CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance denatonium benzoate[1] (approved as denathonium benzoate)

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Denatonium benzoate 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].

Denatonium benzoate 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.

Portugal being the designated rapporteur Member State submitted the DAR on denatonium benzoate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 8 January 2008. The peer review was initiated on 16 May 2008 by dispatching the DAR to the notifier Macfarlan Smith Limited, and on 20 December 2010 to the Member States, for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on denatonium benzoate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of denatonium benzoate as a repellent in forestry, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00257, issued on 2 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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Data gaps were identified in the section physical and chemical properties and analytical methods.

The database in the mammalian toxicology section is very limited: the toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance and a critical area was identified; no reference values could be set and the operator, worker and bystander exposure assessment for uses other than brushing with automatic rolling equipment could not be performed as no data were available.

No data gaps were identified in the residue section.

Limited information is available in the dossier on the fate and behaviour of denatonium benzoate in the environment. However, taking into account the method of application and the fact that the associated application rate is for a maximum of 0.66 g a.s./ 1000 trees, the environmental exposure has been considered negligible and no PEC have been calculated. If other uses resulting in higher exposure were intended in the future, a substantial amount of data would be needed to finalize the environmental exposure assessment.

The risk to non-target organisms was considered low for the representative uses.

KEY WORDS

Denatonium benzoate, peer review, risk assessment, pesticide, repellent

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BACKGROUND

Denatonium benzoate 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].

Denatonium benzoate 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.

Portugal being the designated rapporteur Member State submitted the DAR on denatonium benzoate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 8 January 2008 (Portugal, 2007). The peer review was initiated on 16 May 2008 by dispatching the DAR to the notifier Macfarlan Smith Limited, and on 20 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 B 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 Commission on 16 March 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, 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, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 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

[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

repellent in forestry, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) 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 (16 March 2011),
- the Evaluation Table (28 November 2011),
- the report of the scientific consultation with Member State experts,
- the comments received on the additional information assessment,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2011 containing all individually submitted addenda (Portugal, 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

Denatonium benzoate is a common name for *N*-benzyl-2-[(2,6-dimethylphenyl)amino]-*N*,*N*-diethyl-2-oxoethanaminium benzoate or benzyldiethyl[[2,6-xylylcarbamoyl]methyl]ammonium benzoate (IUPAC).

The representative formulated product for the evaluation was 'Arbinol B', a liquid to be applied undiluted (AL) containing 0.11 g/L pure denatonium benzoate, registered in several EU Member States.

The representative uses evaluated comprise applications by spraying the undiluted product or by coating with brush or dip on deciduous/coniferous forest trees, as a repellent against game browsing damage. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004).

The minimum purity of denatonium benzoate technical material is 995 g/kg. 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, physical, chemical and technical properties of denatonium benzoate or the representative formulation; however a data gap was identified for a two years storage stability study. The main data regarding the identity of denatonium benzoate and its physical and chemical properties are given in appendix A.

Adequate analytical methods are available for the determination of denatonium benzoate in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

The need for methods of analysis for monitoring this compound in food of plant and animal origin has been waived in view of the representative use. Data gaps were identified for the residue analytical methods for the determination of denatonium benzoate in the environmental compartments. A method for residues in body fluids and tissues is also identified as a data gap as the active substance is classified as very toxic.

2. Mammalian toxicity

Denatonium benzoate was discussed in the Peer review meeting 88 (September 2011).

Denatonium benzoate is harmful if swallowed, acutely very toxic after inhalation and severely irritant to the eyes (the risk phrases Xn, R22; T^+, R26 and R41 were proposed). It is neither a skin irritant nor a skin sensitiser. No studies were submitted to clarify toxicokinetics, short- and long- term toxicity, carcinogenicity, neurotoxicity, or reproductive and developmental toxicity.

The toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance. Consequently, a critical area of concern was identified.

With regard to the exposure assessment, only brushing performed with automatic rolling equipment could be assessed based on the available data, showing no concern for the operators, on the assumption that the top of the tree is treated, and that gloves are used. For workers and bystanders it is highly unlikely that a significant exposure could occur, in the light of the very low application rate and

concentration of the a.s. For the other uses (e.g. manual brushing, dipping, and spraying), exposure cannot be excluded based on the lack of exposure data and a critical area of concern was identified.

3. Residues

Denatonium benzoate acts as a repellent against roe and red deer to protect buds and twigs of deciduous and coniferous trees at a maximum rate of 0.66 g a.s./1000 trees. No contact with food or feed items is therefore expected. A quantitative consumer dietary risk assessment can be waived.

4. Environmental fate and behaviour

Denatonium benzoate is a water soluble organic salt with bitter taste. The representative use as a roe and red deer repellent to protect buds and twigs of deciduous and coniferous trees is associated with overall application rates of not more than 0.66 g a.s / 1000 trees.

Very limited information is available in the dossier on fate and behaviour in the environment. Denatonium benzoate is expected to be stable in the environment. It is stable to hydrolysis and is not readily biodegradable. A soil column leaching experiment is available in the dossier. In the DAR rough estimations of Kd are presented on the basis of this experiment but the method used to calculate them needs to be clarified. The results of this experiment indicate that denatonium benzoate may be considered mobile to immobile depending on the soil.

Denatonium benzoate has been estimated to exhibit an atmospheric half-life of less than 2 d (DT_{50} = 2.2 h).

Taking into account the method of application and that the associated application rate is for a maximum of 0.66 g a.s./ 1000 trees, the environmental exposure has been considered to be negligible and no PEC have been calculated. If other uses resulting in higher exposure were intended in the future, a considerable amount of data would be needed to finalise the environmental exposure assessment.

5. Ecotoxicology

Because the method of application is leading to negligible levels of environmental exposure and the application rate is low, 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
Denatonium benzoate	Estimated to be persistent in the environment.	Low risk

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
Denatonium benzoate	No fully reliable data available. Mobile to immobile depending on the soil.	Not relevant for a repellent[(a)]	Yes	Yes	Yes

(a): EFSA's reading of the Council Directive 98/83/EC[15] on the quality of drinking water intended for human consumption is, that as a repellent, denatonium benzoate 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.

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

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Denatonium benzoate	Low risk

6.4. Air

Compound (name and/or code)	Toxicology
Denatonium benzoate	Acutely toxic via inhalation

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).

- Two years storage stability study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Residue analytical methods for the determination of denatonium benzoate in soil (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Residue analytical methods for the determination of denatonium benzoate in water (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Residue analytical methods for the determination of denatonium benzoate in air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Residue analytical methods for the determination of denatonium benzoate in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the notifier: method available, however according to the Regulation 1095/2007 cannot be taken into account in the peer review; see section 1).
- Toxicological profile (in particular toxicokinetics, short- and long- term toxicity, carcinogenicity, neurotoxicity, reproductive and developmental toxicity) of denatonium benzoate (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Operator, worker and bystander exposure assessment of manual brushing, dipping, and spraying application methods (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

- Brushing performed with automatic rolling equipment showed no concern for the operator, based on the assumption that only the top of the tree is treated, and that gloves are used.

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).

- None

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.

1. Operator, worker and bystander exposure and risk assessment could not be performed for uses other than brushing with automatic rolling equipment (e.g. for manual brushing, dipping, and spraying) as no exposure data were available. Furthermore, the toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance.

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 the toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance.

Representative use		**All representative uses**
Operator risk	Risk identified	
	Assessment not finalised	X[1] (b, see footnote below)
Worker risk	Risk identified	
	Assessment not finalised	X[1] (b, see footnote below)
Bystander risk	Risk identified	
	Assessment not finalised	X[1] (b, see footnote below)
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information

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

(b): The operator, worker and bystander risk assessment for uses other than brushing with automatic rolling equipment could not be performed.

REFERENCES

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 denatonium benzoate.

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.

European Commission, 2004. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2008. Review Report for the active substance denatonium benzoate 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 denatonium benzoate in Annex I of Directive 91/414/EEC. SANCO/2607/08 – rev. 1, 01 August 2008.

Portugal, 2007. Draft Assessment Report (DAR) on the active substance denatonium benzoate prepared by the rapporteur Member State Portugal in the framework of Directive 91/414/EEC, December 2007.

Portugal, 2011. Final Addendum to Draft Assessment Report on denatonium benzoate, compiled by EFSA, October 2011.

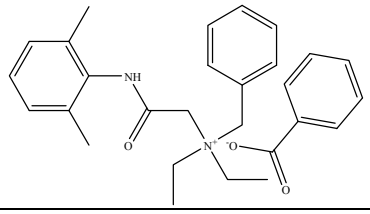
APPENDICES

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

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

Active substance (ISO Common Name) ‡	Denatonium benzoate
Function (*e.g.* fungicide)	Repellent
Rapporteur Member State	Portugal

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-benzyl-2-[(2,6-dimethylphenyl)amino]-*N*,*N*-diethyl-2-oxoethanaminium benzoate or benzyldiethyl[[2,6-xylylcarbamoyl]methyl]ammonium benzoate
Chemical name (CA) ‡	*N*-[2-[(2,6-dimethylphenyl)amino]-2-oxoethyl]-*N*,*N*-diethylbenzenemethanaminium benzoate
CIPAC No ‡	845
CAS No ‡	3734-33-6
EC No (EINECS or ELINCS) ‡	2230952
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	995 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities
Molecular formula ‡	$C_{28}H_{34}N_2O_3$
Molecular mass ‡	446.591 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	164.5 ºC (1001 g/kg)
Boiling point (state purity) ‡	Not relevant
Temperature of decomposition (state purity)	301.0 ºC (1001 g/kg)
Appearance (state purity) ‡	Free flowing, opaque, white, crystalline solid (1001g/kg)
Vapour pressure (state temperature, state purity) ‡	Not submitted.
Henry's law constant ‡	Not submitted.
Solubility in water (state temperature, state purity and pH) ‡	at 20 °C, 1001g/kg pH 3 – 23.3 g/L pH 5 – 91.9 g/L pH 7 – 42.4 g/L pH 9 – 42.1 g/L
Solubility in organic solvents ‡ (state temperature, state purity)	20 ºC, 1001g/kg heptane < 10 g/L *p*-xylene < 10 g/L 1,2-dichloroethane 14 – 20 g/L methanol > 250 g/L acetone < 10 g/L ethyl acetate < 10 g/L
Surface tension ‡ (state concentration and temperature, state purity)	50.7 mN/m for 1% solution in water at 20 ºC, 1001g/kg
Partition co-efficient ‡ (state temperature, pH and purity)	At 22 ºC, 1001g/kg log P_{OW} =0.1970 (pH 9) log P_{OW} =0.1838 (pH 7) log P_{OW} =0.2253 (pH 4)
Dissociation constant (state purity) ‡	1001 g/kg pKa = 4.05
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	1001g/kg neutral – max λ - 190 nm – log ε = 5.1 acidic – max λ - 199 nm – log ε = 4.7 alkaline – max λ - 212 nm – log ε = 4.7 No absorption at λ ≥ 290 nm
Flammability ‡ (state purity)	1001g/kg Not highly flammable Not auto-flammable
Explosive properties ‡ (state purity)	Not explosive (statement)
Oxidising properties ‡ (state purity)	Oxidizing substance (1001g/kg)

Summary of representative uses evaluated (name of active substance or the respective variant)

Crop and/or situation (a)	Member State or Country	Product Name	F, G or I (b)	Pests or Group of pests controlled (c) Weed code	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	interval between applications (min)	g a.s./hl min max	Water (L/ha) min max	g a.s./ha min max		
deciduous/ coniferous forest trees	D	Arbinol B	F	roe and red deer	AL	0.11g/L	spray brush-on dip	against gnawing during summer or winter	1	n.a.	undiluted application	undiluted application	0,22-0,66g per 1000 trees	n.a. application on forest trees only	
deciduous/ coniferous forest trees	AT	Arbinol B	F	roe and red deer	AL	0.11g/L	spray brush-on dip	against gnawing during summer or winter	1	n.a.	undiluted application	undiluted application	0,22-0,66g per 1000 trees	n.a. application on forest trees only	
deciduous/ coniferous forest trees	F	Arbinol B	F	roe and red deer	AL	0.11g/L	spray brush-on dip	against gnawing during summer or winter	1	n.a.	undiluted application	undiluted application	0,22-0,66g per 1000 trees	n.a. application on forest trees only	

Abbreviations: AL = Other liquid to be applied undiluted (water-based, ready-to–use liquid)

Remarks:
(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 sucking insects, soil borne insects, foliar fungi, weeds
(d) e.g. wettable powder (WP),emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No. 2, 1989
(f) All abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/ economic importance/restrictions

Methods of Analysis

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

Technical as (analytical technique)	Titration with perchloric acid
Impurities in technical as (analytical technique)	Loss on drying –CIPAC MT 17.1
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No proposal for residue definition
Food of animal origin		No proposal for residue definition
Soil		Denatonium benzoate
Water	surface	Denatonium benzoate
	drinking/ground	Denatonium benzoate
Air		Denatonium benzoate

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Denatonium benzoate Required
Water (analytical technique and LOQ)	Denatonium benzoate Required
Air (analytical technique and LOQ)	Denatonium benzoate Required
Body fluids and tissues (analytical technique and LOQ)	Not submitted. Required as the active is considered as very toxic

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

	RMS/peer review proposal
Active substance	R 8 – Contact with combustible material may cause fire.

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
Distribution ‡	No data
Potential for accumulation ‡	No data
Rate and extent of excretion ‡	No data
Metabolism in animals ‡	No data
Toxicologically relevant compounds ‡ (animals and plants)	-
Toxicologically relevant compounds ‡ (environment)	-

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	m: 841 mg/kg bw; f: 648 mg/kg bw	Xn, R22
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	-
Rat LC_{50} inhalation ‡	m & f: 0.20 mg/l	T^{+}, R26
Skin irritation ‡	No irritation	-
Eye irritation ‡	Severely irritant	$X_{i,}$ R41
Skin sensitisation ‡	No sensitizing	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data	
Relevant oral NOAEL ‡	No data	
Relevant dermal NOAEL ‡	No data	
Relevant inhalation NOAEL ‡	No data	

Genotoxicity ‡ (Annex IIA, point 5.4)

Apparently not genotoxic; (purity not stated in the studies)	

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

Target/critical effect ‡	No valid data available	
Relevant NOAEL ‡	No valid data available	
Carcinogenicity ‡	No valid data available	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available	
Relevant parental NOAEL ‡	No data available	
Relevant reproductive NOAEL ‡	No data available	
Relevant offspring NOAEL ‡	No data available	

Developmental toxicity

Developmental target / critical effect ‡	No data available	
Relevant maternal NOAEL ‡	No data available	
Relevant developmental NOAEL ‡	No data available	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available	
Repeated neurotoxicity ‡	No data available	
Delayed neurotoxicity ‡	No data available	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available
Studies performed on metabolites or impurities ‡	No data available

Medical data ‡ (Annex IIA, point 5.9)

Some slight effects in the skin of subjects tested at concentrations lower than the recommended for the use of the product

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not derived because of insufficient database		
AOEL ‡	Not derived because of insufficient database		
ARfD ‡	Not derived because of insufficient database		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	No data

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Automatic brushing: No concern based on the assumption that the top of the tree is treated, and that gloves are used Other uses (e.g. manual brushing, dipping, spraying) No data available
Workers	Automatic brushing: Highly unlikely that a significant exposure could occur, in the light of the very low application rate and concentration of the a.s. Other uses (e.g. manual brushing, dipping, spraying)) No data available
Bystanders	Automatic brushing: Highly unlikely that a significant exposure could occur, in the light of the very low application rate and concentration of the a.s. Other uses (e.g. manual brushing, dipping, spraying)) No data available

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

	RMS/peer review proposal
Substance classified (name)	T^+, Xn; R22, R26, R41

Residues

No data were presented due to the fact that this product will not be applied on food or feed.

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?	N/A
Processed commodities	Not required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	N/A
Plant residue definition for monitoring	Not required.
Plant residue definition for risk assessment	Not required.
Conversion factor (monitoring to risk assessment)	N/A

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	N/A
Animal residue definition for monitoring	Not required.
Animal residue definition for risk assessment	Not required.
Conversion factor (monitoring to risk assessment)	N/A
Metabolism in rat and ruminant similar (yes/no)	N/A
Fat soluble residue: (yes/no)	No

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)

Feeding studies not required.

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			

Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

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

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

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

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

An overall consumer risk assessment is not required based on the representative uses.

ADI	
TMDI (% ADI) according to WHO European diet	
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	
IESTI (% ARfD)	
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	

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)

Not required.

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

Mineralization after 100 days ‡	No data submitted
Non-extractable residues after 100 days ‡	No data submitted
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data submitted

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

Anaerobic degradation ‡

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

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted

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

Aerobic - Laboratory studies ‡ No data submitted

Field studies ‡ No data submitted

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

Anaerobic - Laboratory studies ‡ No data submitted

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡‡ No data submitted

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

Column leaching ‡	Eluation (mm): 20 mm Time period (d): 30 d
	Leachate: 0.035 % - 10.5 % radioactivity in leachate < 0.05 % a. s., in 3 soils (Kitleyknowe, Easter Howgate and Balmanno) x % total residues/radioactivity retained in top x cm Kd: 7.9 – 527.8 cm^3/g^*
Aged residues leaching ‡	No data submitted
Lysimeter/ field leaching studies ‡	No data submitted

*These values should be considered with caution, further clarification on the methodology of this study and the calculation methodology needed.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	The PEC in soil was not submitted and since no studies have been submitted for the route and rate of degradation in soil it was not possible to calculate PEC. Regarding the physical and chemical properties of denatonium benzoate and the application, the predicted concentration of the active substance in soil should be negligible.
Application data	Not applicable

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: > 1 year at 25 °C
	pH 7: > 1 year at 25 °C
	pH 9: > 1 year at 25 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	No data submitted
Quantum yield of direct phototransformation in water at Σ > 290 nm	
Readily biodegradable ‡ (yes/no)	Yes, substance considered not readily biodegradable.

Degradation in water / sediment

Parent	No data submitted

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

Parent Parameters used in FOCUSsw step 1 and 2	The PEC in surface water was not submitted. Regarding the physical and chemical properties of denatonium benzoate and the representative use, it is not expected that surface water will be exposed to this substance. PECsw should be negligible.
Parameters used in FOCUSsw step 3 (if performed)	See above
Application rate	Not applicable

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	The PEC in ground water was not submitted. Regarding the physical and chemical properties of denatonium benzoate, the results of the column leaching study and the representative use, groundwater contamination by this substance is not expected. PECgw should be negligible.
Application rate	Not applicable

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

Direct photolysis in air ‡	No data submitted
Quantum yield of direct phototransformation	No data submitted
Photochemical oxidative degradation in air ‡	DT_{50} = 2.2 hours
Volatilisation ‡	No data submitted

PEC (air)

Method of calculation	Not applicable

$PEC_{(a)}$

Maximum concentration	Not applicable

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: denatonium benzoate Surface Water: denatonium benzoate Sediment: denatonium benzoate Ground water: denatonium benzoate Air: denatonium benzoate

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

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

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

R53

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 ‡				
C. virginianus.	Bitrex	Acute	196 mg/kg bw	
C. virginianus.	Bitrex	Short-term	778.3 mg/kg bw/d	> 5200 ppm
Anas platyrhynchos	Bitrex	Short-term	841.8 mg/kg bw/d	> 5200 ppm
Mammals ‡				
Indicate species.	a.s.	Acute	No data available	
	Preparation	Acute		
	Metabolite 1	Acute		
	a.s.	Long-term		
Additional higher tier studies ‡				
None				

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

ARBINOL B is an aqueous repellent which is applied undiluted to young sprouts of deciduous trees and coniferous trees. An ingestion of the product by vertebrates can be excluded since ARBINOL B is applied as a repellent to protect young deciduous trees and coniferous trees against gnawing by game. Due to a very unpleasant bitter taste of the product, an uptake by other vertebrates seems to be very unlikely

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)
Laboratory tests ‡				
Fish				
S. gairdneri	Bitrex	96 hr (static)	Mortality, EC_{50}	> 1000
Aquatic invertebrate				
Cragon sp.	Bitrex	96 h (static)	Mortality, EC_{50}	400
D. magna	Bitrex	48 h (static)	Mortality, EC_{50}	> 500
D. magna	Bitrex	21 d (semi-static)	Reproduction, NOEC	5
Algae				
Nitzschia palea.	Bitrex	70.5 h (static)	Biomass: E_bC_{50}	5 – 10 mg/l
S. subspicatus	ARBINOL B	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 > 100

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Microcosm or mesocosm tests Not submitted				
Indicate if not required 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)

Calculation of PECsw and TER values for aquatic organisms is not possible.

ARBINOL B is used in different ways: It can be applied onto single plants by spraying with a hand held knapsack-sprayer, by dipping the terminal sprouts into the product or by application with a brush.

Only for the spraying application a spray drift to aquatic habitats is possible. ARBINOL B is normally sprayed with coarse droplets and low pressure onto single young plants usually not higher than 1,5 m in the forest to protect them against gnawing by game. This makes a drift from the single application site to aquatic habitats very unlikely. Considering that only negligible exposure will be expected it can be concluded that the risk for aquatic organisms due to the application of ARBINOL B can be considered as low.

Bioconcentration	
	Active substance
$logP_{O/W}$	Log P_{OW} =0.1970 (pH 9) Log P_{OW} =0.1838 (pH 7) Log P_{OW} =0.2253 (pH 4)
Bioconcentration factor (BCF)[1] ‡	Not required

[1] only required if log $P_{O/W}$ >3.

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)
ARBINOL B	> 362.5 µg ARBINOL B/bee	> 400 µg ARBINOL B/bee

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

Crop and application rate

A calculation of Q_{HO} and Q_{HC} for the risk assessment according to Directive 91/414 is not feasible.

ARBINOL B protects young sprouts and branches of small deciduous trees and coniferous trees from gnawing by game and is applied in different ways. It can be applied onto young sprouts of single plants by spraying with a hand held knapsack-sprayer, dipping the terminal sprouts into the product or by application with a brush. Under normal conditions it is very unlikely that bees will be in contact with the product or with areas of application. Therefore the risk is considered to be low for the use of ARBINOL B.

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

Species	Test Substance	End point	Effect (% mortality)
Poecilius cupreus ‡	ARBINOL B 60l/ha in 400 l	Mortality	0%
Drino inconspicua ‡	ARBINOL B 60l/ha in 200 l	Mortality	4.4% No effects on parasitization capacity

Hazard quotients for other arthropod species

Because of the limited data set, calculation of Hazard Quotients according to ESCORT 2 or a calculation of HQ values is not possible. However, it can be concluded that low risk to other arthropods will be expected.

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)

No data submitted

Toxicity/exposure ratios for soil organisms

ARBINOL B is used as a game repellent. It protects young sprouts and branches of small deciduous trees and coniferous trees against gnawing by game. Considering the specific application of ARBINOL B to terminal sprouts of single plants a contamination of soil is very unlikely when the product is applied according to good agricultural practice. The product forms a hard layer on the treated parts of the plants and is not dissolved by precipitation. Therefore, a direct or indirect exposure of earthworms to the product can be excluded.

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

Preliminary screening data

Not required

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

Not required

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

Compartment	
soil	Not applicable
water	Not applicable
sediment	Not applicable

groundwater	Not applicable

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	R51/53

	RMS/peer review proposal
Preparation	No classification

ABBREVIATIONS

1/n	slope of Freundlich isotherm
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
AL	other liquid to be applied undiluted
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 Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
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-UV	high pressure liquid chromatography – ultraviolet detection
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
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