

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance garlic extract¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Garlic extract 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

Garlic extract was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’) and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009,⁵ in accordance with Commission Implementing Regulation (EU) No 540/2011,⁶ as amended by Commission Implementing Regulation (EU) No 541/2011.⁷ In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010,⁸ the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Poland being the designated rapporteur Member State submitted the DAR on garlic extract in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 20 November 2006. The peer review was initiated on 13 June 2008 by dispatching the DAR to the notifier ECOSpray Ltd. and on 16 December 2010 to the Member States, for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that the EFSA should conduct a focused peer review in the area of ecotoxicology and deliver its conclusions on garlic extract.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of garlic extract as an insecticide, nematicide and repellent on swede, turnip,

¹ On request from the European Commission, Question No EFSA-Q-2009-00281, adopted on 16 December 2011.

² Correspondence: pesticides.peerreview@efsa.europa.eu

³ OJ L 379, 24.12.2004, p.13

⁴ OJ L 246, 21.9.2007, p.19

⁵ OJ L 309, 24.11.2009, p.1

⁶ OJ L 153, 11.6.2011, p.1

⁷ OJ L 153, 11.6.2011, p.187

⁸ OJ L 37, 10.2.2010, p.12

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance garlic extract. EFSA Journal 2012;10(2):2520. [40 pp.] doi:10.2903/j.efsa.2012.2520. Available online: www.efsa.europa.eu/efsajournal

cauliflower, head cabbage, broccoli/calabrese, Brussels sprouts, Chinese cabbage/pak choi, carrot, leek, onion, potato, parsnip, sugar beet, strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, red currant, white currant, cranberry, fig, kiwi fruit, grapevine, citrus fruit and grassed sport areas, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis data gaps were identified for further physical and chemical properties of the garlic extract and the formulations and storage stability data, as well as validation of the method of analysis for the granule formulation.

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

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

The data provided do not allow a quantitative fate and behaviour exposure assessment to be performed. Only initial PECs resulting after a single application of garlic extract are available for soil and surface water. A data gap has been identified for a groundwater exposure assessment or data to support the waiver proposed by the applicant.

The risk to birds and mammals was considered to be low. Data gaps were identified for toxicity studies and a risk assessment for aquatic organisms, non-target arthropods, earthworms, soil micro-organisms and biological methods for sewage treatment plants for the representative field uses, whereas the risk to these non-target organisms was assessed as low for the glasshouse uses. A data gap was also identified for toxicity studies and a risk assessment for honeybees for all representative uses (i.e. both field and glasshouse uses).

KEY WORDS

Garlic extract, peer review, risk assessment, pesticide, insecticide, nematocide, repellent.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
The active substance and the formulated product	6
Conclusions of the evaluation	6
1. Identity, physical/chemical/technical properties and methods of analysis.....	6
2. Mammalian toxicity.....	6
3. Residues.....	7
4. Environmental fate and behaviour.....	7
5. Ecotoxicology.....	8
6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments	10
6.1. Soil	10
6.2. Ground water	10
6.3. Surface water and sediment	11
6.4. Air.....	11
7. List of studies to be generated, still ongoing or available but not peer reviewed	12
8. Particular conditions proposed to be taken into account to manage the risk(s) identified.....	13
9. Concerns	13
9.1. Issues that could not be finalised	13
9.2. Critical areas of concern	13
9.3. Overview of the concerns for each representative use considered	14
References	18
Appendices	19
Abbreviations	37

BACKGROUND

Garlic extract 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

Garlic extract was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation') and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009,¹¹ in accordance with Commission Implementing Regulation (EU) No 540/2011,¹² as amended by Commission Implementing Regulation (EU) No 541/2011.¹³ In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010,¹⁴ the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Poland being the designated rapporteur Member State submitted the DAR on garlic extract in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 20 November 2006 (Poland, 2006). The peer review was initiated on 13 June 2008 by dispatching the DAR to the notifier ECOSpray Ltd. and on 16 December 2010 to the Member States, for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 April 2011. On the basis of the comments received and the RMS's evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

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

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an insecticide, nematicide and repellent on swede, turnip, cauliflower, head cabbage, broccoli/calabrese, Brussels sprouts, Chinese cabbage/pak choi, carrot, leek, onion, potato, parsnip, sugar beet, strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, red currant, white currant, cranberry, fig, kiwi fruit, grapevine, citrus fruit and grassed sport areas, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (5 April 2011),
- the Evaluation Table (6 December 2011),
- the report of the scientific consultation with Member State experts (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of July 2011 containing all individually submitted addenda (Poland, 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.

Garlic extract is the given name, for this material there is no ISO common name.

The representative formulated products for the evaluation were 'ECOguard granules', a granule formulation (GR) containing 45 % garlic extract and 'ECOguard liquid', an emulsifiable concentrate formulation containing 99.9 % garlic extract.

The representative uses evaluated comprise indoor and outdoor use on a wide range of crops. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

The substance is 99.9 % garlic extract as defined by its manufacturing process and marker compounds. It is of food grade quality. It should be noted that only one source of the extract was considered and a data gap was identified for the address of the source.

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.

A data gap was identified for a case or data to address the following physical and chemical properties of the technical material: melting point, freezing point or solidification point, boiling point, relative density, vapour pressure, volatility, solubility in water, solubility in organic solvents, partition coefficient, hydrolysis rate, direct phototransformation, quantum yield, dissociation constant, stability in air, flash point, explosive properties, surface tension and oxidising properties.

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

The following data gaps were identified for 'ECOguard granules': explosive properties, oxidising properties, flammability, flowability, accelerated storage and shelf life. For 'ECOguard liquid' explosive properties, oxidising properties, flash point, a more detailed evaluation of the accelerated storage study, low temperature stability study and a shelf life study.

The method of analysis used for the technical material and for 'ECOguard liquid' needs to be validated for 'Ecoguard granules'.

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

2. Mammalian toxicity

Garlic extract is of food grade quality; it is also used in human medicine and public literature has been submitted to address the toxicological endpoints for garlic extract. No evaluation of these data has been provided in the DAR, either on the effects observed or on the reliability of the information available. But it is recognised that garlic has the potential to cause skin sensitisation and asthma under occupational exposure by inhalation. Considering the food grade quality of the product, all

toxicological data requirements were waived; reference values were not allocated and no quantitative risk assessment for operator, worker and bystander exposure was considered necessary.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

The consumer risk assessment was conducted by comparison of the exposure due to the use of garlic extract as a plant protection product with the exposure due to consumption of the plant itself. The assessment is based on the fact that the garlic extract is of food grade quality.

Garlic is commonly used in a variety of dishes and estimates of dietary exposure of the European population to garlic can be extracted from the EFSA PRIMo rev.2 (EFSA, 2007). Chronic dietary intakes of garlic range from 0.0002 to 0.065 g/kg bw/day, corresponding to a daily portion of from 0.013 to 3.9 g depending on the country or region. The 97.5th percentile consumption was recorded as 0.64 g/kg bw/day, corresponding to an intake of 42.7 g/day (UK vegetarian).

As for the representative uses in edible crops, it can be reasonably assumed that any pre-existing daily dietary exposure of humans due to the culinary use of garlic is likely to be significantly higher than the potential exposure from the use of garlic extract as a plant protection product. To underpin the case made, the applicant submitted a calculation of the theoretical residues of polysulfides occurring upon use of the product, which are considered the pertinent compounds in garlic extract. It was concluded that the proposed application rates would lead to much lower polysulfide levels than the amounts naturally occurring in the field when growing *allium* crops.

No areas of concern or data gaps were identified. No MRL is proposed; garlic extract could be considered a candidate for Annex IV of Commission Regulation (EC) No 396/2005.¹⁵

4. Environmental fate and behaviour

The active ingredient is pasteurized garlic juice obtained from crushed cloves of garlic. Most of the components are expected to be unspecific plant material. However, up to 3.5 % of the substance is expected to be composed of a number of organopolysulfides, to which the biological activity as a pesticide and a repellent is attributed. Only a small number of these components have been characterized in the scientific literature and are regarded by the applicant as marker substances (allicins). No specific environmental fate and behaviour data are available for the source of garlic extract under examination. General data from the scientific literature has been presented by the applicant to support the assumed environmental half life < 1d. However, the only quantitative data available is restricted to diallyl-disulfide and trisulfide in the aquatic environment. In the absence of more quantitative information, it may be assumed that the background level of garlic extract active components (organopolysulfides) on a field not cropped with garlic or other species of the *allium* genus is expected to be negligible. The applicant estimated background levels of garlic extract active components in fields planted with onion or garlic crops to be 120-600 times higher than the levels resulting from the use of garlic extract as a plant protection product. However, this estimation is not supported by data.

Initial predicted environmental concentrations in soil (PEC_{soil}) of the bulk extract resulting from a single worst case application in potatoes (13.5 kg/ha) and brassicas (7.5 kg/ha) has been provided by the RMS for the risk assessment. No multiple application calculations are provided assuming that

¹⁵ OJ L 70, 16.3.2005, p. 16

more than 90 % would degrade/dissipate within the 7 d interval period proposed for most of the uses. Whereas on the basis of the scientific literature provided the conclusion seems plausible, the available data do not allow a quantitative estimation of the persistence of the active substance in soil and further data may be needed to confirm the risk assessment when multiple applications are envisaged.

The only data available in the scientific literature in relation to the persistence of active components of garlic extract in water indicate that the only 16 % of the active components diallyl-disulfide and trisulfide remain 24 h after the application, therefore the assessment presented by the RMS assumed a $DT_{50} < 1$ d. Predicted environmental concentrations in surface water (PEC_{SW}) of the bulk extract have been calculated only considering the spray drift loads to surface water. Multiple applications and other routes of entry from the sprayed applications are considered to be covered by the single application spray drift calculations on the basis of the estimated low persistence. The RMS considered these calculations to cover the risk of dust spray drift from the granular formulations. No calculations to consider the run-off from the granular applications have been presented. Whereas it is claimed that the granules will rapidly disaggregate in soil no data to support the case are available.

The RMS proposed to waive the need for calculation of predicted environmental concentrations in groundwater (PEC_{GW}) on the basis of the nature of the substance and the background levels of the related organosulfur compounds in fields where onion and garlic crops are planted. However, no data in the dossier substantiate this statement, and therefore further data are needed to confirm the waiver for the PEC_{GW} calculations.

5. Ecotoxicology

No toxicity studies were submitted in the ecotoxicology section, except an acute toxicity study of garlic extract for *Daphnia magna* (EC_{50} is 9.3 mg/L). Acute toxicity studies for fish and algae that are considered necessary to fulfil the Annex II data requirements are identified as a data gap. Once the new aquatic toxicity studies are available, then a new risk assessment for aquatic organisms will be required for all representative field uses.

Garlic extract is used as a repellent for birds and mammals. Results of available avoidance tests submitted for birds and mammals confirmed that food avoidance was higher with an increase in the amount of garlic. This corroborates the repellent properties of garlic extract to birds and mammals, and consequently it can be concluded that the risk of garlic extract to birds and mammals can be considered as low. Pending on the outcome of the data gap identified in section 1 (partition coefficient), the risk to birds and mammals from secondary poisoning may need to be considered.

There were no standard toxicity tests with honeybees. The only available study was a glasshouse study with bumble bees. There is an indication that bumble bees could be less sensitive than honeybees. Therefore, the Member States experts agreed at the Pesticides Peer Review Experts' Teleconference (TC 57) that standard toxicity studies on honeybees should be submitted to address the risk of garlic extract to honeybees and a data gap was identified for all representative uses.

The notifier provided data on the efficacy of garlic extract to non-target arthropods but the studies were not performed with standard species. The efficacy data that indicate that larval stages are more sensitive is based on the house fly, *Spodoptera exigua* and cabbage root fly. There was 100% mortality in some of the studies. The Member State experts (TC 57) concluded that data and a risk assessment are necessary and therefore a data gap was identified for the field uses.

No toxicity studies for earthworms, soil micro-organisms and biological methods for sewage treatment plants were submitted. Based on the pesticide activity of the garlic extract, and considering the results of the literature studies presented, the risk of garlic extract to earthworms, soil micro-

organisms, and biological methods for sewage treatment plants needs to be addressed and therefore a data gap was identified for the field uses.

With respect to the glasshouse uses, with the exception of honeybees (data gap identified), the risk for all non-target organisms was considered as low.

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
Active components of garlic extract	No data available. Risk assessment based on worst case predicted initial soil concentrations resulting from a single application.	Data gap for field uses

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
Active components of garlic extract. No quantitative assessment provided. Waiving proposed by the RMS. Data gap identified for data to substantiate the waiver.	No data. Not assessed.	No data. Not assessed.	Yes	Yes	Data gap for field uses

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Active components of garlic extract	Data gap for field uses

6.4. Air

Compound (name and/or code)	Toxicology
Active components of garlic extract	Garlic may have the potential to provoke sensitising reactions by inhalation

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

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

- A case or data to address the following physical and chemical properties of the technical material: melting point, freezing point or solidification point, boiling point, relative density, vapour pressure, volatility, solubility in water, solubility in organic solvents, partition coefficient, hydrolysis rate, direct phototransformation, quantum yield, dissociation constant, stability in air, flash point, explosive properties, surface tension and oxidising properties (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Address of the manufacturing plant of the technical material (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- For 'ECOGuard granules' explosive properties, oxidising properties, flammability, flowability, accelerated storage, shelf life and validation of the method of analysis (relevant for all representative uses of the formulation 'ECOGuard granules'; submission date proposed by the notifier: unknown; see section 1).
- For 'ECOGuard liquid' explosive properties, oxidising properties, flash point, a more detailed evaluation of the accelerated storage study, low temperature stability and shelf life (relevant for all representative uses of the formulation 'ECOGuard liquid'; submission date proposed by the notifier: unknown; see section 1).
- Further data are needed to substantiate the statement that the levels of active ingredients of garlic extract released to the environment (including potential all icines) as a result of its use as a pesticide are 120 – 600 times lower than the levels released during the agricultural production of onions and garlic. This needs to be provided to confirm the waiver for groundwater PEC_{GW} calculations (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Acute toxicity studies on aquatic organisms to fulfil the Annex II data requirement (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 5).
- Once the new aquatic toxicity studies are available, then a new risk assessment for aquatic organisms is required for all representative field uses (relevant for all representative field uses; submission date proposed by the notifier: unknown; see section 5).
- Standard toxicity studies on honeybees should be submitted to address the risk of garlic extract to honeybees (relevant for all representative uses; submission date proposed by the notifier: unknown; see section 5).
- Data and a risk assessment are required to assess the risk to non-target arthropods (relevant for all representative field uses ; submission date proposed by the notifier: unknown; see section 5).
- The risk of garlic extract to earthworms, soil micro-organisms and biological methods for sewage treatment plants needs to be assessed (relevant for all representative field uses; submission date proposed by the notifier: unknown; see section 5).

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

None.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. Being active ingredients of garlic extract organic chemical compounds are subject to the legal groundwater limit of 0.1 µg/L, however no exposure assessment is available for garlic extract components and the waiver proposed is not substantiated by data.
2. The risk assessment for aquatic organisms, non-target arthropods, earthworms, soil micro-organisms and biological methods for sewage treatment plants for the representative field uses.
3. The risk assessment for honeybees for all representative uses.

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.

No critical areas of concern were identified.

9.3. Overview of the concerns for each representative use considered

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

Representative use		Swede, turnip, cauliflower, head cabbage, broccoli/calabrese, Brussels sprouts up to 5.4 kg/ha	Brassicas (all types; cauliflower, broccoli, calabrese, Brussels sprouts, Chinese cabbage, pak choi) Root vegetables: (swede, turnip, carrot, leek, onion, potato) 7.2 kg/ha	Potato up to 13.5 kg/ha	Parsnip up to 13.5 kg/ha	Potato Soft fruits (strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, white currant, cranberry, figs, kiwi fruit, grapevines, citrus fruits) Root vegetables (carrot, sugar beet) 5139 g/ha	Brassicas (swede, cauliflower, broccoli/calabrese) Root vegetables (carrot) Drenching 3.7 – 10.2 g per plant Spraying 2569 - 7708 g/ha
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	X ^{2,3}	X ^{2,3}	X ^{2,3}	X ^{2,3}	X ^{2,3}	X ^{2,3}
Risk to aquatic organisms	Risk identified						
	Assessment not finalised	X ²	X ²	X ²	X ²	X ²	X ²

Groundwater exposure active substance	Legal parametric value breached						
	Assessment not finalised	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
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 within section 9.1 and 9.2. Where there is no superscript number, see sections 2 to 6 for more explanation.

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

Representative use		<p>Brassicas (all types; broccoli, cauliflower, calabrese, Brussels sprout, Chinese cabbage, pak choi)</p> <p>Potato & Root vegetables (swede, turnip, radish, carrot, parsnip, leek, onion)</p> <p>Soft fruit (strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, red currant, white currant, red currant, cranberry, figs, kiwi),</p> <p>Grassed sport areas (golf courses, race courses, rugby and football pitches, hockey, baseball athletic stadiums, recreational areas)</p> <p>2569 - 7708 g/ha</p>
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	X ^{2,3}
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X ²
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	X ¹
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L ^(a) breached	
	Assessment not finalised	

Comments/Remarks	
------------------	--

The superscript numbers in this table relate to the numbered points indicated within section 9.1 and 9.2. Where there is no superscript number, see sections 2 to 6 for more explanation.

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

REFERENCES

- EFSA (European Food Safety Authority), 2007. Pesticide Residues Intake Model for assessment of acute and chronic consumer exposure to pesticide residues-rev.2.
- 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 garlic extract.
- European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.
- European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99.
- European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.
- European Commission, 2004. 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 garlic extract 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 garlic extract in Annex I of Directive 91/414/EEC.SANCO/2612/08 – rev. 1, 27 October 2008.
- JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.
- JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.
- Poland, 2006. Draft Assessment Report (DAR) on the active substance garlic extract prepared by the rapporteur Member State Poland in the framework of Directive 91/414/EEC, October 2006.
- Poland, 2011. Final Addendum to Draft Assessment Report on garlic extract, compiled by EFSA, July 2011.

APPENDICES

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

Identity (Annex IIA, Point 1)

Function

Insecticide, nematocide, repellent.

Chemical name (IUPAC)

Food grade garlic juice concentrate

Chemical name (CA)

garlic extract

CIPAC No

Not available

CAS No

8000-78-0, CAS no. used in the ECB database 8008-99-9

EEC No (EINECS or ELINCS)

232-371-1

FAO Specification (including year of publication)

Not available

Minimum purity of the active substance as manufactured (g/kg)

99.9% w/w

Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)

None

Molecular formula

Marker compounds:

1. $C_6H_{10}S$

2. $C_6H_{10}S_2$

3. $C_6H_{10}S_3$

4. $C_6H_{10}S_4$

Molecular mass

1. 114

2. 146

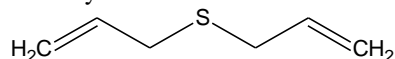
3. 178

4. 210

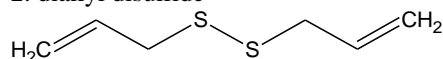
Structural formula

Marker compounds:

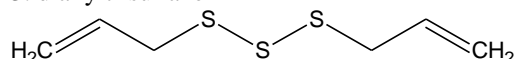
1. diallyl sulfide



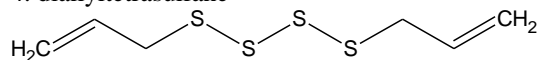
2. diallyl disulfide



3. diallyl trisulfane



4. diallyl tetrasulfane



Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	Open
Boiling point (state purity)	Open
Temperature of decomposition	Open
Appearance (state purity)	Liquid (purity: 99.9% v/v)
Relative density (state purity)	Open
Surface tension	Open
Vapour pressure (in Pa, state temperature)	Open
Henry's law constant (Pa m ³ mol ⁻¹)	Open
Solubility in water (g/L or mg/L, state temperature)	Open
Solubility in organic solvents (ng/L or mg/L, state temperature)	Open
Partition co-efficient (log P _{OW}) (state pH and temperature)	Open
Hydrolytic stability (DT ₅₀) (state pH and temperature)	Open
Dissociation constant	Open
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	-
Photostability (DT ₅₀) (aqueous, sunlight, state pH)	Open
Quantum yield of direct phototransformation in water at > 290 nm	Open
Flammability	Open
Explosive properties	Open
Oxidising properties	Open

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data

No classification proposed

Summary of representative uses evaluated (Annex IIA, point 3)

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of as	method kind	growth stage & season	Nber min /max	interval between applications	g ai /hL min /max	Water L/ha min /max	g ai/ha min-max		
Swede, turnip, cauliflower, head cabbage, broccoli/calabrese brussel sprouts,	UK DK Norway NL	ECOguard® granules	F G	Cabbage root fly (<i>Delia radicum</i> L.) Turnip root fly (<i>Delia floralis</i> F.)	GR	45 %	application to the soil surface (row or individual plants) by conventional granular application equipment or by hand	BBCH 12-19 (spring, summer)	1-4	7 days	-	-	up to 5,4 kg/ha (up to 12 kg of ECOguard® granules per ha)	7	
brassicas: (all types; cauliflower, broccoli, calabrese, brussel sprouts, chinese cabbage, Pak choi), root vegetables: (swede, turnip, carrot, leek, onion, potatoes)	UK DK Norway NL ES DE	ECOguard® granules	F G	Repellent to birds, mammals (rabbit), insects.	GR	45 %	application to the soil surface by conventional granular application equipment	when area is under threat of attack from birds, mammals or insects.	1-4	Not Specified	-	-	7,2 kg /ha (16 kg/ha of ECOguard® granules)	7	
Potatoes	UK DK Norway NL	ECOguard® granules	F G	Free living nematodes e.g.: <i>Longidorus</i> spp., <i>Pratylenchus</i> spp. Cyst nematodes e.g. <i>Globodera</i> spp. <i>Heterodera</i> spp. Root-knot nematodes e.g. <i>Meloidogyne</i> spp.	GR	45 %	application beneath the soil surface at the same time as drilling (row) by standard granular application equipment	at drilling (winter /spring /summer)	1	-	-	-	up to 13,5 kg/ha (up to 30 kg of ECOguard® granules per ha)	7	

Parsnip	UK DK Norway NL	ECOGuard® granules	F	Free living nematodes	GR	45 %	application beneath the soil surface at the same time as drilling (row) by standard granular application equipment	at drilling (winter/spring/summer)	1	-	-	-	up to 13,5 kg/ha (up to 30 kg of ECOGuard® granules per ha)	7	
Potatoes, Soft fruits (strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, white currant, cranberry, figs, kiwi fruit, grapevines, citrus fruits) Root vegetables (carrot, sugar beet)	UK DK FR ES Norway NL	ECOGuard® liquid	F G	Free living nematodes Cyst nematodes	EC	99,9	application beneath the soil surface by trickle feed irrigation system or similar system equipped with an accurate flow metering system	BBCH 10-19	1-6	14 days	-	Not specified. Rate Solution 0,1-0,25%	5139 g/ha (4l of ECOGuard® liquid /ha)	7	

Brassicas (swede, cauliflower, broccoli/calabrese) Root vegetables (carrot)	UK DK Norway NL	ECOGuard® liquid	F G	Cabbage root fly (<i>Delia radicum</i> L.) carrot fly aphids trips, white fly	EC	99,9	drenching of the plants within a day of transplanting and spraying	BBCH 1-19	drenching: 1 spraying: 1-4	7 days in normal weather conditions (in adverse weather conditions or exceptional pest pressure the interval between spray applications may be reduced).	-	Drenching: 1 l per module tray (Rate solution up to 4%) Spraying: low (up 200 l/ha) or high (over 200 l/ha) volume	Drenching: 3,7 -10,2 g per plant (2,9 - 7,9 ml per plant of ECOGuard® liquid based upon 1 l per tray. (2l per square metre) Spraying: 2569-7708 g/ha (2-6l ECOGuard® liquid /ha)	7	Drenching: ECOGuard® liquid is applied to the moist module. Module tray is based upon a standard dimension of 400x600 mm. This is subdivided to produce the module. First spray application can be applied to the crop post transplanting. Application repeated two weeks after transplanting . Additional applications depend on the egg laying by pests.
--	--------------------------	---------------------	--------	---	----	------	---	--------------	--	--	---	--	--	---	---

Brassicac: (all types; broccoli, cauliflower, calabrese, brussel sprouts, chinese cabbage, Pak choi), Potatoes, Root vegetables: swede, turnip, radish, carrot, parsnip, leek, onion, Soft fruit (strawberry, raspberry, blackberry, gooseberry, blueberry, black currant, red currant, white currant, red currant, cranberry, figs, kiwi), Grassed sport areas (golf courses, race courses, rugby and football pitches, hockey, baseball athletic stadiums, recreational areas).	UK, DK Norwa y NL ES DE	ECOgu ard® liquid	F G	Repelent to birds, mammals (rabbit), insects.	EC	99,9	high (over 200 l/ha) or low (up to 200 l/ha) volumen spraying drenching	BBCH 1-19 (winter, spring, summer autum).	1-4	7 days (in adverse weather condition s or exception al pest pressure the interval beetwen spray applicatio n may be reduced).	-	1000 l/ha	2569-7708 g/ha 2-6l of ECOguard® liquid per ha.	7 days	Applied when crop is under threat of attack from birds, mammals or insects.
--	---	-------------------------	--------	---	----	------	--	--	-----	--	---	-----------	---	-----------	---

Methods of Analysis

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

Technical as (principle of method)	Note: As the garlic extract is a vegetable extract active substance was not really identified. Four “finger print” compounds: diallyl sulfide, diallyl disulfide, diallyl trisulfane, diallyl tetrasulfane were used as markers. An analytical method using HPLC with UV detection (240 nm) was developed to quantify these markers.
Impurities in technical as (principle of method)	No method developed as no impurities identified
Plant protection product (principle of method)	No method developed. The plant protection product ECOguard liquid is quite similar to the active substance. Open for validation of the method for ECOguard granules

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable
Soil (principle of method and LOQ)	Not applicable
Water (principle of method and LOQ)	Not applicable
Air (principle of method and LOQ)	Not applicable
Body fluids and tissues (principle of method and LOQ)	Not applicable

Impact on Human and Animal Health

As garlic extract is of food grade quality, all toxicological data requirements are waived.

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

Rate and extent of oral 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)	Garlic extract

Toxicologically relevant compounds ‡
(environment)

Garlic extract

Acute toxicity (Annex IIA, point 5.2)

Rat LD₅₀ oral ‡

No data-not required

Rat LD₅₀ dermal ‡

No data-not required

Rat LC₅₀ inhalation ‡

No data-not required

Skin irritation ‡

Not irritant

Eye irritation ‡

Not irritant

Skin sensitisation ‡

Skin sensitizer (based on human cases reports)

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)

Cases of occupational asthma in occupational workers vulnerable to garlic dust

Summary (Annex IIA, point 5.10)

ADI ‡

Value	Study	Safety factor
Not allocated, not necessary	-	-

AOEL ‡

Not allocated, not necessary	-	-
------------------------------	---	---

ARfD ‡

Not allocated, not necessary*	-	-
-------------------------------	---	---

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Ecoguard)

No data- not required

Exposure scenarios (Annex IIIA, point 7.2)

Operator

No data- not required

Workers

No data- not required

Bystanders

No data- not required

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

Garlic extract

RMS/peer review proposal

May have the potential to provoke sensitising reactions by inhalation and skin contact

Residues

It can be reasonably assumed that consumer exposure from the culinary use of garlic will be significantly higher than exposure from the use as plant protection product. Therefore residue data are not required.

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

Plants groups covered	Not provided and not required
Rotational crops	Not provided and not required
Plant residue definition for monitoring	Not applicable
Plant residue definition for risk assessment	Not applicable
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 provided and not required
Animal residue definition for monitoring	Not applicable
Animal residue definition for risk assessment	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue (yes/no)	Not applicable

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

Not applicable

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

Not applicable

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

Intakes by livestock < 0.1 mg/kg diet/day	Ruminant: yes/no	Poultry: Yes/no	Pig: yes/no
Muscle	no	no	no
Liver	no	no	no
Kidney	no	no	no
Fat	no	no	no
Milk	no		
Eggs		no	

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

Not applicable

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommandation / comments	MRL mg/kg	STMR mg/kg
		Not provided and not required			

Risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not proposed
TMDI (European diet) (% ADI)	not applicable
NEDI (% ADI)	not applicable
Factors included in NEDI	not applicable
ARfD	Not proposed
Acute exposure (% ARfD)	not applicable

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
not applicable			

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

not applicable	
----------------	--

Fate and Behaviour in the Environment

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

Mineralization after 100 days	No data provided
Non-extractable residues after 100 days	No data provided
Relevant metabolites - name and/or code, % of applied (range and maximum)	No data provided

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

Anaerobic degradation	No data submitted, not required
Soil photolysis	No data submitted, not required

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

Method of calculation	No data provided
Laboratory studies (range or median, with n value, with r^2 value)	DT _{50lab} (20°C, aerobic): No data provided. Claimed to be < 1d based on scientific literature data in relation to some studies in the aquatic environment.
	DT _{90lab} (20°C, aerobic): No data provided.
	DT _{50lab} (10°C, aerobic): No data provided.
	DT _{50lab} (20°C, anaerobic): No data provided.
	Degradation in the saturated zone: No data provided.
Field studies (state location, range or median with n value)	DT _{50f} : No data provided.
	DT _{90f} : No data provided.
Soil accumulation and plateau concentration	No data provided. Active ingredients of garlic extract are deemed to be not persistent enough to deserve considerations on potential accumulation.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K _f / K _{oc} K _d pH dependence (yes / no) (if yes type of dependence)	No data provided
--	------------------

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

Column leaching	No data provided
Aged residues leaching	No data provided
Lysimeter/ field leaching studies	No data provided

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	DT ₅₀ : not available
Application rate	Crop: potatoes, Plant interception: 0%, Number of applications: 1 Application rate: 13500 g a. s./ha Method of application: soil incorporation

PEC _(s)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	4.5 mg/kg			

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation

Application rate

DT₅₀ : not available

Crop: brassicas,
Plant interception: 0%,
Number of applications: 1
Application rate: 7200 g a. s./ha
Method of application: soil incorporation

PEC _(s)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	9.6 mg/kg			

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

Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)

Photolytic degradation of active substance and relevant metabolites

Readily biodegradable (yes/no)

Degradation in - DT₅₀ water
water/sediment - DT₉₀ water
- DT₅₀ whole system
- DT₉₀ whole system

Mineralization

Non-extractable residues

Distribution in water / sediment systems (active substance)

Distribution in water / sediment systems (metabolites)

pH = 4 : No data provided

pH = 7 : No data provided

pH = 9 : No data provided

No data provided

No data provided

No data provided

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

Method of calculation

Application rate

Main routes of entry

DT₅₀: not available

CROPS: VEGETABLES (BRASSICAS, UNSPECIFIED)
NUMBER OF APPLICATIONS: 1
APPLICATION RATE: 7708 G A. S./HA (AS NONE DT₅₀ VALUE IS AVAILABLE ONLY INI PEC IS CALCULATED)
TYPE OF WATER BODY: DITCH, STREAM, POND

Spray drift, FOCUS spray drift values for vegetables used.

PEC _(sw)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	ditch: 49.52 µg/l pond: 1.69 µg/l stream: 36.75 µg/l			

PEC (sediment)

Method of calculation

No data provided

Application rate

.

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)

No data provided

Data gap identified for data to substantiate the natural levels claimed to occur in fields cropped with onions and garlic

Application rate

PEC_(gw)

Maximum concentration

Average annual concentration

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

Direct photolysis in air

No data provided

Quantum yield of direct phototransformation

No data provided

Photochemical oxidative degradation in air (DT₅₀)

No data provided

Volatilization

No data provided

PEC (air)

Method of calculation

No data provided

PEC_(a)

Maximum concentration

No data provided

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment

Soil : Active components of garlic extract
Ground and surface water: Active components of garlic extract.
Air: Active components of garlic extract.

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

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

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data

Considered readily biodegradable

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 provided – not required
Sub-chronic toxicity to mammals (90 j)	No data provided – not required
Acute toxicity to birds	No data provided – not required
Dietary toxicity to birds	No data provided – not required
Reproductive toxicity to birds	No data provided – not required

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

Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish				(1)
<i>Daphnia magna</i>	Garlic Juice Concentrate 883	Acute-48h (static)	EC ₅₀	9.3 ⁽²⁾
Algae				(1)
Microcosm or mesocosm tests: no data, not required				

(1) No data have been provided. Data gap.

(2) No analytical measures were done through the test. Data gap.

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

Application rate (g as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger

Calculations could not be performed due to lack of relevant data.

Bioconcentration

Bioconcentration factor (BCF)

Annex VI Trigger: for the bioconcentration factor

Clearance time (CT₅₀)

(CT₉₀)

Level of residues (%) in organisms after the 14 day depuration phase

No data - data gap in section 1
Not applicable
not applicable
not applicable

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

Acute oral toxicity

Acute contact toxicity

No data provided. Data gap
No data provided. Data gap

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
			Calculations could not be performed due to lack of relevant data.	<50
Field or semi-field tests				
no data				

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests: no data provided. Data gap						
Field or semi-field tests: no data provided						

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

Acute toxicity

Reproductive toxicity

No data provided. Data gap
No data provided

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
			Data gap	

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

Nitrogen mineralization

Carbon mineralization

No data. Data gap
No data. Data gap

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

Test type/organism	end point
Activated sludge	No data provided. Data gap

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data

Data not sufficient to propose relevant classification
Data Gap

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ϵ	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
μg	microgram
μm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC ₅₀	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
UESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
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 <i>n</i> -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

