Appendix B - 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)          | Benthiavalicarb-isopropyl (modified ISO common name) Benthiavalicarb (ISO approved name for the free acid). The given data belong to the isopropyl ester of parent acid benthiavalicarb |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Function                                    | Fungicide                                                                                                                             |
| Rapporteur Member State                     | Poland                                                                                                                              |
| Co-rapporteur Member State                  | France                                                                                                                              |

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

| Chemical name (IUPAC)                        | Benthiavalicarb-isopropyl: isopropyl [(S)-1-[[[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl]-2-methylpropyl]carbamate Benthiavalicarb: [(S)-1-[[[(1R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl]-2-methylpropyl]carbamic acid |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chemical name (CA)                           | Benthiavalicarb-isopropyl: 1-methylethyl [(S)-1-[[[(1R)-1-(6-fluoro-2-benzo-thiazoyl)ethyl]amino]carbonyl]-2-methylpropyl]carbamate Benthiavalicarb: [[(S)-1-[[[(1R)-1-(6-fluoro-2-benzo-thiazoyl)ethyl]amino]carbonyl]-2-methylpropyl]carbamic acid |
| CIPAC No                                     | 744 (benthiavalicarb as free acid) 744.204 (benthiavalicarb-isopropyl as ester)                                                                                                                     |
| CAS No                                       | 413615-35-7 (benthiavalicarb) 177406-68-7 (benthiavalicarb-isopropyl as ester)                                                                                                                      |
| EC No (EINECS or ELINCS)                     | 605-799-5                                                                                                                            |
| FAO Specification (including year of publication) | -                                                                                                         |
| Minimum purity of the active substance as manufactured | 930 g/kg                                                                                                                          |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | toluene - 1 g/kg                                                                                                                  |
| Location of the (proposed) reference specification (for significant impurities) | RAR Volume 4 (October 2018)                                                                                                         |
Molecular formula
C_{18}H_{24}F_{3}N_{3}O_{3}S

Molar mass
381.47 g/mol

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

| Property                           | Value                                                                 |
|------------------------------------|-----------------------------------------------------------------------|
| **Melting point**                  | 153.1°C and 169.5°C (> 99.96% pure)                                   |
| **Boiling point**                  | no data available; decomposes before boiling                         |
| **Temperature of decomposition**   | 240°C (> 99.96% pure)                                                |
| **Appearance**                     | white powder (> 99.96% pure)                                         |
|                                    | white powder (94.0% pure)                                            |
| **Vapour pressure**                | < 3.0 × 10⁻⁴ Pa at 25°C (100% pure)                                  |
| **Henry’s law constant**           | 4.53 × 10⁻³ Pa.m³.mol⁻¹ at 20°C (100% pure)                          |
| **Solubility in water**            | 13.14 mg/L at 20°C (pH ~6.3) (100% pure)                             |
|                                    | 10.96 mg/L at 20°C and pH 5 (100% pure)                              |
|                                    | 12.76 mg/L at 20°C and pH 9 (100% pure)                              |
| **Solubility in organic solvents** | in acetone 25.4 g/L at 20°C (> 99.96% pure)                          |
|                                    | in xylene 0.501 g/L at 20°C (> 99.96% pure)                           |
|                                    | in heptane 2.15 × 10⁻² g/L at 20°C (> 99.96% pure)                   |
|                                    | in ethyl acetate 19.4 g/L at 20°C (> 99.96% pure)                    |
|                                    | in 1,2-dichloroethane 11.5 g/L at 20°C (> 99.96% pure)               |
|                                    | in methanol 41.7 g/L at 20°C (> 99.96% pure)                         |
| **Surface tension**                | 63.1 mN/m at 22°C in 90% saturated solution (94.0% pure)             |
| **Partition coefficient**          | 2.56 at ca. 22°C (pH unadjusted) (100% pure)                         |
|                                    | 2.63 at ca. 22°C and pH 5 (100% pure)                                |
|                                    | 2.62 at ca. 22°C and pH 9 (100% pure)                                |
| **Dissociation constant**          | does not dissociate between pH 1 and 13                              |
| **UV/VIS absorption (max.) incl. ε**| solution λ_max (nm) ε (l.mol⁻¹.cm⁻¹)                                 |
|                                    | distilled water 219.0 24,424                                         |
|                                    | 0.1 M HCl 219.0 23,891                                               |
|                                    | 0.1 M NaOH 220.5 23,075                                              |
|                                    | ε = 1.298 l.mol⁻¹.cm⁻² at λ = 292.5 nm                                 |
| **Flammability**                   | not flammable (94.0% pure)                                           |
| **Explosive properties**           | not explosive (94.0% pure)                                           |
| **Oxidising properties**           | not oxidising (94.0% pure)                                           |
Summary of representative uses evaluated, for which all risk assessments needed to be completed (benthiavalicarb) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|--------------|---------------------------------------|-------------|------------|-------------------------------|-------------|---------|
| potato (SOLTU)            | BEL DEU GBR IRL NLD POL | KIF-230 15% WG | F            | late blight Phytophthora infestans (PHYTIN) | WG          | 150 g/kg   | 5 days                         | 7.5-30      | 75      |
|                          |                         |              |              | treatment of aerial parts downward spraying with tractor-mounted equipment |             |            |                                | 250-1000    |         |
|                          |                         |              |              | after emergence up to 3 days before harvest (BBCH 11-97) spring-summer (May-Sep) |             |            |                                |             |         |
|                          |                         |              |              | spring-summer (May-Sep) (BBCH 11-97) |             |            |                                |             |         |
|                          |                         |              |              | number min-max (k) | 1-8 |            |                                |             |         |
|                          |                         |              |              | Interval between application (min) | 5 days |            |                                |             |         |
|                          |                         |              |              | g a.s./L min-max (l) | 7.5-30 |            |                                |             |         |
|                          |                         |              |              | Water L/ha min-max | 250-1000 |            |                                |             |         |
|                          |                         |              |              | g a.s./ha min-max (l) | 75 |            |                                |             |         |
|                          |                         |              |              | PHI - minimum pre-harvest interval | 3 | Timing of application: at beginning of infestation and/or when first symptoms become visible |     |         |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

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

| Proposed label claim: preventive action against late potato blight using KIF-230 15% WG at a use rate of 500 g product per hectare |
| --- |

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

| No evidence of any adverse effects on treated plants; no evidence of unintended side effects on adjacent crops, succeeding crops, seed viability or beneficial and other non-target organisms |
| --- |

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

| The representative use/GAP is supported |
| --- |

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

| Activity against target organism |
| --- |

| No data; not required |
Methods of Analysis

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

|                              |                                                                 |
|-----------------------------|-----------------------------------------------------------------|
| Technical a.s. (analytical technique) | KIF-230R-L: normal phase chiral HPLC with UV detection (254 nm) |
| Impurities in technical a.s. (analytical technique) | Toluene: headspace GC with FID detection |
| Plant protection product (analytical technique) | KIF-230R-L: normal phase chiral HPLC with UV detection (254 nm) |
|                              | Relevant Impurities:                                            |
|                              | Toluene: headspace GC with MS detector.                         |

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

Residue definitions for monitoring purposes

|                              | Sum of fruit and root crops: benthiavalicarb-isopropyl (KIF-230R-L), its diastereomer (KIF-230S-L) and their respective enantiomers (KIF-230S-D and -R-D), expressed as benthiavalicarb-isopropyl |
| Food of plant origin         | Open                                                             |
| Food of animal origin        | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| Soil                        | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| Sediment                    | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| Water                       | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| drinking/ground             | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| Air                         | Bentiavalicarb-isopropyl (KIF-230R-L)                           |
| Body fluids and tissues     | Bentiavalicarb-isopropyl (KIF-230R-L) and its diastereomer (KIF-230S-L) |
## Monitoring/Enforcement methods

| For                      | Method Description                                                                 |
|--------------------------|-----------------------------------------------------------------------------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | DFG S19 multi-residue method with reverse phase HPLC-MS/MS in MRM mode at LOQ of 0.01 mg/kg for each analyte (KIF-230R-L and -S-L) |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Pending on the final residue definition for monitoring in food and feed of animal origin analytical methods might be required. |
| Soil (analytical technique and LOQ) | Reverse phase HPLC-MS/MS in MRM mode with LOQ of 0.01 mg/kg (KIF-230R-L) |
| Water (analytical technique and LOQ) | Reverse phase HPLC-MS/MS in MRM mode with LOQ of 0.05 µg/l (KIF-230R-L) |
| Air (analytical technique and LOQ) | Reverse phase HPLC-MS/MS in MRM mode with LOQ of 0.75 ng/l (KIF-230R-L) |
| Body fluids and tissues (analytical technique and LOQ) | Reverse phase non-enantioselective HPLC-MS/MS in MRM mode with LOQ of 0.05 mg/l for body fluids and 0.01 mg/kg in animal tissues for each analyte (KIF-230R-L and -S-L) |

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

| Substance | Classification |
|-----------|----------------|
| Benthiavalicarb-isopropyl | no classification |
|          | no classification |

---

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

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

| Parameter | Value |
|-----------|-------|
| Rate and extent of oral absorption/systemic bioavailability | 89 - 97% within 48 h (for single dose of 5 mg/kg); 41 - 54% within 48 h (for single dose of 400 mg/kg) |
| Toxicokinetics | Values for [benzyl-14C]-Benthiavalicarb and [valyl-14C]-Benthiavalicarb at 5 mg/kg bw: t<sub>max</sub>: 2-6 hr; C<sub>max</sub>: 0.52-0.68 µg/mL |
| Distribution | Widely distributed (gastro-intestinal tract, bile duct, urinary bladder, liver and kidney) |
| Potential for bioaccumulation | No evidence for true accumulation |
| Rate and extent of excretion | Rapid and extensive (73 - 86% within 48 h), mainly via faeces (65%) and urine (12%) |
| Metabolism in animals | Extensively metabolised; main metabolite B11 (glucoronic acid conjugate of hydroxylated derivative); hydroxylation plus glucoronic acid and glutathione conjugation (major pathways), cleavage of amide bond (minor pathway) |

**In vitro metabolism** Data gap

Toxicologically relevant compounds (animals and plants) Bentiavalicarb-isopropyl (KIF-230R-L), its diastereomer (KIF-230S-L) and their enantiomers (KIF-230S-D and KIF-230R-D)

Toxicologically relevant compounds (environment) Bentiavalicarb-isopropyl (KIF-230R-L) and the metabolites KIF-230-M-1 and -M-5 (based on higher acute oral toxicity compared to the parent compound) and KIF-230-M-4 (based on mutagenic potential).

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

| Route | Value |
|-------|-------|
| Rat LD<sub>50</sub> oral | > 5000 mg/kg bw |
| Rat LD<sub>50</sub> dermal | > 2000 mg/kg bw |
| Rat LC<sub>50</sub> inhalation | > 4.6 mg/l air for 4 hours (whole body) |
| Skin irritation | not irritating |
| Eye irritation | not irritating |
| Skin sensitisation | sensitising (maximisation test) Skin Sens. Cat 1B (H317) |
| Phototoxicity | No data provided (data gap) |

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

| Route | Value |
|-------|-------|
| Target organ / critical effect | Mouse: liver (increased absolute and relative organ weight, histo-pathological effects (necrosis, hypertrophy, bile duct proliferation); and anaemia (red blood cell deficiency)) Rat: liver (increased absolute and relative organ weight, changes in clinical serum parameters (free and total cholesterol, GGT, phospholipids, total protein), hepatocyte hypertrophy, anaemia (haemoglobin deficiency)) Dog: liver (increased absolute and relative liver weight; changes in clinical serum parameters (free |
fatty acids, serum albumin and albumin/globulin ratio), hepatocyte hypertrophy; thymus (changes in absolute and relative organ weight; spleen ( hemosiderin pigment deposits); anaemia (haemoglobin deficiency)

| Relevant oral NOAEL          | 28-day dog: 300 mg/kg bw per day |
|                             | 90-day mouse: 33.0 mg/kg bw per day |
|                             | 90-day rat: 14.1 mg/kg bw per day |
|                             | 90-day dog: 40 mg/kg bw per day |
|                             | 1-year dog: 40 mg/kg bw per day |
| Relevant dermal NOAEL       | 28-day rat: 300 mg/kg bw per day |
| Relevant inhalation NOAEL   | No data; not required |

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

#### In vitro studies
- Bacterial gene mutation assay: negative in 11/13 batches
- Clastogenicity in mammalian cells: negative
- Gene mutation in mammalian cells: negative
- Unscheduled DNA synthesis: negative
- Comet assay: negative

#### In vivo studies
- Mouse bone marrow micronucleus test: negative
- Unscheduled DNA synthesis: negative
- Transgenic rodent mutation assay: negative

#### Photomutagenicity
- No data; not required

#### Potential for genotoxicity
- Benthiavalicarb-isopropyl is unlikely to be genotoxic

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

#### Long-term effects (target organ/critical effect)
Mouse: liver (absolute and relative organ weight, gross lesions, non-neo-plastic lesions (hypertrophy, fatty change, foci of cellular alteration, anisonucleosis, necrosis, accumulation of macrophages, lymphocyte infiltration, bile duct proliferation, extramedullary hematopoiesis); thymus: atrophy without any histopathological lesions; thyroid: follicular cell hyperplasia, dilated thyroid follicles.

Rat: kidney (increased absolute and relative organ weight, histopathological lesions (glomerulosclerosis, calculus, chronic nephropathy, tubular dilatation); liver (increased absolute and relative organ weight, changes in clinical chemistry parameters (GGT, free and total cholesterol, phospholipids), histopathological lesions (hypertrophy, fatty changes, foci of cellular alterations, spongiosis)]

| Relevant long-term NOAEL     | 2-year mouse: 13.7 mg/kg bw per day |
|                             | 2-year rat: 9.9 mg/kg bw per day |

#### Carcinogenicity (target organ, tumour type)
Mouse: liver (hepatocellular adenoma, hepatoblastoma, carcinoma); thyroid (follicular cell adenoma); uterus adenocarcinoma

Rat: liver (hepatocellular adenoma); uterus (adenocarcinoma)

| Relevant NOAEL for carcinogenicity | 2-year mouse: 13.7 mg/kg bw per day |

Cat. 1B (H350)
### Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

#### Reproduction toxicity

| Reproduction target / critical effect | Parental toxicity: increased absolute and relative liver weight, slight hepatocyte hypertrophy | Reproductive effects: no adverse effects on fertility or reproductive performance | Offspring toxicity: increased absolute and relative liver weight, decreased absolute and relative thymus and spleen weights |
|---------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Relevant parental NOAEL               | 10.0 mg/kg bw per day                                                                         | --                                                                               |                                                                                  |
| Relevant reproductive NOAEL            | 702.5 mg/kg bw per day                                                                         | --                                                                               |                                                                                  |
| Relevant offspring NOAEL               | 67.2 mg/kg bw per day                                                                          | --                                                                               |                                                                                  |

### Developmental toxicity

| Developmental target / critical effect | Rat: maternal toxicity: increased absolute and relative adrenal and liver weights | developmental toxicity: visceral malformations | Rabbit: maternal toxicity: increased relative liver weight, two incidences of abortion | developmental toxicity: skeletal retardation, and dwarfism at the highest dose |
|---------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Relevant maternal NOAEL               | rat: 10 mg/kg bw per day                                                         | --                                            | rabbit: 20 mg/kg bw per day                                                        |                                                                                  |
| Relevant developmental NOAEL          | rat: 100 mg/kg bw per day                                                         | --                                            | rabbit: 20 mg/kg bw per day                                                        |                                                                                  |

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

| Neurotoxicity                          | Decreased motor activity (LOAEL 2000 mg/kg bw)                                      | --                                                                               |
|----------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Acute neurotoxicity                    | Decreased motor activity at top dose 1853.7 mg/kg bw per day on week 4               | --                                                                               |
| Repeated neurotoxicity                 | no data; not required                                                                | --                                                                               |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) |                                                                       |                                                                                 |
Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

| Supplementary studies on the active substance | Immunotoxicological potential: benthiavalicarb-isopropyl is unlikely to be immunotoxic |
|-----------------------------------------------|-------------------------------------------------------------------------------------|
| Mechanical studies:                           |                                                                                      |
| Hepatocarcinogenicity studies in rats (*in vivo*) | KIF-230 TG is not an initiating agent in rat liver                                     |
| KIF-230 TG is a promoting agent in rat liver   |                                                                                      |
| Two-stage transformation assay (*in vitro*)   | KIF-230 TG is not an initiating or promoting agent in mouse                            |
| BALB/c 3T3 fibroblasts                        |                                                                                      |
| DMEs and hepatocyte proliferation in mice      | specific CYP enzyme induction (CYP1A2, CYP2B1/2 and CYP3A2), hepatocyte hypertrophy; no increased hepatocellular proliferation |
| DMEs and hepatocyte proliferation in rats      | specific CYP enzyme induction (CYP1A1/2, CYP2B1/2 and CYP3A2), no increased hepatocellular proliferation |
| Cultured human hepatocytes                    | Specific CYP enzyme induction (CYP2B6 and CYP3A4) indicating CAR activation, although effect on PXR cannot be excluded; minor increases in CYP1A1 and CYP1A2, indicating no AHR activation; no increased replicative DNA synthesis. |
| Oxidative DNA damage: no effect on 8-OHdG level|                                                                                      |
| Mechanism study of thyroid tumours in rats    | evidence for rodent specific liver mediated thyroid tumours (not relevant for humans): increased T4 UDGPT activity, decreased serum T4 levels, slight increase of TSH levels |
| Mechanism study of thyroid tumours in mice    | evidence for rodent specific liver mediated thyroid tumours (not relevant for humans): increased T4 UDGPT activity, decreased serum T4 levels, no or slight increase of TSH levels |
Endocrine disrupting properties

**T modality:**
Dog one-year study: increase in absolute and relative thyroid weight.
Rat combined chronic and carcinogenicity study: thyroid follicular cell hyperplasia at 52 weeks.
Rat mechanistic studies: changes in thyroid hormones and TSH
Mouse carcinogenicity study: thyroid follicular cell hyperplasia and adenoma.

**EAS modalities:**
Rat carcinogenicity study: uterine adenocarcinoma, increase levels of circulating estradiol
Mouse 90-day study: reduced number of corpora lutea
Mouse: carcinogenicity study: reduced number of corpora lutea, ovary atrophy, uterine angiectasis.
Dog 90 day-study: delay in sexual maturity.

**Conclusions on ED properties**
ED criteria for human health according to point 3.6.5 of Annex II of Reg 1107/2009 as amended by Commission Regulation (EU) 2018/605, are considered met for EATS modalities.

Studies performed on metabolites or impurities

**Acute oral toxicity**
- KIF-230-M-1: LD$_{50}$ = 467 - 545 mg/kg bw
- KIF-230-M-3: LD$_{50}$ > 2000 mg/kg bw
- KIF-230-M-4: LD$_{50}$ > 2000 mg/kg bw
- KIF-230-M-5: LD$_{50}$ = 545 - 605 mg/kg bw
- KIF-230-M-15: LD$_{50}$ > 2000 mg/kg bw
- KIF-230S-L: LD$_{50}$ > 2000 mg/kg bw
- KIF-230-I-1(R): LD$_{50}$ > 2000 mg/kg bw
- KIF-230-I-1(S): LD$_{50}$ = 2000 mg/kg bw
- KIF-230-I-4: LD$_{50}$ > 2000 mg/kg bw
- KIF-230-I-12: LD$_{50}$ = 840 - 1198 mg/kg bw
- KIF-230-I-13: LD$_{50}$ > 2000 mg/kg bw

**Bacterial gene mutation assay (Ames test)**
- KIF-230-M-1: negative ± S9 mixture
- KIF-230-M-3: negative ± S9 mixture
- KIF-230-M-4: positive + S9 mixture (strain TA98)
- KIF-230-M-5: negative ± S9 mixture
- KIF-230-M-15: negative ± S9 mixture
- KIF-230S-L: negative ± S9 mixture
- KIF-230-I-1(R): negative ± S9 mixture
- KIF-230-I-1(S): negative ± S9 mixture
- KIF-230-I-4: negative ± S9 mixture
- KIF-230-I-12: positive + S9 mixture (strain TA98)
- KIF-230-I-13: positive ± S9 mixture

For KIF-230-M-1, KIF-230-M-4 and KIF-230-M-5 no data available (data gap) for: gene mutation in mammalian cells, clastogenicity and aneugenicity potential and general toxicity (see also section Residues).

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No detrimental effects on health of manufacturing personnel
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) | 0.1                       | rat 2-year chronic                        | 100                |
| Acute Reference Dose (ARfD) | 6.7                       | acute oral neurotoxicity study in rat      | 100                |
| Acceptable Operator Exposure Level (AOEL) | 0.1                       | developmental toxicity study in the rat    | 100                |
| Acute Acceptable Operator Exposure Level (AAOEL) | 6.7                       | acute oral neurotoxicity study in rat      | 300                |

*Extra UF of 3 was applied in the absence of NOAEL.

EFSA 2007; European Commission, 2008:
ADI: 0.1 mg/kg bw per day based on the 2-year rat study (UF=100); ARfD and AAOEL not set.
AOEL: 0.1 mg/kg bw per day based on the teratogenicity study in the rat (UF=100).

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

Representative formulation (KIF-230 15% WG)

- Concentrate: 1% (in vitro human skin study)
- Spray dilution: 13.1% (in vitro human skin study)

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

Operators

- Use: potatoes, tractor-mounted boom spraying, application rate 75 g a.s./ha
- EFSA AOEM model (% AOEL % AAOEL)
  - Workwear without PPE: 3 0.3
  - Margin of Exposure: 3400
  - Workwear with PPE (1): 1 8200

(1) Gloves during mixing/loading and application

Workers

- EFSA AOEM model (DT50: 5.2 days; DFR: 0.1545 µg/cm²; Inspection and irrigation:)
  - Workwear without PPE: 0.94
  - Margin of Exposure: 10600

Bystanders and residents

- EFSA AOEM model (default values):
  - Bystanders (adult): all pathways < 1
  - Bystanders (children): all pathways < 1
  - Margin of exposure: >10000

- Buffer zone 2-3m:
  - Residents (adult): mean value 1
  - Residents (children): mean value 3
  - Margin of exposure: adult: 10500 child: 3500
Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance: Bentiavalicarb-isopropyl |
|-------------------------------------|
| 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]²: |
| No current harmonised classification |
| A CLH report proposing classification as category 2 carcinogen based on uterine adenocarcinoma incidence observed in rats is available on ECHA website (CLH Report, January 2021)³ |
| According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for: |
| **Skin Sens. Cat 1B** |
| H317: May cause an allergic skin reaction |
| **Carc. Cat. 1B** |
| H350: May cause cancer |

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² 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.

³ [https://echa.europa.eu/documents/10162/07ad73f0-8d62-6bd6-3ce1-cc84ea5427c3](https://echa.europa.eu/documents/10162/07ad73f0-8d62-6bd6-3ce1-cc84ea5427c3)
## Residues in or on treated products food and feed

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

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|-------------------------------------|-------------|---------|----------------|------------|
| Fruit crops                         | grapes      | foliar spray mature crop (6 x 0.1 kg a.s./ha) | 17         |
|                                     | tomatoes    | foliar spray mature crop (6 x 0.1 kg a.s./ha) | 14, 28, 35, 49, 56 |
| Root crops                          | potatoes    | 1. foliar spray immature crop (1 x 0.1 kg a.s./ha) | 12         |
|                                     |             | 2. post-emergence soil incorp (1 x 0.1 kg a.s./ha) | 90         |
|                                     |             | 3. foliar spray mature crop (6 x 0.1 kg a.s./ha) | 14         |
| Leafy crops                         |             | -       | -              | -          |
| Cereal (small grain)                |             | -       | -              | -          |
| Other                               |             | -       | -              | -          |

Benthiavalicarb-isopropyl (KIF-230R-L) labelled at benzyl ring and L-valyl side chain has been investigated in fruits (grapes, tomatoes) by foliar applications and in root crops (potatoes) by foliar and soil applications. In grapes, tomatoes and potato foliage, KIF-230R-L is the major residue. In potato tubers, KIF-230R-L was present for 4.7% of TRRs, benzene-hydroxylated compounds and sugar conjugates of KIF-230R-L constituted the remaining radioactivity. In potato foliage, no stereo-isomeric conversion was observed; in grapes, KIF-230S-L present at 10-20% of KIF-230R-L residue.

### Rotational crops (metabolic pattern)

| Rotational crops (metabolic pattern) | Crop groups | PBI (days) | Comments |
|--------------------------------------|-------------|------------|----------|
| Root/tuber crops                     | -           | -          | -        |
| Leafy crops                          | -           | -          | -        |
| Cereal (small grain)                 | -           | -          | -        |
| Other                                | -           | -          | -        |

### Rotational crop and primary crop metabolism similar?

Although benthiavalicarb-isopropyl is moderately persistent in soil, its uses lead to formation of relevant soil metabolites M1 and M5 (see section 4) that need further investigation. Two rotational field trials were provided for lettuce, carrot and barley. They were conducted at lower dose rate (6x0.75 kg/ha) compared to the proposed use (8x0.75 kg/ha) and analyzed for KIF-230R-L, S-isomer, and M1, M4, M5 metabolites. Since the concentration of residues in the soil at planting was limited (see details below), additional data on the comparative plant uptake of the soil metabolites (M1, M4, M5) and the parent is necessary (data gap). Currently no residue definitions are proposed for rotational crops due to lack of data.

### Processed commodities (standard hydrolysis study)

| Conditions | parent (KIF-230R-L) + impurity (KIF-230-M-4) |
|------------|---------------------------------------------|
| 20 min, 90°C, pH 4 |                                    |
| 60 min, 100°C, pH 5 |                                    |
| 20 min, 120°C, pH 6 |                                    |

KIF-230R-L is hydrolytically stable (94-97%-AR); KIF-230-M-4 is impurity in [14C]-KIF-230.

Isomeric conversion of KIF-230R-L into S-L was significant in raisins up to 74% ratio of S-L/R-L, in wine up to 28%, in ketchup tomatoes up to 50%, and in puree 21%.
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes
---|---

| Plant residue definition for monitoring (RD-Mo) | Benthiavalicarb-isopropyl (KIF-230R-L), its diastereomer (KIF-230S-L) and their respective enantiomers (KIF-230S-D and KIF-230R-D), expressed as benthiavalicarb-isopropyl. This residue definition applies to primary fruits and root crops and to the processed commodities |
| Plant residue definition for risk assessment (RD-RA) | Benthiavalicarb-isopropyl (KIF-230R-L), its diastereomer (KIF-230S-L) and their respective enantiomers (KIF-230S-D and KIF-230R-D), expressed as benthiavalicarb-isopropyl. This residue definition applies to primary fruits and root crops and to the processed commodities |

Conversion factor (monitoring to risk assessment) | |

Currently residue definitions for rotational crops cannot be derived due to lack of data.

### Metabolism in livestock (Regulation (EU) No 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 |
|-----------------|--------|-------------------|-----------------|----------------|
| Laying hen      | -      | -                 | -               | -              |
| Goat/Cow        | -      | -                 | -               | -              |
| Pig             | -      | -                 | -               | -              |
| Fish            | -      | -                 | -               | -              |

The calculated DB intake from the representative uses of potatoes as animal feed item was below the trigger value of 0.004 mg/kg bw/day. Thus, it was concluded that livestock metabolism studies were not needed. However, the residues in succeeded crops was not fully investigated and therefore might need to be reconsidered in the view of the identified data gap.

| Time needed to reach a plateau concentration in milk and eggs (days) | - |
| Animal residue definition for monitoring (RD-Mo) | OPEN |
| Animal residue definition for risk assessment (RD-RA) | OPEN |
| Conversion factor (monitoring to risk assessment) | - |
| Metabolism in rat and ruminant similar (Yes/No) | - |
| Fat soluble residues (Yes/No) | - |

### Residues in succeeding crops (Regulation (EU) No 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) | - |
Field rotational crop study

Two trials grown after treated potatoes with (6 x 0.75g/ha) were submitted for barley, carrots, lettuce at PBIs 1, 6 - 8 and 12 months.

Max. concentration in soil (0-20 cm): - KIF-230R-L: 0.08 mg/kg (8 DALA); KIF-230-M-1: < 0.01 mg/kg (8 DALA), KIF-230-M-5: 0.02 mg/kg (8 DALA); KIF-230S-L and -M-4: < 0.003 mg/kg (any time).

In potatoes, highest residue - KIF-230R-L: < 0.01 mg/kg; KIF-230S-L, -M-1, -M-4 and -M-5: < 0.003 mg/kg.
In lettuce, barley (grains and straw) and carrots (roots and leaves), highest residue - KIF-230R-L, S-L, -M-5, -M-4 and -M-1: < 0.003 mg/kg (any PBI).

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

| Plant products (Category) | Commodity        | T (°C) | Stability (Month) |
|---------------------------|------------------|--------|-------------------|
| High water content        | Tomatoes         | ≤ -18  | 12 12 - - - -     |
|                           | Lettuce          |        | - - 6 6 6 6       |
| High oil content          | Oil seed rape    | ≤ -18  | 12 12 - - - -     |
| High protein content      | Field beans      | ≤ -18  | 12 12 - - - -     |
| High starch content       | Potatoes         | ≤ -18  | 12 12 - - - -     |
|                           | Carrot root      |        | - - 6 6 6 Not stable |
| High acid content         | Grapes           | ≤ -18  | 6 - - - - -       |
| Dry commodities           | Barley straw     | ≤ -18  | 6 6 6 3 Not stable |

Throughout all the storage stability studies, acceptable storage stability of parent bentiavalicarb-isopropyl can be demonstrated for up to 6 months in all crop categories according to the current recommendations.
Summary of residues data from the supervised residue trials (Regulation (EU) No 283/2013, Annex Part A, point 6.3)

| 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) |
|------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------|---------------|-----------------|
| Representative uses                  |                   |                                                                                                                                 | 8 trials were conducted throughout Europe. KIF-230 15% WG was applied by broadcast foliar spraying at ca. 1 x the application rate with 5-days re-treatment intervals and a PHI of 3 days. |                     |               |                 |
| Potatoes   | NEU               | KIF-230R-L: 1 x < 0.001 (LOD); 3 x < 0.01 (LOQ) KIF-230S-L: 4 x < 0.001 (LOD)                                                       |                                                                                                            |                     |               |                 |
| Potatoes   | SEU               | KIF-230R-L: 2 x < 0.001 (LOD); 2 x < 0.01 (LOQ) KIF-230S-L: 4 x < 0.001 (LOD)                                                       |                                                                                                            |                     | 0.02 (LOQ)    | < 0.01          |
|            |                   |                                                                                                                                  |                                                                                                            |                     | < 0.01        |                 |

Summary of the data on formulation equivalence

| Crop       | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|
|            |        |                      |                         |

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

| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|
|            |        |                      |                         |

(a): NEU or SEU for northern or southern outdoor trials in EU member states (N+SEU if both zones), Indoor for glasshouse/protected crops, Country if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use Mo/RA to differentiate data expressed according to the residue definition for Monitoring and Risk Assessment.

(c): HR: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR\textsubscript{Mo}).

(d): STMR: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR\textsubscript{Mo}).
### Inputs for animal burden calculations

| Feed commodity         | Median dietary burden (mg/kg) | Comment                              | Maximum dietary burden (mg/kg) | Comment |
|------------------------|------------------------------|--------------------------------------|------------------------------|---------|
| potato, culls          | -                            | not calculated, not required          | 0.01                         | HR      |
| potato, process waste  | -                            | not calculated, not required          | 0.01                         | STMR    |
| potato, dried pulp     | -                            | not calculated, not required          | 0.01                         | STMR    |
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)- (open, pending the finalisation of the rotational crops assessment)

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle 0.0012 | Ram/Ewe 0.0015 | Breeding 0.0010 | Broiler 0.0006 | Carp N/A |
| | Dairy cattle 0.0016 | Lamb 0.0011 | Finishing 0.0009 | Layer 0.0004 | Trout N/A |
| Intake >0.004 mg/kg bw | No | No | No | Turkey 0.0007 | Fish intake >0.1 mg/kg DM |
| Feeding study submitted | No | No | No | No | No |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: - | Dairy: - | Level | Lamb: - | Ewe: - | Level | breed: - | finish: - | Level | broiler: - | turkey: - | layer: - | Level | carp: - | trout: - |
|------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Muscle | Estimated HR(a) at 1N | MRL proposals | Estimated HR(a) at 1N | MRL proposals | Estimated HR(a) at 1N | MRL proposals | Estimated HR(a) at 1N | MRL proposals | Estimated HR(a) at 1N | MRL proposals |
| 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 intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
| STMR calculations                  | Ruminant          | Pig/Swine       | Poultry        | Fish  |
|-----------------------------------|-------------------|-----------------|----------------|-------|
| Median expected intake            | Beef cattle       | Breeding        | Broiler        | Carp  |
| (mg/kg bw/d)                      | -                 | -               | -              | -     |
| (mg/kg DM for fish)               | Dairy cattle      | Finishing       | Layer          | -     |
|                                  | -                 | -               | -              | Beef  |
|                                  | Ram/Ewe           | -               | -              | -     |
|                                  | Breeding          | -               | -              | -     |
|                                  | Ewe               | -               | -              | -     |
|                                  | Broiler           | -               | -              | -     |
|                                  | Lamb              | -               | -              | -     |
|                                  | Finishing         | -               | -              | -     |
|                                  | Turkey            | -               | -              | -     |
| Representative feeding level      | Level             | Level           | Level          | Level |
| (mg/kg bw/d, mg/kg DM for fish)   | Beef: -           | Lamb : -        | broiler: -     | carp: -|
|                                  | Dairy: -          | Ewe: -          | turkey: -      | -     |
|                                  | Level             | Level           | layer: -       | -     |
|                                  | Mean level        | Level           | Level          | Level |
| in feeding level                 | Estimated STMR(b) | Estimated STMR(b)| Estimated STMR(b)| Estimated STMR(b) |
|                                  | at 1N             | at 1N           | at 1N          | at 1N |
| Muscle                           |                  |                 |                |       |
| Fat                              |                  |                 |                |       |
| Meat(a)                          |                  |                 |                |       |
| Liver                            |                  |                 |                |       |
| Kidney                           |                  |                 |                |       |
| Milk                             |                  |                 |                |       |
| Eggs                             |                  |                 |                |       |
| Method of calculation(c)         |                  |                 |                |       |

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

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

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

Not required.

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

Not required

PRIMo 3.1
Consumer risk assessment limited to the representative uses on potatoes) and is provisional only.

|             | 0.1 mg/kg bw per day |
|-------------|----------------------|
| TMDI (% ADI, according to EFSA PRIMo) | Highest TMDI: 0.1% ADI (NL toddler) |
| NTMDI (% ADI, according to (to be specified)) | Highest NTMDI: - |
| IEDI (% ADI, according to EFSA PRIMo) | Highest IEDI: - |
| NEDI (% ADI, according to (to be specified)) | Highest NEDI: - |

Factors included in the calculations

ARfD

| 6.7 mg/kg bw |

IESTI (% ARfD, according to EFSA PRIMo)

| Highest IESTI: 0.05% ARfD |

NESTI (% ARfD, according to (to be specified))

| Highest NESTI: Not required |

Factors included in IESTI and NESTI

Assessment of negligible exposure under realistic conditions of use:
The concentration of bethiavalicarb-isopropyl residues in potatoes were below the LOQ of 0.01 mg/kg. However, the assessment of residues in rotational crops (fate and magnitude of residues) is not finalised and therefore residues in edible crops and feed items cannot be excluded.

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

| Code    | Commodity/Group | MRL/Import tolerance (mg/kg) and Comments |
|---------|-----------------|------------------------------------------|
| 0211000 | potatoes        | 0.02 (*) mg/kg | MRL derived for a more critical GAP, supported by adequate data, without consumer risk and in compliance with existing MRL |

Animal commodities

| - | - | - | No MRL available; default MRL of 0.01 mg/kg is considered or a specific LOQ, i.e. 0.05 mg/kg in honey and other apiculture products |
Environmental fate and behaviour

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

| Mineralisation after 100 days | 44.8% after 120 days; [Val-2-14C]-label (n=1) 3.6 - 11.7% after 120 days; [Bz-U-14C]-label (n=4) |
| Non-extractable residues after 100 days | 36.3% after 120 days; [Val-2-14C]-label (n=1) 22.5 - 58.2% after 120 days; [Bz-U-14C]-label (n=4) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | [Bz-U-14C]-label KIF-230-M-1, max. 4.5 - 27.7% at 120 d (n=4) KIF-230-M-3, max. 2.2 - 12.3% at 28 - 30 d (n=4) KIF-230-M-4, max. 7.6 - 9.8% at 28 - 30 d (n=4) KIF-230-M-5, max. 12.1 - 26.8% at 28 - 30 d (n=4) KIF-230-M-8, max. 2.6% at 14 d (n=1) (minor under aerobic conditions) |

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

| Mineralisation after 100 days | 0.5% after 120 days; [Bz-U-14C]-label (n=1) |
| Non-extractable residues after 100 days | 25.5% after 120 days; [Bz-U-14C]-label (n=1) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | [Bz-U-14C]-label KIF-230-M-3, max. 24.2 at 271 d (n=1) KIF-230-M-4, max. 11.9% at 120 d (n=1) KIF-230-M-5, max. 12.4% at 61 d (n=1) KIF-230-M-8, max. 8.1% at 120 d (n=1 relevant for prolonged anaerobic condition) |

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) | [Bz-U-14C]-label, light exposed KIF-230-M-1, max. 12.1% at 30 d (n=1) KIF-230-M-3, max. 3.8% at 30 d (n=1) KIF-230-M-4, max. 3.5% at 30 d (n=1) KIF-230-M-5, max. 6.4% at 12 d (n=1) |
| Mineralisation at study end | 1.5% after 30 days; [Bz-U-14C]-label (n=1) |
| Non-extractable residues at study end | 32.8% after 30 days; [Bz-U-14C]-label (n=1) |

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

| Parent | Dark aerobic conditions |
| --- | --- |
| Soil type | 14C-labels | pH* | T (°C) / θ (% MWHC) | DT50/DT90 (d) | norm. DT50 (d) | χ²/ν (%) | Method of calculation |
| sandy loam | [Val-2-14C] | 7.0 | 20 / 45 | 16.2 / 53.4 | 18.8 | 3.69 | SFO* |
| | [Bz-U-14C] | | | 21.9 / 72.7 | | 4.17 | SFO |
| sandy loam | [Bz-U-14C] | 5.1 | 20 / 45 | 16.4 / 54.6 | 16.4 | 8.91 | SFO* |
| silt loam | [Bz-U-14C] | 6.7 | 20 / 45 | 11.1 / 36.7 | 11.1 | 5.25 | SFO* |
| clay loam | [Bz-U-14C] | 7.7 | 20 / 45 | 10.6 / 35.4 | 10.6 | 8.57 | SFO* |
| Geometric mean (if not pH dependent) | 13.8 |
pH dependence: no

* measured in water
* for trigger and modelling

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

### KIF-230-M-5

**Dark aerobic conditions. Precursor from which the ffM was derived was parent.**

| Soil type        | pH  | T (°C) / θ (% MWHC) | DT$_{50}$/DT$_{90}$ (d) | ffM $k_f/k_{dp}$ | norm. DT$_{50}$ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|------------------|-----|---------------------|-------------------------|-----------------|---------------------|---------------------|----------------------|
| sandy loam       | 7.0 | 20 / 45             | 28.8 / 95.8             | 0.224           | 28.8                | 28.3                | SFO*                 |
| sandy loam       | 5.1 | 20 / 45             | 66.2 / 220              | 0.384           | 66.2                | 20.9                | SFO*                 |
| silt loam        | 6.7 | 20 / 45             | 42.8 / 142              | 0.214           | 42.8                | 7.64                | SFO*                 |
| clay loam        | 7.7 | 20 / 45             | 15.6 / 52.0             | 0.384           | 15.6                | 19.5                | SFO*                 |

### KIF-230-M-5

**Dark aerobic conditions. Metabolite dosed.**

| Soil type        | pH  | T (°C) / θ (% MWHC) | DT$_{50}$/DT$_{90}$ (d) | ffM $k_f/k_{dp}$ | norm. DT$_{50}$ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|------------------|-----|---------------------|-------------------------|-----------------|---------------------|---------------------|----------------------|
| silt loam        | 5.7 | 20 / 43             | 42.8 / 1480             | -               | 100                 | 3.85                | DFOP§ (k1=0.02918; k2=0.00693; g=0.6885) |
| loamy sand       | 4.9 | 20 / 39             | 26.2 / 178              | -               | 65.2                | 3.37                | DFOP§ (k1=0.6724; k2=0.01063; g=0.3391) |
| loam             | 7.2 | 20 / 66             | 2.13 / 24.2             | -               | 9.76                | 3.99                | DFOP§ (k1=1.652; k2=0.07105; g=0.4336) |

Geometric mean (if not pH dependent) 36.2

Arithmetic mean

pH dependence: no

* measured in water
* for trigger and modelling
§ DT$_{50}$ from slow phase of DFOP model used for modelling

### KIF-230-M-4

**Dark aerobic conditions. Metabolite dosed.**

| Soil type        | pH  | T (°C) / θ (% MWHC) | DT$_{50}$/DT$_{90}$ (d) | ffM $k_f/k_{dp}$ | DT$_{50}$=DT$_{90}$/3.32§ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|------------------|-----|---------------------|-------------------------|-----------------|-----------------------------|---------------------|----------------------|
| sandy loam       | 5.5 | 20 / 45             | 0.08 / 82.0             | -               | 24.7                        | 14.0                | DFOP (k1=0.5014 h$^{-1}$; k2=0.0003 h$^{-1}$; g=0.804) |
| silt loam        | 6.7 | 20 / 45             | 0.06 / 33.7             | -               | 10.1                        | 6.46                | DFOP (k1=0.5975 h$^{-1}$; k2=0.0004 h$^{-1}$; g=0.859) |
| clay loam        | 8.0 | 20 / 45             | 0.18 / 64.3             | -               | 19.4                        | 5.55                | DFOP (k1=0.3446 h$^{-1}$; k2=0.0008 h$^{-1}$; g=0.642) |

Geometric mean (if not pH dependent) 16.9§

Arithmetic mean

Geometric mean (if not pH dependent) 16.9§

Arithmetic mean
**Pesticide Risk Assessment of Benthiavalicarb**

**KIF-230-M-3**

Dark aerobic conditions. Metabolite dosed.

| Soil type       | pH  | T (°C) / 0 ( % MWHC) | DT$_{50}$/DT$_{90}$ (d) | ff$_M$ k/r$_{dp}$ | norm. DT$_{50}$ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|-----------------|-----|----------------------|-------------------------|-------------------|----------------------|---------------------|-----------------------|
| sandy loam      | 5.5 | 20 / 45              | 6.93 / 23.0             | -                 | 6.93                 | 7.78                | SFO*                  |
| silt loam       | 6.7 | 20 / 45              | 7.34 / 24.4             | -                 | 7.34                 | 5.87                | SFO*                  |
| clay loam       | 8.0 | 20 / 45              | 2.34 / 19.8             | -                 | 5.55                 | 5.53 (α=1.053; β=2.509) | FOMC*                |

Geometric mean * (if not pH dependent) 6.56

Arithmetic mean

pH dependence: no

measured in water

DT$_{50}$ from DFOP DT$_{90}$/3.32 to be used for modelling

**KIF-230-M-1**

Dark aerobic conditions. Metabolite dosed.

| Soil type       | pH  | T (°C) / 0 ( % MWHC) | DT$_{50}$/DT$_{90}$ (d) | ff$_M$ k/r$_{dp}$ | norm. DT$_{50}$ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|-----------------|-----|----------------------|-------------------------|-------------------|----------------------|---------------------|-----------------------|
| sandy loam      | 5.5 | 20 / 45              | 12.7 / 249              | -                 | 116                  | 3.95                | DFOP* (k1=0.125; k2=0.006; g=0.594) |
| silt loam       | 6.7 | 20 / 45              | 3.83 / 15.5             | -                 | 4.7~                 | 6.84                | DFOP* (k1=0.197; k2=0.0000693; g=0.943) |
| clay loam       | 8.0 | 20 / 45              | 7.42 / 67.6             | -                 | 20.4~                | 3.51                | DFOP* (k1=0.170; k2=0.019; g=0.629) |

Geometric mean (if not pH dependent) 2.3

Arithmetic mean

pH dependence: no

measured in water

DT$_{50}$ from slow phase of DFOP model to be used for modelling

~ DFOP DT$_{90}$/ 3.32 to be used for modelling

**KIF-230-M-8**

Dark aerobic conditions. Metabolite dosed.

| Soil type       | pH  | T (°C) / 0 ( % MWHC) | DT$_{50}$/DT$_{90}$ (d) | ff$_M$ k/r$_{dp}$ | norm. DT$_{50}$ (d) | $\chi^2_{err}$ (%) | Method of calculation |
|-----------------|-----|----------------------|-------------------------|-------------------|----------------------|---------------------|-----------------------|
| silt loam       | 5.8 | 21 / 65              | 2.87 / 9.53             | -                 | 3.15                 | 4.81                | SFO*                  |
| loamy sand      | 5.4 | 21 / 54              | 7.44 / 24.7             | -                 | 8.18                 | 5.97                | SFO*                  |
| loam            | 7.2 | 21 / 66              | 1.85 / 6.14             | -                 | 2.03                 | 3.72                | SFO*                  |

Geometric mean * (if not pH dependent) 3.74

**Notes:**

- # measured in water
- § pH dependence: no
- § DT$_{50}$ from DFOP DT$_{90}$/3.32 to be used for modelling
- § DFOP DT$_{90}$/ 3.32 to be used for modelling
- * SFO visually and statistically acceptable ($\chi^2_{err}$ = 8.18%), SFO DT$_{50}$ used for modelling
- § FOMC ($\alpha=1.053; \beta=2.509$)
- § Geometric mean
- § Arithmetic mean
Arithmetic mean

| pH dependence: no |
|-------------------|

* measured in water
* for trigger and modelling
§ A correction factor of 1.099 was applied to normalise DT₅₀ to 20°C

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent | No data, not required |
|--------|------------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| pH⁰ | Depth (cm) | DT₅₀ (d) Actual | DT₅₀(d) actual | St. (χ²) | DT₅₀ (d) Norm⁰ | Method of calculation |
| Geometric mean (if not pH dependent) | |
| pH dependence, |

| Metabolite KIF-230-M-1 | Data gap |
|-----------------------|----------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| pH⁰ | Depth (cm) | DT₅₀ (d) Actual | DT₅₀(d) actual | St. (χ²) | DT₅₀ (d) Norm⁰ | Method of calculation |
| Geometric mean (if not pH dependent) | |
| pH dependence, |

| Metabolite KIF-230-M-5 | Data gap |
|-----------------------|----------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| pH⁰ | Depth (cm) | DT₅₀ (d) Actual | DT₅₀(d) actual | St. (χ²) | DT₅₀ (d) Norm⁰ | Method of calculation |
| Geometric mean (if not pH dependent) | |
| pH dependence, |

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

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

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

Kinetic formation fraction (f. f. kᵣ / kᵩ) of transformation products, arithmetic mean

Laboratory endpoints used for modelling

Laboratory endpoints used for modelling

Laboratory endpoints used for modelling
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

| Soil type          | 14C-labels | pH # | T (°C) / % MWHC | DT50/DT90 (d) | norm. DT50 (d) | χ² err (%) | Method of calculation |
|--------------------|------------|------|-----------------|---------------|---------------|------------|----------------------|
| sandy loam         | [Bz-U-14C] | 7.0  | 20 / flooded    | 39.9 / 133    | 39.9          | 3.11       | SFO                  |
| Geometric mean (if not pH dependent) |                 |      |                 |               | 39.9          |            |                      |

* measured in water

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

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

| Parent | Soil photolysis* |
|--------|------------------|
| Soil type | Light source | pH # | t. °C / % MWHC | DT50 / DT90 (d) | St. (χ²) | Method of calculation |
| silt loam | xenon lamp | 7.4  | 25 / ~30        | 20.4 / 67.8     | 8.48      | SFO                 |

* degradation is faster in the dark control and therefore soil photolysis is not expected to be a significant degradation process for benthiavalicarb.

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

| Soil Type                  | OC % | Soil pH | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|---------------------------|------|---------|------------|--------------|------------|--------------|-----|
| Sandy loam PT102          | 2.5  | 7.1     | 3.9 - 7.6  | 155.6 - 302.3| 4.6        | 182.1        | 0.87|
| Loam                      | 5.4  | 7.5     | 5.7 - 12.3 | 106.0 - 227.2| 6.5        | 121.3        | 0.85|
| Silt loam                 | 2.5  | 6.8     | 5.6 - 13.4 | 222.1 - 536.8| 6.5        | 258.2        | 0.84|
| Sand                      | 0.4  | 7.0     | 0.7 - 1.0  | 168.1 - 242.8| 0.8        | 193.8        | 0.93|
| Clay loam PT103           | 1.3  | 5.5     | 1.8 - 2.3  | 135.2 - 173.8| 1.9        | 147.4        | 0.93|
| Geometric mean (if not pH dependent) |      |         |            |              |            |              |     |
| Arithmetic mean (if not pH dependent) |      |         |            |              |            |              | 0.88|

* Measured in water

### Soil Adsorption Transformation Products

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

#### KIF-230-M-5

| Soil Type     | OC % | Soil pH | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|---------------|------|---------|------------|--------------|------------|--------------|-----|
| Loam          | 2.49 | 7.03    | 30.2 - 83.6| 351.0 - 547.2| 24.7       | 990.1        | 0.81|
| Loamy sand    | 0.68 | 4.90    | 5.41 - 14.6| 289.2 - 517.3| 4.5        | 666.0        | 0.795|
| Silt loam     | 1.11 | 7.52    | 14.1 - 33.2| 176.4 - 259.4| 11.1       | 1003.6       | 0.831|
| Geometric mean (if not pH dependent) |      |         |            |              |            |              |     |
| Arithmetic mean (if not pH dependent) |      |         |            |              |            |              | 0.809|

* Measured in water

#### KIF-230-M-4

| Soil Type     | OC % | Soil pH | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|---------------|------|---------|------------|--------------|------------|--------------|-----|
| Loam          | 2.49 | 7.03    | 2.83 - 10.3| 85.2 - 531.0 | 2.0        | 80.1         | 0.766|
| Loamy sand    | 0.68 | 4.90    | 1.49 - 2.62| 220.0 - 512.9| 1.4        | 209.0        | 0.876|
| Silt loam     | 1.11 | 7.52    | 0.95 - 5.03| 106.3 - 501.5| 0.7        | 59.8         | 0.687|
| Geometric mean (if not pH dependent) |      |         |            |              |            |              |     |
| Arithmetic mean (if not pH dependent) |      |         |            |              |            |              | 0.777|

* Measured in water

#### KIF-230-M-3

| Soil Type      | OC % | Soil pH | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|----------------|------|---------|------------|--------------|------------|--------------|-----|
| Loam           | 2.8  | 7.1     | 3.4 - 9.1  | 121.2 - 326.7| 4.2        | 148.8        | 0.81|
| Clay loam      | 4.7  | 8.0     | 4.3 - 12.9 | 92.4 - 275.4 | 5.5        | 116.4        | 0.79|
| Sandy loam     | 0.8  | 5.1     | 1.5 - 3.7  | 186.1 - 465.6| 1.9        | 241.0        | 0.82|
| Geometric mean (if not pH dependent) |      |         |            |              |            |              |     |
| Arithmetic mean (if not pH dependent) |      |         |            |              |            |              | 0.81|

* Measured in water
### KIF-230-M-1

| Soil Type      | OC % | Soil pH | K_d (mL/g) | K_dsc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|----------------|------|---------|------------|--------------|------------|--------------|-----|
| Loam           | 2.8  | 7.1     | 5.4 - 18.3 | 193.1 - 653.3 | 6.6        | 237.2        | 0.78|
| Clay loam      | 4.7  | 8.0     | 9.6 - 39.0 | 203.8 - 830.2 | 11.2       | 239.2        | 0.76|
| Sandy loam     | 0.8  | 5.1     | 2.7 - 8.4  | 335.0 - 1048  | 3.4        | 422.3        | 0.78|

Geometric mean (if not pH dependent) - 288.3
Arithmetic mean (if not pH dependent) - 0.77

pH dependence: No

* Measured in water

### KIF-230-M-8

| Soil Type      | OC % | Soil pH | K_d (mL/g) | K_dsc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | 1/n |
|----------------|------|---------|------------|--------------|------------|--------------|-----|
| Sandy loam     | 1.7  | 5.5     | 0.97       | 56           | 1.00       | 57           | 0.87|
| Sandy loam     | 0.7  | 5.8     | 0.45       | 68           | 0.54       | 81           | 0.83|
| Loam           | 2.0  | 7.2     | 1.70       | 86           | 1.63       | 82           | 0.80|

Geometric mean (if not pH dependent) - 72
Arithmetic mean (if not pH dependent) - 0.83

pH dependence: No

* Measured in water

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

Column leaching: No data; not required

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

Column leaching: No data; not required

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

Lysimeter/ field leaching studies: No data; not required

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

Hydrolytic degradation of the active substance and metabolites > 10 %

- pH 5: stable at 25°C
- pH 7: stable at 25°C
- pH 9: stable at 25°C
Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

DT$_{50}$: 16.2 - 543.0 days (buffer solutions)  
natural light, 41°N; DT$_{50}$: 795 days (SHW) (4)  
No metabolites > 5% AR

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

No data; not required

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

Readily biodegradable  
(Yes/no)  
No

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

| System identifier (indicate fresh, estuarine or marine) | pH | pH | t & °C | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|--------------------------------------------------------|----|----|--------|------------------------------------------------------|----------------|--------------------------------------|----------------|----------------------|
| Fresh                                                  | 8.3 | N/A | 22.9   | N/A                                                 | N/A            | 11 µg/l: 49.9 / 82.2                 | 3.49           | HS                   |
|                                                        |    |    |        |                                                     |                | 108 µg/l: 103 / 256                 | 1.59           | HS                   |

& Temperature of incubation  
N/A Not applicable

KIF-230-M-5  
max. in total system 25.1% after 62 days

| System identifier (indicate fresh, estuarine or marine) | pH | pH | t & °C | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|--------------------------------------------------------|----|----|--------|------------------------------------------------------|----------------|--------------------------------------|----------------|----------------------|
|                                                        |    |    |        |                                                     |                |                                                     |                |                      |

& Temperature of incubation  
N/A Not applicable

KIF-230-M-4  
max. in total system 23.7% after 62 days

| System identifier (indicate fresh, estuarine or marine) | pH | pH | t & °C | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|--------------------------------------------------------|----|----|--------|------------------------------------------------------|----------------|--------------------------------------|----------------|----------------------|
|                                                        |    |    |        |                                                     |                |                                                     |                |                      |

& Temperature of incubation  
N/A Not applicable

KIF-230-M-8  
max. in total system 10.1% after 62 days

(4) SHW: synthetic humic water
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | t. & °C(b) | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|--------------------------------------------------------|----------------|--------|------------|-------------------------------------------------|----------------|--------------------------------|----------------|----------------------|
| KIF-230-M-3                                            | max. in total system 4.8% after 62 days |
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | t. & °C(b) | DT$_{50}$/DT$_{90}$ whole sys. (suspended sediment test) | St. ($\chi^2$) | DT$_{50}$/DT$_{90}$ Water (pelagic test) | St. ($\chi^2$) | Method of calculation |
|                                                       | -              | -      | -          | -                                                | -              | -                                    | -              | -                    |
| & Temperature of incubation                             |                |        |            | N/A                                              |                |                                      |                | N/A                  |

Mineralisation and non extractable residues (for parent dosed experiments)

| System identifier | pH water phase | pH sed | Mineralisation | Non-extractable residues (suspended sediment test) | Non-extractable residues (end of the study) (suspended sediment test) |
|-------------------|----------------|--------|----------------|-----------------------------------------------------|-----------------------------------------------------------------------|
| Fresh             | 8.3            | N/A    | 0.5% after 28 d| N/A                                                 | N/A                                                                   |

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)

| System | pH water | pH sed | T (°C) | DT$_{50}$/DT$_{90}$ whole syst. | $\chi^2_{err}$ (%) | DT$_{50}$/DT$_{90}$ Water | $\chi^2_{err}$ (%) | DT$_{50}$/DT$_{90}$ sediment | $\chi^2_{err}$ (%) | Method of calculation |
|--------|----------|--------|--------|---------------------------------|-------------------|--------------------------|-------------------|-------------------------------|-------------------|----------------------|
| Pond   | 8.0      | 7.2    | 20     | 18.2 / 60.6                    | 1.51              | -                        | 3.69 / 21.5        | 17.2 / 57.3                   | 5.52              | level P-I, SFO         |
| Lake   | 4.8      | 6.1    | 20     | 15.1 / 50.0                    | 7.15              | -                        | 7.71 / 25.6        | 25.7 / 85.3                   | 5.88              | level P-I, DFOP        |
| Geometric mean (DT$_{50}$): | 16.6 | - | 21.0 | - | - | - | - | - | - | level P-I, SFO |

KIF-230-M-1 Max. in total system 5.1% after 100 days and increasing towards study end

Distribution (max. in water 0.4% after 14 days; max. in sediment 5.1% after 100 days)

| System | pH water | pH sed | T (°C) | DT$_{50}$/DT$_{90}$ whole syst. | $\chi^2_{err}$ (%) | DT$_{50}$/DT$_{90}$ Water | $\chi^2_{err}$ (%) | DT$_{50}$/DT$_{90}$ sediment | $\chi^2_{err}$ (%) | Method of calculation |
|--------|----------|--------|--------|---------------------------------|-------------------|--------------------------|-------------------|-------------------------------|-------------------|----------------------|
| Pond   | -        | -      | -      | -                               | -                 | -                        | -                 | -                             | -                 | -                    |
| Lake   | -        | -      | -      | -                               | -                 | -                        | -                 | -                             | -                 | -                    |
| Geometric mean (DT$_{50}$): | 1000 | 1000 | 1000 | worst case default | | | | | | |
KIF-230-M-3 Max. in total system 32.5% after 100 days
Distribution (max. in water 6.1% after 100 days; max. in sediment 26.3% after 100 days)

| System | pH water | pH sed. | T (°C) | DT50/DT90 whole syst. | $\chi^2_{err}$ (%) | DT50/DT90 Water | $\chi^2_{err}$ (%) | DT50/DT90 sediment | $\chi^2_{err}$ (%) | Method of calculation |
|--------|----------|---------|--------|-----------------------|-------------------|----------------|----------------|------------------|----------------|---------------------|
| Pond   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |
| Lake   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |

Geometric mean (DT50): 1000

KIF-230-M-4 Max. in total system 22.7% after 30 days
Distribution (max. in water 0.4% after 30 days; max. in sediment 22.7% after 30 days)

| System | pH water | pH sed. | T (°C) | DT50/DT90 whole syst. | $\chi^2_{err}$ (%) | DT50/DT90 Water | $\chi^2_{err}$ (%) | DT50/DT90 sediment | $\chi^2_{err}$ (%) | Method of calculation |
|--------|----------|---------|--------|-----------------------|-------------------|----------------|----------------|------------------|----------------|---------------------|
| Pond   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |
| Lake   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |

Geometric mean (DT50): 1000

KIF-230-M-5 Max. in total system 11.9% after 59 days
Distribution (max. in water 2.4% after 14 days; max. in sediment 11.9% after 59 days)

| System | pH water | pH sed. | T (°C) | DT50/DT90 whole syst. | $\chi^2_{err}$ (%) | DT50/DT90 Water | $\chi^2_{err}$ (%) | DT50/DT90 sediment | $\chi^2_{err}$ (%) | Method of calculation |
|--------|----------|---------|--------|-----------------------|-------------------|----------------|----------------|------------------|----------------|---------------------|
| Pond   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |
| Lake   | -        | -       | -      | -                     | -                 | -              | -               | -                | -              | -                   |

Geometric mean (DT50): 1000

Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH water phase | pH sed | Mineralisation (end of the study) | Non-extractable residues in sediment | Non-extractable residues in sediment (end of the study) |
|-------------------------|----------------|--------|----------------------------------|-------------------------------------|------------------------------------------------------|
| pond                    | 8.0            | 7.2    | 3.8% after 100 days              | 40.6% after 100 days                | 40.6% after 100 days                                  |
| lake                    | 4.8            | 6.1    | 0.9% after 100 days              | 36.4% after 100 days                | 36.4% after 100 days                                  |

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

Direct photolysis in air: No data; not required

Photochemical oxidative degradation in air: DT50 of 4.68 hours (0.195 day; 1.5 $\times$ 10^6 OH/cm^3) calculated with Atkinson’s model (AOPWIN v1.92).

Volatilisation: From plant surfaces: not tested
From soil surfaces: not tested

Metabolites: DT50 of 4.68 hours (12-day; 1.5 $\times$ 10^6 OH/cm^3) calculated with Atkinson’s model (AOPWIN v1.92).

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

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure: Soil: KIF-230R-L, -M-5, -M-4, -M-3, -M-1, -M-8 (only relevant when prolonged anaerobic conditions are expected)
Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

| Surface water: KIF-230R-L, -M-5, -M-4, -M-3, -M-1, -M-8 (only relevant when prolonged anaerobic conditions are expected) |
| Sediment: KIF-230R-L, -M-5, -M-4, -M-3, -M-1, -M-8 (only relevant when prolonged anaerobic conditions are expected) |
| Ground water: KIF-230R-L, -M-5, -M-4, -M-3, -M-1, -M-8 (only relevant when prolonged anaerobic conditions are expected) |
| Air: KIF-230R-L |

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

| Soil (indicate location and type of study) | Not available |
| Surface water (indicate location and type of study) | Not available |
| Ground water (indicate location and type of study) | Not available |
| Air (indicate location and type of study) | Not available |

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

| Parent Method of calculation |
| DT₅₀: | 18.8 days |
| kinetics: | SFO |
| field or laboratory: | representative worst case from laboratory studies |

| Application data |
| crop: | potatoes |
| depth of soil layer: | 5 cm |
| soil bulk density: | 1.5 g/cm³ |
| crop interception factor: | 15% |
| number of applications: | 8 |
| interval: | 5 days |
| application rate(s): | 75 g a.s./ha |

| PEC₅₅,₆₅,₆₅ (mg/kg) | single application actual | single application time weighted average | multiple application actual | multiple application time weighted average |
|-------------------|-----------------------------|---------------------------------|-----------------------------|---------------------------------|
| initial short term 1 d | 0.085 | 0.083 | 0.389 | 0.382 |
| 2 d | 0.082 | 0.083 | 0.375 | 0.375 |
| 4 d | 0.079 | 0.079 | 0.336 | 0.362 |
| long term 7 d | 0.066 | 0.075 | 0.301 | 0.347 |
| 28 d | 0.030 | 0.053 | 0.139 | 0.308 |
| 50 d | 0.013 | 0.039 | 0.062 | 0.263 |
| 100 d | 0.002 | 0.022 | 0.010 | 0.175 |
| plateau concentration | no accumulation | | | |

PEC₅₅,₆₅,₆₅ (mg/kg)
KIF-230-M-5

Method of calculation

Molecular weight relative to parent: 0.5144

DT$_{50}$ (d): 446 d (based on the longest not normalized DT$_{90}$/3.32)

Note: The DT$_{90}$/3.32 as the worst case was used although the best fit kinetic parameters ($k_1 = 0.02918$, $k_2 = 0.00693$, $g=0.685$, DT$_{50}$ = 24 days (fast phase) DT$_{50}$= 100 days (slow phase)) should have been used.

Kinetics: DFOP

Field or Lab: worst case from laboratory studies

Application data

Application rate assumed: 10.3 g/ha (corresponding to maximum of ~26.8 % of applied parent in case of sequential modelling of a single application)

| PEC$_S$ (mg/kg) | single application | single application | multiple application | multiple application |
|----------------|--------------------|--------------------|----------------------|----------------------|
|                | actual             | time weighted average | actual              | time weighted average |
| initial        | 0.0454             |                     | 0.178                |                      |
| short term     | 1 d                | 0.0453              | 0.0453               | 0.178                |
|                | 2 d                | 0.0452              | 0.0453               | 0.177                |
|                | 4 d                | 0.0451              | 0.0452               | 0.177                |
|                | 7 d                | 0.0449              | 0.0451               | 0.176                |
|                | 28 d               | 0.0435              | 0.0444               | 0.170                |
|                | 50 d               | 0.0421              | 0.0437               | 0.165                |
|                | 100 d              | 0.0389              | 0.0420               | 0.152                |
| plateau        | concentration      | 0.051 mg/kg         | 0.418 mg/kg          |                      |

KIF-230-M-4

Method of calculation

Molecular weight relative to parent: 0.5117

DT$_{50}$ (d): 24.7 days (DT$_{90}$/3.32)

Kinetics: DFOP

Field or Lab: worst case from laboratory studies

Application data

Application rate assumed: 3.76 g/ha (corresponding to a maximum of ~9.8% of applied parent in case of sequential modelling of a single application)

| PEC$_S$ (mg/kg) | single application | single application | multiple application | multiple application |
|----------------|--------------------|--------------------|----------------------|----------------------|
|                | actual             | time weighted average | actual              | time weighted average |
| initial        | 0.0043             |                     | 0.0195               |                      |
| short term     | 1 d                | 0.0041              | 0.0042               | 0.0188               |
|                | 2 d                | 0.0040              | 0.0041               | 0.0182               |
|                | 4 d                | 0.0037              | 0.0040               | 0.0169               |
|                | 7 d                | 0.0033              | 0.0038               | 0.0151               |
|                | 28 d               | 0.0015              | 0.0033               | 0.0070               |
|                | 50 d               | 0.0007              | 0.0031               | 0.0031               |
|                | 100 d              | 0.0001              | 0.0005               | 0.0005               |
| plateau        | concentration      | no accumulation     | 0.0208 mg/kg         |                      |

KIF-230-M-3

Method of calculation

Molecular weight relative to parent: 0.5170

DT$_{50}$ (d): 7.34 days
### Kinetics: SFO

**Field or Lab:** worst case from laboratory studies

**Application rate assumed:** 4.77 g/ha (corresponding to a maximum of 12.3% of applied parent in case of sequential modelling of a single application)

| PEC₅ (mg/kg) | single application actual | single application time weighted average | multiple application actual | multiple application time weighted average |
|--------------|---------------------------|-----------------------------------------|-----------------------------|------------------------------------------|
| Initial      | 0.0054                    | 0.0053                                  | 0.0247                      | 0.0243                                   |
| short term   | 1 d                       | 0.0052                                  | 0.0053                      | 0.0238                                   |
|              | 2 d                       | 0.0050                                  | 0.0052                      | 0.0230                                   |
|              | 4 d                       | 0.0046                                  | 0.0050                      | 0.0214                                   |
| long term    | 7 d                       | 0.0042                                  | 0.0048                      | 0.0191                                   |
|              | 28 d                      | 0.0019                                  | 0.0034                      | 0.0088                                   |
|              | 50 d                      | 0.0008                                  | 0.0025                      | 0.0039                                   |
|              | 100 d                     | < 0.0001                                | 0.0014                      | 0.0006                                   |

**Plateau concentration:** no accumulation

### KIF-230-M-1

**Method of calculation**

Molecular weight relative to parent: 0.4435

DT₅₀ (d): 116 (k₁ = 0.125; k₂ = 0.00060; g = 0.594)

**Kinetics:** DFOP

**Field or Lab:** worst case from laboratory studies

**Application rate assumed:** 9.21 g/ha (corresponding to a maximum of 27.7% of applied parent in case of sequential modelling of a single application)

| PEC₅ (mg/kg) | single application actual | single application time weighted average | multiple application actual | multiple application time weighted average |
|--------------|---------------------------|-----------------------------------------|-----------------------------|------------------------------------------|
| Initial      | 0.0104                    | 0.0102                                  | 0.0478                      | 0.0469                                   |
| short term   | 1 d                       | 0.0101                                  | 0.0102                      | 0.0461                                   |
|              | 2 d                       | 0.0097                                  | 0.0101                      | 0.0445                                   |
|              | 4 d                       | 0.0090                                  | 0.0097                      | 0.0413                                   |
| long term    | 7 d                       | 0.0081                                  | 0.0092                      | 0.0370                                   |
|              | 28 d                      | 0.0037                                  | 0.0065                      | 0.0171                                   |
|              | 50 d                      | 0.0016                                  | 0.0048                      | 0.0076                                   |
|              | 100 d                     | 0.0002                                  | 0.0027                      | 0.0012                                   |

**Plateau concentration:** 0.0119 mg/kg

### KIF-230-M-8

**Method of calculation**

Molecular weight relative to parent: 0.6246

DT₅₀ (d): 7.44 days

**Kinetics:** SFO

**Field or Lab:** worst case from laboratory studies

**Application rate assumed:** 1.22 g/ha (corresponding to a maximum of 2.6% of applied parent in case of sequential modelling of a single application)
### PECs (mg/kg)

|                | single application | multiple application |
|----------------|--------------------|----------------------|
|                | actual             | time weighted average| actual                 | time weighted average |
| **Initial**    |                    |                      |                       |                      |
| short term     |                    |                      |                       |                      |
| 1 d            | 0.0017             | 0.0016               | 0.0076                | 0.0075               |
| 2 d            | 0.0016             | 0.0016               | 0.0073                | 0.0073               |
| 4 d            | 0.0014             | 0.0015               | 0.0066                | 0.0071               |
| **long term**  |                    |                      |                       |                      |
| 7 d            | 0.0013             | 0.0015               | 0.0059                | 0.0068               |
| 28 d           | 0.0006             | 0.0010               | 0.0027                | 0.0060               |
| 50 d           | 0.0003             | 0.0008               | 0.0012                | 0.0051               |
| 100 d          | 0.0000             | 0.0004               | 0.0002                | 0.0034               |

**plateau concentration**: no accumulation

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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)*

| Metabolites: | M-5 | M-4 | M-3 | M-1 | M-8 |
|--------------|-----|-----|-----|-----|-----|
| crop uptake factor: | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| solubility in water (mg/l): | 13100 | 30.0 | 1970 | 172 | 611 |
| vapour pressure (Pa): | 0.101 | 0.0015 | 0.00056 | 1.9×10⁻⁵ | 0.00102 |
| norm DT₅₀ (days): | 50.3* | 58.4∞ | 6.56 | 164§ | 3.74 |
| formation fraction: | 0.386* | 1 | 1 | 1 | 1 |
| Kᵦ (geometric mean): | 871.4 | 100.0 | 161.0 | 288.3 | 72 |
| l/n (arithmetic mean): | 0.809 | 0.777 | 0.81 | 0.77 | 0.83 |

* Future PECgw calculations for metabolite M-5 should be performed with a DT50 of 36.2 and ff value of 0.302
∞ Future PECgw calculations for metabolite M-4 should be performed with a DT50 of 16.9
§ Future PECgw calculations for metabolite M-1 should be performed with a DT50 of 22.3 d

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For field and lysimeter studies: not submitted
Location: N/A
Study type (e.g. lysimeter, field leaching): N/A
Soil properties (pH, OC, MWHC): N/A
Application dates: N/A
Crop (estimated interception): N/A
Number of applications: N/A
Average annual rainfall (mm): N/A
Average annual leachate volume (mm): N/A

**Application rate**

| Gross application rate: | 75 g a.s./ha |
| Crop growth stage: | leaf development | flowering/senescence |
| Crop interception: | 15% | 85% / 50% |
| Net application rate: | 63.75 g a.s./ha | 11.25 / 37.5 g a.s/ha |
PEC\textsubscript{(gw)} - FOCUS modelling results (80\textsuperscript{th} percentile annual average concentration at 1m)

| PEARL 4.4.4 | Scenario | parent (µg/l) | M-5 (µg/l) | M-4 (µg/l) | M-3 (µg/l) | M-1 (µg/l) | M-8 (µg/l) |
|-------------|----------|--------------|------------|------------|------------|------------|------------|
| Châteaudun (C) | < 0.001 | < 0.001 | 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Hamburg (H) | < 0.001 | < 0.001 | 0.067 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Jokioinen (J) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Kremsmünster (K) | < 0.001 | < 0.001 | 0.024 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Okehampton (Ok) | < 0.001 | < 0.001 | 0.054 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Piacenza (P) | < 0.001 | < 0.001 | 0.031 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Porto (O) | < 0.001 | < 0.001 | 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Sevilla (S) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Thiva (T) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |

| PELMO 5.5.3 | Scenario | parent (µg/l) | M-5 (µg/l) | M-4 (µg/l) | M-3 (µg/l) | M-1 (µg/l) | M-8 (µg/l) |
|-------------|----------|--------------|------------|------------|------------|------------|------------|
| Châteaudun (C) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Hamburg (H) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Jokioinen (J) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Kremsmünster (K) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Okehampton (Ok) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Piacenza (P) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |

| PELMO 5.5.3 | Scenario | parent (µg/l) | M-5 (µg/l) | M-4 (µg/l) | M-3 (µg/l) | M-1 (µg/l) | M-8 (µg/l) |
|-------------|----------|--------------|------------|------------|------------|------------|------------|
| Châteaudun (C) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Hamburg (H) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Jokioinen (J) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Kremsmünster (K) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Okehampton (Ok) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
| Piacenza (P) | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |< 0.001 |
### MACRO 5.5.4 potatoes (BBCH 10-19)

| Scenario          | Parent (µg/l) | M-5 (µg/l) | M-4 (µg/l) | M-3 (µg/l) | M-1 (µg/l) | M-8 (µg/l) |
|-------------------|---------------|------------|------------|------------|------------|------------|
| Châteaudun (C)    | < 0.001       | < 0.001    | < 0.001    | < 0.001    | < 0.001    | < 0.001    |
| Hamburg (H)       | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Jokioinen (J)     | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Kremsmünster (K)  | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Okehampton (Ok)   | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Piacenza (P)      | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Porto (O)         | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Sevilla (S)       | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Thiva (T)         | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |

### MACRO 5.5.4 potatoes (BBCH 40-99)

| Scenario          | Parent (µg/l) | M-5 (µg/l) | M-4 (µg/l) | M-3 (µg/l) | M-1 (µg/l) | M-8 (µg/l) |
|-------------------|---------------|------------|------------|------------|------------|------------|
| Châteaudun (C)    | < 0.001       | < 0.001    | < 0.001    | < 0.001    | < 0.001    | < 0.001    |
| Hamburg (H)       | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Jokioinen (J)     | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Kremsmünster (K)  | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Okehampton (Ok)   | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Piacenza (P)      | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Porto (O)         | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Sevilla (S)       | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |
| Thiva (T)         | N/A           | N/A        | N/A        | N/A        | N/A        | N/A        |

PEC_{gw} From lysimeter / field studies

|         | 1st year | 2nd year | 3rd year |
|---------|----------|----------|----------|
| Parent  |          |          |          |
| Annual average (µg/L) | N/A | N/A | N/A |

|         | 1st year | 2nd year | 3rd year |
|---------|----------|----------|----------|
| Metabolite X |          |          |          |
| Annual average (µg/L) | N/A | N/A | N/A |

PEC surface water and PEC sediment (Regulation (EU) No 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

| Parameters used in FOCUS Step 1 and Step 2 | Molecular weight: 381.47 g/mol |
|---------------------------------------------|-------------------------------|
| Parameters used in FOCUS Step 3 and Step 4 | FOCUS software: FOCUS SWASH v. 5.1; TOXSWA version 5.5.3 |
|                                             | Water solubility: 13.1 mg/l |
|                                             | Vapour pressure: 3.0E-4 |
|                                             | Keq: 174.7 |
|                                             | l/n: 0.88 |
|                                             | Q_{10} factor: 2.58 |
B-value (Walker equation): 0.7
Crop uptake factor: 0

Application rate
Crop and growth stage: potatoes (BBCH 10-19) - worst case
Number of applications: 8
Interval: 5 days
Application rate(s): 75 g a.s./ha
Application window: Step 1 and 2: N, summer (Jun-Sep); S, spring (Mar-May)

Potatoes in Step 3: 16th March to 6th August

| Application window | PECsw (µg/l) | PECsed (µg/kg) |
|--------------------|--------------|----------------|
|                     | actual       | TWA            | actual       | TWA            |
| All                |              |                |              |                |
| 0                  | 167.73       |                | 283.39       |                |
| 7                  | 124.44       | 144.62         | 217.40       | 251.96         |
| 21                 | 69.357       | 111.03         | 121.17       | 193.73         |
| 28                 | 51.778       | 98.305         | 90.457       | 171.57         |

FOCUS STEP 1 scenario

| days after overall maximum | PECsw (µg/l) | PECsed (µg/kg) |
|----------------------------|--------------|----------------|
|                            | actual       | TWA            | actual       | TWA            |
| Northern Europe            |              |                |              |                |
| 0                          | 12.332       |                | 20.740       |                |
| 7                          | 9.581        | 10.867         | 16.453       | 18.671         |
| 21                         | 5.7915       | 8.6349         | 9.9691       | 14.852         |
| 28                         | 4.5081       | 7.7571         | 7.7601       | 13.344         |
| Southern Europe            |              |                |              |                |
| 0                          | 23.325       |                | 39.946       |                |
| 7                          | 18.139       | 20.617         | 31.224       | 35.475         |
| 21                         | 10.991       | 16.386         | 18.919       | 28.200         |
| 28                         | 8.5556       | 14.720         | 14.727       | 25.335         |

FOCUS STEP 2 scenario

| days after overall maximum | PECsw (µg/l) | PECsed (µg/kg) |
|----------------------------|--------------|----------------|
|                            | actual       | TWA            | actual       | TWA            |
| Northern Europe            |              |                |              |                |
| 0                          | 12.332       |                | 20.740       |                |
| 7                          | 9.581        | 10.867         | 16.453       | 18.671         |
| 21                         | 5.7915       | 8.6349         | 9.9691       | 14.852         |
| 28                         | 4.5081       | 7.7571         | 7.7601       | 13.344         |
| Southern Europe            |              |                |              |                |
| 0                          | 23.325       |                | 39.946       |                |
| 7                          | 18.139       | 20.617         | 31.224       | 35.475         |
| 21                         | 10.991       | 16.386         | 18.919       | 28.200         |
| 28                         | 8.5556       | 14.720         | 14.727       | 25.335         |

Step 3

| Product & Use | Scenario | Application Window | PECsw (µg/L) | PECsed (µg/L) |
|---------------|----------|--------------------|--------------|---------------|
| Potatoes      |          |                    |              |               |
| 8 x 75 g a.s./ha | D3-Ditch | 11-May              | 0.215        | 0.040         |
|               |          | 08-Sep              | 0.102        | 0.065         |
|               |          |                    |              |               |
|               |          | D4-Pond             | 0.137        | 0.135         |
|               |          | 16-Sep              | 0.350        | 0.349         |
|               |          |                    |              |               |
|               |          | D4-Stream           | 0.187        | 0.133         |
|               |          | 16-Sep              | 0.205        | 0.202         |
|               |          |                    |              |               |
|               |          | D6-Ditch            | 0.215        | 0.038         |
|               |          | 08-Jul              | 0.073        | 0.044         |
|               |          |                    |              |               |
|               |          | D6-Ditch (2nd)      | 1.095        | 0.436         |
|               |          | 18-Nov              | 0.506        | 0.460         |
|               |          |                    |              |               |
|               |          | R1-Pond             | 0.155        | 0.142         |
|               |          | 01-Sep              | 0.280        | 0.279         |
|               |          |                    |              |               |
|               |          | R1-Stream           | 0.939        | 0.121         |
|               |          | 01-Sep              | 0.626        | 0.439         |
|               |          |                    |              |               |
|               |          | R2-Stream           | 1.253        | 0.270         |
|               |          | 08-Jun              | 0.739        | 0.487         |
|               |          |                    |              |               |
|               |          | R3-Stream           | 3.238        | 0.479         |
|               |          | 25-Aug              | 1.275        | 0.640         |

Step 4 10 m vegetative filter strip and 10 m no-pray buffer strip

| Product & Use | Scenario | Application Window | PECsw (µg/L) | PECsed (µg/L) |
|---------------|----------|--------------------|--------------|---------------|
| Potatoes      |          |                    |              |               |
| 8 x 75 g a.s./ha | D3-Ditch | 11-May              | 0.0491       | 0.0121        |
|               |          | 08-Sep              | 0.0320       | 0.0211        |
|               |          |                    |              |               |
|               |          | D4-Pond             | 0.1371       | 0.1357        |
|               |          | 16-Sep              | 0.3520       | 0.3517        |
|               |          |                    |              |               |
|               |          | D4-Stream           | 0.1632       | 0.1325        |
|               |          | 16-Sep              | 0.2053       | 0.2022        |
|               |          |                    |              |               |
|               |          | D6-Ditch            | 0.0448       | 0.0115        |
|               |          | 08-Jul              | 0.0229       | 0.0155        |
|               |          |                    |              |               |
|               |          | D6-Ditch (2nd)      | 1.0950       | 0.4356        |
|               |          | 18-Nov              | 0.4947       | 0.4487        |
### Step 4 20 m vegetative filter strip and 20 m no-pray buffer strip

| Product & Use | Scenario | Application Window | PECsw (µg/L) | PECsed (µg/L) |
|--------------|----------|--------------------|--------------|---------------|
|              |          | First | Last | Global max | 7-day TWA | Global max | 7-day TWA |
| Potatoes 8 x 75 g a.s./ha | D3-Ditch | 11-May | 08-Sep | 0.00262 | 0.0064 | 0.0175 | 0.0116 |
|               | D4-Pond | 23-May | 16-Sep | 0.1357 | 0.1343 | 0.3443 | 0.3440 |
|               | D4-Stream | 23-May | 16-Sep | 0.1632 | 0.1325 | 0.2053 | 0.2022 |
|               | D6-Ditch | 11-Apr | 08-Jul | 0.0245 | 0.0108 | 0.0166 | 0.0147 |
|               | D6-Ditch (2nd) | 06-Aug | 18-Nov | 1.0950 | 0.4356 | 0.4922 | 0.4464 |
|               | R1-Pond | 06-May | 01-Sep | 0.0364 | 0.0339 | 0.0764 | 0.0761 |
|               | R1-Stream | 06-May | 01-Sep | 0.2224 | 0.0289 | 0.0900 | 0.0557 |
|               | R2-Stream | 16-Mar | 08-Jun | 0.2953 | 0.0639 | 0.1365 | 0.0843 |
|               | R3-Stream | 11-Apr | 25-Aug | 0.7748 | 0.1149 | 0.3058 | 0.1476 |

### KIF-230-M-5

**FOCUS Calculator: STEPS 1-2 in FOCUS version 3.2**

**Parameters used in FOCUS Step 1 and Step 2**

- Molecular weight: 196.24 g/mol
- Metabolite in: soil and water
- $K_{oc}$: 871.4 ml/g (geometric mean)
- DT$_{50}$ in soil: not required, Step 1 calculation only
- DT$_{50}$ in water/sediment: 1000 d (worst case default)
- DT$_{50}$ in water: not required, Step 1 calculation only
- DT$_{50}$ in sediment: not required, Step 1 calculation only
- Crop interception: not required, Step 1 calculation only
- Max. occurrence observed in soil: 26.8 %
- Max. occurrence observed in water/sediment: 25.1 % (Note: 11.9% should be used for future calculations)

**Parameters used in FOCUS Step 3**

- FOCUS software: not performed
- Water solubility: 13,100 mg/l
- Vapour pressure: N/A
- $K_{oc}$: N/A
- 1/n: N/A
- Q$_{10}$ factor: 2.58
- B-value (Walker equation): 0.7
- Crop uptake factor: N/A
- Metabolite kinetically generated in simulation (y/n): N/A
- Formation fraction in soil: N/A
- Formation fraction in water/sediment: N/A

**Application rate**

- Crop and growth stage: potatoes (BBCH 10-19) - worst case
- Number of applications: 8
- Interval: 5 days
- Application rate(s): 75 g a.s./ha
- Application window: N, summer (Jun-Sep); S, spring (Mar-May)

**Main routes of entry**

- drainage and run-off
### Parameters used in FOCUS Step 1 and Step 2

| FOCUS Calculator: STEPS 1-2 in FOCUS version 3.2 |
|-----------------------------------------------|
| Molecular weight: 195.21 g/mol |
| Metabolite in: soil and water |
| $K_{oc}$: 100.0 ml/g (geometric mean) |
| $DT_{50}$ in soil: not required, Step 1 calculation only |
| $DT_{50}$ in water/sediment: 1000 d (worst case default) |
| $DT_{50}$ in water: not required, Step 1 calculation only |
| $DT_{50}$ in sediment: not required, Step 1 calculation only |
| Crop interception: not required, Step 1 calculation only |
| Max. occurrence observed in soil: 9.8% |
| Max. occurrence observed in water/sediment: 23.7% (Note: 22.7% should be used for future calculations) |

### Parameters used in FOCUS Step 3

| FOCUS software: not performed |
| Water solubility: 30.0 mg/l |
| Vapour pressure: N/A |
| $K_{oc}$: N/A |
| $1/n$: N/A |
| $Q_{10}$ factor: 2.58 |
| B-value (Walker equation): 0.7 |
| Crop uptake factor: N/A |
| Metabolite kinetically generated in simulation (y/n): N/A |
| Formation fraction in soil: N/A |
| Formation fraction in water/sediment: N/A |

### Application rate

- Crop and growth stage: potatoes (BBCH 10-19) - worst case
- Number of applications: 8
- Interval: 5 days
- Application rate(s): 75 g a.s./ha
- Application window: N, summer (Jun-Sep); S, spring (Mar-May)

### Main routes of entry

- Drainage and run-off

### FOCUS STEP 1 scenario

| scenario | days after overall maximum | actual | TWA | actual | TWA |
|----------|---------------------------|--------|-----|--------|-----|
| All      | 0                         | 25.279 |     | 214.11 |     |
|          | 7                         | 24.778 | 24.865 | 215.91 | 216.23 |
|          | 21                        | 24.538 | 24.727 | 213.83 | 215.32 |
|          | 28                        | 24.420 | 24.665 | 212.79 | 214.82 |

### KIF-230-M-4

| FOCUS Calculator: STEPS 1-2 in FOCUS version 3.2 |
|-----------------------------------------------|
| Molecular weight: 197.22 g/mol |
| Metabolite in: soil and water |
| $K_{oc}$: 161.0 ml/g (geometric mean) |
DT$_{50}$ in soil: not required, Step 1 calculation only
DT$_{50}$ in water/sediment: 1000 d (worst case default)
DT$_{50}$ in water: not required, Step 1 calculation only
DT$_{50}$ in sediment: not required, Step 1 calculation only
Crop interception: not required, Step 1 calculation only
Max. occurrence observed in soil: 12.3%
Max. occurrence observed in water/sediment: 32.5%

Parameters used in FOCUS Step 3
- FOCUS software: not performed
- Water solubility: 1970 mg/l
- Vapour pressure: N/A
- $K_{oc}$: N/A
- $1/n$: N/A
- Q$_{10}$ factor: 2.58
- B-value (Walker equation): 0.7
- Crop uptake factor: N/A
- Metabolite kinetically generated in simulation (y/n): N/A
- Formation fraction in soil: N/A
- Formation fraction in water/sediment: N/A

Application rate
- Crop and growth stage: potatoes (BBCH 10-19) - worst case
- Number of applications: 8
- Interval: 5 days
- Application rate(s): 75 g a.s./ha
- Application window: N, summer (Jun-Sep); S, spring (Mar-May)

Main routes of entry
- drainage and run-off

| FOCUS STEP 1 scenario | days after overall maximum | PEC$_{SW}$ (µg/l) | PEC$_{SED}$ (µg/kg) |
|------------------------|-----------------------------|-------------------|---------------------|
|                        |                             | actual            | TWA                 | Actual | TWA     |
| All                    | 0                           | 39.064            | 61.400              |
|                        | 7                           | 38.712            | 38.817              | 62.326 | 62.389  |
|                        | 21                          | 38.338            | 38.622              | 61.724 | 62.146  |
|                        | 28                          | 38.152            | 38.528              | 61.425 | 62.003  |

KIF-230-M-1
- FOCUS Calculator: STEPS 1-2 in FOCUS version 3.2

Parameters used in FOCUS Step 1 and Step 2
- Molecular weight: 169.17 g/mol
- Metabolite in: soil and water
- $K_{oc}$: 288.3 ml/g (geometric mean)
- DT$_{50}$ in soil: not required, Step 1 calculation only
- DT$_{50}$ in water/sediment: 1000 d (worst case default)
- DT$_{50}$ in water: not required, Step 1 calculation only
- DT$_{50}$ in sediment: not required, Step 1 calculation only
- Crop interception: not required, Step 1 calculation only
- Max. occurrence observed in soil: 27.7%
- Max. occurrence observed in water/sediment: 5.1%

Parameters used in FOCUS Step 3
- FOCUS software: not performed
- Water solubility: 172 mg/l
- Vapour pressure: N/A
- $K_{oc}$: N/A
- $1/n$: N/A
- Q$_{10}$ factor: 2.58
- B-value (Walker equation): 0.7
Crop uptake factor: N/A
Metabolite kinetically generated in simulation (y/n): N/A
Formation fraction in soil: N/A
Formation fraction in water/sediment: N/A

**Application rate**

Crop and growth stage: potatoes (BBCH 10-19) - worst case
Number of applications: 8
Interval: 5 days
Application rate(s): 75 g a.s./ha
Application window: N, summer (Jun-Sep); S, spring (Mar-May)

**Main routes of entry**

drainage and run-off

| FOCUS STEP 1 scenario | days after overall maximum | PEC_{SW} (µg/l) actual | PEC_{SW} (µg/l) TWA | PEC_{SED} (µg/kg) actual | PEC_{SED} (µg/kg) TWA |
|-----------------------|---------------------------|------------------------|----------------------|--------------------------|------------------------|
| All                   | 0                         | 21.139                 | 60.583               |                          |                        |
|                       | 7                         | 21.002                 | 21.055               | 60.548                   | 60.677                 |
|                       | 21                        | 20.799                 | 20.952               | 59.964                   | 60.395                 |
|                       | 28                        | 20.698                 | 20.901               | 59.673                   | 60.252                 |

**KIF-230-M-8**

FOCUS Calculator: STEPS 1-2 in FOCUS version 3.2

**Parameters used in FOCUS Step 1 and Step 2**

Molecular weight: 238.27 g/mol
Metabolite in: soil and water
K_{oc}: 72 ml/g (geometric mean)
DT_{50} in soil: not required, Step 1 calculation only
DT_{50} in water/sediment: 1000 d (worst case default)
DT_{50} in water: not required, Step 1 calculation only
DT_{50} in sediment: not required, Step 1 calculation only
Crop interception: not required, Step 1 calculation only
Max. occurrence observed in soil: 2.6%
Max. occurrence observed in water/sediment: 10.1% (Note: 2.6% should be used for future calculations)

**Parameters used in FOCUS Step 3**

FOCUS software: not performed
Water solubility: 611 mg/l
Vapour pressure: N/A
K_{oc}: N/A
I/n: N/A
Q_{10} factor: 2.58
B-value (Walker equation): 0.7
Crop uptake factor: N/A
Metabolite kinetically generated in simulation (y/n): N/A
Formation fraction in soil: N/A
Formation fraction in water/sediment: N/A

**Application rate**

Crop and growth stage: potatoes (BBCH 10-19) - worst case
Number of applications: 8
Interval: 5 days
Application rate(s): 75 g a.s./ha
Application window: N, summer (Jun-Sep); S, spring (Mar-May)

**Main routes of entry**

drainage and run-off
## Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

| FOCUS STEP 1 scenario | days after overall maximum | PEC<sub>SW</sub> (µg/l) | PEC<sub>SED</sub> (µg/kg) |
|-----------------------|---------------------------|-------------------------|--------------------------|
|                       |                           | actual                  | TWA                      | actual                  | TWA                      |
| All                   | 0                         | 14.823                  | 10.422                   |                          |                          |
|                       | 7                         | 14.722                  | 14.759                   | 10.600                  | 10.609                   |
|                       | 21                        | 14.579                  | 14.687                   | 10.497                  | 10.568                   |
|                       | 28                        | 14.509                  | 14.651                   | 10.446                  | 10.544                   |

Method of calculation
No exposure through dust drift, exposure via sewers or run-off from hard surfaces

EC

Maximum concentration
No data; not required
Ecotoxicology
Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species               | Test substance         | Time scale | End point | Toxicity (mg/kg bw per day) |
|-----------------------|------------------------|------------|-----------|-----------------------------|
| **Birds**             |                        |            |           |                             |
| *Colinus virginianus* | Benthiavalicarb-isopropyl | Acute     | LD₅₀      | >2000                       |
| *Anas platyrhynchos*  | Benthiavalicarb-isopropyl | Acute     | LD₅₀      | >2000                       |
| -                     | Benthiavalicarb-isopropyl | Acute     | LD₅₀      | 3776² (extrapolation)       |
| *Colinus virginianus* | Benthiavalicarb-isopropyl | Short-term | LC₅₀      | 937                         |
| *Anas platyrhynchos*  | Benthiavalicarb-isopropyl | Short-term | LC₅₀      | 1442                        |
| -                     | Benthiavalicarb-isopropyl | Long-term  | LD₅₀/10   | 200.0                       |
| *Colinus virginianus* | Benthiavalicarb-isopropyl | Long-term  | NOAEL     | 105.0                       |
| **Mammals**           |                        |            |           |                             |
| *Rat, mouse*          | Benthiavalicarb-isopropyl | Acute     | LD₅₀      | >5000                       |
| *Rat*                 | KIF-230S-L (inactive isomer) | Acute     | LD₅₀      | >2000                       |
| *Rat*                 | KIF-230 15% WG         | Acute     | LD₅₀      | >2000                       |
| *Rat*                 | Metabolite KIF-230-M-1 | Acute     | LD₅₀      | 467.0                       |
| *Rat*                 | Metabolite KIF-230-M-3 | Acute     | LD₅₀      | >2000                       |
| *Rat*                 | Metabolite KIF-230-M-4 | Acute     | LD₅₀      | >2000                       |
| *Rat*                 | Metabolite KIF-230-M-5 | Acute     | LD₅₀      | 545.0                       |
| *Rat*                 | Metabolite KIF-230-M-15| Acute     | LD₅₀      | >2000                       |
| *Rabbit*              | Benthiavalicarb-isopropyl | Long-term  | NOAEL     | 20.0                        |
Endocrine disrupting properties (Annex Part A, points 8.1.5)

Wild mammals

T-modality:
In the mammalian studies only effects at organ level were observed (changes in thyroid histopathology), but no other more apical effects that could be linked to the thyroid mode of action were noted. Taking this into account, effects observed at organ level were considered to be population non-relevant, in line with indications of the ECHA/EFSA guidance document and the common practice.

EAS-modalities:
For mammals as non-target organisms, the population relevance of the adverse effects observed in mammalian studies could neither be confirmed nor excluded due to the uncertainties in the dataset and the poorly investigated MoA. Taking this into account, no firm conclusion could be drawn regarding the ED properties of benthiavalicarb on mammals as non-target organisms for the EAS-modalities

Non-mammalian species
For non-mammalian species neither the endocrine activity nor the endocrine adversity was sufficiently investigated. The available study with birds (according to OECD TG 206) only provide little information on the potential ED properties of benthiavalicarb. Further data would be needed to draw a conclusion.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
- Not required

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
- Not required

\(^1\) extrapolation factor of 1.888 was applied to LD\(_{50}\) value due to lack of mortality and 10 animals of each species in the test

Values in \textbf{bold} were used in the risk assessment
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Potatoes at 8x75.0 g a.s./ha with 5 days interval, BBCH 11-97

| Growth stage | Indicator or focal species       | Time scale | DDD (mg/kg bw per day) | TER  | Trigger |
|--------------|---------------------------------|------------|------------------------|------|---------|
| Screening Step (Birds) |                                 |            |                        |      |         |
| All          | Small omnivorous bird           | Acute      | 27.8                   | 135.8| 10      |
| All          | Small omnivorous bird           | Long-term  | 8.1                    | 13.0 | 5       |
| Tier 1 (Birds): Not required |                                 |            |                        |      |         |
| Higher tier (birds): Not required |                                 |            |                        |      |         |
| Screening Step (Mammals) |                                 |            |                        |      |         |
| All          | Small herbivorous mammal        | Acute      | 20.7                   | >241.5|10      |
| All          | Small herbivorous mammal        | Long-term  | 6.0                    | 3.3  | 5       |
| Tier 1 (Mammals) |                                 |            |                        |      |         |
| BBCH 10-19   | Small insectivorous mammal      | Long-term  | 0.52                   | 38.5 | 5       |
| BBCH ≥20     | Small insectivorous mammal      | Long-term  | 0.24                   | 83.3 | 5       |
| BBCH ≥40     | Small herbivorous mammal        | Long-term  | 2.71                   | 7.4  | 5       |
| BBCH 10-40   | Large herbivorous mammal        | Long-term  | 1.78                   | 11.2 | 5       |
| BBCH ≥40     | Large herbivorous mammal        | Long-term  | 0.54                   | 37.0 | 5       |
| BBCH 10-39   | Small omnivorous mammal         | Long-term  | 0.97                   | 20.6 | 5       |
| BBCH ≥40     | Small omnivorous mammal         | Long-term  | 0.29                   | 69.0 | 5       |
| Higher tier (Mammals): Not required |                                 |            |                        |      |         |

**Risk from bioaccumulation and food chain behaviour**
Not relevant, log Pow values of the active substance and all metabolites all <3

**Risk from consumption of contaminated water**

**Leaf scenario:**
The morphology of the crops indicated in GAP table does not facilitate the collection of rain/irrigation water in reservoirs that are large enough to attract birds and mammals.
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| **Puddle scenario, Screening step** | **Benthiavalicarb-isopropyl** | | | | |
| Birds: | | | | | |
| 1) acute: 235.5 g a.s./ha/3776 mg a.s./kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 235.5 g a.s./ha/105.0 mg a.s./kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| Mammals: | | | | | |
| 1) acute: 235.5 g a.s./ha/5000 mg a.s./kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 235.5 g a.s./ha/20.0 mg a.s./kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| **Metabolite KIF-230-M-1** | | | | | |
| Birds: | | | | | |
| 1) acute: 28.70 g/ha/377.6 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 28.70 g/ha/10.5 mg/kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| Mammals: | | | | | |
| 1) acute: 28.70 g/ha/467 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 28.70 g/ha/2.0 mg a.s./kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| **Metabolite KIF-230-M-3** | | | | | |
| Birds: | | | | | |
| 1) acute: 15.06 g/ha/377.6 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 15.06 g/ha/10.5 mg/kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| Mammals: | | | | | |
| 1) acute: 15.06 g/ha/2000 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 15.06 g/ha/2.0 mg a.s./kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| **Metabolite KIF-230-M-4** | | | | | |
| Birds: | | | | | |
| 1) acute: 11.77 g/ha/377.6 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 11.77 g/ha/10.5 mg/kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| Mammals: | | | | | |
| 1) acute: 11.77 g/ha/2000 mg/kg bw <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 11.77 g/ha/2.0 mg a.s./kg bw/d <50 (koc<500 L/kg), TER calculation not needed | | | | | |
| **Metabolite KIF-230-M-5** | | | | | |
| Birds: | | | | | |
| 1) acute: 32.19 g/ha/377.6 mg/kg bw <3000 (koc≥500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 32.19 g/ha/10.5 mg/kg bw/d <3000 (koc≥500 L/kg), TER calculation not needed | | | | | |
| Mammals: | | | | | |
| 1) acute: 32.19 g/ha/545 mg/kg bw <3000 (koc≥500 L/kg), TER calculation not needed | | | | | |
| 2) long-term: 32.19 g/ha/2.0 mg a.s./kg bw/d <3000 (koc≥500 L/kg), TER calculation not needed | | | | | |

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

| Group | Test substance | Time-scale (Test type) | End point | Toxicity 1) |
|-------|----------------|------------------------|-----------|-------------|
| Laboratory tests | | | | |
| Group                  | Test substance                  | Time-scale (Test type) | End point          | Toxicity 1) |
|-----------------------|---------------------------------|------------------------|--------------------|-------------|
| Fish                  |                                 |                        |                    |             |
| Oncorhynchus mykiss   | Benthiavalicarb-isopropyl       | Acute 96 hr (flow-through) | Mortality, LC₅₀   | >10.0 mg a.s./L (nom) |
| Cyprinus carpio       | Benthiavalicarb-isopropyl       | Acute 96 hr (flow-through) | Mortality, LC₅₀   | >10.0 mg a.s./L (nom) |
| Lepomis macrochirus   | Benthiavalicarb-isopropyl       | Acute 96 hr (flow-through) | Mortality, LC₅₀   | >10.0 mg a.s./L (nom) |
| Oncorhynchus mykiss   | KIF-230 15% WG                  | Acute 96 hr (static)   | Mortality, LC₅₀   | >100.0 mg prep./L (>15.5 mg a.s./L (nom)) |
| Danio rerio           | Benthiavalicarb-isopropyl       | Chronic 35 d (ELS, semi-static) | Growth, development, behaviour, NOEC | ≥5.0 mg a.s./L (nom) |
| Oncorhynchus mykiss   | Benthiavalicarb-isopropyl       | Chronic 28 d (Fish juvenile growth test, flow-through) | Growth, NOEC      | 1.0 mg a.s./L (nom) |
| Oncorhynchus mykiss   | Metabolite KIF-230-M-1           | Acute 96 hr (static)   | Mortality, LC₅₀   | 14.2 mg pm/L (nom) |
| Oncorhynchus mykiss   | Metabolite KIF-230-M-3           | Acute 96 hr (static)   | Mortality, LC₅₀   | 40.5 mg pm/L (nom) |
| Oncorhynchus mykiss   | Metabolite KIF-230-M-4           | Acute 96 hr (static)   | Mortality, LC₅₀   | >3.36 mg pm/L (nom) |
| Oncorhynchus mykiss   | Metabolite KIF-230-M-5           | Acute 96 hr (semi-static) | Mortality, LC₅₀   | >10.0 mg pm/L (nom) |
| Oncorhynchus mykiss   | Metabolite KIF-230-M-8           | Acute 96 hr (semi-static) | Mortality, LC₅₀   | >100.0 mg pm/L (nom) |
| Aquatic invertebrates |                                 |                        |                    |             |
| Daphnia magna         | Benthiavalicarb-isopropyl       | Acute 48 h (static)    | Immobilisation, EC₅₀ | >10.0 mg a.s./L (nom) |
| Daphnia magna         | KIF-230 15% WG                  | Acute 48 h (semi-static) | Immobilisation, EC₅₀ | >100.0 mg prep./L (>15.5 mg a.s./L (nom)) |
| Daphnia magna         | Benthiavalicarb-isopropyl       | Chronic 21 d (semi-static) | Reproduction, NOEC  | 3.0 mg a.s./L (nom) |
|                       |                                 |                        | Reproduction, EC₁₀ | 4.30 mg a.s./L (nom) |
|                       |                                 |                        | Reproduction, EC₂₀ | 4.91 mg a.s./L (nom) |
| Daphnia magna         | Metabolite KIF-230-M-1           | Acute 48 h (static)    | Immobilisation, EC₅₀ | 14.0 mg pm/L (nom) |
| Daphnia magna         | Metabolite KIF-230-M-3           | Acute 48 h (static)    | Immobilisation, EC₅₀ | 55.3 mg pm/L (nom) |
| Daphnia magna         | Metabolite KIF-230-M-4           | Acute 48 h (static)    | Immobilisation, EC₅₀ | 6.28 mg pm/L (nom) |
| Daphnia magna         | Metabolite KIF-230-M-5           | Acute 48 h (semi-static) | Immobilisation, EC₅₀ | >10.0 mg pm/L (nom) |
### Pesticide Risk Assessment

**Daphnia magna**

| Test substance          | Time-scale (Test type) | End point          | Toxicity 1)               |
|-------------------------|------------------------|--------------------|---------------------------|
| Metabolite KIF-230-M-8  | Acute 48 h (static)    | Immobilisation, EC₅₀| >100.0 mg pm/L (nom)      |

**Sediment-dwelling organisms:**

Studies not performed and not required due to lack of insecticidal activity of benthiavalicarb-isopropyl and its metabolites

**Algae**

| Test substance | Time-scale (Test type) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | Toxicity 1)       |
|----------------|------------------------|--------------------------|-------------------|-------------------|
| *Selenstrum capricornutum* Benthiavalicarb-isopropyl 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | >10.0 mg a.s./L (nom) 2.5 mg a.s./L |
| *Pseudokirchneriella subcapitata* Metabolite KIF-230-M-1 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | 38.6 mg pm/L (nom) 30.1 mg pm/L |
| *Pseudokirchneriella subcapitata* Metabolite KIF-230-M-3 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | 90.9 mg pm/L (nom) 42.0 mg pm/L |
| *Pseudokirchneriella subcapitata* Metabolite KIF-230-M-4 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | >10.0 mg pm/L (nom) 7.42 mg pm/L |
| *Pseudokirchneriella subcapitata* Metabolite KIF-230-M-5 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | 71.1 mg pm/L (nom) 44.0 mg pm/L |
| *Pseudokirchneriella subcapitata* Metabolite KIF-230-M-8 72 h (static) | Growth rate: Eᵣ₅₀ NOEᵣ | Yield: Eᵢ₅₀ NOEᵢ | >100.0 mg pm/L (nom) |

1) Toxicity values in parentheses refer to nominal concentrations.
### Group Test substance Time-scale (Test type) End point Toxicity

| Higher plant: Studies not required since benthiavalicarb-isopropyl is not a herbicide and does not exhibit herbicidal activity. |
|---------------------------------|
| Further testing on aquatic organisms Not required |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) |
| For non-mammalian species neither the endocrine activity nor the endocrine adversity was sufficiently investigated. The available studies with fish (according to OECD TG 206) only provide little information on the potential ED properties of benthiavalicarb. Further data would be needed to draw a conclusion. |

1) (**nom**) nominal concentration; (**mm**) mean measured concentration; prep.: preparation; a.s.: active substance; pm: pure metabolite

Values in **bold** were used in the risk assessment
**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

|                      | Bentiavaliarb-isopropyl | KIF-230-M-1 | KIF-230-M-3 | KIF-230-M-4 | KIF-230-M-5 | KIF-230-M-8 |
|----------------------|--------------------------|-------------|-------------|-------------|-------------|-------------|
| logP<sub>O/W</sub>   | 2.56                     | 2.30        | 2.26        | 2.58        | 1.70        | 1.84        |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) |                       |             |             |             |             |             |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) |                       |             |             |             |             |             |
| Annex VI Trigger for the bioconcentration factor |                       |             |             |             |             |             |
| Clearance time (days) (CT<sub>50</sub>) |                       |             |             |             |             |             |
| (CT<sub>90</sub>) |                       |             |             |             |             |             |
| Level and nature of residues (%) in organisms after the 14 day depuration phase |                       |             |             |             |             |             |
| Higher tier study |                       |             |             |             |             |             |

* based on total 14C or on specific compounds
### Tier-1 RAC<sub>SW</sub> values for aquatic organisms

| Substance                  | Time-scale | Group of species | Endpoint [µg/L] | Assessment factor | Tier-1 RAC<sub>SW</sub> |
|----------------------------|------------|------------------|-----------------|-------------------|--------------------------|
| Benthiavalicarb-isopropyl  | Acute      | Fish             | >10 000         | 100               | >100                     |
|                            | Acute      | Aquatic invertebrates | >10 000 | 100               | >100                     |
|                            | Chronic    | Fish             | 1000            | 10                | 100                      |
|                            | Chronic    | Aquatic invertebrates | 3000    | 10                | 300                      |
|                            | Chronic    | Algae            | >10 000         | 10                | >1000                    |
| KIF-230-M-1                | Acute      | Fish             | 14 200          | 100               | 142                      |
|                            | Acute      | Aquatic invertebrates | 14 000 | 100               | 140                      |
|                            | Chronic    | Algae            | 38 600          | 10                | 3860                     |
| KIF-230-M-3                | Acute      | Fish             | 40 500          | 100               | 405                      |
|                            | Acute      | Aquatic invertebrates | 55 300 | 100               | 553                      |
|                            | Chronic    | Algae            | 90 900          | 10                | 9090                     |
| KIF-230-M-4                | Acute      | Fish             | >3360           | 100               | >33.6                    |
|                            | Acute      | Aquatic invertebrates | 6240    | 100               | 62.4                     |
|                            | Chronic    | Algae            | >10 000         | 10                | >1000                    |
| KIF-230-M-5                | Acute      | Fish             | >10 000         | 100               | >100                     |
|                            | Acute      | Aquatic invertebrates | >10 000 | 100               | >100                     |
|                            | Chronic    | Algae            | 71 100          | 10                | 7110                     |
| KIF-230-M-8                | Acute      | Fish             | >100 000        | 100               | >1000                    |
|                            | Acute      | Aquatic invertebrates | >100 000 | 100               | >1000                    |
|                            | Chronic    | Algae            | >100 000        | 10                | >10 000                  |

Values in **bold** were used in the risk assessment.
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

**FOCUS$_{sw}$ step 1-3 - TERs for benthiavalicarb-isopropyl – 8x75.0 g a.s./ha with 5 days interval, BBCH 11-97**

| Scenario               | PEC global max (µg L) | Tier 1-RAC$_{SW,A}$/PECSW | Tier 1-RAC$_{SW,Ch}$/PECSW |
|------------------------|-----------------------|----------------------------|----------------------------|
| FOCUS Step 1           | 163.73                | >0.61                      | 0.61                       |
| FOCUS Step 2 North Europe | 12.332                | >8.1                       | 8.4                        |
|                        | 23.325                | >4.3                       | 4.3                        |
| FOCUS Step 3           |                       |                            |                            |
| D3 / ditch             |                       |                            |                            |
| D4 / pond              |                       |                            |                            |
| D5 / stream            |                       |                            |                            |
| R1 / pond              |                       |                            |                            |
| R2 / stream            |                       |                            |                            |
| R3 / stream            |                       |                            |                            |
| R4 / stream            |                       |                            |                            |
| Ditch                  |                       |                            |                            |
| Pond                   |                       |                            |                            |
| Stream                 |                       |                            |                            |

Trigger 1 1

Values in **bold** indicate unacceptable risk

**FOCUS$_{sw}$ step 1 - TERs for metabolite KIF-230-M-1**

| Scenario               | PEC global max (µg L) | Tier 1-RAC$_{SW,A}$/PECSW | Tier 1-RAC$_{SW,Ch}$/PECSW |
|------------------------|-----------------------|----------------------------|----------------------------|
| FOCUS Step 1           | 21.139                | 6.6                        | 182.6                      |

Trigger 1 1

**FOCUS$_{sw}$ step 1 - TERs for metabolite KIF-230-M-3**

| Scenario               | PEC global max (µg L) | Tier 1-RAC$_{SW,A}$/PECSW | Tier 1-RAC$_{SW,Ch}$/PECSW |
|------------------------|-----------------------|----------------------------|----------------------------|
| FOCUS Step 1           | 39.064                | 10.4                       | 232.7                      |

Trigger 1 1
### FOCUSsw step 1 - TERs for metabolite KIF-230-M-4

| Scenario         | PEC global max (µg L) | Tier 1-RAC<sub>SW,A</sub> / PEC<sub>SW</sub> | Tier 1-RAC<sub>SW,Ch</sub> / PEC<sub>SW</sub> |
|------------------|-----------------------|-----------------------------------------------|-----------------------------------------------|
| FOCUS Step 1     | 25.471                | >33.6 µg/L                                    | >1000 µg/L                                    |

**Trigger**

1 1

### FOCUSsw step 1 - TERs for metabolite KIF-230-M-5

| Scenario         | PEC global max (µg L) | Tier 1-RAC<sub>SW,A</sub> / PEC<sub>SW</sub> | Tier 1-RAC<sub>SW,Ch</sub> / PEC<sub>SW</sub> |
|------------------|-----------------------|-----------------------------------------------|-----------------------------------------------|
| FOCUS Step 1     | 29.899                | >100 µg/L                                      | 7110 µg/L                                     |

**Trigger**

1 1

### FOCUSsw step 1 - TERs for metabolite KIF-230-M-8

| Scenario         | PEC global max (µg L) | Tier 1-RAC<sub>SW,A</sub> / PEC<sub>SW</sub> | Tier 1-RAC<sub>SW,Ch</sub> / PEC<sub>SW</sub> |
|------------------|-----------------------|-----------------------------------------------|-----------------------------------------------|
| FOCUS Step 1     | 14.823                | >1000 µg/L                                     | >10 000 µg/L                                  |

**Trigger**

1 1
Effects on bees (Regulation (EU) No 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) No 284/2013 Annex Part A, point 10.3.1)*

| Species                | Test substance    | Time scale/type of endpoint | End point     | Toxicity               |
|------------------------|-------------------|------------------------------|---------------|------------------------|
| *Apis mellifera*       | Benthiavalicarb-isopropyl | Acute                        | Oral toxicity (LD<sub>50</sub>) | >100.0 µg a.s./bee      |
| *Apis mellifera*       | KIF-230 15% WG    | Acute                        | Oral toxicity (LD<sub>50</sub>) | >100.0 µg a.s./bee      |
| *Bombus terrestris*    | KIF-230 15% WG    | Acute                        | Oral toxicity (LD<sub>50</sub>) | >740.5 µg a.s./bumblebee|
| *Apis mellifera*       | Benthiavalicarb-isopropyl | Acute                        | Contact toxicity (LD<sub>50</sub>) | >100.0 µg a.s./bee      |
| *Apis mellifera*       | KIF-230 15% WG    | Acute                        | Contact toxicity (LD<sub>50</sub>) | >100.0 µg a.s./bee      |
| *Bombus terrestris*    | KIF-230 15% WG    | Acute                        | Contact toxicity (LD<sub>50</sub>) | >148.1 µg a.s./bumblebee|
| *Apis mellifera*       | KIF-230 15% WG    | Chronic                      | 10 d-LDD50 NOEDD | >124.6 µg a.s./bee/day |
| *Apis mellifera*       | Benthiavalicarb-isopropyl | Bee brood development        | NOED larvae   | 3.69 µg a.s./larva/developmental period |
|                        |                   |                              | Mortality     | 2.5 µg a.s./larva       |
|                        |                   |                              | LD<sub>10</sub> | 13.312 µg a.s./larva    |
|                        |                   |                              | ED<sub>10</sub>| 2.13 µg a.s./larva      |
|                        |                   |                              | Emergence     | 10.46 µg a.s./larva     |
|                        |                   |                              | LD<sub>20</sub>|                         |
|                        |                   |                              | ED<sub>20</sub>|                         |

Potential for accumulative toxicity: No

Semi-field test (Cage and tunnel test): Not required

Field tests: Not required
Risk Assessment for honey bees based on EC (2002)

Application on potatoes at 8x75.0 g a.s./ha

| Test substance          | Route  | Hazard quotient | Annex VI Trigger |
|-------------------------|--------|-----------------|------------------|
| Benthiavalicarb-isopropyl | Contact | <0.75           | 50               |
| Benthiavalicarb-isopropyl | Oral   | <0.75           | 50               |

Risk assessment for potatoes at 8x75.0 g a.s./ha with 5 days interval, BBCH 11-97 based on EFSA (2013)

| Species                  | Test substance          | Risk quotient | HQ/ETR     | Trigger |
|--------------------------|-------------------------|---------------|------------|---------|
| Apis mellifera           | Benthiavalicarb-isopropyl | HQcontact     | <0.75      | <42     |
| Bombus terrestris        | Benthiavalicarb-isopropyl | HQcontact     | <0.10      | <7      |
| Apis mellifera           | Benthiavalicarb-isopropyl | ETRacute adult oral | <0.006 | <0.2    |
| Bombus terrestris        | Benthiavalicarb-isopropyl | ETRacute adult oral | <0.006 | <0.036  |
| Apis mellifera           | Benthiavalicarb-isopropyl | ETRchronic adult oral | <0.005 | <0.03   |
| Apis mellifera           | Benthiavalicarb-isopropyl | ETRlarvae     | 0.09       | <0.2    |

Screening risk assessment for bees exposed to benthiavalicarb-isopropyl via guttation fluid

| Risk quotient             | W [µL/bee] | Solubility in water [µg/µL] | PEC (% of solubility) [µg/µL] | Endpoint        | Value                  | Result     | Trigger |
|---------------------------|------------|-----------------------------|-------------------------------|-----------------|------------------------|------------|---------|
| ETRacute adult oral       | 11.4       | 0.01314                     | 0.01314 (100%)                | LD50oral        | >100.0 µg a.s./bee     | <0.0015    | <0.2    |
| ETRchronic adult oral     | 11.4       | 0.01314                     | 0.003 (22%)                   | LD50chronic,oral | >124.6 µg a.s./bee/day | <0.0003    | <0.03   |
| ETRlarvae                 | 111.0      | 0.01314                     | 0.0095 (72%)                  | NOEDlarvae      | 3.69 µg a.s./larvae/day | 0.286      | <0.2    |

Values in **bold** indicate unacceptable risk

Screening risk assessment for bees exposed to benthiavalicarb-isopropyl via surface water

| Risk quotient             | W [µL/bee] | Step 1 PECsw.max [µg/µL] | Endpoint         | Value                  | Result     | Trigger |
|---------------------------|------------|--------------------------|------------------|------------------------|------------|---------|
| ETRacute adult oral       | 11.4       | 0.00017                  | LD50oral         | >100.0 µg a.s./bee     | <0.0001    | <0.2    |
| ETRchronic adult oral     | 11.4       | 0.00017                  | LD50chronic,oral | >124.6 µg a.s./bee/day | <0.0001    | <0.03   |
| ETRlarvae                 | 111.0      | 0.00017                  | NOEDlarvae       | 3.69 µg a.s./larvae/day | 0.005      | <0.2    |
Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

| Species                  | Test Substance | End point               | Toxicity             |
|--------------------------|----------------|------------------------|----------------------|
| Typhlodromus pyri        | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >75.0 g a.s./ha       |
|                          |                |                        | >75.0 g a.s./ha       |
| Typhlodromus pyri        | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >262.5 g a.s./ha      |
|                          |                |                        | >262.5 g a.s./ha      |
| Aphidius rhopalosiphi    | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >75.0 g a.s./ha       |
|                          |                |                        | >75.0 g a.s./ha       |
| Aphidius rhopalosiphi    | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >262.5 g a.s./ha      |
|                          |                |                        | >262.5 g a.s./ha      |
| Additional species       |                |                        |                      |
| Chrysoperla carnea       | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >75.0 g a.s./ha       |
|                          |                |                        | >75.0 g a.s./ha       |
| Poecilus cupreus         | KIF-230 15% WG | Mortality, LR<sub>50</sub> Reproduction, ER<sub>50</sub> | >75.0 g a.s./ha       |
|                          |                |                        | >75.0 g a.s./ha       |

First tier risk assessment for potatoes at 8x75.0 g a.s./ha g a.s./ha with 5 days interval, BBCH 11-97

| Test substance         | Species                | Effect (LR<sub>50</sub> g a.s./ha) | HQ in-field | HQ off-field for 1 m distance | Trigger |
|------------------------|------------------------|------------------------------------|-------------|-------------------------------|---------|
| KIF-230 15% WG         | Typhlodromus pyri      | >262.5                             | <1.0 (foliar)| <1.6 (soil)                  | <0.02   | 2       |
| KIF-230 15% WG         | Aphidius rhopalosiphi  | >262.5                             | <1.0 (foliar)| <1.6 (soil)                  | <0.02   | 2       |
Extended laboratory tests, aged residue tests:
Not required, acceptable risk at Tier 1

| Semi-field tests : | Not required |
|--------------------|--------------|
| Field studies:     | Not required |
| Additional specific test: | Not required |

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

| Test organism | Test substance | Application method of test a.s./OM | Time scale | End point | Toxicity |
|---------------|----------------|-----------------------------------|------------|-----------|----------|
| **Earthworms**|                |                                   |            |           |          |
| *Eisenia fetida* | Benthiavalicarb-isopropyl | Mixing with soil, 10% OM | Chronic | Reproduction | EC₁₀: not calculated NOEC = 324.0 mg a.s./kg dw soil (NOEC_corr = 162.0 mg a.s./kg dw soil) |
| *Eisenia fetida* | Metabolite KIF-230-M-1 | Mixing with soil, 10% OM | Chronic | Reproduction | EC₁₀ = 203.4 mg pm/kg dw soil EC₂₀ = 249.7 mg pm/kg dw soil NOEC = 180.0 mg pm/kg dw soil (NOEC_corr = 90.0 mg pm/kg dw soil) |

Other soil macroorganisms:
Benthiavalicarb-isopropyl, metabolite KIF-230-M-3 and metabolite KIF-230-M-4: studies not required due to soil DT₉₀ values <100 days.
Metabolite KIF-230-M-1 and KIF-230-M-5: soil DT₉₀ values in range 100-365 days, but studies not required due to TER values for earthworms far above the trigger and effects on soil micro-organisms <25%.

pm: pure metabolite
Values in **bold** were used in the risk assessment

**Higher tier testing (e.g. modelling or field studies): Not required**
Nitrogen transformation  Benthiavalicarb-isopropyl  Nitrate formation  +2.38% effect at day 28 at 4.0 mg a.s./kg d.w.soil

Nitrogen transformation  Metabolite KIF-230-M-1  Nitrate formation  -6.35% effect at day 28 at 0.5 mg pm/kg d.w.soil

Nitrogen transformation  Metabolite KIF-230-M-3  Nitrate formation  -21.5% effect at day 28 at 0.25 mg pm/kg d.w.soil

Toxicity/exposure ratios for soil organisms

Potatoes at 8x75.0 g a.s./ha g a.s./ha with 5 days interval, BBCH 11-97

| Test organism     | Test substance     | Time scale | Soil PEC | TER  | Trigger |
|-------------------|--------------------|------------|----------|------|---------|
| Earthworms        |                    |            |          |      |         |
| Eisenia fetida    | Benthiavalicarb-isopropyl | Chronic   | 0.389 (initial) | 416.5 | 5       |
| Eisenia fetida    | Metabolite KIF-230-M-1 | Chronic   | 0.0597 (accumulation) | 1,507.5 | 5       |
| Eisenia fetida    | Metabolite KIF-230-M-3 | Chronic   | 0.0247 (initial) | 655.9 | 1) 5 |
| Eisenia fetida    | Metabolite KIF-230-M-4 | Chronic   | 0.0208 (accumulation) | 778.8 | 1) 5 |
| Eisenia fetida    | Metabolite KIF-230-M-5 | Chronic   | 0.418 (accumulation) | 38.8 | 1) 5 |
| Eisenia fetida    | Metabolite KIF-230-M-8 2) | Chronic   | 0.0076 (initial) | 2,135.6 | 1) 5 |

Other soil macroorganisms:
Not required

1) In absence of experimentally derived data, 10 times toxicity of the parent was assumed as a worst case.
2) Relevant only for prolonged anaerobic conditions.

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

Screening glasshouse and field trials demonstrated that benthiavalicarb-isopropyl is not phytotoxic at rates ranging from 150 to 10000 g a.s./ha. In all tests and at all rates 0% effects were observed. Worst case predicted off-field rate of KIF-230 15% WG (i.e. 9.12 g a.s./ha, calculated with consideration of annual cumulative rate of 8x75.0 g a.s./ha and spray drift of 1.52% relevant for 8 applications, according to Ganzelmeier drift data) is more than 16 times lower than the single lowest application rate (i.e. 150 g a.s./ha) at which 0% phytotoxic effects were observed during screening trials.

Laboratory dose response tests

Studies not required since benthiavalicarb-isopropyl is a fungicide and does not exhibit herbicidal activity
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\textsubscript{50} > 100.0 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)

Not required

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)
Ecotoxicologically relevant compounds \(^1\)

| Compartiment      | Compound                                    |
|-------------------|---------------------------------------------|
| soil              | Benthiavalicarb-isopropyl (KIF-230R-\textsubscript{L}) |
| water             | Benthiavalicarb-isopropyl (KIF-230R-\textsubscript{L}) |
| sediment          | Benthiavalicarb-isopropyl (KIF-230R-\textsubscript{L}) |
| groundwater       | Benthiavalicarb-isopropyl (KIF-230R-\textsubscript{L}) |

\(^1\) metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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

| Substance                  | Classification                   |
|----------------------------|----------------------------------|
| Benthiavalicarb-isopropyl  | None                             |

According to the peer review, criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:

| Substance                  | Classification                   |
|----------------------------|----------------------------------|
|                             | Chronic 2, H411                   |
|                             | (NOEC for fish is 1.0 mg a.s./L, i.e. \(\leq 1.0\) mg/L, and substance is not rapidly degradable) |

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\(^5\) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1–1355.