CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance pepper dust extraction residue[1] (listed in Annex I to Directive 91/414/EEC as pepper)

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The active substance is listed as 'pepper' in Annex I of Commission Regulation (EC) No. 2229/2004 and is included as 'pepper' in Annex I to Directive 91/414/EEC. The rapporteur Member State submitted the Draft Assessment Report on 'pepper dust'. During the peer review, EFSA concluded that the substance is the residual powder obtained after steam distillation and solvent extraction of oleoresin from black pepper and therefore the substance will be referred to as 'pepper dust extraction residue (PDER)'.

Pepper dust extraction residue (PDER) 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].

PDER 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'). In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[5], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

The United Kingdom being the designated rapporteur Member State submitted the DAR on PDER in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008. The peer review was initiated on 25 June 2008 by dispatching the DAR to the notifier the Pepper Dust Task Force, and on 20 October 2010 to the Member States for consultation. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the areas of identity, physical and chemical properties and deliver its conclusions on PDER.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of PDER as a dog and cat repellent on and around all edible crops, ornamentals, garden plants and on areas not intended to bear vegetation, 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-2009-00265, issued on 29 June 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 37, 10.2.2010, p.12

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A robust specification for this substance is not available and a data gap has been identified. For the formulation the following data gaps were identified: dry sieve test, bulk density, dustability, cold temperature stability and accelerated storage.

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

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

Considering the limited usage in terms of area and restriction to home garden use, a definition of the residue is deemed to be unnecessary for PDER. Environmental exposure (including groundwater exposure) to piperine and other potential active components in PDER are considered to be of no concern due to the localized use.

The risk to non-target organisms was considered low for the representative use, providing it is restricted to home garden use. A data gap was identified for acute toxicity studies to aquatic organisms to fulfil the Annex II data requirements.

KEY WORDS

PDER, pepper dust extraction residue, pepper, pepper dust, peer review, risk assessment, pesticide, repellent

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BACKGROUND

PDER is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[6], as amended by Commission Regulation (EC) No 1095/2007[7].

PDER 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'). 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 (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

The United Kingdom being the designated rapporteur Member State submitted the DAR (The United Kingdom, 2008) on PDER in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008. The peer review was initiated on 25 June 2008 by dispatching the DAR to the notifier the Pepper Dust Task Force, and on 20 October 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the Commission on 15 February 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 identity, physical and chemical properties.

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 May – June 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 dog and cat repellent on and around all edible crops, ornamentals, garden plants and on areas not intended to bear vegetation, 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

[6] OJ L 379, 24.12.2004, p.13
[7] OJ L 246, 21.9.2007, p.19
[8] OJ L 37, 10.2.2010, p.12

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 (15 February 2011),
- the Evaluation Table (23 June 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- 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 May 2011 containing all individually submitted addenda (The United Kingdom, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

The proposed name for this substance was pepper however this name is misleading as the substance is not pepper. The substance is the residual powder obtained after steam distillation and solvent extraction of oleoresin from black pepper (*Piper nigrum*). As this is the case this substance will be referred to as Pepper Dust Extraction Residue (PDER). In the draft review report (European Commission, 2008) with regard to the minimum purity the following is stated 'Being a complex mixture piperine as component has been chosen as marker at 4%'. It should be noted however that this material does not comply with this as it contains a maximum of 0.5 % piperine. There is no ISO common name for this substance.

The representative formulated product for the evaluation is 'Pepper Dust' it is 100 % extracted pepper. The representative uses evaluated are as a dog and cat repellent on and around all edible crops, ornamentals, garden plants and on areas not intended to bear vegetation. Only home garden use has been considered. 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 robust specification was not available for this substance to allow its identification and quantification and therefore a data gap has been identified. Subject to this data gap further data may be required for methods of analysis for the technical material and the formulated product.

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

For the formulation the following data gaps were identified: dry sieve test, bulk density, dustability, cold temperature stability and accelerated storage.

The need for residue methods was waived due to the nature of the substance. A method for body fluids and tissues is not required as the substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10-final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004a).

The hazard assessment has been mainly based on published information available on some of the components of PDER such as piperine. No suitable data are available to set reference values. However it should be taken into account that PDER is produced from food grade black pepper and is the material remaining after steam distillation to remove pepper oil. Thus, black pepper is ground, distilled and extracted with solvents in the manufacturing process. PDER therefore contains a lower amount of piperine, alkaloids and terpenoids than present in food grade black pepper. Furthermore the presence of any residual solvent in PDER is very unlikely. Consumer exposure of piperine, alkaloids and terpenoids from the use of PDER as an animal repellent are unlikely to be significant compared to the intake by the daily culinary use of food grade black pepper (see section 3). As for non-dietary exposure a quantitative risk assessment has been performed by the RMS comparing the exposure to piperine derived from the use of PDER as plant protection product (considering 0.4% content of piperine) to the estimates derived from the dietary exposure to black pepper (considering 4% piperine) indicating that predicted estimates for operators, residents and bystanders are within the average dietary intake range of piperine 0-0.42 mg/kg bw/d (Hoare et al, 2004 in DAR (The United Kingdom, 2008)).

In conclusion, no risks to human health are expected from the use of piperine and related compounds present in PDER. Therefore, data waivers for specific toxicological studies with PDER are supported.

3. Residues

The risk assessment was based on the following document: SANCO/10472/2003 rev.5 (European Commission, 2004b).

Black pepper is used mainly as a food (spice). Estimates of the common dietary exposure to black pepper are available from different sources, amongst others from UK consumption data on spices, giving an estimated intake of black pepper of 0-0.6283 g/d (Hoare et al, 2004 in DAR (The United Kingdom, 2008)). PDER as a ground, distilled and extracted pepper-based product contains a lower amount of piperine, alkaloids and terpenoids than present in food grade black pepper. While PDER may be used for plant protection on and around edible crops, dietary intake of piperine, alkaloids and terpenoids from the use as an animal repellent is normally unlikely to be significant compared to the intake by the daily culinary use of food grade black pepper.

As the GAP allows for an unlimited number of applications, an excessive use of PDER with direct application on edible crops, without removing any potential remainder by washing or peeling the crop before consumption, would probably render the food less palatable and thus limit the intake of large amounts of PDER by the consumer.

In summary, it is considered unlikely that any pre-existing daily dietary exposure of humans to compounds present in black pepper would be significantly increased by the use of PDER as an animal repellent. No areas of concern or data gaps were identified. No MRL is proposed; PDER could be considered a candidate for Annex IV of Commission Regulation (EC) No 396/2005[9].

4. Environmental fate and behaviour

PDER has been notified as an animal repellent for use in the home garden situation. The summary dossier submitted by the notifier indicates that the product is applied at the nominal dose of 30 g/m^2, each container holding up to 225 g of product. Thus, within the context of this review, each container of product is able to treat approximately 7.5 m^2.

No specific data on the environmental fate of PDER have been submitted. The RMS provided some considerations in the DAR on the pepper component piperine. However, this compound is not expected to be found in significant amounts in PDER since piperine and other potentially active components in pepper have been extracted out of this material. The notifier indicates in the summary dossier that pepper is not soluble in water and is known to be biodegradable. Data to substantiate these claims were not submitted. The RMS independently confirmed from other sources that the statement on the solubility can be accepted. The RMS considers that the claim of biodegradability is likely to be correct, but the rate of degradation is unknown.

Given that the representative use of PDER is in the home garden situation, and that the plant protection product appears to be supplied in containers capable of only treating small areas, environmental exposure is likely to be on a small scale, highly localised and fragmented. This exposure profile, together with the fact that the product is an undefined vegetable residue from pepper after steam distillation and solvent extraction of oleoresin, leads to the conclusion that PDER has no components with potential to contaminate groundwater. Contamination of soil will occur, but in a strictly localised manner. At the same time, any potential surface water contamination is likely to be localised and on a very low scale. In both cases the material added to soil or surface water as PDER is not expected to be distinguishable from other vegetable residues of natural origin.

5. Ecotoxicology

No toxicity studies to investigate the effects of PDER to non-target organisms were submitted. According to the representative use (i.e. around edible and non-edible plants and on areas not intended to bear vegetation in the home garden) the environmental exposure is likely to be on a small scale.

[9] OJ L 70, 16.3.2005, p. 16

Therefore the risk assessment to birds and mammals, aquatic organisms, bees and non-target arthropods, earthworms and soil macro- and micro-organisms, non-target terrestrial plants and methods for sewage treatment plants can be considered as low.

No further data are considered necessary, except the acute toxicity studies to aquatic organisms which should be provided to fulfil the Annex II data requirements. A data gap is identified to provide these data.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Not applicable Considering the nature of the substance and the limited exposure from the intended use (restriction to home gardening), a definition of the residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for PDER. Environmental exposure to piperine and other potential active components in pepper are considered to be of no concern due to the fact that the material has been submitted to steam and solvent extraction of oleoresin and the limited usage expected from the representative use.	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 applicable Considering the nature of the substance and the limited exposure from the intended use (restriction to home gardening), a definition of the residue in the environment for groundwater exposure assessment is deemed to be unnecessary for PDER. Environmental exposure to piperine and other potential active components in pepper are considered to be of no concern due to the fact that the material has been submitted to steam and solvent extraction of oleoresin and the limited usage expected from the representative use.	Not assessed	Not assessed	-	-	-

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable Considering the nature of the substance and the limited exposure from the intended use (restriction to home gardening), a definition of the residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for PDER. Environmental exposure to piperine and other potential active components in pepper are considered to be of no concern due to the fact that the material has been submitted to steam and solvent extraction of oleoresin and the limited usage expected from the representative use.	-

6.4. Air

Compound (name and/or code)	Toxicology
Not applicable Considering the nature of the substance and the limited exposure from the intended use (restriction to home gardening), a definition of the residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for PDER. Environmental exposure to piperine and other potential active components in pepper are considered to be of no concern due to the fact that the material has been submitted to steam and solvent extraction of oleoresin and the limited usage expected from the representative use.	-

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

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

- Specification for the substance with supporting batch data for all sources (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Dry sieve test, bulk density, dustability, cold temperature stability, and accelerated storage for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Acute toxicity studies to aquatic organisms to fulfil the Annex II data requirements (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Only uses for home garden situation are covered by the current assessment of environmental exposure (i.e. product is applied at the nominal dose of 30 g/m^2 on localized spots and the example product assessed, was indicated to be packaged in containers of limited size).

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

CRITICAL AREAS OF CONCERN

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

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

- none

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 PDER.

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

European Commission, 2004a. Guidance document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2004b. Draft working document concerning the data requirements for active substances of plant protection products made from plants or plant extracts. SANCO/10472/2003 – rev.5, 6 July 2004.

European Commission, 2008. Review Report for the active substance pepper 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 pepper in Annex I of Directive 91/414/EEC. SANCO/2628/08 – rev.1, 25 July 2008.

Hoare J, Henderson L, Bates CJ, Prentice A, Birch M, Swan G and Farron M. The National Diet and Nutrition Survey of Adults aged 19-64 years. Volume 5: Summary report. TSO (London) 2004.

The United Kingdom, 2008. Draft Assessment Report (DAR) on the active substance pepper dust prepared by the rapporteur Member State The United Kingdom in the framework of Directive 91/414/EEC, January 2008.

The United Kingdom, 2011. Final Addendum to Draft Assessment Report on pepper dust extraction residue, compiled by EFSA, May 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) ‡	Pepper Dust Extraction Residue (PDER) (steam distilled and solvent extracted black pepper)
Function (*e.g.* fungicide)	Repellent
Rapporteur Member State	UK
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Steam distilled and solvent extracted Black pepper – *Piper nigrum*
Chemical name (CA) ‡	NA
CIPAC No ‡	NA
CAS No ‡	NA
EC No (EINECS or ELINCS) ‡	NA
FAO Specification (including year of publication) ‡	NA
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡ - black pepper	NA
Molecular mass ‡ - black pepper	NA
Structural formula ‡ - black pepper	NA
Molecular formula ‡	Open
Molecular mass ‡	Open
Structural formula ‡ -	Open

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Not relevant
Boiling point (state purity) ‡	Not relevant
Temperature of decomposition (state purity)	Not relevant
Appearance (state purity) ‡	Greyish-brown powder
Vapour pressure (state temperature, state purity) ‡	Not relevant
Henry's law constant ‡	Not relevant
Solubility in water (state temperature, state purity and pH) ‡	The material is insoluble in water
Solubility in organic solvents ‡ (state temperature, state purity)	Not relevant
Surface tension ‡ (state concentration and temperature, state purity)	Not relevant
Partition co-efficient ‡ (state temperature, pH and purity)	Not relevant
Dissociation constant (state purity) ‡	Not relevant
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not measured
Flammability ‡ (state purity)	Non-flammable
Explosive properties ‡ (state purity)	Not explosive
Oxidising properties ‡ (state purity)	Non-oxidising

Summary of representative uses evaluated (Pepper Dust Extraction Residue)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
All edible crops, ornamental garden plants and areas not intended to bear vegetation	UK	Pepper Dust	F	Deter cats and dogs from fouling	DP	1000 g/kg	Direct application (on and around)	Any	As required	Not specified	-	-	30 g/m^2	NA	Remove any remains of previous fouling before treatment Only Home Garden use considered.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	Open
Impurities in technical as (analytical technique)	NA
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Proposed use will not result in residues in plant tissues, therefore analytical methods would not be necessary
Food of animal origin		Proposed use will not result in residues in animal tissues, therefore analytical methods would not be necessary
Soil		Proposed use will not result in residues in soil, therefore analytical methods would not be necessary
Water	surface	Proposed use will not result in residues in surface water, therefore analytical methods would not be necessary
	drinking/ground	Proposed use will not result in residues in drinking/ground water, therefore analytical methods would not be necessary
Air		Proposed use will not result in residues in air, therefore analytical methods would not be necessary

Monitoring/Enforcement methods

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

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

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

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

Acute toxicity (Annex IIA, point 5.2)

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

Short term toxicity (Annex IIA, point 5.3)

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

Genotoxicity ‡ (Annex IIA, point 5.4)

Data available of limited validity. No further data required.	

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

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

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

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

Developmental toxicity

Developmental target / critical effect ‡	No data available. Not required.	
Relevant maternal NOAEL ‡		
Relevant developmental NOAEL ‡		

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available. Not required.	
Repeated neurotoxicity ‡		
Delayed neurotoxicity ‡		

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available. Not required.
Studies performed on metabolites or impurities ‡	No data available. Not required.

Medical data ‡ (Annex IIA, point 5.9)

	Data available of limited validity. No further data required.

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	100% (in the absence of data)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Predicted levels of exposure to piperine for operators applying PDER in the manner proposed (hand-held dust applicator) are within the normal dietary intake range (0-0.42 mg/kg bw/d.)
Workers	Not relevant for workers.
Bystanders	Levels of exposure to piperine for bystanders are not expected to exceed those predicted for persons applying the product.
Residents	Predicted levels of exposure to piperine for children playing on areas treated with PDER are within the normal dietary intake range (0-0.42 mg/kg bw/d .).

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

	Peer review proposal
PDER	None

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

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

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

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

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

Not relevant

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)

Intake by livestock ≥0.1mg/kg diet / day	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)	Not relevant	Not relevant	Not relevant
Potential for accumulation (yes/no):	Not relevant	Not relevant	Not relevant

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not relevant	Not relevant	Not relevant
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) 10mg/kg diet cattle and poultry. Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not relevant	Not relevant	Not relevant
Liver	Not relevant	Not relevant	Not relevant
Kidney	Not relevant	Not relevant	Not relevant
Fat	Not relevant	Not relevant	Not relevant
Milk	Not relevant		
Eggs		Not relevant	

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 relevant						(h)

(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 allocated, not required
TMDI (% ADI) according to WHO European diet	Not relevant. No residue expected at levels higher than exposure due to the consumption of black pepper itself.
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 allocated, not required
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 relevant				

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

Not relevant

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

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

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

Anaerobic degradation ‡

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

Soil photolysis ‡

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

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

Laboratory studies ‡

Parent	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
No data available, no data required.						

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	Org. Carbon (%)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
No data available, no data required.									

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

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
No data available, no data required.						

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
No data available, no data required.							
Arithmetic mean							
pH dependence, Yes or No							

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

Column leaching	No data available, no data required.
Aged residues leaching ‡	No data available, no data required.
Lysimeter/ field leaching studies ‡	No data available, no data required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	No data available, no data required.
Application data	No data available, no data 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 available, no data required.
Photolytic degradation of active substance and metabolites above 10 % ‡	No data available, no data required.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data available, no data required.
Readily biodegradable ‡ (yes/no)	No data available, no data required.

Degradation in water / sediment

Parent	Distribution (max in water 91.3 % after 1 d. Max. in sed 51.0 % after 7d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
No data available, no data required.										
Geometric mean/median										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after 100 d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after 100 d (end of the study)
No data available, no data required.					

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

Parent Parameters used in FOCUSsw step 1 and 2	No data available, no data required.
Parameters used in FOCUSsw step 3 (if performed)	No data available, no data required.
Parameters used in FOCUSsw step 4 (if performed)	No data available, no data required.
Application rate	No data available, no data 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 available, no data required.
Application rate	No data available, no data required.

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

Direct photolysis in air ‡	No data available, no data required.
Quantum yield of direct phototransformation	No data available, no data required.
Photochemical oxidative degradation in air ‡	No data available, no data required.
Volatilisation ‡	No data available, no data required.
Metabolites	No data available, no data required.

PEC (air)

Method of calculation	No data available, no data required.

$PEC_{(a)}$

Maximum concentration	No data available, no data required.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for ground water exposure assessment.	Not applicable Considering the nature of the substance and the limited exposure from the intended use (restriction to home gardening), a definition of the residue in the environment is deemed to be unnecessary for PDER.

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

Soil (indicate location and type of study)	None
Surface water (indicate location and type of study)	None
Ground water (indicate location and type of study)	None
Air (indicate location and type of study)	None

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

None, though it would be a candidate for R53, due to the absence of results from a ready biodegradability study

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 ‡ Data available of limited validity. No further data required.				
Mammals ‡ Acute LD_{50} 330 mg piperine/kg bw (mouse)				
Additional higher tier studies Not relevant				

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

Crop and application rate

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)	Not relevant			
Higher tier refinement (Birds)	Not relevant			
Tier 1 (Mammals)	Not relevant			
Higher tier refinement (Mammals)	Not relevant			

Risk to terrestrial vertebrates concluded to be low based on localized application leading to limited exposure.

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 (mg/L)
Laboratory tests ‡Data available on aquatic organisms of limited validity. Data gap to provide acute toxicity studies to fulfil the Annex II data requirement				
Microcosm or mesocosm tests: None submitted				

FOCUS modelling Not relevant

Refined aquatic risk assessment using higher tier FOCUS modelling: Not relevant

Risk to aquatic organisms concluded to be low based on negligible exposure of the aquatic environment.

Bioconcentration Not relevant. Aquatic exposure negligible.	
	Active substance
$logP_{O/W}$	Not available

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

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

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

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

Crop and application rate

PDER is applied as a spot treatment to soil, and on and around the bases of plants. Calculation of standard HQs is not appropriate to this method and scope of application. Based on expert judgement the risk to honeybees is considered as low.

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

Laboratory tests with the standard sensitive species

Species	Life stage	Test substance, substrate and duration	Initial dose (kg a.s./ha)	Mortality	Sublethal effects	Trigger value
Not relevant						
Field or semi-field tests: Not relevant						

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

PDER is applied as a spot treatment to soil, and on and around the bases of plants. Use of the standard assessment of risk to non-target arthropods is not appropriate to this method and scope of application. Based on expert judgement the risk to non-target arthropods is considered as low.

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

Test organism	Test substance	Time scale	End point (all in terms of a.s.)
Earthworms Data available of limited validity. No further data required.			
Field tests: Not relevant			

Soil micro-organisms			
Functional process	Test substance	Time scale (days)	Effect relative to control (%)
Nitrogen mineralisation	Not relevant		
Carbon mineralisation	Not relevant		
Field studies: Not relevant			

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms	Not relevant				
Other soil macro-organisms	Not relevant				

PDER is applied as a spot treatment to soil, and on and around the bases of plants. The standard methods of assessment of risk are not appropriate to this method and scope of application. Based on expert judgement the risk to earthworms, other soil macro-organisms and soil micro-organisms is considered as low.

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

Laboratory dose response tests: Not relevant

Additional studies (eg. semi-field or field studies): Limited evidence indicates no adverse effect on grass species.

PDER is applied as a spot treatment to soil, and on and around the bases of plants. PDER has been in use for this purpose for several years with no instances of crop damage.

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

Test type/organism	end point
Not relevant	

Amounts of pepper already deposited via the sewage system from culinary use is likely to be greater than from the proposed use as an animal repellent and this has raised no concerns to date

Ecotoxicologically relevant compounds

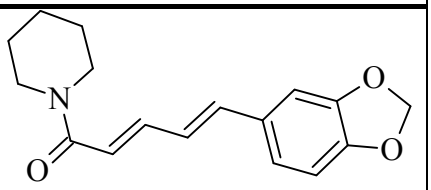
Compartment	
soil	Not relevant
water	Not relevant
sediment	Not relevant
groundwater	Not relevant

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

	RMS/peer review proposal
Active substance	No proposal for classification-possible, data gap

	RMS/peer review proposal
Preparation	No proposal for classification-possible, data gap

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Piperine	(2E,4E)-5-(1,3-benzodioxol-5-yl)-1-(piperidin-1-yl)penta-2,4-dien-1-one	

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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
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-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
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
PDER	pepper dust extraction residue
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