

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/citronella oil¹

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SUMMARY

Citronella oil is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004,³ as amended by Commission Regulation (EC) No 1095/2007.⁴

Citronella oil 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. The 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 citronella oil 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 11 July 2008 by dispatching the DAR to the notifier Barrier Biotech Ltd, and on 24 February 2011 to the Member States, for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on citronella oil.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of citronella oil as a herbicide applied by spot spray treatment on common ragwort

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³ OJ L 379, 24.12.2004, p.13

⁴ OJ L 246, 21.9.2007, p.19

⁵ OJ L 309, 24.11.2009, p.1

⁶ OJ L 153, 11.6.2011, p.1

⁷ OJ L 153, 11.6.2011, p.187

⁸ OJ L 37, 10.2.2010, p.12

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growing on grassland, green cover, amenity grassland and land temporarily removed from production, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

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

An operator and worker risk assessment could not be performed for the representative use because the toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance, and reliable exposure data for workers were not available.

A data gap was set in the residue section to determine an appropriate withholding period before livestock can be allowed to re-enter the treated areas, in order to minimize the exposure of livestock and taking into account that treated ragwort may become more palatable when dying off. In addition, pending on the outcome of the outstanding data gap identified in the fate section on the potential groundwater contamination assessment, a consumer risk assessment through drinking water may be required.

No information is available on the fate and behaviour in the environment of the known active components of citronella oil and its relevant impurities. A number of data gaps have been identified, including a potential groundwater contamination assessment. The proposed residue definition for environmental risk assessment should be considered as tentative only.

The ecotoxicological risk assessment cannot be concluded. A data gap was identified to provide acute toxicity studies on aquatic organisms. Additionally, the risk to birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro-organisms, and terrestrial non-target plants should be further considered, due to the fact that information on fate and behaviour in the environment is missing. Chronic studies on aquatic organisms might be necessary and should be considered when information on fate and behaviour is available. The risk to biological methods of sewage treatment was considered to be low.

KEY WORDS

Citronella oil, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Citronella oil is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004,⁹ as amended by Commission Regulation (EC) No 1095/2007.¹⁰

Citronella oil 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.

The United Kingdom being the designated rapporteur Member State submitted the DAR on citronella oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008 (United Kingdom, 2007). The peer review was initiated on 11 July 2008 by dispatching the DAR to the notifier Barrier Biotech Ltd, and on 24 February 2011 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 rapporteur Member State 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 rapporteur Member State in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the rapporteur Member State, and the European Commission on 20 June 2011. On the basis of the comments received and the rapporteur Member State’s evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

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

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

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

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 use as a herbicide applied by spot spray treatment on common ragwort growing on grassland, green cover, amenity grassland and land temporarily removed from production, 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 (29 June 2011),
- the Evaluation Table (8 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 October 2011 containing all individually submitted addenda (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

Citronella oil is a common name for an extract from tropical grasses of the *Cymbopogon* genus. There is no ISO common name for this substance. Citronella oil is a complex mixture of chemical substances, four marker compounds were selected: citronellal [(3*R*)-3,7-dimethyl-6-octenal], geraniol [(2*E*)-3,7-dimethyl-2,6-octadien-1-ol], citronellol [(3*R*)-3,7-dimethyl-6-octen-1-ol] and geranyl acetate [(2*E*)-3,7-dimethyl-2,6-octadien-1-yl acetate] (IUPAC).

The representative formulated product for the evaluation was 'Barrier H', an oil in water emulsion (EW), containing 22.9% citronella oil.

The representative use evaluated is as a herbicide applied by spot spray treatment using hand-held equipment on common ragwort (*Senecio jacobaea*) growing on grassland, green cover, amenity grassland and land temporarily removed from production. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

The ranges of the marker compounds in citronella oil are: citronellal 30-45%, geraniol 20-25%, citronellol 9-15% and geranyl acetate 3-8%. It should be noted however that the Commission Implementing Regulation (EU) No 540/2011¹⁵ does not contain the ranges for the four marker compounds. This specification complies with the EU Pharmacopeia 2007, however a data gap was identified for analysis of batches of Java citronella oil to support this compliance. No FAO specification exists.

It should be mentioned that citronella oil from *Cymbopogon winterianus* Jowitt was the source evaluated in the DAR. Methyl eugenol and methyl isoeugenol were identified as relevant impurities with a maximum amount of 1 g/kg each. A data gap was identified for 5-batch data to confirm that levels of methyl eugenol and methyl isoeugenol are below 1 g/kg, obtained with validated analytical methods.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of citronella oil or the representative formulation, however data gaps were identified for the determination of the physical and chemical properties of the active substance, for levels of the relevant impurities before and after storage and a cold temperature storage study.

Adequate analytical methods are available for the determination of the active substance(s) in citronella oil technical material. A method is available for the determination of 8 major components of citronella oil in the representative formulation, however, additional validation data of the GC-MS method for the determination of the active substance in the formulation has been identified as a data gap.

The need for methods of analysis for monitoring this compound in food of plant and animal origin has been waived due to the use pattern. Pending on the final residue definition for monitoring in the

¹⁵ OJ L 153, 11.6.2011, p.1

environment, analytical methods might be required. A method for residues in body fluids and tissues is not required as the active substance is not classified as very toxic.

2. Mammalian toxicity

Citronella oil was discussed by the experts in mammalian toxicity during the Pesticides Peer Review Experts' Meeting 88 (September 2011).

Among the components of citronella oil, methyl eugenol and methyl isoeugenol are identified as toxicologically relevant impurities, being potential genotoxic carcinogens.

In the Draft Assessment Report (United Kingdom, 2007), the RMS considered the component citral to be sufficiently structurally similar to the major components of citronella oil (Java type) to use the toxicological data with citral as a surrogate for citronella oil. However, the experts agreed that the toxicological profile of citronella oil (with a composition compliant with the representative technical specification) cannot be concluded based on the available data. Either data were provided for structurally similar compounds with a lack of bridging information to support extrapolation to citronella oil, or data were available for some individual components and not for the sum of the components. Additionally, most of the data consisted of summarised evaluations by third parties, which did not allow for an expert judgement. Therefore no reference values can be derived. It is noted that no Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) are necessary in the absence of consumer exposure through dietary intake (see section 3). Pending on the assessment of the groundwater contamination (see section 4), further data may be required to derive reference values for the consumer risk assessment through drinking water (see section 3).

Operator exposure estimates for the representative use by hand-held spraying for spot treatment of weeds were provided according to HSE data (United Kingdom, 2007), but the risk assessment could not be performed in the absence of an AOEL. Furthermore, reliable exposure data for workers were missing. The bystander is unlikely to be exposed during the application.

3. Residues

The conclusions in the residue section below are based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999).

Citronella oil is used as a spot spray treatment on common ragwort growing on grassland, green cover, amenity grassland and land temporarily removed from production. A quantitative consumer exposure assessment to the residues of citronella oil, its potential metabolites and the known relevant impurities (methyl eugenol and methyl isoeugenol) in animal commodities can be waived since negligible contamination of the feed items is expected in view of the representative use. Nevertheless, a data gap was set to determine an appropriate withholding period before livestock can be allowed to re-enter the treated areas, in order to minimize the exposure of livestock and taking into account that treated ragwort may become more palatable when dying off.

Additionally, pending on the outcome of the outstanding data gap identified in the fate section on the potential groundwater contamination assessment, a consumer risk assessment through drinking water may be required.

4. Environmental fate and behaviour

No information on the fate and behaviour in the environment of the known active components of citronella oil and its relevant impurities is available. A number of data gaps have been identified including a potential groundwater contamination assessment. The definition of residue including

active components of the active substance, metabolites in the environment, and relevant impurities remains open due to the outstanding data gaps identified in the identity section. Therefore the proposed residue definition for environmental risk assessment should be considered as tentative only.

The rapporteur Member State calculated a worst case initial predicted environmental concentration (PEC) in soil. This value could eventually be used to finalise the risk assessment for soil organisms once information on ecotoxicology becomes available. Additionally, the rapporteur Member State calculated a worst case initial predicted environmental concentration in surface water (PEC_{SW}) based only on spray drift loadings. Whereas the initial PEC_{SW} without mitigation could eventually be used in a worst case risk assessment (once ecotoxicological data becomes available), in order to apply any possible mitigation, information on potential contamination by routes other than spray drift (drainage and run-off) would need to be considered in the calculations. Alternatively, further details on the mode of application and the extension of potential worst case field infestation could also be used to refine the current estimates. No estimates are available for the predicted environmental concentration in groundwater (PEC_{GW}) of the active components of citronella oil or its relevant impurities. Whereas the RMS assumed the exposure resulting from the representative use would be expected to be very low, no data or calculation to support this assumption is available in the dossier. A data gap has been identified for calculation of worst case estimates of the PEC_{GW}. This calculation may only be performed once the other data gaps identified are at least partially fulfilled.

5. Ecotoxicology

No studies were provided on the effects to non-target species, except literature search endpoints for aquatic organisms and data for terrestrial non-target plants from efficacy trials. A negligible environmental exposure could not be concluded because no information was available on the fate and behaviour in the environment of the known active components of citronella oil. Therefore, overall, the ecotoxicological risk assessment could not be concluded.

It is likely that the exposure for birds and mammals will be low due to the mode of application (i.e. spot spray) and the repellent properties of the active substance. However, no data were provided to support such a qualitative risk assessment. Additionally, since the log P_{ow} is reported to be greater than 3, the risk from secondary poisoning could not be excluded. Therefore, a data gap was identified to further address the risk to birds and mammals.

Regarding the aquatic organisms, data from a literature search carried out by the rapporteur Member State were available in the DAR. The original source of these studies was not available and not evaluated. Therefore several data gaps were identified for the aquatic environment: 1) to provide acute toxicity tests necessary to fulfil the Annex II data requirements; 2) to further consider the need for chronic studies on fish and aquatic invertebrates and, since the log P_{ow} is greater than 3, the need of a bioaccumulation study on fish; and 3) further assessment of the risk to all aquatic organisms.

The risk for bees, non-target arthropods, earthworms, and soil macro- and micro-organisms should be further considered (data gaps identified).

The risk to terrestrial non-target plants cannot be excluded on the basis of the available data and should be further considered. The risk to biological methods of sewage treatment was considered as low because the contamination of sewage treatment plants would be unlikely for the representative use.

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 ^(a) (name and/or code)	Persistence	Ecotoxicology
citronellal	No data available, data gap	Data gap
geraniol	No data available, data gap	Data gap
citronellol	No data available, data gap	Data gap
geranyl acetate	No data available, data gap	Data gap
relevant impurity: methyl eugenol	No data available, data gap	Data gap
relevant impurity: methyl isoeugenol	No data available, data gap	Data gap

(a): The number and identity of compounds needing environmental assessment may vary when the required information in the section on identity, physical/chemical/technical properties and methods of analysis (on the specifications and analysis of the active substance) and environmental fate and behaviour (on the route of degradation in soil and fate in surface water) becomes available.

6.2. Ground water

Compound ^(a) (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
citronellal	No data available, data gap	No data available, data gap	Yes	Data gap	Data gap
geraniol	No data available, data gap	No data available, data gap	Yes	Data gap	Data gap
citronellol	No data available, data gap	No data available, data gap	Yes	Data gap	Data gap
geranyl acetate	No data available, data gap	No data available, data gap	Yes	Data gap	Data gap
relevant impurity: methyl eugenol	No data available, data gap	No data available, data gap	No data	Yes, genotoxic carcinogen	No data
relevant impurity: methyl isoeugenol	No data available, data gap	No data available, data gap	No data	Yes, genotoxic carcinogen	No data

(a): The number and identity of compounds needing environmental assessment may vary when the required information in the section on identity, physical/chemical/technical properties and methods of analysis (on the specifications and analysis of the active substance) and environmental fate and behaviour (on the route of degradation in soil and fate in surface water) becomes available.

6.3. Surface water and sediment

Compound ^(a) (name and/or code)	Ecotoxicology
citronellal	Data gap
geraniol	Data gap
citronellol	Data gap
geranyl acetate	Data gap
relevant impurity: methyl eugenol	No data
relevant impurity: methyl isoeugenol	No data

(a): The number and identity of compounds needing environmental assessment may vary when the required information in the section on identity, physical/chemical/technical properties and methods of analysis (on the specifications and analysis of the active substance) and environmental fate and behaviour (on the route of degradation in soil and fate in surface water) becomes available.

6.4. Air

Compound (name and/or code)	Toxicology
citronellal	No data available via inhalation
geraniol	No data available via inhalation
citronellol	No data available via inhalation
geranyl acetate	No data available via inhalation
relevant impurity: methyl eugenol	No data available via inhalation (genotoxic carcinogen)
relevant impurity: methyl isoeugenol	No data available via inhalation (genotoxic carcinogen)

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).

- Analysis of batches of Java citronella oil to support the specification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Five batch data to confirm that levels of methyl eugenol and methyl isoeugenol are below 1 g/kg, obtained with validated analytical methods (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Determination of the physical and chemical properties of the active substance (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Determination of the levels of the relevant impurities before and after storage (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Cold temperature storage study of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Additional validation data of the GC-MS method for the determination of the active substance in the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Further information and assessment of the toxicological profile of citronella oil in order to derive an AOEL and perform the risk assessment for operators and workers (relevant for all representative uses evaluated; data gap identified during the peer review; no submission date proposed by the notifier; see section 2).
- Exposure assessment of re-entry workers in representative scenarios and activities (relevant for the representative use evaluated; data gap identified during the peer review; no submission date proposed by the notifier; see section 2).
- Information to determine an appropriate withholding period before livestock can be allowed to re-enter the treated areas, in order to minimize the exposure of livestock and taking into account that treated ragwort may become more palatable when dying off (relevant for the representative use evaluated; data gap identified during the peer review; no submission date proposed by the notifier; see section 3).
- Information on the route and rate of degradation of the active components of citronella oil and its relevant impurities (methyl eugenol and methyl isoeugenol) is needed to refine the surface water exposure assessment and to perform the groundwater exposure assessment (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 4).
- Information on the adsorption/desorption in soil of the active components of citronella oil and its relevant impurities (methyl eugenol and methyl isoeugenol) is needed to refine the surface water exposure assessment and to perform the groundwater exposure assessment (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 4).

- Information on the fate and behaviour of the active components of citronella oil in water and water/sediment systems may be needed to refine the aquatic exposure assessment (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 4).
- Potential groundwater contamination by the known biologically active components of citronella oil and its relevant impurities (methyl eugenol and methyl isoeugenol) needs to be estimated (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; 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).
- The chronic risk to fish and aquatic invertebrates and bioaccumulation in fish should be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 5).
- The risk for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro and micro-organisms, terrestrial non-target plants needs to be further assessed (relevant for all representative uses evaluated; submission date proposed by the notifier: not available; see section 5).

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

- None.

9. Concerns

9.1. Issues that could not be finalised

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

1. The environmental exposure and risk assessment cannot be finalised due to the missing data. This includes assessment of potential groundwater contamination by the active substance components, their potential metabolites, and known relevant impurities.
2. The risk assessment for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro-organisms, and terrestrial non-target plants cannot be finalised.

9.2. Critical areas of concern

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

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

3. An operator and worker risk assessment could not be performed for the representative use because the toxicological database was considered incomplete and not sufficient to identify the hazard of the active substance, and reliable exposure data for workers were not available.

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		Grassland, green cover, amenity grassland and land temporarily removed from production
Operator risk	Risk identified	
	Assessment not finalised	X ³
Worker risk	Risk identified	
	Assessment not finalised	X ³
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X ²
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X ²
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	X ¹
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

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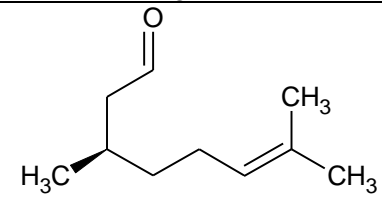
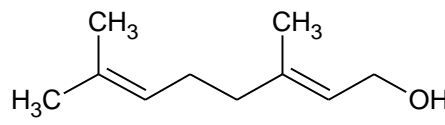
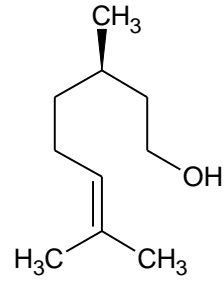
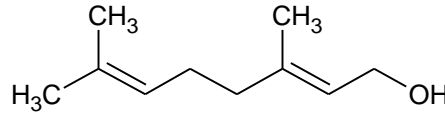
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- United Kingdom, 2011. Final Addendum to Draft Assessment Report on citronella oil, compiled by EFSA, October 2011.

APPENDICES

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

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

Active substance (ISO Common Name) ‡	Citronella oil Java type (No ISO Common Name)
Function (<i>e.g.</i> fungicide)	Herbicide
Rapporteur Member State	UK
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	Marker compounds: citronellal: (3 <i>R</i>)-3,7-dimethyl-6-octenal geraniol: (2 <i>E</i>)-3,7-dimethyl-2,6-octadien-1-ol citronellol: (3 <i>R</i>)-3,7-dimethyl-6-octen-1-ol geranyl acetate: (2 <i>E</i>)-3,7-dimethyl-2,6-octadien-1-yl acetate
Chemical name (CA) ‡	Marker compounds: citronellal: (3 <i>R</i>)-3,7-dimethyloct-6-enal geraniol: (2 <i>E</i>)-3,7-dimethylocta-2,6-dien-1-ol citronellol: (3 <i>R</i>)-3,7-dimethyloct-6-en-1-ol geranyl acetate: (2 <i>E</i>)-3,7-dimethylocta-2,6-dien-1-yl acetate
CIPAC No ‡	905
CAS No ‡	8000-29-1
EC No (EINECS or ELINCS) ‡	294-954-7
FAO Specification (including year of publication) ‡	No FAO specification available. However, the European Pharmacopeia standard must be complied with.
Minimum purity of the active substance as	citronellal: 30-45%

<p>manufactured ‡</p>	<p>geraniol: 20-25% citronellol: 9-15% geranyl acetate: 3-8%</p>
<p>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured</p>	<p>methyl eugenol: max 1g/kg methyl isoeugenol: max 1 g/kg</p>
<p>Molecular formula ‡</p>	<p>Main components: citronellal: C₁₀H₁₈O geraniol: C₁₀H₁₈O citronellol: C₁₀H₂₀O geranyl acetate: C₁₂H₂₀O₂</p>
<p>Molecular mass ‡</p>	<p>Main components: citronellal: 154.25 geraniol: 154.25 g/mol citronellol: 156.27 g/mol geranyl acetate: 196.29 g/mol</p>
<p>Structural formula ‡ Main components</p> <p>Citronellal:</p>	 <p>(3<i>R</i>)-3,7-dimethyl-6-octenal</p>
<p>Geraniol:</p>	 <p>(2<i>E</i>)-3,7-dimethyl-2,6-octadien-1-ol</p>
<p>Citronellol:</p>	 <p>(3<i>R</i>)-3,7-dimethyl-6-octen-1-ol</p>
<p>Geranyl acetate</p>	 <p>(2<i>E</i>)-3,7-dimethyl-2,6-octadien-1-yl acetate</p>

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Substance is a liquid
Boiling point (state purity) ‡	Data gap
Temperature of decomposition (state purity)	No data submitted
Appearance (state purity) ‡	Colourless to light yellow liquid. Pungent, fruity odour. (Purity not known)
Vapour pressure (state temperature, state purity) ‡	Data gap
Henry's law constant ‡	No data submitted
Solubility in water (state temperature, state purity and pH) ‡	Data gap
Solubility in organic solvents ‡ (state temperature, state purity)	Data gap
Surface tension ‡ (state concentration and temperature, state purity)	Data gap
Partition co-efficient ‡ (state temperature, pH and purity)	Data gap
Dissociation constant (state purity) ‡	No data submitted
UV/VIS absorption (max.) incl. ϵ ‡ (state purity, pH)	No data submitted Data gap
Flammability ‡ (state purity)	No data submitted Data gap
Explosive properties ‡ (state purity)	No data submitted Data gap
Oxidising properties ‡ (state purity)	Data gap

Summary of representative uses evaluated (Citronella Oil)

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			PHI (days) (m)	Remarks:
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max (l)		
grass land, green cover, amenity grass land and land temporarily removed from production	UK	Barrier H	F	<i>Senecio jacobaea</i> (Ragwort)	EW	22.9 %	Spot treatment using hand held equipment	BBCH 17 (rosette stage)	1 - 2 *	28 days			3.44 g a.s./plant **	NA	* Weeds should be inspected 28 days after treatment. If re-growth has occurred a 2 nd treatment may be necessary ** Assuming weed density of 200,000 plants/ha this equates to 611.4 kg a.s./ha Treatment of large areas is unlikely.

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and 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 plants - type of equipment used must be indicated

- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) The values should be given in g/kg or (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)	GC with FID detection
Impurities in technical as (analytical technique)	GC with FID detection
Plant protection product (analytical technique)	Ion Trap GC-MS, open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Not required
Food of animal origin	Not required
Soil	Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl isoeugenol
Water surface	Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl isoeugenol
drinking/ground	Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl isoeugenol
Air	Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl isoeugenol

*Note: The number and identity of compounds needing monitoring may vary when the required information in environmental fate and behaviour (on the route of degradation in soil and fate in surface water) becomes available.

Monitoring/Enforcement methods

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

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

Active substance

RMS/peer review proposal
Not required

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	No data available for Citronella oil	
Distribution ‡	No data available for Citronella oil	
Potential for accumulation ‡	No data available for Citronella oil	
Rate and extent of excretion ‡	No data available for Citronella oil	
Metabolism in animals ‡	No data available for Citronella oil	
Toxicologically relevant compounds ‡ (animals and plants)	-	
Toxicologically relevant compounds ‡ (environment)	- Methyl eugenol and methyl isoeugenol	

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡	Insufficient data available	-
Rat LD ₅₀ dermal ‡	Insufficient data available	-
Rat LC ₅₀ inhalation ‡	Insufficient data available	-
Skin irritation ‡	Insufficient data available	-
Eye irritation ‡	Insufficient data available	-
Skin sensitisation ‡	Insufficient data available Evidence of skin sensitisation in humans (see medical data)	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data are available for Citronella oil	
Relevant oral NOAEL ‡	No data available for citronella oil	-
Relevant dermal NOAEL ‡	No data available for citronella oil	-
Relevant inhalation NOAEL ‡	No data available for citronella oil	-

Genotoxicity ‡ (Annex IIA, point 5.4)

Insufficient data available	-
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data available for citronella oil	
Relevant NOAEL ‡	No data available for citronella oil	
Carcinogenicity ‡	No data available for citronella oil	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available for citronella oil	-
Relevant parental NOAEL ‡	No data available for citronella oil	
Relevant reproductive NOAEL ‡	No data available for citronella oil	
Relevant offspring NOAEL ‡	No data available for citronella oil	

Developmental toxicity

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

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available for citronella oil	
Repeated neurotoxicity ‡	No data available for citronella oil	
Delayed neurotoxicity ‡	No data available for citronella oil	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available for citronella oil	
Studies performed on metabolites or impurities ‡	The minor component methyl eugenol is considered to be a genotoxic carcinogen.	

Medical data ‡ (Annex IIA, point 5.9)

Poisoning cases indicate that Citronella oil is of low toxicity. Volunteer studies indicate that Citronella oil is a weak skin sensitiser.
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Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Cannot be derived based on the available data, not required.		
AOEL ‡	Cannot be derived based on the available data.		
ARfD ‡	Cannot be derived based on the available data, not required.		
Dermal absorption ‡ (Annex IIIA, point 7.3)			
Formulation: Barrier H, EW	100% default value		
Exposure scenarios (Annex IIIA, point 7.2)			
Operator	Exposure estimates based on HSE data related to the use of hand-held trigger spray packs for spot treatment of weeds. Risk assessment inconclusive in the absence of an AOEL.		
Workers	Risk assessment inconclusive in the absence of an AOEL and of exposure data		
Bystanders	No significant exposure according to the representative use.		
Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)			
Substance classified – Citronella oil	RMS proposal		
	(R43) ‘May cause sensitisation by skin contact’		

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

⁽¹⁾: Given the representative use of citronella oil as a spot spray treatment on common ragwort growing on grassland, green cover, amenity grassland and land temporarily removed from production, a consumer risk assessment through dietary intake can be waived.

No studies were submitted. Not required⁽¹⁾

Plant residue definition for monitoring

Not required ⁽¹⁾

Plant residue definition for risk assessment

Not required ⁽¹⁾

Conversion factor (monitoring to risk assessment)

Not applicable ⁽¹⁾

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

No studies were submitted. Not required⁽¹⁾.

A data gap was set to determine an appropriate withholding period before livestock can be allowed to re-enter the treated areas, in order to minimize the exposure of livestock and taking into account that treated ragwort may become more palatable when dying off.

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

No studies were submitted. Not required⁽¹⁾

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

No studies submitted. Not required⁽¹⁾

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

No studies submitted. Not required⁽¹⁾

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)

No data submitted. Not required⁽¹⁾

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

- A quantitative consumer exposure assessment through dietary intake to the residues of citronella oil, its potential metabolites and the known relevant impurities (methyl eugenol and methyl isoeugenol) in animal commodities can be waived since negligible contamination of the feed items is expected in view of the representative use.

- A consumer risk assessment through drinking water may be required pending on the outcome of the outstanding data gap identified in the fate section on the potential ground water contamination assessment.

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

Not applicable

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

Not required ⁽¹⁾

No actual data relating to environmental fate and behaviour specific to citronella oil or its components were submitted. Only PEC calculations are provided. Data gaps identified for information on the route and rate of degradation in soil, aquatic systems, mobility in soil and potential contamination of groundwater.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT ₅₀ (d): Not known
Method of calculation	Initial PEC _{soil} from application calculated only
Application data	<p>Situation: 'spot treatment' of individual weeds</p> <p>Depth of soil layer: 5cm</p> <p>Soil bulk density: 1.5g/cm³</p> <p>% plant interception: Assumed to be 75% due to spot treatment</p> <p>Number of applications: 1</p> <p>Interval (d): not applicable</p> <p>Application rate: 611,430 g as/ha (611 kg/ha)</p>

PEC _(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	204 mg/kg			

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

<p>Parent</p> <p>Spray drift only using FOCUS Step 3 Drift Calculator</p> <p>Parameters used in FOCUSsw step 3 drift calculator</p>	<p>Version control no.'s of FOCUS software: Drift calculator v.1</p> <p>Parameters relate only to drift values assumed.</p> <p>Crop assumed to be cereals with total distance of 1m from edge of crop to edge of water body, aeric mean drift of 1.9274% (equivalent to approx 2.77% at nearest edge of water body).</p> <p>Spray drift contamination likely to be mitigated by localised and limited application due to hand-held application.</p>
<p>Application rate</p>	<p>Crop: cereals</p> <p>Crop interception: not applicable</p> <p>Number of applications: 1</p> <p>Interval (d): not applicable</p> <p>Application rate(s): 611,430 g as/ha (611 kg/ha)</p> <p>Application window: not applicable</p>

FOCUS STEP 3 drift calculator	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h (1.9274% drift)	3928 µg/l			

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

<p>Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)</p>	<p>Data gap</p>
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Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

PEC (air)

<p>Method of calculation</p>	<p>Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.</p>
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PEC_(a)

Maximum concentration

Likely to be negligible

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.

Soil: Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl iso eugenol
 Surface Water: Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl iso eugenol
 Sediment: Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl iso eugenol
 Ground water: Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl iso eugenol
 Air: Active components citronellal, geraniol, citronellol, geranyl acetate; relevant impurities methyl eugenol, methyl iso eugenol

Note: The number and identity of compounds needing environmental assessment may vary when the required information on identity (on the specifications and analysis of the active substance) and environmental fate and behaviour (on the route of degradation in soil and fate in surface water) becomes available.

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

Soil (indicate location and type of study)

None available

Surface water (indicate location and type of study)

None available

Ground water (indicate location and type of study)

None available

Air (indicate location and type of study)

None available

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

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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 ‡				
	No data provided or required			
Mammals ‡				
Rat	Citronella oil	acute		
Additional higher tier studies ‡				
No data provided or required				

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
Birds				
Data gap to further consider the risk to birds				
Mammals				
Data gap to further consider the risk to mammals				

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹ (mg/L)
Laboratory tests ‡				
Fish				
Aquatic invertebrate				
Sediment dwelling organisms				
<i>Indicate species.</i>	No data provided			
Algae				

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹ (mg/L)
Higher plant				
<i>Indicate species.</i>	No data provided			
Microcosm or mesocosm tests				
Not provided or required				

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

Crop and application rate: Application rate 3000 mL product/ha (611.43Kg citronella oil/ha) as a spot treatment at 15mL product/plant (3.44 g citronella oil/plant)

The PEC_{sw} has not been calculated according to FOCUS surface water as this was considered inappropriate for this use and the data available. An initial PEC_{sw} of 0.062 mg citronella oil/L from spray drift was established.

Group/species	LC/EC50 mg citronella oil/L	PEC mg citronella oil/L	TER

Bioconcentration – data gap, pending on the data gap identified for fate and behaviour					
	Citronellol (measured)	Citronellol (calc)	Geraniol (calc)	Nerol (calc)	Geranyl acetate (calc)
logP _{O/W}	3.1	3.45	3.45	3.47	4.48
Bioconcentration factor (BCF) [‡]	Not provided	Not provided	Not provided	Not provided	Not provided
Annex VI Trigger for the bioconcentration factor					
Clearance time (days) (CT ₅₀)	Not provided	Not provided	Not provided	Not provided	Not provided
(CT ₉₀)	Not provided	Not provided	Not provided	Not provided	Not provided
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not provided	Not provided	Not provided	Not provided	Not provided

* based on total ¹⁴C or on specific compounds

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. ‡	No data	No data
Preparation ¹	No data	No data
Field or semi-field tests		
Data not provided or required		

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

Crop and application rate Ragwort in grassland. Application rate 3000 mL product/ha (611.43Kg citronella oil/ha) as a spot treatment at 15mL product/plant (3.44 g citronella oil/plant)

Data gap to further consider the risk to bees

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR ₅₀ g/ha ¹)
<i>Typhlodromus pyri</i> ‡		No data provided	
<i>Aphidius rhopalosiphi</i> ‡		No data provided	

Crop and application rate Ragwort in grassland. Application rate 3000 mL product/ha (611.43Kg citronella oil/ha) as a spot treatment at 15mL product/plant (3.44 g citronella oil/plant)

Data gap to further consider the risk to non-target arthropods

Further laboratory and extended laboratory studies ‡

Not available

Field or semi-field tests

Not available or required

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
Earthworms
No data provided
Other soil macro-organisms
Soil mite
No data provided
Collembola
No data provided
Soil micro-organisms
Nitrogen mineralisation
No data provided
Carbon mineralisation
No data provided
Field studies ²
No data provided or required

Toxicity/exposure ratios for soil organisms

Crop and application rate Ragwort in grassland. Application rate 3000 mL product/ha (611.43Kg citronella oil/ha) as a spot treatment at 15mL product/plant (3.44 g citronella oil/plant)

Test organism
Earthworms
Data gap to further consider the risk to earthworms
Other soil macro-organisms
Data gap to further consider the risk
Soil micro-organisms
Data gap to further consider the risk

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

Preliminary screening data

Not required for herbicides as ER₅₀ tests should be provided

Laboratory dose response tests

Studies on 11 species (2 monocotyledons and 9 dicotyledons) in a pre-emergence study and 13 species (2 monocotyledons and 11 dicotyledons) in a post-emergence study showed that all species were sensitive to citronella oil. Ragwort, the target species, was most sensitive and the monocotyledonous species least. EC50s were not calculated.

Additional studies (e.g. semi-field or field studies)

None provided or required.

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

Test type/organism	end point
Activated sludge	EC 20 400 mg citronella oil/L
<i>Pseudomonas sp</i>	No data

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

Compartment	
soil	Citronell oil
water	Citronella oil
sediment	None
groundwater	None

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

Active substance

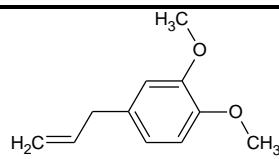
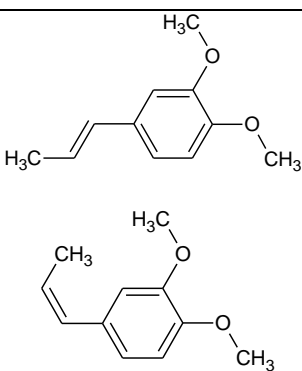
Risk phrases:	R 52	Harmful to aquatic organisms
	R 53	May cause long-term adverse effects in the aquatic environment
Safety phrases:	S 35	This material and its container must be disposed of in a safe way
	S 57	Use appropriate containment to avoid environmental contamination.
Justification for the proposals:		
Risk phrases:	R52	LC/EC50 for fish and aquatic invertebrate 10<100 mg/L
	R 53	In the absence of information on biodegradability
Safety phrases:	S 35	Recommended for substances where special guidance is needed for disposal..
	S 57	Recommended for substances not likely to be used by the general public.

Preparation

RMS/peer review proposal

'Barrier H' does not require classification

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
methyl eugenol	4-allyl-1,2-dimethoxybenzene	
methyl isoeugenol	1,2-dimethoxy-4-[(1 <i>E</i>)-prop-1-en-1-yl]benzene 1,2-dimethoxy-4-[(1 <i>Z</i>)-prop-1-en-1-yl]benzene	

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

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

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