CONCLUSION ON PESTICIDE PEER REVIEW

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# Peer review of the pesticide risk assessment of the active substance sheep fat

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## Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State the Czech Republic (CZ) and co-rapporteur Member State France (FR) for the pesticide active substance sheep fat and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of sheep fat as a repellent on deciduous and coniferous trees in forestry. The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed.



**Keywords:** sheep fat, peer review, risk assessment, pesticide, repellent

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## Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Sheep fat is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), the Czech Republic, and co-rapporteur Member State (co-RMS), France, received an application from Kwizda Agro GmbH for the renewal of approval of the active substance sheep fat. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on sheep fat was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of sheep fat according to the representative uses as field spray applications, using conventional atomisers or knapsack sprayers, on deciduous and coniferous trees in forestry, as proposed at EU level, result in a sufficient game repellent efficacy.

There were no critical issues identified in the section on **identity, physical–chemical and technical properties** of the active substance and the representative formulation and the analytical methods.

No critical issues were identified for the active substance sheep fat in the **mammalian toxicology section**.

In the **residues section**, an assessment was conducted for the representative uses and in parallel for authorised uses according to Article 12 of Regulation (EC) No 396/2005. Considering the proposed Good Agricultural Practices (GAPs), residues from the use of sheep fat are not expected. An maximum residue level (MRL) application for inclusion of sheep fat into Annex IV of Regulation (EC) No 396/2005 has also been submitted. With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, four criteria are considered to be met (II, III, IV, V) for sheep fat.

The data available on **environmental fate and behaviour** were sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed.

No critical issues were identified for the active substance sheep fat in the **ecotoxicology** section.

Sheep fat does not meet the criteria for **endocrine disruption** for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

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## Background

Commission Implementing Regulation (EU) No 844/2012[1], as amended by Commission Implementing Regulation (EU) No 2018/1659[2], (herein after referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States (MSs), the applicant(s), and the public on the initial evaluation provided by the rapporteur Member State (RMS), and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS the Czech Republic and co-RMS France received an application from Kwizda Agro GmbH for the renewal of approval of the active substance sheep fat. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005[4]. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on sheep fat in the RAR, which was received by EFSA on 10 September 2020 (Czech Republic, 2020). Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 27 November 2020, EFSA invited the MSs to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the MSs and the applicant, Kwizda Agro GmbH, for consultation and comments on 30 November 2020. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 30 January 2021. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 19 March 2021. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the area of ecotoxicology.

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 maximum residue level (MRL) review of Regulation (EC) No 396/2005 took place with MSs via a written procedure in November 2021.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of sheep fat as a repellent on deciduous and coniferous trees in forestry as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 27 November 2020 EFSA invited the MSs to submit their GAPs that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for sheep fat according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021a), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (8 April 2021);
- the evaluation table (17 November 2021);
- the report(s) of the scientific consultation with MS experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Czech Republic, 2021), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

## The active substance and the formulated product

Sheep fat is a triglyceride consisting predominantly of glycerine esters of palmitic acid, stearic acid and oleic acid.

The representative formulated product for the evaluation was 'Trico (K 715-4B)' an oil in water emulsion (EW) formulation containing 64.6 g/L (64 g/kg) sheep fat.

The representative uses evaluated comprise field spray applications, using conventional atomisers or knapsack sprayers, on deciduous and coniferous trees in forestry as a game repellent at EU level. Full details of the GAP can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of sheep fat according to the representative uses proposed at EU level results in a sufficient game repellent efficacy, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

# Conclusions of the evaluation

## 1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: European Commission (2000a,b).

The proposed minimum purity specification for sheep fat was based on batch data from industrial scale production. The proposed specification of the active substance as manufactured is 100%, i.e. min. 1,000 g/kg.

There was no specification available at the time of the first evaluation due to missing batch data. Based on the renewal batch data, it is proposed to set the reference specification to the specification proposed by the RMS (see reference specification in the Appendix B). An FAO specification does not exist for sheep fat.

The assessment of the data package revealed no critical areas of concern with respect to the identity, physical, chemical and technical properties of sheep fat or the representative formulation. The main data regarding the identity of sheep fat and its physical and chemical properties are given in Appendix B.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Methods of analysis are provided for the determination of sheep fat and its fatty acids in the technical material and in the representative formulation as well as for the determination of the microbiological contamination in the technical material. Methods for the analysis of residues in food and feed of plant and animal origin, in body fluids, in body tissues and in the environment are not required as no residue definitions were set.

## 2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: ECHA (2017).

By its nature, sheep fat is devoid of intrinsic toxicological properties. It is derived in fact from the sheep fat tissues, which is part of the European diet, and its main natural components consist of glycerine esters of palmitic acid, stearic acid and oleic acid. In the EU, these free fatty acids are authorised as a food additive (E 570) under Regulation (EC) No 1333/2008[5]. EFSA re-evaluated the safety of E 570 in 2017 and concluded it to be of no safety concern. No toxicological studies have been submitted for sheep fat by the applicant. Supportive information from the open literature on sheep fat components indicates that palmitic, stearic and oleic acids are of low or of no toxicity. These fatty acids are not classified in any hazard class according to classification, labelling and packaging (CLP) criteria (Regulation (EC) No 1272/2008[6]). Some CLP notifications for skin irritation and eye irritation have been submitted to ECHA for palmitic, stearic acid and oleic acids. Nonetheless, most publicly available studies on palmitic, stearic and oleic acids do not support a skin or eye irritation potential. Based on its chemical composition (i.e. triglyceride, fatty acids), all toxicological studies can be waived, and toxicological reference values are not required for sheep fat.

Thus, the risk to operators, workers, residents and bystanders related to the exposure to the active substance sheep fat is considered to be negligible (if any).

EFSA notes that the representative plant protection product 'Trico (K 715-4B)' contains a co-formulant of potential concern, i.e. titanium dioxide ($TiO_2$) of unknown particle size at a final concentration higher than 1%. Titanium dioxide is classified as a suspected carcinogen (Category 2) by inhalation according to Regulation (EC) No 1272/2008. This classification specifically applies to $TiO_2$ in powder form containing 1% or more particles with aerodynamic diameter $\leq$ 10 μm. The presence of $TiO_2$ at a level > 1% might trigger the classification of the product as Carcinogen category 2, pending further considerations of the aerodynamic diameter of particles in the product. Additionally, EFSA has recently revised its safety assessment of $TiO_2$ as a food additive (EFSA, 2021b) and has concluded that a genotoxic concern for $TiO_2$ particles (with unknown relationship to particle size) cannot be ruled out (data gap). Consequently, a quantitative non-dietary risk assessment for $TiO_2$ in the representative

[5] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

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

plant protection product cannot be concluded of no safety concern for operators and workers for all representative uses. The use of protective equipment might be considered for national authorisations to reduce the dermal and inhalation exposure to $TiO_2$ in 'Trico (K 715-4B)'.

The second one is a co-polymer of styrene. The monomer of styrene is classified as Skin Irrit. 2, Eye Irrit. 2, Acute tox 4, STOT RE1 and Repr. 2 according to Regulation (EC) No 1272/2008. Additionally, EFSA has recently re-assessed styrene safety for use as a food contact material (EFSA CEP, 2020) and concluded that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. Pending the evidence that styrene is released from the co-polymer in the formulation, further assessment of its potential for genotoxicity in the plant protection product may need to be provided (data gap) (see Section 3).

## 3. Residues

The active substance sheep fat is a natural compound produced from sheep fat tissues classified as foodstuff and part of the European diet. However, the representative plant protection product contains co-formulants of potential concern (see Section 2).

For residues no data nor studies were submitted.

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.

In the context of Article 12 of Regulation (EC) No 396/2005 the collection of GAPs resulted in additional uses in a variety of crops in North European zone (NEU) and Southern Europe and the Mediterranean (SEU). The assessment only considered GAPs that were relevant and clearly reported (see GAP overview file). The application for these uses is intended either as seed treatment or as foliar treatment (broadcast spraying) at a latest growth stage where the edible crop parts are not yet present (up to BBCH 61) or are not directly exposed to the spray (potato tubers up to BBCH 99). Also, with regard to these uses, residues in food items are unlikely to occur.

A quantitative consumer dietary risk assessment is therefore not necessary and can be waived.

With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V), four criteria were considered to be met for sheep fat for the following reasons:

- The application technique reported for the proposed uses on deciduous and coniferous trees in forestry (spraying individual trees) and the application timing for the uses reported under Article 12 procedure are unlikely to result into consumer exposure (criterion V). Toxicological reference values are not required for sheep fat (criterion III) and substance is listed in Annex I of Regulation (EC) No 396/2005 (criterion II).
- The other two criteria are either not applicable (criterion I) or no data were submitted to address consumption of sheep fat as food item (criterion IV). However, for the assessed plant protection uses, residues of sheep fat on edible commodities are unlikely to occur and it can be reasonably assumed that consumer exposure from direct consumption of the food item sheep fat is greater and that also criterion IV is met.

Regarding the assessment of potential residues resulting from the co-formulants in the representative plant protection product (see Section 2), consumer exposure is not expected for the representative uses on deciduous and coniferous trees in forestry.

## 4. Environmental fate and behaviour

The fate and behaviour of sheep fat are expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. During the degradation process of sheep fat only natural compounds like glycerine and fatty acids are formed which are basic and ubiquitous substances.

Some information on the free fatty acids (i.e. not in triglyceride ester forms) oleic, palmitic and stearic acids was reported, the source of the numerical values reported have not been independently

assessed by the RMS. Consequently, these values are not considered in this conclusion and are not included in Appendix B.

For the representative uses, the surface water and sediment exposure assessments (predicted environmental concentration (PEC) calculations) were carried out for sheep fat and fatty acids considering only the entry route via spray drift.

The potential for groundwater exposure by sheep fat from the representative uses assessed would be expected to be low as a consequence of its expected low soil mobility and considering the very low water solubility. The groundwater exposure assessments were carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3.[7] The potential for groundwater exposure from the representative uses by fatty acids above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios.

Considering that sheep fat is a natural compound and its degradation products are ubiquitous substances, it is not expected that the level of residues at the point of abstraction when surface water is abstracted for drinking water would be significantly impacted by the use of this active substance.

The PEC in soil, surface water, sediment and groundwater covering the representative uses can be found in Appendix B.

## 5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2013) and EFSA PPR Panel (2013).

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[8], acute toxicity data with active substances should always be submitted for fish, aquatic invertebrates and algae. Therefore, a data gap was identified.

A low acute and chronic risk to **birds and mammals** was concluded considering the nature of sheep fat (i.e. mixture of compounds naturally presents in many terrestrial and aquatic plants and animals), its low toxicological profile and its mode of action (game repellent for mammals).

Based on the toxicity data on fish, aquatic invertebrates and algae with the representative formulation 'Trico (K 715-4B)' and the risk assessment, a low acute risk for **aquatic organisms** was indicated for sheep fat and its fatty acids. Toxicity data to assess the chronic risk to aquatic organisms was not deemed necessary due to the nature of the substance.

Acute (oral and contact) and chronic (larvae and adult) data on honey **bees** were available for the formulation 'K 743-4' and/or the representative one 'Trico (K 715-4B)'. A low acute risk was identified for the representative uses of sheep fat. Noting that the current risk assessment schemes do not cover the Tier 1 scenarios for the specific uses in forestry and deciduous trees, the experts at the Pesticide Peer Review Experts' Teleconference 63 in September 2021 considered assessing the chronic risk to bees[9] in a qualitative manner. The experts considered that a localised spot application to certain parts of trees, like stems and/or trunks of deciduous and coniferous trees, will result in a low exposure to bees as bees are not expected to actively forage in these parts of the plants. However, the experts noted that if the spot applications at the terminal shoots are made during the flowering period by using conventional atomisers or knapsacks sprayers, the exposure to bees cannot be fully excluded. This would not be an issue for coniferous trees as they are considered to be low-attractive to bees for pollen and nectar collection (e.g. EFSA, 2015). Furthermore, the experts noted that spot application minimises spray drift to surrounding areas, resulting in a lower exposure to flowering weeds near treated trees. Although sheep fat has a non-toxic mode of action, the results of the honey bee larvae study indicate that it might have a negative impact on bee emergence. Based on the above-mentioned assessment, 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). Therefore, further data (e.g. a more refined use) would be needed at MS level for product authorisation (data gap). A low risk via contaminated water was concluded for all uses of sheep fat.

[7] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

[8] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

[9] See experts' consultation 5.1 at the Pesticide Peer Review Teleconference 63 (EFSA, 2021a).

Extended laboratory studies with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted for the representative formulation. A low risk to **non-target arthropods** could not be concluded for the representative uses of sheep fat since the concentration used in the study with *T. pyri* was lower than the intended application rate. However, based on the results of the available studies and the spot application to individual trees with a knapsack sprayer resulting in lower drift values than broadcast applications, a low in-field risk was concluded. Based on the toxicity data and toxicological risk assessment, a low off-field risk to non-target arthropods was indicated.

A low risk was concluded for **earthworms, soil micro-organisms and non-target terrestrial plants** for the representative uses of sheep fat and its fatty acids. A low risk to **soil macro-organisms** other than earthworms was concluded considering the nature of sheep fat, its low toxicological profile and its limited environmental exposure.

No exposure for organisms involved in **sewage treatment processes** would be expected for any of the representative uses and, therefore, a low risk was indicated.

## 6. Endocrine-disrupting properties

With regard to the assessment of the endocrine-disrupting potential of sheep fat for **humans** and **non-target organisms** according to the ECHA/EFSA guidance (2018), although no (eco)toxicological data are available to assess the endocrine-disrupting properties, this does not appear scientifically necessary considering the nature of the substance which is a mixture of naturally occurring compounds (i.e. glycerine esters of palmitic acid, stearic acid and oleic acid). In addition, the substance is used as a repellent and it has a non-toxic mode of action. Therefore, no (sub)chronic studies were available nor considered necessary. Consequently, it is justified to waive the assessment of endocrine disrupting properties of this substance for both humans and non-target organisms.

Considering the above, it can be concluded that sheep fat does not meet the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

## 7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

**Table 1:** Soil

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| **Sheep fat** | Low risk to soil organisms |
| **Fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid)** | Low risk to soil organisms |

**Table 2:** Groundwater[(a)]

| Compound (name and/or code) | > 0.1 µg/L at 1 m depth for the representative uses[(b)] Step 2 | Biological (pesticidal) activity/ relevance Step 3a | Hazard identified Steps 3b and 3c | Consumer RA triggered Steps 4 and 5 | Human health relevance |
|---|---|---|---|---|---|
| **Sheep fat** | No | Not applicable[(c)] | – | – | Yes |
| **Fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid)** | No | Not triggered | No | No | No |

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or a relevant lysimeter.
(c): Attractants and repellents are not defined as pesticides in Council Directive 98/83/EC.[10]

[10] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, p. 32–54.

**Table 3:** Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| **Sheep fat** | Low risk to aquatic organisms |
| **Fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid)** | Low risk to aquatic organisms |

**Table 4:** Air

| Compound (name and/or code) | Toxicology |
|---|---|
| **Fatty acids (glycerol ester of palmitic acid, stearic acid, oleic acid)** | No data submitted |

# 8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of MS and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures, applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses, are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level).

No particular conditions to be taken into account by risk managers were identified.

# 9. Concerns and related data gaps

## 9.1. Concerns and related data gaps for the representative uses evaluated

### 9.1.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[11] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

**The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related**:

Issues not finalised were not identified.

### 9.1.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6)

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

**The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:**

Critical areas of concern were not identified.

### 9.1.3. Overview of the concerns identified for each representative use considered (Table 5)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

**Table 5:** Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

| **Representative use** | | **Deciduous and coniferous trees in forestry**<br>**Hand-held spraying** |
|---|---|---|
| **Operator risk** | Risk identified | |
| | Assessment not finalised | |
| **Worker risk** | Risk identified | |
| | Assessment not finalised | |
| **Resident/bystander risk** | Risk identified | |
| | Assessment not finalised | |
| **Consumer risk** | Risk identified | |
| | Assessment not finalised | |
| **Risk to wild non-target terrestrial vertebrates** | Risk identified | |
| | Assessment not finalised | |
| **Risk to wild non-target terrestrial organisms other than vertebrates** | Risk identified | |
| | Assessment not finalised | |
| **Risk to aquatic organisms** | Risk identified | |
| | Assessment not finalised | |
| **Groundwater exposure to active substance** | Legal parametric value breached | |
| | Assessment not finalised | |
| **Groundwater exposure to metabolites** | Legal parametric value breached[(a)] | |
| | Parametric value of 10 µg/L[(b)] breached | |
| | Assessment not finalised | |

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

## 10. List of other outstanding issues

**Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.**

**These data gaps refer only to the representative uses assessed and are listed in the order of the sections**

- The genotoxic potential of the co-formulant $TiO_2$ (including its relationship with particle size) needs to be elucidated (relevant for all representative uses evaluated; see Section 2).
- Pending on evidence of the release of styrene from the co-polymer in the formulation, further assessment of its potential for genotoxicity in the plant protection product may need to be provided (relevant for all representative uses evaluated; see Section 2).
- Further information on the toxicity of sheep fat on aquatic organisms, i.e. acute toxicity data (data gap not needed for the risk assessment but set because required by the Regulation (EU) No 283/2013, relevant for all representative uses evaluated; see Section 5).
- Further data (e.g. a more refined use) to address the low chronic risk to honey bees (relevant for the uses on deciduous trees during flowering; see Section 5).

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## Abbreviations

| | |
|---|---|
| BBCH | Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie |
| CLP | Classification, Labelling and Packaging |
| DAR | draft assessment report |
| ECHA | European Chemicals Agency |
| EEC | European Economic Community |
| EW | water emulsion |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| GAP | Good Agricultural Practice |
| InChiKey | International Chemical Identifier Key |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| MRL | maximum residue level |
| MS | Member State |
| NEU | North European zone |
| OECD | Organisation for Economic Co-operation and Development |
| PEC | predicted environmental concentration |
| PHI | preharvest interval |
| RAR | Renewal Assessment Report |
| RMS | Rapporteur Member State |
| SEU | Southern Europe and the Mediterranean |
| SMILES | simplified molecular-input line-entry system |
| ToxCAST | (US EPA) Toxicity Forecaster |

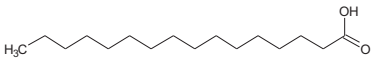
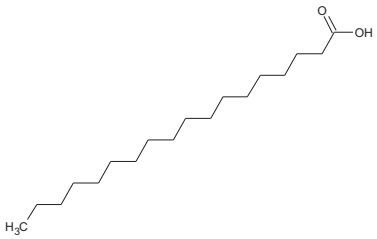
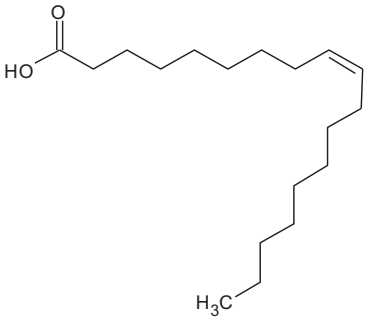
# Appendix A – Consideration of cut-off criteria for sheep fat according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

| Properties | | Conclusion |
|---|---|---|
| CMR | Carcinogenicity (C) | Sheep fat is not considered to be carcinogenic, mutagenic or toxic for reproduction |
| | Mutagenicity (M) | |
| | Toxic for Reproduction (R) | |
| Endocrine-disrupting properties | | Sheep fat is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605 |
| POP | **Persistence** | Sheep fat is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009 |
| | **Bioaccumulation** | |
| | **Long-range transport** | |
| PBT | **Persistence** | Sheep fat is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009 |
| | **Bioaccumulation** | |
| | **Toxicity** | |
| vPvB | **Persistence** | Sheep fat is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009 |
| | **Bioaccumulation** | |

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

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7073

# Appendix C – Used compound codes

| Code/trivial name[a] | IUPAC name/SMILES notation/ InChiKey[b] | Structural formula[c] |
|---|---|---|
| **Palmitic acid** | hexadecanoic acid<br>O=C(O)CCCCCCCCCCCCCCC<br>IPCSVZSSVZVIGE-UHFFFAOYSA-N |  |
| **Stearic acid** | octadecanoic acid<br>O=C(O)CCCCCCCCCCCCCCCCC<br>QIQXTHQIDYTFRH-UHFFFAOYSA-N |  |
| **Oleic acid** | (*9Z*)-octadec-9-enoic acid<br>O=C(O)CCCCCCC/C=C\CCCCCCCC<br>ZQPPMHVWECSIRJ-KTKRTIGZSA-N |  |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).