## CONCLUSION ON PESTICIDE PEER REVIEW

# Conclusion on the peer review of the pesticide risk assessment of the active substance fish oil[1]

**European Food Safety Authority**[2]

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## SUMMARY

Fish oil 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].

Fish oil was included in Annex I to Directive 91/414/EEC on 18 December 2008 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation') and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on fish oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 April 2008. The peer review was initiated on 31 July 2008 by dispatching the DAR for consultation of the notifier (Fluegel GmbH). The commenting period with Member States was launched on 16 December 2010. 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 fish oil. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fish oil as a game repellent in deciduous and coniferous forests and orchards, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis data gaps were identified for a specification and supporting data. Data gaps were also identified for further physical-

[1] On request from the European Commission, Question No EFSA-Q-2009-00280, adopted on 16 December 2011.
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[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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chemical properties of the active substance and the formulation and a translation of some studies. A method of analysis is also required for the formulation.

No agreed technical specification is available and a data gap is identified in the mammalian toxicology section on the presence and maximum level of impurities and/or contaminants of potential toxicological concern; this issue could not be finalised.

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

Fish oil is a natural compound produced from fresh fish. Fate and behaviour of fish oil is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.

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

**KEY WORDS**

Fish oil, peer review, risk assessment, pesticide, repellent

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## BACKGROUND

Fish oil 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].

Fish oil was included in Annex I to Directive 91/414/EEC on 18 December 2008 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13].In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on fish oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 April 2008 (Greece, 2008). The peer review was initiated on 31 July 2008 by dispatching the DAR to the notifier Fluegel GmbH and on 16 December 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notofoer was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the 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, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 2011

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a game repellent in deciduous and coniferous forests and orchards, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011)

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

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

- the comments received on the DAR,
- the Reporting Table (25 March 2011)
- the Evaluation Table (14 December 2011)
- the comments received on the draft EFSA conclusion.

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

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fish oil is the given name for this active substance.

The representative formulated product for the evaluation was 'Morsuvin' a paste formulation containing 43 g/kg fish oil.

The representative uses evaluated are as a game repellent in deciduous and coniferous forests and orchards. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

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

A specification is not available for this material and a data gap for a specification with supporting batch data and analytical methods has been identified. Fish oil may contain environmental contaminants and the following maximum levels are set: 6 pg/g dioxins; 0.5 mg/kg for mercury; 2 mg/kg cadmium and lead 10 mg/kg, PCBs 5mg/kg and pesticides 10 mg/kg. The batch data are also needed to verify theses levels

The notifier stated that if the material is exposed to air during the manufacturing process undesirable chemicals can be formed. A data gap has been set for the notifier to identify these compounds.

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

For the active material a data gap was identified to address melting point, boiling point, vapour pressure, surface tension, dissociation constant, partition co-efficient, flammability, auto-flammability explosive and oxidising properties.

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

For the formulation data gaps were identified to address shelf life, oxidising properties, explosive properties, flammability and auto-flammability. The notifier is also requested to submit a translation of the studies relevant to the emergency measures in case of an accident and of the studies relevant to the suitability of the packaging and closures. A method of analysis that can identify and at least semi-quantify the active material in the formulation is also identified as a data gap.

The need for residue analytical methods is waived due to the nature of this material.

### 2. Mammalian toxicity

A data gap and an issue that could not be finalised have been identified for the levels of impurities and/or contaminants of toxicological concern potentially present in the technical material since no technical specification has been agreed in section 1 on the identity of the active substance. Dioxin, mercury, cadmium, lead, PCBs and pesticides were identified as relevant impurities.

Fish oil does not have a toxic mode of action and does not present a toxicological concern by itself. It is used as feedstuffs obtained from fresh fish by-products not suitable for human consumption; based on its nature, all toxicological studies are waived and reference values are not required. No quantitative exposure and risk assessment was conducted for operators and workers, considering the risk, if any, to be negligible. No exposure is anticipated for bystanders.

### 3. Residues

Metabolism and residue studies were not considered relevant for evaluation due to the nature of the active substance and to the representative use. Fish oil will be used only as protection coating on the

outside of trees in forestry or orchards. Crops destined for human and animal consumption are not intended to receive direct treatment. The risk for contamination of fruits is negligible since GAP defines that applications must be done between November and March when fruits are usually not present. Consumer risk assessments were not required due to 1) the unlikelihood of significant residues and 2) the low toxicological concern for fish oil.

## 4. Environmental fate and behaviour

Fish oil has been notified as mammal repellent for use on trees by application with brush onto the sprouts or on the entire plant.

Fish oil is a natural compound produced from fresh fish. The fate and behaviour of fish oil is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The preparation Morsuvin contains 43.0 g/kg fish oil and it is a game repellent which will be used only as a protection coat on the outside of the plants. No soil contamination is expected to occur during a proper application. The preparation dries within two hours and forms a protective coating on leaves and needles. The dried preparation is not water soluble. Based on the nature of the ingredients and the formulation it is unlikely that residues of the preparation would be detected in air.

## 5. Ecotoxicology

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

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

### 6.1. Soil

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| Not assessed<br><br>Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil. | Not assessed | - |

### 6.2. Ground water

| Compound (name and/or code) | Mobility in soil | >0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| Not assessed<br><br>Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil. | Not assessed | Not relevant (a) | - | No | - |

(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. A toxicological based groundwater limit may however be appropriate.

### 6.3. Surface water and sediment

| **Compound (name and/or code)** | **Ecotoxicology** |
|---|---|
| Not assessed<br><br>Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil. | - |

### 6.4. Air

| **Compound (name and/or code)** | **Toxicology** |
|---|---|
| Not assessed<br><br>Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil. | Study waived based on the low toxicological concern of the active substance |

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

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

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

- A specification for fish oil should be developed and this should be supported by appropriate 5 batch analysis with validated methods of analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Notifier to identify which undesirable chemicals can be formed when fish oil is exposed to the air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information or data to address the following melting point, boiling point, vapour pressure, surface tension, dissociation constant, partition coefficient, flammability, auto-flammability explosive and oxidising properties of the active (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Shelf life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information or data to address the following oxidising and explosive properties, flammability and auto-flammability of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Notifier to submit a translation of the studies relevant to the emergency measures in case of an accident and of the studies relevant to the suitability of the packaging and closures (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Method of analysis for the formulation that can identify and at least semi-quantify the “active substance” (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Analysis and maximum levels of impurities and/or contaminants of toxicological concern have not been specified for the technical specification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2)

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

- 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).

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

### 9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

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

### 9.3. Overview of the assessments for each representative use considered

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

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

| Representative use | | Game repellent | | | |
|---|---|---|---|---|---|
| | | Deciduous & Coniferous in forestry 430 g/1000 plants | Deciduous & coniferous in forestry 130 g/1000 plants | Orchard 430 g /1000 plants | Orchard 130 g /1000 plants |
| **Operator risk** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Worker risk** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Bystander risk** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Consumer risk** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Risk to wild non target terrestrial vertebrates** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Risk to wild non target terrestrial organisms other than vertebrates** | Risk identified | | | | |
| | Assessment not finalised | | | | |
| **Risk to aquatic organisms** | Risk identified | | | | |
| | Assessment not finalised | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Groundwater exposure active substance** | Legal parametric value breached | | | | |
| | Assessment not finalised | | | | |
| **Groundwater exposure metabolites** | Legal parametric value breached | | | | |
| | Parametric value of 10µg/L[(a)] breached | | | | |
| | Assessment not finalised | | | | |
| **Comments/Remarks** | | | | | |

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

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

## REFERENCES

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

Greece, 2011. Final Addendum to Draft Assessment Report on fish oil., compiled by EFSA, June 2011.

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

European Commission, 2008. Review Report for the active substance fish oil. 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 fish oil in Annex I of Directive 91/414/EECSANCO/2629/08 – rev.1, 7 August 2008

## 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) ‡ | Fish Oil |
| Function (*e.g.* fungicide) | Repellent |

| | |
|---|---|
| Rapporteur Member State | Hellas |
| Co-rapporteur Member State | - |

**Identity (Annex IIA, point 1)**

| | |
|---|---|
| Chemical name (IUPAC) ‡ | - |
| Chemical name (CA) ‡ | - |
| CIPAC No ‡ | 918 |
| CAS No ‡ | 100085-40-3 |
| EC No (EINECS or ELINCS) ‡ | 309-181-3 |
| FAO Specification (including year of publication) ‡ | - |
| Minimum purity of the active substance as manufactured ‡ | Specification open |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | The following maximum permissible values have been derived from the German Animal Feed Law and are proposed as follows: In the case of dioxin, 6 pg/g as the maximum permissible value for animal feed. For mercury, 0.5 mg/kg feed derived from fish and other sea food processing; for cadmium, 2 mg/kg feed of animal origin, except in feed for domestic pets; and for lead, 10 mg/kg feed. For PCBs, 5 mg/kg, and for pesticides 10 mg/kg.Data gap for supporting batch data |
| Molecular formula ‡ | - |
| Molecular mass ‡ | > 850 g/mol (calculated) |

| | |
|---|---|
| Structural formula ‡ | - |

**Physical and chemical properties (Annex IIA, point 2)**

| | |
|---|---|
| Melting point (state purity) ‡ | Data gap. |
| Boiling point (state purity) ‡ | Data gap. |
| Temperature of decomposition (state purity) | - |
| Appearance (state purity) ‡ | Yellow up to red, transparent liquid with fishy odour |
| Vapour pressure (state temperature, state purity) ‡ | Data gap. |
| Henry's law constant ‡ | Not applicable. |
| Solubility in water (state temperature, state purity and pH) ‡ | Not water-soluble. |
| Solubility in organic solvents ‡ (state temperature, state purity) | Soluble in organic solvents like ether, benzine, benzene, chloroform, carbon disulfide, tetrachloromethane, tetraline, trichloroethylene but not in cold alcohol. |
| Surface tension ‡ (state concentration and temperature, state purity) | Data gap. |
| Partition co-efficient ‡ (state temperature, pH and purity) | Data gap. |
| Dissociation constant (state purity) ‡ | Data gap |
| UV/VIS absorption (max.) incl. ε ‡ (state purity, pH) | Not applicable. |
| Flammability ‡ (state purity) | Data gap. |
| Explosive properties ‡ (state purity) | Data gap. |
| Oxidising properties ‡ (state purity) | Data gap. |

**Summary of representative uses evaluated (*Fish oil*)**

| Crop and/or situation (a) | Member State or Country | Product name | FG 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 appli-cations | kg as/hL min max | water L/ha min max | kg as/1000 plants min max | | |
| Deciduous and coniferous trees in forestry | Germany | Morsuvin | F | Game repellent | PA | 43.0 g/kg | coating with brush; individual plants; entire plants | September-March | 1-2 | 6-7 months | n. a. | - | 0.43 | n. a. | none |
| Deciduous and coniferous trees in forestry | Germany | Morsuvin | F | Game repellent | PA | 43.0 g/kg | coating with brush; individual plants; terminal sprouts | September-March | 1-2 | 6-7 months | n. a. | - | 0.13 | n. a. | none |
| Orchard | Germany | Morsuvin | F | Game repellent | PA | 43.0 g/kg | coating with brush; individual plants; entire plants | November-March | 1-2 | 6-7 months | n. a. | - | 0.43 | n. a. | none |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Orchard | Germany | Morsuvin | F | Game repellent | PA | 43.0 g/kg | coating with brush;<br>individual plants;<br>terminal sprouts | November-March | 1-2 | 6-7 months | n. a. | - | 0.13 | n. a. | none |

n. a. = not applicable

**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

(c) e.g., biting and suckling insects, soil-born insects, foliar fungi, weeds

(d) e.g., wettable powder (WP), emulsifiable concentrate (EC), granule (GR) of

(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) minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

**Methods of Analysis**

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

| | |
|---|---|
| Technical as (analytical technique) | Open batch data with supporting data which includes the need for a method of analysis. |
| Impurities in technical as (analytical technique) | Data gap. |
| Plant protection product (analytical technique) | Data gap. |

**Analytical methods for residues (Annex IIA, point 4.2)**

**Residue definitions for monitoring purposes**

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

**Analytical methods for residues (Annex IIA, point 4.2)**

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Not required as no residue definition is proposed |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not required as no residue definition is proposed |

| | |
|---|---|
| Soil (principle of method and LOQ) | Not required as no residue definition is proposed |
| Water (principle of method and LOQ) | Not required as no residue definition is proposed |
| Air (principle of method and LOQ) | Not required as no residue definition is proposed |
| Body fluids and tissues (principle of method and LOQ) | As Fish Oil is not classified as toxic or very toxic, no analytical method is required for its determination in body fluids and tissues. |

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

| | RMS/peer review proposal |
|---|---|
| Active substance | RMS proposal: None |

**Impact on Human and Animal Health**

Fish oil does not have a toxic mode of action and does not present a toxicological concern by itself. It is used as a feedstuff obtained from fresh fish by-products not suitable for human consumption; based on its nature, the waiver for toxicological studies was deemed acceptable.

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

| | |
|---|---|
| Rate and extent of absorption ‡ | No data - not required |
| Distribution ‡ | No data - not required |
| Potential for accumulation ‡ | No data - not required |
| Rate and extent of excretion ‡ | No data - not required |
| Metabolism in animals ‡ | No data - not required |
| Toxicologically relevant compounds ‡ (animals and plants) | No data - not required |
| Toxicologically relevant compounds ‡ (environment) | No data - not required |

**Acute toxicity (Annex IIA, point 5.2)**

| | | |
|---|---|---|
| Rat $LD_{50}$ oral ‡ | No data - not required | |
| Rabbit $LD_{50}$ dermal ‡ | No data - not required | |
| Rat $LC_{50}$ inhalation ‡ | No data - not required | |
| Skin irritation ‡ | No data - not required | |
| Eye irritation ‡ | No data - not required | |
| Skin sensitisation ‡ | No data - not required | |

**Short term toxicity (Annex IIA, point 5.3)**

| | | |
|---|---|---|
| Target / critical effect ‡ | No data - not required | |
| Relevant oral NOAEL ‡ | No data - not required | |
| Relevant dermal NOAEL ‡ | No data - not required | |
| Relevant inhalation NOAEL ‡ | No data - not required | |

**Genotoxicity ‡ (Annex IIA, point 5.4)**

| | |
|---|---|
| No data - not required | |

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

| | | |
|---|---|---|
| Target/critical effect ‡ | No data - not required | |
| Relevant NOAEL ‡ | No data - not required | |
| Carcinogenicity ‡ | No data - not required | |

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

| | | |
|---|---|---|
| Reproduction target / critical effect ‡ | No data - not required | |
| Relevant parental NOAEL ‡ | No data - not required | |
| Relevant reproductive NOAEL ‡ | No data - not required | |
| Relevant offspring NOAEL ‡ | No data - not required | |

**Developmental toxicity**

| | | |
|---|---|---|
| Developmental target / critical effect ‡ | No data - not required | |
| Relevant maternal NOAEL ‡ | No data - not required | |
| Relevant developmental NOAEL ‡ | No data - not required | |

**Neurotoxicity (Annex IIA, point 5.7)**

| | | |
|---|---|---|
| Acute neurotoxicity ‡ | No data - not required | |
| Repeated neurotoxicity ‡ | No data - not required | |
| Delayed neurotoxicity ‡ | No data - not required | |

**Other toxicological studies (Annex IIA, point 5.8)**

| | |
|---|---|
| Mechanism studies ‡ | No data |

| | |
|---|---|
| Studies performed on metabolites or impurities ‡ | No data |

**Medical data‡ (Annex IIA, point 5.9)**

| | |
|---|---|
| | An old formulation of this preparation is registered and used in Germany since 1977. No cases of poisoning or illness became known during the years of the use of this preparation. |

| **Summary (Annex IIA, point 5.10)** | Value | Study | Safety factor |
|---|---|---|---|
| ADI ‡ | Not required* | | |
| AOEL ‡ | Not required* | | |
| ARfD ‡ | Not required* | | |

*The setting of reference values was not deemed necessary as the substance is a feedstuff and does not present a toxicological concern

**Dermal absorption‡ (Annex IIIA, point 7.3)**

| | |
|---|---|
| Morsuvin (fish oil 43 g/kg PA) | No data - not required |

**Exposure scenarios (Annex IIIA, point 7.2)**

| | |
|---|---|
| Operator | No exposure assessment was deemed necessary as the substance does not present a toxicological concern. |
| Workers | No exposure assessment was deemed necessary as the substance does not present a toxicological concern. |
| Bystanders | No exposure is foreseen |

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

| | |
|---|---|
| | RMS/peer review proposal |

| | |
|---|---|
| Fish oil | none |

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

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

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

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

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

| |
|---|
| Not provided and not required |

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

| |
|---|
| Not relevant |

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

| | **Ruminant:** | **Poultry:** | **Pig:** |
|---|---|---|---|
| | Conditions of requirement of feeding studies | | |
| Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the evel) | No | No | No |
| Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no) | Not Required | Not Required | Not Required |
| | Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)<br><br>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<br><br>(a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR<br><br>(c) | STMR<br><br>(b) |
|---|---|---|---|---|---|---|
| Not provided and not required considering the representatives uses on deciduous and coniferous trees in forestry and in orchards | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

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

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

**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 provided and not required | | | | |

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

| | |
|---|---|
| Deciduous and coniferous trees in forestry | Not required |
| Orchards | Not required |

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

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

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

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

Anaerobic degradation ‡

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

Soil photolysis ‡

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

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

Laboratory studies ‡

| | |
|---|---|
| Fish Oil | Aerobic conditions: no data submitted, not required. |

Field studies ‡

| | |
|---|---|
| Fish Oil | Aerobic conditions : no data submitted, not required. |

| | |
|---|---|
| pH dependence (yes / no) (if yes type of dependence) ‡ | No data submitted. Not required. |
| Soil accumulation and plateau concentration ‡ | No data submitted. Not required. |

Laboratory studies ‡

| | |
|---|---|
| Fish Oil | Anaerobic conditions: no data submitted, not required. |

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

| |
|---|
| Fish Oil: no data submitted, not required. ‡ |

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

| | |
|---|---|
| Column leaching ‡ | No data submitted. Not required. |
| Aged residues leaching ‡ | No data submitted. Not required. |
| | No data submitted. Not required. |
| Lysimeter/ field leaching studies ‡ | No data submitted. Not required. |

**PEC (soil) (Annex IIIA, point 9.1.3)**

| | |
|---|---|
| Fish Oil | No data submitted. Not required. |

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

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

**Degradation in water / sediment**

| | |
|---|---|
| Fish Oil | No data submitted. Not required |

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

| | |
|---|---|
| Fish Oil | No data submitted. Not required. |

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

| | |
|---|---|
| Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter ) | No data submitted. Not required. |

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

| | |
|---|---|
| Direct photolysis in air ‡ | No data submitted. Not required. |
| Quantum yield of direct phototransformation | No data submitted. Not required. |
| Photochemical oxidative degradation in air ‡ | No data submitted. Not required. |
| Volatilisation ‡ | No data submitted. Not required. |

**PEC (air)**

| | |
|---|---|
| Method of calculation | No data submitted. Not required. |

**$PEC_{(a)}$**

| | |
|---|---|
| Maximum concentration | -No data submitted. Not required. |

**Residues requiring further assessment**

| | |
|---|---|
| Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology). | Soil: Fish Oil<br>Surface Water: Fish Oil<br>Sediment: Fish Oil<br>Ground water: Fish Oil<br>Air: Fish Oil |

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

| | |
|---|---|
| Soil (indicate location and type of study) | -No data submitted. Not required. |
| Surface water (indicate location and type of study) | -No data submitted. Not required. |
| Ground water (indicate location and type of study) | -No data submitted. Not required. |
| Air (indicate location and type of study) | -No data submitted. Not required. |

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

| |
|---|
| - |

**Effects on Non-target Species**

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

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

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

| **Exposure period** | **Crop, use pattern** | **Category (*e.g.*, insectivorous bird)** | **Toxicity endpoint** | **ETE [mg ai/kg bw/day ]** | **TER** | **TER risk trigger (from Annex VI)** |
|---|---|---|---|---|---|---|
| Acute | | | | | | |
| Short-term | | | | | | |
| Long-term | | | | | | |

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

| **Species** | **Test substance** | **Study Type** | **$LC_{50}$ /$EC_{50}$** [mg/L]* | **$LC_0$ /NOEC** [mg/L]* |
|---|---|---|---|---|
| Zebrafish | Morsuvin | Static 96h | >100 | 100 |
| *Daphnia magna* | Morsuvin | Static 48h | >100 | 100 |
| *Desmodesmus subspicatus* | Morsuvin | Static 72h | >100 | 100 |

***** the aquatic studies are of poor quality and informative only

[1] Exposure expected to be negligible
[1] Exposure expected to be negligible

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

| **Organism** | **Test substance** | **Toxicity Endpoint** | **PEC (µg/L)** | **TER a** | **TER risk trigger value (from 91/414/EEC)** |
|---|---|---|---|---|---|
| | | | | | |

**Bioconcentration**

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

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

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

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

| Test substance | Exposure route | Endpoint | Maximum single application rate | Hazard quotient | Annex VI trigger |
|---|---|---|---|---|---|
| | | | | | |

| Field or semi-field tests |
|---|
| |

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

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

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

| | |
|---|---|
| Acute toxicity | No data available[1] |
| Chronic and reproductive toxicity | No data available[1] |

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

| Test substance | Use pattern | Test type | Endpoint | PECs (µg/kg) | TER | Annex VI trigger |
|---|---|---|---|---|---|---|
| | | | | | | |

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

| | |
|---|---|
| Nitrogen mineralization ‡ | No data available – exposure expected to be negligible |
| Carbon mineralization ‡ | No data available – exposure expected to be negligible |

## APPENDIX B – USED COMPOUND CODE(S)

| Code/Trivial name* | Chemical name** | Structural formula** |
|---|---|---|
| --- | | |

* The metabolite name in bold is the name used in the conclusion.

## 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<br>or high performance liquid chromatography |
| HPLC-MS | high pressure liquid chromatography – mass spectrometry |
| HQ | hazard quotient |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| $K_{doc}$ | organic carbon linear adsorption coefficient |
| kg | kilogram |
| $K_{Foc}$ | Freundlich organic carbon adsorption coefficient |
| L | litre |
| LC | liquid chromatography |
| $LC_{50}$ | lethal concentration, median |
| LC-MS | liquid chromatography-mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LDH | lactate dehydrogenase |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| LOQ | limit of quantification (determination) |
| m | metre |
| M/L | mixing and loading |
| MAF | multiple application factor |
| MCH | mean corpuscular haemoglobin |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular volume |
| mg | milligram |
| mL | millilitre |
| mm | millimetre |
| mN | milli-newton |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| MTD | maximum tolerated dose |
| MWHC | maximum water holding capacity |
| NESTI | national estimated short-term intake |
| ng | nanogram |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |

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