Appendix to:

EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance benfluralin. EFSA Journal 2019;17(10):5842, 48 pp. doi:10.2903/j.efsa.2019.5842



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

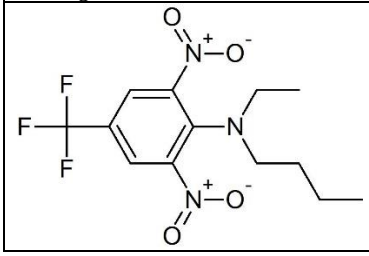
## Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

| | |
|---|---|
| Active substance (ISO Common Name) | Benfluralin |
| Function (e.g. fungicide) | Herbicide |

| | |
|---|---|
| Rapporteur Member State | Norway |
| Co-rapporteur Member State | The Netherlands |

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

| | |
|---|---|
| Chemical name (IUPAC) | *N*-butyl-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine |
| Chemical name (CA) | *N*-butyl-*N*-ethyl-2,6-dinitro-4-(trifluoromethyl)benzenamine |
| CIPAC No | 285 |
| CAS No | 1861-40-1 |
| EC No (EINECS or ELINCS) | 217-465-2 |
| FAO Specification (including year of publication) | Not available |
| Minimum purity of the active substance as manufactured | 960 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | ethyl-butyl-nitrosamine (EBNA): max. 0.085 mg/kg<br>Open for other impurities |
| Molecular formula | $C_{13}H_{16}F_3N_3O_4$ |
| Molar mass | 335.3 g/mol |
| Structural formula |  |

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

| | |
|---|---|
| Melting point (purity) | 66.4 °C (99.9 %) |
| Boiling point (purity) | Not observed |
| Temperature of decomposition (purity) | Decomposition/volatilisation began at 205 °C (99.9 %) |
| Appearance (purity) | Yellow to orange crystalline solid (99.9 %)<br>Munsell notation; Hue: 2.5 Y, Value 8.5, Croma: 10 |
| Vapour pressure (purity) | $1.8 \times 10^{-3}$ Pa at 20 °C (99.9 %)<br>$4.3 \times 10^{-3}$ Pa at 25 °C (99.9 %) |
| Henry's law constant (temperature) | 9.5 Pa $m^3$ $mol^{-1}$ (20 °C) |
| Solubility in water (pH, purity) | 0.064 ± 0.010 mg/L at 20 °C (pH 6.0-7.0, 99.9 %) |
| Solubility in organic solvents (purity) | Determined at 20°C (99.9 %)<br>methanol: 41 g/L<br>*n*-heptane: 40 g/L<br>*n*-octanol: 23 g/L<br>xylene: > 250 g/L<br>acetone: > 250 g/L<br>1,2-dichloroethane: > 250 g/L<br>ethyl acetate: > 250 g/L |
| Surface tension | Not determined. Water solubility is less than 1 mg/L. |
| Partition coefficient (pH, purity) | log $P_{OW}$ = 5.27 ± 0.11 at 20 °C (pH 7.5, 99.9 %) |
| Dissociation constant (state purity) | pKa = -0.59 ± 0.5 (based on a calculation)<br>This indicates that molecule will not be ionized at environmentally relevant pH values. |
| UV/VIS absorption (max.) incl. ε (pH, solution, purity) | *Acidic (pH 1.7, 10 % 1M HCl in acetonitrile, 99.9 %)* |

| $\lambda_{max}$ (nm) | ε (L×$mol^{-1}$×$cm^{-1}$) |
|---|---|
| 248 | 4390 |
| 298 | 4580 |
| 448 | 3870 |

*Neutral (pH 5.9, aqueous acetonitrile, 99.9 %)*

| $\lambda_{max}$ (nm) | ε (L×$mol^{-1}$×$cm^{-1}$) |
|---|---|
| 239 | 9180 |
| 283 | 8010 |

*Basic (pH 11.9, 10 % 1M NaOH in acetonitrile, 99.9 %)*

| $\lambda_{max}$ (nm) | ε (L×$mol^{-1}$×$cm^{-1}$) |
|---|---|
| 238 | 7550 |
| 283 | 6370 |
| 431 | 3720 |

| | |
|---|---|
| Flammability (purity) | not highly flammable (97.5 %)<br>self-ignition temperature = 304 °C (97.5 %) |
| Explosive properties (purity) | not explosive (96.2 %) |
| Oxidising properties (purity) | not oxidising (97.5 %) |

**Summary of representative uses evaluated, for which all risk assessments needed to be completed (*benfluralin*)**
**(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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. a.s. (i) | method kind (f-h) | Range of growth stages & season (j) | Number min-max (k) | Interval between application (min) | kg a.s /hL min-max (l) | Water L/ha min-max | g a.s./ha min-max (l) | | |
| Chicory (chicon/endive production Industrial chicory ('coffee', fructose, inulin production) | Belgium, France, Greece, Italy, Netherlands | Bonalan (EF-1533) | F | Annual weeds and seedlings of some perennial weeds (grasses and dicots) | EC | 180 g/L | Boom sprayer followed by mechanical incorporation in soil | Pre-sowing | 1 | - | 0.36 - 0.72 | 200 - 400 | 1440 | - | |
| Lettuce | Belgium, France, Greece, Italy, Netherlands | Bonalan (EF-1533) | F | Annual weeds and seedlings of some perennial weeds (grasses and dicots) | EC | 180 g/L | Boom sprayer followed by mechanical incorporation in soil | Pre-sowing or pre-planting | 1 | - | 0.36 - 0.72 | 200 - 400 | 1440 | - | |

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

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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

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

| **Crop and/or situation (a)** | **Member State or Country** | **Product name** | **F G or I (b)** | **Pests or Group of pests controlled (c)** | **Preparation** | | **Application** | | | | **Application rate per treatment** | | | **PHI (days) (m)** | **Remarks** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. a.s. (i) | method kind (f-h) | Range of growth stages & season (j) | Number min-max (k) | Interval between application (min) | kg a.s /hL min-max (l) | Water L/ha min-max | g a.s./ha min-max (l) | | |
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) **Additional intended uses were not considered.** | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | |

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

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

**Further information, Efficacy**

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

| |
|---|
| The representative formulation has been authorised at Member State level for > 10 years and has therefore been assessed in line with Uniform Principles. |

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

| |
|---|
| The representative formulation has been authorised at Member State level for > 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable adverse effects are known. |

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

| |
|---|
| The representative formulation has been authorised at Member State level for > 10 years and has therefore been assessed in line with Uniform Principles. No unacceptable side effects are known. |

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

| | B12 |
|---|---|
| Activity against target organism | Not needed. |

## 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) | GC-FID using external standard calibration |
| Impurities in technical a.s. (analytical technique) | GC-FID using external standard calibration |
| | HPLC-MS/MS LOQ 0.01 mg/kg |
| Plant protection product (analytical technique) | GC-FID using external standard calibration |

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

#### Residue definitions for monitoring purposes

| | |
|---|---|
| Food of plant origin | benfluralin (by default) |
| Food of animal origin | benfluralin (by default) |
| Soil | benfluralin |
| Sediment | benfluralin |
| Water surface | benfluralin, propyl-benzimidazole (371R)<br>methyl-benzimidazole (372R) |
| drinking/ground | benfluralin |
| Air | benfluralin |
| Body fluids and tissues | open |

#### Monitoring/Enforcement methods

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Cucumber, strawberry, oilseed rape, wheat grain:<br>HPLC-MS/MS (QuEChERS extraction); LOQ 0.01 mg/kg<br>ILV: apple, lemon, walnut, wheat grain; LOQ: 0.01 mg/kg<br>Data gap for extraction efficiency |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not required for the representative uses. |
| Soil (analytical technique and LOQ) | LC-MS/MS; LOQ 0.01 mg/kg |
| Water (analytical technique and LOQ) | GC-MS (surface, ground and drinking water); LOQ 0.05 µg/L<br>ILV: Drinking water; LOQ 0.05 µg/L<br>Data gap for metabolites in surface water |
| Air (analytical technique and LOQ) | LC-MS/MS, LOQ 0.15 µg/m$^3$ |
| Body fluids and tissues (analytical technique and LOQ) | benfluralin: LC-MS/MS; LOQ (urine) 0.05 mg/L, LOQ (muscle) 0.10 mg/kg<br>open |

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

| | |
|---|---|
| Substance | benfluralin |
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]: | No physical or chemical properties of the active substance benfluralin trigger any harmonised classification according to Regulation (EC) No 1272/2008. |
| Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008: | None |

1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
2 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

## Section 2 Impact on Human and Animal Health

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

| | | | |
|---|---|---|---|
| Rate and extent of oral absorption/systemic bioavailability | Rapid (< 48 h) and incomplete<br>20% based on radioactivity retrieved in urine 168 h after administration of 100 mg/kg bw | | |
| Toxicokinetics | | **100 mg/kg bw** | **500 mg/kg bw** |
| | Tmax (h) | 5-10 | 24 |
| | Cmax (µg/ml) | 9-13 | 34-36 |
| | $T_{1/2}$ (h) | 300-451 | 1739-2286 |
| | AUC (µg-eq/mL × h) | 56-63 | 54-62 |
| Distribution | Widely distributed; higher levels in fat, liver, kidney, blood | | |
| Potential for bioaccumulation | Affinity for fat , but no evidence for accumulation | | |
| Rate and extent of excretion | Rapid and extensive (77-91%) within 48 h<br>mainly faecal (73%), 18% via urine, 10% via bile | | |
| Metabolism in animals | Benfluralin was subject to di-dealkylation and reduction, and further metabolised into numerous polar compounds, each present at < 1 % of the dose. Parent compound present at about 35 % in faeces.<br>Data gap: the applicant to propose a residue definition for body fluids and tissues. | | |
| In vitro metabolism | All metabolites formed in human liver microsomes >5% of the initial substrate concentration were also formed in mouse, rat, dog, and rabbit liver microsomes. Qualitative and quantitative differences in metabolites formation were observed between mouse, rat, dog, and rabbit.<br>Data gap: Two peaks (Peak 3 and Peak 7) should be characterized and their toxicological relevance should be assessed because they are significantly higher in human material than in the other four species tested. | | |
| Toxicologically relevant compounds (animals and plants) | Benfluralin | | |
| Toxicologically relevant compounds (environment) | Benfluralin | | |

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

| | | |
|---|---|---|
| Rat $LD_{50}$ oral | > 5000 mg/kg bw | |
| Rat $LD_{50}$ dermal | > 5000 mg/kg bw | |
| Rat $LC_{50}$ inhalation | > 2.16 mg/L air /4h (dust, nose only) | **H371** |
| Skin irritation | Irritant | **H315** |
| Eye irritation | Irritant | **H319** |
| Skin sensitisation | Sensitising (M&K and Buehler test) | **H317** |
| Phototoxicity | Not phototoxic | |

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

| | | |
|---|---|---|
| Target organ / critical effect | Studies of limited reliability since no validated analytical methods were reported:<br>**Rat:**<br>Kidney tubule pigmentation (females), kidney weight increase; liver weight increase; RBC effects<br>**Dog:**<br>Liver weight increase, liver/spleen pigmentation (indication of haemosiderosis), RBC effects | |
| Relevant oral NOAEL | 90-day rat: 17 mg/kg bw per day<br>1-year & 90-day, dog 25 mg/kg bw per day | |

| | | |
|---|---|---|
| Relevant dermal NOAEL | 21-day, rabbit:<br>Systemic: 100 mg/kg bw per day (decrease in bw in males)<br>Local LOAEL: 100 mg/kg bw per day (skin inflammation) | |
| Relevant inhalation NOAEL | No data - not required | |

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

| | | |
|---|---|---|
| In vitro studies | Benfluralin containing up to 0.085 mg/kg of the impurity EBNA:<br>Gene mutation in bacteria (Ames test): negative ± S9<br>Gene mutation in mammalian cells: negative ± S9<br>*In vitro* micronucleus: negative ± S9<br>UDS (*ex vivo*): negative | |
| In vivo studies | Sister chromatid exchange: negative<br>Mouse bone marrow micronucleus test: not clearly negative<br>Benfluralin containing up to 0.085 mg/kg of the impurity EBNA:<br>Two rat bone marrow micronucleus tests: negative | |
| Photomutagenicity | Not required since phototoxicity study was negative | |
| Potential for genotoxicity | Benfluralin, containing up to 0.085 mg/kg of the impurity EBNA, is devoid of genotoxic potential | |

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

| | | |
|---|---|---|
| Long-term effects (target organ/critical effect) | Liver, thyroid (rat, mouse)<br>The study in mouse was of limited reliability since no validated analytical method was reported. | |
| Relevant long-term NOAEL | 2-year, rat: 0.5 mg/kg bw per day<br>18-month, mouse LOAEL: 6 mg/kg bw per day | |
| Carcinogenicity (target organ, tumour type) | Rat: hepatocellular adenomas and thyroid adenomas and carcinomas at 136.3 mg/kg bw per day.<br>Mouse: hepatocellular carcinomas<br>Non-relevance for humans not clearly demonstrated for liver tumours. Thyroid tumours are considered likely to be rodent-specific. | **H351** |
| Relevant NOAEL for carcinogenicity | 2-year, rat: 5.4 mg/kg bw per day;<br>18-month, mouse: LOAEL: 6 mg/kg bw per day | |

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

| | | |
|---|---|---|
| Reproduction target / critical effect | **Parental toxicity**:<br>↓ body weight (gain), ↑ liver and ↑ kidney weight and histopathological changes<br>**Reproductive toxicity**:<br>↓ viability index ↓ weaning index (sensitive endpoints for ED assessment were not investigated)<br>**Offspring's toxicity**:<br>↓ body weight ($F_1$, $F_2$), ↑ pup mortality ($F_1$) | |
| Relevant parental NOAEL | 5.5 mg/kg bw per day | |
| Relevant reproductive NOAEL | 52,6 mg/kg bw per day | |
| Relevant offspring NOAEL | 5.5 mg/kg bw per day | |

**Developmental toxicity**

| | | |
|---|---|---|
| Developmental target / critical effect | Studies of limited reliability since no validated analytical methods were reported:<br>**Rat:**<br>Maternal toxicity: ↓ bw gain<br>Developmental toxicity: ↑ variations (vertebrae/sternebrae)<br>**Rabbit:**<br>Maternal toxicity: ↓ bw gain, ↓ food consumption<br>Developmental toxicity: effects on accessory skull bones | |
| Relevant maternal NOAEL | Rat: 225 mg/kg bw per day<br>Rabbit: 50 mg/kg bw per day | |
| Relevant developmental NOAEL | Rat: 475 mg/kg bw per day<br>Rabbit: 100 mg/kg bw per day | |

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

| | | |
|---|---|---|
| Acute neurotoxicity | No data, no concern from other studies – not required | |
| Repeated neurotoxicity | No data, no concern from other studies – not required | |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No data, no concern from other studies – not required | |

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

| | |
|---|---|
| Supplementary studies on the active substance | In a mechanistic study non-relevance for humans was not clearly demonstrated for liver and thyroid tumours. However, based on an overall assessment thyroid tumours are considered likely to be rodent-specific.<br><br>Immunotoxicity:<br>There were no adverse effects observed in the overall data package indicating an immunotoxicity potential for benfluralin. |
| Endocrine disrupting properties | The T-modality was sufficiently investigated and no adversity was observed. Therefore benfluralin does not meet the ED criteria for the T-modality.<br>Regarding EAS modalities, no adversity was observed however the EAS-mediated parameters were not sufficiently investigated. The EAS-mediated endocrine activity was sufficiently investigated and no effects were observed. Therefore, based on the available evidence, benfluralin does not meet the ED criteria for the EAS-modalities.<br>It can be concluded that, for human health, benfluralin is not an endocrine disruptor according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. |
| Studies performed on metabolites or impurities | **Metabolite B12**<br>Negative in studies investigating gene mutations *in vitro* in bacteria and in mammalian cells. |

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

| |
|---|
| Based on the reports of the medical surveillance on manufacturing plant personnel from the applicant, no effects were anticipated. One case of occupationally related skin sensitisation was reported in the open literature. |

## Summary[3] (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) | 0.005 (1) | rat, 2-year | 100 |
| Acute Reference Dose (ARfD) | 0.5 (2) | rabbit, developmental toxicity study (maternal toxicity) | 100 |
| Acceptable Operator Exposure Level (AOEL) | 0.011 (3) | rat, 2-generation study (offspring's toxicity) | 500 (4) |
| Acute Acceptable Operator Exposure Level (AAOEL) | 0.1 | rabbit, developmental toxicity study | 500 (4) |

(1) same as previously established (EFSA, 2008b; European Commission, 2008)
(2) No ARfD previously established
(3) AOEL previously established at 0.05 mg/kg bw per day based on the NOAEL of 17 mg/kg bw per day from the 90-day rat study, 30% correction for the limited oral absorption and 100 UF
(4) Standard UF of 100 and including correction for limited oral absorption/bioavailability (20%)

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

| | |
|---|---|
| Representative formulation (Bonalan (EF-1533), an emulsifiable concentrate (EC) formulation containing 180 g/L benfluralin) | Concentrate: 2 %<br>Spray dilution (2.7 mg/ml):11 %<br>Rat *in vivo* and comparative *in vitro* (human/rat skin) – triple pack approach |

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

| | |
|---|---|
| Operators | Tractor mounted equipment followed by mechanical incorporation in soil (pre-sowing of chicory and lettuce or pre-planting of lettuce):<br><br>EFSA calculator — % of AOEL<br>*Long term exposure*:<br>Without PPE (work wear - arms, body and legs covered): 599%<br>PPE (workwear, gloves during M/L): 205%<br>PPE (gloves during M/L & application, RPE during M/L): 30%<br>*Acute exposure*<br>Without PPE (work wear - arms, body and legs covered): 276<br>PPE (workwear, gloves during M/L): 115<br>PPE (workwear, gloves during M/L & application, RPE during M/L): 27%<br>Knapsack sprayers: Not considered |
| Workers | EF-1533 is to be applied directly to soil prior to planting. Re-entry of workers is not foreseen and is not relevant. |
| Bystanders and residents | **Bystander** |

3 If available include also reference values for metabolites

| EFSA calculator 2-3m buffer strip | % of AAOEL |
|---|---|
| *Children:* | |
| Spray drift: | 49% |
| Vapour | 1% |
| Surface deposits | 8% |
| Entry into treated crops(1) | 27% |
| *Adults:* | |
| Spray drift | 13% |
| Vapour | 0.23% |
| Surface deposits | 3% |
| Entry into treated crops(1) | 15% |
| Martin et al (2008)(2) | % of AOEL |
| Children: | 52% |
| Adults: | 66.5% |
| | |
| **Resident** | |
| EFSA calculator 2-3m buffer strip | % of AOEL |
| *Children* | |
| Spray drift(3) | 195% |
| Vapour | 10% |
| Surface deposits | 23% |
| Entry into treated crops(1) | 243% |
| All pathways (mean): | 328% |
| *Adults* | |
| Spray drift | 46% |
| Vapour | 2% |
| Surface deposits | 10% |
| Entry into treated crops(1) | 135% |
| All pathways (mean): | 139% |
| Martin et al (2008)(2) | % of AOEL |
| Children: | 12% |
| Adults: | 7% |
| UK approach (4,5) | % of AOEL |
| *Children:* | |
| Spray drift(6) | |
| Vapour | 6% |
| Surface deposits | |
| -Systemic exposure via the dermal route | 5% |
| -Systemic exposure via the hand-to-mouth route | 2% |
| -Systemic exposure via mouthing activity | 0.4% |
| All pathways (vapour + surface deposits) | 13% |
| *Adults:* | |
| Spray drift (systemic exposure) | 19% |
| Vapour | 2% |
| All pathways (spray drift + vapour) | 21% |

(1) Not considered relevant for benfluralin which is to be applied directly to soil prior to planting.

(2) The Martin et al. approach (2008) is no longer scientifically supported, since limited data were included for 3-dimensional exposure to spray drift and no estimates are provided for exposure to vapour from low volatility compounds. Accordingly the predictions are considered underestimated and are given for informative purpose.

(3) Additional mitigation measures not considered in the RAR such as restricting applications to drift reducing technology and requiring minimum spray volume of 400 L/ha (while the GAP refers to 200-400 L/ha) result in resident child exposures via all relevant pathways being less than 50% of the AOEL.

(4) RAR Diquat: Estimation of resident to Spray Drift according to the approach used for the evaluation of the active substance diquat

(5) Lloyd, G.A. and Bell, G.J. 1983, Hydraulic nozzles: comparative spray drift study [CRD ref.: SC7704] The study estimates resident exposure through dermal and inhalation exposure to spray drift on the basis of direct measurements of simulated exposure for field crop sprayers.

(6) The UK approach does not include the potential exposure of resident children via spray drift.

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

| Substance : | benfluralin |
|---|---|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] : | No current harmonised classification. |
| Peer review proposal[5] for harmonised classification according to Regulation (EC) No 1272/2008: | Skin Sens.1 H317 'May cause an allergic skin reaction'<br>Skin Irrit. 2, H315: 'Causes skin irritation'<br>Eye Irrit. 2, H319: 'Causes serious eye irritation'<br>STOT SE 2, H371 'May cause damage to organs'<br>Carc. 2, H351: 'Suspected of causing cancer' |

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

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

## Section 3 Residues in or on treated products food and feed

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

| | | | | |
|---|---|---|---|---|
| **Primary crops** (Plant groups covered) OECD Guideline 501 | **Crop groups** | **Crop(s)** | **Application(s)** | **DAT (days)** |
| | Leafy crops | Lettuce | Soil, 1 x 4.48 kg a.s./ha | 71 |
| | Cereals/grass crops | Wheat | Foliar, 1 x 1.5 kg a.s./ha | Forage: 19<br>Hay: 37-53<br>Straw: 97-113<br>Grain: 97-113 |
| | Pulses/Oilseeds | Alfalfa<br>Peanuts | Soil, 1 x 4.48 kg a.s./ha<br>Soil, 1 x 5.27 kg a.s./ha | 114<br>132 |
| | Benfluralin was identified at low level (1.3 % TRRs in lettuce) while up to 47% of TRRs remained unextracted of which 17.7% TRRs was found in lignin fraction.<br>Similar pattern was reported for alfalfa and peanuts with the extracted fractions consisting of numerous unidentified metabolites, individually accounting for less than 3% TRRs. However, a metabolism study of benfluralin in peanuts and alfalfa with higher rate of metabolites identification, is available in the public domain. Therefore, and to support a more complete elaboration of the metabolic pathway in plants, this metabolism study on peanuts and alfalfa indicating the presence of potentially relevant metabolites should be assessed, i.e. analysis of the proposed structures of the identified metabolites, their toxicological relevance and whether the study can address the metabolism of benfluralin in the pulses and oilseeds crop group (data gap).<br>In the wheat metabolism study following foliar application, benfluralin was found only in wheat forage (57% TRRs) and hay (2% TRRs), while in the extracted residue radioactivity of straw and grains (up to 57% TRRs and 82%TRRs respectively) no further metabolites' identification occurred. A metabolism study in root crops to support the representative use in chicory roots was not provided. As regards the representative uses following soil application, the presence of benfluralin was shown only in leafy crops at limited level (1.3%TRRs). | | | |

| | | | | |
|---|---|---|---|---|
| **Rotational crops** (metabolic pattern) OECD Guideline 502 | **Crop groups** | **Crop(s)** | **PBI (weeks)** | **Comments** |
| | Root/tuber crops | Sugar beet | 52 | Bare soil application at 1.266 kg a.s./ha followed by incorporation into the soil and planting of tobacco plant as primary crop |
| | Leafy crops | Cabbage | 63 | |
| | Cereal (small grain) | Wheat | 22 | |
| | Other | Maize<br>Soybean | 52<br>52 | |
| Rotational crop and primary crop metabolism similar? | The available confined rotational crop studies showed significant deficiencies in terms of the metabolites' identification and characterisation, similarly to what was observed in primary crops. Therefore a rotational crop metabolism study on leafy crops, cereal small grains and root crops and conducted according to the current guidelines at the appropriate dose rate of application and covering all plant back intervals is needed (data gap). Currently the same residue definitions as for primary crops are applicable to rotational on a provisional basis. | | | |

| | | |
|---|---|---|
| **Processed commodities** (standard hydrolysis study) OECD Guideline 507 | **Conditions** | |
| | 20 min, 90°C, pH 4 | - |
| | 60 min, 100°C, pH 5 | - |
| | 20 min, 120°C, pH 6 | - |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Benfluralin under standard hydrolysis conditions was not investigated and from the level in chicory roots (<0.01 mg/kg) and considering also that lettuce is consumed raw, this would not be triggered. However, since the chicory trials were not supported by storage stability data and the metabolic pattern is also not elucidated, it has to be reconsidered if become necessary. In addition, the water solubility of benfluralin is also 0.064 mg/L. | |

| | |
|---|---|
| Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | benfluralin (by default) |
| Plant residue definition for risk assessment (RD-RA) | benfluralin (provisionally) |
| Conversion factor (monitoring to risk assessment) | Pending on the elucidation of the metabolic pattern in primary and rotational crops, conversion factors might be needed. |

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

| | | | | |
|---|---|---|---|---|
| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)<br>**Animals covered** | **Animal** | **Dose (mg/kg feed)** | **Duration (days)** | **N rate/comment** |
| | Laying hen | 0.19<br>15.4 | 28<br>10 | Not applicable |
| | Cow | 10 | 3 | Not applicable |
| | Pig | - | - | - |
| | Fish | - | - | - |
| | A general low rate of TRRs identification was noted, most of the radioactivity remaining either non extracted (up to 68% TRRs ruminants liver) or extracted without further characterisation and identifications (50% TRRs milk and 17%TRRs and fat). Benfluralin was identified only in poultry skin (up to 34% TRRs) and in eggs (up to 4% TRRs). Based on the available data, the metabolic pattern could not be depicted and therefore no reliable risk assessment residue definition could be proposed. | | | |

| | |
|---|---|
| Time needed to reach a plateau concentration in milk and eggs (days) | **Eggs**<br>For the lowest dosing group: 8 days after the first dosing<br>For the highest dosing group: the number of days of treatment not sufficient to determine a plateau<br><br>**Milk**<br>It cannot be determined. |
| Animal residue definition for monitoring (RD-Mo)<br>OECD Guidance, series on pesticides No 31 | Benfluralin (by default), not triggered for the representative uses |
| Animal residue definition for risk assessment (RD-RA) | No reliable residue definition could be derived based on the available data |
| Conversion factor (monitoring to risk assessment) | Not relevant |
| Metabolism in rat and ruminant similar (Yes/No) | - |
| Fat soluble residues (Yes/No)<br>(FAO, 2009) | Yes |

## Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

| | |
|---|---|
| **Confined rotational crop study**<br>(Quantitative aspect) | Data may be required pending the elucidation of the metabolic pattern of benfluralin in rotational crops. |
| **Field rotational crop study**<br>OECD Guideline 504 | Data may be required pending the elucidation of the metabolic pattern of benfluralin in rotational crops. |

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

OECD Guideline 506

| **Plant products (Category)** | **Commodity** | **T** (°C) | **Stability (Month)** |
|---|---|---|---|
| | | | Benfluralin |
| High water content | Lettuce | -18 | 12 |
| High oil content | - | - | - |
| High protein content | - | - | - |
| High starch content | - | - | - |
| High acid content | - | - | - |
| The storage stability study in lettuce is also valid for witloofs/endives (high water content), but not valid for chicory roots (high starch content**) (data gap).** | | | |
| No storage stability study in animal matrices is available. | | | |

**Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)** OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

| **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** | | | | | | |
| Lettuce | NEU | 3x nd, 1x <0.01 | Since the residue levels in all trials were below the LOQ, a limited number is acceptable. | 0.01* | <0.01 | <0.01 |
| | SEU | 1x nd, 1x <0.01 | | | | |
| Industrial chicory (chicory roots) | NEU | Root: 6x nd, 2x <0.01<br>Leaf: 6x nd, 2x <0.01 | Although the number of trials is sufficient, the trials are not supported by storage stability data and also the metabolic pattern is not elucidated. | - | <0.01 | <0.01 |
| Witloofs/endives | NEU | 4x <0.01 | Although two of the trials do not seem to be independent (two crop varieties but application date and treatment were identical), considering that the residue levels are below the LOQ, the number of trials is considered acceptable. | 0.01* | <0.01 | <0.01 |
| **Summary of the data on formulation equivalence** OECD Guideline 509 | | | | | | |
| **Crop** | **Region** | **Residue data** (mg/kg) | **Recommendations/comments** | | | |
| - | - | - | Not required | | | |
| **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** | | | |
| - | - | - | Although lettuce and chicory are harvested before flowering and they are not expected to be visited by bees for pollen collection, the metabolic pattern in rotational crops has not been elucidated. Benfluralin is a persistent compound and its uptake by the following crops growing in rotation cannot be excluded. Therefore, data addressing the requirement on the residue levels analysed according to the risk assessment residue definition in pollen and honeybee products covering rotational crops need to be submitted to complete the consumer risk assessment (data gap). | | | |

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

**Inputs for animal burden calculations**
Intake calculations for livestock are not necessary as lettuce, witloofs/endives and chicory roots are not animal feedstuffs.

**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)**
OECD Guideline 505 and OECD Guidance, series on pesticides No 73- **the representative uses are not used as feedstuff for livestock**

**Conversion Factors (CF) for monitoring to risk assessment**
Pending the elucidation of the metabolic pattern

**Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)**
**Not applicable**

**Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)**
**Consumer risk assessment limited to the representative uses.**
**The consumer risk assessment is provisional pending on the outcome of the metabolic pattern elucidation.**

| | |
|---|---|
| **ADI** | 0.005 mg/kg bw per day |
| TMDI according to EFSA PRIMo | Highest TMDI: 0.1% ADI (ES adult) |
| NTMDI, according to (to be specified) | Not required |
| IEDI (% ADI), according to EFSA PRIMo | Not required |
| NEDI (% ADI), according to (to be specified) | Not required |
| Factors included in the calculations | TMDI: Current EU MRLs |
| **ARfD** | 0.5 mg/kg bw |
| IESTI (% ARfD), according to EFSA PRIMo | Highest IESTI: 0.1 % ARfD (Witloof, NL diet) |
| NESTI (% ARfD), according to (to be specified) | Not required |
| Factors included in IESTI and NESTI | IESTI: Current EU MRLs |

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

| Code[(a)] | Commodity/Group | MRL/Import tolerance[(b)] (mg/kg) and Comments | |
|---|---|---|---|
| **Plant commodities** | | | |
| **Representative uses** | | | |
| 0251020 | Lettuces | 0.01* | |
| 0255000 | Witloofs/Belgian endives | 0.01* | |
| 0900030 | Chicory roots | - | No MRL has been proposed since the trials were not supported by storage stability data. |

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

## Section 4 Environmental fate and behaviour

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

| | |
|---|---|
| Mineralisation after 100 days | 1.7 % - 17.2 % AR at day 120 – 125 [$^{14}$C-phenyl-ring] (n=6)<br>(Benfluralin was volatile: 0.8 - 8.8% AR in the traps at day 120-125 (n=4)) |
| Non-extractable residues after 100 days | 23.0 % - 63.4 % AR at day 112 – 125 [$^{14}$C-phenyl-ring] (n=6) |
| Metabolites requiring further consideration<br>- name and/or code, % of applied (range and maximum) | None exceeded 5 % AR<br><br>B12 did not exceed 5% AR in aerobic soils, however it was further considered (as a groundwater metabolite) due to the toxicological properties of the parent (regarding at least carcinogenicity) and the chemical structure (of potential concern) of the metabolite. |

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

| | |
|---|---|
| Mineralisation after 100 days | 1.3 % AR at day 120 [$^{14}$C-phenyl-ring] (n=1) |
| Non-extractable residues after 100 days | 50.2 % at day 120 [$^{14}$C-phenyl-ring] (n=1) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | Benfluralin diamine: maximum level of 23.2 % AR at day 1 (DT50 = 2.3 d) (n=1)<br>Ethyl propyl benzimidazole: maximum level of 25.0 % at day 2 (DT50 = 27.2 d) (n=1) |

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

| | |
|---|---|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | Not required<br>The active substance is incorporated in the soil. |

### 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 | pH[a)] | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d)[#] | $DT_{50}$ (d) 20 °C pF2/10kPa[b)] | St. ($\chi^2$) | Method of calculation |
| Kenslow/UK | 5.3 | 20 °C/ pF2 | 119.0/395.0 | 119.0 | 3.6 | SFO |
| Clipstone/UK | 5.3 | 20 °C/ pF2 | 198.0/675.0 | 198.0 | 2.0 | SFO |
| Hareby/UK | 7.7 | 20 °C/ pF2 | 54.4/181.0 | 54.4 | 1.9 | SFO |
| Speyer 2.3/DE | 5.6 | 20 °C/ pF2 | 110.0/367.0 | 110.0 | 3.4 | SFO |
| Speyer 2.3/DE | 5.8 | 20 °C/ approx. pF2 | 32.7/109 | 32.7 | 9.1 | SFO |
| Hareby/UK | 7.6 | 20 °C/ approx. pF2 | 31.7/105 | 27.3 | 7.05 | SFO |
| Geometric mean (if not pH dependent) | | | | 70.8 | | |
| pH dependence, Yes or No | | | | No | | |

a) Measured in $CaCl_2$

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[#] For the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, 2014 and 2017), the range of half-lives in soil normalized to 12 °C is: 58.3–423 d.

**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)**

| 2,6-dinitro-4-(trifluoromethyl)phenol (B12) | Dark aerobic conditions. Metabolite dosed or the precursor from which the f.f. was derived was benfluralin (parent). | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type | pH[a] ($CaCl_2$) | t. °C / % MWHC | $DT_{50}$ (persistence/modelling endpoint) | $DT_{50}$ (d) 20 °C pF2/10kPa[b] (modelling endpoint) | $DT_{90}$ (persistence endpoint) | f.f. | Best fit model (persistence/modelling endpoint | St. ($\chi^2$) (persistence/modelling endpoint |
| Mußbach, Loam | 7.03 | 20 °C/ pF2.5 | 37.2 (53.3[c])/41.3 | 30.1 | 177 | N/A | FOMC (α=2.47 β=115. 1) / SFO | 2.42/3.66 |
| Lufa 2.1, Loamy sand | 4.90 | 20 °C/ pF2.5 | 9.4 (11.1[c])/10.2 | 5.3 | 36.8 | N/A | FOMC (α=5.014 β=63.04) / SFO | 3.54/4.44 |
| Lufa 2.2, Sandy loam | 5.60 | 20 °C/ pF2.5 | 8.3 (10.7[c])/9.3 | 4.4 | 35.5 | N/A | FOMC (α=3.453 β=37.44) / SFO | 2.83/5.36 |
| Attenschwiller, Silt loam | 7.52 | 20 °C/ pF2.5 | 68.3 | 39.6 | 227 | N/A | SFO | 2.68 |
| Bourg-en-Bresse, Sandy loam | 5.84 | 20 °C/ pF2.5 | 16.0 (52.5[d])/26.9 | 16.9 | 93.6 | N/A | DFOP (k1=0.0672 k2= 0.0132 g=0.6599) / FOMC (α=1.778 β=33.65) | 2.43/2.72 |
| Village Neuf, Loam | 7.50 | 20 °C/ pF2.5 | 87.5 (244[c])/89.3 | 46.9 | 811 | N/A | FOMC (α=0.9764 β=84.68) / SFO | 1.95/2.91 |
| Hareby, Loam | 7.64 | 20 °C/ pF2.5 | 41 | 35.3 | 136 | 0.060 | SFO-SFO | 13.2 |
| Geometric mean (if not pH dependent)<br>Geometric mean for soils at pH > 7 | | | | 18.6<br>37.5 | | | | |
| pH dependence, Yes or No | | | | Yes[e] | | | | |

a) Measured in $CaCl_2$
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
c) Slow phase DT50, calculated as DT90/3.32
d) Slow phase DT50
e) Refer to Column E under Data Requirement 4.7 of the Evaluation Table (EFSA, 2018).

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

| Parent | Aerobic conditions | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH ($H_2O$) | Depth (cm) | $DT_{50}$ (d) actual | $DT_{90}$(d) actual | St. ($\chi^2$) | $DT_{50}$ (d) Norm[a)] | Method of calculation |
| Clay loam | N France (Betheniville), 1997 | 8.7 | 0 - 20 | 39.2 | 130 | 16.9 | 37.2 | SFO |
| Silt loam | Belgium (Villers-Perwin), 1997 | 8.6 | 0 - 20 | 63.7 | 212 | 15.5 | 45.4 | SFO |
| Silt loam | N France (Tilloy Les Mofflaines), 1998 | 7.2 | 0 - 20 | 34.5 | 115 | 19.9 | 32.4 | SFO |
| Silt loam | Belgium (Villers-Perwin), 1998 | 7.9 | 0 - 20 | 31.5 [b)] | 349[b)] | 9.7 | 46.1 | SFO |
| Geometric mean (if not pH dependent) | | | | | | | 39.9 | |
| pH dependence, Yes or No | | | | No | | | | |

[a)]Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, $DegT_{50matrix}$
[b)]HS

**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) | Laboratory and field kinetic endpoints for modelling are from different populations according to the EFSA calculator tool. |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) | Not relevant |
| Kinetic formation fraction (f. f. kf / kdp) of transformation products, arithmetic mean | Not relevant |

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

**Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)**

| | |
|---|---|
| Soil accumulation and plateau concentration | Plateau concentration of 1.009 mg/kg reached after 2 years (based on calculation with the tool ESCAPE v. 2) |

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

| Parent | Dark anaerobic conditions | | | | | |
|---|---|---|---|---|---|---|
| Soil type | pH ($CaCl_2$) | t. °C / % MWHC | $DT_{50}$ / $DT_{90}$ (d) | $DT_{50}$ (d) 20 °C[a)] | St. ($\chi^2$) | Method of calculation |
| Sandy silt loam | 5.6 | - | 0.2/0.8 | - | 2.6 | SFO |

[a)]Normalised using a Q10 of 2.58

**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)**

| | |
|---|---|
| Benfluralin diamine | Dark anaerobic conditions. The precursor from which the f.f. was derived was parent. |

| Soil type | pH ($CaCl_2$) | t. °C / % MWHC | $DT_{50}$/ $DT_{90}$ (d) | f. f. $k_f$ / $k_{dp}$ | $DT_{50}$ (d) 20°C[b)] | St. ($\chi^2$) | Method of calculation |
|---|---|---|---|---|---|---|---|
| Sandy silt loam | 5.6 | - | 2.1/6.9 | 0.29 | - | 6.9 | SFO-SFO |

| Ethyl propyl benzimidazole | Dark anaerobic conditions: The precursor from which the f.f. was derived was benfluralin diamine metabolite. | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | pH ($CaCl_2$) | t. °C / % MWHC | $DT_{50}$/ $DT_{90}$ (d) | f. f. $k_f$ / $k_{dp}$ | $DT_{50}$ (d) 20°C[b)] | St. ($\chi^2$) | Method of calculation |
| Sandy silt loam | 5.6 | - | 24.4/81.0 | 1 | - | 6.9 | SFO |

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

| **Parent** | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH ($CaCl_2$) | $K_d$ (mL/g) | $K_{doc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n |
| Silty clay, Bergen-Enkheim | 2.07 | 7.3 | - | - | 272.7 | 13174 | 1.139 |
| Silt loam, Hofheim | 1.44 | 5.8 | - | - | 154.6 | 10736[#] | 1.055[#] |
| Sand, Standard 2.1 | 0.9 | 5.2 | - | - | 129.6 | 14400 | 1.099 |
| Loam, Volcanic (M634)* | 3.80 | 5.2 | - | - | 2027.1 | 53345* | 1.302* |
| Geometric mean | | | | | | n.c. | |
| Arithmetic mean | | | | | | | n.c. |
| pH dependence | | | No | | | | |

[#] endpoint used in exposure modelling since only 3 valid soils are available
*the loam soil was not included in the mean due to its unrepresentative nature
n.c. – not calculated, since n=3

**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)**

| **2,6-dinitro-4-(trifluoromethyl)phenol (B12)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH ($CaCl_2$) | $K_d$ (mL/g) | $K_{doc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n |
| Loam, Mußbach | 2.49 | 7.03 | - | - | 1.09 | 43.78 | 0.79 |
| Loamy sand, Lufa 2.1 | 0.68 | 4.90 | - | - | 0.29 | 43.20 | 0.76 |
| Sandy loam, Lufa 2.2 | 1.73 | 5.60 | - | - | 0.39 | 22.80 | 0.73 |
| Silt loam, Attenschwiller | 1.11 | 7.52 | - | - | 0.53 | 47.34 | 0.80 |
| Sandy loam, Bourg en Bresse | 3.13 | 5.84 | - | - | 1.35 | 43.20 | 0.67 |
| Loam, Village Neuf | 0.88 | 7.50 | - | - | 0.44 | 50.12 | 0.83 |
| Geometric mean | | | | | 0.58 | 40.51 | |
| Arithmetic mean | | | | | | | 0.76 |
| pH dependence | | | No | | | | |

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

| | |
|---|---|
| Column leaching | Not required |
| | Not available |

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

| | |
|---|---|
| Column leaching | Not required<br>Not required |

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

| | |
|---|---|
| Lysimeter/ field leaching studies | Not available |

**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 4, 50°C : hydrolytically stable (99.9 %)<br>pH 7, 50°C : hydrolytically stable (99.9 %)<br>pH 9, 50°C : hydrolytically stable (99.9 %) |

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

| | |
|---|---|
| Photolytic degradation of active substance and metabolites above 10 % | DT50 :-7.9 h (pH 7)<br>Natural summer light, 50°N; $DT_{50}$ 1.7 h (pH 7)<br>Desalkyl benfluralin diamine (358R; max 14.1 % AR)<br>Propyl-benzimidazole (371R; max. 15.4 % AR)<br>Methyl-benzimidazole (372R; max 19.8 % AR),<br>Ethyl-propyl-benzimidazole (379R; max 15.1 % AR) |
| Quantum yield of direct phototransformation in water at Σ > 290 nm | $3.18 \times 10^{-3}$ mol · Einstein $^{-1}$ |

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

| | |
|---|---|
| Readily biodegradable (yes/no) | No; degradation equal to 5 % of the calculated biological demand after 28 days |

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

| Parent | No significant degradation was observed. Benfluralin was highly volatilised from the water with over 90% after 17 days. | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | t. °C[a)] | $DT_{50}$ /$DT_{90}$ whole sys. (suspended sediment test) | | St. ($\chi^2$) | $DT_{50}$ /$DT_{90}$ Water (pelagic test) | | St. ($\chi^2$) | Method of calculation |
| | | | At study temp | Normalised to x °C | | At study temp | Normalised to x °C[b)] | | |
| Fresh (river/pond) | 8.2 | 20 | - | - | - | - | - | - | - |

[a)]Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[b)]Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

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

| Parent | Distribution (max in water 57.6 % after 0 d. Max. sediment 43.4 % after 0 d). Benfluralin was rapidly volatilised from the water phase: 50 % - 52.4 % after 1 d and 58.6 %-63.2 % after 100 d. | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed [a] | t. °C | $DT_{50}$ /$DT_{90}$ whole sys. | St. ($\chi^2$) | $DT_{50}$ /$DT_{90}$ water | St. ($\chi^2$) | $DT_{50}$ /$DT_{90}$ sed | St. ($\chi^2$) | Method of calculation |
| Bickenbach | 7.6 | 7.6 | 20 | 2.6 (2.4*) /8.3 | 0.09 | - | | - | | HS |
| Unter-Widdersheim | 7.9 | 7.2 | 20 | 2.7 (3.7*) /11.3 | 0.09 | - | | - | | HS |
| Geometric mean at 20°C [b] | | | | 3.1* | | | | | | |

[a] Measured in calcium chloride
[b] Normalised using a Q10 of 2.58
*slow phase of HS kinetics

| Benfluralin diamine (B36) | Distribution: detected mainly in sediment with maximum 8.7% (day 2) kinetic formation fraction ($k_f/k_{dp}$): No acceptable degradation kinetics were calculated and therefore there is no acceptable formation fraction for this metabolite. | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed [a] | t. °C | $DT_{50}$ /$DT_{90}$ whole sys. | St. ($\chi^2$) | DT50 /DT90 water | St. ($\chi^2$) | DT50 /DT90 sed | St. ($\chi^2$) | Method of calculation |
| Bickenbach | 7.6 | 7.6 | 20 | - | - | | | | | |
| Unter-Widdersheim | 7.9 | 7.2 | 20 | - | - | | | | | |
| Geometric mean at 20°C [b] | | | | - | | | | | | |

[a] Measured in calcium chloride
[b] Normalised using a Q10 of 2.58

| Mineralisation and non extractable residues (from parent dosed experiments) | | | | | |
|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
| Bickenbach | 7.6 | 7.6 | 2.5% after 100 d | - | 26.0% after 100 d |
| Unter-Widdersheim | 7.9 | 7.2 | 1.7% after 100 d | - | 31.4% after 100 d |

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

| | |
|---|---|
| Direct photolysis in air | Not studied - no data required |
| Photochemical oxidative degradation in air | $DT_{50}$ of 5.76 hours derived by the Atkinson model. OH (12 h) concentration assumed = 1.5 x $10^6$ OH radicals/$cm^3$ |
| Volatilisation | from plant surfaces (BBA guideline): <16.8% after 24 hours |
| | from soil surfaces (BBA guideline): <15.8% after 24 hours (not incorporated) |
| Metabolites | - |

**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:** Benfluralin, benfluralin diamine (B36, anaerobic metabolite not requiring further assessment for the representative uses assessed, except for the aquatic risk assessment), ethyl propyl benzimidazole (379R, anaerobic metabolite not requiring further assessment for |

| |
|---|
| the representative uses assessed, except for the aquatic risk assessment)<br><br>**Surface water**: Benfluralin<br>Desalkyl benfluralin diamine (358R)<br>Propyl-benzimidazole (371R)<br>Methyl-benzimidazole (372R)<br>Ethyl-propyl-benzimidazole (379R)<br><br>**Sediment**: Benfluralin<br>Benfluralin diamine (B36)<br><br>**Ground water**: Benfluralin<br>2,6-dinitro-4-(trifluoromethyl)phenol (B12)*<br><br>**Air**: Benfluralin<br><br>* metabolite B12 did not exceed 5% AR in aerobic soils, however it was further considered (as a groundwater metabolite) due to the toxicological properties of the parent (regarding at least carcinogenicity) and the chemical structure (of potential concern) of the metabolite. |

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

| |
|---|
| See section 5, Ecotoxicology |

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

| | |
|---|---|
| Soil (indicate location and type of study) | No data showing the detection of benfluralin in ground water, surface water or air was found |
| Surface water (indicate location and type of study) | - |
| Ground water (indicate location and type of study) | - |
| Air (indicate location and type of study) | - |

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

| | |
|---|---|
| Parent<br>Method of calculation | DT50 (d): 139 days (slow phase), k1 = 0.022, k2 = 0.005, tb = 33.24 in the tool ESCAPE v. 2<br>Kinetics: HS<br>Field or Lab: non-normalised worst case from field studies. |
| Application data | Crop: lettuce/chicory<br>Depth of soil layer: 10 cm (soil incorporation)<br>Soil bulk density: 1.5g/cm3<br>% plant interception: pre-sowing or pre-planting therefore no crop interception<br>Number of applications: 1<br>Interval (d): -<br>Application rate(s): 1440 g a.s./ha |

| **PEC**(s)<br>(mg/kg) | Single application<br>Actual | Single application<br>Time weighted average |
|---|---|---|
| Initial | 0.96 | - |
| Short term 24 h | 0.939 | 0.950 |

| | | | |
|---|---|---|---|
| | 2 d | 0.919 | 0.939 |
| | 4 d | 0.879 | 0.919 |
| Long term | 7 d | 0.823 | 0.890 |
| | 28 d | 0.518 | 0.717 |
| | 50 d | 0.427 | 0.602 |
| | 100 d | 0.333 | 0.490 |
| Plateau concentration (20 cm) | | 0.049 mg/kg after 2 yr | |
| $PEC_{accumulation}$ ($PEC_{act}$ +$PEC_{soil\ plateau}$) | | 1.009 mg/kg | |

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

| | |
|---|---|
| Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) | For FOCUS gw modelling:<br>Modelling using FOCUS models with appropriate FOCUSgw scenarios, according to FOCUS guidance.<br>Models used: FOCUS PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4<br>Crop: lettuce/chicory (surrogate leafy crop: cabbage in FOCUS PEARL and PELMO and vegetables, leafy, in FOCUS MACRO) and chicory (surrogate crop: carrot in FOCUS PEARL and PELMO and vegetables, root, in FOCUS MACRO)<br>Crop uptake factor: 0<br>Water solubility (mg/L): 0.0648[a] at pH 7 and 20°C<br>Vapour pressure: 1.8 x $10^{-3}$ [b] Pa at 20°C<br>Geometric mean parent $DT_{50}$ field 39.9 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).<br>$K_{OC}$: 10736 mL/g, lowest value, n=3<br>1/n= 1.1[a], arithmetic mean (n=3)<br><br>Metabolites:<br>2,6-dinitro-4-(trifluoromethyl) phenol (B12)<br>Crop uptake factor: 0<br>Water solubility (mg/L): 1000 at pH 7 and 20°C (FOCUS default)<br>Vapour pressure: 0 Pa at 20°C (worst case)<br>Geometric mean $DT_{50}$ lab 38.7d[b] (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).<br>$K_{OC}$: 40.5 (geomean, n=6)<br>1/n= 0.76, arithmetic mean (n=6)<br>Precursor: benfluralin<br>Kinetic formation fraction from the precursor($k_f/k_{dp}$): 0.074 |
| Application rate | Gross application rate: 1440 g/ha.<br>Crop growth stage: pre-sowing or pre-planting<br>Canopy interception %: 0<br>Application rate net of interception: 1440 g/ha.<br>No. of applications: 1<br>Time of application: 14 days post emergence |

[a] Updated value: 1.055 should have been used.
[b] mean value from alkaline soils, n=3 (for future modelling the correct value to be used should be 37.5 days as the geometric mean of 4 neutral/alkaline soils)

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

| **Crop** | **Lettuce / Chicory (surrogate leafy crop: cabbage)** | | | | **Chicory (surrogate root crop: carrots)** | | | |
|---|---|---|---|---|---|---|---|---|
| **Application date** | **14 days before emergence** | | | | | | | |
| **Model** | **PEARL 4.4.4** | | **PELMO 5.5.3** | | **PEARL 4.4.4** | | **PELMO 5.5.3** | |
| **LOCATION** | **Benfl.** | **B12** | **Benfl.** | **B12** | **Benfl.** | **B12** | **Benfl.** | **B12** |
| Châteaudun | < 0.001 | 0.001 | < 0.001 | 0.001 | < 0.001 | 0.001 | < 0.001 | 0.001 |
| Hamburg | < 0.001 | 0.046 | < 0.001 | 0.035 | < 0.001 | 0.042 | < 0.001 | 0.029 |
| Jokioinen | < 0.001 | 0.002 | < 0.001 | 0.001 | < 0.001 | 0.001 | < 0.001 | 0.001 |
| Kremsmünster | < 0.001 | 0.017 | < 0.001 | 0.010 | < 0.001 | 0.017 | < 0.001 | 0.010 |
| Porto | < 0.001 | 0.001 | < 0.001 | 0.008 | < 0.001 | 0.001 | < 0.001 | 0.006 |
| Sevilla | < 0.001 | < 0.001 | < 0.001 | < 0.001 | - | - | - | - |
| Thiva | < 0.001 | 0.001 | < 0.001 | 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

The PECgw calculated with MACRO model for Châteaudun scenario were also below 0.001 µg/L for benfluralin. For B12 the estimated PECgw with the MACRO model and the Châteaudun scenario was 0.003 µg/L.

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

| | |
|---|---|
| Parent<br>Parameters used in FOCUS sw step 1 and 2 | Version control no. of FOCUS calculator: "STEPS 1-2 in FOCUS" calculator, ver 3.2.<br>Molecular weight (g/mol): 335.3<br>KOC/KOM (mL/g): 10736/6227.4<br>DT50 soil (d): 39.9 days (Field. In accordance with FOCUS SFO)<br>DT50 water/sediment system (d): 3.1 d (geomean from sediment water studies)<br>DT50 water (d): 1000<br>DT50 sediment (d): 3.1<br>Crop interception (%): 0 |
| Parameters used in FOCUS sw step 3 | Version control no.'s of FOCUS software:<br>FOCUS SWASH 5.3, including:<br>FOCUS SPIN 2.2<br>PRZM 4.3.1<br>FOCUS MACRO 5.5.4<br>FOCUS TOXSWA 4.4.3<br>SWAN 4.0.1 (Step 4)<br>EVA 3.0 (Step 4)<br>Water solubility (mg/L): 0.064<br>Vapour pressure: 0.0018 Pa at 20°C<br>Kom/Koc (mL/g): 10736/6227.4<br>1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 1.1[a)]<br>Q10=2.58,<br>Walker equation coefficient 0.7<br>Crop uptake factor: 0 |
| Application rate | Gross application rate: 1440 g/ha.<br>Crop growth stage: pre-sowing or pre-planting<br>Crop: Vegetables, root and vegetables, leafy, early (1st) and late (2nd) applications.<br>Canopy interception %: 0<br>Application rate net of interception: 1440 g/ha.<br>No. of applications: 1<br>Time of application: Step 2: March – May and June - September<br>Step 3: 14 days before emergence of the crop. The application window was set to 30 days.<br><br><u>Step 4</u><br>Based on Step 3 simulations. Risk mitigation measures:<br>• 10 or 20 meter spray drift buffers<br>• Drift reducing equipment (RN) of 75% or 90%<br>• 10 or 20 m vegetative filter strips (VFS) |

a) Updated value: Should have been 1.055

| FOCUS STEP 1 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Vegetables, leafy and Vegetables, root | 0 h | 44.59 | | 3360 | |
| | 24 h | 25.75 | 35.17 | 2760 | 3060 |
| | 2 d | 20.59 | 29.12 | 2210 | 2770 |
| | 4 d | 13.17 | 22.86 | 1410 | 2280 |
| | 7 d | 6.733 | 17.18 | 722.9 | 1740 |
| | 14 d | 1.408 | 10.29 | 151.1 | 1050 |
| | 21 d | 0.294 | 7.097 | 31.59 | 728.1 |
| | 28 d | 0.062 | 5.360 | 6.604 | 550.0 |

| | | | | | |
|---|---|---|---|---|---|
| | 42 d | 0.003 | 3.580 | 0.289 | 367.4 |

| FOCUS STEP 2 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Northern EU March to May[a)] Vegetables, leafy and Vegetables, root | 0 | 13.24 | | 670.4 | |
| | 1 | 4.987 | 9.115 | 539.2 | 604.8 |
| | 2 | 2.309 | 6.382 | 438.2 | 546.7 |
| | 4 | 6.794 | 4.667 | 289.4 | 453.3 |
| | 7 | 4.145 | 5.074 | 155.3 | 351.7 |
| | 14 | 0.970 | 3.634 | 36.36 | 217.0 |
| | 21 | 0.227 | 2.594 | 8.513 | 151.1 |
| | 28 | 0.053 | 1.975 | 1.993 | 114.4 |
| | 42 | 0.003 | 1.323 | 0.109 | 76.50 |
| Southern EU March to May[a)] Vegetables, leafy and Vegetables, root | 0 h | 13.24 | | 1300 | |
| | 24 h | 4.990 | 9.115 | 1040 | 1170 |
| | 2 d | 2.309 | 6.382 | 846.1 | 1060 |
| | 4 d | 12.64 | 5.398 | 558.8 | 875.9 |
| | 7 d | 8.004 | 7.698 | 299.9 | 679.4 |
| | 14 d | 1.874 | 5.968 | 70.22 | 419.1 |
| | 21 d | 0.439 | 4.309 | 16.44 | 291.8 |
| | 28 d | 0.103 | 3.290 | 3.849 | 221.0 |
| | 42 d | 0.006 | 2.204 | 0.211 | 147.8 |

a) June to September was also calculated but not presented here, as March to May gave worst case results.

| FOCUS Step 3 Scenario | Water body | Max $PEC_{SW}$ (µg/L) | 21 d $PEC_{SW}$, TWA (µg/L) | Max $PEC_{SED}$ (µg/kg) |
|---|---|---|---|---|
| Vegetables, leafy | | | | |
| D3 1st | ditch | 9.069 | 0.279 | 3.559 |
| D3 2nd | ditch | 9.087 | 0.214 | 2.548 |
| D4 | pond | 0.314 | 0.059 | 0.350 |
| D4 | stream | 7.122 | 0.019 | 0.305 |
| D6 | ditch | 9.159 | 0.195 | 2.065 |
| R1 1st | pond | 0.314 | 0.065 | 0.401 |
| R1 2nd | pond | 0.314 | 0.039 | 0.242 |
| R1 1st | stream | 5.988 | 0.053 | 0.796 |
| R1 2nd | stream | 5.937 | 0.050 | 0.616 |
| R2 1st | stream | 7.852 | 0.032 | 0.440 |
| R2 2nd | stream | 8.052 | 0.037 | 0.566 |
| R3 1st | stream | 8.467 | 0.148 | 1.986 |
| R3 2nd | stream | 8.441 | 0.128 | 1.396 |
| R4 1st | stream | 5.896 | 0.098 | 0.650 |
| R4 2nd | stream | 5.952 | 0.116 | 0.786 |
| Vegetables, root | | | | |
| D3 | ditch | 9.069 | 0.279 | 3.559 |
| D6 | ditch | 6.231 | 0.107 | 1.488 |
| R1 | pond | 0.314 | 0.076 | 0.402 |
| R1 | stream | 5.987 | 0.079 | 0.795 |
| R2 1st | stream | 7.851 | 0.032 | 0.439 |
| R2 2nd | stream | 5.593 | 0.026 | 0.393 |
| R3 | stream | 8.467 | 0.148 | 1.984 |
| R4 | stream | 6.007 | 0.100 | 0.858 |

| FOCUS Step 4* Scenario | Water body | Max $PEC_{SW}$ (µg/L) |
|---|---|---|
| Vegetables, leafy | | |

| | | 10 m buffer** 90% drift reducing nozzles (RN) | 20 m buffer** | 20 m buffer** 75% RN | 20 m buffer** 90% RN |
|---|---|---|---|---|---|
| D3 1st | ditch | nv | 0.678 | nv | nv |
| D3 2nd | ditch | nv | 0.680 | nv | nv |
| D4 | pond | 0.042 | 0.130 | 0.041 | 0.026 |
| D4 | stream | nv | 0.733 | nv | nv |
| D6 | ditch | nv | 0.685 | nv | nv |
| R1 1st | pond | 0.043 | 0.132 | 0.042 | 0.027 |
| R1 2nd | pond | 0.044 | 0.131 | 0.039 | 0.023 |
| R1 1st | stream | nv | 0.616 | nv | nv |
| R1 2nd | stream | nv | 0.615 | nv | nv |
| R2 1st | stream | nv | 0.813 | nv | nv |
| R2 2nd | stream | nv | 0.835 | nv | nv |
| R3 1st | stream | nv | 0.857 | nv | nv |
| R3 2nd | stream | nv | 0.855 | nv | nv |
| R4 1st | stream | 0.374 | 0.614 | nv | nv |
| R4 2nd | stream | 0.364 | 0.615 | nv | nv |
| Vegetables, root | | | | | |
| D3 | ditch | nv | 0.678 | | nv |
| D6 | ditch | nv | 0.466 | | nv |
| R1 | pond | 0.043 | 0.132 | | 0.027 |
| R1 | stream | nv | 0.616 | | nv |
| R2 1st | stream | nv | 0.812 | | nv |
| R2 2nd | stream | nv | 0.588 | | nv |
| R3 | stream | nv | 0.857 | | nv |
| R4 | stream | 0.379 | 0.615 | | nv |

*Results where a reduction of more than 95% of the PECsw value calculated at Step 3 was achieved are not considered valid (nv) and are not presented.
**For the R scenarios, the 10/20 m buffer includes a 10/20 m vegetative filter strip.

| | |
|---|---|
| 371R, 372R, 358R, 379R<br>Parameters used in FOCUS sw step 1 and 2 | Method of calculation: Derived from Step 1 and 2 $PEC_{SW}$ of benfluralin by multiplying by maximum % formation in aqueous photodegradation study and correction for molecular mass differences, i.e.<br>371R: 15.4% × (273/335)<br>372R: 19.8% × (245/335)<br>358R: 14.1% × (221/335)<br>379R: 15.1% × (301/335) |
| Parameters used in FOCUS sw step 3 | Derived from Step 3 $PEC_{SW}$ of benfluralin by multiplying by maximum % formation in aqueous photodegradation study and correction for molecular mass differences as specified for Step 1 and 2 above. |

| **Metabolite** | **Maximum PECsw (µg/L)** | | |
|---|---|---|---|
| | **Step 1** | **Step 2** | **Step 3** |
| Propyl-benzimidazole (371R) | 5.64 | 1.66 | 1.149 |
| Methyl-benzimidazole (372R) | 6.51 | 1.92 | 1.326 |
| Desalkyl benfluralin diamine (358R) | 4.18 | 1.23 | 0.852 |
| Ethyl-propyl-benzimidazole (U6#1/379R) | 6.10 | 1.80 | 1.243 |

| | |
|---|---|
| B36 (benfluralin diamine) | No acceptable calculations available. |
| Parameters used in FOCUS sw step 1 and 2 | - |

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

| | |
|---|---|
| Method of calculation | There are no other routes of exposure |

## Section 5 Ecotoxicology

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

| Species | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|---|---|---|---|---|
| Birds | | | | |
| *Colinus virginianus* | benfluralin | Acute | $LD_{50}$ | >2000 |
| *Serinus canaria* | benfluralin | Acute | $LD_{50}$ | >2000 |
| *Colinus virginianus* | benfluralin | Long-term | $LD_{50/10}$ | 200 |
| *Anas platyrhynchos* | benfluralin | Long-term | NOEL | 16.6[a] |
| *Colinus virginianus* | benfluralin | Long-term | NOEL | <8.6[a] |
| *Colinus virginianus* | benfluralin | Long-term | NOEL | 6.7 |
| Mammals | | | | |
| Rat | benfluralin | Acute | $LD_{50}$ | > 5000 |
| | EF-1533 | Acute | $LD_{50}$ | >342 |
| | benfluralin | Long-term, Reproduction, multi-generation | NOAEL | 50 |
| | benfluralin | Long-term, Reproduction, two-generation | NOAEL | 5.5 |
| Endocrine disrupting properties (Annex Part A, points 8.1.5)<br><br>Level 3 studies on amphibians and fish were available. In addition, the available chronic study on fish (according to OECD 210) and the reproductive toxicity studies with birds were also considered in the overall weight of evidence. Based on the available data and assessment, benfluralin is not considered an endocrine disruptor for non-target organisms according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. | | | | |
| Additional higher tier studies (Annex Part A, points 10.1.1.2):<br>No studies available. | | | | |
| Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):<br>In an amphibian metamorphosis assay (AMA) African clawed frogs, *Xenopus laevis*, were exposed to three concentrations, 2.70, 14.1 and 74.4 µg benfluralin/L (mean measured concentrations), for 21 days under flow-through conditions. Benfluralin is considered 'likely thyroid inactive' in this AMA. | | | | |

[a] Validation of the analytical methodology has not been submitted by the applicant. During Pesticides Peer Review meeting 183 the studies were still considered suitable for risk assessment.

**Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1) Chicory and lettuce at 1 x 1440 g a.s./ha [1 application]**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|---|---|---|---|---|
| Screening Step (Birds) | | | | | |
| Bare soil | Small granivorous bird | Acute | 35.6 | >56.2 | 10 |
| Bare soil | Small granivorous bird | Long-term | 8.7 | 0.8 | 5 |
| Tier 1 (Birds) | | | | | |
| BBCH < 10 | Small granivorous bird "finch" | Long-term | 8.7 | 0.8 | 5 |
| BBCH < 10 | Small omnivorous bird "lark" | Long-term | 6.26 | 1.1 | 5 |
| BBCH < 10 | Small insectivorous bird "wagtail" | Long-term | 4.50 | 1.5 | 5 |
| Higher tier (birds): The choice of focal species is unresolved. The higher tier risk assessment could thus not be finalised. | | | | | |

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|---|---|---|---|---|
| Screening Step (Mammals) | | | | | |
| Bare soil | Small granivorous mammal | Acute | 20.7 | >241 | 10 |
| Bare soil | Small granivorous mammal | Long-term | 5.04 | 1.09 | 5 |
| Tier 1 (Mammals) | | | | | |
| BBCH < 10 | Small omnivorous mammal "mouse" | Long-term | 4.35 | 1.26 | 5 |
| Higher tier (Mammals): The choice of focal species is unresolved. The higher tier risk assessment could thus not be finalised. | | | | | |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|---|---|---|---|
| Earthworm-eating birds | Long-term | 11.82 | 0.6 | 5 |
| Earthworm-eating mammals | Long-term | 14.41 | 0.4 | 5 |
| Fish-eating birds[a] | Long-term | – | – | – |
| Fish-eating mammals[a] | Long-term | – | – | – |
| Higher tier: Outstanding | | | | |
| | | | | |
| | | | | |

**Risk from consumption of contaminated water**

| **Scenarios** | **Indicator or focal species** | **Time scale** | **$PEC_{dw}$xDWR** | **TER** | **Trigger** |
|---|---|---|---|---|---|
| Leaf scenario | Birds | acute | Not relevant | | 5 |

| | | | | | |
|---|---|---|---|---|---|
| **Puddle scenario, Screening step**<br>1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed<br>2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed | | | | | |
| Puddle scenario | Birds | acute | Not needed | Case 2<br><0.72 | 10 |
| Puddle scenario | Mammals | acute | Not needed | Case 2<br><0.29 | 10 |
| Puddle scenario | Birds | Long-term | Not needed | Case 2<br>214.9 | 5 |
| Puddle scenario | Mammals | Long-term | Not needed | Case 2<br>261.8 | 5 |

[a] A data gap for BCF in fish is identified. Based on the assumptions using the agreed long-term endpoints for birds (6.7 mg a.s./kg bw/d) and mammals (5.5 mg a.s./kg bw/d) and the 21d TWA FOCUS PECsw value of 0.000279 mg a.s./L (FOCUS Step 3, D3 scenario early application), a low risk can be concluded for fish-eating birds and mammals if the BCF value is ≤ 30208 (birds) and ≤27763 (mammals). Based on expert judgement it is considered likely that low risk can be concluded for fish-eating birds and mammals as these BCF values are expected to be unrealistically high.

**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 [a)] |
|---|---|---|---|---|
| Laboratory tests | | | | |
| Fish | | | | |
| *Oncorhynchus mykiss* | a.s. | Acute 96 hr (semi-static) | Mortality, $LC_{50}$ | 0.081 mg a.s./L (mm) |
| *Oncorhynchus mykiss* | a.s. | Acute 96 hr (flow-through) | Mortality, $LC_{50}$ | > 0.048 mg a.s./L (mm) |
| *Lepomis macrochirus* | a.s. | Acute 96 hr (flow-through) | Mortality, $LC_{50}$ | > 0.042 mg a.s./L (mm) |
| *Cyprinodon variegatus* | a.s. | Acute 96 hr (flow-through) | Mortality, $LC_{50}$ | > 0.027 mg a.s./L (mm) |
| *Cyprinus carpio* | a.s. | Acute 96 hr (flow-through) | Mortality, $LC_{50}$ | > 0.029 mg a.s./L (mm) |
| *Oncorhynchus mykiss* | a.s. | Chronic (flow-through) | Length, NOEC<br>Mortality, $LC_{10,LL}$ | 0.0019 mg a.s./L (mm)<br>0.0013 mg a.s./L (mm)[a] |
| *Oncorhynchus mykiss* | EF-1533 (prep) | Acute 96 hr (flow-through) | Mortality, $LC_{50}$ | 0.541 mg a.s./L (mm)[b] |
| *Oncorhynchus mykiss* | 358R | Acute 96 hr (static) | Mortality, $LC_{50}$ | 1.0 mg /L (mm) |
| Aquatic invertebrates | | | | |
| *Daphnia magna* | a.s. | Acute 48 h (flow-through) | Immobility, $EC_{50}$ | > 0.034 mg a.s./L (mm) |
| *Mysidopsis bahia* | a.s. | Acute 96 h (flow-through) | Mortality, $EC_{50}$ | 0.043 mg a.s./L (mm) |
| *Daphnia magna* | a.s. | Chronic 21 d (static, or semi-static or flow-through) | Reproduction, survival and growth, NOEC | 0.046 mg a.s./L (mm) |
| *Daphnia magna* | EF-1533 (prep) | Acute 48 h (flow-through) | Immobility, $EC_{50}$ | > 0.064 mg a.s./L (mm)[b] |
| *Daphnia magna* | 358R | Acute 48 h (static) | Immobility, $EC_{50}$ | 3.52 mg mg /L (mm) |
| Sediment-dwelling organisms | | | | |
| *Hyalella azteca* | a.s. | Chronic 42 d (semi-static) | NOEC | 83 mg a.s./kg dry sediment (mm) |
| *Leptocheirus plumulosus* | a.s. | 10 d (semi-static) | NOEC | > 52 mg a.s./kg dry sediment (mm) |
| Algae[c] | | | | |
| *Pseudokirchneriella subcapitata* | a.s. | 96 h (static) | Growth rate: $E_rC_{50}$<br>Yield: $E_yC_{50}$ | > 0.0132 mg a.s./L (mm)<br>> 0.0132 mg a.s./L (mm) |
| *Pseudokirchneriella subcapitata* | 358R | 72 h (static) | Growth rate: $E_rC_{50}$<br>Yield: $E_yC_{50}$ | > 5.56 mg/L (mm)<br>4.09 mg/L (mm) |
| Higher plant[d] | | | | |
| *Lemna gibba* | a.s. | 7 d (semi-static) | Frond density/dry weight, $E_rC_{50}$<br>Frond density, $E_yC_{50}$ | > 0.032 mg a.s./L (mm)<br>0.017 mg a.s./L (mm) |
| *Lemna gibba* | EF-1533 (prep) | 7 d (semi-static) | Fronds number, $E_rC_{50}$<br>Fronds number, $E_yC_{50}$ | 0.0604 mg a.s./L (m.m)<br>0.0193 mg a.s./L (mm) |

| Group | Test substance | Time-scale (Test type) | End point | Toxicity [a)] |
|---|---|---|---|---|
| Further testing on aquatic organisms:<br>A modified 49-day Early Life Stage (ELS) study with rainbow trout (*Oncorhynchus mykiss)* was submitted to refine the chronic risk for fish, as the old ELS endpoint based on length was decisive for the risk to aquatic organisms. The suggested endpoint of 0.012 mg a.s./L, based on survival, has not been considered acceptable for the risk assessment by the RMS. This was also confirmed in the Pesticides Peer review Meeting 183 (see Vol 3.B.9 on the active substance, CA 8.2.2.1/02). Consequently, the LC10,LL of 0.0013 mg a.s./L from the original ELS study is chosen as the relevant chronic endpoint for the risk assessment. The NOEC of 0.0019 mg a.s./L is not used in the risk assessment. However, it is a valid endpoint and therefore it is used for assessing the T criterion for the PBT assessment which is based on NOEC values. | | | | |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3)<br><br>Level 3 studies on amphibians and fish were available. In addition, the available chronic study on fish (according to OECD 210) and the reproductive toxicity studies with birds were also considered in the overall weight of evidence. Based on the available data and assessment, benfluralin is not considered an endocrine disruptor for non-target organisms according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. | | | | |

[1](nom) nominal concentration; (mm) mean measured concentration; (im) initial measured; prep.: preparation; a.s.: active substance

[a] Validation of the analytical methodology has not been submitted by the applicant. During Pesticides Peer Review meeting 183 the studies were still considered suitable for risk assessment.

[b] Validation of the analytical methodology has not been submitted by the applicant. This should be evaluated during product authorisation.

[c] A data gap has been identified for a second algae species to be tested with the active substance.

[d] A data gap has been identified for a second macrophyte species be tested with the active substance. During Pesticides Peer Review 183, a recommendation was made for this second species to be a rooted monocot species.

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

| | Active substance |
|---|---|
| log $P_{O/W}$ | 5.27 |
| Steady-state bioconcentration factor (BCF)<br>(total wet weight/normalised to 5% lipid content) | - |
| Uptake/depuration kinetics BCF<br>(total wet weight/normalised to 5% lipid content) | - |
| Annex VI Trigger for the bioconcentration factor | 100 |
| Clearance time (days) ($CT_{50}$) | - |
| ($CT_{90}$) | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | - |
| Remark:<br>No valid BCF study is available. A data gap has been identified. During the Pesticides Peer Review meeting 183 it was recommended that considering the characteristics of benfluralin and the recommendations included in the OECD 305, in addressing this data gap, information should consider exposure via food as well. | |

**FOCUSsw step 1-3 - TERs for benfluralin – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged |
|---|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* | *Hyalella azteca* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $EC_{50}$ | $EC_{50}$ | NOEC |
| | | 81 µg/L | 1.3 µg/L** | 43 µg/L | 46 µg/L | 13.2 µg/L | 32 µg/L | 83000 µg/kg*** |
| **FOCUS Step 1** | 44.59 | **1.8** | **0.03** | **0.96** | **1.03** | **0.30** | **0.72** | 24.70* |
| **FOCUS Step 2** | | | | | | | | |
| North Europe | 13.24 | **6.1** | **0.10** | **3.25** | **3.47** | **1.00** | **2.42** | - |
| South Europe | 13.24 | **6.1** | **0.10** | **3.25** | **3.47** | **1.00** | **2.42** | - |
| **FOCUS Step 3*** | | | | | | | | |
| D3 / ditch (1st) | 9.069 | **8.9** | **0.14** | **4.74** | **5.07** | **1.46** | **3.53** | - |
| D3 / ditch (2nd) | 9.087 | **8.9** | **0.14** | **4.73** | **5.06** | **1.45** | **3.52** | - |
| D4 / pond | 0.314 | 258 | **4.14** | 136.94 | 146.50 | 42.04 | 101.91 | - |
| D4 / stream | 7.122 | **11.4** | **0.18** | **6.04** | **6.46** | **1.85** | **4.49** | - |
| D6 / ditch | 9.159 | **8.8** | **0.14** | **4.69** | **5.02** | **1.44** | **3.49** | - |
| R1 / pond (1st) | 0.314 | 258 | **4.14** | 136.94 | 146.50 | 42.04 | 101.91 | - |
| R1 / pond (2nd) | 0.314 | 258 | **4.14** | 136.94 | 146.50 | 42.04 | 101.91 | - |
| R1 / stream (1st) | 5.988 | **13.5** | **0.22** | **7.18** | **7.68** | **2.20** | **5.34** | - |
| R1 / stream (2nd) | 5.937 | **13.6** | **0.22** | **7.24** | **7.75** | **2.22** | **5.39** | - |
| R2 / stream (1st) | 7.852 | **10.3** | **0.17** | **5.48** | **5.86** | **1.68** | **4.08** | - |
| R2 / stream (2nd) | 8.052 | **10.1** | **0.16** | **5.34** | **5.71** | **1.64** | **3.97** | - |
| R3 / stream (1st) | 8.467 | **9.6** | **0.15** | **5.08** | **5.43** | **1.56** | **3.78** | - |
| R3 / stream (2nd) | 8.441 | **9.6** | **0.15** | **5.09** | **5.45** | **1.56** | **3.79** | - |
| R4 / stream (1st) | 5.896 | **13.7** | **0.22** | **7.29** | **7.80** | **2.24** | **5.43** | - |
| R4 / stream (2nd) | 5.952 | **13.6** | **0.22** | **7.22** | **7.73** | **2.22** | **5.38** | - |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

*Risk to sediment living organisms acceptable at Step 1 ($PEC_{sed}$ = 3360 µg/kg)

**** The RAC for aquatic organisms in the water phase is 0.13 µg/L**

***** The RAC for sediment dwelling organisms is 8300 µg/kg**

**FOCUS$_{sw}$ step 1-3 - TERs for benfluralin – chicory (root vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged |
|---|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* | *Hyalella azteca* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $EC_{50}$ | $EC_{50}$ | NOEC |
| | | 81 µg/L | 1.3 µg/L** | 43µg/L | 46 µg/L | 13.2 µg/L | 32 µg/L | 83000 µg/kg*** |
| **FOCUS Step 1** | 44.59 | **1.8** | **0.03** | **0.96** | **1.03** | **0.30** | **0.72** | 24.70* |
| | | | | | | | | |
| **FOCUS Step 2** | | | | | | | | |
| North Europe | 13.24 | **6.1** | **0.10** | **3.25** | **3.47** | **1.00** | **2.42** | - |
| South Europe | 13.24 | **6.1** | **0.10** | **3.25** | **3.47** | **1.00** | **2.42** | - |
| **FOCUS Step 3*** | | | | | | | | |
| D3 / ditch (1st) | 9.069 | **8.93** | **0.14** | **4.74** | **5.07** | **1.46** | **3.53** | - |
| D6 / ditch | 6.231 | **13.00** | **0.21** | **6.90** | **7.38** | **2.12** | **5.14** | - |
| R1 / pond | 0.314 | 257.96 | **4.14** | 136.94 | 146.50 | 42.04 | 101.91 | - |
| R1 / stream | 5.987 | **13.53** | **0.22** | **7.18** | **7.68** | **2.20** | **5.34** | - |
| R2 / stream (1st) | 7.851 | **10.32** | **0.17** | **5.48** | **5.86** | **1.68** | **4.08** | - |
| R2 / stream (2nd) | 5.593 | **14.48** | **0.23** | **7.69** | **8.22** | **2.36** | **5.72** | - |
| R3 / stream | 8.467 | **9.57** | **0.15** | **5.08** | **5.43** | **1.56** | **3.78** | - |
| R4 / stream | 6.007 | **13.48** | **0.22** | **7.16** | **7.66** | **2.20** | **5.33** | - |
| **Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 |

*Risk to sediment living organisms acceptable at Step 1 ($PEC_{sed}$ = 3360 µg/kg)

**** The RAC for aquatic organisms in the water phase is 0.13 µg/L**

***** The RAC for sediment dwelling organisms is 8300 µg/kg**

**FOCUSsw step 4 - TERs for benfluralin – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha with risk mitigation measures including a 10 m no-spray buffer zone, 10 m VGF and 90% drift reduction**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant |
|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $ErC_{50}$ | $EC_{50}$ |
| | | 81 | 1.3** | 43 | 46 | 13.2 | 32 |
| **FOCUS Step 4*** | | | | | | | |
| D4 / pond | 0.042 | 1928.57 | 30.95 | 1023.81 | 1095.24 | 314.29 | 761.90 |
| R1 / pond (1st) | 0.043 | 1883.72 | 30.23 | 1000.00 | 1069.77 | 306.98 | 744.19 |
| R1 / pond (2nd) | 0.044 | 1840.91 | 29.55 | 977.27 | 1045.45 | 300.00 | 727.27 |
| R4 / stream (1st) | 0.374 | 216.58 | **3.48** | 114.97 | 122.99 | 35.29 | 85.56 |
| R4 / stream (2nd) | 0.364 | 222.53 | **3.57** | 118.13 | 126.37 | 36.26 | 87.91 |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 |

*** Only FOCUS Step 4 scenarios with <95% drift reduction has been included**
**** The RAC for aquatic organisms in the water phase is 0.13 µg/L**

**FOCUSsw step 4 - TERs for benfluralin – chicory (root vegetables) at 1 x 1440 g a.s./ha with risk mitigation measures including a 10 m no-spray buffer zone, 10 m VGF and 90% drift reduction**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant |
|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $ErC_{50}$ | $EC_{50}$ |
| | | 81 | 1.3** | 43 | 46 | 13.2 | 32 |
| **FOCUS Step 4*** | | | | | | | |
| R1 / pond | 0.043 | 1883.72 | 30.23 | 1000.00 | 1069.77 | 306.98 | 744.19 |
| R4 / stream | 0.379 | 213.72 | **3.43** | 113.46 | 121.37 | 34.83 | 84.43 |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 |

*** Only FOCUS Step 4 scenarios with <95% drift reduction has been included**
**** The RAC for aquatic organisms in the water phase is 0.13 µg/L**

**FOCUSsw step 1-3 - TERs for propyl-benzimidazole (371R) – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant |
|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $ErC_{50}$ | $EC_{50}$ |
| | | 8.1* | 0.13* | 4.3* | 4.6* | 1.32* | 3.2* |
| **FOCUS Step 1** | 5.596 | **1.45** | **0.02** | **0.77** | **0.82** | **0.24** | **0.57** |
| **FOCUS Step 2** | | | | | | | |
| North Europe | 1.662 | **4.87** | **0.08** | **2.59** | **2.77** | **0.79** | **1.93** |
| South Europe | 1.662 | **4.87** | **0.08** | **2.59** | **2.77** | **0.79** | **1.93** |
| **FOCUS Step 3** | | | | | | | |
| D6 / ditch | 1.149 | **7.05** | **0.11** | **3.74** | **4.00** | **1.15** | **2.78** |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 |

*As no toxicity data are available for the metabolite the endpoint is 10x lower than the corresponding active substance endpoint

**FOCUSsw step 1-3 - TERs for methyl-benzimidazole (372R) – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant |
|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Mysidopsis bahia* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $ErC_{50}$ | $EC_{50}$ |
| | | 8.1* | 0.13* | 4.3* | 4.6* | 1.32* | 3.2* |
| **FOCUS Step 1** | 6.457 | **1.25** | **0.02** | **0.67** | **0.71** | **0.20** | **0.50** |
| **FOCUS Step 2** | | | | | | | |
| North Europe | 1.917 | **4.22** | **0.07** | **2.24** | **2.40** | **0.69** | **1.67** |
| South Europe | 1.917 | **4.22** | **0.07** | **2.24** | **2.40** | **0.69** | **1.67** |
| **FOCUS Step 3** | | | | | | | |
| D6 / ditch | 1.326 | **6.11** | **0.10** | **3.24** | **3.47** | **1.00** | **2.41** |
| Trigger | | 100 | 10 | 100 | 10 | 10 | 10 |

*As no toxicity data are available for the metabolite the endpoint is 10x lower than the corresponding active substance endpoint

**FOCUSsw step 1-3 - TERs for desalkyl benfluralin diamine (358R) – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant |
|---|---|---|---|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| | | $LC_{50}$ | $LC_{10,LL}$ | $LC_{50}$ | NOEC | $ErC_{50}$ | $EC_{50}$ |
| | | 1000 | 0.13* | 3520 | 4.6* | 5560 | 3.2* |
| **FOCUS Step 1** | 4.148 | 241.10 | **0.03** | 848.67 | **1.11** | 1340.51 | **0.77** |
| **FOCUS Step 2** | | | | | | | |
| North Europe | 1.232 | 811.98 | **0.11** | 2858.17 | **3.74** | 4514.61 | **2.60** |
| South Europe | 1.232 | 811.98 | **0.11** | 2858.17 | **3.74** | 4514.61 | **2.60** |
| **FOCUS Step 3** | | | | | | | |
| D6 / ditch | 0.852 | 1173.78 | **0.15**** | 4131.69 | **5.40**** | 6526.20 | **3.76**** |
| Trigger | | 100 | 10.00 | 100 | 10 | 10 | 10 |

*As no toxicity data are available for the metabolite the endpoint is 10x lower than the corresponding active substance endpoint
**The chronic risk from metabolite 358R is considered to be covered by the risk assessment for benfluralin, considering PEC/RAC ratios for the metabolite and for benfluralin (for details see Vol3, CP B9.4.2, p. 95-104).

**FOCUSsw step 1-3 - TERs for ethyl-propyl-benzimidazole (379R) – lettuce/chicory (leafy vegetables) at 1 x 1440 g a.s./ha**

| Scenario | PEC global max (µg L) | Fish acute* | Aquatic invertebrates* |
|---|---|---|---|
| | | *Oncorhynchus mykiss* | *Mysidopsis bahia* |
| | | $LC_{50}$ | $LC_{50}$ |
| | | 8.1** | 4.3** |
| **FOCUS Step 1** | 6.050 | **1.34** | **0.71** |
| **FOCUS Step 2** | | | |
| North Europe | 1.796 | **4.51** | **2.39** |
| South Europe | 1.796 | **4.51** | **2.39** |
| **FOCUS Step 3** | | | |
| D6 / ditch | 1.243 | **6.52** | **3.46** |
| Trigger | | 100 | 100 |

* Only the acute risk assessment is included, due to the fast dissipation of the metabolite in water
**As no toxicity data are available for the metabolite the endpoint is 10x lower than the corresponding active substance endpoint

The risk from metabolite 379R is considered to be covered by the chronic risk assessment for benfluralin (for details see Vol3, CP B9.4.2, p. 95-104).

No acceptable calculations are available for the $PEC_{sed}$ of the metabolite B36 (see Section 4). However, based on expert judgement it is likely that low risk can be considered for this metabolite, when assuming that the metabolite is 10 times more toxic than the active substance (RAC = 830 µg a.s./kg sediment for B36) and comparing this RAC with the FOCUS Step 3 $PEC_{sed}$ for the active substance.

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

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

| Species | Test substance | Time scale/type of endpoint | End point | toxicity |
|---|---|---|---|---|
| *Apis mellifera* Adults | Benfluralin | Acute | Oral toxicity ($LD_{50}$) | >110.7 µg a.s./bee |
| *Apis mellifera* Adults | EF-1533 | Acute | Oral toxicity ($LD_{50}$) | >31.25 µg a.s./bee |
| *Apis mellifera* Adults | Benfluralin | Acute | Contact toxicity ($LD_{50}$) | >100 µg a.s./bee |
| *Apis mellifera* Adults | EF-1533 | Acute | Contact toxicity ($LD_{50}$) | >100 µg a.s./bee |

| |
|---|
| Potential for accumulative toxicity: No data available |
| Semi-field test (Cage and tunnel test)<br>No data available – not required |
| Field tests<br>No data available – not required |

**Risk assessment for lettuce and chicory at 1 x 1440 g a.s./ha**

| Species | Test substance | Risk quotient | HQ/ETR | Trigger |
|---|---|---|---|---|
| *Apis mellifera* | Benfluralin,<br>EF-1533 | HQcontact | <14.4<br><14.4 | 42<br>(downward spray) |
| *Apis mellifera* | Benfluralin,<br>EF-1533 | ETRacute adult oral | <0.03 (foraging on crop)<br><0.02 (foraging on weeds)<br><0.002 (foraging in field margin)<br><0.001 (foraging on adjacent crop)<br><0.03 (foraging on following permanent crop or succeeding crop) | 0.2 |
| *Apis mellifera* | Benfluralin,<br>EF-1533 | HQcontact | <14* | 50 |
| *Apis mellifera* | Benfluralin,<br>EF-1533 | HQoral | <44* | 50 |

*HQ values calculated according to SANCO/10329/2002-rev. 2 final, 17 October 2002 (European Commission, 2002a)

**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* | EF-1533 | Mortality, $LR_{50}$<br>Reproduction, $ER_{50}$ | $LR_{50}$ > 1673 g a.s./ha<br>-61% at 1673 g a.s./ha |
| *Aphidius rhopalosiphi* | EF-1533 | Mortality, LR50<br>Reproduction, ER50 | $LR_{50}$ < 83.6 g a.s./ha |
| Additional species | | | |
| *Poecilus cupreus* (adults) | EF-1533 | Mortality<br>Feeding rate | $LR_{50}$ >1673 g a.s./ha<br>17.6% at 1673 g a.s./ha |
| *Chrysoperla carnea* (larvae) | EF-1533 | Mortality<br>Reproduction | $LR_{50}$ >1673 g a.s./ha<br>-15.7% at 83.6 g a.s./ha |

**First tier risk assessment for lettuce and chicory at 1 x 1440 g a.s./ha**

| Test substance | Species | Effect (LR50 g/ha) | HQ in-field | HQ off-field [a)] | Trigger |
|---|---|---|---|---|---|
| EF-1533 | *Typhlodromus pyri* | >1673 | <0.86 | <0.02 (1 m) | 2 |

a) indicate distance assumed to calculate the drift rate

**Extended laboratory tests, aged residue tests**

| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha) [a)b)] | End point | % effect [c)] | $ER_{50}$ |
|---|---|---|---|---|---|---|---|
| *Typhlodromus pyri* | protonymphs | Bean leaves | 14 d | 165, 824, 1647, 2654 and 3294 g a.s./ha, initial | Corrected mortality<br>Reproduction | 10.5% at 3294 g a.s./ha<br>-47.5% at 3294 g a.s./ha | $LR_{50}$ >3294 g a.s./ha |
| *Aphidius rhopalosiphi* | adults | Barley seedlings | 24 h + 10 d | 366, 518, 732, 1035 and 1464 g a.s./ha, initial | Corrected mortality<br>Reproduction | 3.3% at 366 g a.s./ha<br>-34% at 518 g a.s./ha | $LR_{50}$: 473 g a.s./ha |
| *Aleochara bilineata* | adults | Natural sandy soil | 28 d + 35 d | 1647 g a.s./ha, initial | Corrected mortality<br>Reproduction | - 3.99 %<br>-5.4% | - |
| | | | | | | | |

a) indicate whether initial or aged residues
b) for preparations indicate whether dose is expressed in units of a.s. or preparation
c) indicate if positive percentages relate to adverse effects or not

**Risk assessment for lettuce and chicory at 1 x 1440 g a.s./ha based on extended lab test or aged residue tests**

| Species | $ER_{50}$ (g/ha) | In-field rate | Off-field rate [a)] |
|---|---|---|---|
| *Typhlodromus pyri* | >3294 | 1440 g a.s./ha | 19.9 g a.s./ha (1 m – 2D) |
| *Aphidius rhopalosiphi* | 473 | 1440 g a.s./ha | 199 g a.s./ha (1 m – 3D) |

a) indicate distance assumed to calculate the drift rate and if 3D or 2D.

| Semi-field tests |
|---|
| Not required. Laboratory and extended laboratory tests are available and no higher tier testing is required. |
| Field studies |
| Not required. Laboratory and extended laboratory tests are available and no higher tier testing is required. |
| Additional specific test |
| Not required. Laboratory and extended laboratory tests are available and no higher tier testing is 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 [a)] | Time scale | End point | Toxicity |
|---|---|---|---|---|---|
| Earthworms | | | | | |
| *Eisenia foetida* | EF-1533 | Mechanically blended / 10% OM | Chronic 56 d | Reproduction | $NOEC_{corr}$ 15.4 mg a.s./kg d.w.soil |
| Other soil macroorganisms | | | | | |

| Test organism | Test substance | Application method of test a.s./ OM a) | Time scale | End point | Toxicity |
|---|---|---|---|---|---|
| *Folsomia candida* | EF-1533 | Mechanically blended / 10% OM | Chronic 28 d | Mortality:<br><br>Reproduction: | $LC_{50}$ = 154 mg a.s./kg d.w. soil<br>$LC_{50, CORR}$ = 77 mg a.s./kg d.w. soil<br>NOEC = 87.9 mg a.s./kg d.w. soil<br>$NOEC_{CORR}$ = 43.95 mg a.s./kg d.w. soil<br><br>$EC_{10}$ = 38.3 mg a.s./kg d.w. soil<br>$EC_{10, CORR}$ = 19.15 mg a.s./kg d.w. soil<br>$EC_{50}$ = 94 mg a.s./kg d.w. soil<br>$EC_{20, CORR}$ = 47 mg a.s./kg d.w. soil<br>NOEC = 11 mg a.s./kg d.w. soil<br>$NOEC_{CORR}$ = **5.5** mg a.s./kg d.w. soil |
| *Hypoaspis aculeifer* | EF-1533 | incorporated / 5% OM | Chronic 14 d | Mortality<br><br>Reproduction: | $LC_{50}$ = >1000 mg test item/kg soil dw<br>$LC_{20}$ = >1000 mg test item/kg soil dw<br>$LC_{10}$ = >1000 mg test item/kg soil dw<br>NOEC = 1000 mg test item/kg soil dw<br><br>$EC_{50}$ = >1000 mg test item/kg soil dw<br>NOEC = 100 mg test item/kg soil dw<br>NOEC = 19.1 mg a.s./kg soil d.w.<br>**$NOEC_{CORR}$ = 9.55 mg a.s./kg soil d.w.** |

a) To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

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

| | | | |
|---|---|---|---|
| Nitrogen transformation | EF-1533 | Maximum tested rate of 45 L EF-1533/ha | 4.7 % effect at day 28 at 45 L EF-1533/ha (11 mg a.s./kg d.w.soil) |

**Toxicity/exposure ratios for soil organisms**
**Risk assessment for lettuce and chicory at 1 x 1440 g a.s./ha**

| Test organism | Test substance | Time scale | Soil PEC a) | TER | Trigger |
|---|---|---|---|---|---|
| Earthworms | | | | | |
| *Eisenia foetida* | EF-1533 | Chronic | 1.009 | 15.3 | 5 |
| Other soil macroorganisms | | | | | |
| *Folsomia candida* | EF-1533 | Chronic | 1.009 | 5.45 | 5 |
| *Hypoaspis aculeifer* | EF-1533 | Chronic | 1.009 | 9.46 | 5 |

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

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

Screening data

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

Laboratory dose response tests

| Species | Test substance | $ER_{50}$ (g a.s./ha) a) vegetative vigour | $ER_{50}$ (g a.s./ha) a) emergence | Exposure b) (g a.s./ha) a) | TER | Trigger |
|---|---|---|---|---|---|---|
| *Lolium perenne* | EF-1533 | 1263.51 | | 39.9 (1 m) | 31.7 | 5 |
| *Lolium perenne* | EF-1533 | | 48 | 8.21 (5 m) | 5.8 | 5 |
| Extended laboratory studies : Not required<br>Semi-field and field test: Not required | | | | | | |

a) for preparations indicate whether dose is expressed in units of a.s. or preparation
b) explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

**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[a] | - |
| *Pseudomonas sp* | - |

[a] No valid study available. However, at the Pesticides Peer Review Meeting 183, most experts agreed that a high risk is very unlikely, as no effects above 50% were seen in the invalid study at 1000 mg a.s./L dose level and that the exposure is very likely to be negligible for the representative uses of benfluralin (all field uses).

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

| Available monitoring data concerning adverse effect of the a.s.<br>None<br>Available monitoring data concerning effect of the PPP.<br>None |
|---|

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

| Compartment | |
|---|---|
| soil | Benfluralin |
| surface water | Benfluralin, propyl-benzimidazole (371R)[1], methyl-benzimidazole (372R)[1] |

| | |
|---|---|
| sediment | Benfluralin, |
| groundwater | Benfluralin |

1) Toxicity is not addressed in the ecotoxicological risk assessment, thus considered 10x more toxic than benfluralin. Analytical methods for monitoring are not submitted. 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 | Benfluralin |
|---|---|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][6]: | No current harmonised classification. |
| Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008: | Acute 1, H400; M=10<br>Chronic 1, H410; M=10 |

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

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