European Food Safety Authority

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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance repellent by smell of animal or plant origin/sheep fat[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Sheep fat is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Sheep fat was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on sheep fat in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 14 April 2008. The peer review was initiated on 7 August 2008 by dispatching the DAR for consultation of the notifier Kwizda Agro GmbH. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on sheep fat.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of sheep fat as a game repellent on deciduous and coniferous trees in forestry, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00290, issued on 16 December 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p.19
[5] OJ L 309, 24.11.2009, p.1
[6] OJ L 153, 11.6.2011, p.1
[7] OJ L 153, 11.6.2011, p.187
[8] OJ L 37, 10.2.2010, p.12

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For the section on identity, physical/chemical/technical properties and methods of analysis data gaps were identified for a specification and supporting data, a study on the microbiological quality control of sheep fat, and relative density. For the formulation, further details and validation data for the method of analysis used in the shelf-life study, and low temperature and accelerated storage stability studies were identified as data gaps.

No critical areas of concern or data gaps were identified in the toxicology section.

No critical areas of concern or data gaps were identified in the residue section.

Regarding fate and behaviour in the environment, data gaps were identified for a sterile aqueous hydrolysis study, and an estimation of atmospheric half-life, which is needed to assess the potential for long-range transport to remote areas. Consequently the assessment of the potential for long-range transport to remote areas was not finalised.

The risk to non-target organisms was considered as low. Data gaps were identified to submit a toxicity study on earthworms, effects studies on soil micro-organisms and information on the impact on terrestrial non-target plants.

KEY WORDS

Sheep fat, peer review, risk assessment, pesticide, repellent

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BACKGROUND

Sheep fat is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Sheep fat was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on sheep fat in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 14 April 2008 (Greece, 2008). The peer review was initiated on 7 August 2008 by dispatching the DAR to the notifier Kwizda Agro GmbH, and on 16 December 2010 to the Member States, for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 April 2011. On the basis of the comments received and the RMS's evaluation thereof it was concluded that there was no need to conduct an expert consultation.

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, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, 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 took place with Member States via a written procedure in November – December 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a game repellent on deciduous and coniferous trees in forestry, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, 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 (EFSA, 2011)

[9] OJ L 379, 24.12.2004, p.13
[10] OJ L 246, 21.9.2007, p.19
[11] OJ L 309, 24.11.2009, p.1
[12] OJ L 153, 11.6.2011, p.1
[13] OJ L 153, 11.6.2011, p.187
[14] OJ L 37, 10.2.2010, p.12

comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (30 March 2011),
- the Evaluation Table (9 December 2011),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of June 2011 containing all individually submitted addenda (Greece, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Sheep Fat is a triglyceride consisting predominantly of glycerin esters of palmitic acid, stearic acid and oleic acid.

The representative formulated product for the evaluation was 'Trico' an oil in water formulation (EW) containing 64.6 g/l (64/g/kg) sheep fat.

The representative use is as a game repellent on deciduous and coniferous trees in forestry. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

A specification for sheep fat was not proposed and this should be developed and supported by batch data and validated methods of analysis. Data on the microbiological quality control of sheep fat and relative density are also identified as data gaps.

The main data regarding the identity of sheep fat and its physical and chemical properties are given in Appendix A.

Three data gaps were identified for the formulation, for further details and validation data for the method of analysis used in the shelf-life study, and for low temperature and accelerated storage stability studies.

As no residue definitions are proposed the need for methods of analysis can be waived.

2. Mammalian toxicity

Sheep fat is produced from fat tissues of sheep, which is part of a typical European diet. Although information on the microbiological quality control of sheep fat is missing (see section 1) the manufacturing process indicates destruction of potential pathogens. Sheep fat is a triglyceride consisting predominantly of glycerine esters of palmitic acid, stearic acid and oleic acid. The free fatty acids of sheep fat are listed as general food additives and are permitted as carriers. The evaluation of these components as food additives revealed no safety concerns.

In conclusion, sheep fat is of low toxicological concern and no risks to human health are expected from its use as a plant protection product. Therefore, data waivers for specific toxicological studies with sheep fat are supported. In addition, the establishment of dietary references values is not required since the representative use of sheep fat concerns application to non-edible plants.

3. Residues

Metabolism and residue studies were not considered relevant for the evaluation due to the nature of the active substance and the representative uses. If used according to the GAPs as notified, it is very unlikely that crops destined for human and animal consumption will receive an application of sheep fat. Quantitative consumer risk assessments are not required due to the unlikelihood of significant residues, and the low toxicological concern for sheep fat.

4. Environmental fate and behaviour

The environmental fate and behaviour section of the notifier's dossier were empty. Whilst some information on the free fatty acids (i.e. not in triglyceride ester forms) oleic, palmitic and stearic acid was reported in the DAR, the source of the numerical values reported was clarified by the peer review to have not been independently assessed by the RMS. Consequently these values are not considered in this conclusion and are not included in Appendix A. Therefore the environmental fate considerations for the active substance can only be made on the basis of the available physical and chemical

properties of the pertinent triglycerides (glycerine esters, for numerical values see Appendix A). The vapour pressure and Henry's law constant indicate that sheep fat will not volatilise to any significant extent from aqueous / soil water or non-aqueous systems. The very low water solubility gives some indication that mobility in soil is likely to be low. Data on sterile hydrolysis rate and octanol water partition co-efficient were not available, though the very low water solubility and high solubility in xylene and dichloroethane confirm that the glycerine esters will be lipophilic. This is another indication that mobility in soil is likely to be low. A data gap is identified for information on sterile hydrolysis. In the absence of results from ready biodegradability studies, triglyceride (glycerine esters) has been considered to be not readily biodegradable. As the product will be sprayed a simple surface water exposure estimate (predicted environmental concentration, PEC) resulting from spray drift to a 30cm deep static water body using spray drift values from the 2001 version of the aquatic guidance document (European Commission, 2001) was completed. EFSA carried out a PEC soil calculation. Details of these PEC calculations can be found in Appendix A. As the product is sprayed and there is the potential for aerosols to be formed at the time of spraying, a data gap was identified for information to address the potential for long-range atmospheric transport of triglyceride esters. Information on the route and rate of degradation of sheep fat in soil and natural sediment water systems is not available, but the hazard characterisation of the substance (see sections 2 and 5) means that the risk characterisation for consumers and non-target species can be completed without this information (noting that data gaps have been identified in relation to earthworms, soil micro-organisms and terrestrial non-target plants (see section 5)). EFSA's reading of the Council Directive 98/83/EC[15] on the quality of drinking water intended for human consumption is that, as a repellent, sheep fat is not considered a pesticide under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision-making criterion regarding groundwater exposure, does not apply. The potential for groundwater exposure by sheep fat from the representative use assessed would be expected to be low as a consequence of its expected low soil mobility. If sheep fat was to reach groundwater it would not be expected to present a risk to consumers (see section 2).

5. Ecotoxicology

No data were provided regarding the toxicity of sheep fat to birds. Poor quality literature data on mammals were provided in the mammalian toxicology section, indicating a low concern. Due to the mode of application (spray) the contamination of food items for birds and mammals cannot be excluded for the representative uses. However, sheep fat itself could be a food source for omnivorous birds and mammals, or it may act as a repellent for herbivorous mammals. Therefore, overall the risk to birds and mammals could be considered as low and no further data are necessary.

Based on the acute toxicity data submitted with the formulation, sheep fat was not toxic to aquatic organisms. The risk was assessed as low.

A data gap was identified to submit a toxicity study on earthworms and to assess the risk. A study was already available during the peer review, but it was not submitted with the dossier.

The risk was considered as low for bees and non-target arthropods based on the toxicity data provided, which indicated a low concern.

The risk is also expected to be low for soil micro-organisms and terrestrial non-target plants, however, no data were provided and data gap was identified in order to finalise the risk assessment. No exposure for sewage treatment plants would be expected for the representative uses, therefore no data were necessary. The risk needs to be further considered if any contamination of sewage treatment plants may occur.

[15] OJ L 330, 5.12.1998, p.32

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
glycerine esters of fatty acids primarily oleic, palmitic and stearic acids	Data not available	Data gap identified regarding soil-dwelling organisms.

6.2. Groundwater

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
glycerine esters of fatty acids primarily oleic, palmitic and stearic acids	Data not available but expected to be low on the basis of low water solubility.	Not relevant for a repellent	No	-	-

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
glycerine esters of fatty acids primarily oleic, palmitic and stearic acids	The risk was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
glycerine esters of fatty acids primarily oleic, palmitic and stearic acids	No data available.

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Specification with supporting batch data and validated methods of analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Study on the microbiological quality control of sheep fat (relevant for all representative uses evaluated; submission date proposed by the notifier: available but not evaluated; see section 1).
- Relative density of sheep fat (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Further details and validation data for the method of analysis used in the shelf-life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Accelerated and low temperature storage stability studies (relevant for all representative uses evaluated; submission date proposed by the notifier: available but not evaluated; see section 1).
- Information on the hydrolysis of glycerine esters of palmitic, stearic and oleic acids under sterile conditions at pH 5, 7 and 9 (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Information to address the potential for long-range atmospheric transport of the glycerine esters of palmitic, stearic and oleic acids, such as atmospheric half-life estimations for indirect photochemical reaction with hydroxyl radicals (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- A toxicity study on earthworms and consequent risk assessment (relevant for all representative uses evaluated; submission date proposed by the notifier: the study was already available during the peer review, but not submitted with the dossier; see section 5).
- Effect studies on soil micro-organisms (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information on the impact on terrestrial non-target plants (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

None.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where 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).

1. Potential for long-range transport to remote areas via the atmosphere could not be finalised[16].

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude 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 where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude 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.

None.

[16] Note this is not a criterion in the Uniform Principles of Annex VI to Directive 91/414/EEC for decision-making on product authorisations, but is a criterion that managers from Member States have asked to be informed about in relation to obligations Member States have under certain international treaties.

9.3. Overview of the concerns for each representative use considered

(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 this table.)

The column is grey because the potential for long-range transport to remote areas via the atmosphere could not be finalised.

Representative use		**Spray to deciduous/coniferous trees in forestry**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
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 active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information. A column is greyed out if there is a concern for that specific use.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance sheep fat.

European Commission, 2001. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001, 1 October 2001.

European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

European Commission, 2008. Review Report for the active substance sheep fat finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of sheep fat in Annex I of Directive 91/414/EEC. SANCO/2630/08 – rev. 1, 07 August 2008.

Greece, 2008. Draft Assessment Report (DAR) on the active substance sheep fat prepared by the rapporteur Member State Greece in the framework of Directive 91/414/EEC, March 2008.

Greece, 2011. Final Addendum to Draft Assessment Report on sheep fat, compiled by EFSA, June 2011.

APPENDICES

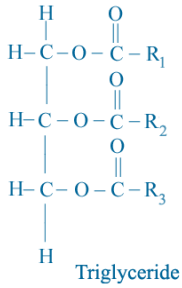
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

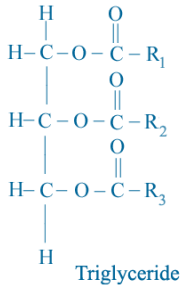
Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Sheep Fat
Function (*e.g.* fungicide)	Repellent

Rapporteur Member State	Greece
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Sheep Fat
Chemical name (CA) ‡	Sheep Fat
CIPAC No ‡	Not allocated
CAS No ‡	98999-15-6
EC No (EINECS or ELINCS) ‡	308-905-5
FAO Specification (including year of publication) ‡	-
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None.
Molecular formula ‡	No definite formula for sheep fat can be given, as it is a triglyceride consisting predominantly of glycerin esters of higher fatty acids with an even number of carbon atoms. Sheep fat can be described with the following formula:  Triglyceride where R1, R2 and R3 represent the hydrocarbon chain of the fatty acid elements of the triglyceride.
Molecular mass ‡	No definite molecular mass for sheep fat can be given, as it is a triglyceride consisting predominantly of glycerin esters of higher fatty acids with an even

	number of carbon atoms.
Structural formula ‡	No definite structural 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. Sheep fat can be described with the following formula:  Triglyceride where R1, R2 and R3 represent the hydrocarbon chain of the fatty acid elements of the triglyceride.

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Melting range: 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) ‡	Estimated vapour pressure of the main triglycerides using calculated melting points: Glycerol ester of palmitic acid: $3.9*10^{-18}$ Pa at 25°C Glycerol ester of oleic acid: $1.3*10^{-18}$ Pa at 25°C Glycerol ester of stearic acid: $2.6*10^{-18}$ Pa at 25°C Estimated vapour pressure of the main triglycerides using experimental melting temperature (44°C): Glycerol ester of palmitic acid: $7.2*10^{-13}$ Pa at 25°C Glycerol ester of oleic acid: $4.6*10^{-15}$ Pa at 25°C Glycerol ester of stearic acid: $9.1*10^{-15}$ Pa at 25°C The vapor pressure of Sheep Fat is estimated to be < 10^{-12} Pa at 25°C.
Henry's law constant ‡	Estimated Henry constant of the main triglycerides (mean of two estimation methods): Glycerol ester of palmitic acid: 18,2 Pa m^3 mol^{-1} Glycerol ester of stearic acid: 112,5 Pa m^3 mol^{-1} Glycerol ester of oleic acid: 49,4 Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	Calculated water solubility: Glycerol ester of palmitic acid: $7.9*10^{-18}$ mg/L at 25°C Glycerol ester of oleic acid: $2.5*10^{-20}$ mg/L at 25°C Glycerol ester of stearic acid: $6.5*10^{-21}$ mg/L at 25°C The water solubility of Sheep Fat is estimated to be < 10^{-17} mg/L at 25°C.

Solubility in organic solvents ‡ (state temperature, state purity)	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.
Partition co-efficient ‡ (state temperature, pH and purity)	Not relevant.
Dissociation constant (state purity) ‡	Not relevant.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/vis spectrum: no absorbance maxima (λ_{max}) above 290 nm were observed
Flammability ‡ (state purity)	Not flammable.
Explosive properties ‡ (state purity)	Non-explosive.
Oxidising properties ‡ (state purity)	Not expected to have oxidizing properties.

Summary of representative uses evaluated (*sheep fat*)

Crop and/ or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha minmax	kg as/ha min max		
Deciduous/coniferous trees in forestry	Austria	Trico	F	Game biting in winter	EW	64g/kg	Spray	Autumn	1	--	na	na	0,64-1,28	na	No water necessary - ready to use formulation
Deciduous/coniferous trees in forestry	Austria	Trico	F	Game biting in summer	EW	64g/kg	Spray	During the vegetation period	1	--	na	na	0,64-1,28	na	No water necessary - ready to use formulation

na – not applicable

Remarks

(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)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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 application 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

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Open
Impurities in technical as (analytical technique)	Not relevant. Sheep Fat does not contain any impurities.
Plant protection product (analytical technique)	IR spectrometry fully validated, acceptable method.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition.
Food of animal origin		No residue definition.
Soil		No residue definition.
Water	surface	No residue definition.
	drinking/ground	No residue definition.
Air		No residue definition.
Blood		No residue definition.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Since no residue definition is proposed for monitoring purposes no analytical method is required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Since no residue definition is proposed for monitoring purposes no analytical method is required.
Soil (principle of method and LOQ)	Since no residue definition is proposed for monitoring purposes no analytical method is required.
Water (principle of method and LOQ)	Since no residue definition is proposed for monitoring purposes no analytical method is required.
Air (principle of method and LOQ)	Since no residue definition is proposed for monitoring purposes no analytical method is required.
Body fluids and tissues (principle of method and LOQ)	As Sheep Fat is not classified as toxic or very toxic, no analytical method is required for its determination in body fluids and tissues.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	RMS proposal: None

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Data of limited validity. No further data needed.
Distribution ‡	Data of limited validity. No further data needed.
Potential for accumulation ‡	No data available; not needed.
Rate and extent of excretion ‡	No data available; not needed.
Metabolism in animals ‡	Data of limited validity. No further data needed.
Toxicologically relevant compounds ‡ (animals and plants)	No data available; not needed.
Toxicologically relevant compounds ‡ (environment)	

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡ Rabbit LD_{50} dermal ‡ Rat LC_{50} inhalation ‡ Skin irritation ‡ Eye irritation ‡ Skin sensitisation ‡	Data of limited validity. No further data needed.

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡ Relevant oral NOAEL ‡ Relevant dermal NOAEL ‡ Relevant inhalation NOAEL ‡	Data of limited validity. No further data needed.

Genotoxicity ‡ (Annex IIA, point 5.4)

	Data of limited validity. No further data needed.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡ Relevant NOAEL ‡ Carcinogenicity ‡	Data of limited validity. No further data needed.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡ Relevant parental NOAEL ‡ Relevant reproductive NOAEL ‡ Relevant offspring NOAEL ‡	Data of limited validity. No further data needed.

Developmental toxicity

Developmental target / critical effect ‡ Relevant maternal NOAEL ‡ Relevant developmental NOAEL ‡ Relevant developmental neurotoxicity NOAEL ‡	No data available; not needed.

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available; not needed.

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available; not needed
Studies on metabolites	No data available; not needed.
Studies on impurities	No data available; not needed.

Medical data‡ (Annex IIA, point 5.9)

	No data available; not needed.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not required due to the characterization of sheep fat as of low toxicological concern and also not applicable since the representative use of sheep fat concerns application to non-edible plants		
AOEL ‡	Not required due to the characterization of sheep fat as of low toxicological concern		

ARfD ‡	Not required due to the characterization of sheep fat as of low toxicological concern and also not applicable since the representative use of sheep fat concerns application to non-edible plants

Dermal absorption‡ (Annex IIIA, point 7.3)

	No data available; not needed.

Exposure scenarios (Annex IIIA, point 7.2)

Operator, workers and bystanders	No exposure assessment was deemed necessary, as the substance is of low toxicological concern.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	peer review proposal
Sheep fat	Data available of limited validity to conclude, no further data

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Not required
Rotational crops	Not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	Not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Not required
Plant residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not required
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not required

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Not required

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the evel)	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not applicable	Not applicable	Not applicable
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-

Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Deciduous and coniferous trees in forestry	N	Not required				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not required
TMDI (% ADI) according to WHO European diet	Not applicable
TMDI (% ADI) according to national (to be specified) diets	Not applicable
IEDI (WHO European Diet) (% ADI)	Not applicable
NEDI (specify diet) (% ADI)	Not applicable
Factors included in IEDI and NEDI	Not applicable
ARfD	Not required
IESTI (% ARfD)	Not applicable
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not applicable
Factors included in IESTI and NESTI	Not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not required				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Deciduous and coniferous trees	Not required

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization 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)	

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	
Mineralization 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.
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Sheep Fat	Aerobic conditions No data submitted

Field studies ‡

Sheep Fat	Aerobic conditions No data submitted

pH dependence ‡ (yes / no) (if yes type of dependence)	No data submitted.
Soil accumulation and plateau concentration ‡	No data submitted.

Laboratory studies ‡

Sheep Fat	Anaerobic conditions No data submitted

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Sheep Fat ‡ No data submitted

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data submitted.
Aged residues leaching ‡	No data submitted.
	No data submitted.
Lysimeter/ field leaching studies ‡	No data submitted.

PEC (soil) (Annex IIIA, point 9.1.3)

Sheep Fat Method of calculation	Soil density 1.5g/cm3 even incorporation over the top 5cm
Application data	Worst case application scenario of 1280 g/ha for a single application, adjusted for 90% crop interception (conservative assumption for a targeted hand held sprayer) to give a dose rate to the soil of 128 g/ha.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.17		-	
Plateau concentration	Not calculated			

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data submitted. Data gap
Photolytic degradation of active substance and metabolites above 10 % ‡	No data submitted.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data submitted.
Readily biodegradable ‡ (yes/no)	No in the absence of experimental data

Degradation in water / sediment

Sheep Fat	No data submitted

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Sheep Fat Parameters used	Input via spray drift Drift values for forest applications do not exist, therefore values for vegetables, ornamentals and small fruit covering both heights <50cm (2.77% at 1m) and heights >50cm (8.02% at 3m) were used for the calculations. Calculations assume a static 30cm deep water body.
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	Worst case application scenario of 1280 g/ha for a single application

PECsw : Spray drift rates into surface water and initial PEC_{SW} after one application of SHEEP FAT at a rate of 1280 g/ha.

distance from field (m)	drift rate (%)		initial PEC_{sw} (µg/L)	
	Vegetables, Ornamentals, Small fruit		Vegetables, Ornamentals, Small fruit	
	Height <50cm	Height >50cm	Height <50cm	Height >50cm
1	2.77	-	11.82	-
3	-	8.02	-	34.22

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No data submitted.
Application rate	-

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	-
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air ‡	Data gap
Volatilisation ‡	-
Metabolites	-

PEC (air)

Method of calculation	No data submitted.

$PEC_{(a)}$

Maximum concentration	-

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines	Soil: glycerine esters of fatty acids such as Oleic

(toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	acid, Palmitic acid, Stearic acid Surface Water: glycerine esters of fatty acids such as Oleic acid, Palmitic acid, Stearic acid Sediment: glycerine esters of fatty acids such as oleic acid, palmitic acid, stearic acid Ground water: glycerine esters of fatty acids such as oleic acid, palmitic acid, stearic acid Air:glycerine esters of fatty acids such as oleic acid, palmitic acid, stearic acid

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for 53 in the absence of reliable information on ready biodegradability.

Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1; Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	No data available[1]
Acute toxicity to birds	No data available[1]
Dietary toxicity to birds	No data available[1]
Reproductive toxicity to birds	No data available[1]
Reproductive/long term toxicity to mammals	No data available[1]

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Exposure period	Crop, use pattern	Category (*e.g.*, insectivorous bird)	Toxicity endpoint	ETE [mg ai/kg bw/day]	TER	TER risk trigger (from Annex VI)
Acute	Forest	Insectivorous bird		69.2		10
Short-term	Forest	Insectivorous bird		38.6		10
Long-term	Forest	Insectivorous bird		38.6		5
Acute	Forest	Small herbivorous mammal		151.23		10
Long-term	Forest	Small herbivorous mammal		43.11		5

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Test substance	Study Type	LC_{50} /EC_{50} [mg/L]	LC_0 /NOEC [mg/L]
Zebrafish	Trico Neu	Semi-Static 96h	>100	≥100(=6.58 mg a.s/L)
Daphnia magna	Trico Neu	Static 48h	>100	≥100(=6.58 mg a.s/L)
Selenastrum caricornutum	Trico Neu	Static 72h	>100	≥100(=6.58 mg a.s/L)

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

[1] Exposure expected to be negligible

Organism	Test substance	Toxicity Endpoint	PEC (µg/L)	TER a	TER risk trigger value (from 91/414/EEC)
Zebrafish, Daphnia, algae	Sheep fat	>6.58	11.82 (1m height<50 cm) 34.22 (3m height>50 cm)	>557 >192	100

Bioconcentration

Bioconcentration factor (BCF)	No data available. Not required.
Annex VI Trigger for the bioconcentration factor	Not required
Clearance time (CT_{50}) (CT_{90})	Not required
Level of residues (%) in organisms after the 14 day depuration phase	Not required

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	No data available[1]
Acute contact toxicity	No data available[1]

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Acute oral toxicity	>63µg a.s./bee (K 715-4) >100µg a.s./bee (K 743-4)
Acute contact toxicity	>63µg a.s./bee (K 715-4) >100µg a.s./bee (K 743-4)

Field or semi-field tests

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Test	Test species	Summary of design	Endpoints
No data available[1]			

Species	Test Substance	Dose	Endpoint	Effect	Annex VI Trigger
Extended laboratory tests					
Typhlodromus pyri	TRICO	10L/ha	Mortality reproduction	18.3 +31%	30
Typhlodromus pyri	TRICO	15L/ha	Mortality reproduction	13 +20%	30

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	No data available – data gap
Chronic and reproductive toxicity	No data available

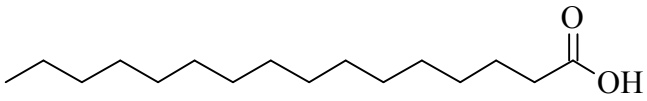
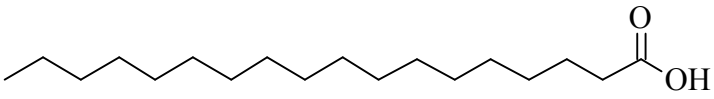
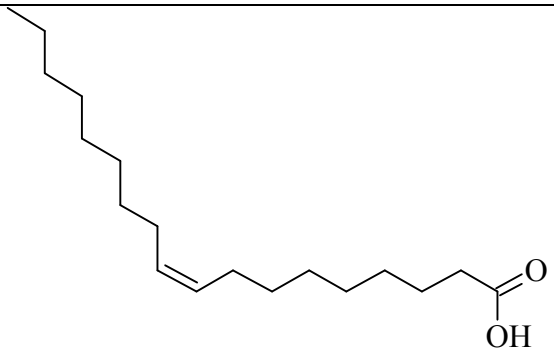
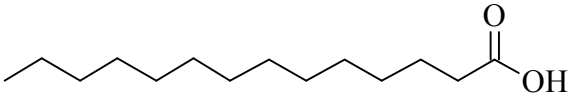
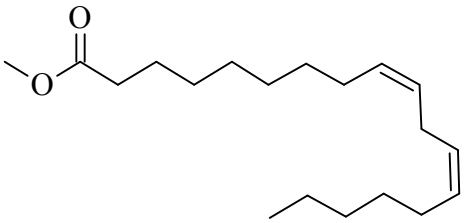
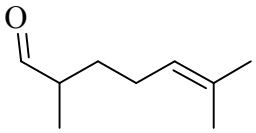
Effects on terrestrial non-target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

No data available – data gap

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	No data available – data gap
Carbon mineralization ‡	No data available – data gap

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
Palmitic acid	Hexadecanoic acid	
Stearic acid	Octadecanoic acid	
Oleic acid	(9Z)-octadec-9-enoic acid	
Myristic acid	Tetradecanoic acid	
Methyl linoleate	methyl (9Z,12Z)-octadeca-9,12-dienoate	
2,6-dimethyl-5-heptenal	2,6-dimethylhept-5-enal	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year