Appendix to:

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance methiocarb. EFSA Journal 2018;16(10):5429, 70 pp. doi:10.2903/j.efsa.2018.5429
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Appendix A- List of end points for the active substance and the representative formulation

| Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2) |
|----------------------------------------------------------------------------------|
| **Active substance (ISO Common Name)** | Methiocarb (ISO) |
| **Function (e.g. fungicide)** | Insecticide and bird repellent |
| **Rapporteur Member State** | UK |
| **Co-rapporteur Member State** | Germany |

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

| **Chemical name (IUPAC)** | 4-methylthio-3,5-xylyl methylcarbamate |
| **Chemical name (CA)** | 3,5-dimethyl-4-(methylthio) phenyl N- methylcarbamate |
| **CIPAC No** | 165 |
| **CAS No** | 2032-65-7 |
| **EC No (EINECS or ELINCS)** | 217-991-2 |
| **FAO Specification (including year of publication)** | 165/TC (June, 2018) |
| **Minimum purity of the active substance as manufactured** | 980g/kg |
| **Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured** | methyl isocyanate max. 0.2 g/kg |
| | toluene max. 1 g/kg |
| | 2,4,6-trichloro-3,5-dimethylphenyl methylcarbamate max. 3 g/kg |
| **Molecular formula** | C₁₁H₁₅NO₂S |
| **Molar mass** | 225.3 g/mol |
| **Structural formula** | ![Structural formula](image) |
### Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| Property                                      | Value/Details                                |
|-----------------------------------------------|----------------------------------------------|
| **Melting point (state purity)**              | 118-119 °C (Purity 99.5%)                    |
| **Boiling point (state purity)**              | 311 ± 37°C estimated for atmospheric pressure (QSAR) |
| **Temperature of decomposition (state purity)**| DTA indicated melting occurred between 120 and 150°C with measurable exothermic decomposition, with its maximum at 300°C, completed at ca 330°C. (Purity 98.3%) |
| **Appearance (state purity)**                 | Colourless crystals, odourless (pure)         \n|                                               | White to beige powder, phenol-like odour (as manufactured) |
| **Vapour pressure (state temperature, state purity)** | 1.5×10⁻⁵ Pa at 20 °C   \n|                                               | 3.6×10⁻⁵ Pa at 25 °C \n|                                               | Very slightly volatile (Purity 99.5%)          |
| **Henry’s law constant (state temperature)**  | Henry’s law constant at 20 °C (calculated): 1.2×10⁻⁴ \n|                                               | Poxₙm³×mol⁻¹                                |
| **Solubility in water (state temperature, state purity and pH)** | 27 mg/L at 20 °C pH unspecified (moderately soluble) \n|                                               | Range of pHs not considered due to the active substance not dissociating and degrading at pH 9 (Purity 99.5%) |
| **Solubility in organic solvents (state temperature, state purity)** | Solubility in g/L at 20 °C: \n|                                               | n-heptane 0.57 \n|                                               | dichloromethane >250 \n|                                               | 2-propanol 42 \n|                                               | xylene 20 \n|                                               | 1-octanol 31 \n|                                               | acetone 144 \n|                                               | acetonitrile 67 \n|                                               | ethylacetate 87 \n|                                               | polyethyleneglycol 72 \n|                                               | dimethylsulfoxide >250 (Purity 99.5%) |
| **Surface tension (state concentration and temperature, state purity)** | 72 mN/m at 20 °C (aqueous solution approx. 15.5 mg/L) \n|                                               | Methiocarb is classified to be non-surface active. (Purity 99.5%) |
| **Partition coefficient (state temperature, pH and purity)** | Methiocarb – 99.5% purity \n|                                               | At 20 °C \n|                                               | unbuffered Pow 1200 log Pow 3.08 \n|                                               | pH 4 Pow 1300 log Pow 3.11 \n|                                               | pH 7 Pow 1500 log Pow 3.18 \n|                                               | pH 9 degradation Metabolite (Methiocarb-methoxy-sulfone): |
At 25°C

| pH  | Pow | log Pow |
|-----|-----|---------|
| 5   | 79  | 1.9     |
| 7   | 79  | 1.9     |
| 9   | 79  | 1.9     |

Metabolite (Methiocarb-phenol):

At 20°C

| pH  | Pow | log Pow |
|-----|-----|---------|
| Unbuffered | 2600 | 3.41    |
| 4   | 2700 | 3.43    |
| 7   | 3000 | 3.48    |
| 9   | 3100 | 3.49    |

Metabolite (methiocarb-sulfone-phenol)

At 21°C

| pH  | Pow | log Pow |
|-----|-----|---------|
| 5   | 36.3 | 1.56    |
| 7   | 32.4 | 1.51    |
| 9   | 2.33 | 0.37    |

Metabolite (Methiocarb-sulfoxide):

At 23°C

| pH  | Pow | log Pow |
|-----|-----|---------|
| 5   | 4.7  | 0.7     |
| 7   | 5.3  | 0.7     |
| 9   | Degradation |

Metabolite (Methiocarb-sulfoxide phenol)

At 23°C

| pH  | Pow | log Pow |
|-----|-----|---------|
| 5   | 12  | 1.1     |
| 7   | 12  | 1.1     |
| 9   | 2.9 | 0.5     |

Dissociation constant (state purity)

Methiocarb shows neither basic nor acidic properties in aqueous systems. It is not possible to specify a pKa value for methiocarb in water. No dissociation.
UV/VIS absorption (max.) incl. $\varepsilon$  
(state purity, pH)

| Methiocarb, purity 99.1% |
|--------------------------|

### UV (methanol/neutral pH)

Absorption Characteristics:

| Peak maxima/ wavelength | Molar extinction coefficient [L/mol x cm] |
|-------------------------|------------------------------------------|
| 203 nm                  | 44762                                    |
| 223 nm                  | 12021                                    |
| 267 nm                  | 2582                                     |

### UV (methanol/buffer solution pH 2)

Absorption Characteristics:

| Peak maxima/ wavelength | Molar extinction coefficient [L/mol x cm] |
|-------------------------|------------------------------------------|
| 203 nm                  | 52548                                    |
| 223 nm                  | 13026                                    |
| 267 nm                  | 3030                                     |

### UV (methanol/buffer solution pH 10)

Absorption Characteristics:

| Peak maxima/ wavelength | Molar extinction coefficient [L/mol x cm] |
|-------------------------|------------------------------------------|
| 219 nm                  | 23298                                    |
| 267 nm                  | 11461                                    |

At pH 10, the molar extinction [\(\varepsilon\)] was measured as 182 L/(mol x cm) at 290 nm.

### Flammability (state purity)

(99.4% purity)  
Not highly flammable in the sense of EC guideline A.10. Does not liberate gases in hazardous amounts as defined in EC guideline A.12.

### Explosive properties (state purity)

(99.4% purity)  
Not explosive in the sense of EC guideline A.14.

### Oxidising properties (state purity)

(99.4% purity)  
No oxidising properties in the sense of EC guideline A.17.
Summary of representative uses evaluated, for which all risk assessments needed to be completed *(Methiocarb)*
(Regulation (EU) No 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a) | Member State or Country | Product name | F or G (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|---------------------------|-------------------------|--------------|------------|----------------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| Maize                     | Europe                  | Methiocarb FS 500 | F          | Oscinella frit repellent for: *Columba livia f.*, *domestica*, *Corvus corone*, *Corvus frugilegus*, *Phasianus colchicus* | FS 500 g/l methio-carb | Seed treatment BBCH 00 | 75 | 150 | Sowing density: 2 Units per ha |

(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
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 (Methiocarb) 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 or G or I (b) | Pests or Group of pests controlled (c) | Preparation Type (d-f) | Conc. a.s. (g) | method kind (h) | range of growth stages & season (i) | number min-max (k) | Interval between application (min) | kg a.s./L min-max (l) | Water L/ha min-max | 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.

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

The representative uses/GAPs are supported.

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

The representative uses/GAPs are supported.

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

| Met1 | Met2 | Met3 | Met4 | Met5 | Met6 |
|------|------|------|------|------|------|
|      |      |      |      |      |      |
| Activity against target organism |
| 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)

| Component | Analytical Method |
|-----------|-------------------|
| Technical a.s. (analytical technique) | HPLC-DAD with external standard. |
| Impurities in technical a.s. (analytical technique) | HPLC-DAD with external standard. GC-Headspace with external standard. GC with external standard. Titration. |
| Plant protection product (analytical technique) | HPLC-DAD with external standard. |

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

Residue definitions for monitoring purposes

| Component | Residue Definition |
|-----------|-------------------|
| Food of plant origin | Methiocarb and methiocarb sulfoxide, expression pending upon outcome of data gap on genotoxicity for M01. |
| Food of animal origin | Not required. |
| Soil | Methiocarb and methiocarb sulfoxide |
| Sediment | Methiocarb and methiocarb sulfoxide |
| Water surface | Methiocarb and methiocarb sulfoxide |
| Drinking/ground water | Methiocarb |
| Air | Methiocarb |
| Body fluids and tissues | Methiocarb phenol, methiocarb sulfone phenol, methiocarb sulfoxide phenol and their conjugates (glucuronides and sulphates) |

Monitoring/Enforcement methods

| Component | Method Details |
|-----------|----------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | QuEChERS HPLC-MS/MS method was provided covering the following analytes: LOQ = 0.01 mg/kg (methiocarb), 0.01 mg/kg (methiocarb sulfoxide), 0.01 mg/kg (methiocarb sulfone). Validated matrices: rape seed (crop with high oil content) An ILV is available rape seed only. Data gap: monitoring method for residue definition in high water content, high acid content and dry matrices |
### Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

Not required, though a modified QuEChERs method using HPLC-MS/MS is available for determining residues in meat, kidney, liver, fat, milk, and eggs.

LOQ = 0.01 mg/kg (methiocarb), 0.01 mg/kg (methiocarb sulfoxide), 0.01 mg/kg (methiocarb sulfone), 0.01 mg/kg (methiocarb phenol), 0.01 mg/kg (methiocarb sulfoxide phenol), 0.01 mg/kg (methiocarb sulfone phenol).

An ILV is available for the method.

### Soil (analytical technique and LOQ)

DFG Method S 19 HPLC/MS-MS, LOQ = 0.02 mg/kg (methiocarb), 0.02 mg/kg (methiocarb sulfoxide).

### Water (analytical technique and LOQ)

HPLC-MS/MS, LOQ = 0.05 µg/L (methiocarb), 0.05 µg/L (methiocarb sulfoxide).

An ILV is available for the method.

### Air (analytical technique and LOQ)

Trapping by Tenax or XAD, then HPLC- fluorescence detection.

LOQ = 0.4 µg/m³ (methiocarb).

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

GC-MS, LOQ = 50 µg/L (body fluids), LOQ = 0.01 mg/kg (tissues) (methiocarb)

Data gap for all components of the residue definition

### Classification and labelling with regard to physical and chemical data (Regulation (EU) No 283/2013, Annex Part A, point 10)

| Substance | Methiocarb |
|-----------|------------|
| 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: | None |
| Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008: | No classification proposed with regard to physical and chemical data |

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

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) No 283/2013, Annex Part A, point 5.1)

| Rate and extent of oral absorption/systemic bioavailability | Rapid absorption, Cmax in plasma at 0.5h. Extensively absorbed after oral dose, 84-90% |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Toxicokinetics                                              | In male/female rats (1 mg/kg bw) Cmax methiocarb ~ 0.77 µg/mL. Tmax 0.5 h T1/2 absorption 0.12 h T1/2 elimination 8.17-17.8 h (m/f) |
| Distribution                                                | Extensively distributed into organs and tissues. Highest concentration of radioactivity in the organs being responsible for the degradation and excretion, i.e. stomach, large and small intestine, kidney, urinary bladder, and liver |
| Potential for bioaccumulation                               | No potential for accumulation. T1/2 for elimination is 8h–21h. |
| Rate and extent of excretion                                | Rapid elimination mainly in urine (84-90%) within 48h. Faeces was 5-10% |
| Metabolism in animals                                       | Extensively metabolised in mammals. Four types of metabolic reactions were inferred following oral and dermal application: - Ester hydrolysis of the carbamate group (major metabolic step) - Hydroxylation of the methyl group of carbamate group (minor reaction) - Oxidation of the thioether group to form the sulfoxide and the sulfone - Conjugation of the phenolic hydroxy group with sulfuric acid or glucuronic acid |
| In vitro metabolism                                         | No unique human metabolite is expected |
| Toxicologically relevant compounds (animals and plants)      | Methiocarb and M03, M04 and M05. |
| Toxicologically relevant compounds (environment)            | Methiocarb and M03, M04 and M05. |

Acute toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.2)

| Rat LD50 oral | 19 mg/kg bw based on weight of evidence of published data with range of 13–135 mg/kg bw. In the submitted study was 33 mg/kg bw. | H300 |
| Rat LD50 dermal | > 5000 mg/kg bw |
| Rat LC50 inhalation | 0.433 mg/L | H330 |
| Skin irritation | Not irritating |
| Property                        | Description                                                                 |
|--------------------------------|-----------------------------------------------------------------------------|
| Eye irritation                  | Not irritating                                                              |
| Skin sensitisation             | Not sensitising (LLNA method)                                               |
| Phototoxicity                  | data gap                                                                    |

**Short-term toxicity (Regulation (EU) Nº 283/2013, Annex Part A, point 5.3)**

| Target organ / critical effect | Description                                                                 |
|-------------------------------|-----------------------------------------------------------------------------|
|                               | Rat and dog: Cholinesterase inhibition, clinical signs indicative of cholinergic inhibition and reduction in body weight gain |
| Relevant oral NOAEL           | 90 day, dog: 0.25 mg/kg bw per day                                           |
|                               | 2-year dog: 2.2 mg/kg bw per day                                            |
|                               | 13-week, rat: 7.34 mg/kg bw per day                                         |
| Relevant dermal NOAEL         | 21 day, rabbit: 150 mg/kg bw per day                                        |
| Relevant inhalation NOAEL     | 21 day, rats: 6 mg/m³                                                       |

**Genotoxicity (Regulation (EU) Nº 283/2013, Annex Part A, point 5.4)**

| In vitro studies               | Description                                                                 |
|-------------------------------|-----------------------------------------------------------------------------|
|                               | Ames Test, HGPRT assay in CHO cells, Pol test in E. coli; UDS assay and SCE assay in CHO cells: Negative. Chromosomal aberration assay in CHO assay: positive. |
| In vivo studies               | Micronucleus assay and mouse dominant lethal test: Negative.                |
| Photomutagenicity             | Not required                                                                |
| Potential for genotoxicity    | Overall methiocarb is unlikely to be genotoxic in vivo.                     |

**Long-term toxicity and carcinogenicity (Regulation (EU) Nº 283/2013, Annex Part A, point 5.5)**

| Long-term effects (target organ/critical effect) | Description                                                                 |
|-------------------------------------------------|-----------------------------------------------------------------------------|
| Rats: significant weight loss                    |                                                                           |
| Mice: significant change in ALT and transient significant cholinesterase inhibition |                                                                           |
| Relevant long-term NOAEL                        | 2-year, rat: 9.3 mg/kg bw per day                                           |
| 2-year, mice: 14.6 mg/kg bw per day             |                                                                           |
| Carcinogenicity (target organ, tumour type)     | Non-carcinogenic in rats and mice                                           |
| Relevant NOAEL for carcinogenicity              | 2-year, rat: ≥9.3 mg/kg bw per day                                         |
| 2-year, mice: ≥ 57 mg/kg bw per day             |                                                                           |

**Reproductive toxicity (Regulation (EU) Nº 283/2013, Annex Part A, point 5.6)**

| Reproduction target / critical effect | Description                                                                 |
|--------------------------------------|-----------------------------------------------------------------------------|
| Parental toxicity: reduced body weights in parental males/females (during lactation for females) |                                                                           |
| Reproduction toxicity: Reduced number of |                                                                           |
pups per litter and reduced lactation index

Offspring toxicity: Reduced lactation index in F1 and F2 pups

Relevant parental NOAEL
4.3 mg/kg bw per day

Relevant reproductive NOAEL
4.3 mg/kg bw per day

Relevant offspring NOAEL
4.3 mg/kg bw per day

Developmental toxicity

Developmental target / critical effect
rat:
Parental toxicity: cholinergic signs, weight loss and muscle fasciculations
No developmental toxicity

rabbit
Parental toxicity: clinical signs of toxicity and reductions in body weight
No developmental toxicity

Relevant maternal NOAEL
0.5 mg/kg bw per day in the rat
3 mg/kg bw per day in the rabbit

Relevant developmental NOAEL
5.0 mg/kg bw per day in the rat
10.0 mg/kg bw per day in the rabbit

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

Acute neurotoxicity
No specific neurotoxicity study. In the available toxicity studies: No acute neurofunctional effects seen in rats and dogs. Cholinergic effects included trembling, cramps, muscular fasciculations, salivation, diarrhoea, vomiting and ataxia in mammals. No specific target organ toxicity observed at non-lethal dose levels

Repeated neurotoxicity
No specific neurotoxicity study. In the available toxicity studies: No neurofunctional effects seen in rats and dogs. No cumulative effect on the acetylcholinesterase activity was observed

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)
No evidence of delayed neurotoxicity in hens. Data gap for a comparative ChE study in adults and offspring rats
### Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

| Supplementary studies on the active substance | Antidote effects: Atropine provided significant antidotal protection against the cholinergic effects of methiocarb. No potentiation effects observed. Open literature: methiocarb may induce oxidative damage in liver and kidney. It does not possess AhR agonistic activity, hPXR and/or mPXR agonistic activity and does not activate PPARα or PPARγ in vitro. |
| Endocrine disrupting properties | Immunotoxicity: no specific study, no indication in the available toxicity studies. |
| Studies performed on metabolites or impurities | Methiocarb is unlikely to be an endocrine disruptor. |

| Methiocarb sulfoxide (M01): | Oral LD<sub>50</sub> = 6 mg/kg bw NOAEL cholinergic effects < 0.5 mg/kg bw per day (estimated to be between 0.1 and 0.2 mg/kg bw per day) in the rat (4 weeks, gavage) NOAEL cholinergic effects = 0.05 mg/kg bw per day in the dog (29-day oral, capsule) Relative potency factor of 3 might apply compared to parent provided genotoxicity is excluded. Data gap for in vitro genotoxicity test battery. |
| Methiocarb sulfone (M02): | Oral LD<sub>50</sub> = >1000 mg/kg bw |
| Methiocarb phenol (M03): | Oral LD<sub>50</sub> > 2000 mg/kg bw Ames Test: negative Likely to be of lower toxicity than parent. |
| Methiocarb sulfoxide phenol (M04): | Oral LD<sub>50</sub> > 2000 mg/kg bw Ames Test: negative Likely to be of lower toxicity than parent. |
| Methiocarb sulfone phenol (M05): | LD<sub>50</sub> > 2000 mg/kg bw Ames Test: negative Likely to be of lower toxicity than parent. |
| N-hydroxymethyl methiocarb: | Oral LD<sub>50</sub> > 112 mg/kg bw |
| N-hydroxymethyl methiocarb sulfone | Oral LD<sub>50</sub> > 160 mg/kg bw |
| N-hydroxymethyl sulfoxide | Oral LD<sub>50</sub> > 112 mg/kg bw |
Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Occupational medical surveillance of twenty five workers exposed to methiocarb did not reveal any unwanted effects in the workers. One fatal poisoning of a human with methiocarb was reported.

Summary (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) (b) | 0.00025                     | Dog, 90-day                 | 1000(a)           |
| Acute Reference Dose (ARfD) (b) | 0.00050                     | Rat, Developmental toxicity | 1000(a)           |
| Acceptable Operator Exposure Level (AOEL) (b) | 0.00025                     | Dog, 90-day                 | 1000(a)           |
| Acute Acceptable Operator Exposure Level (AAOEL) | 0.00050                     | Rat, Developmental toxicity | 1000(a)           |

(a) An additional factor of 10 was added to the standard uncertainty factor of 100 to take into account the lack of a DNT study and the likely higher sensitivity to AChE inhibition of pups compared to adults.  
(b) Different from those set during the first approval (European Commission, 2006) where the ADI, ARfD and AOEL were 0.013 mg/kg bw per day (UF 100).

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

Representative formulation (Mesurol FS 500 g/L)

0.9% for the concentrate  
1% for 1.2 dilution  
2% for 1.8 dilution  
Based on in vitro study in human skin on Mesurol FS 500 g/L.

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

Operators

Operators directly involved in the seed treatment process
Operator exposure study of seed treatment of maize seeds with 500 g/L FS formulation, 0.075 kg a.s./50,000 seeds.
Operator exposure in seed treatment plant with the following control measures:
- Closed transfer systems during mixing/loading
- Automated, closed bagging line
- Automated, enclosed stacking
- Adequate dust aspiration system throughout the seed treatment process
- Enclosed transport of treated seed
- ‘Dry’ cleaning techniques
The following PPE is required to be worn by all personnel throughout the entire working shift, whilst in

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3 If available include also reference values for metabolites
the operational area of the seed-treatment plant:

- Suitable protective coveralls\(^1\) suitable protective gloves, and suitable respiratory protective equipment\(^2\)

\(^1\)Protective coverall – impermeable ‘Tyvek’ type of coverall.
\(^2\) Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

Longer term exposure to methiocarb (sample maximum):
- Machine Operator: 88% AOEL
- Cleaner: 9% AOEL

Acute exposure to methiocarb (parametric 95\(^{th}\) percentile):
- Machine Operator: 96% AAOEL
- Cleaner: 7% AAOEL

Operators within the seed-treatment plant not directly involved in treatment

Seed-TROPEX data for forklift truck drivers whose general work activities were not directly associated with the seed treatment process. Based on the same PPE requirements as detailed above for operators.

Longer term exposure to methiocarb:
- Geometric mean: 19% AOEL
- Parametric 75\(^{th}\) percentile: 33% AOEL
- Sample maximum: 38% AOEL

Acute exposure to methiocarb:
- Parametric 95\(^{th}\) percentile: 93% AAOEL

Workers

Worker exposure during loading and sowing treated seed from worker exposure study. Exposure to methiocarb with the use of workwear, gloves and FFP3 RPE during sowing and loading. Assuming the use of an open cabin tractor during sowing.

Longer term exposure to methiocarb:
- Empirical 75\(^{th}\) percentile: 628% AOEL

Acute exposure to methiocarb:
- Sample maximum: 826% AAOEL

Bystanders and residents

The treatment of maize seeds with ‘Mesurol FS 500’ is usually performed in professional plants where access is restricted to people working at the plant. Therefore it is considered that bystanders and residents will not be exposed to methiocarb during the seed treatment process.
Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

Substance: Methiocarb

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:

| Substance        | Classification                  |
|------------------|----------------------------------|
| Methiocarb       | Acute Tox. 3 (H301 – Toxic if swallowed) |
|                  | Acute Tox. 2 (H300 – Fatal if swallowed) |
|                  | (H330 – Fatal if inhaled)         |

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.
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)       |
|-----------------------------|-------------|----------------------------------|----------------------------------------|-----------------|
| (Plant groups covered)      |             |                                  |                                        |                 |
| Fruit crops                 |             | Apples                           | 1x2 mg a.s./apple (Foliar treatment)    | 0, 4, 29, 36, 43|
|                             |             |                                  | 8x10.1 mg a.s./apple (Foliar treatment)| 3, 7, 14        |
|                             |             | Tomatoes                         | 1x1.12 kg a.s./ha (soil treatment)     | 1, 3, 7, 14     |
| Leafy crops                 |             | Lettuces                         | 1x1.12 kg a.s./ha (soil treatment)     | 1, 3, 7, 14     |
| Cereals/grass crops         | Rice        |                                  | 1x1.12 kg a.s./ha (seed treatment)     | 14, 21, 28, 35  |
|                             |             |                                  | 1x2.24 kg a.s./ha (Foliar treatment)   | 0, 1, 3, 6, 14, 28 |
|                             |             |                                  | 2x2.24 kg a.s./ha (Foliar treatment)   | 0, 6, 14, 21, 28|
| Pulses/Oilseeds             | Oilseed rape|                                  | 5 kg a.s./100 kg seeds                 | 23 (Forage), 181 (straw, seeds) |
|                             |             |                                  | 25 kg a.s./100 kg seeds                |                 |

| Rotational crops            | Crop groups | Crop(s) | PBI (days) | Conditions |
|-----------------------------|-------------|---------|------------|------------|
| (metabolic pattern)         |             |         |            | 20 min, 90°C, pH 4 |
|                             |             |         |            | 60 min, 100°C, pH 5 |
|                             |             |         |            | 20 min, 120°C, pH 6 |

Rotational crop and primary crop metabolism similar? Yes

Processed commodities (standard hydrolysis study)

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

Studies not triggered as residues of all compounds included in the residue definitions for monitoring and risk assessment < LOQ (0.01 mg/kg) of the method in maize grain.
| Plant residue definition for monitoring (RD-Mo) | Methiocarb and methiocarb sulfoxide, expression pending upon outcome of data gap on genotoxicity for methiocarb sulfoxide. All categories of crops upon soil and seed treatments. |
| Plant residue definition for risk assessment (RD-RA) | 1) Methiocarb, 2) Methiocarb sulfoxide (M01) (a potency factor of 3 can be established to consider the sum of parent methiocarb and M01, if any genotoxicity potential can be ruled out for M01), 3) Sum of methiocarb phenol (M03), methiocarb sulfoxide phenol (M04) and methiocarb sulfone phenol (M05), free and conjugated. All categories of crops upon soil and seed treatments. |
| Conversion factor (monitoring to risk assessment) | Open |

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

| Animals covered | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|------------------|-------|------------------|----------------|----------------|
| Animals covered  | Laying hen | 4.4 | 5 | The studies are not considered acceptable according to current OECD recommendations. |
|                  | Goat/Cow | 0.14 | 5 | |
|                  | Pig     |       |       | |
|                  | Fish    |       |       | Not required |

| Time needed to reach a plateau concentration in milk and eggs (days) | Open |
| Animal residue definition for monitoring (RD-Mo) | Not required for the representative use on maize. |
| Animal residue definition for risk assessment (RD-RA) | Not required for the representative use on maize. |
| Conversion factor (monitoring to risk assessment) | N/A |
| Metabolism in rat and ruminant similar (Yes/No) | N/A |
| Fat soluble residues (Yes/No) | Yes for methiocarb and M03 (log P<sub>ow</sub> >3) No for M01, M04, M05, M10 (log P<sub>ow</sub> <3) |

N/A: Not applicable
Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

| Confined rotational crop study (Quantitative aspect) | Residues are <0.01 mg/kg in food and <0.05 mg/kg in feed items for methiocarb, M01, M02, M03, M04 and M05 after 163 days. Significant residues of M03, M04 and M05 are expected mainly in wheat straw and of M04 in Swiss chard and in turnip roots at 30 d PBI. |
| Field rotational crop study | From overdosed field residue trials (2×120 g a.s./ha) conducted in Northern and Southern Europe on wheat grain and straw, leafy crops (cauliflower, cabbage, lettuce) and root crops (potatoes, sugar beet root) and following soil application, residue levels of M04 and M05 (including conjugates) were occasionally recovered above the LOQ in lettuces only (0.024 and 0.013 mg eq/kg, respectively) in a glasshouse trial at 30 d PBI and residues of methiocarb and all analysed compounds were <0.05 mg eq/kg in wheat straw, 90 days after treatment. Residue levels in rotational crops are unlikely to exceed 0.01 mg/kg when maize is treated at GAP rate. |
**Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)**

| Plant products (Category) | Commodity             | T (°C) | MTC sulfoxide (M01) | MTC sulfone (M02) | MTC sulfoxide phenol (M04) | MTC sulfone phenol (M05) | MTC phenol (M03) | Methiocarb |
|---------------------------|-----------------------|--------|---------------------|-------------------|---------------------------|--------------------------|-----------------|------------|
| High water content        | Peas                  | -18    | 24                  | 24                | -                         | -                        | -               | 24         |
|                           | Lettuces              | -18    | -                   | -                 | 23                        | 23                       | 23              | -          |
| High oil content          | Canola/rape seed      | -18    | 24                  | 24                | 23                        | 23                       | 11 months (converted after 352 days) into M04; sum stable for 23 months | 24         |
| High protein content      | Bean dry seed         | -18    | -                   | -                 | 23                        | 23                       | 23              | -          |
| High starch content       | Potatoes              | -18    | 24                  | 24                | -                         | -                        | -               | 24         |
|                           | Wheat grain           | -18    | -                   | -                 | 23                        | 23                       | Not stable (converted within 28 days) into M04; sum stable for 24 months | -          |
High acid content | Grapes | -18 | 24 | 24 | - | - | 6 months (unstable in 9-24 month samples), assumed to be converted into M01 but not confirmed

| Strawberries | -18 | - | - | 23 | 23 | 23 | - |

Additional data were supplied on storage at elevated temperature over a 7 day period and there was no evidence of decline greater than 30% during the storage of the fortified matrices (tomato, wheat green materials, grapes, wheat grain, potato tuber, dry pea and rape seed) for methiocarb, methiocarb sulfoxide (M01), methiocarb sulfone (M02), methiocarb sulfoxide phenol (M04) and methiocarb sulfone phenol (M05).

| Animal | Animal commodity | T (°C) | Stability (Month/Year) |
|--------|------------------|--------|-----------------------|
|        | Muscle           |        |                       |
|        | Liver            | -18    | -                     |
|        | Kidney           | -      | -                     |
|        | Milk             | -      | -                     |
|        | Egg              | -      | -                     |

Not required
### Summary of residues data from the supervised residue trials (Regulation (EU) No 283/2013, Annex Part A, point 6.3)

| Crop          | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) | STMR (mg/kg) |
|---------------|---------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|------------|-------------|
| **Representative uses** | | | | | | |
| Maize         | NEU           | Maize grain: Methiocarb 4 x <0.01
M01 4 x <0.01
M03 4 x <0.01
M04 4 x <0.01
M05 4 x <0.01
Maize forage: Methiocarb 4 x <0.01
M01 4 x <0.01
M03 4 x <0.01
M04 4 x <0.01
M05 4 x <0.01 | | Open | Open | Open |
| SEU           | Maize grain: Methiocarb | | | | | |
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) (d) | STMR (mg/kg) (d)  
--- | --- | --- | --- | --- | --- | ---  
Maize forage: Methiocarb | 4 x <0.01 M01 4 x <0.01 M03 4 x <0.01 M04 4 x <0.01 M05 4 x <0.01 |  |  |  |  |  

Summary of the data on formulation equivalence

Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1):
Though no data was provided the data requirement is addressed considering the very limited translocation of methiocarb and metabolites residues throughout the different plant parts observed from the GAP compliant residue trials on maize. The consumer exposure to residues of methiocarb and metabolites in pollen and bee products is therefore expected to be negligible.
| 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) |
|------|------------------|-------------------------------------------------|---------------------------------------------|---------------------|----------------|----------------|
|      |                  |                                                 |                                             |                     |                |                |

(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).
## Inputs for animal burden calculations\(^{(1)}\)

| Feed commodity         | Median dietary burden (mg/kg) | Comment | Maximum dietary burden (mg/kg) | Comment |
|------------------------|-------------------------------|---------|-------------------------------|---------|
| **Representative uses**|                               |         |                               |         |
| Maize grain            | Open                          | STMR    | Open                          | STMR    |
| Maize forage/silage    | Open                          |         | Open                          |         |
| Maize stover           | Open                          |         | Open                          |         |
| Maize grain by products| Open                          |         | Open                          |         |

\(^{(1)}\): The plant residue definition for risk assessment is not finalised, the calculation of the livestock dietary burden cannot therefore be conducted.
## 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)

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | | | | |
| Beef cattle | N/A | Breeding | N/A | Broiler | N/A | Carp | N/A |
| Dairy cattle | N/A | Finishing | N/A | Layer | N/A | Trout | N/A |
| Ram/Ewe | N/A | | | Turkey | N/A | | |
| Lamb | N/A | | | | | | |
| Intake >0.004 mg/kg bw | Open | Open | Open | Open | N/A | Fish intake >0.1 mg/kg DM |
| Feeding study submitted | No | No | No | No | No | No |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | | | | |
| Level | Beef: N | Lamb: N | Level | N rate | Level | B or T: N | Level | N rate |
| Beef: N | Dairy: N | Ewe: N | Breed/Finish | | Layer: N | | Carp/Trout |
| Estimated HR\(^{a}\) at 1N | MRL proposals | Estimated HR\(^{a}\) at 1N | MRL proposals | Estimated HR\(^{a}\) at 1N | MRL proposals | Estimated HR\(^{a}\) at 1N | MRL proposals |
| Muscle | | | | | | | |
| Fat | | | | | | | |
| Meat\(^{b}\) | | | | | | | |
| Liver | | | | | | | |
| Kidney | | | | | | | |
| Milk\(^{a}\) | | | | | | | |
| Eggs | | | | | | | |
| Method of calculation\(^{c}\) | | | | | | | |

\(^{a}\): 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 extrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
### STMR calculations

| Median expected intake (mg/kg bw/d) (mg/kg DM for fish) | Ruminant | Pig/Swine | Poultry | Fish |
|--------------------------------------------------------|----------|-----------|---------|------|
| Beef cattle                                            | N/A      | N/A       | Breeding | N/A  |
| Dairy cattle                                           | N/A      | Lamb      | Finishing| N/A  |
| Ram/Ewe                                               | N/A      |           |          |      |
| N/A                                                    |          |           |          |      |
| Breeding                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Badger                                                 |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Movie                                                  |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Sheep                                                  |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig                                                    |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Beef                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pork                                                   |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Porcine                                            |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Piglet                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Rabbit                                                 |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Emu                                                |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Feather                                            |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Chicken                                            |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Goose                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Sheep                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Deer                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Donkey                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Camel                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Cow                                                |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Horse                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Goat                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Pig                                                |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Peacock                                            |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Pigeon                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Parrot                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Parake                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Duck                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Chicken                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Goose                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Sheep                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Deer                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Donkey                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Camel                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Cow                                                |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Horse                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Goat                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Pig                                                |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Peacock                                            |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Pigeon                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Parrot                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Parake                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Duck                                               |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Chicken                                             |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Goose                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
| Pig/Sheep                                              |          |           |          |      |
| N/A                                                    |          |           |          |      |
Processing factors (Regulation (EU) No 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies<sup>(a)</sup> | Processing Factor (PF) | Conversion Factor (CF<sub>P</sub>) for RA<sup>(b)</sup> |
|---------------------------------------------------------|-------------------------------|------------------------|----------------------------------|
| Representatives uses                                    |                               | Individual values       | Median PF                        |
| Not required                                            |                               |                        |                                  |

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

<sup>(b)</sup>: When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) No 283/2013, Annex Part A, point 6.9)<sup>(2)</sup>
Including all uses (representative uses and uses related to an MRL application)

**ADI**
- TMDI according to EFSA PRIMo: 0.00025 mg/kg bw per day
- NTMDI, according to UK model: Highest NTMDI: Open
- IEDI (% ADI), according to EFSA PRIMo: Highest IEDI: Open
- NEDI (% ADI), according to (UK model): Highest NEDI: Open

Factors included in the calculations:

**ARfD**
- IESTI (% ARfD), according to EFSA PRIMo: Highest IESTI: Open
- NESTI (% ARfD), according to (UK model): Highest NESTI: Open

Factors included in IESTI and NESTI:

(2): As for the pending finalisation of the plant residue definition for risk assessment in absence of toxicity data to rule out the genotoxicity potential of M01, a dietary risk assessment for the consumer cannot be conducted.

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

| Code<sup>(a)</sup> | Commodity/Group | MRL/Import tolerance<sup>(b)</sup> (mg/kg) and Comments |
|--------------------|----------------|----------------------------------------------------------|
| Plant commodities  |                |                                                          |
| Representative uses|                |                                                          |
| 0500030            | Maize          | -                                                       |

No MRL proposal. Finalisation of the plant monitoring residue definition is pending upon the outcome of the requested data on potential genotoxicity of M01.

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

<sup>(b)</sup>: MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
### Environmental fate and behaviour

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

| Parameter | Description | Values<br>(% of applied) | Notes |
|-----------|-------------|--------------------------|-------|
| Mineralisation after 100 days | | 23.5 – 58.0% at 120 d, median: 36.95% (n=4), [phenyl-1-\(^{14}\)C]methiocarb. Note: minimum value of 23.5% is an underestimate due to losses in the experiment | |
| | | 17% after 91 days (n=1), [phenyl-1-\(^{14}\)C]methiocarb | |
| Non-extractable residues after 100 days | | 31.2 – 49.9% at 120 d, median: 41.3% (n=4), [phenyl-1-\(^{14}\)C]methiocarb | |
| | | 39% after 91 d (n=1), [phenyl-1-\(^{14}\)C]methiocarb | |
| Metabolites requiring further consideration | - name and/or code, % of applied (range and maximum) | methiocarb sulfoxide (M01), phenyl label: max 30.0 – 58.8%, at 1 – 29 d. | |
| | | methiocarb sulfoxide phenol (M04), phenyl label: max 18.0 – 36.0%, at 7 – 64 d | |
| | | methiocarb sulfone phenol (M05), phenyl label: max 6.1 – 19.8% at 17 – 91 d | |
| | | methiocarb methoxy sulfone (M10), phenyl label: max 3.3 – 13.2%, at 17 – 217 d | |

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

| Parameter | Description | Values<br>(% of applied) | Notes |
|-----------|-------------|--------------------------|-------|
| Mineralisation after 100 days | | 4 % at 64 d, \[^{14}\text{C-phenyl-1}\]-label (n= 1) | |
| Non-extractable residues after 100 days | | 12 % at 64 d, \[^{14}\text{C-phenyl-1}\]-label (n= 1) | Study carried out with 14 days under aerobic conditions followed by 64 days anaerobic conditions after flooding. |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | | Methiocarb sulfoxide (M01), phenyl label: 1% at 64 d (n=1). Max: 24% at 0 d [considered to be residual from aerobic phase of study] (n=1) | |
| | | methiocarb phenol (M03), phenyl label: max 47% at 64 d (n=1) | |
Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)  

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

| Metabolite                          | Phenyl label | % of applied (range and maximum) |
|-------------------------------------|--------------|----------------------------------|
| methiocarb sulfoxide (M01)          |              | max 57.2% at 1 d, 28.9% at 9 d (n=1, study ‘a’) |
|                                     |              | max 42.8% at 15 d, 23.1% at 30d (n=1, study ‘b’) |
| methiocarb sulfoxide phenol (M04)   |              | max 28.8% at 7 d, 26.4% at 9 d (n=1, study ‘a’) |

Mineralisation at study end  

| Mineralisation                      | % at 9 d [14C-phenyl-1] label (n=1, study “a”) |
|-------------------------------------|-----------------------------------------------|
|                                     | 7.6 % at 9 d [14C-phenyl-1] label (n=1, study “a”) |

Non-extractable residues at study end  

| Non-extractable residues            | % at 9 d [14C-phenyl-1] label (n=1, study “a”) |
|-------------------------------------|-----------------------------------------------|
|                                     | 12.6 % at 9 d [14C-phenyl-1] label (n=1, study “a”) |

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)  

| Methiocarb | Dark aerobic conditions (normalised modelling endpoints) | Values normalised to 20°C, 100 % FC. |
|------------|----------------------------------------------------------|-------------------------------------|
|            | Soil type                                                | Label | pH | t. °C / % MWHC | DT₅₀ / DT₉₀ (d) | DT₅₀ (d) 20 °C pF2/10kPa | St. (χ²) | Method of calculation |
|            | Loamy sand (BBA 2.2)                                     | phenyl | 6.3 | 20 / 40       | 1.2 / 4.0 | 1.2 | 8.5 | SFO |
|            | Silt loam (Frankenforst)                                 | phenyl | 7.6 | 20 / 40       | 0.9 / 3.1 | 0.68 | 12.4 | SFO |
|            | Silt (Höfchen am Hohenseh)                               | phenyl | 7.2 | 20 / 40       | 0.5 / 1.7 | 0.50 | 15.8 | SFO |
|            | Sandy loam (Laacher Hof)                                 | phenyl | 6.4 | 20 / 40       | 1.1 / 3.5 | 0.91 | 9.2 | SFO |
|            | Sandy loam (Howe)                                        | phenyl | 6.7 | 24 / 75        | 14.5 / 48.1 | 11.0 | 4.3 | SFO |
|            | Geometric mean (if not pH dependent)                     | Geometric mean (if not pH dependent) | 1.33 |
|            | pH dependence                                            | pH dependence | No |

**Notes:**  
a) Measured in calcium chloride solution  
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7  
c) % of soil water content at pF=2.5 or 33 kPa matric potential
Methiocarb | Dark aerobic conditions (trigger endpoints normalised to 20 °C for Howe soil)
---|---
Soil type | Label | pH | t. °C / % MWHC | DT$_{50}$ / DT$_{90}$ (d) | St. (χ²) | Method of calculation
Loamy sand (BBA 2.2) | phenyl | 6.3 | 20 / 40 | 1.06 / 4.7 | 1.3 | DFOP
Silt loam (Frankenforst) | phenyl | 7.6 | 20 / 40 | 0.83 / 3.7 | 1.1 | DFOP
Silt (Höfchen am Hohenseh) | phenyl | 7.2 | 20 / 40 | 0.38 / 2.9 | 4.3 | DFOP
Sandy loam (Laacher Hof) | phenyl | 6.4 | 20 / 40 | 0.94 / 4.2 | 1.7 | DFOP
Sandy loam (Howe) | phenyl | 6.7 | 24 / 75$^{b)}$ | 20.2 / 84$^{c)}$ | 2.79 | FOMC

Geometric mean (if not pH dependent) | No

pH dependence | No

$^{a)}$ Measured in calcium chloride solution
$^{b)}$ % of soil water content at pF=2.5 or 33 kPa matric potential
$^{c)}$ At study temperature (24°C) DT$_{50}$ / DT$_{90}$ are 14.1 / 58.5 days

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

| Methiocarb sulfoxide (M01) | Dark aerobic conditions (normalised modelling endpoints)
---|---
The precursor from which the f.f. was derived was methiocarb

| Soil type | Label | pH | t. °C / % MWHC | DT$_{50}$ / DT$_{90}$ (d) | f. f. k$_f$ / k$_{dp}$ | DT$_{50}$ (d) 20 °C pF2/10kPa$^{b)}$ | St. (χ²) | Method of calculation
|---|---|---|---|---|---|---|---|---|
Loamy sand (BBA 2.2) | phenyl | 6.3 | 20 / 40 | 6.2 / 20.4 | 1 | 6.2 | 12.4 | SFO
Silt Loam (Frankenforst) | phenyl | 7.6 | 20 / 40 | 1.7 / 5.5 | 0.90 | 1.2 | 15.3 | SFO
Silt (Höfchen am Hohenseh) | phenyl | 7.2 | 20 / 40 | 3.8 / 12.6 | 0.81 | 3.6 | 12.5 | SFO
Sandy Loam (Laacher Hof) | phenyl | 6.4 | 20 / 40 | 2.23$^{c)}$ / 27.6$^{d)}$ / 37.0$^{e)}$ | 0.92 | 30.5$^{g)}$ | 14.0 | DFOP$^{g)}$
Sandy Loam (Howe) | phenyl | 6.7 | 24 / 75$^{f)}$ | 14.6 / 48.3 | 0.89 | 11.0 | 10.3 | SFO

Geometric mean (if not pH dependent) | 6.2
Arithmetic mean | 0.9

pH dependence | No

$^{a)}$ Measured in calcium chloride solution
$^{b)}$ Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
$^{c)}$ Fast phase, calculated as ln(2)/K$_1$
$^{d)}$ Slow phase, calculated as ln(2)/K$_2$
$^{e)}$ Overall DT$_{90}$
$^{f)}$ % of soil water content at pF=2.5 or 33 kPa matric potential
$^{g)}$ g = 0.75
### Methiocarb sulfoxide phenol (M04)

#### Dark aerobic conditions (normalised modelling endpoints)

The precursor from which the f.f. was derived was methiocarb sulfoxide phenol.

| Soil type                  | Label | pH | t. °C / % MWHC | DT$_{50}$/ DT$_{90}$ (d) | f. f. k$_{f}$/ k$_{dp}$ | DT$_{50}$ (d) 20 °C pF2/10kPa | St. ($\chi^2$) | Method of calculation |
|----------------------------|-------|----|----------------|--------------------------|-------------------------|-----------------------------|----------------|-----------------------|
| Loamy sand (BBA 2.2)      | phenyl| 6.3| 20 / 40        | 3.8 / 12.6               | 1                       | 3.8                         | 12.5           | SFO                   |
| Silt Loam (Frankenforst)  | phenyl| 7.6| 20 / 40        | 3.6 / 12.1               | 1                       | 2.6                         | 14.2           | SFO                   |
| Silt (Höfchen am Hohenseh)| phenyl| 7.2| 20 / 40        | 2.8 / 9.2                | 1                       | 2.7                         | 23.4           | SFO                   |
| Sandy Loam (Laacher Hof)  | phenyl| 6.4| 20 / 40        | 10.9 / 36.1              | 0.79                    | 9.0                         | 12.2           | SFO                   |
| Sandy Loam (Howe)         | phenyl| 6.7| 24 / 75        | 61.8/205                 | 0.64                    | 46.7                        | 20.5           | SFO                   |

**Geometric mean (if not pH dependent):**

| **Arithmetic mean** | **0.85** |
|---------------------|----------|

**pH dependence:**

No

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*a* Measured in calcium chloride solution  
*b* Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7  
*c* % of soil water content at pF=2.5 or 33 kPa matric potential

### Methiocarb sulfone phenol (M05)

#### Dark aerobic conditions (normalised modelling endpoints)

The precursor from which the f.f. was derived was methiocarb sulfoxide phenol.

| Soil type                  | Label | pH | t. °C / % MWHC | DT$_{50}$/ DT$_{90}$ (d) | f. f. k$_{f}$/ k$_{dp}$ | DT$_{50}$ (d) 20 °C pF2/10kPa | St. ($\chi^2$) | Method of calculation |
|----------------------------|-------|----|----------------|--------------------------|-------------------------|-----------------------------|----------------|-----------------------|
| Loamy sand (BBA 2.2)      | phenyl| 6.3| 20 / 40        | 14.2/47.3                | 0.41                    | 14.2                        | 40.8           | SFO                   |
| Silt Loam (Frankenforst)  | phenyl| 7.6| 20 / 40        | 8.0 / 26.4               | 0.17                    | 5.9                         | 9.2            | SFO                   |
| Silt (Höfchen am Hohenseh)| phenyl| 7.2| 20 / 40        | 4.7 / 15.6               | 0.51                    | 4.5                         | 15.5           | SFO                   |
| Sandy Loam (Howe)         | phenyl| 6.7| 24 / 75        | 61.8/205                 | 0.64                    | 46.7                        | 9.7            | SFO                   |

**Geometric mean (if not pH dependent):**

| **Arithmetic mean** | **11.5** |
|---------------------|----------|

**pH dependence:**

No

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*a* Measured in calcium chloride solution  
*b* Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7  
*c* % of soil water content at pF=2.5 or 33 kPa matric potential
The dark aerobic conditions (normalised modelling endpoints) with the precursor from which the f.f. was derived was methiocarb sulfo analogue (M10).

### Soil type

| Soil type                      | Label | pH | t °C / % MWHC | DT₅₀/ DT₉₀ (d) | f. f. kₜ / kₛₚ | DT₅₀ (d) 20 °C pF2/10kPa | St. (χ²) | Method of calculation |
|-------------------------------|-------|----|--------------|----------------|-------------------|------------------------|----------|----------------------|
| Loamy sand (BBA 2.2)          | phenyl| 6.3| 20 / 40      | 27.5/91.3      | 0.80             | 27.5                   | 13.0     | SFO                  |
| Silt Loam (Frankenforst)       | phenyl| 7.6| 20 / 40      | 25.7 / 85.5    | -                | 18.8                   | 3.1      | SFO - topdown        |
| Silt (Höfchen am Hohenseh)     | phenyl| 7.2| 20 / 40      | 49.8 / 166     | -                | 47.5                   | 8.55     | SFO - topdown        |
| Sandy Loam (Howe)              | phenyl| 6.7| 24 / 75      | 66.7/222       | -                | 50.4                   | 6.4      | SFO                  |
| Geometric mean (if not pH dependent) |       |    |              |                |                  |                        |          | 33.4                 |
| Arithmetic mean                |       |    |              |                |                  |                        |          | 0.80                 |
| pH dependence                  |       |    |              |                |                  |                        |          | No                   |

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

| Parent                                      | Aerobic conditions                                      |
|---------------------------------------------|---------------------------------------------------------|
|                                              | No data submitted and no data required                  |

**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)

No data submitted and no data required

* 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 data submitted and no data required

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

Soil photolysis

Methiocarb DT₅₀ = 3.36 days in natural summer sunlight at 33.3°N (DT₉₀ = 80.9 days). HS kinetics
Soil adsorption active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Soil Type                     | OC % | Soil pH | \(K_d\) (mL/g) | \(K_{SOIL}\) (mL/g) | \(K_F\) (mL/g) | \(K_{FOC}\) (mL/g) | 1/n |
|-------------------------------|------|---------|---------------|------------------|--------------|----------------|-----|
| Sand (Howe)                   | 0.52 | 4.3     | 5.3           | 1000             | 1000         | 0.87           |
| Sandy loam (Howe)             | 0.68 | 4.9     | 4.3           | 632              | 1000         | 0.83           |
| Silt loam (Stanley)           | 1.53 | 5.9     | 9.0           | 600              | 1000         | 0.82           |
| Clay loam (Hagerstown)        | 1.16 | 6.3     | 4.9           | 408              | 1000         | 0.81           |

Geometric mean (if not pH dependent) 627
Arithmetic mean (if not pH dependent) 660 0.83

pH dependence No

* Measured in calcium chloride solution

Soil adsorption transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

**Methiocarb Sulfoxide (M01)**
Estimated value 31.26 mL/g (HPLC method).
pH dependency not tested. pH dependence unlikely due to structural similarity to the parent, which shows neither basic nor acidic properties in aqueous systems.

**Methiocarb Sulfoxide Phenol (M04)**

| Soil Type                      | OC % | Soil pH | \(K_d\) (mL/g) | \(K_{SOIL}\) (mL/g) | \(K_F\) (mL/g) | \(K_{FOC}\) (mL/g) | 1/n |
|-------------------------------|------|---------|---------------|------------------|--------------|----------------|-----|
| Loamy sand (BBA 2.2)          | 2.48 | 6.3     | 0.6611        | 26.7             | 0.8915       |
| Sand (BBA 2.1)                | 0.70 | 5.3     | 0.1885        | 26.9             | 0.9099       |
| Silt loam (Laacher Hof)       | 0.90 | 7.3     | 0.4343        | 48.2             | 0.8902       |
| Silty clay (Lufa Speyer)      | 0.64 | 7.4     | 0.6466        | 101.0            | 0.9009       |

Geometric mean (if not pH dependent)* 43.2
Arithmetic mean (if not pH dependent) 0.4826 50.7 0.9

pH dependence No

* Measured in calcium chloride solution

**Methiocarb Sulfone Phenol (M05)**

| Soil Type                      | OC % | Soil pH | \(K_d\) (mL/g) | \(K_{SOIL}\) (mL/g) | \(K_F\) (mL/g) | \(K_{FOC}\) (mL/g) | 1/n |
|-------------------------------|------|---------|---------------|------------------|--------------|----------------|-----|
| Sand (BBA 2.1)                | 0.38 | 5.6     | 0.6195        | 163.0            | 0.8704       |
| Sandy loam (Laacher Hof AXXa)  | 1.02 | 6.3     | 1.5386        | 150.8            | 0.9023       |
| Silt loam (Laacher Hof AIII)   | 0.98 | 7.4     | 0.9057        | 92.4             | 0.8431       |
| Silt                          | 1.55 | 6.5     | 1.3377        | 86.3             | 0.8886       |
| Soil Type                  | OC % | Soil pH | $K_d$ (mL/g) | $K_{d,oc}$ (mL/g) | $K_F$ (mL/g) | $K_{F,oc}$ (mL/g) | 1/n |
|---------------------------|------|---------|--------------|-------------------|-------------|------------------|-----|
| Sand                      | 0.38 | 5.6     | 0.9027       | 237.6             | 0.8405      |                  |     |
| Sandy loam                | 1.02 | 6.3     | 2.5700       | 252.0             | 0.8586      |                  |     |
| Silt loam                 | 0.98 | 7.4     | 1.2078       | 123.2             | 0.8414      |                  |     |
| Silt                      | 1.55 | 6.5     | 2.4881       | 145.0             | 0.8620      |                  |     |
| (Hoefchen am Hohenseh 4a) |      |         |              |                   |             |                  |     |

**Methiocarb Methoxy Sulfone (M10)**

| Soil Type                  | OC % | Soil pH | $K_d$ (mL/g) | $K_{d,oc}$ (mL/g) | $K_F$ (mL/g) | $K_{F,oc}$ (mL/g) | 1/n |
|---------------------------|------|---------|--------------|-------------------|-------------|------------------|-----|
| Sand                      | 0.38 | 5.6     | 0.9027       | 237.6             | 0.8405      |                  |     |
| Sandy loam                | 1.02 | 6.3     | 2.5700       | 252.0             | 0.8586      |                  |     |
| Silt loam                 | 0.98 | 7.4     | 1.2078       | 123.2             | 0.8414      |                  |     |
| Silt                      | 1.55 | 6.5     | 2.4881       | 145.0             | 0.8620      |                  |     |

**Geometric mean (if not pH dependent)**: 118

**Arithmetic mean (if not pH dependent)**: 1.10, 123, 0.88

**pH dependence**: No

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HOECHEN AM HOHENSEH 4A

Geometric mean (if not pH dependent)

Arithmetic mean (if not pH dependent)

pH dependence

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Geometric mean (if not pH dependent)

Arithmetic mean (if not pH dependent)

pH dependence

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**Measured in calcium chloride solution**
Mobility in soil column leaching active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching | No information submitted. None required. |

Mobility in soil column leaching transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching | No information submitted. None required. |

Lysimeter / field leaching studies (Regulation (EU) No 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) No 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

| Lysimeter/ field leaching studies | No information submitted. None 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 % | pH 5: 321 days at 25 °C (1st order)  
Methiocarb sulfoxide: 54.8 days at 25 °C  
Methiocarb phenol: 46 % AR (30 d)  
Methiocarb sulfoxide: 0.5 days at 25 °C  
Methiocarb phenol: 82 % AR (3 d)  
Methiocarb sulfoxide phenol: 10.5 % AR (1 d) |

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: 8.17 days  
Natural light, 33.3°N; DT50 31 days Phoenix, Arizona  
Natural light, 37.58°N; DT50 48 days Athens, Greece  
DT50 at pH 5 (acetate buffer), exposed to natural sunlight (Kentucky, USA, 38.05°N, 84.30°W) in January and February, mean temperature of solutions 24.9°C: experimental half-life: >30 days in both the irradiated (88 days) and dark control |
Quantum yield of direct phototransformation in water at Σ > 290 nm

A quantum yield Φ of 0.2828 was calculated. The quantum yield and UV absorption were used to estimate the environmental half-life of methiocarb in water by two simulation models (GC-SOLAR and Frank & Klöpffer). The estimates based on these models resulted in environmental direct photolysis half-lives of about 6 to 16 days for all relevant scenarios investigated (ie. spring and summer application at the 50th degree of latitude). The direct photodegradation in water was concluded only to contribute to a small proportion of the elimination of methiocarb from the environment.

DT₅₀ at pH 5 (acetate buffer), exposed to simulated sunlight (xenon lamp, 290 nm UV filter) at 25°C:

Experimental half-life: 8.17 days, corresponding to a predicted environmental half-life of 31 solar summer days at Phoenix, Arizona and 48 solar summer days at Athens, Greece.

DT₅₀ at pH 5 (acetate buffer), exposed to natural sunlight (Kentucky, USA, 38.05°N, 84.30°W) in January and February, mean temperature of solutions 24.9 °C: experimental half-life: >30 days in both the irradiated (88 days) and dark control samples (238 days)

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

Readily biodegradable (yes/no)

No data submitted, none required. In the absence of data this compound is considered to be not readily biodegradable.

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

Methiocarb

No data submitted. None required when only uses as a seed treatment has been requested and there is a statutory condition of use that treated seed must be drilled at 3 cm or deeper.
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)

| Methiocarb | Distribution (max. sed 36.7 % after 3 d) |
|------------|------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | Method of calculation |
| Angler Weiher | 7.6 | 7.1 | 20 | 1.9/6.3 | 3.6 | 1.2/4.0 | 3.0 | 4.3/14.4 | 8.1 | SFO/SFO/SFO |
| Hoenniger Weiher | 8.0 | 6.6 | 20 | 8.3/27.7 | 8.7 | 2.2/7.4 | 12 | 26.9/89.5 | 8.2 | SFO/SFO/SFO |
| Geometric mean at 20°C<sup>a</sup> | 4.0/13.1 | 1.6/5.4 | 10.8/35.9 |

<sup>a</sup> Measured in calcium chloride solution

| Methiocarb phenol (M03) | Distribution (max in water 15.2 % after 3 d. max. sed 16.5 % after 14 d. max in total system 19.2 % after 3 days) |
|------------------------|-------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | Method of calculation |
| Angler Weiher | 7.6 | 7.1 | 20 | 70.1/233 | 13.7 | SFO – top down |
| Hoenniger Weiher | 8.0 | 6.6 | 20 | 154/513 | 4.2 | SFO – top down |
| Geometric mean at 20°C<sup>a</sup> | 103.9/345.7 |

<sup>a</sup> Measured in calcium chloride solution

| Methiocarb sulfoxide phenol (M04) | Distribution (max in water 34.1 % after 7 d. max. sed 7.0 % after 62 d. max in total system 40.2 % after 14 days) |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | DT<sub>50</sub>/DT<sub>90</sub> | St. (χ<sup>2</sup>) | Method of calculation |
| Angler Weiher | 7.6 | 7.1 | 20 | 44.9/149 | 6.7 | SFO – top down |
| Hoenniger Weiher | 8.0 | 6.6 | 20 | 51.0/170 | 13.5 | SFO – top down |
| Geometric mean at 20°C<sup>a</sup> | 47.9/159.2 |

<sup>a</sup> Measured in calcium chloride solution

Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH | pH | 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) |
|------------------------|----|----|------------------------------------------------------|-----------------------------------------------|-----------------------------|
| Angler Weiher | 7.6 | 7.1 | max 25.3 % after 90 d (end of the study). | max 46.3 % after 62 d | max 45.2 % after 90 d (end of the study) |
Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| Fate and behaviour in air | Value |
|---------------------------|-------|
| Direct photolysis in air   | Not studied - no data requested |
| Photochemical oxidative degradation in air | DT50 of 9.5 hours derived by the Atkinson model (version 1.87. OH (24 h) concentration assumed = 1.5 x 10^6) |
| Volatilisation             | from plant surfaces (BBA guideline): not applicable for seed treatment |
|                           | from soil surfaces (BBA guideline): not applicable for seed treatment |
| Metabolites                | not applicable for seed treatment |

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

| Residues requiring further assessment | Value |
|--------------------------------------|-------|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure | Soil/Ground water: methiocarb, methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05), methiocarb methoxy sulfone (M10), Surface water/sediment: methiocarb, methiocarb sulfoxide (M01), methiocarb sulfoxide phenol (M04), methiocarb sulfone phenol (M05), methiocarb methoxy sulfone (M10), methiocarb phenol (M03) |
| Air                                   | Methiocarb |

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)

| Study Type                          | Result                                      |
|-------------------------------------|---------------------------------------------|
| Soil (indicate location and type of study) | None available and none required            |
| Surface water (indicate location and type of study) | None available and none required            |
| Ground water (indicate location and type of study) | None available and none required            |
| Air (indicate location and type of study) | None available and none required            |

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

| Parent       | DT50 (d): Not used |
|--------------|--------------------|
| Method of calculation | Kinetics: Only initial PEC calculated so kinetics not used |
| Field or Lab | Lab                |

**Application data**
- Crop: Maize
- Depth of soil layer: 5cm
- Soil bulk density: 1.5g/cm³
- % plant interception: Seed treatment therefore no crop interception
- Number of applications: 1
- Interval (d): n/a
- Application rate(s): 150 g a.s./ha

| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------------|---------------------------|------------------------------------------|-----------------------------|------------------------------------------|
| Initial                   | 0.200                     |                                          |                             |                                          |
| Plateau concentration     | Not applicable            |                                          |                             |                                          |
| Substance                        | Method of calculation | Application data                                                                 |
|---------------------------------|-----------------------|----------------------------------------------------------------------------------|
| Methiocarb sulfoxide (M01)      |                        | Molecular weight relative to the parent: 1.071 DT₅₀ (d): n/a Kinetics: n/a Field or Lab: n/a |
|                                 |                       | Application rate assumed: 94.46 g/ha (assumed M01 is formed at a maximum of 58.8 % of the applied dose) |
| **PEC**ₙₑₜ (mg/kg)              | Single application    | Single application Time weighted average Multiple application Multiple application |
| Initial                         | 0.126                 | -                                                                                |
| Plateau concentration           |                       |                                                                                  |
| Methiocarb sulfoxide phenol (M04)|                        | Molecular weight relative to the parent: 0.818 DT₅₀ (d): n/a Kinetics: n/a Field or Lab: n/a |
|                                 |                       | Application rate assumed: 43.9 g/ha (assumed M04 is formed at a maximum of 35.8 % of the applied dose) |
| **PEC**ₙₑₜ (mg/kg)              | Single application    | Single application Time weighted average Multiple application Multiple application |
| Initial                         | 0.059                 | -                                                                                |
| Plateau concentration           |                       |                                                                                  |
| Methiocarb sulfone phenol (M05) |                        | Molecular weight relative to the parent: 0.889 DT₅₀ (d): n/a Kinetics: n/a Field or Lab: n/a |
|                                 |                       | Application rate assumed: 26.4 g/ha (assumed M05 is formed at a maximum of 19.8 % of the applied dose) |
| **PEC**ₙₑₜ (mg/kg)              | Single application    | Single application Time weighted average Multiple application Multiple application |
| Initial                         | 0.035                 | -                                                                                |
| Plateau concentration           |                       |                                                                                  |
| Methiocarb methoxy sulfone (M10)|                        | Molecular weight relative to the parent: 0.951 DT₅₀ (d): n/a                     |
|                                 |                       |                                                                                  |
Application data

| Kinetics: n/a  | Field or Lab: n/a |
|----------------|-------------------|
| Application rate assumed: 18.8 g/ha (assumed M10 is formed at a maximum of 13.2 % of the applied dose) |

| **PEC<sub>1</sub>** (mg/kg) | Single application | Single application | Multiple application | Multiple application |
|-----------------------------|--------------------|--------------------|----------------------|----------------------|
|                             | Actual             | Time weighted average | Actual              | Time weighted average |
| Initial                     | 0.025              | -                  | -                    | -                    |
| Plateau concentration       | Not applicable     |                    |                      |                      |
PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, FOCUS MACRO 5.5.4

Crop: Maize
Crop interception: Seed treatment therefore no crop interception

Water solubility 27.0 (mg/L) at unknown pH and 20°C
Vapour pressure: 1.5 x 10^-5 Pa at 20°C
Geometric mean parent DT_50 lab = 1.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). *
* DT_50 value of 1.33 days should be used for future modelling.

K_OC: 627 mL/g geometric mean, 1/n = 0.83
Crop uptake factor: 0

Metabolites:

**Methiocarb sulfoxide (M01)**
Crop uptake factor: 0
Water solubility (mg/L): 10000
Vapour pressure: 0 Pa
Geometric mean DT_50 = 5.9 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). *
KOC: 31.26 mL/g geometric mean
1/n= 1.0.
Formation fraction: 0.9 from methiocarb

* DT_50 value of 6.2 days should be used for future modelling.

**Methiocarb sulfoxide phenol (M04)**
Crop uptake factor: 0
Water solubility (mg/L): 10000
Vapour pressure: 0 Pa
Geometric mean DT_50 = 6.0 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).
KOC: 43.2 mL/g geometric mean
1/n= 0.9.
Formation fraction: 0.85 from methiocarb sulfoxide

**Methiocarb sulfone phenol (M05)**
Crop uptake factor: 0
Water solubility (mg/L): 10000
Vapour pressure: 0 Pa
Geometric mean DT\textsubscript{50} = 11.6 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).*
KOC: 118 mL/g geometric mean
1/n = 0.88.
Formation fraction: 0.43 from methiocarb sulfoxide phenol

* DT\textsubscript{50} value of 11.5 days should be used for future modelling.

**Methiocarb methoxy sulfone (M10)**
Crop uptake factor: 0
Water solubility (mg/L): 10000
Vapour pressure: 0 Pa
Geometric mean DT\textsubscript{50} = 33.7 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).*
KOC: 181 mL/g geometric mean
1/n = 0.85.
Formation fraction: 0.8 from methiocarb sulfone phenol

* DT\textsubscript{50} value of 33.4 days should be used for future modelling.

| Application rate |
|------------------|
| Gross application rate: 150 g/ha. |
| Crop growth stage: 0 |
| Canopy interception %: Seed treatment therefore no crop interception |
| Application rate net of interception: 150 g/ha. |
| No. of applications: 1 |
| Time of application (relative application dates): Date of emergence -10 days |
### PEC(gw) - FOCUS modelling results (80\textsuperscript{th} percentile annual average concentration at 1m)

| Scenario       | Methiocarb (µg/L) | Metabolites (µg/L) | Methiocarb Sulfoxide (M01) | Methiocarb Sulfoxide Phenol (M04) | Methiocarb Sulfone Phenol (M05) | Methiocarb Methoxy Sulfone (M10) |
|----------------|-------------------|--------------------|---------------------------|----------------------------------|-------------------------------|----------------------------------|
| PEARL/Maize, 1 x 150 g a.s./ha |                  |                    |                           |                                  |                               |                                  |
| Chateaudun     | <0.001            | <0.001             | <0.001                    | <0.001                           | <0.001                        | <0.001                           |
| Hamburg        | <0.001            | 0.003              | 0.002                     | 0.001                            | 0.002                         | 0.002                            |
| Kremsmunster   | <0.001            | 0.002              | 0.002                     | 0.001                            | 0.002                         |                                  |
| Okehampton     | <0.001            | 0.005              | 0.007                     | 0.002                            | 0.004                         |                                  |
| 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                           |
| PELMOMaize, 1 x 150 g a.s./ha |                  |                    |                           |                                  |                               |                                  |
| Chateaudun     | <0.001            | <0.001             | <0.001                    | <0.001                           | <0.001                        | <0.001                           |
| Hamburg        | <0.001            | 0.001              | 0.001                     | 0.001                            | 0.007                         |                                  |
| Kremsmunster   | <0.001            | 0.002              | 0.002                     | 0.001                            | 0.008                         |                                  |
| Okehampton     | <0.001            | 0.007              | 0.007                     | 0.002                            | 0.015                         |                                  |
| Piacenza       | <0.001            | <0.001             | <0.001                    | <0.001                           | 0.001                         |                                  |
| Porto          | <0.001            | 0.001              | 0.001                     | 0.001                            | 0.009                         |                                  |
| Sevilla        | <0.001            | <0.001             | 0.000                     | <0.001                           | <0.001                        | <0.001                           |
| Thiva          | <0.001            | <0.001             | 0.000                     | <0.001                           | <0.001                        | <0.001                           |

PEC\textsubscript{(gw)}: From lysimeter / field studies: not applicable
PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in FOCUSsw step 1 and 2

| Version control no. of FOCUS calculator: |
|-----------------------------------------|
| FOCUS STEPS 1+2 version 3.2             |
| Molecular weight (g/mol): 225.3         |
| $K_{OC}/K_{OM}$ (mL/g): 627/364 geometric mean |
| $DT_{50}$ soil (d): 1.4 (geomean lab value) * |

* $DT_{50}$ value of 1.33 days should be used for future modelling.

| $DT_{50}$ water/sediment system (d): 4.0 (geomean from sediment water studies) |
| $DT_{50}$ water (d): 4.0 |
| $DT_{50}$ sediment (d): 4.0 |
| Crop interception (%): 0 % (no canopy) |

Parameters used in FOCUSsw step 3 (if performed)

| Version control no.’s of FOCUS software: |
|-----------------------------------------|
| FOCUS SWASH version 5.3, MACRO version 5.5.4, PRZM version 4.6.2 and FOCUS TOXSWA version 4.4.3 |
| $DT_{50}$ soil (d): 1.4 (geomean lab value) * |

* $DT_{50}$ value of 1.33 days should be used for future modelling.

| $DT_{50}$ water (d): 4.0/1000 (simulations should be run with both combinations for ascribing the whole system $DT_{50}$ and default to $DT_{50}$ water and $DT_{50}$ sediment) |
| $DT_{50}$ sediment (d): 4.0/1000 (simulations should be run with both combinations for ascribing the whole system $DT_{50}$ and default to $DT_{50}$ water and $DT_{50}$ sediment) |
| Water solubility (mg/L): 27 |
| Vapour pressure: $1.5 \times 10^{-5}$ Pa at 20°C |
| $K_{OM}/K_{OC}$ (mL/g): 627/364 geometric mean |
| $1/n$: 0.83 |
| Q10=2.58, Walker equation coefficient 0.7 |
| Crop uptake factor: 0 |
| Drilling Depth: 2cm or 3cm |
Crop and growth stage: Maize BBCH 0
Number of applications: 1
Interval (d): n/a
Application rate(s): 150 g a.s./ha
Application window:

| Scenario | Application Date |
|----------|------------------|
| D3       | 04/05            |
| D4       | 18/04            |
| D5       | 11/05            |
| D6       | 10/04            |
| R1       | 26/04            |
| R2       | 22/04            |
| R3       | 22/04            |
| R4       | 07/04            |

FOCUS STEP 1

| Scenario | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|----------|---------------------------|-----------------|------------------|
|          |                           | Actual          | TWA              | Actual | TWA  |
| 0 h      |                           | 28.6            | 171              |

FOCUS STEP 2

| Scenario | Day after overall maximum | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) |
|----------|---------------------------|-----------------|------------------|
|          |                           | Actual          | TWA              | Actual | TWA  |
| Northern EU | 0 h         | 1.38            | 6.56             |
| Southern EU  | 0 h         | 1.95            | 11.28            |
### Drilling depth 2cm

| FOCUS STEP 3 Scenario | Water body | Day after overall maximum | \( \text{PEC}_{SW} (\mu g/L) \) | \( \text{PEC}_{SED} (\mu g/kg) \) |
|-----------------------|------------|---------------------------|-------------------------------|-------------------------------|
|                       |            | Actual | TWA | Actual | TWA |
| D3 ditch              | 0 h        | <0.001 |     | <0.001 |     |
| D4 pond               | 0 h        | <0.001 |     | <0.001 |     |
| D4 stream             | 0 h        | <0.001 |     | <0.001 |     |
| D5 pond               | 0 h        | <0.001 |     | <0.001 |     |
| D5 stream             | 0 h        | <0.001 |     | <0.001 |     |
| D6 ditch              | 0 h        | <0.001 |     | <0.001 |     |
| R1 pond               | 0 h        | <0.001 |     | <0.001 |     |
| R2 stream             | 0 h        | 0.032  | 0.010|       |     |
| R3 stream             | 0 h        | 0.003  | 0.001|       |     |
| R4 stream             | 0 h        | 0.053  | 0.029|       |     |

### Drilling depth 3cm

| FOCUS STEP 3 Scenario | Water body | Day after overall maximum | \( \text{PEC}_{SW} (\mu g/L) \) | \( \text{PEC}_{SED} (\mu g/kg) \) |
|-----------------------|------------|---------------------------|-------------------------------|-------------------------------|
|                       |            | Actual | TWA | Actual | TWA |
| D3 ditch              | 0 h        | <0.001 |     | <0.001 |     |
| D4 pond               | 0 h        | <0.001 |     | <0.001 |     |
| D4 stream             | 0 h        | <0.001 |     | <0.001 |     |
| D5 pond               | 0 h        | <0.001 |     | <0.001 |     |
| D5 stream             | 0 h        | <0.001 |     | <0.001 |     |
| D6 ditch              | 0 h        | <0.001 |     | <0.001 |     |
| R1 pond               | 0 h        | <0.001 |     | <0.001 |     |
| R1 stream             | 0 h        | <0.001 |     | <0.001 |     |
| R2 stream             | 0 h        | <0.001 |     | <0.001 |     |
| R3 stream             | 0 h        | <0.001 |     | <0.001 |     |
| R4 stream             | 0 h        | <0.001 |     | <0.001 |     |
Metabolite: Methiocarb sulfoxide (M01)

Parameters used in FOCUSsw step 1 and 2

- Molecular weight: 241.3
- Soil or water metabolite: soil
- Koc/Kom (mL/g): 31.26/18.13
- DT$_{50}$ soil (d): 5.9 *
- DT$_{50}$ water/sediment system (d): 1000
- DT$_{50}$ water (d): 1000
- DT$_{50}$ sediment (d): 1000
- Crop interception (%): 0
- Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water and Sediment: 0 %
- Soil: 58.8 %
- Crop uptake factor: 0

* DT$_{50}$ value of 6.2 days should be used for future modelling.

Parameters used in FOCUSsw step 3 (if performed)

- Water solubility (mg/L): 10000
- Vapour pressure: 0 Pa at 20°C
- Koc/Kom (mL/g): 31.26/18.13
- 1/n: 1.0
- DT$_{50}$ soil (d): 5.9 *
- DT$_{50}$ water (d): 1 (from hydrolysis study; Sneikus, 2001)
- DT$_{50}$ sediment (d): 1000
- Q10=2.58, Walker equation coefficient 0.7
- Crop uptake factor:
- Metabolite kinetically generated in simulation (yes/no): Yes
- Formation fraction in soil ($k_f/k_{dp}$): 0.9 from parent
- Formation fraction in sediment water ($k_f/k_{dp}$): n/a
- Cropt uptake factor: 0
- Drilling Depth: 2cm or 3cm

* DT$_{50}$ value of 6.2 days should be used for future modelling.

Application rate

- Crop and growth stage: Maize BBCH 0
- Number of applications: 1
- Interval (d): n/a
- Application rate(s): 150 g a.s./ha

Main routes of entry

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|-----------------------|--------------------------|-------------------|----------------------|
|                       | Actual | TWA  | Actual  | TWA  |
| 0h                    | 30.2   |      | 9.37    |      |
| FOCUS STEP 2 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|-----------------------|--------------------------|----------------------|----------------------|
|                       | Actual                   | TWA                  | Actual               |
| Northern EU           | 0 h                      | 3.78                 | 1.17                 |
| Southern EU           | 0 h                      | 7.56                 | 2.34                 |

**FOCUS STEP 3**

| Water body | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|------------|---------------------------|----------------------|----------------------|
|            | Actual                   | TWA                  | Actual               |
| D3 ditch   | 0 h                       | <0.001               | <0.001               |
| D4 pond    | 0 h                       | <0.001               | <0.001               |
| D4 stream  | 0 h                       | <0.001               | <0.001               |
| D5 pond    | 0 h                       | <0.001               | <0.001               |
| D5 stream  | 0 h                       | <0.001               | <0.001               |
| D6 ditch   | 0 h                       | <0.001               | <0.001               |
| R1 pond    | 0 h                       | <0.001               | <0.001               |
| R1 stream  | 0 h                       | 0.145                | 0.013                |
| R2 stream  | 0 h                       | 0.025                | 0.002                |
| R3 stream  | 0 h                       | <0.001               | <0.001               |
| R4 stream  | 0 h                       | 0.297                | 0.036                |
Drilling depth 3cm

| FOCUS STEP 3 Scenario | Water body | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|-----------------------|------------|---------------------------|-------------------------|-------------------------|
|                       |            | Actual | TWA   | Actual | TWA   |
| D3                    | ditch      | 0 h     | <0.001 |         | <0.001 |
| D4                    | pond       | 0 h     | <0.001 |         | <0.001 |
| D4                    | stream     | 0 h     | <0.001 |         | <0.001 |
| D5                    | pond       | 0 h     | <0.001 |         | <0.001 |
| D5                    | stream     | 0 h     | <0.001 |         | <0.001 |
| D6                    | ditch      | 0 h     | <0.001 |         | <0.001 |
| R1                    | pond       | 0 h     | <0.001 |         | <0.001 |
| R1                    | stream     | 0 h     | <0.001 |         | <0.001 |
| R2                    | stream     | 0 h     | <0.001 |         | <0.001 |
| R3                    | stream     | 0 h     | <0.001 |         | <0.001 |
| R4                    | stream     | 0 h     | <0.001 |         | <0.001 |

Metabolite: Methiocarb sulfoxide phenol (M04)

Parameters used in FOCUSsw step 1 and 2

- Molecular weight: 184.3
- Soil or water metabolite: soil and water
- K<sub>oc</sub>/K<sub>om</sub> (mL/g): 43.2/25.1 geometric mean
- DT<sub>50</sub> soil (d): 6.0
- DT<sub>50</sub> water/sediment system (d): 47.9
- DT<sub>50</sub> water (d): 47.9
- DT<sub>50</sub> sediment (d): 47.9
- Crop interception (%): 0
- Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water and Sediment: 40.2%
- Soil: 35.8%

Application rate

- Crop and growth stage: Maize BBCH 0
- Number of applications: 1
- Interval (d): n/a
- Application rate(s): 150 g a.s./ha

Main routes of entry

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|-----------------------|---------------------------|-------------------------|-------------------------|
|                       |                           | Actual | TWA   | Actual | TWA   |
| 0h                    | 29.9                      |         |        | 12.6   |        |

| FOCUS STEP 2 | Day after | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
| Scenario    | overall maximum | Actual | TWA | Actual | TWA |
|-------------|-----------------|--------|-----|--------|-----|
| Northern EU | 0 h             | 2.59   |     | 1.09   |     |
| Southern EU | 0 h             | 4.76   |     | 2.01   |     |

Metabolite: Methiocarb sulfone phenol (M05)

Parameters used in FOCUSsw step 1 and 2

| Molecular weight: 200.3 |
|-------------------------|
| Soil or water metabolite: soil and water |
| Koc/Kom (mL/g): 118/69 geometric mean |
| DT50 soil (d): 11.6* |
| DT50 water/sediment system (d): 1000 |
| DT50 water (d): 1000 |
| DT50 sediment (d): 1000 |
| Crop interception (%): 0 |
| Maximum occurrence observed (% molar basis with respect to the parent) |
| Total Water and Sediment: 6.6 % |
| Soil: 19.8% |
| * DT₅₀ value of 11.5 days should be used for future modelling. |

Application rate

| Crop and growth stage: maize BBCH 0 |
| Number of applications: 1 |
| Interval (d): n/a |
| Application rate(s): 150 g a.s./ha |

Main routes of entry

| FOCUS STEP 1 | Day after overall maximum | PEC₅₀ (µg/L) | PECSED (µg/kg) |
|--------------|---------------------------|--------------|----------------|
| Scenario     | PEC₅₀ (µg/L)               | Actual       | TWA | Actual       | TWA |
| 0h           | 10.2                      |              |     | 12.0         |     |

| FOCUS STEP 2 | Day after overall maximum | PEC₅₀ (µg/L) | PECSED (µg/kg) |
|--------------|---------------------------|--------------|----------------|
| Scenario     | PEC₅₀ (µg/L)               | Actual       | TWA | Actual       | TWA |
| Northern EU  | 0 h                       | 1.34         |     | 1.58         |     |
| Southern EU  | 0 h                       | 2.61         |     | 3.07         |     |

Metabolite: Methiocarb methoxy sulfone (M10)

Parameters used in FOCUSsw step 1 and 2

| Molecular weight: 214.3 |
|-------------------------|
| Soil or water metabolite: soil |
| Koc/Kom (mL/g): 181/105 geometric mean |
DT50 soil (d): 33.7 *
DT50 water/sediment system (d): 1000
DT50 water (d): 1000
DT50 sediment (d): 1000
Crop interception (%): 0
Maximum occurrence observed (% molar basis with respect to the parent)
Total Water and Sediment: 0%
Soil: 13.2%

* DT$_{50}$ value of 33.4 days should be used for future modelling.

### Application rate

- Crop and growth stage: Maize BBCH 0
- Number of applications: 1
- Interval (d): n/a
- Application rate(s): 150 g a.s./ha

### Main routes of entry

| FOCUS STEP 1 | Scenario | Day after overall maximum | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|--------------|----------|---------------------------|-------------------|---------------------|
|              |          | Actual | TWA              | Actual | TWA              |
|              | 0h       | 5.06   |                  | 9.15   |                  |

| FOCUS STEP 2 | Scenario     | Day after overall maximum | PEC$_{SW}$ (µg/L) | PEC$_{SED}$ (µg/kg) |
|--------------|--------------|---------------------------|-------------------|---------------------|
|              | Northern EU  | 0 h                       | 0.93              | 1.69                |
|              | Southern EU  | 0 h                       | 1.86              | 3.37                |
Metabolite: Methiocarb phenole (M03)

Parameters used in FOCUSsw step 1 and 2

- Molecular weight: 168.3
- Soil or water metabolite: water
- Koc/Kom (mL/g): 0
- DT50 soil (d): 1000
- DT50 water/sediment system (d): 103.9
- DT50 water (d): 103.9
- DT50 sediment (d): 103.9
- Crop interception (%): 0 %
- Maximum occurrence observed (% molar basis with respect to the parent)
- Total Water and Sediment: 19.2 %
- Soil: 0 %

Application rate

- Crop and growth stage: Maize BBCH 0
- Number of applications: 1
- Interval (d): n/a
- Application rate(s): 150 g a.s./ha

Main routes of entry

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|------------------------|--------------------------|-------------------------|-------------------------|
|                        |                          | Actual | TWA | Actual | TWA |
| 0h                     | 7.37                     | <0.001 | <0.001 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|------------------------|--------------------------|-------------------------|-------------------------|
|                        |                          | Actual | TWA | Actual | TWA |
| Northern EU 0 h        | 0.39                     | <0.001 | <0.001 |
| Southern EU 0 h        | 0.59                     | <0.001 | <0.001 |
Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

| There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary. |

PEC

Maximum concentration

| There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary. |
Ecotoxicology
Effects on birds and other terrestrial vertebrates (Regulation (EU) No 283/2013, Annex Part A, point 8.1 and Regulation (EU) No 284/2013, Annex Part A, point 10.1)

| Species                  | Test substance     | Time scale  | End point | Toxicity (mg/kg bw per day) |
|--------------------------|--------------------|-------------|-----------|----------------------------|
| **Birds**                |                    |             |           |                            |
| *Coturnix japonica* (Japanese Quail) | a.s.               | Acute       | LD₅₀      | 5.0 mg a.s./kg bw           |
| *Coturnix japonica* (Japanese Quail) | Methiocarb SC 500 | Acute       | LD₅₀      | 23.3 mg product/kg bw       |
|                          |                    |             |           | 10.37 mg/kg bw (expressed in terms of a.s.) |
| *Coturnix japonica* (Japanese Quail) | a.s.               | Long-term   | LD₅₀/10   | 0.5 mg a.s./kg bw/d         |
| *Anas platyrhynchos* (Mallard Duck) | a.s.               | Long-term   | NOAEL     | 4.51 mg a.s./kg bw/d        |
| **Mammals**              |                    |             |           |                            |
| Multiple                 | a.s.               | Acute       | LD₅₀      | 19 mg a.s./kg bw            |
| *Rattus norvegicus* (rat) | Methiocarb SC 500  | Acute       | LD₅₀      | >5 <50 mg a.s./kg bw        |
| *Rattus norvegicus* (rat; parent) | a.s.               | Long-term   | NOAEL     | 4.3 mg a.s./kg bw/d        |
| *Rattus norvegicus*      | a.s.               | Long term   | NOAEL     | 15 mg a.s./kg bw/day       |
| *Rattus norvegicus* (offspring) | a.s.               | Long term; based on body weight depression and clinical signs of toxicity | NOAEL | 14.8 mg a.s./kg bw/day |

Endocrine disrupting properties (Annex Part A, points 8.1.5)
None provided

Additional higher tier studies (Annex Part A, points 10.1.1.2):
Please refer to Vol 3CP Section B.9

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
None provided
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Maize seeds (planted at a rate of 2 units/ha) treated with Methiocarb FS 500 at 5000 mg a.s./kg seed (equivalent to 150 g a.s./ha)

| Growth stage | Indicator or focal species          | Time scale | Exposure (mg a.s./kg) | TER | Trigger |
|--------------|-------------------------------------|------------|-----------------------|-----|---------|
| Screening Step (Birds – treated seed) | All | Large granivorous bird | Acute | 0.1 x 5000 | 0.01 | 10 |
| | All | Large granivorous bird | Long-term | 0.1 x 5000 x 1 | 0.001 | 5 |
| Screening Step (Birds – contaminated seedlings) | All | Large granivorous bird | Acute | 0.5x (5000/5) | 0.1 | 10 |
| | All | Large granivorous bird | Long-term | 0.5x (5000/5) x 1 | 0.001 | 5 |
| Screening Step (Mammals – treated seed) | All | Small omnivorous mammal | Acute | 0.24 x 5000 | 0.016 | 10 |
| | All | Small omnivorous mammal | Long-term | 0.24 x 5000 x 1 | 0.0036 | 5 |
| Screening Step (Mammals – contaminated seedlings) | All | Small omnivorous mammal | Acute | 0.24 x (5000/5) | 0.08 | 10 |
| | All | Small omnivorous mammal | Long-term | 0.24 x (5000/5) x 1 | 0.018 | 5 |

Risk from bioaccumulation and food chain behaviour

| Indicator or focal species            | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds                | Long-term  | 0.318                  | 1.65| 5       |
| Earthworm-eating mammals              | Long-term  | 0.388                  | 11.08| 5      |
| Fish-eating birds                     | Long-term  | 0.0000143              | 34.940| 5      |
| Fish-eating mammals                   | Long-term  | 0.0000128              | 336.463| 5     |

Risk from consumption of contaminated water – not required for seed treatment

Data gaps identified for addressing the risk to birds including from biaccumulation for earthworm-eating birds and mammals.
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

| Group                        | Test substance                | Time-scale (Test type) | End point         | Toxicity$^1$            |
|------------------------------|-------------------------------|------------------------|-------------------|-------------------------|
| Laboratory tests             |                               |                        |                   |                         |
| Fish                         |                               |                        |                   |                         |
| *Lepomis macrochirus*        | a.s.                          | 96 hr                  | Mortality, LC$_{50}$ | 0.65 mg a.s./L (nom)    |
|                              | a.s.                          | Chronic 56 d (flow-through) | Behaviour (signs of intoxication), NOEC | 0.05 mg a.s./L (nom) |
|                              | Methiocarb sulfoxide          | 96 hr                  | Mortality, LC$_{50}$ | 6.6 mg/L (mm)           |
|                              | Methiocarb phenol             | 96 hr                  | Mortality, LC$_{50}$ | 3.2 mg/L (nom)          |
|                              | Methiocarb sulfoxide phenol   | 96 hr                  | Mortality, LC$_{50}$ | >106 mg/L (mm)          |
|                              | Methiocarb sulfone phenol     | 96 hr                  | Mortality, LC$_{50}$ | 68.7 mg/L (mm)          |
|                              | Methiocarb methoxy sulfone    | 96 hr                  | Mortality, LC$_{50}$ | 26.8 mg/L (mm)          |
| Aquatic invertebrates        |                               |                        |                   |                         |
| *Daphnia magna*              | a.s.                          | 48 h                   | Mortality, EC$_{50}$ | 0.0077 mg a.s./L (mm)   |
|                              | a.s.                          | 21 d (flow-through)    | Reproduction, NOEC | 0.0001 mg a.s./L (mm)   |
|                              | Methiocarb sulfoxide          | 48 h                   | Mortality, EC$_{50}$ | 0.056 mg/L (nom)        |
|                              | Methiocarb sulfoxide          | 21 d (flow-through)    | Mortality, NOEC    | 0.00652 mg/L (mm)       |
|                              | Methiocarb phenol             | 48 h                   | Mortality, EC$_{50}$ | 6.8 mg/L (nom)          |
|                              | Methiocarb sulfoxide phenol   | 48 h                   | Mortality, EC$_{50}$ | 157 mg/L (nom)          |
|                              | Methiocarb sulfone phenol     | 48 h                   | Mortality, EC$_{50}$ | 54 mg/L (nom)           |
|                              | Methiocarb methoxy sulfone    | 48 h                   | Mortality, EC$_{50}$ | >180 mg/L (nom)         |
| Sediment-dwelling organisms  |                               |                        |                   |                         |
| *Chironomus riparius*        | a.s.                          | 48 h                   | EC$_{50}$         | 0.103 mg a.s./L (mm)    |
### Desmodesmus subspicatus

| Group              | Test substance     | Time-scale (Test type) | End point | Toxicity |
|--------------------|--------------------|------------------------|-----------|----------|
| Algae              | a.s.               |                        | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | 2.2 mg a.s./L (mm) [0.82 mg a.s./L (mm)] 0.18 mg a.s./L (mm) |
|                    | Methiocarb sulfoxide |                        | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | 2.75 mg/L (mm) [1.31 mg/L (mm)] 0.41 mg/L (mm) |
|                    | Methiocarb phenol  | 72 h                   | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | 11 mg/L (nom) [6.0 mg/L (nom)] 2.2 mg/L (nom) |
|                    | Methiocarb sulfoxide phenol | (NOEC) | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | >100 mg/L (nom) [>100 mg/L (nom)] 100 mg/L (nom) |
|                    | Methiocarb sulfone phenol |                | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | 120 mg/L (nom) [105 mg/L (nom)] 25 mg/L (nom) |
|                    | Methiocarb methoxy sulfone |                | Growth rate: E₅₀ [Biomass: E₅₀] NOEC | 137 mg/L (nom) [97.7 mg/L (nom)] 40 mg/L (nom) |

Higher plant: None required

Further testing on aquatic organisms
None required

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)
None provided

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**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

|            | Methiocarb | Methiocarb phenol |
|------------|------------|-------------------|
| logP<sub>O/W</sub> | 3.18       | 3.49              |
| Parameter                                                                 | Value | Reference                  |
|---------------------------------------------------------------------------|-------|----------------------------|
| Steady-state bioconcentration factor (BCF) \(\text{total wet weight/normalised to 5\% lipid content}\) | 60-90 (\textit{Lepomis macrochirus}) | 10.9 (\textit{Lepomis macrochirus}) |
| Uptake/depuration kinetics BCF \(\text{total wet weight/normalised to 5\% lipid content}\) | Not available | Not available |
| Annex VI Trigger for the bioconcentration factor                           | 1000  | 1000                       |
| Clearance time \(\text{(days)} (\text{CT}_{50})\)                          | Not available | 0.77 days                 |
| \(\text{(CT}_{90})\)                                                       | Not available | Not available             |
| Level and nature of residues \(\%\) in organisms after the 14 day depuration phase | Not available | Not available             |

* based on total \(^{14}\)C or on specific compounds
**Risk assessment for the most sensitive aquatic organisms** (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS, step 1-3** – Maize seeds (planted at a rate of 2 units/ha) treated with Methiocarb FS 500 at 5000 mg a.s./kg seed (equivalent to 150 g a.s./ha)

| Scenario | PEC global max (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae |
|----------|----------------------|------------|--------------|-----------------------|-------------------------------|-------|
|          |                      | L. macrochirus | O. mykiss | D. magna | NOEC | EC₅₀ | NOEC | EC₅₀ |       |
|          |                      | LC₅₀ | NOEC | EC₅₀ | NOEC |       |       |       |       |
|          |                      | 650 | 50  | 7.7   | 0.1   |       |       | 2200  |       |
| RAC (µg L) |                      | 6.5 | 5   |       | 0.077 | 0.01  | 220  |       |       |
| FOCUS Step 1 |                    | 28.6 | 6.5 | 5    | 0.077 | 0.01  | 220  |       |       |

**FOCUS Step 2**

|          |                      |           |           |           |       |       |       |
|          |                      | L. macrochirus | O. mykiss | D. magna | NOEC | EC₅₀ | NOEC | EC₅₀ |       |
|          |                      | LC₅₀ | NOEC | EC₅₀ | NOEC |       |       | 2200  |       |
|          |                      | 6.5 | 5    | 0.077 | 0.01  | 220  |       |       |       |
|          |                      | North Europe | 1.38 | 6.5 | 5    | 0.077 | 0.01  |       |       |
|          |                      | South Europe | 1.95 | 6.5 | 5    | 0.077 | 0.01  |       |       |

**FOCUS Step 3**

|          |                      |           |           |           |       |       |       |
|          |                      | L. macrochirus | O. mykiss | D. magna | NOEC | EC₅₀ | NOEC | EC₅₀ |       |
|          |                      | LC₅₀ | NOEC | EC₅₀ | NOEC |       |       | 2200  |       |
|          |                      | 6.5 | 5    | 0.077 | 0.01  | 220  |       |       |       |
|          |                      | D3 / ditch | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | D4 / pond | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | D4 / stream | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | D5 / pond | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | D5 / stream | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | D6 / Ditch | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R1 / pond | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R1 / stream | 0.032 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R2 / stream | 0.003 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R3 / stream | 0.001 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R4 / stream | 0.053 |       | 0.077 | 0.01  |       |       |       |
|          |                      | R4 / stream (3 cm drill depth, all scenarios) | 0.001 |       |       |       |       |       | 0.01 |

Numbers in **bold** indicate that the PEC exceeds the RAC and an unacceptable risk is concluded for that scenario.
FOCUS<sub>sw</sub> step 1-3 - TERs for methiocarb sulfoxide – Maize seeds (planted at a rate of 2 units/ha) treated with Methiocarb FS 500 at 5000 mg a.s./kg seed (equivalent to 150 g a.s./ha)

| Scenario | PEC global max (µg L) | fish acute | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae |
|----------|-----------------------|------------|-----------------------|--------------------------------|-------|
|          |                       | O. mykiss  | D. magna              | D. magna                        | D. subspicatus |
|          |                       | LC<sub>50</sub> | EC<sub>50</sub> | NOEC | EC<sub>50</sub> |
| RAC (µg L) | 6600 µg L | 56 µg L | 6.52 µg L | 2750 µg L |
| FOCUS Step 1 | 30.2 | 66 | 0.56 | 0.65 | 275 |
| FOCUS Step 2 | | | | | |
| North Europe | 3.78 | | 0.56 | 0.65 | |
| South Europe | 7.56 | | 0.56 | 0.65 | |
| FOCUS Step 3 | | | | | |
| D3 / ditch | <0.001 | | 0.56 | 0.65 | |
| D4 / pond | <0.001 | | 0.56 | 0.65 | |
| D4 / stream | <0.001 | | 0.56 | 0.65 | |
| D5 / pond | <0.001 | | 0.56 | 0.65 | |
| D5 / stream | <0.001 | | 0.56 | 0.65 | |
| D6 / Ditch | <0.001 | | 0.56 | 0.65 | |
| R1 / pond | <0.001 | | 0.56 | 0.65 | |
| R1 / stream | 0.145 | | 0.56 | 0.65 | |
| R2 / stream | 0.025 | | 0.56 | 0.65 | |
| R3 / stream | <0.001 | | 0.56 | 0.65 | |
| R4 / stream | 0.297 | | 0.56 | 0.65 | |

Numbers in **bold** indicate that the PEC exceeds the RAC and an unacceptable risk is concluded for that scenario
**FOCUS* step 1 - TERs for methiocarb phenol, methiocarb sulfoxide phenol, methiocarb sulfone phenol and methiocarb methoxy sulfone – Maize seeds (planted at a rate of 2 units/ha) treated with Methiocarb FS 500 at 5000 mg a.s./kg seed (equivalent to 150 g a.s./ha)**

| Methiocarb phenol | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|-------------------|-----------------------|------------|----------------------|-------|
|                   |                       | *O. mykiss* | *D. magna*          | *D. subspicatus* |
|                   | \( \text{LC}_{50} \) | \( \text{EC}_{50} \) | \( \text{EC}_{50} \) |
|                   | 3200 µg L              | 6800 µg L  | 11 000 µg L          |
| RAC (µg L)        | 32                     | 68         | 1100                 |
| FOCUS Step 1      | 7.37                   | 32         | 68                   | 1100   |

| Methiocarb sulfoxide phenol | PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|----------------------------|-----------------------|------------|----------------------|-------|
|                             | \( \text{LC}_{50} \) | \( \text{EC}_{50} \) | \( \text{EC}_{50} \) |       |
|                             | \( >106 000 \) µg L  | 157 000 µg L | \( >100 000 \) µg L |       |
| RAC (µg L)                 | 1060                  | 1570       | 10 000               |
| FOCUS Step 1              | 29.9                  | 1060       | 1570                 | 10 000 |
### Methiocarb sulfone phenol

| PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|-----------------------|------------|-----------------------|-------|
|                       | O. mykiss  | D. magna              | D. subspicatus |
|                       | EC₅₀       | EC₅₀                  |         |
|                       | 68 700 µg L| 54 000 µg L           | 120 000 µg L |

| RAC (µg L) | 687 | 540 | 12 000 |
| FOCUS Step 1 | 10.2 | 687 | 540 | 12 000 |

### Methiocarb methoxy sulfone

| PEC global max (µg L) | fish acute | Aquatic invertebrates | Algae |
|-----------------------|------------|-----------------------|-------|
|                       | O. mykiss  | D. magna              | D. subspicatus |
|                       | LC₅₀       | EC₅₀                  |         |
|                       | 26 800 µg L| >180 000 µg L         | 137 000 µg L |

| RAC (µg L) | 268 | 1800 | 13 700 |
| FOCUS Step 1 | 5.06 | 268 | 1800 | 13 700 |
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.           | Acute 48 h                  | Oral toxicity (LD₅₀)    | 0.08 µg/bee       |
|                    | a.s.           | Acute 48 h                  | Contact toxicity (LD₅₀) | 0.23 µg/bee       |
| *Bombus terrestris*| a.s.           | Acute 48 h                  | Contact toxicity (LD₅₀) | 19.3 µg/bee       |
| *Apis mellifera*   | a.s.           | Chronic                     | 10 d-LD50 10 d-NOED (mortality) | 0.0415 µg/bee/day 0.0149 µg/bee/day |
| *Apis mellifera*   | a.s.           | Bee brood development       | 72 h LD50 72 h LD 10    | 0.547 µg/larva 0.043 µg/larva |

Potential for accumulative toxicity: not investigated

Semi-field test (Cage and tunnel test)
3 semi-field studies with Methiocarb FS 500 were submitted in support of the risk assessment. For further details please refer to Vol 3CP Section B.9.5

Field tests
2 field studies with Methiocarb FS 500 were submitted in support of the risk assessment. For further details please refer to Vol 3CP Section B.9.5

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)

Extended laboratory tests

| Species                        | Test substance, substrate                                                                 | Endpoints                                                                 |
|--------------------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| *Aphidius rhopalosiphi*        | Methiocarb FS 500, extended laboratory study with seed treatment dust abraided from maize seeds | LR₅₀ = 8.5 g a.s./ha; ER₅₀ = >6.3 g a.s./ha                                 |
| *Typhlodromus pyri*            | Methiocarb FS 500, extended laboratory study with seed treatment dust abraided from maize seeds | LR₅₀ = >40.9 g a.s./ha; ER₅₀ = >40.9 g a.s./ha                              |
| *Chrysoperla carnea*           | Methiocarb FS 500, extended laboratory study with seed treatment dust abraided from maize seeds | LR₅₀ = 21.2 g a.s./ha; ER₅₀ = >21.2 g a.s./ha                             |
### Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation

(Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s. | Time scale | End point | Toxicity |
|---------------|----------------|---------------------------------|------------|-----------|----------|
| **Earthworms** |                |                                 |            | NOEC (weight gain) | 0.161 mg a.s./kg d.w.soil |
| Eisenia fetida| Methiocarb FS 500 | Homogenously mixed into soil | Chronic (56 days) | NOEC (overall) | 100 mg a.s./kg d.w.soil |
|                | Methiocarb-sulfoxide phenol | Homogenously mixed into soil |           | NOEC (weight gain) | 0.2 mg a.s./kg d.w.soil |
|                | Methiocarb-sulfoxide | Homogenously mixed into soil |              | NOEC (overall) | 100 mg a.s./kg d.w.soil |
|                | Methiocarb-methoxy sulfone | Homogenously mixed into soil |           | NOEC (overall) | 100 mg a.s./kg d.w.soil |
|                | Methiocarb-sulfone phenol | Homogenously mixed into soil |           | NOEC (overall) | 100 mg a.s./kg d.w.soil |
| **Other soil macroorganisms** | | | | | |
| Test organism | Test substance | Application method of test a.s. | Time scale | End point | Toxicity |
|---------------|----------------|--------------------------------|------------|-----------|----------|
| Folsomia candida | Methiocarb FS 500 G | Homogenously mixed into soil | 28 days | NOEC | 37.5 mg a.s./kg d.w. soil |
| | Methiocarb-sulfoxide phenol | | | EC10 | 38.02 mg a.s./kg d.w. soil |
| | Methiocarb-sulfoxide | | | NOEC corr | 18.75 mg a.s./kg d.w. soil |
| | Methiocarb-methoxy sulfone | | | | |
| | Methiocarb-sulfone phenol | | | | |
| Hypoaspis aculeifer | Methiocarb FS 500 G | | 14 days | NOEC | 20.12 mg a.s./kg d.w. soil |
| | Methiocarb-sulfoxide phenol | | | NOEC corr | 10.06 mg a.s./kg d.w. soil |
| | Methiocarb-sulfoxide | | | | |
| | Methiocarb-methoxy sulfone | | | | |
| | Methiocarb-sulfone phenol | | | | |
| | Methiocarb-sulfoxide-phenol | | | | |
| Nitrogen transformation | Methiocarb FS 500 | | 28 days | <25 % effect at day at ≥3.9 mg a.s./kg d.w.soil | |
| | Methiocarb-sulfoxide-phenol | | | <25 % effect at day at ≥1.09 mg a.s./kg d.w.soil | |
| | Methiocarb-sulfoxide | | | <25 % effect at day at ≥1.47 mg a.s./kg d.w.soil | |
| | Methiocarb-methoxy-sulfone | | | <25 % effect at day at ≥1.33 mg a.s./kg d.w.soil | |
| | Methiocarb-sulfone-phenol | | | <25 % effect at day at ≥1.20 mg a.s./kg d.w.soil | |
## Toxicity/exposure ratios for soil organisms

Maize seeds (planted at a rate of 2 units/ha) treated with Methiocarb FS 500 at 5000 mg a.s./kg seed (equivalent to 150 g a.s./ha)

| Species | Test substance | Endpoint | Value (mg test substance/kg dry soil) | Maximum PECsoil (mg/kg) | TER | Trigger |
|---------|----------------|----------|--------------------------------------|------------------------|-----|---------|
| *E. fetida* | Methiocarb FS 500 G | 56 d NOEC | 0.08* (NOEC\textsubscript{corr}, expressed in terms of a.s.) | 0.2 | 0.4025 | |
| | Methiocarb-sulfoxide phenol | ≥100 | 0.059 | ≥1695 | 5 | |
| | Methiocarb-sulfoxide | 0.2 | 0.126 | 1.59 | | |
| | Methiocarb-methoxy sulfone | ≥100 | 0.025 | ≥4000 | | |
| | Methiocarb-sulfone phenol | ≥100 | 0.035 | ≥2857 | | |

| Species | Test substance | Endpoint | Value (mg test substance/kg dry soil) | Maximum PECsoil (mg/kg) | TER | Trigger |
|---------|----------------|----------|--------------------------------------|------------------------|-----|---------|
| *F. candida* | Methiocarb FS 500 G | 28 d NOEC\textsubscript{corr}* | <18.75 (a.s.) | 0.2 | 94 | |
| | Methiocarb-sulfoxide phenol | 50 | 0.059 | 847.5 | | |
| | Methiocarb-sulfoxide | 50 | 0.126 | 397 | | |
| | Methiocarb-methoxy sulfone | 10 | 0.035 | 286 | | |
| | Methiocarb-sulfone phenol | 316 | 0.025 | 12,640 | 5 | |

| Species | Test substance | Endpoint | Value (mg test substance/kg dry soil) | Maximum PECsoil (mg/kg) | TER | Trigger |
|---------|----------------|----------|--------------------------------------|------------------------|-----|---------|
| *H. aculeifer* | Methiocarb FS 500 G | 14 d NOEC\textsubscript{corr}* | 10.06 (a.s.) | 0.2 | 50.3 | |
| | Methiocarb-sulfoxide phenol | ≥100 | 0.059 | ≥1695 | | |
| | Methiocarb-sulfoxide | 10 | 0.126 | 79 | | |
| | Methiocarb-methoxy sulfone | ≥100 | 0.035 | ≥2857 | | |
| | Methiocarb-sulfone phenol | ≥100 | 0.025 | ≥4000 | | |

* The endpoint was corrected by a factor of 2 considering that methiocarb has a Log Pow>2

| Compound | Species | Endpoint [mg/kg] | PEC\textsubscript{soil,max} [mg/kg] | Refinement required |
|----------|---------|------------------|-------------------------------|-------------------|

*The endpoint was corrected by a factor of 2 considering that methiocarb has a Log Pow>2*
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

| Test item                  | Study type                                | Test duration | Lowest ER$_{50}$ | Most sensitive species |
|----------------------------|-------------------------------------------|---------------|------------------|------------------------|
| Methiocarb FS 500          | Pre-emergence screening; 11 species       | 21 days       | > 240 g a.s./ha   | No effect on any species tested |
| Methiocarb FS 500          | Post-emergence screening; 11 species       | 17 days       | > 240 g a.s./ha   | No effect on any species tested |

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism end point

Activated sludge EC$_{50} = >10 000$ mg a.s./L

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

Available monitoring data concerning adverse effect of the a.s.
Available monitoring data concerning effect of the PPP.

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

| Compartment    | Methiocarb and methiocarb sulfoxide | Methiocarb and methiocarb sulfoxide | Methiocarb and methiocarb sulfoxide | Methiocarb |
|----------------|-------------------------------------|-------------------------------------|-------------------------------------|------------|
| soil           |                                     |                                     |                                     |            |
| water          |                                     |                                     |                                     |            |
| sediment       |                                     |                                     |                                     |            |
| groundwater    |                                     |                                     |                                     |            |

*metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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

Substance Methiocarb
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]⁶:

| Harmonised Classification | Value |
|---------------------------|-------|
| H400 Very toxic to aquatic life | |
| H410 Very toxic to aquatic life with long lasting effects | |
| Acute: D. magna 0.0077 mg a.s./L; m factor = 100 | |
| Chronic endpoint: D. magna 0.0001 mg a.s./L; m factor = 1000 | |
| Peer review proposal⁷ for harmonised classification according to Regulation (EC) No 1272/2008: | none |

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⁶ 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.

⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.