Appendix to:
EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance sheep fat. EFSA Journal 2022;20(1):7073, 43 pp. doi:10.2903/j.efsa.2022.7073
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**Appendix B - List of end points for the active substance and the representative formulation**

| Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) No 283/2013, Annex Part A, points 1.3 and 3.2) |
|----------------------------------------------------------------------------------------------------------------------------------|
| Active substance (ISO Common Name) | Sheep fat (No ISO name has been proposed or accepted) |
| Function (e.g. fungicide) | repellent |
| Rapporteur Member State | Czech Republic (CZ) |
| Co-rapporteur Member State | France (FR) |

| Identity (Regulation (EU) No 283/2013, Annex Part A, point 1) |
|---------------------------------------------------------------|
| Chemical name (IUPAC) | Sheep Fat |
| Chemical name (CA) | Sheep Fat |
| CIPAC No | 919 |
| CAS No | 98999-15-6 |
| EC No (EINECS or ELINCS) | 308-905-5 |
| FAO Specification (including year of publication) | No FAO specification exists |
| Minimum purity of the active substance as manufactured | Minimum purity of sheep fat: 100 % |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | No relevant impurity |
| Location of the (proposed) reference specification (for significant impurities) | RAR Volume 4 (August 2021) |
### Molecular formula

No definite formula for sheep fat can be given, as it is a triglyceride consisting predominantly of glycerine esters of higher fatty acids with an even number of carbon atoms.

### Molar mass

No definite formula for sheep fat can be given, as it is a triglyceride consisting predominantly of glycerine esters of higher fatty acids with an even number of carbon atoms.

### Structural formula

Sheep fat can be described with the following formula:

\[
\begin{align*}
&\text{H} \\
&\text{H- C - O - C - R}_1 \\
&\text{O} \\
&\text{H- C - O - C - R}_2 \\
&\text{O} \\
&\text{H- C - O - C - R}_3 \\
&\text{H} \\
\end{align*}
\]

where R1, R2 and R3 represent the hydrocarbon chain of the fatty acid elements of the triglyceride.

The main acids are:
- Palmitic acid (C\(_{16}\) ): \(\text{CH}_3(\text{CH}_2)_{14}\text{COOH}\)
- Stearic acid (C\(_{18}\) ): \(\text{CH}_3(\text{CH}_2)_{16}\text{COOH}\)
- Oleic acid (C\(_{18:1}\) ): \(\text{CH}_3(\text{CH}_2)_{7}\text{CH=CH} (\text{CH}_2)_{7}\text{COOH}\)

### Physical and chemical properties

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

| Property                                           | Value                                      |
|----------------------------------------------------|--------------------------------------------|
| Melting point (state purity)                       | 36 to 44 °C                                |
| Boiling point (state purity)                       | not relevant                               |
| Temperature of decomposition (state purity)        | not relevant                               |
| Appearance (state purity)                          | Yellowish stiff fat (viscous mass) with rancid odour |
| Vapour pressure (state temperature, state purity)  | The vapour pressure of Sheep fat is estimated to be \(< 10^{-12} \text{ Pa at 25 °C}\) |
| Henry’s law constant (state temperature)           | Estimated Henry constant of the main triglycerides (mean of two estimation methods): \(\text{Glycerol ester of palmitic acid: } 18.2 \text{ Pa m}^3 \text{ mol}^{-1}\) \(\text{Glycerol ester of stearic acid: } 112.5 \text{ Pa m}^3 \text{ mol}^{-1}\) \(\text{Glycerol ester of oleic acid: } 49.4 \text{ Pa m}^3 \text{ mol}^{-1}\) |
| Solubility in water (state temperature, state purity and pH) | The water solubility of Sheep Fat is estimated to be \(< 10^{-17} \text{ mg/L at 25 °C}\) |
### Solubility in organic solvents

(state temperature, state purity)

| Organic Solvent | Solubility at 20 °C: |
|-----------------|----------------------|
| n-heptane       | 14 - 20 g/L          |
| p-xylene        | 333 - 500 g/L        |
| 1,2-dichloroethane | 167 - 200 g/L     |
| 2-propanol      | < 10 g/L             |
| acetone         | < 10 g/L             |
| ethyl acetate   | < 10 g/L             |

### Surface tension

(state concentration and temperature, state purity)

| | 71.24 mN/m at 20 °C  |
|-------------------------------|-----------------------|
| | (approx. 90 % saturated solution) |

### Partition coefficient

(state temperature, pH and purity)

| | not required |
|-------------------------------|--------------|

### Dissociation constant

(state purity)

| | Not relevant (dissociation in water does not occur) |
|-------------------------------|---------------------------------------------------|

### UV/VIS absorption (max.) incl. $\varepsilon$

(state purity, pH)

| | No absorbance maxima ($\lambda_{\text{max}}$) above 290 nm were observed |
|-------------------------------|-------------------------------------------------------------------------|

### Flammability

(state purity)

| | Not classified as highly flammable  |
|-------------------------------|-------------------------------------|
| | (Flash point 310.5 °C)             |

### Explosive properties

(state purity)

| | Not classified as explosive |
|-------------------------------|-----------------------------|

### Oxidising properties

(state purity)

| | Not expected to be oxidising |
|-------------------------------|-----------------------------|
### 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) | Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | Remarks |
|--------------------------|---------|--------------|--------------|---------------------------------------|-------------|------------|---------------------------------|---------|
| Deciduous and coniferous trees in forestry, (NNNWL and NNNWN) | All zones | Trico (K 715-4B) | F | Winter game biting by roe, red deer (CAPRCA, CERVSP) | EW 64.6 g/L | spraying using conventional atomiser s or knapsack sprayers | autumn (BBCH 91 – BBCH 00) | 1 - - 1.292 - undiluted spray |
| Deciduous and coniferous trees in forestry, (NNNWL and NNNWN) | All zones | Trico (K 715-4B) | F | Summer game biting by roe, red deer (CAPRCA, CERVSP) | EW 64.6 g/L | spraying using conventional atomiser s or knapsack sprayers | during vegetation period (BBCH 01 – BBCH 91) | 1 - - 1.292 - undiluted spray |
| Deciduous and coniferous trees in forestry, (NNNWL and NNNWN) | All zones | Trico (K 715-4B) | F | Fraying by roe, red deer (CAPRCA, CERVSP) | EW 64.6 g/L | spraying using conventional atomiser s or knapsack sprayers | spring, summer (BBCH 00 – BBCH 91) | 1 - - 1.292 - undiluted spray of the stem/trunk (approx. 5 -10 mL/stem) |
| Deciduous and coniferous trees in forestry, (NNNWL and NNNWN) | All zones | Trico (K 715-4B) | F | Debarking by deer (CERVEL, CERVNI) | EW 64.6 g/L | spraying using conventional atomiser s or knapsack sprayers | autumn, spring (BBCH 97 – BBCH 00) | 1 - - 1.292 - undiluted spray of the stem/trunk (approx. 100 mL/stem or trunk) |

(a) For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(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
| (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 |
| (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) | The minimum and maximum number of applications possible under practical conditions of use must be provided |
| (l) | PHI - minimum pre-harvest interval |
| (m) | Remarks may include: Extent of use/economic importance/restriction |
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))

None
Further information, Efficacy

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

Products with Sheep fat have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

Products with Sheep fat have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

Products with Sheep fat have been registered in several member states in the EU based on detailed national assessments of the efficacy package in compliance with Annex III data requirements of Directive 91/414/EEC and according to the Uniform Principles.

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

Activity against target organism

| fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid) | Yes* |
|---------------------------------------------------------------|-----|

*Fatty acids C7 to C18: EFSA Journal 2013;11(1):3023
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) | Main fatty acids as methyl esters: GC/MS |
|-------------------------------------|----------------------------------------|
| Impurities in technical a.s. (analytical technique) | No relevant impurities |
| Plant protection product (analytical technique) | Main fatty acids as methyl esters: GC/FID |

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 | Not relevant as no residue definition and no MRLs are proposed |
|----------------------|-------------------------------------------------------------|
| Food of animal origin | Not relevant as no residue definition and no MRLs are proposed |
| Soil | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
| Sediment | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
| Water surface | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
| drinking/ground | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
| Air | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
| Body fluids and tissues | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |

Monitoring/Enforcement methods

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Not relevant. See statement above. |
|------------------------------------------------------------------------------------------|-----------------------------------|
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not relevant. See statement above. |
| Soil (analytical technique and LOQ) | Not relevant. See statement above. |
| Water (analytical technique and LOQ) | Not relevant. See statement above. |
Air (analytical technique and LOQ)

Not relevant. See statement above.

Body fluids and tissues (analytical technique and LOQ)

Not relevant. See statement above.

**Classification and labelling with regard to physical and chemical data (Regulation (EU) No 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]\(^1\):

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

| Substance  | Classification |
|------------|----------------|
| Sheep fat  | No harmonised classification |

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

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

| Parameter                                                                 | Information                                                                 |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Rate and extent of oral absorption/systemic bioavailability               | No data available; not required (mixture of natural compounds)               |
| Toxicokinetics                                                            | No data available; not required (mixture of natural compounds)               |
| Distribution                                                              | No data available; not required (mixture of natural compounds)               |
| Potential for bioaccumulation                                             | No data available; not required (mixture of natural compounds)               |
| Rate and extent of excretion                                              | No data available; not required (mixture of natural compounds)               |
| Metabolism in animals                                                     | No data available; not required (mixture of natural compounds)               |
| *In vitro* metabolism                                                     | No data available; not required (mixture of natural compounds)               |
| Toxicologically relevant compounds (animals and plants)                   | None                                                                        |
| Toxicologically relevant compounds (environment)                          | None                                                                        |

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

| Parameter                          | Information                                                                 |
|------------------------------------|-----------------------------------------------------------------------------|
| Rat LD₅₀ oral                      | No data available; not required                                              |
| Rat LD₅₀ dermal                    | No data available; not required                                              |
| Rat LC₅₀ inhalation                | No data available; not required                                              |
| Skin irritation                    | No data available; not required                                              |
| Eye irritation                     | No data available; not required                                              |
| Skin sensitisation                 | No data available; not required                                              |
| Phototoxicity                      | Not required                                                                 |

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

| Parameter                          | Information                                                                 |
|------------------------------------|-----------------------------------------------------------------------------|
| Target organ / critical effect      | None                                                                        |
| Relevant oral NOAEL                | No data available; not required                                              |
| Relevant dermal NOAEL              | No data available; not required                                              |
| Relevant inhalation NOAEL          | No data available; not required                                              |

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

| Column                            | Information                                                                 |
|-----------------------------------|-----------------------------------------------------------------------------|
| *In vitro* studies                | No data available; not required                                              |
### In vivo studies

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Photomutagenicity                     | No data available; not required |
| Potential for genotoxicity            | Sheep fat is unlikely to be genotoxic |

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

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Long-term effects (target organ/critical effect) | No data available; not required |
| Relevant long-term NOAEL               | No data available; not required |
| Carcinogenicity (target organ, tumour type) | No data available; not required |
| Relevant NOAEL for carcinogenicity     | No data available; not required |

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

#### Reproduction toxicity

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Reproduction target / critical effect | No data available; not required |
| Relevant parental NOAEL               | No data available; not required |
| Relevant reproductive NOAEL            | No data available; not required |
| Relevant offspring NOAEL               | No data available; not required |

#### Developmental toxicity

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Developmental target / critical effect | No data available; not required |
| Relevant maternal NOAEL               | No data available; not required |
| Relevant developmental NOAEL           | No data available; not required |

### Neurotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.7)

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Acute neurotoxicity                   | No data available; not required |
| Repeated neurotoxicity                | No data available; not required |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No data available; not required |

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

| Category                              | Result                      |
|---------------------------------------|-----------------------------|
| Supplementary studies on the active substance | No data available; not required |
| Endocrine disrupting properties       | Sheep fat does not to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. |
| Studies performed on metabolites or impurities | No data available |

Endocrine disrupting properties

Sheep fat does not to meet the criteria for endocrine disruption for humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
Medical data (Regulation (EU) No 283/2013, Annex Part A, point 5.9)

| Value                | Study | Uncertainty factor |
|----------------------|-------|--------------------|
| Acceptable Daily Intake (ADI) | Not required | - |
| Acute Reference Dose (ARfD) | Not required | - |
| Acceptable Operator Exposure Level (AOEL) | Not required | - |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not required | - |

Summary2 (Regulation (EU) No 1107/2009, Annex II, point 3.1 and 3.6)

| Value                | Study | Uncertainty factor |
|----------------------|-------|--------------------|
| Acceptable Daily Intake (ADI) | Not required | - |
| Acute Reference Dose (ARfD) | Not required | - |
| Acceptable Operator Exposure Level (AOEL) | Not required | - |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not required | - |

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

Representative formulation (indicate name, type e.g. EC and concentration of active substance)

| ‘Trico (K 715-4B)’ | type: Oil in water emulsion (EW); concentration of active substance (Sheep fat): 6.4% w/w |
|---------------------|-----------------------------------------------------------------------------------------------|
| No study available; not required |

Exposure scenarios (Regulation (EU) No 284/2013, Annex Part A, point 7.2)

Operators

| ‘Trico (K 715-4B)’ | Use: coniferous and deciduous trees in forestry, hand-held spraying of individual plants, application rate max 1.3 kg a.s./ha |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Exposure estimates: | No quantitative exposure assessment was conducted; low toxicological concern for the operator is expected based on its chemical nature. |

Workers

| Exposure to workers can be considered negligible, if any. |

Bystanders and residents

| Exposure to bystanders and residents can be considered negligible, if any. |

2 If available include also reference values for metabolites
Classification with regard to toxicological data (Regulation (EU) No 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]: |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Sheep fat                  | No current harmonised classification.                                                                                                                                                                   |

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

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3 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.
Residues in or on treated products food and feed

Metabolism and residue studies were not considered relevant for the evaluation due to the nature of the active substance and the representative use.

Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups                  | Crop(s)                                      | Application(s) | Sampling (DAT) | Comment/Source                                                                                      |
|----------------------------------|------------------------------|----------------------------------------------|----------------|----------------|-----------------------------------------------------------------------------------------------|
|                                  | Fruit crops                  | No data available; not required.             |                |                | The representative use of sheep fat on deciduous and coniferous trees in forestry applied as a spray to individual trees is unlikely to lead to residues in food. |
|                                  | Root crops                   |                                              |                |                |                                                                                               |
|                                  | Leafy crops                  |                                              |                |                |                                                                                               |
|                                  | Cereals/grass                |                                              |                |                |                                                                                               |
|                                  | Pulses/oilseeds              |                                              |                |                |                                                                                               |
|                                  | Miscellaneous                |                                              |                |                |                                                                                               |
|                                  | Rotational crop and primary crop metabolism similar? | yes/no/inconclusive/not applicable | Not relevant. |
|                                  | Residue pattern in processed commodities similar to residue pattern in raw commodities? | yes/no/inconclusive/not applicable | Not relevant. |
|                                  | Plant residue definition for monitoring (RD-Mo) | Not applicable. |
|                                  | Plant residue definition for risk assessment (RD-RA) | Not applicable. |
|                                  | Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Not applicable. |

| Rotational crops (available studies) | Crop groups                  | Crop(s)                                      | Application(s) | PBI (DAT) | Comment/Source                                                                                      |
|------------------------------------|------------------------------|----------------------------------------------|----------------|-----------|-----------------------------------------------------------------------------------------------|
|                                    | Root/tuber crops             | No data available; not required              |                |           |                                                                                               |
|                                    | Leafy crops                  |                                              |                |           |                                                                                               |
|                                    | Cereal (small grain)         |                                              |                |           |                                                                                               |
|                                    | other                        |                                              |                |           |                                                                                               |

| Processed commodities (hydrolysis study) | Conditions                          | Stable?                                      | Comment/Source |
|------------------------------------------|-------------------------------------|----------------------------------------------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | No data available; not required              |                 |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) |                                       |                 |
|                                          | Sterilisation (20 min, 120°C, pH 6)   |                                               |                 |
|                                          | Other processing conditions         |                                               |                 |

Can a general residue definition be proposed for primary crops? | yes/no/inconclusive | Not relevant. |
Rotational crop and primary crop metabolism similar? | yes/no/inconclusive/not applicable | Not relevant. |
Residue pattern in processed commodities similar to residue pattern in raw commodities? | yes/no/inconclusive/not applicable | Not relevant. |
Plant residue definition for monitoring (RD-Mo) | Not applicable. |
Plant residue definition for risk assessment (RD-RA) | Not applicable. |
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Not applicable. |
### Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Unit | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------------|------|-------------------|----------------|
| High water content                | No data available; not required |
| High oil content                  |          |           |        |                        |      |                   |                |
| High protein content              |          |           |        |                        |      |                   |                |
| High starch content               |          |           |        |                        |      |                   |                |
| High acid content                 |          |           |        |                        |      |                   |                |
| Processed products                |          |           |        |                        |      |                   |                |
| Others                            |          |           |        |                        |      |                   |                |

### Magnitude of residues in plants

#### Summary of residues data from the supervised residue trials – Primary crops

| Commodity | Region/Indoor (a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR (b) (mg/kg) | STMR (c) (mg/kg) | CF (d) |
|-----------|-------------------|-----------------------------------------------------------------|-----------------|------------------------|----------------|------------------|--------|
| Representative uses | | | | | | | |
| Deciduous and coniferous trees in forestry | NEU | Mo: - RA: - | No data available; not required | None | Mo: - RA: - | Mo: - RA: - | None |
| | | | | | | | |
| Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1) | NEU | Mo: - RA: - | No data available; not required | | | | |

* Indicates that the MRL is proposed at the limit of quantification.

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
Residues in rotational crops
Overall summary
Residues in rotational and succeeding crops expected based on confined rotational crop study? not relevant.
Residues in rotational and succeeding crops expected based on field rotational crop study? not relevant.

Summary of residues data from the rotational crops residue trials (if relevant, e.g. MRL, STMR, HR derived from rotational crops)

| Commodity | Region/Indoor (a) | PBI (days) (b) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR (c) (mg/kg) | STMR (d) (mg/kg) | CF (e) |
|-----------|------------------|----------------|-------------------------------------------------------------|----------------|------------------------|---------------|-----------------|--------|
| NEU       | Indoor           | 30             | Mo: - RA: -                                                | No data available; not required | Mo: - RA: - | Mo: - RA: - |
|           |                  | 120            |                                                             |                |                        |               |                 |        |
|           |                  | 365            |                                                             |                |                        |               |                 |        |
| SEU       | Indoor           | 30             |                                                             |                |                        |               |                 |        |
|           |                  | 120            |                                                             |                |                        |               |                 |        |
|           |                  | 365            |                                                             |                |                        |               |                 |        |

* Indicates that the MRL is proposed at the limit of quantification.
Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Country code: if non-EU trials.
(b): Plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.
(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Processing factors

| Processed commodity | Number of valid studies (a) | Processing Factor (PF) | CFp (b) | Comment/ Source |
|---------------------|-------------------------------|------------------------|---------|-----------------|
|                     | Individual values             | Median PF              |         |
| No data available; not required |                  |                        |         |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CFp: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo)
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
(b): Median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited dataset.

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Residues in livestock
Not relevant

Consumer risk assessment
Not relevant since no ARfD has been considered necessary, see mammalian toxicology.

| ADI | TMDI according to EFSA PRIMo | NTMDI, according to (to be specified) | Highest IEDI, according to EFSA PRIMo (rev.x) | NEDI (% ADI), according to (to be specified) | Assumptions made for the calculations |
|-----|---------------------------|---------------------------------|-----------------------------------|--------------------------------------|--------------------------------------|

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Metabolite(s)
ADI (mg/kg bw per day)
Intake of groundwater metabolites (% ADI)

Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
|         | Deciduous and coniferous trees in forestry | Not relevant. | |

Enforcement residue definition: Not applicable

Representative uses

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
### Environmental fate and behaviour

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

| Parameter                                    | Result                                      |
|----------------------------------------------|---------------------------------------------|
| Mineralisation after 100 days                | No data submitted.                          |
| Non-extractable residues after 100 days      | No data submitted.                          |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | No data submitted.                          |

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

| Parameter                                    | Result                                      |
|----------------------------------------------|---------------------------------------------|
| Mineralisation after 100 days                | No data submitted.                          |
| Non-extractable residues after 100 days      | No data submitted.                          |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | No data submitted.                          |

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

| Parameter                                    | Result                                      |
|----------------------------------------------|---------------------------------------------|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | No data submitted.                          |
| Mineralisation at study end                  | No data submitted.                          |
| Non-extractable residues at study end        | No data submitted.                          |

#### 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)

No data submitted.

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

No data submitted.
Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)
No data submitted.

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

| Characteristic                                                                 | Data Submitted |
|-------------------------------------------------------------------------------|----------------|
| Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent) | No data submitted. |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) | No data submitted. |
| Kinetic formation fraction (f. f. $k_f / k_{dp}$) of transformation products, arithmetic mean | No data submitted. |

* 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)
No data submitted.

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)
No data submitted.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
No data submitted.

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)
No data submitted.

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)
No data submitted.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)
No data submitted.
Mobility in soil column leaching active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching | No data submitted. |

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

| Column leaching | No data submitted. |

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

| Lysimeter/ field leaching studies | No data submitted. |

Hydrolytic degradation (Regulation (EU) No 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Sheep fat is almost insoluble in water with a solubility of $< 10^{-17}$ mg/L at 25 °C.
The sheep fat and fatty acids are hydrolysis stable based on available information.

Aqueous photochemical degradation (Regulation (EU) No 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

No data submitted.

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

No data submitted.

‘Ready biodegradability’ (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable

Sheep fat is readily biodegradable.

Aerobic mineralisation in surface water (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.2.1)

No data submitted.

Water / sediment study (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) No 284/2013, Annex Part A, point 9.2.2)

No data submitted.
### Fate and behaviour in air (Regulation (EU) No 283/2013, Annex Part A, point 7.3.1)

| Process                                                      | Description                                                                 |
|--------------------------------------------------------------|-----------------------------------------------------------------------------|
| Direct photolysis in air                                     | No data submitted.                                                          |
| Photochemical oxidative degradation in air                   | Glycerol ester of palmitic acid (C16): DT<sub>50</sub> of 1.997 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 x 10<sup>6</sup> cm<sup>-3</sup>. |
|                                                             | Glycerol ester of stearic acid (C18): DT<sub>50</sub> of 1.765 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 x 10<sup>6</sup> cm<sup>-3</sup>. |
|                                                             | Glycerol ester of oleic acid (C18:1): DT<sub>50</sub> of 0.554 (cis isomer) and 0.504 (trans isomer) hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 x 10<sup>6</sup> cm<sup>-3</sup>. |
| Volatilisation                                               | No data submitted.                                                          |
| Metabolites                                                  | No data submitted.                                                          |

### Residues requiring further assessment (Regulation (EU) No 283/2013, Annex Part A, point 7.4.1)

| Residue type                                                   | Description                                                                 |
|---------------------------------------------------------------|-----------------------------------------------------------------------------|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure | Soil: sheep fat, fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid) |
|                                                              | Surface water: sheep fat, fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid) |
|                                                              | Ground water: sheep fat, fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid) |
|                                                              | Air: fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid) |

### 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)

| Location and type of study                                      | Description                                                                 |
|----------------------------------------------------------------|-----------------------------------------------------------------------------|
| Soil (indicate location and type of study)                     | No data submitted.                                                          |
| Surface water (indicate location and type of study)            | No data submitted.                                                          |
| Ground water (indicate location and type of study)             | No data submitted.                                                          |
| Air (indicate location and type of study)                      | No data submitted.                                                          |
### Peer review of the pesticide risk assessment of the active substance sheep fat

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

**Parent**
- Method of calculation
- DT<sub>50</sub> (d): no degradation data in soil is available, only the initial PEC soil could be calculated.

**Application data**
- Crop: deciduous and coniferous trees in forestry
- Depth of soil layer: 5 cm
- Soil bulk density: 1.5 g/cm<sup>3</sup>
- % plant interception: 50
- Number of applications: 1
- Interval (d): -
- Application rate(s): 1292 g a.s./ha

| PEC<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|--------------------------|---------------------------|----------------------------------------|-----------------------------|-----------------------------------------|
| Initial                  | 0.861                     |                                        |                             |                                         |
| Short term               | 24h                       |                                        |                             |                                         |
|                         | 2d                        |                                        |                             |                                         |
|                         | 4d                        |                                        |                             |                                         |
| Long term                | 7d                        |                                        |                             |                                         |
|                         | 28d                       |                                        |                             |                                         |
|                         | 50d                       |                                        |                             |                                         |
|                         | 100d                      |                                        |                             |                                         |
| Plateau concentration    |                           |                                        |                             |                                         |

**Metabolite Oleic acid**
- Method of calculation
  - Molecular weight relative to the parent: 282.46 / 885.46 = 0.3190
  - DT<sub>50</sub> (d): 3 days”
  - Kinetics: first order
  - Field or Lab: worst case from laboratory studies.

**Application data**
- Application rate assumed: 1292 g/ha (assumed oleic acid is formed at a maximum of 100 % of the applied dose)

"Molar mass for Triglyceride
"Fatty acids C7 to C18: EFSA Journal 2013;11(1):3023
### PEC<sub>(s)</sub>(mg/kg)

|                     | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------|----------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial             | 0.276                      |                                        |                            |                                        |
| Short term 24h      | 0.219                      | 0.246                                  |                            |                                        |
|                     | 0.174                      | 0.221                                  |                            |                                        |
|                     | 0.109                      | 0.180                                  |                            |                                        |
| Long term 7d        | 0.055                      | 0.137                                  |                            |                                        |
|                     | 0.0 | 0.043                                  |                            |                                        |
|                     | 0.0 | 0.024                                  |                            |                                        |
|                     | 0.0 | 0.012                                  |                            |                                        |
| Plateau concentration |                           |                                        |                            |                                        |

**Metabolite Palmitic acid**

**Method of calculation**

Molecular weight relative to the parent:

\[
\frac{256.42}{885.46} = 0.2896
\]

DT<sub>50</sub> (d): 3 days**

Kinetics: first order

Field or Lab: worst case from laboratory studies.

**Application data**

Application rate assumed: 1292 g/ha (assumed palmitic acid is formed at a maximum of 100% of the applied dose)

* Molar mass for Triglyceride

**Fatty acids C7 to C18: EFSA Journal 2013;11(1):3023

### PEC<sub>(s)</sub>(mg/kg)

|                     | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------|----------------------------|----------------------------------------|----------------------------|----------------------------------------|
| Initial             | 0.250                      |                                        |                            |                                        |
| Short term 24h      | 0.198                      | 0.223                                  |                            |                                        |
|                     | 0.157                      | 0.200                                  |                            |                                        |
|                     | 0.099                      | 0.163                                  |                            |                                        |
| Long term 7d        | 0.050                      | 0.124                                  |                            |                                        |
|                     | 0 | 0.039                                  |                            |                                        |
|                     | 0 | 0.022                                  |                            |                                        |
|                     | 0 | 0.011                                  |                            |                                        |
| Plateau concentration |                           |                                        |                            |                                        |
### Metabolite Stearic acid

**Method of calculation**

Molecular weight relative to the parent:

\[
\frac{284.48}{885.46} = 0.3213
\]

\(DT_{50}\) (d): 3 days”

Kinetics: first order

Field or Lab: worst case from laboratory studies.

### Application data

Application rate assumed: 1292 g/ha (assumed oleic acid is formed at a maximum of 100 % of the applied dose)

*Molar mass for Triglyceride

**Fatty acids C7 to C18: EFSA Journal 2013;11(1):3023

| **PEC\(_{(s)}\)** (mg/kg) | Single application | Single application | Multiple application | Multiple application |
|--------------------------|--------------------|--------------------|----------------------|----------------------|
|                          | Actual             | Time weighted      | Actual               | Time weighted average|
| Initial                  | 0.276              |                    |                      |                      |
| Short term 24h           | 0.219              | 0.246              |                      |                      |
| 2d                       | 0.174              | 0.221              |                      |                      |
| 4d                       | 0.109              | 0.180              |                      |                      |
| Long term 7d             | 0.055              | 0.137              |                      |                      |
| 28d                      | 0                  | 0.043              |                      |                      |
| 50d                      | 0                  | 0.024              |                      |                      |
| 100d                     | 0                  | 0.012              |                      |                      |

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

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

For FOCUS gw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Model(s) used: FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 5.5.3)
Crop: deciduous and coniferous trees in forestry

The values PECgw were calculated for fatty acids (representative: oleic acid) according to the LoEP (EFSA Journal 2013;11(1):3023). The fatty acids are produced by natural hydrolysis sheep fat. Oleic acid was calculated as parent. As no values for degradation of sheep fat in soil are available, no PECgw for sheep fat can be calculated.

Crop uptake factor: 0
Water solubility (mg/L): 207.8 at pH 7 and 20°C
Vapour pressure: 0.9 Pa at 20°C
Geometric mean parent DT$_{50_{lab}}$ 3 d
K$_{OC}$: 47.3, mL/g
$
u_a= 1$

**Application rate**

Gross application rate: 1292 g/ha.
Crop growth stage: BBCH 00 - 97
Canopy interception %: 50
Application rate net of interception: 646 g/ha.
No. of applications: 1
Time of application (absolute or relative application dates): apples as a surrogate crop
spring appl.: Ch: 01-Apr
           H: 15-Apr
           J: 10-May
           K: 15-Apr
           O: 23-Mar
           P: 01-Apr
           Po: 15-Mar
           S: 15-Mar
           T: 15-Mar
autumn appl.: 15-Sep
PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| Scenario          | Fatty acids          | 1 x 1292 g a.s./ha, spring appl. | 1 x 1292 g a.s./ha, autumn appl. |
|-------------------|----------------------|----------------------------------|----------------------------------|
|                   | PEARL | PELMO | PEARL | PELMO |
| PECgw [µg/L]      | PECgw [µg/L]        | PECgw [µg/L]            | PECgw [µg/L]            |
| Châteaudun        | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg           | < 0.001 | < 0.001 | 0.0046  | 0.001  |
| Jokioinen         | < 0.001 | < 0.001 | 0.0019  | 0.002  |
| Kremsmünster      | < 0.001 | < 0.001 | 0.0029  | < 0.001 |
| Okehampton        | < 0.001 | 0.001  | 0.0086  | 0.014  |
| Piacenza          | < 0.001 | < 0.001 | 0.0111  | < 0.001 |
| Porto             | < 0.001 | < 0.001 | 0.0093  | < 0.001 |
| Sevilla           | < 0.001 | 0.001  | < 0.001 | < 0.001 |
| Thiva             | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

PEC(gw) From lysimeter / field studies
No data submitted.

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

| Parent | Version control no. of FOCUS calculator: |
|--------|------------------------------------------|
|        | To calculate the PECsw value,            |
|        | - ornamentals: < 50 cm 2.77 % drift rate at 1 m |
|        | - ornamentals: > 50 cm 8.02 % drift rate at 3 m |
|        | In the absence of degradation data and DT50 values, only the initial PECsw could be calculated. |
|        | Standard water depth of 30 cm was used |

| Application rate | Crop and growth stage: wheat BBCH 00-97 |
|------------------|------------------------------------------|
|                  | Number of applications: 1 |
|                  | Interval (d): - |
|                  | Application rate(s): 1292 g a.s./ha |

| Main routes of entry | Spray drift |

Predicted environmental concentrations of sheep fat in surface water

| Distance from field (m) | Spray drift rate (%) | Initial PECsw (µg/L) |
|-------------------------|----------------------|----------------------|
| ornamentals < 50 cm     | 2.77                 | 11.93                |
| ornamentals > 50 cm     | 8.02                 | 34.54                |

Metabolite Fatty acids
Parameters used in FOCUSsw step 1 and 2

The values PECsw were calculated for fatty acids (representative: oleic acid) according to the LoEP (EFSA)
Journal 2013;11(1):3023. The fatty acids are produced by natural hydrolysis sheep fat. Oleic acid was calculated as parent. As no values for degradation of sheep fat in soil are available, no PECsw for sheep fat can be calculated.

Molecular weight: 282.46 (oleic acid)
Molecular weight relative to the parent: 282.46 / 885.46 (Triglyceride) = 0.3190
Water solubility (mg/L): 207.8 at pH 7 and 20 °C
Koc (mL/g): 47.3 mL/g
DT₅₀ soil (d): 3.0 days (geometric mean)
DT₅₀ water/sediment system (d): 1000 d (default)
DT₅₀ water (d): 1000 (default)
DT₅₀ sediment (d): 1000 (default)
Maximum occurrence observed (% molar basis with respect to the parent)
Water: 100%

Application rate

deciduous and coniferous trees in forestry < 50 cm: scenario vegetables leafy
deciduous and coniferous trees in forestry > 50 cm: scenario vine, late appl.
Number of applications: 1
Interval (d): -
Application rate(s): 412.12 g a.s./ha (Application rate = MW Oleic acid / MW Sheep fat * % water)
Application window: Step 1&2 – Mar-May / June–Sep
Crop interception: minimal crop cover

Main routes of entry

Spray drift & run-off

Predicted environmental concentrations of fatty acids in surface water

| Crop | Step | Region (Timing)         | Max. PEC_sw [µg/L] | Max. PEC_sed [µg/kg] |
|------|------|-------------------------|--------------------|-----------------------|
|      | 1    | -                       | 133.02             | 62.77                 |
| deciduous and coniferous trees in forestry < 50 cm (1 x 412.15 g a.s./ha) | 2 | North Europe (June-Sep) | 9.18                | 4.33                   |
|      |      | South Europe (June-Sep) | 13.03              | 6.15                  |
|      |      | North Europe (Mar-May)  | 9.18               | 4.33                  |
|      |      | South Europe (Mar-May)  | 16.87              | 7.97                  |
|      | 1    | -                       | 140.26             | 65.99                 |
| deciduous and coniferous trees in forestry > 50 cm (1 x 412.15 g a.s./ha) | 2 | North Europe (June-Sep) | 11.03               | 4.94                   |
|      |      | South Europe (June-Sep) | 13.56              | 6.39                  |
|      |      | North Europe (Mar-May)  | 11.03              | 4.94                  |
|      |      | South Europe (Mar-May)  | 16.64              | 7.85                  |

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

| Method of calculation | No data submitted. |
|-----------------------|-------------------|

**PEC**

| Maximum concentration | No data submitted. |
|-----------------------|-------------------|
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** | | | | |
| *Indicate species* | a.s. | Acute | LD₅₀ | No data available |
| | Preparation | Acute | LD₅₀ | No data available |
| | Metabolite 1 | Acute | LD₅₀ | No data available |
| | a.s. | Long-term | LD₅₀/10 | No data available |
| | a.s. | Long-term | NOEC/NOAEC/NOAEL | No data available |
| **Mammals** | | | | |
| *Indicate species* | a.s. | Acute | LD₅₀ | No data available |
| | Preparation | Acute | LD₅₀ | No data available |
| | Metabolite 1 | Acute | LD₅₀ | No data available |
| | a.s. | Long-term | NOAEL | No data available |
| | a.s. | Long-term | NOAEL | No data available |

Endocrine disrupting properties (Annex Part A, points 8.1.5)
No data, not relevant. A waiver for the ED assessment for sheep fat is accepted

Additional higher tier studies (Annex Part A, points 10.1.1.2):
No tier data submitted.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
No data submitted.
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

[Representative use] at [application rate] g a.s./ha [x number of applications]

| Growth stage | Indicator or focal species | Time scale  | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|-------------|------------------------|-----|---------|
| Screening Step (Birds) | Earthworm-eating birds | Long-term | -                      | -   | 5       |
| Screening Step (Mammals) | Earthworm-eating mammals | Long-term | -                      | -   | 5       |
| Screening Step (Mammals) | Fish-eating birds | Long-term | -                      | -   | 5       |
| Screening Step (Mammals) | Fish-eating mammals | Long-term | -                      | -   | 5       |
| Screening Step (Mammals) | Higher tier (Mammals): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)] | | | | |
| Risk from bioaccumulation and food chain behaviour [indicate when not relevant i.e if Log kow≤3] | Indicator or focal species | Time scale  | DDD (mg/kg bw per day) | TER | Trigger |
| Earthworm-eating birds | Long-term | -                      | -   | 5       |
| Earthworm-eating mammals | Long-term | -                      | -   | 5       |
| Fish-eating birds | Long-term | -                      | -   | 5       |
| Fish-eating mammals | Long-term | -                      | -   | 5       |
| Higher tier : No refinement needed. |

Risk from consumption of contaminated water

| Scenarios | Indicator or focal species | Time scale  | PEC_{dw}xDWR | TER | Trigger |
|-----------|---------------------------|-------------|--------------|-----|---------|
| Leaf scenario | Birds | acute | -       | -   | 5       |
| Puddle scenario, Screening step |
| 1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed |
| 2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed |
| Puddle scenario | Birds | acute | -       | -   | 10      |
| Puddle scenario | Mammals | acute | -       | -   | 10      |
| Puddle scenario | Birds | Long-term | -       | -   | 5       |
| Puddle scenario | Mammals | Long-term | -       | -   | 5       |

www.efsa.europa.eu/efsajournal 30  EFSA Journal 2022;20(1):7073
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

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

| Group                      | Test substance | Time-scale (Test type) | End point                      | Toxicity† |
|----------------------------|----------------|------------------------|--------------------------------|-----------|
| **Laboratory tests**       |                |                        |                                |           |
| **Fish**                   |                |                        |                                |           |
| Indicate species           | a.s.           | Acute 96 hr (static, or semi-static or flow-through) | Mortality, LC₅₀ | No data available |
|                            |                |                        |                                | mg or µg a.s./L(nom) or (mm) |
| *Brachydanio rerio*        | Trico (K 715-4)| Acute 96 hr (semi-static) | Mortality, LC₅₀ | >89.7 mg form./L |
|                            |                |                        |                                | (geom. mm) |
|                            | a.s.           | Chronic (static, or semi-static or flow-through) | Growth, or development, or behaviour, or reproduction NOEC | No data available |
|                            |                |                        |                                | mg or µg a.s./L(nom) or (mm) |
| **Aquatic invertebrates**  |                |                        |                                |           |
| Indicate species           | a.s.           | 48 h (static, or semi-static or flow-through) | Mortality, EC₅₀ | No data available |
|                            |                |                        |                                | mg or µg a.s./L(nom) or (mm) |
| *Daphnia magna*            | Trico (K 715-4)| 48 h (static)         | Immobility, EC₅₀ | >88 mg form./L |
|                            |                |                        |                                | (geom. mm) |
|                            | a.s.           | 21 d (static, or semi-static or flow-through) | Reproduction or development, NOEC | No data available |
|                            |                |                        |                                | mg or µg a.s./L(nom) or (mm) |
| **Sediment-dwelling organisms** |            |                        |                                |           |
| Indicate species           | a.s.           | 28 d (static, or semi-static or flow-through) | NOEC | No data available |
|                            |                |                        |                                | mg or µg a.s./kg dry sediment(nom) or (mm) |
|                            |                |                        |                                | (mg or µg a.s./L(nom) or (mm)) |
| Group                        | Test substance | Time-scale (Test type) | End point                              | Toxicity¹ |
|-----------------------------|----------------|------------------------|-----------------------------------------|-----------|
| Algae                       |                |                        |                                         |           |
| *Indicate species*          | a.s.           | 72 h (static, or semi- | Growth rate: E_{C50} (NOEC)             | No data available³ |
|                             |                | static or flow-through) | [Biomass: E_{bC50} (NOEC)               | mg or µg  |
|                             |                |                        | Yield: E_{yC50} (NOEC)                 | a.s./L_{(nom)} or (mm) |
| *Pseudokirchneriella*       | Trico (K 715-4)| 72 h (static)          | Growth rate: E_{C50} (NOEC)             | >31.3 mg form./L |
| subcapitata (formerly known |                |                        | Biomass: E_{bC50} (NOEC)               | 31.3 mg form./L |
| as *Selenastrum* capricornutum) |              |                        |                                         | (geom. mm) |
|                             |                |                        | Fronds number, E_{C50} (NOEC)          | No data available |
|                             |                | (static, or semi-     | Frond area/fresh weight/dry weight,     | mg or µg  |
|                             |                | static or flow-through)| E_{aC50} (NOEC)                      | a.s./L_{(nom)} or (mm) |
|                             |                |                        |                                         | mg prep./L |
| Higher plant                |                |                        |                                         | (mg or µg  |
| *Indicate species*          | a.s.           | (static, or semi-     |                                         | mg or µg  |
|                             |                | static or flow-through)| Fronds number, E_{C50} (NOEC)          | a.s./L_{(nom)} or (mm) |
| Preparation                 |                |                        |                                         | No data available |
| Further testing on aquatic organisms |              |                        |                                         | mg prep./L |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) | No data available | Fronds number, E_{C50} (NOEC) | No data available |

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

² Toxicity data with the active substance were not available for any group of non-target organisms. Although these data are not needed to assess the risk to aquatic organisms, according to Regulation (EU) No 283/2013, acute toxicity data with active substances should always be submitted for fish, aquatic invertebrates and algae. Therefore, a data gap was identified.
## Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                          | Active substance | Metabolite 1 | Metabolite 2 | Metabolite 3 |
|--------------------------|------------------|--------------|--------------|--------------|
| logP<sub>O/W</sub>       |                  |              |              |              |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | No data available | X*           |              |              |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) |                  |              |              |              |
| Annex VI Trigger for the bioconcentration factor |                  |              |              |              |
| Clearance time (days) (CT<sub>50</sub>) |                  |              |              |              |
| (CT<sub>90</sub>)        |                  |              |              |              |
| Level and nature of residues (%) in organisms after the 14 day depuration phase |                  |              |              |              |
| Higher tier study        |                  |              |              |              |

* based on total <sup>14</sup>C or on specific compounds
### PEC/RAC comparisons for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

PEC/RAC comparisons for sheep fat – ornamentals (> 50 cm – worst-case) at 20 L product/ha x 1

| Scenario | PEC global max (µg/L) | Fish acute | Fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | Sed. dweller prolonged | Spiked water | Sed. dweller prolonged | Spiked sediment |
|----------|-----------------------|------------|--------------|-----------------------|---------------------------------|-------|--------------|-----------------------|--------------|-----------------------|-----------------|
|          |                       | Brachydanio rerio | Daphnia magna | Selenastrum capricornutum |                                 |       |              |                       |              |                       |                 |
|          |                       | LC₅₀        | NOEC         | EC₅₀                  | NOEC                            | E₅₀C₅₀ | Ec₅₀         | NOEC                  |              |                       |                 |
| RAC      | >89700 µg/L           | >897 µg/L   | >88000 µg/L  | >31300 µg/L           | -                               | -      |              | -                     |              |                       |                 |
| Assessment factor | 100                  | 10          | 100          | 10                    | 10                              | 10     | 10           | 10                    |              |                       |                 |
| FOCUS Step 1 | 540.01 µg/L | 540.01      | 540.01       | 540.01                | -                               | -      |              | -                     |              |                       |                 |

PEC values in bold exceed the relevant RAC, indicating an unacceptable risk.
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

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

| Species | Test substance | Time scale/type of endpoint | End point | toxicity |
|---------|----------------|-----------------------------|-----------|----------|
| **Indicate species** | a.s., | Acute | Oral toxicity (LD<sub>50</sub>) | No data available µg/bee |
| *Apis mellifera* | Trico (K 715-4) | Acute | Oral toxicity (LD<sub>50</sub>) | >100 µg a.s./bee |
| *Apis mellifera* | K 743-4 | Acute | Oral toxicity (LD<sub>50</sub>) | >63 µg a.s./bee |
| a.s., | Acute | Contact toxicity (LD<sub>50</sub>) | No data available µg/bee |
| *Apis mellifera* | Trico (K 715-4) | Acute | Contact toxicity (LD<sub>50</sub>) | >100 µg a.s./bee |
| *Apis mellifera* | K 743-4 | Acute | Contact toxicity (LD<sub>50</sub>) | >63 µg a.s./bee |
| a.s., | Chronic | 10 d-LC<sub>50</sub> | No data available µg/bee/day |
| *Apis mellifera* | Trico | Chronic | 10 d chronic toxicity (LDD<sub>50</sub>) | >1916 µg form./bee/day >111.1 µg a.s./bee/day |
| a.s., | Bee brood development | NOEC<sub>larvae</sub> | No data available µg/larva/developmental period |
| *Apis mellifera* | Trico | Chronic, repeated exposure | Oral toxicity (LD<sub>50</sub>) (NOED) | >1724 µg form./larva >100 µg a.s./larva |
| a.s., | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | No data available |
| preparation | | | No data available |
Potential for accumulative toxicity: No data available
Semi-field test (Cage and tunnel test)
No data available
Field tests
No data available

Risk assessment for honeybees from contact and oral dietary exposure for forest at 1.292 kg a.s/ha x 1, BBCH 0-97

1) Risk assessment according to SANCO/10329/2002 rev.2 (final)

| Species          | Test substance | Risk quotient | HQ   | Trigger |
|------------------|----------------|---------------|------|---------|
| Apis mellifera   | Trico          | HQcontact     | <20.5| 50      |
| Apis mellifera   | Trico          | HQoral        | <20.5| 50      |

2) Risk assessment according to EFSA/2013/3295

Pesticide Peer Review TC 63 (20–23 September 2021):
At TC 63, it was agreed that the risk assessment to bees based on EFSA/2013/3295 is considered informative and will not be used to concluded on the overall risk to bees. The available evaluation can be considered as overconservative and unrealistic for the case under assessment; therefore, the experts at the meeting evaluated the case for bees in a qualitative manner considering the information in the GAP table. A low chronic risk to bees could not be concluded for the uses on deciduous trees at BBCH 00/01 – BBCH 91 (during their flowering period). Further data (e.g. a more refined use) would be needed at MS level for product authorization (data gap).

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  | a.s., preparation | Mortality, LR₅₀ | No data available |
|                    |                | Reproduction, ER₅₀ | g/ha               |
|                    |                |                    | g/ha               |
| Aphidius rhopalosiphi | a.s., preparation | Mortality, LR₅₀ | No data available |
|                    |                | Reproduction, ER₅₀ | g/ha               |
|                    |                |                    | g/ha               |

Additional species
### First tier risk assessment

For – [representative use] at [application rate] g a.s./ha [x number of applications]

| Test substance | Species | Effect (LR<sub>50</sub> g/ha) | HQ in-field | HQ off-field<sup>1</sup> | Trigger |
|----------------|---------|-------------------------------|-------------|--------------------------|---------|
| Typhlodromus pyri | No data available | 2 | | | |
| Aphidius rhopalosiphi | No data available | 2 | | | |

<sup>1</sup>Indicate distance assumed to calculate the drift rate

### Extended laboratory tests, aged residue tests

| Species | Life stage | Test substance, substrate | Study type | Dose (g/ha) | Mortality/ Corr. mortality (%) | Sublethal effects |
|---------|------------|---------------------------|------------|-------------|--------------------------------|------------------|
| Typhlodromus pyri | Protonymph (K 715-4) | Trico (K 715-4) | Tier II | Extended lab Bean leaves (2-D) | 10 L form./ha 15 L form./ha | Control 12.2 16.1 / 4.4 16.7 / 5.1 | LR<sub>50</sub> >15 L form./ha |
| | | | | | | | No. of eggs per female / % adverse effects<sup>1</sup> 5.4 5.3 / 2% 6.5 / -20% |
| Aphidius rhopalosiphi | Adult | Trico | Tier II | Extended lab Barley seedlings (3-D) | Control 0 0 / 0 5 / 5 15 / 15 | 0 0 / 0 5 / 5 15 / 15 | LR<sub>50</sub> >30 L form./ha |
| | | | | | | | ER<sub>50</sub> >30 L form./ha |

<sup>1</sup>Positive percentages relate to adverse effects in comparison with control

### Risk assessment for forest at 1.292 kg a.s/ha x 1, BBCH 0-97 based on extended lab test or aged residue tests
The extended laboratory study with the standard arthropod species *Typhlodromus pyri* indicates an acceptable risk up to a test concentration of 15 L Trico/ha. The study with the parasitoid *Aphidius rhopalosiphi* indicates an acceptable risk up to a test concentration of 30 L Trico/ha. The study with *Typhlodromus pyri* was conducted with a maximal test concentration of 15 L Trico/ha which does not completely cover the intended uses in forestry of 20 L Trico/ha. However, the study results demonstrated very low toxicity of Trico to *Typhlodromus pyri* at 15 L Trico/ha (corrected mortality 5.1% and positive effect on reproduction 20% (i.e. reproduction was higher in the treatment group than in control). Moreover, the highly targeted application of the product, with individual treatment applied directly to stems/trunks of forestry trees significantly reducing exposure to NTAs in forest areas (no spray is directed to tree flowers nor weeds on the forest floor).

Overall, the risk to non-target arthropods other than bees is considered to be low and no further data are required.

| Species              | ER\textsubscript{50} (g/ha) | In-field rate | In-field risk acceptable? | Off-field rate | Off-field risk acceptable? |
|----------------------|-----------------------------|---------------|---------------------------|----------------|-----------------------------|
| *Typhlodromus pyri*  | >15 L form./ha              | 20 L form./ha | no\textsuperscript{1}      | 0.277 L form./ha (<50 cm height, 2.77% drift at 1m) | yes            |
|                      |                             |               |                           | 0.802 L form./ha (>50 cm height, 8.02% drift at 3m) | yes            |
| *Aphidius rhopalosiphi* | >30 L form./ha              | 20 L form./ha | yes                       | 2.77 L form./ha (<50 cm height, 2.77% drift at 1m) | yes            |
|                      |                             |               |                           | 8.02 L form./ha (>50 cm height, 8.02% drift at 3m) | yes            |

\textsuperscript{1} The extended laboratory study with the standard arthropod species *Typhlodromus pyri* indicates an acceptable risk up to a test concentration of 15 L Trico/ha. The study with the parasitoid *Aphidius rhopalosiphi* indicates an acceptable risk up to a test concentration of 30 L Trico/ha. The study with *Typhlodromus pyri* was conducted with a maximal test concentration of 15 L Trico/ha which does not completely cover the intended uses in forestry of 20 L Trico/ha. However, the study results demonstrated very low toxicity of Trico to *Typhlodromus pyri* at 15 L Trico/ha (corrected mortality 5.1% and positive effect on reproduction 20% (i.e. reproduction was higher in the treatment group than in control). Moreover, the highly targeted application of the product, with individual treatment applied directly to stems/trunks of forestry trees significantly reducing exposure to NTAs in forest areas (no spray is directed to tree flowers nor weeds on the forest floor).

Overall, the risk to non-target arthropods other than bees is considered to be low and no further data are required.

**Semi-field tests**
- 

**Field studies**
- 

**Additional specific test**
- 

**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\textsuperscript{1} | Time scale | End point | Toxicity |
|---------------|----------------|-------------------------------------------------------|------------|-----------|----------|
| Earthworms    | a.s.           | Chronic                                               | Growth, reproduction, behaviour | No data available | EC\textsubscript{10}, EC\textsubscript{20}, NOEC mg a.s./kg d.w.soil (mg a.s/ha) |
| Test organism | Test substance | Application method of test a.s./OM<sup>1</sup> | Time scale | End point | Toxicity |
|---------------|----------------|---------------------------------------------|------------|-----------|----------|
| *Eisenia fetida* (K 715-4) | Trico | Mixed through soil / 5% OM | Chronic, 56 days | Growth, reproduction, behaviour (NOEC) | 500 mg form./kg dws |

Other soil macroorganisms

| Test organism | Test substance | Application method of test a.s./OM<sup>1</sup> | Time scale | End point | Toxicity |
|---------------|----------------|---------------------------------------------|------------|-----------|----------|
| *Folsomia candida* | a.s. | | | Mortality, reproduction, behaviour [amend as appropriate] | No data available |
| | preparation | | | | No data available |
| *Hypoaspis aculeifer* | a.s. | | | Mortality, growth, reproduction, behaviour [amend as appropriate] | No data available |
| | preparation | | | | No data available |

<sup>1</sup>To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5% or 10%).

Higher tier testing (e.g. modelling or field studies)
No data available

Nitrogen transformation

| Test substance | Time scale | Soil PEC | TER | Trigger |
|----------------|------------|----------|-----|---------|
| Trico (K 715-4) | Chronic | 13.467 | 37.13 | 5 |

Effects less than 25% after 28 days up to 24.846 mg a.s./kg dry soil (corresponding to an application rate of 18.635-kg a.s./ha or 300 L Trico/ha)

**Toxicity/exposure ratios for soil organisms**

Forest at 1.292 kg a.s./ha x 1, BBCH 0-99

| Test organism | Test substance | Time scale | Soil PEC | TER | Trigger |
|---------------|----------------|------------|----------|-----|---------|
| *Eisenia fetida* (K 715-4) | Trico | Chronic | 13.467 | 37.13 | 5 |

Other soil macroorganisms

| Test organism | Test substance | Time scale | Soil PEC | TER | Trigger |
|---------------|----------------|------------|----------|-----|---------|
| a.s. | | | | | - |
| preparation | | | | | - |
Test organism | Test substance | Time scale | Soil PEC | TER | Trigger |
--- | --- | --- | --- | --- | --- |
| a.s. | | | | - | - |
| preparation | | | | - | - |

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

Screening data
Not required for herbicides or plant growth regulators as ER₅₀ tests should be provided

Laboratory dose response tests

| Species | Test substance | ER₅₀ (L form./ha)² vegetative vigour | ER₅₀ (L form./ha) emergence | Exposure₁ (L form./ha) | TER | Trigger |
| --- | --- | --- | --- | --- | --- | --- |
| Wheat, ryegrass, sorghum, barley, lettuce, tomato, oil seed rape, pea, cucumber, carrot | Trico | ER₅₀ >60 L product/ha | - | 1.64 | > 36.59 | 5 |
| Wheat, ryegrass, sorghum, barley, lettuce, tomato, oil seed rape, pea, cucumber, carrot | Trico | - | ER₅₀ >60 L product/ha | 1.64 | > 36.59 | 5 |

Extended laboratory studies: -
Semi-field and field test: -

₁ The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (based on Ganzelmeier drift data); for the use in forest trees the drift value of 8.02 % as given for ornamentals with > 50 cm height was used (worst case)

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

| Test type/organism | end point |
| --- | --- |
| Activated sludge | No data available |
| Pseudomonas sp. | No data available |

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

Available monitoring data concerning adverse effect of the a.s.
No data available
Available monitoring data concerning effect of the PPP.
No data available
### Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds

| Compartment | Not relevant (sheep fat is a natural non-toxic compound, no residue definition) |
|-------------|--------------------------------------------------------------------------------|
| 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) 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:

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

| Substance   | Classification       |
|-------------|----------------------|
| Sheep fat   | No current harmonised classification |
|             | None                 |

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.
FORMAT FOR THE LISTING OF END POINTS FOR A MICROBIAL OR VIRAL PEST CONTROL AGENT (MPCA) USED IN PLANT PROTECTION

Not applicable.