Appendix to:
EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl. EFSA Journal 2018;16(1):5133, 123 pp. doi:10.2903/j.efsa.2018.5133
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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) | Thiophanate-methyl |
|-----------------------------------|--------------------|
| Function (e.g. fungicide)         | Fungicide          |

Rapporteur Member State
Sweden

Co-rapporteur Member State
Finland

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

| Chemical name (IUPAC) | dimethyl 4,4'- (o-phenylene)bis(3-thioallophanate) |
|-----------------------|---------------------------------------------------|
| Chemical name (CA)    | dimethyl N,N'-[1,2-phenylenebis(iminocarbonothioyl)]bis[carbamate] |

CIPAC No
262

CAS No
23564-05-8
245-740-7

EC No (EINECS or ELINCS)
262/TC/S/F (1993) published in AGP:CP/331, 1995
2.2 Thiophanate-methyl (262/TC/M/3, CIPAC D, p.163). The thiophanate-methyl content shall be declared (not less than 950 g/kg).

IMPURITIES
2,3-diaminophenazine maximum: 0.0005 g/kg of the thiophanate-methyl content found under 2.2.
2-amino-3-hydroxyphenazine maximum: 0.0005 g/kg of the thiophanate-methyl content found under 2.2.

Minimum purity of the active substance as manufactured
950 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured
DAP: 0.50 mg/kg
HAP: 0.50 mg/kg
Carbendazim: 0.9 g/kg

Molecular formula
C$_{12}$H$_{14}$N$_{4}$O$_{4}$S$_{2}$

Molar mass
342.40 g/mol

Structural formula

![Structural formula of thiophanate-methyl]
Physical and chemical properties (Regulation (EU) No 283/2013, Annex Part A, point 2)

| Property                                      | Value                                    |
|-----------------------------------------------|------------------------------------------|
| Melting point (state purity)                  | 165°C (99.88%)                           |
| Boiling point (state purity)                  | Decomposition before boiling (99.88%)    |
| Temperature of decomposition (state purity)   | Decomposition before melting (99.88%)    |
| Appearance (state purity)                     | Pale brown powder (technical 97%)        |
| Vapour pressure (state temperature, state purity) | < 9 × 10⁻⁶ Pa at °C (20°C, 99.9%)    |
| Henry’s law constant (state temperature)      | 1.67 × 10⁻³ Pa m² mol⁻¹ (20°C)           |
| Solubility in water (state temperature, state purity and pH) | 22.4 mg/L at 20°C (pH 4, phthalate buffer) (98.23%) |
|                                               | 21.1 mg/L at 20°C (pH 5, phthalate buffer) (98.23%) |
|                                               | 20.7 mg/L at 20°C (pH 6, phosphate buffer) (98.23%) |
|                                               | 18.5 mg/L at 20°C (pH 7, phosphate buffer) (98.23%) |
|                                               | 16.8 mg/L at 20°C (pH 7.5, phosphate buffer) (98.23%) |
|                                               | unstable at pH > 8 at 20°C (98.23%)      |
|                                               | 24.6 mg/L at 25°C (pH 6.3 distilled, pH 6.3 saturated) (>99%) |
|                                               | 21.8 mg/L at 25°C (pH 5.1 distilled, pH 5.2 saturated) (99%) |
| Surface tension (state concentration and temperature, state purity) | 72.2 mN/m at 20°C (16 mg/L, 86% of the saturation solubility of this technical batch, purity: 97.28%) |
| Partition coefficient (state temperature, pH and purity) | log P_{OW} = 1.40 at 25°C distilled water, pH was not reported (99.88%) |
|                                               | log P_{OW} = 1.41 at pH 4 at 25°C (phthalate buffer) (98.23%) |
|                                               | log P_{OW} = 1.45 at pH 5 (phthalate buffer) (98.23%) |
|                                               | log P_{OW} = 1.47 at pH 6 (phthalate buffer) (98.23%) |
| Dissociation constant (state purity)          | pKₐ = 7.28 at 25°C (>99%)                 |
| UV/VIS absorption (max.) incl. ε (state purity, pH) | State | Absorption Maxima at band width [nm] | Extinction | Extinction coefficient ε [l * mol⁻¹ * cm⁻¹] | Log ε |
| neutral                                       | 269.0          | 0.6447     | 20606.69   | 4.31   |
|                                               | 215.0          | 0.9264     | 29610.73   | 4.47   |
| acidic                                        | 290.0          | 0.4054     | 12957.89   | 4.11   |
|                                               | 268.0          | 0.5754     | 18391.64   | 4.26   |
|                                               | 207.0          | 0.9416     | 30096.57   | 4.48   |
|                                               | 290.0          | 0.3359     | 10736.45   | 4.03   |
| basic*                                        | 252.0          | 0.6836     | 21850.06   | 4.34   |
|                                               | 218.0          | 0.8200     | 26209.84   | 4.42   |
|                                               | 290.0          | 0.2962     | 9467.51    | 3.98   |

* Thiophanate-methyl is unstable at basic condition. The spectrum at pH 10 might be of the decomposition products of thiophanate-methyl

| Property                                      | Value                                    |
|-----------------------------------------------|------------------------------------------|
| Flammability (state purity)                   | Not highly flammable (98.23%)            |
| Explosive properties (state purity)           | Not explosive (97.9%)                    |
| Oxidising properties (state purity)           | Not oxidising (97.9%)                    |
### Summary of representative uses evaluated, for which all risk assessments needed to be completed (Thiophanate-methyl) (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) | Formulation type (d-f) | conc. of as (g/L) (i) | Application method kind (f-h) | growth stage & season (j) | number min-max a) per use b) per crop/season (k) | interval between applications (min days) | Application rate per treatment (l) | PHI (days) (l) | Remarks: (m) |
|--------------------------|-------------------------|--------------|--------------|-----------------------------------------|------------------------|------------------------|-----------------------------|--------------------------|-----------------------------------------------|-------------------------------|---------------------------|----------------|----------------|
| Wine grapes              | CEZ                     | Topsin M 500 SC | F            | Botrytis                                | SC                     | 500                    | Spraying                    | BBCH 57 - 81              | a) 1 b) 1                          | Not relevant                  | 0.22                      | 500            | a) 1.1 b) 1.1 | 35             |
| Wine grapes              | SEZ                     | Topsin M 500 SC | F            | Botrytis                                | SC                     | 500                    | Spraying                    | BBCH 57 - 81              | a) 1 b) 1                          | Not relevant                  | 0.11                      | 1000           | a) 1.1 b) 1.1 | 35             |
| Tomato, aubergine        | CEZ, SEZ                | Topsin M 500 SC | G            | Fusarium Verticilium Rhizoctonia         | SC                     | 500                    | Drip irrigation             | First appl. 60 – 80 days before BBCH 32; 71; 85 or 15 days after transplantation | a) 3 b) 3 | 30 – 40 | Not relevant n.r. | a) 0.70; 1.4; 2.3 b) 0.7+1.4+2.3=4.4 (in sequence) | 7 | Typical watering rates 30-200 hl/ha (0.0035 – 0.077 kg a.s./hl based on min and max appl. rates 0.7 and 2.3 kg a.s./ha, respectively. Greenhouse use in tomato /aubergine covers permanent glasshouses as well as open protected structures. |
| Tomato, aubergine        | SEZ                     | Topsin M 500 SC | F            | Fusarium Verticilium Rhizoctonia         | SC                     | 500                    | Drip irrigation             | First appl. 60 – 80 days before BBCH | a) 3 b) 3 | 30 – 40 | Not relevant n.r. | a) 0.70; 1.4; 2.1 b) 0.7+1.4+2.1=4.2 | 7 | Typical watering rates 30-200 |
| Crop and/or situation (a) | Member State or Country | Product name | F, G or I (b) | Pests or Group of pests controlled (c) | Formulation type (d-f) | conc. of as (g/L) (i) | Application method kind (f-h) | growth stage & season (j) | number min-max a) per use b) per crop/season (k) | interval between applications (min days) | Application rate per treatment kg as/hL min-max | water L/ha min-max kg as/ha a) max. rate per appl. b) max. total rate per crop/season | PHI (days) (l) | Remarks: (m) |
|--------------------------|------------------------|--------------|--------------|--------------------------------------|-----------------------|-----------------------|----------------------------|------------------------|-------------------------------------------------|---------------------------------|---------------------------------------------|---------------------------------------------|----------------------|------------------------|
| Leek                     | CEZ                    | Toppin M 500 SC | F            | Soil fungi except oomycetes          | SC                    | 500                   | Drenching                  | Just after plantation. BBCH 12-15 | a) 1 b) 1                          | Not relevant        | 0.03                                           | 13000                        | a) 4.15 b) 4.15                  | 120                           |
| Fresh beans with pods    | SEZ                    | Toppin M 500 SC | F            | Colletotrichum (Anthracnosis) Rust/Oidium | SC                    | 500                   | Spraying                   | BBCH 61-71                          | a) 2 b) 2                          | 14                                | 0.25                                           | 300                          | a) 0.750 b) 1.5                  | 14                            |
| Fresh beans with pods    | CEZ                    | Toppin M 500 SC | F            | Colletotrichum (Anthracnosis) Rust/Oidium | SC                    | 500                   | Spraying                   | BBCH 61-71                          | a) 2 b) 2                          | 14                                | 0.25                                           | 300                          | a) 0.750 b) 1.5                  | 14                            |
| Winter wheat, durum wheat| CEZ, SEZ               | Toppin M 500 SC | F            | Fusarium                                        | SC                    | 500                   | Spraying                   | BBCH 59 - 70                         | a) 1 b) 1                          | Not relevant     | 0.21                                           | 350                          | a) 0.750 b) 0.750                 | n.r.*                         |

*not relevant

Remarks: (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) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (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. (j) Growth stage at 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 application possible under practical conditions of use (l) PHI – minimum pre-harvest interval
Remarks may include: Extent of use/economic importance/restrictions
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 (Thiophanate-methyl)

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 Type (d-f) | Conc. a.s. (g) | Application method kind (f-h) | Range of growth stages & season (j) | Number min-max (k) | Interval between application (min) | Application rate per treatment kg a.s./ha. min-max (l) | Water L/ha min-max (l) | kg a.s./ha min-max (l) | PHI (days) (m) | Remarks |
|--------------------------|--------------------------|--------------|--------------|----------------------------------------|------------------------|---------------|-------------------------------|-----------------------------|-------------------|-------------------------------|-----------------------------|-------------------|-----------------------------|------------|---------|
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | None | | | | | | | | | | | | | | |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997. Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)
The representative uses GAPs are supported by the available data.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)
No adverse effects on field crops are reported.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)
Not reported

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

| Activity against target organism | Carbendazim | CM-0237 |
|---------------------------------|-------------|---------|
| Leaching to groundwater not expected. Compared to the parent compound carbendazim is considered to have equal or higher activity against target organisms | Leaching to groundwater not expected. No data on biological activity against target organisms available, and not required. |
Methods of Analysis

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

| Technical a.s. (analytical technique) | HPLC-UV |
|-------------------------------------|---------|
| Impurities in technical a.s. (analytical technique) | HPLC-UV, GC-FID, Karl Fischer, IC conductivity detector, LC-PDA-MS/MS and LC-MS |
| Plant protection product (analytical technique) | HPLC-UV |

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

Residue definitions for monitoring purposes

| Food of plant origin | Thiophanate-methyl and carbendazim |
| Food of animal origin | Could not be established: Data gap |
| Soil | Thiophanate-methyl and carbendazim |
| Sediment | Thiophanate-methyl and carbendazim |
| Water surface | Thiophanate-methyl and carbendazim |
| Drinking/ground | Thiophanate-methyl and carbendazim |
| Air | Thiophanate-methyl |
| Body fluids and tissues | Urine: 5-OH-carbendazim-S |
| | Blood and plasma: thiophanate-methyl, carbendazim and 5-hydroxy-carbendazim |

Monitoring/Enforcement methods

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | HPLC-MS/MS (QuEChERS) |
| | 0.01 mg/kg thiophanate-methyl and carbendazim (high water content, high acid content, high oil content and dry crop matrices) |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | HPLC-MS/MS (QuEChERS) |
| | 0.01 mg/kg thiophanate-methyl and carbendazim |
| | 0.01 mg/kg 5-hydroxy-carbendazim |
| | 0.01 mg/kg 5-hydroxy-carbendazim-S (in milk, egg, muscle, liver and fat) |
| Soil (analytical technique and LOQ) | HPLC-UV and HPLC-MS |
| | 0.04 mg/kg thiophanate-methyl |
| | 0.02 mg/kg carbendazim |
| Water (analytical technique and LOQ) | HPLC-MS/MS |
| | 0.05 µg/L thiophanate-methyl and carbendazim |
| Air (analytical technique and LOQ) | HPLC-MS/MS |
| | 20 µg/m³ thiophanate-methyl, data gap for additioanal data for LOQ =12 µg/m³ |
| | 4 µg/m³ carbendazim |
| Body fluids and tissues (analytical technique and LOQ) | Body tissues: |
| | HPLC-MS/MS (QuEChERS) |
| | 0.01 mg/kg thiophanate-methyl |
| | 0.01 mg/kg carbendazim |
| | Body body fluids (blood, urine): |
| | HPLC-MS/MS (modified QuEChERS) |
| | 0.05 mg/kg thiophanate-methyl |
| | 0.05 mg/kg carbendazim |
| | Data gap: 5-hydroxy-carbendazim-S for urine |
| | 5-hydroxy-carbendazim for blood and plasma |

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

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

|          | Harmonised classification according to Regulation (EC) No 1272/2008:
|----------|------------------------------------------------------------------------
|          | No classification

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

|          | No classification

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

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

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

| Rate and extent of oral absorption/systemic bioavailability | Rapidly absorbed. Oral bioavailability; 88-89 % within 48 h (based on urine, bile, carcass and tissues, single administration of 14 mg/kg bw in rats). Indications of lower relative absorption at a higher dose level (170 mg/kg bw) |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | Following administration of 14 mg/kg bw in rats: Plasma, males: $C_{\text{max}} = 4.7$ 5.4 $\mu$g eq/g, $T_{\text{max}} = 2$ hours, $T_{1/2} = 8.87$ hours (plasma), $AUC_{\text{inf}} = 52.0$ $\mu$g h/g. Plasma, females: $C_{\text{max}} = 5.9$ $\mu$g eq/g, $T_{\text{max}} = 2$ hours, $T_{1/2} = 8.9$ hours, $AUC_{\text{inf}} = 56$ $\mu$g h/g. |
| Distribution                                               | Widely distributed. Highest residue levels found in liver, thyroid and kidney (rat) and GI-tract, liver and kidney (mice) |
| Potential for bioaccumulation                              | No evidence for accumulation. |
| Rate and extent of excretion                               | Rapid and extensive: approx. 96 % within 48 h following administration of 14 mg/kg bw in rats, mainly via urine (47 %) and bile (40 %). 7 % excreted via faeces. Indications of a shift towards faecal excretion at higher dose (170 mg/kg bw). |
| Metabolism in animals                                      | Extensively metabolised (>72-88 %); main metabolite 5-hydroxy-carbendazim-S (5-OH-MBC-S) |
| In vitro metabolism                                        | Comparative in vitro metabolism study in rat and human liver microsomes. Metabolites 4-hydroxy-thiophanate-methyl (4-OH-TM), Carbendazim (MBC) and 5-hydroxy-Carbendazim (5-OH-MBC) were detected in microsome preparations from both species. Metabolites unique for humans were not observed. |
| Toxicologically relevant compounds (animals and plants)     | Thiophanate-methyl and Carbendazim (MBC) |
| Toxicologically relevant compounds (environment)            | Thiophanate-methyl and Carbendazim (MBC) |

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

| Rat LD$_{50}$ oral                                         | > 5000 mg/kg bw |
|------------------------------------------------------------|-----------------|
| Rat LD$_{50}$ dermal                                       | > 2000 mg/kg bw |
| Rat LC$_{50}$ inhalation                                   | 1.7 mg/L air/4h (whole body) |
| Skin irritation                                            | Non-irritant |
| Eye irritation                                              | Non-irritant |
| Skin sensitisation                                         | Sensitising (GPMT) |
| Phototoxicity                                               | Not phototoxic |

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

| Target organ / critical effect                             | Rat: liver (increased weight, hypertrophy), thyroid |
|------------------------------------------------------------|-----------------------------------------------------|
| STOT                                                       |                                                     |
(increased weight, follicular cell hypertrophy and hyperplasia, increased T3), kidney (weight increase, tubular lesions), slight anaemia

Dog: thyroid toxicity (increased weight)

**Relevant oral NOAEL**

90-day rat: LOAEL = 14 mg/kg bw per day
1-year, dog: LOAEL = 8 mg/kg bw per day

**Relevant dermal NOAEL**

21-day, rabbit: 1000 mg/kg bw per day

**Relevant inhalation NOAEL**

No data - not required

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

**In vitro studies**

- Ames test (OECD 471): Negative
- Mammalian Cell Gene Mutation Test (OECD 476): Negative
- Mammalian Chromosome Aberration Test: Negative
- Unscheduled DNA Repair Synthesis (OECD 482): Negative
- Micronucleus test (Human peripheral lymphocytes): Negative (-S9), positive (+S9)
- Micronucleus test, Examination of four chromosomes: Positive (+S9)

**In vivo studies**

- Micronucleus test (OECD 474): Positive
- Combined comet assay, micronucleus, chromosome aberration in lizard*: Positive
- Spermatogonial chromosome aberration*: Negative
- Micronucleus test in germ cells*: Negative

**Photomutagenicity**

Based on the negative outcome in the phototoxicity study, thiophanate-methyl was not tested for photomutagenicity.

**Potential for genotoxicity**

Aneugenic and clastogenic potential

*Mutagenic potential

*Studies considered of low reliability

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

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

Rat: liver, kidney and thyroid (follicular hypertrophy, hyperplasia, adenomas).
Mouse: liver hepatocellular centrilobular hypertrophy and follicular cell adenomas (males only)

**Relevant long-term NOAEL**

2-year, rat: 8.8 mg/kg bw per day
18-month, mouse: 28.7 mg/kg bw per day

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

Rat: Thyroid follicular cell hyperplasia and hypertrophy. Benign liver tumours follicular cell adenomas (males only)
Mouse: hepatocellular adenomas

**Relevant NOAEL for carcinogenicity**

2-year, rat: 8.8 mg/kg bw per day;
18-month, mouse: 98.6 mg/kg bw per day

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

#### Reproduction toxicity

| Reproduction target / critical effect | Parental toxicity: increased thyroid and liver weights, histopathological changes in the thyroid and liver, reduced bw | Reproductive toxicity: no adverse effect observed in rat 2-generation study | Offspring’s toxicity: reduced bw |
|---------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------|--------------------------------|
| Relevant parental NOAEL               | LOAEL = 14.6 mg/kg bw per day                           |                                                                         |                               |
| Relevant reproductive NOAEL           | 147 mg/kg bw per day (the highest dose tested)          |                                                                         |                               |
| Relevant offspring NOAEL              | 14.6 mg/kg bw per day                                   |                                                                         |                               |

#### Developmental toxicity

| Developmental target / critical effect | Rat:                                                  | Maternal toxicity: reduced adjusted bw gain                           | Developmental toxicity: no adverse effects |
|---------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------|
|                                       | Rabbit:                                               | Maternal toxicity: ↓ bw and food consumption, abortions                | Developmental toxicity: supernumerary thoracic ribs |
| Relevant maternal NOAEL               | Rat: 1000 mg/kg bw per day                            |                                                                         |                               |
|                                       | Rabbit: 2 mg/kg bw per day                            |                                                                         |                               |
| Relevant developmental NOAEL          | Rat: 1000 mg/kg bw per day                            |                                                                         |                               |
|                                       | Rabbit: 2 mg/kg bw per day                            |                                                                         |                               |

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

#### Acute neurotoxicity

| NOAEL = 2000 mg/kg bw (for both generalised systemic toxicity and neurotoxicity) |

#### Repeated neurotoxicity

| NOAEL\textsubscript{neurotox} = 150 mg/kg bw per day |
| NOAEL\textsubscript{general tox} = 30.3 mg/kg bw; based on ↓ bw/bw gain and food consumption and ↑ liver and thyroid weights at 150/166 mg/kg bw per day. |

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

| Study not required |
Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

| Supplementary studies on the active substance | Mechanistic study: |
|------------------------------------------------|-------------------|
| Results indicate that the hypertrophy of the thyroid and the TSH response are counteracted by T4 supplementation supporting effects being due to a negative feedback mechanism. Data also indicate induction of cytochrome P450 and related drug metabolising enzymes including UDPGT. However, as T4 supplementation did not influence liver weight and as the pattern differed from phenobarbital, the increased UDPGT does not seem to be the sole explanation for the thyroid effects observed. The results indicated an inhibition of thyroid peroxidase in swine thyroids which seems to be the principal reason for the T4 depression. |

| Immunotoxicity: |
| No immunotoxic effects were detected in the standard toxicity testing; these investigations are not considered sufficient to predict immunotoxicity (such as suppression of immune response) (data gap). |

| Endocrine disrupting properties |
| Effects on the thyroid (hypertrophy, hyperplasia, weight increase and effects on hormones) are seen in rats and dogs (with minor effects in mouse) in several studies. These effects are probably due to TPO-inhibition in combination with hepatic clearance via UDPGT. The effects are considered to be adverse and relevant to humans. Although the interim criteria are not met, thiophanate-methyl is considered to be an endocrine disruptor. |

| A published study, considered to provide supportive information, investigated effects of in utero exposure to thiophanate-methyl on adrenal and thyroid histology and histomorphometry. The results support a possible, even though weak, effect of thiophanate-methyl on endocrine homeostasis and, in particular, the potential to elicit subtle effects on the development of endocrine tissues. Developmental landmarks were somewhat delayed and histology revealed an increase of cell alterations in both thyroid and adrenals, not associated with modifications of the microscopic structure. The effects persisted at least until weaning. |

| Studies performed on metabolites or impurities | Carbendazim: |
|------------------------------------------------|-----------|
| Refer to EFSA Conclusion (2010) |

| CM-0237: | Acute toxicity (OECD 401): LD$_{50}$ > 2000 mg/kg bw |
| Genotoxicity: Ames’s test (OECD 471): negative |

| DX-105: | Acute toxicity (OECD 401): LD$_{50}$ > 5000 mg/kg bw |
| Further data required |

| DX-189: | Acute toxicity (OECD 401): LD$_{50}$ > 5000 mg/kg bw |

| FH-613: | Acute toxicity (OECD 401): LD$_{50}$, M: 1776 mg/kg bw, F: 2007 |
mg/kg bw/day

FH-73:
Genotoxicity: Ames’s test (OECD 471): negative

4-OH-TM:
Genotoxicity: In vivo micronucleus: negative (low reliability)

5-OH-MBC:
Genotoxicity: In vivo micronucleus: negative (low reliability)

4-OH-TM, 5-hydroxy-carbendazim (5-OH-MBC), FH-432, FH-73, AV-1951, DX-105, 2-AB, 4-OH-2-AB, 4-OH-TM conj, 5-OH-carbendazim - S (5-OH-MBC):
Genotoxicity: QSAR analyses according to OECD QSAR Toolbox, Vega in silico platform and DEREK Nexus. Concern for all metabolites identified, however, not a higher concern than for the parent.

Carcinogenicity: A concern cannot be excluded for metabolites 5-OH-MBC, FH-73 and 5-OH-MBC-S.

2-AB and FH-432:
No sufficient data – data required

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)
Thiophanate-methyl has been commercially produced since 1969. No adverse effects associated with the production of thiophanate-methyl have been reported.

Summary3 (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|---------------------------|-------|--------------------|
| Acceptable Daily Intake (ADI) | Not established, due to genotoxic concern (1) | |
| Acute Reference Dose (ARfD) | Not established, due to genotoxic concern (2) | |
| Acceptable Operator Exposure Level (AOEL) | Not established, due to genotoxic concern (3) | |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not established, due to genotoxic concern | - |

(1) previously set ADI 0.08 mg/kg bw per day, based on 1-y dog study supported by 2-y rat study (European Commission, 2005)
(2) previously set ARfD 0.2 mg/kg bw, based on developmental toxicity study, rabbit (European Commission, 2005)
(3) previously set AOEL 0.08 mg/kg bw per day, based on 1-year dog study (European Commission, 2005)

3 If available include also reference values for metabolites
*NOTE! For dietary risk assessment of thiophanate-methyl as well as the risk assessment of workers and residents, the reference values for carbendazim (from EFSA Conclusion, 2010) should be used:

### Carbendazim:

| Study                              | Value (mg/kg bw (per day)) | Uncertainty factor |
|------------------------------------|-----------------------------|--------------------|
| Acceptable Daily Intake (ADI)*     | 0.02                        | 100                |
| Acute Reference Dose (ARfD)*       | 0.02                        | 100                |
| Acceptable Operator Exposure Level (AOEL)* | 0.02                     | 100                |
| Acute Acceptable Operator Exposure Level (AAOEL) | 0.02                     | 100                |

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

Representative formulation (Topsin M 500 SC, a suspension concentrate (SC) formulation containing 500 g/L thiophanate-methyl)

| Study                              | Value                                                                 |
|------------------------------------|-----------------------------------------------------------------------|
| Rat in vivo study                  |                                                                       |
| 3% for the neat formulation (500 g/L) |                                                                       |
| 8% for the spray dilution (0.3 g a.s./L) |                                                                       |

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

| Operators                          | Study                              | Value                                                                 |
|------------------------------------|------------------------------------|-----------------------------------------------------------------------|
| No exposure calculations have been presented as no AOEL could be derived for thiophanate-methyl. |                                                                      |                                                                       |
| Workers                            | Study                              | Value                                                                 |
| No exposure calculations have been presented as no AOEL could be derived for thiophanate-methyl. |                                                                      |                                                                       |

**Exposure to Carbendazim: % of AOEL**

*Use: Wine grapes, application rate 0.614 kg a.s./ha*

- No PPE: 1240 %
- No PPE, re-entry after 30 days: 620 %
  
  (DT50=30 days, PHI=35 days)

*Use: Fresh beans with pods, application rate 2 x 0.419 kg a.s./ha*

- No PPE (with workwear): 361 %
- PPE (with workwear and gloves): 84 %

*Use: Winter wheat, durum wheat, application rate 0.419 kg a.s./ha*

- No PPE (with workwear): 29 %
Bystanders and residents

|                          | % of AOEL |
|--------------------------|-----------|
| **Exposure to Thiophanate-methyl:** |           |
| No exposure calculations have been presented as no AOEL could be derived for thiophanate-methyl. |           |
| **Exposure to Carbendazim:** |           |
| Residents: |           |
| *German bystander and resident model* |           |
| Adult | 1.84% |
| Child | 3.76% |
| *High Crop Tractor-Mounted (vehicle-mounted drift reduction must be used):* |           |
| Adults | 40% |
| Child | 76% |
| *High Crop Hand-held (EFSA calculator):* |           |
| Adult | 56% |
| Child | 106% |

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

| Substance: | Thiophanate-methyl |
|------------|---------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴: | Skin Sens. 1, H317 “May cause an allergic skin reaction”  
Acute Tox. 4, H332 “Harmful if inhaled”  
Muta. 2, H341 “Suspected of causing genetic defects”  
Skin Sens. 1, H317 “May cause an allergic skin reaction”  
Acute Tox. 4, H332 “Harmful if inhaled”  
Muta. 1B, H340 “May cause genetic defects”  
Carc. 2, H351 “suspected of causing cancer”  
STOT RE 2, H373 “May cause damage to organs through prolonged or repeated exposure” |
| Peer review proposal⁵ for harmonised classification according to Regulation (EC) No 1272/2008: |           |

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

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
### Section 3 Residues in or on treated products food and feed

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

| Primary crops          | Crop groups       | Crop(s)       | Application(s)                                                                 | DAT (days) |
|------------------------|-------------------|---------------|---------------------------------------------------------------------------------|------------|
| Fruit crops            | Apples            | Foliar, 3 (3.9 kg a.s./ha), maturation stage | 1, 7                                                               |            |
|                        | Grapes            | Foliar, 1 (1.042 kg a.s./ha), 35 days before crop maturity | 0, 14, 35                     |            |
| Root crops             | Sugar beet        | Foliar, 3 (0.39 kg a.s./ha) | 21                                                                |            |
| Leafy crops            |                   |               |                                                                    |            |
| Cereals/grass crops    |                   |               |                                                                    |            |
| Pulses/Oilseeds        | Soya beans        | Run-off, 1 (700 mg a.s./l), 14 days before harvest | 7, 14                                                        |            |
|                        | Green bean        | Run off (assumed), 1 (50 mg/L, 14 days before harvest | 14                                                      |            |
|                        | Lima beans        | Foliar, 2 (1.18 kg a.s./ha), BBCH 63-65 (supportive, not acceptable as a standalone study) | 28                                                      |            |
| Miscellaneous          |                   |               |                                                                    |            |

| Rotational crops       | Crop groups       | Crop(s)       | PBI (days) | Comments                                                                 |
|------------------------|-------------------|---------------|------------|--------------------------------------------------------------------------|
| Root/tuber crops       | Carrots           | 30, 120, 365  | 1x1.6 kg a.s./ha on bare soil, underdosed (0.4 N with regard to PEC soil for most critical GAP) |            |
| Leafy crops            | Lettuce           | 30, 120, 365  |            |                                                                          |            |
| Cereal (small grain)   | Wheat             | 30, 120, 365  |            |                                                                          |            |
| Other                  |                   |               |            |                                                                          |            |

**Processed commodities**

**Conditions**

- 20 min, 90°C, pH 4 101.2% 
- 60 min, 100°C, pH 5 85.4% 
- 20 min, 120°C, pH 6 92.0%

| Conditions | Thiophanate-methyl | Carbendazim | 2-AB |
|------------|--------------------|-------------|------|
|            | 101.2%             | -           | -    |
|            | 85.4%              | 14.2%       | 10.3%|
|            | 92.0%              |             |      |

**Residue pattern in processed commodities similar to residue pattern in raw commodities?**

Yes, the residue definitions proposed for raw commodities are also applicable to processed commodities. A standard hydrolysis study with the major metabolite carbendazim should exclude the formation of further significant compounds (data gap).

### Conversion factor (monitoring to risk assessment)

Pending final expression of the RD.

**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)**

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|------------------------------------------------------|--------|-------------------|-----------------|---------------|
| Animals covered                                      | Laying hen | 2.9-3.5          | 10              | N rate pending |
### Residues in succeeding crops (Regulation (EU) No 283/2013, Annex Part A, point 6.6.2)

| Study Type                          | Details                                                                                                                                                                                                 |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Confined rotational crop study** | The study is not representative of worst case conditions as the applied dose (0.4 N) does not cover the PEC soil for the critical GAPs for the renewal and therefore quantitative conclusions are not possible. |
| **Field rotational crop study**     | Not considered as sufficiently reliable since only thiophanate-methyl and carbendazim were analysed and metabolites in the residue definition were not determined. Moreover the storage stability of residues in samples of cereal straw, spinach, carrot was not demonstrated by the storage stability data (data gap). |

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

| Animal | Time Needed |
|--------|-------------|
| Goat/Cow | 1.15-1.19  |
| Pig    |             |
| Fish   |             |

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

- **OECD Guidance, series on pesticides No 31**
- **No proposal due to uncertainties regarding the most suitable/relevant compound to be monitored** (data gaps).

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

- **Based on study with thiophanate-methyl**:
  - **Ruminants**: thiophanate methyl; carbendazim; 4-OH-MBC, 5-OH-MBC, 5-OH-MBC-S, final expression of the RD pending (data gap)
  - **Poultry**: thiophanate methyl; carbendazim; 4-OH-TM conjugates, 5-OH-MBC, 5-OH-MBC-S; final expression of the RD pending (data gap)

For finalisation of the RD, information should be provided also with regard to carbendazim metabolism in livestock and on the potential behaviour of FH-432 and DX-105 in livestock (data gaps).

### Conversion factor (monitoring to risk assessment)

Pending finalisation of residue definitions.

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

- **Yes**

### Fat soluble residues (Yes/No) (FAO, 2009)

- **No**
Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

| Plant products (Category) | Commodity | T (°C) | Stability (Month/Year) |
|--------------------------|-----------|--------|------------------------|
|                          |           |        | Thiophanate-methyl     | Carbendazim |
| High water content       |           | -      | -                      |             |
| High oil content         | Oilseed (OSR seed, intact) | <-18   | 12 months              | 12 months   |
|                          | Oilseed (OSR seed, homogenised) | <-18   | 1 month                | 3 months    |
| High protein content     | Pulses (Dry peas, intact) | <-18   | 12 months              | 12 months   |
|                          | Pulses (Dry peas, homogenised) | <-18   | 3 months               | 3 months    |
| High starch content      | Cereal grain (Wheat, intact) | <-18   | 12 months              | 12 months   |
|                          | Cereal grain (Wheat, homogenised) | <-18   | 2 weeks                | 3 months    |
| High acid content        | Berries (Strawberries, intact) | <-18   | 9 months               | 12 months   |
|                          | Grapes (intact) | <-18   | 12 months              | 12 months   |
|                          | Grapes (homogenised) | <-18   | <10 days               | 1 month     |

Homogenisation of samples lead to a drastically reduced storage stability as indicated by the information above. Acceptable studies in relevant high water content commodities, root and tuber vegetables and in cereal straw are required (data gap). Conditions of preparation and storage of the residue samples for storage stability tests should be comparable to the conditions applied to the field trial samples.

| Animal | Animal commodity | T (°C) | Stability (Month/Year) |
|--------|------------------|--------|------------------------|
|        |                  |        | Thiophanate-methyl     | Carbendazim | 5-OH-MBC | 5-OH-MBC-S |
| Dairy cattle | Muscle | -20 ± 10 | 8 months | 8 months | - | - |
|            | Liver      | -20 ± 10 | -       | 7 months | 7 months | - |
|            | Milk       | -20 ± 10 | -       | 8 months | - | 8 months |
| Laying hens | Muscle | -25 ca. | -       | 8 months | 8 months | - |
|            | Liver      | -25 ca. | 8 months | - | 8 months | - |
|            | Egg        | -25 ca. | 9 months | 10 months | 10 months |

Data for 4-OH-MBC are still required. (data gap)
Summary of residues data from the supervised residue trials (Regulation (EU) No 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

- Note: The residue trials were not performed in accordance with the proposed residue definition for risk assessment and reflect only data relevant for MRL setting. Further data in line with the residue definition for risk assessment should be generated for all representative uses to facilitate the establishment of appropriate conversion factors for the concerned commodities (data gap)

| Crop                  | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (h) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|-----------------------|---------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------|----------------|------------------|
| **Thiophanate-methyl** |               |                                                                                                   |                                                                                                                |                      |                |                  |
| Wine grapes           | NEU + SEU     | <0.01, 2x0.01, 2x0.02, 0.03, 3x0.04, 0.05, 2x0.06, 0.08, 0.13, 0.21, 0.27, 0.53, 1.07, 1.08, 2.11 | The residue results are merged (NEU 11 and SEU 9) as they refer to the same GAP and are not significantly different. | 3.0                  | 2.11           | 0.06             |
| Tomatoes              | SEU outdoor   | #2x<0.020, 2x<0.01                                                                                  | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) Calculated MRL: 0.02* mg/kg Extrapolated to aubergines | pending              | pending         | pending          |
| Indoor                | #5x<0.020     |                                                                                                   | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) Calculated MRL: 0.02* mg/kg Extrapolated to aubergines | pending              | pending         | pending          |
| Fresh beans with pods | NEU + SEU     | # 18x<0.01, 4x0.01, 0.02, 0.03, 0.05, 0.07                                                        | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) The residue results are merged (NEU 13 and SEU 13) as they refer to the same GAP and are not significantly different. Calculated MRL: 0.08 mg/kg | pending              | pending         | pending          |
| Leek                  | NEU           | #4x<0.01, 4x<0.02                                                                                  | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) Calculated MRL: 0.02* mg/kg | pending              | pending         | pending          |
| Wheat grain           | NEU + SEU     | 8x<0.01, 0.01, 0.02                                                                                | The residue results are merged (NEU 6 and SEU 4) as they refer to the same GAP and are not significantly different. | pending              | pending         | pending          |
| Crop                  | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) (c) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|-----------------------|-------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------------------|----------------|----------------|
|                       |                   | A complete data set requires 8 trials in NEU and 8 trials in SEU (data gap)                                     |                                                                                                                |                          |                |                |
| Wheat straw           | NEU + SEU         | #3x<0.01, 0.08, 0.14, 0.20, 0.24, 0.31, 1.04, 1.63                                                            | # Trials in italic are acceptable only when storage stability for cereal straw is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) The residue results are merged (NEU 6 and SEU 4) as they refer to the same GAP and are not significantly different. A complete data set requires 8 trials in NEU and 8 trials in SEU (data gap) | n/a                      | pending         | pending         |
| Carbendazim           |                   |                                                                                                                |                                                                                                                |                          |                |                |
| Wine grapes           | NEU + SEU         | 2x0.05, 3x0.08, 0.09, 3x0.10, 0.11, 0.13, 0.14, 0.15, 0.18, 0.25, 2x0.29, 0.15, 0.53, 0.56                  | The residue results are merged (NEU 11 and SEU 9) as they refer to the same GAP and are not significantly different. | 0.8                      | 0.56           | 0.12           |
| Tomatoes              | SEU outdoor       | #2x<0.01, 2x<0.011                                                                                               | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) Calculated MRL: 0.01* mg/kg Extrapolated to aubergines | pending                  | pending         | pending         |
| Indoor                |                   | #5x<0.011                                                                                                       | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) Calculated MRL: 0.01* mg/kg Extrapolated to aubergines | pending                  | pending         | pending         |
| Fresh beans with pods | NEU + SEU         | #3x<0.01, 3x0.01, 2 x 0.02, 6x0.03, 6x0.04, 0.05, 3x0.06, 0.07, 0.10                                                | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) The residue results are merged (NEU 13 and SEU 13) as they refer to the same GAP and are not significantly different. Calculated MRL: 0.015 mg/kg | pending                  | pending         | pending         |
| Leek                  | NEU               | # 4x<0.01, 4x<0.02                                                                                               | # Trials in italic are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) | pending                  | pending         | pending         |
### Crop RESIDUE LEVELS OBSERVED IN THE SUPERVISED RESIDUE TRIALS RELEVANT TO THE SUPPORTED GAPs

| Crop       | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|------------|-------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|------------|-------------|
| Wheat grain| NEU + SEU         | 8x<0.01, 2x0.03                                                                                  | The residue results are merged (NEU 6 and SEU 4) as they refer to the same GAP and are not significantly different. A complete data set requires 8 trials in NEU and 8 trials in SEU (data gap) | pending | pending | pending |
| Wheat straw| NEU + SEU         | #<0.01, 0.03, 0.16, 0.27, 0.30, 0.32, 0.42, 0.50, 0.74 #Trials in italic are acceptable only when storage stability for cereal straw is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) | The residue results are merged (NEU 6 and SEU 4) as they refer to the same GAP and are not significantly different. A complete data set requires 8 trials in NEU and 8 trials in SEU (data gap) | pending | pending | pending |

### Summary of the data on formulation equivalence OECD Guideline 509

| Crop       | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|
| Tomatoes   | SEU    | WG                   | Two types of formulations were used, WG (water dispersible granules) and SC (suspension concentrate, representative formulation). The WG and SC were used in a bridging study. The residues at harvest were below the LOQs, differences due to formulations have not been observed, however these trials are acceptable only when storage stability is demonstrated under the conditions and for the period the samples were stored in the trials (data gap) | See above |
| Tomatoes   | Indoor | WG                   | See above               | See above | See above | See above |

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

| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|
| Pollen and bee products | NEU + SEU | None available to address the representative uses | Submitted data in a crop that is not representative use indicate that the use of thiophanate-methyl during flowering could be a source for residues of thiophanate-methyl and carbendazim in honey. No information is available for pollen or other |
| Crop                  | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|-----------------------|-------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|----------------|------------------|
| **bee products. As to how the crops under consideration grapevines, tomatoes, aubergines, leek, fresh beans with pods and winter wheat can contribute to residues in pollen and bee products such as honey, needs further investigation (data gap).** |

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

(2) The values in italics (MRL, HR, STMR) has been replaced by a value based on merged results after a test with the EFSA model 'Mann-Whitney U-test 2015a'. Test statistics are calculated using the individual results from both residue populations and then the smaller test statistic is compared to a tabulated critical value ($\alpha=0.05$). Where the test statistic is less than or equal to the tabulated value, the two median values are considered to be similar.
Inputs for animal burden calculations

- No input data available in line with the RD for risk assessment in plants to consider the full livestock exposure potential. A livestock dietary burden calculation is required (data gap).

| Feed commodity          | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) | Comment   |
|-------------------------|-------------------------------|-------------------------------|-----------|
| **Representative uses** |                               |                               |           |
| Thiophanate-methyl      |                               |                               |           |
| Bean vines (fodder green)| Median residue                | Highest residue               |           |
| Wheat straw             | Median residue                | Highest residue               |           |
| Wheat grain             | Median residue                | Median residue                |           |
| Wheat gluten meal       | Median residue                | Median residue                |           |
| Wheat milled by-products| Median residue x PF           | Median residue x PF           |           |
| Carbendazim             |                               |                               |           |
| Bean vines (fodder green)| Median residue                | Highest residue               |           |
| Wheat straw             | Median residue                | Highest residue               |           |
| Wheat grain             | Median residue                | Median residue                |           |
| Wheat gluten meal       | Median residue                | Median residue                |           |
| Wheat milled by-products| Median residue x PF           | Median residue x PF           |           |
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)
OECD Guideline 505 and OECD Guidance, series on pesticides No 73

- Dietary burden calculations and estimation of potential residues in animal commodities unable to be finalised (data gap)

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) | Beef cattle | Ram/Ewe | Breeding | Broiler |
| (mg/kg DM for fish) | Dairy cattle | Lamb | Finishing | Layer |
| Intake ≥0.004 mg/kg bw | Beef cattle | Ram/Ewe | Breeding | Broiler |
| Feeding study submitted | Dairy cattle | Lamb | Finishing | Layer |
| | | | | Turkey |
| | | | | Fish intake ≥0.1 mg/kg DM |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Beef: N | Dairy: N | Ewe: N | Level | N rate | Breed/Finish | Level | B or T: N | Layer: N | Level | N rate | Carp/Trout |
|--------------------------|--------|----------|--------|-------|--------|-------------|-------|-----------|----------|-------|--------|------------|
| Muscle | Estimated HR<sup>(a)</sup> at 1N | MRL proposals | Estimated HR<sup>(a)</sup> at 1N | MRL proposals | Estimated HR<sup>(a)</sup> at 1N | MRL proposals | Estimated HR<sup>(a)</sup> at 1N | MRL proposals | Estimated HR<sup>(a)</sup> at 1N | MRL proposals |
| Fat | | | | | | | | | | |
| Meat<sup>(b)</sup> | | | | | | | | | | |
| Liver | | | | | | | | | | |
| Kidney | | | | | | | | | | |
| Milk<sup>(c)</sup> | | | | | | | | | | |
| Eggs | | | | | | | | | | |
| Method of calculation<sup>(c)</sup> | | | | | | | | | | |

(a): Estimated HR calculated at 1N level (estimated mean level for milk).
(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
| STMR calculations | Ruminant | Pig/Swine | Poultry | Fish |
|-------------------|----------|-----------|---------|------|
| Median expected intake (mg/kg bw/d) | | | | |
| Beef cattle | | | | |
| Ram/Ewe | | | | |
| Dairy cattle | | | | |
| Lamb | | | | |
| Breeding | | | | |
| Finishing | | | | |
| Broiler | | | | |
| Layer | | | | |
| Turkey | | | | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | | | | |
| Level | Beef: N | Level | Lamb : N | Level | N rate | Level | B or T: N | Level | N rate |
| Muscle | Estimated | Mean level | Estimated | Mean level | Estimated | Mean level | Estimated | Mean level | Estimated |
| Fat | at 1N | in feeding level | at 1N | in feeding level | at 1N | in feeding level | at 1N | in feeding level | at 1N |
| Meat(a) | | | | | | | | | |
| Liver | | | | | | | | | |
| Kidney | | | | | | | | | |
| Milk | | | | | | | | | |
| Eggs | | | | | | | | | |
| Method of calculation(c) | | | | | | | | | |
| (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
No proposal due to unfinished assessment of residues in animal commodities

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)
OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

- The available processing residue trials address only the residue definition for monitoring. Further data in line with the residue definition for risk assessment should be generated to facilitate the establishment of appropriate conversion factors (data gap).
- The validity of the available processing residue trials on grapes cannot be concluded on for wine and juice, considering the storage time period of the samples (3 to 125 days) and the instability observed in homogenised grape samples. Storage stability data in grapes processed commodities (wine, juice) and covering the maximum storage time interval of the residue samples should be provided (data gap).

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies (a) | Processing Factor (PF) Individual values | Median PF | Conversion Factor (CF_P) for RA (b) |
|--------------------------------------------------------|----------------------|----------------------------------------|------------|---------------------------------|
| Representative uses                                    |                      |                                        |            |                                 |
| Thiophanate-methyl                                     | 5                    | 0.50, 0.25, 1.00, 0.08, 0.19            | 0.25       | Data gap                        |
| Raisins                                                |                      |                                        |            |                                 |
| Carbendazim                                            | 5                    | 3.07, 2.53, 3.64, 2.00, 3.21            | 3.07       | Data gap                        |
| Raisins                                                |                      |                                        |            |                                 |

(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
(b): When the residue definition for risk assessment differs from the residue definition for monitoring
Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

**Note:** Several metabolites cannot be considered of lower toxicity concern than thiophanate-methyl and therefore cannot be excluded a priori from the consumer risk assessment. In the absence of toxicological reference values for thiophanate-methyl and for its metabolites in plant and animal commodities the consumer risk assessment cannot be finalised.

**Thiophanate-methyl**

| Parameter | Value |
|-----------|-------|
| ADI       | Not established, due to genotoxic concern |
| TMDI      | Not applicable |
| IEDI (%) ADI | - |
| NEDI (%) ADI | - |

Factors included in the calculations

**ARfD**

| Parameter | Value |
|-----------|-------|
| IESTI (%) ARfD | Not established, due to genotoxic concern |
| NESTI (%) ARfD | Not applicable |

Factors included in IESTI and NESTI

**Carbendazim**

| Parameter | Value |
|-----------|-------|
| ADI       | 0.02 mg/kg bw (Commission Directive 2006/135/EC) |
| TMDI      | Indicative: 16 % ADI |
| IEDI (%) ADI | Unable to calculate as the RD for RA is not finalised |
| NEDI (%) ADI | - |

Factors included in the calculations

**ARfD**

| Parameter | Value |
|-----------|-------|
| IESTI (%) ARfD | 0.02 mg/kg bw (Commission Directive 2006/135/EC) |
| NESTI (%) ARfD | Indicative: 27 % ARfD Grape juice (DE child) |

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) | Value |
|---------------|-------|
| ADI (mg/kg bw per day) | Not relevant |
| Intake of groundwater metabolites (% ADI) | - |
| WHO Guideline (WHO, 2009) | - |

| Intake of groundwater metabolites (% ADI) | Value |
|------------------------------------------|-------|
| Adult (60 kg bw, 2 L) | -- % ADI |
| Child (10 kg bw, 1 L) | -- % ADI |
| Infant (5 kg bw, 0.75 L) | -- % ADI |
Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

| Code\(^{(a)}\) | Commodity/Group       | MRL/Import tolerance\(^{(b)}\) (mg/kg) and Comments                                                                 |
|---------------|-----------------------|----------------------------------------------------------------------------------------------------------------------|
| **Plant commodities** |                        |                                                                                                                     |
| **Thiophanate-methyl** |                        |                                                                                                                     |
| 0151020       | Wine grapes           | MRLs are not proposed since a consumer safety concern was identified for the representative uses.                  |
| 0231010       | Tomatoes              |                                                                                                                     |
| 0231030       | Aubergines            |                                                                                                                     |
| 0260010       | Beans (with pods)     |                                                                                                                     |
| 0270060       | Leeks                 |                                                                                                                     |
| 0500090       | Wheat grain           |                                                                                                                     |
| **Carbendazim** |                        |                                                                                                                     |
| 0151020       | Wine grapes           | MRLs are not proposed since a consumer safety concern was identified for the representative uses.                  |
| 0231010       | Tomatoes              |                                                                                                                     |
| 0231030       | Aubergines            |                                                                                                                     |
| 0260010       | Beans (with pods)     |                                                                                                                     |
| 0270060       | Leeks                 |                                                                                                                     |
| 0500090       | Wheat grain           |                                                                                                                     |
| **Animal commodities** |                        |                                                                                                                     |
| 1000000       | Products of animal origin - terrestrial animals | The assessment whether MRLs would be required for animal commodities is not finalised. However, MRLs were not to be proposed since a consumer safety concern was identified for the representative uses. |
| 1040000       | Honey and other apiculture products |                                                                                                                     |

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

\(^{(b)}\): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
Section 4 Environmental fate and behaviour

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

| Description | Value |
|-------------|-------|
| Mineralisation after 100 days | 7.3 - 25.7% after 120 d, \([{}^{14}\text{C}}\text{-phenyl}\)-label (n= 4) |
| Non-extractable residues after 100 days | 39.7 - 73.2% after 120 d, \([{}^{14}\text{C}}\text{-phenyl}\)-label (n= 4) |
| Metabolites requiring further consideration | Carbendazim 48.3 - 75.8% at 3 - 7 d (n= 4) CM-0237 4.2 - 9.8% at 1 - 28 d (n= 4) 2-AB 2.2 - 6.1% at 14 d (n= 4) \([{}^{14}\text{C}}\text{-phenyl}\)-label |
| | Sterile conditions: no standard study; metabolites not reported |

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

| Description | Value |
|-------------|-------|
| Mineralisation after 100 days | 4.1% after 12 months, \([{}^{14}\text{C}}\text{-phenyl}\)-label (n= 1) |
| Non-extractable residues after 100 days | 83.7% after 12 months, \([{}^{14}\text{C}}\text{-phenyl}\)-label (n= 1) |
| Metabolites that may require further consideration for risk assessment | Carbendazim 56% at 14 d (n= 1) \([{}^{14}\text{C}}\text{-phenyl}\)-label |

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

| Description | Value |
|-------------|-------|
| Metabolites that may require further consideration for risk assessment | Carbendazim 20.8% at 28 d natural sunlight 35°N (n= 1) Carbendazim 66.6% at 7 d continuous artificial sunlight (n=1) \([{}^{14}\text{C}}\text{-phenyl}\)-label |
| Mineralisation at study end | not reported |
| Non-extractable residues at study end | 41.2 % after 28 d natural sunlight 35°N (n= 1) 33.4% after 17 d continuous artificial sunlight (n=1) \([{}^{14}\text{C}}\text{-phenyl}\)-label |

*a* n corresponds to the number of soils.
Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Thiophanate-methyl | Dark aerobic conditions |
|--------------------|------------------------|
| Soil type          | pH         | t. °C / % MWHC | DT_{50} / DT_{90} (d) | DT_{50} (d) 20 °C pF2/10kPa | St. (χ2) | Method of calculation |
| Bretagne silt loam | 5.8        | 20°C / 46% MWHC | 0.44 / 1.5             | 0.44/1.5                   | 5.0      | SFO                  |
| Mussig clay loam   | 7.5        | 20°C / 46% MWHC | 0.70 / 2.3             | 0.70/2.3                   | 5.8      | SFO                  |
| Speyer 2.3 sandy loam | 6.5   | 20°C / 46% MWHC | 0.59 / 1.9             | 0.56/1.9                   | 1.7      | SFO                  |
| Speyer 5M sandy loam | 7.9    | 20.9°C / pF 2   | 0.27 / 0.96            | 0.29/0.96                  | 9.0      | SFO                  |
| Geometric mean (n=4) |            |                |                        | 0.47                      |          |                      |

pH dependence, Yes or No: No

a) Measured in CaCl$_2$.
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7.

c) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).
d) Medium not stated.
e) Carbendazim dosed study therefore no formation fraction determined.
f) Geometric mean of DT$_{50}$ values (n=3) for one soil tested at three temperatures, although, for future evaluations, only the DT$_{50}$ derived from incubation closest to the FOCUS reference conditions should be selected.

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)

| Carbendazim | Dark aerobic conditions. The precursor from which the f.f. was derived was thiophanate-methyl |
|------------|---------------------------------------------------------------|
| Soil type  | pH     | t. °C / % MWHC | DT$_{50}$ / DT$_{90}$ (d) | f. f. $k_f$ / $k_{dp}$ | DT$_{50}$ (d) 20 °C pF2/10kPa | St. (χ2) | Method of calculation |
| Bretagne silt loam | 5.8 $^a$ | 20°C / 46% MWHC | 63.2 / 210 | 0.79 | 63.2/210 | 4.7 | SFO-SFO |
| Mussig clay loam   | 7.5 $^b$ | 20°C / 46% MWHC | 22.0 / 73.2 | 0.72 | 22.0/73.2 | 2.1 | SFO-SFO |
| Speyer 2.3 sandy loam | 6.5 $^c$ | 20°C / 46% MWHC | 37.6 / 125 | 0.69 | 35.5/125 | 5.0 | SFO-SFO |
| Speyer 5M sandy loam | 7.9 $^d$ | 20.9°C / pF 2 | 40.1 / 133 | 0.53 | 43.6/133 | 9.1 | SFO-SFO |
| Sand 1 $^e$ | 6.8 $^f$ | 22°C / 40% MWHC | 37 / 123 | - $^g$ | 37 | 7 | SFO |
| Loamy sand $^e$ | 5.2 $^h$ | 22°C / 40% MWHC | 37 / 226 | - $^g$ | 37 | 3 | DFOP |
|  | 44 / 146 | - $^g$ | 40 | 9 | SFO |
| Sand 2 $^e$ | 4.7 $^i$ | 15°C / 40% MWHC | 34 / 112 | - $^g$ | 34 | 4 | SFO |
|  | 20°C / 40% MWHC | 31 / 102 | - $^g$ | 27 | 5 | SFO |
|  | 25°C / 40% MWHC | 26 / 86 | - $^g$ | 33 | 5 | SFO |
| Geometric mean (n=7) | | | | | 36.3 | | |
| Arithmetic mean (n=4) | | | | | 0.68 | | |

pH dependence, Yes or No: No

a) Measured in CaCl$_2$.
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7.
c) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).
d) Medium not stated.
e) Carbendazim dosed study therefore no formation fraction determined.
f) Geometric mean of DT$_{50}$ values (n=3) for one soil tested at three temperatures, although, for future evaluations, only the DT$_{50}$ derived from incubation closest to the FOCUS reference conditions should be selected.

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7 X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.
**CM-0237**  Dark aerobic conditions. The precursor from which the f.f. was derived was thiophanate-methyl

| Soil type          | X' | pH  | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | f. f. kᵣ / k₃₀ | DT₅₀ (d) 20 °C pF2/10kPa | St. (γ²) | Method of calculation |
|--------------------|----|-----|----------------|----------------|-----------------|---------------------------|----------|----------------------|
| Mussig clay loam   | 7.5<sup>a</sup> | 20°C / 46% MWHC | 86.5 / 287 | 0.064 | 86.5 | 8.5 | SFO-SFO |
| Speyer 2.3 sandy loam | 6.5<sup>a</sup> | 20°C / 46% MWHC | 46.5 / 154 | 0.099 | 43.9 | 7.7 | SFO-SFO |
| Geometric mean (n=2) | | | | | | | |
| Arithmetic mean (n=2) | | | | | | | |
| pH dependence, Yes or No | | | | | | | 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.

* data gap for an additional soil DT<sub>50</sub>

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**2-AB**  Dark aerobic conditions. The precursor from which the f.f. was derived was carbendazim

| Soil type          | X' | pH  | t. °C / % MWHC | DT₅₀/ DT₉₀ (d) | f. f. kᵣ / k₃₀ | DT₅₀ (d) 20 °C pF2/10kPa<sup>b</sup> | St. (γ²) | Method of calculation |
|--------------------|----|-----|----------------|----------------|-----------------|---------------------------------|----------|----------------------|
| Bretagne silt loam | 5.8<sup>a</sup> | 20°C / 46% MWHC | 13.5 / 44.8 | 0.36 | 13.5 | 20 | SFO-SFO |
| Mussig clay loam   | 7.5<sup>a</sup> | 20°C / 46% MWHC | 11.5 / 38.2 | 0.33 | 11.5 | 16 | SFO-SFO |
| Speyer 5M sandy loam | 7.9<sup>a</sup> | 20.9°C / pF 2 | 5.3 / 17.5 | 0.75 | 5.8 | 24 | SFO-SFO |
| Geometric mean (n=3) | | | | | | 9.7 | |
| Arithmetic mean (n=3) | | | | | | 0.48 | |
| pH dependence, Yes or No | | | | | | | 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)

#### Thiophanate-methyl

| Soil type (bare soils were used) | Location (country or USA state) | X<sup>a</sup> | pH<sup>b</sup> | Depth (cm) | D<sub>IsT<sub>50</sub></sub> (d) actual | D<sub>IsT<sub>90</sub></sub> (d) actual | St. (t<sub>2</sub>) | DT<sub>50</sub> (d) Norm<sup>c</sup> | Method of calculation |
|---------------------------------|---------------------------------|--------------|--------------|-------------|----------------|----------------|-------------|----------------|-------------------|
| Passo Segni Loamy fine sand     | Italy                           | 8.0          | 0-30         | 1.8         | 6.0            | 32            | -           | -               | SFO               |
| San Pietro di Terme Clay loam  | Italy                           | 7.7          | 0-30         | 1.0         | 3.3            | 13            | -           | -               | SFO               |
| Bakum Fine sandy loam           | Germany                         | 5.8          | 0-10         | 1.8         | 6.1            | 17            | -           | -               | SFO               |
| Bad Camberg Silt                | Germany                         | 6.2          | 0-10         | 3.3         | 11.1           | 17            | -           | -               | SFO               |

Geometric mean (if not pH dependent): No

**pH dependence, Yes or No**: No

- a) Measured in CaCl<sub>2</sub>
- b) Measured in KCl.
- c) Measured in CaCl<sub>2</sub>.  
- d) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).

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

#### Carbendazim

| Soil type (bare soils were used) | Location (country or USA state) | X<sup>a</sup> | pH<sup>b</sup> | Depth (cm) | D<sub>IsT<sub>50</sub></sub> (d) actual | D<sub>IsT<sub>90</sub></sub> (d) actual | St. (t<sub>2</sub>) | DT<sub>50</sub> (d) Norm<sup>c</sup> | f. f. k<sub>f</sub> / k<sub>b</sub> | Method of calculation |
|---------------------------------|---------------------------------|--------------|--------------|-------------|----------------|----------------|-------------|----------------|-------------------|-------------------|
| Passo Segni Loamy fine sand     | Italy                           | 8.0          | 0-30         | 18.9        | 62.6           | 12            | -           | 0.41           | SFO-SFO           |
| San Pietro di Terme Clay loam  | Italy                           | 7.7          | 0-30         | 13.6        | 45.1           | 18            | -           | 0.31           | SFO-SFO           |
| Bakum Fine sandy loam           | Germany                         | 5.8          | 0-10         | 24.8        | 82.4           | 26            | -           | 0.34           | SFO-SFO           |
| Bad Camberg Silt                | Germany                         | 6.2          | 0-10         | 22.1        | 73.4           | 19            | -           | 0.61           | SFO-SFO           |
| Frankfurt-Schwamheim Silty sand | Germany                         | 5.8<sup>b)</sup> | 0-20       | 78          | 257            | 13            | -           | -              | SFO               |
| Gersthofen Loam<sup>c)</sup>    | Germany                         | 5.6<sup>b)</sup> | 0-20       | 11          | 36             | 20            | -           | -              | SFO               |
| Bornheim Loam<sup>c)</sup>      | Germany                         | 6.9<sup>b)</sup> | 0-20       | 18          | 59             | 30            | -           | -              | SFO               |
| Stelle Loamy sand<sup>c)</sup>  | Germany                         | 4.8<sup>b)</sup> | 0-20       | 16          | 54             | 22            | -           | -              | SFO               |

Geometric mean (if not pH dependent): No

- Arithmetic mean

**pH dependence, Yes or No**: No

- a) Measured in CaCl<sub>2</sub>
- b) Measured in KCl.
- c) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, state whether values are DegT<sub>50</sub>matrix
- d) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).

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

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

Aerobic conditions. Time-step normalised result; decline from peak after 10 mm cumulative rainfall. Not used in this evaluation.

| Soil type (bare soils were used) | Location | X° | pH | Depth (cm) | DT₅₀ (d) actual | DT₉₀ (d) actual | St. (γ²) | DT₅₀ (d) Normᵇ | f. e. kᵢ / kₛ₀ | Method of calculation |
|---------------------------------|----------|----|----|------------|----------------|----------------|----------|----------------|-----------------|---------------------|
| Passo Segni Loamy fine sand     | Italy    | 8.0 | 0-30 | -         | -              | 6.2            | 29.7     | -              | SFO             |                     |
| San Pietro di Terme Clay loam  | Italy    | 7.7 | 0-30 | -         | -              | 14             | 29.7     | -              | SFO             |                     |
| Bakum Fine sandy loam           | Germany  | 5.8 | 0-10 | -         | -              | 19             | 22.5     | -              | SFO             |                     |
| Bad Camberg Silt               | Germany  | 6.2 | 0-10 | -         | -              | 5.1            | 13.9     | -              | SFO             |                     |

Geometric mean (n=4) 22.9

Arithmetic mean -

pH dependence, Yes or No  No

a) Measured in CaCl₂.
b) Normalised using a Q₁₀ of 2.58 and Walker equation coefficient of 0.7.

c) Normalised using a Q₁₀ of 2.58 and Walker equation coefficient of 0.7, values do not represent DegT₅₀ matrix.
d) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010). For Gerstofen site, the DT₅₀ was estimated as: FOMC DT₉₀ / 3.32.

* data gap for normalised DT₅₀ with the correct Q₁₀ value of 2.58

### Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

Kinetic formation fraction (f. e. kᵢ / kₛ₀) of transformation products, arithmetic mean

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

### 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

No study available, not requested.
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)

| Thiophanate-methyl | Dark anaerobic conditions |
|--------------------|---------------------------|
| Soil type          | X<sup>10</sup> | pH<sup>10</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | DT<sub>50</sub> (d) 20 °C<sup>b</sup> | St. (\(\chi^2\)) | Method of calculation |
| Silt loam          | 6.2 | 21°C / - | 0.37 / 1.5 | - | 3.3 | DFOP |
| (Geometric mean (if not pH dependent)) | | | | | |

a) Medium not stated.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Carbendazim | Dark anaerobic conditions | The precursor from which the f.f. was derived was thiophanate-methyl. |
|-------------|---------------------------|---------------------------------------------------------------------|
| Soil type   | X<sup>10</sup> | pH<sup>10</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | f. f. \(k_f / k_{dp}\) | DT<sub>50</sub> (d) 20°C<sup>b</sup> | St. (\(\chi^2\)) | Method of calculation |
| Silt loam   | 6.2 | 21°C / - | 68 / 226 | 0.70 | - | 10 | DFOP-SFO |
| (Geometric mean (if not pH dependent)) | | | | | |
| Arithmetic mean | | | | | - |

a) Medium not stated.

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

| Thiophanate-methyl | Soil photolysis |
|--------------------|-----------------|
| Soil type          | X<sup>11</sup> | pH | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) calculated at \(\theta\)N | St. (\(\chi^2\)) | Method of calculation |
| Sandy loam         | 7.4<sup>11</sup> | outdoor (Dec-Jan) / 27% MWHC | 3.9 / - , at 35°N | - | estimated from graph |
| Silt loam          | 6.0<sup>11</sup> | 19.6°C / pH<sub>2</sub> | 1.4 / 4.6 , at 30°N - 50°N | 7.5 | SFO |

a) Medium not stated.
b) Measured in CaCl<sub>2</sub>.

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

| Soil Type       | OC % | Soil pH | $K_d$ (mL/g) | $K_{dsc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | $1/n$ |
|-----------------|------|---------|--------------|-----------------|-------------|-----------------|-------|
| Speyer 6S Clay  | 1.64 | 7.1     | -            | -               | 1.42        | 87              | 0.89  |
| Speyer 2.2 Loamy sand | 1.87 | 5.5     | -            | -               | 1.49        | 79              | 0.99  |
| Speyer 2.3 Sandy loam | 0.99 | 6.7     | -            | -               | 0.88        | 89              | 0.96  |
| Speyer 2.4 Loam | 2.42 | 7.1     | -            | -               | 1.32        | 54              | 0.97  |
| Geometric mean (n=4) * |       |         | 1.25          |                 |             |                 |       |
| Arithmetic mean (n=4) |       |         | 1.28          |                 |             |                 | 0.95  |

pH dependence, Yes or No: No

a) Measured in CaCl$_2$.

* Only relevant after implementation of the published EFSA guidance.

### 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)

| Soil Type   | OC % | Soil pH | $K_d$ (mL/g) | $K_{dsc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | $1/n$ |
|-------------|------|---------|--------------|-----------------|-------------|-----------------|-------|
| Sand        | 0.8  | 7.0     | -            | -               | 1.6         | 200             | 0.87  |
| Sand        | 2.58 | 6.8     | -            | -               | 6.3         | 246             | 1.12  |
| Sandy loam  | 1.0  | 5.2     | -            | -               | 2.3         | 230             | 0.91  |
| Geometric mean (n=3) * |       |         | 2.85          |                 |             | 224.5           |       |
| Arithmetic mean (n=3) |       |         | 3.40          |                 |             | 225.3           | 0.97  |

pH dependence, Yes or No: No

a) Medium not stated.
b) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).

* Only relevant after implementation of the published EFSA guidance.
### DX-105

| Soil Type               | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | 1/n |
|-------------------------|------|---------------------|----------------------|-----------------------|---------------------|-----------------------|-----|
| Fresno Sandy soil       | 0.35 | 7.1                 | -                    | -                     | 0.73                | 209                   | 0.90|
| Burkesville Loam        | 0.71 | 6.4                 | -                    | -                     | 0.93                | 131                   | 0.88|
| Chico Clay loam         | 1.65 | 5.2                 | -                    | -                     | 11.88               | 720                   | 0.77|
| Rosa Loam               | 0.41 | 6.9                 | -                    | -                     | 1.32                | 322                   | 0.86|
| Phelps Loamy sand       | 1.24 | 6.5                 | -                    | -                     | 1.42                | 114                   | 0.85|
| Geometric mean (n=5)    |      |                     | 1.72                 |                       |                     |                       |     |
| Arithmetic mean (n=5)   |      |                     | 3.26                 |                       |                     |                       |     |
| pH dependence, Yes or No|      |                     | No                   |                       |                     |                       |     |

<sup>a</sup> Medium not stated.  
* Only relevant after implementation of the published EFSA guidance.

### FH-432

| Soil Type               | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | 1/n |
|-------------------------|------|---------------------|----------------------|-----------------------|---------------------|-----------------------|-----|
| Fresno Sandy soil       | 0.35 | 7.1                 | -                    | -                     | 0.67                | 191                   | 0.94|
| Burkesville Loam        | 0.71 | 6.4                 | -                    | -                     | 0.75                | 106                   | 0.91|
| Chico Clay loam         | 1.65 | 5.2                 | -                    | -                     | 10.11               | 613                   | 0.81|
| Rosa Loam               | 0.41 | 6.9                 | -                    | -                     | 1.06                | 258                   | 0.90|
| Phelps Loamy sand       | 1.24 | 6.5                 | -                    | -                     | 1.31                | 106                   | 0.86|
| Geometric mean (n=5)    |      |                     | 1.48                 |                       |                     |                       |     |
| Arithmetic mean (n=5)   |      |                     | 2.78                 |                       |                     |                       |     |
| pH dependence, Yes or No|      |                     | No                   |                       |                     |                       |     |

<sup>a</sup> Medium not stated.  
* Only relevant after implementation of the published EFSA guidance.

### CM-0237

| Soil Type               | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | 1/n |
|-------------------------|------|---------------------|----------------------|-----------------------|---------------------|-----------------------|-----|
| Chelmorton Silt loam    | 2.8  | 6.1                 | -                    | -                     | 111                 | 3970                  | 0.75|
| Empingham Clay loam     | 4.6  | 7.6                 | -                    | -                     | 71                  | 1553                  | 0.75|
| Warsop Sandy loam       | 0.8  | 4.0                 | -                    | -                     | 15                  | 1929                  | 0.73|
| Geometric mean (n=3)    |      |                     | 49.1                 |                       |                     |                       |     |
| Arithmetic mean (n=3)   |      |                     | 65.7                 |                       |                     |                       |     |
| pH dependence, Yes or No|      |                     | No                   |                       |                     |                       |     |

<sup>a</sup> Measured in CaCl<sub>2</sub>.  
* Only relevant after implementation of the published EFSA guidance.

### 2-AB

K<sub>oc</sub> = 175 mL/g (estimated with PCKOCWIN Program, from EFSA Conclusion on carbendazim, 2010)
Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching | Not required. |
|-----------------|---------------|

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

| Column leaching | Not required. |
|-----------------|---------------|

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

| Lysimeter/ field leaching studies | Not required. |
Hydrolytic degradation (Regulation (EU) No 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %
Study with Thiophanate-methyl as test substance

| pH | DT50 (d) | Condition |
|----|----------|-----------|
| 5  | stable at 22°C | |
| 7  | 46.8 (1st order, χ2=1.4) | pH 22°C |
|    | Carbendazim: 28.6% AR (33 d) |  |
| 9  | 1.0 (1st order, χ2=3.3) | pH 22°C |
|    | Carbendazim was stable at pH 9 and 22°C |  |
|    | Carbendazim: 58.7% AR (4 d) |  |
|    | Carbendazim was stable at pH 9 and 22°C |  |
|    | DT50 12.6 at pH 9 and 45°C |  |
|    | AV-1951: 24.9% AR (4 d) |  |
|    | DT50 5.4 days at pH 9 and 22°C (SFO-SFO, χ2=0.8) |  |

Study with Carbendazim as test substance

| pH | DT50 (d) | Condition |
|----|----------|-----------|
| 7  | > 350 | 22 - 25°C |
|    | Met 2-AB: 3% AR (30 d) |  |
| 9  | > 350 | 22 - 25°C |
|    | Met 2-AB: 3% AR (30 d) |  |
|    | 54 - 124 | 20 - 25°C |
|    | Met 2-AB: 30% AR (30 d) |  |

a) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).

Aqueous photochemical degradation (Regulation (EU) No 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

| DT50 | Condition |
|------|-----------|
| 2.3  | Natural light, 35°CN, mid-Dec |
|      | From the quantum yield DT50 at 40°CN was calculated to |
|      | 1.0 d (summer), 2.0 d (spring) and 5.0 d (winter) |
|      | Carbendazim: 49.7% AR (5.5 d) |
|      | DX-105: 14.3% AR (5.5 d) |

Quantum yield of direct phototransformation in water at Σ > 290 nm

3.84 x 10\(^{-7}\) mol · Einstein\(^{-1}\)

‘Ready biodegradability’ (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)

No
Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Thiophanate-methyl | pH | pH | t | DT$_{50}$/DT$_{90}$ | St. | DT$_{50}$/DT$_{90}$ | St. | Method of calculation |
|--------------------|----|----|---|----------------|-----|----------------|-----|---------------------|
| System identifier  |    |    |   | whole sys.  |     | whole sys.  |     |                     |
| (indicate fresh,   |    |    |   | (suspended sediment |     | (suspended sediment |     |                     |
| estuarine or      |    |    |   | test) |     | test) |     |                     |
| marine)           |    |    |   | At study temp |     | At study temp |     |                     |
| Fresh lake water  | 7.6-9 | - | 20°C | - | - | - | 0.64 | 1.4 | 2.1 | DFOP |
| low dose          |    |    |   |      |     |      |     |                     |
| Fresh lake water  | 7.6-9 | - | 20°C | - | - | - | 2.2 | 4.7 | 2.5 | SFO |
| high dose         |    |    |   |      |     |      |     |                     |

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Temperature of incubation.
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

| Carbendazim       | Max in total system 82.8% after 14 days |
|-------------------|----------------------------------------|
| System identifier | pH | pH | t | DT$_{50}$/DT$_{90}$ | St. | DT$_{50}$/DT$_{90}$ | St. | Method of calculation |
| (indicate fresh,   |    |    |   | whole sys.  |     | whole sys.  |     |                     |
| estuarine or      |    |    |   | (suspended sediment |     | (suspended sediment |     |                     |
| marine)           |    |    |   | test) |     | test) |     |                     |
| Fresh lake water  | 7.6-9 | - | 20°C | - | - | - | 64.8 | 138 | 6.4 | DFOP-SFO |
| low dose          |    |    |   |      |     |      |     |                     |

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Temperature of incubation.
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

| FH-432            | Max in total system 11.3% after 4 days |
|-------------------|----------------------------------------|
| System identifier | pH | pH | t | DT$_{50}$/DT$_{90}$ | St. | DT$_{50}$/DT$_{90}$ | St. | Method of calculation |
| (indicate fresh,   |    |    |   | whole sys.  |     | whole sys.  |     |                     |
| estuarine or      |    |    |   | (suspended sediment |     | (suspended sediment |     |                     |
| marine)           |    |    |   | test) |     | test) |     |                     |
| Fresh lake water  | 7.6-9 | - | 20°C | - | - | - | 5.2 | 11 | 7.1 | SFO-SFO |
| high dose         |    |    |   |      |     |      |     |                     |

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Temperature of incubation.
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

| UM 1               | Max in total system 11.4% after 30 days |
|--------------------|----------------------------------------|
| System identifier  | pH | pH | t | DT$_{50}$/DT$_{90}$ | St. | DT$_{50}$/DT$_{90}$ | St. | Method of calculation |
| (indicate fresh,   |    |    |   | whole sys.  |     | whole sys.  |     |                     |
| estuarine or      |    |    |   | (suspended sediment |     | (suspended sediment |     |                     |
| marine)           |    |    |   | test) |     | test) |     |                     |
| Fresh lake water  | 7.6-9 | - | 20°C | - | - | - | not reliable | - | - |

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Temperature of incubation.
c) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).
Mineralisation and non-extractable residues (for thiophanate-methyl dosed experiment)

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
|--------------------------------------------------------|----------------|--------|-----------------------------------------------|---------------------------------------------------------------|-----------------------------------------------|
| Fresh lake water                                       | 7.6-9          | -      | 0.5% AR in traps (30 d)                        | -                                                             | -                                                             |

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)

| Thiophanate-methyl | Distribution: Max in water 98.4% day 0. Max. in sed 8.1 % after 8 d. |
|---------------------|---------------------------------------------------------------|
| Water / sediment system | pH water phase | pH sed | t. °C | DT_{50}/DT_{90} whole sys. | St. (χ²) | DT_{50}/DT_{90} water | St. (χ²) | DT_{50}/DT_{90} sed | St. (χ²) | Method of calculation |
| Pond system         | 7.7-8.4          | 7.6     | 20°C | 3.5 / 11.6          | 6.7     | 2.8 / 9.2     | 5.0  | -                  | -       | SFO                  |
| River system        | 7.9-8.4          | 7.8     | 20°C | 1.6 / 5.4           | 3.3     | 1.6 / 5.4     | 3.2  | -                  | -       | SFO                  |
| Geometric mean at 20°C (n=2) | 2.4             |         | |

a) Measured in CaCl_2.

| Carbendazim | Distribution: Max in total system (river system) 81.6% after 8 d. Max in water 39.0% after 8 d. Max in sediment 50.4% after 58 d. Kinetic formation fraction (k_f/k_dp): 0.81 (pond total system) and 0.76 (river total system). Arithmetic mean formation fraction: 0.78. Precursor: Thiophanate-methyl. |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH water phase | pH sed | t. °C | DT_{50}/DT_{90} whole sys. | St. (χ²) | DT_{50}/DT_{90} water | St. (χ²) | DT_{50}/DT_{90} sed | St. (χ²) | Method of calculation |
| Pond system  | 7.7-8.4          | 7.6     | 20°C | 76.2 / 253.2          | 8.5     | -                 | -    | -                  | -       | SFO                  |
| River system | 7.9-8.4          | 7.8     | 20°C | 91.6 / 304.2          | 6.4     | -                 | -    | -                  | -       | SFO                  |
| Bickenbach   | 8.5              | 8.0     | 20°C | 15.1 / 50            | 11      | 10.8 / 36       | 0.995| -                  | -       | SFO                  |
| Unter Widderheim | 8.1            | 7.5     | 20°C | 75.2 / 249.7         | 12      | 5.8 / 19.2     | 0.965| -                  | -       | SFO                  |
| Geometric mean at 20°C (n=4) | 53.1           |         | |

a) Measured in CaCl_2.
b) Medium not stated.
c) Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010).

| 4-OH-TM | Distribution: Max in total system (river system) 9.5% after 8 d. Max in water 4.4% after 8 d. Max in sediment 5.7% after 30 d. Results obtained by considering only on data from maximum observed onwards. |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH water phase | pH sed | t. °C | DT_{50}/DT_{90} whole sys. | St. (χ²) | DT_{50}/DT_{90} water | St. (χ²) | DT_{50}/DT_{90} sed | St. (χ²) | Method of calculation |
| Pond system  | 7.7-8.4          | 7.6     | 20°C | 32.4 / 108            | 12      | -                 | -    | -                  | -       | SFO                  |
| River system | 7.9-8.4          | 7.8     | 20°C | 26.2 / 87.2           | 13      | -                 | -    | -                  | -       | SFO                  |
| Geometric mean at 20°C | 29.2           |         | |

a) Measured in CaCl_2.
### 2-AB

Distribution: Max in total system (pond system) 7.5% after 58 d. Max in water 0.7% after 16 d. Max in sediment 7.0% after 58 d. Results obtained by considering only data from maximum observed onwards.

| Water / sediment system | pH water phase | pH sed | t. °C | DT50 / DT90 whole sys. | St. (χ2) | DT50 / DT90 water | St. (r²) | DT50 / DT90 sed | St. (χ2) | Method of calculation |
|-------------------------|----------------|--------|-------|------------------------|----------|-------------------|----------|----------------|----------|----------------------|
| Pond system             | 7.7-8.4        | 7.6 a) | 20°C  | 189 / 629              | 6.3      | -                 | -        | -              | -        | SFO                  |
| River system            | 7.9-8.4        | 7.8 a) | 20°C  | -                      | -        | -                 | -        | -              | -        | -                    |
| Geometric mean at 20°C  | -              |        |       |                        |          |                   |          |                 |          |                      |

a) Measured in CaCl₂.

### M10

Distribution: Max in total system (pond system) 9.3% after 140 d. Max in water 2.2% after 100 d. Max in sediment 7.7% after 140-202 d.

| Water / sediment system | pH water phase | pH sed | t. °C | DT50 / DT90 whole sys. | St. (χ2) | DT50 / DT90 water | St. (r²) | DT50 / DT90 sed | St. (χ2) | Method of calculation |
|-------------------------|----------------|--------|-------|------------------------|----------|-------------------|----------|----------------|----------|----------------------|
| Pond system             | 7.7-8.4        | 7.6 a) | 20°C  | -                      | -        | -                 | -        | -              | -        | -                    |
| River system            | 7.9-8.4        | 7.8 a) | 20°C  | -                      | -        | -                 | -        | -              | -        | -                    |
| Geometric mean at 20°C  | -              |        |       |                        |          |                   |          |                 |          |                      |

a) Measured at 20°C.

### Mineralisation and non-extractable residues (from thiophanate-methyl dosed experiments)

| Water / sediment system | pH water phase | pH sed | t. °C | Mineralisation x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|----------------|--------|-------|-------------------------------------------------|--------------------------------------------------|-------------------------------------------------|
| Pond system             | 7.7-8.4        | 7.6 a) | 5.2 % after 301 d | 70% after 301 d | 70% after 301 d |
| River system            | 7.9-8.4        | 7.8 a) | 1.3% after 100 d | 48.1 % after 100 d | 48.1 % after 100 d |

a) Measured in CaCl₂.
Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| Process                                      | Description                                                                 |
|----------------------------------------------|-----------------------------------------------------------------------------|
| Direct photolysis in air                     | Not studied - no data requested                                              |
| Photochemical oxidative degradation in air   | DT$_{50}$ of 1.8 hours derived by the Atkinson model (Aop Win version 1.92). |
| Volatilisation                               | OH (12 h) concentration assumed = $1.5 \times 10^6$ OH/cm$^3$               |

| Metabolites                                   |                                                                              |
|----------------------------------------------|------------------------------------------------------------------------------|
| Residues requiring further assessment        |                                                                              |
| Environmental occurring residues requiring   | Soil: Thiophanate-methyl, Carbendazim, CM-0237, 2-AB                        |
| further assessment by other disciplines       | Surface water: Thiophanate-methyl, Carbendazim, CM-0237, 2-AB, DX-105       |
| (toxicology and ecotoxicology) and or         | Sediment: Thiophanate-methyl, Carbendazim, CM-0237,                          |
| requiring consideration for groundwater      | 2-AB, 4-OH-TM, M10 (=UM2)                                                   |
| exposure                                      | Groundwater: Thiophanate-methyl, Carbendazim, CM-0237, 2-AB                 |
|                                              | Air: Thiophanate-methyl                                                     |

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

See section 5, Ecotoxicology

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

| Soil (indicate location and type of study)   | No data, not required                                                        |
|----------------------------------------------|------------------------------------------------------------------------------|
| Surface water (indicate location and type of study) | The RMS identified data from the Swedish monitoring programme at the national level for the years 2011-2013. There was no reported use of thiophanate-methyl in the four catchments (type areas) in 2011-2013, and there was no observation of the substance in these areas. Carbendazim was detected in concentrations above LOQ (0.002 µg/l for most samples) in 12% of the samples. The maximum weekly average concentration was 0.012 µg/L. The maximum duration of levels of carbendazim >LOQ was 18 weeks during which the weekly average concentrations ranged from 0.02 µg/L to 0.012 µg/L. The main source for these residues was believed to be cultivation of (imported) potato tubers or seeds treated with thiophanate-methyl or carbendazim. Additionally, in momentary samples taken from two stream thiophanate-methyl was found in 1/54 samples (0.002 µg/L). Carbendazim was found > LOQ in 46% of these samples (0.002 - 0.24 µg/L). |
| Ground water (indicate location and type of study)  | The RMS identified limited data from Swedish monitoring; no findings of thiophanate-methyl or the main metabolite carbendazim. |
| Rainwater (indicate location and type of study)    | The RMS identified data from the Swedish monitoring programme at the national level for the years 2011-2013. Two locations (Southern Sweden and close to Stockholm, respectively) and 89 samples in total. Carbendazim was detected (>LOD) in 34% of the samples (0.001-0.009 µg/L). Thiophanate-methyl was not detected in any of the samples. |
| Air (indicate location and type of study)          | No data, not required.                                                       |

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

**Method of calculation**

| Crop | Plant interception | Number of applications | Application rate (kg a.s./ha) |
|------|--------------------|-------------------------|-----------------------------|
| Grapes, early application | 60% | 1 | 1.1 |
| Grapes, late application | 75% | 1 | 1.1 |
| Tomato/aubergine | 0% (drip irrigation) | 3 | 0.7; 1.4; 2.3 |
| Leek | 0% (drenching) | 1 | 4.15 |
| Fresh beans | 70% | 1 or 2 | 0.75 |
| Winter cereals, early application | 90% | 1 | 0.75 |
| Winter cereals, late application | 80% | 1 | 0.75 |

**Application data**

| Crop | Plant interception | Number of applications | Application rates (kg a.s./ha) | Interval (d) | Depth of soil layer (cm) | Soil bulk density (g/cm³) |
|------|--------------------|-------------------------|-------------------------------|-------------|--------------------------|---------------------------|
| Grapes, early application | 60% | 1 | 1.1 | | 5 | 1.5 |
| Grapes, late application | 75% | 1 | 1.1 | | 5 | 1.5 |
| Tomato/aubergine | 0% (drip irrigation) | 3 | 0.7; 1.4; 2.3 | 30 | 5 | 1.5 |
| Leek | 0% (drenching) | 1 | 4.15 | | 5 | 1.5 |
| Fresh beans | 70% | 1 or 2 | 0.75; 1.4; 2.3 | | 5 | 1.5 |
| Winter cereals, early application | 90% | 1 | 0.75 | | 5 | 1.5 |
| Winter cereals, late application | 80% | 1 | 0.75 | | 5 | 1.5 |

**PEC(s) (mg/kg)**

| Crop | Initial | Plateau concentration |
|------|---------|-----------------------|
| Grapes, early application | 0.587 | Not required |
| Grapes, late application | 0.367 | |
| Tomato/aubergine | 0.933 | |
| Leek | 1 appl: 0.933 2 appl: 1.868 3 appl: 3.070 | 5.533 |

**PEC(s) (mg/kg)**

| Crop | Initial | Plateau concentration |
|------|---------|-----------------------|
| Fresh beans | 0.300 | Not required |
| Winter cereals, early application | 0.100 | |
| Winter cereals, late application | 0.200 | |

**Carbendazim**

**Method of calculation**

| Crop | Molecular weight relative to thiophanate-methyl: 0.558 | DT₅₀ (d): 78 days | Kinetics: SFO | Field or Lab: longest non-normalised field dissipation DT₅₀ |
|------|--------------------------------------------------|-----------------|--------------|-----------------------------|

In refinement for tomato/aubergine and leek, degradation of parent (thiophanate-methyl) and formation of carbendazim was taken into account using model Escape 2.0. The shortest non-normalised field dissipation DT$_{50}$ 0.99 days was used for the parent and the corresponding formation fraction 0.61 (parent → carbendazim) was used in these calculations.

| Application data |  |
|------------------|------------------|
| **PEC(s)** (mg/kg) |  |
| **Grapes, early application** Actual | **Grapes, late application** Actual | **Tomato/aubergine** Actual | **Leek** Actual |
| Initial | 0.248 | 0.155 | 1 appl: 0.395 | 2 appl: 1.093 | 3 appl: 2.135 | Refinement: 3rd appl: 1.642 | Refinement: 1.790 |
| Plateau concentration | | | | | |
|  |

Application rate assumed in standard calculations: assumed that carbendazim is formed at a maximum of 75.8% of the applied dose

| Application data |  |
|------------------|------------------|
| **PEC(s)** (mg/kg) |  |
| **Fresh beans** Single application Actual | **Fresh beans** Two application Actual | **Winter cereals, early application** Actual | **Winter cereals, late application** Actual |
| Initial | 0.127 | 0.239 | 0.042 | 0.085 |
| Plateau concentration | Not required |
|  |  |

Application rate assumed: assumed that CM-0237 is formed at a maximum of 9.8% of the applied dose

| CM-0237 |  |
|------------------|------------------|
| **Method of calculation** |  |
| **Application data** |  |
| **PEC(s)** (mg/kg) |  |
| **Grapes, early application** Actual | **Grapes, late application** Actual | **Tomato/aubergine** Actual | **Leek** Actual |
| Initial | 0.055 | 0.034 | 1 appl: 0.087 | 2 appl: 0.241 | 3 appl: 0.475 | 0.514 |
| Plateau concentration | 0.057 | 0.036 | 3 appl: 0.501 | 0.521 |
|  |  |

Molecular weight relative to thiophanate-methyl: 0.947
DT$_{50}$ (d): 86.5 days
Kinetics: SFO
Field or Lab: longest non-normalised laboratory DT$_{50}$

| Application data |  |
|------------------|------------------|
| **PEC(s)** (mg/kg) |  |
| **Fresh beans** Single application Actual | **Fresh beans** Two application Actual | **Winter cereals, early application** Actual | **Winter cereals, late application** Actual |
| Initial | 0.028 | 0.053 | 0.009 | 0.019 |
| Plateau concentration | -- | 0.053 | 0.009 | 0.019 |
|  |  |

Molecular weight relative to thiophanate-methyl: 0.389
DT$_{50}$ (d): 13.5 days
Kinetics: SFO
Field or Lab: longest non-normalised laboratory DT$_{50}$

| Application data |  |
|------------------|------------------|
| **PEC(s)** (mg/kg) |  |
| **Fresh beans** Single application Actual | **Fresh beans** Two application Actual | **Winter cereals, early application** Actual | **Winter cereals, late application** Actual |
| Initial | 0.057 | 0.036 | 3 appl: 0.501 | 0.521 |
| Plateau concentration | | |  |

| Application data |  |
|------------------|------------------|
| **PEC(s)** (mg/kg) |  |
| **Fresh beans** Single application Actual | **Fresh beans** Two application Actual | **Winter cereals, early application** Actual | **Winter cereals, late application** Actual |
| Initial | 0.0028 | 0.053 | 0.009 | 0.019 |
| Plateau concentration | -- | 0.053 | 0.009 | 0.019 |
|  |  |

Molecular weight relative to thiophanate-methyl: 0.389
DT$_{50}$ (d): 13.5 days
Kinetics: SFO
Field or Lab: longest non-normalised laboratory DT$_{50}$

Application rate assumed: assumed that 2-AB is formed at a maximum of 6.1% of the applied dose
| PEC(s) (mg/kg) | Grapes, early application Actual | Grapes, late application Actual | Tomato/aubergine Actual | Leek Actual |
|----------------|---------------------------------|---------------------------------|-------------------------|------------|
| Initial        | 0.014                           | 0.009                           | 1 appl: 0.022           | 0.131      |
|                |                                 |                                 | 2 appl: 0.049           |            |
|                |                                 |                                 | 3 appl: 0.083           |            |
| Plateau concentration | Not required |                                 |                         |            |

| PEC(s) (mg/kg) | Fresh beans Single application Actual | Fresh beans Two application Actual | Winter cereals, early application Actual | Winter cereals, late application Actual |
|----------------|-------------------------------------|----------------------------------|------------------------------------------|----------------------------------------|
| Initial        | 0.007                               | 0.011                            | 0.002                                    | 0.005                                  |
| Plateau concentration | Not required |                                 |                                           |                                        |
PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

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

| Substance          | Method of calculation and type of study | Crop uptake factor | For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7 |
|--------------------|----------------------------------------|-------------------|----------------------------------------------------------------------------------|
| Thiophanate-methyl | Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, MACRO 5.5.4 (only for grapes, tomatoes, leek and winter cereals where the pre-defined scenario Chateaudun is available) | 0 (thiophanate-methyl and metabolites) |                                                                                      |
| Carbendazim        | For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.0.2911, based on normalised field data. Note that data from all sampling points were used to derive endpoints from field study. |                                                                                      |                                                                                      |
| CM-0237            | Kinetic formation fraction (thiophanate-methyl → CM-0237): data gap |                                                                                      |                                                                                      |
| 2-AB               | Kinetic formation fraction (carbendazim → 2-AB): 0.48 (PEARL), 0.2016 (MACRO), 0.01664 (PELMO) |                                                                                      |                                                                                      |

Application rate

| Crop               | Crop uptake factor | For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7 |
|--------------------|-------------------|----------------------------------------------------------------------------------|
| Grapes             | 0 (thiophanate-methyl and metabolites) |                                                                                      |

Thiophanate-methyl:
Water solubility (mg/L): 18.5 at pH 7 and 20°C
Vapour pressure: 8.8 x 10^-6 Pa at 20°C
Geometric mean DT50: 1.0 d (overall mean based on normalised lab and normalised field data). Note that data from all sampling points were used to derive endpoints from field study.
KOC/KOM: geometric mean: 75.8 / 43.97 mL/g (n=4)
arithmetic mean 1/n: 0.95 (n=4)

Crop uptake factor: 0 (thiophanate-methyl and metabolites)

For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7

Carbendazim:
Water solubility (mg/L): 8 (24°C, pH 7)
Vapour pressure: 9 x 10^-3 Pa at 20°C
Geometric mean DT50: 20.0 d* (overall mean based on normalised field data). Note that data from all sampling points were used to derive endpoints from field study.
Kinetic formation fraction (thiophanate-methyl → carbendazim) (PEARL/MACRO): 0.42 (in PELMO 0.2911), based on normalised field data. Note that data from all sampling points were used to derive endpoints from field study.
KOC/KOM: geometric mean: 224.5 / 130.2 mL/g (n=3)
arithmetic mean 1/n: 0.967 (n=3)

* Inadequate value calculated based on incorrect normalised field DT50 values from carbendazim EFSA Conclusion (2010). It is considered that it is unlikely that this deficiency will change the conclusion on groundwater exposure assessment for the representative uses on wine grapes, tomatoes/aubergine, beans and winter cereals.

CM-0237:
Water solubility (mg/L): 1000
Vapour pressure: 0 Pa at 20°C
Geometric mean DT50: data gap
Kinetic formation fraction (thiophanate-methyl → CM-0237): data gap
KOC/KOM: geometric mean: 2283 / 1324 mL/g.
arithmetic mean 1/n= 0.743

2-AB:
Water solubility (mg/L): 1000
Vapour pressure: 0 Pa at 20°C
Geometric mean DT50: 9.7 d (n=3, parent-dosed studies)
Kinetic formation fraction (carbendazim → 2-AB): 0.48 (PEARL), 0.2016 (MACRO), 0.01664 (PELMO)
KOC/KOM: geometric mean: 175 / 101.5 mL/g (estimated with PCKOCWIN Program, from EFSA Conclusion on carbendazim, 2010), default 1/n= 1.0

Application rate

| Crop               | Crop uptake factor | For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7 |
|--------------------|-------------------|----------------------------------------------------------------------------------|
| Grapes             | 0 (thiophanate-methyl and metabolites) |                                                                                      |

For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7

Crop uptake factor: 0 (thiophanate-methyl and metabolites)

Application rate

| Crop               | Crop uptake factor | For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7 |
|--------------------|-------------------|----------------------------------------------------------------------------------|
| Grapes             | 0 (thiophanate-methyl and metabolites) |                                                                                      |

For normalisation of data to 20°C and pF2: Q10 of 2.58 and Walker eq. coefficient 0.7

Crop uptake factor: 0 (thiophanate-methyl and metabolites)
Canopy interception: 60% (early), 75% (late)
Application rate net of interception: 0.44 kg a.s./ha (early), 0.275 kg a.s./ha (late)
No. of applications: 1
Time of application (relative application dates): Early appl. set to 9 weeks after emergence. Late appl. set to 35 days before harvest

Crop: Tomato/aubergine
Gross application rate: 0.7; 1.4; 2.3 kg a.s./ha
Crop growth stage: 60-80 days before BBCH 32; BBCH 71; BBCH 85
Canopy interception: 0% (drip irrigation)
Application rate net of interception: 0.7; 1.4; 2.3 kg a.s./ha
No. of applications: 3
Interval (d): 30
Time of application (relative application dates): 1st appl. 15 days after transplantation harvest - 3rd appl. 7 d before harvest.

Crop: Leek
Gross application rate: 4.15 kg a.s./ha
Crop growth stage: BBCH 12-15
Canopy interception: 0% (drenching)
Application rate net of interception: 4.15 kg a.s./ha
No. of applications: 1
Time of application (relative application dates): planting date.

Crop: Fresh beans
Gross application rate: 0.75 kg a.s./ha
Crop growth stage: BBCH 61-71
Canopy interception: 70%
Application rate net of interception: 0.225 kg a.s./ha
No. of applications: 2
Interval (d): 14
Time of application (relative application dates): 1st appl. set to 3 months after emergence.

Crop: Winter cereals, early or late application
Gross application rate: 0.75 kg a.s./ha
Crop growth stage: BBCH 59-70
Canopy interception: 90% (early), 80% (late)
Application rate net of interception: 0.075 kg a.s./ha (early), 0.15 kg a.s./ha (late)
No. of applications: 1
Time of application (relative application dates): Early appl. set to 3 months before harvest. Late appl. set to 1 month before harvest.

* Only relevant after implementation of the published EFSA guidance.

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

| PELMO: | Thiophanate-methyl µg/L | Carbendazim µg/L | CM-0237 µg/L data gap | 2-AB µg/L |
|---|---|---|---|---|
| | early | late | early | late | early | late |
| Grapes | 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 |
| | Kremsmünster | <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 |
| Tomatoes | Châteaudun | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.001 |
| | Piacenza | <0.001 | <0.001 | 0.004 | 0.007 | 0.005 | 0.011 |
| | Porto | <0.001 | <0.001 | 0.001 | 0.005 | 0.003 | 0.001 |
| Crop        | Scenario                  | Thiophanate-methyl µg/L | Carbendazim µg/L | CM-0237 µg/L data gap | 2-AB µg/L |
|------------|---------------------------|--------------------------|------------------|-----------------------|-----------|
|            | early | late | early | late | early | late |
| Seville    | <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 |
| Leek       | Châteaudun | <0.001 | - | <0.001* | - | <0.001* | - |
|             | Hamburg | <0.001 | - | 0.002* | - | 0.001* | 0.003 |
|             | Jokioinen | <0.001 | - | <0.001* | - | <0.001* | - |
|             | Kremsmünster | <0.001 | - | 0.001* | - | 0.002* | - |
|             | Porto | <0.001 | - | 0.002* | - | 0.003* | - |
|             | Thiva | <0.001 | - | <0.001* | - | <0.001* | - |
| Beans, field | All 3 scenarios | - | <0.001 | - | <0.001 | - |
| Beans, vegetables | All 3 scenarios | - | <0.001 | - | <0.001 | - |
| Winter cereals | All 9 scenarios | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

* indicative PECgw values based on incorrect normalised field DT50 value of carbendazim (data gap for new GW modelling)

**PEARL:**

| Crop | Scenario | Thiophanate-methyl µg/L | Carbendazim µg/L | CM-0237 µg/L data gap | 2-AB µg/L |
|------|----------|--------------------------|------------------|-----------------------|-----------|
|      | early | late | early | late | early | late |
| Grapes | 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 |
|        | Kremmünster | <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 |
|        | Seville | <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 |
| Tomatoes | Châteaudun | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
|        | Piacenza | <0.001 | <0.001 | 0.002 | 0.006 | 0.002 | 0.005 |
|        | Porto | <0.001 | <0.001 | <0.001 | 0.003 | 0.002 | 0.005 |
|        | Seville | <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 |
| Leek | Châteaudun | <0.001 | - | 0.006* | - | 0.007* | - |
|        | Hamburg | <0.001 | - | 0.113* | - | 0.079* | - |
|        | Jokioinen | <0.001 | - | 0.036* | - | 0.043* | - |
|        | Kremsmünster | <0.001 | - | 0.118* | - | 0.071* | - |
|        | Porto | <0.001 | - | 0.010* | - | 0.013* | - |
|        | Thiva | <0.001 | - | <0.001* | - | <0.001* | - |
| Beans, field | All 3 scenarios | - | <0.001 | - | <0.001 | - |
| Beans, vegetables | All 3 scenarios | - | <0.001 | - | <0.001 | - |
| Winter cereals | All 9 scenarios | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

* indicative PECgw values based on incorrect normalised field DT50 value of carbendazim (data gap for new GW modelling)

**MACRO:**

| Crop        | Scenario                  | Thiophanate-methyl µg/L | Carbendazim µg/L | CM-0237 µg/L data gap | 2-AB µg/L |
|------------|---------------------------|--------------------------|------------------|-----------------------|-----------|
|            | early | late | early | late | early | late |
| Grapes      | Châteaudun | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Tomatoes *  | Châteaudun | <0.001 | <0.001 | 0.001 | 0.002 | 0.001 | <0.001 |
| Leek        | Châteaudun | <0.001 | - | <0.001* | - | <0.001* | - |
| Winter cereals | Châteaudun | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
* indicative PECgw values based on incorrect normalised field DT50 value of carbendazim (data gap for new GW modelling)

PEC(gw) From lysimeter / field studies

|            | 1st year | 2nd year | 3rd year |
|------------|----------|----------|----------|
| Thiophanate-methyl |        |          |          |
| Annual average (µg/L) | Not required | Not required | Not required |
| Metabolites |          |          |          |
| Annual average (µg/L) | Not required | Not required | Not required |
**PEC surface water and PEC sediment (Regulation (EU) No 284/2013, Annex Part A, points 9.2.5 / 9.3.1)**

### Thiophanate-methyl

Parameters used in FOCUSsw step 1 and 2

| Property | Value |
|----------|-------|
| Version control no. of FOCUS calculator | ver 3.2 |
| Molecular weight (g/mol) | 342.4 |
| $K_{OC}$ (mL/g) | 110.1 |
| RMS: The agreed geomean $K_{OC}$ is 75.8 |
| $DT_{50}$ soil (d): 1.0 days (lab + field, SFO) |
| $DT_{50}$ water/sediment system (d): 2.4 d (geomean, water/sed) |
| $DT_{50}$ water (d): 2.4 |
| $DT_{50}$ sediment (d): 2.4 |
| Crop interception: |
| Full canopy (Grapes 60%, Beans, winter cereals 70%) |
| Tomato/aubergine, leek no interception (soil incorporation) |

Parameters used in FOCUSsw step 3 and 4

| Property | Value |
|----------|-------|
| Version control no.’s of FOCUS software: FOCUS SWASH 5.3, PRZM 3.3.1, FOCUS MACRO 5.5.4, FOCUS TOXSWA 3.3.4, SWAN 4.0.1 |
| Water solubility (mg/L): | 18.5 |
| Vapour pressure: | $8.8 \times 10^{-6}$ Pa at 20°C |
| $K_{OC}/K_{OM}$ (mL/g): | 75.8 / 43.97 |
| $1/n$: | 0.95 |
| $DT_{50}$ water (d): | 2.4 |
| $DT_{50}$ sediment (d): | 1000 |
| Q10=2.58, Walker equation coefficient 0.7 |

**Application rate**

| Crop | Application method | No. of applications | Application rate | Application window |
|------|--------------------|---------------------|------------------|--------------------|
| Grapes, early application BBCH 57 | CAM 1, 4 cm incorporation depth | 1 | 1.1 kg/ha | start set to 9 weeks after emergence, early spray drift selected |
| Grapes, late application BBCH 81 | CAM 1, 4 cm incorporation depth | 1 | 1.1 kg/ha | end set to 35 days before harvest, late spray drift selected |
| Fresh beans BBCH 61-71 | CAM 1, 4 cm incorporation depth | 1 or 2 | 0.75 kg/ha | end set to 14 days before harvest |
| Winter cereals, early application BBCH 59 | CAM 1, 4 cm incorporation depth | 1 | 0.75 kg a.s./ha | start set to 3 months before harvest |
| Winter cereals, late application BBCH 70 | CAM 1, 4 cm incorporation depth | 1 | 0.75 kg a.s./ha | end set to 1 months before harvest |
| Tomato/aubergine | CAM 1, 4 cm incorporation depth | 3 | 0.7 – 1.4 – 2.3 kg/ha | |
| Leek | CAM 1, 4 cm incorporation depth | 1 | 4.15 kg a.s./ha | just after plantation BBCH 12-15 |

**Application rate**

| Crop | Application method | No. of applications | Application rate | Application window |
|------|--------------------|---------------------|------------------|--------------------|
| Grapes, early application BBCH 57 | CAM 1, 4 cm incorporation depth | 1 | 0.7 – 1.4 – 2.3 kg/ha | |
| Grapes, late application BBCH 81 | CAM 1, 4 cm incorporation depth | 1 | 0.75 kg a.s./ha | start set to 3 months before harvest |
| Fresh beans BBCH 61-71 | CAM 1, 4 cm incorporation depth | 1 or 2 | 0.75 kg/ha | end set to 14 days before harvest |
| Winter cereals, early application BBCH 59 | CAM 1, 4 cm incorporation depth | 1 | 0.75 kg a.s./ha | start set to 3 months before harvest |
| Winter cereals, late application BBCH 70 | CAM 1, 4 cm incorporation depth | 1 | 0.75 kg a.s./ha | end set to 1 months before harvest |
| Tomato/aubergine | CAM 1, 4 cm incorporation depth | 3 | 0.7 – 1.4 – 2.3 kg/ha | |
| Leek | CAM 1, 4 cm incorporation depth | 1 | 4.15 kg a.s./ha | just after plantation BBCH 12-15 |
### FOCUS STEP 1

| Thiophanate-methyl | Day after overall maximum | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|---------------------|--------------------------|-------------------|---------------------|
|                     | Actual | TWA | Actual | TWA |                     |
| Grapes, 1 x 1.1 kg a.s./ha | 0 h | 352.9 | | 323.8 |                     |
| Field beans 1/2 x 0.75 kg a.s./ha | 0 h | 227.5 | | 220.8 |                     |
| Winter cereals 1 x 0.75 kg a.s./ha | 0 h | 227.5 | | 220.8 |                     |
| Tomato (greenhouse) 3 x 2.3 kg a.s./ha | 0 h | 676.4 | | 677.1 |                     |
| Tomato (field) 3 x 2.1 kg a.s./ha | 0 h | 617.6 | | 618.2 |                     |
| Leek 1 x 4.15 kg a.s./ha | 0 h | 1220 | | 1220 |                     |

### FOCUS STEP 2

| Thiophanate-methyl | Day after overall maximum | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|---------------------|--------------------------|-------------------|---------------------|
|                     | Northern EU | Southern EU | Northern EU | Southern EU |                     |
| Grapes, Oct-Feb 1 x 1.1 kg a.s./ha | 0 h | 29.44 | 29.44 | 12.98 | 12.98 |
| Field beans, Oct-Feb 1/2 x 0.75 kg a.s./ha | 0 h | 6.898 | 6.898 | 3.401 | 3.042 |
| Winter cereals, Oct-Feb 1 x 0.75 kg a.s./ha | 0 h | 6.898 | 6.898 | 3.401 | 3.042 |
| Tomato (greenhouse), Oct-Feb 3 x 2.3 kg a.s./ha | 0 h | 21.14 | 16.91 | 21.16 | 16.93 |
| Tomato (field), Oct-Feb 3 x 2.1 kg a.s./ha | 0 h | 19.30 | 15.44 | 19.32 | 15.46 |
| Leek, Oct-Feb 1 x 4.15 kg a.s./ha | 0 h | 38.14 | 30.51 | 38.18 | 30.54 |
### FOCUS STEP 3

**Thiophanate-methyl**

| Water body | Day after overall maximum | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|------------|---------------------------|---------------------|-----------------------|

#### Grapes, early application, 1 x 1.1 kg a.s./ha

|  |  |  |  |
|---|---|---|---|
| D6 | ditch | 0 h | 6.231 | 1.206 |
| R1 | pond | 0 h | 0.228 | 0.111 |
| R1 | stream | 0 h | 4.561 | 0.694 |
| R2 | stream | 0 h | 6.110 | 0.300 |
| R3 | stream | 0 h | 6.423 | 1.303 |
| R4 | stream | 0 h | 4.487 | 0.267 |

#### Grapes, late application, 1 x 1.1 kg a.s./ha

|  |  |  |  |
|---|---|---|---|
| D6 | ditch | 0 h | 18.880 | 4.730 |
| R1 | pond | 0 h | 0.672 | 0.223 |
| R1 | stream | 0 h | 13.850 | 1.097 |
| R2 | stream | 0 h | 18.560 | 0.928 |
| R3 | stream | 0 h | 19.520 | 3.034 |
| R4 | stream | 0 h | 13.850 | 1.068 |

#### Beans, single application, 1 x 0.75 kg a.s./ha

|  |  |  |  |
|---|---|---|---|
| D2 | ditch | 0 h | 3.983 | 1.126 |
| D2 | stream | 0 h | 3.717 | 1.052 |
| D3 | ditch | 0 h | 3.944 | 0.693 |
| D4 | pond | 0 h | 0.159 | 0.048 |
| D4 | stream | 0 h | 3.538 | 0.289 |
| D6, 1<sup>st</sup> crop | ditch | 0 h | 3.883 | 0.412 |
| D6, 2<sup>nd</sup> crop | ditch | 0 h | 3.886 | 0.398 |
| R1 | pond | 0 h | 0.492 | 0.244 |
| R1 | stream | 0 h | 13.240 | 2.040 |
| R2 | stream | 0 h | 3.658 | 0.187 |
| R3 | stream | 0 h | 3.840 | 0.400 |
| R4 | stream | 0 h | 11.440 | 2.194 |

#### Beans, multiple application, 2 x 0.75 kg a.s./ha

|  |  |  |  |
|---|---|---|---|
| D2 | ditch | 0 h | 23.400 | 3.755 |
| D2 | stream | 0 h | 14.980 | 2.144 |
| D3 | ditch | 0 h | 3.427 | 0.751 |
| D4 | pond | 0 h | 0.136 | 0.062 |
| D4 | stream | 0 h | 3.071 | 0.313 |
| D6, 1<sup>st</sup> crop | ditch | 0 h | 3.439 | 0.838 |
| D6, 2<sup>nd</sup> crop | ditch | 0 h | 3.417 | 0.546 |
| R1 | pond | 0 h | 0.677 | 0.376 |
| R1 | stream | 0 h | 13.240 | 2.380 |
| R2 | stream | 0 h | 3.149 | 0.173 |
| R3 | stream | 0 h | 14.260 | 2.207 |
| R4 | stream | 0 h | 20.910 | 4.258 |

#### Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth

|  |  |  |  |
|---|---|---|---|
| D3 | ditch | 0 h | < 0.001 | < 0.001 |
| D4 | pond | 0 h | < 0.001 | < 0.001 |
| D4 | stream | 0 h | < 0.001 | < 0.001 |
| D6, 1<sup>st</sup> crop | ditch | 0 h | < 0.001 | < 0.001 |
| D6, 2<sup>nd</sup> crop | ditch | 0 h | < 0.001 | < 0.001 |
| R1 | pond | 0 h | 0.001 | < 0.001 |
| R1 | stream | 0 h | 0.130 | 0.019 |
| R2 | stream | 0 h | 0.084 | 0.013 |
| R3 | stream | 0 h | 0.793 | 0.113 |
| R4 | stream | 0 h | 0.638 | 0.126 |

#### Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, early

|  |  |  |  |
|---|---|---|---|
| D6 | ditch | 0 h | < 0.001 | < 0.001 |
| R2 | stream | 0 h | 0.156 | 0.031 |
| R3 | stream | 0 h | 10.180 | 2.253 |
| R4 | stream | 0 h | 9.778 | 1.856 |

#### Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late

|  |  |  |  |
|---|---|---|---|
| D6 | ditch | 0 h | < 0.001 | < 0.001 |
| R2 | stream | 0 h | 0.104 | 0.024 |
| R3 | stream | 0 h | 10.180 | 2.253 |
| R4 | stream | 0 h | 28.460 | 4.763 |
| FOCUS STEP 3 | Water body | Day after overall maximum | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|--------------|------------|----------------------------|---------------------|----------------------|
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, early | D6 ditch | 0 h | < 0.001 | < 0.001 |
| | R2 stream | 0 h | 0.156 | 0.028 |
| | R3 stream | 0 h | 10.180 | 2.253 |
| | R4 stream | 0 h | 9.778 | 1.856 |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late | D6 ditch | 0 h | < 0.001 | < 0.001 |
| | R2 stream | 0 h | 0.095 | 0.022 |
| | R3 stream | 0 h | 10.180 | 2.253 |
| | R4 stream | 0 h | 28.460 | 4.763 |
| Winter cereals, early application, 1 x 0.75 kg a.s./ha | D1 ditch | 0 h | 4.812 | 1.718 |
| | D1 stream | 0 h | 4.207 | 0.759 |
| | D2 ditch | 0 h | 28.900 | 6.718 |
| | D2 stream | 0 h | 20.890 | 3.677 |
| | D3 ditch | 0 h | 4.757 | 0.780 |
| | D4 pond | 0 h | 0.164 | 0.060 |
| | D4 stream | 0 h | 3.965 | 0.225 |
| | D5 pond | 0 h | 0.164 | 0.072 |
| | D5 stream | 0 h | 4.190 | 0.200 |
| | D6 ditch | 0 h | 4.776 | 1.078 |
| | R1 pond | 0 h | 0.164 | 0.066 |
| | R1 stream | 0 h | 3.389 | 0.490 |
| | R3 stream | 0 h | 4.424 | 0.823 |
| | R4 stream | 0 h | 12.260 | 2.113 |
| Winter cereals, late application, 1 x 0.75 kg a.s./ha | D1 ditch | 0 h | 4.812 | 1.539 |
| | D1 stream | 0 h | 4.207 | 0.829 |
| | D2 ditch | 0 h | 4.815 | 1.433 |
| | D2 stream | 0 h | 4.284 | 1.278 |
| | D3 ditch | 0 h | 4.762 | 0.806 |
| | D4 pond | 0 h | 0.164 | 0.050 |
| | D4 stream | 0 h | 4.111 | 0.386 |
| | D5 pond | 0 h | 0.164 | 0.057 |
| | D5 stream | 0 h | 4.435 | 0.482 |
| | D6 ditch | 0 h | 4.795 | 1.189 |
| | R1 pond | 0 h | 0.411 | 0.168 |
| | R1 stream | 0 h | 3.281 | 0.816 |
| | R3 stream | 0 h | 15.040 | 2.267 |
| | R4 stream | 0 h | 3.144 | 0.255 |
| FOCUS STEP 4 | Thiophanate-methyl | Water body | Day after overall maximum | 10 m vegetated buffer zone | 20 m vegetated buffer zone |
|--------------|---------------------|------------|---------------------------|----------------------------|----------------------------|
|              |                     |            |                           | PECsw, µg/l, Actual | PECsed, µg/kg, Actual | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
| **Grapes, early application, 1 x 1.1 kg a.s./ha** |                     |            |                           |                           |                           |                           |
| D6           | ditch               | 0 h        | 1.308                     | 0.263                     | 0.446                     | 0.092                     |
| R1           | pond                | 0 h        | 0.134                     | 0.056                     | 0.066                     | 0.028                     |
| R1           | stream              | 0 h        | 1.438                     | 0.302                     | 0.751                     | 0.157                     |
| R2           | stream              | 0 h        | 1.554                     | 0.078                     | 0.529                     | 0.035                     |
| R3           | stream              | 0 h        | 2.506                     | 0.575                     | 1.312                     | 0.300                     |
| R4           | stream              | 0 h        | 1.141                     | 0.069                     | 0.389                     | 0.024                     |
| **Grapes, late application, 1 x 1.1 kg a.s./ha** |                     |            |                           |                           |                           |                           |
| D6           | ditch               | 0 h        | 4.135                     | 1.070                     | 1.450                     | 0.384                     |
| R1           | pond                | 0 h        | 0.430                     | 0.144                     | 0.216                     | 0.074                     |
| R1           | stream              | 0 h        | 3.654                     | 0.296                     | 1.282                     | 0.106                     |
| R2           | stream              | 0 h        | 4.898                     | 0.250                     | 1.718                     | 0.089                     |
| R3           | stream              | 0 h        | 6.496                     | 1.311                     | 3.395                     | 0.676                     |
| R4           | stream              | 0 h        | 3.654                     | 0.289                     | 1.281                     | 0.103                     |
| **Beans, single application, 1 x 0.75 kg a.s./ha** |                     |            |                           |                           |                           |                           |
| D2           | ditch               | 0 h        | 1.833                     | 0.284                     | 1.833                     | 0.247                     |
| D2           | stream              | 0 h        | 1.211                     | 0.243                     | 1.211                     | 0.165                     |
| D3           | ditch               | 0 h        | 0.686                     | 0.125                     | 0.356                     | 0.066                     |
| D4           | pond                | 0 h        | 0.102                     | 0.031                     | 0.068                     | 0.021                     |
| D4           | stream              | 0 h        | 0.790                     | 0.066                     | 0.411                     | 0.035                     |
| D6, 1<sup>st</sup> crop | ditch | 0 h        | 0.675                     | 0.074                     | 0.351                     | 0.039                     |
| D6, 2<sup>nd</sup> crop | ditch | 0 h        | 0.676                     | 0.073                     | 0.352                     | 0.039                     |
| R1           | pond                | 0 h        | 0.204                     | 0.108                     | 0.105                     | 0.058                     |
| R1           | stream              | 0 h        | 5.983                     | 0.903                     | 3.126                     | 0.475                     |
| R2           | stream              | 0 h        | 0.817                     | 0.043                     | 0.425                     | 0.022                     |
| R3           | stream              | 0 h        | 0.857                     | 0.092                     | 0.446                     | 0.048                     |
| R4           | stream              | 0 h        | 5.200                     | 0.996                     | 2.725                     | 0.528                     |
| **Beans, multiple application, 2 x 0.75 kg a.s./ha** |                     |            |                           |                           |                           |                           |
| D2           | ditch               | 0 h        | 23.400                    | 2.994                     | 23.400                    | 2.919                     |
| D2           | stream              | 0 h        | 14.980                    | 1.678                     | 14.980                    | 1.615                     |
| D3           | ditch               | 0 h        | 0.562                     | 0.128                     | 0.286                     | 0.066                     |
| D4           | pond                | 0 h        | 0.086                     | 0.040                     | 0.056                     | 0.026                     |
| D4           | stream              | 0 h        | 0.652                     | 0.068                     | 0.332                     | 0.035                     |
| D6, 1<sup>st</sup> crop | ditch | 0 h        | 0.564                     | 0.143                     | 0.287                     | 0.074                     |
| D6, 2<sup>nd</sup> crop | ditch | 0 h        | 0.566                     | 0.111                     | 0.291                     | 0.068                     |
| R1           | pond                | 0 h        | 0.283                     | 0.165                     | 0.146                     | 0.089                     |
| R1           | stream              | 0 h        | 5.983                     | 1.013                     | 3.126                     | 0.531                     |
| R2           | stream              | 0 h        | 0.669                     | 0.038                     | 0.340                     | 0.019                     |
| R3           | stream              | 0 h        | 6.480                     | 0.990                     | 3.393                     | 0.525                     |
| R4           | stream              | 0 h        | 9.467                     | 1.923                     | 4.952                     | 1.017                     |
| **Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth** |                     |            |                           |                           |                           |                           |
| D3           | ditch               | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| D4           | pond                | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| D4           | stream              | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| D6, 1<sup>st</sup> crop | ditch | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| D6, 2<sup>nd</sup> crop | ditch | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| R1           | pond                | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| R1           | stream              | 0 h        | 0.054                     | 0.008                     | 0.028                     | 0.004                     |
| R2           | stream              | 0 h        | 0.037                     | 0.006                     | 0.019                     | 0.003                     |
| R3           | stream              | 0 h        | 0.355                     | 0.051                     | 0.185                     | 0.027                     |
| R4           | stream              | 0 h        | 0.289                     | 0.058                     | 0.151                     | 0.031                     |
| **Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, early** |                     |            |                           |                           |                           |                           |
| D6           | ditch               | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| R2           | stream              | 0 h        | 0.070                     | 0.013                     | 0.036                     | 0.007                     |
| R3           | stream              | 0 h        | 4.643                     | 0.934                     | 2.435                     | 0.486                     |
| R4           | stream              | 0 h        | 4.423                     | 0.841                     | 2.312                     | 0.445                     |
| **Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late** |                     |            |                           |                           |                           |                           |
| D6           | ditch               | 0 h        | < 0.001                   | < 0.001                   | < 0.001                   | < 0.001                   |
| R2           | stream              | 0 h        | 0.047                     | 0.010                     | 0.024                     | 0.005                     |
| R3           | stream              | 0 h        | 4.643                     | 0.934                     | 2.435                     | 0.486                     |
FOCUS STEP 4
Thiophanate-methyl

| Water body | Day after overall maximum | 10 m vegetated buffer zone | 20 m vegetated buffer zone |
|------------|---------------------------|---------------------------|---------------------------|
|            | PECsw, µg/l, Actual       | PECsed, µg/kg, Actual     | PECsw, µg/l, Actual       | PECsed, µg/kg, Actual |
| R4         | 0 h                       | 12.780                    | 2.138                     | 6.660                  | 1.126                |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, early |
| D6         | ditch 0 h                 | < 0.001                   | < 0.001                   | < 0.001                 | < 0.001               |
| R2         | stream 0 h                | 0.070                     | 0.012                     | 0.036                   | 0.006                 |
| R3         | stream 0 h                | 4.643                     | 0.934                     | 2.435                   | 0.486                 |
| R4         | stream 0 h                | 4.423                     | 0.841                     | 2.312                   | 0.445                 |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late |
| D6         | ditch 0 h                 | < 0.001                   | < 0.001                   | < 0.001                 | < 0.001               |
| R2         | stream 0 h                | 0.043                     | 0.009                     | 0.022                   | 0.005                 |
| R3         | stream 0 h                | 4.643                     | 0.934                     | 2.435                   | 0.486                 |
| R4         | stream 0 h                | 12.780                    | 2.138                     | 6.660                   | 1.126                 |
| Winter cereals, early application, 1 x 0.75 kg a.s./ha |
| D1         | ditch 0 h                 | 0.694                     | 0.339                     | 0.361                   | 0.225                 |
| D1         | stream 0 h                | 0.815                     | 0.204                     | 0.424                   | 0.144                 |
| D2         | ditch 0 h                 | 28.900                    | 6.151                     | 28.900                  | 6.105                 |
| D2         | stream 0 h                | 20.890                    | 3.199                     | 20.890                  | 3.144                 |
| D3         | ditch 0 h                 | 0.684                     | 0.117                     | 0.356                   | 0.062                 |
| D4         | pond 0 h                  | 0.102                     | 0.037                     | 0.068                   | 0.025                 |
| D4         | stream 0 h                | 0.768                     | 0.045                     | 0.399                   | 0.023                 |
| D5         | pond 0 h                  | 0.102                     | 0.045                     | 0.068                   | 0.031                 |
| D5         | stream 0 h                | 0.812                     | 0.040                     | 0.422                   | 0.021                 |
| D6         | ditch 0 h                 | 0.687                     | 0.162                     | 0.357                   | 0.085                 |
| R1         | pond 0 h                  | 0.102                     | 0.041                     | 0.068                   | 0.027                 |
| R1         | stream 0 h                | 1.395                     | 0.198                     | 0.704                   | 0.101                 |
| R3         | stream 0 h                | 1.552                     | 0.350                     | 0.814                   | 0.184                 |
| R4         | stream 0 h                | 5.533                     | 0.960                     | 2.888                   | 0.508                 |
| Winter cereals, late application, 1 x 0.75 kg a.s./ha |
| D1         | ditch 0 h                 | 0.693                     | 0.601                     | 0.361                   | 0.596                 |
| D1         | stream 0 h                | 0.815                     | 0.399                     | 0.424                   | 0.398                 |
| D2         | ditch 0 h                 | 0.692                     | 0.215                     | 0.360                   | 0.113                 |
| D2         | stream 0 h                | 0.830                     | 0.257                     | 0.431                   | 0.135                 |
| D3         | ditch 0 h                 | 0.685                     | 0.121                     | 0.356                   | 0.064                 |
| D4         | pond 0 h                  | 0.102                     | 0.031                     | 0.068                   | 0.021                 |
| D4         | stream 0 h                | 0.797                     | 0.077                     | 0.414                   | 0.041                 |
| D5         | pond 0 h                  | 0.102                     | 0.036                     | 0.068                   | 0.024                 |
| D5         | stream 0 h                | 0.860                     | 0.096                     | 0.447                   | 0.051                 |
| D6         | ditch 0 h                 | 0.690                     | 0.178                     | 0.358                   | 0.094                 |
| R1         | pond 0 h                  | 0.168                     | 0.075                     | 0.085                   | 0.041                 |
| R1         | stream 0 h                | 1.494                     | 0.326                     | 0.784                   | 0.169                 |
| R3         | stream 0 h                | 6.837                     | 1.016                     | 3.580                   | 0.539                 |
| R4         | stream 0 h                | 0.609                     | 0.051                     | 0.317                   | 0.027                 |
Metabolite Carbendazim

Parameters used in FOCUSsw step 1 and 2

- Molecular weight (g/mol): 191.21
- \( K_{OC} (\text{mL/g}) \): 394.0
- RMS: The agreed \( K_{OC} \) is 224.5
- \( DT_{50} \) soil (d): 20.0 days (field, SFO)
- \( DT_{50} \) water/sediment system (d): 53.1 (geomean, water/sed)
- \( DT_{50} \) water (d): 53.1
- \( DT_{50} \) sediment (d): 53.1
- Crop interception:
  - Full canopy (Grapes 60%, Beans, winter cereals 70%)
  - Tomato/aubergine, leek no interception (soil incorporation)
- Maximum occurrence observed (% molar basis with respect to the parent)
  - Total Water and Sediment: 82.8% (in water without sediment)
  - Soil: 75.8%

*It should be noted that the available PECsw/PECsed for carbendazim need to be confirmed when the correct normalised field DT50 will be available.

Parameters used in FOCUSsw step 3 and 4

- Water solubility (mg/L): 8
- Vapour pressure: \( 9 \times 10^{-5} \text{ Pa at } 20^\circ \text{C} \)
- \( K_{OC}/K_{OM} (\text{mL/g}) \): 224.5 / 130.2
- 1/n: 0.9675
- Q10=2.58, Walker equation coefficient 0.7
- Crop uptake factor: 0
- Metabolite kinetically generated in simulation: yes
- Formation fraction in soil (kf/kdp): 0.42 (field)
- (thiophanate-methyl \( \rightarrow \) carbendazim)
- Formation fraction in sediment water (kf/kdp): 0.78
- (thiophanate-methyl \( \rightarrow \) carbendazim)

Application rate

See thiophanate-methyl module

| FOCUS STEP 1 Carbendazim | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------------------|---------------------------|-----------------|-------------------|
|                          | Actual                    | TWA             | Actual            | TWA           |
| Grapes, 1 x 1.1 kg a.s./ha| 0 h                       | 226.5           | 839.0             |
| Field beans, 1/2 x 0.75 kg a.s./ha| 0 h                    | 296.7           | 1140              |
| Winter cereals, 1 x 0.75 kg a.s./ha| 0 h                    | 148.3           | 572.0             |
| Tomato (greenhouse), 3 x 2.3 kg a.s./ha| 0 h                    | 1340            | 5260              |
| Tomato (field), 3 x 2.1 kg a.s./ha| 0 h                      | 1220            | 4810              |
| Leek, 1 x 4.15 kg a.s./ha| 0 h                       | 803.2           | 3170              |
| FOCUS STEP 2 | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|--------------|---------------------------|-----------------|-------------------|
|              |                           | Northern EU     | Southern EU       |
|              |                           | Northern EU     | Southern EU       |
| Grapes, Oct-Feb 1 x 1.1 kg a.s./ha | 0 h | 28.67 | 24.85 | 107.3 | 92.39 |
| Field beans, Oct-Feb 1/2 x 0.75 kg a.s./ha | 0 h | 18.98 | 15.91 | 72.20 | 60.26 |
| Winter cereals, Oct-Feb 1x 0.75 kg a.s./ha | 0 h | 12.01 | 10.06 | 45.72 | 38.12 |
| Tomato (greenhouse), Oct-Feb 3 x 2.3 kg a.s./ha | 0 h | 144.2 | 115.3 | 568.2 | 454.6 |
| Tomato (field), Oct-Feb 3 x 2.1 kg a.s./ha | 0 h | 131.6 | 105.3 | 518.8 | 415.0 |
| Leek, Oct-Feb 1 x 4.15 kg a.s./ha | 0 h | 180.2 | 144.2 | 710.1 | 568.1 |
| FOCUS STEP 3 Carbazim | Water body | Day after overall maximum | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|-----------------------|------------|--------------------------|---------------------|----------------------|
| Grapes, early application, 1 x 1.1 kg a.s./ha |
| D6                    | ditch      | 0 h                      | 0.369               | 0.174                |
| R1                    | pond       | 0 h                      | 0.210               | 0.410                |
| R1                    | stream     | 0 h                      | 1.834               | 0.541                |
| R2                    | stream     | 0 h                      | 1.270               | 0.503                |
| R3                    | stream     | 0 h                      | 1.624               | 1.755                |
| R4                    | stream     | 0 h                      | 0.188               | 0.030                |
| Grapes, late application, 1 x 1.1 kg a.s./ha |
| D6                    | ditch      | 0 h                      | 4.268               | 3.432                |
| R1                    | pond       | 0 h                      | 0.212               | 0.507                |
| R1                    | stream     | 0 h                      | 1.502               | 0.039                |
| R2                    | stream     | 0 h                      | 0.656               | 0.046                |
| R3                    | stream     | 0 h                      | 7.092               | 2.094                |
| R4                    | stream     | 0 h                      | 0.855               | 0.287                |
| Beans, single application, 1 x 0.75 kg a.s./ha |
| D2                    | ditch      | 0 h                      | 5.687               | 5.385                |
| D2                    | stream     | 0 h                      | 3.770               | 1.960                |
| D3                    | ditch      | 0 h                      | 0.295               | 0.123                |
| D4                    | pond       | 0 h                      | 0.069               | 0.240                |
| D4                    | stream     | 0 h                      | 0.147               | 0.075                |
| D6, 1st crop          | ditch      | 0 h                      | 0.062               | 0.025                |
| D6, 2nd crop          | ditch      | 0 h                      | 0.165               | 0.072                |
| R1                    | pond       | 0 h                      | 0.522               | 1.003                |
| R1                    | stream     | 0 h                      | 4.134               | 0.934                |
| R2                    | stream     | 0 h                      | 0.131               | 0.059                |
| R3                    | stream     | 0 h                      | 1.816               | 0.391                |
| R4                    | stream     | 0 h                      | 5.310               | 1.541                |
| Beans, multiple application, 2 x 0.75 kg a.s./ha |
| D2                    | ditch      | 0 h                      | 15.920              | 13.980               |
| D2                    | stream     | 0 h                      | 11.800              | 5.202                |
| D3                    | ditch      | 0 h                      | 0.299               | 0.158                |
| D4                    | pond       | 0 h                      | 0.174               | 0.554                |
| D4                    | stream     | 0 h                      | 0.197               | 0.196                |
| D6, 1st crop          | ditch      | 0 h                      | 0.555               | 0.332                |
| D6, 2nd crop          | ditch      | 0 h                      | 0.371               | 0.314                |
| R1                    | pond       | 0 h                      | 0.771               | 1.573                |
| R1                    | stream     | 0 h                      | 4.288               | 1.272                |
| R2                    | stream     | 0 h                      | 0.310               | 0.180                |
| R3                    | stream     | 0 h                      | 6.847               | 1.642                |
| R4                    | stream     | 0 h                      | 6.992               | 2.199                |
| Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth |
| D3                    | ditch      | 0 h                      | < 0.001             | < 0.001              |
| D4                    | pond       | 0 h                      | 0.009               | 0.028                |
| D4                    | stream     | 0 h                      | 0.015               | 0.012                |
| D6, 1st crop          | ditch      | 0 h                      | 0.001               | 0.002                |
| D6, 2nd crop          | ditch      | 0 h                      | 0.303               | 0.185                |
| R1                    | pond       | 0 h                      | 0.010               | 0.020                |
| R1                    | stream     | 0 h                      | 0.318               | 0.064                |
| R2                    | stream     | 0 h                      | 0.276               | 0.057                |
| R3                    | stream     | 0 h                      | 0.738               | 0.152                |
| R4                    | stream     | 0 h                      | 0.855               | 0.244                |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, early |
| D6                    | ditch      | 0 h                      | 0.004               | 0.002                |
| R2                    | stream     | 0 h                      | 6.078               | 2.701                |
| R3                    | stream     | 0 h                      | 12.350              | 5.392                |
| R4                    | stream     | 0 h                      | 7.308               | 2.305                |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late |
| D6                    | ditch      | 0 h                      | 0.005               | 0.002                |
| R2                    | stream     | 0 h                      | 5.950               | 2.102                |
| R3                    | stream     | 0 h                      | 12.350              | 5.392                |
| R4                    | stream     | 0 h                      | 15.670              | 5.493                |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, early |
| D6                    | ditch      | 0 h                      | 0.003               | 0.002                |
| FOCUS STEP 3 Carbendazim | Water body | Day after overall maximum | PEC\(_{sw}\), µg/l, Actual | PEC\(_{sed}\), µg/kg, Actual |
|--------------------------|-----------|--------------------------|-----------------------------|-----------------------------|
| R2                       | stream    | 0 h                      | 5.608                       | 2.516                       |
| R3                       | stream    | 0 h                      | 11.510                      | 5.001                       |
| R4                       | stream    | 0 h                      | 7.308                       | 2.305                       |

**Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late**

| Day after overall maximum | PEC\(_{sw}\), µg/l, Actual | PEC\(_{sed}\), µg/kg, Actual |
|---------------------------|-----------------------------|-----------------------------|
| D6                        | 0 h                         | 0.004                       | 0.002                       |
| R2                        | stream                      | 0 h                         | 0.002                       |
| R3                        | stream                      | 0 h                         | 0.002                       |
| R4                        | stream                      | 0 h                         | 0.002                       |

**Winter cereals, early application, 1 x 0.75 kg a.s./ha**

| Day after overall maximum | PEC\(_{sw}\), µg/l, Actual | PEC\(_{sed}\), µg/kg, Actual |
|---------------------------|-----------------------------|-----------------------------|
| D1                        | ditch                       | 0 h                         | 1.429                       | 2.938                       |
| D2                        | stream                      | 0 h                         | 0.365                       | 0.667                       |
| D2                        | ditch                       | 0 h                         | 4.367                       | 4.524                       |
| D2                        | stream                      | 0 h                         | 9.168                       | 2.705                       |
| D3                        | ditch                       | 0 h                         | 0.212                       | 0.076                       |
| D4                        | pond                        | 0 h                         | 0.055                       | 0.158                       |
| D4                        | stream                      | 0 h                         | 0.144                       | 0.035                       |
| D5                        | pond                        | 0 h                         | 0.066                       | 0.183                       |
| D5                        | stream                      | 0 h                         | 0.213                       | 0.043                       |
| D6                        | ditch                       | 0 h                         | 0.415                       | 0.254                       |
| R1                        | pond                        | 0 h                         | 0.129                       | 0.274                       |
| R3                        | stream                      | 0 h                         | 1.271                       | 0.347                       |
| R4                        | stream                      | 0 h                         | 2.823                       | 0.911                       |

**Winter cereals, late application, 1 x 0.75 kg a.s./ha**

| Day after overall maximum | PEC\(_{sw}\), µg/l, Actual | PEC\(_{sed}\), µg/kg, Actual |
|---------------------------|-----------------------------|-----------------------------|
| D1                        | ditch                       | 0 h                         | 1.534                       | 3.145                       |
| D2                        | stream                      | 0 h                         | 0.393                       | 0.810                       |
| D2                        | ditch                       | 0 h                         | 1.593                       | 3.272                       |
| D3                        | stream                      | 0 h                         | 1.502                       | 2.538                       |
| D4                        | ditch                       | 0 h                         | 0.268                       | 0.102                       |
| D4                        | pond                        | 0 h                         | 0.060                       | 0.213                       |
| D4                        | stream                      | 0 h                         | 0.183                       | 0.056                       |
| D5                        | pond                        | 0 h                         | 0.075                       | 0.235                       |
| D5                        | stream                      | 0 h                         | 0.258                       | 0.092                       |
| D6                        | ditch                       | 0 h                         | 1.131                       | 0.917                       |
| R1                        | pond                        | 0 h                         | 0.320                       | 0.638                       |
| R1                        | stream                      | 0 h                         | 1.838                       | 0.570                       |
| R3                        | stream                      | 0 h                         | 6.355                       | 1.410                       |
| R4                        | stream                      | 0 h                         | 0.140                       | 0.016                       |
FOCUS STEP 4 Carbendazim

| Water body | Day after overall maximum | 10 m vegetated buffer zone | 20 m vegetated buffer zone |
|------------|---------------------------|---------------------------|---------------------------|
|            | PECsw, µg/l, Actual | PECsed, µg/kg, Actual | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
| Grapes, early application, 1 x 1.1 kg a.s./ha |
| D6 ditch | 0 h | 0.787 | 0.040 | 0.028 | 0.016 |
| R1 pond | 0 h | 0.999 | 0.197 | 0.049 | 0.099 |
| R1 stream | 0 h | 0.829 | 0.244 | 0.433 | 0.128 |
| R2 stream | 0 h | 0.572 | 0.215 | 0.299 | 0.112 |
| R3 stream | 0 h | 2.346 | 0.787 | 1.229 | 0.413 |
| R4 stream | 0 h | 0.048 | 0.014 | 0.019 | 0.007 |
| Grapes, late application, 1 x 1.1 kg a.s./ha |
| D6 ditch | 0 h | 0.933 | 0.772 | 0.443 | 0.303 |
| R1 pond | 0 h | 0.135 | 0.326 | 0.068 | 0.165 |
| R1 stream | 0 h | 0.132 | 0.016 | 0.046 | 0.006 |
| R2 stream | 0 h | 0.173 | 0.019 | 0.061 | 0.010 |
| R3 stream | 0 h | 3.213 | 0.942 | 1.680 | 0.493 |
| R4 stream | 0 h | 0.383 | 0.128 | 0.199 | 0.067 |
| Beans, single application, 1 x 0.75 kg a.s./ha |
| D2 ditch | 0 h | 5.684 | 4.763 | 5.683 | 4.700 |
| D2 stream | 0 h | 3.770 | 1.734 | 3.770 | 1.703 |
| D3 ditch | 0 h | 0.051 | 0.022 | 0.027 | 0.011 |
| D4 pond | 0 h | 0.066 | 0.212 | 0.065 | 0.196 |
| D4 stream | 0 h | 0.076 | 0.074 | 0.076 | 0.074 |
| D6, 1st crop ditch | 0 h | 0.035 | 0.024 | 0.035 | 0.024 |
| D6, 2nd crop | 0 h | 0.090 | 0.070 | 0.090 | 0.070 |
| R1 pond | 0 h | 0.226 | 0.439 | 0.119 | 0.233 |
| R1 stream | 0 h | 1.869 | 0.414 | 0.977 | 0.217 |
| R2 stream | 0 h | 0.043 | 0.020 | 0.023 | 0.010 |
| R3 stream | 0 h | 0.811 | 0.174 | 0.422 | 0.091 |
| R4 stream | 0 h | 2.415 | 0.697 | 1.265 | 0.367 |
| Beans, multiple application, 2 x 0.75 kg a.s./ha |
| D2 ditch | 0 h | 15.920 | 13.150 | 15.920 | 13.070 |
| D2 stream | 0 h | 11.800 | 4.965 | 11.800 | 4.933 |
| D3 ditch | 0 h | 0.049 | 0.026 | 0.025 | 0.013 |
| D4 pond | 0 h | 0.169 | 0.508 | 0.166 | 0.481 |
| D4 stream | 0 h | 0.197 | 0.195 | 0.197 | 0.195 |
| D6, 1st crop ditch | 0 h | 0.118 | 0.086 | 0.118 | 0.086 |
| D6, 2nd crop | 0 h | 0.371 | 0.306 | 0.371 | 0.305 |
| R1 pond | 0 h | 0.332 | 0.683 | 0.174 | 0.362 |
| R1 stream | 0 h | 1.947 | 0.562 | 1.020 | 0.294 |
| R2 stream | 0 h | 0.141 | 0.063 | 0.074 | 0.031 |
| R3 stream | 0 h | 3.114 | 0.749 | 1.631 | 0.395 |
| R4 stream | 0 h | 3.167 | 0.995 | 1.657 | 0.523 |
| Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth |
| D3 ditch | 0 h | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| D4 pond | 0 h | 0.009 | 0.028 | 0.009 | 0.028 |
| D4 stream | 0 h | 0.015 | 0.012 | 0.015 | 0.012 |
| D6, 1st crop ditch | 0 h | 0.001 | 0.002 | 0.001 | 0.002 |
| D6, 2nd crop | 0 h | 0.303 | 0.185 | 0.303 | 0.185 |
| R1 pond | 0 h | 0.004 | 0.008 | 0.002 | 0.004 |
| R1 stream | 0 h | 0.134 | 0.027 | 0.068 | 0.014 |
| R2 stream | 0 h | 0.123 | 0.026 | 0.064 | 0.013 |
| R3 stream | 0 h | 0.331 | 0.068 | 0.172 | 0.036 |
| R4 stream | 0 h | 0.388 | 0.111 | 0.203 | 0.059 |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, early |
| D6 ditch | 0 h | 0.004 | 0.002 | 0.004 | 0.002 |
| R2 stream | 0 h | 2.746 | 1.016 | 1.436 | 0.514 |
| R3 stream | 0 h | 5.632 | 2.035 | 2.954 | 1.036 |
| R4 stream | 0 h | 3.323 | 1.043 | 1.742 | 0.549 |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late |
| D6 ditch | 0 h | 0.005 | 0.002 | 0.005 | 0.002 |
| R2 stream | 0 h | 2.676 | 0.826 | 1.395 | 0.421 |
| R3 stream | 0 h | 5.632 | 2.035 | 2.954 | 1.036 |
| R4 stream | 0 h | 7.127 | 2.337 | 3.735 | 1.216 |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, early |
| FOCUS STEP 4 Carbazendazim | Water body | Day after overall maximum | 10 m vegetated buffer zone | 20 m vegetated buffer zone |
|-----------------------------|------------|---------------------------|---------------------------|---------------------------|
|                             |            |                           | PEC<sub>sw</sub>, µg/l, Actual | PEC<sub>sed</sub>, µg/kg, Actual | PEC<sub>sw</sub>, µg/l, Actual | PEC<sub>sed</sub>, µg/kg, Actual |
| D6                          | ditch      | 0 h                       | 0.003                     | 0.002                     | 0.003                     | 0.002                     |
| R2                          | stream     | 0 h                       | 2.534                     | 0.945                     | 1.325                     | 0.478                     |
| R3                          | stream     | 0 h                       | 5.251                     | 1.884                     | 2.755                     | 0.959                     |
| R4                          | stream     | 0 h                       | 3.323                     | 1.043                     | 1.742                     | 0.549                     |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late |            |                           |                           |                           |                           |                           |
| D6                          | ditch      | 0 h                       | 0.004                     | 0.002                     | 0.004                     | 0.002                     |
| R2                          | stream     | 0 h                       | 2.468                     | 0.768                     | 1.287                     | 0.391                     |
| R3                          | stream     | 0 h                       | 5.251                     | 1.884                     | 2.755                     | 0.959                     |
| R4                          | stream     | 0 h                       | 6.503                     | 2.162                     | 3.408                     | 1.124                     |
| Winter cereals, early application, 1 x 0.75 kg a.s./ha |            |                           |                           |                           |                           |                           |
| D1                          | ditch      | 0 h                       | 0.556                     | 1.123                     | 0.556                     | 1.088                     |
| D1                          | stream     | 0 h                       | 0.365                     | 0.665                     | 0.365                     | 0.665                     |
| D2                          | ditch      | 0 h                       | 4.367                     | 4.477                     | 4.367                     | 4.474                     |
| D2                          | stream     | 0 h                       | 9.168                     | 2.662                     | 9.168                     | 2.657                     |
| D3                          | ditch      | 0 h                       | 0.031                     | 0.011                     | 0.016                     | 0.006                     |
| D4                          | stream     | 0 h                       | 0.035                     | 0.127                     | 0.034                     | 0.111                     |
| D5                          | pond       | 0 h                       | 0.039                     | 0.035                     | 0.039                     | 0.035                     |
| D5                          | stream     | 0 h                       | 0.045                     | 0.135                     | 0.034                     | 0.108                     |
| D6                          | stream     | 0 h                       | 0.046                     | 0.033                     | 0.026                     | 0.032                     |
| D6                          | ditch      | 0 h                       | 0.060                     | 0.039                     | 0.031                     | 0.021                     |
| R1                          | pond       | 0 h                       | 0.063                     | 0.137                     | 0.036                     | 0.081                     |
| R1                          | stream     | 0 h                       | 0.577                     | 0.156                     | 0.302                     | 0.082                     |
| R3                          | stream     | 0 h                       | 1.288                     | 0.407                     | 0.676                     | 0.214                     |
| R4                          | stream     | 0 h                       | 1.722                     | 0.450                     | 0.900                     | 0.236                     |
| Winter cereals, late application, 1 x 0.75 kg a.s./ha |            |                           |                           |                           |                           |                           |
| D1                          | ditch      | 0 h                       | 0.440                     | 1.201                     | 0.440                     | 1.182                     |
| D1                          | stream     | 0 h                       | 0.345                     | 0.808                     | 0.345                     | 0.807                     |
| D2                          | ditch      | 0 h                       | 1.591                     | 1.625                     | 1.591                     | 1.517                     |
| D2                          | stream     | 0 h                       | 1.022                     | 0.723                     | 1.022                     | 0.627                     |
| D3                          | ditch      | 0 h                       | 0.038                     | 0.015                     | 0.020                     | 0.008                     |
| D4                          | pond       | 0 h                       | 0.056                     | 0.180                     | 0.054                     | 0.162                     |
| D4                          | stream     | 0 h                       | 0.063                     | 0.055                     | 0.063                     | 0.055                     |
| D5                          | pond       | 0 h                       | 0.054                     | 0.190                     | 0.043                     | 0.166                     |
| D5                          | stream     | 0 h                       | 0.050                     | 0.071                     | 0.027                     | 0.071                     |
| D6                          | ditch      | 0 h                       | 0.162                     | 0.135                     | 0.084                     | 0.070                     |
| R1                          | pond       | 0 h                       | 0.140                     | 0.288                     | 0.075                     | 0.157                     |
| R1                          | stream     | 0 h                       | 0.837                     | 0.252                     | 0.439                     | 0.132                     |
| R3                          | stream     | 0 h                       | 2.891                     | 0.643                     | 1.514                     | 0.339                     |
| R4                          | stream     | 0 h                       | 0.027                     | 0.005                     | 0.014                     | 0.002                     |
### Parameters used in FOCUSw step 1 and 2

| Metabolites | **CM-0237:** | | **DX-105:** | | **4-OH-TM:** | | **M 10** |
|-------------|---------------|---------------|---------------|---------------|---------------|---------------|
| **2-AB:** | Data gap | | Molecular weight: 133.15 | | Molecular weight: 326.33 | | Molecular weight: 202.17 |
| Soil or water metabolite: | Soil and water (without sediment) | Soil or water metabolite: Water | Soil or water metabolite: Water | Soil or water metabolite: Water | Soil or water metabolite: Water | Soil or water metabolite: Water |
| $K_{OC}$ (mL/g): | 0 | 146.1 | 146.1 | 235.6 | 235.6 | 235.6 |
| **RMS:** | The agreed soil DT$_{50}$ is 9.7 days | | The agreed soil DT$_{50}$ is 0.175 (EFSA conclusion on carbendazim, 2010) | | The agreed soil DT$_{50}$ is 2.356 | | The agreed soil DT$_{50}$ is 0.175 (EFSA conclusion on carbendazim, 2010) |
| DT$_{50}$ soil (d): | 6.4 d (lab, SFO) | 1000 d | 1000 d | 1000 d | 1000 d | 1000 d |
| DT$_{50}$ water/sediment system (d): | 189.3 | 1000 | 29.2 | 1000 | 29.2 | 1000 |
| DT$_{50}$ water (d): | 189.3 | 1000 | 29.2 | 1000 | 29.2 | 1000 |
| DT$_{50}$ sediment (d): | 189.3 | 1000 | 29.2 | 1000 | 29.2 | 1000 |
| Crop interception: | | | | | | |
| Full canopy (Grapes 60%, Beans, winter cereals 70 %) | | | | | | |
| Tomato/aubergine, leek no interception (soil incorporation) | | | | | | |
| Max occurrence obs (% molar basis with respect to the parent) | | | | | | |
| Total Water and Sediment: 9.5% (without sediment) | | | | | | |
| Soil: 6.1% | | | | | | |
| **4-OH-TM:** | | | | | | |
| Molecular weight: 358.40 | | | | | | |
| Soil or water metabolite: Water | | | | | | |
| $K_{OC}$ (mL/g): | 0 | | | | | |
| DT$_{50}$ soil (d): | 1000 d | | | | | |
| DT$_{50}$ water/sediment system (d): | 29.2 | | | | | |
| DT$_{50}$ water (d): | 29.2 | | | | | |
| DT$_{50}$ sediment (d): | 29.2 | | | | | |
| Crop interception: | | | | | | |
| Full canopy (Grapes 60%, Beans, winter cereals 70 %) | | | | | | |
| Tomato/aubergine, leek no interception (soil incorporation) | | | | | | |
| Max occurrence obs (% molar basis with respect to the parent) | | | | | | |
| Total Water and Sediment: 14.3% (photolysis) | | | | | | |
| Soil: 5.5% | | | | | | |
| **M 10:** | | | | | | |
| Molecular weight: 202.17 | | | | | | |
| Soil or water metabolite: Water | | | | | | |
| $K_{OC}$ (mL/g): | 0 | | | | | |
| DT$_{50}$ soil (d): | 1000 | | | | | |
| DT$_{50}$ water/sediment system (d): | 1000 | | | | | |
| DT$_{50}$ water (d): | 1000 | | | | | |
| DT$_{50}$ sediment (d): | 1000 | | | | | |
| Crop interception: | | | | | | |
| Full canopy (Grapes 60%, Beans, winter cereals 70 %) | | | | | | |
| Tomato/aubergine, leek no interception (soil incorporation) | | | | | | |
| Max occurrence obs (% molar basis with respect to the parent) | | | | | | |
| Total Water and Sediment: 9.3% (total water/sediment) | | | | | | |
| Soil: 0.001% | | | | | | |

**Application rate**

See thiophanate-methyl module
Main routes of entry

| FOCUS STEP 1 | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------|---------------------------|-------------------------|--------------------------|
| 2-AB Grapes, 1 x 1.1 kg a.s./ha | 0 h | 19.12 | 31.56 |
| Field beans 1/2 x 0.75 kg a.s./ha | 0 h | 25.10 | 43.04 |
| Winter cereals 1x 0.75 kg a.s./ha | 0 h | 12.55 | 21.52 |
| Tomato (greenhouse) 3 x 2.3 kg a.s./ha | 0 h | 113.1 | 198.0 |
| Tomato (field) 3 x 2.1 kg a.s./ha | 0 h | 103.3 | 180.8 |
| Leek 1 x 4.15 kg a.s./ha | 0 h | 68.04 | 119.1 |

| FOCUS STEP 2 | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------|---------------------------|-------------------------|--------------------------|
| 2-AB Grapes, Oct-Feb 1 x 1.1 kg a.s./ha | 0 h | 1.979 | 1.769 |
| Field beans, Oct-Feb 1/2 x 0.75 kg a.s./ha | 0 h | 1.015 | 0.887 |
| Winter cereals, Oct-Feb 1x 0.75 kg a.s./ha | 0 h | 0.755 | 0.648 |
| Tomato (greenhouse), Oct-Feb 3 x 2.3 kg a.s./ha | 0 h | 5.691 | 4.553 |
| Tomato (field), Oct-Feb 3 x 2.1 kg a.s./ha | 0 h | 5.196 | 4.157 |
| Leek, Oct-Feb 1 x 4.15 kg a.s./ha | 0 h | 9.921 | 7.937 |

| FOCUS STEP 1 | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------|---------------------------|-------------------------|--------------------------|
| DX-105 Grapes, 1 x 1.1 kg a.s./ha | 0 h | 61.92 | 84.61 |
| Field beans 1/2 x 0.75 kg a.s./ha | 0 h | 80.85 | 115.4 |
| Winter cereals 1x 0.75 kg a.s./ha | 0 h | 40.43 | 57.69 |
| Tomato (greenhouse) 3 x 2.3 kg a.s./ha | 0 h | 363.3 | 530.7 |
| Tomato (field) 3 x 2.1 kg a.s./ha | 0 h | 331.7 | 484.6 |
| Leek 1 x 4.15 kg a.s./ha | 0 h | 218.5 | 319.2 |

| FOCUS STEP 2 | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|---------------|---------------------------|-------------------------|--------------------------|
| DX-105 Grapes, Oct-Feb 1 x 1.1 kg a.s./ha | 0 h | 7.272 | 6.526 |
| Field beans, Oct-Feb 1/2 x 0.75 kg a.s./ha | 0 h | 4.992 | 4.286 |
| Winter cereals, Oct-Feb 1x 0.75 kg a.s./ha | 0 h | 2.738 | 2.356 |
| Tomato (greenhouse), Oct-Feb 3 x 2.3 kg a.s./ha | 0 h | 52.02 | 41.61 |
| Tomato (field), Oct-Feb 3 x 2.1 kg a.s./ha | 0 h | 47.50 | 58.00 |
| Leek, Oct-Feb 1 x 4.15 kg a.s./ha | 0 h | 35.19 | 28.15 |
### FOCUS STEP 1

| Crop Type | Pesticide Application | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|-----------|-----------------------|---------------------------|----------------|------------------|
|           |                       | Actual                     | TWA            | Actual           | TWA             |
| Grapes, 1 x 1.1 kg a.s./ha | 0 h | 39.39 | <0.001 |
| Field beans, 1/2 x 0.75 kg a.s./ha | 0 h | 51.10 | <0.001 |
| Winter cereals, 1x 0.75 kg a.s./ha | 0 h | 25.55 | <0.001 |
| Tomato (greenhouse), 3 x 2.3 kg a.s./ha | 0 h | 228.7 | <0.001 |
| Tomato (field), 3 x 2.1 kg a.s./ha | 0 h | 208.8 | <0.001 |
| Leek, 1 x 4.15 kg a.s./ha | 0 h | 137.6 | <0.001 |

### FOCUS STEP 2

| Crop Type | Pesticide Application | Day after overall maximum | PEC_{SW} (µg/L) Northern EU | PEC_{SW} (µg/L) Southern EU | PEC_{SED} (µg/kg) Northern EU | PEC_{SED} (µg/kg) Southern EU |
|-----------|-----------------------|---------------------------|-----------------------------|----------------------------|-------------------------------|-----------------------------|
| Grapes, Oct-Feb, 1 x 1.1 kg a.s./ha | 0 h | 3.118 | 3.027 | <0.001 | <0.001 |
| Field beans, Oct-Feb, 1/2 x 0.75 kg a.s./ha | 0 h | 1.180 | 1.134 | <0.001 | <0.001 |
| Winter cereals, Oct-Feb, 1x 0.75 kg a.s./ha | 0 h | 0.857 | 0.811 | <0.001 | <0.001 |
| Tomato (greenhouse), Oct-Feb, 3 x 2.3 kg a.s./ha | 0 h | 2.394 | 1.915 | <0.001 | <0.001 |
| Tomato (field), Oct-Feb, 3 x 2.1 kg a.s./ha | 0 h | 2.186 | 1.749 | <0.001 | <0.001 |
| Leek, Oct-Feb, 1 x 4.15 kg a.s./ha | 0 h | 4.306 | 3.445 | <0.001 | <0.001 |

### FOCUS STEP 1

| Crop Type | Pesticide Application | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|-----------|-----------------------|---------------------------|----------------|------------------|
|           |                       | Actual                     | TWA            | Actual           | TWA             |
| Grapes, 1 x 1.1 kg a.s./ha | 0 h | 21.75 | <0.001 |
| Field beans, 1/2 x 0.75 kg a.s./ha | 0 h | 28.22 | <0.001 |
| Winter cereals, 1x 0.75 kg a.s./ha | 0 h | 14.11 | <0.001 |
| Tomato (greenhouse), 3 x 2.3 kg a.s./ha | 0 h | 126.3 | <0.001 |
| Tomato (field), 3 x 2.1 kg a.s./ha | 0 h | 115.3 | <0.001 |
| Leek, 1 x 4.15 kg a.s./ha | 0 h | 75.97 | <0.001 |

### FOCUS STEP 2

| Crop Type | Pesticide Application | Day after overall maximum | PEC_{SW} (µg/L) Northern EU | PEC_{SW} (µg/L) Southern EU | PEC_{SED} (µg/kg) Northern EU | PEC_{SED} (µg/kg) Southern EU |
|-----------|-----------------------|---------------------------|-----------------------------|----------------------------|-------------------------------|-----------------------------|
| Grapes, Oct-Feb, 1 x 1.1 kg a.s./ha | 0 h | 1.864 | 1.814 | <0.001 | <0.001 |
| Field beans, Oct-Feb, 1/2 x 0.75 kg a.s./ha | 0 h | 0.793 | 0.768 | <0.001 | <0.001 |
| Winter cereals, Oct-Feb, 1x 0.75 kg a.s./ha | 0 h | 0.507 | 0.481 | <0.001 | <0.001 |
| Tomato (greenhouse), Oct-Feb, 3 x 2.3 kg a.s./ha | 0 h | 1.322 | 1.058 | <0.001 | <0.001 |
| Tomato (field), Oct-Feb, 3 x 2.1 kg a.s./ha | 0 h | 1.207 | 0.966 | <0.001 | <0.001 |
| Leek, Oct-Feb, 1 x 4.15 kg a.s./ha | 0 h | 2.378 | 1.902 | <0.001 | <0.001 |
Metabolites
CM-0237
2-AB
DX-105

Parameters used in FOCUSsw step 3 and 4

| Metabolite | Data gap | Water solubility (mg/L) | Vapour pressure | KOC/KOM (mL/g) | 1/n | Q10 | Walker equation coefficient | Crop uptake factor | Metabolite kinetically generated in simulation | Formation fraction in soil (kf/kdp): | Formation fraction in sediment water (kf/kdp): |
|------------|----------|-------------------------|-----------------|----------------|-----|-----|---------------------------|-----------------|---------------------------------|-------------------------------|---------------------------------|
| CM-0237    | Data gap | 1000                    | 0               | 175 / 101.5    | 1.0 | 2.58 | 0.7                       | 0               | yes                              | 0.2016                        | 0.195                           |
| 2-AB       |          | 1000                    | 0               |                |     |      |                           | 0               |                                 |                               |                                 |
| DX-105     |          | 1000                    | 0               | 235.6 / 136.7  | 0.85| 2.58 | 0.7                       | 0               | yes                              | 0.1                           | 0.25                            |

RMS: ff in water/sed 0.25 (used also to calculate 0.195) was not considered reliable.

Application rate
Main routes of entry

See thiophanate-methyl module
## FOCUS STEP 3

### 2-AB

| Water body | Day after overall maximum | PEC\(_{sw}\), µg/l, Actual | PEC\(_{sed}\), µg/kg, Actual |
|------------|---------------------------|-----------------------------|-----------------------------|
| **Grapes, early application, 1 x 1.1 kg a.s./ha** | | | |
| D6 | ditch | 0 h | 0.065 | 0.025 |
| **Grapes, late application, 1 x 1.1 kg a.s./ha (R-scenarios covering early application)** | | | |
| D6 | ditch | 0 h | 0.769 | 0.514 |
| R1 | pond | 0 h | 0.007 | 0.022 |
| R2 | stream | 0 h | < 0.001 | < 0.001 |
| R3 | stream | 0 h | 0.035 | 0.010 |
| R4 | stream | 0 h | 0.080 | 0.020 |
| **Beans, multiple application, 2 x 0.75 kg a.s./ha (covering single application)** | | | |
| D2 | ditch | 0 h | 5.953 | 4.345 |
| D3 | stream | 0 h | 4.784 | 1.348 |
| D4 | ditch | 0 h | 0.053 | 0.022 |
| D4 | pond | 0 h | 0.018 | 0.054 |
| D4 | stream | 0 h | 0.024 | 0.011 |
| D6, 1\(^{st}\) crop | ditch | 0 h | 0.099 | 0.048 |
| D6, 2\(^{nd}\) crop | ditch | 0 h | 0.059 | 0.036 |
| R1 | pond | 0 h | 0.049 | 0.147 |
| R2 | stream | 0 h | 0.082 | 0.020 |
| R3 | stream | 0 h | 0.105 | 0.036 |
| R4 | stream | 0 h | 0.179 | 0.032 |
| **Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth** | | | |
| D3 | ditch | 0 h | < 0.001 | < 0.001 |
| D4 | pond | 0 h | < 0.001 | 0.001 |
| D4 | stream | 0 h | < 0.001 | < 0.001 |
| D6, 1\(^{st}\) crop | ditch | 0 h | 0.058 | 0.026 |
| D6, 2\(^{nd}\) crop | ditch | 0 h | 0.014 | 0.003 |
| R1 | pond | 0 h | 0.001 | 0.003 |
| R2 | stream | 0 h | 0.013 | 0.002 |
| R3 | stream | 0 h | 0.012 | 0.003 |
| R4 | stream | 0 h | 0.017 | 0.004 |
| **Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late (covering early applications)** | | | |
| D6 | ditch | 0 h | < 0.001 | < 0.001 |
| R2 | stream | 0 h | 0.720 | 0.195 |
| R3 | stream | 0 h | 1.124 | 0.368 |
| R4 | stream | 0 h | 0.829 | 0.221 |
| **Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late (covering early application)** | | | |
| D6 | ditch | 0 h | < 0.001 | < 0.001 |
| R2 | stream | 0 h | 0.677 | 0.184 |
| R3 | stream | 0 h | 1.028 | 0.340 |
| R4 | stream | 0 h | 0.758 | 0.204 |
| **Winter cereals, early application, 1 x 0.75 kg a.s./ha** | | | |
| D1 | ditch | 0 h | 0.270 | 0.446 |
| D1 | stream | 0 h | 0.061 | 0.090 |
| D2 | ditch | 0 h | 2.761 | 1.282 |
| D2 | stream | 0 h | 2.792 | 0.692 |
| D3 | ditch | 0 h | 0.037 | 0.011 |
| D4 | pond | 0 h | 0.010 | 0.024 |
| D4 | stream | 0 h | 0.025 | 0.002 |
| D5 | pond | 0 h | 0.011 | 0.027 |
| D5 | stream | 0 h | 0.037 | 0.003 |
| D6 | ditch | 0 h | 0.073 | 0.036 |
| R1 | pond | 0 h | 0.009 | 0.028 |
| R1 | stream | 0 h | 0.064 | 0.013 |
| R3 | stream | 0 h | 0.123 | 0.034 |
| R4 | stream | 0 h | 0.037 | 0.008 |
| **Winter cereals, late application, 1 x 0.75 kg a.s./ha** | | | |
| D1 | ditch | 0 h | 0.290 | 0.479 |
| D1 | stream | 0 h | 0.071 | 0.116 |
| D2 | ditch | 0 h | 0.285 | 0.588 |
### FOCUS STEP 3 2-AB

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D2 stream  | 0 h                       | 0.286                           | 0.410                           |
| D3 ditch   | 0 h                       | 0.047                           | 0.014                           |
| D4 pond    | 0 h                       | 0.011                           | 0.026                           |
| D4 stream  | 0 h                       | 0.032                           | 0.005                           |
| D5 pond    | 0 h                       | 0.013                           | 0.036                           |
| D5 stream  | 0 h                       | 0.046                           | 0.010                           |
| D6 ditch   | 0 h                       | 0.204                           | 0.136                           |
| R1 pond    | 0 h                       | 0.024                           | 0.073                           |
| R1 stream  | 0 h                       | 0.096                           | 0.024                           |
| R3 stream  | 0 h                       | 0.080                           | 0.015                           |
| R4 stream  | 0 h                       | 0.007                           | 0.002                           |

### FOCUS STEP 4 2-AB

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| 20 m vegetated buffer zone | | | |
| D6 ditch   | 0 h                       | 0.005                           | 0.002                           |

#### FOCUS STEP 4 2-AB: Grapes, early application, 1 x 1.1 kg a.s./ha

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D6 ditch   | 0 h                       | 4.188                           | 1.303                           |

#### FOCUS STEP 4 2-AB: Grapes, late application, 1 x 1.1 kg a.s./ha (R-scenarios covering early application)

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D6 ditch   | 0 h                       | 0.024                           | 0.073                           |

#### FOCUS STEP 4 2-AB: Beans, multiple application, 2 x 0.75 kg a.s./ha (covering single application)

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D2 ditch   | 0 h                       | 5.953                           | 4.188                           |
| D2 stream  | 0 h                       | 4.784                           | 1.303                           |
| D3 ditch   | 0 h                       | 0.004                           | 0.002                           |
| D4 pond    | 0 h                       | 0.011                           | 0.037                           |
| D4 stream  | 0 h                       | 0.010                           | 0.011                           |
| D6, 1st crop ditch | 0 h | 0.008                           | 0.004                           |
| D6, 2nd crop ditch | 0 h | 0.011                           | 0.024                           |

#### FOCUS STEP 4 2-AB: Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late (covering early applications)

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D6 ditch   | 0 h                       | < 0.001                         | < 0.001                         |

#### FOCUS STEP 4 2-AB: Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late (covering early application)

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D6 ditch   | 0 h                       | < 0.001                         | < 0.001                         |

#### FOCUS STEP 4 2-AB: Winter cereals, early application, 1 x 0.75 kg a.s./ha

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D1 ditch   | 0 h                       | 0.149                           | 0.089                           |
| D1 stream  | 0 h                       | 2.761                           | 1.272                           |
| D2 ditch   | 0 h                       | 2.792                           | 0.680                           |
| D3 ditch   | 0 h                       | 0.003                           | 0.001                           |
| D4 pond    | 0 h                       | 0.004                           | 0.010                           |
| D4 stream  | 0 h                       | 0.003                           | 0.001                           |
| D5 pond    | 0 h                       | 0.006                           | 0.013                           |
| D5 stream  | 0 h                       | 0.004                           | 0.001                           |
| D6 ditch   | 0 h                       | 0.006                           | 0.003                           |

#### FOCUS STEP 4 2-AB: Winter cereals, late application, 1 x 0.75 kg a.s./ha

| Water body | Day after overall maximum | $\text{PEC}_{\text{sw}}, \mu\text{g/l, Actual}$ | $\text{PEC}_{\text{sed}}, \mu\text{g/kg, Actual}$ |
|------------|---------------------------|---------------------------------|---------------------------------|
| D1 ditch   | 0 h                       | 0.168                           | 0.116                           |
| D1 stream  | 0 h                       | 0.264                           | 0.185                           |
| D2 ditch   | 0 h                       | 0.169                           | 0.099                           |
| D3 ditch   | 0 h                       | 0.004                           | 0.001                           |
| D4 pond    | 0 h                       | 0.005                           | 0.013                           |
| D4 stream  | 0 h                       | 0.003                           | 0.002                           |
| D5 pond    | 0 h                       | 0.007                           | 0.021                           |
| D5 stream  | 0 h                       | 0.005                           | 0.005                           |
| D6 ditch   | 0 h                       | 0.015                           | 0.010                           |
| FOCUS STEP 3 | Water body | Day after overall maximum | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|-------------|------------|--------------------------|---------------------|----------------------|
| DX-105      |            |                          |                     |                      |
| Grapes, late application, 1 x 1.1 kg a.s./ha (covering early application) | | | | |
| D6          | ditch      | 0 h                      | 1.944               | 2.677                |
| R1          | pond       | 0 h                      | 0.100               | 0.517                |
| R1          | stream     | 0 h                      | 0.233               | 0.035                |
| R2          | stream     | 0 h                      | 0.304               | 0.128                |
| R3          | stream     | 0 h                      | 2.985               | 1.275                |
| R4          | stream     | 0 h                      | 0.723               | 0.363                |
| Beans, multiple application, 2 x 0.75 kg a.s./ha (covering single application) | | | | |
| D2          | ditch      | 0 h                      | 10.130              | 22.400               |
| D2          | stream     | 0 h                      | 6.350               | 12.710               |
| D3          | ditch      | 0 h                      | 0.136               | 0.133                |
| D4          | stream     | 0 h                      | 1.662               | 8.084                |
| D6, 1st crop | ditch     | 0 h                      | 1.944               | 2.677                |
| D6, 2nd crop | ditch    | 0 h                      | 2.957               | 4.844                |
| R1          | pond       | 0 h                      | 0.372               | 1.742                |
| R1          | stream     | 0 h                      | 1.864               | 0.858                |
| R2          | stream     | 0 h                      | 0.587               | 1.169                |
| R3          | stream     | 0 h                      | 3.186               | 1.099                |
| R4          | stream     | 0 h                      | 3.232               | 1.443                |
| Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth | | | | |
| D3          | ditch      | 0 h                      | 0.567               | 3.969                |
| D4          | pond       | 0 h                      | 4.459               | 26.46                |
| D4          | stream     | 0 h                      | 3.564               | 9.403                |
| D6, 1st crop | ditch    | 0 h                      | 0.136               | 0.133                |
| D6, 2nd crop | ditch    | 0 h                      | 0.587               | 1.169                |
| R1          | pond       | 0 h                      | 0.008               | 0.048                |
| R1          | stream     | 0 h                      | 0.110               | 0.045                |
| R2          | stream     | 0 h                      | 0.071               | 0.029                |
| R3          | stream     | 0 h                      | 0.270               | 0.081                |
| R4          | stream     | 0 h                      | 0.318               | 0.136                |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late (covering early applications) | | | | |
| D6          | ditch      | 0 h                      | 0.690               | 1.119                |
| R2          | stream     | 0 h                      | 3.255               | 2.738                |
| R3          | stream     | 0 h                      | 5.841               | 4.018                |
| R4          | stream     | 0 h                      | 6.483               | 3.524                |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late (covering early application) | | | | |
| D6          | ditch      | 0 h                      | 0.690               | 1.119                |
| R2          | stream     | 0 h                      | 3.255               | 2.738                |
| R3          | stream     | 0 h                      | 5.841               | 4.018                |
| R4          | stream     | 0 h                      | 6.483               | 3.524                |
| Winter cereals, early application, 1 x 0.75 kg a.s./ha | | | | |
| D1          | ditch      | 0 h                      | 2.429               | 11.22                |
| D1          | stream     | 0 h                      | 1.515               | 6.231                |
| D2          | ditch      | 0 h                      | 5.382               | 16.55                |
| D2          | stream     | 0 h                      | 5.097               | 9.437                |
| D3          | ditch      | 0 h                      | 0.097               | 0.061                |
| D4          | pond       | 0 h                      | 0.782               | 3.991                |
| D4          | stream     | 0 h                      | 0.765               | 1.389                |
| D5          | pond       | 0 h                      | 0.813               | 5.854                |
| D5          | stream     | 0 h                      | 0.589               | 1.345                |
| D6          | ditch      | 0 h                      | 0.574               | 0.838                |
| R1          | pond       | 0 h                      | 0.068               | 0.376                |
| R1          | stream     | 0 h                      | 0.575               | 0.238                |
| R3          | stream     | 0 h                      | 1.221               | 0.600                |
| R4          | stream     | 0 h                      | 1.638               | 0.602                |
| Winter cereals, late application, 1 x 0.75 kg a.s./ha | | | | |
| D1          | ditch      | 0 h                      | 1.408               | 8.538                |
| D1          | stream     | 0 h                      | 0.942               | 4.694                |
| D2          | ditch      | 0 h                      | 2.547               | 9.384                |
| D2          | stream     | 0 h                      | 1.594               | 5.749                |
### Table: FOCUS STEP 3

**DX-105**

| Water body | Day after overall maximum | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|------------|---------------------------|---------------------|-----------------------|
| D3 ditch   | 0 h                       | 0.122               | 0.082                 |
| D4 pond    | 0 h                       | 0.554               | 2.849                 |
| D4 stream  | 0 h                       | 0.549               | 0.999                 |
| D5 pond    | 0 h                       | 0.435               | 3.503                 |
| D5 stream  | 0 h                       | 0.328               | 0.784                 |
| D6 ditch   | 0 h                       | 0.513               | 0.863                 |
| R1 pond    | 0 h                       | 0.161               | 0.803                 |
| R1 stream  | 0 h                       | 0.809               | 0.421                 |
| R3 stream  | 0 h                       | 2.722               | 0.842                 |
| R4 stream  | 0 h                       | 0.288               | 0.187                 |

### Table: FOCUS STEP 4

**DX-105**

| Water body | Day after overall maximum | 20 m vegetated buffer zone | PECsw, µg/l, Actual | PECsed, µg/kg, Actual |
|------------|---------------------------|-----------------------------|---------------------|-----------------------|
| Grapes, late application, 1 x 1.1 kg a.s./ha (covering early application)  | | | | |
| D6 ditch   | 0 h                       | 1.109                       | 1.440               |
| R1 pond    | 0 h                       | 0.032                       | 0.179               |
| R1 stream  | 0 h                       | 0.022                       | 0.003               |
| R2 stream  | 0 h                       | 0.051                       | 0.029               |
| R3 stream  | 0 h                       | 0.707                       | 0.315               |
| R4 stream  | 0 h                       | 0.169                       | 0.089               |
| Beans, multiple application, 2 x 0.75 kg a.s./ha (covering single application)  | | | | |
| D2 ditch   | 0 h                       | 10.13                       | 21.84               |
| D2 stream  | 0 h                       | 6.350                       | 12.54               |
| D3 ditch   | 0 h                       | 0.011                       | 0.013               |
| D4 pond    | 0 h                       | 1.655                       | 7.997               |
| D4 stream  | 0 h                       | 1.683                       | 2.843               |
| D6, 1st crop ditch | 0 h | 2.003 | 3.486 |
| D6, 2nd crop ditch | 0 h | 2.957 | 4.840 |
| R1 pond    | 0 h                       | 0.084                       | 0.436               |
| R1 stream  | 0 h                       | 0.443                       | 0.198               |
| R2 stream  | 0 h                       | 0.140                       | 0.143               |
| R3 stream  | 0 h                       | 0.759                       | 0.277               |
| R4 stream  | 0 h                       | 0.766                       | 0.360               |
| Leek, 1 x 4.15 kg a.s./ha, CAM5, 10 cm depth | | | | |
| D3 ditch   | 0 h                       | 0.567                       | 3.969               |
| D4 pond    | 0 h                       | 4.459                       | 26.46               |
| D4 stream  | 0 h                       | 3.564                       | 9.403               |
| D6, 1st crop ditch | 0 h | 0.715 | 1.687 |
| D6, 2nd crop ditch | 0 h | 0.829 | 1.921 |
| R1 pond    | 0 h                       | 0.002                       | 0.011               |
| R1 stream  | 0 h                       | 0.026                       | 0.011               |
| R2 stream  | 0 h                       | 0.016                       | 0.007               |
| R3 stream  | 0 h                       | 0.063                       | 0.020               |
| R4 stream  | 0 h                       | 0.075                       | 0.034               |
| Tomato, greenhouse, 0.7 + 1.4 + 2.3 kg a.s./ha, late (covering early applications)  | | | | |
| D6 ditch   | 0 h                       | 0.731                       | 1.187               |
| R2 stream  | 0 h                       | 0.813                       | 0.465               |
| R3 stream  | 0 h                       | 1.531                       | 0.873               |
| R4 stream  | 0 h                       | 1.701                       | 0.849               |
| Tomato, field, 0.7 + 1.4 + 2.1 kg a.s./ha, late (covering early application)  | | | | |
| D6 ditch   | 0 h                       | 0.690                       | 1.119               |
| R2 stream  | 0 h                       | 0.763                       | 0.440               |
| R3 stream  | 0 h                       | 1.397                       | 0.816               |
| R4 stream  | 0 h                       | 1.546                       | 0.788               |
| Winter cereals, early application, 1 x 0.75 kg a.s./ha | | | | |
| D1 ditch   | 0 h                       | 2.429                       | 10.750              |
| D1 stream  | 0 h                       | 1.515                       | 6.228               |
| D2 ditch   | 0 h                       | 5.382                       | 16.52               |
| D2 stream  | 0 h                       | 5.097                       | 9.407               |
| D3 ditch   | 0 h                       | 0.007                       | 0.005               |
| D4 pond    | 0 h                       | 0.778                       | 3.929               |
## FOCUS STEP 4

| Water body | Day after overall maximum | 20 m vegetated buffer zone |
|------------|---------------------------|---------------------------|
|            |                           | PECsw, µg/l, Actual        | PECsed, µg/kg, Actual       |

### DX-105

|   |                | 0 h  | 0.765 | 1.389 |
|---|----------------|------|-------|-------|
| D4| stream         |      |       |       |
| D5| pond           |      |       |       |
| D5| stream         |      | 0.589 | 1.345 |
| D6| ditch          |      | 0.589 | 1.345 |
| R1| pond           |      | 0.574 | 0.816 |
| R1| stream         |      | 0.019 | 0.113 |
| R3| stream         |      | 0.137 | 0.057 |
| R4| stream         |      | 0.292 | 0.146 |

### Winter cereals, late application

|   |                | 0 h  | 1.408 | 8.027 |
|---|----------------|------|-------|-------|

### Application rate 1 x 0.75 kg a.s./ha

|   |                | 0 h  | 0.942 | 4.691 |
|---|----------------|------|-------|-------|
| D1| stream         |      |       |       |
| D2| ditch          |      | 2.547 | 8.719 |
| D2| stream         |      | 1.594 | 5.264 |
| D3| ditch          |      | 0.009 | 0.007 |
| D4| pond           |      | 0.549 | 2.786 |
| D4| stream         |      | 0.549 | 0.998 |
| D5| pond           |      | 0.431 | 3.433 |
| D5| stream         |      | 0.328 | 0.783 |
| D6| ditch          |      | 0.399 | 0.595 |
| R1| pond           |      | 0.038 | 0.212 |
| R1| stream         |      | 0.193 | 0.093 |
| R3| stream         |      | 0.649 | 0.210 |
| R4| stream         |      | 0.069 | 0.043 |
Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

| Method of calculation |  |
|-----------------------|---|
| **PEC**               |  |
| Maximum concentration | Not required |
Section 5 Ecotoxicology

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

| Species          | Test substance         | Time scale | End point | Toxicity (mg /kg bw per day) |
|------------------|------------------------|------------|-----------|-----------------------------|
| Birds            |                         |            |           |                             |
| Bobwhite quail   | Thiophanate-methyl     | Acute      | LD₅₀      | >4640                       |
| Mallard duck     | Thiophanate-methyl     | Acute      | LD₅₀      | >4640                       |
|                  | Topsin M 500 SC        | Acute      | LD₅₀      | No data                     |
| Bobwhite quail   | Carbazalazim           | Acute      | LD₅₀      | >2250                       |
| Birds            | FH-432                 | Acute      | -         | No data                     |
| Birds            | 2-AB                   | Acute      | -         | No data                     |
| Mallard duck     | Carbazalazim           | Short term | dietary LD₅₀ | 615                         |
| Bobwhite quail   | Thiophanate-methyl     | Long-term  | NOAEL     | 9.1                         |
| Mallard duck     | Thiophanate-methyl     | Long-term  | NOAEL     | 9.7                         |
| Mallard duck     | Carbazalazim           | Long-term  | NOAEL     | 26.4                       |

Mammals

| Species          | Test substance         | Time scale | End point | Toxicity (mg /kg bw per day) |
|------------------|------------------------|------------|-----------|-----------------------------|
| Rat              | Thiophanate-methyl     | Acute      | LD₅₀      | >5000                       |
| Rat              | Thiophanate-methyl     | Acute      | LD₅₀      | 7500 in males, 6640 in females |
| Mouse            | Thiophanate-methyl     | Acute      | LD₅₀      | 3514 in males, 3400 in females |
| Guinea pig       | Thiophanate-methyl     | Acute      | LD₅₀      | 3640 in males, 6700 females |
| Rabbit           | Thiophanate-methyl     | Acute      | LD₅₀      | 2270 in males, 2500 in females |
| Rat              | Carbazalazim           | Acute      | LD₅₀      | 408 (a.s.)                  |
| Mouse            | FH-432                 | Acute      | LD₅₀      | 4300                        |
| Rat              | 2-AB                   | Acute      | LD₅₀      | 3400                        |
| Rabbit           | Thiophanate-methyl     | Long-term  | NOAEL     | 2.0                         |
| Rabbit           | Carbazalazim           | Long-term  | NOAEL     | 22.5                        |

Endocrine disrupting properties (Annex Part A, points 8.1.5):
Although none of the presented studies provides a conclusive picture, taken together the presented data indicate that Thiophanate-methyl and/or its metabolite Carbendazim might
- disrupt thyroid function (effects on thyroidea and thyroid hormones were also observed in mammalian studies).
- interfere with adrenal steroid synthesis, although results are contradicting and observation might be rather a general stress response.
- interfere with estrogen and androgen receptor
- and/or generally interfere with steroid synthesis
The mode(s) of action and possible adverse impact need further elucidation in order to conclude whether or not Thiophanate-methyl (and/or Carbendazim) is an endocrine disrupter.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
Available data on residue decline in plants (Scherer, 2015)

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
Data were available on the genotoxicity and testicular toxicity to the lizard Podarcis sicula (Capriglione et al., 2011; Cardone, 2012), and on morphological and functional changes in the thyroid gland (Sciarrillo et al., 2008). However, these data were not used for risk assessment.
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Grapes at 1100 g a.s./ha [single application, BBCH 57-81]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous bird | Acute (a.s.) | 105 | >44.3 | 10 |
| All | Small omnivorous bird | Acute (Carbendazim) | 58.5 | 10.5 | 10 |
| All | Small omnivorous bird | Acute (FH-432) | 95.0 | >48.8 | 10 |
| All | Small omnivorous bird | Acute (2-AB) | 40.8 | >113.7 | 10 |
| All | Small omnivorous bird | Long-term (a.s.) | 22.5 | **0.40** | 5 |
| All | Small omnivorous bird | Long-term (Carbendazim) | 12.6 | **2.10** | 5 |
| Tier 1 (Birds) | | | | | |
| BBCH >20 | Small insectivorous bird | Acute* | 14.98 | 164 | 10 |
| BBCH >40 | Small granivorous bird | Acute* | 4.31 | 570 | 10 |
| Ripening | Frugivorous bird | Acute* | 16.85 | 146 | 10 |
| BBCH >40 | Small omnivorous bird | Acute* | 4.20 | 586 | 10 |
| BBCH >20 | Small insectivorous bird | Long-term (a.s.) | 5.74 | **1.59** | 5 |
| BBCH >40 | Small granivorous bird | Long-term (a.s.) | 1.97 | **4.61** | 5 |
| Ripening | Frugivorous bird | Long-term (a.s.) | 8.34 | **1.09** | 5 |
| BBCH >40 | Small omnivorous bird | Long-term (a.s.) | 1.91 | **4.76** | 5 |
| BBCH >20 | Small insectivorous bird | Long-term (Carbendazim) | 3.20 | 8.25 | 5 |
| BBCH >40 | Small granivorous bird | Long-term (Carbendazim) | 1.10 | 24.0 | 5 |
| Ripening | Frugivorous bird | Long-term (Carbendazim) | 4.66 | 5.67 | 5 |
| BBCH >40 | Small omnivorous bird | Long-term (Carbendazim) | 1.07 | 24.7 | 5 |

*Note that based on mammalian data, the representative formulation is ca 10 times more toxic than the active ingredient, and no formulation data is available for birds.

Higher tier (birds):
The long term risk assessment was refined by PT/PD values derived from generic field studies on the focal species, including analysis of faeces content and radio-tracking. Proposed refinements of residue decline was not considered acceptable by RMS. See RMS evaluation in Volume 3CP, section 9. No acceptable refinement for small insectivors, small granivors, frugivors and small omnivors.

Overall, the RMS considers that the available residue data and radio-tracking data are not sufficiently robust for the refinement.

| All | Cirl bunting | Long term (a.s.) | 3.74 | **2.43** | 5 |
| All | Great tit | Long term (a.s.) | 0.724 | 12.6 | 5 |
| All | Linnet | Long term (a.s.) | 6.41 | **1.42** | 5 |
| All | Wood lark | Long term (a.s.) | 2.19 | **4.16** | 5 |

Screening Step (Mammals)

| All | Small herbivorous mammal | Acute (a.s.) | 150 | **2.7** | 10 |
| All | Small herbivorous mammal | Acute (Carbendazim) | 83.7 | 59.7 | 10 |
| All | Small herbivorous mammal | Acute (FH-432) | 136 | 31.6 | 10 |
| All | Small herbivorous mammal | Acute (2-AB) | 58.4 | 58.2 | 10 |
| All | Long-term (a.s.) | Not calculated | | | 5 |

Tier 1 (Mammals)

| BBCH>40 | Large herbivorous mammal | Acute (a.s.) | 8.9 | 46 | 10 |
| BBCH>20 | Small insectivorous mammal | Acute (a.s.) | 5.9 | 69 | 10 |
| BBCH>40 | Small herbivorous mammal | Acute (a.s.) | 45.0 | **9.1** | 10 |
| BBCH>40 | Small omnivorous mammal | Acute (a.s.) | 5.7 | 72 | 10 |
| BBCH>40 | Large herbivorous mammal | Long-term (a.s.) | 1.91 | **1.04** | 5 |
### Growth stage Indicator or focal species Time scale DDD (mg/kg bw per day) TER Trigger

| Growth stage | Indicator or focal species | Time scale          | DDD  | TER  | Trigger |
|--------------|---------------------------|---------------------|------|------|---------|
| BBCH > 20    | Small insectivorous       | Long-term (a.s.)    | 1.10 | 1.81 | 5       |
| BBCH > 40    | Small herbivorous         | Long-term (a.s.)    | 12.6 | 0.16 | 5       |
| BBCH > 40    | Small omnivorous          | Long-term (a.s.)    | 1.33 | 1.50 | 5       |
| BBCH > 40    | Large herbivorous         | Long-term (Carbendazim) | 1.07 | 21.1 | 5       |
| BBCH > 20    | Small insectivorous       | Long-term (Carbendazim) | 0.615 | 36.6 | 5       |
| BBCH > 40    | Small herbivorous         | Long-term (Carbendazim) | 7.02 | 3.21 | 5       |
|              | Small omnivorous          | Long-term (Carbendazim) | 0.744 | 30.3 | 5       |

### Higher tier (mammals):

The risk assessment was refined by PT/PD values derived from generic field studies on the focal species, including analysis of faeces content and radio-tracking. Proposed refinements of residue decline was not considered acceptable by RMS. See RMS evaluation in Volume 3CP, section 9.

| Indicator or focal species | Time scale          | DDD  | TER  | Trigger |
|----------------------------|---------------------|------|------|---------|
| All Wood mouse             | Long-term (a.s.)    | 3.98 | 0.53 | 5       |
| All Algerian mouse         | Long-term (a.s.)    | 4.18 | 0.48 | 5       |

### Risk from bioaccumulation and food chain behaviour

Not relevant

### Risk from consumption of contaminated water

**Scenarios**

| Indicator or focal species | Time scale          | PEC<sub>dw</sub>xDWR | TER  | Trigger |
|----------------------------|---------------------|-----------------------|------|---------|
| Birds                      | acute               | Not relevant          |      |         |

#### Puddle scenario, Screening step

1) Application rate (g a.s./ha)/relevant endpoint <50 (k<sub>oc</sub>&lt;500 L/kg), TER calculation not needed for Thiophanate-methyl
2) Application rate (g a.s./ha)/relevant endpoint &lt;3000 (k<sub>oc</sub>&gt;500 L/kg), TER calculation not needed for Carbendazim

| Indicator or focal species | Time scale          | PEC<sub>dw</sub>xDWR | TER  | Trigger |
|----------------------------|---------------------|-----------------------|------|---------|
| Birds                      | Acute               | Not needed            | 10   |         |
| Mammals                    | Acute               | Not needed            | 10   |         |
| Birds                      | Long-term, a.s.     | 0.29                  | 31.4 | 5       |
| Birds                      | Long-term, Carbendazim | Not needed          |      |         |
| Mammals                    | Long-term, a.s.     | 0.15                  | 335  | 5       |
| Mammals                    | Long-term, Carbendazim | Not needed        |      |         |

### Beans at 750 g a.s./ha [two applications, BBCH 61-71]

**Growth stage Indicator or focal species Time scale DDD (mg/kg bw per day) TER Trigger**

| Growth stage | Indicator or focal species | Time scale          | DDD  | TER  | Trigger |
|--------------|---------------------------|---------------------|------|------|---------|
| Screening Step (Birds) |                       |                     |      |      |         |
| All          | Small omnivorous bird     | Acute (a.s.)        | 143  | &gt;32.5 | 10      |
| All          | Small omnivorous bird     | Acute (Carbendazim) | 79.8 | 7.70  | 10      |
| All          | Small omnivorous bird     | Acute (FH-432)      | 130  | &gt;35.7 | 10      |
| All          | Small omnivorous bird     | Acute (2-AB)        | 169  | &gt;27.5 | 10      |
| All          | Small omnivorous bird     | Long-term (a.s.)    | 35.3 | 0.26  | 5       |
| All          | Small omnivorous bird     | Long-term (Carbendazim) | 19.7 | 1.34  | 5       |
| Tier 1 (Birds) |                       |                     |      |      |         |
| BBCH &gt;50  | Small granivorous bird    | Acute               | 3.53 | 697   | 10      |
| BBCH &gt;50  | Small omnivorous bird     | Acute               | 3.43 | 716   | 10      |
| BBCH &gt;20  | Small insectivorous bird  | Acute               | 12.02| 204   | 10      |
| BBCH &gt;50  | Small granivorous bird    | Long-term (a.s.)    | 1.85 | 4.92  | 5       |
| BBCH &gt;50  | Small omnivorous bird     | Long-term (a.s.)    | 1.80 | 5.05  | 5       |
| BBCH &gt;20  | Small insectivorous bird  | Long-term (a.s.)    | 5.28 | 1.72  | 5       |
| BBCH &gt;50  | Small granivorous bird    | Long-term (Carbendazim) | 1.03 | 25.5  | 5       |
Growth stage | Indicator or focal species | Time scale               | DDD (mg/kg bw per day) | TER | Trigger |
--- | --- | --- | --- | --- | --- |
BBCH >50 | Small omnivorous bird | Long-term (Carbendazim) | 1.00 | 26.3 | 5 |
BBCH >20 | Small insectivorous bird | Long-term (Carbendazim) | 2.95 | 8.94 | 5 |

*Note that based on mammalian data, the representative formulation is ca 10 times more toxic than the active ingredient, and no formulation data is available for birds.

**Higher tier (birds):**
The risk assessment was refined by PT/PD values derived from generic field studies on the focal species, including analysis of faeces content and radio-tracking. Proposed refinements of residue decline was not considered acceptable by RMS. See RMS evaluation in Volume 3CP, section 9.

**Screening Step (Mammals)**

| All | Serin | Long term (a.s.) | 3.00 | 3.03 | 5 |
| All | Yellow wagtail | Long term (a.s.) | 1.16 | 1.72 | 5 |
| All | Crested lark | Long term (a.s.) | 2.04 | 0.96 | 5 |
| All | Skylark | Long term (a.s.) | 2.45 | 3.71 | 5 |
| All | Corn bunting | Long term (a.s.) | 3.81 | 2.39 | 5 |
| All | Wood pigeon | Long term (a.s.) | 1.76 | 5.17 | 5 |

**Tier 1 (Mammals)**

| BBCH >20 | Small insectivorous mammal | Acute (a.s.) | 4.9 | 83 | 10 |
| BBCH >50 | Small herbivorous mammal | Acute (a.s.) | 36.8 | 11 | 10 |
| BBCH >50 | Large herbivorous mammal | Acute (a.s.) | 9.5 | 43 | 10 |
| BBCH >50 | Small omnivorous mammal | Acute (a.s.) | 4.7 | 87 | 10 |
| BBCH >20 | Small insectivorous mammal | Long-term (a.s.) | 1.04 | 1.92 | 5 |
| BBCH >50 | Small herbivorous mammal | Long-term (a.s.) | 11.8 | 0.17 | 5 |
| BBCH >50 | Large herbivorous mammal | Long-term (a.s.) | 2.34 | 0.85 | 5 |
| BBCH >50 | Small omnivorous mammal | Long-term (a.s.) | 1.25 | 1.60 | 5 |
| BBCH >20 | Small insectivorous mammal | Long-term (Carbendazim) | 0.578 | 39.9 | 5 |
| BBCH >50 | Small herbivorous mammal | Long-term (Carbendazim) | 6.60 | 3.4 | 5 |
| BBCH >50 | Large herbivorous mammal | Long-term (Carbendazim) | 1.31 | 17.2 | 5 |
| BBCH >50 | Small omnivorous mammal | Long-term (Carbendazim) | 0.700 | 32.1 | 5 |

**Higher tier (mammals):**
Refinement by providing justification for lack of relevance for the vole scenario in leafy vegetables since this is not a primary habitat and potential for re-colonisation. No refinement option was presented for large herbivorous mammals. No acceptable refinement for small insectivores, large herbivores and small omnivores.

**Risk from bioaccumulation and food chain behaviour**
Not relevant

**Risk from consumption of contaminated water**
### Scenarios

| Scenarios                          | Indicator or focal species | Time scale | PEC_{dw}xDWR | TER | Trigger |
|-----------------------------------|---------------------------|------------|--------------|-----|---------|
| Leaf scenario                     | Birds                     | acute      |              |     |         |
| **Puddle scenario, Screening step** |                           |            |              |     |         |
| 1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for Thiophanate-methyl | Birds | acute | Not needed | 10 |
| 1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc>500 L/kg), TER calculation not needed for Carbendazim | Birds | Long-term, relevant endpoint | 0.20 | 45.5 | 5 |
| Puddle scenario                   | Mammals                   | Acute      |              |     |         |
| Puddle scenario                   | Mammals                   | Long-term, relevant endpoint | Not needed | | |
| Puddle scenario                   | Mammals                   | Long-term, relevant endpoint | Not needed | | |

### Wheat at 750 g a.s./ha [single application, BBCH 59-70]

| Growth stage  | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------|---------------------------|------------|------------------------|-----|---------|
| **Screening Step (Birds)** |                           |            |                        |     |         |
| All           | Small omnivorous bird     | Acute (a.s.) | 119                    | > 39.0 | 10 |
| All           | Small omnivorous bird     | Acute (Carbendazim) | 66.5           | 9.24  |
| All           | Small omnivorous bird     | Acute (FH-432) | 108                  | >43.0  | 10 |
| All           | Small omnivorous bird     | Acute (2-AB)  | 256                   | >18.1  | 10 |
| All           | Small omnivorous bird     | Long-term (a.s.) | 25.6              | 0.36  | 5 |
| All           | Small omnivorous bird     | Long-term (Carbendazim) | 14.3           | 1.85  | 5 |
| Tier 1 (Birds) |                           |            |                        |     |         |
| BBCH >40      | Small omnivorous bird     | Acute       | 2.86                  | 859 | 10 |
| Late season   | Graniv/insectiv. bird     | Acute*      | 10.73                | 229 | 10 |
| BBCH >40      | Small omnivorous bird     | Long-term (a.s.) | 1.30             | 7.00 | 5 |
| Late season   | Graniv/insectivorous bird | Long-term (a.s.) | 4.97            | 1.83  | 5 |
| BBCH >40      | Small omnivorous bird     | Long-term (Carbendazim) | 0.728         | 36.3  | 5 |
| Late season   | Graniv/insectivorous bird | Long-term (Carbendazim) | 2.76            | 9.57  | 5 |
| *Note that based on mammalian data, the representative formulation is ca 10 times more toxic than the active ingredient, and no formulation data is available for birds.* |

### Higher tier (birds)

The risk assessment was refined by PT/ PD values derived from generic field studies on the focal species, including analysis of faeces content and radio-tracking. Proposed refinements of residue decline was not considered acceptable by RMS. See RMS evaluation in Volume 3CP, section 9.

| Growth stage  | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------|---------------------------|------------|------------------------|-----|---------|
| All           | Yellowhammer              | Long-term (a.s.) | 4.03                 | 2.26 | 5 |
| All           | Tree sparrow              | Long-term (a.s.) | 2.69                 | 3.38 | 5 |
| All           | Quail                     | Long-term (a.s.) | 1.16                 | 7.84 | 5 |
| All           | Yellow wagtail            | Long-term (a.s.) | 0.485              | 18.8 | 5 |

*Screening Step (Mammals) |  
| All           | Small herbivorous mammal | Acute (a.s.) | 88.8 | 4.6 | 10 |
| All           | Small herbivorous mammal | Acute (Carbendazim) | 49.6 | > 101 | 10 |
| All           | Small herbivorous mammal | Acute (FH-432) | 80.5 | 53.4 | 10 |
| All           | Small herbivorous mammal | Acute (2-AB)  | 34.6 | 98.3 | 10 |
| All           | Long-term (a.s.)          | Not calculated | -              | -   | 5 |

*Tier 1 (Mammals) |  
| BBCH >20      | Small insectivorous mammal | Acute (a.s.) | 4.1 | 100 | 10 |
| BBCH >40      | Small herbivorous mammal  | Acute (a.s.) | 30.7 | 13 | 10 |
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

**Growth stage**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| BBCH >40 Small omnivorous mammal | Acute (a.s.) | 3.9 | 105 | 10 |
| BBCH >20 Small insectivorous mammal | Long-term (a.s.) | 0.751 | 2.66 | 5 |
| BBCH >40 Small herbivorous mammal | Long-term (a.s.) | 8.57 | 0.23 | 5 |
| BBCH >40 Small omnivorous mammal | Long-term (a.s.) | 0.909 | 2.20 | 5 |
| BBCH >20 Small insectivorous mammal | Long-term (Carbendazim) | 0.419 | 53.7 | 5 |
| BBCH >40 Small herbivorous mammal | Long-term (Carbendazim) | 4.79 | 4.70 | 5 |
| BBCH >40 Small omnivorous mammal | Long-term (Carbendazim) | 0.508 | 44.3 | 5 |

### Higher tier (mammals):

No accepted refinement options available for this use.

### Risk from bioaccumulation and food chain behaviour

Not relevant

### Risk from consumption of contaminated water

#### Scenarios

| Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|----------------------------|------------|-----------------------|-----|---------|
| Leaf scenario | Birds | Acute | Not calculated | - | 5 |

**Puddle scenario, Screening step**

1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for Thiophanate-methyl

1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc>500 L/kg), TER calculation not needed for Carbendazim

#### Puddle scenario

| Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|----------------------------|------------|-----------------------|-----|---------|
| Puddle scenario | Birds | Acute | Not needed | 10 |
| Puddle scenario | Mammals | Acute | Not needed | 10 |
| Puddle scenario | Birds | Long-term, a.s. | 0.20 | 45.5 | 5 |
| Puddle scenario | Birds | Long-term, Carbendazim | Not needed |
| Puddle scenario | Mammals | Long-term, a.s. | 0.10 | 500 | 5 |
| Puddle scenario | Mammals | Long-term, Carbendazim | Not needed |

### Leek at 4150 g a.s./ha [drenching]

#### Screening Step (Birds) Not reported

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| All Lark | Acute* | 659 | >7.0 | 10 |
| All Sparrow | Acute* | 83.0 | >55.9 | 10 |
| All Thrush | Acute* | 54.6 | >85 | 10 |
| All Lark | Acute (Carbendazim) | 369 | 1.67 | 10 |
| All Sparrow | Acute (Carbendazim) | 46.4 | 13.2 | 10 |
| All Thrush | Acute (Carbendazim) | 30.7 | 20.0 | 10 |
| All Lark | Acute (FH-432) | 597 | >7.77 | 10 |
| All Sparrow | Acute (FH-432) | 75.2 | >61.7 | 10 |
| All Thrush | Acute (FH-432) | 49.8 | >93.2 | 10 |
| All Lark | Acute (2-AB) | 256 | >18.1 | 10 |
| All Sparrow | Acute (2-AB) | 32.2 | >144 | 10 |
| All Thrush | Acute (2-AB) | 21.3 | >218 | 10 |
| All Lark | Long-term (a.s.) | 71.3 | 0.12 | 5 |
| All Sparrow | Long-term (a.s.) | 10.2 | 0.89 | 5 |
| All Thrush | Long-term (a.s.) | 7.92 | 1.15 | 5 |
| All Lark | Long-term (Carbendazim) | 39.9 | 0.66 | 5 |
| All Sparrow | Long-term (Carbendazim) | 5.68 | 4.64 | 5 |
| All Thrush | Long-term (Carbendazim) | 4.43 | 5.96 | 5 |
Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger
---|---|---|---|---|---
*Note that based on mammalian data, the representative formulation is ca 10 times more toxic than the active ingredient, and no formulation data is available for birds.*

**Higher tier (birds):**
Thiophanate: Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants (extrapolated to leek), not considered sufficient for refinement. Further refinement needed for acute and long term risk assessment.

Carbendazim: Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants (extrapolated to leek), considered sufficient for the acute risk assessment but further refinement needed for long term risk assessment.

Screening Step (Mammals) Not reported

| Tier 1 (Mammals) | | | | |
| --- | --- | --- | --- | --- |
| All Herbivorous mouse | Acute (a.s.) | 490 | 0.832 | 10 |
| All Granivorous mouse | Acute (a.s.) | 61.4 | 6.65 | 10 |
| All Shrew | Acute (a.s.) | 76.7 | 5.32 | 10 |

**Higher tier (mammals):**
Thiophanate: Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants (extrapolated to leek), not considered sufficient for refinement. Further refinement needed for acute and long term risk assessment.

Carbendazim: Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants (extrapolated to leek), considered sufficient for the acute risk assessment but further refinement needed for long term risk assessment.

Risk from bioaccumulation and food chain behaviour
Not relevant

**Risk from consumption of contaminated water**

| Scenarios | Indicator or focal species | Time scale | PEC_{a.s}xDWR | TER | Trigger |
| --- | --- | --- | --- | --- | --- |
| Leaf scenario | Birds | acute | Not relevant | 5 |

**Puddle scenario, Screening step**
1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for Thiophanate-methyl
1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc>500 L/kg), TER calculation not needed for Carbendazim

| Puddle scenario | Indicator or focal species | Time scale | PEC_{a.s}xDWR | TER | Trigger |
| --- | --- | --- | --- | --- | --- |
| Puddle scenario Birds | Acute | Not needed | 10 |
| Puddle scenario Mammals | Acute | Not needed | 10 |
| Puddle scenario Birds | Long-term, a.s. | 1.12 | 8.13 | 5 |
| Puddle scenario Mammals | Long-term, a.s. | 0.174 | 151 |
| Puddle scenario Birds | Long-term, Carbendazim | 0.58 | 83 | 5 |
| Puddle scenario Mammals | Long-term, Carbendazim | 0.091 | 247 |

Tomato/aubergine at 2100 g a.s./ha [drip irrigation]
## Risk from bioaccumulation and food chain behaviour

### Screening Step (Birds) Not reported

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Tier 1 (Birds) | All Lark | Acute (formulation)* | 434 | >10.7 | 10 |
|               | All Sparrow | Acute (formulation)* | 54.6 | >85 | 10 |
|               | All Thrush | Acute (formulation)* | 36.2 | >128 | 10 |
|               | All Lark | Acute (Carbendazim) | 369 | 1.67 | |
|               | All Sparrow | Acute (Carbendazim) | 46.4 | 13.2 | |
|               | All Thrush | Acute (Carbendazim) | 30.7 | 20.0 | |
|               | All Lark | Acute (FH-432) | 392 | >11.8 | 10 |
|               | All Sparrow | Acute (FH-432) | 49.4 | >93.9 | 10 |
|               | All Thrush | Acute (FH-432) | 32.7 | >141.9 | 10 |
|               | All Lark | Acute (2-AB) | 169 | >27.5 | 10 |
|               | All Sparrow | Acute (2-AB) | 21.3 | >218 | 10 |
|               | All Thrush | Acute (2-AB) | 14.1 | >329 | 10 |
|               | All Lark | Long-term (a.s.) | 41.1 | 0.22 | 5 |
|               | All Sparrow | Long-term (a.s.) | 5.87 | 1.55 | 5 |
|               | All Thrush | Long-term (a.s.) | 4.37 | 1 | 5 |
|               | All Lark | Long-term (Carbendazim) | 22.9 | 1.15 | 5 |
|               | All Sparrow | Long-term (Carbendazim) | 3.27 | 8.08 | 5 |
|               | All Thrush | Long-term (Carbendazim) | 2.54 | 10.4 | 5 |

*Note that based on mammalian data, the representative formulation is ca 10 times more toxic than the active ingredient, and no formulation data is available for birds.

### Higher tier (birds):

**Thiophanate:** Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants, not considered sufficient for refinement. Further refinement needed for acute and long term risk assessment.

**Carbendazim:** Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants, considered sufficient for the acute risk assessment but further refinement needed for long term risk assessment.

### Screening Step (Mammals) Not reported

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Tier 1 (Mammals) | All Herbivorous mouse | Acute (a.s.) | 283 | 1.44 | 10 |
|               | All Granivorous mouse | Acute (a.s.) | 35.4 | 11.5 | 10 |
|               | All Shrew | Acute (a.s.) | 44.3 | 9.22 | 10 |
|               | All Herbivorous mouse | Acute (Carbendazim) | 180 | >27.8 | 10 |
|               | All Granivorous mouse | Acute (Carbendazim) | 22.5 | >222 | 10 |
|               | All Shrew | Acute (Carbendazim) | 28.1 | >178 | 10 |
|               | All Herbivorous mouse | Acute (FH-432) | 292 | 14.7 | 10 |
|               | All Granivorous mouse | Acute (FH-432) | 36.5 | 118 | 10 |
|               | All Shrew | Acute (FH-432) | 45.7 | 94.1 | 10 |
|               | All Herbivorous mouse | Acute (2-AB) | 125 | 27.1 | 10 |
|               | All Granivorous mouse | Acute (2-AB) | 15.7 | 216 | 10 |
|               | All Shrew | Acute (2-AB) | 19.6 | 173 | 10 |
|               | All Herbivorous mouse | Long-term (a.s.) | 61.2 | 0.03 | 5 |
|               | All Granivorous mouse | Long-term (a.s.) | 8.67 | 0.23 | 5 |
|               | All Shrew | Long-term (a.s.) | 12.8 | 0.16 | 5 |
|               | All Herbivorous mouse | Long-term (Carbendazim) | 34.1 | 0.660 | 5 |
|               | All Granivorous mouse | Long-term (Carbendazim) | 4.83 | 4.66 | 5 |
|               | All Shrew | Long-term (Carbendazim) | 7.10 | 3.17 | 5 |

**Higher tier (mammals):**

**Thiophanate:** Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants, not considered sufficient for refinement. Further refinement needed for acute and long term risk assessment.

**Carbendazim:** Proposed weight of evidence for herbivorous birds based on residue data indicating low uptake in tomato plants, considered sufficient for the acute risk assessment but further refinement needed for long term risk assessment.
Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger
---|---|---|---|---|---
Not relevant

### Risk from consumption of contaminated water

| Scenarios | Indicator or focal species | Time scale | PECₐ₈xDWR | TER | Trigger |
|---|---|---|---|---|---|
| Leaf scenario | Birds | acute | Not relevant | 5 |

#### Puddle scenario, Screening step
1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed for Thiophanate-methyl

1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc>500 L/kg), TER calculation not needed for Carbendazim

| Puddle scenario | Birds | Acute | Not needed | 10 |
|---|---|---|---|---|
| Puddle scenario | Mammals | Acute | Not needed | 10 |

*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 (mg/L) |
|---|---|---|---|---|
| Laboratory tests | Thiophanate-methyl | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 11.0 (mm) |
| Fish | BAS 325 10 F | Acute 96 hr | Mortality, LC₅₀ | No reliable data |
| Ictalurus punctatus | Carbendazim* | 96 hr | Mortality, LC₅₀ | 0.019 (nom) |
| Oncorhynchus mykiss | Carbendazim* | 96 hr | Mortality, LC₅₀ | 0.54 (nom)** |
| Cyprinodon variegatus | Carbendazim | 96 hr | Mortality, LC₅₀ | >1.158 |
| Lepomis macrochirus | Carbendazim | 96 hr | Mortality, LC₅₀ | >3.2 |
| Cyprinus carpio | Carbendazim | 96 hr | Mortality, LC₅₀ | 0.44 |
| Oncorhynchus mykiss | 4-OH-TM | 96 h, static | Mortality, LC₅₀ | >10 (mm, filtrated) |
| Oncorhynchus mykiss | CM-0237 | 96 h, static | Mortality, LC₅₀ | >0.14 (mm, filtrated) |
| Fish | CM-0237 | Acute | LC₅₀ | 1.1 (as Thiophanate-methyl/10) |
| Fish | UM 2(M10) | Acute | LC₅₀ | 1.1 (as Thiophanate-methyl/10) |
| Danio rerio | Thiophanate-methyl | 35 days, ELS, flow-through | NOEC, EC₀, EC₁₀ | <0.12*** (mm), 0.39 (mm) |
| Oncorhynchus mykiss | Carbendazim* | 21 days, flow-through | NOEC | 0.0032 (nom) |
| Fish | 4-OH-TM | Chronic | NOEC | 0.039 (as Thiophanate-methyl/10) |
| Fish | CM-0237 | Chronic | NOEC | 0.0032 (as Carbendazim) |
| Fish | 2-AB | Chronic | NOEC | 0.0032 (as Carbendazim) |
| Fish | DX-105 | Chronic | NOEC | 0.039 (as Thiophanate-methyl/10) |
| Fish | UM 2(M10) | Chronic | NOEC | 0.039 (as Thiophanate-methyl/10) |
| Group | Test substance | Time-scale (Test type) | End point | Toxicity (mg/L) |
|-------|----------------|------------------------|-----------|----------------|
|       |                |                        |           |                |
| **Aquatic invertebrates** | | | | |
| *Daphnia magna* | Thiophanate-methyl | 48 h, flow-through | EC$_{50}$ NOEC | 5.4 (mm) <4.2 (mm) |
| *Daphnia magna* | BAS 325 10 F | 48 h, static | EC$_{50}$ NOEC | 4.4 (mm; a.s.) 3.1 (nom; a.s.) |
| *Daphnia magna* | Carbendazim* | 48 h | EC$_{50}$ NOEC | 0.15 (nom) |
| *Daphnia magna* | 4-OH-TM | 48 h, static | EC$_{50}$ | >17.6 (mm, filtrated) |
| *Daphnia magna* | CM-0237 | 48 h, static | EC$_{50}$ | >0.256 (mm, filtrated) |
| *Chironomus riparius* | 4-OH-TM | 48 h, static | EC$_{50}$ NOEC | >14.0 (mm, filtrated) |
| Aquatic invertebrates | 2-AB | Acute | EC$_{50}$ NOEC | 0.15 (as Carbendazim) |
| Aquatic invertebrates | DX-105 | Acute | EC$_{50}$ | 0.44 (as Thiophanate-methyl/10) |
| Aquatic invertebrates | UM 2(M10) | Acute | EC$_{50}$ | 0.44 (as Thiophanate-methyl/10) |
| *Daphnia magna* | Thiophanate-methyl | 21 d, semi-static | NOEC EC$_{10}$ EC$_{20}$ | 0.16 (mm) Not reported |
| *Daphnia magna* | TOPSIN M WDG (Thiophanate-methyl) | 21 d, aged test item* | NOEC EC$_{10}$ | 0.0373 (mm; a.s.) 0.0285 (mm; a.s.) |
| *Daphnia magna* | TOPSIN M WDG (Carbendazim) | 21 d, aged test item* | NOEC EC$_{10}$ | 0.0177 (mm; a.s.) 0.0149 (mm; a.s.) |
| *Daphnia magna* | Carbendazim* | 21 d, semi-static | NOEC EC$_{10}$ EC$_{20}$ | 0.0015 (mm) Not reported |
| Aquatic invertebrates | 4-OH-TM | Chronic | NOEC | 0.016 (as Thiophanate-methyl/10) |
| Aquatic invertebrates | CM-0237 | Chronic | NOEC | 0.015 (as Carbendazim) |
| Aquatic invertebrates | 2-AB | Chronic | NOEC | 0.015 (as Carbendazim) |
| Aquatic invertebrates | DX-105 | Chronic | NOEC | 0.016 (as Thiophanate-methyl/10) |
| Aquatic invertebrates | UM 2(M10) | Chronic | NOEC | 0.016 (as Thiophanate-methyl/10) |
| **Sediment-dwelling organisms** | | | | |
| *Chironomus riparius* | Thiophanate-methyl | 28 d, water spiked | NOEC EC$_{10}$ EC$_{20}$ | 0.44 (init. meas.) Not reported |
| *Chironomus riparius* | Carbendazim* | 28 d, water spiked | NOEC EC$_{10}$ EC$_{20}$ | 0.0133 (nom) Not reported |
| **Algae** | | | | |
| *P. subcapitata* | Thiophanate-methyl | 72 h, static | E$_{1}$E$_{10}$ E$_{1}$E$_{20}$ | 11.8 4.38 3.13 |
| | | | E$_{1}$C$_{50}$ E$_{1}$C$_{50}$ | 4.93 37.2 n.d. 6.74 |
| | | | E$_{1}$C$_{20}$ E$_{1}$C$_{20}$ | 12.1 (mm) |
| *S. subspicatus* | Topsin 500 SC | 72 h, static | E$_{1}$E$_{10}$ | 11.2 ≤ 0.33 2.7 |
| | | | E$_{1}$C$_{50}$ E$_{1}$C$_{50}$ | 4.4 27.3 3.3 |
| | | | E$_{1}$C$_{20}$ E$_{1}$C$_{20}$ | 10.5 14.6 (mm; a.s.) |
| *P. subcapitata* | Carbendazim* | 72 h, static | E$_{1}$E$_{10}$ | 7.7 mg/L (mm) > 11 mg/L (mm) |
| | | | E$_{1}$C$_{50}$ EC$_{10}$ EC$_{20}$ NOEC | Not reported Not reported Not reported |

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Group | Test substance | Time-scale (Test type) | End point | Toxicity (mg/L)
---|---|---|---|---
P. subcapitata | 4-OH-TM | 72 h, static | Ec50, Er10, Er20, NOEC | > 15 Not reported Not reported (15 mm, dissolved)
P. subcapitata | CM-0237 | 72 h, static | Ec50, Er10, Er20, NOEC | > 0.182 Not reported Not reported (0.182 mm, dissolved)
Algae | M10 | 96 h, static | Ec50 | 0.523 (ECOSAR)
Algae | 2-AB | 96 h, static | Ec50 | 0.349 (ECOSAR)
Algae | DX-105 | 96 h, static | Ec50 | 0.024 (ECOSAR)

Further testing on aquatic organisms
Proposed SSD for acute toxicity to fish not considered reliable since more than one unbound value was included in the calculation. Exclusion of those values resulted in insufficient number of data for an SSD-calculation.

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)
As reported in section 2, thiophanate-methyl is considered an endocrine disrupter for mammals. In addition, published literature data are available showing that the potential for endocrine disruption of thiophanate-methyl and carbendazim cannot be excluded.

* Refer to the EFSA conclusion on the peer review of the active substance Carbendazim, EFSA (2010)
**Geomean value from five tests on O. mykiss. The LC50 values ranged from 1.19 – 0.98 mg/L for this species.
***NOEC for fish based on increased body length and dry weight at all treatment levels. Not considered as an adverse effect.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| log P_O/W | Thiophanate-methyl | Carbendazim | Other metabolites |
|---|---|---|---|
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 1.45 | 1.5 | <3 |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) | - | - | - |
| Annex VI Trigger for the bioconcentration factor | - | - | - |
| Clearance time (days) (CT50) | - | - | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | - | - | - |
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2).

PEC/RAC ratios for Thiophanate-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in grapes (late)

| Group                           | Fish  | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------------------------|-------|---------------|-------|----------------------|
|                                 |       |               |       |                      |
| Test species                    | O. mykiss | O. mykiss | D. magna | D. magna | P. subcapitata | C. riparius |
| Endpoint                        | LC50  | EC10          | EC50  | NOEC | ErC50 | NOEC |
| [µg a.s./L]                     | 11000 | 390           | 4400  | 161 | 27300 | 440 |
| AF                             | 100   | 10            | 100   | 10 | 10 | 10 |
| RAC [µg a.s./L]                 | 110   | 39            | 44    | 16.1 | 2730 | 44 |
| FOCUS Scenario                 |       |               |       |      |      |     |
| Step 1                          | n.c. * | -            | -     | -   | -   | -   |
| Step 2                          | n.c. * | -            | -     | -   | -   | -   |
| Step 3                          | D6/ditch | 0.172     | 0.484 | 0.429 | 1.173 | 0.007 | 0.429 |
|                                 | R1/pond | 0.006     | 0.017 | 0.015 | 0.042 | 0.000 | 0.015 |
|                                 | R1/stream | 0.126     | 0.355 | 0.315 | 0.860 | 0.005 | 0.315 |
|                                 | R2/stream | 0.169     | 0.476 | 0.422 | 1.153 | 0.007 | 0.422 |
|                                 | R3/stream | 0.177     | 0.501 | 0.444 | 1.212 | 0.007 | 0.444 |
|                                 | R4/stream | 0.126     | 0.355 | 0.315 | 0.860 | 0.005 | 0.315 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* not calculated

Refined chronic PEC/RAC ratios for daphnids based on initial FOCUS Step 4 PECsw values for Thiophanate-methyl for the use in grapes considering risk mitigation measures

| Test substance      | Crop          | RAC [µg/L] | FOCUS scenario | Vegetated buffer zone [m] * | Initial FOCUS Step 4 PECsw [µg/L] | PEC/RAC ratio ** |
|---------------------|---------------|------------|----------------|----------------------------|-----------------------------------|-----------------|
| Thiophanate-methyl  | Grapes, late  | 16.1       | D6 ditch       | 10                         | 4.14                              | 0.257           |
|                     |               |            | R2 stream      | 10                         | 4.90                              | 0.304           |
|                     |               |            | R3 stream      | 10                         | 6.50                              | 0.403           |

* including vegetated filter strip
** ratios calculated with unrounded PECsw values as presented in Annex B.8 for the formulated product.

**PEC/RAC ratios for Thiophanate-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in beans (multiple applications)**

| Group                  | Fish       | Invertebrates | Algae      | Sed. dwell. prolonged |
|------------------------|------------|---------------|------------|-----------------------|
| Test species           |            |               |            |                       |
| Endpoint               |            |               |            |                       |
| LC50                   | Acute      | Chronic       | Acute      | P. subcapitata        |
|                        | O. mykiss  | O. mykiss     | D. magna   | C. riparius           |
| EC10                   |            |               | EC50       |                       |
|                        |            |               | NOEC       |                       |
| [µg a.s./L]            | 11000      | 390           | 4400       | 27300                 |
| AF                     | 100        | 10            | 100        | 10                    |
| RAC [µg a.s./L]        | 110        | 39            | 44         | 2730                  |
| FOCUS Scenario         |            |               |            |                       |
| Step 1                 | PECSW [µg a.s./L] | -       | -          | -                     |
| Step 2                 | n.c. *     | -             | -          | -                     |
| Step 3                 |            |               |            |                       |
| D2/ditch               | 23.4       | 0.213         | 0.600      | 0.532                 |
| D2/stream              | 15.0       | 0.136         | 0.385      | 0.532                 |
| D3/ditch               | 3.43       | 0.031         | 0.088      | 0.213                 |
| D4/pond                | 0.136      | 0.001         | 0.003      | 0.001                 |
| D4/stream              | 3.07       | 0.079         | 0.070      | 0.001                 |
| D6/ditch, 1st         | 3.44       | 0.031         | 0.088      | 0.001                 |
| R1/pond                | 0.67       | 0.006         | 0.017      | 0.000                 |
| R1/stream              | 13.2       | 0.120         | 0.338      | 0.001                 |
| R2/stream              | 3.15       | 0.029         | 0.081      | 0.001                 |
| R3/stream              | 14.3       | 0.130         | 0.367      | 0.001                 |
| R4/stream              | 20.9       | 0.190         | 0.536      | 0.001                 |
| D6/ditch, 2nd         | 3.42       | 0.031         | 0.088      | 0.001                 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
Refined chronic PEC/RAC ratios for daphnids based on initial FOCUS Step 4 PECsw values for Thiophanate-methyl for the use in beans considering risk mitigation measures

| Test substance       | Crop                | RAC [µg/L] | FOCUS scenario | Vegetated buffer zone [m] * | Initial FOCUS Step 4 PECsw [µg/L] | PEC/RAC ratio ** |
|----------------------|---------------------|------------|----------------|-----------------------------|----------------------------------|-----------------|
| Thiophanate-methyl   | Beans, multiple     | 16.1       | D2 ditch       | 10                          | 23.4                             | 1.45            |
|                      |                     |            | R4 stream      |                             | 9.47                             | 0.588           |

* including vegetated filter strip
** ratios calculated with unrounded PECsw values as presented in Annex B.8 for the formulated product.
Values in bold are above the trigger of 1

PEC/RAC ratios for Thiophanate-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in cereals (early)

| Group | Fish | Chronic | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------|---------------|-------|-----------------------|
|       | Acute| O. mykiss | D. magna | P. subcapitata | C. riparius |
|       |      |         | Acute | Prolonged |                 |          |
| Test species |     |         |      |            |              |       |
| Endpoint | LC50 | EC10 | EC50 | NOEC | ErC50 | NOEC |
| [µg a.s./L] | 11000 | 390 | 4400 | 161 | 27300 | 440 |
| AF     | 100  | 10   | 100  | 10  | 10   | 10   |
| RAC [µg a.s./L] | 110 | 39  | 44   | 16.1 | 2730  | 44 |
| FOCUS Scenario | PECSW [µg a.s./L] | n.c. * | - | - | - | - |
| Step 1 | n.c. * | - | - | - | - | - |
| Step 2 | n.c. * | - | - | - | - | - |
| Step 3 | D1/ditch | 4.812 | 0.044 | 0.123 | 0.109 | 0.299 | 0.002 | 0.109 |
|        | D1/stream | 4.207 | 0.038 | 0.108 | 0.096 | 0.261 | 0.002 | 0.096 |
|        | D2/ditch | 28.9 | 0.263 | 0.741 | 0.657 | 1.795 | 0.011 | 0.657 |
|        | D2/stream | 20.89 | 0.190 | 0.536 | 0.475 | 1.298 | 0.008 | 0.475 |
|        | D3/ditch | 4.757 | 0.043 | 0.122 | 0.108 | 0.295 | 0.002 | 0.108 |
|        | D4/pond | 0.164 | 0.001 | 0.004 | 0.004 | 0.010 | 0.000 | 0.004 |
### Table 1: Pesticide Risk Assessment of Thiophanate-Methyl

| Group          | Fish      | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------|-----------|---------------|-------|----------------------|
|                | Acute     | Chronic       |       |                      |
| D4/stream      | 3.965     | 0.102         | 0.090 | 0.246                |
| D5/pond        | 0.164     | 0.004         | 0.004 | 0.010                |
| D5/stream      | 4.19      | 0.107         | 0.095 | 0.260                |
| D6/ditch       | 4.776     | 0.122         | 0.109 | 0.297                |
| R1/pond        | 0.164     | 0.004         | 0.004 | 0.010                |
| R1/stream      | 3.389     | 0.087         | 0.077 | 0.210                |
| R3/stream      | 4.424     | 0.113         | 0.101 | 0.275                |
| R4/stream      | 12.26     | 0.314         | 0.279 | 0.761                |

**Group**
- D4/stream: Direct stream
- D5/pond: Direct pond
- D5/stream: Direct stream
- D6/ditch: Direct ditch
- R1/pond: Residual pond
- R1/stream: Residual stream
- R3/stream: Residual stream
- R4/stream: Residual stream

The table shows acute and chronic PEC/RAC ratios for different organism groups and environmental compartments. The ratios are calculated using the Assessment Factor (AF) and the Predicted Environmental Concentration (PEC) in relation to the Regulatory Acceptable Concentration (RAC).

### Table 2: Refined Chronic PEC/RAC Ratios for Daphnids

| Test substance | Crop       | RAC [µg/L] | FOCUS scenario | Vegetated buffer zone [m] * | Initial FOCUS Step 4 PECsw [µg/L] | PEC/RAC ratio ** |
|----------------|------------|------------|----------------|-----------------------------|-----------------------------------|------------------|
| Thiophanate-methyl | Cereals, early | 16.1 | D2 ditch | 20 | 28.9 | 1.80 |

* including vegetated filter strip

** ratios calculated with unrounded PECsw values as presented in CP 9.2.5

Values in bold are above the trigger of 1

### Table 3: PEC/RAC Ratios for Thiophanate-Methyl

| Group          | Fish      | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------|-----------|---------------|-------|----------------------|
|                | Acute     | Chronic       |       |                      |
| Test species   |           |               |       |                      |
| Endpoint       |           |               |       |                      |
| [µg a.s./L]    |           |               |       |                      |
| O. mykiss LC50 | 11000     | 390           | 4400  | 161                  |
| AF             | 100       | 10            | 100   | 10                   |
| RAC [µg a.s./L]| 110       | 39            | 44    | 16.1                 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* not calculated
### PEC/RAC ratios for Thiophanate-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in tomato / aubergine (multiple applications)

| Group | Test species | Fish | Chronic | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|--------------|------|---------|---------------|-------|----------------------|
|       |              | Acute | Chronic | Acute | Prolonged | ErC50 | NOEC | ErC50 | NOEC | ErC50 | NOEC |
|       |              | O. mykiss | O. mykiss | D. magna | D. magna | P. subcapitata | C. riparius |
|       |              | LC50 | EC10 | EC50 | NOEC | ErC50 | NOEC |
|       | [µg a.s./L] | 11000 | 390 | 4400 | 161 | 27300 | 440 |
|       | AF | 100 | 10 | 100 | 10 | 10 | 10 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

* not calculated
### RAC \( [\mu g\text{ a.s./L}] \) PECSW \( [\mu g\text{ a.s./L}] \)

| Test substance | Crop | RAC [µg/L] | FOCUS scenario | Vegetated buffer zone [m] * | Initial FOCUS Step 4 PECsw [µg/L] | PEC/RAC ratio ** |
|----------------|------|------------|----------------|-------------------------------|-----------------------------------|------------------|
| Thiophanate-methyl | Tomato, late | 16.1 | R4 stream | 10 | 12.8 | 0.794 |

* including vegetated filter strip

** ratios calculated with unrounded PECsw values as presented in CP 9.2.5

Values in bold are above the trigger of 1

** Carbendazim

### PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in grapes (late)

| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
| Test species | | | | |
| Endpoint | | | | |
| LC50 | | | | |
| I. punctatus | | | | |
| O. mykiss | | | | |
| NOEC | | | | |
| D. magna | | | | |
| D. magna | | | | |
| P. subcapitata | | | | |
| C. riparius | | | | |
| EC50 | | | | |
| NOEC | | | | |
| ErC50 | | | | |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* not calculated

** not calculated for greenhouse, covering field applications

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Refined chronic PEC/RAC ratios for daphnids based on initial FOCUS Step 4 PECsw values for Thiophanate-methyl for the use in tomato/aubergine considering risk mitigation measures

### Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged
|-------|------|---------------|-------|----------------------|
| FOCUS Scenario | | | | |
| Step 1 | | | | |
| Step 2 | | | | |
| Step 3 (late applications) ** | | | | |
| D6/ditch | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| R2/stream | 0.104 | 0.001 | 0.003 | 0.002 | 0.006 | 0.000 | 0.002 |
| R3/stream | 10.18 | 0.093 | 0.261 | 0.231 | 0.632 | 0.004 | 0.231 |
| R4/stream | 28.46 | 0.259 | 0.730 | 0.647 | 1.768 | 0.010 | 0.647 |
## Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

### Group

| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
|       | Acute | Chronic       | Acute | Prolonged            |
| [µg a.s./L] | 19 | 3.2 | 150 | 1.5 | >11000 | 13.3 |
| AF    | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC [µg a.s./L] | 0.19 | 0.32 | 1.5 | 0.15 | 1100 | 1.33 |

### FOCUS Scenario

**PEC SW [µg a.s./L]**

| Step | AF | RAC |
|------|----|-----|
| Step 1 | 100 | 10 |
| Step 2 | 100 | 10 |

### FOCUS Scenario

**FOCUS Scenario**

| Step | AF | RAC |
|------|----|-----|
| Step 3 | 100 | 10 |

### Test species

#### Endpoint

| [µg a.s./L] | AF |
|------------|----|
| 19 | 100 |

### EC50

| LC50 | NOEC |
|------|------|
| 19   | 3.2  |

### NOEC

| EC50 | NOEC |
|------|------|
| 150  | 1.5  |

### Sed. dwell. prolonged

| [µg a.s./L] | AF |
|------------|----|
| 13.3 | 10 |

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Refined PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Step 4 calculations considering risk mitigation measures for the use of Topsin M 500 SC in grapes

| Group       | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------------|------|---------------|-------|----------------------|
|             | Acute | Chronic       | Acute | Prolonged            |
| Test species| I. punctatus | O. mykiss | D. magna | D. magna | C. riparius |
| Endpoint    | LC50 | NOEC          | EC50  | NOEC                 | NOEC |
| [µg a.s./L] | 19   | 3.2           | 150   | 1.5                  | 13.3 |
| AF          | 100  | 10            | 100   | 10                   | 10 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* not calculated
### Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in grapes considering risk mitigation measures

| Group     | Fish | Invertebrates | Sed. dwell. prolonged |
|-----------|------|---------------|----------------------|
|           | Acute| Chronic       | Acute               | Prolonged   |                        |
| RAC [µg a.s./L] | 0.19 | 0.32         | 1.5                 | 0.15        | 1.33                   |
| FOCUS Scenario | PECSW [µg a.s./L] |                       |                      |             |                        |
| Step 4 (late) | 20 m buffer zone with vegetated filter strip |               |                      |             |                        |
| D6/ditch  | 0.443| 2.33         | 1.384               | 0.295       | 2.95        | 0.333                  |
| R1/pond   | 0.068| 0.358        | 0.213               | 0.045       | 0.453       | 0.051                  |
| R1/stream  | 0.046| 0.242        | 0.144               | 0.031       | 0.307       | 0.035                  |
| R2/stream  | 0.061| 0.321        | 0.191               | 0.041       | 0.407       | 0.046                  |
| R3/stream  | 1.68 | 8.84         | 5.250               | 1.12        | 11.2        | 1.26                   |
| R4/stream  | 0.199| 1.05         | 0.622               | 0.133       | 1.33        | 0.150                  |

**AF**: Assessment factor; **PEC**: Predicted environmental concentration; **RAC**: Regulatory acceptable concentration; **PEC/RAC** ratios above the relevant trigger of 1 are shown in bold

**Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in grapes considering risk mitigation measures**

| Group     | Fish | Invertebrates |
|-----------|------|---------------|
|           | Acute| Prolonged     |
| Test species | 5 species | D. magna     |
| Endpoint   | Geomean LC50 | Higher tier EC10 |
| [µg a.s./L] | 441  | 14.9          |
| AF         | 100  | 10            |
| RAC [µg a.s./L] | 4.41 | 1.49          |
| FOCUS Scenario | PECSW [µg a.s./L] |                   |
| Step 4 (late) | 20 m buffer zone with vegetated filter strip |               |
| D6/ditch  | 0.443| 0.100         | 0.297               |
| R1/pond   | 0.068| 0.015         | 0.046               |
| R1/stream  | 0.046| 0.010         | 0.031               |
| R2/stream  | 0.061| 0.014         | 0.041               |
### PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in beans (multiple applications)

| Group      | Fish       | Invertebrates | Algae       | Sed. dwell. prolonged |
|------------|------------|---------------|-------------|-----------------------|
|            | Acute      | Chronic       | Acute       | Prolonged             |
| Test species |           |               |             |                       |
|             | I. punctatus | O. mykiss | D. magna | D. magna | P. subcapitata | C. riparius |
| Endpoint [µg a.s./L] | LC50 | NOEC | EC50 | NOEC | ErC50 | NOEC |
|             | 19 | 3.2 | 150 | 1.5 | > 11000 | 13.3 |
| AF         | 100 | 10  | 100 | 10   | 100   | 100 |
| RAC [µg a.s./L] | 0.19 | 0.32 | 1.5 | 0.15 | 1100 | 1.33 |
| FOCUS Scenario | PECSW [µg a.s./L] | | | | | |
| Step 1     | n.c. *     | -           | -           | - | - | - |
| Step 2     | n.c. *     | -           | -           | - | - | - |
| Step 3     | D2/ditch   | 15.92      | 83.8        | 49.750 | 10.6 | 106 | 0.014 | 12.0 |
|            | D2/stream   | 11.8       | 62.1        | 36.875 | 7.87 | 78.7 | 0.011 | 8.87 |
|            | D3/ditch   | 0.299      | 1.57        | 0.934  | 0.199 | 1.99 | 0.000 | 0.225 |
|            | D4/pond    | 0.174      | 0.916       | 0.544  | 0.116 | 1.16 | 0.000 | 0.131 |
|            | D4/stream   | 0.197      | 1.04        | 0.616  | 0.131 | 1.31 | 0.000 | 0.148 |
|            | D6/ditch, 1st | 0.555 | 2.92        | 1.734  | 0.370 | 3.70 | 0.001 | 0.417 |
|            | R1/pond    | 0.771      | 4.06        | 2.409  | 0.514 | 5.14 | 0.001 | 0.580 |
|            | R1/stream   | 4.288      | 22.6        | 13.400 | 2.86 | 28.6 | 0.004 | 3.22 |
Refined PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Step 4 calculations for the use of Topsin M 500 SC in beans (multiple applications)

| Group       | Test species | Fish          | Invertebrates          | Algae | Sed. dwell. prolonged |
|-------------|--------------|---------------|------------------------|-------|-----------------------|
|             |              | Acute | Chronic | Acute | Prolonged |                 |                     |                     |
| R2/stream   | I. punctatus | 0.31  | 1.63    | 0.969 | 0.207     | 2.07          | 0.000               | 0.233               |
| R3/stream   | O. mykiss    | 6.847 | 36.0    | 21.397| 4.56      | 45.6          | 0.006               | 5.15                |
| R4/stream   | D. magna     | 6.992 | 36.8    | 21.850| 4.66      | 46.6          | 0.006               | 5.26                |
| D6/ditch, 2nd | D. magna   | 0.371 | 1.95    | 1.159 | 0.247     | 2.47          | 0.000               | 0.279               |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* not calculated
### Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in beans considering risk mitigation measures

| Group | Fish | Invertebrates |
|-------|------|--------------|
|       | Acute | Chronic | Acute | Prolonged | Sed. dwell. prolonged |
| R2/stream | 0.074 | 0.389 | 0.231 | 0.049 | 0.493 | 0.056 |
| R3/stream | 1.631 | 8.58 | 5.097 | 1.09 | 10.9 | 1.23 |
| R4/stream | 1.657 | 8.72 | 5.178 | 1.10 | 11.0 | 1.25 |
| D6/ditch, 2nd | 0.371 | 1.95 | 1.159 | 0.247 | 2.47 | 0.279 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
### PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in cereals (early)

| Group       | Fish          | Invertebrates | Algae       | Sed. dwell. prolonged |
|-------------|---------------|---------------|-------------|-----------------------|
|             | Acute         | Chronic       | Acute       | Prolonged             |
| Test species|               |               |             |                       |
| Endpoint    |               |               |             |                       |
| [µg a.s./L] |               |               |             |                       |
| AF          |               |               |             |                       |
| RAC [µg a.s./L] |         |               |             |                       |
| FOCUS Scenario|             |               |             |                       |
| Step 1      |               |               |             |                       |
| Step 2      |               |               |             |                       |
| Step 3      |               |               |             |                       |

| Group          | Fish       | Invertebrates | Algae     | Sed. dwell. prolonged |
|----------------|------------|---------------|-----------|-----------------------|
|                | Acute      | Chronic       | Prolonged |                       |
| R3/stream      | 1.631      | 0.370         | 1.095     |                       |
| R4/stream      | 1.657      | 0.376         | 1.112     |                       |
| D6/ditch, 2nd | 0.371      | 0.084         | 0.249     |                       |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
### Refined PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Step 4 calculations for the use of Topsin M 500 SC in cereals (early)

| Group          | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------|------|---------------|-------|-----------------------|
|               |      | Acute         | Chronic | Acute | Prolonged |                |                |
|               |      |               |        |       |           |                |                |
| Test species  |      | Acute         | Chronic | Acute | Prolonged |                |                |
| Endpoint      |      |               |        |       |           |                |                |
| [µg a.s./L]   |      |   I. punctatus | O. mykiss | D. magna | D. magna | C. riparius |                |
|               |      |   LC50        | NOEC   | EC50   | NOEC      | NOEC          |                |
|               |      |  19           | 3.2    | 150    | 1.5       | 13.3          |                |
| AF            | 100  | 10            | 100    | 10     | 10        | 10            |                |
| RAC [µg a.s./L]| 0.19 | 0.32          | 1.5    | 0.15   | 1.33      |                |                |
| FOCUS Scenario|     | PECSW         |        |        |           |                |                |
|               |      | [µg a.s./L]   |        |        |           |                |                |
| Step 4        |      |              |        |        |           |                |                |
| D1/ditch      | 0.556 | 2.93 | 1.738 | 0.371 | 3.71 | 0.418 |
| D1/stream     | 0.365 | 1.92 | 1.141 | 0.243 | 2.43 | 0.274 |
| D2/ditch      | 4.367 | 23.0 | 13.647 | 2.91 | 29.1 | 3.28 |
| D2/stream     | 9.168 | 48.3 | 28.650 | 6.11 | 61.1 | 6.89 |
| D3/ditch      | 0.016 | 0.084 | 0.050 | 0.011 | 0.107 | 0.012 |
| D4/pond       | 0.034 | 0.179 | 0.106 | 0.023 | 0.227 | 0.026 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* not calculated

Refined PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Step 4 calculations for the use of Topsin M 500 SC in cereals (early)

| Group          | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------|------|---------------|-------|-----------------------|
|               |      | Acute         | Chronic | Acute | Prolonged |                |                |
|               |      |               |        |       |           |                |                |
| Test species  |      | Acute         | Chronic | Acute | Prolonged |                |                |
| Endpoint      |      |               |        |       |           |                |                |
| [µg a.s./L]   |      |   I. punctatus | O. mykiss | D. magna | D. magna | C. riparius |                |
|               |      |   LC50        | NOEC   | EC50   | NOEC      | NOEC          |                |
|               |      |  19           | 3.2    | 150    | 1.5       | 13.3          |                |
| AF            | 100  | 10            | 100    | 10     | 10        | 10            |                |
| RAC [µg a.s./L]| 0.19 | 0.32          | 1.5    | 0.15   | 1.33      |                |                |
| FOCUS Scenario|     | PECSW         |        |        |           |                |                |
|               |      | [µg a.s./L]   |        |        |           |                |                |
| Step 4        |      |              |        |        |           |                |                |
| D1/ditch      | 0.556 | 2.93 | 1.738 | 0.371 | 3.71 | 0.418 |
| D1/stream     | 0.365 | 1.92 | 1.141 | 0.243 | 2.43 | 0.274 |
| D2/ditch      | 4.367 | 23.0 | 13.647 | 2.91 | 29.1 | 3.28 |
| D2/stream     | 9.168 | 48.3 | 28.650 | 6.11 | 61.1 | 6.89 |
| D3/ditch      | 0.016 | 0.084 | 0.050 | 0.011 | 0.107 | 0.012 |
| D4/pond       | 0.034 | 0.179 | 0.106 | 0.023 | 0.227 | 0.026 |
### Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in cereals considering risk mitigation measures

| Group          | Fish | Invertebrates |
|----------------|------|---------------|
|                | Acute| Chronic       | Acute| Prolonged |
| D4/stream      | 0.039| 0.205         | 0.122| 0.026 | 0.260 | 0.029 |
| D5/pond        | 0.034| 0.179         | 0.106| 0.023 | 0.227 | 0.026 |
| D5/stream      | 0.026| 0.137         | 0.081| 0.017 | 0.173 | 0.020 |
| D6/ditch       | 0.031| 0.163         | 0.097| 0.021 | 0.207 | 0.023 |
| R1/pond        | 0.036| 0.189         | 0.113| 0.024 | 0.240 | 0.027 |
| R1/stream      | 0.302| 1.59          | 0.944| 0.201 | 2.01 | 0.227 |
| R3/stream      | 0.676| 3.56          | 2.113| 0.451 | 4.51 | 0.508 |
| R4/stream      | 0.9  | 4.74          | 2.813| 0.600 | 6.00 | 0.677 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in cereals considering risk mitigation measures

| Group          | Fish | Invertebrates |
|----------------|------|---------------|
|                | Acute| Prolonged |
| Test species   | 5 species | D. magna |
| Endpoint       | Geomean LC50 | Higher tier NOEC |
| [µg a.s./L]    | 441 | 14.9 |
| AF             | 100 | 10 |
| RAC [µg a.s./L]| 4.41| 1.49 |
| FOCUS Scenario | PECSW [µg a.s./L]| |
| Step 4 (early) | 20 m buffer zone with vegetated filter strip | |
| D1/ditch       | 0.556 | 0.126 | 0.373 |
| D1/stream      | 0.365 | 0.083 | 0.245 |
| D2/ditch       | 4.367 | 0.990 | 2.931 |
| D2/stream      | 9.168 | 2.08 | 6.153 |
| D3/ditch       | 0.016 | 0.004 | 0.011 |
Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

| Group     | Fish       | Invertebrates |   |
|-----------|------------|---------------|---|
|           | Acute      | Prolonged     |   |
| D4/pond   | 0.034      | 0.008         | 0.023 |
| D4/stream | 0.039      | 0.009         | 0.026 |
| D5/pond   | 0.034      | 0.008         | 0.023 |
| D5/stream | 0.026      | 0.006         | 0.017 |
| D6/ditch  | 0.031      | 0.007         | 0.021 |
| R1/pond   | 0.036      | 0.008         | 0.024 |
| R1/stream | 0.302      | 0.068         | 0.203 |
| R3/stream | 0.676      | 0.153         | 0.454 |
| R4/stream | 0.900      | 0.204         | 0.604 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Tonsin M 500 SC in leek (10 cm soil incorporation)

| Group     | Fish               | Invertebrates | Algae          | Sed. dwell. prolonged |
|-----------|--------------------|---------------|----------------|----------------------|
|           | Test species       |               | Endpoint       |                      |
|           |                    |               |                |                      |
|           |                    |               | LC50           | NOEC                 |
|           |                    |               | EC50           | NOEC                 |
|           |                    |               | ErC50          | NOEC                 |
|           | [µg a.s./L]        |               |                |                      |
|           | 19                 | 3.2           | 150            | 1.5                  |
|           | 100                | 10            | 100            | 10                   |
|           | 0.19               | 0.32          | 1.5            | 0.15                 |
|           | 1100               | 1.33          |                |                      |
| Step 1    | n.c. *             | -             | -              | -                    |
| Step 2    | n.c. *             | -             | -              | -                    |
| Step 3    | n.c. *             | -             | -              | -                    |
| D3/ditch  | 0.000              | 0.000         | 0.000          | 0.000                |

| Group     | Fish       | Invertebrates |   |
|-----------|------------|---------------|---|
|           | Acute      | Prolonged     |   |
| D4/pond   | 0.034      | 0.008         | 0.023 |
| D4/stream | 0.039      | 0.009         | 0.026 |
| D5/pond   | 0.034      | 0.008         | 0.023 |
| D5/stream | 0.026      | 0.006         | 0.017 |
| D6/ditch  | 0.031      | 0.007         | 0.021 |
| R1/pond   | 0.036      | 0.008         | 0.024 |
| R1/stream | 0.302      | 0.068         | 0.203 |
| R3/stream | 0.676      | 0.153         | 0.454 |
| R4/stream | 0.900      | 0.204         | 0.604 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
**Peer review of the pesticide risk assessment of the active substance thiophanate-methyl**

| Group         | Fish          | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------|---------------|---------------|-------|-----------------------|
|               | Acute         | Chronic       |       |                       |
|               |               |               |       |                       |
| D4/pond       | 0.009         | 0.028         | 0.006 | 0.000                 |
| D4/stream     | 0.015         | 0.047         | 0.010 | 0.000                 |
| D6/ditch, 1st | 0.001         | 0.003         | 0.001 | 0.000                 |
| D6/ditch, 2nd | 0.303         | 1.59          | 0.202 | 0.000                 |
| R1/pond       | 0.01          | 0.031         | 0.007 | 0.000                 |
| R1/stream     | 0.318         | 0.994         | 0.212 | 0.000                 |
| R2/stream     | 0.276         | 0.863         | 0.184 | 0.000                 |
| R3/stream     | 0.738         | 2.306         | 0.492 | 0.001                 |
| R4/stream     | 0.855         | 4.50          | 0.570 | 0.001                 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* not calculated

Refined PEC/RAC ratios for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in leek (10 cm soil incorporation) considering risk mitigation measures

| Group         | Fish          | Invertebrates |
|---------------|---------------|---------------|
|               | Acute         | Prolonged     |
|               |               |               |
| Test species  | *I. punctatus*| *D. magna*    |
| Endpoint      | LC50          | NOEC          |
| [µg a.s./L]   | 19            | 1.5           |
| AF            | 100           | 10            |
| RAC [µg a.s./L] | 0.91         | 0.15          |
| FOCUS Scenario | PECSW [µg a.s./L] |       |
| Step 4        | 20 m buffer zone with vegetated filter strip |       |
| D3/ditch      | 0.000         | 0.000         |
| D4/pond       | 0.009         | 0.047         |
| D4/stream     | 0.015         | 0.079         |
| Group          | Fish Acute | Invertebrates Prolonged |
|---------------|------------|------------------------|
| D6/ditch, 1st | 0.001      | 0.005                  |
| D6/ditch, 2nd | 0.303      | 1.59                   |
| R1/pond       | 0.002      | 0.011                  |
| R1/stream      | 0.068      | 0.358                  |
| R2/stream      | 0.064      | 0.337                  |
| R3/stream      | 0.172      | 0.905                  |
| R4/stream      | 0.203      | 1.07                   |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in leek (10 cm soil incorporation) considering risk mitigation measures:

| Test substance | Species           | RAC [µg/L] | FOCUS scenario | vegetated buffer zone [m] | Initial FOCUS Step 4 PECsw [µg/L] | PEC/RAC ratio ** |
|----------------|-------------------|------------|----------------|---------------------------|----------------------------------|-----------------|
| Carbendazim    | Fish, acute       | 4.41       | D6 ditch, 2nd  | 20                        | 0.303                            | 0.069           |
|                |                   |            | R4 stream      |                           | 0.388                            | 0.088           |
|                | Daphnids, chronic | 1.49       | D6 ditch, 2nd  | 20                        | 0.303                            | 0.203           |
|                |                   |            | R3 stream      |                           | 0.331                            | 0.222           |
|                |                   |            | R4 stream      |                           | 0.388                            | 0.260           |

* including vegetated filter strip
** ratios calculated with unrounded PECsw values as presented in CP 9.2.5

Values in bold are above the trigger of 1

PEC/RAC ratios for Carbendazim for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Topsin M 500 SC in tomato / aubergine (multiple applications):

| Group          | Fish Acute | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------|------------|---------------|-------|-----------------------|
| Test species  | I. punctatus | O. mykiss     | D. magna | P. subcapitata          |
| Endpoint      | LC50       | NOEC          | EC50  | ErC50                 |
| [µg a.s./L]   | 19         | 3.2           | 150   | > 11000               |
| AF            | 100        | 10            | 100   | 10                    |

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### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
|       | Acute | Chronic | Acute | Prolonged |
| RAC [µg a.s./L] | 0.19 | 0.32 | 1.5 | 0.15 |
| FOCUS Scenario | PECSW [µg a.s./L] | n.c.* | - | - |
| Step 1 | n.c.* | - | - | - |
| Step 2 | n.c.* | - | - | - |
| Step 3 | Late applications ** | | | |
| D6/ditch | 0.005 | 0.026 | 0.016 | 0.003 | 0.033 | 0.000 | 0.004 |
| R2/stream | 5.95 | 31.3 | 18.594 | 3.97 | 39.7 | 0.005 | 4.47 |
| R3/stream | 12.35 | 65.0 | 38.594 | 8.23 | 82.3 | 0.011 | 9.29 |
| R4/stream | 15.67 | 82.5 | 48.969 | 10.4 | 104 | 0.014 | 11.8 |

**AF:** Assessment factor; **PEC:** Predicted environmental concentration; **RAC:** Regulatory acceptable concentration; **PEC/RAC** ratios above the relevant trigger of 1 are shown in bold

* not calculated

** calculated for greenhouse use, covering field use

### Higher tier risk assessment for fish and daphnids based on initial FOCUS Step 4 PECsw values for Carbendazim for the use in tomato/aubergine (late) considering risk mitigation measures

| Group | Fish | Invertebrates |
|-------|------|---------------|
|       | Acute | Prolonged |
| Test species | 5 species | D. magna |
| Endpoint | Geomean LC50 | Higher tier NOEC |
| [µg a.s./L] | 441 | 14.9 |
| AF | 100 | 10 |
| RAC [µg a.s./L] | 4.41 | 1.49 |
| FOCUS Scenario | PECSW [µg a.s./L] | |
| Step 4 (late) | 20 m buffer zone with vegetated filter strip | |
| D6/ditch | 0.005 | 0.001 | 0.003 |
| R2/stream | 1.395 | 0.316 | 0.936 |
Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

| Group   | Fish (Acute)  | Invertebrates (Prolonged) |
|---------|---------------|---------------------------|
| R3/stream | 2.954         | 1.983                     |
| R4/stream | 3.735         | 2.507                     |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* greenhouse application, covering field application
** field application, covering greenhouse application

### 4-OH-TM

PEC/RAC ratios for 4-OH-TM for each organism group based on FOCUS Steps 1 and 2 calculations for the uses of Topsin M 500 SC

| Group     | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-----------|------|---------------|-------|-----------------------|
| Test species |      |               |       |                       |
| Endpoint  |      |               |       |                       |
|          | Acute | Chronic       | Acute | Chronic               |
|          | O. mykiss | O. mykiss | D. magna | D. magna |
|          | LC50   | EC10 *        | EC50  | NOEC                  |
|          | > 10000 | 39*           | >17600 | 16*                   |
|          | 100    | 10            | 100   | 10                    |
|          | >100   | 3.9           | 176   | 1.6                   |
|          | 1500   |               |       |                       |
|          | 146    |               |       |                       |
|          | 4.4    |               |       |                       |
| FOCUS Scenario | PECSW [µg a.s./L] |       |       |                       |
| Step 1   |      |               |       |                       |
| Beans    | 51.097 | 0.511         | 13.10 | 0.290                 |
| Grapes   | 39.392 | 0.394         | 10.10 | 0.224                 |
| Leek     | 137.572 | 1.376       | 35.27 | 0.782                 |
| Tomato / aubergine | 228.734 ** | 2.287    | 58.65 | 1.300                 |
| Cereals  | 25.548 | 0.255         | 6.55  | 0.145                 |
| Step 2   |      |               |       |                       |
| Beans    | 1.180 *** | 0.012      | 0.30  | 0.007                 |
| Grapes   | 3.118 *** | 0.031      | 0.80  | 0.018                 |
| Cereals  | 0.857 *** | 0.009      | 0.22  | 0.005                 |
### DX-105

PEC/RAC ratios for DX-105 for each organism group based on FOCUS Steps 1 and 2 calculations for the uses of Topsin M 500 SC

| Group                | Fish Acute | Fish Chronic | Invertebrates Acute | Invertebrates Chronic | Algae Acute | Algae Chronic | Sed. dwell. prolonged Acute | Sed. dwell. prolonged Chronic |
|----------------------|------------|--------------|---------------------|----------------------|-------------|---------------|-----------------------------|-------------------------------|
| Leek                 | 4.306 ***  | 0.043 1.10   | 0.024 2.69          | 0.003                | 0.029       | 0.98          |
| Tomato / aubergine   | 2.394 ***  | 0.024 0.61   | 0.014 1.50          | 0.002                | 0.016       | 0.54          |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* as for Thiophanate-methyl divided by 10
** worst-case for greenhouse use
*** Worst-case for N-Europe, October – February
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

**Group** | **Fish** | **Invertebrates** | **Algae** | **Sed. dwell. prolonged**
---|---|---|---|---
Leek | 35.192 | 9.02 | 8.00 | 21.86 | 14.663 | 8.00
Tomato / aubergine | 52.018 | 13.34 | 11.82 | 32.31 | 21.674 | 1.182

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoints as for Thiophanate-methyl divided by 10
** worst-case for greenhouse use
*** Worst-case for N-Europe, October – February

### PEC/RAC ratios for DX-105 for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in grapes (late applications)

**Group** | **Fish** | **Invertebrates** | **Algae** | **Sed. dwell. prolonged**
---|---|---|---|---
Test species | O. mykiss | O. mykiss | D. magna | D. magna | P. subcapitata | C. riparius
Endpoint | LC50 | EC10 * | EC50 | NOEC | ErC50 | NOEC
[μg a.s./L] | 1100* | 39* | 440 * | 16 * | 24 | 44*
AF | 100 | 10 | 100 | 10 | 10 | 10
RAC [μg a.s./L] | 11 | 3.9 | 4.4 | 1.61 | 2.40 | 4.4
FOCUS Scenario | PECSW [μg a.s./L] | | | | |
Step 3 | | | | | |
D6/ditch | 1.944 | 0.177 | 0.498 | 0.442 | 1.215 | 0.810 | 0.442
R1/pond | 0.1 | 0.009 | 0.026 | 0.023 | 0.063 | 0.042 | 0.023
R1/stream | 0.233 | 0.021 | 0.060 | 0.053 | 0.146 | 0.097 | 0.053
R2/stream | 0.304 | 0.028 | 0.078 | 0.069 | 0.190 | 0.127 | 0.069
R3/stream | 2.985 | 0.271 | 0.765 | 0.678 | **1.866** | 1.244 | 0.678
R4/stream | 0.723 | 0.066 | 0.185 | 0.164 | 0.452 | 0.301 | 0.164

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoints as for Thiophanate-methyl divided by 10
### PEC/RAC ratios for DX-105 for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in beans (multiple applications)

| Group                      | Fish         | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------------------|--------------|---------------|-------|-----------------------|
|                            | Acute        | Chronic       | Acute | Chronic               |
| Test species               | O. mykiss    | O. mykiss     | D. magna | D. magna | P. subcapitata | C. riparius |
| Endpoint                   | LC50         | EC10 *        | EC50  | NOEC                 | ErC50 | NOEC |
| [µg a.s./L]                | 1100 *       | 39 *          | 440 * | 16 *                 | 24    | 44*  |
| AF                        | 100          | 10            | 100   | 10                   | 10    | 10   |
| RAC [µg a.s./L]            | 11           | 3.9           | 4.4   | 1.6                  | 2.40  | 4.4  |
| FOCUS Scenario            | PECSW [µg a.s./L] |         |       |                      |       |      |
| Step 3                     |              |               |       |                      |       |      |
| D2/ditch                  | 10.13        | 0.921         | 2.597 | 2.302                | 6.331 | 4.221 | 2.302 |
| D2/stream                  | 6.35         | 0.577         | 1.628 | 1.443                | 3.969 | 2.646 | 1.443 |
| D3/ditch                  | 0.136        | 0.012         | 0.035 | 0.031                | 0.085 | 0.057 | 0.031 |
| D4/pond                   | 1.662        | 0.151         | 0.426 | 0.378                | 1.039 | 0.693 | 0.378 |
| D4/stream                  | 1.683        | 0.153         | 0.432 | 0.383                | 1.052 | 0.701 | 0.383 |
| D6/ditch, 1st             | 2.003        | 0.182         | 0.514 | 0.455                | 1.252 | 0.835 | 0.455 |
| D6/ditch, 2nd             | 2.957        | 0.269         | 0.758 | 0.672                | 1.848 | 1.232 | 0.672 |
| R1/pond                   | 0.372        | 0.034         | 0.095 | 0.085                | 0.233 | 0.155 | 0.085 |
| R1/stream                  | 1.864        | 0.169         | 0.478 | 0.424                | 1.165 | 0.777 | 0.424 |
| R2/stream                  | 0.587        | 0.053         | 0.151 | 0.133                | 0.367 | 0.245 | 0.133 |
| R3/stream                  | 3.186        | 0.290         | 0.817 | 0.724                | 1.991 | 1.328 | 0.724 |
| R4/stream                  | 3.232        | 0.294         | 0.829 | 0.735                | 2.020 | 1.347 | 0.735 |
| Step 4, 20 m buffer       |             |               |       |                      |       |      |      |
| D2/ditch                  | 10.13        | 0.921         | 2.597 | 2.302                | 6.331 | 4.221 | 2.302 |
| D2/stream                  | 6.350        | 0.577         | 1.628 | 1.443                | 3.969 | 2.646 | 1.443 |
| D3/ditch                  | 0.011        | 0.001         | 0.003 | 0.003                | 0.007 | 0.005 | 0.003 |
| D4/pond                   | 1.655        | 0.150         | 0.424 | 0.376                | 1.034 | 0.690 | 0.376 |
### PEC/RAC ratios for DX-105 for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in cereals (early applications)

| Group          | Fish | Invertebrates | Algae          | Sed. dwell. prolonged |
|----------------|------|---------------|----------------|----------------------|
|                |      | Acute         | Chronic        |                      |                      |
|                |      | Acute         | Chronic        |                      |                      |
|                |      | Acute         | Chronic        |                      |                      |
| Test species   |      | O. mykiss     | O. mykiss      | D. magna             | P. subcapitata       |
| Endpoint       |      | LC50          | EC10 *         | EC50                 | ErC50                |
|                |      |               |                | NOEC                 |                      |
| [µg a.s./L]    |      | 1100 *        | 39 *           | 440 *                | 16 *                 |
| AF             | 100  | 10            | 100            | 10                   | 24                   |
| RAC [µg a.s./L]| 11   | 3.9           | 4.4            | 1.6                  | 2.40                 |
| FOCUS Scenario | PECSW [µg a.s./L] |               |                |                      |
| Step 3         |      |               |                |                      |
| D1/ditch       | 2.429| 0.221         | 0.623          | 0.552                | 1.518                |
|                |      |               |                |                      | 1.012                |
| D1/stream      | 1.515| 0.138         | 0.388          | 0.344                | 0.947                |
| D2/ditch       | 5.382| 0.489         | 1.380          | 1.223                | 3.364                |
| D2/stream      | 5.097| 0.463         | 1.307          | 1.158                | 3.186                |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* endpoints as for Thiophanate-methyl divided by 10
### PEC/RAC ratios for DX-105 for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in leek (10 cm)

| Group       | Fish               | Invertebrates           | Algae                   | Sed. dwell. prolonged |
|-------------|--------------------|-------------------------|-------------------------|----------------------|
|             | Acute  | Chronic | Acute    | Chronic | Acute | Chronic | Algae | Sed. dwell. prolonged |
| D3/ditch    | 0.097  | 0.009   | 0.025    | 0.022   | 0.061 | 0.040   | 0.022 |
| D4/pond     | 0.782  | 0.071   | 0.201    | 0.178   | 0.489 | 0.326   | 0.178 |
| D4/stream   | 0.765  | 0.070   | 0.196    | 0.174   | 0.478 | 0.319   | 0.174 |
| D5/pond     | 0.813  | 0.074   | 0.208    | 0.185   | 0.508 | 0.339   | 0.185 |
| D5/stream   | 0.589  | 0.054   | 0.151    | 0.134   | 0.368 | 0.245   | 0.134 |
| D6/ditch    | 0.574  | 0.052   | 0.147    | 0.130   | 0.359 | 0.239   | 0.130 |
| R1/pond     | 0.068  | 0.006   | 0.017    | 0.015   | 0.043 | 0.028   | 0.015 |
| R1/stream   | 0.575  | 0.052   | 0.147    | 0.131   | 0.359 | 0.240   | 0.131 |
| R3/stream   | 1.221  | 0.111   | 0.313    | 0.278   | 0.763 | 0.509   | 0.278 |
| R4/stream   | 1.638  | 0.149   | 0.420    | 0.372   | 1.024 | 0.683   | 0.372 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as for Thiophanate-methyl
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

| Group               | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------------|------|---------------|-------|-----------------------|
|                     | Acute| Chronic       |       |                       |
|                     |      |               |       |                       |
| D6/ditch 1st        | 0.715| 0.183         | 0.163 | 0.298                 |
|                     | 0.166| 0.447         | 0.163 |                       |
| D6/ditch 2nd        | 0.829| 0.213         | 0.188 | 0.345                 |
|                     | 0.188| 0.518         | 0.188 |                       |
| R1/pond             | 0.008| 0.002         | 0.002 | 0.003                 |
|                     | 0.002| 0.005         | 0.002 |                       |
| R1/stream            | 0.11 | 0.028         | 0.025 | 0.046                 |
|                     | 0.025| 0.069         | 0.046 |                       |
| R2/stream            | 0.071| 0.018         | 0.016 | 0.030                 |
|                     | 0.016| 0.044         | 0.030 |                       |
| R3/stream            | 0.27 | 0.069         | 0.061 | 0.113                 |
|                     | 0.061| 0.169         | 0.113 |                       |
| R4/stream            | 0.318| 0.082         | 0.072 | 0.133                 |
|                     | 0.072| 0.199         | 0.133 |                       |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as for Thiophanate-methyl

### PEC/RAC ratios for DX-105 for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in tomato / aubergine (late; greenhouse use covering field use)

| Group               | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------------|------|---------------|-------|-----------------------|
|                     | Acute| Chronic       |       |                       |
|                     |      |               |       |                       |
| Test species Endpoint |      |              |       |                       |
|                     |      |              |       |                       |
| FOCUS Scenario      |      |              |       |                       |
|                     |      |              |       |                       |
| Step 3              |      |              |       |                       |
|                     |      |              |       |                       |
| D6/ditch            | 0.731| 0.187         | 0.166 | 0.305                 |
|                     | 0.166| 0.457         | 0.305 |                       |
| R2/stream            | 3.466| 0.889         | 0.788 | 1.444                 |
|                     | 0.788| 2.166         | 1.444 |                       |
| R3/stream            | 6.402| 1.642         | 1.455 | 2.668                 |
|                     | 1.455| 4.001         | 2.668 |                       |
| R4/stream            | 7.135| 1.829         | 1.622 | 2.973                 |
|                     | 1.829| 4.459         | 2.973 |                       |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as for Thiophanate-methyl
### UM-2 (M10)

PEC/RAC ratios for UM-2 (M10) for each organism group based on FOCUS Steps 1 and 2 calculations for the uses of Topsin M 500 SC:

| Group            | Test species | Endpoint | Invertebrates | Algae | Sed. dwell. prolonged |
|------------------|--------------|----------|---------------|-------|-----------------------|
|                  |              | LC50     | Acute         | EC50  | NOEC                  |
|                  |              |          | Chronic       |       |                       |
|                  |              | EC10 *   |               |       |                       |
|                  |              |          | Acute         | EC50  | ErC50                 |
|                  |              |          | Chronic       |       | NOEC                  |
|                  |              |          |               |       |                       |
| Fish             | O. mykiss    | 1100 *   | 440 *         | 16 *  | 523                   |
| Invertebrates    | O. mykiss    | 39 *     | 100           | 10    | 10                    |
|                  | D. magna     | 440 *    | 100           | 10    | 10                    |
|                  | D. magna     | 16 *     | 10            | 10    | 10                    |
|                  | P. subcapitata| 523      | 10            | 10    | 10                    |
|                  | C. riparius  | 44 *     | 10            | 10    | 10                    |
| AF               |              | 100      | 10            | 10    | 10                    |
| RAC [µg a.s./L]  |              | 11       | 4.4           | 52.3  | 4.4                   |
| FOCUS Scenario   |              | PECSW [µg a.s./L] | | | |
| Step 1           |              |          |               |       |                       |
| Beans            | 28.216       | 2.57     | 7.23          | 6.41  | 5.40                  |
| Grapes           | 21.753       | 1.98     | 5.58          | 4.94  | 4.16                  |
| Leek             | 75.970       | 6.91     | 19.48         | 17.53 | 14.53                 |
| Tomato / aubergine | 126.311 ** | 11.48    | 32.39         | 28.71 | 24.15                 |
| Cereals          | 14.108       | 1.28     | 3.62          | 3.21  | 2.70                  |
| Step 2 ***       |              |          |               |       |                       |
| Beans            | 0.793        | 0.07     | 0.20          | 0.18  | 0.15                  |
| Grapes           | 1.864        | 0.17     | 0.48          | 0.42  | 0.36                  |
| Cereals          | 0.507        | 0.05     | 0.13          | 0.12  | 0.10                  |
| Leek             | 2.378        | 0.22     | 0.61          | 0.54  | 0.45                  |
| Tomato / aubergine | 1.322       | 0.12     | 0.34          | 0.30  | 0.25                  |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* as for Thiophanate-methyl divided by 10

** worst-case for greenhouse use

*** Worst-case for N-Europe, October – February
### 2-AB

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Steps 1 and 2 calculations for the uses of Topsin M 500 SC

| Group                | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------------|------|---------------|-------|-----------------------|
|                      | Acute | Chronic       | Acute | Chronic               |
| Test species         |       |               |       |                       |
| O. mykiss            | LC50  | NOEC          | EC50  | NOEC                  |
|                      | 19 *  | 3.2 *         | 150 * | 1.5 *                 |
|                      | 100   | 10            | 100   | 10                    |
| Endpoints            |       |               |       |                       |
| Endpoint             |       |               |       |                       |
| [µg a.s./L]          |       |               |       |                       |
| AF                   | 0.19  | 0.32          | 1.50  | 0.15                  |
| RAC [µg a.s./L]      |       |               |       |                       |
| FOCUS Scenario       | PECSW [µg a.s./L] | |   |                       |
| Step 1               |       |               |       |                       |
| Beans                | 25.103 | 132.121       | 78.447 | 16.735 | 167.353 | 0.719 | 18.874 |
| Grapes               | 19.123 | 100.647       | 59.759 | 12.749 | 127.487 | 0.548 | 14.378 |
| Leek                 | 68.042 | 358.116       | 212.631 | 45.361 | 453.613 | 1.950 | 51.159 |
| Tomato / aubergine   | 113.130** | 595.421      | 353.531 | 75.420 | 754.200 | 3.242 | 85.060 |
| Cereals              | 12.552 | 66.063        | 39.225 | 8.368 | 83.680 | 0.360 | 9.438 |
| Step 2               |       |               |       |                       |
| Beans                | 1.015  | 5.342         | 3.172  | 0.677 | 6.767 | 0.029 | 0.763 |
| Grapes               | 1.979  | 10.416        | 6.184  | 1.319 | 13.193 | 0.057 | 1.488 |
| Cereals              | 0.755  | 3.974         | 2.359  | 0.503 | 5.033 | 0.022 | 0.568 |
| Leek                 | 9.921  | 52.216        | 31.003 | 6.614 | 66.140 | 0.284 | 7.459 |
| Tomato / aubergine   | 5.691  | 29.953        | 17.784 | 3.794 | 37.940 | 0.163 | 4.279 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim
** worst-case for greenhouse use
*** Worst-case for N-Europe, October – February

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in grapes

| Group                | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------------|------|---------------|-------|-----------------------|
|                      |      |               |       |                       |
|                      |      |               |       |                       |
|                      |      |               |       |                       |
| Test species | Endpoint | [µg a.s./L] | AF | RAC [µg a.s./L] | FOCUS Scenario | PECSW [µg a.s./L] |
|--------------|----------|-------------|----|---------------|---------------|-----------------|
| Fish         | Acute    | Chronic     | Invertebrates | Acute | Chronic | Algae | Sed. dwell. prolonged |
|              | O. mykiss| O. mykiss | D. magna | D. magna | P. subcapitata | C. riparius     |
|              | LC50     | NOEC       | EC50    | NOEC    | ErC50       | NOEC            |
|              | 19 *     | 3.2 *      | 150 *   | 1.5 *   | 349         | 13.3 *          |
|              | 100      | 10         | 100     | 10      | 10          | 10              |
|              | 0.19     | 0.32       | 1.50    | 0.15    | 34.9        | 1.33            |

**PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Tospin M 500 SC in beans**

| Group          | Fish         | Invertebrates | Algae | Sed. dwell. prolonged |
|----------------|--------------|---------------|-------|-----------------------|
| Test species   | O. mykiss    | D. magna     | P. subcapitata | C. riparius |
| Endpoint       | LC50         | EC50          | ErC50 | NOEC                  |
| [µg a.s./L]    | 19 *         | 150 *         | 349   | 13.3 *                |
| AF             | 100          | 100           | 10    | 10                    |
| RAC [µg a.s./L]| 0.19         | 1.5           | 34.9  | 1.33                  |
| FOCUS Scenario | PECSW [µg a.s./L] |             |       |                       |
| Step 3         |              |               |       |                       |
| Group            | Fish          | Invertebrates     | Algae          | Sed. dwell. prolonged |
|------------------|---------------|-------------------|----------------|----------------------|
|                  | Acute | Chronic | Acute | Chronic |                     |
| D2/ditch         | 5.953 | 31.332 | 18.603 | 3.969 | 39.687 | 0.171 | 4.476 |
| D2/stream        | 4.784 | 25.179 | 14.950 | 3.189 | 31.893 | 0.137 | 3.597 |
| D3/ditch         | 0.053 | 0.279  | 0.166  | 0.035 | 0.353  | 0.002 | 0.040 |
| D4/pond          | 0.018 | 0.095  | 0.056  | 0.012 | 0.120  | 0.001 | 0.014 |
| D4/stream        | 0.024 | 0.126  | 0.075  | 0.016 | 0.160  | 0.001 | 0.018 |
| D6/ditch 1st    | 0.099 | 0.521  | 0.309  | 0.066 | 0.660  | 0.003 | 0.074 |
| D6/ditch 2nd    | 0.059 | 0.311  | 0.184  | 0.039 | 0.393  | 0.002 | 0.044 |
| R1/pond          | 0.049 | 0.258  | 0.153  | 0.033 | 0.327  | 0.001 | 0.037 |
| R1/stream        | 0.082 | 0.432  | 0.256  | 0.055 | 0.547  | 0.002 | 0.062 |
| R2/stream        | 0.105 | 0.553  | 0.328  | 0.070 | 0.700  | 0.003 | 0.079 |
| R3/stream        | 0.179 | 0.942  | 0.559  | 0.119 | 1.193  | 0.005 | 0.135 |
| R4/stream        | 0.094 | 0.495  | 0.294  | 0.063 | 0.627  | 0.003 | 0.071 |
| Step 4, 20 m vegetated buffer zone | | | | | |
| D2/ditch         | 5.953 | 31.332 | 18.603 | 3.969 | 39.687 | 0.171 | 4.476 |
| D2/stream        | 4.784 | 25.179 | 14.950 | 3.189 | 31.893 | 0.137 | 3.597 |
| D3/ditch         | 0.004 | 0.021  | 0.013  | 0.003 | 0.027  | 0.000 | 0.003 |
| D4/pond          | 0.011 | 0.058  | 0.034  | 0.007 | 0.073  | 0.000 | 0.008 |
| D4/stream        | 0.01  | 0.053  | 0.031  | 0.007 | 0.067  | 0.000 | 0.008 |
| D6/ditch 1st    | 0.008 | 0.042  | 0.025  | 0.005 | 0.053  | 0.000 | 0.006 |
| D6/ditch 2nd    | 0.011 | 0.058  | 0.034  | 0.007 | 0.073  | 0.000 | 0.008 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as Carbendazim

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in cereals

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as Carbendazim

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in cereals

| Group            | Fish          | Invertebrates     | Algae          | Sed. dwell. prolonged |
|------------------|---------------|-------------------|----------------|----------------------|
|                  | Acute | Chronic | Acute | Chronic |                     |

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| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
|       |      |               |       |                      |
| Test species |       |               |       |                      |
| Endpoint |       |               |       |                      |
| [µg a.s./L] |       |               |       |                      |
| Acute | O. mykiss | D. magna | P. subcapitata | C. riparius |
| Chronic | O. mykiss | D. magna | ErC50 |                     |
| LC50 | NOEC | EC50 | NOEC | NOEC |
| AF | 100 | 100 | 10 | 10 |
| RAC [µg a.s./L] | 0.19 | 0.32 | 1.50 | 13.3 * |
| FOCUS Scenario | PECSW |       |       |                      |
| [µg a.s./L] |       |       |       |                      |
| Step 3 |       |       |       |                      |
| D1/ditch | 0.29 | 1.526 | 0.906 | 1.933 | 0.008 | 0.218 |
| D1/stream | 0.071 | 0.374 | 0.222 | 0.047 | 0.473 | 0.002 | 0.053 |
| D2/ditch | 0.285 | 1.500 | 0.891 | 0.190 | 1.900 | 0.008 | 0.214 |
| D2/stream | 0.286 | 1.505 | 0.894 | 0.191 | 1.907 | 0.008 | 0.215 |
| D3/ditch | 0.047 | 0.247 | 0.147 | 0.031 | 0.313 | 0.001 | 0.035 |
| D3/stream | 0.058 | 0.034 | 0.073 | 0.000 | 0.008 |
| D4/pond | 0.011 | 0.168 | 0.100 | 0.021 | 0.213 | 0.001 | 0.024 |
| D4/stream | 0.032 | 0.068 | 0.041 | 0.049 | 0.087 | 0.000 | 0.010 |
| D5/pond | 0.032 | 0.242 | 0.144 | 0.031 | 0.307 | 0.001 | 0.035 |
| D5/stream | 0.046 | 0.204 | 1.074 | 0.638 | 1.360 | 0.006 | 0.153 |
| R1/pond | 0.024 | 0.126 | 0.075 | 0.016 | 0.160 | 0.001 | 0.018 |
| R1/stream | 0.096 | 0.505 | 0.300 | 0.064 | 0.640 | 0.003 | 0.072 |
| R3/stream | 0.08 | 0.421 | 0.250 | 0.053 | 0.533 | 0.002 | 0.060 |
| R4/stream | 0.007 | 0.037 | 0.042 | 0.005 | 0.047 | 0.000 | 0.005 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in leek

| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
|       |      |               |       |                      |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Topsin M 500 SC in leek

| Group | Fish | Invertebrates | Algae | Sed. dwell. prolonged |
|-------|------|---------------|-------|----------------------|
|       |      |               |       |                      |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

#### Table 1: Acute and Chronic LC50/EC50/NOEC/ErC50 (µg a.s./L) for different test species

| Test species | Endpoint | LC50 | NOEC | EC50 | NOEC | ErC50 | NOEC |
|--------------|----------|------|------|------|------|-------|------|
| O. mykiss   | Acute    | 19 * | 3.2 *| 150 *| 1.5 *| 349   | 13.3 *|
| D. magna    | Chronic  |      |      |      |      |       |      |
| P. subcapitata |      |      |      |      |      |       |      |
| C. riparius |          |      |      |      |      |       |      |

#### Table 2: FOCUS Scenario PEC/RAC for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Tospin M 500 SC in tomato / aubergine (late, greenhouse covering field use)

| Step 3 | D3/ditch   | D4/pond   | D4/stream | D6/ditch, 1st | D6/ditch, 2nd | R1/pond   | R1/stream | R2/stream | R3/stream | R4/stream |
|--------|------------|-----------|-----------|---------------|---------------|-----------|-----------|-----------|-----------|-----------|
|        | 0.001      | 0.001     | 0.001     | 0.001         | 0.001         | 0.001     | 0.001     | 0.001     | 0.001     | 0.001     |
|        | 0.005      | 0.005     | 0.005     | 0.005         | 0.005         | 0.005     | 0.005     | 0.005     | 0.005     | 0.005     |
|        | 0.003      | 0.003     | 0.003     | 0.003         | 0.003         | 0.003     | 0.003     | 0.003     | 0.003     | 0.003     |
|        | 0.001      | 0.001     | 0.001     | 0.001         | 0.001         | 0.001     | 0.001     | 0.001     | 0.001     | 0.001     |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* same endpoints as Carbendazim

PEC/RAC ratios for 2-AB for each organism group based on FOCUS Step 3 calculations for the use of Tospin M 500 SC in tomato / aubergine (late, greenhouse covering field use)

| Group                  | Fish                  | Acute | Chronic | Invertebrates | Acute | Chronic | Algae | Sed. dwell. prolonged |
|------------------------|-----------------------|-------|---------|---------------|-------|---------|-------|-----------------------|
| Test species           | O. mykiss             | LC50  | NOEC    | D. magna      | EC50  | NOEC    |       | C. riparius           |
| Endpoint               | 19 *                  | 3.2 * | 150 *   | 1.5 *         | 349   |         |       | 13.3 *                |
| [µg a.s./L]            |                       |       |         |               |       |         |       |                       |
| Group          | Fish          | Invertebrates | Algae | Sed. dwell. prolonged |
|---------------|--------------|---------------|-------|----------------------|
|               | Acute        | Chronic       | Acute | Chronic              |
| AF            | 100          | 10            | 100   | 10                   |
| RAC [µg a.s./L] | 0.19         | 0.32          | 1.50  | 0.15                 |
| FOCUS Scenario | PECSW [µg a.s./L] |               |       |                      |
| Step 3        |              |               |       |                      |
| D6/ditch      | 0.001        | 0.005         | 0.003 | 0.001                |
| R2/stream      | 0.72         | 3.789         | 2.250 | 0.480                |
| R3/stream      | 1.124        | 5.916         | 3.513 | 0.749                |
| R4/stream      | 0.829        | 4.363         | 2.591 | 0.553                |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* same endpoints as Carbendazim
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 |
|---------|----------------|-----------------------------|-----------|----------|
| *Apis mellifera* a.s., Thiophanate-methyl | Acute | Oral toxicity (LD$_{50}$) | No data |
| *Apis mellifera* Topsis M 500 SC | Acute | Oral toxicity (LD$_{50}$) | 114.7 μg a.s./bee |
| *Apis mellifera* a.s., Thiophanate-methyl | Acute | Contact toxicity (LD$_{50}$) | >100 μg a.s./bee |
| *Apis mellifera* Topsis M 500 SC | Acute | Contact toxicity (LD$_{50}$) | >100 μg a.s./bee |
| *Apis mellifera* a.s., Thiophanate-methyl | Chronic | 10 d-LC$_{50}$ | >48.3 μg/bee/day |
| *Apis mellifera* Topsis M 500 SC | Chronic | 10 d-LC$_{50}$ | No data |
| *Apis mellifera* a.s., Thiophanate-methyl | Bee brood development | NOEClarvae | No data |
| *Apis mellifera* a.s., Thiophanate-methyl | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | No data |

Potential for accumulative toxicity: no data

Semi-field test (Cage and tunnel test)
Study on the effect of Thiophanate-methyl 500 SC on honey bee brood (*Apis mellifera* L.) under semi-field conditions - tunnel test (Sekine and Eichler 2013). Possible effect on colony strength development at 1500 g a.s./ha, resulting in a NOEC of 750 g a.s./ha.

Field tests
No data

**Risk assessment** for – Grapes at 1100 g a.s./ha [single application]

| Screening step | Test substance | Risk quotient | HQ/ETR | Trigger |
|----------------|----------------|---------------|--------|---------|
| Tier I | a.s., Thiophanate-methyl Topsis M 500 SC | ETRchronic adult oral | Treated crop <0.134 | 0.03 |

*ETRlarvae could not be calculated since the available results were expressed as g a.s./ha instead of the μg a.s./larva per developmental period as needed for the calculation proposed in the EFSA GD 2013. Risk assessment based on brood study by Sekine and Eichler 2013, where no effects were observed at doses up to 750 g a.s./ha. At 1100 g a.s./ha, risk for bees cannot be excluded based on available data.

**Risk assessment** for – Beans at 750 g a.s./ha [two applications]
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

#### Test substance Risk quotient HQ/ETR Trigger

**Screening step**

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|---------|----------------|---------------|--------|---------|
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | HQcontact | 0.21 | 42 |
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | ETRacute adult oral | >0.050 | 0.2 |
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | ETRchronic adult oral | <0.118 | 0.03 |
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | ETRlarvae | Not relevant* | - |
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | ETRhpg | No data | - |

**Tier I**

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|---------|----------------|---------------|--------|---------|
| *Apis mellifera* | a.s., Thiophanate-methyl Topsin M 500 SC | ETRchronic adult oral | Treated crop <0.156 Weeds <0.017 Field margin <0.0005 Adjacent crop <0.0004 Next crop <0.010 | 0.03 |

*ETRlarvae could not be calculated since the available results were expressed as g a.s./ha instead of the μg a.s./larva per developmental period as needed for the calculation proposed in the EFSA GD 2013. Risk assessment based on brood study by Sekine and Eichler 2013, where no effects were observed at doses up to 750 g a.s./ha. Hence, at the representative use in beans, the risk to bees can be considered as low.

### Laboratory tests with standard sensitive species

| Species | Test Substance | End point | Toxicity |
|---------|----------------|-----------|----------|
| *Typhlodromus pyri*, Tier I | Topsin M 500 SC | Mortality, LRso | >1575 g a.s./ha |
| | | Reproduction, ERso | >1575 g a.s./ha |
| *Aphidius rhopalosiphi*, Tier I | Topsin M 500 SC | Mortality, LR50 | >1500 g a.s./ha |
| | | Reproduction, ER50 | 175-525 g a.s./ha |

### 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)

- *Typhlodromus pyri*, Tier I: The test substance was found to be toxic to this species, with mortality and reproduction effects observed at doses of 1575 g a.s./ha. Additional species...
### Peer review of the pesticide risk assessment of the active substance thiophanate-methyl

| Species                | Test Substance | End point                     | Toxicity            |
|------------------------|----------------|-------------------------------|---------------------|
| *Poecilus cupreus*, Tier I | Topsin M 500 SC | Mortality, LR50 Reproduction, ER50 | >525 g a.s./ha >525 g a.s./ha |

### First tier risk assessment for – Grapes at 1100 g a.s./ha [single application]

| Test substance | Species                  | Effect (LR50 g a.s./ha) | HQ in-field | HQ off-field | Trigger |
|----------------|--------------------------|--------------------------|-------------|-------------|---------|
| Topsin M 500 SC | Typhlodromus pyri       | >1575                    | <0.698      | <0.056      | 2       |
| Topsin M 500 SC | Aphidius rhopalosiphi   | >1500                    | <0.733      | <0.059      | 2       |

Note: a) 3 meter spray distance

### First tier risk assessment for – Beans at 750 g a.s./ha [two applications]

| Test substance | Species                  | Effect (LR50 g a.s./ha) | HQ in-field | HQ off-field | Trigger |
|----------------|--------------------------|--------------------------|-------------|-------------|---------|
| Topsin M 500 SC | Typhlodromus pyri       | >1575                    | <0.810      | <0.019      | 2       |
| Topsin M 500 SC | Aphidius rhopalosiphi   | >1500                    | <0.851      | <0.020      | 2       |

Note: a) 1 meter spray distance

### First tier risk assessment for – Cereals at 750 g a.s./ha [single application]

| Test substance | Species                  | Effect (LR50 g a.s./ha) | HQ in-field | HQ off-field | Trigger |
|----------------|--------------------------|--------------------------|-------------|-------------|---------|
| Topsin M 500 SC | Typhlodromus pyri       | >1575                    | <0.476      | <0.013      | 2       |
| Topsin M 500 SC | Aphidius rhopalosiphi   | >1500                    | <0.500      | <0.014      | 2       |

Note: a) 1 meter spray distance

### Extended laboratory tests, aged residue tests

| Species                  | Life stage | Test substance, substrate | Time scale | Dose (g a.s./ha) | End point                  | % effect | ER50  |
|--------------------------|------------|----------------------------|------------|-----------------|----------------------------|----------|-------|
| *Aphidius rhopalosiphi*  | Adult females | Topsin M 500 SC, barley seedlings | 48 hours   | 100             | Mortality                    | 5        | >1500 |
|                          |            |                             | 500        |                 | Parasitation rate            | 2.2      |       |
|                          |            |                             | 1500       |                 | Mortality                    | 0        | 14.5  |
|                          |            |                             |            |                 | Parasitation rate            | 0        | 44.9  |

### Risk assessment based on extended lab test or aged residue tests

- Not required

### Semi-field tests

- Not available

### Field studies

- A field study in apple orchards in Germany was available with the SC formulation, where no adverse effect on populations of the predatory mite *T. pyri* was observed after three applications at 525 g a.s./ha. Questionable relevance for the representative uses of Thiophanate-methyl.

- Additional specific test

- Not available
Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) No 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) No 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s./ OM a) | Time scale | End point | Toxicity (mg a.s./kg d.w.soil) |
|---------------|----------------|----------------------------------------|------------|-----------|--------------------------------|
| **Earthworms**|                |                                        |            |           |                                |
| *Eisenia fetida* | Thiophanate-methyl | Mixed into soil, 10% peat | Chronic, 56 days | Growth, reproduction, behaviour NOEC EC<sub>10</sub> | 1.60 1.36 |
| *Eisenia fetida* | Carbendazim | Mixed into soil, OM content not reported | Chronic, 56 days | Growth, reproduction, behaviour NOEC | 1.0<sup>b)</sup> |
| *Eisenia andrei* | Carbendazim | Mixed into soil, 10% OM | Chronic, 56 days | Growth, reproduction, behaviour NOEC | 0.58* |

| Other soil macroorganisms | | | | | |
| *Folsomia candida* | Tropsin M 500 SC | Mixed into soil, 5% peat | Chronic, 28 days | NOEC | 100 (a.s.) |
| *Hypoaspis aculeifer* | Tropsin M 500 SC | Mixed into soil, 5% peat | Chronic, 14 days | NOEC | 100 (a.s.) |

a) To indicate whether the test substance was over-sprayed/to indicate the organic content of the test soil (e.g. 5% or 10%).
b) From EFSA conclusion for Carbendazim (2010)
*endpoint derived from the peer-review literature paper from Chelinho et al. (2014).

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

**Earthworms:**
Ehlers, H.A. (2001): Field study to evaluate the effects of Cercobin FL on earthworms (Germany).
As a surrogate to a NOEC value (that could not be determined from the data), we would support the conclusion from the previous evaluation that the EC<sub>10</sub> from 11 months after application (0.17 kg a.s./ha, corresponding to 0.23 mg a.s./kg dw soil) should be used for the risk assessment. This is to assure that sufficient recovery can be anticipated before a possible treatment in the next season and is consistent with the previously agreed endpoint.

Moser, T., Scheffczyk, A. et al. (2009): Thiophanate-methyl 500 SC: Effects on Abundance, Biomass and Species Composition of Earthworm Populations under Field Conditions (Germany)
Based on biologically significant effects no NOEC (<170 g a.s./ha) could be determined from this study for the most sensitive group of earthworms.

Strömel, C., Brockmann, A., Teresiak, H. (2006): The effects of TOPSIN M 500 SC (Thiophanate-methyl) after use as a dipping solution for flower bulbs on survival, reproduction and biomass of earthworms under field conditions (Germany)
Low reliability and questionable relevance for the representative uses of Thiophanate-methyl.

The experts’ meeting 165 agreed that the available higher tier field data on earthworms did not change the outcome of the Tier I risk assessment. Hence, these data are not useful for refinement.

**Nitrogen transformation**

| Medium loamy sand (org. C 1.34%) | Thiophanate-methyl | 28 days | +24% effect at day at 35 mg a.s./kg d.w.soil (mg a.s/ha) |
| Two soils; Loamy sand (org. C 0.8%); Sandy loam (org. C 1.6%) | Tropsin M 500 SC | 28 days | -4% effect at day at 7.0 mg a.s./kg d.w.soil (mg a.s/ha) |
| Low org. C silty sand soil | Carbendazim | 42 days | +5 effect at day at 4.8 mg a.s./kg d.w.soil (mg a.s/ha) |
Toxicity/exposure ratios for soil organisms

### Wine Grapes at 1100 g a.s./ha [single application]

| Test organism       | Test substance         | Time scale | Soil PEC | TER     | Trigger |
|---------------------|------------------------|------------|----------|---------|---------|
| **Earthworms**      |                        |            |          |         |         |
| Thiofanate-methyl   | Chronic                | 0.587      | **2.31** | 5       |         |
| Carbendazim         | Chronic                | 0.248      | **2.34** | 5       |         |
| CM-0237(9)          | Chronic                | 0.055      | 2.47     | 5       |         |
| 2-AB(9)             | Chronic                | 0.014      | 9.71     | 5       |         |
| **Other soil macroorganisms** |                |            |          |         |         |
| *Folsomia candida*  | Thiofanate-methyl      | Chronic    | 0.587    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.587      | 170      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.248      | 40.3     | 5       |         |
| CM-0237(9)          | Chronic                | 0.055      | 182      | 5       |         |
| 2-AB(9)             | Chronic                | 0.014      | 714      | 5       |         |
| *Hypoaspis auleifer*| Thiofanate-methyl      | Chronic    | 0.587    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.587      | 170      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.248      | 40.3     | 5       |         |
| CM-0237(9)          | Chronic                | 0.055      | 182      | 5       |         |
| 2-AB(9)             | Chronic                | 0.014      | 714      | 5       |         |

a) maximum initial PEC soil was used
b) TER values based on the conservative assumption that the metabolites are 10 times more toxic than the active ingredient.

### Fresh Beans at 750 g a.s./ha [two applications]

| Test organism       | Test substance         | Time scale | Soil PEC | TER     | Trigger |
|---------------------|------------------------|------------|----------|---------|---------|
| **Earthworms**      |                        |            |          |         |         |
| Thiofanate-methyl   | Chronic                | 0.300      | **4.53** | 5       |         |
| Carbendazim         | Chronic                | 0.235      | **2.47** | 5       |         |
| CM-0237(9)          | Chronic                | 0.053      | **2.56** | 5       |         |
| 2-AB(9)             | Chronic                | 0.007      | 19.4     | 5       |         |
| **Other soil macroorganisms** |                |            |          |         |         |
| *Folsomia candida*  | Thiofanate-methyl      | Chronic    | 0.300    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.300      | 333      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.235      | 42.6     | 5       |         |
| CM-0237(9)          | Chronic                | 0.053      | 189      | 5       |         |
| 2-AB(9)             | Chronic                | 0.007      | 1428     | 5       |         |
| *Hypoaspis auleifer*| Thiofanate-methyl      | Chronic    | 0.300    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.300      | 333      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.235      | 42.6     | 5       |         |
| CM-0237(9)          | Chronic                | 0.053      | 189      | 5       |         |
| 2-AB(9)             | Chronic                | 0.007      | 1428     | 5       |         |

a) maximum initial PEC soil was used
b) TER values based on the conservative assumption that the metabolites are 10 times more toxic than the active ingredient.

### Cereals at 750 g a.s./ha [single late application]

| Test organism       | Test substance         | Time scale | Soil PEC | TER     | Trigger |
|---------------------|------------------------|------------|----------|---------|---------|
| **Earthworms**      |                        |            |          |         |         |
| Thiofanate-methyl   | Chronic                | 0.200      | 6.80     | 5       |         |
| Carbendazim         | Chronic                | 0.085      | 6.82     | 5       |         |
| CM-0237(9)          | No data, not needed    | 0.019      | 7.16     | 5       |         |
| 2-AB(9)             | Chronic                | 0.005      | 27.2     | 5       |         |
| **Other soil macroorganisms** |                |            |          |         |         |
| *Folsomia candida*  | Thiofanate-methyl      | Chronic    | 0.200    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.200      | 500      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.085      | 118      | 5       |         |
| CM-0237(9)          | Chronic                | 0.019      | 526      | 5       |         |
| 2-AB(9)             | Chronic                | 0.005      | 2000     | 5       |         |
| *Hypoaspis auleifer*| Thiofanate-methyl      | Chronic    | 0.200    | -       | 5       |
| Topsin M 500 SC     | Chronic                | 0.200      | 500      | 5       |         |
| Carbendazim(9)      | Chronic                | 0.085      | 118      | 5       |         |
| CM-0237(9)          | Chronic                | 0.019      | 526      | 5       |         |
| 2-AB(9)             | Chronic                | 0.005      | 2000     | 5       |         |

a) maximum initial PEC soil was used
b) TER values based on the conservative assumption that the metabolites are 10 times more toxic than the active ingredient.
Leek at 4150 g a.s./ha [drenching]

| Test organism       | Test substance       | Time scale | Soil PEC a) | TER | Trigger |
|---------------------|----------------------|------------|--------------|-----|---------|
| Earthworms          |                      |            |              |     |         |
|                     | Thiophanate-methyl   | Chronic    | 5.53         | 0.24| 5       |
|                     | Carbendazim          | Chronic    | 2.34         | 0.25| 5       |
|                     | CM-0237 b)           | No data, not needed | 0.514 | 0.26| 5       |
|                     | 2-AB b)              | Chronic    | 0.131        | 1.04| 5       |
| Other soil macroorganisms |                  |            |              |     |         |
| Folsomia candida    | Thiophanate-methyl   | Chronic    | 5.53         | -   | 5       |
|                     | Topsin M 500 SC      | Chronic    | 5.53         | 18.1| 5       |
|                     | Carbendazim          | Chronic    | 2.34         | 4.27| 5       |
|                     | CM-0237 b)           | Chronic    | 0.514        | 19.5| 5       |
|                     | 2-AB b)              | Chronic    | 0.131        | 76.3| 5       |
| Hypoaspis aculeifer | Thiophanate-methyl   | Chronic    | 5.53         | -   | 5       |
|                     | Topsin M 500 SC      | Chronic    | 5.53         | 18.1| 5       |
|                     | Carbendazim          | Chronic    | 2.34         | 4.27| 5       |
|                     | CM-0237 b)           | Chronic    | 0.514        | 19.5| 5       |
|                     | 2-AB b)              | Chronic    | 0.131        | 76.3| 5       |

a) maximum initial PEC soil was used
b) TER values based on the conservative assumption that the metabolites are 10 times more toxic than the active ingredient.

Tomato/aubergine 2100 g a.s./ha [drip irrigation]

| Test organism       | Test substance       | Time scale | Soil PEC a) | TER | Trigger |
|---------------------|----------------------|------------|--------------|-----|---------|
| Earthworms          |                      |            |              |     |         |
|                     | Thiophanate-methyl   | Chronic    | 3.07         | 0.44| 5       |
|                     | Carbendazim          | Chronic    | 2.06         | 0.28| 5       |
|                     | CM-0237 b)           | No data, not needed | 0.475 | 0.29| 5       |
|                     | 2-AB b)              | Chronic    | 0.083        | 1.64| 5       |
| Other soil macroorganisms |                  |            |              |     |         |
| Folsomia candida    | Thiophanate-methyl   | Chronic    | 3.07         | -   | 5       |
|                     | Topsin M 500 SC      | Chronic    | 3.07         | 32.6| 5       |
|                     | Carbendazim          | Chronic    | 2.06         | 4.85| 5       |
|                     | CM-0237 b)           | Chronic    | 0.475        | 21.1| 5       |
|                     | 2-AB b)              | Chronic    | 0.083        | 120.5| 5     |
| Hypoaspis aculeifer | Thiophanate-methyl   | Chronic    | 3.07         | -   | 5       |
|                     | Topsin M 500 SC      | Chronic    | 3.07         | 32.6| 5       |
|                     | Carbendazim          | Chronic    | 2.06         | 4.85| 5       |
|                     | CM-0237 b)           | Chronic    | 0.475        | 21.1| 5       |
|                     | 2-AB b)              | Chronic    | 0.083        | 120.5| 5     |

a) maximum initial PEC soil was used
b) TER values based on the conservative assumption that the metabolites are 10 times more toxic than the active ingredient.

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

Screening data
Not available. Covered by the available laboratory data.

Laboratory dose response tests

| Species                        | Test substance         | ER50 (g a.s./ha) vegetative vigour | ER50 (g a.s./ha) emergence | Exposure (g a.s./ha) | TER | Trigger |
|--------------------------------|------------------------|-----------------------------------|---------------------------|----------------------|-----|---------|
| Cabbage, corn, cucumber, lettuce, oat, onion, radish, ryegrass, tomato, soybean | Thiophanate-methyl     | >1570                             | >1680                     | 88 Grapes, 8.02% drift, 3 m | >15.2 | 5       |
| Cabbage, corn, cucumber, lettuce, oat, onion, radish, ryegrass, tomato, soybean | Thiophanate-methyl     | >1570                             | >1680                     | 30 Beans, 2.38% drift, 1 m   | >46.7 | 5       |
| Cabbage, corn, cucumber, lettuce | Thiophanate-methyl     | >1570                             | >1680                     | 21 Cereals,          | >63.8 | 5       |
Species | Test substance | ER_{50} (g a.s./ha) vegetative vigour | ER_{50} (g a.s./ha) emergence | Exposure (g a.s./ha) | TER | Trigger
--- | --- | --- | --- | --- | --- | ---
oat, onion, radish, ryegrass, tomato, soybean |  |  |  | 2.77% drift, 1 m |  | Extended laboratory studies: Not available, not needed
Semi-field and field test: Not available, not needed.

**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 | NOEC 1000 mg a.s./L |
| *Pseudomonas sp* | No data, not required |

**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)**

No monitoring data on effects in the environment is available.

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

Ecotoxicologically relevant compounds a)

| Compartment | Thiophanate-methyl, Carbendazim (MBC) |
| --- | --- |
| soil | Thiophanate-methyl, Carbendazim (MBC) |
| water | Thiophanate-methyl, Carbendazim (MBC) |
| sediment | Thiophanate-methyl, Carbendazim (MBC) |
| groundwater | Thiophanate-methyl, Carbendazim (MBC) |

a) metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent. In this case, comparison was made against Carbendazim, a major environmental metabolite that is formed rapidly from the parent and is more toxic than the active ingredient.
Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance               | Thiophanate-methyl |
|-------------------------|--------------------|
| 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] | H400 | H410 |
| Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008 | - |

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.