CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance trimethylamine hydrochloride[1]

European Food Safety Authority[2]

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SUMMARY

Trimethylamine hydrochloride 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].

Trimethylamine hydrochloride 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.

Belgium being the designated rapporteur Member State submitted the DAR on trimethylamine hydrochloride in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 19 September 2006. The peer review was initiated on 12 June 2008 by dispatching the DAR to the notifier Suterra LLC, 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 trimethylamine hydrochloride.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of trimethylamine hydrochloride as an insect attractant on fruit crops where

[1] On request from the European Commission, Question No EFSA-Q-2009-00301, 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

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance trimethylamine hydrochloride. EFSA Journal 2012;10(1):2503. [37 pp.] doi:10.2903/j.efsa.2012.2503. Available online: www.efsa.europa.eu/efsajournal

Ceratitis capitata (Mediterranean fruit fly) causes damage, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified in the section for identity, physical and chemical properties and analytical methods.

Based on the representative uses no data gaps or critical areas of concern were identified in the mammalian toxicology section.

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

Data gaps were identified for satisfactory information on the ready biodegradability of trimethylamine salts, information on its hydrolytic stability under sterile conditions and information on the fate and behaviour of the chlorine that will be added to the environment. Most importantly, there is a data gap for a comparison of the estimated quantity of trimethylamine that may reach the different environmental compartments (primarily air but also soil, groundwater and surface water) and then form salts, consequent to the representative uses assessed, compared to natural background levels. The environmental exposure assessment was not finalised in the absence of this information.

A data gap is identified to re-consider the risk assessment for non-target organisms once information on the background levels of trimethylamine salts is available. Additionally a data gap was identified for the acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement.

KEY WORDS

Trimethylamine, trimethylamine hydrochloride, peer review, risk assessment, pesticide, insect attractant

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BACKGROUND

Trimethylamine hydrochloride 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].

Trimethylamine hydrochloride 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.

Belgium being the designated rapporteur Member State submitted the DAR on trimethylamine hydrochloride in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 19 September 2006 (Belgium, 2006). The peer review was initiated on 12 June 2008 by dispatching the DAR to the notifier Suterra LLC, 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 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' 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 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 an insect attractant on fruit crops where *Ceratitis capitata* (Mediterranean fruit fly) causes damage, 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

[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

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 (12 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 (Belgium, 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

Trimethylamine hydrochloride (IUPAC) is considered by the International Organization for Standardization not to require a common name. The European Commission confirmed that the organic salt trimethylamine hydrochloride should be considered as the active substance as it was already included in Annex I. It should be noted that trimethylamine hydrochloride can be considered as a variant of trimethylamine.

The representative formulated product for the evaluation was 'BioLure Med Fly', a vapour releasing product, (VP) consisting of three individual, retrievable, polymeric, hand-applied dispensers used in combination to make one plant protection product, containing 91 g/kg trimethylamine hydrochloride, 211.3 g/kg ammonium acetate and 2.7 g/kg 1,4-diaminobutane (putrescine), registered under different trade names in several EU countries.

The representative uses evaluated comprise applications by hand of the dispensers into physical traps in orchards, where *Ceratitis capitata* (Mediterranean fruit fly) causes damage, as an insect attractant. It should be emphasized however that the product is not used alone for mass trapping, but in combination with insecticides for the control of *C. capitata.* Full details of the representative uses 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

The following guidance document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

The minimum purity of trimethylamine hydrochloride is open as a data gap was identified for five-batch data generated with validated methods. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity of the active substance, however data gaps were identified for the specification of the purity of the active substance and information about the impurities. With respect to the physical, chemical and technical properties of trimethylamine hydrochloride and the representative formulation, data gaps were identified for the vapour pressure and volatility of the active substance, for a shelf-life study of the preparation and for justifications to waive the requirements for studies for the physical properties.

A data gap was also identified for an analytical method for the determination of the active substance in the respective dispenser for monitoring purposes.

The need for methods of analysis for monitoring this compound in food of plant and animal origin has been waived due to the specific kind of application. Data gaps need to be filled (see section 4) before a conclusion on the need for monitoring methods in the environment can be finalised. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

None of the data requirements according to Annex II of Directive 91/414/EC have been fulfilled. Only an evaluation of bibliographical references has been provided. However, this was considered sufficient considering mainly the low exposure to trimethylamine hydrochloride arising from the representative uses. In addition, trimethylamine hydrochloride is a synthetic replica of the naturally occurring substance trimethylamine resulting from the decomposition of animal and plant material under normal environmental conditions. Trimethylamine is derived from the diet either directly from the consumption of food containing trimethylamine, or by the intake of food containing precursors to trimethylamine such as trimethylamine-*N*-oxide (TMNO). It is a natural product of mammalian catabolism.

The limited data package indicated that following oral absorption in humans, trimethylamine undergoes N-oxidation to form trimethylamine-*N*-oxide. Trimethylamine has been classified as Xn R20 (harmful by inhalation), R37/R38 (irritating to respiratory system and skin) and R41 (risk of serious damage to eyes) (Annex VI to Regulation (EC) No 1272/2008[15]; CLP 00). According to the IUCLID dataset (2000) no classification is proposed for acute toxicity of trimethylamine hydrochloride; an Ames test was negative, a maternal and developmental NOAEL of 250 mg/kg bw/day is described, and oral administration of 1.3 g and 2.3 g to 3 volunteers did not result in collateral effects or toxic reactions.

Based on the limited available information, it is not possible to propose an acceptable daily intake (ADI), an acceptable operator exposure level (AOEL) or an acute reference dose (ARfD). However, reference values are not needed for the representative uses since operator, worker and bystander exposure to trimethylamine hydrochloride can be considered negligible, and there is no consumer exposure.

Additionally, the RMS has performed a quantitative risk assessment comparing a theoretical emission rate of 0.14 mg a.s./m^3/day (0.046 mg a.s/m^3/8 hours) with the DE-MAK occupational limit established for trimethylamine of 2 ppm (4.9 mg/m^3), resulting in 0.9 % of the occupational limit. Exposure estimates have been based on a worst-case scenario, considering that workers might be exposed during 8 hours to the vapours. Furthermore, the use of an occupational exposure limit is probably representing a conservative exposure estimate for agricultural settings.

In conclusion, no risks to human health are expected from trimethylamine hydrochloride arising from the representative uses. Therefore data waivers for specific toxicological studies with trimethylamine hydrochloride are supported.

3. Residues

The conclusion is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999).

According to the representative uses, trimethylamine hydrochloride is contained in a vapour releasing dispenser with two other individual active substances, respectively ammonium acetate and 1,4-diaminobutane (putrescine) in the preparation 'BioLure Med Fly'. These active substances are placed inside hand-applied physical traps in the canopy of the trees, and, held within the dispensers, never come into direct contact with the crops. Because of the low estimated emission rate of trimethylamine hydrochloride in the air (0.14 mg a.s./m^3/day), it can be reasonably assumed that residues of trimethylamine hydrochloride on fruits through volatilisation and deposition will be insignificant. Therefore a quantitative consumer dietary risk assessment can be waived due to the specific kind of application.

4. Environmental fate and behaviour

Satisfactory data on the vapour pressure and consequently estimates of the Henry's Law constant of the trimethylamine hydrochloride variant, present in traps were not available. Trimethylamine is reported by the notifier to be volatile, and to be effective in the way described it would need to be volatile. Information on hydrolysis under sterile conditions and ready biodegradability in the presence of a sewage sludge inoculum was not available. No information was provided on the fate and behaviour of the chlorine that is added to the traps as the hydrochloride counter ion of the variant. Consequently data gaps were identified for this missing information. As trimethylamine hydrochloride is placed as an attractant in traps for mass trapping, the primary route of exposure to the environment is via volatilisation to air. In the upper atmosphere trimethylamine will not be expected to be subject to long-range atmospheric transport, as it was estimated to have a half-life in the upper atmosphere as a consequence of indirect photodegradation reactions with hydroxyl radicals of < 2 days (0.18 days

[15] OJ L 353, 31.01.2008, p.1

estimated on the basis of a measured rate constant). The notifier made the case that exposure to the environmental compartments including air would be low and within the range of naturally occurring background levels. Consequently, further data on the route and rate of degradation of trimethylamine in soil and natural surface water systems and an assessment of the potential for the exposure of groundwater were proposed to be unnecessary. However, as the dossier provided no estimates of the naturally occurring background levels of trimethylamine in its possible salt forms (neither in air nor the other compartments), it was not possible to validate that this was in fact the case. Therefore a data gap was identified for the provision of a comparison of the estimated quantity of trimethylamine that may reach the different environmental compartments and then form salts, consequent to the representative uses assessed, compared to natural background levels.

5. Ecotoxicology

The risk to non-target organisms could be considered as low for the representative uses provided that the exposure is below the background levels of trimethylamine salts. However, in view of the data gap identified in section 4 for information on the background levels, the ecotoxicology risk assessment could not be finalised. A data gap is identified to re-consider the risk assessment for non-target organisms once such information is available. Additionally a data gap was identified for the acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement.

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
trimethylamine and its salts, but provisional in the absence of a comparison to natural background concentrations.	Data gap. Not relevant if it is demonstrated that levels in soil consequent to the use would not be above natural background concentrations.	Data gap pending on the information on the background level.

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)[(a)]	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
trimethylamine and its salts, but provisional in the absence of a comparison to natural background concentrations.	Data Gap. Not relevant if it is demonstrated that levels in soil consequent to the use would not be above natural background concentrations.	Data gap. Not relevant if it is demonstrated that levels in soil consequent to the use would not be above natural background concentrations.	No	Data available of limited validity.	Data gap pending on the information on the background level.

(a): EFSA's reading of the Council Directive 98/83/EC[16] on the quality of drinking water intended for human consumption is, that as an attractant, trimethylamine 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 criteria regarding groundwater exposure, does not apply. However, a groundwater exposure estimate to enable a risk assessment from the human consumption of groundwater as drinking water and an aquatic risk assessment, in the situation that groundwater becomes surface water, would be appropriate, if soil exposure would be demonstrated to be above natural background concentrations.

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

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
trimethylamine and its salts, but provisional in the absence of a comparison to natural background concentrations.	Data gap pending on the information on the background level.

6.4. Air

Compound (name and/or code)	Toxicology
trimethylamine and its salts	Data available of limited validity.

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).

- Five batch data generated with validated methods (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Specification of purity of the active substance, information about the impurities (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Vapour pressure and volatility of the active substance (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Shelf-life study of the preparation (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Justifications to waive the requirements for studies for the physical properties (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Method for the determination of the active substance in the respective dispenser for monitoring purposes (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)
- Information of the hydrolysis of trimethylamine salts under sterile conditions at pH 5, 7 and 9 is not available (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)
- Satisfactory information on the ready biodegradability of trimethylamine present in a salt form is not available (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)
- An assessment of the environmental fate and behaviour of the chlorine that is added to the environment is not available (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)
- A comparison of the estimated quantity of trimethylamine that may reach the different environmental compartments and then form salts, compared to natural background levels that can occur, is not available (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)
- Ecotoxicology risk assessment should be re-considered based on the information on the background levels of trimethylamine salts (relevant for all representative uses evaluated;

submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 5)

- Acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; 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. The environmental exposure assessment to air and consequently due to potential wet and dry deposition, the exposure assessment to soil, groundwater and surface water. Consequently the risk assessment for non-target organisms could not be finalised.

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 identified 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.)

Representative use		**Fruit crops**
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	X[1]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[1]
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	X[1]
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	X[1]
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated as concerns 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

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European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

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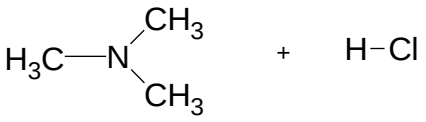
APPENDICES

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) ‡	trimethylamine hydrochloride (No ISO common name is attributed)
Function (*e.g.* fungicide)	Attractant
Rapporteur Member State	Belgium

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	trimethylamine hydrochloride
Chemical name (CA) ‡	*N*,*N*-dimethylmethanamine hydrochloride
CIPAC No ‡	Not applicable
CAS No ‡	593-81-7
EEC No (EINECS or ELINCS) ‡	209-810-0 ,
FAO Specification (including year of publication)‡	No FAO specification exists
Minimum purity of the active substance as manufactured (g/kg) ‡	Open
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Open
Molecular formula ‡	$C_3H_9N.HCl$
Molecular mass ‡	95.57
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	279.1°C (pure a.s., purity not reported)
Boiling point (state purity) ‡	data gap
Temperature of decomposition	data gap
Appearance (state purity) ‡	white monoclinic deliquescent crystals with pungent, fishy, ammoniacal odour (stated in MII)
Vapour pressure (in Pa, state temperature) ‡	data gap
Henry's law constant (Pa m^3 mol^{-1}) ‡	data gap
Solubility in water (g/l or mg/l, state temperature) ‡	soluble in water and alcohol (ethanol) (no study, result given in MII)
Solubility in organic solvents (in g/l or mg/l, state temperature) ‡	moderately soluble in chloroform, insoluble in ether (no study, result given in MII)
Surface tension ‡	data gap
Partition co-efficient (log P_{OW}) (state pH and temperature) ‡	data gap
Dissociation constant ‡	data gap
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡	data gap
Flammability ‡	Not highly flammable (statement given in MII)
Explosive properties ‡	data gap
Oxidising properties:	data gap

Summary of uses supported by available data (trimethylamine hydrochloride)

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 & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Orchards (apples, pears, peaches, nectarines, cherimoya)	Southern Europe	BioLure Med Fly	F	Mediterranean fruit fly (*Ceratitis capitata*)	VP FFA FFT FFP	 21.13% 9.1% 0.27%	Application by hand of 3 dispensers into traps	Mass trapping: begin of *C. capitata* flights, or when fruits become susceptible to damage Monitoring: begin of flight of *C. capitata*	Mass trapping: max 1	-	Mass trapping: (75-100 traps/ha) Monitoring: (1 trap/2 ha)			•	
Citrus	Southern Europe	BioLure Med Fly	F	Mediterranean fruit fly (*Ceratitis capitata*)	VP FFA FFT FFP	 21.13% 9.1% 0.27%	Application by hand of 3 dispensers into traps	Mass trapping: begin of *C. capitata* flights, or when fruits become susceptible to damage Monitoring: begin of flight of *C. capitata*	Mass trapping: max 2	6-8 weeks, depending on environmental factors such as climate and topography	Mass trapping: min 50 traps/ha Monitoring: (1 trap/2 ha)			0	

VP: vapor dispenser

FFA: ammonium acetate, FFT: trimethylamine hydrochloride, FFP: putrescine

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(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	(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 (principle of method)	Data gap
Impurities in technical as (principle of method)	Data gap
Plant protection product (principle of method)	Data gap

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition is required
Food of animal origin		No residue definition is required
Soil		Data gaps need to be filled before this can be finalised
Water	surface	Data gaps need to be filled before this can be finalised
	drinking/ground	Data gaps need to be filled before this can be finalised
Air		trimethylamine and its salts

Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Soil (principle of method and LOQ)	Open
Water (principle of method and LOQ)	Open
Air (principle of method and LOQ)	Open
Body fluids and tissues (principle of method and LOQ)	Not required, a.s. is not classified as T or T+

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	-

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Data available of limited validity. No further data needed.
Distribution ‡	-
Potential for accumulation ‡	-
Rate and extent of excretion ‡	-
Metabolism in animals ‡	Data available of limited validity. No further data needed.
Toxicologically relevant compounds ‡ (animals and plants)	-
Toxicologically relevant compounds ‡ (environment)	-

Acute toxicity (Annex IIA, point 5.2)

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

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data. No further data needed	
Relevant oral NOAEL ‡	-	
Relevant dermal NOAEL ‡	-	
Relevant inhalation NOAEL ‡	-	

Genotoxicity ‡ (Annex IIA, point 5.4)

Data available of limited validity. No further data needed.	

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

Target/critical effect ‡	No data. No further data needed	
Relevant NOAEL ‡	-	
Carcinogenicity ‡	-	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

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

Developmental toxicity

Developmental target / critical effect ‡	Data available of limited validity. No further data needed.	
Relevant maternal NOAEL ‡	-	
Relevant developmental NOAEL ‡	-	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data. No further data needed	
Repeated neurotoxicity ‡	No data. No further data needed	
Delayed neurotoxicity ‡	No data. No further data needed	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data. No further data needed
Studies performed on metabolites or impurities ‡	No data. No further data needed

Medical data ‡ (Annex IIA, point 5.9)

Data available of limited validity. No further data needed.

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (BioLure Med Fly)	Data available of limited validity. No further data needed.

Exposure scenarios (Annex IIIA, point 7.2)

Operator, worker and bystanders	Negligible

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

Trimethylamine	According to Annex VI to Regulation (EC) No 1272/2008[17]; CLP 00: Xn R20 (harmful by inhalation), R37/R38 (irritating to respiratory system and skin) and R41 (risk of serious damage to eyes).

[17] OJ L 353, 31.01.2008, p.1

Residues

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

Plant groups covered Rotational crops Plant residue definition for monitoring Plant residue definition for risk assessment Conversion factor (monitoring to risk assessment)	No data available. Not required according to the representative uses.

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

Animals covered Animal residue definition for monitoring Animal residue definition for risk assessment Conversion factor (monitoring to risk assessment) Metabolism in rat and ruminant similar (yes/no) Fat soluble residue: (yes/no)	No data available. Not required according to the representative uses.

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

No data available. Not required according to the representative uses.

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

No data available. Not relevant.

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle Liver Kidney Fat Milk Eggs	No data available. Not required according to the representative uses.		

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern Europe	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL (mg/kg)	STMR (mg/kg) (b)
No data available. Not required according to the representative uses.					

(a) : Number of trials in which particular residue levels were reported.
(b) : Supervised Trials Median Residue: The median residue level estimated on the basis of supervised trials relating to the critical GAP

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

ADI TMDI (European Diet) (% ADI) NEDI (% ADI) Factors included in NEDI ARfD Acute exposure (% ARfD)	A quantitative consumer dietary risk assessment can be waived due to the specific kind of application.

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
No data available. Not required according to the representative uses.			

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

Not required.

Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	Trimethylamine is a synthetic replica of the naturally occurring substance resulting from the decay of organic matter in plants, animals, sewage and animal waste. Trimethylamine is formed by microbial breakdown of both choline and betaine (common constituents of plants and animals) and by bacterial reduction of trimethylamine N-oxide, a common metabolite and excretory product of aquatic organisms. The substance is volatilised from dispensers to surrounding air. The dispensers are contained in traps. Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Non-extractable residues after 100 days ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

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

Anaerobic degradation ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Soil photolysis ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

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

Method of calculation	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Laboratory studies (range or median, with n value, with r^2 value) ‡	DT_{50lab} (20°C, aerobic): ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
	DT_{90lab} (20°C, aerobic): ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but but to demonstrate this is a data gap.
	DT_{50lab} (10°C, aerobic): ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
	DT_{50lab} (20°C, anaerobic): ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
	degradation in the saturated zone: ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

Field studies (state location, range or median with n value) ‡	DT_{50f}: ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
	DT_{90f}: ‡ Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Soil accumulation and plateau concentration ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence (yes / no) (if yes type of dependence) ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

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

Column leaching ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Aged residues leaching ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Lysimeter/ field leaching studies ‡	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	Negligible soil exposure in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
Application rate	-

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡	Data gap
Photolytic degradation of active substance and relevant metabolites ‡	Trimethylamine is a synthetic replica of the naturally occurring substance resulting from the decay of organic matter in plants, animals, sewage and animal waste. Trimethylamine is formed by microbial breakdown of both choline and betaine (common constituents of plants and animals) and by bacterial reduction of trimethylamine N-oxide, a common metabolite and excretory product of aquatic organisms. The substance is volatilised from dispensers to surrounding air. The dispensers are contained in traps. Negligible soil and water exposure in the situation that exposure to air and/or surface water is demonstrated to be comparable to natural background levels, but to

	demonstrate this is a data gap.
Readily biodegradable (yes/no) ‡	Data gap, considered not readily biodegradable whilst reliable data are not in the dossier
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡ Mineralization Non-extractable residues Distribution in water / sediment systems (active substance) ‡ Distribution in water / sediment systems (metabolites) ‡	Negligible surface water exposure in the situation that exposure to air and/or surface water is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap. Trimethylamine is a synthetic replica of the naturally occurring substance resulting from the decay of organic matter in plants, animals, sewage and animal waste.

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

Method of calculation Application rate Main routes of entry	The substance is volatilised from dispensers to surrounding air. The dispensers are contained in traps. Negligible surface water exposure in the situation that exposure to air and/or surface water is demonstrated to be comparable to natural background levels, but to demonstrate this is data gap.

PEC (sediment)

Method of calculation Application rate	The substance is volatilised from dispensers to surrounding air. The dispensers are contained in traps. Negligible surface water exposure in the situation that exposure to air and/or surface water is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter) Application rate	Trimethylamine is a synthetic replica of the naturally occurring substance resulting from the decay of organic matter in plants, animals, sewage and animal waste. The substance is volatilised from dispensers to surrounding air. The dispensers are contained in traps. Negligible groundwater exposure is expected in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

$PEC_{(gw)}$

Maximum concentration	-
Average annual concentration	-

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

Direct photolysis in air ‡	No data, not required.
Quantum yield of direct phototransformation	No data, not required
Photochemical oxidative degradation in air ‡	Trimethylamine K_{OH} = 6.09 x 10^{-11} cm^3/molecule.sec at 298.7 K-This value corresponds to a DT_{50} of 0.18 day (based on an average OH-concentration of 1.5 x 10^6 OH/cm^3 during a 12 hours daylight)
Volatilization ‡	from plant surfaces: negligible exposure of plant surfaces anticipated in the situation that exposure to air is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.
	from soil: ‡ negligible soil exposure anticipated in the situation that exposure to air and/or soil is demonstrated to be comparable to natural background levels, but to demonstrate this is a data gap.

PEC (air)

Method of calculation	theoretical PEC air submitted by the notifier

$PEC_{(a)}$

Maximum concentration	Application and emission rate based on Mass Trapping: A maximum of 100 traps per hectare. Application rate: 100 dispensers/ha x 1.71 g a.s./dispenser = 171 g a.s./ha Emission rate (m^2) = 0.349 mg a.s./m^2/day Emission rate (m^3) = 0.14 mg a.s./m^3/day Application and emission rate based on Monitoring: One trap recommended for every 2 hectares. Application rate: 0.5 dispenser/ha x 1.71 g a.s./dispenser = 0.855 g a.s./ha Emission rate (m^2) = 0.00174 mg a.s./m^2/day Emission rate (m^3) = 0.0007 mg a.s./m^3/day

Residues requiring further assessment (Annex IIA, point 7.3)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil:	Trimethylamine and its salts
	Surface water:	Trimethylamine and its salts
	Sediment:	Trimethylamine and its salts
	Ground water:	Trimethylamine and its salts
	Air:	Trimethylamine and its salts

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R53 whilst there is a data gap for a ready biodegradability study.

Effects on Non-target Species

[1] Pending on the outstanding data in the fate and behaviour section, the risk assessment of trimethylamine hydrochloride to non-target organisms for the representative uses should be re-considered.

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

Acute toxicity to mammals ‡	Not required[1].
Reproductive toxicity to mammals ‡	Not required[1].
Acute toxicity to birds ‡	Not required[1].
Dietary toxicity to birds ‡	Not required[1].
Reproductive toxicity to birds ‡	Not required[1].

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

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
Not required[1].					

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	Endpoint	Toxicity (mg/l)
Laboratory tests				
‡ *Leuciscus idus*	Active substance	96 hours	LC_{50}	> 500 mg a.s./L
‡ *Daphnia magna*	Active substance	48 hours	EC_{50}	259 mg a.s./L
‡ *Navicula pelliculosa*	Active substance	96 hours	EC_{50}	0.2 mg a.s./L
‡ *Scenedesmus subspicatus*	Active substance	72 hours	EC_{50}	90 mg a.s./L
‡ *Selenastrum capricornutum*	Active substance	96 hours	EC_{50}	0.19 mg a.s./L

The data were obtained from IUCLID dataset, (ECB, 2000). Consequently, these studies were not assessed and could not be used in the risk assessment. Data gap identified for acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement.

Microcosm or mesocosm tests

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

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
Not required[1].						

Bioconcentration

Bioconcentration factor (BCF) ‡	Not required.
Annex VI Trigger for the bioconcentration factor	Not required.
Clearance time (CT_{50}) (CT_{90})	Not required. 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 ‡	Not required[1].
Acute contact toxicity ‡	Not required[1].

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
Not required[1].				

Field or semi-field tests
Not required[1].

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
Not required[1]						

Field or semi-field tests
Not required[1]

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

Acute toxicity ‡	Not required[1].
Reproductive toxicity ‡	Not required[1].

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
Not required[1].				

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

Nitrogen mineralization ‡	Not required[1].
Carbon mineralization ‡	

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

Laboratory dose response tests

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

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

Test type/organism	end point
Activated sludge	Not required[1]
Pseudomonas sp	

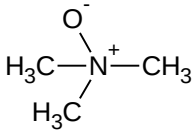
Ecotoxicologically relevant compounds (consider all relevant metabolites requiring further assessment from the fate section)

Compartment	Ecotoxicologically relevant residue
soil	Data gaps need to be filled before this can be finalized.
water	Data gaps need to be filled before this can be finalized.
sediment	Data gaps need to be filled before this can be finalized.
groundwater	Data gaps need to be filled before this can be finalized.

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

Active substance	Data gap.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
trimethylamine-*N*-oxide TMNO	trimethylamine oxide	

* 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	Kelvin
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
MAK	maximale Arbeitsplatzkonzentrationen
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
VP	vapour releasing product
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year