Appendix to:
EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(7):5389, 28 pp. doi:10.2903/j.efsa.2018.5389
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Appendix A — List of end points for the active substance and the representative formulation

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

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

| Active substance (ISO Common Name)          | Clopyralid          |
| Function (e.g. 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 or 3,6-dichloropicolinic 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 available                            |
| 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 | Open                                                                  |
| Molecular formula                          | C₆H₃Cl₂NO₂                                                     |
| Molar mass                                 | 191.96 g/mol                                                     |
| Structural formula                         | ![Structural formula](structure.png) |
**Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

| Property                                      | Value                  |
|-----------------------------------------------|------------------------|
| Melting point (state purity)                  | 149.6 ± 0.2 °C (99.8%) |
| Boiling point (state purity)                  | Decomposes at 164 ± 2 °C (99.8%)<br>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<br>Physical State - Powdery Solid |
|                                                | (99.8%): Color - white<br>Physical State - Crystalline Solid |
| Vapour pressure (state temperature, state purity) | 1.36x10^-6 kPa at 25°C (99.6%) |
| Henry’s law constant                          | **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<br>pH 5.0: 11.8 g/100 mL<br>pH 7.0: 14.3 g/100 mL<br>pH 9.0: 15.7 g/100 mL |
| Solubility in organic solvents (state temperature, state purity) | (95.9%): | xylene | 4.61 g/L<br>1,2-dichloroethane | 20.7 g/L<br>acetone | >250 g/L<br>ethyl acetate | 102 g/L |
|                                               | (96.4%): | n-hexane | 0.6% (wt/wt)<br>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%) |
| Partition coefficient (state temperature, pH and purity) | (20°C, 99.2%): pH 5 buffer: log _P_{OW} = -1.81<br>pH 7 buffer: log _P_{OW} = -2.63<br>pH 9 buffer: log _P_{OW} = -2.55 |
Dissociation constant (state purity)

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

| 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%)
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 | FG or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|-------------|--------------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Winter cereal (wheat, barley oat, rye, triticale, spelt) | CEU/S EU | GF-1374 | F | Broad-leaf weeds | EC | Clopyralid: 0.02 to 0.1 kg as/hL + Florasulam 0.0000625 to 0.0003125 kg as/hL + Fluroxypyr meptyl 0.036 to 0.18 kg as/hL (0.025 to 0.125 kg ae/hL) | 1 n/a | 80-400 | 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 | CEU/S EU | GF-1374 | F | Broadleaf weeds | EC | Clopyralid: 0.03 to 0.15 kg as/hL + Florasulam 0.00009375 to 0.00046875 kg as/hL + Fluroxypyr meptyl 0.144 kg as/ha (0.100 kg ae/ha) | 1 n/a | 100-400 | 7 to 14 days (see note 1) Dose: 1.5L GF-1374/ha. Note 1: PHI: 7 days for CEU and 14 days for SEU is the interval before any crop cutting or grazing. Fluroxypyr is the limiting factor. |
| Crop and/or situation (a) | Member State or Country | Product name | F or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|------------------------|--------------|------------|--------------------------------------|-------------|------------|-------------------------------|----------------|---------|
|                          |                        | flouroxypyr r) |            |                                      |             |            |                               |                |         |

(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
(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. flouroxypyr). 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)

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. Manure produced from animals fed on grass or forage treated with clopyralid can be used on or before the planting of crops such as grass, cereals and maize.
### Crop and/or situation (a)
- [Member State or Country]
- [Product name]

| FG or I (b) | Pests or Group of pests controlled (c) | Preparations (d-f) | Application (g) | Application rate per treatment (h) | PHI (days) (i) | Remarks (j) |
|-------------|--------------------------------------|--------------------|-----------------|-----------------------------------|---------------|------------|
|             |                                      | Type (Type)       | Conc. a.s. (Conc.) | method kind (Method) | range of growth stages & season (Stage) | number min-max (Number) | Interval between application (Interval) | kg a.s./L (kg) | Water L/ha (L) | kg a.s./ha min-max (kg) | PHI - minimum pre-harvest interval |

*Remarks:*

- (a) Crop and/or situation
- (b) Member State or Country
- (c) Pests or Group of pests controlled
- (d) Type
- (e) Conc. a.s.
- (f) Method kind
- (g) Range of growth stages & season
- (h) Number min-max
- (i) Interval between application
- (j) PHI - minimum pre-harvest interval

*Used must be indicated.*
**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 or G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|---------------------------|-------------------------|--------------|----------------|---------------------------------------|-------------|------------|-------------------------------|----------------|---------|
|                           |                         |              |                |                                       | Typ 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./ha min-max (l) | Water l/ha min-max (l) | 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. fluoroxypr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Further information, Efficacy
Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

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 GAP-table.

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.

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 has been evaluated. There are no relevant groundwater metabolites. Therefore, no assessment of biological activity is required.
Methods of Analysis

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

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

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

Residue definitions for monitoring purposes

| Food of plant origin | clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) pending the outstanding clarification on the nature of “polar clopyralid” |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Food of animal origin | Clopyralid and its salts |
| Soil                 | Clopyralid |
| Sediment             | Clopyralid |
| Water                | Clopyralid |
| 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) QuEChERS LC-MS/MS, LOQ = 0.01 mg/kg (wet and acidic 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) QuEChERS LC-MS/MS, LOQ = 0.01 mg/kg (fat and milk) Data gap: extraction efficiency |
| 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/m³ |
| Body fluids and tissues (analytical technique and LOQ)                                       | body fluids: LC-MS/MS (blood and urine) ; LOQ = 0.05 mg/L body tissues: LC-MS/MS |

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 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]¹:

| Substance | Classification |
|-----------|----------------|
| Clopyralid | none           |

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

| Substance | Proposal |
|-----------|----------|
| Clopyralid | none     |

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

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
## Section 2 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 | > 80% (based on urinary excretion after low dose, repeated dose and intravenous administrations (5 mg/kg bw) |
|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Toxicokinetics | Mice treated with 10 mg/kg bw: C<sub>max</sub>= 0.3% of TRR, T<sub>max</sub> 0.5h, T<sub>1/2</sub>= 11.2h |
| 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 48h), mainly via urine (≥ 71% within 24h, app. 1-4% via faeces) |
| Metabolism in animals | Not metabolised in rats |
| In vitro metabolism | No unique human metabolites formed; no observed metabolism |
| Toxicologically relevant compounds (animals and plants) | Clopyralid |
| Toxicologically relevant compounds (environment) | Clopyralid |

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

| Rat LD<sub>50</sub> oral | > 5000 mg/kg bw |
|--------------------------|-----------------|
| Rat LD<sub>50</sub> dermal | > 2000 mg/kg bw |
| Rat LC<sub>50</sub> inhalation | > 1.0 mg/L air/4h (nose only, highest attainable concentration) |
| Skin irritation | Non-irritant, however skin irritation was observed after 21-day dermal applications (H315) |
| Eye irritation | Severe irritant (H318) |
| Skin sensitisation | No acceptable study available; skin sensitisation potential could not be excluded (data gap) |
| Phototoxicity | No data - data gap (however there is no validated test method to address the phototoxicity of UVB absorbers) |

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

---
### Target organ / critical effect

| Animal          | Effect Description                                                                 |
|-----------------|-------------------------------------------------------------------------------------|
| Rat             | stomach (histopathological changes/acanthosis and folding of non-glandular epithelium of the limiting ridge) and kidney (weight ↑) |
| Mouse           | liver (relative weight ↑, microscopical changes)                                     |
| Dog             | haematological effects, liver (weight ↑)                                            |
| Rabbit (p.o.)   | stomach (erosion, ulceration)                                                      |
| Rabbit (dermal) | epidermal hyperplasia and inflammation of dermis                                    |

### Relevant oral NOAEL

- 28-day, rat: < 150 mg/kg bw per day
- 90-day, mouse: 750 mg/kg bw per day
- 1-year, dog: 100 mg/kg bw per day
- 13-day, rabbit: < 350 mg/kg bw per day

### Relevant dermal NOAEL

- 21-day, rabbit: Systemic: 1000 mg/kg bw per day (highest dose tested)
- Local: < 100 mg/kg bw per day

### Relevant inhalation NOAEL

No data – data not required

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

#### In vitro studies

- Ames test: negative
- In vitro mammalian cell forward mutation: negative
- In vitro chromosome aberration test: equivocal

#### In vitro spiked impurities:

- Ames test: negative
- In vitro mammalian cell forward mutation test: negative
- In vitro chromosome aberration test: negative

#### In vivo studies

- Clopyralid spiked impurities:
- In vivo micronucleus test: No evidence for bone marrow exposure

#### Photomutagenicity

No data - data gap (however there is no validated test guideline available to address this endpoint)

#### Potential for genotoxicity

Unlikely to have a genotoxic potential

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

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

| Animal | Effect Description |
|--------|--------------------|
| Rat    | Stomach (lesions of the gastric limiting ridge)  |
| Mouse  | body weight ↓, alkaline phosphatase ↓ |
### 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 & 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 (highest dose tested) |
|----------|--------------------------------------------------------|
|          | 2-year, mouse: 2000 mg/kg bw per day (highest dose tested) |

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

#### Reproduction toxicity

- **Reproduction target / critical effect**
  - Study of limited reliability due to deviations from the test guidelines and uncertainty on the doses tested
  - Parental: no clear systemic effects.
  - Offspring: reduction in organ weights, reduced terminal body weight
  - Reproductive: no adverse effects

- **Relevant parental NOAEL**
  - Rat: 825 mg/kg bw per day
  - Rabbit: < 50 mg/kg bw per day

- **Relevant reproductive NOAEL**
  - Rat: 825 mg/kg bw per day
  - Rabbit: < 50 mg/kg bw per day

- **Relevant offspring NOAEL**
  - Rat: 275 mg/kg bw per day

### Developmental toxicity

#### Developmental target / critical effect

- **Rat** (study of limited reliability since no validated analytical method was reported):
  - Maternal toxicity: decreased corrected maternal bodyweight gain; at higher dose level (250 mg/kg bw per day): mortality
  - Developmental toxicity: malformations (hemivertebrae and polydactyly)

- **Rabbit**:
  - Maternal toxicity: body weight gain↓, gastric lesions, clinical signs, morbidity; at higher dose level (250 mg/kg bw per day): mortality
  - Developmental toxicity: mean foetal weight↓, delayed ossification, increased malformations (hydrocephaly, severe forelimb flexure at the highest dose level)

#### Relevant maternal NOAEL

|          | Rat: 15 mg/kg bw per day |
|----------|--------------------------|
|          | Rabbit: < 50 mg/kg bw per day |

#### Relevant developmental NOAEL

|          | Rat: 75 mg/kg bw per day |
|----------|--------------------------|
|          | Rabbit: < 50 mg/kg bw per day |
Neurotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.7)

| Neurotoxicity                                | Study  |
|----------------------------------------------|--------|
| Acute neurotoxicity                         | Not reqd. |
| Repeated neurotoxicity                      | Not reqd. |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No studies submitted |

Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)

| Study on the active substance | Details |
|-------------------------------|---------|
| Supplementary studies on the active substance | Assessment of immunotoxic potential of clopyralid, after 28-day dietary exposure to rats: NOAEL 150 mg/kg bw per day (increased thymus weight) |
| Endocrine disrupting properties | Unlikely to produce endocrine mediated adverse effects |
| Studies performed on metabolites or impurities | No studies submitted |

Medical data (Regulation (EU) No 283/2013, Annex Part A, point 5.9)

| No detrimental effects on health in manufacturing personnel. |

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

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|----------------------------|-------|--------------------|
| Acceptable Daily Intake (ADI) | 0.15(1) | rat, 2-year chronic toxicity and oncogenicity study | 100 |
| Acute Reference Dose (ARfD) | 0.17(2) | rabbit, developmental toxicity | 300 |
| Acceptable Operator Exposure Level (AOEL) | 0.15(3) | rat, developmental study | 100(4) |
| Acute Acceptable Operator Exposure Level (AAOEL) | 0.17(2) | rabbit, developmental toxicity | 300(4) |

(1) same as previously set (EFSA, 2006 and European Commission, 2006)
(2) previously not established (EFSA, 2006 and European Commission, 2006)
(3) previous value: 1 mg/kg bw per day (EFSA, 2006 and European Commission, 2006)
(4) no correction needed regarding oral absorption/bioavailability

Dermal absorption (Regulation (EU) No 284/2013, Annex Part A, point 7.3)

(1) If available include also reference values for metabolites
Representative formulation (GF-1374, EC formulation containing 80 g clopyralid/L)

Concentrate: 25 %
Spray dilution: 75 %
Default dermal absorption values according to Guidance on Dermal Absorption (EFSA PPR Panel, 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

Exposure to clopyralid alone:

| Exposure estimates (model): | % of AOEL |
|-----------------------------|-----------|
| UK POEM                     |           |
| Without PPE:                | 583       |
| PPE (gloves):               | 82        |
| German model                |           |
| Without PPE:                | 244       |
| PPE (gloves, coverall, sturdy footwear): | 16 |
| EFSA calculator             |           |
| Without PPE:                | 101       |
| PPE (gloves and work wear): | 3         |

| Exposure estimates (model): | % of AAOEL |
|-----------------------------|------------|
| Without PPE:                | 560        |
| PPE (gloves and work wear): | 41         |

Combined exposure to clopyralid, florasulam and fluoroxypry-meptyl:

| Exposure estimates (model): | % combined exposure |
|-----------------------------|---------------------|
| UK POEM                     |                      |
| Without PPE:                | 865                  |
| PPE (gloves):               | 121                  |
| German model                |                      |
| Without PPE:                | 366                  |
| PPE (gloves, coverall, sturdy footwear): | 71 |
| EFSA calculator             |                      |
| Without PPE:                | 193                  |
| PPE (gloves and work wear): | 5                    |

Workers

Exposure to clopyralid alone:

Crop inspection

| % of AOEL |
|-----------|
| 15        |

EUROPOEM II

| Without PPE: | 8 |
|---------------|---|
| EFSA calculator |   |
### Combined exposure to clopyralid, florasulam and fluoroxypr-mepyl:

| Crop inspection                                                                 | % combined exposure |
|---------------------------------------------------------------------------------|---------------------|
| **EUROPOEM II**                                                                 |                     |
| Without PPE:                                                                    | 21                  |
| EFSA calculator                                                                 |                     |
| Without PPE (Work wear – arms, body and legs covered):                          | 12                  |

#### Bystanders and residents

| **Exposure to clopyralid alone:**                                               | % of AOEL          |
|---------------------------------------------------------------------------------|-------------------|
| **Bystander**                                                                   |                   |
| EUROPOEM II:                                                                    | 2                 |
| Martin et al.                                                                   |                   |
| adult:                                                                         | 6                 |
| child:                                                                         | 7                 |
| Exposure to vapours                                                            |                   |
| adult:                                                                         | 0.15              |
| child:                                                                         | 0.7               |
| EFSA calculator                                                                |                   |
| adult:                                                                         | 22                |
| child:                                                                         | 39                |

**Resident**

| Martin et al.                                                                   |                   |
| adult:                                                                         | 0.39              |
| child:                                                                         | 0.64              |
| EFSA calculator                                                                |                   |
| adult:                                                                         | 3                 |
| child:                                                                         | 12                |

| **Combined exposure to clopyralid, florasulam and fluoroxypr-mepyl:**          | % combined exposure |
|---------------------------------------------------------------------------------|---------------------|
| **Bystander**                                                                   |                     |
| EUROPOEM II:                                                                    | 3                  |
| Martin et al.                                                                   |                   |
| adult:                                                                         | 9                 |
| child:                                                                         | 10                |
| Exposure to vapours                                                            |                   |
| adult:                                                                         | 0.64              |
| child:                                                                         | 3                 |
| **Resident**                                                                   |                   |
| Martin et al.                                                                   |                   |
| adult:                                                                         | 1                 |
| child:                                                                         | 2                 |
| EFSA calculator                                                                |                   |
| adult:                                                                         | 5                 |
| child:                                                                         | 19                |

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:

| Substance | Classification and Description |
|-----------|-------------------------------|
| Clopyralid | Eye Dam. 1 - H318 ‘Causes serious eye damage’ |
|           | Eye Dam. 1 - H318 ‘Causes serious eye damage’ |
|           | Skin Irrit. 2 – H315 ‘Causes skin irritation’ |
|           | STOT RE 2 – H373 ‘May cause damage to organs through prolonged or repeated exposure’ |
|           | Repr. 2 – H361d ‘Suspected of damaging the unborn child’ |

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

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

Metabolism in plants (Regulation (EU) No 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|--------------------------------------|-------------|---------|----------------|------------|
| Fruit crops                          |             |         |                |            |
| Root crops                           | sugarbeet   | 300 g as/ha, foliar, BBCH 36, | 0, 28 and 105 d (maturity) |
| Leafy crops                          | cabbage    | 420 g as/ha, foliar, BBCH 31 (at the 8 – 10 leaf stage) | 0, 5 and 38d |
| Cereals/grass crops                  | oilseed rape | 300 g as/ha, foliar BBCH 36, | 0, 28 and 77 d (maturity) |
| Pulses/Oilseeds                      |             |         |                |            |

All 3 studies are GLP and guideline compliant and conducted with radiolabelled clopyralid. Characterisation of metabolism is limited in the study with cabbage as the extraction was performed with caustic methanol implying a cleavage of the potentially present conjugates.

Of cereals only uptake of clopyralid into wheat in a hydroponic setting has been studied. An overdosed (1.121 kg as/ha) and non-GLP and non/guideline compliant study on pasture grass provided limited insight in metabolism as extraction was done with caustic methanol and only parent was detected.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| Root/tuber crops                     | Turnip, Radish | 125, 319 30 | The 30 DAT mature cabbage was harvested at 128 days (9+ leaves/head; heads failed to fully close due to heat, BBCH 53). |
| Leafy crops                          | Lettuce, Cabbage | 125, 319 30 |
| Cereal (small grain)                 | Wheat | 30, 125, 319 |
| Other                                | Soybean (green plant and beans) | 125, 319 |

Rotational crop and primary crop metabolism similar? Yes

| Processed commodities (standard hydrolysis study) | 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 also major residue and included in the proposed residue definitions.
### Plant residue definition for monitoring (RD-Mo)  
OECD Guidance, series on pesticides No 31

Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid”

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

Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar 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.s./kg feed per day, equivalent to 0.56-0.65 mg/kg bw per day | 7 | N rates can be established only once HR and STMR for cereal straw and grass from valid residue trials are available. |
| | Goat/Cow | 50.9 mg a.s./kg dry feed/day equivalent to 0.484 mg/kg bw per day | 5 | N rates can be established only once HR and STMR for cereal straw and grass from valid residue trials are available. |
| | Pig | Not considered necessary. | | |
| | Fish | No studies submitted. | | |

In milk over 21% of TRR (corresponding to 0.002 mg eq/kg) was found as clopyralid-glycine conjugate (X36538). Clopyralid comprised from 54% to over 70% of the TRR in milk, urine and faeces.

In the tissues unchanged clopyralid was the major residue along with minor amounts of conjugate X36538.

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

For clopyralid residues in milk dosing was once a day and the residues had already declined to low levels within one day. Any accumulating potential could not
be demonstrated. Plateau was reached at day 1. For eggs residue levels are still slightly increasing at the end of the experiment, i.e. after 7 days of dosing, but a plateau can be assumed at day 7.

| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | clopyralid and its salts |
| Animal residue definition for risk assessment (RD-RA) | clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) |
| Conversion factor (monitoring to risk assessment) | The conversion factor monitoring / risk assessment is only relevant for milk and is based on the new ruminant metabolism study as 1.3. |
| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Fat soluble residues (Yes/No) (FAO, 2009) | No |

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 conjugates (up to 81%TRR) most abundant residue at all PBIs. Unconjugated clopyralid correspond from 10 to 50 %TRR. Clopyralid taken up by the plants as glucose conjugate of clopyralid

Field rotational crop study OECD Guideline 504
Data gap: Rotational crop field trials according to current guidelines should be submitted as residues of free and conjugated parent were found in all plant parts at PHI 30.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1) OECD Guideline 506

| Plant products (Category) | Commodity          | T (°C) | Stability (Months) |
|--------------------------|--------------------|--------|--------------------|
| High water content       | Pasture grass      | -20    | 17                 |
|                          | Maize fodder forage| -20    | 13                 |
| High oil content         | Oilseed rape       | -20    | 24                 |
|                          | Olive (fruit and oil) | -18  | 10                 |
| High protein content     |                    |        |                    |
| High starch content      | Maize              | -20    | 13                 |
Stability of conjugates has not been tested, though clopyralid conjugates are major metabolites comprising up to 50 % of TRR depending on crop studied. It is assumed that conjugated clopyralid will be also stable.

| Animal     | Animal commodity | T (°C) | Stability (Months) |
|------------|------------------|--------|--------------------|
| Bovine     | Muscle           | -20    | 19                 |
| Bovine     | Liver            | -20    | 19                 |
| Bovine     | Kidney           | -20    | 19                 |
| Bovine     | Milk             | -20    | 19                 |
| Hen        | Egg              | -20    | 19                 |
| Bovine     | Fat              | -20    | 24                 |

Stability of conjugates has not been tested, though clopyralid conjugates are major metabolites as well. It is assumed that conjugated clopyralid will be also stable.
## 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             |                                                                                                 | Sufficient number of valid field trials seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible. |
| Grass forage / pasture        | S-EU             |                                                                                                 | Sufficient number of valid field trials seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible. |
| Cereal grain (barley and wheat) | N-EU             |                                                                                                 | Sufficient number of valid field trials seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible. |
| Cereal grain (barley and wheat) | S-EU             |                                                                                                 | Sufficient number of valid field trials seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible. |
| Cereal straw (barley and wheat) | N-EU             |                                                                                                 | Sufficient number of valid field trials seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible. |
| Cereal straw                  | S-EU             |                                                                                                 | Sufficient number of valid field trials |

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(barley and wheat) seems to be available but due to inconsistent reporting in the RAR a transparent evaluation and calculation of STMR was not possible.

### 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 |
|------------|--------|----------------------|-------------------------|
|            |        |                      |                         |

No data available (data gap).

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

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

(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, **HR** according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).

(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<sub>Mo</sub>).
## Inputs for animal burden calculations

| Feed commodity                  | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) | Comment |
|---------------------------------|------------------------------|--------------------------------|---------|
| **Pasture**                     |                              |                                |         |
| **Wheat grain and straw**       |                              |                                |         |
| **Barley grain and straw**      |                              |                                |         |

*Representative uses (row to be deleted if not relevant)*

Values to be calculated from valid residue trials
### Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

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

MRL calculation is pending the presentation of residue values from valid residue trials for the representative uses on cereals and grass.

| Highest expected intake (mg/kg bw/d) | Beef cattle | Ram/Ewe | Breeding | Broiler | Poultry | Fish |
|-------------------------------------|-------------|---------|----------|---------|---------|------|
| (mg/kg DM for fish)                 | Dairy cattle | Lamb    | Finishing | Layer   | Turkey  | 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 – but not valid for RA | Yes | No study submitted |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Beef: Dairy: | Sheep: Ewe: | Level | 1 N rate Breed/Finish | Level | B or T: Layer: | 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 | Fat | Meat(b) | Liver | Kidney | Milk(a) | Eggs | Method of calculation(c) |
|-------------------------|-------|------|--------|-------|--------|--------|-----|--------------------------|
| Estimated HR calculated at 1N level (estimated mean level for milk). |
| HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry |
| 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.
STMR Calculation is pending the presentation of residue values from valid residue trials for the representative uses on cereals and grass.

| STMR calculations | Ruminant | Pig/Swine | Poultry | Fish |
|-------------------|----------|-----------|---------|------|
| **Median expected intake** (mg/kg bw/d) | Beef cattle | Ram/Ewe | Breeding | Broiler |
| (mg/kg DM for fish) | Dairy cattle | Lamb | Finishing | Layer |
| | | | | Turkey |
| **Representative feeding level** (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: Dairy: | Level | Lamb: Ewe: | Level | Level | B or T: | Level | N rate |
| | Mean level in feeding level | Mean level in feeding level | Estimated STMR(b) at 1N | 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 | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fat | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Meat(a) | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Liver | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Kidney | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Milk | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Eggs | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method of calculation(c) | --- | --- | --- | --- | --- | --- | --- | --- | --- |

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

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

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

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         | N/A          |         |         |         | N/A     |         |         |         |
| Fat            | N/A          |         |         |         | N/A     |         |         |         |
| Liver          | N/A          |         |         |         | N/A     |         |         |         |
| Kidney         | N/A          |         |         |         | N/A     |         |         |         |
| Milk           | 10           |         |         |         | N/A     |         |         |         |
| Egg            | N/A          |         |         |         |         |         | 2       |         |

Comments (up to 250 characters)

The values above are based on radio-probed metabolism studies.

In some egg samples only 52 %TRR was identified as clopyralid, otherwise CF=1 in other egg samples.

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              |                                 |
| 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                             |
| 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                             |

\(^{(a)}\): 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)

The consumer risk assessment is pending the presentation of residue values from valid residue trials for the representative uses on cereals and grass and the resulting calculation of the MRL and STMR for animal commodities.

Consumer risk assessment limited to the representative uses
ADIs

| ADI                          | Value       |
|------------------------------|-------------|
| TMDI (% ADI), according to EFSA PRIMo | 0.15 mg/kg bw/day |
| 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

ARfDs

| ARfD                          | Value       |
|------------------------------|-------------|
| IESTI (% ARfD, according to EFSA PRIMo) | 0.17 mg/kg bw |
| NESTI (% ARfD, according to (to be specified) |                      |

Factors included in IESTI and NESTI

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)

| Barley grain | Cereal         | Pending presentation of valid residue trials |
|--------------|----------------|-----------------------------------------------|
| Wheat grain  | Cereal         | Pending presentation of valid residue trials |

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
Section 4 Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.1)

| Mineralisation after 100 days | CO₂: 47.5 – 70.3 % AR after 90-92 days 20 °C, [2,6-pyridinyl-14C]-label (n=9) |
|------------------------------|----------------------------------------------------------------------------------|
| Non-extractable residues after 100 days | 11.2 – 35.1 % of AR after 90-92 days at 20 °C, [2,6-pyridinyl-14C]-label (n=9) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | None |

Route of degradation (anaerobic) in soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.2)

| Mineralisation after 100 days | No mineralisation |
|------------------------------|-------------------|
| Non-extractable residues after 100 days | Non-extractable residues 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-14C]-label (n=1) |

Route of degradation (photolysis) on soil (Regulation (EU) No 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. |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Mineralisation at study end | 3 % CO₂ after 30 days |
| | 2.1 % CO₂ after 16 days |
| | [2,6-pyridinyl-14C]-label (n=2) |
| Non-extractable residues at study end | max 5 % of AR after 30 days |
| | 4.3 % of AR after 16 days |
| | [2,6-pyridinyl-14C]-label (n=2) |
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                  | Biomass mgC/100 g       | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | DT<sub>50</sub> (d) 20 °C pF2/10kPa<sup>b</sup> | St. (χ<sup>2</sup>) | Method of calculation |
| Parabraunerde (silt loam) | 47                      | 7.7 | 20 / 18.63<sup>c</sup> | 44.4 / 147.3 | 34.2 | 6.796 | SFO |
| Marcham (sandy clay loam)  | 170                     | 8.3 | 20 / 20.19<sup>c</sup> | 34.5 / 114.7 | 32.4 | 5.478 | SFO |
| Castle Rising (sandy loam)| 313                     | 8   | 20 / 65.13<sup>c</sup> | 26.3 / 87.3 | 26.3 | 8.284 | SFO |
| Speyer 2.1 (sand)          | NA                      | 6.5 | 20 / 12.58<sup>c</sup> | 64.6 / 214.6 | 64.6 | 5.466 | SFO |
| Speyer 2.2 (sand)          | 110                     | 6.3 | 20 / 18.56<sup>c</sup> | 16.2 / 53.8 | 16.2 | 7.78  | SFO |
| Marshall county (silt loam)| 11.92                   | 6   | 25 / 23.42<sup>d</sup> | 8.6 / 28.5  | 11.6 | 6.49  | SFO |
| A (sandy loam)             | 33.2                    | 6.2 | 20 / 24.28<sup>e</sup> | 16.5 / 54.8 | 16.5 | 4.856 | SFO |
| B (clay loam)              | 78.2                    | 7.6 | 20 / 28.05<sup>e</sup> | 23 / 76.4   | 23.0 | 6.767 | SFO |
| C (clay loam)              | 48.5                    | 5.6 | 20 / 48.17<sup>e</sup> | 4.9 / 16.2  | 4.9  | 12.73 | SFO |
| D (loam)                   | 70.9                    | 7.5 | 20 / 35.30<sup>e</sup> | 9.8 / 32.4  | 9.8  | 10.17 | SFO |
| Geometric mean (if not pH dependent) |                       |    | 19.1 |                |     |       |     |

pH dependence: No

<sup>a</sup> Measured in water
<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
<sup>c</sup> Reported soil moisture: 40% of maximum WHC
<sup>d</sup> Reported soil moisture: 75% of 1/3 bar WHC
<sup>e</sup> Reported soil moisture: 45% WHC
Field studies, 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                  | Location (country or USA state) | pH | Depth (cm) | DT$_{50}$ (d) actual | DT$_{90}$ (d) actual | St. ($\chi^2$) | DT$_{50}$ (d) Norm | Method of calculation |
|-------------------------|---------------------------------|----|------------|---------------------|---------------------|----------------|-------------------|---------------------|
| Loamy sand (bare)       | Bargstedt, Germany              | 4.3| 0-100      | 21                  | 69.6                | 23.9           | 13                | SFO                 |
| Loam (bare)             | Wilson, UK                      | 6.2| 0-100      | 16.7                | 55.6                | 22.6           | 13.5              | SFO                 |
| Silty clay loam (bare)  | Sermaises, France               | 7  | 0-100      | 16.3                | 54                  | 19.3           | 7.5               | SFO                 |
| Silty clay loam (bare)  | Ansonville, France              | 8.2| 0-20       | 0.16                | 12.1                | 5.36           | 2.07              | DFOP / SFO Norm     |
| Clay loam (bare)        | Mainbervilliers, France         | 7.1| 0-20       | 6.04                | 28.3                | 7.22           | 2.7               | DFOP / SFO Norm     |
| Silty clay loam (bare)  | Oederquart, Germany             | 7.5| 0-20       | 16.2                | 53.9                | 12             | 5.69              | SFO                 |
| Sandy clay loam (bare)  | Middlefart, Denmark             | 7.5| 0-20       | 23.7                | 78.7                | 13.1           | 8.46              | SFO                 |
| Clay loam (bare)        | Canals, Spain                   | 8.0| 0-100      | 13.7                | 45.5                | 19.2           | 12.3              | SFO                 |
| Silty clay loam (bare)  | B. Württemberg, Germany         | 7.4⁺| 0-100      | 10.2                | 33.9                | 7.94           | 9.34              | SFO                 |
| Silt loam (bare)        | B. d’Islemade, France           | 7.3⁺| 0-100      | 9.11                | 30.3                | 17.6           | 7.41              | SFO                 |

| Geometric mean (if not pH dependent) | 7.05 |

**pH dependence**

|                              | No    |

| Notes: a) Measured in water b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix c) 0-30 cm |

**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)                |
| Kinetic formation fraction ($f_{f/k_d}$) of transformation products, arithmetic mean                                 |

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.
Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

| Parent | Dark anaerobic conditions |
|--------|---------------------------|
| Soil type | Biomass mgC/100 g | pH\(\text{a)}\) | t. °C / % MWHC | DT\(_{50}\) / DT\(_{90}\) (d) | DT\(_{50}\) (d) 20 °C\(\text{b)}\) | St. \(\chi^2\) | Method of calculation |
| Sandy loam | 8.9 | 7.4 | 20 / flooded | >1 year | > 1 year | n/a | First-order |

Geometric mean (if not pH dependent)

\(\text{a)}\) Measured in 0.01M CaCl2
\(\text{b)}\) Normalised using a Q10 of 2.58

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

\(\text{a)}\) Measured in water
\(\text{b)}\) Not reported

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)
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 | 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$^b$ | 0.9$^c$ |
| Kaldenkirchen | 0.98 | 5.34 | 0.048 | 0.0267 | 2.72$^b$ | 0.9$^c$ |
| Lanna | 2.06 | 6.62 | 0.151 | 0.0054 | 0.26$^b$ | 0.9$^c$ |
| Overhetfeld | 0.93 | 6.49 | 0.032 | 0.0125 | 1.34$^b$ | 0.9$^c$ |
| 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 | 0.9$^c$ |
| LUFA 2.1 loamy sand | 0.68 | 4.9 | 0.040$^b$ | 0.03 | 4.1 | 0.9$^c$ |
| 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)*

| Geometric mean (if not pH dependent)* | 0.026 | 1.41 |

Arithmetic mean (if not pH dependent)

| Arithmetic mean (if not pH dependent) | 0.836 |

pH dependence

| 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.

* Only relevant after implementation of the published EFSA guidance.

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 |

| Column leaching | 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 |

| Column leaching | Not relevant |
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. Unidentified radioactivity was 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. (It was considered very unlikely that a single unknown substance would exceed an annual concentration of 0.1 μg/L.)

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).
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  | DT₅₀/DT₉₀ > 1 year (Smith 2000) |
|-----|-------------------------------|
| 4   |                               |
| 7   |                               |
| 9   |                               |

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

Photolytic degradation of active substance and metabolites above 10 %

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 $\lambda > 290$ nm

1.01 x· 10⁻⁶ mol · 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)

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) | DT₅₀/DT₉₀ whole sys. (suspended sediment test) | St. (χ²) | DT₅₀ /DT₉₀ Water (pelagic test) | St. (χ²) | Method of calculation |
|--------|--------------------------------------------------------|----------------|-----------|----------|-----------------------------------------------|-----------|---------------------------------|-----------|----------------------|
|        | Fresh water (lake), 10.3 µg/L                         | 7.3            | NA        | 20       | NA                                            | NA        | Stable                          | NA        | No degradation        |
|        | Fresh water (lake), 83.1 µg/L                          | 7.3            | NA        | 20       | NA                                            | NA        | Stable                          | 1107 d    | 0.75 / 47             |

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) |
|----------------------------------------------------------|----------------|--------|-----------------------------------------------------|---------------------------------------------------------------------|
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)                                          |
| Loamy sand |            | 6.5                                                                              | >500 days                                                                      |
| Sandy silt loam |        | 8.16                                                                             | >500 days                                                                      |
|        |            | Geometric mean at 20°Cb)                                                        |                                                                                |
|        |            |                                                                                  | 148                                                                             |

| Method of calculation | DT_{50} /DT_{90} water | DT_{50} /DT_{90} sed | St. (χ^2) |
|----------------------|------------------------|----------------------|------------|
| Loamy sand            | n/a                    | n/a                  | 128        |
| Sandy silt loam       | n/a                    | n/a                  | 167        |

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58

(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 DT_{50} = 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: Clopyralid                                                              |                  |
### Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

### Monitoring data, if available (Regulation (EU) No 283/2013, Annex Part A, point 7.5)

| Type of Study | Details |
|--------------|---------|
| Soil | No data provided nor required. |
| Surface water | Survey on monitoring data in Europe in 2006-2015 (Aldous & al. 2015):
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 µg l⁻¹ in ≥4,172 samples which represented ≤19.71% of all samples. However, there were LoDs >0.1 µg l⁻¹ and this has exaggerated the number of samples exceeding the limit. Maximum concentrations in excess of the 0.1 µg l⁻¹ drinking water limit were reported in the Czech Republic, Finland, France, Norway, Slovakia, Sweden, Switzerland and the United Kingdom (England, and Scotland). |
| Ground water | Survey on monitoring data in Europe in 2007-2015 (Aldous & al. 2015):
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 µg l⁻¹ drinking water limit in ≤0.35% of groundwater samples (≤85 samples). Maximum concentrations in excess of 0.1 µg 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 µg l⁻¹ was reported in the Czech Republic. |
| Air | No data provided nor required. |

### PEC soil (Regulation (EU) No 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

| Source | DT₅₀ (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/cm³
% 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<sub>so</sub> (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<sub>so</sub> (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                                    |                            |                                          |
| 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) No 284/2013, Annex Part A, point 9.2.4.1)

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

| 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 / 0.0002711 |
| Water solubility (mg/L): 1.43 x 10^5 at pH 7 and 20°C |
| Vapour pressure: set to 0 Pa as worst case |
| Geometric mean parent DT_50 field 7.05 d (n = 10) (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.

1 Tier 1 / Tier 2; Tier 2 value according to Briggs equation (Briggs et al., 1982) with log(K_{OW}) = -2.63

\[ TSCF = 0.774 \exp\left[-\left(\log K_{OW} - 1.78\right)^2/2.44\right] \]
PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to winter cereals 1 x 80 g clopyralid/ha. TSCF = 0 / 0.000271.*

| Scenario          | Parent (µg/L) |          |          |          |          |
|-------------------|---------------|----------|----------|----------|----------|
|                   |               | 1-Feb    | 1-Mar    | 1-Apr    | 1-May    | 1-Jun    |
| Chateaudun        | 0.022         | 0.006    | 0.006    | 0.013    | 0.012    |
| Hamburg           | 0.354         | 0.205    | 0.118    | 0.213    | 0.494    |
| Jokioinen         | 0.577         | 0.279    | 0.182    | 0.196    | 0.334    |
| Kremsmunster      | 0.220         | 0.107    | 0.119    | 0.121    | 0.143    |
| Okehampton        | 0.375         | 0.205    | 0.115    | 0.193    | 0.222    |
| Piacenza          | 0.164         | 0.080    | 0.066    | 0.046    | 0.009    |
| Porto             | 0.386         | 0.056    | 0.015    | 0.007    | 0.001    |
| Sevilla           | <0.001        | <0.001   | <0.001   | <0.001   | <0.001   |
| Thiva             | 0.001         | <0.001   | <0.001   | <0.001   | <0.001   |

| Scenario          | Parent (µg/L) |          |          |          |          |
|-------------------|---------------|----------|----------|----------|----------|
|                   |               | 1-Feb    | 1-Mar    | 1-Apr    | 1-May    | 1-Jun    |
| Chateaudun        | 0.015         | 0.009    | 0.005    | 0.005    | 0.003    |
| Hamburg           | 0.983         | 0.521    | 0.134    | 0.052/0.051 | 0.079   |
| Jokioinen         | 3.181/3.180   | 2.427/2.426 | 0.774   | 0.229    | 0.303    |
| Kremsmunster      | 0.418         | 0.190    | 0.160    | 0.104    | 0.125    |
| Okehampton        | 0.832         | 0.574    | 0.177    | 0.184    | 0.225    |
| Piacenza          | 0.804         | 0.224    | 0.151    | 0.030    | 0.004    |
| Porto             | 1.847         | 0.167    | 0.014    | 0.006    | 0.002    |
| Sevilla           | 0.004         | <0.001   | <0.001   | <0.001   | <0.001   |
| Thiva             | 0.011         | <0.001   | <0.001   | <0.001   | <0.001   |

*If the same PECgw value has been obtained using the TSCF value of 0 and 0.000271, the PECgw value has been presented only once.

| Scenario (TSCF = 0) | Parent (µg/L) |          |          |          |          |
|---------------------|---------------|----------|----------|----------|----------|
|                     |               | 1-Feb    | 1-Mar    | 1-Apr    | 1-May    | 1-Jun    |
| Chateaudun          | 0.024         | 0.006    | 0.003    | 0.004    | 0.002    |
PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) following annual application to grassland 1 x 120 g clopyralid/ha. TSCF = 0 / 0.000271.*

| Scenario | Parent (µg/L) |
|----------|---------------|
|          | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun | 1-Jul | 1-Aug |
| Chateaudun | 0.008 | 0.004 | 0.005 | 0.004 | 0.002 | 0.004 | 0.007 |
| Hamburg   | 0.0021 | 0.015 | 0.010 | 0.017 | 0.027 | 0.056 | 0.119 |
| Jokioinen | 0.130  | 0.069 | 0.046 | 0.031 | 0.055 | 0.054 | 0.145 |
| Kremsmunster | 0.026 | 0.009 | 0.008 | 0.008 | 0.006 | 0.011 | 0.019 |
| Okehampton | 0.066  | 0.034 | 0.009 | 0.009 | 0.015 | 0.015 | 0.024 |
| Piacenza  | 0.043  | 0.020 | 0.009 | 0.004 | 0.002 | 0.001 | 0.010 |
| Porto     | 0.068  | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | <0.001 |
| 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 |

*=If the same PECgw value has been obtained using the TSCF value of 0 and 0.000271, the PECgw value has been presented only once.

| Scenario | Parent (µg/L) |
|----------|---------------|
|          | 1-Feb | 1-Mar | 1-Apr | 1-May | 1-Jun | 1-Jul | 1-Aug |
| Chateaudun | 0.005 | 0.002 | 0.001 | 0.003 | 0.002 | 0.003 | 0.007 |
| Hamburg   | 0.071  | 0.034 | 0.009 | 0.004 | 0.008 | 0.019 | 0.032 |
| Jokioinen | 0.358  | 0.262 | 0.077 | 0.029 | 0.040 | 0.041 | 0.131 |
| Kremsmunster | 0.034 | 0.010 | 0.009 | 0.008 | 0.007 | 0.016 | 0.022 |
| Okehampton | 0.098 | 0.061 | 0.014 | 0.017 | 0.019 | 0.020 | 0.018/0.017 |
| Piacenza  | 0.167/0.166 | 0.112 | 0.069 | 0.020 | 0.006 | 0.004 | 0.016 |
| Porto     | 0.226  | 0.048 | 0.016 | 0.004 | 0.001 | 0.001 | 0.004 |
| 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 | 0.008 | 0.002 | <0.001 | <0.001 | <0.001 | 0.001 | 0.005 |
**PEC<sub>gw</sub>** From lysimeter studies (4 studies in DE)

| Parent (µg/L) | 1<sup>st</sup> year | 2<sup>nd</sup> year | 3<sup>rd</sup> 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<sup>st</sup> year | 2<sup>nd</sup> year | 3<sup>rd</sup> year |
|---------------|---------------------|---------------------|---------------------|
| Annual average (µg/L) | - | - | - |

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

**Parent**

Parameters used in FOCUSsw step 1 and 2

- Version control no. of FOCUS calculator: FOCUS STEPS 1-2 v. 3.2
- Molecular weight (g/mol): 191.96
- $K_{FOC}$ (mL/g): 1.41 (geometric mean, n = 9)
- $DT_{50}$ soil (d): 7.05 d, field (geometric mean, n = 10)
- $DT_{50}$ water/sediment system (d): 1000 d (conservative FOCUS default)
- $DT_{50}$ water (d): 1000 d
- $DT_{50}$ sediment (d): 1000 d
- Crop interception (%): 0 % (minimal crop cover, winter cereals), 75% (full canopy, grassland)

Parameters used in FOCUSsw step 3 (if performed)

- 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)
- Water solubility (mg/L): $1.43 \times 10^5$
- Vapour pressure: $1.36 \times 10^{-3}$ Pa at 20°C
- $K_{FOC}$ (mL/g): 1.41 (geometric mean, n = 9)
- $1/n$: 0.836 (arithmetic mean, n = 9)
- $Q_{10}$=2.58
- Plant Uptake Factor: 0

**Application rate**

- Crop and growth stage: winter cereals BBCH 13, established grassland
- Number of applications: 1
- Interval (d): -
- Application rate(s): 80 g a.s./ha (winter cereals), 120 g a.s./ha (grassland)
- Application window: 30 days; start of application window: 1<sup>st</sup> of each month (Feb – Jun for winter cereals, Feb – Aug for grassland)
| FOCUS STEP 1 | Day after overall maximum | PECSW (µg/L) | PECSED (µg/kg) |
|--------------|---------------------------|--------------|----------------|
| Scenario     | Actual                    | Actual       |
| Winter cereals| 0 h                       | 27.4         | 0.385 (1-4 days after max. peak) |
| Grasland     | 0 h                       | 41.0         | 0.578 (1-2 days after max. peak) |

| FOCUS STEP 2 | Day after overall maximum | PECSW (µg/L) | PECSED (µg/kg) |
|--------------|---------------------------|--------------|----------------|
| Scenario     | Actual                    | Actual       |
| Northern EU / Winter cereals |                          |              |
| Oct - Feb    | 0 h                       | 9.71         | 0.137          |
| Mar - May    | 0 h                       | 4.33         | 0.061          |
| Jun - Sep    | 0 h                       | 4.33         | 0.061          |
| Southern EU / Winter cereals |                          |              |
| Oct - Feb    | 0 h                       | 7.92         | 0.112          |
| Mar - May    | 0 h                       | 7.92         | 0.112          |
| Jun - Sep    | 0 h                       | 6.12         | 0.086          |
### FOCUS STEP 2

| Scenario | Day after overall maximum | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) |
|----------|---------------------------|-----------------------------|-------------------------------|
|          |                           | Actual                      | Actual                        |
| Northern EU / Grassland          |                           |                             |                               |
| Oct - Feb                         | 0 h                       | 4.47                        | 0.063                         |
| Mar - May                          | 0 h                       | 2.45                        | 0.035                         |
| Jun - Sep                          | 0 h                       | 2.45                        | 0.035                         |
| Southern EU / Grassland           |                           |                             |                               |
| Oct - Feb                          | 0 h                       | 3.79                        | 0.053                         |
| Mar - May                          | 0 h                       | 3.79                        | 0.053                         |
| Jun - Sep                          | 0 h                       | 3.12                        | 0.044                         |

### FOCUS STEP 3 / Winter cereals – TSCF = 0

| Appl. period | Scenario | Water body | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) | Main entry route |
|--------------|----------|------------|------------------------------|-------------------------------|------------------|
| February     |          |            |                              |                               |                  |
| D1           | D1       | d          | 7.56                         | 2.15                          | Drainage         |
|               | D1       | s          | 4.84                         | 1.32                          | Drainage         |
|               | D2       | d          | 10.3                         | 1.45                          | Drainage         |
|               | D2       | s          | 6.89                         | 0.758                         | Drainage         |
|               | D3       | d          | 0.508                        | 0.030                         | Drift            |
|               | D4       | p          | 0.019                        | 0.011                         | Drift            |
|               | D4       | s          | 0.394                        | 0.008                         | Drift            |
|               | D5       | p          | 0.450                        | 0.279                         | Drainage         |
|               | D5       | s          | 2.61                         | 0.157                         | Drainage         |
|               | D6       | d          | 0.509                        | 0.028                         | Drift            |
|               | D6       | p          | 0.022                        | 0.012                         | Runoff           |
|               | R1       | s          | 0.928                        | 0.046                         | Runoff           |
|               | R3       | s          | 1.08                         | 0.063                         | Runoff           |
|               | R4       | s          | 0.336                        | 0.012                         | Drift            |
| March        |          |            |                              |                               |                  |
| D1           | D1       | d          | 10.1                         | 2.65                          | Drainage         |
|               | D1       | s          | 6.30                         | 1.64                          | Drainage         |
|               | D2       | d          | 7.95                         | 1.48                          | Drainage         |
|               | D2       | s          | 4.99                         | 0.905                         | Drainage         |
|               | D3       | d          | 0.508                        | 0.033                         | Drift            |
|               | D4       | p          | 0.018                        | 0.011                         | Drift            |
|               | D4       | s          | 0.402                        | 0.008                         | Drift            |
|               | D5       | p          | 0.018                        | 0.010                         | Drift            |
|               | D5       | s          | 0.401                        | 0.005                         | Drift            |
|               | D6       | d          | 0.540                        | 0.055                         | Drift            |
|               | R1       | p          | 0.040                        | 0.021                         | Runoff           |
|               | R1       | s          | 1.08                         | 0.067                         | Runoff           |
|               | R3       | s          | 3.10                         | 0.201                         | Runoff           |
|               | R4       | s          | 0.334                        | 0.011                         | Drift            |
| April        |          |            |                              |                               |                  |
| D1           | D1       | d          | 11.2                         | 2.55                          | Drainage         |
|               | D1       | s          | 7.03                         | 1.41                          | Drainage         |
|               | D2       | d          | 10.7                         | 1.64                          | Drainage         |
|               | D2       | s          | 7.12                         | 0.923                         | Drainage         |
| Appl. period | Scenario | Water body | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|---------------------------|-------------------|
| May          | D3       | d          | 0.508                    | 0.036                     | Drift             |
|              | D4       | p          | 0.019                    | 0.011                     | Drift             |
|              | D4       | s          | 0.388                    | 0.008                     | Drift             |
|              | D5       | p          | 0.018                    | 0.011                     | Drift             |
|              | D5       | s          | 0.405                    | 0.006                     | Drift             |
|              | D6       | d          | 0.511                    | 0.061                     | Drift             |
|              | R1       | p          | 0.021                    | 0.012                     | Runoff            |
|              | R1       | s          | 0.689                    | 0.040                     | Runoff            |
|              | R3       | s          | 0.801                    | 0.071                     | Runoff            |
|              | R4       | s          | 1.30                     | 0.092                     | Runoff            |
| June         | D1       | d          | 0.908                    | 0.386                     | Drainage          |
|              | D1       | s          | 0.833                    | 0.157                     | Drainage          |
|              | D2       | d          | 17.9                     | 1.75                      | Drainage          |
|              | D2       | s          | 11.3                     | 1.00                      | Drainage          |
|              | D3       | d          | 0.511                    | 0.041                     | Drift             |
|              | D4       | p          | 0.020                    | 0.012                     | Drift             |
|              | D4       | s          | 0.424                    | 0.012                     | Drift             |
|              | D5       | p          | 0.018                    | 0.011                     | Drift             |
|              | D5       | s          | 0.473                    | 0.022                     | Drift             |
|              | D6       | d          | 0.512                    | 0.105                     | Drift             |
|              | R1       | p          | 0.025                    | 0.014                     | Runoff            |
|              | R1       | s          | 0.926                    | 0.053                     | Runoff            |
|              | R3       | s          | 3.24                     | 0.193                     | Runoff            |
|              | R4       | s          | 2.22                     | 0.154                     | Runoff            |

FOCUS STEP 3 / Grassland - TSCF = 0

| Appl. period | Scenario | Water body | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) | Main entry route |
|--------------|----------|------------|--------------------------|---------------------------|-------------------|
| February     | D1       | d          | 25.8                     | 7.89                      | Drainage          |
|              | D1       | s          | 18.4                     | 4.65                      | Drainage          |
|              | D2       | d          | 30.4                     | 8.21                      | Drainage          |
|              | D2       | s          | 24.7                     | 3.67                      | Drainage          |
|              | D3       | d          | 0.759                    | 0.047                     | Drift             |
|              | D4       | p          | 0.027                    | 0.014                     | Drift             |
|              | D4       | s          | 0.603                    | 0.011                     | Drift             |
|              | D5       | p          | 1.14                     | 0.680                     | Drainage          |
|              | D5       | s          | 6.68                     | 0.430                     | Drainage          |
| Appl. period | Scenario | Water body | PEC_{SW} (µg/L) | PEC_{SED} (µg/kg) | Main entry route |
|-------------|----------|------------|----------------|------------------|-----------------|
| March       | R2       | s          | 0.640          | 0.026            | Drift           |
|             | R3       | s          | 0.709          | 0.033            | Drift           |
|             | D1       | d          | 30.8           | 6.65             | Drainage        |
|             | D1       | s          | 19.2           | 4.11             | Drainage        |
|             | D2       | d          | 34.7           | 4.89             | Drainage        |
|             | D2       | s          | 25.4           | 2.53             | Drainage        |
|             | D3       | d          | 0.761          | 0.052            | Drift           |
|             | D4       | p          | 0.026          | 0.014            | Drift           |
|             | D4       | s          | 0.613          | 0.012            | Drift           |
|             | D5       | p          | 0.027          | 0.015            | Drift           |
|             | D5       | s          | 0.623          | 0.010            | Drift           |
|             | R2       | s          | 0.662          | 0.014            | Drift           |
|             | R3       | s          | 0.705          | 0.029            | Drift           |
| April       | D1       | d          | 26.3           | 6.01             | Drainage        |
|             | D1       | s          | 16.6           | 3.24             | Drainage        |
|             | D2       | d          | 30.0           | 6.56             | Drainage        |
|             | D2       | s          | 26.0           | 3.44             | Drainage        |
|             | D3       | d          | 0.763          | 0.060            | Drift           |
|             | D4       | p          | 0.027          | 0.015            | Drift           |
|             | D4       | s          | 0.586          | 0.010            | Drift           |
|             | D5       | p          | 0.027          | 0.017            | Drift           |
|             | D5       | s          | 0.628          | 0.011            | Drift           |
|             | R2       | s          | 0.663          | 0.014            | Drift           |
|             | R3       | s          | 1.21           | 0.109            | Runoff          |
| May         | D1       | d          | 0.830          | 0.341            | Drift           |
|             | D1       | s          | 0.673          | 0.082            | Drift           |
|             | D2       | d          | 49.9           | 5.92             | Drainage        |
|             | D2       | s          | 33.3           | 3.48             | Drainage        |
|             | D3       | d          | 0.767          | 0.069            | Drift           |
|             | D4       | p          | 0.027          | 0.016            | Drift           |
|             | D4       | s          | 0.652          | 0.024            | Drift           |
|             | D5       | p          | 0.028          | 0.017            | Drift           |
|             | D5       | s          | 0.710          | 0.033            | Drift           |
|             | R2       | s          | 0.674          | 0.017            | Drift           |
|             | R3       | s          | 0.709          | 0.032            | Drift           |
| June        | D1       | d          | 0.797          | 0.337            | Drift           |
|             | D1       | s          | 0.673          | 0.122            | Drift           |
|             | D2       | d          | 0.792          | 0.398            | Drift           |
|             | D2       | s          | 0.707          | 0.285            | Drift           |
|             | D3       | d          | 0.784          | 0.095            | Drift           |
|             | D4       | p          | 0.032          | 0.020            | Drift           |
|             | D4       | s          | 0.655          | 0.027            | Drift           |
|             | D5       | p          | 0.038          | 0.025            | Drift           |
|             | D5       | s          | 0.710          | 0.035            | Drift           |
|             | R2       | s          | 0.674          | 0.045            | Drift           |
|             | R3       | s          | 2.05           | 0.185            | Runoff          |
| July        | D1       | d          | 0.781          | 0.319            | Drift           |
|             | D1       | s          | 0.673          | 0.073            | Drift           |
|             | D2       | d          | 0.787          | 0.398            | Drift           |
|             | D2       | s          | 0.697          | 0.280            | Drift           |
|             | D3       | d          | 0.838          | 0.143            | Drift           |
|             | D4       | p          | 0.038          | 0.025            | Drift           |
| Appl. period | Scenario | Water body | **PEC\textsubscript{SW} (µg/L)** | **PEC\textsubscript{SED} (µg/kg)** | Main entry route |
|--------------|----------|------------|-------------------------------|-----------------------------------|-----------------|
| August       | D4       | s          | 0.658                         | 0.030                             | Drift           |
|              | D5       | p          | 0.030                         | 0.019                             | Drift           |
|              | D5       | s          | 0.710                         | 0.033                             | Drift           |
|              | R2       | s          | 0.674                         | 0.017                             | Drift           |
|              | R3       | s          | 0.709                         | 0.043                             | Drift           |
|              | D1       | d          | 0.773                         | 0.310                             | Drift           |
|              | D2       | d          | 2.65                          | 1.18                              | Drainage        |
|              | D2       | s          | 4.24                          | 1.44                              | Drainage        |
|              | D3       | d          | 0.959                         | 0.263                             | Drift           |
|              | D4       | p          | 0.078                         | 0.068                             | Drainage        |
|              | D4       | s          | 0.658                         | 0.046                             | Drift           |
|              | D5       | p          | 0.079                         | 0.062                             | Drift           |
|              | D5       | s          | 0.710                         | 0.037                             | Drift           |
|              | R2       | s          | 0.674                         | 0.017                             | Drift           |
|              | R3       | s          | 0.709                         | 0.046                             | Drift           |

Metabolite: Not relevant, as no metabolites identified
## 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 (Anas platyrhynchos) | Clopyralid     | Acute           | LD$_{50}$ | 1465                        |
| Mallard duck (Anas platyrhynchos) | Clopyralid     | Long-term       | NOEC      | 118                         |
| Bobwhite quail (Colinus virginianus) | GF-1374       | Acute           | LD$_{50}$ | $>$ 2250$^7$               |
| **Mammals**                  |                |                 |           |                             |
| Rat                          | Clopyralid     | Acute           | LD$_{50}$ | $>$ 5000                    |
| Rat                          | GF-1374        | Acute           | LD$_{50}$ | 3378$^6$                   |
| Rabbit                       | Clopyralid     | Long-term       | LOAEL     | 50                          |
| Rat                          | Clopyralid     | Long-term       | NOAEL     | 75                          |
| Rat                          | Clopyralid     | Long-term       | NOAEL     | 275                         |
| Rat                          | Clopyralid     | Long-term       | NOEAL     | 50$^6$                      |

### Endocrine disrupting properties (Annex Part A, points 8.1.5)

Based on the information in Section 2 it is unlikely that clopyralid is an endocrine disruptor for mammals. However, further data might be necessary to address the potential endocrine disrupting properties for other vertebrate non-target organisms.

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$^6$ For risk assessment an estimated endpoint of 2559 mg/kg bw/d based on dose addition and calculated using the ‘Finney’ equation (Appendix B; EFSA Journal 2009; 7(12):1438) was used as a worst case scenario.

$^7$ For risk assessment an estimated endpoint of 1756 mg/kg bw/d based on dose addition and calculated using the ‘Finney’ equation (Appendix B; EFSA Journal 2009; 7(12):1438) was used.

$^8$ The NOEAL used in the wild mammals risk assessment is based on an endpoint derived from a two year rat study. It is noted that this study was not considered acceptable in the Pesticide Peer Review experts’ meeting 175 (mammalian toxicology) due to fundamental deviations from the study protocol. The outcome of the risk assessment does not change when the available reproductive NOEAL is considered being the latter higher than the endpoint used in the risk assessment. It is noted that uncertainties still stand on whether the endpoint used in the risk assessment would cover developmental effects in rabbit noting that a developmental LOEAL of 50 mg/kg bw/d (based on mean foetal weight decrease and delayed ossification) was agreed at the Pesticide Peer Review experts’ meeting 175. Considering that a clear dose response was not observed in the effects on body weight and delayed ossification and that the incidence of delayed ossification was relatively low, the ecotoxicological relevance of the effects seen in the rabbit study is not confirmed as a consequence the risk assessment was not changed; the NOEAL of 50 mg/kg bw/d was still considered.
| 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                                                                       |
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 I (Birds) Tier I assessment not necessary due to all relevant scenarios passing the screening step |               |            |                        |     |         |
| 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:
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.

Risk from consumption of contaminated water:
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.

The maximum application rate for clopyralid is 120 g/ha and the relevant endpoint for the mammalian risk assessment is the reproduction NOEL of 50 mg/kg bw/d. The ratio of these figures is 2.4, which is lower than 50, so a formal assessment of the risk to birds from exposure to clopyralid through drinking water is not necessary.
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

| Group                               | Test substance | Time-scale (Test type) | End point   | Toxicity[^1]               |
|-------------------------------------|----------------|------------------------|-------------|---------------------------|
| Laboratory tests                    |                |                        |             |                           |
| **Fish**                            |                |                        |             |                           |
| *Oncorhynchus mykiss*               | Clopyralid     | 96 hr                  | Mortality, LC₅₀ | > 99.9 mg a.s./L (mm)     |
| *Oncorhynchus mykiss*               | GF-1374        | 96 hr                  | Mortality, LC₅₀ | 7.1 mg product./L (nom.)  |
| *Pimephales promelas*              | Clopyralid     | ELS                    | NOEC        | 10.8 mg a.s./L (mm)       |
| Aquatic invertebrates               |                |                        |             |                           |
| *Daphnia magna* (Marino & al. 2000c) | Clopyralid     | 48 h                   | Mortality, EC₅₀ | > 99.0 mg a.s./L (mm)     |
| *Daphnia magna* (Sayers 2005b)     | GF-1374        | 48 h                   | Mortality, EC₅₀ | 6.9 mg product./L (nom.)  |
| *Daphnia magna* (Douglas & al. 1992) | Clopyralid     | 21 d                   | NOEC        | 17 mg a.s./L (mm)         |
| *Daphnia magna* (Douglas & al. 1992) | Clopyralid     | 21 d                   | EC₁₀        | 23.5 mg a.s./L (mm)       |
| Sediment-dwelling organisms         |                |                        |             |                           |
| *Chironomus riparius* (Barrett 2001) | Clopyralid     | 28 d (static)         | NOEC        | 50 mg a.s./L (mm)         |
| Algae                              |                |                        |             |                           |
| *Selenastrum capricornutum* (Kirk & al. 2000) | Clopyralid     | 72 h                   | Growth rate: E₅₀C₅₀ | 30 mg a.s./L (mm)         |
| *Selenastrum capricornutum* (Kirk & al. 2000) | Clopyralid     | 72 h                   | Yield: E₅₀C₅₀ | 30.9 mg a.s./L (mm)       |
| *Navicula pelliculosa* (Aufderheide 2014) | Clopyralid     | 72 h                   | Growth rate: E₅₀C₅₀ | 31.3 mg a.s./L (mm)       |
| *Navicula pelliculosa* (Aufderheide 2014) | Clopyralid     | 72 h                   | Yield: E₅₀C₅₀ | 31.5 mg a.s./L            |
Group & Test substance & Time-scale (Test type) & End point & Toxicity

Higher plant

*Lemma gibba* (Cowgill & al. 1990) & Clopyralid & 14 day & EC$_{50}$ & 89 mg a.s./L (mm)

*Myriophyllum spicatum* (Banman & Moore 2015) & Clopyralid & 14 day & E$_r$C$_{50}$ & > 3.0 mg a.s./L (mm)

Further testing on aquatic organisms needed for effects of the product on algae and macrophytes.

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

*Based on the information in Section 2 it is unlikely that Clopyralid is an endocrine disruptor for mammals. However, further data might be necessary to address the potential endocrine disrupting properties for other vertebrate non-target organisms.*

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 |
|---|---|---|---|
| Clopyralid | 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 | |

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 (120 g clopyralid/ha) and 1.0 L GF-1374/ha (80 g clopyralid/ha), respectively

| Group & Test species & Grassland |
|---|---|
| Test species & Max PEC$_{sw}$ (µg a.s/L) |
| Endpoint (µg a.s/L) & Fish acute & Fish chronic & Inverteb. acute & Inverteb. prolonged & Algae | Sed. dwell. prolonged | Aquatic plants |
| Clopyralid & O. mykiss & P. promelas & D. magna & D. magna & P. Subc apitata & C. riparius & M. spicatum |
| TER (toxicity/exposure) & | | | | | | |
### Focus Step 1

| Group          | Max PECsw (µg/L) | Cereals | Clopyralid |
|----------------|-----------------|---------|------------|
| Fish acute     | 2437            | 263     | 2437       |           |
| Fish chronic   | 415             | 732     | 1220       | 73        |
| Inverteb. acute|                 |         |            |
| Inverteb. prolonged |           |         |            |
| Algae          |                 |         |            |
| Sed. dwell. prolonged |           |         |            |
| Aquatic plants |                 |         |            |

**Trigger**

| Cereals | Clopyralid |
|---------|------------|
| Fish acute |           |
| Inverteb. acute |           |
| Algae |            |
| Sed. dwell. prolonged |          |
| Aquatic plants |         |

| Group          | Max PECsw (µg/L) | Cereals | Clopyralid |
|----------------|-----------------|---------|------------|
| Fish acute     | 27.4            | 3646    | 394        |
| Fish chronic   |                 | 3646    | 620        |
| Inverteb. acute|                 | 479     | 1095       |
| Inverteb. prolonged |           | 3 000   | 1825       |
| Algae          |                 | 109     | 10         |
| Sed. dwell. prolonged |           | 10      |            |
| Aquatic plants |                 | 10      |            |

| Test species   | O. mykiss | P. promel as | D. magna | p. Subcap itata | C. riparius | M. spicatum |
|----------------|-----------|--------------|----------|-----------------|-------------|-------------|
| Endpoint (µg a.s./L) | LC$_{50}$ | NOEC | EC$_{50}$ | NOEC | E$_{C_{50}}$ | NOEC | E$_{C_{50}}$ |
| Focus Step 1   | 99900     | 10800       | 99900    | 17000          | 30 000     | 50000       | 3 000       |
| Trigger        | 100       | 10          | 100      | 10             | 10         | 10          | 10          |

### Cereals and grassland

| Group          | Max PECsw (µg product/L) | Cereals and grassland | GF - 1374 |
|----------------|--------------------------|-----------------------|-----------|
| Fish acute     | O. mykiss                | D. magna              | P.subcapitata | M. spicatum |
| Inverteb. acute|                           |                       |            |
| Algae          |                           |                       |            |
| Aquatic plants |                           |                       |            |

| Test species   | Apis mellifera GF-1374 |
|----------------|-------------------------|
| Endpoint (µg product/L) | 14.4 | 493 | 479 |
| Spray drift based   | 100 | 100 | 10 |

**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)**

| Species | Test substance | Time scale/type of endpoint | End point          | toxicity       |
|---------|----------------|------------------------------|--------------------|----------------|
| Apis mellifera (Wainwright 2001a) | Clopyralid | Acute | Oral toxicity (LD$_{50}$) | > 100 µg a.s./bee |
| Apis mellifera | GF-1374 | Acute | Oral toxicity | > 86.7 µg/bee |
| Species                  | Test substance       | Risk quotient | HQ/TER | Trigger |
|-------------------------|---------------------|---------------|--------|---------|
| *Apis mellifera*        | Clopyralid (grassland) | < 1.2         | < 7.8  | 42      |
|                         | Clopyralid (cereals)  | < 0.82        | < 5.2  |         |
|                         | GF-1374              | < 0.82        | < 5.2  |         |

Potential for accumulative toxicity: *no*

Semi-field test (Cage and tunnel test)
The acute toxicity of GF-1374 to honey bees is considered low based on the ETR and HQHC values (see below risk assessments).

Field tests
-

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

Acute oral risk to honeybees from GF-1374 applications to grassland and cereals at maximum use rates of 1.5 L formulated product/ha for grassland and 1.0 L formulated product/ha for cereals.

| Test substance | Crop       | SV | Application rate (kg/ha) | LD50 (µg a.s./bee) | ETR   | Trigger |
|----------------|------------|----|--------------------------|--------------------|-------|---------|
| Clopyralid     | Grassland  | 7.6| 0.120                    | > 100              | 0.009 | 0.2     |
| GF-1374        |            |    |                          | > 86.7             | 0.137 | 0.2     |
| Clopyralid     | Cereals    | 7.6| 0.080                    | > 100              | 0.006 | 0.2     |
| GF-1365        |            |    |                          | > 86.7             | 0.091 | 0.2     |

*: Based on a formulation density of 1.04 g/mL.
### Screening level risk assessment for chronic oral exposure

| Test group  | Exposure scenario | App. rate (kg a.s./ha) | Short-cut value | Endpoint | ETR oral | Trigger value | Acceptable risk? |
|-------------|-------------------|------------------------|----------------|----------|----------|--------------|-----------------|
| Honey bee (adult) | Chronic oral (cereals) | 0.08 | 7.6 (downward spray) | LDD$_{50}$ > 71.2 µg a.s./bee/d | < 0.009 | 0.03 | Yes |
| Honey bee (adult) | Chronic oral (grassland) | 0.12 | 7.6 (downward spray) | LDD$_{50}$ > 71.2 µg a.s./bee/d | < 0.013 | 0.03 | Yes |
| Honey bee (larvae) | Chronic oral (cereals) | 0.08 | 4.4 (downward spray) | NOED 12.5 µg a.s./larvae | 0.03 | 0.2 | Yes |
| Honey bee (larvae) | Chronic oral (grassland) | 0.12 | 4.4 (downward spray) | NOED 12.5 µg a.s./larvae | 0.04 | 0.2 | Yes |

### Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

#### Laboratory tests with standard sensitive species

| Species | Test Substance | End point | Toxicity |
|---------|----------------|-----------|----------|
| Typhlodromus pyri (Loose 2005) | GF-1374 | Mortality, LR$_{50}$ (extended study) | 2000 mL/ha |
| Typhlodromus pyri (Sankanu 2000a) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (glass plates) | >200 g a.s./ha |
| Aphidius rhopalosiphi (Loose 2004a) | GF-1374 | Mortality, LR$_{50}$ (extended study) | >2000 mL/ha |
| Aphidius rhopalosiphi (Sankanu 2000b) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (glass plates) | >200 g a.s./ha |
| Aphidius rhopalosiphi (Halsall 2005) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (glass plates) | >300 g a.s./ha |
| Additional species |
| Chrysoperla carnea (Loose 2004b) | GF-1374 | Mortality, LR$_{50}$ (extended study) | >2000 mL/ha |
| Chrysoperla carnea (Miles 2002) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (glass plates) | >200 g a.s./ha |
| Poecilus cupreus (Miles 2002) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (spray application) | >200 g a.s./ha |
| Poecilus cupreus (Römbke 1991) | EF-1136 (clopyralid) | Mortality, LR$_{50}$ (spray application) | >120 g a.s./ha |
| Aleochara bilineata (Römbke and Vickus 1991) | Lontreal 100 (clopyralid) | Mortality, LR$_{50}$ (spray application) | >120 g a.s./ha |
Species | Test Substance | End point | Toxicity
---|---|---|---
*Pardosa sp.* (Heimann and Vickus 1993) | Lontreal 100 (clopyralid) | Mortality, LR50 (spray application) | >120 g a.s./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) | Exposure ml f.p./ha | Acceptable risk? |
|---|---|---|---|---|
| GF-1374 (grassland) | *Typhlodromus pyri* | 2000 | 1040 | yes |
|  | *Aphidius rhopalosiphi* | 2000 | 1040 | yes |
|  | *Chrysoperla carnea* | 2000 | 1040 | yes |
| GF-1374 (cereals) | *Typhlodromus pyri* | 2000 | 1560 | yes |
|  | *Aphidius rhopalosiphi* | 2000 | 1560 | yes |
|  | *Chrysoperla carnea* | 2000 | 1560 | yes |

1 calculated 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

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

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

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

### Nitrogen transformation

| Test organism                  | Test substance | Application                          | Time scale | Endpoint                                      | Toxicity                                  |
|-------------------------------|----------------|--------------------------------------|------------|-----------------------------------------------|-------------------------------------------|
| Soil micro-organisms          | Clopyralid     | Incorporation into soil (0.417 and 209 mg a.s/kg d.w. soil) | 56 d       | < 25 % deviation in nitrate formation to the control | 209 mg a.s./kg d.w.soil                   |
| (Schöbinger 2013)             |                |                                      |            |                                               |                                           |
| Soil micro-organisms          | GF-1374        | Incorporation into soil (2.77 and 13.9 mg product/kg d.w. soil) | 28d        | < 25 % deviation in nitrate formation to the control | 13.9 mg product/kg d.w.soil              |
| (Rix 2005)                    |                |                                      |            |                                               |                                           |

### 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                    |                |            |                |     |         |
| *E. fetida* (grassland)       | Clopyralid     | Chronic    | 0.016          | 123 | 5       |
| *E. fetida* (cereals)         | Clopyralid     | Chronic    | 0.107          | 18.4| 5       |
| Other soil macroorganisms     |                |            |                |     |         |
| *F. candida*                  | GF-1374        | Chronic    | 2.08           | 12.0| 5       |
| *H. aculeifer*                | GF-1374        | Chronic    | 2.08           | 24.0| 5       |

\(^1\) Maximum PEC soil was used in the risk assessment
### Effects on and TER values for 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} () vegetative vigour | ER_{50} seedling emergence | Exposure\(^1\) (mL product/ha) | TER | Trigger |
|---------------------|----------------|------------------------------|---------------------------|-------------------------------|-----|---------|
| *Lactuca sativa*    | GF-1374        | -                            | 460 (mL product/ha)       | 41.6 at 1 m with 0% DRN      | 11.1| 5       |
| (Eley 2005b)        |                |                              |                           |                               |     |         |
| *Lactuca sativa*    | Clopyralid     | 33.78 (g a.s./ha)            | Cereals: 2.2 g a.s/ha     | Cereals: 15.3 Grassland: 10.2| 5   |         |
| (Rockliff 2013b)    |                |                              |                           |                               |     |         |
| *Soybean*           | Clopyralid     | 21.47 (g a.s/ha)             | Grassland: 3.3 g a.s./ha  | Cereals: 9.8 Grassland: 6.5  | 5   |         |
| *Glycine max*       |                |                              | (at 1 m with 0% DRN)      |                               |     |         |
| (Rockliff 2013a)    |                |                              |                           |                               |     |         |

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)

### 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) |
| *Pseudomonas sp*    |                | No data available, not required |
Monitoring data (Regulation (EU) No 283/2013, Annex Part A, point 8.9 and Regulation (EU) No 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) No 283/2013, Annex Part A, point 7.4.2)
Ecotoxicologically relevant compounds

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

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent.
Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

Substance

| Clopyralid |
|------------|
| Hazard pictograms |
| GHS09 (environmental hazard) |
| Signal word: |
| Danger (health hazard) ; environmental classification would trigger signal word “Warning”, but only one signal word per classification is used and Danger takes precedence. |
| Hazard statements: H410 (environmental hazard) |
| Precautionary statements: P273 (environmental), P501 (environmental) |
| Supplemental labelling: EUH401 (applies to all PPP products) |

Peer review proposal\(^8\) for harmonised classification according to Regulation (EC) No 1272/2008:

| No additional classification is proposed for Clopyralid |

\(^7\) 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.