CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance extract from tea tree[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Extract from tea tree 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].

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

Latvia being the designated rapporteur Member State submitted the DAR on extract from tea tree in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 25 October 2007. The peer review was initiated on 18 June 2008 by dispatching the DAR for consultation of the notifier (SIA 'Biomor Latvija'; the new notifier from 04/2010 is 'Biomor Europe Ltd.'). Subsequently the DAR was dispatched for consultation of the Member States on 24 February 2011. 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 extract from tea tree.

[1] On request from the European Commission, Question No EFSA-Q-2009-00296, 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 tea tree oil. EFSA Journal 2012; 10(2):2542. [60 pp.] doi:10.2903/j.efsa.2012.2542. Available online: www.efsa.europa.eu/efsajournal

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of extract from tea tree as a fungicide on potatoes, carrots, herbs, cucumber, watermelons, tomatoes, pepper and ornamentals 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 validation data for the method used in the GLP batch study and spectra for the marker compounds and methods of analysis for appropriate marker compounds in environmental compartments. Data gaps for the formulation were identified for accelerated and shelf life storage studies and flash point.

Data gaps were identified for investigation of the *in vitro* mammalian cell gene mutation potential of extract from tea tree, providing sufficient toxicological information to allow the derivation of reference values, ADI, ARfD and AOEL. The composition of the batches used in the toxicological studies should be presented, as well as an assessment of the toxicological relevance of impurities and components of the tea tree mixture. As no AOEL could be derived, no conclusion could be reached on the operator, worker and bystander exposure risk assessment. Considering the complete lack of data on toxicokinetic and metabolism, short-term, long-term, reproductive and developmental toxicity, a critical area of concern was identified.

There is no conclusion in the residues area. The nature of residues in plants is unknown and a critical area of concern is identified.

Data gaps have been identified for information to address the route and rate of degradation of extract from tea tree components in soil, surface water and sediment. More specific data gaps for disappearance time (DT) values in soil of the components: tirpenene-4-ol, alpha-terpineol and 1,8-cineole and consequent FOCUS groundwater exposure modelling for these components were also identified along with the need for FOCUS surface water assessments for all extract from tea tree components consequent to the representative uses outdoors in the field. The data gaps lead to the conclusion that the groundwater exposure assessment for tirpenene-4-ol, alpha-terpineol and 1,8-cineole was not finalised, that the soil, groundwater and aquatic exposure assessments from potential soil or aquatic system transformation products of globulol and viridiflorol (should they be formed) could not be finalised and that the aquatic exposure assessment for all 12 components of extract from tea tree could not be finalised for the representative outdoor field uses.

The data available for the ecotoxicological assessments were insufficient. The risk assessments for birds and mammals, honeybees and other non-target arthropods, earthworms and non-target soil macro and micro-organisms and for the potential effects on the biological methods of sewage treatment could not be finalised.

KEY WORDS

Extract from tea tree, peer review, risk assessment, pesticide, fungicide

TABLE OF CONTENTS

BACKGROUND

Extract from tea tree.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].

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

Latvia being the designated rapporteur Member State submitted the DAR on extract from tea tree.in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 25 October 2007 (Latvia, 2007). The peer review was initiated on 18 June 2008 by dispatching the DAR for consultation of the notifier (SIA 'Biomor Latvija'; the new notifier from 04/2010 is 'Biomor Europe Ltd.') Subsequently the DAR was dispatched for consultation of the Member States on 24 February 2011. 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 20 June 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November/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 a fungicide on potatoes, carrots, herbs, cucumber, watermelons, tomatoes, pepper and ornamentals 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 (20 June 2011)
- the Evaluation Table (12 December 2011)
- the report of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the points of clarification (where relevant),
- the comments received on the draft EFSA conclusion.

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

Extract from tea tree is the name of the substance under consideration there is no ISO common name for this mixture of compounds. A number of the constituents of extract from tea tree have one or more asymmetric carbon atoms, so enantiomers and diastereoisomers are present in the mixture as applied. A number of the risk characterisations presented in this conclusion do not address the potential for change in enantiomer ratios of pertinent constituents following use.

The representative formulated product for the evaluation was 'Timorex' an emulsifiable concentrate (EC) containing 622.4 g/l tea tree oil.

The representative uses evaluated comprise indoor foliar spraying against powdery mildew in cucumber and tomato and outdoor foliar spraying on potato, carrots, herbs, cucumber, tomato, pepper, ornamentals and watermelon also for powdery mildew control. 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 document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000)

The tea tree oil has been shown to comply with ISO 4730:2004. There is no FAO specification. A data gap was identified to validate the method used in the GLP batch analysis study as well as for spectra of the marker compounds.

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

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

It should be noted for the formulation that the data on surface tension and viscosity for R65 classification are not available. Data gaps were identified for accelerated and shelf life storage studies and the flash point.

Depending on the outcome of the metabolism data gap identified monitoring method for products of plant and animal origin may be a data gap in the future. Methods of analysis for appropriate marker compounds in environmental compartments are a data gap. A method for body fluids and tissues is not required as extract from tea tree is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: SANCO/222/2000 rev. 7 (European Commission, 2004b).

Extract from tea tree was discussed at the Pesticides Peer Review Meeting 88 in September 2011.

It is unknown whether the toxicological batches are representative of the technical specification as their complete composition is not available. The relevance of impurities and components of the mixture has not been assessed. A data gap has been identified to address this issue.

Studies performed with extract from tea tree were limited to acute toxicity and two genotoxicity studies. A short summary of reports regarding some components of extract from tea tree were provided accounting between 8 to 50% of the whole mixture, that could not be assessed in detail. Data gaps were identified for *in vitro* genotoxicity investigation on mammalian cells gene mutation potential of extract from tea tree, and toxicological information that would allow to set reference values. It is unclear whether an acceptable daily intake (ADI) and acute reference dose (ARfD) are required, once residue data are missing to assess the consumer exposure. No conclusion could be reached regarding operator, worker and bystander exposure risk assessment, as no acceptable operator exposure level (AOEL) could be determined. Considering the complete lack of data on toxicokinetic and metabolism, short-term, long-term, reproductive and developmental toxicity, a critical area of concern was identified.

3. Residues

The issue of plant metabolism data was raised in the commenting period by EFSA. In the evaluation table the rapporteur Member State agreed with the data gap proposed by EFSA. It was agreed that without further data no conclusion can be drawn. A valid risk assessment cannot be conducted leading to a critical area of concern for the consumer risk assessment. Subject to the data gap for elucidation of the relevant residue in plants, all of the other data in the residues area will have to be re-assessed.

4. Environmental fate and behaviour

Extract from tea tree is made up of the 15 components (see sections 1 and 6 of this conclusion). Information was not available on the route and rate of degradation of any of these components in soil (see section 7 where a consequent data gap is indicated). The available measured and quantitative structure activity relationship (QSAR) estimates of the vapour pressures of these components were considered sufficient to conclude that persistence in soil for 10 of these components would be low (see section 6.1). For the components globulol and viridiflorol, that have lower vapour pressures, it cannot be excluded with the available information, that they would exhibit moderate to high persistence in soil (see section 6.1). Four of these 12 components were immobile in soil with the remaining 8 exhibiting low to slight soil mobility (see section 6.2). The component alpha-terpineol, exhibited very high soil mobility, with tirpenene-4-ol and 1,8-cineole exhibiting high mobility. These mobility classifications are all based on QSAR estimated soil adsorption (K_{doc}) values. Due to the higher soil mobility of tirpenene-4-ol, alpha-terpineol and 1,8-cineole (these last three making up the balance of the 15 components), to better characterise their leaching potential, data gaps have been identified for soil DT estimates for these components, that would enable FOCUS groundwater simulations to be completed for these three components (see section 7). Consequent to these data gaps the groundwater exposure assessment for the components tirpenene-4-ol, alpha-terpineol and 1,8-cineole could not be finalised. Also the need for potential soil transformation products of globulol and viridiflorol (the least volatile components) to be further assessed could not concluded upon.

Information was not available on the route and rate of degradation of any of the 15 active substance components in natural sediment water systems (see section 7 where a consequent data gap is indicated). Appropriate predicted environmental concentrations (PEC) in surface water and sediment from the outdoor (field) representative uses applied for were not available as only spray drift as an annual total load had been assessed. To be appropriate, PEC in surface water and sediment from these outdoor uses, need to follow FOCUS (2001) and FOCUS (2008) guidance. This guidance clarifies that in addition to spray drift, short range atmospheric deposition and drainage or runoff from soil have to be assessed. Consequent data gaps are therefore identified in section 7. Consequently the aquatic exposure and risk assessments for the field uses could not be finalised. For the representative protected

crop uses, the necessary surface water and sediment exposure assessments (PEC) were carried out using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator), which was then modified by post processing the spray drift input results (option no runoff or drainage was selected) to obtain a 0.1 % emission of each extract from tea tree component from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate, except when applications are made with ultra low volume application techniques when 0.2% emission is prescribed. It has to be concluded that even for the glasshouse uses, the exposure assessment for potential surface water system transformation products could not be finalised. This conclusion is considered most pertinent for the potential transformation products of the active substance components globulol and viridiflorol, that have the lower vapour pressures.

All 15 components of extract from tea tree will be present in the atmosphere as a consequence of their volatilisation from soil and plant surfaces (the relatively high vapour pressures of each component are indicated in section 6.1 or appendix A) or as a consequence of aerosols that may be formed at the time of spraying. Appropriate QSAR calculations following the methods of Atkinson are available to indicate that no component would be expected to be prone to long range atmospheric transport, as all half lives estimated for conditions in the upper atmosphere were less than 48 hours (the longest value was for viridiflorol estimated as *ca.* 7.hours).

PEC are included in appendix A for soil consequent to all representative uses and surface water and sediment consequent to the representative uses requested when crops are grown under protection.

5. Ecotoxicology

For the risk assessments the following documents were considered: European Commission 2002a and 2002c.

It is noted that it is unknown whether the batches used in the (eco)toxicological studies are representative of the technical specification (see relevant data gap in section 2). It is also noted that given the high volatility of terpenes (the constituents of extract from tea tree), in addition to the standard routes of exposure, the inhalation route of exposure for terrestrial organisms may also be relevant.

The available studies revealed relatively low acute toxicity to **birds and mammals**. Based on the first tier risk assessments, high acute risk to birds however could not be excluded. It is noted however that these assessments based on a study where the exact level of toxicity was not established (there was no mortality observed at the highest dose tested). No short-term or long-them data or the associated assessments were available. Also no assessments for the exposure route via consumption of contaminated water or assessments for the potential bioaccumulation were available. Therefore a data gap was identified for all these issues discussed above regarding the open field uses. For the greenhouse uses the risk to birds and mammals was considered as low.

No reliable data were available for **aquatic organisms** therefore no risk assessments were performed. A data gap for the necessary data and the associated risk assessments was therefore identified.

Only an acute oral endpoint was available for **honeybees**. Based on this data, the risk to honeybees was concluded to be low. A data gap was identified for risk assessments considering the contact route of exposure.

No reliable data were available for **non-target arthropods** and for **earthworms** or non target soil macro-organisms therefore no risk assessments were performed. Relevant data gaps for these issues were therefore identified.

Regarding the potential effects of the constituents of extract from tea tree to microorganisms, some data (that were submitted for the evaluation of the behaviour of the constituents in soil) indicated that some micro-organisms isolated from soils were capable of degrading several terpenes within a reasonable time frame. Additionally some terpenes were demonstrated as readily biodegradable in activated sludge. Reliable data for soil processes like **nitrogen transformation** or **carbon mineralisation** were however not available except for a few constituents of extract from tea tree only for nitrogen transformation. These data indicated no significant impact on the nitrogen transformation in soil. Relevant data gaps for assessments of potential effects of all the constituents of extract from tea tree on nitrogen transformation and carbon mineralization were identified. Also, no specific data or reliable assessments were available for the potential effects of the constituents of extract from tea tree on the **biological methods of sewage treatment**, although, as discussed above, some available data indicated that some terpenes can be decomposed by microorganisms. Moreover the constituents of extract from tea tree are considered as relatively volatile. Regarding the representative field uses, the exposure of sewage treatment plants was expected to be low. This was however not the case for the greenhouse uses where the sewage might reach the sewage treatment plants directly via closed systems. A data gap for an assessment for the potential effects on biological methods for sewage treatments for the greenhouse uses was therefore identified. The risk regarding the open field uses was considered to be low.

The risk to **non-target terrestrial plants** was considered to be 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
terpinene-4-ol	Data gap, for DT50 values, considered necessary to address the leaching risk, see 6.2 below.	Data gap
gamma- terpinene	Information not available from studies in soil, but argumentation based on measured vapour pressure (103 Pa at 23.5ºC) was accepted as sufficient to conclude low persistence	Data gap
alpha-terpinene	Information not available from studies in soil, but argumentation based on QSAR estimated vapour pressure (106 Pa at 20ºC) was accepted as sufficient to conclude low persistence	Data gap
alpha-terpineol	Data gap, for DT50 values, considered necessary to address the leaching risk, see 6.2 below.	Data gap
alpha-terpinolene	Information not available from studies in soil, but argumentation based on QSAR estimated vapour pressure (79 Pa at 25ºC) was accepted as sufficient to conclude low persistence	Data gap
alpha-pinene	Information not available from studies in soil, but argumentation based on measured vapour pressure (544 Pa at 23.5ºC) was accepted as sufficient to conclude low persistence	Data gap

p-cymene	Information not available from studies in soil, but argumentation based on measured vapour pressure (199.5 Pa at 25ºC) was accepted as sufficient to conclude low persistence	Data gap
1,8- cineole (eucalyptol)	Data gap, for DT50 values , considered necessary to address the leaching risk, see 6.2 below.	Data gap
limonene	Information not available from studies in soil, but argumentation based on measured vapour pressure (202 Pa at 23.5ºC) was accepted as sufficient to conclude low persistence	Data gap
aromadendrene	Information not available from studies in soil, but argumentation based on QSAR[15] estimated vapour pressure (3.1 Pa at 20ºC) was accepted as sufficient to conclude low persistence	Data gap
delta-cadinene	Information not available from studies in soil, but argumentation based on QSAR[16] estimated vapour pressure (0.68 Pa at 20ºC) was accepted as sufficient to conclude low persistence	Data gap
sabinene	Information not available from studies in soil, but argumentation based on QSAR[17] estimated vapour pressure (726 Pa at 20ºC) was accepted as sufficient to conclude low persistence	Data gap

[15] MPBPWIN v1.43 contained in EPIWEB 4.1 copyright US EPA (presented by EFSA)
[16] MPBPWIN v1.43 contained in EPIWEB 4.1 copyright US EPA (presented by EFSA)
[17] MPBPWIN v1.43 contained in EPIWEB 4.1 copyright US EPA (presented by EFSA)

globulol	Information not available from studies in soil, QSAR[18] estimated vapour pressure (0.0166 Pa at 20ºC), from the representative uses individual application are up to 26.4 g/ha, therefore PEC soil have been based on annual total dose, persistence needs to be considered moderate to high	Data gap
viridiflorol	Information not available from studies in soil, QSAR[19] estimated vapour pressure (0.008 Pa at 20ºC), from the representative uses individual application are up to 26.4 g/ha, therefore PEC soil have been based on annual total dose, persistence needs to be considered moderate to high	Data gap
ledene	Information not available from studies in soil, but argumentation based on QSAR[20] estimated vapour pressure (1.57 Pa at 20ºC) was accepted as sufficient to conclude low persistence	Data gap

6.2. Ground water

Compound (name and/or code)	**Mobility in soil (based on QSAR estimates)**	**>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
terpinene-4-ol	High mobility K_{doc} 61.5 mL/g	Data gap	Yes	No data, data may be required	Data gap

[18] MPBPWIN v1.43 contained in EPIWEB 4.1 copyright US EPA (presented by EFSA)
[19] MPBPWIN v1.43 contained in EPIWEB 4.1
[20] MPBPWIN v1.43 contained in EPIWEB 4.1

gamma- terpinene	Slight mobility K_{doc} 2886 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
alpha-terpinene	Low mobility K_{doc} 1324 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
alpha-terpineol	Very high mobility K_{doc} 7 mL/g	Data gap	Yes	No data, data may be required	Data gap
alpha-terpinolene	Slight mobility K_{doc} 2632 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
alpha-pinene	immobile K_{doc} 6495 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
p-cymene	Slight mobility K_{doc} 4732 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap

1,8- cineole (eucalyptol)	High mobility K_{doc} 106.7 mL/g	Data gap	Yes	No data, data may be required	Data gap
limonene	Slight mobility K_{doc} 4821 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
aromadendrene	immobile K_{doc} 18430 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
delta-cadinene	immobile K_{doc} 19800 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap
sabinene	Low mobility K_{doc} 1077 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, nor required	Data gap
globulol	Low mobility K_{doc} 1306 mL/g	No, expert judgement based on application amount and mobility classification.	Yes	No data, not required	Data gap

viridiflorol	Low mobility K_{doc} 1240 mL/g	No, expert judgement based on application amount and mobility classification.	Yes	No data, not required	Data gap
ledene	immobile K_{doc} 18430 mL/g	No, expert judgement based on application amount, mobility classification and vapour pressure.	Yes	No data, not required	Data gap

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
terpinene-4-ol	Data gap
gamma- terpinene	Data gap
alpha-terpinene	Data gap
alpha-terpineol	Data gap
alpha-terpinolene	Data gap
alpha-pinene	Data gap
p-cymene	Data gap
1,8- cineole (eucalyptol)	Data gap
limonene	Data gap

aromadendrene	Data gap
delta-cadinene	Data gap
sabinene	Data gap
globulol	Data gap
viridiflorol	Data gap
ledene	Data gap

6.4. Air

Compound (name and/or code)	**Toxicology**
terpinene-4-ol	No data
gamma- terpinene	No data
alpha-terpinene	No data
alpha-terpineol	No data
alpha-terpinolene	No data
alpha-pinene	No data
p-cymene	No data
1,8- cineole (eucalyptol)	No data
limonene	No data

aromadendrene	No data
delta-cadinene	No data
sabinene	No data
globulol	No data
viridiflorol	No data
ledene	No data

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).

- Validation of the method used in the GLP batch analysis study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Spectra for the marker compounds (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Flash point of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Accelerated and shelf life storage studies for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Methods of analysis for appropriate marker compounds in environmental compartments (relevant for all edible crop uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Plant metabolism data, subject to the outcome of this data further data gaps may be identified (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1 and 3)
- Composition of the batches used in the toxicological studies and an assessment of the toxicological relevance of impurities and components of tea tree oil mixture (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2)
- Sufficient toxicological information to allow the derivation of reference values – ADI, ARfD, AOEL, including an investigation of *in vitro* mammalian cell gene mutation potential (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2)
- Information on the route and rate of degradation of components of extract from tea tree in soil or information on natural background levels that may be present in soil that were eligible to be considered by the peer review were not available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Information on the route and rate of degradation of components of extract from tea tree in natural surface water systems **or** information on natural background levels that may be present in such systems that were eligible to be considered by the peer review were not available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Appropriate PEC in surface water and sediment from the outdoor (field) representative uses applied for were not available that include short range atmospheric deposition and drainage or runoff from soil (currently only spray drift as an annual total load has been assessed), (relevant for all representative uses outdoors; submission date proposed by the notifier: unknown, though it has been indicated that for the EU level assessment field uses are no longer defended; see section 4)
- Information on the potential for groundwater exposure for soil transformation products of components of extract from tea tree were not available. Soil DT estimates for components of extract from tea tree that are less strongly adsorbed (terpinene-4-ol, alpha-terpineol & 1,8-cineole),

are necessary to finalise the groundwater exposure assessment, that when completed should follow up to date FOCUS groundwater guidance (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- Long-term and short-term risk assessments for birds and long-term risk assessment for mammals. Additionally, the risk assessment for acute scale for birds should be further addressed (relevant for all representative uses outdoors; submission date proposed by the notifier: unknown; see section 5)

- Reliable toxicological data set for aquatic organisms and the subsequent risk assessments (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for honeybees considering the contact route of exposure (relevant for all representative uses evaluated; submission date proposed by the notifier: it was indicated that a new study is already available on a formulation; see section 5)

- Risk assessment for non-target arthropods (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for earthworms and non target soil macro-organisms (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for non target soil micro-organisms (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for biological methods for sewage treatments (relevant for the greenhouse uses evaluated; 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. The consumer risk assessment cannot be finalised as the identity of the residue is unknown.

2. The groundwater exposure assessment for tirpenene-4-ol, alpha-terpineol and 1,8-cineole could not be finalised

3. The groundwater and soil exposure assessments from potential soil transformation products of globulol and viridiflorol (if any would be formed) could not be finalised. Consequently the risk assessment to soil dwelling organisms from exposure to transformation products of globulol and viridiflorol for the representative uses could not be finalised.

4. The exposure assessment for aquatic systems (for all active substance components and potential transformation products of globulol and viridiflorol, if any would be formed in soil or surface water systems) could not be finalised for the representative outdoor field uses. Consequently the aquatic risk assessment for the representative outdoor field uses could not be finalised.

5. The exposure assessment for aquatic systems for potential transformation products of globulol and viridiflorol, (if any would be formed in soil or surface water systems) could not be finalised for the representative protected uses. Consequently the aquatic risk assessment from exposure to transformation products of globulol and viridiflorolfor the representative protected uses could not be finalised.

6. The ecotoxicological risk assessment for birds and mammals, aquatic organisms, honeybees and other non-target arthropods, earthworms and non-target soil macro and micro-organisms for the representative outdoor uses could not be finalised.

7. The ecotoxicological risk assessment for aquatic organisms honeybees and other non-target arthropods, earthworms and non-target soil macro and micro-organisms and for the potential effects on the biological methods of sewage treatment for the representative protected uses could not 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.

8. No reference values could be derived due to the insufficient toxicological data base, considering the complete lack of data on toxicokinetic and metabolism, short-term, long-term, reproductive and developmental toxicity.

9. Operator, worker and bystander exposure risk assessment and the consumer risk assessment could not be assessed as no reference values could be derived.

9.3. Overview of the concerns for each representative use considered

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

All columns are grey as the technical material specification proposed could not be compared to the material tested.

Representative use		Field application to potato	Field application to carrots	Field application to herbs	Field application to cucumber	Field application to watermelon
Operator risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]	X[8,9]	X[8,9]
Worker risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]	X[8,9]	X[8,9]
Bystander risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]	X[8,9]	X[8,9]
Consumer risk	Risk identified					
	Assessment not finalised	X[1,8]	X[1,8]	X[1,8]	X[1,8]	X[1,8]
Risk to wild non target terrestrial vertebrates	Risk identified					
	Assessment not finalised	X[6]	X[6]	X[6]	X[6]	X[6]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[3,6]	X[3,6]	X[3,6]	X[3,6]	X[3,6]
Risk to aquatic organisms	Risk identified					
	Assessment not finalised	X[4,6]	X[4,6]	X[4,6]	X[4,6]	X[4,6]
Groundwater exposure active substance	Legal parametric value breached					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure metabolites	Legal parametric value breached					
	Parametric value of 10µg/L[(a)] breached					
	Assessment not finalised	X[3]	X[3]	X[3]	X[3]	X[3]
Comments/Remarks						

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2
Where there is no superscript number see sections 2 to 6 for further information
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

Representative use		Field application to tomato	Field application to pepper	Field application to ornamentals	Application to protected cucumber	Application to protected tomato
Operator risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]	X[8,9]	X[8,9]
Worker risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]	X[8,9]	X[8,9]
Bystander risk	Risk identified					
	Assessment not finalised	X[8,9]	X[8,9]	X[8,9]		
Consumer risk	Risk identified					
	Assessment not finalised	X[1,8]	X[1,8]		X[1,8]	X[1,8]
Risk to wild non target terrestrial vertebrates	Risk identified					
	Assessment not finalised	X[6]	X[6]	X[6]		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[3,6]	X[3,6]	X[3,6]	X[3,7]	X[3,7]
Risk to aquatic organisms	Risk identified					
	Assessment not finalised	X[4,6]	X[4,6]	X[4,6]	X[5,7]	X[5,7]
Groundwater exposure active substance	Legal parametric value breached					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure metabolites	Legal parametric value breached					
	Parametric value of 10µg/L[(a)] breached					
	Assessment not finalised	X[3]	X[3]	X[3]	X[3]	X[3]

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2
Where there is no superscript number see sections 2 to 6 for further information
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

Latvia, 2007. Draft Assessment Report (DAR) on the active substance extract from tea tree prepared by the rapporteur Member State Latvia in the framework of Directive 91/414/EEC, October 2007.

Latvia, 2011. Final Addendum to Draft Assessment Report on extract from tea tree., compiled by EFSA, November 2011.

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

European Commission, 2008. Review Report for the active substance extract from tea tree finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 1 August 2008 in view of the inclusion of extract from tea tree in Annex I of Directive 91/414/EEC, SANCO/2609/08 –rev. 1, 1 August 2008

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

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, 2004b. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

FOCUS (2001). “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

FOCUS (2008). “Pesticides in Air: Considerations for Exposure Assessment”. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 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.

OECD (Organisation for Economic Co-operation and Development), 2006. Guidance Document on Overview of Residue Chemistry Studies. ENV/JM/MONO(2006)32, 10 October 2006.

APPENDICES

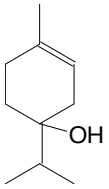
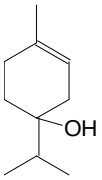
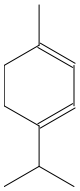
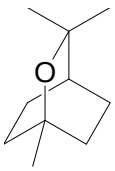
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Tea Tree Oil
Function (*e.g.* fungicide)	Fungicide
Rapporteur Member State	Latvia
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Tea Tree Oil is a complex mixture of chemical substances. List of endpoints is limited to 4 major constituents: terpinene-4-ol (30-48%) 1-methyl-4-isopropyl-1-cyclohexen-4-ol gamma-terpinene (10-28%) 1-methyl-4-isopropyl-1,4-cycloheyadiene alpha-terpinene (5-13) 1-methyl-4-isopropyl-1,3-cyclohexadiene 1,8-cineole (0.1-15%) 1,33-trimethyl-2-oxabicyclo[2.2.2]octane
Chemical name (CA) ‡	
CIPAC No ‡	Not applicable
CAS No ‡	Tea Tree Oil 68647-73-4 terpinene-4-ol 562-74-3 gamma-terpinene 99-85-4 alpha-terpinene 99-86-5 1,8-cineole 470-82-6
EC No (EINECS or ELINCS) ‡	Tea Tree Oil 285-377-1 terpinene-4-ol 209-235-5 gamma-terpinene 202-794-6 alpha-terpinene 202-795-1 1,8-cineole 207-431-5
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured ‡	terpinene-4-ol 300 g/kg gamma-terpinene 100 g/kg alpha-terpinene 50 g/kg 1,8-cineole 1 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	-
Molecular formula ‡	Not relevant for Tea Tree Oil terpinene-4-ol $C_{10}H_{18}O$ gamma-terpinene $C_{10}H_{16}$ alpha-terpinene $C_{10}H_{16}$ 1,8-cineole $C_{10}H_{18}O$
Molecular mass ‡	Not relevant for Tea Tree Oil terpinene-4-ol 154.25 g/mol gamma-terpinene 138.25 g/mol alpha-terpinene 138.25 g/mol 1,8-cineole 154.25 g/mol
Structural formula ‡	Not relevant for Tea Tree Oil terpinene-4-ol  gamma-terpinene  alpha-terpinene  1,8-cineole 

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Not available for Tea Tree Oil (TTO is known to be a liquid at ambient temperature, therefore, melting point is ambient temperature)
Boiling point (state purity) ‡	Not available for Tea Tree Oil (based on the available data for the components Tea Tree Oil is expected to have a boiling point of ca 200 °C)
Temperature of decomposition (state purity)	Not specified
Appearance (state purity) ‡	Clear liquid (technical Tea Tree Oil)
Vapour pressure (state temperature, state purity) ‡	Not available for Tea Tree Oil (based on the values reported for the individual components TTO is expected to be volatile). terpinene-4-ol 53.2 Pa at 20°C* 14.9 Pa at 20°C (97%) (experimental) gamma-terpinene 93.1 Pa at 20°C* 103 Pa at 23.5°C alpha-terpinene 106.4 Pa at 20°C* 1,8-cineole 253 Pa at 25°C alpha terpineol 5.69 Pa at 23.5°C* (98%) (experimental) * *calculations using EPI suite*
Henry's law constant ‡	Not available for Tea Tree Oil terpinene-4-ol 4.64 Pa m^3 mol^{-1}* 699.5 Pa L mol^{-1} (based on experimental values gamma-terpinene 1476 Pa m^3 mol^{-1}* alpha-terpinene 2485 Pa m^3 mol^{-1}* 1,8-cineole 71 Pa m^3 mol^{-1}* **calculations of water solubility and/or vapour pressure*
Solubility in water (state temperature, state purity and pH) ‡	Not available for Tea Tree Oil terpinene-4-ol 1767 mg/L* 3280 mg/L (20°C, 97%, pH 5.85) (experimental) gamma-terpinene 8.72 mg/L at 22-25°C alpha-terpinene 5.92 mg/L* 1,8-cineole 552 mg/L* **calculations using EPI suite*

Solubility in organic solvents ‡ (state temperature, state purity)	Tea Tree Oil Miscibility with 85% ethanol at 20 °C 0.7 No values available for individual components
Surface tension ‡ (state concentration and temperature, state purity)	45.6 mN/m (1%, 20 °C, TTO batch 011204)
Partition co-efficient ‡ (state temperature, pH and purity)	Not available for Tea Tree Oil terpinene-4-ol Log Kow 3.33* Log K_{OW} 2.643 (23.5°C, experimental) gamma-terpinene Log Kow 4.47 (purity 97%) alpha-terpinene Log Kow 4.75* alpha-terpineol Log K_{OW} = 2.98 alpha-terpinolene* Log K_{OW} = 4.88 alpha-pinene Log K_{OW} = 4.83 *p*-cymene Log K_{OW} = 4.44 1,8-cineole Log Kow 3.13* limonene Log K_{OW} = 4.57 * *calculations using EPI suite*
Dissociation constant (state purity) ‡	No dissociation expected based on the molecular structures of compounds.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No data provided
Flammability ‡ (state purity)	55 °C (Tea Tree Oil batch 011204)
Auto-flammability (state purity)	269 °C (Tea Tree Oil batch 011204)
Explosive properties ‡ (state purity)	Not explosive theoretical argument
Oxidising properties ‡ (state purity)	Not oxidising theoretical argument

Summary of intended uses evaluated (Tea tree oil/'Timorex') (Annex IIA, point 3)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or group controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number, min/max (k)	Interval between applic. (min)	4 as/hL (l) 5 min – max	6 ater L/ha 7 min – max	kg as/ha min max		
Potato	Northern, Southern Europe	Timorex	F	Early blight	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	
Carrots	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	
Herbs	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	
Cucumber	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	61-89	3	7-10 days	0.622	150-400	0.934-2.5	1	
Cucumber	Northern Europe	Timorex	G	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	61-89	3	7-10 days	0.311	500-800	1.56-2.5	2	

Crop and/or situation (a)	Member State or Country	Product name	FG or I (b)	Pests or group controlled (c)	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number, min/max (k)	Interval between applic. (min)	4 as/hL (l) 5 min – max	6 ater L/ha 7 min – max	kg as/ha min max	(l)	(m)
Cucumber	Southern Europe	Timorex	G	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	71-77	3	7-10 days	0.311	500-800	1.56-2.5	2	
Watermelon	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	
Tomato	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	71-89	3	7-10 days	0.622	150-400	0.934-2.5	1	
Tomato	Northern Europe	Timorex	G	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	61-71	3	7-10 days	0.311	500-800	1.56-2.5	1	
Tomato	Southern Europe	Timorex	G	Powdery mildew	EC	622.4 g/l (660 g/kg)	Foliar sprayer	65-83	3	7-10 days	0.311	500-800	1.56-2.5	1	
Pepper	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or group controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number, min/max (k)	Interval between applic. (min)	4 as/hL (l) 5 min – max	6 ater L/ha 7 min – max	kg as/ha min max		
Ornamentals	Northern, Southern Europe	Timorex	F	Powdery mildew	EC	660 g/kg	Foliar sprayer	nr	3	7 days	0.66	400	2.64	3	

* For uses where the column "Remarks" is marked in grey further consideration is necessary.
Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

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

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

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	GC-FID European Pharmacopoeia 01/2005: 1837 & ISO 11024-1 11024-2
Impurities in technical as (analytical technique)	GC-FID European Pharmacopoeia 01/2005: 1837 & ISO 11024-1 11024-2
Plant protection product (analytical technique)	Same GC-FID method employed for technical as (not validated)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Due to the lack of metabolism in plants, a conclusion cannot be made.
Food of animal origin		Due to the lack of metabolism in plants, a conclusion cannot be made.
Soil		Open
Water	surface	Open
	drinking/ground	Open
Air		Open

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Due to the lack of metabolism in plants, a conclusion cannot be made.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Due to the lack of metabolism in plants, a conclusion cannot be made.
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 as tea tree oil is not classified as toxic or very toxic.

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

	RMS/peer review proposal
Active substance	Tea Tree Oil is classified as flammable based on its physical/chemical properties.

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	No valid data - Because of its lipophilic nature, Tea Tree Oil is assumed to be readily absorbed by dermal and by oral routes.
Distribution ‡	No valid data
Potential for accumulation ‡	No valid data
Rate and extent of excretion ‡	No valid data
Metabolism in animals ‡	No valid data
Toxicologically relevant compounds ‡ (animals and plants)	Tea Tree Oil
Toxicologically relevant compounds ‡ (environment)	Tea Tree Oil

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1682-1721 mg/kg bw	**Xn R22**
Rat LD_{50} dermal ‡	> 2,000 mg/kg bw (rabbits)	
Rat LC_{50} inhalation ‡	No data	
Skin irritation ‡	Irritant	**Xi R38**
Eye irritation ‡	Irritant	**Xi R41**
Skin sensitisation ‡	Not sensitising (Magnusson & Kligman) Sensitising to human skin (based on clinical cases and poisoning incidents)	**R43**

Short term toxicity (Annex IIA, point 5.3)

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

Genotoxicity ‡ (Annex IIA, point 5.4)

Not mutagenic *in vitro* (Ames test) and *in vivo* (micronucleus assay); investigation on *in vitro* mammalian cell gene mutation required	

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

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

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

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

Developmental toxicity

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

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available; not suspected to possess neurotoxic/ delayed neurotoxic potential based on chemical structure	
Repeated neurotoxicity ‡	No data	
Delayed neurotoxicity ‡	No data	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	30-day dermal irritation study in rabbits: Hyperplastic dermatitis observed at 25 % in paraffin oil B.P.
Studies performed on metabolites or impurities ‡	No data

Medical data ‡ (Annex IIA, point 5.9)

Skin irritation and skin sensitization in susceptible humans after dermal contact. Reversible neurological effects such as ataxia, unresponsiveness and drowsiness following ingestion of Tea Tree Oil; one case of coma and disturbances of consciousness reported after ingestion of half a cup of tea tree oil.

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Timorex 660 g/kg EC)	No valid data; because of its lipophilic nature, Tea Tree Oil is assumed to be readily absorbed through the skin. 100% default value

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Exposure risk assessment could not be concluded as no AOEL could be set.
Workers	Exposure risk assessment could not be concluded as no AOEL could be set.
Bystanders	Exposure risk assessment could not be concluded as no AOEL could be set.

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

RMS/peer review proposal

Tea tree oil	**Xn** "harmful" **R22** "harmful if swallowed" **R38** "irritating to skin" **R41** "risk of serious damage to eyes" **R43** "may cause sensitisation by skin contact"

Residues

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

PRAPeR 88: "Based on the actual residue situation, the need for setting an ADI and ARfD should be considered. If there is in fact no dietary exposure, it is not necessary to establish such reference values for Annex I inclusion.". The conclusion from DAR addenda/revision August 2011 was that due to insufficient data package for metabolism in plants and fate and behaviour, conclusion on the relevance of dietary exposure cannot be made.

Plant groups covered	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Rotational crops	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Metabolism in rotational crops similar to metabolism in primary crops?	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Processed commodities	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Plant residue definition for monitoring	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Plant residue definition for risk assessment	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Conversion factor (monitoring to risk assessment)	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.

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

Animals covered	Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.
Time needed to reach a plateau concentration in milk and eggs	-
Animal residue definition for monitoring	-
Animal residue definition for risk assessment	-
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	Based on Log P_{ow} values for most components being > 3 residue is expected to be fat soluble

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

Due to insufficient data package for metabolism in plants and fate and behaviour conclusion on the relevance of dietary exposure cannot be made.

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

Trials analysed within 30 days

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information (a)	Trials results relevant to the representative uses	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Tomato	Glass house	2 × < 0.05		None proposed	< 0.05	< 0.05
Cucumber	Glass house	2 × < 0.05		None proposed	< 0.05	< 0.05

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

[3] MRL proposal derived from supervised residue trials according to Guidance Document Appendix I. When the MRL is estimated at the LOQ, this should be annotated by an asterisk after the figure.
[4] STMR value from results of supervised residue trials.
[5] If several representative uses or European regions are foreseen for one crop, one row must be used for each specific situation
[6] For some crop/pesticide combinations, the residue definition for monitoring and RA may differ. If trials are reported in this table with analysis of the residues accordingly to both definitions, the results are reported in the format x(y), x being the result according to the definition for monitoring and y the result according to the definition for RA. The same applies for the HR and the STMR

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

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

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

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

Due to insufficient data package for metabolism in plants, conclusion on the relevance of dietary exposure can not be made.

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
-	None			

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

Proposed MRLs	
Tomatoes.	Due to insufficient data package for metabolism in plants, conclusion on the relevance of dietary exposure cannot be made.
Cucumber	Due to insufficient data package for metabolism in plants, conclusion on the relevance of dietary exposure cannot be made.

Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	Not available
Non-extractable residues after 100 days ‡	Not available
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not available

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

Anaerobic degradation ‡

Mineralization after 100 days	Not available
Non-extractable residues after 100 days	Not available
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not available

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not available

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

Laboratory studies ‡

Parent	Aerobic conditions
Not relevant for Tea Tree Oil because it is a mixture of components. Data not available for any components of Tea Tree Oil.	

Field studies ‡

Parent	No data available, not required

pH dependence ‡ (yes / no) (if yes type of dependence)	Not available
Soil accumulation and plateau concentration ‡	Not relevant

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡

Not relevant for Tea Tree Oil because it is a mixture of components.

For constituents of Tee Tree Oil:

[a)]Koc values have been calculated according equation published in Wauchope *et al.* (2002):
log Koc = 0.4507 log Kow - log Sw + 2.3739

[b)] Results calculated using EPI-suite (v3.12)

c)Results determined via EPI-Suite (v4.10) calculations

Compound	**Estimated log Koc**	**Estimated Koc, mL g^{-1}**
terpinene-4-ol	1.786 [b)]	61.15 [b)]

gamma-terpinene	3.460 [a)]	2886 [a)]
alpha-terpinene	3.122 [b)]	1324 [b)]
alpha-terpineol	0.865 [a)]	7 [a)]
alpha-terpinolene	3.420 [a)]	2632 [a)]
alpha-pinene	3.813 [a)]	6495 [a)]
p-cymene	3.675 [a)]	4732 [a)]
1,8-cineole	2.028 [b)]	106.7 [b)]
limonene	3.683 [a)]	4821 [a)]
sabinene	3.032 [c)]	1077 [c)]
aromadendrene	4.265 [c)]	18430 [c)]
delta-cadinene	4.296 [c)]	19800 [c)]
ledene	4.265 [c)]	18430 [c)]
globulol	3.115 [c)]	1306 [c)]
viridiflorol	3.093 [c)]	1240 [c)]

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

Column leaching ‡	Not available
Aged residues leaching ‡	Not available
Lysimeter/ field leaching studies ‡	Not available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): not available, but due to high vapour pressures all components except globulol and viridiflorol assumed to volatilize completely between applications. For globulol and viridiflorol, it was assumed there was no dissipation.
Application data	Crop: bare soil Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0% crop interception Number of applications: 3 Interval (d): 7 Application rate(s): 2640 g as/ha

Compound	Max % in TTO	Application rate [g a.s./ha] per treatment	Initial PECs [mg/kg] expected following 3 treatments
Tea Tree Oil	**100**	**2640**	**3.66***
terpinene-4-ol	48	1267.2	1.690
gamma-terpinene	28	739.2	0.986
alpha-terpinene	13	343.2	0.458
alpha-terpineol	8	211.2	0.282
alpha-terpinolene	5	132	0.176
alpha-pinene	6	158.4	0.211
p-cymene	8	211.2	0.282
1,8-cineole (Eucalyptol)	15	396	0.528
d-limonene	1,5	39.6	0.053
aromadendrene	3	79.2	0.106
delta-cadinene	3	79.2	0.106
sabinene	3,5	92.4	0.123
globulol	1	3x26.4	0.105
viridiflorol	1	3x26.4	0.105
ledene	3	79.2	0.106

* The value for total tea tree oil in row 1 is the sum of all the individual components, so assumes no additive residue from the three applications (due to volatlisation) except for globulol and viridiflorol (Calculated using the formula ($2640/750000-0.105/3_{\text{globulol one app}}-0.105/3_{\text{viridiflorol one app}}+0.105_{\text{globulol three app}}+0.105_{\text{viridiflorol three app}}$), where 750000 is the factor for soil bulk density and depth of soil layer).

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Not available. Based on chemical structures main constituents of Tea Tree Oil are not hydrolysable
Photolytic degradation of active substance and metabolites above 10 % ‡	Not available
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not available
Readily biodegradable ‡ (yes/no)	Not applicable for Tea Tree Oil p-cymene, limonene, alpha-terpineol demonstrated as readily biodegradable. No information for other components.

Degradation in water / sediment

Parent	No data available

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

For field uses: Data gap

PEC surface water for glasshouse uses

Parameters used in FOCUSsw step 1 and 2	FOCUS Step 1&2 calculator version 1.1 Spring cereals selected, giving 2.759% drift. The result of the model (initial PECsw) was multiplied by 0.036245, resulting in the glasshouse emission redeposited on the FOCUS surface water body being 0.1% of the applied amount. Option no runoff or drainage was selected. (note for the initial PEC the calculator is insensitive to the substance properties entered, so any value entered results in the concentrations tabulated below).
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Annual total load as tabulated below for each tea tree oil constituent.

Compound	Max % in TTO	Max application rate per season [g a.s./ha]	Initial PECsw, [µg/L]
TTO	**100**	**7920**	**2.64**
Terpinene-4-ol	48	3801.6	1.267
gamma-terpinene	28	2217.6	0.739
alpha-terpinene	13	1029.6	0.343
alpha-terpineol	8	633.6	0.211
alpha-terpinolene	5	396.0	0.132
alpha-pinene	6	475.2	0.158
p-Cymene	8	633.6	0.211
1,8-Cineole (Eucalyptol)	15	1188.0	0.396
d-Limonene	1.5	118.8	0.040
Aromadendrene	3	237.6	0.079
delta-cadinene	3	237.6	0.079
Sabinene	3.5	277.2	0.092
Globulol	1	79.2	0.026
Viridiflorol	1	79.2	0.026
Ledene	3	237.6	0.079

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	FOCUS gw modelling not applicable to Tea Tree Oil because it is a mixture of components. Modelling for separate constituents not possible due to the lack of necessary input data. Data gaps for tirpene-4-ol, alpha terpineol and 1,8-cineole. Due to the combination of expected high soil adsorption and high vapour pressure (QSAR estimates), expert judgement was used to conclude low potential for groundwaterexposure for the representative uses assessed for the remaining components.

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

Direct photolysis in air ‡

Not available

Quantum yield of direct phototransformation

Not available

Photochemical oxidative degradation in air ‡

Lifetime with respect to reaction with*:

	OH^-	O_3	NO_3^-
d-Limonene	1.1 h	1.9 h	53 min
alpha-pinene	3.4 h	4.6 h	2.0 h
alpha-terpinene	31 min	3 min	4 min
gamma-terpinene	1.0 h	2.8 h	24 min
Terpinolene	49 min	17 min	7 min
1,8-Cineole	1.4 d	>110 d	7.8 yr
p-Cymene	1.0 d	>300 d	1.3 yr

* *literature data*

Half-lives (h) (calculated using EPI-suite) with respect to reactions with:

	OH^-	O_3
terpinene-4-ol	1.24	0.64
gamma-terpinene	0.72	0.32
alpha-terpinene	0.48	0.03
alpha-terpineol	1.25	0.64
alpha-pinene	1.30	0.64
limonene	0.88	0.62

Half-lives in air determined via EPI-Suite (v.4.10) calculations

Substance	Hydroxyl Radicals Reaction	Ozone Reaction (at 7E11 mol/cm3)
terpinen-4-ol	1.235 h	38.4 min
terpinolene	0.640 h	10.1 min

	α-pinene	1.414 h	38.4 min
	terpineol	1.245 h	38.4min
	y-terpinene	0.721 h	19.2 min
	α-terpinene	29.1 min	1.7 min
	p cymene	15.036 h	no est. made
	limonene	0.884 h	37.4 min
	1,8-cineole	5.687 h	no est. made
	sabinene	2.299 h	22.9 h
	aromadendrene	2.054 h	22.9 h
	δ-cad nene	0.609 h	10.1min
	ledene	1.081 h	13.8 min
	globulol	6.349 h	no est. made
	viridiflorol	7.431 h	no est. made

Volatilisation ‡	from plant surfaces: Not available
	from soil surfaces: Not available
Metabolites	Not available

PEC (air)

Method of calculation	Hydroxyl reaction and ozone reaction half-life were estimated to be 0.48-1.3 h and 0.3-0.64 h respectively, by EPI-suite calculations. The compounds will degrade quickly in the air and no significant residues are expected.

$PEC_{(a)}$

Maximum concentration	

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater.	Soil, surface water, sediment, ground water and air: all 15 constituents (terpenes) of TTO – terpinene-4-ol, gamma-terpinene, alpha-terpinene, alpha-terpineol, alpha-terpinolene, alpha-pinene, p-cymene, 1,8-cineole (eucalyptol), d-limonene, aromadendrene, delta-cadinene, sabinene, globulol, viridiflorol, ledene. Data gaps need to be filled before the definition of residues requiring further assessment for all compartments except air can be finalised (in particular potential transformation products of globulol and viridiflorol).

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)	-World wide; natural emission from forests and other vegetation- Terpenes 480 M tons/year. - U.S.A.; an estimated amount of 25 to 50 M tons terpenes/year are released into the athmosphere. This is equivalent to an average emission of ca. 0.071 to 0.142 g/ha/day. -UK; Foliage of *Picea sitchensis*- total monoterpenes 1290 µg/m²/h ((equivalent to 113 kg/ha/yr) -U.S.A.; coniferous and deciduous forests monoterpene emission rates - µg C/m2/h (at leaf tº of 30ºC) alpha-pinene 5.2 – 225 d-limonene 0.6 – 118 alpha-terpinene 0.1 – 11.8 p-cymene 0.5 – 28.4 Terpinolene 0.3 – 2.5 gamma-terpinene 0.016 – 0.8 total monoterpenes 20.5-825

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

Candidate for R53

Ecotoxicology

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)	End point (mg/kg feed)
Birds				
Coturnix coturnix japonica	Preparation "Timorex"	Acute	>1320 a.s. (>2000 prep.)	-
Mammals				
Rattus norvegicus	a.s. TTO	Acute	1682 a.s.	-
Rattus norvegicus	Preparation "Timorex"	Acute	> 2000 prep.	-
Additional higher tier studies				
No data available				

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

Crop and application rate

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivorous bird/ leafy crops	Acute	297	> 4.4	10
Insectivorous bird/leafy crops	Acute	142.77	> 9.3	10
Tier 1 (Mammals)				
Medium herbivorous mammal/ leafy crops	Acute	109	15.4	10

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				
				No reliable data available
Aquatic invertebrate				
				No reliable data available
Sediment dwelling organisms				
				No data. Not required.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Algae				
				No data. Not required.
Higher plant				
				No data. Not required.
Microcosm or mesocosm tests				
Data not required.				

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

Not available – data gap

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	Not submitted			
Bioconcentration factor (BCF)[1]	No data. Data gap			
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})	-			
(CT_{90})	-			
Level and nature of residues (%) in organisms after the 14 day depuration phase	-			

[1] only required if log $P_{O/W}$ >3. Several constituents of tea tree oil has log P_{OW} >3

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Preparation "Timorex"	> 66 µg a.s./bee	No data available
Field or semi-field tests.		
No data is available		

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

Field crops and ornamentals, application rate 3 x 2.64 kg a.s./ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
Preparation “Timorex”	oral	< 40	50
Preparation “Timorex”	contact	Data gap	50

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])
Typhlodromus pyri ‡	No data. Data gap.	Mortality	-
Aphidius rhopalosiphi ‡	No data. Data gap.	Mortality	-

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

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

Test organism	Test substance	Time scale	End point
Earthworms			
	a.s.	Acute 14 days	No data available
	a.s.	Chronic 8 weeks	No data available
	Preparation	Acute	No data available
	Preparation	Chronic	No data available
Soil macro-organisms No data is available.			
Soil micro-organisms			
Nitrogen mineralisation Data gap for nitrogen transformation study and risk assessment			
	Constituent of TTO: alpha-terpinene	14 d	10 % effect at day 14 at 250 mg alpha-terpinene /kg d.w.soil
	Constituent of TTO: alpha-pinene	14 d	11 % effect at day 14 at 250 mg alpha-pinene /kg d.w.soil
	Constituent of TTO: limonene	14 d	4 % effect at day 14 at 250 mg limonene/kg d.w.soil
Carbon mineralisation			
Data gap for carbon mineralization study and risk assessment			
Field studies			
No data available.			

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure $(g/ha)^2$	TER	Trigger
No data. Not required.						

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

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

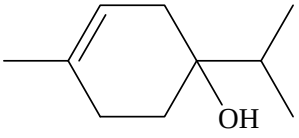
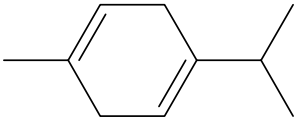
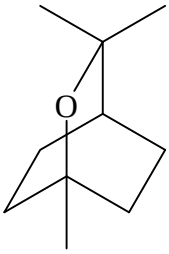
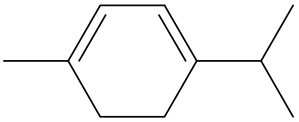
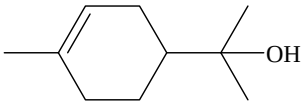
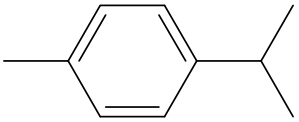
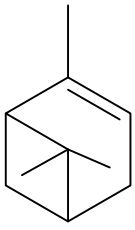
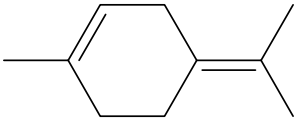
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

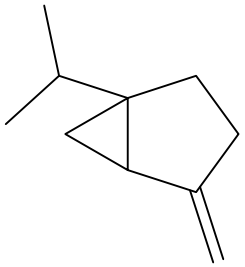
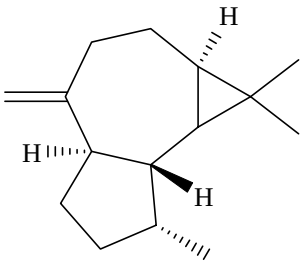
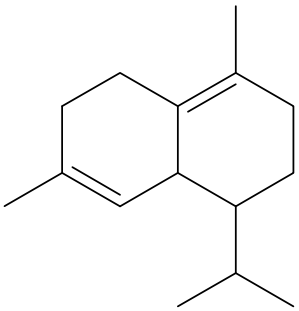
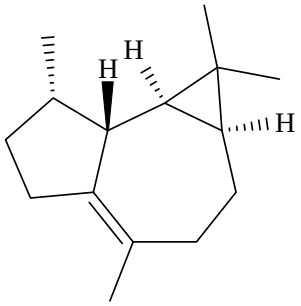
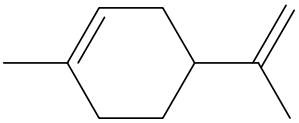
Compartment	
soil	Terpinene-4-ol; gamma- terpinene; alpha-terpinene; alpha-terpineol; alpha-terpinolene; alpha-pinene; p-Cymene; 1,8- Cineole (Eucalyptol); Limonene; Aromadendrene; delta-cadinene; Sabinene; Globulol; Viridiflorol; Ledene
water	Terpinene-4-ol; gamma- terpinene; alpha-terpinene; alpha-terpineol; alpha-terpinolene; alpha-pinene; p-Cymene; 1,8- Cineole (Eucalyptol); Limonene; Aromadendrene; delta-cadinene; Sabinene; Globulol; Viridiflorol; Ledene
sediment	Terpinene-4-ol; gamma- terpinene; alpha-terpinene; alpha-terpineol; alpha-terpinolene; alpha-pinene; p-Cymene; 1,8- Cineole (Eucalyptol); Limonene; Aromadendrene; delta-cadinene; Sabinene; Globulol; Viridiflorol; Ledene
groundwater	Terpinene-4-ol; gamma- terpinene; alpha-terpinene; alpha-terpineol; alpha-terpinolene; alpha-pinene; p-Cymene; 1,8- Cineole (Eucalyptol); Limonene; Aromadendrene; delta-cadinene; Sabinene; Globulol; Viridiflorol; Ledene

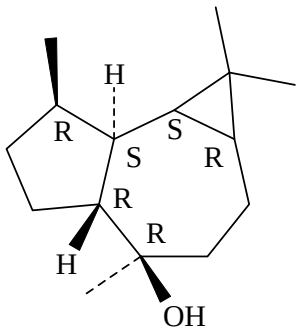
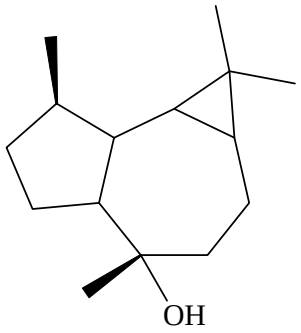
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	Considering the available data set, no classification could be proposed.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Terpinene-4-ol	*R,S*-1-Methyl-4-isopropyl-1-cyclohexen-4-ol	
gamma-terpinene	1-Methyl-4-isopropyl-1,4-cycloheyadiene	
1,8-Cineole (Eucalyptol)	1,33-trimethyl-2-oxabicyclo[2.2.2]octane	
alpha-terpinene	1-Methyl-4-isopropyl-1,4-cycloheyadiene	
alpha-terpinenol	2-[(4-methyl-1-cyclohex-3-enyl)]propan-2-ol	
***p*-Cymene**	1-Methyl-4-isopropylbenzene	
alpha - pinene	2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene	
alpha-terpinolene	4-Isopropylidene-1-methylcyclohexene	

Sabinene	1-Isopropyl-4-methylenebicyclo[3.1.0] hexane	
Aromadendrene	1H-Cycloprop[e]azulene, decahydro-1,17-trimethyl-4-methylene-,[1 ar-1aalpha,4aalpha, 7alpha, 7beta, 7baplha]-	
delta-cadinene	1,2,3,5,6,8a-Hexahydro-1-isopropyl-4,7-dimethylnaphthalene	
Ledene (Viridiflorene)	1,1,4,7-Tetramethyl-1alpha,2,3,5,6,7,7alpha,7b-octahydro-1H-cyclopropa[e]azulene	
Limonene	1-Methyl-4-1(1-methylethenyl) cyclohexene	

Globulol	1*H*-Cycloprop[e]azulen-4-ol,decahydro-1,1,4,7-tetramethyl,(1a*R*,4*R*,4a*R*,7*R*,7a*S*,7b*S*)-(8cl,9Cl)	
Viridiflorol	Viridiflorol (±)-viridiflorol, δ-viridiflorol,decahydro-1,1,4,7-tetramethyl,(1aR,4S,4aS,7R,7aS,7bS)-1H-Cycloprop[e] azulen-4-ol,himbaccol	

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

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