CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance fat distillation residues[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Fat distillation residues 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]

Fat distillation residues 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.

The Czech Republic being the designated rapporteur Member State submitted the DAR on fat distillation residues in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 5 November 2007. The peer review was initiated on 16 May 2008 by dispatching the DAR to the notifier NeraAgro spol. s.r.o. and on 16 December 2010 to the Member States for consultation and comments. 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 fat distillation residues.

[1] On request from the European Commission, Question No EFSA-Q-2009-00278, adopted 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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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fat distillation residues as a game repellent on tree seedlings, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis, data gaps were identified for further batch analysis and a specification. For the formulation, data gaps were identified for a method and storage stability data.

No agreed technical specification is available and a data gap is identified in the mammalian toxicology section for an assessment of the toxicological relevance of any additional impurities and/or contaminants and of their maximum proposed levels in the specification; this issue could not be finalised.

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

Fat distillation residues is a compound produced from animal and vegetable fat. The environmental fate and behaviour of fat distillation residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and the limited usage, a definition of residue in the environment for risk assessment is deemed to be unnecessary for fat distillation residues.

The risk to non-target organisms is considered as low for the representative use.

KEY WORDS

Fat distillation residues, peer review, risk assessment, pesticide, repellent.

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BACKGROUND

Fat distillation residues 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]

Fat distillation residues 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.

The Czech Republic being the designated rapporteur Member State submitted the DAR on fat distillation residues in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 5 November 2007 (Czech Republic, 2007). The peer review was initiated on 16 May 2008 by dispatching the DAR to the notifier NeraAgro spol. s.r.o. 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 tree seedlings, as proposed by the notifier. A list of the relevant end points for the

[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

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) 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 (5 April 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 July 2011 containing all individually submitted addenda (Czech Republic, 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

The material is fat distillation residues, for which there is no ISO common name.

The representative formulated product for the evaluation was 'Morsuvin', a paste formulation containing 4 % w/w fat distillation residues.

The representative uses evaluated are outdoor application by brush or hand coating to tree seedlings.

CONCLUSIONS OF THE EVALUATION

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

The substance is fat distillation residues but a full specification is not available and further analysis of batches for possible relevant impurities is identified as a data gap. Nickel was considered as a relevant impurity with a maximum content of 200 mg/kg.

No information was given on the level of microbial contamination and the mechanism for control of such contamination and its possible increase on storage.

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

A specific method of analysis and storage stability data were identified as a data gaps for the formulation.

Methods of analysis for residues are not required given the nature of this compound. A method of analysis for body fluids and tissues is not required as the material is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance document was used in the production of this conclusion: SANCO/222/2000 rev. 7 (European Commission, 2004).

A data gap and an issue that could not be finalised have been identified for an assessment of the toxicological relevance and proposed levels of impurities and/or contaminants potentially present in the technical material since no technical specification has been agreed in section 1 on the identity of the active substance. The proposed maximum nickel concentration of 200 mg/kg is acceptable from a toxicological point of view, being below the concentration triggering classification for human health hazards.

Based on the available data, fat distillation residues (with no agreed technical specification) has no significant acute toxicity via the oral and dermal routes of exposure. It is not an eye or skin irritant and does not cause skin sensitisation. No genotoxicity was shown in the available Ames test. No other toxicological studies were reported.

Based on the available database, no reference value can be set for fat distillation residues. However, as there is no consumer exposure, the derivation of an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) is not needed. With regard to the operators, based on the available studies and the general knowledge about the fatty acids described in Volume 4 of the DAR, there is a low toxicological concern for the operators handling the formulation containing fat distillation residues

and no AOEL needs to be derived. Therefore no quantitative exposure and risk assessment was conducted for operators considering the risk, if any, to be negligible. In view of the representative use, i.e. one application on trees by paintbrush and/or glove application, it can also be considered that there is no exposure of workers and bystanders.

3. Residues

Metabolism and residue studies were not considered relevant for the evaluation of fat distillation residues. Since the representative uses are in forestry and in forest nursery, no exposure of food and feed items is expected. Consequently, due to the unlikelihood of significant residues a quantitative consumer risk assessment is not required for these uses.

4. Environmental fate and behaviour

Fat distillation residues is a compound produced from distillation of fat from animal and vegetable origin. The environmental fate and behaviour of fat distillation residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The preparation 'Morsuvin' is a game repellent which will be used only as a protective coating on the outside of tree trunks. No soil contamination is expected to occur during a correct application. The preparation dries and forms a protective coating. The dried preparation is not water soluble. Based on the nature of the ingredients and the formulation it is unlikely that residues of the preparation would be detected in air.

5. Ecotoxicology

Due to the method of application leading to negligible levels of environmental exposure, the risk can be considered low for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro-organisms, terrestrial non-target plants and biological methods for sewage treatment plants.

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
Not applicable. Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for fat distillation residues.	Not applicable	–

6.2. Ground water

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
Not applicable. Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for groundwater exposure assessment is deemed to be unnecessary for fat distillation residues	Not applicable	Not applicable	–	Not applicable	–

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable. Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for fat distillation residues.	–

6.4. Air

Compound (name and/or code)	Toxicology
Not applicable. Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for fat distillation residues.	Not applicable.

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).

- A detailed analysis of the Lipix material is required to demonstrate that it does not contain any additional relevant impurities. Batches should be tested covering all types of fat sources (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).

- Subject to the data gap for further batch testing for possible relevant impurities, a full specification should be proposed to include all compounds and other parameters identified in the batch analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).

- Method of analysis for the formulation to identify and at least semi-quantify the content of fat distillation residues (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).

- Shelf life and accelerated storage studies that demonstrates the stability of the "active components" (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).

- Assessment of the toxicological relevance of the additional impurities and/or contaminants and their maximum proposed levels in the technical specification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).

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

- Application by paintbrush and/or glove application on tree trunks is the only use considered in the risk assessment.

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).

- There is no agreed technical specification and no analysis of the maximum levels of impurities and/or contaminants of toxicological concern.

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.

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.)

All columns are grey as there is no agreed technical specification and no analysis of the maximum levels of impurities and/or contaminants of toxicological concern.

Representative use		**Tree seedlings – coniferous seedlings, broadleaved seedlings (seedlings younger than 2 years)**	**Tree seedlings – coniferous seedlings, broadleaved seedlings (seedlings older than 2 years)**
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			

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

REFERENCES

Czech Republic, 2007. Draft Assessment Report (DAR) on the active substance Fat Distillation Residue prepared by the rapporteur Member State the Czech Republic in the framework of Directive 91/414/EEC, October 2007.

Czech Republic, 2011. Final Addendum to Draft Assessment Report on Fat distillation residues, compiled by EFSA, July 2011.

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 fat distillation residues.

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, 2004. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2008. Review Report for the active substance Fat destilation residues 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 Fat destilation residues in Annex I of Directive 91/414/EEC. SANCO/2610/08 – rev. 1, 6 August 2008.

APPENDICES

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

Active substance (ISO Common Name) ‡	Fat Distillation Residues
Function (*e.g.* fungicide)	repellent
Rapporteur Member State	Czech Republic
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	not available
Chemical name (CA) ‡	not available
CIPAC No ‡	915
CAS No ‡	not available
EC No (EINECS or ELINCS) ‡	not available
FAO Specification (including year of publication) ‡	not available
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	nickel max. 200 mg/kg
Molecular formula ‡	not available
Molecular mass ‡	not available
Structural formula ‡	not available

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	above 60 °C
Boiling point (state purity) ‡	not available
Temperature of decomposition (state purity)	not available
Appearance (state purity) ‡	black paste at 20°C, viscous liquid above 60 °C. Very intensive odour after decomposed fat.
Vapour pressure (state temperature, state purity) ‡	not available
Henry's law constant ‡	not available
	not available
	not available
Solubility in water (state temperature, state purity and pH) ‡	insoluble
Solubility in organic solvents ‡ (state temperature, state purity)	Acetone 20 g/l at 20°C
	Heptane <0.001 g/l at 20°C
	Xylene 500 g/l at 20°C
	Dichloromethane 100 g/l at 20°C
	1-butanol 20 g/l at 20°C
	Ethylacetate 20g/l at 20°C
Surface tension ‡ (state concentration and temperature, state purity)	not relevant
Partition co-efficient ‡ (state temperature, pH and purity) *log* $P_{O/W}$ = *at °C (pH (99.9%)*	not relevant
Dissociation constant (state purity) ‡	not relevant
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	not relevant
Flammability ‡ (state purity)	Not highly flammable Not auto-flammable
Explosive properties ‡ (state purity)	No explosive properties
Oxidising properties ‡ (state purity)	No oxidising properties

Crop and/or situation (a)	Member State or 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 (BBCH) (j)	Number min-max (k)	Interval between applications (min)	kg as/hL min-max	water L/1000 seedlings min-max	kg as/1000 seedlings max		
Tree seedlings – coniferous seedlings, broadleaved seedlings (seedlings younger than 2 years)	Czech Repuplic	Morsuvin	F	Game	PA	4 % w/w	Brush/ hand coating	BBCH 00 (dormancy period)	one	Not applicable	80	0.2-0.25	0.160-0.200	Not applicable	
Tree seedlings – coniferous seedlings, broadleaved seedlings (seedlings older than 2 years)	Czech Repuplic	Morsuvin	F	Game	PA	4 % w/w	Brush/ hand coating	BBCH 00 (dormancy period)	one	Not applicable	80	0.25-0.30	0.200-0.240	Not applicable	

(a) For crops, the EU and Codex classifications (both) 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), paste (PA)
(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 plant - 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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical as (analytical technique)	determination of acid, saponification value, iodine value, water and volatile material
Impurities in technical as (analytical technique)	spectrometry, polarography
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	not relevant
Food of animal origin	not relevant
Soil	not relevant
Water surface	not relevant
drinking/ground	not relevant
Air	not relevant

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	not relevant
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	not relevant
Soil (analytical technique and LOQ)	not relevant
Water (analytical technique and LOQ)	not relevant
Air (analytical technique and LOQ)	not relevant
Body fluids and tissues (analytical technique and LOQ)	not relevant

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

	RMS/peer review proposal
Active substance	no

Impact on Human and Animal Health

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

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

Acute toxicity (Annex IIA, Point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw (female)
Rat LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC50 inhalation ‡	No data available; not needed
Skin irritation ‡	Non irritant
Eye irritation ‡	Slight irritant (no required classification)
Skin sensitisation (Maximisation test)‡	Non sensitiser

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data available; not needed
Relevant oral NOAEL ‡	No data available; not needed
Relevant dermal NOAEL ‡	No data available; not needed
Relevant inhalation NOAEL ‡	No data available; not needed

Genotoxicity ‡ (Annex IIA, point 5.4)

Fat distillation residues does not produce gene mutations in bacterial cells *in vitro* (Ames).

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

Target/critical effect ‡	No data available; not needed
Relevant NOAEL ‡	No data available; not needed
Carcinogenicity ‡	No data available; not needed

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available; not needed
Relevant parental NOAEL ‡	No data available; not needed
Relevant reproductive NOAEL ‡	No data available; not needed
Relevant offspring NOAEL ‡	No data available; not needed

Developmental toxicity

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

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available; not needed
Repeated neurotoxicity ‡	No data available; not needed
Delayed neurotoxicity ‡	No data available; not needed

Other toxicological studies (Annex IIA, point 5.8)

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

Medical data ‡ (Annex IIA, point 5.9)

No evidence of toxicological concern.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data available; not needed		
AOEL (systemic) ‡	No data available; not needed		
ARfD ‡	No data available; not needed		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (MORSUVIN)	100% (default value)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Low toxicological concern for the operators applying fat distillation residues contained in a paste by paintbrush and/or gloves application.
Workers	Exposure of workers is not expected.
Bystanders	Exposure of bystanders is not expected.

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

	RMS/peer review proposal
Fat distillation residues	None based on the limited data available.

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 required
Processed commodities	Not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required
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 required
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 required
Fat soluble residue: (yes/no)	Not required

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:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Not required		
Potential for accumulation (yes/no):			

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	
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)
Tree seedlings	Northern	Not required	None	Not established	Not relevant	Not relevant

(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 available
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 available
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)

None

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

Mineralization after 100 days ‡	No data provided, not required
Non-extractable residues after 100 days ‡	No data provided, not required
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data provided, not required

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

Anaerobic degradation ‡

Mineralization after 100 days	No data provided, not required
Non-extractable residues after 100 days	No data provided, not required
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data provided, not required

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data provided, not required

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

Laboratory studies ‡ No data provided, not required

Field studies ‡ No data provided, not required

pH dependence ‡ (yes / no) (if yes type of dependence)	No data provided, not required
Soil accumulation and plateau concentration ‡	No data provided, not required

Laboratory studies ‡

Parent	Anaerobic conditions: No data provided, not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡ No data provided, not required	
pH dependence, Yes or No	No data provided, not required

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

Column leaching ‡	Not submitted, not required
Aged residues leaching ‡	No data provided, not required
Lysimeter/ field leaching studies ‡	No data submitted, none required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	No data provided, the contamination of soil is negligible.
Application data	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data provided, not required
Photolytic degradation of active substance and metabolites above 10 % ‡	No data provided, not required
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data provided, not required
Readily biodegradable ‡ (yes/no)	No data provided, not required

Degradation in water / sediment

Parent	No data provided, not required

Mineralization and non extractable residues	No data provided, not required

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

Parent Parameters used in FOCUSsw step 1 and 2	No data provided, the risk of contamination of surface water is negligible.
Application rate	

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No data provided, the risk of contamination of ground water is negligible.
Application rate	-

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

Direct photolysis in air ‡	No data provided, not required
Quantum yield of direct phototransformation	No data provided, not required
Photochemical oxidative degradation in air ‡	No data provided, not required
Volatilisation ‡	No data provided, not required
Metabolites	

PEC (air)

Method of calculation	No data provided, not required

$PEC_{(a)}$ Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Not relevant

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

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

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

None

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
	a.s.	Acute	Not available	-
	Preparation	Acute	Not available	-
	a.s.	Short-term	Not available	-
	a.s.	Long-term	Not available	-
Mammals ‡				
Rat	a.s.	Acute	LD_{50}>2000	-
	a.s.	Long-term	Not available	-
Additional higher tier studies ‡				
Not required				

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

Crop and application rate

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
	Acute	-	-	10
	Short-term	-	-	10
	Long-term	-	-	5
Higher tier refinement (Birds)				
	Acute	-	-	10
	Short-term	-	-	10
	Long-term	-	-	5
Tier 1 (Mammals)				
	Acute	-	-	10
	Long-term	-	-	5
Higher tier refinement (Mammals)				
	Acute	-	-	10
	Long-term	-	-	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L) nominal
Laboratory tests ‡				
Fish				
Poecilia retucilata	a.s.	96 hr (static)	Mortality, EC_{50}	>140
	a.s.	28 d (static)	Growth NOEC	Not available
	Morsuvin	96 hr (static)	Mortality, EC_{50}	46
	Preparation	28 d(flow-through)	Growth NOEC	Not available
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	>150
	a.s.	21 d (static)	Reproduction, NOEC	Not available
	Morsuvin	48 h (static)	Mortality, EC_{50}	91.9
	Preparation	21 d (static)	Reproduction, NOEC	Not available
Sediment dwelling organisms				
	a.s.	28 d (static)	NOEC	Not available
	Metabolite 2	28 d (static)	NOEC	Not available
Algae				
Scenedesmus subscapitatus	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	28.8 144
	Morsuvin	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	8.57 38
	Metabolite 1	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	Not available
Higher plant				
	a.s.	14 d (static)	Fronds, EC_{50}	Not available
	Preparation	14 d (static)	Fronds, EC_{50}	Not available
Microcosm or mesocosm tests				
Not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

FOCUS Step1

Crop and application rate

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger[1]
a.s.	Fish		Acute			-	100
a.s.	Fish		Chronic			-	10
a.s.	Aquatic invertebrates		Acute			-	100
a.s.	Aquatic invertebrates		Chronic			-	10
a.s.	Algae		Chronic			-	10
a.s.	Higher plants[2]		Chronic			-	10
a.s.	Sediment-dwelling[3] organisms		Chronic			-	10
Metabolites	Relevant organisms					-	
Product	Relevant organisms					-	

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

[2] only required for herbicides

[3]consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

FOCUS Step 2

State crop, application rate and growth stage, Northern Europe or Southern Europe

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
a.s.		Fish		Acute		-	100
a.s.		Fish		Chronic		-	10
a.s.		Aquatic invertebrates		Acute		-	100
a.s.		Aquatic invertebrates		Chronic		-	10
a.s.		Algae		Chronic		-	10
a.s.		Higher plants[5]		Chronic		-	10
a.s.		Sediment-dwelling organisms[6]		Chronic		-	10
Metabolites		Relevant organisms				-	
Product		Relevant organisms				-	

[1] indicate whether Northern of Southern

[2] include critical groups which fail at Step 1.

[3] indicate whether maximum or twa values have been used.

[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.
FOCUS Step 3
State crop and application rate

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4]	TER	Annex VI trigger[5]
a.s.							-	
Metabolites							-	
Product							-	
							-	
							-	

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

FOCUS Step 4
Crop and application rate

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
							-	
							-	
							-	
							-	

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bioconcentration				
	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	Not available	-	-	-
Bioconcentration factor (BCF)[1] ‡	X*			
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	-	-
Preparation[1]	-	-
Metabolite 1	-	-
Field or semi-field tests		
Not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	-	50
a.s.	oral	-	50
Preparation	Contact	-	50
Preparation	oral	-	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡		Mortality	Not available
Aphidius rhopalosiphi ‡		Mortality	Not available

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri		-	-	2
	Aphidius rhopalosiphi		-	-	2

[1] indicate distance assumed to calculate the drift rate

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	a.s. ‡	Acute 14 days	Not available

Test organism	Test substance	Time scale	End point[1]
	a.s. ‡	Chronic 8 weeks	Not available
	Preparation	Acute	Not available
	Preparation	Chronic	Not available
	Metabolite 1	Acute	Not available
	Metabolite 1	Chronic	Not available
Other soil macro-organisms			
Soil mite	a.s. ‡		Not available
	Preparation		Not available
	Metabolite 1		Not available
Collembola			
	a.s. ‡	Chronic	Not available
	Preparation		Not available
	Metabolite 1		Not available
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		Not available
	Metabolite 1		Not available
Carbon mineralisation	a.s. ‡		Not available
	Metabolite 1		Not available
Field studies[2]			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms
Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute	-	-	10
	a.s. ‡	Chronic	-	-	5
	Preparation	Acute	-	-	10
	Preparation	Chronic	-	-	5
	Metabolite 1	Acute	-	-	10
	Metabolite 1	Chronic	-	-	5
Other soil macro-organisms					
Soil mite	a.s. ‡		-	-	

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	Preparation		-	-	
	Metabolite 1		-	-	
Collembola	a.s. ‡		-	-	
	Preparation		-	-	
	Metabolite 1		-	-	

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)
Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Not available				-	-	

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Additional studies (e.g. semi-field or field studies)

-

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	Not available
Pseudomonas sp	Not available

Ecotoxicologically relevant compounds **(consider parent and all relevant metabolites requiring further assessment from the fate section)**

Compartment	
soil	Not relevant
water	Not relevant
sediment	Not relevant
groundwater	Not relevant

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	None

	RMS/peer review proposal
Preparation	R 52 Harmful to aquatic organisms

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