Appendix to:
EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate. EFSA Journal 2018;16(10):5454, 115 pp. doi:10.2903/j.efsa.2018.5454
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**Appendix A – List of end points for the active substance and the representative formulation**

**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) | Dimethoate |
|-----------------------------------|------------|
| Function (e.g. fungicide)         | Insecticide|
| Rapporteur Member State           | Italy      |
| Co-rapporteur Member State        | Bulgaria   |

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

| Chemical name (IUPAC) | $O,O$-dimethyl-$S$-methylcarbamoylmethyl phosphorodithioate; $2$-dimethoxyphosphinothioylthio-$N$-methylacetamide |
|-----------------------|---------------------------------------------------------------------------------------------------------------|
| Chemical name (CA)    | $O,O$-dimethyl $S$-[2-(methylamino)-2-oxoethyl] phosphorodithioate                                           |
| CIPAC No              | 59                                                                                                           |
| CAS No                | 60-51-5                                                                                                       |
| EC No (EINECS or ELINCS) | 200-480-3                                                                                       |
| FAO Specification (including year of publication) | $>950$ g/kg FAO specification ($59$/TC, May 2005) Omethoate max 2 g/kg Isodimethoate max 3 g/kg Water max 2 g/kg |
| Minimum purity of the active substance as manufactured | 970 g/kg                                                                                               |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Omethoate max 1 g/kg Isodimethoate max 3 g/kg Open for others |
| Molecular formula     | $C_5H_{12}NO_3PS_2$                                                                                      |
| Molar mass            | 229.3                                                                                                       |
Structural formula

![Structural formula of dimethoate](image)
**Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

| Property                                                        | Value                                                                 |
|----------------------------------------------------------------|----------------------------------------------------------------------|
| Melting point (state purity)                                    | 49.0 to 52.0°C (99.4%)                                               |
| Boiling point (state purity)                                    | No boiling temperature determined. Test substance decomposed at temperatures above 113°C (99.4%) |
| Temperature of decomposition (state purity)                     | 113 ºC (99.4%) with a change in colour from white to pale yellow at 115 ºC |
| Appearance (state purity)                                       | Dimethoate (pure active substances) White solid (99.6%)              |
|                                                                | Dimethoate (Technical material) White, pelletised solid with mercaptanic odour (97-99%) |
| Vapour pressure (state temperature, state purity)              | 2.5 x 10⁻³ Pa at 25°C (99.1%)                                        |
| Henry's law constant (state temperature)                        | 1.52 x 10⁻⁵ Pa m³/mol at 20°C                                        |
| Solubility in water (state temperature, state purity and pH)    | 25.8 g/L at 20°C, pH 5 (99.1%)                                       |
|                                                                | 25.9 g/L at 20°C, pH 7 (99.1%)                                       |
|                                                                | 27.1 g/L at 20°C, pH 9 (99.1%)                                       |
| Solubility in organic solvents (state temperature, state purity)| at 25 ºC (99.5%)                                                   |
|                                                                | aliphatic hydrocarbon:                                               |
|                                                                | n-hexane: 0.295 g/L                                                  |
|                                                                | n-heptane: 0.242 g/L                                                 |
|                                                                | dodecane: 0.430 g/L                                                  |
|                                                                | aromatic hydrocarbon:                                                |
|                                                                | xylene: 313 g/L                                                      |
|                                                                | toluene: 1030 g/L                                                    |
|                                                                | halogenated hydrocarbon:                                             |
|                                                                | 1,2-dichloroethane: 1210 g/L                                        |
|                                                                | dichloromethane: 1500 g/L                                            |
|                                                                | alcohol:                                                            |
|                                                                | methanol: 1590 g/L                                                   |
|                                                                | isopropyl alcohol: 1200 g/L                                          |
|                                                                | 1-octanol: 522 g/L                                                   |
|                                                                | ketone:                                                             |
|                                                                | acetone: 1390 g/L                                                    |
|                                                                | ester:                                                              |
|                                                                | ethyl acetate: 1240 g/L                                              |
|                                                                | others:                                                             |
|                                                                | acetonitrile: 1420 g/L                                               |
|                                                                | cyclohexanone: 1220 g/L                                              |
| Surface tension (state concentration and temperature, state purity) | 2% w/v = 69.5 mN/m at 20°C (98%)                                    |
Partition coefficient (state temperature, pH and purity)

| Substance                                      | Log $P_{ow}$  | State and pH       |
|------------------------------------------------|---------------|--------------------|
| Dimenthoate OECD 107 (Shake flask method)     | 0.75          | 20°C (pH 7) (Purity: 99.1%) |
| Omethoate OECD 117 (Shake flask method)       | -0.9          | 20°C (pH 7) (Purity: 96.3%) |
| O-desmethyl dimethoate (free acid) OECD 117   | < 0           | 20°C (pH 7) (Purity: 94.7%) |
| Dimethoate carboxylic acid (MET-III)          | 1.06          | 25°C               |
| Isodimethoate (MET-IX)                        | -0.14         | 25°C               |
| O-desmethyl omethoate (MET-XI)                | -0.84         | 25°C               |
| O-desmethyl iso-dimethoate (MET-XII)          | -0.20         | 25°C               |
| O,O-dimethyl thiophosphoric acid (MET-XVI)    | 1.11          | 25°C               |
| O,O-dimethyl phosphoric acid (MET-XVII)       | -0.66         | 25°C               |
| O-desmethyl omethoate carboxylic acid (MET-XX)| -0.76         | 25°C               |
| O-desmethyl N-desmethyl omethoate (MET-XXIII) | -1.31         | 25°C               |

**in silico** prediction (EPISuite v 4.11)

Dissociation constant (state purity)

This value was not determined because Dimethoate is not ionized between a pH of 4 and 10. Therefore, the pKa is not of environmental relevance.

UV/VIS absorption (max.) incl. $\varepsilon$ (state purity, pH)

No absorbance maxima observed above 200 nm (99.5%)

| Substance                                      | $\varepsilon$ at 290 nm | State and pH       |
|------------------------------------------------|------------------------|--------------------|
| Dimethoate                                     |                         | Neutral (pH 7): no absorbance |
|                                                |                         | Acidic (pH 0.5): 5405 at 207.5 nm |
|                                                |                         | Basic (pH 13.5): 3175.6 at 226.5 nm |
| Omethoate                                      |                         | Neutral (pH 7): no absorbance |
|                                                |                         | Acidic (pH 0.5): 2401.2 at 207.5 nm |
|                                                |                         | Basic (pH 13.5): 3020.7 at 233.5 nm |
| Isodimethoate                                  |                         | Neutral (pH 7): no absorbance |
|                                                |                         | Acidic (pH 0.5): 3404.3 at 207.5 nm |
|                                                |                         | Basic (pH 13.5): 5690.4 at 239.0 nm |

Flammability (state purity)

Flammability: Dimethoate melted and did not ignite. It classified as no flammable solids. (Purity: 98.0%)

Auto flammability:

| Substance                                         | State and pH       |
|---------------------------------------------------|--------------------|
| Auto ignition temperature (liquids and gases)      | 350°C at 1009 to 1014 mbar (Purity: 98.0%) |

Explosive properties (state purity)

Not explosive to thermal, mechanical shock or to friction (98%)

Oxidising properties (state purity)

Dimethoate is non oxidising (99.9%)
### Summary of representative uses evaluated, for which all risk assessments needed to be completed Dimethoate (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| 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 |
|---------------------------|-------------------------|--------------|--------------|--------------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Sugar beet (Turnip, Beetroot) | SE, CE, NE | CHA 3621-04 | F | Aphids (Aphids fabae - APHIFA) | EC | 400 g/L | Spraying >BBCH 30 | 1 | NA | 0.1 | 200 | 0.20 | 28 |
| Sugar beet (Turnip, Beetroot) | SE, CE, NE | CHA 3621-04 | F | Leaf miner (Pegomya hyoscyami – PEGOHY) | EC | 400 g/L | Spraying >BBCH 30 | 1 | NA | 0.06 | 200 | 0.12 | 28 |
| Wheat (TRZAX) (Rye, Triticale, Durum wheat) | SE, CE, NE | CHA 3621-04 | F | Leaf & Ear aphids (Sitobion avenae, Rhopalosiphum padi and Metopolophium dirhodum) | EC | 400 g/L | Spraying BBCH: 30-69 | 1 | nr | 0.1 | 200 | 0.2 | nr |

(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 pesticides

(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
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) No 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 (k-h) | range of growth stages & season (l) | 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) |

(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. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. bentiavalcarb-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)

Dimethoate is an insecticide belonging to the organophosphate group, which acts by inhibition of the enzyme Acetylcholinesterase (AChE), IRAC group 1B. Dimethoate's mode of action and combined systemic and contact action allow it to be used on a wide range of crops to control a number of key pests.

The plant protection product, Dimethoate 400 g/L EC (CHA 3621-04), containing the active substance dimethoate, is registered in EU members States as described in the GAP. It has been tested in a large number of field development trials which demonstrate efficacious activity.

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

No adverse effects on field crops are expected when dimethoate is used in accordance with the GAP.

The plant protection product, Dimethoate 400 g/L EC (CHA 3621-04), containing the active substance dimethoate, is registered in EU members States as described in the GAP. It has been tested in a large number of field development trials which demonstrate excellent crop safety and no unintended effects on yield and quality of the crops.

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

No undesirable or unintended side-effects have been observed on succeeding or adjacent crops when using the plant protection product, Dimethoate 400 g/L EC (CHA 3621-04), containing the active substance dimethoate when used in accordance with the GAP.

Significant toxicity of dimethoate is observed on aquatic organisms, bees and terrestrial non-target arthropods other than bees. Mitigation measures to limit the exposure are therefore necessary.

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

No metabolites of dimethoate requires screening for biological activity to address risk assessment groundwater.
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)

| Analytical methods for the active substance (analytical technique) | GC/FID method evaluated under first inclusion in Annex I. HPLC/DAD method – Dissolution in acetonitrile. Analysis performed by HPLC/DAD at 210 nm. CIPAC method 59/TC/M3 - HPLC/UV using a reversed phase column C8 at 210 nm with external calibration. |
|---|---|
| Impurities in technical a.s. (analytical technique) | Omethoate and Isodimethoate after extraction with acetonitrile determined by HPLC/UV at 210 nm with external standard quantification. |
| Plant protection product (analytical technique) | HPLC/DAD method – Dissolution in acetonitrile. Analysis performed by HPLC/DAD at 210 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

| Matrices | Residue definitions for monitoring purposes |
|---|---|
| Food of plant origin | Dimethoate and Omethoate, to be considered separately (provisional) |
| Food of animal origin | Dimethoate and Omethoate, to be considered separately (provisional) |
| Soil | Dimethoate and Omethoate (to be considered separately) |
| Sediment | Dimethoate and Omethoate (to be considered separately) |
| Water | Dimethoate and Omethoate (to be considered separately) |
| Surface drinking/ground | Dimethoate and Omethoate (to be considered separately) |
| Air | Dimethoate and Omethoate (to be considered separately) |
| Body fluids and tissues | Dimethoate, Omethoate, dimethyldithiophosphate (met XV) and dimethoate carboxylic acid (met III) |

Monitoring/Enforcement methods

| Matrices | Separation/Quantitation: QuEChERS MRM and HPLC/MS/MS LOQ: 0.01 mg/kg wheat and olive Dimethoate, Omethoate LOQ: 0.01 mg/kg for sugar beet and lettuce Dimethoate and Omethoate LOQ: 0.01 mg/kg for orange Dimethoate and Omethoate |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | QuEChERS multi residue method on bovine milk, bovine fat, liver, kidney, muscle and poultry egg. HPLC/MS/MS - LOQ for dimethoate and omethoate 0.001 mg/kg |
| Soil (analytical technique and LOQ) | Separation/Quantitation: GC/FPD for Dimethoate and Omethoate LOQ = 0.01 mg/kg HPLC-MS/MS for Dimethoate, Omethoate LOQ: 0.01 mg/kg HPLC-MS/MS for Omethoate LOQ: 0.005 mg/kg |
### Water (analytical technique and LOQ)

| Technique and LOQ                                                                 |
|----------------------------------------------------------------------------------|
| Tap water and surface water HPLC/MS/MS, LOQ for dimethoate and omethoate 0.05 µg/L |
| Drinking water GC/MS for Dimethoate and Omethoate LOQ: 0.05 µg/L (ILV available). |

### Air (analytical technique and LOQ)

| Technique and LOQ |
|-------------------|
| GC-FPD LOQ for dimethoate and omethoate 0.01 µg/m³ |

### Body fluids and tissues (analytical technique and LOQ)

| Technique and LOQ                                                                 |
|----------------------------------------------------------------------------------|
| Separation/Quantitation: QuECHERS MRM and HPLC/MS/MS for dimethoate, omethoate and dimethoate carboxylic acid (Met III) |
| LOQ: 0.01 mg/L                                                                 |
| Data gap: for dimethyldithiophosphate (Met XV)                                    |

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

**Substance**

**Dimethoate**

**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]:**

- **Pictogram:** GHS02, GHS07, GHS09
- **Signal word:** Warning

- Self-reactive substance Type F (H242)
- Acute oral toxicity Category 3 (H301) **
- Acute dermal toxicity: Category 4 (H312) *
- Acute inhalation toxicity: Category 4 (H332)
- Serious eye irritation: Cat 2 (H319)
- Hazards to the aquatic environment, chronic: Category 1 (H410)

**Hazard Statement:**

- H242: Heating may cause a fire.
- H301: Toxic if swallowed
- H312: Harmful in contact with skin.
- H319: Causes serious eye irritation.
- H332: Harmful if inhaled.
- H410: Very toxic to aquatic life with long lasting effects.

**Supplementary hazard statement:**

- EUH401: To avoid risks to human health and the environment, comply with the instructions of use.

**Precautionary statement:**

- P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261: Avoid breathing vapours.
- P264: Wash hands thoroughly after handling.
- P280: Wear protective gloves, protective clothing and eye protection.
- P312: Call a POISON CENTER or doctor/physician if you feel unwell.
- P501: Dispose of contents/container as hazardous waste.

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

Harmonised classification available, see above.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
## Impact on Human and Animal Health

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

| Rate and extent of oral absorption/systemic bioavailability | Rapidly and extensively absorbed, approx. 90% based on urine excretion (80-90%) within 24 hours |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | No differences among concentrations and gender.                                           |
| Dose level (mg/kg bw):                                     | 0.5 10 100                                                                                |
| Cmax (mg equiv./L)                                         | ≈1 1 50-93                                                                                 |
| Tmax (h)                                                   | 0.7-1 0.5-1 0.25-0.5                                                                       |
| T½ (h)                                                     | 22-27 42-59 13-15                                                                          |
| AUC (mg eq. h.L)                                           | 4-5 ≈49 417-687                                                                           |

### Distribution

Widely and evenly distributed, highest concentration in the contents of the gastrointestinal tract, liver and kidneys. Higher levels of radioactivity were observed in the Harderian and intra- and exorbital lachrymal glands and also possibly the preputial gland.

### Potential for bioaccumulation

No evidence for accumulation

### Rate and extent of excretion

Rapidly excreted (80 - 90% in urine within 24h)

### Metabolism in animals

Extensive: unchanged dimethoate in urine accounted for 0.4-2% of the administered dose by oral or intravenous dosing Cleavage to dimethoate carboxylic acid (metabolite III) as major metabolite with dimethyldithiophosphate (metabolite XV); oxidation to omethoate (~5%), at least other 4 metabolites were identified, none of them conjugates. There were no qualitative differences in the metabolic profiles between routes of administration, dose levels, or between genders.

### In vitro metabolism

Dimethoate underwent in vitro moderate metabolism in microsomes (10-30%, in different species). The ranking: dog (33%) > mouse (30%) > rat (24%) > human (11%) could be strongly affected by different P450 content. No attempt to identify the metabolites was carried out, but the same phase I metabolites were identified in all the species. A study of human in-vivo urinary metabolites can be supportive of a similar metabolite profile between human and experimental animal species.

### Toxicologically relevant compounds (animals and plants)

Dimethoate, omethoate

### Toxicologically relevant compounds (environment)

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

|                          | Description                                                                 | Category |
|--------------------------|-----------------------------------------------------------------------------|----------|
| Rat LD₅₀ oral            | 245 mg/kg bw (rat)                                                          | H301     |
|                          | 160 mg/kg bw (mouse)                                                        | Cat 3    |
| Rat LD₅₀ dermal          | > 2000 mg/kg bw                                                             |          |
| Rat LC₅₀ inhalation      | 1.68 mg/L air (4 hours, whole body); study with a manufacturing concentrate  | H332     |
|                          |                                                                             | Cat 4    |
| Skin irritation          | Not irritating                                                               |          |
| Eye irritation           | Irritant                                                                    | H319     |
|                          |                                                                             | Cat 2    |
| Skin sensitisation       | Non sensitizing (Buehler test 3-inductions and Maximization test M&K)         |          |
| Phototoxicity            | No data – data not required                                                  |          |

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

| Target organ / critical effect | Description                                                                 |
|-------------------------------|-----------------------------------------------------------------------------|
| Inhibition of erythrocyte and brain cholinesterase activity in rats and dogs after oral and dermal exposure |

| Relevant oral NOAEL           | 1-year, dog: 0.18 mg/kg bw per day                                          |
|                              | 28-day, rat, supported by other studies: 0.5 mg/kg bw per day               |
|                              | 2-year, rat (90-day interim sacrifice): 0.06 mg/kg bw per day              |

| Relevant dermal NOAEL        | 21-day, rabbit: 1000 mg/kg bw per day                                      |
|                              | 28-day rat: 31.5 mg/kg bw per day (data available on a formulation- containing 40% a.i.) |

| Relevant inhalation NOAEL    | No data - not required                                                   |

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

#### In vitro studies

The submitted studies provide some evidence for dimethoate being weakly genotoxic in bacterial and mammalian cells in vitro assays.

- Ames test: 2 strains positive
- Mammalian cell mutation (CHO/HGPRT): positive at high dose levels
- UDS in rat hepatocytes: positive
- Comet assay in human lymphocyte: positive at the 2 high dose levels
- Induction of micronuclei in HepG2 cell line: positive at the 2 high dose levels

#### In vivo studies

No adequate in vivo follow up was submitted to contravene the positive genotoxicity results in vitro.

Negative results were obtained in
Peer review of the pesticide risk assessment of the active substance dimethoate

| Chromosomal aberration submitted studies in vivo. Exposure of target tissues indirectly estimated by systemic toxicity and ADME studies. |
| --- |
| Photomutagenicity |
| Not required |
| Potential for genotoxicity |
| Dimethoate genotoxicity in vivo cannot be excluded. No potential for chromosomal aberration in vivo. |

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

| Long-term effects (target organ/critical effect) | Inhibition of erythrocyte and brain cholinesterase activity in rats and mice |
| --- | --- |
| Relevant long-term NOAEL | 0.04 mg/kg bw per day (rat, 2-year study) LOAEL: 3.6 mg/kg bw per day (mouse, 18-month study) |
| Carcinogenicity (target organ, tumour type) | brain (granular cell tumours) in rats No carcinogenic effects observed in mice |
| Relevant NOAEL for carcinogenicity | Evidence for carcinogenicity is weak but cannot be excluded in rats No evidence of carcinogenicity in mice |

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

**Reproduction toxicity**

| Reproduction target / critical effect | Rat: Parental toxicity: inhibition of RBC and brain AChE activity. Reproductive toxicity: reduced pregnancy rate; at higher dose levels: weight and histopathological findings in male reproductive organs (prostate and epididymides) Offspring’s toxicity: reduced bw gain, increase in peri-natal mortality Mice: Reproductive toxicity: effect on fertility, reproductive performance and sperm parameters where substantial AChE inhibition was observed. |
| --- | --- |
| Relevant parental NOAEL | Rat: 0.08 mg/kg bw per day |
| Relevant reproductive NOAEL | Rat: 0.08 mg/kg bw per day Mouse: 7 mg/kg bw per day |
| Relevant offspring NOAEL | Rat: 1 mg/kg bw per day |
### Developmental toxicity

**Developmental target / critical effect**

| Species | Maternal toxicity | Developmental toxicity |
|---------|-------------------|------------------------|
| Rat:    | cholinergic clinical signs and AChE inhibition | skeletal abnormalities (malformations) |
| Rabbit: | reduced body weight gain | no adverse effects |

**Relevant maternal NOAEL**

| Species | NOAEL (mg/kg bw per day) |
|---------|-------------------------|
| Rat     | 7                      |
| Rabbit  | 10                     |

**Relevant developmental NOAEL**

| Species | NOAEL (mg/kg bw per day) |
|---------|-------------------------|
| Rat     | 7                      |
| Rabbit  | 40 (the highest dose tested) |

---

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

**Acute neurotoxicity**

Neurotoxic signs indicative of cholinesterase inhibition. No histopathological changes to nervous tissue.

**Acute neurotoxicity (rats, diet) NOAEL:** 1 mg/kg bw, based on RBC AChE inhibition

**Repeated neurotoxicity**

90-day dietary neurotoxicity study:

- Signs of cholinesterase inhibition. No impact on functional observation parameters, or evidence of neuropathology to tissues examined histopathologically.
- NOAEL: 0.06 mg/kg bw per day, based on RBC AChE inhibition.

**Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)**

No evidence for delayed neurotoxicity in the hen, although some neuropathology target esterase inhibition was observed.

No evidence for neurotoxicity (other than cholinesterase inhibition) in acute, sub-chronic and developmental neurotoxicity studies in the rat.

**Developmental neurotoxicity study:**

- Maternal NOAEL: 0.5 mg/kg bw per day based on AChE inhibition
- Developmental neurotoxicity NOAEL: 0.1 mg/kg bw per day, based on reduced pup survival

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

**Supplementary studies on the active substance**

No signs of immunotoxicity in a 28-day immunotoxicity study in mice
Endocrine disrupting properties

*In vitro* studies indicate that dimethoate does not bind to ER and AR, is negative in a steroidogenesis assay and is not an aromatase inhibitor. The *in vivo* data package confirmed that dimethoate has no potential to disrupt estrogen and androgen signaling pathway.

An interaction of dimethoate with the thyroid pathway in mammals and wildlife cannot be excluded (due to some no dose dependent effects on thyroid weight in the absence of histopathological alterations in the two generation study, supported by the amphibian metamorphosis assay positive results) (data gap 3)

Studies performed on metabolites or impurities

Omethoate as well as Metabolites III, X, XI, XII, XX and XXIII where found to be present at varying levels in crop metabolism studies.

**A complete data package is available on omethoate (see below for a complete separate LoEP for omethoate).**

Genotoxicity, acetyl-cholinesterase inhibiting potential, general toxicity and reproductive/developmental screening studies performed on the other metabolites demonstrated a lower toxicological potency versus the parent compound.

Metabolite III (Dimethoate Carboxylic Acid):

**Acute oral toxicity:** rat: none at 1000 mg/kg bw

**Repeated toxicity:** 28-day rat-oral: NOAEL 90 mg/kg bw per day (AChE inhibition)

**Genotoxicity:** Unlikely to be genotoxic *in vivo*

- Ames test: negative
- Mammalian cell gene mutation assay: positive after continuous treatment
- In-vitro micronucleus assay: positive after continuous treatment
- In-vivo micronucleus and comet assay (rat): negative

**Reproductive/developmental** study (rat):

- NOAEL parental: 300 mg/kg bw per day (highest dose tested)
- NOAEL reproductive: 300 mg/kg bw per day (highest dose tested)
- NOAEL offspring: 300 mg/kg bw per day (highest dose tested)

**ADI:** 0.09 mg/kg bw per day, based on the NOAEL of 90 mg/kg bw per day from the 28-day study in rats, UF 1000

**ARfD:** not needed

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3 See evaluation table, Section 2, experts' consultation 2.7
Metabolite X (O-Desmethyl dimethoate):

**Acute oral toxicity** rat: LD$_{50}$=337 mg/kg bw. No significant inhibition of brain ChE up to 1000 mg/kg bw

**Genotoxicity:** No genotoxic potential  
Ames test: negative  
Mammalian cell gene mutation assay: negative  
In-vitro micronucleus assay: negative

For repeated toxicity and reproductive toxicity accepted read across with results obtained for Metabolite XI  
**Reference values of metabolite XI are applicable**

Metabolite XI (O-Desmethyl omethoate):

**Acute oral** toxicity rat : none at 1000 mg/kg bw  

**Repeated toxicity** :28-day rat: NOAEL: 100 mg/kg bw per day (general toxicity : reduction in body weight gain and changes in hematology)

**Genotoxicity:** No genotoxic potential  
Ames test: negative  
Mammalian cell gene mutation assay: negative  
In-vitro micronucleus assay: negative

**Reproductive/developmental** study (rat):  
NOAEL parental: 450 mg/kg bw per day,  
NOAEL reproductive: 450 mg/kg bw per day,  
NOAEL offspring: 450 mg/kg bw per day (no effect, highest dose tested)

**ADI:** 0.1 mg/kg bw per day, based on a 28-day study in rats with a NOAEL of 100 mg/kg bw per day for reduced bw gain and haematological changes, applying an UF of 1000.  
**ARfD:** not needed

Metabolite XII (Des-O-methyl isodimethoate):

**Acute oral toxicity** rat : none at 1000 mg/kg bw  

**Repeated toxicity** 28-day rat: LOAEL= 250 mg/kg bw per day (hematological and clinical chemistry alterations)

**Genotoxicity:** No genotoxic potential  
Ames test: negative  
Mammalian cell gene mutation assay: negative  
In-vitro micronucleus assay: negative

**Reproductive/developmental** study (rat):  
NOAEL parental: 15 mg/kg bw per day (based on effects on spleen)  
NOAEL reproductive: 450 mg/kg bw per day (no effect, highest dose tested)  
NOAEL offspring: 450 mg/kg bw per day (no effect, highest dose tested)

**ADI:** 0.015 mg/kg bw per day based on the parental NOAEL of 15 mg/kg bw per day for effects on the spleen (organ weight changes and histopathological findings), 1000 UF applied (reproductive toxicity study)
Metabolite XX (O-Desmethyl omethoate carboxylic acid):

**Acute oral toxicity** rat: LD$_{50}$ >300 mg/kg bw

**Repeated toxicity** 28-day rat: NOAEL 100 mg/kg bw per day (general toxicity)

**Genotoxicity:** No genotoxic potential

- Ames test: negative
- Mammalian cell gene mutation assay: negative
- In-vitro micronucleus assay: negative

**Reproductive/developmental** study (rat):

- NOAEL parental: 100 mg/kg bw per day,
- NOAEL reproductive: 300 mg/kg bw per day,
- NOAEL offspring: 100 mg/kg bw per day

**ADI:** 0.1 mg/kg bw per day, based on the parental and offspring's NOAEL of 100 mg/kg bw per day, also seen in the 28-day toxicity study in rat, UF of 1000 applied.

**ARfD:** not needed.

Metabolite XXIII (O-Desmethyl N-desmethyl Omethoate):

**Acute oral toxicity** rat: no AChE inhibition at 1000 mg/kg bw

**Repeated toxicity** 28-day rat: NOAEL 100 mg/kg bw per day

**Genotoxicity:** No genotoxic potential

- Ames test: negative
- Mammalian cell gene mutation assay: negative
- In-vitro micronucleus assay: negative

**Reproductive/developmental** screening study (rat):

- NOAEL parental: 75 mg/kg bw per day (general toxicity),
- NOAEL reproductive: 450 mg/kg bw per day,
- NOAEL offspring: 450 mg/kg bw per day (no effect; highest dose tested)

**ADI:** 0.075 mg/kg bw per day from the parental NOAEL of 75 mg/kg bw per day, 1000 UF applied

**ARfD:** not needed.

O,O dimethyl phosphoric acid

No toxicological data are available, no cholinesterase activity is expected.

Other Toxicological Studies – Studies on omethoate

Absorption, distribution, metabolism and excretion (toxicokinetics) - omethoate

**Rate and extent of oral absorption/systemic bioavailability**

Rapidly and extensively absorbed, approx 90%, based on urine excretion (90%) within 24 hours (oral and i.v.)
Toxicokinetics parameters

- Plasma concentration peak reached within 40-60 minutes
- AUC and Cmax similar in all groups
- Cmax: 1.1 mg/L
- Tmax: 0.7-1 hours
- Plasma T1/2: 13-15 hours at 10 mg/kg bw;
- Plasma T1/2: 22-28 hours at the low dose (0.5 mg/kg bw)
- AUC: 4-5 (0.5 and 10 mg/kg bw per day)

Distribution

- Widely and evenly distributed, highest concentration in the liver and the thyroid

Potential for bioaccumulation

- No evidence for accumulation. Radioactivity in most organs and tissues (including the GIT) was very low

Rate and extent of excretion

- Rapidly excreted (90% in urine within 24h)

Metabolism in animals

- Moderate: unchanged omethoate in urine accounted for ca 30-40% in iv and oral administration at the low dose, and ca 45-62% of the administered dose at the high dose orally administered.
- The major pathways are: hydrolysis of the thiophosphoric acid structure to yield the desmethylated metabolite (the predominant one) or the sulphur-containing side chain, which is then S-methylated, followed by sulfoxidation to form the sulphinyl metabolite

In vitro metabolism

- Not available.

Toxicologically relevant compounds (animals and plants)

- Omethoate

Toxicologically relevant compounds (environment)

- Omethoate

Acute toxicity - omethoate

| Test | Route | NOAEL | Hazard class |
|------|-------|-------|--------------|
| Rat LD₅₀ oral | 22 mg/kg bw | H300 | cat. 2 |
| Rat LD₅₀ dermal | 145 mg/kg bw | H310 | cat. 2 |
| Rat LC₅₀ inhalation | 0.287 mg/L air (4 hours; nose only) | H330 | cat. 2 |

Skin irritation, Eye irritation and skin sensitization not required for a metabolite

Short-term toxicity - omethoate

| Test | Route | NOAEL | Hazard class |
|------|-------|-------|--------------|
| Relevant oral NOAEL | 28 and 90-day, rat: 0.08 mg/kg bw per day |
| | 1-year, dog: 0.025 mg/kg bw per day |
| Relevant dermal NOAEL | 21-day, rabbit: 2.5 mg/kg bw per day |
### Relevant inhalation NOAEL

| Value   |
|---------|
| No data |

### Genotoxicity - omethoate

#### In vitro studies

- The submitted studies provide some evidence for omethoate being weakly genotoxic in bacterial and mammalian cells in *vitro* assays
- Ames test positive (Strains TA 100 and TA1535)
- Mammalian cell gene mutation mouse lymphoma: negative (+/- S9)
- Mammalian cell gene mutation: positive
- CHO/HGPRT (+/- S9)
- SCE (CHO cells) positive
- UDS (rat hepatocytes) positive

#### In vivo studies

- Negative results were obtained in submitted studies *in vivo* for chromosomal aberration (mouse MN and dominant lethal tests).
- Exposure of target tissues indirectly estimated by systemic toxicity and ADME studies
- Positive results obtained in the only *in vivo* mutagenicity test in line with *in vitro* results (mouse spot test)

Potential for genotoxicity | Omethoate showed genotoxic potential *in vivo*

### Long-term toxicity and carcinogenicity - omethoate

#### Long-term effects (target organ/critical effect)

| Description                                      |
|--------------------------------------------------|
| In rats and mice inhibition of erythrocyte and   |
| brain cholinesterase activity                    |

#### Relevant long-term NOAEL

| Description                                      |
|--------------------------------------------------|
| 0.03 mg/kg bw per day (2-year, rat)              |
| LOAEL: 0.1 mg/kg bw per day (18 month, mouse)    |

#### Carcinogenicity (target organ, tumour type)

| Description |
|-------------|
| No evidence of carcinogenicity in rat and mouse |

#### Relevant NOAEL for carcinogenicity

| Description |
|-------------|
| Rat: 3 mg/kg bw per day (highest dose tested)  |
| Mouse: 6.5 mg/kg bw per day (highest dose tested) |

### Reproductive toxicity - omethoate

#### Reproduction toxicity

| Description |
|-------------|
| Parental toxicity: inhibition of RBC and brain  |
| ACHE activity |
| Reproductive toxicity: reduced mating and fertility |
| Offspring’s toxicity: increased post-natal loss and lower pup weight gain |

#### Relevant parental NOAEL

| Description |
|-------------|
| 0.07 mg/kg bw per day |
### Relevant reproductive NOAEL

0.2 mg/kg bw per day

### Relevant offspring NOAEL

0.2 mg/kg bw per day

### Developmental toxicity - omethoate

**Developmental target / critical effect**

| Rat: Maternal toxicity: clinical signs for AChE inhibition | Rat: Developmental toxicity: reduced foetal weight |
| Rabbit: Maternal toxicity: reduced body weight, AChE inhibition | Rabbit: Developmental toxicity: malformations, reductions in gravid uterine weights, foetal body weights and delayed skeletal ossification |

### Relevant maternal NOAEL

- Rat: 1 mg/kg bw per day
- Rabbit: 0.2 mg/kg bw per day

### Relevant developmental NOAEL

- Rat: 1 mg/kg bw per day
- Rabbit: 0.2 mg/kg bw per day

### Neurotoxicity - omethoate

**Acute neurotoxicity**

Neurotoxic signs indicative of cholinesterase inhibition. No histopathological changes to nervous tissue.

**NOAEL = 0.2 mg/kg bw (rat, AChE inhibition)**

**Repeated neurotoxicity**

No data available

**Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)**

No evidence for delayed neurotoxicity in the hen

Comparative study of cholinesterase inhibition among adults an pups:

- Time to peak effect, rat: adult rats 3 hours, pups (PND 11) 4 hours

Acute dose comparative cholinesterase study, rat: no difference in AChE inhibition in adults and pups (PND 11), BMD ratio 1.07 - 1.32

### Summary - omethoate

**Value (mg/kg bw (per day))**

| Study | Uncertainty factor |
|-------|--------------------|
| Considering that **omethoate** showed genotoxic potential in vivo the setting of reference values is not considered appropriate. | | |

4 See evaluation table, Section 2, open point 2.20
Classification with regard to toxicological data - omethoate

| Substance: | omethoate |
| 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]⁵: | |
| Peer review proposal ⁶ for harmonised classification according to Regulation (EC) No 1272/2008: | |
| CLP00: | |
| Acute Tox. 3*, H301, ‘Toxic if swallowed’ | |
| Acute Tox. 4*, H312, ‘Harmful in contact with skin’ | |
| Acute Tox. 2, H300, ‘Fatal if swallowed’ | |
| Acute Tox. 2, H310, ‘Fatal in contact with skin’ | |
| Acute Tox. 2, H330, ‘Fatal if inhaled’ | |
| Muta. 2, H341, ‘Suspected of causing genetic defects’⁷ | |

Medical data (Regulation (EU) Nº 283/2013, Annex Part A, point 5.9)

| No indication of adverse effects in manufacturing personal | |
| Some reports of intermediate syndrome following dimethoate poisoning. | |
| A human volunteer study identified a NOAEL of 0.202 mg/kg bw per day for cholinesterase inhibition. | |

**Epidemiological studies:** Despite a number of uncertainties in the exposure assessment and differences in study design, multiple investigators have identified associations with neurodevelopmental outcomes (DNT) referred to the OP class in general.

These studies do not allow for a quantitative risk assessment and it is not possible to differentiate exposure to dimethoate from some other OPs (exposure based on common metabolite to OPs). No direct observation on dimethoate is available.

Additional uncertainty factor should apply to the setting of reference values (ARfD, ADI, AOEL and/or AAOEL) taking into account the (indirect) indication by epidemiological studies in case the reference values are based on DNT studies.

**Summary⁸ (Regulation (EU) Nº 1107/2009, Annex II, point 3.1 and 3.6)**

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|---------------------------|-------|-------------------|
| Acceptable Daily Intake (ADI) | Considering that a genotoxic potential of the active | |
| Acute Reference Dose (ARfD) | | |

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⁵ 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.

⁶ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

⁷ See evaluation table, Section 2, experts’ consultation 2.9.

⁸ If available include also reference values for metabolites.
Acceptable Operator Exposure Level (AOEL) | substance cannot be excluded reference values cannot be set.
Acute Acceptable Operator Exposure Level (AAOEL) | 

**Metabolite III (Dimethoate Carboxylic Acid):**

| Acceptable Daily Intake (ADI) | 0.09 | Rat, 28-day study | 1000 |
| Acute Reference Dose (ARfD) | Not established, not required | - | - |

**Metabolite X (O-Desmethyl dimethoate):**

| Acceptable Daily Intake (ADI) | Read-across from metabolite XI |
| Acute Reference Dose (ARfD) | 

**Metabolite XI (O-Desmethyl omethoate):**

| Acceptable Daily Intake (ADI) | 0.1 | Rat, 28-day study | 1000 |
| Acute Reference Dose (ARfD) | Not established, not required | - | - |

**Metabolite XII (Des-O-methyl isodimethoate):**

| Acceptable Daily Intake (ADI) | 0.015 | Rat, reproduction/developmental toxicity screening test | 1000 |
| Acute Reference Dose (ARfD) | Not established, not required | - | - |

**Metabolite XX (O-Desmethyl omethoate carboxylic acid):**

| Acceptable Daily Intake (ADI) | 0.1 | Rat, reproduction/developmental toxicity screening test, supported by the 28-day study | 1000 |
| Acute Reference Dose (ARfD) | Not established, not required | - | - |

**Metabolite XXIII (O-Desmethyl N-desmethyl Omethoate):**

| Acceptable Daily Intake (ADI) | 0.075 mg/kg bw per day | Rat, reproduction/developmental toxicity screening test | 1000 |
| Acute Reference Dose (ARfD) | Not established, not required | - | - |

**Omethoate**
Acceptable Daily Intake (ADI)
Acute Reference Dose (ARfD)
Acceptable Operator Exposure Level (AOEL)
Acute Acceptable Operator Exposure Level (AAOEL)

Considering that dimethoate showed genotoxic potential in vivo the setting of reference values is not considered appropriate.

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

Representative formulation (CHA 3621-04, an EC formulation containing 400 g/L dimethoate)

1.0% (concentrate: 400g/L)
2% (lowest spray dilution: 0.6g/L)

NB: absorption values derived from combined results of human and rat in-vitro and rat in-vivo studies (triple pack approach). The formulation used is the representative formulation.

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

Operators
Workers
Bystanders and residents

A non-dietary exposure risk assessment cannot be conducted since toxicological reference values were not established.

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

Substance:

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]9:

Peer review proposal 10 for harmonised classification according to Regulation (EC) No 1272/2008:

| Substance | Dimethoate |
|-----------|------------|
| Acute Tox. 4 – H302 ‘Harmful if swallowed’ |
| Acute Tox. 4 – H312 ‘Harmful in contact with skin’ |
| Acute Tox. 3 – H301 ‘Toxic if swallowed’ |
| Acute Tox. 4 – H332 ‘Harmful if inhaled’ |
| Eye Irrit. 2 – H319 ‘Causes serious eye irritation’ |
| Repr. 2 - H361d ‘Suspected of damaging the unborn child’ |

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9 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.

10 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
### 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 | Crop(s) | Application(s) | DAT (days) |
|---------------------------------------|-------------|---------|----------------|------------|
| Fruit crops                           | Olives      | Foliar: | 4 x 0.72 kg a.s./ha | -          |
|                                       |             | BBCH 51-69 |                  | 0          |
|                                       |             | BBCH 71-78 |                  | 30         |
|                                       |             | BBCH 73-79 |                  | 15, 29, 43 |
|                                       |             | BBCH 75-89 |                  | 14, 21, 28 |
| Root crops                            | Potatoes    | Foliar: | 2 x 0.34 kg a.s./ha | 14         |
|                                       |             | 1st appl.: | 28 days before harvest | 2, 7, 14, 21, 28 |
|                                       |             | 2nd appl.: | 14 days before harvest | -          |
| Cereals/grass crops                   | Wheat       | Foliar: | 1x0.68 kg a.s./ha | -          |
|                                       |             | BBCH 24  |                  | -          |
|                                       |             | +1x0.4 kg a.s./ha BBCH 69 | -          |

Metabolism studies were conducted using [methoxy-\(^{14}\)C]-dimethoate.

| Rotational crops *(metabolic pattern)* | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| Root/tuber crops                     | Turnip      | 30, 120 | Bare soil application at 0.56 kg a.s./ha (2.8 N rate) |
| Leafy crops                          | Lettuce     | 30, 120 |            |          |
| Cereal (small grain)                 | Wheat       | 30, 120 |            |          |
| Other                                |             |         |            |          |

Rotational crop and primary crop metabolism similar? Metabolism studies were conducted using [methoxy-\(^{14}\)C]-dimethoate. Dimethoate and metabolites observed in primary plant metabolism were not observed in immature or mature lettuce, turnip or wheat commodities. Although identification of residues in rotational crops was not conducted, residue levels are expected to be below 0.01 mg/kg when the primary crops are treated according to the representative uses.

| Processed commodities *(standard hydrolysis study)* | Conditions | Dimethoate | Met. XII | Met. X | Results expressed as % of the applied radioactivity. A specific residue definition for processed commodities is not proposed as based on the ADI values derived respectively for metabolites X and XI (0.1 mg/kg bw per day) and in absence of cholinesterase activity for metabolite XVII, these compounds are of lower toxicity compared to dimethoate toxicological profile. The residue definitions for primary crops are applicable to processed commodities. |
|-----------------------------------------------------|------------|------------|----------|--------|---------------------------------------------------------------|
|                                                     | 20 min, 90°C, pH 4 | 93.3 | 0.3 | 4.7 | [methoxy-\(^{14}\)C]-dimethoate |}
|                                                     | 60 min, 100°C, pH 5 | 66.4 | 0.9 | 28.1 | |
|                                                     | 20 min, 120°C, pH 6 | 29.5 | 5.3 | 59.5 | |

|                                                     | Conditions | Omethoate | Met. XI | Met. XVII | Results expressed as % of the applied radioactivity. A specific residue definition for processed commodities is not proposed as based on the ADI values derived respectively for metabolites X and XI (0.1 mg/kg bw per day) and in absence of cholinesterase activity for metabolite XVII, these compounds are of lower toxicity compared to dimethoate toxicological profile. The residue definitions for primary crops are applicable to processed commodities. |
|-----------------------------------------------------|------------|-----------|---------|-----------|---------------------------------------------------------------|
|                                                     | 20 min, 90°C, pH 4 | 92.9 | 6.3 | 0.2 | [methoxy-\(^{14}\)C]-omethoate |}
|                                                     | 60 min, 100°C, pH 5 | 61.3 | 36.2 | 1.5 | |
|                                                     | 20 min, 120°C, pH 6 | 5.5 | 62.6 | 19.2 | |
### Plant residue definition for monitoring (RD-Mo)

Dimethoate and Omethoate, to be considered separately \(\textit{provisional}\) – Pending finalisation of the assessment of the mutagenic potential of dimethoate and considering that omethoate showed mutagenic potential \(\text{in vivo}\). All categories of crops.

### Plant residue definition for risk assessment (RD-RA)

Dimethoate and Omethoate \(\textit{provisional}\) – Pending finalisation of the assessment of the mutagenic potential of dimethoate and considering that omethoate showed mutagenic potential \(\text{in vivo}\). All categories of crops.

### Conversion factor (monitoring to risk assessment)

Open
Pending finalisation of residue definitions for monitoring and risk assessment.

### 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)

| Animal            | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|-------------------|-------------------|-----------------|----------------|
| Laying hen        | 0.9               | 7               | 100 /poultry layer |
| Goat              | 1.6               | 3               | 94/lamb |
| Pig               | N/A               | N/A             | N/A |
| Fish              | N/A               | N/A             | N/A |

Metabolism studies were conducted using \([\text{methoxy-}^{14}\text{C}]\)-dimethoate.

N/A: Not applicable

Time needed to reach a plateau concentration in milk and eggs (days)

- **Milk** – 3 days
- **Eggs** – 4 days (whites); 6-7 days (yolks)

### Animal residue definition for monitoring (RD-Mo)

Dimethoate and Omethoate, to be considered separately \(\textit{provisional}\) – Pending finalisation of the assessment of the mutagenic potential of dimethoate and considering that omethoate showed mutagenic potential \(\text{in vivo}\).

### Animal residue definition for risk assessment (RD-RA)

Dimethoate and Omethoate \(\textit{provisional}\) – Pending finalisation of the assessment of the mutagenic potential of dimethoate and considering that omethoate showed mutagenic potential \(\text{in vivo}\).

### Conversion factor (monitoring to risk assessment)

Open
Pending finalisation of residue definitions for monitoring and risk assessment.

### Metabolism in rat and ruminant similar (Yes/No)

Yes

### Fat soluble residues (Yes/No)

Yes for dimethoate:
Although Log Pow for dimethoate is <3, it is noted that in the ruminant feeding study, residues of dimethoate were recovered in fat at all dosing levels (0.0014-0.0268 mg eq/kg).

No for omethoate:

Log Pow for omethoate <3

In the ruminant feeding study, quantifiable residues of omethoate in fat (>0.001 mg/kg) were observed at the highest dimethoate dosing level (ca. 135 N) only.
Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study
(Quantitative aspect)

Transfer of residues from soil into crops was limited as for total residue of <0.05 mg/kg in the mature crops at 30 day PBI and ranged between <0.01 mg/kg and 0.02 mg/kg at 120 day PBI. Although further identification of residues in rotational crops was not conducted, residue levels are expected to be below 0.01 mg/kg when the primary crops are treated according to the representative uses.

Field rotational crop study

Not required Dimethoate, omethoate and metabolites exhibited low and very low persistence in soil.

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

| Plant products (Category) | Commodity       | T (°C) | Stability (Months) |
|--------------------------|-----------------|--------|--------------------|
|                          |                 |        | Dimethoate | Omethoate | III | XX | XXIII | XII | XI | X  |
| High water content       | Cherries        | -18    | 6            | 6           |     |     |       |     |     |    |
|                          | Sugar beet leaves | -20   | 12           | 12          | 12  | 0   | 0 wks | 0   | 0   | 0   |
|                          | Wheat whole plant | -20   | 12           | 3           |     |     |       |     |     |    |
|                          | Sorghum forage  | -20    | 6            | 27          | 2   | wks |       |     |     |    |
| High oil content         | Cotton seed     | -20    | 27           | 0           |     |     |       |     |     |    |
|                          | Olives          | -20    | 12           | 12          | 8   | 3   | 5 wks | 3   | 3   | 3   |
| High starch content      | Potatoes        | -20    | 27           | 27          |     |     |       |     |     |    |
|                          | Sorghum grain   | -20    | 27           | 27          |     |     |       |     |     |    |
|                          | Sugar beet root | -20    | 12           | 0           | 12  | 0   | 0 wks | 4   | 1   | 12  |
|                          | Wheat grain     | -20    | 12           | 3           | 0   | wks | 14.5  | 14.5 | 12  |
|                          | Oranges         | -20    | 27           | 27          |     |     |       |     |     |    |
|                          | Wheat straw     | -20    | No data      | No data     | 12  | 14.5| 2 wks | 12  | 0   | 6   |

Wks: weeks
Data gap:
Storage stability data for dimethoate and omethoate residues in cereal straw and covering the maximum storage time period of the samples from the residue trials on wheat.

| Animal | Animal commodity | T (°C) | Stability (Months) |
|--------|------------------|--------|--------------------|
|        |                  |        | Dimethoate | Omethoate |
| Bovine | Muscle           | -18    | 12         | 9         |
| Bovine | Liver            | -18    | 6          | 7 days    |
| Bovine | Kidney           | -18    | 6          | 0         |
| Bovine | Milk             | -18    | 12         | 12        |
### Table

| Category   | Product | MRL  | LOQ  | LOQ/FRD |
|------------|---------|------|------|---------|
| Poultry    | Eggs    | -18  | 12   | 2       |
| Bovine     | Fat     | -18  | 12   | 12      |
## Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

| Crop | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|------|---------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------|----------------|----------------|
|      | (a)           | (b)                                                                                                                                                        |                                                                                   |                      |                |                |
| Wheat grain (extrapolation to rye and triticale grain) | NEU | Dimethoate: $7 \times <0.001$, $0.002$, $8 \times <0.01$ | | D: $0.03$ (provisional) | 0.01 | 0.01 |
| | | Omethoate: $8 \times <0.001$, $8 \times <0.01$ | | O: - No proposal | 0.01 | 0.01 |
| | SEU | Dimethoate: $5 \times <0.001$, $0.002$, $0.005$, $5 \times <0.01$ | | D: $0.03$ (provisional) | 0.01 | 0.01 |
| | | Omethoate: $7 \times <0.001$, $5 \times <0.01$ | | O: - No proposal | 0.01 | 0.01 |
| | NEU+SEU | Dimethoate: $12 \times <0.001$, $2 \times 0.002$, $0.005$, $13 \times <0.01$ | | D: $0.03$ (provisional) | 0.01 | 0.001 |
| | | Omethoate: $15 \times <0.001$, $13 \times <0.01$ | | O: - No proposal | 0.01 | 0.001 |
| Wheat straw (extrapolation to rye and triticale straw) | NEU | Dimethoate: $13 \times <0.01$, $2 \times 0.01$, $0.02$ | Data gap: Storage stability data for dimethoate and omethoate residues in cereal straw and covering the maximum storage time period of the samples from the residue trials on wheat are required. | D: - | 0.02 | 0.01 |
| | | Omethoate: $16 \times <0.01$ | | O: - | 0.01 | 0.01 |
| | SEU | Dimethoate: $3 \times <0.01$, $2 \times 0.02$, $2 \times 0.05$, $0.08$, $0.19$, $0.65$, $0.68$, $0.83$ | | D: - | 0.83 | 0.05 |
| NEU+SEU | Dimethoate: - | According to the Mann-Whitney U-test, NEU and SEU residue populations for dimethoate in wheat straw are not similar. | D: - | - | - |
|---------|----------------|-------------------------------------------------------------------------------------------------|-----|-----|-----|
|         | Omethoate: 23 x <0.01, 0.01, 0.02, 0.04, 0.05, 0.06 |                                                                                               | O: - | 0.06 | 0.01 |
| Sugar beet root (extrapolation to turnips and beetroots) | NEU | Dimethoate: 7 x <0.001 | Data gap: Sufficient residue trials on sugar beet compliant with the NEU GAP and analysing omethoate residues in the roots within 1 month after sampling. | D: 0.01* (provisional) | 0.01 | 0.01 |
|         | Omethoate: No data |                                                                                               | O: - | - | - |
|         | Omethoate: No data |                                                                                               |       |       |       |
|         | Omethoate: No data |                                                                                               |       |       |       |
|         | Omethoate: 10 x <0.001 |                                                                                               | D: 0.01* (provisional) | 0.01 | 0.01 |
|         | Omethoate: No data |                                                                                               | O: - | - | - |
|         | Omethoate: 4 x <0.01, 0.01, 2 x 0.02 |                                                                                               |       |       |       |
|         | Omethoate: 3 x <0.01 |                                                                                               |       |       |       |
|         | Omethoate: 3 x <0.01 |                                                                                               |       |       |       |
| SEU     | Dimethoate: 3 x <0.001 | Data gap: One residue trial on sugar beet compliant with the SEU GAP for the determination of dimethoate residues in roots and tops and leaves. | D: 0.01* (provisional) | 0.01 | 0.01 |
|         | Omethoate: No data |                                                                                               | O: - | - | - |
| Sugar beet tops and leaves (extrapolation to turnips leaves) | NEU | Dimethoate: 7 x <0.01 | Data gap: One residue trial on sugar beet compliant with the SEU GAP for the determination of dimethoate residues in roots and tops and leaves. | D: - | 0.01 | 0.01 |
|         | Omethoate: 4 x <0.01, 0.01, 2 x 0.02 |                                                                                               | O: - | 0.02 | 0.01 |
|         | Omethoate: 3 x <0.01 |                                                                                               |       |       |       |
|         | Omethoate: 3 x <0.01 |                                                                                               |       |       |       |
Summary of the data on formulation equivalence **OECD Guideline 509**

| NEU+SEU | Dimethoate: $10 \times <0.01$ | D: | 0.01 | 0.01 |
|---------|-------------------------------|----|------|------|
|         | Omethoate: $7 \times <0.01, 0.01, 2 \times 0.02$ | O: | 0.02 | 0.01 |

Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Data gap: Data on residue levels of dimethoate and omethoate in pollen and bee products for human consumption as set out in current data requirements in Reg. 283/2013.

(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.* $3 \times <0.01, 0.01, 6 \times 0.02, 0.04, 0.08, 3 \times 0.10, 2 \times 0.15, 0.17$). 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$_{Mo}$).

D: Dimethoate
O: Omethoate
Inputs for animal burden calculations

Risk assessment residue definition: Dimethoate and omethoate (provisional)

The livestock dietary intake calculation cannot be concluded yet pending a final conclusion on the mutagenic potential of dimethoate and considering that omethoate is concluded to be mutagenic in vivo. Currently the livestock dietary burden has to be conducted considering separately the dimethoate and omethoate residues in feed items and is also considered as provisional pending upon the outcome of the identified data gaps.

| Feed commodity      | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) |
|---------------------|-------------------------------|-------------------------------|
| **Representative uses** |
| **Risk assessment residue definition: Dimethoate** |
| **Forage** |
| Sugar beet tops     | 0.01 STMR\(^{(1)}\)           | 0.01 HR\(^{(1)}\)             |
| Rye straw           | 0.05 STMR\(^{(2)}\)           | 0.83 HR\(^{(2)}\)             |
| Triticale straw     | 0.05 STMR\(^{(2)}\)           | 0.83 HR\(^{(2)}\)             |
| Turnip tops         | 0.01 STMR\(^{(1)}\) Extrapolation from sugar beet | 0.01 HR\(^{(1)}\) Extrapolation from sugar beet |
| Wheat straw         | 0.05 STMR\(^{(2)}\)           | 0.83 HR\(^{(2)}\)             |
| **Roots and tubers** |
| Turnip roots        | 0.01 STMR\(^{(1)}\) Extrapolation from sugar beet | 0.01 HR\(^{(1)}\) Extrapolation from sugar beet |
| **Cereal grains**   |
| Rye grain           | 0.01 STMR                     | 0.01 STMR                     |
| Triticale grain     | 0.01 STMR                     | 0.01 STMR                     |
| Wheat grain         | 0.01 STMR                     | 0.01 STMR                     |
| **By-products**     |
| Sugar beet – dried pulp | 0.01\(^{(1)}\) STMR x PF (1) | 0.01\(^{(1)}\) STMR x PF (1) |
| Sugar beet – ensiled pulp | 0.01\(^{(1)}\) STMR x PF (1) | 0.01\(^{(1)}\) STMR x PF (1) |
| Sugar beet - molasses | 0.01\(^{(1)}\) STMR x PF (1) | 0.01\(^{(1)}\) STMR x PF (1) |
| Distiller’s grain   | 0.01                          | 0.01 STMR                     |
| Wheat gluten- meal  | 0.01                          | 0.01 STMR                     |
| Wheat – milled byproducts | 0.01 STMR x PF (1) | 0.01 STMR x PF (1) |

Default PF of 1 was used in case residues in RAC<LOQ.

\(^{(1)}\)Provisional STMR/HR values considering the data gap for one residue trial on sugar beet compliant with the SEU GAP for the determination of dimethoate residues in roots and tops and leaves.

\(^{(2)}\)Data gap identified for storage stability data for dimethoate and omethoate residues in cereal straw and covering the maximum storage time period of the samples from the residue trials on wheat.
| Feed commodity         | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) |
|------------------------|------------------------------|-------------------------------|
|                        | Comment                      | Comment                      |
| **Representative uses**|                              |                               |
| Risk assessment residue definition: Omethoate |                              |                               |
| **Forage**             |                              |                               |
| Sugar beet tops        | 0.01 STMR                    | 0.02 HR                      |
| Rye straw              | 0.01 STMR(2)                 | 0.06 HR(2)                   |
| Triticale straw        | 0.01 STMR(2)                 | 0.06 HR(2)                   |
| Turnip tops            | 0.01 STMR                    | 0.02 HR                      |
|                       | Extrapolation from sugar beet |                               |
| Wheat straw            | 0.01 STMR(2)                 | 0.06 HR(2)                   |
| **Roots and tubers**   |                              |                               |
| Turnip root            | 0.01 STMR(3)                 | 0.01 HR(3)                   |
|                       | Extrapolation from sugar beet |                               |
| **Cereal grains**      |                              |                               |
| Rye grain              | 0.01 STMR                    | 0.01 STMR                    |
| Triticale grain        | 0.01 STMR                    | 0.01 STMR                    |
| Wheat grain            | 0.01 STMR                    | 0.01 STMR                    |
| **By-products**        |                              |                               |
| Sugar beet – dried pulp| 0.01(3) STMR x PF (1)        | 0.01(3) STMR x PF (1)         |
| Sugar beet – ensiled pulp| 0.01(3) STMR x PF (1)        |                               |
| Sugar beet – molasses  | 0.01(3) STMR x PF (1)        |                               |
| Distiller's grain      | 0.01(3) STMR x PF (1)        |                               |
| Wheat gluten- meal     | 0.01(3) STMR x PF (1)        |                               |
| Wheat – milled byproducts| 0.01(3) STMR x PF (1)        |                               |

Default PF of 1 was used in case residues in RAC<LOQ.
(2) Data gap identified for storage stability data for dimethoate and omethoate residues in cereal straw and covering the maximum storage time period of the samples from the residue trials on wheat.
Provisional STMR/HR values considering the data gap for sufficient residue trials on sugar beet compliant respectively with the NEU and SEU GAPs and analysing omethoate residues in the roots within 1 month after sampling.
### 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)

Enforcement residue definition: Dimethoate and omethoate, to be considered separately (Provisional) - Dimethoate

#### MRL calculations

| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | Ruminant | Pig/Swine | Poultry | Fish |
|---------------------------------------------------------|----------|-----------|---------|------|
| Beef cattle                                            | 0.005    |           |         |      |
| Ram/Ewe                                                | 0.013    |           |         |      |
| Breeding                                               | 0.001    |           |         |      |
| Broiler                                                | 0.001    |           |         |      |
| Dairy cattle                                           | 0.009    |           |         |      |
| Lamb                                                    | 0.017    |           |         |      |
| Finishing                                              | 0.001    |           |         |      |
| Layer                                                   | 0.008    |           |         |      |
| Turkey                                                  | 0.001    |           |         |      |
| Intake >0.004 mg/kg bw                                  | Yes      | Yes       | No      | Yes  |
| Feeding study submitted                                 | Yes      | No        | No      | Yes  |
| Fish intake >0.1 mg/kg DM                               |          |           |         | No   |

#### Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates

| Level         | Beef: 6.9 N | Lamb: 2.2N | Breeding: 43.7N | Level | Broiler: 8.3N |
|---------------|-------------|------------|-----------------|-------|---------------|
| 0.037         | 4.2 N       | 2.7N       | 36.8 N          | 0.01  | 1.3 N         |

#### MRL proposals

| Muscle        | 0.001       | 0.001*     | 0.001           | 0.001* | 0.001*        |
|---------------|-------------|------------|-----------------|--------|---------------|
| Fat           | 0.006       | 0.007      | 0.012           | 0.015  | 0.001         |
| Meat(b)       | -           | -          | -               | -      | -             |
| Liver         | 0.001       | 0.001*     | 0.001           | 0.001* | 0.001*        |
| Kidney        | 0.001       | 0.001*     | 0.001           | 0.001* | -             |
| Milk(a)       | 0.001       | 0.001*     | 0.001           | 0.001* | -             |
| Eggs          | -           | -          | -               | -      | 0.001         |
| Method of calculation(c) | - | - | - | - | - |

Table presented for sum of dimethoate and omethoate calculated using MW CF 1.08 for omethoate

1 HR based on dietary burden for dairy, 2 HR based on dietary burden for lamb

*Values based on total fat residues observed in perirenal, subcutaneous and omental fat, dimethoate only seen in 1 sample of perirenal fat with all other dimethoate residues in fat <0.005 mg/kg, no dose relationship observed, omethoate <0.001 mg/kg

(a): Estimated HR calculated at 1N level estimated mean level for milk.
**Peer review of the pesticide risk assessment of the active substance diemthoate**

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**STMR calculations**

| Enforcement residue definition: Dimethoate and omethoate, to be considered separately (Provisional) - Dimethoate |
|---|
| **Median expected intake** |
| (mg/kg bw/d) | Beef cattle | 0.0011 | Ram/Ewe | 0.0017 | Breeding | 0.001 | Broiler | 0.001 | Carp |
| (mg/kg DM for fish) | Dairy cattle | 0.0021 | Lamb | 0.0021 | Finishing | 0.001 | Layer | 0.002 | Trout |
| **Representative feeding level** (mg/kg bw/d, mg/kg DM for fish) and N rates |
| Level: 0.037 | Beef: 33.6N Dairy: 17.6N | Level: 0.037 | Lamb: 17.6N Ewe: 21.7N | Level: 0.037 | Breed/Finish 37N | Level: 0.01 | B or T: 10 N Layer: 5 N | Level: n.a. | N rate Carp/Trou: n.a. |
| **Mean level in feeding level** | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N | Estimated STMR (b) at 1N |
| Muscle | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | n.a. | n.a. |
| Fat | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | n.a. | n.a. |
| Meat (a) | - | - | - | - | - | - | - | - | - |
| Liver | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Kidney | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Milk | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Eggs | - | - | - | - | - | - | - | - | - |
| **Method of calculation** (c) | Tf | Tf | Tf | Tf | Not applicable |

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(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 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.
Residues from livestock feeding studies (Regulation (EU) No 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

Enforcement residue definition: Dimethoate and omethoate, to be considered separately (Provisional) – Omethoate

Data gap: Ruminant and poultry feeding studies conducted with omethoate or with simultaneous administration of dimethoate and omethoate at a ratio representative of the ratio of both substances in feed items and analysing dimethoate and omethoate residues.

### MRL calculations

|             | Ruminant | Pig/Swine | Poultry | Fish |
|-------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) | Beef cattle 0.001 | Ram/Ewe 0.002 | Breeding 0.001 | Broiler 0.001 |
|             | Dairy cattle 0.003 | Lamb 0.002 | Finishing 0.001 | Layer 0.002 |
| Intake >0.004 mg/kg bw | No | No | No | No |
| Feeding study submitted | No | No | No | No |

### 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 | Breeding: Finishing: | Level | Broiler: N | Layer: N | Level | N rate | Carp/Troun |
|----------------|-------|---------|----------|-------|---------|--------|-------|----------------------|-------|-------------|-----------|-------|---------|------------|
| Estimatted HR(a) at 1N² | 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 | Estimated HR(a) at 1N | MRL proposals | Estimated HR(a) at 1N | MRL proposals |
| Muscle         | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Fat            | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Meat(b)        | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Liver          | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Kidney         | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Milk(a)        | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Eggs           | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |
| Method of calculation(c) | -     | -       | -        | -     | -       | -      | -     | -                    | -     | -           | -         | -     | -       | -          |

Table presented for sum of dimethoate and omethoate calculated using MW CF 1.08 for omethoate

¹ HR based on dietary burden for dairy; ² HR based on dietary burden for lamb

*Values based on total fat residues observed in perirenal, subcutaneous and omental fat, dimethoate only seen in 1 sample of perirenal fat with all other dimethoate residues in fat <0.005 mg/kg, no dose relationship observed, omethoate <0.001 mg/kg

(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

| Enforcement residue definition: Dimethoate and omethoate, to be considered separately *(Provisional) - Omethoate* |
|---------------------------------------------------------------|
| **Median expected intake**                                    |
| (mg/kg bw/d)                                                  |
| (mg/kg DM for fish)                                           |
| Beef cattle                                                  | 0.0011 | Ram/Ewe | 0.0013 | Breeding | 0.001 | Broiler | 0.001 | Carp |
| Dairy cattle                                                 | 0.0021 | Lamb    | 0.0016 | Finishing| 0.001 | Layer   | 0.002 | Trout|
|                                                           |        |         |        |          |       |         |       |       |
| **Representative feeding level**                             |
| (mg/kg bw/d, mg/kg DM for fish) and N rates                   |
| Level                                                        | Beef: N | Level   | Lamb: N | Level   | Breed/Finish | Level | B or T: N | Layer: N | Level: n.a. | N rate |
| Level: Beef: N                                              | Dairy: N | Level: Lamb: N | Ewe: N | Level: Breed/Finish | N | Level: B or T: N | Layer: N | Level: n.a. | N rate |
| 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                                                      |         | Fat    |         |         |         |         |         |         |         |         |
| Meat *(a)*                                                  |         | Liver  |         |         |         |         |         |         |         |         |
| Kidney                                                      |         | Milk   |         |         |         |         |         |         |         |         |
| Eggs                                                       |         |        |         |         |         |         |         |         |         |         |
| Method of calculation *(c)*                                  | Tf      | Tf     | Tf      | Tf      | Not applicable |

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*(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.
Conversion Factors (CF) for monitoring to risk assessment

Open - Definitive plant residue definitions for monitoring and risk assessment for plant and animal matrices could not be concluded on as a mutagenic potential could not be ruled out for dimethoate and omethoate showed mutagenic potential in vivo.

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

| Crop / processed crop | Number of studies | Mean processing factor |
|-----------------------|-------------------|------------------------|
|                       |                   | Dimethoate | Omethoate |
| Wheat - White flour   | 4                 | 0.09       | 0.18      |
| Wheat - Bran          | 4                 | 2.03       | 1.40      |
| Wheat - Type 550 flour| 4                 | 0.08       | 0.18      |
| Wheat - Wholemeal bread| 4              | 0.85       | 0.63      |

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).

Dimethoate

Since a mutagenic potential could not be excluded for dimethoate, no toxicological reference values could be established.

ADI

TMDI according to EFSA PRIMo - Open
NTMDI, according to (to be specified) - Open
IEDI (% ADI), according to EFSA PRIMo - Open
NEDI (% ADI), according to (to be specified) - Open
Factors included in the calculations - Open

ARfD

IESTI (% ARfD), according to EFSA PRIMo - Open
NESTI (% ARfD), according to (to be specified) - Open
Factors included in IESTI and NESTI - Open

Omethoate

Considering that omethoate is concluded to be mutagen in vivo the setting of reference values is not considered appropriate.

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 (to be specified)

Factors included in IESTI and NESTI

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

Metabolite(s)
Not relevant

ADI (mg/kg bw per day)
- 

Intake of groundwater metabolites (% ADI)
- 

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

The safety of the derived MRLs for dimethoate in products of plant and animal origin can only be concluded once the assessment of the mutagenic potential of dimethoate and the risk assessment residue definitions in plant and animal matrices are finalised. The proposed MRLs for dimethoate have therefore to be considered provisional. As omethoate is concluded to be mutagenic in vivo, the setting of reference values is not considered appropriate and MRLs cannot be derived for this compound for plant and animal commodities.

| Code   | Commodity/Group                  | MRL/Import tolerance (mg/kg) and Comments |
|--------|----------------------------------|-----------------------------------------|
| 500090 | Wheat (triticale)                | 0.03 Provisional                         |
| 500070 | Rye                             | 0.03 Provisional                         |
| 900010 | Sugar beet                       | 0.01* Provisional                       |
| 213010 | Beetroot                        | 0.01* Provisional                       |
| 213110 | Turnips                          | 0.01* Provisional                       |

### Plant commodities - Omethoate

No MRL proposals

### Animal commodities - Dimethoate

| Code                     | Commodity/Group                                          | MRL/Import tolerance (mg/kg) and Comments |
|--------------------------|----------------------------------------------------------|-----------------------------------------|
| 1010000 except 1012020/1| Commodities of terrestrial Animals, except sheep, goat, bovine, equine fat tissues | 0.001* Provisional                      |
| 1012020/1013020/1014020/1015020 | Bovine, equine fat tissues                             | 0.007                                   |
| 1013020/1014020         | Sheep/goat – fat tissue                                 | 0.015                                   |
| 1020000                  | Milk                                                    | 0.001*                                   |
| 1030000                  | Birds eggs                                              | 0.001*                                   |

### Animal commodities - Omethoate

No MRL proposals for omethoate

(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.
# 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 | Non-extractable residues after 100 days | Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) |
|---------------------------|-------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------|
|                           | 53.3% after 21 d, 20 °C (n\(^{11}\)=1) [\(^{14}\)C-carbonyl]-label | 42.4% after 21 d, 20 °C (n=1) [\(^{14}\)C-carbonyl]-label | No metabolites requiring further consideration
|                           |                               |                                        | O-Desmethyl dimethoate (MET X); max. 4.3% at 2 d (n=1)                                        |
|                           |                               |                                        | Omethoate (MET II); not detected                                                             |
|                           |                               |                                        | Note: Omethoate found at max. 15.4% in bare ground field study in California                 |

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

|                           | Mineralisation after 100 days | Non-extractable residues after 100 days | Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) |
|---------------------------|-------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------|
|                           | 41.0% after 62 d, 25 °C (n=1) [\(^{14}\)C-dimethoate]-label | 2.0% after 62 d, 25 °C (n=1) [\(^{14}\)C-dimethoate]-label | O-Desmethyl dimethoate (MET X); max. 9.6% at 16 d (n=1) [\(^{14}\)C-dimethoate]-label |

## 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) |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------|
|                           | O,O-Dimethyl thiophosphoric acid (MET XVI); max. 58.9% at 20 d in dark controls (n=1), [\(^{14}\)C-dimethoate]-label |
|                           | O,O-Dimethyl phosphoric acid (MET XVII); max. 27.9% at 30 d (n=1), [\(^{14}\)C-dimethoate]-label |
| Mineralisation at study end | 1.9% after 30 d, 25 °C label (n=1)                                                                                         |
| Non-extractable residues at study end | 12.2% after 30 d, 25 °C (n=1)                                                                                         |

## 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)

\(^{11}\) n corresponds to the number of soils.
### Dimethoate

| Soil name | Soil type (USDA) | pH\(^a\) | Temp. (°C) / % MWHC | DT\(_{50}\) / DT\(_{90}\) (d) | DT\(_{50}\) (d) 20 °C, pF 2\(^b\) | χ\(^2\) (%) | Method of calculation |
|-----------|-----------------|---------|---------------------|-----------------------------|-----------------------------|-------------|----------------------|
| Riverside | CL              | 6.9     | 20 / 40             | 2.4 / 7.9                   | 2.4                          | 14.4       | SFO                  |
| Middlefield | SiC            | 6.0     | 20 / 40             | 2.3 / 7.8                   | 1.9                          | 20.9       | SFO                  |
| Somersham | SL              | 7.3     | 20 / 40             | 4.3 / 14.1                  | 4.3                          | 11.6       | SFO                  |
| LUFA 2.3  | SL              | 5.8     | 20 / 40             | 2.6 / 8.6                   | 2.1                          | 9.2        | SFO                  |
| Geometric mean (n=4) |        |         |                     |                             |                             | 2.5        |                      |

**pH dependence, No**

\(\text{a) Measured in CaCl}_2\)

\(\text{b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7}\)

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### 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)

| Met II | Omethoate, dark aerobic conditions, metabolite dosed | Soil name | Soil type (USDA) | pH\(^a\) | Temp. (°C) / % MWHC | DT\(_{50}\) / DT\(_{90}\) (d) | f.f. | DT\(_{50}\) (d) 20 °C, pF 2\(^b\) | χ\(^2\) (%) | Method of calculation |
|--------|---------------------------------------------------|-----------|-----------------|---------|---------------------|-----------------------------|-----|-----------------------------|-------------|----------------------|
|        |                                                   | LUFA 2.2  | LS              | 5.5     | 20 / 40             | 0.1 / 0.2                   | n.a.| 0.1                          | 3.6         | SFO                  |
|        |                                                   | LUFA 2.3  | SL              | 5.8     | 20 / 40             | 0.4 / 1.2                   | n.a.| 0.3                          | 2.6         | SFO                  |
|        |                                                   | LUFA 2.4  | L               | 7.2     | 20 / 40             | 0.1 / 0.4                   | n.a.| 0.1                          | 2.5         | SFO                  |
|        | Geometric mean (n=3) |        |                   |         |                     |                             |     |                             |             | 0.1                  |
|        | Arithmetic mean                                |           |                 |         |                     |                             |     | na                           |             |                      |

**pH dependence, No**

\(\text{a) Measured in CaCl}_2\)

\(\text{b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7}\)
| Met X       | O-Desmethyl dimethoate, dark aerobic conditions, metabolite dosed |
|-------------|---------------------------------------------------------------|
| Soil name   | Soil type (USDA) | pH<sup>a</sup> | Temp. (°C) / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | f.f. | DT<sub>50</sub> (d) 20 °C<sub>b</sub>, pF 2<sup>b</sup> | χ² (%) | Method of calculation |
| LUFA 2.2    | LS              | 5.5             | 20 / 40              | 0.6 / 2.0                      | n.a. | 0.6          | 12.1              | SFO               |
| LUFA 2.3    | SL              | 6.0             | 20 / 40              | 0.4 / 1.2                      | n.a. | 0.3          | 6.5               | SFO               |
| LUFA 2.4    | L               | 7.2             | 20 / 40              | 0.3 / 1.0                      | n.a. | 0.2          | 12.3              | SFO               |
| Geometric mean (n=3) |               |                 |                      |                              |      |              | 0.3               |                   |
| Arithmetic mean |               |                 |                      |                              |      |              | na                |                   |
| pH dependence, No |           |                 |                      |                              |      |              |                   |                   |

<sup>a</sup> Measured in CaCl<sub>2</sub>  
<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

| Met XVI | O,O-Dimethyl thiophosphoric acid, dark aerobic conditions, metabolite dosed |
|---------|---------------------------------------------------------------------------|
| Soil name | Soil type (USDA) | pH<sup>a</sup> | Temp. (°C) / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | f.f. | DT<sub>50</sub> (d) 20 °C<sub>b</sub>, pF 2<sup>b</sup> | χ² (%) | Method of calculation |
| LUFA 2.2 | LS              | 5.5             | 20 / 40              | 0.3 / 1.0                      | n.a. | 0.3          | 6.7               | SFO               |
| LUFA 2.3 | SL              | 5.8             | 20 / 40              | 0.3 / 1.0                      | n.a. | 0.2          | 7.1               | SFO               |
| LUFA 2.4 | L               | 7.2             | 20 / 40              | 0.4 / 1.4                      | n.a. | 0.3          | 5.8               | SFO               |
| Geometric mean (n=3) |               |                 |                      |                              |      |              | 0.3               |                   |
| Arithmetic mean |               |                 |                      |                              |      |              | na                |                   |
| pH dependence, No |           |                 |                      |                              |      |              |                   |                   |

<sup>a</sup> Measured in CaCl<sub>2</sub>  
<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

| Met XVII | O,O-Dimethyl phosphoric acid, dark aerobic conditions, metabolite dosed |
|----------|--------------------------------------------------------------------------|
| Soil name | Soil type (USDA) | pH<sup>a</sup> | Temp. (°C) / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | f.f. | DT<sub>50</sub> (d) 20 °C<sub>b</sub>, pF 2<sup>b</sup> | χ² (%) | Method of calculation |
| LUFA 2.2 | LS              | 5.5             | 20 / 40              | 0.3 / 1.0                      | n.a. | 0.3          | 17.6              | SFO               |
| LUFA 2.3 | SL              | 5.8             | 20 / 40              | 1.4 / 4.7                      | n.a. | 1.1          | 11.5              | SFO               |
| LUFA 2.4 | L               | 7.2             | 20 / 40              | 0.6 / 2.1                      | n.a. | 0.5          | 6.4               | SFO               |
| Geometric mean (n=3) |               |                 |                      |                              |      |              | 0.5               |                   |
| Arithmetic mean |               |                 |                      |                              |      |              | na                |                   |
| pH dependence, No |           |                 |                      |                              |      |              |                   |                   |

<sup>a</sup> Measured in CaCl<sub>2</sub>  
<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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)

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### Dimethoate

| Location          | Soil type (USDA) | pH<sup>a</sup> | Depth (cm) | DT<sub>50</sub> / DT<sub>90</sub> (d) actual | DT<sub>50</sub> (d) 20 °C, pF 2<sup>b</sup> | χ<sup>2</sup> (%) | Method of calculation |
|-------------------|------------------|----------------|------------|---------------------------------|--------------------------|---------------------|----------------------|
| California, US    | SL               | 5.6            | 0 – 30     | 7.8/25.9                        | 5.0                      | 33.0                | SFO                  |
| Vlagtwedde, NL    | S                | 4.0            | 0 – 30     | 5.8/19.3                        | 3.0                      | 14.7                | SFO                  |
| Halen, DE         | S                | 4.1            | 0 – 30     | 4.1/23.3                        | 1.9                      | 9.8                 | SFO                  |
| Zafarraya, ES     | SiL              | 6.9            | 0 – 30     | 7.0/23.3                        | 3.5                      | 13.3                | SFO                  |
| Vittoria, IT      | SL               | 7.0            | 0 – 30     | 2.2/7.4                         | 2.4                      | 13.7                | SFO                  |
| Geometric mean (n=5) |                 |                |            |                                 |                          | 3.0                 |                      |

pH dependence, No

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<sup>a</sup> Measured in CaCl<sub>2</sub>

<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

### Met II

| Location          | Soil type (USDA) | pH<sup>a</sup> | Depth (cm) | DT<sub>50</sub> / DT<sub>90</sub> (d) actual | f.f. | DT<sub>50</sub> (d) 20 °C, pF 2<sup>b</sup> | χ<sup>2</sup> (%) | Method of calculation |
|-------------------|------------------|----------------|------------|---------------------------------|------|--------------------------|---------------------|----------------------|
| California, US    | SL               | 5.6            | 0 – 30     | 22.7/75.4                       | 0.302| 10.6                     | 27.3                | HS/SFO               |
| Vlagtwedde, NL    | S                | 4.0            | 0 – 30     | 1.4/4.5                         | 0.074| 0.3                      | 30.1                | SFO/SFO              |
| Halen, DE         | S                | 4.1            | 0 – 30     | 1.3/4.4                         | 0.079| 0.4                      | 45.5                | SFO/SFO              |
| Zafarraya, ES     | SiL              | 6.9            | 0 – 30     | 2.9/9.8                         | 0.069| 1.3                      | 54.6                | SFO/SFO              |
| Vittoria, IT      | SL               | 7.0            | 0 – 30     | 1.7/5.6                         | 0.128| 0.5                      | 16.3                | SFO/SFO              |
| Geometric mean (n=5) |                 |                |            |                                 |     |                          |                     |                      |
| Arithmetic mean (n=5) |                   |                |            |                                 | 1.0 |                          |                     |                      |
| pH dependence, No |                  |                |            |                                 |     |                          |                     |                      |

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<sup>a</sup> Measured in CaCl<sub>2</sub>

<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

| Description                                                                 | Value                           |
|-----------------------------------------------------------------------------|---------------------------------|
| Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent) | 2.8 days                        |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) | Omethoate (MET II) 0.6 days     |
| Kinetic formation fraction ($f. f. k_f / k_{dp}$) of transformation products, arithmetic mean | 0.130 – from dimethoate         |

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 | Data not required |
|--------------------------------------------|-------------------|

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)

| Dimethoate | Soil name | Soil type (UK) | pH | Temp. (°C) / % MWHC | DT$_{50}$ / DT$_{90}$ (d) | DT$_{50}$ (d) 20 °C, pH 2 | $\chi^2$ (%) | Method of calculation |
|------------|-----------|----------------|----|---------------------|--------------------------|----------------------------|-------------|-----------------------|
| Dimethoate | Somersham | SL             | 6.0| 25 / na             | 25.4 / na                | na                         | 3.7         | HS                    |
| Geometric mean (n=1) | | | | | | | |
| pH dependence, na | | | | | | | |

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### 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)

#### Dimethoate

| Soil name     | Soil type (USDA) | OC (%) | Soil pH\(^a\) | \(K_d\) (L/kg) | \(K_{dOC}\) (L/kg) | \(K_F\) (L/kg) | \(K_{FOC}\) (L/kg) | 1/n    |
|---------------|------------------|--------|----------------|----------------|-------------------|----------------|-------------------|-------|
| Speyer        | S/LS             | 0.5    | 6.0            | -              | 0.25              | 52             | 1.05              |
| Somersham     | SL               | 2.1    | 7.1            | -              | 0.33              | 16             | 1.05              |
| Itingen       | SiL              | 1.4    | 7.7            | -              | 0.42              | 30             | 0.97              |
| Les Evouettes | L/SiL            | 1.4    | 6.1            | -              | 0.42              | 30             | 1.03              |
| Neustadt a.R. | S                | 1.5    | 5.7            | -              | 0.34              | 23             | 1.01              |
| Geometric mean (n=8) |               |        |                |                |                   |                |                   | 28.0  |
| Arithmetic mean (n=8) |            |        |                |                |                   |                |                   | 1.02  |
| pH dependence, No |                   |        |                |                |                   |                |                   |       |

\(^a\) Measured in Ca\(_2\)Cl

### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

The soil adsorption of omethoate (MET II) could not be determined accurately in a laboratory study because of its weak adsorption and rapid degradation (Deg\(T50_{lab}\) = 0.1 days). Therefore, the soil adsorption of omethoate has been estimated by QSPR. Using EPISuite (v. 4.11) the estimated \(K_{OC}\) of omethoate is 10 L/kg.

O-Desmethyl dimethoate (MET X) has similarly rapid degradation in soil to omethoate (Deg\(T50_{lab}\) = 0.3 days) and weak adsorption would be expected from its structure. Therefore, the soil adsorption of O-desmethyl dimethoate has been estimated by QSPR. Using (EPISuite (v. 4.11) the estimated \(K_{OC}\) of O-desmethyl dimethoate is 10 L/kg.

O,O-Dimethyl thiophosphoric acid (MET XVI) has similarly rapid degradation in soil to omethoate (Deg\(T50_{lab}\) = 0.3 days) and weak adsorption would be expected from its structure. Therefore, the soil adsorption of O,O-dimethyl thiophosphoric acid has been estimated by QSPR. Using (EPISuite (v. 4.11) the estimated \(K_{OC}\) of O,O-dimethyl thiophosphoric acid is 12 L/kg.

O,O-Dimethyl phosphoric acid (MET XVII) has similarly rapid degradation in soil to omethoate (Deg\(T50_{lab}\) = 0.5 days) and weak adsorption would be expected from its structure. Therefore, the soil adsorption of O,O-dimethyl phosphoric acid has been estimated by QSPR. Using (EPISuite (v. 4.11) the estimated \(K_{OC}\) of O,O-dimethyl phosphoric acid is 5 L/kg.
**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)**

| Method                           | Description                                                                 |
|----------------------------------|-----------------------------------------------------------------------------|
| Column leaching                  | 4 soils, 1 litre of leaching water, 71.8 – 100.6% AR in leachate, of which 77 – 93% of radioactivity in leachate present as unchanged dimethoate. |
| Aged residues leaching           | 1 soil, 30 day ageing period, 4.9% AR as dimethoate in aged soil prior to leaching. 5.1% AR in leachate after leaching, presumed to be unchanged dimethoate. |

**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)**

| Method                             | Description                                                                 |
|------------------------------------|-----------------------------------------------------------------------------|
| Lysimeter/ field leaching studies  | The lysimeter study has not been carried out according to current guidelines, however the study design provides useful information on the mobility of dimethoate and can be used qualitatively only with respect to representative uses. No field leaching study was performed. |

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

| pH       | DT$_{50}$  | Temp.  | Metabolite                                   | % Degradation |
|----------|------------|--------|----------------------------------------------|---------------|
| pH 5     | 158 d      | 25°C   | O-Desmethyl dimethoate                        | 12.2% (30 d)  |
| pH 7     | 68 d       | 25°C   | O-Desmethyl dimethoate                        | 22.1% (30 d)  |
| pH 9     | 4.4 d      | 25°C   | O-Desmethyl dimethoate                        | 62.2% (21 d)  |
|          |            |        | O$_2$O-Dimethyl thiophosphoric acid:          | 36.0% (30 d)  |

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

| Method                                                  | Description                                                                 |
|---------------------------------------------------------|-----------------------------------------------------------------------------|
| Photolytic degradation of active substance and metabolites above 10 % | No significant degradation compared to dark control over 15 day time period. |
| DT$_{50}$                                               | 175 d                                                                       |
| Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm | Not applicable                                                               |

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

| Method                          | Description                                      |
|---------------------------------|--------------------------------------------------|
| Readily biodegradable (yes/no)  | Not readily biodegradable                         |
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)

Mineralisation after 100 days

18.8 – 25.7% after 58 d, 20°C

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)

O-Desmethyl dimethoate; max. 66.3% at 58 d

| Dimethoate | Surface water – aerobic conditions |
|------------|------------------------------------|
|            | pH water phase | DT_{50} water (d) | DT_{90} water (d) | χ² (%) | Method of calculation |
| Berghäuser | 7.6             | 14.8             | 49.2             | 8.5     | SFO                   |
| Altrhein   |                 |                  |                  |         |                       |

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)

| Dimethoate | Distribution (max. in sediment 11.9% after 7 d) |
|------------|-----------------------------------------------|
| Water / sediment system | pH water / sed. | DT_{50} / DT_{90} whole sys. (d) | St. (χ²) | DisT_{50} / DisT_{90} water (d) | St. (χ²) | DisT_{50} / DisT_{90} sed. (d) | Method of calc. |
| System I (Rhine)         | 8.2 / 7.8   | 18.8 / 62.3                        | 3.55     | 15.5 / 51.6                      | 4.25     | nd                         | SFO |
| System II (Pond)         | 7.2 / 7.1   | 12.8 / 42.4                        | 2.41     | 10.2 / 33.7                      | 4.58     | nd                         | SFO |
| Geometric mean (n=2)     |              |                                  |          |                                   |          |                           |     |
|                          | 15.5        |                                  |          | 12.6                              |          |                           |     |

O-Desmethyl dimethoate Distribution (Max in water 17.6% after 30 d.; Max. sed 4.6% after 30 d.; Max in total system 22.2 % after 30 d.)

Mineralization and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH water | pH sed | Mineralisation % after 105 d (end of the study) | Non-extractable residues in sed. max % after 105 d | Non-extractable residues in sed. max % after 105 d (end of the study) |
|-------------------------|---------|--------|-----------------------------------------------|---------------------------------------------------|---------------------------------------------------------------------|
| System I (Rhine)        | 8.2     | 7.8    | 28.0                                          | 40.4                                              | 40.4                                                                |
| System II (Pond)        | 7.2     | 7.1    | 24.5                                          | 51.5                                              | 51.5                                                               |
Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| Phenomenon                                      | Description                                                                 |
|-------------------------------------------------|-----------------------------------------------------------------------------|
| Direct photolysis in air                        | Not studied                                                                 |
| Photochemical oxidative degradation in air      | **Dimethoate**

  * DT₅₀ of 1.6 hours derived by the Atkinson model (EPI Suite v. 4.11). OH radical (12 h) concentration assumed = 1.6 × 10⁵ cm⁻³

  * **Omethoate**

  * DT₅₀ of 4.9 hours derived by the Atkinson model (EPI Suite v. 4.11). OH radical (12 h) concentration assumed = 1.6 × 10⁵ cm⁻³

| Volatilisation                                  | from plant surfaces (BBA guideline): 13.1 – 13.8% after 24 hours |
|-------------------------------------------------|------------------------------------------------------------------|
|                                                 | from soil surfaces (BBA guideline): 1.3% after 24 hours          |

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

| Environment                                      | Residues                                                                 |
|-------------------------------------------------|--------------------------------------------------------------------------|
| Soil                                            | dimethoate, omethoate*, O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid, O,O-dimethyl phosphoric acid |
| Ground water                                    | dimethoate, omethoate*, O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid, O,O-dimethyl phosphoric acid |
| Surface water                                   | dimethoate, omethoate*, O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid, O,O-dimethyl phosphoric acid |
| Sediment                                        | dimethoate, omethoate*, O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid, O,O-dimethyl phosphoric acid |
| Air                                             | dimethoate, omethoate*                                                   |

* the inclusion of the metabolite omethoate in the definition of the residue for risk assessment is precautionary since omethoate is an active substance (although not approved under Regulation (EC) 1107/2009)

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

| Environment                                      | Residue                                      |
|-------------------------------------------------|----------------------------------------------|
| Soil                                            | dimethoate, omethoate                        |
| Ground water                                    | dimethoate, omethoate                        |
| Surface water                                   | dimethoate, omethoate                        |
| Sediment                                        | dimethoate, omethoate                        |
| Air                                             | dimethoate, omethoate                        |
Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

Surface water (indicate location and type of study)

Ground water (indicate location and type of study)

Air (indicate location and type of study)

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

Parent

Method of calculation

Application data

Crop: Sugar beets, Winter cereals

Depth of soil layer (cm): 5

Soil bulk density (g/cm³): 1.5

Plant interception (%): Sugar beets, 70 – BBCH 30, Winter cereals, 80 – BBCH 30

Number of applications: 1

Interval (d): na

Application rate (g a.s./ha): 200

Sugarbeets

| PEC(s) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------|---------------------------|------------------------------------------|-----------------------------|--------------------------------------------|
| Initial | 0.080                     | -                                        | -                           | -                                          |
| Short term | 24h | 0.070                     | 0.075                                   | -                           | -                                          |
|         | 2d  | 0.061                     | 0.070                                   | -                           | -                                          |
|         | 4d  | 0.046                     | 0.061                                   | -                           | -                                          |
| Long term | 7d  | 0.030                     | 0.051                                   | -                           | -                                          |
|         | 14d | 0.011                     | 0.035                                   | -                           | -                                          |
|         | 21d | 0.004                     | 0.026                                   | -                           | -                                          |
|         | 28d | 0.002                     | 0.020                                   | -                           | -                                          |
|         | 50d | 0.000                     | 0.012                                   | -                           | -                                          |
|         | 100d | 0.000                    | 0.006                                   | -                           | -                                          |

Plateau concentration: na

DT₅₀ (d): 5.0 days (the correct value is 7.8 d)

Field or Lab: worst case from field studies.

Parent Method of calculation

Kinetics: SFO

Application data

Crop: Sugar beets, Winter cereals

Depth of soil layer (cm): 5

Soil bulk density (g/cm³): 1.5

Plant interception (%): Sugar beets, 70 – BBCH 30, Winter cereals, 80 – BBCH 30

Number of applications: 1

Interval (d): na

Application rate (g a.s./ha): 200
### Winter cereals

| PEC(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------------|---------------------------|------------------------------------------|-----------------------------|------------------------------------------|
| Initial        | 0.053                     | -                                        | -                           | -                                        |
| Short term 24h | 0.046                     | 0.050                                    | -                           | -                                        |
| 2d             | 0.040                     | 0.047                                    | -                           | -                                        |
| 4d             | 0.031                     | 0.041                                    | -                           | -                                        |
| Long term 7d   | 0.020                     | 0.034                                    | -                           | -                                        |
| 14d            | 0.008                     | 0.024                                    | -                           | -                                        |
| 21d            | 0.003                     | 0.017                                    | -                           | -                                        |
| 28d            | 0.001                     | 0.014                                    | -                           | -                                        |
| 50d            | 0.000                     | 0.008                                    | -                           | -                                        |
| 100d           | 0.000                     | 0.004                                    | -                           | -                                        |
| Plateau concentration | na                  |                                           |                             |                                           |
Omethoate

Method of calculation

Molecular weight relative to the parent: 0.930

DT₅₀ (d): 10.6 days (the correct value is 22.7 d)

Kinetics: SFO

Field or Lab: worst case from field studies.

Application data

Assumed omethoate is formed at a maximum of 15.4% of the applied dose

| Sugarbeets | PEC₅₀ (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|------------|---------------|---------------------------|----------------------------------------|----------------------------|------------------------------------------|
| Initial    |               | 0.011                     | -                                      | -                          | -                                        |
| Short term | 24h           | 0.011                     | 0.011                                  | -                          | -                                        |
| 2d         |               | 0.010                     | 0.011                                  | -                          | -                                        |
| 4d         |               | 0.009                     | 0.010                                  | -                          | -                                        |
| Long term  | 7d            | 0.007                     | 0.009                                  | -                          | -                                        |
| 14d        |               | 0.005                     | 0.008                                  | -                          | -                                        |
| 21d        |               | 0.003                     | 0.006                                  | -                          | -                                        |
| 28d        |               | 0.002                     | 0.005                                  | -                          | -                                        |
| 50d        |               | 0.000                     | 0.003                                  | -                          | -                                        |
| 100d       |               | 0.000                     | 0.002                                  | -                          | -                                        |
| Plateau concentration | na |
## Winter cereals

| PEC(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|----------------|---------------------------|------------------------------------------|----------------------------|-------------------------------------------|
| Initial        | 0.008                     | -                                        | -                          | -                                         |
| Short term     |                           |                                          |                            |                                           |
| 24h            | 0.007                     | 0.007                                    | -                          | -                                         |
| 2d             | 0.007                     | 0.007                                    | -                          | -                                         |
| 4d             | 0.006                     | 0.007                                    | -                          | -                                         |
| Long term      |                           |                                          |                            |                                           |
| 7d             | 0.005                     | 0.006                                    | -                          | -                                         |
| 14d            | 0.003                     | 0.005                                    | -                          | -                                         |
| 21d            | 0.002                     | 0.004                                    | -                          | -                                         |
| 28d            | 0.001                     | 0.004                                    | -                          | -                                         |
| 50d            | 0.000                     | 0.002                                    | -                          | -                                         |
| 100d           | 0.000                     | 0.001                                    | -                          | -                                         |
| Plateau concentration | na                      |                                          |                            |                                           |
O-Desmethyl dimethoate

Method of calculation

Molecular weight relative to the parent: 0.939

DT$_{50}$ (d): 0.6 days

Kinetics: SFO

Field or Lab: worst case from lab studies.

Application data

Assumed O-desmethyl dimethoate is formed at a maximum of 9.6% of the applied dose

| Sugarbeets |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| 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 | 0.002 | 0.004 | - | - |
| 2d | 0.001 | 0.003 | - | - |
| 4d | 0.000 | 0.002 | - | - |
| Long term 7d | 0.000 | 0.001 | - | - |
| 14d | 0.000 | 0.000 | - | - |
| 21d | 0.000 | 0.000 | - | - |
| 28d | 0.000 | 0.000 | - | - |
| 50d | 0.000 | 0.000 | - | - |
| 100d | 0.000 | 0.000 | - | - |
| Plateau concentration | na | | | |


| Winter cereals | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------|---------------------------|----------------------------------------|----------------------------|----------------------------------------|
| **PEC(s)** (mg/kg) |                            |                                        |                            |                                        |
| Initial       | 0.005                     | -                                      | -                          | -                                      |
| Short term    | 0.002                     | 0.003                                  | -                          | -                                      |
| 2d            | 0.000                     | 0.002                                  | -                          | -                                      |
| 4d            | 0.000                     | 0.001                                  | -                          | -                                      |
| Long term     | 0.000                     | 0.001                                  | -                          | -                                      |
| 7d            | 0.000                     | 0.000                                  | -                          | -                                      |
| 14d           | 0.000                     | 0.000                                  | -                          | -                                      |
| 21d           | 0.000                     | 0.000                                  | -                          | -                                      |
| 28d           | 0.000                     | 0.000                                  | -                          | -                                      |
| 50d           | 0.000                     | 0.000                                  | -                          | -                                      |
| 100d          | 0.000                     | 0.000                                  | -                          | -                                      |
| Plateau concentration | na                      |                                        |                            |                                        |
### O,O-Dimethyl thiophosphoric acid

**Method of calculation**

- Molecular weight relative to the parent: 0.620
- DT$_{50}$ (d): 0.3 days
- Kinetics: SFO
- Field or Lab: worst case from lab studies.

**Application data**

Assumed O,O-dimethyl thiophosphoric acid is formed at a maximum of 58.9% of the applied dose.

### Sugarbeets

| PEC$_{as}$ (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------|---------------------------|------------------------------------------|----------------------------|------------------------------------------|
| Initial           | 0.029                     | -                                        | -                          | -                                        |
| Short term 24h    | 0.003                     | 0.011                                    | -                          | -                                        |
| 2d                | 0.000                     | 0.006                                    | -                          | -                                        |
| 4d                | 0.000                     | 0.003                                    | -                          | -                                        |
| Long term 7d      | 0.000                     | 0.002                                    | -                          | -                                        |
| 14d               | 0.000                     | 0.001                                    | -                          | -                                        |
| 21d               | 0.000                     | 0.001                                    | -                          | -                                        |
| 28d               | 0.000                     | 0.000                                    | -                          | -                                        |
| 50d               | 0.000                     | 0.000                                    | -                          | -                                        |
| 100d              | 0.000                     | 0.000                                    | -                          | -                                        |
| Plateau concentration | na                       |                                          |                            |                                          |
### Winter cereals

| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------------|---------------------------|----------------------------------------|-----------------------------|----------------------------------------|
| Initial                   | 0.019                     | -                                      | -                           | -                                      |
| Short term 24h            | 0.002                     | 0.008                                  | -                           | -                                      |
| 2d                        | 0.000                     | 0.004                                  | -                           | -                                      |
| 4d                        | 0.000                     | 0.002                                  | -                           | -                                      |
| Long term 7d              | 0.000                     | 0.001                                  | -                           | -                                      |
| 14d                       | 0.000                     | 0.001                                  | -                           | -                                      |
| 21d                       | 0.000                     | 0.000                                  | -                           | -                                      |
| 28d                       | 0.000                     | 0.000                                  | -                           | -                                      |
| 50d                       | 0.000                     | 0.000                                  | -                           | -                                      |
| 100d                      | 0.000                     | 0.000                                  | -                           | -                                      |
| Plateau concentration     | na                        |                                        |                             |                                        |
O,O-dimethyl phosphoric acid
Method of calculation

Molecular weight relative to the parent: 0.550
DT$_{50}$ (d): 1.1 days
Kinetics: SFO
Field or Lab: worst case from lab studies.

Application data
Assumed O,O-dimethyl phosphoric acid is formed at a maximum of 27.9% of the applied dose.

### Sugarbeets

| PEC$_{(s)}$ (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------|--------------------------|---------------------------------------|----------------------------|--|
| Initial             | 0.012                    | -                                     | -                          | -                          |
| Short term 24h      | 0.007                    | 0.009                                 | -                          | -                          |
| 2d                  | 0.003                    | 0.007                                 | -                          | -                          |
| 4d                  | 0.001                    | 0.004                                 | -                          | -                          |
| Long term 7d        | 0.000                    | 0.003                                 | -                          | -                          |
| 14d                 | 0.000                    | 0.001                                 | -                          | -                          |
| 21d                 | 0.000                    | 0.001                                 | -                          | -                          |
| 28d                 | 0.000                    | 0.001                                 | -                          | -                          |
| 50d                 | 0.000                    | 0.000                                 | -                          | -                          |
| 100d                | 0.000                    | 0.000                                 | -                          | -                          |
| Plateau concentration | na                      |                                       |                            |                            |
| Winter cereals | PEC(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------|----------------|---------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial       | 0.008          | -                         | -                                      | -                          | -                                      |
| Short term    | 24h            | 0.004                     | 0.006                                  | -                          | -                                      |
|               | 2d             | 0.002                     | 0.005                                  | -                          | -                                      |
|               | 4d             | 0.001                     | 0.003                                  | -                          | -                                      |
| Long term     | 7d             | 0.000                     | 0.002                                  | -                          | -                                      |
|               | 14d            | 0.000                     | 0.001                                  | -                          | -                                      |
|               | 21d            | 0.000                     | 0.001                                  | -                          | -                                      |
|               | 28d            | 0.000                     | 0.000                                  | -                          | -                                      |
|               | 50d            | 0.000                     | 0.000                                  | -                          | -                                      |
|               | 100d           | 0.000                     | 0.000                                  | -                          | -                                      |
| Plateau       | concentration  | na                        |                                        |                            |                                        |
**PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)**

| Substance                        | Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) | Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. | Model(s) used: FOCUS PEARL (v. 4.4.4), FOCUS PELMO (v. 5.5.3) and FOCUS MACRO (v. 5.5.4) |
|----------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Parent                           | Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. | Model(s) used: FOCUS PEARL (v. 4.4.4), FOCUS PELMO (v. 5.5.3) and FOCUS MACRO (v. 5.5.4) | Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. |
| **Geometric mean DT$_{50}$ (d):** 2.8 | Geometric mean $K_{oc}$ (L/kg): 70 (geometric mean $K_{oc}$ of 28.0 (L/kg) should be used in future assessments) | Arithmetic mean $1/n$: 0.91 (arithmetic mean $1/n$ of 1.02 should be used in future assessments) | Arithmetic mean $1/n$: 0.91 (arithmetic mean $1/n$ of 1.02 should be used in future assessments) |
| **Arithmetic mean $1/n$:** 0.91 | **Crop uptake factor:** 0.51 (calculated according to guidance from measured log $K_{ow}$) | **Water solubility (mg/L):** $2.8 \times 10^4$ at 20°C | **Water solubility (mg/L):** $2.8 \times 10^4$ at 20°C |
| **Water solubility (mg/L):** $2.8 \times 10^4$ at 20°C | **Vapour pressure (Pa):** $2.5 \times 10^{-3}$ at 25°C | **Vapour pressure (Pa):** $2.5 \times 10^{-3}$ at 25°C | **Vapour pressure (Pa):** $2.5 \times 10^{-3}$ at 25°C |
| **Geometric mean DT$_{50}$ (d):** 0.6 | **Arithmetic mean f.f.:** 0.130 (from parent) | **Geometric mean $K_{oc}$ (L/kg):** 10 (calculated with EPISuite) | **Geometric mean $K_{oc}$ (L/kg):$10$ (calculated with EPISuite) |
| **Arithmetic mean $1/n$:** 1 | **Arithmetic mean $1/n$:** 1 (linear relation assumed) | **Crop uptake factor:** 0.04 (calculated according to guidance from measured log $K_{ow}$) | **Crop uptake factor:** 0.04 (calculated according to guidance from measured log $K_{ow}$) |
| **Water solubility (mg/L):** $5.0 \times 10^5$ at 20°C | **Water solubility (mg/L):** $5.0 \times 10^5$ at 20°C | **Vapour pressure (Pa):** $1.9 \times 10^{-2}$ at 25°C (calculated with EPISuite) | **Vapour pressure (Pa):** $1.9 \times 10^{-2}$ at 25°C (calculated with EPISuite) |
| **Vapour pressure (Pa):** $1.9 \times 10^{-2}$ at 25°C | **Vapour pressure (Pa):** $1.9 \times 10^{-2}$ at 25°C | **Vapour pressure (Pa):** $1.9 \times 10^{-2}$ at 25°C | **Vapour pressure (Pa):$1.9 \times 10^{-2}$ at 25°C |
| **Geometric mean DT$_{50}$ (d):** 0.3 | **Maximum occurrence (%):** 9.6 | **Geometric mean $K_{oc}$ (L/kg):$10$ (calculated with EPISuite) | **Geometric mean $K_{oc}$ (L/kg):$10$ (calculated with EPISuite) |
| **Maximum occurrence (%):** 9.6 | **Arithmetic mean $1/n$:** 1 (linear relation assumed) | **Crop uptake factor:** 0 | **Crop uptake factor:** 0 |
| **Water solubility (mg/L):** $3.6 \times 10^4$ at 25°C (calculated with EPISuite) | **Water solubility (mg/L):$$8.2 \times 10^4$ at 25°C (calculated with EPISuite) | **Vapour pressure (Pa):$$3.4$ at 25°C (calculated with EPISuite) | **Vapour pressure (Pa):$$3.4$ at 25°C (calculated with EPISuite) |
| **Vapour pressure (Pa):$$3.4$ at 25°C | **Vapour pressure (Pa):$$3.4$ at 25°C | **Vapour pressure (Pa):$$3.4$ at 25°C | **Vapour pressure (Pa):$$3.4$ at 25°C |
O,O-Dimethyl phosphoric acid (Met XVII)

- Geometric mean DT$_{50}$ (d): 0.5
- Maximum occurrence (%): 27.9
- Geometric mean K$_{oc}$ (L/kg): 5 (calculated with EPISuite)
- Arithmetic mean 1/n: 1 (linear relation assumed)
- Crop uptake factor: 0
- Water solubility (mg/L): $9.5 \times 10^4$ at 25°C (calculated with EPISuite)
- Vapour pressure (Pa): $4.6 \times 10^1$ at 25°C (calculated with EPISuite)

Application rate

- Crop and growth stage: Sugar beets, BBCH 30, Winter cereals, BBCH 30 (spring application; no autumn use due to BBCH ≥30)
- Crop interception (%): Sugar beets: 70, Winter cereals: 80
- No. of applications: Sugarbeets and Winter cereals: 1
- Application rate (g a.s./ha): Sugarbeets and Winter cereals: 200
- Application rate net of interception: Sugar beets: 60, Winter cereals: 40
- Time of application: Sugar beets: 6 weeks after crop emergence, Winter cereals: according to AppDate v..2.01

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

| Scenario   | Parent (µg/L) | Met II | Met X | Met XVI | Met XVII |
|------------|--------------|--------|-------|---------|----------|
| Châteaudun | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Hamburg    | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Jokioinen  | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Kremsmünster | < 0.001  | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Okehampton | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Piacenza   | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Porto      | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Sevilla    | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Thiva      | < 0.001      | < 0.001| < 0.001| < 0.001 | < 0.001  |
### FOCUS Tier 1 PEC(gw) - modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

#### FOCUS PEARL / winter cereals

| Scenario   | Parent (µg/L) | Metabolite (µg/L) | Met II | Met X | Met XVI | Met XVII |
|------------|---------------|-------------------|--------|-------|---------|----------|
| Châteaudun | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Hamburg    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Jokioinen  | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Kremsmünster | < 0.001     | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Okehampton | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Piacenza   | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Porto      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Sevilla    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Thiva      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |

#### FOCUS PELMO / Sugar beets

| Scenario   | Parent (µg/L) | Metabolite (µg/L) | Met II | Met X | Met XVI | Met XVII |
|------------|---------------|-------------------|--------|-------|---------|----------|
| Châteaudun | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Hamburg    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Jokioinen  | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Kremsmünster | < 0.001      | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Okehampton | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Piacenza   | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Porto      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Sevilla    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Thiva      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |

#### FOCUS PELMO / winter cereals

| Scenario   | Parent (µg/L) | Metabolite (µg/L) | Met II | Met X | Met XVI | Met XVII |
|------------|---------------|-------------------|--------|-------|---------|----------|
| Châteaudun | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Hamburg    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Jokioinen  | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Kremsmünster | < 0.001      | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Okehampton | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Piacenza   | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Porto      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Sevilla    | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
| Thiva      | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001  |
### FOCUS MACRO / Sugar beets Scenario

| Scenario | Parent (µg/L) | Metabolite (µg/L) | Met II | Met X | Met XVI | Met XVII |
|-----------|---------------|-------------------|--------|-------|---------|----------|
| Châteaudun | < 0.001       | < 0.001           | < 0.001| < 0.001| < 0.001 | < 0.001 |

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

**Method of calculation**

Modelling using FOCUS model(s), with appropriate FOCUSsw scenarios, according to FOCUS guidance.

Version control no.'s of FOCUS software: Steps 1-2 in FOCUS calculator (v. 3.2), MACRO (v. 5.5.4), PRZM (v. 4.3.1), TOXSWA (v. 4.4.3), SWASH (v. 5.3) SWAN (v. 4.0.1).

**Parent Parameters used in FOCUSsw step 1 and 2**

- Molecular weight (g/mol): 229.3
- Water solubility (mg/L): $2.8 \times 10^4$
- $DT_{50}$ soil (d): 2.8
- $K_{OC}$ (L/kg): 70 (geometric mean $K_{OC}$ of 28.0 (L/kg) should be used in future assessments)
- $DT_{50}$ water/sediment (d): 15.5

**Parameters used in FOCUSsw step 3 and 4**

- Freundlich exponent, 1/n: 0.91
- Crop uptake factor: 0.51 (calculated according to guidance from measured log $K_{ow}$)
- $DT_{50}$ water (d): 15.5
- $DT_{50}$ sediment (d): 1000
- $DT_{50}$ crop (d): 10
- Wash-off coefficient (/cm): 0.5
### Omethoate (Met II)

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 213.2 |
| Water solubility (mg/L): 5.0 × 10^5 |
| Max. occurrence soil (%): 15.4 |
| DT<sub>50</sub> soil (d): 0.6 |
| K<sub>oc</sub> (L/kg): 10 |
| Max. occurrence water/sediment (%): 0.1 |
| DT<sub>50</sub> water/sediment (d): 1000 |

### O-Desmethyl dimethoate (Met X)

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 215.2 |
| Water solubility (mg/L): 3.6 × 10^4 |
| Max. occurrence soil (%): 9.6 |
| DT<sub>50</sub> soil (d): 0.3 |
| K<sub>oc</sub> (L/kg): 10 |
| Max. occurrence water/sediment (%): 22.2 |
| DT<sub>50</sub> water/sediment (d): 1000 |

### O,O-Dimethyl thiophosphoric acid (Met XVI)

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 142.1 |
| Water solubility (mg/L): 8.2 × 10^4 |
| Max. occurrence soil (%): 58.9 |
| DT<sub>50</sub> soil (d): 0.3 |
| K<sub>oc</sub> (L/kg): 12 |
| Max. occurrence water/sediment (%): 0.1 |
| DT<sub>50</sub> water/sediment (d): 1000 |

### O,O-Dimethyl phosphoric acid (Met XVII)

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 126.1 |
| Water solubility (mg/L): 9.5 × 10^4 |
| Max. occurrence soil (%): 27.9 |
| DT<sub>50</sub> soil (d): 0.5 |
| K<sub>oc</sub> (L/kg): 5 |
| Max. occurrence water/sediment (%): 0.1 |
| DT<sub>50</sub> water/sediment (d): 1000 |
Application rate

1. Crop and growth stage: winter cereals BBCH 30
   - Crop interception (%): Average crop cover
   - Number of applications: 1
   - Interval (d): na
   - Application rate: 200 g a.s./ha
   - Application window: Steps 1-2; Mar. – May, Step 3; selected based on estimated spring points; no autumn use due to BBCH ≥30

2. Crop and growth stage: sugar beets, BBCH 30
   - Crop interception (%): Average crop cover
   - Number of applications: 1
   - Interval (d): na
   - Application rate: 200 g a.s./ha
   - Application window: Steps 1-2; Mar. – May, Step 3; 30 days from 6 weeks post-emergence

### Parent Compartment

|          | Compartment | STEP 1 | STEP 2 – North EU | STEP 2 – South EU |
|----------|-------------|--------|-------------------|-------------------|
| Winter cereals: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 62.81 | 5.07              | 8.70              |
|          | Max. PEC<sub>SED</sub> (µg/kg) | 42.68 | 3.37              | 5.79              |
| Sugar beets: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 62.81 | 2.81              | 4.17              |
|          | Max. PEC<sub>SED</sub> (µg/kg) | 42.68 | 1.85              | 2.76              |

### Omethoate Met II

|          | Compartment | STEP 1 | STEP 2 – North EU | STEP 2 – South EU |
|----------|-------------|--------|-------------------|-------------------|
| Winter cereals: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 9.48  | 0.02              | 0.04              |
|          | Max. PEC<sub>SED</sub> (µg/kg) | 0.95  | < 0.01            | < 0.01            |
| Sugar beets: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 9.48  | 0.01              | 0.02              |
|          | Max. PEC<sub>SED</sub> (µg/kg) | 0.95  | < 0.01            | < 0.01            |
| Met X | Compartment | STEP 1 | STEP 2 – North EU | STEP 2 – South EU |
|-------|-------------|--------|-------------------|-------------------|
|       | Winter cereals: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 20.02 | 1.19 | 2.01 |
|       | | Max. PEC<sub>SED</sub> (µg/kg) | 2.00 | 0.12 | 0.20 |
|       | Sugar beets: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 20.02 | 0.68 | 0.99 |
|       | | Max. PEC<sub>SED</sub> (µg/kg) | 2.00 | 0.07 | 0.10 |

| Met XVI | Compartment | STEP 1 | STEP 2 – North EU | STEP 2 – South EU |
|---------|-------------|--------|-------------------|-------------------|
| Winter cereals: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 23.99 | < 0.01 | 0.01 |
| | Max. PEC<sub>SED</sub> (µg/kg) | 2.88 | < 0.01 | < 0.01 |
| Sugar beets: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 23.99 | < 0.01 | < 0.01 |
| | Max. PEC<sub>SED</sub> (µg/kg) | 2.88 | < 0.01 | < 0.01 |

| Met XVII | Compartment | STEP 1 | STEP 2 – North EU | STEP 2 – South EU |
|----------|-------------|--------|-------------------|-------------------|
| Winter cereals: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 10.2 | 0.01 | 0.02 |
| | Max. PEC<sub>SED</sub> (µg/kg) | 0.51 | < 0.01 | < 0.01 |
| Sugar beets: 1 × 200 g a.s./ha from BBCH 30 | Max. PEC<sub>SW</sub> (µg/L) | 10.2 | < 0.01 | 0.01 |
| | Max. PEC<sub>SED</sub> (µg/kg) | 0.51 | < 0.01 | < 0.01 |
| Parent FOCUS STEP 3 | Waterbody | Max. PEC\textsubscript{SW} (µg/L) | Dominant entry route | 7 d TWA PEC\textsubscript{SW} (µg/L) | Max. PEC\textsubscript{SED} (µg/kg) |
|---------------------|-----------|---------------------------------|---------------------|--------------------------------|---------------------|
| **Winter cereals: 1 × 200 g a.s./ha from BBCH 30** |           |                                 |                     |                                |                     |
| D1                  | ditch     | 1.3260                          | drift               | 1.1620                         | 1.0510              |
| D1                  | stream    | 1.1360                          | drift               | 0.1632                         | 0.2940              |
| D2                  | ditch     | 15.7900                         | drainage            | 5.9010                         | 4.2720              |
| D2                  | stream    | 10.0600                         | drainage            | 2.9550                         | 2.2270              |
| D3                  | ditch     | 1.2670                          | drift               | 0.1865                         | 0.2449              |
| D4                  | pond      | 0.0437                          | drift               | 0.0390                         | 0.0425              |
| D4                  | stream    | 1.0570                          | drift               | 0.0185                         | 0.0652              |
| D5                  | pond      | 0.0437                          | drift               | 0.0401                         | 0.0467              |
| D5                  | stream    | 1.1170                          | drift               | 0.0155                         | 0.0584              |
| D6                  | ditch     | 1.2740                          | drift               | 0.3950                         | 0.3643              |
| R1                  | pond      | 0.0437                          | drift               | 0.0397                         | 0.0637              |
| R1                  | stream    | 0.8948                          | run-off             | 0.0533                         | 0.1443              |
| R3                  | stream    | 1.1730                          | drift               | 0.0790                         | 0.1579              |
| R4                  | stream    | 0.8350                          | drift               | 0.0221                         | 0.0702              |
| **Sugar beets: 1 × 200 g a.s./ha from BBCH 30** |           |                                 |                     |                                |                     |
| D3                  | ditch     | 1.0480                          | drift               | 0.1476                         | 0.1988              |
| D4                  | pond      | 0.0423                          | drift               | 0.0371                         | 0.0379              |
| D4                  | stream    | 0.8396                          | drift               | 0.0056                         | 0.0244              |
| R1                  | pond      | 0.2555                          | run-off             | 0.2244                         | 0.2177              |
| R1                  | stream    | 3.1930                          | run-off             | 0.3787                         | 0.7442              |
| R3                  | stream    | 4.5740                          | run-off             | 0.4698                         | 0.7695              |
| Omethoate FOCUS STEP 3 | Waterbody | Max. PEC<sub>SW</sub> (µg/L) | Dominant entry route | 7 d TWA PEC<sub>SW</sub> (µg/L) | Max. PEC<sub>SED</sub> (µg/kg) |
|------------------------|-----------|-----------------------------|----------------------|-----------------------------|-----------------------------|
| **Winter cereals: 1 × 200 g a.s./ha from BBCH 30** |           |                             |                      |                             |                             |
| D1                     | ditch     | 0.0103                      | drainage             | 0.0081                      | 0.0057                      |
| D1                     | stream    | 0.0070                      | drainage             | 0.0049                      | 0.0031                      |
| D2                     | ditch     | 1.3800                      | drainage             | 0.7953                      | 0.2575                      |
| D2                     | stream    | 0.9692                      | drainage             | 0.4178                      | 0.1223                      |
| D3                     | ditch     | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D4                     | pond      | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D4                     | stream    | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D5                     | pond      | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D5                     | stream    | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D6                     | ditch     | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| R1                     | pond      | 0.0005                      | run-off               | 0.0004                      | 0.0003                      |
| R1                     | stream    | 0.0208                      | run-off               | 0.0012                      | 0.0013                      |
| R3                     | stream    | 0.0095                      | run-off               | 0.0013                      | 0.0009                      |
| R4                     | stream    | 0.0051                      | run-off               | 0.0002                      | 0.0003                      |
| **Sugar beets: 1 × 200 g a.s./ha from BBCH 30** |           |                             |                      |                             |                             |
| D3                     | ditch     | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D4                     | pond      | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| D4                     | stream    | < 0.0001                    | drainage             | < 0.0001                    | < 0.0001                    |
| R1                     | pond      | 0.0044                      | run-off               | 0.0043                      | 0.0024                      |
| R1                     | stream    | 0.0620                      | run-off               | 0.0073                      | 0.0057                      |
| R3                     | stream    | 0.0935                      | run-off               | 0.0102                      | 0.0065                      |
### Parent FOCUS STEP 4

| Nozzle reduction | Scenario | PEC<sub>sw</sub> (µg/L) |
|------------------|----------|-------------------------|
|                  | VFS (m)  | None        | None        | None        | None        | 10  | 20  |
|                  | Buffer (m) | None     | 3           | 5           | 10          | 20  | 10  | 20  |

Winter cereals: 1 × 200 g a.s./ha from BBCH 30

|                   | D1 ditch | D1 stream | D2 ditch | D2 stream | D3 ditch | D3 stream | D4 pond | D4 stream | D5 pond | D5 stream | D5 stream | D6 ditch |
|-------------------|----------|-----------|----------|-----------|----------|-----------|---------|-----------|---------|-----------|-----------|---------|
| None              | -        | -         | -        | -         | -        | -         | -       | -         | -       | -         | -         | -       |
| 50%               |          |           |          |           |          |           |         | 0.2435    | 0.2435  | 0.2435    | 0.2435    |         |
| 75%               |          |           |          |           |          |           |         | 0.2315    | 0.2315  | 0.2315    | 0.2315    |         |
| None              |          |           |          |           |          |           |         | 15.7900   | 15.7900 | 15.7900   | 15.7900   |         |
| 50%               |          |           |          |           |          |           |         | 0.2435    | 0.2435  | 0.2435    | 0.2435    |         |
| 75%               |          |           |          |           |          |           |         | 0.2315    | 0.2315  | 0.2315    | 0.2315    |         |
| None              |          |           |          |           |          |           |         | 10.0600   | 10.0600 | 10.0600   | 10.0600   |         |
| 50%               |          |           |          |           |          |           |         | 0.2435    | 0.2435  | 0.2435    | 0.2435    |         |
| 75%               |          |           |          |           |          |           |         | 0.2315    | 0.2315  | 0.2315    | 0.2315    |         |
| None              |          |           |          |           |          |           |         | 0.1821    | 0.1821  | 0.1821    | 0.1821    |         |
| 50%               |          |           |          |           |          |           |         | 0.0947    | 0.0947  | 0.0947    | 0.0947    |         |
| 75%               |          |           |          |           |          |           |         | 0.0947    | 0.0947  | 0.0947    | 0.0947    |         |
| None              |          |           |          |           |          |           |         | 0.0305    | 0.0305  | 0.0305    | 0.0305    |         |
| 50%               |          |           |          |           |          |           |         | 0.0199    | 0.0199  | 0.0199    | 0.0199    |         |
| 75%               |          |           |          |           |          |           |         | 0.0199    | 0.0199  | 0.0199    | 0.0199    |         |
| None              |          |           |          |           |          |           |         | 0.2093    | 0.2093  | 0.2093    | 0.2093    |         |
| 50%               |          |           |          |           |          |           |         | 0.1095    | 0.1095  | 0.1095    | 0.1095    |         |
| 75%               |          |           |          |           |          |           |         | 0.1095    | 0.1095  | 0.1095    | 0.1095    |         |
| None              |          |           |          |           |          |           |         | 0.0306    | 0.0306  | 0.0306    | 0.0306    |         |
| 50%               |          |           |          |           |          |           |         | 0.0199    | 0.0199  | 0.0199    | 0.0199    |         |
| 75%               |          |           |          |           |          |           |         | 0.0199    | 0.0199  | 0.0199    | 0.0199    |         |
| None              |          |           |          |           |          |           |         | 0.2210    | 0.2210  | 0.2210    | 0.2210    |         |
| 50%               |          |           |          |           |          |           |         | 0.1155    | 0.1155  | 0.1155    | 0.1155    |         |
| 75%               |          |           |          |           |          |           |         | 0.1155    | 0.1155  | 0.1155    | 0.1155    |         |
| None              |          |           |          |           |          |           |         | 0.1869    | 0.1869  | 0.1869    | 0.1869    |         |
| 50%               |          |           |          |           |          |           |         | 0.0980    | 0.0980  | 0.0980    | 0.0980    |         |
| 75%               |          |           |          |           |          |           |         | 0.0980    | 0.0980  | 0.0980    | 0.0980    |         |
|             |                  |                  |                  |       |
|-------------|------------------|------------------|------------------|-------|
| None        | R1 pond          | -                | 0.0352           | 0.0295|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R1 stream        | -                | 0.8948           | 0.8948|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R3 stream        | -                | 0.5732           | 0.5732|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R4 stream        | -                | 0.2818           | 0.2818|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |

Sugar beets: 1 × 200 g a.s./ha from BBCH 30

|             |                  |                  |                  |       |
|-------------|------------------|------------------|------------------|-------|
| None        | D3 ditch         | -                | 0.1821           | 0.0947|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | D4 pond          | -                | 0.0302           | 0.0196|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | D4 stream        | -                | 0.1904           | 0.0994|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R1 pond          | -                | 0.2479           | 0.2400|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R1 stream        | -                | 3.1930           | 3.1930|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| None        | R3 stream        | -                | 4.5740           | 4.5740|
| 50%         |                  |                  |                  |       |
| 75%         |                  |                  |                  |       |
| Omethoate FOCUS STEP 4 | Scenario | PEC<sub>sw</sub> (µg/L) |
|------------------------|----------|-------------------------|
| Nozzle reduction       | VFS (m)  | None | None | None | None | 10 | 20 |
| Buffer (m)             | None | 3   | 5   | 10   | 20   |

Winter cereals: 1 × 200 g a.s./ha from BBCH 30

| None | 50% | 75% | None | 50% | 75% | None | 50% | 75% | None | 50% | 75% | None | 50% | 75% | None | 50% | 75% | None | 50% | 75% | None | 50% | 75% |
|------|-----|-----|------|-----|-----|------|-----|-----|------|-----|-----|------|-----|-----|------|-----|-----|------|-----|-----|------|-----|-----|
| -    |     |     | 0.0103 | 0.0103 | 0.0103 | 0.0103 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | 0.0070 | 0.0070 | 0.0070 | 0.0070 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | 1.3800 | 1.3800 | 1.3800 | 1.3800 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | 0.9692 | 0.9692 | 0.9692 | 0.9692 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | <0.0001 | <0.0001 | <0.0001 | <0.0001 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | <0.0001 | <0.0001 | <0.0001 | <0.0001 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | <0.0001 | <0.0001 | <0.0001 | <0.0001 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | <0.0001 | <0.0001 | <0.0001 | <0.0001 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| -    |     |     | <0.0001 | <0.0001 | <0.0001 | <0.0001 |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|                | R1 pond   | R1 stream | R3 stream | R4 stream |
|----------------|-----------|-----------|-----------|-----------|
| None           | -         | 0.0005    | 0.0095    | 0.0051    |
| 50%            |            | 0.0208    | 0.0095    | 0.0051    |
| 75%            |            | 0.0086    | 0.0043    | 0.0021    |
| None           | -         | 0.0044    | 0.0095    | 0.0044    |
| 50%            |            | 0.018     | 0.0043    | 0.0021    |
| 75%            |            | 0.001     | 0.0023    | 0.0010    |

Sugar beets: 1 × 200 g a.s./ha from BBCH 30

|                | D3 ditch  | D4 pond   | D4 stream | R1 pond  |
|----------------|-----------|-----------|-----------|-----------|
| None           | -         | <0.0001   | <0.0001   | 0.0044    |
| 50%            |            | <0.0001   | <0.0001   | 0.0044    |
| 75%            |            | <0.0001   | <0.0001   | 0.0044    |
| None           | -         | <0.0001   | <0.0001   | 0.0044    |
| 50%            |            | <0.0001   | <0.0001   | 0.0044    |
| 75%            |            | <0.0001   | <0.0001   | 0.0044    |
| None           | -         |          | <0.0001   | 0.0044    |
| 50%            |            |          | <0.0001   | 0.0044    |
| 75%            |            |          | <0.0001   | 0.0044    |
| None           | -         | 0.0620    | 0.0620    | 0.0935    |
| 50%            |            | 0.0282    | 0.0282    | 0.0935    |
| 75%            |            | 0.0148    | 0.0148    | 0.0935    |
| None           | -         | 0.0935    | 0.0424    | 0.0935    |
| 50%            |            | 0.0424    | 0.0424    | 0.0935    |
| 75%            |            | 0.0222    | 0.0222    | 0.0935    |
Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

| Method of calculation | Maximum concentration of omethoate in drinking water resulting from water treatment and conversion of dimethoate calculated using an adapted version of DROPLET equation |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------|
| PEC                   | Maximum concentration                                                                                                                                                                 |


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**          |                |            |           |                            |
| Ring-necked Pheasant | a.s.          | Acute      | LD₅₀      | 14.1 mg a.s/kg bw          |
| Ring-necked Pheasant | Omethoate     | Acute      | LD₅₀, NOEL| 29 mg a.s/kg bw, 2.5 mg a.s/kg bw |
| Bobwhite quail     | a.s.           | Acute      | LD₅₀      | 10.5 mg a.s/kg bw          |
| Bobwhite quail     | Omethoate      | Acute      | LD₅₀, NOEL| 9.9 mg a.s/kg bw, 1.0 mg a.s/kg bw |
| Canary             | a.s.           | Acute      | LD₅₀, NOEL| 147 mg a.s/kg bw, 62.5 mg a.s/kg bw |
| Mallard            | a.s.           | Acute      | LD₅₀      | 44 mg a.s/kg bw            |
| Bobwhite quail     | a.s.           | 5-day      | LC₅₀      | 154 mg a.s/kg diet         |
| Ring-necked Pheasant | a.s.          | 5-day      | LC₅₀      | 369 mg a.s/kg diet         |
| Bobwhite quail     | Omethoate      | 5-day      | LC₅₀, NOEC| 90 mg a.s/kg diet, 3 mg/kg bw/d (11.8 mg a.s/kg diet) |
| Mallard            | Omethoate      | 5-day      | LC₅₀, NOEC| 1374 mg a.s/kg diet, 34 mg/kg bw/d (94 mg a.s/kg diet) |
| Mallard            | a.s.           | Long-term  | NOEC      | 10.1 mg a.s/kg diet, 1.0 mg a.s/kg bw/d |
| **Mammals**        |                |            |           |                            |
| Mouse              | a.s.           | Acute      | LD₅₀      | 160 mg a.s/kg bw           |
| Rat                | Formulation 400 g a.s./L EC | Acute | LD₅₀ | 550 mg a.s/kg bw |
| Rat                | Omethoate      | acute      | LD₅₀      | 22 mg/kg bw                |
| Rat                | a.s.           | Long-term  | NOEL      | 1.0 mg a.s/kg bw/d         |
| Rat                | Omethoate      | Long-term  | NOEL      | 0.4 mg/kg bw/d             |

Endocrine disrupting properties (Annex Part A, points 8.1.5)

No evidence of dimethoate having endocrine effects in mammals. Among wildlife, available information from two avian reproduction studies (northern bobwhite quail and mallard duck) do not indicate endocrine mediated
effects. This is confirmed by the histopathological findings.

In the available Fish Short Term Reproduction assay effects on fecundity (number of eggs per female) and gonadosomatic index in males were observed at the highest tested dose. However, the effects in males were observed in conjunction with effects on body weight.

In the amphibian metamorphosis assay (AMA), histopathological effects were observed such as increased incidence of thyroid gland hypertrophy and increase in follicular cell height at the highest tested concentration of 100 mg a.i./L. Although those effects were only observed at the highest tested concentration, there were no other signs attributable to overt toxicity such as mortality, growth or developmental effect at that concentration.

Additional higher tier studies (Annex Part A, points 10.1.1.2):

**Residue decline on vegetation and arthropods:**
Residue decline data in ground vegetation and arthropods are available in Hanebeck and Hankes (2011). Data for arthropods have been reanalyzed (Payne and Nicholson, 2016). These data are not used to refine the chronic risk assessment of mammals because one study alone is considered not sufficient at EU level. Nevertheless, at national level, the available data may be considered further.

**Higher tier effect studies:**

Only the study by Dittrich & Benito (2016) was considered reliable. The study was conducted to investigate potential effects on birds following application of dimethoate 400 g/L EC 1 × 200 g a.s./ha in sugar beet fields in Germany. The field study provides no evidence for adverse acute effects in the focal species skylark and yellow wagtail which were the only species investigated. Information on unaffected nest success of skylark and yellow wagtail, was also available.

The study was discussed at the Peer Review Experts’ meeting 177 (April, 2018). Overall the majority of experts agreed not to use this study for RA, because is not enough for demonstrating low acute and chronic risk.

A field effect study on mammals (Hofmann et al., 2013) was conducted in Germany on sugarbeet. Dimethoate was applied twice at 240 g a.s./ha. The study included three treated and three untreated plots, over a total area of 19.9 hectares. A large number of small mammals was captured during the study, including bank voles (2184 captures, 479 individuals), yellow-necked mice (1213 captures, 391 individuals), common voles (1035 captures, 357 individuals) and wood mice (692 captures, 325 individuals). The high number of voles across the study plots was associated with a population explosion in 2012, with most individuals being caught in the off-crop areas. No carcasses were recovered during the field phase of the study. Additionally, the study report concludes that there were no treatment related effects on body weight development, sex ratio, reproductive status or minimum number alive for any of the four small mammal species captured. It was therefore concluded that there were no acute or long-term effects on any of the small mammal populations trapped during the 5-month post application monitoring period following two applications of dimethoate (240 g a.s./ha).

The experts at the Peer Review experts’ meeting 177 agreed that the study is not reliable and as such not used in risk assessment.

**Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Regulation (EU) N° 284/2013 Annex Part A, points 8.1.4):**

| Bullfrog a.s. | Acute | LD<sub>50</sub> Males | 1459 mg a.s./kg bw |
|--------------|-------|----------------------|-------------------|

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

Toxicity endpoints:

**Dimethoate**

Bird Acute toxicity endpoint: LD<sub>50</sub>geomean = 31.2 mg a.s./kg bw

Bird Long-term toxicity endpoint: not available.
Mammal acute toxicity endpoint: LD$_{50}$ 160 mg a.s./kg bw
Mammal long-term endpoint: 1.0 mg a.s./kg bw/d

**Omethoate**

Bird Acute toxicity endpoint: LD$_{50 \text{geo mean}} = 16.9$ mg a.s./kg bw
Bird Long-term toxicity endpoint: not available.

Mammal acute toxicity endpoint: LD$_{50}$ 22 mg a.s./kg bw
Mammal long-term endpoint: NOAEL 0.4 mg a.s./kg bw/d

| Growth Stage | Indicator or focal species | Time scale | DDD (mg/kg bw/d) | TER | Trigger |
|--------------|----------------------------|------------|------------------|-----|---------|
| Screenin... | No screening step conducted |            |                  |     |         |
| **Tier 1 (Birds, Dimethoate, Wheat 1 application at 200 g a.s./ha)** |

| Cereals BBCH 30-39 | Small omnivorous bird ‘lark’ Woodlark (Lullula arborea) | acute | 2.4 | 13.04 | 10 |
|--------------------|--------------------------------------------------------|-------|-----|-------|----|
| Cereals BBCH ≥40 | Small omnivorous bird ‘lark’ Woodlark (Lullula arborea) | acute | 1.44 | 21.7  | 10 |
| **Tier 1 (Birds, Dimethoate, Sugarbeet 1 application at 200 g a.s./ha)** |

| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (Carduelis cannabina) | acute | 4.94 | **6.3** | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 1.54 | 20.3  | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 5.04 | **6.2** | 10 |
| Stage | Plant | Bird Type | Species | Toxicity | Exponential | Mortality | Notes |
|-------|-------|-----------|---------|----------|-------------|----------|-------|
| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (Carduelis cannabina) | acute | 3 | 10.56 | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 0.9 | 33.9 | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 3 | 10.35 | 10 |

**Tier 1 (Birds acute, Omethoate, Wheat 1 application at 200 g a.s./ha)**

| Stage | Plant | Bird Type | Species | Toxicity | Exponential | Mortality | Notes |
|-------|-------|-----------|---------|----------|-------------|----------|-------|
| Cereals BBCH 30-39 | Small omnivorous bird ‘lark’ Woodlark (Lullula arborea) | acute | 2.40 | **7.04** | 10 |
| Cereals BBCH ≥40 | Small omnivorous bird ‘lark’ Woodlark (Lullula arborea) | acute | 1.44 | 11.7 | 10 |

**Tier 1 (Birds, Omethoate, Sugarbeet 1 application at 200 g a.s./ha)**

| Stage | Plant | Bird Type | Species | Toxicity | Exponential | Mortality | Notes |
|-------|-------|-----------|---------|----------|-------------|----------|-------|
| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (Carduelis cannabina) | acute | 4.94 | **3.4** | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 1.54 | 11.0 | 10 |
| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (Motacilla flava) | acute | 5.04 | **3.3** | 10 |

**Tier 1 (Birds, Omethoate, Sugarbeet 1 application at 120 g a.s./ha)**
| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (*Carduelis cannabina*) | acute | 3 | 5.7 | 10

| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (*Motacilla flava*) | acute | 0.9 | 18.3 | 10

| Sugar beet BBCH 20-49 | Small insectivorous bird ‘wagtail’ Yellow wagtail (*Motacilla flava*) | acute | 3 | 5.6 | 10

**Acute exposure refinement; Dimethoate, Sugarbeet 1 application at 120 g a.s./ha**

**Crop interception**

| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (*Carduelis cannabina*) | acute | 1.48* | 21.8 | 10

*Based on a deposition factor of 0.3

**Acute exposure refinement; Omethoate, Wheat 1 application at 200 g a.s./ha**

**Crop interception**

| Cereals BBCH 30-39 | Small omnivorous bird ‘lark’ Woodlark (*Lullula arborea*) | acute | 1.39 | 12.2* | 10

*Based on a deposition factor of 0.2 for crop leaves and weed seeds

**Acute exposure refinement; Omethoate, Sugar beet 1 application at 200 g a.s./ha**

**Crop interception**

| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (*Carduelis cannabina*) | acute | 1.48 | 11.4 | 10

**Acute exposure refinement; Omethoate, Sugar beet application at 120 g a.s./ha**

| Sugar beet BBCH 30-49 late summer | Small granivorous bird ‘finch’ Linnet (*Carduelis cannabina*) | acute | 0.89 | 19 | 10

**Long-term risk assessment**

No long-term toxicity endpoints on birds for dimethoate and omethoate are available.
Mammals

Screening Step (Mammals)

*No screen step conducted*

| Growth | Indicator or focal | Time scale | DDD | TER | Trigger |
|--------|-------------------|------------|-----|-----|---------|
| **Tier 1 (Mammals, Dimethoate, Wheat 1 application at 200 g a.s./ha)** | | | | | |
| Cereals BBCH ≥20 | Small insectivorous mammal 'shrew' | Acute | 1.07 | 150 | 10 |
| Cereals BBCH ≥40 | Small herbivorous mammal 'vole' | Acute | 8.16 | 19.6 | 10 |
| Cereals BBCH 30-39 | Small omnivorous mammal 'mouse' | Acute | 1.77 | 89.9 | 10 |
| Cereals BBCH ≥40 | Small omnivorous mammal 'mouse' | Acute | 1.11 | 144 | 10 |
| Cereals BBCH ≥20 | Small insectivorous mammal 'shrew' | Long-term | 0.20 | 5 | 5 |
| Cereals BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 2.29 | 0.44 | 5 |
| Cereals BBCH 30-39 | Small omnivorous mammal 'mouse' | Long-term | 0.42 | 2.38 | 5 |
| Cereals BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.26 | 3.85 | 5 |
| **Tier 1 (Mammals, Dimethoate, Sugarbeet 1 application at 200 g a.s./ha)** | | | | | |
| Sugar beet BBCH ≥20 | Small insectivorous mammal 'shrew' | Acute | 1.07 | 150 | 10 |
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Acute | 6.80 | 23.5 | 10 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Acute | 7.03 | 22.8 | 10 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Acute | 1.76 | 91.0 | 10 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Acute | 3.43 | 46.7 | 10 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Acute | 0.96 | 167 | 10 |
| Sugar beet BBCH ≥20 | Small insectivorous mammal 'shrew' | Long-term | 0.20 | 5 | 5 |
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 1.91 | 0.52 | 5 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Long-term | 1.52 | 0.66 | 5 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Long-term | 0.38 | 2.63 | 5 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Long-term | 0.82 | 1.22 | 5 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.22 | 4.55 | 5 |
| **Tier 1 (Mammals, Dimethoate, Sugarbeet 1 application at 120 g a.s./ha)** | | | | | |
| Sugar beet BBCH ≥20 | Small insectivorous mammal 'shrew' | Acute | 0.6 | 247 | 10 |
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Acute | 4.1 | 39.1 | 10 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Acute | 4.2 | 38 | 10 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Acute | 1.1 | 151 | 10 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Acute | 2.1 | 77.5 | 10 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Acute | 0.5 | 310 | 10 |
### Tier 1 (Mammals, Omethoate, Wheat 1 application at 200 g a.s./ha)

| Plant          | Stage          | Animal                        | Type          | EC50 (mg/kg) | LC50 (mg/kg) | WP |
|----------------|----------------|-------------------------------|---------------|--------------|--------------|----|
| Sugar beet     | BBCH ≥20       | Small insectivorous mammal 'shrew' | Long-term     | 0.1          | 8.3          | 5  |
| Sugar beet     | BBCH ≥40       | Small herbivorous mammal 'vole' | Long-term     | 1.1          | 0.9          | 5  |
| Sugar beet     | BBCH 10-39     | Large herbivorous mammal 'lagomorph' | Long-term | 0.9          | 1.1          | 5  |
| Sugar beet     | BBCH ≥40       | Large herbivorous mammal 'lagomorph' | Long-term  | 0.2          | 4.4          | 5  |
| Sugar beet     | BBCH 10-39     | Small omnivorous mammal 'mouse' | Long-term     | 0.5          | 2            | 5  |
| Sugar beet     | BBCH ≥40       | Small omnivorous mammal 'mouse' | Long-term     | 0.1          | 8.3          | 5  |

### Tier 1 (Mammals, Omethoate, Sugarbeet 1 application at 200 g a.s./ha)

| Plant          | Stage          | Animal                        | Type          | EC50 (mg/kg) | LC50 (mg/kg) | WP |
|----------------|----------------|-------------------------------|---------------|--------------|--------------|----|
| Cereals        | BBCH ≥20       | Small insectivorous mammal 'shrew' | Acute        | 1.07         | 20.6         | 10 |
| Cereals        | BBCH ≥40       | Small herbivorous mammal 'vole' | Acute        | 8.16         | 2.7          | 10 |
| Cereals        | BBCH 30-39     | Small omnivorous mammal 'mouse' | Acute        | 1.78         | 12.48        | 10 |
| Cereals        | BBCH ≥40       | Small omnivorous mammal 'mouse' | Acute        | 1.11         | 21.2         | 10 |
| Cereals        | BBCH ≥20       | Small insectivorous mammal 'shrew' | Long-term    | 0.20         | 2            | 5  |
| Cereals        | BBCH ≥40       | Small herbivorous mammal 'vole' | Long-term    | 2.29         | 0.17         | 5  |
| Cereals        | BBCH 30-39     | Small omnivorous mammal 'mouse' | Long-term    | 0.42         | 0.95         | 5  |
| Cereals        | BBCH ≥40       | Small omnivorous mammal 'mouse' | Long-term    | 0.26         | 1.54         | 5  |

### Tier 1 (Mammals, Omethoate, Sugarbeet 1 application at 120 g a.s./ha)

| Plant          | Stage          | Animal                        | Type          | EC50 (mg/kg) | LC50 (mg/kg) | WP |
|----------------|----------------|-------------------------------|---------------|--------------|--------------|----|
| Sugar beet     | BBCH ≥20       | Small insectivorous mammal 'shrew' | Acute        | 1.07         | 20.6         | 10 |
| Sugar beet     | BBCH ≥40       | Small herbivorous mammal 'vole' | Acute        | 6.8          | 3.2          | 10 |
| Sugar beet     | BBCH 10-39     | Large herbivorous mammal 'lagomorph' | Acute    | 7.03         | 3.1          | 10 |
| Sugar beet     | BBCH ≥40       | Large herbivorous mammal 'lagomorph' | Acute    | 1.76         | 12.5         | 10 |
| Sugar beet     | BBCH 10-39     | Small omnivorous mammal 'mouse' | Acute        | 3.43         | 6.4          | 10 |
| Sugar beet     | BBCH ≥40       | Small omnivorous mammal 'mouse' | Acute        | 0.96         | 22.9         | 10 |
| Sugar beet     | BBCH ≥20       | Small insectivorous mammal 'shrew' | Long-term    | 0.20         | 2            | 5  |
| Sugar beet     | BBCH ≥40       | Small herbivorous mammal 'vole' | Long-term    | 1.91         | 0.21         | 5  |
| Sugar beet     | BBCH 10-39     | Large herbivorous mammal 'lagomorph' | Long-term | 1.52         | 0.26         | 5  |
| Sugar beet     | BBCH ≥40       | Large herbivorous mammal 'lagomorph' | Long-term  | 0.38         | 1.05         | 5  |
| Sugar beet     | BBCH 10-39     | Small omnivorous mammal 'mouse' | Long-term    | 0.82         | 0.49         | 5  |
| Sugar beet     | BBCH ≥40       | Small omnivorous mammal 'mouse' | Long-term    | 0.22         | 1.82         | 5  |

### Tier 1 (Mammals, Omethoate, Sugarbeet 1 application at 120 g a.s./ha)

| Plant          | Stage          | Animal                        | Type          | EC50 (mg/kg) | LC50 (mg/kg) | WP |
|----------------|----------------|-------------------------------|---------------|--------------|--------------|----|
| Sugar beet     | BBCH ≥20       | Small insectivorous mammal 'shrew' | Acute        | 0.6          | 34           | 10 |
| Sugar beet     | BBCH ≥40       | Small herbivorous mammal 'vole' | Acute        | 4.1          | 5.4          | 10 |
| Sugar beet     | BBCH 10-39     | Large herbivorous mammal 'lagomorph' | Acute    | 4.2          | 5.2          | 10 |
| Sugar beet     | BBCH ≥40       | Large herbivorous mammal 'vole' | Acute        | 1.1          | 20.8         | 10 |
### Peer review of the pesticide risk assessment of the active substance dimethoate

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| BBCH ≥40 | mammal 'lagomorph' | Acute | 2.1 | 10.7 | 10 |
|----------|---------------------|-------|-----|------|-----|
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' |       | 0.5 | 42.6 | 10 |
| Sugar beet BBCH ≥40 | Small insectivorous mammal 'shrew' | Long-term | 0.1 | 3.3 | 5 |
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 1.1 | 0.3 | 5 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Long-term | 0.2 | 1.8 | 5 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Long-term | 0.5 | 0.8 | 5 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.1 | 3.3 | 5 |

**Higher tier (Mammals, Dimethoate)**:

Exposure refinement - Crop interception (FOCUS groundwater report, 2014, Wheat 1 application rate at 200 g a.s./ha)

| Growth | Indicator or focal | Time scale | DDD | TER | Trigger |
|---------|-------------------|------------|-----|-----|---------|
| Cereals BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 0.76 | 1.31 | 5 |
| Cereals BBCH 30-39 | Small omnivorous mammal 'mouse' | Long-term | 0.19 | 5.2 | 5 |
| Cereals BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.11 | 9.1 | 5 |

**Sugar beet 1 application rate at 200 g a.s./ha**

| Growth | Indicator or focal | Time scale | DDD | TER | Trigger |
|---------|-------------------|------------|-----|-----|---------|
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 0.76 | 1.31 | 5 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Long-term | 1.52 | 0.65 | 5 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Long-term | 0.15 | 6.8 | 5 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Long-term | 0.06 | 3.85 | 5 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.11 | 9.1 | 5 |

*Only the scenario that can be refined using crop interception are reported*

**Higher tier (Mammals, Omethoate)**:

Exposure refinement - Crop interception (FOCUS groundwater report, 2014, Wheat 1 application rate at 200 g a.s./ha)

| Growth | Indicator or focal | Time scale | DDD | TER | Trigger |
|---------|-------------------|------------|-----|-----|---------|
| Cereals BBCH ≥40 | Small herbivorous mammal 'vole' | Acute | 2.72 | 8.1 | 10 |
| Cereals BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 0.76 | 0.5 | 5 |
| Cereals BBCH 30-39 | Small omnivorous mammal 'mouse' | Long-term | 0.19 | 2.1 | 5 |
| Cereals BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.11 | 3.6 | 5 |

**Sugar beet at application rate 200 g a.s./ha**

| Growth | Indicator or focal | Time scale | DDD | TER | Trigger |
|---------|-------------------|------------|-----|-----|---------|
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Acute | 2.72 | 8.1 | 10 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Acute | 2.11 | 10.4 | 10 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Acute | 0.70 | 31.4 | 10 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Acute | 1.11 | 19.8 | 10 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Acute | 0.45 | 48.9 | 10 |
| BBCH ≥40 | mammal 'mouse' | PECwxDWR | TER | Trigger |
|----------|----------------|-----------|-----|---------|
| Sugar beet BBCH ≥40 | Small herbivorous mammal 'vole' | Long-term | 0.76 | 0.5 | 5 |
| Sugar beet BBCH 10-39 | Large herbivorous mammal 'lagomorph' | Long-term | 1.52 | 0.3 | 5 |
| Sugar beet BBCH ≥40 | Large herbivorous mammal 'lagomorph' | Long-term | 0.15 | 2.7 | 5 |
| Sugar beet BBCH 10-39 | Small omnivorous mammal 'mouse' | Long-term | 0.26 | 1.5 | 5 |
| Sugar beet BBCH ≥40 | Small omnivorous mammal 'mouse' | Long-term | 0.11 | 3.6 | 5 |

*Only the scenario that can be refined using crop interception are reported

### Risk from bioaccumulation and food chain behaviour

**Not required for dimethoate or Omethoate as LogP < 3**
Dimethoate: 0.75
Omethoate: -0.9

### Risk from consumption of contaminated water

| Scenarios | Indicator or focal species | Time scale | PECwxDWR | TER | Trigger |
|-----------|---------------------------|------------|----------|-----|---------|
| Leaf scenario | | | Not applicable | | |
| Puddle scenario | | Long-term* | | - | - | 5 |
| Puddle Scenario | Small granivorous bird | Long-term | - | - | 5 |
| Puddle scenario, dimethoate | Small granivorous mammals | Long-term | 0.074 | 13.5 | 5 |
| Puddle scenario, omethoate | Small granivorous mammals | Long-term | 0.074 | 5.4 | 5 |

*Non long-term endpoint available for birds

### 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 |
|-------|----------------|------------------------|-----------|----------|
| Laboratory tests | | | | |
## Group Test substance Time-scale (Test type) End point Toxicity\(^1\)

### Fish

**Oncorhynchus mykiss** a.s. Acute (semi-static) 96-h LC\(_{50}\) mm 24 mg a.s./L

**Lepomis macrochirus** a.s. Acute (semi-static) 96-h LC\(_{50}\) mm 31 mg a.s./L

**Cyprindon variegatus** a.s. Acute (static) 96-h LC\(_{50}\) mm &gt;111 mg a.s./L

**Lepomis macrochirus** Formulation 400 g a.s/L EC Acute (semi-static) 96-h LC\(_{50}\) mm 43.98 mg f.p./L 17.6 mg a.s./L

**Lepomis macrochirus** Formulation CHA 3621-04 Acute (semi-static) 96-h LC\(_{50}\) mm &gt; 100 mg f.p./L 37.7 mg a.s./L

**Oncorhynchus mykiss** Formulation 400 g a.s/L EC Acute (semi-static) 96-h LC\(_{50}\) mm 61.3 mg f.p./L 24.5 mg a.s./L

**Oncorhynchus mykiss** O-desmethyl dimethoate (Met X) Acute (static) 96-h LC\(_{50}\) nom &gt;100 mg met/L

**Oncorhynchus mykiss** O,O-dimethyl thiophosphoric acid (Met XVI) Acute (static) 96-h LC\(_{50}\) nom &gt;1000 mg met/L

**Onecrhyonchus mykiss** O,O-dimethyl phosphoric acid (Met XVII) Acute (static) 96-h LC\(_{50}\) nom &gt;1000 mg met/L

**Lepomis macrochirus** Omethoate Acute (semi-static) 96-h LC\(_{50}\) mm 7.7 mg met/L

**Oncorhynchus mykiss** Omethoate Acute (semi-static) 96-h LC\(_{50}\) mm 5.2 mg met/L

**Oncorhynchus mykiss** a.s. Prolonged toxicity study* 21-d NOEC\(_{\text{mm}}\) (body weight) 21-d NOEC\(_{\text{mm}}\) (body weight) 0.4 mg a.s./L 2 mg a.s./L

**Oncorhynchus mykiss** a.s. Chronic (flow-through) 96-d NOEC\(_{\text{mm}}\) (60-d post hatch length and weight) EC10 (60-d post hatch wet weight) EC20 (60-d post hatch wet weight) EC10 (60-d post hatch length) 1.5 mg a.s./L 1.30 mg a.s./L 4.29 mg a.s./L 5.14 mg a.s./L

### Aquatic invertebrates

**Daphnia magna** a.s. Acute (static) 48-h EC\(_{50}\) nom 2.0 mg a.s./L

**Daphnia magna** Formulation 400 g a.s./L EC Acute (static) 48-h EC\(_{50}\) mm 5.44 mg f.p./L 2.2 mg a.s./L
| Group                | Test substance                                      | Time-scale (Test type) | End point          | Toxicity¹  |
|---------------------|-----------------------------------------------------|------------------------|-------------------|------------|
| Daphnia magna       | Formulation CHA 3621-04                             | Acute (static)         | 48-h EC₅₀ nom     | 8.9 mg f.p./L |
|                     |                                                     |                        |                   | 3.4 mg a.s./L |
| Daphnia magna       | O-desmethyl dimethoate (Met X)                      | Acute (static)         | 48-h EC₅₀ nom     | >100 mg met/L |
| Daphnia magna       | O,O-dimethyl thiophosphoric acid (Met XVI)          | Acute (static)         | 48-h EC₅₀ nom     | 70.5 mg met/L |
| Daphnia magna       | O,O-dimethyl phosphoric acid (Met XVII)             | Acute (static)         | 48-h EC₅₀ nom     | >1000 mg met/L |
| Daphnia magna       | Omethoate                                           | Acute (static)         | 48-h EC₃₅ nom EC₂₀ nom EC₅₀ nom | 0.018 mg met/L |
|                     |                                                     |                        |                   | 0.022 mg met/L |
|                     |                                                     |                        |                   | 0.033 mg met/L |
| Mysidopsis bahia    | a.s.                                                | Acute (static)         | 96-h EC₅₀ mm      | 15.0 mg a.s./L |
| Perla sp            | Omethoate                                           | Acute (semi-static)    | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.63 mg met/L |
|                     |                                                     |                        |                   | 0.87 mg met/L |
|                     |                                                     |                        |                   | 1.60 mg met/L |
| Hyalella azteca     | Omethoate                                           | Acute (semi-static)    | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.24 mg met/L |
|                     |                                                     |                        |                   | 0.29 mg met/L |
|                     |                                                     |                        |                   | 0.38 mg met/L |
| Gammarus pulex      | Omethoate                                           | Acute (semi-static)    | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.34 mg met/L |
|                     |                                                     |                        |                   | 0.36 mg met/L |
|                     |                                                     |                        |                   | 0.42 mg met/L |
| Ephemerelela sp     | Omethoate                                           | Acute (semi-static)    | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.10 mg met/L |
|                     |                                                     |                        |                   | 0.14 mg met/L |
|                     |                                                     |                        |                   | 0.27 mg met/L |
| Culex pipiens       | Omethoate                                           | Acute (static)         | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.15 mg met/L |
|                     |                                                     |                        |                   | 0.17 mg met/L |
|                     |                                                     |                        |                   | 0.22 mg met/L |
| Chironomus riparius | Omethoate                                           | Acute (static)         | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 0.18 mg met/L |
|                     |                                                     |                        |                   | 0.25 mg met/L |
|                     |                                                     |                        |                   | 0.46 mg met/L |
| Asellus aquaticus   | Omethoate                                           | Acute (semi-static)    | 96-h EC₁₀ nom EC₂₀ nom EC₅₀ nom | 1.00 mg met/L |
|                     |                                                     |                        |                   | 1.30 mg met/L |
|                     |                                                     |                        |                   | 2.15 mg met/L |
| Daphnia magna       | a.s.                                                | Chronic (semi-static)  | 21-d NOEC₉₀ nom   | 0.04 mg a.s./L |
| Daphnia magna       | Omethoate                                           | Chronic (semi-static)  | 21-d NOEC mm (age at first brood) | 0.00025 mg/L |
| Daphnia magna       | Omethoate                                           | Chronic (semi-static)  | 21-d NOEC mm      | 0.0058 mg/L** |
| Group                              | Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|-----------------------------------|----------------|------------------------|-----------|-----------|
|                                   |                | Double 24-h pulsed     |           | 0.0066 mg/L (ini) |
| **Daphnia magna**                 | Omethoate      | Chronic Single 24-h pulsed | 21-d NOEC mm | 0.0054 mg/L** |
| **Americamysis bahia**            | a.s.           | Chronic (flow-through) | 32-d NOEC mm (adult survival) EC₁₀₀ mm (adult survival) EC₂₀₀ mm (adult survival) | 0.14 mg a.s./L 0.28 mg/L 1.00 mg/L |
| **Sediment-dwelling organisms**   |                |                        |           |           |
| *Chironomus riparius*             | a.s.           | Chronic (water-spike)  | 28-d NOEC mm | 0.0451 mg a.s./L 0.0431 mg a.s./L |
| **Algae**                         |                |                        |           |           |
| *Pseudokirchneriella subcapitata* | a.s.           | Chronic (static)       | Growth rate: 72/96-h Er₅₀ mm Biomass: 72/96-h Eb₅₀ mm | >95 mg/L >95 mg/L |
| *Pseudokirchneriella subcapitata* | Formulation 400 g a.s./L EC | Chronic (static)       | Growth rate: 72-h Er₅₀ mm | 499 mg f.p. |
| *Pseudokirchneriella subcapitata* | Formulation CHA 3621-04 | Chronic (static)       | Growth rate: 72-h Er₅₀ mm geo 72-h Er₂₀₀ mm geo 72-h Er₅₀ mm geo Biomass: 72-h Eb₂₀₀ mm geo 72-h Eb₅₀ mm geo | 209 mg f.p./L 92.7 mg a.s./L 303 mg f.p./L 78.8 mg a.s./L 533 mg f.p./L 201 mg a.s./L 47.3 mg f.p./L <17.8 mg a.s./L 246 mg f.p./L 92.7 mg a.s./L |
| *Pseudokirchneriella subcapitata* | Omethoate      | Chronic (static)       | 72-h Er₅₀ mm geo 72-h Er₂₀₀ mm geo | >74.7 mg met/L >74.7 mg met/L |
| *Skeletonema costatum*            | a.s.           | Chronic (static)       | 96-h Er₂₀₀ mm 96-h Er₅₀ mm | >96.0 mg a.s./L >96.0 mg a.s./L |
| *Pseudokirchneriella subcapitata* | O-Desmethyl dimethoate (Met X) | Chronic (static)       | 72-h Er₅₀ mm | >100 mg met/L |
### Group Testing on Aquatic Species

| Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|----------------|------------------------|-----------|-----------|
| Higher plant   |                        |           |           |
| *Not triggered for dimethoate* |                        |           |           |

### Further Testing on Aquatic Organisms

**Xenopus laevis** a.s.

- **Acute**
- **96-h LC₅₀**
- **>98 mg a.s./L**

¹ nom: nominal concentrations / mm: mean measured concentrations / twa: time weighted average concentrations / geo: geometric mean measured

*Although the study gives a lower endpoint, this was not used for risk assessment as this type of study is no longer required and does not address potential reproductive effects.

**Not used for risk assessment, as the risk was low with mitigation measures.

### Bioconcentration in Fish (Annex Part A, point 8.2.2.3)

|                      | Active substance | Omethoate |
|----------------------|------------------|-----------|
| **logP**₀/W          | 0.75 at 20°C     | -0.9      |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | Not triggered | Not triggered |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | - | - |
| Annex VI Trigger for the bioconcentration factor | - | - |
| Clearance time (days) (CT₅₀) | - | - |
| (CT₉₀) | - | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | - | - |
| Higher tier study | *None* | |

*based on total ^14C*
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS<sub>sw</sub> step 1-3 - TERs for dimethoate – modelled on use in Wheat (BBCH >30) at 200 g a.s./ha x 1**

| Scenario   | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae                |
|------------|-----------------------|------------|--------------|-----------------------|---------------------------------|------------------------|----------------------|
|            |                       | L. macrochirus | O. mykiss | D. magna | D. magna | C. riparius | P. subcapitata |
|            |                       | 96-h LC<sub>50</sub> | 96-d EC<sub>10</sub> | 48-h EC<sub>90</sub> | 21-d NOEC | 28-d EC<sub>10</sub> | 96-h EC<sub>90</sub> |
|            |                       | 24000 µg/L | 1300 µg/L | 2000 µg/L | 40 µg/L | 43.1µg/L | >95,000 µg/L |
| **FOCUS Step 1** | 62.81 | 382 | 20.7 | 31.8 | 0.64 | 0.69 | >1512 |
| **FOCUS Step 2** | 5.07 | 394 | 7.89 | 8.50 |
| North Europe | 8.7 | 230 | 4.6 | 4.95 |
| **FOCUS Step 3** | 1.326 | 30.17 |
| D1 ditch | 1.136 | 35.21 |
| D1 stream | 10.06 | 3.9 | 4.28 |
| D2 ditch | 15.79 | 31.57 |
| D2 stream | 2.53 | 2.73 |
| D3 ditch | 31.57 | 34.02 |
| D3 stream | 4.6 | 4.95 |
| D4 ditch | 0.0437 | 915.3 |
| D4 stream | 1.057 | 37.84 |
| D5 pond | 0.0437 | 915.3 |
| D5 stream | 1.117 | 35.81 |
| R1 pond | 0.0437 | 915.3 |
| R1 stream | 0.8948 | 44.70 |
| R3 stream | 0.835 | 47.90 |
| R4 stream | 915.3 | 986 |

*Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 1-2 should be included in step 3.*
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS sw step 1-3 - TERs for dimethoate – modelled on use in Sugar beet (BBCH >30) at 1 × 200 g a.s./ha**

| Scenario               | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | P. subcapitata |
|------------------------|-----------------------|------------|--------------|-----------------------|---------------------------------|------------------------|----------------|
|                        |                       | Lepomis macrochirus | O. mykiss | D. magna | D. magna | C. riparius | 96-h E/C50 |
|                        | 96-h LC50             | 96-d EC10 | 48-h EC50 | 21-d NOEC | 28-d EC10 | >95,000 µg/L |
|                        | 24000 µg/L            | 1300 µg/L | 200 µg/L   | 40 µg/L    | 43.1 µg/L | |

**FOCUS Step 1**

|                     | 62.81 | 382 | 20.7 | 31.8 | 0.64 | 0.69 | >1512 |

**FOCUS Step 2**

|                   | North Europe | 2.81 | 712 | 14.2 | 15.34 |
|-------------------|--------------|------|-----|------|-------|
|                   | South Europe | 4.17 | 480 | 9.6  | 10.34 |

**FOCUS Step 3**

|                    | D3 ditch | 1.048 | -   | -    | 38.2  | 41.1 | -    |
|--------------------|----------|-------|-----|------|-------|------|------|
|                    | D4 pond  | 0.0423 | -   | -    | 945.6 | 1018 | -    |
|                    | D4 stream | 0.8396 | -   | -    | 47.64 | 51.3 | -    |
|                    | R1 pond  | 0.2555 | -   | -    | 156.6 | 168.7 | -    |
|                    | R1 stream | 3.193  | -   | -    | 12.53 | 13.5 | -    |
|                    | R3 stream | 4.574  | -   | -    | 8.75  | 9.4  | -    |

**Trigger**

|                    | 100 | 10 | 100 | 10 | 10 | 10 |

*[Only scenarios where the trigger is not met at FOCUS sw step 1-2 should be included in step 3.]
* *[Only scenarios where the trigger is not met at FOCUS sw step 1-2 should be included in step 3.]*
FOCUS<sub>sw</sub> step 4 – Daphnia Chronic TER for dimethoate – modelled on use in Wheat (BBCH >30) and sugar beet (BBCH >30) at 1 × 200 g a.s./ha with spray mitigation

| Crop              | Species          | Test substance | 21-d NOEC (µg a.s./L) | FOCUS Scenario | PEC<sub>sw</sub> (µg/L) | TER<sub>A</sub> | Trigger value |
|-------------------|------------------|----------------|-----------------------|----------------|-------------------------|----------------|----------------|
| **FOCUS Step 4 with 20 m VFS+ 20 m Buffer zone** |                 |                |                       |                |                        |                |                |
| Wheat             | *Daphnia magna* | Dimethoate     | 40                    | D2 ditch       | 15.79                   | 2.53           | 10             |
|                   |                  |                |                       | D2 stream      | 10.06                   | 3.98           |                |
| **FOCUS Step 4 with 10 m VFS+10 m Buffer zone** |                 |                |                       |                |                        |                |                |
| Sugar beet        | *Daphnia magna* | Dimethoate     | 40                    | R3 stream      | 2.074                   | 19.3           | 10             |
| Sugar beet        | *C. riparius*   | Dimethoate     | 43.1                  | R3 stream      | 2.074                   | 20.2           | 10             |
### Metabolites

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

**FOCUS<sub>sw</sub> step 1-3 - TERs for the metabolite omethoate – modelled on use in Wheat (BBCH >30) at 1 × 200 g a.s./ha**

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae |
|----------|-----------------------|------------|--------------|-----------------------|----------------------------------|-------|
|          |                       | O. mykiss  | O. mykiss    | D. magna              | SSD n=8                           | D. magna |
|          |                       | 96-h LC<sub>50</sub> 5200 µg/L | 96-d EC<sub>10</sub> 130<sup>1</sup> 33 µg/L | 48-h EC<sub>50</sub> 42.7 µg/L | 21-d NOAEC 0.247 µg/L | P. subcapitata |
| FOCUS Step 1 | 9.48 | 549 | 13.71 | 3.48 | **4.50** | 0.03 | 7806 |
| FOCUS Step 2 | North Europe | 0.02 | - | 1650 | 2135 | 12.35 |
| | South Europe | 0.04 | - | 825 | 1067 | 6.18 |
| FOCUS Step 3 | | | | | | |
| D1 ditch | 0.0103 | - | 4146 | 24.0 |
| D1 stream | 0.007 | - | 6100 | 35.3 |
| D2 ditch | 1.38 | 94.2 | 23.9 | 30.9 | **0.18** |
| D2 stream | 0.9692 | - | 34 | 44 | **0.25** |
| D3 ditch | < 0.0001 | - | - | >2470 |
| D4 pond | < 0.0001 | - | - | >2470 |
| D4 stream | < 0.0001 | - | - | >2470 |
| D5 pond | < 0.0001 | - | - | >2470 |
| D5 stream | < 0.0001 | - | - | >2470 |
| D6 ditch | < 0.0001 | - | - | >2470 |
| R1 pond | 0.0005 | - | 85400 | 494 |
| R1 stream | 0.0208 | - | 2053 | 11.9 |
| R3 stream | 0.0095 | - | 4495 | 26.0 |
| R4 stream | 0.0051 | - | 8373 | 48.4 |

| Trigger** | 100 | 10 | 100 | 5 | 10 | 10 |
|-----------|-----|----|-----|---|----|----|

*Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 1-2 should be included in step 3.*

- not needed

1 Risk assessment conducted assuming the metabolite as 10 times more toxic than the dimethoate. Although the metabolite showed to be more than 100 times more toxic than the parent to aquatic invertebrates, the screening assessment for fish performed considering omethoate as 10 times more toxic is still deemed acceptable, taking into account the margin of safety in the resulting TER.
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS**

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### FOCUSsw step 1-3 - TERs for the metabolite omethoate – modelled on use in Sugar beet (BBCH >30) at 1 × 200 g a.s./ha

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae |
|----------|-----------------------|------------|--------------|-----------------------|-----------------------|---------------------------------|-------|
|          |           |            |             | O. mykiss | O. mykiss | D. magna | SSD n=8 | D. magna | P. subcapitata |
|          | 96-h LC₅₀ | 96-d EC₁₀¹ | 48-h EC₉₀ | 21-d NOAEC | 0.247 µg/L | 72-h EC₅₀ |
|          | 5200 µg/L | 130¹      | 33         | 42.7 µg/L  | 74,700 µg/L |

**FOCUS Step 1**

| North Europe | 9.48 | 549 | 13.7 | 3.48 | 4.50 | 0.03 | 7806 |
| South Europe | 0.01 | -   | 3300 | 4270 | 24.7 |

**FOCUS Step 2**

| North Europe | 0.01 | - | 1650 | 2135 | 12.35 |
| South Europe | 0.02 | - |  -  |  -  |  -   |

**FOCUS Step 3**

| Organism  | Toxicity endpoint | Mitigation options | TER |
|-----------|-------------------|--------------------|-----|
| D3 ditch  | < 0.0001          |                    |     |
| D4 pond   | < 0.0001          |                    |     |
| D4 stream | < 0.0001          |                    |     |
| R1 pond   | 0.0044            |                    |     |
| R1 stream | 0.062             |                    |     |
| R3 stream | 0.0935            |                    |     |

**Trigger**

|     | 100 | 10  | 100 | 5  | 10  | 10  |

*Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.*

- not needed

¹ Risk assessment conducted assuming the metabolite as 10 times more toxic than the dimethoate. Although the metabolite showed to be more than 100 times more toxic than the parent to aquatic invertebrates, the screening assessment for fish performed considering omethoate as 10 times more toxic is still deemed acceptable, taking into account the margin of safety in the resulting TER.

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**FOCUSsw step 4 – Daphnia Chronic TER for omethoate – modelled on use in Wheat (BBCH 30) and sugar beet (BBCH 30) at 1 × 200 g a.s./ha with spray mitigation**

| Organisms: | Invertebrate chronic: *D. magna* |
|------------|----------------------------------|
| Toxicity endpoint: | 21-d NOEC 0.247 µg a.s/L |

| Mitigation options | [x] m non-spray buffer zone | [x] m vegetated buffer strip (corresponding to ≤ 90 % run-off) | PECsw | TER | Trigger |
|-------------------|-----------------------------|---------------------------------------------------------------|-------|-----|--------|

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| FOCUS Step 4* | (corresponding to ≤ 95 % drift reduction) | reduction | (µg/L) |
|---------------|------------------------------------------|-----------|--------|
| Cereals: D2 ditch | 20 | 20 | 1.38 | 0.18 | 10 |
| Cereals: D2 stream | 20 | 20 | 0.9692 | 0.25 | 10 |
| Sugar beet: R1 stream | 20 | 20 | 0.0148 | 16.7 | 10 |
| Sugar beet: R3 stream | 20 | 20 | 0.0222 | 11.1 | 10 |

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].
Metabolites continued

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

**FOCUS sw step 1-3 - TERs for the metabolite O-desmethyl dimethoate (Met X) – modelled on use in Cereals and sugar beet (BBCH >30) at 1 x 200 g a.s./ha**

| Scenario       | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae       |
|----------------|-----------------------|------------|-----------------------|-------------|
|                |                       | *O. mykiss* | *D. magna*           | *P. subcapitata* |
|                |                       | 96-h LC50  | 48-h EC50             | 96-h EC50   |
|                |                       | >100,000   | >100,000              | >100,000 µg/L |
| **FOCUS Step 1** | 20.02                 | 4995       | 4995                  | > 4995      |
| **FOCUS Step 2** |                       |            |                       |             |
| **Cereals**    |                       |            |                       |             |
| North Europe   | 1.19                  | -          | -                     | -           |
| South Europe   | 2.01                  | -          | -                     | -           |
| **FOCUS Step 2** |                       |            |                       |             |
| **Sugar beet** |                       |            |                       |             |
| North Europe   | 0.68                  | -          | -                     | -           |
| South Europe   | 0.99                  | -          | -                     | -           |
| **Trigger**    |                       | 100        | 100                   |             |

1 Comparison to the RAC for dimethoate
Metabolites continued

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

**FOCUS** step 1-3 - TERs for the metabolite O,O-dimethyl thiophosphoric acid (Met XVI) – modelled on use in Cereals and sugar beet (BBCH >30) at 1 × 200 g a.s./ha

| Scenario          | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae          |
|-------------------|-----------------------|------------|-----------------------|----------------|
|                   |                       | O. mykiss  | D. magna              | P. subcapitata |
|                   |                       | 96-h LC50  | 48-h EC50              | 96-h EC50      |
|                   |                       | >1,000,000 µg/L | 70,500            | >9,500*        |
| **FOCUS Step 1**  | 23.99                 | 41684      | 2939                  | >397           |
| **FOCUS Step 2**  |                       |            |                       |                |
| Cereals           |                       |            |                       |                |
| North Europe      | <0.01                 | -          | -                     |                |
| South Europe      | <0.01                 | -          | -                     |                |
| **FOCUS Step 2**  |                       |            |                       |                |
| Sugar beet        |                       |            |                       |                |
| North Europe      | <0.01                 | -          | -                     |                |
| South Europe      | <0.01                 | -          | -                     |                |
| **Trigger**       | 100                   | 100        |                       |                |

1 Comparison to the RAC for dimethoate

*Metabolite assumed 10 times more toxic than the parent
Metabolites continued

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

**FOCUS<sub>sw</sub> step 1-3** - TERs for the metabolite O,O-dimethyl phosphoric acid (Met XVII)– modelled on use in Cereals and sugar beet (BBCH >30) at 1 × 200 g a.s./ha

| Scenario     | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae     |
|--------------|-----------------------|------------|-----------------------|-----------|
|              |                       |            | O. mykiss             | D. magna  |
|              |                       |            | 96-h LC₅₀              | >1,000,000 µg/L |
|              |                       |            | 48-h EC₅₀              | >1,000,000 µg/L |
|              |                       |            | 96-h E₅₀              | >9,500* µg/L |
| FOCUS Step 1 | 10.2                  | 98039      | 98,039                | >931      |
| FOCUS Step 2 |                       |            |                       |           |
| Cereals      |                       |            |                       |           |
| North Europe | 0.01                  | -          | -                     | -        |
| South Europe | 0.02                  | -          | -                     | -        |
| FOCUS Step 2 |                       |            |                       |           |
| Sugar beet   |                       |            |                       |           |
| North Europe | <0.01                 | -          | -                     | -        |
| South Europe | 0.01                  | -          | -                     | -        |
| Trigger      | 100                   | 100        |                       |           |

*Metabolite assumed 10 times more toxic than the parent

**Combined acute toxicity of dimethoate and omethoate** - Acute TER values for *Daphnia magna* at the FOCUS Step 3 combined peak PEC<sub>sw</sub>.

| Crop            | Species    | Combined substances | Calculated 48-h EC₅₀ combined (µg total/L) | FOCUS Scenario | PEC<sub>sw</sub> (combined µg/L) | TER<sub>A combined</sub> | Trigger value |
|-----------------|------------|---------------------|--------------------------------------------|----------------|---------------------------------|--------------------------|----------------|
| FOCUS Step 3    |            |                     |                                            |                |                                 |                          |                |
| Winter cereals  | *Daphnia magna* | dimethoate + omethoate | 1549.5                                     | D1 ditch       | 1.3325                          | 1163                     | 100            |
|                 |            |                     | 1479.2                                      | D1 stream      | 1.1428                          | 1294                     |                |
|                 |            |                     | 345.4                                       | D2 ditch       | 17.17                           | 20.1                     |                |
|                 |            |                     | 320.6                                       | D2 stream      | 11.03                           | 29.1                     |                |
|                 |            |                     | 849.6                                       | R1 stream      | 0.9156                          | 928                      |                |
### Combined chronic toxicity of dimethoate and omethoate - Chronic TER values for *Daphnia magna* at FOCUS Step 3 combined peak PECsw.

| Crop          | Species       | Combined substances | Calculated NOEC<sub>combined</sub> (µg total/L) | FOCUS Scenario | PEC<sub>SW combined</sub> (µg/L) | Chronic TER<sub>CH combined</sub> | Trigger value |
|---------------|---------------|---------------------|-----------------------------------------------|----------------|---------------------------------|--------------------------------|---------------|
| **FOCUS Step 3**                                                                                                                             | 10                                                                 |
| Winter cereals | *Daphnia magna* | dimethoate + omethoate | 22.4                                        | D1 ditch       | 1.3325                          | 16.8                          | 10            |
|               |                |                     | 20.5                                        | D1 stream      | 1.1428                          | 17.9                          |               |
|               |                |                     | 2.9                                         | D2 ditch       | 17.17                           | **0.17**                      |               |
|               |                |                     | 2.6                                         | D2 stream      | 11.03                           | **0.24**                      |               |
|               |                |                     | 8.6                                         | R1 stream      | 0.9156                          | **9.39**                      |               |
|               |                |                     | 11.1                                        | R3 stream      | 0.5845                          | 19.0                          |               |
|               |                |                     | 10.2                                        | R4 stream      | 0.2801                          | 36.4                          |               |
| Sugar beet    | *Daphnia magna* | dimethoate + omethoate | 10.7                                        | R1 pond        | 0.2599                          | 41.2                          | 10            |
|               |                |                     | 9.8                                         | R1 stream      | 3.255                           | **3.01**                      |               |
|               |                |                     | 9.5                                         | R3 stream      | 4.6675                          | **2.04**                      |               |
### Refined combined chronic toxicity of dimethoate and omethoate - Chronic TER values for *Daphnia magna* at FOCUS Step 4 (with mitigation) combined peak PEC<sub>sw</sub>.

| Crop                  | Species       | Combined substances | Calculated NOEC<sub>combined</sub> (µg total/L) | FOCUS Scenario | PEC<sub>sw</sub> combined (µg/L) | Chronic TER<sub>CH</sub> combined | Trigger value |
|-----------------------|---------------|---------------------|-----------------------------------------------|----------------|-------------------------------|----------------------------------|---------------|
| **FOCUS Step 4 with 10 m VFS** |               |                     |                                               |                |                               |                                  |               |
| Winter cereals        | *Daphnia magna* | dimethoate + omethoate | 8.6                                           | R1 stream      | 0.3769                        | 22.8                             | 10            |
| Sugar beet            | *Daphnia magna* | dimethoate + omethoate | 9.8                                           | R1 stream      | 1.4792                        | **6.6**                           | 10            |
|                       |               |                     | 9.5                                           | R3 stream      | 2.1164                        | **4.5**                           |               |
| **FOCUS Step 4 with 20 m VFS** |               |                     |                                               |                |                               |                                  |               |
| Sugar beet            | *Daphnia magna* | dimethoate + omethoate | 9.8                                           | R1 stream      | 0.7759                        | 12.6                             | 10            |
|                       |               |                     | 9.5                                           | R3 stream      | 1.1072                        | **8.6**                           |               |
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                   |
|--------------------------|----------------|-----------------------------|-----------|----------------------------|
| Honeybee * Apis mellifera* | a.s.           | Acute oral                  | 24-h LD$_{50}$ | 0.1 µg a.s./bee*          |
| Honeybee * Apis mellifera* | a.s.           | Acute contact               | 24-h LD$_{50}$ | 0.1 µg a.s./bee*          |
| Honeybee * Apis mellifera* | Formulation CHA 3621-04 | Acute oral                  | 48-h LD$_{50}$ | 0.37 µg f.p./bee 0.14 µg a.s./bee |
| Honeybee * Apis mellifera* | Formulation CHA 3621-04 | Acute contact               | 48-h LD$_{50}$ | 0.294 µg f.p./bee 0.111 µg a.s./bee |
| Bumblebee * Bombus terrestris* | a.s.           | Acute oral                  | 48-h LD$_{50}$ | 0.58 µg a.s./bee          |
| Bumblebee * Bombus terrestris* | a.s.           | Acute contact               | 48-h LD$_{50}$ | 5.6 µg a.s./bee           |

Potential for accumulative toxicity: no

Semi-field test (Cage and tunnel test)

A tunnel test (Schmitzer 2005a) was conducted to simulate exposure and foraging on artificial honeydew on winter wheat following application at 400 g a.s./ha in the evening after bee flight. Increased mortality was observed for three days, reduced foraging occurred throughout the 7-day exposure phase. No effect on survival or development of the test colonies. Some deficiencies were noted such as small colonies, no toxic reference, no residue analysis. The study was only performed for 28 days (1 brood cycle). A treatment colony was excluded leaving only two replicates for the brood and colony strength analysis.

A tunnel test was conducted to investigate the effects of fresh and aged residues following application at 200 g a.s./ha to flowering Phacelia. Fresh residues and residues aged by up to 5 days resulted in treatment related effects on mortality foraging and behaviour in reducing intensity. Residues aged by 7 to 10 days exhibited no effects on honeybee survival or foraging and effects on colony or brood development during post exposure monitoring phase. Residue analysis confirmed exposure to both dimethoate and omethoate ion foliage and in pollen and nectar.

A semi-field test (Franke, 2016) was conducted to investigate the effects of a low rate (5.54 g a.s./ha) applied to flowering Phacelia during bee flight, including detailed brood assessments according to OECD 75. There were no treatment related effects on honeybee survival or colony development during the 7 days exposure and during post exposure monitoring up to 41 days after application. However, it has to be noted that semi-field tests are not ideal for colony strength analysis. Residue analysis confirmed exposure to both dimethoate and omethoate on foliage and in pollen and nectar.

A semi-field trial (Barth, 2015) was conducted in which bees were exposed to fresh and aged residues on flowering Phacelia tanacetifolia, treated at various time-points from 10 days prior to exposure in the tunnels up to application during bee flight. Applications were made at 200 g a.s./ha. Treatments were; T2 applied on day 0 during bee flight (Days after treatment 0 = DAT 0), T3 applied 2 days prior to start of exposure, DAT -2, T4 applied at DAT -5, T5 applied at DAT -7 and T6 applied at DAT -10 and the water treated control which was applied on 0 DAT during bee flight. To confirm exposure, samples of flowers (pre- and post treatment), pollen (from pollen traps on the hive), nectar (from forager bees), forager honeybees and old larvae were collected and analysed. Overall, based on the results of this study, Dimethoate 400 g/L EC (CHA 3621-04) applied at a rate of 500 mL/ha, equivalent to 200 g a.s./ha) 10 days before exposure did not adversely affect adult mortality or foraging activity or behaviour of bees or colony strength. Foraging activity was the most sensitive endpoint.
Field tests

Field testing has been conducted in order to investigate effects on honeybees foraging on simulated honeydew following application at 200 g a.s./ha in winter wheat (Rexer, 2000). Flight intensity assessments indicated few bees foraging pre and post application (usually <1 bees per m²). The EPPO guideline indicates that 2 - 3 bees per m² should be foraging before applications but this is for attractive crops (noting that this is not validity criteria). There are no suggested levels for sugar sprayed wheat and therefore the level of foraging may reflect reality for this crop. No residue assessments were performed as part of this study and therefore there is uncertainty regarding the level of residues entering the hive. It was noted that there was notably lower colony strength in 1 of the control replicates in the pre-application assessment. There was a clear statistically significant effect on mortality on days 1, 2, 3 and 4 after application. It was noted that the colony strength assessments were only performed for 26 days. Nevertheless, the experts noted that there were no clear effects on the colony strength assessments which were performed. In 3 of the 4 colonies in the control there were 0% of eggs and larvae in the final assessment on day 26.

Additionally a field test was available to investigate exposure following application at 750 g a.s./ha in Phacelia (Schmitzer, 2005b). The study included an assessment of pollen load. On 2 of the days after application (5 and 6) the bees were noted to switch to other food sources. There was a clear and remarkable higher level of mortality on day 1. Although not statistically significant there was a notably higher level of mortality in the treatment up to and including day 3. In addition, there was a high level of mortality in the control on day 4. There was no pollen collection on days 1 and 2 in the dimethoate groups therefore the interpretation of the results is not considered straightforward. The colony strength assessments were only performed by counting the number of occupied combs which is not sufficient.

*Extended summaries of the studies were not available and therefore those could not be appropriately peer-reviewed.

Risk assessment

Hazard quotients for honeybees (Wheat at 200 g a.s./ha and Sugarbeet at 120 and 200 g a.s./ha) based on SANCO (2002)

| Substance  | Exposure pathway | Rate (g a.s./ha) | LD₅₀ (µg/bee) | HQ   | Trigger |
|------------|------------------|-----------------|---------------|------|---------|
| Dimethoate | Oral             | 120             | 0.1           | 1200 | 50      |
|           |                  | 200             |               | 2000 |         |
| Contact   |                  | 120             | 0.1           | 1200 | 50      |
|           |                  | 200             |               | 2000 |         |

**Tier 1 Contact HQ values for the proposed use in Wheat BBCH 30-69**

| Type of bee | Scenario       | Crop growth stage (BBCH) | AR g a.s./ha | LD₅₀ µg a.s/bee | HQ   | Trigger |
|-------------|----------------|--------------------------|--------------|-----------------|------|---------|
| Honey bee   | Treated crop   | 30 - 39                  | 200          | 0.1             | 2000 | 42      |
|             | Weeds in-field |                         |              |                 | 1000 | 42      |
|             | Field margin   |                         |              |                 | 56   | 42      |
|             | Weeds in-field | > 40                     |              |                 | 600  | 42      |
| Bumble bee  | Treated crop   | 30 - 39                  | 200          | 5.6             | 35.7 | 7       |
|             | Weeds in-field |                         |              |                 | 17.9 | 7       |
|             | Field margin   |                         |              |                 | 1    | 7       |
|             | Weeds in-field | > 40                     |              |                 | 10.7 | 7       |
### Tier 1 Contact HQ values for the proposed use in sugar beet BBCH >30

| Type of bee   | Scenario          | Crop growth stage (BBCH) | AR g a.s./ha | LD50 µg a.s/bee | HQ   | Trigger |
|---------------|-------------------|--------------------------|--------------|-----------------|------|---------|
| Honey bee     | Treated crop      | < 40                     | 200          | 0.1             | 2000 | 42      |
|               |                   | Field margin             |              |                 | 56   | 42      |
|               | Weeds in-field    | > 40                     |              |                 | 500  | 42      |
| Bumble bee    | Treated crop      | < 40                     | 200          | 5.6             | 35.7 | 7       |
|               |                   | Field margin             |              |                 | 35.7 | 7       |
|               | Weeds in-field    | > 40                     |              |                 | 8.9  | 7       |

### Tier 1 Contact HQ values for the proposed use in sugar beet BBCH >30 at 120 g a.s./ha (EFSA, 2013)

| Type of bee   | Scenario          | Crop growth stage (BBCH) | AR g a.s./ha | LD50 µg a.s/bee | HQ   | Trigger |
|---------------|-------------------|--------------------------|--------------|-----------------|------|---------|
| Honey bee     | Treated crop      | < 40                     | 120          | 0.1             | 1200 | 42      |
|               |                   | Field margin             |              |                 | 33.6 | 42      |
|               | Weeds in-field    | > 40                     |              |                 | 300  | 42      |
| Bumble bee    | Treated crop      | < 40                     | 120          | 5.6             | 21.4 | 7       |
|               |                   | Field margin             |              |                 | 21.4 | 7       |
|               | Weeds in-field    | > 40                     |              |                 | 0.6  | 7       |
|               |                   |                          |              |                 | 5.4  | 7       |
### Tier 1 Acute oral ETR values for the proposed use in Wheat BBCH 30-69

| Type of bee | Scenario          | Crop growth stage (BBCH) | AR kg a.s./ha | LD<sub>50</sub> µg a.s/bee | ETR  | Trigger |
|-------------|-------------------|--------------------------|---------------|-----------------------------|------|---------|
| Honey bee   | Treated crop      | 30 - 39                  | 0.2           | 0.1                         | 1.84 | 0.2     |
|             | Weeds in-field    |                          |               |                             | 3.70 | 0.2     |
|             | Field margin      |                          |               |                             | 0.07 | 0.2     |
|             | Adjacent crop     |                          |               |                             | 0.05 | 0.2     |
|             | Succeeding crop   |                          |               |                             | 1.40 | 0.2     |
|             | Weeds in-field    | > 40                     |               |                             | 2.22 | 0.2     |
| Bumble bee  | Treated crop      | 30 - 39                  | 0.2           | 0.58                        | 0.79 | 0.036   |
|             | Weeds in-field    |                          |               |                             | 1.12 | 0.036   |
|             | Field margin      |                          |               |                             | 0.02 | 0.036   |
|             | Adjacent crop     |                          |               |                             | 0.012| 0.036   |
|             | Succeeding crop   |                          |               |                             | 0.31 | 0.036   |
|             | Weeds in-field    | > 40                     |               |                             | 0.67 | 0.036   |

### Tier 1 Acute oral ETR values for the proposed use in sugar beet BBCH >30

| Type of bee | Scenario          | Crop growth stage (BBCH) | AR kg a.s./ha | LD<sub>50</sub> µg a.s/bee | ETR  | Trigger |
|-------------|-------------------|--------------------------|---------------|-----------------------------|------|---------|
| Honey bee   | Treated crop      | < 40                     | 0.2           | 0.1                         | 15.2 | 0.2     |
|             | Weeds in-field    |                          |               |                             | 7.4  | 0.2     |
|             | Field margin      |                          |               |                             | 0.07 | 0.2     |
|             | Adjacent crop     |                          |               |                             | 0.05 | 0.2     |
|             | Succeeding crop   |                          |               |                             | 1.40 | 0.2     |
|             | Weeds in-field    | > 40                     |               |                             | 1.85 | 0.2     |
| Bumble bee  | Treated crop      | < 40                     | 0.2           | 0.58                        | 3.86 | 0.036   |
|             | Weeds in-field    |                          |               |                             | 2.24 | 0.036   |
|             | Field margin      |                          |               |                             | 0.02 | 0.036   |
|             | Adjacent crop     |                          |               |                             | 0.012| 0.036   |
|             | Succeeding crop   |                          |               |                             | 0.31 | 0.036   |
|             | Weeds in-field    | > 40                     |               |                             | 0.56 | 0.036   |
Tier 1 Acute oral ETR values for the proposed use in sugar beet BBCH >30 at 120 g a.s.

| Type of bee | Scenario                      | Crop growth stage (BBCH) | AR kg a.s./ha | L50 µg a.s./bee | ETR     | Trigger |
|-------------|-------------------------------|--------------------------|---------------|----------------|---------|---------|
| Honey bee   | Treated crop                 | < 40                     | 0.2           | 0.1            | 9.1     | 0.2     |
|             | Weeds in-field               |                          |               |                | 4.4     | 0.2     |
|             | Field margin                 |                          |               |                | 0.04    | 0.2     |
|             | Adjacent crop                |                          |               |                | 0.03    | 0.2     |
|             | Succeeding crop              |                          |               |                | 0.84    | 0.2     |
|             | Weeds in-field               | > 40                     |               |                | 1.1     | 0.2     |
| Bumble bee  | Treated crop                 | < 40                     | 0.2           | 0.58           | 2.32    | 0.036   |
|             | Weeds in-field               |                          |               |                | 1.34    | 0.036   |
|             | Field margin                 |                          |               |                | 0.01    | 0.036   |
|             | Adjacent crop                |                          |               |                | 0.01    | 0.036   |
|             | Succeeding crop              |                          |               |                | 0.19    | 0.036   |
|             | Weeds in-field               | > 40                     |               |                | 0.34    | 0.036   |

Due to the lack of a reliable chronic endpoint, the chronic risk assessment for both honey bees and honey bee larvae cannot be carried out.

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

| Species                | Test Substance | End point                  | Toxicity                                                   |
|------------------------|----------------|----------------------------|------------------------------------------------------------|
| *Typhlodromus pyri*    | Formulation EC 400 g a.s./L | Mortality, 7-d LR50 | 2.24 g a.s./ha                                              |
|                        | Reproduction   |                            | Reproductive capacity as % control                         |
|                        |                |                            | 95% at 0.13 g a.s./ha                                       |
|                        |                |                            | 77% at 0.42 g a.s./ha                                       |
|                        |                |                            | 69% at 1.34 g a.s./ha                                       |
| *Aphidius rhopalosiphi*| Formulation EC 400 g a.s./L | Mortality, 48-h LR50 | 0.014 g a.s./ha                                             |
|                        | Reproduction, ER50 |                            | 0.01 g a.s./ha                                              |
|                        |                |                            | 0.67 of control                                            |

First tier risk assessment for dimethoate applied at 1 × 200 g a.s./ha in Wheat or sugar beet

| Test substance | Species | Effect (LR50 g/ha) | PER_in-field (g a.s./ha) | HQ in-field | PER_off-field (g a.s./ha) | HQ off-field | Trigger |
|----------------|---------|-------------------|-------------------------|------------|--------------------------|-------------|---------|
| Formulation 400 g | *T. pyri* | 2.24 g a.s./ha | 200                     | 89.3       | 5.54                     | 2.471       | 2       |
| a.s./L        |                      |     |    |    |          |          |
|--------------|----------------------|-----|----|----|----------|----------|
| Formulation  |                      |     |    |    |          |          |
| 400 g        | T. pyri              | 2.24 g | 200 | 89.3| 1.14     | 0.5²     | 2        |
| Formulation  |                      |     |    |    |          |          |
| 400 g        | T. pyri              | 2.24 g | 120 | 53.6| 3.32     | 1.48¹    | 2        |
| Formulation  |                      |     |    |    |          |          |
| 400 g        | A. rhopalosphi       | 0.014 g | 200 | 14286| 5.54     | 396¹     | 2        |
| Formulation  |                      |     |    |    |          |          |
| 400 g        | A. rhopalosphi       | 0.014 g | 200 | 14286| 0.12     | 8.57³    | 2        |
| Formulation  |                      |     |    |    |          |          |
| 400 g        | A. rhopalosphi       | 0.014 g | 120 | 8571 | 3.32     | 237¹     | 2        |

¹ Based on 1 m drift rate  
² Based on 5 m drift rate  
³ Based on 50 m drift rate
### Extended laboratory tests, aged residue tests

| Species                  | Life stage | Test substance, substrate | Time scale | Dose (g/ha)
|--------------------------|------------|----------------------------|------------|------------------|
| **Aphidius rhopalosiphi** | adults     | EC Formulation 400 g/L Barley seedlings | Fresh      | g a.s./ha 1.5 11.2 374 625 748 (3.6 – 1800 mL/ha) |
|                          |            |                            | 14-day aged| g a.s./ha 1.5 11.2 374 625 748 (3.6 – 1800 mL/ha) |
|                          |            |                            | 21-day aged| g a.s./ha 374 625 748 (900 – 1800 mL/ha) |
| **Aphidius rhopalosiphi** | adults     | EC Formulation 400 g/L Barley seedlings 3D | Fresh      | g a.s./ha 0 0.75 1.5 3.0 6.0 12.0 |
| **Chrysoperla**          | larvae     | EC Formulation 400 g/L Vine leaves | Fresh      | g a.s./ha 1.5 374 748 |

| % effect | LR<sub>50</sub>/ ER<sub>50</sub> |\(^1\,^2\) |
|----------|---------------------------------|----------|
| 100%     | n/a                             |          |
| 1.5 to 374 g a.s./ha = No significant reduction compared to control |
| No significant reduction compared to control |
| 3.07 g a.s./ha (7.68 mL/ha) |
| 3%       | n/a                             |          |
| 92%      |                                  |          |
| 100%     |                                  |          |
| Control 31; |

\(^1\) Lethal rate (LR)  
\(^2\) Effective rate (ER)  
\(^3\) Categorical mortality: 2%, 4%, 6%, 96%, 100%.

**End point**

- **Mortality**
- **Reproduction** (mummies per female)
## Tier II - Extended laboratory risk assessment for dimethoate applied at 1 × 200 g a.s./ha

### In-field

In the laboratory, at in-field PER of 200 g a.s./ha, effects were demonstrated to be <50% after 14 days of aging for the most sensitive of the Tier I indicator species, *A. rhopalosiphi* (Baxter, 2006). Same conclusion can be drawn for *Chrysoperla carnea*. However, at the Peer review Experts’ meeting 177 (April, 2018), it was discussed and agreed that the field studies conducted in alfalfa crops at 43.5 g a.i./ha and 47 g a.i./ha (off-field rates) in Germany and Italy, respectively, indicate long-lasting effects and as such do not support the conclusion of the Tier II risk assessment.

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| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha) | End point | % effect | LR₅₀/ ER₅₀ |
|---------|------------|---------------------------|------------|-------------|-----------|----------|-----------|
|         |            |                            |            | 14-day aged |           |          |           |
|         |            |                            |            | 374 748     | (eggs; egg viability) | 91% | 1.5 g a.s./ha 30; 90% |
|         |            |                            |            |             | Mortality | 6% | 39% |
|         |            |                            |            | 21-day aged |           |          |           |
|         |            |                            |            | 748         | Reproduction (eggs; egg viability) | Control 28; 87% 374 g a.s./ha 35; 87% |
|         |            |                            |            |             | Mortality | 0% |        |
|         |            |                            |            |             | Reproduction (eggs; egg viability) | Control 35; 89% 748 g a.s./ha 36; 89% |

1. indicate whether fresh 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
Semi-field tests

*Semi-field studies were not conducted with dimethoate*

Field studies

Two studies with low application rates of 9 g a.s./ha and 43.5 g a.i./ha (Knäbe, 2009a) and 9 g a.s./ha and 47.0 g a.i./ha (Knäbe, 2009b) (Dimethoate 400 g/L EC), one performed in central and one in the southern zone, each provided a NOER < 2 × 9 g a.s./ha, and a NOEAER at 2 × 9 g a.s./ha (slight and transient effects, class 2) following extensive sampling of the in-field natural arthropod community in alfalfa crops. At 2 × 9 g a.s./ha, quantitatively restricted response on some taxa were observed on one sampling occasion. At the community level, in Knäbe (2009a), the multivariate analysis showed slight and transient effects at 2 × 9 g a.s./ha (DAT 7) on the community composition of non-target arthropods for the yellow water traps only, while in Knäbe (2009b) no sampling type showed significant effects at this rate or at the higher one.

At 43.5 g a.i./ha (Knäbe, 2009a) and 47.0 g a.i./ha (Knäbe, 2009b), indicate long lasting effects for several taxa, which did not recover within the study periods of 78–84 d and 82–89 days after the first treatment, respectively.

Both studies were rated as reliability 2.

Additional specific test

Additional studies were not conducted

**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./OM | Time scale | End point | Toxicity |
|---------------|----------------|----------------------------------|------------|-----------|----------|
| *Eisenia fetida* | a.s. | Incorporation 10% peat | Chronic | 56-d NOEC<sub>reproduction</sub> | 2.87 mg a.s./kg dry soil |
| *Eisenia fetida* | Omethoate | Incorporation 10% peat | Chronic | 56-d EC<sub>10</sub>reproduction | 0.28 mg a.s./kg dry soil |
| *Eisenia fetida* | O,O-dimethyl thiophosphoric acid (Met XVI) | Incorporation 10% peat | Chronic | 56-d NOEC<sub>reproduction</sub> | 3.36 mg a.s./kg dry soil |
| *Eisenia fetida* | O,O-dimethyl phosphoric acid (Met XVII) | Incorporation 10% peat | Chronic | 56-d NOEC<sub>reproduction</sub> | 1.42 mg a.s./kg dry soil |
## Other soil macroorganisms

| Test organism                  | Test substance                         | Application method of test a.s./OM | Time scale | End point | Toxicity                                      |
|-------------------------------|----------------------------------------|-----------------------------------|------------|-----------|-----------------------------------------------|
| **Hypoaspis aculeifer**       | a.s.                                   | Incorporated 5%                   | Chronic    | 14-d mortality NOEC                          | 1.9 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>10</sub>                              | 1.6 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>20</sub>                              | 2.3 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>50</sub>                              | 4.7 mg a.s./kg dry soil |
|                               |                                        |                                   |            | 14-d reproduction NOEC                       | 0.4 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>10</sub>                              | 4.0 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>20</sub>                              | 4.6 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | 6.1 mg a.s./kg dry soil |
| **Folsomia candida**          | a.s.                                   | Incorporated 5%                   | Chronic    | 28-d mortality NOEC                          | 2.5 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>10</sub>                              | 2.6 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>20</sub>                              | 4.6 mg a.s./kg dry soil |
|                               |                                        |                                   |            | LC<sub>50</sub>                              | 13.0 mg a.s./kg dry soil |
|                               |                                        |                                   |            | 28-d reproduction NOEC                       | 2.5 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>10</sub>                              | 2.1 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>20</sub>                              | 3.3 mg a.s./kg dry soil |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | 8.1 mg a.s./kg dry soil |
| **Hypoaspis aculeifer**       | Omethoate                              | Incorporated 5%                   | Chronic    | 14d mortality NOEC                           | 1.7 mg/kg dry soil     |
|                               |                                        |                                   |            | LC<sub>50</sub>                              | 1.4 mg/kg dry soil     |
|                               |                                        |                                   |            | 14d reproduction NOEC                        | 1.6 mg/kg dry soil     |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | 2.3 mg/kg dry soil     |
| **Hypoaspis aculeifer**       | O,O-didesmethyl thiophosphoric acid (Met XVI) | Incorporated 5%               | Chronic    | 14d mortality NOEC                           | 1.7 mg/kg dry soil     |
|                               |                                        |                                   |            | LC<sub>50</sub>                              | 1.4 mg/kg dry soil     |
|                               |                                        |                                   |            | 14d reproduction NOEC                        | 1.6 mg/kg dry soil     |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | 2.3 mg/kg dry soil     |
| **Hypoaspis aculeifer**       | O,O-didesmethyl phosphoric acid (Met XVII) | Incorporated 5%               | Chronic    | 14d mortality NOEC                           | 50 mg/kg dry soil      |
|                               |                                        |                                   |            | LC<sub>50</sub>                              | >50 mg/kg dry soil     |
|                               |                                        |                                   |            | 14d reproduction NOEC                        | 50 mg/kg dry soil      |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | >50 mg/kg dry soil     |
| **Hypoaspis aculeifer**       | O,O-didesmethyl phosphoric acid (Met XVII) | Incorporated 5%               | Chronic    | 14d mortality NOEC                           | 100 mg/kg dry soil     |
|                               |                                        |                                   |            | EC<sub>50</sub>                              | >100 mg/kg dry soil    |
|                               |                                        |                                   |            | 14d reproduction NOEC                        | ≥100 mg/kg dry soil    |
Higher tier testing (e.g. modelling or field studies)
Higher-tier testing on earthworms has not been conducted.

A GLP study was submitted which investigated the long-term effects on soil macro-arthropods (Dimethoate 400 g/L EC), Collembola and Acari under field conditions in grassland following applications at 1 × 200 g a.s./ha and 2 × 480 g a.s./ha. Arthropods were sampled by soil core over a 1 year duration and identified to the lowest taxonomic level – family, genus or species. Both treatment groups resulted in reductions in Collembola and Acari populations prolonged in time. Multivariate analysis indicates recovery of communities at 297 days after application. At the population level recovery to control levels was confirmed at 297 days and 365 days for all Collembola and Acari taxa, respectively. Therefore following effects lasting several months, recovery was demonstrated within one year at application rates of 1 × 200 g a.s./ha and 2 × 480 g a.s./ha.

| Parameter | Test Substance | Effect Criteria | Result |
|-----------|----------------|----------------|--------|
| Nitrogen transformation | a.s. | <25% effects | 2.225 mg a.s./kg dry soil |
| Nitrogen transformation | Dimethoate EC 400 g a.s./L | <25% effects | 10 mg a.s./kg dry soil |
| Nitrogen transformation | Omethoate | <25% effects | 1.43 mg/kg dry soil |
| Nitrogen transformation | O-desmethyl dimethoate\(^2\) (Met X) | <25% effects | 0.2225 mg/kg dry soil |
| Nitrogen transformation | O,O-dimethyl thiophosphoric acid (Met XVI) | <25% effects | 9.07 mg/kg dry soil |
| Nitrogen transformation | O,O-dimethyl phosphoric acid (Met XVII) | <25% effects | 9.07 mg/kg dry soil |

**Toxicity/exposure ratios for soil organisms for dimethoate applied at 1 × 200 g a.s./ha in sugar beet**

| Test organism | Test substance | Time scale | Soil PEC\(^1\) maximum | TER | Trigger |
|---------------|----------------|------------|------------------------|-----|---------|
| Earthworms    |                |            |                        |     |         |
| *Eisenia fetida* | a.s. | Chronic | 0.08 | 35.9 | 5 |
| *Eisenia fetida* | omethoate | Chronic | 0.011 | 25.5\(^3\) | 5 |

\(^1\) No experimental data available therefore 10x toxicity to parent assumed as a worst-case
|            |            |            |            |            |            |
|------------|------------|------------|------------|------------|------------|
| *Eisenia fetida* | O-desmethyl dimethoate<sup>2</sup> (Met X) | Chronic | 0.007 | 41.4<sup>2</sup> | 5 |
| *Eisenia fetida* | O,O-dimethyl thiophosphoric acid (Met XVI) | Chronic | 0.029 | 116 | 5 |
| *Eisenia fetida* | O,O-dimethyl phosphoric acid (Met XVII) | Chronic | 0.012 | 118 | 5 |

**Other soil macroorganisms**

|            |            |            |            |            |            |
|------------|------------|------------|------------|------------|------------|
| *Folsomia candida* | a.s. | Chronic | 0.08 | 26.25<sup>3</sup> | 5 |
| *Folsomia candida* | Omethoate | Chronic | 0.011 | 19.1<sup>2</sup> | 5 |
| *Folsomia candida* | O-desmethyl dimethoate (Met X) | Chronic | 0.007 | 30<sup>2</sup> | 5 |
| *Folsomia candida* | O,O-Dimethyl thiophosphoric acid (Met XVI) | Chronic | 0.029 | 7.2<sup>2</sup> | 5 |
| *Folsomia candida* | O,O-Dimethyl phosphoric acid (Met XVII) | Chronic | 0.012 | 17.5<sup>2</sup> | 5 |
| *Hypoaspis aculeifer* | a.s. | Chronic | 0.08 | 5.0 | 5 |
| *Hypoaspis aculeifer* | Omethoate | Chronic | 0.011 | 155 | 5 |
| *Hypoaspis aculeifer* | O-desmethyl dimethoate (Met X) | Chronic | 0.007 | 5.71<sup>2</sup> | 5 |
| *Hypoaspis aculeifer* | O,O-Dimethyl thiophosphoric acid (Met XVI) | Chronic | 0.029 | 1724 | 5 |
| *Hypoaspis aculeifer* | O,O-Dimethyl phosphoric acid (Met XVII) | Chronic | 0.012 | 8333 | 5 |
| *Folsomia candida* | Omethoate | Chronic | 0.011 | 19.1<sup>2</sup> | 5 |

<sup>1</sup> Indicate which PEC soil was used (e.g. plateau PEC)

<sup>2</sup> No experimental data available therefore 10x toxicity to parent assumed as a worst-case

<sup>3</sup> EC<sub>10</sub> value used for the risk assessment
Toxicity/exposure ratios for soil organisms for dimethoate applied at 1 × 200 g a.s./ha in sugarbeet

| Test organism | Test substance | Time scale | Soil PEC maximum | TER | Trigger |
|---------------|----------------|------------|------------------|-----|---------|
| **Earthworms**|                |            |                  |     |         |
| *Eisenia fetida* | a.s.           | Chronic    | 0.0533           | 53.85 | 5       |
| *Eisenia fetida* | omethoate      | Chronic    | 0.00481          | 59.67 | 5       |
| *Eisenia fetida* | O-desmethyl dimethoate (Met X) | Chronic | 0.01947 | 172.6 | 5 |
| *Eisenia fetida* | O,O-dimethyl thiophosphoric acid (Met XVI) | Chronic | 0.00818 | 173.6 | 5 |
| *Eisenia fetida* | O,O-dimethyl phosphoric acid (Met XVII) | Chronic | 0.0533 | 53.85 | 5 |

| **Other soil macroorganisms** | | | | | |
| *Folsomia candida* | a.s. | Chronic | 0.0533 | 39.4² | 5 |
| *Hypoaspis aculeifer* | a.s. | Chronic | 0.0533 | 7.50 | 5 |
| *Hypoaspis aculeifer* | Omethoate | Chronic | 0.00764 | 222.5 | 5 |
| *Hypoaspis aculeifer* | O-desmethyl dimethoate (Met X) | Chronic | 0.00481 | 8.32¹ | 5 |
| *Hypoaspis aculeifer* | O,O-dimethyl thiophosphoric acid (Met XVI) | Chronic | 0.01947 | 2568 | 5 |
| *Hypoaspis aculeifer* | O,O-dimethyl phosphoric acid (Met XVII) | Chronic | 0.00818 | 12225 | 5 |
| *Folsomia candida* | Omethoate | Chronic | 0.00764 | 19.1¹ | 5 |

¹ No experimental data available therefore 10x toxicity to parent assumed as a worst-case
² EC₅₀ value used for the risk assessment

**Summary effects on non-target soil meso- and macrofauna**

In addition to the laboratory studies a higher-tier field study with the formulated product CHA 3621-04 has been conducted to investigate micro-arthropod Collembola and Acari communities and representative taxa. The results of the field trial confirmed a low long-term risk to soil micro-arthropods based on the proposed uses of CHA 3621-04.

**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)**

| Test organism | Test substance | Test design | Results |
|---------------|----------------|-------------|---------|
| Carrot, cabbage, pea, | Formulation | GLP | Phytotoxic symptoms |
**Non-target plant toxicity and risk assessment for dimethoate applied at 1 × 200 g a.s./ha in wheat or sugar beet**

| Species                              | Test substance | ER$_{50}$ (g a.s./ha)$^{2}$ vegetative vigour | ER$_{50}$ (g a.s./ha)$^{2}$ emergence | Exposure$^1$ (g a.s/ha) (1 m drift at 2.77%) | TER  | Trigger |
|--------------------------------------|----------------|-----------------------------------------------|--------------------------------------|---------------------------------------------|------|---------|
| Carrot, cabbage, pea, sunflower, oats and onion | Formulation 400 g a.s./L | 1800 | - | 5.54 | 325 | 5 |

$^1$ based on Ganzelmeier drift data

Extended laboratory studies: Additional higher-tier studies were not required for dimethoate

Semi-field and field test: Additional higher-tier studies were not required for dimethoate
**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   | 3-h EC₅₀ >1000 mg/L (dimethoate) |
| *Pseudomonas sp*    | Dimethoate  |
|                    | 18-h NOEC 574 mg a.s./L |
|                    | 18-h EC₅₀ 806 mg a.s./L |
|                    | 18-h EC₅₀ 1731 mg a.s./L |

**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.  
Monitoring of adverse effects concerning dimethoate has not been conducted, no reports of such effects have been received  

Available monitoring data concerning effect of the PPP.  
Monitoring of adverse effects concerning dimethoate containing products has not been conducted, no reports of such effects have been received

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

| Compartment   |          |
|---------------|----------|
| soil          | Dimethoate and omethoate (to be considered separately) |
| surface-water | Dimethoate and omethoate (to be considered separately) |
| sediment      | Dimethoate and omethoate (to be considered separately) |
| groundwater   | Dimethoate and omethoate (to be considered separately) |

Footnote: 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) No 283/2013, Annex Part A, Section 10)

Substance

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]12:

| Substance | Dimethoate |
|-----------|------------|
| Hazards to the aquatic environment: | No existing harmonised classification |
| Acute Category 1 (H400) | |
| Chronic Category 1 (H410) | |

Peer review proposal13 for harmonised classification according to Regulation (EC) No 1272/2008:

| Substance | Dimethoate |
|-----------|------------|
| Hazards to the aquatic environment: | Acute Category 1 (H400) |
| Chronic Category 1 (H410) | |

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12 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.

13 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.
### Used compounds code(s)

| Trivial name (Code) | Chemical name/SMILES notation | Structural formula |
|---------------------|--------------------------------|------------------|
| Dimethoate (DMT)    | Phosphorodithioic acid, O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] ester | ![Structural formula image](image1) |
|                     | P(=O)(SCC(=S)NC)(OC)OC C₂H₁₂NO₃PS₂ | |
| Omethoate (OMT, Metabolite II) | O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorothioate | ![Structural formula image](image2) |
|                     | P(=O)(SCC(=O)NC)(OC)OC C₂H₁₂NO₄PS | |
| Dimethoate carboxylic acid (Metabolite III) | Acetic acid, [((dimethoxyphosphinothioyl)thio]-O(C)P(=S)(SCC(=O)(O))OC | ![Structural formula image](image3) |
|                     | C₄H₉O₄P S₂ | |
| Isodimethoate (Metabolite IX) | Phosphorodithioic acid, O,S-dimethyl S-[2-(methylamino)-2-oxoethyl] ester | ![Structural formula image](image4) |
|                     | P(=O)(SCC(=O)NC)(OC)SC C₂H₁₂NO₃PS₂ | |
| O-Desmethyl dimethoate (Metabolite X) | O-methyl S-[2-(methylamino)-2-oxoethyl] hydrogen phosphorodithioate | ![Structural formula image](image5) |
|                     | CNC(=O)CSP(O)(=S)OC C₄H₁₀NO₃PS₂ | |
| O-Desmethyl omethoate (Metabolite XI) | O-methyl S-[2-(methylamino)-2-oxoethyl] hydrogen phosphorothioate | ![Structural formula image](image6) |
|                     | CNC(=O)CSP(O)(=O)OC C₄H₁₀NO₄PS | |
| Metabolite Name                                      | Chemical Structure                                      | Molecular Formula       |
|-----------------------------------------------------|----------------------------------------------------------|-------------------------|
| O-Des-methyl isodimethoate                          | ![Structure](https://example.com/structure1.png)         | C_{10}H_{18}NO_{3}PS    |
| (Metabolite XII)                                    | S-methyl S-[2-(methylamino)-2-oxoethyl] hydrogen phosphorodithioate |                        |
|                                                     | CNC(=O)CSP(=O)(O)SC                                       |                         |
| O, O-Dimethyl thiophosphoric acid                   | Phosphorodithioic acid, O, O-dimethyl ester              | ![Structure](https://example.com/structure2.png) |
| (Metabolite XVI)                                    | O(C)P(O)(=S)OC                                            | C_{2}H_{7}O_{3}S         |
| O, O-Dimethyl phosphoric acid                      | Phosphoric acid, dimethyl ester                          | ![Structure](https://example.com/structure3.png) |
| (Metabolite XVII)                                   | O(C)P(O)(=O)OC                                            | C_{2}H_{7}O_{4}P         |
| O-Desmethyl omethoate carboxylic acid              | ([hydroxy(methoxy)phosphoryl]sulfanyl) acetic acid        | ![Structure](https://example.com/structure4.png) |
| (Metabolite XX)                                     | (C)P(O)(=O)SCC(=O)O                                      | C_{2}H_{7}O_{3}PS        |
| O-Desmethyl N-desmethyl omethoate                  | S-(2-amino-2-oxoethyl) O-methyl hydrogen phosphorothioate | ![Structure](https://example.com/structure5.png) |
| (Metabolite XXIII)                                  | O(C)P(O)(=O)SCC(=O)N                                      | C_{2}H_{8}NO_{4}PS       |