CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/spearmint oil[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Spearmint oil is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

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

Sweden being the designated rapporteur Member State submitted the DAR on spearmint oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 9 November 2007. The peer review was initiated on 18 June 2008 by dispatching the DAR for consultation of the notifier (XEDA International). 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 areas of mammalian toxicology and deliver its conclusions on spearmint oil.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of spearmint oil as a plant growth regulator on potatoes as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00293 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 plant oils/spearmint oil. EFSA Journal 2012;10(11):2541. [50 pp.] doi:10.2903/j.efsa.2012.2541. Available online: www.efsa.europa.eu/efsajournal

In the area of identity, physical/chemical/technical properties and methods of analysis a data gap was identified for an Annex II data package for the active components that make up spearmint oil. Data gaps for the formulation are auto-flammability, accelerated storage and shelf life. No methods of analysis were available for products of plant and animal origin and for soil, water and air.

In the mammalian toxicology area data gaps were identified for the definition of the toxicological profile of spearmint oil; the database was insufficient to set reference values and the risk assessment is inconclusive.

In the residues section it was concluded that significant levels of residues of (R)-carvone will occur in potatoes upon application of spearmint oil according to the proposed use scenario. However, several data gaps were identified and a final residue definition for risk assessment and monitoring could not be derived. Furthermore, in absence of agreed toxicological reference values a consumer risk assessment could not be performed.

The environmental fate and behaviour section of the dossier was empty. Consequently 4 data gaps have been identified. Quantitative structure activity relationship (QSAR) approaches have been used to obtain more uncertain than usual input parameters to carry out groundwater exposure modelling for the main constituent of spearmint oil. When the uncertainty in the use of the QSAR approach is included in the modelling strategy, these modelling results indicate a high potential for groundwater contamination by the pesticide active substance carvone, consequent to the representative use assessed, in the situation when treated potatoes are used as seed potatoes.

The data set for the ecotoxicological assessments was not sufficient, therefore the risk assessments for non-target organisms could not be finalised.

KEY WORDS

Spearmint oil, (R)-carvone, L-carvone, (5R)-2-methyl-5-(prop-1-ene-2-yl)cyclohex-2-en-1-one, peer review, risk assessment, pesticide, plant growth regulator

TABLE OF CONTENTS

BACKGROUND

Spearmint oil is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

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

Sweden being the designated rapporteur Member State submitted the DAR on spearmint oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 9 November 2007 (Sweden, 2007). The peer review was initiated on 18 June 2008 by dispatching the DAR for consultation of the notifier (XEDA International). 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 areas 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 plant growth regulator on potatoes, 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(s) 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 (Sweden, 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

Spearmint oil is the given name for a mixture that contains (R)-carvone as the main constituent and other identified compounds. There is no ISO common name. A number of the constituents of spearmint oil 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 following use.

The representative formulated product for the evaluation was „BIOX-M' a hot fogging concentrate containing 949 g/l spearmint oil.

The representative uses evaluated is as a post harvest treatment to potatoes as a sprout suppressant. 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 notifier has stated that all of the compounds in spearmint oil are the active substances and full details of their identity and content range are given in Appendix C and the Addendum to Volume 4 of the DAR (Sweden, 2011). It should be noted that the ratio of isomers was not confirmed by the analytical method used. There are no relevant impurities. There is no FAO specification.

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

A full Annex II data package was identified as a data gap for the active components.

The following data gaps were identified for the formulated product: auto-flammability, accelerated storage and shelf life.

Data gaps have been identified for methods of analysis for products of plant and animal origin and soil, water and air. A method for body fluids and tissues is not required as there is no classification for toxic or very toxic.

2. Mammalian toxicity

Spearmint oil was discussed in the Pesticides Peer Review meeting 88 (September 2011).

For spearmint oil the only original toxicity studies available in the dossier are acute oral, dermal, inhalation, irritation and skin sensitisation studies, showing that spearmint oil is not acutely toxic, not irritating to skin and eye, but it is a skin sensitiser (R43 proposed). Spearmint oil is composed of alicyclic hydrocarbons, and meets the physico-chemical characteristics for assignment of the risk phrase R65 "Harmful: may cause lung damage if swallowed".

The amount of (R)-carvone in spearmint oil was stated in volume 4 as being up to 75-80%. The question was raised whether the studies performed on carvone should be considered at all for spearmint oil as at least 20% of the technical material is missing. Furthermore the raw data were not available. From the open literature, the carvone tested in many of the studies could not be well identified.

The experts concluded that the majority of the data is based on carvone and reviews from other authorities that did not allow for an independent assessment. Data gaps were identified for toxicological information on spearmint oil, including genotoxicity studies. The database is therefore insufficient to set reference values for spearmint oil, or for (R)- or (S)-carvone, and the risk assessment is inconclusive.

3. Residues

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

No metabolism study with spearmint oil was submitted. It was argued that the high volatility of spearmint oil contraindicated significant absorption and residues were unlikely to occur. The main component of spearmint oil is (R)-carvone (up to 75-80%).

The formation of residues of (R)-carvone and (S)-carvone upon treatment of potatoes has previously been assessed in the DAR for carvone (The Netherlands, 2000). Only information for (R)-carvone is considered here. Within the tested three weeks of storage residue levels increased in both potato peel and tubers, indicating the compound was gradually absorbed from the air into the crop. (R)-carvone was a major residue at any sampling time investigated. Also residues of metabolite neodihydrocarveol, a diastereoisomer of dihydrocarveol, were found to be significant (14% and 62% of the identified residue in tubers and peeled tubers, respectively, after 3 weeks). Identification of the terminal residue might not be complete in this study. However, it can be reasonably deduced that significant residues are likely to occur and that investigation of the nature of residues of spearmint oil cannot be waived, taking also into account the presence of compounds in spearmint oil other than (R)-carvone. In addition, residue trials with spearmint oil performed according to the proposed use scenario demonstrated that significant levels of (R)-carvone were present in potatoes. Other compounds were not analysed for in these trials.

Subsequently, a data gap had to be set for data addressing the nature of residues in potatoes. Currently, a residue definition for consumer risk assessment can not be concluded. Furthermore, the open issue regarding clarification of the toxicological role of compounds present in spearmint oil other than (R)-carvone (refer to section 2) may possibly also impact the selection of an appropriate residue definition for risk assessment. Accordingly, it is deemed premature to propose a residue definition for monitoring even if based on the available data (R)-carvone might appear a suitable marker.

In addition, a data gap was set for a sufficient number of residue trials in potatoes according to critical GAP criteria, and for a freezer storage stability study to validate the results found in the residue studies. Possibly, data on processed potatoes may become necessary to demonstrate reduction of residue levels. Lastly, data and information to address potential residues in food of animal origin are required since treated potatoes or their products may be fed to livestock and the trigger value for livestock dietary exposure is exceeded.

Although the available data would permit a preliminary assessment of consumer intakes of (R)-carvone from the consumption of potatoes, a reliable consumer risk assessment cannot be performed due to several data gaps that could have an impact on the final result and, not least, due to the absence of agreed toxicological reference values (refer to section 2).

4. Environmental fate and behaviour

Measured experimental data for any of the components that constitute the active substance spearmint oil and how they behave in environmental matrices was not available in the applicants dossier. For the predominant component reported to be (R)-carvone, quantitative structure activity relationship calculations (QSAR) estimates were provided for the properties water solubility (WSKOW v.1.41: 367.1 mg/L at 25ºC), vapour pressure (MPBPWIN v.1.42: 17.3 Pa at 25ºC), soil DT_{50} (30 days) water and sediment DT_{50}, (15 and 135 days respectively) (DT values calculated with Biowin v4.10 with ultimate values transferred to the Level III fugacity model LEVEL3NT.EXE), soil adsorption (PCKOC v1.66: K_{doc} of 124 mL/g) and for indirect photolytic reaction with hydroxyl radicals in the upper atmosphere (AOP v.1.92; atmospheric half life 0.114 days), all models contained in EPI Suite v3.20[15]. For an other active component (listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR; Sweden, 2011)[16] these values were: water solubility (WSKOW v.1.42: 4.6 mg/L at 25ºC), vapour pressure (MPBPVP v.1.43: 193 Pa at 25ºC), soil DT_{50} (30 days) water and sediment DT_{50}, (15 and 135 days respectively) (DT values calculated with Biowin v4.10 with ultimate values transferred to the Level III fugacity model LEVEL3NT.EXE), soil adsorption (KOCWIN v2.0: K_{doc} of 1120 mL/g) and for indirect photolytic reaction with hydroxyl radicals in the upper atmosphere (AOP v.1.92; atmospheric half life 0.074 days) all models contained in EPI Suite v4.1[17].

In line with the assessment of other substances, as QSAR estimates have more uncertainty than experimentally measured values, it was agreed that predicted environmental concentration (PEC) estimates could be made using the following substance values: soil DT_{50} 300 days, water DT_{50} 150 days, sediment DT_{50} 1000 days for (R)-carvone and for the component listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011), with K_{doc} being 12.4mL/g and 112mL/g for each of these compounds respectively (all these values are a factor of 10 more conservative than the their QSAR estimates. This reflects the reported uncertainty in these key QSAR estimations). In addition, for groundwater PEC, the actual QSAR values for vapour pressure and water solubility were used as modelling input. The PEC in soil, surface water and sediment (calculated using the FOCUS (2001) step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator) for surface water and sediment) and groundwater (calculated using FOCUS (FOCUS, 2009) scenarios and the model PEARL 4.4.4[18]) can be found in appendix A. The basis for these calculations was carvone residues measure in stored potatoes at the time potatoes are removed from storage (as described in section 3), to cover the situation when seed potatoes are treated. Using these PEC groundwater calculations all 9 pertinent FOCUS vulnerable shallow groundwater scenarios were predicted to have carvone present in groundwater at concentrations above the parametric drinking water limit for pesticides[19] of 0.1µg/L. Consequently a data gap is identified to provide a more refined groundwater exposure assessment for carvone (see section 7). The provision of less uncertain (R)-carvone soil DT_{50} and adsorption values than those provided by QSAR estimates would be one way of addressing this data gap. Because of its predicted higher soil adsorption and higher vapour pressure, any refined environmental exposure assessment for carvone would cover the exposure that would occur for the component listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) in soil, natural surface water systems and groundwater. However until a refined exposure assessment becomes available for carvone, the environmental exposure assessment for the compound listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) for these compartments also has to be considered a data gap (see section 7). Data gaps are also identified for the environmental exposure assessment to be addressed for the majority of the other components that

[15] Copyright U.S. Environmental Protection Agency.

[16] The components of the active substance spearmint oil other than (R)-carvone are not disclosed in the published EFSA conclusion upon advice from the European Commission following a confidentiality claim made by the applicant as provided for in Article 14 of Council Directive 91/414/EEC.

[17] Copyright U.S. Environmental Protection Agency.

[18] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

[19] The pertinent legislation Council Directive 98/83/EC (OJ L330, 5.12.1998, p.32) defines plant growth regulators as pesticides. Carvone is approved for use as a plant growth regulator.

make up spearmint oil as no assessment was available for them (see section 7). A data gap is also identified for information on the potential transformation products in soil of any of the constituents that are reported to make up the active substance, that it cannot be excluded would be residues on treated potatoes when they are used as seed potatoes (see section 7). Though (R)-carvone and the component listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) are volatile, they are not expected to be subject to long range atmospheric transport as their atmospheric half lives, consequent to photooxidative reaction with hydroxyl radicals present in the upper atmosphere are calculated to be less than 2 days. Assessments to address the potential for long range transport for the majority of the other components that make up spearmint oil have been identified as a data gap (see section 7).

In the Member States' and EFSA's comments on the DAR it was discussed that sewage water including cleaning water (that could involve high volumes of water used to wash potatoes when removed from store) would be collected and transported to a management facility for chemical waste. In this situation it was appropriate to assume that environmental exposure from these activities would be precluded (negligible). Other approaches, to adequately manage and appropriately dispose of any water used to wash potatoes and handling equipment such as grading conveyors and packaging equipment might also be devised by Member States. This issue has therefore been included in section 8 of this conclusion, to make it clear that such measures, or local risk assessments, consequent to the disposal of wash waters will be needed, as the outcome from a range of the possible practices has not been addressed in this EU level assessment. Neither the applicant nor the RMS provided environmental exposure assessments where volatile spearmint oil components might be re-deposited on soil or natural surface water systems when potato stores are vented prior to removal of potatoes from store for sale to consumers. When asked to provide such an assessment, the argument was made and accepted that environmental exposure from this situation was likely to be lower than when treated potatoes were used as seed potatoes. Consequently, as the environmental exposure and risk assessment from the use on seed potatoes remains open, these assessments for potatoes destined for human consumption also remain open.

5. Ecotoxicology

No experimental data were available for the ecotoxicological risk assessments for spearmint oil with the exception of the available mammalian data from section 2.

Exposure of the terrestrial environment cannot be excluded if residues (constituents of spearmint oil and their transformation products) remain on potato tubers when they are planted out. The aquatic environment can be contaminated via soil. Moreover contamination of soils and surface waters via aerial deposition of the potentially volatile constituents of spearmint oil cannot be excluded as well (see section 4). Therefore non-target organisms can potentially be exposed to these residues, directly or indirectly via the food chain.

Available data on mammals indicated potential low acute toxicity for spearmint oil (see section 2). The treated tubers are planted in soil therefore the availability of them to birds and to some wild mammal species was considered to be limited. Moreover potato plants (leaves) are not palatable for birds. Nevertheless, since other essential information (e.g. long-term toxicity, systemic properties or potential for bioaccumulation of the constituents) is unknown, complete and reliable assessments for birds and mammals could not be performed.

With regard to the aquatic organisms, acute toxicity of the single compound of spearmint oil, (R)-carvone, was estimated by QSAR analysis for fish and daphnids and the toxicity to algae was also estimated. If these data were compared with the estimated PECsw values, low risk to aquatic organisms could be concluded for (R)-carvone. Non peer-reviewed data indicated however that another constituent of spearmint oil (listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of

the DAR; Sweden, 2011) was more toxic to aquatic organisms than the estimated values for (R)-carvone. No assessments were available for long-term scale, neither any reliable assessments were available for the other constituents of spearmint oil.

As for birds, mammals and aquatic organisms, neither the magnitude of the environmental contamination nor the toxicological profile of the constituents were well characterised for bees, non-target arthropods, earthworms, soil macro and micro-organisms, terrestrial non-target plants and regarding the potential effects on biological methods of sewage treatment. Therefore a data gap was identified for the necessary data and assessments for non-target terrestrial and aquatic organisms.

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
carvone (expected to be (R)-carvone / L-carvone / (5R)-2-methyl-5-(prop-1-ene-2-yl)cyclohex-2-en-1-one on the basis of taste and smell)	moderately persistent based on QSAR DT_{50} of 30days,	Data gap
[redacted]	moderately persistent based on QSAR DT_{50} of 30days,	Data gap
[redacted]	Data gap	Data gap
[redacted]	Data gap	Data gap
[redacted]	Data gap	Data gap
[redacted]	Data gap	Data gap
Other less prominent constituents, see Addendum to Volume 4 of the DAR for further details.	Data gap	Data gap

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
carvone (expected to (R)-carvone)	High mobility QSAR estimated K_{doc} 124mL/g	Yes at all 9 FOCUS scenarios with the available uncertain estimates.	Yes	No data available	Data gap
[redacted]	Low mobility QSAR estimated K_{doc} 1120mL/g	Data gap	Yes, claimed	No data available	Data gap
[redacted]	Data gap	-	Yes, claimed	No data available	Data gap
[redacted]	Data gap	-	Yes, claimed	No data available	Data gap
[redacted]	Data gap	-	Yes, claimed	No data available	Data gap

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
[redacted]	Data gap	-	Yes, claimed	No data available	Data gap
Other less prominent constituents, see Addendum to Volume 4 of the DAR for further details	Data gap	-	Yes, claimed	No data available	Data gap

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
carvone (expected to (R)-carvone)	Data gap
[redacted]	Data gap
[redacted]	Data gap
[redacted]	Data gap

[redacted]	Data gap
[redacted]	Data gap
Other less prominent constituents, see Addendum to Volume 4 of the DAR for further details	Data gap

6.4. Air

Compound (name and/or code)	**Toxicology**
carvone (expected to (R)-carvone)	No data available
[redacted]	No data available
[redacted]	No data available
[redacted]	No data available
[redacted]	No data available
[redacted]	No data available
Other less prominent constituents, see Addendum to Volume 4 of the DAR for further details	No data available

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).

- Annex II data package for the active components (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- For the formulation auto-flammability, accelerated storage and shelf life (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Methods of analysis for products of plant and animal origin, soil, water and air (relevant for all representative uses evaluated ; submission date proposed by the notifier: unknown; see section 1)
- Toxicological profile of spearmint oil except for acute toxicity (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2)
- A freezer storage stability study (relevant for all representative uses evaluated; submission date proposed by the notifier: new study available but not eligible for peer review; see section 3)
- Data on the nature of residues of spearmint oil in potato tuber taking into account the critical use scenario (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 3)
- Data and information to address residues in livestock or justification of the potential non-relevance of such data (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 3)
- A sufficient number of critical GAP conforming residue trials with spearmint oil in potatoes, and possibly residue data on processed potatoes to sufficiently demonstrate reduction of residues (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 3)
- Information to allow a more refined groundwater exposure assessment for the active substance constituents (R)-carvone and the component listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) are considered necessary (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- A satisfactory exposure assessment for soil, surface water and sediment for the active substance constituent listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) was not available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Environmental exposure assessments (including potential for long range atmospheric transport) were not available for the majority of the constituents that are reported to make up the active substance (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Information on the potential transformation products in soil of any of the constituents that are reported to make up the active substance, that it cannot be excluded would still be present on seed potatoes when planted out, was not available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- Ecotoxicological risk assessments for non-target terrestrial and aquatic organisms (relevant for the representative use in potato; 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

- Management measures tailored to local practice and legislation need to be put in place to control the waste disposal of potato wash water or wash water from the cleaning of potato grading or packaging equipment, to limit spearmint oil constituents entering sewers or surface water drains to negate possible impacts on natural water systems; see section 4).

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. Environmental exposure assessments were not available for the majority of the constituents that are reported to make up the active substance.

2. The soil, surface water, sediment and groundwater exposure assessments for the active substance constituent listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR (Sweden, 2011) could not be finalised with the available information.

3. Soil, natural surface water system (via drainage) and groundwater exposure assessments for the potential transformation products in soil of any of the constituents that are reported to make up the active substance, that might be present on seed potatoes when planted out could not be finalised.

4. The data set for the ecotoxicological assessments was insufficient, therefore the risk characterization (risk assessments) for non-target organisms 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.

5. The database was insufficient to set reference values and the operator, worker, bystander and consumer risk assessment is inconclusive.

6. When the uncertainty in the available input parameters used in groundwater exposure modelling (that are QSAR estimates) is accounted for in the modelling, this modelling for the representative use, indicates a high potential for groundwater contamination by the pesticide active substance carvone, under the geoclimatic conditions represented by all 9 FOCUS groundwater scenarios.

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		**Post harvest treatment of potatoes in store including seed potatoes**
Operator risk	Risk identified	
	Assessment not finalised	X[5]
Worker risk	Risk identified	
	Assessment not finalised	X[5]
Bystander risk	Risk identified	
	Assessment not finalised	X[5]
Consumer risk	Risk identified	
	Assessment not finalised	X[5]
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X[4]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X[1,2,3,4]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[1,2,3,4]
Groundwater exposure active substance	Legal parametric value breached	X[6]
	Assessment not finalised	X[1,2]
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	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

Sweden, 2007. Draft Assessment Report (DAR) on the active substance Spearmint oil prepared by the rapporteur Member State Sweden in the framework of Directive 91/414/EEC, November 2007

Sweden, 2011. Final Addendum to Draft Assessment Report on Spearmint oil, compiled by EFSA, November 2011.

The Netherlands, 2000. Draft Assessment Report (DAR) on the active substance carvone prepared by the rapporteur Member State The Netherlands in the framework of Directive 91/414/EEC, September 2000.

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 Spearmint oil

EFSA (European Food Safety Authority), 2007. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.

European Commission, 2008. Review Report for the active substance plant oils/spear mint oils finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of plant oils/spear mint oils in Annex I of Directive 91/414/EEC., SANCO/2624/08 – rev. 1

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.

European Commission, 2001. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO Doc 7525/VI/95-rev.7. pp.1-31.

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 (2006). "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.

FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 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.

FOCUS (2009). "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU". Report of the FOCUS Workgroup, EC Document Reference SANCO/13144/2010-version.1. 604 pp, as outlined in Generic Guidance for Tier 1 FOCUS groundwater Assessment, version 2.0 dated January 2011.

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.

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

APPENDICES

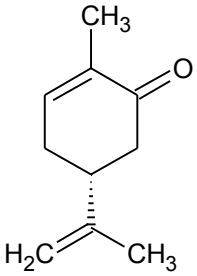
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Spearmint oil
Function (*e.g.* fungicide)	Plant Growth Regulator
Rapporteur Member State	Sweden
Co-rapporteur Member State	Not assigned

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	IUPAC-name not applicable for spearmint oil. For main constituent (R)-carvone : (*R*)-5-isopropenyl-2-methylcyclohex-2-en-1-one For the other constituents: See the EFSA conclusion
Chemical name (CA) ‡	For spearmint oil : Oil, spearmint For main constituent (R)-carvone : (*R*) 2-methyl-5-(1-methylethenyl)-2-cyclohexen-1-one For the other constituents: See the EFSA conclusion
CIPAC No ‡	908
CAS No ‡	For spearmint oil: 8008-79-5 For main constituent (R)-carvone :6485-40-1
EC No (EINECS or ELINCS) ‡	No number for Spearmint oil (Spearmint extract 283-656-2, CAS-number 84696-51-5) For main constituent (R)-carvone : 229-352-5
FAO Specification (including year of publication) ‡	Not available.
Minimum purity of the active substance as manufactured ‡	See EFSA conclusion.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities.
Molecular formula ‡	For spearmint oil: Not applicable For main constituent (R)-carvone : $C_{10}H_{14}O$
Molecular mass ‡	Not applicable for spearmint oil

	For main constituent (R)-carvone : 150.21 g/mol
Structural formula ‡	Not applicable for Spearmint oil (R)-Carvone main constituent of Spearmint oil  For the other components see the EFSA conclusion

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Open
Boiling point (state purity) ‡	Open
Temperature of decomposition (state purity)	Open
Appearance (state purity) ‡	Open
Vapour pressure (state temperature, state purity) ‡	Open
Henry's law constant ‡	Open
Solubility in water (state temperature, state purity and pH) ‡	Open
Solubility in organic solvents ‡ (state temperature, state purity)	Open
Surface tension ‡ (state concentration and temperature, state purity)	Open
Partition co-efficient ‡ (state temperature, pH and purity)	log P_{ow} is 2.4 for carvone. (No data on Spearmint oil) Not available. Data gap for the individual substances included in the specification of spearmint oil Open
Dissociation constant (state purity) ‡	Open
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Open
Flammability ‡ (state purity)	Flammability: Not applicable as spearmint oil is a liquid. Flash point: 92.0 °C for spearmint oil.
Explosive properties ‡ (state purity)	Open
Oxidising properties ‡ (state purity)	Open

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES

(Application on agricultural and horticultural crops)

XEDA INTERNATIONAL S.A.
2 Zone Artisanale de la Crau
13670 SAINT-ANDIOL, FRANCE

Date : 18 May 2007
Page : 1
Countr y : EU Member States

Pesticide(s) (common name(s)) : SPEARMINT OIL
EEC, CIPAC and CCPR No(s). : 283-656-2, not applicable and not applicable
Trade name(s) : BIOX-M
Main uses e.g. insecticide, fungicide : Plant growth regulator (sprout inhibitor)
Applicant : XEDA INTERNATIONAL S.A.

Use Pattern

1	2	3	4	5	6			7			8	9
Crop and / or situation	For G	Pest or group of pests controlled	Formulation Type	Conc. of a.i.	Application method, kind	growth stage	number (range)	Application rate per treatment kg a.i./hl	water l/ha	kg a.i./ha	PHI (days)	Remarks:
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Potato	G*	Sprouting	HN	949 g/L	Hot fogging	Harvested product (BBCH 99)	1-11	94.9	Not applicable	Not applicable	Not applic-able	*Indoor storage post-harvest undiluted treatment (not glasshouse)

Remarks: (a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), or glasshouse application (G)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WG), emulsifiable concentration (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

Methods of Analysis

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

Technical as (analytical technique)	GC-MS (individual substances included in the specification of spearmint oil)
Impurities in technical as (analytical technique)	Not applicable to spearmint oil extract.
Plant protection product (analytical technique)	Technical as and plant protection product is identical Additionally a validated GC/FID method ~~of~~ for analysis of R-carvone by external calibration is available

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin, method 1	Open
Food of plant origin, method 2	Open
Food of animal origin	Open
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)	Open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Open
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 spearmint oil is not classified as T or T^+

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

RMS/peer review proposal

Active substance	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	No data available with Spearmint oil, only data from studies with (R)-carvone: Rapid and virtually complete
Distribution ‡	No data available with Spearmint oil
Potential for accumulation ‡	No data available with Spearmint oil
Rate and extent of excretion ‡	No data available with Spearmint oil
Metabolism in animals ‡	No data available with Spearmint oil
Toxicologically relevant compounds ‡ (animals and plants)	No data available with Spearmint oil
Toxicologically relevant compounds ‡ (environment)	No data available with Spearmint oil

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	>2000 mg kg^{-1}	
Rat LD_{50} dermal ‡	>2000 mg kg^{-1}	
Rat LC_{50} inhalation ‡	>5.43 mg/L	
Skin irritation ‡	No	
Eye irritation ‡	Slightly irritant	
Skin sensitisation ‡	Sensitiser	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data available with Spearmint oil	
Relevant oral NOAEL ‡	No data available on Spearmint oil.	
Relevant dermal NOAEL ‡	No data available with Spearmint oil	
Relevant inhalation NOAEL ‡	No data available with Spearmint oil	

Genotoxicity ‡ (Annex IIA, point 5.4)

No data available on Spearmint Oil.	

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

Target/critical effect ‡	No studies are available on Spearmint oil.
Relevant NOAEL ‡	No data available with Spearmint oil

Carcinogenicity ‡	No data available with Spearmint oil	

Reproductive toxicity (Annex IIA, point 5.6)
Reproduction toxicity

Reproduction target / critical effect ‡	No studies are available on Spearmint oil or carvone.	
Relevant parental NOAEL ‡	No data available with Spearmint oil	
Relevant reproductive NOAEL ‡	No data available with Spearmint oil	
Relevant offspring NOAEL ‡	No data available with Spearmint oil	

Developmental toxicity

Developmental target / critical effect ‡	No data available with Spearmint oil	
Relevant maternal NOAEL ‡	No data available with Spearmint oil	
Relevant developmental NOAEL ‡	No data available with Spearmint oil	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available with Spearmint oil	
Repeated neurotoxicity ‡	No data available with Spearmint oil	
Delayed neurotoxicity ‡	No data available with Spearmint oil	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available - not required
Studies performed on metabolites or impurities ‡	No conclusion could be reached for the toxicological profile of an other active substance constituent (listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR)

Medical data ‡ (Annex IIA, point 5.9)

	No data available with Spearmint oil Contact allergy to carvone flavouring in toothpastes has been reported.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Database insufficient		
AOEL ‡	Database insufficient		
ARfD ‡	Database insufficient		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Spearmint oil	Default values of 100% for dermal absorption

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**Spearmint oil** An operator using PPE is exposed to 0.06 mg spearmint oil/kg bw/day, when 20L containers are used and 0.01 mg/kg bw/day when 5L containers are used.
Workers	**Spearmint oil** Working with anti sprouting potatoes will expose the worker with 0.0008 mg/kg bw/day
Bystanders	**Spearmint oil** Not relevant due to exclusive indoor use.

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

	RMS/peer review proposal
Spearmint oil	Xn Harmful R43 May cause sensitization by skin contact R65 May cause lung damage if swallowed

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

Plant groups covered	No data available (data gap)
Rotational crops	Not relevant due to exclusive indoor use
Metabolism in rotational crops similar to metabolism in primary crops	Not applicable
Processed commodities	Not tested
Residue pattern in processed commodities similar to residue pattern in raw commodities	Not applicable
Plant residue definition for monitoring	Possibly (R)-carvone, to be confirmed by further data
Plant residue definition for risk assessment	Open (data gap)
Conversion factor (monitoring to risk assessment)	Currently not applicable

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

Animals covered	GAP does not include feeding restriction, livestock exposure trigger value exceeded → to be addressed further (data gap)
Time needed to reach plateau concentration in milk and eggs	Currently-not applicable
Animal residue definition for monitoring	Currently-not applicable
Animal residue definition for risk assessment	Currently-not applicable
Conversion factor (monitoring to risk assessment)	Currently-not applicable
Metabolism in rat and ruminant similar (yes/no)	Currently-not applicable
Fat soluble residue: (yes/no)	No data on Spearmint oil log P_{ow} is 2.4 for carvone. log P_{ow} may be >3 for other components of spearmint oil and metabolites of R-carvone.

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

Not relevant due to exclusive indoor use post-harvest

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

New study available but not eligible for peer review (data gap)

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: Yes	Poultry: Yes	Pig: Yes
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not available	Not available	Not available
	Residue levels in feeding studies (dose level: mg/kg) Mean (max) mg/kg		
Muscle	n/a	n/a	n/a
Liver	n/a	n/a	n/a
Kidney	n/a	n/a	n/a
Fat	n/a	n/a	n/a

Milk	n/a	n/a	n/a
Eggs	n/a	n/a	n/a

N/R=Not require

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Potato	Indoor, in storage	Waiting period 0 days *; analyte R-carvone ** [mg/kg]: 1.11, 1.19, 1.84 Waiting period 7±1 days *; analyte R-carvone ** [mg/kg]: 0.56, 0.57, 2x 0.93, 1.22, 1.49	* Waiting period/ post-treatment-interval not defined in the GAP table. ** Residue definition for monitoring and risk assessment currently not agreed on Total number of residue trials insufficient (data gap)	open	open	open

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

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

(c) Highest residue

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

ADI	Agreed toxicological reference values not available
TMDI (% ADI)	Risk assessment not finalised
TMDI (% ADI) according to national (to be specified) diets	Risk assessment not finalised
IEDI (%ADI)	Currently not applicable
NEDI (specify diet) (% ADI)	No data available
Factors included in IEDI and NEDI	Not applicable
ARfD	Agreed toxicological reference values not available
IESTI	Risk assessment not finalised
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Risk assessment not finalised
Factors included in NESTI	Not applicable

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

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Currently no data available, possibly to be addressed further depending on the outcome of consumer risk assessment			

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

Potatoes	Open (pending monitoring residue definition and complete set of residue trials)

When the MRL is proposed at the LOQ this should be annotated by an asterisk after the number.

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

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

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

Anaerobic degradation ‡

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

Soil photolysis ‡

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

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

Anaerobic degradation ‡

K_f/K_{oc}	No data available.
K_d	No data available.
pH dependence (yes/no) (if yes type of dependence)	No data available.

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

Column leaching	No data available.
Age residues leaching	No data available.
Lysimeter/ field leaching studies	Not submitted, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Carvone Method of calculation	Calculation assuming that potatoes with residue levels of 1.84 mg (R)-carvone/kg potato are planted out and that the (R)-carvone is left in the top 5 cm of soil. Soil DT_{50} based on QSAR estimation including an assessment factor of 10: 300 days
Application data	Plantation rate of seed tubers: 7.5 tonnes/ha Application rate: 13.8 g (R)-carvone/ha

$PEC_{(s)}$ (mg/kg) Carvone	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0185	-	0.032	-

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Not available. Data gap for the individual substances included in the specification of spearmint oil according to Sanco/10472/2003-rev.5
Photolytic degradation of active substance and relevant metabolites	Not available. Data gap for the individual substances included in the specification of spearmint oil according to Sanco/10472/2003-rev.5
Readily biodegradable (yes/no)	No data available
Degradation in - DT_{50} water water/sediment - DT_{90} water - DT_{50} whole system - DT_{90} whole system	No data available
Mineralization	No data available
Non-extractable residues	No data available
Distribution in water / sediment systems (active substance)	No data available
Distribution in water / sediment systems (metabolites)	No data available

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

Method of calculation	FOCUS Step 2. Input data based on QSAR

	estimates including an assessment factor of 10: DT_{50} soil 300 days DT_{50} water/sediment 1000 days K_{oc} 12.4
Application rate	Calculation assuming that potatoes with residue levels of 1.84 mg (R)-carvone /kg potato are planted out. Plantation rate of seed tubers: 7.5 tonnes/ha Application rate: 13.8 g/ha Season of application March to May.
Main routes of entry	Run-off and drainage (4% for S Europe 2% for S Europe) option no spray drift selected as the use is a seed treatment.

S Europe

$PEC_{(sw)}$ (µg/L) Carvone	Single application Global maximum	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.793	-	-	-

N Europe

$PEC_{(sw)}$ (µg/L) Carvone	Single application Global maximum	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.897	-	-	-

S Europe

$PEC_{(sed)}$ (µg/kg) Carvone	Single application Global maximum	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.222	-	-	-

N Europe

$PEC_{(sed)}$ (µg/kg) Carvone	Single application Global maximum	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.111	-	-	-

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	FOCUS PEARL v4.4.4 Input data based on QSAR estimates including an assessment factor of 10: DT_{50} soil 300 days K_{oc} 12.4 Q10= 2.58, Walker equation coefficient 0.7.
Application rate	Calculation assuming that potatoes with residue levels of 1.84 mg (R)-carvone /kg potato are planted out and that the (R)-carvone is applied at the soil surface (best case, relative to defining an incorporation depth). Plantation rate of seed tubers: 7.5 tonnes/ha Application rate: 13.8 g (R)-carvone/ha Data of application 5 days before the date of emergence defined for each scenario.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Carvone (µg/L)	Metabolite (µg/L)
			1
FOCUS PEARL 4.4.4 /potato	Chateaudun	1.339	-
	Hamburg	0.769	-
	Jokioinen	0.827	-
	Kremsmunster	1.461	-
	Okehampton	0.975	-
	Piacenza	0.695	-
	Porto	0.686	-
	Sevilla	0.555	-
	Thiva	0.880	-

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

Direct photolysis in air	Estimated carvone atmospheric half-life 1.5-3 h (AOP Program v1.92) Assumed OH radicals' concentration: 0.5 x 10^6 OH/cm^3 (24-hr day value) Estimated atmospheric half-life 0.884 h (AOP Program v1.92) for the active substance constituent listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR

	Assumed OH radicals' concentration: 1.5 x 10^6 OH/cm^3 (12-hr day value)
Quantum yield of direct phototransformation	No data
Photochemical oxidative degradation in air	Latitude: ……. Season: ……. DT_{50}: 2 hours
Volatilization	No data

PEC (air)

Method of calculation	Estimation based on short half-life.

$PEC_{(a)}$

Maximum concentration	Negligible.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil, Surface Water, Sediment, Ground water, Air: carvone (expected to (R)-carvone) [redacted] other less prominent constituents, see Addendum to Volume 4 of the DAR for further details

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

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of	No data available

study)	
Air (indicate location and type of study)	No data available

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

Candidate for R53, Not readily biodegradable.

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

Acute toxicity to mammals	LD_{50} > 2000 mg/kg (rat)
Acute toxicity to birds	No data available
Dietary toxicity to birds	No data available
Reproductive toxicity to birds	No data available

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

Application rate (kg as/hL)	Crop	Category	Time-scale	TER	Annex VI Trigger
		Birds and mammals		Data gap	

Toxicity data for aquatic species (most sensitive species of each group)

(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish *(Oncorhynchus mykiss)*	(R)-Carvone	96 hour	LC_{50}	Data gap, QSAR estimation: 20.3-32.9*
Invertebrate *(Daphnia magna)*	(R)-Carvone	48 hour	EC_{50}	Data gap, QSAR estimation: 9.59-15.1*
Algae	(R)-Carvone	5 day	EC_{50}	Data gap, QSAR estimation: 4.58-7.36*
Aquatic plant *(Lemna gibba)*	-	14 day	IC_{50}	No data available
Microcosm or mesocosm tests				
Not available				

*no experimental data available, values based on QSAR estimations (ECOSAR v0.99h)

Toxicity/Exposure Ratios for the Most Sensitive Aquatic Organisms (Annex IIIA, Point 10.2)

Application rate (kg as/hL)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
		Fish	Acute	Not relevant	Not provided	100
		Invertebrate	Acute	Not relevant	Not provided	100
		Alga	Acute	Not relevant	Not provided	10

Bioconcentration

Bioconcentration factor (BCF)	Log Kow for Carvone reported as 2.4. Data gap for the individual constituents.
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	Not relevant. No data available
Level of residues (%) in organisms after the 14 day depuration period	Not relevant. No data available

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

Acute oral toxicity	No data available
Acute contact toxicity	No data available

Hazard Quotients for Honey Bees (Annex IIIA, Point 10.4)

Application rate (kg as/hL)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
		Oral	Data gap	
		Contact	Data gap	

Field or semi-field tests
No data available

Effects on Other Arthropod Species (Annex IIA, Point 8.3.2, Annex IIIA, Point 10.5)

Species	Stage	Test Substance	Dose (Kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
Aphidius rhopalosiphi	adult	-	-	LR_{50}	No data available - Data gap	-
Typhlodromus pyri	protonymph	-	-	LR_{50}	No data available - Data gap	-

Field or semi-field tests
Not available

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

Acute toxicity	No data available
Reproductive toxicity	No data available

Toxicity/Exposure Ratios for Earthworms (Annex IIIA, Point 10.6)

Application rate (Kg as/hL)	Crop	Time-scale	TER	Annex VI Trigger
		Acute	Data gap	
		Long term	Data gap	

Effects on Soil Micro-Organisms (Annex IIA, Point 8.5, Annex IIIA, Point 10.7)

Nitrogen mineralization	No data available - Data gap
Carbon mineralization	No data available - Data gap

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

No data available - Data gap

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

Test type/organism	Endpoint
Activated sludge	No data available
Pseudomonas sp	No data available

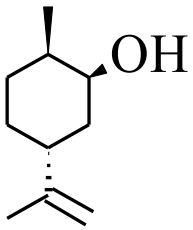
Residue definition (ecotoxicologically relevant compounds)

carvone (expected to (R)-carvone) [redacted] other less prominent constituents, see Addendum to Volume 4 of the DAR for further details

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

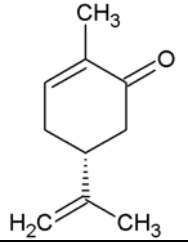
	RMS/peer review proposal (as a „worst case approach')
Active substance/Product	N, R50-53, based on the content of the component (listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR) in the five batch analysis but probably can be higher. A read-across to the component listed in row 2 in Table C.1.2-1 of the Addendum to Volume 4 of the DAR is also relevant as (R)-carvone and the above component are structurally similar compounds.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
neodihydrocarveol	(1*S*,2*R*,5*R*)-2-methyl-5-(prop-1-en-2-yl)cyclohexanol**	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

APPENDIX C – CONSTITUENTS OF THE ACTIVE SUBSTANCE SPEARMINT OIL

Common name	IUPAC	Min. % w/w	Max. % w/w	Structural formula
(R)-carvone L-carvone	(5*R*)-2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one**	55.00	See Addendum to Volume 4 of the DAR (Sweden, 2011)	
Other constituents of spearmint oil*	See Addendum to Volume 4 of the DAR (Sweden, 2011)	See Addendum to Volume 4 of the DAR (Sweden, 2011)	See Addendum to Volume 4 of the DAR (Sweden, 2011)	See Addendum to Volume 4 of the DAR (Sweden, 2011)

*The components of the active substance spearmint oil other than (R)-carvone are not disclosed in the published EFSA conclusion upon advice from the European Commission following a confidentiality claim made by the applicant as provided for in Article 14 of Council Directive 91/414/EEC.
**ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

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