1 | 1.8 | 11.9 | SFO |
| Sandy loam Lowden, 1997 | | 6.7 | 20/45% MWHC | 3.1 / 10.1 | -* | 3.1 | 10 | SFO |
| Silty Clay loam Lowden, 1997 | | 7.8 | 20/45% MWHC | 2.4 / 8.0 | -* | 2.4 | 9.1 | SFO |
| Clay loam Lowden, 1997 | | 7.2 | 20/45% MWHC | 5.6 / 18.5 | -* | 5.6 | 9.8 | SFO |
| Geometric mean (if not pH dependent) | | | | | | 2.7 | | |
| Arithmetic mean | | | | | 0.67 | | | |
| pH dependence, <i>No</i> | | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

| IM-1-5 | | Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid | | | | | | |
|--------------------------------------|----------|---|-----------------------|--|--|--|---------------------|--------------------------|
| Soil type | χ^2 | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | f. f. k _f / k _{dp} | DT ₅₀ (d) 20 °C pF2/10kPa b) | St. (χ^2) | Method of calculation |
| Silty Clay loam Burr, 1997 | | 7.9- 8.5 | 20/45% MWHC | 319 / 1059 | 0.21 | 319 | 5.1 | SFO |
| Sandy loam Simmonds 2002 | | 8.0 | 20/45% MWHC | - | 0.16 ^{c)} | 1000 ^{d)} | - | SFO |
| Clay Simmonds 2002 | | 7.7 | 20/45% MWHC | - | 0.12 ^{c)} | 1000 ^{d)} | - | SFO |
| Clay loam Simmonds 2002 | | 7.9 | 20/45% MWHC | 486 / 1614 | 0.12 | 486 | 10.3 | SFO |
| Loam (France) Jewkes 2014 | | 7.5 | 78.4% pF2 moisture | 663/2203 | - | 559 | 4.7 | SFO |
| Loam (Hungary) Jewkes 2014 | | 7.8 | 60.7% pF2 moisture | 420/1395 | - | 296 | 3.5 | SFO |
| Sandy Clay Loam Jewkes 2014 | | 7.6 | 66.4% pF2 moisture | 378/1254 | - | 284 | 2.8 | SFO |
| Geometric mean (if not pH dependent) | | | | | | 495 | | |
| Arithmetic mean | | | | | 0.15 | | | |
| pH dependence, <i>No</i> | | | | | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} formation fraction based on maximum fraction of occurrence (persistent metabolite)

^{d)} default DT50 value used as no decline of IM-1-5 was observed for this soil

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent | Aerobic conditions | | | | | | | | |
|--|----------------------------------|----------|--------------------|------------|-----------------------------|-----------------------------|------------------|---|--|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | χ^9 | pH | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ^2) | DT ₅₀ (d) Norm ^{c)} | Method of calculation |
| Clay loam Wicks 1999 | Italy | | 8.9 ^{a)} | 0 – 30 | 0.4 | 19.8 | 14.1 | | DFOP k1:4.122808 k2:0.071185 g: 0.589717 |
| Sandy loam Wicks 1999 | United Kingdom | | 5.9 ^{a)} | 0 – 30 | 3.7 | 22.7 | 19.5 | | FOMC α :1.544681 β :6.600352 |
| Silty clay loam Wicks 1999 | France | | 8.7 ^{a)} | 0 – 30 | 9.6 | 31.3 | 16.4 | | SFO |
| Sandy loam Wicks 1999 | Spain | | 7 ^{a)} | 0 – 30 | 0.7 | 11.2 | 11.4 | | FOMC α :0.67159 β :0.374289 |
| Loam Kellner 2012a | Spain | | 7.45 ^{b)} | 0 - 50 | 12.96 | 43.06 | 28.1 | | SFO |
| Loam Kellner 2012b | Southern France | | 7.36 ^{b)} | 0 – 50 | 2.26 | 7.52 | 13.0 | | SFO |
| Loam Kellner 2012c | Northern France | | 7.49 ^{b)} | 0 – 50 | 2.24 | 7.43 | 12.1 | | SFO |
| Loam Finger 2013 | Hungary | | 8.06 ^{b)} | 0 - 50 | 2.14 | 15.32 | 25.9 | | FOMC α : and β :values not reported |
| pH dependence, No | | | | | | | | | |

^{a)} Measured in 1 M KCl

^{b)} Measured in 0.01 M CaCl

^{c)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

⁹ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Field study, metabolite maximum occurrence

| Metabolite formation | Aerobic conditions, metabolite max. formation proportion of maximum measured parent. | | | | | | |
|--|--|-------------|--------------------|------------|---------------|-------------------|----------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | χ^{10} | pH | Depth (cm) | IM-1-4 | IM-1-2 | IM-1-5 |
| Clay loam Wicks 1999 | Italy | | 8.9 ^{a)} | 0 – 10 | 50% after 28d | 39% after 4d | Not analysed |
| Sandy loam Wicks 1999 | United Kingdom | | 5.9 ^{a)} | 0 – 10 | 50% after 30d | < 3.9% after 2-7d | Not analysed |
| Silty clay loam Wicks 1999 | France | | 8.7 ^{a)} | 0 – 10 | 73% after 28d | 18% after 2d | Not analysed |
| Sandy loam Wicks 1999 | Spain | | 7 ^{a)} | 0 – 10 | 55% after 31d | 9% after 2d | Not analysed |
| Loam Kellner 2012a | Spain | | 7.45 ^{b)} | 0 - 10 | Not analysed | Not analysed | 60% after 28d |
| Loam Kellner 2012b | Southern France | | 7.36 ^{b)} | 0 – 10 | Not analysed | Not analysed | 25% after 29d |
| Loam Kellner 2012c | Northern France | | 7.49 ^{b)} | 0 – 10 | Not analysed | Not analysed | 45% after 7d |
| Loam Finger 2013 | Hungary | | 8.06 ^{b)} | 0 - 10 | Not analysed | Not analysed | 24% after 169d |

^{a)} Measured in 1 M KCl^{b)} Measured in 0.01 M CaCl**Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)**

Soil accumulation and plateau concentration

Studies Not required – plateau concentration of persistent metabolites obtained by modelling

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark anaerobic conditions | | | | | | |
|-----------|---------------------------|------|----------------|-----------------|------------------|----------|------------------------------|
| Soil type | χ^{11} | pHa) | t. oC / % MWHC | DT50 / DT90 (d) | DT50 (d) 20 °Cb) | St. (χ2) | Method of calculation |
| Loam | | 7.4 | 20 / 100% MWHC | 69.0 / 410.6 | | 4.7 | FOMC α:1.591 β:126.319 |

^{a)} Measured in water^{b)} Normalised using a Q10 of 2.58**Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)**

| Parent | Soil photolysis | | | | | |
|------------|-----------------|------|---------------------|--|----------|-----------------------|
| Soil type | χ^{12} | pHa) | t. oC / % MWHC | DT50 (d) calculated continuous irradiation | St. (χ2) | Method of calculation |
| Loamy sand | | | 20 / 75% of 1/3 bar | 17 | unknown | SFO |

^{a)} Measured in unknown medium¹⁰ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.¹¹ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.¹² X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Parent | | | | | | | | |
|---------------------------------------|------------|------|-----------------------|--------------------------|---|--------------------------|--|-------|
| Soil Type | | OC % | Soil pH ^{a)} | K _d (mL/g) | K _d _{doc} (mL/g) | K _F (mL/g) | K _F _{oc} (mL/g) | 1/n |
| I | Sand | 0.43 | 5.7 | | | 0.60 | 138.39 | 0.842 |
| II | Loamy sand | 1.04 | 7.6 | | | 1.35 | 129.98 | 0.825 |
| III | Sandy loam | 1.57 | 7.1 | | | 1.12 | 71.09 | 0.893 |
| IV | Silt loam | 1.39 | 7.7 | | | 1.69 | 121.81 | 0.835 |
| V | Silt loam | 4.39 | 7.1 | | | 3.13 | 71.38 | 0.907 |
| Arithmetic mean (if not pH dependent) | | | | | | | 106.5 | 0.860 |
| pH dependence, No | | | | | | | | |

^{a)} Measured in unknown medium

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| IM-1-2 | | | | | | | | |
|---------------------------------------|--|------|-----------------------|--------------------------|---|--------------------------|--|-------|
| Soil Type | | OC % | Soil pH ^{a)} | K _d (mL/g) | K _d _{doc} (mL/g) | K _F (mL/g) | K _F _{oc} (mL/g) | 1/n |
| Clay Loam 02/06 | | 2.3 | 7.6 | | | 0.45 | 19 | 0.886 |
| Sandy Loam 02/16 | | 1.3 | 7.5 | | | 0.27 | 21 | 0.856 |
| Clay Loam 01/24 | | 3.8 | 6.1 | | | 3.60 | 95 | 0.927 |
| Sandy Loam 02/18 | | 0.2 | 7.4 | | | 0.16 | 80 | 0.944 |
| Arithmetic mean (if not pH dependent) | | | | | | | 54 | 0.903 |
| pH dependence, No | | | | | | | | |

^{a)} Measured in CaCl₂ medium

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| IM-1-4 | | | | | | | | |
|---------------------------------------|------------|------|-----------------------|--------------------------|---|--------------------------|--|-------|
| Soil Type | | OC % | Soil pH ^{a)} | K _d (mL/g) | K _d _{doc} (mL/g) | K _F (mL/g) | K _F _{oc} (mL/g) | 1/n |
| I | Sand* | 0.43 | 5.7 | | | 2.1 | 488 | 0.597 |
| II | Loamy sand | 1 | 7.6 | | | 2.24 | 223 | 0.714 |
| III | Sandy loam | 1.57 | 7.1 | | | 2.16 | 138 | 0.712 |
| IV | Silt loam | 1.39 | 7.7 | | | 2.67 | 192 | 0.816 |
| V | Silt loam | 4.39 | 7.1 | | | 5.79 | 132 | 0.813 |
| Arithmetic mean (if not pH dependent) | | | | | | | 171 | 0.764 |
| pH dependence, No | | | | | | | | |

^{a)} Measured in unknown medium

* Sand soil was excluded during the previous evaluation due to low 1/n value

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| IC-0 | | | | | | | | |
|---------------------------------------|------|-----------------------|--------------------------|---|--------------------------|--|-------|--|
| Soil Type | OC % | Soil pH ^{a)} | K _d (mL/g) | K _d _{doc} (mL/g) | K _F (mL/g) | K _F _{oc} (mL/g) | 1/n | |
| I Sand | 0.43 | 5.7 | | | 0.643 | 258 | 0.967 | |
| II Loamy sand | 2.54 | 7.6 | | | 1.027 | 70 | 1.007 | |
| III Sandy loam | 0.76 | 7.1 | | | 0.569 | 129 | 0.971 | |
| IV Silt loam | 2.05 | 7.7 | | | 0.833 | 70 | 0.894 | |
| V Silt loam | 1.41 | 7.1 | | | 0.69 | 84 | 0.926 | |
| Pond sediment* | 4.32 | | | | 2.121 | 85 | 0.867 | |
| Arithmetic mean (if not pH dependent) | | | | | | 122 | 0.953 | |
| pH dependence, No | | | | | | | | |

^{a)} Measured in unknown medium

* Sediment excluded during the previous evaluation

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| IM-1-5 | | | | | | | | |
|---------------------------------------|------|-----------------------|--------------------------|---|--------------------------|--|--------|--|
| Soil Type | OC % | Soil pH ^{a)} | K _d (mL/g) | K _d _{doc} (mL/g) | K _F (mL/g) | K _F _{oc} (mL/g) | 1/n | |
| Spain (Canals) | 3.3 | 7.6 | | | 5.70 | 173 | 0.8788 | |
| S France (Meauzac) | 1.14 | 7.6 | | | 4.89 | 429 | 0.9030 | |
| Hungary | 2.03 | 7.8 | | | 7.58 | 374 | 0.8454 | |
| N France (Meistratzheim) | 2.04 | 8.3 | | | 6.60 | 324 | 0.9176 | |
| Arithmetic mean (if not pH dependent) | | | | | | 325 | 0.886 | |
| pH dependence, No | | | | | | | | |

^{a)} Measured in CaCl₂

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

no data submitted and no data required
 Leachate: 0.3-1.3 % total residues/radioactivity in leachate
 0.06 % active substance, 0.84 % IM-1-4
 88.9- 93.7 % total residues/radioactivity retained in the four upper soil layers

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Elution (mm): 1038 mm
 Time period (d): 20 d
 Leachate: 4.14 – 22.22 % total residues/radioactivity in leachate, all associated with metabolite IC-0
 4.5 - 5.3 % total residues/radioactivity retained in top 6 cm

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

no data submitted and no data required

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Acetamiprid: stable at pH 4, 5 and 7 at temperatures 22, 35 and 45°C

pH 9: 420 days at 25 °C

pH 9: 52.9 days at 35 °C

pH 9: 13 days at 45 °C

(calculated from Arrhenius plot)

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

DT₅₀ : 34 days (irradiated samples)
no photodegradation in dark samples

IB-1-1: 35%AR (30 d)

Quantum yield of direct phototransformation in water at $\lambda > 290$ nm

 Φ_{dc} of 0.10

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable
(yes/no)

No

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Parent | | | | | | | | | | |
|---|----------------|----------------------|---------------------|---|----------------------------------|-----------------------|---|---|-----------------------|-----------------------|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed ^{a)} | t. °C ^{b)} | DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test) | | St. (χ ²) | DT ₅₀ /DT ₉₀ Water (pelagic test) | | St. (χ ²) | Method of calculation |
| | | | | At study temp | Normalised to x °C ^{c)} | | At study temp | DT ₅₀ at 12 °C ^{c)} | | |
| Kolbenwoog low dose system (2 µg/L) | 5.41 | | 20 | | | | 2.4 / 36.9 | 5.1 | 4.2 | DFOP |
| Kolbenwoog high dose system (10 µg/L) | 5.41 | | 20 | | | | 6.8 / 87.8 | 14.5 | 7.1 | FOMC |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling

| Mineralisation and non extractable residues (for parent dosed experiments) | | | | | |
|--|----------------|--------|---|---|--|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
| Kolbenwoog low dose system (2 µg/L) | 5.41 | | 0.35 %, 59 d | n.r. | n.r. |
| Kolbenwoog high dose system (10 µg/L) | 5.41 | | 0.16 %, 59 d | n.r. | n.r. |

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

| Parent | Distribution (max in water 101.42% after 0 d. Max. sed 39.05 % after 14 d) | | | | | | | | | |
|--------------------------------------|--|----------------------|-------|--|-----------------------|---|-----------------------|---|-----------------------|-----------------------|
| Water / sediment system | pH water phase | pH sed ^{a)} | t. °C | DT ₅₀ / DT ₉₀ whole sys. | St. (χ ²) | DT ₅₀ / DT ₉₀ water | St. (χ ²) | DT ₅₀ / DT ₉₀ sed | St. (χ ²) | Method of calculation |
| Manningtree | 6.37/5.9 | n.r. | 20 | 23.1 | 7.6 | 4.9 | 8.3 | n.c. | | SFO/DFOP |
| Ongar | 7.58/7.3 | n.r. | 20 | 31.6 | 6.7 | 6.1 | 5.9 | n.c. | | SFO/DFOP |
| Geometric mean at 20°C ^{b)} | | | | 27 | | | | | | |

^{a)} Measured in unknown medium

^{b)} Normalised using a Q10 of 2.58

| | |
|-------------------|--|
| Metabolite IM-1-2 | Distribution (max in water 10.96 % after 7 d. Max. sed 3.93 % after 14 d). Max in total system 13.4 % after 7 days No acceptable fit possible |
| Metabolite IM-1-4 | Distribution (max in water 12.33 % after 30 d. Max. sed 30.71 % after 30 d). Max in total system 43 % after 30 days; Max 81.5% in aerobic mineralisation study No acceptable fit possible |
| Metabolite IC-0 | Distribution (max in water 26.15 % after 62 d. Max. sed. 5.61 % after 100 d). Max in total system 29.5 % after 62 days No acceptable fit possible |

| Mineralisation and non extractable residues (from parent dosed experiments) | | | | | |
|---|----------------|--------|---|--|---|
| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
| Manningtree | 6.37/5.9 | n.r. | 10.03 %, 155 d | 40.65%, 155 d | 40.65%, 155 d |
| Ongar | 7.58/7.3 | n.r. | 28.31 %, 155 d | 21.12%, 155 d | 21.12%, 155 d |

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air

Not studied - no data requested

Photochemical oxidative degradation in air

Overall rate constant: $76.435 \text{ cm}^3 \times \text{molecule}^{-1} \times \text{sec}^{-1}$ DT₅₀ of 0.140 days, derived by the Atkinson model (version 1.70) assuming a OH (12 h)

| | |
|----------------|---|
| Volatilisation | concentration of 1.5×10^6 OH/cm ³ |
| | from plant surfaces (BBA guideline): <1 % after 24 hours |
| | from soil surfaces (BBA guideline): negligible after 24 hours |
| Metabolites | No data |

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

Soil: Acetamiprid, IM-1-2, IM-1-4, IC-0, IM-1-5
 Surface water: Acetamiprid, IM-1-2, IM-1-4, IC-0, IB-1-1 (photolysis), IM-1-5 (via soil)
 Sediment: Acetamiprid, IM-1-2, IM-1-4, IC-0, IB-1-1 (photolysis), IM-1-5 (via soil)
 Ground water: Acetamiprid, IM-1-2, IM-1-4, IC-0, IM-1-5
 Air: Acetamiprid

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

| | |
|---|----------------|
| Soil (indicate location and type of study) | None available |
| Surface water (indicate location and type of study) | None available |
| Ground water (indicate location and type of study) | None available |
| Air (indicate location and type of study) | None available |

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

| | |
|-----------------------|---|
| Parent | DT ₅₀ (d): 12.96 days |
| Method of calculation | Kinetics: SFO Field or Lab: maximum field dissipation half-life. |
| Application data | Crop: pome fruit Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ % plant interception: 80% Number of applications: 2x Interval (d): 14 Application rate(s): 75 g a.s./ha |

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.029 | |
| Short term 24h | | | 0.028 | 0.029 |
| 2d | | | 0.026 | 0.028 |
| 4d | | | 0.024 | 0.027 |
| Long term 7d | | | 0.020 | 0.025 |
| 28d | | | 0.007 | 0.015 |
| 50d | | | 0.002 | 0.010 |
| 100d | | | 0.000 | 0.005 |
| Plateau concentration | | | | |

Metabolite IM-1-2
Method of calculation

Molecular weight relative to the parent: 1.08
DT₅₀ (d): 1.9 days
Kinetics: SFO
Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 44.6 g/ha (assumed IM-1-2 is formed at a maximum of 55 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average | Single application Time weighted average |
|-------------------------------|---|-----------------------------------|---|---|
| Initial | | | 0.012 | |
| Short term 24h | | | 0.008 | 0.010 |
| 2d | | | 0.006 | 0.008 |
| 4d | | | 0.003 | 0.006 |
| Long term 7d | | | 0.001 | 0.004 |
| 28d | | | 0.000 | 0.001 |
| 50d | | | 0.000 | 0.001 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-4
Method of calculation

Molecular weight relative to the parent: 0.70
DT₅₀ (d): 146 days
Kinetics: SFO
Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 38.0 g/ha (assumed IM-1-4 is formed at a maximum of 72 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|--|---|-----------------------------------|---|
| Initial | | | 0.020 | |
| Short term 24h | | | 0.020 | 0.020 |
| 2d | | | 0.019 | 0.020 |
| 4d | | | 0.019 | 0.019 |
| Long term 7d | | | 0.019 | 0.019 |
| 28d | | | 0.017 | 0.018 |
| 50d | | | 0.015 | 0.017 |
| 100d | | | 0.012 | 0.016 |
| Plateau concentration | 0.024 mg/kg after x yr (based on soil depth of 5 cm) | | | |

Metabolite IC-0

Method of calculation

Molecular weight relative to the parent: 0.70

DT₅₀ (d): 5.6 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 6.0 g/ha (assumed IC-0 is formed at a maximum of 11.3 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.002 | |
| Short term 24h | | | 0.002 | 0.002 |
| 2d | | | 0.001 | 0.002 |
| 4d | | | 0.001 | 0.001 |
| Long term 7d | | | 0.001 | 0.001 |
| 28d | | | 0.000 | 0.001 |
| 50d | | | 0.000 | 0.000 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-5

Method of calculation

Molecular weight relative to the parent: 0.89

DT₅₀ (d): 1000 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 13.3 g/ha (assumed IM-1-5 is formed at a maximum of 20 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|--|---|-----------------------------------|---|
| Initial | | | 0.007 | |
| Short term 24h | | | 0.007 | 0.007 |
| 2d | | | 0.007 | 0.007 |
| 4d | | | 0.007 | 0.007 |
| Long term 7d | | | 0.007 | 0.007 |
| 28d | | | 0.007 | 0.007 |
| 50d | | | 0.007 | 0.007 |
| 100d | | | 0.007 | 0.007 |
| Plateau concentration | 0.032 mg/kg after x yr (based on soil depth of 5 cm) | | | |

Parent

Method of calculation

Application data

DT₅₀ (d): 5.4 days

Kinetics: DFOP

Field or Lab: worst case from lab studies.

Crop: potato

Depth of soil layer: 5cm

Soil bulk density: 1.5g/cm³

% plant interception: 80%

Number of applications: 3x

Interval (d):7

Application rate(s): 50 g a.s./ha

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.029 | |
| Short term 24h | | | 0.027 | 0.028 |
| 2d | | | 0.026 | 0.027 |
| 4d | | | 0.023 | 0.026 |
| Long term 7d | | | 0.020 | 0.024 |
| 28d | | | 0.006 | 0.015 |
| 50d | | | 0.002 | 0.010 |
| 100d | | | 0.000 | 0.005 |
| Plateau concentration | | | | |

Metabolite IM-1-2

Method of calculation

Application data

Molecular weight relative to the parent: 1.08

DT₅₀ (d): 1.9 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application rate assumed: 29.7 g/ha (assumed IM-1-2 is formed at a maximum of 55 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.009 | |
| Short term 24h | | | 0.006 | 0.007 |
| 2d | | | 0.004 | 0.006 |
| 4d | | | 0.002 | 0.005 |
| Long term 7d | | | 0.001 | 0.003 |
| 28d | | | 0.000 | 0.001 |
| 50d | | | 0.000 | 0.000 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-4

Method of calculation

Molecular weight relative to the parent: 0.70

DT₅₀ (d): 146 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 25.3 g/ha (assumed IM-1-4 is formed at a maximum of 72 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---|---|-----------------------------------|---|
| Initial | | | 0.020 | |
| Short term 24h | | | 0.020 | 0.020 |
| 2d | | | 0.019 | 0.020 |
| 4d | | | 0.019 | 0.019 |
| Long term 7d | | | 0.019 | 0.019 |
| 28d | | | 0.017 | 0.018 |
| 50d | | | 0.015 | 0.017 |
| 100d | | | 0.012 | 0.016 |
| Plateau concentration | 0.021 mg/kg after x yr (based on soil depth of 20 cm) | | | |

Metabolite IC-0

Method of calculation

Molecular weight relative to the parent: 0.70

DT₅₀ (d): 5.6 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 4.0 g/ha (assumed IC-0 is formed at a maximum of 11.3 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.002 | |
| Short term 24h | | | 0.002 | 0.002 |
| 2d | | | 0.001 | 0.002 |
| 4d | | | 0.001 | 0.001 |
| Long term 7d | | | 0.001 | 0.001 |
| 28d | | | 0.000 | 0.000 |
| 50d | | | 0.000 | 0.000 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-5

Method of calculation

Molecular weight relative to the parent: 0.89

DT₅₀ (d): 1000 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 8.9 g/ha (assumed IM-1-5 is formed at a maximum of 20 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---|---|-----------------------------------|---|
| Initial | | | 0.007 | |
| Short term 24h | | | 0.007 | 0.007 |
| 2d | | | 0.007 | 0.007 |
| 4d | | | 0.007 | 0.007 |
| Long term 7d | | | 0.007 | 0.007 |
| 28d | | | 0.007 | 0.007 |
| 50d | | | 0.007 | 0.007 |
| 100d | | | 0.007 | 0.007 |
| Plateau concentration | 0.013 mg/kg after x yr (based on soil depth of 20 cm) | | | |

Parent

Method of calculation

DT₅₀ (d): 5.4 days

Kinetics: DFOP

Field or Lab: worst case from lab studies.

Application data

Crop: tomato (glasshouse)

Depth of soil layer: 5cm

Soil bulk density: 1.5g/cm³

% plant interception: 80%

Number of applications: 2x

Interval (d):7

Application rate(s): 100 g a.s./ha

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.045 | |
| Short term 24h | | | 0.043 | 0.044 |
| 2d | | | 0.040 | 0.043 |
| 4d | | | 0.036 | 0.041 |
| Long term 7d | | | 0.031 | 0.038 |
| 28d | | | 0.010 | 0.023 |
| 50d | | | 0.003 | 0.016 |
| 100d | | | 0.000 | 0.008 |
| Plateau concentration | | | | |

Metabolite IM-1-2

Method of calculation

Molecular weight relative to the parent: 1.08

DT₅₀ (d): 1.9 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 59.5 g/ha (assumed IM-1-2 is formed at a maximum of 55 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------------|---|-----------------------------------|---|
| Initial | | | 0.017 | |
| Short term 24h | | | 0.012 | 0.014 |
| 2d | | | 0.008 | 0.012 |
| 4d | | | 0.004 | 0.009 |
| Long term 7d | | | 0.001 | 0.006 |
| 28d | | | 0.000 | 0.002 |
| 50d | | | 0.000 | 0.001 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-4

Method of calculation

Molecular weight relative to the parent: 0.70

DT₅₀ (d): 146 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 50.6 g/ha (assumed IM-1-4 is formed at a maximum of 72 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---|--|--------------------------------|--|
| Initial | | | 0.027 | |
| Short term 24h | | | 0.026 | 0.027 |
| 2d | | | 0.026 | 0.026 |
| 4d | | | 0.026 | 0.026 |
| Long term 7d | | | 0.026 | 0.026 |
| 28d | | | 0.023 | 0.025 |
| 50d | | | 0.021 | 0.024 |
| 100d | | | 0.017 | 0.021 |
| Plateau concentration | 0.028 mg/kg after x yr (based on soil depth of 20 cm) | | | |

Metabolite IC-0

Method of calculation

Molecular weight relative to the parent: 0.70

DT₅₀ (d): 5.6 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 8.0 g/ha (assumed IC-0 is formed at a maximum of 11.3 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|------------------------------|--|--------------------------------|--|
| Initial | | | 0.003 | |
| Short term 24h | | | 0.003 | 0.003 |
| 2d | | | 0.002 | 0.003 |
| 4d | | | 0.002 | 0.002 |
| Long term 7d | | | 0.001 | 0.002 |
| 28d | | | 0.000 | 0.001 |
| 50d | | | 0.000 | 0.000 |
| 100d | | | 0.000 | 0.000 |
| Plateau concentration | | | | |

Metabolite IM-1-5

Method of calculation

Molecular weight relative to the parent: 0.89

DT₅₀ (d): 1000 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Application rate assumed: 17.8 g/ha (assumed IM-1-5 is formed at a maximum of 20 % of the applied dose)

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---|---|-----------------------------------|---|
| Initial | | | 0.009 | |
| Short term 24h | | | 0.009 | 0.009 |
| 2d | | | 0.009 | 0.009 |
| 4d | | | 0.009 | 0.009 |
| Long term 7d | | | 0.009 | 0.009 |
| 28d | | | 0.009 | 0.009 |
| 50d | | | 0.009 | 0.009 |
| 100d | | | 0.009 | 0.009 |
| Plateau concentration | 0.018 mg/kg after x yr (based on soil depth of 20 cm) | | | |

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Model(s) used: FOCUS PEARL 4.4.4, FOCUS PELMO 4.4.3

Crop: apples, potato, tomato (winter cereals as surrogate for tomato at H, J, K and N scenarios)

Crop uptake factor: 0

Water solubility (mg/L): 2950 at pH 7 and 25°C

Vapour pressure: 1×10^{-6} Pa at 20°C

Geometric mean parent $DT_{50 \text{ lab}}$ 1.6 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). *Note that the correct geomean lab DT_{50} value is 1.45 days*

K_{OC} : arithmetic mean 106.5 mL/g, arithmetic mean $1/n=0.86$.

Metabolites:

IM-1-2

Crop uptake factor: 0

Water solubility (mg/L): 1×10^6 at pH 7 and 25°C

Vapour pressure: 1×10^{-8} Pa at 20°C

Geometric mean $DT_{50 \text{ lab}}$ 1.7 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

K_{OC} : arithmetic mean 54 mL/g, arithmetic mean $1/n=0.90$.

formation fraction:0.77 (from parent)

IM-1-4

Crop uptake factor: 0

Application rate

Water solubility (mg/L): 1×10^6 at pH 7 and 25°C
 Vapour pressure: 1×10^{-8} Pa at 20°C
 Geometric mean $DT_{50 \text{ lab}}$ 17.6 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). *Note that the correct geometric mean DT_{50} value is 14.6 days*
 K_{OC} : arithmetic mean 171 mL/g, arithmetic mean $1/n=0.764$.
 formation fraction:0.74 (from IM-1-2) *Note that the correct arithmetic mean ff value is 0.72*

IC-0

Crop uptake factor: 0
 Water solubility (mg/L): 1×10^6 at pH 7 and 25°C
 Vapour pressure: 1×10^{-8} Pa at 20°C
 Geometric mean $DT_{50 \text{ lab}}$ 2.7 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
 K_{OC} : arithmetic mean 122 mL/g, arithmetic mean $1/n=0.953$.
 formation fraction:0.67 (from IM-1-4)

IM-1-5

Crop uptake factor: 0.5
 Water solubility (mg/L): 1×10^6 at pH 7 and 25°C
 Vapour pressure: 1×10^{-8} Pa at 20°C
 Geometric mean $DT_{50 \text{ lab}}$ 495 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
 K_{OC} : arithmetic mean 325 mL/g, arithmetic mean $1/n=0.886$.
 formation fraction:0.15 (from parent)

Apples:

Gross application rate: 75 g/ha.
 Crop growth stage: BBCH 77 – 87 (July - September)
 Canopy interception %: 80%
 Application rate net of interception: 15 g/ha.
 No. of applications: 2
 Time of application (absolute or relative application dates): 1 July, 15 July

Potato: application every third year

Gross application rate: 50 g/ha.
 Crop growth stage: BBCH 45 – 93 (May - September)
 Canopy interception %: 80%

Application rate net of interception: 10 g/ha.
 No. of applications: 3
 Time of application (absolute or relative application dates):
 15 May, 22 May, 29 May (spring application)
 1 September, 8 September, 15 September (autumn application: Hamburg, Jokioinen, Kremsmünster)
 27 August, 3 September, 10 September (autumn application Piacenza)

Tomato: (glasshouse application)
 Gross application rate: 100 g/ha.
 Crop growth stage: BBCH 61 – 89 (January - December)
 Canopy interception %: 80%
 Application rate net of interception: 20 g/ha.
 No. of applications: 2
 Time of application (absolute or relative application dates): 25 May, 1 June

* Only relevant after implementation of the published EFSA guidance.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| FOCUS PEARL 4.4.4 /apples | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|---------------------------|--------------|------------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.090 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.098 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.068 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.085 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.076 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.049 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.056 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.082 |

| FOCUS PELMO 4.4.3 /apples | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|---------------------------|--------------|------------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.078 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.072 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.058 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.088 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.076 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.048 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.017 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.05 |

| FOCUS PEARL 4.4.4 /potato spring | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|----------------------------------|--------------|------------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.010 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.018 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.004 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.014 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.018 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.013 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.008 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.001 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.004 |

| FOCUS PELMO 4.4.3 / potato spring | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|-----------------------------------|--------------|---------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.006 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.014 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.004 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.011 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.017 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.012 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.009 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.006 |

| FOCUS PEARL 4.4.4 / potato autumn | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|-----------------------------------|--------------|---------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.019 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.005 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.014 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.014 |

| FOCUS PELMO 4.4.3 / potato autumn | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|-----------------------------------|--------------|---------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.015 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.004 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.011 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.013 |

| FOCUS PEARL 4.4.4 /tomato | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|---------------------------|--------------|---------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.062 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.106 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.079 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.113 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.082 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.051 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.002 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.024 |

| FOCUS PELMO 4.4.3 / tomato | Scenario | Parent (µg/L) | Metabolite (µg/L) | | | |
|----------------------------|--------------|---------------|-------------------|--------|-------|--------|
| | | | IM-1-2 | IM-1-4 | IC-0 | IM-1-5 |
| | Chateaudun | 0.000 | 0.000 | 0.000 | 0.000 | 0.027 |
| | Hamburg | 0.000 | 0.000 | 0.000 | 0.000 | 0.085 |
| | Jokioinen | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Kremsmunster | 0.000 | 0.000 | 0.000 | 0.000 | 0.073 |
| | Okehampton | 0.000 | 0.000 | 0.000 | 0.000 | 0.107 |
| | Piacenza | 0.000 | 0.000 | 0.000 | 0.000 | 0.076 |
| | Porto | 0.000 | 0.000 | 0.000 | 0.000 | 0.049 |
| | Sevilla | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | Thiva | 0.000 | 0.000 | 0.000 | 0.000 | 0.015 |

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: 2.1
Molecular weight (g/mol): 223
 K_{OC} (mL/g): 106.5
 DT_{50} soil (d): 1.45
 DT_{50} water/sediment system (d): 27 d (geomean from sediment water studies if not pH dependent)
 DT_{50} water (d): 27 (system value)
 DT_{50} sediment (d): 27 (system value)
Crop interception (%):
Apples: 70% (full canopy)
Potato: 70% (full canopy)

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift)
no interception; no drainage/runoff
crop type: appln aerial (33.2% drift)
PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Parameters used in FOCUSsw step 3 (if performed)

Version control no.'s of FOCUS software:
SWASH v3.1, FOCUS PRZM v3.1.1, FOCUS MACRO v 5.5.3, FOCUS TOXSWA v3.3.1
Water solubility (mg/L): 2950
Vapour pressure: 1×10^{-6} Pa at 20°C
 K_{om}/K_{oc} (mL/g): 106.5 (arithmetic mean)
1/n: 0.86 (Freundlich exponent general or for soil, susp. solids or sediment respectively)
 DT_{50} water (d): 27
 DT_{50} sediment (d): 1000 (default)
 $Q_{10}=2.58$, Walker equation coefficient 0.7
Crop uptake factor: 0.5 (a value of 0 should have been used as root systemicity has not been demonstrated)

Application rate

Pome fruit:
Crop and growth stage: apples BBCH 77 – 87 (July - September)
Number of applications: 2
Interval (d): 14
Application rate(s): 75 g a.s./ha
Application window: late application

Potato:
Crop and growth stage: potato BBCH 45 – 93 (May - October)

Main routes of entry

Number of applications: 3
Interval (d): 7
Application rate(s): 50 g a.s./ha
Application window:

Spray drift, runoff

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 4.9668 | | 4.2909 | |
| | 24 h | 4.5969 | 4.7818 | 4.1821 | 4.2365 |
| | 2 d | 4.4706 | 4.6578 | 4.0761 | 4.1828 |
| | 4 d | 4.3286 | 4.518 | 3.8721 | 4.0782 |
| | 7 d | 3.8454 | 4.3075 | 3.5851 | 3.9277 |
| | 14 d | 3.2129 | 3.9137 | 2.9954 | 3.6046 |
| | 21 d | 2.6844 | 3.5894 | 2.5027 | 3.317 |
| | 28 d | 2.2429 | 3.3064 | 2.0911 | 3.0605 |
| | 42 d | 1.5657 | 2.8323 | 1.4598 | 2.6259 |
| Pome fruit Southern EU June - Sept | 0 h | 4.9668 | | 4.3333 | |
| | 24 h | 4.5969 | 4.7818 | 4.2235 | 4.2784 |
| | 2 d | 4.4706 | 4.6578 | 4.1165 | 4.2242 |
| | 4 d | 4.3696 | 4.5231 | 3.9104 | 4.1185 |
| | 7 d | 3.8834 | 4.3274 | 3.6206 | 3.9665 |
| | 14 d | 3.2447 | 3.941 | 3.025 | 3.6403 |
| | 21 d | 2.711 | 3.6174 | 2.5275 | 3.3498 |
| | 28 d | 2.2651 | 3.3334 | 2.1118 | 3.0908 |
| | 42 d | 1.5812 | 2.8565 | 1.4742 | 2.6518 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 0.8101 | | 0.7552 | |
| | 24 h | 0.7624 | 0.7863 | 0.736 | 0.7456 |
| | 2 d | 0.742 | 0.7693 | 0.7174 | 0.7361 |
| | 4 d | 0.76 | 0.7532 | 0.6815 | 0.7177 |
| | 7 d | 0.6768 | 0.734 | 0.631 | 0.6912 |
| | 14 d | 0.5654 | 0.6767 | 0.5272 | 0.6344 |
| | 21 d | 0.4724 | 0.6237 | 0.4405 | 0.5838 |
| | 28 d | 0.3947 | 0.5759 | 0.368 | 0.5386 |
| | 42 d | 0.2756 | 0.4944 | 0.2569 | 0.4621 |
| Potato Southern EU June - Sept | 0 h | 0.8101 | | 0.7837 | |
| | 24 h | 0.7624 | 0.7863 | 0.7638 | 0.7737 |
| | 2 d | 0.742 | 0.7693 | 0.7445 | 0.7639 |
| | 4 d | 0.7876 | 0.7566 | 0.7072 | 0.7448 |
| | 7 d | 0.7023 | 0.7473 | 0.6548 | 0.7173 |
| | 14 d | 0.5868 | 0.6951 | 0.5471 | 0.6583 |
| | 21 d | 0.4903 | 0.6424 | 0.4571 | 0.6058 |
| | 28 d | 0.4096 | 0.594 | 0.3819 | 0.559 |
| | 42 d | 0.286 | 0.5107 | 0.2666 | 0.4796 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|---------------------------------------|---------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Tomato glasshouse No draianage/runoff | 0 h | 0.0588 | | 0.0376 | |
| | 24 h | 0.0546 | 0.0567 | 0.0375 | 0.0376 |
| | 2 d | 0.0531 | 0.0553 | 0.0366 | 0.0373 |
| | 4 d | 0.0505 | 0.0535 | 0.0348 | 0.0365 |
| | 7 d | 0.0467 | 0.0514 | 0.0322 | 0.0352 |
| | 14 d | 0.0390 | 0.0471 | 0.0269 | 0.0323 |
| | 21 d | 0.0326 | 0.0433 | 0.0225 | 0.0297 |
| | 28 d | 0.0272 | 0.0399 | 0.0188 | 0.0275 |
| | 42 d | 0.0190 | 0.0343 | 0.0131 | 0.0236 |

The maximum Step 3 PEC_{SW} and PEC_{SED} values obtained for acetamiprid for the use pome fruit (late application)

| Scenario | Application dates | PEC _{sw} (µg/l) | PEC _{sed} * (µg/kg) | Dominant Entry route to SW | Application regime** |
|-----------|-------------------|--------------------------|------------------------------|----------------------------|----------------------|
| D3 Ditch | 30 Jun, 24 Jul | 2.756 | 0.947 | Drift | Respective Single |
| D4 Pond | 4 Jul, 27 Aug | 0.132 | 0.332 | Drift | Multiple |
| D4 Stream | 4 Jul, 27 Aug | 2.762 | 0.361 | Drift | Respective Single |
| D5 Pond | 19 Jul, 4 Aug | 0.170 | 0.322 | Drift | Multiple |
| D5 Stream | 19 Jul, 4 Aug | 2.985 | 0.480 | Drift | Respective Single |
| R1 Pond | 11, 28 Jul | 0.165 | 0.300 | Drift | Multiple |
| R1 Stream | 11, 28 Jul | 2.074 | 0.160 | Drift | Respective Single |
| R2 Stream | 31 Jul, 14 Aug | 2.837*** | 0.184 | Drift | Respective Single |
| R3 Stream | 31 Jul, 14 Aug | 2.983 | 0.471 | Drift | Respective Single |
| R4 Stream | 3, 17 Jul | 2.116 | 0.237 | Drift | Respective Single |

* worst case PEC_{sed} always from single applications, except for the value for D3, D4 pond, D5 pond and R1 pond

** in the case of the respective single application, the first date stated is the date of application, except

*** = 5 Aug

The maximum Step 4 PEC_{SW} and PEC_{SED} values obtained for acetamiprid for the use pome fruit (late application)

| Scenario | Application dates | PEC _{sw} (µg/l) | PEC _{sed} * (µg/kg) | Dominant Entry route to SW | Application regime** |
|---|-------------------|--------------------------|------------------------------|----------------------------|----------------------|
| 20m buffer zone (spray drift and runoff mitigated) | | | | | |
| D3 Ditch | 30 Jun, 24 Jul | 0.256 | 0.105 | drift | Respective Single |
| D4 Pond | 4 Jul, 27 Aug | 0.0356 | 0.0913 | drift | Respective Single |
| D4 Stream | 4 Jul, 27 Aug | 0.297 | 0.0425 | drift | Respective Single |
| D5 Pond | 19 Jul, 4 Aug | 0.0442 | 0.0914 | drift | Multiple |
| D5 Stream | 19 Jul, 4 Aug | 0.321 | 0.0574 | drift | Respective Single |
| R1 Pond | 11, 28 Jul | 0.0429 | 0.0852 | drift | Multiple |
| R1 Stream | 11, 28 Jul | 0.223 | 0.0181 | drift | Respective Single |
| R2 Stream | 31 Jul, 14 Aug | 0.305*** | 0.021 | drift | Respective Single |
| R3 Stream | 31 Jul, 14 Aug | 0.321 | 0.0562 | drift | Respective Single |
| R4 Stream | 3, 17 Jul | 0.228 | 0.0278 | drift | Respective Single |

* worst case PEC_{sed} always from single applications, except for the value for D3, D4 pond, D5 pond, R1 pond and R4 stream

** in the case of the respective single application, the first date stated is the date of application, except

*** = 5 Aug

The maximum Step 3 PEC_{SW} and PEC_{SED} values obtained for acetamiprid for the use potato (early & late application)

| Scenario | Application dates | PEC _{sw} (µg/l) | PEC _{sed} (µg/kg) | Dominant Entry route to SW | Application regime* |
|--------------|--------------------|-----------------------------|-------------------------------|-------------------------------|---------------------|
| D3 Ditch | 4, 14, 24 May | 0.262 | 0.0908 | Drift | Respective Single |
| D4 Pond | 17, 24, 31 May | 0.0193 | 0.0462 | Drift | Multiple |
| D4 Stream | 17, 24, 31 May | 0.217 | 0.0108 | Drift | Respective Single |
| D6 Ditch (1) | 1, 23 Aug, 4 Sept | 0.264 | 0.183 | Drift | Respective Single |
| D6 Ditch (2) | 4, 13, 21, Sept | 0.257 | 0.0443 | Drift | Respective Single |
| R1 Pond | 2, 9, May, 13 June | 0.0232 | 0.0659 | Run-off | Multiple |
| R1 Stream | 2, 9, May, 13 June | 0.271 | 0.0742 | Run-off | Multiple |
| R2 Stream | 7, 20, 27 May | 0.244 | 0.0364 | Drift | Respective Single |
| R3 Stream | 18 May, 1, 11 June | 0.299 | 0.0851 | Run-off | Multiple |

* In all cases the PEC_{sed} value came from the multiple application; in the case of the respective single application, the first date stated is the date of application

The maximum Step 4 PEC_{SW} and PEC_{SED} values obtained for acetamiprid for the use potato (early & late application)

| Scenario | Application dates | PEC _{sw} (µg/l) | PEC _{sed} * (µg/kg) | Dominant Entry route to SW | Application regime** |
|--|---------------------|-----------------------------|---------------------------------|-------------------------------|----------------------|
| 10 m buffer zone (spray drift and runoff mitigated) | | | | | |
| D3 Ditch | 4, 14, 24 May | 0.0457 | 0.017 | Drift | Respective single |
| D4 Pond | 17, 24, 31 May | 0.0122 | 0.0301 | Drift | Multiple |
| D4 Stream | 27 Aug, 10, 28 Sept | 0.0483 | 0.0287 | Drift | Respective single |
| D6 Ditch (1) | 3, 17, 24 May | 0.0461 | 0.0357 | Drift | Respective single |
| D6 Ditch (2) | 4, 13, 21 Sept | 0.0449 | 0.00813 | Drift | Respective single |
| R1 Pond | 2, 9 May, 13 June | 0.0119 | 0.0368 | Run-off | Multiple |
| R1 Stream | 2, 9 May, 13 June | 0.111 | 0.031 | Run-off | Multiple |
| R2 Stream | 7, 20, 27 May | 0.0544 | 0.0149 | Drift | Respective single |
| R3 Stream | 18 May, 1, 11 June | 0.136 | 0.0375 | Run-off | Multiple |

* worst case PEC_{sed} always from multiple applications, except for the value for R2 stream

** In the case of the respective single application, the first date stated is the date of application

Metabolite IM-1-2

Parameters used in FOCUS_{sw} step 1 and 2

Molecular weight: 240.69
 Soil or water metabolite: soil and water
 Koc (mL/g): arithmetic mean 54 mL/g, arithmetic mean $1/n=0.90$
 DT₅₀ soil (d): 1.7
 DT₅₀ water/sediment system (d): 1000 (default)
 DT₅₀ water (d): 1000 (default)
 DT₅₀ sediment (d): 1000 (default)
 Crop interception (%):
 Apples: 70% (full canopy)
 Potato: 70% (full canopy)

 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 13.4%
 Soil: 55%

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift); no interception; no drainage/runoff

crop type: appln aerial (33.2% drift)

PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Pome fruit:

Crop and growth stage: apples BBCH 77 – 87 (July - September)

Number of applications: 2

Interval (d): 14

Application rate(s): 75 g a.s./ha

Application window: late application

Potato:

Crop and growth stage: potato BBCH 45 – 93 (May - October)

Number of applications: 3

Interval (d): 7

Application rate(s): 50 g a.s./ha

Application window:

Main routes of entry

-

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|------------------------------------|---------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 0.8591 | | 0.4538 | |
| | 24 h | 0.8405 | 0.8498 | 0.4535 | 0.4537 |
| | 2 d | 0.8399 | 0.845 | 0.4532 | 0.4535 |
| | 4 d | 0.8387 | 0.8421 | 0.4526 | 0.4532 |
| | 7 d | 0.837 | 0.8403 | 0.4516 | 0.4527 |
| | 14 d | 0.8329 | 0.8376 | 0.4495 | 0.4516 |
| | 21 d | 0.8289 | 0.8354 | 0.4473 | 0.4506 |
| | 28 d | 0.8249 | 0.8333 | 0.4451 | 0.4495 |
| | 42 d | 0.8169 | 0.8291 | 0.4408 | 0.4473 |
| Pome fruit Southern EU June – Sept | 0 h | 0.8851 | | 0.4679 | |
| | 24 h | 0.8664 | 0.8758 | 0.4676 | 0.4677 |
| | 2 d | 0.8658 | 0.871 | 0.4672 | 0.4676 |
| | 4 d | 0.8646 | 0.8681 | 0.4666 | 0.4672 |
| | 7 d | 0.8628 | 0.8662 | 0.4656 | 0.4667 |
| | 14 d | 0.8587 | 0.8635 | 0.4634 | 0.4656 |
| | 21 d | 0.8545 | 0.8612 | 0.4611 | 0.4645 |
| | 28 d | 0.8504 | 0.859 | 0.4589 | 0.4634 |
| | 42 d | 0.8422 | 0.8548 | 0.4545 | 0.4611 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 0.1696 | --- | 0.0899 | --- |
| | 24 h | 0.1665 | 0.1681 | 0.0898 | 0.0899 |
| | 2 d | 0.1664 | 0.1672 | 0.0898 | 0.0898 |
| | 4 d | 0.1661 | 0.1668 | 0.0897 | 0.0898 |
| | 7 d | 0.1658 | 0.1664 | 0.0895 | 0.0897 |
| | 14 d | 0.165 | 0.1659 | 0.089 | 0.0895 |
| | 21 d | 0.1642 | 0.1655 | 0.0886 | 0.0893 |
| | 28 d | 0.1634 | 0.1651 | 0.0882 | 0.089 |
| | 42 d | 0.1618 | 0.1642 | 0.0873 | 0.0886 |
| Potato Southern EU June – Sept | 0 h | 0.1871 | --- | 0.0993 | --- |
| | 24 h | 0.1839 | 0.1855 | 0.0993 | 0.0993 |
| | 2 d | 0.1838 | 0.1847 | 0.0992 | 0.0993 |
| | 4 d | 0.1836 | 0.1842 | 0.0991 | 0.0992 |
| | 7 d | 0.1832 | 0.1838 | 0.0989 | 0.0991 |
| | 14 d | 0.1823 | 0.1833 | 0.0984 | 0.0989 |
| | 21 d | 0.1814 | 0.1828 | 0.0979 | 0.0986 |
| | 28 d | 0.1805 | 0.1824 | 0.0974 | 0.0984 |
| | 42 d | 0.1788 | 0.1815 | 0.0965 | 0.0979 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Tomato glasshouse No draianage/runoff | 0 h | 0.0091 | --- | 0.0032 | --- |
| | 24 h | 0.0089 | 0.0090 | 0.0032 | 0.0032 |
| | 2 d | 0.0089 | 0.0090 | 0.0032 | 0.0032 |
| | 4 d | 0.0089 | 0.0089 | 0.0032 | 0.0032 |
| | 7 d | 0.0089 | 0.0089 | 0.0032 | 0.0032 |
| | 14 d | 0.0088 | 0.0089 | 0.0032 | 0.0032 |
| | 21 d | 0.0088 | 0.0089 | 0.0032 | 0.0032 |
| | 28 d | 0.0087 | 0.0088 | 0.0031 | 0.0032 |
| | 42 d | 0.0087 | 0.0088 | 0.0031 | 0.0032 |

Metabolite IM-1-4

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 156.61

Soil or water metabolite: soil and water

K_{OC}: arithmetic mean 171 mL/g, arithmetic mean $1/n=0.764$.

DT₅₀ soil (d): 17.6 *Note the that correct geomean lab DT₅₀ value is 14.6 days*

DT₅₀ water/sediment system (d): 1000 (default)

DT₅₀ water (d): 1000 (default)

DT₅₀ sediment (d): 1000 (default)

Crop interception (%):

Apples: 70% (full canopy)

Potato: 70% (full canopy)

Maximum occurrence observed (% molar basis with respect to the parent)

Total Water and Sediment: 81.5 % (aerobic

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Main routes of entry

mineralisation study)
Soil: 72%

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift); no interception; no drainage/runoff
crop type: appln aerial (33.2% drift)
PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Pome fruit:
Crop and growth stage: apples BBCH 77 – 87 (July - September)
Number of applications: 2
Interval (d): 14
Application rate(s): 75 g a.s./ha
Application window: late application

Potato:
Crop and growth stage: potato BBCH 45 – 93 (May - October)
Number of applications: 3
Interval (d): 7
Application rate(s): 50 g a.s./ha
Application window:

-

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{sw} (µg/L) | | PEC _{sed} (µg/kg) | |
|------------------------------------|---------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 3.7953 | | 6.1710 | |
| | 24 h | 3.6088 | 3.7021 | 6.1668 | 6.1689 |
| | 2 d | 3.6063 | 3.6548 | 6.1625 | 6.1668 |
| | 4 d | 3.6013 | 3.6293 | 6.1540 | 6.1625 |
| | 7 d | 3.5938 | 3.6157 | 6.1412 | 6.1561 |
| | 14 d | 3.5764 | 3.6004 | 6.1115 | 6.1412 |
| | 21 d | 3.5591 | 3.5895 | 6.0819 | 6.1264 |
| | 28 d | 3.5419 | 3.5798 | 6.0524 | 6.1115 |
| | 42 d | 3.5077 | 3.5614 | 5.9940 | 6.0821 |
| Pome fruit Southern EU June – Sept | 0 h | 4.2062 | | 6.8731 | |
| | 24 h | 4.0193 | 4.1128 | 6.8683 | 6.8707 |
| | 2 d | 4.0166 | 4.0654 | 6.8636 | 6.8683 |
| | 4 d | 4.0110 | 4.0396 | 6.8541 | 6.8636 |
| | 7 d | 4.0027 | 4.0255 | 6.8398 | 6.8564 |
| | 14 d | 3.9833 | 4.0093 | 6.8067 | 6.8398 |
| | 21 d | 3.9640 | 3.9974 | 6.7738 | 6.8233 |
| | 28 d | 3.9448 | 3.9866 | 6.7410 | 6.8068 |
| | 42 d | 3.9067 | 3.9663 | 6.6759 | 6.7740 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 1.3071 | | 2.1811 | |
| | 24 h | 1.2755 | 1.2913 | 2.1796 | 2.1804 |
| | 2 d | 1.2746 | 1.2832 | 2.1781 | 2.1796 |
| | 4 d | 1.2729 | 1.2785 | 2.1751 | 2.1781 |
| | 7 d | 1.2702 | 1.2755 | 2.1706 | 2.1758 |
| | 14 d | 1.2641 | 1.2713 | 2.1601 | 2.1706 |
| | 21 d | 1.2579 | 1.2679 | 2.1496 | 2.1653 |
| | 28 d | 1.2519 | 1.2646 | 2.1392 | 2.1601 |
| | 42 d | 1.2398 | 1.2584 | 2.1185 | 2.1497 |
| Potato Southern EU June – Sept | 0 h | 1.7125 | | 2.8739 | |
| | 24 h | 1.6807 | 1.6966 | 2.8719 | 2.8729 |
| | 2 d | 1.6795 | 1.6883 | 2.8700 | 2.8719 |
| | 4 d | 1.6772 | 1.6833 | 2.8660 | 2.8700 |
| | 7 d | 1.6737 | 1.6800 | 2.8600 | 2.8670 |
| | 14 d | 1.6656 | 1.6748 | 2.8462 | 2.8600 |
| | 21 d | 1.6575 | 1.6704 | 2.8324 | 2.8531 |
| | 28 d | 1.6495 | 1.6662 | 2.8187 | 2.8462 |
| | 42 d | 1.6336 | 1.6580 | 2.7915 | 2.8325 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Tomato glasshouse No draianage/runoff | 0 h | 0.0354 | | 0.0374 | |
| | 24 h | 0.0330 | 0.0342 | 0.0374 | 0.0374 |
| | 2 d | 0.0328 | 0.0335 | 0.0373 | 0.0374 |
| | 4 d | 0.0328 | 0.0332 | 0.0373 | 0.0373 |
| | 7 d | 0.0327 | 0.0330 | 0.0372 | 0.0373 |
| | 14 d | 0.0325 | 0.0328 | 0.0370 | 0.0372 |
| | 21 d | 0.0324 | 0.0327 | 0.0368 | 0.0371 |
| | 28 d | 0.0322 | 0.0326 | 0.0367 | 0.0370 |
| | 42 d | 0.0319 | 0.0324 | 0.0363 | 0.0368 |

Metabolite IC-0

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 157.55
 Soil or water metabolite: soil and water
 K_{OC} : arithmetic mean 122 mL/g, arithmetic mean $1/n=0.953$.
 DT_{50} soil (d): 2.7
 DT_{50} water/sediment system (d): 1000 (default)
 DT_{50} water (d): 1000 (default)
 DT_{50} sediment (d): 1000 (default)
 Crop interception (%):
 Apples: 70% (full canopy)
 Potato: 70% (full canopy)

Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 29.5%
 Soil: 11.3%

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift); no interception; no drainage/runoff
 crop type: appln aerial (33.2% drift)
 PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Pome fruit:
 Crop and growth stage: apples BBCH 77 – 87 (July - September)
 Number of applications: 2
 Interval (d): 14
 Application rate(s): 75 g a.s./ha
 Application window: late application

Potato:
 Crop and growth stage: potato BBCH 45 – 93 (May - October)
 Number of applications: 3
 Interval (d): 7
 Application rate(s): 50 g a.s./ha
 Application window:

Main routes of entry

-

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 1.1775 | | 1.3251 | |
| | 24 h | 1.1187 | 1.1481 | 1.3242 | 1.3247 |
| | 2 d | 1.1153 | 1.1326 | 1.3233 | 1.3242 |
| | 4 d | 1.1389 | 1.1266 | 1.3215 | 1.3233 |
| | 7 d | 1.0847 | 1.1128 | 1.3187 | 1.3219 |
| | 14 d | 1.0794 | 1.0974 | 1.3123 | 1.3187 |
| | 21 d | 1.0742 | 1.0906 | 1.3060 | 1.3155 |
| | 28 d | 1.0690 | 1.0858 | 1.2997 | 1.3124 |
| | 42 d | 1.0587 | 1.0785 | 1.2871 | 1.3060 |
| Pome fruit Southern EU June – Sept | 0 h | 1.1775 | | 1.3405 | |
| | 24 h | 1.1187 | 1.1481 | 1.3396 | 1.3401 |
| | 2 d | 1.1153 | 1.1326 | 1.3387 | 1.3396 |
| | 4 d | 1.1515 | 1.1282 | 1.3368 | 1.3387 |
| | 7 d | 1.0973 | 1.1192 | 1.3341 | 1.3373 |
| | 14 d | 1.0920 | 1.1069 | 1.3276 | 1.3341 |
| | 21 d | 1.0867 | 1.1010 | 1.3212 | 1.3308 |
| | 28 d | 1.0814 | 1.0968 | 1.3148 | 1.3276 |
| | 42 d | 1.0710 | 1.0899 | 1.3021 | 1.3212 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 0.2042 | | 0.2383 | |
| | 24 h | 0.1954 | 0.1998 | 0.2382 | 0.2383 |
| | 2 d | 0.1952 | 0.1975 | 0.238 | 0.2382 |
| | 4 d | 0.195 | 0.1963 | 0.2377 | 0.238 |
| | 7 d | 0.1945 | 0.1956 | 0.2372 | 0.2378 |
| | 14 d | 0.1936 | 0.1949 | 0.236 | 0.2372 |
| | 21 d | 0.1927 | 0.1943 | 0.2349 | 0.2366 |
| | 28 d | 0.1917 | 0.1938 | 0.2338 | 0.236 |
| | 42 d | 0.1899 | 0.1928 | 0.2315 | 0.2349 |
| Potato Southern EU June – Sept | 0 h | 0.2133 | | 0.2495 | |
| | 24 h | 0.2045 | 0.2089 | 0.2493 | 0.2494 |
| | 2 d | 0.2044 | 0.2067 | 0.2492 | 0.2493 |
| | 4 d | 0.2041 | 0.2055 | 0.2488 | 0.2492 |
| | 7 d | 0.2037 | 0.2048 | 0.2483 | 0.2489 |
| | 14 d | 0.2027 | 0.204 | 0.2471 | 0.2483 |
| | 21 d | 0.2017 | 0.2034 | 0.2459 | 0.2477 |
| | 28 d | 0.2007 | 0.2028 | 0.2447 | 0.2471 |
| | 42 d | 0.1988 | 0.2018 | 0.2424 | 0.2459 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Tomato glasshouse No draianage/runoff | 0 h | 0.0130 | --- | 0.0100 | --- |
| | 24 h | 0.0123 | 0.0127 | 0.0100 | 0.0100 |
| | 2 d | 0.0123 | 0.0125 | 0.0100 | 0.0100 |
| | 4 d | 0.0123 | 0.0124 | 0.0100 | 0.0100 |
| | 7 d | 0.0122 | 0.0123 | 0.0099 | 0.0100 |
| | 14 d | 0.0122 | 0.0123 | 0.0099 | 0.0099 |
| | 21 d | 0.0121 | 0.0122 | 0.0098 | 0.0099 |
| | 28 d | 0.0121 | 0.0122 | 0.0098 | 0.0099 |
| | 42 d | 0.0120 | 0.0121 | 0.0097 | 0.0098 |

Metabolite IM-1-5

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 197.66
Soil or water metabolite: soil
 K_{OC} : arithmetic mean 325 mL/g, arithmetic mean $1/n=0.886$.
DT₅₀ soil (d): 495
DT₅₀ water/sediment system (d): 1000 (default)
DT₅₀ water (d): 1000 (default)
DT₅₀ sediment (d): 1000 (default)
Crop interception (%):
Apples: 70% (full canopy)
Potato: 70% (full canopy)

Maximum occurrence observed (% molar basis with respect to the parent)
Total Water and Sediment: -
Soil: 20%

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift); no interception; no drainage/runoff
crop type: appln aerial (33.2% drift)
PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Pome fruit:
Crop and growth stage: apples BBCH 77 – 87 (July - September)
Number of applications: 2
Interval (d): 14
Application rate(s): 75 g a.s./ha
Application window: late application

Potato:
Crop and growth stage: potato BBCH 45 – 93 (May - October)
Number of applications: 3
Interval (d): 7
Application rate(s): 50 g a.s./ha
Application window:

Main routes of entry

-

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 0.3641 | --- | 1.1833 | --- |
| | 24 h | 0.3638 | 0.3640 | 1.1825 | 1.1829 |
| | 2 d | 0.3636 | 0.3638 | 1.1816 | 1.1825 |
| | 4 d | 0.3631 | 0.3636 | 1.1800 | 1.1816 |
| | 7 d | 0.3623 | 0.3632 | 1.1776 | 1.1804 |
| | 14 d | 0.3606 | 0.3623 | 1.1719 | 1.1776 |
| | 21 d | 0.3588 | 0.3615 | 1.1662 | 1.1747 |
| | 28 d | 0.3571 | 0.3606 | 1.1605 | 1.1719 |
| | 42 d | 0.3536 | 0.3588 | 1.1493 | 1.1662 |
| Pome fruit Southern EU June – Sept | 0 h | 0.5461 | --- | 1.7749 | --- |
| | 24 h | 0.5458 | 0.5459 | 1.7737 | 1.7743 |
| | 2 d | 0.5454 | 0.5458 | 1.7725 | 1.7737 |
| | 4 d | 0.5446 | 0.5454 | 1.7700 | 1.7725 |
| | 7 d | 0.5435 | 0.5448 | 1.7663 | 1.7706 |
| | 14 d | 0.5409 | 0.5435 | 1.7578 | 1.7663 |
| | 21 d | 0.5382 | 0.5422 | 1.7493 | 1.7621 |
| | 28 d | 0.5356 | 0.5409 | 1.7408 | 1.7578 |
| | 42 d | 0.5305 | 0.5383 | 1.7240 | 1.7493 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 0.3641 | --- | 1.1832 | --- |
| | 24 h | 0.3638 | 0.3639 | 1.1824 | 1.1828 |
| | 2 d | 0.3636 | 0.3638 | 1.1816 | 1.1824 |
| | 4 d | 0.3631 | 0.3636 | 1.1800 | 1.1816 |
| | 7 d | 0.3623 | 0.3632 | 1.1775 | 1.1804 |
| | 14 d | 0.3606 | 0.3623 | 1.1718 | 1.1775 |
| | 21 d | 0.3588 | 0.3614 | 1.1661 | 1.1747 |
| | 28 d | 0.3571 | 0.3606 | 1.1605 | 1.1718 |
| | 42 d | 0.3536 | 0.3588 | 1.1493 | 1.1662 |
| Potato Southern EU June – Sept | 0 h | 0.5461 | --- | 1.7749 | --- |
| | 24 h | 0.5457 | 0.5459 | 1.7736 | 1.7742 |
| | 2 d | 0.5454 | 0.5457 | 1.7724 | 1.7736 |
| | 4 d | 0.5446 | 0.5454 | 1.7699 | 1.7724 |
| | 7 d | 0.5435 | 0.5448 | 1.7663 | 1.7706 |
| | 14 d | 0.5408 | 0.5435 | 1.7577 | 1.7663 |
| | 21 d | 0.5382 | 0.5422 | 1.7492 | 1.7620 |
| | 28 d | 0.5356 | 0.5408 | 1.7407 | 1.7577 |
| | 42 d | 0.5304 | 0.5382 | 1.7239 | 1.7493 |

Metabolite IB-1-1

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 204.23
 Soil or water metabolite: water (photolytic metabolite)
 K_{OC} : 0 (default).
 DT_{50} soil (d): -
 DT_{50} water/sediment system (d): 1000 (default)
 DT_{50} water (d): 1000 (default)
 DT_{50} sediment (d): 1000 (default)
 Crop interception (%):
 Apples: 70% (full canopy)
 Potato: 70% (full canopy)

Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 35%
 Soil: -

Tomato (glasshouse use): Step 2 simulation based on an overall emission percentage of 0.1% (simulated as spray drift); no interception; no drainage/runoff
 crop type: appln aerial (33.2% drift)
 PEC-values divided by 332 to obtain PEC-values based on 0.1% drift.

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Pome fruit:
 Crop and growth stage: apples BBCH 77 – 87 (July - September)
 Number of applications: 2
 Interval (d): 14
 Application rate(s): 75 g a.s./ha
 Application window: late application

Potato:
 Crop and growth stage: potato BBCH 45 – 93 (May - October)
 Number of applications: 3
 Interval (d): 7
 Application rate(s): 50 g a.s./ha
 Application window:

Main routes of entry

-

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Pome fruit Northern EU June – Sept | 0 h | 1.9288 | | 0.1905 | |
| | 24 h | 1.9189 | 1.9239 | 0.1904 | 0.1905 |
| | 2 d | 1.9176 | 1.9211 | 0.1903 | 0.1904 |
| | 4 d | 1.9149 | 1.9187 | 0.1900 | 0.1903 |
| | 7 d | 1.9026 | 1.9132 | 0.1896 | 0.1901 |
| | 14 d | 1.8934 | 1.9056 | 0.1887 | 0.1896 |
| | 21 d | 1.8842 | 1.9000 | 0.1878 | 0.1891 |
| | 28 d | 1.8751 | 1.8949 | 0.1869 | 0.1887 |
| | 42 d | 1.8570 | 1.8853 | 0.1851 | 0.1878 |
| Pome fruit Southern EU June – Sept | 0 h | 1.9288 | | 0.1905 | |
| | 24 h | 1.9189 | 1.9239 | 0.1904 | 0.1905 |
| | 2 d | 1.9176 | 1.9211 | 0.1903 | 0.1904 |
| | 4 d | 1.9149 | 1.9187 | 0.1900 | 0.1903 |
| | 7 d | 1.9026 | 1.9132 | 0.1896 | 0.1901 |
| | 14 d | 1.8934 | 1.9056 | 0.1887 | 0.1896 |
| | 21 d | 1.8842 | 1.9000 | 0.1878 | 0.1891 |
| | 28 d | 1.8751 | 1.8949 | 0.1869 | 0.1887 |
| | 42 d | 1.8570 | 1.8853 | 0.1851 | 0.1878 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--------------------------------------|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Potato Northern EU June – Sept | 0 h | 0.3214 | --- | 0.0318 | --- |
| | 24 h | 0.3202 | 0.3208 | 0.0318 | 0.0318 |
| | 2 d | 0.3200 | 0.3205 | 0.0317 | 0.0318 |
| | 4 d | 0.3196 | 0.3201 | 0.0317 | 0.0317 |
| | 7 d | 0.3175 | 0.3192 | 0.0316 | 0.0317 |
| | 14 d | 0.3160 | 0.3180 | 0.0315 | 0.0316 |
| | 21 d | 0.3144 | 0.3170 | 0.0313 | 0.0316 |
| | 28 d | 0.3129 | 0.3162 | 0.0312 | 0.0315 |
| | 42 d | 0.3099 | 0.3146 | 0.0309 | 0.0313 |
| Potato Southern EU June – Sept | 0 h | 0.3214 | --- | 0.0318 | --- |
| | 24 h | 0.3202 | 0.3208 | 0.0318 | 0.0318 |
| | 2 d | 0.3200 | 0.3205 | 0.0317 | 0.0318 |
| | 4 d | 0.3196 | 0.3201 | 0.0317 | 0.0317 |
| | 7 d | 0.3175 | 0.3192 | 0.0316 | 0.0317 |
| | 14 d | 0.3160 | 0.3180 | 0.0315 | 0.0316 |
| | 21 d | 0.3144 | 0.3170 | 0.0313 | 0.0316 |
| | 28 d | 0.3129 | 0.3162 | 0.0312 | 0.0315 |
| | 42 d | 0.3099 | 0.3146 | 0.0309 | 0.0313 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | | PEC _{SED} (µg/kg) | |
|--|---------------------------------|--------------------------|--------|----------------------------|--------|
| | | Actual | TWA | Actual | TWA |
| Tomato glasshouse No draianage/runoff | 0 h | 0.0214 | --- | 0.0000 | --- |
| | 24 h | 0.0214 | 0.0214 | 0.0000 | 0.0000 |
| | 2 d | 0.0214 | 0.0214 | 0.0000 | 0.0000 |
| | 4 d | 0.0213 | 0.0214 | 0.0000 | 0.0000 |
| | 7 d | 0.0213 | 0.0213 | 0.0000 | 0.0000 |
| | 14 d | 0.0212 | 0.0213 | 0.0000 | 0.0000 |
| | 21 d | 0.0211 | 0.0212 | 0.0000 | 0.0000 |
| | 28 d | 0.0210 | 0.0212 | 0.0000 | 0.0000 |
| | 42 d | 0.0208 | 0.0211 | 0.0000 | 0.0000 |

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

No other relevant routes of exposure

PEC

Maximum concentration

-

Section 5 Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|---|------------------------|---|----------------------|---|
| Birds | | | | |
| <i>Anas platyrhynchos</i> (mallard duck) | a.s. | Acute | LD ₅₀ | 98 |
| <i>Colinus virginianus</i> (bobwhite quail) | a.s. | Acute | LD ₅₀ | >100 |
| <i>Poephila guttata</i> (zebra finch) | a.s. | Acute | LD ₅₀ | 5.7 |
| Geometric mean | a.s. | Acute | LD ₅₀ | 38.2 |
| | a.s. | Long-term | LD ₅₀ /10 | 3.8 |
| <i>Anas platyrhynchos</i> (mallard duck) | a.s. | Long-term | NOAEL | 9.5 |
| Mammals | | | | |
| Rat | a.s. | Acute | LD ₅₀ | 146 |
| | Preparation EXP 60707B | Acute | LD ₅₀ | 1065 mg /kg bw ♀ 1000 – 2000 mg /kg bw ♂ |
| Rat | a.s. | Long-term [90-d study] | NOAEL | 12.4 |
| Rat | a.s. | Long-term [developmental neurotoxicity study] | NOAEL | 2.5 |
| Endocrine disrupting properties (Annex Part A, points 8.1.5) | | | | |
| The mammalian toxicology data was considered, along with the amphibian metamorphosis assay and the fish early life-stage test. These data do not indicate an endocrine-system-specific pathway of toxicity. | | | | |
| Additional higher tier studies (Annex Part A, points 10.1.1.2): | | | | |
| Radiotracking study in orchards in UK, determining PT data for four bird species. | | | | |
| Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): | | | | |
| No data. | | | | |

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Pome fruit at 2x 75 g a.s./ha, interval 14 d

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|-------------------------------|---------------------------------------|------------|------------------------|------------|---------|
| Screening Step (Birds) | | | | | |
| All | small insectivorous bird | Acute | 4.21 | 9.1 | 10 |
| | | Long-term | 1.01 | 3.8 | 5 |
| Tier 1 (Birds) | | | | | |
| Spring/summer | small insectivorous bird | Acute | 4.21 | 9.1 | 10 |
| | | Long-term | 1.01 | 3.8 | 5 |
| Crop directed, BBCH \geq 40 | small insectivorous/worm feeding bird | Acute | 0.20 | 193 | 10 |
| | | Long-term | 0.04 | 86 | 5 |
| Crop directed, BBCH \geq 40 | small granivorous bird | Acute | 0.74 | 52 | 10 |
| | | Long-term | 0.21 | 18 | 5 |

Higher tier (birds):

For acute RA a quantitative risk assessment refinement was considered necessary (data gap).

Chronic RA:

Radiotracking study in orchards in UK, determining PT data for four bird species. Uncertainties: 1) the PT is averaged over a large period and may be higher in part of that period; 2) and furthermore the data for focal species and PT may not be representative for the whole of Europe. With blue tit as focal species and a PT=0.79, the TER was **4.8** (data gap was identified for further refinement)

Screening Step (Mammals)

| | | | | | |
|-------------------------------|--------------------------|-----------|------|-------------|----|
| All | small herbivorous mammal | Acute | 12.3 | 11.9 | 10 |
| | | Long-term | 4.02 | 0.62 | 5 |
| Tier 1 (Mammals) | | | | | |
| Crop directed, BBCH \geq 40 | small herbivorous mammal | Long-term | 4.02 | 2.07 | 5 |
| Crop directed, BBCH \geq 40 | large herbivorous mammal | Long-term | 0.24 | 10.4 | 5 |
| Crop directed, BBCH \geq 40 | small omnivorous mammal | Long-term | 0.13 | 19.2 | 5 |

Higher tier (Mammals): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]

Refinements include a discussion of the default deposition factors (no change in risk assessment), refined residues for dicotic portions of the diet ($DT_{50} = 2.3$ days, $fTWA = 0.16$), and a discussion of the relevance of vole in orchards. The RMS calculated a refined TER of **3.4** for the use in orchards and did not consider arguments about the relevance of voles in orchards acceptable. A risk to small herbivorous mammal in orchards remains (data gap).

Potatoes at 3x 50 g a.s./ha, interval 7 d

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--|------------------------------------|------------|------------------------|-----------------|---------|
| Screening Step (Birds) | | | | | |
| All | small omnivorous bird | Acute | 12.7 | 3.0 | 10 |
| All | small omnivorous bird | Long-term | 3.43 | 1.1 | 5 |
| Tier 1 (Birds) | | | | | |
| BBCH \geq 40 | small omnivorous/worm feeding bird | Acute | 0.58 | 66 | 10 |
| | | Long-term | 0.17 | 22 | 5 |
| BBCH \geq 20 | small insectivorous bird | Acute | 2.02 | 19 | 10 |
| | | Long-term | 0.51 | 7.4 | 5 |
| Higher tier (birds): not required | | | | | |
| - | | | | | |
| Screening Step (Mammals) | | | | | |
| All | small herbivorous mammal | Acute | 9.47 | 15.4 | 10 |
| | | Long-term | 2.55 | 0.98 | 5 |
| Tier 1 (Mammals) | | | | | |
| BBCH \geq 40 | small herbivorous mammal | Long-term | 1.15 | 2.17 | 5 |
| BBCH \geq 40 | Frugivorous mammals | Long-term | 1.2 | 2.0 | 5 |
| BBCH \geq 40 | large herbivorous mammal | Long-term | 0.23 | 10.9 | 5 |
| BBCH \geq 40 | small omnivorous mammal | Long-term | 0.12 | 20.8 | 5 |
| BBCH \geq 20 | small insectivorous mammal | Long-term | 0.10 | 25 ² | 5 |
| Higher tier (Mammals): Refinements include a discussion of the default deposition factors (no change in risk assessment), refined residues for dicotic portions of the diet ($DT_{50} = 2.3$ days, $fTWA = 0.16$), and a discussion of the relevance of vole in orchards. The RMS calculated a refined TER of 3.7 for the use in potatoes but considered the field study evidence presented sufficient to suggest that voles are unlikely to spend > 74% of their time foraging in potato fields (only at 74% or greater PT is a risk likely). Thus, the use in potatoes is considered acceptable based on a weight of evidence conclusion. | | | | | |
| Risk from bioaccumulation and food chain behaviour <i>not relevant, $\log K_{ow} \leq 3$</i> | | | | | |
| Risk from consumption of contaminated water | | | | | |
| Puddle scenario, Screening step Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg) for both field uses, TER calculation not needed. | | | | | |

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|--------------------------------|-----------------------|--------------------------------|------------------------------|---|
| Laboratory tests | | | | |
| Fish | | | | |
| <i>Oncorhynchus mykiss</i> | a.s. | Acute 96 hr (static) | Mortality, LC ₅₀ | >100 mg a.s./L (nom) |
| <i>Lepomis macrochirus</i> | a.s. | Acute 96 hr (flow through) | Mortality, LC ₅₀ | >119.3 mg a.s./L _(mm) |
| <i>Cyprinodon variegatus</i> | a.s. | Acute 96 hr (flow through) | Mortality, LC ₅₀ | 100 mg a.s./L (nom) |
| <i>Pimephales promelas</i> | a.s. | Chronic 35 days (flow-through) | Hatchability | NOEC _{hatch} = 9.4 mg a.s./L _(mm) EC10 _{hatch} = >150 mg a.s./L _(mm) |
| <i>Oncorhynchus mykiss</i> | Metabolite IM-1-4 | 96 hr (semi-static) | Mortality, LC ₅₀ | >98.1 mg a.s./L (mm) |
| Amphibians | | | | |
| <i>Xenopus laevis</i> | a.s. | 21 days (flow-through) | growth | 2.6 mg a.s./L _(mm) |
| Aquatic invertebrates | | | | |
| <i>Daphnia magna</i> | a.s. | 48 h (static) | Mortality, EC ₅₀ | 49.8 mg a.s./L (mm) |
| <i>Chironomus riparius</i> | a.s. | 48-h (static) | Mortality, EC ₅₀ | 0.0207 mg a.s./L (mm) |
| <i>Gammarus fasciatus</i> | a.s. | 96-h (static) | Mortality, EC ₅₀ | 0.1 mg a.s./L (mm) |
| <i>Mysidopsis bahia</i> | a.s. | 96-h (flow-through) | Mortality, EC ₅₀ | 0.066 mg a.s./L (mm) |
| <i>Gammarus pulex</i> | a.s. | 96-h (static) | Mortality, EC ₅₀ | 0.050 mg a.s./L (mm) |
| <i>Simulium latigonium</i> | a.s. | 96-h (static) | Mortality, EC ₅₀ | 0.0037 mg a.s./L (mm) |
| Geometric mean aquatic insects | a.s. | | Mortality, EC ₅₀ | 0.0085 mg a.s./L (mm) |
| <i>Daphnia magna</i> | EXP60707A | 48 h (static) | Mortality, EC ₅₀ | >31.8 mg a.s./L _(mm) |
| <i>Chironomus riparius</i> | Acetamiprid 20% SP | 48-h (static) | Mortality, EC ₅₀ | 0.0196 mg a.s./L _(mm) |
| <i>Daphnia magna</i> | a.s. | 21 d (semi-static) | Reproduction or development, | NOEC = 5 mg a.s./L _(mm) EC10 = 2.96 mg a.s./L _(mm) |
| <i>Daphnia magna</i> | Metabolite IM-1-2 | 48 h (semi-static) | Mortality, EC ₅₀ | >99.8 mg pm/L |
| <i>Chironomus riparius</i> | Metabolite IM-1-2 | 48 h (static) | Mortality, EC ₅₀ | 15.0 mg pm/L |
| <i>Daphnia magna</i> | Metabolite IM-1-4 | 48 h (semi-static) | Mortality, EC ₅₀ | 43.9 mg pm/L |
| <i>Mysidopsis bahia</i> | Metabolite IM-1-4 | 48 h (static) | Mortality, EC ₅₀ | 19 mg pm/L |

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|------------------------------------|--------------------|---------------------------|--|---|
| <i>Chironomus riparius</i> | Metabolite IM-1-4 | 48 h (static) | Mortality, EC ₅₀ | 76.0 mg pm/L |
| <i>Daphnia magna</i> | Metabolite IM-1-5 | 48 h (static) | Mortality, EC ₅₀ | 25 mg pm/L |
| <i>Chironomus riparius</i> | Metabolite IM-1-5 | 48 h (static) | Mortality, EC ₅₀ | 68 mg pm/L |
| <i>Daphnia magna</i> | Metabolite IM-1-5 | 21-d (semi-static) | Reproduction or development, NOEC | 26 mg pm/L |
| <i>Daphnia magna</i> | Metabolite IC-0 | 48 h (semi-static) | Mortality, EC ₅₀ | >95.1 mg pm/L |
| <i>Chironomus riparius</i> | Metabolite IC-0 | 48 h (static) | Mortality, EC ₅₀ | >100 mg pm/L |
| <i>Daphnia magna</i> | Metabolite IB-1-1 | 48 h (semi-static) | Mortality, EC ₅₀ | >100.8 mg pm/L |
| <i>Chironomus riparius</i> | Metabolite IB-1-1 | 48 h (static) | Mortality, EC ₅₀ | >100 mg pm/L |
| Sediment-dwelling organisms | | | | |
| <i>Chironomus riparius</i> | a.s. | 28 d (static) | Emergence | NOEC = 0.00096 mg a.s./L _(mm) ; EC10 = 0.000235 mg a.s./L _(mm) |
| Algae | | | | |
| <i>Scenedesmus subspicatus</i> | a.s. | 72 h (static) | Biomass: E _b C ₅₀ & growth rate: ErC ₅₀ | >98.3 mg a.s./L _(mm) |
| <i>Anabaena flos-aquae</i> | a.s. | 120-h (static) | EC ₅₀ | >1.3 mg a.s./L _(mm) |
| <i>Scenedesmus subspicatus</i> | Acetamiprid 20% SP | 72 h (static) | Biomass: E _b C ₅₀ | >19.6 mg a.s./L _(mm) |
| Higher plant | | | | |
| <i>Lemna gibba</i> | a.s. | 14 d (static) | Fronds number, EC ₅₀ | >1.0 mg a.s./L _(mm) |

Further testing on aquatic organisms

Outdoor mesocosm study: Effect assessment on macroinvertebrates, zooplankton, phytoplankton, periphyton and macrophytes in outdoor mesocosms. Test substance: Acetamiprid 20 SG (Mospilan 20 SG). 2 applications with a 14 day interval. Study duration: 82 days. Treatment rates: 0.5, 1.1, 2.6 and 6.0 µg a.s./L.

Endpoints: NOEC and NOEAEC <0.5 µg/L based on class 5B effects on Naididae at 0.5-6.0 µg/L. Considering however the uncertainty associated with the findings for Naididae (not expected to be more sensitive than insects based on mode of action; relatively low numbers in control, although MDD was low) the reported conclusion by the study author NOEC based on class 2 effects to derive the ETO-RAC 1.1 µg/L; NOEAEC to derive ERO-RAC 1.1 µg/L based on class 5B effects on *Cloeon dipterum* at 2.6 µg/L) could be acceptable in case the findings for Naididae in the present study are negated by prolonged toxicity laboratory studies (e.g. at least 28 days duration) with representative taxa of Naididae.

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

The mammalian toxicology data was considered, along with the amphibian metamorphosis assay and the fish early life-stage test. These data do not indicate an endocrine-system-specific pathway of toxicity (i.e. systemic toxicity is indicated, as opposed to direct interaction with estrogen, androgen or thyroidal systems).

¹(_{nom}) nominal concentration; (_{mm}) mean measured concentration; prep.: preparation; a.s.: active substance

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| | Active substance | Metabolite 1 | Metabolite 2 | Metabolite 3 |
|--|------------------|--------------|--------------|--------------|
| logP _{O/W} | 0.80 | | | |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | X* | | | |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | | | | |
| Annex VI Trigger for the bioconcentration factor | | | | |
| Clearance time (days) (CT ₅₀) | | | | |
| (CT ₉₀) | | | | |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | | | | |

Higher tier study

* based on total ¹⁴C or on specific compounds

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} step 1-2 - TERs for acetamiprid – pome fruit at 75 g a.s./ha x 2 (14 d interval) (most critical use)

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Amphibians |
|----------------------|-----------------------|------------------------------|----------------------------|---|---------------------------------|----------------------------|--------------------|----------------------------|------------|
| | | <i>Cyprinodon variegatus</i> | <i>Pimephales promelas</i> | Geomean of EC50 of 2 aquatic insect species** | <i>Daphnia magna</i> | <i>Anabaena flos-aquae</i> | <i>Lemna gibba</i> | <i>Chironomus riparius</i> | |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC | NOEC |
| | | 100000 µg/L | 9400 µg/L | 8.5 µg/L | 2960 µg/L | >1300 µg/L | >1000 µg/L | 0.235 µg/L | 2600 µg/L |
| FOCUS Step 1 | | | | | | | | | |
| FOCUS Step 2 | | | | | | | | | |
| North Europe | 4.9668 | >1000 | >1000 | 1.7 | 596 | >262 | >201 | 0.047 | 523 |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | | | | | | | | | |
| D3 Ditch | 2.756 | | | 3.1 | | | | 0.1 | |
| D4 Pond | 0.132 | | | 64.4 | | | | 1.8 | |
| D4 Stream | 2.762 | | | 3.1 | | | | 0.1 | |
| D5 Pond | 0.170 | | | 50.0 | | | | 1.4 | |
| D5 Stream | 2.985 | | | 2.8 | | | | 0.1 | |
| R1 pond | 0.165 | | | 51.2 | | | | 1.4 | |
| R1 Stream | 2.074 | | | 4.1 | | | | 0.1 | |
| R2 Stream | 2.837 | | | 3.0 | | | | 0.1 | |
| R3 Stream | 2.983 | | | 2.8 | | | | 0.1 | |
| R4 Stream | 2.116 | | | 4.0 | | | | 0.1 | |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 10 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**Daphnia magna excluded, because the endpoint is considered as an outlier

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 1-3 TERs for acetamiprid based on mesocosm endpoint– pome fruit at 75 g a.s./ha x 2 (14 d interval) (most critical use)

| Scenario | PEC global max (µg L) | Mesocosm |
|----------------------|--------------------------|--------------------------|
| | | NOEC/NOEAEC: 1.1 µg as/L |
| FOCUS Step 1 | | |
| FOCUS Step 2 | | |
| North Europe | 4.9668 | 0.22 |
| South Europe | | |
| FOCUS Step 3* | | |
| D3 Ditch | 2.756 | 0.40 |
| D4 Pond | 0.132 | 8.33 |
| D4 Stream | 2.762 | 0.40 |
| D5 Pond | 0.170 | 6.47 |
| D5 Stream | 2.985 | 0.37 |
| R1 pond | 0.165 | 6.63 |
| R1 Stream | 2.074 | 0.53 |
| R2 Stream | 2.837 | 0.39 |
| R3 Stream | 2.983 | 0.37 |
| R4 Stream | 2.116 | 0.52 |
| Trigger | | 3 |

FOCUS_{sw} step 1-3 - TERs for acetamiprid – potatoes at 50 g a.s./ha x 3 (7 d interval)

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Amphibians |
|----------------------|-----------------------|------------------------------|----------------------------|--|---------------------------------|----------------------------|--------------------|----------------------------|------------|
| | | <i>Cyprinodon variegatus</i> | <i>Pimephales promelas</i> | <i>Geomean of EC50 of 2 aquatic insect species**</i> | <i>Daphnia magna</i> | <i>Anabaena flos-aquae</i> | <i>Lemna gibba</i> | <i>Chironomus riparius</i> | |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC | NOEC |
| | | 100000 µg/L | 9400 µg/L | 8.5 µg/L | 2960 µg/L | >1300 µg/L | >1000 µg/L | 0.235 µg/L | 2600 µg/L |
| FOCUS Step 1 | | | | | | | | | |
| FOCUS Step 2 | | | | | | | | | |
| North Europe | 0.8101 | >1000 | >1000 | 1.7 | >1000 | >262 | >201 | 0.29 | 523 |
| South Europe | | | | | | | | | |
| FOCUS Step 3* | | | | | | | | | |
| D3 Ditch | 0.262 | | | 32.4 | | | | 0.9 | |
| D4 Pond | 0.0193 | | | 440 | | | | 12.2 | |
| D4 Stream | 0.217 | | | 39.2 | | | | 1.1 | |
| D6 Ditch 1 | 0.264 | | | 32.2 | | | | 0.9 | |
| D6 Ditch 2 | 0.257 | | | 33.1 | | | | 0.9 | |
| R1 pond | | | | | | | | | |
| R1 Stream | | | | | | | | | |
| R2 Stream | 0.0473 | | | 180 | | | | 5.0 | |
| R3 Stream | 0.463 | | | 18.4 | | | | 0.5 | |
| | 0.224 | | | 37.9 | | | | 1.0 | |
| | 0.706 | | | 12.0 | | | | 0.3 | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 10 |

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

FOCUS_{sw} step 1-3 – TERs for acetamiprid – tomatoes at 100 g a.s./ha x 2 (7 d interval) (permanent greenhouse)

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Amphibians |
|---------------------|-----------------------|------------------------------|----------------------------|---|---------------------------------|----------------------------|--------------------|----------------------------|------------|
| | | <i>Cyprinodon variegatus</i> | <i>Pimephales promelas</i> | Geomean of EC ₅₀ of 2 aquatic insect species** | <i>Daphnia magna</i> | <i>Anabaena flos-aquae</i> | <i>Lemna gibba</i> | <i>Chironomus riparius</i> | |
| | | LC ₅₀ | NOEC | EC ₅₀ | NOEC | EC ₅₀ | EC ₅₀ | NOEC | NOEC |
| | | 100000 µg/L | 9400 µg/L | 8.5 µg/L | 2960 µg/L | >1300 µg/L | >1000 µg/L | 0.235 µg/L | 2600 µg/L |
| FOCUS Step 1 | | | | | | | | | |
| FOCUS Step 2 | | | | | | | | | |
| North Europe | 0.0588 | >1000 | >1000 | 145 | >1000 | >1000 | >1000 | 4.0 | >1000 |
| South Europe | | | | | | | | | |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 10 |

FOCUS_{sw} step 4 - TERs for acetamiprid – pome fruit at 75 g a.s./ha x 2 (14 d interval) (most critical use)

| Organisms : <i>mesocosm study: aquatic invertebrates*</i> | | | | | |
|---|--|---|----------------------------------|------|---------|
| Toxicity endpoint: NOEC/NOEAEC: 1.1 µg as/L | | | | | |
| Mitigation options | 20 m non-spray buffer zone corresponding to ≤ 95 % drift reduction) | 5 m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction) | PEC _{sw} (x.xx µg/L) | TER | trigger |
| FOCUS Step 4* | | | | | |
| D3 / ditch | | X | 0.256 | 4.3 | 3 |
| D4 / pond | | X | 0.0356 | 30.9 | |
| D4 / stream | | X | 0.297 | 3.7 | |
| D5 / pond | | X | 0.0442 | 24.9 | |
| D5 / stream | | X | 0.321 | 3.4 | |
| R1 / pond | | X | 0.0429 | 25.6 | |
| R1 / stream | | X | 0.223 | 4.9 | |
| R2 / stream | | X | 0.305 | 3.6 | |
| R3 / stream | | X | 0.321 | 3.4 | |
| R4 / stream | | X | 0.228 | 4.8 | |

*Only the risk assessment is included for aquatic invertebrates, because this is the most critical group

Metabolites

| | IM-1-2 PECsw FOCUS step2 (µg/L) | | IM-1-4 PECsw FOCUS step2 (µg/L) | | IC-0 PECsw FOCUS step2 (µg/L) | | IM-1-5 PECsw FOCUS step2 (µg/L) | | IB-1 PECsw FOCUS step2 (µg/L) | |
|------------|---------------------------------------|---------|---------------------------------------|--------|-------------------------------------|---------|---------------------------------------|-------------|-------------------------------------|---------|
| | tox endpoint 15000 µg/L | TER | tox endpoint 19000 µg/L | TER | tox endpoint 95100 µg/L | TER | tox endpoint 25000 µg/L | | tox endpoint 100000 µg/L | TER |
| pome fruit | 0.8851 | 16947 | 4.2062 | 4517 | 1.1775 | 80764 | 0.5461 | 45779.16133 | 1.9288 | 51846 |
| potatoes | 0.1871 | 80171 | 1.7125 | 11095 | 0.2133 | 445851 | 0.5461 | 45779.16133 | 0.3214 | 311139 |
| tomatoes | 0.0091 | 1648352 | 0.0354 | 536723 | 0.013 | 7315385 | n.a. | | 0.0214 | 4672897 |

Effects on bees (Regulation (EU) N° 283/2013. Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

| Species | Test substance | Time scale/type of endpoint | End point | toxicity |
|--------------------------|------------------------|---|--------------------------------------|--|
| <i>Bombus terrestris</i> | preparation EXP 60707A | Acute | Contact toxicity (LD ₅₀) | >100 µg a.s./bee |
| <i>Apis mellifera</i> | preparation EXP 60707A | Acute | Oral toxicity (LD ₅₀) | 8.85 µg a.s./bee |
| <i>Apis mellifera</i> | preparation EXP 60707A | Acute | Contact toxicity (LD ₅₀) | 9.26 µg a.s./bee |
| <i>Apis mellifera</i> | a.s. | Chronic | 10 d-LC50 | 11.7 µg a.s./bee/day |
| <i>Apis mellifera</i> | a.s. | Bee brood development | EC10larvae | 1.3 µg/larva/developmental period (total dose over 6 days feeding) |
| | a.s. | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | not available |

Semi-field test (Cage and tunnel test)

Five acceptable semi-field studies. Application during full flowering and bee flight at 1x 100-120 g a.s./ha, one study had an additional application one week before introduction of the bees. Generally, transient reduced foraging activity was seen. No increased mortality. No clear brood effects. Details per study are shown below:

Due to concerns identified regarding the robustness and reliability of the semi-field and field studies, they could not be used to draw any conclusion, and in particular to exclude potential chronic effects and effects on the brood development.

| Species | Test substance | Nature of the study | Results |
|-----------------------|-------------------------------|--|--|
| <i>Apis mellifera</i> | Acetamiprid 20 SG | Spray during bee flight on full-flowering Phacelia crop, preceded by one spraying event 8 days earlier. Test rate 2x and 100 g a.s./ha. Location: S-DE | No effects on bee mortality, number of bees, behaviour and brood development. Reduction of flight intensity on DALA0-7 (statistically significant at DALA0 and DALA1 and in overall period 0-7). |
| <i>Apis mellifera</i> | Acetamiprid 20 SP | Spray during bee flight on full-flowering Phacelia crop. Test rate 1x 120 g a.s./ha. Location: S-DE | No effects on number of bees and behaviour (evaluated for 8 days after the last treatment). Reduction of flight intensity on DAA0-5 (not statistically analysed). Results for mortality cannot be evaluated due to unexplained effects in one colony. Results for brood are inconclusive due to the short study duration. |
| <i>Apis mellifera</i> | Acetamiprid 20 SP | Spray during bee flight on full-flowering Phacelia crop. Test rate 1x 100 g a.s./ha. Location: S-DE | No effects on bee mortality and behaviour. Reduction of flight intensity on DAA0 (statistically significant). Results for brood are inconclusive due to the short study duration. |
| <i>Apis mellifera</i> | Acetamiprid 20 SP | Spray during bee flight on full-flowering Phacelia crop. Test rate 1x 100 g a.s./ha. Location: N-DE | No effects on bee mortality and behaviour. Reduction of flight intensity on DAA0 (statistically significant). Decrease in brood area cannot be excluded, but results for brood are inconclusive due to the short study duration. |
| <i>Apis mellifera</i> | EXP60707A: Acetamiprid 20% SP | Spray during bee flight on full-flowering Phacelia crop. Test rate 1x 100 g a.s./ha. Location: S-DE | No effects on bee mortality, flight intensity and behaviour. Effect on brood termination rate cannot be excluded. |
| <i>Apis mellifera</i> | Acetamiprid 20 Sg | Spray during bee flight on full-flowering oilseed rape crop. Test rate 1x 50 g a.s./ha (alone or with 175 g prothioconazole/ha or 175 g tebuconazole/ha). Location: S-DE | All treatments: No effects on number of bees and brood development. No effects on flight intensity on DAA0 and 4-7, but not measured on DAA1-3. Some intoxication symptoms on DAA0. Acetamiprid alone or in combination with prothioconazole caused no effects on mortality. Acetamiprid in combination with tebuconazole caused increased mortality on DAA0. |

Field tests

Two acceptable field studies (one on two locations). Application during full flowering and bee flight at 1x 50-75 g a.s./ha. Transient reduced foraging activity in one study. Transient increased mortality. No brood effects. Details per study are shown below:

| Species | Test substance | Nature of the study | Results |
|-----------------------|-------------------|--|--|
| <i>Apis mellifera</i> | Acetamiprid 20 SG | Spray during bee flight on full-flowering oilseed rape crop. Test rate 1x 50 g a.s./ha. Location: S-DE | Increase of mortality on DAA1 cannot be excluded. Clear effect (not statistically analysed) on flight intensity on DAA0 and 1, not measured on DAA3 and 4. No effects on number of bees and brood development. Some intoxication symptoms on DAA0. |
| <i>Apis mellifera</i> | Acetamiprid 20 SG | Spray during bee flight on | Clear increase of mortality on DAA4- |

| | | | |
|-----------------------|-------------------|--|--|
| | | full-flowering oilseed rape crop. Test rate 1x 50 g a.s./ha. Location: N-DE | 7 (not statistically analysed). No apparent effect (not statistically analysed) on flight intensity, but not measured on DAA1 and 2. No effects on number of bees, behaviour and brood development. |
| <i>Apis mellifera</i> | Acetamiprid 20 SG | Spray during bee flight on full-flowering Phacelia crop: test rate 1x 75 g a.s./ha (alone (T1) or with 375 g prothioconazole/ha (T2). Spray after bee flight on full-flowering Phacelia crop: test rate 1x 75 g a.s./ha with 375 g prothioconazole/ha (T3). Location: C-DE | <p>Bee mortality: T1: Sign.increase on DAT1, 3, 4, 6 and 7 and DAT0-7. T2: Sign.increase on DAT1. T3: Sign.increase on DAT3, 4 and 7.</p> <p>Flight intensity: T1: No effect. T2: Sign. decrease on DAA0aa T3: Sign. decrease on DAA4</p> <p>All treatments: No effects on flight intensity, number of bees and brood development. No effects on behaviour apart from two intensively cleaning foragers in T2 one hour after application.</p> <p>Study setup not worst case due to alternative forage (weeds) in surroundings.</p> |

Risk assessment according to European Commission (2002a)

Risk assessment for pome fruit at 2x 75 g a.s./ha

| Species | Test substance | Risk quotient | HQ | Trigger |
|-----------------------|----------------|---------------|------|---------|
| <i>Apis mellifera</i> | preparation | HQoral | 8.47 | 50 |
| <i>Apis mellifera</i> | preparation | HQcontact | 8.10 | 50 |

Risk assessment for potato at 3x 50 g a.s./ha

| Species | Test substance | Risk quotient | HQ | Trigger |
|-----------------------|----------------|---------------|------|---------|
| <i>Apis mellifera</i> | preparation | HQoral | 5.65 | 50 |
| <i>Apis mellifera</i> | preparation | HQcontact | 5.40 | 50 |

Risk assessment for tomato at 2x 100 g a.s./ha (indoor use)

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|-----------------------|----------------|---------------|--------|---------|
| <i>Apis mellifera</i> | preparation | HQoral | 11.3 | 50 |
| <i>Apis mellifera</i> | preparation | HQcontact | 10.8 | 50 |

Risk Assessment to bees performed by EFSA, according to EFSA (2013)

Risk assessment for potato at 3x 50 g a.s./ha

Contact route of exposure –screening assessment

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|-----------------------|----------------|---------------|--------|---------|
| <i>Apis mellifera</i> | preparation | HQcontact | 5.4 | 42 |
| Bumble bee | preparation | HQcontact | 0.5 | 7 |

Oral route of exposure –tier 1 risk assessment

| category | scenario | BBCH | Honeybee | |
|----------|---------------|---------|----------|---------|
| | | | ETR | trigger |
| acute | treated crop | 40 - 69 | 0.01 | 0.2 |
| acute | treated crop | ≥ 70 | 0.00 | 0.2 |
| acute | weeds | 40 - 69 | 0.01 | 0.2 |
| acute | weeds | ≥ 70 | 0.01 | 0.2 |
| acute | field margin | 40 - 69 | 0.00 | 0.2 |
| acute | field margin | ≥ 70 | 0.00 | 0.2 |
| acute | adjacent crop | 40 - 69 | 0.00 | 0.2 |
| acute | adjacent crop | ≥ 70 | 0.00 | 0.2 |
| acute | next crop | 40 - 69 | 0.00 | 0.2 |
| acute | next crop | ≥ 70 | 0.00 | 0.2 |
| chronic | treated crop | 40 - 69 | 0.00 | 0.03 |
| chronic | treated crop | ≥ 70 | 0.00 | 0.03 |
| chronic | weeds | 40 - 69 | 0.00 | 0.03 |
| chronic | weeds | ≥ 70 | 0.00 | 0.03 |
| chronic | field margin | 40 - 69 | 0.00 | 0.03 |
| chronic | field margin | ≥ 70 | 0.00 | 0.03 |
| chronic | adjacent crop | 40 - 69 | 0.00 | 0.03 |
| chronic | adjacent crop | ≥ 70 | 0.00 | 0.03 |
| chronic | next crop | 40 - 69 | 0.00 | 0.03 |
| chronic | next crop | ≥ 70 | 0.00 | 0.03 |
| larva | treated crop | 40 - 69 | 0.00 | 0.2 |
| larva | treated crop | ≥ 70 | 0.00 | 0.2 |
| larva | weeds | 40 - 69 | 0.02 | 0.2 |
| larva | weeds | ≥ 70 | 0.02 | 0.2 |
| larva | field margin | 40 - 69 | 0.00 | 0.2 |
| larva | field margin | ≥ 70 | 0.00 | 0.2 |
| larva | adjacent crop | 40 - 69 | 0.00 | 0.2 |
| larva | adjacent crop | ≥ 70 | 0.00 | 0.2 |
| larva | next crop | 40 - 69 | 0.01 | 0.2 |
| larva | next crop | ≥ 70 | 0.01 | 0.2 |

Risk assessment for potato at 2x 75 g a.s./ha

Contact route of exposure –screening assessment

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|-----------------------|----------------|---------------|--------|---------|
| <i>Apis mellifera</i> | preparation | HQcontact | 8.1 | 42 |
| Bumble bee | preparation | HQcontact | 0.8 | 7 |

Oral route of exposure –tier 1 risk assessment

| category | scenario | BBCH | Honeybee | |
|----------|---------------|------|----------|---------|
| | | | ETR | trigger |
| acute | treated crop | ≥ 70 | 0.00 | 0.2 |
| acute | weeds | ≥ 70 | 0.01 | 0.2 |
| acute | field margin | ≥ 70 | 0.00 | 0.2 |
| acute | adjacent crop | ≥ 70 | 0.00 | 0.2 |
| acute | next crop | ≥ 70 | 0.01 | 0.2 |
| chronic | treated crop | ≥ 70 | 0.00 | 0.03 |
| chronic | weeds | ≥ 70 | 0.00 | 0.03 |
| chronic | field margin | ≥ 70 | 0.00 | 0.03 |
| chronic | adjacent crop | ≥ 70 | 0.00 | 0.03 |
| chronic | next crop | ≥ 70 | 0.00 | 0.03 |
| larva | treated crop | ≥ 70 | 0.00 | 0.2 |
| larva | weeds | ≥ 70 | 0.03 | 0.2 |
| larva | field margin | ≥ 70 | 0.01 | 0.2 |
| larva | adjacent crop | ≥ 70 | 0.01 | 0.2 |
| larva | next crop | ≥ 70 | 0.02 | 0.2 |

Effects on other arthropod species (Regulation (EU) N° 283/2013. Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species (Tier 1)

| Species | Test Substance | End point | Toxicity |
|----------------------------------|--------------------------|--------------|---------------------------------|
| <i>Typhlodromus pyri</i> | Preparation (EXP 60707A) | Mortality | 100% at 0.09 and 0.18 kg as/ha) |
| <i>Aphidius rhopalosiphi</i> | preparation (EXP 60707A) | Reproduction | No eggs |
| | | Mortality | 100% at 0.2 and 0.4 kg as/ha) |
| | | Reproduction | No fecundity |
| Additional species | | | |
| <i>Coccinella septempunctata</i> | Preparation (EXP 60707A) | Mortality | 100% at 0.09 and 0.18 kg as/ha) |
| <i>Poecilus cupreus</i> | preparation (EXP 60707A) | Reproduction | No fecundity |
| | | Mortality | 3.3% at 0.2 and 0.4 kg as/ha |
| | | Feeding rate | 0.17% |

First tier risk assessment for – all uses: no appropriate first tier risk assessment is possible, because 100% mortality was observed at the lowest tested dose rates.

| Test substance | Species | Effect (LR ₅₀ kg/ha) | HQ in-field | HQ off-field ¹ | Trigger |
|----------------|------------------------------|---------------------------------|-------------|---------------------------|---------|
| EXP 60707A | <i>Typhlodromus pyri</i> | | | | 2 |
| EXP 60707A | <i>Aphidius rhopalosiphi</i> | | | | 2 |

¹indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

| Species | Life stage | Test substance, substrate | Time scale | Dose (kg as/ha) ^{1,2} | End point | % effect ³ | LR ₅₀ |
|----------------------------------|-------------|--|------------|--|---------------------------|--|------------------|
| Extended laboratory tests | | | | | | | |
| <i>Typhlodromus pyri</i> | protonymphs | EXP 60707A, leaves (2-D) | 14 d | 0.01 0.018 0.032 0.057 0.1 | Mortality | 20.5 43.8 34.1 82.6 94.2 | 0.0297 kg as/ha |
| | | | | | Reproduction | No statistically significant effects on the reproductive performance at rates up to 0.032 kg as/ha | |
| <i>Aphidius rhopalosiphi</i> | adult | EXP 60707A, Potted barley plants (3-D) | 48 h | 0.000207 0.000621 0.00186 0.00559 0.0168 | Mortality | 0.0 9.4 53.1 87.5 93.8 | 0.0020 kg as/ha |
| | | | | | Reproduction | No statistically significant effects on the reproductive performance at rates up to 0.00186 kg as/ha | |
| Aged residue tests | | | | | | | |
| <i>Typhlodromus pyri</i> | protonymphs | EXP 60707A, Apple trees (3-D) | 14 d | 0.013 0.1 | Mortality Reproduction | -1.1 (day 0) 6.2 | |
| | | | | | Mortality Reproduction | 39.1 (day 0) n.a. (day 0) -1.1 (day 7) | |
| <i>Aphidius rhopalosiphi</i> | adult | EXP 60707A, Apple trees (3-D) | 21 d | 0.013 0.1 | Mortality Reproduction | 90 (day 0) 10.3 (day 7) n.a. (day 0) 42.4 (day 7) | |
| | | | | | Mortality Reproduction | 70 (day 0) 31.6 (day 14) 54.7 (day 7) 20.7 (day 14) | |
| <i>Coccinella septempunctata</i> | Larvae | EXP 60707A, Apple trees (3-D) | 28 d | 0.013 0.1 | Mortality Reproduction | 42.9 (day 0) n.a. (day 0) -16.4 (day 7) | |
| | | | | | Mortality Reproduction | 95.9 (day 0) 45.8 (day 7) 14.4 (day 28) | |
| <i>Chrysoperla carnea</i> | larvae | EXP 60707A, Apple trees (3-D) | 14 d | 0.013 0.1 | Mortality Reproduction | 2.3 (day 0) 2.4. (day 0) | |
| | | | | | Mortality Reproduction | 16.3 (day 0) 6.6. (day 0) | |

| Species | Life stage | Test substance, substrate | Time scale | Dose (kg as/ha) ^{1,2} | End point | % effect ³ | LR ₅₀ |
|----------------------------------|------------|-------------------------------------|------------|--------------------------------|--|---|------------------|
| Extended laboratory tests | | | | | | | |
| <i>Aphidius rhopalosiphi</i> | adult | Acetamiprid 20SG, Apple trees (3-D) | 56 d | 0.0206 0.170 | Mortality Reproduction Mortality Reproduction | 100 (day 0) 17.2 (day 14) 56.8 (day 14) 17.3 (day 21) 100 (day 0) 26.7 (day 49) 24.6 (day 49) | |
| <i>Coccinella septempunctata</i> | larvae | Acetamiprid 20SG, Apple trees (3-D) | 49 d | 0.0206 0.170 | Mortality Reproduction Mortality Reproduction | 53.1 (day 0) 11.4 (day 14) 0 (day 14) 100 (day 0) 0 (day 42) 0 (day 14) 0 (day 42) | |

¹ indicate whether initial or aged residues

² for preparations indicate whether dose is expressed in units of a.s. or preparation

³ indicate if positive percentages relate to adverse effects or not

Risk assessment for – pome fruit at 75 g a.s./ha x 2 (14 days interval) : based on extended lab test and aged residue tests

| Species | L(E)R ₅₀ (g/ha) | In-field rate | Off-field rate | HQin-field (trigger is 1)* | HQoff-field (trigger is 1)** |
|------------------------------|----------------------------|---------------|----------------|----------------------------|------------------------------|
| <i>Typhlodromus pyri</i> | 29.7 | 128 | 7.73 (2-D) | 4.3 | 0.26 |
| <i>Aphidius rhopalosiphi</i> | 2.0 | 128 | 77.3 (3-D) | 64 | 38.7 |

*the aged residue studies for both indicator organisms showed that potential recovery/recolonisation is possible within an acceptable period; hence, the in-field risk is considered to be acceptable

**the off-field risk for *A. rhopalosiphi* can be reduced to an acceptable level by applying a buffer zone of at least 40 meters. However, this is more than 95% reduction, which is not considered acceptable.

Risk assessment for – potatoes at 50 g a.s./ha x 3 (7 days interval): based on extended lab test and aged residue tests

| Species | L(E)R ₅₀ (g/ha) | In-field rate | Off-field rate | HQin-field (trigger is 1)* | HQoff-field (trigger is 1)** |
|------------------------------|----------------------------|---------------|----------------|----------------------------|------------------------------|
| <i>Typhlodromus pyri</i> | 29.7 | 115 | 1.16 (2-D) | 3.9 | 0.04 |
| <i>Aphidius rhopalosiphi</i> | 2.0 | 115 | 11.6 (3-D) | 57.5 | 5.8 |

*the aged residue studies for both indicator organisms showed that potential recovery/recolonisation is possible within an acceptable period; hence, the in-field risk is considered to be acceptable

**the off-field risk for *A. rhopalosiphi* can be reduced to an acceptable level by applying a buffer zone of at least 10 meters.

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013. Annex Part A, points 8.4. 8.5, and Regulation (EU) N° 284/2013 Annex Part A points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s./ OM1 | Time scale | End point | Toxicity |
|---|-------------------|--------------------------------------|------------|------------------------------------|---|
| Earthworms | | | | | |
| <i>Eisenia foetida</i> | IM-1-5 | Homogenous mixing | Chronic | Growth, reproduction and behaviour | NOEC = 62.5 mg metabolite/kg d.w. soil E/LC ₁₀ = > 62.5 |
| Considering the similar acute toxicity as IM-1-5, the much lower persistence than IM-1-5, and the fact that IM-1-4 is structurally farther removed from the parent acetamiprid, IM-1-4 is not expected to be more toxic to earthworms than metabolite IM-1-5 or the parent acetamiprid. In addition, metabolites IM-1-2 and IC-0 also show similar acute toxicity as IM-1-5 and are less persistent. All of these metabolites are expected to have formed in the field study (discussed below). | | | | | |
| Other soil macroorganisms | | | | | |
| <i>Folsomia candida</i> | Acetamiprid 20 SG | Homogenous mixing; 5% OM | 28 days | Mortality and reproduction | NOEC _{mortality} = 0.49 mg a.s./kg soil d.w. LC ₁₀ = 0.82 mg a.s./kg soil d.w. NOEC _{reproduction} = 0.27 mg a.s./kg soil d.w. EC ₁₀ = 0.47 mg a.s./kg soil d.w. |
| <i>Folsomia candida</i> | IM-1-5 | Homogenous mixing | 28 days | Mortality and reproduction | NOEC _{mortality} = 62.7 mg/kg dw soil No EC values could be calculated as there were no effects below the highest tested value. NOAEC _{reproduction} = 12.5 mg/kd dw soil No EC values were calculated as the data were not appropriate for modelling. |
| <i>Hypoaspis aculeifer</i> | Acetamiprid 20 SG | Homogenous mixing; 5% OM | 14 days | Mortality and reproduction | NOEC _{mortality and reproduction} = 180 mg a.s./kg soil d.w. LC ₅₀ = > 180 mg a.s./kg soil d.w. EC ₁₀ = 50.8 |

¹To indicate whether the test substance was over-sprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies)

An earthworm field study was performed with the formulation Acetamiprid 20 SG. Two applications of 25, 50 and 80 g a.s./ha with a 7 day interval were sprayed onto bare soil in Althen, Germany. 20 plots of 10 x 10m, separated by 2m strips, with 4 replicates, were used. A toxic reference (Nutzdazim 50 Flow, 500 g/L carbendazim nominal) was applied to the reference plot(s) at the same time as the first test substance application (28 April 2009). The temperature during first application was 20-23 °C and in the 3 days after the first application 6 mm rainfall occurred. The temperature during second application was 8-11 °C, and 5.5 mm rainfall occurred in the 3 days post application. Temperatures varied from 8.7 to 17.4 °C and soil moisture was 10.7 – 16.8% during soil sampling. Analytical sampling occurred after application and before irrigation. 5 subsamples of soil were taken per plot, which were pooled to one specimen. The analytical method was acceptable. Earthworm sampling took place 2 weeks before application (14 April 2009), 1 month after first application (1 May 2009), 6 months after first application (12 October 2009) and 1 year after first application (26 April 2010). On each sampling occasion the soil surface was monitored to check for dead earthworms, in two 1m strips in the middle of a plot. 4 sub-plots of 0.25m² per plot were sampled in the middle 6 x 6m of the plots, to a depth of 20 cm per sample.

The results show that none of the acetamiprid treatments cause significant effects (>50%) on total abundance or biomass, as compared to the control. In the middle and high acetamiprid treatments of 50 and 80 g a.s./ha, a decline in abundance and biomass is present at the 1st sampling after application, both when compared to the control and to pre-treatment sampling. This effect is generally <50% as compared to the control and no dose-related differences are seen 6 months and 1 year after treatment. Individual species show occasional significant decreases in biomass at either 1 or 6 months, but the differences are no longer present after 1 year.

Acetamiprid 20 SG at rates up to 80 g a.s./ha did not cause any adverse effects >50% on total earthworm abundance and biomass.

| | | |
|-------------------------|-------------------|---|
| Nitrogen transformation | Acetamiprid 20 SG | <25% effect at day 28 at 0.2 kg a.s./ha |
|-------------------------|-------------------|---|

Toxicity/exposure ratios for soil organisms

Use in pome fruit 75 g a.s./ha x 2 (14 day interval)

| Test organism | Test substance | Time scale | Soil PEC ¹ | TER | Trigger |
|----------------------------------|-------------------|------------|-------------------------------|------|---------|
| Earthworms | | | | | |
| <i>Eisenia foetida</i> | IM-1-5 | Chronic | 0.032 mg/kg soil dw (plateau) | 1953 | 5 |
| Other soil macroorganisms | | | | | |
| <i>Folsomia candida</i> | Acetamiprid 20 SG | Chronic | 0.045 mg/kg soil dw (init) | 6 | 5 |
| <i>Folsomia candida</i> | IM-1-5 | Chronic | 0.032 mg/kg soil dw (plateau) | 391 | 5 |
| <i>Hypoaspis aculeifer</i> | Acetamiprid 20 SG | Chronic | 0.045 mg/kg soil dw (init) | 1129 | 5 |

¹indicate which PEC soil was used (e.g. plateau PEC)

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013. Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER50 tests should be provided

Laboratory dose response tests

| Species | Test substance | ER ₅₀ (g a.s./ha) ² vegetative vigour | ER ₅₀ (g a.s./ha) ² emergence | Exposure ¹ (g/ha) ² | TER ³ | Trigger |
|---|-----------------|--|--|--|------------------|---------|
| Cucumber | Acetamiprid 20G | >500 | 650 | 11.8 | 55.1 | 5 |
| Cabbage, corn, lettuce, oat, onion, perennial ryegrass, soybean, tomato, turnip | Acetamiprid 20G | >500 | >700 | | | |

Extended laboratory studies:

Semi-field and field test:

¹ exposure estimated based on Ganzelmeier drift data for the worst-case use in pome fruit² for preparations indicate whether dose is expressed in units of a.s. or preparation³ Based on most sensitive endpoint and only calculated for most sensitive species**Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)**

| | |
|-----------------------|---|
| Test type/organism | end point |
| Activated sludge | EC ₅₀ > 1000 mg a.s./L (extrapolated 1500 mg a.s./L) |
| <i>Pseudomonas sp</i> | not available |

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

| | |
|---|---------------|
| Available monitoring data concerning adverse effect of the a.s. | Not available |
| Available monitoring data concerning effect of the PPP. | Not available |

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

| | |
|-------------|-------------|
| Compartment | |
| soil | Acetamiprid |
| water | Acetamiprid |
| sediment | Acetamiprid |
| groundwater | Acetamiprid |

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent**Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)**

Substance

acetamiprid

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹³:

Hazard category: Aquatic Acute 1 and Aquatic Chronic 1

Symbol: GHS09;

Signal word: danger

Hazard statement: H400/H410: Very toxic to aquatic life with long lasting effects

M-factor acute: 100

M-factor chronic: 10

Precautionary statement: P391 and P501

Peer review proposal¹⁴ for harmonised classification according to Regulation (EC) No 1272/2008:

Hazard category: Aquatic Acute 1 and Aquatic Chronic 1

Symbol: GHS09;

Signal word: danger

Hazard statement: H400/H410: Very toxic to aquatic life with long lasting effects

Precautionary statement: P391 and P501

¹³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

¹⁴ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Abbreviations

| | |
|-------------------|---|
| 1/ <i>n</i> | slope of Freundlich isotherm |
| λ | wavelength |
| ε | decadic molar extinction coefficient |
| a.s. | active substance |
| AChE | acetylcholinesterase |
| ADE | actual dermal exposure |
| ADI | acceptable daily intake |
| AF | assessment factor |
| AAOEL | acute acceptable operator exposure level |
| AOEL | acceptable operator exposure level |
| AP | alkaline phosphatase |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| AST | aspartate aminotransferase (SGOT) |
| AUC | area under the blood concentration/time curve |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| BUN | blood urea nitrogen |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CFU | colony-forming units |
| ChE | cholinesterase |
| CI | confidence interval |
| CIPAC | Collaborative International Pesticides Analytical Council Limited |
| CL | confidence limits |
| C _{max} | concentration achieved at peak blood level |
| DAA | days after application |
| DAT | days after treatment |
| DDD | daily dietary dose |
| DM | dry matter |
| DT ₅₀ | period required for 50% dissipation (define method of estimation) |
| DT ₉₀ | period required for 90% dissipation (define method of estimation) |
| dw | dry weight |
| EbC ₅₀ | effective concentration (biomass) |
| EC ₅₀ | effective concentration |
| ECHA | European Chemicals Agency |
| EEC | European Economic Community |

| | |
|-----------------------|---|
| EMDI | estimated maximum daily intake |
| ER ₅₀ | emergence rate/effective rate, median |
| ErC ₅₀ | effective concentration (growth rate) |
| ETR | exposure toxicity ratio |
| ETR _{acute} | exposure toxicity ratio for acute exposure |
| ETR _{larvae} | exposure toxicity ratio for chronic exposure |
| ETR _{larvae} | exposure toxicity ratio for larvae |
| ETR _{HPG} | exposure toxicity ratio for effects on honeybee hypopharyngeal glands |
| EU | European Union |
| EUROPOEM | European Predictive Operator Exposure Model |
| f(twa) | Time-weighted average factor |
| FAO | Food and Agriculture Organization of the United Nations |
| FID | flame ionisation detector |
| FIR | food intake rate |
| FOB | functional observation battery |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GCPF | Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP) |
| GGT | gamma glutamyl transferase |
| GM | geometric mean |
| GS | growth stage |
| GSH | glutathione |
| Hb | haemoglobin |
| Hct | haematocrit |
| HPLC | high-pressure liquid chromatography or high-performance liquid chromatography |
| HPLC-MS | high-pressure liquid chromatography–mass spectrometry |
| HPG | hypopharyngeal glands |
| HQ | hazard quotient |
| HQ _{contact} | hazard quotient for contact exposure |
| HR | hazard rate |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| iv | intravenous |

| | |
|-------------------|--|
| JMPR | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| K_{doc} | organic carbon linear adsorption coefficient |
| K_{Foc} | Freundlich organic carbon adsorption coefficient |
| LC | liquid chromatography |
| LC ₅₀ | lethal concentration, median |
| LC-MS | liquid chromatography–mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| LD ₅₀ | lethal dose, median; dosis letalis media |
| LDD ₅₀ | lethal dietary dose; median |
| LDH | lactate dehydrogenase |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| LOQ | limit of quantification |
| M/L | mixing and loading |
| MAF | multiple application factor |
| MCH | mean corpuscular haemoglobin |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular volume |
| mm | millimetre (also used for mean measured concentrations) |
| mN | milli-newton |
| MRL | maximum residue level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| MTD | maximum tolerated dose |
| MWHC | maximum water-holding capacity |
| NESTI | national estimated short-term intake |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| NPD | nitrogen–phosphorus detector |
| OECD | Organisation for Economic Co-operation and Development |
| OM | organic matter content |
| Pa | pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |

| | |
|---------------------|--|
| PEC _{air} | predicted environmental concentration in air |
| PEC _{gw} | predicted environmental concentration in groundwater |
| PEC _{sed} | predicted environmental concentration in sediment |
| PEC _{soil} | predicted environmental concentration in soil |
| PEC _{sw} | predicted environmental concentration in surface water |
| PHED | pesticide handler's exposure data |
| PHI | pre-harvest interval |
| PIE | potential inhalation exposure |
| pK _a | negative logarithm (to the base 10) of the dissociation constant |
| P _{ow} | partition coefficient between <i>n</i> -octanol and water |
| PPE | personal protective equipment |
| ppm | parts per million (10 ⁻⁶) |
| PT | proportion of diet obtained in the treated area |
| PTT | partial thromboplastin time |
| QSAR | quantitative structure–activity relationship |
| r ² | coefficient of determination |
| RPE | respiratory protective equipment |
| RUD | residue per unit dose |
| SC | suspension concentrate |
| SD | standard deviation |
| SFO | single first-order |
| SMILES | simplified molecular-input line-entry system |
| SPG | specific protection goal |
| SSD | species sensitivity distribution |
| STMR | supervised trials median residue |
| t _{1/2} | half-life (define method of estimation) |
| TER | toxicity exposure ratio |
| TER _A | toxicity exposure ratio for acute exposure |
| TER _{LT} | toxicity exposure ratio following chronic exposure |
| TER _{ST} | toxicity exposure ratio following repeated exposure |
| TK | technical concentrate |
| TLV | threshold limit value |
| Tmax | time until peak blood levels achieved |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| TSH | thyroid-stimulating hormone (thyrotropin) |
| TWA | time-weighted average |
| UDS | unscheduled DNA synthesis |

| | |
|-----|---------------------------|
| UF | uncertainty factor |
| UV | ultraviolet |
| W/S | water/sediment |
| w/v | weight per unit volume |
| w/w | weight per unit weight |
| WBC | white blood cell |
| WG | water-dispersible granule |
| WHO | World Health Organization |