

Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



CLOPYRALID
List of Endpoints

RMS: Finland
Co-RMS: Poland

May 2017

Volume 1

Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application

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Volume 3

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Version History

| When | What |
|----------|---------------------------------------|
| 2017/May | DRAR- First version submitted to EFSA |
| | |
| | |

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| Rapporteur Member State | Month and year | Active Substance |
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| Finland | May 2017 | Clopyralid |

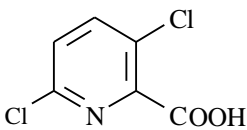
Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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) | Clopyralid |
| Function (<i>e.g.</i> fungicide) | Herbicide |
| Rapporteur Member State | Finland |
| Co-rapporteur Member State | Poland |

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

| | |
|---|--|
| Chemical name (IUPAC) | 3,6-dichloropyridine-2-carboxylic acid |
| Chemical name (CA) | 3,6-dichloro-2-pyridinecarboxylic acid |
| CIPAC No | 455 |
| CAS No | 1702-17-6 |
| EC No (EINECS or ELINCS) | 216-935-4 |
| FAO Specification (including year of publication) | Not Applicable |
| Minimum purity of the active substance as manufactured | 950 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Not applicable |
| Molecular formula | C ₆ H ₃ Cl ₂ NO ₂ |
| Molar mass | 191.96 g/mol |
| Structural formula |  |

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

| Melting point (state purity) | 149.6 ± 0.2 °C (99.8%) | | | | | | | | | | | | | | | | |
|---|--|---------|--|------------|--------------------------|--------------------|--------------------------|---------|--------------------------|---------------|--------------------------|---------|--------------------|----------|--------------|----------|---------------|
| Boiling point (state purity) | Decomposes at 164 ± 2 °C (99.8%) A thermal effect due to boiling was not observed. | | | | | | | | | | | | | | | | |
| Temperature of decomposition (state purity) | Decomposes at 164 ± 2 °C (99.8%) | | | | | | | | | | | | | | | | |
| Appearance (state purity) | (95.3%): Color - Cream Physical State - Powdery Solid (99.8%): Color - white Physical State - Crystalline Solid | | | | | | | | | | | | | | | | |
| Vapour pressure (state temperature, state purity) | 1.36x10 ⁻⁶ kPa at 25°C (99.6%) | | | | | | | | | | | | | | | | |
| Henry's law constant | <table border="1"> <thead> <tr> <th>pH</th><th>Henry's Law Constant (Pa m³/mol) at 20°C</th></tr> </thead> <tbody> <tr> <td>Unbuffered</td><td>3.28 x 10⁻¹⁰</td></tr> <tr> <td>5</td><td>2.18 x 10⁻¹¹</td></tr> <tr> <td>7</td><td>1.80 x 10⁻¹¹</td></tr> <tr> <td>9</td><td>1.64 x 10⁻¹¹</td></tr> </tbody> </table> | pH | Henry's Law Constant (Pa m ³ /mol) at 20°C | Unbuffered | 3.28 x 10 ⁻¹⁰ | 5 | 2.18 x 10 ⁻¹¹ | 7 | 1.80 x 10 ⁻¹¹ | 9 | 1.64 x 10 ⁻¹¹ | | | | | | |
| pH | Henry's Law Constant (Pa m ³ /mol) at 20°C | | | | | | | | | | | | | | | | |
| Unbuffered | 3.28 x 10 ⁻¹⁰ | | | | | | | | | | | | | | | | |
| 5 | 2.18 x 10 ⁻¹¹ | | | | | | | | | | | | | | | | |
| 7 | 1.80 x 10 ⁻¹¹ | | | | | | | | | | | | | | | | |
| 9 | 1.64 x 10 ⁻¹¹ | | | | | | | | | | | | | | | | |
| Solubility in water (state temperature, state purity and pH) | (20°C, 99.2%): Unbuffered water (pH 1.7): 0.785 g/100 mL pH 5.0: 11.8 g/100 mL pH 7.0: 14.3 g/100 mL pH 9.0: 15.7 g/100 mL | | | | | | | | | | | | | | | | |
| Solubility in organic solvents (state temperature, state purity) | (95.9%): <table border="1"> <thead> <tr> <th>Solvent</th><th>Solubility at 20°C</th></tr> </thead> <tbody> <tr> <td>Xylene</td><td>4.61 g/L</td></tr> <tr> <td>1,2-dichloroethane</td><td>20.7 g/L</td></tr> <tr> <td>Acetone</td><td>>250 g/L</td></tr> <tr> <td>Ethyl acetate</td><td>102 g/L</td></tr> </tbody> </table> (96.4%): <table border="1"> <thead> <tr> <th>Solvent</th><th>Solubility at 20°C</th></tr> </thead> <tbody> <tr> <td>n-hexane</td><td>0.6% (wt/wt)</td></tr> <tr> <td>Methanol</td><td>10.4% (wt/wt)</td></tr> </tbody> </table> | Solvent | Solubility at 20°C | Xylene | 4.61 g/L | 1,2-dichloroethane | 20.7 g/L | Acetone | >250 g/L | Ethyl acetate | 102 g/L | Solvent | Solubility at 20°C | n-hexane | 0.6% (wt/wt) | Methanol | 10.4% (wt/wt) |
| Solvent | Solubility at 20°C | | | | | | | | | | | | | | | | |
| Xylene | 4.61 g/L | | | | | | | | | | | | | | | | |
| 1,2-dichloroethane | 20.7 g/L | | | | | | | | | | | | | | | | |
| Acetone | >250 g/L | | | | | | | | | | | | | | | | |
| Ethyl acetate | 102 g/L | | | | | | | | | | | | | | | | |
| Solvent | Solubility at 20°C | | | | | | | | | | | | | | | | |
| n-hexane | 0.6% (wt/wt) | | | | | | | | | | | | | | | | |
| Methanol | 10.4% (wt/wt) | | | | | | | | | | | | | | | | |
| Surface tension (state concentration and temperature, state purity) | 71.5 mN/m at 20°C (1 g/L aqueous solution) (99.9%) | | | | | | | | | | | | | | | | |

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Partition coefficient
(state temperature, pH and purity)

(20°C, 99.2%):
pH 5 buffer: log P_{OW} = -1.81
pH 7 buffer: log P_{OW} = -2.63
pH 9 buffer: log P_{OW} = -2.55

Dissociation constant (state purity)

pK_a = 2.01 +/- 0.11 at 25°C (99.6%)

UV/VIS absorption (max.) incl. ε
(state purity, pH)

(99.9%):

| pH | Concentration (μg/mL) | ε (L mol ⁻¹ cm ⁻¹) | λ (nm) |
|-----|--------------------------|--|-----------|
| <2 | 19.4 | 19468 | 201 |
| | | 8771 | 226 |
| | | 3609 | 282 |
| | | 2777 | 290 |
| <2 | 58.3 | 11247 | 206 |
| | | 8263 | 223 |
| | | 3614 | 282 |
| | | 2820 | 290 |
| 7 | 19.4 | 16355 | 198 |
| | | 8951 | 221 |
| | | 4640 | 280 |
| | | 2832 | 290 |
| 7 | 58.3 | 9581 | 202 |
| | | 8533 | 220 |
| | | 4592 | 280 |
| | | 2875 | 290 |
| >10 | 19.4 | 15262 | 199 |
| | | 9395 | 221 |
| | | 4904 | 280 |
| | | 3072 | 290 |
| >10 | 58.3 | 9695 | 203 |
| | | 8884 | 219 |
| | | 4788 | 280 |
| | | 3019 | 290 |

Flammability (state purity)

Not flammable (95.9%)

Explosive properties (state purity)

No sign of ignition or explosion (95.4%)

Oxidising properties (state purity)

Non-oxidising (95.9%)

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Details of Uses:

Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)

(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./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| Winter cereal (wheat, barley oat, rye, triticale, spelt) | CZ/SZ | GF-1374 | F | Broad-leaf weeds | EC | 80 g/L Clopyralid + 2.5 g/L florasulam + 144 g/L fluroxypyr-methyl (equivalent to 100 g ae/ha fluroxypyr) | Over all broad cast foliar spray | BBCH 13-39 (1 st Feb to 30 th of June) | 1 | n/a | Clopyralid: 0.02 to 0.1 kg as/hL + Florasulam 0.0000625 to 0.0003125 kg as/hL + Fluroxypyr-methyl: 0.036 to 0.18 kg as/hL (0.025 to 0.125 kg ae/hL) | 80-400 | Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-methyl 0.144 kg as/ha (0.100 kg ae/ha) | n/a | Dose: 1L GF-1374/ha Due to clopyralid content, straw treated with GF-1374 must not be used for compost production (for cultivating susceptible vegetables). |
| Established permanent pasture | CZ/SZ | GF-1374 | F | Broadleaf weeds | EC | 80 g/L Clopyralid + 2.5 g/L florasulam + 144 g/L fluroxypyr-methyl | Over all broad cast foliar spray | 1 st Feb to 30 th September | 1 | n/a | Clopyralid: 0.03 to 0.15 kg as/hL + Florasulam 0.00009375 to 0.00046875 | 100-400 | Clopyralid 0.12 kg as/ha + Florasulam 0.00375 kg as/ha + Fluroxypyr | 7 to 14 days (see note 1) | Dose: 1.5L GF-1374/ha. Note 1: PHI: 7 days for CZ and 14 days for SZ is the interval before any crop cutting or |

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| 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 applicati on (min) | kg a.s /hL min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| | | | | | | (equivalent to 100 g ae/ha fluroxypyr) | | | | | kg as/hL + Fluroxypyr meptyl: 0.054 to 0.27 kg as/hL (0.0375 to 0.1875 kg ae/hL) | | r-meptyl 0.216 kg as/ha (0.15kg ae/ha) | | grazing. Fluroxypyr is the limiting factor. Clopyralid residues in plant tissue (including manure) which has not completely decayed may affect succeeding susceptible crops. Do not use any plant material treated with GF-1374 for composting. Do not use manure from animals fed on crops treated with GF-1374 for composting or mulching. |

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

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Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)
Regulation (EC) 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 e (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 | kg a.s./ha min-max (l) | | |
| MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |

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

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. 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

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Further information, Efficacy

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

All types of winter cereals and Established permanent pasture can be treated in the spring to control important dicotyledonous species including the range listed in the table below. The GAP of the representative formulation is fully supported.

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

When used according to the dose rates and application timings detailed in the directions for use and the GAP no adverse effects on treated crops are expected.

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

When used according to the dose rates and application timings detailed in the directions for use and the GAP no undesirable or unintended side effects are expected adverse effects on treated crops are expected.

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

Potential leaching of metabolites into groundwater due to the representative GAP have been evaluated. The trigger value of 0.1 µg/L is not exceeded. Therefore no assessment of biological activity is required.

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

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) | Gas Chromatography (GC/FID) |
| Impurities in technical a.s. (analytical technique) | Gas Chromatography (GC/FID) |
| Plant protection product (analytical technique) | Liquid Chromatography (LC) |

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 | Clopyralid, its salts and conjugates, expressed as clopyralid |
| Food of animal origin | Clopyralid, its salts and conjugates, expressed as clopyralid |
| Soil | Clopyralid |
| Sediment | Clopyralid |
| Water surface | Clopyralid |
| drinking/ground | Clopyralid |
| Air | Clopyralid |
| Body fluids and tissues | Clopyralid |

Monitoring/Enforcement methods

| | |
|---|--|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | LC-MS/MS, LOQ = 0.01 mg/kg (dry, wet, acidic and oily crops) |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | LC-MS/MS, LOQ = 0.01 mg/kg (muscle, fat, kidney, milk, liver, and egg) |
| Soil (analytical technique and LOQ) | LC-MS/MS, LOQ = 0.50 µg/kg |
| Water (analytical technique and LOQ) | LC-MS/MS, LOQ = 0.05 µg/L |
| Air (analytical technique and LOQ) | LC-MS/MS, LOQ = 4.5 µg/m ³ |
| Body fluids and tissues (analytical technique and LOQ) | body fluids: LC-MS/MS. However, the method is not acceptably validated. body tissues: no method has been given. According to the new data requirements, methods for body fluids and tissues are always required. |

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

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Substance

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

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

| |
|------|
| name |
| |
| |

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. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

Section 2 Mammalian Toxicology

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 | app. 80% (based on urinary excretion within 48 h, single dose administration high and low dose level, repeated dose, intravenous dose) |
| Toxicokinetics | |
| Distribution | Three days after administration tissue levels were negligible (< 0.01% of the administered dose). |
| Potential for bioaccumulation | No evidence for accumulation. |
| Rate and extent of excretion | Rapid and extensive (at minimum app. 77 % within 48 h), mainly via urine (≥71 % within 24 h, app. 1-4 % via faeces) |
| Metabolism in animals | Not metabolised in rats. |
| <i>In vitro</i> metabolism | No unique human metabolites formed, no observed metabolism. |
| Toxicologically relevant compounds (animals and plants) | Parent compound (clopyralid) |
| Toxicologically relevant compounds (environment) | No environmental degradation products or ecotoxicologically relevant metabolites. |

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

| | | |
|---------------------------------|---|-------------|
| Rat LD ₅₀ oral | > 5000 mg/kg bw | |
| Rat LD ₅₀ dermal | > 2000 mg/kg bw | |
| Rat LC ₅₀ inhalation | > 1.0 mg/L/4h (nose only, highest attainable concentration) | |
| Skin irritation | Non-irritant | |
| Eye irritation | Severe irritant | H318 |
| Skin sensitisation | No acceptable study available. | |
| Phototoxicity | Could not be determined from the available data | |

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

| | | |
|--------------------------------|---|--|
| Target organ / critical effect | Rat: stomach (histopathological changes/ acanthosis and folding of non-glandular epithelium of the limiting ridge), liver and | |
|--------------------------------|---|--|

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Section 2 Mammalian Toxicology

| | | |
|---------------------------|---|--|
| | kidney (weight ↑) Mouse: liver (relative weight ↑, microscopical changes) Dog: haematological effects, liver (weight ↑) | |
| Relevant oral NOAEL | 4- week rat: < 150 mg/kg bw/day 3- month rat: < 300 mg/kg bw/day 13-week mouse: 750 mg/kg bw per day 12-month, dog: 100 mg/kg bw per day | |
| Relevant dermal NOAEL | 21-day, rabbit: >1000 mg/kg bw per day | |
| Relevant inhalation NOAEL | No data - not required | |

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

| | | |
|----------------------------|---|--|
| <i>In vitro</i> studies | Ames test: negative <i>In vitro</i> mammalian cell forward mutation: negative <i>In vitro</i> chromosome aberration test: equivocal | |
| <i>In vivo</i> studies | No acceptable studies available. | |
| Photomutagenicity | No data | |
| Potential for genotoxicity | Clastogenic and aneugenic potential of clopyralid not excluded. | |

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

| | | |
|--|---|--|
| Long-term effects (target organ/critical effect) | Rat: Stomach (lesions of the gastric limiting ridge) Mouse: body weight ↓ | |
| Relevant long-term NOAEL | 2-year, rat: 15 mg/kg bw per day 2-year, mouse: 500 mg/kg bw per day | |
| Carcinogenicity (target organ, tumour type) | Rat: no evidence that clopyralid caused increased incidence of malignant or non-malignant tumours Mouse: no evidence that clopyralid caused increased incidence of malignant or non-malignant tumours Clopyralid is unlikely to pose a hazard to humans | |
| Relevant NOAEL for carcinogenicity | 2-year, rat: >1500 mg/kg bw per day 2-year, mouse: > 2000 mg/kg bw per day | |

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

Reproduction toxicity

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| Finland | May 2017 | Clopyralid |

Section 2 Mammalian Toxicology

| | | |
|---------------------------------------|--|--|
| Reproduction target / critical effect | Parental toxicity: body weight ↓, food consumption ↓, stomach lesions Reproductive toxicity: a potential of reproductive toxicity is unlikely Offspring's toxicity: F1 pup weights↓, liver weight↑ | |
| Relevant parental NOAEL | 150 mg/kg bw per day | |
| Relevant reproductive NOAEL | >1500 mg/kg bw per day | |
| Relevant offspring NOAEL | 500 mg/kg bw per day | |

Developmental toxicity

| | | |
|--|---|--|
| Developmental target / critical effect | Rat: Maternal toxicity: liver weight↓, food consumption↓ Developmental toxicity: no treatment related malformations Rabbit: Maternal toxicity: body weight↓, body weight gain↓, gastric lesions, clinical signs, morbidity Developmental toxicity: mean foetal weight↓, slightly increased spontaneous malformations | |
| Relevant maternal NOAEL | Rat: 15 mg/kg bw per day Rabbit: 110 mg/kg bw per day | |
| Relevant developmental NOAEL | Rat: >250 mg/kg bw per day Rabbit: 110 mg/kg bw per day | |

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

| | | |
|--|----------------------|--|
| Acute neurotoxicity | Study not required | |
| Repeated neurotoxicity | Study not required | |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No studies submitted | |

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

| | | |
|---|--|--|
| Supplementary studies on the active substance | A comparison of technical material produced by two different manufacturing processes showed similar toxicity profiles. Assessment of immunotoxic potential of clopyralid, after 28- day dietary exposure to rats: NOAEL 150 mg/kg bw/day (increased thymus weight). | |
| Endocrine disrupting properties | No studies submitted. Clopyralid does not fulfill the interim criteria for endocrine disruptive properties | |

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Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

No studies submitted.

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

No detrimental effects on health in manufacturing personnel.

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

| | Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|--|-------------------------------|---|--------------------|
| Acceptable Daily Intake (ADI) | 0.15 | rat, 2-year chronic toxicity and oncogenicity study | 100 |
| Acute Reference Dose (ARfD) | | | |
| Acceptable Operator Exposure Level (AOEL) | 0.15 | rat, developmental study | 100 |
| Acute Acceptable Operator Exposure Level (AAOEL) | | | |

* Including correction for limited oral absorption/bioavailability (xx %).

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

Representative formulation (GF-1374, EC, 80 g clopyralid/L)

Concentrate: 25 %
Spray dilution: 75 %
Default dermal absorption values according to Guidance on Dermal Absorption, EFSA 2012.

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

Operators

Use: winter cereal and established permanent pasture, tractor mounted sprayer, application rate 0.12 kg clopyralid/ha

| <u>Exposure estimates (model):</u> | <u>% of AOEL</u> |
|--|------------------|
| <u>UK POEM</u> | |
| Without PPE: | 583 |
| PPE (gloves): | 82 |
| <u>German model</u> | |
| Without PPE: | 244 |
| PPE (gloves, coverall, sturdy footwear): | 16 |

³ If available include also reference values for metabolites

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Section 2 Mammalian Toxicology

| | | |
|--------------------------|-----------------------------|------------------|
| Workers | <u>EFSA model</u> | |
| | Without PPE: | 101 |
| | PPE (gloves and work wear): | 3 |
| | Crop inspection | <u>% of AOEL</u> |
| Bystanders and residents | <u>Europoem II</u> | |
| | Without PPE: | 15 |
| | <u>EFSA model</u> | |
| | Without PPE: | 8 |
| | Bystander | <u>% of AOEL</u> |
| | Europoem II: | 2 |
| | Martin et al., adult: | 6 |
| | child: | 7 |
| | Exposure to vapours | |
| | adult: | 0.15 |
| | child: | 0.7 |
| | Resident | |
| | Martin et al., adult: | 0.39 |
| | child: | 0.64 |
| | EFSA model, adult: | 3 |
| | child: | 12 |

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

Substance :

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴ :

Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

| |
|---|
| Clopyralid |
| Eye Dam. 1 - H318 "Causes serious eye damage" |
| Eye Dam. 1 - H318 "Causes serious eye damage" |

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. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 3 Residues

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) |
| | Fruit crops | | | | |
| | Root crops | sugarbeet | 300 g as/ha, BBCH 36, foliar | | 0, 28 and maturity |
| | Leafy crops | cabbage | 0.42 kg as/ha, foliar at at the 8 – 10 leaf stage | | up to 38 |
| | Cereals/grass crops | | | | |
| | Pulses/Oilseeds | oilseed rape | 300 g as/ha, foliar | | 0, 28 and maturity |
| | Miscellaneous | pasture | 1.121 kg as/ha Spring/summer | | 7, 14, 28, 56, and 126 |
| | Of cereals only uptake of clopyralid into wheat in a hydroponic setting has been studied. Pasture cannot fully be used to cover cereals. Furthermore the pasture study does not meet GLP requirements. | | | | |
| Rotational crops (metabolic pattern) OECD Guideline 502 | Crop groups | Crop(s) | PBI (days) | Comments | |
| | Root/tuber crops | Turnip Radish | 319 30 | The 30 DAT cabbage was not fully grown to maturity. The heads were collected before fully grown. The residues indicate similar results. | |
| | Leafy crops | Lettuce, Cabbage | 125, 319 30 | | |
| | Cereal (small grain) | Wheat | 30, 125, 319 | | |
| | Other | | | | |
| Rotational crop and primary crop metabolism similar? | Yes | | | | |
| Processed commodities (standard hydrolysis study) OECD Guideline 507 | Conditions | Parent % of initial dose | | | |
| | 20 min, 90°C, pH 4 | 99.3 | | | |
| | 60 min, 100°C, pH 5 | 96.9 | | | |
| | 20 min, 120°C, pH 6 | 97.1 | | | |
| | | | | | |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | No changes proposed in residue definition on basis of hydrolysis test. | | | | |
| | Only parent has been tested. Clopyralid conjugates are major residue species and included in the proposed residue definitions and, consequently, should be tested for hydrolytic stability. | | | | |
| | As far as olives are concerned, stability tests involving basic conditions (pH>7) are recommended due to the pH of the process employed in olive production. | | | | |

List of Endpoints

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Section 3 Residues

| | |
|--|---|
| Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Clopyralid, its salts and conjugates, expressed as clopyralid |
| Plant residue definition for risk assessment (RD-RA) | Clopyralid, its salts and conjugates, expressed as clopyralid |
| Conversion factor (monitoring to risk assessment) | Residue definitions are the same, i.e. conversion factor is not 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) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|---|---|---|--------------------|---|
| Animals covered | Laying hen | 11.4 mg a.i./kg bw/d | 7 | 13N (both for max and median) |
| | Goat/Cow | 1.852 kg a.i./day | 7 | 2.5N -4.8N (max.) 4.5N – 8.3N (med.) |
| | Pig | | | Not considered necessary. |
| | Fish | mg/kg DM | | No studies available |
| | In milk over 21% of TRR was found as conjugate X36538. Clopyralid comprised from 54% to over 70% of the TRR in milk, urine and feces. In the tissues unchanged clopyralid was the major residue species along with minor amounts of conjugate X36538. | | | |
| Time needed to reach a plateau concentration in milk and eggs (days) | | For clopyralid residues in milk, steady state is reached within 2 days. For conjugates steady state is reached already on day 1. For eggs parent compound is stable from day 1 on. | | |
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | | Clopyralid, its salts and conjugates, expressed as clopyralid | | |
| Animal residue definition for risk assessment (RD-RA) | | Clopyralid, its salts and conjugates, expressed as clopyralid | | |
| Conversion factor (monitoring to risk assessment) | | Residue definitions are the same, i.e. conversion factor is not needed | | |
| Metabolism in rat and ruminant similar (Yes/No) | | Yes | | |
| Fat soluble residues (Yes/No) (FAO, 2009) | | No | | |

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| Finland | May 2017 | Clopyralid |

Section 3 Residues

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

| | |
|--|--|
| Confined rotational crop study (Quantitative aspect) OECD Guideline 502 | In rotational crop intervals majority of the residue identified was clopyralid. Free and conjugated clopyralid was the most abundant residue at all PBIs. Clopyralid taken up by the plants as glucose conjugate of clopyralid. |
| Field rotational crop study OECD Guideline 504 | Field rotational crop study currently on-going. Results from confined rotational residue study, when taking into account the less critical GAP supported for clopyralid AIR, indicate that residues in rotational crops planted after normal maturity / harvest of treated cereal crops is unlikely and that a further waiting period would not be needed. |

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1) 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 Year) | | | |
|--|----------------------|-----------|------------------------|--|--|--|
| | | | 0.5 mg/kg | | | |
| High water content | Pasture | -20 | 18 | | | |
| High oil content | Oilseed rape | -20 | 24 | | | |
| High oil content | Olive (processed) | -20 | 10 | | | |
| High protein content | | | | | | |
| High starch content | Corn | -20 | 12 | | | |
| High acid content | Orange | -20 | 10 | | | |
| Stability of conjugates have not been tested, though clopyralid conjugates are major metabolites comprising up to 50 % of TRR depending on crop studied. | | | | | | |
| Animal | Animal commodity | T (°C) | Stability (Month/Year) | | | |
| | | | | | | |
| Bovine | Muscle | -20 | 18 | | | |
| Bovine | Liver | -20 | 18 | | | |
| Bovine | Kidney | -20 | 18 | | | |
| Bovine | Milk | -20 | 18 | | | |
| Hen | Egg | -20 | 18 | | | |
| Bovine | Fat | -20 | 24 | | | |
| Stability of conjugates have not been tested, though clopyralid conjugates are major metabolites as well. | | | | | | |

List of Endpoints

| Rapporteur Member State | Month and year | Active Substance |
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| Finland | May 2017 | Clopyralid |

Section 3 Residues

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 (row to be deleted if not relevant) | | | | | | |
| Grass forage / pasture | N-EU | 2.49, 2.6, 2.8, 3.0, 3.48, 3.73, 4.4, 5.0, 5.4, 6.95 | Livestock dietary burden is calculated based on the N EU STMR and HR since these values are greater than corresponding values from the S-EU trials. | --- | 6.95 | 3.61 |
| Grass forage / pasture | S-EU | 1.66, 2.49, 2.91, 3.06, 3.21, 3.31, 3.93, 4.09 | See above | --- | 4.09 | 3.14 |
| Cereal grain (combined barley and wheat) | N-EU | 0.07, 0.14, 0.23, 0.24, 0.34, 0.37, 0.38, 0.47, 0.61, 0.73, 0.79, 0.82, 0.93, 0.95, 1.06, 1.11, 1.26 | Combined results from barley and wheat trials for Active Approval. No change in MRL proposed since same data relied upon. | 2 | 1.26 | 0.61 |
| Cereal grain (combined barley and wheat) | S-EU | 0.13, 0.26, 0.68, 0.68, 1.16, 1.16, 1.34, 1.42 | Combined results from barley and wheat trials for Active Approval. STMR of 0.92 mg/kg based on S-EU data. Extrapolate to oat and rye. No change in MRL proposed since same data relied upon. | 2 | 1.42 | 0.92 |
| Cereal straw (combined barley and wheat) | N-EU | 0.17, 0.26, 0.28, 0.31, 0.40, 0.50, 0.59, 0.79, 0.87, 0.93, 1.05, 1.06, 1.08, 1.11, 1.26 | Combined results from barley and wheat trials for Active Approval. HR for straw based on N-EU | --- | 1.26 | 0.79 |
| Cereal straw (combined barley and wheat) | S-EU | 0.39, 0.59, 0.63, 0.84, 0.99, 1.16, 1.18, 1.20 | Combined results from barley and wheat trials for Active Approval. | --- | 1.20 | 0.93 |
| MRL application (row to be deleted if not relevant) | | | | | | |
| | | | | | | |
| | | | | | | |

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Section 3 Residues

| Summary of the data on formulation equivalence OECD Guideline 509 | | | | | | |
|--|--------|----------------------|--------------------------|--|--|--|
| Crop | Region | Residue data (mg/kg) | Recommendations/comments | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1) | | | | | | |
| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments | | | |
| | | | | | | |
| | | | | | | |

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

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Section 3 Residues

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)

Inputs for animal burden calculations

| Feed commodity | Median dietary burden | | Maximum dietary burden | |
|--|-----------------------|--|------------------------|--|
| | (mg/kg) | Comment | (mg/kg) | Comment |
| Representative uses (row to be deleted if not relevant) | | | | |
| | | | | |
| | | | | |
| | | | | |
| MRL application (row to be deleted if not relevant) | | | | |
| Grass forage (pasture) | 3.61 | STMR, N-EU | 6.95 | HR, N-EU |
| Wheat / barley grain | 0.92 | STMR, N-EU, data from Active Approval | 0.92 | STMR, N-EU, data from Active Approval |
| Wheat bran (milled by products) / barley bran | 5.61 | Grain STMR of 0.92 mg/kg x mean processing factor of 6.1 | 5.61 | Grain STMR of 0.92 mg/kg x mean processing factor of 6.1 |
| Wheat / barley straw | 0.93 | STMR – SEU, data from Active Approval | 1.26 | HR – NEU, data from Active Approval |

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Section 3 Residues

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

| MRL calculations | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|---|--------------------------------------|---------------------|--------------------------------------|-------------------|--------------------------------------|------------------------|--------------------------------------|-----------------------|--------------------------------------|----------------------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle | 0.385 | Ram/Ewe | 0.891 | Breeding | 0.209 | Broiler | 0.142 | Carp | 0.385 |
| | Dairy cattle | 0.719 | Lamb | 0.726 | Finishing | 0.111 | Layer | 0.147 | Trout | |
| | | | | | | | Turkey | 0.140 | Fish intake >0.1 mg/kg DM N/A | |
| Intake >0.004 mg/kg bw | Yes/No | | Yes/No | | Yes/No | | Yes/No | | Yes/No | |
| Feeding study submitted | Yes | | Yes | | Yes | | Yes | | No study submitted | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: N Dairy: N | Level | Lamb: N Ewe: N | Level | N rate Breed/Finish | Level | B or T: N Layer: N | Level | N rate Carp/Trout |
| | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals | Estimated HR ^(a) at 1N | MRL proposals |
| Muscle | 0.012 | 0.08 | 0.015 | 0.08 | 0.004 | 0.05 | 0.006 | 0.05 | | |
| Fat | 0.065 | 0.07 | 0.081 | 0.09 | 0.019 | 0.05 | 0.002 | 0.05 | | |
| Meat ^(b) | 0.023 | | 0.028 | | 0.006 | | 0.005 | | | |
| Liver | 0.057 | 0.06 | 0.071 | 0.08 | 0.017 | 0.05 | 0.017 | 0.05 | | |
| Kidney | 0.966 | 1 | 1.197 | 1.5 | 0.281 | 0.3 | --- | 0.05 | | |
| Milk ^(a) | 0.033 | 0.05 | 0.004 | 0.05 | | | | | | |
| Eggs | | | | | | | 0.003 | 0.05 | | |
| Method of calculation ^(c) | Tf | Tf | Tf | Tf | Tf | Tf | Tf | Tf | | |

^(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).

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

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

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Section 3 Residues

| STMR calculations | Ruminant | | | | Pig/Swine | | Poultry | | Fish | |
|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|-----------------------------|--|
| Median expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle | 0.224 | Ram/Ewe | 0.468 | Breeding | 0.147 | Broiler | 0.142 | Carp | |
| | Dairy cattle | 0.411 | Lamb | 0.442 | Finishing | 0.111 | Layer | 0.145 | Trout | |
| | | | | | | | Turkey | 0.140 | | |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level 0.451* | Beef: 2.01N Dairy: 1.1N | Level 0.451* | Lamb: 1N Ewe: 0.96N | Level 0.451* | 3.1/4.1N Breed/Finish | Level 0.280 | B or T: 2N Layer: 1.93N | Level N/A | N rate Carp/Trout |
| | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N | Mean level in feeding level | Estimated STMR ^(b) at 1N |
| Muscle | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | --- | --- |
| Fat | 0.023 | 0.021 | 0.023 | 0.024 | 0.023 | <0.01 | <0.01 | <0.01 | --- | --- |
| Meat ^(a) | 0.013 | 0.012 | 0.013 | 0.013 | 0.013 | <0.01 | <0.01 | <0.01 | | |
| Liver | 0.032 | 0.029 | 0.032 | 0.033 | 0.032 | 0.010 | 0.019 | <0.01 | | |
| Kidney | 0.429 | 0.391 | 0.429 | 0.445 | 0.429 | 0.140 | --- | --- | | |
| Milk | <0.01 | <0.01 | <0.01 | <0.01 | | | | | | |
| Eggs | | | | | | | <0.01 | <0.01 | | |
| Method of calculation ^(c) | Tf | Tf | Tf | Tf | Tf | Tf | Tf | Tf | | |

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

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

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

* *Milk and muscle residues estimated based on feeding level of 1.67 mg/kg bw/day since residues were <0.01 at the 0.451 mg/kg bw/day feeding level. The 1.67 mg/kg bw/day feeding level is 7.46N for beef cattle, 4.06 N for dairy cattle, 3.57 N for Ram/ewe, 3.78 N for lamb, 11.4 N for breeding swine, and 15.04N for finishing swine

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| Finland | May 2017 | Clopyralid |

Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Animal products

Table to be deleted if not relevant (RD-Mo = RD-RA)

| Conversion factors derived from the livestock feeding studies at the different feeding levels | | | | | | | | |
|---|-------------------|---------|---------|---------|---------|---------|---------|---------|
| Study | Ruminant/Pig | | | | Poultry | | | |
| Feeding levels | Level 1 | Level 2 | Level 3 | Level 4 | Level 1 | Level 2 | Level 3 | Level 4 |
| Muscle | | | | | | | | |
| Fat | | | | | | | | |
| Liver | | | | | | | | |
| Kidney | | | | | | | | |
| Milk | | | | | | | | |
| Egg | | | | | | | | |
| Comments (up to 250 characters) | CF=1 in all cases | | | | | | | |

Plant products

Table to be deleted if not relevant (RD-Mo = RD-RA)

| Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials ^(a) OECD Guidance, series on Pesticides No 66 | | | | | | | | |
|--|--|--|--|--|--|--|--|----------|
| PHI ^(b) (days) | | | | | | | | Comments |
| Representative uses (row to be deleted if not relevant) | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| MRL application (row to be deleted if not relevant) | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Current MRLs in force (Reg. (EU) No 322/2012, 17.4.2012) are based on residue definitions comprising of parent only. As the residue definition has been proposed to include conjugates as well, new MRL applications are consequently necessary. | | | | | | | | |

^(a): CF calculated at the supported PHI are underlined.

^(b): 0-/0+ for samples collected just before/after the last application

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

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies ^(a) | Processing Factor (PF) | | Conversion Factor (CF _P) for RA ^(b) |
|---|--|------------------------|-----------|--|
| | | Individual values | Median PF | |
| Representative uses (row to be deleted if not relevant) | | | | |
| Wheat / bran | 4 | 3.5, 4.3, 6.1, 10.4 | 6.1 / 5.2 | N/A |
| Wheat / white flour | 4 | 0.1, 0.2, 0.3, 0.6 | 0.3 / 0.3 | N/A |
| Wheat / wholemeal flour | 2 | 0.8, 1.2 | 1 / 1 | N/A |
| Wheat / germ | 2 | 2.3, 4.3 | 3.3 | N/A |

List of Endpoints

| Rapporteur Member State | Month and year | Active Substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 3 Residues

| | | | | |
|--|---|----------|-----------|-----|
| Wheat / white bread | 2 | 0.1, 0.1 | 0.1 / 0.1 | N/A |
| Wheat / wholemeal bread | 2 | 0.5, 0.6 | 0.6 / 0.6 | N/A |
| Barley / malt sprouts | 2 | 0.2, 0.2 | 0.2 / 0.2 | N/A |
| Barley / brewing malt | 2 | 0.6, 0.7 | 0.7 / 0.7 | N/A |
| Barley / spent grains and flocs | 2 | 0.1, 0.2 | 0.2 / 0.2 | N/A |
| Barley / brewer's yeast | 2 | 0.1, 0.1 | 0.1 / 0.1 | N/A |
| Barley / beer | 2 | 0.1, 0.1 | 0.1 / 0.1 | N/A |
| MRL application (row to be deleted if not relevant) | | | | |
| | | | | |
| | | | | |

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

(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

ARfD

UESTI (% ARfD), according to EFSA PRIMo

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

Factors included in IESTI and NESTI

| | | |
|---|-----------|--------------------------------|
| 0.15 mg/kg bw per day | | |
| Highest TMDI: | 27 % ADI | (UK, toddler, sugar beet root) |
| Highest NTMDI: | XX % ADI | (MS, diet) |
| Highest IEDI: | XX % ADI | (MS, diet) |
| Highest NEDI: | XX % ADI | (MS, diet) |
| aRfD for clopyralid has been considered unnecessary | | |
| Highest IESTI: | XX % ARfD | (Commodity) |
| Highest NESTI: | XX % ARfD | (commodity) |
| | | |

Consumer risk assessment limited to the representative uses

To be deleted if not relevant

TMDI (% ADI), according to EFSA PRIMo

NTMDI (% ADI), according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

UESTI (% ARfD), according to EFSA PRIMo

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

Factors included in IESTI and NESTI

| | | |
|----------------|-----------|-------------|
| Highest TMDI: | XX % ADI | (MS, diet) |
| Highest NTMDI: | XX % ADI | (MS, diet) |
| Highest IEDI: | XX % ADI | (MS, diet) |
| Highest NEDI: | XX % ADI | (MS, diet) |
| | | |
| Highest IESTI: | XX % ARfD | (Commodity) |
| Highest NESTI: | XX % ARfD | (commodity) |
| | | |

Additional contribution to the consumer intakes through drinking water resulting from groundwater

List of Endpoints

| Rapporteur Member State | Month and year | Active Substance |
|-------------------------|----------------|------------------|
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Section 3 Residues

metabolite(s) expected to be present above 0.75 µg/L

To be deleted if not relevant

Metabolite(s)

ADI (mg/kg bw per day)

Intake of groundwater metabolites (% ADI)

WHO Guideline (WHO, 2009)

Adult (60 kg bw, 2 L): XX % ADI

Child (10 kg bw, 1 L): XX % ADI

Infant (5 kg bw, 0.75 L): XX % ADI

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

| Code ^(a) | Commodity/Group | MRL/Import tolerance ^(b) (mg/kg) and Comments | |
|---|-----------------|---|--|
| Plant commodities | | | |
| Representative uses (row to be deleted if not relevant) | | | |
| | | | |
| | | | |
| MRL application (row to be deleted if not relevant) | | | |
| | | | |
| | | | |
| Animal commodities | | | |
| | | | |
| | | | |

(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.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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 | CO ₂ : 47.5 – 65.5 % AR after 92 days, 72.9 – 83.3 % of AR after 374 days at 20 °C, [2,6-pyridinyl- ¹⁴ C]-label (n=5) (Baloch & Grant 1991) 64.9 - 70.3 % of AR after 90 days (n=4) (Wardrope 2009) |
| Non-extractable residues after 100 days | 11.2 – 35.1 % of AR after 92 days at 20 °C, [2,6-pyridinyl- ¹⁴ C]-label (n=5) (Baloch & Grant 1991) 24.4 - 32.9 % after 90 days (n=4) (Wardrope 2009) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | No major metabolites in addition to CO ₂ Unidentified minor metabolites: Max. 7.7% of AR at 20 °C (Skinner & al. 1995) One unidentified polar metabolite < 3 % of AR at 20 °C (Wardrope 2009) |

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

| | |
|---|---|
| Mineralisation after 100 days | No mineralisation |
| Non-extractable residues after 100 days | NER max 13.4 % of AR after 30 days |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | no metabolites at 20 °C, [2,6-pyridinyl- ¹⁴ C]-label (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) | No photoproducts were identified, DT ₅₀ >12 years, [2,6-pyridinyl- ¹⁴ C]-label (n=1) (Batzer & al. 1994) DT ₅₀ 553 d (n=1) (Ponte 2014) |
| Mineralisation at study end | 3 % CO ₂ after 30 days (Batzer & al. 1994) 2.1 % CO ₂ after 16 days (Ponte 2014) |
| Non-extractable residues at study end | NER max 5 % of AR after 30 days (Batzer & al. 1994) 4.3 % of AR after 16 days (Ponte 2014) |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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 | Biom ass mgC/ 100g | pH ^{a)} | t. °C / % MWHC | DT ₅₀ /DT ₉₀ (d) | DT ₅₀ (d) 20 °C pF2/10kPa ^{b)} | St. (χ^2) | Method of calculation |
| Parabraunerde (silt loam) | 47 | 7.7 | 20 / 18.63 ^c | 44.4 / 147.3 | 34.2 | 6.796 | SFO |
| Marcham (sandy clay loam) | 170 | 8.3 | 20 / 20.19 ^c | 34.5 / 114.7 | 32.4 | 5.478 | SFO |
| Castle Rising (sandy loam) | 313 | 8 | 20 / 65.13 ^c | 26.3 / 87.3 | 26.3 | 8.284 | SFO |
| Speyer 2.1 (sand) | NA | 6.5 | 20 / 12.58 ^c | 64.6 / 214.6 | 64.6 | 5.466 | SFO |
| Speyer 2.2 (sand) | 110 | 6.3 | 20 / 18.56 ^c | 16.2 / 53.8 | 16.2 | 7.78 | SFO |
| Mississippi (silty clay loam) | 11.9 2 | 6 | 25 / 23.42 ^d | 8.6 / 28.5 | 11.6 | 6.49 | SFO |
| A (sandy loam) | 33.2 | 5.8 | 20 / 24.28 ^e | 16.5 / 54.8 | 16.5 | 4.856 | SFO |
| B (clay) | 78.2 | 7.1 | 20 / 28.05 ^e | 23 / 76.4 | 15.9 | 6.767 | SFO |
| C (clay loam) | 48.5 | 5.1 | 20 / 48.17 ^e | 4.9 / 16.2 | 4.9 | 12.73 | SFO |
| D (clay loam) | 70.9 | 7 | 20 / 35.30 ^e | 9.8 / 32.4 | 9.8 | 10.17 | SFO |
| Geometric mean (if not pH dependent) | | | | | 18.4 | | |
| pH dependence | | | | | No | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Reported soil moisture: 40% of maximum WHC

^{d)} Reported soil moisture: 75% of 1/3 bar WHC

^{e)} Reported soil moisture: 45% WHC

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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). | χ^6 | pH ^{a)} | Depth (cm) | DT ₅₀ (d) actual | DT ₉₀ (d) actual | St. (χ^2) | DT ₅₀ (d) Norm ^{b)} | Method of calculation |
| Loamy sand (bare) | Bargstedt, Germany | | 4.3 | 0-100 | 21 | 69.6 | 23.9 | 13 | SFO / SFO |
| Loam (bare) | Wilson, UK | | 6.2 | 0-100 | 16.7 | 55.6 | 22.6 | 13.5 | SFO / SFO |
| Silty clay loam (bare) | Sermaises, France | | 7 | 0-100 | 16.3 | 54 | 19.3 | 7.5 | SFO / SFO |
| Silty clay loam (bare) | Ansonville, France | | 8.2 | 0-20 | 0.16 | 12.1 | 5.36 | 2.07 | DFOP / SFO |
| Clay loam (bare) | Spalding, UK | | 7.8 | 0-20 | 0.61 | 47.4 | 16.8 | - ^c | DFOP / - |
| Clay loam (bare) | Mainbervilliers, France | | 7.1 | 0-20 | 6.04 | 28.3 | 7.22 | 2.7 | DFOP / SFO |
| Silty clay loam (bare) | Oederquart, Germany | | 7.5 | 0-20 | 16.2 | 53.9 | 12 | 5.69 | SFO / SFO |
| Sandy clay loam (bare) | Middlefart, Denmark | | 7.5 | 0-20 | 23.7 | 78.7 | 13.1 | 8.46 | SFO / SFO |
| Clay loam (bare) | Canals, Spain | | 8.0 | 0-100 | 13.7 | 45.5 | 19.2 | 12.3 | SFO / SFO |
| Silt loam (bare) | Elne, Southern France | | 6.3 | 0-100 | (49.3) ^d | (164) ^d | (49.3) ^d | - ^c | (SFO) ^d / - |
| Geometric mean (if not pH dependent), n = 8 | | | | | | | | 6.76 | |
| pH dependence | | | | | No | | | | |

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

^{c)} No statically reliable fit could be obtained

^{d)} Model fit not statistically or visually acceptable (according to FOCUS, 2006, 2014)

⁶ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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 EFSA calculator tool. | |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) | Not relevant | Not relevant |
| Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean | Not relevant | 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

Not relevant since trigger is not exceeded.

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 | Biom ass mgC/ 100g | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) | DT ₅₀ (d) 20 °C ^{b)} | St. (χ^2) | Method of calculation |
| Sandy loam | 8.9 | 7.4 | 20 / 59.6 | >1 year | > 1year | n/a | First-order |
| Geometric mean (if not pH dependent) | | | | | | | |

^{a)} Measured in 0.01M CaCl₂

^{b)} Normalised using a Q10 of 2.58

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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

| Parent | Soil photolysis | | | | | |
|------------|-----------------------------|------------------|----------------------------|---|---------------------|-----------------------|
| Soil type | Biom ass mgC/ 100g | pH ^{a)} | t. °C / % MWHC | DT ₅₀ / DT ₉₀ (d) calculated at ??°N | St. (χ^2) | Method of calculation |
| Sandy loam | 167 | 5.4 | 20 / 75% FMC at 1/3 bar | > 1 year | ^b | SFO |

^{a)} Measured in water

^{b)} Not reported

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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 ^{a)} | K _d (mL/g) | K _{doc} (mL/g) | K _F (mL/g) | K _{Foc} (mL/g) | 1/n |
| Merzenhausen | 1.00 | 7.19 | 0.051 | Not Calculated | 0.0057 | 0.57 ^b | 0.5577 |
| Kaldenkirchen | 0.98 | 5.34 | 0.048 | | 0.0267 | 2.72 ^b | 0.8602 |
| Lanna | 2.06 | 6.62 | 0.151 | | 0.0054 | 0.26 ^b | 0.3881 |
| Overhetfeld | 0.93 | 6.49 | 0.032 | | 0.0125 | 1.34 ^b | 0.7830 |
| Calke sandy loam | 3.15 | 5.7 | 0.139 ^b | Not Calculated | 0.01 | 0.5 | 0.489 |
| Longwoods sandy loam | 3.13 | 7.4 | 0.069 ^b | | 0.08 | 2.5 | 1.047 |
| LUFA 2.1 loamy sand | 0.68 | 4.9 | 0.040 ^b | | 0.03 | 4.1 | 0.889 |
| Quilen loam | 4.02 | 6.9 | 0.356 ^b | | 0.16 | 3.9 | 0.804 |
| DU-L-PF clay loam | 6.47 | 6.3 | 0.282 ^b | | 0.14 | 2.1 | 0.829 |
| Geometric mean (if not pH dependent)* | | | | | 0.026 | 1.41 | |
| Arithmetic mean (if not pH dependent) | | | | | | | 0.739 |
| pH dependence | | | | No | | | |

^{a)} Measured calcium chloride solution

^{b)} Calculated and reported in M-CA, not in the study report

^{c)} For modelling each soil was checked against OECD 106 reliability criterion (K_d > 0.1 for direct method and K_d > 0.3 for indirect method). Freundlich coefficient of soils not meeting the criterios was set to 0.9. The resulting arithmetic mean of 1/n for modelling is 0.836.

* Only relevant after implementation of the published EFSA guidance.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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 relevant

Not relevant

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 relevant

Not relevant

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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

The uses on oilseed rape and sugar beet studied in the lysimeter studies are no longer supported as representative for clopyralid in the AIR3 evaluation. The data have however been attached as additional information, as evaluated during the first approval of clopyralid.

1) Germany, spring application of 150 or 200 g clopyralid/ha on oilseed rape + partly a second application of 125 g a.s./ha on winter wheat 1 year later:

A total of 935 mm of precipitation was received in year 1 and 895.5 mm in year 2. 438 – 478 L of leachate was collected in year 1 and 411-437 L in year 2.

In the first year of application the annual average concentration in leachate was < 0.050 µg/L ai equivalent, however occasional exceedings of 0.10 µg/L were detected.

In the second year the annual average concentration in leachate was < 0.055 µg/L. In the soil cores the majority of radioactivity remained in the top layers of 0 – 40 cm. 11.49 – 12.38 % of AR was found in soil 2 years after the single application.

In the third year the annual average concentration in leachate was 0.001 – 0.019 µg/L. Maximum concentration of ai equivalents in leachate of the third year was 0.043 µg/L in the lysimeter which received two applications. In the soil cores 9.82 – 10.11 % of RA was found 2 years after the second application. The total recovery of RA in the three year monitoring period was 12.81 – 17.53 % of the applied RA, considering the both applications.

2) Germany, winter oilseed rape, 120 or 141 g clopyralid/ha, 847 and 1011 mm rain in years 1 and 204 – 417 mm of leachate was collected in two lysimeters in years 1 and 2. In the lysimeter with higher application rate the annual average concentration of unidentified radioactivity was 0.127 µg/L equivalent in year 1, but taken over the whole study period of two years, the average concentration was 0.064 – 0.078 µg/L equivalent. Occasional exceedings of 0.1 µg/L were detected soon after the application in both lysimeters.

3) Germany, sugar beet, spring application of 118 g clopyralid/ha, 754 and 871 mm rainfall in years 1 and 2: 113 and 196 mm of leachate was collected in years 1 and 2. Annual average concentrations of clopyralid were 0.010 and 0.002 µg/L in years 1 and 2. Non-extractable radioactivity was also present in the leachate at annual average concentrations of 0.113 and 0.031 µg/L equivalent in years 1 and 2, respectively. Dissolved CO₂ was the major metabolite observed in the leachate. 24.6 % of AR was measured in soil after 111 days, and after 2 years 13.2 % of AR was recovered.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

4) Germany, sugar beet, spring application of 99 or 185 g clopyralid/ha, ca 700 mm rainfall/year:

In year 1 the leachate volume was 180 and 248 mm, and in year 2 70 to 79 mm. Annual average concentrations in the leachate were not calculated, but in individual samples the clopyralid concentrations up to 0.135 µg/L were detected occasionally. 26 months after application 20 % of AR was recovered from the soil, majority of it in tillage layer (0 – 30 cm).

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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: DT₅₀>1 year (Smith 2000)

pH 7: 50 °C: DT₅₀>1 year

pH 9: 50 °C: DT₅₀>1 year

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 %

Xenon lamp for an equivalent of 41.6 days of summer sunlight at 40 °N, DT₅₀ ca 38000 days, no photolytic degradation products in aqueous sterile buffer could be observed. Photolysis is not a significant route of degradation of clopyralid in waters

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

$1.01 \times 10^{-6} \text{ mol} \cdot \text{Einstein}^{-1}$ (Ponte 2014)

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

Readily biodegradable
(yes/no)

No: in the Modified Sturm Test the cumulative CO₂ production of clopyralid was 5-10% of the theoretical maximum after 27 days. (Jenkins 1991)

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
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Section 4 Environmental fate and behaviour

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 | | | | | | | | | | |
|--|----------------|----------------------|---------------------|---|---|-----------------------|---|---|-----------------------|-----------------------|
| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed ^{a)} | t. °C ^{b)} | DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test) | | St. (χ ²) | DT ₅₀ /DT ₉₀ Water (pelagic test) | | St. (χ ²) | Method of calculation |
| | | | | At study temp | Normalised to <i>x</i> °C ^{c)} | | At study temp | Normalised to <i>x</i> °C ^{c)} | | |
| Fresh water (lake), 10.3 µg/L | 7.3 | NA | 20 | NA | NA | NA | Stable | | NA | No degradation |
| Fresh water (lake), 83.1 µg/L | 7.3 | NA | 20 | NA | NA | NA | Stable ^{d)} 1107 d | | 0.75 47 | SFO |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

^{d)} No significant difference in the degradation was observed between the high dose, low dose and sterile samples

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues. max x % after n d (suspended sediment test) |
|--|----------------|--------|--|--|
| Fresh water (lake), 10.3 µg/L | 7.3 | NA | 0.1% after 48 d | NA |
| Fresh water (lake), 83.1 µg/L | 7.3 | NA | 1.0% after 60 d (end of study) | NA |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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 Clopyralid | Distribution: max in water 100.13 % at 0d, max. sediment 19 % at 100 d (Loamy sand) Distribution: max in water 99.0 % at 0 d, max sediment 26 % at 100 d (Sandy silt loam) | | | | | | | | | |
|--------------------------------------|---|-------------------------|----------|--|---------------------|--|---------------------|---|---------------------|--------------------------|
| Water / sediment system | pH water phase | pH sed ^{a)} | t. °C | DT ₅₀ /DT ₉₀ whole sys. | St. (χ^2) | DT ₅₀ /DT ₉₀ water | St. (χ^2) | DT ₅₀ /DT ₉₀ sed | St. (χ^2) | Method of calculation |
| Loamy sand | 6.5 | 5.5 | 20 | Not determined | n/a | 128 | n/a | Not determined | n/a | First-order |
| Sandy silt loam | 8.16 | 7.7 | 20 | Not determined | n/a | 167 | n/a | Not determined | n/a | First-order |
| Geometric mean at 20°C ^{b)} | | | | | | 148 | | | | |

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

| 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 |
|----------------------------|-------------------|--------|--|---|
| Loamy sand | 6.5 | 5.5 | 2% after 100 d | 5% at 100 d |
| Sandy silt loam | 8.1 | 7.7 | 5% after 100 d | 5% at 100 d |

(Hall & al. 2002)

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

Direct photolysis in air

No data submitted nor required

Photochemical oxidative degradation in air

Atkinson calculation using AOPWIN v.1.90
DT₅₀ = 19.5 days (Madsen 2002)

Volatilisation

BBA guideline: from plant surfaces: ≤4 % in 24 hours
(Day & Rudel 1994)

BBA guideline: from soil: <2 % in 24 hours
(Day & Rudel 1994)

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: Clopyralid
Surface water: Clopyralid
Sediment: Clopyralid
Ground water: Clopyralid
Air: -

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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 provided nor required. |
| Surface water (indicate location and type of study) | <p>Survey on monitoring data in Europe in 2006-2015 (Aldous & al. 2015):</p> <p>Surface freshwater monitoring data showed that clopyralid was monitored in eleven countries (Austria, Belgium (Wallonia), Czech Republic, Finland, France, Norway, Slovakia, Sweden, Switzerland, the Netherlands and the United Kingdom). It was generally more frequently found and at higher concentrations than in groundwater, though with more variability as is typical of surface freshwater. There were greater than 1,678 sites monitored and 21,159 samples analysed. Clopyralid was detected and exceeded $0.1 \mu\text{g l}^{-1}$ in $\geq 4,172$ samples which represented $\leq 19.71\%$ of all samples. However, there were LoDs $>0.1 \mu\text{g l}^{-1}$ and this has exaggerated the number of samples exceeding the limit. Maximum concentrations in excess of the $0.1 \mu\text{g l}^{-1}$ drinking water limit were reported in the Czech Republic, Finland, France, Norway, Slovakia, Sweden, Switzerland and the United Kingdom (England, and Scotland).</p> |
| Ground water (indicate location and type of study) | <p>Survey on monitoring data in Europe in 2007-2015 (Aldous & al. 2015):</p> <p>Groundwater monitoring data showed that clopyralid was only monitored in groundwater in eight countries (Austria, Belgium (Wallonia), Czech Republic, Ireland, Norway, Slovakia, Sweden and the United Kingdom). There were greater than 4,459 sites and over 24,538 samples. Clopyralid was detected and exceeded the $0.1 \mu\text{g l}^{-1}$ drinking water limit in $\leq 0.35\%$ of groundwater samples (≤ 85 samples). Maximum concentrations in excess of $0.1 \mu\text{g l}^{-1}$ were reported in Belgium (Wallonia), Czech Republic, Slovakia, Sweden and the United Kingdom (England and Wales). A maximum clopyralid concentration of $17.1 \mu\text{g l}^{-1}$ was reported in the Czech Republic.</p> |
| Air (indicate location and type of study) | No data provided nor required. |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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

| | |
|-----------------------|--|
| Parent | DT ₅₀ (d): 23.7 days |
| Method of calculation | Kinetics: SFO Field or Lab: representative worst case from field studies |
| Application data | Crop: winter cereals (BBCH 13), established grasslands Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm ³ % plant interception: 0% (winter cereals), 90% (grassland) Number of applications: 1 Interval (d): N/A Application rate(s): 80 g a.s./ha (winter cereals), 120 g a.s./ha (grassland) |

Winter cereals

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|------------------------------|--|--------------------------------|--|
| Initial | 0.107 | | - | |
| Short term 24h | 0.104 | 0.105 | - | - |
| 2d | 0.101 | 0.104 | | |
| 4d | 0.095 | 0.101 | | |
| Long term 7d | 0.087 | 0.096 | - | - |
| 28d | 0.047 | 0.073 | | |
| 50d | 0.025 | 0.056 | | |
| 100d | 0.006 | 0.035 | | |
| Plateau concentration | Not required | | | |

Grassland

| PEC _(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|------------------------------|--|--------------------------------|--|
| Initial | 0.016 | | - | |
| Short term 24h | 0.016 | 0.016 | - | - |
| 2d | 0.015 | 0.016 | | |
| 4d | 0.014 | 0.015 | | |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| | | | | |
|-----------------------|--------------|-------|---|---|
| Long term 7d | 0.013 | 0.014 | - | - |
| 28d | 0.007 | 0.011 | | |
| 50d | 0.004 | 0.008 | | |
| 100d | 0.001 | 0.005 | | |
| Plateau concentration | Not required | | | |

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

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

(Robinson 2016)
 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
 Model(s) used: FOCUS PEARL v4.4.4, FOCUS PELMO v.5.5.3, FOCUS MACRO v.5.5.4
 For FOCUS gw modelling, values used:
 Crop: winter cereals, grassland
 Plant Uptake Factor: 0 / 0.5
 Water solubility (mg/L): 1.43×10^5 at pH 7 and 20°C
 Vapour pressure: set to 0 Pa as worst case
 Geometric mean parent $DT_{50 \text{ field}}$ 6.76 d (n = 8) (normalisation to pF2, 20°C with Q10 of 2.58)
 K_{FOC} : parent, geometric mean 1.41 mL/g (n = 9), arithmetic mean $1/n = 0.836$ (n = 9)
 Metabolites: -

Application rate

Gross application rate: 80 g a.s./ha (winter cereals), 120 g a.s./ha (grassland)
 Crop growth stage: BBCH 13 (winter cereals), established (grassland)
 Canopy interception %: 0% (winter cereals), 90% (grassland)
 Application rate net of interception: 80 g a.s./ha (winter cereals), 12 g a.s./ha (grassland)
 No. of applications: 1/ year
 Time of application (absolute or relative application dates): 1st of each month (Feb – Jun for winter cereals, Feb – Aug for grassland)

* Only relevant after implementation of the published EFSA guidance.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to winter cereals 1 x 80 g clopyralid/ha. PUF = 0.

| FOCUS PEARL/ winter cereals | Scenario | Parent (µg/L) | | | | |
|-----------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.018 | 0.005 | 0.004 | 0.010 | 0.009 |
| | Hamburg | 0.312 | 0.176 | 0.097 | 0.178 | 0.426 |
| | Jokioinen | 0.513 | 0.238 | 0.152 | 0.162 | 0.287 |
| | Kremsmunster | 0.194 | 0.089 | 0.100 | 0.100 | 0.120 |
| | Okehampton | 0.341 | 0.179 | 0.095 | 0.165 | 0.191 |
| | Piacenza | 0.147 | 0.070 | 0.055 | 0.039 | 0.007 |
| | Porto | 0.351 | 0.049 | 0.012 | 0.005 | 0.001 |
| | Sevilla | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS PELMO/ winter cereals | Scenario | Parent (µg/L) | | | | |
|-----------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.013 | 0.007 | 0.004 | 0.004 | 0.003 |
| | Hamburg | 0.916 | 0.459 | 0.113 | 0.041 | 0.063 |
| | Jokioinen | 3.00 | 2.32 | 0.697 | 0.191 | 0.259 |
| | Kremsmunster | 0.385 | 0.166 | 0.137 | 0.085 | 0.104 |
| | Okehampton | 0.775 | 0.520 | 0.149 | 0.156 | 0.196 |
| | Piacenza | 0.760 | 0.208 | 0.144 | 0.027 | 0.003 |
| | Porto | 1.77 | 0.156 | 0.012 | 0.005 | 0.001 |
| | Sevilla | 0.004 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | 0.011 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS MACRO/ winter | Scenario | Parent (µg/L) | | | | |
|------------------------|------------|---------------|-------|-------|-------|-------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.021 | 0.005 | 0.002 | 0.003 | 0.002 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to winter cereals 1 x 80 g clopyralid/ha. PUF = 0.5

| FOCUS PEARL/ winter cereals | Scenario | Parent (µg/L) | | | | |
|-----------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.015 | 0.003 | 0.003 | 0.007 | 0.008 |
| | Hamburg | 0.199 | 0.111 | 0.057 | 0.114 | 0.303 |
| | Jokioinen | 0.272 | 0.110 | 0.074 | 0.096 | 0.194 |
| | Kremsmunster | 0.153 | 0.062 | 0.069 | 0.069 | 0.091 |
| | Okehampton | 0.312 | 0.125 | 0.056 | 0.099 | 0.138 |
| | Piacenza | 0.119 | 0.054 | 0.035 | 0.030 | 0.007 |
| | Porto | 0.309 | 0.037 | 0.009 | 0.004 | <0.001 |
| | Sevilla | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS PELMO/ winter cereals | Scenario | Parent (µg/L) | | | | |
|-----------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.010 | 0.005 | 0.002 | 0.003 | 0.002 |
| | Hamburg | 0.726 | 0.242 | 0.056 | 0.016 | 0.032 |
| | Jokioinen | 2.08 | 1.55 | 0.338 | 0.074 | 0.123 |
| | Kremsmunster | 0.286 | 0.104 | 0.089 | 0.051 | 0.068 |
| | Okehampton | 0.630 | 0.367 | 0.089 | 0.083 | 0.124 |
| | Piacenza | 0.619 | 0.165 | 0.126 | 0.023 | 0.003 |
| | Porto | 1.64 | 0.129 | 0.009 | 0.004 | 0.001 |
| | Sevilla | 0.004 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | 0.010 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS MACRO/ winter | Scenario | Parent (µg/L) | | | | |
|---------------------|------------|---------------|-------|-------|-------|-------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.020 | 0.004 | 0.001 | 0.002 | 0.001 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to grassland 1 x 120 g clopyralid/ha. PUF = 0.

| FOCUS PEARL/ grassland | Scenario | Parent (µg/L) | | | | | | |
|------------------------|--------------|---------------|--------|--------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun | 1-Jul | 1-Aug |
| | Chateaudun | 0.007 | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.006 |
| | Hamburg | 0.017 | 0.013 | 0.008 | 0.014 | 0.023 | 0.046 | 0.102 |
| | Jokioinen | 0.112 | 0.060 | 0.039 | 0.026 | 0.041 | 0.045 | 0.126 |
| | Kremsmunster | 0.024 | 0.008 | 0.007 | 0.007 | 0.005 | 0.009 | 0.016 |
| | Okehampton | 0.060 | 0.030 | 0.008 | 0.008 | 0.013 | 0.013 | 0.020 |
| | Piacenza | 0.039 | 0.018 | 0.008 | 0.003 | 0.001 | 0.001 | 0.008 |
| | Porto | 0.063 | 0.006 | 0.002 | 0.001 | <0.001 | 0.001 | 0.002 |
| | Sevilla | 0.003 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS PELMO/ grassland | Scenario | Parent (µg/L) | | | | | | |
|------------------------|--------------|---------------|--------|--------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun | 1-Jul | 1-Aug |
| | Chateaudun | 0.004 | 0.001 | 0.001 | 0.002 | 0.002 | 0.003 | 0.005 |
| | Hamburg | 0.067 | 0.030 | 0.008 | 0.003 | 0.006 | 0.016 | 0.027 |
| | Jokioinen | 0.339 | 0.244 | 0.068 | 0.024 | 0.034 | 0.034 | 0.112 |
| | Kremsmunster | 0.030 | 0.009 | 0.008 | 0.007 | 0.005 | 0.013 | 0.019 |
| | Okehampton | 0.091 | 0.055 | 0.012 | 0.014 | 0.017 | 0.017 | 0.014 |
| | Piacenza | 0.156 | 0.105 | 0.063 | 0.018 | 0.005 | 0.003 | 0.013 |
| | Porto | 0.214 | 0.043 | 0.015 | 0.003 | 0.001 | 0.001 | 0.003 |
| | Sevilla | 0.004 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.001 |

| FOCUS MACRO/ grassland | Scenario | Parent (µg/L) | | | | | | |
|------------------------|------------|---------------|-------|--------|--------|--------|-------|-------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun | 1-Jul | 1-Aug |
| | Chateaudun | 0.007 | 0.001 | <0.001 | <0.001 | <0.001 | 0.001 | 0.004 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to winter cereals 1 x 120 g clopyralid/ha. PUF = 0.5

| FOCUS PEARL/ grassland | Scenario | Parent (µg/L) | | | | |
|------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.006 | 0.003 | 0.003 | 0.003 | 0.001 |
| | Hamburg | 0.014 | 0.007 | 0.004 | 0.007 | 0.012 |
| | Jokioinen | 0.047 | 0.030 | 0.018 | 0.015 | 0.021 |
| | Kremsmunster | 0.020 | 0.006 | 0.005 | 0.005 | 0.004 |
| | Okehampton | 0.054 | 0.025 | 0.007 | 0.005 | 0.010 |
| | Piacenza | 0.034 | 0.015 | 0.006 | 0.002 | <0.001 |
| | Porto | 0.061 | 0.005 | 0.001 | <0.001 | <0.001 |
| | Sevilla | 0.003 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS PELMO/ grassland | Scenario | Parent (µg/L) | | | | |
|------------------------|--------------|---------------|--------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.004 | 0.001 | 0.001 | 0.001 | 0.001 |
| | Hamburg | 0.058 | 0.015 | 0.004 | 0.001 | 0.003 |
| | Jokioinen | 0.249 | 0.169 | 0.032 | 0.011 | 0.017 |
| | Kremsmunster | 0.024 | 0.005 | 0.005 | 0.005 | 0.003 |
| | Okehampton | 0.081 | 0.046 | 0.007 | 0.008 | 0.010 |
| | Piacenza | 0.126 | 0.090 | 0.050 | 0.014 | 0.004 |
| | Porto | 0.193 | 0.034 | 0.012 | 0.002 | <0.001 |
| | Sevilla | 0.003 | <0.001 | <0.001 | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

| FOCUS MACRO/ | Scenario | Parent (µg/L) | | | | |
|--------------|------------|---------------|-------|--------|--------|--------|
| | | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun |
| | Chateaudun | 0.007 | 0.001 | <0.001 | <0.001 | <0.001 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

PEC_(gw) From lysimeter studies (4 studies in DE)

| Parent (µg/L) | 1 st year | 2 nd year | 3 rd year |
|-------------------|----------------------|------------------------------|----------------------|
| 1) Annual average | <0.050 | <0.055 | 0.001 – 0.019 |
| 2) Annual average | 0.127 | 0.064 – 0.078 (over 2 years) | |
| 3) Annual average | 0.010 | 0.002 | |
| 4) Occasionally | up to 0.135 | | |

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

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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

| | |
|--|--|
| Parent | (Robinson 2016) |
| Parameters used in FOCUSsw step 1 and 2 | <p>Version control no. of FOCUS calculator: FOCUS STEPS 1-2 v. 3.2</p> <p>Molecular weight (g/mol): 191.96</p> <p>K_{FOC} (mL/g): 1.41 (geometric mean, n = 9)</p> <p>DT₅₀ soil (d): 18.4 d, lab (geometric mean, n = 10)</p> <p>DT₅₀ water/sediment system (d): 1000 d (conservative FOCUS default)</p> <p>DT₅₀ water (d): 1000 d</p> <p>DT₅₀ sediment (d): 1000 d</p> <p>Crop interception (%): 0 % (minimal crop cover, winter cereals), 75% (full canopy, grassland)</p> |
| Parameters used in FOCUSsw step 3 (if performed) | <p>Version control no.'s of FOCUS software: FOCUS SWASH v.5.3 (FOCUS MACRO v. 5.5.4, FOCUS PRZM v. 4.3.1, FOCUS TOXSWA v. 4.4.3)</p> <p>Water solubility (mg/L): 1.43×10^5</p> <p>Vapour pressure: 1.36×10^{-3} Pa at 20°C</p> <p>K_{FOC} (mL/g): 1.41 (geometric mean, n = 9)</p> <p>1/n: 0.836 (arithmetic mean, n = 9)</p> <p>Q10=2.58</p> <p>Plant Uptake Factor: 0 / 0.5</p> |
| Application rate | <p>Crop and growth stage: winter cereals BBCH 13, established grassland</p> <p>Number of applications: 1</p> <p>Interval (d): -</p> <p>Application rate(s): 80 g a.s./ha (winter cereals), 120 g a.s./ha (grassland)</p> <p>Application window:</p> <p>30 days; start of application window: 1st of each month (Feb – Jun for winter cereals, Feb –Aug for grassland)</p> |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| FOCUS STEP 1 Scenario | Day after overall maximum | PECSW (µg/L) | PECS _{ED} (µg/kg) |
|--------------------------|---------------------------|--------------|----------------------------|
| | | Actual | Actual |
| Winter cereals | 0 h | 27.4 | 0.385 |
| Grassland | 0 h | 41.0 | 0.578 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) |
|------------------------------|---------------------------|--------------------------|----------------------------|
| | | Actual | Actual |
| Northern EU / Winter cereals | | | |
| Oct - Feb | 0 h | 12.2 | 0.172 |
| Mar - May | 0 h | 5.31 | 0.075 |
| Jun - Sep | 0 h | 5.31 | 0.075 |
| Southern EU / Winter cereals | | | |
| Oct - Feb | 0 h | 9.89 | 0.139 |
| Mar - May | 0 h | 9.89 | 0.139 |
| Jun - Sep | 0 h | 7.60 | 0.107 |

| FOCUS STEP 2 Scenario | Day after overall maximum | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) |
|--------------------------|---------------------------|--------------------------|----------------------------|
| | | Actual | Actual |
| Northern EU / Grassland | | | |
| Oct - Feb | 0 h | 5.39 | 0.076 |
| Mar - May | 0 h | 2.82 | 0.040 |
| Jun - Sep | 0 h | 2.82 | 0.040 |
| Southern EU / Grassland | | | |
| Oct - Feb | 0 h | 4.53 | 0.064 |
| Mar - May | 0 h | 4.53 | 0.064 |
| Jun - Sep | 0 h | 3.67 | 0.052 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

FOCUS STEP 3 / Winter cereals - PUF = 0

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| Appl. period | Scenario | Water body | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|----------------------------|------------------|
| February | D1 | d | 7.78 | 2.28 | Drainage |
| | D1 | s | 4.98 | 1.39 | Drainage |
| | D2 | d | 10.4 | 1.70 | Drainage |
| | D2 | s | 6.96 | 0.928 | Drainage |
| | D3 | d | 0.699 | 0.262 | Drift |
| | D4 | p | 0.405 | 0.306 | Drainage |
| | D4 | s | 0.517 | 0.122 | Drift |
| | D5 | p | 0.504 | 0.324 | Drainage |
| | D5 | s | 2.74 | 0.173 | Drainage |
| | D6 | d | 0.522 | 0.034 | Drift |
| | R1 | p | 0.022 | 0.012 | Runoff |
| | R1 | s | 0.968 | 0.048 | Runoff |
| | R3 | s | 1.17 | 0.067 | Runoff |
| | R4 | s | 0.336 | 0.012 | Drift |
| March | D1 | d | 10.23 | 2.83 | Drainage |
| | D1 | s | 6.45 | 1.75 | Drainage |
| | D2 | d | 9.01 | 1.74 | Drainage |
| | D2 | s | 5.65 | 1.06 | Drainage |
| | D3 | d | 0.707 | 0.222 | Drift |
| | D4 | p | 0.394 | 0.298 | Drainage |
| | D4 | s | 0.514 | 0.119 | Drift |
| | D5 | p | 0.064 | 0.053 | Drift |
| | D5 | s | 0.419 | 0.019 | Drift |
| | D6 | d | 0.563 | 0.067 | Drift |
| | R1 | p | 0.042 | 0.022 | Runoff |
| | R1 | s | 1.17 | 0.073 | Runoff |
| | R3 | s | 3.30 | 0.213 | Runoff |
| | R4 | s | 0.334 | 0.011 | Drift |
| April | D1 | d | 12.1 | 2.94 | Drainage |
| | D1 | s | 7.60 | 1.59 | Drainage |
| | D2 | d | 11.2 | 1.86 | Drainage |
| | D2 | s | 7.47 | 1.07 | Drainage |
| | D3 | d | 0.699 | 0.172 | Drift |
| | D4 | p | 0.338 | 0.267 | Drainage |
| | D4 | s | 0.518 | 0.103 | Drift |
| | D5 | p | 0.072 | 0.053 | Drift |
| | D5 | s | 0.423 | 0.021 | Drift |
| | D6 | d | 0.514 | 0.064 | Drift |
| | R1 | p | 0.021 | 0.013 | Runoff |
| | R1 | s | 0.769 | 0.044 | Runoff |
| | R3 | s | 0.932 | 0.082 | Runoff |
| | R4 | s | 1.48 | 0.104 | Runoff |
| May | D1 | d | 1.11 | 0.525 | Drainage |
| | D1 | s | 1.03 | 0.230 | Drainage |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| Appl. period | Scenario | Water body | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|----------------------------|------------------|
| | D2 | d | 19.5 | 2.01 | Drainage |
| | D2 | s | 12.3 | 1.16 | Drainage |
| | D3 | d | 0.763 | 0.226 | Drift |
| | D4 | p | 0.356 | 0.277 | Drainage |
| | D4 | s | 0.508 | 0.105 | Drift |
| | D5 | p | 0.070 | 0.051 | Drift |
| | D5 | s | 0.473 | 0.032 | Drift |
| | D6 | d | 0.512 | 0.105 | Drift |
| | R1 | p | 0.025 | 0.014 | Runoff |
| | R1 | s | 0.985 | 0.057 | Runoff |
| | R3 | s | 3.33 | 0.198 | Runoff |
| | R4 | s | 2.37 | 0.165 | Runoff |
| June | D1 | d | 0.647 | 0.327 | Drift |
| | D1 | s | 0.449 | 0.149 | Drift |
| | D2 | d | 7.55 | 2.79 | Drainage |
| | D2 | s | 8.23 | 1.60 | Drainage |
| | D3 | d | 0.866 | 0.328 | Drift |
| | D4 | p | 0.407 | 0.321 | Drainage |
| | D4 | s | 0.525 | 0.122 | Drift |
| | D5 | p | 0.164 | 0.123 | Drainage |
| | D5 | s | 0.473 | 0.048 | Drift |
| | D6 | d | 0.512 | 0.105 | Drift |
| | R1 | p | 0.089 | 0.043 | Runoff |
| | R1 | s | 0.563 | 0.048 | Runoff |
| | R3 | s | 1.36 | 0.122 | Runoff |
| | R4 | s | 0.336 | 0.012 | Drift |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

FOCUS STEP 3 / Winter cereals - PUF = 0.5

| Appl. period | Scenario | Water body | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|----------------------------|------------------|
| February | D1 | d | 7.69 | 2.22 | Drainage |
| | D1 | s | 4.92 | 1.36 | Drainage |
| | D2 | d | 9.91 | 1.60 | Drainage |
| | D2 | s | 6.65 | 0.867 | Drainage |
| | D3 | d | 0.639 | 0.217 | Drift |
| | D4 | p | 0.239 | 0.181 | Drainage |
| | D4 | s | 0.456 | 0.073 | Drift |
| | D5 | p | 0.483 | 0.310 | Drainage |
| | D5 | s | 2.71 | 0.167 | Drainage |
| | D6 | d | 0.520 | 0.034 | Drift |
| | R1 | p | 0.022 | 0.012 | Runoff |
| | R1 | s | 0.932 | 0.047 | Runoff |
| | R3 | s | 1.12 | 0.065 | Runoff |
| | R4 | s | 0.336 | 0.012 | Drift |
| March | D1 | d | 10.2 | 2.77 | Drainage |
| | D1 | s | 6.40 | 1.71 | Drainage |
| | D2 | d | 8.82 | 1.69 | Drainage |
| | D2 | s | 5.53 | 1.03 | Drainage |
| | D3 | d | 0.629 | 0.162 | Drift |
| | D4 | p | 0.225 | 0.170 | Drainage |
| | D4 | s | 0.454 | 0.068 | Drift |
| | D5 | p | 0.044 | 0.034 | Drift |
| | D5 | s | 0.411 | 0.014 | Drift |
| | D6 | d | 0.562 | 0.066 | Drift |
| | R1 | p | 0.040 | 0.021 | Runoff |
| | R1 | s | 1.10 | 0.068 | Runoff |
| | R3 | s | 3.28 | 0.212 | Runoff |
| | R4 | s | 0.334 | 0.011 | Drift |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| | | | | | |
|-------|----|---|-------|-------|----------|
| April | D1 | d | 11.7 | 2.78 | Drainage |
| | D1 | s | 7.34 | 1.51 | Drainage |
| | D2 | d | 11.0 | 1.80 | Drainage |
| | D2 | s | 7.30 | 1.03 | Drainage |
| | D3 | d | 0.618 | 0.115 | Drift |
| | D4 | p | 0.164 | 0.133 | Drainage |
| | D4 | s | 0.448 | 0.053 | Drift |
| | D5 | p | 0.049 | 0.034 | Drift |
| | D5 | s | 0.415 | 0.015 | Drift |
| | D6 | d | 0.514 | 0.063 | Drift |
| | R1 | p | 0.021 | 0.013 | Runoff |
| | R1 | s | 0.736 | 0.043 | Runoff |
| | R3 | s | 0.877 | 0.078 | Runoff |
| | R4 | s | 1.37 | 0.097 | Runoff |
| May | D1 | d | 1.05 | 0.483 | Drainage |
| | D1 | s | 0.977 | 0.208 | Drainage |
| | D2 | d | 19.0 | 1.94 | Drainage |
| | D2 | s | 11.9 | 1.12 | Drainage |
| | D3 | d | 0.657 | 0.149 | Drift |
| | D4 | p | 0.204 | 0.159 | Drainage |
| | D4 | s | 0.467 | 0.060 | Drift |
| | D5 | p | 0.051 | 0.037 | Drift |
| | D5 | s | 0.473 | 0.029 | Drift |
| | D6 | d | 0.512 | 0.105 | Drift |
| | R1 | p | 0.025 | 0.014 | Runoff |
| | R1 | s | 0.959 | 0.055 | Runoff |
| | R3 | s | 3.31 | 0.198 | Runoff |
| | R4 | s | 2.33 | 0.162 | Runoff |
| June | D1 | d | 0.626 | 0.305 | Drift |
| | D1 | s | 0.449 | 0.121 | Drift |
| | D2 | d | 7.33 | 2.71 | Drainage |
| | D2 | s | 7.99 | 1.55 | Drainage |
| | D3 | d | 0.717 | 0.209 | Drift |
| | D4 | p | 0.262 | 0.211 | Drainage |
| | D4 | s | 0.490 | 0.083 | Drift |
| | D5 | p | 0.142 | 0.107 | Drainage |
| | D5 | s | 0.473 | 0.042 | Drift |
| | D6 | d | 0.512 | 0.105 | Drift |
| | R1 | p | 0.086 | 0.042 | Runoff |
| | R1 | s | 0.541 | 0.046 | Runoff |
| | R3 | s | 1.36 | 0.122 | Runoff |
| | R4 | s | 0.336 | 0.012 | Drift |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

FOCUS STEP 3 / Grassland - PUF = 0

| Appl. period | Scenario | Water body | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|-----------------------------|-------------------------------|------------------|
| February | D1 | d | 25.9 | 7.92 | Drainage |
| | D1 | s | 18.5 | 4.67 | Drainage |
| | D2 | d | 30.5 | 8.24 | Drainage |
| | D2 | s | 24.8 | 3.70 | Drainage |
| | D3 | d | 0.899 | 0.134 | Drift |
| | D4 | p | 0.149 | 0.118 | Drainage |
| | D4 | s | 0.667 | 0.089 | Drift |
| | D5 | p | 1.17 | 0.717 | Drainage |
| | D5 | s | 6.76 | 0.441 | Drainage |
| | R2 | s | 0.640 | 0.026 | Drift |
| | R3 | s | 0.709 | 0.033 | Drift |
| March | D1 | d | 31.0 | 6.79 | Drainage |
| | D1 | s | 19.4 | 4.20 | Drainage |
| | D2 | d | 35.2 | 5.02 | Drainage |
| | D2 | s | 25.7 | 2.68 | Drainage |
| | D3 | d | 0.948 | 0.169 | Drift |
| | D4 | p | 0.141 | 0.108 | Drainage |
| | D4 | s | 0.659 | 0.088 | Drift |
| | D5 | p | 0.093 | 0.064 | Drift |
| | D5 | s | 0.650 | 0.031 | Drift |
| | R2 | s | 0.662 | 0.014 | Drift |
| | R3 | s | 0.705 | 0.029 | Drift |
| April | D1 | d | 26.7 | 6.20 | Drainage |
| | D1 | s | 16.8 | 3.35 | Drainage |
| | D2 | d | 30.5 | 6.67 | Drainage |
| | D2 | s | 26.1 | 3.53 | Drainage |
| | D3 | d | 0.959 | 0.196 | Drift |
| | D4 | p | 0.117 | 0.091 | Drift |
| | D4 | s | 0.658 | 0.063 | Drift |
| | D5 | p | 0.128 | 0.088 | Drift |
| | D5 | s | 0.665 | 0.040 | Drift |
| | R2 | s | 0.663 | 0.014 | Drift |
| | R3 | s | 1.36 | 0.122 | Runoff |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| | | | | | |
|--------|----|---|-------|-------|----------|
| May | D1 | d | 0.916 | 0.401 | Drift |
| | D1 | s | 0.673 | 0.137 | Drift |
| | D2 | d | 50.3 | 6.18 | Drainage |
| | D2 | s | 33.6 | 3.68 | Drainage |
| | D3 | d | 1.16 | 0.347 | Drift |
| | D4 | p | 0.121 | 0.099 | Drift |
| | D4 | s | 0.669 | 0.070 | Drift |
| | D5 | p | 0.140 | 0.105 | Drift |
| | D5 | s | 0.710 | 0.049 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.032 | Drift |
| June | D1 | d | 0.830 | 0.430 | Drift |
| | D1 | s | 0.673 | 0.201 | Drift |
| | D2 | d | 0.867 | 0.452 | Drift |
| | D2 | s | 0.778 | 0.336 | Drift |
| | D3 | d | 1.49 | 0.645 | Drift |
| | D4 | p | 0.287 | 0.220 | Drift |
| | D4 | s | 0.682 | 0.158 | Drift |
| | D5 | p | 0.416 | 0.286 | Drainage |
| | D5 | s | 0.710 | 0.122 | Drift |
| | R2 | s | 0.674 | 0.050 | Drift |
| | R3 | s | 2.25 | 0.202 | Runoff |
| July | D1 | d | 0.803 | 0.363 | Drift |
| | D1 | s | 0.673 | 0.162 | Drift |
| | D2 | d | 0.925 | 0.530 | Drift |
| | D2 | s | 0.773 | 0.372 | Drift |
| | D3 | d | 2.16 | 1.13 | Drift |
| | D4 | p | 0.381 | 0.307 | Drainage |
| | D4 | s | 0.658 | 0.215 | Drift |
| | D5 | p | 0.308 | 0.245 | Drainage |
| | D5 | s | 0.710 | 0.066 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.053 | Drift |
| August | D1 | d | 0.784 | 0.401 | Drift |
| | D1 | s | 0.673 | 0.214 | Drift |
| | D2 | d | 2.95 | 1.34 | Drainage |
| | D2 | s | 4.80 | 1.64 | Drainage |
| | D3 | d | 2.57 | 1.66 | Drift |
| | D4 | p | 0.712 | 0.550 | Drainage |
| | D4 | s | 0.888 | 0.393 | Drift |
| | D5 | p | 0.924 | 0.603 | Drainage |
| | D5 | s | 0.710 | 0.243 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.057 | Drift |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

FOCUS STEP 3 / Grassland - PUF = 0.5

| Appl. period | Scenario | Water body | PEC _{SW} (µg/L) | PEC _{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|----------------------------|------------------|
| February | D1 | d | 25.9 | 7.90 | Drainage |
| | D1 | s | 18.4 | 4.66 | Drainage |
| | D2 | d | 30.4 | 8.22 | Drainage |
| | D2 | s | 24.7 | 3.69 | Drainage |
| | D3 | d | 0.796 | 0.067 | Drift |
| | D4 | p | 0.058 | 0.048 | Drainage |
| | D4 | s | 0.623 | 0.036 | Drift |
| | D5 | p | 1.16 | 0.711 | Drainage |
| | D5 | s | 6.75 | 0.438 | Drainage |
| | R2 | s | 0.640 | 0.026 | Drift |
| | R3 | s | 0.709 | 0.033 | Drift |
| March | D1 | d | 30.9 | 6.73 | Drainage |
| | D1 | s | 19.3 | 4.16 | Drainage |
| | D2 | d | 35.1 | 4.99 | Drainage |
| | D2 | s | 25.7 | 2.65 | Drainage |
| | D3 | d | 0.808 | 0.083 | Drift |
| | D4 | p | 0.056 | 0.044 | Drainage |
| | D4 | s | 0.625 | 0.036 | Drift |
| | D5 | p | 0.053 | 0.035 | Drift |
| | D5 | s | 0.633 | 0.019 | Drift |
| | R2 | s | 0.662 | 0.014 | Drift |
| | R3 | s | 0.705 | 0.029 | Drift |
| April | D1 | d | 26.5 | 6.12 | Drainage |
| | D1 | s | 16.7 | 3.30 | Drainage |
| | D2 | d | 30.2 | 6.64 | Drainage |
| | D2 | s | 26.0 | 3.51 | Drainage |
| | D3 | d | 0.809 | 0.094 | Drift |
| | D4 | p | 0.046 | 0.030 | Drift |
| | D4 | s | 0.602 | 0.023 | Drift |
| | D5 | p | 0.069 | 0.047 | Drift |
| | D5 | s | 0.644 | 0.024 | Drift |
| | R2 | s | 0.663 | 0.014 | Drift |
| | R3 | s | 1.27 | 0.113 | Runoff |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

| | | | | | |
|--------|----|---|-------|-------|----------|
| May | D1 | d | 0.881 | 0.376 | Drift |
| | D1 | s | 0.673 | 0.104 | Drift |
| | D2 | d | 50.2 | 6.10 | Drainage |
| | D2 | s | 33.5 | 3.64 | Drainage |
| | D3 | d | 0.885 | 0.156 | Drift |
| | D4 | p | 0.048 | 0.035 | Drift |
| | D4 | s | 0.657 | 0.034 | Drift |
| | D5 | p | 0.079 | 0.056 | Drift |
| | D5 | s | 0.710 | 0.041 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.032 | Drift |
| June | D1 | d | 0.814 | 0.362 | Drift |
| | D1 | s | 0.673 | 0.150 | Drift |
| | D2 | d | 0.854 | 0.442 | Drift |
| | D2 | s | 0.767 | 0.328 | Drift |
| | D3 | d | 1.12 | 0.348 | Drift |
| | D4 | p | 0.104 | 0.073 | Drift |
| | D4 | s | 0.662 | 0.053 | Drift |
| | D5 | p | 0.299 | 0.212 | Drainage |
| | D5 | s | 0.710 | 0.089 | Drift |
| | R2 | s | 0.674 | 0.047 | Drift |
| | R3 | s | 2.23 | 0.201 | Runoff |
| July | D1 | d | 0.795 | 0.346 | Drift |
| | D1 | s | 0.673 | 0.121 | Drift |
| | D2 | d | 0.843 | 0.460 | Drift |
| | D2 | s | 0.736 | 0.317 | Drift |
| | D3 | d | 1.69 | 0.786 | Drift |
| | D4 | p | 0.154 | 0.130 | Drainage |
| | D4 | s | 0.658 | 0.088 | Drift |
| | D5 | p | 0.195 | 0.160 | Drainage |
| | D5 | s | 0.710 | 0.044 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.051 | Drift |
| August | D1 | d | 0.781 | 0.344 | Drift |
| | D1 | s | 0.673 | 0.167 | Drift |
| | D2 | d | 2.76 | 1.25 | Drainage |
| | D2 | s | 4.42 | 1.52 | Drainage |
| | D3 | d | 2.11 | 1.27 | Drift |
| | D4 | p | 0.392 | 0.313 | Drainage |
| | D4 | s | 0.658 | 0.219 | Drift |
| | D5 | p | 0.818 | 0.535 | Drainage |
| | D5 | s | 0.710 | 0.217 | Drift |
| | R2 | s | 0.674 | 0.017 | Drift |
| | R3 | s | 0.709 | 0.055 | Drift |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

Metabolite: Not relevant, as no metabolites identified

Parameters used in FOCUSsw step 1 and 2

Molecular weight:
 Soil or water metabolite:
 Koc/Kom (mL/g):
 DT₅₀ soil (d): *x days (If necessary, Lab or field. In accordance with FOCUS SFO)*
 DT₅₀ water/sediment system (d): *x d (representative worst case from sediment water studies)*
 DT₅₀ water (d):
 DT₅₀ sediment (d):
 Crop interception (%): *e.g. X % (no, minimal, average or full canopy)*
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment:
 Soil: *(if necessary)*

Parameters used in FOCUSsw step 3 (if performed)

Water solubility (mg/L):
 Vapour pressure: *X* Pa at 20°C
 Kom/Koc (mL/g):
 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively)
 Q10=2.58, Walker equation coefficient 0.7
 Crop uptake factor:
 Metabolite kinetically generated in simulation (yes/no):
 Formation fraction in soil (k_f/k_{dp}): *(If formation / degradation of metabolite is kinetically simulated by PRZM and MACRO) the identity of the precursor should also be included (e.g. from parent).*
 Formation fraction in sediment water (k_f/k_{dp}): *(If formation / degradation of metabolite is kinetically simulated by TOXSWA) the identity of the precursor should also be included (e.g. from parent).*

Application rate

Crop and growth stage: *wheat BBCH X-X*
 Number of applications: *x*
 Interval (d): *x*
 Application rate(s): *x* g a.s./ha
 Application window:
early or late spray drift selected (for vines and top fruit)

Main routes of entry

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 4 Environmental fate and behaviour

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

Method of calculation

Not required

PEC

Maximum concentration

Not required

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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 | | | | |
| Mallard duck (<i>Anas platyrhynchos</i>) [REDACTED] 1989) | Clopyralid | Acute | LD ₅₀ | 1465 |
| Mallard duck (<i>Anas platyrhynchos</i>) [REDACTED] 1985) | Clopyralid | Long-term | NOEC | 118 |
| Bobwhite quail (<i>Colinus virginianus</i>) [REDACTED] 2005 | GF-1374 | Acute | LD ₅₀ | > 2250 |
| Mammals | | | | |
| Rat [REDACTED] & al. 1987) | Clopyralid | Acute | LD ₅₀ | > 5000 |
| Rat [REDACTED] 2005) | GF-1374 | Acute | LD ₅₀ | 3378 |
| Rat [REDACTED] & al. 1977-78) | Clopyralid | Long-term | NOAEL | 50 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

Endocrine disrupting properties (Annex Part A, points 8.1.5)

Clopyralid has undergone a comprehensive battery of in vivo toxicology cover a broad spectrum of endocrine endpoints. This testing covered a tiered battery of acute, sub-chronic, chronic and reproductive tests. Furthermore, these studies have robust experimental designs, follow internationally accepted protocols and have a high level of replication and a long history of use in hazard identification and risk assessment. The results from these studies indicate no evidence of endocrine-mediated effects by clopyralid.

In addition to in vivo studies, clopyralid is included in the U.S. Endocrine Disruption Screening program. In vitro study results for endocrine endpoints are summarized in the EDSP21 Dashboard (<http://actor.epa.gov/edsp21/>). Specifically, various in vitro assays were conducted for its estrogenic, androgenic, and thyroid activities. Clopyralid does not show any bioactivity in estrogen receptor (ER)-, androgen receptor (AR)-, or thyroid receptor (ThR)-related assays. Clopyralid (cytotoxic limit = 161.9274 µM) was negative in 14/15 ER assays (not tested in 3 assays). Although it was positive in one ER assay Tox21_ERa_LUC_BG1_Agonist with an AC50 of 46.3512 µM, this is likely a non-specific outcome, because only one ER assay was positive. Clopyralid also was negative in 8/8 AR assays (not tested in 3 assays), and negative in 3/3 TR assays (not tested in 1 assay). ToxCast Model Predictions for bioactivity for clopyralid were 0 for all measures including ER agonist and antagonist AUCs and AR agonist and antagonist AUCs (all equaled 0).

Studies specific to evaluating endocrine disruption in terrestrial vertebrate species were not conducted. However, chronic reproductive studies with the avian species, northern bobwhite quail, demonstrated no effects on the reproductive performance at any test concentrations. Since no reproductive effects were observed, it is unlikely that clopyralid is inducing an endocrine effect in the bobwhite quail. This finding is consistent with what was documented in mammalian species where clopyralid did not directly impact the endocrine system (estrogen receptor, androgen receptor, etc.) of vertebrate species.

Overall, robust and consistent in vivo and in vitro data provides no evidence of endocrine disrupting properties of clopyralid so further ecotoxicological studies with reptiles and amphibians were not conducted.

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

Higher tier studies were not required

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

*No further study with vertebrate wildlife necessary since low risk to birds and mammals was demonstrated.
Additional data was not submitted*

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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

GF-1374 at 1.5 L formulated product/ha x 1 applications to grassland and 1.0 L product to cereals

| Compound | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---|----------------------------|------------|---------------------------|------|---------|
| Screening Step (Birds) | | | | | |
| Clopyralid | Large herbivorous | Acute | 3.66 | 400 | 10 |
| GF-1374 | Large herbivorous | Acute | 47.6 | 36.9 | 10 |
| Clopyralid | Small omnivorous | Acute | 12.7 | 115 | 10 |
| GF-1374 | Small omnivorous | Acute | 165 | 10.6 | 10 |
| Clopyralid | Large herbivorous | Long-term | 1.03 | 115 | 5 |
| Clopyralid | Small granivorous | Long-term | 2.75 | 42.9 | 5 |
| Tier 1 (Birds) <i>Tier 1 assessment not necessary due to all relevant scenarios passing the screening step</i> | | | | | |
| Screening Step (Mammals) | | | | | |
| Clopyralid | Small herbivorous | Acute | 9.47 | 528 | 10 |
| GF-1374 | Small herbivorous | Acute | 123 | 20.8 | 10 |
| Clopyralid | Small herbivorous | Acute | 16.4 | 305 | 10 |
| GF-1374 | Small herbivorous | Acute | 213 | 12.0 | 10 |
| Clopyralid | Small herbivorous | Long-term | 2.05 | 24.4 | 5 |
| Clopyralid | Small herbivorous | Long-term | 4.60 | 10.9 | 5 |
| Risk from bioaccumulation and food chain behaviour: <i>Not relevant, as clopyralid is not expected to bioaccumulate in animal tissues as indicated by a log P_{ow} of -2.63 and a fish BCF < 1.</i> | | | | | |
| Risk from consumption of contaminated water: <i>The K_{oc} for clopyralid is 1.41, so the approach above for less sorptive substances can be applied to this active substance. The maximum application rate for clopyralid is 120 g/ha and the relevant endpoint for the avian risk assessment is the reproduction NOEL of 118 mg/kg bw/d. The ratio of these figures is 1.02, which is lower than 50, so a formal assessment of the risk to birds from exposure to clopyralid through drinking water is not necessary</i> | | | | | |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|--|----------------|---------------------------|---|----------------------------|
| Laboratory tests | | | | |
| Fish | | | | |
| <i>Oncorhynchus mykiss</i> (██████ & al. 2000a) | Clopyralid | 96 hr | Mortality, LC ₅₀ | > 99.9 mg a.s./L (mm) |
| <i>Oncorhynchus mykiss</i> (██████ 2005a) | GF-1374 | 96 hr | Mortality, LC ₅₀ | 7.1 mg a.s./L (nom.) |
| <i>Pimephales promelas</i> (██████ & al. 2000b) | Clopyralid | ELS | NOEC | 10.8 mg a.s./L (mm) |
| Aquatic invertebrates | | | | |
| <i>Daphnia magna</i> (Marino & al. 2000c) | Clopyralid | 48 h | Mortality, EC ₅₀ | > 99.0 mg a.s./L (mm) |
| <i>Daphnia magna</i> (Sayers 2005b) | GF-1374 | 48 h | Mortality, EC ₅₀ | 6.9 mg a.s./L (nom.) |
| <i>Daphnia magna</i> (Douglas & al. 1992) | Clopyralid | 21 d | NOEC | 17 mg a.s./L (mm) |
| Sediment-dwelling organisms | | | | |
| <i>Chironomus riparius</i> (Barrett 2001) | Clopyralid | 28 d (static) | NOEC | 50 mg a.s./L (mm) |
| Algae | | | | |
| <i>Selenastrum capricornutum</i> (Kirk & al. 2000) | Clopyralid | 72 h | Growth rate: E _r C ₅₀ | 30 mg a.s./L (mm) |
| <i>Navicula pelliculosa</i> (Aufderheide 2014) | Clopyralid | 72 h | Growth rate: E _r C ₅₀ | 31.3 mg a.s./L (mm) |
| <i>Pseudokirchneriella subcapitata</i> (Hoberg 2005a) | GF-1374 | 72 h | Yield: E _y C ₅₀ | 1.1 mg product/L (nom.) |
| <i>Navicula pelliculosa</i> (Hoberg 2005b) | GF-1374 | 72 h | Biomass: E _b C ₅₀ | 1.4 mg product/L (nom.) |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

| Group | Test substance | Time-scale (Test type) | End point | Toxicity ¹ |
|---|----------------|---------------------------|--------------------------------|--------------------------------|
| Higher plant | | | | |
| <i>Lemna gibba</i> (Cowgill & al. 1990) | Clopyralid | 14 day | EC ₅₀ | 89 mg a.s./L (mm) |
| <i>Myriophyllum spicatum</i> (Banman & Moore 2015) | Clopyralid | 14 day | E _r C ₅₀ | > 3.0 mg a.s./L (mm) |
| <i>Lemna gibba</i> (Hoberg 2005c) | GF-1374 | 14 day | E _r C ₅₀ | 0.42 mg product/L (nom.) |
| <i>Myriophyllum spicatum</i> (Gonsior 2013) | GF-1374 | 14 day | E _r C ₅₀ | 0.44 mg product/L (nom.) |
| Further testing on aquatic organisms <i>Due to low acute and chronic risk to aquatic organisms demonstrated during the risk assessments, further data on aquatic organisms was deemed unnecessary and no further data has been presented.</i> | | | | |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) <i>Mammalian and other terrestrial studies indicate the clopyralid or its metabolites do not demonstrate any potential for endocrine disruption so further study was not required.</i> | | | | |
| | | | | |

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

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| | |
|---|--|
| | Clopyralid |
| logP _{ow} | -2.63 |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | Bluegill sunfish: BCF < 1.0 in 28 days (Bidlack 1982) |
| Annex VI Trigger for the bioconcentration factor | < 100 |
| Clearance time (days) (CT ₅₀) | Not calculated |
| (CT ₉₀) | |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | negligible |
| Higher tier study: Not required | |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

Minimum TERs for the most sensitive aquatic species after applications of GF-1374 to pasture and cereals at rates of 1.5 L GF-1374/ha and 1.0 L GF-1374/ha, respectively

| Substance | Time frame | Critical Endpoint (µg/L) | Distance from treated area | PEC _{sw} (µg/L) | RAC | TER ^a | TER trigger |
|----------------------|------------|---|--|--------------------------|------|------------------|-------------|
| Fish | | | | | | | |
| Clopyralid | Acute | 99900 | Step 1 broadcast application Grassland | 41.0 | 999 | 24.4 | 1 |
| Clopyralid | Acute | 99900 | Step 1 broadcast application Cereals | 27.4 | 999 | 36.5 | 1 |
| GF-1374 | Acute | 7100 (measured) | Spray drift 1 m buffer 0% drift reduce nozzle | 14.4 | 71 | 4.93 | 1 |
| GF-1374 | Acute | 2900 (predicted by mixture toxicity) | Spray drift 1 m buffer 0% drift reduce nozzle | 14.4 | 29 | 2.01 | 1 |
| Clopyralid | Chronic | 10800 | Step 1 broadcast application Grassland | 41.0 | 1080 | 26.3 | 1 |
| Clopyralid | Chronic | 10800 | Step 1 broadcast application Cereals | 27.4 | 1080 | 39.4 | 1 |
| Invertebrates | | | | | | | |
| Clopyralid | Acute | > 99000 | Step 1 broadcast application Grassland | 41.0 | 990 | 24.1 | 1 |
| | Acute | | Step 1 broadcast application Cereal | 27.4 | | 36.1 | 1 |
| GF-1374 | Acute | 6900 (measured) | Spray drift 1 m buffer 0% drift reduce nozzle | 14.4 | 69 | 4.79 | 1 |
| GF-1374 | Acute | 3500 (predicted by mixture toxicity) | Spray drift 1 m buffer 0% drift reduce nozzle | 14.4 | 35 | 2.43 | 1 |
| Clopyralid | Chronic | 17000 | Step 1 broadcast application Grassland | 41.0 | 170 | 41.5 | 1 |
| Clopyralid | Chronic | 17000 | Step 1 broadcast application Cereal | 27.4 | 170 | 62.0 | 1 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

| Invertebrates (<i>Chironomus riparius</i>) | | | | | | | |
|---|---------|---|---|------|------|-----|---|
| Clopyralid | Chronic | 50000 | Step 1 broadcast application Grassland | 41.0 | 5000 | 122 | 1 |
| | Chronic | | Step 1 broadcast application Cereal | 27.4 | | 182 | 1 |
| Green Algae | | | | | | | |
| Clopyralid (<i>S. capricornutum</i>) | 30000 | Step 1 broadcast application grassland | 41.0 | 3000 | 73.2 | 1 | |
| | | Step 1 broadcast application cereals | 27.4 | | 109 | 1 | |
| GF-1374 (<i>P. subcapitata</i>) | 1100 | Spray drift 1 m buffer zone 0% drift reduce nozzle | 14.4 | 110 | 7.64 | 1 | |
| Diatoms | | | | | | | |
| Clopyralid (<i>Navicula pelliculosa</i>) | 31300 | Step 1 broadcast application grassland | 41.0 | 3130 | 76.3 | 1 | |
| | | Step 1 broadcast application cereals | 27.4 | | 114 | 1 | |
| GF-1374 (<i>Navicula pelliculosa</i>) | 1400 | Spray drift 1 m buffer zone 0% drift reduce nozzle | 14.4 | 140 | 9.72 | 1 | |
| Macrophytes (<i>Lemna gibba</i>) | | | | | | | |
| Clopyralid | 89000 | Step 1 broadcast application grassland | 41.0 | 8900 | 217 | 1 | |
| | | Step 1 broadcast application cereals | 27.4 | | 325 | 1 | |
| GF-1374 | 420 | Spray drift 1 m buffer zone 0% drift reduce nozzle | 14.4 | 42 | 2.92 | 1 | |
| Macrophytes (<i>Myriophyllum spicatum</i>) | | | | | | | |
| Clopyralid | 3000 | Step 1 broadcast application grassland | 41.0 | 300 | 7.32 | 1 | |
| | | Step 1 broadcast application cereals | 27.4 | | 10.9 | 1 | |
| GF-1374 | 440 | Spray drift 1 m | 14.4 | 44 | 3.05 | 1 | |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

| | | | | | | |
|---|--|--|--|--|--|--|
| | | buffer zone 0% drift reduce nozzle | | | | |
| ^a Relevant acute or long term TER value compared to the trigger value of 1 | | | | | | |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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 |
|---|----------------|-----------------------------|---|---------------|
| <i>Apis mellifera</i> (Wainwright 2001a) | Clopyralid | Acute | Oral toxicity (LD ₅₀) | > 100 µg/bee |
| <i>Apis mellifera</i> (Hughes 2004a) | GF-1374 | Acute | Oral toxicity (LD ₅₀) | > 86.7 µg/bee |
| <i>Apis mellifera</i> (Wainwright 2001b) | Clopyralid | Acute | Contact toxicity (LD ₅₀) | > 98.1 µg/bee |
| <i>Apis mellifera</i> (Hughes 2004b) | GF-1374 | Acute | Contact toxicity (LD ₅₀) | > 200 µg/bee |

| |
|---|
| Potential for accumulative toxicity: <i>no</i> |
| <p>Semi-field test (Cage and tunnel test)</p> <p>The acute toxicity of GF-1374 to honey bees is considered low based on the Q_{HO} and Q_{HC} values are below the Annex VI trigger of 50 (see above risk assessments). Consequently, the acute oral and contact risk to honeybees is low following applications of GF-1374 at rates of up to 1.5 L formulated product/ha to pasture and 1.0 product/ha for cereals. Based on predicted exposure and acute contact endpoints for both actives as well as the formulated product and from predicted exposure from visiting off field plants following applications of GF-1374 to grassland and cereals, low risk was demonstrated. Also, dietary risk from consumption of nectar and pollen for both adult and larvae is considered low based on predicted exposure and acute oral endpoints. Finally, no sublethal effects were reported in acute contact and oral studies for clopyralid suggesting sublethal effects should not be anticipated. Overall, semi field tests are not considered necessary and have not been performed.</p> |
| <p>Field tests</p> <p>The acute toxicity of GF-1374 to honey bees is considered low based on the Q_{HO} and Q_{HC} values are below the Annex VI trigger of 50 (see above risk assessments). Consequently, the acute oral and contact risk to honeybees is low following applications of GF-1374 at rates of up to 1.5 L formulated product/ha to pasture and 1.0 product/ha for cereals. Based on predicted exposure and acute contact endpoints for both actives as well as the formulated product and from predicted exposure from visiting off field plants following applications of GF-1374 to grassland and cereals, low risk was demonstrated. Also, dietary risk from consumption of nectar and pollen for both adult and larvae is considered low based on predicted exposure and acute oral endpoints. Finally, no sublethal effects were reported in acute contact and oral studies for clopyralid suggesting sublethal effects should not be anticipated. Overall, field tests are not considered necessary and have not been performed.</p> |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

Risk assessment for GF-1374 applied once to grassland and cereals at 1.5 and 1.0 L product/ha, respectively

| Species | Test substance | Risk quotient | HQ/TER | Trigger |
|-----------------------|--|-----------------------|-----------------------------------|---------|
| <i>Apis mellifera</i> | Clopyralid (grassland) GF-1374 Clopyralid (cereals) GF-1374 | HQ _{oral} | < 1.2 < 18 < 0.8 < 12 | 50 |
| <i>Apis mellifera</i> | Clopyralid (grassland) GF-1374 Clopyralid (cereals) GF-1374 | HQ _{contact} | < 1.2 < 7.8 < 0.82 < 5.2 | 50 |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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 |
|---|----------------|-----------------------------|------------|
| <i>Typhlodromus pyri</i> (Loose 2005) | GF-1374 | Mortality, LR ₅₀ | 2000 mL/ha |
| <i>Aphidius rhopalosiphi</i> (Loose 2004a) | GF-1374 | Mortality, LR ₅₀ | 2000 mL/ha |
| Additional species | | | |
| <i>Chrysoperla carnea</i> (Loose 2004b) | GF-1374 | Mortality, LR ₅₀ | 2000 mL/ha |

First tier risk assessment for one application of GF-1374 at 1.5 L product/ha to grassland and 1.0 L product/ha cereals.

| Test substance | Species | Effect (LR ₅₀ mL/ha) | HQ in-field | HQ off-field ¹ | Trigger |
|---------------------|------------------------------|------------------------------------|-------------|---------------------------|---------|
| GF-1374 (grassland) | <i>Typhlodromus pyri</i> | 2000 | < 0.78 | < 0.01 | 2 |
| | <i>Aphidius rhopalosiphi</i> | 2000 | < 0.78 | < 0.01 | |
| | <i>Chrysoperla carnea</i> | 2000 | < 0.78 | < 0.01 | |
| GF-1374 (cereals) | <i>Typhlodromus pyri</i> | 2000 | < 0.52 | < 0.007 | |
| | <i>Aphidius rhopalosiphi</i> | 2000 | < 0.52 | < 0.007 | |
| | <i>Chrysoperla carnea</i> | 2000 | < 0.52 | < 0.007 | |

¹calculated on the drift rate of 2.77%

| |
|---|
| Semi-field tests |
| No effects were observed following laboratory testing in accordance with the requirements put forth in point 8.3.2 of Part A of the Annex to Regulation (EU) no 283/2013 point 10.3.2 Annex Regulation (EU) 284/2013. Since Annex trigger values were not breached under these scenarios, semi field testing is not required. |
| Field studies |
| Part A of the Annex Regulation (EU) No 283/2013 or in accordance with points 10.3.2.2 or 10.3.2.3 of Annex Regulation (EU) 284/2013. Calculated Risk Quotients (RQs) did not indicate risk to non-target arthropods so field testing was not required. |
| Additional specific test |
| Not needed |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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

| Test organism | Test substance | Application method of test a.s./ OM | Time scale | End point | Toxicity (mg a.s./kg sdw) |
|--|----------------|-------------------------------------|------------|-----------|---------------------------|
| Earthworms | | | | | |
| <i>Eisenia fetida</i> (Hayward 2001) | Clopyralid | Overspray / 10% OM | Chronic | 28 d NOEC | 1.97 |
| <i>Eisenia fetida</i> (Davies 2005) | GF-1374 | | Chronic | 56 d NOEC | > 59.3 |
| Other soil macroorganisms | | | | | |
| <i>Folsomia candida</i> (Ganssmann 2012a) | GF-1374 | Overspray / 5% OM | Chronic | NOEC | > 50 |
| <i>Hypoaspis aculeifer</i> (Ganssmann 2012a) | GF-1374 | | Chronic | NOEC | 100 |

Higher tier testing (e.g. modelling or field studies)
Not available, not required

Toxicity/exposure ratios for soil organisms

GF-1374 at 2 L product/ha x 1 application

| Test organism | Test substance | Time scale | Soil PEC ¹ | TER | Trigger |
|---------------------------|------------------------|------------|-----------------------|-------------------|---------|
| Earthworms | | | | | |
| <i>E. fetida</i> | Clopyralid (grassland) | Chronic | 0.016 | 123 | 5 |
| <i>E. fetida</i> | GF-1374 (grassland) | Chronic | 2.08 | 14.3 ² | 5 |
| <i>E. fetida</i> | Clopyralid (cereals) | Chronic | 0.107 | 18.4 | 5 |
| <i>E. fetida</i> | GF-1374 (cereals) | Chronic | 2.08 | 14.3 ² | 5 |
| Other soil macroorganisms | | | | | |
| <i>F. candida</i> | GF-1374 | Chronic | 2.08 | 12.0 | 5 |
| <i>H. aculeifer</i> | GF-1374 | Chronic | 2.08 | 24.0 | 5 |

¹Maximum PEC soil was used in the risk assessment

²Endpoint adjusted by a factor of 0.5 to allow for a high organic C content of soil

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

| Test type | Test substance | Max PEC _{soil} ¹ | Effects <25 % (mg/kg sdw) | TER |
|------------------|------------------------------|--------------------------------------|---------------------------|------|
| N transformation | Clopyralid (Schöbinger 2013) | 0.107 | 209 | 1953 |
| | GF-1374 (Rix 2005) | 2.08 | 13.9 | 6.68 |
| C transformation | Clopyralid (Schöbinger 2013) | 0.107 | 209 | 1953 |
| | GF-1374 (Rix 2005) | 2.08 | 13.9 | 6.68 |

¹Maximum PEC soil was used in the risk assessment

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 ER ₅₀ tests should be provided |
|---|

Laboratory dose response tests

| Species | Test substance | ER ₅₀ (mL product/ha) vegetative vigour | ER ₅₀ (mL product/ha) emergence | Exposure ¹ (mL product/ha) | TER | Trigger |
|------------------------------------|----------------|--|--|---------------------------------------|-------------|---------|
| <i>Lactuca sativa</i> (Eley 2005a) | GF-1374 | 21 | -- | 4.16 at 1 m 90% DRN | 5.04 | 5 |
| | | | | 2.14 5 m buffer with 75% DRN | 9.81 | |
| | | | | 10 m | 4.82 | |
| | | 11.5 ² | | 5 m 0% DRN | 1.35 | 1 |
| <i>Lactuca sativa</i> (Eley 2005b) | GF-1374 | -- | 460 | 41.6 at 1 m with 0% DRN | 11.1 | 5 |

Extended laboratory studies : Not necessary since low risk was demonstrated

Semi-field and field test: Not necessary since low risk was demonstrated

¹ exposure estimates have been estimated using application rate at the following % drift values (2.77% for 1m; 0.57% for 5 m; 0.29% for 10 m) assuming drift reducing nozzles (DRN)

²based on probabilistic assessment and 5th percentile

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

| Test type/organism | Test substance | End point |
|-----------------------|----------------|--|
| Activated sludge | Clopyralid | 3 h EC ₅₀ > 100 mg/L (Mallett 2000) |
| <i>Pseudomonas sp</i> | | No data available, not required |

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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.

Ecotoxicological monitoring data for the active substance clopyralid has not been submitted for review and not required.

Available monitoring data concerning effect of the PPP.

Ecotoxicological monitoring data for the plant protection product GF-1374 has not been submitted for review and not required.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

| Compartment | |
|-------------|------------|
| soil | Clopyralid |
| water | Clopyralid |
| sediment | Clopyralid |
| groundwater | Clopyralid |

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

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2017 | Clopyralid |

Section 5 Ecotoxicology

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

| | |
|--|---|
| Substance | Clopyralid |
| 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] ⁷ : | <p>Hazard pictograms</p> <p>GHS09 (environmental hazard)</p> <p>Signal word:</p> <p>Danger (health hazard) ; environmental classification would trigger signal word “Warning”, but only one signal word per classification is used and Danger takes precedence.</p> <p>Hazard statements: H410 (environmental hazard)</p> <p>Precautionary statements: P273 (environmental), P501 (environmental)</p> <p>Supplemental labelling: EUH401 (applies to all PPP products)</p> |
| Peer review proposal ⁸ for harmonised classification according to Regulation (EC) No 1272/2008: | |

⁷ 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.

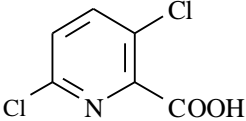
⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of Endpoints

| Rapporteur Member State | Month and year | Active substance |
|-------------------------|----------------|------------------|
| Finland | May 2016 | Clopyralid |

Appendix - Used compounds code(s)

Used compounds code(s)

| Code/Trivial name* | IUPAC name/SMILES notation | Structural formula |
|------------------------------------|---|---|
| Clopyralid | 3,6-dichloropyridine-2-carboxylic acid |  |
| GF-1374 Lot No. 187/76 A | <p>The representative formulation of clopyralid: Emulsifiable concentrate (EC) containing</p> <p>clopyralid 80 g/L</p> <p>fluroxypyr 144 g/L</p> <p>florasulam 2.5 g/L.</p> | |

* The compound code / trivial name in bold is the name used in the list of endpoints.